Recommendations for the prevention of recurrence of medical accidents
Number 19

# Analysis of Deaths Related to Pulmonary Artery Catheters

## Part 1 Open-heart Surgery

## Part 2 PA Catheterization

February 2024

Medical Accident Investigation and Support Center
(Japan Medical Safety Research Organization)

Materials related to the recommendations
- Video explaining the recommendations
- For the prevention of accidental entrapment of pulmonary artery catheter in the suture (poster)

# The Purpose of “Recommendations for the Prevention of Recurrence”

These recommendations are provided as information based on the medical accident investigation reports from the concerned medical institutions. Among those reports, the Medical Accident Investigation and Support Center accumulates similar cases, investigates and analyzes their common or similar points, and provides them as recommendations.

These recommendations should be regarded as recurrence prevention measures focusing on the importance of avoiding accidents that may result in death, and should be distinguished from the “Guidelines” issued by the government and academic societies. Thus, this leads to the fact that the recommendations do not set any limit to the discretion of healthcare professionals, nor impose any new obligations or responsibilities.

Based on these considerations, we hope these recommendations will be widely used, taking into account comprehensively various situations such as the user’s medical decision-making, each patient’s condition and age, the wishes of the patient and family, as well as the medical institution’s practice systems and size.

In addition, these recommendations are to provide information to avoid similar deaths, to prevent recurrence, and to ensure patient safety. It is based on the provisions of Medical Care Act, and is not intended to be used as a means for resolving disputes.

# In Publishing the Recommendations for the Prevention of Recurrence of Medical Accidents (Number 19)

Takashi Kadowaki
Chair of the Board of Directors
Japan Medical Safety Research Organization

Based on the Medical Accident Investigation System launched in October 2015, the Medical Accident Investigation and Support Center (ISC) of the Japan Medical Safety Research Organization (Medsafe Japan) has been working with every effort to promote patient safety, to prevent recurrence of medical accidents, and to improve medical quality.

Along with the increasing advancement and diversification of the medical environment in recent years, medical institutions strive every day to prevent serious medical accidents from occurring. However, serious events do in fact occur in medical settings, at times resulting in the unexpected death of patients. Such cases have been reported to the ISC. Since the system's launch eight years and four months ago, more than 2,500 in-hospital investigation reports have been sent to the ISC. Based on these reports, to date we have published 18 recommendations as "Recommendations for the Prevention of Recurrence of Medical Accidents."

We, ISC, have published our nineteenth report compiled to prevent recurrence of medical accidents. As the theme of analysis, we decided to take up the cases of deaths related to pulmonary artery catheters. Although fatal incidents during the insertion or removal of pulmonary artery catheters are rare, our recommendation focuses on this issue in consideration of the significance of the multiple fatal cases reported to the ISC. The analysis includes a total of nine target cases reported through the Medical Accident Investigation System, consisting of five cases of open-heart surgery and four cases of PA catheterization.

The purpose of the Medical Accident Investigation System is to promote safety in medical settings, and providing safe medical care requires widespread initiatives and efforts. "Recommendations for the Prevention of Recurrence of Medical Accidents" have been compiled after examining the cases of death reported to the ISC based on the expertise of that time and in terms of patient safety. The purpose is to "avoid unexpected deaths." These recommendations should be distinguished from guidelines published by academic societies and other organizations, which are examined based on broad knowledge, and do not limit the discretion of health-care professionals or impose any obligations on them. While each medical institution differs in environment and circumstances including its size and structure, we hope that these recommendations will be widely utilized in medical institutions to avoid accidents associated with the insertion or removal of pulmonary artery catheters. Additionally, we will continue to review our recommendations to ensure that they aid clinical practice, and will remain committed to providing information that reflects actual medical settings, based on reported cases.

Finally, we would like to express our sincere gratitude to the medical institutions and bereaved families who cooperated in providing in-hospital investigation reports and offering additional information, as well as to the experts of the analysis subcommittee who analyzed the cases in detail and explored the measures to prevent recurrence, for their understanding and cooperation.

Recommendations for the Prevention of Recurrence of Medical Accidents (Number 19)

# Analysis of Deaths Related to Pulmonary Artery Catheters

Part 1

## Open-heart Surgery

**<Relevant professions>** Cardiovascular surgeon, anesthesiologist, intensive care physician, nurse engaged in open-heart surgeries, clinical engineer, etc.

**<Characteristics of the five cases of open-heart surgery>**

- Unintended advancement of the pulmonary artery (hereinafter, "PA") catheter associated with surgical manipulation resulted in pulmonary artery injury and pulmonary hemorrhage in two cases.
- The PA catheter was sewn into the suture during suturing of the heart wall in a surgery, resulting in cardiac injury upon catheter removal in three cases.

### [Review of the indication]

**Recommendation 1**

Use of the PA catheter is associated with a risk of fatal complications. It is necessary to review the indication based on the assessment of the necessity of PA catheter and associated risks, rather than uniformly applying it to all patients undergoing an open-heart surgery.

### [Prevention and management of pulmonary artery injury]

**Recommendation 2**

«Manipulations to prevent pulmonary artery injury»
The PA catheter may advance accidentally because of factors such as reduction of cardiac chamber contents after starting cardiopulmonary bypass and rotation and displacement of the heart during surgery. Prior to the start of cardiopulmonary bypass, the catheter should be pulled for about 3 to 5 cm from the vicinity of the right pulmonary artery trunk (near the hilus). Furthermore, the operator should confirm that the PA catheter tip pressure remains stable after each operational manipulation.

**Recommendation 3**

«Management of pulmonary hemorrhage»
If pulmonary hemorrhage occurs during surgery, a bronchial blocker should be inserted first to prevent blood from flowing into the contralateral lung. The application of ECMO to stabilize the hemodynamics and to reduce the amount of pulmonary bleeding, transcatheter hemostasis, or surgical treatment such as lobectomy should be considered.

### [Prevention and management of entrapment of the PA catheter in the suture]

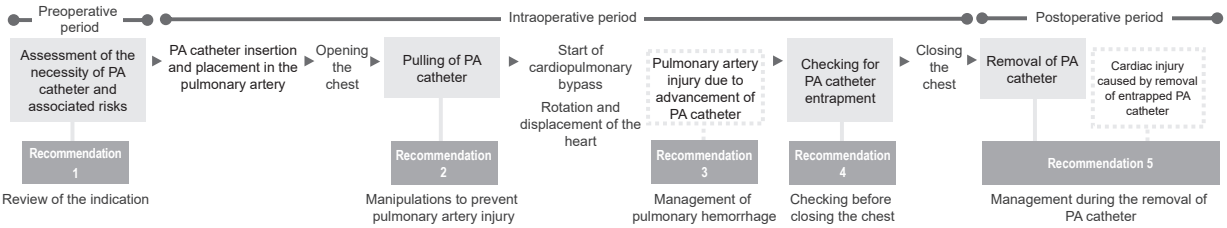
**Recommendation 4**

«Checking before closing the chest»
After suturing the surgical area and before closing the chest, the surgeon should ensure that the PA catheter is not entrapped in the suture through palpation by picking up all sutured sites with their fingers. The anesthesiologist should then confirm the mobility of the PA catheter, and the surgeon should check for contraction by visual inspection and palpation on sites where entrapment may occur.

**Recommendation 5**

«Management during the removal of PA catheter»
The PA catheter should be withdrawn slowly enough for any resistance to be felt, with attention paid to possible PA catheter entrapment in the suture. If there is even a slight resistance, catheter removal should be discontinued and a confirmation by X-ray fluoroscopy, etc., should be made. If entrapment is suspected, thoracotomy needs to be performed in the operation room to remove the catheter.

### [Workflow from the decision to insert the PA catheter through its removal with corresponding recommendations]



Part 2

# PA Catheterization

**<Relevant professions>** Cardiovascular physician, respiratory physician, intensive care physician, nurse engaged in catheterization, clinical engineer, clinical radiologist, etc.

**<Characteristics of the four target cases of PA catheterization>**

- Pulmonary artery was damaged and pulmonary hemorrhage occurred during a PA catheterization, causing respiratory symptoms such as cough and bloody sputum in four cases.
- A guidewire was used for inserting the PA catheter in three cases, and the balloon was inflated beyond its proper capacity in three cases.

## [Review of the indication]

### Recommendation 6

A PA catheterization is associated with a risk of fatal complications. Although it is indispensable for a definitive diagnosis of pulmonary hypertension and for determining the disease type, the possibility of substituting it with echocardiography should be considered in the case of preoperative examinations. Risk factors for pulmonary artery injury and fatal hemorrhage, such as advanced age, being female, blood coagulation disorder, and chronic use of steroids, should be assessed to review the indication for a PA catheterization based on the necessity and risks.

## [PA catheter insertion]

### Recommendation 7

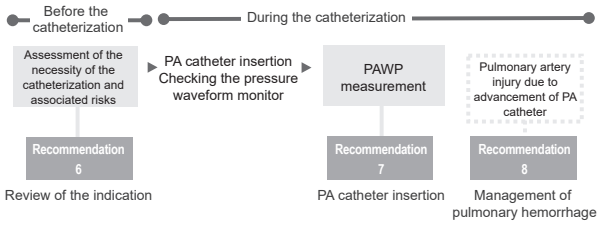
- If the balloon is repeatedly inflated and deflated within the pulmonary artery when the pulmonary artery wedge pressure (PAWP) cannot be measured, the catheter may bend and advance into the periphery. The catheter should be manipulated while observing the tip location under X-ray fluoroscopy.
- If the catheter tip strays into the periphery, the pulmonary artery may be injured even within proper capacity. Air should be injected slowly into balloon while feeling the resistance. Air should not be injected beyond the proper volume even though resistance is not felt.
- The use of a guidewire should be avoided as much as possible. If its use is imperative, the operator should ensure that the guidewire is not protruding from the PA catheter tip.
- If the PAWP cannot be measured, the use of another indicator as a substitute should be considered, rather than sticking to the PAWP measurement.

## [Management of pulmonary hemorrhage]

### Recommendation 8

If respiratory symptoms such as cough and bloody sputum are observed during the PA catheterization, pulmonary artery injury should be suspected first and the procedure must be discontinued immediately. The bleeding site should be identified with angiography, and transcatheter hemostasis or other hemostatic techniques should be attempted.

## [Judgment to perform PA catheterization and procedures with corresponding recommendations]



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# 1. Introduction

## 1) Pulmonary artery catheters

Since its first clinical use by Swan, Ganz and others[1] in 1970, pulmonary artery (PA) catheter has been widely used in patients with serious conditions such as severe heart failure, pulmonary hypertension, and shock for the purposes of diagnosis and treatment strategy determination, including hemodynamic assessment, fluid management, assessment of the response to vasoactive agents (e.g., catecholamine and vasodilators), and their dose modification.

Parameters that can be measured by the PA catheter include: (1) pulmonary artery pressure, (2) pulmonary artery wedge pressure (PAWP), (3) central venous pressure, (4) cardiac output, (5) mixed venous oxygen saturation (MVOS), and (6) right ventricular ejection fraction. These parameters are used to calculate important indicators for the assessment of hemodynamics such as pulmonary vascular resistance, systemic vascular resistance, and right ventricular volume. For many of these indicators, the catheter must be moved into the pulmonary artery in order to obtain accurate values, and it is difficult to completely replace the PA catheter with other methods. While in recent years, transesophageal echocardiography (TEE) is generally used for intraoperative management in open-heart surgeries, PA catheters are still widely used worldwide for intra- and perioperative monitoring. However, none of the multiple meta-analyses conducted to date has been successful in demonstrating the significant benefit of the PA catheter.[2] The difficulty in demonstrating its benefit may be due to the nature of the PA catheter, which is used for determining the treatment strategy, and not for providing treatment itself. Nevertheless, many healthcare providers have empirically recognized the usefulness of the PA catheter in selecting the treatment method and continue to use it.

On the other hand, various complications associated with PA catheter insertion, including pulmonary artery injury and cardiac perforation, have been reported with a considerable number of fatal cases. However, the actual status such as frequencies of complications in Japan remains unclear, and there is also a limited number of reports worldwide.[3] The Japanese Society for Cardiovascular Surgery conducted a questionnaire survey in 2019 on the current usage of the PA catheter in cardiac surgeries after a report of death from cardiac injury during the removal of a PA catheter after an open-heart surgery in Japan.[4] The survey results revealed that approximately 70% of the medical institutions were using the PA catheter in more than 90% of cardiac surgeries, showing that the PA catheter is still routinely used in open-heart surgeries in many centers. The results also showed that entrapment of the PA catheter in the suture was experienced by approximately 30% of the hospitals, and pulmonary artery injury or pulmonary hemorrhage has been observed in approximately 20% of the medical institutions. Meanwhile, the PA catheter is used not only during open-heart surgeries, but also in the catheterization laboratory and intensive care unit for purposes such as definitive diagnosis, disease type determination, and hemodynamic assessment in patients with cardiac failure.

In consideration of the different purposes of the PA catheter as well as the different situations during cannulation between an open-heart surgery and a PA catheterization, our recommendations consist of two parts: “Open-heart Surgery” and “PA Catheterization.” Each part aims to contribute to the safe use of the PA catheter over the entire process from the review of the indication and handling during cannulation through catheter removal. We hope that these recommendations will be widely used in medical institutions to avoid accidents associated with PA catheters.

## 2) Background of the establishment of the Expert Analysis Subcommittee and its significance

To prevent the recurrence of similar medical accidents, the Committee for Prevention of Recurrence (see page 44) at the Medical Accident Investigation and Support Center (hereinafter referred to as ISC) selects the subject (theme) of analysis from the cases of accidents reported to the Center. The Committee then establishes an Expert Analysis Subcommittee for each theme (see page 44) that consists of medical specialists in the theme and prepares recommendations.

PA catheters are utilized in surgeries, tests, and management of serious cases in various departments, including surgery, internal medicine, anesthesiology, and intensive care, and the procedures and manipulations differ between surgeries and catheterization. In the target open-heart surgery cases, pulmonary artery injury associated with surgical manipulations and entrapment of the PA catheter in the suture resulted in fatal cardiac injuries, while in the PA catheterization cases, fatal pulmonary artery injury occurred during cannulation of the PA catheter. For our recommendations, the Expert Analysis Subcommittee was established to analyze the fatal cases associated with PA catheters, while considering that it is important to take feasible measures in open-heart surgeries and catheterization separately.

## 3) Patient safety approaches that have been taken in relation to the recommendations

○ Committee for Joint Statement of the Japanese Society for Cardiovascular Surgery and Japanese Society of Cardiovascular Anesthesiologists
Consensus Statement on Pulmonary Artery Catheter Use during Cardiac Surgery (March 3, 2020)[5)]

# 2. Methods of analysis

## 1) Extraction of target cases

Of the 2,207 in-hospital investigation reports on medical accidents sent to the ISC (October 2015-November 2022), nine reports were regarding deaths related to PA catheters. The Expert Analysis Subcommittee included a total of nine cases in its analysis, consisting of five open-heart surgery cases and four PA catheterization cases.

## 2) Collecting and sorting of information on target cases

The Expert Analysis Subcommittee analyzed the target cases based on the information submitted in the in-hospital investigation reports notified to the ISC. Regarding some ambiguous parts of the reports, additional information was collected to the extent possible with cooperation of the reporting medical institutions. Information collected was organized according to the investigation items checklist (see Section 10 “Materials”).

## 3) Meetings of the Expert Analysis Subcommittee

○ First meeting: April 25, 2022
○ Second meeting: August 31, 2022
○ Third meeting: November 29, 2022
○ Fourth meeting: July 19, 2023

• In addition, opinions were exchanged through electronic media and other means.

# Part 1 Open-heart Surgery

<Professions relevant to the Open-heart Surgery Part>
We hope those in relevant professions will read this part:


Cardiovascular surgeon, anesthesiologist, intensive care physician


Nurse engaged in open-heart surgeries


Clinical engineer, etc.

# 3. Overview of the target cases in the Open-heart Surgery Part

The case overview was prepared by the Expert Analysis Subcommittee by organizing the information according to the following (1) to (5) based on in-hospital investigation and additional reports:

(1) Patient information, (2) process from PA catheter insertion to placement, (3) intraoperative PA catheter manipulations, (4) process after bleeding was discovered, and (5) cause of death and other information.

<Cases of pulmonary artery injury caused by unintentional advancement of the PA catheter (including presumed cases)>

## Case 1 Pulmonary artery injury

(1) The patient was a woman in her 70s with severe aortic stenosis and atrial fibrillation. Her height was 150-159 cm. Aortic valve replacement, pulmonary vein isolation, and left atrial appendage closure were performed. Antithrombotic agents were interrupted from three days before the surgery.

(2) The PA catheter was inserted from the right internal jugular vein, and was placed in the pulmonary artery at 48 cm after measuring the PAWP.

(3) After starting the cardiopulmonary bypass, the PA catheter was pulled by 2 to 3 cm. During the pulmonary vein isolation and left atrial appendage, the entire heart, including the pulmonary artery, was displaced to the right to keep the surgical field.

(4) During the withdrawal of cardiopulmonary bypass, blood was observed in the endotracheal tube. To prevent blood from flowing into the contralateral lung, an attempt was made to insert a bronchial blocker, but it was not successful because of excessive bleeding. Protamine sulfate was administered, and the bronchial blocker was inserted into the right main bronchus. As bleeding continued, right middle and lower lobectomy was performed. Circulatory failure and other conditions resulting from pulmonary hemorrhage led to myocardial wall edema, pericarditis, and mediastinitis. The patient died about one month after the surgery.

(5) Cause of death: Multiple organ failure triggered by pulmonary hemorrhage due to right pulmonary artery rupture (about 2 mm) in the hilar region of the right middle lobe. Autopsy imaging (hereinafter, “Ai”): absent. Autopsy: present.

## Case 2 Pulmonary artery injury (presumed)

(1) The patient was a woman in her 80s with aortic stenosis and atrial fibrillation. Her height was 150-159 cm. Aortic valvuloplasty and maze operation were performed. Antithrombotic agents were interrupted from the preoperative period (duration unknown).

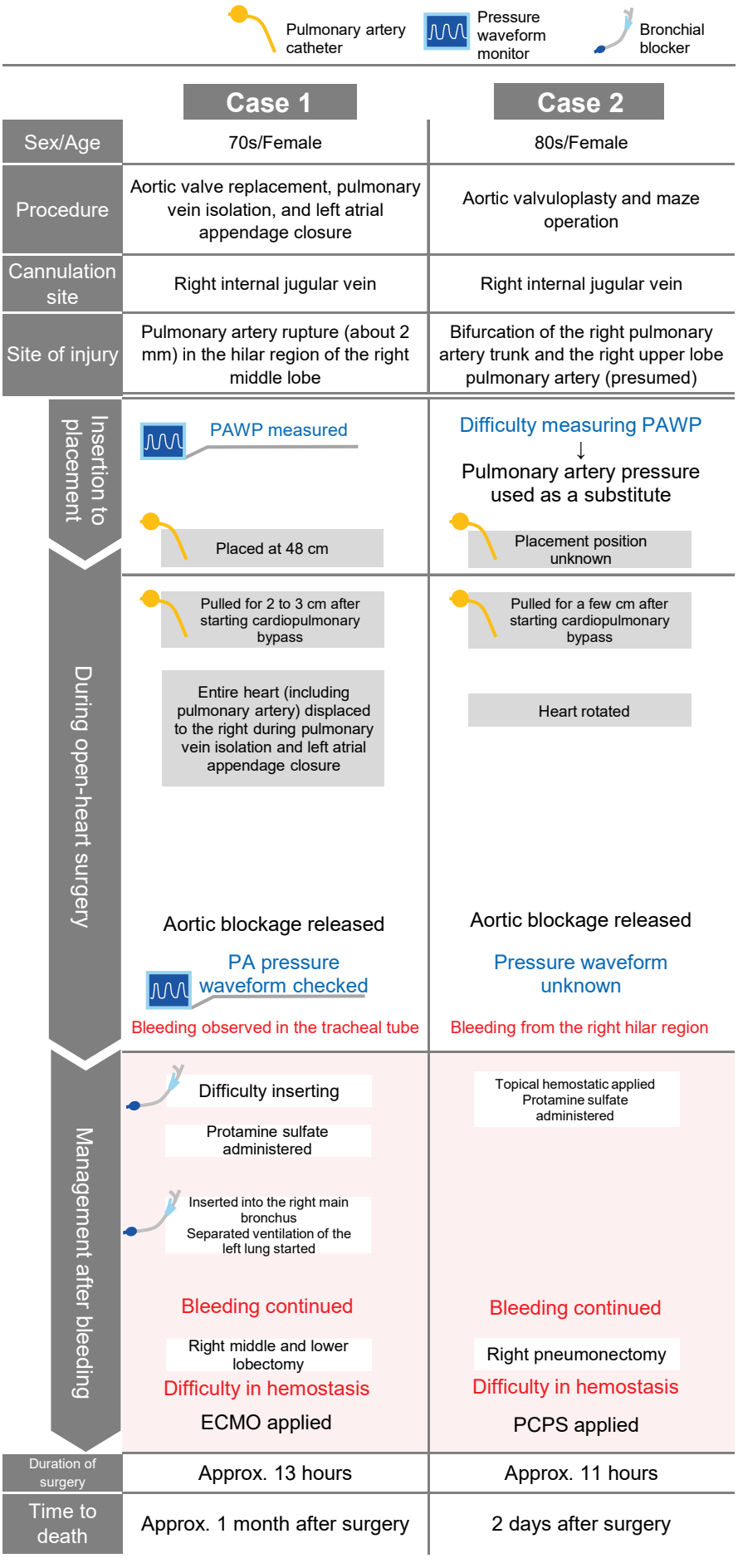
(2) The PA catheter was inserted from the right internal jugular vein. The measurement of PAWP was difficult, so the catheter tip was placed in the pulmonary artery (length unknown) and the pulmonary artery pressure was used as a substitute measurement.

(3) After starting the cardiopulmonary bypass, the PA catheter was pulled for a few centimeters (length unknown).

(4) After releasing the aortic blockage, bleeding was observed around the right hilum. Repair was attempted for a suspected pulmonary artery injury, but the bleeding site could not be identified and hemostasis was not successful. Right pneumonectomy was performed. The patient died two days after the surgery.

(5) Cause of death: Hemorrhagic shock due to injury at the bifurcation of the right pulmonary artery trunk and the right upper lobe pulmonary artery (presumed). Ai: present. Autopsy: present (the bleeding point was not identified because suturing was performed multiple times for hemostasis during bleeding).

Figure 1　Details of the target cases (cases of pulmonary artery injury during surgery)



The case overview was prepared by the Expert Analysis Subcommittee by organizing the information according to the following (1) to (5) based on in-hospital investigation and additional reports:

(1) Patient information, (2) process from PA catheter insertion to placement, (3) intraoperative manipulations, (4) process after catheter removal, and (5) cause of death and other information.

<Cases of entrapment of the PA catheter in the suture>

## Case 3 Entrapment of the PA catheter in the suture

(1) The patient was a woman in her 70s with mitral valve incompetence and angina pectoris. Her height was 150-159 cm. Mitral valve repair and coronary artery bypass surgery were performed. Antithrombotic agents were interrupted from three days before the surgery.

(2) The PA catheter was inserted from the right internal jugular vein and placed.

(3) During the surgery, the cannulation site of the inferior vena cava, incision site of the right atrium, and cannulation site of the superior vena cava were sutured. Before closing the chest, the surgeon checked for entrapment in the suture by palpation of the cannulation site of the superior vena cava.

(4) During the removal of the PA catheter in the intensive care unit on Day 2 after surgery, resistance was felt when the PA catheter was pulled for about 20 cm and the patient complained of chest pain. The procedure was discontinued. Immediately after that, an extensive amount of dark red blood came out of the thoracic, pericardial, and anterior mediastinal drainage tubes, and the blood pressure dropped. In the emergency thoracotomy for hemostasis, a right atrial wall defect was found at the presumed cannulation site of the inferior vena cava and was closed by suturing. However, spontaneous heart rate could not be restored after the operation. The patient died on the same day.

(5) Cause of death: Hemorrhagic shock due to a right atrial wall injury. Ai: absent. Autopsy: absent.

## Case 4 Entrapment of the PA catheter in the suture

(1) The patient was a man in his 70s with mitral valve incompetence and pulmonary hypertension. His height was 160-169 cm. Mitral valve repair and tricuspid valvuloplasty were performed. The patient was not using any antithrombotic agents.

(2) The PA catheter was inserted from the right internal jugular vein and placed.

(3) During the surgery, the cannulation site of the inferior vena cava, incision site of the right-side left atrium, incision site of the right atrium, vent cannulation site of the left atrium and the left ventricle, and cannulation site of the superior vena cava were sutured. During an incision of the Waterston's groove, the right atrial side was damaged and was sutured. It was difficult to check the site by visual inspection, so the surgeon checked for entrapment of the PA catheter in the suture by palpation. To check for entrapment in the suture before closing the chest, the anesthesiologist moved the PA catheter for 2 to 3 cm, and the surgeon confirmed the mobility of the PA catheter, as well as the absence of contraction on the sutured parts of the superior vena cava cannulation site and the right atrial wall.

(4) Immediately after the removal of the PA catheter in the intensive care unit on Day 1 after surgery, the artery blood pressure dropped and the drainage fluid increased. In the emergency thoracotomy for hemostasis, an injury of the Waterston's groove was found and closed by suturing. After surgery, the patient did not recover from serious cerebral ischemic injury and died about two weeks later.

(5) Cause of death: Multiple organ failure triggered by hemorrhagic shock due to right atrial wall injury. Ai: absent. Autopsy: present.

## Case 5 Entrapment of the PA catheter in the suture

(1) The patient was a woman in her 60s with aortic stenosis. Her height was 150-159 cm. Aortic valve replacement was performed. The patient was not using antithrombotic agents.

(2) An attempt was made to insert the PA catheter from the right internal jugular vein, but the PA catheter could not reach the pulmonary artery. The surgery was started with the PA catheter remaining in the right atrium.

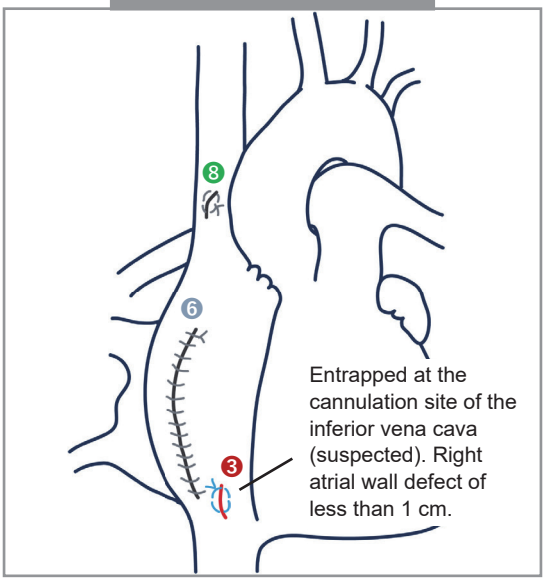
(3) During surgery, the cannulation site of the inferior vena cava, retrograde cardioplegia cannulation site, vent cannulation sites of the left atrium and the left ventricle, and cannulation site of the superior vena cava were sutured. After valve replacement, insertion of the PA catheter was attempted again in the surgical field. However, the catheter tip was not seen within the pulmonary artery by TEE, and the chest was closed (checking for entrapment in the suture was not performed).

(4) X-ray fluoroscopy after closing the chest revealed bending of the PA catheter in the right atrium. When the PA catheter was pulled slowly for about 10 cm, an extensive amount of blood came out of the pericardial and anterior mediastinal drainage tubes. In the emergency thoracotomy for hemostasis, an injury starting from the vicinity of the right atrial appendage to the area near the inferior vena cava was found and closed by suturing. As resistance was noticed when trying to remove the whole PA catheter, the superior vena cava was incised. Tissue fragments and sutures were found about 5 cm away from the PA catheter tip, showing that the PA catheter had been entrapped in the suture. After surgery, the patient did not recover from cerebral hypoxia and multiple organ failure and died about four months after surgery.

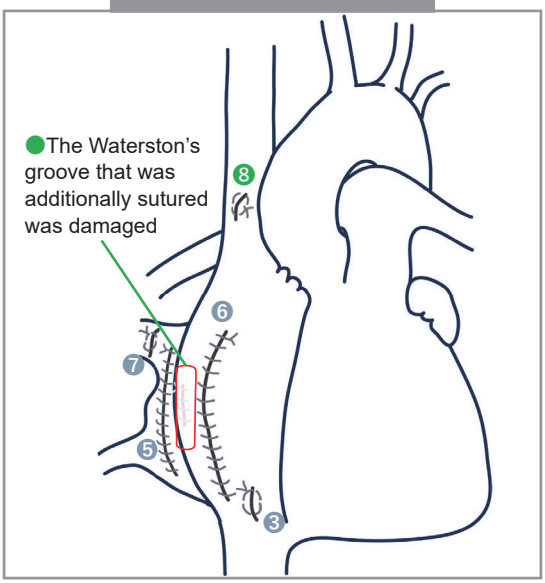
(5) Cause of death: Multiple organ failure triggered by hemorrhagic shock due to a right atrial wall injury. Ai: absent. Autopsy: present.

Figure 2　Cases of entrapment of the PA catheter in the suture

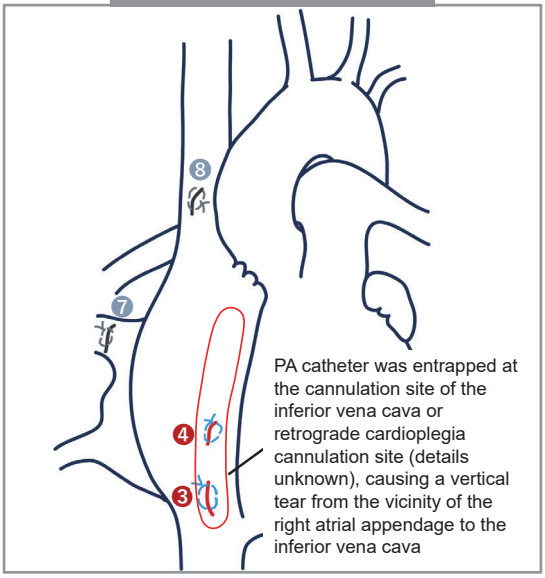
Case 3



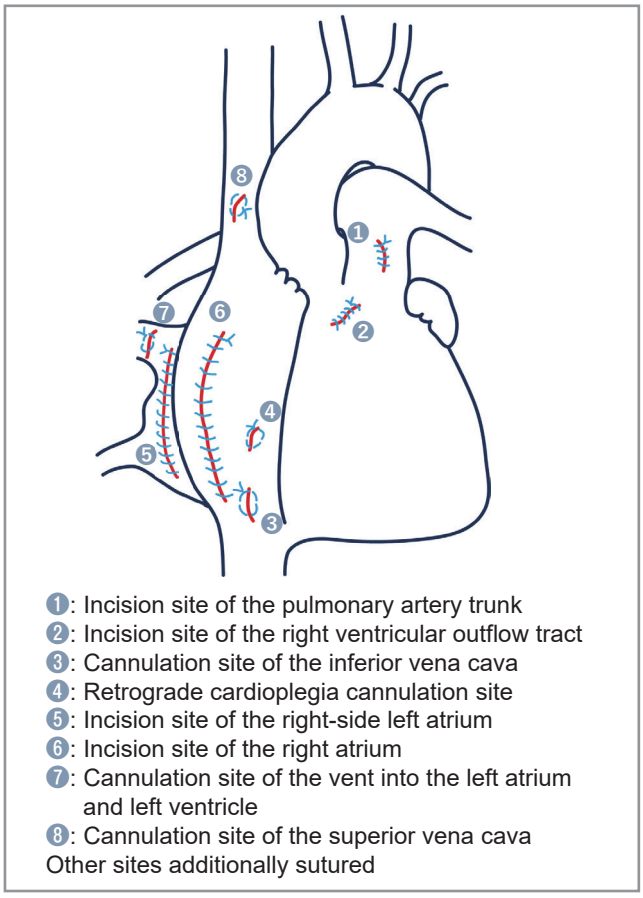

Case 4




Case 5




(Ref.) Sites of predilection for PA catheter entrapment




●: Sites checked for PA catheter entrapment

●: Injured sites

# 4. Recommendations and explanations to prevent recurrence in the Open-heart Surgery Part

## [Review of the indication]

**Recommendation 1**

Use of the PA catheter is associated with a risk of fatal complications. It is necessary to review the indication based on the assessment of the necessity of PA catheter and associated risks, rather than uniformly applying it to all patients undergoing an open-heart surgery.

### Risk of fatal complications associated with the use of PA catheter during open-heart surgery

It is important to obtain real-time accurate hemodynamics and to normalize it promptly in the perioperative management for open-heart surgery. Among various monitoring methods used to obtain hemodynamics, the PA catheter provides important information for normalization of hemodynamics, including pulmonary artery pressure, PAWP, central venous pressure, cardiac output, mixed venous oxygen saturation (hereinafter, "$SvO_2$"), and right ventricular ejection fraction. It is considered beneficial in open-heart surgery especially for severe heart failure and reduced cardiac function. However, pulmonary arteries consist of a loose distribution of smooth muscle and elastic fibers compared to the arteries of systemic circulation,[6] and the vascular wall is thin at about 1 mm, which causes a risk of pulmonary artery injury by the PA catheter during surgery (see Recommendations 2 and 3). There is also a risk of fatal complications, including cardiac injury caused by extracting the PA catheter entrapped in the suture (see Recommendations 4 and 5).

The five target cases of open-heart surgery consisted of two cases of pulmonary artery injury caused by the PA catheter during surgery and three cases of right atrial injury resulting from entrapment in the suture in the heart wall and subsequent removal of the PA catheter. It is essential to review the indication for PA catheter insertion in consideration of the possible fatal complications.

### Review of the indication of the PA catheter for each patient

According to the questionnaire survey conducted by the Japanese Society for Cardiovascular Surgery in 2019, 72% of the medical institutions responded that they were using PA catheters in more than 90% of cardiac surgeries,[4] showing that PA catheters are used in many hospitals (see Column 1).

At the medical institutions related to the five cases of open-heart surgery, PA catheters were being inserted in open-heart surgeries in all patients or in all patients except those with acute aortic dissection.

Currently, there are no guidelines or equivalent documents that provide the criteria for the indication of PA catheters in an open-heart surgery.

However, it is not desirable to use the PA catheter uniformly in all patients undergoing an open-heart surgery because insertion of the PA catheter is associated with a risk of fatal complications such as pulmonary artery injury during the insertion, as well as cardiac injury caused by removal of the catheter sewn in the suture. The necessity of the PA catheter should be reviewed for each patient based on factors such as planned procedure, expected duration of cardiac arrest, left ventricular function, right ventricular function, and status and severity of pulmonary hypertension and cardiac failure.

The review of the indication of PA catheters needs to include the risk of a pulmonary artery injury. Of the five cases of open-heart surgery, two cases of pulmonary hemorrhage occurred in female patients aged 70 years or older with a height of 150-159 cm who were taking antithrombotic agent(s). Risk factors for pulmonary artery injury and fatal hemorrhage include advanced age, being female, pulmonary hypertension, use of antithrombotic agents, and chronic use of steroids.[7][8]

Before using the PA catheter, its necessity and the risk of pulmonary artery injury and fatal hemorrhage should be assessed and the indication reviewed for each patient during the preoperative conference or other situations.

## Sharing the information on the necessity and risks of PA catheter insertion with patients and their families

Sharing the information on the necessity and risks of PA catheter insertion with the patient and their family before surgery is significant when the use of the PA catheter is deemed necessary. Currently, preoperative information for patients usually includes details such as the procedure, anesthesia, blood transfusion, and central venous catheterization, and not the necessity and risks of PA catheter insertion.

In the five target cases of open-heart surgery, information on fatal complications such as pulmonary artery injury and cardiac injury associated with PA catheter insertion was not provided to the patients and their families. PA catheter insertion is associated with a risk of fatal complications such as pulmonary artery injury and cardiac injury, which may occur accidentally despite caution and confirmation by the operator.

Prior to the surgery, the physician should explain the necessity of PA catheter insertion and the risk of pulmonary artery injury and fatal hemorrhage using simple terms that are readily understood by the patient and their family to share the information with them (see Table 1).

Table 1 Example of preoperative information for patients on PA catheter

During the preoperative consultation before an open-heart surgery, it is important to share the information on the possibility of pulmonary artery injury and cardiac injury occurring as fatal complications when using the device during the operation, in addition to the risks of serious arrhythmia, cardiac valve damage, and infection and thrombosis associated with catheter placement, with patients and their families. Please refer to the following information.

(1) Pulmonary artery injury caused by accidental dislocation (advancement) of the PA catheter during surgery

Pulmonary artery injury by the PA catheter is a rare event with an incidence of 0.016% to 0.2%; however, it is a significant complication with a mortality of 50% or higher.[9] During surgery, the location of the catheter tip is adjusted so that the PA catheter does not damage the pulmonary artery, but the PA catheter may accidentally move (advance) and damage the blood vessel.

(2) Cardiac injury caused by removing the PA catheter entrapped in the suture in the heart wall

Before closing the chest, the operator should check to see that the PA catheter is not entrapped in the suture in the heart wall or blood vessels that have been sutured. However, if the PA catheter is entrapped in the suture, it may be difficult to detect it depending on the extent and site of the entrapment. When the PA catheter is removed, it should be pulled out while paying attention to possible entrapment and observing the patient's condition. When the PA catheter is removed in the ward, speak to the patient during removal. If possible entrapment of the PA catheter in the suture is suspected, open the thorax under general anesthesia in the operation room and remove the PA catheter.

## Consideration of the use of a substitute monitoring device

If PA catheter insertion is considered to be of little necessity after reviewing the indication, PA catheter insertion should be avoided and the use of a substitute monitoring device should be considered.

In the five target cases of open-heart surgery, the use of a substitute monitoring device was not considered because the PA catheter was being inserted in all cases of open-heart surgery.

For example, cardiac output may be measured by the instrument for percutaneous arterial oxygen saturation (hereinafter, "$SpO_2$") or may be substituted by continuous monitoring of the arterial pressure-based cardiac output (hereinafter, "APCO") with direct arterial sphygmomanometry. However, APCO measurements may deviate from the values obtained by PA catheter in patients with aortic valve insufficiency, patients using intra-aortic balloon pumping (IABP), or patients with severe arrhythmia, sepsis, or hepatic cirrhosis whose vascular resistance is significantly altered.

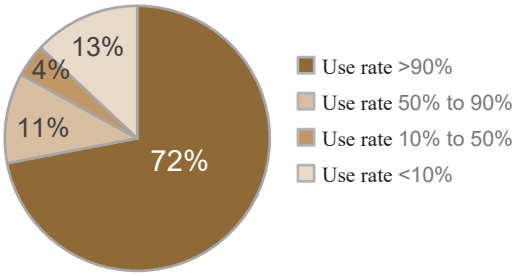
$SvO_2$, an indicator of oxygen supply-demand balance, can be substituted by central venous oxygen saturation (hereinafter, "$ScvO_2$") that is continuously monitored by an oximetry catheter (i.e., central venous catheter with an oxygen saturation sensor attached at the tip). However, since $SvO_2$ and $ScvO_2$ are not always consistent depending on the patient's condition and the position of the central venous catheter, it is important to make comprehensive judgement based on the absolute values and the changes over time in conjunction with other indicators.[11]

Measurements by the monitoring devices currently used as a substitute may deviate from the values obtained by the PA catheters depending on the patient's condition, and they require comprehensive judgment in conjunction with multiple indicators. Therefore, it is necessary to conduct research and development of non-invasive monitoring devices that can provide information equivalent to those obtained by the PA catheters in the future.

### Column 1: Frequency of PA catheter use during open-heart surgeries -from the questionnaire survey by the Japanese Society for Cardiovascular Surgery-

According to the questionnaire survey conducted in Japan by the Japanese Society for Cardiovascular Surgery in 2019, approximately 70% of the medical institutions responded that they were using the PA catheter in more than 90% of cardiac surgeries while only approximately 10% of the medical institutions were using the PA catheter in less than 10% of cardiac surgeries.[4] A questionnaire survey conducted mainly in Europe and the U.S. in 2015 also reported that approximately 70% of the medical institutions were using the PA catheter in more than 75% of cardiac surgeries.[12] Although transesophageal echocardiography (TEE) and non-invasive monitors, including extracorporeal continuous cardiac output monitor, are now generally used, the PA catheter is still widely used for perioperative monitoring in open-heart surgeries.

PA catheter use rate in cardiac surgeries at each medical institution[4]



## [Prevention and management of pulmonary artery injury]

**Recommendation 2**

«Manipulations to prevent pulmonary artery injury»
The PA catheter may advance accidentally because of factors such as reduction of cardiac chamber contents after starting cardiopulmonary bypass and rotation and displacement of the heart during surgery. Prior to the start of cardiopulmonary bypass, the catheter should be pulled for about 3 to 5 cm from the vicinity of the right pulmonary artery trunk (near the hilus). Furthermore, the operator should confirm that the PA catheter tip pressure remains stable after each operational manipulation.

### Location of the PA catheter placement after PAWP measurement

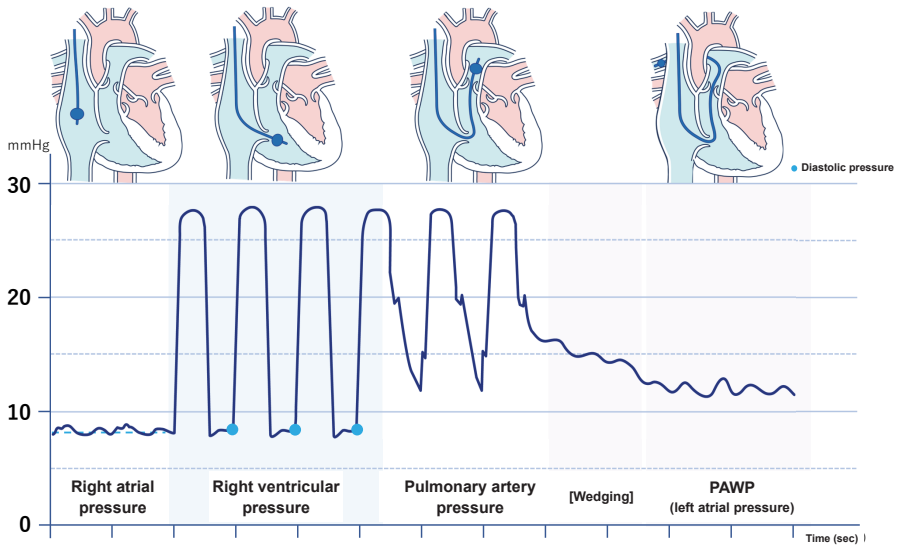
During surgery, the right atrial pressure, right ventricular pressure, and pulmonary artery pressure are determined in that order following the insertion of the PA catheter. The PA catheter moves in an arc shape from the right atrium through the right ventricle to the pulmonary artery, and often advances into the right pulmonary artery physiologically because of the blood flow ratio (right : left = 3 : 2). As it proceeds like an arc, the PA catheter strays into the right middle and lower lobe pulmonary artery branches in most cases and rarely enters the right upper lobe pulmonary artery. Therefore, pulmonary artery injury often occurs at the right middle and lower lobe pulmonary artery.

Pulmonary hemorrhage occurred in two of the five target cases of open-heart surgery. In one of these two cases, a vascular injury was presumed to have occurred at the bifurcation of the right pulmonary artery trunk and the right upper lobe pulmonary artery, and in the other case, the PA catheter strayed into the right middle lobe pulmonary artery, leading to pulmonary artery injury.

During PA catheter insertion, the position of the PA catheter tip should be monitored by TEE or other means, in addition to pressure waveform monitoring (see Figure 3). Following PAWP measurement, deflate the balloon, and pull the PA catheter for about 3 cm and place it in the vicinity of right pulmonary artery trunk (around the hilum).[5)]

A rapid elevation shown by the pressure monitor during the placement can indicate that the PA catheter has come into contact with the vascular wall, and pulmonary artery pressure measured at a deeper position than predicted from the body build and height may be an indication of the PA catheter bending within the pulmonary artery. It is therefore essential to confirm the location of the PA catheter tip and the absence of bending by methods such as pressure waveform monitoring and TEE. If such confirmation is not possible, the PA catheter should be pulled for 1 to 2 cm to confirm its mobility (see Column 2).

Figure 3　PA catheter tip location and pressure waveform



## Optimal location of catheter placement to prevent pulmonary artery injury due to dislocation (advancement) of the PA catheter

### <Unintended dislocation (advancement) of the PA catheter after the start of cardiopulmonary bypass>

In the two target cases of pulmonary hemorrhage, the PA catheter was pulled for a few cm or 2 to 3 cm after starting the cardiopulmonary bypass. Once the cardiopulmonary bypass starts, the cardiac cavity volume decreases as blood moves out of the body. As a result, the PA catheter may be drawn into a peripheral pulmonary artery, resulting in unintended advancement. Thus, the anesthesiologist should place the PA catheter after pulling it about 3 cm from the vicinity of the right pulmonary artery trunk (near the hilus) before starting the cardiopulmonary bypass.[5)]

### <Unintended dislocation (advancement) of the PA catheter due to rotation or displacement of the heart>

During surgery, rotation and displacement of the heart may cause dislocation (advancement) of the PA catheter. Therefore, it is advisable to pull the PA catheter for 1 to 2 cm, in addition to the 3 cm or so pulled before starting the cardiopulmonary bypass.

Of the two target cases of pulmonary hemorrhage, rotation of the heart was performed during surgery in one case, and the entire heart (including the pulmonary artery) was displaced to the right to keep the surgical area for pulmonary vein isolation, and during left atrial appendage closure in the other case.

In the cases where rotation or displacement of the heart is required, it is advised to pull the PA catheter for 4 to 5 cm[5)] from the vicinity of the right pulmonary artery trunk (near the hilus) before the start of the cardiopulmonary bypass in consideration of possible dislocation (advancement) of the PA catheter. The anesthesiologist should determine the length to pull the PA catheter, keeping in mind that 5 cm is not sufficient in some cases.

## Minimize the manipulations to inflate the balloon and/or to move the PA catheter during surgery

After starting the cardiopulmonary bypass, manipulations to move the PA catheter should be avoided as much as possible because confirmation of the PA catheter tip position by pressure waveform monitor or TEE can be difficult as the cardiac cavity volume decreases and also because bleeding is not controllable owing to the use of heparin sodium.

Vascular injury caused by the PA catheter may also occur at sites where the tissue is thin and weak such as those in the right atrium and directly below the pulmonary artery valve, as well as peripheral pulmonary artery sites. Inflating the balloon or advancing or pulling the PA catheter while the PA catheter tip position cannot be determined during surgery is associated with a risk of vascular injury. For that reason, the number of manipulations to move the PA catheter during surgery should be minimized.

The PA catheter tip pressure during cardiopulmonary bypass is typically displayed as minus to 0 mmHg. An increase in the pressure may suggest that the catheter is wedged into a peripheral pulmonary artery. In that case, the PA catheter needs to be pulled slowly for 2 to 3 cm. Therefore, the pressure waveform monitor should be observed continuously during the cardiopulmonary bypass.

The anesthesiologist should record the length pulled of the PA catheter from the vicinity of the right pulmonary artery trunk (near the hilus) before placement in the operative note or anesthesia chart so that the length of advancement can be determined in the case of unintended advancement of the PA catheter during surgery.

Since currently marketed PA catheters are marked at 10 cm increments, manipulations at the centimeter scale requires visual estimation to determine the position. We hope that PA catheters will be modified to have finer markings, at least over the length from 40 to 60 cm, where confirmation at the centimeter scale is required.

## Column 2: Considerations in placing the PA catheter

● Abnormal waveform on pressure waveform monitor

Any sudden elevation of the pressure waveform during PA catheter placement may suggest that the PA catheter is wedged into a peripheral pulmonary artery or the PA catheter tip has come into contact with a hollow or bifurcation of the pulmonary artery. In that case, pull the PA catheter slowly for 1 to 2 cm without inflating the balloon and check the pressure waveform monitor to see whether it displays the pulmonary artery pressure.

● Length at which the PA catheter is placed (in the case of the right jugular)

The length at which the PA catheter is inserted to a position close to the junction of the right atrium and the superior and inferior vena cava is generally 15 to 20 cm from the jugular vein in typical adults. In contrast, the length at which the PA catheter is wedged into a peripheral pulmonary artery varies widely from 38 to 60 cm[13] among individuals. According to the report by Walz, et al., the optimal insertion length for the PA catheter from the right internal jugular vein to the vicinity of the right pulmonary artery trunk (near the hilum) for a person with a height of 150 cm is calculated to be about 40 cm.[14]

PA catheter insertion depth: Height (cm) ÷ 2.35 − 23.5

Approximate PA catheter insertion lengths versus body height

| Height (cm) | 145 | 150 | 155 | 160 | 165 | 170 |
|---|---|---|---|---|---|---|
| Insertion length (cm) | 38 | 40 | 42 | 45 | 47 | 49 |

## [Prevention and management of pulmonary artery injury]

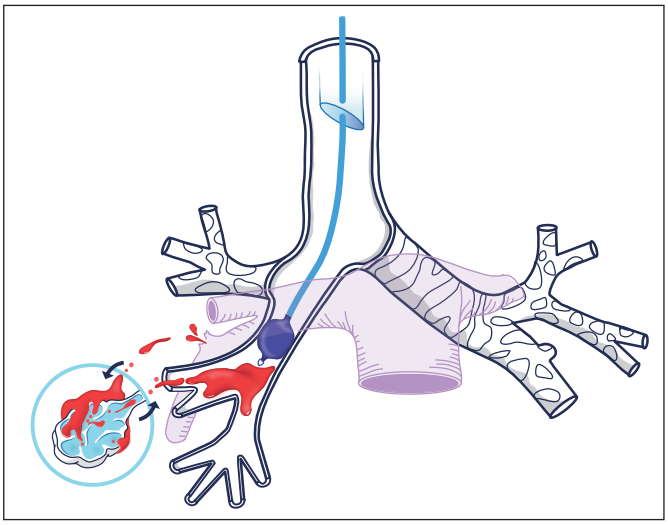
**Recommendation 3**

«Management of pulmonary hemorrhage»
If pulmonary hemorrhage occurs during surgery, a bronchial blocker should be inserted first to prevent blood from flowing into the contralateral lung. The application of ECMO to stabilize the hemodynamics and to reduce the amount of pulmonary bleeding, transcatheter hemostasis, or surgical treatment such as lobectomy should be considered.

### Insertion of a bronchial blocker to prevent blood from flowing into the contralateral lung

The possibility of pulmonary artery injury caused by some manipulation should be suspected if there is extensive bleeding through the tracheal tube during surgery. The amount of pulmonary bleeding decreases during cardiopulmonary bypass but increases after weaning of the cardiopulmonary bypass. It is therefore important to identify the bleeding segment using a bronchoscope during cardiopulmonary bypass and insert a bronchial blocker from the tracheal tube toward the bleeding segment to prevent blood from flowing into the contralateral lung (see Figure 4).

Figure 4 Rough sketch of a bronchial blocker inserted during pulmonary bleeding



### Management of pulmonary hemorrhage

Pulmonary artery injury by the PA catheter is a rare event with an incidence of 0.016% to 0.2%; however, its mortality is 50% or higher[9] because the bleeding is extremely difficult to stop. In the two target cases of pulmonary hemorrhage, the bleeding point could not be identified during surgery and the patients died after right lobectomy.

Currently, there are no standard hemostatic methods or guidelines for pulmonary hemorrhage, and various methods are used for the treatment.

First, after weaning of the cardiopulmonary bypass, protamine sulfate is administered intravenously to neutralize the heparin sodium used with cardiopulmonary bypass. Hemostatic methods include coil embolization, sterile absorbable gelatin sponge, and transcatheter hemostasis using a vascular embolization plug, etc. In a reported case,[15] after the application of ECMO, gradual decrease in pulmonary hemorrhage led to improvement in hemodynamics and oxygenation, and the patient was eventually cured by transcatheter hemostasis. In some cases, surgical treatments such as lobectomy[16] or angioplasty that are more invasive than endovascular treatments have to be selected. Treatment methods should be considered according to the patient's condition.

Pulmonary artery injury is associated with a sudden exacerbation of hemodynamics and a high mortality. Each medical institution is advised to discuss in advance how to manage pulmonary hemorrhage based on the hospital facilities and equipment. It is also advisable to cooperate in advance with related departments that can collaborate, such as cardiovascular surgery, anesthesiology, respiratory surgery, and radiology (especially the IVR physician) in the hospital, so that prompt intervention can be made.

## [Prevention and management of entrapment of the PA catheter in the suture]

**Recommendation 4**

«Checking before closing the chest»
After suturing the surgical area and before closing the chest, the surgeon should ensure that the PA catheter is not entrapped in the suture through palpation by picking up all sutured sites with their fingers. The anesthesiologist should then confirm the mobility of the PA catheter, and the surgeon should check for contraction by visual inspection and palpation on sites where entrapment may occur.

### Sutured sites where the PA catheter may be entrapped

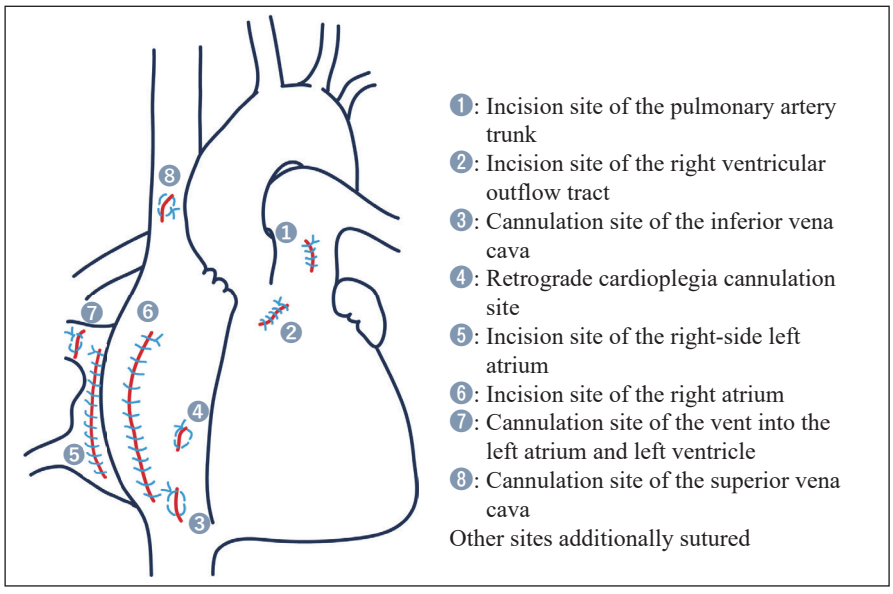
If suturing has been performed for purse-string suturing after cannulation or closing of the atrial incision line during open-heart surgery, there is a possibility that the string involves or passes through the PA catheter.[5)]

Entrapment can occur in the following: ① suturing of the pulmonary artery trunk incision line, ② incision site of the right ventricular outflow tract: aortic root surgery or suturing of the right ventricular outflow tract incision line, ③ purse-string suturing at the inferior vena cava cannulation site, ④ purse-string suturing at the retrograde cardioplegia cannulation site, ⑤ suturing of the right-side left atrial incision line, ⑥ suturing of the right atrial incision line, ⑦ purse-string suturing at the left atrial and left ventricle vent cannulation site, and ⑧ purse-string suturing at the superior vena cava cannulation site (see Figure 5).

PA catheter entrapment in the suture in the heart wall occurred in three of the five target open-heart surgery cases.

The most frequent site of entrapment is the site of additional suturing for bleeding from the cannulation of the inferior vena cava as shown in ③, followed by ① pulmonary artery trunk incision site and ⑧ superior vena cava cannulation site. Entrapment may also occur at the ② right ventricle wall, ⑥ right atrial wall, and ⑤ left atrial wall. Cases have also been reported in which the string for ⑦ cannulation site of the vent into the left atrium and left ventricle passed through the PA catheter in the right atrium.[5)]

Figure 5 Sites where entrapment of the PA catheter is likely to occur




1: Incision site of the pulmonary artery trunk
2: Incision site of the right ventricular outflow tract
3: Cannulation site of the inferior vena cava
4: Retrograde cardioplegia cannulation site
5: Incision site of the right-side left atrium
6: Incision site of the right atrium
7: Cannulation site of the vent into the left atrium and left ventricle
8: Cannulation site of the superior vena cava
Other sites additionally sutured

The PA catheter was entrapped at the cannulation site of the inferior vena cava in two of the three target cases of entrapment.

When closing the incision line on the right atrium, etc., suturing should be performed while making sure that the PA catheter does not come close to the sutured site by visual inspection and palpation. When the purse-string suturing or other suturing patterns are applied from the outer surface, it is difficult to visualize the site, and the passing of the needle through the PA catheter may not be perceived tactually because the PA catheter becomes softer when it is warmed up by body temperature compared to when it is palpated outside the body.[5)] It is therefore important to keep in mind that entrapment of the PA catheter in the suture may occur at any site where suturing is performed.

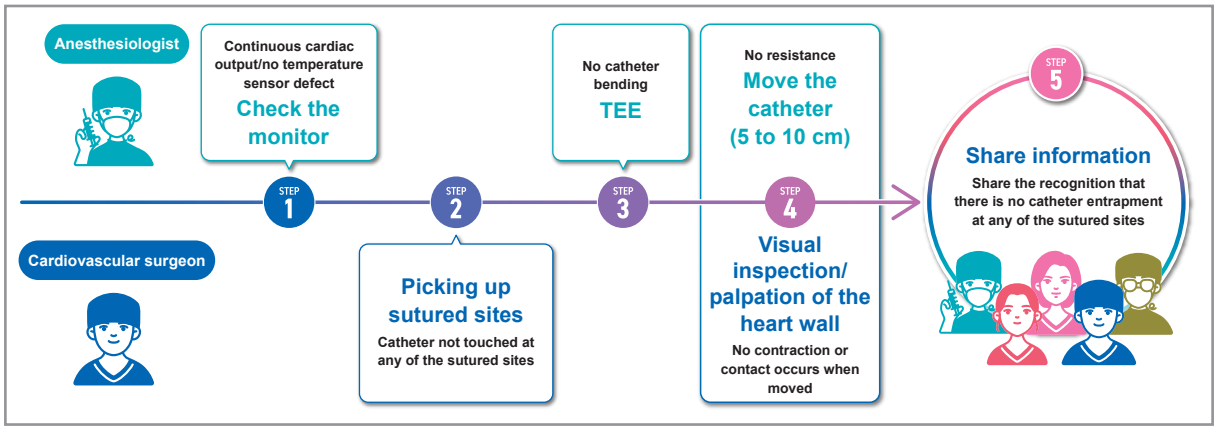
## How to check for PA catheter entrapment in the suture

The risk of overlooking the entrapment of a PA catheter in the suture can be reduced by checking all sites where suturing has been performed.

Entrapment was considered to have been checked before closing the chest in two of the three cases, but no visual inspection and/or palpation was conducted at all sutured sites in any of the cases (see Figure 2).

Checking for PA catheter entrapment in the suture should be performed after removing the cannulae used for cardiopulmonary bypass and completing the hemostatic procedure for the surgical field and before closing the chest, and the surgeon and the anesthesiologist should check all sutured sites (see Figure 6). Joint checking by the surgeon and the anesthesiologist enables systematic inspection for entrapment. Medical institutions are encouraged to clarify these procedures for checking for entrapment and to establish the rules.

Figure 6 Procedures for checking for PA catheter entrapment in the suture before closing the chest




### Procedure 1: The anesthesiologist checks the pressure waveform monitor for abnormal values and sensor defectiveness.

First, the anesthesiologist confirms that the pressure waveform monitor displays the pulmonary artery pressure waveform. If the needle went through the PA catheter while suturing, the pressure waveform monitor may display abnormal continuous cardiac output values and the tip temperature sensor may be defective.[5] However, the pressure waveform monitor may fail to show the abnormality when the needle string only slightly entraps the PA catheter or goes along the outer surface of the PA catheter. It is therefore essential to check for entrapment in the suture by visual inspection and palpation. Although the pressure waveform monitor is used as a supplemental method, the anesthesiologist should check the pressure waveform monitor for abnormal values or sensor defectiveness first.

### Procedure 2: The surgeon checks for entrapment in the suture by palpation by picking up all sutured sites with their fingers.

After the anesthesiologist checks the pressure waveform monitor for abnormalities, the surgeon should perform palpation of the PA catheter pathway, including the right side of the heart and the neighboring left atrium and pulmonary vein, as well as all sutured sites.

In the two cases where checking for entrapment in the suture was performed before closing the chest, sites other than the entrapped position were checked or the entrapped site was checked by palpation alone.

At sites where tissues overlap with each other such as ⑤ right-side left atrial incision site in Figure 5, checking can be difficult even when the part is picked up. It is important for the surgeon to use their fingers to pick up the tissues where the string is threaded and see if the PA catheter is palpable in it.[5]

## Procedure 3: The anesthesiologist confirms using TEE that the PA catheter is not deflected.

After the surgeon has performed checking by picking up all sutured sites, the anesthesiologist should observe the track of PA catheter with TEE to confirm that the catheter is not deflected. There is a report that pulling the PA catheter for 5 to 10 cm is sufficient for checking for entrapment;[17] however, if the PA catheter is deflected within the right atrium or the right ventricle, pulling the PA catheter for 5 to 10 cm may not be sufficient to rule out entrapment.[18] It is therefore advised to use TEE for confirmation before the surgeon and the anesthesiologist jointly check for entrapment in the suture as described in Procedure 4.

## Procedure 4: The surgeon and the anesthesiologist jointly checks for entrapment in the suture.

Basically, checking for PA catheter entrapment in the suture is a collaborative process by the surgeon and the anesthesiologist.

The anesthesiologist should confirm with TEE that the PA catheter is not deflected, move the PA catheter for 5 to 10 cm to ensure that there is no resistance, and confirm with TEE that the superior and inferior vena cava or the right atrial wall is not tightened or dragged. During this time, the surgeon should perform visual inspection and palpation to see that there is no contraction at all sutured sites. However, since visual inspection may be difficult at sites where tissues overlap with each other such as ⑤ right-side left atrial incision site in Figure 5, it is essential to check for resistance when moving the PA catheter or for contraction by palpation. In the case of entrapment in the suture in the inferior vena cava or right atrial wall, straining of the heart wall is observed with TEE. However, this should be used as a supplementary method because it is difficult to detect entrapment in the suture at the superior vena cava or right ventricular wall using TEE for anatomical reasons.

These procedures for checking for entrapment in the suture should be taken not only when the surgeon suspects the possibility of catheter entrapment, but for all sutured sites, including the right heart and the neighboring left atrium and pulmonary vein.[5]

## Procedure 5: Share the information concerning the check for PA catheter entrapment in the suture.

Before closing the chest, the surgeon is encouraged to share information with the staff involved in the surgery by saying out loud that all sutured sites have been checked for entrapment.

In addition, since the PA catheter removal may be performed by someone other than the surgeon, the anesthesiologist and scrub nurse are advised to document the checks for entrapment in the suture and to hand it over to the postoperative team.

## Actions to take when entrapment of the PA catheter in the suture is recognized

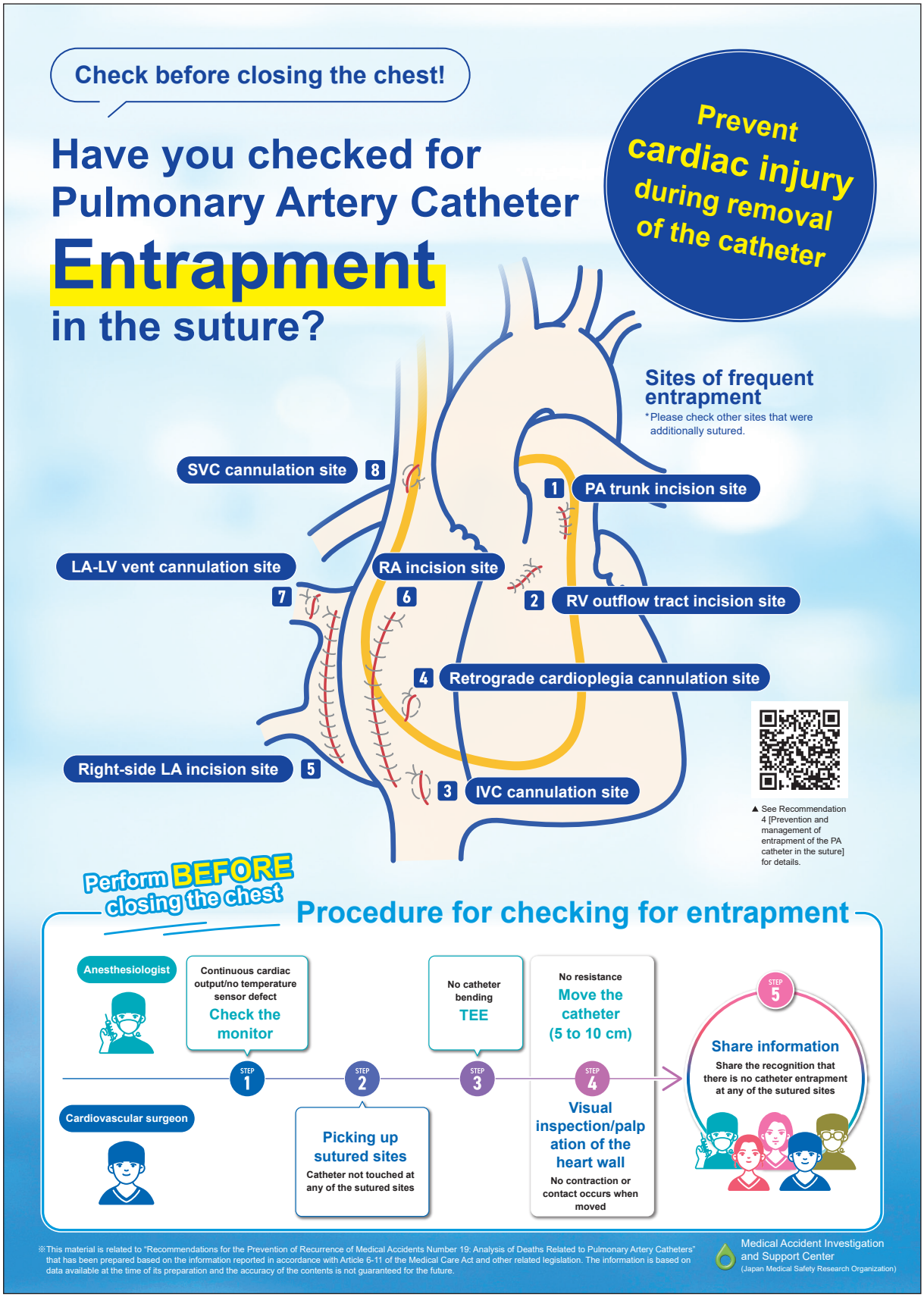
When a resistance is felt upon checking the mobility of the PA catheter or when entrapment in the suture is suspected, the site of entrapment should be identified immediately by TEE, visual inspection, and/or palpation.

If the entrapment is due to purse-string suturing at the ③ inferior vena cava cannulation site, ④ retrograde cardioplegia cannulation site, ⑦ left atrial and left ventricle vent cannulation site, or ⑧ superior vena cava cannulation site shown in Figure 5, another purse-string suturing should be applied so that it goes around outside the sutures, the causative suture should be cut, and the PA catheter should be removed, so a new purse-string suturing is formed.

If the PA catheter is entrapped in the suture line of the atrial incision such as ⑤ right-side left atrial incision site or ⑥ right atrial incision site, the following procedure should be taken: ligate the suture line before and after the entrapment site by horizontal mattress suturing, cut the causative string in between, remove the catheter, and close the site by suturing. Forming a purse-string suturing in advance is also acceptable. The patient has been weaned from the cardiopulmonary bypass when checking for entrapment, but this method is expected to help with handling entrapment without using cardiopulmonary bypass in most cases.[5)]

Figure 7　For the prevention of accidental entrapment of pulmonary artery catheter in the suture (poster)

We prepared a poster showing the sites of frequent PA catheter entrapment in the suture and the procedures for checking for PA catheter entrapment in the suture before closing the chest.



## [Prevention and management of entrapment of the PA catheter in the suture]

**Recommendation 5**

«Management during the removal of PA catheter»
The PA catheter should be withdrawn slowly enough for any resistance to be felt, with attention paid to possible PA catheter entrapment. If there is even a slight resistance, catheter removal should be discontinued and a confirmation by X-ray fluoroscopy, etc., should be made. If entrapment is suspected, thoracotomy needs to be performed in the operation room to remove the catheter.



### Consider the possibility of PA catheter entrapment in the suture

The frequency of PA catheter entrapment in the suture is not presented even in the Cochrane Library that performs systematic reviews.[19] An investigation conducted in Japan reports that 28% of medical institutions experienced PA catheter entrapment in blood vessel or heart wall.[4]

In one of the three target cases of entrapment, the possibility of PA catheter entrapment was not taken into consideration. Similarly, the possibility of entrapment at all sutured sites was not recognized in the other two cases. The possibility of entrapment must be kept in mind during removal of the PA catheter because checking for PA catheter entrapment in the suture before closing the chest alone cannot completely rule out the possibility of entrapment.

### Pull the PA catheter slowly enough for resistance to be felt

Tissues of peripheral pulmonary arteries, the right atrium, and immediately below the pulmonary artery valve are thin and vulnerable to vascular injury, so any critical bleeding during the removal of a PA catheter may be fatal.

In two of the three target cases of entrapment in the suture, no resistance was felt during removal. In the other case, a resistance was felt and the patient complained of chest pain after the PA catheter was pulled for about 20 cm, and the catheter removal was discontinued.

During removal of the PA catheter, resistance may not be felt if the PA catheter is pulled out quickly. Therefore, it is essential to remove the PA catheter at a low, constant speed to detect any resistance, while keeping the possibility of PA catheter entrapment in the suture in mind.

However, the meaning of “low speed” or “slowly” differs among individuals. Physicians with little experience in catheter removal may find it difficult to determine the appropriate speed, so it is important to provide educational programs to instruct them, such as demonstration by a senior physician. Each medical institution is advised to provide education and training on PA catheter removal and to establish rules, for example, stipulating that physicians must finish the training course to perform catheter removal. It is also advisable to perform PA catheter removal with more than one physician who have been educated on PA catheter removal, and not by a single physician.

## Discontinue catheter removal and consider entrapment in the suture if there is even a slight resistance

Even a slight resistance felt during the removal of a PA catheter can suggest entrapment of the PA catheter. In such a case, it is important not to pull the PA catheter forcibly. The resistance may have been caused by knotting or entrapment of the catheter. If resistance is felt, catheter removal should be discontinued and X-ray fluoroscopy performed. While checking for knotting of the PA catheter, all sutured sites should be checked. However, since some sites are difficult to visualize by X-ray fluoroscopy, such as superior vena cava and right-side left atrium, critical bleeding can be prevented by opening the chest and removing the catheter following tracheal intubation in the operation room and observation by TEE.

In most cases, the PA catheter is removed a few days after surgery. The PA catheter was removed in intensive care unit in two of the three target cases of entrapment. Pulling out the entrapped PA catheter is likely to result in extensive injury of the heart wall, so open-chest repair is the first choice.

In one of the two cases in which the PA catheter was removed in the intensive care unit, cardiac injury was suspected immediately after removal of the PA catheter and thoracotomy was started 1 minute later, which failed to save the patient's life. Despite preparation for critical bleeding, it is difficult to save the patient's life in many cases once heart wall injury occurs. When the PA catheter is removed in the intensive care unit, etc., attention should be paid to the possibility of critical bleeding and preparation should be considered so that repeat open-chest hemostasis can be performed promptly.

# Part 2 PA Catheterization

<Professions relevant to the PA Catheterization Part>
We hope those in relevant departments and professions will read this part.


Cardiovascular physician, respiratory physician, intensive care physician


Nurse engaged in catheterization


CClinical engineer, clinical radiologist, etc.

# 5. Overview of the target cases in the PA Catheterization Part

The case overview was prepared by the Expert Analysis Subcommittee by organizing the information according to the following (1) to (5) based on the in-hospital investigation and additional reports:

(1) Patient information, (2) purpose of the catheterization, (3) process of the catheterization, (4) course after symptom onset, and (5) cause of death and other information.

## Case 6

(1) The patient was a woman in her 70s with cerebral infarction, cardiac failure, and (suspected) mitral stenosis. Her height was 140-149 cm. The patient was taking antithrombotic agent(s).

(2) PA catheterization and left ventriculography were performed to investigate cardiac failure and valvular heart disease in detail (appropriate volume of the catheter balloon used: 1.5 mL).

(3) The PA catheter was inserted from the right femoral vein under X-ray fluoroscopy. The PAWP could not be measured after inflating the balloon to 1.5 mL, and the balloon was inflated to 2.25 mL, but PAWP measurement failed again. A guidewire was then used to advance the catheter and the PAWP was measured.

(4) Approximately 15 minutes after measuring the PAWP, cough and bloody sputum were observed. The SpO2 was 93%. Protamine sulfate was administered, 2 L of oxygen was started, and left ventriculography was performed. When the patient was transferred to the CT room for evaluation of hemorrhage after the catheterization, blood pressure could not be measured and tracheal intubation was performed. Ultrasonography showed suspected bloody pleural effusion, and thoracic drainage was placed. After an extensive amount of dark red fluid was drained, the patient went into cardiac arrest. Emergency thoracotomy for hemostasis was performed. An injury of about 1 cm on the right pulmonary artery between the upper and lower lobes was found and repaired. However, the bleeding could not be controlled, and the patient died about 9 hours after the start of the catheterization.

(5) Cause of death: Hemorrhagic shock due to an injury of the right interlobar pulmonary artery. Ai: present. Autopsy: present.

## Case 7

(1) The patient was a woman in her 70s with severe mitral stenosis, cardiac failure, and atrial fibrillation. Her height was 150-159 cm. She was taking antithrombotic agent(s).

(2) PA catheterization was performed for preoperative detailed examination (appropriate volume of the catheter balloon used: 1.5 mL).

(3) The PA catheter was inserted from the right femoral vein under X-ray fluoroscopy. The catheter could not be introduced into the pulmonary artery, and then a guidewire was used to advance the catheter. The balloon was inflated 1 mL at a time up to 2 mL, but the PAWP could not be measured.

(4) After measurement of the right intracardiac pressure, the patient developed coughing and hemoptysis. Immediately after that, inguinal artery became impalpable. Chest compression was initiated. Tracheal intubation was conducted, and percutaneous cardiopulmonary support (PCPS) was implemented. Ultrasonography revealed fluid retention in the thoracic cavity, and pulmonary angiography was attempted but not successful in identifying the bleeding point. The patient died about 8 hours after start of the catheterization.

(5) Cause of death: Hemorrhagic shock due to (suspected) left pulmonary artery injury. Ai: present. Autopsy: present.

## Case 8

(1) The patient was a woman in her 40s with (suspected) pulmonary hypertension, hepatic cirrhosis, esophageal varices, and decreased platelets (16,000/μL). The patient was referred to the emergency department with suspected ischemic cardiac disease. Her height was 150-159 cm. The patient was not using antithrombotic agents.

(2) A PA catheterization and coronary angiography were performed for a detailed examination of acute coronary syndrome and pulmonary hypertension (appropriate volume of the catheter balloon used: 1.0 mL).

(3) The PA catheter was inserted from the right jugular vein under X-ray fluoroscopy. The catheter could not be guided into the pulmonary artery, and then a guidewire was used to advance the catheter. Subsequently, the patient started coughing. The balloon was inflated to 2 mL to measure the PAWP, and coronary artery angiography was performed.

(4) After completion of the catheterization, productive cough persisted. $SpO_2$ decreased to 80-89%, and 2 L of oxygen was administered. The patient had bloody sputum. When the patient was transferred to the intensive care unit for suspected esophageal variceal rupture, a moderate amount of hemoptysis was noted. The patient went into cardiopulmonary arrest, and died about 3 hours after the start of the catheterization.

(5) Cause of death: Right cardiac failure triggered by an injury at the bifurcation of the right middle lobe pulmonary artery or bifurcation of right front basal segment artery. Ai: present. Autopsy: present.

## Case 9

(1) The patient was a woman in her 90s with acute myocardial infarction, severe mitral insufficiency, and pulmonary hypertension. Her height was 150-159 cm. The patient was taking antithrombotic agent(s).

(2) The PA catheter was inserted to assess hemodynamics (appropriate volume of the catheter balloon used: 1.5 mL).

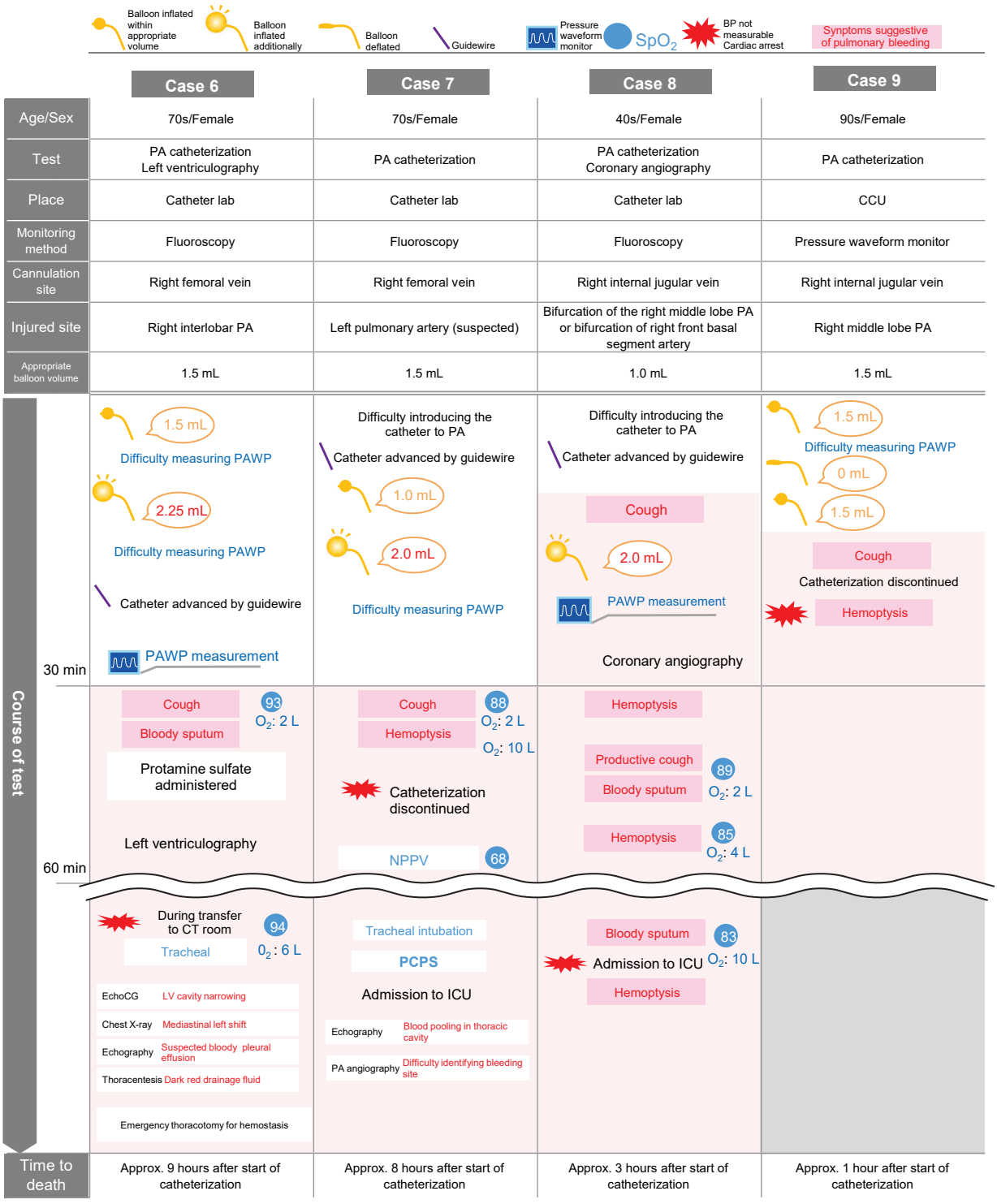
(3) The PA catheter was inserted from the right internal jugular vein while observing with the pressure waveform monitor. The PA catheter was introduced to the pulmonary artery and the balloon was inflated to 1.5 mL. However, the PAWP measurement failed and the balloon was deflated. When the balloon was inflated again to 1.5 mL, the syringe resistance disappeared.

(4) The patient started coughing immediately after re-inflation. The procedure was discontinued because of suspected pulmonary artery injury. Immediately after that, massive hemoptysis was observed, and the patient went into cardiopulmonary arrest and died about 1 hour after the start of the catheterization.

(5) Cause of death: Hemorrhagic shock due to an injury of the right middle lobe pulmonary artery. Ai: present. Autopsy: present.


Part 1 Open-heart Surgery

Figure 8　Details of the target cases (cases of PA catheterization)



# 6. Recommendations and explanations to prevent recurrence in the PA Catheterization Part

**[Review of the indication]**

**Recommendation 6**

A PA catheterization is associated with a risk of fatal complications. Although it is indispensable for a definitive diagnosis of pulmonary hypertension and for determining the disease type, the possibility of substituting it with echocardiography should be considered in the case of preoperative examinations. Risk factors for pulmonary artery injury and fatal hemorrhage, such as advanced age, being female, blood coagulation disorder, and chronic use of steroids, should be assessed to review the indication for a PA catheterization based on the necessity and risks.


Part 1 Open-heart Surgery

## Risk of fatal complications associated with PA catheterization

The pulmonary artery consists of a loose distribution of smooth muscle and elastic fibers compared to arteries of systemic circulation,[6] and the vascular wall is thin at about 1 mm. This poses a risk of fatal complications, including pulmonary artery injury by excessive inflation of the balloon or by the guidewire protruding from the catheter tip during the PA catheterization.

In the four target cases of PA catheterization, pulmonary hemorrhage resulted from a pulmonary artery injury (including a suspected case) due to balloon manipulation or guidewire operation during the PA catheterization. The injury was located at the right middle lobe pulmonary artery in three cases and at the left pulmonary artery (suspected) in one case.

The PA catheter, which is directly inserted into the heart, can result in a fatal outcome if the catheter damages the pulmonary artery or heart wall. It is essential to review the indication of PA catheterization while recognizing the possibility of fatal complications before PA catheter insertion.

## Consideration of the use of cardiac echocardiography as a substitute

PA catheterization is essential for definitive diagnosis and disease type determination of pulmonary hypertension, such as pulmonary arterial hypertension and chronic thromboembolic pulmonary hypertension, which are designated intractable diseases, as well as when submitting an application to the academy for a heart transplantation and ventricular assist device. It also provides significant indicators for the assessment of hemodynamics in the preoperative phase and other situations. However, PA catheterization is not mandatory for the diagnosis and severity assessment of valvular heart diseases and to review the indication of surgery for valvular heart diseases, because these assessments can be performed with echocardiography or TEE.

The PA catheter was used for the diagnosis of pulmonary arterial hypertension in one of the four target cases of PA catheterization and for the preoperative examination and disease assessment of mitral valve disease in the other three cases.

Due to the risk of fatal complications associated with PA catheterization, the possibility of using the data provided by less invasive methods such as echocardiography as a substitute should be discussed before performing the PA catheterization. In addition, when a request for a catheterization for preoperative disease assessment is received, one should investigate whether PA catheterization is required based on the review of data from echocardiography or other methods.

## Review of the indication based on the necessity and risk assessment of PA catheterization

Both the necessity of the catheterization and the risk of pulmonary artery injury and fatal hemorrhage should be taken into consideration when reviewing the indication of PA catheterization. The risk factors of pulmonary artery injury and fatal hemorrhage include advanced age, being female, pulmonary hypertension, use of thromboembolic agents, and chronic use of steroids.[7)8)] In some reported cases, a small body build was also more likely to lead to excessive insertion of the PA catheter and to result in pulmonary artery injury.[20)]

Of the patients in the four target cases of PA catheterization, three were at least 70 years old, four were female, and one had pulmonary hypertension. In addition, three were taking antithrombotic agents and one had decreased platelets.

To review the indication of PA catheterization, the necessity of the catheterization and the risks of pulmonary artery injury and fatal hemorrhage should be assessed for each patient in occasions such as preoperative conference.

## Sharing the recognition on the necessity and risks of PA catheterization with patients and their families

PA catheterization has a risk of fatal complications including pulmonary artery injury. Therefore, the patient and their family should be informed of the necessity and risks of the catheterization in advance.

In the four target cases of PA catheterization, written information on issues such as bleeding from the cannulation site and allergic reactions to contrast agents was provided to the patients and their families during the meeting before the catheterization. However, in three of the four cases, information on pulmonary artery injury, etc., was not provided. It is important for physicians to explain and share the information on the necessity of PA catheterization and the associated risks of pulmonary artery injury and fatal hemorrhage using plain language that can be understood by patients and their families.

[PA catheter insertion]

**Recommendation 7**

- If the balloon is repeatedly inflated and deflated within the pulmonary artery when the PAWP cannot be measured, the catheter may bend and advance into the periphery. The catheter should be manipulated while observing the tip location under X-ray fluoroscopy.
- If the catheter tip strays into the periphery, the pulmonary artery may be injured even within proper capacity. Air should be injected slowly into balloon while feeling the resistance. Air should not be injected beyond the proper volume even though resistance is not felt.
- The use of a guidewire should be avoided as much as possible. If its use is imperative, the operator should ensure that the guidewire is not protruding from the PA catheter tip.
- If the PAWP cannot be measured, the use of another indicator as a substitute should be considered, rather than sticking to the PAWP measurement.

### Insert the PA catheter under X-ray fluoroscopy as much as possible

PA catheters are designed to flow in the blood stream upon inflation of the balloon and are manipulated under continuous monitoring of the intracardiac pressure and pulmonary artery pressure. It is therefore thought to be a method that can be used at bedside without X-ray fluoroscopy. However, if the catheter is deflected, it may accidentally advance into the periphery when the deflection is resolved by catheter manipulation such as inflation and deflation of the balloon.

In one of the target cases of PA catheterization, the catheter was being inserted while monitoring the pressure waveform at the bedside. However, the catheter proceeded to and damaged the middle lobe pulmonary artery. Manipulating the PA catheter blindly will increase the risk of injuring the pulmonary artery and heart wall. Attention should especially be paid to the possibility of a pulmonary artery injury due to the advancement of the catheter into the periphery upon balloon deflation, and the catheter should be inserted carefully while observing the catheter tip position by X-ray fluoroscopy wherever possible.

### Slow inflation of the balloon and adherence to the appropriate volume

Failure to measure the PAWP may suggest that the balloon is not appropriately wedged into the blood vessel (e.g., the balloon is located at the bifurcation of the blood vessel).

In one of the target cases of PA catheterization, after failure to measure the PAWP, the balloon was deflated and inflated again within the appropriate volume, which resulted in a pulmonary artery injury. In other cases, a pulmonary artery injury possibly occurred when the balloon was inflated beyond the appropriate volume after failing to measure the PAWP.

When the balloon is inflated to the appropriate volume, the catheter tip is covered and the catheter center is located at the center of the intravascular space within the pulmonary artery, and vascular injury can be prevented. However, even when the balloon is inflated within the appropriate volume, advancement of the catheter into a peripheral pulmonary artery may result in damage to the pulmonary artery.

Injection of additional air into the balloon is possible when the inflation valve is locked and connected with the dedicated syringe. Meanwhile, excessive inflation of the balloon beyond the appropriate volume or sudden inflation of the balloon will cause excessive expansion of the pulmonary artery and the balloon diameter to exceed the vascular diameter, possibly causing vascular injury or the balloon to burst. The balloon should be inflated slowly while observing the pulmonary artery pressure on the pressure waveform monitor and feeling for any resistance, and air injection should be stopped once the PAWP appears in order to prevent excessive inflation beyond the appropriate volume.

## Avoid the use of a guidewire as much as possible

In two of the four target cases of PA catheterization, a guidewire was used because advancing the catheter after insertion was difficult. In one case, the catheter was advanced with the guidewire protruding from the catheter tip. A guidewire can be used to advance the catheter in cases where the PA catheter is inserted from the femoral vein or when the PA catheter does not flow in the blood stream and does not float through the right ventricular to the pulmonary artery. Manipulation of the PA catheter with a guidewire protruding from the PA catheter tip poses a risk of damaging the pulmonary artery or heart wall, which may be fatal.

If the use of a guidewire cannot be avoided, it should be used under X-ray fluoroscopy to make sure that the guidewire does not protrude from the catheter tip. The guidewire needs to be removed once the catheter enters the pulmonary artery, and the catheter should be manipulated while observing the pressure waveform monitor.

## Use a surrogate indicator when measurement of the PAWP is difficult

In one of the four target cases of PA catheterization, an injury of the right middle lobe pulmonary artery occurred when the balloon was inflated again to the appropriate volume after failing to measure the PAWP.

As the pulmonary arterial wall is thin, even a slight injury may lead to massive hemorrhage, especially in patients with pulmonary hypertension.

If measurement of the PAWP is not available, PAWP measurement should be discontinued, rather than persistently trying to measure it. The possibility of using surrogate indicators should be considered. Possible surrogate indicators to be considered include pulmonary artery diastolic pressure in the case of right-heart catheterization and the left ventricular end-diastolic pressure for left-heart catheterization.

Part 1 Open-heart Surgery

## [Management of pulmonary hemorrhage]

**Recommendation 8**

If respiratory symptoms such as cough and bloody sputum are observed during the PA catheterization, pulmonary artery injury should be suspected first and the procedure must be discontinued immediately. The bleeding site should be identified with angiography, and transcatheter hemostasis or other hemostatic techniques should be attempted.

### Consider pulmonary artery injury if cough or bloody sputum is observed

In all four target cases of PA catheterization, respiratory symptoms such as cough and bloody sputum were noted during the catheterization. A sudden change in the patient's condition occurred immediately after the appearance of cough, blood sputum, and/or sensation of dyspnea in two of the cases. In the other two cases, a sudden change was noted while esophageal varices was suspected based on pulmonary alveolar hemorrhage, exacerbation of cardiac failure, and medical history.

If respiratory symptoms such as cough and bloody sputum are observed during PA catheterization, a pulmonary artery injury should be suspected first, and the catheterization procedure should be discontinued immediately and the patient's condition observed.

In the case of hypoxemia, patients should be managed by oxygenation and positive pressure ventilation, including non-invasive positive pressure ventilation (NPPV). If the respiratory condition is not improved by these interventions, respiratory control by mechanical ventilator such as invasive positive-pressure ventilation (IPPV) needs to be performed.

### Identification of bleeding site and management during pulmonary hemorrhage

If a pulmonary artery injury is suspected in patients using heparin sodium, protamine sulfate should be administered intravenously to neutralize it. After discontinuation of the procedure, the bleeding site should be identified by angiography. A CT may be used to confirm the bleeding site, but it is not capable of identifying the bleeding site. In addition, a sudden change may occur while transferring the patient to the CT imaging facility.

In two of the target cases of PA catheterization, cardiac arrect occurred approximately 10 minutes after symptom onset.

It may be difficult to save the patient's life because hemodynamics worsens rapidly once the pulmonary artery is damaged. Nevertheless, if cough and/or bloody sputum is observed, it is crucial to perform angiography immediately and stop the bleeding by transcatheter hemostasis.

If the bleeding site is identified by angiography, hemostatic measures such as transcatheter hemostasis using balloon or coil embolization, sterile absorbable gelatin sponge, and vascular embolization plug, etc., can be used. The equipment available in the catheterization laboratory varies among medical institutions, and the preparation of equipment may be difficult in some cases. In a reported case, a decrease in pulmonary hemorrhage after the application of ECMO led to improvement in hemodynamics and oxygenation, and the patient was eventually cured by transcatheter hemostasis. There are also cases in which surgical treatments such as lobectomy[16] or angioplasty that are more invasive than endovascular treatments have to be selected. Treatment methods should be considered according to the patient's condition (see Recommendation 3).

If the bleeding is shown to have been caused by any other factors than PA catheterization, differential diagnosis should be conducted while observing the respiratory conditions and in consideration of medical history and other factors.

## Establishment of a system in preparation for critical hemorrhage

In two of the four target cases of PA catheterization, the operator performed PA catheterization alone. PA catheterization is associated with a risk of fatal complications. Thus, it is important to perform the procedure with multiple physicians and to establish a system that can address critical hemorrhage as a team. It is also advisable to cooperate in advance as much as possible with related departments, such as respiratory surgery and radiology (especially the IVR physician), so that assistance can be requested smoothly.

# 7. What we expect of (or what we want to propose to) academic societies and companies

We expect academic societies and companies to tackle the following issues and thereby make it easier to further improve patient safety.

## What we expect of academic societies

The following items are what we expect of academic societies related to PA catheter, including the Japanese Association for Thoracic Surgery, the Japanese Society for Cardiovascular Surgery, Japanese Society of Anesthesiologists, Japanese Society of Cardiovascular Anesthesiologists, and the Japanese Circulation Society.

### (1) Preparation and dissemination of the criteria for the indication of PA catheter insertion in open-heart surgery

When reviewing the indication of PA catheter insertion during an open-heart surgery, it is important to assess and examine the necessity of PA catheter insertion and catheterization and risks in individual patients. Academic societies are expected to summarize the risk assessment items and viewpoints and to prepare draft criteria for the indication.

### (2) Discussion on how to provide information to patients before the use of PA catheter

Use of PA catheter has a risk of fatal complications such as pulmonary artery injury and heart wall injury. Academic societies are expected to clarify the matters to explain in the preoperative period or during the catheterization and how the information should be provided specifically.

## What we expect of companies

### (1) Research and development of monitoring devices that can replace the PA catheter

Currently, there is no equipment that is accurate enough to provide information equivalent to the data obtained by a PA catheter. Therefore, research and development of monitoring devices should be conducted. Examples of expectations include the realization of a non-invasive method to estimate the pulmonary artery pressure based on the detection of electric potential change from the body surface, as well as the development of an algorithm to estimate cardiac output to correct the deviation in measured values in various pathological conditions.

### (2) Improvement of graduations shown on the PA catheters

The body of the PA catheter is marked at 10 cm increments, whereas the PA catheter is manipulated and moved in units of centimeters during surgery. In order to determine the correct position of the PA catheter, the design should be modified so that the insertion length can be confirmed at a glance, for example, by using finer markings.

# 8. Conclusion

The Expert Analysis Subcommittee analyzed and examined the cases of deaths caused by the use of a PA catheter and presented the recommendations to avoid fatal complications due to manipulations of the PA catheter.

The analysis of fatal cases revealed that fatal complications due to the PA catheter are broadly classified into two categories: pulmonary hemorrhage caused by a pulmonary artery injury, and cardiac injury caused by the removal of the PA catheter without noticing that the PA catheter was sewn in the suture during an open-heart surgery. For both categories, patients had sudden symptom onsets, rapidly went into shock, and died within a short period in many cases. These cases showed that once such complications develop, they are not easily managed. Therefore, prevention is considered to be of utmost importance and is the main point of our recommendations.

In our recommendations, we first explained the importance of reviewing the indication considering the risk of fatal complications. There are limited studies that demonstrated the usefulness of the PA catheter in various conditions, with no research of high evidence level. We proposed that the related departments in each medical institution should fully discuss and limit the indication as much as possible. Going forward, the academic society should make efforts to establish evidence. In addition, although some methods are available for clinical use as a substitute of the PA catheter, their limitation has been recognized. Research and development of less invasive monitoring device with improved accuracy should be conducted.

In the preoperative explanation, information on the PA catheter is often included in the information on central venous catheterization, etc., probably because the PA catheter is seen as one of the test procedures to assess the disease condition. We recommended that the necessity of the PA catheter and the associated risks be explained to share the recognition.

It is hard to detect any accidental catheter entrapment in the suture at the time of occurrence although full effort should be taken to avoid such accidents. However, according to the questionnaire survey conducted by the Japanese Society for Cardiovascular Surgery, an accident was actually avoided in many cases where entrapment occurred but only detected upon the removal of the catheter. In our recommendations, we suggested that the possibility of entrapment should always be kept in mind when removing the catheter and that the system should be established so that thoracotomy can be performed when there is even a slight resistance to address cardiac injury.

We also presented the points to be considered regarding the insertion of the catheter into the pulmonary artery, handling during catheter placement, and use of the balloon, which may all cause a pulmonary artery injury. In particular, we recommended that the guidewire should be used with utmost attention because the use of a guidewire was suspected to have caused an injury when inserting the catheter tip into the pulmonary artery in several cases.

Finally, we would like to express our sincere gratitude to the medical institutions that worked on investigating the causes of the accidents and the prevention of recurrence, and cooperated in sharing the in-hospital investigation reports. We would also like to express our deepest condolences to the patients who died due to the accidents and to the bereaved families. We hope that the Recommendations will be useful to healthcare professionals as a step toward improving patient safety.

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# 10. Materials

The table below lists the items identified during investigation for the recommendations. Please utilize it for similar case research.

## Pulmonary artery catheter (open-heart surgery)/Investigation items checklist

| Item | | Viewpoints | | Concrete items |
|---|---|---|---|---|
| Basic information | Patient information | Age/Sex | | Age: Sex: ☐ Male ☐ Female |
| | | Height/body weight (Date measured) | | Height: cm Body weight: kg ( ) |
| | | Diagnosis | | |
| | | Medical history | | |
| | | Oral drug (antithrombotic drug) | | Drug interruption: ☐ Yes ☐ No |
| | Blood tests | Blood count (blood collection date: ) | | ☐ Hb: g/dL ☐ Plt: 0,000/μL ☐ Other: |
| | | Coagulation (blood collection date: ) | | ☐ PT: % ☐ PT: sec ☐ APTT: sec<br>☐ PT-INR: ☐ Fib: mg/dL ☐ Other: |
| Cause of death | Autopsy/Ai | Autopsy results: Site of injury (including assumptions) | | |
| | | Ai results: Site of injury (including assumptions) | | |
| Indication | Assessment of necessity and risks | Method of review | | ☐ Conference ☐ Attending physician only ☐ Other: |
| | | Necessity of catheter insertion | | ☐ Procedure: ☐ Duration of cardiac arrest:<br>☐ LV function: ☐ RV function:<br><Risk><br>☐ Severity of pulmonary hypertension: ☐ Severity of cardiac failure:<br>☐ Other: |
| | | Risk of pulmonary artery injury and fatal hemorrhage | | ☐ Advanced age ☐ Female ☐ Pulmonary hypertension<br>☐ Use of antithrombotic agent ☐ Chronic use of steroids |
| | | Substitute considered | | ☐ $SpO_2$ measuring device ☐ APCO ☐ $SvO_2$ ☐ $ScvO_2$ |
| | Information | Method of information provision | | ☐ Informed consent form ☐ Oral ☐ Other: |
| | | Information provided | | ☐ Necessity of catheter insertion<br>☐ Risk of pulmonary artery injury associated with surgical procedure<br>☐ Risk of cardiac injury associated with catheter removal ☐ Other: |
| Information on surgery | Equipment used | Catheter product name | | |
| | | Equipment used during insertion | | ☐ Pressure waveform monitor ☐ TEE ☐ Other: |
| | Catheter insertion manipulation and placement | Site of insertion | | ☐ Internal jugular vein (left/right) ☐ Femoral vein (left/right) ☐ Other: |
| | | Pressure measurement checked | | ☐ RA pressure ☐ RV pressure ☐ PA pressure ☐ PAWP |
| | | Balloon inflation volume | | ☐ Actual inflation volume ( ) mL *Appropriate volume of specification ( ) mL |
| | | Method of confirming placement at the vicinity of the right pulmonary artery trunk | | ☐ Pressure waveform monitor ☐ TEE ☐ Other: |
| | | Position of placement before the start of cardiopulmonary bypass | Length pulled | ( ) cm from the vicinity of the right PA trunk (near the hilus) |
| | | | Length of placement | ( ) cm |
| | Surgical procedure | Rotation/displacement of the heart | | ☐ Yes ☐ No |
| | | Sites of string threaded/sutures | | ☐ PA trunk incision site ☐ RV outflow tract incision site<br>☐ Inferior vena cava cannulation site ☐ Retrograde cardioplegia cannulation site<br>☐ Right-side LA incision site ☐ RA incision site<br>☐ LA-LV vent cannulation site ☐ Superior vena cava cannulation site |
| | | Method of checking for catheter entrapment in the suture before closing the chest | | ☐ Anesthesiologist: Abnormal continuous cardiac output, tip temperature sensor defectiveness<br>☐ Surgeon: Entrapment of PA catheter in the suture when picking up all sutured site<br>☐ Anesthesiologist: Deflection in the right atrium/ventricle under TEE<br>Joint work ☐ Anesthesiologist: Resistance upon moving the PA catheter for 5 to 10 cm<br>☐ Surgeon: Contraction of all sutured sites (visual inspection/palpation) |
| | | Sites checked | | ☐ All sutured sites ☐ Part of sutured site:<br>☐ Other: |
| Management of hemorrhage | During removal | Place of removal | | ☐ Intensive care unit ☐ Operation room ☐ Other: |
| | | Number of physicians who attended | | ( ) |
| | | Resistance upon pulling | | ☐ Yes ☐ No |
| | | Method of checking when entrapment was suspected | | ☐ X-ray ☐ Xray fluoroscopy ☐ TEE ☐ Other: |
| | For complication | Bleeding site | | Site: ☐ Identification difficult |
| | | Intervention, treatment, etc. | | ☐ Insertion of bronchial blocker ☐ Application of ECMO<br>☐ Transcatheter hemostasis:<br>☐ Surgical treatment: ☐ Other: |
| Management system | Education | Educational program for catheter removal in place | | ☐ Yes ☐ No |

## Pulmonary artery catheter (examinations)/Investigation items checklist

| Item | | Viewpoints | Concrete items |
|---|---|---|---|
| Basic information | Patient information | Age/Sex | Age: Sex: ☐ Male ☐ Female |
| | | Height/body weight (Date measured) | Height: cm Body weight: kg (DD/MM/YYYY) |
| | | Diagnosis | |
| | | Medical history | |
| | | Oral drug (antithrombotic drug) | Drug interruption: ☐ Yes ☐ No |
| | Blood tests | Blood count (blood collection date: ) | ☐ Hb: g/dL ☐ Plt: 0,000/μL ☐ Other: |
| | | Coagulation (blood collection date: ) | ☐ PT: % ☐ PT: sec ☐ APTT: sec<br>☐ PT-INR: ☐ Fib: mg/dL ☐ Other: |
| Cause of death | Autopsy/Ai | Autopsy results: Site of injury (including presumption) | |
| | | Ai results: Site of injury (including presumption) | |
| Indication | Assessment of necessity and risks | Method of review | ☐ Conference ☐ Attending physician only ☐ Requested to other department<br>☐ Other: |
| | | Purpose of insertion | ☐ Definitive diagnosis/disease type determination of pulmonary hypertension<br>☐ Application submitted to the academy<br>☐ Diagnosis/severity assessment of valvular disease<br>☐ Review of indication of surgery ☐ Other: |
| | | Risk of pulmonary artery injury and fatal hemorrhage | ☐ Advanced age ☐ Female ☐ Pulmonary hypertension<br>☐ Use of antithrombotic agent ☐ Chronic use of steroids |
| | | Substitute considered | ☐ Echocardiogram ☐ TEE ☐ Other: |
| | Information | Method of information provision | ☐ Informed consent form ☐ Oral ☐Other: |
| | | Information provided | ☐ Necessity of catheter insertion<br>☐ Risk of pulmonary artery injury and fatal hemorrhage ☐ Other: |
| Information during examination | Place | Place of insertion | ☐ Angiography lab (or similar treatment room) ☐ Ward ☐ Other: |
| | Equipment used | Catheter product name | |
| | | Equipment used during insertion | ☐ Pressure waveform monitor ☐ X-ray fluoroscopy ☐ Other: |
| | Course during catheterization | Site of insertion | ☐ Internal jugular vein (left/right) ☐ Femoral vein (left/right)<br>☐ Other: |
| | | Use of guidewire | ☐ Yes Reason:<br>☐ No |
| | | Action taken when PAWP measurement was difficult | ☐ Substituted by PA diastolic pressure ☐ Substituted by LV end-diastolic pressure<br>☐ Other: |
| | | Pressure measurement checked | ☐ RA pressure ☐ RV pressure ☐ PA pressure ☐ PAWP |
| | | Balloon inflation volume | ☐ Actual inflation volume ( ) mL *Appropriate volume of specification ( ) mL |
| Management of hemorrhage | For complication | Respiratory symptom | ☐ Yes [☐ Cough ☐ Hemoptysis ☐ Bloody sputum ☐ Sensation of dyspnea ☐ Other: ]<br>☐ No |
| | | Method of identification of bleeding site | ☐ Angiography ☐ Other: |
| | | Bleeding site | Site: ☐ Identification difficult |
| | | Hemostatic method | ☐ Application of ECMO ☐ Transcatheter hemostasis:<br>☐ Surgical treatment: ☐ Other: |
| Management system | Collaboration | Collaboration with related departments | ☐ Yes ☐ No |

## Members of the Expert Analysis Subcommittee

| | | |
|---|---|---|
| Subcommittee chairman | Goro Matsumiya | Japanese Society for Cardiovascular Surgery |
| Subcommittee members | Yoshihiko Ohnishi | Japanese Society of Cardiovascular Anesthesiologists |
| | Tetsufumi Sato | Japanese Society of Anesthesiologists |
| | Koichiro Sugimura | Japanese Pulmonary Circulation and Pulmonary Hypertension Society |
| | Go Haraguchi | Japanese Society of Intensive Care Medicine |
| | Yoshihiro Fukumoto | Japanese Circulation Society |
| | Hiroshi Maeda | Japan Operative Nursing Academy |
| | Takeshi Miyairi | Japanese Society for Cardiovascular Surgery |
| | Atsushi Yamaguchi | Japanese Society for Cardiovascular Surgery |

Conflicts of interest
The Medical Accident Investigation and Support Center has confirmed the status of conflicts of interest self-declared by the respective members of the Expert Analysis Subcommittee in terms of the contents of this report of recommendations.

## Members of the Committee for Prevention of Recurrence

| | | |
|---|---|---|
| Chairperson | Hisahiro Matsubara | Professor, Department of Frontier Surgery, Graduate School of Medicine, Chiba University |
| Vice chairperson | Shin Ushiro | Director/Professor, Division of Patient Safety, Kyushu University Hospital |
| Committee members | Yasuo Arai | Special Profession/Section Chief, Health Information Management Office, Department of Medical Support, Kitasato University Hospital |
| | Michio Ueno | Senior Advisor, Fukuoka Prefecture Medical Association |
| | Yoshio Kato | Lawyer, Sakae Law Office |
| | Tetsuya Kusakabe | Director, Office of Manufacturing Quality and Vigilance for Medical Devices, Pharmaceuticals and Medical Devices Agency (PMDA) |
| | Hiraku Kumamaru | Associate Professor, Department of Healthcare Quality Assessment, Graduate School of Medicine, University of Tokyo |
| | Yasushi Kodama | Attorney at Law Admitted in Japan and the State of New York, Shinsei Sogo Law Offices |
| | Akinori Komatsubara | Professor, Department of Industrial and Management Systems Engineering, School of Creative Science and Engineering, Faculty of Science and Engineering, Waseda University |
| | Hiromi Sakai | Assistant Manager, Crisis Management Office, Tokyo Nursing Association |
| | Yoshiro Sakai | Director, Japan Psychiatric Hospitals Association |
| | Mineko Terai | Director of Nursing Department, Medical Research Institute, Kitano Hospital, PIIF Tazuke-kofukai |
| | Masumi Hara | Director, Teikyo University Hospital, Mizonokuchi |
| | Kenji Fukushi | Director, Japan Dental Association |
| | Akemi Fuse | Senior Executive Director, Japanese Midwives Association |
| | Ryokan Funakoshi | Director, Japanese Society of Hospital Pharmacists |
| | Hidekazu Hosokawa | Executive Board Member, Japan Medical Association |
| | Morio Matsumoto | Director, Japanese Medical Science Federation |
| | Makoto Yano | President, General Welfare Center, Japanese Red Cross Society |
| | Ikuko Yamaguchi | Chief Director, Authorized NPO: Consumer Organization for Medicine & Law (COML) |

The list of Committee for Prevention of Recurrence members is as of the time when the “Recommendations for the Prevention of Recurrence of Medical Accidents” (Number 19) was approved.

Recommendations for the prevention of recurrence of medical accidents (Number 19)
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**Part 1 Open-heart Surgery / Part 2 PA Catheterization**

Issued in February 2024

Edited and published by Medical Accident Investigation and Support Center
(Japan Medical Safety Research Organization)
TEL: +81-3-5401-3021 (main)
E-mail: contact@medsafe.or.jp
Hamamatsu-cho TS Building 2F, 2-8-14 Hamamatsu-cho, Minato-ku, Tokyo,
105-0013, JAPAN