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Low Invasive Pediatric Cardiac Surgery

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Preface

Being a pediatric cardiac surgeon for 36 years, I have believed that reducing the invasion involving surgery to the living body, that is to say, minimizing invasion of surgery, was an essential duty for surgeons. Especially in neonatal open-heart surgery, the reason is that the success of postoperative ICU recovery does not only affect the final surgical outcome, but the future quality of life (QOL), including growth and psychomotor development, is affected more than the surgery itself. In addition, rapid recovery after surgery is a status of the hospital which indicates that team medical care is functioning very well. Until now, we have been taking measures against minimally invasive by learning from seniors and improving their ideas. However, if it was asked whether there was a measure that could be realized that there was a clear clinical effect, of course, it can be convinced that it is less invasive than before. But it must be answered honestly that it was unsure. There was only a strong vague feeling that it became minimally invasive before we knew. Since many factors are involved in the invasion of cardiac surgery, it may be difficult to produce a direct clinical effect from a single measure. Although minimally invasive is now a popular word, how should we interpret and practice it from now on?

Since 2007, the patients' condition in the postoperative ICU has gradually changed. In particular, diuretic drop and edema augmentation, which pediatric cardiac surgeons mostly dislike, have become increasingly visible. The postoperative quality which should be emphasized is clearly different from that before 2006. Sakakibara Heart Institute is proud to have developed world's first new heart–lung machine devices and extracorporeal circulation management methods. As been reporting a lot of their minimal invasiveness and clinical effects so far, there is a little guilty conscience. What is the cause of this? Has minimally invasive extracorporeal circulation progressed? First of all, in this book, I would like to explain about extracorporeal circulation, which is the greatest invasion to living body, and how it became minimally invasive.

There is one more thing to consider when discussing minimally invasive. It is not only the ability of the surgeon but also how to mature the overall capabilities of the surgical team. This is extremely important in the sense that it directly leads to minimal invasiveness of the patient. Surgery is performed by human hands. However, the evaluation of maturity is also difficult and vague and it cannot be measured numerically. However, if it can be quantified, would not time be the only one? As long as the surgery itself is invasive, shortening the time is the most fundamental for considering minimal invasiveness. Moreover, the fact that the time can be shortened means that minimally invasive is functioning. The author has made many proposals for minimally invasiveness from this point of view. Newcomers who became members of a team that performs many surgeries in a short time will grow further beyond that situation, and how to improve under this naturalness will also be necessary to establish new measures for less invasiveness in the future. In addition, if the surgery is completed early and the patient's condition is stable, each team member can secure more private time. This is also a standard that indicates the good functionality of the surgical team and it will also mean minimally invasive for us healthcare providers. Currently, the training of surgeons is a pressing challenge. However, there are still only few reports on the efficiency of surgery and team development for minimizing invasiveness. Secondly, I would like to explain how to raise functional cardiac surgery teams, their strategies, and their minimally invasive nature.

Research on minimally invasive surgery continues to advance, and many results have been reported. However, this book does not cover these general matters in textbooks. To the last, I would like to describe the contrivance and process of minimal invasiveness and the countermeasures from the reflection and raise future issues as one surgeon's thought. It may be criticized for not being scientific or logical, but I hope that it will serve not only cardiac surgeons but also all young doctors, nurses, and clinical engineers.

Fuchu, Japan Yukihiro Takahashi

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About the Author

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1981, Graduated from Kumamoto University School of Medicine

1981, Kumamoto Red Cross Hospital Resident

1983, Sakakibara Heart Institute, Cardiovascular Surgery Resident

1987, Researcher

1994, Deputy General Manager

1998, Director, General Manager

2003, Chief manager

2006, Chief Director and Deputy Director

Surgery is done to seek the important result of “success.” Of course, knowledge is necessary for that. However, I think that the process and ideas leading up to that understanding, as well as the action and final results with realistic clinical effects, are more important. Therefore, I wrote not only the knowledge but also my experience, the treatment technique focusing on the clinical effect, and the process of thinking.

Some of the devices and drugs used are currently being changed and may change in the future. Please refer to the manufacturer’s information about these. I am very careful about binding and calibration, but since it is an editorial work by the author alone, I would like to apologize for any deficiencies in binding such as typographical errors or design.

Part I

Extracorporeal Circulation and Low Invasiveness

1 Experience of Minimally Invasive Extracorporeal Circulation

Contents

1.1 Introduction

An emergency operation has been completed. Thank god, I finally got home.

After 10 PM, a regular line mail about the postoperative course arrived. It mentioned that urine output was low, ascites was stored, and a peritoneal dialysis tube was inserted. Before surgery, the patient had bloody stools and was very edematous, so the course was as expected. But why low urine output, despite good hemodynamics and respiratory status? Good gracious, I cannot understand it at all. I called the on-duty physician and instructed on what to do. Tomorrow, a total of three elective and one semi-emergency surgery are scheduled, and at 7:30 AM, the details of the surgery will be explained to the patient's parents. I am going to struggle with securing ICU beds again this week. It has been the same for the last 20 years.

Most cardiac surgery uses an auxiliary means called extracorporeal circulation. Putting it simply, venous blood is drained from the superior and inferior vena cava to a heart–lung machine, oxygenated by the oxygenator, and sent from the ascending aorta to the whole body. In other words, it is means for artificially regulating the blood circulation (oxygen supply) of the whole body from outside the body, during which the heart is arrested and repaired. However, it is naturally unphysiological because the circulation is performed by machines and humans. In particular, newborns and low-weight infants with premature organs are subject to more severe biological invasion, such as edema of the whole body and reduced functions of the heart, lungs, kidneys, and brain.

Pediatric cardiac surgery has advanced dramatically over the last 30 years. It is not an exaggeration to say that the less invasive measures to reduce the adverse effects of extracorporeal circulation have greatly contributed to the achievement of its results, as well as the establishment of surgical techniques and perioperative management in line with the pathophysiology of each disease. Even today, research on new devices and more physiological extracorporeal circulation methods are ongoing. However, nonetheless, there is a noticeable reduction in the quality of the postoperative course that pediatric cardiac surgeons are most concerned with, such as reduced diuresis and enhanced edema. This means that postoperative recovery is time consuming, which results in longer treatment times. I presume that many surgeons have their own minimally invasive measures from their experience. This section describes the significance of minimally invasive cardiac surgery and discusses the author's history and experience of the minimally invasive extracorporeal circulation.

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1.2 Implications of Invasion and Minimally Invasiveness in Cardiac Surgery

It is known that a living body causes many changes in its functions, such as circulation, respiration, metabolism, endocrine, immunity, etc., against an invasion called surgery. One of the most important substances when considering surgical invasion is Cytokine. Cytokines are information transfer substances that control biological responses to invasion in order to maintain homeostasis. It plays a role as a messenger that is guided from the invasive site and circulates throughout the body. Cytokines activate neutrophils. If the cause of invasion is a bacterial infection, activated neutrophils will attack the bacteria. These reactions are normal biological defense reactions (Fig. 1.1, left). However, with hypercytokinemia, the body exhibits symptoms of increased inflammation such as fever, tachycardia, hyperpnea, and leukocyte increase. Activated neutrophils adhere to vascular endothelial cells and migrate outside the blood vessel. As a result, it destroys its own normal tissue and causes increased vascular permeability, as well as organ dysfunction. Although it is a proper defensive reaction of a living body, the living body is adversely affected (right in Fig. 1.1). This is the Systemic Inflammatory Response Syndrome (SIRS) [1].

In the field of cardiac surgery, this kind of increased inflammatory response and postoperative organ dysfunction is called Systemic Inflammatory Response After Bypass (SIRAB), taking the involvement of extracorporeal circulation into the diagnostic criteria. In this SIRAB concept, the most peculiar point of heart surgery is that the circulating blood is in contact with each cardiopulmonary device, circuit tube, and air (Fig. 1.2, Video 1.1). This contact activates the

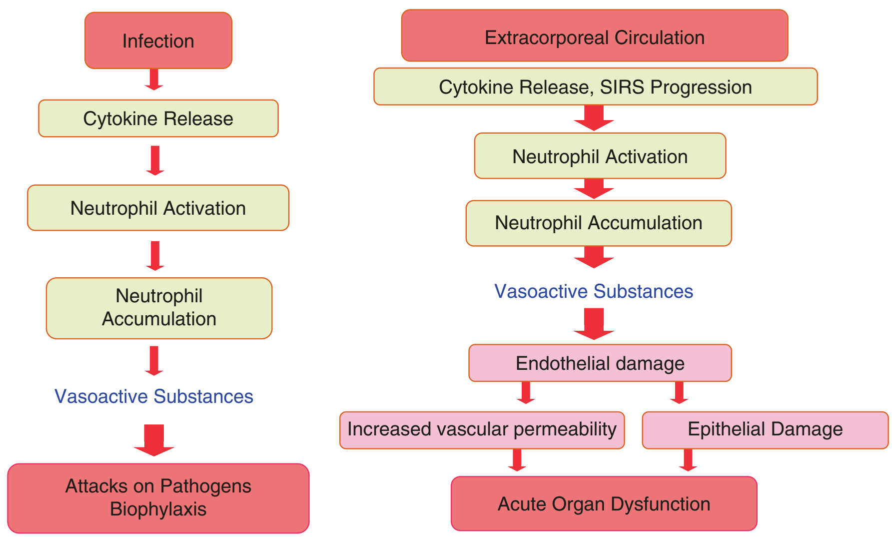


Fig. 1.1 SIRS and organ dysfunction

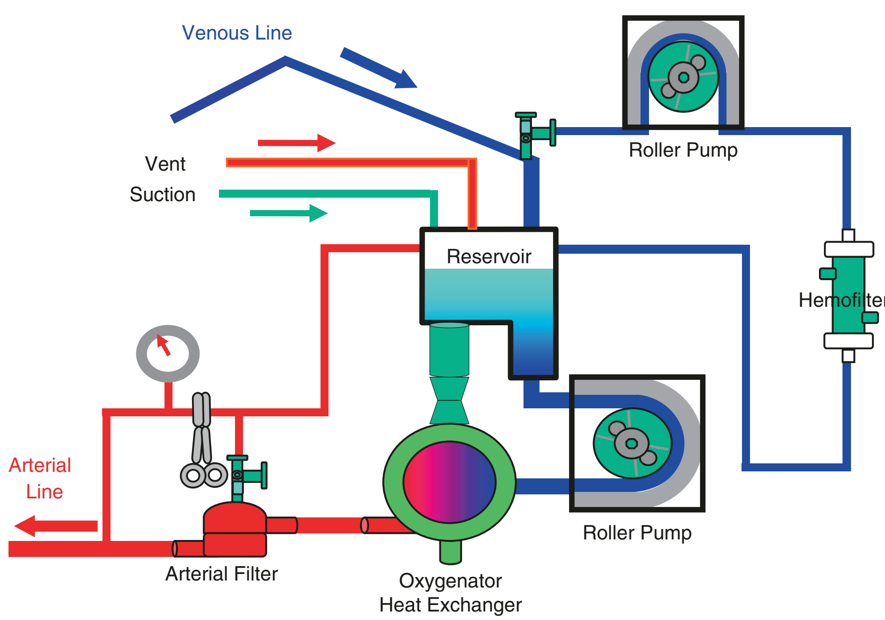


Fig. 1.2 Extracorporeal circuit diagram

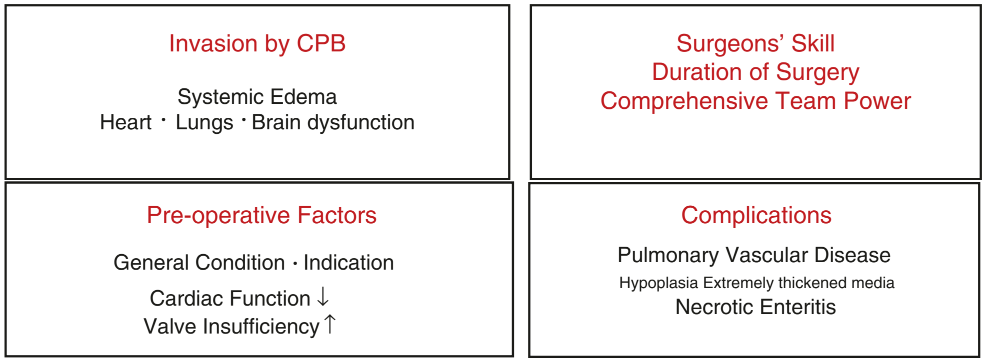


Fig. 1.3 Risk factors in pediatric open-heart surgery, and factors that determine the quality of surgery. CPB: cardiopulmonary bypass

coagulation system, fibrinolytic system, and complement system. Each system has a close network, including immune cells and vascular endothelial cells, and the inflammatory reaction is further amplified by linking one activation to the activation of another system. This is the reason why extracorporeal circulation becomes the greatest invasion of a living body. Furthermore, extracorporeal circulation uses a machine called heart–lung machine to regulate the general circulation with human hands. Naturally, the living body is subject to many fluctuations, such as changes in oxygen supply, imbalance in electrolyte and acid-base balance, changes in body temperature, and hemodilution.

Since cardiac surgery is to repair the heart by creating this non-physiological state, it is thought that even in patients with good preoperative conditions, functional deterioration of the whole body organs and physiological changes in the living body will occur more or less. Patients with severe preoperative circulatory or respiratory failure, renal or hepatic impairment, or premature organ function, such as in neonates and low-weight infants, may cause fatal damage to various organs. This is why heart surgery is more invasive than other surgeries. Therefore, the minimally invasiveness for cardiac surgeons is first summarized in measures to reduce the adverse effects of extracorporeal circulation. The intended clinical effect is not only to improve the surgical outcome, but also to return the cardiac function quickly, to have good oxygenation, to have good diuresis, and to result in the early exit of ICU from early ventilator weaning.

Secondly, it is also necessary to minimize the invasiveness of surgeons and teams. If surgery or extracorporeal circulation itself is invasive, reducing the time is naturally the most primitive and important minimally invasive measure for patients. Although it cannot be said very loudly, if the time can be shortened and the patient can be made less invasive, aside from medical and material cost savings, it will also lead to improvement of our working environment. This is a mandatory minimally invasive procedure that must be considered by the surgeon for both patients and team members. The term minimally invasive should also be adapted to the health care professionals in cardiac surgery.

However, there are some points to be noted about minimally invasiveness. There is no meaning if the measures for minimally invasiveness do not produce clinical improvement and lead to a reduction in the safety of the operation itself as well as a burden on health care professionals. This is not minimally invasive, but changes to the words of the surgeon's commitment. In order to reduce the invasiveness, it is considered that the minimum condition is to realize a clinical effect proportional to it by taking a certain measure. Figure 1.3 shows the factors that determine the surgical outcome and quality in pediatric cardiac surgery. There are some things that cannot be cured by any effort, such as morphological abnormalities of the atrioventricular valve or pulmonary vascular abnormalities that exist before surgery. However, if you make the effort, you can at least take measures to increase the chances of lifesaving by solidifying your surroundings, such as improving edema and preventing organ failure. That is the minimally invasive extracorporeal circulation and the improvement of the surgical team power that the surgeon should consider [2].

Q&A Knowledge of Minimally invasive in extracorporeal circulation (Question in 2017)

Question: Why should surgeons become familiar with extracorporeal circulation?

Answer: When a slightly elderly surgeon who has been performing heart surgery for nearly 40 years hears the word "minimally invasive," the image of extracorporeal circulation springs up intuitively. Even for ASD (Atrial septal defect) and VSD(Ventricular septal defect), which are now considered to be mild cases, young surgeons at the time who often performed postoperative management fully overnight had a very bad impression of extracorporeal circulation, especially in terms of systemic edema. I think they have experienced many cases where it would have been possible to save lives if there were no adverse effects of extracorporeal circulation.

When I was a novice, it was only the young surgeon who managed everything from surgery to post-surgery, staying at the hospital overnight almost every time. Therefore, it was natural for surgeons to think about extracorporeal circulation to improve the postoperative clinical course and to consult or instruct an anesthesiologist or perfusionist (although, of course, I sometimes had a bad face ...). I think it was natural for surgeons to become familiar with the extracorporeal circulation devices and their methods.

A cardiac surgeon's assessment is determined not only by the surgical outcome, but also by the total quality of the operation, such as the degree of perioperative recovery. Especially in newborns, the postoperative condition and the degree of recovery are considered to play a major role in the quality of life in the remote period, including psychomotor development. Therefore, not only the surgeon, but also the members of the cardiac team should be familiar with the extracorporeal circulation that stabilizes the postoperative condition and its pitfalls. The perfusionist is a matter of course, but the same goes for pediatric cardiologists and nurses. You do not need to know the specific techniques of extracorporeal circulation, but you should at least know what is a good minimally invasive extracorporeal circulation and what is a bad highly invasive extracorporeal circulation. In cardiac surgery, when complications occur, there are cases where the cause may not be known. Sometimes I have to explain to parents that the cause cannot be identified, and this is a remark unworthy of a doctor. Thus, I believe you should study extracorporeal circulation to identify possible causes and to take new measures as much as possible. The minimally invasive measures of extracorporeal circulation and the evaluation of its effects may be something that can be done only by a surgeon who works hard both during and after surgery [3].

Q&A Necessity of minimally invasive measures (Question in 2017)

Question: The current extracorporeal circulation is quite satisfactory. Why are you so involved in minimal invasion?

Answer: Indeed, as you say, today's extracorporeal circulation is extremely safe.

I also think that measures to minimize invasiveness have already been devised for each facility. Therefore, there is, of course, doubt that what I have been talking about minimally invasive so far is truly effective and minimally invasive and may not be meaningful in some facilities. Perhaps, at the moment, when thinking about making the extracorporeal circulation less invasive, the only difference might be to accept slight edema and diuresis to some extent or thinking about measures persistently. However, the new findings and pitfalls of extracorporeal circulation, which will be described in this document, may lead to the elucidation of the causes of intra and postoperative complications, as well as perioperative quality deterioration, for which the cause has not been identified until now. I would like you to consider them as one of those solutions. For example, in infants with severe abnormalities of atrioventricular valve morphology or pulmonary vascular disease, residual valve regurgitation or pulmonary hypertension after surgery may be a significant factor in inhibiting postoperative recovery. You may also need to enter emergency surgery with very bad preoperative conditions. However, even in such situations, efforts can at least improve the surrounding environment, such as reducing edema or maintaining cardiac function. From such a point of view, it is extremely important to always consider low invasive measures.

To be clear, I am not satisfied with the current extracorporeal circulation. I hate edema and decreased diuresis. The reason is that the postoperative course before 2006 was most stable. For example, the duration on intubation for bloodless open-heart surgery for VSD PH weighing 3–4 kg was 5–6 h. I think that extracorporeal circulation at that time was minimally invasive in many ways, so early extubation was possible. The success rate of bloodless open-heart surgery for Jatene's procedure weighing 4 kg or more was 100%. But this is not possible now. If extracorporeal circulation before 2006 was the most minimally invasive, is it now moderate minimally invasive? Of course, It is nostalgia that talks about the old days, but I would like to focus on minimally invasiveness so that the quality of the extracorporeal circulation will return as in the past.

1.3 Extracorporeal Circulation Method for Minimally Invasive

There is no doubt that extracorporeal circulation has some non-physiological effect on most organs. In particular, the adverse effects in newborns and low-weight infants are significant. The reasons are that in addition to the extracorporeal circuit being oversized compared to the body, immature functions of various organs such as the brain and lungs, coagulation and endocrine systems, basic oxygen consumption and water balance which are different from older children, and in addition, special extracorporeal circulation methods that match anatomical features are required, such as left heart hypoplasia syndrome. Therefore, measures for minimizing invasiveness to suppress the influence are essential. In short, with respect to biological fluctuations associated with extracorporeal circulation, (1) strive not to cause fluctuations "Constant Perfusion," (2) strive to restore biological reactions caused by fluctuations.

Q&A Characteristics of Pediatric Cardiac Surgery (Question in 2003)

Question: What are the characteristics of Pediatric Heart Surgery?

Answer: First, there are many types of diseases, many comorbid diseases other than heart, and more easily affected by extracorporeal circulation than adult cases. In addition, there are many types of procedures for different diseases, and conversely, the same procedure may be used for different diseases, and even when the disease is the same, the time of onset of symptoms varies, and the timing and indications of surgery differ for each case. For example, Blalock-Taussig procedure is useful for many diseases to improve oxygenation or to stimulate the development of the pulmonary artery, but it has a drawback to the heart. Performing this procedure on babies weighing 2 kg improves oxygenation but can cause heart failure. In a sense, surgeries are often carried out based on the trade-off between advantages and disadvantages. In addition, the number of cases where surgery is planned in stages are increasing; the first palliative operation immediately after birth, the second operation after 3–6 months, and the last operation after 1 year. The last operation is the well-known Fontan procedure, which creates an extremely non-physiological circulation by anastomosis of the superior vena cava and inferior vena cava directly to the pulmonary artery. Also, future problems and issues, such as pregnancy and childbirth in women with residual heart disease, reoperation for residual or new lesions, and so-called developmental disorders (delayed psychomotor development, learning disabilities, and autism), are increasing. In particular, the problems related to growth and development may possibly be the postoperative acute complications associated with surgery, and from this perspective, it is important to make surgery less invasive. And, unfortunately, we often feel painful when there are children being out of indication of surgery, being forced to stay in the hospital for long periods, and loss of children. These are the characteristics of Pediatric Heart Surgery.

Q&A Measures for SIRAB (Question in 2013)

Question: What are the measures for SIRAB?

Answer: Basic measures from the viewpoint of prevention include miniaturization of the extracorporeal circulation circuit (reduction of foreign surface contact area) to suppress complement activation and the generation of inflammatory reactants due to contact and use an extracorporeal circulation circuit coated with a biocompatible material such as Heparin, Phosphorylcholine, or Poly-2-methoxyethylacrylate, and to reduce blood transfusion. Although blood transfusion reduction will be described later, during the extracorporeal circulation, the values of electrolytes and acid-base balance in the blood often show abnormal values and may contain large amounts of vasoactive substances such as bradykinin. In addition to invasion of the extracorporeal circulation itself, which is the biggest cause of SIRAB, we cannot deny the possibility of vasoactive agents in the homologous blood to cause detrimental effects synergistically with extracorporeal circulation. Regarding foreign surface contact, it is necessary to consider the removal of foreign substances in the initial priming solution and the method of suction and venting blood so that circulating blood does not come into contact with air as much as possible. On the other hand, measures to be taken after the occurrence of SIRAB include removal of inflammatory reactants by ultrafiltration during extracorporeal circulation, washing and filtration of the initial priming solution, and suppression of inflammatory reactions by steroids and neutrophil elastase inhibitors.

There are many reports on these methods and their effects, and we would like you to judge the specific methods and their effects, including their advantages and disadvantages. Of course, there are some measures that you may find effective or ineffective based on your clinical experience. However, it is important to keep in mind that some measures have synergistic effects, while others have conflicting effects, and excessive measures to improve effectiveness can have adverse effects. Unfortunately, there is no magic to completely suppress SIRAB [4, 5].

Column: Constant Perfusion (2003)

Extracorporeal circulation changes the physiological environment in the living body. Because it fluctuates, the living body will be invaded. Therefore, extracorporeal circulation management that minimizes fluctuations is necessary. "Constant Perfusion" is a coined word meaning an extracorporeal circulation that maintains the arterial and venous blood flow rate, PaO2 and PaCO2, electrolyte and acid-base balance, blood concentration, regional brain oxygen saturation, and inflammatory reaction substances, etc. Figure 1.4 is the progress of Norwood surgery for HLHS. The method of "Constant Perfusion" is shown below.

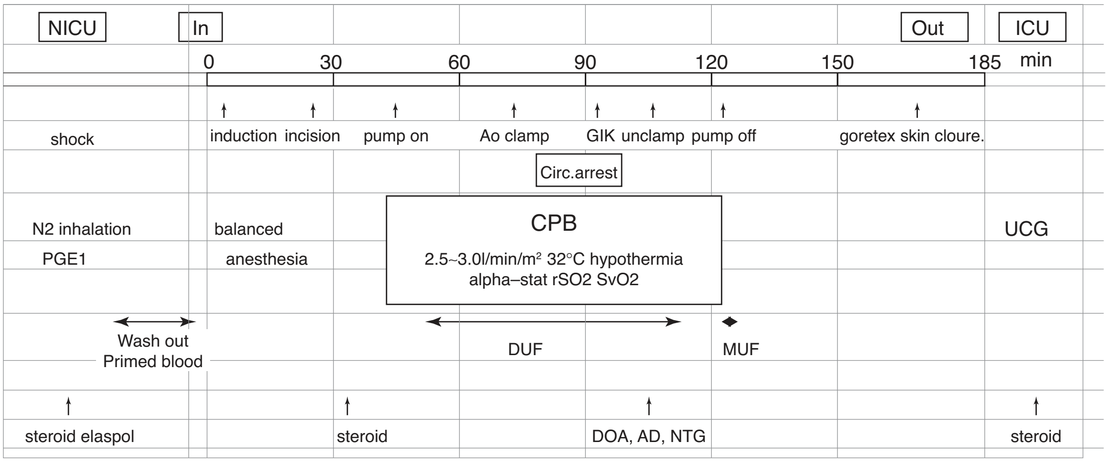


Fig. 1.4 Norwood procedure: progress of surgery and management means. The insults from conducting cardiopulmonary bypass itself, namely development of general edema or reduced cardiorespiratory function may be an inducing factor for death. This may also prolong ICU stay and affect higher brain function. Therefore it is especially important in Norwood patients, whose mortality is not zero, to consider how to reduce invasiveness of cardiopulmonary bypass more strictly.
PGE1: Prostaglandin E1
Circ.arrest: Circulatory Arrest in the Lower Body
rSO2: Regional Cerebral Oxygen Saturation
SvO2 : Mixed Venous Oxygen Saturation
UCG: Ultrasound Cardio Graphy
DUF: Dilutional Ultrafiltlation
MUF: Modified Ultrafiltration
DOA: Dopamine
AD: Adrenaline
NTG: Nitroglycerin

1. First of all, we need to ensure oxygen supply to the brain. In the experience of measuring the regional brain oxygen saturation (rSO2), the decrease or fluctuation of rSO2 level is observed mainly at three points. One at the time of initial hypotension right after the initiation of bypass, two right before aortic unclamp where the arterial blood flow rate is reduced to half, and three at the time of rewarming. It is likely that blood pressure fluctuations are directly involved (Fig. 1.5).

   There is much debate about the interpretation and evaluation of rSO2 values, but it is considered useful to understand changes in brain oxygen supply and metabolism. Therefore, first, "Constant Perfusion" that does not change this value as much as possible is necessary. Specifically, using mild hypothermia, maintain a high-flow extracorporeal circulation of 150 mL/kg/min or more, and adjust the perfusion rate and oxygen concentration according to changes seen in the rSO2 value. In particular, it is necessary to pay attention to the balance between the arterial and venous blood flow rate at the start of extracorporeal circulation, initiate the extracorporeal circulation slowly while paying attention to the initial drop, and manage to increase the perfusion rate after the start of rewarming.

   In open-heart surgery for newborns and low-weight infants, it is necessary to maintain reliable oxygenation of the brain at all points of extracorporeal circulation, taking into account the occurrence of cerebral ischemic disorders such as periventricular leukomalacia (PVL) and distant psychomotor developmental disorders.

   Figure 1.6 shows the rSO2 transition of 4.1 kg VSD bloodless open-heart surgery. The value progressed at almost constant value.
2. Deterioration of water balance and abnormalities of electrolyte and acid-base balance are also causes of invasion. In order to maintain water balance, first of all, definite venous drainage is indispensable, and we maintain cooperation with the perfusionist from beginning to end. Also, maintain high osmotic pressure from the initiation of extracorporeal circulation. Based on experience, the standard for using protein preparations is when the total protein amount is <3.0 g/dL. However, except for asthma cases, the initial priming of Saline HES is followed by dehydration with dilutional ultrafiltration (DUF). In addition, thoroughly correct electrolyte and base excess. Na value is also an important factor in maintaining water balance, targeting 135–140 mEq/L. Currently, blood gas data can be viewed continuously by using a CDI monitor, but in the past ASD and VSD open-heart surgeries, only two measurements were made after achieving total flow and during aortic cross-clamp. In particular, Na and Base Excess values need to be corrected proactively rather than being reduced. "Constant Perfusion" is performed from these viewpoints as well.

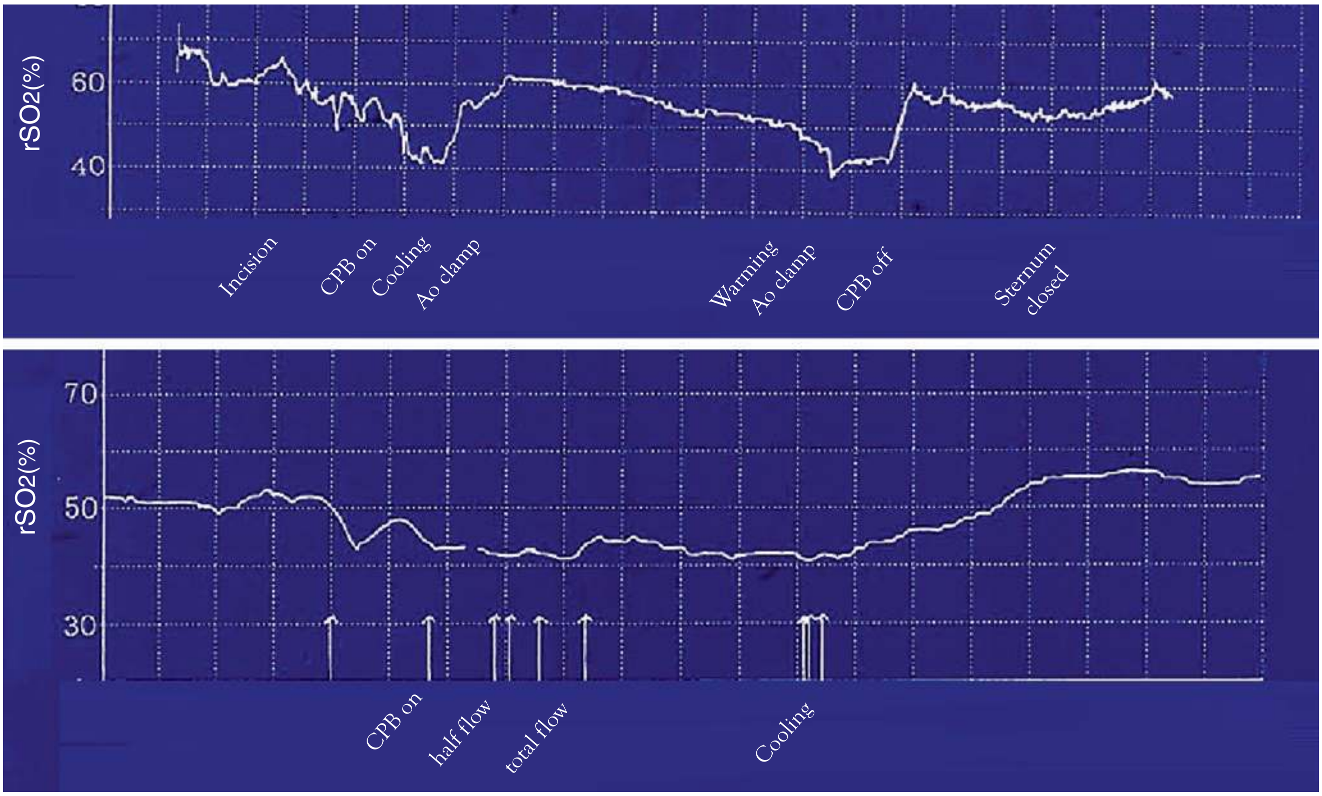
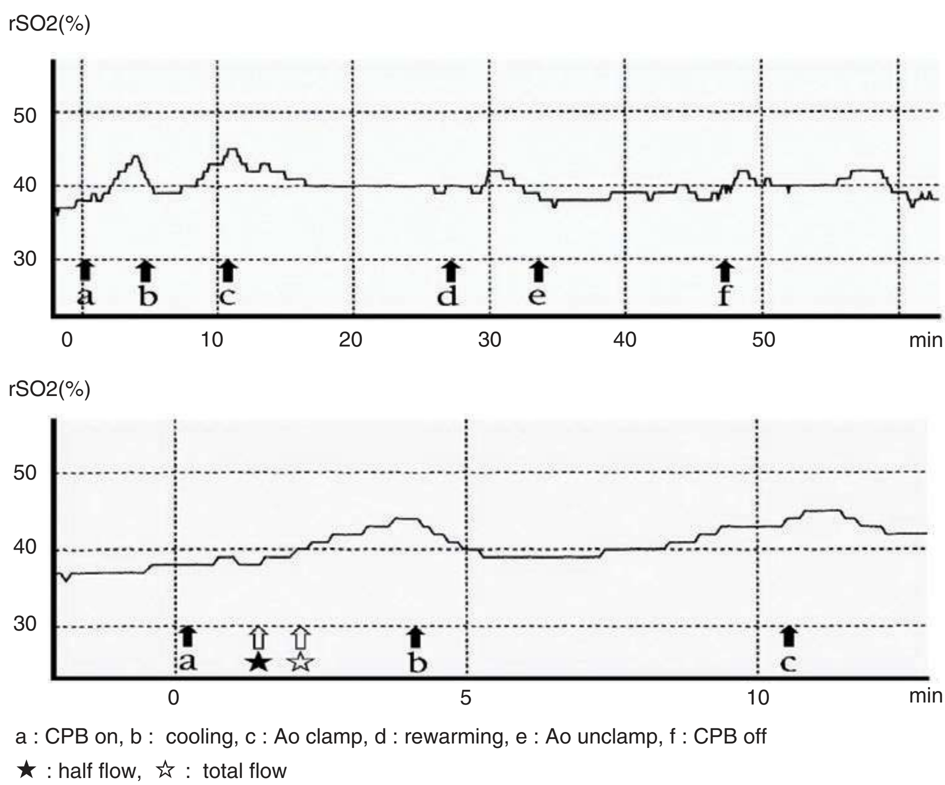


Fig. 1.5 Regional cerebral oxygen saturation in TOF repair weighing 13.2 kg

Fig. 1.6 Regional cerebral oxygen saturation in VSD repair weighing 4.1 kg (Asanguinous CPB) [6].
Upper panel: No significant changes in rSO_2 was observed during and after CPB.
Lower panel: Reduction in rSO_2 was not seen following influx of clear prime solution immediately after initiation of CPB



3. Deterioration of postoperative circulation and respiratory dynamics also leads to a vicious cycle of invasion, contributing to long-term management. Therefore, it is necessary to take measures against SIRAB even in a short extracorporeal circulation. At Sakakibara Heart Institute, in order to reduce myocardial injury and lung injury during reperfusion, high-flow rate DUF was performed with polyacrylonitrile membrane hemofilter for the purpose of suppressing vasoactive substances from rewarming before aortic unclamp until partial bypass. By this method, the generation of vasoactive substances was suppressed, use of catecholamine was reduced, and early respiratory withdrawal was possible, especially in neonatal and infant open-heart surgeries. We also implement thorough "Constant Perfusion" to prevent the increase of vasoactive substances.
4. The invasion of the living body accompanying extracorporeal circulation increases with time. Long-term extracorporeal circulation can amplify the inflammatory response beyond what the body can control. Therefore, as a matter of course, it is also necessary to finish the operation in a short time. Ending the surgery within the range of "Constant" before it becomes unacceptably variable is another part of "Constant Perfusion."

   "Constant Perfusion" is an extracorporeal circulation management method where non-physiological fluctuations of the living body do not occur. The point is to perform preventive and accurate basic procedures during extracorporeal circulation, such as perfusion and temperature adjustment, correction, and DUF before measurement data changes. "Constant Perfusion" is considered the most basic and important measure that directly leads to minimal invasiveness [6–11].

Q&A Effects of minimally invasive cure (Question in 2003)

Question: There are too many factors involved in the invasion of cardiac surgery. Therefore, I feel that it is difficult to achieve the effect by one method. What do you think about that?

Answer: As you said, many factors are involved in surgical invasion, so I think there are still many issues that need to be solved to improve clinical effectiveness. When asked if there were truly minimally invasive measures that showed a clear clinical effect, the answer was unclear. To be honest, while taking various measures, I also feel that it has become naturally minimally invasive. A minimally invasive effect may only be noticed after a while. However, even if there is a certain measure that has an absolute clinical effect, it may be possible that some other factor has eliminated that effect. I think that less invasive measures should be considered more comprehensively and extensively.

I think that each facility has their own thoughts about the effectiveness of the measures reported so far. For example, in 1980s, our hospital used steroids to prevent laryngeal edema after extubation. I noticed a reaction that increased blood pressure when given intravenously and thought that steroids were an interesting drug. Figure 1.7 shows the transition of serum cortisol values following open-heart surgery for neonates. In the group in which hydrocortisone was not used, there was a clear reduction of its level and almost diminished at 24 h after operation. Steroids are effective in suppressing activated neutrophils or vasoactive substances, preventing edema and improving cardiopulmonary function, but their use in extracorporeal circulation has been controversial. However, looking at this result, apart from the effects, I would like to actively replenish it.

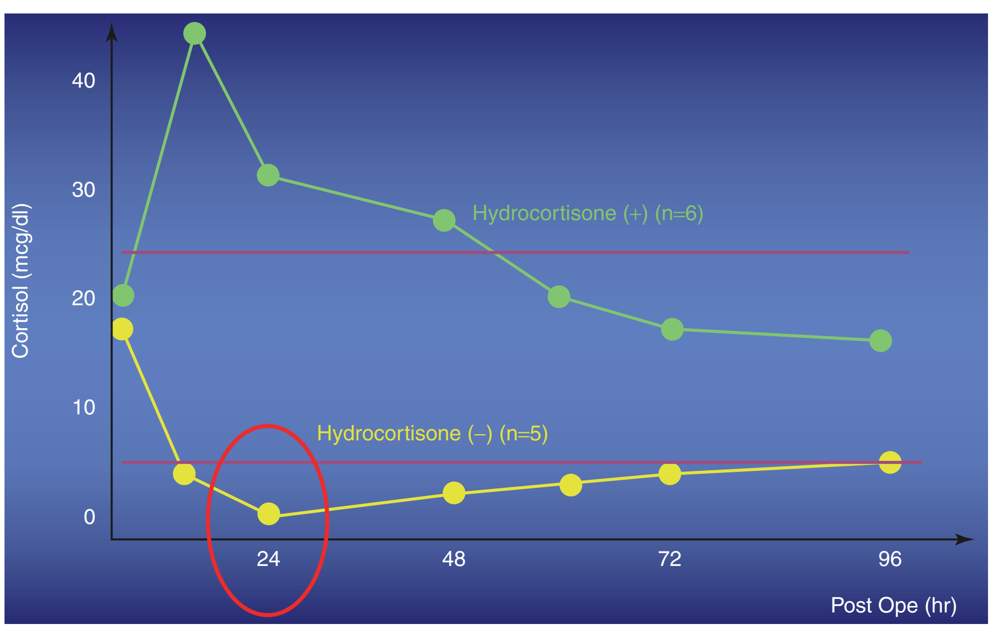


Fig. 1.7 Cortisol reaction in neonatal open-heart surgery [12] modified

Also, I'm sorry to talk a little bit different, but there is some debate over whether if small incision can be called minimally invasive. I think it can be said to be minimally invasive in terms of suppressing pain, maintaining respiratory function, and cosmetic point of view.

In reporting on minimally invasive measures, care should be taken in assessing the results. Despite the fact that it is an effective minimally invasive measure, it may be judged to be bad, or vice versa. For example, in terms of the timing of data measurement, suppose that an inflammatory reactant was measured under the same conditions when aortic clamp was released. However, even if the data are measured at the same timing of aortic unclamp, the measurement conditions will completely differ if the aortic cross-clamp time is 30 min or 60 min. In addition, even if the results were judged as no significant difference, it may be judged that it is an extremely effective measure depending on the case. Furthermore, no matter how the comparison conditions are prepared, such as the disease, physique, extracorporeal circulation method, and duration, the measured values will naturally change depending on the quality of "Constant Perfusion" described previously. In previous reports, I think that even if the same examination was performed, the results differed greatly between reports, and even if excellent results were obtained, they often did not lead to real clinical effects. Of course, there are many invasive factors as mentioned, but the fact that each facility has its own extracorporeal circulation method may also complicate the problem.

In the future, it is necessary to conduct research with a focus on clinical effects, not just to determine the significant difference of measured data. If we do so, a new extracorporeal circulation method with a truly clinical effect will be established, and we will be able to develop cardiopulmonary bypass devices with a focus on clinical effects. Of course, I know well that it is difficult in clinical research [12–17].

Q&A Actual clinical effect (Question in 2013)

Question: Are there any measures that make you feel it is extremely effective clinically?

Answer: If you have been a surgeon for a long time, you may find that the patient's clinical course has become extremely stable, and you may experience a turning point in which your surgical results will improve dramatically. One of them for me was to use ultrafiltration during extracorporeal circulation. In the 1980s, the main purpose of ultrafiltration was to prevent hemodilution and to wash to reduce the K value of the initial priming blood (in the era of whole blood priming, old blood had a high K value, so cardiac arrest and ventricular fibrillation occurred shortly after the initiation of extracorporeal circulation). After reading a report in 1990 that ultrafiltration allowed for one-stage sternum closure with open-heart surgery for aortic interruption, I started to believe that ultrafiltration was undoubtedly effective in suppressing edema, and this effect would not only prevent hemodilution but also control some invasive factors. I immediately tried to mimic this, but the problem was in the extracorporeal circulation of newborns and infants, if a safe reservoir level for ultrafiltration without adding volumes such as blood and protein products could be secured, and also, it was not clear when and how much water removal should be clinically effective.

In actual clinical practice, this could only be done when there was enough reservoir level, but the following comment came out from our perfusionist. "When the rewarming starts, there is a reaction that the reservoir level increases and hemodilution progresses, I don't know why, but at least during this period, ultrafiltration can be safely performed." Since then, I have begun examining the clinical effectiveness of these ultrafiltration methods centering on water removal during rewarming. Minimally invasive is meaningful only with clinical effects. The specific goals are good postoperative diuresis, early ventilator weaning and early ICU exit. For me, this ultrafiltration method after rewarming was the only minimally invasive measure that I realized for the first time as having realized clinical efficacy [18].

1.4 History of Minimally Invasive Measures at Sakakibara Heart Institute

1.4.1 Establishment and Clinical Effect of Ultrafiltration Method

The clinical effectiveness of performing extracorporeal ultrafiltration method (ECUM) during extracorporeal circulation has also been confirmed in infant open-heart surgery. However, when ECUM was started, the problem was when and how much water removal should be performed in the extracorporeal circulation of newborns and low-weight infants, which should lead to clinical effects. In reality, it will be done at a high reservoir level, but if possible, avoid adding blood or protein preparations. At that time, our perfusionist commented that the reservoir level increased when rewarming began and that this reaction seemed to return water.

Therefore, we first evaluated changes in Hct and total protein levels before and after rewarming (approximately 10 min after the release of aortic clamp) in 33 VSD and 34 adult MVR (Mitral valve replacement) patients where ECUM was not performed. The initial priming volume of VSD was 750 mL (600 mL of whole blood, no protein preparation), and adult MVR was 1000–1200 mL (no blood transfusion). A moderate hypothermia extracorporeal circulation at 28 °C was performed. Blood and protein preparations during the extracorporeal circulation were not added.

VSD averaged a significant decrease of 2% Hct, 0.3 g/dL total protein, and in MVR, 2% and 0.2 g/dL (Fig. 1.8). These were obvious hemodilution reactions, suggesting an calculated increase in water of 50–100 mL for VSD and 300–700 mL for MVR. During this rewarming, the reservoir level increased, and prevention of hemodilution at this time was considered to be meaningful from the viewpoint of reducing myocardial reperfusion injury. Therefore, it was decided to remove only the amount of myocardial protective fluid (Blood GIK) and correction fluid during aortic cross-clamp, and to remove water as much as possible while observing the reservoir level after rewarming.

1.4.1.1 ECUM Effect in Infant VSD (1990)

The effect of this ECUM method was evaluated with VSD patients under 10 kg body weight. There were 20 cases with ECUM and 33 cases without ECUM (Table 1.1). In the ECUM group, the amount of urine output in the extracorporeal circulation tended to be small, but the total filtration volume was 168 mL on average, about half of which was after the start of rewarming. In the ECUM group, no decrease in Hct and total protein levels were observed, and the hemodilution from the start of rewarming until unclamp disappeared (Fig. 1.9).

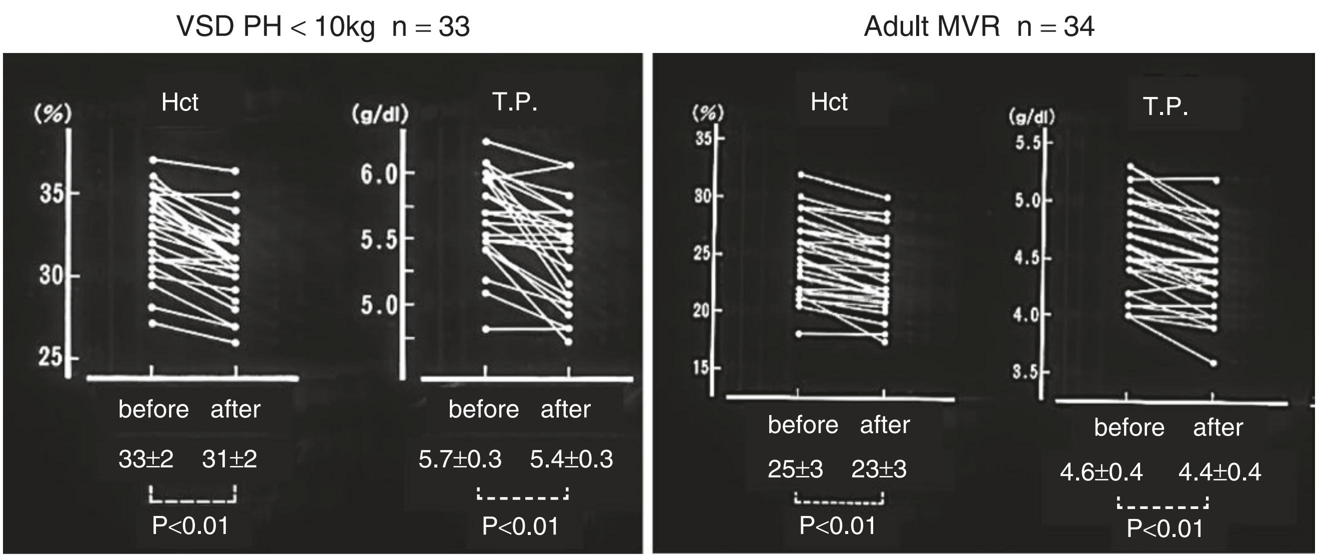


Fig. 1.8 Hemodilution during rewarming.
Hct: Hematocrit
T.P.: Total protein

Table 1.1 Comparison between ECUM group and non-ECUM group in VSD repair weighing less than 10 kg.
ECUM: Extracorporeal Ultrafiltration Method
CPB: Cardiopulmonary Bypass

	n	Pp/Ps	Pre-ope ventilation	CPB time (min)	Ao clamp time (min)	Rectal temp. (°C)
ECUM(+)	20	0.9±0.1	3	93±26	41±15	27±1
ECUM(−)	33	0.9±0.1	3	84±21	45±15	28±1

	Urine output (ml)	Filtrate vol. (ml)	Dilution rate (%)	
ECUM(+)	57±66	168±108	6±3	P<0.001
ECUM(−)	67±43	—	11±3	

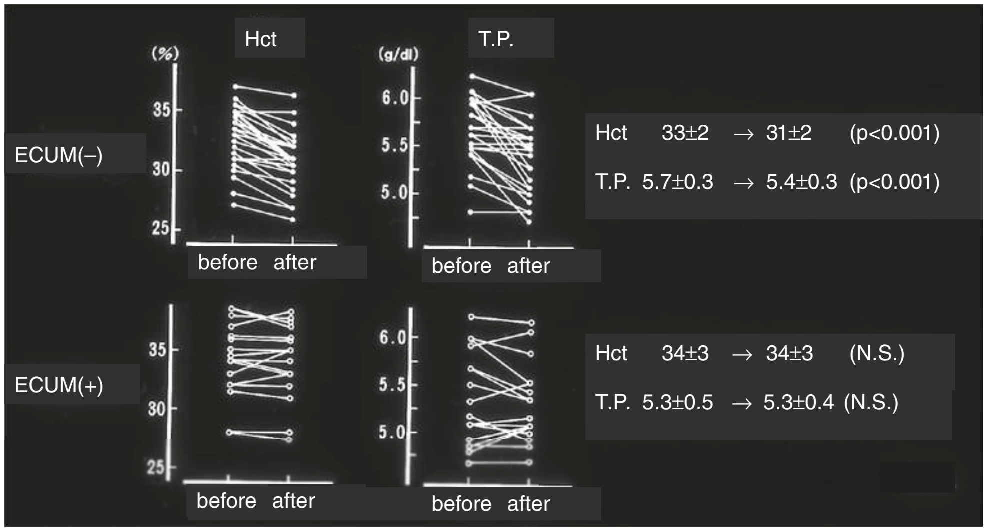


Fig. 1.9 Comparison of Hct and total protein between ECUM group and non-ECUM group in VSD repair weighing less than 10 kg

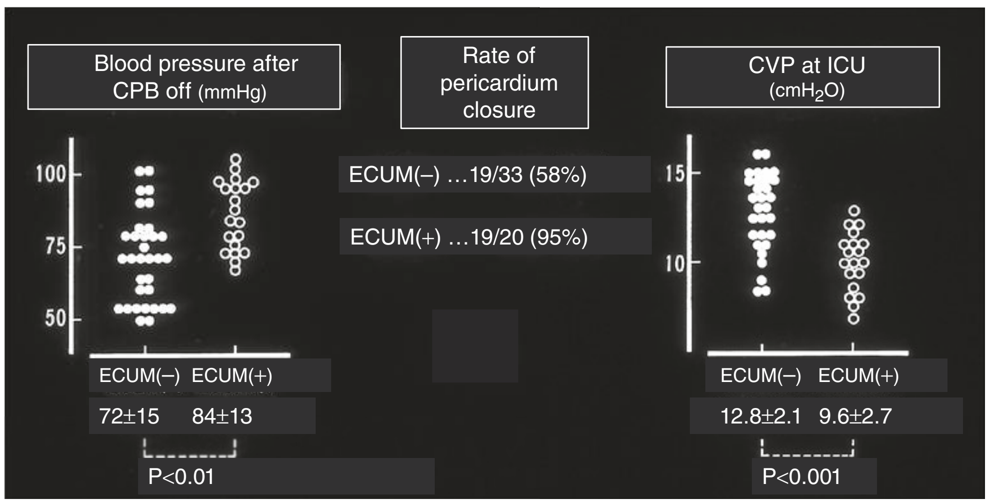


Fig. 1.10 Comparison of hemodynamic parameters between ECUM and non-ECUM groups in VSD repair weighing less than 10 kg

Arterial pressure at the time of weaning from the extracorporeal circulation, autologous pericardial closure rate, and CVP after ICU return were all good in the ECUM group (Fig. 1.10) and had a strong impression that the pericardium could be closed easily. In the ECUM group, some cases showed a decrease in PaO2 at the end of extracorporeal circulation. However, the recovery time till PaO2 became over 100 mmHg (FiO_2 0.5), which is the respirator weaning criteria, was significantly shortened (Fig. 1.11).

Conclusion

ECUM aimed at preventing hemodilution after the start of rewarming improved hemodynamics and respiratory status after open-heart surgery. Especially in infant VSD, in most cases, ventilator weaning was possible at the same time as the awakening from anesthesia.

1.4.1.2 ECUM Effect in Complete Atrioventricular Septal Defect (AVSD) (1992–1993)

The same comparison was performed in six ECUM cases (body weight 5.4 ± 0.6 P, Pp/Ps 1.0 ± 0.1) and seven non-ECUM cases (body weight 5.7 ± 0.9 kg, Pp/Ps 1.0 ± 0.0). In the non-ECUM group, the Hct before and after the start of rewarming decreased 2% (35 ± 3 → 33 ± 3) on average and total protein decreased 0.2 g/dL (5.6 ± 0.2 → 5.4 ± 0.2) on average. On the other hand, in the ECUM group, Hct (35 ± 3 → 35 ± 3) and total protein (5.7 ± 0.2 → 5.6 ± 0.4) did not change. The average amount of ultrafiltration was 205 mL, of which 60–150 mL was after the start of rewarming. There was no difference in water balance and final dilution rate between the two groups. It is thought that the difference was in the ECUM group, Blood GIK was sucked into the reservoir, and the amount was

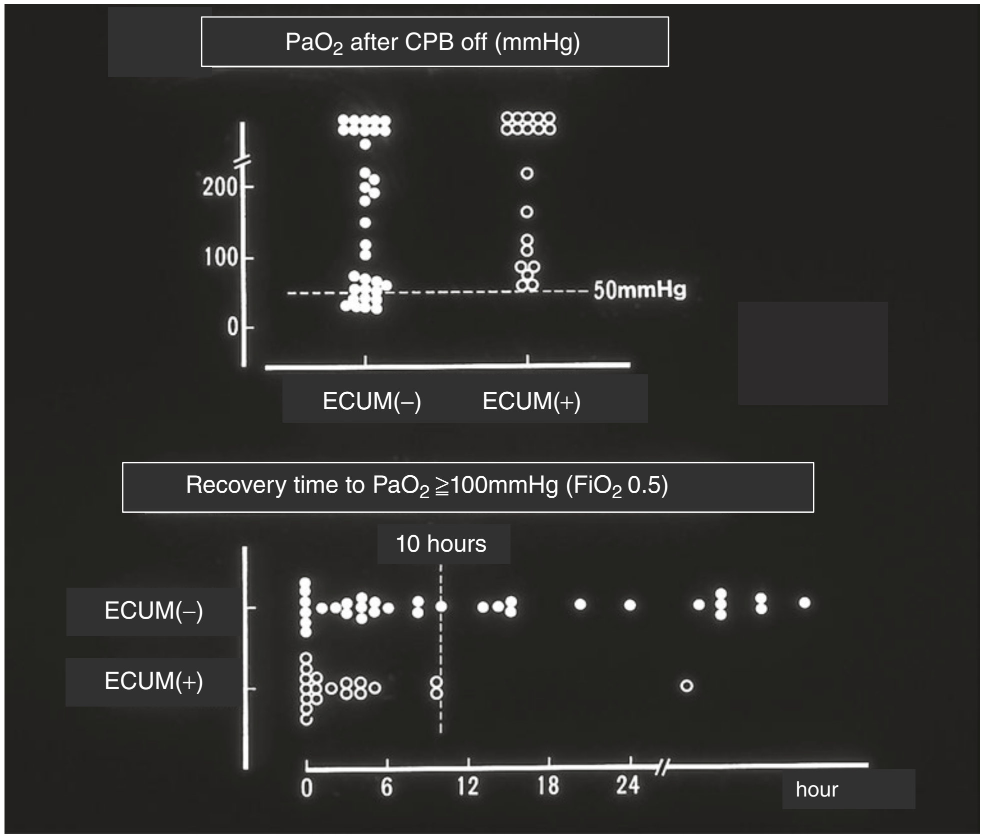


Fig. 1.11 Comparison of respiratory parameters between ECUM group and non-ECUM in VSD repair weighing less than 10 kg. One case in which the improvement in oxygenation was delayed in the ECUM group was a case in which subaortic stenosis and mitral valvuloplasty were performed in addition to VSD closure. In this case, transient bradycardia and hypotension were observed in the ICU. In 1990, VSD cases often showed cardiac enlargement, high CVP, and extreme hypoxia. It was an era when the residents often worried about postoperative oxygenation and diuretic status, and changes in CVP

Table 1.2 Comparison between ECUM group and non-ECUM group in AVSD infants

	CPB (min)	Ao clamp (min)	Lowest Temp. (℃)	Lowest Hct (%)	Lowest T.P. (g/dl)
ECUM(−)	137±33	87±27	26±2	31±3	5.0±0.5
ECUM(+)	140±10	93±13	26±1	31±4	4.6±0.3

	Urine output	Filtrate vol.	Filtrate vol. after rewarming	Water Balance	Dilution Ratio
ECUM(−)	136±58	–	–	54±55	9±8
ECUM(+)	142±116	205±80	60~150	47±30	8±4

removed by ultrafiltration, while blood was added to the non-treatment group without Blood GIK suction in the non-ECUM group.

There was no difference in the minimum Hct or total protein levels between the two groups (Table 1.2). CVP and oxygenation improvement time after returning to ICU in the treatment group were significantly better in the ECUM group (Fig. 1.12).

Conclusion
Postoperative management for complete atrioventricular septal defect surgery at that time was difficult. However, in the ECUM group, all cases reached the ventilator weaning criteria by the time of awakening from anesthesia, and three cases weaned on the day of surgery. Also, around this time, the number of cases in which sternum closure is possible even with neonatal surgery was clearly increasing.

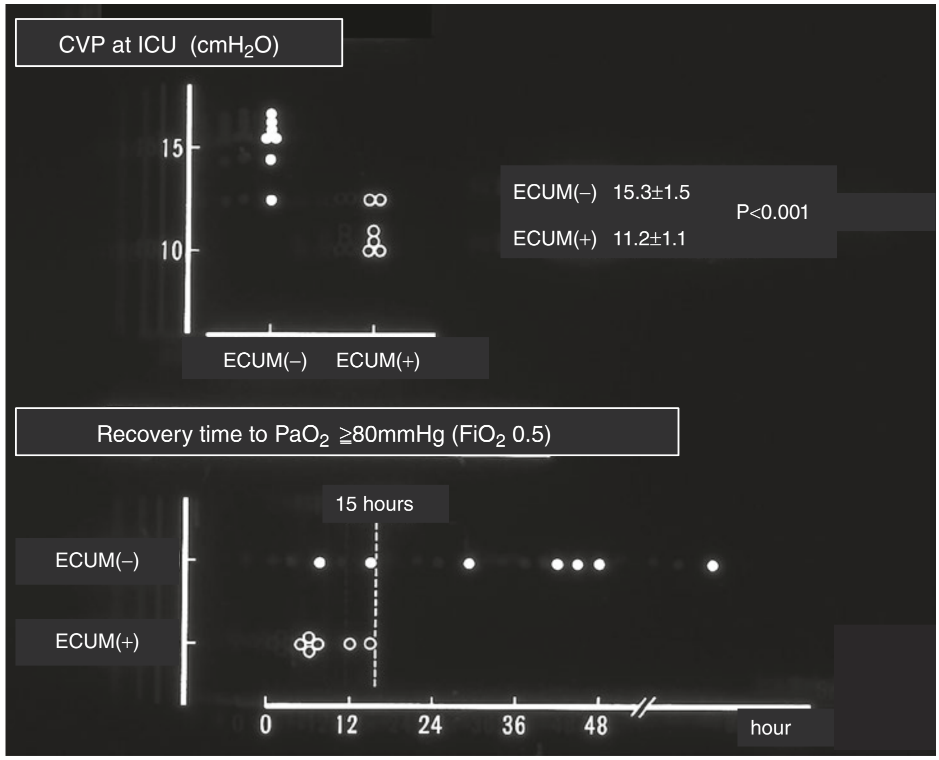


Fig. 1.12 Comparison of CVP and respiratory status between ECUM group and non-ECUM in AVSD infants

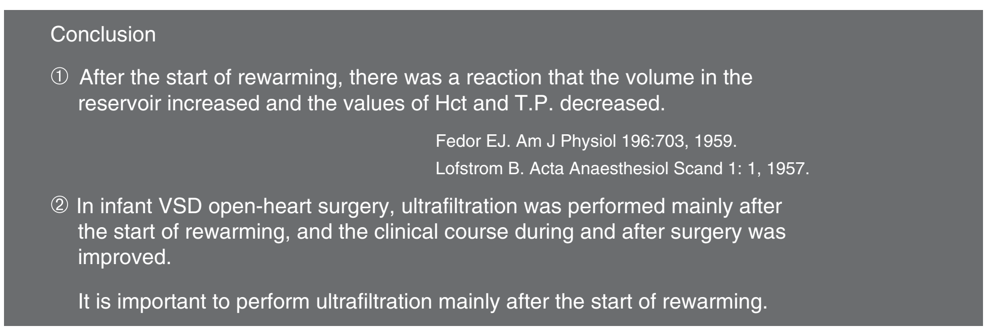


Fig. 1.13 Conclusion slide on ECUM effect. After the rewarming, there was a reaction that the reservoir level increased and the values of Hct and total protein decreased. In infant VSD open-heart surgery, ultrafiltration was performed, mainly after rewarming, and the clinical course during and after surgery was improved. From the above, it is important to perform ultrafiltration after the start of rewarming

The time after unclamping of aorta is an critical for the heartbeat to resume. I realized that it is important to perform ECUM so as to eliminate hemodilution after the start of rewarming, rather than simply transfusing additional blood to concentrate circulating blood. In open-heart surgery for patients with severe pulmonary hypertension where strict water management is required, ECUM, especially after rewarming, was an effective method for safe and clinically effective water removal.

Column: Hemodilution During Rewarming, Sone's Ultrafiltration Method (1991)
(Comments at the research presentation held at Sakakibara Heart Institute)

I will make an additional comment. Currently, we are still conducting clinical research on the effects of the ultrafiltration method mentioned in the presentation.

Figure 1.13 shows the conclusion of the presentation at this year's Annual Meeting of the Japanese Association for Thoracic Surgery, on the clinical efficacy of this ECUM method in VSD open heart surgery weighing less than 10 kg. The clinical efficacy of this method is also evident from rapid extubation in postoperative cases with pulmonary hypertension.

Most importantly, although the reasons are unknown, it is the discovery of a phenomenon in which rewarming during extracorporeal circulation increases the reservoir level, caus-

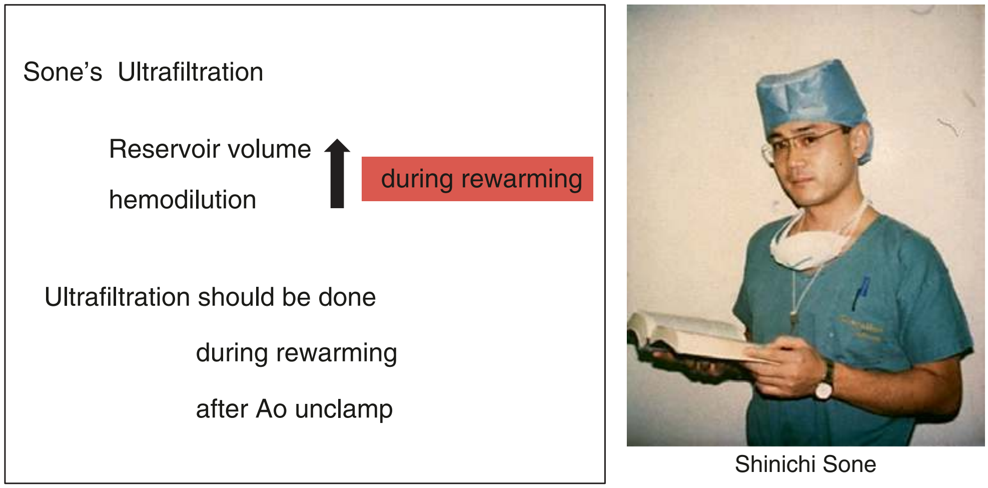


Fig. 1.14 Mr. Shinichi Sone, Perfusionist at Sakakibara Heart Institute

ing hemodilution as if water were returning. In addition, in the 1950s, there were already reports that surface cooling hypothermia reduces circulating blood volume and increases interstitial water, and this reaction is reversible upon rewarming.

This is the world's first report of clinically effective ultrafiltration using the hemodilution reaction during rewarming. Here, I must introduce to you a perfusionist who noticed this phenomenon in actual clinical practice and taught me that ultrafiltration can be safely performed at this time. His name is Shinichi Sone (Fig. 1.14), 38 years old this year. We call this "Sone's ultrafiltration method." We believe that this method is safe for everyone and clinically effective. At least, it is clear that this method has made a great contribution to pediatric open-heart surgery of the Sakakibara Heart Institute. Our perfusionist is extremely talented.

1.4.2 Problems with Ultrafiltration

Since then, as the ECUM technique has become more familiar, extracorporeal circulation can be started safely even when the reservoir level at the initial priming was low. In 1992, with the aim of saving 1 unit of whole blood, the initial priming volume was 650 mL using the same circuit of 750 mL (priming 500 mL (2.5 units) of whole blood and using the remaining 100 mL (0.5 unit) during or after surgery). In this case, the reservoir level at the time of initial priming will be about 50 mL. During aortic cross-clamp, even if hemodilution progresses, only the amount of Blood GIK and correction fluid that has been aspirated is ultrafiltrated, and then water is removed mainly after the start of rewarming while maintaining the reservoir level. If the level was low, 50 mL of whole blood was added.

At that time, the fundamental principle was not to add blood and protein preparations in extracorporeal circulation, but in severe cases such as neonates, they were added to actively remove water. This was not just adding blood to concentrate circulating blood but to perform ECUM. The purpose of transfusion and volume addition during extracorporeal circulation has become more evident. However, a problem that seems to be caused by ultrafiltration occurred. That is, increase in the amount of protein preparation used and arrhythmia.

1.4.2.1 Protein Leakage (1991–1992)

At the time, the hemofilter used, HC-30M, had a polypropylene membrane. Although it was developed to enable the removal of plasma-free hemoglobin, there was a drawback of protein leakage, and the total amount of protein in the filtrate in actual clinical practice was 1.8 ± 0.2 g/dL. As a result, the total protein level decreased, and the protein preparation usage rate increased (protein use criteria was <3.0 g/dL).

Polysulfone membrane, HP-300, was also used. It is characterized by low complement activation and no protein filtration. In fact, no significant protein leakage was observed with HP-300 (Fig. 1.15).

1.4.2.2 Arrhythmia (1991–1993)

In open-heart surgery for newborns and infants, little attention was paid to the Na concentration during the extracorporeal circulation. The reason was that Na in the initial priming was rather high with whole blood priming. However, an increase in cases with low Na levels was observed due to the introduction of ECUM and reduced use of blood and protein products. Figure 1.16 shows an electrocardiogram after complete AVSD open-heart surgery. There are two cases: a case with sinus rhythm, but bradycardia with a heart rate of 80 per minute after surgery and a case with complete atrioventricular block. Both were transient, and there were no problems with hemodynamics. The common point of both cases is that the Na value after returning to ICU was under 130 mEq/L. It was speculated to be functional with electrolyte imbalance, including Na.

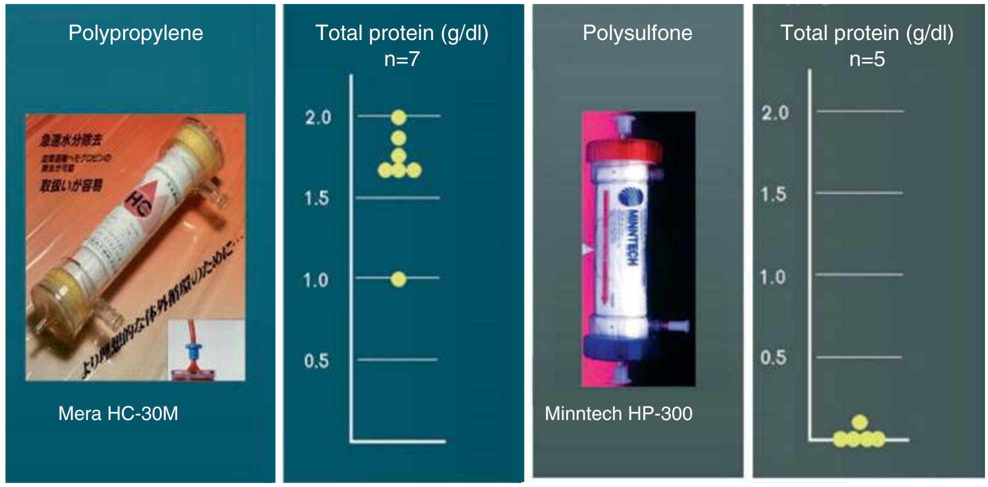


Fig. 1.15 Total protein in filtrate of HC-30M and HP-300

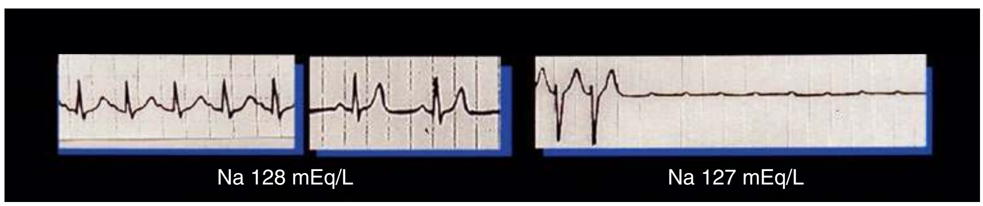


Fig. 1.16 Postoperative arrhythmia in AVSD open-heart surgery. AVSD: Atrio-Ventricular Septal Defect

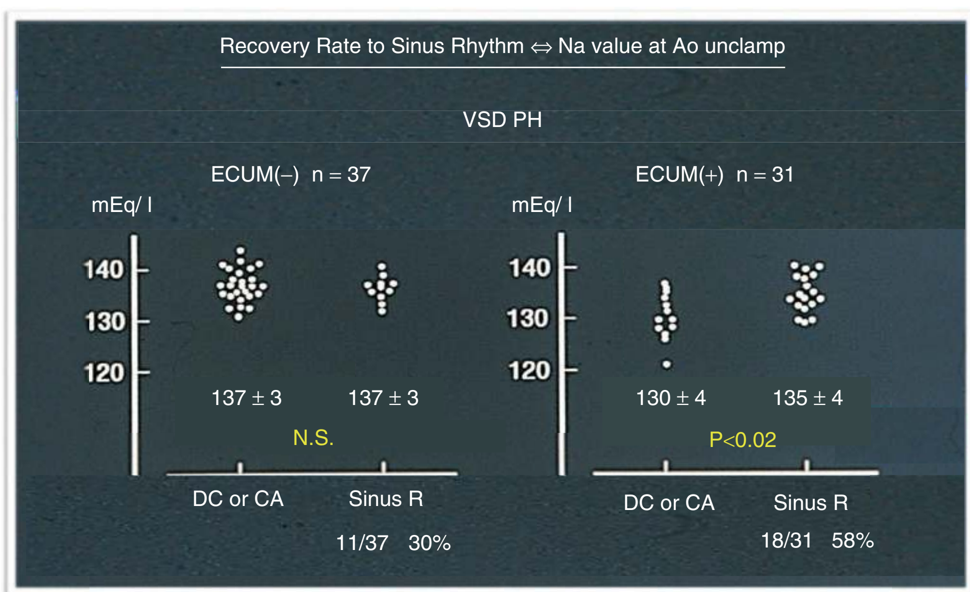


Fig. 1.17 The rate of spontaneous recovery to sinus rhythm and Na value in infant VSD.
At that time, there were many cases of transient atrioventricular block after aortic unclamp, for which isoproterenol was administered.
DC: direct cardioversion
CA: catecholamine

These arrhythmias were not recognized before ECUM was introduced. In addition to the washing of priming blood and ECUM during extracorporeal circulation, it was speculated that the cause was saving blood transfusions and protein preparations without Na correction. In addition, hyponatremia is also a factor enhancing systemic edema. After this, aggressive Na correction was started using 10% NaCL. However, on the other hand, there was also a question of whether Na correction during extracorporeal circulation in low-weight children is safe. Based on the above, the effect of Na correction in infant open heart surgery and its effects were examined.

The subjects were 31 infants with ECUM and 37 infants without ECUM. First, the blood Na level at the time of aortic unclamp was compared between cases that naturally returned to sinus rhythm and that required DC or a cathecholamin to return to sinus rhythm (Fig. 1.17). The rate of spontaneous return to sinus rhythm in the non-ECUM group was 30%, and the average Na value was 137 mEq/L, which was not different. On the other hand, the rate of spontaneous reversion to sinus rhythm in the ECUM group increased to 58%, but cases with Na values of 120 mEq/L increased, and Na values in patients using DC or cathecholamin were significantly lower, with an average of 130 mEq/L. Therefore, the correction was started so that the Na value would be 135–140 mEq/L in the extracorporeal circulation of children.

The rate of spontaneous recovery to sinus rhythm increased to 85%, especially in cases where Na before unclamp was corrected to 135 mEq/L or more where the rate was 96%, and conversely, in cases where the correction was insufficient DC or catecholamine was required (Fig. 1.18).

There was an opinion that circulatory and respiratory dynamics might deteriorate due to Na correction, but CVP and oxygenation after returning to ICU did not change (Fig. 1.19), and the respirator duration was rather shortened. There were no clinical problems with Na correction in newborns or low-weight children.

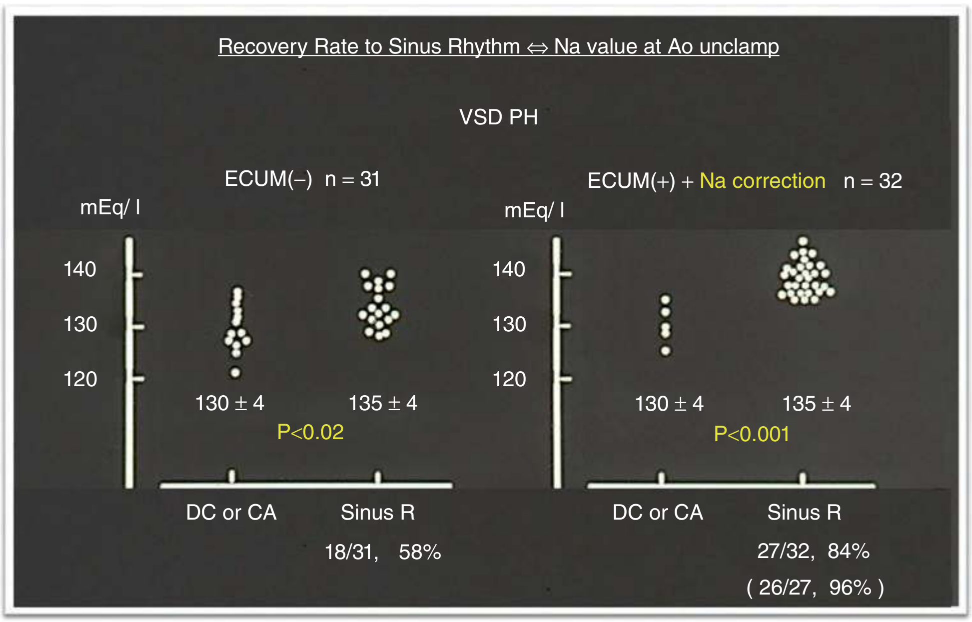


Fig. 1.18 Na correction and change of spontaneous return rate to sinus rhythm in infant VSD

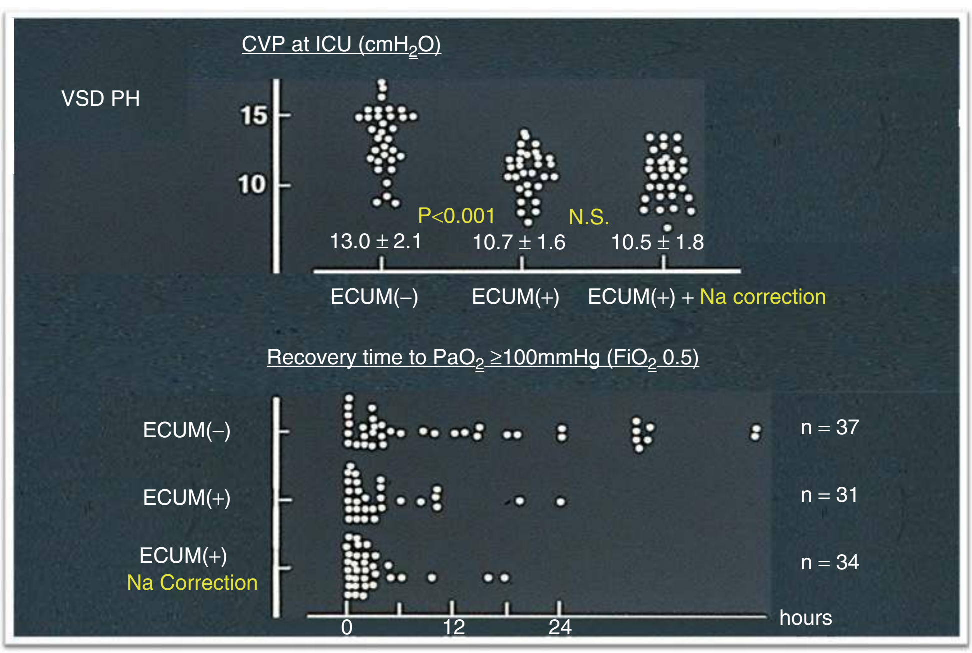


Fig. 1.19 Na correction. Change of CVP, and duration to improve oxygenation in Infant VSD

Table 1.3 Initial priming composition and blood gas data for a VSD case weighing 19 kg. ACD: Acid-Citrate-Dextrose

Initial priming solution Priming volume 750mL

ACD	Meylon	Mannitol	5% Glu.	Ringer sol.	Carcicol	Vit. C	Glycyol	Antibiotics	Heparin	Exocorpol
–	20mL	100mL	290mL	290mL	–	1g	20mL	1g	20mg	20mL

No.	Time		PH	PO_2	PCO_2	BE	SB	Ht	TP	Na	K	BS
Pre	Control	CPB	8.244	373	5.8	+6.4	27.1	–	3.1	68	1.9	680
		Patient / ACT	7.519	260	29.0	+1.6	23.6	34.5	6.2	136	3.8	147
1	/	297	7.661	366	13.4	−5.2	17.6	17	3.7	106	3.0	800↑
2	15	506	7.584	454	16.2	−6.0	17.3	17.5	3.7	110	3.2	800↑
3	32	381	7.607	324	19.1	−1.9	21.1	16.5	3.8	118	3.2	800↑
4	47	294	7.397	444.2	32.8	−4.2	19.9	18	3.5	120	3.4	800↑
5	63		7.638	467	19.0	−0.2	21.5	18	3.4	124	4.0	800↑
6												

Conclusion

It is necessary to sort out the conditions of circulating blood to be reperfused in order to prevent myocardial reperfusion injury or to recover cardiac function early. The above results suggested the importance of Na correction during extracorporeal circulation. Attention should be paid to electrolyte imbalance for early recovery of cardiomyocyte metabolism. It is also easy to imagine that hyponatremia during extracorporeal circulation causes systemic edema augmentation. In fact, since 1991, when correction was started, postoperative eyelid edema and vomiting after weaning from the ventilator were significantly reduced.

Of course, there are a variety of factors that affect reperfusion injury and postoperative edema. However, the low Na concentration during the extracorporeal circulation became a new problem to be addressed with the introduction of ECUM and the savings in blood and protein products.

Q&A Sodium and Edema (Question in 2010)

Question: I think many factors are involved in the development of edema. Please tell me more about the involvement of Na.

Answer: At the time of 1983, there were many patients entering the ICU with severe blepharedema, even in ASD cases. The patient had good cardiac function and was able to extubate immediately but often vomiting after drinking, indicating that generalized edema was quite severe. For me as a novice at that time, I had an impression that extracorporeal circulation worsens the postoperative course of patients with good preoperative conditions, and conversely, I thought that it was easy to improve the worsening condition because the extracorporeal circulation only makes patients with good preoperative conditions worsen transiently. Anyway, the management of removing water from the patient was the night job of a resident.

What I noticed simply about this edema was that the Na value of the initial priming solution for bloodless extracorporeal circulation was extremely low, and there were many cases in which it was 120 mEq/L or less after the initiation of extracorporeal circulation. Table 1.3 shows the initial priming composition and blood gas data of a VSD case weighing 19 kg who underwent intracardiac repair using a circuit with an priming volume of 750 mL (bloodless). The Na value at the initiation of extracorporeal circulation has decreased to 106 mEq/L.

I thought that this was just a water intoxication and mentioned the need for amendment, but I remember that it was immediately dismissed. The reason was that at that time, Na correction was thought to overload the circulation. We used 5% glucose for the initial priming, and the basic infusion at postoperative ICU was also 5% glucose to prevent salt retention. Regarding the reason why Na correction was necessary, I had thought about various reasons, such as the Na channel or the relationship with Ca during reperfusion, but there was no doubt that the clinical effect of Na correction was clear. At that time, there was no word for minimally invasive, but I believed that the constant correction of the Na value to a normal value was a simple and effective minimally invasive measure that would improve the postoperative condition from the viewpoint of edema [19, 20].

1.4.3 Advances in Ultrafiltration Methods

The clinical effect of ECUM is obvious. It was speculated that the mechanism of the effect was not only prevention of hemodilution but also suppression of increasing inflammatory reactive substances accompanying rewarming and reduction of myocardial reperfusion injury. Focusing on the systemic inflammatory response syndrome (SIRS), which was prevalent at the time, we began investigating the suppression of inflammatory response substances [21, 22].

1.4.3.1 Measurement of Inflammatory Reactive Substances (1991–1993)

Inflammatory reactive substances cause myocardial and lung damage. In particular, suppression of inflammatory reaction substances at the time of aortic unclamp and before the start of partial extracorporeal circulation is considered to be important in terms of preventing reperfusion injury of the myocardium and lungs.

In infant VSD open-heart surgery, C3a, C5a, and leukotriene C4 (LTC4) in blood and filtrate before the start of rewarming and before the aortic unclamp were measured to evaluate the inhibitory effect of ECUM. The molecular weight of C3a is 9000, C5a 11,000, and LTC4 625. The subject was an infant with VSD, consisted of an initial proming volume of 650 mL (500 mL whole blood, no protein preparation) and ECUM using HC-30M and HP-300.

ECUM Only After the Start of Rewarming

HP-300 three cases (Fig. 1.20) Filtration volume was 95 ± 49 mL (55–150). C3a in the blood increases 2413 ± 1326 (1470–3930) before rewarming → 3510 ± 1636 (2020–5260) ng/mL before aortic unclamp, and C5a increases in all cases, <10–11 → 23 ± 9 (14–34) ng/mL increased in all cases, and LTC4 increased in two cases. In the filtrate, C3a was 208 ± 58 (152–267), C5a in all cases were less than 10, and LTC4 in all cases were less than 20 pg/mL.

Seven cases of HC-30M (Fig. 1.21) Filtration volume 139 ± 87 mL (45–283). Blood C3a increased in all cases from 2910 ± 1186 (1570–4450) → 5120 ± 2545 (1890–8360) ng/mL, C5a less than 10 to 22 → 25 ± 12 (11–41) ng/mL in all cases. The LTC4 decreased in three cases. In the filtrate, C3a was 3444 ± 2308 (1230–7220), C5a in four cases were 11–29 (three cases less than 10), and LTC4 in three cases were 26–97 (four cases less than 20).

Conclusion In ECUM only after the start of rewarming using HP-300, inflammatory reaction substances increased, and no significant filtration was observed. On the other hand, in HC-30M, filtration in proportion to each blood concentration was observed in the filtrate. In addition, blood LTC4 decreased. However, C3a and C5a were considered to have more complement activation than the amount in filtrate during rewarming, and the value at aortic unclamp did not decrease. It was concluded that effective filtration of active complement could not be expected with ECUM only after the start of rewarming.

From the above, in addition to ECUM after the start of rewarming, the method was changed to add washing filtration (Dilutional Ultrafiltration: DUF) during aortic cross-clamp using Ringer's solution. The ECUM pump flow rate in DUF was 28 mL/min, and the target filtrate volume was 200 mL/h.

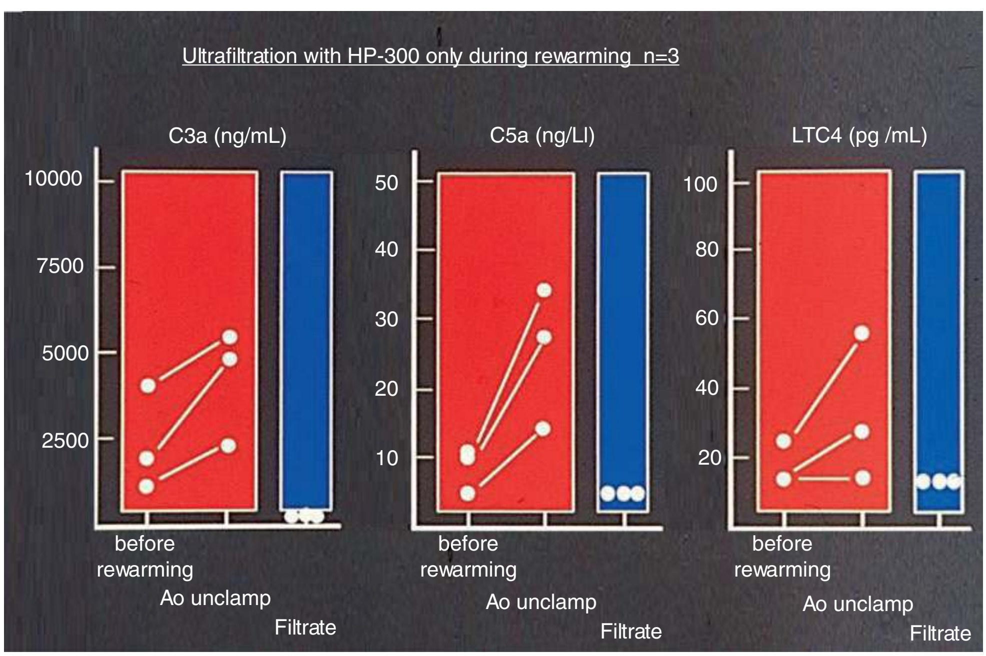


Fig. 1.20 HP-300; ECUM only during rewarming

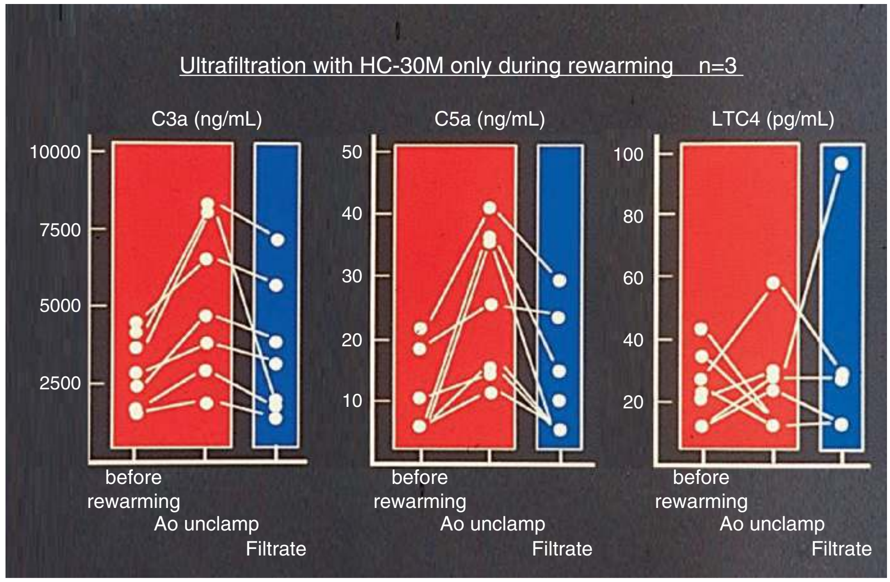


Fig. 1.21 HC-30M; ECUM only during rewarming

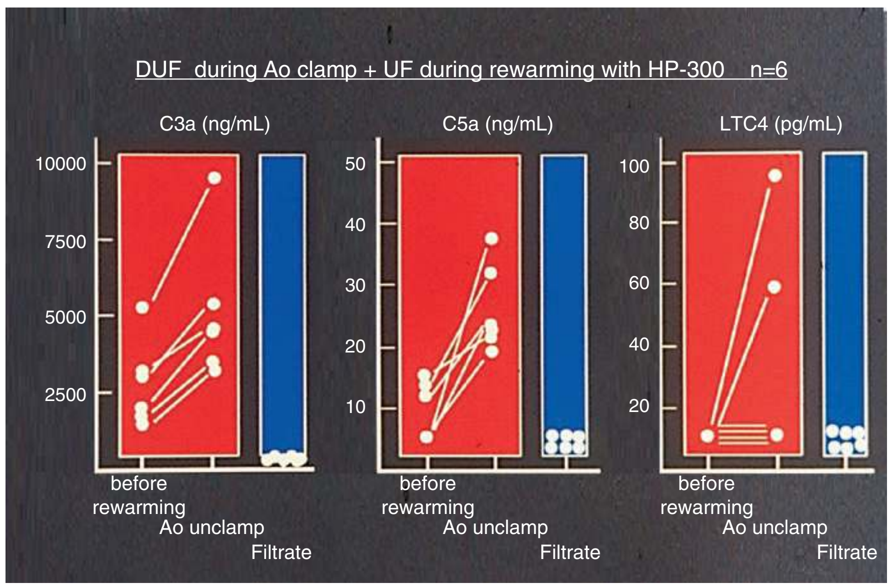


Fig. 1.22 HP-300; DUF during Ao cross-clamp + UF during rewarming

Ultrafiltration During Aortic Cross-Clamp + During Rewarming

HP-300 six cases (Fig. 1.22) Filtration volume 239 ± 129 mL (130–445). Blood C3a increased 2772 ± 1540 (1680–5330) before rewarming → 4960 ± 2442 (3500–9280) ng/mL before aortic unclamp, and C5a was less than 10 to 16 → 27 ± 8 (19–38) ng/mL increased in all cases, LTC4 increased in two cases, and three cases were less than 20. The filtrate contained C3a 179 ± 70 (82–263), C5a less than 10 in all cases, and LTC4 less than 20 in all cases.

HC-30M six cases (Fig. 1.23) Filtration volume 227 ± 100 mL (95–375). Blood C3a decreased in three cases (2910 → 2840, 5490 → 3930, 2250 → 1730), 3682 ± 1143 (2910–5490) before rewarming → 4385 ± 2076 (2840–7590) ng/mL before aortic unclamp. There was no difference. C5a increased from less than 10 to 19 → 21 ± 6 (16–31) ng/mL in all cases, but there was no case of 30 ng/mL or more as in the above three methods. LTC4 was less than 20 in all cases. The filtrate contained C3a 3780 ± 1319 (2190–5160), C5a 13–17, and LTC4 less than 20 in all cases.

Conclusion In HP-300, there were cases where LTC4 did not increase, but effective filtration of C3a and C5a could not be expected even if aggressive DUF was performed during aortic cross-clamp. On the other hand, in HC-30M, LTC4 did not increase in all cases, and C3a decreased in three cases. However, the values of C3a and C5a before aortic unclamp

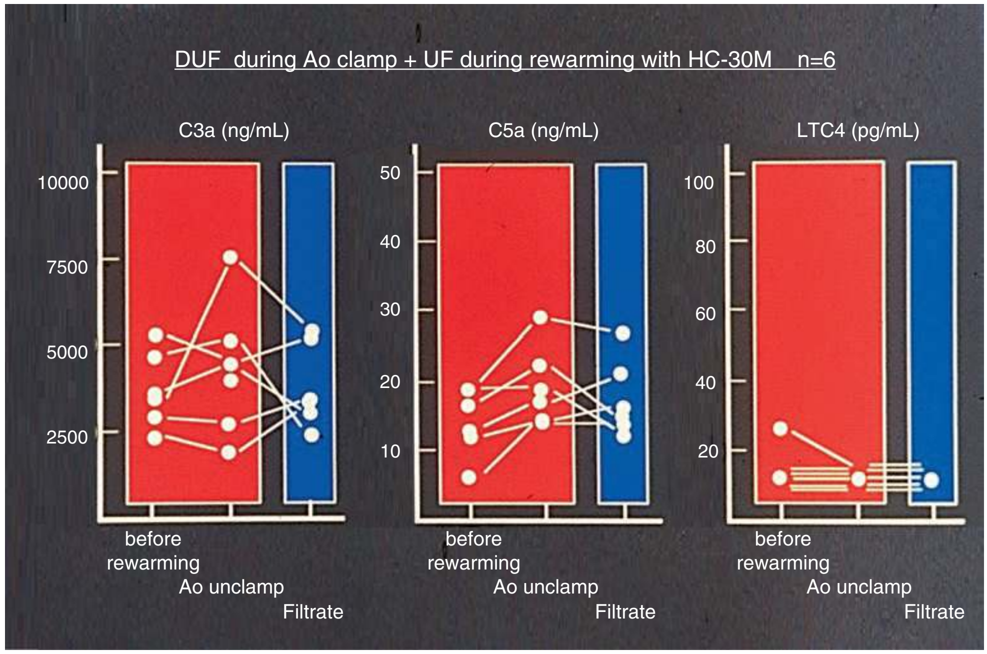


Fig. 1.23 HC-30M; DUF during Ao cross-clamp + UF during rewarming

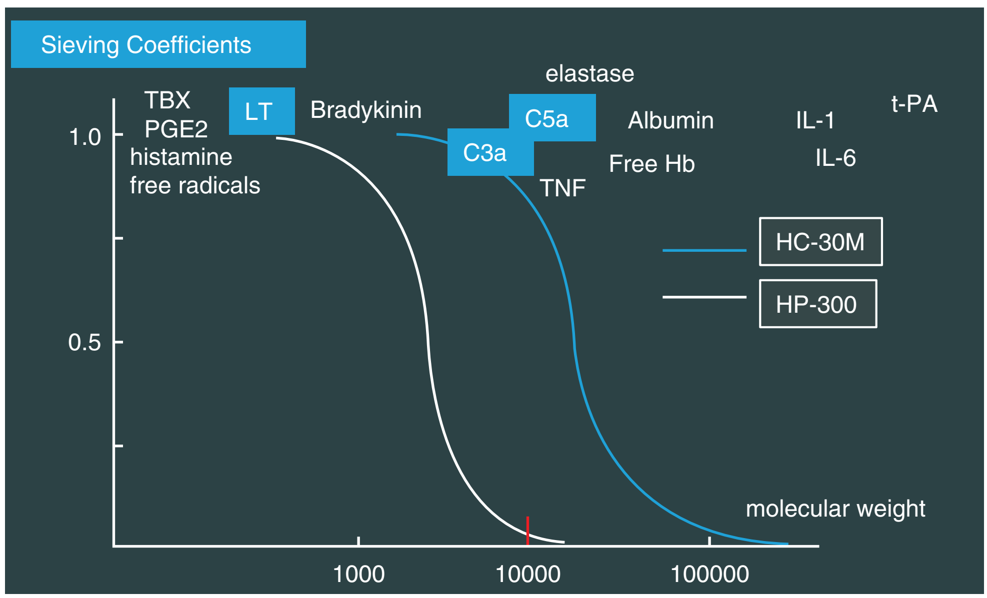


Fig. 1.24 Sieving coefficients of HC-30M and HP-300.
TBX: thromboxane
LT: leukotriene
TNF: tumor necrosis factor
Hb: hemoglobin
IL: interleukin
T-PA: tissue plasminogen activator

were not significantly reduced. ECUM with DUF during aortic cross-clamp using HC-30M was thought to be able to reduce active complement at the time of aortic unclamp, although it was incomplete.

Q&A: ECUM devices (Question in 1994)

Question: There are several types of ECUM devices, please tell us about their features.

Answer: Each ECUM device has its own characteristics. Figure 1.24 is a graph of the approximate sieving coefficients for HP-300 and HC-30M devices. These were simply created from the results of C3a and C5a measured during extracorporeal circulation using these devices, but the result was different from the value written in the instruction manuals.

As you know, C3a and C5a act as anaphylatoxins. First of all, it should be kept in mind that substances with molecular weight that can be filtered according to the instructions may not be filtered in actual clinical situations. In addition, LTC4 is a substance that enhances vascular permeability in microvessels, promotes mucus secretion into airways and visceral tissues, and recruits leukocytes to inflammatory sites. Since its molecular weight is small, it was determined that sufficient filtration is possible. However, HP-300 showed no significant filtration. On the other hand, in ECUM using HC-30M to which DUF was added, the blood LTC4 values before aortic unclamp were all within the normal range, and it was possible that not only filtration but also realization itself was suppressed.

I once asked the manufacturer how to determine the sieving coefficients of ECUM equipment. The reply was, "There is no data on complements, all extracorporeal circulation-related devices are themselves responsible for activation of complements, and ECUM devices are just hemoconcentrators, so we do not recommend using them for the purpose of removing active complements." Regarding the measurement of inflammatory substances, it is considered that not only individual differences among patients but also the timing of their onset and the timing of measurement influence the measured values. In clinical research, it is necessary to develop a sufficient protocol such as selection of ECUM device to achieve the desired goal and determination of the measurement timing in consideration of the characteristics of the measurement target and its reaction kinetics.

1.4.3.2 Measurement of Inflammatory Reactive Substances (1994–1995)

Focusing on Endothelin-1 (ET-1: molecular weight of about 2500), which has a strong vasoconstrictive effect, we evaluated changes in circulating ET-1 when ECUM was performed in the extracorporeal circulation of patients with severe pulmonary hypertension. The main objective is to investigate whether ET-1 is a direct factor in myocardial reperfusion injury that occurs after aortic unclamp. The reason is that it was speculated that filtration with HC-30M was possible from the molecular weight of ET-1 and that it was thought to be one of the reasons that enabled early ventilator weaning in pulmonary hypertension cases.

Group I Four cases of ASD without ECUM (age 8.8 ± 3.8 years, weight 26.0 ± 10.3 kg, Pp/Ps 0.28 ± 0.07). Priming volume was 470 mL or 750 mL (no blood and protein preparations). The patient was repaired under mild hypothermia (32 °C) and electrical ventricular fibrillation, and no catecholamine was used. Ventricular fibrillation time was 27 ± 13 min, and extracorporeal circulation time was 42 ± 19 min. ET-1 increased slowly until partial extracorporeal circulation and decreased after weaning from extracorporeal circulation. Although the response increased again after returning to the ICU, all of them passed within the normal range (Fig. 1.25).

Group II Four VSD and two complete AVSD infants undergoing ECUM from the start of aortic cross-clamp to aortic unclamp (age 4.4 ± 3.9 months, body weight 4.3 ± 0.8 kg, Pp/Ps 0.95 ± 0.07). Initial priming volume was 400 or 470 mL (no blood transfusion, no extra blood in extracorporeal circulation). Repaired under moderate hypothermia (28 °C) and Blood GIK cardiac arrest, dopamine 6 γ/kg/min was used. The aortic cross-clamp time was 68 ± 24 min, the extracorporeal circulation time was 118 ± 30 min, and the ultrafiltration volume was 221 ± 72 mL. ET-1 decreased after the initiation of extracorporeal circulation and was within the normal value range in all cases before aortic unclamp. The ET-1 value in the filtrate was about 65% of the blood value before aortic unclamp. Thereafter, it increased in all cases from partial extracorporeal circulation to the time after ICU return to room, and in one case of VSD and two cases of complete AVSD that were high at the time of induction of anesthesia were also high after returning to ICU (Fig. 1.26).

Group III VSD four cases, complete AVSD two cases, TAPVR two cases (age 2.1 ± 2.3 months, body weight 3.4 ± 0.8 kg, Pp/Ps 0.94 ± 0.06). In addition to ECUM from aortic cross-clamp to unclamp, ECUM was performed up to

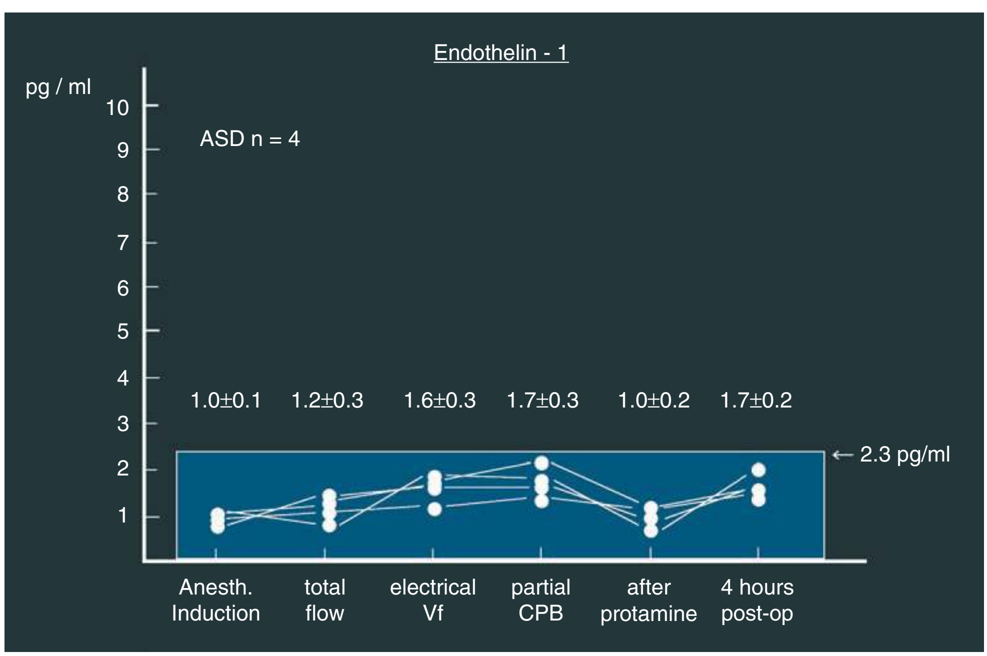


Fig. 1.25 ET-1 transition in ASD open-heart surgery (ECUM not implemented). The normal value of ET-1 is 0.49–2.34 (1.4 ± 0.5) pg/ml
ECUM: extracorporeal ultrafiltration method
ASD: atrial septal defect
Vf: ventricular fibrillation

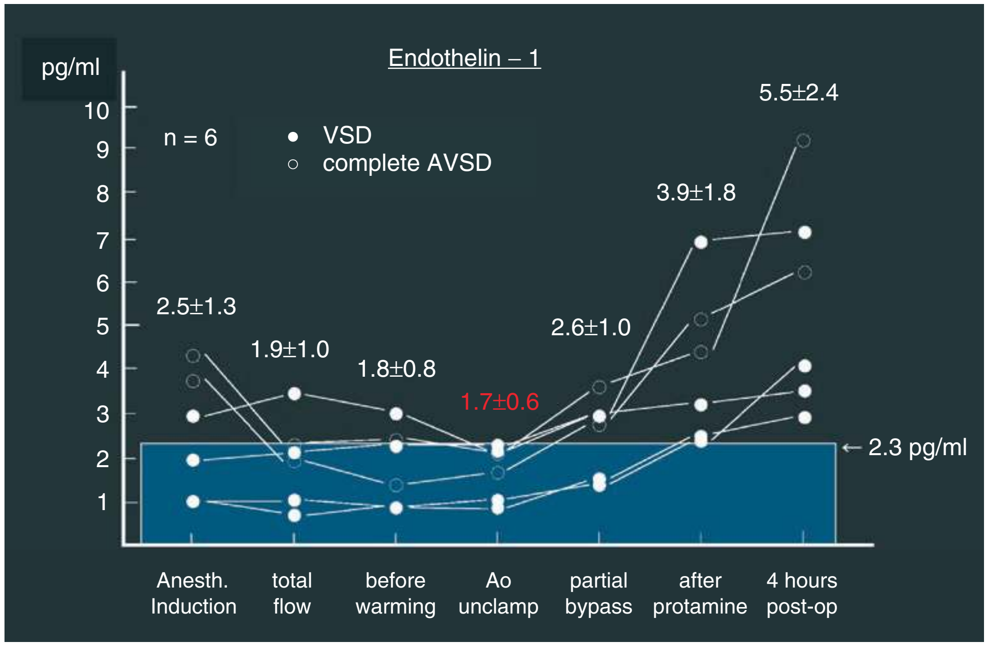


Fig. 1.26 ET-1 transition in pulmonary hypertension cases (ECUM performed from aortic cross-clamp to unclamp).
VSD: ventricular septal defect
AVSD: atrio-ventricular septal defect

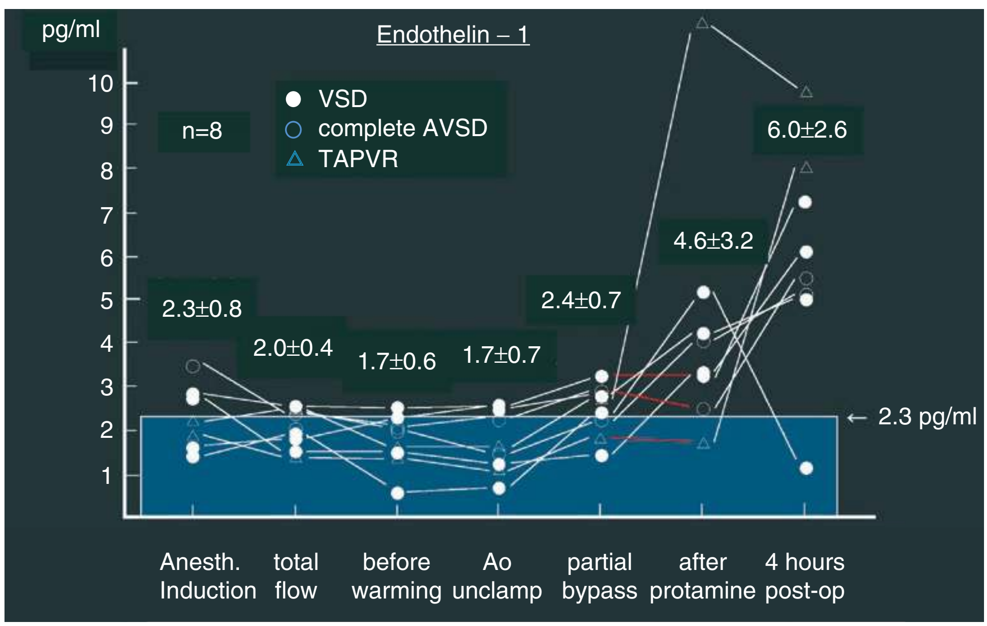


Fig. 1.27 ET-1 transition in pulmonary hypertension cases (ECUM performed from aortic cross-clamp to partial CPB).
TAPVR: total anomalous pulmonary venous return

partial extracorporeal circulation. Initial priming volume was 370–400 mL (whole blood priming, no extra blood in extracorporeal circulation). Repaired under moderate hypothermia (28 °C) and Blood GIK cardiac arrest, dopamine 6 γ/kg/min was used. The aortic cross-clamp time was 52 ± 22 min, the extracorporeal circulation time was 100 ± 26 min, and the ultrafiltration volume was 323 ± 102 mL. ET-1 showed a tendency to decrease until aortic unclamp, as in Group II. Thereafter, the partial extracorporeal circulation value increased in all cases, but decreased in three cases after the end of the extracorporeal circulation (Fig. 1.27).

Conclusion ET-1 is a vasoconstrictor derived from vascular endothelial cells. The blood concentration in patients with congenital heart disease with pulmonary hypertension is high, suggesting an involvement in organ damage during extracorporeal circulation, particularly the occurrence of PH crisis.

All Group I patients without pulmonary hypertension were within the normal range. On the other hand, in cases with ECUM from the start of aortic cross-clamp to unclamp in the group with advanced pulmonary hypertension II, the ET-1 value before aortic unclamp was in the normal range. It is unlikely that ET-1 is involved in reperfusion myocardial injury when aortic clamp is released. ET-1 was also observed in the filtrate, and ECUM using HC-30M until unclamp was considered to be an effective means for reducing ET-1. In Group III, there were cases in which ET-1 levels decreased after extracorporeal circulation by adding ECUM up to partial extracorporeal circulation. It may also be effective in preventing reperfusion injury to the lungs. However, it was extremely high after returning to ICU.

In the future, it is necessary to study ECUM (Modified Ultrafiltration: MUF) until the weaning from extracorporeal circulation or after the weaning from extracorporeal circulation. Perhaps the clinical effect associated with MUF after the weaning from extracorporeal circulation may be due to a decrease in ET-1 levels [23–25].

Q&A: ECUM Policy (Question in 1996)

Question: Please tell us about the basic policy of ECUM at Sakakibara Heart Institute.

Answer: At present, the initial priming volume of the extracorporeal circulation circuit in infants weighing less than 8 kg has been reduced to 370 mL, and we have expanded the indications for bloodless open-heart surgery to VSD cases up to a body weight of 5 kg. Along with this, even among patients with other diseases requiring blood priming, the number of cases in which the total blood transfusion amount was only 1 unit (whole blood 400 mL) was increasing.

The primary purpose of ECUM is the prevention of reperfusion injury of the heart and lungs, so using HC-30M, ECUM is performed up to partial extracorporeal circulation, including DUF during Ao cross-clamp. The measurement results of inflammatory substances are as described in the lecture. In addition, from experience, in the case of VSD cases weighing 6 kg or more with bloodless extracorporeal circulation, the total protein amount does not decrease below 3.0 g/dL, so in principle, protein preparations are not used. However, since HC-30M has the disadvantage of protein leakage, DUF is performed using protein preparation in cases where the cross-clamp time is expected to be long.

Finally, of course, precise correction of Na values is essential [26].

1.4.3.3 New Heart-Lung Machine and Inflammatory Reactive Substances (1997–1998)

In 1997, thanks to the development of a new heart-lung machine with isolated pump-controller system (described later), the initial priming volume became 195 mL, and the indication for bloodless open-heart surgery was expanded up to 3 kg. In addition, APF-01D hemofilter with 12 mL priming volume was adopted for ECUM. APF-01D is characterized by adsorbing active complement with polyacrylonitrile (PAN) membrane. Using this, active complement was evaluated in 83 cases of VSD, complete AVSD, TGA, and TAPVR weighing 2.7–8.8 kg. In particular, in order to evaluate the ability of adsorbing complement, C3a was measured at the inlet and outlet of APF-01D and compared with HC-30M and HP-300. The ECUM pump flow rate was 28 mL/min, and the filtrate volume was 200 mL/h. For bloodless initial priming cases, DUF from total flow to just before weaning from extracorporeal circulation was performed (Fig. 1.28), with supplemental administration of Ringer acetate and Saline HES 5 mL/kg for body weight 5 kg or more, and Ringer acetate and 25% albumin 10 mL for body weight 4 kg or less.

Figure 1.29 shows (1) the C3a value in the blood and filtrate at the time of unclamp, (2) the C3a value at the inlet

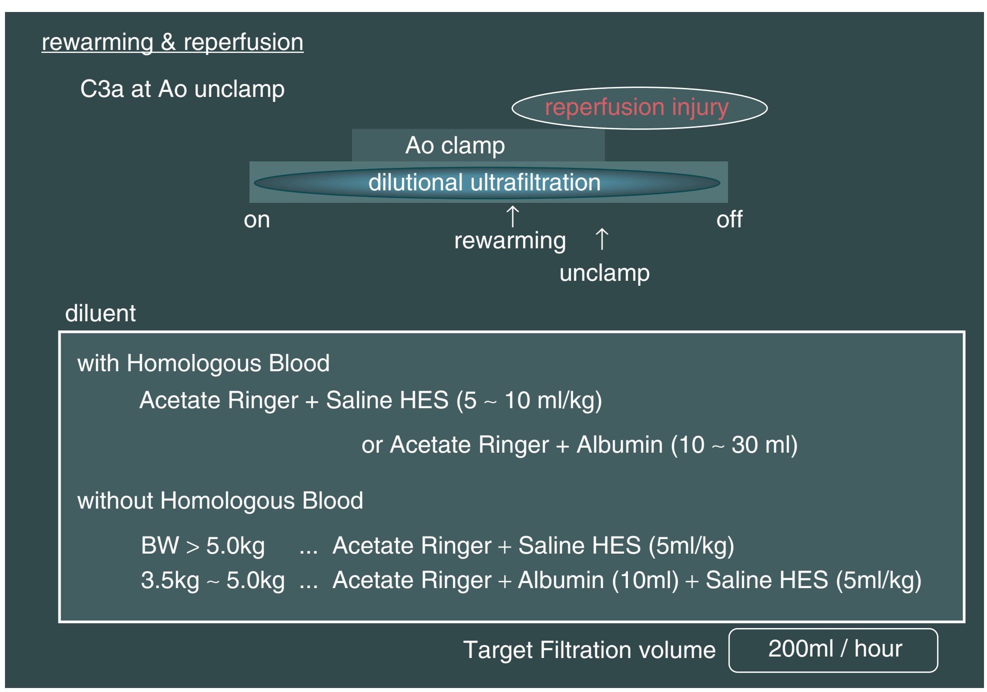


Fig. 1.28 ECUM planning. C3a: complement 3a

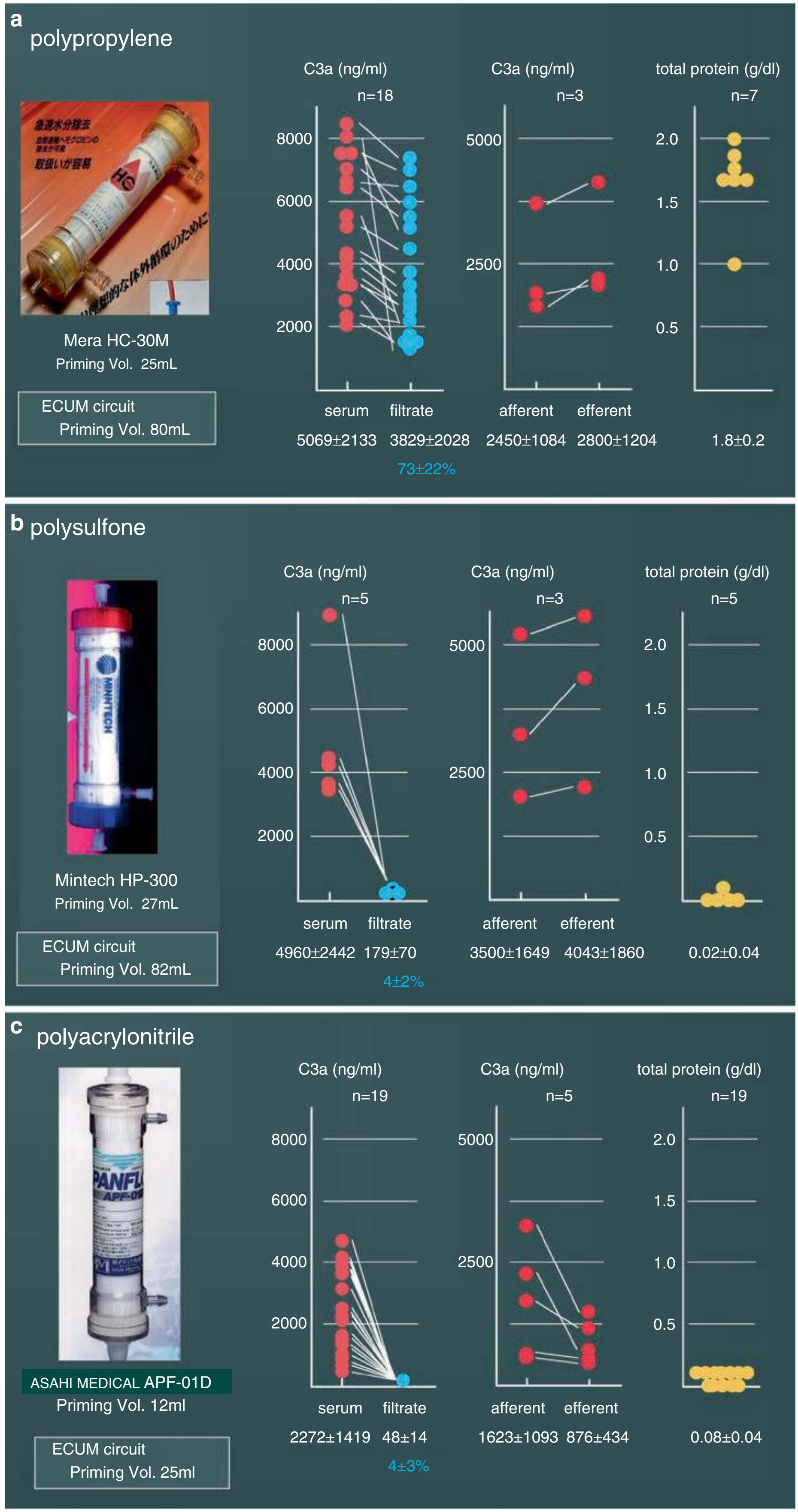


Fig. 1.29 Comparison of ECUM devices. (**a**) The left graph shows the C3a concentration in the serum and the filtrate. The middle one shows C3a concentration at the inlet and outlet of filter. The right one shows the filtrate total protein level. When looking at the concentration of C3a in the filtrate, it was removed in proportion to the C3a concentration in the serum, and also the protein was removed copiously. This indicate the high removing ability of C3a by this membrane, however, some still showed a high serum C3a concentration. Moreover, there was a rise in the concentration of the C3a at outlet and also there was a downside of removing the serum protein.
(**b**) Polysulfone membrane hemofilter is good in the way that the protein is not filtered at all. However, C3a is also barely, if any, filtered and the C3a concentration is increased at outlet as well. The porosity of this membrane should allow C3a to be filtered, but this was not the case in our test.
(**c**) C3a was barely removed as well. However, the C3a concentration was rather reduced at outlet of hemofilter. Also in many of the cases, their serum concentration of C3a stayed below 2000 numbers per mL, meaning that it is more efficient in removing C3a compared with the other two membranes, even though concentration of serum C3a varied extensively from those stayed low to those exceed 4000

and outlet of the filter, and (3) the total protein values in the filtrate for each filter. The initial total priming volume using HC-30M and HP-300 was 550–650 mL, and APF-01D was 195–370 mL. Although the comparison conditions between the three were not the same, the singular point of APF-01D was that although C3a was not filtered, the C3a value at the outlet of the filter decreased, which meant it was adsorped. On the contrary, it increased in HC-30M and HP-300. The biggest feature of APF-01D was an increase in cases where the blood C3a level was less than 2000 ng/mL. There was also the advantage that there was no significant leakage of protein [27–31].

There was a very interesting reaction as the measurement proceeded. Although there was a difference in the initial priming volume, serum C3a level was clearly low in complex cases requiring long-term extracorporeal circulation such as TAPVR and complete AVSD with blood priming, while higher C3a level was more frequently seen in simple cases such as VSD with shorter perfusion time and bloodless priming (Fig. 1.30).

We speculated that it takes some time before the ultrafiltration becomes effective.

So then, we looked at the correlation between serum C3a level and the duration from CPB initiation to clamp removal. There was a significant negative correlation between serum C3a level and this duration (Fig. 1.31). For patients that were on bypass for more than 60 min,

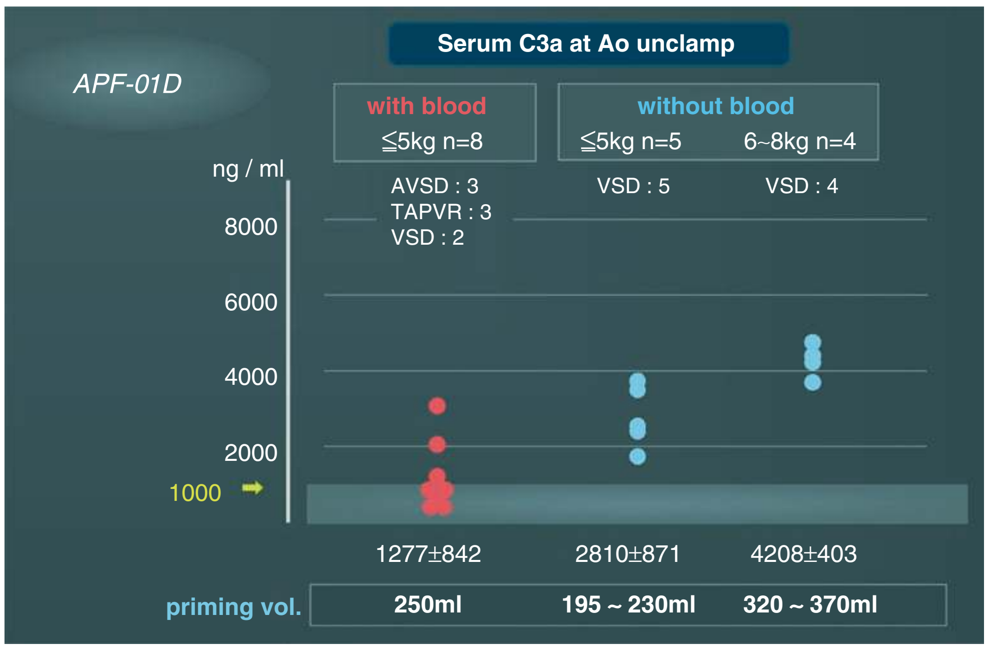


Fig. 1.30 C3a at unclamp [32] modified

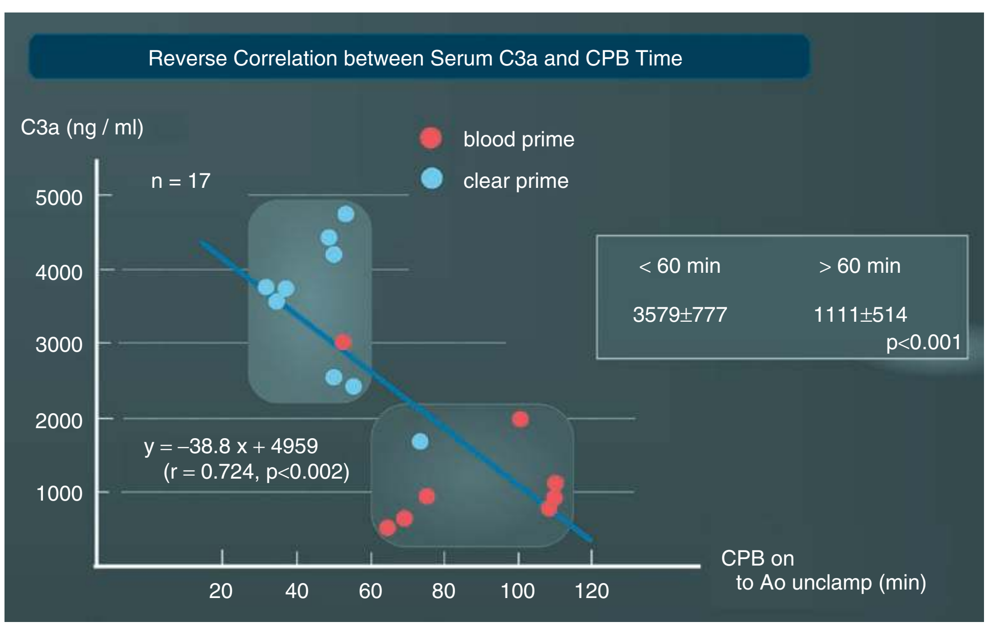


Fig. 1.31 Relationship between C3a and CPB time to Ao unclamp [32] modified

the mean C3a level was 1111 ng/mL. On the other hand, for patients less than 60 min, this mean level was 3579 ng/mL.

In long-term extracorporeal circulation, C3a value decreased more. This suggests that if DUF is performed at a higher flow rate, C3a will decrease even in patients without transfusion and with short extracorporeal circulation time.

Thereafter, the ECUM pump flow rate was increased five times to 140 mL/min while the target filtration rate remained at 200 mL/h. The C3a value decreased by 1/3 of the low flow rate DUF, and no difference in the C3a value was observed even when the body size and initial priming volume were different (Fig. 1.32). In addition, the C3a was clearly lower than that of HC-30M, including cases with blood transfusion (Fig. 1.33).

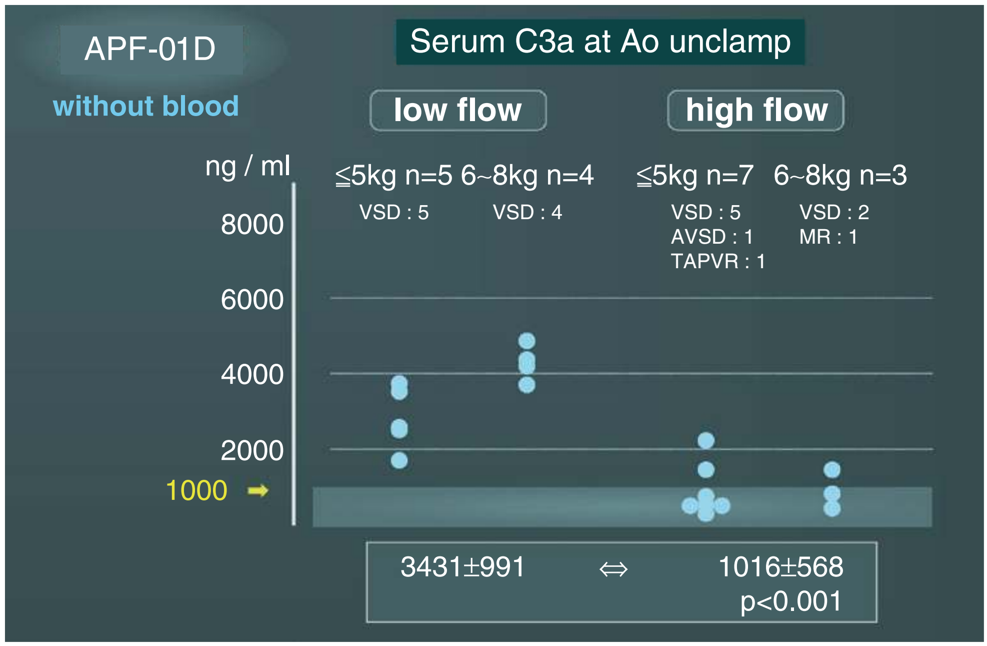


Fig. 1.32 Comparison of C3a between low-flow DUF and high-flow DUF [32] modified

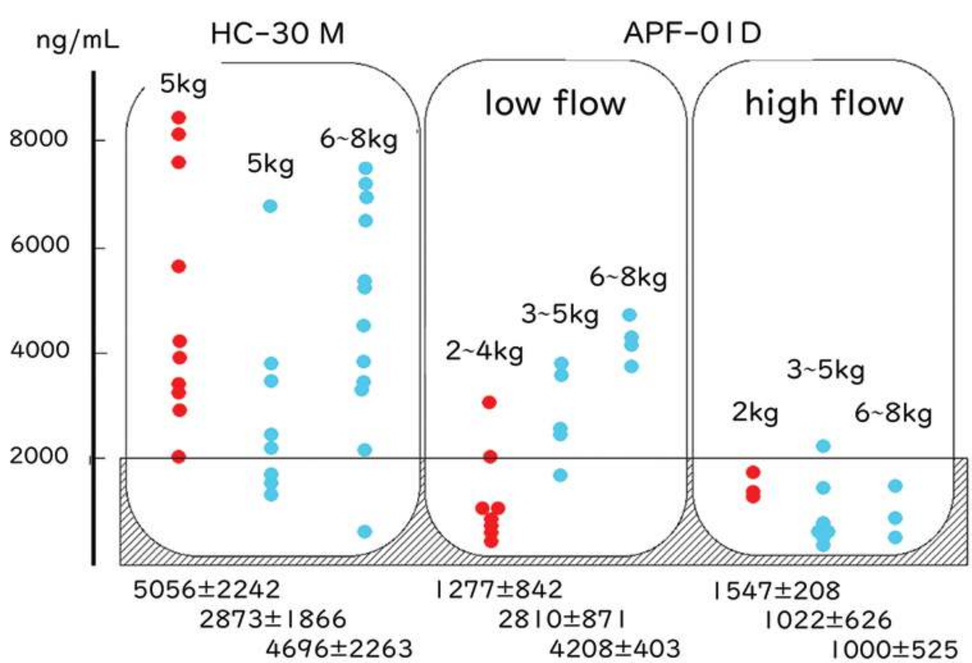


Fig. 1.33 Comparison between HC-30M and APF-01D [32] modified

Figure 1.34 shows the transition of serum C3a level in complete AVSD repair weighing 3.3 kg subjected to high-flow rate DUF using APF-01D. C3a level was maintained under 1000 ng/mL except for the transient increase after protamine administration.

In general, active complement is thought to increase with time after commencing extracorporeal circulation, but C3a was thought to be well controlled by the high-flow rate DUF with APF-01D [33, 34].

The blood C5a values before aortic unclamp were also compared between the filters. Although there are difference of the times, such as initial priming volume and with or without blood transfusion, C5a of APF-01D high-flow rate DUF decreased significantly (Fig. 1.35).

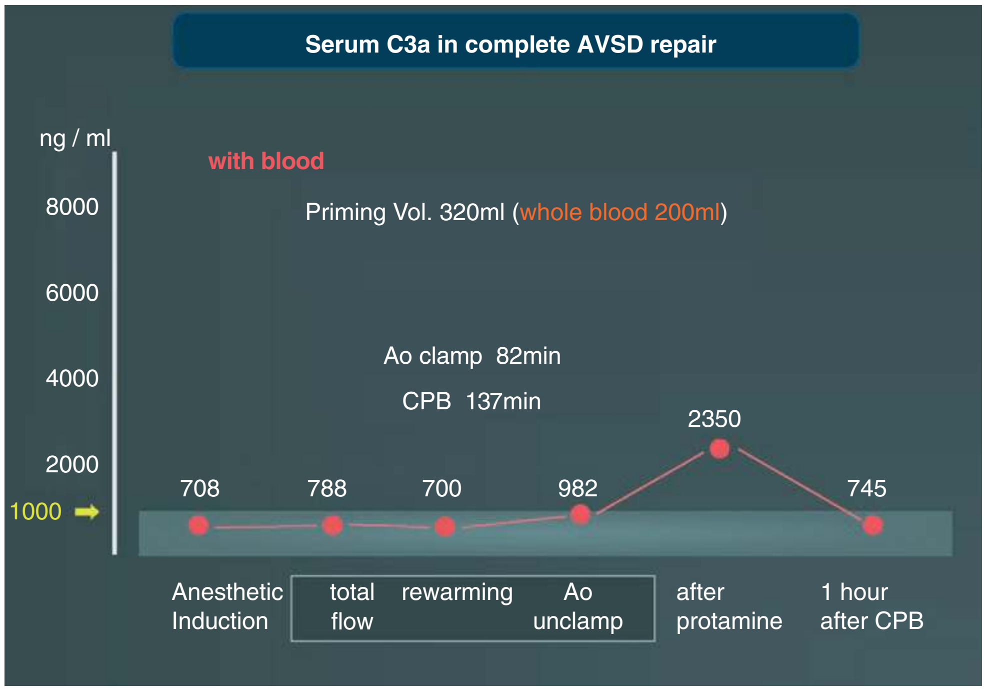


Fig. 1.34 C3a transition in complete AVSD repair. C5a: Complement 5a

Fig. 1.35 Comparison of C5a between 3 types of ECUM devices [32] modified

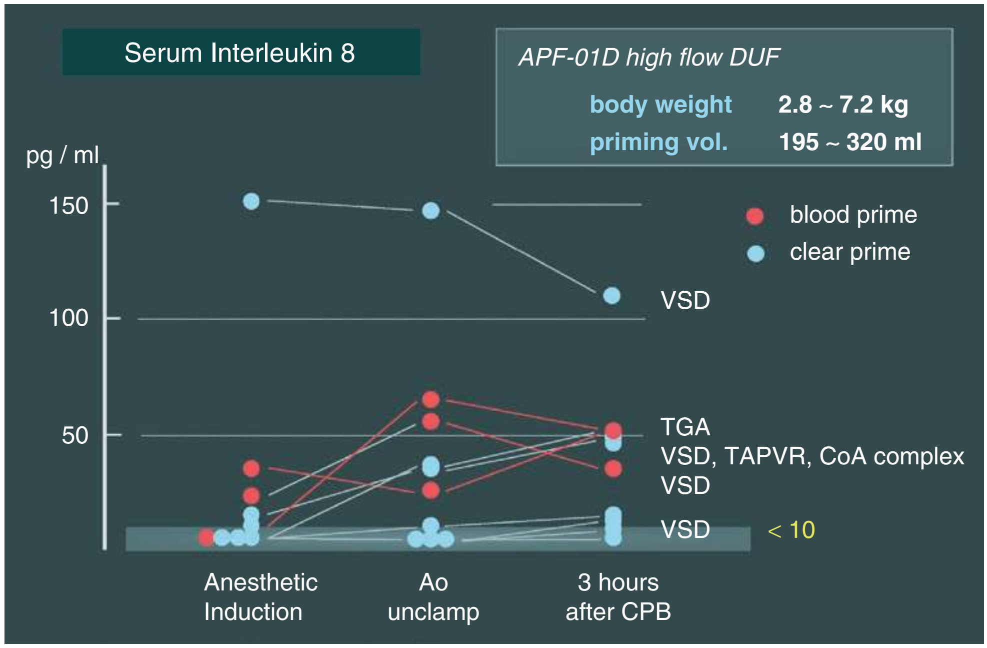


Fig. 1.36 Changes in interleukin-8 [32] modified. TGA: Transposition of Great Artery CoA complex: Coarctation complex

Additionally, serum level of interleukin-8 with high-flow dilutional ultrafiltration using polyacrylonitrile membrane hemofilter was measured after anesthetic induction, at unclamp, and 3 h after weaning from CPB (Fig. 1.36).

It was generally believed that the level of interleukin-8 increases dramatically several hours after weaning from CPB, but it was fairly constant, and no incremental reaction did not occur [35–40].

Conclusion When the study of ultrafiltration was started, the final goal was to make the C3a value less than 1000 ng/mL. Miniaturization of cardiopulmonary equipment has progressed year by year, and although the comparison conditions have not been constant, we believe that this objective has been almost achieved by APF-01D high-flow rate DUF.

Figure 1.37 shows a biological reaction flow caused by contact between blood and foreign substance. The mechanism of SIRAB generation by vasoactive substances is as follows: early vascular endothelial activation by C5a active complement (first wave), and then, there is delayed vascular endothelial activation (second wave, 2–3 h after the weaning from extracorporeal circulation) by cytokines produced from monocytes or macrophages with complement activity. As a result, it is believed that tissue damage occurs via activated neutrophils. From the measurement results of C5a and Interleukin-8, it was suggested that high-flow rate DUF using APF-01D reduces the C3a value that triggers SIRAB and blocks this biological reaction flow. By this, the generation of mediators such as C5a and cytokines may be reduced.

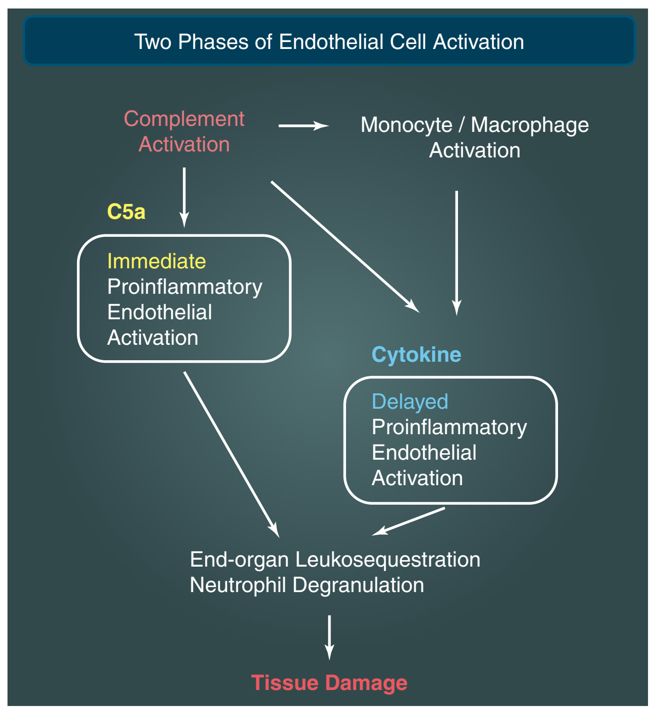
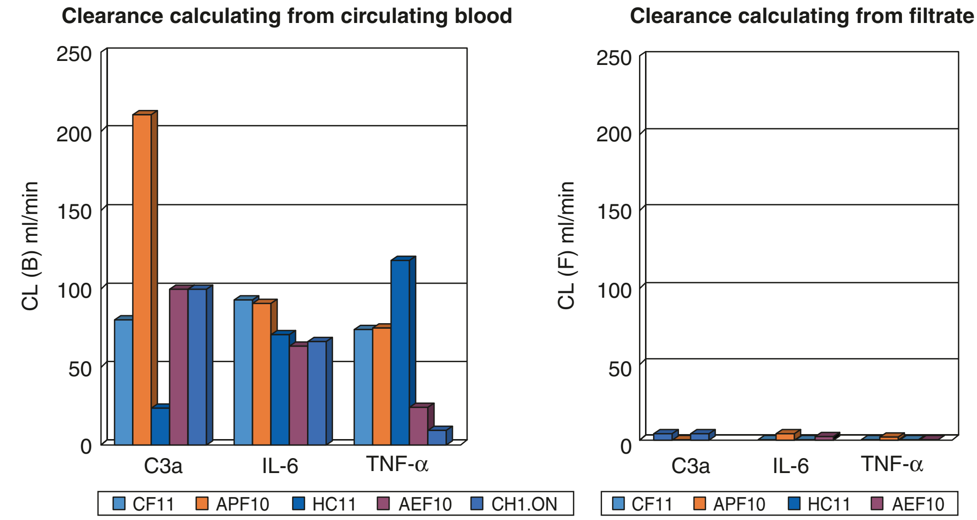


Fig. 1.37 Complement activity and biological reactions [32] modified

In bloodless open-heart surgery with a body weight of 3–4 kg VSD described below, the amount of dopamine used when returning to the ICU was 2.9 ± 1.8 γ/kg/min, and the duration of intubation time was 5.5 ± 2.6 h. Circulation and respiratory dynamics were extremely stable. There is no doubt that APF-01D high-flow DUF, including neonatal



n	6	6	6	6	4
Filtrate (mL)	2092	2975	3695	4542	3350
CPB (min)	120	151	147	123	117

Fig. 1.38 Clearance of C3a, IL-6, TNF-α. CL(B): clearance (blood) CL(F): clearance (filtrate) CF-11: Polyethersulfone membrane hemofilter APF-10S: Polyacrylonitrile membrane hemofilter HC-11 and AEF10: Polysulfone membrane hemofilter CH1.0N: Polymethyl Methacrylate membrane hemofilter

open-heart surgery, was involved in reducing catecholamine use and early ventilator weaning. Of course, we believe that bloodless open-heart surgery was possible because the condition was stable [32, 41–46].

Column: C3a Level in Adult Open-Heart Surgery

We compared the clearances of C3a, IL-6, and TNF-α between APF-10S (polyacrylonitrile membrane), and HC-11 and CF-11 (polyethersulfone membranes) in open-heart surgery for adult valve disease. The removal capacity of C3a in APF-10S was better (Fig. 1.38).

Q&A: Measures for SIRAB (Question in 2010)

Question: Is there anything I should be careful about SIRAB measures? Also, please tell us how you think about SIRAB.

Answer: We all know that contact of circulating blood with foreign materials activates not only the coagulation system but also the fibrinolytic system, kallikrein-kinin system, and complement system. In particular, the molecular structure of complement changes upon contact with foreign materials, and the activation reaction then proceeds in a chain. The activation pathways are mainly the classical pathway and the alternative pathway, and finally, become the membrane-attack complex (MAC). Active complement stimulates monocytes and macrophages to produce many cytokines, and further, neutrophil migration, protease, and active oxygen generation cause tissue damage, leading to increased vascular permeability and tissue edema (Fig. 1.39).

Countermeasures against SIRAB depend on which points in these flows are focused and how they are blocked. For example, there are the following means: (1) Shorten or use of biocompatible coating of the extracorporeal circulation circuit to suppress complement activity, (2) ultrafiltration and

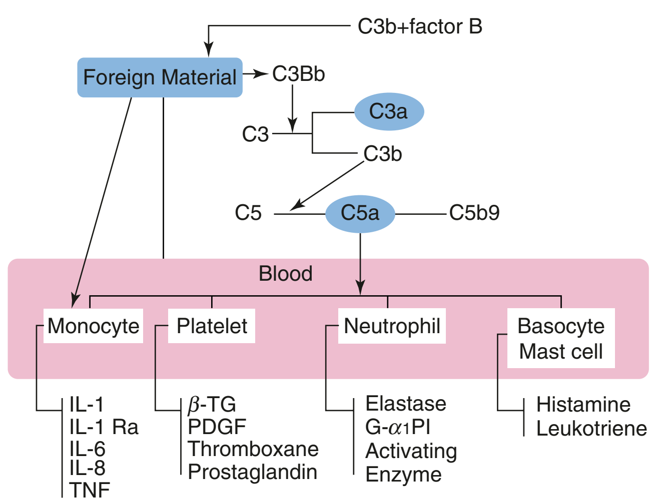


Fig. 1.39 Biological reaction caused by contact between blood and foreign material

cytokine adsorption to remove inflammatory substances, and (3) administration of neutrophil elastase inhibitors, steroids, and aprotinin as anti-inflammatory drugs. The point is to deal with them before they occur or after they occur.

However, I cannot say the concrete mean that this is the best. Improvements in the measured data will always be observed if certain measures are taken, but there may be few reports that are directly linked to clinical effects. One of the reasons is that there are too many factors involved in the invasion of extracorporeal circulation. But I think there is no doubt that it has become less invasive than before and over time. From my experience, the countermeasures that I realized to be clinically effective are high-flow rate DUF using APF-01D and reduction of priming volume by a isolated Pump-Controller Heart–Lung Machine. However, I often feel that it has finally improved over time. In the future, I would like to confirm the experiences of many surgeons once more and build up one by one.

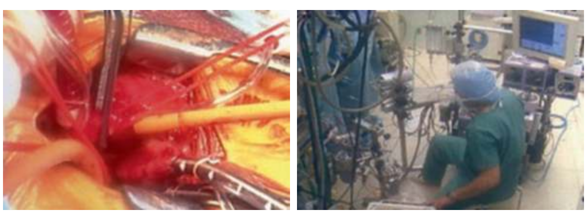
As I have said many times, as a surgeon, there are lesions that cannot be repaired clinically, which means that some lesions remain. However, even if that is the case, I think that a more minimally invasive postoperative condition can be created by making efforts to improve edema and oxygenation. The primary objective of clinical research on minimally invasive is to improve the postoperative condition of patients. (Dare to say, even if there is no improvement in the measurement data, it is sufficient if there is a clinical effect. Conversely, even if there is an improvement in the measurement data, it is meaningless if there is no clinical effect). Therefore, it is necessary to first set a clear goal of which problem should be made less invasive and to develop a protocol. In short, it is a pinpointing study. Of course, it is necessary to maintain constant comparison conditions for intraoperative and postoperative management methods such as extracorporeal circulation methods, drug and blood administration methods, and ventilator withdrawal policies. In particular, regarding the timing of measuring inflammatory substances, their dynamics over time and the mechanism involved in SIRAB development should be fully understood. However, the most important point to note when conducting research is that "the effort to eliminate the reaction of the living body caused by the invasion is the purpose of the minimally invasive in the extracorporeal circulation, but this is a normal self-defense reaction for the living body. Therefore, there is a possibility that it will be counterproductive if the measures are over-executed and their significance is lost." I think that this should always be kept in mind [47–51].

1.5 Summary of Minimally Invasive

In this chapter, I have described my experience regarding the concept of minimally invasive heart surgery and its effects. Minimally invasive measures progress with the development of new devices, but they are meaningless unless accompanied by clinical effectiveness. Reflection and re-evaluation from the results must always be considered.

Minimally invasive measures should be taken for all operations. However, now that safe surgery is possible, minimally invasive measures must be done strictly in underweight patients with extremely poor preoperative conditions, surgery that requires long-term extracorporeal circulation, and disease groups in which some lesions may remain.

Figure 1.40 shows an example of surgery for total pulmonary venous return weighing 1148 g using the ECUM method



Heart Lung Machine : Isolated Pump-Controller System (PV 230ml)
Oxygenator : Safe Micro
Hemofilter : APF-01D

Perfusion Rate : 2.5L/min/m² Moderate Hypothermia : 28°C
Cardioplegia: Blood GIK Dilutional Ultrafiltration with Albumin

			pump on						pump off
	CPB		0	15	30	45	60	75	82 min
				↑ Ao clamp			↑ unclamp		
Temp. (°C)			34.0	28.0		28.2	33.4		35.4
Blood gas	Na (mEq/l)	125	135	137		141		140	140
	K (mEq/l)	4.8	4.4	3.7		5.6		5.6	4.4
	B.E.	6.7	−3.8	−3.7		−5.2		−4.8	−2.4
	Hct (%)	33	23.0	21.0		25.0		30.0	18.5
	T.P. (g/dl)	4.6	4.2	3.6		4.2		4.3	3.5
		Initial priming							
Correction	25% albumin (ml)	30	20ml drip (+Ringer)						
	MAP (ml)	100	10	10	10	10	10 50		
	10% NaCl (ml)			2	2				
	KCl (mEq)		1		1				
	D-mannitol (ml)	3			4				
	NaHCO3 (ml)	10	2 2	2		3 2	3		
	Ringer (ml)	72	190ml drip (+alb.)						
	C.H. (mg)			1	1	1	2 1		
	CaCl2 (ml)							3	

Fig. 1.40 Open heart surgery in a case of total anomalous of pulmonary venous return weighing 1148 g [52] modified

described above. Many measures are needed to reduce the invasiveness of open-heart surgery for low-weight infants, but miniaturization of the extracorporeal circuit is indispensable. In the next section, I will describe the progress of cardiopulmonary apparatus and related equipment aimed at minimally invasive [52].

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2 Development of Cardiopulmonary Bypass System and Devices Aiming for Minimally Invasive

Contents

2.1 Introduction

In order to minimize the invasiveness of pediatric extracorporeal circulation, it is necessary to know the specificities of newborns and low-weight infants. The simplest and basic feature is that the capacity (priming volume) of the extracorporeal circuit is excessive compared to the circulating blood volume of the child. This requires a lot of allogeneic blood and blood products at the initial priming and is disadvantageous in terms of circuit area (contact surface) from the viewpoint of SIRAB generation due to contact with circulating blood. It is easy to imagine any kind of non-physiological effects or fluctuations on the body can happen just by looking at a cute little baby and a strict big heart–lung machine. Therefore, first of all, it is necessary to reduce the overall size of the heart–lung machine and related devices. Although there are many different opinions on the devices used (e.g., the method of extracorporeal circulation, and the concept of safety management), here, I would like to describe the background at the Sakakibara Heart Institute, especially the miniaturization that realized the obvious clinical effect.

Methods for downsizing include the development of low-volume devices, shortening and diameter reduction of the circuit, and changes in device and circuit layout. However, in addition to these techniques, the perfusionist's technique that can sufficiently cope with a low reservoir level is naturally essential. Figure 2.1 shows annual changes in the number of extracorporeal circulations, and Fig. 2.2 shows changes in the number of pediatric cardiac surgery cases at the Sakakibara Heart Institute [1].

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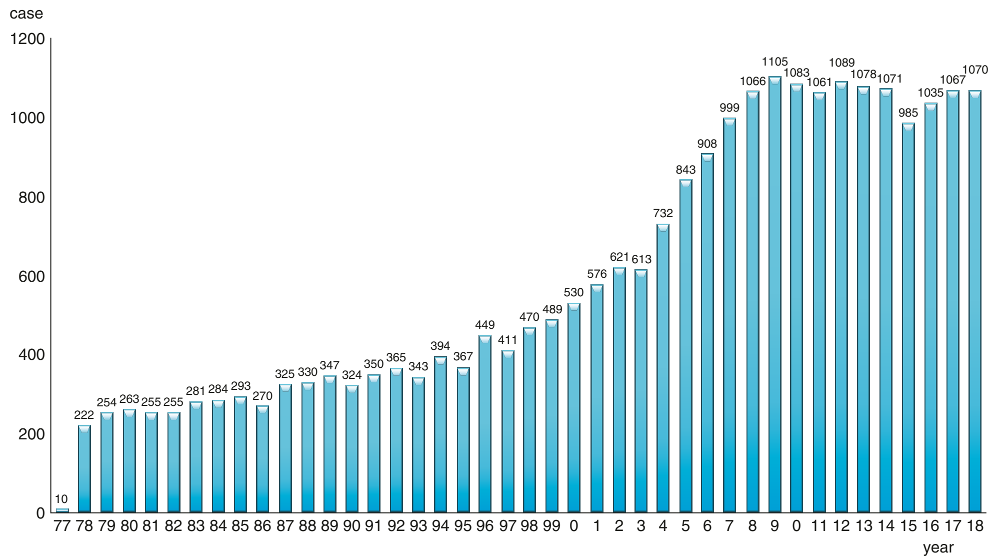


Fig. 2.1 Annual numbers of extracorporeal circulation's at Sakakibara Heart Institute. Sakakibara Heart Institute was opened in Yoyogi, Shibuya-ku in November 1977 and moved to Fuchu City in December 2003. Until 2017, the total number of extracorporeal circulation is 23,813 cases

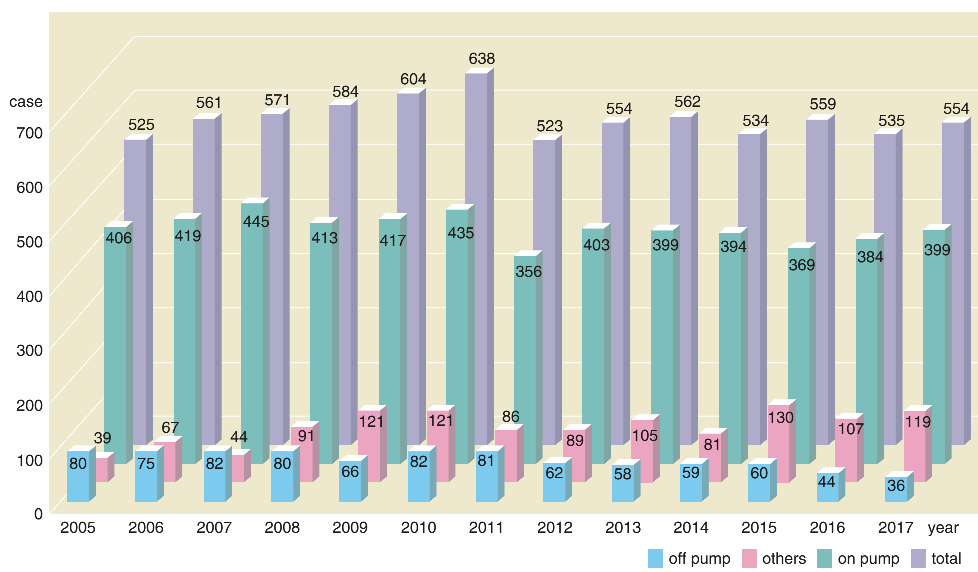


Fig. 2.2 Annual number of pediatric heart surgeries at Sakakibara Heart Institute

2.2 Development History

Figure 2.3 shows the annual transition of the minimum priming volume (weight 4.5 kg or less). At the time of opening in 1977, it was 1400 mL, and now it is reduced to 88 mL.

2.2.1 Low-Volume Oxygenator 1

In 1984, a polypropylene hollow fiber oxygenator, CAPIOX II08, with an integrated heat exchanger was adopted. The priming volume was 90 mL, and the maximum flow rate was 0.8 L/min (Fig. 2.4). The priming volume of the S circuit used for the body weight of 13 kg or less was reduced to 600 mL. Until 1983, it was 1200 mL using silicon membrane coil type oxygenator, Kolobow 0.8, and it was a revolutionary miniaturization at that time [2].

On the other hand, for older children, the vinyl sheet bubble oxygenator, Kolobow oxygenator, and TMO membrane laminated oxygenator were used, and the M circuit priming volume of 10–30 kg of weight was 1300–1800 mL, L circuit of 30 kg or more was 1800–2400 mL.

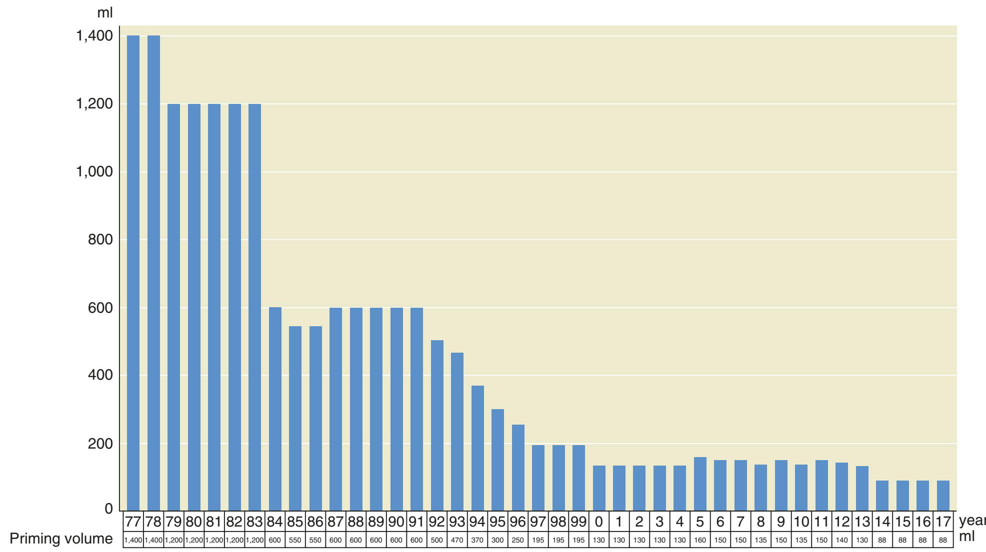


Fig. 2.3 Annual change in minimum priming volume of extracorporeal circulation circuit

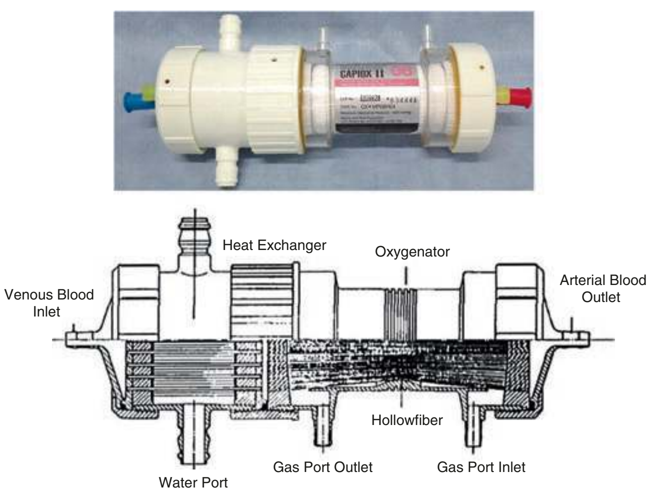


Fig. 2.4 CAPIOX II08 oxygenator [2] modified

Since 1985, the Bio-5 bubble oxygenator was adopted, and in 1986, venous drainage was changed from pump drainage to gravity drainage. The priming volume of the M circuit was reduced to 750 mL, and the L circuit was reduced to 1100 mL. Bubble oxygenator was used for cases of extracorporeal circulation for a short time due to problems such as hemolysis. It was an era when we began to actively consider bloodless open-heart surgery for ASD and VSD, weighing around 20 kg. However, CAPIOX II 08 was an internal perfusion type oxygenator in which circulating blood flowed inside the fibers, and because of the fact that it experienced a decrease in oxygenation during rewarming. A large oxegenator, CAPIOX II 16, was used for patients with a body weight of 13 kg or less (priming volume was 800 mL).

Column: Cardiopulmonary Apparatus in 1980s

In the 1980s, the heart–lung machine used at Sakakibara Heart Institute were models DV-2, DV-3D, and FL2300. The DV-2 is a vertical machine developed by Tokyo Women's Medical University for use with the Vinyl Sheet Disposable bubble oxygenator (Fig. 2.5). As a feature, the balance of blood delivery and venous drainage can be easily read by hanging this sheet oxygenator on a central weighing scale. At present, there is a safety monitoring function using a level sensor to detect the decrease in blood volume in the reservoir. This weigh scale also has an alarm function for a decrease in blood volume in the oxygenator and an automatic stop function of the arterial pump. It was also used for emergency open-heart surgery because it can be primed in about 15 min using a dedicated circuit set that has been sterilized, and it was easy to transport and operate. The sterilized circuit set was composed of; (1) oxygenator and arterial line circuit, (2) venous line circuit, and (3) cardiotomy suction circuit. Circuit priming volume was 1300 mL and 1100 mL for adults, 800 mL for children, and 500 mL for infants (Fig. 2.6).

Fig. 2.5 DV-2 heart–lung machine

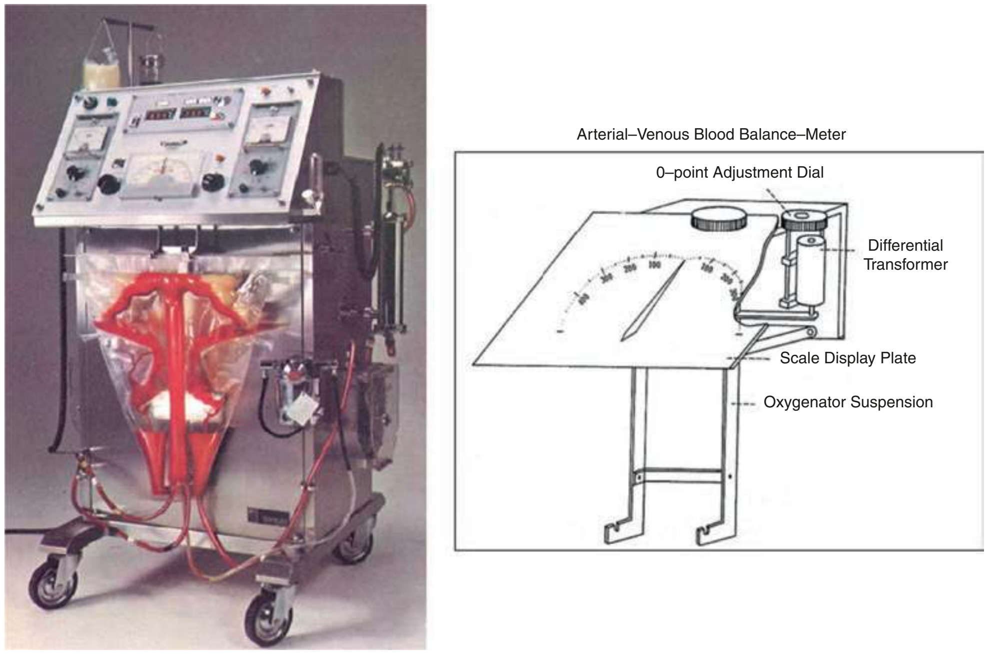


Fig. 2.6 Vinyl sheet disposable bubble oxygenator and circuits

Figure 2.7 shows the circuit diagram and related devices. The cardiotomy reservoir had a structure in which venous blood passes through a stainless steel screen to remove air bubbles and then flows down the acrylic surface to the oxygenator (maximum capacity 1000 mL). The priming volume of heat exchangers was 350 mL and 80 mL, and when the other small parts for infants were attached, it became 40 mL and was used for infant cases. The arterial filter and air bubble remover was equipped with a nylon screen and a stainless steel mesh and was equipped with a stopcock for easy elimination of air bubbles from both sides. The femoral arterial cannula was made of stainless steel and had a lock nut for fixing the tube [3–5].

The DV-3D incorporates a DV-2 weighing scale, and was able to use not only the bubble oxygenator but also the membrane oxygenator (Silicone membrane-laminated Lande-Edwards or Kolobow oxygenator). The lower half of the device was pentagonal so that the arterial and venous pumps could be monitored from the front (Fig. 2.8). Figure 2.9 shows the control panel with automatic pump rotation control. It was used at Sakakibara Heart Institute until 1986 (Fig. 2.10). The pump was detachable and could be changed to a pump that fits the patient's physique (Fig. 2.11)

The FL2300 was a heart–lung machine using a membrane oxygenator and a hard shell bubble oxygenator. It was a horizontal type, which is different from the vertical type DV, and had a control panel in the hands of the perfusionist (Fig. 2.12). Figure 2.13 shows coronary artery bypass surgery in the first operating room of the former Sakakibara Heart Institute. The circuit was a semi-closed type using a soft reservoir (SR) and a cardiotomy reservoir (CR), and a TMO membrane oxygenator was used. By placing a soft reservoir between two poles, it was easy to see the increase or decrease blood volume in the reservoir. The initial priming volume was 2400 mL. The heart–lung machine was located behind the first assistant, but after that, it was changed to be behind the surgeon to shorten the circuit tube. Figure 2.14 shows the membrane oxygenator used at that time.

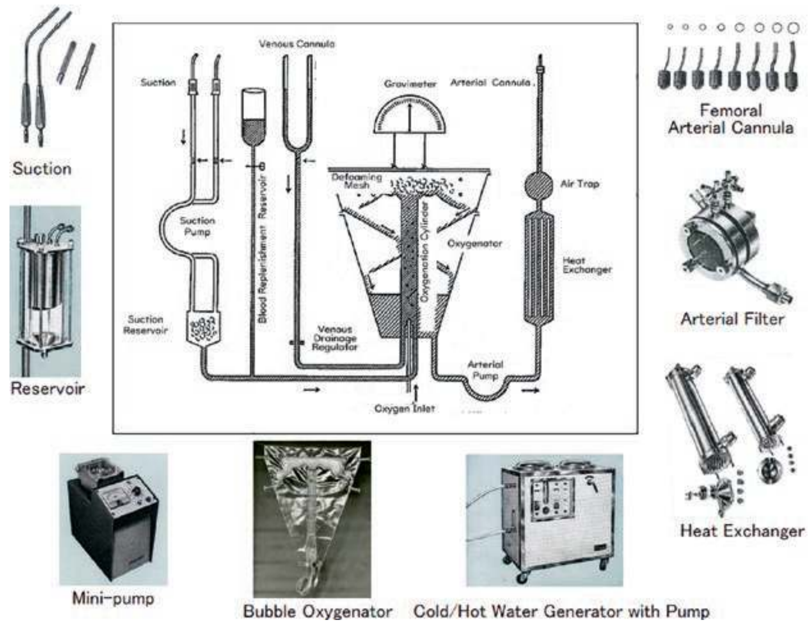


Fig. 2.7 Vinyl sheet disposable bubble oxygenator: circuit diagram and devices

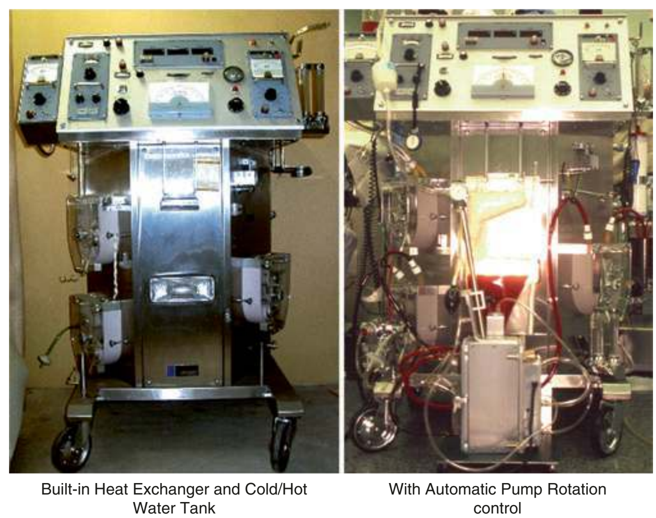


Fig. 2.8 DV-3D heart–lung machine

Fig. 2.9 Control panel of DV-3D heart–lung machine. With automatic pump rotation control

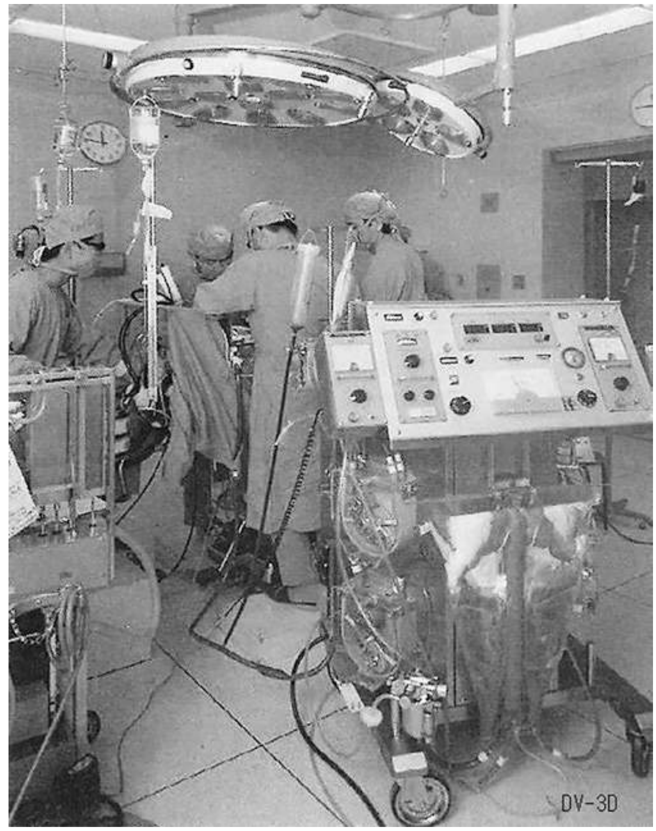


Fig. 2.10 Second operating room in the former Sakakibara Heart Institute. Aortic valve replacement by Dr. Mitsuhiko Kawase. Anesthesia was performed by Dr. Takayuki Sakakibara

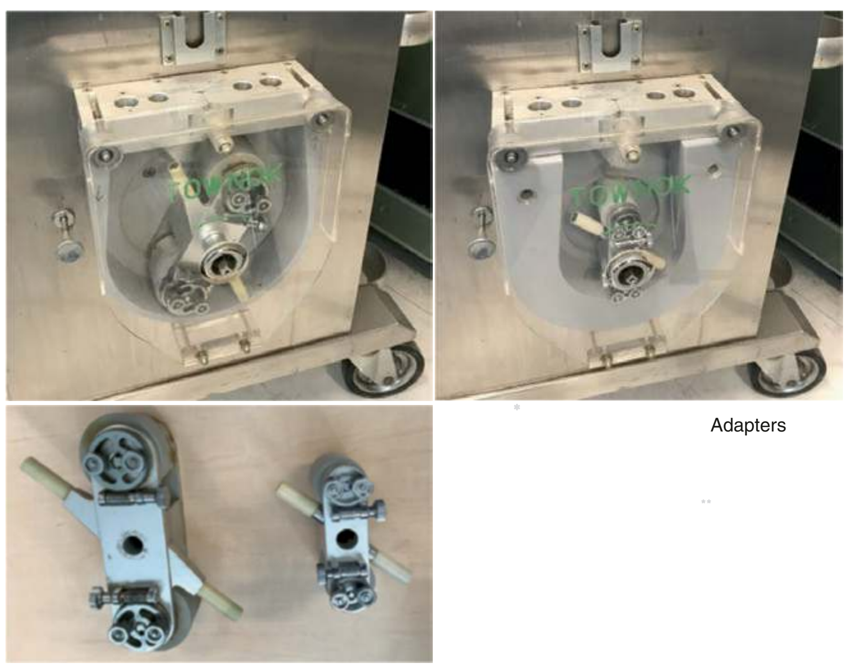


Fig. 2.11 Pumps used in DV-3D heart–lung machine. By attaching an attached raceway and a small roller, it can be used as a pediatric pump. The perfusion flow rate could be adjusted from 15 mL to 6000 mL

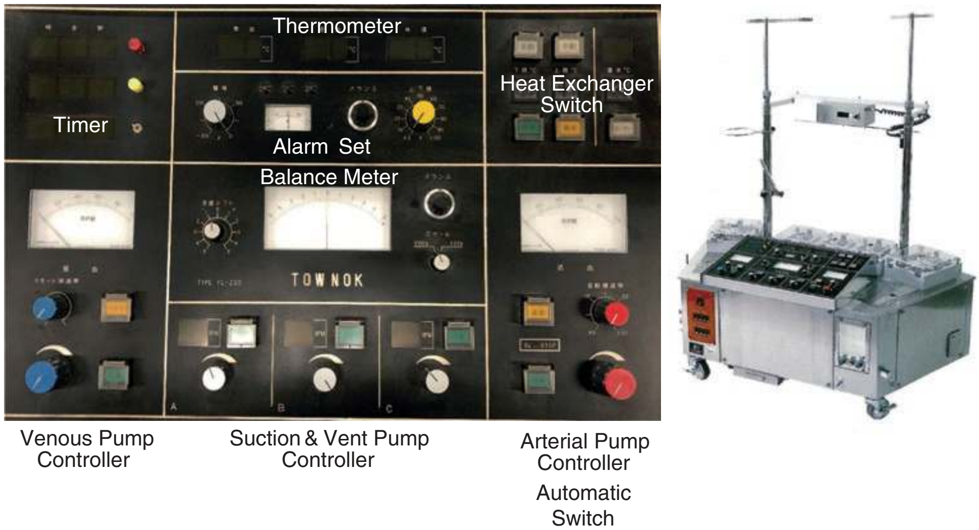


Fig. 2.12 FL2300 heart–lung machine

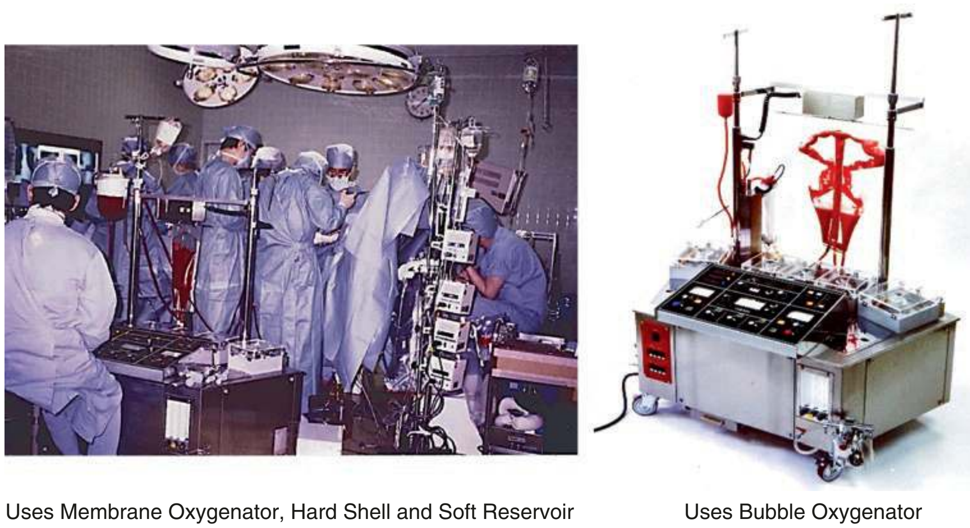


Fig. 2.13 First operating room of the former Sakakibara Heart Institute. Coronary artery bypass surgery by Dr. Takayuki Sakakibara. Anesthesia was performed by the author

Fig. 2.14 Former membrane oxygenators

Q&A: Extracorporeal Circulation in the 1980s (Question in 2018)

Question: Please tell us about Sakakibara Heart Institute's unique methods and memories of extracorporeal circulation in the 1980s.

Answer: After graduating from Kumamoto University in 1981, I completed two years of initial training at the Kumamoto Red Cross Hospital without entering a university medical office and joined the Sakakibara Heart Institute in April 1983. To be honest, I visited Sakakibara Heart Institute once when I was a student and hoped to join the job immediately after graduation, but at that time, I was refused, being said that there was no need for a newcomer who would not even be able to perform ligating techniques. In the first year after joining the Sakakibara Heart Institute, I was trained in Dr. Takayuki Sakakibara's coronary artery disease group, Dr. Katsuhiko Tatsuno's congenital heart disease group, and Dr. Mitsuhiko Kawase's valvular disease group for four months each, and from the second year to the present, I am in the congenital group.

Regarding the question about Sakakibara's extracorporeal circulation method, I would have to apologize to you first. At that time, a technician specializing in extracorporeal circulation (perfusionist) had already been enrolled, and to date, I have no experience of operating a cardiopulmonary bypass in actual clinical practice. I'm sorry to talk about extracorporeal circulation like an expert. Of course, my boss told me to study extracorporeal circulation well, but since surgery and ICU management were all I could do, I had no image of the extracorporeal circulation used at the time. I seemed to have an arrogant idea that the results were determined by the surgeon's skill rather than the quality of extracorporeal circulation. Therefore, I do not really remember the specific method of extracorporeal circulation at that time. I am sorry. However, there was a strong impression that there were many devices to see for the first time, and they were operating extremely smoothly, and it was a fact that I received a culture shock by the fresh discussion of extracorporeal circulation by the seniors. But, on the other hand, there were many cases where edema was significant, and oxygenation was poor at that time.

This will be a little be off. The most surprising thing at the time of employment was that when a patient deteriorates rapidly, a large number of laboratory technicians and radiologists, as well as physicians, immediately gathered. I was surprised at the speed of the response. I thought that hospitals in Tokyo were truly amazing. However, it turns out later that the young singles stayed at the hospital after drinking alcohol. It seems that the different environment from Kumamoto, where Kabukicho (typical downtown in Tokyo) is near, was doing so. Data 2.1 presents a paper on Sakakibara Heart Institute written by Prof. Shigeru Sakakibara in 1978 [6] (Data 2.2).

Q&A: Surgery Training

Question: How was the surgical training at that time? (2018)

Answer: About 5 years after joining the Sakakibara Heart Institute, I became a staff surgeon who was able to take a consent for surgery, but my first job was to measure the exercise capacity of postoperative children, So, other surgeons thought that a cardiology pediatrician, not a surgeon, named Takahashi was enrolled in the department of cardiac surgery at Sakakibara Heart Institute. However, many new findings were obtained from the measurement of exercise capacity, and I received praise from seniors in internal cardiology and pediatric surgery. Most importantly, the approximate quality of life associated with the growth can be determined based on the child's surgical procedure and the degree of residual defect.

The best thing about the first surgical training was that I was able to manage many postoperative children by myself, and almost 500 heart operations performed in about 10 years, although they were mostly simple cases. At that time, there were only two residents, including me. Although it is unacceptable now, I have the highest number of night duties in the history of Sakakibara Heart Institute, 25 times a month.

There is still about once a month where I feel convinced that surgery is interesting or feel something new. I think it is an honor to feel like that once a month, but at the time, I thought everything I see, hear, touch, were fresh and interesting, and if I missed them, it was a loss.

2.2.2 Component Type Heart–Lung Machine

In 1987, we started using the so-called "Component-type" heart–lung machine. It was characterized by slimming, placing one left ventricular venting and two suction pumps at the top of the body (Fig. 2.15). This slimming has made the heart–lung machine easier to transport outside of the operating room, enabling open-heart surgery in places other than OR such as cardiac catheter lab and NICU.

In 1988, an external perfusion type polypropylene hollow fiber oxygenator (blood flowing outside the fibers), Masterflow D-701, was adopted for patients weighing 13 kg or less (Fig. 2.16). The priming volume was 120 mL, and the maximum flow rate was 1.5 L/min. The S circuit priming volume for patients with a body weight of 13 kg or less was 600–750 mL. Thereafter, the measurement of inflammatory reaction substances described in Sect. 2.1 was performed using this circuit. Figure 2.17 shows a congenital heart disease operation in the second operating room of the former Sakakibara Heart Institute.

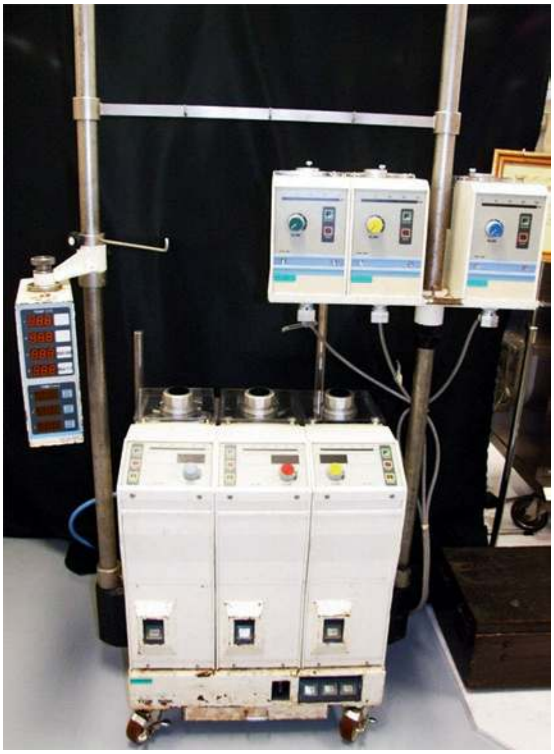


Fig. 2.15 Component type heart–lung machine

Total Priming Vol. of CPB Circuit : 650 mL (1992)

Fig. 2.16 Masterflo D-701 oxygenator

Fig. 2.17 Second operating room in former Sakakibara Heart Institute. Tetralogy of Fallot surgery performed by Dr. Katsuhiko Tatsuno. Anesthesia was performed by the author

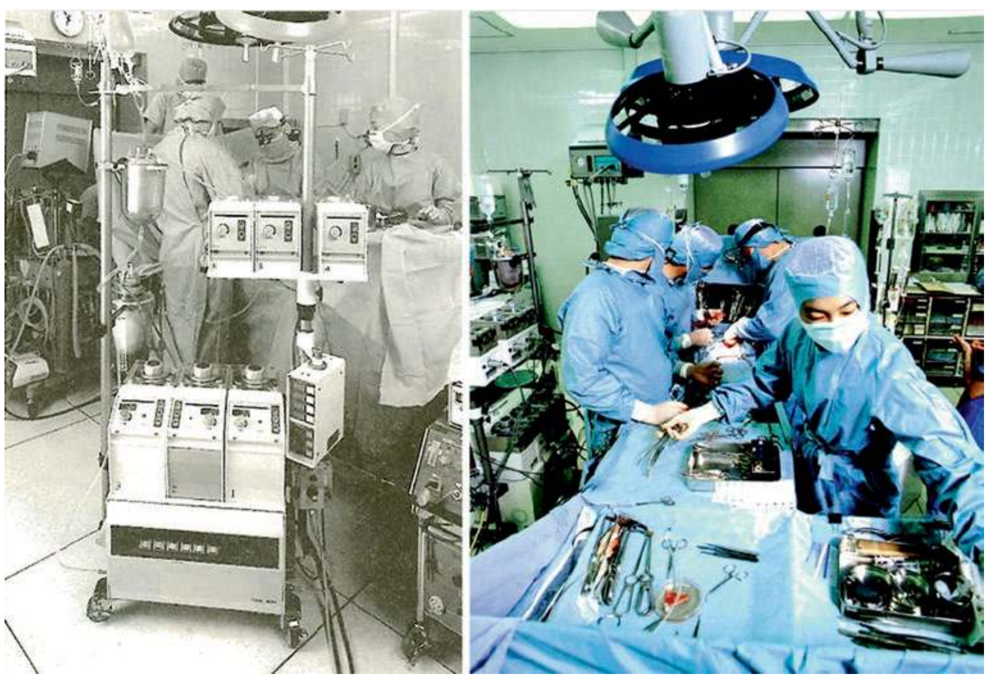


Fig. 2.18 The former Sakakibara Heart Institute. The hospital was named after its founder Professor Shigeru Sakakibara, who was called the "father of cardiac surgery" in Japan

Q&A: Component Type Heart–Lung Machine (Question in 2010)

Question: What are the features of the Component-type heart–lung machine?

Answer: The second operating room used by the congenital team was quite small, so I felt that the use of a Component-type heart–lung machine provided a sense of spaciousness, and also that each of the tubes extending from the heart–lung machine to the operating field were no longer crowded.

The former Sakakibara Heart Institute was a vertical and narrow building with eight floors above ground and one basement below (Fig. 2.18). The operating room was on the third floor, the cardiac catheterization room was on the fourth floor, and the NICU was on the eighth floor. In the event of a critical emergency where the patient could not be transported to the operating room, the extracorporeal circulation circuit was rapidly primed during the patient's resuscitation and transported from the operating room to the cath lab and NICU. This device has actually saved some lives. Because the elevator of the old hospital was really small (about 3.45 m^2), I felt it was a really compact device. At this time, the transport cart for the emergency surgical instrument set was completed, and I remember that it was extremely easy to use. Figure 2.19 shows the emergency cart used in 2006 and today [7].

As an aside, Fig. 2.20 shows the same second operating room, but in the figure on the right, the entrance to the operating room was facing the patient's head. Previously, it was reversed, as shown on the left. In addition, the arch that sepa-

Fig. 2.19 Emergency surgical instrument set cart

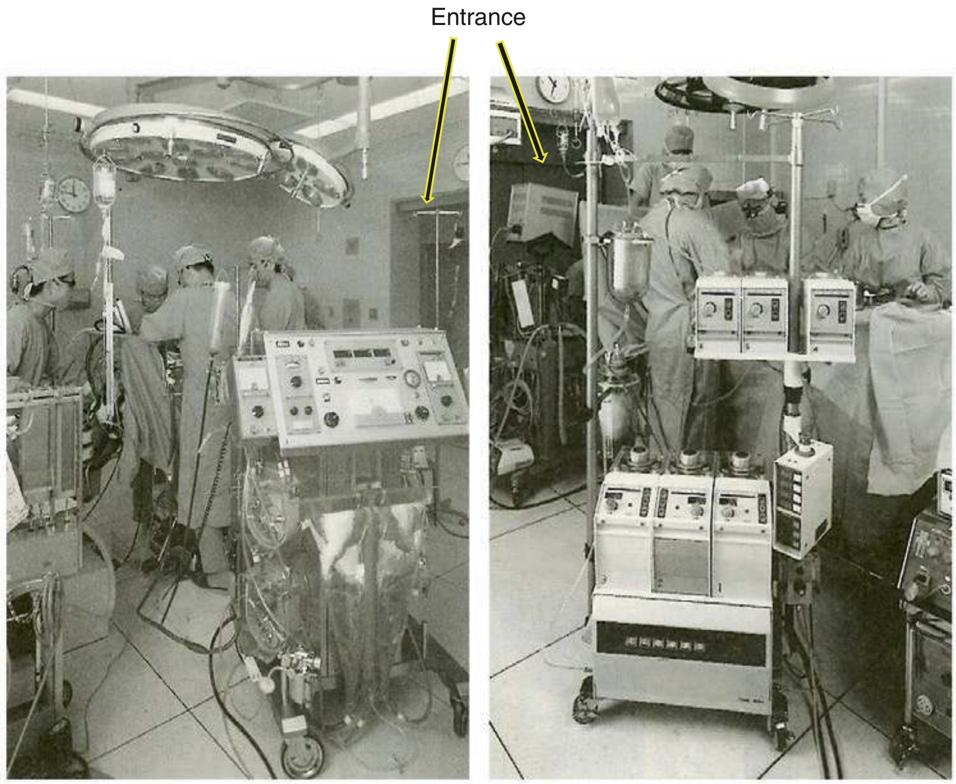


Fig. 2.20 Second operating room in former Sakakibara Heart Institute

rates the surgical field from the anesthesiologist was quite high. In 1981, the boss, Dr. Tatsuno, referred to a hospital in Munich and changed them in consideration of infection and the convenience of anesthesiologists.

As an aside again, the author is standing at the anesthesia position in the figure on the right, and the clock is already about 7 o'clock in the evening.

2.2.3 Low-Volume Oxygenator 2

In 1993, polyolefin hollow fiber oxygenator, AL-2000, was adopted (Fig. 2.21). The priming volume was 80 mL, and the maximum flow rate was 2.0 L/min. The S circuit priming volume for patients weighing less than 17 kg was 470 mL. As a result, the indications for bloodless open-heart surgery have been extended to infants, mainly VSD. The priming volume of M circuit for patients weighing over 18 kg was 750–850 mL, the same as in 1986, but since then, it was possible to perform ASD with bloodless open-heart surgery in almost all cases.

Fig. 2.21 AL-2000 oxygenator

Column: Problems with Surfactants

Along with the use of AL-2000, we began to recognize cases in which there was an extreme decrease in oxygenation after the start of rewarming. As a cause of this, the influence of the surfactant used for the initial priming to prevent hemolysis

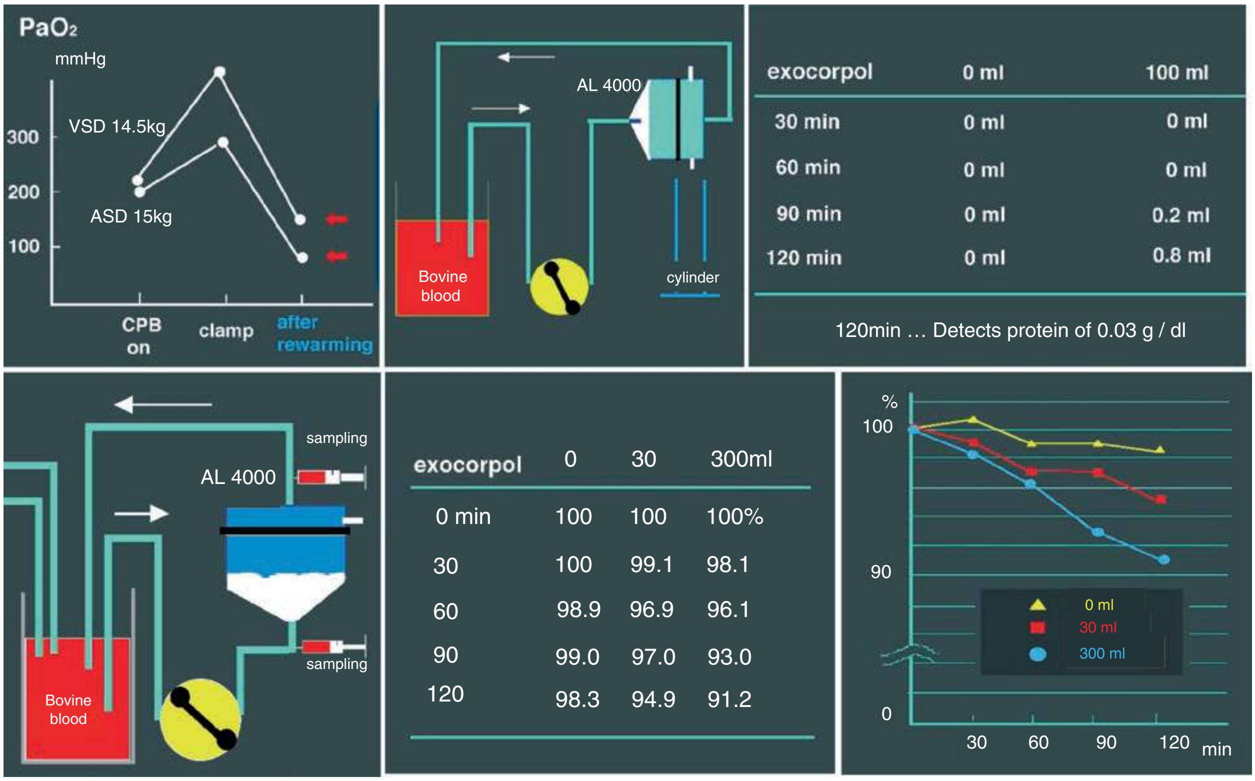


Fig. 2.22 Adverse effect of surfactant on polyolefin membrane oxygenator

was considered. Surfactants may cause plasma leakage by hydrophilizing the hollow fibers of the membrane oxygenator that are hydrophobic. Therefore, the effect of Poloxamer 188 (Exocorpol), which is a surfactant, on hollow fibers was examined. In simulated extracorporeal circulation using bovine blood, leakage of plasma was observed in the presence of Exocorpol and decreased oxygenation, as well as carbon dioxide removal, were observed (Fig. 2.22). Thereafter, in the extracorporeal circulation using the polyolefin membrane AL2000, the initial priming of the surfactant was stopped.

Column: Circuit Configuration 1

At that time, in extracorporeal circulation using a membrane oxygenator, a roller pump was also used for venous blood drainage, and it was a semi-closed circuit using a softshell reservoir (Soft Reservoir: SR) and a cardiotomy reservoir (Cardiotomy Reservoir: CR) . In the Kolobow oxygenator and TMO oxygenator, the generation of air from the oxygenator has been regarded as a problem. Therefore, SR was placed after the oxygenator for the purpose of air removal. In addition, blood from the CR was configured to flow into the SR from a separate circuit. However, this configuration has a drawback that oxygenation decreases in cases with a large amount of suction.

After that, the circuit structure was changed, so that blood from the blood and CR flowed into the SR, and an oxygenator was placed behind the SR (Fig. 2.23). This was because the performance and safety of the oxygenator have improved.

2.2.4 Low-Volume Oxygenator 3

In 1994, the polypropylene-type hollow fiber oxygenator, D-901, was adopted (Figs. 2.24 and 2.25). The priming volume was 60 mL, the maximum flow rate was 0.8 L/min, and the membrane surface area was 0.34 m^2. Both open and semi-closed circuits were supported. The open type used the attached SR and CR integrated reservoir, and the semi-closed type used SR with a flow control function (maximum capacity 90 mL) [8].

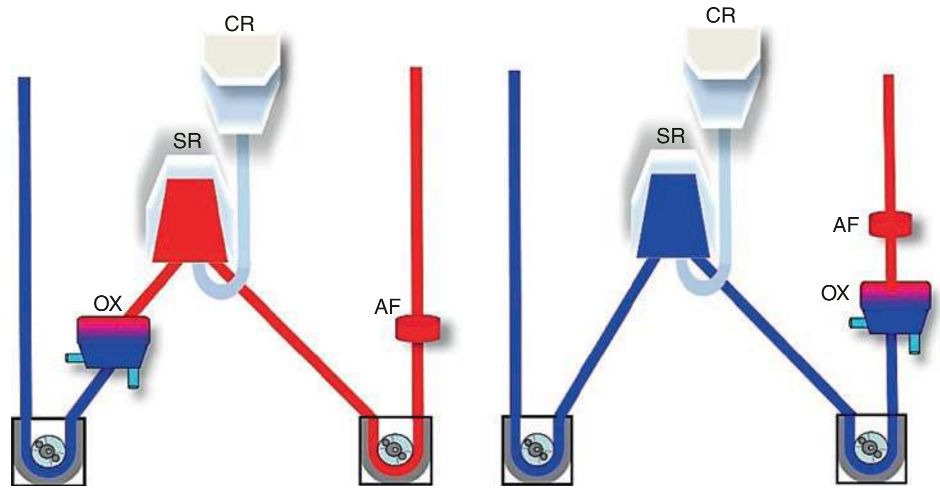


Fig. 2.23 Change of device layout in semi-closed circuit.
OX: Oxygenator
SR: Soft reservoir
CR: Cardiotomy reservoir
AF: Arterial filter

Fig. 2.24 D-901 oxygenator polypropylene hollow fiber

Initially, a semi-closed circuit was used. In patients with a body weight of 7.9 kg or less, the total priming volume was 370 mL for a SS circuit, and the indication of bloodless open-heart surgery was expanded to 5 kg. Video 2.1 shows bloodless extracorporeal circulation using D-901.

In 1995, the priming volume of the M circuit for patients with body weight of 18–44 kg was 750 mL or 850 mL for venous blood drainage with pump (SX-10 oxygenator: priming volume 135 mL, maximum flow rate 4 L/min), 1100 mL for L circuit with weight over 45 kg (Affinity oxygenator: priming volume 270 mL, maximum flow rate 7 L/min). Since the priming volume of the previous M circuit used for long-term extracorporeal circulation was 1100 mL, this reduction of priming volume expanded the indication of bloodless open-heart surgery for cyanotic heart disease, especially in the body weight range of 18–44 kg.

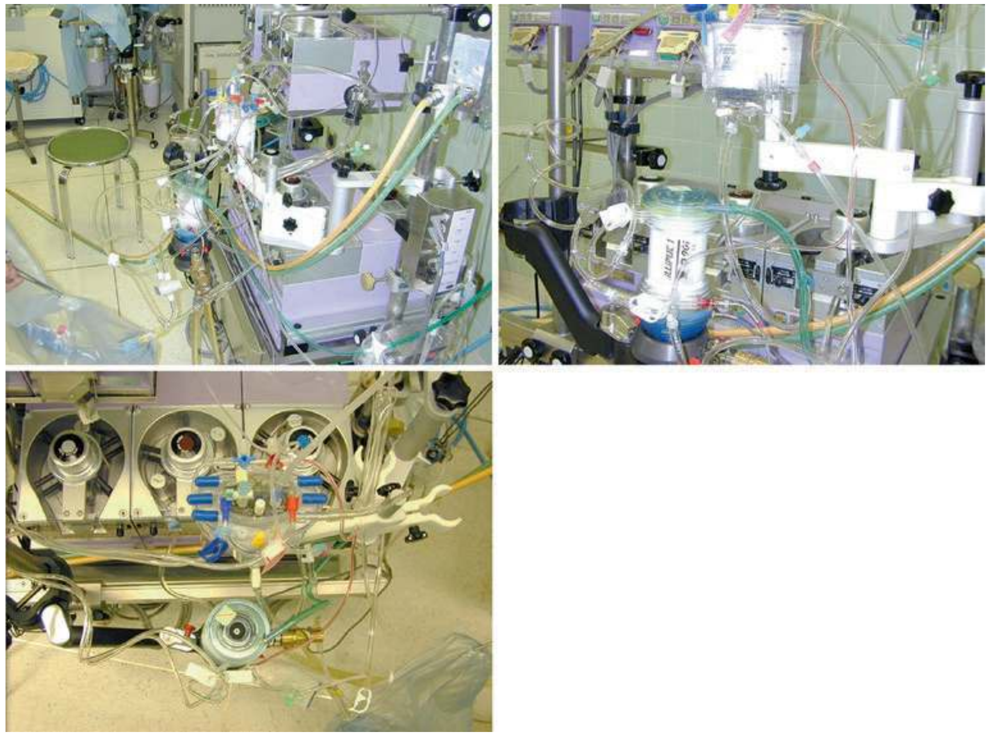


Fig. 2.25 Extracorporeal circulation circuit using D901 oxygenator

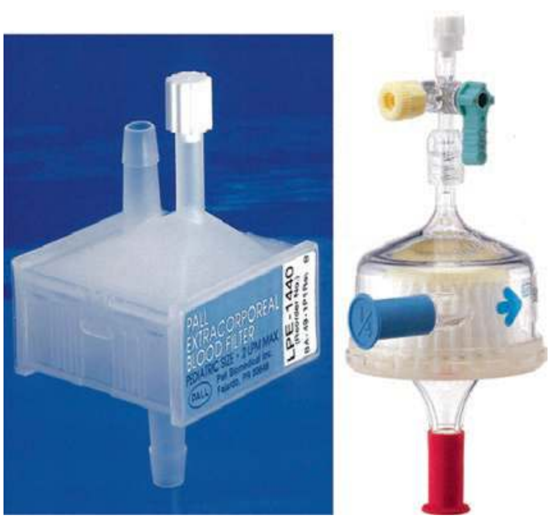


Fig. 2.26 Arteria filters LPE-1440 & AF02

Column: Arterial Filter 1

In the 1980s, the priming volume of an arterial filter averaged around 200 mL. Small arterial filters used for AL-2000 and D-901 oxygenators were LPE-1440 (polyester mesh size 40 μ, priming volume 35 mL, maximum flow rate 2 L/min) and AF02 (polyester mesh size 32 μ, priming amount 40 mL, maximum flow rate 2.5 L/min) (Fig. 2.26). As the total priming volume of the extracorporeal circuit was reduced, the ratio of the volume of the arterial filter naturally increased. Development of a smaller arterial filter was desired.

2.2.5 Isolated Pump-Controller Heart–Lung Machine 1

In 1996, clinical application of an isolated pump-controller heart–lung machine started. The feature was that the pump unit and the control unit were separated so that the pump was able to be set apart from the heart–lung machine's main body (console) and placed near the operative field for the purpose of reducing the priming volume by shortening the circuit (Fig. 2.27) [9]. In addition, the BP 75cIII ultra-compact pump was developed, and a dedicated mast for the pumps was created (pump section). This allowed flexible pump placement near the operative field. Initially, the existing heart–lung machine, Compo III, was used to drive the pump (drive unit or control unit), and the pump unit was removable at any time. In the conventional extracorporeal circulation, the circuit tubes used for arterial, venous, suction, and vent were fixed on the right side of the surgeon (Fig. 2.28) [10]. On the other hand, in the isolated pump-controller heart–lung machine, the arterial and venous line were on the left side of the surgeon, and the suction and vent were on the right side. The venous drainage pump was placed behind the surgeon's left knee (Fig. 2.29). With these modifications, the overall length of the circuit was shortened by 191 cm as compared with the conventional approach.

Videos 2.2–2.9 show extracorporeal circulation using an Isolated pump-controller heart–lung machine.

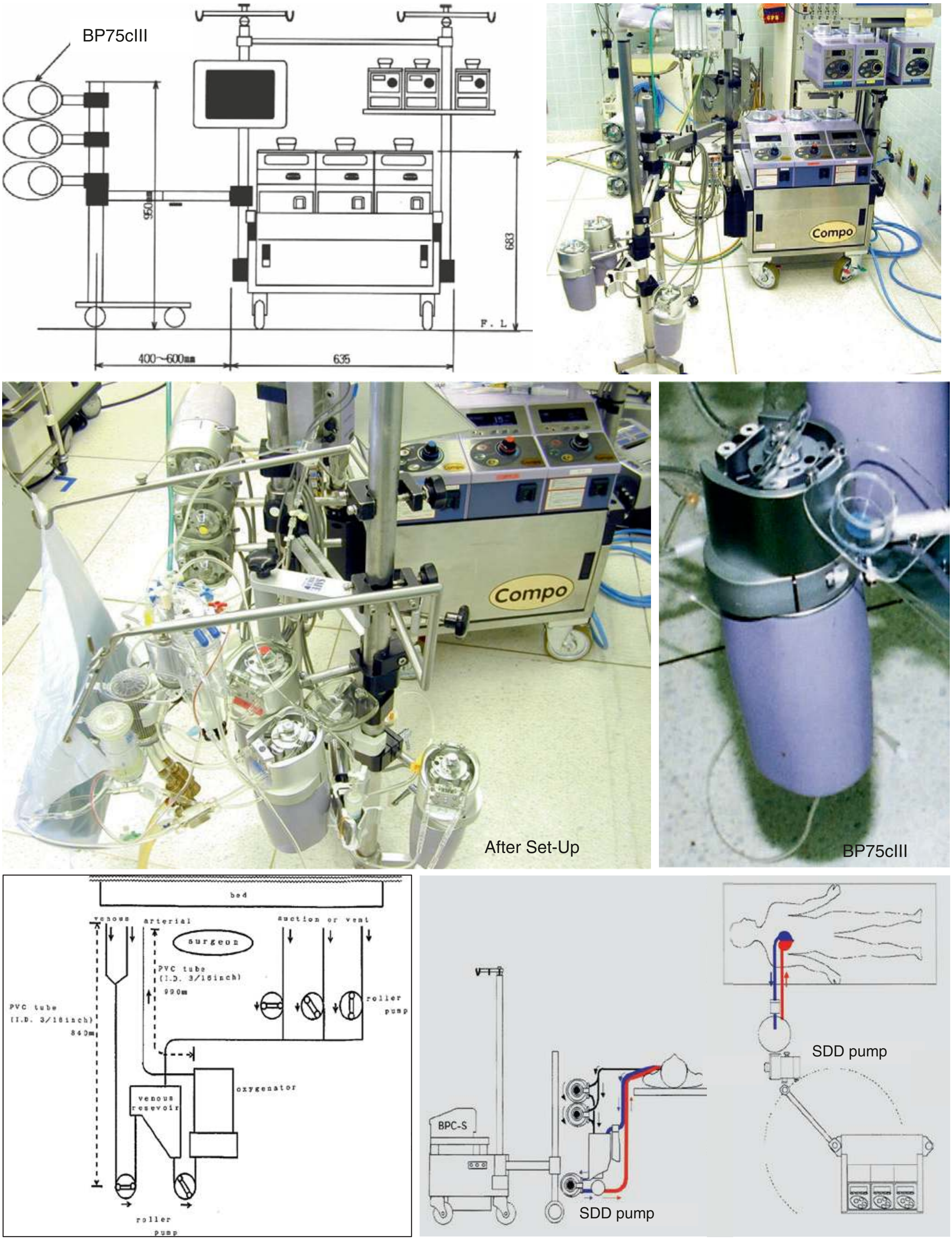


Fig. 2.27 Isolated pump-controller heart–lung machine and small pump BP 75cIII (75 mm Φ). The pump mast is equipped with six small pumps BP 75cIII

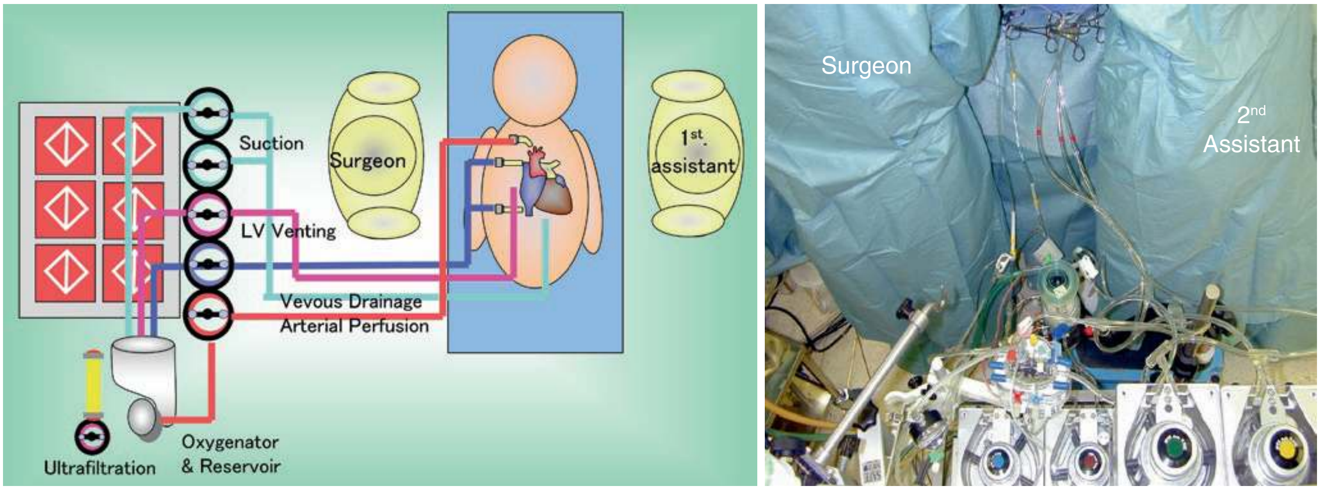


Fig. 2.28 Circuit layout of conventional heart–lung machine

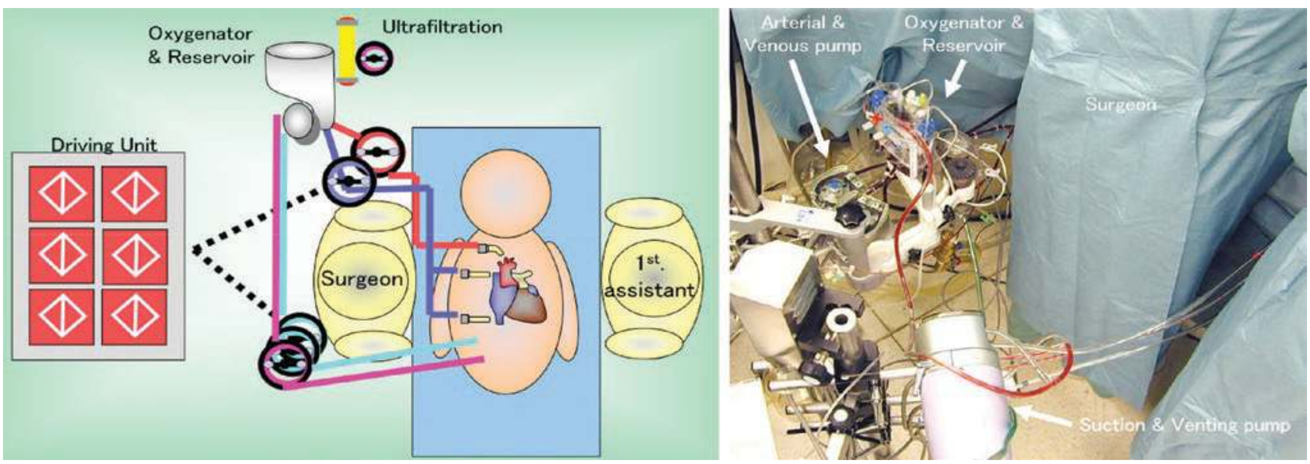


Fig. 2.29 Circuit layout of isolated pump-controller heart–lung machine

Column: Extracorporeal Circulation Circuit in Sterilized Pack

The extracorporeal circuit is contained in a sterilized pack (Fig. 2.30) [11] and is primed before the patient enters the operation room. The surgeon takes out the circuit from the bag and cuts it into arterial circuit and venous circuit in the surgical field. This system was originally developed for emergency cardiopulmonary support outside the operation room in 1984. This allows the CPB to be set up smoothly and quickly.

Column: Dr. Katsuhiko Tatsuno

In 1993, Dr. Tatsuno already had the idea of a concept developing a small cardiopulmonary bypass device that would allow infants to be performed with bloodless open-heart surgery. The main points were as follows: (1) Total priming volume less than 250 mL, which is the volume of one Coca-Cola can, (2) Creating a very small and high-performance pump, (3) Creating a mast that can freely arrange this pump near the surgeon, and clean vinyl sheet that shields between the surgeon and the pumps, and as a result, a create a device that can perform bloodless open-heart surgery even with a patient weighing less than 4 kg. In response to this, the idea of separating the small pumps from the main body (console) of the heart–lung machine and connecting them with cables was proposed, and further, the form of small pumps and masts was devised (Fig. 2.31) [11, 12].

Finally, the priming volume was minimized to 195 mL, and clinical application was started in 1997. Bloodless open-heart surgery was successfully performed for a VSD case weighing 3.7 kg. This article is from the first page of Asahi Shinbun, a major newspaper in our country, in May of 1997 (Fig. 2.32).

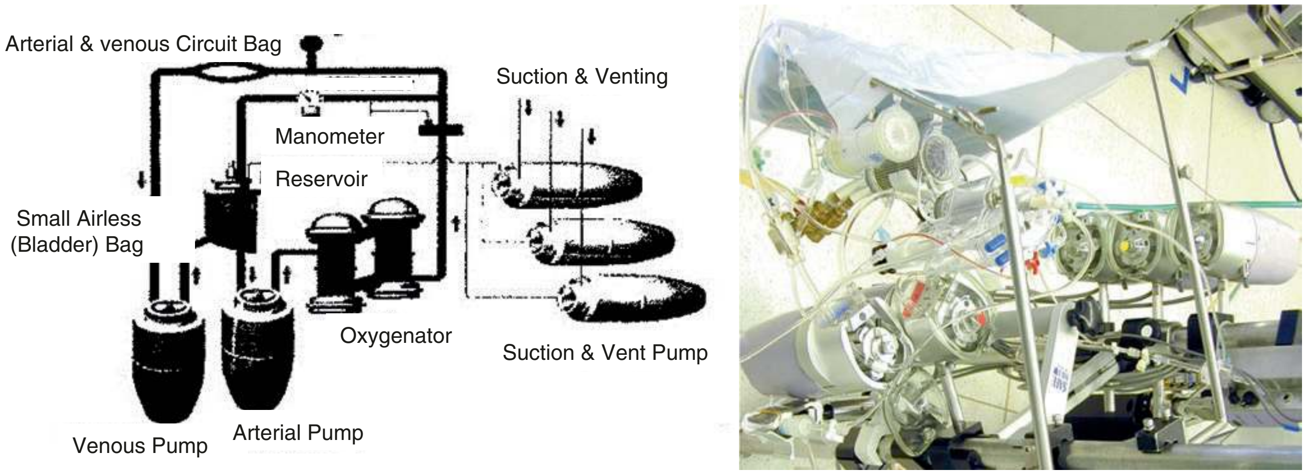


Fig. 2.30 After set-up and initial priming

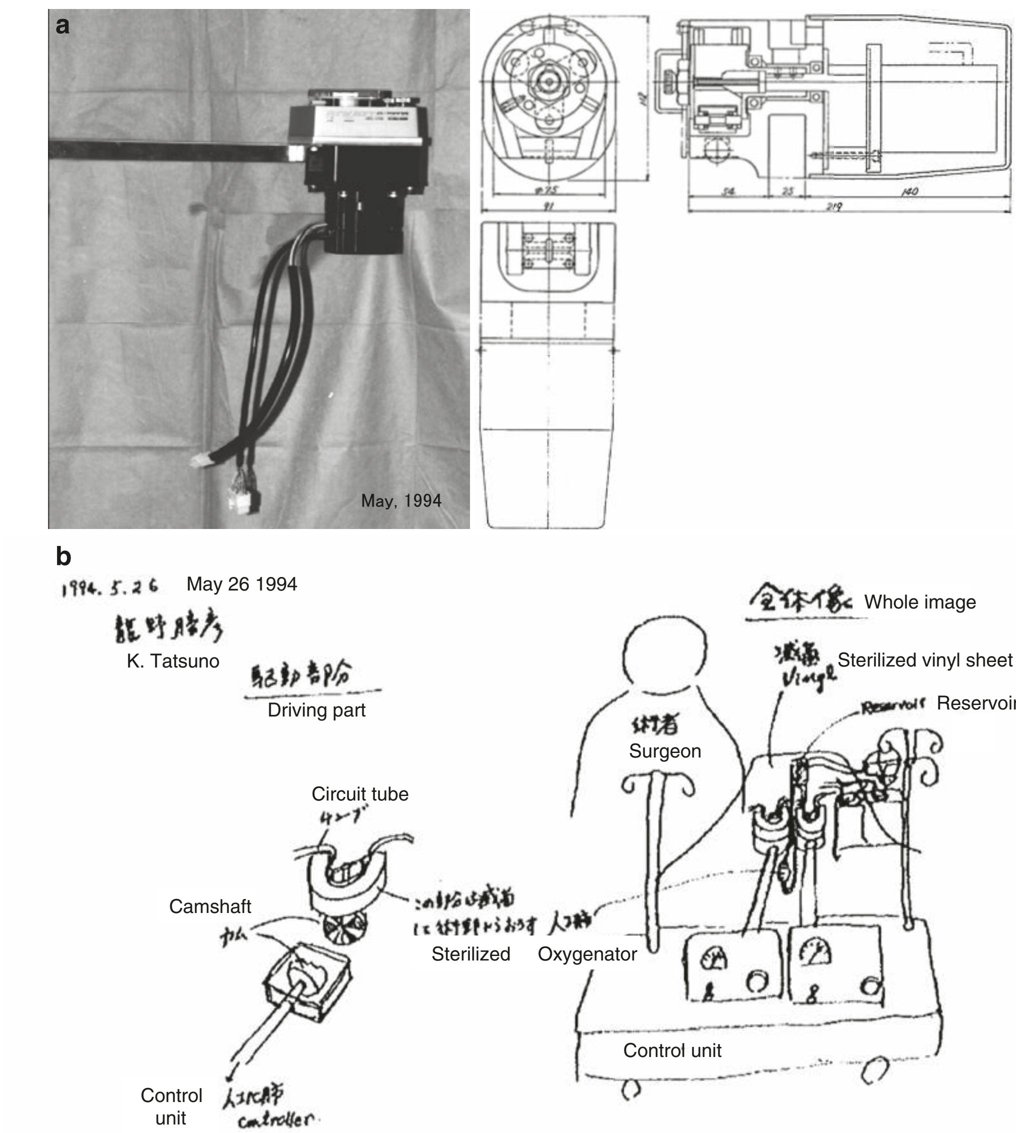


Fig. 2.31 (**a**) Small pump prototype. A small pump head created in May 1994 is shown. Regarding the arrangement of the pump, it was considered that the pump portion was completely sterilized and placed on the operative field for extracorporeal circulation. The figure below is a sketch of a remote pump controller heart–lung machine, drawn by Dr. Tatsuno on May 26, 1994. (**b**) Conceptual Drawing written by Developer Dr. Tatsuno. (**c**) Layout Plan

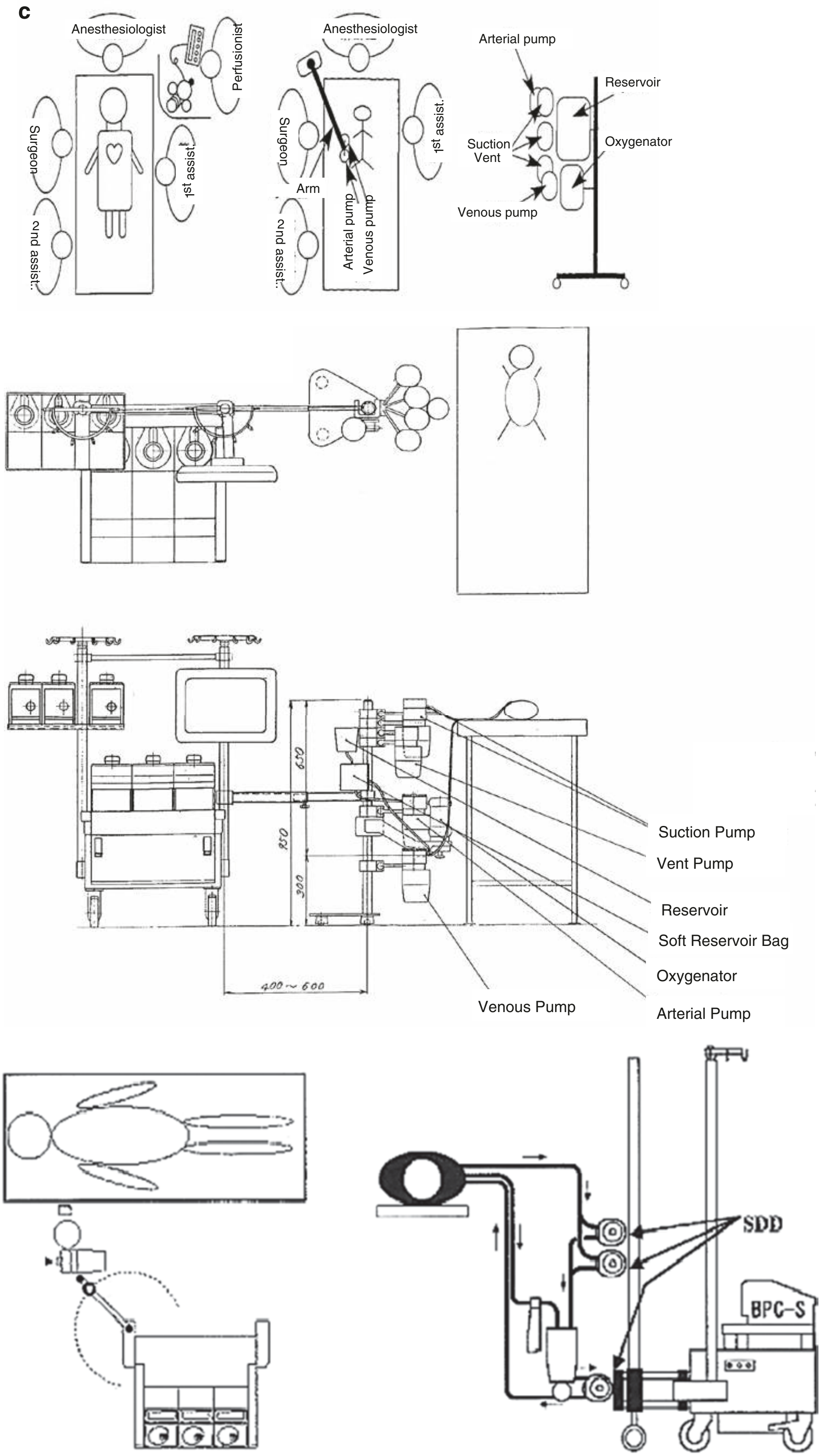


Fig. 2.31 (continued)


3650グラム、輸血せず心臓手術

生後4カ月 女児元気に

Doctor Yukihiro Takahashi, who performed surgery on the baby girl in April, with his patient. The baby's identity is withheld to protect her privacy, but her parents consented to letting Asahi Shimbun take and run her photo.

THE SMALLEST HEART PATIENT

Asahi Shimbun

A four-month old baby girl was released Thursday from Sakakibara Hospital in Tokyo after she underwent successful heart surgery without blood transfusions in mid-April.

Doctors avoided giving the baby blood transfusions for fear she would develop viral infections.

The baby weighed only 3.65 kilograms when she received the operation on April 17. She was the lightest heart-surgery patient ever in Japan, doctors said. The lighter a patient is, the more difficult heart surgery without blood transfusions becomes, they said.

The surgery was necessary because the baby girl was born with heart defects as well as with pulmonary hypertension. The heart ailments and the high blood pressure made it difficult for her to breathe.

They said that the successful surgery proved technologies for heart surgery for babies weighing less than 4 kilograms have been established.

In an effort to make heart surgery for small babies possible, the doctors at the hospital last year had developed a micro heart-lung machine that pumps 230 milliliters of blood—half the regular amount.

For the latest surgery, the doctors made an even more smaller heart-lung machine, which runs only 195 milliliters.

Thanks to the micro heart-lung machines, about 10 babies weighing less than 6 kilograms and three others weighing less than 5 kilograms have received heart surgery at the hospital.

The latest recipient is the daughter of a Saitama Prefecture family. Her name was withheld to protect her privacy.

Fig. 2.32 Asahi newspaper articles on bloodless open-heart surgery

> Dr. Tatsuno is a person with many ideas. He has designed and developed the previously mentioned FL-2300 and the Component type heart–lung machine, created a sterile vinyl bag to pack the circuit for the operative field, measured the exercise function postoperatively of congenital heart disease (exhaled gas analysis), developed a new plasty procedure for common atrioventricular valves, created an instrument set cart for emergency operation, designed the operation room and simplified the management of surgical instruments, established training program and subsidy program as a hospital dedicated for cardiovascular…, the ideas which were clinically effective were countless.

The author received much guidance from Dr. Tatsuno, and there are no words of gratitude, but there are four things to apologize for. (1) The description of the Isolated pump-controller heart–lung machine exhibited at the main entrance of Sakakibara Heart Institute mentions the author's name as the lead developer. However, the author hardly participated in the development. (2) Along with the advance of bloodless open-heart surgery for low-weight infants, it was more often taken up in medical journals and newspapers, and often, only the author was in the foreground. It was extremely grateful. (3) There were many cases of Fallot's tetralogy in the past where the length of stay in ICU was more than a week. During a preop review meeting in 1985, I have made a statement that despite there were zero death for 100 consecutive Fallot's tetralogy cases, which was very good, the postoperative right heart failure was strong due to too much scraping of the right ventricular muscle. I reflect with youthful folly. (4) Dr. Tatsuno's operation record schema was extremely exquisite and artistic. Although I learned many techniques, mainly the surgical techniques, but only the skill of drawing was something I could not inherit. I have no artistic talent (unfortunately) yet. The history of Dr. Tatsuno at Sakakibara Heart Institute is described on "Sakakibara Journey to the West" within the website of Tatsuno Internal Medicine/Cardioscular Disease, so I wish you could take a look. (Sorry, the site is in Japanese. And "Journey to the West" is is an old Chinese novel.) Most probably, the author is Sha Wujing (the "water buffalo") [13] (Data 2.3).

2.2.6 Low-Volume Oxygenator 4

In 1996, we adopted the polypropylene hollow fiber oxygenator, Safe Micro (Fig. 2.33). The priming volume was 52 mL, the maximum flow rate is 0.8 L/min, and the membrane surface area was 0.33 m^2. The attached reservoir was an integrated type of Venous and Cardiotomy Reservoir and was an open circuit. Using the Isolated pump-controller heart–lung machine and the tube diameter for arterial and venous circuits with 3/16 in., the priming volume for patients with body weight of 6.2 kg or less was reduced to 230 mL for a SSS circuit.

Fig. 2.33 Safe micro oxygenator; Polypropylene hollow fiber. Total Priming Vol. of CPB Circuit : 230mL (1996)

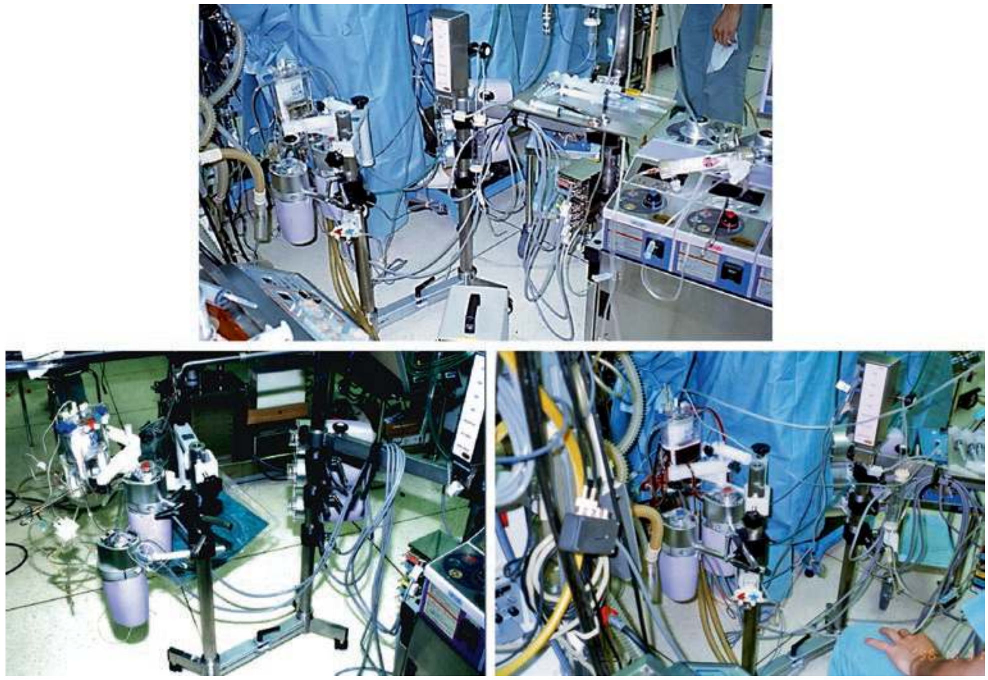


Fig. 2.34 Clinical application of an isolated pump-controller heart–lung machine (1st Case, Oct. 1996)

Column: Isolated Pump-Controller Heart–Lung Machine and Safe Micro Oxygenator

In October 1996, clinical application of the isolated pump-controller heart–lung machine was started. HC-30M hemofilter was used for ECUM. Initially, the total initial priming volume was 250 mL, and eventually reduced to 230 mL with familiarity. At this time, the initial reservoir level was 30 mL, so thereafter, the total priming volume was defined as the amount adding this level of 30 mL.

There were many cables that extended to the pump section, and there was a memory with the impression that it was quite complicated when setting the pumps behind the surgeon. Figure 2.34 shows the first operation photos. However, I could not recall any specific management performed by the perfusionist during extracorporeal circulation, such as adjusting perfusion flow and correcting drugs. Looking at the surgery record, I was the surgeon (Of course…).

Fig. 2.35 ECUM circuit.
Circuit Priming Vol. : 25mL (<6.2kg)

Column: Priming Volume of ECUM Circuit

The priming volume of the ECUM circuit in a conventional heart–lung machine was 80 mL using HC-30M. With the reduction of the extracorporeal circuit priming volume, the priming ratio of the ECUM circuit has increased. From 1997, the hemofilter PANFLO (priming volume of 12 mL), described in Sect. 2.1, was adopted. This reduced the priming volume of the ECUM circuit to 25 mL for cases weighing less than 6.2 kg using the isolated pump-controller heart–lung machine (The BP 75cIII pump was used for the ECUM) (Fig. 2.35). For a body weight of 6.3 kg or more using a conventional heart–lung machine, it was 62 mL using another external small pump.

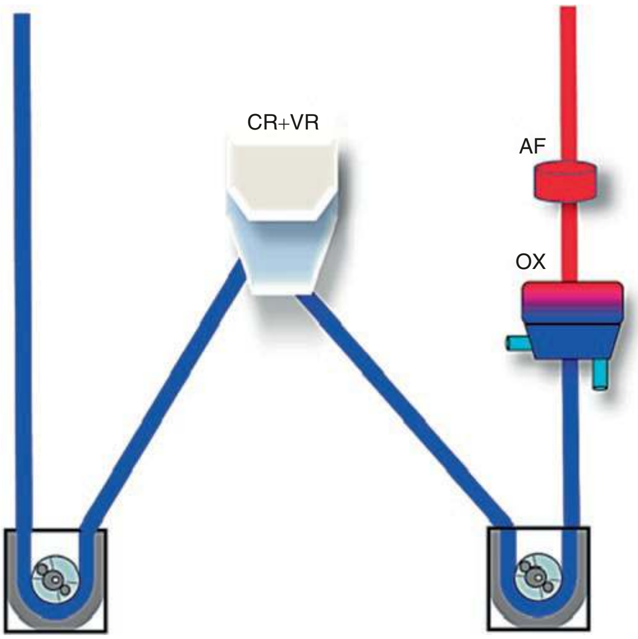


Fig. 2.36 Open type circuit.
OX: Oxygenator
VR: Venous Reservoir
CR: Cardiotomy Reservoir
AF: Arterial Filter

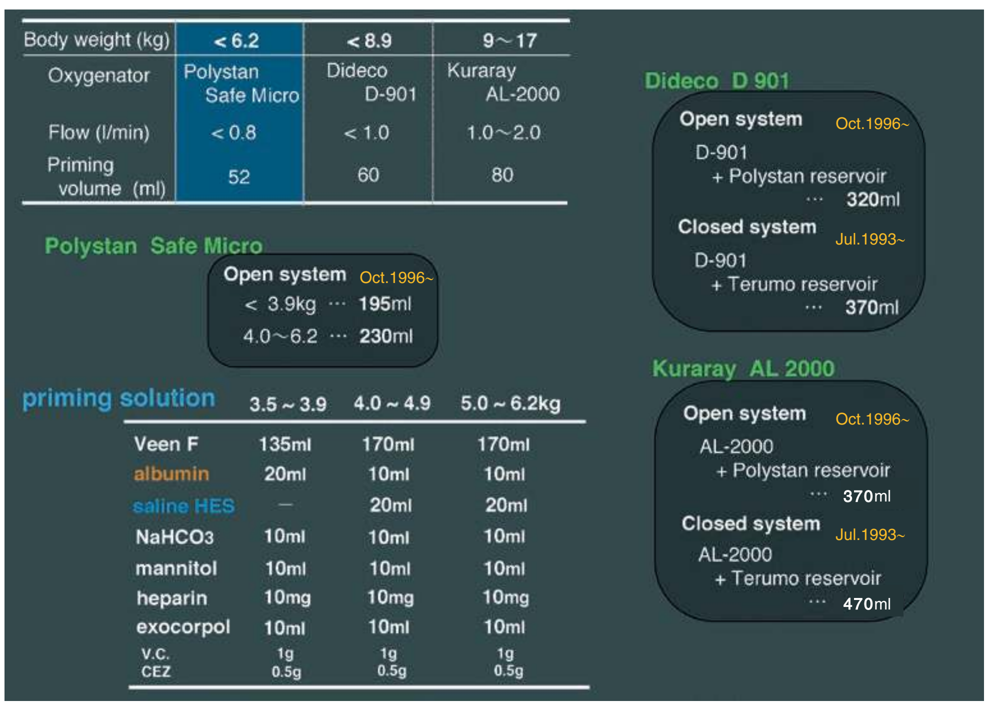
Column: Circuit Configuration 2

As the extracorporeal circulation using the open circuit became accustomed, the circuit using the D-901 and AL2000 oxygenators was changed to the open type using the Safe Micro reservoir (Fig. 2.36). The total priming volume of cases with body weight of 8.5 kg or less was reduced to 320 mL, and those with weight of 17 kg or less to 370 mL (Fig. 2.37). This priming volume reduction in this body weight range greatly contributed to the improvement of the achievement rate of bloodless open-heart surgery for infants 1–3 years old who need extracorporeal circulation for a long time. However, the priming volume of the circuit used for cases with body weight of 17 kg or more was still 750 mL, and reduction of the priming volume in older children was a problem yet to be solved.

2.2.7 Isolated Pump-Controller Heart–Lung Machine 2

There are several ways to reduce the priming volume, but shortening the circuit and reducing the diameter are the most effective methods. In 2000, arterial and venous pumps were placed higher, and the circuit diameter was reduced to 5/32 in. Both pumps were to be placed on the left rear side of

Fig. 2.37 Priming volume by weight in open circuit



Body weight (kg)	< 6.2	< 8.9	9～17
Oxygenator	Polystan Safe Micro	Dideco D-901	Kuraray AL-2000
Flow (l/min)	< 0.8	< 1.0	1.0～2.0
Priming volume (ml)	52	60	80

Polystan Safe Micro
Open system Oct.1996~
< 3.9kg … 195ml
4.0～6.2 … 230ml

priming solution	3.5～3.9	4.0～4.9	5.0～6.2kg
Veen F	135ml	170ml	170ml
albumin	20ml	10ml	10ml
saline HES	–	20ml	20ml
NaHCO3	10ml	10ml	10ml
mannitol	10ml	10ml	10ml
heparin	10mg	10mg	10mg
exocorpol	10ml	10ml	10ml
V.C. CEZ	1g 0.5g	1g 0.5g	1g 0.5g

Dideco D 901
Open system Oct.1996~
D-901 + Polystan reservoir … 320ml
Closed system Jul.1993~
D-901 + Terumo reservoir … 370ml

Kuraray AL 2000
Open system Oct.1996~
AL-2000 + Polystan reservoir … 370ml
Closed system Jul.1993~
AL-2000 + Terumo reservoir … 470ml

Fig. 2.38 Layout of arterial and venous pumps [14]. This pump arrangement was possible because we were doing a pump-assisted venous drainage at the time

Fig. 2.39 Sterilized pack with circuit

the surgeon (Fig. 2.38). The priming volume of cases with body weight of 4.5 kg or less was reduced to 130 mL excluding the arterial filter (SSSS circuit). Since arterial and venous pumps were located on the rear side of the surgeon, a sterilized bag for circuit packing, larger than the previous type, was used, and it was kept sterile by intervening between the surgeon and the pumps (Fig. 2.39). Figure 2.40 shows the circuit diagram.

For details on arterial filters, see Column "Arterial Filters" (Sect. 2.2.4).

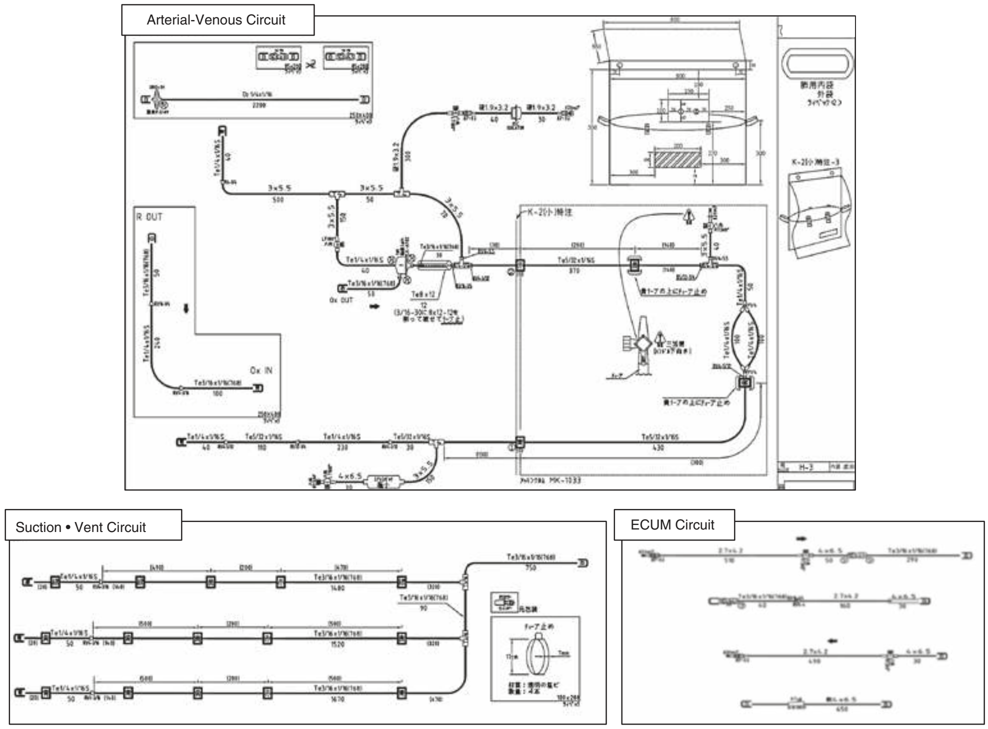


Fig. 2.40 Diagram of a circuit with a priming volume of 130 mL (pump venous drainage)

2.2.8 Isolated Pump-Controller Heart–Lung Machine 3

The reduction of priming volume puts great stress on the perfusionist in terms of strict regulation of the reservoir level. In the management of the isolated pump-controller heart–lung machine, the perfusionist initially adjusted the rotation speed of the pump by turning to the right where the drive unit was located and then administered the drug solution in the direction of the surgical field where the reservoir was located (Fig. 2.41). In addition, when a conventional heart–lung machine was used as a driving device to regulate the small pump, fine adjustment of the blood flow rate was difficult. Therefore, an isolated control panel with a control knob that allows fine adjustment of the pump speed was developed and placed in front of the reservoir (Fig. 2.42).

As a result, not only fine adjustment of blood flow and blood removal, but also administration of drugs and correction fluid, and confirmation of the status of the biological monitor, reservoir level, urine volume, ECUM volume, and pump rotation were simplified (Fig. 2.43). Simultaneously with the development of the isolated panel, a dedicated drive unit device was also developed and was named isolated pump-controller heart–lung machine No. 2 (Fig. 2.44). The small pump was the new BP 75cIII.

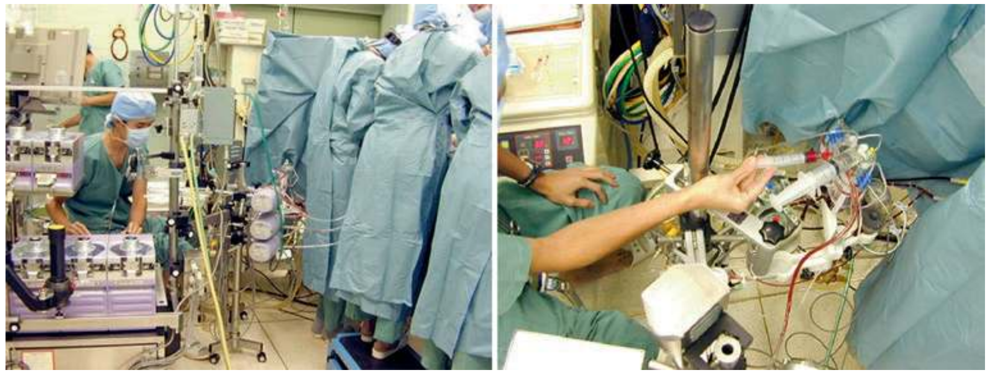


Fig. 2.41 Layout of isolated pump-controller heart–lung machine and perfusionist's management

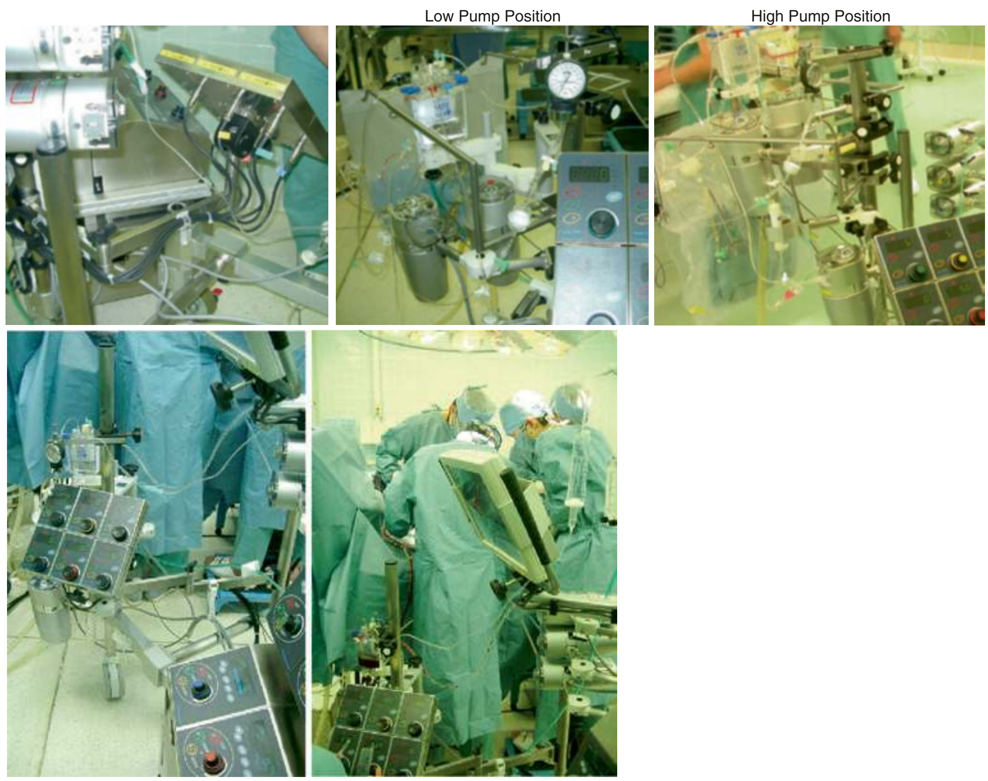


Fig. 2.42 Isolated control panel

Fig. 2.43 Layout of isolated pump-controller heart–lung machine and perfusionist's management. Control panel was separated so that the pump controller and the drug infusion lines are aligned in the same direction, on the right side of the reservoir

Fig. 2.44 Dedicated drive unit for isolated pump-controller heart–lung machine

Column: Developing a Large Isolated Pump

In 1999, large isolated pumps, BP 120cIII (120 mmΦ) and BP 150 cIII (150 mmΦ) that can be used for older children to adults were developed (Fig. 2.45). In extracorporeal circulation using these pumps, the arterial and venous circuits, suction and venting circuits were fixed on the right side of the surgeon. The isolated panel was equally good in operation and visibility (Fig. 2.46). However, although the length of the circuit could be shortened to some extent, the priming volume could not be effectively reduced. Also, unlike the isolated type 1 heart–lung machine, the mast of the pump portion was joined to the drive portion, and the pump was heavy, which makes it difficult to move the device. Data 2.4 shows the features of each isolated pump.

Fig. 2.45 Large isolated pump

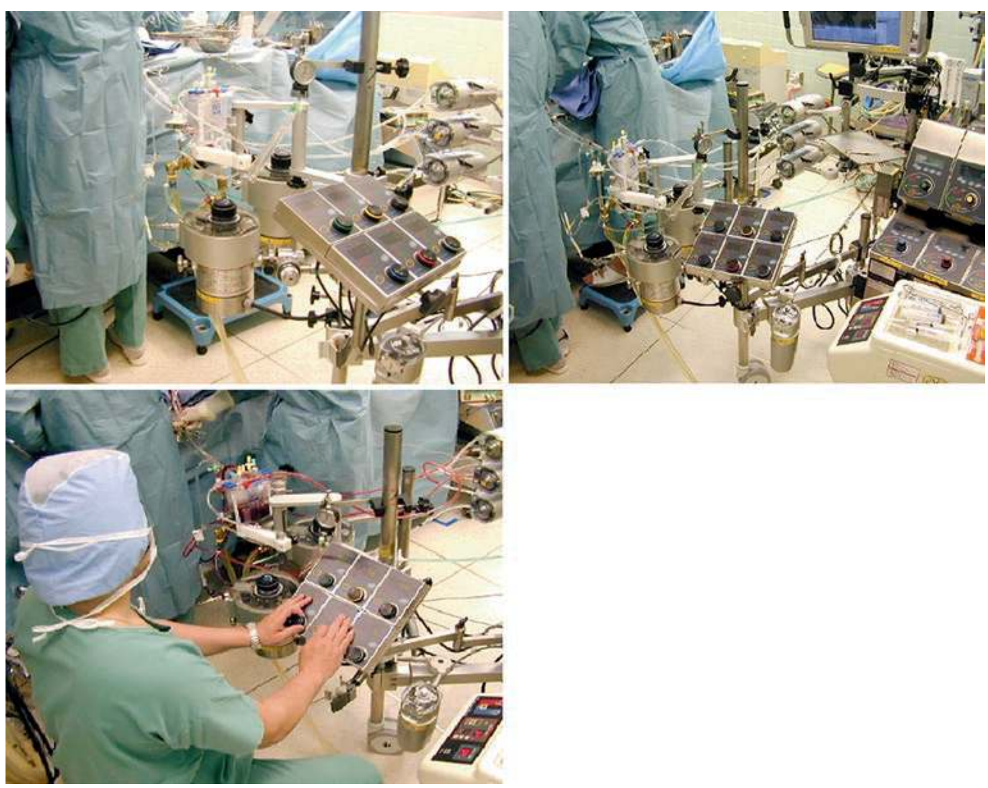


Fig. 2.46 Extracorporeal circulation using large isolated pumps

Fig. 2.47 The New Sakakibara Heart Institute

Fig. 2.48 The New Sakakibara Heart Institute

2.2.9 The New Sakakibara Heart Institute

On December 24, 2003, surgery was started at a new hospital in Fuchu City, Tokyo (Fig. 2.47). Videos 2.10–2.12 show the whole view of the hospital, operating room, and ICU.

Q&A: New Sakakibara Heart Institute (Question in 2004)

Question: What is your impression of the new hospital?

Answer: We moved to Fuchu city at the end of 2003. Unlike the former hospital, it is a building that is nearly square, with seismic isolation structure (Fig. 2.48). In the event of a disaster, furniture and walls in the entrance hall and waiting room can be removed (Fig. 2.49), and there are systems that can utilize rainwater. Unique features include (1) Staff room which is an open space that is not separated by job organization such as doctors, nurses, and office clerks (Fig. 2.50), (2) In outpatient settings, clerks and pharmacists will go to patients and give explanations without calling out the names of individual patients on the broadcast. (3) In the general ward, a counter is set up in front of each room as a nurse's workplace for the purpose of nursing close to patients (Fig. 2.51).

There is a large elevator at the emergency entrance, where patients can be transported directly to the operating room, cardiac catheterization laboratory, ICU, NICU, and CCU. In addition, ICU's and NICU's are widely deployed to allow emergency surgery (Fig. 2.52). Web slide shows the concept map of the new hospital (Data 2.5).

Anyway, each one is large and big. However, what I do is the same, so I feel like I have lived here before, but the most different point from the Shinjuku era (accurately Yoyogi) is that there is only one convenience store around. And at night, it is just darkness except for the car lights on the Koshu Kaido highway. Within a month coming to Fuchu, I could not do the trick of walking while avoiding pedestrians and bicycles.

There are four operating rooms, and the congenital surgery team mainly uses the first operating room (Fig. 2.53). The first operation was the Jatene operation at the end of 2003. The operating room is still quite large (old hospital 37.8 m^2, new hospital 99.4 m^2). I think it is a luxury problem, but the distance to the wall is far. There is a feeling that I am stuck in the middle performing surgery lonely, and have the impression that it is necessary to communicate with a loud voice. In addition, the building itself has wide floors, so the population density has been considerably reduced. As a hospital specializing in cardiovascular diseases and as a community support hospital, we intend to protect "Sakakibara-ism," which never refuse emergency cases.

Fig. 2.49 Outpatient waiting hall

Fig. 2.50 Staff center

Fig. 2.51 Working space at the entrance to the hospital room

Fig. 2.52 (**a**) ICU; (**b**) NICU

Fig. 2.53 First operating room

2.2.10 Transition of Priming Volume Reduction, Vacuum-Assisted Venous Drainage (VAVD)

In 2005, we adopted the polypropylene-type hollow fiber oxygenator, RX-05 (Fig. 2.54). The priming volume was 43 mL, the maximum flow rate was 1.5 L/min, and the membrane surface area was 0.5 m^2. Along with this, the attached reservoir, RR-10 was used, and the venous blood drainage method was changed from pump assist to vacuum assist. The minimum total priming volume was 160 mL (using arterial filter AF-02). In 2006, the minimum priming volume was reduced to 150 mL with the development of the arterial filter FT-15 (priming volume 15 mL, maximum flow rate 2.5 L/min) (Fig. 2.55).

In 2008, the priming volume was reduced to 135 mL using an oxygenator, FX-05 (priming volume 43 mL, maximum flow rate 1.5 L/min, membrane area 0.5 m^2) with an integrated arterial filter (Fig. 2.56). Since 2007, we have also adopted a polypropylene hollow fiber oxygenator, Oxia-IC (Fig. 2.57). The priming volume is 37 mL, the maximum flow rate is 2.0 L/min, and the membrane surface area is 0.39 m^2. It was an era when the development of low volume and high blood flow devices originated from Japan. Table 2.1 shows the device and circuit priming volume used by weight at the time of 2009.

Fig. 2.54 FX-05 oxygenator

Fig. 2.55 Arterial filter FT-15

Fig. 2.56 FX-05 oxygenator with built-in arterial filter

Fig. 2.57 Oxia-IC oxygenator

Table 2.1 Oxygenator used in 2009 and circuit priming volume by weight. In order to suppress SIRS, it is necessary to devise ways to reduce the contact surface area with blood. The contact surface area of the oxygenator is the largest. Therefore, to reduce the contact surface area, it is most effective to reduce the size of the oxgenator rather than shortening or reducing the diameter of the extracorporeal circuit

Circuits	SSS	SS	S			M
Arterial Diameter inch	3/16	3/16	1/4			3/8
Venous Diameter inch	1/4	1/4	1/4			3/8
Pump Head Diameter inch	Ø75 1/4	Ø150 3/16	Ø150 1/4			Ø150 3/8 (1/2)
BW kg	~7	~9	9~13	13~19	19~24	24~
Oxygenator	FX-05 OXIA-ic	FX-05 OXIA-ic	FX-05	B-CUBE HPO-06	HILITE D-902	FX-15 OXIA-LP
Reservoir	RR-10 HVR-12	RR-10 HVR-12	RR-10	HVR12	HVR12	RR-40 OXIA
Priming Volume mL	135 150	150 190	175	210 220	280 290	350 (400) 450
Patient'No.	68	145	127			77

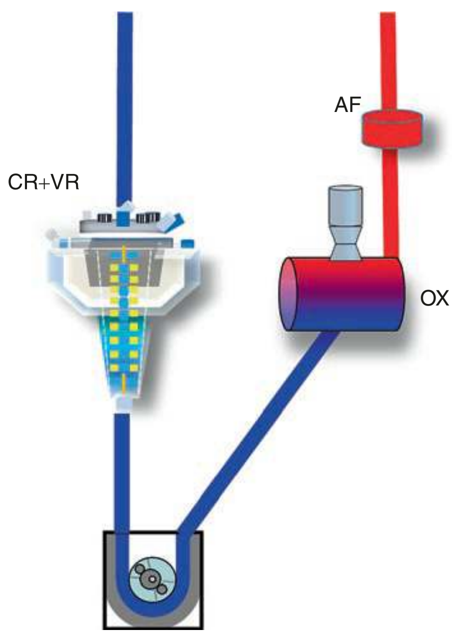


Fig. 2.58 Open circuit diagram (Vacuum-assisted venous drainage).
OX: Oxygenator
VR: Venous Reservoir
CR: Cardiotomy Reservoir
AF: Arterial Filter

Column: Circuit Configuration 3

With the use of the RR-10 reservoir, the pump-assisted venous drainage was changed to vacuum-assisted drainage (Fig. 2.58). With the Safe Micro reservoir, venous blood enters from the lower rear of the reservoir to the center portion. On the other hand, RR-10 has a structure in which venous blood enters the bottom from the upper part of the reservoir through a single duct (Fig. 2.59).

Fig. 2.59 Reservoir structure

Characteristically, the stagnation time of inflowing blood is short (= dynamic priming volume is small), and the liquid level is stable, so that safe management is possible even with a low reservoir level of 15 mL. In fact, the control of venous drainage was relatively easy. It also has the advantage that the amount of residual blood in the reservoir after collecting the blood in the circuit was small (Fig. 2.60). In pump-assisted venous drainage, a small bladder bag was built into the venous circuit, and the pump rotation speed was adjusted while confirming whether drainage was good or not based on the presence or absence of this collapse (see Videos 2.2–2.9). After the adoption of vacuum-assisted venous drainage, the adjustment of blood removal volume was managed at the vacuum pressure and reservoir level. Since then, this type of reservoir has become the mainstream. However, this structure leads to the generation of pitfalls of extracorporeal circulation, described in Fig. 2.61 shows a circuit diagram for using vacuum-assisted venous drainage with a priming volume of 135 mL.

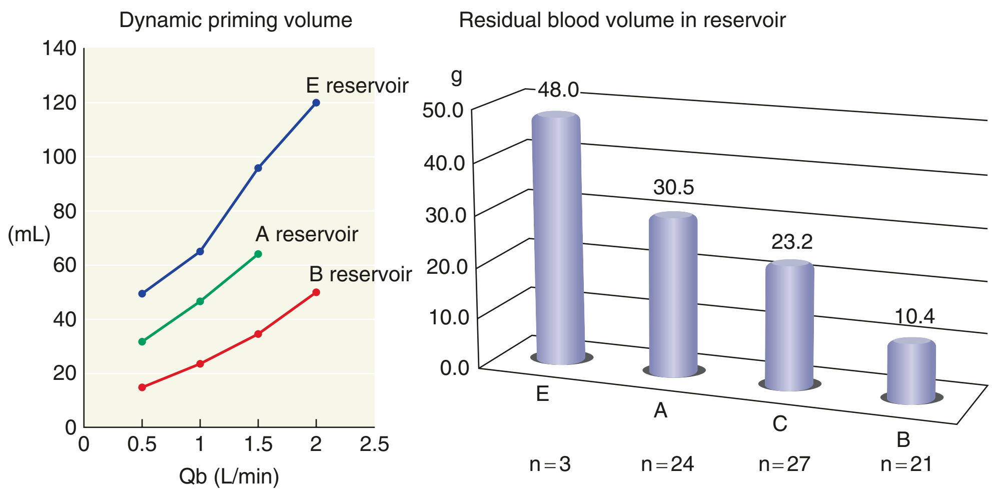


Fig. 2.60 Dynamic priming volume and residual blood volume in reservoir. The amount of residual blood in the reservoir after re-infusion blood collection was evaluated in 75 patients with congenital heart disease weighing less than 24 kg. Priming volume: 150-230 mL, Average extracorporeal circulation time: 72 min

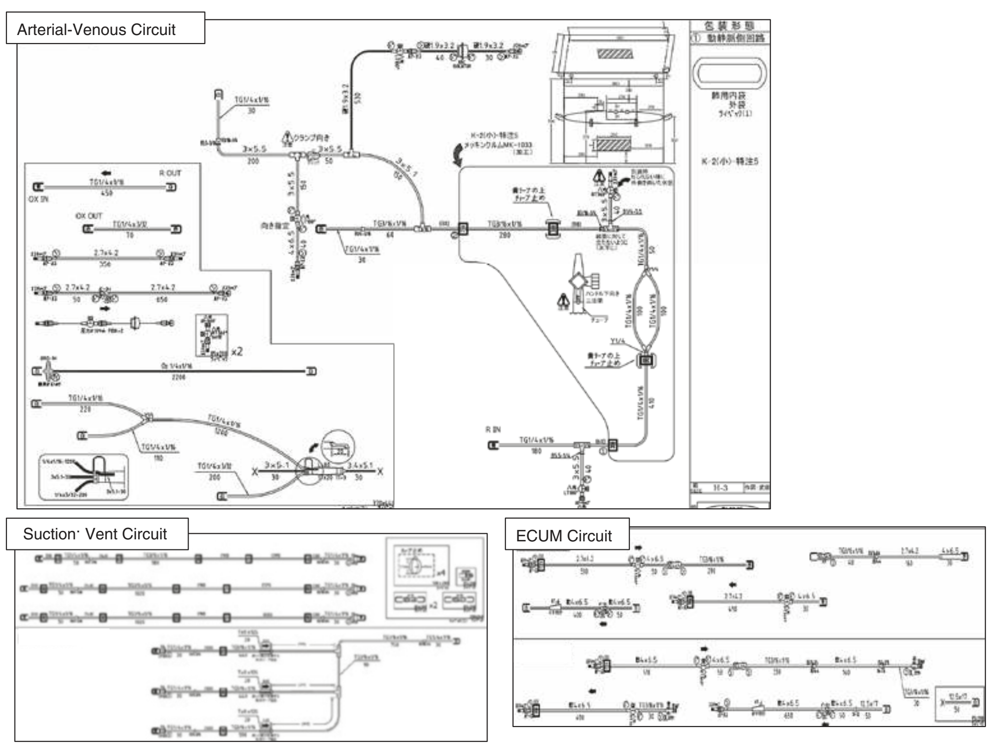


Fig. 2.61 Diagram of a circuit with a priming volume of 135 mL (Vacuum-assisted venous drainage)

Table 2.2 Changes in the priming volume in patients weighing over 20 kg since 2006

BW (kg)	20.0~23.9	24.0~29.9	30.0~
Oxygenator	HILITE 2800	HILITE 2800	RX15
Priming Vol.(mL)	310	430	650

BW (kg)	20.0~23.9	24.0~
Oxygenator	HILITE 2800 D-902	FX15 Oxia LP
Priming Vol.(mL)	310	400 500

BW (kg)	17.0~23.9	24.0~79.9	80.0~
Oxygenator	Quadrox-i P	FX15	RX-15
Priming Vol.(mL)	200	350 or 400	500

BW (kg)	17.0~23.9	24.0~79.9	80.0~
Oxygenator	D-101 Quadrox-i P	FX15	Fusion Skipper
Priming Vol.(mL)	200	350 or 400	600

The dynamic priming volume indicates the amount of blood stored in the reservoir when the extracorporeal circulation is suddenly stopped. A large value means that a lot of blood is passing through the reservoir and that the passage time is long. Clinically, these suggest that the responsiveness of the reservoir liquid level is slow and the responsiveness of the administered drug or correction fluid is low.

Column: Priming Volume in Older Children

Table 2.2 shows the oxygenator used in older children and adults weighing 20 kg or more and the total priming volume by weight since 2006. It was significantly reduced compared to before and was particularly useful for preventing hemodilution in cases of cyanotic heart disease and re-operation that take a long time to repair. During this period, each time a low-volume and high-flow oxygenator was developed, each circuit was created for the purpose of reducing the priming volume. It was a time when eight different oxygenators were used in the congenital surgery group. That was the evidence that high-performance and low-volume oxygenator have been developed, and the advantages and disadvantages of each were fully understood.

2.2.11 Isolated Pump-Controller Heart–Lung Machine 4

In the current operating room, there is a control room for the heart–lung machine. Here, the extracorporeal circuit is set on the heart–lung machine, and it is primed after being transported to the operating room. The reason is to avoid opening the cardboard box for circuit packaging in the operating room to prevent dust generation. However, the isolated pump-controller heart–lung machine No. 2 had a structure in which the drive unit and the pump unit were joined (Fig. 2.62), and it was difficult to transport from the control room to the operating room. In 2008, we developed the isolated pump-controller heart–lung machine No. 3 with the pump part completely separated by making the cable even longer, similar to isolated pump-controller heart–lung machine No. 1 (Fig. 2.63). A heavy drive unit is fixed in the operating room, and only the pump unit is moved. Not only

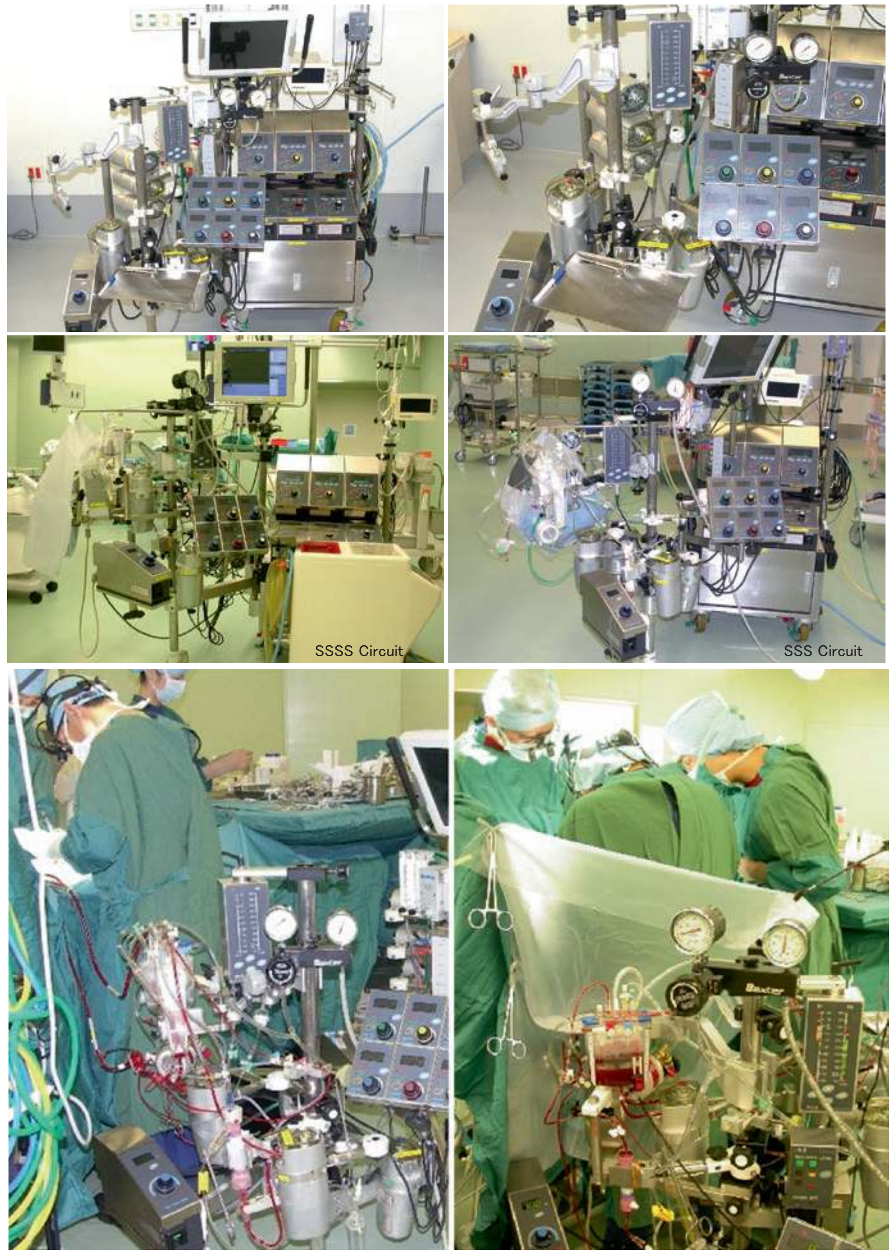


Fig. 2.62 Isolated pump-controller heart–lung machine No2

the circuit setting and the transport was simplified, but also the degree of freedom, such as the placement of pumps in the operating room has increased. It has the same isolated control panel as the No2 heart–lung machine and can be used for all body weight ranges using three types of pump sizes. The perfusionist will operate on the right side of the operating table, behind the anesthesia machine (Fig. 2.64). The rear of the second assistant surgeon is an open space, and because of its increased visibility, we called the device "Skeleton type" (Videos 2.13–2.15).

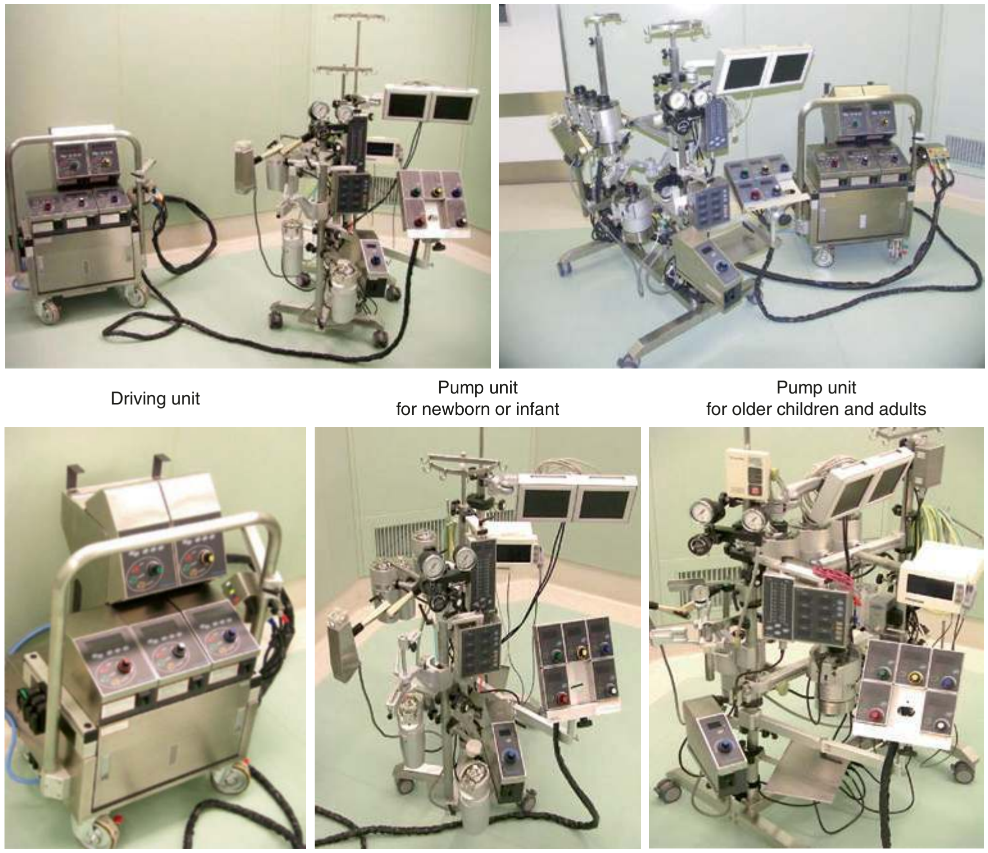


Fig. 2.63 Isolated pump-controller heart–lung machine No3 [9]

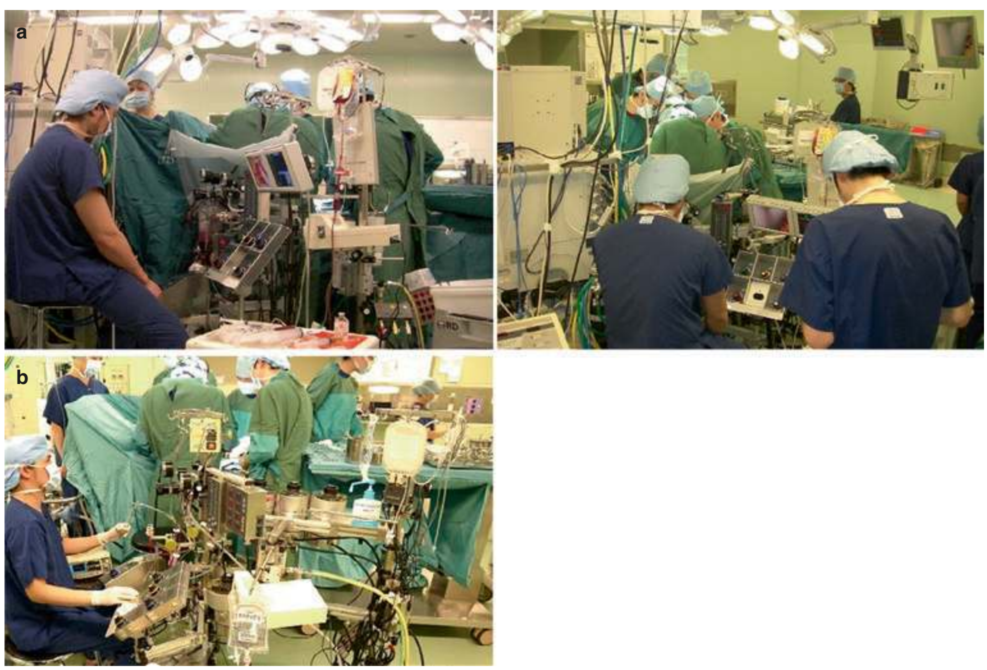


Fig. 2.64 Isolated pump-controller heart–lung machine No3. (**a**) Small pump BP75cIII, (**b**) Large pump BP150cIII BP120cIII

2.2.12 Change in Priming Volume New Device

As of 2019, HAS II, manufactured by Senko Ika Kogyo Co., Ltd. and S5 manufactured by Liva Nova, are the heart–lung machines used. Characteristically, HASII is a device very easy to attach and detach each pump by weight, and all pumps, including suction and vent have a feedback function as a safety feature. On the other hand, S5 has an automatic recording device for various perfusion data and a Goal-Directed Perfusion (GDP) monitoring function that assists the adjustment of the appropriate perfusion flow based on oxygen delivery (DO_2), oxygen consumption (VO_2), and carbon dioxide production (VCO_2).

Table 2.3 Pediatric oxygenators

Maker		LivaNova	Medos	JMS	MAQUET	Terumo	Nipro	Senko	Medtronic	JMS
Product and Appearance		D100 KIDS	HILITE 1000	OXIA IC (neo)	Quadrox-i	CX-FX05	BIOCUBE 2000	Excelung Kids	Pixie	OXIA IC (06, 10)
										
Max.Flow (L/min)		0.7	1.0	1.0	1.5	1.5	2.0	2.0	2.0	2.0
Gas Exchange SA (m^2)		0.22	0.39	0.21	0.38	0.50	0.40	0.6	0.67	0.39
P.Vol. (mL)	MO	31	57	23	38	43	75	49	48	37
	Filter	16	(+α)	15			(+α)	(+α)	(+α)	15
O2 Trans. (mL/min/L)		66	62	60	60	60	60	60	57	60
Pressure Drop (mmHg)		175	60	80	63	100	130	125	107	130
Heat transfer efficiency		0.65	0.63	0.45	0.50	0.60	0.67	0.50	0.64	0.45

Table 2.3 shows a list of recent pediatric oxygenators. In 2015, we adopted a polypropylene hollow fiber oxygenator, Oxia IC neo (priming volume 23 mL, maximum flow rate 1.0 L/min, membrane surface area 0.21 m^2), to create an extracorporeal circuit with a total priming volume of 88 mL (Fig. 2.65). It is used for cases with a body weight of 4.5 kg or less. It can be expected to reduce hemodilution in bloodless extracorporeal circulation and to minimize the use of blood transfusion in neonates or other high-risk patients for whom the use of transfusion is mandatory.

I have so far mentioned about reducing the length of the tubing. However, for the sake of reducing blood–contact surface as a countermeasure against SIRS, miniaturization of the oxygenator and arterial filter, are more efficient than reducing the length of the tubing. Video 2.16 shows the assembly and extracorporeal circulation of this circuit.

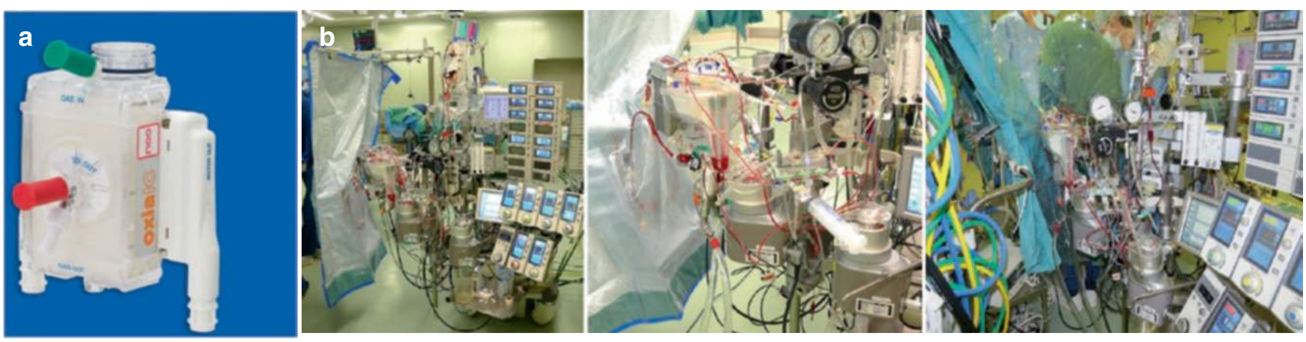


Fig. 2.65 (**a**) Oxia IC neo oxygenator and extracorporeal circulation circuit with priming volume of 88 mL; (**b**) Extracorporeal circulation circuit with priming volume of 88 mL. Place the arterial and venous circuit tubes to the left side of the surgeon. The initial priming composition is 55 mL of erythrocyte preparation, 20 mL of 25% albumin, 2.5 mL/kg of mannitol, 100 u/kg of heparin

Column: Pre-Bypass Filter

Foreign particles that cannot be seen with the naked eye can be mixed in the extracorporeal circuit. These microparticles are thought to be involved in SIRS development as well as embolism issues. In the extracorporeal circulation, pre-bypass filter was developed for the purpose of filtering the initial priming fluid (Fig. 2.66). Figure 2.67 shows the actual foreign particles observed in the initial priming fluid of our extracorporeal circulation. Foreign particles of 2–40 μm have been confirmed. Moreover, in the examination by the fine particle measuring device, no foreign materials were observed in the priming fluid after filtration.

On the other hand, when only rinsing was performed without using the pre-bypass filter, tens to thousands of foreign particles were confirmed per 1 mL of the priming fluid. The amount of rinsing volume was 1000 mL, which suggested that tens of thousands to millions of foreign particles were present in the initial priming fluid.

Fig. 2.66 Pre-bypass filter

2.2.13 Current Priming Volume

Table 2.4 shows the device and circuit priming volume used as of 2019.

Q&A: Minimal Invasiveness of Miniaturization(Question in 2016)

Question: Can we say miniaturization = minimally invasive?

Answer: The miniaturization has made it possible to reduce blood transfusions. There is no doubt that issues with blood transfusion at that time was avoided, and in that sense, it can be said to be minimally invasive. However, there are some doubts regarding the improvement of clinical effects due to miniaturization.

Even with current cardiac surgery, especially in newborns, edema and reduced diuresis may be observed even if echocardiography determines that the postoperative repair status or cardiac output is good. (Of course, there is a slight decrease in cardiac function, such as the Starling curve moving to the lower left). It was around 2000 that I realized that postoperative clinical course had improved in terms of edema and diuresis. The strategy at that time was to downsize the device (reduce the amount of priming volume), wash and filter the initially primed blood, ECUM using a PAN membrane hemofilter, ensure thorough “Constant Perfusion,” reduce transfusion, and saving time. Each are important minimally invasive measures, but the main purpose of miniaturization is to prevent SIRAB by reducing the contact surface area. However, from our experience, the amount of the inflammatory reactants does not significantly decrease only by miniaturization, and the degree of increase of the inflammatory reactant varies among individuals even under the same conditions. In addition, high levels of inflammatory reactants do not always mean a poor clinical course. In particular, there is little impression that the postoperative condition has been visibly improved just because a circuit having a priming volume of

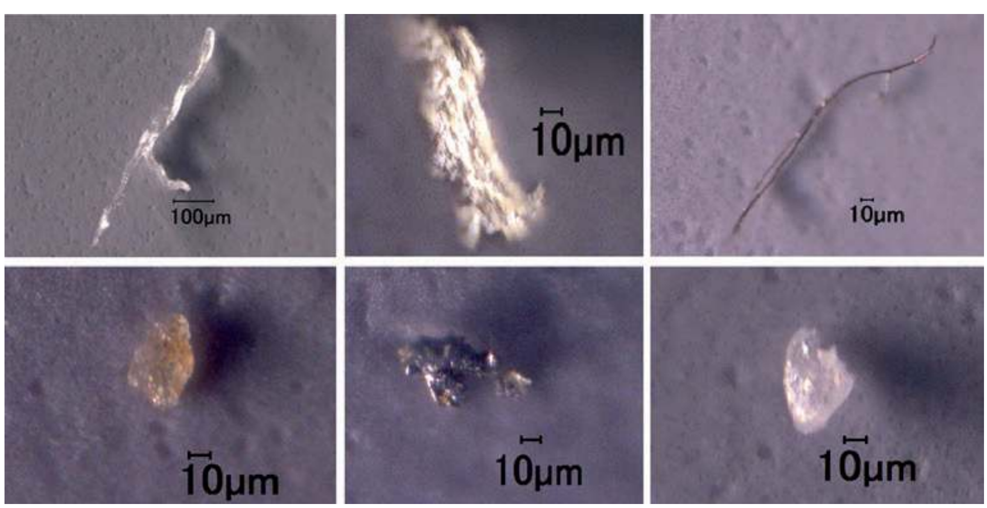


Fig. 2.67 Foreign particles in initial priming solution. The foreign particle when the initial priming fluid is rinsed and filtered in the extracorporeal circulation circuit for adults is shown

88 mL is used. In terms of clinical efficacy, it may not be possible to say that miniaturization = immediate minimally invasive.

However, in terms of "Constant Perfusion," miniaturization may be a meaningful less invasive measure. I believe that edema enhancement and diuresis reduction are not only due to the effects of SIRAB, but also due to inadequate "Constant Perfusion," that is, the non-physiological fluctuations of the living body associated with extracorporeal circulation. The management method during extracorporeal circulation, that is, fine adjustment of circulating blood flow, the addition of blood transfusion to decrease hemodilution, correction of electrolyte and acid-base equilibrium, body temperature adjustment, management of DUF, etc., are certainly easy due to miniaturization. As a result, it is quite possible that this has led to "Constant Perfusion." In that sense, miniaturization

Extracorporeal Circulation Circuit

Perfusion Rate [mL/min]	Perfusion Rate [L/min/m²]	BSA [m²]	BW [kg]	Pump Dia.	Circuit Dia.	Circuit	Priming Vol.	Filter	Oxygenator	Reservoir	Arterial Cannula [mm]	Venous Cannula [Fr]	Vent [Fr]
540	2.8	0.18	2.0	75	Arteial 4.2mm Venous 4.8mm Pump 1/4Fr (ϕ75)	SSS pre-connected.	120	FT-15	OXIA neo	OXIA	2.0	12+12	
600		0.20	3.0								2.6		8
660		0.22	4.0									12+14	
780		0.26	5.0	100	Arteria 3/16Fr Venous 1/4Fr Pump 1/4Fr (ϕ100)	SS pre-con. | SS pre-con.	150 | 140		OXIA IC				
900		0.30	6.0									14+14	
1020		0.34	7.0										
1140		0.38	8.0								3.0		
1260		0.42	9.0									14+16	10
1150	2.5	0.46	10.0	150	Arteria 1/4Fr Venous1/4Fr Pump1/4Fr (ϕ150)	S pre-con.	175	FX-05		RR-10			
1250		0.50	11.0									16+16	
1350		0.54	12.0										
1400		0.56	13.0			S pre-con.	260	D-101/QUADROXi		D101/QDX			12
1450		0.58	14.0								3.5	16+18	
1500		0.63	15.0										
1700		0.68	16.0										
1800		0.72	17.0										
1850		0.74	18.0									18+18	
1950		0.78	19.0										14
2000		0.80	20.0										
2050		0.82	21.0								4.0		
2100		0.84	22.0										
2150		0.86	23.0									18+20	
2200		0.88	24.0		Arterial 3/8Fr Venous 3/8Fr Pump 3/8Fr	M	350/450	AL20	FX-15	RR40			
2250		0.90	25.0										
2300		0.92	26.0										16
2375		0.95	27.0										
2450		0.98	28.0									20+20	
2500		1.00	29.0								4.7		
2750		1.10	30.0										
2875		1.15	31.0									20+22	
3300		1.30	40.0		A-V 3/8Fr Pump 1/2Fr	M	400/500						18
4000		1.60	60.0								5.3	22+22	

size	M	S	SS	SSS
Pre connect	O(FX15 only)	O(QUADROX only)	O	O
tube Φ V・A pump (inch)	3/8・3/8 ①3/8 ②③④⑤1/2	1/4・1/4 1/4	1/4・3/16 1/4	4.8㎜・4.2㎜ 1/4
Pump size (mm)	ϕ 150	ϕ 150	ϕ 100	ϕ 75
Oxygenator	①②FX-15 ③FUSION ④INSPIRE ⑤SKIPPER	①FX05 ②D-101 ③QUADROXI	①FX05 ②OXIA-IC	OXIA-neo
Reservoir	①②RR-40 ③FUSION ④INSPIRE ⑤SKIPPER	①RR10 ②D-101 ③QUADROXI	①RR10 ②OXIA	OXIA
Weight (kg)	①24~39 ②40~70 ③④⑤70~	①9~12.9 ②③13~24	~8.9	~4.5
PV (mℓ)	①350 ②400 ③④⑤600	①175 ②③260	①140 ②150	88/120 ※Difference of circuit length

ECUM Circuit

Circuit	PV ml	Sepxiris60	BC20+	BHC030	HC05	HC11
		44ml	17ml	23ml	34ml	67ml
SSS	12ml	56	29	35	46	
SS	18ml	62	35	41	52	
	16ml	60	33	39	50	
	12ml	56	29	35	46	
S	14ml	58	31	37	48	
	14ml	58	31	37	48	
M	36ml	80			70	103

Table 2.4 Devices and circuit priming volume used as of 2019

plays a part in minimizing invasiveness. After all, is not it a synergistic effect? However, downsizing can complicate operation and management and may impair safety. Always keep an eye for actual clinical benefits.

Q&A: Development of extracorporeal circulation device (Question in 2016)

Question: I am in charge of developing extracorporeal circulation devices for children. What do you expect from manufacturers regarding extracorporeal circulation devices?

Answer: It might be very rude, but I have been completely upset by manufacturers several times. That is, the discontinuation of the device being used. The news comes suddenly. Until now, there were oxygenators, hemofilters, arterial filters, reservoirs, actually everything. It seems that the biggest reason is that the demand is small and it does not lead to the profit of the company. Selection, as a natural providence, is understandable, including the reason for the discontinuation, but it is quite a problem. Until now, I have no intention of favoring specific companies, but some devices have been considered indispensable for minimally invasive measures, and it is true that I thought they were companies that did not understand the clinical reality at all. However, we may need to reflect on the fact that us surgeons, as users, were not able to communicate their extremely high clinical efficacy, including the manufacturers, widely.

There is a lot I wish. One of these is that I want manufacturers to fully consider the development of a system that allows perfusionists to make "Constant Perfusion" management super easy. It is important for "Constant Perfusion" to be able to react quickly and easily to fluctuations. For example, Goal Directed Perfusion (GDP) is considered as a new management method of adequate perfusion rate aiming at "Constant Perfusion" from monitoring of cell respiration in patients. As an aside, Fig. 2.68 shows the KTH-332S, an extracorporeal circulation machine with an automatic recording device at Tokyo Women's Medical University in 1981. Even at that time, automation of extracorporeal circulation was the ultimate goal, and with this device, it was attempted to standardize extracorporeal circulation by recording the flow rate of each pump, the temperature, the blood supply/drainage balance, myocardial temperature, and the timing of myocardial protection. At present, regulation of perfusion rate and correction fluid administration during extracorporeal circulation are stipulated by law to be performed by a perfusionist in principle. However, in the future, using artificial intelligence and a CDI monitor, at least, automatic correction of electrolyte, acid-base equilibrium, and ACT should be easy.

Fig. 2.68 Heart–lung machine with an automatic recording system KTH-332S

Medical device manufacturers continue to develop many new devices based on a lot of experience and new concepts. Among them, is not Japan the most advanced country in the development of extracorporeal circulation devices? However, with regard to the performance of each device, I think that we need no more detailed improvements, such as good durability, simple operation, low priming volume, low inflammatory response, low platelet consumption, better oxygenation, and lower pressure loss. Recent devices are hard to say which is better.

The important point is whether the device used has significantly improved the postoperative clinical course. Specific examples include less bleeding, better circulation and respiratory status, better diuresis, less edema, and early withdrawal of ventilators. Manufacturers are encouraged to actively participate in clinical practice, see if there is any actual clinical effect, and then consider once again.

A long time ago, I have told a medical device manufacturer executive, "Japanese devices are extremely good. It is no exaggeration to say that Japanese devices are extremely excellent. So, about twice a year, how about holding a study group to discuss the development and issues of Japanese devices, gathering the leaders and developers of each company? Of course you don't have to talk about company confidentials and you must adhere to your corporate code of conducts. From the European and American perspectives, they may wonder and think what you say is stupid, but at least it's good that you get along well. Show them the flexibility of Japan!" Of course, the meeting was unfortunately not realized. But again, it is only if there is any real clinical benefit. It is important to note that more detailed the device development concept and process gets, or if the device is more advanced, it can create new clinical problems.

I have detailed the recent pitfalls of extracorporeal circulation devices and their countermeasures [15] in PART II.

2.3 Summary of Extracorporeal Circulation Devices

The history was described focusing on the extracorporeal circulation devices that I used. We believe that the development of new device could be one of the measures to minimize invasiveness. In the next section, let us talk about the progress of bloodless open-heart surgery using these devices.

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Advances in Bloodless Open-Heart Surgery

3

Contents

3.1 Introduction

The purpose of allogeneic blood transfusion in cardiac surgery is to supplement the dilution of red blood cells, clotting factors, platelets, and proteins associated with extracorporeal circulation and to prevent bleeding tendency and enhanced edema associated with these dilutions. In addition, in pediatric heart surgery, blood transfusion increases the oxygen delivery and cardiac output, thereby promptly recovering from invasive effects associated with extracorporeal circulation, such as edema and reduced organ function. This means that blood transfusion reduces the invasiveness and is one of the important minimally invasive means.

Now, in a bloodless open-heart surgery case with tetralogy of Fallot patient weighing 7 kg, let us assume that the minimum Hct during extracorporeal circulation is 18%, and after administration of residual blood after extracorporeal circulation is 26%. If there are any concerns, such as a decrease in diuresis associated with a low cardiac output or continuous bleeding from the drainage tube, it is natural to prepare for blood transfusion. However, if it is determined that the ventilator can be withdrawn early without such a situation, should transfusion be performed?

Unlike the 1980s, when post-transfusion hepatitis was a major problem, the side effects of current blood transfusions have been significantly reduced. Therefore, when considering the reduction of transfusion, the risk of not transfusing has become more important than the risk of transfusion. Many people say that they do not worry about reduction. However, on the other hand, there are many opinions that blood transfusion reduction management in consideration of permissive anemia is more minimally invasive, and there are also opinions that there is no clinical difference with or without blood transfusion. But I think that every cardiac surgeon has felt that if the postoperative hemorrhage is low and the blood circulation is a little better, the last transfusion would not be necessary. Therefore, in the current blood reduction in which transfusion has become extremely safe, it is first necessary to establish a comprehensive and minimally invasive measure for the operation itself. If a stable general condition can be created at the stage of surgery, at least, blood transfusion can be reduced. Secondly, clinical judgment is made on a case-by-case basis as to whether adding blood transfusions improves the patient's condition. For blood transfusion in cardiac surgery, it is necessary to always consider both blood transfusion as a treatment for minimally invasiveness and measures that lead to minimally invasive even if blood transfusion is reduced.

The previous section described the miniaturization of extracorporeal circulatory devices, which is essential for bloodless open-heart surgery. This section focuses

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on the practice and clinical management of bloodless open-heart surgery. I hope that the experience of bloodless open-heart surgery at that time will lead to blood reduction [1, 2].

3.2 Bloodless Open-Heart Surgery and Homologous Blood Transfusion

Bloodless open-heart surgery was performed for 2678 congenital heart diseases between July 1994 and December 2006. Transfusion was avoided in 2546 cases (94.8%) (Table 3.1). During this period, with special attention to the occurrence of clinical problems associated with bloodless open-heart surgery and the review of extracorporeal circulation devices, as well as the correction of perioperative management methods, the adaptation of bloodless open-heart surgery gradually changes and expanded. Of course, bloodless open-heart surgery requires reduction of priming volume and reliable hemostasis. However, measures that are considered to be more effective and essential for improving the rate of achieving bloodless open-heart surgery were

1. Dissemination of the significance of bloodless open-heart surgery
2. Perioperative management in consideration of permissive anemia and technical improvement of surgical team members for transfusion-free techniques
3. Accurate prediction of hemodilution
4. Thorough basic extracorporeal circulation techniques and “Constant Perfusion”
5. Reduction of extracorporeal circulation time, operation time, anesthesia time,
6. Deciding when to start transfusion, and
7. Understanding the factors of blood transfusion and determination of cases that should not be indicated for bloodless open-heart surgery

Q&A: Homologous blood transfusion (Questions in 2018)

Question: I think that there is almost no problem with the side effects of current blood transfusion. If you still have issues to work on or need to address, please tell us.

Answer: Currently, the number of blood supplies in Japan is about 5 million per year. We all know that 10 years later, about 850,000 blood shortages will occur annually. First of all, this alone requires preparation for blood transfusion reduction. Figure 3.1 shows changes in blood usage at Sakakibara Heart Institute. We use quite a lot of blood. Of course, there is a specialty of the hospital specializing in cardiovascular diseases, but blood is discarded a lot, and the use of FFP, platelets, and protein products is increasing. It is necessary to review their proper use.

- *Post-Transfusion Hepatitis*

In 1983, we had a hard time with hemostasis after extracorporeal circulation. It often took 1–2 h, and I remember that I continued to do compression hemostasis by gauze while changing with others for meals. Also, on the day of the surgery, fresh blood was prepared from the parents, relatives, and acquaintances of the patient for the purpose of hemostasis. I thought that if there was little bleeding, I would be a favorite surgeon in terms of the complexity of transfusion preparation and time savings. In addition, in the postoperative management of the ICU, there were cases in which hypoxia and hypotension occurred when new blood transfusion was performed other than the residual blood, so I thought that unnecessary blood transfusions should be avoided as much as possible.

But anyway, I really hate post-transfusion hepatitis. When I joined Sakakibara Heart Institute in 1983, the incidence of hepatitis in Japan was 14.3% (Fig. 3.2), and at that time, I had the impression that hepatitis after cardiac surgery was almost inevitable. I have had a child who underwent ASD

Table 3.1 Non-transfusion rate (Jul. 1994 to Dec. 2006) [3]
ASD: Atrial Septal Defect
VSD : Ventricular Septal Defect
AVSD : Atrio-Ventricular Septal Defect
CoA : Coarctation
TOF : Tetralogy of Fallot

Non-cyanosis			Cyanosis		
ASD	541/542	99%	TOF	262/273	96%
VSD	939/954	98%	Rastelli proc.	63/74	85%
Incomplete AVSD	72/72	100%	Fontan proc.	137/160	86%
Complete AVSD	61/64	95%	Open Palliation	182/200	91%
Valve, Re-do etc.	260/308	84%	Arterial Switch (BW>4kg)	8/8	100%
CoA complex (BW>4kg)	5/6	83%	AVSD with TOF	16/17	94%

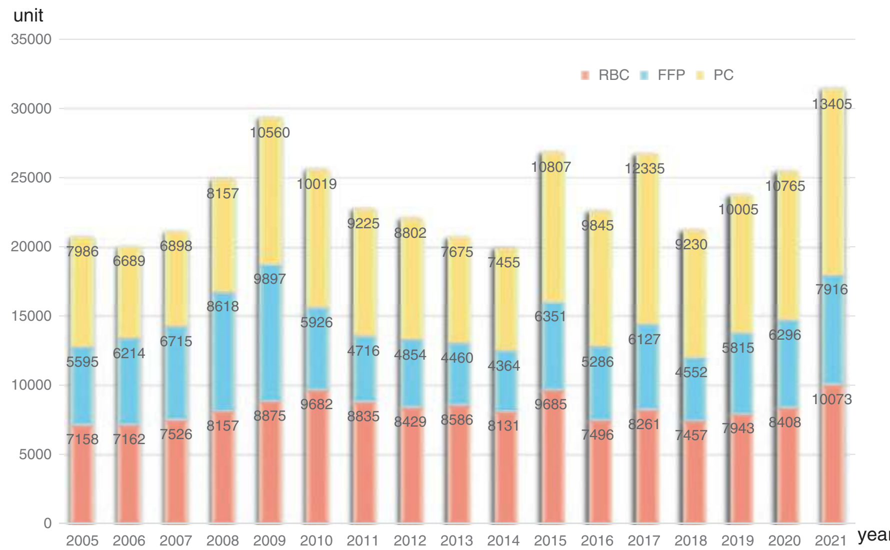


Fig. 3.1 Annual changes in blood usage at Sakakibara Heart Institute.
RBC: red blood cell product
FFP: fresh frozen plasma
Plt: platelet

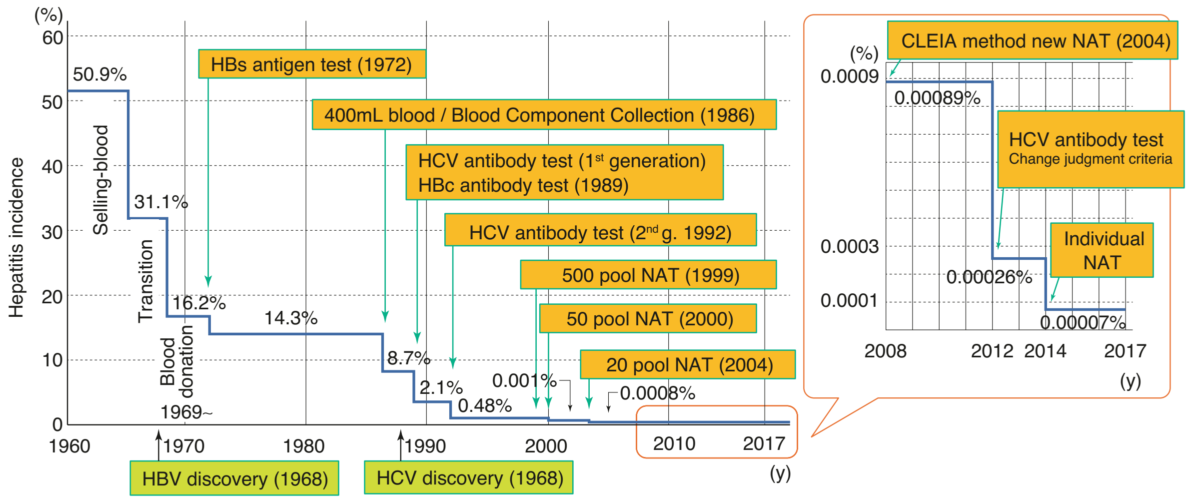


Fig. 3.2 Incidence of post-transfusion hepatitis in Japan [4] modified.
HBV: hepatitis B virus
HCV: hepatitis C virus
CLEIA: chemiluminescent enzyme immunoassay
NAT: nucleic acid amplification test

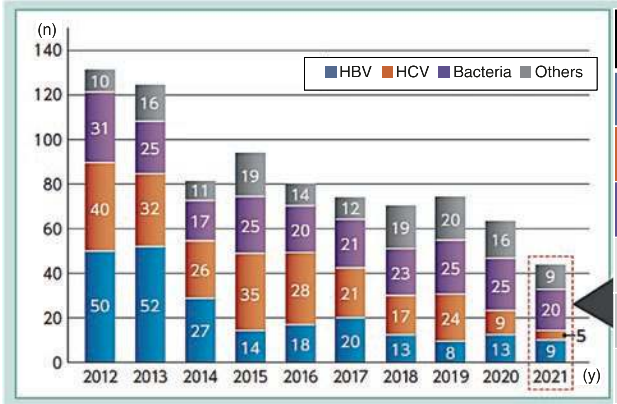
surgery and died of postoperative acute liver failure due to this hepatitis. At that time, Hepatitis C was called non A non B hepatitis. In the 1980s, not only patients but also many other medical professionals became victims of blood.

In the 1990s, HCV antibody tests reduced post-transfusion hepatitis. The incidence rate until 2000 was 0.48%. However, since this value indicated the incidence rate for one patient who received blood transfusion, it was assumed that the hepatitis incidence rate in cardiac surgery was naturally higher because cardiac surgery required blood transfusion from several people. Efforts to reduce blood transfusion were still needed.

On the other hand, in the 2000s, hepatitis after blood transfusion decreased dramatically by NAT (Nucleic acid Amplification Test). The risk of not transfusing was attracting more attention than the risk associated with blood transfusion, and many surgeons have decided not to hesitate to perform a blood transfusion. Looking at the changes in the incidence of HBV, HCV, and HIV after blood transfusion (Fig. 3.3), it can be said that the virus infection was almost completely resolved by individual NAT and a thorough retrospective investigation.

- *Two Issues in Post-Transfusion Hepatitis*

However, two problems remain with post-transfusion viral hepatitis. One of them is the occult infection of Hepatitis B virus (HBV), which is a condition in which HVB is found



Pathogen	No.of reports	Identified
HBV	9	2
HCV	5	0
Bacteria	20	0
CMV	5	0
HEV	4	0
total	43	2

Fig. 3.3 Changes in the occurrence of blood transfusion infections [4] modified.
HBV: hepatitis B virus,
HCV: hepatitis C virus,
CMV: cytomegalovirus,
HEV: hepatitis E virus

in the liver but is negative with all examinations. If HBV appears in the blood of this occult HBV carrier and is donated during the early part of the window period, it will be used as a transfusion product without being identified at all. At present, there are very few cases of HBV infection after blood transfusion, but the risk of infection from this occult HBV carrier is still thought to be unpredictable. Of course, if you receive a blood transfusion, you will need a detailed HBV test. Furthermore, it should also be known that 70% of current HBV hepatitis is sexually transmitted.

And the second is Hepatitis E virus (HEV). Traditionally, transmission has been thought to occur through foods such as drinking water and raw meat, but it can also be transmitted through blood transfusions. The estimated number of people infected with HEV in Japan is estimated to be more than 5 million. The biggest problem with HEV infection is that NAT tests for blood donation are only conducted in Hokkaido. Five cases were identified as the causes of blood transfusion in 2019 (Fig. 3.4), but it is undeniable that in this global world, larger cities such as Tokyo may be more dangerous. In fact, the website of the Ministry of Health, Labor and Welfare reports that the HEV NAT positive rate of blood donated in the Kanto Koshinetsu area is 0.073%, which is higher than that of 0.036% in Hokkaido. The risk of HEV infection in the Kanto Koshinetsu area is 0.44%, assuming that the capture rate is 1/6. The number of blood donations is about 1.8 million a year, so it is estimated that about 8000 people are infected by transfusion in the Kanto Koshinetsu area alone. This is a surprising value, comparable to the incidence of hepatitis in the 1990s before NAT on HBV and HCV began. HEV infections are not likely to become severe or chronic. However, in Japan, the death toll from HEV infection due to blood transfusion has just recently been reported for the first time in the world. The UK already supplies HEV-negative blood to organ transplants, leukemia and hematopoietic stem cell transplant cases, newborns and infants. Although it is transient, the function of systemic organs, including the immune function, decreases after

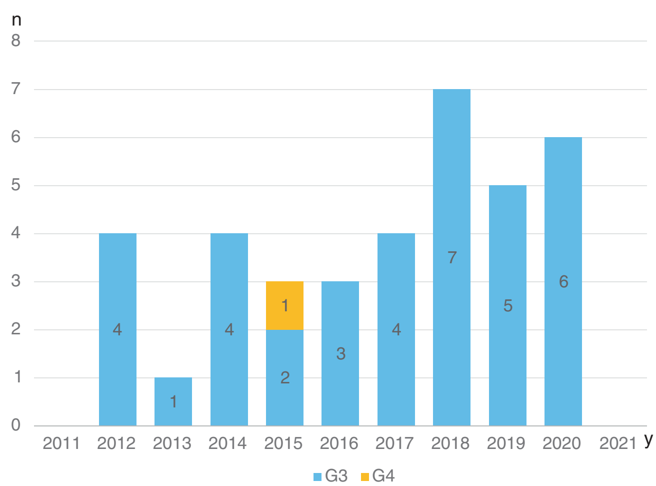


Fig. 3.4 Annual number of HEV infections due to blood transfusion [4] modified

open-heart surgery. If we imagine HEV infection at this period in newborns and low-birthweight infants, it seems that future measures will still be necessary. I have said that the virus infection has almost been resolved, but I personally still need to carefully consider the need for blood transfusion reduction. (In Japan, since the first post-transfusion HEV infection was confirmed in 2002, 45 cases of infection have been confirmed by 2020. The Japanese Red Cross Society has started HEV NAT for all donated blood from blood collection on August 5, 2020. As of June 2022, no HEV infection has been confirmed with blood products for transfusion after the introduction of NAT.)

Also, particular attention should be paid not only for viruses but also for bacterial infections caused by blood transfusions. Just recently, a death from a platelet transfusion was reported. No examinations have been conducted for the presence of bacteria in the transfusion products. Even if bacteria are contaminated in the blood transfusion, it is undeniable that they may have been masked by using antibiotics after surgery. I think that this also requires some countermeasures [5–8].

- *Blood Transfusion Side Effects*

Figure 3.5 shows the transfusion side effects. Although not described in detail, at least, the pathophysiology and measures for TRALI (Transfusion-related acute lung injury) and TACO (Transfusion-associated circulatory overload) should be made aware. The aforementioned transient hypoxia associated with blood transfusion may be a TRALI-like response (Fig. 3.6). The number of non-hemolytic side effects reported to the Japanese Red Cross Society is about 2500 per year (Fig. 3.7), but it is expected to be probably ten times of that (0.5% assuming 5 million blood supplies per year). Some say that the incidence of problems with blood transfusions can be as high as 4–5% when including very small events [4, 9].

It is easy to imagine that transfusion in SIRS situations due to extracorporeal circulation could have a synergistic adverse effect. In addition, the safer the blood transfusion, the problems of overuse increased. Since the introduction of transfusing red blood cells, FFP, and platelet components, it is certain that the number of blood transfusion donors used per patient has increased. The idea of not caring about transfusion is still a problem.

In the future, regarding blood transfusion in pediatric heart surgery, we need to study specific blood transfusion methods that will lead to clinical effectiveness. For example,

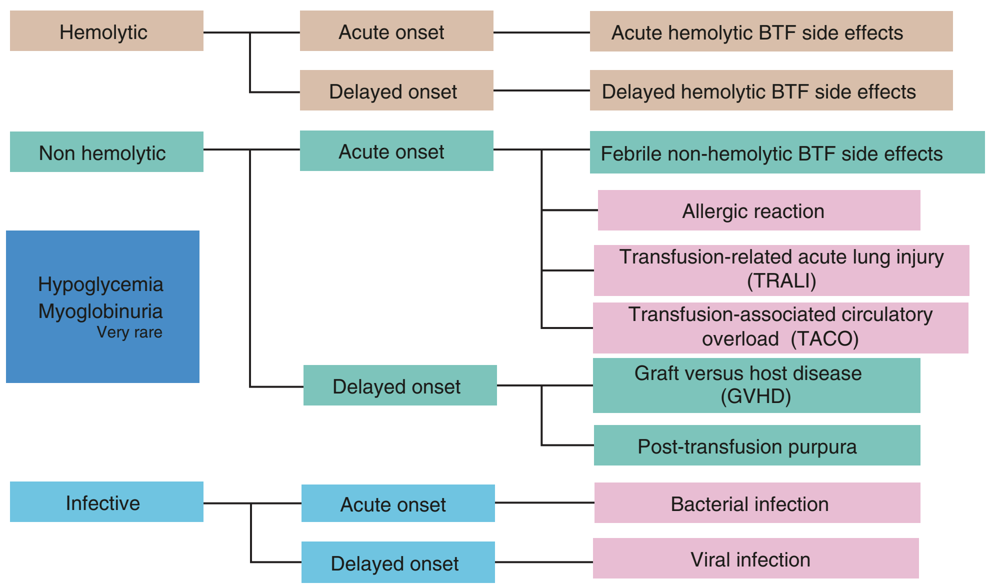


Fig. 3.5 Transfusion side effects [4] modified

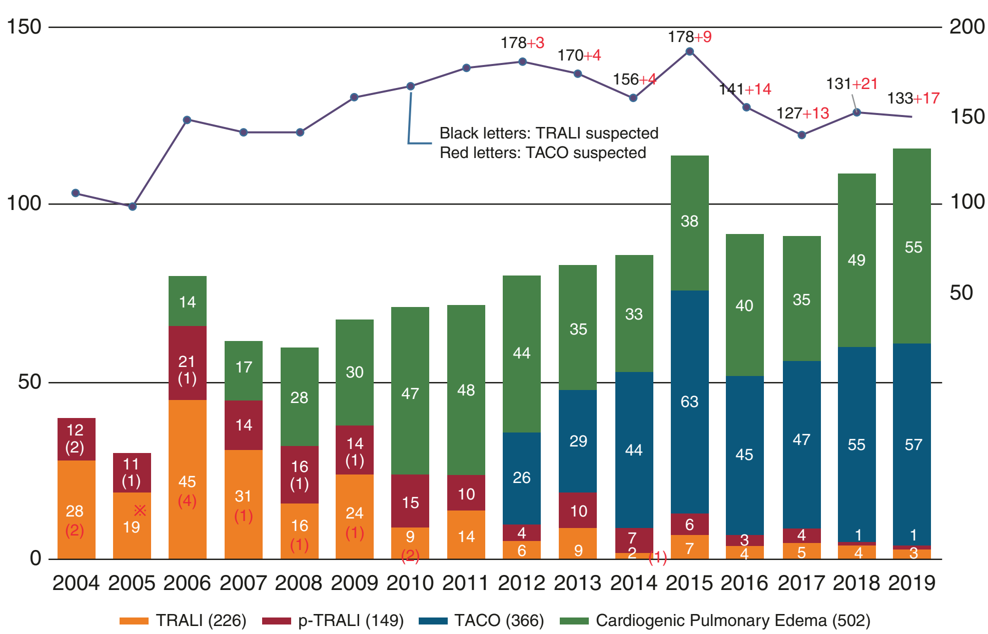


Fig. 3.6 Annual number of TRALI and TACO [4] modified

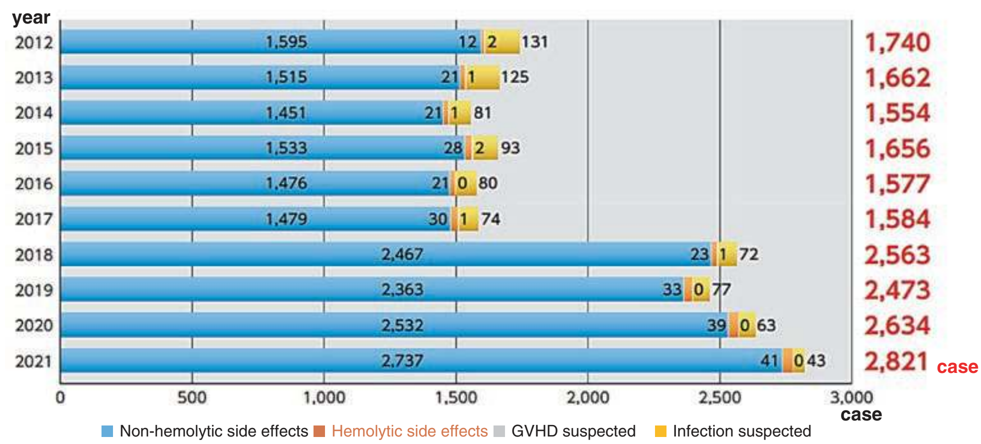


Fig. 3.7 Changes in side effects and infectious diseases due to blood transfusion [4] modified

considering how much Hb, coagulation factors, platelets, and protein levels should be maintained to shorten the treatment time in the ICU and effective hemostasis. Clinical indicators for this would include cardiac function, urine output, lactate, oxygenation, bleeding, duration of respirator management, and ICU stay. It is necessary to show clinical data to say it would be better to reduce blood transfusion when aggressively promoting blood transfusion reduction, and conversely, to show that blood transfusion is better when being broad-minded to blood transfusion. In particular, it is important to show their usefulness in terms of time saving and ease of postoperative management, in actual clinical practice and for staff working in the field. Whether you are broad-minded about blood transfusions or reducing transfusions, the complex management is annoying.

These are the current problems with blood transfusions. Even at the time when blood transfusions are considered safe, unnecessary blood transfusions should at least be avoided, and consider reducing or reviewing blood transfusion methods [10–15].

Q&A: Bloodless open-heart surgery considered by the operation team (Question in 2000)

Question: Please tell us about the ingenuity of the surgical team to develop bloodless open-heart surgery.

Answer: As you know, advanced hemodilution carries the risk of increased systemic edema due to reduced oncotic pressure, reduced oxygen delivery, and metabolic acidosis. In addition, there are concerns about decreased systemic organ function such as hemodynamics and respiratory failure, bleeding tendency due to coagulation factors and platelet dilution, susceptibility to infection due to decreased immune function, and deterioration of psychomotor development in the postoperative period. Therefore, it is necessary for the team to work on measures to reduce hemodilution (reducing the priming volume) first, then consider a reliable oxygen delivery method under hemodilution, and consider measures to prevent systemic edema by SIRS. Now that transfusion has become extremely safe, and it is the minimum requirement for bloodless open-heart surgery that the overall perioperative quality is as good or better than open-heart surgery with blood transfusion. Bloodless open-heart surgery has no meaning if it leads to worsening of the patient's condition and complicated procedures and management. To that end, the members of the surgical team should know the purpose and significance of bloodless open-heart surgery and become accustomed to the specialty and course of bloodless open-heart surgery to enhance their skills, especially thorough basic extracorporeal circulation procedures covering the drawbacks of hemodilution, postoperative infusion management in consideration of permissive anemia, and reduction of operation time are considered essential. In short, always consider the minimally invasive nature of the surgery itself. Also, if something goes wrong with a bloodless open-heart surgery, the opinion that "bloodless" is bad, may be raised, and the team may be demotivated. Therefore, surgeons need to demonstrate to the team members the clinical significance of bloodless open-heart surgery, especially the rapid recovery of the child and reduced postoperative management time. The indications for bloodless open-heart surgery need to be gradually expanded with sufficient experience of the surgical team, that is, with the conviction that bloodless open-heart surgery can be achieved safely and reliably. This concludes the discussion of bloodless open-heart surgery that should be considered as a surgical team. It is desirable that the final indication for bloodless open-heart surgery should be determined not only by the surgeon but also individually by the pediatrician, anesthesiologist, ICU intensivist, and perfusionist.

Bloodless open-heart surgery aims to minimize the invasiveness of children by avoiding the side effects of blood transfusion. However, blood bloodless open-heart surgery for minimally invasiveness is meaningful only in terms of improving hemodynamics and respiratory status, as well as reducing costs and shortening treatment duration, that is, improving overall QOL of surgery and Fast Track. There are always conditions under which bloodless open-heart surgery should not be performed. If there is any anxiety in your team, you should not do bloodless open-heart surgery.

3.3 Bloodless Open-Heart Surgery for Acyanotic Congenital Heart Disease with Pulmonary Hypertension

3.3.1 1983–1992

As of 1983, blood usage per patient averaged 1108 mL for patients with body weight under 10 kg in congenital heart disease surgery, 1150 mL for 10–30 kg, 2040 mL for valve surgery, and 1640 mL for coronary artery bypass surgery. It was an era that required a lot of blood. At present, even in ASD, where bloodless surgery is possible in all cases, the achievement rate of bloodless surgery was 28–35% in 1983–1985 for the total number of cases per year. Since 1987, it has improved to 80–90%. This was thought to be due to the benefit of reducing the priming volume of the 13–40 kg body weight from 1100 to 1300 mL down to 750 mL in 1986 (refer to Sect. 2.2.1). Prior to 1986, the indication for bloodless open-heart surgery was 18 kg or more, and then gradually expanded to around 14 kg, and the achievement rate of bloodless ASD surgery from 1991 to 1992 was over 90%.

3.3.2 1993

In the bloodless open-heart surgery at that time, a protein preparation was used in consideration of the enhancement of edema. However, there were many opinions that it would not be bloodless.

In 1993, the total priming volume under 17 kg was reduced to 470 mL (refer to Sect. 2.2.3). In addition to expanding the indications for bloodless open-heart surgery, we aimed for bloodless open-heart surgery without the use of protein preparations.

Bloodless open-heart surgery without protein preparation was performed on 21 consecutive cases weighing 6.6–14.5 kg. Three patients required blood transfusion. The rate of non-transfusion was 86%. Figure 3.8 shows changes in Hct and total protein in nine cases with body weights of 10 kg or more and nine cases with body weights of 9 kg or less, in which bloodless open-heart surgery without protein preparation was possible. The total protein in the group with a body weight of 9 kg or less decreased to 2.8–3.6 (3.3 ± 0.3) g/dL but recovered to the pre-extracorporeal value approximately 5 h after returning to ICU. The duration of the

prime solution

lactated Ringer	Oxygenator	Menox AL-2000
mannitol NaHCO3	ECUM	HC-30M HP 300
10% glucose	Flow rate	2.21/min/BSA
exocorpol	Cardioplegia	blood GIK
total 470ml	Hypothermia	26~28°C (bladder)

BW 10.6 ~ 14.5kg

Patient	Weight (kg)	Age (yr)	Diagnosis	(Pp/Ps)	Procedure	Bypass (min)	Ao clamp (min)	Ope. (min)	Anesthes (min)
1	13.6	5.1	ASD	(0.38)	ICR	63	(-)	147	190
2	10.6	4.6	ASD PS Mr		ICR	51	15	119	165
3	13.0	2.1	ECD PH	(0.60)	ICR	73	37	133	165
4	10.5	2.2	ECD	(0.45)	ICR	74	35	156	200
5	14.5	3.8	VSD	(0.24)	ICR	50	20	170	215
6	13.5	3.7	VSD	(0.25)	ICR	66	36	152	190
7	14.0	3.5	PPS postBrock		ASD cl. RVO reconst.	75	(-)	260	295
8	12.5	3.0	TOF		ICR	172	82	342	380
9	13.5	3.1	TOF		ICR	108	57	201	245
	12.8±1.4	3.4±1.0				81±38	40±23 (n=7)	187±71	227±7

BW 6.6 ~ 9.7kg

Patient	Weight (kg)	Age (mo)	Diagnosis	(Pp/Ps)	Procedure	Bypass (min)	Ao clamp (min)	Ope. (min)	Anesthes (min)
1	8.8	14	VSD PH	(0.82)	ICR	52	26	109	150
2	8.0	18	VSD PH	(0.85)	ICR	75	32	169	210
3	9.1	10	VSD	(0.20)	ICR	43	21	145	210
4	8.5	16	VSD PH	(0.90)	ICR	75	34	160	215
5	9.5	18	VSD PH	(0.94)	ICR	60	29	125	155
6	6.6	10	VSD PH	(0.75)	ICR	56	27	117	155
7	7.5	9	VSD	(0.30)	ICR	77	37	174	210
8	9.7	21	PPS PFO		PFO cl. RVO reconst.	53	(-)	119	160
9	9.5	16	TOF		ICR	92	51	152	195
	8.6±1.0	14.6±4.2				65±16	32±9 (n=8)	141±241	84±2

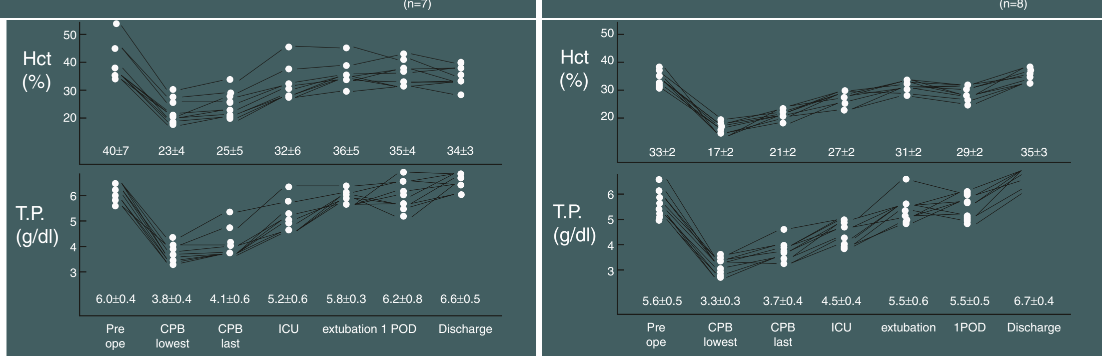


Fig. 3.8 Bloodless open-heart surgery without protein preparations

ventilation time was within 7 h in all cases, and there were no clinical problems such as the expected enhancement of edema. Bloodless open-heart surgery without the use of protein preparations was possible for infants weighing 6 kg.

Column: Bloodless Open-Heart Surgery Without Protein Preparation

During this period, sodium correction during extracorporeal circulation was strictly performed (refer to Chap. 1, Q&A Sodium and edema). In nine cases with a body weight of less than 10 kg that could be operated without blood transfusion, the postoperative duration of intubation was 4–7 (5 ± 1) h, and the average time to drinking water was 11 h, 6 h after intubation. VSD and TOF are the main target diseases in bloodless open-heart surgery with a body weight of less than 10 kg. The postoperative quality of the bloodless open-heart surgery without protein preparation was judged to be good compared with the previous cases with blood priming.

The extracorporeal circulation time was 43–92 (65 ± 16) min, the operation time was 109–174 (141 ± 24) min, and the anesthesia time was 150–215 (184 ± 22) min. During this period, the number of cases with anesthesia time of less than 3 h increased, enabling 2–3 open-heart surgeries in one operating room per day.

On the other hand, the extracorporeal circulation time of three cases requiring blood transfusion was long as 111–187 min, and the cause of blood transfusion was the progression of anemia, bleeding and hemolysis (Table 3.2). In order to expand the indication of bloodless open-heart surgery in the future, it was concluded that shortening the time was essential in addition to reducing the circuit priming volume.

3.3.3 1994

In 1994, the priming volume for patients weighing less than 7.9 kg was reduced to 370 mL (refer to Sect. 2.2.4), and the indication for bloodless open-heart surgery was expanded to 5 kg. Table 3.3 shows VSD open-heart surgery cases from 1993 to 1994. Seventeen cases with clear priming with a body weight of 5.2–9.5 kg were classified into Group 1, 15 patients with a body weight of 5.0–7.1 kg, and 15 patients with a body weight of 3.4–4.9 kg were Group 2 and 3, respectively. In Group 1, bloodless open-heart surgery was possible in all cases. In Groups 2 and 3, of course, there were reasons for blood priming such as differences in physique, preoperative anemia, respiratory failure, etc., but postoperative circulatory and respiratory dynamics were better in Group 1, and the duration of anesthesia was shortened. It was considered that there was no problem in adopting bloodless open-heart surgery for at least 5 kg of body weight [16].

Q&A: Extracorporeal circulation using D-901 oxygenator (Question in 1995)

Question: Please tell us about the bloodless extracorporeal circulation using D-901 oxygenator.

Answer: Finally, the priming volume became less than 400 mL. Currently, bloodless open-heart surgery can be indicated for patients weighing 5 kg. There were no problems with the use of D-901 oxygenator, such as gas exchange capacity or operability during extracorporeal circulation, but the softshell reservoir was once damaged during extracorporeal circulation. Since then, a different softshell reservoir has been used. The blood outlet port of D-901 was able to con-

Table 3.2 Three cases requiring blood transfusion. At that time, I also paid special attention to the factor of improvement in postoperative oxygenation. This means that there were many cases in which oxygenation immediately after the end of extracorporeal circulation was considerably poor

Weight (kg)	Age (yr)	Diagnosis	Procedure	Bypass (min)	Ao clamp (min)	Ope. (min)	Anesthe. (min)
12.0	3.8	ECD post ICR MR	MV plasty	111	57	357	425
13.8	3.3	VSD PS AR	ICR AV plication	187	151	315	360
8.8	0.8	TOF	ICR	133	78	240	285

Reasons for Blood Transfusion	Complication
anemia Hct 16% during ECC residual MR & MS	(-)
hemolysis	(-)
bleeding before ECC hemolysis	(-)

Table 3.3 Comparison of clinical features among three groups [16] modified.
At that time, I also paid special attention to the factor of improvement in postoperative oxygenation.
This means that there were many cases in which oxygenation immediately after the end of extracorporeal circulation was considerably poor.
The values are the mean ± the standard error
CPB: cardiopulmonary bypass
CVP: contral venous pressure
BE: base excess

	group 1 (n = 17)	group 2 (n = 15)	group 3 (n = 15)
Body weight (kg)	7.6 ± 1.5※	6.0 ± 0.7	4.3 ± 0.5
Down's syndrome (cases)	4/17	4/15	3/15
Aortic cross-clamp time (min)	28 ± 6※	37 ± 7	35 ± 7
CPB time (min)	61 ± 11※	77 ± 13	79 ± 16
Operation time (min)	135 ± 20※	163 ± 26	168 ± 40
Anesthesia time (min)	181 ± 24※※	209 ± 33	210 ± 42
Blood loss (mL/kg)	2.5 ± 1.3 a	4.0 ± 1.9	4.8 ± 1.7
Hct after anesthetic induction (%)	33 ± 2	33 ± 5	30 ± 3
during CPB			
Lowest temperature (℃)	28 ± 1	26 ± 1	27 ± 1
Lowest Hct (%)	17 ± 3※※※	27 ± 3	26 ± 3
Lowest total protein (g/dL)	3.4 ± 0.5※※※	4.3 ± 0.5	4.4 ± 0.6
Lowest B.E. (mEq/L)	−3.7 ± 1.9 b	−2.2 ± 1.9	−0.9 ± 2.1
$NaHCO_3$ infused (mL/kg)	2.9 ± 1.3	2.0 ± 1.0	3.0 ± 1.8
Urine output (mL/kg)	8.9 ± 9.4	8.2 ± 11.4	6.9 ± 7.3
Hemofiltrate volume (mL)	180 ± 89	214 ± 96	225 ± 92
immediately after CPB			
CVP (mmHg)	8.8 ± 2.2 c	10.9 ± 2.4	9.7 ± 2.2
Blood pressure (mmHg)	70 ± 9	68 ± 11	71 ± 11
PaO_2 (mmHg)	202 ± 95	176 ± 106	123 ± 57
after ICU admission			
CVP (mmH_2O)	9.7 ± 2.1※※	11.4 ± 1.6	11.3 ± 1.5
dopamine ≦ 6/kg/min (cases)	16/17	13/15	12/15
recovery time of PaO_2 (hr) to 100 mmHg (FiO_2 0.5)	0.8 ± 1.1	2.6 ± 3.2	3.2 ± 3.4
Intubation time (hr)	6.0 ± 2.9 c, d	9.3 ± 4.9	9.6 ± 3.8
ICU stay (day)	2.9 ± 1.3	2.6 ± 1.2	3.4 ± 1.4

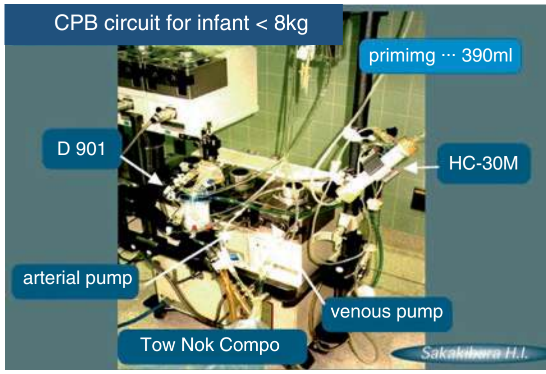
※: p<0.01 vs 2 group & 3 group, ※※: p<0.05 vs 2 group & 3 group, ※※※: p<0.001 vs 2 group & 3
a: p<0.001 vs 3 group, b: p<0.01 vs 3 group, c: p<0.05 vs 2group, d: p<0.02 vs 3group

nect not only 1/4 in. but also 3/16 in. tube, so the diameter of the arterial circuit was changed from 1/4 to 3/16 in., and the total priming volume was decreased from 390 mL to 370 mL. Figure 3.9 shows the heart–lung machine after circuit priming and the composition of the initial priming solution. In the beginning, patients weighting 5 kg were initially primed with protein preparations. Figure 3.10 shows the changes in Hct and total protein in the first four cases (BW: 5.5–7.1 kg) of bloodless open-heart surgery using D-901 oxygenator. The minimum Hct was reduced to 12%, but the duration of intubation was within 6 h, and the postoperative condition was stable. However, of these two cases, about 100 mL of residual blood in the circuit could not be collected. This is due to the blood collection from the venous drainage side of the circuit, and has since been changed to the collection from the arterial side.

In VSD patients, the success rate of bloodless open-heart surgery to the total number of VSD operations per year was 25–34% in 1987–1992. After that, it increased to 49% in 1993 using AL2000 oxygenator, 65% in 1994 for D-901, and 75% in 1995. Recalling the early 1980s, when the incidence of post-transfusion hepatitis was 14.3%, the fact that bloodless open-heart surgery was possible up to 5 kg infants was a feeling of being in a different world. And, of course, it is flattering, but I felt that the D-901 had a wonderful Italian design (refer to Video 2.1). In the future, devices should be designed with emphasis on its appearance, despite it is a medical device.

Q&A: Bloodless and clinical effects (Question in 1995)
Question: From the lecturer's talk, I have the impression that postoperative clinical course is better with bloodless open-heart surgery. Blood transfusion itself can be a factor in SIRS, so is bloodless an advantage from that perspective?

Answer: In 1995, we compared the postoperative course of 14 cases without blood priming (BW: 7.1 ± 1.2 kg) and 14 cases with blood priming (BW: 6.8 ± 0.8 kg) in open-heart surgery for infant VSDs. The results showed that CVP immediately after returning to the ICU was 9.7 ± 2.1 ⇔ 11.4 ± 1.6 cmH_2O, the duration required for PaO_2 to



Priming solution	5.0~5.9kg	6.0~7.9kg
Lactated Ringer	230ml	325ml
PPF	100ml	
Mannitol	10ml	15ml
NaHCO3	10ml	10ml
heparin	10mg	10mg
Vitamin C	1g	1g
Cefamezin	0.5g	0.5g
Exocorpol	10ml	10ml

Fig. 3.9 Component type heart–lung machine with D-901 and initial priming solution

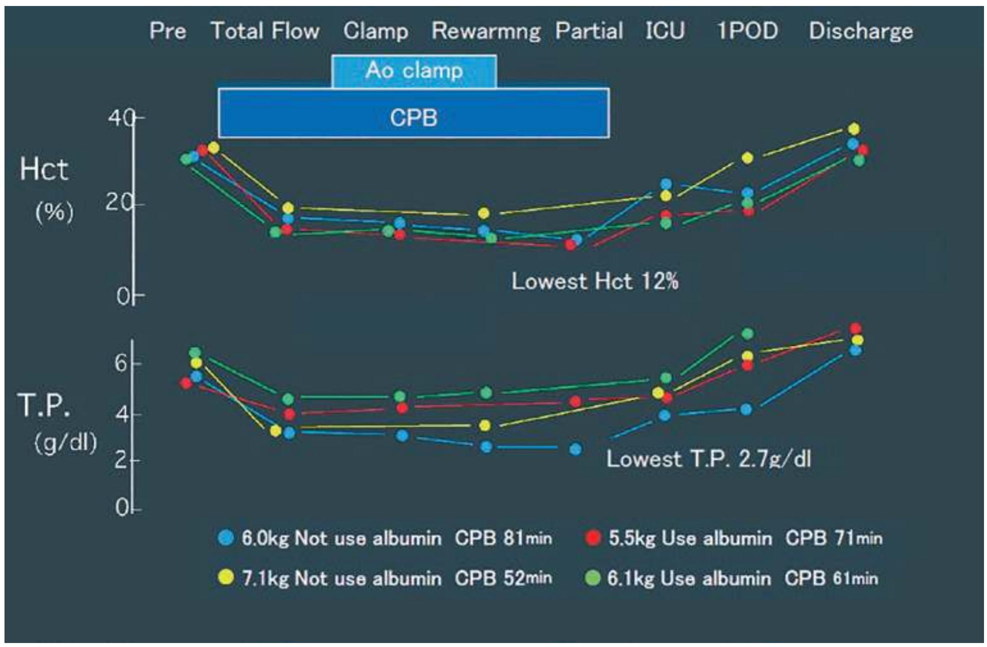


Fig. 3.10 Four VSD cases weighing 5.5–7.1 kg performed with bloodless open-heart surgery using D-901 oxygenator

improve to 100 mmHg (FiO_2 0.5) was 0.8 ± 1.1 ⇔ 2.6 ± 3.2 h, and postoperative respirator management time was 6.3 ± 3.1 ⇔ 9.3 ± 4.9 h, and the bloodless group was rather good. Both groups started drinking water 7 h after weaning from the ventilator, and no complications, including reintubation and cranial nervous system were observed.

Certainly, with the expansion of indications for bloodless open-heart surgery, I feel that postoperative hemodynamics and respiratory status are better than in blood priming cases. However, blood priming cases are mostly with severe pulmonary hypertension, preoperative anemia, and poor respiratory status. As a result, each postoperative data may be slightly worse. Previously, we examined the possibility of low activated complement levels in bloodless priming cases, but the level of C3a before unclamp was 1000–7000 ng/mL. Even under the same conditions of bloodless priming, considerable variation was observed in each case (Fig. 3.11).

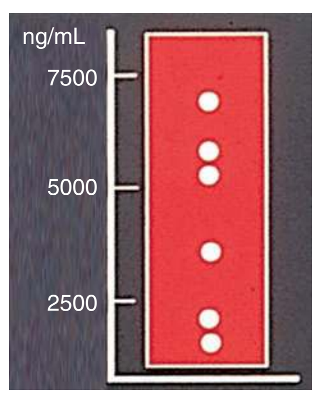


Fig. 3.11 C3a values in bloodless open-heart surgery for infant VSD

There was no difference when compared to blood primed cases (refer to Fig. 1.33). Furthermore, there was no impression that the level of this C3a value was proportional to the quality of the postoperative condition. However, there was no doubt that, with the use of the ultrafiltration device HC-30M, the DUF during aortic cross-clamp, the ECUM from the start of rewarming to partial extracorporeal circulation, and the active correction of Na, early weaning from the ventilator was possible. (refer to Sect. 1.4.3). The postoperative status of patients of bloodless open-heart surgery was stable, but the degree of increase in individual active complement could not be predicted, so I think that efforts are needed to reduce it in all cases, whether transfusions are used or not [17, 18].

Column: Postoperative Convulsion

In 1995, when the indication of bloodless open-heart surgery was expanded to cases with a body weight of 5 kg, we experienced transient convulsions in three cases with a weight of 6.2–7.3 kg VSD (Table 3.4). These patients were able to withdraw from the respirator 4–6 h after the operation and returned to the general ward the next day, but all three patients developed convulsions on the third day postoperatively. There were no abnormal findings in CT or EEG, and there was no problem in the subsequent course.

As a countermeasure against convulsions, first, the perfusion flow was increased from 120 mL/kg/min to 150 mL/kg/min, and the operation and extracorporeal circulation time were shortened. Also, at that time, there was a report that EEG abnormalities would occur if the extracorporeal circulation was started rapidly, so at the initiation of extracorporeal circulation, the blood pump speed was adjusted so that the initial priming fluid slowly flows into the body. Since then, no neurological complications have been experienced, including convulsions. Bloodless open-heart surgery for low-weight infants requires not only reduction in priming volume but also extracorporeal circulation management that does not cause rapid changes in the physiological state of the body (refer to Chap. 1, Column: Constant Perfusion) [19].

3.3.4 Possibility of Bloodless Open-Heart Surgery for VSD Infant Weighing 4 kg (1995)

In 21 consecutive infants with infant VSD weighing 5.2–9.5 kg who underwent bloodless open-heart surgery, transfusion was avoided in all cases, and postoperative circulatory and respiratory status were good (Fig. 3.12). It was considered clinically appropriate to apply bloodless open-heart surgery up to a weight of 5 kg. Figure 3.13 shows the course of Hct during extracorporeal circulation.

6.6 kg or more cases were almost constant (18 ± 2 after starting → 19 ± 1 during blocking → 19 ± 2% after rewarming), but decreased in all cases during rewarming in five cases of 6.1 kg or less (16 ± 1 → 16 ± 2 → 14 ± 2%). Therefore, in order to expand the indication of bloodless open-heart surgery to patients with body weight of 4 kg or less, it was necessary to determine the safety threshold of hemodilution in consideration of the possibility that hemodilution after rewarming would become advanced. Based on the above, we examined from the viewpoint of hemodilution whether or not the 370 mL semi-closed circuit using the D-901 oxygenator can be expanded to a VSD of 4 kg or less.

First, a method for predicting hemodilution was examined. In general, the circulating blood volume is calculated as body weight × 80 mL. However, in the calculation formula, the predicted Hct value after the initiation of extracorporeal circulation was often different from the actual measured value. Therefore, the preoperative circulating blood volume in the cases shown in Fig. 3.12 was calculated backward from the measured Hct at the time of anesthesia induction, Hct after the initiation of extracorporeal circulation, and the priming volume. A calculation formula of circulating blood volume = body weight × 72–13 ($r = 0.85$) was obtained, which was lower than the value of body weight

Table 3.4 Three VSD infants with transient convulsions after surgery

	Age	BW	CPB	Ope.	Lowest Hct	Lowest T.P.	Intubation
1.	9m	7.3kg	110min	254min	17.5%	3.0g/dL	4hr
2.	9m	6.7kg	67min	155min	14.5%	2.7g/dL	6hr
3.	9m	6.2kg	87min	148min	17.0%	3.1g/dL	4hr

Patient 1	3POD	whole body tonic	CT, EEG ⋯ W.N.L
Patient 2	3POD	left lower limb	CT, EEG ⋯ W.N.L
Patient 3	3POD	left half body	CT, EEG ⋯ W.N.L

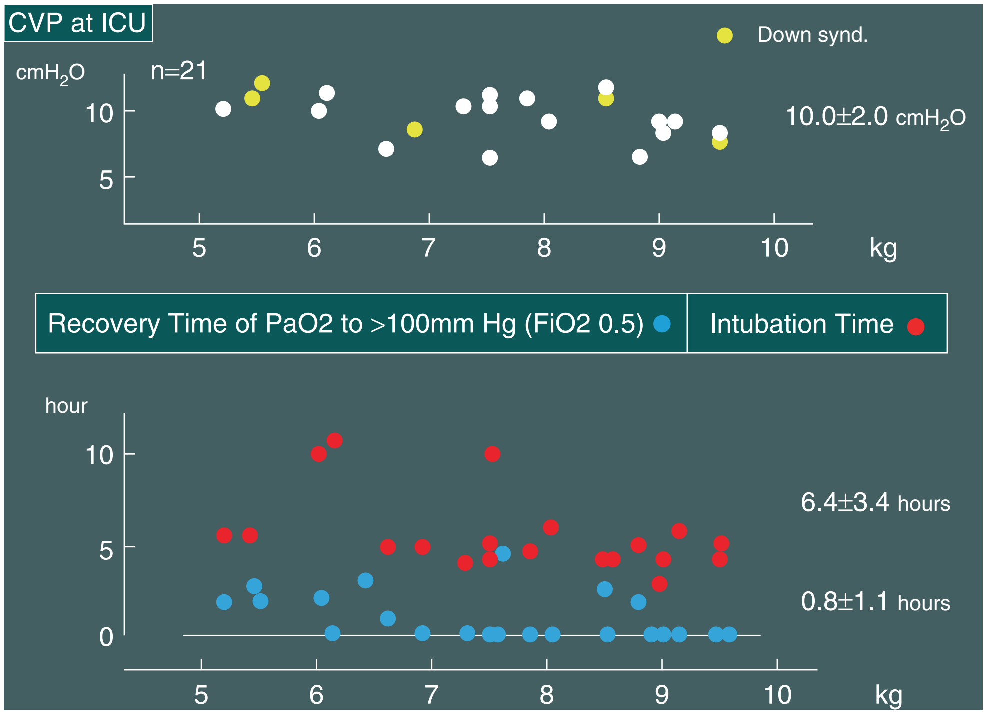


Fig. 3.12 Hemodynamics and respiratory status after bloodless open-heart surgery for VSD weighting 5.2–9.5 kg

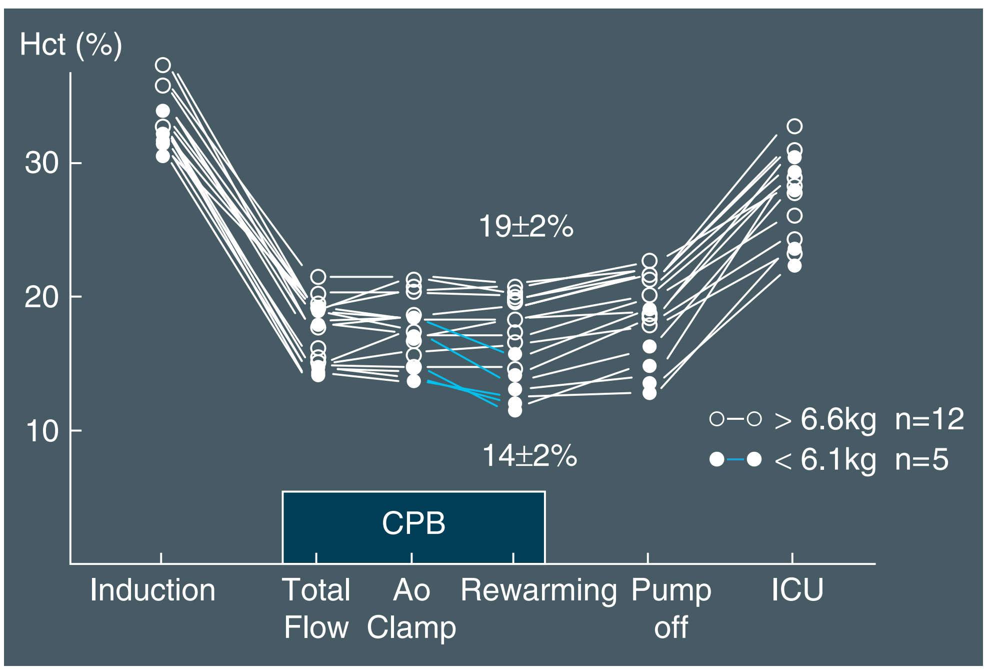


Fig. 3.13 Hct change in VSD weighing under 6 kg [20]

× 80 (Fig. 3.14). In particular, the calculation formula for nine cases under 8.9 kg was even lower, with circulating blood volume = body weight × 70–17 ($r = 0.92$). Of course, this equation included various conditions such as the amount of bleeding from the induction of anesthesia to extracorporeal circulation, infusion volume, and operation time. However, it was possible to accurately predict the hemodilution in bloodless open-heart surgery for infant VSD. It was considered to be a clinically useful formula.

Regarding the safety threshold of hemodilution, since the lowest Hct actually experienced was 15% immediately after the initiation of extracorporeal circulation and 12% at the time of weaning, Hct of 15% after the initiation of extracorporeal circulation was set as the hemodilution threshold in cases of 4 kg or less. Based on this assumption, the circulating blood volume of 3.5–5.0 kg cases was calculated from the formula of circulating blood volume = weight × 70−17. Then, in the extracorporeal circulation using a circuit with a

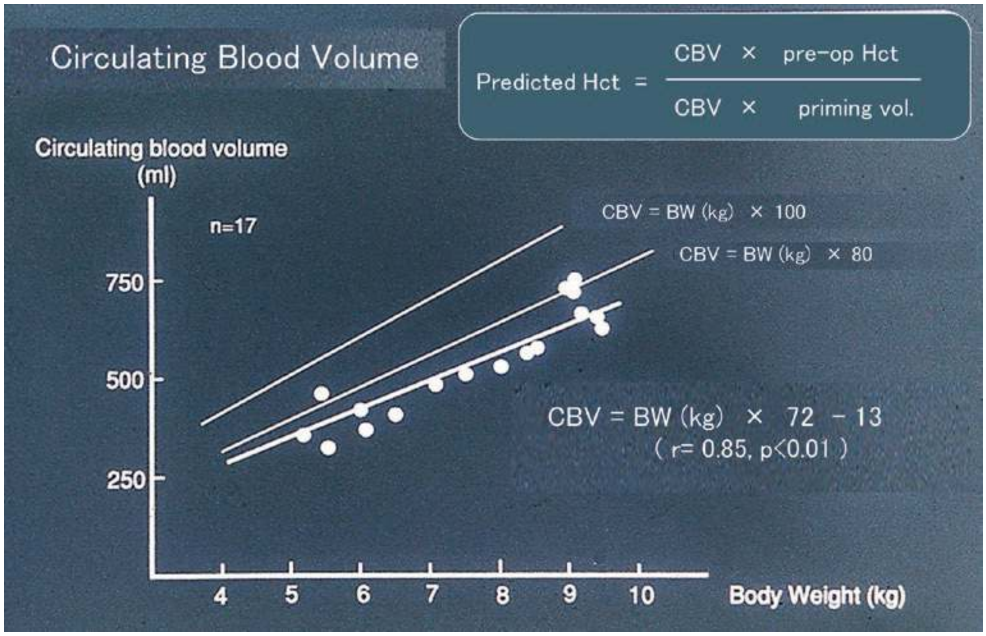


Fig. 3.14 Circulating blood volume calculated backward from Hct after anesthetic induction and immediately after initiation of CPB [20]

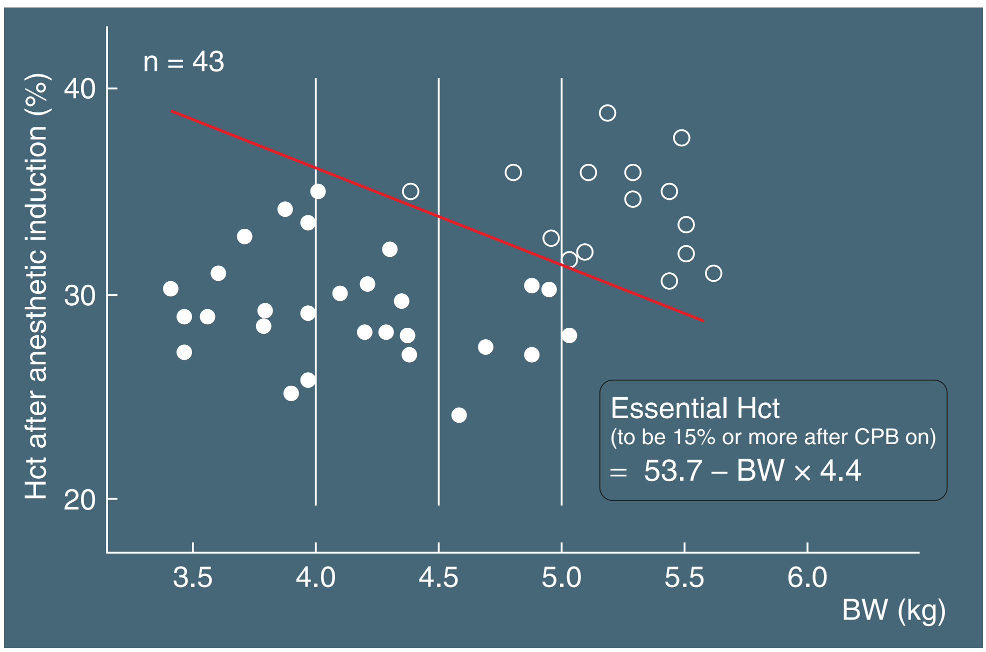


Fig. 3.15 Relationship between prediction formula of Hct value at the time of anesthesia induction and measured value [20]

priming volume of 370 mL, the Hct value at the time of anesthesia induction for the Hct value to be 15% after the initiation of extracorporeal circulation was calculated backward. The calculation formula of Hct value at the time of anesthesia induction = 53.7 − body weight × 4.4 was obtained, and 5.0 kg—32%, 4.5 kg—34%, 4.0 kg—36%, and 3.5 kg—39% were calculated as thresholds. Comparing these values with the measured Hct values at the time of anesthesia induction in 43 cases of 3.5–5.9 kg VSD subjected to bloodless open-heart surgery, 12 cases (92%) were judged to be in the safe range in 13 cases with a body weight of 5.0–5.9 kg. On the other hand, 3 cases (18%) were judged to be safe out of 17 cases with a body weight of 4.0–4.9 kg, and 0 cases (0%) out of 13 cases with a body weight of 3.5–3.9 kg (Fig. 3.15).

Conclusion

When using a circuit with a priming volume of 370 mL, assuming that the hemodilution threshold of VSD bloodless open-heart surgery is Hct of 15% after the initiation of extracorporeal circulation, most cases of 5 kg or more are within the safe range, and actually bloodless open-heart surgery was possible with stable condition. On the other hand, the number of cases that deviated from the safe range increased in cases of 4 kg or less.

In low-weight cases, hemodilution during rewarming may progress to a higher degree, and there are concerns that there will be more cases that require long-term management after surgery. First of all, it was essential to create an extracorporeal circuit with a priming volume of 200 mL, and we thought that strict management should be performed mainly on minimally invasive measures. One of the absolute requirements for bloodless open-heart surgery is that postoperative quality does not deteriorate [20].

3.3.5 Bloodless Open-Heart Surgery in VSD Infants Weighing 3–4 kg (1997)

In addition to clinical evaluation of bloodless open-heart surgery for VSD patients with a body weight of 5 kg or more, we reduced the priming volume by developing an isolated pump-controller heart–lung machine (refer to Sect. 2.2.5), and with the use of PAN membrane ultrafilters for the purpose of suppressing inflammatory reaction substances, postoperative condition was more stable (refer to Sect. 1.4.3.3). Therefore, since 1997, we have expanded the indications for bloodless open-heart surgery to 3 kg only in infant VSDs, where Hct was expected to be 15% or more after the initiation of extracorporeal circulation.

From February 1997 to July 1999 (first half: minimum priming volume 195 mL), 40 (80%) of 50 VSD patients weighing 3–4 kg were indicated for bloodless open-heart surgery. The main reasons for the ten cases which were excluded, were preoperative anemia and symptoms of strong heart failure such as depressed breathing. Thirty-four patients (85%) were able to perform bloodless open-heart surgery. Figure 3.16 shows the cause of blood transfusion in six cases. The serious complication was PH crisis in a case of 3.7 kg body weight. In this case, a clear decrease in pulmonary artery pressure was observed in the oxygen load test during cardiac catheterization. The Pp/Ps ratio immediately after extracorporeal circulation was 0.35, and the respirator was weaned 9 h postoperatively. The Pp/Ps ratio on echocardiography on the first day after surgery was estimated to be 0.45, but a PH crisis occurred immediately after the administration of oxygen was stopped. Microscopic lung tissue examination revealed abnormal thickening of the media (% wall thickness 33% or more) in 30% of small pulmonary arteries (extremely thickened

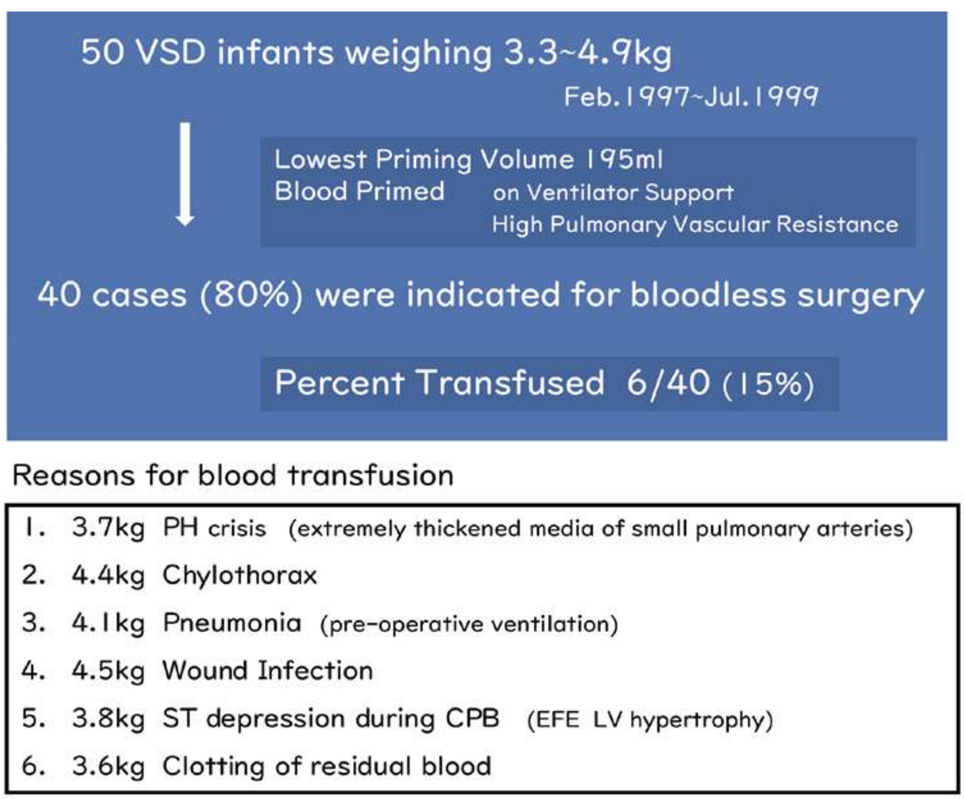


Fig. 3.16 Results of the first half and reasons for blood transfusion

media of small pulmonary artery) (Fig. 3.17). It was judged not applicable for surgery.

Based on the blood transfusion factors shown in Fig. 3.16, first, cases with preoperative respirator management were excluded from the indication of bloodless open-heart surgery. In addition, we determined the indication more strictly in cases with high pulmonary vascular resistance and considered blood priming or pulmonary artery constriction + lung biopsy in some cases.

From August 1999 to February 2002 (second half: minimum priming volume of 130 mL), 73 of the 90 patients (81%) were indicated for bloodless open-heart surgery, and in all cases, bloodless open-heart surgery was possible (Fig. 3.18). The lowest Hct during extracorporeal circulation was 15.2 ± 2.4%, and the lowest was 11.0%, with a body weight of 4.3 kg (Fig. 3.19). The amount of dopamine used was 4.5 ± 1.2 γ/kg/min after the weaning from extracorporeal circulation and 2.9 ± 1.8 γ/kg/min after returning to

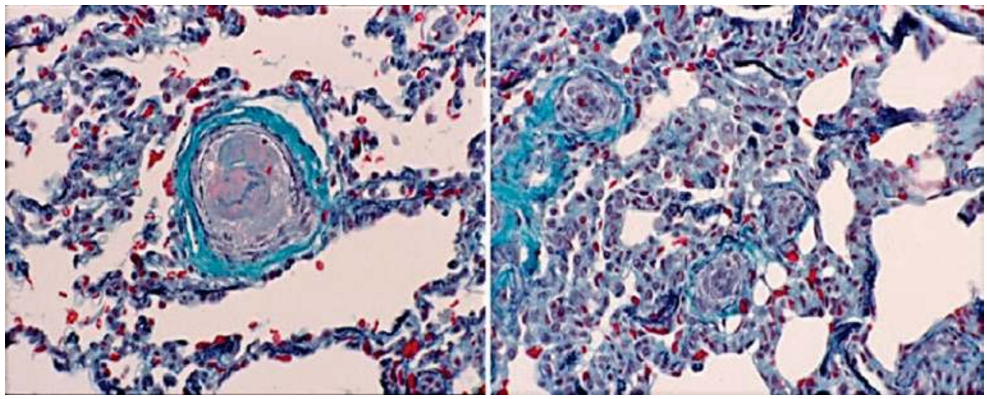


Fig. 3.17 Pulmonary pathological findings of case 1 weighing 3.7 kg [21]. Small pulmonary arteries with abnormal medial thickness (% wall thickness 33% or more) are observed

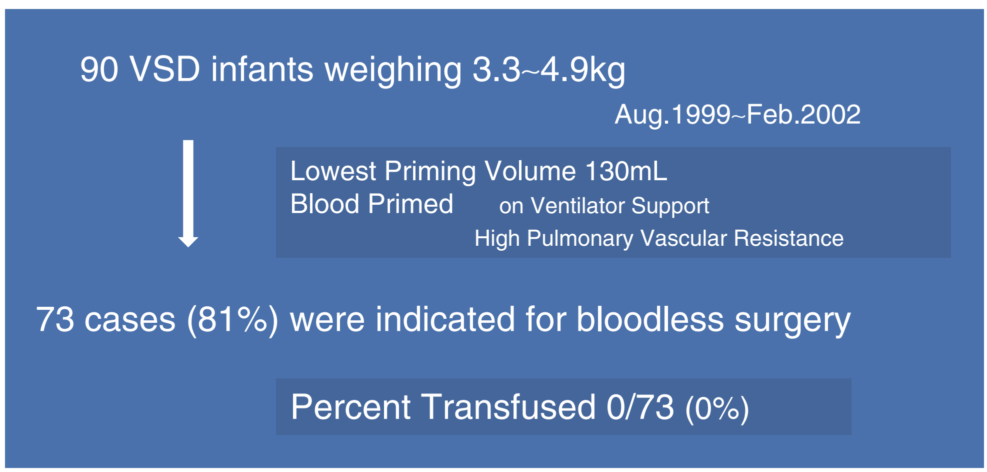


Fig. 3.18 Results of the second half

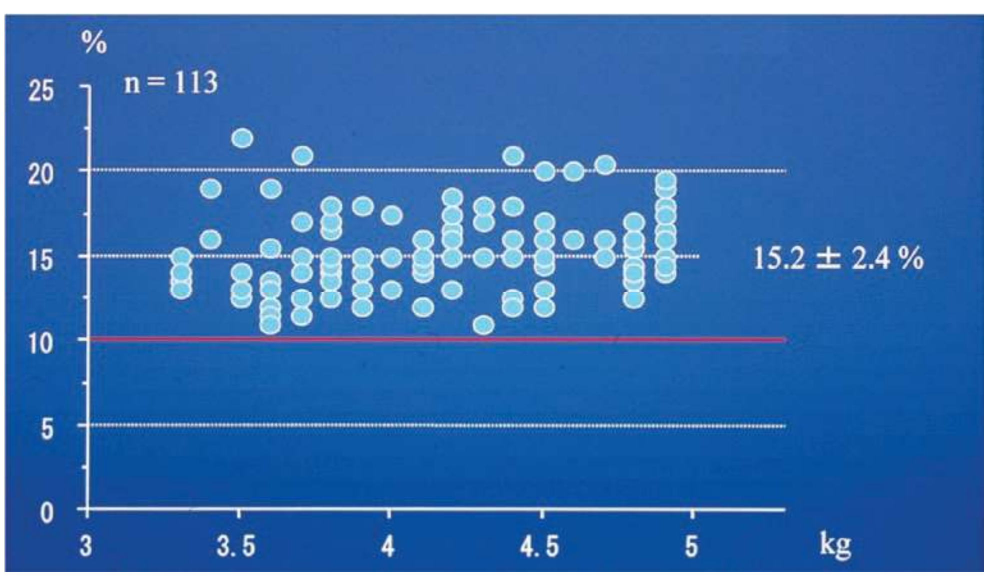


Fig. 3.19 Minimum Hct during cardiopulmonary bypass

ICU, and 37 patients returned to ICU without inotropic support (Fig. 3.20).

The duration of ventilation in the ICU was 5.5 ± 2.6 h (Fig. 3.21) (seven cases required more than 10 h). In the second half, there were no clinical problems, including transfusion factors observed in the first half. Figure 3.22 shows the course of extracorporeal circulation of VSD with a minimum body weight of 3.3 kg [21, 22].

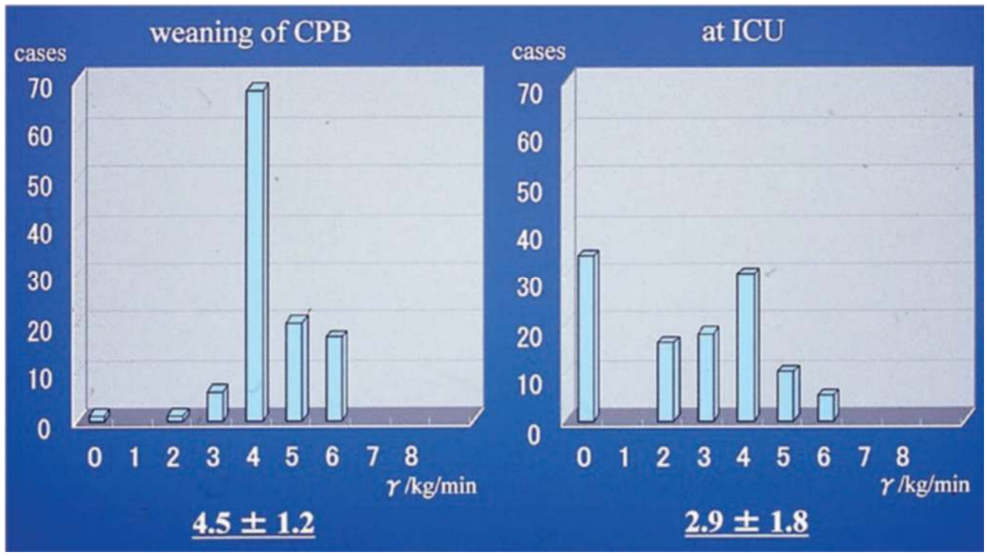


Fig. 3.20 Dopamine usage

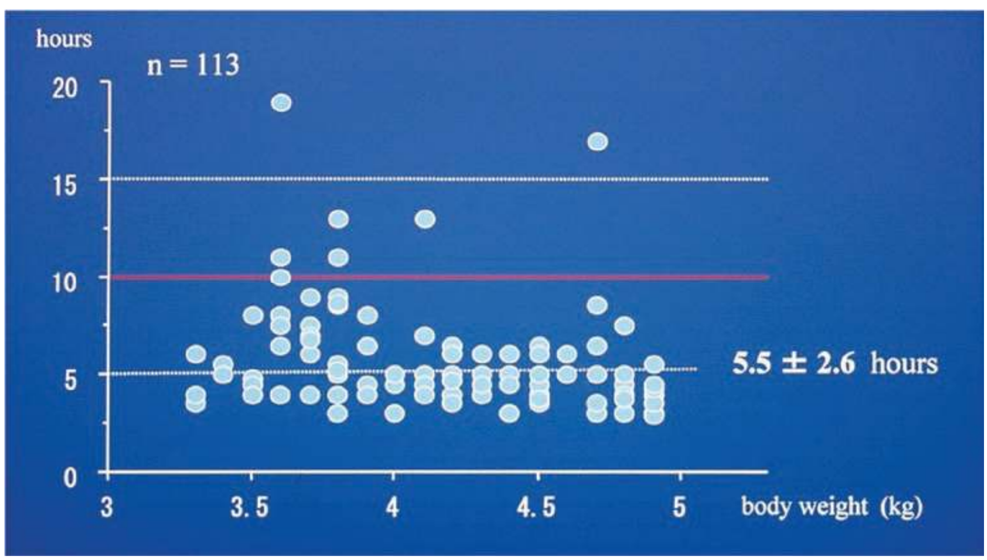


Fig. 3.21 Duration of intubation after surgery

	CPB Time		0	10	20	30	40	50	55 min
			pump on						pump off
				Ao clamp		rewarming	unclamp		
Temp. (℃)			35.3	35.0	31.8	32.7	35.1	35.9	
Blood gas	Na (mEq/l)	130		133		137	137		139
	K (mEq/l)	4		3.6		5.1	4.6		4.1
	B.E.	4.3		−0.6		−1.4	−3.8		−2.5
	Hct (%)、Hb(g/dl)	35.0 12.0		15.5 5.6		16.5 5.7	13.5 4.8		15
	T.P. (g/dl)	5.2		3.0		3.3	3.1		3.4
		Initial Priming							
Correction	25% albumin (ml)	10	DUF (albumin 5 ml + Veen F 95 ml)×2						
	salin HES (ml)								
	10% NaCl (ml)			3		3			
	KCl (mEq)				2 2				
	D-mannitol (ml)	5			4				
	NaHCO3 (ml)	10		3		2 2	3		
	Veen F (ml)	155	20 20	20		20	40		
	C.H. (mg)						3 3		

Fig. 3.22 Extracorporeal circulation in a VSD case weighing 3.3 kg (Minimum Weight of Bloodless Open-Heart Surgery, 1999). Total priming volume 195 mL. Priming composition (Veen F 155 mL, 25% albumin 10 mL, $NaHCO_3$ 5 mL, Mannitol 10 mL VC 1000 mg, Exocorpol 5 mL, CEZ 500 mg, heparin 400 u, KCL 0.4 mL). Initial primind fluid data (PH 8.1, PO_2 459 mmHg, PCO_2 5.5, BE +8.0, Na 160 mEq/L, K 5.2). Perfusion rate 150 mL/kg/min. DUF cleaning solution: alb 5 mL + Veen F 95 mL × 2. Urine volume 64 mL. ECUM filtration volume 145 mL. Fluid balance + 165 mL. Extracorporeal circulation time 55 min, operation time 101 min, anesthesia time 150 min

Column: First Three VSD Cases Weighing 4 kg Undergoing Bloodless Open-Heart Surgery (1997)

In February 1997, bloodless open-heart surgery for VSD infants weighing 4 kg was started (refer to Videos 2.2–2.9). Figure 3.23 shows the intraoperative data of the initial three cases. Hemodynamics and respiratory status were good, and early ventilator weaning was possible. As expected, the Hct level was lowest at rewarming, and the lowest Hct during extracorporeal circulation was lower than that in cases weighing 5 kg or more (Fig. 3.24).

These results were submitted as a paper. A reviewer commented, “Even if the postoperative clinical course of bloodless open-heart surgery is better than that with blood transfusion, it is too early to conclude that bloodless open-heart surgery is safe.

Also, current transfusions are safe. So, I don’t understand why so much attention is paid to pursuing bloodless open heart surgery. It is not an Olympic game.” It was certainly true, and since then, with the aim of resolving problems predicted from hemodilution and enhancing the safety of bloodless extracorporeal circulation, we have improved extracorporeal circulation devices and reviewed patient management methods. There seem to be negative opinions regarding bloodless open-heart surgery, even more, if transfusions are considered to be safe. Of course, if the clinical course of open-heart surgery with blood transfusion is better, bloodless open-heart surgery should not be performed [23].

Column: Evaluation of Bloodless Open-Heart Surgery for VSD Infants Weighing 3–4 kg (2002)

1. In bloodless open-heart surgery for low-weight infants, there is a risk of deterioration in postoperative hemodynamics and respiratory status. Therefore, I thought that it was necessary to always evaluate the validity of the indication expansion clinically. The duration of intubation for 57 consecutive cases using the isolated pump-controller

Priming Solution	total 230mL
acetate Ringer	170mL
25% albumin	10mL
saline HFS	20mL
mannitol	10mL
$NaHCO_3$	10mL
exocorpol	10mL
heparin 1,000u cefamezin 0.5g vitamin C 1g	

	Patient 1	Patient 2	Patient 3
Sex	male	female	male
Age (mo)	5	7	2
Height (cm)	59	61	55
Body weight (g)	4,210	4,575	4,145
BSA (m2)	0.26	0.27	0.23
Type of VSD	total conus defect	perimembranous outlet	perimembranous inlet
L-R shunt ratio (%)	80	55	83
Pp/Ps	0.77	0.88	0.65

	Patient 1	Patient 2	Patient 3
Hct after anesthetic Induction (%)	29.0	31.0	28.5
During CPB			
Lowest temperature (°C)	30.4	30.2	31.0
Lowest Hct (%), Hb (g/dL)	14.0,5.0	12.0,4.3	12.0,4.9
Lowest total protein (g/dL)	3.8	3.6	3.7
Lowest BE (mEq/L)	–1.3	–3.0	–0.2
Lowest Na (mEq/L)	134	132	129
$NaHCO_3$ infused (mL)	10	20	10
10% NaCl infused (mL)	5	0	10
Urine output (mL)	5	10	10
Hemofiltrate volume (mL)	220	200	200
Fluid balance (mL)	+80	+67	+51
Immediately after CPB			
Dopamine (µg/kg/min)	4	3	4
PaO_2 (mmHg) FiO_2 0.8	357	123	279
Residual perfusate of bypass (mL)	210	220	230
Aortic cross-clamp time (min)	23	26	23
CPB time (min)	50	51	47
Operation time (min)	110	108	96
Anesthesia time (min)	175	155	142
Blood loss (mL)	5	10	10
Total fluid balance (mL)	+260	+213	+188
In ICU			
CVP (cmH_2O)	9.8	9.0	6.5
PaO_2 (mmHg) FiO_2 0.5	180	158	140
Duration of intubation (hr)	4	5	4
ICU stay (day)	3	3	3

Fig. 3.23 Clinical data of first three bloodless VSD cases weighing 4 kg

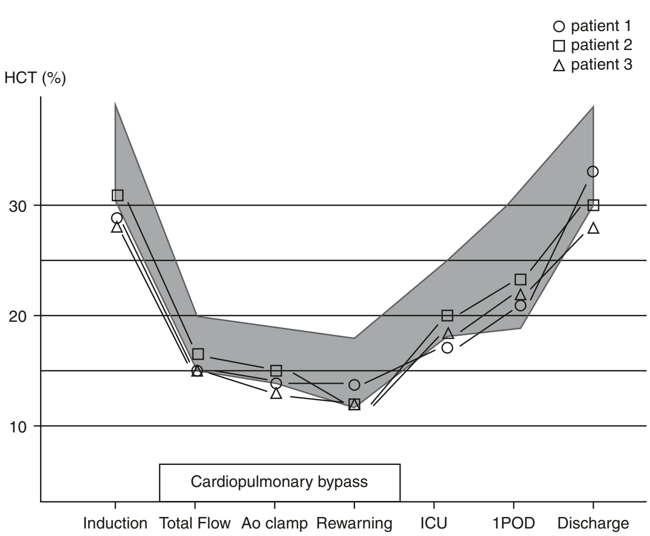


Fig. 3.24 Hct change in three cases of VSD weighting 4 kg. The shaded area shows the Hct values in 11 VSD infants weighing 5.1~6.1 kg using a circuit with a priming volume of 370 mL

heart–lung machine since February 1997 was significantly shortened compared to cases using a conventional heart–lung machine with blood priming before 1996 (Fig. 3.25). Figure 3.26 shows 61 cases (weight 3 kg: 21 cases, 4 kg: 40 cases) from August 1999 to June 2001, in which the priming volume was 130 mL. The success rate of bloodless open-heart surgery was 100%, and there were no clinical problems predicted by open-heart surgery for low-weight infants, such as respiratory deterioration due to hemodilution and cranial nervous system problems. Dopamine was used at an average of 4.3 γ/kg/min immediately after extracorporeal circulation and 2.7 γ/kg/min when returning to ICU, and 16 patients returned to ICU without catecholamine. No other catecholamines, nitric oxide, or vasodilators were used. The average postoperative duration of intubation was 5.1 h. Although long-term management cases of 10 h or more were observed in two cases, there was no difference between 3 kg and 4 kg cases (Fig. 3.27).

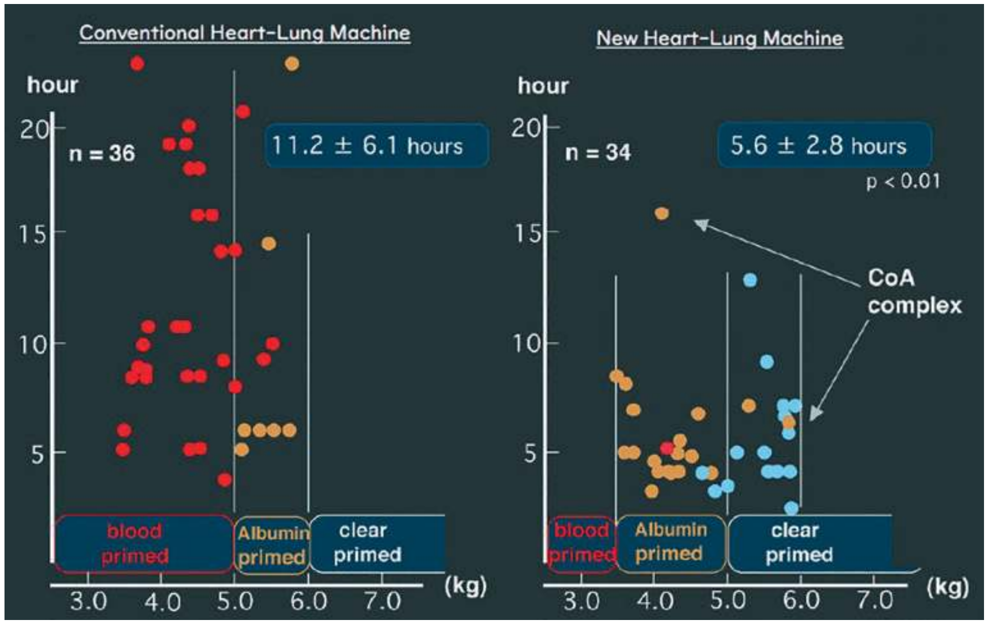
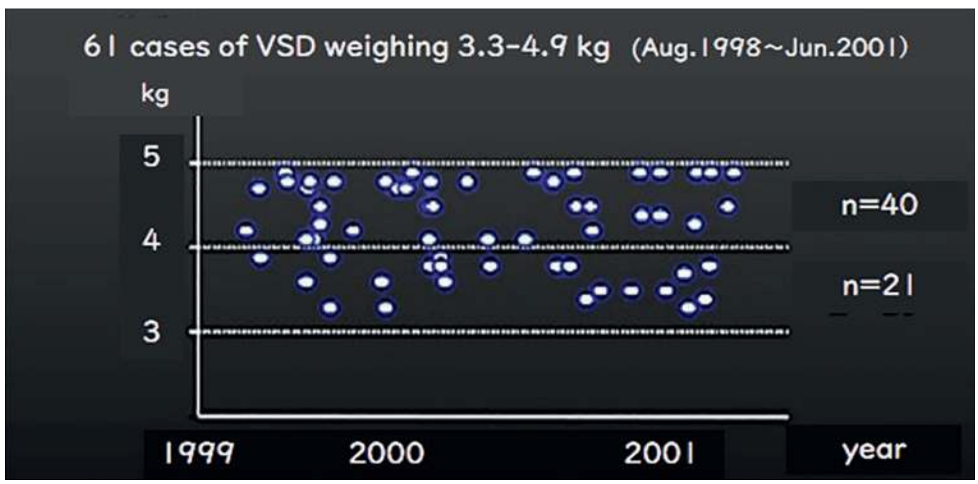


Fig. 3.25 Comparison of intubation time between conventional heart–lung machine and isolated pump-controller heart–lung machine [24] modified. The priming volume was 195 or 230 mL for the isolated pump-controller heart–lung machine, and 370 mL for the conventional type (100–200 mL of whole blood was initially primed)



Expected Clinical Problems in Bloodless Open Heart Surgery

Difficulty weaning from CPB
Fluctuation of rSO_2, Awaken delay
Cranial nervous system complications
Decreased diuresis, Peritoneal dialysis
Hypoxia, Reintubation
ICU stay 4 days or more
Delayed wound healing, Wound infection
Upgrowth problems after discharge

Fig. 3.26 Annual number of VSD surgery weighing 3–4 kg and expected clinical problems in bloodless open-heart surgery

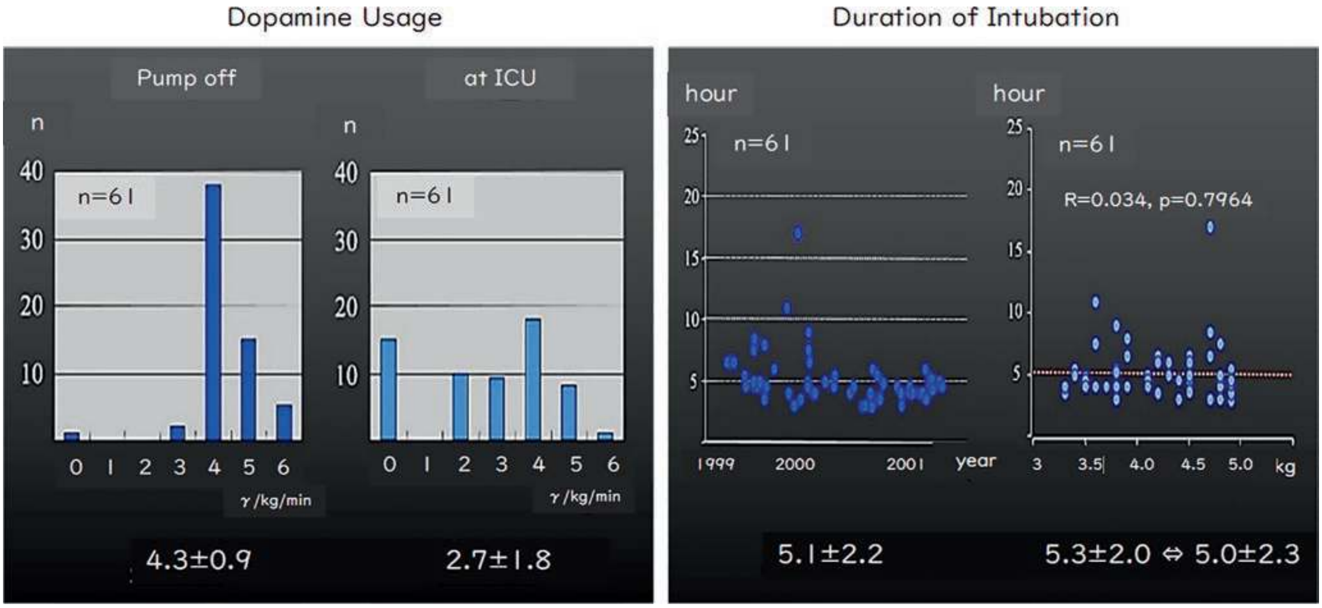


Fig. 3.27 Dopamine usage and duration of intubation

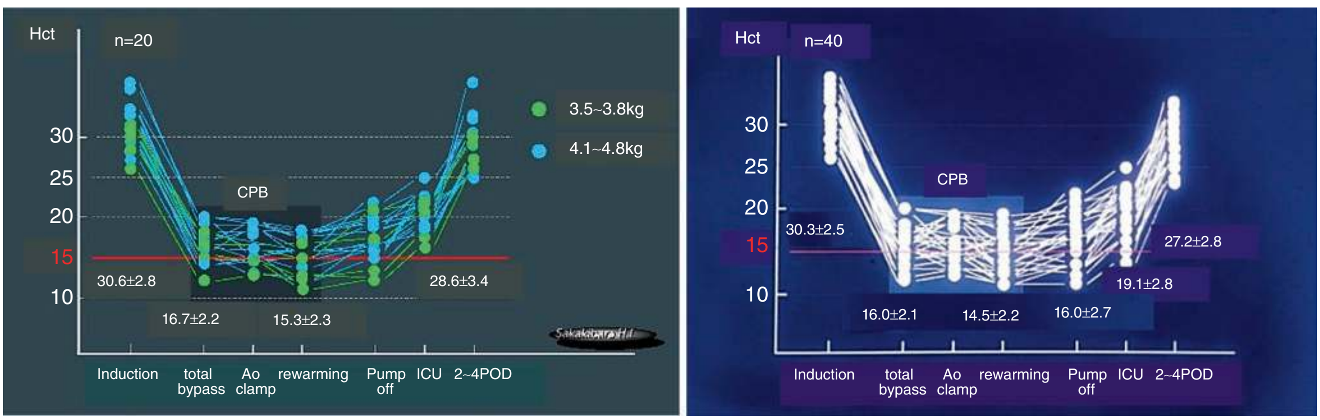


Fig. 3.28 Hct change using 195 mL priming volume circuit [25] modified

2. Indications for bloodless open-heart surgery for VSD cases weighing 3–4 kg were those in which Hct immediately after the initiation of extracorporeal circulation could be predicted to be 15% or more, except for neonatal and ventilator management cases.

   Figure 3.28 shows the Hct transition of the initial 20 consecutive cases using a priming volume of 195 mL, and 40 cases, including the subsequent 20 cases. The lowest Hct during extracorporeal circulation of 3 kg cases was lower than that of 4 kg cases and further decreased with the increase of 3 kg cases. There were cases of Hct less than 15% after the initiation of extracorporeal circulation and less than 20% after returning to ICU, but when exiting ICU (2–4 POD), it recovered to a value of −3% of Hct after induction of anesthesia.

   Figure 3.29 shows the change in minimum Hct during extracorporeal circulation in a total of 122 cases up to August 2002. An increase over time was observed with the use of a 130 mL priming volume circuit and a 25 mL ECUM circuit (refer to Chap. 2, Column: Priming Volume of ECUM Circuit). In cases with a body weight of 3 kg only, the minimum Hct during extracorporeal circulation was 13.8 ± 2.0% (minimum value 11.0%) in 15 cases with a priming volume of 195 mL, whereas in 25 cases with 130 mL priming volume, it increased to 16.0 ± 3.0% (minimum 12.5%).
3. At the time, the word “Fast Track” was popular. Figure 3.30 shows secular changes in extracorporeal circulation time, operation time, and anesthesia time. Since 2000, the number of cases with 60 min of operation and 90 min of anesthesia has increased, making it possible to plan open-heart surgery in the same operating room for 2–4 patients per day. The fact that the time could be shortened indicated that the bloodless open-heart surgery itself was not a time-consuming operation, and conversely, it meant that the bloodless surgery was completed quickly

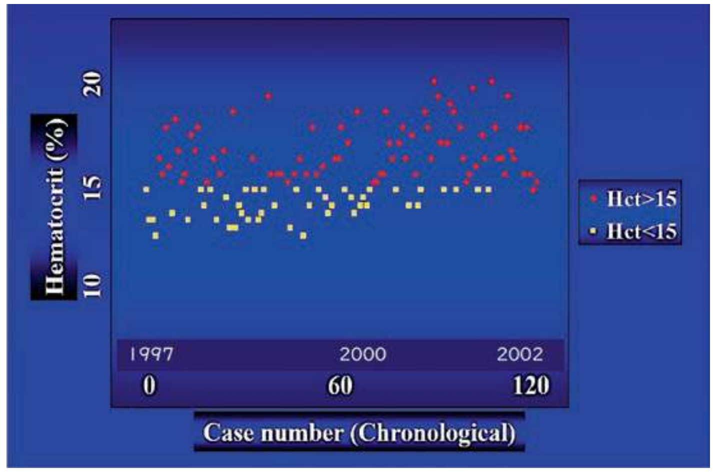


Fig. 3.29 Annual change of minimum Hct during extracorporeal circulation

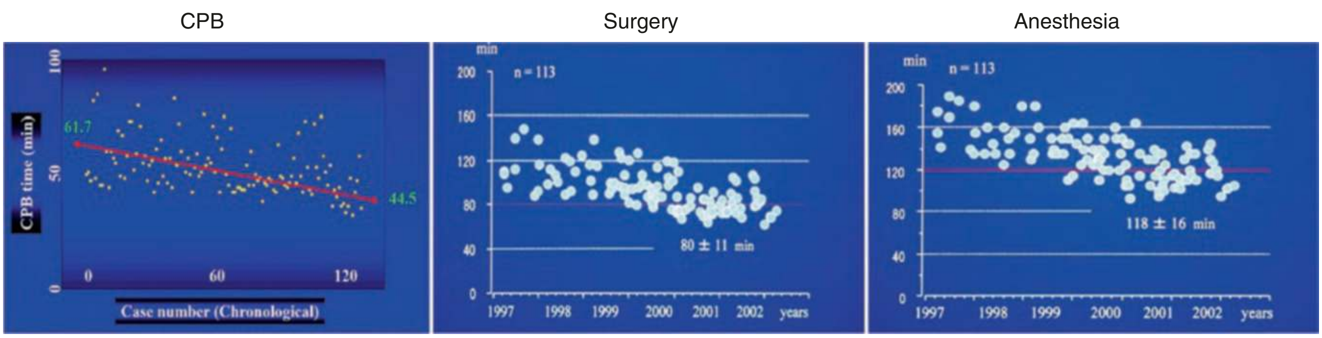


Fig. 3.30 Annual changes in duration of CPB, surgery, and anesthesia. In the first half with the minimum priming volume of 195 mL, the operation time was 108 ± 17 min and the anesthesia time was 150 ± 19 min, while with the latter stage of 130 mL was 86 ± 13 min and 124 ± 13 min

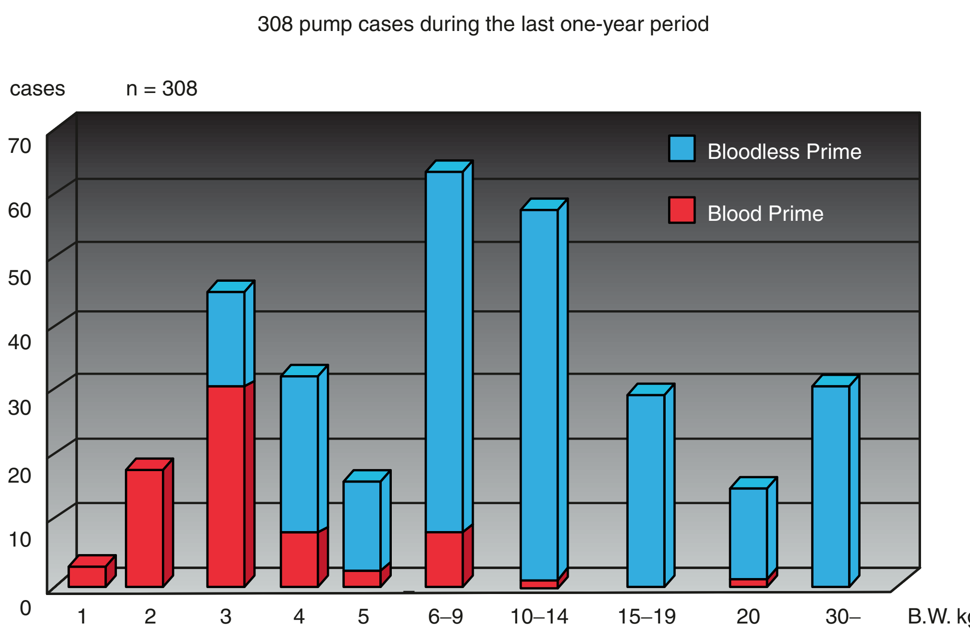


Fig. 3.31 Bloodless priming ratio by weight in 2002

because the hemodynamics and respiratory status were stable. Bloodless open-heart surgery for low-weight VSD was considered a surgery that deserves a fast track.

In 2002, I performed 308 operations throughout the year. The number of bloodless cases in the low body weight region was increasing (Fig. 3.31). At the time, there were many issues to be solved in bloodless open-heart surgery for low-weight children, and many critics had already said that it was overkill. It was necessary to consider the risk and benefits associated with advanced hemodilution and priming volume reduction. However, the overall quality of 3–4 kg VSD bloodless open-heart surgery was higher than that with blood transfusion and was considered clinically appropriate.

As an aside, in response to a negative question about bloodless open-heart surgery at one lecture, I answered as follows, “Of course, if your open-heart surgery with blood transfusion can further reduce the use of inotropic drugs and reduce the time required for ventilator management and surgery, I will definitely stop bloodless open-heart surgery. It was an extremely impudent response, reflecting on youthful folly.” [26].

3.3.6 Bloodless Open-Heart Surgery for Complete AVSD: Comparison with VSD

From October 1996 to September 1999, there were 29 cases of primary intracardiac repair for complete AVSD. Sixteen patients (55%) underwent bloodless open-heart surgery. Reasons not applicable for bloodless open-heart surgery in 13 cases were weight under 4.0 kg, severe anemia, and preoperative ventilator management.

Sixteen patients who underwent bloodless open-heart surgery weighed 4.0–7.9 kg (5.4 ± 1.0), were 3–9 months (5.4 ± 1.6), and 14 had Down syndrome. In Rastelli classification, six cases were Type A, seven cases were Type C, and three cases were so-called intermediate type. These 16 cases were compared with 69 cases (81%) of the 85 cases weighing 3.7–6.2 kg VSD during the same period, which were indicated for bloodless open-heart surgery. The extracorporeal circulation circuit priming volume was 195–250 mL for a body weight of 6.0 kg or less and 320 mL for a body weight of 6.1 kg or more.

The success rate of bloodless open-heart surgery in complete AVSD was 94% (15/16). One 5 months patient with a body weight of 5.6 kg had a PH crisis. At the time of weaning from extracorporeal circulation, the patient experienced severe low cardiac output and hypoxia. Immediately, PH crisis was suspected and blood transfusion was performed. He was able to wean from extracorporeal circulation by administering a large dose of catecholamine and prostaglandin E1. Since then, hemodynamics and respiratory status have stabilized, cardiac function and repair status on echocardiography on the first day were good, and Pp/Ps ratio was estimated to be about 0.3–0.4. The respirator was removed 17 h postoperatively. However, on the second day, immediately after removing the oxygen tent, blood pressure and oxygenation decreased rapidly. Echocardiography revealed dilation of the right heart and severe pulmonary hypertension. Thereafter, the decrease in PaO_2 persisted and did not respond to various treatments. Preoperative cardiac catheterization revealed a clear response to oxygen load, so it was judged that primary intracardiac repair was indicated. However, microscopic pulmonary histology revealed that 20% of total pulmonary arterioles had abnormal medial thickening of the media, and it was judged that the primary repair was not applicable (Fig. 3.32).

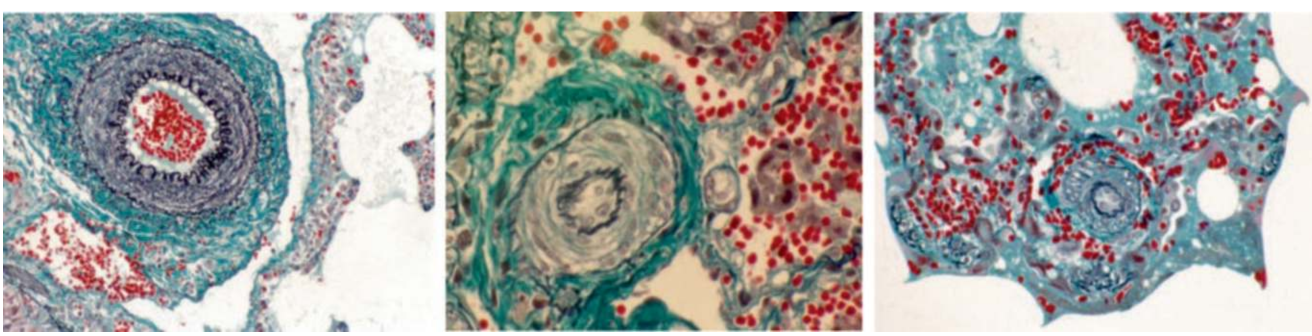


Fig. 3.32 Pulmonary pathological findings in cases with PH crisis. Small pulmonary arteries with diameters of 200 μ, 100 μ, 20–30 μ. There was no intimal lesion, but there was abnormal thickening of the media

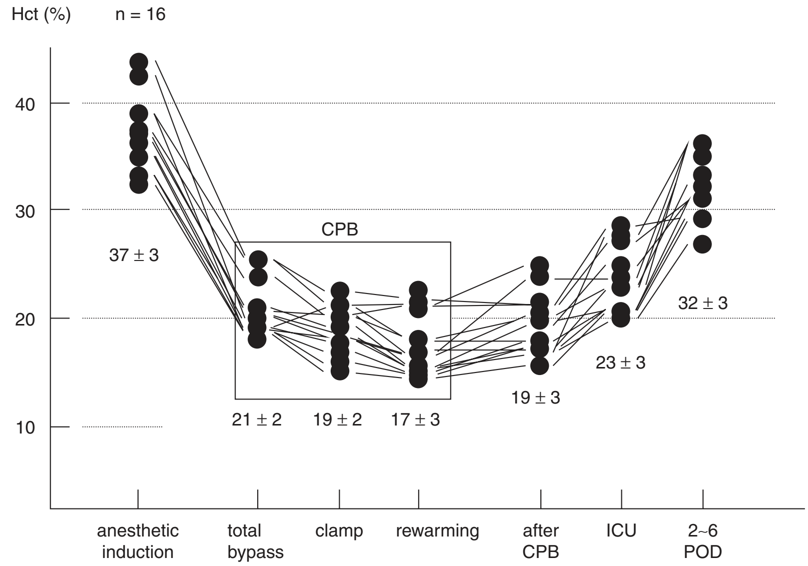


Fig. 3.33 Hct change in bloodless open-heart surgery for complete AVSD infants

In 15 complete AVSD cases, except for PH crisis cases, the aortic cross-clamp time was 78 ± 19 min, extracorporeal circulation time 113 ± 24 min, operation time 177 ± 36 min, and anesthesia time 223 ± 36 min, which were longer than that of VSD cases (25 ± 7 min, 53 ± 7 min, 104 ± 17 min, and 145 ± 19 min).

Figure 3.33 shows changes in the Hct values. During the extracorporeal circulation, all cases remained at 15.0% or more, with the exception of one case that dropped to 14.0%. Compared with VSD only in cases with a body weight of 4 kg, Hct after induction of anesthesia was significantly higher in the complete AVSD ($p < 0.02$) (6 complete AVSD cases: 36.3 ± 3.6% ⇔ 25 VSD cases: 30.6 ± 2.3%). There was no difference in the lowest Hct during extracorporeal circulation (16.4 ± 1.1% ⇔ 15.1 ± 2.0%). In addition, there was no difference in the circulating blood volume in the 4 kg cases calculated from the Hct at the initiation of extracorporeal circulation and the priming volume after the induction of anesthesia (complete AVSD: 55 ± 8 mL/kg ⇔ VSD: 57 ± 10 mL/kg).

All cases returned to sinus rhythm. The use of catecholamine at the time of weaning from extracorporeal circulation was only dopamine (4–6 γ/kg/min) in VSD. On the other hand, adrenaline (0.05 γ/kg/min) was administered prophylactically in addition to dopamine in 14 patients with complete AVSD whose extracorporeal circulation time exceeded 100 min. Except for the PH crisis case, there were no problems with weaning from the extracorporeal circulation, and no pulmonary vasodilator was used. The CVP at the time of respirator weaning was 9.4 ± 1.8 cmH_2O (7.0–12.5), which was not different from 8.7 ± 2.2 (7.0–11.5) cmH_2O in 49 VSD patients over 4.0 kg. The diuretic condition was good, and the fluid balance until the morning of the first day of the illness was −200 to −300 mL. In addition, there were no cases that showed extreme fluctuations or reductions in rSO_2 during surgery, and no problems with the cranial nervous system were observed.

Figure 3.34 shows the transition of PaO_2 from immediately after extracorporeal circulation to the weaning from the ventilator. The duration of intubation was 8.6 ± 4.3 h (2.5–17.0) in 16 complete AVSD patients. Although significantly longer than 4.0 kg or more VSD [5.1 ± 2.0 h (3.0–13.0)] ($p < 0.01$), relatively early ventilator withdrawal was possible. The average ICU stay was 4.1 days, longer than the VSD average of 2.1 days. Figure 3.35 shows the surgical course of a case with a minimum body weight of 4.0 kg.

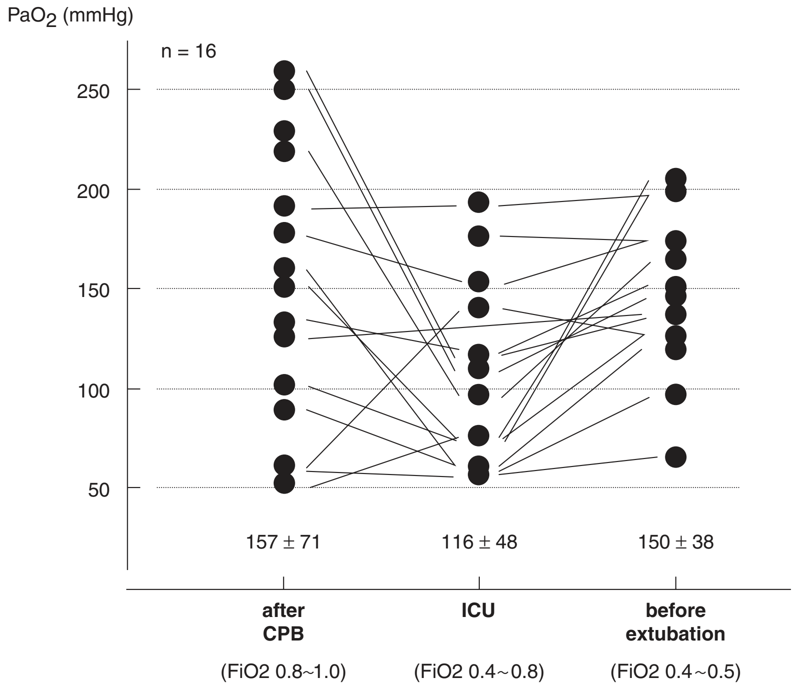


Fig. 3.34 Change of PaO_2 in bloodless open-heart surgery for complete AVSD infants

			pump on				pump off		
	CPB Time		0	20	40	60	80	100	105 min
			↑ Ao clamp		↑ GIK	↑ rewarming	↑ unclamp		
Temp. (℃)			34.8	28.6	27.3	28.2	34.8		
Blood gas	Na (mEq/l)	135	136	135	136	145	140		143
	K (mEq/l)	4.2	3.6	3.3	7.7	5.8	5.7		6.1
	B.E.	4.7	4.3	2.5	−0.6	0.2	−1.3		1.6
	Hct (%)、Hb(g/dl)	42.0 12.9	20.0 6.6	21.0 7.0	18.0 6.2	19.0 6.7	15.5 5.5		18.5
	T.P. (g/dl)	6.0	3.5	3.7	3.8	4.0	3.5		4
		Initial priming							
Correction	25% albumin (ml)	10	DUF (albumin 5 ml + Veen F 95 ml)×2						
	salin HES (ml)								
	10% NaCl (ml)				5	5			
	KCl (mEq)		2	3 1	2 2 4				
	D-mannitol (ml)	10	5		5				
	NaHCO3 (ml)	10				5	5 5		
	Veen F (ml)	150	20		20 20	20 20	20 20 20 20	30	
	C.H. (mg)		2	2	2 2 2 3	3	4		
	CaCl2 (ml)						2		

Fig. 3.35 Extracorporeal circulation in a complete AVSD case weighing 4.0 kg. Rastelli type C AVSD. Initial priming volume 195 mL. Priming fluid: Veen F 150 mL, 25% albumin 10 mL, $NaHCO_3$ 10 mL, mannitol 10 mL, VC 1000 mg, exocorpol 5 mL, CEZ 500 mg, heparin 400 u, KCL 0.4 mL. Initial priming fluid data: PH 8.1, PO_2 312 mmHg, PCO_2 12.2, BE +23.4, Na 178 mEq/L, K 5.7. Perfusion flow 150 mL/kg/min. DUF washing solution: alb 5 mL + Veen F 95 mL × 2, urine volume 238 mL, ECUM filtration volume 254 mL, fluid balance + 89 mL. Extracorporeal circulation time 105 min, operation time 159 min, anesthesia time 235 min

Column: Clinical Evaluation of Bloodless Open-Heart Surgery for Complete AVSD Infants (1999)

Complete AVSD required longer extracorporeal circulation than VSD and was often associated with severe pulmonary hypertension. Therefore, before 1996, it was excluded from applying bloodless open-heart surgery. However, for the following two reasons, a complete AVSD weighing 4 kg or more was also indicated for bloodless open-heart surgery:

1. In infantile VSD, bloodless open-heart surgery indications were expanded to a body weight of 3.5 kg, and postoperative hemodynamics and respiratory status were as good as or better than open-heart surgery with blood priming. (In VSD weighing 5.9 kg or less, postoperative duration of intubation was 11.2 ± 6.1 h for 36 patients with blood priming before September 1996, and 5.6 ± 2.8 h for 67 patients without blood priming after October 1996.)
2. Bloodless open-heart surgery became possible for incomplete AVSD, complete AVSD after pulmonary artery banding, and complete AVSD with tetralogy of Fallot (since July 1994, in 29 cases of incomplete AVSD, 8 cases of complete AVSD after pulmonary artery banding and 7 cases of AVSD with TOF, bloodless open-heart surgery was possible in all cases).

Complete AVSD cases required longer ICU management compared to that of VSD cases, but circulatory and respiratory status were generally better. Postoperative mitral insufficiency was less than trivial regurgitation, and mitral blood flow velocity was less than 1.5 m/s. These showed that bloodless open-heart surgery did not affect the repair status. In addition, there were no problems with adrenaline used prophylactically.

In infancy complete AVSD, the Hct value after induction of anesthesia was higher than that of VSD, and the circulating blood volume calculated backward was equivalent to VSD. It was shown that there is an advantage over VSD in terms of hemodilution during extracorporeal circulation.

It is considered that there are few clinical problems of performing bloodless open-heart surgery in complete AVSD up to 4 kg body weight, and it was decided to be continued thereafter. However, the lowest Hct during extracorporeal circulation was equivalent to VSD, and the rate of indication for bloodless open-heart surgery was 55%, lower than that of VSD, which was 81%. In order to expand the indication, measures such as further reduction of the priming and improvement of preoperative anemia and preoperative conditions in 3 kg cases were necessary.

3.3.7 Number of Blood Transfusions Used in Blood Priming Cases

In 47 cases of VSD less than 5.0 kg and 16 cases of complete AVSD with blood priming from January 1994 to August 1996, when the minimum priming volume was 370 mL, the rate of cases in which discharge was possible using only 200 mL or 400 mL of fresh whole blood (one pack) was 78% (37/47) for VSD and 75% (12/16) for complete AVSD (Fig. 3.36). On the other hand, from February 1997 to March 2000, when the priming volume was at least 195 mL (this is the time when bloodless open-heart surgery was performed on 63 of 85 VSD under 5.0 kg and 16 of 26 complete AVSD), the total blood usage of 22 cases of VSD with blood priming was only 200 mL in all cases, and only 400 mL in all 10 complete AVSD cases (Fig. 3.37).

Advances in bloodless open-heart surgery have also contributed to transfusion reduction in cases where transfusion was essential. However, HLHS and visceral complex syndrome required blood transfusion of 400 mL or more, which was a future issue.

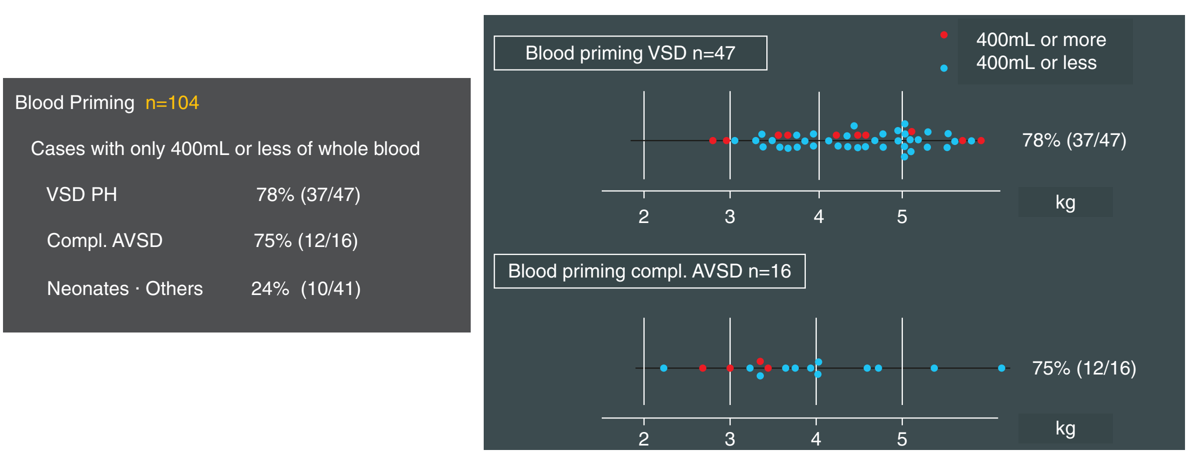


Fig. 3.36 Blood usage in cases with blood priming (minimum priming volume 370 mL)

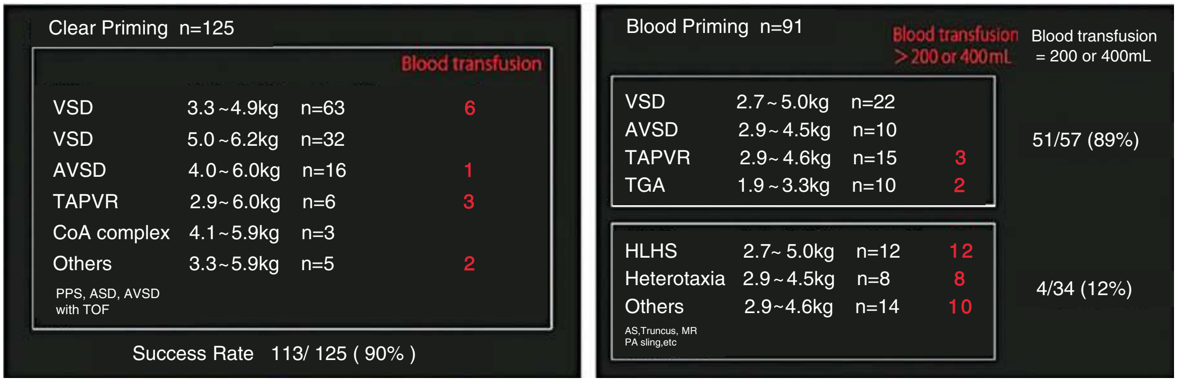


Fig. 3.37 Blood usage in cases with and without blood priming (minimum priming volume 195 mL). The number of VSD and AVSD open-heart surgery cases during this period was 117 and 28, respectively. 22 of 117 cases with VSD (19%) and 10 of 28 cases with AVSD (38%) were not indicated for bloodless open-heart surgery. It is believed that an extracorporeal circulation circuit with a priming volume of about 100 mL was necessary to improve the indication rate for bloodless

3.4 Management and Measures for Bloodless Open-Heart Surgery in Low-Weight Infant

As shown in the column "Postoperative convulsion," we experienced postoperative convulsions in 1995 when we expanded the bloodless indication of VSD to 5 kg.

In bloodless open-heart surgery in low-weight infants, there are concerns about the effects of high hemodilution on cerebral circulation and metabolism. However, cranial nervous system complications also involve factors other than hemodilution, such as oxygen delivery during extracorporeal circulation, excessive fluid balance, prolonged extracorporeal circulation, and deterioration of postoperative circulatory and respiratory dynamics. Based on these points, the management points of bloodless open-heart surgery for low-weight infants, as of 2003, are described. Figure 3.38 shows the course of performing bloodless open-heart surgery for a VSD weighing 3.7 kg and Fig. 3.39 shows the summary of management points.

3.4.1 Determination of Indication for Bloodless Open-Heart Surgery

3.4.1.1 Indication Decision by Clinical Evaluation

The final indication of bloodless open-heart surgery and its expansion will be determined case-by-case based on the patient's clinical course experience, assessment of problems, and team experience.

As shown in Fig. 3.16, postoperative pneumonia in patients who needed respirator management before surgery was one of the causes of blood transfusion in 3–4 kg VSD bloodless open-heart surgery.

Figure 3.40 shows the duration of intubation for 26 consecutive cases under body weight less than 6.2 kg who underwent bloodless open-heart surgery in 1997. AVSD with TOF case requiring respirator management before surgery required respirator management for 6 days postoperatively. And in the three cases of TAPVR, including newborns who had bloodless open-heart surgery due to rapid deterioration of the condition and blood type mismatch between mother and child, all patients required blood transfusion because of the PH crisis-like reaction postoperatively and the lack of circulating blood volume associated with the use of vasodilators. The duration of ventilator management was over 3 days.

Based on these experiences, first, cases needing preoperative ventilator management and neonates were excluded from applying bloodless open-heart surgery. Furthermore, in patients with severe pulmonary vascular resistance, the indication of bloodless open-heart surgery was determined strictly from cardiac catheterization and echocardiography, and in some cases, it was excluded. At the same time, the priming volume has been further reduced, and the extracorporeal circulation management method has been modified. After this policy decision, there were no clinical problems presumed to be involved with bloodless open-heart surgery, including previous transfusion causes such as PH crisis, pneumonia and wound infection.

Column: Bloodless Open-Heart Surgery for TAPVR

In eight cases of TAPVR who underwent surgery without blood priming in 1997–2000, bloodless open-heart surgery was possible in five cases more than 1 month old and weigh-

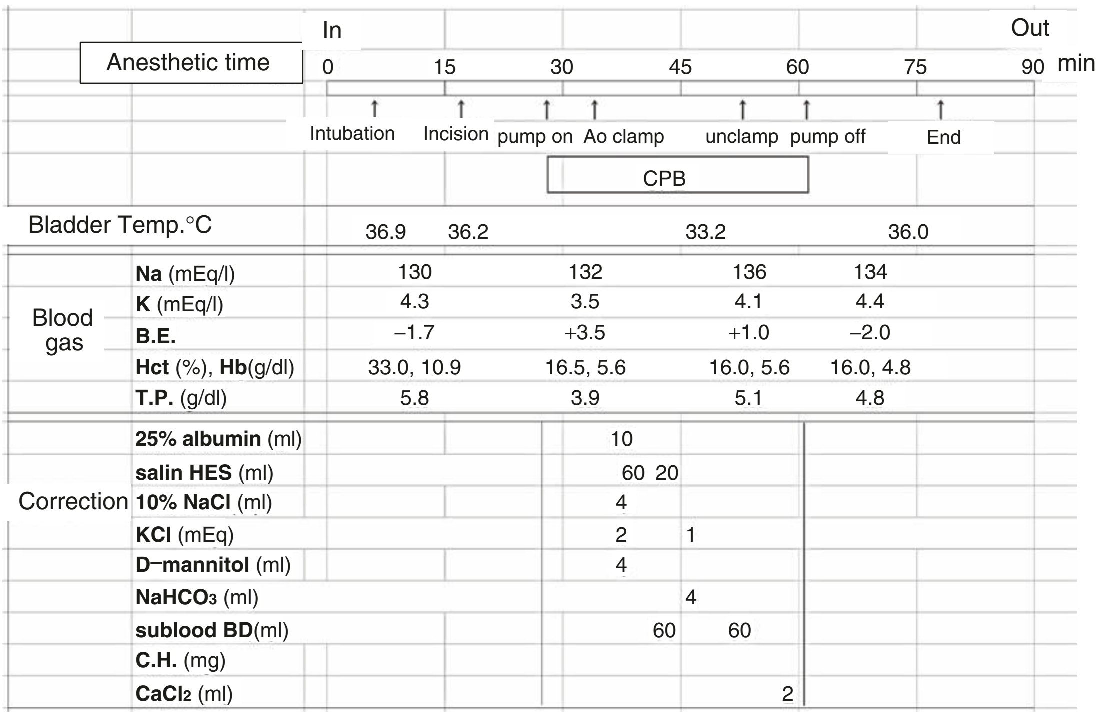


Fig. 3.38 Chart of bloodless open-heart surgery for 3.7 kg VSD [27]

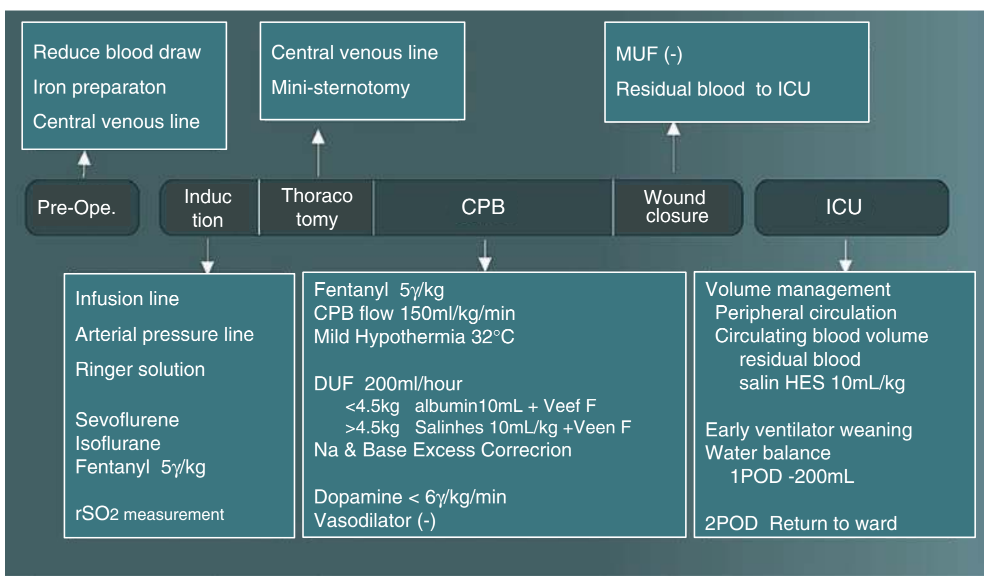


Fig. 3.39 Management points of bloodless open-heart surgery for low-weight infants

ing 4 kg or more, while blood transfusion was needed in three cases less than 4 kg, including two newborns. Hct after the initiation of extracorporeal circulation in these three cases was higher than that in VSD patients weighing 3 kg. Furthermore, there were no problems associated with hemodilution, such as progression of metabolic acidosis and deterioration of hemodynamics and the respiratory status during the operation. TAPVR was more advantageous for bloodless

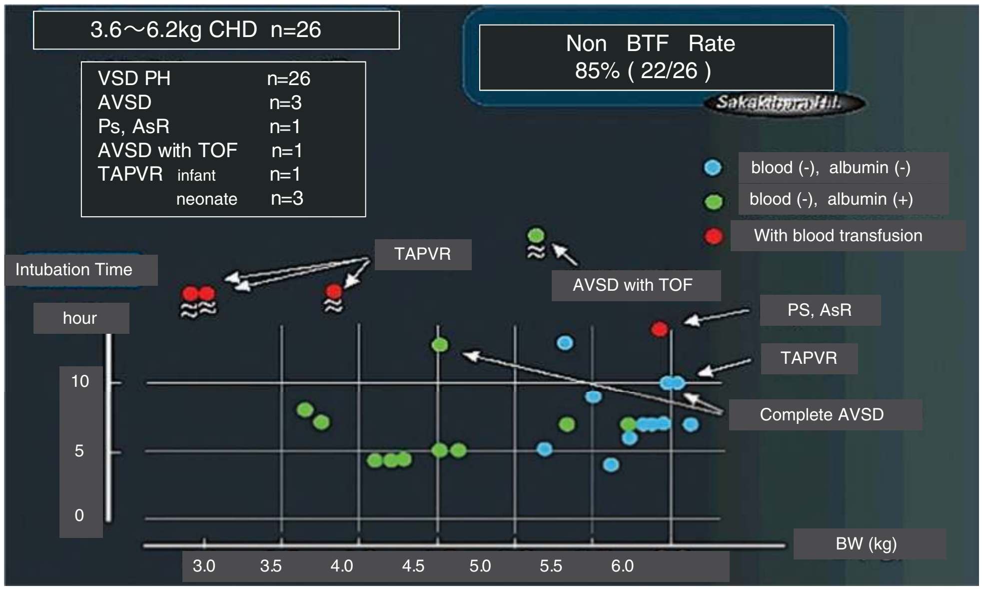


Fig. 3.40 Duration of intubation of 26 consecutive cases weighing less than 6.2 kg

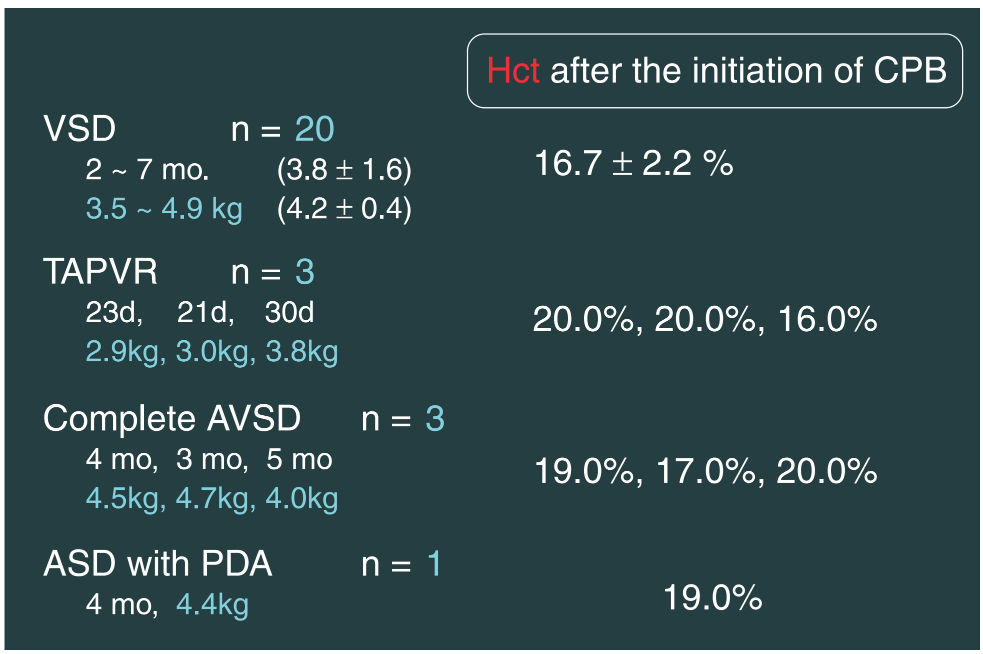


Fig. 3.41 Comparison of Hct values after initiation of cardiopulmonary bypass

open-heart surgery in terms of hemodilution (Fig. 3.41). Figure 3.42 shows the course of extracorporeal circulation in cases with a minimum body weight of 2.9 kg.

However, the above three cases required long-term ICU management. Therefore, neonates with other diseases were excluded from applying bloodless open-heart surgery.

Column: PH Crisis and Lung Pathology

In patients with severe pulmonary hypertension, cardiac function and pulmonary artery pressure were evaluated over time by echocardiography, regardless of blood or bloodless priming. Including these results, pulmonary vasodilators were not used as a general rule when there was no problem with postoperative oxygenation or diuretic status. This is because excessive vasodilation was a disadvantage of bloodless open-heart surgery in terms of postoperative volume management.

However, we experienced a case of death due to the aforementioned PH crisis. This experience has led to the need for a review of bloodless surgery indications and to consider measures to prevent PH crisis in open-heart surgery.

	pump on						pump off		
CPB Time	0	10	20	30	40	50	60	68 min	
			↑ Ao clamp		↑ rewarming	↑ unclamp			
		35.6	32.4	28.7		29.7	30.7	35.3	
Na (mEq/L)	134	134			136		138		137
K (mEq/L)	3.1	3.3			3.3		4.4		3.9
B.E.	4.7	0.1			−0.6		−1.3		−1.5
Hct (%)、Hb(g/dl)	42.0 15.0	20.0 7.3			16.0 6.5		16.0 6.1		18
T.P. (g/dl)	5.4	3.7			3.5		3.5		3.8
	Initial priming								
25% albumin (mL)	30		5			5			
Salinhes (mL)					DUF (albumin 5 mL + Veen F 95 mL)×2				
10% NaCl (mL)			3			3			
KCl (mEq)			1.6			2			
D-mannitol (mL)	10			3					
NaHCO3 (mL)	10			3		2		2	
Veen F (mL)	120	15		15	10				
C.H. (mg)						2 2			
CaCl2 (mL)							1.5	2	

Fig. 3.42 Bloodless extracorporeal circulation in TAPVR case weighing 2.9 kg

In cases where residual pulmonary hypertension or PH crisis was a concern, especially when pulmonary vasodilators were used in cases with complete AVSD Down syndrome older than 6 months, TAPVR in infancy, aortic coarctation complex, etc., we dealt with additional administration of protein preparations and Salinhes, and delaying the weaning from ventilator. And if there should be anxiety about PH crisis, blood transfusion would be immediately performed. Of course, depending on the case, blood was primed from the beginning of extracorporeal circulation, or palliative surgery and lung biopsy was performed.

In this respect, nitric oxide inhalation therapy has no systemic vasodilatory effect.

Therefore, improvement of the results of bloodless open-heart surgery was expected by this therapy to prevent PH crisis and reducing pulmonary vascular resistance after Fontan surgery.

Factors that cause PH crisis include not only the abnormal thickening of the media mentioned above but also the hypoplasia of pulmonary arterioles and cellular thickening of the intima. Figure 3.43 shows the pulmonary vascular pathological findings of a 1-month-old patient who had undergone a primary Jatene + CoA repair for Taussig-Bing anomaly and who had a PH crisis immediately after returning to ICU. The pulmonary arteriole diameter was extremely narrow compared with the bronchial diameter, and it was judged not applicable for surgery. A similar finding is seen in the 3-day-old TAPVR case shown in Fig. 3.44. Figure 3.45 shows a 5-month VSD case in which complete obliteration of the pulmonary arteriole is observed due to

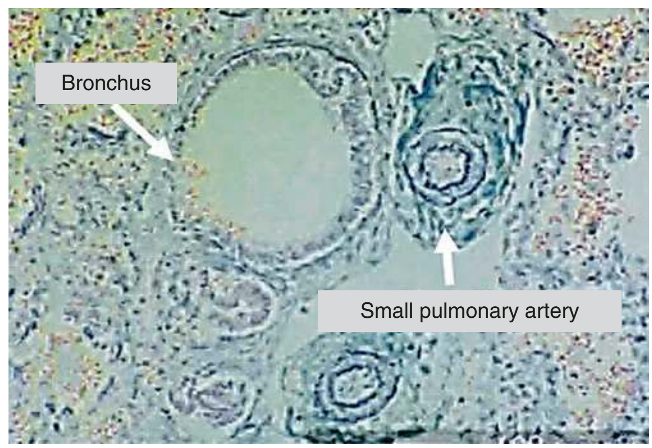


Fig. 3.43 Pulmonary vascular pathology in a Taussig-Bing anomaly + CoA case

abnormal thickening of the media and cellular thickening of the intima.

It is unclear how bloodless open-heart surgery will affect the occurrence of PH crisis in patients with these pulmonary vascular lesions. However, it is always necessary to pay attention to the occurrence of PH crisis in bloodless open-heart surgery for patients with pulmonary hypertension.

Looking at the pulmonary vascular pathology, I recall the late Dr. Shigeo Yamaki of the Japanese Research Institute of Pulmonary Vasculature. He gave me a lot of advice on determining the indication for surgery and identifying the cause of death. The remaining website of the Japanese Research

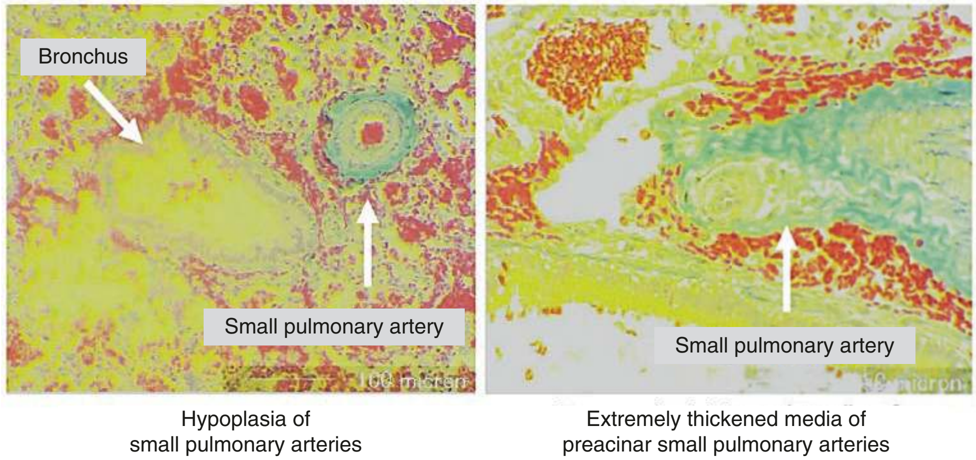


Fig. 3.44 Pulmonary vascular pathology in a TAPVR case

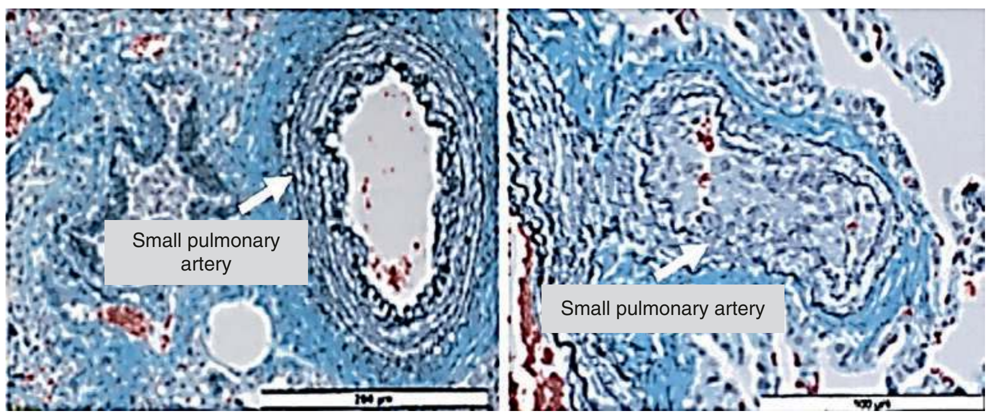


Fig. 3.45 Pulmonary vascular pathology in a VSD case

Institute of Pulmonary Vasculature shows the results of pulmonary pathology examination until October 2007. Sakakibara Heart Institute requested the lung pathological examination most frequently. I would like to take this opportunity to thank you again from the bottom of my heart [28–30].

Column: Growth After Bloodless Open-Heart Surgery in Low-Weight Infant

1. Psychomotor development after bloodless open-heart surgery in patients with body weight 3–4 kg VSD was evaluated using the Tsumori-Image mental development test. The subjects were 42 cases up to April 2000 (excluding cases with chromosomal abnormalities, cleft palate, and gestational age less than 36 weeks), and the response rate to the test was 83% (35 cases). Average age at surgery was 3.3 months (1–6), body weight 4.3 kg (3.3–4.9), extracorporeal circulation time 56 min (42–85), anesthesia time 140 min (105–180), average minimum Hct during extracorporeal circulation 15.4 ± 2.4%, dopamine usage 2.9 ± 1.9 γ/kg/min when returning to the ICU, and duration of postoperative intubation 5.4 ± 2.7 h.

Preoperative clinical problems were: three cases of ventilator management, one case of developmental delay and muscle tonus reduction, one case of low left heart function with EFE from the fetal period, and postoperative complications were: two cases of supraventricular arrhythmia, one case of wound infection, and one case of pneumonia. Three cases required blood transfusion. The causes were coagulation of residual blood, electrocardiogram ST decrease immediately after the initiation of extracorporeal circulation, and reintubation due to postoperative pneumonia.

The average age at the time of the examination was 22 months (9 months to 3 years), height −0.3 ± 1.0 SD (−2 SD or less: one case), body weight −0.3 ± 0.8 SD (−2 SD or less: none), and there were no cases of abnormalities in the cranial nervous system postoperatively. There were five developmental concerns, two with poor weight gain, two with slightly slower language development, and one with walk delay. Tsumori-Image mental development index (development age/calendar age × 100) was 102 ± 15, among which four cases with preoperative problems such as preoperative ventilator management declined to 73–83% were

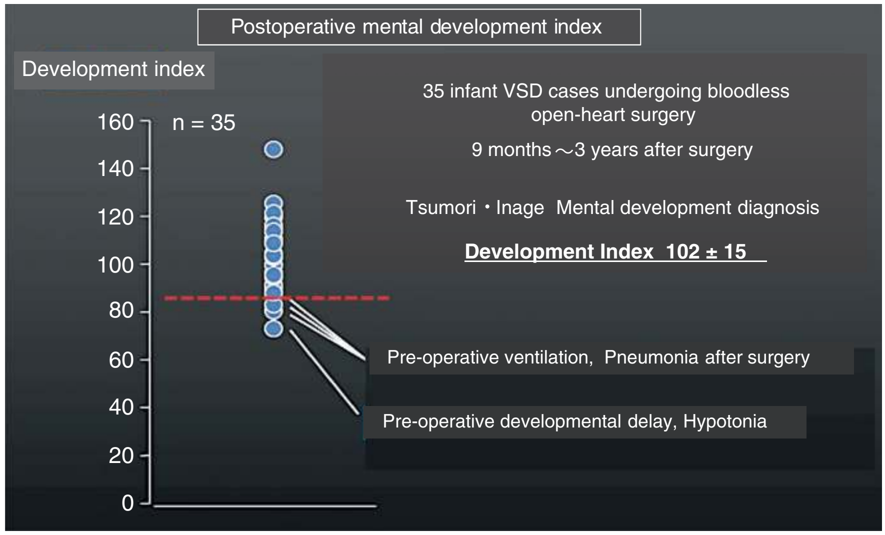


Fig. 3.46 Psychomotor development index after bloodless open-heart surgery in body weight 3–4 kg VSD [31] modified

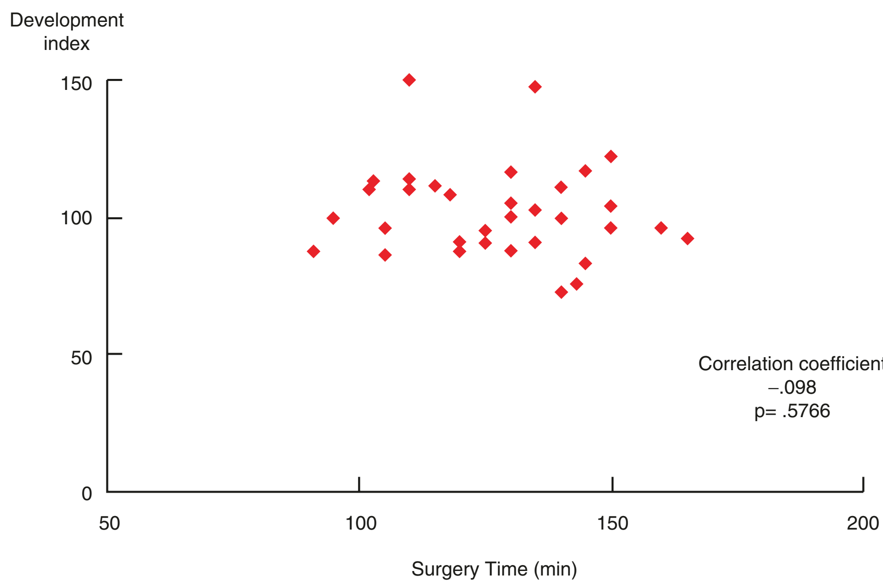


Fig. 3.47 Relationship between surgery time and mental development index

observed (Fig. 3.46). This was the reason why preoperative ventilator management cases were not indicated for bloodless open-heart surgery. The remaining 31 cases averaged 105% and were within the normal range in all cases. The postoperative psychomotor development of patients with no preoperative problems was considered normal (2001).

2. After that, only 35 cases with a survey age of 1 year (12–23 months) were examined for the effects of the minimum Hct during the extracorporeal circulation and the operation time on the psychomotor development index (Figs. 3.47 and 3.48). Average age at surgery: 3.1 months (1–6), body weight 4.4 kg (3.3–4.9), extracorporeal circulation time 54 min (36–85), anesthesia time 129 min (91–165), minimum Hct 15.6% during extracorporeal circulation (12–21).

There was no significant correlation between the minimum Hct during extracorporeal circulation and the operation time on the mental development index (2002).

3. A similar study was conducted 1 year later.

The subjects were 41 cases (71%) where responses to the test were obtained among 58 cases. Age at study 35 ± 3 months (28–42), mean age at surgery 2.9 months (1–6), body weight 4.3 kg (3.3–4.9), extracorporeal circulation time 53 min (38–76), anesthesia time 130 min (93–180), and the lowest Hct 15.2% (11–21) during extracorporeal circulation. Preoperative clinical problems include one case of low left ventricular function with EFE from fatal period, one case of ventilator management, one case of developmental delay and muscle tonus reduction, one case of unique facial,

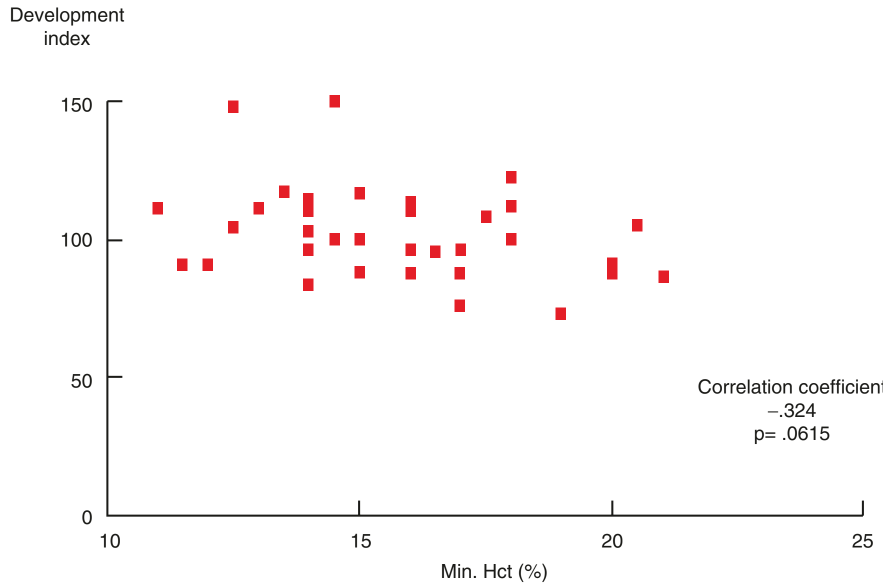


Fig. 3.48 Relationship between minimum Hct and mental development index [32] modified

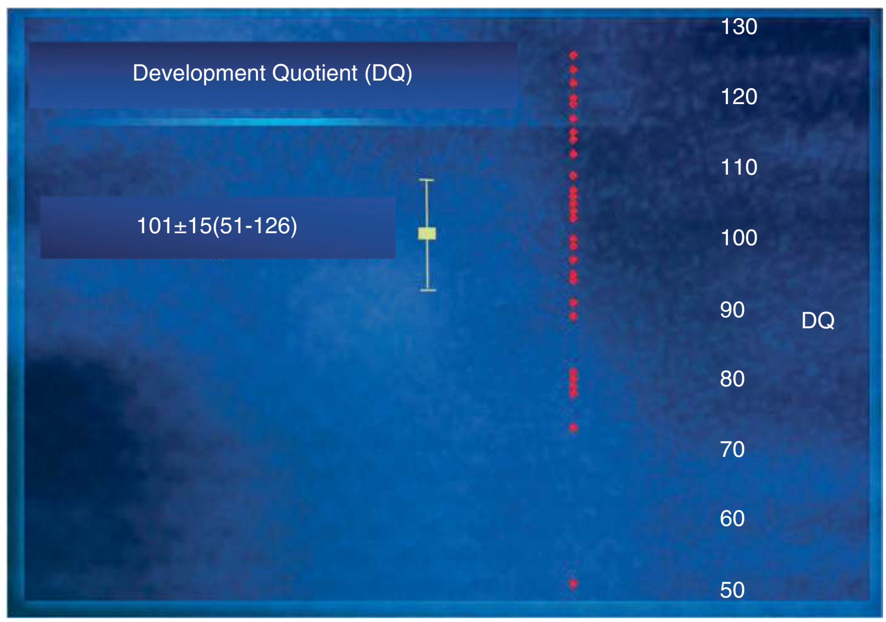


Fig. 3.49 Psychomotor development quotient after bloodless open-heart surgery in body weight 3–4 kg VSD

one case of funnel chest. Postoperative complications were two cases of supraventricular arrhythmia and two cases of pneumonia, and blood transfusion was performed in one case of preoperative ventilator management. Height at the time of investigation −0.3 ± 1.1 SD (−2 SD or less: one case), body weight −0.4 ± 0.8 SD (−2 SD or less: one case). There were no cases of abnormalities in the cranial nervous system.

There were five cases of developmental worries, two cases of poor weight gain and three cases with slightly slower language development. Tsumori-Image mental development index (development age / calendar age × 100) was 101 ± 15 (51–126) (Fig. 3.49). There was no significant correlation between mental development index and anesthesia time or minimum Hct during extracorporeal circulation (Figs. 3.50 and 3.51). Figure 3.52 shows the mental development index of cases with clinical problems before and after surgery, and Fig. 3.53 shows six cases with a mental development index of less than 85. Four of them are cases with preoperative problems, and there was a high possibility of developmental delay, especially in cases of preoperative ventilator management.

However, two of these patients had no problems before and after surgery. In these two cases, the effects of bloodless open-heart surgery should not be ruled out, so further observation was necessary in the future. Furthermore, Fig. 3.54

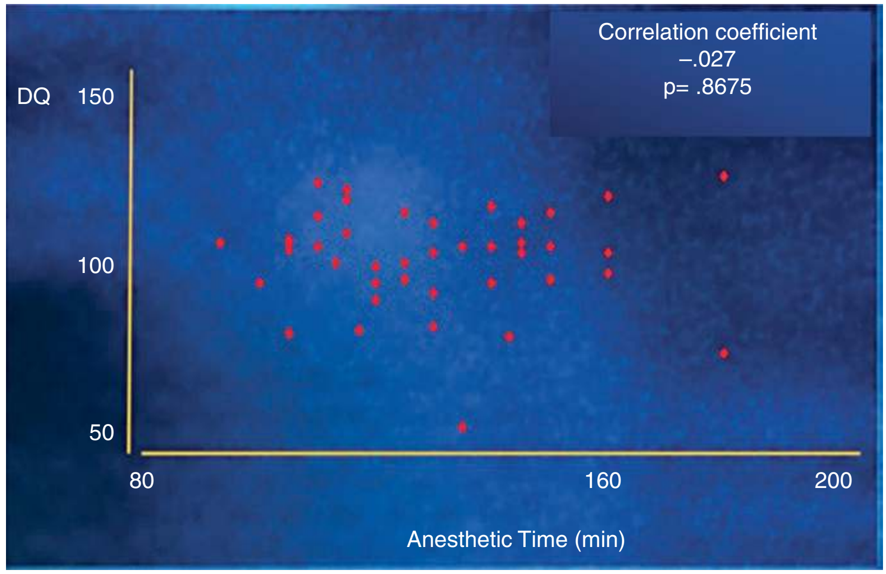


Fig. 3.50 Relationship between anesthesia time and mental development quotient

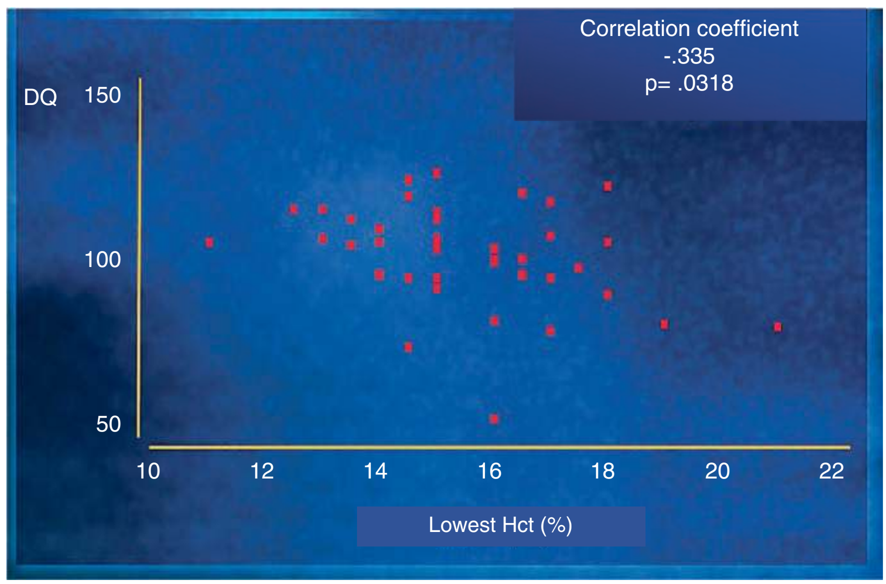


Fig. 3.51 Relationship between minimum Hct and mental development quotient

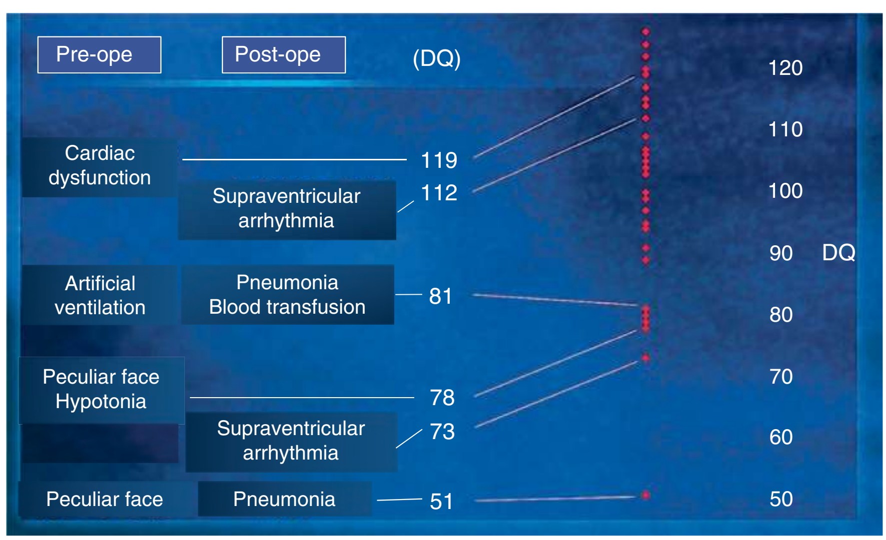


Fig. 3.52 Mental development quotient in case with clinical problems

Fig. 3.53 Six cases with mental development quotient less than 85

	DQ	Age (mo)	BW (kg)	Anesthesia (min)	Lowest Hct (%)	Perioperative course
1	51	2	3.4	135	16.0	Peculiar face Pneumonia
2	73	5	4.5	180	14.5	Hypotoia
3	78	4	4.3	143	15.5	Peculiar face
4	79	3	4.4	105	14.0	(-)
5	80	6	4.9	117	18.5	(-)
6	81	3	4.1	130	16.0	Artificial ventilation Pneumonia Blood transfusion
	101	2.9	4.3	130	15.2	(Average)

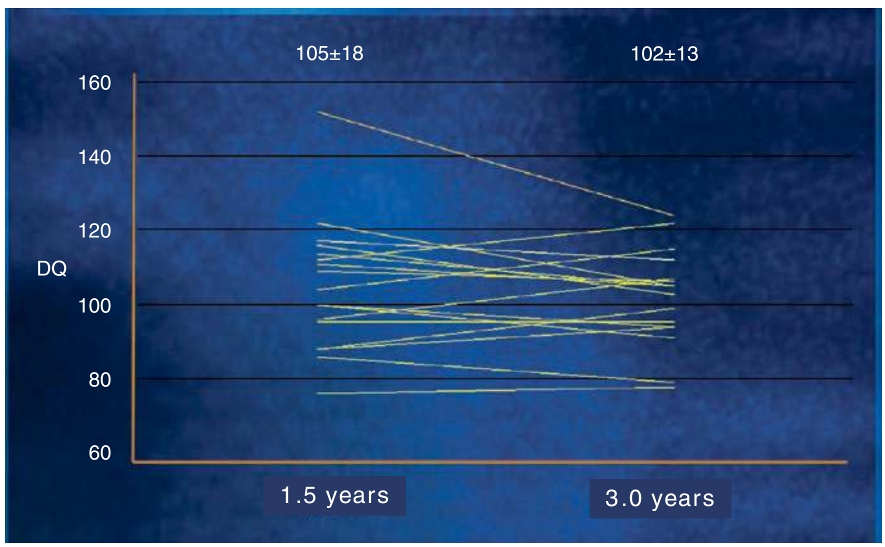


Fig. 3.54 Changes in mental development quotient

shows 17 cases that could be investigated over time (average age at survey: 22 months and 35 months), but there was no change from 105 ± 18 to 102 ± 13 (2003) [1, 31–36].

Conclusion

Although only Tsumori and Image mental development tests were evaluated, psychomotor development after bloodless open-heart surgery in patients weighing 3–4 kg was generally within the normal range. Therefore, we decided to continue bloodless open-heart surgery for infant VSD.

However, the development of cases with clinical problems before surgery tended to be delayed. In these cases, it would be necessary to review the timing of surgery and the indication of bloodless open-heart surgery. Of course, many factors, not just hemodilution, are involved in the late psychomotor development delay. Deterioration of perioperative conditions and long-term treatment can also have a significant impact. Therefore, in the future, it is important for surgeons to consider the minimally invasive surgery from the viewpoint of development and growth.

At present, the problems of development and mental growth are not just issues for pediatric cardiovascular medicine. I personally think that the most important thing in group life is to be able to hear people first (auditory short-term memory) and to have sufficient discussion. I would like to think about measures that should be taken during the perioperative period to prevent this developmental disorder.

3.4.1.2 Indication Decision by Hemodilution

Since 1997, the reduction of priming volume had progressed further, and patients with a body weight of 3 kg or more who were predicted to have Hct of 15% or more after the initiation of extracorporeal circulation had been indicated for bloodless open-heart surgery. Empirically, if an heart–lung system with a priming volume of 130 mL was used and Hct was 28–30% after induction of anesthesia, the standard of Hct 15% could be met even in cases with a body weight of 3 kg.

However, surgery within 1–2 days after cardiac catheterization, so-called Cath-op, may cause anemia beyond expectations. It is necessary to cooperate with pediatricians, including reduction of blood sampling in the catheter and preoperative examinations and oral administration of iron preparations.

On the other hand, the standard for using protein preparations was that the total amount of protein in the extracorporeal circulation was less than 3.0 g/dL.

Prior to 1996, when the minimum priming volume was 370 mL, patients with a body weight of 5 kg or more were indicated for bloodless open-heart surgery and no protein preparation for 6.0 kg. Currently, excluding cases with clinical problems before surgery, cases with body weight of 4 kg or more are replaced with Salinhes without using a protein preparation, and 20 mL of albumin is prophylactically primed only for 3 kg cases. These criteria are values determined from clinical evaluations in which the postoperative quality is not deteriorated.

Blood and protein preparations should not be used after Hct, and total protein levels have fallen below acceptable levels. Rather, it is important to accurately predict the need to use them prior to surgery and to make initial primings if deemed necessary.

Column: Hct After Induction of Anesthesia (1998)

In the initial 14 cases of bloodless open-heart surgery for VSD weighing 3.5–4.8 kg (Fig. 3.55), the average Hct after induction of anesthesia was 30.4%, and the Hct after the initiation of extracorporeal circulation was 15.0% or more except for one case.

When the circulating blood volume was calculated backward from the measured Hct value and the priming volume, a relational expression of circulating blood volume = body weight × 57 + 17 ($r = 0.67$, $p < 0.01$) was obtained. Using this formula, the Hct after induction of anesthesia required for Hct to be 15% or more after the start of extracorporeal circulation was 28% or more in patients with body weight 3–4 kg VSD.

Since then, in bloodless open-heart surgery for low-weight infants using a 195 mL priming volume circuit, Hct 28% or higher after anesthesia induction became the standard for bloodless surgery indication.

As shown in the column "Priming Volume of ECUM Circuit" (Chapter 2, p.58), the ECUM circuit priming volume was reduced to 25 mL by using the hemofilter PANFLO (priming volume 12 mL) and the small pump BP 75cIII as an ECUM pump.

In 20 consecutive VSD patients weighing 3.5–4.9 kg who were able to perform bloodless open-heart surgery, the Hct in the extracorporeal circulation was compared between 7 cases (4.1 ± 0.4 kg) using a conventional ECUM circuit with priming volume of 80 mL and 13 cases (4.2 ± 0.5 cm) using the new circuit with priming volume of 25 mL. In the 80 mL group, there was a significant Hct decrease of 2.8% on average, whereas, in the 25 mL group, no decrease was observed (Fig. 3.56). Reduction of ECUM circuit priming volume was also necessary to prevent hemodilution.

Figure 3.57 shows the change in Hct in 71 consecutive patients who underwent bloodless open-heart surgery for VSD weighing 3–4 kg. As shown in Fig. 3.15, the minimum Hct during extracorporeal circulation showed an increasing trend. In some cases (for example, low-weight but relatively tall cases), the indications for bloodless open-heart surgery have expanded to cases where Hct is around 25% after induction of anesthesia.

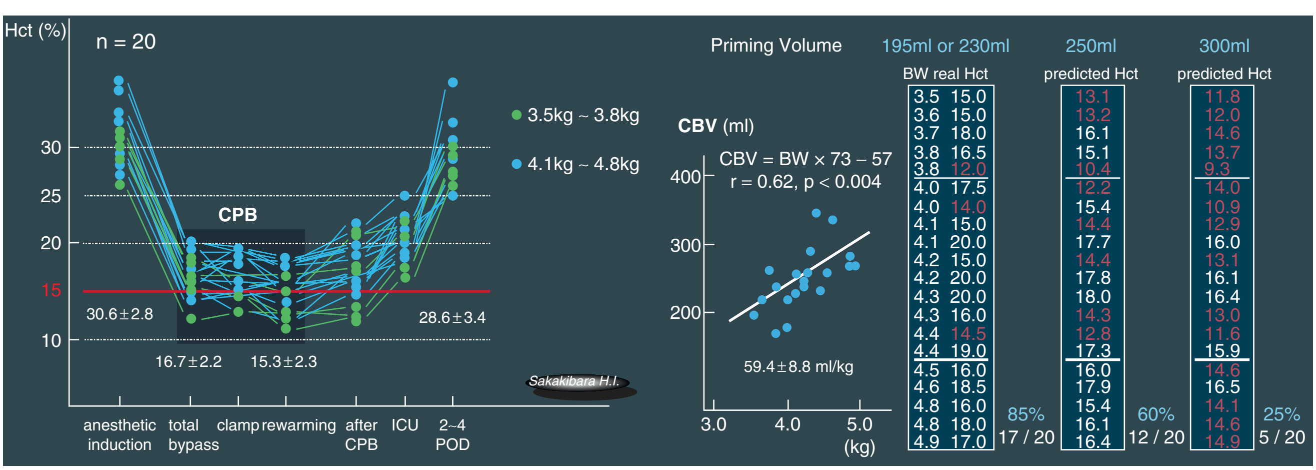


Fig. 3.55 Hct change, circulating blood volume and predicted Hct in bloodless open-heart surgery in VSD cases weighing 3.5–4.8 kg VSD

Fig. 3.56 Comparison of Hct during CPB between 83 mL and 25 mL of ECUM circuit priming volume [37]

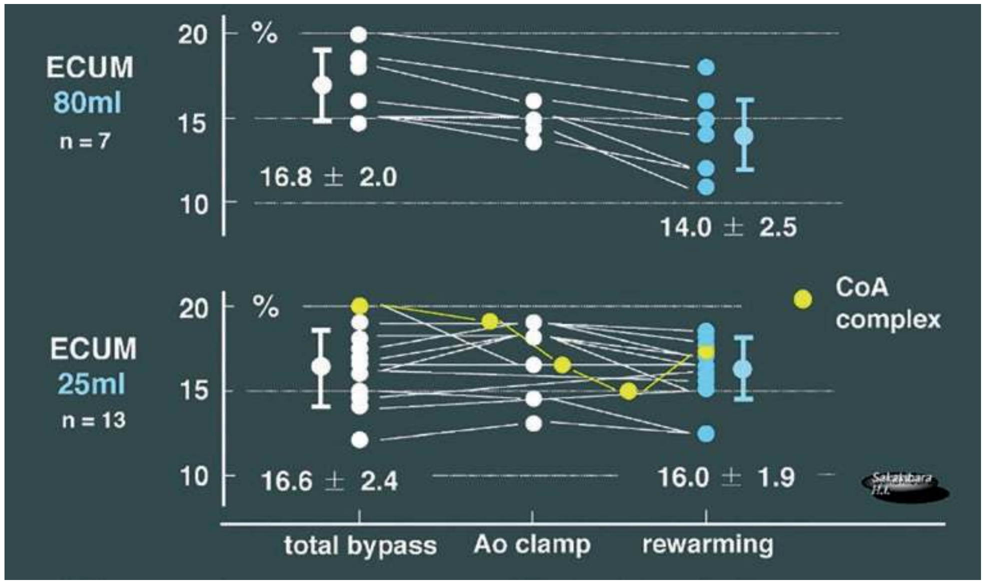
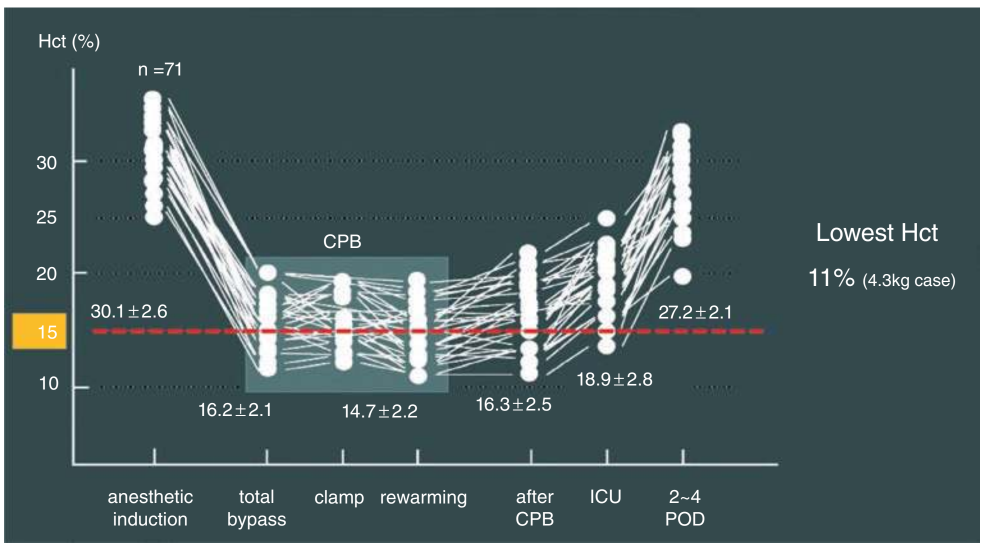


Fig. 3.57 Hct change in 71 consecutive VSD infants weighing 3–4 kg who underwent bloodless open-heart surgery. From the time of aortic cross-clamp to rewarming, there were some cases in which there was no decrease in Hct



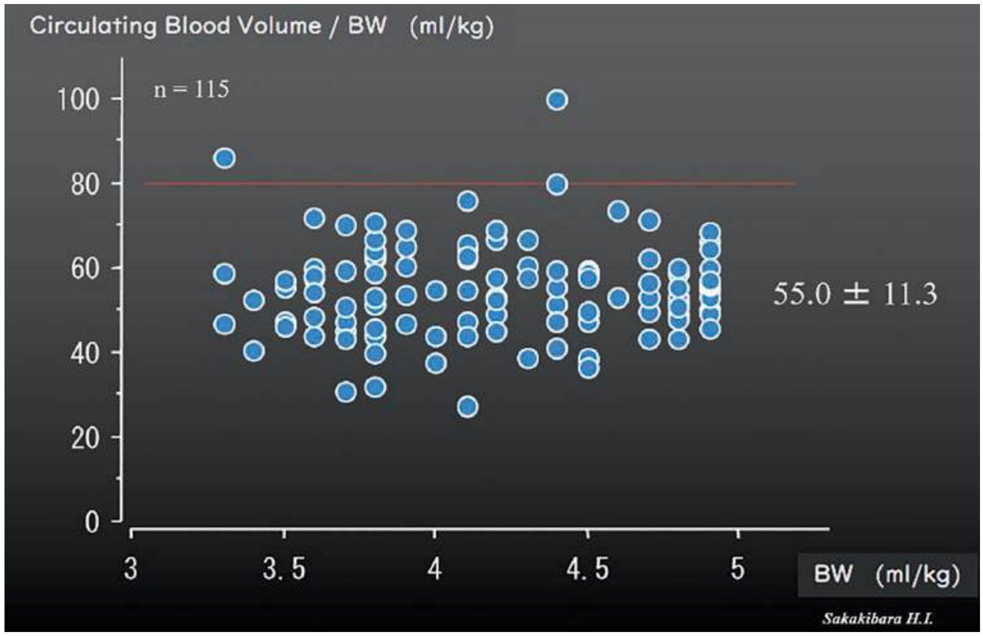
Column: Priming Volume Required for Bloodless Open-Heart Surgery in Low-Weight Infants (2002)

Hct during extracorporeal circulation varied from patient to patient even at the same body weight, and even when the body weight was 4 kg or more, it might decrease more than expected. For the purpose of reducing the priming volume further, the minimum acceptable Hct after the initiation of extracorporeal circulation was set to five levels, and using the circulating blood volume (Fig. 3.58) calculated from 115 bloodless open-heart surgery infants with VSD weighing 3–4 kg, the initial priming volume required to exceed the five acceptable Hct levels was calculated (Fig. 3.59).

The current minimum priming volume is 130 mL for cases of 4.5 kg or less using a Isolated pump-controller heart–lung machine, 160 mL for 5.9 kg or less, and 220 mL for 11.9 kg or less using a conventional heart–lung machine. Assuming an acceptable Hct of 15%, bloodless open-heart surgery is possible in the case of VSD patients weighing 3–4 kg even with the current priming volume. However, with an acceptable Hct of 18%, 65% (75/115) cases were judged to be indicated for bloodless open-heart surgery, and with an acceptable Hct of 20%, only 33% (38/115) (Table 3.5). In order to increase the acceptable Hct, it was considered that it would be necessary to create a circuit with a priming volume of less than 100 mL in the future [24].

Figure 3.60 shows the circulating blood volume in 101 infants with body weight of 2.9–9.7 kg who underwent open-heart surgery without blood priming using a circuit with a priming volume of 195–470 mL. Only 16 cases (16%) had a circulating blood volume of “body weight × 80 mL” or more.

Fig. 3.58 Circulating blood volume of VSD infants weighing 3.3–4.9 kg [38] modified



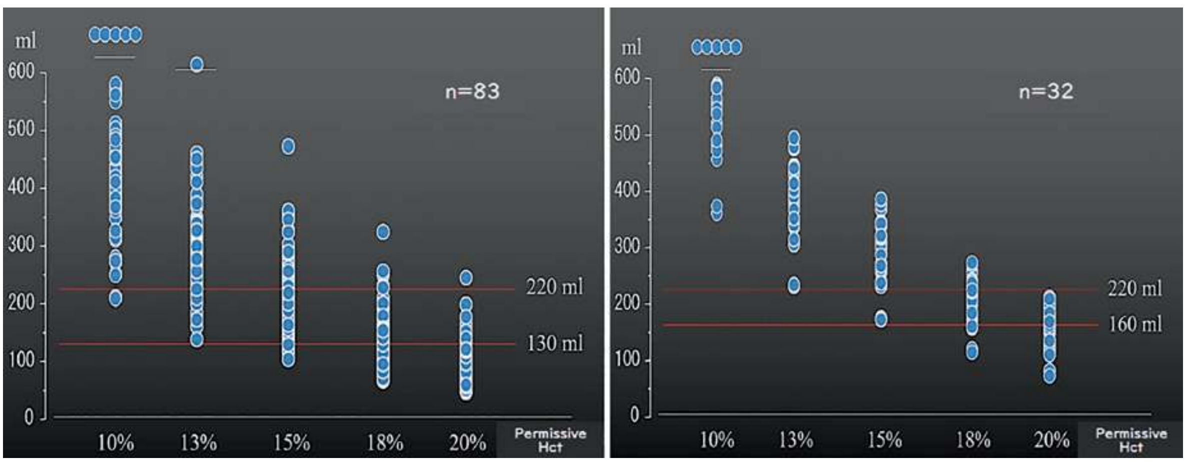


Fig. 3.59 Required initial priming volume for each permissive Hct levels [38] modified

Table 3.5 Indication rate for bloodless open-heart surgery by each permissible Hct

Permissive Hct	10%	13%	15%	18%	20%
New machine	115/115 100%	115/115 100%	108/115 94%	75/115 65%	38/115 33%
Conventional machine	113/115 98%	97/115 84%	67/115 58%	16/115 14%	1/115 0.7%

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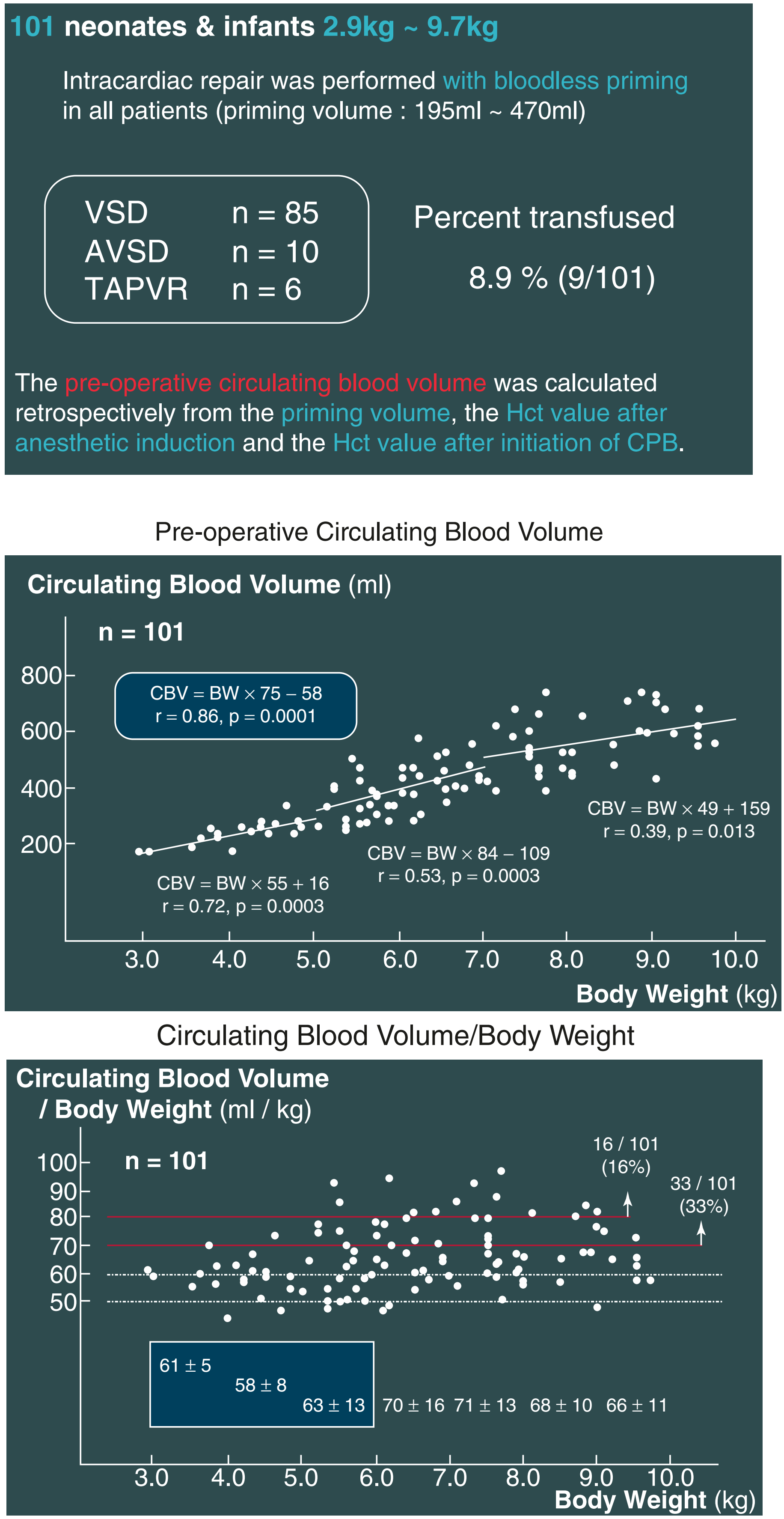

Fig. 3.60 Circulating blood volume in CHD cases weighing 2.9–9.7 kg [39] modified. The calculated circulated blood volume is different from the actual circulated blood volume, which is influenced by the amount of bleeding from the induction of anesthesia to the extracorporeal circulation, the infusion volume, and the operation time. However, at our institution, we consider this as a more practical and clinically useful formula for determining the correct hemodilution

Column: Protein Preparations (2000)

Along with the reduction in priming volume, the indication for bloodless open-heart surgery without the use of protein preparations gradually expanded to low-weight children.

After clinical application of isolated pump-controller heart–lung machine, patients who weighed more than 4.5 kg were indicated for bloodless open-heart surgery without the use of protein preparations, and Salinhes was substituted (Fig. 3.61).

In the study of bloodless open-heart surgery without the use of protein preparations in 14 cases of VSD weighing 4.5–4.9 kg, the total protein level in 2 cases was less than 3.0 g/dL. However, the recovery was rapid, and when returning to ICU, the average value recovered to about 80% of the preoperative value and was comparable on days 2–4 (Fig. 3.62).

Unlike the change in Hct, there was no decrease in total protein during rewarming.

Finally, we decided not to use protein preparations for cases with a body weight of 4.0 kg or more using an extracorporeal circuit with a priming of 130 mL and an ECUM circuit with 25 mL. Also, during this period, the priming volume of the circuit used for cases with a body weight of 17 kg or less was reduced to 370 mL, and this greatly contributed to the reduction of protein preparation usage, especially in the cases of 1–3 years old infants who required a long extracorporeal circulation.

Column: Arterial filter 2

In the 1990s, the minimum priming volume of the arterial filter was 35 mL, which was relatively excessive. In addition, there was much debate about its necessity because of the doubt about the air removal ability of the arterial filter and the air removal capability inherent to the membrane oxygenator. There were many hospitals that actually did not use arterial filters. It was a time when more detailed research was

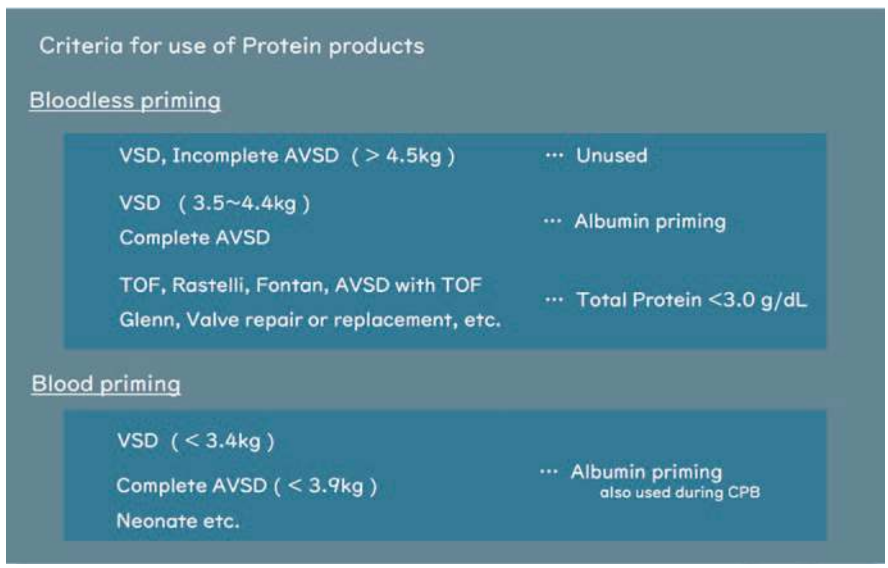

Fig. 3.61 Guidelines for the use of protein products

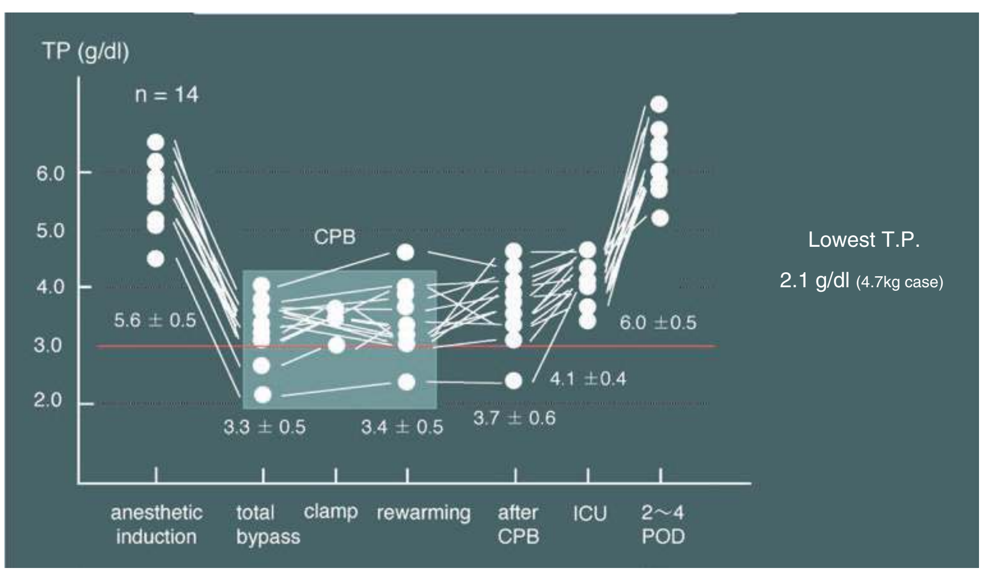

Fig. 3.62 Total protein during bloodless open-heart surgery without using protein preparations for VSD weighing 4.5–4.9 kg

needed, especially on the use of arterial filters in pediatric open-heart surgery.

In 2000, the author also stated, “With regard to the need for an arterial filter in children, detailed evaluation of microembolization using pulse doppler, measurement of S-100 protein, and psychomotor development in the remote postoperative period is necessary. In the experience of bloodless open-heart surgery in an infant weighing 3 kg, neurological abnormalities associated without the use of arterial filter were not clinically observed, and postoperative quality including hemodynamics and respiratory status is not different from cases with body weight of 4 kg or more using an arterial filter. However, sub-clinical problems cannot be denied. Although not perfect, the effect of removing microbubble by the arterial filter is obvious. Development of an arterial filter with low volume and high efficacy is desired for bloodless open-heart surgery in low-weight infants.”

As for cranial nervous system complications, since 2000, it has been found that there is a problem of delayed psychomotor development in the postoperative period and intracerebral lesions that are not manifested as clinical symptoms in the postoperative acute stage. Of course, the exclusion of arterial filters is not the only cause. Even at that time, revisions were made to the extracorporeal circulation perfusion for sufficient oxygen delivery and perioperative management methods to stabilize circulation and respiratory dynamics. However, when the arterial filter is not used, microembolus smaller than the filter pore size captured by the arterial filter surely flow into the living body. It is considered essential for extracorporeal circulation. At present, high-performance and ultra-small arterial filters have been developed and are now used in all cases [40].

However, it is also true that the effectiveness of the low-volume arterial filter is questionable in terms of the removal of microbubbles described later. The generation of microbubbles during extracorporeal circulation and countermeasures are described in Chap. 2.

3.4.2 Surgery

Most of the surgical results and postoperative quality are determined by the quality of the operation itself. Therefore, the surgeon must aim to make a perfect repair and allow the patient to return to the ICU in a minimally invasive status. Minimizing invasiveness requires thorough SIRAB measures and “Constant Perfusion” as mentioned previously, but quick surgery is the most direct minimally invasive procedure for children. In fact, in bloodless open-heart surgery for VSD with a body weight of 3–4 kg, postoperative duration of intubation has no correlation with the minimum Hct, whereas extracorporeal circulation time, operation time, and anesthesia time have significant correlation (refer to p95).

Also, as will be described later, appropriate volume management after extracorporeal circulation is important for enhancing the success rate of bloodless open-heart surgery. Specifically, the target time for facilitating volume management is 15–20 min from operating room entry to incision, 30 min to aortic cross-clamp, 20 min to close VSD, 20 min to close chest, and anesthesia time of less than 100 min.

Shortening the time in VSD open-heart surgery is also essential for expanding the indication of bloodless open-heart surgery in other diseases that require longer duration. Time reduction is the most important factor in enhancing postoperative quality of pediatric bloodless open-heart surgery. With anesthesiologists, nurses, and perfusionists, it is necessary to understand the problems that can occur in the flow of surgery and establish smooth cooperation.

The development of surgical teams and time saving will be discussed in PART III.

3.4.3 Anesthesia Management

Attention should always be paid to the quality of “Constant Perfusion.” In particular, urine volume during extracorporeal circulation is an important indicator. However, for the success of bloodless open-heart surgery, management from the end of extracorporeal circulation until ICU return is more important.

Increasing Hct does not necessarily increase oxygen delivery. In order to increase oxygen delivery, it is first of all necessary to determine the dose of catecholamine from the evaluation of cardiac function and repair status, and then adjust the circulating blood volume taking into account permissive anemia. In addition to diuresis, confirm basic data improvements such as increased peripheral temperature, increased arterial pressure, decreased heart rate and lactate levels.

In bloodless open-heart surgery, diuresis after returning to the ICU is generally good, and a relatively large volume is required until peripheral circulation improves. It is also an important task for anesthesiologists to have the surgeon expedite hemostasis and chest closure time to ensure about 100 mL of residual blood when returning to the ICU.

In situations where the use of blood and protein preparations is reduced, prolonged surgery is stressful for the team. In cardiac surgery using extracorporeal circulation, anesthesia itself is considered to be a cause of invasion of the living body, and naturally, it should be shortened (Fig. 3.63).

The basic anesthesia method is as follows. Premedication is atropine sulfate 0.01–0.015 mg/kg and diazepam 0.4 mg/kg, given 2 h before admission. GO + sevoflurane is used

Sufficient Oxygen Delivery → Adequate Circulating Blood Volume
(Permissive Anemia & Volume Management)

① Fast Chest Closure
(Use 100 mL of residual blood in ICU)
② Confirm the Peripheral Circulation Status
(Heart Rate ↓ Blood Pressure ↑ Lactic Acid ↓)

Fig. 3.63 Management points of infant after extracorporeal circulation. This figure was used in the 2002 lecture. The shortening of the chest closure time is the point that makes ICU volume management easier. Permissive Anemia: it means to accept anemia and manage patient. What is important for this management is that oxygen delivery is determined not only by blood concentration but also by circulating blood volume, so the cardiac function should be first stabilized and then secure a sufficient intravascular volume

to introduce anesthesia, and a peripheral infusion route is secured. Intratracheal intubation is performed with vecuronium bromide 0.1 mg/kg and fentanyl citrate 5 γ/kg, and at the same time, an arterial pressure line is secured, and urination is performed. The central venous line (double lumen) is inserted through the femoral vein in parallel with the thoracotomy. In cases where a central venous line is secured during preoperative cardiac catheterization, anesthesia is introduced with diazepam 0.4 mg/kg, vecuronium bromide, and fentanyl, and at the same time, peripheral infusion routes and arterial pressure are secured. For ASD and VSD weighing over 10 kg, an external jugular vein line for central venous pressure measurement is secured.

Thereafter, anesthesia is maintained with balanced anesthesia of diazepam, GO + isoflurane, and fentanyl. Veen F and Solita T3 are used for infusion. After the introduction of anesthesia, regional brain oxygen saturation is continuously monitored.

Heparin sodium 2 mg/kg and methylprednisolone 15 mg/kg are administered before extracorporeal circulation, and protamine sulfate 2 mg/kg is administered after extracorporeal circulation. Dopamine is administered at 5 γ/kg/min or less when weaning from extracorporeal circulation, and adrenaline 0.025–0.05 γ/kg/min is prophylactically added for long-term extracorporeal circulation. As a general rule, vasodilators and nitric oxide are not used.

3.4.4 Management of Extracorporeal Circulation

This article describes the bloodless extracorporeal circulation for VSD in 2002.

3.4.4.1 Initial Priming Composition

The priming composition of short-term extracorporeal circulation consists of D-mannitol 2.5 mL/kg, $NaHCO_3$ 1 mL/kg, heparin sodium 100 u/kg, vitamin C 1 g, cefamezin 200 mg. For cases with a body weight of 4.0 kg or more, Salinhes 10 mL/kg is added, for 3.9 kg or less, 20 mL of 25% albumin is added, and then add Sublood-BD to make the total amount. On the other hand, for long-term extracorporeal circulation such as complete AVSD and cyanotic heart disease, exocorpol, which amounts to 1% of priming volume + circulatory blood volume calculated by the body weight × 0.8 × 100 is added (not used with polyolefin membrane oxygenator; refer to Column "Problems with surfactants" on page 48). After priming, pancuronium bromide 2 mg, KCl 0.4 mEq, ulinastatin 5000 u/kg are added, and methylprednisolone 15 mg/kg and fentanyl citrate 5 γ/kg are administered immediately after the initiation of extracorporeal circulation.

In long-term extracorporeal circulation, pancuronium bromide 1 mg, exocorpol 5 mL, vitamin C 500 mg, and D-mannitol 4 mL are added in the first hour, and cefamezine 200 mg is added in the second hour.

3.4.4.2 Extracorporeal Circulation Method

In extracorporeal circulation, neurological problems and deterioration of cardiopulmonary function may occur even under safe conditions without hemodilution. "Constant Perfusion" should be thoroughly performed with no fluctuation in all aspects of blood flow, electrolyte and acid-base balance, and inflammatory reaction substances. It is important to keep in mind to maintain sufficient oxygen delivery to systemic organs, especially paying attention to lactic acid levels and diuretic status. Extracorporeal circulation perfusion rate is 150 mL/kg/min or more at mild hypothermia of 32–33 °C.

Monitoring of arterial blood during extracorporeal circulation is performed twice immediately after achieving total flow and during aortic cross-clamp. Electrolyte and base excess should be corrected thoroughly. The target Na value is

135–140 mEq/L. It is especially important to make a preventive correction in extracorporeal circulation when not using albumin (refer to Chap. 1, Q&A Sodium and Edema).

Deterioration of circulation and respiratory dynamics leads to prolonged treatment. Measures against SIRAB are necessary even for short-term extracorporeal circulation. High-flow rate DUF using polyacrylonitrile membrane hemofilter is performed for the purpose of suppressing vasoactive substances. For washing fluid, 5 mL/kg of Salinhes and Sublood-BD for short-term extracorporeal circulation are used, and albumin for long-term extracorporeal circulation is added. The target filtration rate is 200 mL/h.

After the extracorporeal circulation, 60 mL of residual blood is given to the anesthesiologist. Residual blood in the heart–lung system is collected in a blood bag without being concentrated. Hemodynamics after bloodless open-heart surgery is generally good. Because the chest closure is rushed to leave 100 mL of residual blood for ICU management, MUF for the purpose of improving hemodynamics is almost unnecessary.

In order to reduce the priming volume, a method of emptying the venous circuit and initiating extracorporeal circulation according to retrograde autologous priming is also useful, and a reduction of about 30 mL is possible. However, in reality, the reservoir level at the initiation of extracorporeal circulation is often not maintained, and volume is often added, and this method is not currently used. But this experience has enabled stable extracorporeal circulation even at low reservoir levels.

When cutting the circuit, care is taken not to spill the priming fluid and returned it to the venous line. This increases the reservoir level by 5–10 mL. For bloodless open-heart surgery, it is important to maintain reservoir levels and minimize the addition of protein preparations and crystalloids, which requires good venous drainage. At the initiation of extracorporeal circulation, blood is slowly and slightly over-drainaged while maintaining blood pressure. After confirming that the upper and lower venous drainage is good at half flow, flow is increased to total. This increases the reservoir level by approximately 30 mL and collects blood for blood GIK (cardioplegia). During extracorporeal circulation, close cooperation with the perfusionist is maintained regarding the quality of venous drainage. Good venous drainage is most important for fluid balance management.

Q&A: Bloodless extracorporeal circulation (Question in 2007)

Question: What are the tips for bloodless extracorporeal circulation?

Answer: I will talk not only for bloodless extracorporeal circulation. During the extracorporeal circulation, the surgeon asks the perfusionist several times, "Is everything OK?" The word "OK" has many meanings. These include the confirmation of perfusion flow, arterial pressure, circuit pressure, blood gas data, fluid balance, etc., but the most important thing to confirm is urine volume. In many cases, the answer is "OK," but in fact the urine output is low, so I question back and say "It's not OK." Ensuring urine output can be addressed by increasing perfusion flow rate, maintaining oncotic pressure, and administering diuretics. But I think the most important thing is to maintain an effective renal blood flow, that is, a sufficient amount of circulating blood in the blood vessels. Since the use of vacuum-assisted venous drainage, the impression became stronger that the amount of circulating blood in the blood vessels was insufficient (refer to PART II Pitfalls). Replenishment management that considers only the fluid balance at the weaning of extracorporeal circulation is still not "OK," but a sufficient urine volume means "OK."

Also, the surgeon is not just looking at the surgical field. The surgeon is watching the monitor frequently from the initiation of extracorporeal circulation to its weaning, especially after aortic unclamp. When the arterial pressure on the monitor drops, the surgeon asks the perfusionist, "What has been administered?" and responds with "Volume was not enough and blood was transfused." Getting little further, the surgeon mentions, "Hey, if you do a blood transfusion, do it at the ECUM during aortic cross-clamp." and, "Prepare the conditions of circulating blood before the cross-clamp is released." The point is that "Constant Perfusion" is not working. Red blood cell products will be supplied 5 days after donation. Therefore, it may contain a large amount of vasoactive substances such as bradykinin and is in a state of high potassium and high acidity. During the extracorporeal circulation, which is the largest cause of SIRS, it is undeniable that rapid blood administration during extracorporeal circulation, especially in neonates, may cause a synergistic vicious cycle (refer to PART II). I think that understanding the amount of circulating blood in consideration of maintaining urine volume and the timing and speed of correction and replenishment are particularly important in bloodless extracorporeal circulation.

In addition, I would like to request for management that suits the surgical procedure. Words like "Let's wean from extracorporeal circulation," "Still warming up," "Why ...?" do not need to be repeated. A perfusionist who manages these well, whether or not they use blood, has a good taste.

Neonatal extracorporeal circulation requires relatively complicated operations. Most notable are incidents associated with human errors. Although it may be necessary to take many safety measures for heart–lung machines, our hospital always has a policy of performing extracorporeal circulation management with two perfusionists. It is also necessary to experience a lot of extracorporeal circulation and maintain or enhance the operation skill. There are 1000 cases of extracorporeal circulation in our hospital every year, and five perfusionists are enrolled.

The number of extracorporeal circulation actually handled by one perfusionist averages 150 cases per year and 250–300 cases with the addition of assisting cases. The important thing is to gain a good grasp of the specifics and flow of each surgery from much experience, like surgeon training for surgeries. Specifically, it is necessary to become accustomed to the surgeon's habits, such as the timing of cardioplegia dosage, cooling and rewarming, air removal, and the duration required for each procedure. I think that the first thing to do when dealing with incidents is to establish rigorous team medical care [41, 42].

Column: Coarctation Complex

Based on the experience of bloodless open-heart surgery for VSD with a body weight of 3 kg, coarctation complex with a body weight of 4 kg or more excluding newborns was also indicated for bloodless open-heart surgery [43].

In a one-stage open-heart surgery for coarctation complex in 1998, reconstruction of the aorta was performed under heart beat with the circulatory arrest of lower body (moderate hypothermia at 28 °C), using extracorporeal circulation from the brachiocephalic artery. After that, intracardiac repair was performed under aortic cross-clamp. This was intended to shorten the cross-clamp time.

The total perfusion flow rate at that time was 2.5 L/min/m^2, and 1/5 of that was used as the blood flow from the brachiocephalic artery during the reconstruction of the aorta under heart beat. This was in accordance with the flow rate of the selective cerebral perfusion in adults. However, with this method, the Base Excess value after reconstruction of the aorta was drastically reduced, requiring a large amount of Meylon correction. Figure 3.64 shows the Base Excess value for two cases of coarctation complex, and Fig. 3.65 shows the course of extracorporeal circulation with a minimum body weight of 4.1 kg.

Considering low perfusion as the cause of the decrease in Base Excess value, the total flow rate was first increased to 3.0 L/min/m^2, and the aorta was reconstructed under cardiac arrest. During that time, the blood flow from the brachiocephalic artery was about half of the total flow. Since then, the Base Excess has not declined.

Column: Venous Cannula

Good venous drainage is essential in pediatric extracorporeal circulation. Although there are many types of venous cannula, there is a demand for a venous cannula that is not only easy to insert and flexible but also provides a stable blood flow without poor drainage such as tipping.

We developed a new venous cannula with a longer side hole and wider inner diameter by making the tip basket part longer than the conventional type (Fig. 3.66).

3.4.5 Postoperative Management

First, stabilization of the cardiac function is necessary. Dopamine is used as a catecholamine and can be managed at almost 5 γ/kg/min or less. In ICU, cardiac function is evaluated over time by echocardiography, and a small amount of adrenaline is added if it is determined that the systolic function is reduced. The point of circulatory management in the postoperative acute phase is the same as that of management immediately after weaning from extracorporeal circulation. First, the cardiac function is stabilized, and appropriate volume adjustment is performed while considering the circulating blood volume in the blood vessel. If the timing is incorrect, problems such as tachycardia, decreased blood pressure, and decreased diuresis will appear. This is the main reason why transfusion is required in ICU.

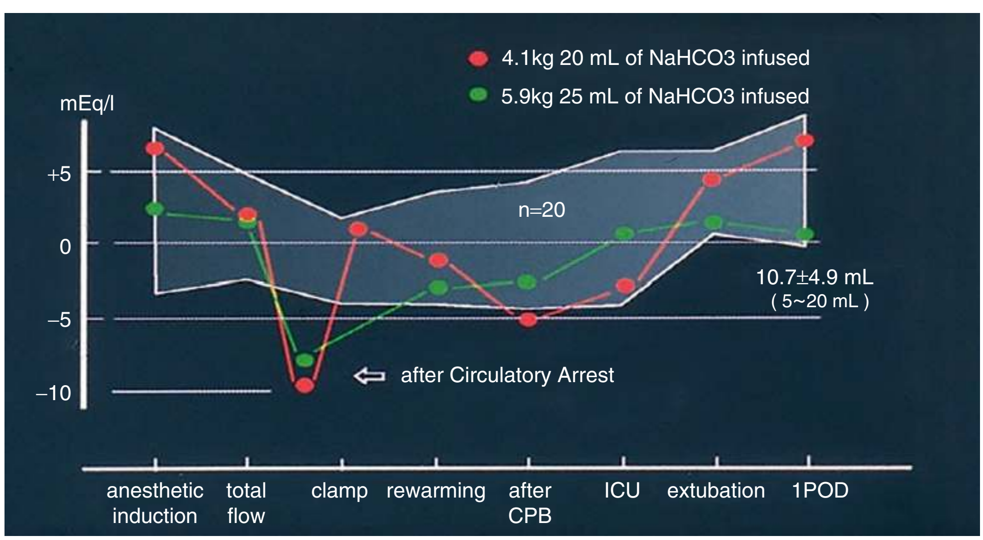

Fig. 3.64 Base excess in bloodless open-heart surgery for coarctation complex. The shaded area shows the Base Excess values of 20 consecutive cases of coarctation complex that had undergone single-stage open-heart surgery with blood priming using the same perfusion rate

			pump on					pump off	
	CPB Time		0	20	40	60	80	100	121 min
				↑ Circ. arrest		↑ Circ. restart ↑ Ao clamp		↑ unclamp	
Remp. (℃)			27.0	20.5	22.4	24.7	34.4	35.4	
Blood gas	Na (mEq/L)	131	134	133		133	138	145	139
	K (mEq/L)	3.8	3.4	3.1		4.3	5.8	5.7	4.4
	B.E.	6.7	6.7	1.9		−9.4	1.2	−1.0	−2.4
	Hct (%)、Hb(g/dlL	47.0 15.3	20.0 7.1	19.0 6.6		16.0 5.2	15.0 5.2	17.7 6.1	18.5
	T.P. (g/dL)	6.1	3.2	3.3		3.5	3.4	3.7	3.5
		Initial priming							
Correction	25% albumin (mL)		5		DUF (albumin 5 mL + Veen F 95 mL)×3				
	Salinhes (mL)	20							
	10% NaCl (mL)			3	4				
	KCl (mEq)		1	1	2 2	2	2		
	D-mannitol (mL)	10			4				
	NaHCO3 (mL)	10					10 5	5	
	Veen F (mL)	135		20	20 20	20 10 30	20		
	C.H. (mg)						3 5		
	CaCl2 (mL)							2	

Fig. 3.65 Bloodless extracorporeal circulation in coarctation complex case with a minimum body weight of 4.1 kg [44]. Initial priming volume 195 mL. Priming composition (Veen F 136 mL, Salinhes 20 mL, $NaHCO_3$ 10 mL, mannitol 10 mL, VC 1000 mg, exocorpol 10 mL, CEZ 500 mg, heparin 400 u, KCL 0.4 mL). Initial priming fluid data (PH 8.1, PO_2 298 mmHg, PCO_2 3.3, BE +28.8, Na 180 mEq/L, K 4.3). Perfusion rate 120 mL/kg/min. Additional volume for DUF: alb 5 mL + Veen F 95 mL × 3, urine volume 22 mL, ECUM filtration volume 314 mL, fluid balance + 266 mL. Extracorporeal circulation time 121 min, operation time 197 min, anesthesia time 265 min

Fig. 3.66 Venous cannula

In general, diuresis after bloodless open-heart surgery is good, and a relatively large amount of infusion is required. If about 100 mL of residual blood is used after returning to the ICU, the peripheral circulatory condition improves in about 2–3 h, and the ventilator can be weaned. We believe that this volume management is the most important factor for successful bloodless open-heart surgery. If it is determined that the volume is insufficient, Salinhes up to 10 mL/kg is administered. It is important to start ventilator weaning after confirming a decrease in heart rate, an increase in blood pressure, and an improvement in peripheral circulation.

Then, after peripheral circulation improvement, diuresis is actively measured. The fluid balance until the morning of the first day is around −200 mL. Figures 3.67 and 3.68 show the changes in heart rate and fluid balance after extracorporeal circulation in 20 cases of bloodless open-heart surgery for VSD weighing 3–4 kg.

The duration of intubation after surgery was 5–6 h, which indicated that early ventilator withdrawal was possible. These control points and fluid balance were used as a guideline for ICU members [45].

Column: Vasodilator

Vasodilators are effective in increasing cardiac output and unloading the left ventricle in terms of hemodynamics such as decreased cardiac function and mitral regurgitation and are often used especially in neonatal open-heart surgery.

However, in principle, vasodilators are not used in bloodless open-heart surgery. The reason is that we do not observe the need for use to improve cardiac function. In general, postoperative peripheral circulation improves in 2–3 h, and it is sufficient to use residual blood for volume adjustment during this time.

However, in cases where residual pulmonary hypertension or PH crisis is a concern, it may be used immediately after weaning from the extracorporeal circulation. In that case, attention is necessary in terms of volume management. In VSD infants weighing 4.4 kg who received prostaglandin E1, additional administration of a protein preparation was required because of diuresis reduction due to insufficient circulating blood volume. The fluid balance until the first day postoperatively was usually around −200 mL, but only in this case was + balance (Fig. 3.69). The vasodilatory effect of vasodilators is a disadvantage of bloodless open-heart surgery. Similarly, attention should be paid to rapid administration of sedatives such as cercin and

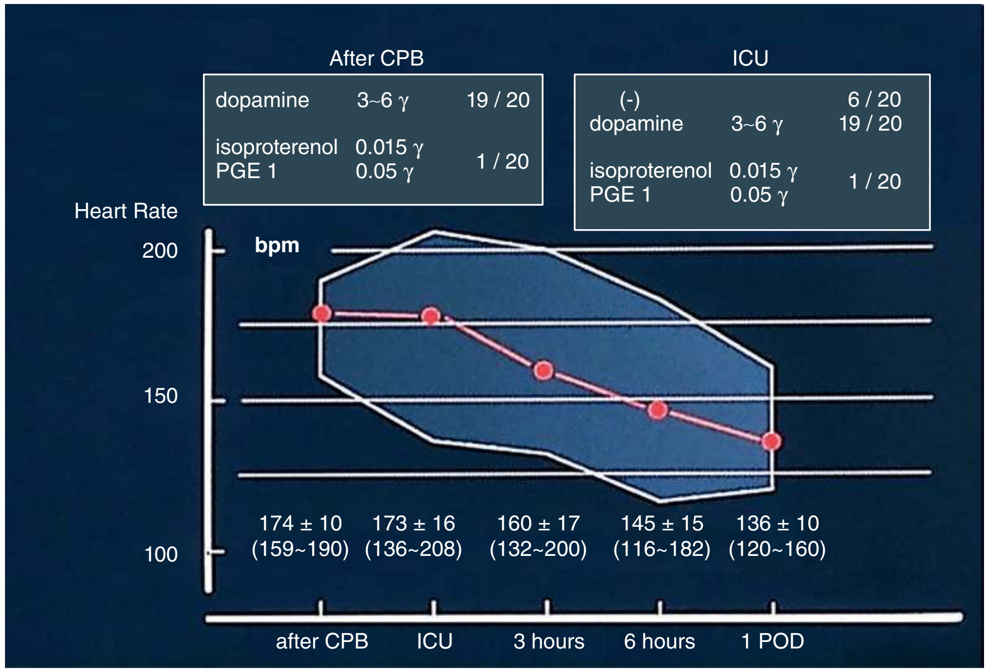

Fig. 3.67 Heart rate in bloodless open-heart surgery for VSD infants weighing 3–4 kg

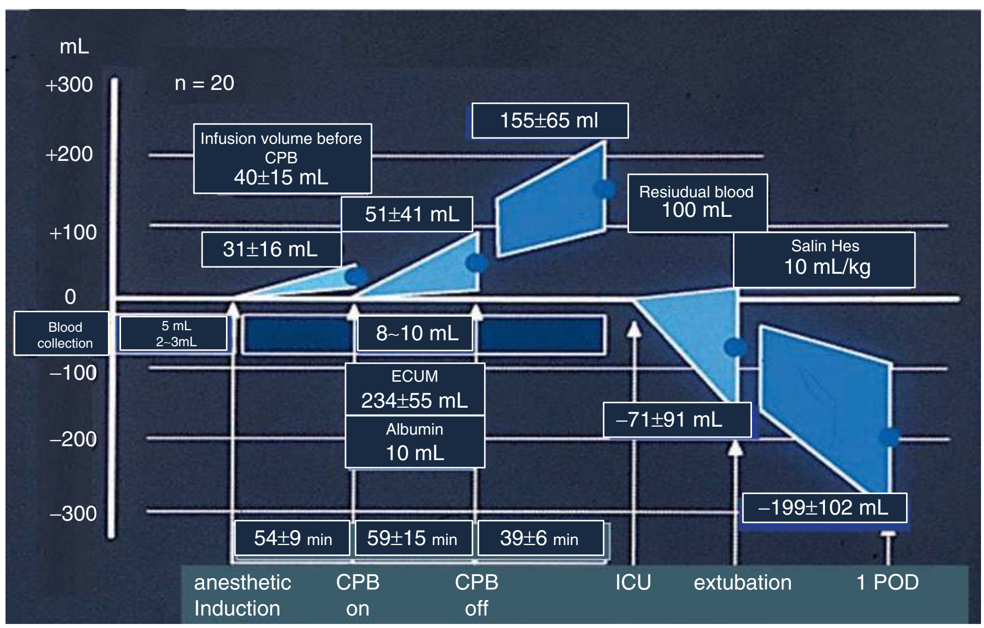

Fig. 3.68 Fluid balance in bloodless open-heart surgery for VSD weighing 3–4 kg

precedex in the early stage after ICU return, where peripheral circulation has not improved. Especially in cyanotic heart disease, the effects of excessive vasodilation will require a lot of infusion, and the use of vasodilators is rather a drawback.

The basic management of bloodless open-heart surgery is how to adjust the volume while maintaining cardiac function, then maintaining a slightly higher blood pressure with the peripheral blood vessels somewhat contracted, and ensuring diuresis.

Q&A: Transfusion decision (Question in 2006)

Question: What is the timing of blood transfusion in bloodless open-heart surgery?

Answer: Additional blood transfusions after using residual blood are determined by the patient's overall status. Considering permissive anemia, there is no particular clinical problem even if Hct value is less than 20%. However, if postoperative management is prolonged due to being particular to not transfuse blood, there is no point in performing a bloodless open-heart surgery.

The average postoperative ventilator management time for bloodless open-heart surgery for VSD infants weighing 3–4 kg was 5.5 h, which was shorter than the previous open-heart surgery with blood. However, seven cases required long-term ventilator management for more than 10 h. Of these, 3.6 kg patient who received another blood transfusion due to coagulation of residual cardiopulmonary blood were managed on the ventilator

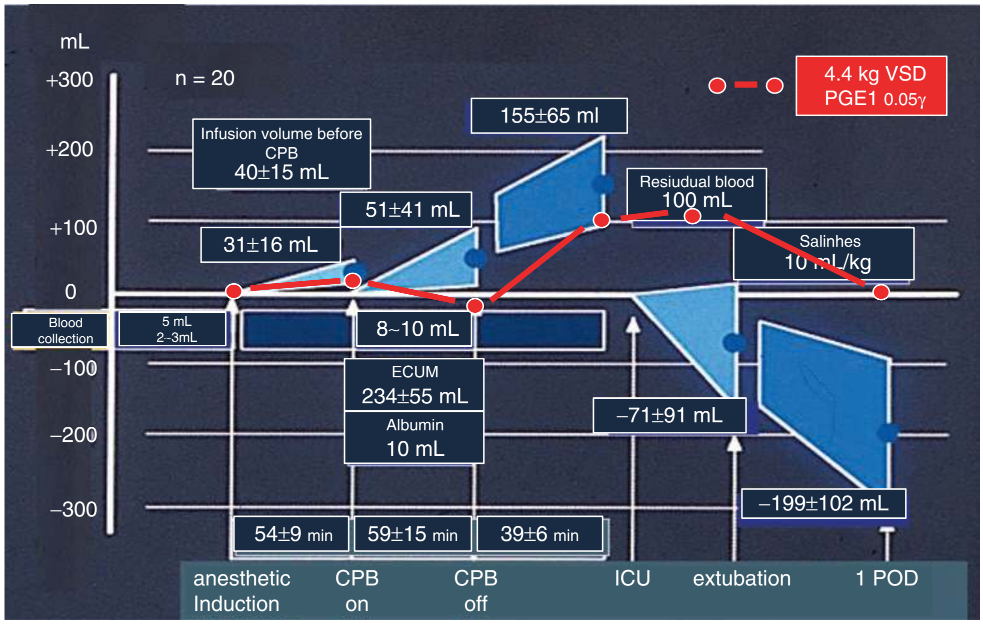

Fig. 3.69 Fluid balance in infant VSD case given vasodilator

for up to 19 h. The reason was hypoxia after blood transfusion. At that time, fresh whole blood was used, and I think it was probably a TRALI-like reaction. In this case, additional blood transfusion was considered to be the factor of adverse effects. Considering that the Hct value at the time of returning to the ICU was 22%, this case strongly suggested the importance of patient management in consideration of permissive anemia.

The current minimum requirement for bloodless open-heart surgery, where blood is relatively safe, is that postoperative quality is better or equal to open-heart surgery with blood. Blood transfusions should be given if a clinical problem occurs, especially if it is deemed necessary to administer a ventilator for more than 10 h postoperatively or to use a large amount of protein preparation. However, in the current situation where only old blood after 5 days after blood donation can be used, care should be taken when using it during the acute postoperative period.

3.5 Bloodless Open-Heart Surgery for Cyanotic Congenital Heart Disease

3.5.1 Characteristics of Cyanotic Heart Disease in Bloodless Open-Heart Surgery

Cases of cyanotic heart disease aiming to avoid blood transfusions are generally polycythemic and have a weight of 5 kg or more. Therefore, it is more advantageous than non-cyanotic heart disease in terms of hemodilution during extracorporeal circulation.

However, considering the special hemodynamics such as Fontan-type surgery, residual lesions such as postoperative pulmonary and atrioventricular regurgitation, and pros and cons of surgical indications associated with poor pulmonary vascular bed growth and cardiac function deterioration after palliative surgery, there are many factors that require long-term management with ICU. Furthermore, not only the procedure itself is complicated, but also the extracorporeal circulation and the operation time naturally become longer due to the combined operation procedures such as atrioventricular valve repair and exfoliation of adhesion in re-operative cases.

Therefore, the expected causes of blood transfusion are the replenishment of platelets and FFP for postoperative bleeding, the use of erythrocyte and protein preparations to increase circulating blood volume, and the discard of residual cardiopulmonary blood due to high hemolysis. It has different characteristics from non-cyanotic diseases.

3.5.2 Autologous Blood Donation After Induction of Anesthesia

In 1994, we started bloodless open-heart surgery for cyanotic heart disease. However, unlike non-cyanotic heart disease, achieving bloodless surgery has been difficult. The non-transfusion rate from January to August 1994 was 17% (1/6) in the Rastelli group, 67% (2/3) in the Fontan group, 67% (8/12) in the TOF group. The main cause of blood transfusion was postoperative hemorrhage and severe hemolysis of residual blood of the heart–lung system.

For this reason, autologous blood donation after induction of anesthesia was started for the purpose to use after extracorporeal circulation. As a general rule, autologous blood donation was indicated for patients with Hct > 45% after induction of anesthesia. From September 1994 to August 1995 (anaphase) after the start of blood collection, the non-transfusion rate was improved to 75% (6/8) in Rastelli, 86% (6/7) in Fontan, and 93% (13/14) in TOF (Fig. 3.70).

The average body weight was 25 kg in Rastelli, 25 kg in Fontan, and 16 kg in TOF. And an average of 12 mL/kg blood could be donated. Hct after induction of anesthesia and after blood donation were from 53 ± 6% → 48 ± 8% in Rastelli, 52 ± 6% → 46 ± 4% in Fontan, and 51 ± 9% → 47 ± 7% in TOF. The lowest Hct value was 39.5% of TOF weighing 12.5 kg with 150 mL of blood donated. The circuit priming volume was 470 mL for body weights under 17 kg, and 750 mL and 850 mL for 18–44 kg (refer to Sect. 2.2.3).

The minimum Hct during extracorporeal circulation was 19% or more in all cases (Rastelli 25 ± 4%, Fontan 24 ± 4%, TOF 25 ± 4%), and Hct was less than 30% when returning to ICU in only one case of TOF. Blood transfusion was performed in two cases of Rastelli, who had anastomotic hemorrhage and re-operation for bleeding. One case of Fontan with persistent pleural effusion, and one case of TOF with Hct 28% 4 days after surgery. Table 3.6 shows the patient background of each group.

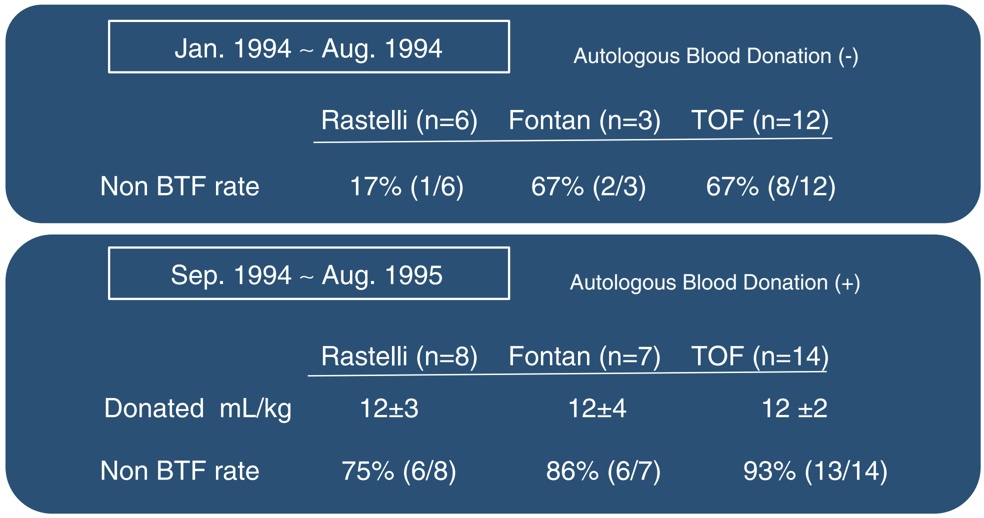

Fig. 3.70 Efficacy of autologous blood donation after anesthetic induction

Table 3.6 Patient background [46].
It was an era when valveless conduit was used in Rastelli surgery, and there were few TCPCs in Fontan surgery, and many cases that did not go through Glenn surgery

	Rastelli		Fontan		TOF	
	Jan. ~ Aug. 1994	Sept. 1994 ~ Aug. 1995	Jan. ~ Aug. 1994	Sept. 1994 ~ Aug. 1995	Jan. ~ Aug. 1994	Sept. 1994 ~ Aug. 1995
No. of patients	6	8	3	7	12	14
Age (year)	8.5±3.5 (3.1~12.2)	9.9±2.7 (5.3~13.3)	11.9±2.2 (10.5~14.4)	9.6±5.1 (4.0~19.4)	7.7±10.9 (1.2~41.4)	5.7±8.9 (1.2~36.0)
Body weight (kg)	23.2±9.6 (13.5~36.0)	25.6±11.9 (14.1~51.6)	25.6±6.3 (19.0~31.5)	27.5±11.4 (13.7~44.0)	17.1±10.7 (10.6~48.1)	16.4±10.8 (8.7~51.5)
Diagnosis (cases)	TOF 3 DORV 1 d-TGA 1 ℓ-TGA 1	TOF 5 DORV 1 d-TGA 1 ℓ-TGA 1	TA 1 SV 2	TA 3 SV 3 PA with IVS 1		
Previous procedures (cases)	BTS 4 Waterston 1	BTS 6 ASD creation 1	BTS 1 PAB 2	BTS 4 PAB 1 bid. Glenn 2 VSD creation 1	BTS 6	BTS 4
Procedures (cases)	non-valved conduit 3 valved conduit 2 non conduit 1	non-valved conduit 3 valved conduit 2 non conduit 3	RA-PA anastomosis 2 TCPC 1	RA-PA anastomosis 1 RA-PA anastomosis + bid. Glenn 3 TCPC 3	transannular patch 7 m-PA patch 3 RV & m-PA patch 2	transannular patch 7 RV patch 2 RV & m-PA patch 4 non patch 1
Associated anomalies required repair (cases)	PDA 3 small VSD 1 PA branch stenosis 1 TR 2	PDA 1 small VSD 1 PA branch stenosis 4 TR 1	TAPVC 1 AVVR 1	small VSD 1 AVVR 1	PA branch stenosis 2	PDA 2 aortic valve prolapse 1 PA branch stenosis 6

(continued)

Table 3.6 (continued)

	Rastelli		Fontan		TOF	
Autologous blood donation	(−)	(+)	(−)	(+)	(−)	(+)
No. of patients	6	8	3	7	12	14
Aortic cross-clamp time (min)	143±39	122±28	92±23	62±54	82±35	83±24
CPB time (min)	221±48	211±32	168±20	156±18	145±49	150±48
Operation time (min)	463±103	484±85	450±83	424±67	292±120	262±59
Blood loss (mℓ/kg)	22.4±17.6	11.5±5.8	9.2±5.3	9.2±4.1	9.2±11.3	4.6±3.4
Hct after anesthetic induction (%)	54±13	53±9	51±8	52±6	46±10	51±9
during CPB						
Lowest Hct (%)	26.8±5.8	25.4±4.2	29.3±5.8	23.9±4.2	24.1±5.4	24.8±4.3
Lowest total protein (g/dℓ)	3.5±0.6	3.3±0.4	4.2±0.4	3.2±0.4 ※	3.5±0.4	3.1±0.3 ※
Lowest B.E. (mEq/ℓ)	-3.5±1.2	-4.3±1.3	-4.2±3.1	-4.4±2.0	-4.4±2.2	-5.7±2.4
$NaHCO_3$ infused (mℓ/kg)	5.9±0.6	5.6±0.7	5.5±3.1	6.1±1.4	4.7±1.5	5.4±1.5
Urine output (mℓ/kg)	17.9±10.9	28.0±14.7	18.6±11.5	14.9±6.2	17.3±15.1	16.6±7.8
after ICU admission						
CVP (cmH_2O)	11.6±2.8	10.8±2.7	19.9±4.8	16.3±1.8	11.4±2.1	9.6±1.7 ※
Intubation time (hr)	11.5±4.2	10.6±3.1	8.0±4.2 (n=2)	8.7±1.3 (n=6)	7.1±3.5	6.7±2.3
Hct (%)	39±3	39±4	41±4	40±5	35±6	37±6
Total protein (g/dℓ)	5.2±0.5	5.1±0.5	5.6±1.0	5.1±0.4	4.9±0.5	4.8±0.5

*P value 1 ≤ 0.05

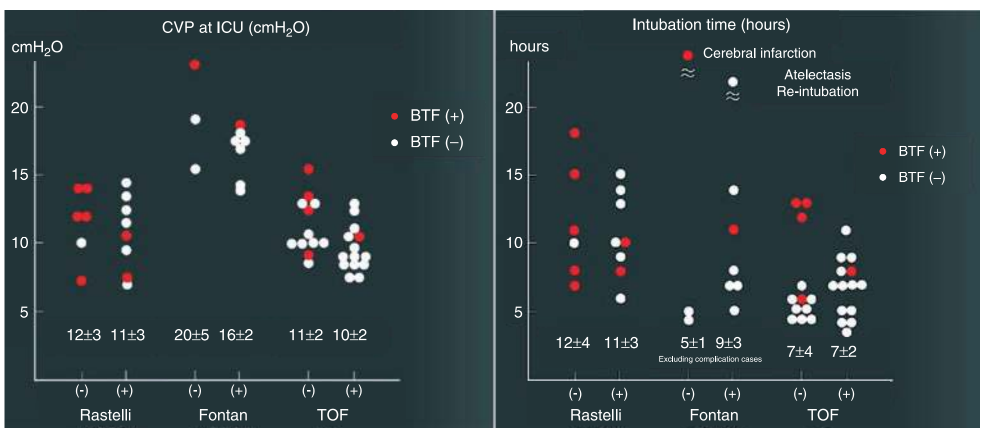

Fig. 3.71 CVP and duration of intubation

Figure 3.71 shows CVP (cmH_2O) and duration of intubation after returning to ICU. In Fontan, there were cerebral infarction case requiring peritoneal dialysis and reintubation case due to diaphragmatic nerve paralysis, but the hemodynamics and respiratory status were generally stable.

In the Rastelli and Fontan groups, all cases were prophylactically primed with protein preparations but not with TOF. The standard used for protein preparations was less than 3.0 g/dL of total protein in the extracorporeal circulation, as in non-cyanotic heart disease, but was used in about half of the TOF group (Table 3.7). Reducing protein preparations in bloodless open-heart surgery for cyanotic heart disease was a future challenge.

Column: "Evaluation of Autologous Blood Donation After Induction of Anesthesia" (1998)

Autologous blood donation after induction of anesthesia markedly enhanced the non-transfusion rate in cyanotic heart disease (Fig. 3.72). There were no clinical problems such as decreased blood pressure or infection associated with autologous blood donation. In low-weight cases, there were cases where the minimum Hct during extracorporeal circulation was less than 20% (Fig. 3.73), but this did not affect the non-transfusion rate.

However, there was no doubt that hemodilution was increased by autologous blood donation, and a reduction in priming volume was necessary first. Figure 3.74 shows the autologous blood donation volume and the cause of blood transfusion for each disease and each operation. In the Fontan group, with increasing Heterotaxy syndrome and single ventricle cases, the number of cases requiring ICU long-term management increased due to the accumulation of pleural and ascitic fluid and the non-transfusion rate was low.

Table 3.7 Non-usage rate of protein preparations [46]

Rastelli (n=14)	Fontan (n=10)	TOF (n=26)
0% (0/14)	0% (0/10)	54% (14/26)

Column: Rastelli Procedure

Figure 3.75 shows CVPs at the time of ICU return in 14 consecutive patients who underwent the Rastelli procedure after the start of autologous blood donation. At that time, non-valved conduits were often used to avoid re-operation for early stenosis of conduits with biological valves. However, CVP was still high. I remember that the 100th TOF case since the opening of the Sakakibara Heart Institute was Rastelli surgery using this non-valved conduit [47, 48].

3.5.3 Disadvantages of Autologous Blood Donation After Induction of Anesthesia

There was an impression that the usage rate of protein preparations increased with the start of autologous blood donation. In open-heart surgery (initial priming volume 470 mL) for TOF

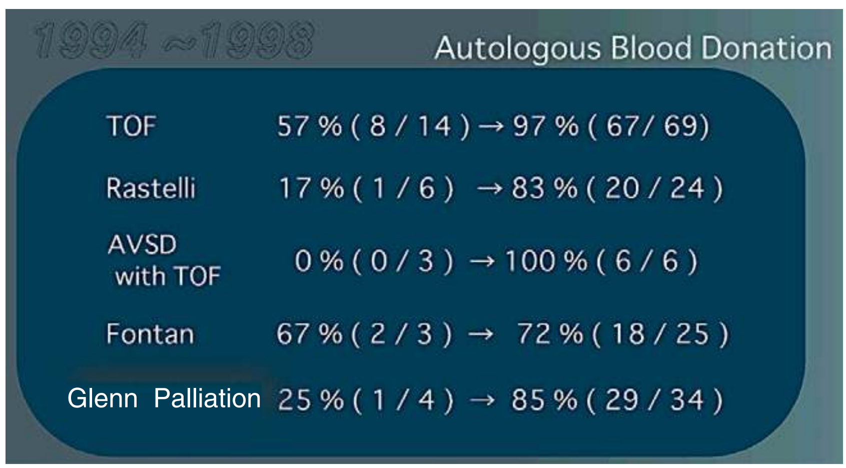

Fig. 3.72 Change in success rate of bloodless open-heart surgery.
Non-transfusion rate 89% (140/158)

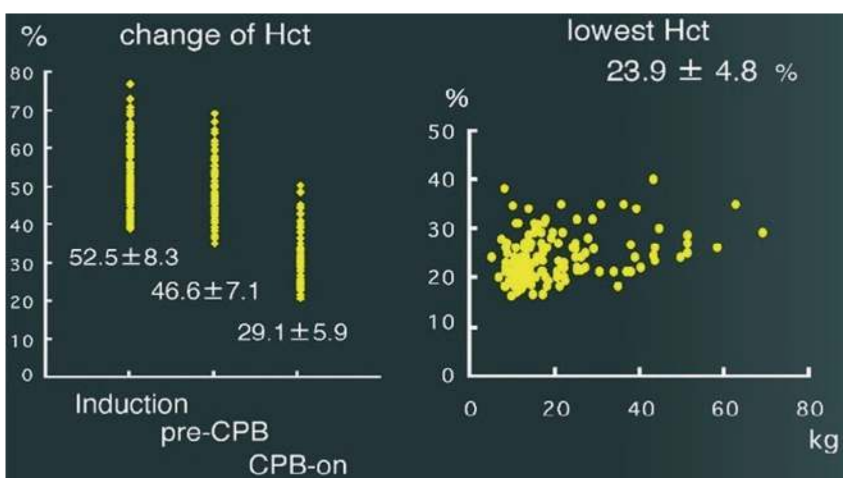

Fig. 3.73 Hct change and minimum Hct by weight during extracorporeal circulation

Fig. 3.74 Donated blood volume and reasons for transfusion by each disease and surgery

Fig. 3.75 CVP in rastelli cases with non-valved conduit

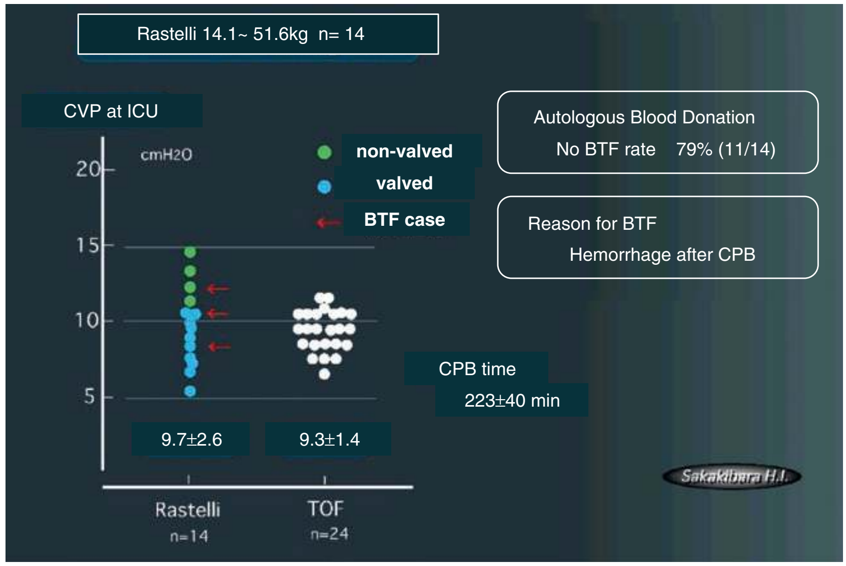

Table 3.8 Change in the usage rate of protein preparations by autologous blood donation after induction of anesthesia

TOF 13 cases 8～17kg
Initial priming vol. 470mL (without protein product)

Donation	(-) n=7		(+) n=6
Lowest Hct	3.5±0.5 g/dL	→	2.9±0.2 g/dL
Protein usage	1/7 (14%)	→	3/6 (50%)

donatd blood 12±2 mL/kg

weighing 8–17 kg, the total protein level during the extracorporeal circulation was compared between seven cases without blood donation and six cases with blood donation. The total protein immediately after the start of extracorporeal circulation was 3.8 ± 0.5 ⇔ 3.1 ± 0.5 g/dL, and the minimum total protein was 3.5 ± 0.5 ⇔ 2.9 ± 0.2 g/dL, which was significantly reduced in the blood donation group. The protein product usage rate was increased from 14% (1/7) to 50% (3/6) (Table 3.8).

Autologous blood donation was a drawback in protein dynamics during the extracorporeal circulation. Based on this, we examined the usefulness of using Salinhes as a surrogate colloid for the purpose of reducing the usage of protein preparations.

Twenty-one consecutive TOF patients weighing ≤16 kg between 1994 and 1996 were divided into three groups with or without autologous blood storage and Salinhes usage (Fig. 3.76). Salinhes was not used for initial priming, but 5 mL/kg was continuously administered during extracorporeal circulation as a DUF washing solution. Even if the minimum total protein was less than 3.0 g/dL, no protein preparations were used.

The number of cases where the minimum total protein was less than 3.0 g/dL was one in the C1 group, six in the C2 group, and five in the H group. Blood transfusion was performed in two cases of C1 group, and protein preparation was used in four cases of C2 group. As a result, non-transfusion rate without using protein product was 71% (5/7) in C1 group, 43% (3/7) in C2 group, and 100% (7/7) in H group (Fig. 3.77).

Total protein levels in C2 and H groups decreased in all patients after autologous blood donation and decreased significantly compared to C1 group after the initiation of extracorporeal circulation. Thereafter, the total protein of the C2 group using protein preparations in four cases increased but decreased over time in the C1 group and the H group. In H group, the level was significantly lower during rewarming and immediately after extracorporeal circulation but recovered to almost the same level 3 h after returning to ICU (Fig. 3.78).

In H group, dopamine consumption at the time of ICU return was 3–8 γ/kg/min, CVP 7.5–11.5 (9.1 ± 1.4) cmH_2O, and ventilator management time was 3–4 (3.1 ± 0.4) h.

Fig. 3.76 Background of each group

	C1 group	C2 group	H group
	n = 7	n = 7	n = 7
Autologous Blood	(–)	(+)	(+)
saline HES	(–)	(–)	(+)
BW (kg)	12.2 ± 2.1 (10.6~16.5)	11.5 ± 2.8 (8.7~15.5)	12.0 ± 2.7 (7.0~16.0)
Palliation	BTS 2	(–)	BTS 3
Donated Blood (mL/kg)	(–)	12 ± 4	12 ± 4
CPB time	134 ± 23	140 ± 37	119 ± 23
Surgery time	243 ± 29	247 ± 58	220 ± 40
ECUM (mL)	298 ± 140	389 ± 269	381 ± 192

priming vol. <8kg … 370ml >8kg … 470ml

Fig. 3.77 Total protein and non-BTF rate

CPB	C1 group	C2 group	H group
Lowest Hct (%)	22.0±4.0	26.0±4.8	20.9±2.4
Lowest T.P. (g/dL)	3.5±0.5	2.9±0.3	2.9±0.1
T.P. ≦3.0g/dL	1 / 7	6 / 7	5 / 7

	C1	C2	H
BTF rate	29 %, 2/7	0%, 0/7	0%, 0/7
Protein Usage rate	14%, 1/7	57%, 4/7	0%, 0/7
Total Bloodless rate	71%, 5/7	43%, 3/7	100%, 7/7

Circulation and respiratory dynamics are better than the C1 and C2 groups (Fig. 3.79). Since then, in TOF surgery, bloodless open-heart surgery without the use of protein preparations has become possible at a high rate, and the duration of intubation has also been shortened (Fig. 3.80).

Column: Total Protein Level and Serum Na Value (1998)

Figure 3.81 shows the minimum total protein during the extracorporeal circulation by body weight, the minimum serum Na value, and the corrected volume of 10% NaCl in 69 cases of TOF subjected to autologous blood donation after induction of anesthesia.

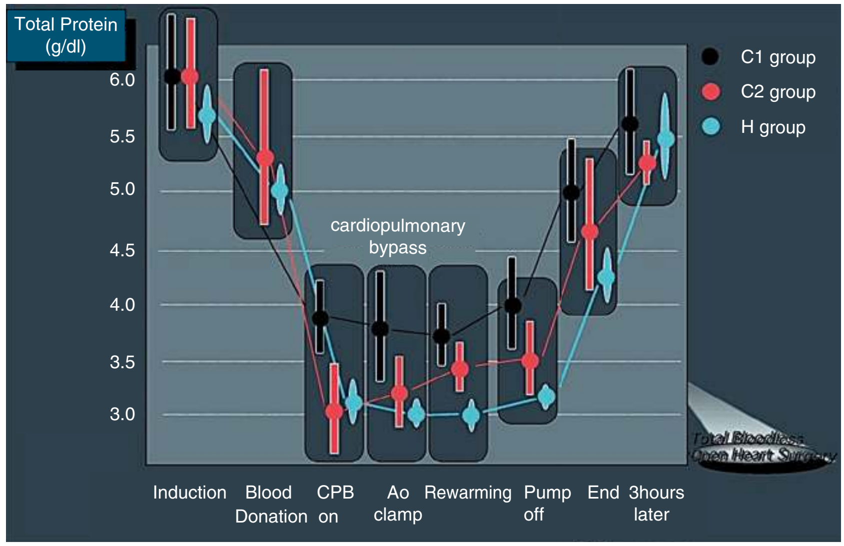

Fig. 3.78 Changes in total protein [49] modified

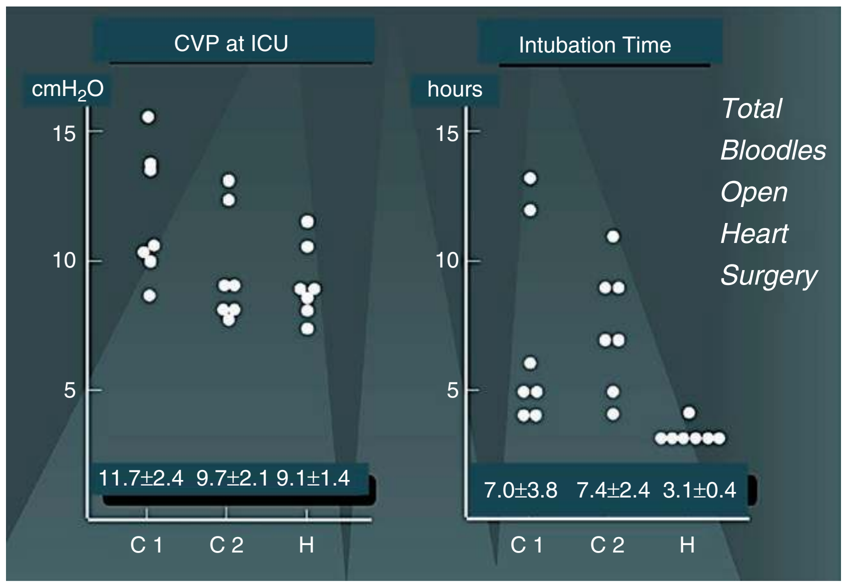

Fig. 3.79 CVP and duration of intubation

More cases of declined values were observed in the lower body weight range.

Protein preparations in cardiac surgery are mainly used for the purpose of preventing the reduction of colloid osmotic pressure and increasing circulating blood volume. In 1994, the primary cause of the decrease in total protein and Na levels was leakage due to HC-30M ultrafiltration (refer to Fig. 3.20). As shown in Fig. 3.78, total protein values during the extracorporeal circulation decreased with time. The second cause was autologous blood donation after induction of anesthesia. In addition to the decrease in serum Na level, the number of cases in which the total protein was below the standard value for the use of protein preparations (less than 3.0 g/dL) increased.

The purpose of HC-30M ultrafiltration was to remove vasoactive substances, and the purpose of autologous blood donation was to enhance the non-transfusion rate in cyanotic heart disease. However, both were disadvantageous in terms of protein and electrolyte dynamics.

For these shortcomings, Salinhes has begun to be used as a surrogate colloid. Salinhes is a 6% HES solution with 0.9% saline as a solvent. Colloid osmotic pressure is as low as 18.6 mmHg on average, but crystalloid osmotic pressure is 306 mOsm/kgH_2O on average and higher than PPF (average 272). The use of Salinhes was to maintain the crystalloid osmotic pressure as a prevention of edema associated with hyponatremia, and the continuous administration during DUF was to make the colloid and crystalloid osmotic pressure dur-

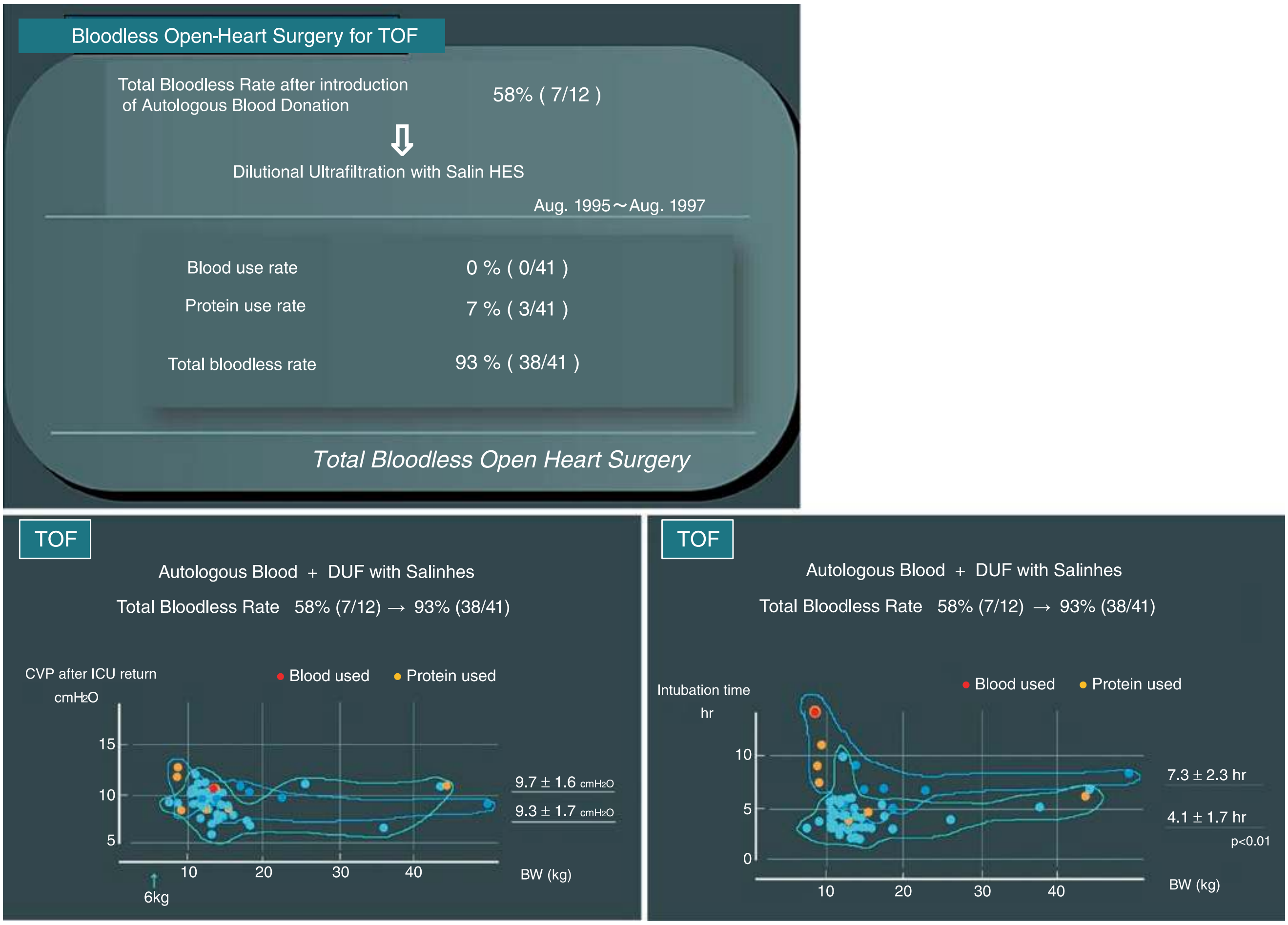

Fig. 3.80 (**a**) Non-transfusion rate without protein preparations. "Total Bloodless Open-Heart Surgery" means that allogeneic homologous blood and blood preparations including protein preparations and hemostatic agents are not used. (**b**) CVP and duration of intubation after returning to ICU

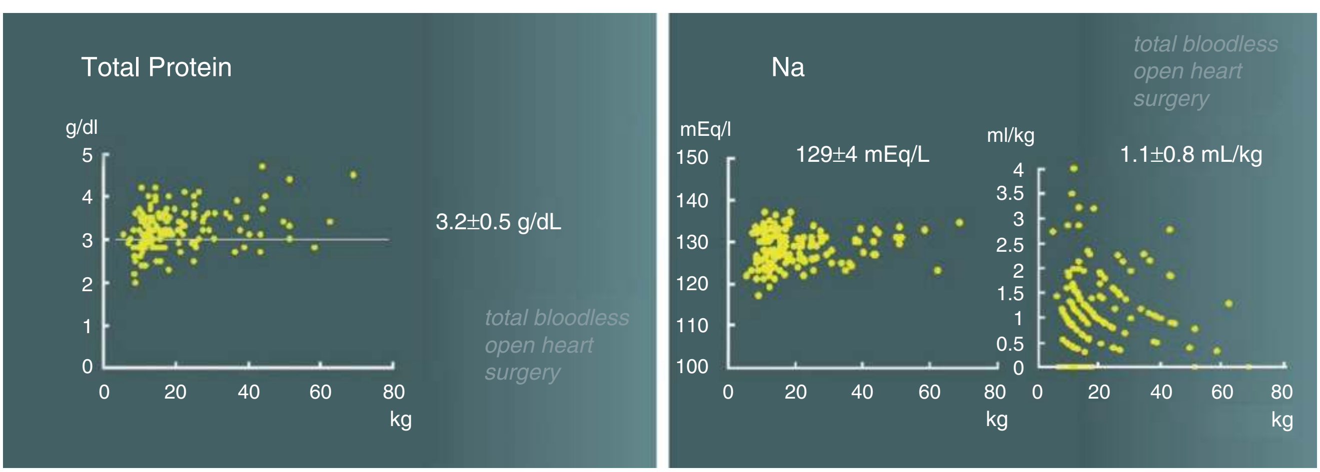

Fig. 3.81 Minimum total protein level, minimum Na value, and Na correction volume in TOF cases undergoing autologous blood donation

ing the extracorporeal circulation constant. (refer to column "Constant Perfusion"). In actual clinical practice, there were no problems such as coagulopathy or hypersensitivity associated with the use of Salinhes, and postoperative hemodynamics and respiratory status were rather good. As shown in Fig. 3.28, recovery of the total protein after the extracorporeal circulation was rapid even without the use of protein preparations.

3.5.4 Bloodless Open-Heart Surgery for Cyanotic Heart Disease Since 1997

Bloodless open-heart surgery for cyanotic heart disease from 1997 to 2003 (Table 3.9) will be described here. During this period, the age at the time of surgery also tended to decrease in cyanotic heart disease.The minimum priming volume was reduced to 195 mL or 130 mL for body weights of 6.2 kg or less and to 370 mL for weights of 19 kg or less (refer to Sect. 2.2.7). Figure 3.82 shows the change of Hct.

3.5.4.1 108 TOF Cases

In low-birth-weight infants and pink TOF cases, preoperative anemia was common, resulting in a low autologous blood donation rate of 47% (51/108). The total non-transfusion rate was 97% (105/108). Overall, with an increase in one-stage intracardiac repair and the number of low-weight infant, the anesthesia time in 2003 was reduced to an average of 142 min. Ventilator management time after surgery was 4.7 ± 3.2 h (1–11).

Blood transfusion was performed in three cases; (1) BW 5.6 kg: Hct at the time of induction of anesthesia was low as 35%, so autologous blood donation was not performed. Blood transfusion was performed because Hct during extracorporeal circulation decreased to 18%. (2) BW 6.6 kg: Hct

Table 3.9 Success rate of bloodless open-heart surgery in cyanotic heart disease [50]

	Jatene	AVSD with TOF	Rastelli	Fontan	Glenn	TOF
n	8	9	26	52	39	108
Age (y)	1.2±1.2 (0.4~4.0)	1.8±0.7 (0.7~3.0)	9.3±6.5 (1.0~22.0)	6.2±4.2 (2.0~19.0)	4.7±6.9 (0.8~30.0)	1.9±1.6 (0.3~10.0)
BW (kg)	7.4±2.6 (4.1~11.5)	9.1±2.1 (5.1~11.5)	26.0±13.8 (8.5~50.0)	19.9±10.4 (10.3~51.6)	13.7±9.5 (6.2~49.6)	10.8±4.1 (5.6~32.5)
Re-stemotomy	2/8 (25%)	0/9 (0%)	7/26 (27%)	45/52 (87%)	10/39 (26%)	3/108 (3%)
CPB (min)	176±37 (125~248)	171±29 (129~214)	179±55 (96~319)	104±47 (37~223)	55±34 (20~137)	99±30 (44~221)
Anesthesia (min)	308±78 (192~420)	288±48 (228~355)	394±128 (200~625)	292±81 (148~465)	181±64 (95~357)	196±53 (100~440)
Autologous Blood	8/8 (100%)	8/9 (89%)	22/26 (85%)	46/52 (89%)	33/39 (85%)	51/108 (47%)
Hct after Anesthetic Induction (%)	59.6±5.5 (52.0~68.5)	51.3±8.9 (44.0~71.5)	50.5±8.8 (36.0~71.0)	49.1±6.0 (39.0~68.0)	51.4±6.6 (39.0~77.5)	42.5±6.9 (31.0~60.5)
Lowest Hct during CPB (%)	26.4±2.0 (23.0~30.0)	23.3±4.8 (16.0~33.5)	25.0±3.5 (18.0~30.0)	25.0±5.2 (17.0~47.5)	29.4±4.8 (18.5~44.0)	20.8±3.3 (13.5~31.0)
Bloodless Rate	8/8 (100%)	8/9 (89%)	22/26 (85%)	49/52 (94%)	37/39 (95%)	105/108 (97%)

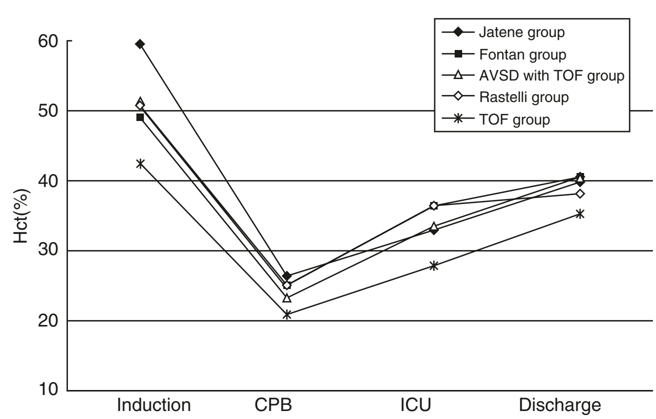

Fig. 3.82 Change of Hct

36% at the time of induction of anesthesia. Autologous blood donation (−). The lowest Hct during extracorporeal circulation was 16%, and the Hct at ICU return was 23%. Blood transfusion was performed because diuresis was reduced due to insufficient circulating blood volume. (3) BW 13 kg: The presence of intramural VSD was found after surgery, and blood transfusion was performed at re-operation.

3.5.4.2 26 Rastelli Procedure Cases

The average anesthesia time was as long as 394 min due to many cases of resternotomy and older children after palliative surgery. The total non-transfusion rate was 85% (22/26). The duration of intubation was 9.6 ± 5.9 h (2.5–24.5).

Blood transfusion was performed in four patients, (1) BW 12 kg ℓ-TGA, PA: Hct 36% at induction of anesthesia. Autologous blood donation (−). Blood transfusion started immediately after the initiation of extracorporeal circulation, considering long-term extracorporeal circulation. (2) BW 48 kg PA with VSD: Hct 40.5% at induction of anesthesia. Autologous blood donation (−). Blood transfusion was performed due to anastomotic bleeding. (3) BW 16.5 kg ℓ-TGA, PA: Transfusion due to postoperative drain bleeding. (4) BW 37.5 kg PA with VSD: Transfusion for anastomotic bleeding.

3.5.4.3 52 Fontan Procedure Cases

There were many combined procedures such as valvuloplasty as well as resternotomy after Glenn operation. The anesthesia time in 2003 averaged 292 min. The total non-transfusion rate was 94% (49/52).

Duration of intubation of 51 patients except one was 5.9 ± 3.5 h (2–20). Transfusion was performed in three cases, (1) BW 44.8 kg TA: Hct 42% at induction of anesthesia, transfusion for drain bleeding. (2) BW 13.8 kg SV, PA: Hct 41% at induction of anesthesia, autologous blood donation (−). Blood transfusion was performed because Hct decreased to 19% during extracorporeal circulation. (3) BW 12.5 kg SV, PS: Blood pressure decreased and CVP increased after returning to the ICU, and transfusion was performed. A fenestration operation was performed on the third day due to the failure of Fontan circulation, but the hemodynamics were unstable, and he died of severe hypoxia. Lung histology revealed inadequate regression of the medial thickening of the pulmonary arteries and was diagnosed as not applicable for the Fontan procedure.

Column: Non-Transfusion Rate in Fontan Procedure (1997)

Table 3.10 shows non-transfusion rate up to June 1997. The non-transfusion rate was low even after the start of autologous blood donation. The cause was an increase in long-term ICU management cases such as pleural effusion.

Of course, the previously mentioned good results of non-transfusion rate, 94%, since 1997 might be attributed to reduced priming volume and improved patient management, but Fontan's non-transfusion rate was unstable. This suggested that the indication itself and the postoperative condition (increased pleural and ascites) affect the non-transfusion rate. Fontan's indication for bloodless open-heart surgery should be considered on a case-by-case basis.

Column: Pulmonary Vascular Pathology in Fontan Cases

Indications for Fontan surgery are determined by: (1) pulmonary blood flow dynamics determined by pulmonary blood vessel growth, pulmonary artery pressure, and pulmonary vascular resistance, (2) degree of atrioventricular valve regurgitation, (3) cardiac function, and (4) development of collateral circulation to the lungs. Detailed examination was required before surgery. However, caution should be exercised in the presence of potential pulmonary vascular lesions, even when judged to be indicated for Fontan surgery.

Table 3.10 Change in non-transfusion rate in Fontan operation (Jan. 1994~Jun. 1997)

	Jan. 1994 ~		Jun. 1997
Rastelli	1 / 6 (17%)	→	17 / 21 (81%)
Fontan	2 / 3 (67%)	→	10/ 17 (59%)
TOF	8 / 12 (67%)	→	52 / 53 (98%)
AVSD with TOF	0 / 3 (0%)	→	5 / 5 (100%)

Figure 3.83 shows pulmonary pathological findings of a DORV AVSD SAS CoA case who underwent Fontan operation at the age of 2 years after Norwood and Glenn operation.

Despite a low CVP of 12–15 mmHg on return to the ICU, he died of a PH crisis reaction. As in the pulmonary hypertension disease group (refer to Figs. 3.17 and 3.32), abnormal thickening of the pulmonary arteriole media was observed, indicating that Fontan surgery was not applicable. The median thickening may not have regressed over time after Glenn's surgery, and care must be taken when deciding on Fontan's indication.

There are some cases of palliative surgery in the neonatal period aiming for Fontan operation, in which respiratory management is difficult. Figures 3.84 and 3.85 show lung pathology images of a DORV MA SAS CoA case that underwent Norwood surgery on the ninth day of life and an AVSD hypoLV SAS CoA case that underwent bilateral pulmonary artery banding on the first day of life. Both died without improvement in postoperative severe hypoxia and hypercapnia. In the former case, abnormal thickening of the pulmonary small artery media and pulmonary vein occlusion was observed, and in the latter case, severe hypoplasia of the pul-

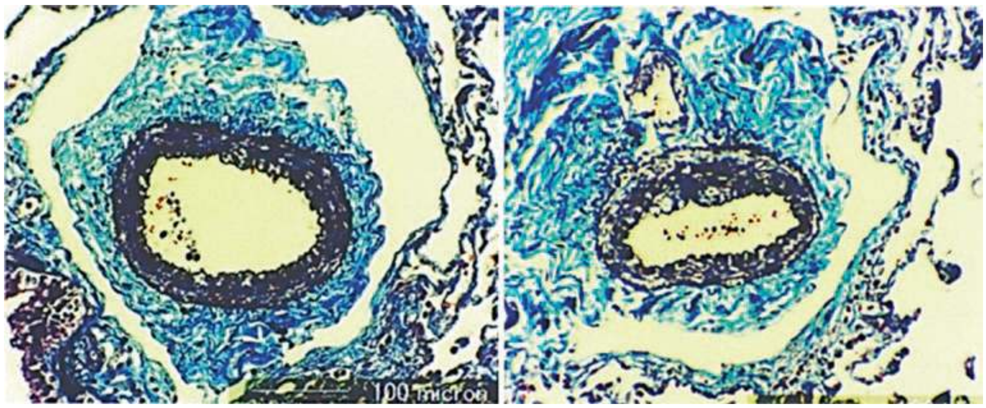

Fig. 3.83 Pulmonary pathological findings in case of DORV AVSD SAS CoA undergoing Fontan operation

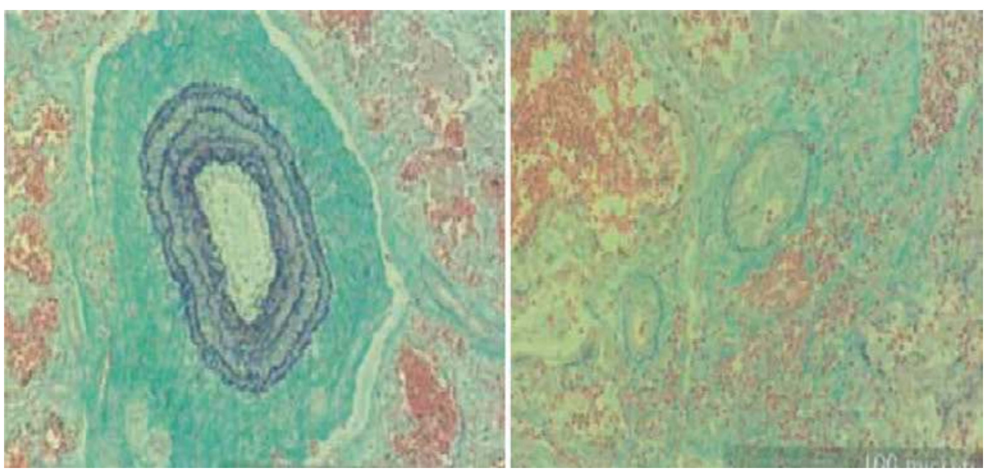

Fig. 3.84 Pulmonary pathological findings in DORV MA SAS CoA patient undergoing Norwood operation

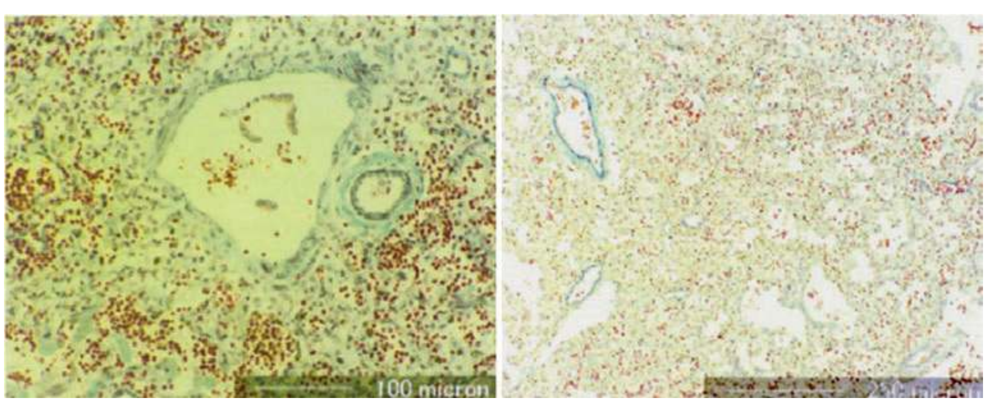

Fig. 3.85 Pulmonary pathological findings in AVSD hypo LV SAS CoA case undergoing bilateral pulmonary artery banding

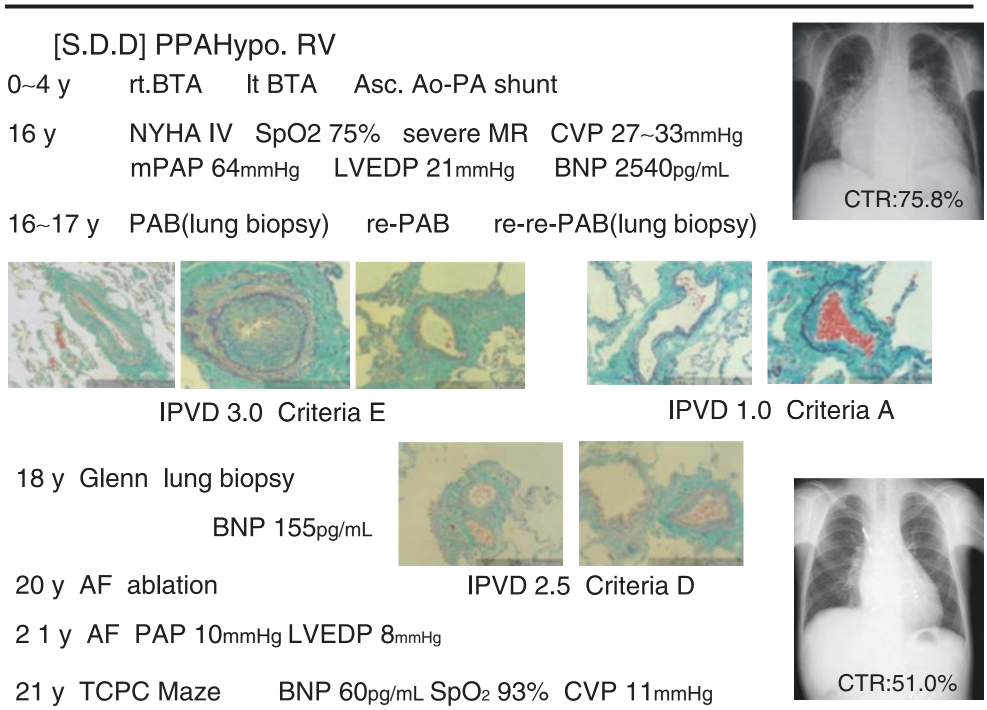

Fig. 3.86 Treatment course of PPA hypo RV case finally able to perform TCPC operation. IPVD : Index of Pulmonary Vascular Disease

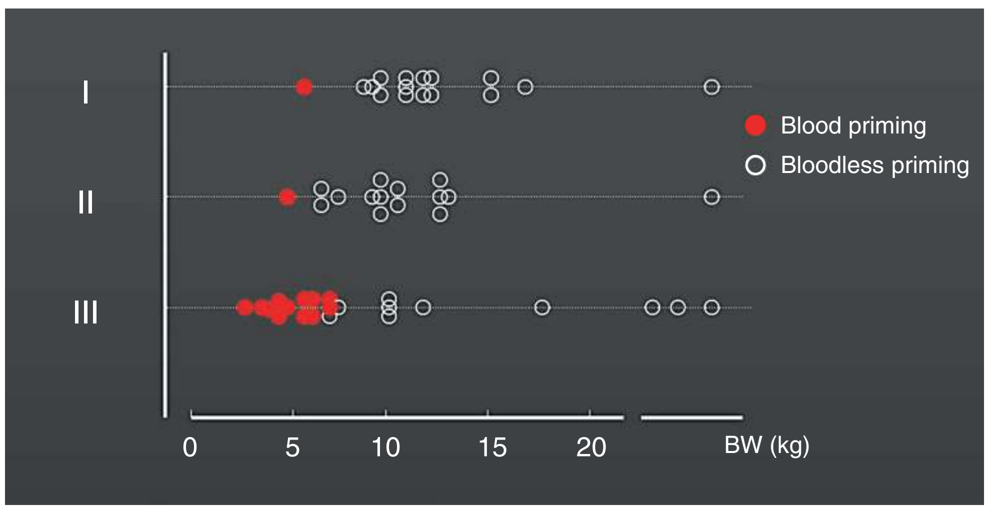

Fig. 3.87 Blood priming in Glenn surgery [52].
Group I: BTA closure + Glenn anastomosis, Glenn anastomosis while leaving PA band.
Group II: Combined surgery for Glenn anastomosis + atrioventricular valve or pulmonary artery repair.
Group III: Re-sternotomy

monary arterioles, alveoli and bronchi were determined, and both were judged not applicable for surgery.

Figure 3.86 shows the course of treatment for PPA hypo RV case. From the neonatal period, repeated BT shunts of the pulmonary artery were performed. At age 16, pulmonary hypertension and severe mitral regurgitation were noted, and the NYHA grade was 2. After that, pulmonary artery banding and lung biopsy were repeated, and as a result, Glenn operation was performed at the age of 18, and final TCPC and Maze operations were performed at the age of 21.

Similarly, in surgery for cyanotic heart disease, pulmonary vascular lesions themselves cause death. In addition, in the presence thereof, it is difficult to adjust the balance between postoperative body blood flow and pulmonary blood flow. Pediatric cardiac surgeons often suffer from complications of organs other than the heart. Pulmonary vascular lesions are the third most disliked after edema and diuresis [51].

3.5.4.4 39 Glenn Operation Cases (Since 2001)

Glenn operation has become an important position as heart volume reduction toward Fontan operation with the improvement of operation results of HLHS and Heterotaxy syndrome, so a significant decrease in the age of surgery was observed.

Figure 3.87 shows the state of blood priming at the time of initial priming. Out of 53 cases, 6 cases weighing 5 kg or less, mainly HLHS, and 4 cases with cardiac dysfunction with atrioventricular valve regurgitation, and 4 cases with postoperative Hct estimated to be less than 30% were blood primed. Remaining 39 patients weighing 6.7 kg or more were primed without blood.

Non-transfusion rate 95% (37/39). Transfusion was performed in two cases; (1) BW 6.7 kg DORV, MA, PS: Hct 42.5% at induction of anesthesia, 27% at ICU return, transfusion due to postoperative drain bleeding, (2) 49 kg SV, PS, advanced AVVR (Glenn + atrioventricular valve replacement): transfusion due to postoperative drain bleeding.

3.5.4.5 Nine AVSD with TOF Cases

Non-transfusiont rate 89% (8/9). Except for 5.1 kg case with preoperative respirator management and 10.5 kg case with prolonged hypoxia due to the residual shunt between the atriums (ventilator management until the sixth and third days, respectively), the duration of intubation was 7.1 ± 1.2 h (5.8–9.0).

Transfusion was performed in one case weighing 9.8 kg. He had thrombocytopenia and recruited platelets immediately after extracorporeal circulation.

Column: AVSD with TOF and Reduction of Priming Volume

AVSD with TOF requires longer extracorporeal circulation to repair compared to simple TOF.

Also, residual lesions such as the pulmonary valve and mitral regurgitation may contribute to low cardiac output. However, the non-transfusion rate with a single TOF has been enhanced, and the total priming volume has been reduced. Thus, since 1995, bloodless open-heart surgery has been indicated. Table 3.11 shows six cases up to 1998.

Figure 3.88 shows changes in Hct, total protein, and Base Excess values in cases 1 and 2. In case 1 weighing 20.8 kg, the minimum Hct during extracorporeal circulation was 20%

Table 3.11 Bloodless open-heart surgery for AVSD with TOF: initial six cases

No.	Diagnosis	BW	Donated Blood	Prim. Vol.	CPB time	BTF
1	complete AVSD with TOF	20.8 kg	260 mL	750 mL	254 min	(−)
2	complete AVSD with TOF	8.8 kg	150 mL	470 mL	161 min	(−)
3	incomplete AVSD with TOF	9.6 kg	260 mL	470 mL	195 min	(−)
4	complete AVSD with PS	26.5 kg	200 mL	750 mL	245 min	(−)
5	complete AVSD with TOF	10.5 kg	110 mL	470 mL	192 min	(−)
6	complete AVSD with TOF	5.1 kg	60 mL	230 mL	193 min	(−)
			14±7 mL/kg		207±36 min	

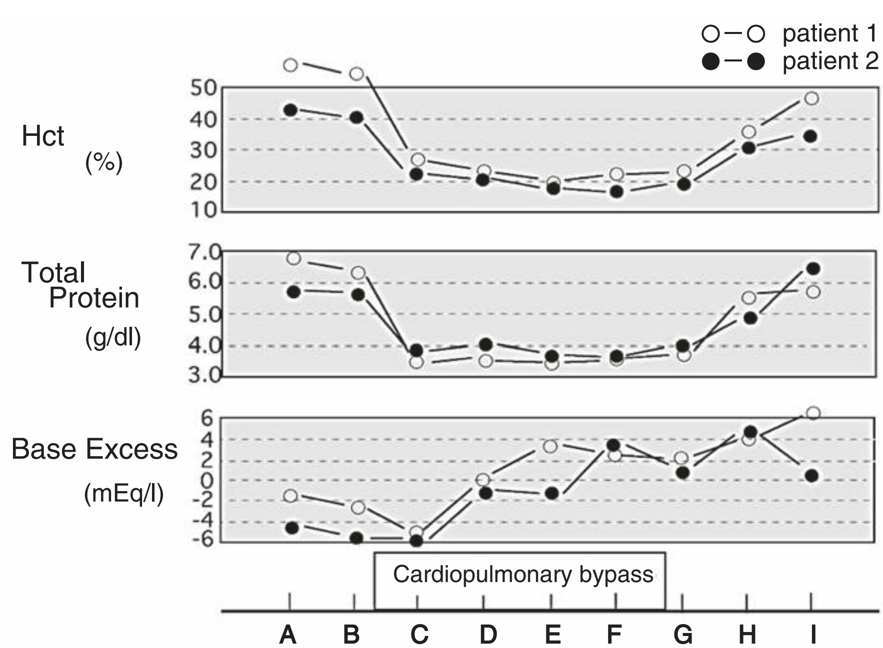

Fig. 3.88 Changes in Hct, total protein and base excess in cases 1 and 2 [53].
A : Anesthetic Induction
B : After blood donation
C : Total bypass
D : Ao clamp
E : Rewarming
F : Before CPB off
G : After CPB
H : ICU
I : 1POD

with autologous blood donation of 260 mL, and in case 2 weighing 8.8 kg, the minimum Hct 18%, autologous blood donation 100 mL. The transfusion criteria for cyanotic heart disease was less than 18–20% Hct during extracorporeal circulation, and in case 2, 30 mL of autologous blood was used during extracorporeal circulation.

The priming volume in 1995 was 370 mL for those weighing 8.5 or less, 470 mL for 8.6–17.9 kg, and 750 mL for 18–30 kg. Cases 1 and 2 are close to the minimum body weight in each priming volume range.

Case 1 was the first successful case of AVSD with TOF bloodless open-heart surgery. At that time, we reported that the success factor was to reduce the membrane oxygenator circuit used for severe cases from 1100 mL to 750 mL (Fig. 3.89). But, especially for non-cyanotic diseases, cases weighing around 9 kg and 20 kg were the most disadvantageous in terms of hemodilution. When performing autologous blood donation after induction of anesthesia, it was necessary to further reduce the priming volume even in cyanotic heart disease patients with relatively high body weight and high Hct. On the other hand, in 5.1 kg case 6 using a priming volume of 230 mL, the lowest Hct during extracorporeal circulation was 24% with 60 mL of autologous blood donation (Fig. 3.90).

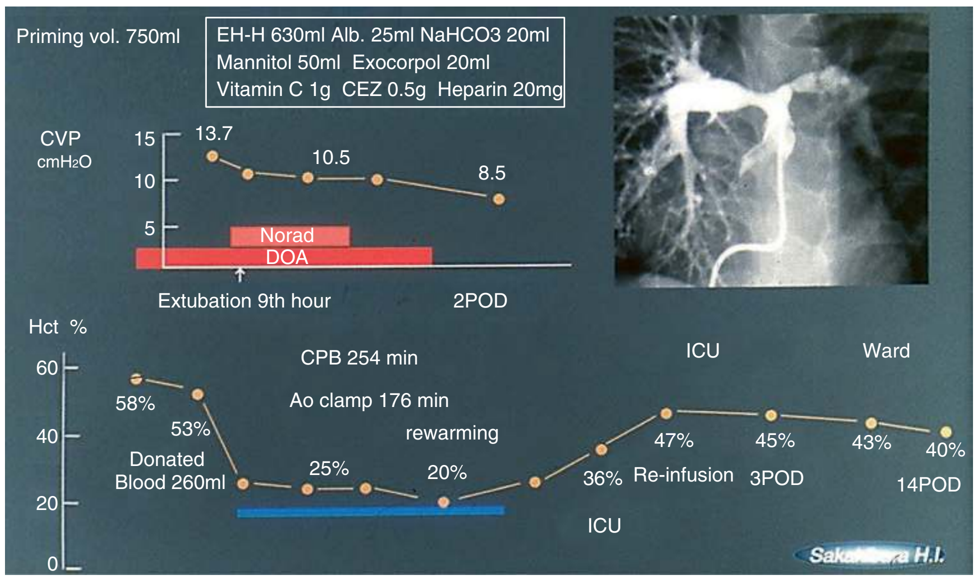

Fig. 3.89 Fitst case of AVSD with TOF undergoing bloodless open-heart surgery. The extracorporeal circulation time was 254 min, which was a long time, because the stenosis of the pulmonary artery bifurcation was also repaired. The lowest Hct during extracorporeal circulation is 20%

			0 30 60 90 120 150 180 193 min	
		Autologous Blood Donation 30mL	↑ Ao clamp, ↑ GIK, ↑ GIK, ↑ GIK, ↑ GIK, ↑ rewarming, ↑ unclamp	
Temp (℃)		36.5	33.1 27.8 26.9 27.1 35.5 36.1	
Blood gas	Na (mEq/L)	121	132 129 133 124 143 141	143
	K (mEq/L)	3.3	3.5 3.6 5.0 4.6 3.7 6.9	4.9
	B.E.	3	1.8 −0.9 −1.3 −2.2 −2.0 1.1	4
	Hct (%)	51.5	27.0 26.0 25.0 26.0 24.0 24.0	28
	T.P. (g/dL)	5.1	3.3 3.1 3.5 3.6 3.3 3.3	3.7
		Initaial priming		
Correction	25% albumin (mL)	10	DUF (albumin 10 mL + Veen F 90 mL) × 4	
	10% NaCl (mL)		3 3 4 5 3	
	KCl (mEq)		1.5 3 3 3 2	
	D-mannitol (mL)	12	5 5	
	$NaHCO_3$ (mL)	10	5 5 5 5	
	Veen F (mL)	180	30 30 60 30 60 30 60 60 60 30 60 30 30	
	C.H. (mg)		2 2 4 2 2 2 2 2	

Fig. 3.90 Extracorporeal circulation in infant with a minimum body weight of 5.1 kg. Initial priming volume 230 mL. Autologous blood donation 60 mL. priming composition (Veen F 180 mL, 25% albumin 20 mL, $NaHCO_3$ 10 mL, mannitol 12 mL, VC 1000 mg, exocorpol 10 mL, CEZ 500 mg, heparin 400 u, KCL 0.4 mL). Initial priming fluid data (PH 8.1, PO_2 129 mmHg, PCO_2 12.7, BE +34.9, Na 150 mEq/L, K 4.2). Perfusion flow 150 mL/kg/min. DUF washing volume: alb 5 mL + Veen F 95 mL × 4, urine volume 630 mL, ECUM volume 610 mL, fluid balance +328 mL. Extracorporeal circulation time 193 min, operation time 311 min, anesthesia time 355 min

As shown in “Current priming volume,” the priming volume in 2018 was reduced to 260 mL for cases weighing 13–23 kg, to 350 mL for 24–50 kg, and hemodilution was significantly reduced. However, reducing the priming volume means that the amount of residual blood used for increasing circulating blood after surgery is reduced as well, which may be disadvantageous from the viewpoint of postoperative infusion management [52–54].

3.5.4.6 Eight Jatene Procedure Cases

The non-transfusion rate was 100% (8/8). There were many cases of severe polycythemia, and relatively large amount of autologous blood donation was possible. The duration of intubation was 9.4 ± 5.4 h (3.8–18), except in one case, which needed 41 h postoperative ventilation due to diaphragmatic paralysis.

Figure 3.91 shows the progress of surgery and extracorporeal circulation in a case of TGAII, CoA weighing 5.1 kg, who underwent one-stage Jatene + CoA repair. Figure 3.92 shows extracorporeal circulation in a case of TGAII,CoA with a minimum body weight of 4.1 kg (two-stage Jatene operation was performed after CoA repair and pulmonary artery banding) [55–59].

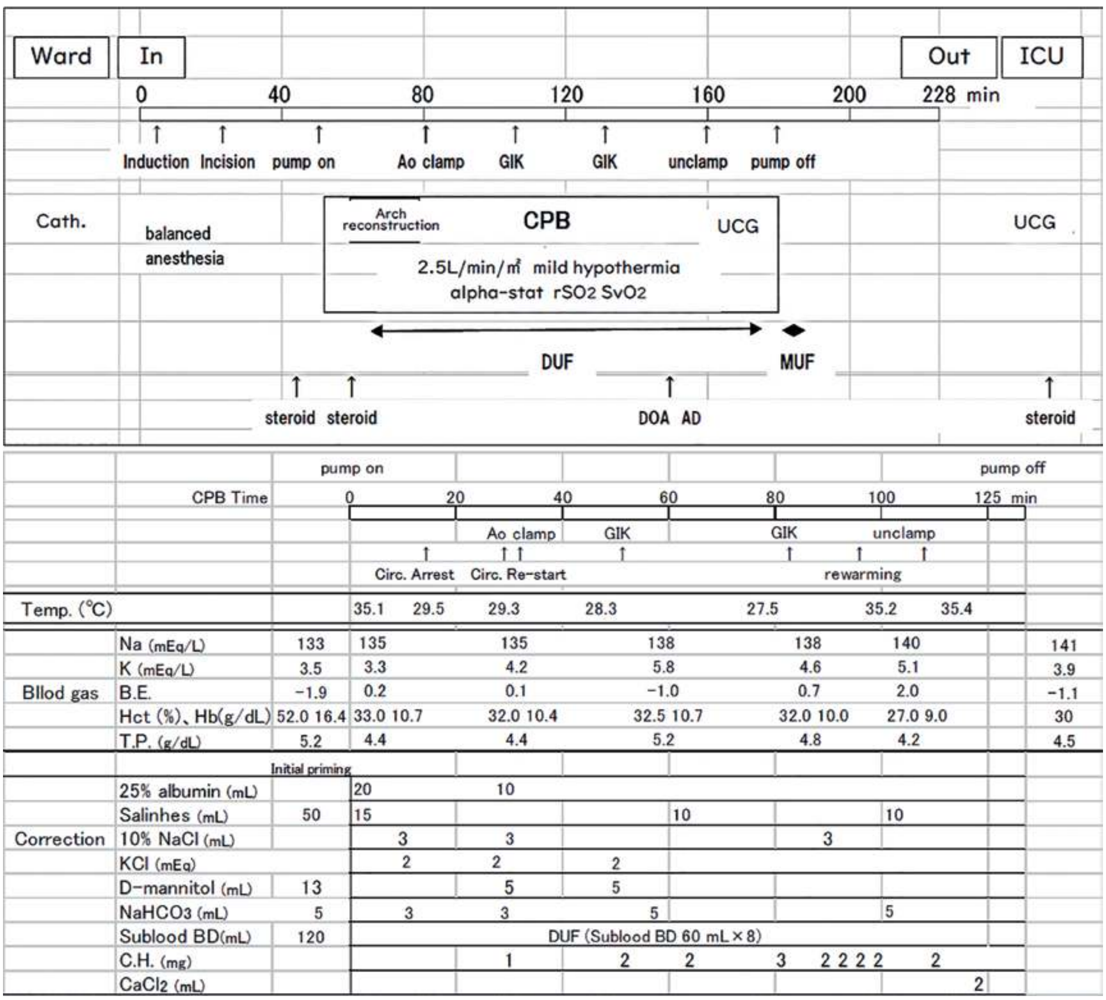

Fig. 3.91 Course of surgery and extracorporeal circulation in a case of TGAII, CoA case. Initial priming volume 200 mL. Autologous blood donation 80 mL. priming composition (sublood 106 mL, 25% albumin 20 mL, $NaHCO_3$ 5 mL, mannitol 13 mL, VC 1000 mg, exocorpol 6 mL, CEZ 500 mg, heparin 400 u, KCL 0.4 mL). Initial priming fluid data (PH 8.3, PO_2 290 mmHg, PCO_2 7.3, BE +34.9, Na 167 mEq/L, K 5.0). Perfusion flow 150 mL/kg/min. DUF wash volume: Sublood 60 mL × 13, urine volume 210 mL, ECUM volume 912 mL, fluid balance +17 mL. Extracorporeal circulation time 125 min, surgery time 192 min, anesthesia time 228 min

			0–30 min	30–60 min	60–90 min	90–120 min	120–150 min	150–180 min	
		Autologous Bllod Donation 50mL	cooling	Ao clamp, GIK	GIK	GIK		Ao unclamp, rewarming	
Temp. (℃)		36.0	33.2	27.8	27.2	28.2		35.8	
Blood gas	Na (mEq/L)	135	135	139	138	140 142	143		142
	K (mEq/L)	3.9	3.7	4.3	4.8	4.2 4.7	4.6		4.8
	B.E.	−4.4	−0.1	−0.5	−2.7	−1.9 −1.7	+1.2		2.1
	Hct (%)	55	31	27	28.5	28 29	28.5		26
	T.P. (g/dL)	5.7	3.8	3.5	3.9	4.1 4.4	4.5		4.5
Correction	25% albumin (mL)			DUF (albumin 5 mL + Veen F 95 mL)×4				5 5	
	10% NaCl (mL)		5						
	KCl (mEq)		1 2	2	1 1	1	1	1 1	
	D-mannitol (mL)				4		4		
	$NaHCO_3$ (mL)		5	4 3	4 5	3	4	4	
	Veen F (mL)		60	60 60	60	60 60 60	60 60	60	
	C.H. (mg)		1	1 1	2 1			2	

Fig. 3.92 Extracorporeal circulation in a case of TGAII, CoA (criss-cross heart) weighing 4.1 kg [55]. BW 4.1 kg, 4 months old. TGA (II), criss-cross heart, CoA, PDA. PDA ligation, CoA repair, and PA banding were performed on the 18th day of life. The initial priming volume was 230 mL (20 mL albumin was primed). After induction of anesthesia, 50 mL of autologous blood was stored. The ECUM volume 441 mL, the urine volume 627 mL, fluid balance +170 mL. Aortic cross-clamp time 149 min, extracorporeal circulation time 184 min, surgery time 275 min, anesthesia time 317 min. After extracorporeal circulation, dopamine 4 γ/kg/min, adrenaline 0.1 γ/kg/min, and nitroglycerin 1 γ/kg/min were used. The duration of intubation was 11 h. All blood GIK was aspirated into the reservoir. Long-term extracorporeal circulation was required, but no problems with electrolytes were observed

Column: Blood Transfusion in Jatene's Operation (2003)

In 1999, the blood supply system from the Japanese Red Cross Society was changed from whole blood to component transfusion of concentrated red blood cells (MAP), frozen plasma (FFP), and platelets. The aim was to avoid transfusion of unnecessary components and to reduce the burden on the circulatory system (heart, kidney, etc.). However, in cardiac surgery using extracorporeal circulation, all components are diluted.

Since 1997, out of 46 cases of Jatene surgery have been performed, 27 neonates who underwent single-stage Jatene surgery and had no obvious transfusion factors such as drain bleeding were classified into 9 cases in the first half, before 1999 when fresh whole blood was used, and 18 cases in the second half, after 2000 with component transfusion, and compared their blood usage status (Table 3.12). In the former, eight out of nine patients (89%) could be discharged using only 400 mL of whole blood, and one patient who was found to have CoA after Jatene surgery received additional blood transfusion during CoA re-operation. On the other hand, in the latter, two units (from one donor) of MAP was used in only three cases, MAP + FFP, MAP + platelets, MAP + FFP + platelets (all from one donor) were used in eight cases, and in the remaining seven cases, MAP, FFP and platelets were used from two blood donors or more. In the latter period, the number of transfusions used increased significantly. This increase was primarily due to the uniqueness of the newborn. That is, (1) not only erythrocytes but also coagulation factors and proteins are highly diluted, and (2) the results of Jatene's operation are stable but still require strict management. Persistent bleeding and minor abnormalities in various data may contribute to deterioration of general condition and long-term management. Therefore, in the latter cases, if there was such anxiety, preparation of not only MAP but also FFP and platelets were performed, and in many cases, the prophylactic administration was performed after extracorporeal circulation. At present, the blood to be prepared for Jatene's operation is, in principle, three units of MAP are only prepared, and FFP and platelets are requested as needed. However, in consideration of the possibility that platelets cannot be prepared in an response to emergency situations, the components must be requested on the day before the operation, and there is also a problem of discarding or overdosing them. Empirically, if you have 400 mL of fresh whole blood, you can use 100–150 mL for the initial priming and leave at least 150 mL after extracorporeal circulation. There is no doubt that the use of fresh whole blood was the most effective means of reducing blood transfusion in neonatal open-heart surgery.

Table 3.13 shows the blood usage status of Jatene's operation at eight pediatric cardiac surgery centers in

Table 3.12 Comparison of blood usage status in Jatene operation [52].
The priming volume was 300 mL or 370 mL in 1997 and 230 mL in 1998 and thereafter. The anesthesia time was 283 ± 46 min (225–360) in 9 cases until 1999, and 230 ± 40 min (172–365) in 18 cases since 2000

	1997～ 1999	2000～
No. of cases	9	18
	TGA I 5 TGA II 2 TGA II CoA 2	TGA I 14 TGA II 3 TGA II CoA 1
BW (kg)	2.9±0.2	3.0±0.5
CPB time (min)	144±27	118±32
Blood use for 1 unit or more	1/9(11%)	15/18(83%)
Priming Volume	300 or 370mL (1997) 230mL (1998～99)	230mL

Table 3.13 Blood usage in Jatene operation at eight pediatric cardiac centers [52]

HP	Blood preparation	Priming vol. & Composition	Blood usage Criteria	Blood usage per patient
a	MAP(2u) …5 pac Plt …10 u FFP …5 u ※ Fresh blood be prepared	Priming vol.…350mL MAP 2 u + 5% alb. 100mL	Not use residual blood Use MAP Prophylactic plt &FFP use	MAP(2u) … 3 pac Plt … 10 u FFP … 5 u
b	MAP(2u) …3 pac Plt …10 u FFP …6 u	Priming vol.…380mL MAP 200mL + 25% alb. 80mL	Use residual blood Prophylactic plt &FFP use	MAP(2u) … 1 pac Plt … 5 u FFP … 1 u
c	MAP(2u) …2 pac Plt …5 u FFP …2 u	Priming vol.…340mL MAP 2 u + 25% alb. 60mL	Use residual blood Prophylactic plt &FFP use	MAP(2u) … 1 pac Plt … 0 or 5 u FFP … 0 or 2 u
d	MAP(2u) …2 pac Request Plt & FFP if necessary	Priming vol.…400mL MAP 200mL + 25% alb. 60mL ※ FFP priming by PT value	Not use residual blood No prophylactic use of Plt & FFP	MAP(2u) … 2 pac Plt … 0～5 u FFP … 1～3 u
e	MAP(2u) …1 pac Plt …10 u	Priming vol.…230mL MAP 100mL + 25% alb. 50mL	Use residual blood Prophylactic Plt use No prophylactic use of FFP	MAP(2u) … 1 pac Plt … 10 u
f	MAP(2u) …1 pac Plt … 5 u FFP … 5 u Whole blood … 5pac	Priming vol.…350mL MAP 140mL Wash primed blood with 5%Alb. 500mL	Use whole blood Use Plt as needed Prophylactic FFP use	MAP(2u) … 2 pac Plt … 5 u FFP … 10～12 u Whole blood … 1 pac
g	MAP(2u) …3 pac Plt … 10 u FFP … 6 u Fresh blood … 1pac	Priming vol.…350mL MAP 260mL + 25% alb. 50mL	Not use residual blood Prophylactic use of Plt & FFP Use fresh blood as needed	MAP(2u) … 3 pac Plt … 10 u FFP … 4 u Fresh blood … 1 pac
h	MAP(2u) …2 pac MAP(1u) …1 pac Request Plt & FFP if necessary	Priming vol.…230ml MAP 100ml + 25% alb. 30ml ※ FFP priming by patient	Use residual blood No prophylactic use of Plt & FFP	MAP(2u) … 1 pac Plt … 0 ～10 u FFP … 0 ～1 u

Japan. Among the facilities, there were differences in the blood preparation system and usage policy, including the blood supply system from the Japanese Red Cross Society, the blood management system, and the concept of the effectiveness of whole blood. There were many facilities that prepared and used prophylactically FFP and platelets. In the future, even in neonatal cardiac surgery, where blood transfusion is essential, it is necessary to study clinically effective blood transfusion methods and their proper use [52, 60].

Column: Precautions for Jatene's Operation (2004)
Figure 3.93 shows five cases of two-stage bloodless Jatene surgery. Two of them had multiple VSD. Prior to aortic unclamp, a thorough search for residual shunt is required in a lung pressurization [61].

3.5.5 Causes of Blood Transfusion in Cyanotic Heart Disease (Since 1997)

The main causes of blood transfusion were: (1) an increase in cases with blood priming due to a decline in age at surgery and anemia cases in which autologous blood cannot be donated, (2) lack of circulating blood volume due to bleeding from the anastomosis and drainage, (3) long-term management of ICU by pleural and ascites storage in Fontan operation, and (4) repeated extracorporeal circulation for residual lesions. Most were transfused immediately after the end of extracorporeal circulation until the early period in the ICU. Due to the reduction in priming volume, there was little need for transfusion during extracorporeal circulation due to low hemodilution. Also, blood transfusions were rarely required from poor hemodynamics and respiratory status. In bloodless open-heart surgery for cyanotic heart disease, the most important thing was to shorten the operation time and to ensure suturing and thorough hemostasis.

Column: Preoperative Autologous Blood Donation (2001)
We believe that there is no objection to securing as much autologous blood as possible in cardiac surgery. Since 1997, there has been an increase in pediatric cardiac surgery facilities that provide autologous blood donation not only after induction of anesthesia but also prior to surgery. However, it is not clear in which cases preoperative blood donation is required. It is also a fact that there are many cases where preoperative blood donation is practically impossible, and there are problems such as excess autologous blood and complicated work. Therefore, the necessity of preoperative blood donation in pediatric heart surgery was examined. The subjects were 986 patients with non-cyanotic heart disease and 360 cases with cyanotic heart disease who underwent bloodless open-heart surgery (Fig. 3.94). The method of autologous blood transfusion is to use only residual blood in non-cyanosis patients and to store blood after induction of anesthesia in addition to residual blood in cyanosis patients.

Blood transfusions were required in 5% of non-cyanosis patients and 10% of cyanosis patients. Figure 3.95 shows the non-transfusion rate and blood transfusion factors for each group. Many of the cyanosis groups were transfused after extracorporeal circulation and early stage in the ICU, and the amount of donated blood and residual blood alone was insufficient. If there is preoperative blood donation at around 10–15 mL/kg at this time, not only for the progression of anemia but also for

Fig. 3.93 Five cases of two-stage bloodless Jatene surgery

Staged Arterial Switch Operation without Homologous Blood Transfusion

	1	2	3	4	5
Diagnosis	DORV CoA	DORV CoA	TGA CoA	TGA CoA	TGA CoA
	Previous Procedure		PDA closure	PA banding	CoA repair
Procedure	Arterial Switch & VSD closure				
Age (mo)	18	53	13	5	16
BW (kg)	7.5	11.0	7.0	4.1	6.1
Shaher	7A	7B	1	1	2B
	Multiple VSD		Multiple VSD		

Hct after ICU admission 44.8% (42.0〜50.0)
CVP after ICU admission 12.5 cmH2O (9.0〜14.5)
Duration of Intubation 7.8 hours (3.5〜18.0)

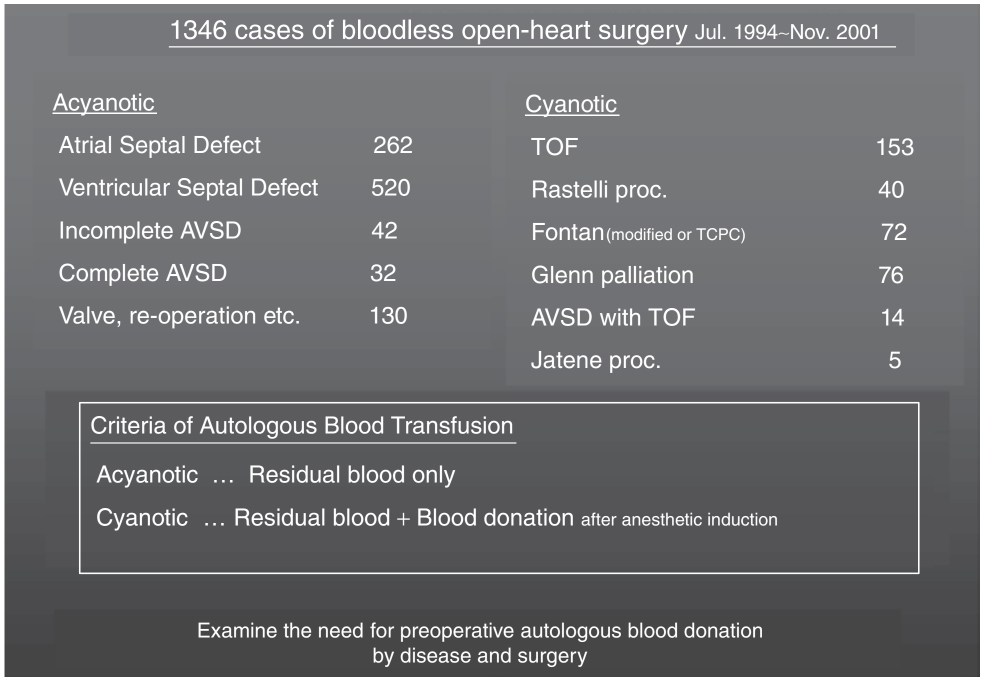

Fig. 3.94 Bloodless open-heart surgery until 2001

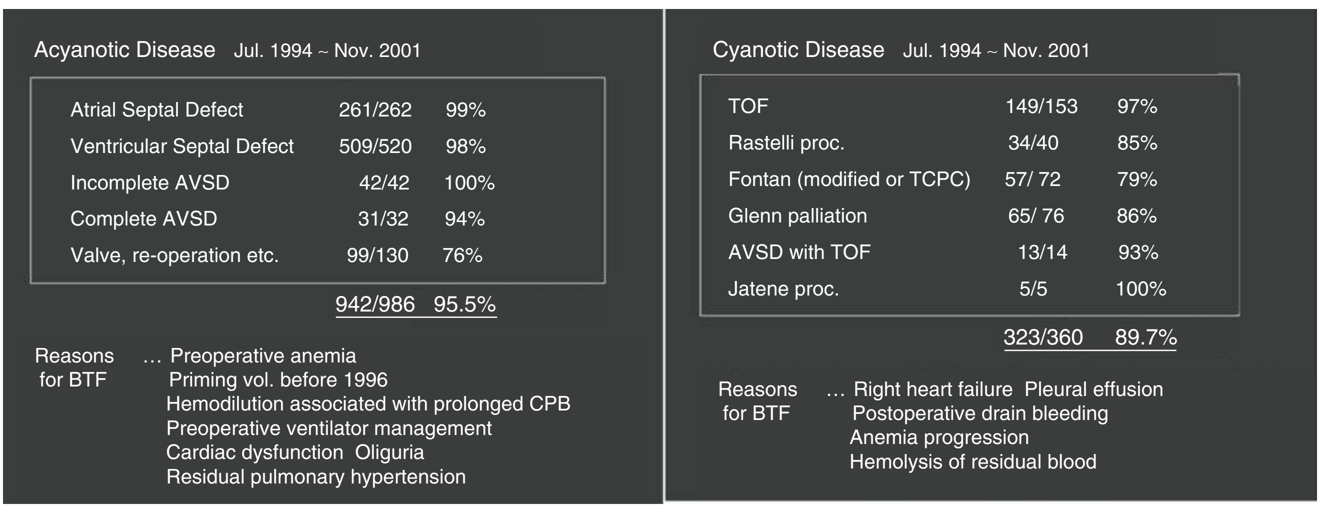

Fig. 3.95 Results of bloodless open-heart surgery and transfusion factors in non-cyanotic and cyanotic heart disease [62] Modified

increasing circulating blood volume and replenishing coagulation factors and platelets, we believe that the non-transfusion rate will further improve. There is a realistic method of storing blood, for example, storing it under sedation during cardiac catheterization even in patients under 10 kg. On the other hand, blood transfusions in the non-cyanosis group were mostly cases weighing less than 4.5 kg. Since these have symptoms of heart failure and respiratory failure and are often operated on a semi-emergency basis, preoperative blood donation is almost impossible. In addition, from the actual non-transfusion rate, preoperative blood donation with ASD, VSD, AVSD, and TOF is considered unnecessary. However, if there is even a small amount of preoperative blood donation, its use in the initial priming may be useful in the sense of improving hemodilution during extracorporeal circulation as much as possible. Preoperative blood donation in children is often difficult and impossible. The risk and benefits of preoperative blood donation should be considered on a case-by-case basis.

Q&A: Bloodless open-heart surgery for cyanotic heart disease (Question in 2007)

Question: What are the management points and precautions of bloodless open-heart surgery for cyanotic heart disease?

Answer: Extracorporeal circulation devices and their management are similar to those for non-cyanotic heart disease. "Constant Perfusion" and permissive anemia should be thoroughly managed. Regarding hemodilution, I think there is no data on the limit of hemodilution in cyanotic heart disease. Bloodless open-heart surgery is indicated when the Hct at the initiation of extracorporeal circulation is predicted to be 20%

or more, and protein preparations are used when the total protein is less than 3.0 g/dL. With the extracorporeal circuit of the current priming volume, it is unlikely that these values will be below these, and in our experience, there is little effect on hemodynamics and respiratory status under these conditions. With regard to protein preparations, prolonged extracorporeal circulation requires prophylactic use of albumin or continuous administration of Salinhes, but the recovery of total protein is rapid (refer to Fig. 3.78), and there is little need to administer it to increase total protein levels. Rather, I think it is often used to increase circulating blood volume in terms of infusion management.

The important thing in management is that the volume adjustment after extracorporeal circulation should be more rigorous. Perhaps because children with cyanotic heart disease have abundant peripheral vascular beds, the volume load required to adjust the circulating blood volume and improve peripheral circulation is more necessary than that for non-cyanotic heart disease. In particular, early administration of vasodilators and sedatives without improvement in peripheral circulation may require more volume due to lower blood pressure, so caution is required. The point to make volume management easier in bloodless open-heart surgery is to leave enough residual blood when returning to the ICU. Thus, surgery time for cyanotic heart disease is generally longer, but at least you should strive to reduce the time to close the chest. Prolonged surgery puts a lot of stress on the team members, and if it is determined that long operation time was a factor that required blood transfusion, negative opinions will be expressed in performing bloodless open-heart surgery. In order to improve the success rate of bloodless open-heart surgery, it is necessary to reduce time, stabilize cardiac function, and properly manage the volume in consideration of permissive anemia, even in cyanotic heart disease.

In recent years, the number of cases of resternotomy has increased, including replacement for conduit stenosis after Rastelli procedure, TCPC conversion after conventional Fontan procedure, and re-operation for residual pulmonary valve and mitral valve regurgitation. They are called adult congenital heart disease. The main transfusion factor of these is chest drain bleeding. It is important to stop bleeding from the sternum, collateral vessels, and detached surface before extracorporeal circulation. Pediatric cardiac surgery is now called exfoliative surgery, and it is necessary to learn the art of exfoliating without bleeding in a short time. In addition, since these cases were formerly cyanotic heart disease and do not have polycythemia, unlike the previous operation, reduction of the priming volume is indispensable for preventing hemodilution. And in addition, preoperative autologous blood donation is easier. Furthermore, as mentioned previously, in Glenn and Fontan procedures, the number of cases that are considered to be not applicable for bloodless open-heart surgery prior to surgery is increasing. The reason is that the number of anemia cases increases with the declining age and weight of the patients, and is an increase in the number of cases in which postoperative hemodynamica deterioration and a large amount of pleural and ascitic fluid accumulation is expected due to low cardiac function accompanied by atrioventricular valve regurgitation or poor growth of the pulmonary vascular bed. Currently, blood transfusion will be used if the patient's body weight is less than 5 kg, cardiac function is reduced, or if postoperative Hct is estimated to be less than 30%, mainly for HLHS and Heterotaxy syndrome.

3.6 Future Blood Transfusion Therapy and Blood Transfusion Reduction

The important status of pediatric cardiac surgeons is not only the outcome of surgery but also the achievement of minimally invasive extracorporeal circulation and early exit from the ICU. The most important considerations for this purpose are, of course, prevention of poor diuresis and edema during extracorporeal circulation and increased diuresis and improvement of edema during the acute postoperative ICU phase.

The purpose of transfusion in pediatric heart surgery is replenishment for hemodilution and bleeding associated with extracorporeal circulation, increase oxygen delivery and preload for postoperative LOS, replenishment for edema and pleural effusion ascites, high Hct management after open palliative surgery. Blood transfusion is an important therapeutic measure for recovery if the surgical invasion is large and the systemic organs are severely impaired, so transfusion is essential in such cases. If reducing blood transfusion aggressively may lead to worsening of the condition and prolongation of treatment time, there is no meaning in blood transfusion reduction. However, conversely, if a very stable general condition can be achieved at the time of surgery, blood transfusion reduction will be possible. Therefore, in order to reduce blood transfusion, it is first necessary to consider a comprehensive and minimally invasive measure for surgery, especially for extracorporeal circulation. In heart surgery, it is important to consider both; transfusion methods as a treatment for minimally invasiveness and measures to be minimally invasive even without blood transfusion. In the future, in pediatric cardiac surgery, it will be necessary to determine the optimal level of Hb, coagulation factors, platelets, and protein to maintain, especially in terms of diuresis and edema, and in terms of time reduction and early recovery of patients. Of course, the most basic measure to reduce blood transfusions is for the surgeon to perform adequate hemostasis [63].

Q&A: Limitations of bloodless open-heart surgery (Question in 2007)

Question: What are the limitations of bloodless open-heart surgery, that is, the limitations of hemodilution? Additionally, please tell us about the current risk and benefit of bloodless *open-heart surgery, as well as your thoughts on future transfusion therapy.*

Answer: The equipment used for extracorporeal circulation and its management method, the condition of the patient, the timing of surgery, the standard for bloodless open-heart surgery as a team vary greatly between individual facilities, so the limitations of bloodless open-heart surgery will, of course be different. Again, the minimum requirement for bloodless extracorporeal circulation is that the postoperative circulatory and respiratory dynamics should be equal to or greater than that with blood transfusion. Experience has shown that the limiting cases of bloodless open-heart surgery under these conditions are ASD weighting 4.4 kg, VSD 3.3 kg, complete AVSD 4.0 kg, constriction complex 4.1 kg, AVSD with TOF 5.1 kg, total anomalous pulmonary venous drainage 4.4 kg, and Jatene procedure after palliation 4.1 kg. And the limit Hct for hemodilution was 11.0%, the lowest during extracorporeal circulation in a VSD weighing 4.3 kg.

Since 2002, there has been a number of negative opinions regarding bloodless open-heart surgery, especially in low-weight infant, in view of the drastic reduction in virus infections and the potential for reduced psychomotor development in the postoperative period. I would like to introduce a sentence that describes my concept and idea of bloodless open-heart surgery in 2002.

[In recent years, the safety of blood has greatly improved, and almost no side effects have occurred with blood transfusions. Therefore, if we aim for minimally invasive surgery in terms of preventing complications associated with blood transfusion, that would be a bit true and probably a lie. There may not be much need to be particular about bloodless open-heart surgery.

What Is the Significance of Bloodless Open-Heart Surgery?

Better patient status after bloodless open-heart surgery, no complications, effective medical cost savings, and less burden on healthcare workers. In other words, if the overall quality of bloodless open-heart surgery itself is high and it leads to minimally invasiveness, negative opinions may not occur. Of course, these are the minimum requirements, but I think the significance of bloodless open-heart surgery is to avoid problems relating to transfusion without using what is not necessary. However, there are important issues that need to be resolved as soon as possible, such as a detailed evaluation of brain metabolism during hemodilution and postoperative psychomotor development. At the least, the benefits of bloodless open-heart surgery should be made aware.

Requirements for Performing Bloodless Open-Heart Surgery

At Sakakibara Heart Institute, the number of bloodless open-heart surgery cases since July 1994 exceeded 1000 cases. Not all cases were without problems. As an initial experience, there were some cases with convulsions, as mentioned previously. In addition, although it was not necessarily the only problem associated with bloodless open-heart surgery, I also think over that it was better not to perform bloodless open-heart surgery, as in the case where long-term management in the ICU was necessary. This includes cases with a body weight of 10 kg or more and a minimum Hct of 20% or more. From these experiences, we have understood the outline of whether to use blood or not and what should be done or what should not be done in bloodless open-heart surgery. Until now, I have mainly examined the conditions for expanding the indication for bloodless open-heart surgery, but based on these experiences, I would like to state the clinical conditions under which the indication should not be expanded.

1. Experience of Team Members

The following three requirements are necessary to perform a bloodless open-heart surgery; (1) Pediatirc cardiologists, anesthesiologists, perfusionists, and scrub nurses should have sufficient experience in bloodless open-heart surgery, (2) Ability to perform quick surgery, and (3) Before expanding the bloodless indication to low-weight infants, the postoperative condition of the disease for which the indication is expanded is good, and the success rate of bloodless is high. Conversely, it is better not to extend the indication for bloodless open-heart surgery for patients under 10 kg even if an extracorporeal circuit with a priming volume of 250 mL is used if; (a) Less than 100 bloodless open-heart surgeries were performed, (b) Anesthesia time of VSD open-heart surgery is more than 3 h, and (c) The success rate of bloodless in TOF open-heart surgery which is a good indication of bloodless, is less than 80%.

2. Postoperative Status and Quality

If someone feels that the overall quality of surgery has declined, as shown below, compared to previous surgery with blood transfusion, the indication for bloodless open-heart surgery should not be expanded: (1) Usage of a large amount of inotrope, (2) Long-term ventilator management, (3) Delay in awakening after anesthesia, and occurrence of neurological problems, (4) Usage of large amounts of protein preparations and drugs, (5) Many equipments to prepare for bloodless open-heart surgery, (6) Long operation time which annoys nurses, anesthesiologists and ICU doctors, (7) A child who underwent a bloodless open-heart surgery has a pale face and is walking in the ward with a flutter, and (8) Long hospital stay. Specifically, it is better not to perform bloodless open-heart surgery in a situation in which a ventilator needs to be managed for 10 h or more after bloodless open-heart operation for a VSD weighing 5 kg. A better clinical course and less invasive judgment than open-heart surgery with blood are considered the minimum requirements for expanding indications.

3. Palliative Procedure

Before 1994, when a patient weighing 5 kg or more was indicated for bloodless open-heart surgery, the patient had to wait for weight gain or perform palliative surgery in the case of Interruption and Coarctation complex in order to perform bloodless open-heart surgery. However, these ideas are contrary to recent advances in cardiac surgery. Unless there is a parent's desire or religious reason, it is very unlikely that it would be better to have a palliative operation to perform a bloodless open-heart procedure.

4. Limits of Hemodilution

Currently, the lowest clinical hemodilution safety limits are reported to be 3–4 g/dL for Hb and 10% Hct based on animal studies. There are large differences between institutions in setting the hemodilution threshold for bloodless open-heart surgery. It is presumed that this reflects the philosophy of each facility, such as differences in surgeon treatment policies and patient management methods.

The dilution limit Hct value we experienced was 11.0%. This value is based on the previously mentioned significance of bloodless open-heart surgery, in which the quality of surgery is high and bloodless leads to minimally invasiveness in 75 patients with VSD weighing 3.3–4.9 kg. So, this cannot be applied to all diseases and cases. If the extracorporeal circulation time is more than 60 min, the threshold, for example, in complete atrioventricular septal defect, should of course be higher. Hemodilution limits for bloodless open-heart surgery ultimately require assessment of psychomotor development in the late postoperative period, but it is important to determine this from a number of experiences. It should be performed for each disease, case, and facility. At least, the limits of what others say should not be trusted. Hemodilution limits cannot be determined unambiguously.

The Hct values of the above-mentioned cases of convulsions and those who felt that it was better not to do bloodless open-heart surgery were relatively high (minimum Hct during extracorporeal circulation > 20%). This suggests that bloodless open-heart surgery should be considered a risky or risk-bearing operation, even if the hemodilution is acceptable (of course, all clinical problems are not due to bloodless). Even if the minimum Hct value is set to a safety margin of 20% or more, it is not safe. If there are many conditions in which the indications for bloodless open-heart surgery should not be expanded as described above, I think it is better not to perform bloodless open-heart surgery.

By the way, in 75 VSD patients weighing 3.3–4.9 kg who underwent bloodless open-heart surgery, only 5 cases had a minimum Hct of 18% or more. Assuming a limit of 18%, few patients weigh less than 4 kg are eligible for bloodless open-heart surgery. I believe that it is important to determine the limit of bloodless open-heart surgery based on the clinical course of the patient and the quality of the operation, rather than determining the limit only with the lowest Hct value. As I said many times, it is not just to set 20% or more.

I think that bloodless open-heart surgery will continue to advance as an important issue. In fact, even in open-heart surgery that requires transfusion, the experience of bloodless open-heart surgery has led to a reduction in the amount of blood to be prepared and used, as well as a improvement of the problem of overdose and disposal. Even if transfusion is safe, it is still meaningful to advance bloodless open-heart surgery, especially for children. We believe that more positive research will contribute to improving the quality of life of children in the future. Y. Takahashi, Department of Pediatric Cardiac Surgery, Sakakibara Heart Institute.]

It is probably a cheeky sentence. It was in July 1993 that bloodless open-heart surgery began to be actively conducted. This was because the priming volume has been reduced, and the introduction of ECUM has realized that the management time of the ventilator after surgery has been shortened.

If the risk and benefits of bloodless open-heart surgery based on our experience are considered, benefits include not only avoiding the problems associated with blood transfusion but also; (1) reducing blood reserves and total blood transfusion in newborns and low-weight infants who require blood transfusion and improving the problem of overdosing and discarding blood, (2) increasing the number of operations and simplifying the operation plan (2–4 cases per day) due to shortening of the duration of operation and anesthesia for the purpose of improving the success rate of bloodless open-heart surgery, (3) improving the skills of scrub nurses and perfusionists, and (4) less invasiveness of extracorporeal circulation itself due to advances in equipment. There is no doubt that there have been many spreading effects from the experience of bloodless open-heart surgery.

On the other hand, the drawback is that postoperative hemodynamics, and respiratory status are rather good, but (1) the possibility of psychomotor development delay and subclinical problems in the remote period, (2) possibility of increased pleural and ascites due to Glenn or Fontan procedure, and (3) possibility of extending the medication or fluid restriction period after returning to the general ward. Of course, these drawbacks can occur without hemodilution, but considering that extracorporeal circulation is the greatest biological invasion, and taking into account the synergistic effect of the negative factor of hemodilution associated with bloodless open-heart surgery, there are, of course, conditions under which transfusion reductions must be avoided.

In the future, in order to reduce blood transfusions, it is necessary to fully understand the differences from other surgical operations and pursue transfusion therapy with the highest clinical effectiveness. It is also important to create original guidelines for proper blood usage, taking into account the balance of blood supply and demand [64–70].

3.7 Summary of Bloodless Open-Heart Surgery

In Japan, extracorporeal circulatory devices for children have a development concept that fully considers the specialty of newborns and low-weight children and have achieved the intended clinical effects. However, since 2007, the most notable and important quality of increased diuresis and improved edema has started to have an impression which were slightly reduced. This is the biggest drawback of bloodless open-heart surgery, and the percentage of cases in which bloodless bloodless open-heart surgery is actually indicated has decreased (Figs. 3.96 and 3.97). In addition, during this period, the postoperative ICU management became prolonged even in neonatal open-heart surgery with blood priming. At first, the cause was not well understood, but during the management of extracorporeal circulation, we noticed that there was an unusual biological reaction. In the next chapter, I will discuss new findings on pitfalls in the current extracorporeal circulation and how to deal with them.

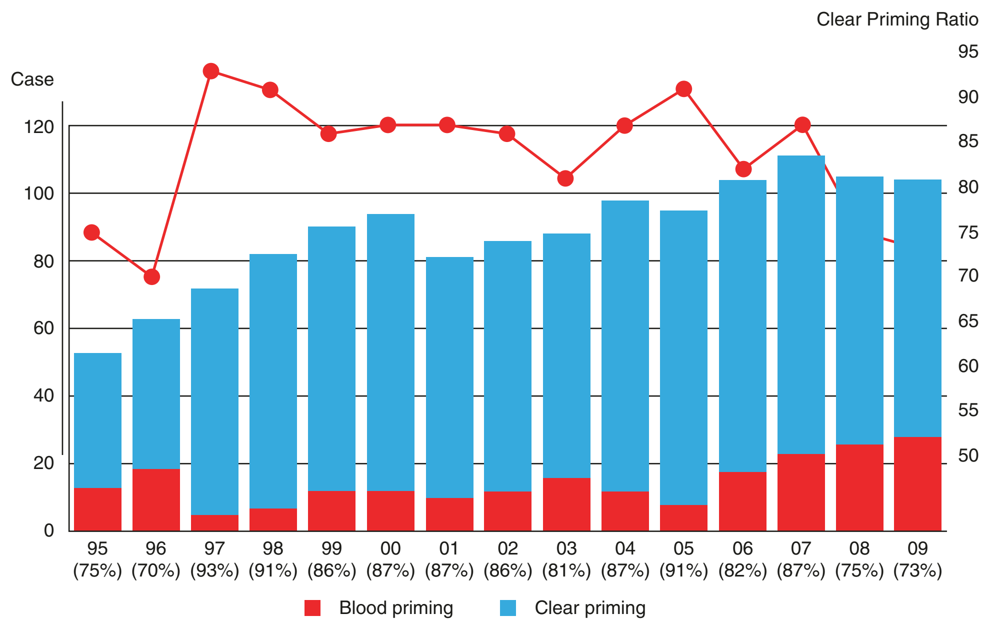

Fig. 3.96 Change of bloodless priming rate in VSD open-heart surgery

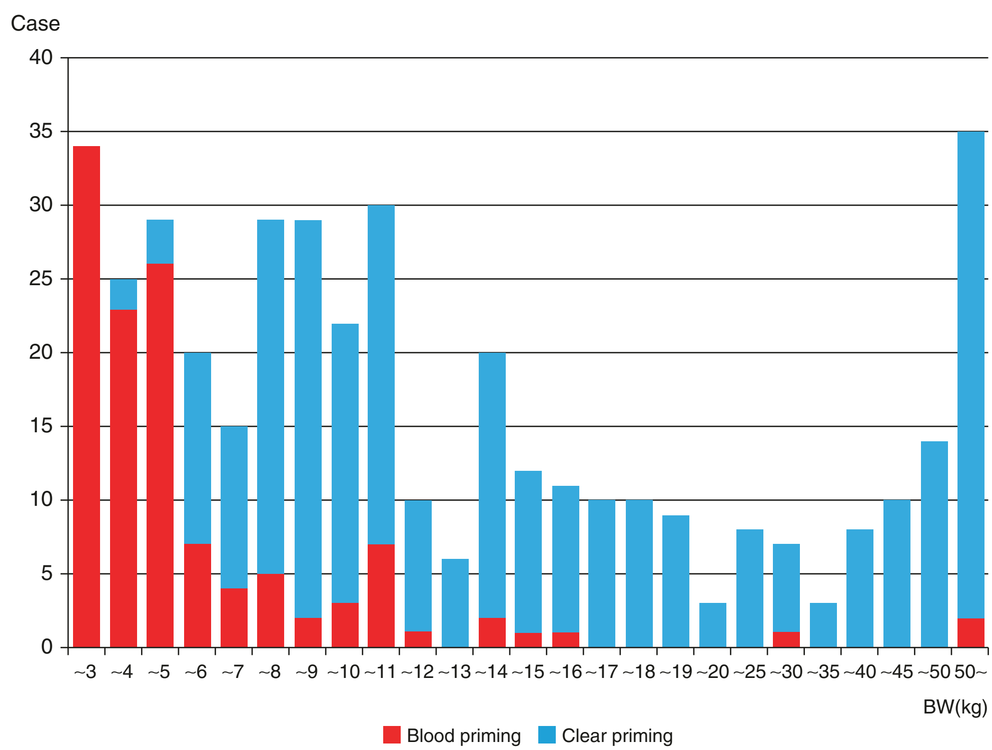

Fig. 3.97 Percentage of bloodless priming by weight (2009)

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Part II

Pitfalls in Recent Extracorporeal Circulation and Countermeasures

Problems with New Devices

4

Contents

4.1 Introduction

The era of developing new pediatric extracorporeal circulation devices under the slogan of minimizing invasiveness further was around 2007. At the same time, some devices were discontinued. Along with this, the heart–lung machine and related devices, as well as the management method of extracorporeal circulation were changed. The main changes were; (1) venous reservoir, (2) venous drainage method, and (3) oxygenator.

Since 2007, the rate of bloodless open-heart surgery has declined. This was not only because the safety of allogeneic blood was enhanced but also that the concept of bloodless open-heart surgery itself has changed due to concerns over delayed psychomotor development in the postoperative period. Indeed, it was true that the prerequisites for performing bloodless open-heart surgery, in which the postoperative hemodynamics and respiratory status were better than those with blood priming, could not be maintained anymore. The specific factors were; reduced perfusion pressure and increased water balance during extracorporeal circulation, and decreased diuresis in the ICU as well as increased amount of volume added. These suggest that peripheral blood vessels were excessively dilated. In addition, increased edema and increased pleural and ascites retention were noticeable in neonatal open-heart surgery. However, despite the change of equipments, the perfusionist mentioned that there were no noticeable changes, such as the management during extracorporeal circulation.

Under normal circumstances, the clinical effect of the new device should be recognized. What was the cause of vasodilation and vascular hyperpermeability? This was our big question since 2007. Figure 4.1 below shows the management method and tips in the above-mentioned bloodless open-heart surgery. Although the sales of PAN (polyacrylonitrile) membrane dialyzers had already been discontinued in 2007, the cause of the excessive vasodilation was assumed to be the possibility of inadequate "Constant Perfusion," that is, a new occurrence of some non-physiological fluctuations in the living body was assumed.

Table 4.1 shows the equations in extracorporeal circulation. Not only changes in hemodynamics and the occurrence of SIRS, but also non-physiological fluctuations that arise from the necessary management during extracorporeal circulation, such as correction and supplementation, etc., may adversely affect the living body. Therefore, it is important to manage to reduce the width of this fluctuation as much as possible. Inspection of these has begun.

In this section, I would like to discuss the pitfalls of current extracorporeal circulation.

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Anesthetic time: In 0 — 20 — 40 — 60 — 80 min Out

↑ Induction ↑ Incision ↑ pump on ↑ Ao clamp ↑ unclamp ↑ pump off ↑ End

CPB

		Pre-CPB	CPB	Post-CPB
Bladder Temp (°C)		36.9	35.0	36.0
Blood gas	Na (mEq/l)	137	137	141
	K (mEq/l)	4.1	3.7	3.3
	B.E.	–1.4	+0.3	–2.0
	Hct (%), Hb(g/dl)	36.5	20.0	26.0
	T.P. (g/dl)	6.4	3.9	4.7
Correction	25% albumin (ml)			
	salin HES (ml)		60	
	10% NaCl (ml)		5	
	KCl (mEq)		4	
	D-mannitol (ml)		5	
	$NaHCO_3$ (ml)		5	
	sublood BD (ml)			
	C.H. (mg)		2	
	$CaCl_2$ (ml)		3	

Bloodless Open-Heart Surgery in VSD infact weighing 3.3kg

Isolated Pump-Controller Heart-Lung Machine
(Reduction of Priming Volume)

DUF using PAN Membrane Hemofilter

"Constant Perfusion"
Measures against SIRS Accurate Basic CPB Procedure

Permissive Anemia

Time Saving

Fig. 4.1 Tips for bloodless open-heart surgery.
PAN: Polyacrylonitrile

Table 4.1 Equations in extracorporeal circulation.
*SIRS: Systemic Inflammatory Response Syndrome

- Non-Pulsatile Circulation with Roller or Centrifugal Pump
- Physical Damage to Blood by Pump
- Artificially Controlled Systemic Perfusion
- Loss of Pulmonary Circulation
- Blood Contact with Foreign Surface
- Inflammatory Reaction Cytokine Release / SIRS*
- Hemodilution
- Hypothermia
- Gas Exchange by Oxygenator Acid-base Balance Control
- Use of Anticoagulants Bleeding / Embolism
- Foreign Materials in Circuit
- Bubble Gaseous MicroEmboli / SIRS*

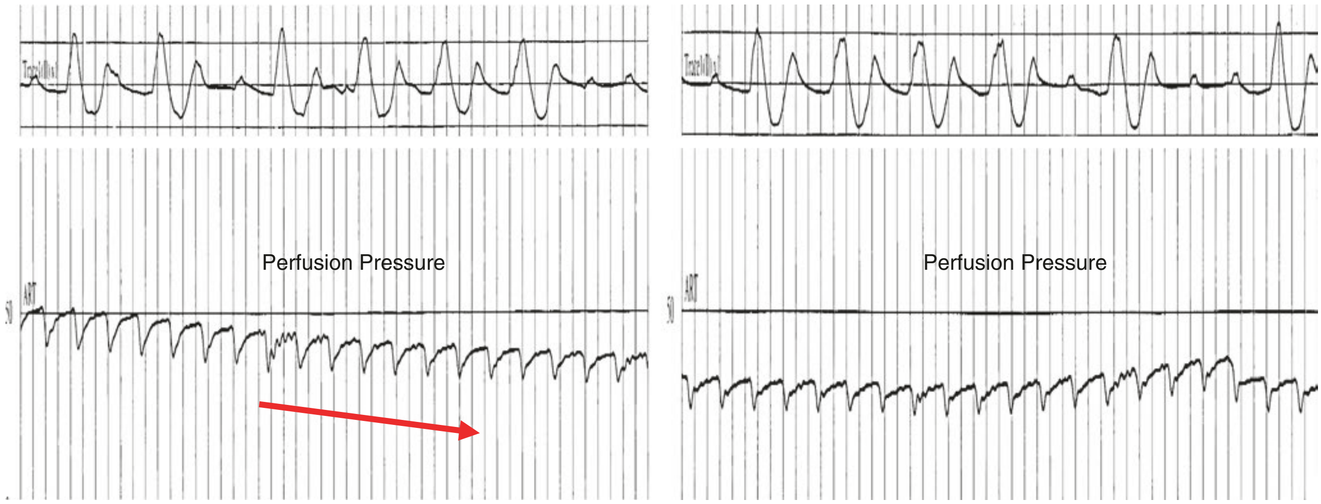


Fig. 4.2 Decreased perfusion pressure during extracorporeal circulation with 10% NaCl correction. Left figure: VSD weighing 10 kg, Initial priming volume 175 mL (without blood priming). After aortic declamping, 1 mL of 10% NaCl was administered by bolus injection. A rapid drop in perfusion pressure was noted. Thereafter, bolus injection was contraindicated. Right figure: VSD weighing 11 kg, Initial priming volume 175 mL (without blood priming). 1 mL of 10% NaCl was administered over about 5 s. No significant change in perfusion pressure was observed

4.2 Correction During Extracorporeal Circulation

4.2.1 Bolus Injection Correction During Extracorporeal Circulation

In one case, a unique blood pressure response occurred during extracorporeal circulation. It was a decline in perfusion pressure that occurred during the re-start of heartbeat after declamping the aorta (Fig. 4.2). When I asked what the perfusionist did, he said that he added 1 mL of 10% NaCl. This was a reaction that has never been experienced before. Thereafter, when corrected (injected) slowly, this reaction was not observed.

Figure 4.3 shows a cross-sectional view of venous reservoirs used in pediatric extracorporeal circulation. Reservoirs A to D (Bottom release) are types where the drained venous blood flows into the bottom of the reservoir through one duct, and E to G (Middle release) are types where the drained venous blood flows to the center of the reservoir. Reservoir B was used in the case with reduced perfusion pressure, shown in Fig. 4.1. In this reservoir, there are two routes for injecting drugs or correction fluid; the upper part of the venous drainage port (venous blood inlet) and the upper part of the cardiotomy port (medical fluid inlet). The 10% NaCl was corrected from the venous drainage port. From this, it was assumed that the cause of the decrease in the perfusion pressure was a vasodilatory reaction due to the rapid influx of 10% NaCl into the living body at a high concentration. Since then, we have begun to study the characteristics of reservoirs from the viewpoint of correcting electrolyte and acid-base balance during extracorporeal circulation, as well as blood transfusion and protein supplementation.

4.2.2 Experiment on Bolus Injection Correction

4.2.2.1 Red Reagent Administration

A simulated extracorporeal circulation circuit was created using Reservoir B (Fig. 4.4). Under the condition using saline priming (1000 mL) and a perfusion flow rate of 1.5 L/min with a reservoir level of 300 mL, 2 mL of red reagent was injected from the venous drainage port (Venous blood inlet). The difference in the style of the spill was visually assessed (Videos 4.1 and 4.2). Similarly, 1 mL of red reagent was injected from the venous drainage port and cardiotomy port under the condition with a perfusion flow rate of 0.8 L/min with a reservoir level of 80 mL (Videos 4.3 and 4.4).

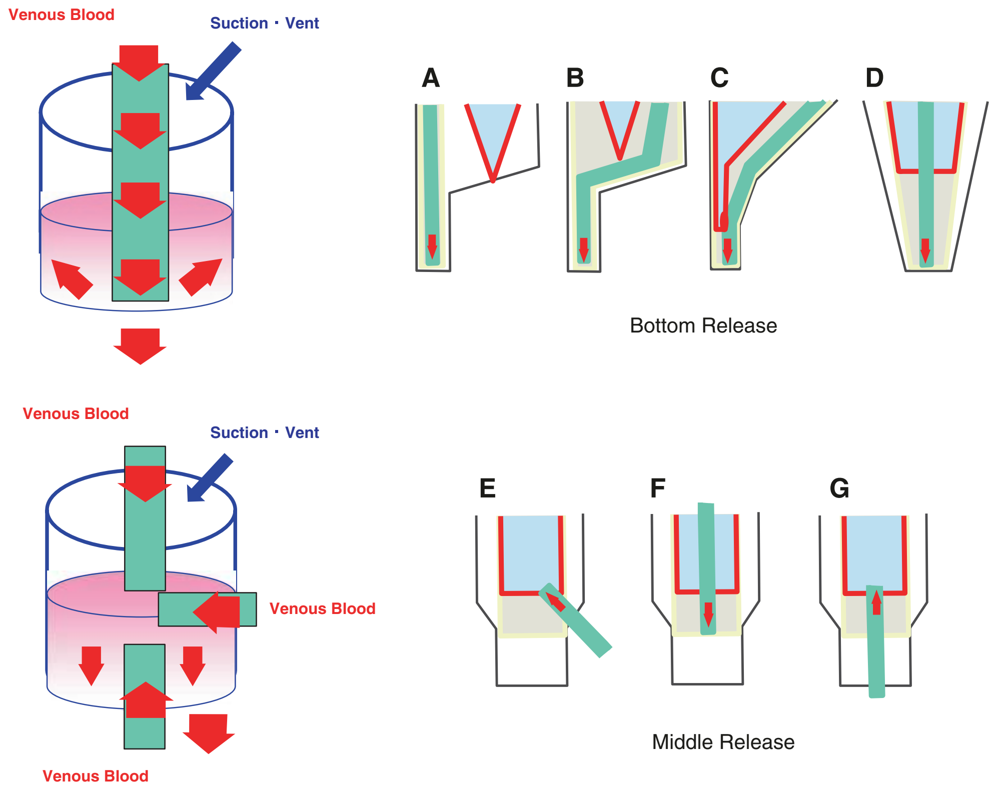


Fig. 4.3 Structures of reservoir. In many of the reservoirs currently used in Japan, the drained venous blood flows from the top of the reservoir through a single duct to the bottom of the reservoir, and flows out from the bottom of the reservoir after mixing with aspirated and vented blood. As described in column "Circuit configuration" (3), this structure has the advantage of low dynamic priming volume as well as quick response to the reservoir fluid level. The routes for injecting drugs and correction fluids are at the venous drainage port and cardiotomy port. In particular, since the correction fluid from the venous drainage port is directly mixed into the venous blood, the drug effect is fast. On the other hand, in the previously used Safe Micro reservoir, the drained venous blood flows from the lower part of the reservoir to the central part, and flows out from the bottom of the reservoir after mixing with aspirated and vented blood

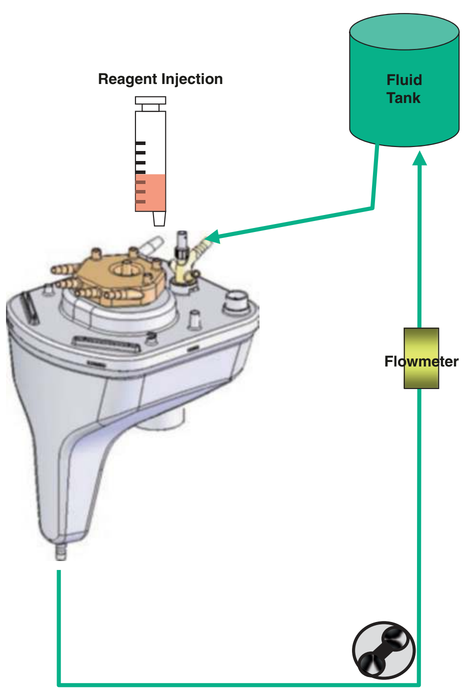


Fig. 4.4 Extracorporeal circuit mock up used for red reagent injection test

4.2.2.2 Measurement of Na Concentration

At what concentration does the correction fluid administered during extracorporeal circulation flow into the living body? Next, using simulated extracorporeal circuit, the Na concentration in the circulating fluid at the reservoir outlet and the arterial filter outlet was measured by the following three methods (Fig. 4.5). The perfusion flow rates used were 0.6, 0.8, 1.0, 1.2 L/min, and the reservoir levels were 80 and 300 mL. The three methods were: (1) Bolus injection of 10% NaCl from Venous blood inlet, (2) Sustained injection for 5 s from Venous blood inlet, and (3) Bolus injection from Service port on top of the reservoir.

Data 4.1 shows the protocol for measuring Na concentration and the equipment used. Figures 4.6, 4.7, and 4.8 show photographs of the change over time when 2 mL of the red reagent was injected under the conditions of the perfusion flow rate of 1.0 L/min and the reservoir level of 80 mL.

Figure 4.9 shows the change in Na concentration at the reservoir outlet and the arterial filter outlet after 1 mL bolus injection of 10% NaCl from the Venous blood inlet (using Reservoir B. The priming volume was 600 mL of saline, perfusion flow rate 0.8 L/min, reservoir level 80 mL). At the reservoir outlet, it temporarily increased to 190 mEq/L. On the other hand, it was around 150 mEq/L at the arterial filter outlet.

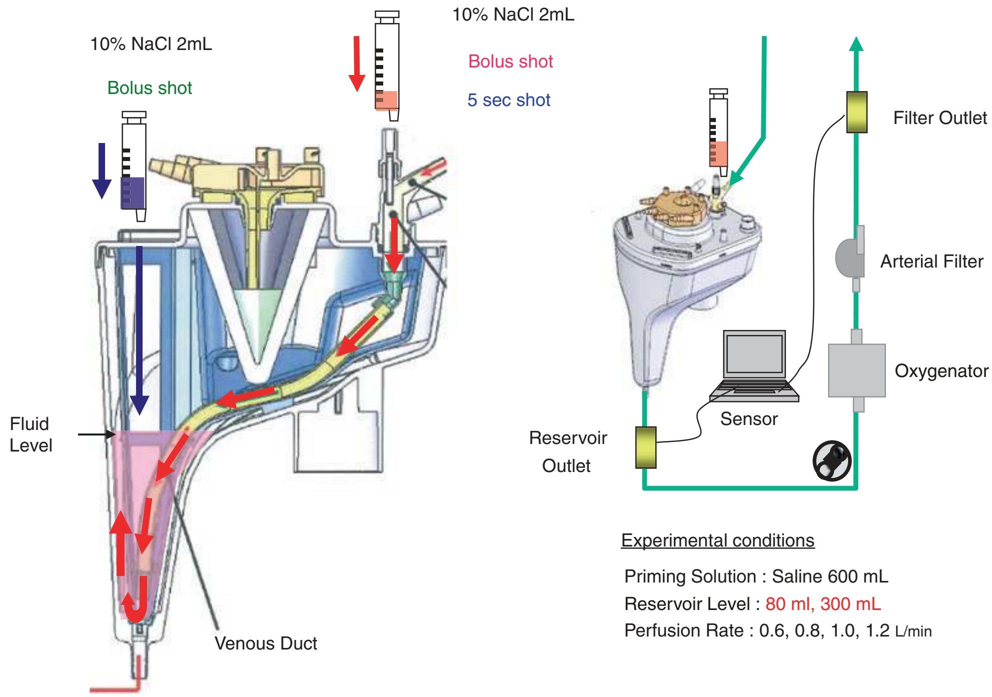


Fig. 4.5 Measurement of Na concentration. The Venous blood inlet is an inlet for injecting drugs and correction fluid in the venous drainage port, and the Medical fluid inlet is an inlet for injecting drugs and correction fluid in the Cardiotomy port. The Service port is another inlet on the top of the reservoir to deal with failures of the Cardiotomy reservoir

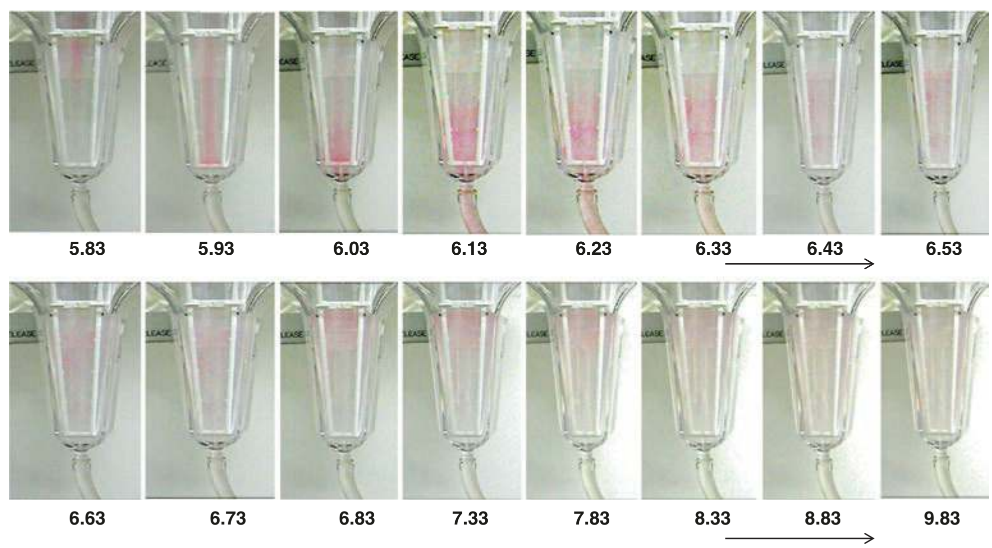


Fig. 4.6 Bolus injection to Venous blood inlet. Some of the red reagent that has passed through the venous duct rapidly flows out of the lower part of the reservoir without mixing, and then the liquid in the reservoir stains upward from the lower part

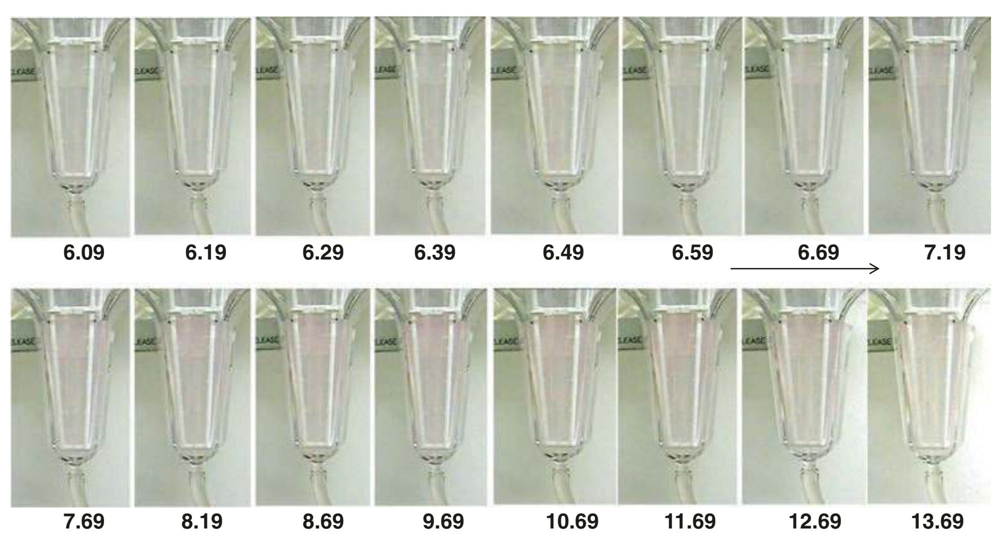


Fig. 4.7 Sustained Infusion for 5 s to Venous Blood Inlet. The entire liquid in the reservoir slowly stains over time

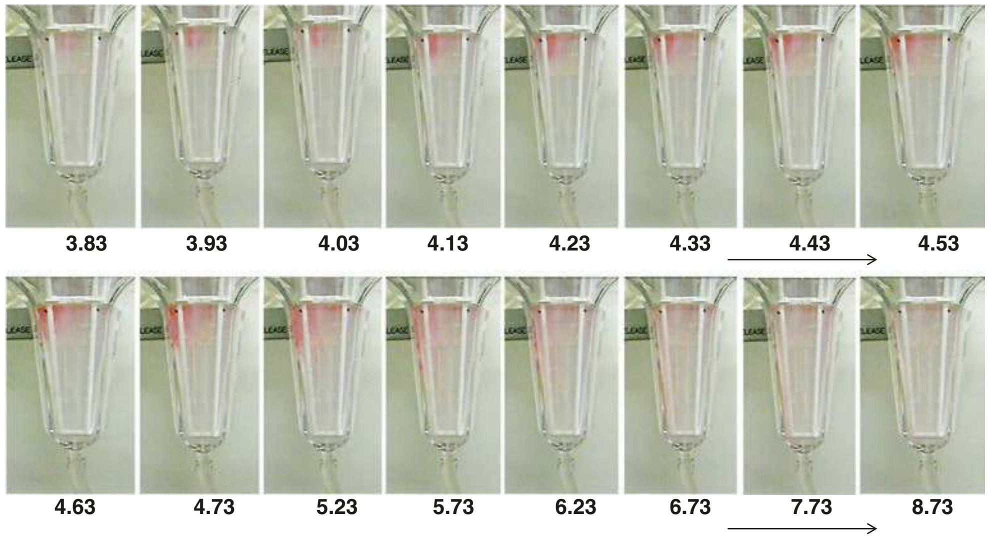


Fig 4.8 Bolus injection to service port. The red reagent slowly descends from above the liquid level in the reservoir, and the liquid in the entire reservoir slowly dyes

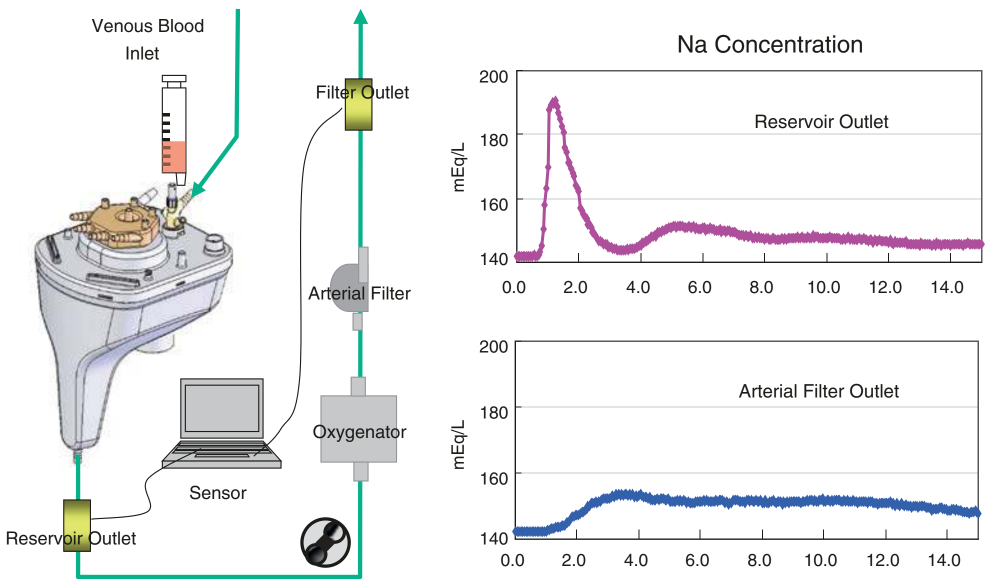


Fig. 4.9 Bolus shot of 10% NaCl 1 mL (to Venous blood inlet)

Table 4.2 shows the maximum Na concentration at the arterial filter outlet when 2 mL of 10% NaCl was injected under each conditions of perfusion flow rate and the reservoir level.

With the bolus injection from the service port, the maximum Na value increased to about 160 mEq/L under the condition of the reservoir level of 80 mL, but was around 146 mEq/L under the condition of the reservoir level of 300 mL. There was no significant difference in the perfusion flow rate. On the other hand, with the administration from the Venous blood inlet, the maximum Na value in the bolus injection increased to 160 mEq/L or more. There were no difference between the level of the reservoir level and the level of perfusion flow rate. With the sustained infusion for 5 s, the Na concentration under the condition of the reservoir level of 300 mL tended to be slightly lower but increased to 150 mEq/L or more.

Figure 4.10 shows the change in Na concentration at the arterial filter outlet when the dose of 10% NaCl was changed under the conditions of a perfusion flow rate of 0.8 L/min with reservoir levels of 80 mL and 300 mL.

Table 4.2 Na concentration at arterial filter outlet (10% NaCl injection)

Reservoir level	Perfusion flow	Venous Blood Inlet						Service Port		
		Bolus Injection			5 sec. Injection			Bolus Injection		
mL	L/min	Peak	Average Value for 0.5sec		Peak	Average Value for 0.5sec		Peak	Average Value for 0.5sec	
		Na mEq/L	Na mEq	Na mEq/L	Na mEq/L	Na mEq	Na mEq/L	Na mEq/L	Na mEq	Na mEq/L
80	1.2	165.4	1.65	164.7	153.1	1.5	152.5	155.5	1.5	154.9
	1.0	167.0	1.38	166.3	158.1	1.3	157.4	160.6	1.3	159.8
	0.8	164.0	1.09	162.7	159.9	1.1	158.0	162.7	1.1	161.1
	0.6	162.2	0.81	161.2	158.1	0.8	157.6	159.5	0.8	159.0
300	1.2	166.3	1.66	165.6	150.5	1.5	150.0	145.6	1.5	145.0
	1.0	167.8	1.38	166.7	153.4	1.3	152.8	146.4	1.2	145.7
	0.8	163.5	1.09	162.4	154.4	1.0	153.2	146.4	1.0	145.4
	0.6	160.2	0.80	159.0	154.0	0.8	153.2	147.7	0.7	145.0

Experimental Conditions: Normal Blood Na conc. 142 mEq/L

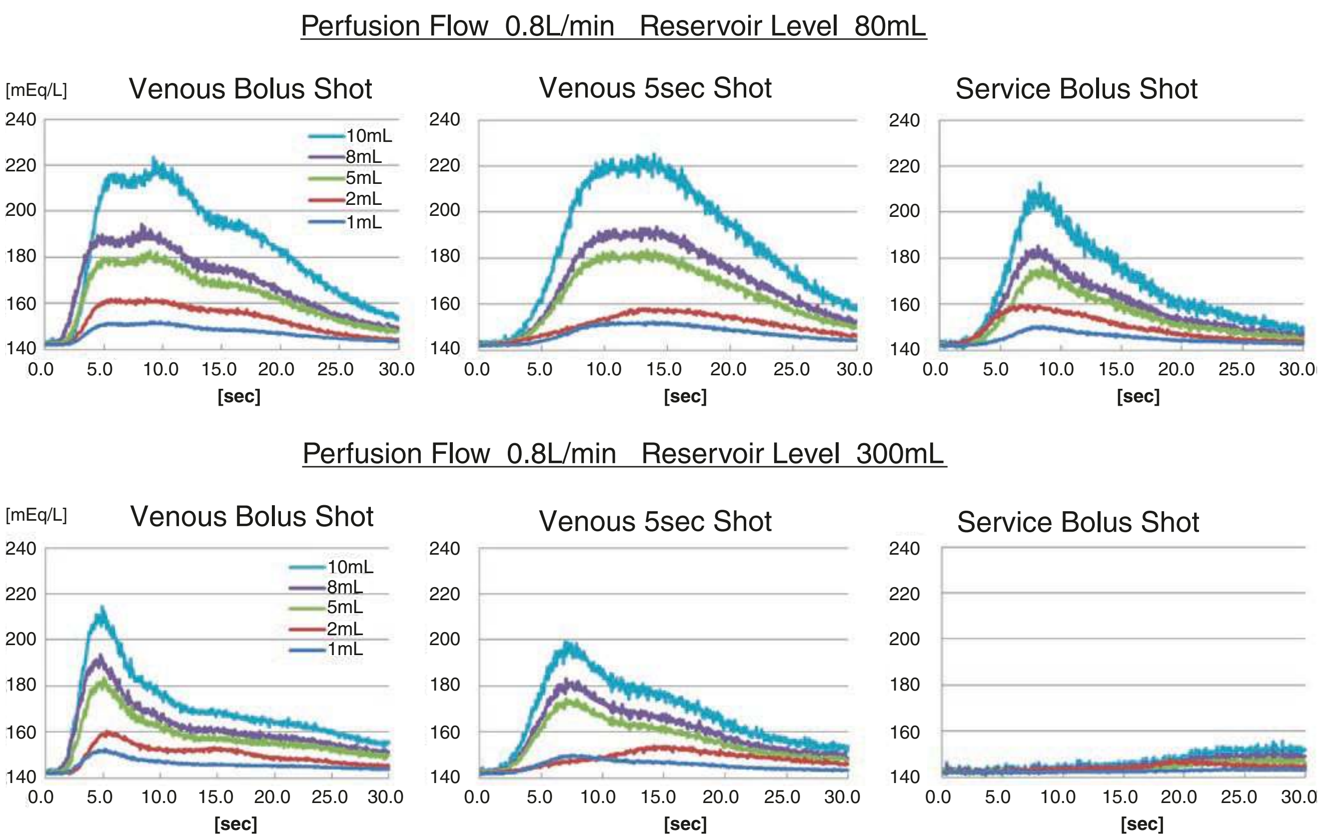


Fig. 4.10 Changes in Na concentration (10% NaCl injection). Except for bolus injection from the service port (reservoir level 300 mL), all had high Na concentration

With the injection from the Venous blood inlet, both the bolus injection and the continuous injection for 5 s showed a high concentration regardless of the reservoir level and remained high for about 15 s. On the other hand, with the bolus injection from the service port, the same Na concentration increase was observed under the condition of the reservoir level of 80 mL, but there was no increase under 300 mL. Table 4.3 shows the maximum Na value for each 10% NaCl dose for bolus injection and continuous infusion for 5 s from the Venous blood inlet.

Figure 4.11 shows a change in Na concentration with bolus injection of NaHCO3 (Meylon) from the Venous blood inlet. Even with a correction of 5 mL, the concentration exceeded 160 mEq/L and remained at a high Na concentration for about 10 s.

Injection from the Venous blood inlet revealed that the Na concentration at the arterial filter outlet was high and persisted for about 10–15 s, regardless of the administration time and the reservoir level. On the other hand, injection from the service port showed a similar increase in Na concentration only at low reservoir levels. It can be considered that this is due to the structure of the reservoir in which the drained venous blood flows into the reservoir bottom through one duct and the behavior of mixing the circulating fluid in the reservoir. Adult patients with relatively high reservoir levels may respond similarly. Interestingly, in the sustained injection of red reagent for 5 s from the Venous blood inlet, the circulating fluid in the reservoir seemed to be mixed and dyed slowly, but the maximum value of Na concentration did not differ from the bolus injection. It only moved to the right (Fig. 4.10).

The injection amount of 10% NaCl for the Na concentration at the outlet of the arterial filter to be 160 mEq/L or more was 2 mL, and Meylon was 5 mL. These injection amounts are correction amounts that could be used in actual clinical

Table 4.3 Na concentration at arterial filter outlet (10% NaCl injection)

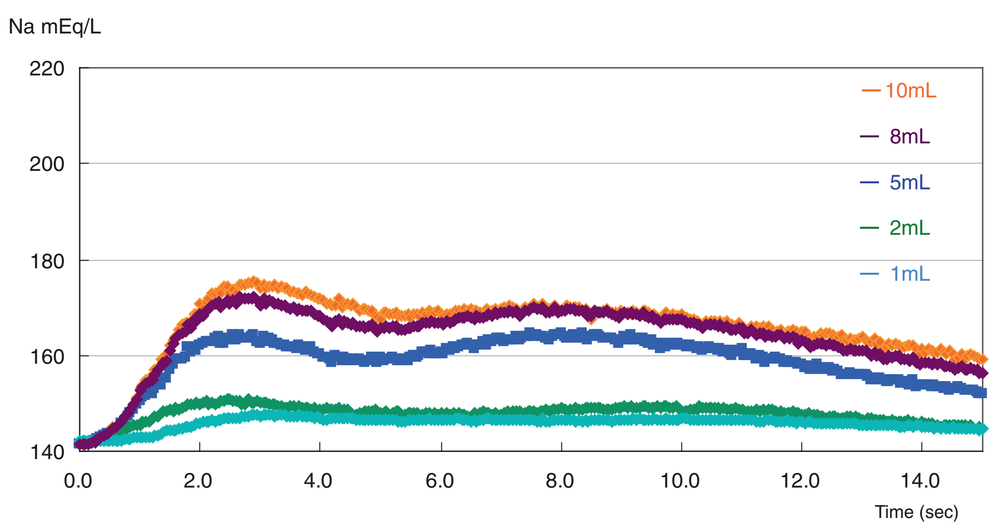
Bolus Injection

Dose	Venous Blood Inlet		
	Bolus Shot		
	Peak	Average Value for 0.5sec	
mL	Na conc.	Na amt.	Na conc.
	mEq/L	mEq	mEq/L
1.0	153.8	1.065	159.0
2.0	163.9	1.123	167.7
5.0	196.0	1.303	194.5
8.0	204.3	1.321	197.2
10.0	219.9	1.331	198.7

5sec. Injection

Dose	Venous Blood Inlet		
	5sec Shot		
	Peak	Average Value for 0.5sec	
mL	Na conc.	Na amt	Na conc.
	mEq/L	mEq	mEq/L
1.0	153.6	1.024	152.9
2.0	159.9	1.058	158.0
5.0	180.6	1.203	179.6
8.0	209.9	1.392	207.8
10.0	232.1	1.543	230.4

Experimental Conditions: Perfusion flow 0.8 L/min, Reservoir level 80 mL, Normal blood Na conc. 142 mEq/L
With the 10% NaCl injection from the Venous blood inlet, the Na concentration increased in proportion to the dose in both the bolus injection and 5-s injections



Experimental Conditions: Perfusion Flow 0.8L/min, Reservoir Level 80mL, Normal Blood Na conc. 142 mEq/L

Fig. 4.11 Na concentration at arterial filter outlet (10% $NaHCO_3$ injection). With the bolus injection from the Venous blood inlet, the transition of Na concentration was bimodal. This is because, as shown in Video 4.1, a part of the correction liquid quickly flows out of the lower part of the reservoir without being mixed, and then the correction fluid that has jumped upward from the lower part of the reservoir flows out again at a high concentration practice for cases weighing 4–5 kg with anticipated perfusion rate of 0.8 L/min. As shown in Fig. 4.1, a decrease in the perfusion pressure was observed only with the correction of 1 mL of 10% NaCl.

The Na concentration of 10% NaCl is 1700 mEq/L, pH 6.3, and that of Meylon is 833 mEq/L, pH 8.0. It can easily be imagined that the blood vessel function is broken not only by the concentration of the electrolyte but also by the rapid inflow of the high osmotic pressure, high acidity, and high alkalinity correction solution into the living body.

In the bolus injection of a drug or a correction fluid from the Venous blood inlet, there is a risk that the administered fluid may enter the living body at a high concentration regardless of the reservoir level or the perfusion rate. It is necessary to understand the characteristics of the structure of the reservoir and to select appropriate correction method and administration speed.

Q&A: Correction During Extracorporeal Circulation (Question in 2017)

Question: I was surprised at the concentration of the correction solution flowing into the living body. Please tell us about the appropriate correction method.

Answer: When I first saw the results of the bolus injection experiment shown here, I was disappointed that "Constant Perfusion," which had been talked to all of you so far, had not been acheived at all. Since I have not done any experiments with the Safe Micro reservoir which was used before, there is nothing so much to say. However, given the structure of the Safe Micro reservoir and how it was corrected at the time (see Fig. 2.60), such a rapid drop in perfusion pressure is unlikely to occur and is a response that has not been experienced before. In extracorporeal circulation, Na, K, and Base Excess values generally decrease over time, so these corrections in long extracorporeal circulation are essential. Previously, blood gas data was measured about every 30 min. Therefore, instead of compensating for the results, proactive and preventive correction was made considering "Constant Perfusion." The measurement of blood gas was a verification of the correction made. The experiment with a perfusion rate of 0.8 L/min described in the lecture assumes extracorporeal circulation in infants weighing 4–5 kg. In this weight range, the bolus injection correction amount in actual clinical practice is approximately 1–3 mL for 10% NaCl and 3–5 mL for Meylon. For this reason, the correction method was changed to drip Ringer solution (total volume of 20–30 mL, including 3 mL of Meylon, 2 mL of 10% NaCl, 3 mL of KCL, and 5 mL of Mannitol) from the Cardiotomy port while checking each value on the CDI monitor. At least, bolus injection from the Venous fluid inlet should not be performed.

Since joining Sakakibara Heart Institute, bolus injection of the drug and correction fluid from the central venous line was contraindicated, especially in the postoperative management of neonates. The risk of cerebral hemorrhage was anticipated because they flow into the body at high concentrations. Of course, in biventricular repair cases, the administered drug solution will reach the brain after flowing through the lungs, left atrium, and left ventricle, so it may be diluted to some extent. However, in extracorporeal circulation with the cannulation at the ascending aorta, they will reach the brain directly without dilution and continues to flow for about 15 s. Although it is an assumption, this bolus injection might be involved in postoperative ischemic brain lesions such as PVL, cerebral edema or cerebral hemorrhage of unknown cause. It is thought to be the same in adult extracorporeal circulation, where the reservoir level is 500–1000 mL or more due to the structure of the reservoir.

I also think that the adverse effects of this bolus injection are on the heart, too. Especially in a newborn infant, if the aortic cross-clamp is released immediately after bolus injection, it is easy to imagine that the high-concentration correction fluid will flow into the coronary arteries and cause reperfusion injury (myocardial damage). In fact, I experienced a case of TOF in which heartbeat did not recover for a while. After the unclamping, the coronary arteries became thin and over dilated, and the myocardium remained completely flaccid. I waited for recovery with an assisted circulation, but did not recover at all. About an hour later, when I started thinking about using ECMO, heartbeat suddenly resumed, and we were able to wean from the extracorporeal circulation immediately and easily. I did not understand the cause, but I suspect it was reperfusion injury due to rapid correction.

As for the correction in extracorporeal circulation, it is necessary to avoid the rapid administration from the Venous blood inlet and to perform the correction method that leads to "Constant Perfusion."

Column: Additional Administration of Blood During Extracorporeal Circulation

Attention should also be paid to the additional transfusion and fluid replenishment during extracorporeal circulation. Figure 4.12 shows the perfusion pressure during surgery for total anomalous venous return. Before weaning from the extracorporeal circulation, a decrease in blood pressure was observed immediately after administration of 30 mL of the red blood cell product from the Cardiotomy port. Red blood cell products have a very high K value and high acidity, with potassium 20 to unmeasurable mEq/L, lactic acid 7–14 mmol/L, pH 6.5–6.9, BE −20 to −32 mmol/L (Fig. 4.13).

In this case, it was considered that rapid vasodilation was caused by the rapid influx of the red blood cell product into the living body. Rapid bolus administration in newborns and underweight children should be avoided, even during extracorporeal circulation.

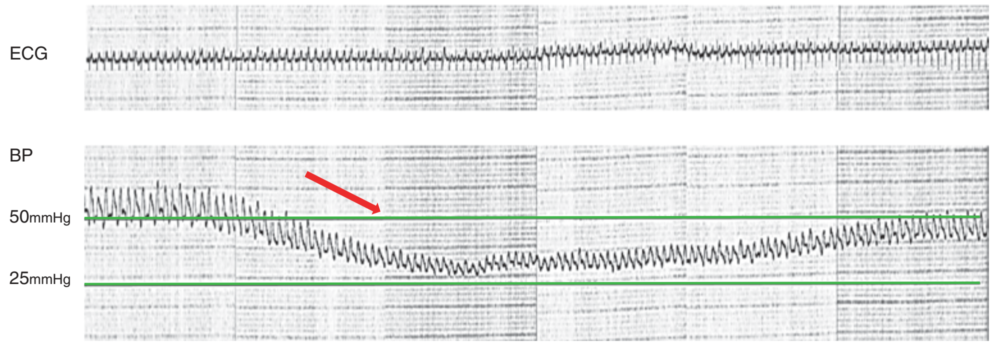


Fig. 4.12 Sudden arterial pressure drop by administration of red blood cell product

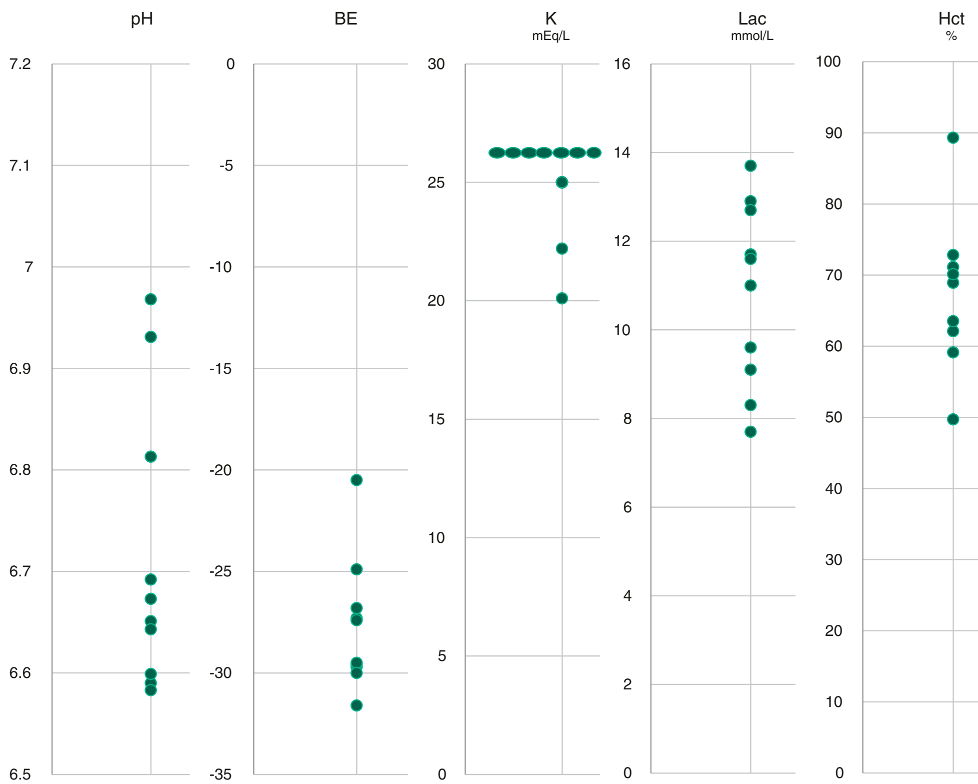


Fig. 4.13 Blood gas data of red blood cell product. In blood priming cases, a fresh red blood cell product is selected as much as possible, but the K value is often higher than 25 mEq/L, which makes measurement impossible

From this, the same precautions must be taken when adding a volume during extracorporeal circulation or injecting a replenisher used for DUF. In particular, when the crystalloid is rapidly replenished in a situation where the reservoir level is low, circulating blood in a state close to the composition of a crystalloid flows into the living body. It can also affect cardiac function.

Rapid transfusion and fluid replenishment in newborns and underweight infants, even from the cardiotomy port, should be avoided. Of course, injection from the Venous fluid inlet is out of the question. Transfusion, volume replenishment, drug administration and electrolyte correction should be performed slowly during hemoconcentration before aortic declamping, and aortic declamping (reperfusion) should be performed after adjusting circulating blood conditions.

Column: Use of Whole Blood and Changes in Blood Priming Methods

In 2018, we changed the initial priming method in cases using blood priming. In the conventional method, washing and correction were performed after adding an amount of red blood cell product equivalent to the amount of circuit priming volume into the reservoir. Then, after the initiation of extracorporeal circulation, the remaining red blood cell product was appropriately replenished according to the Hct value and the reservoir level. At present, two units of red blood cell product with Ringer's solution (about three times the red blood cell volume) is washed first. 100–150 mL of the washed blood is then collected in a blood bag for use after extracorporeal circulation or in the ICU, and extracorporeal circulation is initiated after correcting the remaining washed blood in the reservoir (level 100–

150 mL). This is intended to avoid the addition of red blood cell products during extracorporeal circulation. Figure 4.14 shows the CDI monitor screen before washing and after washing/correction. With this method, volume addition and correction management during extracorporeal circulation are simplified, and frequent replenishment due to a decrease in reservoir level or DUF is no longer necessary. Of course, one of the purposes of this method is to complete the operation with only two units of blood transfusion.

Blood supplied by the Japanese Red Cross Society includes whole blood in addition to red blood cells, plasma, and platelet products. Also, in whole blood products, platelets are removed at the stage of leukocyte removal before preservation. However, it was thought that the use of whole blood in neonatal extracorporeal circulation, in which red blood cells, coagulation factors, and proteins were all diluted, could be effective in saving protein products and FFP. This has been used for blood promising cases since January 2018. The characteristics of whole blood are that the total protein level in extracorporeal circulation can be maintained at a high level without using albumin products (minimum measured value of 4.3–5.8 g/dL), and except for the neonatal palliative open-heart surgery such as Norwood surgery, most cases can be discharged by transfusion of 400 mL of whole blood (only one blood donor) without platelets, protein products, or FFP. Figure 4.15 shows a

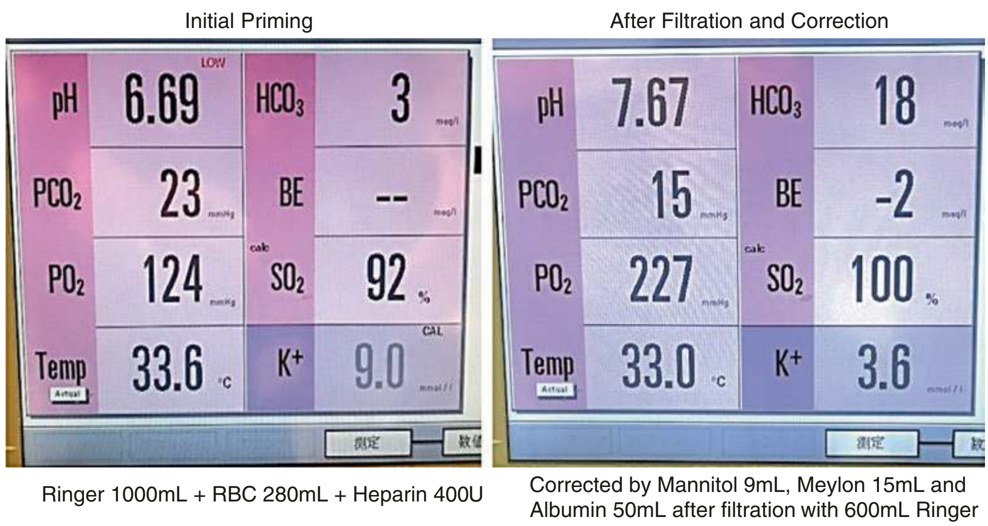


Fig. 4.14 CDI monitor data before and after filtration and correction. In the red blood cell product used in this case, the pH was 6.76, BE −30.8, and the K value could not be measured

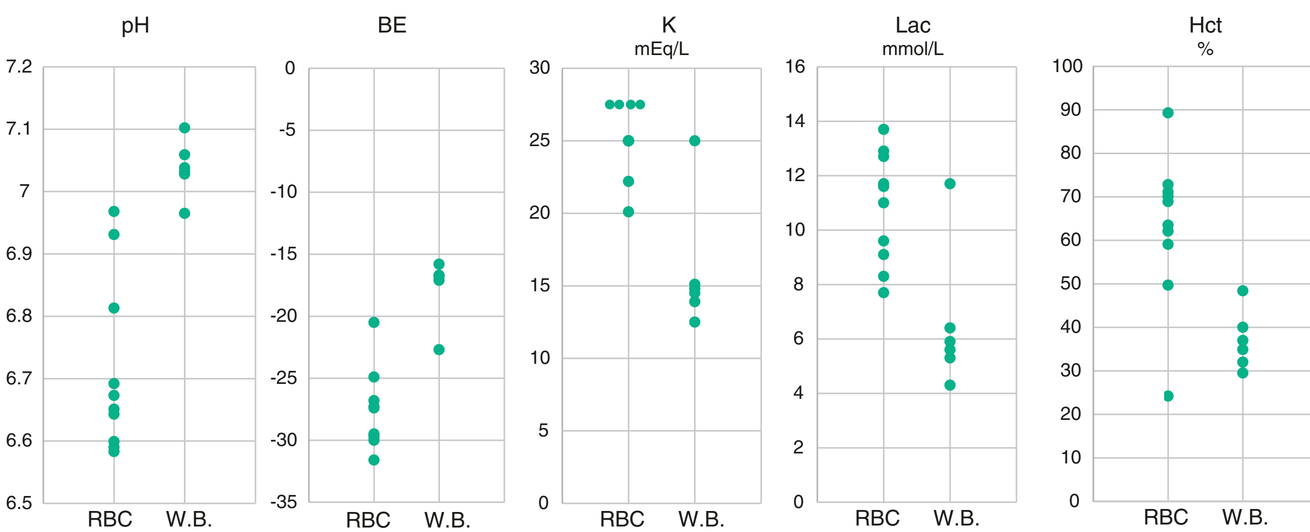


Fig. 4.15 Comparison of Red blood cell product with whole blood product.
RBC: Red Cell Product
W.B.: Whole Blood Product
BE: Base Excess
Lac: Lactate
Hct: Hematocrit

comparison of pH, Base Excess, K, lactic acid, and Hct values between the red blood cell products and the whole blood. The whole blood has a slightly better value since the duration after blood donation may be short, but at the time of initial priming, washing is performed in the same manner as the red blood cell product. Figure 4.16 shows the change of each data after washing.

As an aside, all blood products are not originally recommended for mixing with anything but saline. Nevertheless, extracorporeal circulation is a matter of course.

4.3 Vacuum Assisted Venous Drainage

Vacuum assisted venous drainage made the control of venous drainage relatively easy. However, there was an impression that the number of cases in which the perfusion pressure decreased immediately after the initiation of extracorporeal circulation increased. This reaction referred to as initial drop, has been considered to be an effect of vasoactive substances in the blood, but was similarly observed in extracorporeal circulation without blood priming (Fig. 4.17).

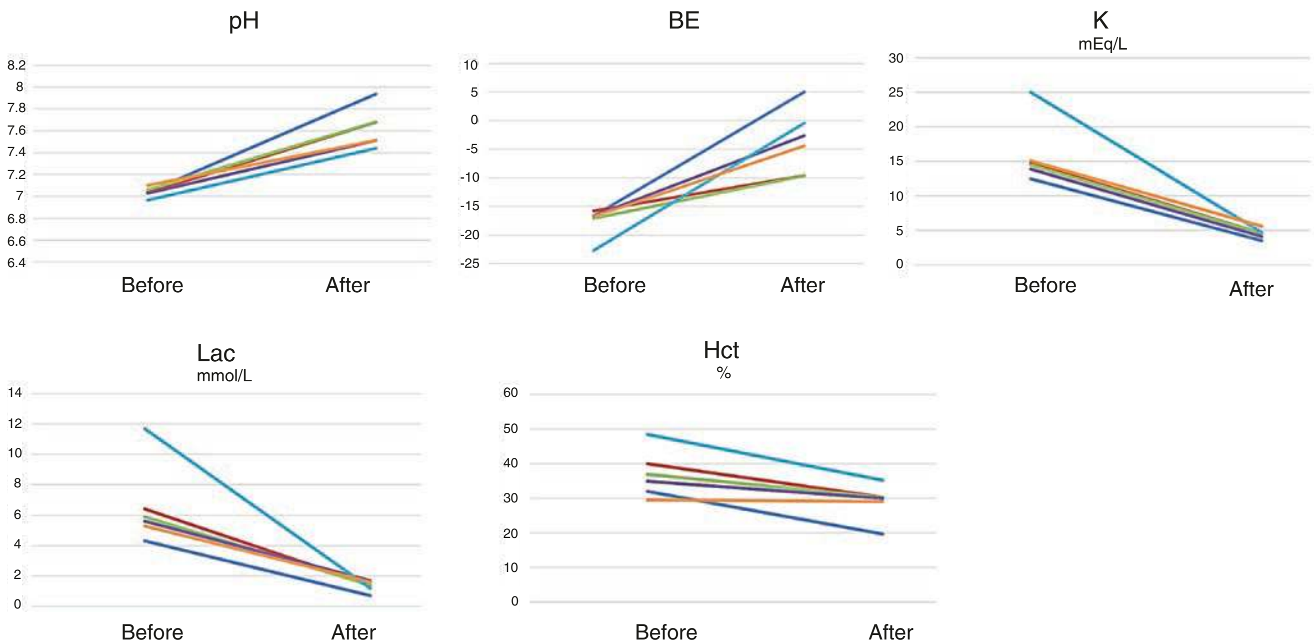


Fig. 4.16 Blood gas data of whole blood product before and after filtration

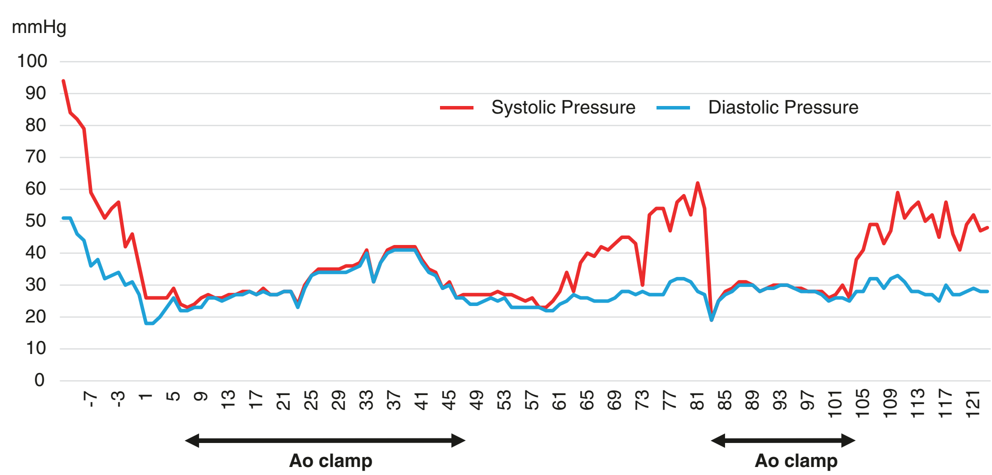


Fig. 4.17 Initial drop in bloodless extracorporeal circulation. The perfusion pressure of a patient weighing 28.7 kg with hypertrophic cardiomyopathy who underwent Morrow surgery (Initial priming volume 350 mL, with non-blood priming). Remnants of the stenosis required another extracorporeal circulation. By injecting carbon dioxide gas described below into the initial priming solution, each data of the initial priming solution before the initiation of extracorporeal circulation was well corrected, but immediately after the initiation of extracorporeal circulation, the perfusion pressure was decreased to the 20 mmHg range. The systolic arterial pressure after the start of heartbeat was also low, around 50 mmHg

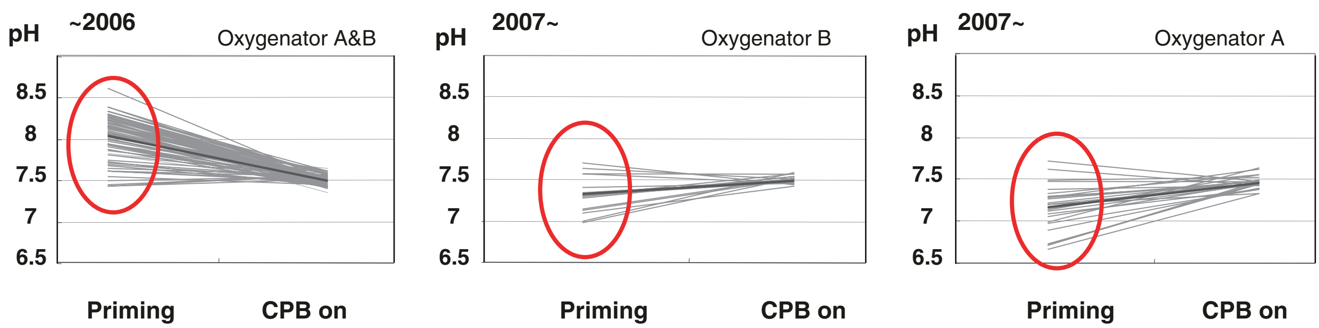


Fig. 4.18 pH value of initial priming fluid. As a cause of thrombus occlusion in the oxygenator, morphological changes (echinocytes) of red blood cells due to strong alkalinization of the initial priming fluid were suspected. So, measures were taken to exclude Meylon from the primng composition, and as a result, there was a period when the initial priming solution was inclined to be acidic. A and B indicate the respective oxygenator used

Videos 4.5 and 4.6 show the conventional kinetic venous drainage using a pump and current vacuum assisted venous drainage. In the latter, it can be seen that the initial priming solution is rapidly flowing into the living body. The initial drop in non-blood priming was thought to be caused by the speed of the pump at the initiation of extracorporeal circulation. No matter how the initial priming composition is adjusted, it can be easily imagined that a rapid change in the blood vessel function is caused by a rapid inflow of the crystalloid associated with rapid hemodilution. This vasodilator reaction, unlike the initial drop in blood priming, does not respond to the vasopressor more than expected. As a result, the reservoir level drops immediately after the start of extracorporeal circulation, and extra volume adjustment must be needed. Thorough "Constant Perfusion" should also be performed from the viewpoint of regulating the blood flow at the initiation of extracorporeal circulation (see Chap. 3, Column: Postoperative convulsion) [1, 2].

Q&A: Precautions for Vacuum Assisted Venous Drainage(Question in 2018)

Question: What are the precautions of vacuum-assistedvenous drainage?

Answer: As I mentioned in my talk, the initial drop response of bloodless priming does not improve much. The associated diuresis and volume replacement during extracorporeal circulation is the worst thing. In vacuum assisted venous drainage, it is relatively difficult to gradually increase the perfusion flow rate while maintaining the reservoir level and keeping the arterial and venous blood flow rate equivalent, as in pump venous drainage. As I will explain later, the hemoconcentration circuit is currently redesigned to reduce the generation of microbubbles by changing blood flow from (1) venous drainage circuit→ small pump → hemofilter → reservoir, to (2) venous drainage circuit → small pump → hemofilter → venous drainage circuit. In particular, at the initiation of extracorporeal circulation in low-birth-weight infants, this hemoconcentration circuit is used for venous drainage in order to start extracorporeal circulation slowly. Then, when a certain amount of perfusion flow has been achieved, it is shifted to vacuum assisted venous drainage. This is a good method to prevent the initial drop by adjusting the arterial and venous blood flow.

Regarding the initial drop, which will also be described later, it has been reported that the cause of the high-pressure excursion in the oxygenator is a strong alkaline initial priming solution. For this reason, no Meylon was used in the initial priming after 2007. As a result, the pH of the initial priming solution became acidic (Fig. 4.18). Of course, before the initiation of extracorporeal circulation, oxygen was blown into the oxygenator and circulated, so it is assumed that the pH value in priming solution was higher than those shown in Figure 4.18, but the acidification of the initial priming fluid may have also contributed to the initial drop in bloodless priming extracorporeal circulation.

However, the most important thing to note about vacuum assisted venous drainage is simply excess venous drainage. In the era of pump venous drainage, the quality of venous drainage was confirmed by the collapsing status of the small reservoir bag built into the venous drainage circuit (see Videos 2.2–2.9). On the other hand, with vacuum assisted venous drainage, there is the impression that any amount of venous blood can be removed by negative pressure. In fact, when the perfusionist points out that the venous drainage is poor, it may be that there is too much venous blood drainage enough to collapse the superior vena cava. The most important thing for maintaining perfusion pressure and urine volume is how to manage to maintain circulating blood volume. Excessive and rapid venous drainage may also be a factor in the decline of perfusion pressure.

4.4 High-Pressure Excursion in Oxygenator

Reasons for high-pressure excursion in oxygenators include poor anticoagulant control (ACT), cold agglutinin disease, ATIII deficiency, cryoglobulinemia, and thrombocytosis. However, since 2007, even in cases without these problems, the number of cases requiring change-out of the oxygenator increased due to the continuous increase in the pressure gradient across the oxygenator. The change in erythrocyte morphology (Fig. 4.19 echinocyte) due to strong alkalinization of the initial priming solution and rapid administration of Meylon is considered to be the cause. However, thrombus occlusion of the oxygenator by echinocytes has been reported since the 1980s. Perhaps the increase in the number of cases of oxygenator change-out is related to the change of cardiopulmonary bypass devices since 2007. There is a possibility that extracorporeal circulation management may be performed such that sudden non-physiological changes to the circulating blood, that is, thrombus or blood cell aggregates, are easily generated. We discuss the causes and countermeasures based on the clinical experience of the increasing pressure gradient (high-pressure excursion) across the oxygenator and experiments using simulated extracorporeal circulation [3].

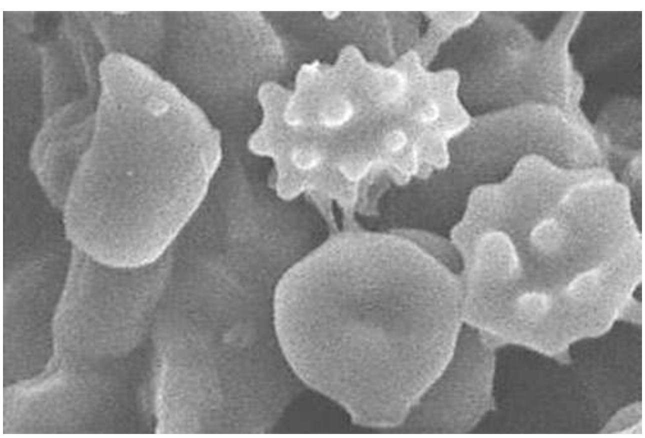


Fig. 4.19 Echinocyte

4.4.1 Experiment on High-Pressure Excursion Across Oxygenator

4.4.1.1 Increase in Pressure Gradient Across Oxygenator Due to Alkalization

Using an extracorporeal circuit model with bovine blood priming, we examined the increase in the pressure gradient of various oxygenators when NaHCO3 (Meilon) was initially primed (Fig. 4.20). The pressure gradient increased in all the oxygenators over time. This suggests that the alkalinization of the initial priming fluid is one of the causes of the high-pressure excursion.

4.4.1.2 Study on Factors of High-Pressure Excursion

Factors involved in high-pressure excursion may include temperature, Hb, total protein, ACT, and pH. The effect of change of each value on the pressure gradient increase over time was examined (Fig. 4.21).

1. The pressure gradient became larger with lower temperature, higher Hb and higher total protein, probably due to the increased blood viscosity. However, no increase in pressure gradient over time was observed. Therefore, it was considered that the temperature, Hb, and total protein did not contribute to the high-pressure excursion over time during extracorporeal circulation. Regarding ACT, coagulation was observed at 130 s. However, this was a natural result, and there was no similar increase with time at values of 150 s or more (Fig. 4.22).
2. pH is determined by bicarbonate ion and carbon dioxide values as shown in the Henderson Hasselbalch equation. In order to evaluate the effect of the high pH on the pressure gradient, the change in the pressure gradient was measured by changing both values. Using an extracorporeal circuit model primed with bovine blood and Ringer's solution (total volume of 700 mL), the pressure gradient was measured between the case where Meylon was added to increase the pH and the case where carbon dioxide was reduced to increase the pH (Fig. 4.23). In order to observe the relationship between pH and pressure increase, the difference in pressure gradient per 30 min was evaluated as the ΔP.

Oxygenator	Fluid Composition (ml) Priming: Linger	Fluid Composition (ml) Priming: 7% Meylon	Fluid Composition (ml) Bovine Blood (Hb=12g/dl)	Priming Vol. (ml)	HCO_3 conc. (mEq/L)	Perfusion flow (L/min)	initial PH	Temp.	Duration
A (Control)	750	0	300	1050	0				
A									
B									
C	150	300	300	1050	476	4	8.3	37°C	1h
D									
E									

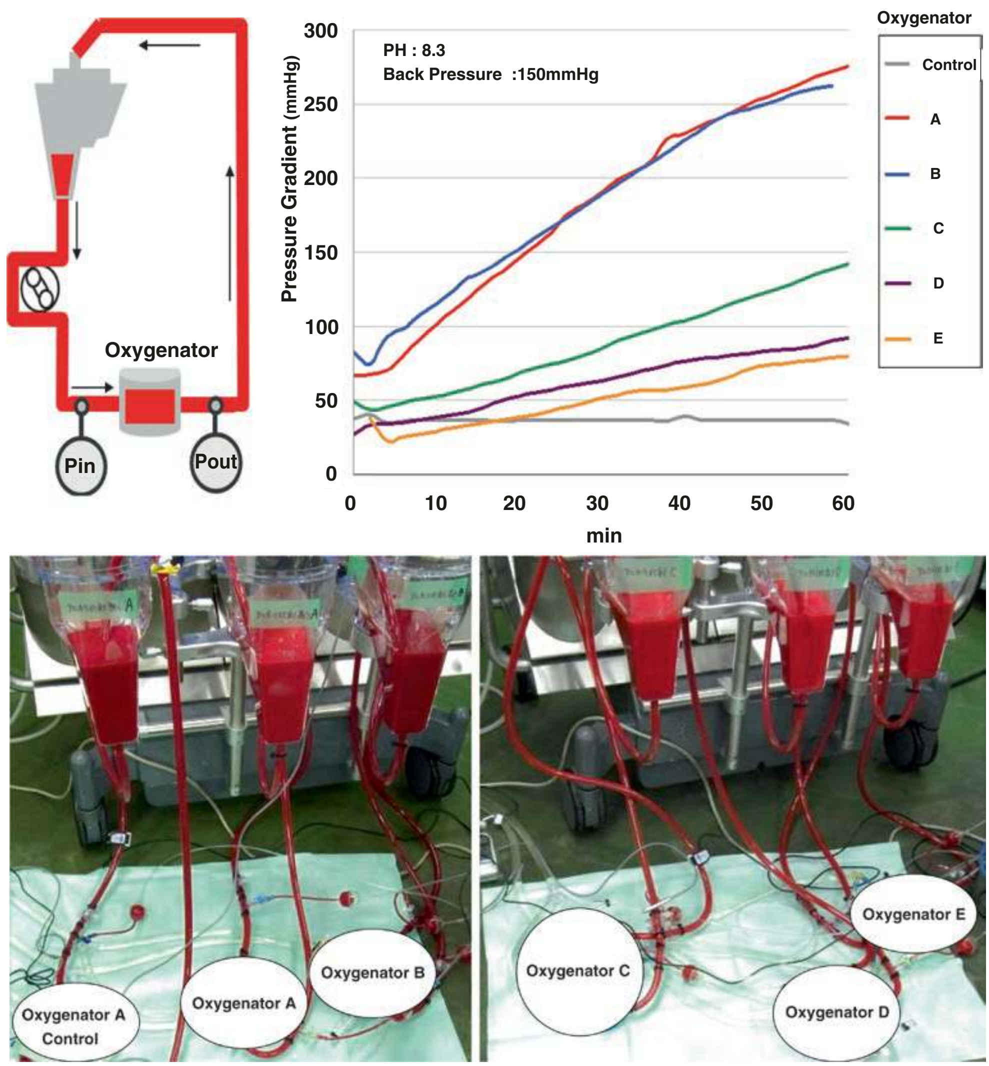
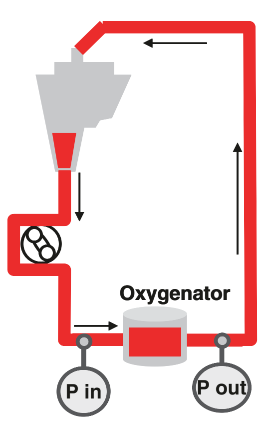


Fig. 4.20 Effect of $NaHCO_3$ priming on high-pressure excursion. Although the amount of Meylon was not clinically realistic, the high-pressure excursion across the oxygenator could be reproduced experimentally by the adding the alkalizing agent. Regardless of the structure and characteristics of each oxygenator, a continuous pressure gradient increase occurs depending on the properties of circulating blood



Factor	Temp. °C	Hb g/dL	TP g/dL	ACT sec	pH
Temp.	20,30,37	12	6	<1000	7.5
Hb	37	3,8, 10,12,15	6	<1000	7.5
TP	37	12	3,6,8	<1000	7.5
ACT	37	12	6	130, 150 200, 400 <1000	7.5
pH	37	3	1	<1000	7.0~8.5

Fig. 4.21 Factors involved in high-pressure excursion

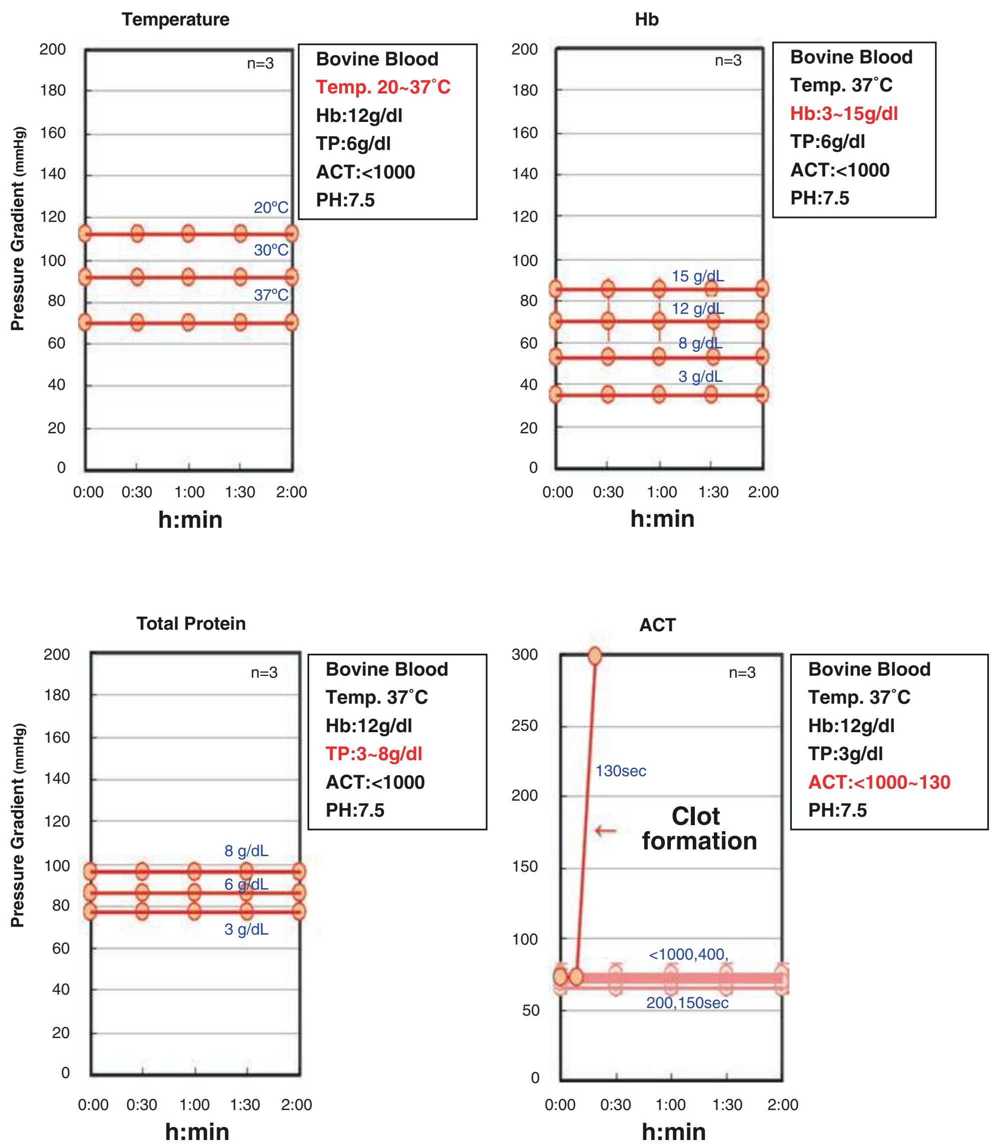


Fig. 4.22 Effects of temperature, Hb, total protein,and ACT on high-pressure excursion

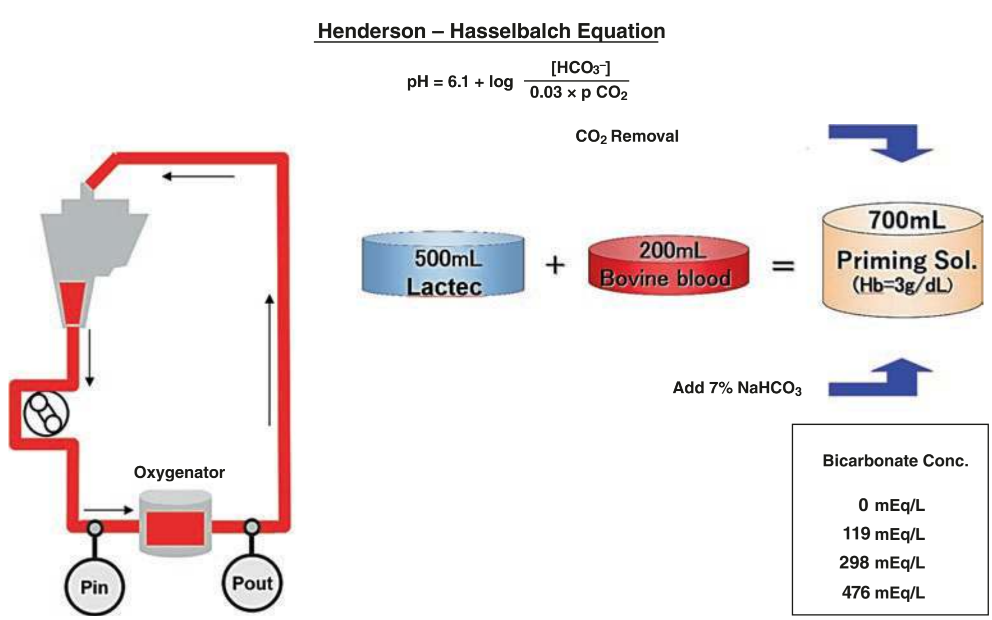


Fig. 4.23 Effect of pH value on pressure gradient

In the case of alkalizing by lowering carbon dioxide only by flushing gas, no increase in the pressure gradient over time was observed even when the pH became high (Fig. 4.24).

On the other hand, when Meylon was added, the pressure gradient increased in proportion to the bicarbonate concentration when the pH was 8.0 or more (Fig. 4.25).

Figure 4.26 shows the pressure gradient change over time when the bicarbonate concentration was changed while the pH is fixed at 7.0 and 8.0. The pressure gradient increased over time in proportion to the bicarbonate concentration and became higher at pH 8.0. This suggests that not only pH but also bicarbonate concentration is involved in high-pressure excursion across the oxygenator. From this, it is clinically conceivable that the initial priming of Meylon and flushing gas into the oxygenator until the initiation of extracorporeal circulation will result in a high pH state, which may cause a Type I high-pressure excursion described later.

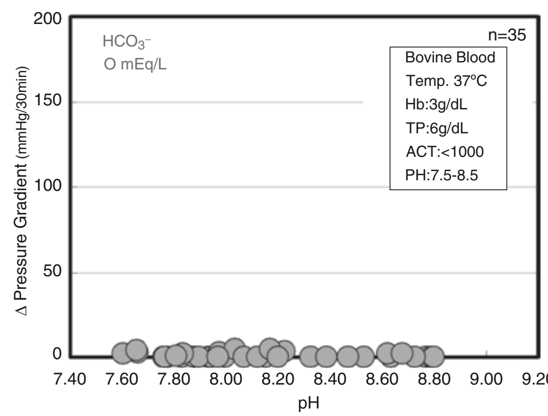


Fig. 4.24 Effect of carbon dioxide decrease on pressure gradient

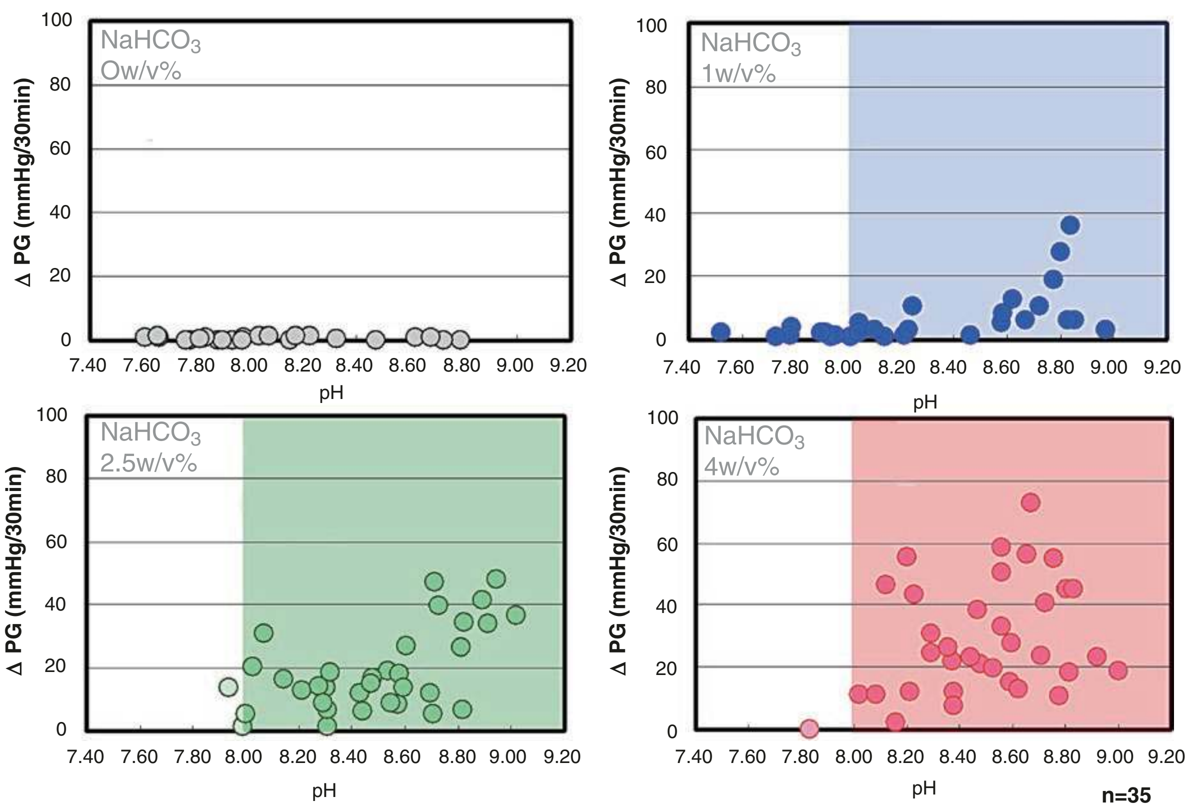


Fig. 4.25 Effect of bicarbonate concentration on pressure gradient

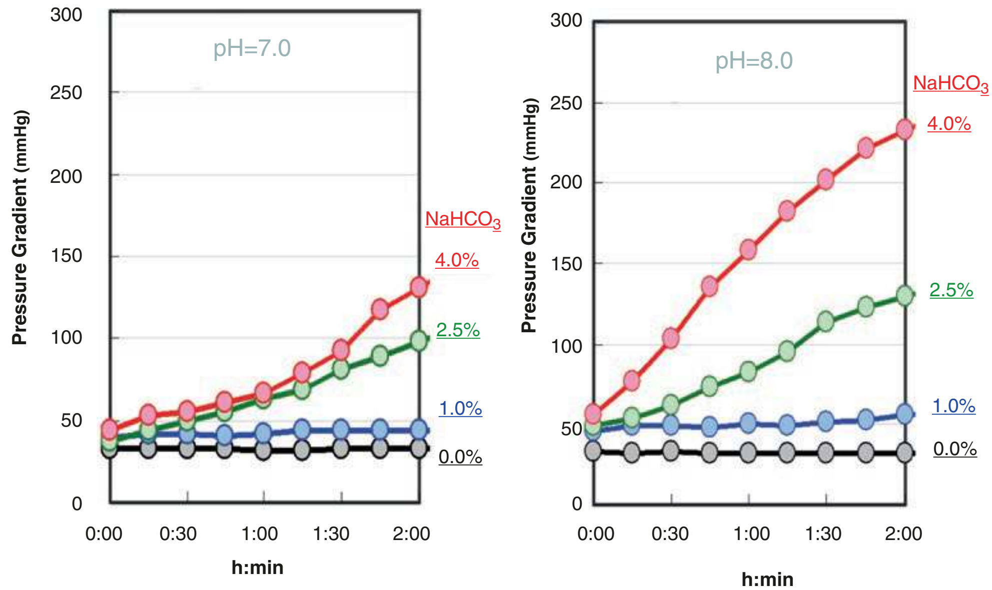


Fig. 4.26 Effect of pH and $NaHCO_3$ on pressure gradient

4.4.2 Clinical Study on High-Pressure Excursion Across Oxygenator

4.4.2.1 Type of High-Pressure Excursion Across Oxygenator

There are several types of high-pressure excursion across oxygenators. It is classified into Type I, which shows a rapid pressure gradient increase immediately after the initiation of extracorporeal circulation, and Type II, which increases during extracorporeal circulation (Fig. 4.27). Figure 4.28 shows actual cases [4].

Q&A: Countermeasures for High-Pressure Excursion Across Oxygenator(Question in 2018)

Question: Please tell us about the factors behind the high-pressure excursion across the oxygenator and its specific measures.

Answer: As a countermeasure, it is first necessary to verify the change in pressure gradient accurately and promptly. Recent heart-lung machines can display pressure gradient on a monitor so that they can be perceived in real time (Fig. 4.29). And second, is prevention. High alkalosis of the initial priming fluid is attracting attention as one of the causes of the high-pressure excursion. However, in the past days' extracorporeal circulation, I think it was more alkalized than now. Of course, circuit pressure was not monitored prior to 2006, but even at that time, I had no experience in oxygenator change-out, even in adult cardiac surgery. Now that circuit pressure monitoring has become mandatory, it is likely that there is a tendency to change-out the oxygenator sooner. And the reality is that the pressure gradient is so high that the perfusion cannot be maintained, and the number of cases requiring change-out of the oxygenator is increasing. The causes of the high-pressure excursion are various and it is difficult to identify the exact cause, but it is necessary to examine the cause for each individual case and to consider some way of coping with the result.

We believe that the high-pressure excursion Type I (Fig. 4.27) also involves the velocity of venous drainage in today's extracorporeal circulation. In vacuum assisted venous drainage (Video 4.7), the drained venous blood falls so as to jump into the bottom of the reservoir and flows into the oxygenator rapidly. If the high alkalinity of the initial priming solution should be the cause of echinocyte generation, it would be thought that a large amount of echinocyte be generated at this point and will flow directly into the oxygenator and increase the pressure gradient. On the other hand, in the previous pump venous drainage, extracorporeal circulation was initiated quite slowly. Venous blood is slowly agitated in the reservoir and flows into the oxygenator (Video 2.1). The structure of the bottom release reservoir and the characteristics of vacuum assisted venous drainage may be related to this Type II. First, it is necessary to slowly guide venous blood to the reservoir. As mentioned in the Q&A: Precautions for Vacuum Assisted Venous Drainage (Question in 2018) (page 169), with vacuum assisted venous drainage used for low-weight infants, arterial and venous blood flow is slowly adjusted using a hemoconcentrator circuit pump at the initiation of extracorporeal circulation.

Figure 4.30 shows a case of Type II high-pressure excursion. Prior to the high-pressure excursion, Mannitol and Meylon were infused rapidly from the Venous blood inlet. Considering the change in Na concentration at the time of the bolus infusion of Meylon mentioned previously, bicar-

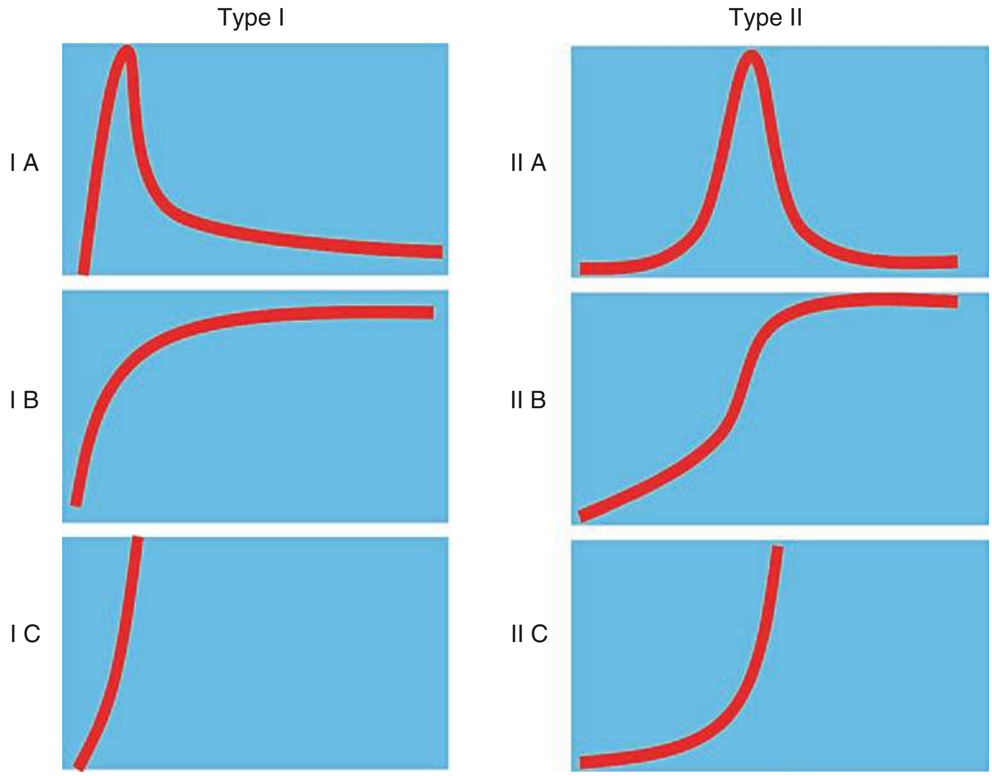


Fig. 4.27 Classification of high-pressure excursion.
Type I: The pressure gradient increases immediately after the initiation of extracorporeal circulation.
IA: The pressure gradient decreases after a while.
IB: The pressure gradient continues to increase, but extracorporeal circulation can be continued.
IC: Extracorporeal circulation cannot be continued and change-out of the oxygenator is required.
Type II: The pressure gradient increases during extracorporeal circulation.
IIA: The pressure gradient decreases after a while.
IIB: The pressure gradient continues to increase, but extracorporeal circulation can be continued.
IIC: Extracorporeal circulation cannot be continued and change-out of the oxygenator is required

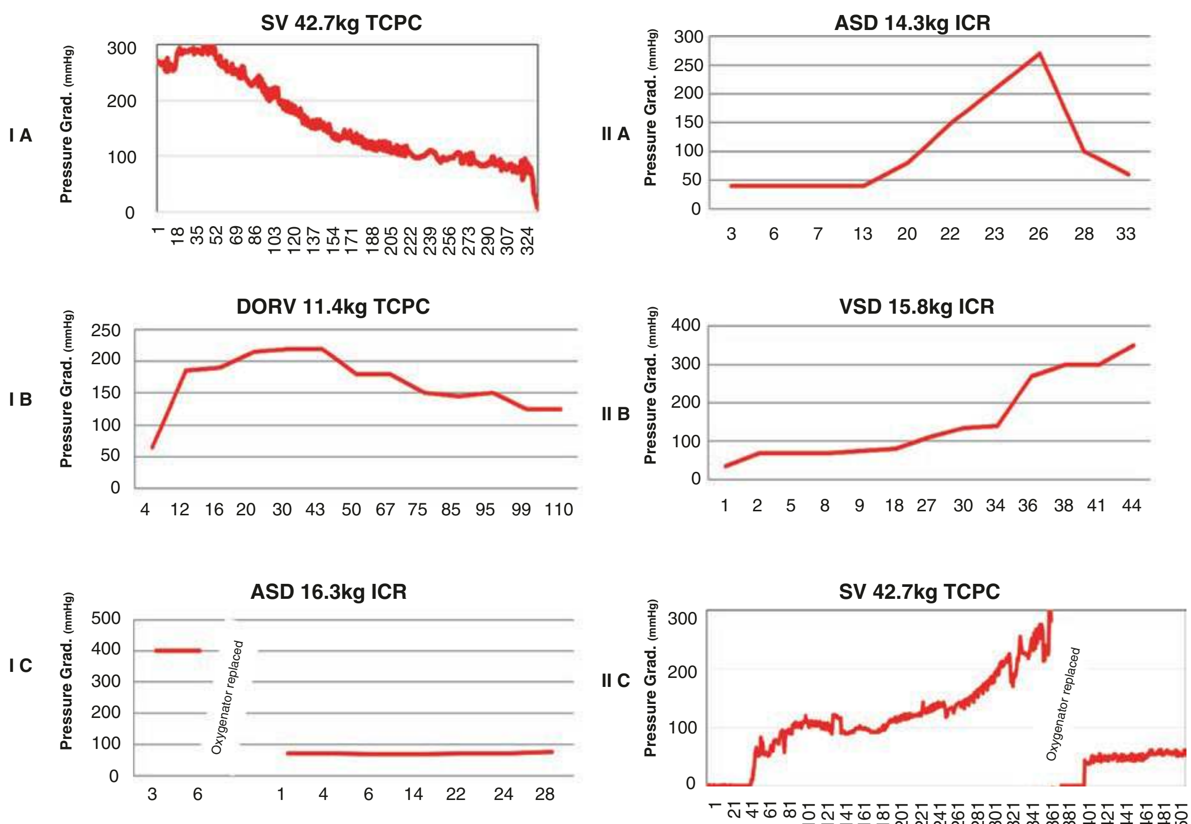


Fig. 4.28 Cases with high-pressure excursion.
SV: Single Ventricle
TCPC: Total Cavo-Pulmonary Connection
DORV: Double Outlet of Right Ventricle
ASD: Atrial Septal Defect
ICR: Intra-Cardiac Repair
VSD: Ventricular Septal Defect

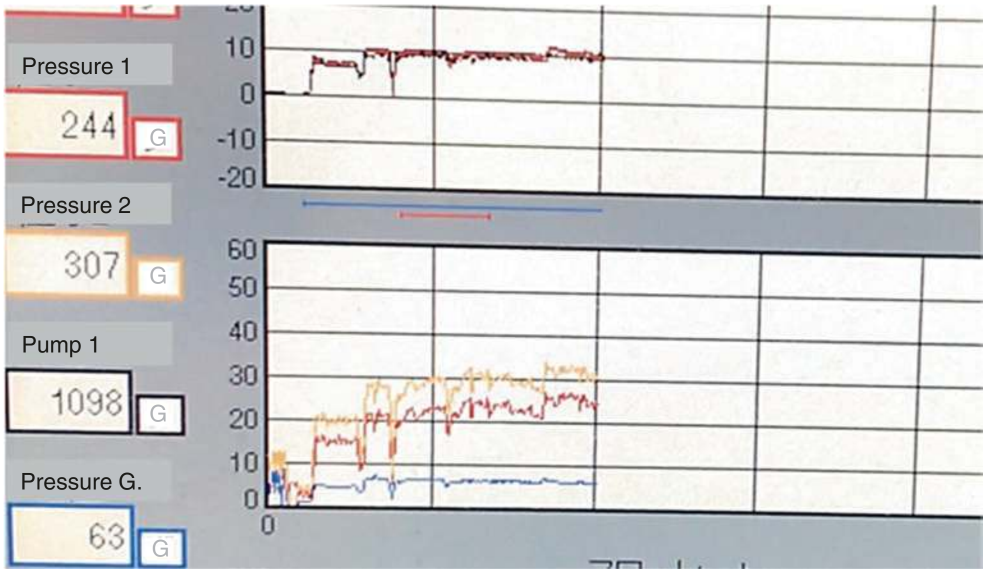


Fig. 4.29 Monitor screen during pressure gradient measurement. The circuit pressure is measured before the oxygenator and after the arterial filter, and the pressure gradient is displayed on a monitor screen

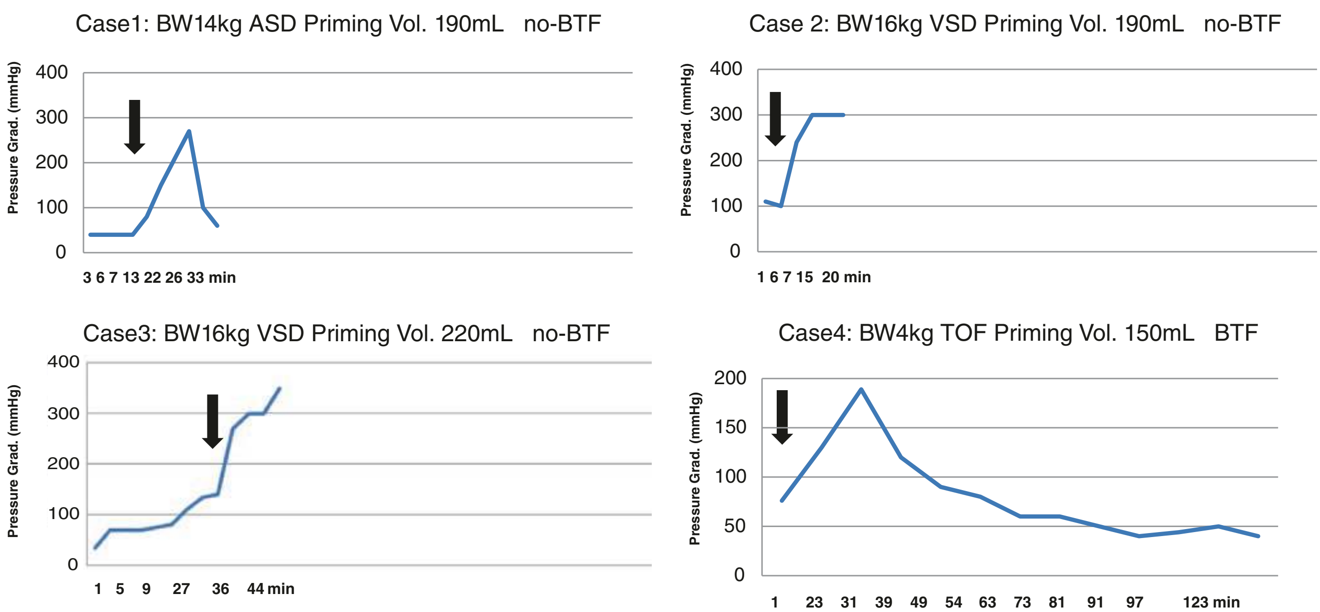


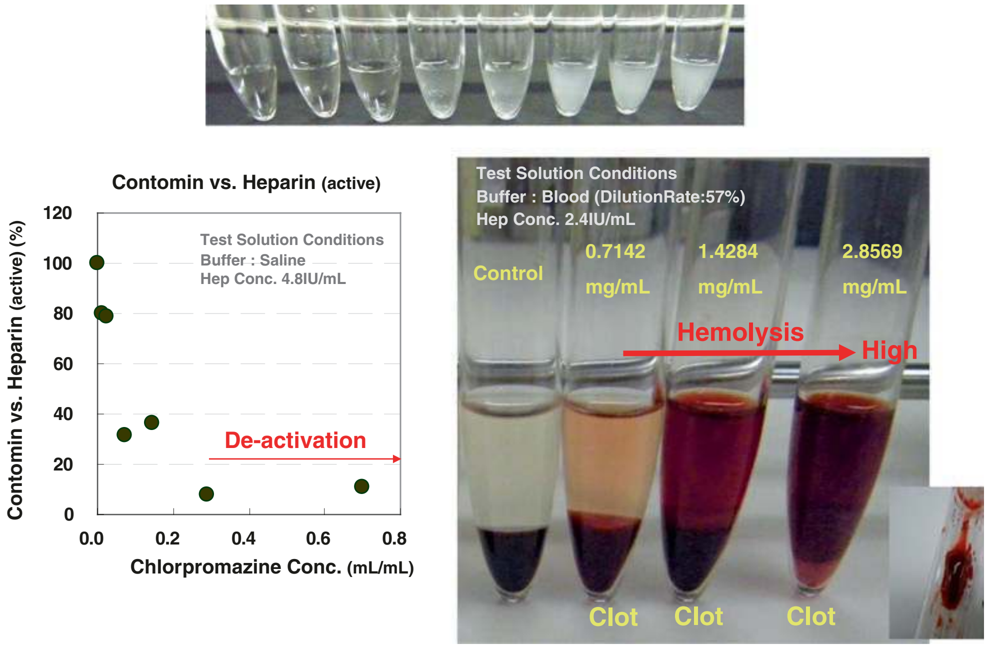
Fig. 4.30 Cases of Type II high-pressure excursion. Case 1: At the time of the arrow (⇓), 15 mL of mannitol, 15 mL of Meylon, and 60 mL of Salinhes were rapidly administered. Case 2: Mannitol 15 mL Meylon 10 mL. Case 3: 15 mL of mannitol and 15 mL of meylon. Case 4: Extracorporeal circulation was initiated urgently due to anoxic spell (BE of the patient was −18). Meylon 10 mL, Mannitol 5 mL.

ASD: Atrial Septal Defect
VSD: Ventricular Septal Defect
TOF: Tetralogy of Fallot
BTF: Blood Transfusion

bonate will flow into the oxygenator without being diluted. I believe this is probably due to the bolus injection correction drawdown in the Bottom release reservoir. From the viewpoint of high-pressure excursion, it is necessary to correct slowly, that is, “Constant Perfusion.”

In addition, caution is required for the administration of Contomin (chlorpromazine hydrochloride) for bolus injection. In vitro experiments have shown that when heparin and Contomin were mixed, white crystals precipitated, and heparin activity decreased as the concentration of Contomin increased. Similarly, when both were mixed with bovine blood, thrombus formation was observed as the concentration of contomin increased (Fig. 4.31). Contomin is a drug that is frequently used as a vasodilator, but we also need to be careful about the amount and speed of infusion.

Fig. 4.31 Effect of Contomin on heparin activity



Both Type I and Type II reactions were completely unnoticed before 2006 when circuit pressure was not monitored. Given the structure of the Safe Micro reservoir and the previous correction method from the Cardiotomy port, I think that even if there was a slight increase in the pressure gradient, it was probably not clinically problematic.

At present, there is no case where the pressure gradient rises during extracorporeal circulation, as well as oxygenator change-out, by adjusting the arterial and venous blood flow at the initiation of extracorporeal circulation and not performing bolus injection correction. The point is to strictly perform "Constant Perfusion."

However, in some cases, strict "Constant Perfusion" was not strictly true. Figure 4.32 shows a DORV case treated with Damus-kaye-stansel + Rastelli (Yasui operation). The preoperative Hct was 76%, and the Hct at the initiation of extracorporeal circulation was 66%. For the purpose of hemodilution, circulating blood was collected in a blood bag, and the same amount of Sublood B (bicarbonate supplemental fluid) was added from the Cardiotomy port. Although this was a matter of course, the pressure gradient rapidly increased and resulted in the change-out of the oxygenator. A large amount of blood clots was found in the heat exchanger and oxygenator. The cause of the high-pressure excursion across the oxygenator was thought to be thrombus generation due to some sudden fluctuations in the circulating blood. It was suggested that extracorporeal circulation management that takes into account the characteristics of current cardiopulmonary bypass devices is necessary.

It is important to keep in mind that, even if it is intended to manage the proper correction or replenishment, it may not be able to achieve the desired "Constant Perfusion" management. At Sakakibara Heart Institute, this case was the last case with oxygenator change-out, and since 2015, high-pressure excursion has not been observed. If a high-pressure excursion is observed, it would be an evidence that "Constant Perfusion" is not working, and the cause should be sought individually for each possible cause of "Unconstant." However, last but not least, it goes without saying that measurement and accurate adjustment of ACT value just before the initiation of extracorporeal circulation is of paramount importance.

4.4.3 Change-Out of Oxygenator

In actual clinical practice, it is necessary not only to prevent high-pressure excursion, but also to always prepare for the possibility of oxygenator change-out. If a Type I high-pressure excursion occurs immediately after the initiation of extracorporeal circulation, notify the surgeon of that fact and prepare for weaning from extracorporeal circulation. If the pressure gradient is extremely high from the beginning of the extracorporeal circulation or shows a continuous increase, and if it is determined that maintaining the perfusion is difficult, the extracorporeal circulation should be immediately weaned to change-out the oxygenator.

Similarly, in the case of a Type II high-pressure excursion during extracorporeal circulation, change-out of the oxygen-

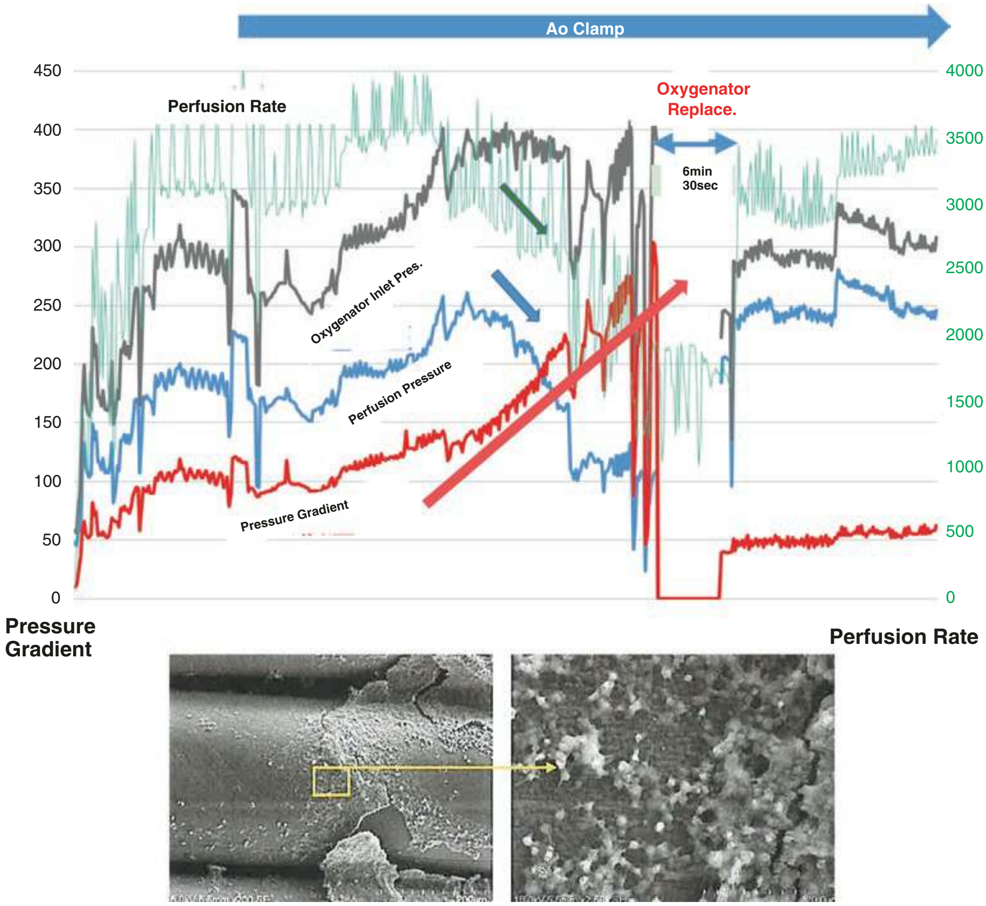


Fig. 4.32 Thrombosis in Oxygenator in a Case of Type II Increased Pressure Gradient. BW 41.1 kg, DORV IAA. Initial priming volume 400 mL. The pressure gradient increased about 20 min after the initiation of extracorporeal circulation. By this time, 880 mL of Sublood B has been administered. High-pressure excursion was addressed by reducing flow rate, but increased pressure gradients were persistent and required change-out of the oxygenator. A large amount of thrombus was observed in the heat exchanger and the oxygenator

ator should be considered as soon as possible in the case of a sustained pressure gradient rise. However, in the case of Type II, there is a situation in which change-out must be performed during aortic cross-clamping, so, a certain device is required to change-out the oxygenator. Of course, change-out of the oxygenator is the last resort, and it is important to carefully observe the transition of the pressure increase and take measures to reduce it.

Q&A: Change-Out of Oxygenator (2017)

Question: Please tell me how to change-out the oxygenator.

Answer: Figure 4.33 shows a case in which the perfusion flow decreased as the pressure gradient increased during extracorporeal circulation using a centrifugal pump. In this case, the perfusion flow could be maintained by increasing the pump speed, and the pressure gradient thereafter decreased. However, if the pressure gradient increases even if the pump speed is increased and the target perfusion flow cannot be maintained, change-out of the oxygenator must be considered. Techniques that do not stop perfusion are needed for oxygenator change-out during extracorporeal circulation, especially during aortic cross-clamping. Data 4.2 and Video 4.8 show how to do this.

First, a new oxygenator is set using the pressure monitoring port just before the oxygenator and the side tube of the arteriovenous shunt port after the arterial filter (Fig. 4.34). This is to make the perfusion channel a double route. With this method, the air in the new oxygenator can be evacuated without stopping the extracorporeal circulation, and it is considered to be an extremely useful method that enables the change-out of the oxygenator without stress. As an aside, perfusionists also need the skills to quickly set up and prime the extracorporeal circuit for very emergency open-heart surgery. Video 4.9 shows an educational video of emergency preparation of extracorporeal circulation. In any case, perfusionists are often required to respond quickly, so I think training is necessary first [5–9].

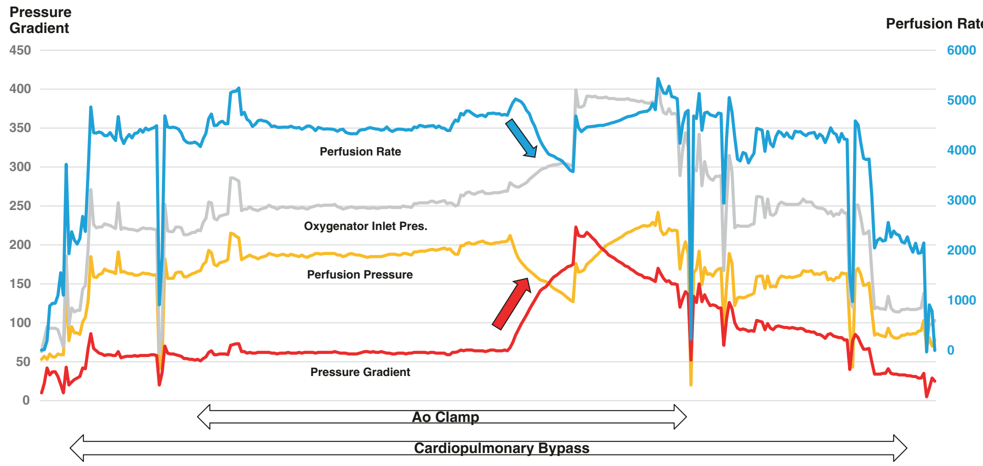


Fig. 4.33 A case of Type II increased pressure gradient. Diagnosis of left atrial myxoma. Bloodless priming with a priming volume of 700 mL. Centrifugal pump used. During the aortic clamp, an increase in pressure gradient was observed, and a decrease in perfusion flow was observed. The cause of the pressure gradient increase could not be identified

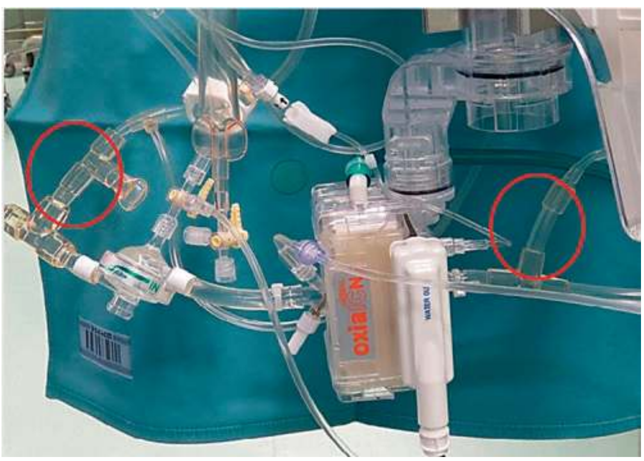


Fig. 4.34 Ports for oxygenator change-out. Shows the pressure monitoring port just before the oxygenator and the arteriovenous shunt port after the arterial filter

Column: How to Deal with TypeI High-Pressure Excursion

Figure 4.35 shows an example of the Type I high-pressure excursion. The patient weighed 6.1 kg, diagnosed with aortic stenosis, supravalvular stenosis, pulmonary stenosis, and foramen ovale. Repair of supravalvular stenosis, pulmonary valvotomy, and PFO closure was performed using a circuit with a priming volume of 150 mL (without blood priming). The pressure gradient increased from the point where the perfusion flow was half, and at the time of the total flow, the pressure before the oxygenator increased to 400 mmHg and the pressure gradient to 200 mmHg. Following shows the thoughts and actions of the perfusionist at that time.

First, the perfusion flow was reduced from 900 mL/min to 800 mL/min. At this point, if the steep rise in pressure gradient persisted, I was planning to call on other staff and wean from the extracorporeal circulation immediately. ACT, of course, was rechecked. However, the speed of the pressure gradient increase was still gentle, and I thought it was okay from my experience, so I started the cooling. After that, the pressure gradient decreased (at 115 point on the horizontal axis), which is thought to be due to hemodilution of the circulating blood by the amount of Blood GIK aspirated. In this case, reducing the blood viscosity with about 50 mL of crystalloid might have been a measure. However, the pressure gradient has since increased again. At this point, the bladder temperature was 32 °C, so the perfusion flow was further reduced to 750 mL/min. After that, a decrease in pressure gradient was observed, and the perfusion flow could be restored while maintaining body temperature. At the initiation of extracorporeal circulation, of course, I think that there was an option to wean immediately and change-out the oxygenator. But even during aortic cross-clamping, safe change-out of the oxygenator is possible using the method shown on Data 4.2 and video in the previous section "Q&A: Change-Out of Oxygenator (2017)", so we took such measures in this case. However, I think that decreasing the pressure gradient means that clogging in the oxygenator will be released. Those cloggings smaller than the pore size of the arterial filter will still flow into the body. In this case, I considered that the alkalinization of the initial priming composition may have caused the pressure gradient to increase. I think that the Type I high-pressure excursion can be solved by careful attention not only to this alkalizing but also to the pump speed at the initiation of extracorporeal circulation. After all, preventive measures not to cause the excursion are essential.

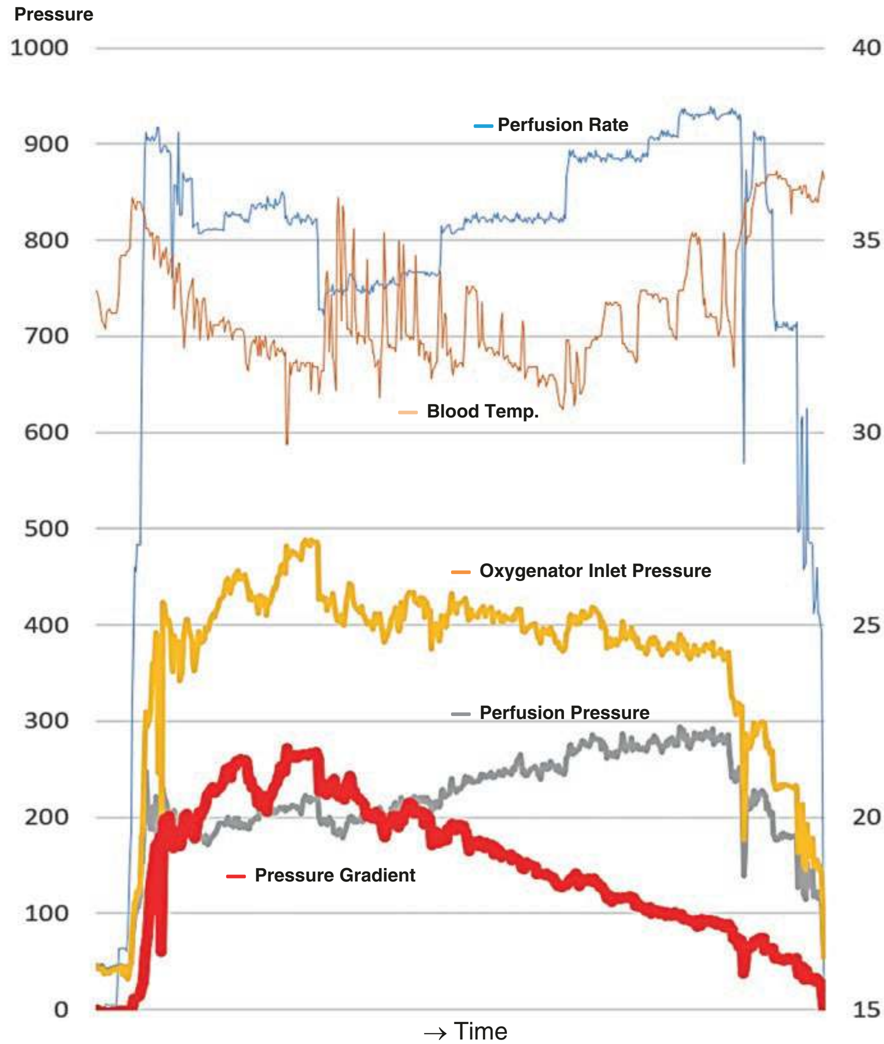


Fig. 4.35 Type I Pressure gradient rise

Column: Experiment of Circuit Tube Detachment
An experiment was conducted on the circuit pressure when the extracorporeal circulation tube was detaching.

No cable ties were applied to the connection between the tube and the oxygenator.

Pressure was applied to the outlet of the oxygenator using clamps, and the circuit pressure was measured when the tube and the oxygenator came off (Figs. 4.36 and 4.37).

It is considered that there is no damage to the extracorporeal circulation circuit at the degree of increase in the circuit pressure observed clinically.

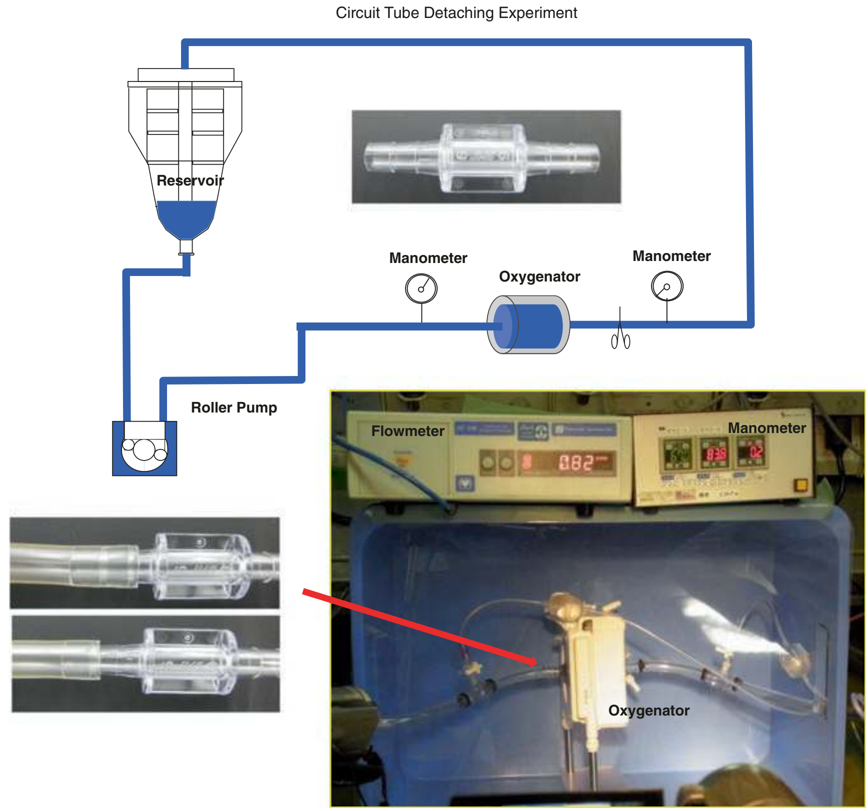


Fig. 4.36 Circuit tube detaching experiment. When the tube was fitted to the second barb of the connector, it did not come offeven when the circuit internal pressure reached 2000 mmHg. So, the fitting of the tube was limited to the first barb of the connector

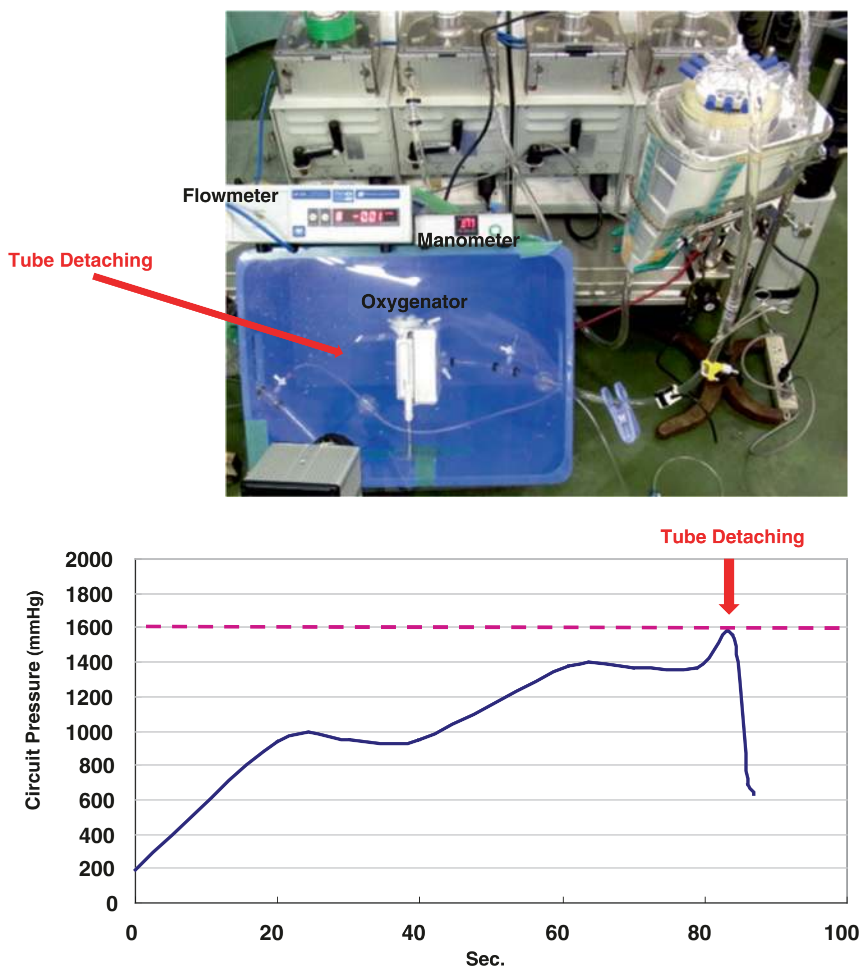


Fig. 4.37 The tube came off when the circuit pressure reached about 1600 mmHg

4.5 Problems in Pediatric Oxygenators

Many recently developed pediatric oxygenators have higher gas exchange performance (oxygen and carbon dioxide transfer capacity) while ensuring less membrane surface area and lower pressure drop. They can be used in infants as well as newborns (In other words, the greater embraces, the less). There is no doubt that the development of these small, high-performance oxygenators has greatly contributed to the minimally invasive pediatric heart surgery, including the expansion of indications for bloodless open-heart surgery. However, it has been pointed out that the excellent gas exchange ability causes a problem in extracorporeal circulation management in low-weight children. That is, the PaCO2 becomes extremely low.

Q&A: Oxygenator for Low-Weight Infant (Question in 2016)

Question: In extracorporeal circulation of low-weight infants, it may be difficult to control PaO_2, $PaCO_2$, pH, and Base Excess values. Is there a realistic and easy management method?

Answer: The regulation of PaO_2, $PaCO_2$, pH and BE is, so to speak, respiratory management during extracorporeal circulation. If it shows extreme abnormal values even in normal extracorporeal circulation, there should be some obvious cause, so the extracorporeal circulation itself needs to be reviewed. However, the living body responds to metabolic and respiratory acidosis and alkalosis associated with extracorporeal circulation and makes corrections accordingly. Most of the fluctuations in the measured values are the result. Therefore, in most cases, slight variations in these values are unlikely to lead to clinical problems.

Still, the most troublesome management is dealing with respiratory alkalosis. The important thing is to first determine whether to make corrections based on fluctuations in $PaCO_2$, pH, and BE, or not to perform corrections because they are within the allowable range. For example, if BE is −5.0, $PaCO_2$ is 25 mmHg, and pH is 7.55, at least you may not consider correction with Meylon. If so, this would be adjusting the insufflation gas flow by judging it as a respiratory alkalosis. However, this adjustment is particularly difficult for low-weight children. The second is to maintain a constant $PaCO_2$ value from the beginning of extracorporeal circulation to prevent respiratory alkalosis. This is one of "Constant Perfusion." Although it is doubtful whether the answer is appropriate, from this point of view, I would like to talk about the choice of oxygenator and the prevention of respiratory alkalosis by adding CO_2.

Figure 4.38 shows the oxygen and carbon dioxide transfer capacity and pressure drop of five types of pediatric oxygenator. All have excellent gas exchange performance up to the high blood flow region. However, this means that using these oxygenators at lower perfusion rates will naturally increase carbon dioxide removal. The only countermeasure to this is to adjust the gas flow to the oxygenator. Until now, this has not been noticeable, but it has recently been pointed out that excess removal of carbon dioxide may be a problem in neonatal and low-birth weight open-heart surgery.

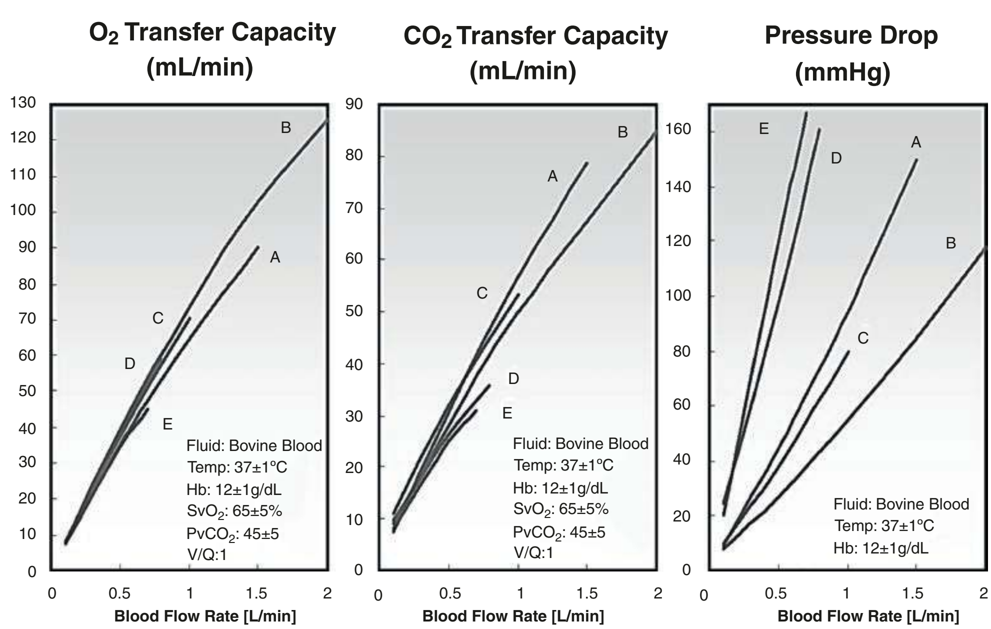


Fig. 4.38 Gas exchange capacity and pressure drop in oxygenators

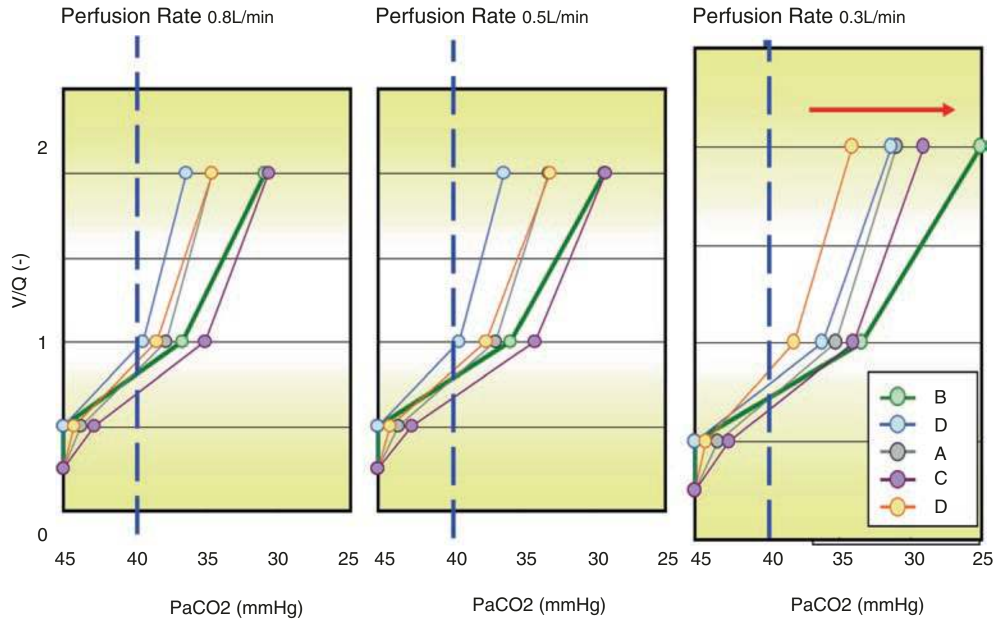


Fig. 4.39 V/Q ratio and $PaCO_2$ by perfusion flow rate. In the low perfusion flow rate region, the decrease in $PaCO_2$ is larger.
V/Q Ratio: Ventilation Perfusion (Gas to blood flow) Ratio

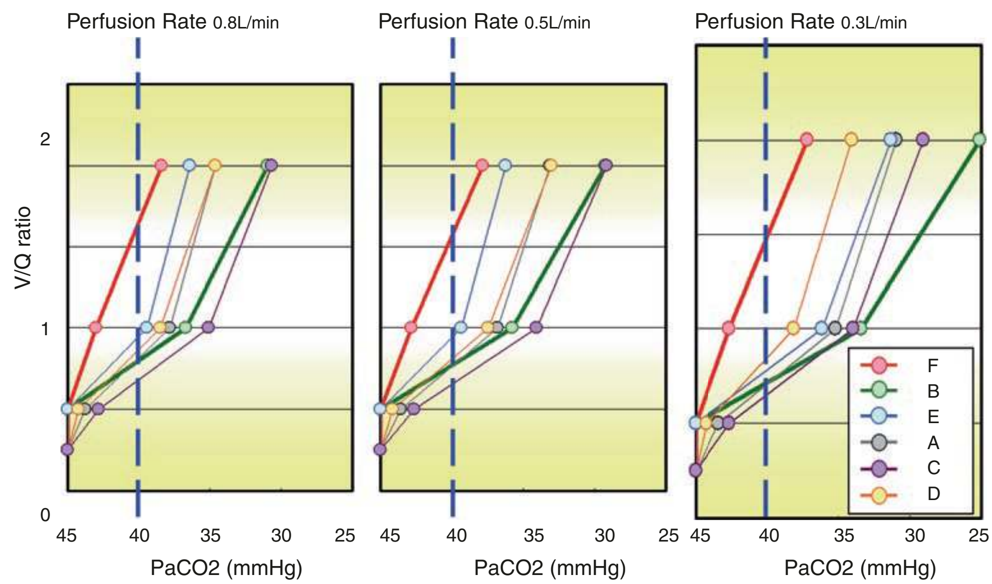


Fig. 4.40 Carbon dioxide dynamics of oxygenator for low-weight infant. With the new Oxygenator F for low-weight children, $PaCO_2$ can be kept relatively high even at low perfusion flow rates

Figure 4.39 shows the carbon dioxide transfer capacity of each oxygenator. Under the conditions that the perfusion flow is set to 0.8, 0.5, 0.3 L/min and the carbon dioxide partial pressure of venous blood is 45 mmHg, changes in arterial blood $PaCO_2$ were measured when the V/Q (gas to blood flow, or ventilation perfusion) ratio was increased to 0.25, 0.5, 1.0, and 2.0. The more the graph shifts to the right, the greater the carbon dioxide removal with the same V/Q ratio, which means that the oxygenator is more likely to reduce $PaCO_2$. Especially at a low perfusion flow rate of 0.3 L/min, it decreased significantly. In actual clinical practice, the target $PaCO_2$ is around 40 mmHg by adjusting the gas flow rate insufflated into the oxygenator. In order to achieve the target of 40 mmHg indicated by the blue dashed line, the lower the perfusion flow rate, the lower the V/Q ratio must be. That is, if the gas flow rate is not significantly reduced, carbon dioxide will be excessively removed.

However, gas flowmeters currently in use tend to be unstable, especially at flow rates below 200 mL/min, that is, oxygenation itself may be unstable. Therefore, it is considered that the current situation is to adjust the gas flow rate with a slightly higher V/Q ratio. As a result, oxygenators with good gas exchange performance have excessively low $PaCO_2$, resulting in respiratory alkalosis. Of course, it is possible to adjust the blood $PaCO_2$ value by insufflating carbon dioxide through the oxygenator, but to solve this problem, it is also required to create an oxygenator that matches the carbon dioxide transfer capacity to low-weight children. The point is that the maximum blood flow may be low, keeping the oxygenation performance and pressure drop the same, and the carbon dioxide transfer is low, that is, an oxygenator that can easily regulate $PaCO_2$. Recently, an oxygenator for low-weight infants with a maximum blood flow of less than 1.0 L/min has been developed with this concept. The measurement of carbon dioxide dynamics using this oxygenator resulted in good control of $PaCO_2$ even at high gas flow rates (Figs. 4.40 and 4.41). It was also found that the gas flow rate was easier to control than the conventional oxygenator (Fig. 4.42).

In extracorporeal circulation with low perfusion flow, the selection of an oxygenator is one of the measures for respiratory management during extracorporeal circulation. Figure 4.43 shows the comparison of V/Q ratio, $PaCO_2$, and pH in extracorporeal circulation using Oxygenator F for low-weight children and conventional Oxygenator B. Although there is variation, better control is possible with Oxygenator F. In extracorporeal circulation in low-birthweight children, and it is necessary to understand the characteristics of each oxygenator and to select the appropriate oxygenator for each case ("Right oxygenator in the right place").

Of course, I think that $PaCO_2$ adjustment by adding carbon dioxide gas is also effective. In particular, in cases weighing less than 3.0 kg, carbon dioxide is over-exhausted. So at present, instead of decreasing the gas flow rate, the gas flow rate is fixed at 1 L/min, and carbon dioxide gas is added at a rate of 50 mL/min to adjust the pH to 7.4. Adjustment is relatively easy now that a CDI monitor is available. In addition, carbon dioxide gas is insufflated for pH adjustment during initial priming. As a result, since 2015, there has been no Type I high-pressure excursion and no oxygenator change-out. It may be an effective method for the increasing pressure gradient of the oxygenator.

I mentioned respiratory management during extracorporeal circulation. I think that such management is also an important point as one of "Constant Perfusion."

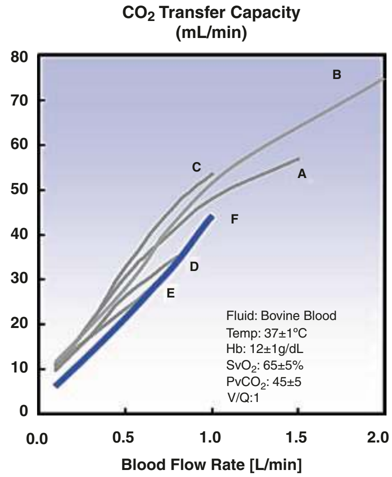


Fig. 4.41 Carbon dioxide transfer ability in oxygenator for low-weight infant. Oxygenator F has low carbon dioxide transfer ability even at low perfusion flow rate

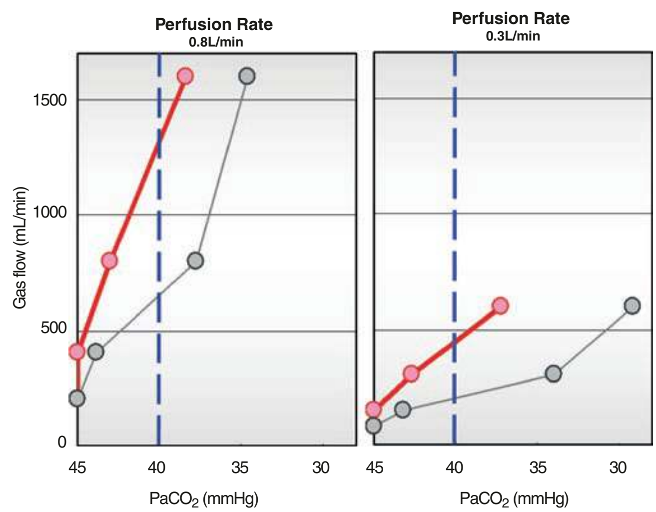


Fig. 4.42 Relationship of gas flow rate with $PaCO_2$ in oxygenator for low-weight infants. This figure shows the arterial blood $PaCO_2$ at the outlet of the oxygenator when the gas flow rate is changed under the condition that the venous blood carbon dioxide partial pressure on the inlet of the oxygenator is set at 45 mmHg. In a low flow region with a perfusion flow rate of 0.3 L/min, the gas flow rate for obtaining a carbon dioxide partial pressure of 40 mmHg is less than 200 mL/min with a conventional oxygenator (●), while the oxygenator for low-weight infants (●) is about 450 mL/min, which indicates that the gas flow rate in the low perfusion rate region is easily adjusted

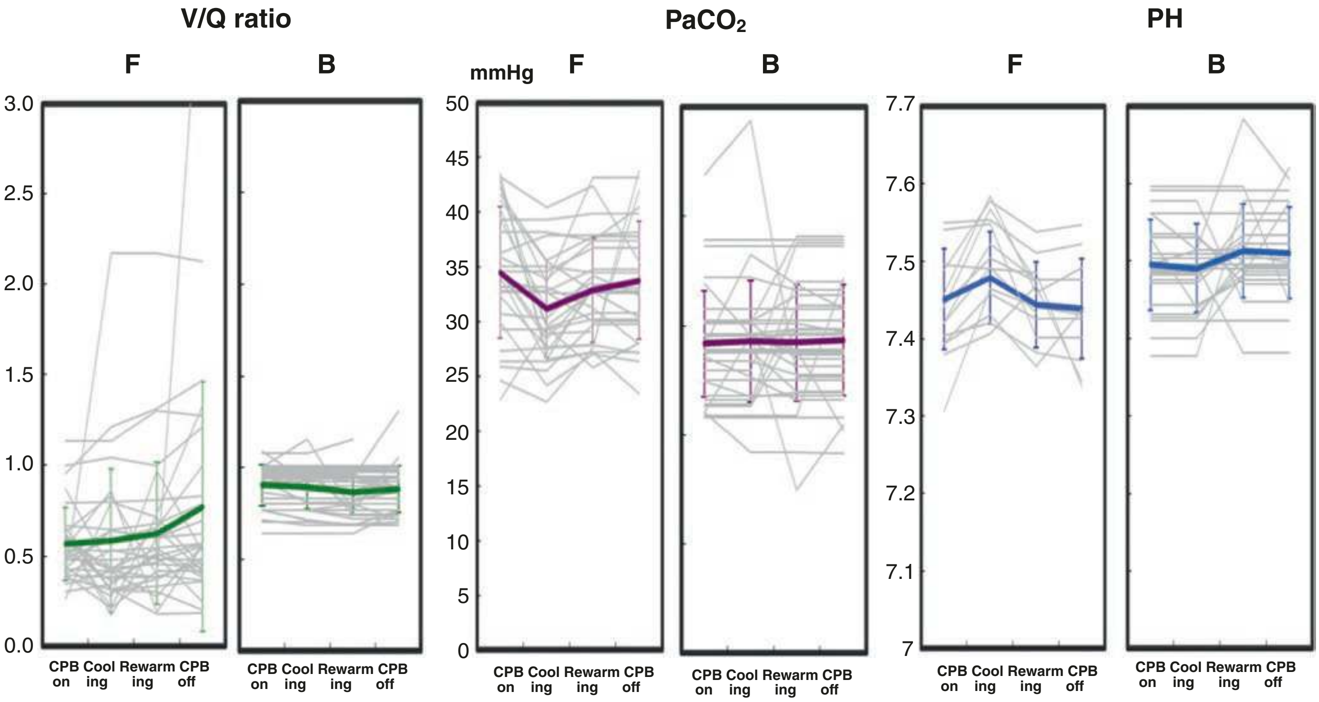
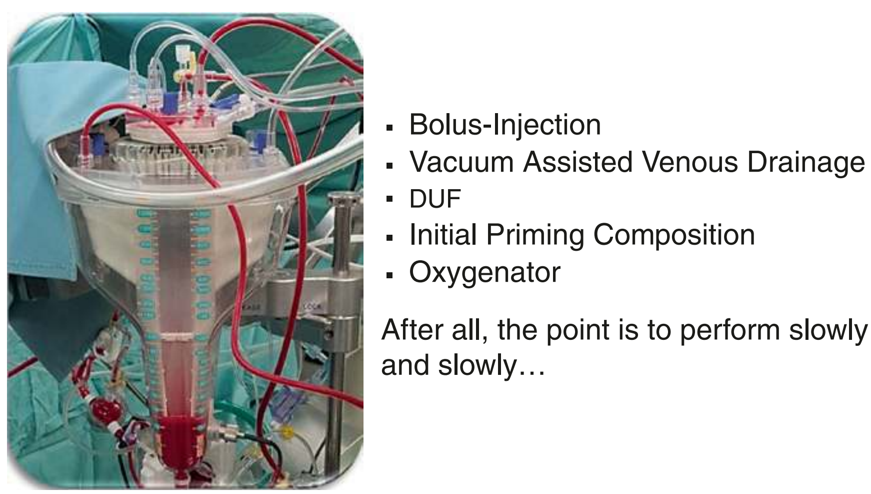


Fig. 4.43 V/Q ratio, $PaCO_2$ and pH in oxygenator for low-weight infants. The V/Q ratio, $PaCO_2$, and pH during extracorporeal circulation were compared between 35 patients using Oxygenator F and 36 patients of the same weight using Oxygenator B. Oxygenator F (November 2012–March 2014): Average body weight 3 kg (nine patients less than 2.5 kg, minimum 1.9 kg), average extracorporeal circulation time 80 min, average perfusion rate 0.82 L/min. Oxygenator B (November 2007–March 2008): Weight, extracorporeal circulation time, and perfusion rate were not different from those of Oxygenator F. In Oxygenator F, the V/Q ratio was 0.6–0.7 on average, $PaCO_2$ was around 35 mmHg, and pH was around 7.45. There was some variation, but it was controlled better than Oxygenator B

Fig. 4.44 Fluctuation points that occur during extracorporeal circulation



4.6 Summary of New Problems

With regard to the fluctuations in the circulation dynamics and blood status in the living body due to extracorporeal circulation, it was suggested that those fluctuations associated with current extracorporeal circulation devices were larger than previous devices. Of course, changing the reservoir and extracorporeal circulation method alone is not the only cause of clinical problems such as increased vascular permeability and decreased diuresis. However, it should be noted that advances in equipment have some pitfalls, especially in the extracorporeal circulation of newborns and low-weight infants. In a sense, it can be said that it is iatrogenic.

In the future, it is important to reconsider more strict measures for "Constant Perfusion," especially the thorough review and reinforcement of basic extracorporeal circulation technique. The point is that every procedure of extracorporeal circulation should be performed slowly and slowly so as not to change the physiological balance of the living body.

In the next section, we discuss "Constant Perfusion" in terms of microbubbles during extracorporeal circulation (Fig. 4.44).

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5 Microbubbles in Extracorporeal Circulation and Its Countermeasures

Contents

5.1 Introduction

Bubbles having a diameter of less than 50 μm are called microbubbles. Since microbubbles have a small buoyancy, they will flow into the living body without disappearing when they are generated, especially in the reservoir during extracorporeal circulation. The capillary diameter of a living body is 4–9 μm, and microbubbles with diameters less than this value are considered to pass through the capillaries. However, microbubbles of 10 μm or more may stay or fuse in the blood vessel, which may block the tissue blood flow or cause a change in the function of the capillary wall. It is also known that even if it is less than 10 μm, damage to the capillary endothelium is caused. Pathophysiology associated with microbubbles includes: (1) microinfarction due to occlusion of capillaries, (2) increased vascular permeability and local inflammatory response due to impaired capillary endothelium, (3) thrombus formation, and (4) SIRS due to contact with circulating blood. In particular, it is considered to be a cause of cognitive dysfunction and neurological deficits in adult cardiac surgery.

Capillaries can be classified into continuous and fenestrated, and most capillaries in the brain are continuous capillaries consisting of a single layer of endothelial cells. It is considered that microbubbles always cause some problems that cannot be grasped as clinical symptoms. It may contribute to postoperative cranial nervous system complications of unknown cause, such as periventricular leukomalacia (PVL) and brain atrophy. In this section, the occurrence of microbubbles in extracorporeal circulation clinically and experimentally will be examined, and the microbubble suppression measures based on the results will be discussed [1–3].

Supplementary Information The online version contains supplementary material available at [https://doi.org/10.1007/978-981-16-6730-5_5].

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5.2 Measuring Method

5.2.1 Experiment

BC100, manufactured by GAMPT mbH, and FURUHATA (HDK-BM001), manufactured by Hashimoto Electronic Industry Co., Ltd., were used for microbubble measurement in experiments using simulated extracorporeal circulation. Using an extracorporeal circulation circuit primed with bovine blood, the air was injected from the venous inlet port and cardiotomy port, and the size and number of microbubbles were measured at the reservoir outlet and the arterial filter outlet (Figs. 5.1 and 5.2).

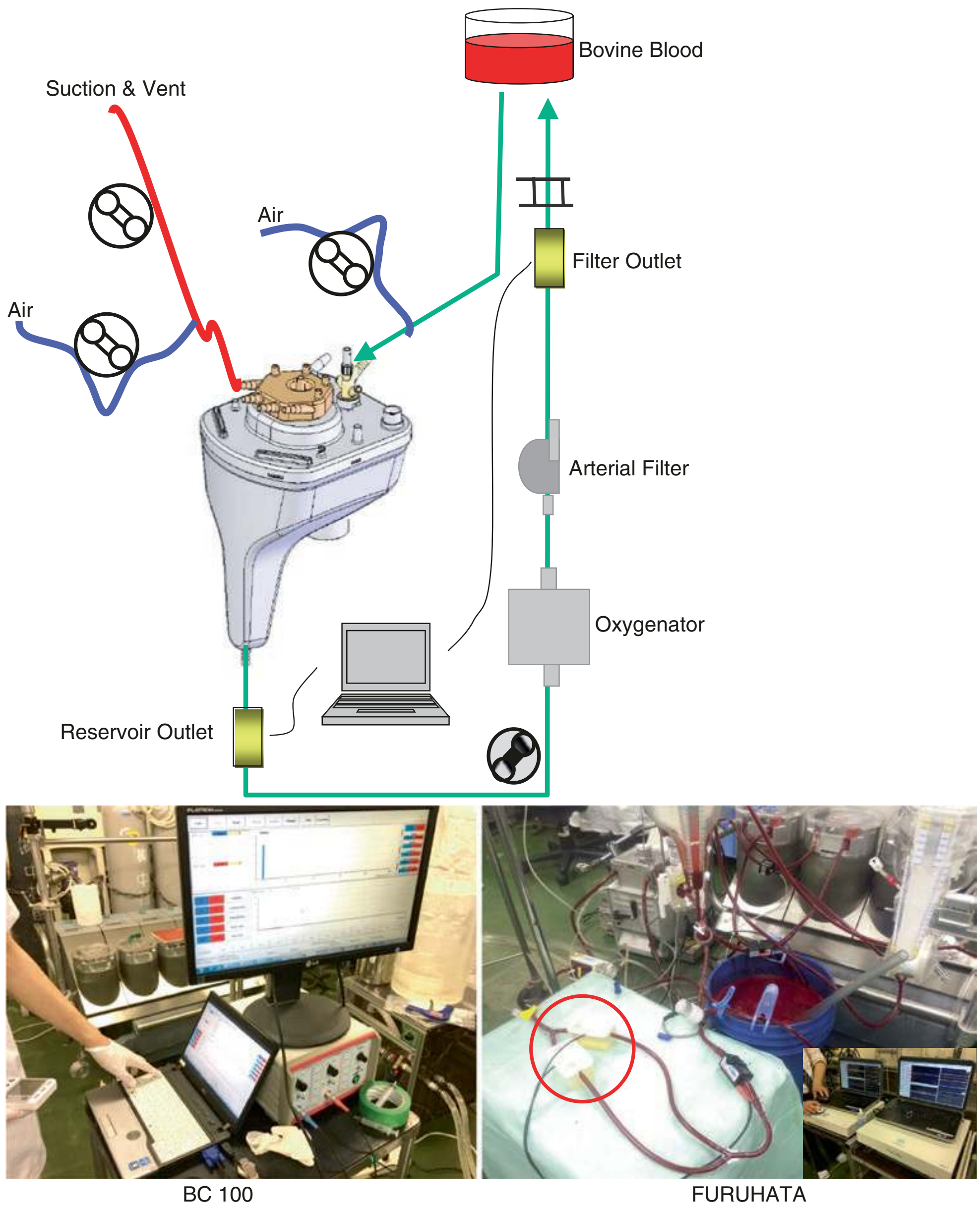


Fig. 5.1 Experimental microbubble measurement with BC 100 and HDK-BM001 (FURUHATA)

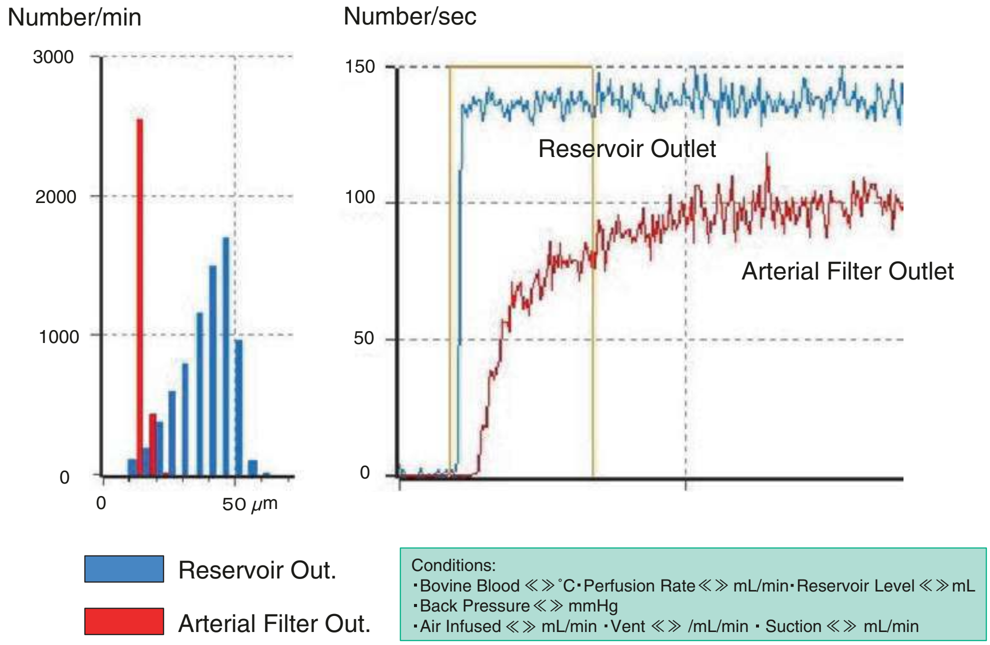


Fig. 5.2 Monitor screen during microbubble measurement with BC100. Left figure: The number per minute of microbubbles by size is displayed. Right: The number of microbubbles per second is displayed over time. The measurement limit is 150 per second

5.2.2 Clinical

For microbubble measurement in clinical situation, FURUHATA (HDK-BM001), was used (Fig. 5.3). Figure 5.4 shows the confirmation monitor screen after measurement, and Fig. 5.5 shows the number of microbubbles generated over time in DORV PS case.

Q&A: Significance of microbubble measurement (Question in 2017)

Question: What is the meaning of measuring microbubbles and their suppression?

Answer: I have lost a child with acute global brain damage after open-heart surgery. We examined all the causes but could not identify them. Since then, we have considered microbubbles as one of the possibilities and have started experimental verification and clinical measurement.

During extracorporeal circulation, microbubbles are always generated and will enter the patient's body. But I still think that in most cases, nothing happens clinically. However, clinical measurements have shown that significantly more microbubbles are generated than expected. As we proceeded with the measurements, especially in newborns and low-weight children, as the involvement of microbubbles in cognitive dysfunction and neurological deficits in adult cardiac surgery has been reported, we have come to believe that microbubbles may be involved in the development of cerebral ischemic lesions and delays in growth and development, for which the causes have not been well understood. In addition, it is easy to imagine the involvement of microbubbles is a factor in SIRAB. Taking these factors into account, of course, the number of scattered microbubbles should be reduced. In particular, microbubbles with a diameter of 10 μm or more that could block capillaries should be actively suppressed.

Microbubbles do not normally exist in the living body. Establishing measures to suppress the generation of microbubbles is also one of "Constant Perfusion" and one of the less invasive methods.

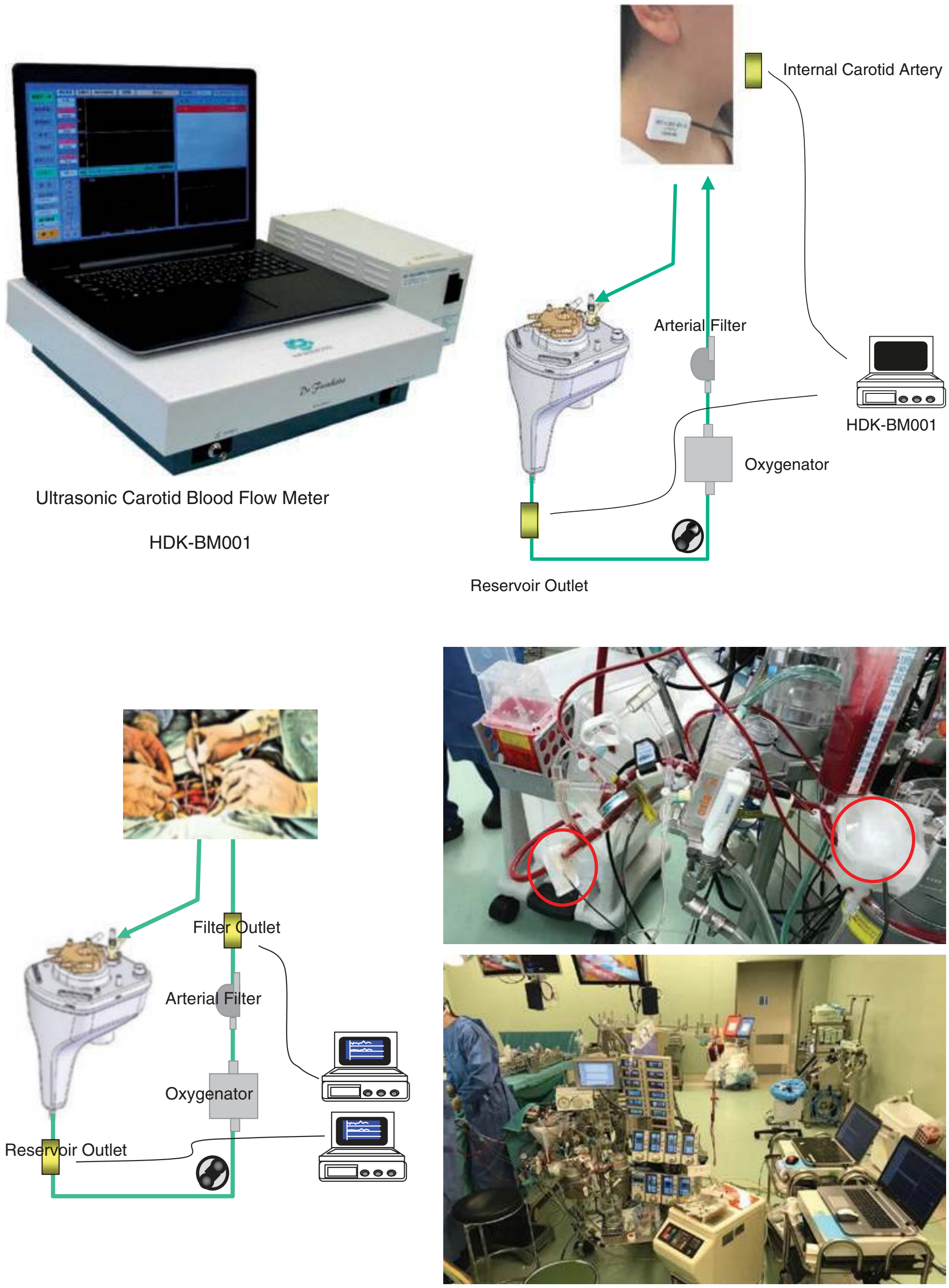


Fig. 5.3 Clinical microbubble measurement with HDK-BM001 (FURUHATA): Internal carotid artery and extracorporeal circuits. In clinical measurement, a probe is attached to the skin above the internal carotid artery. Since the blood flow limit for measurement is 800 mL/min, measurement can be performed at the reservoir outlet or at the arterial filter outlet in patients weighing less than 4.5 kg. The limit number of detections is 20 per second

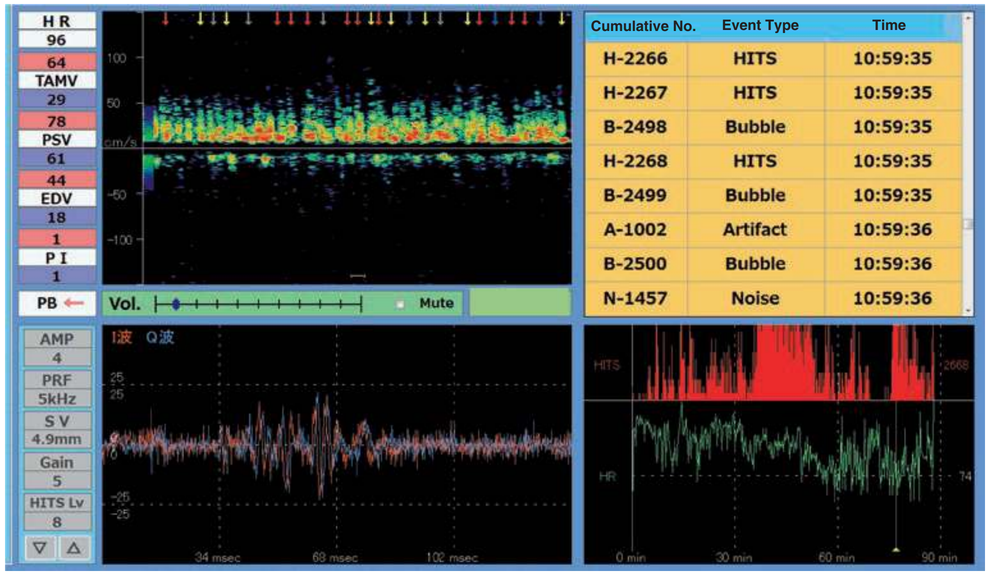


Fig. 5.4 Confirmation monitor screen in FURUHATA. The red dots in the upper left figure are events such as bubbles were observed. The lower right red graph shows the number of measurements per minute over time. By placing the yellow cursor on the time axis, the eight samples measured before and after that time will be identified as bubble, HITS, Noise, or Artifact, and displayed in the upper right figure. The accuracy of each measured event can be reconfirmed in the frequency waveform (lower left figure).
HITS: High Intensity Transient Signal

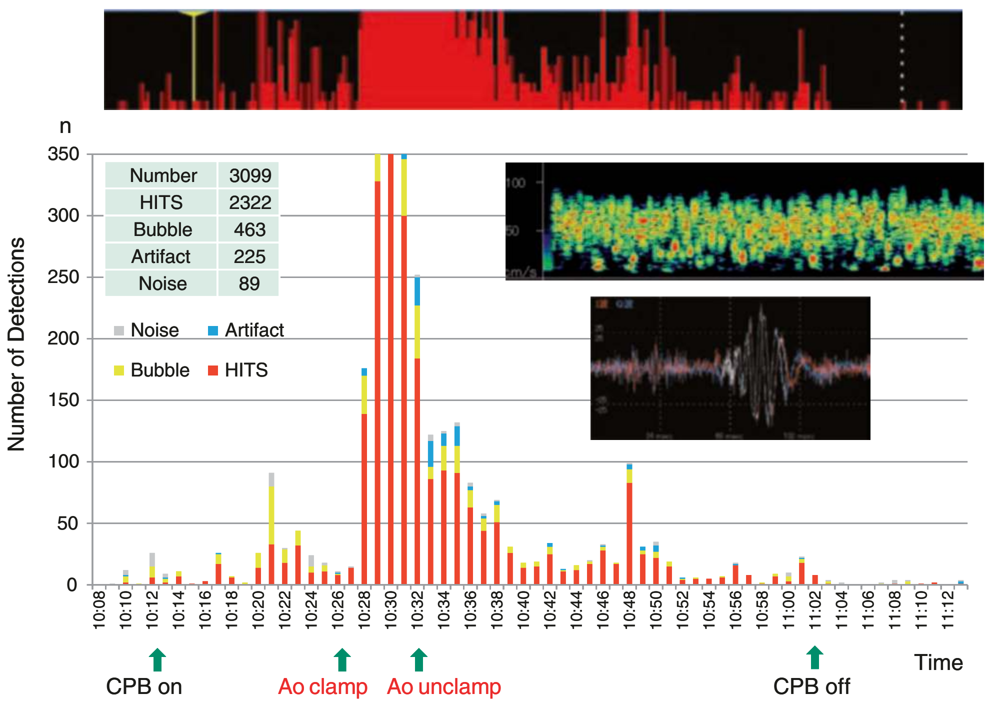


Fig. 5.5 Result in a DIRV PS case weighing 7.6 kg (Glenn and ASD Creation performed). ASD enlargement was performed during cardiac arrest, and then Glenn anastomosis was performed under heartbeat. The number per minute of microbubbles can be color-coded by bubble, HITS, Noise, and Artifact

Column: Calibration of Microbubble Measuring Device

In the measurement of microbubbles using BC100, bubbles much larger than the pore size of the filters in the reservoir or the arterial filter were sometimes detected (100 μm or more). These are improbable values in actual clinical practice. Since it is clinically necessary to measure microbubbles with a diameter of 10–50 μm, the calibration data of the measuring device was modified to accurately measure the size and quantity of microbubbles. Blood and air were injected into a simulated extracorporeal circuit incorporating a centrifugal pump, and the air was broken into small bubbles by the centrifugal pump. The images of the air bubbles were taken with an optical microscope equipped with a high-speed camera. Figure 5.6 shows a bubble image obtained by a microscope camera. The size of the bubble was measured from the obtained image (optical counting method). After that, the BC100 was connected to this circuit, and the calibration variable was adjusted so that the peak of the bubble size distribution indicated by the BC100 became equal to the peak of the bubble size distribution obtained from the image. On the other hand, FURUHATA (HDK-BM001) performs verification and calibration using fine particles. However, since the calibration was not for a bubble, the calibration program was modified so that the bubble size could be displayed based on the measurement result of the bubble size by the BC100. Although several methods have been proposed for measuring microbubbles, in this test, microbubbles were measured using this calibrated BC100 and FURUHATA. As a result, it is considered that the measurement up to around 10 μm was relatively accurate. Figure 5.7 shows the number of detected microbubbles for each size measured with a VSD case weighing 5.7 kg. In addition, Data 5.1 shows the principle of microbubble measurement by FURUHATA.

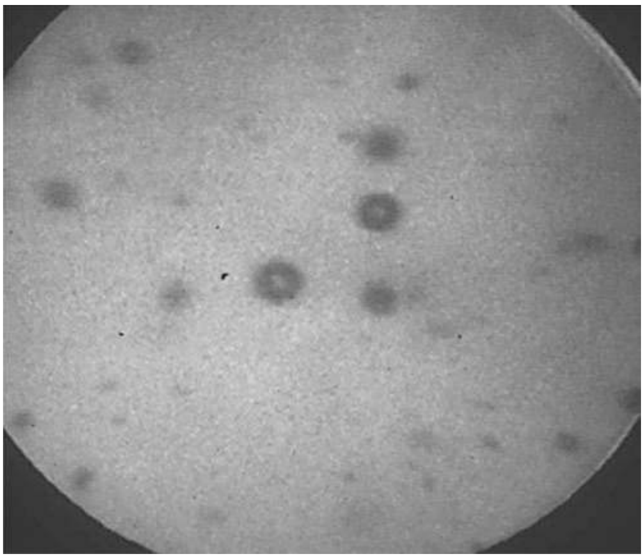


Fig. 5.6 Bubble image by microscope camera

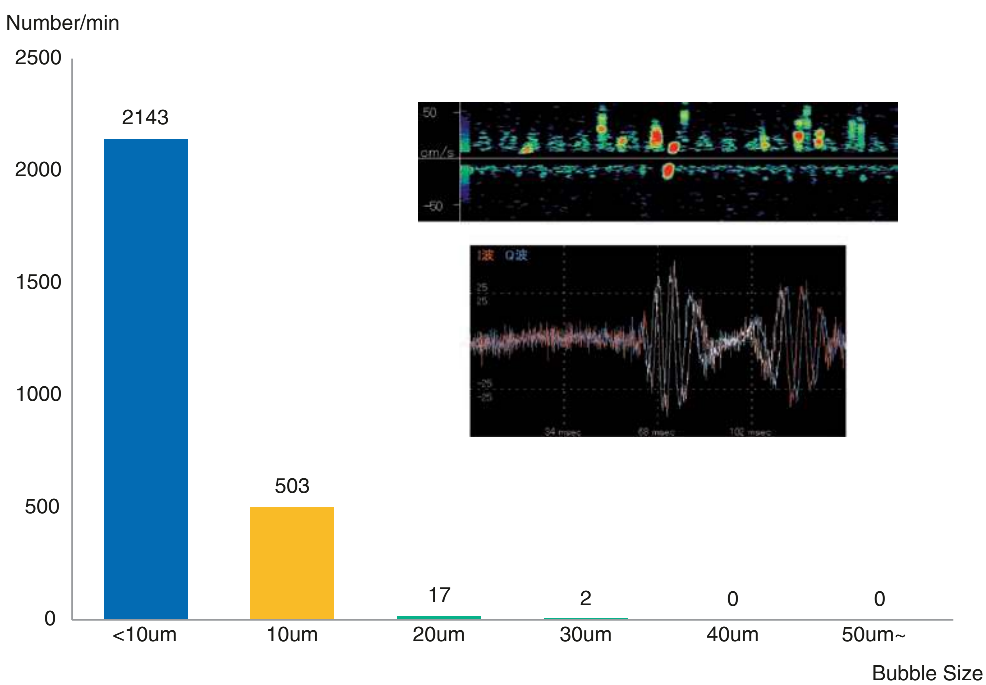


Fig. 5.7 Microbubble size in VSD weighing 5.7 kg

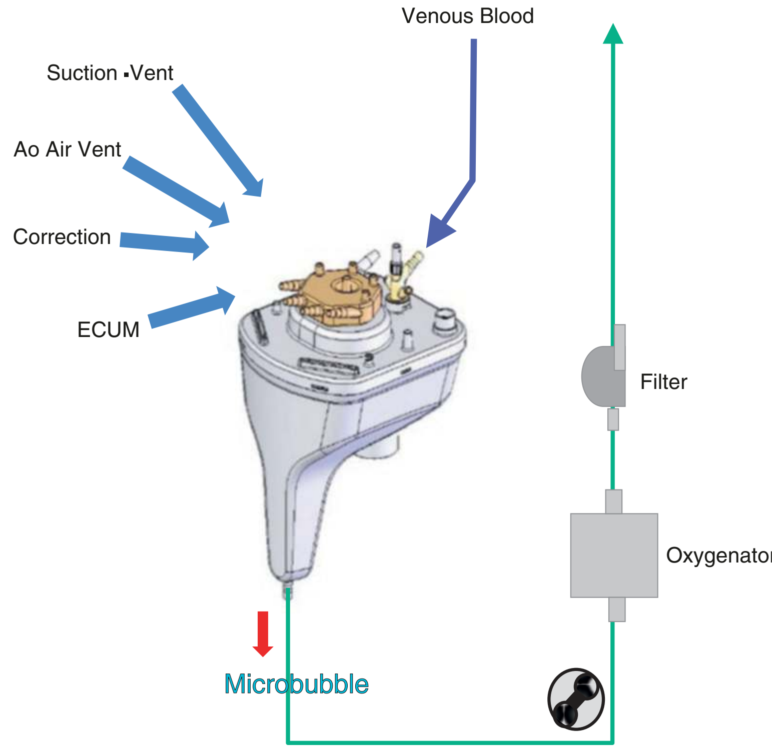


Fig. 5.8 Source of microbubble

5.3 Generation Path of Microbubble

Microbubbles are generated by air flowing into the reservoir, and all routes shown in Fig. 5.8 can be the source. In the Bottom release type reservoir, the inflowing venous blood flows out directly from the lower part of the reservoir (refer to Fig. 4.2). In particular, it is considered that most of the mixed air is directly directed to the oxygenator under total perfusion flow. Therefore, strict attention must be paid to the incorporation of air into venous blood. On the other hand, the blood of the suction and vent flowing into the cardiotomy reservoir, the blood from the ECUM circuit and the aortic air vent, and the drug and correction fluid administered by the perfusionist always come into contact with the air in the reservoir and are mixed. It is considered that most of the microbubbles are generated in this section. Therefore, in order to suppress the microbubbles entering the living body, the number and size of the microbubbles flowing out of the reservoir and the time course, that is, the dynamics of the microbubbles during extracorporeal circulation, should be evaluated for each air inflow route and each reservoir. In addition, it is necessary to examine the ability of the oxygenator and the arterial filter to eliminate and capture microbubbles.

5.4 Measurement of Microbubbles in Experiments

Air was injected from the venous inlet port and cardiotomy port to measure microbubbles.

5.4.1 Neonatal and Pediatric Oxygenator

5.4.1.1 Air Injection from Venous Inlet Port

Evaluation 1 Assuming extracorporeal circulation of 3–4 kg body weight cases, the circulating blood flow rate was set to 0.6 L/min. The air injection volume is 120 mL/min. In Oxygenators B and F having the maximum blood flow of 1.0 L/min or less; (1) The reservoir outlet: microbubbles less than 40 μm flowed out. It decreased with increasing reservoir levels (Fig. 5.9). (2) Arterial filter outlet: BC100 measurement showed almost no outflow of microbubbles, but FURUHATA confirmed its outflow. The number of microbubbles in Oxygenator B did not differ between the reservoir levels, but decreased in Oxygenator F at the 200 mL level (Fig. 5.10).

Evaluation 2 Assuming extracorporeal circulation of 5–7 kg body weight, the circulating blood flow rate was set to 1.0 L/min. Since the measurement limit blood flow of FURUHATA was 800 mL, two units were measured in parallel. The air injection volume is 200 mL/min. In Oxygenators A and B with a maximum blood flow of 2.0 L/min or less; (1) Reservoir outlet: microbubbles less than 60 μm were observed. At the 200 mL reservoir level, the number of

Fig. 5.9 Number of microbubbles detected at reservoir outlet.
QB: High Intensity Transient Signal
VR: Venous Reservoir

	Sample		B	F	B	F
	Qb(VR)		0.6L/min			
	Air injection(VR)		120mL/min			
	Qb(Vent)		-			
	Air injection(Vent)		-			
	VR level		20mL		200mL	
	Pout		200mmHg			
	No.		14	18	13	16
	mesurement time [sec]		60	60	60	60
	1~19	[μm]	1906	2412	1143	713
	20~39	[μm]	159	102	68	5
BC100	40~59	[μm]	0	0	0	0
	60~79	[μm]	0	0	0	0
	80~99	[μm]	0	0	0	0
	>100	[μm]	0	0	0	0
	Total		2065	2514	1211	718

Fig. 5.10 Number of microbubbles detected at arterial filter outlet

	Sample		B	F	B	F
	Qb(VR)		0.6L/min			
	Air injection(VR)		120mL/min			
	Qb(Vent)		-			
	Air injection(Vent)		-			
	VR level		20mL		200mL	
	Pout		200mmHg			
	No.		14	18	13	16
	mesurement time [sec]		60	60	60	60
	1~19	[μm]	1	0	0	0
	20~39	[μm]	0	0	0	0
BC100	40~59	[μm]	0	0	0	0
	60~79	[μm]	0	0	0	0
	80~99	[μm]	0	0	0	0
	>100	[μm]	0	0	0	0
	Total		1	0	0	0
		FURUHATA	98	171	111	34

detections above 20 μm decreased but increased below 19 μm (Fig. 5.11). (2) Arterial filter outlet: Microbubbles less than 20 μm were observed in the measurement of BC100 and decreased as the reservoir level increased. In Oxygenator B, the number of detections decreased with the increase of back pressure. However, in the FURUHATA measurement, the number of detections was greater than BC100, and there was no difference due to the difference in the level of the reservoir level and the back pressure (Fig. 5.12).

Fig. 5.11 Number of microbubbles detected at reservoir outlet. The measurement limit detection number of FURUHATA is 20 per second. Therefore, it is not possible to measure after the reservoir outlet with this device

	Sample		A	B	B	A	B
	Qb(VR)		1.0L/min				
	Air injection(VR)		200mL/min				
	Qb(Vent)		–				
	Air injection(Vent)		–				
	VR level		20mL			200mL	
	Pout		200mmHg		300mmHg	200mmHg	
	No.		1	9–1	9–2	2	8
	mesurement time [sec]		60	60	60	60	60
	1~19	[μm]	4066	2849	3018	4226	4263
	20~39	[μm]	2893	4284	4102	335	2032
BC100	40~59	[μm]	1	36	27	0	4
	60~79	[μm]	0	0	0	0	0
	80~99	[μm]	0	0	0	0	0
	>100	[μm]	0	0	0	0	0
	Total		6960	7169	7147	4561	6299

Fig. 5.12 Number of microbubbles detected at arterial filter outlet

	Sample		A	B	B	B	A
	Qb(VR)		1.0L/min				
	Air injection(VR)		200mL/min				
	Qb(Vent)		–				
	Air injection(Vent)		–				
	VR level		20mL			200mL	
	Pout		200mmHg		300mmHg	200mmHg	
	No.		1	9–1	9–2	2	8
	mesurement time [sec]		60	60	60	60	60
	1~19	[μm]	127	184	47	15	93
	20~39	[μm]	0	0	0	0	0
BC100	40~59	[μm]	0	0	0	0	0
	60~79	[μm]	0	0	0	0	0
	80~99	[μm]	0	0	0	0	0
	>100	[μm]	0	0	0	0	0
	Total		127	184	47	15	93
	FURUHATA		396	442	475	412	420

Venous Inlet Port, Discussion 1
In both evaluations 1 and 2, the air injection volume was 1/5 of the perfusion flow. The reason why the number of microbubbles generated in Evaluation 2 was higher than that in Evaluation 1 was considered to be due to the difference in perfusion flow rate.

In the measurement of the arterial filter outlet in Evaluation 1, no microbubbles were generated in the measurement of BC100, but they were confirmed in FURUHATA.

In addition, the number of detections did not change with the difference in the reservoir level in Oxygenator B, but decreased in Oxygenator F at the level of 200 mL. This is due to the difference in structure between the Bottom release type reservoir (Oxygenator B) and the Middle release type reservoir (Oxygenator F). In the study of 10% NaCL correction from Venous fluid inlet using Bottom release type reservoir, high concentration of Na flowed out (refer to Fig. 4.9). This suggests that microbubbles show similar outflow kinetics in this reservoir.

In Evaluation 2, the number of detections decreased with an increase in the reservoir level in the measurement of the arterial filter outlet with BC100, but there was no difference in the measurement with FURUHATA. It was speculated that this was due to the fact that FURUHATA's higher measurement sensitivity also measured microbubbles of less than 10 μm. Furthermore, in FURUHATA, there was no difference depending on the level of the reservoir level. The reason is considered to be that both Oxygenators A and B were Bottom release type reservoirs.

5.4.1.2 Air Injection from Cardiotomy Port

Evaluation 3 The perfusion flow rate was 0.6 L/min, and the vent flow rate was 0.2 L/min. The air injection rate into the vent circuit was 600 mL/min.

In Oxygenators B and F with a maximum blood flow of 1.0 L/min or less; (1) reservoir outlet: microbubbles less than 30 μm flowed out, and decreased as the reservoir level increased. (2) Arterial filter outlet: No detection was observed in the measurement of BC100, but the outflow of microbubbles of less than 10 μm was confirmed in FURUHATA and decreased with an increase in the reservoir level (Figs. 5.13 and 5.14).

Oxygenator	Venous Circuit		Venting Circuit		Reservoir Level [mL]	Back Pressure [mmHg]
	Flow Rate [L/min]	Air Infused [mL/min]	Flow Rate [mL/min]	Air Infused [mL/min]		
B	0.6	0	200	600	20,200	200

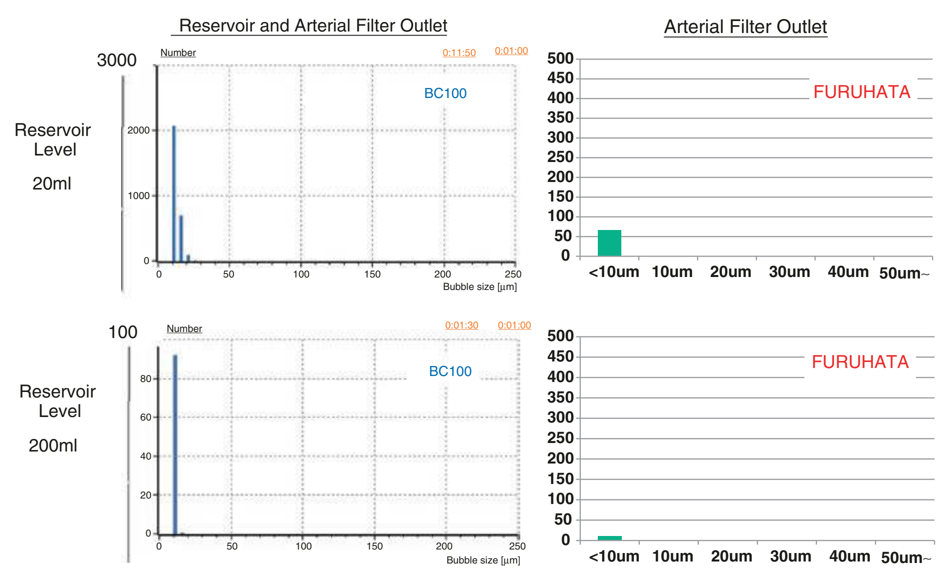


Fig. 5.13 Oxygenator B. In the measurement of BC100, microbubbles were not detected at the arterial filter outlet displayed in red, but were detected in FURUHATA

Fig. 5.14 Oxygenator F

Oxygenator	Venous Circuit		Venting Circuit		Reservoir Level	Back Pressure
	Flow Rate [L/min]	Air Infused [mL/min]	Flow Rate [mL/min]	Air Infused [mL/min]	[mL]	[mmHg]
F	0.6	0	200	600	20, 200	200

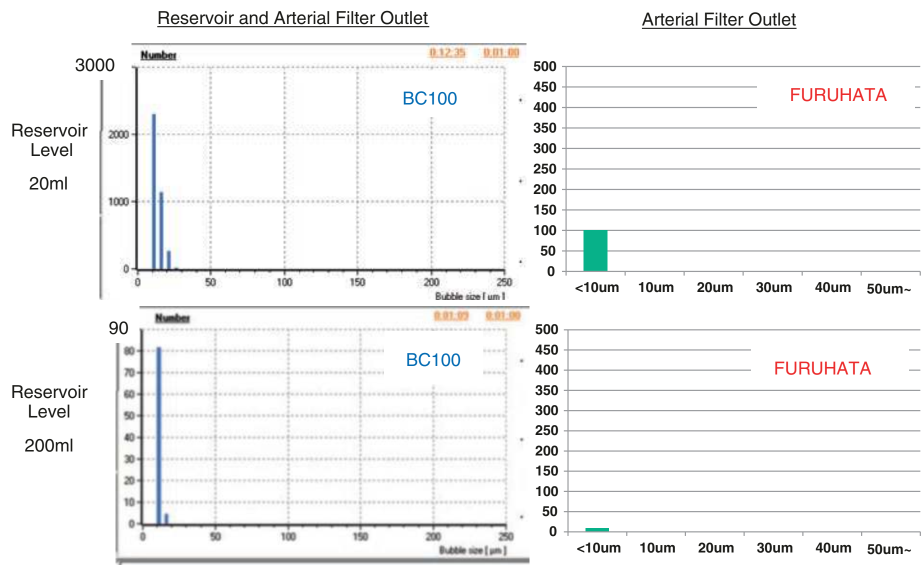
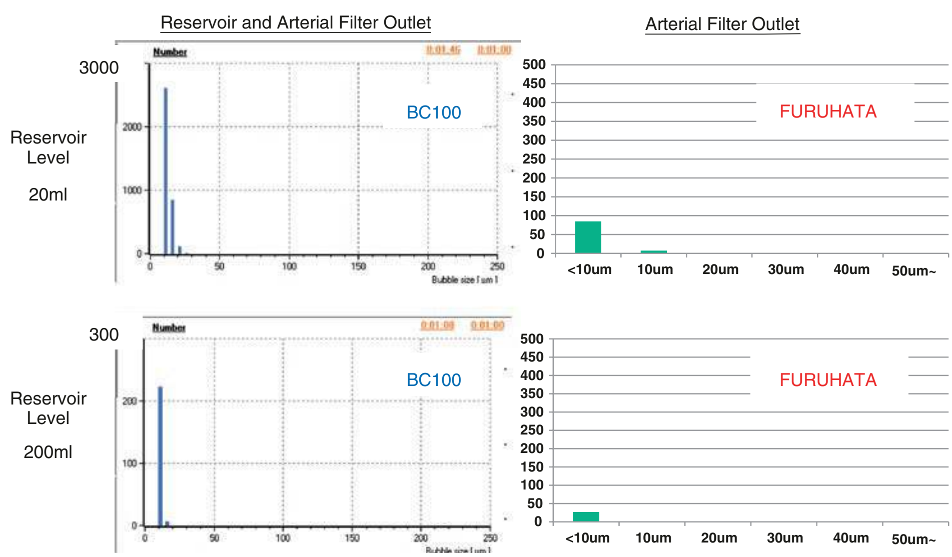


Fig. 5.15 Oxygenator A

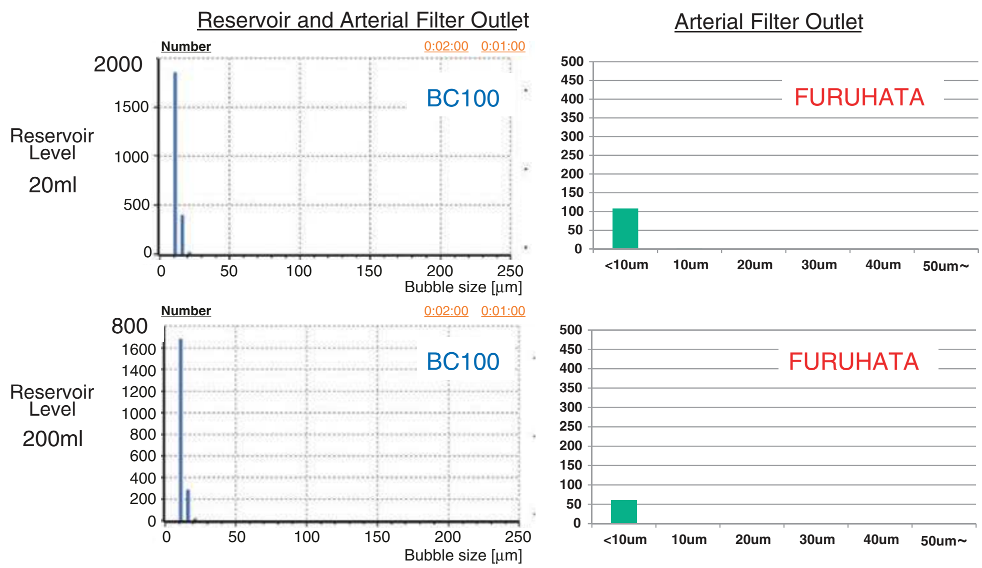
Oxygenator	Venous Circuit		Venting Circuit		Reservoir Level	Back Pressure
	Flow Rate [L/min]	Air Infused [mL/min]	Flow Rate [mL/min]	Air Infused [mL/min]	[mL]	[mmHg]
A	1	0	200	600	20,200	200



Evaluation 4 The perfusion flow rate was 1.0 L/min, and the vent flow rate was 0.2 L/min. The air injection volume was 600 mL/min. In Oxygenators A and B with a maximum blood flow of 1.0 L/min or less; (1) reservoir outlet: microbubbles less than 30 μm flowed out, and decreased with an increase in the reservoir level. (2) arterial filter outlet: No outflow of microbubbles was observed in the measurement of BC100, but the outflow of less than 10 μm microbubbles was confirmed in FURUHATA and decreased with an increase in the reservoir level (Figs. 5.15 and 5.16).

Fig. 5.16 Oxygenator B

検体	Venous Circuit		Venting Circuit		Reservoir Level	Back Pressure
	Flow Rate [L/min]	Air Infused [mL/min]	Flow Rate [mL/min]	Air Infused [mL/min]	[mL]	[mmHg]
B	1	0	200	600	20,200	200



Cardiotomy Port Discussion 2

The setting of 0.2 L/min of vent flow and 600 mL/min of air injection allows visual image of blood and air flow in the suction and vent circuit in actual clinical practice of cyanotic heart disease cases with many collateral circulations (Video 5.1). The number of microbubbles generated by air injection from the cardiotomy port was reduced compared to the air injection from the venous inlet port. In the measurement of BC100, no outflow of microbubbles at the arterial filter outlet was recognized, but in FURUHATA, microbubbles smaller than 10 μm were confirmed. In addition, the difference in the number of microbubbles due to the difference in the reservoir level was observed in both Oxygenators A and B. Both were Bottom release type reservoirs. In the examination of 10% NaCL correction from the service port, a difference in Na concentration was recognized depending on the level of the reservoir level (refer to Fig. 4.10). Microbubbles dynamics are considered to be the same.

5.4.2 Adult Oxygenator

5.4.2.1 Air Injection from Venous Inlet Port

Evaluation 1 An experiment of injecting air from the venous inlet port was performed in a simulated extracorporeal circulation circuit primed with bovine blood using an adult oxygenator. BC100 was used for the measurement of microbubbles. Although the set volume of air injection was an amount that cannot be improbable in actual clinical practice, it was confirmed that the microbubbles flowing out of the reservoir became smaller in diameter and decreased in number as they passed through the oxygenator and the arterial filter. In addition, the number and size of microbubbles after the arterial filter increased with an increase in the amount of air injected (Figs. 5.17, 5.18 and 5.19).

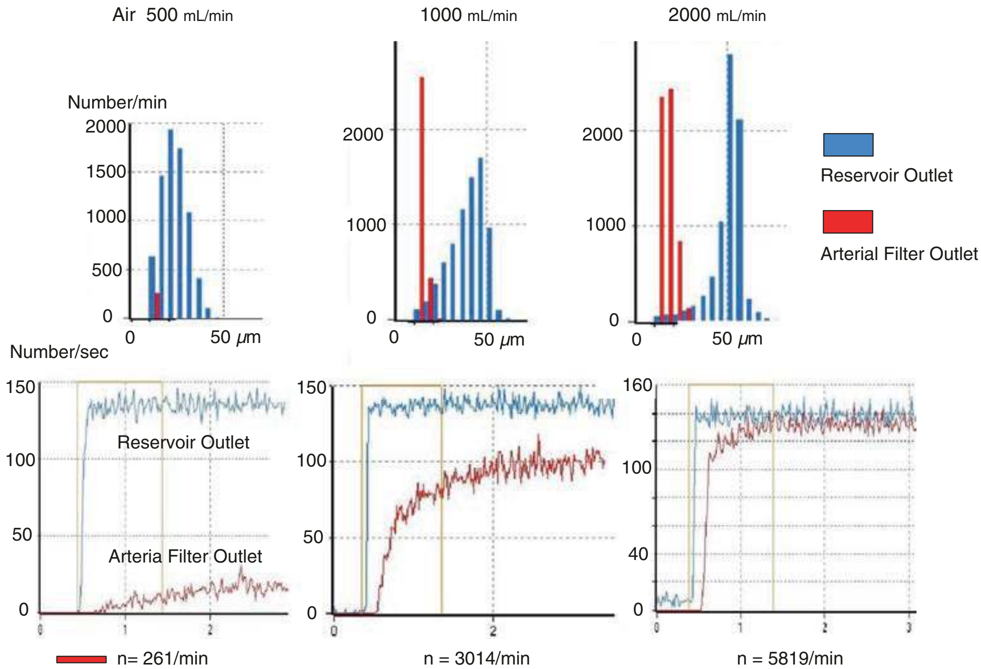


Fig. 5.17 Oxygenator A. Experimental conditions: bovine blood 37 °C, perfusion rate 3.0 L/min, reservoir level 500 mL, back pressure 150 mmHg, air injection volume 0.5, 1.0, 2.0 L/min

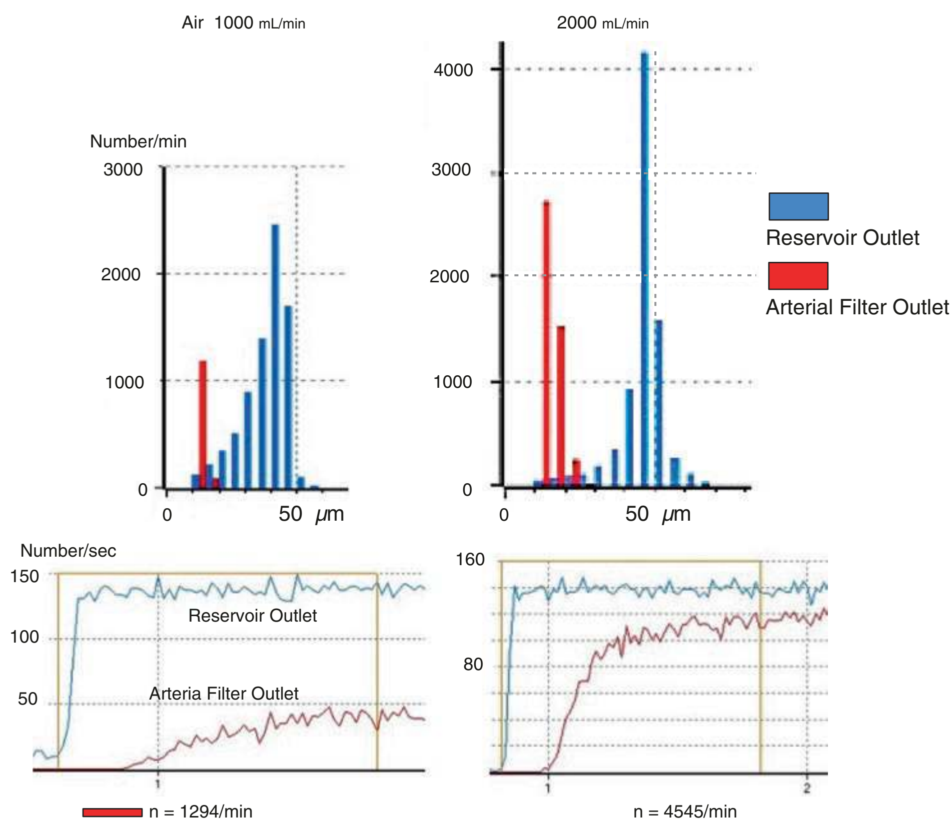


Fig. 5.18 Oxygenator B. Experimental conditions: bovine blood 37 °C, perfusion rate 3.0 L/min, level 500 mL, back pressure 150 mmHg, air injection volume 1.0, 2.0 L/min

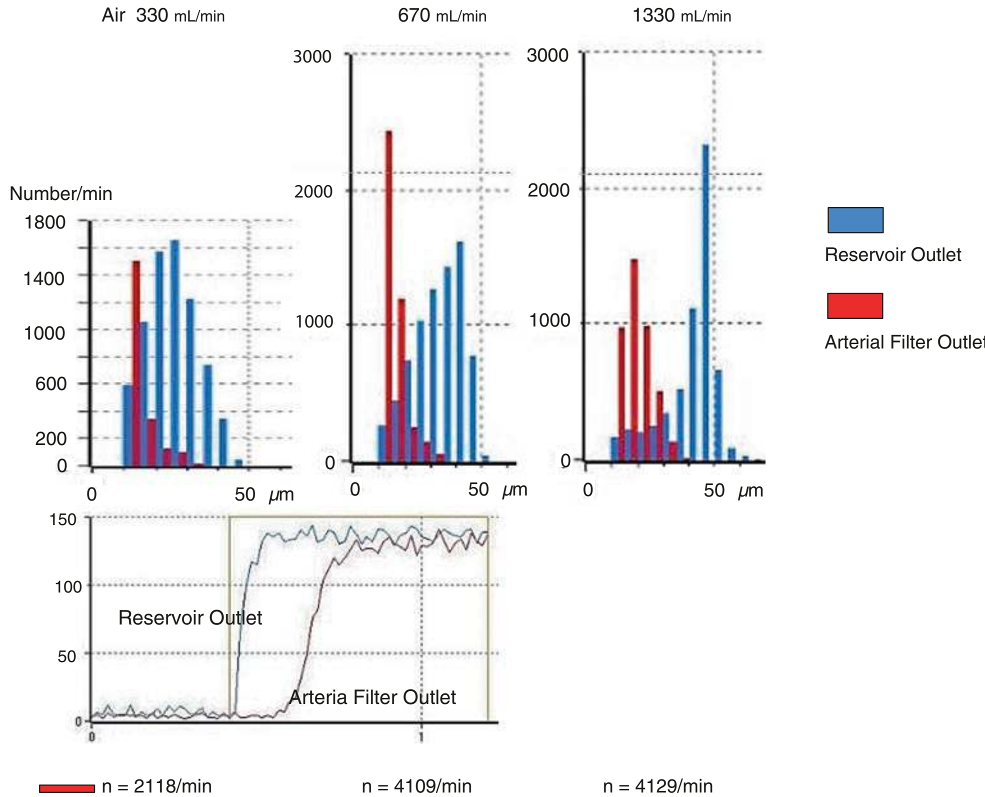
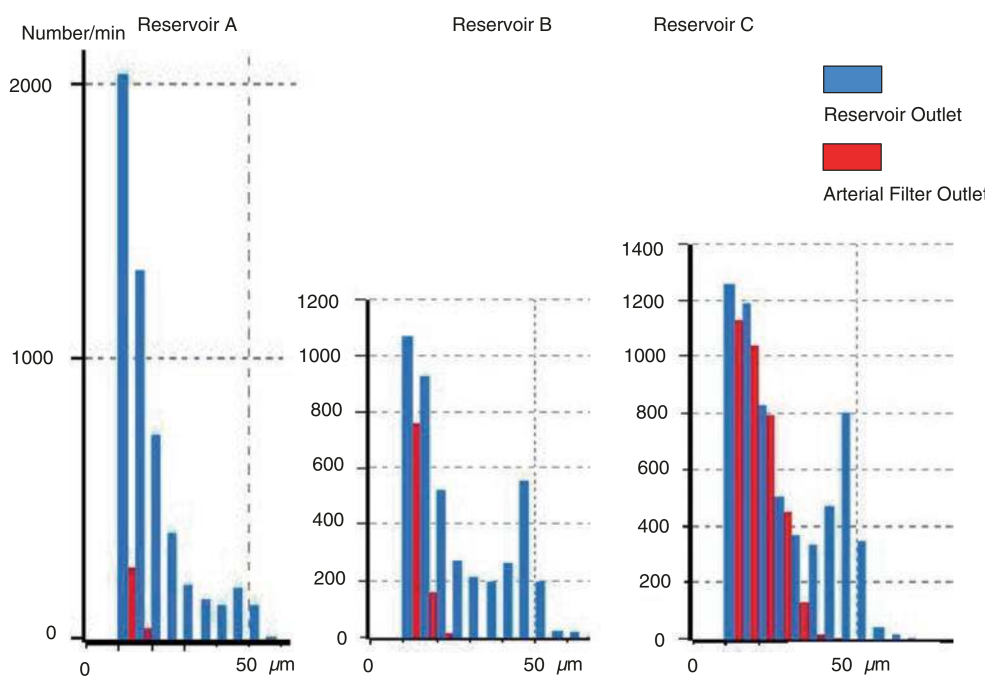


Fig. 5.19 Oxygenator C. Experimental conditions: bovine blood 37 °C, perfusion flow 2.0 L/min, level 300 mL, back pressure 150 mmHg, air injection volume 0.33, 0.67, 1.33 L/min



Reservoir	A	B	C
Reservoir Outlet	4795	4865	6193
Arterial Filter Outlet	239	1075	3571
Clearance Ration (%)	95.0	77.9	42.3

Fig. 5.20 A bolus injection of 50 mL of air from venous inlet port

Evaluation 2 Under the same conditions, a bolus of 50 mL of air was administered from the venous inlet port (Fig. 5.20). This assumes accidental removal of the venous cannula. The number and size of the microbubbles after the arterial filter showed a difference between the reservoirs. The removal rates of microbubbles flowing out from the reservoir by the oxygenator and arterial filter were 95% (239/4795) for A, 78% (1075/4865) for B, and 42% (3571/6193) for C.

Evaluation 3 Assuming retrograde autologous blood priming, extracorporeal circulation was started with the venous circuit empty. The reservoir level was 200 mL. (1) The venous circuit was slowly filled with venous blood, and immediately thereafter, extracorporeal circulation was initiated at a perfusion rate of 2 L/min. No microbubbles were detected after the arterial filter (Fig. 5.21, left). (2) Extracorporeal circulation was rapidly initiated with the empty venous circuit. Similarly, no microbubbles were detected (Fig. 5.21, right).

Evaluation 4 The effect on the generation of microbubbles was examined using carbon dioxide gas. This was an experiment assuming that carbon dioxide gas was insufflated into the pericardium. First, 1 L/min air was injected into the venous inlet port, and the occurrence of microbubbles after the arterial filter was confirmed (upper figure in Fig. 5.22). Under these conditions, air and carbon dioxide were injected into the vent blood. Microbubble generation increased with air (lower left figure in Fig. 5.22), but microbubble generation diminished with carbon dioxide (lower right figure in Fig. 5.22). However, the partial pressure of carbon dioxide in arterial blood, PaCO2, at this point exceeded the upper measurement limit.

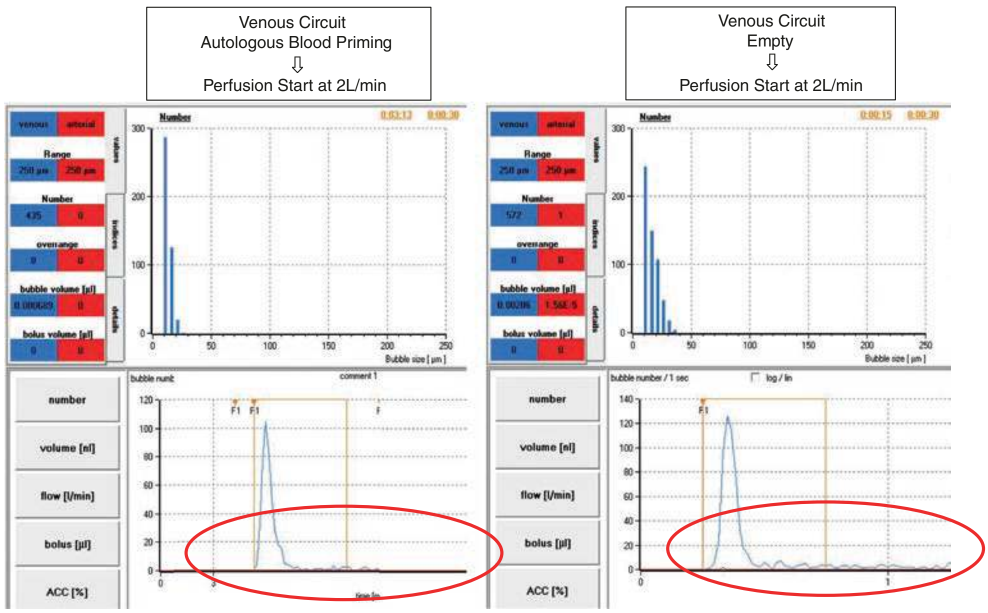


Fig. 5.21 Influence of air influx into venous circuit at the initiation of extracorporeal circulation on microbubble generation. Microbubbles after the arterial filter are displayed in red

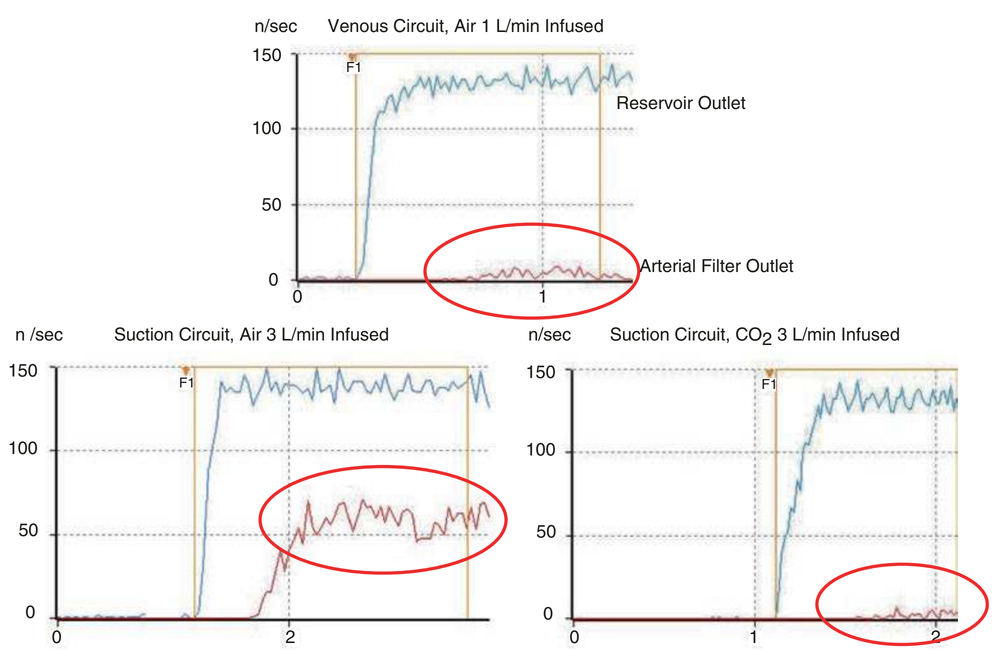


Fig. 5.22 Microbubble suppression by carbon dioxide gas. Data is showing the high solubility of carbon dioxide in blood. Conversely, this indicates that the events measured as microbubbles in BC100 are clearly microbubbles

Venous Inlet Port, Discussion 1

Figure 5.23 shows the number of generated microbubbles at the arterial filter outlet under each condition. The number of microbubbles in the adult oxygenator increased compared to the pediatric oxygenator. This was thought to be due to the difference in circulating blood flow rate (flow velocity) [4].

5.4.2.2 Air Injection from Cardiotomy Port

Air was injected into the venting blood. As the air volume was increased, the number and size of microbubbles at the arterial filter outlet increased (Figs. 5.24 and 5.25).

Cardiotomy Port, Discussion 2

In the air injection from the cardiotomy port, microbubbles of the same number and size as the venous inlet port were detected.

5.4.3 Summary of the Experiment

Adult Oxygenator—Although the air injection volume from the venous inlet port in the experiment cannot be possible in actual clinical practice, larger microbubbles than the expected diameter of 20–39 μm were observed. This indicates that special attention should be paid to air entrapment into the venous circuit under total flow in adult extracorporeal circulation. On the other hand, the air injection volume from the cardiotomy port was determined assuming actual clinical practice. Although it was assumed that the number was significantly reduced as compared with the venous inlet port, equivalent amount of microbubbles were detected. Countermeasures against microbubbles generated from the cardiotomy port were considered more important.

Pediatric Oxygenator—Air into the venous circuit requires the same care as in adults. However, in the experiment of injecting air into the cardiotomy port, the number of microbubbles at the arterial filter outlet was small, and most of them were less than 10 μm in diameter. This suggested that there were few clinical problems in extracorporeal circulation in children.

Column: High-Pressure Excursion Through the Oxygenator During Experiment (2016)

Clogging of the oxygenator occurred during the experiment. Observation with an electron microscope showed that a large amount of thrombus had formed up to the outside of the hollow fiber (Fig. 5.26), suggesting that the contact of air and circulating blood alone could cause a significant change in the coagulation system.

	Sample														
Condition	Qb(VR)	3.0L/min			2.0L/min	3.0L/min				2.0L/min		3.0L/min	3.0L/min		
	Air injection(VR)	0.5L/min	1.0L/min	2.0L/min	1.0L/min	Bolus 50mL				1.0L/min	2.0L/min	2.0L/min	2.0L/min		Bolus 50mL
	Qb(Vent)	-	-	-	1.0L/min	-				1.0L/min	1.0L/min	-	-		-
	Air injection(Vent)	-	-	-	1.0L/min	-				3.0L/min	3.0L/min	-	-		-
	VR level	500mL	500mL	500mL	500mL	500mL				500mL	500mL	500mL	500mL		500mL
	Pout	150mmHg	150mmHg	150mmHg	150mmHg	150mmHg		200mmHg	250mmHg	150mmHg	150mmHg	150mmHg	150mmHg		150mmHg
	Purge line	OFF	OFF	OFF	OFF	OFF	ON	OFF	OFF	OFF	OFF	OFF	OFF	ON(FT)	ON(FT)
Number and size	1~19 [μm]	264	2991	4801	1574	288	187	47	101	3737	4680	3213	913	811	18
	20~39 [μm]	0	23	1018	0	1	2	0	0	40	193	42	2	2	0
	40~59 [μm]	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	60~79 [μm]	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	80~99 [μm]	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	>100 [μm]	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	Total	264	3014	5819	1574	289	189	47	101	3777	4873	3255	915	813	18

Condition	2.0L/min					1.5L/min	1.0L/min			2.0L/min		2.0L/min					
	0.33L/min	0.5L/min	0.67L/min	1.33L/min	Bolus 50mL	-	-			Bolus 50mL		0.5L/min	1.0L/min	2.0L/min	Bolus 50mL		
	-	-	-	-	-	0.5L/min	1.0L/min			-		-	-	-	-		
	-	-	-	-	-	1.5L/min	1.5L/min		3.0L/min	-		-	-	-	-		
	300mL	300mL	300mL	300mL	300mL	300mL	300mL	50mL	300mL	300mL		500mL	500mL	500mL	500mL		
	150mmHg	150mmHg	150mmHg	150mmHg	150mmHg	150mmHg	150mmHg	150mmHg	150mmHg	150mmHg		150mmHg	150mmHg	150mmHg	150mmHg	200mmHg	250mmHg
	OFF	OFF	OFF	OFF	OFF	OFF	OFF	OFF	OFF	OFF	ON(FT)	ON	ON	ON	ON	ON	ON
Number and size	1857	4816	3641	2465	2171	929	3928	1501	3332	2342	2314	85	1292	4277	922	386	249
	261	441	468	1663	1394	309	565	10	3054	1076	376	0	2	268	12	0	0
	0	1	0	1	6	0	0	0	7	0	0	0	0	0	0	0	0
	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2118	5258	4109	4129	3571	1238	4493	1511	6393	3418	2690	85	1294	4545	934	386	249

Fig. 5.23 Adult oxygenator, experiment conditions and microbubbles generation

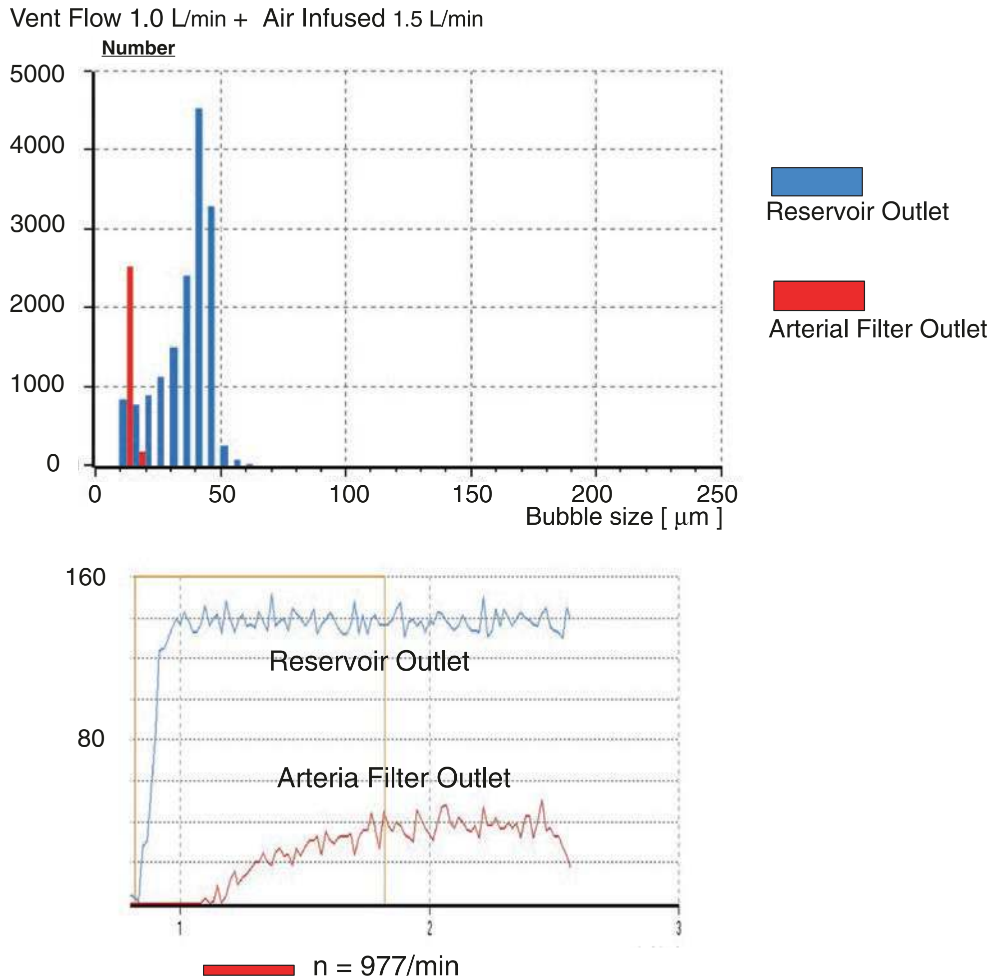


Fig. 5.24 Oxygenator B. Experimental conditions: bovine blood 37 °C, perfusion flow 2.0 L/min, reservoir level 300 mL, back pressure 150 mmHg, vent blood flow 1.0 L/min, air injection volume 1.5 L/min

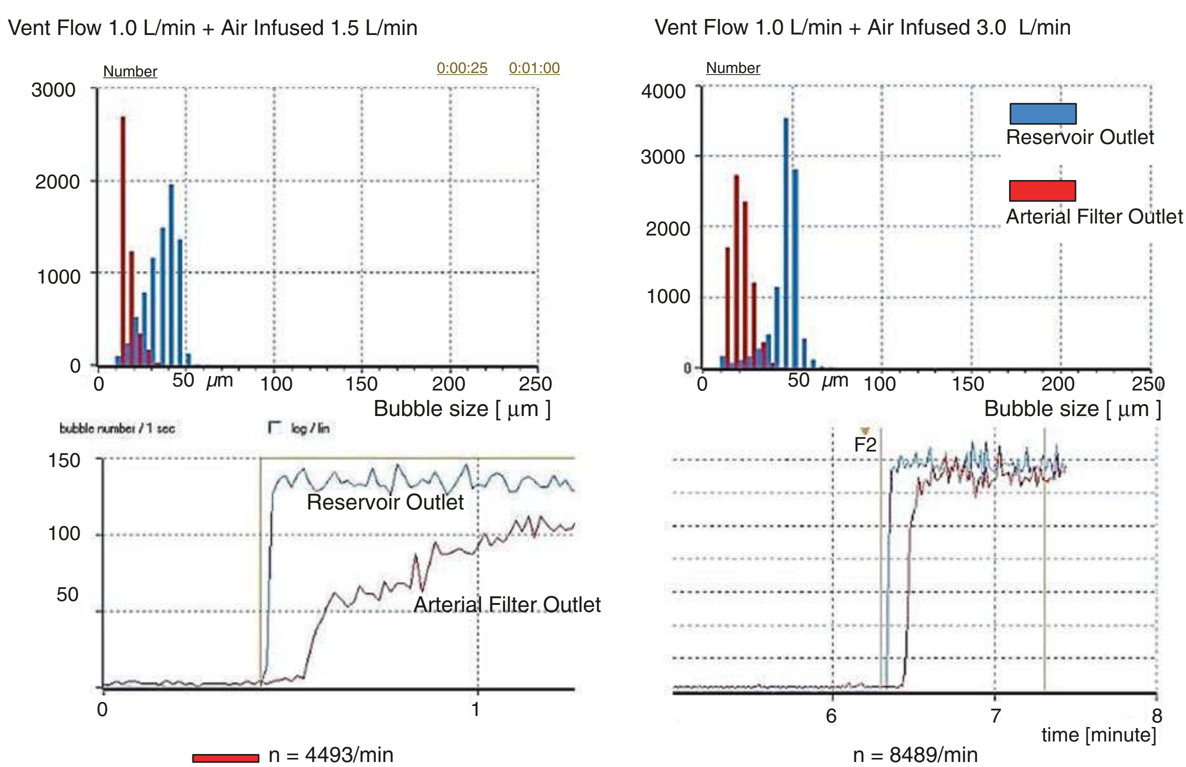


Fig. 5.25 Oxygenator C. Experimental conditions: bovine blood 37 °C, perfusion flow 2.0 L/min, reservoir level 300 mL, back pressure 150 mmHg, vent blood flow 1.0 L/min, air injection volume 1.5, 3.0 L/min

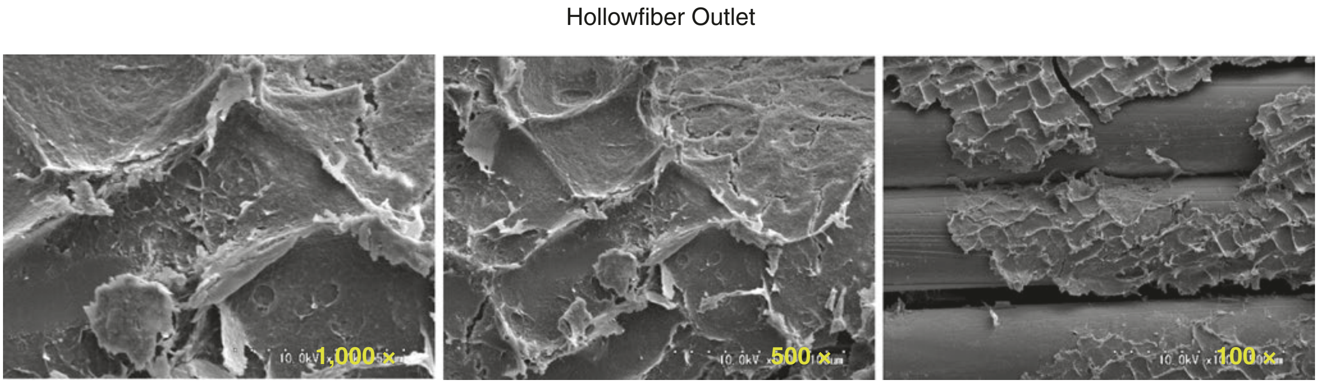


Fig. 5.26 Thrombus in oxygenator. Although the ACT value was maintained well, a sudden increase in the circuit pressure was observed and the experiment was interrupted

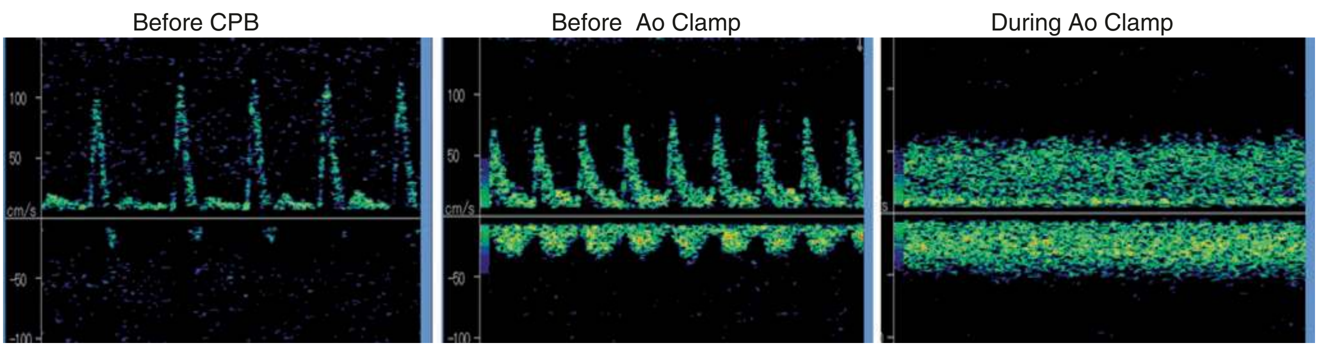


Fig. 5.27 Carotid artery waveform measured with FURUHATA (HDK-BM001)

5.5 Measurement of Microbubbles in Clinical Practice

Microbubble measurement by FURUHATA is easy and non-invasive. However, experience has shown that microbubbles are judged as not generated due to probe displacement, and noise and artifact waveforms are sometimes recognized as Bubble, so care must be taken when evaluating measurement results. In the first 170 consecutive cases since the start of the measurement, data from 45 cases were determined to be unreliable from post-measurement verification. It is important to always check the quality of the blood flow waveform during measurement on the monitor screen. In particular, when a significant difference in the number or size of microbubbles is determined, it is necessary to review the measurement results (redetermine bubble, artifact, and noise). Based on the above, the results of microbubble measurement in actual clinical practice will be described.

Q&A: Notes on microbubble measurement

Question: Please advice the points to note when measuring and evaluating microbubbles

Answer: Figure 5.27 shows the carotid waveform measured by FURUHATA. With this device, the measurement limit number is 20 per second, and the measurement speed range is 0–150 cm/s (blood flow rate 800 mL/min), the blood vessel diameter is 3.4–7.1 mm, the measurement depth is 10–120 mm, the ultrasonic frequency is 2.0 MHz, the minimum measurable microbubble diameter is 10 μm (less than 10 μm may be measurable). It can detect bubbles and HITS and can also detect artifacts generated by displacement of the probe, and noise from other devices such as electric scalpels (Fig. 5.28). Since it is considered that the occurrence of HITS is small in the measurement in children, the total number of bubbles includes the number of HITS. However, since the detection limit is 20 numbers per second, if a higher number is generated, it can be visually recognized on the real monitor screen, but it may not be recorded or counted as Noise, so care must be taken in the judgment of a significant difference in absolute number (Fig. 5.29). Figure 5.30 shows a microbubble detection image in the jugular vein. The brain has an arteriovenous bypass route called "Through fare channel." Probably, microbubbles smaller than the capillary diameter pass through the brain.

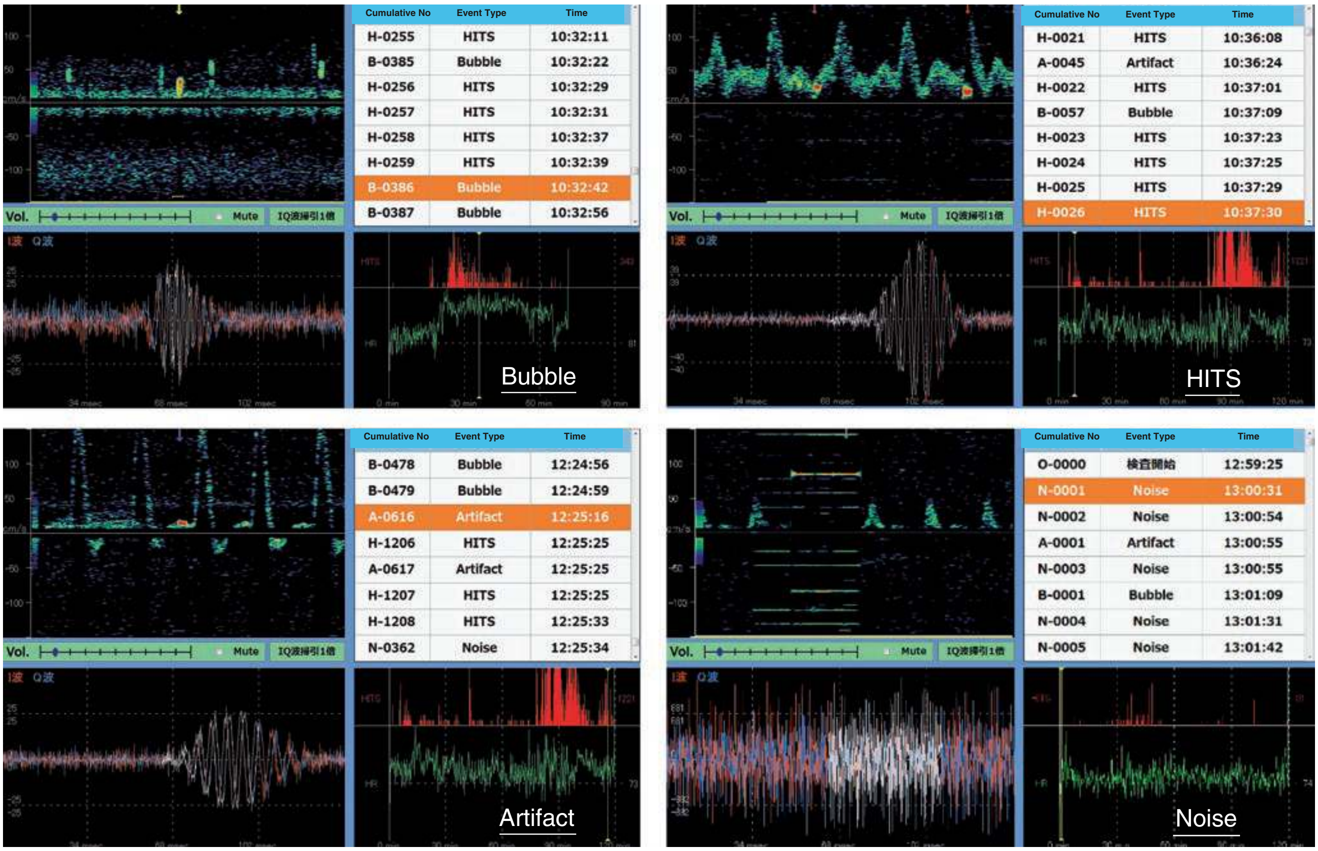


Fig. 5.28 Characteristic waveform of bubble, HITS, artifact, noise

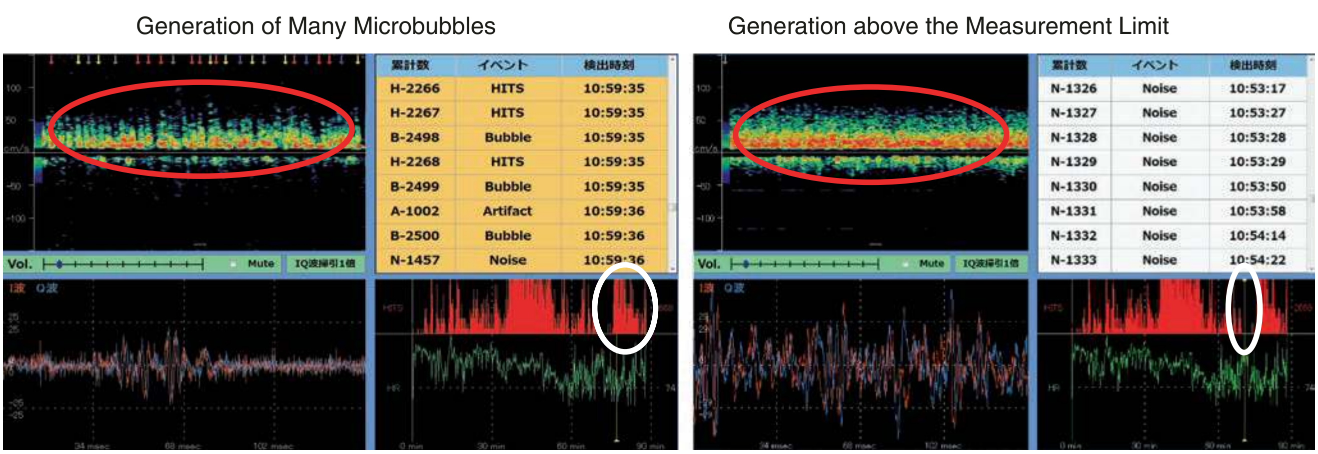


Fig. 5.29 Microbubble generation exceeding the measurement limit. Left figure: Many microbubbles were generated, but the number of microbubbles was less than the measurement limit of 20 cells per second, so it was possible to determine the events. It was also displayed as a time change graph in the lower right figure (highlighted in white circle). Right figure: Extremely large number of microbubbles can be confirmed, but the number of microbubbles exceeded the measurement limit of 20 cells per second, and all were judged to be noise. In the lower right figure showing the change with time, the result was displayed that no microbubbles were detected at this time (highlighted in white circle)

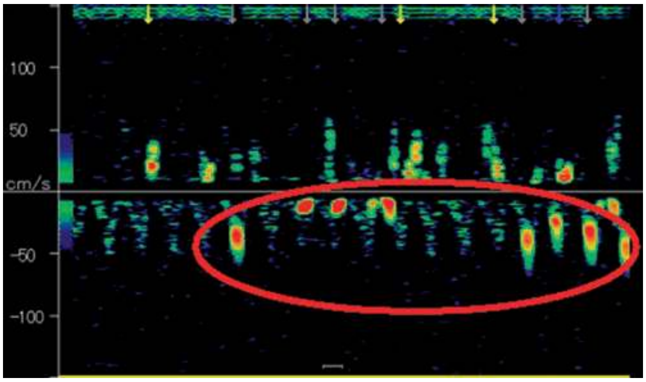


Fig. 5.30 Detection of microbubbles in the internal jugular vein

5.5.1 Suction and Venting

Figures 5.31 and 5.32 show measurement data of microbubbles in VSD and ASD cases. There was almost no detection of microbubbles. On the other hand, in TOF and DORV PS cases, a large amount of microbubbles was detected, particularly during aortic cross-clamp (Figs. 5.33 and 5.34). To examine this difference, we compared 22 cases where the total number of detected microbubbles was 1000 or more with 23 cases where the total number was less than 1000. There was no difference in extracorporeal circulation time between the two groups, but a difference was observed in the pump rotation speed per minute of suction and venting (Fig. 5.35). It was speculated that

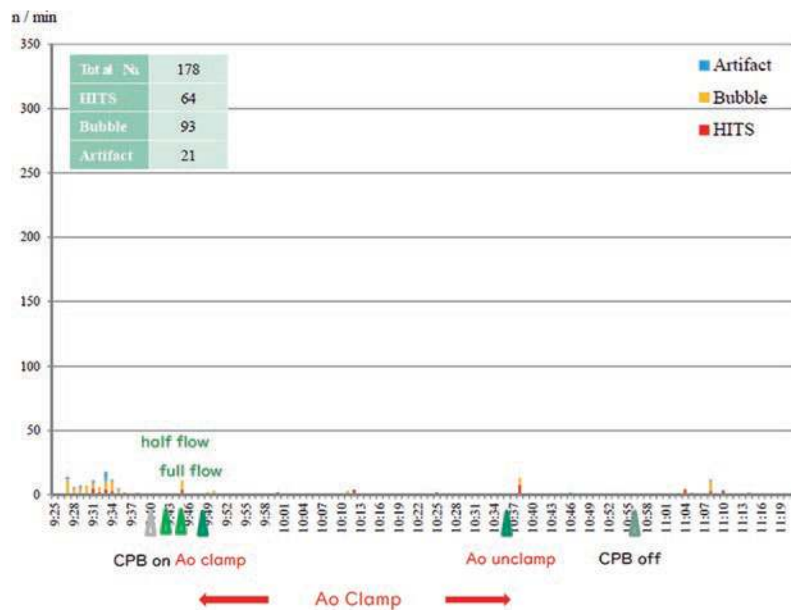


Fig. 5.31 BW3.7 kg VSD. VSD closure was performed under cardiac arrest

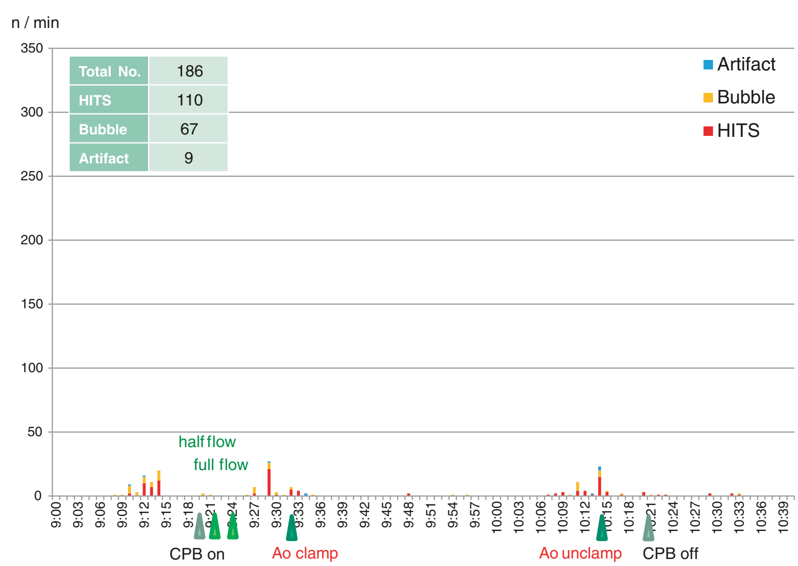


Fig. 5.32 BW10.7 kg ASD. ASD closure was performed under cardiac arrest

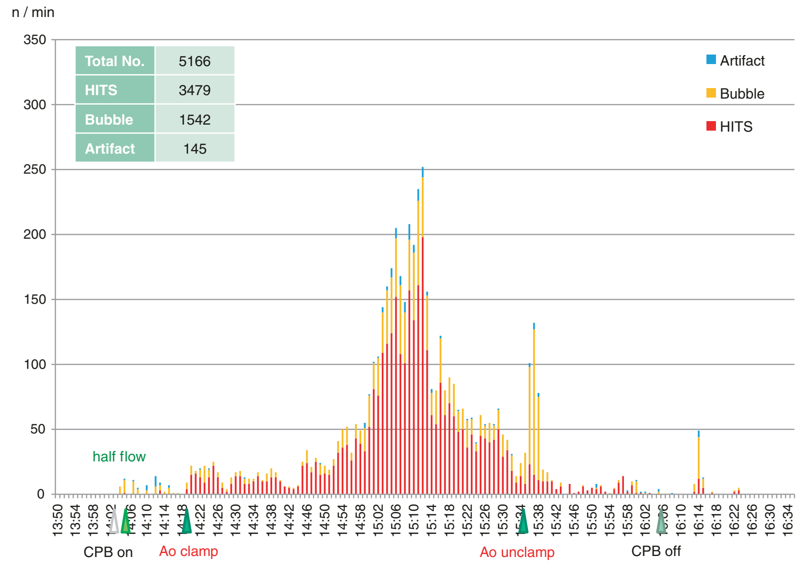


Fig. 5.33 BW12.1 kg TOF MAPCA. Replacement of the conduit between the right ventricle and the pulmonary artery was performed under cardiac arrest

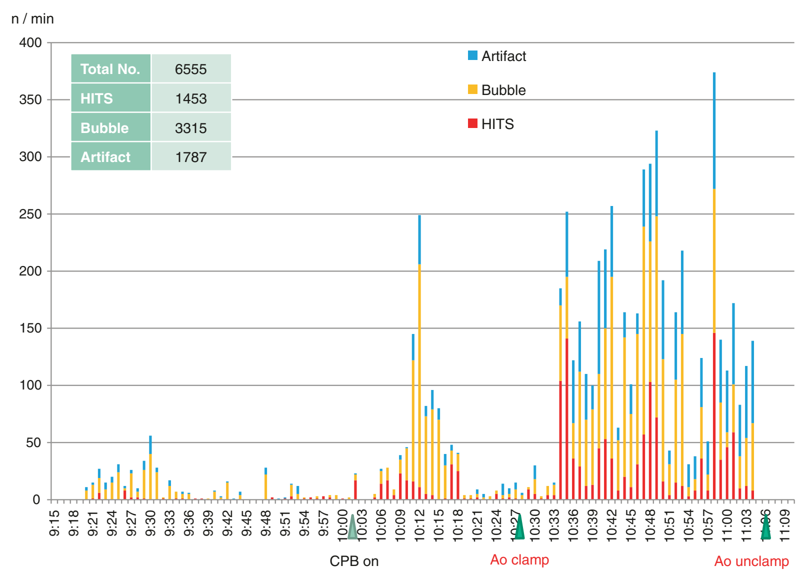


Fig. 5.34 BW8.6 kg DORV PS. Tricuspid valve repair and TCPC were performed under cardiac arrest

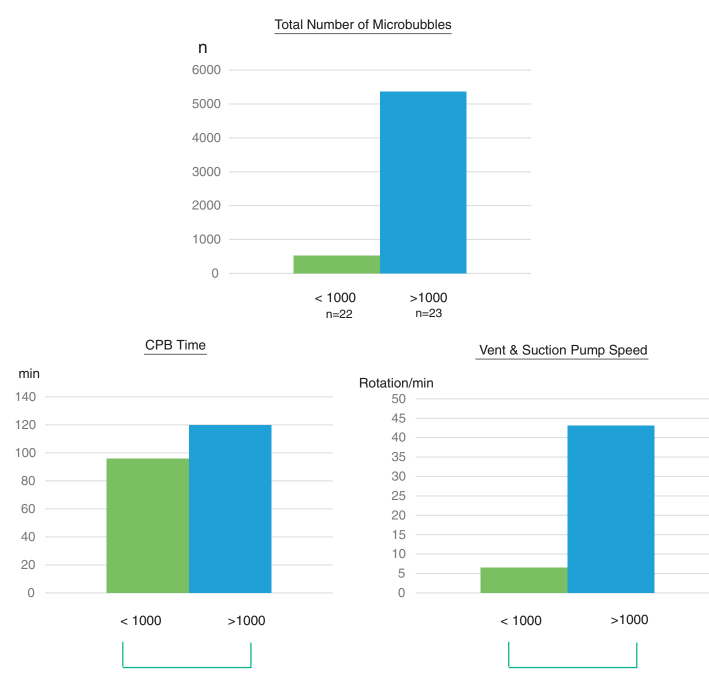


Fig. 5.35 Comparison between Groups with 1000 or more Microbubbles and with less than 1000. The number of detected microbubbles depends on the rotation speed of the suction per vent pump

the increase in the number of generated microbubbles was due to the increase in blood volume at the suction and vent.

Figure 5.36 shows a TAIc case in which Glenn operation was performed. With venous drainage from the SVC and the right atrium, Glenn anastomosis was performed under heartbeat by clamping the pulmonary artery. Therefore, the amount of aspirated blood was small, and the number of generated microbubbles was hardly recognized. On the other hand, in the HLHS case in Fig. 5.37, SVC venous drainage was performed by suction during Glenn anastomosis. An increase in the number of microbubbles was observed. Figure 5.38 shows an HLHS case in which TCPC was performed under a heartbeat. When the conduit was anastomosed with the pulmonary artery, the number of microbubble detections increased with an increase in the amount

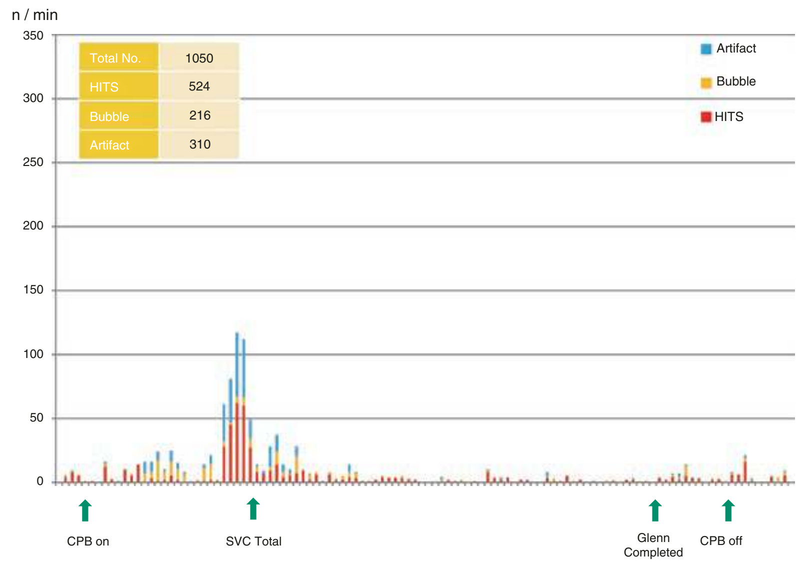


Fig. 5.36 BW16.9 kg TAIc. Glenn operation was performed under heartbeat

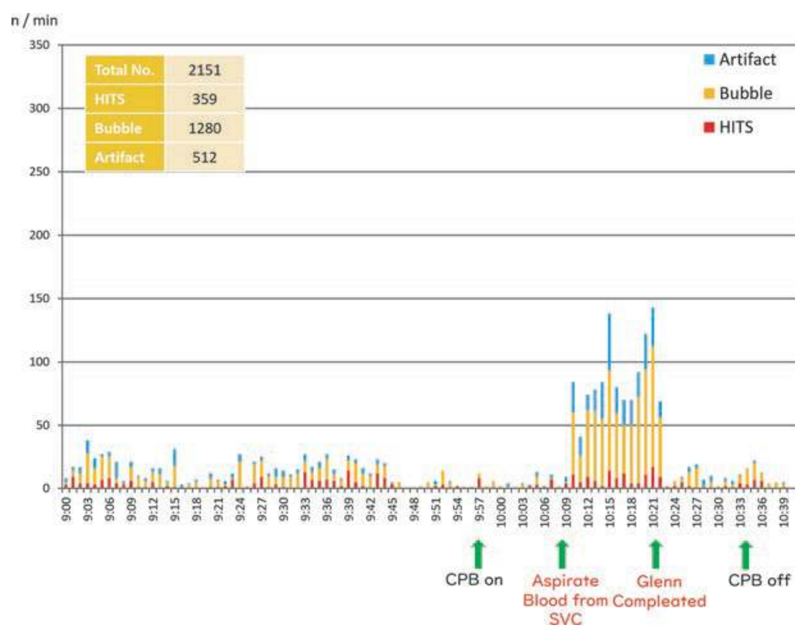


Fig. 5.37 BW4.8 kg HLHS. Glenn's operation was performed with suction because of difficulty in inserting the venous cannula into the SVC

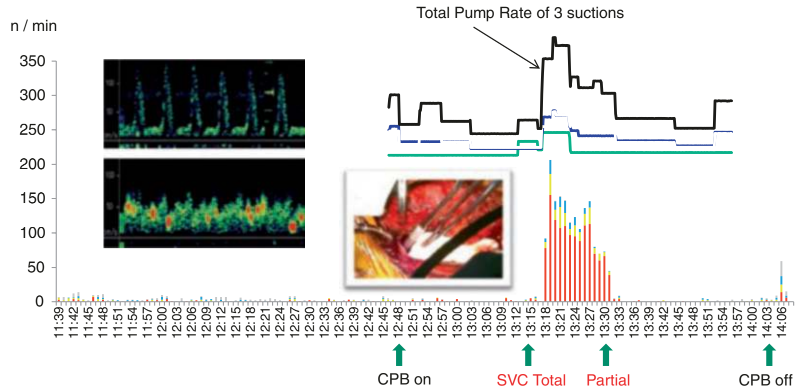


Fig. 5.38 BW10.1 kg HLHS. TCPC was performed under heartbeat. Microbubbles were detected only during pulmonary artery anastomosis of the conduit. The number of microbubbles correlated with the speed of suction pump

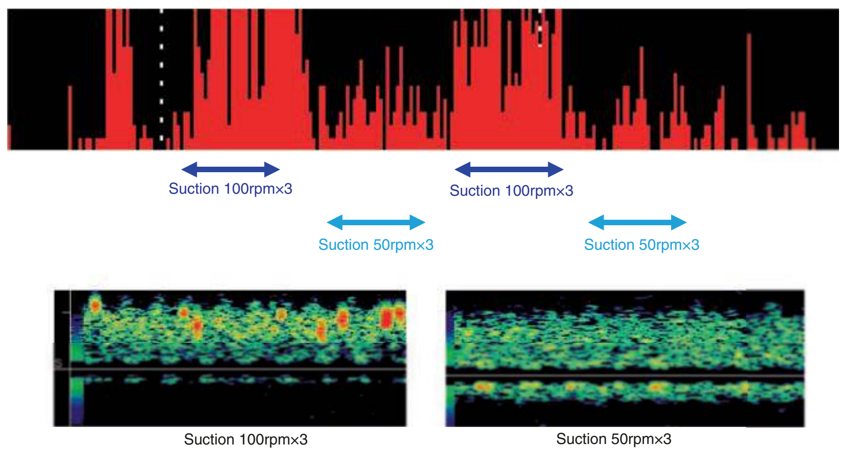


Fig. 5.39 BW15.3 kg TOF PA. Rastelli operation and pulmonary artery repair under cardiac arrest

of aspirated blood from the pulmonary artery because the anastomosis was performed without clamping the pulmonary artery.

From the above, it was found that the number of microbubbles increased in cases where the blood volume of suction and vent was larger. In many cases of cyanotic heart disease, the rotation speed of the suction pump is increased, and thus the rotation speed needs to be adjusted according to the course of the operation. Figure 5.39 shows a TOF case in which Rastelli surgery and pulmonary artery repair were performed. The number of microbubbles decreased by reducing the pump speed. Figure 5.40 shows a TOF case in which pulmonary artery unifocalization and right ventricular-pulmonary artery shunt operation were performed. Microbubbles increased in proportion to the suction pump speed. Figure 5.41 shows an adult DCRV case undergoing intracardiac repair. The number of microbubbles decreased by reducing the pump rotation speed of the vent. Videos 5.2 and 5.3 show the flow of blood and air in the suction and vent circuits with vent rotations of 80 and 140 rpm. When a large amount of air in the vent circuit is visible such as at 140 rpm, many microbubbles are entering the living body.

Suction and Venting, Conclusion 1

Unlike experimental results (refer to Sect. 4.1—Neonatal and Pediatric Oxygenators), depending on the conditions of extracorporeal circulation, a large amount of microbubbles was also observed during pediatric open-heart surgery. There are various factors that cause microbubbles, but it is possible to suppress the generation of microbubbles by finely adjusting the rotation speed of the suction and vent pumps while monitoring with FURUHATA. This also indicates that the events measured by FURUHATA are microbubbles. FURUHATA, which can observe the occurrence of microbubbles in real time, is useful as a new extracorporeal circulation management device [5].

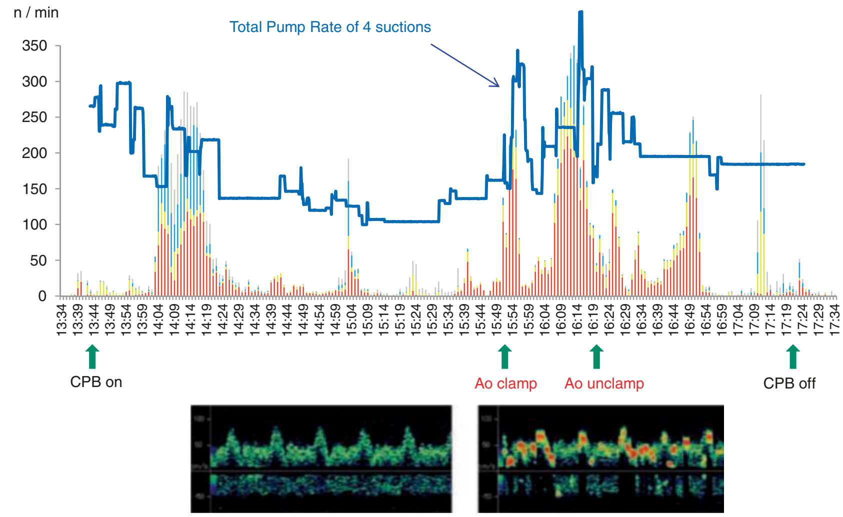


Fig. 5.40 BW30.9 kg TOF PA. Pulmonary artery unifocalization were integrated under heartbeat, and then palliative Rastelli operation was performed under cardiac arrest

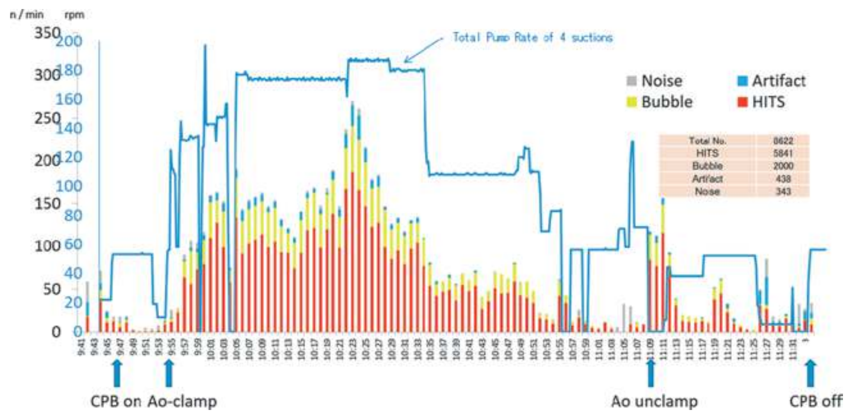


Fig. 5.41 BW47 kg DCRV VSD. Intracardiac repair was performed under cardiac arrest

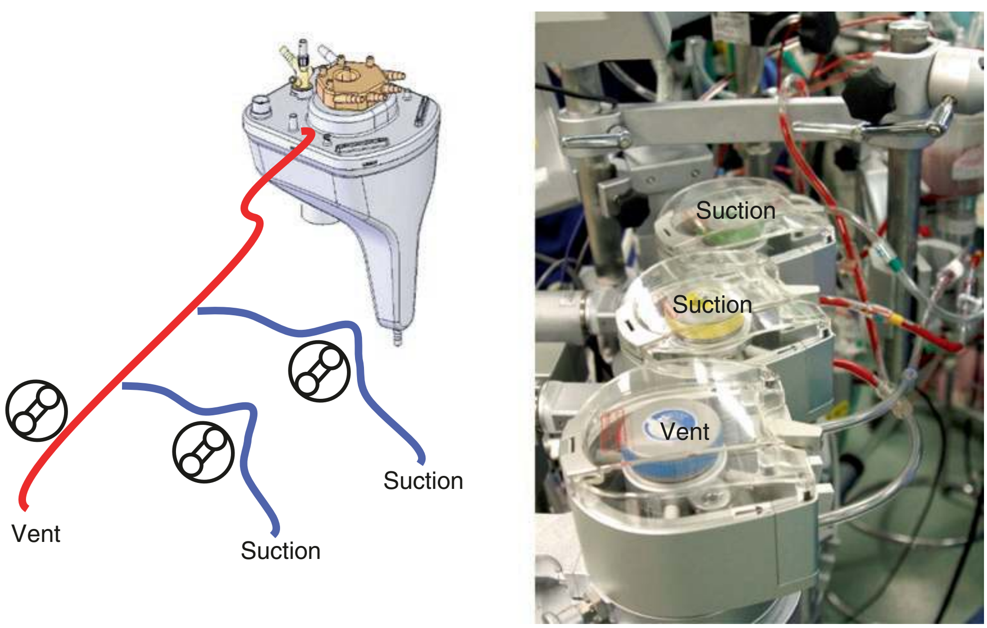


Fig. 5.42 Conventional circuits for suction and vent

Column: Changing the Configuration of the Suction and Vent Circuits (2017)

Figure 5.42 shows a conventional suction and vent circuit, which is a circuit in which suction blood flows into the vent circuit. In this configuration, air from the suction is mixed into the vent blood, and a large amount of microbubbles is generated. Therefore, at present, the circuit configuration was changed so that the blood in the suction circuit and the blood in the vent circuit flowed separately into the reservoir (Fig. 5.43).

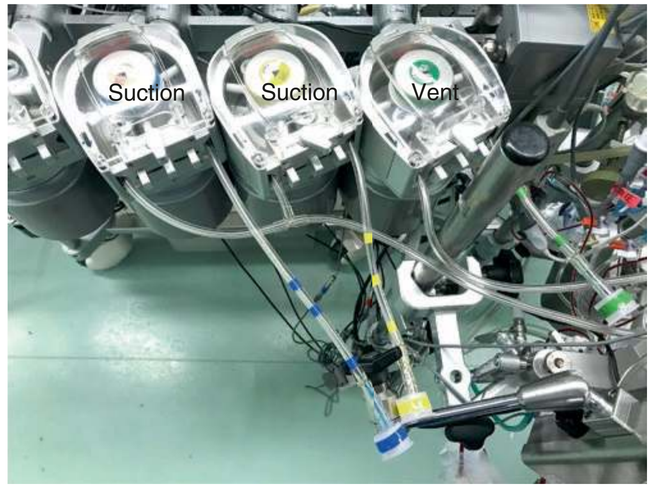


Fig. 5.43 New circuits for suction and vent

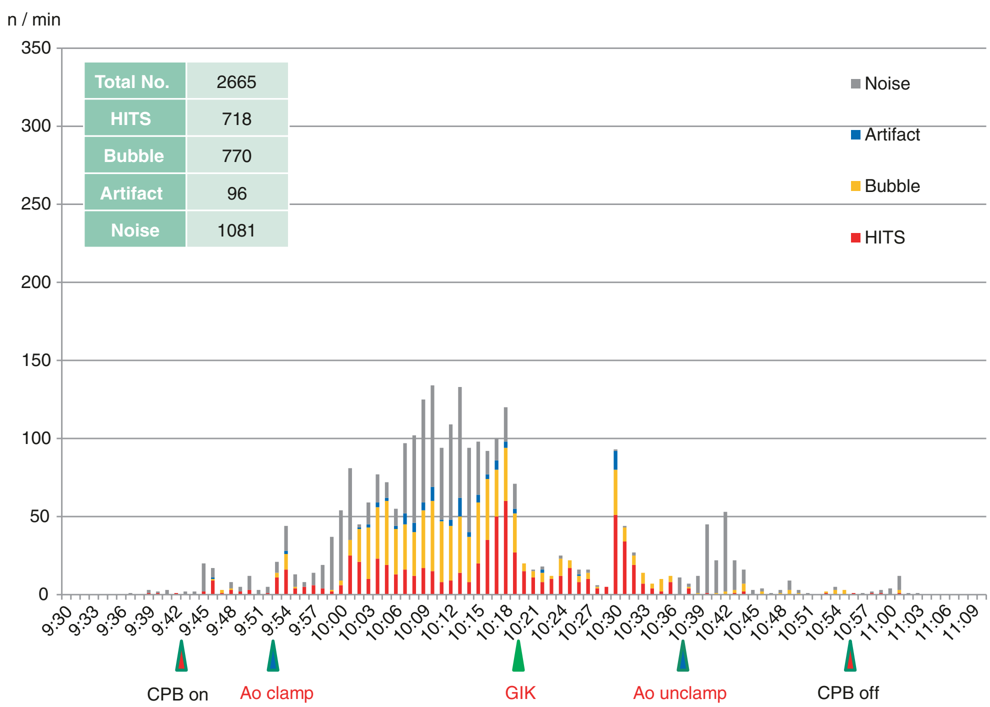


Fig. 5.44 BW5.7 kg VSD. The VSD was closed under cardiac arrest

5.5.2 Reservoir Level

1. In a VSD case weighing 5.7 kg, a video of the reservoir level during extracorporeal circulation was taken to evaluate the relationship between the reservoir level and the number of microbubbles (Fig. 5.44). A negative correlation was observed between the reservoir level and the number of microbubbles (Fig. 5.45). Figure 5.46 shows the transition of the number of microbubbles and the number of microbubbles by size. As shown in Figs. 5.13 to 5.16, the number of microbubbles changes even when the reservoir level is high or low.

In this case, a Bottom release type reservoir was used. This reflects the result of the Na concentration measurement of the 10% NaCL bolus injection from the service port (refer to Fig. 4.10).

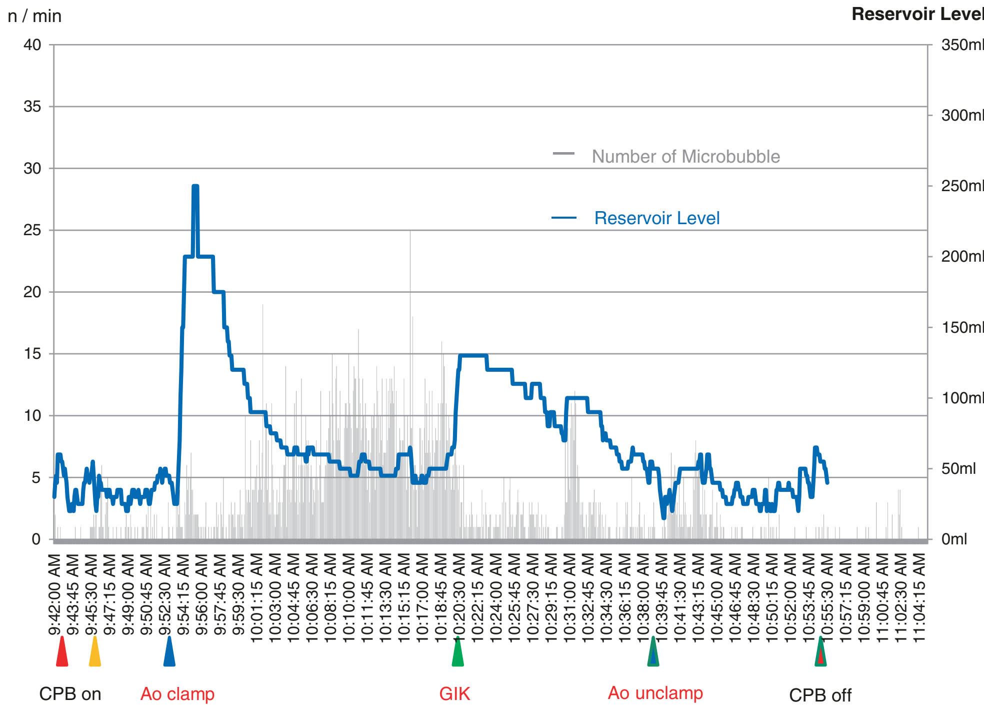


Fig. 5.45 Relationship between Microbubble Number and Reservoir Level. Blood GIK was used for myocardial protection, and Blood GIK returned to the right atrium was aspirated into the reservoir. At this point, the reservoir level increased and the number of microbubbles decreased

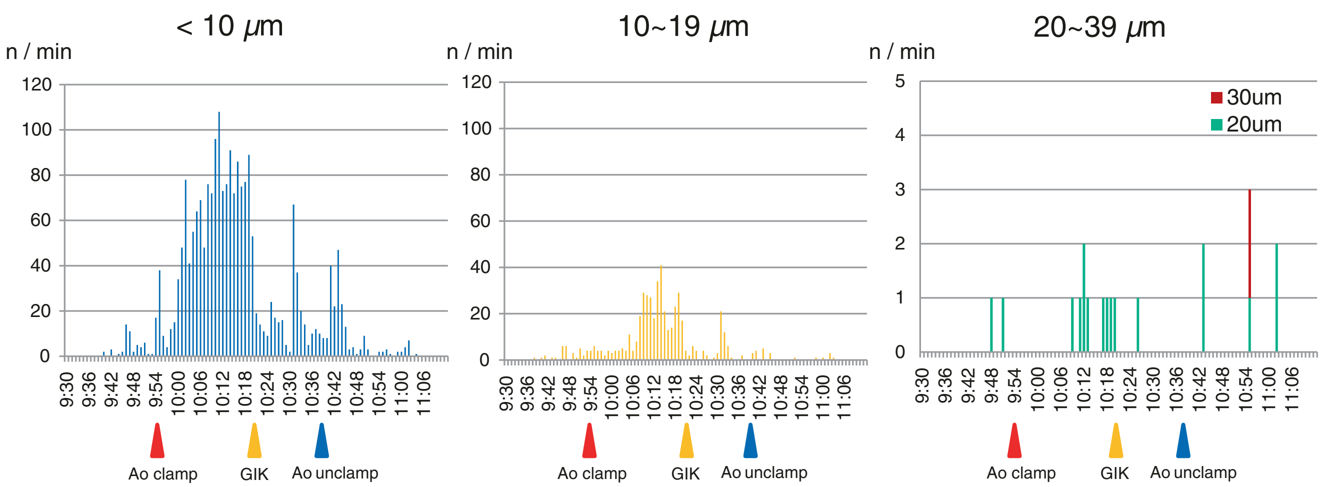


Fig. 5.46 Transition in microbubble number by size

Column: How to Measure Reservoir Level

Some Bottom release type reservoirs have two venous ducts. Using this configuration, the water pressure at the bottom of the reservoir is converted into the volume of stored blood (Fig. 5.47), and the relationship between the number of microbubbles and the stored blood volume can be evaluated. Figure 5.48 shows a TOF weighing 7.4 kg. The number of microbubbles was inversely proportional to the stored blood volume.

2. Using the currently used reservoir, the number of microbubbles associated with changes in the reservoir level was measured. Figure 5.49 shows a cross-sectional view of the reservoir and Fig. 5.50 shows an experimental scene.

At a reservoir level of 200 mL or more, the number of microbubbles was low (100 per minute or less) at both the reservoir outlet and the arterial filter outlet. At 200 mL or less, the number of microbubbles at the reservoir outlet increased, and the degree of increase was different between the reservoirs (Fig. 5.51a). On the other hand, the number of microbubbles at the arterial filter outlet was less than 30 per minute in all reservoirs (Fig. 5.51b). The detected microbubble diameter was less than 20 μm.

The difference in the number of microbubbles between reservoirs at a reservoir level of 200 mL or less may be related to differences in the structure of the cardiotomy reservoir, such as the filter material, pore size, and effective length.

In this study, in the Bottom release type reservoirs A to D, the open position (height) of the cardiotomy reservoir tended to coincide with the reservoir level at which the number of microbubbles increased (Fig. 5.52). On the other hand, in the Middle release type reservoir F, the number of microbubbles was small even if the reservoir level was low. The middle release type reservoir has a large dynamic priming volume and is disadvantageous in terms of the responsiveness of drugs and correction solutions, but this property may be advantageous for microbubble dynamics.

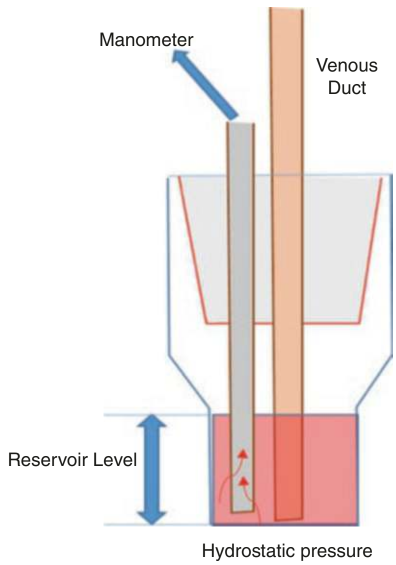


Fig. 5.47 Measuring reservoir blood volume. Perform zero point calibration when the reservoir is empty. The reservoir height is calculated by multiplying the measured pressure by 1.34

Reservoir Level, Conclusion 2

Reservoir level also contributes to the number of microbubbles. It is necessary not only to control the rotation speed of the suction and vent pumps but also to control the reservoir level during extracorporeal circulation, taking into account the characteristics of the various reservoirs [6, 7].

Fig. 5.48 BW7.4 kg TOF. Intracardiac repair and pulmonary artery repair were performed under cardiac arrest

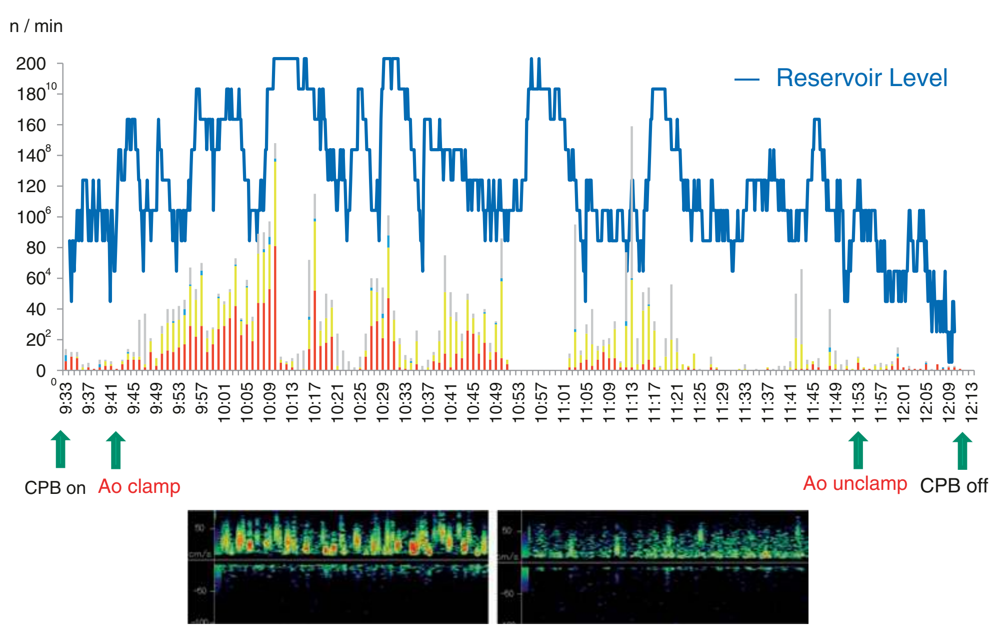
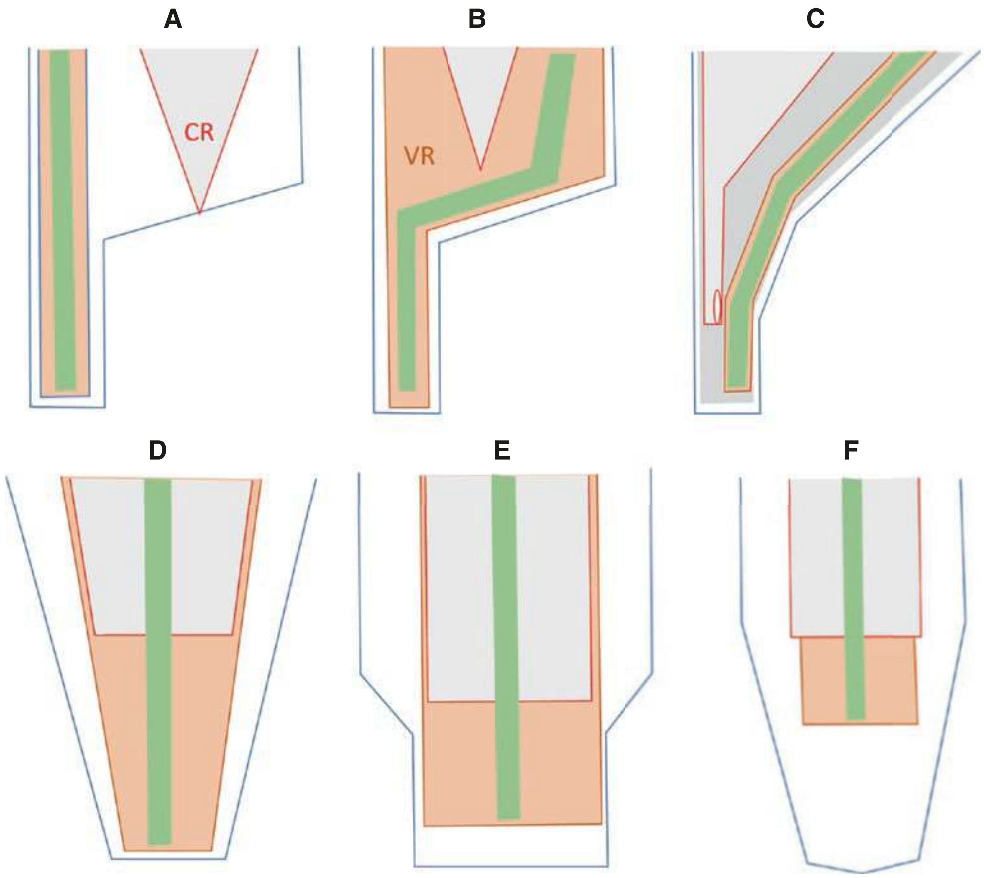


Fig. 5.49 Sectional view of each reservoir



Experiment Condition	
Total Perfusion Flow	1.0 L/min
Venous Drainage	0.9 L/min
Vent Flow	0.1 L/min
Air Infused	0.4 L/min
Reservoir Level	600 ~ 20mL
Back Pressure	200 mmHg
Bovine Blood 37˚C HT35% FURUHATA	

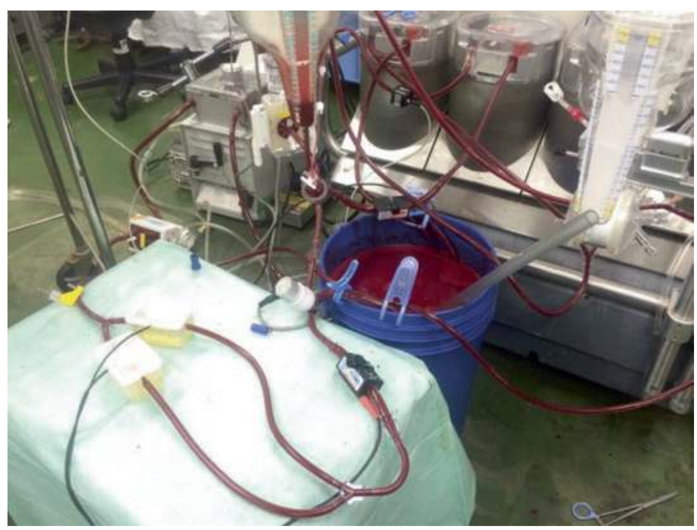


Fig. 5.50 Experimental scenery. A simulated extracorporeal circulation circuit primed with bovine blood was created (perfusion flow rate 1 L/min, temperature 37 °C, Hct 35%, using a roller pump). The blood flow rate in the vent circuit was set at 0.1 L/min (10% of the perfusion flow rate), and 0.4 L/min of air was mixed with a suction pump and introduced into the cardiotomy port. The number of microbubbles was measured at the reservoir outlet and the arterial filter outlet while changing the reservoir level from 600 mL to 20 mL. FURUHATA was used for the measurement

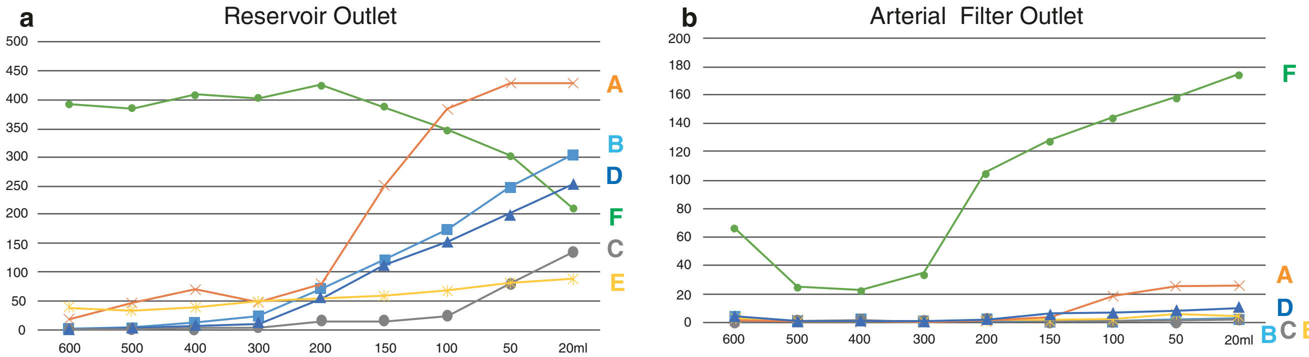
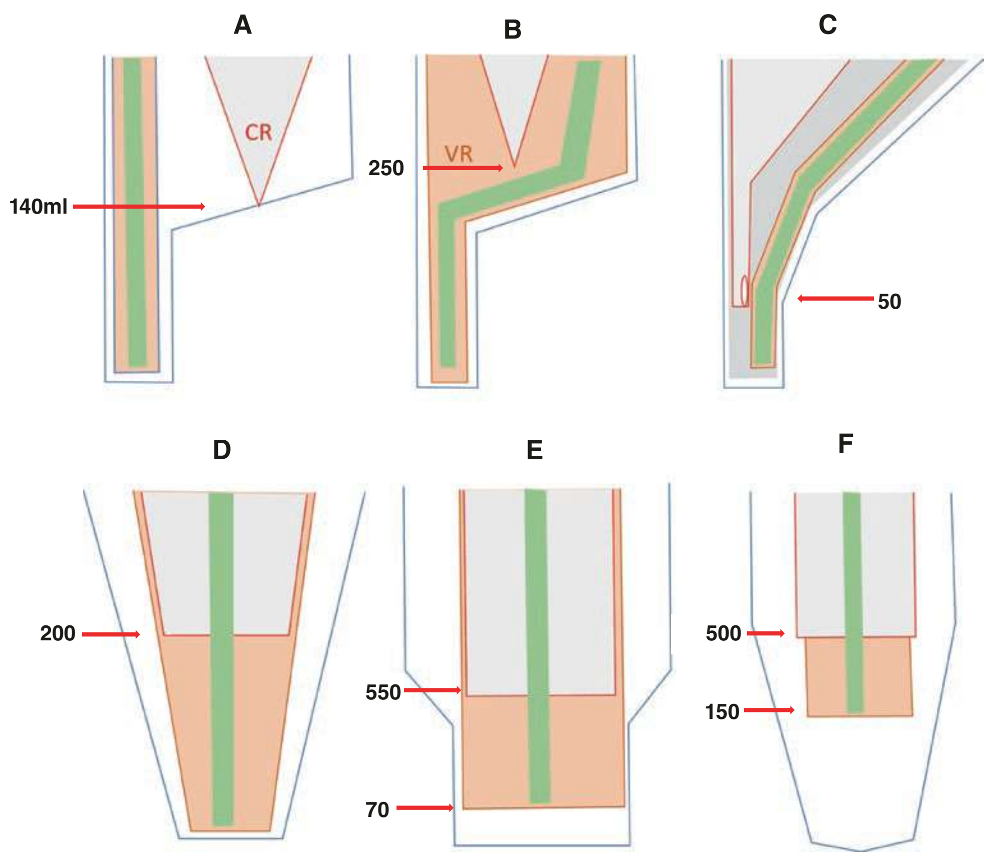


Fig. 5.51 Microbubble characteristics of each reservoir. The decrease in the number of microbubbles generated due to the decrease in the reservoir level in the F reservoir (left fig.) is considered to be due to the measurement limit being exceeded. (**a**) Reservoir Outlet (**b**) Arterial Filter Outlet

Fig. 5.52 Opening position (reservoir level) of cardiotomy reservoir



5.5.3 Reservoir Selection

The generation and outflow of microbubbles was found to be affected by the blood flow of the suction and vent, reservoir level, and the characteristics of each reservoir.

The result in the case using Reservoir C is shown. Figure 5.53 shows a complete AVSD case. Microbubbles were measured at the reservoir outlet, but almost no outflow of microbubbles was observed by maintaining the reservoir level at around 100 mL. Figure 5.54 shows an L-TGA case. Suction and vent blood volumes were high, but no microbubbles were observed during aortic cross-clamp by maintaining a reservoir level of 100 mL.

Figure 5.55 shows a complete AVSD case. In this case, the outflow of microbubbles was confirmed when the reservoir level reached 50 mL. Figure 5.56 shows AS and CoA case. During the intracardiac procedure, the blood volume of suction was large, and the number of microbubbles exceeded the measurement limit but decreased with increasing reservoir level.

Figure 5.57 shows a DORV CoA case using Reservoir A. Despite measurements at the reservoir outlet, the outflow of microbubbles was scarcely observed during aortic cross-clamp by constantly maintaining the reservoir level above 100–200 mL. Figure 5.58 shows a TOF case using Reservoir A, in which microbubbles were observed when the reservoir level became less than 100 mL.

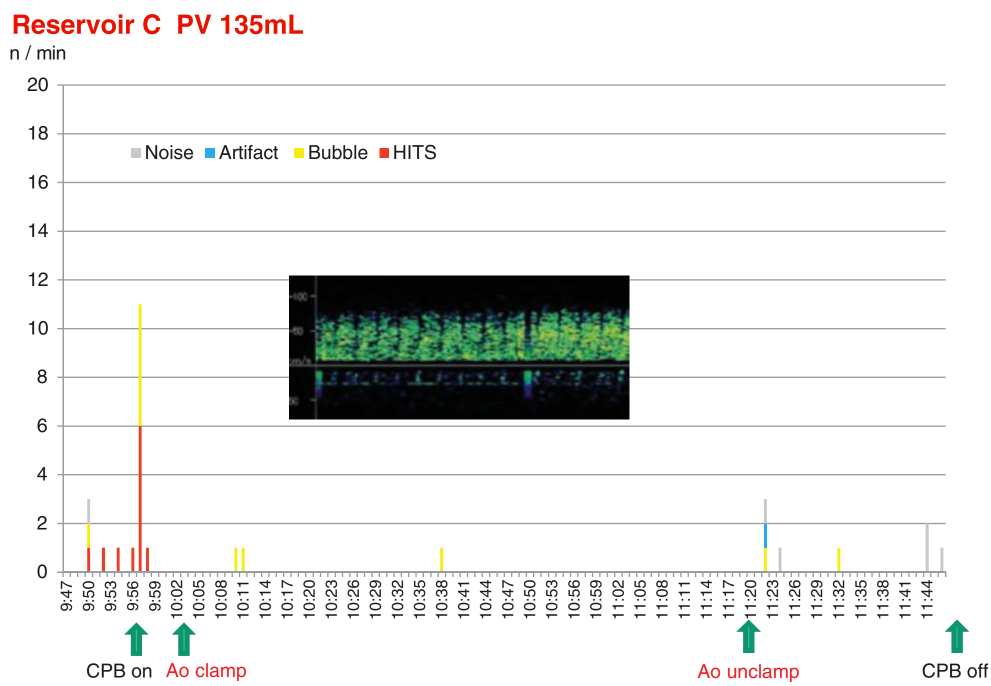


Fig. 5.53 BW3.9 kg complete AVSD, measurement at reservoir outlet. Intracardiac repair was performed under cardiac arrest. AVSD originally had low blood volumes at the suction and vent, but no microbubble outflow was observed despite measurements at the reservoir outlet

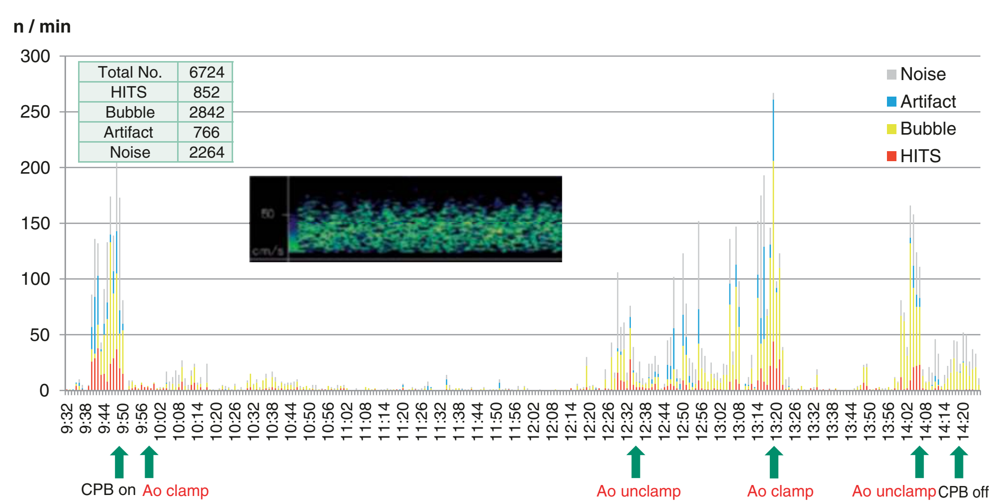


Fig. 5.54 BW10.9 kg L-TGA. Double switch operation was performed under cardiac arrest. Re-extracorporeal circulation was performed due to stenosis at the IVC inflow. The number of microbubbles during aortic cross-clamp was small

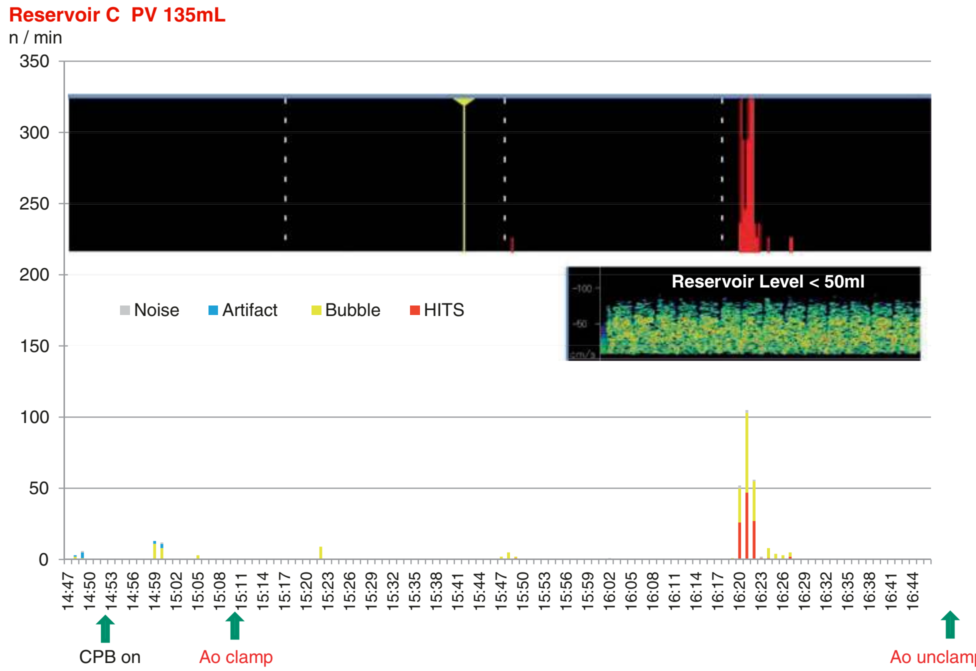


Fig. 5.55 BW2.8 kg complete AVSD, measurement at reservoir outlet. Intracardiac repair was performed under cardiac arrest. Outflow of microbubbles was confirmed at a reservoir level of less than 50 mL

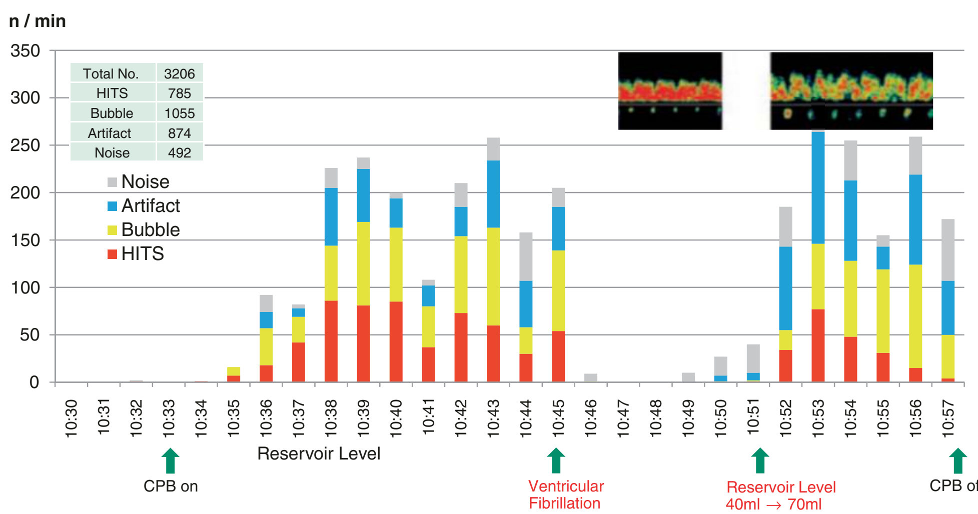


Fig. 5.56 BW2.9 kg AS CoA, measurement at reservoir outlet. ASD was enlarged under electrical ventricular fibrillation, and bilateral pulmonary artery banding was performed under heartbeat. At the time when the reservoir level is low (10: 46–51), many microbubbles are flowing out, but are not displayed on the bar graph because the number of measurement limits has been exceeded. By increasing the reservoir level, the outflow of microbubbles was still high, but decreased until it was displayed on the graph

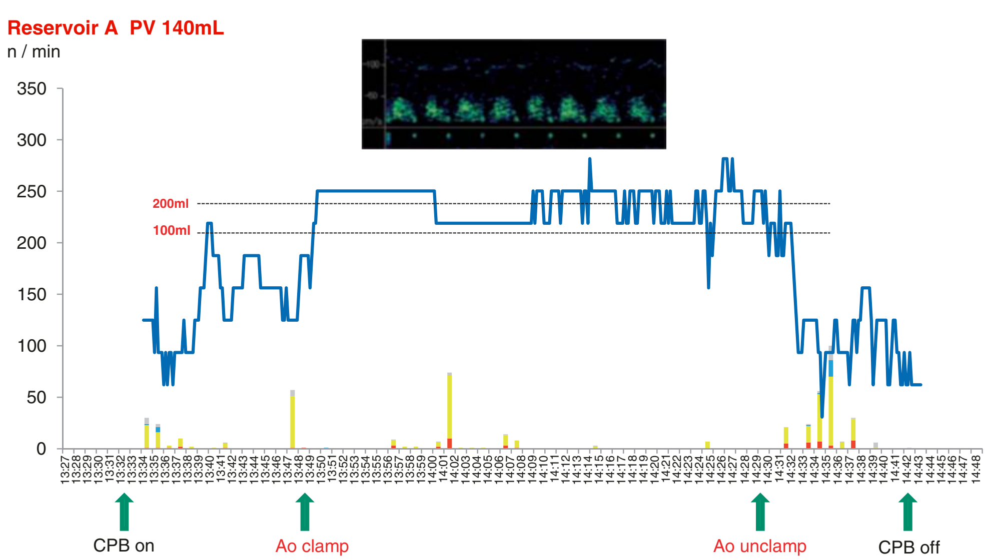


Fig. 5.57 BW3.9 kg DORV CoA, measurement at reservoir outlet. CoA repair and ASD enlargement were performed under cardiac arrest, and pulmonary artery banding was performed under heartbeat

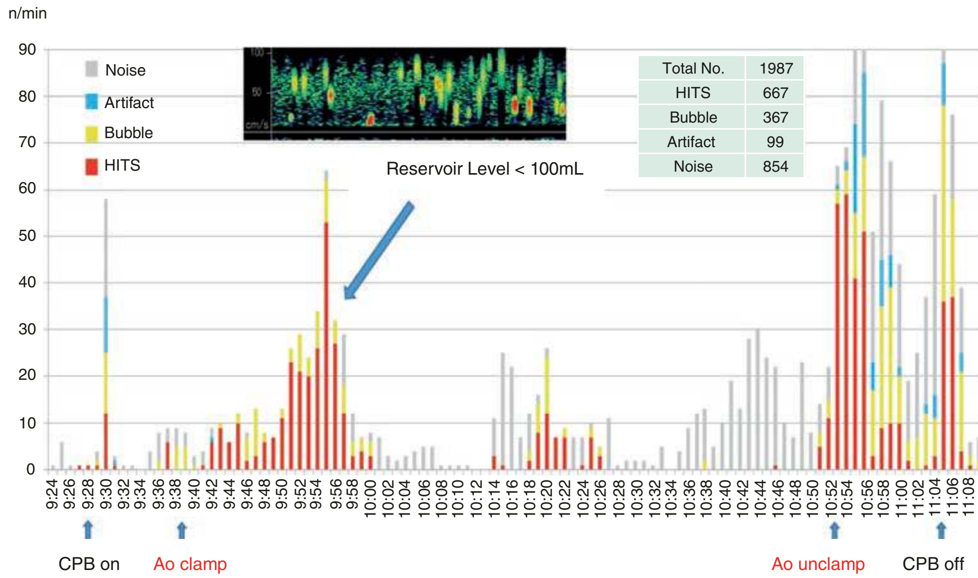


Fig. 5.58 BW12.7 kg TOF PA. Rastelli procedure was performed under cardiac arrest

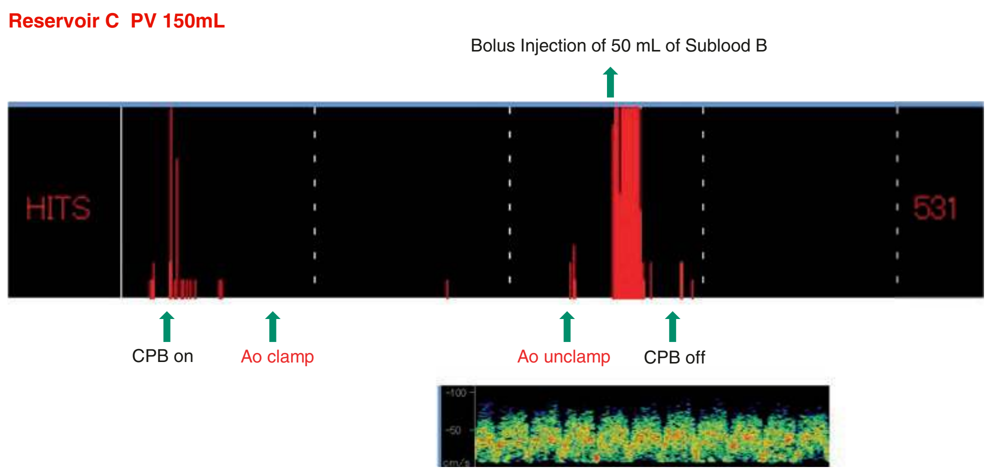


Fig. 5.59 BW5.9 kg VSD. VSD was closed under cardiac arrest

Reservoir Selection, Conclusion 3
The characteristics of microbubble generation in each reservoir were also confirmed in clinical practice. Selecting a reservoir in consideration of each case was also effective in suppressing microbubbles.

5.5.4 Correction and Replenishment

Figure 5.59 shows a VSD case using Reservoir C. Microbubbles were observed immediately before weaning from the extracorporeal circulation. This was due to the rapid administration of 50 mL of Sublood B to the cardiotomy port.

In Videos 5.4–5.7, the difference in the number of microbubbles flowing out of the reservoir due to the difference in the correction method was shown under the conditions of extracorporeal circulation perfusion rate 0.8 L/min and reservoir level 80 mL.

Correction and Replenishment, Conclusion 4
Even with a small volume of correction, a large amount of microbubbles flowing out of the reservoir was observed in the correction from the venous inlet port. In addition, in the correction to the cardiotomy port, rapid and large volume load contributed to microbubble generation. The result of measuring the Na concentration of 10% NaCL bolus injection from the service port (refer to Fig. 4.9) was reflected [8].

Column: Microbubbles During Initial Priming
In the circuit circulation (at a flow rate of 400 mL/min) during the initial priming, the priming solution was injected by bolus injection, and the time until the microbubbles disappeared was measured by FURUHATA. It disappeared within about 20 s (Fig. 5.60).

5.5.5 ECUM

Figure 5.61 shows HLHS case that underwent the Norwood procedure. The suction blood volume was low, and the reservoir level was kept relatively high using Reservoir C. However, a large amount of microbubbles flowed out at the reservoir

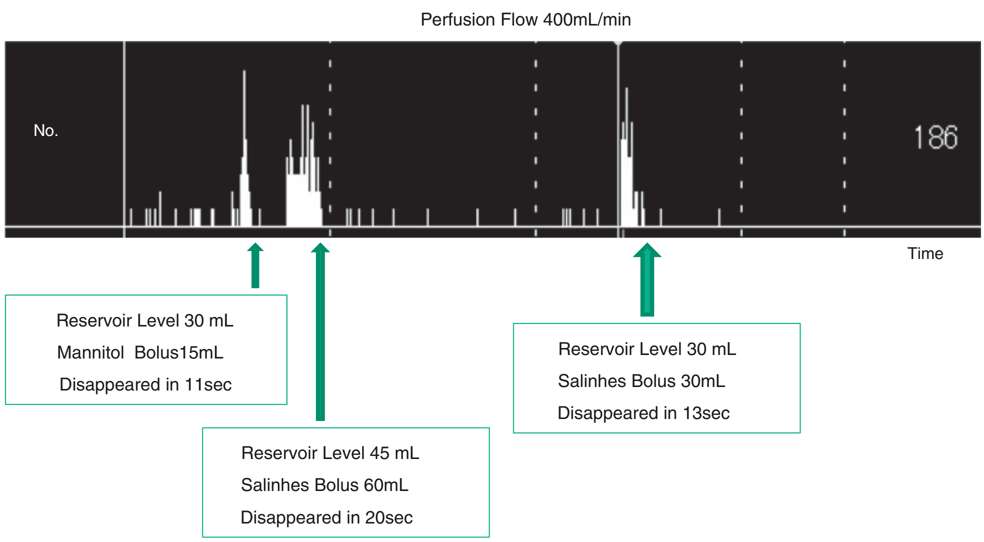


Fig. 5.60 Microbubble generation during Initial Priming

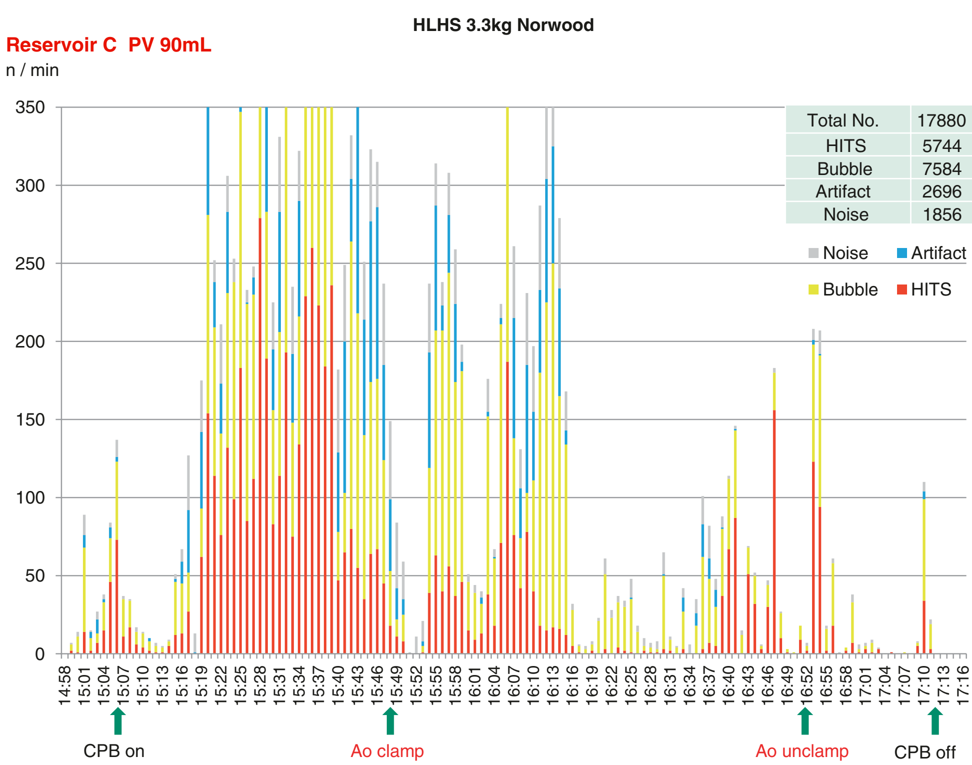


Fig. 5.61 BW3.3 kg AA VSD, measurement at reservoir outlet. Norwood procedure was performed under cardiac arrest

outlet. One of the reasons I noticed was returning of the blood from the ECUM circuit to the cardiotomy port.

Therefore, first, in a coarctation complex case using Reservoir C, microbubble generation when ECUM was stopped during extracorporeal circulation was evaluated. The number of outflowing microbubbles decreased sharply, and when ECUM was restarted, a large amount of microbubbles was generated again (Fig. 5.62). Returning ECUM blood to the cardiotomy port generated microbubbles proportional to the ECUM blood flow rate.

From this, we thought that this problem could be solved by returning ECUM blood to the venous inlet port. First, we examined the absence of microbubbles in ECUM blood. No microbubbles were found in the circulating blood at the ECUM outlet (Fig. 5.63). Therefore, the ECUM circuit was changed from the conventional circuit (Venous-CR (V-CR) ECUM: venous inlet port → small pump → ultrafiltration device → cardiotomy port) to a new circuit (Venous-Venous (V-V) ECUM: venous inlet port → small pump → ultrafilter → venous inlet port) (Figs. 5.64 and 5.65). (Refer “Q&A: Precautions for Vacuum assisted venous drainage” in Chap. 4.)

Figure 5.66 shows a case of transposition of the great arteries in which V-V ECUM was performed. A conventional V-CR ECUM circuit was also prepared in consideration of the possibility of some problems caused by changing to the V-V ECUM. A large amount of microbubbles flowed out in the V-CR ECUM and disappeared when switching to the V-V ECUM.

The number of microbubbles at the reservoir outlet was compared between 12 cases of the Venous-CR ECUM group and 12 cases of the Venous-Venous ECUM group in 24 consecutive cases of open-heart surgery with a body weight of 4.5 kg or less (Table 5.1). There was a significant decrease in the Venous-Venous ECUM group.

Figures 5.67 and 5.68 show TGA II case and complete AVSD (with coarctation) case in which V-V ECUM was performed. Compared with the conventional V-CR ECUM cases, the outflow number of microbubbles was clearly reduced.

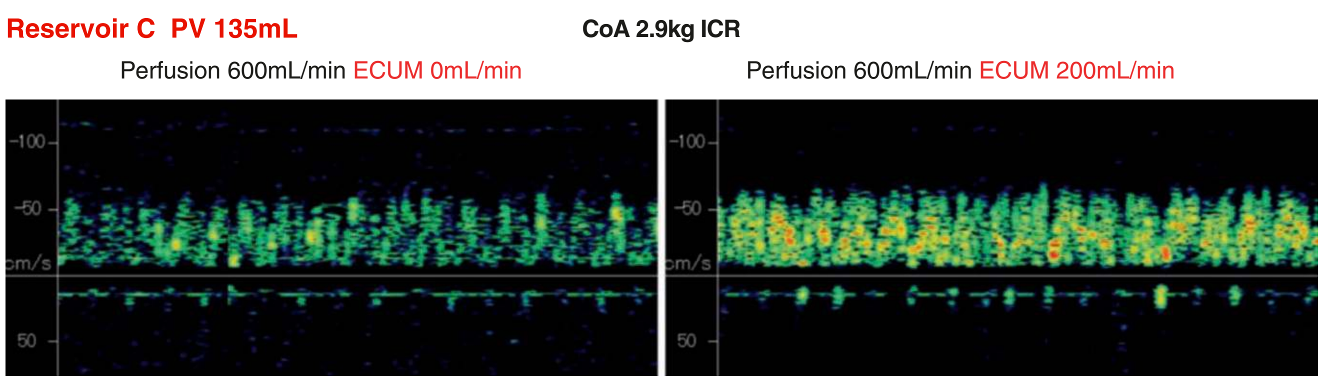
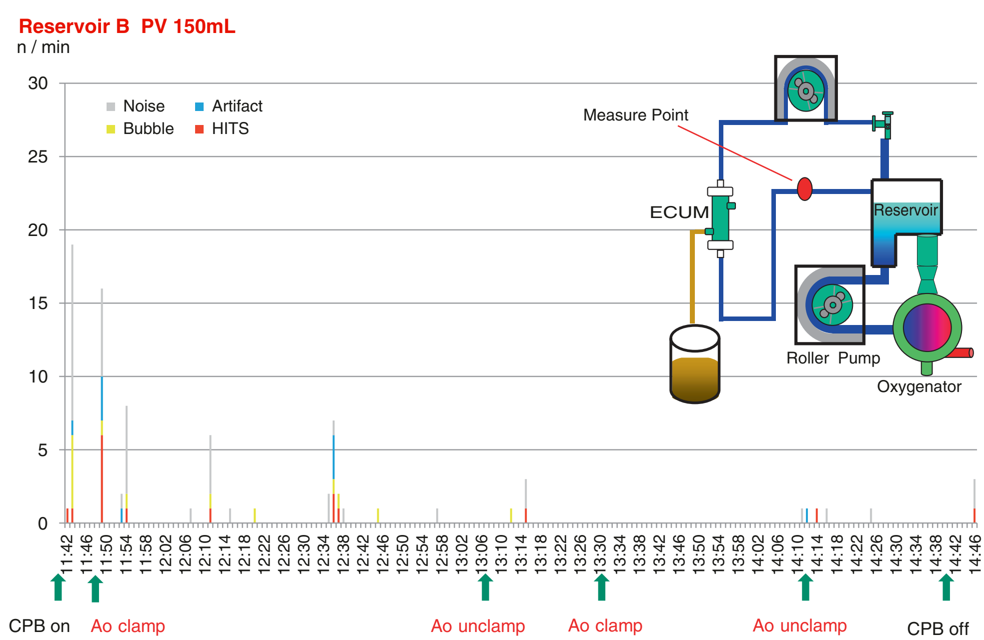


Fig. 5.62 BW2.9 kg CoA complex measurement at reservoir outlet. One-stage intracardiac repair was performed under cardiac arrest

Fig. 5.63 BW 7.1 kg mitral regurgitation, measurement at ECUM outlet. Mitral valve replacement was performed under cardiac arrest. Measured at the exit of ECUM equipment



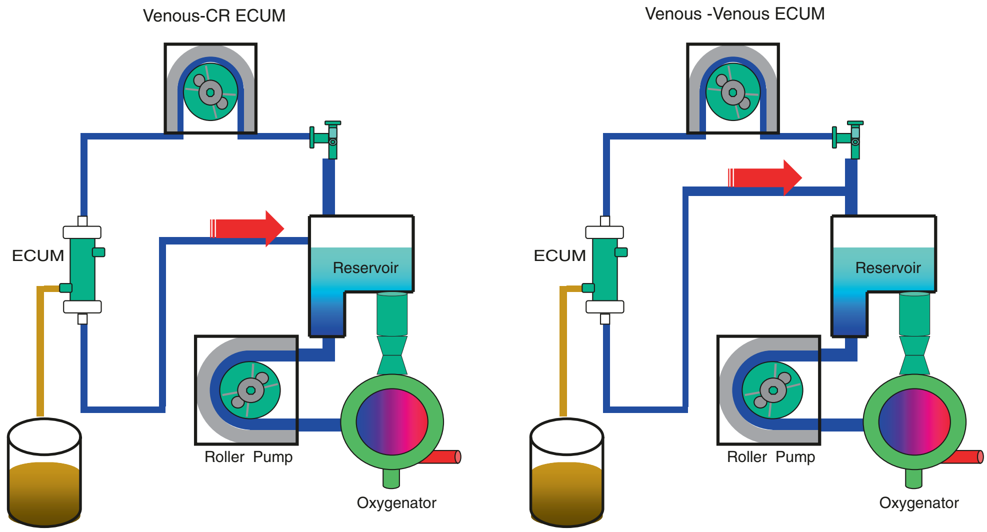


Fig. 5.64 Change of ECUM Circuit

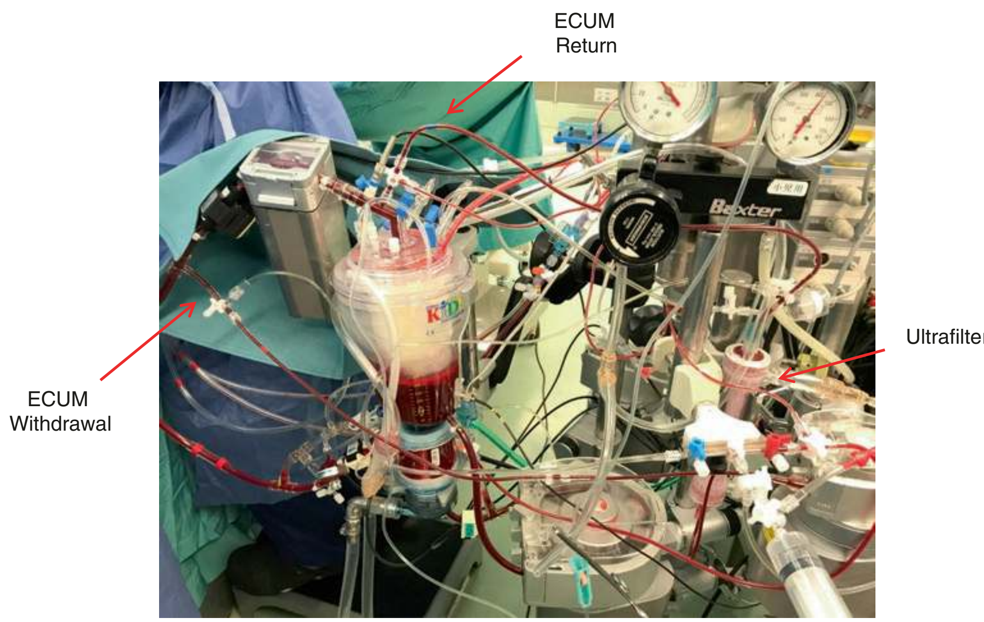


Fig. 5.65 V-V ECUM

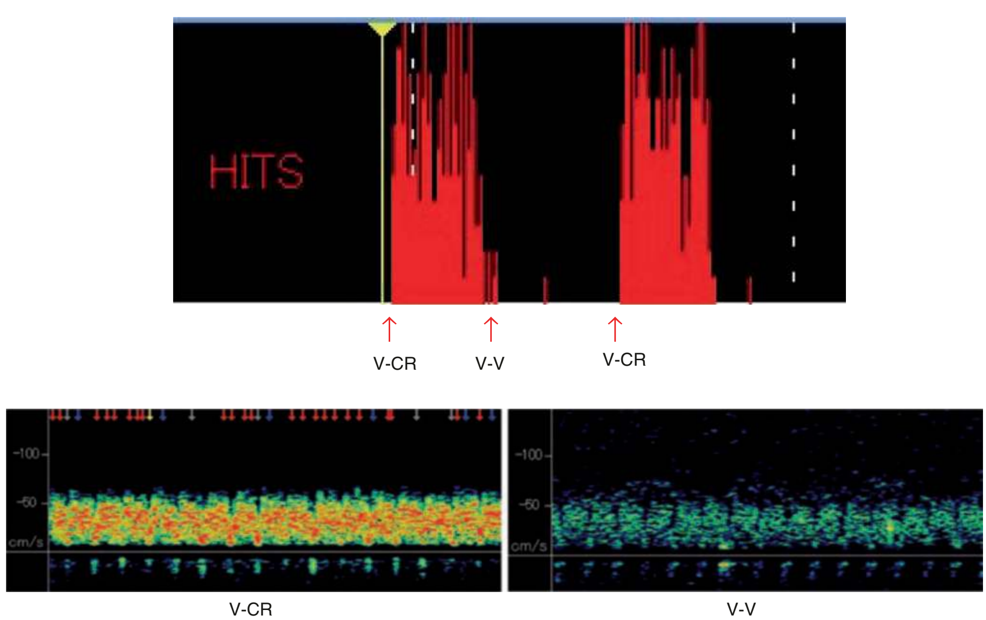


Fig. 5.66 BW3.2 kg TGAI, measurement at reservoir outlet. Jatene's procedure was performed under cardiac arrest

Table 5.1 Comparison of microbubbles between Venous-CR and Venous-venous ECUM

	V-CR	V-V	P value
BW (kg)	3.86 ± 0.86	3.42 ± 0.57	0.11
Height (cm)	53.4 ± 3.7	52.4 ± 2.7	0.21
BSA (m^2)	0.23 ± 0.03	0.21 ± 0.02	0.12
Perfusion Rate (mL/min)	688.6 ± 99.6	640.0 ± 70.5	0.12
CPB time (min)	102.6 ± 56.5	97.9 ± 38.4	0.35
Priming Volume (mL)	137.3 ± 4.7	136.7 ± 4.4	0.41
ECUM Flow (mL/min)	111.6 ± 27.1	112.6 ± 54.3	0.65
Suction • VentFlow (mL/min)	310.4 ± 96.5	299.1 ± 70.3	0.76
No.of Microbubble (n)	1182.7 ± 1178.2	341.7 ± 454.2	0.01 $p < 0.05$

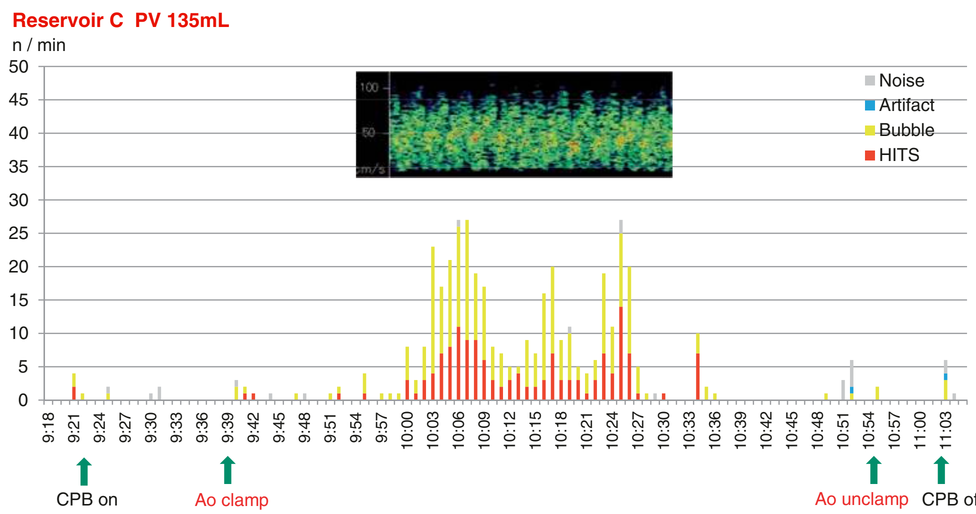


Fig. 5.67 BW3.3 kg TGAI, V-V ECUM, measurement at reservoir outlet. Jatene's procedure was performed under cardiac arrest

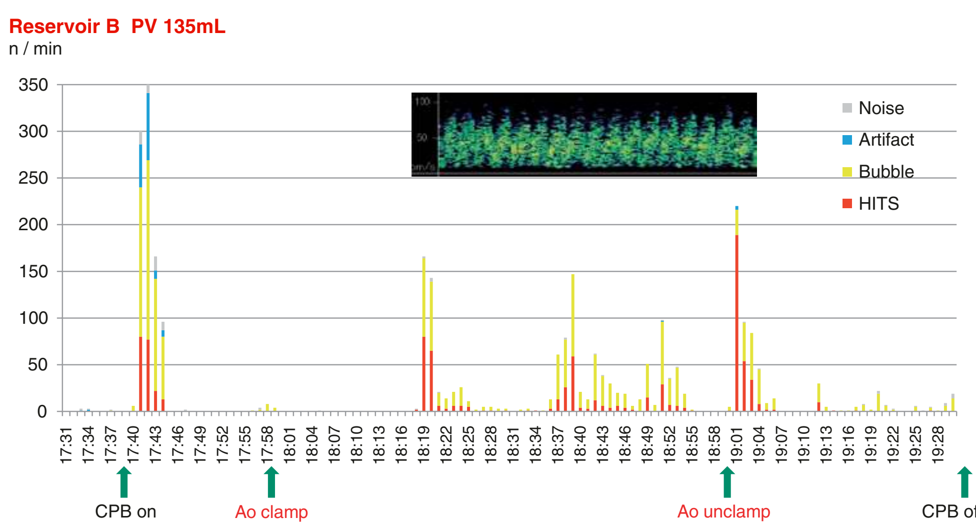


Fig. 5.68 BW3.2 kg AVSD CoA, V-V ECUM, measurement at reservoir outlet. CoA repair and atrioventricular valve repair were performed under cardiac arrest, and then pulmonary artery banding was performed under heartbeat

ECUM, Conclusion 5
In addition to suction and venting, reservoir levels, and the characteristics of each reservoir, returning ECUM blood to the cardiotomy port was also a major factor in generating microbubbles. Microbubble generation was reduced by V-V ECUM.

5.5.6 Oxygenator

In order to evaluate the microbubble removal ability of the oxygenator and the arterial filter, the microbubbles at the reservoir outlet and the arterial filter outlet were measured simultaneously using two FURUHATA's. Figure 5.69 shows a complete AVSD case using Oxygenator B and Reservoir C, and Fig. 5.70 shows a complete AVSD case using Oxygenator B and Reservoir B. AVSD originally had a small amount of blood to be aspirated and vented, but the number of microbubbles was small due to V-V ECUM and strict adjustment of the reservoir level. At the reservoir outlet, an increase in the number of microbubbles was observed after aortic unclamp. This was thought to be due to returning blood to the cardiotomy port for venting air via cardioplegia cannula. Microbubbles flowing out of the reservoir were reduced through the oxygenator and the arterial filter.

Oxygenator, Conclusion 6
The number of microbubbles was reduced by adjusting the suction and vent pump speeds, maintaining the reservoir level, selection of the reservoir, and usage of V-V ECUM. In addition, microbubbles were reduced by the flow through the oxygenator and arterial filter. The degree of its removal capacity was thought to be determined by the characteristics of each oxygenator, such as the difference in pressure drop.

In adult oxygenators, the number of microbubbles decreased with increasing back pressure, but this result was measured with BC100. As shown in Fig. 5.12, measurement in pediatric oxygenator using FURUHATA showed no difference in the number of microbubbles due to the difference in back pressure. The decrease in the number of microbubbles due to increased back pressure in an adult oxygenator may be due to the reduced diameter of the microbubbles and not simply being measured.

Column: Back Pressure
Using an adult oxygenator, the effect of back pressure on microbubble suppression was studied experimentally. A bolus of 50 mL of air was administered from the venous inlet port. Increased back pressure reduced the number of microbubbles at the arterial filter outlet (Fig. 5.71).

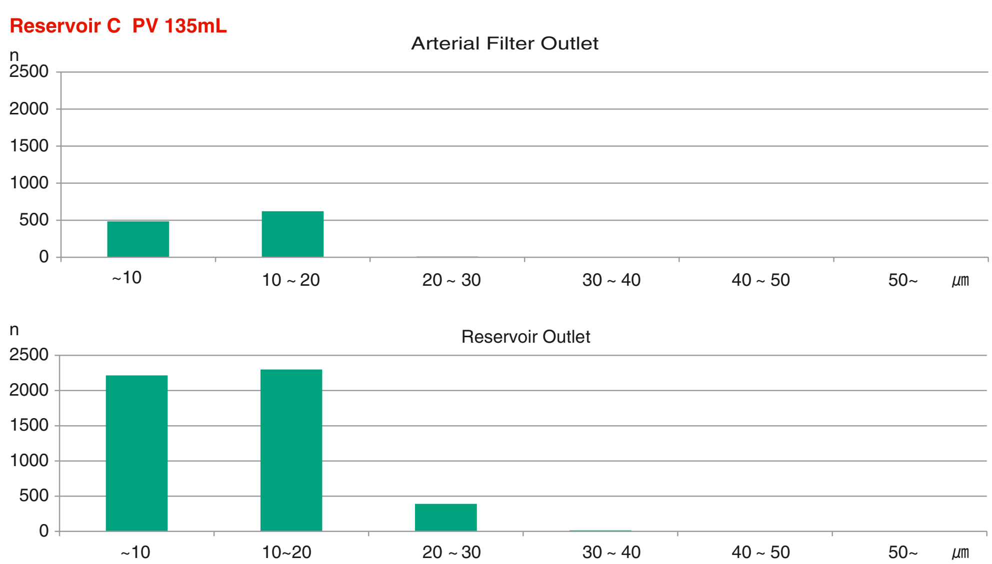
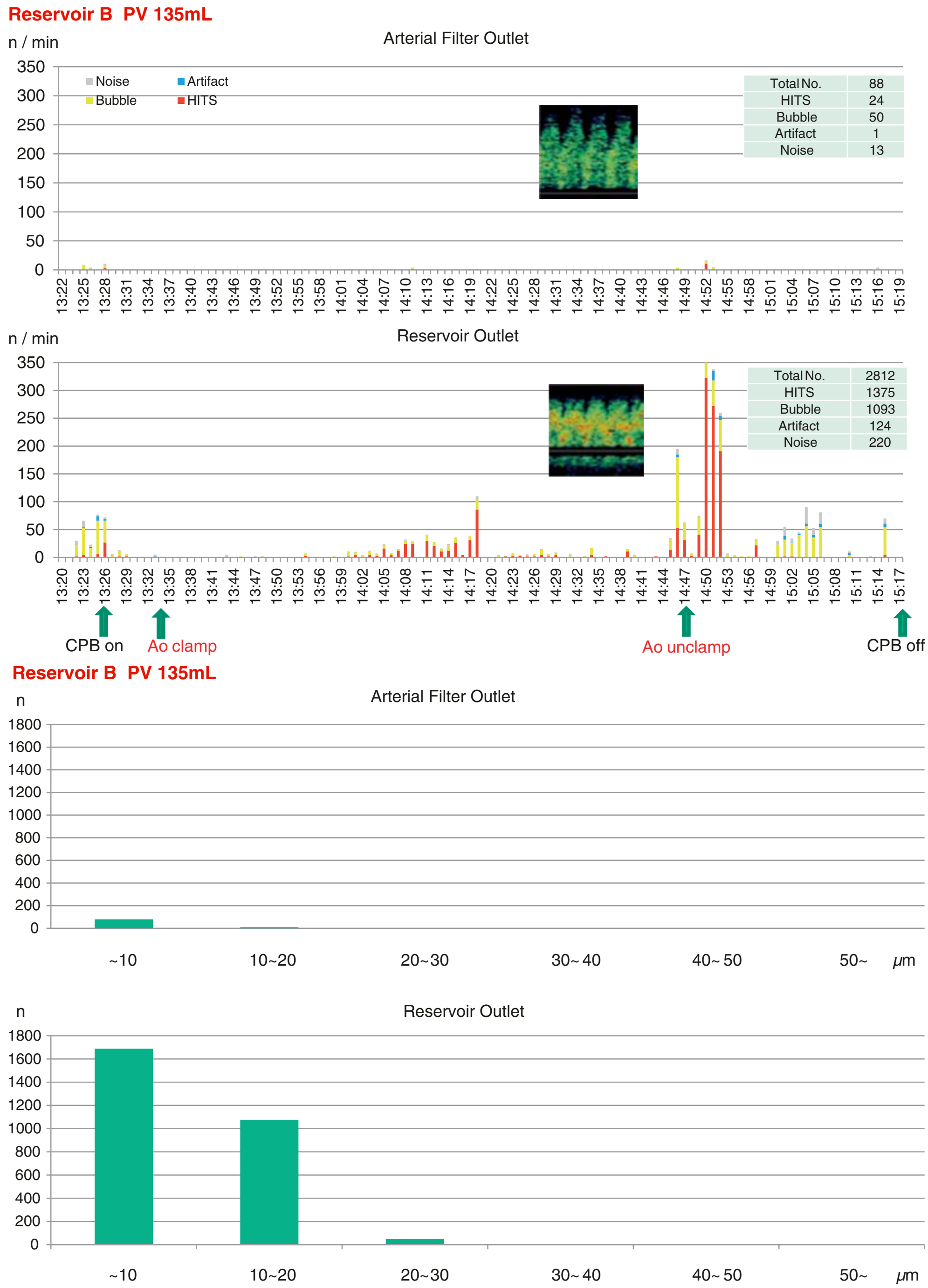


Fig. 5.69 BW4.1 kg complete AVSD. Intracardiac repair was performed under cardiac arrest

Fig. 5.70 BW3.2 kg complete AVSD. Intracardiac repair was performed under cardiac arrest



5.5.7 Arterial Filter

In clinical practice, the procedure with the largest number of microbubbles was TCPC conversion, which is due to a large volume of aspirated blood. Figures 5.72 and 5.73 show the two cases. In particular, in the case of Fig. 5.73, the reservoir level and the suction rotation speed were strictly adjusted, but a large amount of microbubbles was observed. For this reason, it was decided to additionally use the arterial filter, AL20, only in adult open-heart surgery in which a large amount of microbubbles are expected to be generated.

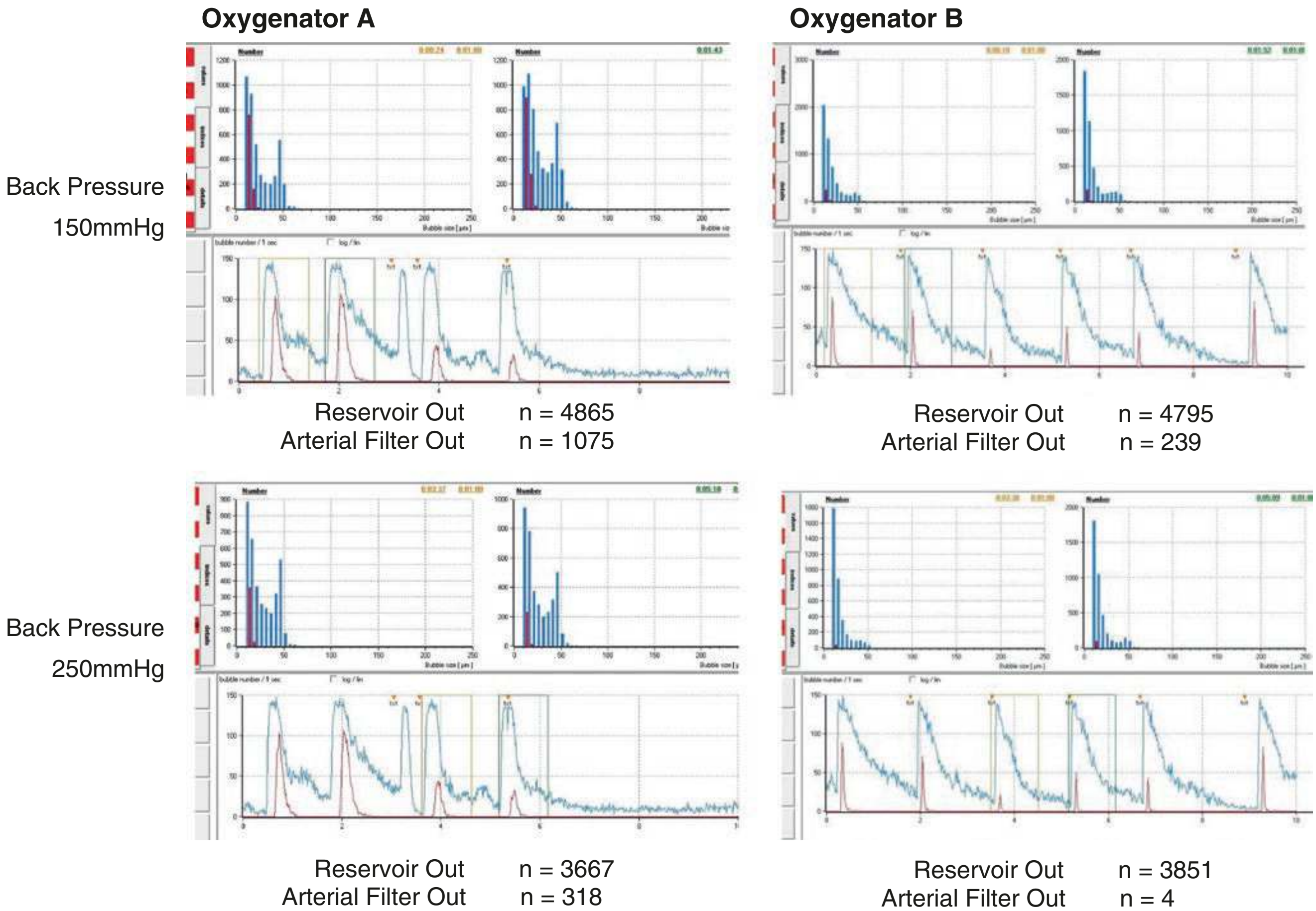
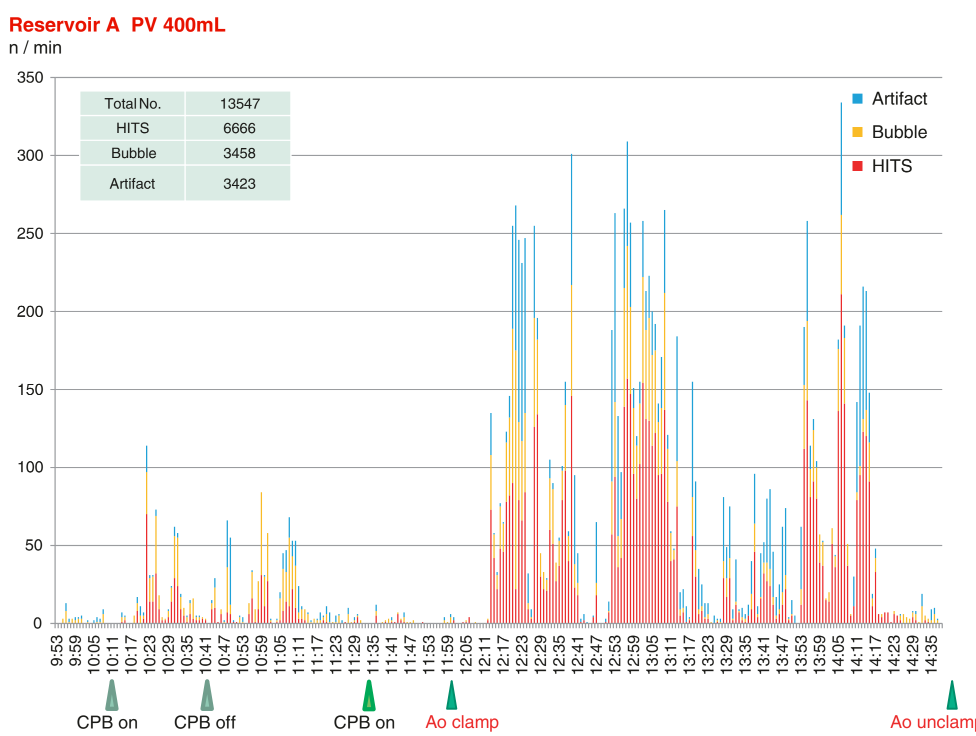


Fig. 5.71 Microbubble suppression by back pressure. Experimental condition: bovine blood 37 °C, perfusion rate 3.0 L/min, reservoir level 500 mL, back pressure 150, 250 mmHg, Injection of air into the venous inlet port: bolus 50 mL

Fig. 5.72 BW55.7 kg DORV PS SAS. TCPC conversion and subaortic stenosis repair were performed under cardiac arrest



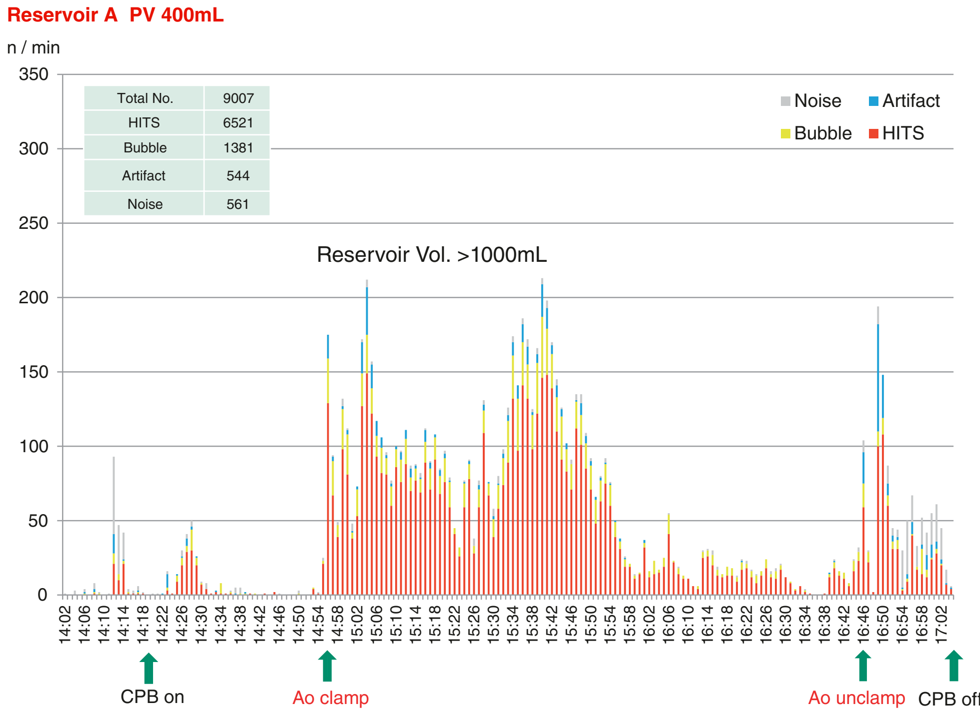


Fig. 5.73 BW59.5 kg DORV PS. TCPC conversion and pulmonary artery repair were performed under cardiac arrest

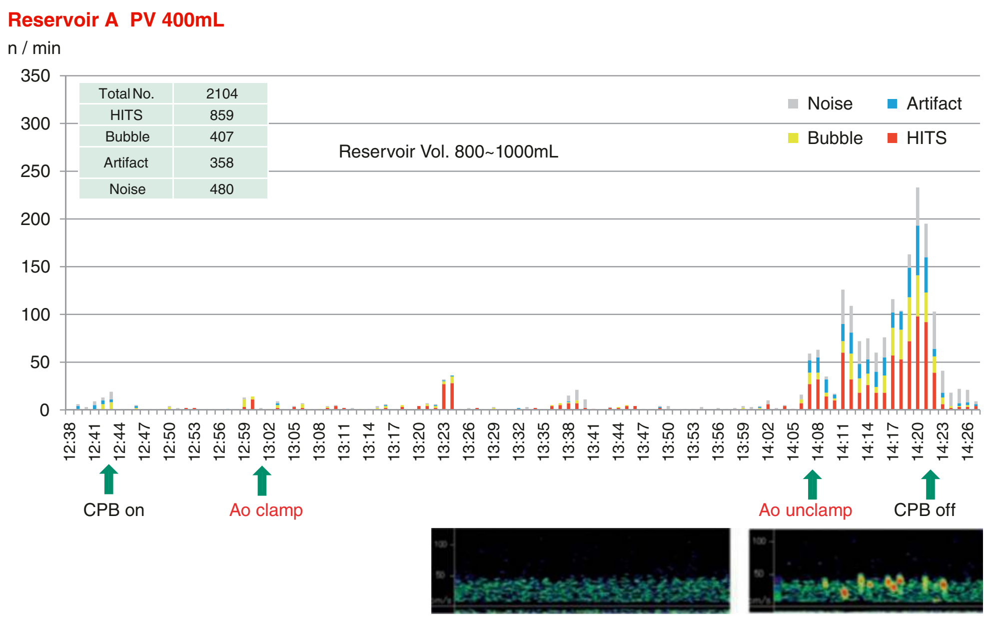


Fig. 5.74 BW64.4 kg DORV PA adding AL20. TCPC conversion was performed under cardiac arrest

Figures 5.74, 5.75 and 5.76 show TCPC conversion cases, and Fig. 5.77 shows TOF case undergoing resection of vegetation and pulmonary valve replacement for bacterial endocarditis. In all cases, the amount of aspirated blood was also large, but the number of microbubbles during aortic cross-clamp was dramatically reduced by the addition of AL20. In Fig. 5.76, microbubbles were observed during aortic cross-clamp because IVC venous drainage was obtained using suction at the time of vascular prosthesis anastomosis to the IVC (14:6–14:18 min).

Arterial Filter, Conclusion 7

In adult open-heart surgery, the effect of adding an arterial filter on the suppression of microbubbles was evident.

Column: Effect of Arterial Filter

In an experiment using a simulated extracorporeal circuit with bovine blood priming (bolus injection of 50 mL of air into the venous inlet port), the number of microbubbles was reduced by adding an arterial filter (Fig. 5.78) [9].

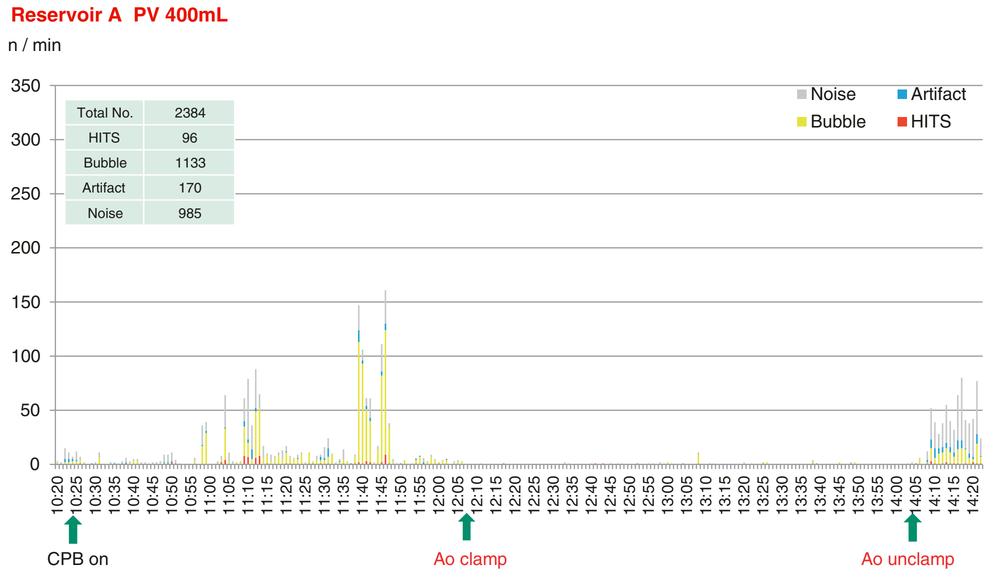


Fig. 5.75 BW42.2 kg SLV AR adding AL20. TCPC conversion and aortic valve replacement were performed under cardiac arrest

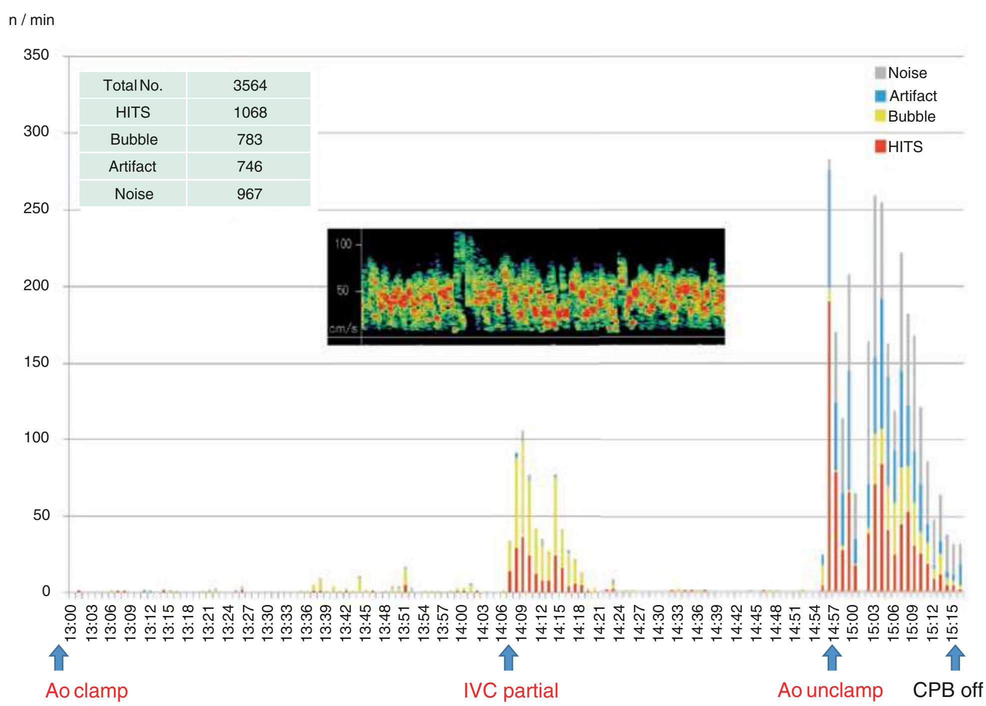


Fig. 5.76 BW69.9 kg DORV adding AL20. TCPC conversion, aortic valve replacement, and tricuspid valvuloplasty were performed under cardiac arrest

Column: The Importance of Microbubble Monitor Screen

At the time point indicated by the red arrow (Fig. 5.79), it was determined that no microbubbles were generated, but during the actual measurement, a large amount of microbubbles was observed as shown in the right figure. FURUHATA is an extremely useful device as a microbubble monitor during extracorporeal circulation. With respect to the generation of such a large amount of microbubbles shown on the monitor screen, it is necessary to take prompt measures such as adjusting the suction rotation speed described above. However, when performing a statistical evaluation, care must be taken particularly in determining a significant difference in the absolute number.

5.5.8 Microbubbles Generated After Aortic Unclamp

Since most of the microbubbles occur during aortic cross-clamp, we have initially considered suppression measures around this time. However, after the suppression effect during aortic cross-clamp was observed, the microbubbles after the aortic unclamp became more prominent. Figure 5.80

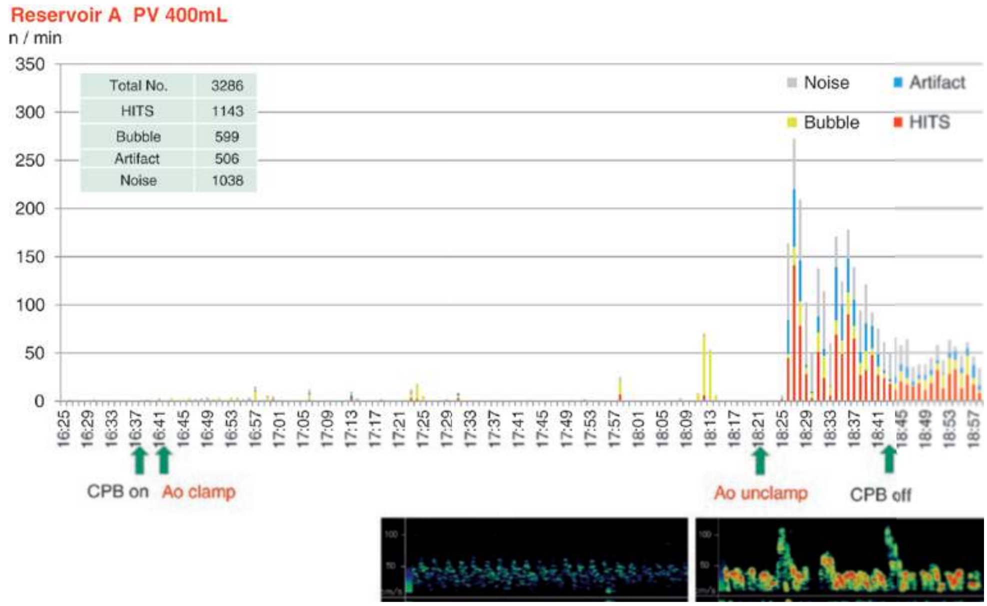


Fig. 5.77 BW50.9 kg DORV IE adding AL20. Resection of vegetation and pulmonary valve replacement were performed under cardiac arrest

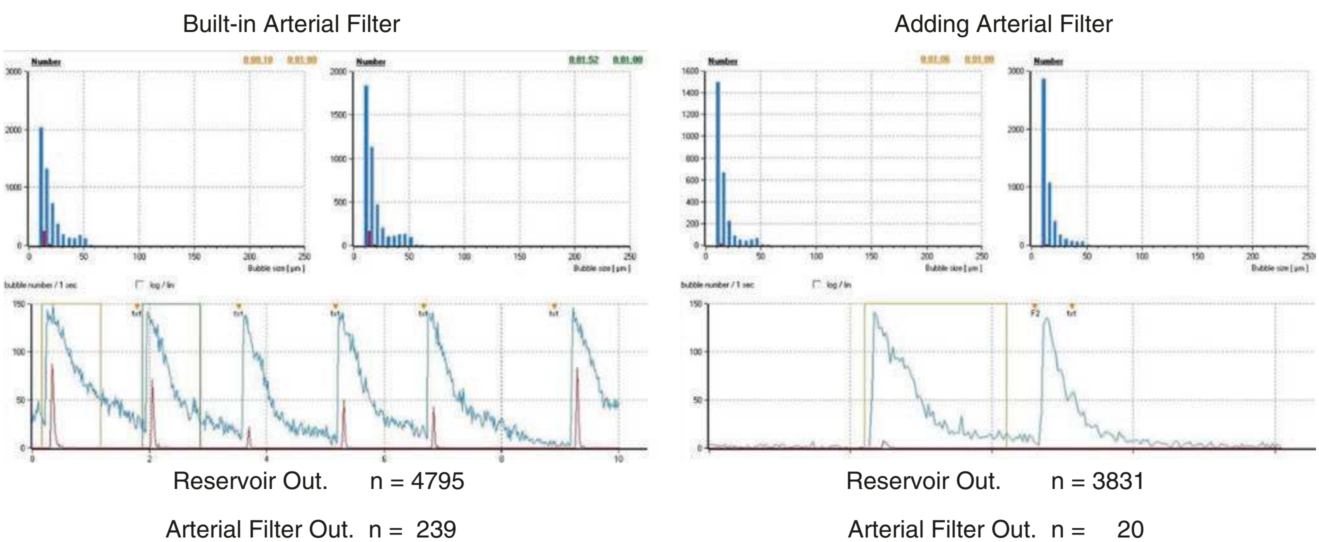


Fig. 5.78 Adding arterial filter. Experimental conditions: bovine blood 37 °C, perfusion rate 3.0 L/min, reservoir level 500 mL, back pressure 150 mmHg

shows PA with VSD case in which Rastelli procedure was performed using AL-20, and Fig. 5.81 shows aortic valve stenosis case in which aortic valve replacement surgery was performed. In both cases, microbubbles were observed after the aortic unclamp.

One of the possible causes was to return the vented blood from the cardioplegia cannula to the cardiotomy port. However, the diameter of microbubbles flowing into the living body was thought to be almost less than 20 μm when AL-20 was used, and the number of microbubbles actually generated during aortic cross-clamp was small. Therefore, the detection of microbubbles of 20 μm or more after aortic unclamp might be caused by residual air in the heart. In addition, as described above, in experiments on adult extracorporeal circulation, it was also confirmed that large microbubbles of 20 μm or more were generated depending on the extracorporeal circulation conditions (such as the equipment used and the amount of air injected) Fig. 5.23 [10].

Microbubbles Generated After Unclamp, Conclusion 8
The size of the residual air in the heart that can be confirmed by esophageal echography is unknown, but it may be 20 μm or more. Therefore, sufficient air removal is necessary, especially in elderly patients with arteriosclerosis.

5.5.9 Difference in Number of Microbubbles by Physique

Figures 5.82 and 5.83 show the results of an experiment of injecting air into the venous inlet port. The number of microbubbles flowing out of the reservoir was about 7000–8000

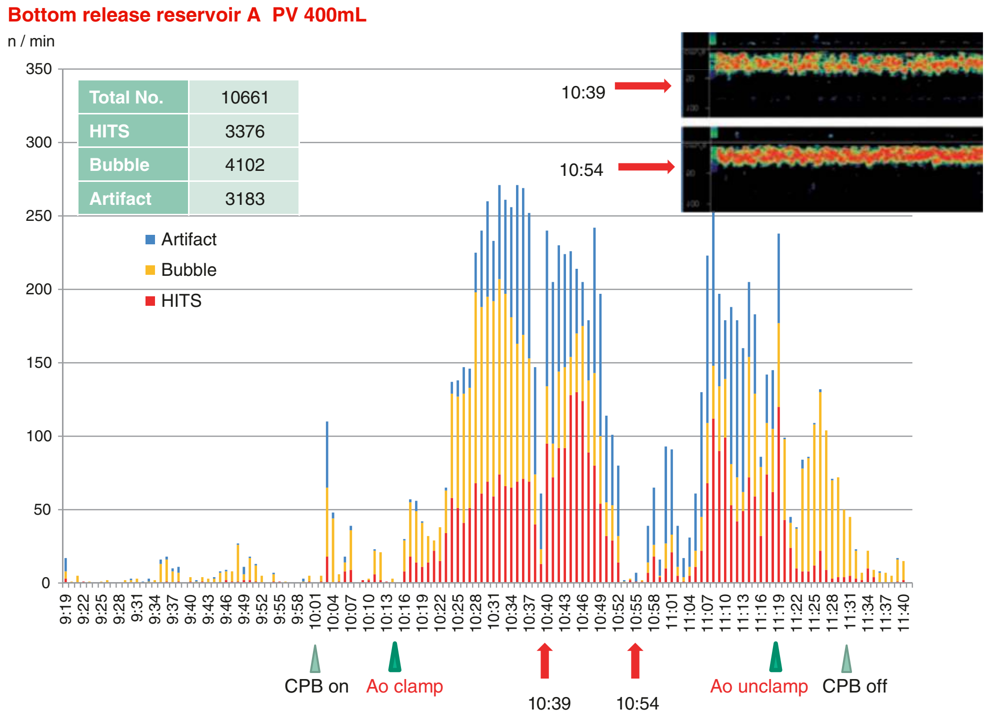


Fig. 5.79 BW8.1 kg TOF

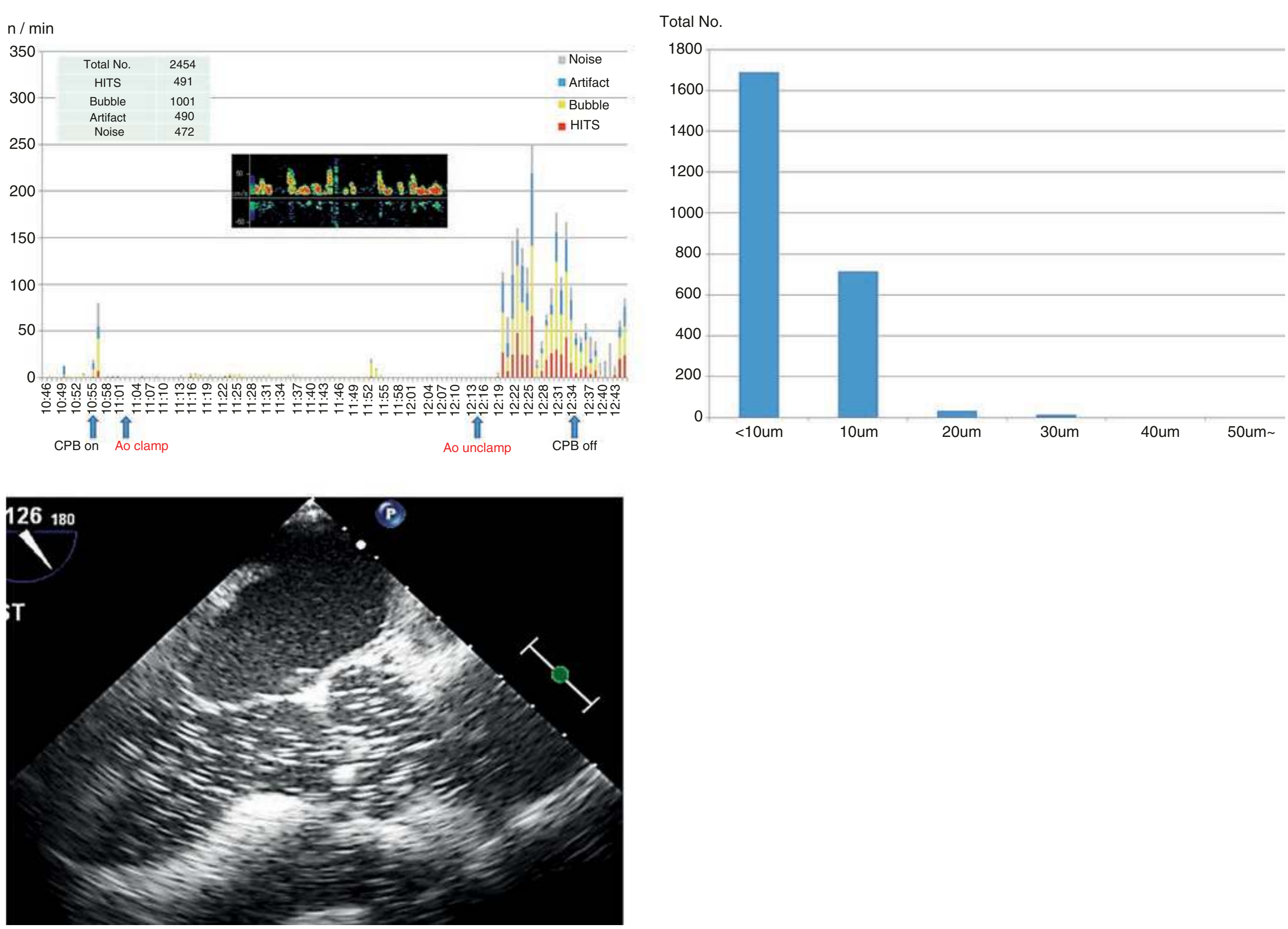


Fig. 5.80 BW30.6 kg PA with VSD adding AL20. Rastelli procedure was performed under cardiac arrest

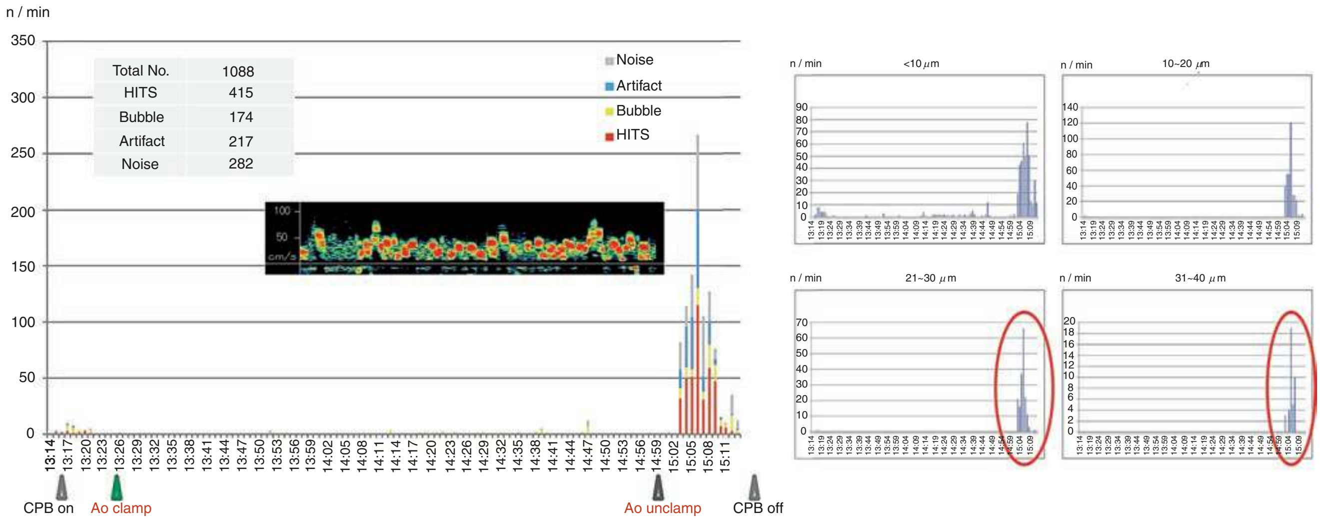


Fig. 5.81 BW30.7 kg AS adding AL20. Re-Konno procedure was performed for valvular stenosis after Konno procedure under cardiac arrest

Qb (VR)	3.0L/min			2.0L/min			2.0L/min		
Air injection (VR)	0.5L/min	1.0L/min	2.0L/min	0.33L/min	0.5L/min	0.67L/min	0.5L/min	1.0L/min	2.0L/min
Qb (Vent)	-	-	-	-	-	-	-	-	-
Air injection (Vent)	-	-	-	-	-	-	-	-	-
Reservoir level	500mL	500mL	500mL	300mL	300mL	300mL	500mL	500mL	500mL
Pout	150mmHg	150mmHg	150mmHg	150mmHg	150mmHg	150mmHg	150mmHg	150mmHg	150mmHg
Purge line	OFF	OFF	OFF	OFF	OFF	OFF	ON	ON	ON
1~19 [μm]	2111	321	149	1659	512	720	1722	357	126
20~ 39 [μm]	5186	2962	665	5199	5380	4503	5513	3162	746
40~ 59 [μm]	114	4278	6460	404	2212	2462	364	4288	6988
60~ 79 [μm]	0	0	0	0	0	0	0	0	0
80~ 99 [μm]	0	0	0	0	0	0	0	0	0
>100 [μm]	0	0	0	0	0	0	0	0	0
Total	7411	7561	7274	7262	8104	7685	7599	7807	7860

Fig. 5.82 Adult extracorporeal circuit: experiment conditions and microbubbles generation at reservoir outlet

Fig. 5.83 Pediatric extracorporeal circuit: experiment conditions and microbubbles generation at reservoir outlet

Sample	A	B	B	A	B
Qb(VR)	1.0L/min				
Air injection(VR)	200mL/min				
Qb(Vent)	-				
Air injection(Vent)	-				
Reservoir Level	20mL			200mL	
Pout	200mmHg		300mmHg	200mmHg	
No.	1	9-1	9-2	2	8
mesurement time [sec]	60	60	60	60	60
1~19 [μm]	4066	2849	3018	4226	4263
20~39 [μm]	2893	4284	4102	335	2032
40~59 [μm]	1	36	27	0	4
60~79 [μm]	0	0	0	0	0
80~99 [μm]	0	0	0	0	0
>100 [μm]	0	0	0	0	0
Total	6960	7169	7147	4561	6299

per minute in the adult circuit and sometimes exceeded 7000 per minute in the pediatric circuit.

Figure 5.84 shows three cases of an adult, an infant, and a newborn having the largest number of microbubbles in the measurement using FURUHATA. The number during aortic cross-clamp was 8890 per hour in adult cases, 7530 in infant cases, and 6220 in neonatal cases.

Microbubble by Physique, Conclusion 9

This is not to say that microbubbles are less likely to generate due to low weight. That is, even in a newborn baby, approximately the same number of microbubbles as in an adult come into contact with the circulating blood in or after the reservoir. It was speculated that this might be one reason that low-weight infants were susceptible to adverse

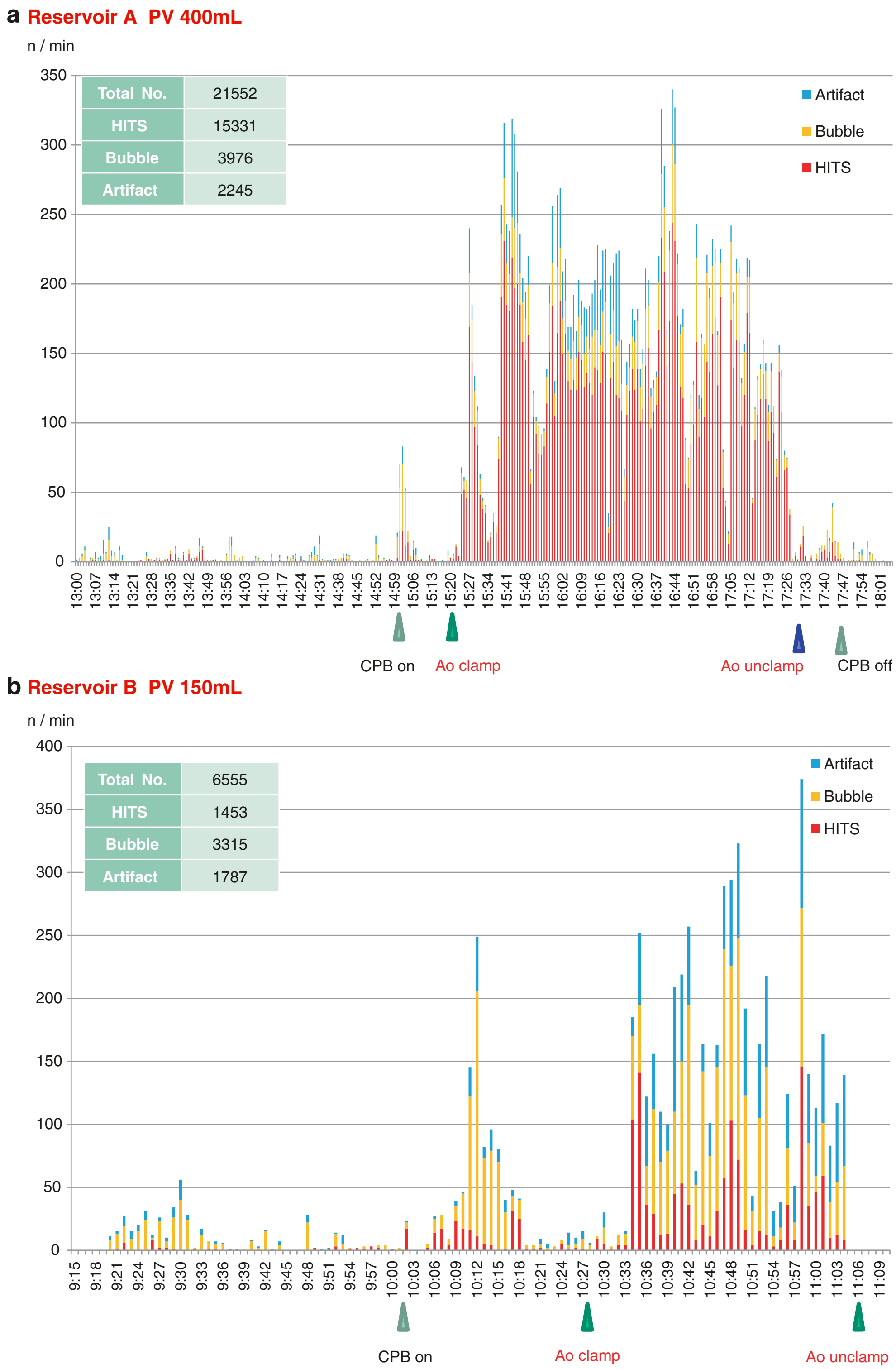
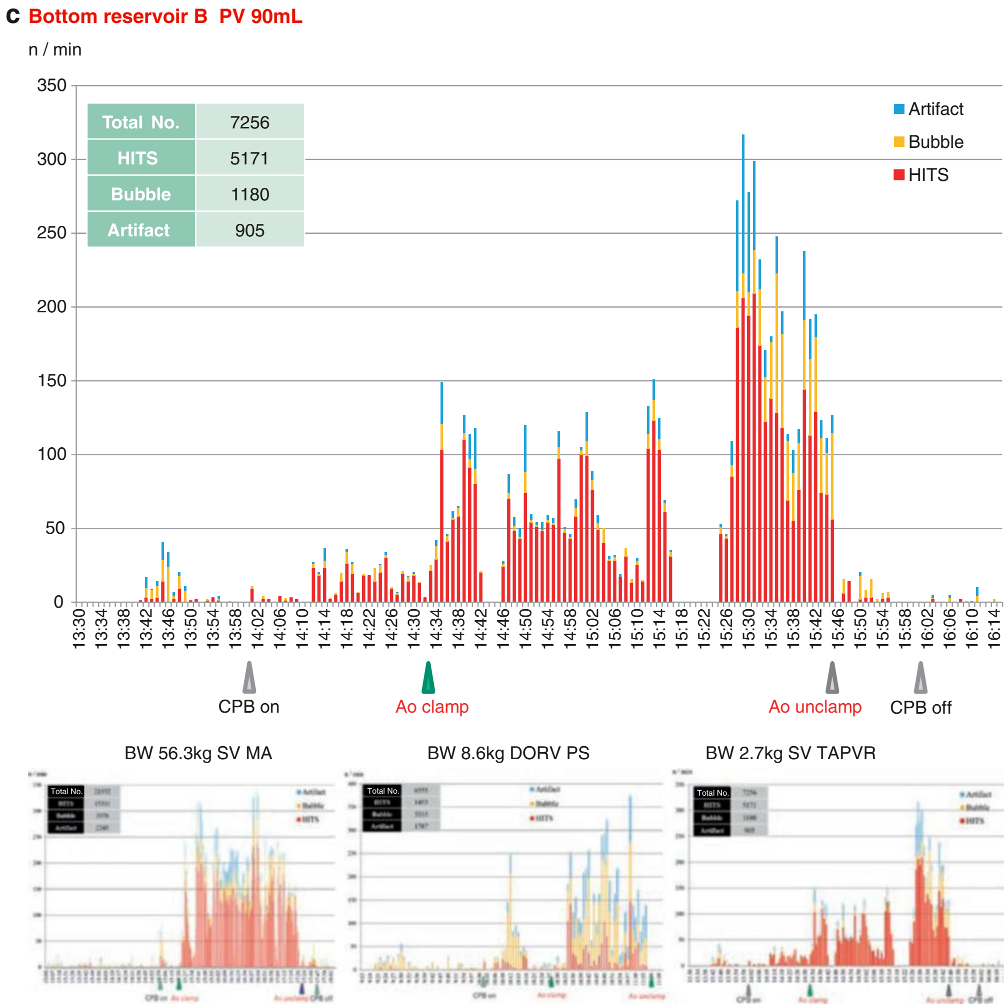


Fig. 5.84 Comparison of microbubbles among adult, infant and newborn.
(**a**) SV MA BW56.3 kg TCPC conversion
(**b**) DORV PS BW8.6 kg Intracardiac Repair
(**c**) SV TAPVR BW2.7 kg PV-LA anastomosis and RV-PA shunt

Fig. 5.84 (continued)



effects of extracorporeal circulation. In particular, microbubble suppression may be important in newborn susceptible to SIRAB, such as enhanced edema and reduced diuresis [11–14].

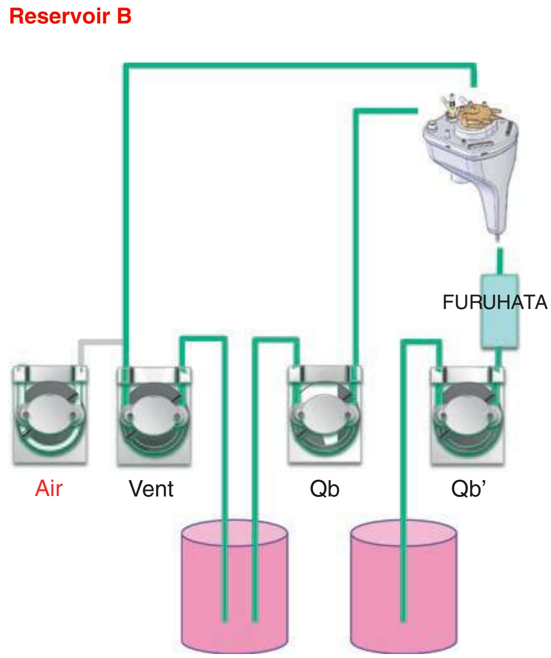
5.5.10 Conventional Extracorporeal Circuit

It was confirmed that many microbubbles were generated than expected even with the newly developed oxygenator and reservoir. Then, was the generation of microbubbles in the conventional extracorporeal circuit more than that?

The simulated extracorporeal circulation circuit (semi-closed circuit using a soft reservoir, refer to Video 2.1) used in 1995 was created for the experiment. Air was mixed with vent blood and injected into the cardiotomy port, and the number of microbubbles flowing out of the reservoir was measured. In the currently used Bottom release type reservoir, the number of microbubbles increased with decreasing reservoir level (Fig. 5.85). On the other hand, in the semi-closed circuit using the soft reservoir, the number of microbubbles decreased significantly when the cardiotomy reservoir level was high (Fig. 5.86).

Conventional Circuit, Conclusion 10
The semi-closed circuit using a soft reservoir has a larger blood storage capacity with the cardiotomy reservoir and the soft reservoir than the current circuit and also has a difference in blood flow dynamics and flow velocity dynamics of circulating blood. It is thought that they led to a decrease in the number of microbubbles. The semi-closed circuit used in 1995 may have generated less microbubbles than it did today.

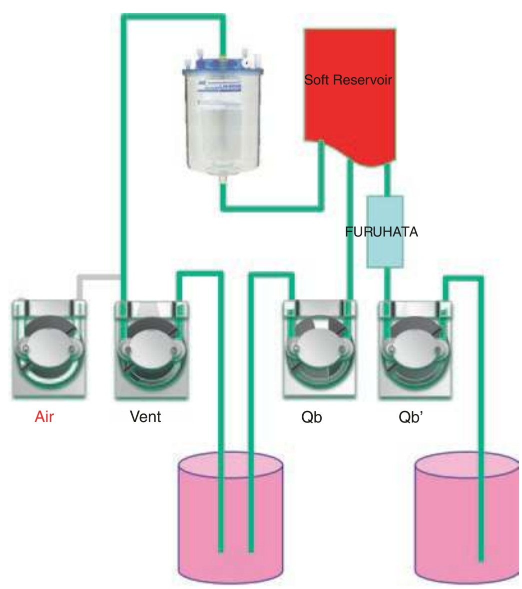
Fig. 5.85 Number of microbubbles generated using the current CPB circuit



	Flow [L/min]
Qb,Qb'	0.9
Vent	0.1
Vent Air	0.4

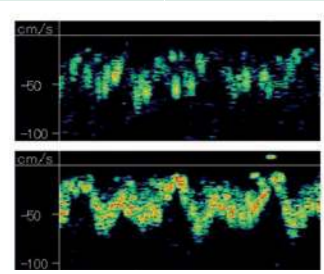
Level (mL)	No.of Microbubble [/min]
	Current CPB Circuit
200	278
150	304
100	369
50	403
20	418

Fig. 5.86 Number of microbubbles generated using the conventional CPB circuit



	Flow [L/min]
Qb,Qb'	0.9
Vent	0.1
Vent Air	0.6

Reservoir Level	Microbubble [/min]
High Level	9
Low Level	169



5.6 Microbubble Summary

It is easy to imagine that microbubbles may be involved in lesions that do not appear as clinical findings. Microbubbles are not originally present in the blood vessels of a living body and should be considered as one of the invasive factors. In particular, the control of microbubbles in newborns and the elderly will be an important issue in the future.

Q&A: Enhancement of SIRAB

Question: Do microbubbles in vivo enhance SIRAB?

Answer: To be clear, I do not understand. Since the start of microbubble measurement in clinical practice in 2015, there have been no complications of the cerebral nervous system, such as delayed arousal from anesthesia, convulsions, and paralysis. In addition, there was no impression that the problem of increased postoperative edema or decreased diuresis was significantly increased in cases where the number of detected microbubbles was high.

Until now, the main focus of SIRAB suppression in extracorporeal circulation has been to reduce the surface area of contact with blood cells. However, when you think about it, nothing was in contact with blood cells as much as the air mixed into the circulating blood. Regarding microbubbles in extracorporeal circulation, the era of the bubble oxygenator probably had many problems with the cranial nervous system. However, even in the current extracorporeal circulation, the suppression of microbubbles is considered to be an issue to be noted as a measure against SIRAB. In addition, the reduction in priming volume for expanding the indications for bloodless open-heart surgery and the management of extracorporeal circulation at low reservoir levels may have created a considerable disadvantage for the generation of microbubbles.

Involvement of microbubbles in extracorporeal circulation in SIRAB pathology includes, in part, the development of inflammation and increased vascular permeability as a result of the occlusion of capillaries. The other is the inflammatory response caused by contact with blood cells. Regarding the former, clinical studies are needed to determine whether suppressing the inflow of microbubbles into the body will lead to SIRAB suppression. However, regarding the latter, since air already comes into contact with circulating blood in the reservoir, it may not be meaningful to examine the relationship between the number of microbubbles flowing into the living body and SIRAB. Creating research protocols is difficult. However, there has been no comparative factor of microbubbles in SIRAB studies so far, so we would like to proceed in the future [15–17].

5.7 PART II Summary

This chapter described Pitfalls in the current extracorporeal circulation. While new devices have useful benefits for minimal invasiveness, they also have new and notable problems. It is a deviation from "Constant Perfusion."

In the Bottom release type reservoir, the correction fluid flows out at a high concentration. It is also conceivable that there is a common blood flow dynamic between this and the mode of movement of the microbubbles that can be understood from the structure of the reservoir. In order to maintain "Constant Perfusion," it is necessary to sufficiently consider the characteristics of the device, and also to consider a new management method that makes it easy to manage "Constant Perfusion." Newly occurred Pitfalls and the increase in the number of microbubbles may be the result of a demand for miniaturization, and we think that it is particularly necessary to reflect on them.

Extracorporeal circulation is the greatest invasion of the body. Fluctuations and inflammatory reactions that occur in the circulating blood naturally increase over time. Therefore, the longer the time, the more countermeasures and corrections must be performed. Figure 5.87 shows the progress of the number of microbubbles in a Coarctation complex case. The aortic cross-clamp time was 50 min, and the extracorporeal circulation time was 76 min. As the extracorporeal circulation time becomes longer, the number of scattered microbubbles naturally increases. Considering the microbubble dynamics, shortening the operation time is essential as a minimally invasive measure. In the next chapter, we will discuss the most basic and simple minimally invasive measures, time reduction and team development.

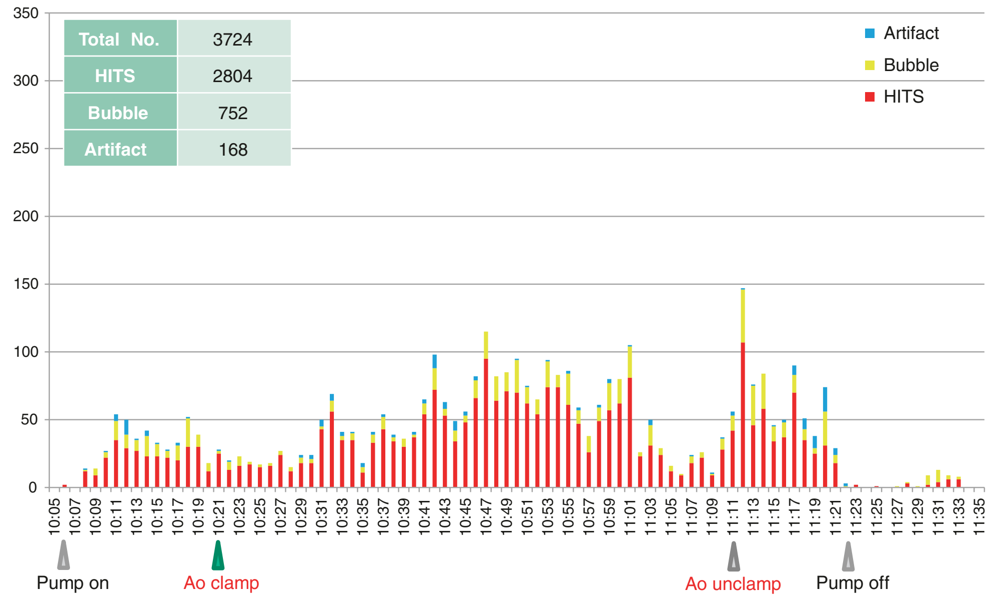


Fig. 5.87 BW3.5 kg coarctation complex. One-stage intracardiac repair was performed under cardiac arrest

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Part III

Minimally Invasive and Time Saving

6 Time Saving and Team Development

Contents

6.1 Time Saving and Team Development

Postoperative edema and decreased diuresis, which pediatric cardiac surgeons dislike most, are still present. There is no doubt that these phenomena are mainly due to biological invasion associated with extracorporeal circulation. Therefore, as mentioned in Parts I and II, each team member should first become familiar with the measures to reduce the invasiveness of extracorporeal circulation and their pitfalls. However, the staff involved in cardiac surgery should not forget that as long as the surgery and anesthesia itself are invasive, not just the extracorporeal circulation, they should strive to reduce their duration. And, as long as cardiac surgery is called team medical care, it is naturally necessary to make efforts to improve the clinical ability of each member.

In 1999, the number of operations for congenital heart disease at our hospital exceeded 300 cases a year, and it became difficult in terms of operation planning and bed control in the ICU. In addition to the minimally invasive measures for early recovery of the patient, we began to think about countermeasures for never refusing surgery requests for children and allowing our team members to perform many operations with time to spare.

I have received a lot of questions in my lectures on the themes of surgical techniques, extracorporeal circulation, and the education for youth. In this chapter, I will discuss the most basic and direct means for minimally invasive, time saving and team development, including their background.

6.2 Objective of Time Saving

1. Extracorporeal circulation is a non-physiological circulation. So, It is necessary to shorten the time, especially in consideration of systemic organ dysfunction associated with SIRS and possible complications. In pediatric cardiac surgery, it may not be an exaggeration to say that only time reduction is a minimally invasive measure.

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2. It is very rude to refuse a request for surgery, both for the sick child and for the doctor who requested it. In addition, surgery must be performed at the most appropriate time for the child without delay. Time reduction is also necessary from the viewpoint of surgical planning and Fast Track.
3. All planned operations must be accomplished without problems. The shorter the operation, the more free time the team staff can have. Shortening the time also makes medical staff less invasive. Performing many surgeries with good results, giving team members time to spare, and giving them a sense of job satisfaction are the qualifications that a surgeon should have. This is a prerequisite for many young people to gather, and it will change to an operating room where sufficient training can be provided.

Q&A: Time Saving(Question in 2009)

Question:Does reducing time really minimally invasive?

Answer: From the perspective of SIRS, the duration of extracorporeal circulation and the degree of increase in inflammatory response parameters are not necessarily proportional, and in actual clinical practice, there are many cases in which early ventilator weaning is possible even if the surgery duration is long. In addition, there are, of course, cases where a rather complicated and time-consuming surgical procedure is selected in consideration of the QOL of the patient in the remote period after surgery, and there is also a time frame during which a procedure is performed slowly. I think these are proofs that safer extracorporeal circulation management has become possible. However, most papers on surgical outcomes still conclude that the duration factor is a significant risk of mortality and morbidity. It is easy to imagine that shorter duration for repair is less invasive, and there is always the "duration" to significantly increase mortality, especially in small children with poor preoperative conditions.

In this lecture, I talked about various measures against SIRS. I think there is no doubt that each devised measure leads to the current clinical effect, but SIRS is complicated by invisible complex factors, and it is difficult to solve all of them. However, is not time saving a simple measure that can be made possible by individual efforts? If the Jatene procedure can be completed within 30 min of extracorporeal circulation, then SIRS measures need not be considered difficult. On the other hand, time saving for team members who are forced to undergo emergency surgery and who are extremely busy is important to ensure sufficient private time. In this sense, it can be definitely declared that time saving is equal to being less invasive. It is not a bad thing to spend time on an important procedure, but I think there are cases that slow speed may not be allowed.

6.3 Explanation of VSD Surgery Video

This will be an explanation of a video recording of open-heart surgery in a VSD infant weighing 12.2 kg from four directions (Video 6.1). The course of the operation and points to be noted are explained from the viewpoints of the surgeon, the first assistant, the second assistant, and the scrub nurse. Figure 6.1 shows chart of anesthesia and extracorporeal circulation, and the way of thinking that each team members should consider and share with each other.

Important points to reduce operative time for VSD closure include several things (Fig. 6.2).

From the standpoint of surgeon,

- It is mandatory for surgeon to finish closing the VSD within 20 min which is the interval between cardioplegias. Also, the surgeon should get accustomed to a small skin incision technique. These things can also lead to reduction of the time required for hemostasis and the chest closure.

As for anesthesiologist,

- He (or she) must make an effort to reduce the time to establish arterial and venous accesses. For instance, for uncomplicated cases such as VSD, central venous access can be replaced by external jugular venous line. This makes the time required for the total anesthetic induction about 10–15 min.

As for perfusionists,

- They need to appropriately take preventive measures against SIRS and conduct a fundamental CPB procedure appropriately so that patient can have a stable hemodynamics and respiratory function after operation even for a short CPB.

As for scrub nurse,

- He (or she) must make an effort to reduce the time of each procedure. In particular, read the flow of surgery and devote himself (herself) to smooth handing over of the surgical instruments.

What is needed first is that all of the staffs in the OR think how to reduce the operative time and improve their skill for that sake in this VSD closure which is the most basic procedure in congenital heart surgery.

The establishment of this system leads to minimally invasive procedure for high-risk patients.

		In 0	10	20	30	40	50	60	Out 70 min
	Anesthesia Time	Intubation		incision, on	Ao clamp	unclamp, off		end	
					CPB				
Temperature (°C)		36.3		36.2	35.4	36.0			
Blood gas	Na (mEq/L)	138			136		136		
	K (mEq/L)	4.2			3.8		3.4		
	B.E.	–3.2			–3.9		–1.2		
	Hct (%), Hb (g/dL)	33.0, 11.1			24.0, 8.3		23.0, 8.1		
	T.P. (g/dL)	5.8			4.8		4.3		
Correction	25% albumin (mL)								
	Ringer (mL)				60				
	10% NaCl (mL)								
	KCl (mEq)				4	2			
	D-mannitol (mL)				15				
	$NaHCO_3$ (mL)				15, 5				
	C.H. (mg)			2	2				
	$CaCl_2$ (mL)				3				

Initial priming solution Priming volume 175mL Perfusion rate 2.5L/min/m²

Ringer sol.	Heparin	Salin HES	Meylon	Mannitol
96mL	1200u	60ML	–	18mL

Ao Clamp 9min, CPB 19min, Operation 39min, Anesthesia 70min
Urine Output 3mL, ECUM 292mL, Fluid Balance –79mL, Final Dilution Rate 10.7%

Fig. 6.1 Chart of anesthesia and extracorporeal circulation in VSD infant weighing 12.2 kg

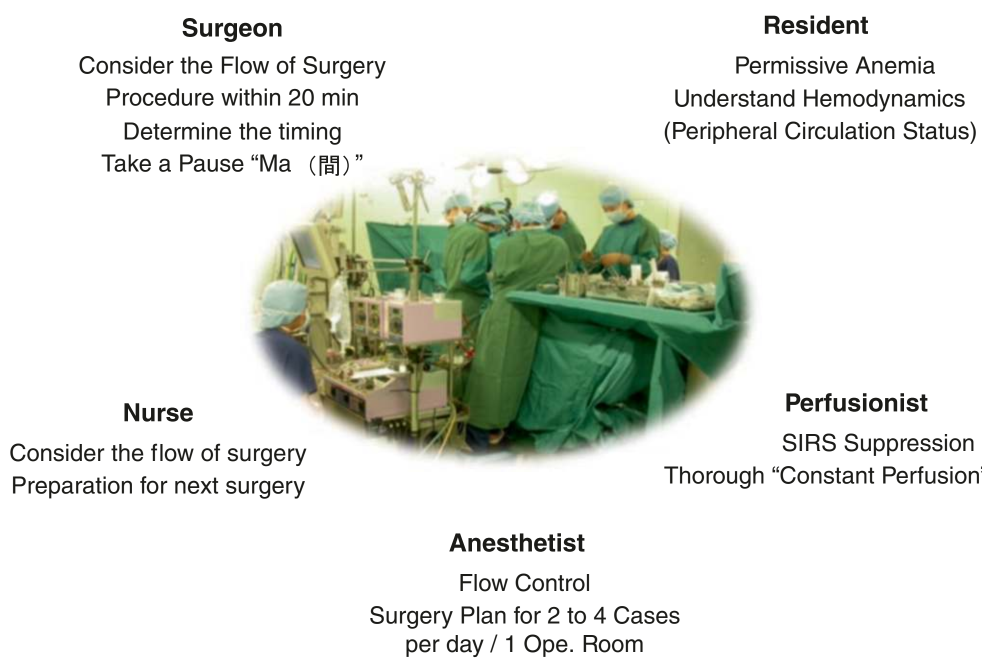


Fig. 6.2 Perspectives to be shared by each team members

6.3.1 From Anesthetic Induction to Skin Incision (22 min)

Anesthesia was slowly inducted with GO + sevoflurane, and a peripheral infusion route was secured. After administration of Vecuronium bromide 0.1 mg/kg and fentanyl citrate 5 γ/kg, endotracheal intubation was performed, and at the same time, an arterial pressure monitor line was secured and urination was performed. Central venous pressure was measured in the right external jugular vein. (If catecholamine is needed, insert a double lumen through the femoral vein). After induction of anesthesia, put a shoulder pillow on the back, draw a skin incision line, and scrub the hands. The duration from patient entry into the operating room to scrub-up was 10 min.

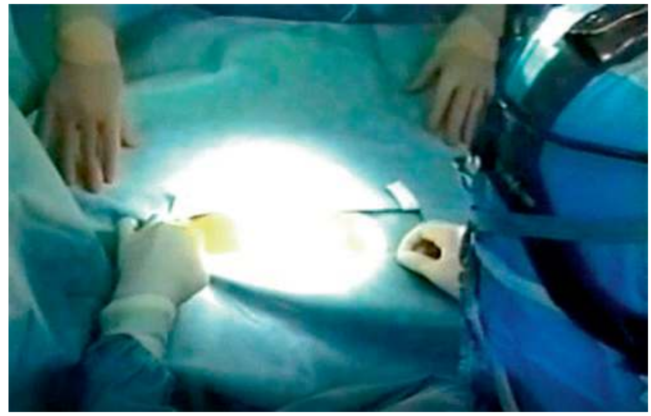


Fig. 6.3 View point 1

6.3.1.1 Viewpoint (1)

Surgeon, First Assistant, Second Assistant

1. The surgeon should know the condition of the child at the time of anesthetic induction. So, young surgeons should participate in anesthetic induction as much as possible. Not only can you get along well with an anesthesiologist, but you can also learn the actual anesthesia method in pediatric open-heart surgery.
2. The skin incision is made as small as possible on the caudal side. But, for safety and reducing the time of arterial cannula insertion, the incision was made from 1 cm towards the cephalic side of the nipple to the lower edge of the sternum and not to the lower edge of the xiphoid process. Although the position of the aorta and the height of the nipple are individually different, most surgeries for VSD's can be accommodated by this incision.

Scrub Nurse

1. Surgical instruments are packed beforehand as a set according to each procedure. Select the necessary instruments for patient's physique and prepare the minimum necessary instruments on the instrument table.
2. Prepare the minimum necessary number of double arm needle sutures. Fix sutures for the central venous line and the pericardium are attached to the needle of the forceps ahead of time (Fig. 6.3).

6.3.2 From Skin Incision to Pericardial Fixation (33 min and 20 s)

Make a skin incision of about 5 cm using a circular blade scalpel. The subcutaneous tissue is cut off with an electric scalpel. Mark the sternum incision line with an electric scalpel. Next, the lower edge of the skin incision is opened using a small retractor, and the center of the rectus abdominis and the xiphoid process are incised with an electric scalpel while pulling the lower edge to the caudal side with a muscle hook. Insert a Pean forceps in the lower edge of the sternum and incise the sternal cartilage with an electric scalpel. After that, the sternum is incised with a sternum saw while holding up the sternum with Pean forceps, and only the body at the upperside of the sternum is incised with scissors while protecting the right lung with a suction wand. The thymus is detached only on the back surface that contacts the pericardium. Make an incision in the pericardium and fix the two points on the right side of the skin.

6.3.2.1 Viewpoint (2)

Surgeon

1. Today is the era to make patients minimally invasive, including the beauty of wounds. Young surgeons should keep this in mind and become familiar with the thoracotomy method, which is the safest and smallest incision and allows the rapid establishment of extracorporeal circulation.
2. The skin incision need not extend to the lower edge of the xiphoid process. In addition, subcutaneous peeling for securing the mobility of the skin is also not necessary. This is to prevent dead space during wound closure.
3. Be careful of damage to the pericardium and heart during xiphoid incision. Also, be careful not to open the right pleural cavity during sternotomy or pericardiotomy near the diaphragm surface.
4. The areas where bleeding is likely to persist are the upper edge of the incised sternum, around the xiphoid process, and the posterior surface of the thymus. Achieve hemostasis with an electric scalpel before extracorporeal circu-

lation. Astriction is performed to the bone marrow at the upper edge of the sternum with bone wax.
5. Request the anesthesiologist to administer heparin during pericardiotomy.
6. Note the increase in superior vena cava pressure (central venous pressure) due to pericardial suspension.

First Assistant
1. Make sure that the surgical drape does not distort the skin incision line.
2. Get accustomed to the left femoral vein puncture or cut-down technique. Pay attention to the ligation strength of fixing the suture of the central venous line. If it is loose, there is a risk of accidental removal, and if it is too strong, problems will occur with injecting drugs and measuring central venous pressure.
3. When a muscle hook is applied to the upper edge of the skin incision, the skin tissue may be torn and crushed if it is strongly pulled to the ventral side. Lightly pull to cephalad.
4. When incising with a sternum saw, be careful of damaging the upper edge of the skin.
5. During sternotomy with scissors, protect the right lung with a suction wand to prevent lung damage.
6. After the sternotomy, check for bleeding sites until the surgeon fixes the pericardium to the skin.
7. When pulling the posterior surface of the thymus with a muscle hook, pull lightly to prevent bleeding from the posterior surface blood vessels and hematoma.
8. The suture used for the intracardiac procedure is easily entangled in the suture for fixing the pericardium to the skin. So the knot should be cut short.

Second Assistant
1. Prepare the extracorporeal circuit. The arterial and venous cannulas are preliminarily attached to the arterial and the venous circuit beforehand. Thoroughly remove small air. Circuits for arterial and venous, vent and suction circuits are fixed between the surgeon and the second assistant. At that time, the fixed position and the length of the circuits should be considered so that the insertion of cannulas by the surgeon and the suction by the first assistant can be performed easily.
2. After fixing the circuits, cover the circuits with a surgical drape, but be careful not to accidental removal of the central venous line. And also, be careful because the area of draping is a place where the surgical instruments can easily slip off.
3. Predict the next procedure performed by the surgeon and secure the field of surgical view beforehand. During pericardiotomy, aspirate the pericardial effusion, and when the upper edge of the pericardium is incised by an electric scalpel, the ascending aorta is protected with a tongue depressor.

Scrub Nurse
1. The smooth flow of the thoracotomy procedure makes a good flow throughout the surgery. Many surgeons have a tendency to be in a good mood if they can perform thoracotomy quickly. But, by nature, cardiac surgeons are impatient. So, it is important to be prepared to receive some cautions and treat them appropriately when participating in the surgery.
2. Prepare a double arm needle suture for closing the right pleura in case of right pleural cavity open.
3. The point of thoracotomy is how to hand over the electric scalpel, suction tube, and gauze. Promptly hand them to the surgeon's right hand. For example, the points to hand the electric scalpel are: (1) After making a skin incision with the scalpel (and then cut the subcutaneous tissue with the electric scalpel), (2) After applying a retractor to the lower edge of the incised skin, (and then incise the xiphoid process and rectus abdominis with an electric scalpel), (3) After inserting a small Pean forceps under the sternum, (and then incise the cartilage part of the lower sternal border with an electric scalpel), (4) After incising the upper edge of the sternum with a scissor, (and then achieve hemostasis of the sternum with an electric scalpel), (5) After cutting the pericardium with scissors, (and then the remaining pericardiotomy is performed with an electric scalpel). The surgeon gently puts the instruments after the procedure in front of the second assistant without directly handing over to the scrub nurse. Focus on what to hand for the next procedure, while working with the second assistant in putting them back (Fig. 6.4).

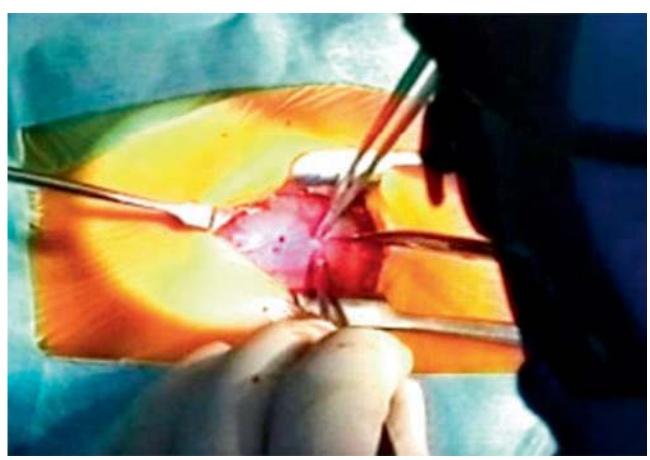


Fig. 6.4 View point 2

6.3.3 From Cannulation to Aortic Cross-Clamp (8 min 35 s)

While pulling the ascending aorta to the caudal side with dissecting forceps, double purse string suture are placed on it. And insert a 3.5 mm diameter arterial cannula. The perfusionist verifies the arterial pressure with a pressure gauge attached to the arterial circuit, and the pulsation status of the circuit is verified as well. A 6Fr Atom tube is used for the tourniquet of purse string suture. The arterial cannula and the purse-string suture are fixed with ligation by the first assistant at site of Atom tube near the ascending aorta and its peripheral side, and the arterial circuit is fixed with a towel clamp to the surgical drape at the upper side of the incised skin. During this procedure, the second assistant holds the clamp for pulling the ascending aorta and the arterial circuit so that the first assistant can easily ligate and fix them.

Next, clamp the right atrial appendage with Hanlon forceps, and the muscle bundle in the right atrial appendage is incised. Place purse string suture, and insert 16Fr venous cannula. After that, initiate extracorporeal circulation immediately. Ligation for fixing the venous cannula and the purse string suture is performed at the Atom tube portion near the heart by the first assistant, band its peripheral side by the second assistant. The perfusion flow rate is increased to half flow while slowly making a negative balance by in creasing the venous flow. Next, the right atrial wall on the cranial side of the inferior vena cava is pulled by gauze ball (Tupfer), a purse string suture is placed, and insert a 16Fr venous cannula. Under the half flow rate, check the perfusion flow of the upper and lower vena cava separately and increase the perfusion to the total flow rate. Then, taping is performed in the order of the inferior vena cava and the superior vena cava. The taping tourniquet used is a long cut No. 8 Nelaton's catheter.

Place a purse string suture on the base of the aorta and insert the cardioplegia cannula. Start cooling, place a purse string suture in the right upper pulmonary vein, and insert the left venting cannula. First, the tourniquet of the superior vena cava is squeezed, and after checking the perfusion flow, the aorta is cross-clamped. Blood GIK (15 mL/kg) is infused while increasing the left venting and overdrainaging of venous blood slightly. After confirming the cardiac arrest, squeeze the tourniquet of the inferior vena cava, and achieve total extracorporeal circulation. Verify again the condition of venous drainage.

6.3.3.1 Viewpoint (3)

Surgeon

1. In a small incision, cannulation procedure must be performed while pressing or pulling the heart. Therefore, the extracorporeal circulation should be initiated immediately after the insertion of venous cannula into the right atrial appendage. Taping and other purse string sutures should be done later. If the perfusion rate does not reach half flow when inserting the venous cannula into the inferior vena cava, taping of the superior vena cava and purse string suture for cardioplegia cannula are prioritized. Get synchronised with the perfusionist.
2. The purse string suture bites for the aortic cannulation should be thin so as not to bleed from the needle insertion site. Since the arterial cannula will be pulled toward the upper edge of the skin incision and fixed, the circuit pressure after fixation should be reconfirmed. Pay sufficient attention to the rapid increase in arterial circuit pressure, and cooperate and work with the perfusionist until the total flow rate is achieved.
3. Good venous drainage is of the utmost importance, and check not only under half flow rate but also after achieving total flow rate and total extracorporeal circulation. At this time, be careful of the central venous pressure increase in the superior vena cava even if venous drainage is good. If so, it may be solved by correcting the position of the venous cannula or removing the pericardial fixation suture. In addition, as bleeding around the venous cannula interferes with the following cannulation procedure, the purse string suture should be done with certainty.
4. The purse string suture of the cardioplegia solution injection cannula should be done so as not to approach the right coronary artery and avoid bleeding from the needle insertion site.
5. The cardioplegia solution is manually infused. Before infusion, check the back flow of the cardioplegia cannula, and infuse slowly while paying attention to the expansion of the heart.

First Assistant

1. The arterial cannula is fixed to the surgical drape with towel clamp. Check the pulsation after fixation.
2. When doing a purse string suture to the inferior vena cava and right pulmonary vein, gently pull the right atrium wall diagonally upward and ventrally with the right hand without pressing the right atrium wall dorsally, and use the suction wand to secure the field of surgical view with the left hand.
3. Ligation for fixing the venous cannula and purse string suture should be performed gently and surely so that the cannula does not collapse.
4. At the time of aortic cross-clamp, check the lower edge of the ascending aorta carefully, and clamp slowly while paying attention not to collapse the arterial and cardioplegia cannula.

Second Assistant

1. Since the venous cannula is preliminarily attached to the venous circuit beforehand, hold it during cannula insertion, so the circuit tube is not pulled, and for easy ligation for fixing by the first assistant. Also, the ligation for fixing

of the venous cannula should be performed with appropriate strength so as not to collapse the tube and the purse string suture not to come off from the tube. The primary surgeon always looks at the heart and moves forward with the procedure, the second assistant standing on the right side should ligate so as not to obstruct the surgical view of the surgeon, without squaring elbows.
2. Before starting the purse string suture of the right atrial appendage, perform a quick aspiration on that incision. And, before the purse string suture of the inferior vena cava and right upper pulmonary vein, aspirate the blood quickly in the pericardium.
3. Get used to put the purse string sutures or tape through the tourniquet (using Atom or Nelaton tube). At that time, be careful not to pull on the purse string suture or tape.
4. After the purse string suture, the primary surgeon places the needle holder with used needles in front of the second assistant. Cooperate and work with the scrub nurse to put them away.
5. After the initiation of extracorporeal circulation till the aortic cross-clamp, confirm the perfusion pressure and central venous pressure on the patient monitor screen at the upper right. Also, the reservoir and pumps can be seen on the left rear, so verify if extracorporeal circulation is well established.

Scrub Nurse

1. During cannulation, the flow of surgery becomes more complicated. As a general rule, scrub nurses do not receive the used surgical instruments, needles or sutures directly from the primary surgeon. However, only scalpels used for inserting the arterial, venous and vent cannula should be received directly. Take great care when handling the scalpel.
2. The method of holding the double arm needle depends on the surgeon's preference, but especially the needles for purse string sutures of the inferior vena cava or the pulmonary vein should be held long as close as possible to the suture. The needle tip can be pierced with a single insertion and can be easily removed. Also, when handing the double arm needle, be careful not to entangle the opposite suture with the needle holder.
3. A lot of sutures with needles will come back. This management and counting method should be devised independently. Unlike the timeframe for thoracotomy, the duration of each procedure is prolonged. So, it could be said that this timeframe is enjoyable one for observing and evaluating the skills of the primary surgeon from the side.
4. The blood used for cardioplegia is given by the perfusionist after the total flow rate is achieved and mixed with GIK solution on the instrument table. This preparation should be done promptly, but its aspiration with a syringe should be done gently not to introduce fine air.

6.3.4 VSD Closure (9 min 10 s)

After making an oblique incision in the right atrium, fix the right atrium wall to the surgeon side with 4-0 nylon suture. The first assistant pulls the right atrium wall to the left side with two eyelid hooks to to secure the field of view. Pass a right-angled clamp through the PFO, and place a 5-0 suture which is used for air venting of the left heart and closing the PFO before aortic unclamp.

Pass the suture through the tricuspid valve chordae and pull it toward the primary surgeon to observe the VSD morphology. In this case, a fish mouth-like perimembranous defect covered by a tricuspid valve and a jet lesion was closed with sutures with pledget. Prior to the final ligation, the left vent was stopped, the left heart air was evacuated from the VSD and the PFO. After that, request the anesthesiologist to inflate the lungs and confirm the residual shunt, muscle VSD, and stenosis of the right ventricular outflow tract. Since the tricuspid valve was slightly deformed by the VSD patch, the septal and anterior commissures were fixed with one suture.

6.3.4.1 Viewpoint (4)

6.3.4.2 Surgeon

1. VSD closure requires a thorough understanding of the morphology of each type VSD. However, the structures around the VSD, such as the direction of the extension, the position of chordae, and the degree of development of the TSM posterior-limb, are different in each case, and there are many complex and transition type of VSD. So, it is important not to close in accordance with each VSD type, but to learn the reliable and quick closure skills according to the actual form, i.e., no residual shunt, no damage to the surrounding structures such as the conduction system and the tricuspid chordae, and in addition, secure VSD closure within one cardioplegia re-infusion interval of 20 min. This is an important qualification for young surgeons to perform more time-consuming surgical procedures such as CoA complex or TOF.
2. The first suture is performed from the tricuspid valve at the posterior lower edge of VSD. After that, suture clockwise to the front upper edge of VSD, and finally suture posterior inferior margin of VSD counterclockwise. By pulling the suture and the tricuspid valve chordae tendineae, the field of surgical view is improved, especially in the type of VSD where the infundibular septum to theTSM anterior limb is deep or posterior inferior margin in VSD just below the tricuspid valve.
3. The sutures are ligated after confirming that the patch is sufficiently adhered to the myocardium around the VSD margin, the sutures are not loose, and the pledget, the myocardium and the patch are closely aligned. The first ligature is lightly tightened, and the second ligature is

tightened to the extent that the myocardium between the patch and pledget slightly come close.

As a general rule, ligation in the perimembranous VSD is performed clockwise from the first suture to the tricuspid valve annulus, with the posterior inferior margin last. In the case of perimembranous outlet type or CoA type VSD in which the infundibular septum is displaced, there are some cases where the ligation starts from the innermost infundibular septum or the anterior limb of the TSM. And, in the pulmonary subvalvular type VSD that closes from the main pulmonary artery incision, ligation is started from the upper edge of the medial papillary muscle where the pledget is difficult to see, with the pulmonary valve annulus last. Before closing, stop the left venting pump and evacuate air from the left ventricle while ligating the last 1–2 sutures. Check all sutures and perform additional sutures if there are concerns for the residual shunt.

4. After closure, request the anesthesiologist to inflate lungs, perform air evacuation from the PFO and cardioplegia cannula, and at the same time confirm the existence of residual shunt and muscular VSD. In addition, check for stenosis of the right ventricular outflow tract, and add myocardial resection if necessary. Also, the morphology of the tricuspid valve after closure is observed. In particular, when the space between the anterior and septal leaflet in the outlet type VSD is widened, or when the tip of the septal leaflet in the trabecular type VSD is opened by a patch, it is repaired so as to eliminate tricuspid valve regurgitation.
5. The quality of extracorporeal circulation determines postoperative hemodynamics and respiratory status. The surgeon continues to operate in cooperation with the perfusionist, considering whether or not ideal extracorporeal circulation is achieved.
6. When ligating, as a general rule, pull down the knot of the suture with the left hand. This secures the field of surgical view around the ligature and also allows to keep an eye on the second assistant and the scrub nurse. Particularly in the case of live surgery broadcast, it can provide a good field of surgical view.

First Assistant

1. Use the eyelid hook to develop the field of surgical view. By making good use of the hook on the right hand, the first assistant can grasp the internal structure of the heart and the procedure itself.
2. During the intracardiac procedures, care more about the quality of the extracorporeal circulation than the primary surgeon. The face of the perfusionist is visible over the surgeon's shoulder. Check the patient monitor screen on the right front, the CDI monitor, and the diuretic status for judging the quality.

Second Assistant

1. Hold the VSD patch so that the primary surgeon can easily put the suture through the patch. Each sutures are grasped with a Pean forceps, and the needles are cut off. At this time, be careful not to pull the sutures, because the myocardium around the VSD is easy to tear. Make the action faster than the primary surgeon.
2. Be careful of bleeding from the insertion site of the central venous line and bending of circuit tubes for extracorporeal under the surgical drape.
3. During the intracardiac procedures, care more about the quality of the extracorporeal circulation than the first assistant. The reservoir and pump can be seen at the left rear, and the quality can be judged from the CDI monitor, the upper left or upper right patient monitor screen, and the diuretic status. Cooperate with perfusionists so as to proceed the extracorporeal circulation without problems.
4. In case of long-term aortic cross-clamp time, always be aware of cardioplegia infusion intervals.

Scrub Nurse

1. The duration for each procedures performed by primary surgeon is more longer than that for cannulation. It is also the most enjoyable time to evaluate the skill of the surgeon from the side.
2. The most important thing is to hand over the instruments in order not to tear the myocardium around the VSD. When handing a needle holder with double arm needle suture for VSD suture, be careful not to pull suture, and another needle does not get caught in the surgical drape or extracorporeal circulation circuit. The angle of the needle attached to the needle holder is adjusted by the primary surgeon according to the VSD morphology, so it is only necessary to hold it at a right angle.
3. Estimate the required number of sutures. If necessary, cooperate with the second assistant and circulating nurse so as to get them available immediately or not to waste them.
4. Prepare a syringe for deaeration from the cardioplegia cannula (Fig. 6.5).

Fig. 6.5 View point 4

6.3.5 From Aortic Unclamp to Weaning from Extracorporeal Circulation (6 min 52 s)

To prevent air inflow into the coronary arteries, perform aortic unclamp while pinching the aortic root with forceps and forcing deairing by connecting the cardioplegic cannula to suction pump.

The right atriotomy is closed with a 5-0 suture. The air in the right heart is evacuated prior to total closure by partial extracorporeal circulation.

After the resumption of heartbeat, first, the tip of the venous cannula for the superior vena cava is transferred to the right atrium, and the venous cannula for the inferior vena cava is removed. Wean from extracorporeal circulation while confirming cardiac function, arterial pressure, and oxygen saturation. Remove each cannulas in the order of inferior vena cava, vent, cardioplegia, and superior vena cava. Place additional suture in each of the removed sites to ensure hemostasis. An intrapericardial drain is inserted during the weaning from extracorporeal circulation. Lastly, remove the arterial cannula after administration of protamine.

6.3.5.1 Viewpoint (5)

Surgeon

1. If residual shunt or tricuspid regurgitation is suspected, echocardiography is performed from the surface of the heart before weaning from the extracorporeal circulation.
2. After closing the right atrium, the tip of cannula for the superior vena cava is transferred to the right atrium. Doing this, additional hemostasis suture at the sites of cannula removal of inferior vena cava and vent, where the most deep sites in the pericardium are, can be reliably performed because the total flow rate can be maintained. In addition, when performing MUF after weaning from the extracorporeal circulation, be careful of the air in the venous circuit.
3. After confirming the data of blood gas with the perfusionist, start the weaning procedure. Watch out for cardiomegaly and decreased oxygen saturation.
4. Until the removal of superior vena cava cannula, perform the weaning procedure while observing whether there is blood retention in the pericardium. In particular, the removal site of the inferior vena cava cannula and the right atriotomy may bleed again even after confirmation of hemostasis. Devise a way for suturing the right atriotomy that does not bleed.

First Assistant

1. Proceed weaning while confirming not only bleeding points of the sternum but also whether there is blood retention in the pericardium.

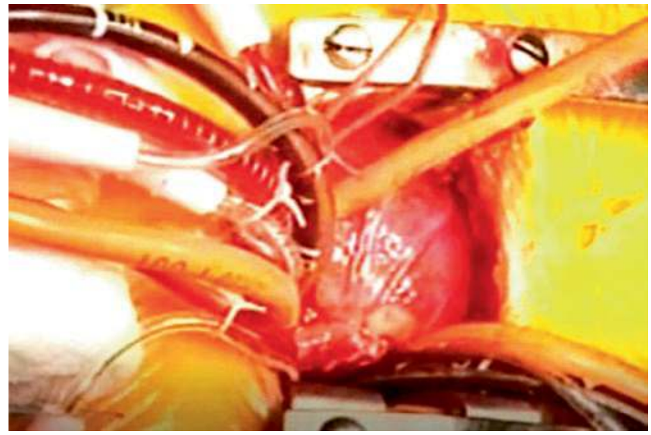


Fig. 6.6 View point 5

2. Be careful of the pulling direction and strength of the suture so that the myocardium does not tear while closing the right atriotomy.
3. Pay more attention to the quality extracorporeal circulation during weaning than that of during intracardiac procedures. Determine the appropriateness for weaning by grasping the data on patient monitor screen, CDI monitor, and diuretic status.

Second Assistant

1. Reconfirm that the central venous line is not bent under the surgical drape.
2. Pay more attention to the quality extracorporeal circulation during weaning than that of during intracardiac procedures. Cooperate with the perfusionist to determine if there are any problems with weaning.
3. Be careful not to spill residual blood in the circuit during its removal, especially on the primary surgeon's feet.

Scrub Nurse

1. When performing additional suturing for bleeding from the removal site of cannulas for inferior vena cava or vent, the primary surgeon receives the needle holder while securing the surgical view of the bleeding point with the forceps held in the left hand and immediately starts suturing. So, the needle should be held as long as possible near the suture. The needle tip can be pierced with a single insertion without having to re-hold the needle and can be easily removed.
2. Prepare beforehand the additional sutures for bleeding. If the used double arm needle has long suture remaining on one side, it should be used. But be careful so you do not lose the needles (Fig. 6.6).

6.3.6 Chest Closure (11 min and 13 s)

The rectus abdominis muscle was closed with No. 2 nylon suture, the sternum was closed with three 0.8 mm wires, and the wound was closed with an interrupted and buried suture method by two layers.

6.3.6.1 Viewpoint (6)

Surgeon

1. At the upper edge of the sternum, be careful not to create dead space, and also suture not to bulge the skin after legation by piercing the needle too deeply.
2. Hemostasis points are the upper edge of the sternotomy, the insertion sites of the pacing wire and the drain tube, and the posterior surface of the thymus. In case of hematoma, the posterior surface should be removed.
3. Cardiac pacing after surgery is almost unnecessary, but if there should be any concern, pacing wire should be inserted.

First Assistant

1. Help with the chest closure, checking for persistent bleeding from the sternum or in the pericardium. Prior to sternum closure, confirm whether or not there is blood retention in the pericardium.
2. Make sure that the sutures on the rectus abdominis muscle are not tangled up with the drain tube.
3. During muscular suturing, the primary surgeon pierces the needle through the periosteum on the surface of the sternum for preventing dead space. When ligating, ligate it so as not to come off the sternum by pulling strongly.

Second Assistant

1. Hand the extracorporeal circulation circuit to perfusionist. Be careful not to spill blood and to be filthy or spill on the surgeon's foot.
2. After closing the sternum, attach a suction to the drain tube for verification of bleeding and blood properties in the drain.
3. During chest closure, confirm that the hemodynamics is becoming stable, such as an increase in blood pressure, a decrease in heart rate, and an increase in peripheral temperature. In addition, estimate the amount of fluid replacement for postoperative ICU care by checking the volume of residual blood and predict the time for weaning from the respirator. Furthermore, from the perspective of the second assistant, consider ICU bed control for the next day.
4. If you are tasked with closing the chest, show off to team members that you can do better than your seniors. However, re-operation due to bleeding is out of the question.

Scrub Nurse

1. When suturing the muscle or skin, the number of interrupted sutures increase. So, quick threading of the needle and handing are required. But be careful for needle stick injury. These skills can be acquired in actual surgical situations. Therefore, training for each procedures are not so meaningful, but only training for threading the needle would be necessary in advance.
2. Check the number of suture needles and gauze in collaboration with the circulating nurse (Fig. 6.7).

Fig. 6.7 View point 6

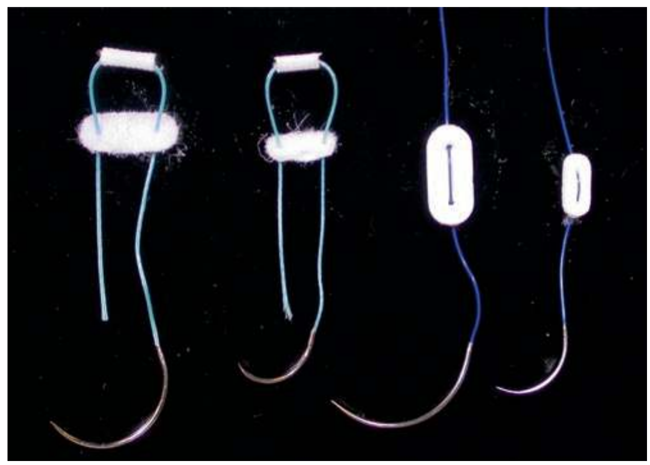


Fig. 6.8 Sutures for VSD closure

Column: Creativity and Originality

It has become common now, but there is a unique device of the Sakakibara Heart Institute from the 1980s. One is a suture for closing the VSD. At that time, there were many adult cases, and they used three types of pledget sutures; large, medium and small sizes. At present, there are two types shown in Fig. 6.8, which are used according to the disease and physique and set for a minimum number of usage.

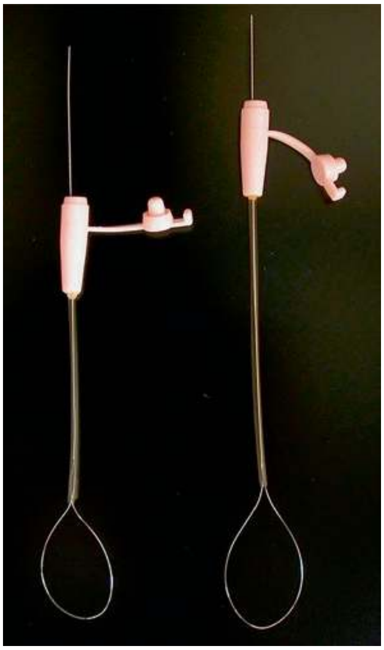


Fig. 6.9 Tourniquet. It was developed with the idea of Dr. Katsuhiko Tatsuno. Used since the 1980s

A 6F Atom tube (Fig. 6.9) was used as a tourniquet for the drawstring suture (currently a marketed product). In particular, the surgical field of view for small incisions is better than that for Nelaton tubes (Fig. 6.10). Figure D shows the hand movements of the surgeon and the scrub nurse. The surgeon places the used instrument directly on the operating table without handing it to the nurse, so that the nurse can hand over the next instrument more quickly (Fig. 6.11).

Q&A: Time Saving from the Standpoint of Circulating Nurse (Question in 2011)

Question:I am a first year nurse after graduation. I was assigned to the operating room. Currently, I am studying as an apprenticeship for circulating nurse. Please tell me how to save the time that the circulating nurse should learn.

Answer: I have said several recurring complaints when operating with a new circulation nurse, as follows: (1) When DC could not be prepared in an emergency, (2) When additional sutures or devices required could not be prepared immediately, (3) A large amount of air bubbles were added when mixing the cardioplegia solution and blood. (4) When

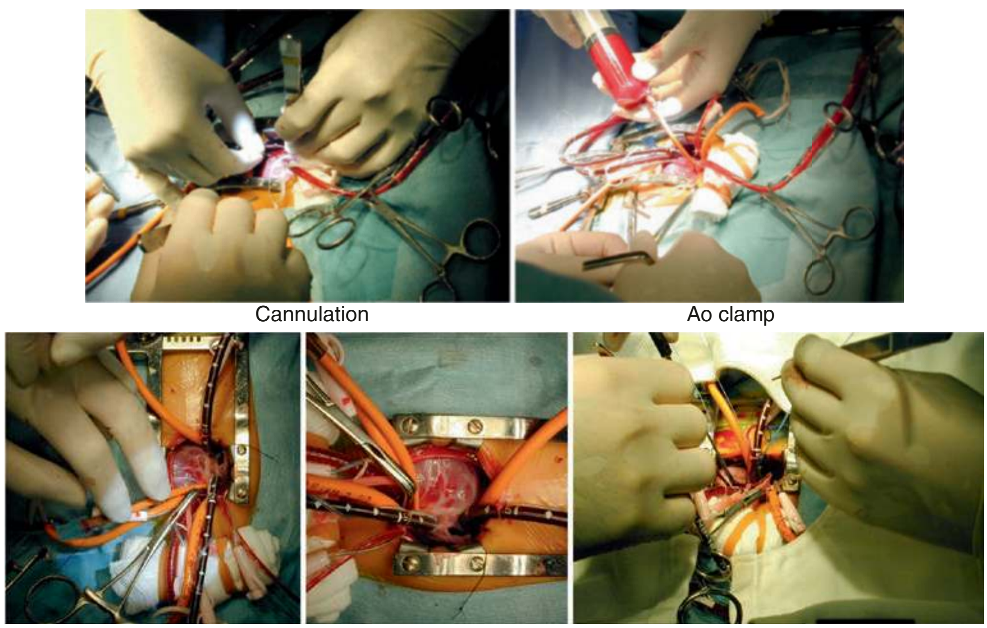


Fig. 6.10 Surgical field in a case of VSD weighing 4.1 kg ([1] modified). Since the PLSVC diameter was small, the VSD was closed with Nelaton tourniquet shut off. For small incisions, it is necessary to ensure a visual field so that tourniquets and venous cannula are not in the way

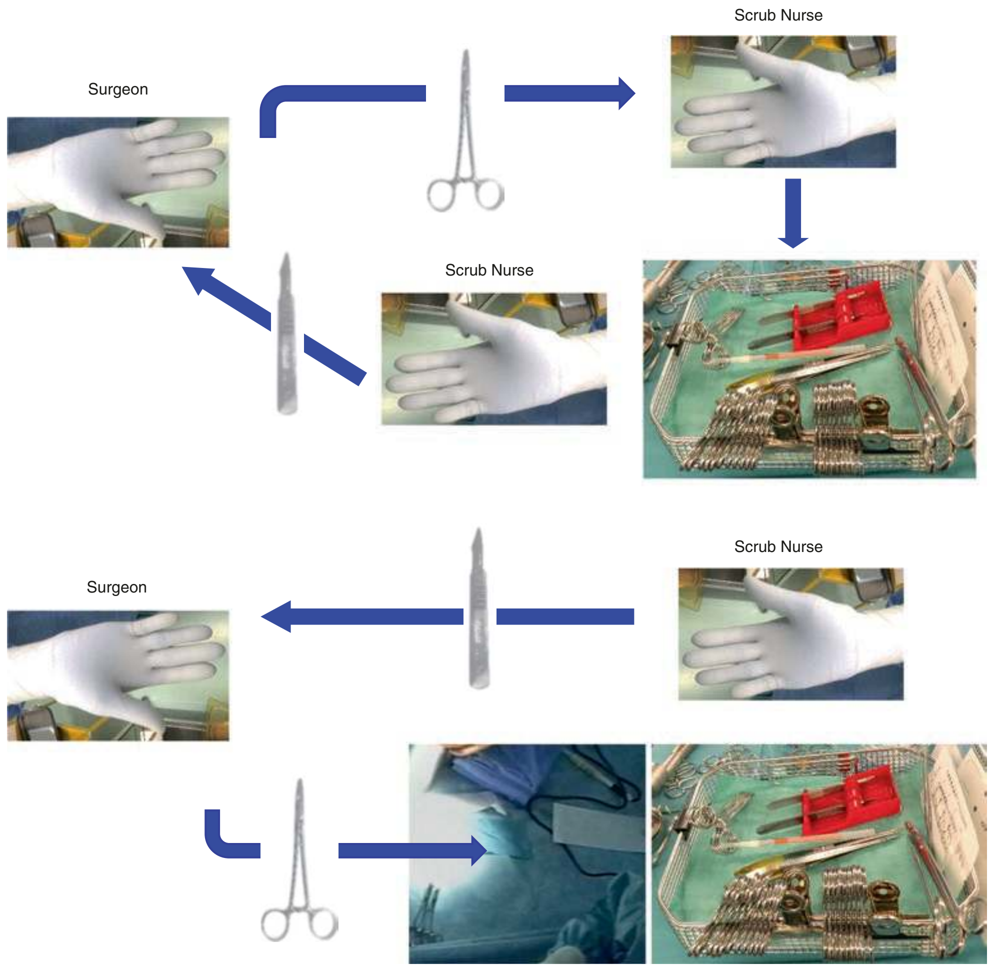


Fig. 6.11 Handing of surgical instruments. When the surgeon gives the used equipment to the scrub nurse, it takes more time for the nurse to put the equipment on the equipment table and take the next equipment. Placing it directly on the operating table allows the next device to be immediately received from the scrub nurse

the newborn's arterial line is loosely fixed and accidentally removed. However, these are not really a problem as they will get used to them eventually.

Regarding the proposition of saving the time, you will be able to smoothly perform various surgical procedures in the future, and as you think that your power has been added to the lifesaving of severely ill patients, you will feel a great attraction to surgery. However, that is still a mere learning of the basics, so to speak, "it made just one point." What is important is whether or not it is possible to make an action by connecting a line between each of those acquired points. For example, during surgery, you will hear conversations between surgeons, anesthesiologists, and perfusionists, as well as data on hemodynamics and respiratory status, and blood data. You may be able to understand each one. But not only that, it is more important to comprehensively judge the present status of the patient and the quality of treatment, such as, "is Constant Perfusion working?" and "Are SIRS measures working well?" To put it more simply, It means whether or not you can understand what good anesthesia is without experience of anesthesia, what bad extracorporeal circulation is without its experience, and what good surgery is without detailed knowledge of surgical procedures.

When it comes possible to evaluate or criticize each other's actions during surgery from each position, it will be unnecessary to rely on the manual at all. As a surgeon, at this point, I feel that the "hands" of the team had been trained, and we can make progress as a new team. Especially if the circulating nurse can judge the treatment from the same viewpoint as the surgeon, I personally admit that it is a fascinating "Nurse Practitionaer" of surgery. This is a non-technical skill in the original sense.

I may have been little off the topic, but this is the basis for saving time. I would like newcomers to get used to saving the time in this sense. It is more important not just to rush to save time, but gaining non-technical skills early on allows you to have the time for your work and to have the feeling that it actually led to a reduction in time. If you go that far, you will be able to cope with the occurrence of irregular clinical events and eventually improve the overall quality of surgery. However, this is impossible to learn unless you are in the operating room, and you cannot learn unless being proactive. Please do your best.

Q&A: Saving Time from the Perspective of a Perfusionist (Question in 2012)

Question:It has been 5 years since I became a perfusionist. I think that the only way to shorten the operative time is to leave it to the surgeon, but is there anything I should think about time saving as a perfusionist?

Answer: As you say, the protagonist of saving time is the surgeon. The longer the extracorporeal circulation time, the greater the possibility of SIRS exacervation and the need for unnecessary correction management during extracorporeal circulation, so, I know well that you are screaming in your heart to “do it fast.”

In this lecture, I talked about the importance of “Constant Perfusion.” First, from this perspective, I would like to talk about the opposite of saving time. In other words, it is a situation where you should not save time as as a perfusionist. The first is to start the extracorporeal circulation slowly so as not to cause initial drop, and the second is to confirm the good venous drainage not only at the half perfusion flow but also at the total flow and after achieving the total extracorporeal circulation. It is most important to confirm these issues completely before the aortic cross-clamp. So it is not a problem to ignore any complaints from the surgeon during these times.

The most important thing in saving time as a perfusionist is to have confidence such as “I can manage the extracorporeal circulation that leads to good postoperative circulation and respiratory status, so, as a result, it is possible to not only shortening the operative time but also reducing the postoperative management time.” As I mentioned, thorough ”Constant Perfusion” that eliminates non-physiological fluctuations in the living body will actually lead to the time saving.

But one last thing to say. When saying, “Let’s start weaning,” but the reply is “Rewarming still takes time”… “Oh no, give me a break….”

Column: The Flow of Surgery

“What is the most important thing to create a good flow in surgery?” is a question frequently asked not only by young surgeons but also by nurses and perfusionists.

To be honest, I do not have the answer for this question. Surgery is a process of completing one procedure after another by assisting the strong-headed primary surgeon. If a surgery does not flow smoothly when a certain staff member joins the surgery, the reason for the poor flow is the person who cannot cope with the flow and not the surgical method or the person managing the flow. This is definitely true. What is more, one often hears comments that someone works well with a particular primary surgeon but not with another surgeon. In that case, this person is not qualified to participate in the surgery. Therefore, if you feel that you have some shortcomings, you just have to work hard to improve them.

I will tell you an episode that in one of my presentations on “The flow of surgery,” someone made a challenging comment: “I absolutely cannot understand what you are saying.”

There are different flows of surgery. One kind of flow is like: “If you eat rice according to the amount of dishes you have, you end up having rice left over.” Or you can have a flow like this: “You are extremely hungry and start eating rice first, leaving the dishes behind. Then when you are finishing off the dishes, for some reason you feel you have benefited.” Although both are not very good manners, the way of deciding the flow of surgery is probably something like this.

Certainly, they are difficult to understand, but at least it is impossible to maintain the high energy flowing into surgery continuously from the beginning to the end. On the other hand, it may be unforgivable to relax and lose speed just when the goal is in sight. In short, it is important to learn about “the flow that is considered good manner surgically” in terms of taking actions appropriate to the circumstances. I think it is necessary to get used to not putting very important things and less important ones together indiscriminately. However, we must not forget that to acquire the flow of surgery, the biggest difference between newcomers and veterans is the difference in the amount of information and the amount of knowledge.

Column: Anesthesiologist “Dr. Ayako Takao”

For the past 15 years, I have asked Dr. Takao to anesthetize more than 500 cases of pediatric heart surgery each year. She is the best “monster” anesthesiologist in Japan. The other day, I asked her what the knack of anesthesia for open-heart surgery in low-weight infants is. Her reply was, “everything is speed and timing! Recent surgeons are not good!” A little understandable, but completely mysterious answer….

Speaking of which, in a lecture on the theme of team building and time saving for pediatric heart surgery, I said that my colleague anesthesiologist does not react after seeing, listening and thinking, nor is reacting via the right frontal lobe. Maybe she is using the spinal primordial reflex to respond. I remember I was frowned upon by the audience.

I would be glad to have newcomers joining the Sakakibara Heart Institute to experience the feeling and practice created by Dr. Takao, that it is natural to plan three to four heart cases in one operating room and end at 17:00. Perhaps a slightly exhilarating sensation will emerge. However, at the same time, a sense of rigor and awe-inspiring of work also appears. Learning a job also means learning how veterans use their time.

6.4 Significance of Time Saving

As with extracorporeal circulation, as long as the surgery and anesthesia themselves are also invasive, the fast and efficient surgery obviously leads to less invasiveness. Therefore, surgeons must strive to reduce this duration. Nowadays, a safer extracorporeal circulation management become possible, so, it is said that taking time to ensure repair is rather important. However, I think that if the surgeon in charge of the operating room is not hung up on saving time, there would be no progress of the surgery team. Particularly, in the open-heart surgery for VSD, which is an r basic procedure, there is no doubt that thorough revision of the points of concern as a team will develop a stronger team in case of performing more complicated surgeries for poorly ill babies. In addition, a young surgeon`s ability to complete VSD repair in a short time is a certification for allowing to operate more complex procedures. However, more than that, I think that the team should share the awareness that thorough management for stabilizing hemodynamics and respiratory status can lead to time saving as a result. So, of course, it is necessary to develop less invasive measures in perioperative management with the progress of time saving. However, even if the time is shortened, it is meaningless and counterproductive to cause an increase in medical expenses and a decrease in safety. This is the most important thing to keep in mind when saving time.

In 1996, three cases of infant VSD developed transient postoperative seizures, as shown in Column "Postoperative Seizures." One of the possible reasons was the long duration of extracorporeal circulation and operation. Prolonged duration of extracorporeal circulation can certainly contribute to cranial nervous system disorders. It is said to that the cause of periventricular leukomalacia is not only hypoxia or hypotension in the early postoperative period but also a prolonged extracorporeal circulation. In 19 cases who underwent bloodless open-heart surgery weighing 3.6–6.2 kg in 1997–1998, a significant correlation was found between the postoperative duration of intubation and the anesthesia time (Fig. 6.12). Until now, we have aimed at minimizing invasiveness from the viewpoint of suppressing SIRAB and reducing blood transfusion by miniaturizing extracorporeal circulation devices. However, as long as it is said that the surgery itself is invasive, we have to consider the overall reduction of surgery time, which is a direct basic invasive measure for infants. In addition, time saving is essential to deal with the increasing number of surgeries. Therefore, first, reducing the operative time of VSD repair was the issue for the operation team, also including pediatric cardiologists. However, on the other hand, there were some negative opinions about time saving for reasons of safety management or accident prevention, and surgeries should be done slowly but surely with plenty of mental leeway. However, originally, the safety in cardiac surgery means that the members of the surgical team become accustomed to the flow of the operation and to enhance and maintain their skills. I thought it was more important to gain a lot of experience intensively in a short period, and of course,to share the significance of time saving as a team.

In a study of VSD bloodless open-heart surgery under 5 kg, time on ventilator and inotropes, length of ICU and hospital stay were all positively correlated with the operative time (Fig. 6.13). Even if operation has been completed safely, the possibility of cerebral injury or cardiorespiratory compromise is a non-zero. Even in short-time open-heart surgery such as VSD repair, time reduction is necessary.

In a study of Jatene's operation for neonatal TGAI, the anesthesia time correlated more strongly with the time of chest closure (Fig. 6.14). This was considered to be the difference in the time required for hemostasis. Figure 6.15 shows the operation and anesthesia time. Lactate levels just after surgery correlated not with extracorporeal circulation time but with chest closure time. These suggested that it was necessary to ensure hemostasis and reduce the time for chest closure.

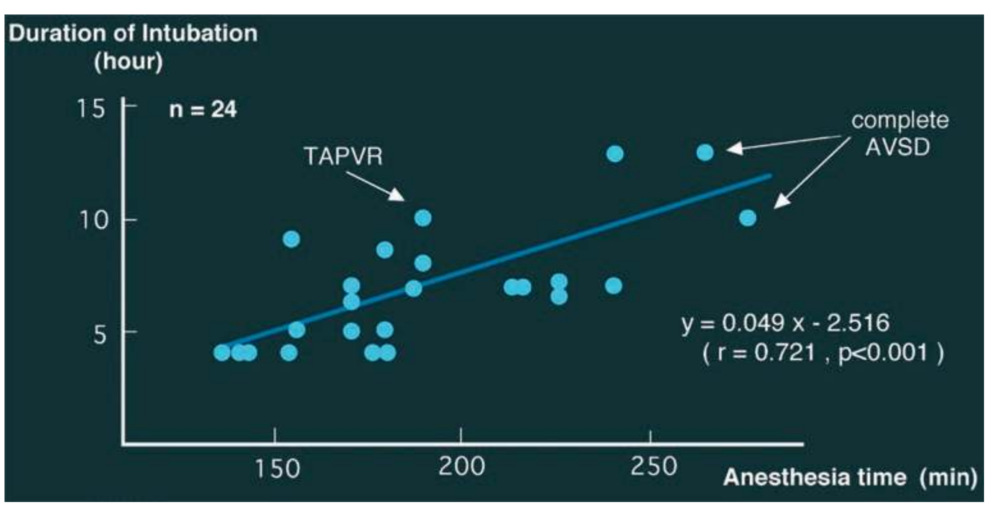


Fig. 6.12 Relationship between postoperative duration of intubation and anesthetic time

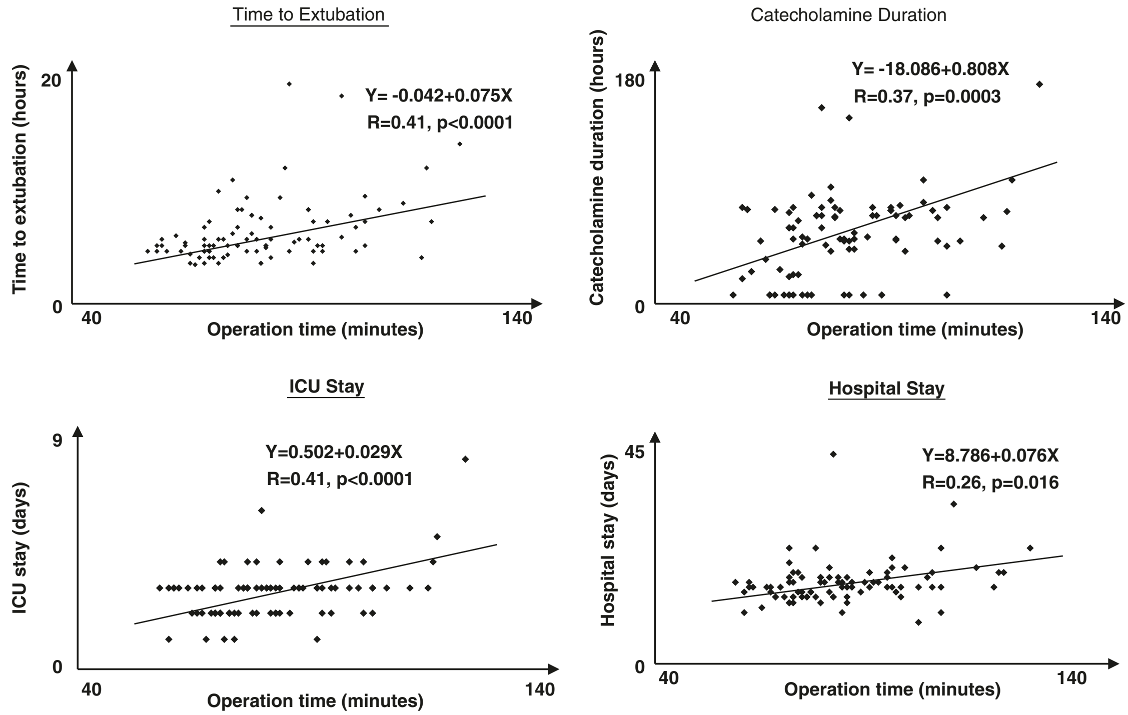
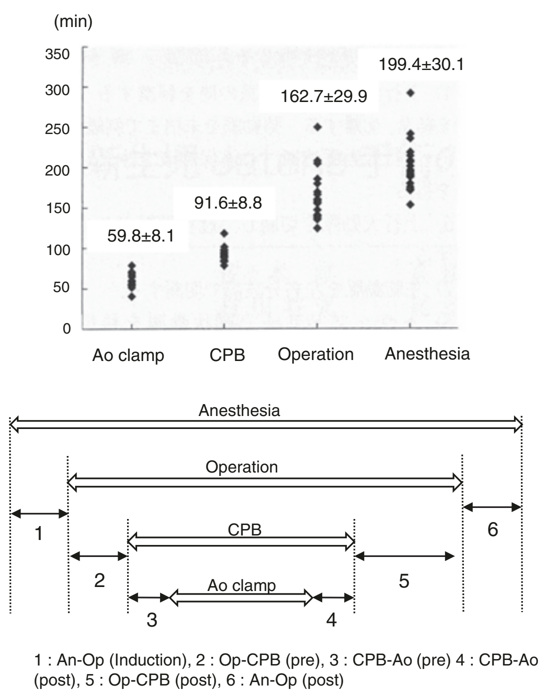


Fig. 6.13 Relationship between operative time and postoperative recovery in VSD infants ([2] modified). 90 cases of VSD weighing less than 5 kg who underwent bloodless open-heart surgery. Weight 4.1 ± 0.7 kg, aortic cross-clamp time 28 ± 8 min, extracorporeal circulation time 46 ± 10 min, operative time 80 ± 13 min



	Duration (min)	r	p
Anesthesia (An)	199.4±30.1	-	-
Operation (Op)	162.7±29.9	0.984	< 0.001
CPB	91.6±8.8	0.734	< 0.001
Ao clamp (Ao)	59.8±8.81	0.658	0.002
An-Op	36.7±5.3	0.149	0.530
An-Op (pre)	27.4±5.0	0.13	0.585
An-Op (post)	9.3±2.3	0.062	0.795
Op-CPB	71.2±24.6	0.931	**< 0.001**
Op-CPB (pre)	13.2±2.5	0.405	0.076
Op-CPB (post)	58.0±23.9	0.919	**< 0.001**
CPB-Ao	31.8±5.3	0.208	0.379
CPB-Ao (pre)	13.6±2.4	0.088	0.712
CPB-Ao (post)	18.3±4.7	0.189	0.425

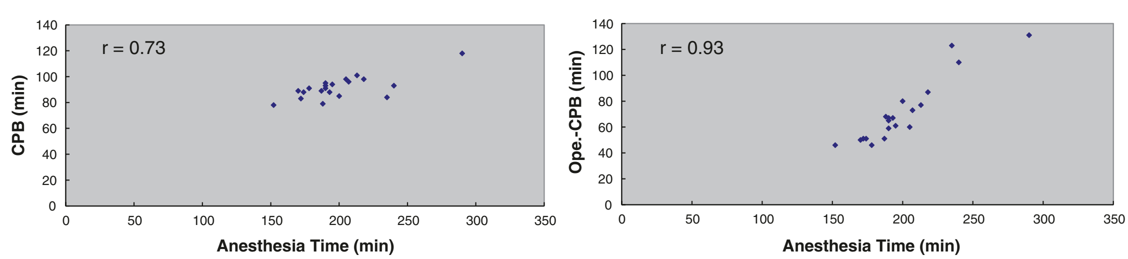
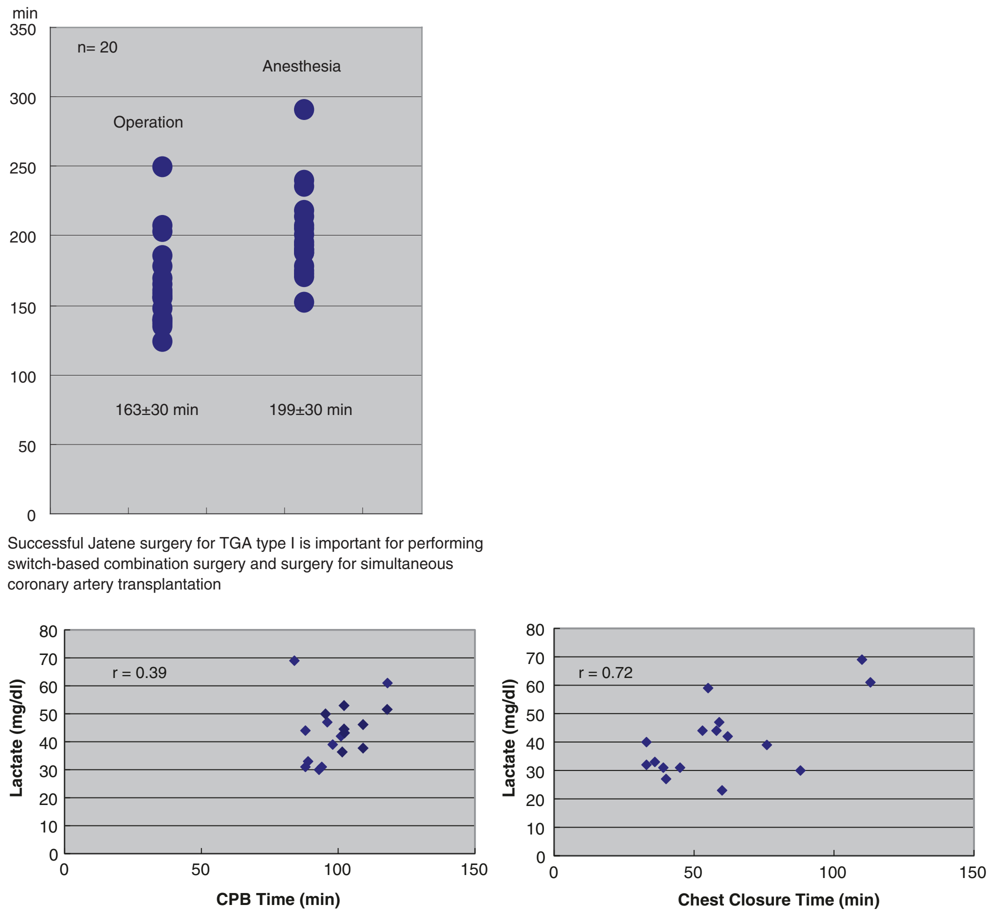


Fig. 6.14 Correlation of each duration in Jatene procedure for TGAI ([3] modified)

Fig. 6.15 Correlation between lactate levels and durations in Jatene procedure for TGAI



Column: Jatene Procedure

In the 1990s, the good outcome of the Jatene procedure was a status for pediatric cardiac surgeons. However, in the subsequent 2000s, life saving became a matter of course, and at present, it is said that if you miss it, you are a second-class surgeon. From my experience, the points for Jatene's surgery are (1) Divide the pulmonary artery at a slightly higher position for transplanting the right coronary artery higher to prevent coronary twisting, (2) always keep in mind the possibility of intramural coronary artery, (3) In DORV cases, it is relatively common to have multiple VSDs, and residual shunts should be confirmed after closure. Of course, it is essential not only to make the extracorporeal circulation less invasive and to ensure thorough perioperative management, but also to shorten the time (Fig. 6.16). Video 6.2 shows the cannulation procedure of Jatene's operation.

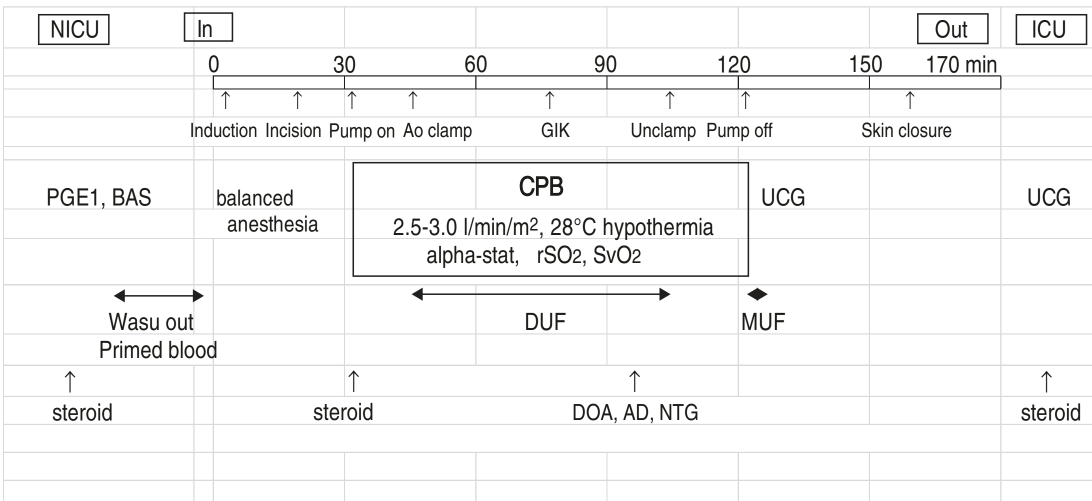


Fig. 6.16 Management measures in neonatal Jatene operation for TGAI ([4] modified).
PGE1: prostaglandin E1
BAS: balloon artial septostomy
rSO2: regional cerebral oxygen saturation
SvO2: mixed venous oxygen saturation
DOA: dopamine
AD: adrenaline
NTG: nitroglycerin
UCG: ultrasound cardiography

6.5 Operation Planning

6.5.1 Operation Planning 1

Assuming that the entering time of operation room is 8:45, the exiting time is 16:45, and the cleaning and preparation time between each operation is 40 min, it would be simply calculated that the anesthesia time of one surgery is 3 h 40 min for two operations/day, and 2 h and 13 min for three operations/day (Fig. 6.17). Figure 6.18 shows the average anesthesia time for each typical disease and procedure at Sakakibara Heart Institute. Our surgical planning will be based on these times.

6.5.1.1 Research Paper at S.H.I Study on Surgical Planning 1

The 2001 manuscript is shown. At the time, only one operating room was available, so I examined the challenges for performing 400 operations per year in one operating room.

Introduction

In our hospital, it is necessary to establish the Fast Track Recovery to complete treatment in a shorter time. The purpose is not only for dealing with an increased number of surgery or keeping the "Sakakibara-ism" which means not to refuse surgery request, but also for improving the quality of operations, considering education for young surgeons, and for dealing with changing reimbursement policies or cost reductions.

The establishment of the Fast Track requires the cooperation of each members of team. As the first stage of the study, I examined the issues for aiming an efficient surgery based on the operation status of the pediatric surgery group at Sakakibara Heart Institute.

Methods

In the current operating room environment, I discussed the challenges to achieve 400 cases/year in one operating room based on the experience of the surgeries over the past year.

Result

1. From November 2000 to October 2001 (272 work days, 93 holidays), the total number of operations of the pediatric surgery group was 355 cases/1 operating room, and 2 cases a day were operated on 100 days, and for 3 cases a day, 16 days. As a general rule, two cases for simple heart disease per day, one case for complex heart disease or re-operation case per day are performed, but emergency and semi-emergency cases increased significantly to 113 cases, most of which operated within one week after receiving the request of surgery. In particular, infancy VSD had a relatively short anesthesia time of 125 min (n = 61) on average, so two or three operations per day were performed in combination with other VSD cases. By month, April and September each had a small number of 22 cases, and the largest number 39 cases in October.
2. The number of operations performed by the author was 323. In the 246 days of the weekday, the day without my operation was 21 days, excluding outpatient consultation days, conferences and lectures, and summer vacation. Of these, my boss, Dr. Kikuchi, had 11 days of surgery, and as a result, the pediatric team had no surgery for 10 days on week-day. The first, third, and fifth Saturday of the work day were 26 days/year, of which 22 days had no surgery.

Discussion

In Europe and the United States, there are many studies on Fast Track, but in Japan there are still few. This may involve not only differences in reimbursement policies or each hospital-specific systems, but also an environment that does not require the Fast Track in Japan. In order to deal with the changes of reimbursement policies and the increase in the number of operations by keeping the "Sakakibara-ism," and to allow each team members to have extra time and satisfaction, it is necessary to create Sakakibara Heart Institute's own Fast Track methods that is unique from Europe and the USA.

Performing 400 surgeries per year would simply require one additional surgery per week. However, in the current situation, there is no doubt that it will put a burden on operating room staff who has already been in almost 100% full operation. Therefore, we have to plan the surgeries to be completed efficiently by 5:00 pm on weekdays. In the past year, two or three surgery cases per day can be completed by 5:00 pm, and the surgery times for re-operation cases have been reduced. Thus, it is necessary to increase the number of surgery days performing three cases per day and also to schedule two cases of surgeries per day for re-operation cases. The number of surgeries of which the duration cannot be estimated, such as emergency and re-operation cases, is increasing. But, I think that can be achieved by combining with short-time surgery such as ASD, VSD, TOF, or palliative surgery. In my experience, it is less burdensome to perform the surgery that must be performed without procrastinating, and it is also effective to use Saturdays, which are work days.

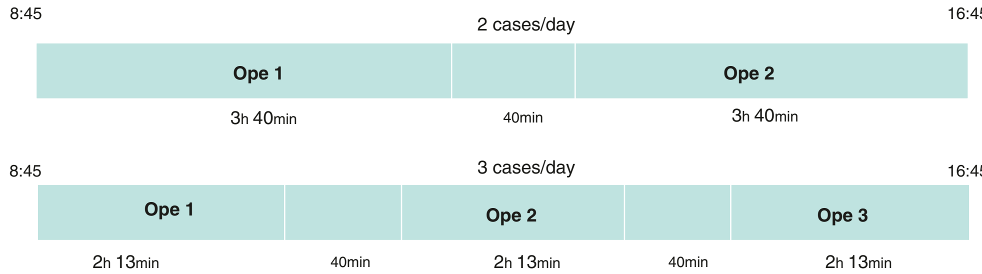


Fig. 6.17 Anesthesia time required for multiple operations in one operating room

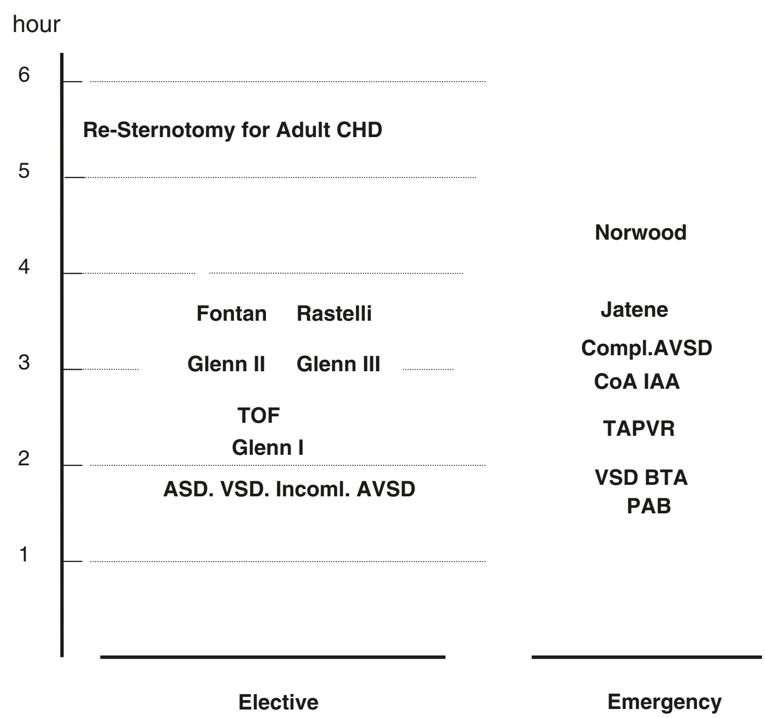


Fig. 6.18 Average anesthesia time for each disease and procedure ([5] modified)

Cardiac surgery is a team medical care, so increasing the number of surgeries will increase the burden not only on surgeons but also on anesthesiologists, operating room nurses, perfusionists, pediatricians, staff of pediatric wards and ICU. Therefore, when implementing the Fast Track, great care should be taken to give each team members more time and satisfactory feeling. Although increasing the number of staff or expediting the starting time might be a simple method, but it will be far from cost savings and also puts a burden on staff. The primary surgeon must first understand the allowable capacity for surgeries of the operating room and should present extremely practical and concrete measures for improvement. In a situation that only one operating room can be available, and the number of beds in ICU or pediatric ward are limited, a flexible management system such as adjusting the number of staff according to busy times may also be necessary. However, it depends on the surgeon for realizing the fast track. Team members may not be convinced unless the surgeon himself achieves the basics of Fast Track, such as shortening surgery time or speeding up the recovery of the child. Of course, increasing salary is the ultimate means, but…

Conclusion

Time-consuming surgery makes surgery planning difficult and may lead to worsening working conditions. Therefore all of the staffs in the OR should consider how to reduce the anesthetic time as much as possible. At the moment, the surgeon first implements the basics of Fast Track and then demonstrates its effectiveness, which is essential for having emotional leeway to staff and responding to further increases in surgery. At the same time, it is also necessary to consider measures to be taken when the team's capacity is exceeded. Furthermore, creating a Fast Track unique to Sakakibara Heart Institute is an important issue for human resources development to create a next-generation Fast Track that is superior to the current Fast Track.

6.5.2 Operation Planning 2

Planning for surgery within 2 min of anesthesia is easy. However, with the increase in severe cases and emergency surgery that take time to repair, it has become difficult to deal with them. Of course, there is always a limit that you should not perform more than this number of surgeries. We examined it as a new issue.

6.5.2.1 Research Paper at S.H.I Study on Surgery Planning 2-a

The 2003 manuscript is shown. The surgery planning for emergency or semi-emergency surgery was examined.

Introduction

From July 2002 to June 2003, the number of pediatric cardiac surgeries was 345 with extracorporeal circulation and 75 without extracorporeal circulation. (2 cases per day: 124 days, 3 cases per day: 28 days). In addition, there were another 30 surgeries for pacemaker implantation and wound resuture, etc. With the increase in the number of operations, it has become necessary to evaluate the time required for each operation and utilize it in the surgery planning in order to perform efficient surgery. This time, in cases where emergency or semi-emergency surgery was requested, we examined their positions when planning surgery.

Methods

The subjects were 107 patients since 2001 who required emergency or semi-emergency surgery in the neonatal or early infancy (complete AVSD: 14 cases; TAPVR: 20; CoA/IAA complex: 20; Jatene: 9, Norwood: 16, PA banding: 8, BTA: 18). We compared these anesthesia time with that of 54 cases of ASD, 90 cases of VSD, and 22 cases of TOF, which were elective operations during the year 2002, and examined the positioning of emergency and semi-emergency operations when making a surgery plan.

Results

Figure 6.19 shows the duration of anesthesia; complete AVSD 167 ± 24 min (117–212), TAPVR 153 ± 35 min (101–235), CoA, IAA complex 186 ± 29 min (143–226), Jatene 219 ± 19 min (190–245), Norwood 287 ± 26 min (245–330), PA banding 103 ± 17 min (85–130), BTA 107 ± 16 min (69–130). ASD 112 ± 26 min (83–200), VSD 111 ± 19 min (85–188), and TOF 175 ± 26 min (125–225).

Discussion

With the advance of preoperative management, the number of cases in which surgery is performed immediately after admission has decreased, and the number of cases in which surgery is performed after the condition has stabilized has increased. Therefore, it is possible to plan the surgery relatively easily in response to the request for emergency surgery. On the other hand, the background of this study is also the peculiarity of our operating room. That is, (1) only one operating room can be used, and (2) the number of operations is allowed to increase, and it is necessary to have a surgery plan that does not postpone the elective cases, (3) There is no night duties for operating room nurses, and there are many housewives, so it is desirable for patients to leave the operation room before 17:00. Assuming that the patient enters at 8:45 and leaves at 16:45, with taking 40 min of cleaning and preparation time

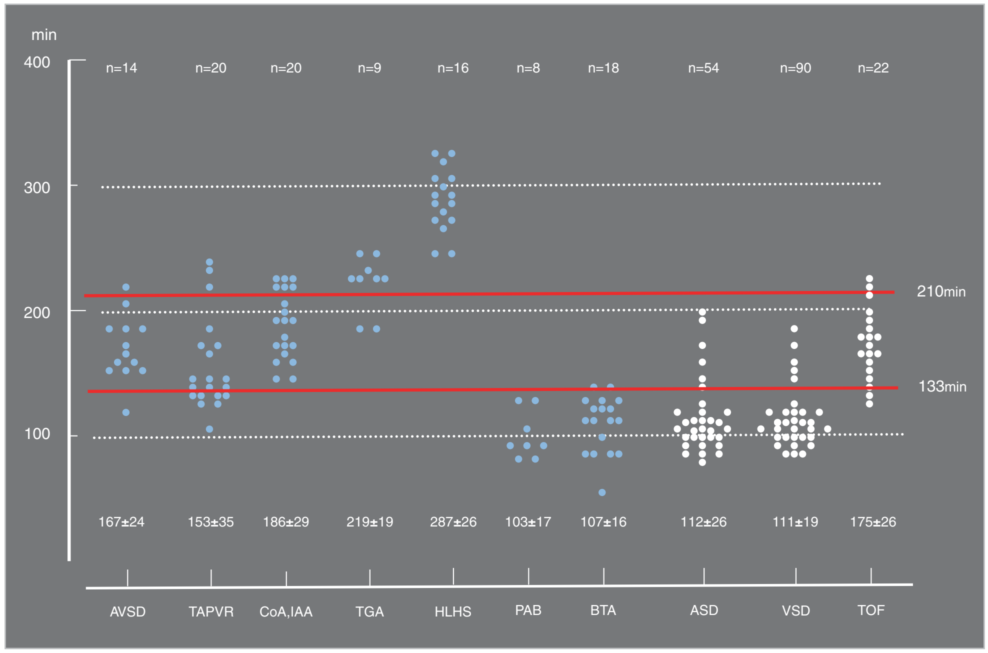


Fig. 6.19 Duration of anesthesia.
AVSD: atrial-ventricular septal defect
TAPVR: total anomalous venous return
CoA: coarctation
IAA: interruption of aortic arch
TGA: transposition of great arteries
HLHS: hypoplastic left heart syndrome
PAB: pulmonary artery banding
BTA: Blalock-Taussig anastomosis
ASD: atrial septal defect
VSD: ventricular septal defect
TOF: tetralogy of Fallot

between each operation, the simple calculation showed that surgery must be completed within 7 h 20 min (220 min each) for 2 cases per day and within 6 h 40 min (133 min each) for 3 cases per day (Fig. 6.17).

The following results were obtained from this study: (1) Even in Jatene and Norwood operations, which require a long operative time, two operations per day are possible by combining with VSD or ASD, (2) Similarly, for complete AVSD, TAPVR, CoA/IAA complex, two operations per day are possible by combining with TOF, (3) For complete AVSD, TAPVR, PA banding, and BTA, three operations per day can be planned by combining with VSD or ASD. However, in fact, in 30 days out of a total of 236 days of surgery in 2002, patients were unable to leave until 16:45. In the future, it is necessary to consider ways to further reduce the time.

The duration of anesthesia for semi-emergency infancy VSD cases was reduced to 102 ± 10 min (75–125), mostly within 2 h (Fig. 6.18). This involves the insertion of the central venous line while awaiting surgery. Thanks to the pediatrician.

Shortening the time for surgery and anesthesia is necessary not only to reduce medical and labor costs, but also as a measure for the introduction of DRG/PPS in the future. However, most importantly, the time saving itself directly leads to the reduction of invasiveness of the patient. In particular, it has a great significance in congenital heart diseases in which extracorporeal circulation, which is the greatest invasion to the living body, is essential. Of course, in order for staff to be able to work with mental leeway, it is necessary to increase the number of operating rooms, increase the number of staff, establish a night duty system, and increase salaries. However, from the perspective of education for young staff, a system in which a small number of elite teams are formed and the ability is developed in a short period of time is also necessary for the current Japanese cardiac surgery.

It seems that it is unthinkable in other hospitals in japan to perform more than 400 heart surgeries a year in one operating room. Of course, there is a peculiarity of our hospital as a hospital specializing in cardiovascular diseases, but I am convinced that making the best use of this peculiarity and growing the team will lead to further improvement of the QOL of the surgery. In the near future, fostering a surgical team that can perform surgery in a short time will be required in Japanese cardiac surgery. Of course, there is no doubt that shortening the time has great significance in terms of reducing the invasiveness of medical staff and increasing the QOL.

Conclusion

This time, we examined the positioning of emergency and semi-emergency surgery when making surgery plans. Although the number of severe cases is increasing, it is possible to plan surgery for 2 or 3 cases a day by combining them with other diseases. As a next study, it would be necessary to evaluate not only the time saving, but also the overall quality of the operation, such as the quality of the postoperative condition of the patient and the reduction of the length of stay in the ICU.

6.5.2.2 Research Paper at S.H.I Study on Surgery Planning 2-b

The 2003 manuscript is shown. With the increase in the number of surgeries for HLHS and Heterotaxia syndrome, and as a preparatory surgery before Fontan procedure, Glenn surgery is now performed earlier and at a younger age. This was a time when the image of Glenn surgery changed considerably. As the number of Glenn surgeries increased, we also examined their position in the surgery plan.

Introduction

In recent years, Glenn surgery has been increasingly indicated for low-weight infants. This is probably because, in Japan, the outcome of the Norwood operation was improved by using the RV-PA conduit. Along with this, the position of Glenn surgery in the surgery plan also changed significantly. Specifically, cases requiring combined procedures other than SVC-PA anastomosis (Glenn) were increased, such as re-sternotomy, atrioventricular valvuloplasty, or pulmonary artery angioplasty, and also cases with a limit of surgical indications that may consider takedown. In this report, we evaluate the anesthesia time of recent Glenn surgery and discuss the positioning of Glenn surgery in surgery planning.

Methods

The subjects were 40 cases who underwent Glenn surgery from January 2001 to April 2003. It was divided into three groups. GroupI—16 cases who underwent only Glenn anastomosis (including BTA closure), GroupII—15 cases who underwent combined procedures such as atrioventricular valvuloplasty or pulmonary artery repair etc., and GroupIII—22 cases with re-sternotomy. Table 6.1 shows the background of each group. We evaluated the anesthesia time of 3 groups of Glenn surgery and compared with 54 cases of ASD, 90 cases of VSD, and 22 cases of TOF who had elective surgery in 2002.

Results

Figure 6.20 shows the anesthesia time. Group I was 142 ± 33 min (103–225), Group II 193 ± 51 min (103–310), and Group III 238 ± 73 min (142–357). Among them, the number of cases within 210 min was 11 cases (11/12, 92%) in Group I, 9 cases (9/13, 69%) in Group II, 7 cases (7/15, 47%) in Group III, and cases exceeding 240 min were

Table 6.1 Patient background of Each Glenn Group [6] modified

No	16		15		22	
BW(kg)	5.7～17.3(11.6±2.5, n=15) 55.2		4.9～13.0(9.6±2.6, n=14) 49.8		2.8～7.5(5.4±1.5, n=14) 10.0, 10.0, 10.0, 17.5, 25.0, 32.0, 47.8	
Dignosis	TA	6	SV	9	HLHS	11
	SV, CoA	3	DORV, PS	2	SV, TAPVR, PS	3
	SV	3	DORV, PS, MA	1	SV, MA	2
	DORV, PS	2	DORV, CoA	1	SV, TAPVR, PA	1
	DORV CoA	1	DORV, AVSD	1	SV, MA, PA	1
	PPA	1	TA	1	TOF, hypo RV	1
					TA	1
					DORV, PS	1
					I-TGA, IAA	1
					IAA, AS, VSD	1
Previous. Procedures	PAB	7	BTA	11	Norwood	11
	PAB, CoA repair	4	PAB	1	TAPVR repair, PAB	3
	BTA	5	PAB, CoA repair	1	TVP, ASD creation, RV-PA conduit closure	1
			none	2	TAPVR repair, TVP, RV-PA conduit closure	1
					TVR, PA plasty, PAB	1
					Central palliation	1
					BTA, ASD creation	1
					PAB, ASD creation	1
					Central shunt	1
					IAA repair ⇒DKS, BTA	1
Glenn Procedures	Glenn only	12	Glenn＋PA plasty＋PDA or BTA closure	3	Glenn only	9
	Glenn＋BTA clos.	4	PA plasty	1	Glenn＋RV-PA conduit closure	5
			ASD creation	2	ASD creation＋BTA closure	1
			ASD creation＋PA plasty＋BTA closure	1	PA plasty	1
			ASD creation＋valvuloplasty＋BTA closure	1	PA plasty＋BTA closure	1
			ASD creation＋SAS release	1	RV closure＋BTA closure	1
			ASD creation＋valvuloplasty＋PA plasty	1	TVR	1
			ASD creation＋BTA closure	1	PV stenosis repair	1
			ASD creation＋Valvuloplasty	1	TVP, RV-PA conduit closure	1
			Valvuloplasty	1	ASD creation	1
			Valvuloplasty＋PV stenosis repair	1		
			Valve Replacement	1		

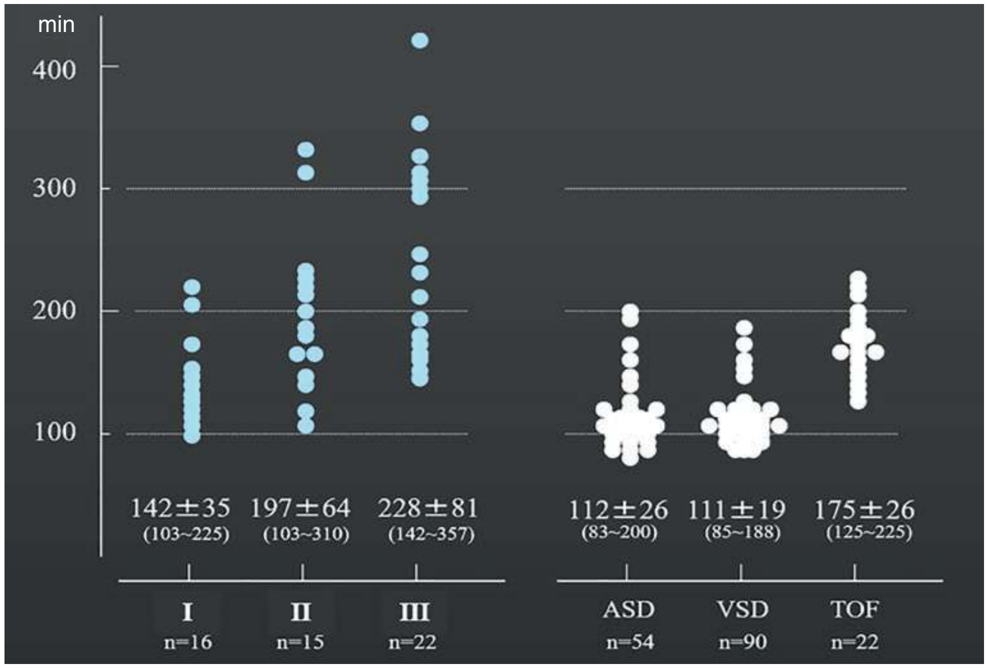


Fig. 6.20 The duration of anesthesia in Glenn procedure ([6] modified)

observed in 1 case in Group II and 7 cases in Group III. The anesthesia time in Group III tended to be long, but it was relatively short in low-weight infants and cases with only Glenn anastomosis.

On the other hand, ASD was 112 ± 26 min (83–200), VSD was 111 ± 19 min (85–188), and TOF was 175 ± 26 min (125–225). Most of the ASD and VSD cases were around 100 min, and three cases of TOF were more than 210 min.

Discussion

Surgery planning for Glenn surgery is considered possible for 2 cases per day, such as (1) Groups I + II, Group I + Group III (Glenn anastomosis only), (2) Group I or II + TOF, (3) Group III + ASD or VSD, and also for 3 cases per day such as Group I + ASD or VSD.

We plan on similar studies for various diseases and operations.

Conclusion

The position of Glenn surgery in surgery planning was discussed. Although the number of severe cases is increasing, it was possible to plan two or three surgeries a day in combination with other diseases. With the improvement of surgical outcomes in patients with HLHS and Heterotaxia syndrome, Glenn's surgery has also become even more important as a step-up to Fontan surgery. In the future, in addition to aiming at improving the quality of the Glenn surgery itself, we would like to conduct a similar study of the Fontan operation in patients who underwent Glenn surgery with low weight (Fig. 6.21).

6.5.3 Operation Planning 3

During the summer vacation in Japan from late July to August, we need to operate a total of more 60 cases using only one operating room (Fig. 6.22). However, due to requests for emergency and semi-emergency surgery, scheduled surgery may be postponed for one or two days, or patients who need early surgery may have to wait. During this period, all operations must be completed by 17:00, and the team members are tied up. The surgeon is required to show each staff not only the fast surgery but also early postoperative recovery and good outcomes. Summer vacation is an important season to improve the team's power and is a time for surgeons to shine. Adequate cooperation with pediatricians is, of course, necessary.

Q&A: Points to Note About Fast Track in Pediatric Open-Heart Surgery (Question in 2011)

Question:It hass been 10 years since I graduated. To date, I have operated on about 150 cases of congenital heart disease. I would like to major in pediatric cardiac surgery.

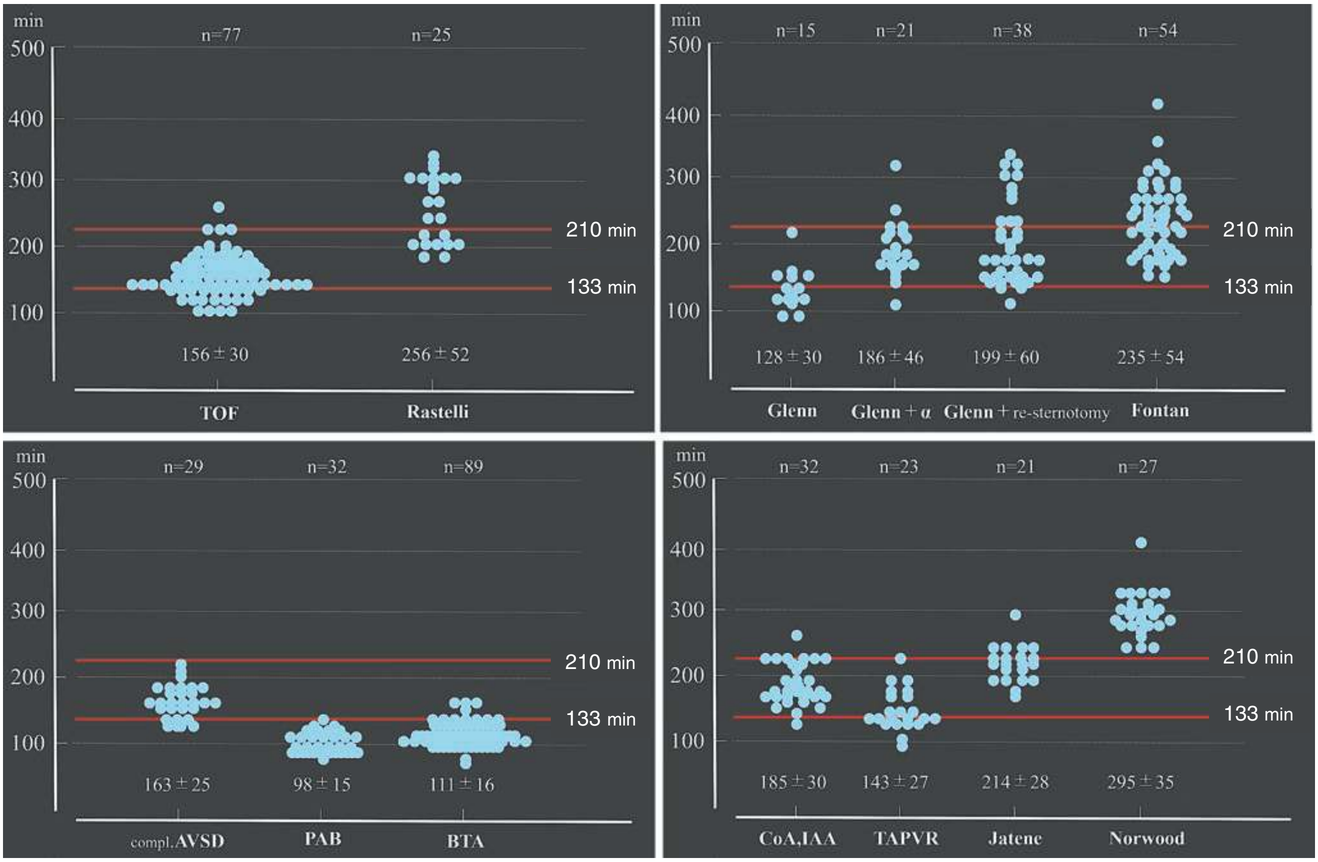


Fig. 6.21 The duration of Anesthesia (2004). It is a figure when re-examined by adding Rastelli and Fontan operation in 2004. Even in the same operations, anesthesia time were different individually. This is considered to be involved in the presence or absence of palliative surgery or re-sternotomy, and the difference in the duration required for induction of anesthesia and hemostasis. For both Rastelli and Fontan operations, two cases can be planned a day in combination with ASD and VSD cases

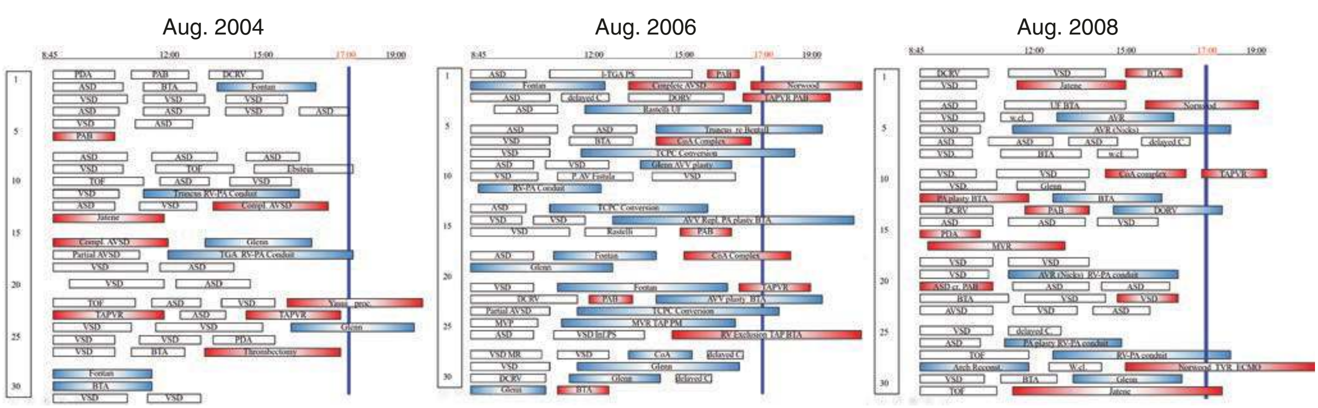


Fig. 6.22 Surgery schedule in Augusts. White frame: elective, blue frame: re-sternotomy, red frame: emergency or semi-urgent

Please tell about the most important points in child Fast Track and time saving.

Answer: As I grow older, I would like to keep the team members fixed if possible, but if I say such things from my standpoint, I will get a lot of repulsion and scolding. Curiously, it's almost impossible to do so in Japanese hospitals.

However, there are some things that must be considered as a surgeon. One of them is that there are many opinions that doing "Fast Track" may cause inconvenience. Therefore, the surgeon must first show to the team members that Fast Track will improve the postoperative condition of the child. Rather than simply saying "Let's do it quickly," it is necessary to convince them that saving the time is a direct minimally invasive measure. And it is also necessary to show that the sooner the surgery is done, the better you feel so much, and the more time you will have. So to speak, it is a comprehensive minimal invasiveness.

The "members" here include, of course, the director, the director of the nursing department and the safety and crisis management office. In a case of basic surgery such as VSD, I will strictly guide team staff with Fast Track, which I think. However, if I arouse the member's antipathy, there the following opinions may appear that "Impatience leads to mistakes," "Do operation according to the ability of the team," "Dont's despises safety," or ultimately, "it's power harassment." Fast Track will never progress anymore. However,

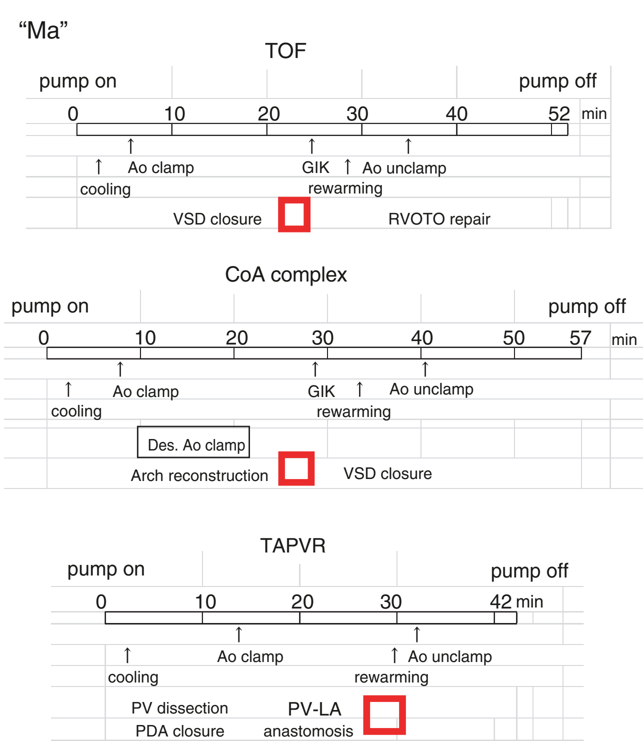


Fig. 6.23 Timing of cardioplegia injection "Ma"

when performing surgery in a team that has a good understanding of Fast Track's invasiveness, the "members" may be complained on the contrary, "Your surgery is too slow, so please do it sooner." That's how it should be essentially.

I think what is important in saving the time is the sense of time during aortic cross-clamp. In other words, it means how to inject the cardioplegia solution in a timely manner. Figure 6.23 shows the chart of extracorporeal circulation in TOF, CoA Complex, and TAPVR open-heart surgery. We inject Blood GIK (cardioplegia) by hand every 20 min. In order to improve the flow of surgery, it is important to make effective use of the time between each procedure. For example, in TOF, after closing VSD, the main pulmonary artery is dissected by using 3–5 min until the second GIK administration. Then, after the second GIK administration, proceed to valvotomy, muscle resection, and reconstruction of the right ventricular outflow tract. In the CoA Complex, 5 min prior to the second GIK administration after arch reconstruction is used for the right atriotomy and inspection of the VSD, and VSD closure is performed after the second GIK administration. In TAPVR, 2–3 min after PV-LA anastomosis is used for ASD closure and air evacuation, and then do the aortic unclamp. In short, considering the time limit of 20 min for one cardioplegia injection, how to effectively use the time between each procedure is the key to time saving. To gain this sense of time, it would be necessary to be able to complete VSD closure, which is the most basic technique, within 20 min. This is the most important thing to improve the flow of surgery in the Jatene procedure for TGAII, the Rastelli procedure for Truncus Arteriosus Communis, and further more, the Norwood procedure mainly for aortic reconstruction technique, which takes longer time. Figure 6.24 shows the course of extracorporeal circulation during Norwood surgery.

In Japan we call this "ma," which means the time interval which leads to enhanced proceeding of the procedure. In the world of "Rakugo," a Japanese traditional comic storytelling, to keep this "ma" constant is quite important, and we specifically call this "Kotoba wo kuwanai (do not eat what you say)" meaning do not interfere with what is going on naturally.

Then I would like to add one more comment. Considering your career of 10 years after graduation, I think that you are the general manager in postoperative ICU, who controls the flow of surgery behind the scenes. Once again, especially during the extremely busy seasons such as summer vacation, how about considering about surgery planning and overall surgery management from your standpoint?

Figure 6.25 shows a weekly surgery schedule. There are two cases of ASD, two cases of VSD, five cases of TOF, and two cases of Glenn with relatively short operative time. Experience has shown that a week like this will provide the

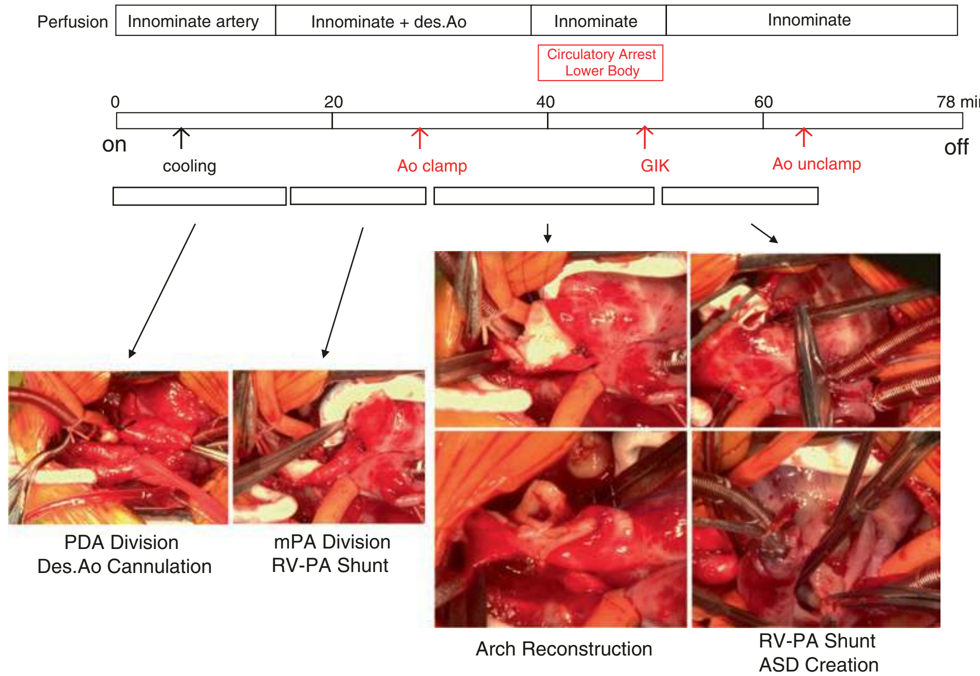


Fig. 6.24 Extracorporeal circulation in Norwood procedure ([7] modified)

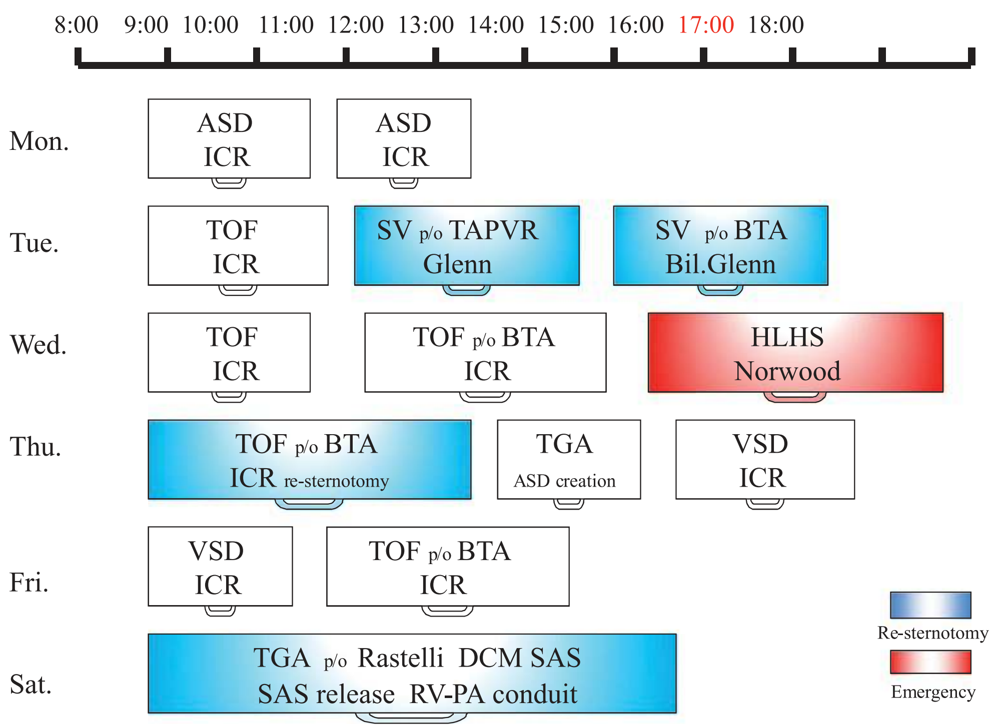


Fig. 6.25 My one week

most enhancement for young surgeons', nurses' and perfusionists' skills. For example, when tomorrow's ICU bed control seems difficult, how about considering the following, "What is the best way to manage today's surgery infant to return to the ward by tomorrow?" "What time should the patient return to the ward?" "By what time should the surgery tomorrow be completed in order to perform the surgery scheduled for the day after tomorrow?" When is the best time of surgery for baby born from now ?"etc.

From that perspective, if you approach each team member proactively, non-technical skill that has its primary meaning will be immediately created in the team. As a result, team-specific Fast Tracks will be slowly created. I think that an important point in planning a summer vacation surgeries is how to properly arrange VSD's.

6.5.3.1 Research Paper at S.H.I Study on Surgery Planning 3

This is a manuscript in 2000 examining the minimally invasiveness obtained by shortening the operative time in VSD surgery.

Introduction

Bloodless open-heart surgery aims for minimizing the invasiveness of surgery from the perspective of preventing side effects associated with blood transfusion. We evaluated the minimal invasiveness in VSD infant who underwent bloodless open-heart surgery by evaluating the relationship of each duration of surgery.

Methods

The subjects were 71 cases of VSD infants from February 1997 to June 2000, Age—1–11 months (3.4 ± 1.8), weight—3.3–4.9 kg (4.2 ± 0.5). All patients had poor weight gain and severe pulmonary hypertension with Pp/Ps of 0.8 or higher. Two patients required mechanical ventilation before surgery.

We evaluated the time course from the entry to the operating room to weaning from mechanical ventilation. Evaluated times were; aortic cross-clamp, extracorporeal circulation, operation, anesthesia, extracorporeal circulation minus cross-clamp (extracorporeal circulation excluding the aortic cross-clamp), thoracotomy (from the start of operation to the start of extracorporeal circulation), chest closure (from the end of extracorporeal circulation to skin closure (chest closure), thoracotomy plus chest closure (surgery excluding extracorporeal circulation), induction of anesthesia (from entry to skin incision), exit (skin closure to leaving the operation room), induction of anesthesia plus exit (anesthesia excluding operation), and mechanical ventilation after surgery.

The subjects were classified into 40 cases before 1998 (3.5 ± 1.6 months, 4.1 ± 0.4 kg) and 31 cases after 1999 (3.3 ± 1.9 months, 4.2 ± 0.5 kg). By evaluating the factors affecting the time for surgery and anesthesia, future issues for achieving Fast Track were examined.

Conclusion 1

(1) The time for surgery and anesthesia were shortened over time. In the latter period, the number of cases with less than 90 min of operation and less than 120 min of anesthesia also increased. On the other hand, the time for extracorporeal circulation did not reduce (Fig. 6.26). The time for thoracotomy and chest closure reduced over time (Fig. 6.27). Extracorporeal circulation time was more strongly correlated with aortic cross-clamp time (Fig. 6.28).

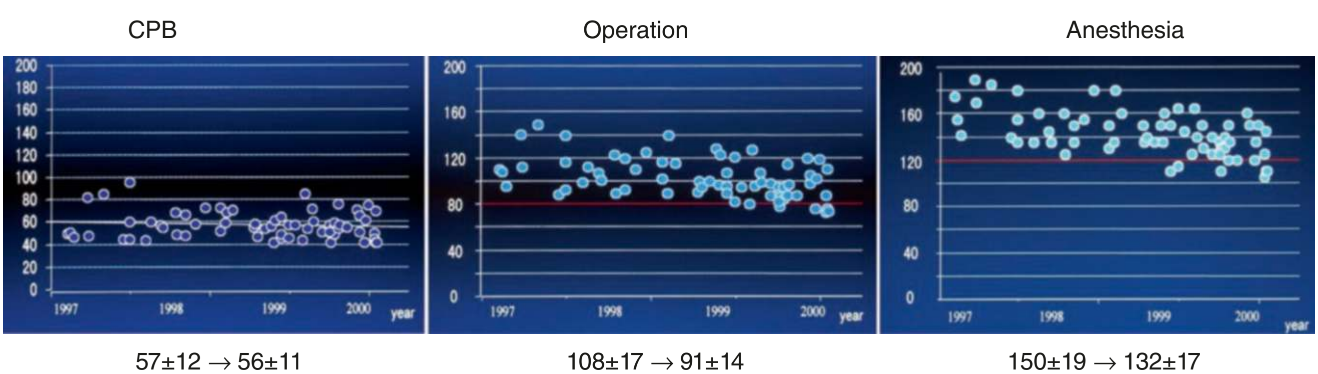


Fig. 6.26 Annual changes in duration of extracorporeal circulation, surgery, and anesthesia

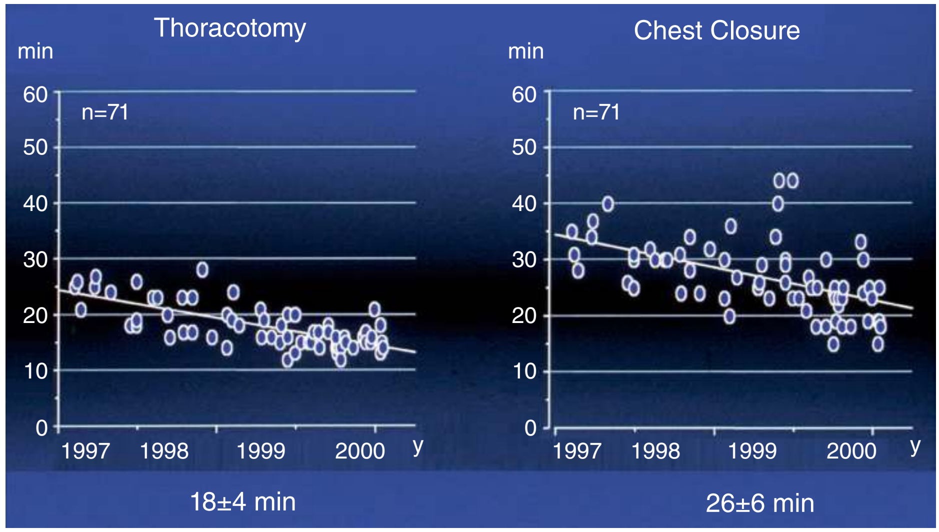


Fig. 6.27 Annual changes in duration of thoracotomy and chest closure

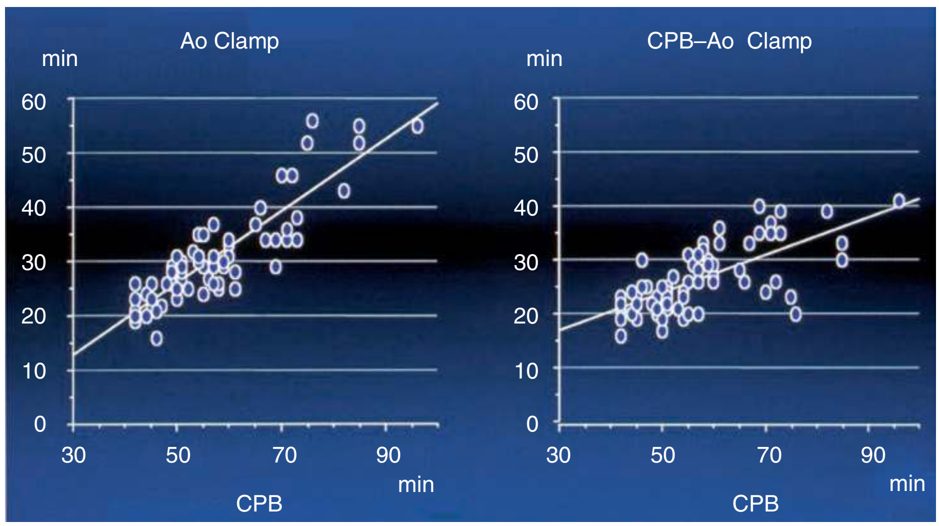


Fig. 6.28 Correlation with extracorporeal circulation time. *CPB-Ao Clamp* CPB time excluding Ao clamp time

Discussion 1

The reduction in times for surgery and anesthesia over time was due to the reduction of times for thoracotomy and chest closure, suggesting the familiarity with small incision procedure and the skill enhancement of the scrub nurse. In addition, we thought the length of the aortic cross-clamp time was largely related to the complexity of VSD morphology which requires a long closing time, such as total conus defect, which was closed from both the pulmonary artery and the right atrium, inlet VSD with complicated chordae tendineae of tricuspid valve, or large outlet VSD, etc.

The aortic cross-clamp time was more strongly correlated with the extracorporeal circulation time, so it was essential to shorten the aortic cross-clamp time to shorten the extracorporeal circulation time. On the other hand, the extracorporeal circulation time minus the cross-clamp time was considered to be influenced by the time required for the recovery of heartbeat and to sinus rhythm. It is necessary for the surgeon's attention such as prevention of air inclusion in the coronary arteries and complete air evacuation.

Conclusion 2

The anesthesia time was more correlated with the operative time (Fig. 6.29). There was no significant reduction in anesthesia induction time plus exit time, and in cases with a central venous line when entering the operating room, the time from entry to skin incision was reduced by an average of 8 min (Fig. 6.30).

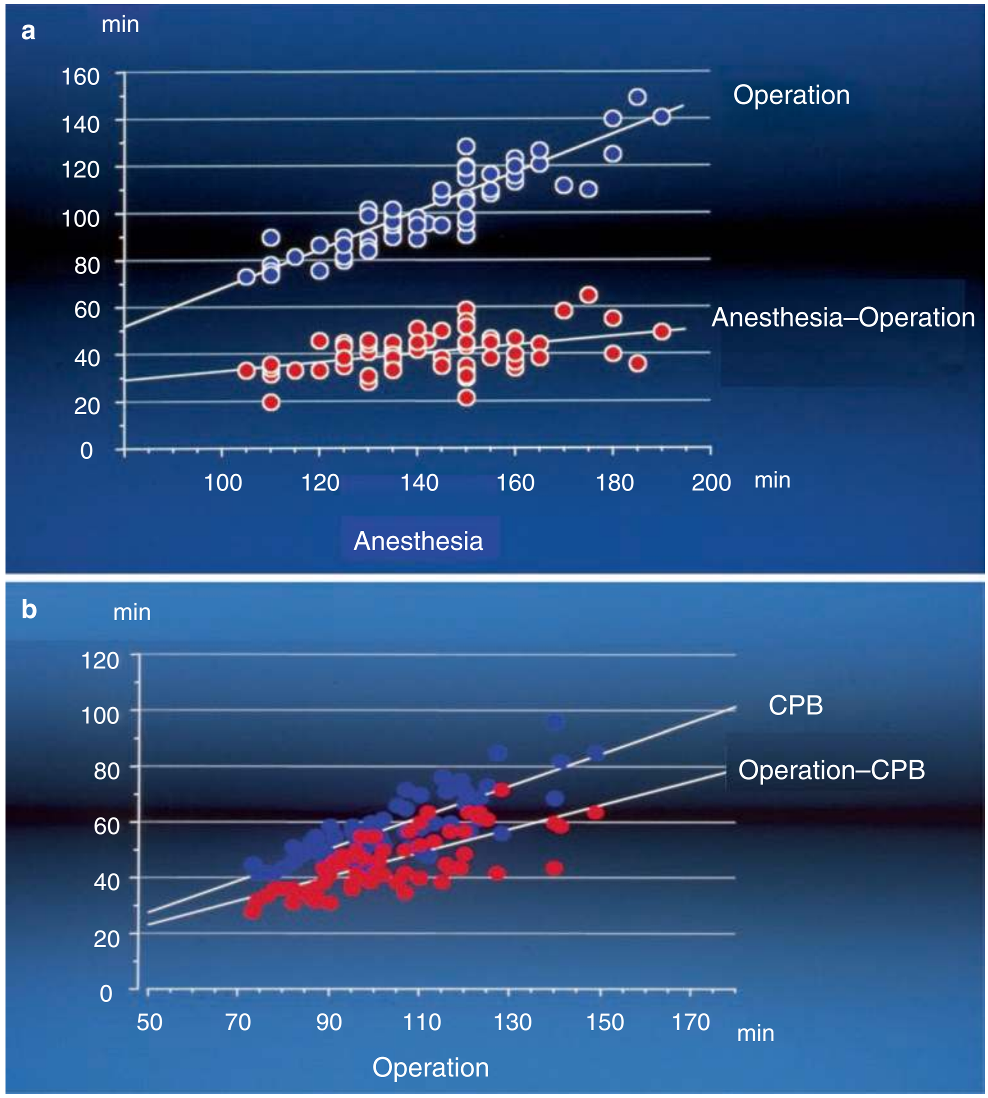


Fig. 6.29 (**a**) Correlation with anesthesia time. Anesthesia ⇔ Operation, Anesthesia ⇔ Anesthe.-Ope. *Anesth.-Ope*. Anesthetic time excluding operation time. (**b**) Correlation with operative time. Operation ⇔ CPB, Operation ⇔ Ope.-CPB

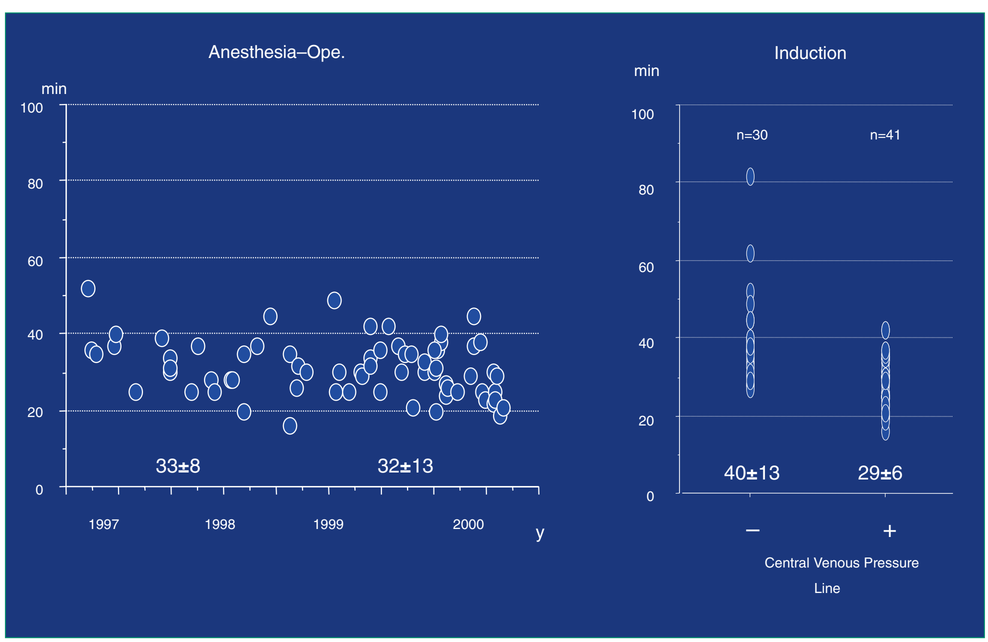


Fig. 6.30 Duration for anesthetic induction

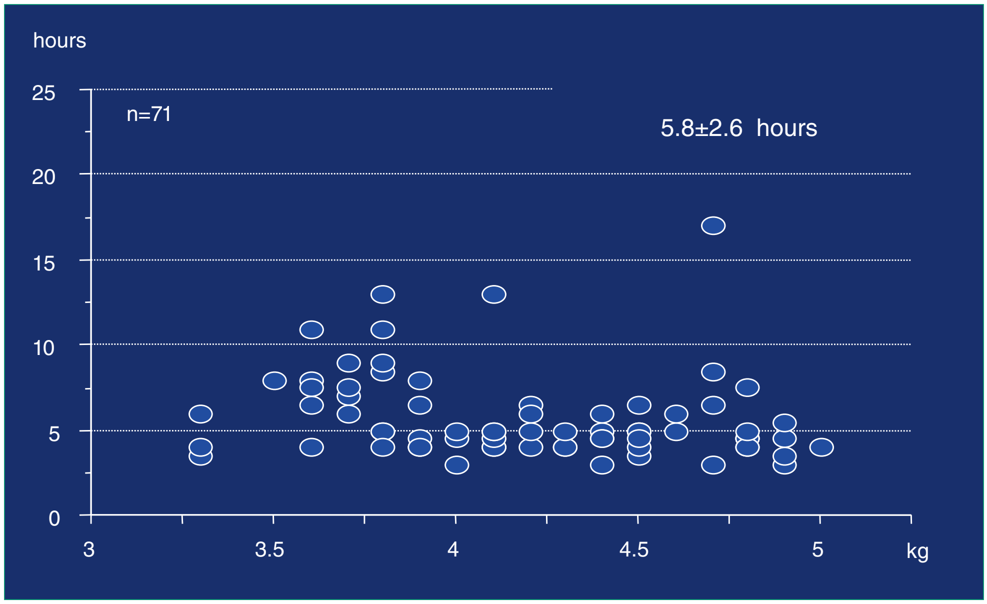


Fig. 6.31 Duration of intubation

Discussion 2

The chronological reduction of time for anesthesia induction was small, which was probably involved in the difference in the time required for inserting the arterial pressure line or the central venous line in each patient. On the other hand, in the case having a central venous line, the time for anesthesia induction was significantly reduced.

Conclusion 3

The duration of intubation after surgery was 5.8 ± 2.6 h (Fig. 6.31). Examination of factors affecting the intubation time showed a significant positive correlation with body weight, extracorporeal circulation time, operative time, or anesthesia time (weight: $r = 0.302$, $p = 0.0028$, extracorporeal circulation: $r = 0.319$, $p = 0.0015$, anesthesia: $r = 0.203$, $p = 0.0478$). On the other hand, there was no correlation with elapsed time or the lowest Hct during extracorporeal circulation (elapsed time: $r = 0.131$, $p = 0.2408$, lowest Hct: $r = 0.182$, $p = 0.0777$).

Discussion 3

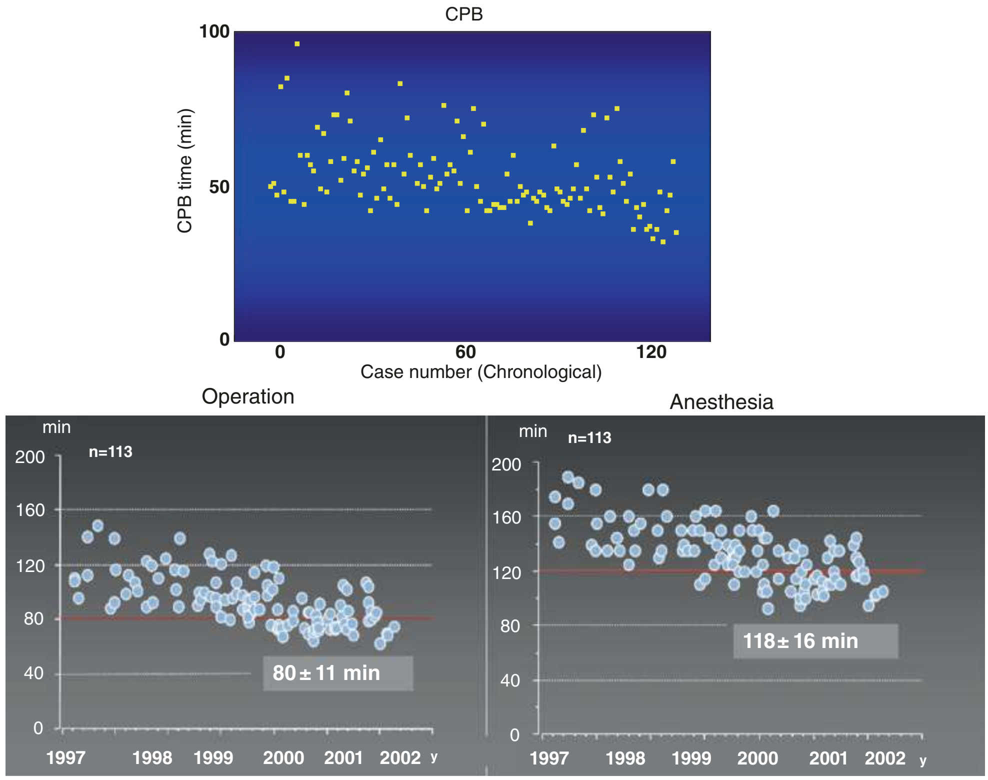
Postoperative intubation time was correlated with the length of each time during operation.

Summary

In open-heart surgery for infant VSD, preliminary studies to reduce the operation and anesthesia time were performed. In general, the times were shortened over time, and early respirator weaning was possible after operation. However, reduction of extracorporeal circulation time was considered as a future issue.

In 1999, our hospital performed 314 cases of congenital heart disease surgery using only one operating room, and more than two cases a day were operated on 90 days. Simple and efficient surgery is considered to be useful not only for early postoperative recovery but also for cost reduction, including medical expenses. We believe that the establishment of Fast-Track will be an important issue in surgery for congenital heart disease. In the future, the standard time in infancy VSD surgery will be 90 min for surgery and 120 min for anesthesia (Figs. 6.32, 6.33, and 6.34).

More than anything, operating room staff should strive to reduce the time required for the most basic VSD surgery in congenital heart disease surgery. There is no doubt that this will lead to less invasiveness in more serious illnesses and more complex surgery.



Duration (min)	First Half (n=40)	Second Half (n=73)	p value
Ao Clamp	30±9 (16~55)	32±8 (20~58)	N.S.
CPB	58±13 (42~96)	52±10 (38~76)	P=0.0227
Operation	108±17 (80~149)	80±13 (65~120)	P< 0.0001
Anesthesia	150±19 (110~190)	118±17 (93~165)	P< 0.0001
CPB - Ao Clamp	28±6 (17~41)	20±5 (13~36)	P< 0.0001
Ope. - CPB	51±9 (31~72)	34±6 (23~49)	P< 0.0001
Incision~CPB on	20±4 (12~28)	14±2 (10~21)	P< 0.0001
CPB off~End	30±6 (20~44)	19±4 (12~33)	P< 0.0001
Anesth. -Ope.	41±9 (20~65)	39±11 (25~89)	N.S.
In~Incision	33±7 (16~52)	32±12 (19~82)	N.S.
End~Out	10±2 (7~16)	7±2 (4~13)	P=0.0005

Fig. 6.32 Annual changes of duration of CPB, surgery and anesthesia in VSD cases weighing 3–4 kg. Since 2000, the average operative time is 80 min and the anesthetic time is 118 min.
CPB-Ao clamp: CPB time excluding Ao clamp time
Ope.-CPB: operative time excluding CPB time
Anesth.-Ope.: anesthetic time excluding operative time

The purpose of this manuscript was also to examine the position of infant VSD in surgery planning for Fast Track. Infancy VSD should be operated in a short time, and it should be said that it is a Fast Track operation judged by the postoperative good state.

However, Japan's anesthesia insurance (reimbursement) score at that time was 18,350 points until two hours and increased by 1800 every 30 min thereafter. Therefore, shortening the time has led to a decrease in revenue, and there have been opinions that surgery should be performed more slowly in my hospital. I remember that I wrote this manuscript with a little unpleasant feeling, thinking that if the surgery was completed within 2 h and the number of surgeries increased, no stupid complaints would be made. This was presented at a hospital study meeting without difficulties or problems.

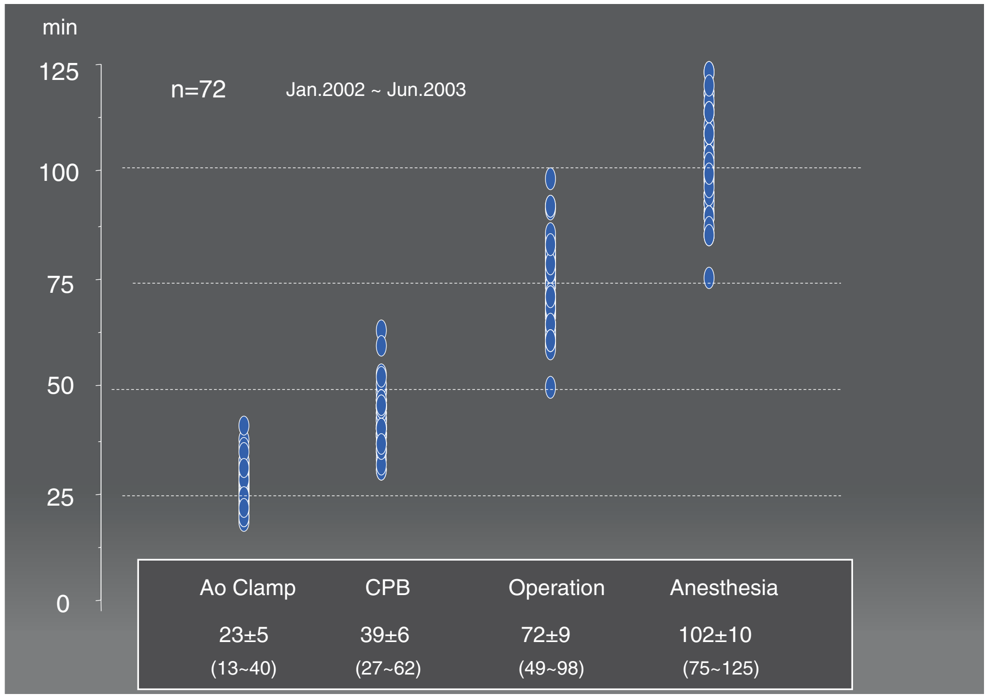


Fig. 6.33 Duration of surgery and anesthesia in VSD cases weighing under 6 kg. In VSD cases weighing less than 6 kg since 2002, the average operation and anesthesia time were 72 and 102 min. In 2005, the number of pediatric cardiovascular operations was 514 in one operating room, and two to four operations per day were performed for 188 days. VSD open-heart surgery was able to be performed in a short time, and early exit from the ICU was possible. VSD open-heart surgery was the most useful procedure for considering fast track recovery. In order to facilitate anesthesia and ICU management, the goal should be within 45 min from admission to aortic cross-clamp and anesthesia time within 2 h

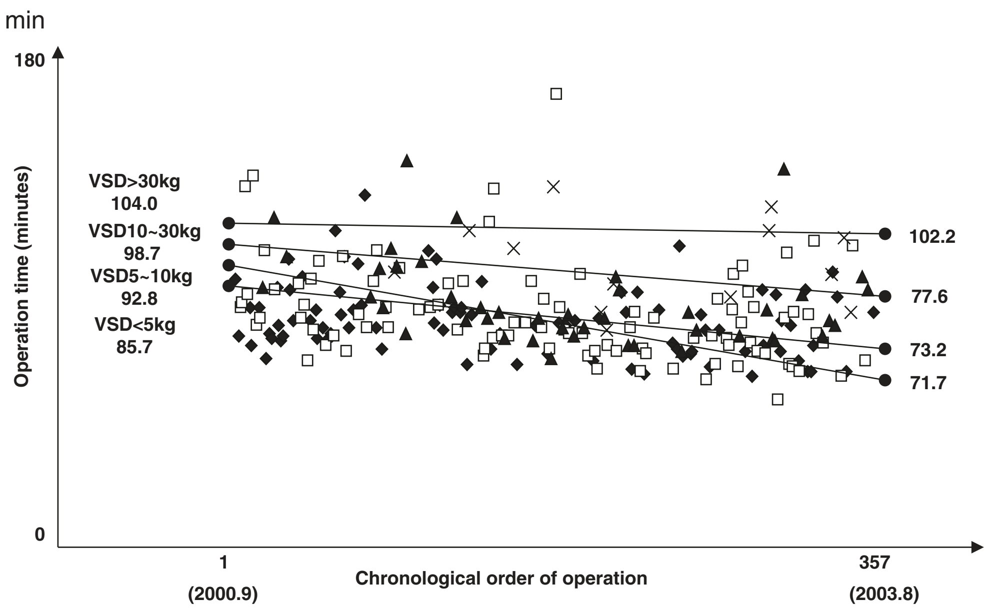


Fig. 6.34 Changes in operative time for VSD by weight ([8] modified). Shortening of surgery time in high body weight patients was small. It was considered that there was no reduction in the thoracotomy and chest closure time

Column: Preparation for Surgery

The perfusionist collects the residual blood in the operating room, discards the used circuit, moves the heart–lung machine to the machine preparation room, sets up the new circuit for the next surgery, carry it back to the same operation room after cleaning and then primes the circuit (Fig. 6.35). The outer corridor of the operating room communicates with the surgical instrument packing room of the central sterilization room. The nurse deploys the instruments for the next surgery on the instrument table in this corridor and carries them to the operating room (Fig. 6.36). Data 4.1 shows a basic set of pediatric surgical instruments.

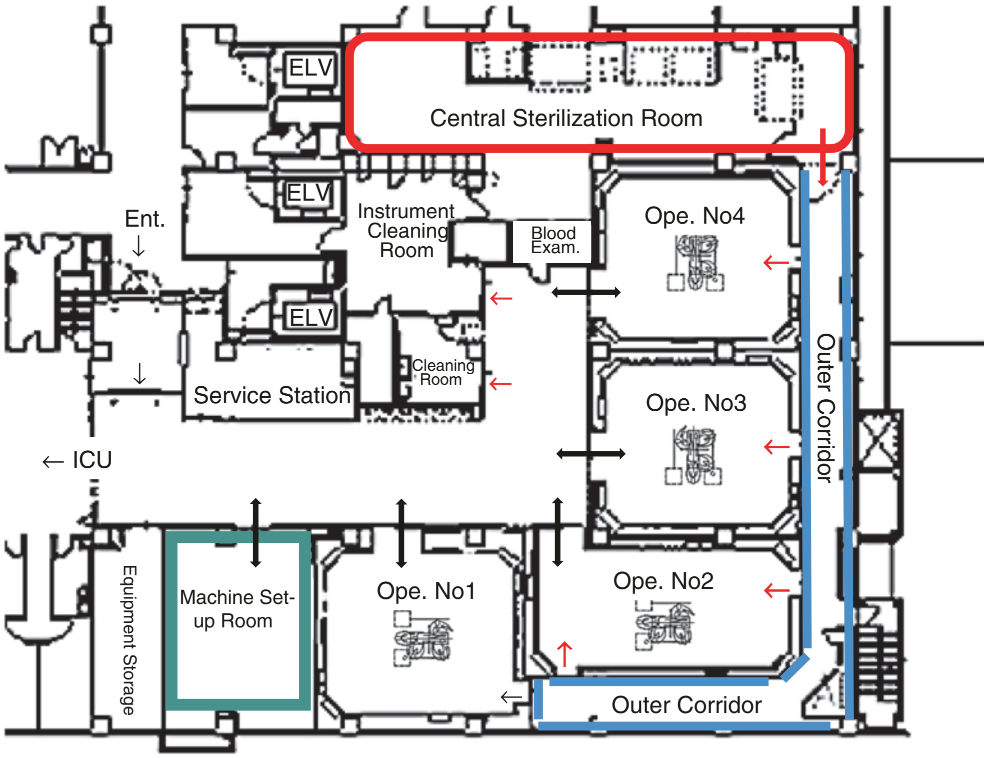


Fig. 6.35 Outer corridor for instrument preparation and heart–lung machine preparation room

Fig. 6.36 Outer corridor and instrument table

Column: Academic Meeting of Extracorporeal Circulation in Akita City

Figure 6.37 shows the time course of 3 VSD surgeries in series, which was planned in one operation room.

On the day of the surgery, elective surgery for two cases of VSD was planned originally. On that day, A shocked VSD case was admitted urgently, and emergency surgery was performed as the third case. This is the slide presented at the lecture of Akita Extracorporeal Circulation meeting in March, 2000. Dr. Fumio Yamamoto, the President of the School of Medicine, Akita University, gave me a great compliment on the fact that three open-heart surgery operations were completed in one operating room by 17:00.

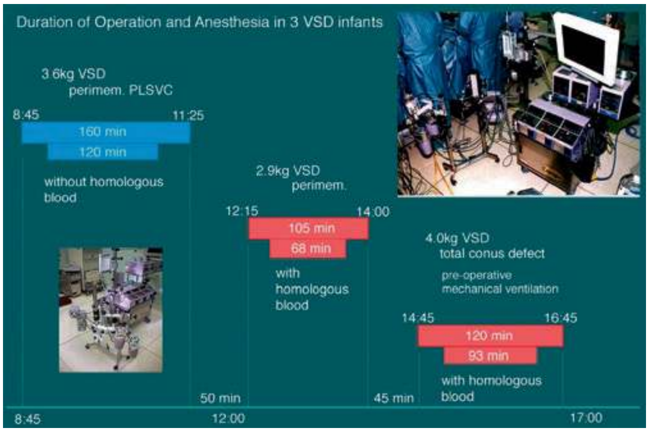


Fig. 6.37 Slide used at Akita Extracorporeal Circulation Conference (2000)

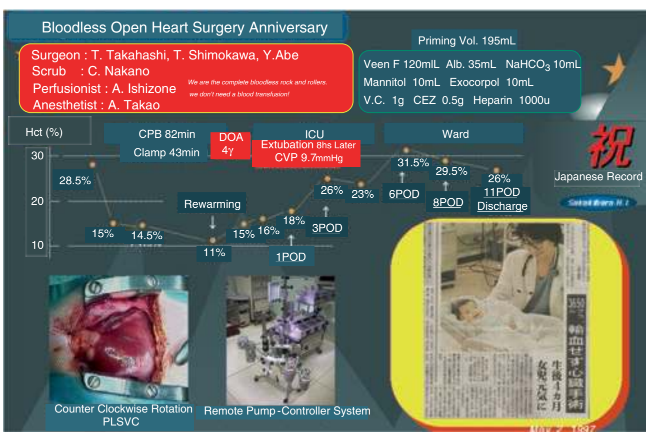


Fig. 6.38 Bloodless open-heart surgery in a case of VSD weighing 3.6 kg. This is the first VSD case when the indication for bloodless open-heart surgery was expanded to a weight of 3 kg using the isolated pump controller heart–lung machine and safe micro oxygenator

As an aside, Fig. 6.38 shows the lowest weight VSD case who underwent bloodless open-heart surgery. This was a propaganda slide for hospitals aiming to increase research expenses (and increasing salaries). Citing a popular Japanese song of the time, I wrote a playful sentence that said, "We are the absolute bloodless rock and rollers…we don't need a blood transfusion!" Apparently, this sentence was frowned upon by many people, so, unfortunately, the increase of salary did not come true.

6.5.4 Operation Planning 4

It is also necessary to consider the duration of surgery performed by the trainee in the surgery plan.

6.5.4.1 Research Paper at S.H.I Study on Surgery Planning 4

This 1999 manuscript considered in terms of time the ASD open-heart surgery that a resident had experienced for the first time. The objectives were: (1) Consider the position of ASD open-heart surgery in the surgery plan, as the number of days to perform two to three surgeries in a day has increased, (2) Identify the time zone during surgery that should be attempted to reduce time from the perspective of educating surgery. I thought it was necessary for young surgeons not only to have the confidence to perform the procedure itself, but also to acquire the sense of time.

Introduction

It is important to establish a system that can complete treatment in a shorter period of time, even in congenital heart disease. This requires the cooperation of all staff involved in the treatment, but, first and foremost,it is imperative for surgeons to aim for shorter surgery and shorter ICU stays. In this paper, we report on the reduction of surgery time for ASD, which is the most typical surgery in Fast Track.

Subjects and Methods

The subjects were 78 ASD cases (weight 7.0–34.8 kg) from 1997 to 1999. There were 42 mid-sternotomy cases and 36 right thoracotomy cases. The study was done by considering future issues for the Fast Track by the assessment of surgery and anesthesia time.

Results

1. Figure 6.39 shows the surgery and anesthesia time for each resident. Extracorporeal circulation 44 ± 11 min, Surgery 135 ± 23 min, Anesthesia 175 ± 25 min, Thoracotomy + chest closure 91 ± 21 min, Induction of anesthesia + preparation for exit 42 ± 8 min.

In addition, Fig. 6.40 shows the difference of times by incision site or supervising surgeon.

Mid-sternotomy: extracorporeal circulation 47 ± 11 min, Thoracotomy + chest closure chest 81 ± 20 min, surgery 123 ± 23 min, anesthesia 167 ± 25 min.

Right thoracotomy: extracorporeal circulation 40 ± 11 min, Thoracotomy + chest closure 103 ± 17 min, surgery 142 ± 21 min, anesthesia 185 ± 22 min.

In the right thoracotomy, the operation and anesthesia time was longer because time for thoracotomy + chest closure was about 20 min longer. In addition, among the supervising doctors, the difference of time for thoracotomy + chest closure affected the difference in surgery and anesthesia time (Fig. 6.40).

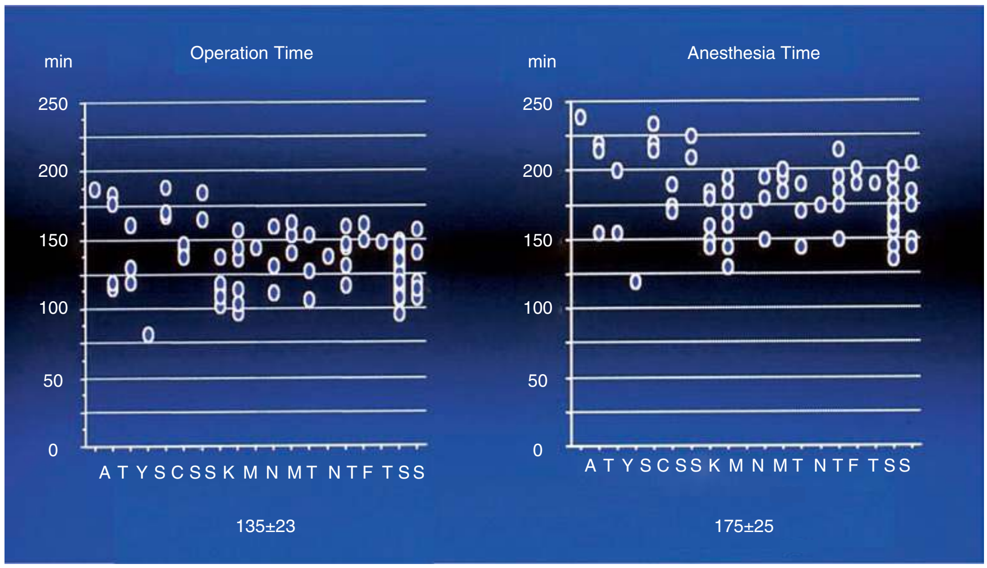


Fig. 6.39 Duration of operation and anesthesia in ASD repair for each resident

ASD 1997~ 1999 n= 78

CPB	Operation	Anesthesia	Ope.-- CPB	
44±11	135±23	175±25	91±21	min

	CPB	Ope.	Anesthe.	Ope.-CPB
Median Sternotomy n=42	47±11	123±23	167±25	81±20
Right Thoracotomy n=36	40±11	142±21	185±22	103±17
Staff 1 n=47	44±12	146±21	188±23	102±19
Staff 2 n=31	43±11	118±14	157±15	75±12

Fig. 6.40 Difference in operative time by incision site and supervising surgeon

2. Figure 6.41 shows the correlation of the time for extracorporeal circulation or the time for thoracotomy + chest closure between the time for surgery, and the correlation of the time for surgery or the time for anesthesia induction + exit between the time for anesthesia. A stronger correlation was found between the operation and the thoracotomy + chest closure, and also the anesthesia and the surgery.

Discussion and Conclusion

In recent years, Fast Track Recovery has been drawing increasing attention in congenital heart disease surgery. So, various efforts have been made for the purpose of early postoperative recovery, early discharge, and reduction of medical costs by modifying surgery and anesthesia policy, or improving the management of extracorporeal circulation, and developing new surgical methods. However, it is counterproductive to extend treatment time or increase medical costs due to aiming for Fast Track. The top priority is simply for the surgeon to save time. It goes without saying that lean and prompt surgery leads to minimal invasiveness. However, in reality, it is difficult to realize, and there is almost no study on its effect in Japan. From this perspective, we examined means for shortening the ASD operative time for the purpose of establishing a Fast Track in ASD surgery by a resident.

At our hospital, the anesthesia time for ASD was 5–6 h 15–16 years ago (1980s), but since 1997 it has been reduced to less than 3 h on average, which is about half. As shown in Fig. 6.42, the number of cases with anesthesia time of

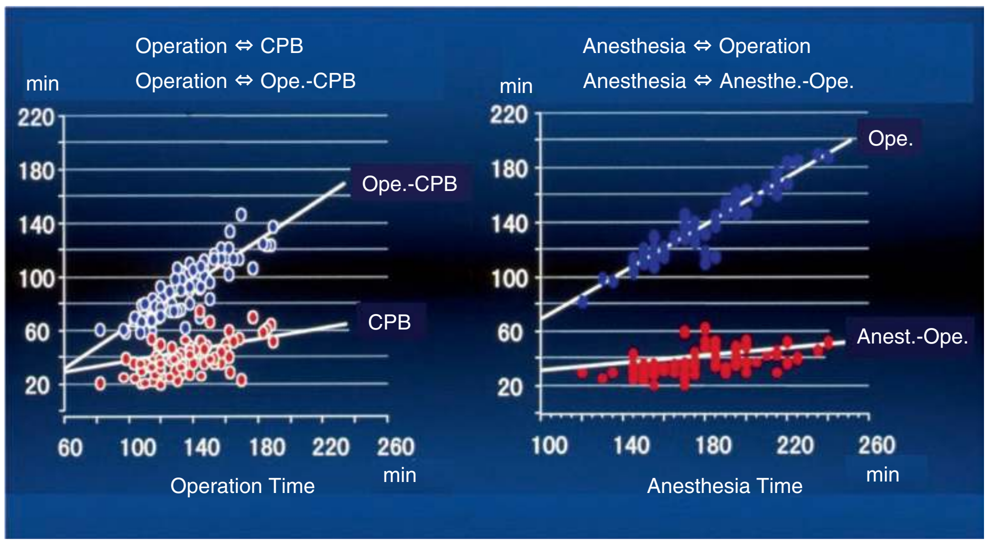


Fig. 6.41 Correlation of times in ASD surgery

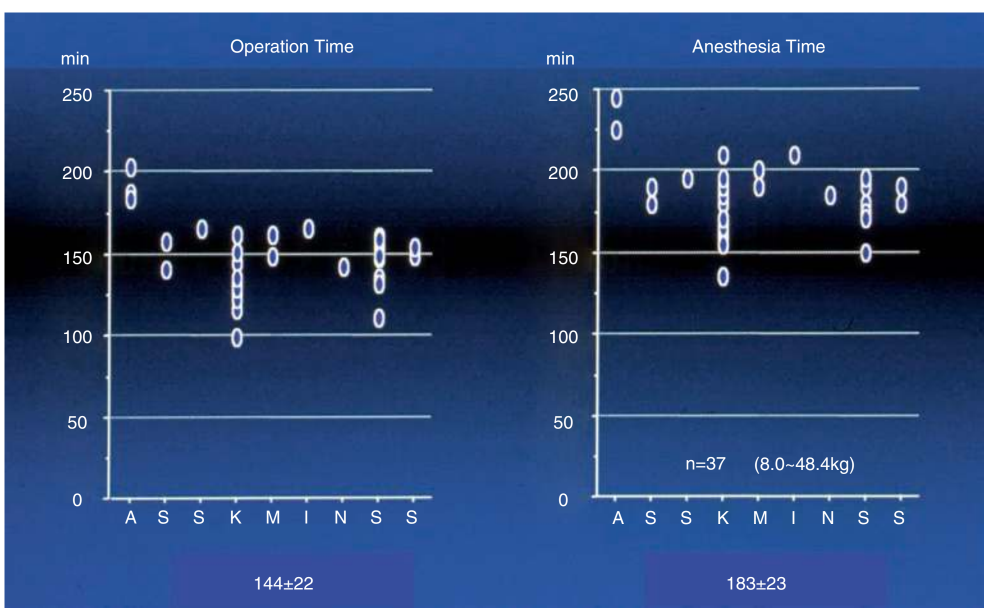


Fig. 6.42 Duration of operation and anesthesia in VSD repair by resident

150 min or less has increased, and recently it has become possible to start the second operation before 12:00. This study showed that the duration of surgery and anesthesia was directly correlated with the time for thoracotomy + chest closure, so first, it was considered necessary to shorten this time. Also, the difference in the operative time depending on the supervising doctor was due to the difference in the thoracotomy + chest closure time, so the teaching method of the thoracotomy and chest closure procedure should be reconsidered as well. In the future, the standard time for median incision ASD surgery by residents will be 100 min for surgery and 150 min for anesthesia.

In this subject, the intubation times after surgery were all within 5 h, and returned to the general ward on the first day. In addition, bloodless surgery was possible in all cases, and there were no perioperative problems. The most important thing is not to establish a Fast Track simply by shortening the operative time, but to aim for a Fast Track that sufficiently improves the postoperative condition. In the future, it will be necessary to conduct similar studies not only for ASD surgery but also for surgery for various diseases. Then, we will reconsider whether or not the Fast Track created for each disease is acceptable ("permissive Fast Track"), and evolve our own Fast Track.

Figure 6.43 shows the results of similar examination in VSD open-heart surgery. The operative time was longer than that of ASD, but similarly, the operative time was more strongly correlated with the thoracotomy + chest closure time, and the anesthesia time was also correlated with the operative time.

Figure 6.44 shows the CPB system, which was actually used by professor Shigeru Sakakibara in 1962. The priming volume of this machine was over 3000 mL. The excellent outcome of operations even by using this primitive machine may owe much to Professor Sakakibara's quick procedure. If the current surgeons can fly back to this era, It's not hard to imagine they may not work well. It is necessary for the supervising doctor to educate the residents with this in mind.

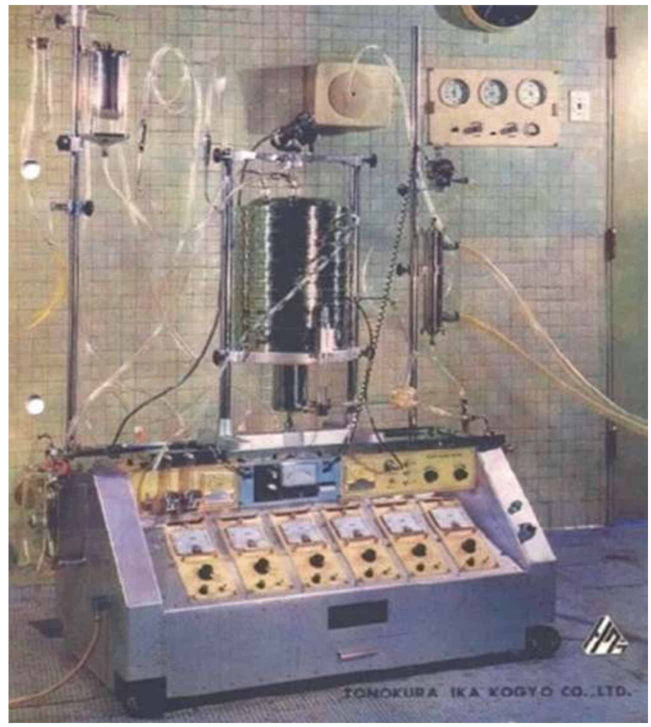
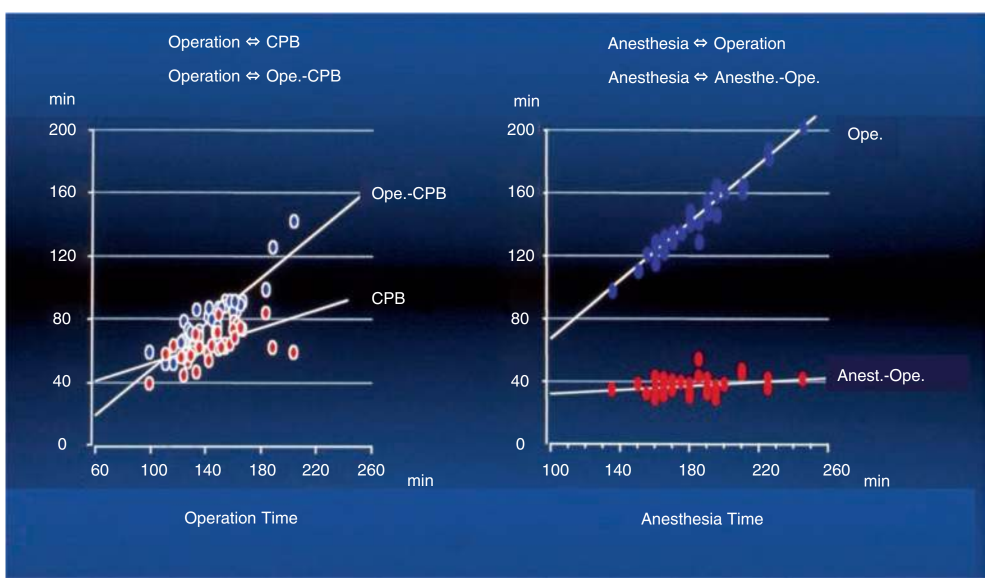


Fig. 6.44 Heart–lung machine with centrifugal type oxygenator

Fig. 6.43 Correlation of the times in VSD surgery



Column: Underground Cafeteria in the Former Sakakibara Heart Institute

When I joined Sakakibara Heart Institute in 1983, the most important goal for the trainees who perform ASD surgery was to finish it by 2:00 pm, which was the closing time of the hospital cafeteria in the basement. It was an era when it was said that today's surgery would have been quick if lunch could be taken by that time. So, at 2:00 pm in the underground dining room at that time, it was also a place for reflection and communication with the boss.

The operating time of the resident will naturally be long. The supervising surgeon must consider the teaching method with that in mind. At the least, basic surgical procedures such as ligation and suturing should be practiced well in advance, and basic knowledge about the invasion of extracorporeal circulation and management of postoperative ICU should be mastered.

At that time, there were many opinions that it was dangerous to have a trainee to perform a surgery in a hurry, and they should have more experience with careful surgery until they get used to it. That's true. However, more than that, the surgical instructor needs to make an effort to create the sense that the ASD surgery performed by resident is natural to be completed in a short time. Figure 6.45 shows the course of surgery for ASD case weighing 20 kg and Fig. 6.46 shows changes in the operative time of ASD cases for each weight after the year 2000. Finishing ASD surgery in a short time is a qualifying factor for residents to perform more complicated surgery and is also an essential requirement popular to anesthesiologists, pediatricians, and nurses.

Q&A: Surgeon's Hand (Question in 2017)

Question: I am a first-year resident after graduation. My future dream is to become a leading cardiac surgeon. During surgery, I'm always warned that my hands are not moving. Please give me advice.

Answer: The surgeon's large hands are interlaced in a small surgical field, especially in open-heart surgery for neonates. I think that what is important is the skin sensation not to interfere with each other's hands. In your case, you may not have that sense yet. Most surgeons are self-centered, so they will not like you to come into their territories. Of course, you will receive a warning. But well, you should get used to it soon, So don't worry too much. One thing to keep in mind, however, is to view the whole surgery, not just the most important intra-operative procedure, until you would not receive warning. Of course, you don't have to look hard. I think that staying in the operating room as much as possible is the quickest solution to develop skin sensation. It's easy to see that in a well-flowing surgery, everyone cares for each other naturally and creates a flow of surgery where they don't hit their hands and get in the way.

I mentioned that many surgeons were self-centered, but once they gained this cutaneous sensation, they became per-

		In					Out
	Anesthesia Time	0	15	30	45	60	75 min
		↑ Intubation	↑ Incision	↑ Pump on	↑ Pump off		↑ End
				CPB			
Bladder Temp. (℃)		36.7		35.1		36.0	
Blood gas	Na (mEq/L)	138		132		137	
	K (mEq/L)	3.7		3.5		3.5	
	B.E.	+1.3		+3.5		+2.7	
	Hct (%), Hb (g/dL)	41.0, 14.0		29.0		28.8	
	T.P. (g/dL)	6.7		4.4		4.8	
Correction	25% albumin (mL)						
	salin HES (mL)						
	10% NaCl (mL)			20			
	KCl (mEq)			5			
	D-mannitol (mL)			5			
	$NaHCO_3$ (mL)			30	4		
	sublood BD (mL)						
	C.H. (mg)						
	$CaCl_2$ (mL)				4		

Fig. 6.45 Surgical course in a case of ASD surgery

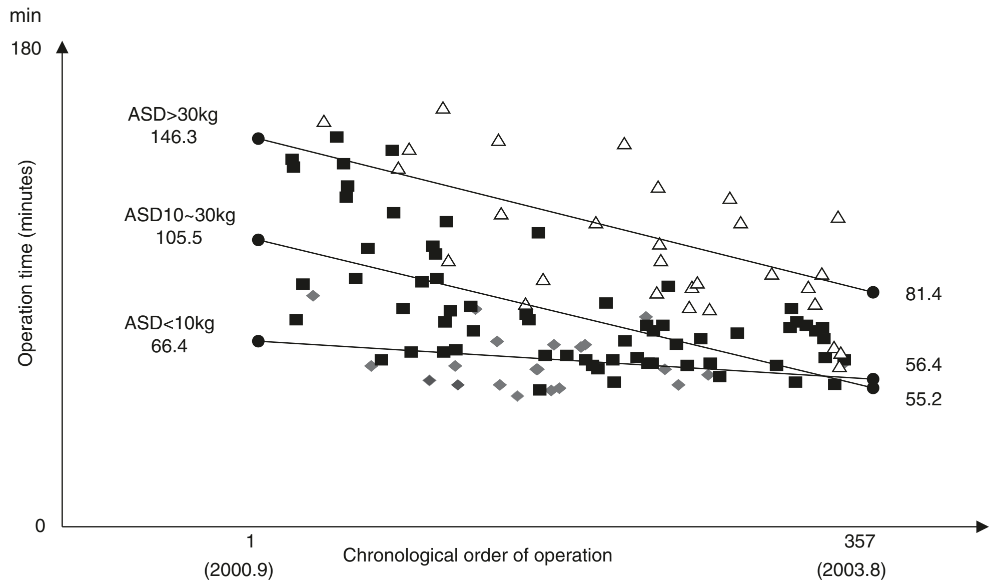


Fig. 6.46 Annual changes of operative time in ASD cases by physique ([9] modified)

fect pacifists and hated to compete with others. The reason is that we know that competing with others is not only a disadvantage for our mental state but is our patients' disadvantages. For some reason, some doctors and nurses say that "there is a need for reform" or "we must fight for it." I think it is probably because they could not feel the cutaneous sensation in their clinical experience.

You have to do a lot of work right now, and I think you are pretty busy, but it is one of your talents as a surgeon to spend some time in the operating room even if you feel unproductive. It will become useful again later. Please persevere.

Q&A: Tips for Shortening Operation Time (Question in 2017)

Question: I joined the cardiac surgery department three years ago. I operated on an ASD in my second year, and just the other day, I operated on VSD for the first time. The anesthesia time was 5 h 30 min. Could you please give me some tips on how to shorten the operative time

Answer: "Before answering your question, I shall say a couple of things that may make you feel that I am harsh. First, the operative time is indeed a little too long. You need to reflect on your skills carefully and try to improve them. Second, it is the way you asked the question. You asked for tips, but I cannot answer you straight away. I cannot give an answer if you do not ask specific questions about the problems you felt about the operation and your thoughts of how to solve them; for example, "Will it be better if I have done such and such?" and "To be able to do that, what kind of training do I need, or whose surgical technique should I refer to?" Please excuse my tedious talk. I may not give you the answer you are looking for, but when I operate with young surgeons or when I teach them during operation, I notice certain things. Please allow me to talk about them.

1. Whether you are dexterous or not is not that important, it will come with practice. Also, each of the techniques, such as VSD closure, will be acquired through practice on many cases. These are not major concerns. During the operation, the nurses who pass you instruments will take care of you like a mother, and the anesthesiologist and the perfusionist will manage the whole body of the patient for you. All you have to do is to concentrate on the operative technique. However, when young surgeons do their first operation, I find every time that they are not moving efficiently to maintain the smooth flow. It makes me wonder why I bother to demonstrate 500 cases of surgery every year. I think the main reason is that an observer who does not actually participate in the operation does not make an effort to see the surgery in its entirety. They will not be able to move efficiently to catch up with the flow just by watching the surgical monitor screen outside the operating room or by observing only the maneuvers inside the heart. It has been said that surgery is done by the head, but this is not true. Surgeries are done by the hands, not by the head. And, if you come to the operating room earlier than anyone else, you have more time to think about the flow of the surgery. The sense of time is truly a sensory perception. The operating room is an important place for a surgeon to think of time in a physical dimension.
2. I often hear people say that they are so nervous that they cannot move their hands. But, that is just an evidence that they are not properly trained to control their nervousness. The primary surgeon must not be nervous. There is no need to get nervous about things that are not happening. However, it is important to create an atmosphere of comfortable tension to work as a team. In this way, the entire team can handle with ease the tremendous tension that is to come next. I also often hear comments after the surgery

Fig. 6.47 A device for practicing deep suture

that certain parts should have been done more carefully taking longer time. However, if you hold the idea to operate slowly from the beginning, you will never learn to shorten your operative time.

3. Another thing that I notice in terms of the flow of surgery is the practice of some surgeons to cut off the needles on both ends before ligation every single time. Please practice every day to tie sutures without cutting off the needles. A long suture left after ligation can be reused for hemostasis. Figure 6.47 is a device for practicing deep suture used in 1984. We tied a piece of cloth to the inner ring and repeatedly practiced ligation and suturing. However, an important thing about practicing like this is that you should not take it seriously or practice too earnestly (I may be told off for saying that). You can practice at ease while watching television or talking, without looking at the needles and suture. Soon you will not puncture your fingers with the needles anymore. I may add that when I recently received raw oysters from a friend in Tohoku, I struggled so hard to remove the shells. But, when I see the scenes on television of ladies shelling oysters in places famous for oysters, they are all chatting and working leisurely with fun. Ligation practice is probably the same. In any case, it is mostly unlikely that you can do things during the actual operation, which you were not able to do during practice.
4. Surgeons have the traditional belief that they must watch, imitate and "steal" the surgical techniques of senior surgeons. I suppose there are some senior surgeons whom you aspire to become in the future. However, imitating is like wearing a costume with the face of the senior surgeon. It is fine at first, but soon you will find things that do not work well, and gradually people around you will find it annoying. I think it is necessary to take off the costume early and to feel the change in yourself after taking it off.

I have done enough preaching, now let me return to VSD. Not only just to improve your surgical skills, but being confident that you have mastered the ability as a primary surgeon to shorten operative time will be a certificate allowing you to perform operations smoothly for serious cases that take longer time. This is because pediatric heart surgery is a combination of individual surgical techniques.

From the viewpoint of educating newcomers, for the basic techniques of VSD closure, I believe trainees should at least acquire a level of skills that they can be proud of as a medical personnel in the cardiovascular specialty. For this, I am giving slightly intensive and thorough training for the newcomers, including perfusionists and nurses. I reprimand them for not scoring 200 points for a surgery with a full score of 100 points. Being able to work fast also means that the person has achieved the ability of making decisions on how to act appropriately according to the circumstances. There is no point in praising someone for accomplishing a job at low level. Figure 6.48 shows the VSD model created in a porcine heart used in the wet lab; Figure 6.49 shows the Jatene surgical model; and Fig. 6.50 shows a scene of the wet lab at the 200 Club, a society for surgeons who perform more than 200 surgeries a year. You are welcome to participate in these activities, even just to try it once.

I think you are already doing your best, but please do not lose confidence and do your best a little more from now on."

Column: First Surgery

A young surgeon is so nervous during the first surgery. Even if you know the recipe well, it is very impossible to get the same taste as your boss. But do not be nervous. The first surgery is like a virgin actor playing a kissing scene, pretending to be a gigolo.

So, for that, you should only prepare your mind.

However, once the surgery is performed, it gives some strange confidence. You don't know the details yet, but you can feel that it moves naturally. In addition, if you can feel that being nervous is a waste of time early, you are already a full-fledged surgeon.

However, as you get used to it, your body may remember the good results you had before, resulting in unknowingly crude surgery. At least, it may be better if you are always very nervous like the first surgery. It's often said that "don't forget the good image," but when something unexpected happens, you may not be able to deal with it. Sometimes it's not good to stick to the previous good results. This is not just surgery, but life, romance, etc., all the same truth.

If you think a little loosely like that, there are many things you cannot do at first, but there will be more and more things you can do. The degree of mental preparation and results of the first surgery will vary from surgeon to surgeon.

However, the new starting line that begins after the first surgery is exactly the same for all young surgeons. That is the first surgery.

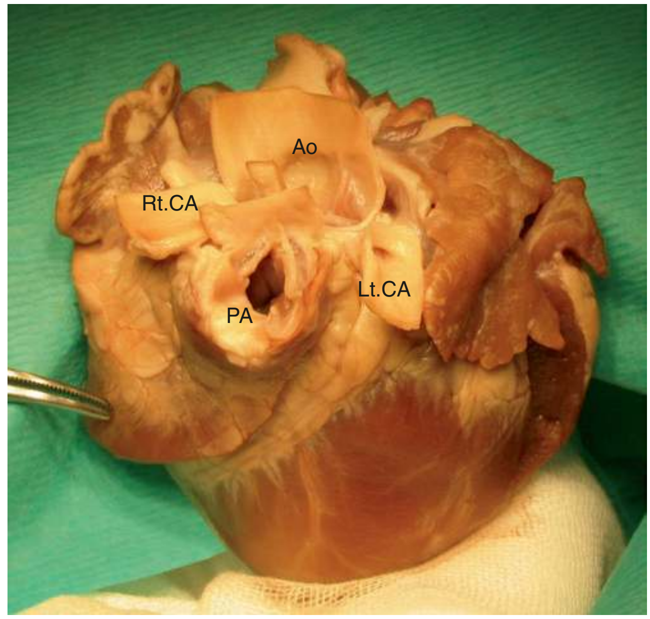


Fig. 6.49 The Jatene surgical model

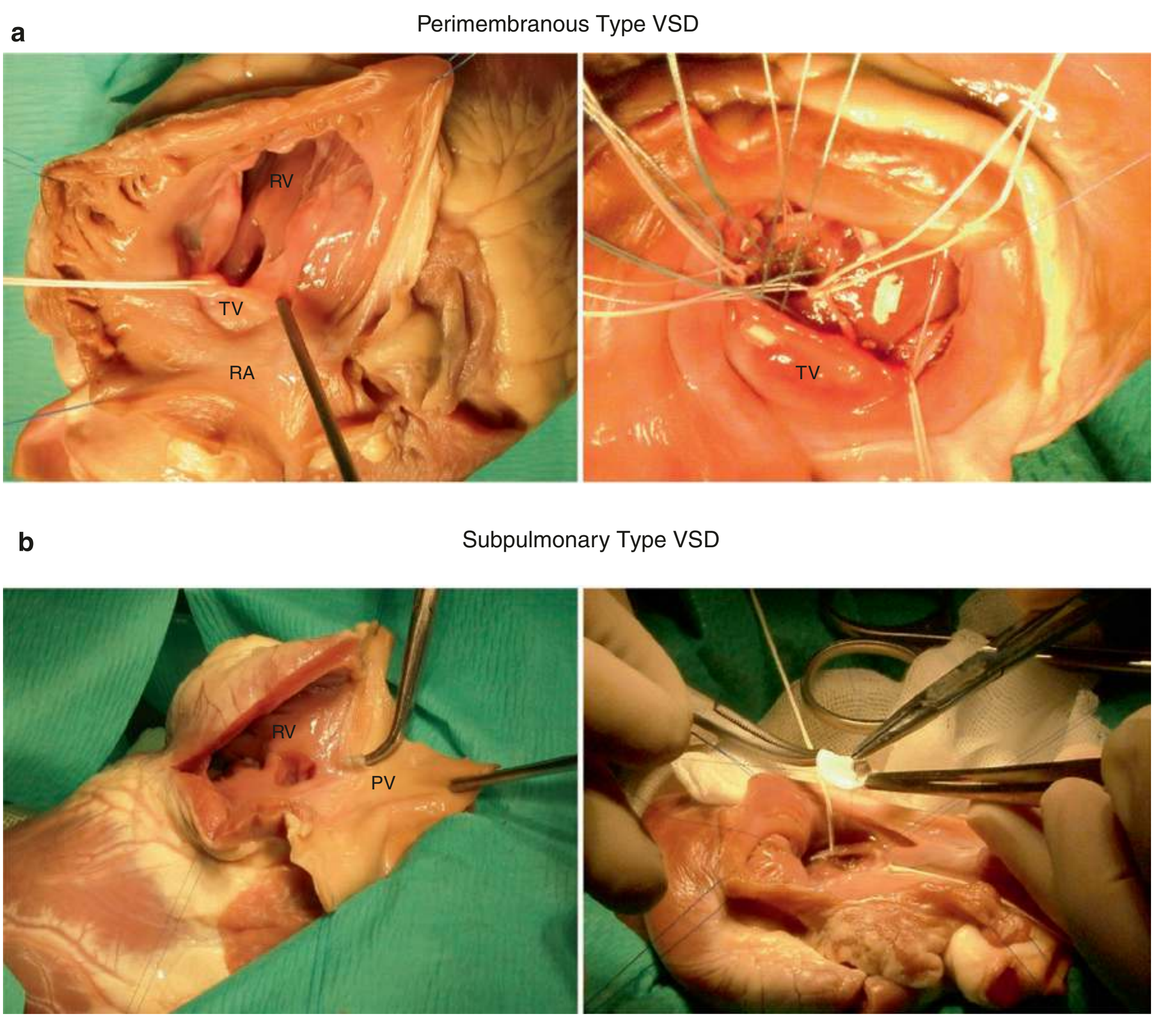


Fig. 6.48 VSD model created in a porcine heart. (**a**) Perimembranous defect. (**b**) Subpulmonary defect
RA: Right Atrium
RV: Right Ventricle
TV: Tricuspid Valve
PV: Pulmonary Valve

Fig. 6.50 A scene of the wet lab at the 200 Club

Column: Medical Progress and Declining Birthrate

In recent pediatric heart surgery, the number of operations for ASD and PDA has been drastically reduced with the progress of catheter treatment. Of course, there may be an impact on the declining birthrate. On the other hand, reoperation cases such as adult congenital heart disease and Glenn or Fontan surgery after palliative surgery increased. It now accounts for more than one-third of the total number of operations, and pediatric cardiac surgery can also be called exfoliative surgery. Eventually, the time may come when the trainee's first surgery will be conduit replacement after Rastelli surgery or Fontan surgery. It is expected that the hurdles for obtaining qualifications for trainees will be considerably high, and these things will be quite annoying in terms of surgical training for young surgeons. Regarding the training of pediatric cardiac surgeons in the future, it is necessary to have a sufficient discussion, including the medical system, how to develop excellent surgeons.

In my junior high and high school days, there was a totally nasty guy who easily became a class hero by doing whatever sports he did. Young surgeons in the future may need to be the most disliked type of person, who can easily do anything with his first surgery.

Column: Infection

Shortening the operative time is also important in terms of reducing the risk of infection. However, most sepsis and severe mediastinitis after cardiac surgery should be considered as bloodstream infections, not due to intraoperative bacterial exposure. The compilation of infection not only prolongs treatment but also leads to failure of surgery planning. The biggest misconception a newcomer makes is to perform line management such as intravenous injection without changing disposable gloves after aspirating sputum or writing medical records. Line management needs to be taught strictly. Also, the longer the postoperative management, the more infusion and arterial lines will be left. Therefore, it is important to recover the patient early and remove the line as quickly as possible. In terms of infection, it is essential to build comprehensive minimally invasive measures aimed at early recovery.

6.6 ePTFE Valve

I have never contributed to the minimal invasiveness by developing a new surgical technique. However, it can be said that it is minimally invasive if the improvement of the results and the postoperative quality can be achieved by adding the ingenuity.

Since October 1997, we have started using a trileaflet valved conduit made of ePTFE sheet for right ventricle-pulmonary artery reconstruction (so-called Rastelli procedure). This was triggered by observing the Rastelli procedure using the trileaflet valved conduit made of equine pericardium at the National Cardiovascular Center in Osaka in May 1992. Currently, 12–26 mm diameter conduits are created by hand and widely applied clinically to neonates with Truncus Arteriosus Cummunis and Absent pulmonary valve deficiency, Ross procedure, and adult re-operation cases with residual pulmonary regurgitation. It was used in about 600 cases by 2019. Hemashield is used for the conduit. The reason is not only less anastomotic bleeding but also flexibility and a gentle curve from the right ventricle to the pulmonary artery to reduce blood turbulence as much as possible.

The function and durability of the ePTFE valve are good, and the evade rate for re-operation is higher than that of Xenograft. Also, the time for the procedure for replacing the conduit is relatively short, and the postoperative circulatory dynamics are stable. In particular, the fact that it is unnecessary to take Warfarin is most beneficial to the children. Previously, we used a valveless conduit or Xenograft, as shown in the column "Rastelli surgery," but we have used this e-PTFE conduit since 1997 (Fig. 6.51). Figure 6.52 shows a conduit-size-specific mold for cutting an ePTFE sheet [10, 11, 12, 13].

Videos 6.3, 6.4, 6.5, 6.6, 6.7, 6.8, and 6.9 shows how to make a conduit with an ePTFE valve and the operation using this conduit. It is called the ORIGAMI technique overseas. Regarding the good function of the ePTFE valve created by this method, in 2000, Dr. Takehisa Fukada of the Department of Mechanical Engineering (Umezu Lab), Faculty of Science and Engineering, Waseda University, conducted a static characteristic test under steady flow and a dynamic characteristic test under pulsatile flow. From this result, the valve height of the ePTFE valve with respect to the diameter of the conduit was set to the diameter with the least valve regurgitation x 0.8.

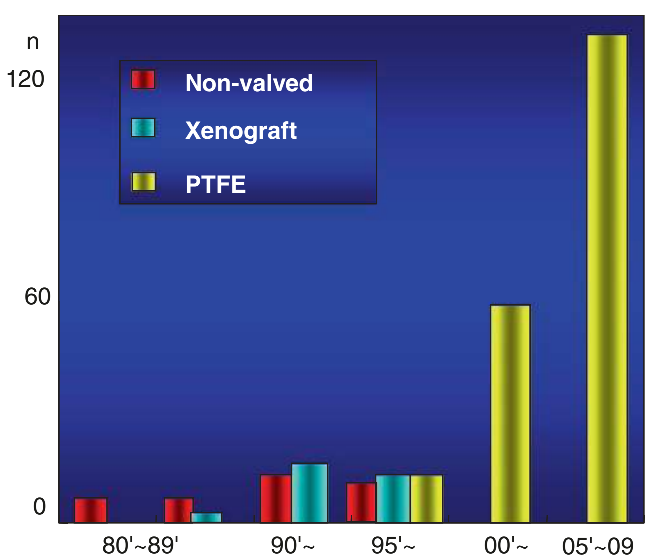


Fig. 6.51 Annual change of conduit material

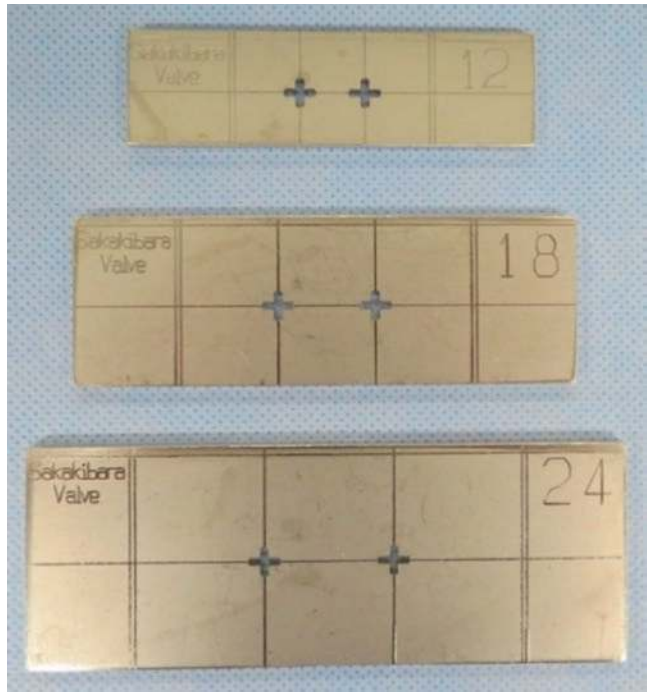


Fig. 6.52 Mold for cutting ePTFE3 sheet. Utility model registration No. 3175944

Column: Reconstruction of Right Ventricular Outflow Tract in Neonatal and Infantile Ross Procedure (2020)
I have performed surgery for about 7000 congenital diseases so far. In March 2020, I was able to get a medical degree. Acquisition at the age of 64 is quite rare in Japan. The theme chosen for Thesis was neonatal and infantile Ross surgery, and the title was "The Ross Procedure in Neonates and Infants-Surgical Outcomes and Issues to be solved in Japan-." Although the number of subjects was as small as 13 cases (Table 6.2), the survival rate was 100% at a median follow-up of 10.8 years, and QOL in the postoperative remote period was good. In this Ph.D. thesis, we discussed the usefulness of the e-PTFE valve in reconstruction or re-operation for the right ventricular outflow tract. As you know, it is difficult to obtain homograft in Japan, and it is often necessary to use a handmade ePTFE valve. The results and consideration of the ePTFE valve described in this thesis are presented.

6.6.1 Result

The right ventricular outflow tract reconstruction materials used in Ross surgery were were ePTFE single leaflet valve patch in 2 cases, equine or bovine bicuspid valved conduit in 4 cases (10 mm 3 cases, 13 mm 1 case), and ePTFE tir-leaflet valved conduit in 7 cases (12 mm 2 cases, 14 mm 2 cases and 16 mm 3 cases). In 4 patients (10–65 days old, weight 2.8–4.2 kg) using a 10 mm equine or bovine bicus-

Table 6.2 Patient characteristics [14]

No.	Age at Ross (d)	Height (cm)	Weight (kg)	First Diagnosis	Baloon valvuloplastv	Previous Surgery	Hemodynamic Diagnosis at Ross	Pre EF (%)	Emergency
1	186	59	4.5	AS	yes	none	AS AI MI EFE	50	yes
2	120	61	5.7	AS	yes	none	AS AI	70	no
3	171	68	7.5	AS	yes	none	AS Ai	60	no
4	166	64	7.2	AI MI	no	none	AI MI	66	yes
5	207	66	6.7	AI	no	none	AI MI	66	yes
6	208	68	7.5	AI MI	no	none	AI MI Valsalva aneurysm	32	yes
7	12	48	3.4	AS Ai	no	none	AS Ai	85 → 66	yes
8	65	54	4.2	AS AI CoA LCA hypoplasia	no	none	AS AI MI CoA LCA atresia	29	yes
9	356	71	7.9	AS	yes	none	AS MI SVAS	57.8	no
10	9	50	2.9	AS PDA PFO	no	none	AS PDA PFO	70	yes
11	251	64	8.9	AS CoA PSVT	no	none	AS CoA PSVT	62.6	no
12	60	54	4.8	AS Ai	no	none	AS Ai	59 → 24.5	yes
13	23	51	2.8	AS Ai CoA ASD PDA	no	BAS ASD creation + bilateral PAB	AS Ai PDA CoA PFO	30 → 52	yes

Nine of the 13 patients underwent Ross surgery urgently or semi-emergency. In particular, cases 6 and 8 in which the left ventricular ejection fraction decreased at the time of admission and cases 7 and 12 in which a rapid decrease in ejection fraction occurred after admission were treated as emergency

In case 13 in which left ventricular ejection fraction decreased from the fetal period, bilateral pulmonary artery banding was performed first, and Ross surgery was performed after improvement of left ventricular ejection fraction

AS As: aortic stenosis (S ≧ 40 mmHg, s < 30 mmHg)
ASD: atrial septal defect
AI Ai: aortic insufficiency (I ≧ moderate, i < mild)
BAS: balloon atrioseptostomy
CoA: coactation of the aorta
EF: ejection fraction
EFE: endocardial fibroelastosis
LCA: left coronary artery
MI: mitral insufficiency
PAB: pulmonary artery band
PDA: patent ductus arteriosus
PFO: patent foramen ovale
PSVT: paroxysmal supraventricular tachycardia
SVAS: supravalvular aortic stenosis

pid valved conduit, or a 12 mm ePTFE trileaflet valved conduit at the time of Ross operation, re-operation was performed 0.8 to 2.7 years after the Ross operation (6.4–14.7 kg). The conduit diameters used at that time were 14 mm or 16 mm ePTFE trileaflet valved conduit. In contrast, In 5 patients (14–356 days old, weight 6.7–8.9 kg) using a 14 mm or 16 mm ePTFE trieleaflet valved conduit, re-operation was performed 3.8–10.3 years after the Ross operation (15.1–30.9 kg) (Fig. 6.53). The conduit diameter used was 18–22 mm. Pulmonary valve insufficiency at the last observation was moderate in case of the ePTFE single leaflet valve patch without re-operation and in case of the 12 mm ePTFE trileaflet valved conduit, whereas the other 11 cases were mild or less. The pressure gradient in the right ventricular outflow tract was 12–38 mmHg (Fig. 6.54).

Fig. 6.53 Materials used for reconstruction of right ventricular outflow tract ([14] modified)

	Ross		1st Reoperation	
No.	Reconstruction Material	Dia. (mm)	Reconstruction Material	Years after Ross
1	Equine Patch Bicusp	13	ePTFE Monocusp	4.9
2	ePTFEMonocusp	13	ePTFE Tricusp 22mm	10.3
3	ePTFE Monocusp	14	none	18.7
4	ePTFE Tricusp	16	ePTFE Tricusp 22mm	9.9
5	ePTFE Tricusp	16	ePTFE Tricusp 20mm	4.8
6	ePTFE Tricusp	16	ePTFE Tricusp 18mm	5.8
7	Equine Patch Bicusp	10	ePTFE Tricusp 14mm	1.2
8	ePTFE Tricusp	12	ePTFE Tricusp 14mm	0.8
9	ePTFE Tricusp	14	ePTFE Tricusp 18mm	4.6
10	Equine Patch Bicusp	10	ePTFE Tricusp 16mm	2.7
11	ePTFE Tricusp	14	ePTFE Tricusp 18mm	3.6
12	ePTFE Tricusp	12	none	3.5
13	Bovine Patch Bicusp	10	ePTFE Tricusp 14mm	1.1

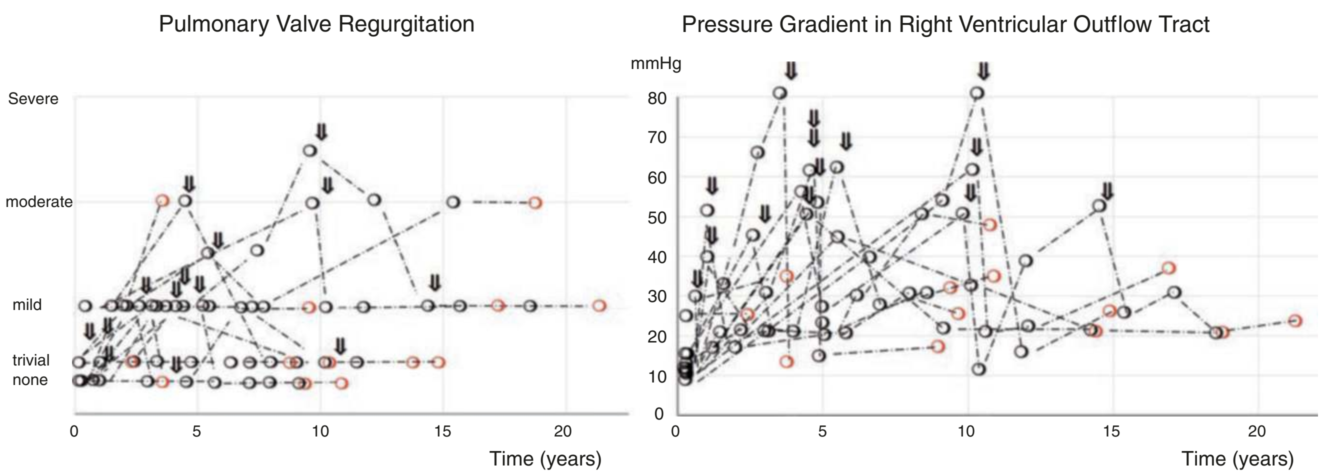


Fig. 6.54 Hemodynamics in right ventricular outflow tract. Red circles show data at the time of final echocardiography in each case. Indicates the timing of reoperation for the right ventricular outflow tract.

Left figure ... In the final observation, 11 cases had mild or less regurgitation.

Right figure ... In 8 cases, reoperation was required less than 5 years after Ross operation

6.6.2 Discussion

Aortic or pulmonary homografts are often used for reconstruction of the right ventricular outflow tract in the less than 1-year-old Ross operation in Europe and the United States. The average homograft diameter used was 14–15 mm (8–24), and the freedom from re-operation was reported to be 44–85% in 5 years, 47–71.5% in 10 years, and 19–23% in 15 years. On the other hand, it is difficult to obtain homograft in Japan. In addition, there is also a restriction on the use of a Contegra pulmonary valved conduit, which was approved for use in 2012. Therefore, there is no choice but to use a valved conduit that is made by hand using a bovine patch or ePTFE sheet.

In this study, the freedom from re-operation for the right ventricular outflow tract was 25% for 5 years, 9% for 10 years, and 9% for 15 years, and relatively early re-operation was required. Eight of the 11 patients who underwent re-operation had re-operation within 5 years. The first reason for the lower freedom from re-operation than in the USA and Europe was considered to be the use of a heterologous pericardial patch bicuspid valved conduit, mainly in neonates. Poor mobility of valves due to hardening, and the branch pulmonary stenosis progressed at an early stage. The second reason was the small diameter of the conduit. The diameter of the conduit used in this study is 13 mm (10–16) on average, but the commissures of each valve are sewn about 1 mm in consideration of valve coaptation (Fig. 6.55). As a result, the actual diameter was reduced by about 1 mm from the conduit diameter. First of all, it was of course necessary to use a larger conduit to postpone the re-operation.

We have been using an ePTFE trileaflet valved conduit for the reconstruction of the right ventricular outflow tract since October 1997. This is a modification of the equine patch conduit used at that time. ePTFE sheet was said to have little cell infiltration, degeneration, calcification and adhesion with surrounding tissues, so we expected the long-term durability of ePTFE. The first case using the ePTFE trileaflet valved conduit was a 12-year-old patient with aortic regurgitation who underwent Ross' operation on a 24 mm conduit. Subsequently, the indication for the use of this ePTFE trileaflet valved conduit was extended to other diseases requiring reconstruction of the right ventricular outflow tract and used from neonates to adults. The conduit diameter was 12–26 mm in every 2 mm, and the total number of cases used was 593 by December 2019.

In our report of 139 ePTFE trileaflet valved conduits up to 2007, the freedom from re-operation was favorable at 3 years 98%, 5 years 94%, and 10 years 88%, and pulmonary valve insufficiency remained in mild or less in 75% of cases 10 years after surgery. In addition, the mean time until the pressure gradient in the right ventricular outflow tract reached 20 mmHg was 2 years after the operation for 12 and 14 mm conduits and 4 years for 16 and 18 mm conduits. On the other hand, in te case of a conduit of 20 mm or more, the mean pressure range increased to 20 mmHg 5 years after the operation, but it did not increase until 10 years and remained constant (Fig. 6.56). From this result, the use of a conduit of 20 mm or more was our final goal in the reconstruction of the right ventricular outflow tract. With this conduit diameter, it is expected that pulmonary valve insertion by catheter treatment will be performed in the future. In this study, 5 cases using 14 mm or 16 mm ePTFE trileaflet valved conduit for Ross surgery were re-operated 3.8–10.3 years later, and the diameter of the used conduit was 18–22 mm. From the perspective of ultimately aiming to use a conduit of 20 mm or more, it is desirable to use a conduit of 14 mm or more at the first Ross operation.

The greatest advantage of the ePTFE trileaflet valved conduit is that it does not require anticoagulant therapy (Warfarin). In the case of Ross surgery using ePTFE trileaflet valved conduit, the longest case without re-operation was a woman with aortic regurgitation who underwent Ross surgery with a 24 mm conduit at the age of 27 years. 20 years and 8 months after the operation, aortic regurgitation was mild, the pressure gradient in the right ventricular outflow tract was 15 mmHg, and pulmonary regurgitation was none. Under these conditions, pregnancy and childbirth are fully possible. Especially in the Ross operation, which performs aortic root replacement with autograft, it can be said that ePTFE trileaflet valved conduit is the most useful conduit in Japan at present from the perspective of postoperative exercise, pregnancy and delivery.

The comments from thesis reviewers are as follows. "This study is the only comprehensive study of neonatal and infantile Ross surgery in Japan, showing good surgical outcomes

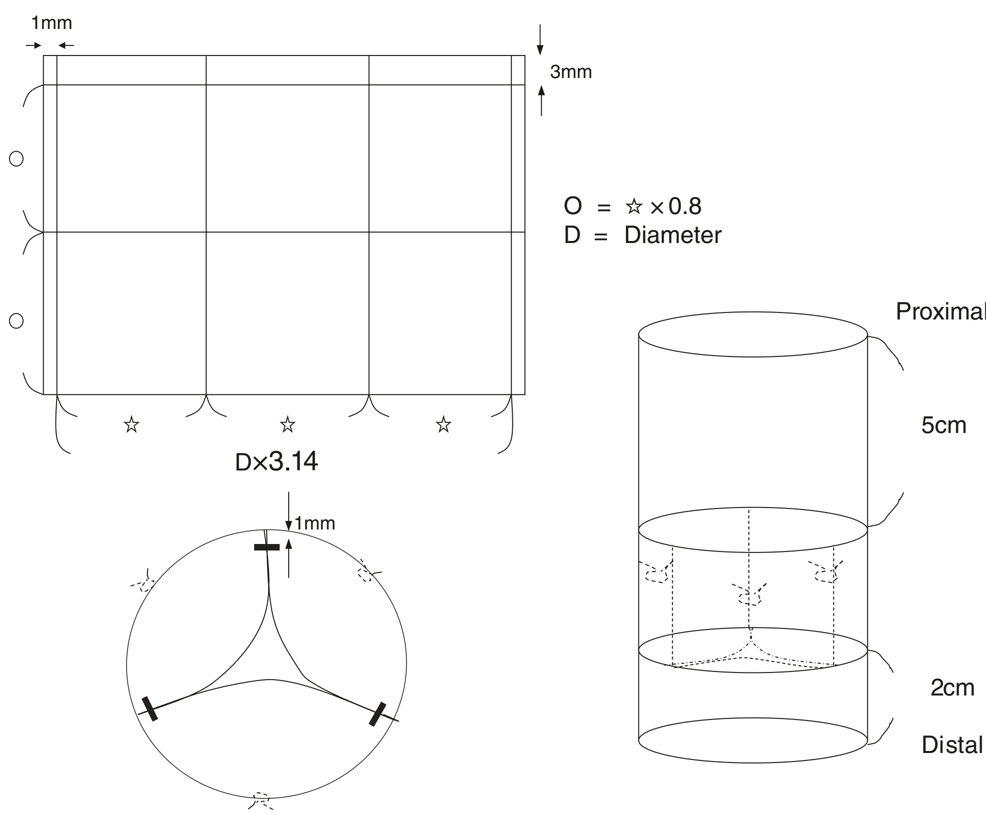


Fig. 6.55 How to make a conduit with ePTFE trileaflet valve ([15] modified)

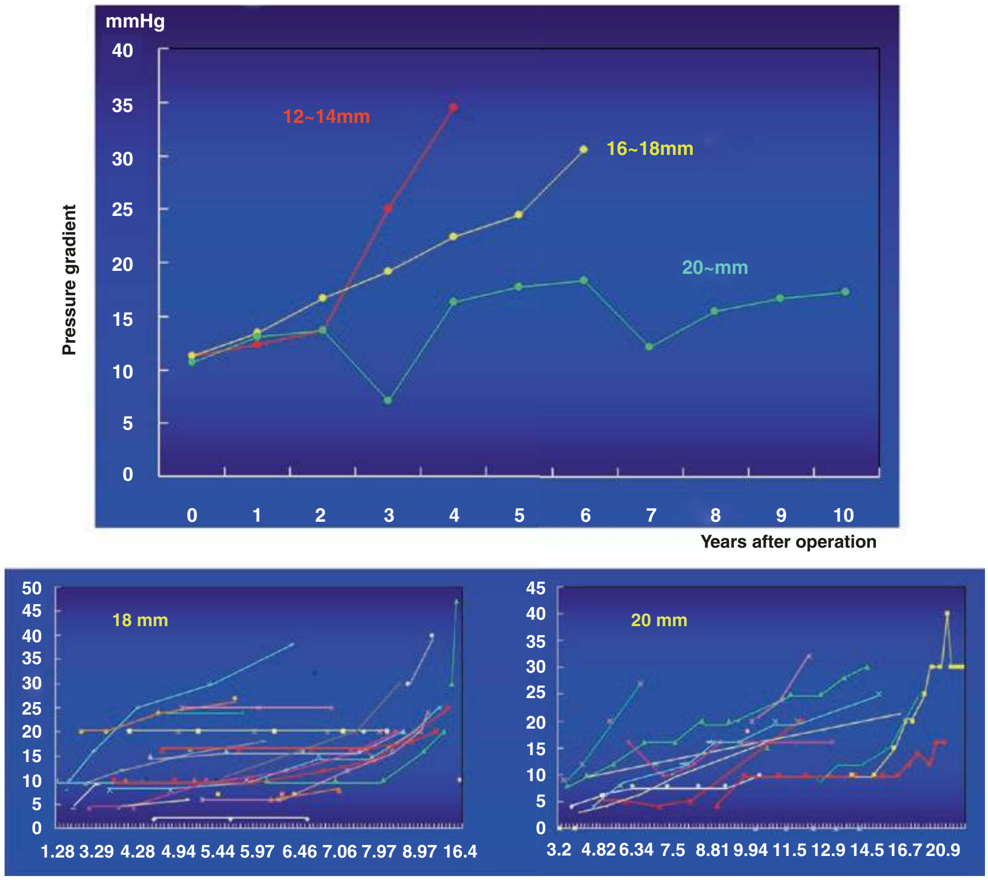


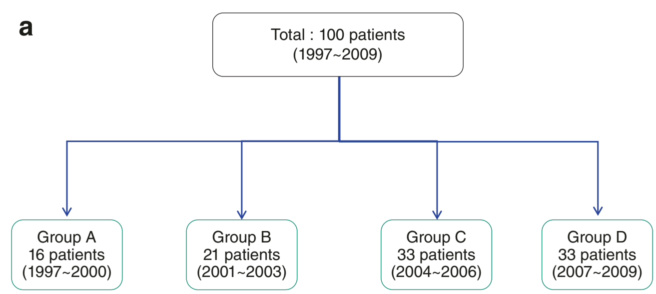
Fig. 6.56 Annual change of pressure gradient by conduit size ([16] modified)

and long-term autograft function. Discussions on the use of e-PTFE trileaflet valved conduit and re-operation for right ventricular outflow provide important new insights into the unique problems in Japan. We recognize that it is valuable as a dissertation" [14, 15, 16, 17, 18, 19, 20, 21].

Column: Reproducibility of Quality of Conduit with ePTFE Valve (Qusetion in 2010)

The re-operation evade rate of the Hemashield conduit with ePTFE trileaflet valve was relatively good at about 90% in 10 years. However, this conduit is hand-made each time according to the disease and the physique of the patient, and therefore consistent results and reproducibility are desired regardless of the technical skill of the individual surgeon who creates the conduit. From 1997 to 2009, surgery using an ePTFE conduit with a diameter of 20 mm or more was divided into four stages (Figs. 6.57 and 6.58) to compare the degree of progression of valvular stenosis and insufficiency.

Figure 6.59 shows the changes in conduit stenosis and valve insufficiency. There was little difference in their progress between groups. Re-operation will be necessary in some cases using a small-diameter conduit, and we aim finally to replace it with a conduit of 20 mm or more. It is considered that there is little difference in conduit function due to different creators in the current technique of making conduits of 20 mm or more.

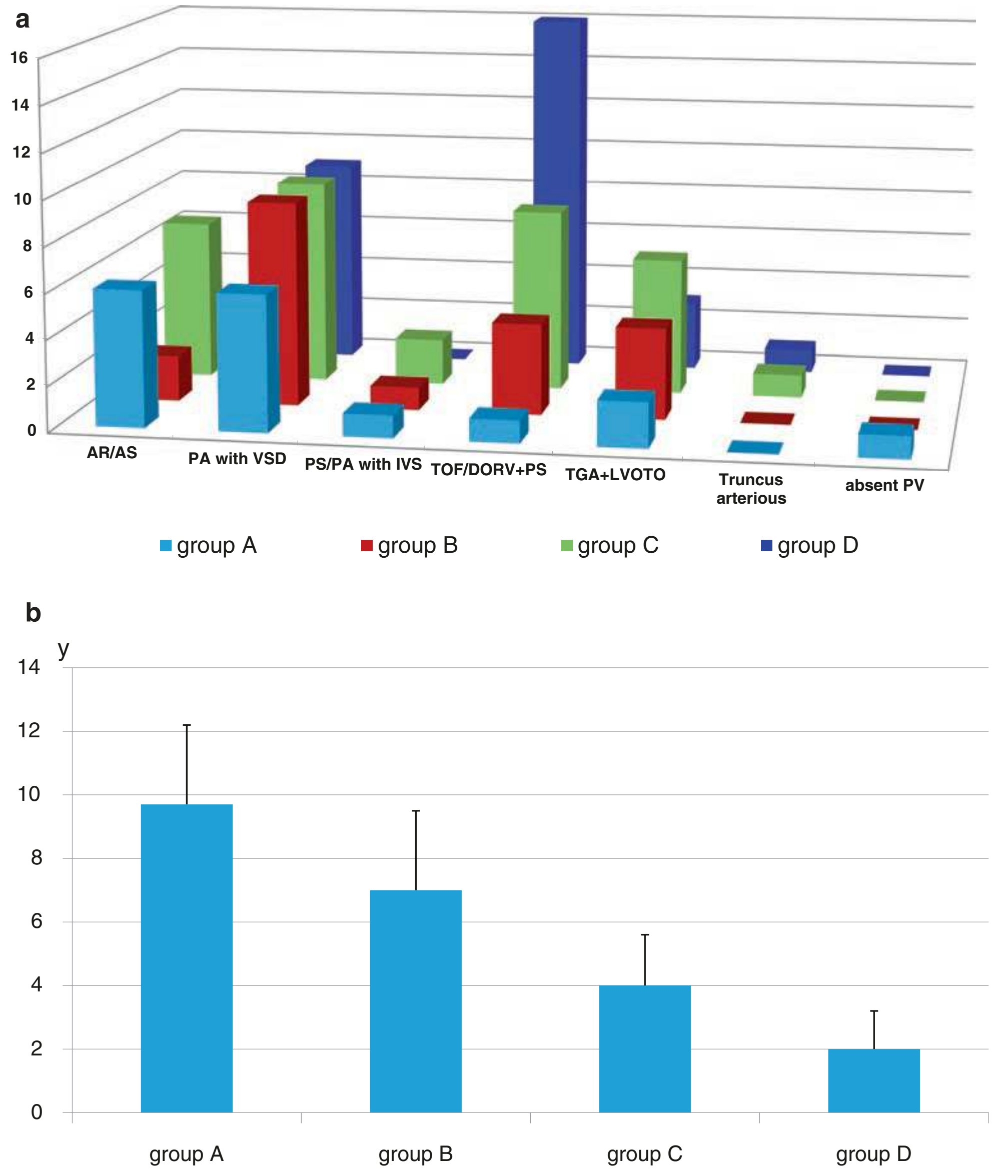


b

	Group A	Group B	Group C	Group D
Age(y)	16.3±8.4	22.5±1.9	18.7±12.5	24.7±12.0
Gender (M:F)	10 : 6	8 : 13	14 : 19	14 : 16
BSA (m^2)	1.26±0.3	1.22±0.4	1.34±0.4	1.40±0.3
BW (kg)	38.8±15.0	37.3±14.0	47.6±19.0	47.0±16.7
Conduit size (mm)	22.5±1.9	22.7±1.8	23.7±2.3	24.0±2.3
Z-score	0.82±0.9	1.01±0.8	0.92±0.8	0.91±0.7

Fig. 6.57 Group classification and patient' characteristics. (**a**) Group Classification (**b**) Patient Characteristics

Fig. 6.58 Number of cases in each group and average follow-up period.
(**a**) Diseases in each group
(**b**) Average follow-up period



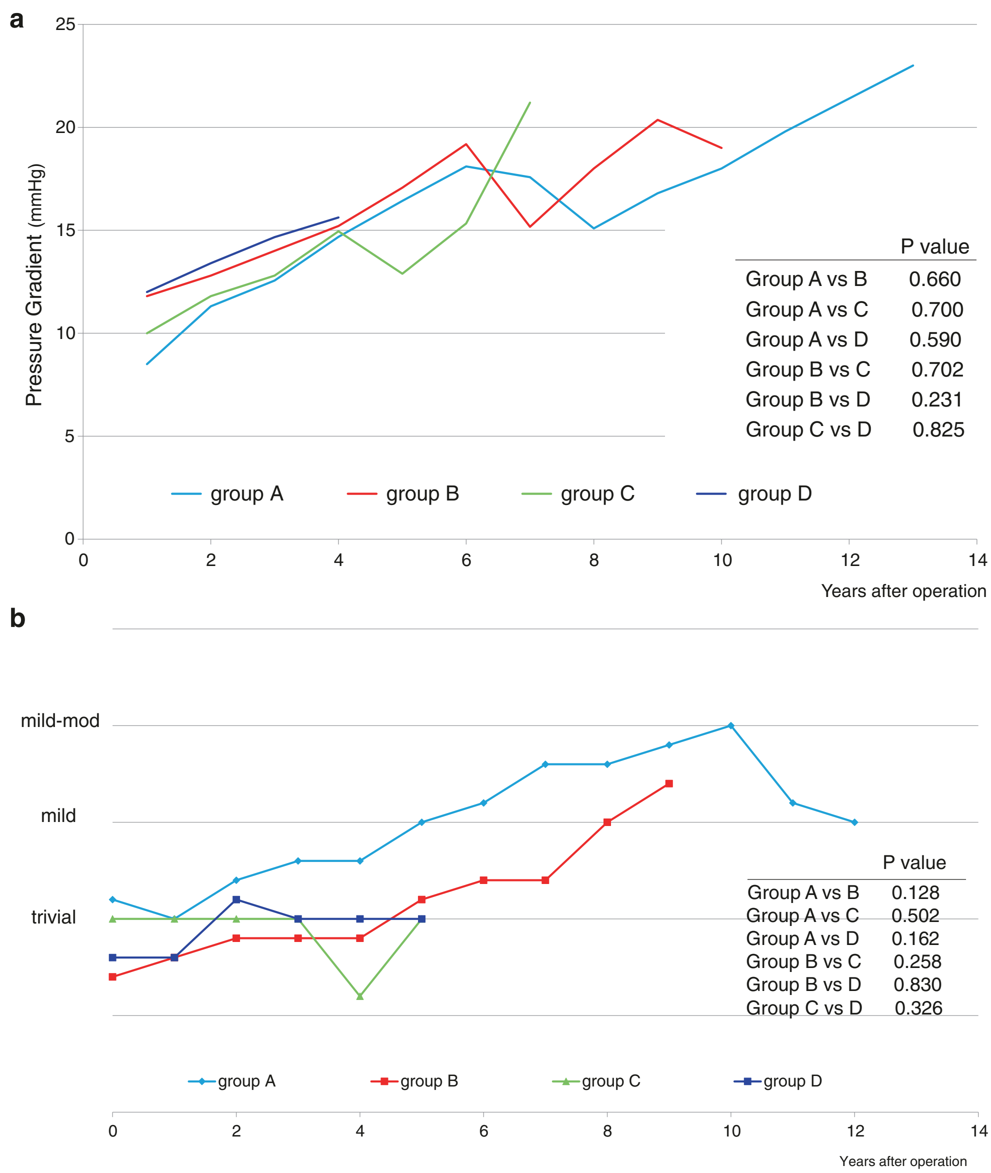


Fig. 6.59 Change of pressure gradient and valve insufficiency.
(**a**) Pressure gradient
(**b**) Valve insufficiency

Column: Exercise Capacity (2000)

After surgery for congenital heart disease, pulmonary valve insufficiency often remains, especially after intracardiac repair of Tetralogy of Fallot (TOF). The heart after surgery is in a state of compensating for this residual lesion and maintains the cardiac output, but the degree of compensation and its sustainability depend on the quality of the cardiac function and the presence of lesions such as pulmonary artery stenosis and pulmonary hypertension, and varies in individual cases. Therefore, in order to maintain QOL in the future, it is necessary to consider the timing of re-operation (prosthetic valve replacement) before sequelae incidence such as cardiac depression and arrhythmia, by grasping not only the extent of the lesion and its progression but also changes in cardiopulmonary compensation (cardiopulmonary reserve). One way to do this is to measure exercise capacity using exercise expired gas analysis. It is possible to determine the permissive conditions for exercise and the timing of re-operation by estimating changes in hemodynamics and cardiopulmonary reserve during exercise.

Figure 6.60 shows the characteristics of exercise capacity in cases after TOF intracardiac repair. Compared to healthy children, the maximum oxygen consumption (VO_2) and the maximum heart rate (HR) are low, but the maximum oxygen pulse (O_2 pulse) was not different. This phenomenon of low heart rate response is called chronotropic incompetence (CI). In addition, a comparison between 22 cases (179 ± 8) with a maximum HR of 170 bpm or more (179 ± 8), and 19 cases with less than 160 bpm (150 ± 8) showed that the maximum VO_2 was significantly higher in the former (44 ± 6 ⇔ 37 ± 6 mL/kg min), and the maximum O2 pulse was significantly higher in the latter (6.9 ± 0.6 ⇔ 7.8 ± 0.7 mL/beat m^2, $p < 0.01$). Furthermore, in 29 patients with a maximum HR of less than 170 bpm, a significant correlation was found between the maximum HR and the maximum O_2 pulse. These results suggested that postoperative TOF cases had a compensatory increase in stroke volume during exercise. In hearts with residual lesions and CI response, it is necessary to consider the adverse effects of such compensation on right heart function and arrhythmia development.

Figure 6.61 shows a case of Rastelli surgery in which deterioration of hemodynamics during exercise was suggested with increased load. With increasing load, a rapid increase in HR (bursting) was shown from the time points of anaerobic threshold (AT) and respiratory compensation (RC), and plateau of VO_2 and decrease of O_2 pulse were observed. This reaction suggested hemodynamic deterioration (decreased stroke volume) at exercise intensity exceeding AT, and it was considered that strict exercise restriction was necessary in this case.

Figure 6.62 shows the exercise capacity of a case after the Rastelli procedure, in which the timing of re-operation was determined based on the change in exercise function. At the age of 8, the Rastelli operation was performed using a valveless conduit. The ratio of right ventricular pressure to left ventricular pressure was 0.5 in cardiac catheterization one year after surgery, and the maximum VO_2 was 40 mL/kg min, which was favorable. After that, conduit stenosis progressed, and the right ventricular pressure/left ventricular pressure became 0.88 in the 7th year. He was advised to have re-operation, but the patient and family refused because of no medication and no subjective symptoms. Since there was no decrease in max VO_2 even after that, we made an outpatient observation, but the maximum heart rate response gradually decreased 8 years after the operation (CI reaction), and frequent PVC occurred in the 9th year, at which point re-operation (ePTFE

a

Max.VO2/kg	mL/kg/min	TOF 41±6	<	Control 48±9
Max.HR	beat/min	TOF 166±15	<	Control 187±10
Max.O2pulse	mL/beat/m^2	TOF 7.2±0.9	≒	Control 7.4±1.1

TOF n=64, Control n=77

b

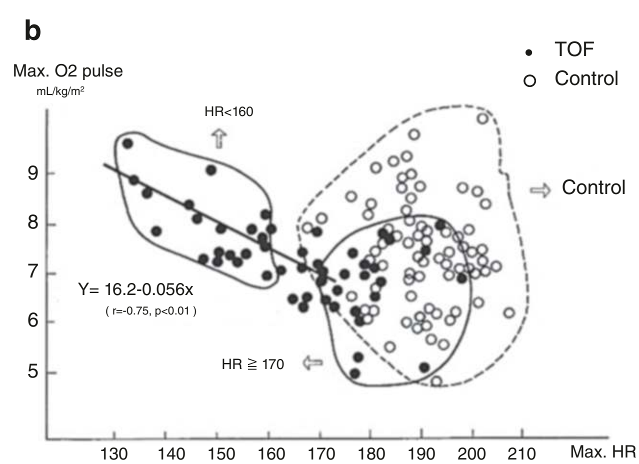


Fig. 6.60 Exercise capacity and chronotropic incompetence (CI) after intracardiac repair for TOF ([22] modified).
(**a**) Exercise capacity
(**b**) Chronotropic incompetence

According to Fick's principle, VO_2 is expressed as HR x O_2 pulse (stroke volume x arteriovenous oxygen difference). From this relationship, the reason why the maximum VO_2 in TOF was low is that the maximum HR in TOF was low

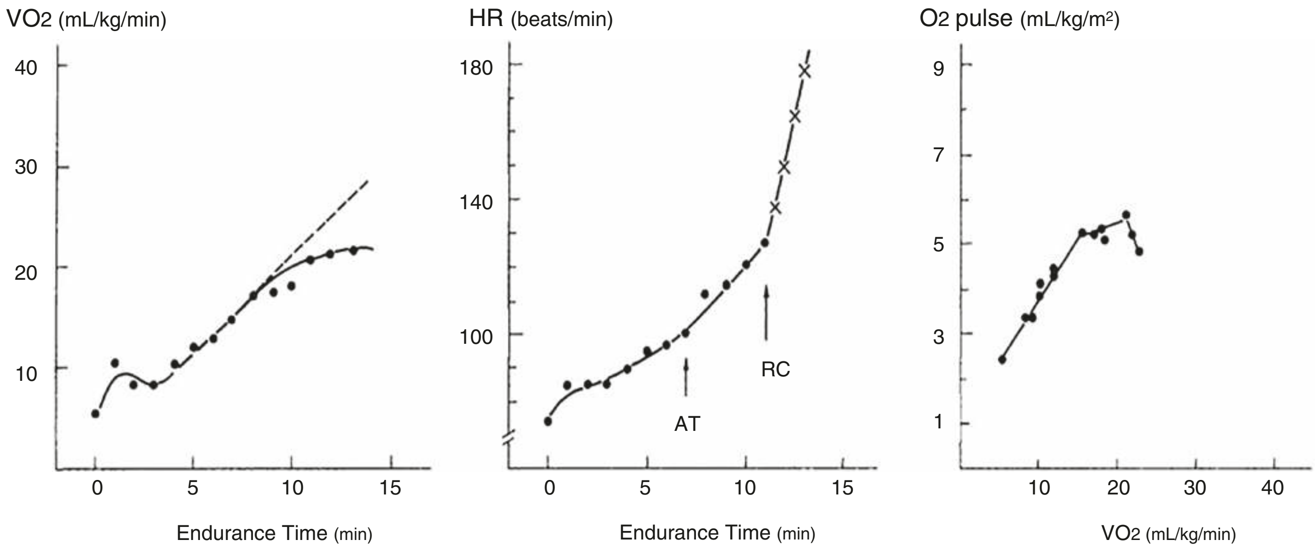


Fig. 6.61 Exercise capacity in a case after Rastelli procedure suggesting deterioration of hemodynamics during exercise ([22] modified). Diagnosis is PA with VSD. Rastelli procedure was performed at the age of 11. Cardiac catheterization revealed right ventricular pressure of 75 mmHg, right pulmonary artery hypertension (62 mmHg), left pulmonary bifurcation stenosis, and severe pulmonary regurgitation. The heart rate after the endurance time of 12 min in the graph shows the value every 30 s

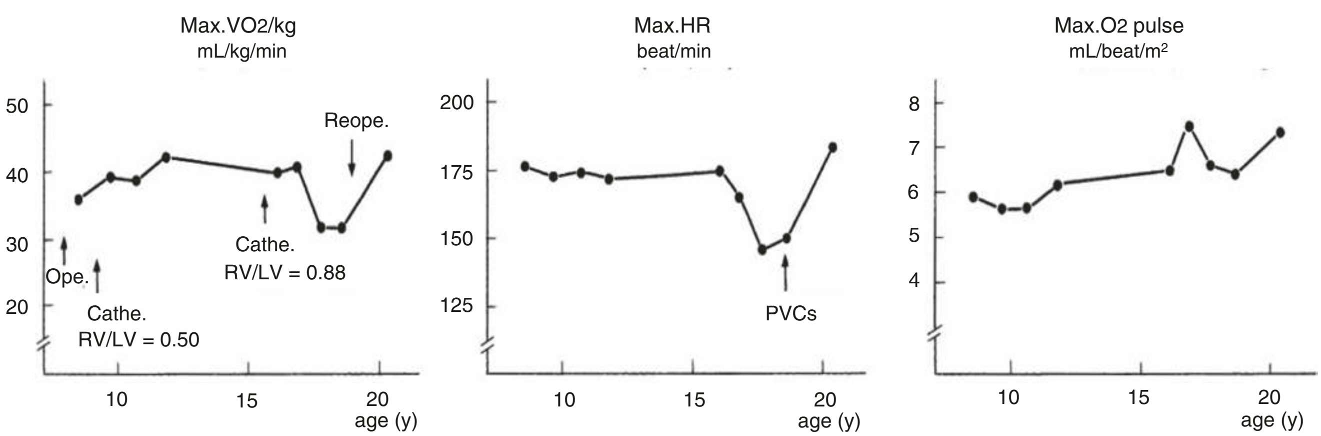


Fig. 6.62 Exercise capacity in a case after Rastelli procedure ([22] modified) (Timing of re-operation was determined based on the change in exercise capacity)

valve) was approved. After re-operation, recovery of exercise function, including heart rate response was observed.

Data suggesting the progression of residual lesions and deterioration of hemodynamics during exercise are as follows: (1) increase in HR, decrease in VO_2 and O_2 pulse, (2) flattening of VO_2 and O_2 pulse due to load increase, rapid increase in HR (bursting), (3) changes in ventilation response, (4) increased arrhythmia and merged CI reaction. VO_2 in CI cases is generally significantly lower, but with a compensatory increase in O_2 pulse. Many of these can live without problems. However, we experienced a case in which atrial fibrillation occurred after CI emerged, and the incidence of PVC during exercise was increased. Patients with the above changes should be evaluated for residual lesions and changes in cardiac function by echocardiography.

There are many points that surgeons should consider in order to improve exercise-functional QOL. It is important to consider the surgical method that suits each case by considering the overall quality of life in the future, and not only the doctor but also the QOL required by the patient and the parents should be emphasized in the surgical plan. The ePTFE valve has good function, hemodynamics, and durability, and has a high re-operation evasion rate. In particular, I think that not having to take Warfarin is most useful for children in terms of exercise (Fig. 6.63)

Fig. 6.63 Bicycle ergometer. Left: The height of the saddle was lowered to analyze the expired gas during exercise in elementary school students with a height of around 120 cm

Fig. 6.64 Medical lectures for junior high school and high school students

6.7 Junior High and High School Students

Recently, I have had more opportunities to talk with junior high and high school students (Fig. 6.64). There is a Medical Science Department in the senior high school from which I graduated. This class is specialized for students who aim to become medical professionals in the future. Also, there is a curriculum to visit senior alumnis during the school excursion to Tokyo. Therefore, we are having visits of those students who aim at a medical career. It is also an opportunity for me to hear the nostalgic real-life Nobeoka dialect. High school students these days are extremely polite and have a clear vision of their future. The conversation with these students is indeed meaningful. Their visits remind me of my high school days.

Q&A: Things to Do in Senior High School (Question in 2015)

Question: "I am in the second year of senior high school. I decided to become a surgeon from watching the television drama series called "Iryu: Team Medical Dragon"–a somewhat impure motive perhaps. Many of my relatives are doctors. While they are all happy that I want to become a doctor, they advise me to quit trying to be a surgeon because surgery is a difficult specialty. If you do not mind, I would like to hear your opinion. Also, what did you do in senior high school to prepare to become a doctor? Thank you."

Answer: "You motive is by no means impure. There are still many Black Jack followers, including myself. ("Black Jack" is a superdoctor from a well-known Japanese cartoon.) I began thinking about becoming a doctor in the second year of elementary school. My uncle was a surgeon, and during that time, there was an American medical drama series on television, called Ben Casey. Perhaps due to these influences, I said that I wanted to become a doctor, and to become a surgeon if I did not have to inject or cut a patient. Motive is just something like that. Of course, there are people who exaggerate that the event is a turning point of their lives. For most people, however, it is just a chance encounter and the decision is made before they know it. By the way, for the surgical specialty, it takes a long time to become a surgeon who can work on his/her own, the competition is intense, and the risk is high. What your relatives say are fully understandable. But, surgery is fun, too. There are new discoveries even at my age. It is indeed a great pleasure to be able to experience surgeries that ordinary people can never experience, despite the hardship involved. As a surgeon, I maximumly respect your opinion.

Regarding what should be done in senior high school, nothing particular comes into my mind. During my senior high school days, there were many episodes that are embarrassing even when I recall them. Whenever I attend class reunions, for some reason, there are always many classmates who remind me of memories that I would rather forget. However, I think my senior high school days were very rich indeed, much more so than when I was at university, or when I became a new doctor, or even now. It is quite strange even thinking about it now, but I definitely think those were incredible days. Although I did not do anything special during that time, life must have been very meaningful and serious. Or, it could just be that I had not reached the rebellious phase or my mental maturity was delayed … Apart from what you are doing now, such as studying for examinations, extracurricular activities, having a crush on someone, etc., I do not think there is anything else you should do. However, one thing you can do is to work hard in your study. I wish you will be accepted to the university as early as possible without failing your entrance examination. This is your sole responsibility. And if you become a surgeon, please learn as many things as possible and as soon as possible, or even ahead of time. Because if you do not, some patients may lose out. Despite my delayed rebellious phase and mental maturity, I feel sorry to my homeroom teacher of senior high school for being disobedient at that time; such as "why do I have to take classes in classical literature and geoscience when I am going to become a doctor." Good luck, I have high expectation of you."

Q&A: Stress Relief Methods (Question in 2015)

Question: I am in the third year of junior high school. I guess you are often mentally exhausted because of your difficult work. Do you have any special methods to relieve stress?

Answer: That is an interesting question. I get a little worried when a junior high school student ask me this kind of question. Well, it would be good if I can do something; for example, sailing a yacht from Zushi out to the Pacific Ocean or racing down the Tomei Expressway with a Porsche. Unfortunately, I do not have the time or money to do those. In fact, I do not have interest in them. But, I do not work like a workaholic or a work addict. And, although people say that those who do not relieve stress do not live long, that is not necessarily correct. I have actually lived to this age. Well still, when I sing karaoke at a party or show my knowledge by talking about Japanese gods, people comment that I have a wide range of hobbies. As to your question of how I relief stress, I cannot give you an exact answer. I also get comment that I have a good personality. But, I feel slightly offended by this comment, because it has a sarcastic implication that I just forget bad things right away. Sure enough though, that may be a talent for a surgeon. However, it also has an undesirable effect of forgetting things that should not be forgotten. Recently, forgetfulness has become a slight problem for me, I am trying to change my mind that the ability to keep on remembering is also a talent. Surgeons carry a lot of mentally challenging burden on their shoulders, so it all comes to how good we are in forgetting in a good way, and how good we are in remembering also in a good way.

I am afraid that I have gone off track. Certainly, I do feel that I am always carrying some sort of responsibilities on my shoulders. They are probably stress for me. But, for this stress, I do not contemplate taking time off today or proactively taking some measures to prepare for the stress that is expected to come tomorrow. If it becomes necessary to take a break for every stress or take stress-relieving measures to deal with strong stresses, then I would say it is time to quit that profession. Lastly, may I ask you a favor. Instead of saying surgery is a difficult professional, could you say that surgery looks fun? All right, I got it, so this is called workaholic! Please excuse me for this answer.

Q&A: Do You Like Surgery? (Question in 2015)

Question: I am in the first year of senior high school. I heard that your surgery is super speedy. But, the way that you put in so much effort to finish surgery as early as possible, that would also mean that you hate surgery that much. Do you like surgery?

Answer: I cannot really answer whether I like or hate surgery, but I must do the surgeries, and it is true that sometimes I do feel so discouraged that it is painful. Anyway, this is a philosophical question, or is it a Zen question? Nevertheless, it is a tricky question and is one that I do not really want to be asked. But, it is a way of thinking that has never crossed my mind. I was really surprised. Are you really a senior high school student? I am sorry, that was rude of me.

Now then, let me see how I should tackle your question and answer without being defeated.

Well, if my answer is, "As you said, I absolutely hate surgery, so I try to finish it quickly." Of course, this answer will not be convincing, and I shall be called a liar. If the answer is, "I like surgery so much that I finish each surgery quickly so that I can start the next one." This answer too would not be correct. If the answer is, "There is no patient who likes surgery. Therefore, although I really love doing surgery, I complete the surgery quickly giving an impression that I do not like it." This is also no good. What about, "I tend to keep a distance from the things I like. That is why I finish surgery early." That is even worse. I am in trouble. Please pardon me. I need to restart my austere training.

Q&A: Have You Ever Thought of Quitting? (Question in 2016)

Question: I am in the second year of senior high school. When I listen to your talk, the work of a doctor seems to be very rewarding and enjoyable. However, I can imagine that there must be many instances when this is not the case. Have you ever thought of quitting in your career?

Answer: Regarding the situation that prevents me from quitting, I am in charge of the surgical team, and at the same time, I am the primary surgeon, and I am very pleased with the sense of achievement at each surgery, and would not want to hand it over to anyone else. Especially, the experience of a miraculously successful surgery makes this profession addictive, if that is the right word to describe it. This may be undoubtedly the biggest reason why I have not quitted so far. On the other hand, I have started thinking about something else recently.

In my presentation to this group, I showed a video of Ross procedure where the patient's pulmonary valve is removed and transplanted as the aortic valve in a newborn baby. It is the most delicate procedure requiring the greatest attention that I have ever experienced. My question is, after retiring from surgery, what use is this technique for the rest of my life? Thinking about life after pediatric heart surgery, there may be no other profession that has less utility than pediatric cardiac surgery. However, if there is only one expectation, I think that the fighting spirit and perseverance needed to do these techniques, or acquired by doing them, will last me a lifetime.

The thought that work is no fun is a common phenomenon no matter what kind of job you have chosen. By the way, this is a difficult question to answer. Certainly, having fun at work does not result in someone not quitting the job. Rather, the lack of reason for not continuing to work, or not able to continue working, would make someone not quitting the job. Even so, it is also true that after continuing the same job for a long time, what we learn from our distinguished mentors overlap with our own experience, and it makes us think about Zen even more. Even if our dreams have been fulfilled, the harder we work, the more we feel the gap between ideal and reality, which may be unavoidable to some extent. The more enthusiastic we get, the greater the disappointment we feel about this gap from ideal, and this too may be inevitable. Nevertheless, so far, I have had the good fortune of doing operations with many colleagues who show me incredible kindness. So, if I do not do my best until I die, I will be punished by Heaven. It is unlikely that I shall be enlightened about the meaning of surgery until the end of my life.

Q&A: Mysterious Happening (Question in 2015)

Question: I am in the third year of senior high school. It may be the strong influence of television, but I wish to know, in the world of the medical profession that deals with people's life, are there miracles, very mysterious happenings, or things that happen because of good fortune? I think it is a weird question, but please give me your view.

Answer: You asked your question casually! I am in trouble again. Medical science is a branch of practical science aiming to play a useful role in real life. Therefore, we do not think too much about such things (miracles, mysterious happenings, etc.). But, there again, the harder we try to save life, the more it becomes impossible to separate medical science from philosophy, religion and spirituality. It is also true that I sometimes encountered cases with problems that I would not have been able to solve by myself, which eventually turned out to be all right. While I do not think it is good to completely forget about miracles and spirituality, it will be a problem to impose on others to believe them. On the other hand, denying them completely because I have not experienced them is also a problem. There may be miracles or mysteries, but I do not understand them. However, when we built the current Sakakibara Heart Institute, we held the groundbreaking ceremony. And, in "yaku-doshi" (unlucky years), we go to shrines to pray and be purified. For Japanese, these are undoubtedly traditional customs, but it is also strange when you think more about it. If gods exist, they probably help our hard work by only removing obstacles that get in our way and not actually helping us. I really need to restart austere training again. Please excuse me.

Q&A: How to Interact with a Baby (Question in 2017)

Question: I am in the first year of senior high school. How do you interact with the baby when you are operating on a newborn baby? I am curious because obviously conversation with them is not possible.

Answer: There are different types of children. For children who can talk, it is of course necessary to speak, paying special attention for each of them. It is rather impolite to talk down to a child, totally from the standpoint and feeling of the adult. It is because even a child has personality and should be given due respect. It is the same for babies. For newborn babies, although they probably have no will power, they make eye contact as if they wish to communicate something. "Hi, are you Takahashi?" or, "Hey doctor, do your best to cure me." While they are probably just my illusions, there are babies who communicate like that. I strongly feel that they are competent human beings. Babies are very interesting. However, when it comes to surgery, pediatric surgery may bring out the worst characters in some surgeons, whose disruptive behaviors due to stress from a difficult surgery may make their colleagues uncomfortable. I always hope that such bad characters would not be transmitted to the babies. On the other hand, I think it is important to be attentive to the patients' parents, especially the mothers and grandmothers (Fig. 6.65).

Fig. 6.65 Lecture at the gymnasium of my alma mater

6.8 Education for Young Surgeons and Build Up of Surgery Team

There is the word team medical care. In particular, heart surgery consists of more staff and is said to be the ultimate of team medical care. However, it is important to remember that surgery itself is a collective treatment of the individual abilities of each member of the team. Ultimately, raising the abilities of each individual will be the status of the team, so the surgeon must carry out the surgery by keeping in mind how to train the team members to enhance their ability in the shortest time and acquire the non-technical skill early. Of course, cherishing team relationship, respecting each other, firmly managing safety, and being patient as a professional are of course important. But they should be done outside the operating room.

In Japan today, there are very few facilities that perform surgery with fixed team members. The surgeon is not allowed to nominate a perfusionist or scrub nurse. As a surgeon, I often feel "Gime me a break!" during surgery. Also, of course, conversely, it is not possible for a perfusionist, a nurse, or an anesthesiologist to choose a surgeon. During surgery, you may feel very uncomfortable or be in a bad mood. Dissatisfaction and anxiety occur.

For the past five years, I have given lectures to young surgeons, perfusionists, and scrub nurses all over the country. What I felt there was that they had a strong desire for knowledge, and they were more knowledgeable and motivated than I had imagined. However, on the other hand, it seems that there are often questions about future career development, youth education policy, ideal team medical care, and the current state of medical care in Japan. I was often surprised at the content of their questions after the lecture. Here, I will introduce these questions and answers.

Q&A: Education for Young Surgeons (Question in 2012)
Question:I am a trainee. I want to be a cardiac surgeon. I am already prepared to the reality for requiring 15 years to be recognized as a cardiac surgeon. I would appreciate your advice based on your experience.

Answer: When I was a trainee doctor, I always wanted to have a textbook that says, "You can definitely do it! The road to be a leading surgeon." But, at the moment, I would like to have a textbook, "Accomplished by all means! Anyone educated like this will be a leading surgeon." I do not know if I can answer, but I will talk a little about my first three years as a resident.

Once you have set your goals, there is no detour anymore. However, trying hard to achieve one goal naturally entails many difficulties. Some of the issues to avoid in the first stage are: "I don't know what your seniors are talking about," "I don't know why I'm scolded," "Even if I am asked if I have any questions, I don't even know what I don't understand." As expected, these are problems. So, at the very least, study not only the field of cardiac surgery but the terminology spoken by perfusionists and scrub/circulating nurses. Also, since I mentioned in the lecture about the acquisition of Non-technical skill, I will omit it, but I think that surgeons should be a nice fellow in a good way.

There will be no responsibility for at least the first year. The boss is responsible for everything. So do not think too much about it, and do not worry about it. That is the most enjoyable time. I cannot say it well, but I think it is important to accumulate more experience and memories during this training period than others, and how to spend this period where there is no responsibility. However, not being responsible also means not being trusted at all. The only thing you have to be careful is never do the very thing that your superior does not want you to do. Anyway, take a good look at how your seniors use their time.

Well, some time soon, you be in a responsible position, but only the responsibility becomes excessive. Moreover, the more you get used to it, the more you often feel, "This is not a surgical training. There are many unnecessary things. why?" Also, It is common for others to get in the way. Please dodge well. Not to resist is the talent a surgeon needs. In addition, You may also feel that your boss does not teach you or you are left alone, but in my experience, spoonfeeding education at that time isn't very good, but rather annoying.

Surgeons do not use their brains much. Conversely, you should not be bothered or lost about anything other than surgery. There are only two places to use the head; deciding treatment strategies for increased cardiac output in the ICU and procedural decisions in the operating room. For example, if you find a method that works better or is more efficient as a surgeon, evolve that method further. Again, these are things that can only be felt in the operating room, and taking time to visit the operating room is another talent. After that, you need some luck as for whether you can be a leading surgeon, work in the hospital you want, or move to another. You have no choice but to confront it. If you come to that stage, let us talk again. Enjoy the inconvenience and freedom of being a trainee.

Q&A: Training Hospital After Graduation (Question in 2013)

Question:I will be graduating next year. I am looking for the first training hospital right now. What is the difficulty level of the surgical procedure that can be acquired by the surgical training at Sakakibara Heart Institute? What are the characteristics of the training?

Answer: Of course, I think about the trainees enough, but if I don't teach them surgery, and they don't have surgery case, criticisms will come out, such as; "My boss is too heartless," "Does not guard us," or "What a waste."

On the other hand, there are rather difficult realities on this side, such as; "I'm disliked by trainee if I teach them tightly," or "If a trainee resigns, I'm told you don't have the ability to manage." Furthermore, "the surgeon has no choice but to grow slowly," off course I know, but if they don't grow up, I'm told I don't have leadership. "The order of education, that is, how to arrange the contents to be taught, is different for each individual, and I get stressed every year.

I think that it is possible to naturally learn the basic things just by staying at Sakakibara Heart Institute. However, I will not teach you step by step, and I will not say extra things that will not be beneficial for later on, because I rather think it is more likely that the growth will stop. You are half responsible for whether you grow up or not. And I would like to encourage your half responsibility to grow as much as possible, such as the temperament to sustain your growth on your own in the future or the possibility that surgery will be better than us. But in the future training, I think that there is a 100% chance that there will be many people who are better than yourselves, and you will be compared with other trainees and will be depressed compared to others. Well, no need to rush. Just go with the flow.

Today, I talked about obtaining a surgeon's qualifications. The sooner you get the qualifications you need, the sooner you can move to the next step. What to do with you will be decided after coming. But Sakakibara Heart Institute is an interesting hospital, and there are about 1500 heart surgery cases a year, so why do not you come to study with me?

Column: Joy and Education for Surgeons

In my younger days, the only thing I could say was, "It was very tough, yet a lot of fun." I feel very blessed that I can still say "those were the days…" with old friends who understand each other. However, talking about things of the past usually gets a little rowdy, and the more we talk about fair argument, the further we are away from the common sense of today. Let us talk about education for surgeons.

Talking about the ideal education for surgeons, I think that a young surgeon should be able to discover some clinical problems that will allow him/her to achieve the following goals: (1) to make surgery less invasive to the patients, (2) to improve the quality of his/her surgery, (3) to be told that he performs better than his superior, and (4) to succeed in the future to become the top surgeon.

We surgeons repeatedly perform "niban-senji" (meaning "second brew of tea," and is also used as a word meaning "rehash") surgeries (not their own original) almost every day. However, if "niban-senji" is tastier, then this may lead to a major innovation. Well then, what do you do? As always, opposite opinions and the present inconsequential common sense get mixed up in my brain, and I stop thinking.

Let us suppose that newcomers wish to study my surgery and become part of my team. Naturally, most of the newcomers have absolutely no surgical skills, even though they have some knowledge. Since I also want to train them to be independent surgeons, I sometimes give demanding commands or instructions that they should not repeat making the same mistakes and that they should do the procedures without delay. However, nowadays, this kind of education is often disputed as being improper. It seems that even trying to guide newcomers to express their own opinions and thoughts and to talk about their goals may induce psychological pain. Using stress rather than reducing stress seems to be out of fashion these days.

But if the newcomers themselves have the pure goal of gaining surgical skills, and if the newcomers can be convinced to some extent about the pros and cons of the surgical policy of their superior, then regardless of the relationship between the trainer and the newcomers, there will exist a common mission of saving life. Based on my perception of the necessity for work and education, I entrust the newcomers to do some difficult tasks that they have never experienced, or, conversely, I give him tasks outside the scope of surgery. Even these tasks may mean mental hardship for the newcomers at that time, if the results are acceptable to both sides, I think that they will become a memory that the experience was fun and useful when we recall later on.

The memories of those days with wild enthusiasm are embarrassing but interesting. Of course, it is probably because I felt satisfied more easily at that time when I did not have that much skill in surgery.

Of course, I am not saying that you have to work so intensely all the time. I would like you to be in an environment where you can temporarily forget the seriousness and take some time off to think and where you can soon get used to a certain level of criticism or stimulation.

But it takes some time to reach this stage. I have a strong impression that it takes a long time to be able "to develop from a small discovery to achieving the goal," "to find an empathic mission," and "to express one's own opinion." Unfortunately, there are cases where these are never achieved. In particular, there are many complaints from newcomers about not able to communicate. Most of the time, I guess the problem is simply whether or not people get along with each other. However, I think one of the reasons is that the newcomers may have a vague desire to become excellent surgeons, but have not yet decided on the goal that they need to achieve by all means. It is the lack of a clear goal.

The present situation is that the education that hospitals aim to provide and the expectations of newcomers are changing considerably, and the rate of growth as a medical practitioner also differs from person to person. Therefore, it may not be totally appropriate to repeat our own experience and education methods just because they seem to be "good." Furthermore, regarding the necessity of talking about our own experience in advance, this may conversely be a factor that hinders the growth of newcomers, and, if it makes the newcomers feel uncomfortable, it may even become power harassment.

For the newcomers, the most important time after all is the period when they are newcomers. I will say it again, the newcomers have no responsibilities during this time. To put it the other way around, this is the time when newcomers should be able to devote their attention to the operating room and observe the procedures thoroughly. If during this time they can clinically find some small discoveries, that will clearly define their goal and countermeasures. And, if recognized by the superior, it will lead to certification in the future, although that will also mean further increase in stress.

Then, all we can do is simply to provide an environment that will not discourage the newcomers and simply show them as many surgeries as possible without obstruction. If bosses have the misconceptions that they have the ability and the privilege to educate newcomers, there is a risk that they may educate in a pushy manner. It is important to realize that young surgeons improve naturally as they go through training. For that purpose, it is necessary to build an excellent fast-working team with consideration of placing the right person in the right job, and to have an operating room where newcomers will grow naturally. These are very basic requirements, but in the current situation in which human resources are diversifying, they are difficult to achieve. Since these issues cannot be solved, all we can do is to keep them in our mind. But, they are the most important things we need to consider.

To us senior surgeons, the "qualities of a surgeon" desired or conceived by the general public other than health professionals are the minimum qualities of a surgeon. Therefore, we must educate them to acquire these qualities. In time, there may be criticism from newcomers who demand more demanding training and surgery. But, I think that is evidence that these newcomers have finished my education and they are ready to enter the next step.

Q&A: Recruiting Young Doctor and Turnover (Question in 2015)

Question:Recently, there are few young doctors who want be a pediatric cardiac surgeon in Japan. Also, even if became a surgeon, they do not last long. This may be a problem not only in cardiac surgery but in other whole surgical department.

How about Sakakibara Heart Institute, such as recruitment of young doctor and measures to prevent measures against turnover?

Answer: At a luncheon seminar a few years ago, I remember that I was frowned upon by saying that "pediatric cardiac surgeons are an endangered species." Also, when I told this story to a famous monk, he gave me a pep talk, "Katsu!(喝)", that it was not an extinction rarity, it was simply because there were no human resources worthy of the word rarity. But at that time, I also told him that "although things can't be solved with guts or willpower, if they did, it become a tradition." At that moment, I didn't know why but I was praised.

Now, in the last few years, I think that the number of young doctors who want to become pediatric cardiac surgeons is increasing. When I have surgery with them for a while, I can feel their strong desire to continue pediatric heart surgery. At least, they don't express fascination to the conditions expressed in "numbers," such as salary, work style, or how many surgery cases can be done. There seems to be no small-minded idea for austere training. Moreover, as I mentioned in the lecture, they have already the good skill to manage the night ICU, and and has finished the work to be done without noticing. So basically, they have a work hacks to be loved by nurses and laboratory technicians.

Of course, in order to secure doctors and nurses, it is necessary to fully consider treatment and work style reform. However, looking at these young doctors, it would be rude and embarrassing to them to advertise such things out loud or to let them rest or put them work according to our convenience. These are completely different from the time when I was a resident. On the other hand, our side that welcomes them needs considerable readiness. That is, how to continue the training. About 20 years ago, I was asked how we would like to evolve pediatric heart surgery of Sakakibara Heart Institute, and I answered that "I would like to make a mecca where many new doctors would gather, and I would do what is necessary for that." Specifically, first of all, it is a cozy hospital. In other words, it is an environment where they can participate in a lot of surgeries that were never seen before, can satisfy the desire for knowledge, can train to approach the image of a future surgeon, and reduce the work other than surgery as much as possible. We must firmly have a spirit as a hospital for nurturing young people by carefully considering the difference of common sense between the society and the medical care. I still remember that my answer was laughed down, but I still have the same idea without evolving.

Now, although they are excellent, one thing I always think is a problem is to start comparing yourself to others early. This always comes out at a certain point of growing process.

Feeling the victory or defeat or superiority or inferiority, the idea of leaving cardiac surgery or moving to a more convincing hospital comes up. In addition, words that want to build a career more or live globally also come up.

If I am told that there is nothing to learn at this hospital, unfortunately, it is the saddest but convincing, and even more convincing by feeling “Is it a bond?” However, such hospitals do not exist in Japan, and the word of global is ambiguous and strange. Of course, I do not think that is the case, but I do not think they exactly understand the real meaning for the words of “career and global.” But they are serious.

Of course, unfortunately, the speed at which young surgeon grow up varies individually. However, it is not good to evaluate an individual based on its difference alone. Also, a curriculum that trains all trainees to the same may be annoying to them. However, it is certainly impossible for all residents to take the desired position. I’m really worried what I should do for them during this troubled time because we’ve been through it all together.

I’m sorry I can’t answer well, but, as the surgeon grows older, the sense of mission of education for young surgeons emerges for some reason. However, conversely, it is natural that young surgeons also want to ask the excellent surgeons to teach. It is necessary for us to be a little more prepared so that there is no remorse, such as forgetting important surgery education by teaching only safety management.

Q&A: Collapse of the Medical System (Question in 2013)

Question: I am a physician. I have already retired and am 83 years old. It has been a long time since I hear about collapse of the medical system, but I do not really understand the recent situation. I would like to ask you to explain it to me. If the medical system has collapsed or is in the process of collapse, can you suggest some countermeasures? What is the role of Sakakibara Heart Institute?

Answer: Thank you very much. This is the most difficult question. Recently, I have often been criticized for saying too many things that I should not have said. Please allow me to say something just between ourselves, without considering the trouble I may cause to others. Collapse of the medical system means that the number of medical personnel is not enough, or even if the number is enough, they lack the ability to provide medical care. Or, it may mean even if the capacity is there, there is no system to provide care. However, when I talk about this kind of thing, people in the general public would say to me, “Yes, so what? Isn’t it obvious that a professional should make efforts to improve it?”

In my presentation, I said that the quality of a hospital is determined by the young doctors working in night shift. What I mean is that it depends on whether the young doctors can manage alone when there are no senior doctors around. To be able to manage, it is important is that the young surgeons are well acquainted with the specialists in departments other than their own, and thus can consult with them any time. And, they should be able to talk with these specialists using technical terms; in other words, they can apply themselves to any specialty; or, although they cannot give treatments of other specialties, they are able to do so in their head. These are general doctors with a focus on the cardiovascular system. To achieve the abilities to manage alone and communicate with other specialists, I think it is essential for young medical graduates to fully immerse themselves in the acute care for the cardiovascular system for about three years. They need this education for the certification to step up their career, and at least not to become a professional who knows nothing but their own specialty. And I think this is one way that may prevent deterioration of the quality of medical care. Up to this point, it is the responsibility of Sakakibara Heart Institute. Regarding the large number of surgeries done in Sakakibara Heart Institute, people make various comments, such as “Is there a need to work so hard?” or “Sakakibara is overdoing it!” Despite what people say, we have to maintain being the top in the number of surgeries done in Japan, and by all means, maintain an environment to attract people to our institute. That is the role of Sakakibara Heart Institute. And of course, it is even more important to train competent cardiovascular clinical specialists who are trusted by the general public and doctors of other hospitals.

Recently, the education structure and system have undergone major reforms. Although people may regard preserving all the old-fashioned stuff as being unreasonable, I think that we must not lose the fundamentals, including the all-important medical practice that characterizes our hospital and the philosophy inherited from our predecessors. I would like to try to pass on these traditions and not dismissing them due to our own convenience.

Column: Staff Get Together

Cardiac surgery is said to be the ultimate of team medical care. But do not get me wrong with the term team medical care. It is not simply defined as team medical care because it cannot be achieved by one person, nor because everyone works happily and devises to avoid stress and power harassment.

Cardiac surgery is a harsh profession because the final outcome (such as saving life and quality of life afterwards) can be judged by anyone.

In other words, even if the factors of each individual in the team do not immediately impact the outcome, multiple processes caused by even a slight lack of skill of not only the surgeons but also perfusionists and nurses will lead ultimately to the outcome. Therefore, from the viewpoint that the outstanding skills of each individual are exhibited and shared among team members in the setting of surgery, cardiac surgery has come to be regarded as the ultimate of team medical care. That is why you can never say that something that is not good is good.

Team leader should carefully consider what a team is for staff to get together. "We happened to meet by chance." I think there is some inevitability there, and it may also be the great luck of the team itself to be able to think of it as inevitable, which may lead to saving the life of the child. In the current situation in Japan where leaders cannot build their own surgical teams, a well-functioning surgical team may be such a mysterious one. It is a miracle of chance that people who wouldn't normally happen across are sitting around the same table and talking, "Let's do something interesting now."

Of course, if we get together, there will be time to break up. It's not so good that they hang on each other even after they have done their best together. Sometimes it is better to stay away for a while. But if it is really inevitable, the inevitability of chance may bring us together again.

What I thought when I was called a young surgeon at that time (probably a delusion…).

- Everyone is doing something that looks interesting, I want to do it, too.
- Everyone is doing surgery happily, I am going to smile in spite of myself!
- Here, I will be able to study and be a real surgical idiot.
- I may have sweet dreams in the future.

What I think now, that I am no longer a young surgeon (although it is a more annoying delusion.)

- Whether young people can be given the material to think deeply only once a day (Beginning to think for yourself means that the time of the day suddenly feels short, which will be the basis of austere training and innovation.)
- Do not lead young surgeons around by the nose for anything other than surgery, and do not disappoint and disturb them, especially with surgery.
- Show off surgery that makes them feel even a little inspiring.
- Give the feeling of "choosing easy things is boring."
- Make them feel "this team is cool and fashionable."
- A surgery that makes them feel better etc.

These are ideas of as if arrogant customer service agents, but, we must have the feeling that we should provide some service to for young staff. If they can be impressed with the service of surgery, they may become fans of heart surgery. But too much service and its oversold may, on the contrary, make them sick. At the very least, I think it is most important not to replace learning surgery with something else, such as working styles or educational policies.

If young staff could think about surgery and create something new by providing them with a service like no other, the word is extremely bad, but it seems that it will be possible to provide "medical services in the name of business" for children forever. You should never have embarrassing discussions about how to take care of young staff, create new medical care, or improve management, etc.

I think this is the extend of the original "Practitioner" and it will be a consistent tradition that never changes.

Column: Human Bond

These two photographs are the old and the present heart–lung machines (Fig. 6.66). Naturally, at a glance, the one on the right is the state-of-the-art machine being used now. The one on the left was the then state-of-the-art machine exhibited at the 4th World Congress of Cardiology held in Mexico in 1962.

The next three photographs are oxygenators (Fig. 6.67).

In heart surgery, these devices are used to artificially create the systemic circulation. Hence, both in the past and at present, we repair the heart while posing a heavy burden on the patient's entire body. This is heart surgery. Compared with surgery using the modern machine, heart surgery using the old equipment imposes greater invasiveness to the body, takes longer to operate, and have more problems and complications. That is why for heart surgeons of that era, heart surgeries were a race against time.

Fig. 6.66 The old and the present heart–lung machines

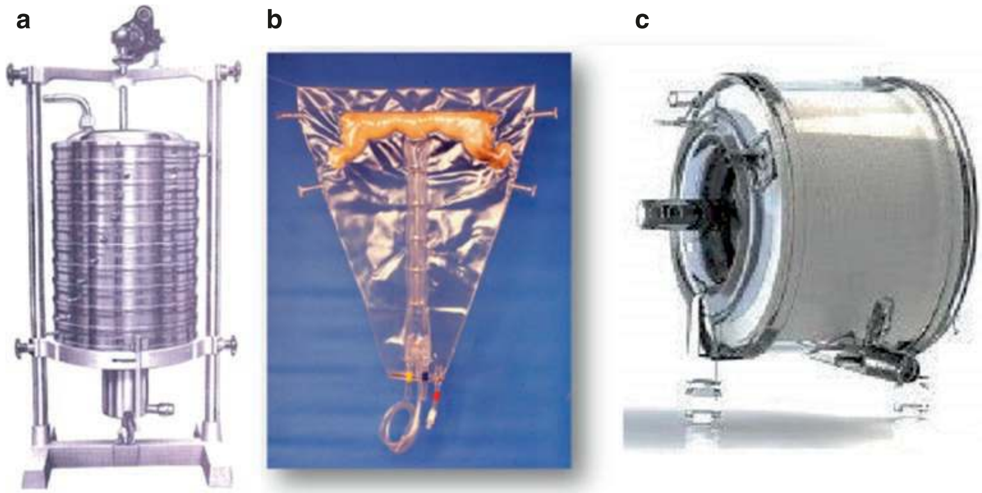


Fig. 6.67 Oxygenators. (**a**) Horizontal rotary disk type (**b**) Bubble type (**c**) Hollow fiber type

Fig. 6.68 Practice device for suture of deep part

There is a world of difference between the heart–lung machine used in heart surgeries in the old days and those at present (talking about the old days, it was about 60 years ago.). It is no exaggeration to say that the development of heart surgery is due to the advances of these machines. Each field in medicine has its own history of development, including the development of new treatment methods and devices. However, with regard to the devices used in heart surgery, I have to admire the advances that have been made in such a short period of time.

Now, I wonder whether you may already have a big question in your mind. Probably something like this. "I fully understand the advances of the equipment, but have the surgeons improved their skills?" Sure enough, the current surgical outcome has improved exceptionally. However, just as what you have been thinking, we cannot confidently say, "The development of heart surgery we see today is due to the improvement of surgeons' skills." How disappointing! If the surgeons of today travel back in time to the old days, they will be of no use at all. But then, it will be the same for us surgeons who are called veterans. If I were told to do surgery with the equipment of 1962, I do not think I can manage it. Even if I can do the surgery, if you ask me whether I can achieve the same or better result of the old days, I am not confident at all. Likewise, I will be of no use at all. There you are, the surgical skills of surgeons of the old days were speedy and precise, just wonderful craftsmanship. To put it strongly, without the many tools that ensure safety, surgeons of today may not be able to fulfill their skills as surgeons.

Repairing the heart while creating many non-physiological burden (invasion) to the whole body: this is heart surgery. Therefore, if you do surgery slowly, usually you do not succeed, both in the old days and at present. I feel extremely jealous (in Japanese: like grilling three grilled rice cakes) of the skills of the surgeons in the old days.

The next photograph is the training device for suturing that I used in 1984 (Fig. 6.68). We mounted a piece of cloth over the ring in the center and practiced suturing and then ligation form the hole (the whole can be reduced in size as shown in the photograph on the right).

I remember practicing really hard using this device during the first three years after joining Sakakibara Heart Institute.

But now, no one, including me, is using it. This training device is now standing covered in dust in the depths of the library of Sakakibara Herat Institute (at one time, it was in danger of being disposed, but was saved with my desperate effort)

By the way, the older baseball players and soccer players, etc. become, the more efforts they make to maintain their body and do basic training seriously and repeatedly so as not to lose the feel of the ball and the feel of the game. Just because they are veteran players, they make efforts so that their body reacts better than the young players' reaction to the ball. This is the obvious thing to do, because the older one gets, the more the physical strength is lost.

I have never heard that surgeons who are getting older practice basic training such as suturing and ligation.

But then, veteran surgeons have the advantage of possessing experience unsurpassed by young surgeons. Therefore, even without training, if veteran surgeons use the latest equipment, they can perform highly sophisticated surgeries unrivaled by young surgeons. However, when we get older, our skills become blunted, and our physical strength declines, consequently the operation takes longer to complete. Now then, is it a good thing to miss out on basic training? Is it enough if the surgeon can manage to do surgeries with a steady form? Before long, we may get to shout out loudly without embarrassment, "Surgery is something you do with your head."

In Japanese writing, the kanji for surgery (手術) literally means an art done by hand. I think it remains true even today: surgery is something one does by the hands, not by the head.

In the old days, surgeons who used the heart–lung machine of that era could not save the life of children unless they completed the surgeries promptly and sutured precisely. For that reason, they must acquire these skills solidly one by one and maintain them. We must polish our skills to the extent of excess—is this kind of idea already being called "analog?"

I am fully aware that bringing up old things and talking about them will probably be regarded as gauche. But, the development of convenient equipment and the improvement of surgeon's skill, are these two inversely proportional to each other?

The other day, I watched the document of late Kanzaburo Nakamura, a Kabuki actor, on television. For me who is not familiar with Kabuki, there was an expression that I did not quite understand, which was "to gain mellowness (en-juku-mi)" with experience. If that is the evaluation from leading figures and the audience, it would be a pleasure indeed to hear it. But, will there come a time when I can evaluate myself as having gained "en-juku-mi?" Is that something that can be felt by performing plays over and over again in front of an audience, in other words, accumulating experience?

We surgeons do the same thing (surgery) over and over again for years and years. As a result, we accumulate a lot of experience. By doing so many difficult operations over a long period of time, gradually, I was able to demonstrate, with some confidence, surgeries to young surgeons. And, I even got to think that the surgeries bring happiness to children. Certainly, I can have that kind of pride.

However, even though I have become a veteran surgeon, the feeling of accumulating experience or learning still stays with me; that is to say, I am still in the training process. Unfortunately, I have not reached the stage of completion in the path of surgery. … For surgeons, "en-juku-mi" is like a dream of a dream. Will there be a time when I can feel it ("en-juku-mi") myself, be convinced, and retire?

As I mentioned before, in the short history of only 60 years, the field of heart surgery has advanced tremendously. But, during this time, very unfortunately, we do not see the emergence of a super-gifted surgeon in terms of physical capability, who competes only with his skills; something like the thrill of the first human achieving the 9-second record for the 100 meter dash. Could it be that there are functional limitations of the human hands for the maneuvers involved in surgical skills? And, at my age, I suppose I will not be able to feel the "en-juku-mi" as a surgeon. What a dreary thought.

It may sound like an excuse, but the quality of heart surgery is not determined just by the advances in equipment and the skills of the surgeons. There is another important element, which is the flow of surgery. The condition of a child before surgery varies from one to the other. Among the patients, there are those who are admitted to the emergency in a shocked state; the heart has stopped before surgery, and the patient is transported to the operating room while receiving heart massage.

In order to save the lives of these children, rather than the performance of the machines and the skills of the surgeons, the absolute requirement for success is a good flow or timing of the surgery, including the state of preparation and the team assembled.

As I mentioned before, heart surgery is said to be the ultimate of team medical care.

Let me iterate, heart surgery is "a harsh profession because the final outcome of heart surgery (such as saving life and quality of life afterwards) can be judged by anyone. In other words, even if the factors of each individual in the team do not immediately impact the outcome, multiple processes caused by even a slight lack of skill of not only the surgeons but also perfusionists and nurses will lead ultimately to the outcome. Therefore, from the viewpoint that the outstanding skills of each individual are exhibited and shared among team members in the setting of surgery, heart surgery has come to be regarded as the ultimate of team medical care."

A team member just happened to participate by chance, or someone just happened to be there, or excellent team members just happen to assemble, but all these must have occurred by fate, and this fate is the luck of the team, which may lead to saving the life of the child.

This is the time when one feels the bond between people. It may be that there is no other profession that takes human bond more seriously than the heart surgery profession. I think that an environment in which the bond between people can be felt is truly wonderful, because it will lead to respect and appreciation for other parties. Conversely, the development of medical science cannot be expected in an environment in which bonding cannot be felt or in an environment that does not foster bonding in the future. Feeling the bond may be the "en-juku-mi" of a heart surgeon or even the "en-juku-mi" of the hospital.

However, it is necessary for surgeons to be meticulous about the basic surgical skills at all times, such as how to suture speedily and neatly, no matter how experienced they have become. After all, the surgeon's skill is essential to gain "en-juku-mi" of the team. With my retirement age approaching, I should do surgeries with greater belief in the children's bright future after surgery and further development of heart surgery. Without delay, I took the training device out from the library.

When I newly joined Sakakibara Heart Institute, I was totally immature. However, I remember vividly that everyone in the surgical team seemed to be having fun, and I also remember that when I was able to take part in surgery with them, I also felt the fun. Undoubtedly, I sensed the bond. By using this training device again, even this surgeon who is approaching retirement may be able to rediscover something new and with greater fun.

Q&A: Turning Point of Surgeons (Question in 2013)

Question: I think the young surgeons these days are brilliant. Without effort, they are ready to get the certificate that you mentioned. However, the problem is what happens after that. They have to struggle before they can work on their own. What is your opinion, please?

Answer: Perhaps, at that stage, they have good knowledge about the general cardiovascular system. For example, for adults, the knowledge includes not only arrhythmia and heart failure, but also diseases of adjacent organs that are inseparable from the cardiovascular system, such as diseases of the central nervous system and metabolic diseases, including diabetes. In the case of children, the knowledge includes abdominal complications, respiratory disease, and genetic diseases. In other words, they are general doctors with a special focus on heart surgery, which is the most important specialty in acute medical care. I think it is our responsibility to help them obtain the certificate up to this point. Now then, after that, these doctors must learn to deal with the challenges on their own. The problem is, can they eventually manage to confront the challenges on their own? Moreover, whether they are acknowledged by the cardiologists, pediatricians, nurses, and perfusionists is decisively important. During this time, the only thing the trainer surgeon can do is to secure enough surgical cases for these trainees. The point is that surgical trainees should be able to perform many surgeries properly. Unfortunately, it also depends on luck during this time. For example, how many more senior trainees are there between the new trainee and the top surgeon, and are there openings in other hospitals and abroad? What is more, as the trainees go up the career ladder, they will have to compete with more capable fellow surgeons. Meanwhile, the hospital should show the important policies of being a hospital good at training young medical personnel. Since surgeons who have been certified may become full-fletched surgeons in the future, do not apply the brake, do not talk about replacing surgery with something else, and do not obstruct their training with inappropriate instructions which may change their fate. Do not treat them in a patronizing manner and provide them an environment that allows them to talk like an adult, wait until they develop the aura of a surgeon. Most of all, bosses should not decide or reject someone as incompetent just from one mistake. Incidentally, Dr. Saichi Hosoda became Director of Sakakibara Heart Institute in 1997. Soon after that, I was told that I did not have to do anything other than surgery, that I only needed to be in the operating room and ICU, and that my position and salary would also go up, although just a little. May be surgeons get carried away easily. I just accepted it without a second thought, and before I know it, here I am. This may sound disrespectful, but at that time, surgery was really fun. Of course, there were annoying moments and moments of being obstructed, but 70% of the time was definitely fun. And, I actually felt a little guilty about the promotion and pay raise. It may be that I had so much fun that I did not feel the pressure. Again, with due respect, surgeons do not move up the ladder due to recognition of their surgical results and their performance, but it may be that those who move up the ladder eventually improve their skills in surgery.

Figure 6.69 shows the changes in the number of surgeries recorded by the author. Surgeons have their own turning points. For me, I think my turning point was around this time (enclosed in red line). It was a real pleasure to be recognized by someone from whom I wanted so much to be recognized. A surgeon who can operate with the trust from a pediatrician feels the joy of being able to fight a real challenge. When friends who are not supposed to meet gather by chance and talk about doing interesting things together, this by itself is miraculous and makes one feel lucky and great joy. However, with too many things to do and think about, my memory of that time seems to be fading, and I am forgetting the kindness that was bestowed on me."

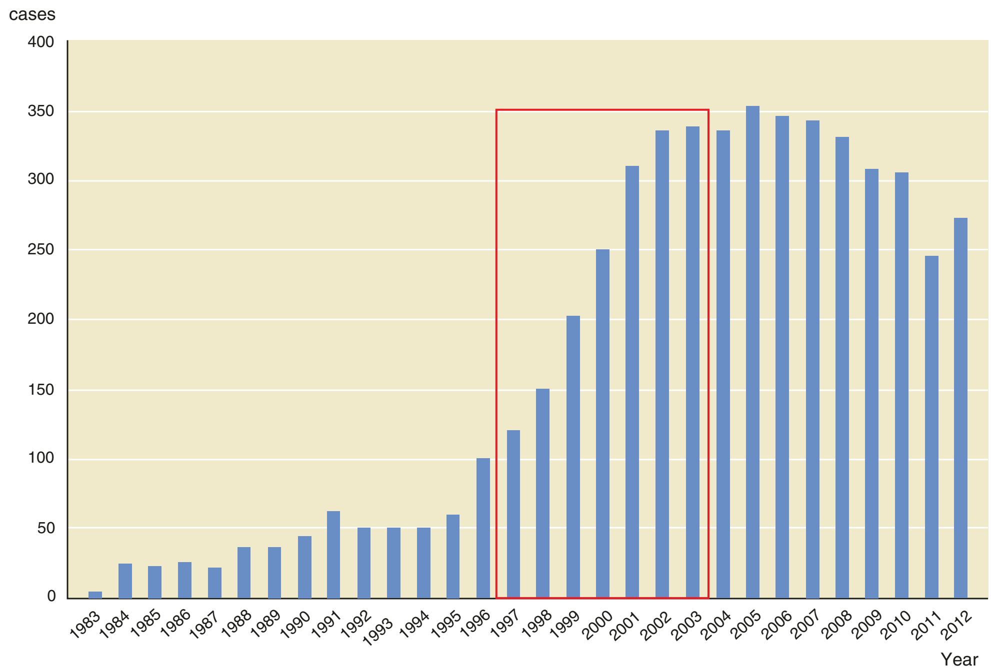


Fig. 6.69 Number of annual surgeries by the author

Column: Work-Style Reform

In recent years, overwork has become a major social problem in all occupations, regardless of medical personnel. Up until now, our hospital has practiced "Sakakibara ism," which never refuses a patient's transportation request. In particular, in cardiovascular treatment, the higher the reputation of the hospital and the higher the popularity of one doctor, the stronger the tendency to overwork certain individuals or teams. Of course, In order to meet all the demands of not only patients, but also referral doctors, it is necessary to prepare a large number of teams and staff capable of treating at the same level, but it is also a fact that it cannot be realized.

On the other hand, from the standpoint of educating young medical professionals individually or fostering team medical care, there is of course the opinion that in order to quickly acquire realistic and live medical care, it is necessary to train with making some sacrifices. In fact, it was no exaggeration to say that a surgeon a long time ago had only this kind of tendency.

Definitely, the education I received from my boss at that time and the things I learned deeply were certainly useful for saving more patients, and that is why I had such enthusiasm, it may be possible to feel that it was a very enjoyable and meaningful time.

Of course, it may be overstated, but, from my experience, if I was asked whether I have feeled the happiness in working on time or having some private time during the training period, I will answer "No, not at all!" Even if I worked hard all the time, I had at least enough time to think and devise and laugh at each other at that time. That is why I think that I had a good memory. I think surgery is something that should not be wavering between hope and despair, but there may be times of wavering. When I hear the word "overwork," of course, I don't think it should be said too loudly, but I feel that it may be a little rude to the predecessors who have contributed to the development of surgery up to date. What used to be commonplace is now often denied. New perspectives and measures are needed for the education and work style reform of young people.

However, on the other hand, there seems to be a question as to whether or not training without long breaks is a really effective educational method. Certainly, continuous treatment centered on doctors who have a good understanding of medical treatment is extremely reliable for patients. So, the general public will, of course, think that they should firmly practice until they acquire effective treatment techniques. However, it is unlikely that working for a long time and studying for a long time will surely lead to the acquisition of strong essence and skills as a doctor or acquisition of mental strength and guts. I myself hate having such things at all. If so, there should be many other ways, such as fire-walking ritual (HIWATARI), practice religious austerities under water-fall (TAKIGYOU), or ZAZEN.

Evaluation of medical treatment is definitely determined by treatment results, and emergency requests should never be refused. These are prerequisites for education. So, in current medical education, it is important to talk about treatment points in advance so as not to do useless work. Of course, there are many things that young people cannot really understand until some time has passed. Therefore, it may also be necessary to have a way of speaking that does not interfere with their growth. In the future, it is necessary to consider medical education from these viewpoints. And we veterans must be more immersed in education to save time so that they can acquire many experiences within a fixed time.

Q&A: Manuals (Question in 2018)

Question: I am an operating room nurse. Recently I have become a member of the Safety Risk Management Committee. I find it very worthwhile. However, there are too many manuals, and I am wondering how to make them more functional and easier to follow. Please give me your opinion.

Answer: Certainly, it makes one feel uncomfortable when there are too many rules. The manuals are a collection of documents unique to a hospital. Probably whenever something happened, it results in a manual. So, first of all, it is necessary to strictly follow the manuals. However, I was very surprised that you felt that way. I think it is wonderful. Let me talk a little about the manuals, although some of it may not be what I really think.

First of all, if there are too many clinical problems, it is necessary to make a complete formal manual or review the surgery itself. However, in that case, it is essential to write the manual with someone who has a good understanding of the clinical practice. Of course, there are things that cannot be written in a manual, such as courage, generosity, flexibility, accommodating, luck, etc. But, conversely, you do not get these from following the manual. "We did it according to the manual, but in the end, the situation got worse." At least this is not an excuse to tell the patient, and it means that there is no flexibility that we, in the operating room, should place the most importance on. In reality, in today's operating rooms and ICUs, response to events that are not written in the manual is often improved by the unseen support provided by healthcare personnel whom we call "veteran" or "craftsman." While medical care requires flexible responses, I find it incredible that the flow of treatment is actually planned according to the manual and that the staff is directed in the same way.

The manuals are meant to make your life easier. Of course, you need some kind of qualification to feel that the manuals make your work easier. If a person finds difficulties with a manual even though it is not that difficult, I think it is a sign that the person is not qualified enough. On the other hand, I also wonder about those who are insensitive enough to bring up the manual in a clinical setting where a severe battle of nerves is being waged. Nevertheless, I agree that it may be ideal to write manuals that users find simple and easy enough to comprehend, and while there are rules, they are not restrictive in normal situations. Of course, the presence of veterans and craftsmen is a hidden secret menu. Furthermore, I think it is better not to disperse the responsibilities to all the staff members; rather, all responsibilities should be directed to the superior. In any case, regardless of how good a manual is, wrong interpretations and operations will be dangerous and have grave effects on the patient. Some people say that our operating room is like "aun-no-kokyu," an extremely simple expression that just means "not say something that is understood even without saying." It is true and not an exaggeration at all.

Although there may be an impression that manuals guide smooth movements and provide a good working environment, in some ways, manuals may not be helpful to young surgeons after all. Too many shortcuts can stop growth. Written materials may provide knowledge but will never become an experience. A manual should not be written to highlight events that are extraordinary or to reflect surgical results. I always think that an ideal manual should describe what should be done so that the surgery proceeds smoothly without problem and should aim at peaceful and safe medical treatment.

Manuals are by no means bad. However, once written, it is difficult to abolish them. Clinical medicine will not become a field of study unless it is fun and unless the environment allows one to immerse in learning. There are many things that should be taught before teaching the use of manual. Particularly in clinical practice, it is obviously better to teach hands-on rather than to teach using manuals. It will be great when the young surgeons grow up and start thinking that they do not need the manuals anymore. Thank you for your question. If you come to some conclusions regarding the manuals, please also let me know.

Q&A: Communication (Question in 2018)

Question: I am a nurse in operating room. I am currently the leader of the Pediatric Heart Surgery Group. My supervisor often warns me that "there is no communication in your group, so, you should value teamwork more and share information." Please give me advice.

Answer: "I will confine my remarks to the surgery. You have just said three words I dislike most. I think each of them has its own meaning, but now it is often used in a jumble. Actually, there are many people who cannot communicate unless they use sentences or cannot share teamwork or information unless gathering everyone as a meeting. I said the non-technical skills during the operation in my talk, so I will not talk about it, but these three words may be unnecessary in the team that has acquired this skill.

Now, when using the terms "communication" and "teamwork," it is necessary to consider how did you set the level of essentiality to the terms. I think that the meaning of teamwork for Yankees described by Hideki Matsui is completely different from the meaning of teamwork that we think of as amateurs in baseball. The teamwork he said means the result of surviving the competition. Of course, in clinical practice, it is related to the therapeutic outcome of the patient, so there is no doubt that it is important to all levels.

If the problem solving seems to be difficult simply because of a bad relationship between the staff, there may be a destiny from the previous life, so it is impossible for healing a relationship. In that case, since it would be annoying for the patient, neither person should be participated in the surgery. By the way, unbelievably, there seems to be some people who do not want to join in surgery with who do not attend meetings or conferences just for the reason that they cannot communicate.

I think that the word "teamwork" should be used on the premise that there is an improvement in the skills of individuals and the principle of competition. Surgery is more like a theater to show off the techniques that each member has created, centered on the surgeon, rather than only completing it together. Especially in the case of highly difficult surgery, it's necessary to have teamwork saying each member's skill is already outstanding. Ultimately, it is also a battleground (theater) between the surgeon and the scrub nurse. However, if you are too obsessed about skills, you may scare someone with a kind heart, so the Japanese minded skill (Omote-nashi mind) is necessary.

On the other hand, there are some solutions for information sharing. Most recent in-hospital information comes by e-mail. Or, sometimes, it is left on the desk as a handwritten message. I think they use such means because it is not important information, but I cannot read it the same day if I do not have time to check it. Most importantly, even if the information is obtained and is shared within the team menbers, the boss must ultimately go to the work site ("gemba") using his feet and communicate in words. I think that will solve most of communication problems. Information has many uncertainties and sublimates immediately, so if communication, teamwork, or information sharing is not functioning, it will all be the supervisor's responsibility. Here, supervisor means the person who cannot understand like that. However, in many cases, it is simply due to human relationships. It is just a miracle that all the people who get along well with each other come together. You do not have to be so worried. But, even if no matter how much you are struggling, it is necessary to pretend to act in front of team members as if you are working comfortably. You should only try to ignore your boss's attention just a little and make it as long as possible to stay on site. An environment where communication is good and teamwork is good is not born only by measures that satisfy the other person actively. I think it's only necessary to have a passive action that does not make the other person unpleasant. It is important to have an environment where things go well before members fight or get angry each other.

The other day my mother was admitted to the Sakakibara Heart Institute. A young nurse in charge asked my mother and wife, "I heard that Dr. Takahashi is your son. What is his department? What kind of work is he doing?" My mother and wife bursted out laughing. I rarely have to go to the adult wards, so I suppose she did not know that I'm a pediatric cardiac surgeon. My wife was sarcastic with me that "you are not very famous." The nurse's saying shows the lack of information sharing, but I don't know why but I felt a slight happiness. However, on the one hand, I reflected on that. Unless I go around all wards, We veterans surgeons may be forgotten eventuall.

Column: Kanto Pediatric Heart Surgeon Club

On August 11, 2001, the Kanto Pediatric Heart Surgeon Club (KPHSC) was established. Dr. Toshihide Aso from Kitasato University, Dr. Shiori Kawasaki from Juntendo University, Dr. Arata Murakami from The University of Tokyo, and the author were the caretakers.

The purpose of this association is to have a heart-to-heart discussion about future challenges and questions in pediatric cardiovascular care by all medical staff, not only surgeons but also nurses, perfusionists, pediatricians, anesthesiologists, medical assistants, etc. It has been held 24 times so far, and ten facilities in the Kanto area have participated (Table 6.3). We are proud of the meeting because you can hear quite interesting and memorable discussions, unlike ordinary academic societies and research groups.

Table 6.3 Event record of Kanto Pediatric Heart Surgeons' Club (KPHSC)

Kanto Pediatric Heart Surgens' Club (KPHSC) Event Record			
No.	Date	Organizer	Discussion theme
1	Aug. 2001	Asou	Nursing in the operating room
2	Dec..2001	Kawasaki	Nursing at ICU
3	Sept. 2002	Takahashi	Let's enjoy the training
4	Dec. 2002	Murakami	Problems and countermeasures in management at PICU. Cooperation between surgeon and ME
5	Jun. 2003	Asou	Education for young surgeons
6	Nov. 2003	Kawasaki	Pre.& post-oprative management by pediatric cardiologist
7	Jun. 2004	Takahashi	Measures against comprehensive changes of medical insurance
8	Feb. 2005	Asou	Think about explanations in the medical field
9	Feb. 2006	Murakami	Measures for infection
10	Jul. 2006	Kawasaki	Management of long-term insertion tube and prevention for complication
11	Apr. 2007	Takahashi	Response and problem in emergency cardiac surgery
12	Mar. 2008	Murakami	Challenges to save children with congenital heart disease
13	Jun. 2009	Asou	Measures for sudden deterioration
14	Mar. 2010	Katougi	Respiratory management
15	Jul. 2010	Kawada	Problems and measures for long-term hospitalized children. Live demonstration (VSD)
16	Sept. 2011	Ozawa	Safety management in pediatric cardiac surgery. Explanation to family
17	Mar. 2012	Asou	Measures in case of disaster
18	Mar. 2014	Takahashi	Fontan procedure
19	Nov. 2014	Suzuki	ECMO in congenital heart disease
20	May. 2015	Kawada	Risk management in cardiovascular surgery
21	Jul. 2016	Masuda	Peri-operative monitoring. Pediatric valvular disease
22	Nov. 2016	Sasaki	Team medical care in pediatric cardiac surgery
23	Jun. 2017	Hirata	Preoperative management in neonatal heart surgery
24	Jul. 2018	Aoki	Decision making in the medical field

Q&A: Guidance During Surgery (Question in 2005)

Question:I am a perfusionist. I can be quite persistently rebuked by surgeons during surgery.

Even so, when I think about it, I often regret that it is the right thing to do. But considering team medical care, I don't think it's a good thing either. I would like to hear your thoughts.

Answer:It is hard to accept the blame. Surgery can only be achieved by having someone to go together with the surgeon and doing things that cannot be done alone. I am sorry, but if you cannot do that, you will not be able to participate in surgery.

Also, in my surgery, I also tell the perfusionist a lot of details, so I guess they might be wondering, "Is your surgery only possible if you make others uncomfortable?" This is where safety managers want to jump on the most.

However, the most important thing is the quality of the postoperative circulatory and respiratory status of the child, that is, the result. Therefore, I think that the cause and validity of the attention should be judged only from the result.

By the way, is your facility able to maintain good urine output and oxygenation after open-heart surgery for newborns and underweight infants?—Can they be extubated early?—It is also true that there are many things that the surgeon should reflect on, such as the quality of repair and the time required for surgery. But more than that, the quality of the postoperative condition may be the responsibility of the perfusionist. If you feel that the clinical efficacy is still low, or if there is a postoperative course that does not go as expected, it is rather important to think so.

The requirements for becoming a first-class medical staff are still strict.

Unless the surgeon is familiar with extracorporeal circulation, such a story will probably not come out. If he knows it well, so I think he will want it to be his ideal.

As I have said many times, I will give strict instructions to perfusionists, nurses, and young surgeons about the poor postoperative quality of VSD surgery, which is the basic procedure. It is because being able to successfully operate on VSD surgery has a good ripple effect on more difficult surgeries. But a more important consideration is that there is of course, a time limit, even if there is the potential for young surgeon to grow well. If the time limit that will affect your future destiny is coming soon, I will give you strong guidance. Normally, we should discuss the policy of extracorporeal circulation in advance, but whether or not we can deal with it flexibly is also one of the status of the team.

The operating room is also a place to get used to as soon as possible so that you do not make the same mistakes and the same reflections, and you do not feel sad in the future. At least, I can say that a surgeon who is always amiable is probably uncomfortable and unreliable. Let us get along well.

Column: The Surgery Which Is Dependent of the Perfusionist's Ability

Among the heart surgery performed in the neonatal period, Ross surgery has the highest mortality rate. The reason for this is that in addition to serious preoperative conditions such as decreased cardiac function, a long extracorporeal circulation time is required. In order to save lives and survive the postoperative acute phase, minimally invasive management of extracorporeal circulation for preventing edema, diuresis deterioration, and deterioration of cardiac function and oxygenation is essential. Surgery is accomplished by the power of individual team members, but it is important to remember that this neonatal Ross operation is the only operation that the perfusionist will determine the outcome.

Q&A: Scrub Nurse Training in Operating Room 1 (Question in 2016)

Question:I am the chief nurse of the operating room. I think that there are many nurses applying to the Sakakibara Heart Institute due to the quantity and quality of surgery. How much surgical experience and how many years before you are convinced that the nurse become independent?

Answer: To reiterate, I think that what a newcomer who seeks for training in operating room nursing wants from the Sakakibara Heart Institute is the comfortable environment in the hospital, such as being able to experience many operations and being convinced of the training effect. These are exactly the same as a young surgeon who wants to gain more experience and get ahead faster than anyone else. No, maybe not. Could it be that the desire is stronger for nurses than for doctor? Well, we must provide a training environment for that.

Table 6.4 shows the number of surgeries experienced by novice nurses in 2004 and 2005. Even among the novice nurses who are in their first year after graduation, some have experienced about 150 cases of surgeries in one year. It may seem like a fair amount, but they did the job well and can acquire non-technical skills faster and better than doctors. Perhaps it's because they can think a lot of things by devoting themselves to one thing. And because they acquired it early, it would be possible to participate in surgery for more severe cases sooner.

Table 6.4 Number of cardiac surgeries experienced by newcomer nurse in the first year after graduation

2004	Pediatric		Adult		Total No.
	Scrub	Circulating	Scrub	Circulating	
A	58	53	66	21	198
B	54	48	36	58	196
C	39	38	72	47	196
D	29	43	47	53	172
E	56	47	43	48	194
F	20	25	23	63	131

2005	Pediatric		Adult		Total No.
	Scrub	Circulating	Scrub	Circulating	
A	53	59	75	63	250
B	33	20	61	110	224
C	50	58	38	123	269

The time it takes to be satisfied with the training varies from nurse to nurse For nurses who have to go back to their home hospital one year later or plan to go to graduate school one year later, I will ask them ”Learn the strategies to improve your hospital surgery,” and “Learn enough to earn a PhD.” On the other hand, a nurse who will be here for three years will be asked to study pediatric cardiology, internal medicine, and cardiac rehabilitation, etc., and to make future plans and study freely. Although it is somewhat non-interference policy, but that is what the freedom of the operating room at Sakakibara Heart Institute is. From my experience, if they have been here for a year, they can be a decent nurse that I judge. No,that is wrong, I should say that it used to be. This is because there is a strong opinion recently that overwork is greatly involved in early employee turnover, and it seems that the education policy has been slightly revised so as not to make them feel uncomfortable, not to leave, and to slowly grow. In fact, they now debut as scrub nurses more than half a year later than they used to, and they can experience less than half the number of surgeries.

Even so, I think you can still study more than three times the number of operations at other facilities. It is a pretty interesting hospital, so young nurses, I would like you to join Sakakibara Heart Institute while I am fine.

Q&A: Scrub Nurse Training in Operating Room 2 (Question in 2013)

Question:I am a cardiac surgeon. In our hospital, about 100 pediatric cardiac surgeries are performed annually by two surgeons. I would like to ask about the team building. In Japanese hospitals, the nurses in the operating room often participate in surgery in many departments, and it is often impossible to fix the team members. I think this is not a good system for raising professional nurses. I would like to hear your opinion.

Answer: I have received the same question many times. I think each hospital has its own training policy for nurses. I only know about my hospital, so let me talk about Sakakibara Heart Institute.

In my experience, after working for three months with novice nurses, they begin to play young surgeons like a violin, and after half a year, they will be able to function as scrub or circulating nurses. Like a surgeon, I think it's important to deal with a large number of surgery and get used to the scene. However, currently, they cannot experience as many surgeries as they wish. They don't seem to experience many surgeries without being worried about the time, as it used to. Certainly, as you say, sometimes I feel that growth is slow from the perspective of securing qualifications as well.

Sakakibara Heart Institute is a hospital specialized in cardiovascular. However, even then, the surgeon is not able to choose a scrub nurse or a perfusionist. It is the current situation to perform surgery with a nurse or a perfusionist who has little experience. However, if you think about it carefully, this is the same as when the surgeons who came to be called the experienced performed their first surgery. Looking back, there is a lot of embarrassing things when we were young. Perhaps the veteran nurse at that time would have seen me in the long run. So, no matter how short the period of training is, it is one of lifelong training that is meaningful to them. You should rather say "thank you" for coming to an unpopular cardiac surgery. However, of course, the flow of surgery will be slow.

The following things are important when performing surgery in an environment different from those in Western countries. (1) Cardiac surgery should be considered as a collective medical treatment of individual team members, although of course it is a team medical care. Therefore, it is necessary to be aware that it is meaningless without raising the ability of the individual. (2) A newcomer should first have the ability to flow a basic operation such as VSD as an individual without any delay. If this is not possible, surgery for severe cases will be impossible. Therefore, basic surgery should be taught repeatedly and rigorously. (3) Still, the surgeon should be obsessed with enough care so that the newcomer can do it well or instilling the confidence and delusion that they were successful (sometimes with a wheedling voice not to sexually harass). If novice nurses can work together in heart surgery even for a short period of time and feel pediatric heart surgery is enjoyable, I think they will come back as a nurse in cardiac surgery with a powerful and different power. After all, it is important to see them in the long run.

Last but not least, nurses and perfusionists also cannot choose a surgeon, which surgeons should keep in mind out of all. But more than that, you said your institution had 100 surgeries with only two surgeons. Is not the hospital director or the director of the nursing department cautioned against your overwork?

Q&A: Question from a Newcomer Nurse 1 (Question in 2012)

Question:I am a newcomer operating room nurse. I am told by my boss "Anyway, study by observing your seniors." where should I start learning? How should I study?

Answer: There is minimum required knowledge and technique that I want you to learn. First is the basic anatomy. However, the anatomy referred to here is not the anatomy that appears in textbooks but the practical anatomy in the surgical field. For example, in coarctation complex surgery, they will be the position of the ductus arteriosus, phrenic nerve and recurrent laryngeal nerve in mid-sternotomy, and the points to note when ligating and cutting ductus arteriosus. In the Jatene procedure, they will be the morphology of coronary arteries and their device for anastomosis, and in TOF surgery, characteristics of VSD morphology and precautions for closing. More basically, the position of the left pulmonary vein, the method of ensuring the visual field by the first assistant at the time for inserting the left venting tube, and the position and direction of the mitral valve through which the vent tube passes, etc. There are many observation points, so please watch the surgery with that feeling and check them later in the anatomy textbook. You can do it when you have free time. It is not urgent!

However, in actual clinical practice, the procedure and flow of surgery are different, even for the same disease and surgery. I think that veteran scrub nurses are doing their best to improve work efficiency and share the idea with the surgeon. So, I think it is important to observe your seniors closely in that sense. After all, it is important to devise time so that you can stay in the operation room as long as possible.

Column: Question from a Newcomer Nurses 2

It seems that some operating room nurses are worried about having doubts about nursing in the operating room, that is, not feeling that they are nursing. This feeling seems to be stronger the more excellent the nurse is, or the more the knowledge of the surgical technique and the skill as a scrub nurse are enhanced. Unlike nurses in wards, one factor is that there is less time to find a specific method and direction of nursing by a direct conversation with the patient. So, it may be that there are relatively few opportunities for nurses in the operating room to be aware of the nursing sense.

Of course, it is not appropriate for a surgeon to speak of nursing, but I believe there is certainly some kind of operating room-specific nursing that the patient desires. It is not only accurate procedures such as the prevention for infection and residual in the body. It is the integration of treatments and sharing awareness as surgery team medical treatment tokeep hemodynamics stable (in short, sharing management for "Constant Perfusion"). I think that this practice is the nursing in the operating room itself. In the current situation where there are still children who can not be saved, interacting with an unconscious child under anesthesia in the operating room with a feeling of fighting without giving up, that is the intelligence of the operating room, and that is the operating room nursing.

Q&A: Advice to Young Nurses (Question 2014)

Question:I am an operating room nurse. You talked about the importance of "Teaching in advance." Please tell me more specifically.

Answer: Most of the current pediatric cardiac surgery, such as Jatene surgery and Norwood surgery, are the "niban-senji" (meaning "second brew of tea" or rehash) surgeries (not their own original). But, surgeon doing "niban-senji" strives to outperform the original surgeon and also tries to do better than his boss. This will be a certification for the next step as a surgeon.

These are also the same for the scrub nurses. I would like you to tell the young nurse about your experience of efforts doing "niban-senji" so far in your own voice. When young staff start to work in the operating room, they grow while taking the own standard capabilities of the operating room as a common sense. Therefore, it is of course important for the operating room manager to improve the degree of its common sense. If the senior staff talks to them about their experiences and common sense in advance, their worries will be disappeared, and also their starting point for austere training will be changed upwards. Come to think of it, in the old days, and my uncle had the idea that if you learned how to drink alcohol early, you would not fail later (naturally, a man without common sense…).

Now, when I think about it, there are many important things that were taught in advance by veteran nurses in the past. If it is said that heart surgery is a team medical treatment, it is important to quickly close the gap in the amount of experience between the superior and young staff. In particular, be sure to talk about the habits during surgery of the surgeon you dislike. But, depending on what you speak, there are things that will be solved only after a while, and naturally, there are inextricable problems that no matter how hard you try on the spot. So, don't talk too persistently.

However, while continuing to teach in advance, some young people may come out who would be able to obtain just their abilities that I have finally acquired after more than 30 years in a year. Probably, I will be disappointed, though. I think its a lie that "experience is everything"…

Q&A: Specific Training (Question in 2018)

Question: I am a nurse at the operating room. Are there any specific training methods that must be done for time saving and team building ?

Answer: I suppose you came up with that question because you felt that there were no specific measures in my talk. Also, there may be many audiences whose brain is overloaded or confused. I'm sorry. It's an excuse, but unfortunately, I don't think there is a special training method that will surely see results for education of surgical skills, although, like a surgeon who needs to practice of handling a needle, basic training as a scrub nurse will be required naturally, such as holding a needle in the needle holder or handing a needle holder to surgeon.

At one seminar, a nurse told me her training methods to improve surgical skill. Amazingly, I heard that she had been sleeping with a pair of scissors in her hand for three nights or walking in the operating room wearing a loupe used by a surgeon.

I immediately told her "What's wrong with you?" but it seems that the method was effective for her. Anyway, regardless of the method, I think that the necessary measures that you believe should be implemented immediately. If you have a goal, there are always basic techniques to train to reach it. Therefore, you just have to earn it.

I think there is nothing in particular for the training method to acquire the surgical skill, but it is important to repeat each time considering the basics according to the goals and the basics according to the tactics. As I said about minimally invasiveness in this lecture, I had the experience that the minimally invasive measures, which were not immediately effective, produced effective clinical effects when I almost forgot about them. Similarly, as long as the boss and each member of the team have the unswerving willpower to surgery, apart from the training method or the process of reaching the results, I think that it will eventually lead to time saving and team development. This is the only thing off the top of my head.

Oh! And one last thing. I would truly appreciate it if all scrub nurses does not roam in the operating room with scissors and a loupe.

Q&A: Certification (Question in 2014)

Question:I am a seventh year nurse at ICU. Currently, I am teaching nursing care for children after cardiac surgery. In this lecture, the word "Certification" came out. Please tell me a little more.

Answer: Newcomer nurses will be in a new position to go to the next step if they earn certain conditions, and further improve their skills, and come to instruct young nurses. It's called "Ladder" in the nurse's world. In its process of each step, if your boss wants to support your further step-up sincerely, it means that you have already certificate been certified. I think this is the same for surgeons and perfusionists.

While each boss may have their own ideas about the decision to allow the next step up, there are some important things to consider. This is my experience, so please take it with a grain of salt. When new members comes in, the clinical problems that have been repeated so far tend to occur frequently. For example, an increase in infection or a mistake in receiving instructions, etc.

First of all, I would like you to tell the newcomer from your own experience only the most urgent and preventable things. Newcomers have a lot to learn and get used to, but as I said in this talk, the dexterity of each procedure, the attention to the surroundings, the knowledge, the correspondence to other occupations and families are acquired by getting used to them. So, these will work out simply by accumulating experience. The newcomer may not initially understand the details of what you say. But that's fine. The time will definitely come when newcomers can realize the real meaning of what you were saying at that time. If that time comes, it will be your own career and it will be a tradition of team. You should talk about your way of life without being shy.

I am sorry for my preachy talk, but just one more. I mentioned before the non-technical skill in the question from the scrub nurse. So, I want to talk about non-technical skills in terms of postoperative management of patients.

In palliative open-heart surgery for newborns with reduced cardiac function or severe atrioventricular regurgitation, it is common these days to tightly control the height of the starling curve by adjusting the proportion of pulmonary blood flow, preload and afterload, heart rate, and the amount of cardiac stimulants and vasodilators while observing the ever-changing circulatory-respiratory dynamics. This is one of the most difficult postoperative management. I think it is a true non-technical skill in pediatric cardiac surgery to share and practice the treatment with the whole team that you do not know how it is going to unfold until the end. It is a quite difficult management for a newcomer, but I think it is important to always consider the appropriateness of their factors related to cardiac output and to examine the patient in more detail. It is just on the job training in the truest sense. If you acquire these non-technical skills as soon as possible, your first certification will be completed, and you will not need any support from seniors.

Column: What Is the Certification?

In any profession, there will be a time when your superior will say to you, "You should go for it!" Obtaining a certificate from a professional body is called "certification." Of course, the criteria of judgment will vary depending on the superior and job type. However, as I said in the beginning, surgery is all about outcome. If you do surgery, the required condition is that you finish it a little better than your superior, who gave your permission to do the surgery.

One often hear comments such as, "I am confident that I can do it better than that person," or "There won't be any problem because I already have this much experience." But in my experience, it is better not to trust those statements. Most of these people are far from being ready. Let me say it again, there is no human race more useless than surgeons who have just graduated from medical school. For me, this is obvious, because when I was a medical student, I did not receive any training at all on the fundamental surgical technique.

However, the individual techniques of pediatric heart surgery are not that difficult. I think anyone can get certified if they are a little dexterous. Excuse me for a digression. In the old days, there was a lady peddler in my hometown who was selling fish. When my mother asked for a sole, she cut out the "engawa" (muscle of the fin) using a single blade, and the technique was fantastic. But, you do not need to be able to do that.

Let me talk more about certification for pediatric heart surgery.

First of all, I will tell you the first condition according to the superior: "Can this person earn a living as the primary surgeon?" This is surgery for ventricular septal defect. In Chap. 1, I mentioned that in pediatric heart surgery, there are basic techniques, and we do different combinations of them in surgeries. Repair of ventricular septal defect is the most basic surgery. If you cannot fully master this one, you will not be allowed to do more difficult and time-consuming surgeries. However, if you can clear it, you can move on to the next stage (although after that, you will need a new certificate again). After the final certification, you can become a director in surgery with your own team. It takes about 15 years after graduating from university at the earliest. Until then you are just a surgeon.

By the way, I guess readers may now have a question. I have said that clearing the surgery for ventricular septal defect is a certification to be the primary surgeon, but what is the certificate needed to do the surgery for ventricular septal defect? Of course, every certification step requires outcome, but the important thing is that for each step-up, you need to be able to convince your superior, the team's nurses and perfusionists, and moreover, the pediatrician who referred the child, that they are ready to support your certification. The support is not for successfully performing the surgery, but for being convinced that you will get even better if you go to the next step. If you get your certification without this step, from my experience, some problems often occur later.

Now then, what should be done?

Surgeons who have not experienced the ventricular septal defect surgery are not even "ordinary surgeons" but simply "ordinary people" who have a doctor's license. They are not useful, as I mentioned earlier. However, when I think of it now, during this time, the biggest advantage of ordinary people is that they have no responsibility. In other words, senior surgeons take responsibility for everything. Since you do not have to take responsibility, you do not have to think too much about it. How to spend this time is important.

Instead, you must be totally objective toward surgery. This is the flow of surgery described in Chap. 1, especially knowing the sense of time and condition of the skin. It is about whether or not you can feel the flow of surgery when the child is in an extremely good condition during the course of surgery, the flow of efforts made to improve the child's condition as much as possible, and the flow of the procedure progressing in a timely manner. Unfortunately, these are only cut outs of parts of the whole picture and are difficult to understand. Of course, there are many chores for "ordinary people" (actually, they are not just chores), and you should make yourself popular by saying to the pediatrician, "You are a good person," or chatting with nurses in the operating room, and especially saying to the domineering "otsubone-sama" (senior lady manager), "How nice!"

Of course, each surgical procedure has its own meaning, and it is relatively easy to give meaning to each. However, it is difficult to give meaning to the flow of the entire surgery. Within the flow, there are different timings that are considered important by the surgeons, the nurses, the perfusionists, and the anesthesiologist, respectively, and there is also the integrated overall flow. The era of "ordinary person" is an important preparation period for successfully performing the first ventricular septal defect surgery and for becoming an absurd surgeon who knows nothing but surgery. For things that can be understood just by using the brain, you can leave them to be understood later. However, the only thing you have to be careful is never do the very thing that your superior does not want you to do.

By the way, in my junior and senior high school days, there were these most unlikeable classmates who excelled in whatever sports they played and became class heroes without any effort. Young surgeons of the future have to be able to do anything they are asked to do; in a sense, they need to become the most unlikable type of person. The point is how to prepare for the period when you have no responsibility. For example, it is like before you declare your love to a woman, you have already made mental preparation for a refusal and already made a reservation at a shop to drink away your sorrows (may be different…). If you are living with surgery 24 h a day, 365 days a year, your ability in surgery will come later. There are surely other things you can only do now.

However, it is not enough to learn only the techniques. It is also necessary to study and accumulate a large amount of knowledge while you are young.

Column: The Era of COVID-19 1

This is the opinion of a person working in cardiac medicine.

"From the experience of the COVID-19 era, perhaps the medical care in Japan will undergo drastic changes. Needless to say, treatment for COVID-19 together with the development of preventive measures must continue. Meanwhile, we must also give attention to the treatments for patients with other diseases who have become reluctant to visit the hospitals. The issues of the inadequacy of remote working are also going to surface. However, as of today, I feel that the incidence of heart disease itself has not changed much compared to before COVID-19, although I have the impression that the number of patients who require emergency treatment or patients with sudden progression of symptoms has declined remarkably for some reason. The main factor is perhaps the paradoxical success of the government policy of requesting people to stay at home and to avoid the 3Cs (Closed spaces, Crowded places and Close-contact settings). COVID-19 may have given us an opportunity to reconsider the issues concerning the health and lifestyle of Japanese people."

Here is a question from a senior high school student who aims to become a doctor.

"In this era of COVID-19, we often see on the television that there is a shortage of medical personnel and beds. My grandmother used to go to the outpatient clinic by train once a week. But right now, she only receives remote medical service and medication. Her physical condition looks better, probably because now there is no need for her to travel or wait at the clinic. To tell the truth, it is good that she no longer comes home from the hospital looking tired. Of course, I fully understand the significance of receiving face-to-face medical consultations. But I began to have some doubts about the current medical care system, in terms of the necessity and the frequency of visiting outpatient clinics. For example, would it be better to have more discussions about delivering medical care from new perspectives which apply technologies such as IT (information and communication technology) and AI (artificial intelligence)?"

Money is necessary to deliver the ideal medical care that each medical practitioner aims for. Therefore, even at the expense of large loans, the dedicated medical professionals with the intention to provide medical care do their best. All gather and work together, anticipating the long-term and short-term situations. And, when the financial situation reveals a little surplus despite the big obligation of loan repayment, these medical professionals believe that the present ideal will be maintained, and work even harder to pursue further ideals (It seems that the decrease in medical care reimbursement is showing no sign of slowing down…). However, if the hospital treats COVID-19 patients, it will get into the red. Even if those patients are not treated, it will also get into the red. Really, it makes one wonder what to do. Of course, to the ordinary people, management is just a world of plus and minus. A hospital does not have its own assets and just borrow repeatedly from the very beginning, so the sense of management of medical personnel cannot be sound, no matter how much they are working for the patients. The outside world may have the impression of: "You people there, what are you doing~?" But, even at a time like this, people should not underestimate the sense of mission of the dedicated medical personnel in Japan (actually I am a little tired…), we are seriously doing our best.

Let me return to the topic.

When a surgeon of the older generation like me hears a senior high school student talking about AI, it intuitively reminds me of the story "Brain" (U-18) of Blackjack. Blackjack was appointed by the AI, U-18, itself to treat U-18 (Osamu Tezuka's manga (cartoon), a tearful story).

I would like to explain about "Constant Perfusion" (I am sorry to go off track again…).

In heart surgery, a method called extracorporeal circulation is used to maintain the systemic circulation during the process of stopping and repairing the heart. Although this is essential for heart surgery, extracorporeal circulation creates many non-physiological changes in the human body, such as alterations of hemodynamics and blood data (resulting in edema and organ dysfunction). Therefore, it is important to reduce these changes as much as possible, and the extracorporeal circulation method for this purpose is called “Constant Perfusion” (this term, in fact, is a coined name that I created).

To minimize these changes, various correction treatments are applied. Subtle adjustments are needed.

Since it is so subtle, I think that this correction will be more accurately done by AI than by human hands. But, the current rule states that AI should not be adopted. It must be done by human beings themselves using their hands. To be honest, I would rather leave this job to AI. If we can use AI, perfusionists operating the extracorporeal circulation should be able to manage “Constant Perfusion” more easily. Regarding this, I would like to ask someone who really knows the problems of extracorporeal circulation to make the decision.

But…, while there are still people who are trying hard to provide the best possible medical care, I would like to leave this management to those people.

Even if AI is used, and even if AI can self-learn, it must be created by someone who understands the subtlety of extracorporeal circulation and the mind of AI. Forgetting this will be grave consequences. For the initial adjustments, human beings must first experience and assess the results; and above all, they have to be more friendly with AI.

Now, let me go back to pediatric heart surgery.

Pediatric heart surgery is a treatment to repair a heart with congenital malformation to a near normal heart. Given that some conditions such as cardiac hypertrophy and other complications are not curable, “near normal” means to repair the heart to be as functionally and structurally normal as possible, just as the term “intracardiac repair” (meaning not a radical surgery) implies. From this perspective, pediatric heart surgery is something that needs only to repair well.

In this regard, AI may be able to make elaborate conclusions very easily. For that, AI will provide us with a mechanically fantastic miracle technique. However, AI may be a lonely existence because it cannot understand the subtleties of the healing process, especially the thoughts of the children being treated, the feelings of the parents, and even the experience of skilled surgeons. Even AI itself may be troubled by this situation. Rather than competing with AI like Go and Shogi (Japanese chess), I think it is necessary to establish a relationship between us and AI in the future, something like the conversation of Blackjack with U-18.

Taking all these together, if there is an illusion in the hospital today that the hospital will function well even with no communication with doctors, nurses, perfusionists, and especially the top-level management, then it may be a better option to promote AI.

And then, if AI is something that is more human, one might fall in love with the machine (like Blackjack…).

By adopting the Western ideas and styles in many things, from medical education and treatment methods to hospital management and working style, we have made great progress in medical care. However, it may just be my prejudice, and I cannot help thinking that we have given up many things that characterize our own culture. I am worried that the perception that “surgeries must be done successfully, that’s why specialized training is important to ensure success” will also disappear in due course.

Having said that, one may be called gauche by proudly talking about nothing but things of the past. When old things have stayed on for years without being changed, they are probably good things Therefore, I think it is also important to leave them alone. Just keep them without losing them. When I go to Italy, while I see extremely creative designs, I also somehow sense the smell of the nineteenth century there. Of course, old things have to be carefully preserved, but from these old things, someone may sense a new smell from them (actually, I am not good at decluttering).

Up until now, in the operation room, I have been saying to keep those things which if changed will get us into trouble, and make appropriate changes to those things that ought to be changed. Despite this intention, I still try not to make changes where possible, by solving the problems as they emerge.

In Japanese writing, the kanji for surgery (手術) literally means an art done by hands, something done by the human hands. In this era of COVID-19, instead of getting carried away by AI, I think we should consider the importance of the perception of the mission of human beings. We must not forget the fundamentals of medical services. Under the banner of “rules” and “reform,” so many things were changed blindly before we know it, and I am tired of getting this surprise every time.

I feel that there will be no next step without knowing the important medical care and the fundamental spiritual strength that characterize our country.

But anyway, if drinking at home and not walking outside are going to contribute to protect the health of the Japanese people, I need to seriously reflect on it. (I am already drinking at home while writing this…).

Column: The Era of COVID-19 2

Heart surgery is the ultimate of team medical care. Come to think of it, team care means that people gather together to deliver care, which means “close contact” among people “crowded together” in a “closed space;” or the “three C’s.” Social distancing is out of the question.

Especially in the case of heart surgery for small infants, we have three grown-up men (surgical team consists of three surgeons) putting their heads together, staring at an extremely small surgical field. In this situation, even if we wear surgical caps, surgical gowns, and robust surgical masks, we should consider that the chance of infecting each other is extremely high. In particular, if you ate a bowl of stamina-enhancing ramen noodles with plenty of garlic the day before surgery, the primary surgeon will have no hesitation to show you a red card, and you will be sent out of the operating room in no time. The operating room is just such a closed space (Of course, I know that young people have a lot to do after surgery, and I fully understand that you need to boost your power and vigor…).I do not know whether these are the right words, but we medical professionals who are engaged in heart surgery work in a relationship of trust that we are not infecting each other (Obviously, this is only natural because our job is to save lives).

"Don't breath." Of course, that is not possible. But, we have to think about various measures against infection. For example, wearing two layers of surgical masks or using an N95 mask which is specially made to prevent infection. I actually tried it… It makes one feel suffocated and slightly dizzy. You will need to breath pure oxygen.

Well then, what should we do?

In the end, there is a need to make the operating room a place where people can communicate without having to talk and without having to give instructions all the time. Moreover, it is important to complete the surgery speedily.

We often heard a comment from many people who came to visit our hospital, "The operation room here is quiet. It is really like "aun-no-kokyu" (knowing what to do without exchanging words). At that time, I interpreted "aun-no-kokyu" as just "not saying something that is understood without saying," an extremely simple expression and a somewhat twisted personality. It took me about a year to realize that it was a great compliment. It is true that the only sound audible in our First Operating Room is the background music of "Rock of the 80's" broadcasted on the cable radio, and it is so quiet that even the music sounds a little loud.

Now let me get off track for a while.

There was a report from the French National Center for Scientific Research (I saw it on Yahoo News). It seems that even when people listen to the same music, the heartbeat varies markedly from person to person. In other words, when listening to the same piece of music, some people may have a sense of relaxation, while others may feel stressed. As a result, creating personalized music may help control blood pressure and reduce heart rate disorder. Needless to say, this method does not have the side effects associated with drug treatment.

After reading this report, I reflected on our operating room, just a little. This rock music of the 80s that is played in our operating room, does it have a good effect on the heartbeat of the team members? May be the primary surgeon should have the role to provide tailor-made music to suit the sense of relaxation for individual staff members. Well, I should think about music selection.

Let me return to the topic of "closeness."

I think that it is necessary to review the custom of Japanese hospitals to hold countless meetings and conferences and think about whether these meetings and conferences are necessary. It is especially essential to reflect on these issues in the current situation. At a time like this, quiet surgery conducted in a so-called "aun-no-kokyu" manner is exactly what we need. "Have this ready, let's do this, and then do that…," we should finish the preoperative conference in about 30 s. In order to make the operating room with only music playing softly, the administrator must think about "shortening operative time," which can also be considered as a form of social distancing. During a time like this, it is especially important to have an administrator who can provide new trainees or employees with this kind of education and who can communicate with them.

Please note, though, one should never consider about ad-hoc introduction of oxygen inhalation.

However, in silent surgeries, young surgeons are less likely to be corrected or receive instructions during surgery. They are going to receive less on-the-job training. Therefore, young surgeons should keep in mind that they should study hard before starting surgery. While you are drinking at home, read as many books as you can, not just medical books. After you have read those books, sell them at Book Off (a place to sell books). In any case, the books you sold will be helpful to your juniors.

However, please do not sell my book "Sakakibara Heart Institute Manual of Minimally Invasive Surgery." Later, you may be able to use it to make fire for cooking rice… (I was very sad to see my book being sold as second-hand book at Amazon soon after it was released).

In this manner, heart surgery is "close contact in a closed space." There is no way to practice social distancing.

Speaking of which, I think that everything was so "close" then, even during surgical training. Thinking about it now, all of us were able to respond to emergencies efficiently just because it was so "close." Of course, closeness applies not only to surgery, but also to postoperative management in the middle of the night, and even further, in a sense, to heated discussions about treatment policies, I think that closeness was the fundamental of heart medical care. In addition, I have a feeling that from the perspective of the patients, the way we medical personnel deal with patients was also very "close." Nevertheless, the patients may have approved our care just because it was "close" (Sakakibara Heart Institute does not use the term "patient satisfaction" much, but prefers "patient approval").

Recently, more doctors, nurses, and perfusionists are given titles as professionals.

Of course, in the heart specialty also, there are several specialty positions for performing the specialized treatment. This specialty seems to imply that an incredible amount of knowledge and skills is involved. However, I think there is one drawback of this assumption; as we get more specialized, we are allowed to, or we choose to limit our work to our own specialty alone. I may be using completely wrong words again, but patients are surrounded by crowds of many different health professionals. However, I think that from the standpoint of the patients, they would prefer to have someone who "is close to them in a comprehensive sort of way." For example, someone who listens to what they are thinking now, their worries, and their complaints about the doctors ….

The more specialized medical care becomes, the more benefits it will bring to the patients. Of course, it also leads to the advancement of medicine science. In this era of COVID-19, we have to avoid situations of being "close." However, we medical professionals should rethink not only the closeness related to our patients, but also the closeness concerning our human relationship, how much closeness forms the basis of medical care, and how important closeness is. We medical personnel must care for the children with unswerving determination.

Q&A: Minimally Invasive (Question in 2018)
Question: This is the third time I have heard your lecture. I enjoy it very much because the content is from a different perspective each time. I feel that I have finally understood the meaning of comprehensive minimal invasiveness in pediatric cardiac surgery. I am sorry, but I heard that you have celebrated your 60th birthday (Kanreki). There are many young surgeons from this area at the lecture today, so would you please talk about your philosophy of minimally invasive surgery?.

- *"Kanreki" is when a person makes a complete cycle on the calendar from when they were born*

Answer: Thank you for coming many times. I was often pointed out that my talk was conceptual and incomprehensible. And sometimes, audience do a "Tsukkomi " to me, such as "Speak in more detail and interestingly."

- In Osaka culture, when somebody says a joke or a stupid thing, you are expected to react to it in a funny way. It's called "tsukkomi."

In such cases, it is probably an excuse, but I always think in my mind that it's because you've never felt in the surgical setting what I said. However, when I listened to the recording of my lecture later, it was certainly the case, so I often have regretted on that. Also, many people have pointed out why it can be said so categorically. Of course, I have to be more responsible for my talk, but I have nothing left to answer except I just felt about surgery that way. Well, either way, my lecture may need to be heard by taking something with a grain of salt.

As surgeons grow older, they seem to come to think of difficult theories, education, and preaching about surgery. However, on the other hand, the quality of surgery is slightly improved. There is no doubt that surgery that could only be done with 70–80% score when I was young can now be done with perfect score without too much effort. However, emotionally, I no longer have the fervency of aiming for 100 % score no matter what. In a good way, it may be judicious person, but it s a proof of old age. Still, sometimes, maybe once a month, there are some surgeries that I think "Yeah that's right!" and "It is so hard to experience." I feel I am blessed.

I have talked about how to reduce invasiveness in cardiac surgery, but to be honest, I have not reached a conclusion. Maybe, I have been just only saying something on my own. Moreover, in reality, there are many measures that are less effective none the less saying incomprehensible things, by looking at the surface of minimally invasive, and picturing that vague image, they dose not put a burden on the body. However, there is no doubt that minimally invasive measures had contributed to the progress of current cardiac surgery. I think that you young surgeons often cannot immediately find out the reasons or countermeasures for the clinical problems you felt during their surgery. However, I would like you to contemplate about ways to solve them one by one.

Currently, there are more opportunities to operate with young surgeons in their late 20s. There is always something that comes to my mind at that time. Its a bit irresponsible, but let me tell you. I probably may not make a great advance of pediatric heart surgery, or solving the remaining problems for minimal invasiveness. That means it have become the jobs and obligations of you young surgeons in front of me. I will forcibly entrust you. It was your destiny to come to this lecture and listen to my talk, so please be convinced and do your best. This is an absolutely undeclinable instruction. I think you can do it.

Column: Conceptual
I received many comments that "Dr. Takahashi's talk is too conceptual and lacks concreteness, so I don't understand it well." According to the Japanese dictionary Kojien, "conceptual" means "perceived in a general and abstract manner, regardless of individuality," "general understanding of matters," and "general and abstract notions deduced or derived from specific cases."

Now, allow me to make an excuse. There are no clearly established answers and conclusions for all things, such as human life, education, ideology, coping with the mind, and way of living. Based on our own experience and the conceptual ideas derived from it, we develop some means to interpret them, and each person draws his/her conclusion at any given time. Especially in anthropology and people's path of life, many concepts are developed from the knowledge obtained from occupations different from our own. Also, for conceptual opinions that we hear for the first time, often we digest them so as not to upset our stomach.

I talk about conceptual ideas because I hope that I can involve the audience to think about it together, and I speak in such a way because I expect that there are some people in the audience who think and feel the same way as I do. I also think about how to discuss what the presenter and audience share and feel in common and how to obtain mutual understanding. Without such awareness, the initial unsteady premise will not develop and may not proceed any further. Both the audience and the presenter must run at the same speed.

I think there is a trend these days that there is no point to discuss something unless everyone can understand it. Typical of surgeons, I have some twisted ideas such as, “Who is going to read a book that is touching and easy to understand?” and “There is no meaning to rewrite arguments that everyone understands.” Another thing is, as a surgeon who is involved in the lives of children and who trains successors, I feel that I cannot permit myself to be moved by books and stories that only provide knowledge.

Of course, for surgeons, robust skills and evidence to prove their skills are needed. That is exactly why I stubbornly think I should live as a person with conceptual thoughts and be a conceptual person. Naturally, some people would call me “a vague person” or “someone who makes no sense.”

Although one should not miss important things in somebody’s talk, from experience though, it seems that a talk regarded by some as “don’t know what the speaker is talking about” may be just the right level for those who are listening. Some things that are very important to me are unexpectedly considered mundane by the society at large. But, for something so mundane, I pursue it with all my might. I find that very interesting and am pleased with myself.

Therefore, I would like to be a surgeon lacking common sense who conveys conceptual pleasure to others.

Column: Surgery

It was the fall of 2003, before the Sakakibara Heart Institute moved to Fuchu City. At a dinner banquet, the late Professor Atsuyoshi Takao told me. “Mr. Takahashi, how many surgeries do you do each year now?” After answered that it has exceeded 300 cases so far, he said “Hmm…, oh yeah, then, if you go to Fuchu City, how about doing 500 cases by yourself.”

At that time, my surgical team consisted of only four surgeons, and even at the facility where the most pediatric heart surgery was performed, the number of cases was less than 500 per year, so I remember wondering what he was saying. However, in the 4th year after the move, the number of cases has greatly exceeded 500 (only one operating room was used). It’s like, “Oh, I see, 500 cases?”

I’m not proud of it, but when I have such an experience, for some reason, the sense of urgency for surgery and the feeling of being chased all the time have disappeared despite my busy schedule. I was able to perform many surgery in a very comfortable mood. Also, as I started to perform more difficult operations, I felt like a delusion that I felt so much better because I had the illusion that I was no longer responsible for the easy operations that I had done so far.

All the staff of the surgery team were able to work with a smile with some strange pride.

Of course, 500 operations could not be done by a surgeon alone. Naturally, shortening the operative time is essential. But more than that, what we were most particular about was improving the management of patients during surgery to ensure good momentum and the management of patients for early postoperative recovery to improve bed control in the ICU. We believe that 500 operations per year were able to be achieved because of the good flow not only in the operating room but also in the ICU and general ward. Of course, the biggest factor was the change in the team staff’s awareness of “I can do it.”

Well, I always want my successors to experience that kind of feeling.

However, in the present of work style reform, if we try to create an environment where one surgeon can perform 500 operations, an immediate improvement order will be issued. Also, if you try to educate in the same way, it will be the same. Based on the current work style reforms, we now need several times more human resources than at that time. Even if you wish to create a history that surpasses your boss, there are some difficult realities. However, I think that only the actual know-how of being able to do 500 cases in one operating room that is ingrained in our heart can be passed on to juniors. Of course, it’s inappropriate to say that this was the case when I was young, but I’ll just tell you how you can work to do 500 cases even if you can’t do it, and the heart that you can do it. This may give you more room in mind and help you grow a conceptual surgeon in a good way.

“The elderly show themselves and speak,” which is probably the last job that a veteran surgeon can do. It is also the duty of a surgeon who has lived in a very happy era surgically.

Column: Handover of Surgery to Juniors, and Retirement

As we get older, we start to think about things like sermons, such as difficult theories and education about surgery. However, on the other hand, the quality of surgery itself is slightly improved. There is no doubt that you will be able to perform surgery with scoring100 points without much involvement in surgery that you could only do with 70–80 points (of course, it is a passing score) when you were young.

However, emotionally, I no longer have the seriousness of aiming for a perfect score of 100 points. In a good way, it is thoughtful, but it is a sign that I have become aged.

We veteran surgeons are by no means inferior to the next generation of junior surgeons in terms of our experience in surgery and the feeling of not being involved during surgery. It is still impossible to physically bridge these differences. I always say to those who are aiming for my position, "Come again in 200 years. Dream on."

But if, by any chance, it is time to give young surgeon my current position, or, frustratingly, it is time to lose to young surgeon, of course I only dare to say it, it' is only when two things happen.

One is when I feel intellectual jealousy towards my juniors in terms of abundant surgical knowledge. And the other is when young people get more trust from their parents and nurses, that is, when I feel that their juniors are more popular.

Of course, if possible, I definitely want them to have some more realistic surgical techniques than any other surgeon. But even if the generation changes, I would still be nervous about their surgery. I want my juniors to bear something big that will lead to the development of cardiac surgery, and I want them to make a history that goes beyond me.

As an aside, as the retirement age approaches, the bigwigs asks me when and what to do with the change of generations. It is annoying to be asked too often, so I always answer as follows. "I present my conclusions, which scientifically examined the difference between love and romance, to my juniors with evidence, but if my juniors do not understand it, there is no alternation of generations!"

How should I bring an end to cardiac surgery?

Column: Informed Consent for Minimizing Invasion to the Mind

Accompanying the advances in prenatal diagnosis in recent years, there is a sharp increase in cases of parents giving up treatment during the fetal stage. I once received questions from a mid-career pediatric heart surgeon. He seemed to be considerably troubled.

"Even for some surgeries that I am absolutely confident of doing well, because of the safety management policy of the hospital, I can't tell the patient's parents that the surgery will be 100% success. Instead, I tell them details of many possible complications. As a result, the parents wait for the surgery with plenty of worries. On the contrary, there are times when the surgery itself is relatively safe, but because of the very poor condition before surgery, I feel in my heart that there is only fifty-fifty chance of success. However, I sometimes can't tell the parents of the high possibility of death. What's more, with the recent advances in prenatal diagnostic technology, there is an increase in cases of parents giving up treatment in the fetal stage. To encourage the parents, I just wonder whether there is a way of explanation which, to borrow your words, minimize invasion to the parents' mind. Can you share your opinions with me?"

Giving explanations to parents about their child's surgery is called Mund Therapie in Japanese (*briefing* about a disease; corned from the German word "Mund" meaning mouth) or informed consent. The ways of explanation vary tremendously among surgeons. Of course, there is no best way.

My answer is, give the best considerations and use ingenuity. It is important both to convince the parents about the surgeon's own treatment policy (briefing) as well as to give the parents all the information about the disease and treatments, involve them in choosing treatment option, then obtain their consent (informed consent). First, it is necessary to try to bridge the imbalance of knowledge, that is, knowledge asymmetry, between the surgeon and the parents. My impression is that assembling the explanations from the referring doctor, explanations from the attending pediatrician, and information from the surgeon, together with collecting information from the internet and second opinion, will narrow the asymmetry considerably.

However, even for the same disease and the same surgical technique, the postoperative course differs depending on individual patients. And, if complications occur and long-term management is needed, result that deviates from expectation is frequently encountered. At least one can say the following. During briefing, naturally the surgeon has to explain about the result of surgery and the probability of risk based on his/her own data. If the result of surgery is as expected from the content of the explanation, there will be no problem. But, if any unexpected event occurs, the explanation would end up to be a "lie," although it is not a good word to use. At least, the surgeon cannot complain about it. Obviously, the surgeon has taken all the measures to prevent unexpected problem. Still, it happens sometimes.

Of course, the surgeon tries his/her best to talk about all the possible aspects concerning the surgery. But, talking about all the aspects would, as you said, put a lot of stress on the patient's family and increase their anxiety…. The strategies and techniques of surgical treatment improve every day. Treatments that have been regarded to be the latest until now may be abandoned with time. Medical practice can be said to be a profession in which many good memories of the past have to be discarded. I have been working with the determination of never refusing a surgical request, and doing my best because I believe that miracle always happen even if the surgery has a fifty-fifty chance of success. But, as a pediatric heart surgeon, I sometimes feel sad.

Regarding heart diseases in children, saving life is extremely difficult for some illnesses, and serious problems such as developmental disorders and learning disorders may remain after surgery for other diseases. When the diseases are diagnosed in the fetal stage, sometimes the choice of treatment may be left to the parents. Whether to go ahead with treatment and whether to give up treatment are both very difficult choices, and of course, nobody is to be blamed. I fully respect the parents' will. In these cases, a briefing that minimizes invasion to their feeling is especially important. Briefing contents should aim to encourage and not to disappoint. However, as surgeons, all we can do is to think thoroughly of how to minimize invasion of the surgery, further improve techniques to obtain better surgical result, and refine management method aiming to improve QOL in the long term. In short, surgeons must try hard to keep on improving surgeries. In doing so, surgeons can more confidently recommend surgery as the treatment option.

I am aware that it may not be appropriate to say this. I just would like to mention that whenever I encounter a case of giving up treatment in fetal stage, it always remind me of that spiritual television program. When I hear a child saying, "I remember that I flew into my mother's womb," as a pediatric heart surgeon, I will not be defeated; the next time it will surely be happier, and I will definitely save life if there is a chance to do so. As such, I am contented to remain an expert ignoramus even to this age.

Regarding prenatal diagnosis, the big debate is expected to continue further. This is another one of those difficult problems. When I was young, there were occasions in which parents became worried about the contents of my briefing, and they reconfirmed it with my superior or nursing staff. The age of someone who can be regarded as a veteran may be a requisite for effective dialogue with other persons. In order to convince the other person or to make the explanation less invasive to that person's mind, learning the way of speaking may be necessary.

Column: Going Against God's Will

Having been operating on infants' hearts for so many years, I sometimes think that "this is fate" or "this is my destiny." I may be rude, but I just cannot help thinking it that way. "A baby having heart disease, is this a trial given from god?" "Is doing surgery also a mission given to the surgeon by god?" An infant cannot speak and cannot choose a surgeon for its own operation. Of course, god is always silent.

During a lecture that I presented in a provincial city, an elderly man asked me a question. "Dr. Takahashi, as you just said, I think some lives are miraculously saved. But, well…, Doctor, let me say it little clear. Isn't the miracle you talked about against god's will? What do you think of that?"

Miraculously saving life, and conversely, regretfully losing life due to some accidental problems are experienced by all who work in the medical field. One can say that they are inevitable. But, this comment about me working so hard to operate is against god's will …. Does it mean that god originally decided to take this baby to heaven, and here I am, going against god's will? I thought, "O, oh, I am in trouble. If I don't answer properly, this could be ridiculous".

I contemplated while looking at the face of the man and replied, "I have been speaking all over the country. As soon as I arrive at a place, I go straight to the local deity of the land to offer my respect. There are two purposes. One is to ask for permission to share a sip of the sacred sake (wine) of the land. The other is to ask the deity to watch over me, explaining that my job is to operate on children with heart diseases who come close to death, and I do my best to have them stay in our world so that they can live happily. Then, I add that I will be continuing with this job for some time yet, and ask for god's pardon and understanding. So far, I haven't met any big punishment yet, so I suppose at least I haven't been going against god's will."

Although my answer did not really make much sense, the man seemed to understand me very well and sat down on the chair. He probably thought I was not much of a surgeon anyway. However, I can't get this question out of my mind. This was the most surprising comment, and in a sense the most miraculous remark I have received in all my talks so far.

But still, I cannot totally convince myself that god would deny the life of an infant. That's why I go against his will. However, even if god's will is to save life, some infants do pass away. This too would be against god's will, or it is simply that the surgeon is not skillful enough. …. Anyway, it seems that everything is in the hands of god. No matter how hard a surgeon like me tries to find the answer, it will be in vain. All we surgeons can do is to operate without putting burden on the children and without stressing the parents. I can hear the voice of the man who asked the question, "Doctor, brace up!"

Only skillful surgery, and nothing else, can defy god's will. However, there is no easy way to acquire skill. This question has made me fiercely aware that I need to reconsider the nature of surgical science.

Column: Heart Surgery and Japanese Spirit

At the final presentation to bid for the 2020 Olympics, I heard the word "hospitality" (omotenashi). Now then, how do we extend our hospitality to foreigners? Originally, Japan has a wonderful tradition of hospitality. If many visitors to Japan already sense this Japanese spirit, it may not be necessary for them to think about it again. For the Japanese side that extends hospitality, it is a great pleasure to realize that the Japanese has this spirit by nature.

By the way, there are also two sides to hospitality in medical care. For all surgeons, hospitality in the operating room is to provide the optimal and best quality surgery. The recipient side is, first of all, the patient, and the conditions for hospitality are that the surgery has a smooth flow, has no mistakes, and is as minimally invasive as possible. However, surgeons have more important recipients, and they are the new trainees who work as part of the team. Creating an environment conducive to training, research and education, and utilizing surgery as a venue for passing down the traditions of medical practice: these are the important hospitality that even surgeons who have advanced a little in career should contemplate.

Each year, our hospital schedules approximately 500 pediatric heart surgeries longitudinally in one operating room. Although we may be criticized for the somewhat tight schedule from the viewpoint of safety risk management and rules of employment, this schedule has evolved as a result of some overlapping inevitable and coincidental conditions. Naturally, shortening the operative time is of outmost important. For pediatric heart surgeries, shortening the operative time is without doubt the only means to minimize the invasiveness. In addition, this schedule allows young surgeons to study many surgeries from the beginning to the end within a short period of time, which is an important merit from the viewpoint of creating a comfortable learning environment for young surgeons. Our goal is to achieve anesthesia time for ASD, VSD, etc. of less than 2 h, and to finish all the surgeries by 17:00, and strive to achieve this goal. For young surgeons, these surgeries serve as one of the check points for performing complicated surgeries that require longer time; in other words, there are an indicator for qualification. Also, most of the surgical techniques are "niban-senji," of repeating the same techniques over and over again. Therefore, more important than inventing original techniques, it is necessary to consider how to modify the techniques to make them different and more interesting than the original techniques developed by our predecessors. For newcomers, the atmosphere in the operating room that they first enter becomes the standard. Taking this as the norm, it is important to establish an environment that allows them to grow beyond what they are now. Of course, the greatest significance in shortening operative time is to secure more private time. There is nothing more annoying than a long and poorly planned operation, and shortening the time also minimizes the invasiveness for us.

Currently, surgery is performed by a team of three surgeons, one anesthesiologist, two perfusionists, one scrub nurse and one circulating nurse. The newcomers nowadays are knowledgeable, motivated, and very talented. But, if I have to say one complaint, I think they have not received enough training of their hands. The term "training of the hands" has two meanings. One is to acquire techniques and knowledge. Nowadays, surgical videos of leading surgeons are easily accessible on the internet, and it is possible to freely participate in technical training sessions using porcine heart and in many academic societies.

For pediatric heart surgery, each procedure is not that difficult, and a child's heart that has been completely repaired will function according to expectation. Therefore, to start with, it is necessary to brush up on each technique. However, this is just the basic manual for the surgeon; in other words, it is nothing but the training to score one point for each technique. Another meaning of training the hands is whether the surgeon can accomplish the act of connecting all the points he scored with a line; that is, to make a smooth flow and feel the time margin and the space in time ("ma" 間) during surgery. I have no actual experience of performing extracorporeal circulation, but I know what a poor extracorporeal circulation is. I have never administered cardiac anesthesia, but I know what a good anesthesia is. The important thing is to be able to grasp how individual team members are doing and manage the flow and to judge whether it is a good or bad flow. When we become able to evaluate or criticize each other's actions during surgery from our respective standpoints, that is the time when we are liberated from being bound by manuals and rules, and that finally, we have adequately trained our hands as a team. However, these are things that we can never learn unless we are in the operating room. There is no way to teach people unless they move proactively by themselves. The operating room these days is quiet. It may just be that while approaching my 60th birthday, I have become able to do surgery peacefully with a merciful heart like Buddha. But, the reason for the quietness is simply there are few young surgeons who come to see surgeries. Young people have a lot of work to do other than surgery, but making time is one of the talents. I think just being in the operating room is extremely important, even if it may seem unproductive.

The importance of non-technical skill (NOTS) in operating rooms has been pointed out since a long time ago. Simply put, NOTS is communication and teamwork, and a lack of NOTS seems to be greatly associated with the occurrence of incidents. I think that NOTS is almost synonymous with the second meaning of training the hands described above. Especially, when nurses and perfusionists become able to judge treatment from the same perspective as a doctor, and when there is room to follow each other's actions during surgery, one can say that NOTS is truly achieved. With due respect, for me, NOTS is also the condition for the qualification of nurse practitioners. After all, it all depends on how much time you are spending in the operating room. Until now, many young surgeons have been trained, but it seems that it will take at least 10 years to acquire the skills and NOTS which are required to be in charge of the operating room as the primary surgeon; in other words, to acquire the aura of a surgeon. On the other hand, for some reason, nurses can manage that in about three years. Surgeons may feel envious, but nurses seem to do best in managing physical time and mental time. Of course, it goes without saying that communication through drinking together is the most valuable way to acquire NOTS.

However, no matter how perfect a team is in techniques and NOTS, being a medical care setting, there are times when misfortune and injustice just land on the team.

Therefore, we just cannot do without luck in the team. In particular, good human relationship is just plain luck, and having excellent colleagues joining the team by chance is also the luck that a team cannot do without. Now, I am thinking about how to grow luck, but there is nothing I can do about it. The least I can say is that, it is the primary surgeon's duty to purify and pray before, during and after the "yakudoshi" (bad years). Another thing is, before new surgeons join the department, they call on the executive surgeon to pay their respect, but they do not pay respect to the local guardian deity, which is completely beyond my comprehension.

The surgical manager of a cardiovascular hospital feels sad when young doctors move to other hospitals because the clinical care of our institution there is not the ideal they seek, which is due to their misconception that smooth flow of surgery, although important, is simply flowing having no heart. Everyone knows that nobody is more unreasonable than a surgeon and that a surgeon's logic may deviate greatly from the common sense of the world, but do we lack a benevolent heart, is our hospital such an uncomfortable place to work in? However, we should reflect the possibility that when medical personnel talks about "humanistic medicine," it could be an escape from immature techniques and reality, in a sense, taking the easy way out. The field of pediatric cardiovascular medicine has a wide scope. New knowledge will emerge whether you make a vertical cut, a horizontal cut, or an oblique cut at an angle of 35 degrees. It takes time to learn this branch of medicine, but if you stop halfway through, you will never know what it is, and it will end up wasting everything…. The essence of medical care is to save patient's life, to guarantee the quality of care, and to sustain that quality. If you do not first of all make efforts to show good results with the best of your ability, then what you discuss about "humanistic medicine" will not resonate in the heart of your audience.

Surgery is an art that is performed by hand by a group of humans getting together. Therefore, it is necessary to establish unique systems and methodologies for building team capacity and safety risk management. However, the Japanese subconsciously knows that by reconciling irrationality and repeating the same processes so as to be honest to a fault, and immersing themselves in an unproductive world without neglecting their human qualities; in a way, it is a world of unyielding, serious perseverance where outstanding craftsmanship is born, and the only place where we can capture luck and where the spirit (the heart) is nurtured. I firmly, naturally and confidently believe that actively focusing on "the heart," which can also be called the esthetic sense of Japan, is the quickest way to create a solid team. Until now, my work has been focused on surgery, but in the future, I will have to strive to create an environment in which efforts will be rewarded and to provide education and hospitality for reliable transmission of techniques to next generations. Although hospitality is delivered only when the receiver feels comfortable, if you feel that you have done your very best to be hospitable, then you may feel convinced that you have successfully extended your hospitality, even though it could be perceived as unappreciated kindness. In the world of pediatric cardiovascular medicine into which I happened to have entered, I will continue to put in my best efforts to do the tasks in front of me; to have little regard for fame and glory; to engage in surgery, education and team capacity building fully aware of the mission of a surgeon, and to continue my pursuit of the Japanese spirit.

6.9 Summary

Unfortunately, there is no easy way to play an active part on the front line, like there is no textbook titled "A must-win! First-class cardiac surgery team you can enter." At least what can be said is that if it is easy to qualify, it is either an operating room with a really good education policy or simply an overprotected operating room. And one more thing, at least, is that if you quit along the way, working in this operating room itself would be ended with a waste of time.

Surgery is determined by the absolute evaluation of the results and postoperative quality. As described above, there are many factors in the invasion of cardiac surgery. Among them, only prolonged surgery that crosses a certain line definitely increases mortality and morbidity. Therefore, it is a natural duty for the cardiac surgery team to be involved in time reduction, and the only minimally invasive means that can be obtained through effort is time reduction. Heart surgery is called team medicine. However, unless individual team members improve their individual skills, clinical effects, original teamwork and non-technical skills will not be born. To that end, it is necessary to create an operating room environment in which individual abilities can be enhanced just by being there as a surgeon in charge of surgery. It is an environment where something is always hanging in front of you, and you can feel something early. The point is the provision of a lot of experience, which is the biggest reason why the Sakakibara Heart Institute has to continue many operations.

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Postscript

Thank you for reading to the end. I get the feeling that I wrote a lot of things that would normally be done in a few lines. I have also tried to use as much of the original figures and photos as possible, but I think there were many parts that were difficult to see.

Readers may have felt a sense of fatigue and rebel to the contents of this book. In particular, some content of the answer to the question (Q&A) has already been changed with reflection, but I have posted my thoughts and hesitations as they are at the time. I am sorry that I was exaggerating too much without hesitation. It is also true that I have received some very disappointing opinions that this text would limit the numbers of customers as the contents were based only on the author and the Sakakibara Heart Institute's data. However, I think that it is impossible, at least from general textbooks, to acquire the effective minimal invasiveness required for surgery. It is necessary to think with flexibility.

There have been many ideas for minimally invasive measures, and it has already been practiced. However, if you are asked what is a surely effective minimally invasive measure, you can think for yourself, but you just have to say that you do not know. I am in trouble if I am told to explain it to people other than healthcare professionals. However, the evaluation of the quality and proficiency of surgery can ultimately be obtained from the results of comprehensive actions of the surgery team members. And the development of surgical device aiming for minimal invasiveness can be created as a result of human thoughts, and of course, surgery is to be performed by human hands. I think it is necessary to go back to the basic again and consider comprehensive minimal invasiveness focused on clinical efficacy. Let us think together about what it is and how it can be established.

In surgical treatment, the treatment policy that was believed to be correct at that time may be denied over time, become obsolete as a study, and as a result may be judged as a lie. Regarding the content of my book, I guess some people may think "this is just an idea," "there is no evidence," "why the author exaggerates such a trivial matter and speaks categorically," etc. However, I still perform a lot of difficult surgeries, and I know some tips about them. So, I am confident that about half of my opinion in this book is true, and that there is some content that is fairly relevant and cannot be underestimated.

Suppose I drop the needle holder into a fountain. If Nymph of fountain asks me the following, "Is your needle holder this gold? Or this silver? Or this stainless steel?" I am now confident that I will immediately and honestly answer that it is stainless steel. So, even though you find it unpleasant about my stories, please forgive me. If you have any questions, please contact me.

Perhaps my job as a surgeon will be over soon. Will the future work be the "Jisai"[1] that allowed bath and alcohol?

As I have said, many times, minimally invasive can be said to be minimally invasive only after the clinical effect is recognized. So, this is a difficult task. However, by reading a textbook for minimally invasive surgery written by one surgeon, if young surgeons can confirm in advance that they will experience for the first time in clinical practice, and if they can extend the starting line of growth far ahead, I think that will clinically effective minimally invasive measure.

Thank you for your hard work. If possible, see you again in the world of surgery.

August 31, 2021

[1]A witch doctor who prays for safety when sailing from Japan to China in ancient times. It was thought that the safety of the voyage could be maintained by making a "vow (such as abstinent life such as not drinking alcohol or taking a bath, etc.)" before the voyage and continuing to "pray" without breaking it.

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