Recommendations for the prevention of recurrence of medical accidents
Number 17

Analysis of Deaths Related to "Insertion/Removal of Central Venous Catheters"

-Second report (Revised edition)-

March 2023

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

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. So, 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 17)

Morito Monden
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 seven years and five months ago, more than 2,000 in-hospital investigation reports have been sent to the ISC. Based on these reports, to date we have published 16 recommendations as "Recommendations for the Prevention of Recurrence of Medical Accidents."

In our first recommendations published, Recommendations Number 1 in March 2017, we focused on "Deaths related to the complications of Central Venous Catheterization," and presented our recommendations based on the results of our analysis. Now, five years after publication, we regrettably found that the number of reports on deaths associated with central venous catheters has not decreased and felt the need to evaluate our recommendations. We have reflected on the reasons why the recommendations were not put into practice, which led us to publish a new, tangible revised edition, "Analysis of Deaths Related to "Insertion/Removal of Central Venous Catheters" - Second Report (Revised edition)."

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 insertion/removal of central venous 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.

Analysis of Deaths Related to "Insertion/Removal of Central Venous Catheters" - Second report (Revised edition)

[Standardizing risk assessment and determining indications]

Recommendation 1

Central venous catheterization should be recognized as a high-risk medical practice (high-risk procedure), which may lead to fatal complications. Risk assessment of the patient's general condition and anatomical risk assessment (pre-scan) should be performed in advance, using a standardized method. If the risk is high, measures to avoid the risk, including the use of a peripherally inserted central catheter (PICC) instead, should be considered. Indications should be determined through discussion.

[Sharing information and risks]

Recommendation 2

The patients and families should be provided with written information on the need for central venous catheterization, the results of their risk assessment, potential complications associated with insertion/removal of the catheter and how complications are managed if they occur, the possibility of another operator taking over the procedure or discontinuing catheterization, and alternative treatments. Especially in high-risk patients, the risk should be shared with the patients and their families by providing information on the need of catheterization even if the risk of death is present.

[Cannulation: taking a time-out]

Recommendation 3

Before cannulation, the operator and the assistant should take a time-out to share the results of the patient's risk assessment as well as the rules for another operator taking over or discontinuing catheterization in case the procedure is difficult.

[Cannulation: selecting introducer needles]

Recommendation 4

When cannulating, a pre-scan should be done again to re-evaluate the anatomical risks based on the size, presence/absence of collapse, depth and positional relationship to arteries of the target vein. To prevent or minimize injury to arteries and other organs, the introducer needle used should have a length suitable for the depth of the vein and be as thin as possible.

[Cannulation: inserting a guidewire]

Recommendation 5

Once the guidewire has been inserted into the target vein, both short- and long-axis ultrasound images should be used to check whether the guidewire is located inside the vein. After confirmation, the operator should advance the guidewire slowly, anticipating veins into which the guidewire may stray. If any resistance is met, the guidewire should not be forced ahead. For internal jugular vein cannulation, the guidewire should be inserted no more than 20 cm. Upon removal of the guidewire, check for any guidewire that may have been left behind.

[Cannulation: inserting a dilator]

Recommendation 6

Because a dilator is made of hard materials, it presents a risk of causing vascular injury. The dilator should be inserted by gently advancing it along the guidewire without the use of excessive force. It should be inserted no deeper than 5 cm. If the skin is hard, make a small incision with a scalpel.

[Confirming catheter location]

Recommendation 7

Malposition of the catheter should be suspected if any of the following apply: "resistance was met during catheter insertion," "no blood reflux or smooth aspiration" or "malposition of the catheter is suspected on the X-ray frontal view." In such cases, obtain an X-ray lateral view and, if necessary, perform a CT scan or a contrast examination to verify the catheter's location.

[How to manage a misplacement into an artery and extravascular placement]

Recommendation 8

Because improper removal of a catheter misplaced in an artery may cause fatal bleeding, the catheter must not be removed right away. Even with an extravascular placement, there is a possibility that a vessel has been damaged. Therefore, if a misplacement into an artery or extravascular placement occurs, consider performing a CT scan or a contrast examination and consult with relevant clinical departments.

[Patient observation]

Recommendation 9

The physicians and nurses who manage the patient after catheterization should observe the patient, being aware of the catheterization details. If (1) dyspnea, decreased SpO_2 level, tachypnea; (2) tachycardia, decreased blood pressure; or (3) restlessness is observed from immediately after the start of the catheter use to several days after the catheterization, extravascular placement of the catheter should be suspected, and the transfusion should be discontinued first, and then a thorough examination should be performed.
Even when the catheter could not be inserted, the patient should be observed, keeping in mind the possibility of a vessel injury during the procedure.

[Air embolisms]

Recommendation 10

An air embolism is a fatal complication and may occur associated with insertion/removal of a catheter into or from the internal jugular vein or the subclavian vein. To prevent air embolisms, the catheter should be inserted/removed with the patient's legs elevated or other positions that increase venous pressure. After catheter removal, the puncture site should be covered with an airtight dressing.

[Establishing an organized management system]

Recommendation 11

The manager of a medical institution should manage the organization system regarding insertion/removal of central venous catheters. The manager should define a responsible department (team) to: (1) be aware of the current status of insertion/removal, including occurrence of complications, manage adverse events if any occur, and review past cases; (2) select a safe location and equipment for performing, focusing on safety; (3) prepare a manual that describes how to respond and collaborate in case an abnormality occurs; and (4) consider establishing an educational system.

[Dialysis catheters]

Recommendation 12

Regarding dialysis catheters, which have a large diameter, a vascular injury at insertion can lead to serious bleeding. Because the use of extracorporeal circulation without the catheter placed in the target vein will lead directly to fatal complications, when the risk of catheterization is considered high, the catheter should be inserted under fluoroscopy. This enables more reliable verification of the catheter's location.

***Although the following points overlap with Recommendations 5-10, information on dialysis catheters is summarized and presented again.**

[Cannulation]

- If the guidewire cannot be confirmed as being in the target vein on both short- and long-axis ultrasound views, the dilator should not be inserted (See Recommendation 5).

[Confirming catheter location]

- If there is a possibility of the catheter being mispositioned, obtain a lateral-view X-ray image and, if necessary, perform a CT scan, a contrast examination, or other imaging to verify the location of the catheter. If the catheter is inserted under fluoroscopy, the catheter's location should be accurately ascertained with a contrast examination (see Recommendation 7).
- If blood cannot be drawn during dialysis even though reverse blood aspiration was obtained from the blood removal and return routes at the time of catheter insertion, the route should not be used for blood return. Instead, another measure to better identify the catheter's location should be considered.

[Removal procedure]

- Due to its large diameter, placement of a dialysis catheter tends to form a fistula at the insertion site. To prevent air embolisms, the catheter should be removed with the patient's legs elevated or other positions that increase venous pressure, and it is desirable to cover the removal site with an airtight dressing (see Recommendation 10).

The full text of Recommendations No. 17, "Analysis of Deaths Related to "Insertion/Removal of Central Venous Catheters" - Second Report (Revised edition)," as well as related materials are available on the website of the Medical Accident Investigation and Support Center.

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[Definition of terms used in this document]

Central venous cannulation	Cannulation procedure for central venous catheterization
PICC	Peripherally Inserted Central Venous Catheter
Pre-scan	Anatomical risk assessment performed before cannulation using ultrasound to determine the characteristics of the target vein (size and presence/absence of collapse), depth, and positional relationship to arteries and nerves. *See “Column 1” on page 13.
Ultrasound- guided procedure	Cannulation procedure using ultrasound. There are two approaches: (1) Real-time ultrasound-guided cannulation: a technique to insert a needle while viewing the target vein and the introducer needle on ultrasound tomographic images. (2) Static ultrasound: an approach to observe the surrounding of the target vein on ultrasound tomographic images in order to determine the positional relationship to an anatomical landmark on the surface of the patient body before cannulation.

1. Introduction

1) On analyzing deaths related to “insertion/removal of central venous catheters”

While central venous catheterization is a routine medical practice in patient care, it is also a high-risk procedure. The number of accidents that have occurred associated with this procedure is not small, and preventive efforts against reoccurrence have been made for it. The Medical Accident Investigation and Support Center (ISC) published “Analysis of deaths related to the complications of “Central Venous Catheterization” - First Report”[1] in March 2017. This document examined ten deaths that resulted from complications of central venous cannulation and offered the first recommendations for preventing the recurrence of medical accidents. These deaths were reported over a period of one year and three months, between the launch of the medical accident investigation system and December 2016 in Japan. The reason we chose this topic as the first report was that we determined that a critical goal of avoiding deaths related to complications associated with central venous cannulation is not easily achieved, and continuous efforts remain vital. In fact, among the medical accidents reported to the ISC in the following four years, between December 2016 and December 2020, 62 cases were deaths associated with central venous catheters, which can hardly be considered fewer. Therefore, the Committee for Prevention of Recurrence placed its analysis focus on this type of incident again and established the Expert Analysis Subcommittee to further examine the cases in order to prevent recurrence.

Examining the newly reported 62 cases of death associated with central venous catheters in detail, we found that of those 62, in 7 cases it was not clear whether there was a causal relationship between the cause of the death and the central venous catheter. Excluding those 7 cases, 55 cases were grouped by procedure step: cannulation, 40 cases; removal, 4 cases; management, 9 cases; PICC insertion into a neonate, 2 cases. The 9 cases associated with post insertion catheter management occurred in the inpatient ward: bleeding, 7 cases (disconnected line, 3 cases; damaged line, 1 case; the patient pulled out the catheter, 2 cases; accidental removal of the catheter, 1 case); air embolism, 2 cases (after replacing the infusion set, 1 case; after drawing blood from the line, 1 case). The 2 neonate cases: pulmonary embolism caused by catheter tip dislodged into a ventricle, 1 case; cardiac tamponade, 1 case. While all of these present critical issues requiring detailed examination, the Expert Analysis Subcommittee decided to examine the cases associated with catheter management and cases with neonates separately, and to focus on examining the 44 cases of death associated with insertion/removal of central venous catheters in this document in order to provide more targeted recommendations. Although PICCs represent a class of central venous catheters, as these are inserted from a peripheral vein, besides neonates, no fatal complications associated with insertion/removal were reported. Therefore, the cases presented in this document are those that a central venous catheter was inserted/removed into/from the internal jugular vein, subclavian vein or femoral vein. Because PICCs allow relatively safe insertion/removal, PICCs are recommended as an option for high-risk patients.

Unlike guidelines and guidance issued by academic societies and other organizations, the Recommendations for Prevention of Recurrence of Medical Accidents published by the ISC are characterized by the accumulation of what the ISC learned from cases of death from the perspective of “avoiding accidents leading to death,” and are intended for prompt return to clinical practice. In our First Report, we were able to present important concepts for safer central venous catheterization; however, when examining how the newly reported cases occurred, we found that some of the accidents occurred because the recommendations in the First Report were still not followed. On the other hand, some accidents resulted in death even though the recommended steps were followed, so they failed to have the desired preventive effect. After reviewing and analyzing the First Report, keeping such cases in mind, and examining the course of the revised edition, the Expert Analysis Subcommittee announced more tangible recommendations utilizing checklists and images following the insertion/removal steps. The subcommittee also emphasized the importance of organizational management. We hope the lessons learned from these cases are promptly and effectively applied in clinical practice through these recommendations.

Today, ultrasound is widely recognized by healthcare professionals as an essential method for safe cannulation. Therefore, we again focused on examining cannulation procedures using ultrasound. However, as it was in the previous recommendations, the use of the ultrasound method is not mandatory as, in some circumstances, central venous catheterization may need to be performed without ultrasound equipment. To avoid the confusion of thinking these recommendations are different from those in First Report, this recommendation document is titled “Second Report (Revised edition).”

2) Past primary initiatives for patient safety related to the recommendations (in Japanese)

As of February 2023

○ Safety Committee of Japanese Society of Anesthesiologists
Practical guide for safe central venous catheterization and management 2017 (Revised in June 2017)[2)]

○ CVC Study Group of Conference of Accredited Hospitals for Patient Safety Promotion, Japan Council for Quality Health Care
Guidelines on Central Venous Catheterization and Management (3rd revision, 2020) (published in April 2020)[3)]

○ Project to Collect Medical Near-miss/Adverse Event Information, Japan Council for Quality Health Care
<Medical safety Information>
No. 113 “Air Embolism after Removal of a Central Venous Catheter” (April 2016)[4)]
No. 164 “Central Venous Catheter Guide Wire Left Behind” (July 2020)[5)]
(Abovementioned materials are available in Japanese.)

○ Japan Medical Safety Research Organization (Medical Accident Investigation and Support Center)
Recommendations for prevention of recurrence of medical accidents Number 1
Analysis of deaths related to the complications of “Central Venous Catheterization” - First Report -
(March 2017)[1)]

2. Methods of analysis

1) Extraction of target cases

Of the 1,627 in-hospital investigation reports on medical accidents sent to the ISC (October 2015-December 2020), 72 reports were regarding death related to central venous catheters. Of those, 10 cases were presented in the Recommendations for Prevention of Recurrence of Medical Accidents "Analysis of deaths related to the complications of "Central Venous Catheterization" - First Report -" (March 2017) and in-hospital investigation results for 62 cases were reported thereafter. The 62 cases were: cases related to central venous cannulation, 40; cases related to removal, 4; cases related to a patient pulling out the catheter after insertion, a disconnected line, or other post-insertion management, 9; neonate cases, 2; cases in which the causal relationship between the central venous cannulation and death was unclear, 7.

Of the 62 cases, the Expert Analysis Subcommittee included a total of 44 cases in its analysis: namely the 40 cases and 4 cases where death was suspected to be related to insertion and removal, respectively, of a central venous catheter. The 9 cases related to a patient pulling out the catheter after insertion, a disconnected line, or other post-insertion management, the 2 cases of neonates, and the 7 cases with an unclear causal relationship were excluded. While these recommendations were intended for procedures in adults, some similar pediatric procedures are also included.

2) Collecting and sorting information on target cases

Based on the information on the in-hospital investigation reports sent to the ISC, the Expert Analysis Subcommittee analyzed the cases, and for information requiring verification, we collected additional information to the extent possible with the cooperation of the reporting institutions. The information was organized using the Investigation Items Checklist (see 8. Material).

3) Meetings of the Expert Analysis Subcommittee

○ First meeting: May 13, 2021
○ Second meeting: September 9, 2021
○ Third meeting: November 10, 2021
○ Fourth meeting: December 14, 2021
○ Fifth meeting: February 14, 2022
○ Sixth meeting: April 7, 2022
○ Seventh meeting: April 19, 2022
○ Eighth meeting: July 6, 2022

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

3. About review and analysis of the recommendations in the First Report and the direction of the Second Report (Revised edition)

Analysis of deaths related to the complications of “Central Venous Catheterization” - First Report -includes 10 cases reported during the one year and three months between October 2015 and December 2016. After publishing the recommendations, in the four years to December 2020, 40 similar cases related to cannulation were reported, showing no decrease in the number of cases. Upon reviewing the implementation status of the recommendations in the First Report, we found that the recommendations had not been implemented overall. We suspect that the fact that the First Report did not offer tangible recommendations is a factor in why they had not been correctly implemented. For the revised edition, we aimed to present more tangible procedural methods following a series of steps, and to prepare checklists and other tools that are easy to use in clinical practice. The Second Report therefore covers almost all of the recommendations in the First Report but also includes some new ones. Except for the details of the characteristics and pitfalls of ultrasound described in Recommendation 4 in the First Report, please see Figures 4 and 5 on page 19 of the First Report.

The review and analysis of the nine recommendations in the First Report and primary points in the revised edition based on the review and analysis are presented in the following table.

<<Review and analysis of the recommendations in the First Report>>

	Recommendations in the First Report	Review and analysis of the First Report
Indication of CVC	[Recommendation 1] It is essentially important to become aware that Central Venous Catheterization (CVC) is a hazardous medical intervention having a possibility of fatal complications. Especially, a patient with blood coagulation disorder or with intravascular dehydration has a high potential danger of death and the CVC intervention should be decided after careful discussion, keeping in mind a possibility of substitution of Peripherally Inserted Central Catheter (PICC).	• Although all the cases included were high risk, the healthcare professionals in many of those cases were not aware of the risk of death, so sufficient risk assessment may not have been performed. • Reasons for not selecting a PICC included being not used to using it and having little experience.
Informed consent	[Recommendation 2] Prior to the catheterization, its necessity should be explained to the patient and consent given to the specific risk peculiar to him-/herself as well, and that should be recorded in writing. Especially in the case of serious illness, if CVC is indispensable even after considering the risk of death, it is important for the physician to explain the risk sufficiently and to obtain understanding from the patient or family.	• In more than half of the cases, information about individual risks was not provided, even in high-risk cases. A risk assessment needs to be performed and a way to utilize the results, including risk management, in the explanations needs to be devised.
Intervention techniques	[Recommendation 3] At the start of intervention to the internal jugular vein cannulation, it is recommended to perform ultrasound “Pre-Scan,” for identifying the vein and its appearance (its diameter, collapsed or not), its position (the depth from the skin), and the anatomical relationship to the artery.	• While pre-scanning is becoming more common, it tends to be understood as a tool for internal jugular vein localization, but may not be understood as a tool for risk assessment in advance. • In many cases, the puncture depth was unknown or a long introducer needle was used. It seemed many were not paying attention to the puncture depth. • It has become clear that, in a real-time ultrasound-guided cannulation, the guidewire was not confirmed to be in the target vein with both the short- and long-axis views. • We found that few operators and supervisors have taken simulation training.
	[Recommendation 4] “Real-time ultrasound-guide” has become an essential assisting method for CVC, but at the same time, it has a “Pitfall” that could misguide toward serious complications. It is advised that the operator should receive a training on the simulator in advance.	
	[Recommendation 5] The needles in the “CVC kit” are mostly too long for the internal jugular vein cannulation. Therefore, do not insert beyond the reach of jugular vein. Especially in the case of an emaciated patient, the operator should pay attention not to insert too deep.	
	[Recommendation 6] During the intervention, confirm that the guide wire is in the lumen of intended vein by ultrasound or X-ray fluoroscopy. Especially in the route of internal jugular vein cannulation, the inserted guide wire should not exceed 20 cm in order to reduce the occurrence of arrhythmia and vein wall injury by the guide wire contact.	
Verification of place of the catheter	[Recommendation 7] If sufficient reverse aspiration from the indwelling catheter cannot be seen, the catheter should not be applied as a general rule. Particularly in the case of intravenous double-lumen catheter for dialysis, it is mandatory to confirm the position of the catheter because the malposition of the catheter may cause fatal complications.	• Even when there was no reverse blood aspiration, the catheter was used with the assumption that the catheter tip was against the vessel wall.
Patient care	[Recommendation 8] In the management after the catheter insertion into the central vein, careful observation is necessary, keeping in mind the possibility of fatal complications. If the patient shows newly developed signs, such as a decrease in blood pressure, dyspnea, restlessness, and an unnatural reverse flow in the infusion line, it is necessary to promptly examine and diagnose the possibility of hemothorax, pneumothorax, and airway narrowing as well as of the catheter tip malposition. Physicians and nurses should share all the information and observe the patients' condition, including problems at the time of intervention.	• The problems that occurred during cannulation were not shared, resulting in a failure to recall complications associated with cannulation when the patient’s condition suddenly changed.
	[Recommendation 9] In order to respond promptly to the event of complications, the cooperation with other departments including transfer to other hospitals should be provided in the manual.	• Only in half of the cases was there collaboration with other departments, and few of the clinics had a manual for collaboration with other institutions. The reason for this seems to be a lack of designated department in charge of managing insertion/removal of central venous catheters.

<<Primary points of the recommendations in the Second Report (Revised edition): information added and changed based on the review and analysis of the First Report>>

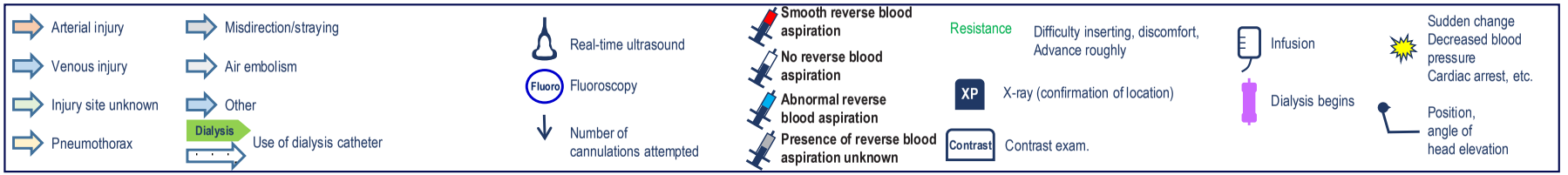
Item		Details
Standardizing risk assessment and determining indications		[Recommendation 1] • Emphasized that the indication needs to be determined after performing the patient's risk assessment using a predefined standardized method and considering the measures for avoiding the risks. • Stated that there are two types of risks (general and anatomical risks) and emphasized the importance of performing a pre-scan in advance as a tool to assess anatomical risks. Have prepared, as a tool to assess risks, "Pre-central Venous Catheterization Checklist (Example)" (Table 1) and posted it on the ISC website. • Included a statement about promotion of training and other initiatives for increased use of PICCs.
Sharing information and risks		[Recommendation 2] • Prepared an "Informed Consent Form for Central Venous Catheterization (example)" that links a risk assessment and informed consent, and posted it on the ISC website.
Cannulation	Taking a time-out*	[Recommendation 3] • Proposed taking a time-out before cannulation to review the risks and share the rules for another operator taking over the procedure and for discontinuing the procedure.
	Selecting introducer needles	[Recommendation 4] • Reiterated the need to perform pre-scan again at the time of cannulation to review anatomical risks such as the presence of vessel collapse and the depth of the vessel. • Emphasized the need to use a needle with a length suitable to the depth of the vein and with a small diameter in order to prevent injury or to minimize the injury to arteries and the surrounding organs.
	Inserting a guidewire	[Recommendation 5] • Emphasized the need to use both the short- and long-axis ultrasound views to check whether the guidewire is located inside the target vein. • Prepared the video "Anatomical diagram of potential guidewire pathways," which enables operators to anticipate veins and other organs into which a guidewire may stray, and posted it on the ISC website.
	Inserting a dilator*	[Recommendation 6] • Added instructions on how to insert a dilator based on the lessons learned from the cases where vascular injury occurred during dilator insertion procedures.
Confirming catheter location		[Recommendation 7] • Emphasized the importance of confirming the catheter's location. • Proposed the idea of suspecting a malposition of the catheter and to obtain an X-ray lateral view if "resistance was met during catheter insertion," "no reverse blood aspiration or smooth aspiration" or " malposition of the catheter is suspected on the X-ray frontal view." • Added images related to catheter tip malposition
How to manage a misplacement into an artery and extravascular placement*		[Recommendation 8] • Included a statement on how to manage misplacement into an artery of a catheter based on the lessons learned from the cases where bleeding occurred due to catheter removal with the recognition that the catheter was misplaced. • Emphasized that even in a case of extravascular placement, a vessel may have been injured and removing the catheter may cause bleeding that leads to a fatal condition.
Patient observation		[Recommendation 9] • Created a "Central Venous Catheterization Record (Example)" (Table 4) for information sharing details of actual central venous catheterizations performed, and posted it on the ISC website. • Emphasized the need to suspect a complication related to central venous catheterization if a breathing problem, tachycardia, or other abnormality occurs within several days after initiation of transfusion, and to discontinue the transfusion and perform a thorough examination.
Air embolisms*		[Recommendation 10] • Added descriptions on preventive measures against air embolisms based on the lessons learned from the cases where catheter insertion/removal caused an air embolism.
Establishing an organized management system		[Recommendation 11] • Emphasized the importance of establishing an organized management system for insertion/removal of central venous catheters.
Dialysis catheters*		[Recommendation 12] • As 13 cases were related to dialysis catheters, we re-presented our recommendation, which we believe to be important in the insertion/removal of dialysis catheters and emphasized it for healthcare professionals involved in dialyses.

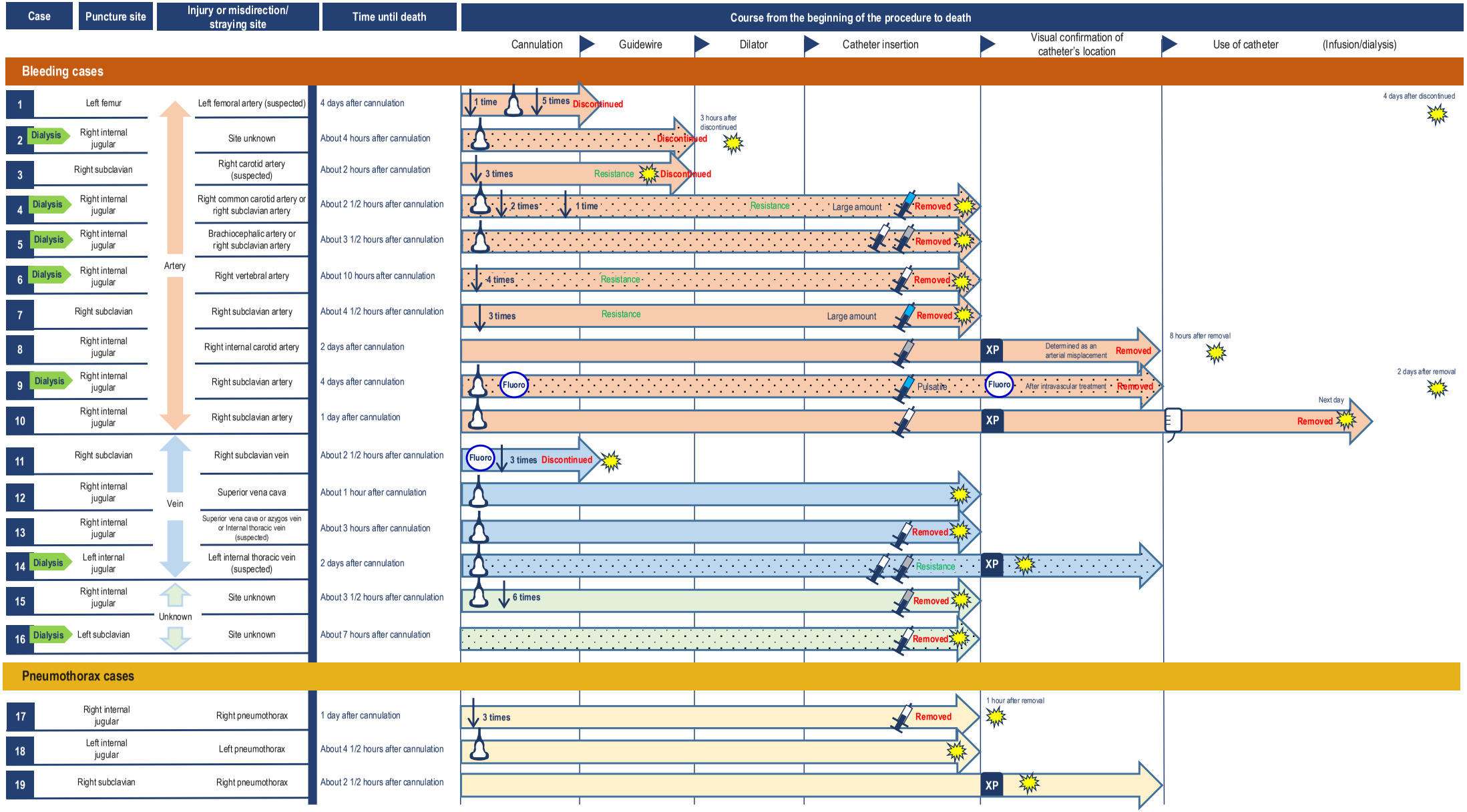
*Newly added recommendations

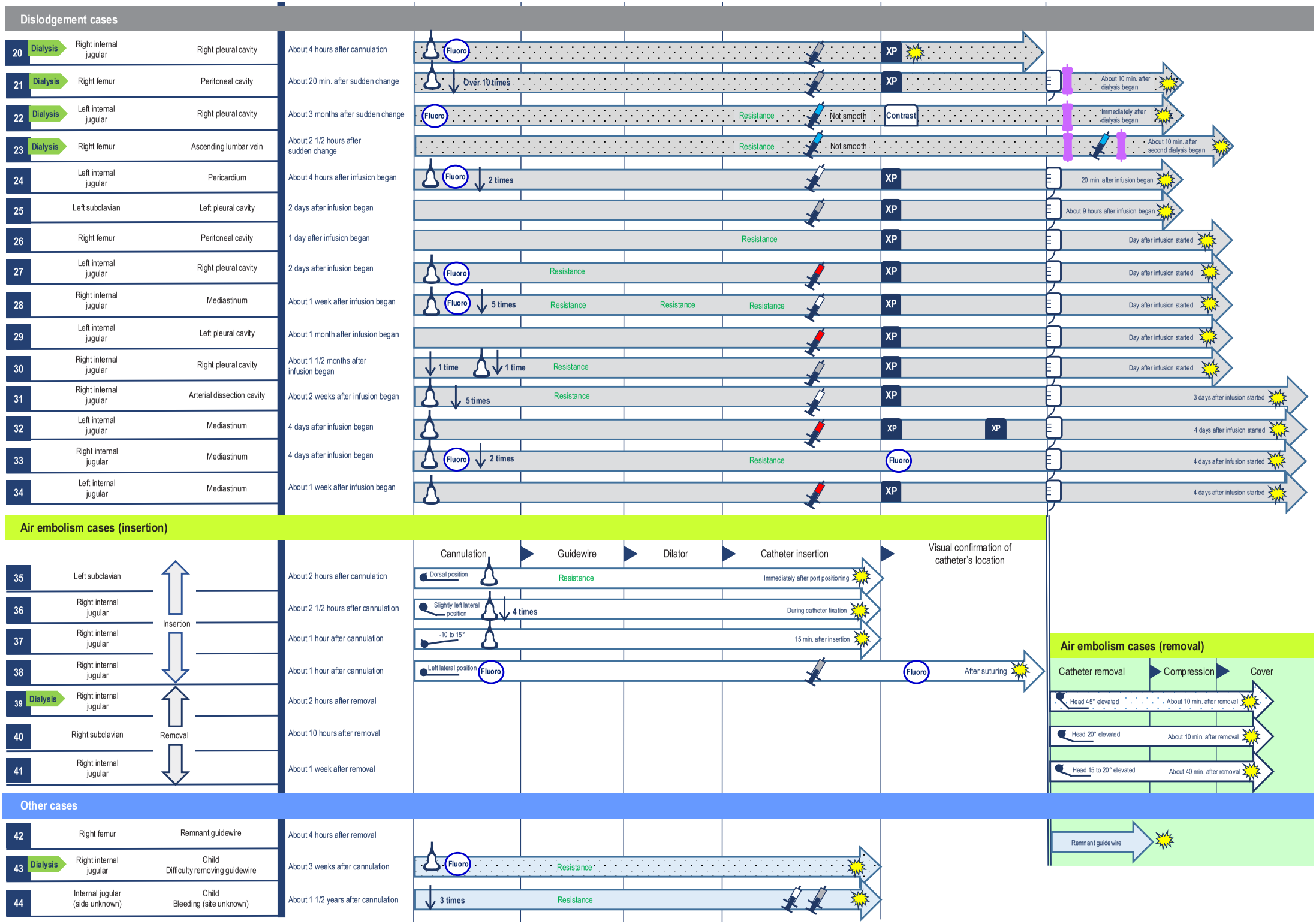
Overview of cases examined

Note 1: This chart has been created based on the in-hospital investigation reports

Note 2: Length of the arrows represent the steps performed in the central vein






Dislodgement cases
20 Dialysis Right internal jugular Right pleural cavity About 4 hours after cannulation Fluoro XP
21 Dialysis Right femur Peritoneal cavity About 20 min. after sudden change Over 10 times XP About 10 min. after dialysis began
22 Dialysis Left internal jugular Right pleural cavity About 3 months after sudden change Fluoro Resistance Not smooth Contrast Immediately after dialysis began
23 Dialysis Right femur Ascending lumbar vein About 2 1/2 hours after sudden change Resistance Not smooth About 10 min. after second dialysis began
24 Left internal jugular Pericardium About 4 hours after infusion began Fluoro 2 times XP 20 min. after infusion began
25 Left subclavian Left pleural cavity 2 days after infusion began XP About 9 hours after infusion began
26 Right femur Peritoneal cavity 1 day after infusion began Resistance XP Day after infusion started
27 Left internal jugular Right pleural cavity 2 days after infusion began Fluoro Resistance XP Day after infusion started
28 Right internal jugular Mediastinum About 1 week after infusion began Fluoro 5 times Resistance Resistance Resistance XP Day after infusion started
29 Left internal jugular Left pleural cavity About 1 month after infusion began XP Day after infusion started
30 Right internal jugular Right pleural cavity About 1 1/2 months after infusion began 1 time 1 time Resistance XP Day after infusion started
31 Right internal jugular Arterial dissection cavity About 2 weeks after infusion began 5 times Resistance XP 3 days after infusion started
32 Left internal jugular Mediastinum 4 days after infusion began XP XP 4 days after infusion started
33 Right internal jugular Mediastinum 4 days after infusion began Fluoro 2 times Resistance Fluoro 4 days after infusion started
34 Left internal jugular Mediastinum About 1 week after infusion began XP 4 days after infusion started
Air embolism cases (insertion)
Cannulation Guidewire Dilator Catheter insertion Visual confirmation of catheter's location
35 Left subclavian Insertion About 2 hours after cannulation Dorsal position Resistance Immediately after port positioning
36 Right internal jugular About 2 1/2 hours after cannulation Slightly left lateral position 4 times During catheter fixation
37 Right internal jugular About 1 hour after cannulation -10 to 15° 15 min. after insertion
38 Right internal jugular About 1 hour after cannulation Left lateral position Fluoro Fluoro After suturing
39 Dialysis Right internal jugular Removal About 2 hours after removal
40 Right subclavian About 10 hours after removal
41 Right internal jugular About 1 week after removal
Air embolism cases (removal)
Catheter removal Compression Cover
Head 45° elevated About 10 min. after removal
Head 20° elevated About 10 min. after removal
Head 15 to 20° elevated About 40 min. after removal
Other cases
42 Right femur Remnant guidewire About 4 hours after removal
43 Dialysis Right internal jugular Child Difficulty removing guidewire About 3 weeks after cannulation Fluoro Resistance
44 Internal jugular (side unknown) Child Bleeding (site unknown) About 1 1/2 years after cannulation 3 times Resistance
Remnant guidewire

4. Recommendations and explanations to prevent recurrence

[Standardizing risk assessment and determining indications]

Recommendation 1

Central venous catheterization should be recognized as a high-risk medical practice (high-risk procedure), which may lead to fatal complications. Risk assessment of the patient's general condition and anatomical risk assessment (pre-scan) should be performed in advance, using a standardized method. If the risk is high, measures to avoid the risk, including the use of a peripherally inserted central catheter (PICC) instead, should be considered. Indications should be determined through discussion.

● Central venous catheterization is a high-risk medical practice (high risk procedure) that may result in a fatal complication.

While central venous catheterization is a routine medical practice for managing a patient's general condition, the general condition of many of the patients who undergo this procedure is serious. When inserting a catheter in patients with low physical reserve, complications should be expected to be fatal. However, of the 40 cases where complications were related to insertion, in 21 cases, the healthcare professionals did not recognize central venous catheterization as a high-risk procedure.

If any abnormalities or problems occur during central venous catheterization, an immediate response is required. Before performing the procedure, operators must recognize central venous catheterization as a medical practice with a high risk of fatal complications such as arterial injury.

● Standardizing risk assessment

The most important factor in safe cannulation is risk assessment. The risks consist of risks to general condition and anatomical risks. It is therefore important to assess both risks of the general condition and anatomical risks in advance and consider measures to avoid them before catheterization. Evaluating risks and considering ways to avoid them provides operators an opportunity to re-think the risk to patients. Ideally, standardizing risk assessment involves preparing and employing a checklist within your institution referencing the "Pre-central Venous Catheterization Checklist (example)" (Table 1).

<Assessing risks to the patient's general condition>

Assessing risks of the patient's general condition means evaluating patient conditions such as intravascular dehydration, emaciation or obesity, and a blood coagulation disorder (see Table 1). Intravascular dehydration can make the target vein difficult to reach, which in turn can cause extravascular placement or incorrect arterial puncture. If the patient is emaciated or obese, the depth of the vessel differs from normal, causing a high risk of inadvertent puncture.[2)] Furthermore, for patients with a blood coagulation disorder, hemostasis would be difficult if vascular injury occurs. Of the 40 cases where the complication was related to insertion, patients showed a sign of dehydration in 19 cases, had low body weight (emaciation, BMI < 20)[2)] in 19 cases, were obese (BMI > 30)[2)] in 3 cases, and had a blood coagulation disorder in 16 cases before central venous catheterization. There were 23 cases where the patients also had a respiratory disorder, and in 1 case, the subclavian vein on the side of the unaffected lung was punctured in a patient with atelectasis, causing pneumothorax on the side of the unaffected lung. If the patient also has a respiratory disorder, any pneumothorax or hemothorax is likely to result in a fatal complication. Especially when the lesion is in one side of the lung, it is vital to be aware that catheter insertion into

the side of the unaffected lung carries a great risk of deteriorating the patient's condition if a pneumothorax forms. In addition, if the patient cannot be placed flat due to restrictions on the patient posture (such as kyphosis and orthopnea), it is not only difficult to increase the diameter of the vein at the time of cannulation, but also tends to cause an air embolism to occur.

<"Pre-scan"; anatomical risk assessment>

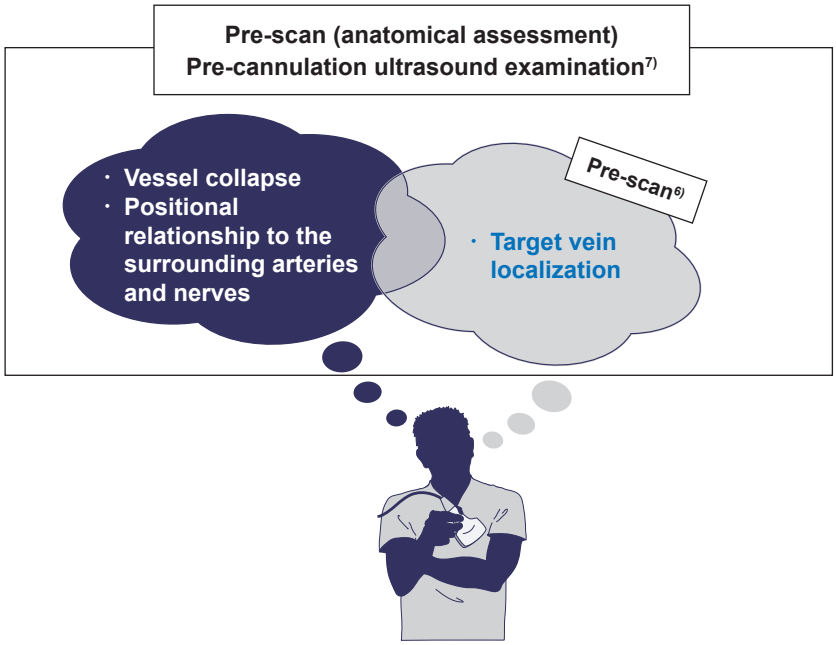
"Anatomical risk assessment" includes assessing the risk of cannulation by determining the condition of the target vein (size and presence/absence of collapse), depth, and positional relationship to the surrounding arteries and nerves using ultrasound (see Table 1). Imaging that covers such risk assessment is called a "pre-scan" (see Column 1).

Of the 29 cases where the internal jugular vein was cannulated, the target vein was evaluated using ultrasound before cannulation in 28 cases. Of those, the size of the vein, presence/absence of collapse, depth, and positional relationship to arteries were evaluated in 16 cases.

Currently, ultrasound is often used only for localization of the target vein immediately before cannulation, but not many doctors in medical institutions perform a pre-scan to assess anatomical risks in advance. However, it is important to assess anatomical risks along with risks of the patient's general condition so as to consider measures to avoid risks related to central venous catheterization. Therefore, a "pre-scan" should be performed not only immediately before cannulation, but also in advance.

Column 1: About the term pre-scan

In Japan, the term "pre-scan" is used to describe a technique with two different purposes. One is imaging performed before static ultrasound imaging for the purpose of vein localization, which was first used by Schummer et al.[6] The other is imaging for the purpose of not just localization of the vein for cannulation, but also to assess anatomical risks by determining the presence/absence of collapse, the positional relationship to arteries and nerves, and other characteristics of the vein. This corresponds to "pre-cannulation ultrasound examination" which is recommended in the guidelines recognized worldwide.[7] Because the same term "pre-scan" describes imaging with two different purposes, the purposes are often mixed up.



Decision to perform central venous catheterization and considering measures to avoid risk

The decision of whether to perform central venous catheterization needs to be discussed based on a comprehensive review of risk assessment of the patient's general condition and the results of the anatomical risk assessment (pre-scan). When the procedure is required despite the risk being high, it should be considered using both available measures and fluoroscopy to minimize the risk (see Table 1).

Considering an alternative method (PICC)

One class of central venous catheters, PICCs, have fewer fatal complications associated with cannulation because they are inserted from a peripheral vein. On the other hand, these catheters are not widely used in clinical settings (see Column 2). Of the 19 cases where an alternative method was considered in order to avoid the risk, a PICC was not used in 6 cases for reasons such as the operator not being familiar with PICC insertion. We hope that PICC insertion procedures become more widely performed as a measure to avoid death arising from central venous catheterization, and hope that operators consider using a PICC as an option especially for high-risk patients.

Column 2: Current situation where PICCs are not used more widely

A PICC is a peripherally inserted central venous catheter that is inserted into a vein in the upper arm. Although PICC placement has been reported as a highly safe method, at present it is not widely used. Factors behind this are the cost of the medical equipment and the need to learn a new skill.

As of December 2022, while the medical service fee points for PICC placement are 700, the points for central venous catheterization other than PICC placement are 1,400. In addition, although the sales price of a PICC kit is higher than the price of other central venous catheterization kits, the insurance reimbursements are about the same. Because, on top of these medical-financial reasons, PICC placement is a different technique from central venous catheterization and one that operators need to acquire separately, so PICCs are still not used widely.

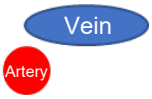
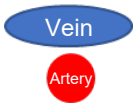
To promote the use of PICCs, medical service fees should be revised, and training for physicians and nurses who have completed the Training for Specified Acts for acquiring the PICC placement technique should become more widely available.

Table 1. Pre-central Venous Catheterization Checklist (Example)

*See Recommendation 1

Patient name				Patient ID					
Date of birth		Age		Height	cm	Weight	kg	BMI	

(1) Risks in general condition Check if yes	Measure to avoid risk	**Implementation of measures** Check if yes (details)
☐ Intravascular dehydration	Consider improving dehydration by rehydrating through a peripheral vein	☐ ( )
☐ Emaciated (BMI < 20)	Pay special attention to the puncture depth (the risk of inadvertent puncture is higher in emaciated patients) Consider using a short needle	☐ ( )
☐ Obese (BMI > 30)	Assess the puncture depth (as the target vein is located deep, the risk of inadvertent puncture is high) Consider an alternative therapy	☐ ( )
☐ Blood coagulation disorder	Consider giving a platelet transfusion, adding clotting factors, etc.	☐ ( )
☐ Antithrombotic medication	Consider taking the patient off the antithrombotic medication	☐ ( )
☐ Respiratory disorder	Reconsider the puncture site carefully (avoid the risk of the unaffected lung developing a pneumothorax by subclavian vein or internal jugular vein cannulation)	☐ ( )
☐ Position restriction (kyphosis, orthopnea)	Consider elevating the legs using an electric bed, etc. (Puncture sites above the heart level pose the risk of an air embolism)	☐ ( )
☐ Restlessness, difficulty communicating	Reconsider the indication of central venous catheterization. If necessary, the catheterization can be done under sedation. However, pay attention to complications arising from sedation.	☐ ( )
☐ Considerably poor prognosis	Reconsider the indication carefully	☐ ( )

(2) Review of anatomical risks	Review items		
Target vein	☐ Internal jugular vein (right/left) ☐ Femoral vein (right/left)	☐ Subclavian vein (right/left) ☐ Vein in the upper arm (right/left) PICC	
	Size: mm Depth: mm	Collapse: ☐ Yes ☐ No	
Positional relation to the internal jugular vein and common carotid artery	☐ Apart 	☐ Partially overlapping 	☐ Completely overlapping 
Organ behind the vein	☐ Yes (☐ artery ☐ lung ☐ nerve ☐ Other:) ☐ No		
Final decision on catheterization ((1), (2))	☐ Yes, catheterization will be performed (☐ under fluoroscopy) ☐ Yes, catheterization with PICC will be performed ☐ No, catheterization will not be performed		
Puncture site	☐ Internal jugular vein (right/left) ☐ Femoral vein (right/left)	☐ Subclavian vein (right/left) ☐ Vein in the upper arm (right/left) PICC	
Comments:			

*See Recommendation 3

Review during time-out			
Informed consent for central venous catheterization	☐ Yes ☐ No (Reason:)		
Allergies	☐ Yes (☐ Alcohol ☐ Iodine ☐ Contrast agent) ☐ No		
Monitoring during procedure	☐ Electrocardiogram ☐ Blood pressure ☐ Oxygen saturation		
Operator	Name		
License to perform central venous catheterization	☐ Yes: In-hospital or academic societies ☐ No		
Assistant	Name	Supervisor	Name
Rules for another operator taking over the procedure or discontinuing catheterization	**(Enter the rules of the organization)** <Example> If the catheter cannot be inserted after three punctures at one site by one operator: a more experienced operator would take over the procedure (one operator only) or discontinue the procedure		

[Sharing information and risks]

Recommendation 2

Patients and their families should be provided with written information on the need for central venous catheterization, the results of their risk assessment, potential complications associated with insertion/removal of the catheter and how complications are managed if they occur, the possibility of another operator taking over the procedure or discontinuing catheterization, and alternative treatments. Especially with high-risk patients, the risk should be shared with the patients and their families by providing information about the need for catheterization even if the risk of death is present.

● Providing information, including the results of the patient's risk assessment

Patients and their families need to be provided with information using an informed consent form advising that central venous catheterization is "a high-risk medical practice that may cause a lethal complication," and if a serious complication occurs, their condition could become worse than before the catheterization or could lead to death. Of the 40 cases where the complication was related to insertion, 34 patients were provided with information on central venous catheterization. Of those, an informed consent form was used in 22 cases and only oral information was provided in 12 cases.

Consent forms that provide information need to use plain language so it is easy for patients and their families to understand the risks and results of the patient's risk assessment (see Tables 1 and 2).

● Risk-sharing with patients/families when the risk is considered high

Of the 17 cases where information on patient-specific risks was provided, information on whether catheterization was needed even if considering the risk of death was provided in 3 cases. It is important to provide the patients/families with information about the need for catheterization, and share the results of the patient's risk assessment, before the catheterization. In particular, when catheterization is deemed necessary for high-risk patients even if considering the risk of death, using an informed consent form to let the patients/families know the reason for the decision and how any complications will be managed if they occur, will help them to understand and the operator to mentally prepare for the procedure. In addition, if informed consent cannot be obtained due to a sudden change in the patient condition, it is also important to provide information after catheterization.

Table 2. Information to provide

☐ Purpose and the specific method of central venous catheter insertion
☐ Risks associated with central venous catheters (complications)
☐ Results of risk assessment (risks to the general condition, and anatomical risks)
☐ How complications will be managed if they occur
☐ Possibility of another operator taking over the procedure or discontinuing catheterization
☐ What will be done if central venous catheterization is not performed (alternative methods)

[Cannulation: taking a time-out]

Recommendation 3

Before cannulation, the operator and the assistant should take a time-out to share the results of the patient's risk assessment as well as the rules for another operator taking over or discontinuing catheterization in case the procedure becomes difficult.

Pre-cannulation time-out using a checklist

Taking a time-out before cannulation and using a checklist (see Table 1) to share the patient's risks, as well as the rules for another operator taking over the procedure or discontinuing the catheterization, ensures that the risks specific to the patient can be reviewed, which leads to safe insertion. For that reason, rules should be established within each medical institution on different operators taking over the procedure or discontinuing the catheterization (see Table 3).

Of the 40 cases where the complication was related to insertion, the operators were aware that they had difficulty during the procedure in 21 cases. Of those, rules or customs to discontinue procedures were in place in 6 cases. In addition, there were 13 cases where the assistant was unable to suggest discontinuation. The reasons included, "The operator was my superior physician," "Only one inexperienced nurse was assisting with the procedure," and "The atmosphere made it difficult to communicate with the operator and suggest halting the procedure."

Taking a time-out before cannulation not only allows for the operator to review the risks, but also to create an atmosphere in which the assistant can suggest, if the operator is having difficulty, to have another operator take over the procedure or to discontinue the catheterization. If the patient's percutaneous oxygen saturation (hereinafter the "SpO_2 level") decreases, the patient complains of pain or other changes in his or her condition during catheter insertion, or the operator experiences difficulty, such as having to make multiple punctures, it is desirable to pause the procedure and consider complications and risks based on the information shared during the pre-cannulation time-out.

Table 3. Examples of information to verify during time-out

☐ Patient's name and date of birth
☐ Results of the patient's risk assessment (risks to general condition and anatomical risks)
☐ Puncture site
☐ Whether consent for central venous catheterization has been obtained
☐ Allergies: alcohol, iodine, contrast agent, etc.
☐ Items to monitor during the procedure: electrocardiogram, blood pressure, SpO_2 level
☐ Operator
☐ Whether the operator is licensed for central venous catheterization
☐ Assistant
☐ Supervisor
☐ Rules for another operator taking over the procedure or discontinuing catheterization

[Cannulation: selecting introducer needles]

Recommendation 4

When cannulating, a pre-scan should be done again to re-evaluate the anatomical risks based on the size, presence/absence of collapse, depth and positional relationship to arteries of the target vein. To prevent or minimize injury to arteries and other organs, the introducer needle used should have a length suitable for the depth of the vein and be as thin as possible.

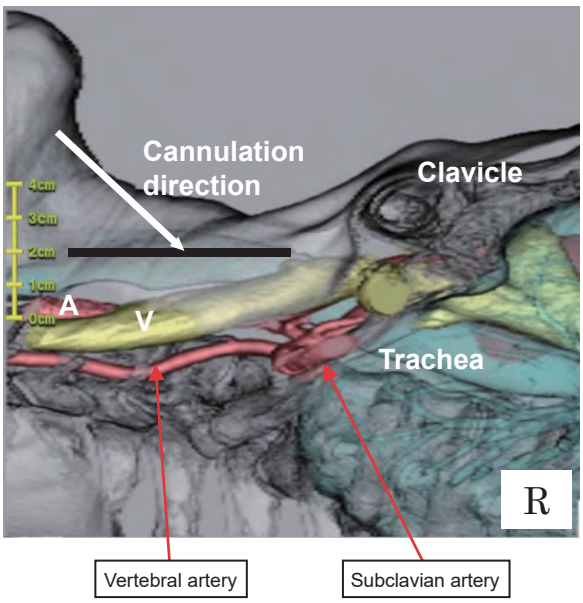
Review the anatomical risks at the time of cannulation

Before starting central venous catheterization, an anatomical risk assessment (pre-scan) should be performed in advance (see Recommendation 1). In addition to the assessment, perform a pre-scan again using ultrasound at the time of cannulation to review the size of the target vein, the presence/absence of collapse, vein depth, overlaps with arteries, and organs located behind the vein. If the pre-scan performed at the time of cannulation shows a collapse of the target vein, attempt to increase the diameter of the target vein by elevating the patient's legs or using other methods. If no improvement is observed, consider another method for safe cannulation such as selecting another puncture site or having an experienced physician perform the cannulation.

Select an introducer needle appropriate for the depth of the target vein

To prevent injury to vessels and organs surrounding the target vein during cannulation, it is desirable to select an introducer needle appropriate to the distance between the surface of the skin and the target vein. Anatomically speaking, the internal jugular vein is located about 1 cm below the skin, and normally venous blood can be aspirated with less than 2 cm of insertion (see Figure 1). In addition, because the internal jugular vein and the common carotid artery overlap each other, using a long introducer needle carries a high risk of a deep insertion, leading to arterial injury and other complications. Therefore, it is important not to insert the needle too deep, especially in emaciated patients.

Figure 1. Depth of the internal jugular vein and its positional relationship to arteries and other organs



When cannulated at an angle of about 30-45° to the skin from the apex of Sedillot's triangle, the needle will reach the internal jugular vein within 2 cm from the apex in the average Japanese physique. At about 4 cm deep, incorrect puncture of the subclavian artery may occur and, at 5 cm deep, a pneumothorax may form. Furthermore, cannulating to 3-4 cm from the medial side may cause inadvertent puncture into the vertebral artery.

Joho Tokumine "Ultrasound-guided Central Venous Cannulation: Establishment of Educational System" *The Journal Of Japan Society For Clinical Anesthesia* 2010;30 (5): 785-791.[8] (Altered with permission)

Of 29 cases where the internal jugular vein was cannulated, an introducer needle longer than 65 mm was used in 7 cases. Of those, an arterial injury occurred in 3 cases. There are two types of central venous catheter kits currently available in Japan: kits that include both short and long introducer needles and kits that include only long introducer needles. To cannulate the internal jugular vein, using a short introducer needle is recommended to ensure safety. To prevent inserting the needle too deep, a needle guide that enables the operator to advance the introducer needle along with the ultrasound scanning surface can also be used. Future development of products based on the concept of foolproofness, such as a needle stopper to which an insertion depth can be configured, is anticipated.

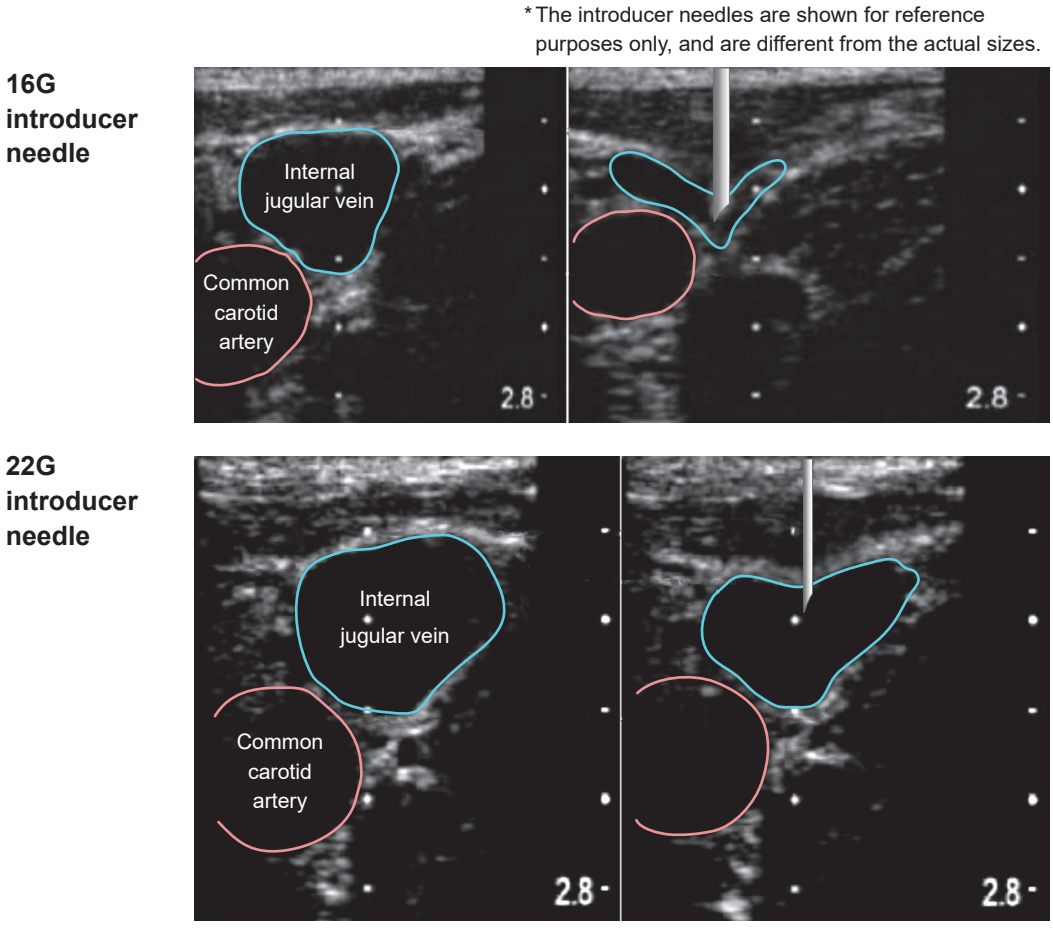
Select a thin introducer needle to minimize an injury

To minimize an injury in case an artery or other organs are incorrectly punctured, a thin needle should be selected. In addition, compared to a thick needle, a thin needle is beneficial in that it can be inserted into the vessel wall with low resistance. Inserting a thick needle into a venous wall that is nearly collapsed causes the vein to collapse due to the needle's insertion pressure, and if that vein is the internal jugular vein cannulation, there is an increased risk of injuring the common carotid artery and subclavian artery located behind the vein. Furthermore, a thin introducer needle can reach the inner cavity of a vein with a lower insertion pressure (see Figure 2).

While the worldwide average (thickness) of the introducer needle for central venous catheters is 18G, smaller 20-22G introducer needles called microneedles are marketed in Japan. To minimize the risk of injury, a thin needle should be selected.

Figure 2. Impact of insertion pressure on veins by introducer needles of different sizes

The images are taken from the same patient. Whereas the 16G needle collapses the vein due to a high insertion pressure, the 22G needle is easy to insert into the vein with a low insertion pressure.



Toshiyasu Suzuki, Safety of Vessel Cannulation from the Viewpoint of Cannulation Equipment: Understanding Cannulation Equipment! *LiSa Collection Central Venous/Arterial Cannulation* Edited by Riichiro Chuma, Toshiyasu Suzuki. Medical Science International, Tokyo, 2011, pp. 50-58.[9] (Altered With Permission)

[Cannulation: inserting a guidewire]

Recommendation 5

Once the guidewire has been inserted into the target vein, both short- and long-axis ultrasound images should be used to check whether the guidewire is located inside the vein. After confirmation, the operator should advance the guidewire slowly, anticipating veins into which the guidewire may stray. If any resistance is met, the guidewire should not be forced ahead. For internal jugular vein cannulation, the guidewire should be inserted no more than 20 cm. Upon removal of the guidewire, check for any guidewire that may have been left behind.

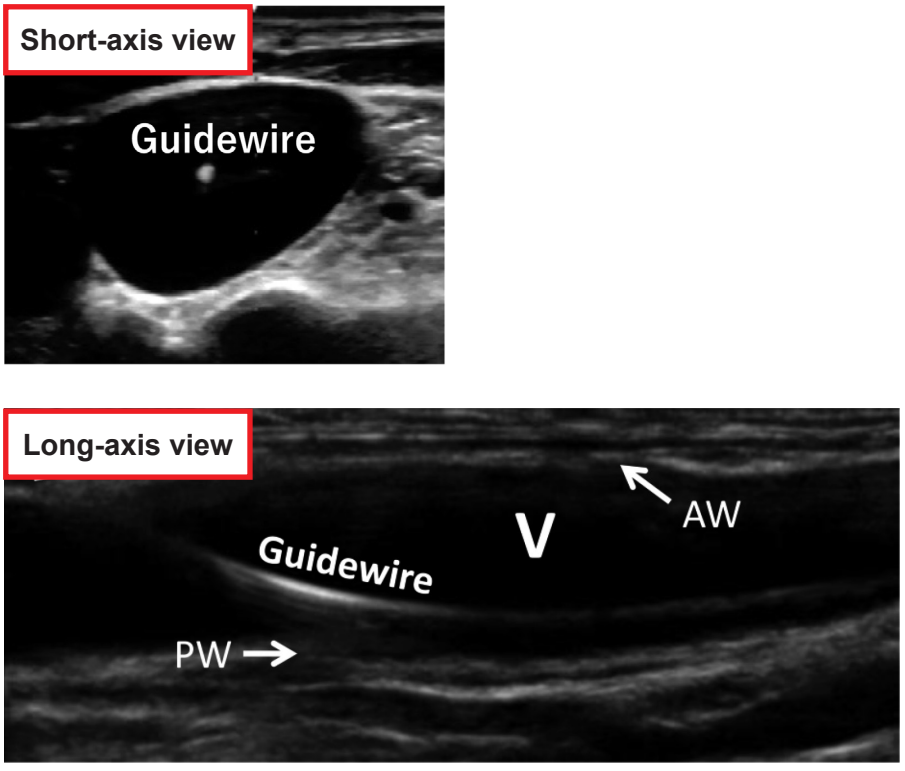
● Using the short- and long-axis ultrasound views, check whether the guidewire is located inside the vein

Even if the guidewire migrates outside the vein and is removed during the guidewire insertion procedure, as the diameters of introducer needles and guidewires are small, it is rare that removal of a guidewire leads to fatal bleeding. On the other hand, because dilator diameters are large and an injury could lead to fatal bleeding, it is important to confirm via both short- and long-axis ultrasound views that the guidewire is inside the target vein before inserting a thick dilator (see Figure 3).

Of the 22 cases where the internal jugular vein was cannulated under real-time ultrasound guidance, the guidewire location was confirmed on the ultrasound image in 8 cases, but there were no cases where the guidewire location was confirmed on both short-and long-axis views. Even if the guidewire appears to be inside the vein on either the short-axis view or long-axis view, it may actually be mispositioned outside the vessel. Therefore, it is important to check the guidewire's location with both short- and long-axis views.

In addition, there are two types of internal jugular vein cannulations: the high approach and the low approach. Compared to the high approach where cannulation starts around the apex of Sedillot's triangle, the low approach where cannulation starts from caudal to the mid-point of Sedillot's triangle makes it difficult to verify the guidewire location using ultrasound. Therefore, to the extent possible, the high approach for internal jugular vein cannulation should be used.

Figure 3. Ultrasound images showing a guidewire inside a vein (short-axis view and long-axis view)



V : vein
AW: anterior wall
PW: posterior wall

Guidance for Safe Insertion and Management of Central Catheter Revision WG, Safety Committee of Japanese Society of Anesthesiologists, *Practical guide for safe central venous catheterization and management 2017*. Tokyo, 2017.[2] (Altered with permission)

The guidewire should not be forced to advance if resistance is felt

After confirming that the guidewire is located inside the target vein, slowly advance the guidewire, anticipating veins into which the guidewire may stay. Anticipating which veins the guidewire could enter requires a thorough prior understanding of the anatomical vessel paths surrounding the puncture site (see Figure 4).

There were ten cases where the operator felt resistance during guidewire insertion. In one case of those ten, the patient condition changed suddenly during guidewire insertion. In the other nine cases, a vessel injury, extravascular dislocation, or other complications had occurred. Normally, resistance is not met during guidewire insertion, so if any resistance is met, misdirection of the guidewire into an unintended vessel should be suspected and the guidewire should not be forced ahead. Furthermore, because using a metal needle poses a risk of guidewire breakage due to withdrawing the guidewire, the guidewire together with the needle introducer should be removed and then re-inserted.

Since ultrasound does not reach deep into the body, even if the guidewire had unintentionally entered a thin vein, it is difficult to confirm the dislocation using ultrasound. Therefore, verifying the guidewire's position under fluoroscopy is recommended. However, since it is difficult to move the patient to the fluoroscopy room during a procedure, especially with high-risk patients, considering the patient's general condition, the cannulation procedure should be performed under fluoroscopy from the beginning.

For internal jugular vein cannulation, the guidewire should not be inserted more than 20 cm.

For internal jugular vein cannulation, the catheter's insertion length is supposed to be about 13 cm (12-15 cm, estimated based on the patient's height) for average adults.[2)] Therefore, inserting the guidewire about 20 cm, should be sufficient.

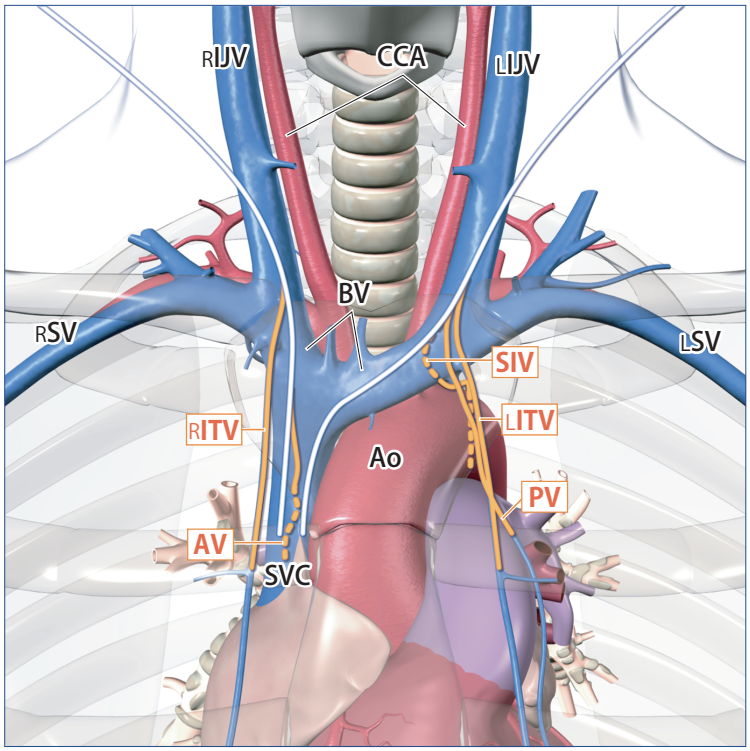
Of the 29 cases where the internal jugular vein was cannulated, the guidewire was inserted further than 20 cm in 5 cases. Deeply inserting the guidewire and worrying about it being accidently pulled out poses a risk of guidewire unintentionally entering a tributary, causing a vessel wall injury, or the guidewire reaching the heart, causing a fatal arrhythmia. To eliminate the risks, a guidewire should not be inserted more than 20 cm.

Preventing remnant guidewire

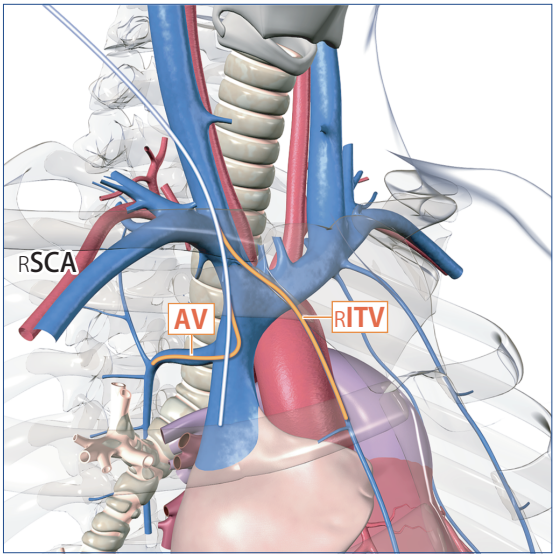
There was a case where a residual guidewire caused a cardiac injury, resulting in cardiac tamponade. Because any remnant guidewire could lead to fatal complications, after catheter insertion, both the operator and the assistant should confirm that the guidewire has been retrieved. In addition, if any remnant guidewire is found in the heart, discuss with relevant departments to decide on how to retrieve it.

Figure 4. Anatomical diagram of potential guidewire pathways

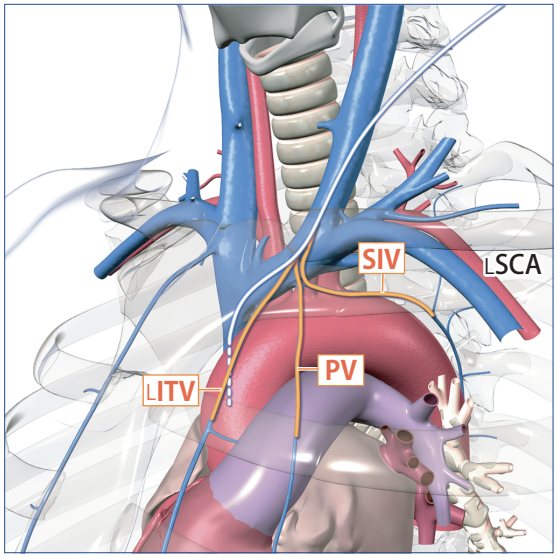
(1) Neck and chest regions



Front



Right side (45°)



Left side (45°)

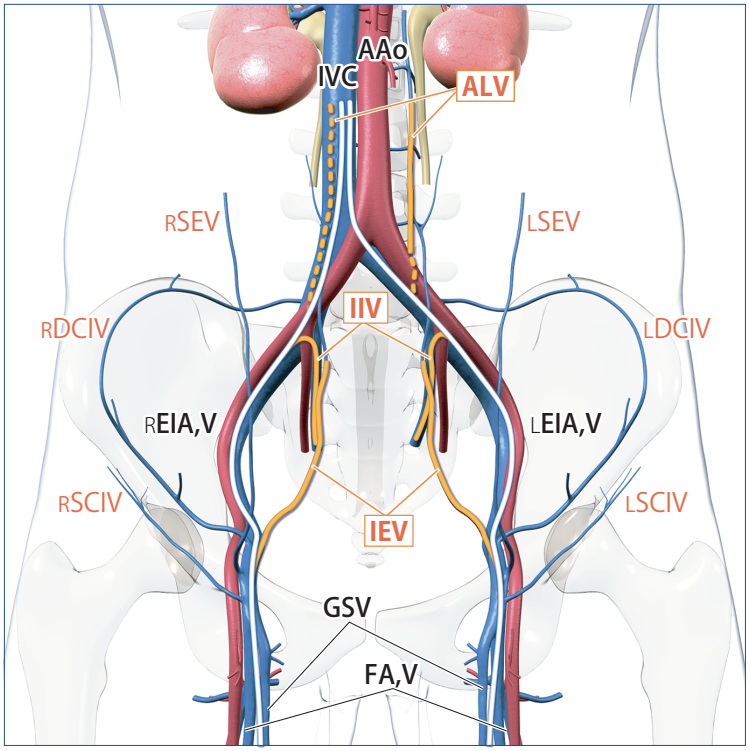
(Abbreviations)

Ao: Aorta AV: Azygos vein BV: Brachiocephalic vein CCA: Common carotid artery IJV: Internal jugular vein
ITV: Internal thoracic vein PV: Pericardiacophrenic veins SCA: Subclavian artery
SIV: Superior intercostal vein SV: Subclavian vein SVC: Superior vena cava

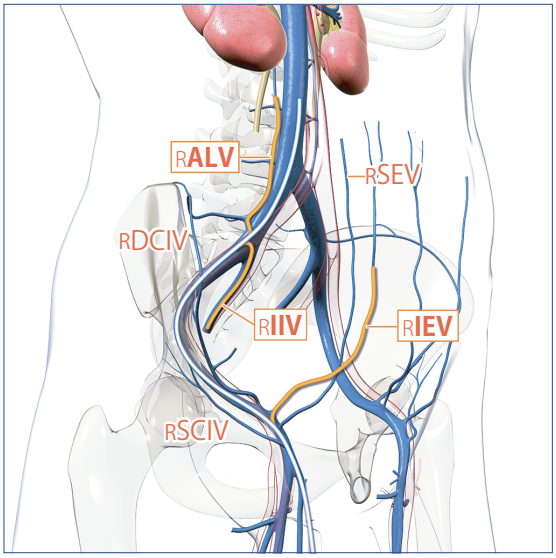
: Correctly inserted guidewire : Misdirected/strayed guidewire

Abbreviations in orange: Veins into which a guidewire may be misdirected or stray

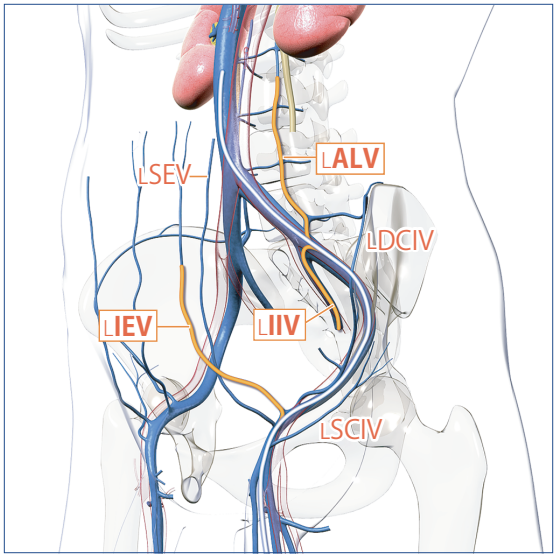
(2) Lumbar and femoral regions



Front



Right side (45°)



Left side (45°)

(Abbreviations)

ALV : Ascending lumbar vein AAo: abdominal aorta DCIV : Deep circumflex iliac vein EIA,V : External iliac artery and vein
SEV : Superficial epigastric vein FA,V: Femoral artery and vein GSV: Great saphenous vein
IEV : Inferior epigastric vein IIV : Internal iliac vein IVC:Inferior vena cava SCIV : Superficial circumflex iliac vein

: Correctly inserted guidewire : Misguided/stray guidewire

Abbreviations in orange : Veins into which a guidewire may be misdirected or stray

[Cannulation: inserting a dilator]

Recommendation 6

Because a dilator is made of hard materials, it presents a risk of causing vascular injury. The dilator should be inserted by gently advancing it along the guidewire without the use of excessive force. It should be inserted no deeper than 5 cm. If the skin is hard, make a small incision with a scalpel.

● Dilator insertion procedure

When inserting a dilator, be sure to pay careful attention to insertion force as well as insertion depth.

Of the 40 cases where a complication was related to insertion, in 36 cases the procedure was performed until catheter insertion. Of those, a vessel injury was presumed to have occurred, likely associated with dilator insertion in six cases. In all these six cases, the dilator was inserted via the right internal jugular vein, and the brachiocephalic artery or vertebral artery had been injured. Owing to the large diameter of the dilator, any vascular damage that might arise could be serious. Therefore, it is important to handle the dilator with the utmost care, paying attention to insertion force as well as insertion depth.

<Force needed to insert the dilator>

The dilator is made to fit the guidewire so that the former can be smoothly inserted along the latter. If the user inserts the dilator too forcefully, the dilator and the guidewire advance together, and the dilator could move straight ahead instead of moving in the direction guided by the guidewire, which could damage the blood vessel. To prevent this, the guidewire should be fixed and the dilator should be inserted gently along the guidewire without the use of excessive force. If the skin is hard and more force is required to insert the dilator, it is important to make a small incision with a scalpel to facilitate smooth insertion of the dilator.

<Dilator insertion depth>

The purpose of using the dilator is to dilate the opening of the anterior wall of the vein at the puncture site so that the catheter can be smoothly inserted. Therefore, there is no need to insert the dilator deeply. The depth of insertion exceeded 5 cm in four of the six cases where a vascular injury caused by dilator insertion was suspected. If inserted too deeply, the dilator may move directly to the posterior wall of the vein and damage the vessel. Except for cases of severe obesity, the depth of insertion should not exceed 5 cm.[2)]

[Confirming catheter location]

Recommendation 7

Malposition of the catheter should be suspected if any of the following apply: “resistance was met during catheter insertion,” “no reverse blood aspiration or smooth aspiration” or “malposition of the catheter is suspected on the X-ray frontal view.” In such case, obtain an X-ray lateral view and, if necessary, perform a CT scan or a contrast examination to verify the catheter's location.

● Importance of confirming catheter location

With regard to peripheral veins, if the injected fluid leaks out of the vessel, that area bulges, allowing the operator to identify dislocation of the catheter. However, for central venous catheters, if the fluid leaks out of the superior vena cava or the inferior vena cava, the fluid will leak into the mediastinum, pericardium, pleural cavity or retroperitoneal space, leaving no indicator of the catheter’s location. Also, there are no absolute indicators that the catheter is located in the intended position. If any of the following applies, the catheter may be mispositioned: “resistance was met during catheter insertion” or “no reverse blood aspiration or smooth aspiration.” In addition, even if the catheter can be inserted without any resistance and smooth reverse blood aspiration is observed, if “the catheter is suspected to be mispositioned in the X-ray frontal view,” the catheter may also be mispositioned. If any of these is observed, malposition of the catheter should be strongly suspected and not only an X-ray frontal view, but also a lateral view should be obtained to verify the catheter’s location. If CT scanning or a contrast examination is available, the catheter’s location can be confirmed more accurately.

<Resistance during catheter insertion>

Normally, no resistance should be met during catheter insertion. There were 21 cases where the procedure was performed to the point of visual confirmation of the catheter’s location in images. Of those, the operator felt resistance during catheter insertion in six cases. In these six cases, the catheter had unintentionally strayed into: the mediastinum, 2 cases; the pleural cavity, 2 cases; and the peritoneal cavity and the ascending lumbar vein, one case each. If resistance is met during catheter insertion, there is a possibility of the catheter unintentionally entering the mediastinum or a small vein.

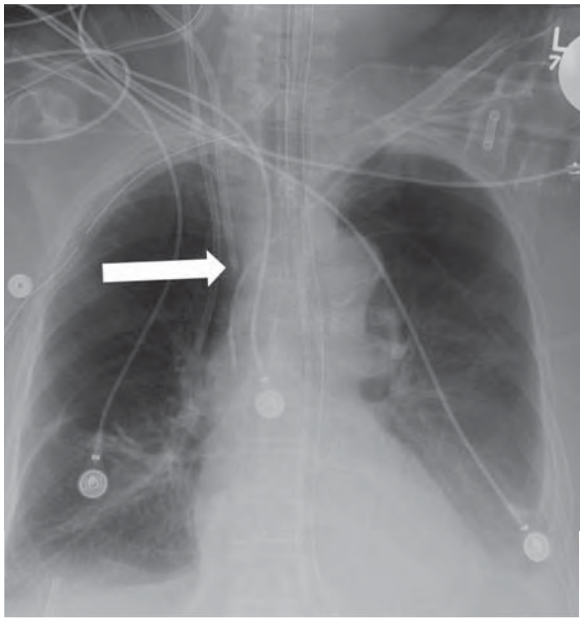
<Reverse blood aspiration from the catheter>

Once the catheter has been placed, there should be reverse blood aspiration, which ensures that the catheter tip is positioned inside the vein. Normally, when venous blood is smoothly aspirated by connecting a syringe and applying slight negative pressure, reverse blood aspiration is considered normal. If no reverse blood aspiration is obtained from the catheter, the catheter has likely been placed outside the vessel. Of the 21 cases where the procedure was performed up to the point of visually confirming the catheter’s location, reverse blood aspiration was obtained upon catheter placement in 18 cases. Of those, reverse blood aspiration could be smoothly aspirated in four cases, reverse blood aspiration was not obtained in four cases, and reverse blood aspiration was obtained but smooth aspiration was not possible in two cases. In the four cases where reverse blood aspiration was not obtained, there were cases where the operator started an infusion assuming that “the catheter tip is against the vessel wall,” or “the vein is severely dehydrated or collapsed” because saline solution was able to be injected. However, the catheter had actually strayed into the mediastinum, pleural cavity, or false cavity of the dissected brachiocephalic artery. Even if the catheter tip migrated outside the vessel and had unintentionally entered the pleural cavity or other cavities, the solution could still be infused. Therefore, if reverse blood aspiration is not obtained, the catheter should not be assumed to be inside the vein, even if the solution can be infused.

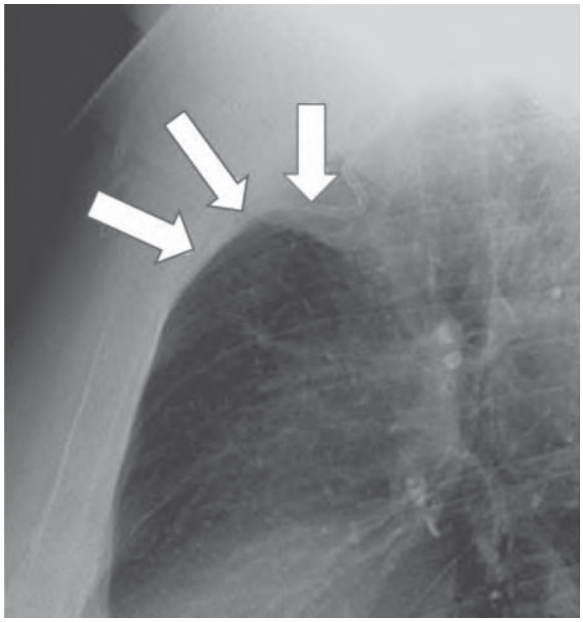
Examining the two cases where reverse blood aspiration could not be smoothly aspirated, one of those was a case where the catheter had strayed into the pleural cavity, forming a hematoma. Some literature reports poor reverse blood aspiration due to the catheter unintentionally entering the left internal thoracic vein (see Figure 5). While the determination of "whether the blood was smoothly aspirated" is subjective, if reverse blood aspiration cannot be smoothly aspirated, the catheter should not be assumed to be inside the vein because the situation may be that leaked blood or hematoma is being aspirated.

Figure 5. Example of the catheter location being difficult to confirm in the X-ray frontal view only, due to poor reverse blood aspiration

(1) Frontal view



(2) Lateral view



A catheter was inserted into the right internal jugular vein and the catheter tip was determined to be approximately in the appropriate position in the superior vena cava according to the X-ray frontal view (1). However due to poor reverse blood aspiration, an X-ray lateral view (2) was obtained, which showed that the catheter had strayed into the left internal thoracic vein.

Roldan CJ, Paniagua L: Central venous catheter intravascular malpositioning: causes, prevention, diagnosis, and correction. West Journal of Emergency Medicine. 2015; 16 (5): 658-664.[10] (Altered with permission)

<If catheter malpositioning is suspected in the X-ray frontal view>

The chest X-ray frontal view may show that the catheter tip is in a desirable position even if it has strayed into an unintended vein, making it difficult to determine.

To confirm the catheter tip's position via X-ray, it is important to interpret the image based on anatomical knowledge. Because a catheter is placed inside a vein, if an X-ray view shows the catheter at a location where no veins exist, the catheter should be considered as mispositioned. Taking into account the information obtained during cannulation (such as resistance during guidewire insertion), inadvertent arterial insertion, or straying into an unintended vein, the pleural cavity, the peritoneal cavity, or the mediastinum must always be suspected while verifying the catheter's location. (See Figure 4 for veins into which a catheter may stray.)

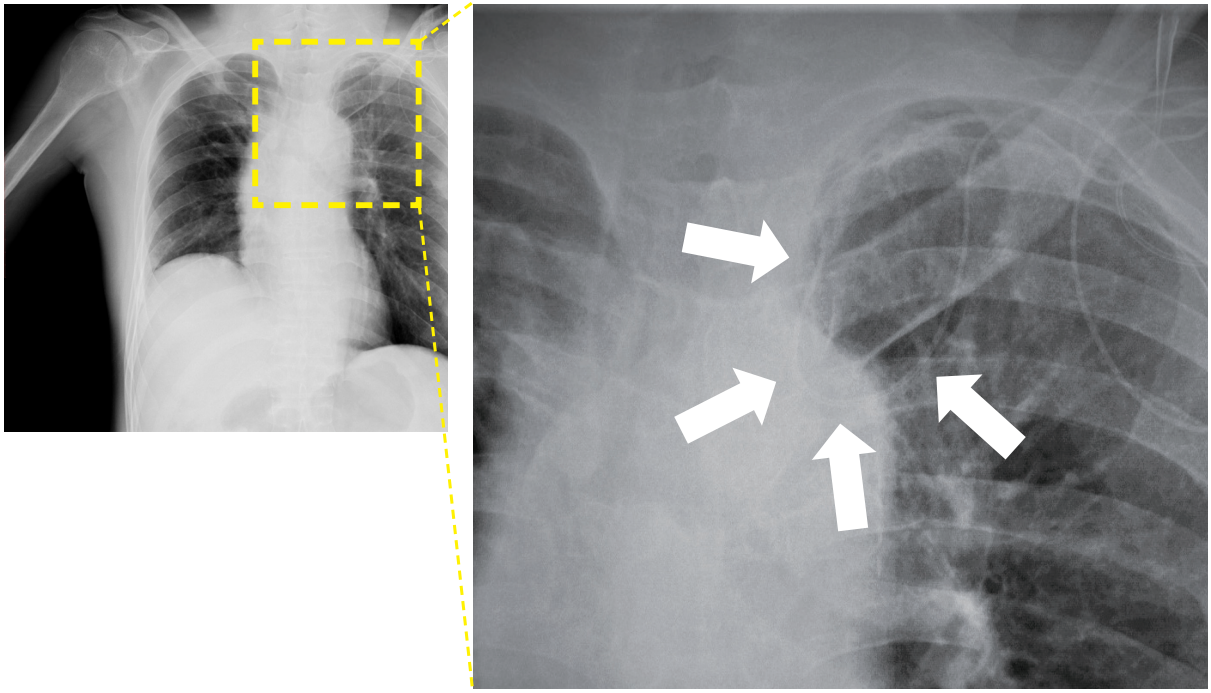
Of the 21 cases where the procedure was performed until the point of confirming the catheter's location in images, the catheter tip position was visually verified in 20 cases. There were 16 cases where the location was verified in the X-ray frontal view. Of those, catheter malpositioning was suspected in seven cases. In none of those seven cases was the catheter location reverified using an X-ray lateral view, a CT scan, or a contrast examination. When the catheter's malposition is suspected in the X-ray frontal view, with extravascular placement in mind, the location should be reassessed in an X-ray lateral view, a CT scan, or a contrast examination (see Figure 6).

In addition, depending on the patient's position (oblique position), medical condition, and other conditions such as scoliosis, the catheter may seem to be in a desirable position on the X-ray frontal view even when the catheter tip has strayed into an unintended vein, making the actual position difficult to determine. In particular, the insertion length of the catheter that has strayed into the azygos vein will appear to be significantly shorter, in the X-ray frontal view, than it actually is because the catheter runs in the posterior side. Therefore, if there is a difference between the insertion length and the imaged length, it is important to suspect misdirection of the catheter into an unintended vein. If correct placement of the catheter inside the target vein cannot be absolutely ascertained, obtain an X-ray lateral view or perform a CT scan or a contrast examination, and then have multiple physicians verify the catheter's location.

Of the seven cases where a malposition was suspected, in three cases the catheter's position was adjusted by either pushing it further in or withdrawing it. In the two cases where the catheter was pushed in a few centimeters, the catheter tip had strayed into the mediastinum or the pleural cavity. Advancing a catheter without using a guidewire is dangerous as it may puncture the venous wall with its tip. Also, in the case where the catheter was withdrawn a few centimeters, the catheter's location was not verified by X-ray after the withdrawal, and the catheter tip had strayed into the pericardium. This demonstrates that when the catheter's position is adjusted, the location must be reverified by X-ray or other methods.

Of the cases where a dialysis catheter was inserted, there were some where the catheter's location was not verified by X-ray. Especially when inserting a dialysis catheter, verification of the catheter's location with a contrast examination should be considered. This is because using a mispositioned catheter can lead to a fatal complication (see Recommendation 12).

Figure 6. Image based on which catheter malpositioning was suspected



Although catheter malpositioning was suspected in the X-ray frontal view, the tip of the catheter, which was inserted into the left subclavian vein, was assumed to be in the left internal jugular vein (arrows). On a later day it was found, by performing a CT scan, that the catheter tip had strayed into the left pleural cavity. When the X-ray frontal view suggests malpositioning of the catheter, the catheter's location should be verified by obtaining an X-ray lateral view, or in some cases, performing a CT scan or a contrast examination.

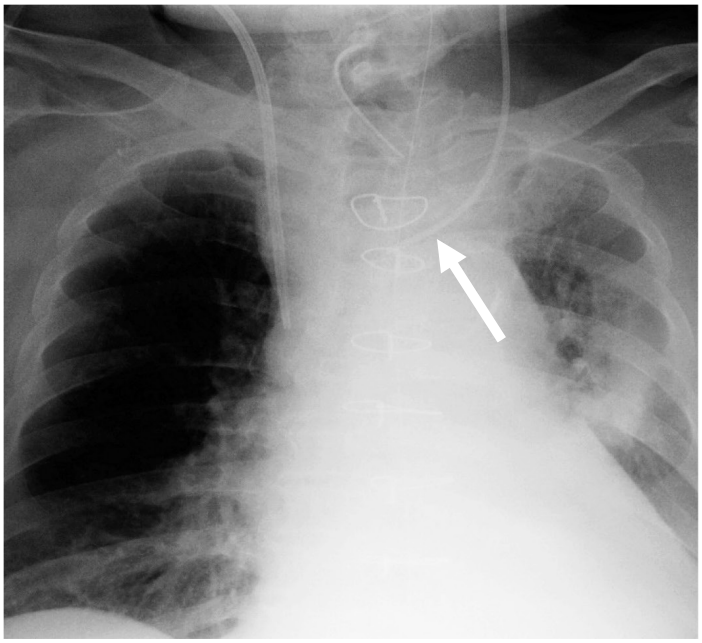
Column 3: A case where the catheter tip was in a vein immediately after insertion, but had migrated outside the vessel four days later

The tip of a catheter placed in the left internal jugular vein or the left subclavian vein may be shifted by movement of the neck or breathing, as the path to the optimal location of the catheter tip is a winding one. Some reports show that compared to the catheters placed in the right internal jugular vein, the catheters placed in the left internal jugular vein are more likely to be moved.[11] In one case among those examined in this document, although the catheter was correctly placed in the left internal jugular vein at the time of insertion, malpositioning of the catheter tip was discovered several days later.

When a catheter is inserted into the left internal jugular vein or the left subclavian vein, even if the catheter tip is placed parallel to the venous wall, the catheter tip may come into contact with the venous wall or stray into a thin vein due to the movement of the catheter and may end up puncturing a venous wall.

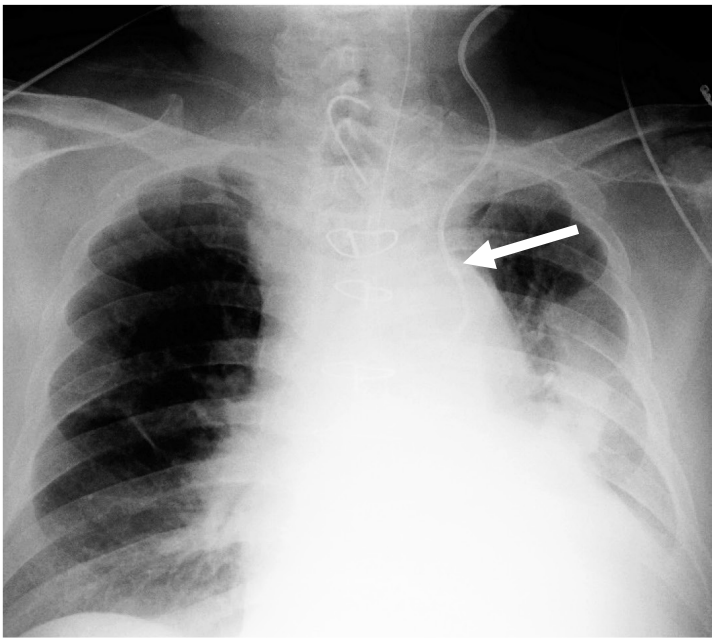
(1) The day catheter was inserted

The tip of the central venous catheter was in the left brachiocephalic vein (the left innominate vein peripheral to the superior vena cava).



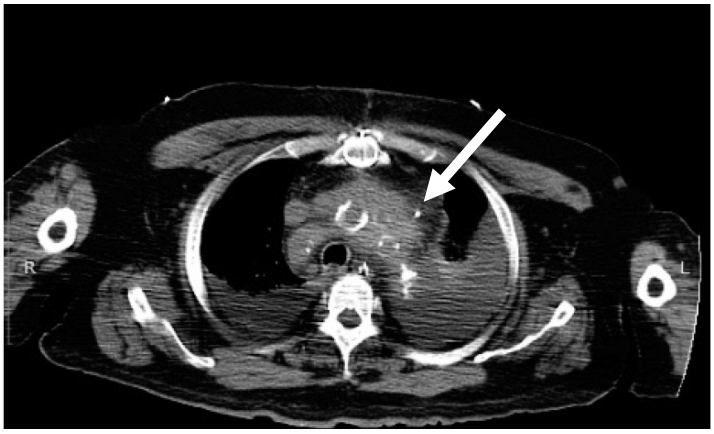
(2) 3 days after the catheter insertion

The catheter tip had moved to a different position.

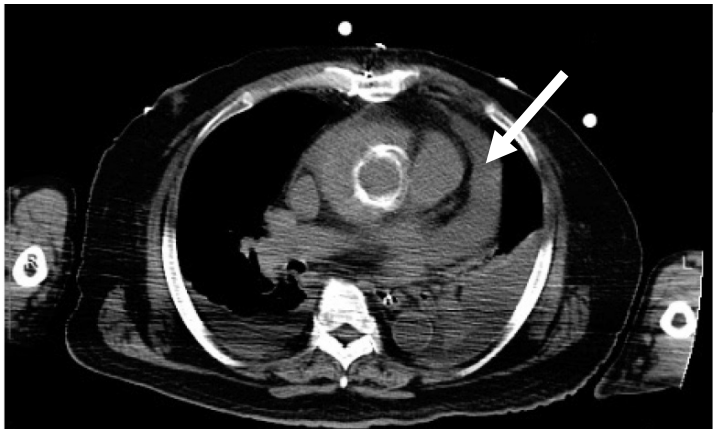


(3) 4 days after catheter insertion

A CT scan was performed due to ventricular fibrillation, and showed that the catheter tip had migrated outside of the left edge of the aortic arch (the arrow in Figure A). After the surgery for aortic dissection, the pericardium was opened, causing cardiac tamponade (the arrow in Figure B).



(Figure A) The catheter is located outside the vessel (arrow)



(Figure B) Finding of cardiac tamponade (arrow)

Column 4: What we think about optimal location for catheter placement

The optimal position for central venous catheter tip placement can be rephrased as “a position where the fewest complications associated with catheter placement are likely to occur.” Complications associated with catheter insertion besides infection include: (1) arrhythmia or heart injury; (2) cardiac tamponade; (3) venous wall injury; (4) straying of the catheter into an unintended vein; and (5) thrombus. Thrombi are more likely to form when the catheter tip is positioned between the brachiocephalic vein and the upper part of the superior vena cava.[12),13)] In addition, catheters can move an average of 9 mm[14)] with a breath and about 2-3 cm with a body movement.[15)] When the catheter tip is positioned above the superior vena cava, the possibility of the catheter tip dislodging into an unintended small vein increases, leading to venous wall injury. With these factors as their backdrop, many guidelines published worldwide state that the optimal position for a central venous catheter tip with the lowest probability of complications occurring is “between the lower third of the superior vena cava and the upper third of the right atrium.”[16),17),18)]

Regardless of the location of catheter placement, even when the catheter tip is placed parallel to the venous wall, movement of the catheter may bring the tip into contact with the venous wall, resulting in venous wall injury due to its physical pressure. The wall can be injured even with a soft catheter. Furthermore, an injury to the wall of the right atrium in which a catheter is placed can lead to a cardiac tamponade. In Analysis of deaths related to the complications of “Central Venous Catheterization” - First Report -, we stated “In an X-ray frontal view, it is ideal that the catheter runs almost parallel to the vessel wall within the shadow of the superior vena cava, the tip lies caudal to the inferior border of the clavicle, in the third intercostal space or between the thoracic vertebra 4 and 5, and is cranial to the bifurcation of the trachea or the base of the right main bronchus.”[19)] The reason we stated this was that in order to avoid the most serious complication, cardiac tamponade, the catheter tip needs to be positioned cranial to the pericardial reflection. After publication, we received some comments from several medical institutions indicating that the position we specified might be slightly too high. However, since not all medical institutions are able to promptly respond to cardiac tamponade that has occurred, we suggested a position cranial to the pericardial reflection as the optimal position.

In addition, for dialysis catheters, placement in the right atrium is also being discussed. This is because inserting not deeply enough will lead to poor blood removal.

[How to manage a misplacement into an artery and extravascular placement]

Recommendation 8

Because improper removal of a catheter misplaced in an artery may cause fatal bleeding, the catheter must not be removed right away. Even with an extravascular placement, there is a possibility that a vessel has been damaged. Therefore, if a misplacement into an artery or extravascular placement occurs, consider performing a CT scan or a contrast examination and consult with relevant clinical departments.

How to manage when a misplacement into an artery is determined or suspected

If a large amount of pulsatile flashback from the catheter is observed, there is a possibility of misplacement into an artery.

Of the 40 cases where the complication was related to insertion, there were 36 cases where the procedure was performed up to the point where the catheter insertion was completed. Of those, misplacement into an artery was suspected due to pulsatile reverse blood aspiration after catheter insertion in five cases. In one of those five cases, misplacement into an artery was diagnosed based on a contrast enhanced CT scan, after which the cardiovascular surgery department was called for assistance. In the other four cases, the operator determined misplacement into an artery and then removed the catheter. In all four cases, operators attempted hemostasis by manually applying pressure or other methods; however, the patients died of hemorrhage within several hours to two days after the removal.

Removing the catheter when the catheter is misplaced in an artery may lead to bleeding where hemostasis cannot be achieved by applying pressure and cause airway compression due to hemothorax or hematoma, resulting in a fatal condition. In addition, in the case where the cardiovascular surgery department was called for assistance after catheter removal, the bleeding site could not be identified because the catheter had been removed. When misplacement into an artery is determined or suspected, because removing the catheter causes severe bleeding, making it difficult to identify the bleeding site, a CT scan or angiography should be performed with the catheter still in place to verify the catheter's location. The risk of fatal bleeding after catheter removal is high especially when the patient is undergoing anticoagulation therapy or has a blood coagulation disorder.

When a catheter is misplaced in an artery or misplacement is suspected, before managing the possible misplacement it is desirable to consult with the vascular surgery, thoracic surgery, neurosurgery, radiology, cardiovascular internal medicine, or other relevant clinical departments to prepare an environment where hemostasis can be achieved by surgical repair under direct vision or endovascular treatment. For that, a system that enables operators to consult with other departments should be established at the institution. Furthermore, establishing a collaboration system for emergency situations, such as that patients can be transferred to another medical institution due to difficulty with managing the condition within the medical institution, is also important.

How to manage extravascular placement

If reverse blood aspiration from the catheter is not obtained, even after the central venous catheter has been placed, there is a possibility that a vessel was injured during catheter insertion, and removing the catheter may cause bleeding. Of 36 cases where the procedure was performed until catheter insertion, there were 6 cases where reverse blood aspiration was not obtained during catheter insertion, and when the catheter was withdrawn a few centimeters or removed, the patient's condition suddenly changed. A vessel was injured in all of these cases. If reverse blood aspiration cannot be obtained during catheter insertion, it is important, taking into account the possibility of a vessel injury, to consider performing a CT scan or a contrast examination without withdrawing the catheter improperly. Especially, when multiple cannulation attempts were made due to the difficulty of the procedure, the introducer needle may have come into contact with the arterial wall; therefore, the situation needs to be managed with an arterial injury in mind.

In addition, there was a case where a day after a catheter was placed and infusion was initiated, accumulation of pleural effusion was observed, and a CT scan indicated that the catheter had strayed into the pleural cavity. When the catheter was removed, the blood spurted out, leading to death. Later, it was found that the catheter had passed through an artery. Even if extravascular placement is found after catheter insertion, the situation needs to be managed in the same way as discovering extravascular placement immediately after insertion.

[Patient observation]

Recommendation 9

The physicians and nurses who manage the patient after catheterization should observe the patient, being aware of the catheterization details. If (1) dyspnea, decreased SpO_2 level, tachypnea; (2) tachycardia, decreased blood pressure; or (3) restlessness is observed from immediately after the start of the catheter use to several days after the catheterization, extravascular placement of the catheter should be suspected, and the transfusion should be discontinued first, and then a thorough examination should be performed.
Even if the catheter could not be inserted, the patient should be observed, keeping in mind the possibility of a vessel injury during cannulation.

● Being aware of the details of the central venous catheterization

After central venous catheterization, it is important to observe the patient, being aware of the details of the catheter insertion and taking into account possible complications.

Of the 13 cases where the solution was infused, multiple cannulation attempts were made in 6 cases, resistance was met during guidewire or catheter insertion in 6 cases, and reverse blood aspiration was not obtained from the catheter in 4 cases. Multiple attempts at cannulation increases the risk of a vessel injury. Furthermore, if resistance is met during guidewire or catheter insertion or reverse blood aspiration cannot be obtained, there is a greater possibility of the catheter not being placed in the target vein. It is desirable to keep records of the details on the catheterization because the physicians and the nurses who manage the patient after the insertion, being aware of the details, can, if a complication occurs, link the patient's condition to the insertion procedure. Patients should be observed based on such information along with the results of the patient's risk assessment before catheterization. Please refer to "Central Venous Catheterization Record (Example)" (see Table 4).

● The patients should be observed with complications associated with central venous catheterization in mind for several days after initiation of infusion

In the 13 cases in whom a solution was infused, the catheter tip had migrated outside the vessel. The sites into which the catheter had strayed were: the pleural cavity, five cases; the mediastinum, four cases; the peritoneal cavity, two cases; the pericardium, one case; and false cavity of the dissected brachiocephalic artery, one case. Of the cases where the catheter tip had strayed into the mediastinum, there was a case in whom the catheter moved, which caused a delayed vessel injury resulting in cardiac tamponade (see Column 3).

If dyspnea, decreased SpO_2 level, tachypnea, tachycardia, decreased blood pressure, or restlessness is observed after initiating infusion, there is a possibility of extravascular catheter placement. Of the 13 cases where a solution was infused, deterioration of respiratory symptoms, such as decreased SpO_2 level, or development of conditions such as decreased blood pressure occurred on or the day following initiating infusion in eight cases, and there was also a case where symptoms appeared between the day following and the fourth day of infusion. Time elapsed before a symptom appears differs according to the site where the catheter was placed, such as the pleural cavity and the mediastinum, as well as the rate of infusion. Therefore, it is important for the physicians and the nurses who manage the patient after catheterization to observe the patient, keeping the fact that symptoms can appear even days after catheterization in mind.

If symptoms appear after initiating infusion, discontinue the infusion first

If deteriorating respiratory symptoms, such as decreased SpO_2 level, or development of conditions such as decreased blood pressure occurred after a catheter was placed and infusion was initiated, malpositioning of the catheter should be suspected and the infusion should be discontinued for the time being.

There was a case where occurrence of a respiratory symptom was assumed to be worsening of asthma, and so infusion was continued, but the catheter tip had strayed into the pleural cavity. There was also a case where adrenaline infusion was administered via a central venous catheter when the patient condition changed suddenly, but the infusion was being administered into the pleural cavity. In these cases, when a symptom appeared, the drug infusion was continued without realizing that the symptom was related to the central venous catheter.

When symptoms appear, the first thing to do should be to discontinue infusion. Furthermore, as the possibility of extravascular placement is high, verifying the catheter's location with a CT scan or a contrast examination is important.

In addition, when using an infusion pump, keep in mind that the occlusion alarm may not be triggered even if the solution is being injected into an artery. There was a case where an infusion pump was used and the solution kept being infused into a false cavity of the dissected aorta.

Even if the procedure is discontinued, there is a possibility that a vessel has been injured

Even if a procedure is discontinued after being unable to insert a catheter, a vessel may have been injured. There were four cases where the patient condition suddenly changed a long time after the procedure was discontinued. These were: a case where the patient's neck swelled during the procedure and the patient entered cardiorespiratory arrest about three hours later; a case where the patient experienced dyspnea about eight hours after catheter removal due to inadvertent arterial insertion; a case where retroperitoneal bleeding occurred two days after cannulation; and a case where the patient suddenly entered cardiorespiratory arrest four days after the procedure had been discontinued due to being unable to insert a guidewire.

Even if a catheter cannot be placed, there might be a vessel injury associated with the cannulation. Especially when an artery has been inadvertently punctured or there is a possibility of a vessel injury due to multiple cannulation attempts, the changes in vital signs and respiratory symptoms need to be monitored for several days.

Table 4 Central Venous Catheterization Record (Example) Date: , 20

Patient name		Patient ID	
Date of birth		Age	

Details of procedure			
Catheterization date			Date , 20 ( )
Start time/End time			Start time : am/pm to End time : am/pm
Flow of cannulation	Patient position		☐ Flat dorsal ☐ Legs elevated ☐ Other ( )
	Puncture site		☐ Internal jugular vein (right/left) ☐ Subclavian vein (right/left) ☐ Femoral vein (right/left) ☐ Vein in the upper arm (right/left) PICC
	Collapse of target vein (during cannulation)		☐ No ☐ Yes
	Introducer needle		Length ( ) cm Size ( ) G
	Puncture depth		( ) cm
	Insertion length	Guidewire	( ) cm
		Dilator	( ) cm
		Catheter	( ) cm
	Resistance during insertion	Guidewire	☐ No ☐ Yes
		Catheter	☐ No ☐ Yes
	Smoothness of flashback	During cannulation	☐ Smooth ☐ Not smooth aspiration ☐ No aspiration ☐ Pulsatile
		After catheter placement	☐ Smooth ☐ Not smooth aspiration ☐ No aspiration ☐ Pulsatile
	Image confirmation of catheter location		☐ X-ray (Frontal/Lateral) ☐ CT (with contrast/without contrast) ☐ Contrast
	Change in patient condition		☐ No ☐ Yes (☐ Dyspnea ☐ Decreased SpO_2 level ☐ Tachypnea ☐ Tachycardia ☐ Decreased blood pressure ☐ Restlessness ☐ Pain (site:) ☐ Other ( ))
Verification of complication(s) at the end of the procedure			☐ No ☐ Yes (☐ Hematoma formation ☐ Hemothorax ☐ Pneumothorax ☐ Inadvertent arterial puncture ☐ Other ( ))
Insertion length/fixation			Fixed at the length of ( ) cm Suture ☐ Yes ☐ No
Start of infusion	Start time		: am/pm
	Immediately before infusion		Infusion resistance ☐ No ☐ Yes
			Poor drop ☐ No ☐ Yes
	Patient condition at start of infusion Note: continuously observe		☐ No ☐ Yes (☐ Dyspnea ☐ Decreased SpO_2 level ☐ Tachypnea ☐ Different breathing sounds between right and left ☐ Tachycardia ☐ Decreased blood pressure ☐ Restlessness ☐ Other ( ))

Enter if multiple cannulation attempts made or discontinued	
Number of cannulations attempted	( ) times
Introducer needle	☐ The same introducer needle was used for all attempts ☐ Different introducer needle was used: Length ( ) cm Size ( ) G
Surgeon change	☐ No ☐ Yes (Reason)
Insertion discontinued	☐ No ☐ Yes (Reason:)

[Air embolisms]

Recommendation 10

An air embolism is a fatal complication and may occur associated with insertion/removal of a catheter into or from the internal jugular vein or the subclavian vein. To prevent air embolisms, the catheter should be inserted/removed with the patient's legs elevated or other positions that increase venous pressure. After catheter removal, the puncture site should be covered with an airtight dressing.

Air embolisms associated with catheter insertion/removal

An air embolism is one of the fatal complications associated with insertion/removal of a central venous catheter. In particular, air embolisms occur more frequently during insertion/removal of the catheter into/from the internal jugular vein or the subclavian vein (see Column 5).

Of the 44 cases examined, 7 resulted in an air embolism. An air embolism occurred during catheter insertion in four cases and during removal in three cases. Puncture sites were: internal jugular vein, five cases; subclavian vein, two cases.

An air embolism can occur when a large amount of air enters a vein through the opening of the introducer needle or catheter or the catheter removal site when the catheter insertion site is above the heart level, the patient strains (strong air aspiration after coughing), or the venous pressure is low due to dehydration. With an internal jugular vein or subclavian vein approach, an air embolism could occur because the catheter insertion site may be above the heart level. On the other hand, with a femoral vein approach, an air embolism is not likely to occur because the pressure of the femoral vein is unlikely to become negative.

Preventing air embolisms during catheter insertion

During central venous catheter insertion, when the vein and atmosphere meet, such as while removing the inner cylinder of the introducer needle, or inserting a guidewire or catheter, air tends to be aspirated. To prevent air from being aspirated, it is important to perform the procedure with the patient placed in a way that the insertion site is below heart level. Of the four cases where an air embolism occurred during catheter insertion, in two cases, the patient was placed in a left lateral position due to kyphosis, causing the puncture site to be higher than the right atrium. In one case, cannulation was initiated with the patient in the right lateral position to reduce low back pain and later, the patient was repositioned into a dorsal position due to difficulty with cannulation.

For the internal jugular vein or subclavian vein approach, the catheterization should be performed with the patient's legs elevated or other positions to increase the venous pressure as a measure to prevent air aspiration. If a position that increases the venous pressure cannot be obtained, the procedure should be performed with the patient holding his/her breath, where he/she breathes in as much as possible and holds it. If breath holding is difficult, the catheter can be inserted while the patient is exhaling without being allowed to talk. When the patient is not allowed to talk, it is important for the assistant to observe the patient's general condition including facial expressions.

On the other hand, there was a case where an air embolism occurred even with the patient's legs elevated. Because reduced venous pressure, which can cause an air embolism, can occur due to dehydration or inspiration, keep in mind that an air embolism may not be prevented by the patient's position only.

Prevention of air embolisms during catheter removal

In the three cases where an air embolism occurred during catheter removal, the catheter was removed with the patient's head elevated (15-45°) due to kyphosis, dyspnea, or pain.

With venous pressure decreased, air may be aspirated into the vein through the catheter removal site. As with preventing air embolisms during insertion, the removal should be performed with the patient in a position that increases venous pressure to prevent air from being aspirated and with the patient holding his/her breath by breathing in and holding it. Be aware that an air embolism, a fatal complication, can occur during catheter removal and perform the procedure by getting as much cooperation as possible from the patient.

An airtight dressing is desirable for covering the removal site

One factor associated with air embolisms during catheter removal is fistula formation at the catheter insertion site. Fistulas are caused by prolonged placement of a catheter, a large-diameter catheter (such as dialysis catheters), and dermal fragility (such as emaciation and malnutrition). As the internal jugular vein is located only about 1 cm from the skin, even if a formed fistula is not visible with the naked eye, the removal site might not be blocked, posing a risk. For removal from the subclavian vein, as the catheter is inserted passing through the greater pectoral muscle, unless a visible fistula is observed, the skin and veins are unlikely to meet. If the patient is emaciated, however, the greater pectoral muscle has thinned and is close to subcutaneous tissues and so may meet with veins.

Unless the removal site is occluded immediately after removal, air will be aspirated as respiration restarts. For that reason, gauze is commonly used to apply pressure to the removal site; however as gauze is air-permeable, it is not suitable as the covering. The duration of catheter placement in the three cases where an air embolism occurred during removal was two to four weeks. In all cases, pressure was manually applied on the site for three to five minutes after removal and then gauze was secured with breathable tape. When removing the catheter, taking fistula formation on the skin into account, removal site should be covered with an airtight dressing immediately after removal and pressure should be applied for a minimum of five minutes. Even if fistula formation cannot be observed with the naked eye, whenever formation is suspected, longer application of pressure should be considered. When a fistula is likely to form due to emaciation or other conditions, suturing of the removal site should also be considered. The removal site should be covered with an airtight dressing for 24-72 hours. In addition, observation of the patient after removal is also important (see Column 6).

Column 5: Mechanism of air embolisms

An air embolism occurs when air enters a blood vessel through the puncture site or catheter. Air may enter the pulmonary artery or systemic circulation, or a retrograde flow of air may enter the cerebral venous network, which can cause a serious condition.

1. [When air enters the pulmonary artery]

The air that entered the blood vessel through the punctured vein, traveled through the right ventricle and the pulmonary artery and reached the lungs embolizes the pulmonary capillaries, causing hypoxemia, shock, or disturbance of consciousness.

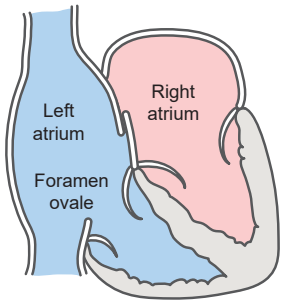
2. [When air enters systemic circulation]

Air entering systemic circulation embolizes critical organs such the brain and heart.

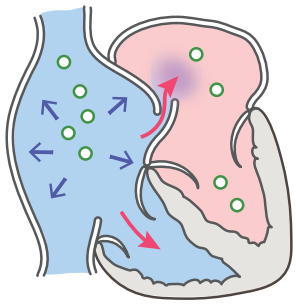
(1) Involvement of the foramen ovale: Increased pressure in the right atrium causes opening of the foramen ovale in one out of three to five people, allowing air into systemic circulation.

Images of the foramen ovale

Normal state
Right atrial pressure < left atrial pressure



During straining or being severely dehydrated
Right atrial pressure > left atrial pressure



(2) Involvement of arteriovenous shunts in the lungs: In patients with chronic respiratory diseases, air enters systemic circulation through arteriovenous shunts, many of which exist in the lungs.

3. [When retrograde flow of air enters the cerebral venous network]

A large amount of air that progressed upward from the internal jugular vein and was collected in the cavernous sinus blocks cerebral perfusion, causing a retrograde cerebral air embolism.[20)]

Column 6: How to manage when an air embolism is suspected

The initial response determines the prognosis of a cerebral air embolism. When an air embolism is suspected, the recommendation is to immediately occlude the catheter insertion site or the removal site and place the patient in the left lateral position with his/her head tilted down.20) This position makes it possible to prevent air further entering into the vein and moving into the heart and the brain. Next, help should be gathered while initiating oxygenation. If resuscitation is necessary, BLS and ACLS* should be performed. If the general condition is stable, hyperbaric oxygen therapy should also be considered in order to prevent a prolonged cerebral disorder.

*BLS stands for Basic Life Support and is a type of care provided in response to a cardiorespiratory arrest or a respiratory arrest. ACLS stands for Advanced Cardiovascular Life Support and is an emergency medical care provided in medical institutions. ACLS is the most known ALS (Advanced Life Support).

[Establishing an organized management system]

Recommendation 11

The manager of a medical institution should manage the organization system regarding insertion/removal of central venous catheters. The manager should define a responsible department (team) to: (1) be aware of the current status of insertion/removal, including occurrence of complications, manage adverse events if any occur, and review past cases; (2) select a safe location and equipment for performing, focusing on safety; (3) prepare a manual that describes how to respond and collaborate in case an abnormality occurs; and (4) consider establishing an educational system.

● Establishment of a permanent organizational management system for insertion/removal of central venous catheters.

Since central venous catheter insertion/removal is performed in various clinical departments, a department (team), within the organization, should be defined as being in charge of management and implementation of measures. For example, a clinical department that performs the greatest number of central venous catheterizations or that responds when a mechanical complication occurs, or a patient safety department, are candidates for being such a department. Alternatively, a working group that consists of various occupations can be formed to take on this responsibility. The system should be established according to the size and the situation of the medical institution. In addition, this department should hold periodic meetings to implement the following daily management of central venous catheter insertion/removal and manage the situation in case of an adverse event.

(1) Being aware of the current insertion/removal situation including occurrence of complications, managing the situation in case of an adverse event, and reviewing past cases

Establish a system for being aware of the current central venous catheter insertion/removal situation, including the occurrence of adverse events, and gather information for the department (team) in charge of management and implementation of measures. The department provides advice on how to manage an adverse event if one occurs, and examines and evaluates past cases in order to apply the information to daily management (non-emergency management).

(2) Securing a place to perform procedures and select equipment, focusing on safety

Of the 40 cases where complications were related to insertion, the central venous catheter was inserted in a patient room in 17 cases. The desirable situation is to select a place where X-ray fluoroscopy can be performed or vital signs can be monitored, according to patient risk.

Also, selection of safety-focused equipment is important. To prioritize safety, introduce sets of introducer needles that are as thin as possible and consider ultrasound equipment suitable for central venous cannulation.

(3) Preparing a manual that describes how to manage and collaborate in case an abnormality occurs

Of the 44 cases examined, 21 medical institutions had an in-hospital collaboration system in place in case of a patient's sudden change of condition, and of those, 10 medical institutions had the collaboration system in writing. An in-hospital collaboration system in place in case of a patient's sudden change of condition and an inter-hospital collaboration system according to its size need to be established, and a specific manual containing the information listed in Table 5 needs to be prepared. The system must then be communicated throughout the institution.

Table 5. Information to include in the manual (Example)

- Risk assessment and indication
- Informed consent and its details
- How to insert/remove a central venous catheter
- Observation after insertion/removal
- How to manage in case an abnormality occurs (including inter-department collaboration and inter-hospital collaboration)

(4) Establishing an educational system

Of the 40 cases where the complications were related to insertion, 18 medical institutions had an educational system for central venous catheterization in place and 8 institutions had an in-hospital certification system in place.

Today, an ultrasound-guided procedure is prevalent for central venous catheterization. For safe central venous catheterization, the characteristics of ultrasound and the pitfall of each procedure need to be understood before catheterization is performed. To help understand them, taking simulation training and work to improve catheterization skills is useful (see Column 7).

Medical institutions should try to provide organization-led simulation training. Even when unable to provide the training, it is important for medical institutions to establish a system that proactively encourages their staff to participate in courses and hands-on seminars hosted by other institutions or academic societies and to form a qualification system. In addition, there were cases where PICC was not selected due to the reason of "lack of experience." An educational system that enables nurses who have completed the Training for Specified Acts and physicians to acquire PICC skills should be established.

Furthermore, it is desirable to properly manage the progress of central venous catheterization (including PICC) simulation training, to be aware of the skills achieved by the operators (team), and, as necessary, to define their privileges.

Column 7: Reason why training is required to perform real-time ultrasound-guided cannulation

While real-time ultrasound-guided cannulation is an excellent method, sufficient prior training is required. That is because dangerous pitfalls exist, such as that even if the introducer needle tip has passed through the target vein, depending on the angle that the ultrasound reaches the vein, the catheter may be imaged as if the tip is inside the vein, leading to misidentification of the tip position. It is advised that the surgeon receive simulation training to grasp the characteristics of ultrasound in advance.

[Dialysis catheters]

Recommendation 12

Regarding dialysis catheters, which have a large diameter, a vascular injury at insertion can lead to serious bleeding. Because the use of extracorporeal circulation without the catheter placed in the target vein will lead directly to fatal complications, when the risk of catheterization is considered high, the catheter should be inserted under fluoroscopy. This enables more reliable verification of the catheter's location.

*Although the following points overlap with Recommendations 5-10, information on dialysis catheters is summarized and presented again.

[Cannulation]

- If the guidewire cannot be confirmed as being in the target vein on both short- and long-axis ultrasound views, the dilator should not be inserted (See Recommendation 5).

[Confirming catheter location]

- If there is a possibility of the catheter being mispositioned, obtain a lateral-view X-ray image and, if necessary, perform a CT scan or a contrast examination to verify the catheter's location. If the catheter is inserted under fluoroscopy, the catheter's location should be accurately ascertained with a contrast examination (see Recommendation 7).
- If blood cannot be drawn during dialysis even though reverse blood aspiration is obtained from the blood removal and return routes at catheter insertion, the route should not be used for blood return. Instead, another measure to better identify the catheter's location should be considered.

[Removal procedure]

- Due to its large diameter, placement of a dialysis catheter tends to form a fistula at the insertion site. To prevent air embolism, the catheter should be removed with the patient's legs elevated or other positions that increase venous pressure, and it is desirable to cover the removal site with an airtight dressing (see Recommendation 10).

● Due to its large diameter, a vascular injury associated with insertion of a dialysis catheter can directly lead to a serious complication.

As the diameter of dialysis catheters is larger than that of central venous catheters and their dilators are also thick and hard, an inadvertent arterial puncture and a vessel injury can directly lead to a fatal complication. There were 12 cases where a dialysis catheter was inserted and of those, a long-term intravascular catheter was inserted in 1 case.

For blood purification therapy, the blood pump works at 150-250 mL per minute in hemodialysis and 80-100 mL per minute in continuous hemodiafiltration, removing and returning blood. Therefore, as a certain level of pressure is applied on the vein, even a very small vessel injury can cause the vessel to break, which could lead to major bleeding. Furthermore, if the catheter is placed outside a vessel or has strayed into a small vein, initiating hemodialysis in such a condition will result in a large amount of extravasation in a short time, which could become fatal. For dialysis catheter insertion, as the equipment has a larger diameter, the impact in case of a vessel injury is large and the complications may be amplified with the initiation of hemodialysis.

- **If the guidewire cannot be confirmed as being in the target vein with both short- and long-axis ultrasound views, the dilator should not be inserted (See Recommendation 5).**

Since migration of a guidewire to outside the vein only will unlikely cause a fatal complication, ultrasound should be used to confirm that the guidewire is located inside the target vein before inserting the dilator.

Of the 12 cases where a dialysis catheter was inserted, the catheter was inserted under real-time ultrasound guidance in 8 cases; however, the guidewire was not verified with both short- and long- axial ultrasound views in any cases. It is important to insert the dilator after confirming with short- and long axial ultrasound views that the guidewire is placed inside the target vein.

- **If there is a possibility of the catheter being mispositioned, obtain an X-ray lateral view and, if necessary, perform a CT scan or a contrast examination to verify the location of the catheter. When the catheter is inserted under fluoroscopy, correct location of the catheter should be verified with a contrast examination (see Recommendation 7).**

Initiating hemodialysis with a dialysis catheter placed outside the blood vessel causes a large amount of blood extravasation in a short time, which may become a fatal complication. Therefore, absolute confirmation that the catheter is placed inside the target vein is required.

Of the 12 cases where a dialysis catheter was inserted, the procedure was performed up to the point of confirming the catheter's location in 4 cases, and of those 4 cases, the catheter's location was verified using images in 3 cases: with fluoroscopy in 2 cases, and with the X-ray frontal view only in 1 case. In all of the three cases where the catheter's location was verified, the operator had determined that the catheter tip was inside the vein by himself/herself but there were findings such as abnormality in the path of the catheter, a small amount of contrast agent leakage, and a bent guidewire. Straying of the catheter into an organ other than the intended vein may be difficult to determine with the X-ray frontal view only. To verify the catheter's location, an X-ray lateral view should also be obtained in addition to the X-ray frontal view, and, if necessary, a CT scan or a contrast examination should be performed. When the catheter is inserted under fluoroscopy, a contrast examination should be performed to verify the correct location of the catheter. In addition, it is desirable that multiple physicians verify the image. If catheter insertion is attempted and meets difficulty in an institution that does not have access to fluoroscopic or contract equipment, consider promptly transferring the patient.

● When the blood cannot be aspirated during dialysis even though reverse blood aspiration is obtained from the blood removal and return routes when inserting the catheter, the route should not be used for blood return. Instead, a measure to better identify the catheter's location should be considered.

At catheter insertion, reverse blood aspiration from the blood removal and return routes should be obtained. The three cases where the patient condition suddenly changed after initiation of dialysis were as follows: reverse blood aspiration was obtained at catheter insertion, but blood could not be aspirated smoothly in one case; whether there was smooth reverse blood aspiration was unknown in one case; and an adequate amount of reverse blood aspiration could not be obtained, but slightly withdrawing the catheter improved the reverse blood aspiration in one case. In the first two cases, even though not enough blood was removed to perform dialysis, because the solution could be infused, the route was used for blood return; however, the catheter had been placed outside the blood vessel, which caused a sudden change in the patient's condition. As hemodialysis flow is high, initiating hemodialysis without the catheter placed in the target vein can lead to a fatal condition in a short time. Therefore, unless the catheter is confirmed as being placed inside the vein, a route that does not allow blood removal should not be used to return blood.

In addition, in the case where a sufficient amount of reverse blood aspiration was not obtained, but slightly withdrawing the catheter improved the amount of reverse blood aspiration, the operator assumed that the catheter tip was in contact with the venous wall and continued using the catheter; however, the tip had strayed into a small vein, which caused the vein to break during the dialysis and take a fatal course. Even when reverse blood aspiration is obtained, if blood cannot be aspirated smoothly, catheter malposition should be suspected and verification of the location should be considered, instead of determining quickly that the catheter tip is simply in contact with the venous wall.

● Owing to its large diameter, placement of a dialysis catheter tends to form a fistula at the insertion site. To prevent an air embolism, the catheter should be removed with the patient's legs elevated or other positions that increase venous pressure, and the removal site should be covered with an airtight dressing (see Recommendation 10).

The diameter of dialysis catheters is large, and they are often placed for long periods of time. Especially when the catheter is placed in the internal jugular vein, the possibility arises that an air embolism could occur during catheter removal. In one of the three cases where an air embolism occurred after catheter removal, the dialysis catheter was removed after placement in the internal jugular vein for about three weeks with the patient's head elevated to 45°.

To increase the venous pressure so as to prevent air from being aspirated during catheter removal from the internal jugular vein, the catheter should be removed with the patient's legs elevated and breath held, with the patient breathing in as much as possible and holding it. After catheter removal, the removal site should be covered with an airtight dressing.

5. What we expect of (or what we want to propose to) academic societies, companies, etc.

We expect academic societies, companies, etc. 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 academic societies, including the Japanese Society of Internal Medicine, Japan Surgical Society, Japan Radiological Society, Japanese Society of Anesthesiologists, Japanese Association for Acute Medicine, Japanese Society for Dialysis Therapy, Japanese Society of Interventional Radiology, Japanese Association for Medical Simulation to continuously promote and disseminate in relation to central venous catheter insertion/removal.

(1) Standardization and dissemination of central venous catheterization

- We would like to see central venous catheterization using real-time ultrasound-guided cannulation, including pre-scans, be standardized and that the standards are promoted using videos and other media.
- We would like to see discussion of where to place dialysis catheters.

(2) Preparation of educational curriculums and promotion of simulation training

- We would like to see standardized educational curriculums prepared for acquiring skills for central venous catheterization.
- We would like to see proactive provision of hands-on seminars as simulation training for acquiring skills for central venous catheterization according to educational curriculums.
- We would like to see, as a prerequisite for obtaining speciality in basic clinical fields that perform procedures (internal medicine, surgery, neurosurgery, anesthesiology, OB-GYN, emergency, general practice, etc.) receiving mandatory simulation training to be considered.

(3) Establishment and promotion of qualification and registration systems for operators and supervisors

- We would like to see that qualification and registration systems for operators and supervisors ensuring the skill of central venous catheterization are established and promoted.
- We would like to see the rule “at least one qualified supervisor is required” to be a core institution for the Specialist Program.

What we expect of companies

(1) Development of cannulation equipment

- With real-time ultrasound-guided cannulation, because the operator looks at the ultrasound tomography image during cannulation, the only way to know that insertion is too deep is by assistants pointing out the fact. For that reason, we would like to see development of a product, such as a needle stopper, that is based on the concept of being foolproof.
- We would like to see introducer needles with a tip enhancement function that prevents inadvertent puncture become more widely available.

(2) Wide availability and promotion of safe equipment

- We would like to see kit products that contain short introducer needles dedicated to cannulation of internal jugular vein, to prevent puncturing too deep, be available.
- Currently, although the selling prices of PICC catheterization kit products are higher than those of central venous catheterization kits, insurance reimbursements are about the same and the medical service fee points are fewer. We would like to see the prices for PICC catheterization kits revised so that PICCs become more widely used.

(3) Wider availability of ultrasound diagnosis equipment

We would like to see a probe specialized for central venous cannulation and general-purpose ultrasound diagnosis equipment that is easy to carry and use become more widely available.

What we expect of the government

(1) Revision of medical service fee points

Currently, although the selling prices of PICC catheterization kit products are higher than those of central venous catheterization kits, the medical service fee points are fewer. We would like to see the medical service fee points for PICC catheterization revised so that PICCs become more widely used.

6. Overview of target cases

The case overview was prepared by the Expert Analysis Subcommittee based on the in-hospital investigation reports and the additional information.

Case 1: Bleeding

(1) The patient was in his/her 70s, with acute respiratory distress syndrome, had undergone mitral valvuloplasty for post-infectious endocarditis and severe mitral regurgitation, and was undergoing dialysis for acute renal failure. Replacement of the dialysis catheter into the right internal jugular vein was scheduled due to suspected infection of the catheter while the catheter was in the left internal jugular vein.

(2) Central venous catheter placement was scheduled after failure of attempted PICC insertion to gain vessel access for administration of fluid.

(3) BMI 41.4 kg/m2. The patient was receiving continuously administered heparin for deep vein thrombosis prophylaxis and arrhythmia.

(4) The left femoral vein was cannulated without using ultrasound. Five cannulation attempts were made; these were done under real-time ultrasound guidance after the first attempt. The guidewire could not be inserted and the procedure was discontinued. A change in the color of the left inguinal region was observed on the following day, but it was not swollen. Four days later, the pulse rate suddenly rose to in the 110s per minute and then the patient entered cardiorespiratory arrest. A tumor mass the size of a child's head was found in the left inguinal region during resuscitation. The patient died on the same day.

(5) Cause of death: Hemorrhage due to (suspected) disruption at the left femoral artery injury site. Ai: present (hematoma about 800 mL). Autopsy: present.

Case 2: Bleeding

(1) The patient was in his/her 60s, undergoing dialysis due to chronic renal failure. The patient had cranial bleeding (left hemiplegia) sequelae.

(2) A dialysis catheter was scheduled for placement due to suspected infection of the subcutaneously fixed superficial arteriovenous site.

(3) BMI 11.6 kg/m^2. Platelet count: in the 100,000s/μL. Antithrombotic medications: No.

(4) The right internal jugular vein was cannulated under real-time ultrasound guidance. No resistance was met during guidewire insertion, but the patient's neck was swollen. The introducer needle was removed and hemostasis was attempted by applying compression with the guidewire in place; however, because the swelling increased, the guidewire was removed to apply compression. The swelling increased from the right neck to the right axilla. Later the patient entered cardiorespiratory arrest and died about four hours after cannulation.

(5) Cause of death: Hemorrhage caused by an arterial injury (suspected). The injury site is unknown. Ai: present. Autopsy: absent.

Case 3: Bleeding

(1) The patient was in his/her 80s, with thrombocytopenic purpura, myelodysplastic syndromes, chronic cardiac failure, and atrial fibrillation.

(2) Central venous catheter placement was scheduled because gaining peripheral vessel access was difficult.

(3) BMI 21.2 kg/m^2. Dehydrated. Platelet count: in the 100,000s/μL. Anticoagulant: Yes, no off-therapy period.

(4) The right subclavian vein was cannulated without using ultrasound. Reverse blood aspiration was obtained during the third exploratory puncture, but no reverse blood aspiration was obtained during the main puncture. Reverse blood aspiration was obtained during another exploratory puncture and main puncture, and the guidewire was inserted but resistance was met. Although the guidewire was withdrawn and inserted 25 cm again, resistance was met. Immediately afterwards, the patient experienced dyspnea and entered cardiorespiratory arrest. The patient died about 1 hour and 30 minutes after the sudden change in condition.

(5) Cause of death: Hemorrhage caused by right carotid artery injury (suspected) and asphyxiation caused by tracheal compression. Ai: present. Autopsy: present.

Case 4: Bleeding

(1) The patient was in his/her 50s, undergoing dialysis for IgA nephropathy and chronic renal failure. The patient had pancreatic cancer and bilateral pleural effusion.

(2) A dialysis catheter (triple lumen) placement was scheduled for shunt occlusion.

(3) BMI 14.7 kg/m^2. Dehydrated. Ultrasound showed collapse of the internal jugular vein. Antithrombotic medications: No.

(4) The right internal carotid vein was cannulated twice using a long needle under real-time ultrasound guidance, but reverse blood aspiration was not obtained. For the third attempt, cannulation was done under static ultrasound guidance and a guidewire was inserted 20 cm. Although resistance was met while inserting dilator 5 cm, the operator assumed it was resistance passing through a vein and inserted the dilator a further 5 cm. As a catheter was inserted, blood spurted out from a part of the route. The operator determined that the catheter had strayed into an artery and removed the catheter. The patient entered cardiorespiratory arrest 10 minutes after the removal and died about 1 hour and 30 minutes later.

(5) Cause of death: pleural hemorrhage caused by injury to the right common carotid artery or right subclavian artery. The dilator penetrated an artery and was dislodged into the pleural cavity (suspected). Ai: present. Autopsy: absent.

Case 5: Bleeding

(1) The patient was in his/her 60s, with acute renal failure, and had undergone colorectal cancer surgery.

(2) A dialysis catheter placement was scheduled for introduction of hemodialysis.

(3) BMI 22.4 kg/m^2. Dehydrated. An internal jugular vein was slightly collapsed. Antithrombotic medications: No.

(4) The right internal jugular vein was cannulated under real-time ultrasound guidance. A dilator was inserted about 12 cm. After catheter insertion, because air was aspirated without reverse blood aspiration, the catheter was withdrawn 10 cm and reverse blood aspiration was obtained. Because the patient's neck was swollen, the catheter was removed. Immediately afterwards, the patient entered cardiorespiratory arrest. A right pleural cavity drainage tube was placed, which removed a large amount of blood. Thoracotomy for hemostasis was performed and a percutaneous cardiopulmonary support system was put in place; however, the patient died about 3 hours and 30 minutes after the removal.

(5) Cause of death: Pleural hemorrhage caused by injury to the brachiocephalic artery or right subclavian artery. Ai: absent. Autopsy: absent.

Case 6: Bleeding

(1) The patient was in his/her 90s, with a right femoral neck fracture and acute exacerbation of chronic renal failure.

(2) A dialysis catheter placement was scheduled for introduction of hemodialysis.

(3) BMI 16.3 kg/m^2. Antithrombotic medications: unknown.

(4) The right internal jugular vein was cannulated using a long needle under static ultrasound guidance. A guidewire could not be inserted, but on the fourth attempt it passed through without resistance and a dilator was inserted. Although a catheter was inserted, it was removed because no reverse blood aspiration was obtained. After that, the patient experienced an SpO_2 level of 80%, decreased level of consciousness, conjugate deviation to the left, and ataxic respiration. MRI showed multiple cerebral infarctions from the brain stem to the cerebellum and a CT scan showed right pleural bleeding. The patient died about 10 hours after cannulation.

(5) Cause of death: Right pleural hemorrhage and brain stem infarction caused by right vertebral artery injury. Ai: absent. Autopsy: absent.

Case 7: Bleeding

(1) The patient was in his/her 60s, with post malignant lymphoma therapy, secondary acute myeloid leukemia, and pleurisy.

(2) Central venous catheter placement was scheduled for chemotherapy.

(3) BMI: 21.8 kg/m^2. Platelet count: in the 20,000s/μL. Antithrombotic medications: No.

(4) Cannulation was performed below the right clavicle without use of ultrasound. After the cannulation, no guidewire could be inserted. For the third insertion, a guidewire and a catheter were inserted; however, because a large amount of reverse blood aspiration was obtained, the operator determined that the catheter was misplaced in the subclavian artery and removed the catheter. The patient experienced dyspnea during manual compression. Because X-ray imaging revealed mediastinum hematoma and right pleural bleeding, cardiovascular surgery assistance was requested. A pleural cavity drainage tube was placed, a skin incision was made, and direct compression was applied to the subclavian artery; however, the bleeding site was unknown. The patient died about 4 hours and 30 minutes after cannulation.

(5) Cause of death: Atelectasis and respiratory failure associated with mediastinum, and right pleural hemorrhage caused by catheter removal after misplacement in the right subclavian artery. Ai: absent. Autopsy: present (hematoma 2,700 g).

Case 8: Bleeding

(1) The patient was in his/her 60s, with TAFRO syndrome and bilateral pleural effusion.

(2) Central venous catheter placement was scheduled because gaining peripheral vessel access was difficult.

(3) BMI: 30.3 kg/m^2. Platelet count: in the 40,000s/μL. Antithrombotic medications: No. The patient had severe edema and tension of the neck, making it difficult to identify arteries and veins even with ultrasound.

(4) The right internal jugular vein was cannulated under static ultrasound guidance. Based on post catheter placement X-ray images and blood drawn through the catheter, the operator determined that the catheter was misplaced in the right internal carotid artery and removed the catheter. A hematoma was found in the neck and was compressed manually. The operator confirmed with ultrasound that the hematoma was not enlarged, and switched to tape compression. About eight hours after the removal, the patient complained of dyspnea and entered cardiorespiratory arrest. The pharyngeal edema was prominent. Cardiopulmonary resuscitation was performed, but the patient died two days later.

(5) Cause of death: Asphyxiation associated with airway edema caused by bleeding and hematoma that developed following catheter removal after misplacement in the right internal carotid artery (suspected). Ai: present. Autopsy: absent.

Case 9: Bleeding

(1) The patient was in his/her 60s, undergoing hemodialysis for diabetic renal disease and chronic renal failure. The patient had undergone percutaneous coronary angioplasty for unstable angina about one month earlier.

(2) Exchange of the dialysis catheters was scheduled due to catheter infection.

(3) BMI: 22.2 kg/m^2. Antiplatelet medications: Yes, dual antiplatelet therapy (whether off therapy unknown).

(4) The right internal jugular vein was cannulated under fluoroscopy and real-time ultrasound guidance. A long needle was used to cannulate, but pulsatile reverse blood aspiration was observed. The guidewire position was verified under fluoroscopy, and the operator determined that the guidewire was placed inside the vein so inserted a catheter. Later, a blood gas analysis and a contrast-enhanced CT scan revealed that the catheter had dislodged into the brachiocephalic artery from the right subclavian artery. After endovascular treatment of the right subclavian arterial injury by cardiovascular surgery, the catheter was removed. Two days later, the patient presented a decreased level of consciousness and was diagnosed with acute cerebral infarction by MRI. Chest CT showed increased bilateral pleural effusion, and ascites in the upper abdomen and blood accumulation in the left retroperitoneum (suspected) was found within the range of the X-ray image. The patient died four days after the removal.

(5) Cause of death: Hemorrhagic shock caused by retroperitoneum bleeding (suspected: bleeding source unknown) or respiratory arrest caused by new cerebral infarction (suspected). Ai: absent. Autopsy: absent.

Case 10: Bleeding

(1) The patient was in his/her 40s, and had developed pneumonia while being connected to a gastrostomy tube and ventilator due to cerebral palsy. Midazolam was frequently being administered intravenously for sedation.

(2) Central venous catheter (triple lumen) placement was scheduled because gaining peripheral vessel access was difficult.

(3) BMI: Unknown (small physique). Antithrombotic medications: Unknown. Ultrasound revealed that the right subclavian artery ran immediately dorsal to the right internal jugular vein.

(4) The right internal jugular vein was cannulated under real-time ultrasound guidance. Although the vein was compressed and unable to be imaged, reverse blood aspiration was obtained. The operator verified the guidewire location with ultrasound and inserted the guidewire 20 cm. No resistance was met during catheter insertion. While reverse blood aspiration was not obtained from the route farthest from the puncture site, it was obtained from two other routes. The operator determined based on X-ray imaging that there were no issues with the location or path of the catheter and so initiated the infusion. On the following day, X-ray imaging showed right pneumothorax and accumulation of pleural effusion, and dislodgement of the catheter into the pleural cavity was suspected via CT. After the catheter was removed, blood spurted out and the patient went into shock. The patient died about one hour later.

(5) Cause of death: Hemorrhage caused by injury to the right subclavian artery (penetration). Ai: absent. Autopsy: absent.

Case 11: Bleeding

(1) The patient was in his/her 50s, in the terminal stage of left lung cancer and was receiving palliative care for metastases to left subclavian skin.

(2) Central venous port placement was scheduled as nutrition management, and gaining peripheral vessel access was difficult.

(3) BMI: 24.3 kg/m^2. Dehydrated. Antithrombotic medications: No.

(4) The right subclavian vein was cannulated under fluoroscopy. Although reverse blood aspiration was obtained during the third insertion, a guidewire could not be inserted. The insertion was discontinued due to dyspnea and an SpO_2 level of 90%. The patient entered respiratory arrest during transfer from the fluoroscopy room to the ward, and died about 2 hours and 30 minutes after cannulation.

(5) Cause of death: Hemorrhage caused by injury to the right subclavian vein and respiratory failure (suspected) associated with bleeding in the right pleural cavity. Ai: present. Autopsy: present (about 1,400 mL of blood in the pleural cavity).

Case 12: Bleeding

(1) The patient was in his/her 60s, with fulminant hepatitis and hepatic encephalopathy, and was undergoing continuous plasma exchange.

(2) Central venous catheter placement was scheduled for nutrition management.

(3) BMI: 26.1 kg/m^2. Dehydrated. Platelet count: in the 50,000s/μL. Antithrombotic medications: No. The operator determined that a catheter should be inserted while the patient was off anticoagulant during exchange of the line for plasma exchange, and so the catheter was inserted at that time.

(4) The right internal jugular vein was cannulated under real-time ultrasound guidance. The operator verified the guidewire's location with the short-axis ultrasound view and inserted the guidewire 30 cm. The patient moved during dilator insertion and the SpO_2 level decreased. The patient presented respiratory irregularity and bradycardia during catheter insertion and entered cardiorespiratory arrest. Cardiopulmonary resuscitation was attempted, but the patient died about one hour after cannulation.

(5) Cause of death: Hemorrhage due to superior vena cava injury caused by guidewire manipulation, while effective circulating blood volume decreased (suspected). Ai: absent. Autopsy: present.

Case 13: Bleeding

(1) The patient was in his/her 60s, with ischemic enteritis, reduced renal function, myelodysplastic syndrome, and type 1 diabetes.

(2) Central venous catheter placement was scheduled because gaining peripheral vessel access was difficult.

(3) BMI: 26.0 kg/m^2. Dehydrated. Platelet count: in the 20,000s/μL. Antithrombotic medications: No.

(4) The right internal jugular vein was cannulated under real-time ultrasound guidance. After inserting a guidewire 15 cm, the operator inserted a dilator about 5 cm and placed a catheter; however, reverse blood aspiration was not obtained and the catheter was removed. After five minutes of compression hemostasis, the patient experienced a decreased level of consciousness, an SpO_2 level of 75% and jaw breathing, and entered cardiorespiratory arrest. Hemothorax was diagnosed with X-ray imaging and a large amount of blood was removed through a pleural cavity drainage tube. The patient died about three hours after catheter removal.

(5) Cause of death: Hemopneumothorax caused by superior vena cava injury, azygos venous injury, or internal thoracic venous injury (suspected). Ai: present. Autopsy: absent.

Case 14: Bleeding

(1) The patient was in his/her 70s, with bilateral lower lobe atelectasis. The patient developed hepatorenal failure after major bleeding post-surgery for cancer of the head of the pancreas and was scheduled to undergo hemodialysis.

(2) A dialysis catheter placement in the left internal jugular vein was scheduled for introduction of hemodialysis.

(3) BMI: 28.5 kg/m^2. Platelet count: in the 50,000s/μL. PT extended. Antithrombotic medications: No. The patient had a central venous catheter in the right internal jugular vein and a sheath from splenic embolization in the right femoral artery, and had a left groin hematoma.

(4) The left internal jugular vein was cannulated under real-time ultrasound guidance. Although no resistance was met during guidewire insertion, after a catheter was inserted 20 cm, no reverse blood aspiration was obtained. When the catheter was withdrawn 10 cm, reverse blood aspiration was obtained, but the catheter could not be advanced back due to resistance. The operator confirmed straying into the pleural cavity with X-ray imaging and suspected a vessel injury. Immediately afterwards, the patient went into shock. A drainage tube was inserted into the left hemothorax site and a large amount of bleeding was found. Emergency thoracotomy was performed. During the surgery, the patient entered cardiac arrest. A percutaneous cardiopulmonary support system was put in place and the thoracotomy incision was closed. On the following day, thoracotomy was performed again for consistent bleeding and the left internal thoracic vein was ligated, but the patient died two days after the cannulation.

(5) Cause of death: Hemorrhage caused by left internal thoracic venous injury associated with dislodgement of the guidewire (suspected). Ai: present. Autopsy: absent.

Case 15: Bleeding

(1) The patient was in his/her 20s, with mixed connective-tissue disease, interstitial pneumonia, and moderate pulmonary hypertension.

(2) Central venous catheter placement was scheduled for nutrition management.

(3) BMI: 21.6 kg/m^2. The patient had leg edema, pleural effusion and ascites, and was dehydrated. Vein identification by ultrasound was difficult due to vessel collapse. Platelet count: in the 20,000s/μL. Antithrombotic medications: No.

(4) The right internal jugular vein was cannulated under real-time ultrasound guidance. Due to difficulty in vessel identification, reverse blood aspiration was not obtained until the sixth cannulation attempt. The operator verified the guidewire location with short-axis ultrasound view. Upon insertion of the guidewire the patient experienced severe pain and also mild dull pain on the right back. Because the pain was reduced by changing the patient's position, the dilator was inserted about 5 cm. When the guidewire was removed, excessive venous hemorrhaging occurred. The site was compressed for hemostasis. Because the catheter was only able to be inserted 10 cm, misplacement into an artery was suspected and the catheter was removed. Immediately afterwards, the patient complained of dyspnea, presented decreased blood pressure and loss of consciousness, and entered cardiorespiratory arrest. A large amount of pleural effusion in the right pleural cavity and deviation of mediastinum to the left were confirmed with X-ray imaging. A pleural cavity drainage tube was inserted, removing about 1,000 mL of hemorrhagic pleural effusion. The patient died about 3 hours and 30 minutes after the removal.

(5) Cause of death: Right pleural hemorrhaging caused by a vessel injury (site unknown). Ai: absent. Autopsy: absent.

Case 16: Bleeding

(1) The patient was in his/her 60s, with multiple myeloma and had undergone intestinal obstruction surgery.

(2) Exchange of the central venous catheter in place and a dialysis catheter was scheduled in order to collect peripheral blood stem cells.

(3) BMI: 18.3 kg/m^2. Antithrombotic medications: Yes, for blood stem cell collection.

(4) Exchange to a dialysis catheter into the left subclavian vein was attempted without ultrasound, but no reverse blood aspiration was obtained. A dialysis catheter was inserted again into the left supraclavicular fossa this time, but again no reverse blood aspiration was obtained. Upon removal of the catheter, the SpO_2 level dropped to 70%. X-ray imaging showed decreased left pulmonary permeability and guidewire dislodgement into the pleural cavity. The catheter was removed. The dialysis catheter was again inserted into the right femoral vein this time; however, while peripheral-blood stem cells were being collected, the patient presented decreased blood pressure and spasm, and entered cardiorespiratory arrest. The patient died about seven hours after cannulation.

(5) Cause of death: Excessive hemorrhaging in the pleural cavity and the perirenal space caused by vessel injury (site unknown). Ai: present. Autopsy: absent.

Case 17: Pneumothorax

(1) The patient was in his/her 70s, and had undergone valve substitution for aortic valve insufficiency. The patient had dementia and aspiration pneumonia.

(2) Central venous catheter placement was scheduled as gaining peripheral vessel access was difficult.

(3) BMI: 13.8 kg/m^2. Anticoagulant: Yes, no off-therapy period

(4) The right internal jugular vein was cannulated under static ultrasound guidance. A long needle was used and a catheter was inserted for the third cannulation attempt, but no reverse blood aspiration was obtained and the catheter was removed. The removed guidewire tip was bent. About one hour after cannulation, the SpO_2 level fell to 80%. Oxygenation and mucus aspiration improved the level. Three hours later, the patient presented wheezing after initiation of tube feeding. X-ray imaging confirmed right pneumothorax so a pleural cavity drainage tube was inserted, but the SpO_2 level gradually decreased. Tracheal intubation improved the level; however, on the day following cannulation, the patient presented decreased blood pressure to the 60s in mmHg and a reduced SpO_2 percentage to the 70s, and CT showed aggravated pneumothorax. Although the position of the drainage tube was adjusted, the respiratory condition deteriorated. The patient died on the same day.

(5) Cause of death: Cardiorespiratory failure associated with tension pneumothorax. There was a possibility that the drainage tube tip had dislodged into the lung tissues that were adhered to the pleura, causing insufficient degassing of the lungs. Ai: absent. Autopsy: absent.

Case 18: Pneumothorax

(1) The patient was in his/her 80s, on a ventilator for aspiration pneumonia (right lung) and had undergone gastric cancer surgery. The patient had disseminated intravascular coagulation syndrome (DIC).

(2) Central venous catheter placement was scheduled for DIC treatment.

(3) BMI: 17.5 kg/m^2. Dehydrated. Platelet count: in the 100,000s/μL. PT extended. Antithrombotic medications: No.

(4) The left internal jugular vein was cannulated using a long needle under real-time ultrasound guidance. A small number of air bubbles entered during cannulation. Immediately after catheter insertion, the patient presented decreased blood pressure and the SpO_2 level became 85%. The patient was diagnosed with left pneumothorax via X-ray imaging. Degassing was applied, but the patient died about 4 hours and 30 minutes after cannulation.

(5) Cause of death: Pneumonia with septic shock and respiratory failure caused by tension pneumothorax of the unaffected lung (left) (suspected). Ai: absent. Autopsy: absent.

Case 19: Pneumothorax

(1) The patient was in his/her 70s with amyotrophic lateral sclerosis, post left thoracoplasty, and left atelectasis.

(2) Exchange of the central venous catheters was scheduled due to suspected catheter infection.

(3) BMI: Unknown. Antithrombotic medications: Unknown.

(4) The catheter was inserted into the right subclavian vein (use of ultrasound and presence/absence of reverse blood aspiration are unknown). X-ray imaging showed no abnormalities immediately after the insertion. About 1 hour and 30 minutes later, the patient presented an aggravated respiratory condition, decreased SpO_2 level, reduced level of consciousness, and lower blood pressure. The patient died about 2 hours and 30 minutes after cannulation.

(5) Cause of death: Acute respiratory failure caused by pneumothorax of the unaffected lung (right). Ai: absent. Autopsy: absent.

Case 20: Stray catheter

(1) The patient was in his/her 70s, undergoing dialysis for chronic renal failure.

(2) Transition to hemodialysis and long-term dialysis catheter placement were scheduled for peritonitis due to long-term peritoneal dialysis.

(3) BMI: Unknown. Antithrombotic medications: Unknown.

(4) The right internal jugular vein was cannulated under real-time ultrasound guidance. The location of the catheter was verified as necessary using fluoroscopy. Upon insertion of a long-term intravascular catheter, reverse blood aspiration was obtained. The tip of the guidewire used was bent. During catheter fixation by suturing, the blood pressure decreased. The operator confirmed by X-ray imaging that there were no abnormalities in the catheter tip position and that pneumothorax was not present. Immediately afterwards, however, the patient presented decreased level of consciousness and entered cardiorespiratory arrest. The patient died about four hours after the cannulation.

(5) Cause of death: Sequential occurrence of cardiovascular events caused by decreased blood pressure associated with stimulation and reflection to the vagal nerve adjacent to the descending aorta after the dialysis catheter migrated outside the internal jugular vein (suspected). Ai: present. Autopsy: present (the catheter had strayed into the right pleural cavity. Mediastinum hematoma and hemorrhagic pleural effusion about 100 mL).

Case 21: Stray catheter

(1) The patient was in his/her 50s, undergoing dialysis for chronic renal failure. The patient had congestive heart failure, right pneumothorax and pyothorax, and was JCSII-10.

(2) Although the artery had been subcutaneously fixed and was superficial, because blood return to the vein was difficult, placement of a dialysis catheter was scheduled.

(3) BMI: 15.6 kg/m^2. Antithrombotic medications: unknown.

(4) The right femoral vein was cannulated under real-time ultrasound guidance. During insertion, the patient complained of pain and moved intensely. Cannulation was attempted over 10 times while holding the patient. No resistance was met during guidewire insertion, and reverse blood aspiration was obtained after catheter insertion. Although X-ray imaging showed an abnormality in the path of the catheter, because reverse blood aspiration was obtained and infusion was smooth, high-calorie infusion using an infusion pump was initiated. About one hour later, dialysis was initiated. Because removal of blood through the catheter was difficult, blood was removed from the subcutaneously fixed superficial artery and returned through the catheter. A little over 10 minutes after the initiation of dialysis, blood pressure decreased and dialysis was discontinued. The patient died about 20 minutes after the sudden change in condition.

(5) Cause of death: Intraperitoneal bleeding caused by blood return to the catheter, which was placed outside the vessel (presumed). Ai: absent. Autopsy: absent.

Case 22: Stray catheter

(1) The patient was in his/her 70s, undergoing dialysis for chronic renal failure. The patient had atrial fibrillation.

(2) Exchange of the dialysis catheters was scheduled due to insufficient blood removal of the catheter placed in the left internal jugular vein.

(3) BMI: 22.2 kg/m^2. Anticoagulant: Yes, no off-therapy period. Ultrasound showed narrowing of right internal jugular vein.

(4) A guidewire was inserted into the indwelling catheter, and the location of the catheter was verified under fluoroscopy. Then the catheter was removed. Although catheter insertion was difficult and re-insertion was also difficult, the operator determined that the catheter was placed inside the vessel by contrast examination. Although reverse blood aspiration was not smooth, because a solution could be infused, the catheter was connected to the dialysis line. Blood could not be removed so dialysis was discontinued. Immediately after dialysis was initiated by removing blood from an artery and returning it via the catheter, the patient entered cardiorespiratory arrest. CT revealed that the catheter penetrated near the brachiocephalic vein and strayed into the right pleural cavity. On the following day, thoracotomy was performed and about 2,000 mL of hematoma was removed. The perforated site on the superior vena cava wall and injury to the right lung were repaired. After the anticoagulant therapy was discontinued, the patient developed cerebral infarction and died about three months after the sudden change in condition.

(5) Cause of death: Aspiration pneumonia (suspected). After a vessel injury, anticoagulant therapy was discontinued. This led to the development of cerebral infarction and repeated aspiration pneumonia, which caused death (presumed). Ai: absent. Autopsy: absent.

Case 23: Stray catheter

(1) The patient was in his/her 70s, with chronic renal failure.

(2) A dialysis catheter placement was scheduled for introduction of hemodialysis.

(3) BMI: Unknown. Antithrombotic medications: No.

(4) The right femoral vein was cannulated without use of ultrasound. The operator felt discomfort during catheter insertion. Although reverse blood aspiration was not smooth, because withdrawing the catheter slightly improved the situation, the catheter was fixed. Without verifying the catheter tip position by imaging, the first dialysis was performed. On the following day, as reverse blood aspiration before dialysis initiation improved by slightly withdrawing the catheter, as it had the day before, dialysis was initiated. Ten minutes later the patient complained of low back pain and went into shock, so dialysis was discontinued. CT showed intraperitoneal bleeding. The patient entered cardiorespiratory arrest while transfer to another medical institution was being prepared. The patient died about 2 hours and 30 minutes after the sudden change in condition.

(5) Cause of death: Intraperitoneal bleeding (straying of the catheter into the ascending lumbar vein and collapse of the ascending lumbar vein). Ai: absent. Autopsy: absent.

Case 24: Stray catheter

(1) The patient was in his/her 40s, with prerenal failure, chronic obstructive pulmonary disease, a giant cyst in the apex of the right lung, and chronic pancreatitis, and was alcohol dependent.

(2) Central venous catheter placement was scheduled for treatment of severe dehydration.

(3) BMI: 10.8 kg/m^2. Dehydrated. Antithrombotic medications: No.

(4) The left internal carotid artery was cannulated using a long needle under fluoroscopy and real-time ultrasound guidance. The guidewire tip bent at the first insertion. For the second insertion, the hard end, the opposite side of the guidewire, was inserted and advanced towards the superior vena cava. The catheter was inserted and the tip position was verified under fluoroscopy. Although reverse blood aspiration was not obtained, a solution could be infused. The operator determined that the catheter tip position was too deep and withdrew the catheter a few centimeters and fixed it in place. The location was not verified. The patient experienced precordial pain. Analgesic drug administration through the catheter was initiated. Twenty minutes later the SpO_2 percentage dropped to the 70s, and CT revealed that the catheter had strayed into the mediastinum. Infusion was discontinued. About 2 hours and 30 minutes after infusion began, the patient entered cardiorespiratory arrest. Cardiac ultrasonography showed accumulated fluid in the pericardium. The patient died about four hours after the initiation of dialysis.

(5) Cause of death: Straying of the central venous catheter into the pericardium and cardiac tamponade caused by accumulated infusion solution in the pericardium. Ai: absent. Autopsy: absent.

Case 25: Stray catheter

(1) The patient was in his/her 50s, with moderate mental deficiency, and had repeated intestinal obstruction and pneumonia.

(2) Exchange of the central venous catheters was scheduled due to suspected catheter infection.

(3) BMI: 16.7 kg/m^2. Platelet count: in the 70,000s/μL. Antithrombotic medications: No.

(4) A new cannula was inserted along with the indwelling catheter in the left subclavian vein, and the catheter was removed. A new catheter was inserted and reverse blood aspiration was obtained. Using X-ray imaging, the operator determined that the catheter tip was inside the left internal jugular vein and so initiated infusion. About nine hours after the exchange, the SpO_2 percentage dropped to the 60s and consciousness decreased. Left pneumothorax was suspected and the patient was transferred to another medical institution. CT showed straying of the catheter into the pleural cavity. The thoracic cavity was drained, but the patient died two days after initiation of infusion.

(5) Cause of death: A large amount of infusion solution in the pleural cavity caused by straying of the central venous catheter into the left pleural cavity, or respiratory failure caused by hemothorax (suspected). Ai: absent. Autopsy: present.

Case 26: Stray catheter

(1) The patient was in his/her 70s, with persistent disturbance of consciousness after subarachnoid bleeding, quadriplegia, difficulty in oral feeding, and aspiration pneumonia.

(2) Central venous catheter placement was scheduled because nutrition management and gaining peripheral vessel access were difficult.

(3) BMI: 18.6 kg/m^2. Dehydrated. Antithrombotic medications: No.

(4) The right femoral vein was cannulated without use of ultrasound. Because the catheter did not advance more than 15 cm, it was fixed at that position. Although reverse blood aspiration was not obtained, the operator verified the catheter location with X-ray imaging and initiated a high-calorie infusion. On the following day, the patient presented cyanosis, blood pressure reduced to the 70s mmHg, and was diagnosed with septic shock. Administration of vasopressor through the catheter was initiated, but the SpO_2 level became unmeasurable. The patient entered cardiorespiratory arrest. CT showed ascites or bleeding in the peritoneal cavity. The patient died about one hour later. CT revealed the possibility that the catheter had strayed from the inferior epigastric vein to the peritoneal cavity.

(5) Cause of death: Septic shock caused by pneumonia and urinary tract infection (presumed). Ai: absent. Autopsy: absent.

Case 27: Stray catheter

(1) The patient was in his/her 90s, and had undergone radiotherapy for pharyngeal cancer. The patient had suspected aspiration pneumonia or chemical pneumonia, and dementia.

(2) Central venous port placement was scheduled for nutrition management.

(3) BMI: 16.9 kg/m^2. Antithrombotic medications: No.

(4) The left internal jugular vein was cannulated under fluoroscopy and real-time ultrasound guidance. Although resistance was met during guidewire insertion, the catheter was inserted to the inferior vena cava, passing through the diaphragm. The port was connected and smooth reverse blood aspiration was obtained. The site was closed. X-ray imaging showed no abnormalities in the catheter's location. On the following day, high-calorie infusion using a infusion pump was initiated. On the day after the infusion, the patient presented with an SpO_2 level in the 80s, low blood pressure, and prominent sweating. X-ray imaging showed a large amount of right pleural effusion, so infusion was discontinued. The patient presented a reduced level of consciousness and labored respiration. Thoracentesis was performed. About 500 mL of pleural effusion was removed. Based on its components, leakage of the infusion solution into the pleural cavity was suspected. The patient died about two days after infusion was initiated.

(5) Cause of death: Respiratory failure caused by a large amount of infusion solution leaking into the right pleural cavity. There was a possibility that the catheter placed in the inferior vena cava had migrated outside the vessel. Ai: absent. Autopsy: absent.

Case 28: Stray catheter

(1) The patient was in his/her 80s, with interstitial pneumonia, chronic renal failure, disuse syndrome, and dementia.

(2) Central venous port placement was scheduled for nutrition management.

(3) BMI: 18.9 kg/m^2. Dehydrated. Platelet count: in the 120,000s/μL. Anticoagulant: Yes, off treatment (since five day prior). The patient presented thoracic deformity.

(4) Cannulation was attempted five times into the right internal jugular vein under fluoroscopy and real-time ultrasound guidance. Although resistance was met during guidewire insertion, the operator determined via fluoroscopy and ultrasound that the guidewire was inside the vein. Resistance was met during insertion of a dilator and a catheter, and no reverse blood aspiration was obtained. The operator assumed that the catheter tip was in contact with the venous wall and verified the catheter tip's location with X-ray imaging. Four days after the surgery, high-calorie infusion was initiated. On the day after infusion was initiated, the patient experienced dyspnea, wheezing, tachycardia, and edema of the face and both upper extremities. Extravascular straying of the catheter was suspected via CT, and use of the CV port was discontinued. On the third day of infusion, contrast-enhanced CT showed straying of the catheter into the mediastinum. About one week after infusion had begun, the patient entered cardiorespiratory arrest and died.

(5) Cause of death: Asphyxiation caused by phlegm (suspected). There was a possibility that the infusion solution leaked into the mediastinum, causing an aggravated respiratory condition. Ai: absent. Autopsy: absent.

Case 29: Stray catheter

(1) The patient was in his/her 80s with pneumonia, was on a ventilator for acute respiratory distress syndrome, and had undergone valve replacement (after being hospitalized for multiple rib fractures, traumatic pneumothorax, and pulmonary contusion due to a fall, the patient's respiratory condition deteriorated, requiring a ventilator).

(2) Exchange of the central venous catheters was scheduled due to prolonged placement of the catheter dwelling in the right internal jugular vein.

(3) BMI: 17.9 kg/m^2. Anticoagulant: Yes. Antiplatelet medications: Yes, no off-therapy period.

(4) The left internal jugular vein was cannulated using a long needle under static ultrasound guidance. A guidewire was inserted 20 cm. After catheter insertion, smooth reverse blood aspiration was obtained and the catheter was fixed in place. However, the operator determined through X-ray imaging that the catheter was in the brachiocephalic vein, and withdrew the catheter 12 cm and advanced it 4 cm and fixed it in place again. Infusion was initiated without verifying the catheter's location by X-ray imaging. On the following day, blood pressure gradually decreased and the patient entered cardiorespiratory arrest. An emergency treatment drug was administered through the catheter. X-ray imaging showed decreased permeability in the entire left lung field, and ultrasound indicated accumulated fluid in the left pleural cavity. Thoracentesis was performed and after about 2,200 mL of pleural effusion was drained, SpO_2 became 100%. The patient died about one month after infusion was initiated.

(5) Cause of death: Septic shock and exacerbated ARDS. Ai: absent. Autopsy: present (the central venous catheter did not enter the internal jugular vein, but passed dorsal to the internal jugular vein, penetrated the brachiocephalic vein and then strayed into the pleural cavity).

Case 30: Stray catheter

(1) The patient was in his/her 60s, with a consciousness disorder and digestive tract disease (ulcerative colitis: diarrhea, and prominent malnutrition).

(2) Central venous catheter placement was scheduled for nutrition management.

(3) BMI: 19.2 kg/m^2. Dehydrated. Antithrombotic medications: No.

(4) The right internal jugular vein was cannulated under static ultrasound for the first insertion and under real-time ultrasound guidance for the second insertion. Because resistance was met during guidewire insertion, the operator verified the guidewire location with a long-axis ultrasound view. After catheter insertion, reverse blood aspiration was obtained. The operator verified the catheter tip's position with X-ray imaging, and initiated a high-calorie infusion. On the following day, the SpO_2 percentage dropped to the 70s, and the patient entered cardiorespiratory arrest. Emergency drug treatment was administered through the catheter during resuscitation. The X-ray and CT images obtained during the sudden change in the patient's condition showed dislodgement of the catheter into the right pleural cavity. The patient developed hypoxic encephalopathy and died about one and a half months after initiation of infusion.

(5) Cause of death: Hypoxic encephalopathy (there was a possibility that the respiratory failure associated with accumulation of infusion solution in the pleural cavity had affected the condition). Ai: absent. Autopsy: absent.

Case 31: Stray catheter

(1) The patient was in his/her 70s, with Stanford Type A aortic dissection, difficulty with communication due to progressive supranuclear palsy, and dysphagia.

(2) Central venous catheter placement was scheduled to improve nutrition.

(3) BMI: 21.6 kg/m^2. Severely dehydrated. Ultrasonography showed collapse of an internal jugular vein. Antithrombotic medications: No.

(4) Cannulation was attempted five times into the right internal jugular vein under real-time ultrasound guidance. Because using a probe collapses the internal jugular vein, the operator removed the probe during cannulation. Although resistance was met during guidewire insertion, the operator inserted a catheter after verifying the guidewire's location with a short-axis ultrasound view. No reverse blood aspiration was obtained, but infusion of the drug solution was smooth. Although X-ray imaging showed tortuosity of the catheter, the operator determined that there were no abnormalities in the catheter's location and initiated infusion using an infusion pump. On the third day of infusion, the patient presented dyspnea, mild respiratory distress, and decreased SpO_2 levels in the 80% range. On the following day, the level of consciousness declined. CT showed dislodgement of the catheter into the isolated cavity and exacerbated dissection. The patient died about two weeks after infusion was initiated.

(5) Cause of death: Myocardial infarction due to occlusion of the right coronary artery associated with progression of aortic dissection (there was a possibility that the pressure from the solution infused through the catheter, which had been placed in the isolated cavity near the right subclavian artery and the right brachiocephalic artery, affected the condition). Ai: present. Autopsy: present.

Case 32: Stray catheter

(1) The patient was in his/her 40s, with ulcerative colitis with the complications of Crohn's disease, ileus, wheezing, and schizophrenia.

(2) Exchange of the central venous catheters was scheduled due to long-term placement for nutrition management.

(3) BMI: 16.6 kg/m^2. Antithrombotic medications: No.

(4) To exchange the catheter placed in the right internal jugular vein, the left internal jugular vein was cannulated under real-time ultrasound guidance. Because X-ray imaging showed that the catheter was located in a position where its tip could not reach the superior vena cava, the operator pushed the catheter forward without resistance and smooth reverse blood aspiration was obtained. The operator verified the catheter tip's location again by X-ray imaging and initiated a high-calorie infusion. On the third day of infusion, the patient presented dyspnea and respiratory distress. The respiratory department was consulted. The condition did not improve even after administering a bronchodilator. The patient entered respiratory arrest and died four days after infusion was initiated.

(5) Cause of death: Straying of the central venous catheter into the mediastinum (details unknown). Ai: absent. Autopsy: absent.

Case 33: Stray catheter

(1) The patient was in his/her 80s, with paroxysmal atrial fibrillation, right pleural effusion, cognitive decline and had undergone PCI for myocardial infarction and gastric cancer surgery.

(2) Central venous port placement was scheduled for nutrition management and because gaining peripheral vessel access was difficult.

(3) BMI: 20.9 kg/m^2. Dehydrated. Anticoagulant: Yes, dual-antiplatelet therapy. The patient discontinued the therapy by self-judgement two weeks prior.

(4) Cannulation was attempted twice into the right internal jugular vein under fluoroscopy and real-time ultrasound guidance. The operator verified the guidewire location with a short-axis ultrasound view and inserted the guidewire 20 cm. The catheter was advanced under fluoroscopy, but there was a difficulty advancing it caudal near the bifurcation of the trachea. The catheter was fixed in place there. Although reverse blood aspiration was not obtained, a solution could be infused without meeting any resistance, and the operator verified the catheter location under fluoroscopy. On the following day, the patient was transferred to a long-term care facility and a high-calorie infusion was initiated using a infusion pump. The patient experienced chest pain and dyspnea on the day after infusion began. On the fourth day of infusion, X-ray imaging revealed right pleural effusion, so the patient was referred to the emergency department. CT showed dislodgement of the catheter into the mediastinum. Thoracentesis removed 1,000 mL of pleural effusion. Later, the patient entered cardiorespiratory arrest and died on the same day.

(5) Cause of death: Myocardial infarction caused by in-stent thrombosis (suspected). There was a possibility that a large amount of pleural effusion caused by dislodgement of the central venous catheter into the mediastinum aggravated the respiratory condition. Ai: present. Autopsy: present.

Case 34: Stray catheter

(1) The patient was in his/her 80s, and had undergone partial arch replacement for acute Stanford Type A aortic dissection.

(2) Central venous catheter placement was scheduled for post-operation and nutrition management.

(3) BMI: 35.2 kg/m^2. Dehydrated. Antithrombotic medications: No.

(4) The left internal jugular vein was cannulated under real-time ultrasound guidance. The operator verified the guidewire's location with a long-axis ultrasound view and inserted a catheter. Smooth reverse blood aspiration was obtained, and infusion was initiated after verifying the location with X-ray imaging. On the fourth day of infusion, the patient presented ventricular fibrillation and entered cardiorespiratory arrest. Spontaneous circulation returned after emergency resuscitation. CT showed cardiac tamponade. Pericardial drainage removed 600 mL of fluid. X-ray imaging revealed malposition of the catheter tip and contrast examination showed extravasation. The catheter was removed. Head CT showed extensive hypoxic encephalopathy. The patient died one week later.

(5) Cause of death: Cardiac tamponade and extensive hypoxic encephalopathy associated with delayed left brachiocephalic vein injury (suspected) caused by migration of the catheter tip in the left internal jugular vein due to body movement. Ai: absent. Autopsy: present.

Case 35: Air embolism

(1) The patient was in his/her 70s, with multiple hepatic metastases, bone metastasis, left pneumothorax and interstitial pneumonia, and had undergone gastric cancer surgery.

(2) Central venous port placement was scheduled for nutrition management and because gaining peripheral vessel access was difficult.

(3) BMI: 16.1 kg/m^2. Antithrombotic medications: No.

(4) Cannulation was performed from below the left clavicle under real-time ultrasound guidance. Although the procedure was initiated with the patient in the right lateral position in order to reduce the low back pain caused by the metastases, the procedure was performed with the patient in the dorsal position due to difficulty gaining access. As the vessel was tortuous, the guidewire could not be inserted smoothly. With the guidewire left in the body, the needle was removed and a catheter was inserted along the guidewire. Immediately after the port was positioned, the patient's level of consciousness decreased, the electrocardiogram showed elevated ST, and the patient developed bradycardia. Because cardiac ultrasonography showed bubble-like opacity in the right atrium, myocardial infarction caused by an air embolism was suspected. The patient died about two hours after the cannulation.

(5) Cause of death: Cerebral embolism and myocardial infarction caused by air embolisms. Ai: present (a large amount of air in the cardiac chambers, as well as air in the cerebral vessels, hepatic vessels, and near the right coronary arteries). Autopsy: present (presence of atrial septal defect).

Case 36: Air embolism

(1) The patient was in his/her 80s, with cardiac failure, pneumonia and respiratory failure (on NPPV), and difficulty walking without support.

(2) Central venous catheter placement was scheduled for nutrition management.

(3) BMI: 19.8 kg/m^2. Dehydrated. The patient had difficulty extending the neck due to thorax deformity and kyphosis. Antithrombotic medications: No.

(4) The right internal jugular vein was cannulated under real-time ultrasound guidance with the patient's head elevated and the patient's body slightly in the left lateral position. After seeing reverse blood aspiration during the fourth insertion, the operator advanced the cannula, and the guidewire's location was verified by short-axis ultrasound view. The cannula remained open and while the catheter was being fixed, the SpO_2 level dropped to the range of 60%. The patient died about 2 hours and 30 minutes after cannulation.

(5) Cause of death: Air embolisms in the right-side vessels. Ai: present (air entered the veins in the head and neck, right subclavian vein, right atrial, right ventricular, and pulmonary arteries. In particular, the interior of the right superior pulmonary artery was filled with dense air shadows). Autopsy: absent.

Case 37: Air embolism

(1) The patient was in his/her 80s, with repeated bouts of aspiration pneumonia.

(2) Central venous catheter placement was scheduled for nutrition management and because gaining peripheral vessel access was difficult.

(3) BMI: 14.4 kg/m^2. Dehydrated. The patient presented collapse of the internal jugular vein. Antithrombotic medications: No.

(4) The right internal jugular vein was cannulated seven to eight times without use of ultrasound, with the patient's legs elevated about 10°. Inadvertent arterial puncture occurred. Pressure was applied for hemostasis. At a different site, in the same way, the right femoral vein was cannulated seven to eight times and again, an inadvertent arterial puncture occurred. Pressure was applied for hemostasis and the procedure was discontinued. On the following day, the patient presented a throat filled with phlegm and a low SpO_2 level of 70%. Because the condition improved with aspiration and oxygenation, the right internal jugular vein was cannulated under real-time ultrasound guidance with the patient's legs elevated (in the dorsal position with the head tilted down 10-15°). A catheter was inserted and reverse blood aspiration was obtained. However, 15 minutes later, blood pressure decreased and the SpO_2 level dropped to 60%. The patient died about one hour later.

(5) Cause of death: Respiratory failure caused by suppurative pneumonia. Ai showed air in the internal jugular vein, subclavian vein, and right ventricle, as well as in the pulmonary artery, but it was a minimal amount. The conclusion was that the amount was not enough to affect circulatory dynamics. Ai: present. Autopsy: present.

Case 38: Air embolism

(1) The patient was in his/her 90s, with aspiration pneumonia, cerebral infarction, hypertension, dementia, and disuse syndrome.

(2) Central venous catheter placement was scheduled for nutrition management.

(3) BMI: 19.1 kg/m^2. Dehydrated. Kyphosis. Antithrombotic medications: No.

(4) As the patient had severe kyphosis and could not be placed in the dorsal position, the right internal jugular vein was cannulated with the patient in the left lateral position under fluoroscopy. After catheter insertion, reverse blood aspiration was obtained. The patient's position was changed to the dorsal position to verify the catheter's location under fluoroscopy. After the location was verified, the patient was placed back in the left lateral position. Upon completion of the suture, the patient entered respiratory arrest and died about one hour after the cannulation.

(5) Cause of death: Air embolism (suspected). Ai: present (opacity of the air concentration level in the right atrium and the right ventricle. The interior of the pulmonary artery was almost opaque with dense air shadows). Autopsy: absent.

Case 39: Air embolism

(1) The patient was in his/her 80s, undergoing dialysis for chronic renal failure. The patient had septicemia.

(2) Exchange of the dialysis catheter, placed about three weeks prior in the right internal jugular vein, was scheduled due to the reduced effect of dialysis.

(3) BMI: 19.6 kg/m^2. Antithrombotic medications: unknown.

(4) As it was after a meal, the catheter was removed with the patient's head elevated 45° and with the patient holding his/her breath. After the removal site had been compressed manually for five minutes, the site was covered with an adhesive bandage and the patient was positioned with his/her head elevated about 60°. About 10 minutes after removal, the patient's level of consciousness decreased and the patient entered cardiorespiratory arrest. The patient died about two hours after catheter removal.

(5) Cause of death: Air embolism. Ai: present (air was found in the intracranial arterial and venous sinuses, right and left head and neck veins, right atrium, right ventricle, from the main pulmonary arteries to the origin of the right and left pulmonary arteries, and coronary arteries). Autopsy: absent.

Case 40: Air embolism

(1) The patient was in his/her 70s, with generalized erythroderma and dementia.

(2) Removal of the central venous catheter, placed about two weeks prior into the right subclavian vein, was scheduled because the general condition improved and the patient had become able to eat.

(3) BMI: 19.3 kg/m^2. Dehydrated. Kyphosis. Antithrombotic medications: Unknown.

(4) The catheter was removed with the patient in the dorsal position with his/her head and right shoulder elevated 20° due to kyphosis while the patient held his/her breath, and pressure was being applied with gauze to the insertion site. After pressure was manually applied for 3 minutes, the site was closed with gauze and tape, with pressure being applied, and the patient was placed at rest for 10 minutes. Upon making the patient sit upright from the left lateral position for dressing, about 10 minutes after catheter removal, the level of consciousness decreased and the patient entered respiratory arrest. The patient died about 10 hours after catheter removal.

(5) Cause of death: Air embolism in the cerebral veins (suspected). Ai: present. Autopsy: present.

Case 41: Air embolism

(1) The patient was in his/her 70s, with Parkinson's disease and pulmonary suppuration, and had undergone chemo- and radiation therapies for esophageal cancer.

(2) Removal of the central venous catheter, placed about one month prior into the right internal jugular vein, was scheduled because the patient had become able to eat.

(3) BMI: 17.6 kg/m^2. Dehydrated. Antithrombotic medications: No.

(4) The catheter was removed with the patient in the dorsal position with his/her head elevated 15-20°, because the patient experienced pain and dyspnea in the flat position. After pressure was manually applied for 3 minutes, the site was closed with gauze and tape, with pressure being applied. Although the patient's head was elevated about 45°, the patient was temporarily placed flat to adjust the position about 40 minutes after the removal. When the patient's head was elevated again to about 40°, the patient's eyes rolled up and the level of consciousness decreased. The patient entered respiratory arrest. An air embolism in the head was diagnosed with head CT. The patient was transferred and hyperbaric oxygen therapy was given, but the patient died about one week after catheter removal.

(5) Cause of death: Pulmonary alveolar bleeding (suspected). There was a possibility that the air embolism had affected the condition. Ai: present. Autopsy: absent.

Case 42: Other

(1) The patient was in his/her 60s, with pneumonia, atrial fibrillation, and post-cerebral infarction disuse syndrome, and was JCSII-10.

(2) Removal of the central venous catheter, which had been inserted via the right femoral vein by the patient's previous physician, was scheduled because a central venous port had been placed.

(3) BMI: 18.1 kg/m^2. Antithrombotic medications: unknown.

(4) Although removal was attempted several times, resistance was met. X-ray imaging revealed that a guidewire had remained in the catheter, which had looped into the right ventricle and the tip was in the superior vena cava. The guidewire was unwound under fluoroscopy and removed. Immediately afterwards, the patient entered cardiorespiratory arrest, and ultrasonography showed pericardial effusion. The patient died about four hours after catheter removal.

(5) Cause of death: Cardiac tamponade caused by abrasion on the anterior aspect of the right ventricle. Ai: present. Autopsy: present.

Case 43: Other

(1) The patient was a young child with peritoneum inflammation associated with peritoneal dialysis, and had been undergoing peritoneal dialysis for acute renal failure since he/she was a newborn.

(2) Dialysis catheter placement was scheduled for introduction of hemodialysis.

(3) Height: 92 cm. Dehydrated. Antithrombotic medications: No.

(4) The right internal jugular vein was cannulated under fluoroscopy and real-time ultrasound guidance. When a guidewire was inserted about 15 cm, resistance was met. After catheter insertion, the guidewire could not be removed, and during this period a large amount of hemorrhaging occurred around the neck through the cannula, and the blood pressure dropped. Thoracotomy was performed and ECMO was initiated; however, sufficient flow could not be obtained. Right thoracotomy revealed about 3,000 mL of accumulated blood. A part of the guidewire had penetrated from the apical portion of the lung into the pleural cavity and bleeding was observed from that site as well. The patient died about three weeks after cannulation.

(5) Cause of death Hemorrhage. Ai: present. Autopsy: present. (The thin chordae tendineae of the tricuspid valve were caught between the spiral structure of the metal part of the guidewire, and the leaflet was also tangled with them.)

Case 44: Other

(1) The patient was a young child who had undergone emergency craniectomy for hematoma evacuation for bleeding due to cerebral arteriovenous malformation. The patient had global cerebral ischemia.

(2) Central venous catheter placement into the internal jugular vein was scheduled for nutrition management.

(3) Height: 118 cm (weight unknown). Antithrombotic medications: unknown.

(4) The internal jugular vein was cannulated (right/left unknown) under static ultrasound. Although resistance was met during guidewire insertion, the guidewire could be inserted on the third attempt. The operator verified via ultrasound that the guidewire was inside the vein. The operator inserted a catheter 9-11 cm without obtaining reverse blood aspiration. As the catheter was being withdrawn, there was backflow of blood. Around this time, the blood pressure started to decrease, and the patient entered cardiorespiratory arrest. As the image showed hemothorax, thoracentesis was performed, removing hemorrhagic pleural effusion (200 mL). Sternal compression, defibrillation, blood transfusion, etc. were performed and spontaneous circulation occurred. Later, the patient experienced repeated pneumonia, urinary tract infection, and more, and died about one year and six months after cannulation.

(5) Cause of death: Brain stem function disorder caused by cerebral bleeding and sepsis. Ai: absent. Autopsy: present.

7. Conclusion

The Expert Analysis Subcommittee presented 12 recommendations as the result of examining the cases. Recommendation 1 describes "Standardizing risk assessment and determining indications," Recommendation 2 "Sharing information and risks," Recommendations 3-6 "Cannulation," Recommendation 7 "Confirming catheter location," Recommendation 8 "How to manage a misplacement into an artery and extravascular placement," Recommendation 9 "Patient observation," Recommendation 10 "Air embolism," Recommendation 11 "Establishing an organized management system," and Recommendation 12 "Dialysis catheters." These recommendations further clarified those in the First Report, reiterating that the most important thing is for medical professionals to recognize that central venous catheter insertion/removal is a medical practice with a high risk of fatal complications, and to share information about the risk with patients and their families.

Just like a risk assessment of patients who are undergoing surgery is performed before the surgery, patients who are undergoing central venous catheter insertion should also undergo a risk evaluation before the procedure. Our goal was that standard practice when preparing for central venous catheterization would be for physicians to use checklists to perform standardized assessments and take appropriate measures to avoid the risks based on the results in advance. In particular, we emphasized that the purpose of a pre-scan is to assess anatomical risks of cannulation, and that a pre-scan should be carried out before the insertion day in accordance with predefined procedures and, depending on the results, the indication and the puncture site should be reviewed. Furthermore, we suggested sharing the risks facing the patient among the medical team by taking a time-out before cannulation. For cannulation, we presented tangible precautions including taking needle diameters and lengths into account, using ultrasound equipment to verify the location of the guidewire after insertion, envisioning which veins and other organs into which a guidewire may stray while being advanced, and not applying excessive force during dilator insertion. We emphasized the importance of performing thorough examinations, suspecting malposition of the placed catheter if any of the following apply during catheter placement: resistance during catheter insertion, abnormality in reverse blood aspiration, and suspected malposition in a plain X-ray image. Although this was not mentioned in the First Report, we addressed the need to consider countermeasures in case a catheter is inadvertently placed in a non-target vein, before removing the catheter. This is because improper removal of a catheter can lead to unmanageable bleeding. In order to quickly detect abnormalities in post-procedure patients, we suggested sharing any abnormal findings during cannulation among the team and to create a checklist of observations to be used as standard practice. Other things that we did not address in the First Report are that fatal air embolisms can be caused by cannulation or catheter removal, and that a patient's position during the procedure and covering of the puncture site after the catheter removal need close attention, given the known pathologic physiology of air embolisms. In addition, we emphasized the importance of organizations making efforts to establish an organizational management system with a defined responsible department that would be aware of the current insertion/removal situation, including occurrence of complications, to select a place to perform procedures and appropriate equipment, to prepare a manual that describes how to manage and collaborate in case an abnormality/emergency situation occurs, and to establish an educational system that includes simulation trainings and an operator qualification system. Furthermore, as the diameter of dialysis catheters is large, a vessel injury during cannulation or use of a mispositioned catheter can directly lead to a fatal situation. Therefore, as an independent recommendation, we emphasized the need for extreme care when using the dialysis catheters.

In general, the principles of preventing major accidents are: reducing the likelihood of error; if an error occurs, preventing the error from leading to an accident; and if an accident occurs, minimizing its effects. To compile these recommendations, we examined the cases following these principles. When performing a high-risk medical procedure that could cause a fatal complication, you need to be fully familiarized with the complications that could occur and to keep those complications in mind while performing the procedure.

While we hope to see the number of reports of deaths associated with central venous catheter insertion/removal decline in the future, we realize, unfortunately, that it is not as simple as just following guidelines and recommendations to eliminate all medical accidents. Improving patient safety and medical quality is an important ongoing agenda that must be pushed forward with the tireless efforts of healthcare professionals.

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

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8. Materials

Central venous catheterization insertion/Investigation items checklist

Item		Viewpoints		Concrete items
Basic information	Patient information	Age/Sex		Age: Sex: ☐ Male ☐ Female
		Primary disease/history		
		Height/weight (Date measured)		Height: cm Weight: kg ( ) BMI: kg/m^2
		Oral drug (antithrombotic drug)		Drug name: Dose interruption: ☐ Yes ☐ No
	Blood tests	Blood count		☐ Hb: g/dL ☐ Ht: % ☐ Plt: 0K/μL ☐ Other:
		Biochemical		☐ T-P: g/dL ☐ Alb: g/dL ☐ Other:
		Coagulation		☐ PT-INR: ☐ APTT: sec. ☐ D-dimer: μg/mL
				☐ Fib: mg/dL ☐ Other:
Cause of death	Autopsy/Ai	Autopsy results (vessel injury: including presumption)		
		Ai results (vessel injury: including presumption)		
Indication	Central venous catheterization risk assessment	Risks in general condition		☐ Intravascular dehydration ☐ Emaciated (BMI < 20 kg/m^2) ☐ Obese (BMI > 30 kg/m^2) ☐ Blood coagulation disorder ☐ Respiratory disorder/lesion ☐ Position restriction (hunchback, orthopnea) ☐ Restlessness, difficulty communicating ☐ Considerably poor prognosis
		Anatomical risk (Pre-scan)	Target vein	☐ Internal jugular vein (right/left) ☐ Subclavian vein (right/left) ☐ Femoral vein (right/left) ☐ Vein in the upper arm (right/left) PICC
			Size/collapse/depth	Size: mm Collapse: ☐ Yes ☐ No Depth: mm
			Positional relation to arteries	☐ Apart ☐ Partially overlapping ☐ Completely overlapping
			Tissues/organs behind	☐ Artery ☐ Lung ☐ Nerve ☐ Other:
IC	Provision of information and risk sharing	Method of information provision		☐ Informed consent form ☐ Oral ☐ Other:
		Information provided		☐ Purpose of catheterization ☐ Specific method of insertion ☐ Risks (complications) ☐ Results of risk assessment ☐ How complications will be managed, if any ☐ Possibility of another operator taking over the procedure/discontinuation of the procedure ☐ What will be done if central venous catheterization is not performed (alternative methods)
		Response of the patient and his/her family		
Cannulation	Information on cannulation	Place where procedure was performed		☐ Patient room ☐ Treatment room ☐ Angiography room ☐ Operating room ☐ Emergency treatment room ☐ Other:
		Puncture site		☐ Internal jugular vein (right/left) ☐ Subclavian vein (right/left) ☐ Femoral vein (right/left)
		Position during cannulation		☐ Flat dorsal ☐ Legs elevated ☐ Other:
	Equipment used	Product name/specifications		Product name: Specifications:
		Introducer needle		Size: Length: cm
		Catheter		Size: Length: cm
	Information sharing	Time-out		☐ Yes ☐ No

Item		Viewpoint	Information
Cannulation	Cannulation method		☐ Ultrasound guidance (☐ Real-time ultrasound-guided cannulation ☐ Static ultrasound) ☐ Fluoroscopy ☐ Other:
	Introducer needle	Confirmation of introducer needle's location	☐ Short-axis view ☐ Long-axis view
		Number of cannulations attempted	times
	Guidewire	Insertion method	☐ Metal needle (Seldinger technique) ☐ Needle with cannula (modified Seldinger technique)
		Insertion depth	cm from the surface of the skin
		Resistance during insertion	☐ Yes ☐ No ☐ Other:
		Confirmation of location	☐ Ultrasound (☐ Short-axis view ☐ Long-axis view) ☐ Fluoroscopy
	Dilator	Insertion depth	cm from the surface of the skin
		Resistance during insertion	☐ Yes ☐ No ☐ Other:
	Catheter	Insertion depth	cm from the surface of the skin
		Resistance during insertion	☐ Yes ☐ No ☐ Other:
		Smoothness of reverse blood aspiration during catheter placement	☐ Smooth ☐ Not smooth ☐ No aspiration ☐ Pulsatile
	Confirmation with image	Confirmation method	☐ X-ray (☐ Frontal ☐ Lateral) ☐ CT ☐ Contrast
		Interpretation	
Observation	During insertion	Change in patient condition	☐ No change ☐ Changed (☐ Dyspnea ☐ Decreased SpO_2 level ☐ Tachypnea ☐ Tachycardia ☐ Decreased blood pressure ☐ Restlessness ☐ Pain (Site:) ☐ Other:)
		Complication(s)	☐ Yes (☐ Hematoma ☐ hemothorax ☐ Pneumothorax ☐ Inadvertent arterial puncture ☐ Other:) ☐ No
		Operator change	☐ Yes Reason: ☐ No
		Discontinued insertion	☐ Yes Reason: ☐ No
	After insertion	Date/Time infusion started	Time: : am/pm Date:
		Infusion method	☐ Gravity ☐ Infusion pump
		Resistance during infusion	☐ Yes ☐ No
		Change in patient condition	☐ No change ☐ Changed (☐ Dyspnea ☐ Decreased SpO_2 level ☐ Tachypnea ☐ Different breathing sounds between right and left ☐ Tachycardia ☐ Decreased blood pressure ☐ Restlessness ☐ Other:)
Removal procedure	Information on removal	Position during removal	☐ Flat dorsal ☐ Legs elevated ☐ Other:
		Duration of catheter placement	days
		Duration of manual compression after removal	minutes
		Method for covering the removal site	☐ Airtight dressing ☐ Other:
Organizational management system	Management of CV	Activities	☐ Be aware of the insertion/removal situation, including occurrence of complications ☐ Manage the situation in case of any adverse events ☐ Review past cases ☐ Prepare a manual
	Educational system	In-hospital certification system	☐ Yes ☐ No
		Simulation training participation system	☐ Real-time ultrasound-guided cannulation ☐ PICC

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Observer	Mariko Miyazaki	Japanese Society for Dialysis Therapy

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.

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