Recommendations for the prevention of recurrence of medical accidents

Number 1

Analysis of deaths related to the complications of "Central Venous Catheterization"

— First Report —

March 2017

Medical Accident Investigation and Support Center
Japan Medical Safety Research Organization

In publishing the recommendations for the prevention of recurrence of medical accidents（Number 1）

Fumimaro Takaku
Chair of the Board of Directors
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Based on the Medical Accident Investigation System enforced 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 medical safety and to prevent recurrences of medical accident. Along with the advancement and diversification of the medical surroundings, medical institutions are supposed to have taken preventive measures against medical accidents, accumulating reports of near-miss incident cases so as not to allow serious accidents to occur. However, serious events do occur in fact, at times resulting in the death of the patient. Such cases have been reported to ISC. I believe that the mission of the Medical Accident Investigation System is to accumulate these reports, to investigate and analyze each case and to provide information for preventing recurrence of serious events.

One year has elapsed since the enforcement of the Medical Accident Investigation System, and we, ISC, have published our first report for the recurrence prevention of medical accidents which was compiled in our Expert Analysis Subcommittee. The number of "In-Hospital Investigations" reported to ISC was 226 cases in total for one year and three months from the enforcement of the system until December 2016. ISC decided to take up the deaths caused by complications of "Central Venous Catheterization" as the first theme of analysis. Although the target cases reported were only 10 out of 226, similar accidents and death cases had occurred repeatedly in the past. In view of the seriousness of the accidents that resulted in death, these recommendations have been compiled as the first report for preventing recurrence of accidents.

ISC's measures to prevent recurrences of accidents are based on the analyses of 10 "Death" cases, focusing on the importance of avoiding accidents that may lead to death. "Guidelines" released by the government and academic societies were examined from broad knowledge. We believe that our measures should be distinguished from such guidelines. The purpose of this report is to provide recommendations on how to avoid life-threatening accidents. With this in mind, we hope that the recommendations will be widely utilized to the secure "Central Venous Catheterization" in each institution.

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 10 cases in detail and explored the measures to prevent recurrence, for their understanding and cooperation.

Analysis of deaths related to the complications of "Central Venous Catheterization"

— First Report —

March 2017

Expert Analysis Subcommittee for
Central Venous Catheterization

Committee for Prevention of Recurrence
Medical Accident Investigation and Support Center

Recommendations for the prevention of recurrence of medical accidents（Number 1）

Analysis of deaths related to the complications of "Central Venous Catheterization" — 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）.

【Informed consent】

Recommendation 2 Prior to the catheterization, the patient should be explained its necessity and give consent 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 understandings from the patient or family.

【Intervention techniques】 See the video［*Pitfalls of Ultrasound-guided CVC*］(http://www.medsafe.or.jp/movie/)

Recommendation 3 At the start of intervention to the internal jugular vein, 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.

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 needle in the "CVC kit" is mostly too long for the internal jugular vein. Therefore, do not insert beyond the reach of jugular vein. Especially in the case of 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, 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.

【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.

Recommendation 9 In order to respond promptly to the event of complications, the cooperation with other departments including transfer to other hospitals should be designed in manual.

March 2017
Expert Analysis Subcommittee for Central Venous Catheterization
Committee for Prevention of Recurrence, Medical Accident Investigation and Support Center
Japan Medical Safety Research Organization

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［**Glossary**］

CVC	Central venous catheterization.
Ai	Autopsy imaging（Postmortem imaging）
PICC	Peripherally inserted central venous catheter
Ultrasound-guided method	Intervention method with the guide of ultrasound （1）“Image drawing method with Pre-Scan” A method of performing ultrasound “Pre-Scan” before the intervention, 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 and for assessing the risk of complications. （2）“Real-time ultrasound-guided intervention” A method of performing intervention under the real-time ultrasound guide. After the pre-scan, the intervention is done while observing both the target vein and the needle under ultrasound tomographic image.
Landmark method	A method of performing intervention referring to the anatomical landmarks of the bones and muscles, with imaging of the anatomical position and relationship of the vessels without using ultrasound.

1. Introduction

1）The background and significance of the establishment of the Expert Analysis Subcommittee

Insertion of a central venous catheter is a routine medical practice in patient care today, but it is also a risky intervention with serious complications. The accidents associated with this intervention occurred more frequently than we had anticipated, and the preventive efforts against reoccurrences have been made. However, since the start of this system, it has become clear that the deaths associated with this intervention have been continuously reported. Therefore, we took focus on this fact and chose it as a theme for the Expert Analysis Subcommittee for CVC to study the prevention of recurrences.

The Expert Analysis Subcommittee chose the 10 cases from the in-hospital investigation reports related to the complications of CVC. Though it is difficult to completely eliminate the complications, but the way to reduce death-threatening complications should be explored. The Subcommittee summarized the results into the nine recommendations for the prevention of recurrences.

In the six cases out of 10, the intervention was done with the aid of the ultrasound-guided method. The ultrasound-guided method is the procedure recommended by the concerned medical societies, on the grounds that the higher intervention success rate and the lower occurrence of complications were clear with the ultrasound-guided method than with the conventional method（landmark method）. However, the investigation reports showed relatively high percentage of accidents due to the catheterization performed by this ultrasound-guided method. For this reason, the report of Expert Analysis Subcommittee focused on the procedure associated with the ultrasound-guided method. Considering the situation of medical front, however, where the ultrasound cannot be used, the ultrasound-guided method is not defined as a mandatory essential procedure in the guidelines of medical society.

In summarizing the prevention of recurrences, Expert Analysis Subcommittee realized that avoiding life-threatening complications of CVC is an important issue which needs continuous consideration including revision of the recommendations. Therefore, the Committee for Prevention of Recurrence named this analysis as the “First Report” and will continue to analyze the in-hospital investigation report for the “Second Report”.

2）Efforts for medical safety in the investigation of CVC

The insertion of a central venous catheter is one of the routine medical practices widely performed in many departments in the medical institution regardless of its scale. Securing safety is the basic requirement, but medical accidents, including death, associated with this intervention have been reported to a considerable number. Although it can be inferred that the frequency of deaths due to complications of CVC is far less than that of the surgery, but the actual data related CVC is not clear. Because it is a routine medical practice, however, recommendations for the prevention of recurrence of accidents related to CVC are urgently needed.

Among the efforts to prevent reoccurrences so far, there is a hospital where an advanced approach has been taken. Under an environment where X-ray fluoroscopy and ultrasound are available in the hospital, all CVC intervention are performed by specialized personnel systematically, in principle.

In addition, the following guidelines have been published as a systematic approach to the medical safety associated with CVC.

○ Japanese Society of Anesthesiology
"Guidance for safe insertion and management of a central venous catheter 2009"（revised in 2017）
○ Conference of Accredited Hospitals for Patient Safety Promotion, Japan Council for Quality Health Care
"Guidelines for Insertion of Central Venous Catheterization（CVC）（revised edition）"（revised in 2007）

3）About the related medical accident reports

［Publically available data of the Project to Collect Medical Near-miss/Adverse Event Information, Japan Council for Quality Health Care］（January 1, 2010 to August 22, 2016）

As a result of keyword searches for central veins, central venous catheter, dialysis catheter, and blood access catheter, 122 cases of deaths associated with the central venous catheter were reported.

Of 122 cases, 31 cases（25％）were "associated with catheterization" and the most common, followed by "pulmonary thromboembolism at withdrawal" and "related to infection during placement."

［Model Project for Survey and Analysis of Deaths Associated with Clinical Practice, Japan Medical Safety Research Organization］
（September 2005 to the end of project in 2015）

224 cases of medical accidents were reported in 10 years from 2005 to 2015. Three cases（1.3%）of deaths associated with CVC were reported, two of which were related to complications of CVC.

2. Method of analysis

1）Extraction of target cases

Of the 226 cases of the in-hospital investigation reports reported during one year and three months from October 2015 to December 2016, 12 cases of death were associated with CVC.

When observed by content, among the 12 cases 10 cases were related to complications of CVC, and two other cases were related to myocardial injury due to the trocar insertion after the onset of pneumothorax, and spontaneous dislodgment. Also, the 12 cases involved three cases associated with dialysis double-lumen catheter insertion. For this reason, in the Expert Analysis Subcommittee, 10 cases of death related to complications of CVC were taken as analysis target cases.

With regard to the causes of death in 10 cases, Cases 1–8 were cases of death related to intervention complications（including estimates）, Case 9 was a case where the cause of death was unknown, and Case 10 was a case where the condition worsened due to catheterization complications.

In addition, when examining the procedures for the insertion of a central venous catheter for catheterization, six cases were performed by the ultrasound-guided method, and four cases were performed by the landmark method.

2）Collecting and sorting information from target cases

The cases were analyzed based on the information described in the in-hospital investigation report submitted to the Center. With regard to the parts that require confirmation in the in-hospital investigation report, additional information was collected with the cooperation of the reporting facilities as far as possible. They were arranged according to the items of information collection.（See 7. “Materials"）

3）Meetings of the Expert Analysis Subcommittee

○First meeting　August 16, 2016
○Second meeting　October 18, 2016
○Third meeting　November 29, 2016
・In addition, opinions were exchanged through electronic media, etc.

3. Overview of target cases

Case 1

- The patient suffered from disseminated intravascular coagulation syndrome, occurred during advanced cancer chemotherapy. Difficulty in communication.
- The cause of death was suffocation due to cervical hematoma.
  Ai data: present, autopsy data: absent.
- For the purpose of infusion therapy to improve the general condition, insertion of the central venous catheter through the right internal jugular vein was tried with the aid of the ultrasound-guided pre-scan, but the carotid artery was punctured and treated with astriction. Subsequently, CVC was attempted in the left internal jugular vein with the real-time ultrasound-guided method, but the catheter did not move ahead. After removal, hematoma was detected and treated with astriction again. Respiratory stenotic sounds were heard at 10 minutes after the end of the procedure, and in another 50 minutes, the rightward deviation of the trachea was confirmed by chest X-ray. Immediately after that, decreased breath sounds and immeasurable low blood pressure were observed, and the patient died.

Case 2

- The patient was at the terminal cirrhosis, with bleeding tendency.
- The cause of death was the bleeding in upper mediastinum and right side hemothorax, due to right vertebral artery injury.
  Ai data: present, autopsy data: present.
- In order to correct hypokalemia, CVC（triple lumen catheter）to the right internal jugular vein was done with the aid of the ultrasound-guided method. But when the guide wire was inserted, there was a resistance against the inserted guide wire, so it was once removed. Although there was a complaint of dyspnea during the re-intervention, the catheter was inserted smoothly with no ultrasound findings suspected of pneumothorax. From 15 minutes after the end of the procedure, decrease in SpO2 and blood pressure were observed. With the treatment of infusion and blood transfusion implemented, there was no improvement. And the intensive treatment with respirator, continuous hemofiltration, etc. were followed, but the patient died three days after the CVC.

Case 3

- Because of the advanced age, the patient had difficulties in eating and also in communicating.
- The cause of death was a change in hemodynamics related to pneumothorax and suspected hemothorax.
  Ai data: absent, anatomy data: absent.
- Because of the difficulty in securing the peripheral blood vessels for infusion, the interventions of CVC were done multiple times to the internal jugular vein and the subclavian vein by the landmark method. The intervention did not succeed in securing the insertion. Several arterial punctures were observed. Another insertion was tried from the inguinal region but failed and discontinued. The chest CT taken approximately 40 minutes after the procedure showed right pneumothorax, and the aspiration had no effect, resulting in cardiopulmonary arrest and death.

Case 4

- The patient was in the condition of post-hepatectomy and under treatment with heparin for the portal vein thrombosis. An emergency surgery was performed for the panperitonitis due to perforation of duodenum.
- The cause of death was suspected of right side hemothorax immediately after the removal of the catheter.
  Ai data: absent, autopsy data: absent.
- For managing the general condition, CVC（double lumen catheter）was performed to the right internal jugular vein with the aid of the ultrasound-guided method in the operating room under general anesthesia. It was confirmed that the position of the catheter tip was judged in good position and no problem on chest X-ray. The infusion started. Next morning, because of the decreased permeability in the right lung on the chest X-ray and decreased SpO_2, the infusion was discontinued, and thoracic cavity drainage was performed. CT showed that the catheter tip was deviated into the thoracic cavity, but it could not be judged the catheter was running through the artery. After removal of the catheter, the patient fell into shock in several minutes and underwent emergency thoracotomy, but later died.

Case 5

- The patient had suffered from ulcerative colitis.
- The cause of death was lethal arrhythmia induced by the diastolic disturbance of heart due to cardiac tamponade.
  Ai data: present, autopsy data: present.
- For the purpose of intravenous hyper-alimentation, a femoral catheter（60 cm length）was inserted into the right subclavian vein with the assist of Landmark method and fixed at 25 cm. Because the chest X-ray showed no problem, intravenous hyper-alimentation was started. Abnormal backflow was observed occasionally through the infusion line. After two weeks, the patient showed dysphoria and fell into shock. On the CT, the catheter tip was located in the right ventricle and at the same time, cardiac tamponade was detected. When the catheter was withdrawn 5 cm, ventricular fibrillation occurred immediately after. The patient was transferred to another hospital with continuing cardiopulmonary resuscitation but died on the same day.

Case 6

- The patient had been under the treatment of maintenance hemodialysis for chronic renal failure and taking anticoagulant drugs for atrial fibrillation.
- The cause of death was right side hemothorax due to the azygos vein injury by the guide wire.
  Ai data: present, autopsy data: present.
- For the purpose of hemodialysis, a long-term dialysis catheter was inserted into the right internal jugular vein with the assistance of landmark method. The guide wire was inserted as far as 30 cm, with no feeling of resistance. After the intervention, wheezing occurred. On the chest X-ray for the confirmation of the position of the catheter, cardiomegaly and right pleural effusion were observed, which was diagnosed as an exacerbation of heart failure. An urgent hemodialysis was performed for the purpose of removing the tissue water. Soon after the start of dialysis, with abnormal intense body motion, cardiopulmonary arrest occurred, resulting in death.

Case 7

- The patient had suffered from myelodysplastic syndrome. And was also under the treatment of maintenance hemodialysis for chronic renal failure and tube feeding（gavage）for quadriplegia. Difficulty in communication.
- The cause of death was suggested as mediastinal hematoma and hemothorax due to the vascular injury.
  Ai data: absent, autopsy data: absent.
- For the purpose of replacing the long-term dialysis catheter, the intervention to the left internal jugular vein was performed with the aid of X-ray fluoroscopy and of the real-time ultrasound-guided method. The carotid artery was punctured. After the temporary hemostasis obtained, the intervention to the same left internal jugular vein was performed again. At that time, resistance was felt at the insertion of the guide wire, so its position was confirmed by X-ray fluoroscopy, then a catheter was inserted 30 cm. Hemorrhage continued from the insertion site, but on the next day hemostasis was confirmed. Respiratory condition changed during dialysis on the second day after the insertion, and mediastinal hematoma was confirmed on the third day by CT. The patient died on the seventh day after the intervention.

Case 8

- The patient had been under the treatment of maintenance hemodialysis for chronic renal failure. V-P shunt was inserted for subarachnoid hemorrhage.
- The cause of death was suspected of mediastinal hematoma due to extravascular catheter placement.
  Ai data: present, autopsy data: absent.
- For the hemodialysis, a long-term dialysis catheter was inserted to the left internal jugular vein with X-ray fluoroscopy and real-time ultrasound-guided method. Although the reverse blood flow through the catheter was not observed, the procedure itself was smooth, so it was judged that the catheter was inserted into the target blood vessel. On the next day, hemodialysis was started, and a catheter was used as a blood return route. With the dialysis blood flow rate increased, rolling of the eyes and loss of consciousness appeared, and respiratory arrest followed. Mediastinal hematoma was observed on chest X-ray, and the patient died one hour later.

Case 9

- The patient had to discontinue the tube-feeding, due to an acute exacerbation of interstitial pneumonia and gastroduodenal ulcer. Difficulty in communication.
- The definite cause of death is unknown. Regarding the insertion of CVC, the catheter tip placed in the retroperitoneum was suspected as a factor of exacerbation of the general condition.
  Ai data: absent, autopsy data: absent.
- For the purpose of intravenous hyper-alimentation, the insertion of CVC（double lumen）from the right inguinal region was done with the assistance of landmark method, but the insertion was difficult due to the collapse of the vein. After multiple punctures the catheter was inserted from the left inguinal region and was checked with the abdominal X-ray. Twelve hours after the start of drip infusion, the patient fell into shock. A distention and mild pain in lower abdomen were observed. Abdominal CT revealed that the catheter tip was inserted into the retroperitoneum and drip infusion was discontinued. An examination puncture to abdominal space was performed, and there was no sign of perforative peritonitis. Conservative treatment was continued, but the condition gradually worsened, and the patient died four days after the insertion.

Case 10

- The patient had suffered from advanced cancer and ileus, taking antiplatelet drugs for arteriosclerosis obliterans.
- The cause of death was suspected as a cerebral hemorrhagic infarction due to the hematogenous metastasis of cancer.
  Ai data: absent, autopsy data: absent.
- For the purpose of intravenous hyper-alimentation, CVC was done to the right internal jugular vein with the aid of real-time ultrasound-guided method. After the confirmation with chest X-ray, drip infusion was started using an infusion pump. Approximately 9 hours after the insertion, the patient complained of difficulty in breathing, subsequently cough and chest pain occurred, and pneumothorax was pointed out. Therefore, a chest drainage tube was inserted. Two days after the insertion, pulsatile backflow of blood was observed during the exchange of the drip infusion line. CT revealed that the catheter had penetrated the internal jugular vein and the subclavian artery and dwelled in the aorta. The catheter was removed successfully without major bleeding, which was done with platelet transfusion and under the cardiovascular surgeon on standby. Approximately one month later, the patient died of complications related to the original disease.

4. Recommendations and explanations for the prevention of recurrence

【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）.

It is most important to recognize that the insertion of a central venous catheter is a high-risk medical intervention（risky procedure）that can have fatal complications. Seven of the 10 patients had blood coagulation disorders due to comorbidity, such as liver cirrhosis, myelodysplastic syndrome, and disseminated intravascular coagulation syndrome, and the influence of anticoagulant drugs and antiplatelet drugs. Three of these patients were on maintenance dialysis treatment for chronic renal failure. Although vascular injury might occur at a certain frequency as complication of intervention, it was confirmed that if a patient with hemorrhagic risk had blood vessel injury, it was difficult to respond for the arrest of bleeding and that the risk to become fatal was high.

Furthermore, edema, ascites and hypoalbuminemia were observed in all cases, and intravascular dehydration was suspected. It was suggested that when the blood vessels collapsed, it was difficult to insert a catheter and also difficult to maintain circulation that could tolerate complications as vascular injury, and that there was the high risk to become fatal.

As the risks peculiar to the patients who developed complications of CVC, obesity（BMI >30）, low weight（emaciation, BMI < 20）, edema, blood coagulation disorder, surgical wound of the catheterization site, respiratory functional disorder, and history of difficulty in securing central venous catheter, etc. have been reported. The insertion of a central venous catheter is a procedure performed when the general condition is worsened or when it is judged to be indispensable for treatment. However, in the high-risk patients with blood coagulation disorders and intravascular dehydration, it is difficult to respond to hemostasis, etc. by surgery if complications of vascular injury occur. For this reason, it is important to decide carefully on the indication of insertion of central venous catheter, keeping in mind a high probability of a lethal situation.

Although it has been reported that a peripherally inserted central venous catheter（hereinafter referred to as "PICC"）inserted into the basilic vein of the upper arm has high safety in catheterization, none of the PICC options were examined in any of the cases. In addition, the number of the cases where we were able to confirm that the indication was approved after discussion was five out of 10 cases. Therefore, it is hoped that an intervention of CVC, including a substitute in a secure manner, will be decided by a consensual decision-making, exchanging opinions among more than one person.

● When considering the implementation in the patient with a high risk, the following items should be considered by more than one person.

- □ Do you have to insert the central venous catheter definitely?
- □ Can the patients under anticoagulant therapy and antiplatelet therapy withdraw the drugs?
- □ Can it be replaced with PICC?
- □ Have individual consents been obtained after explaining individual risks including fatal complications?
- □ Do you have a backup system that can respond to vascular injuries?
- □ In the cases, including vascular collapse, where it is difficult to insert a catheter, is it possible to cooperate with a local key hospital, etc.?

【Informed consent】

Recommendation 2 Prior to the catheterization, the patient should be explained its necessity and give consent 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 understandings from the patient or family.

The CVC is routinely performed, but it is also a risky procedure. Five cases out of 10 confirmed that the patients and/or families had received the explanation on CVC using the explanation sheet, and that in two cases the explanation had been made verbally.

Even among the five cases that were explained using the explanation sheet, the explanation was only about the common complications, and it was only one case that the individual risk of hemorrhage was explained. Even though the physician explained it was "dangerous," the family recognized that "there was no explanation that it could be fatal." As such, in some cases, there was difference in recognition between the two parties. In the cases where verbal explanation was made, there was also the opinion of the family that "we wouldn't have requested the CVC if there had been enough explanations."

Informed consent (explanation and consent, hereinafter referred to as "IC"), is the basis for implementing medical practice in modern medical care that assures the right to self-determination of the patient. In the IC, the physician explains the patient's medical condition and disease name as well as the treatment policy, for the purpose of obtaining consent from the patient and family. However, in the cases assessed this time, we cannot but say that there is doubt as to whether the IC was implemented properly. That is, even if an explanation was made, a question still remains whether the patient was fully satisfied with the content of explanation and was led to "consent." It may result in an endless dispute that the physician says "explained" and the patient and family say "not informed." Therefore, it is the essence of the IC that the physician makes it sure whether the "consent" was obtained as a consequence of "agreement" following "satisfaction" with the "explanation". Physicians need to make efforts so that the patients are "satisfied."

The patients who require the insertion of a central venous catheter basically have poor general condition. Regarding CVC, physicians should explain the following three factors to the patients and families in order to obtain their satisfaction: the advantages to be obtained by the CVC, the risks of the individual patient associated with catheterization, and the possibilities for selecting alternative methods. Especially to the high-risk patients, it is important to explain that insertion is still necessary even after considering the fatal risk, so that the patient or family can be satisfied with the information. In order to help patients and families understand and be satisfied, it is necessary to prepare an explanation sheet with detailed and concrete explanations and to record their consent in writing that they were satisfied with the explanation. Undergoing these procedures leads to sharing the CVC risk as a team and to focusing on prevention of complications and patient care.

Furthermore, if the IC cannot be made in advance to the patient under urgent circumstances, it is desirable to explain to the family beforehand. When the procedure is included in a series of advanced life support practices, it is desirable to explain the history early after the intervention and obtain approval.

● What we expect of (or what we want to propose to) academic societies and companies

It is hoped that the standard specification of "Explanation and informed consent forms of the insertion of a central venous catheter" will be prepared, which is available for many institutions.

● An example of the explanation detail items about the insertion of a central venous catheter

- □ What is a central venous catheter?
- □ The reason why the CVC is necessary
- □ Comparison of options, such as other alternative methods
- □ Outline of the CVC method (type of the insertion site and the predetermined insertion site)
- □ Insertion procedure, time required
- □ Daily living after the insertion
- □ Complications
- □ Individual risk explanation (including those that may become fatal)
- □ Signature of the patient and family

【Intervention techniques】

Recommendation 3 At the start of intervention to the internal jugular vein, 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.

The ultrasound-guided method for CVC has the two types of procedures: (1) One is "Image drawing method with Pre-Scan" in which intervention is performed after a pre-scan to clarify the vein appearance (diameter, presence or absence of collapse), depth, and the positional relationship with the artery and to implement risk assessment; and (2) the other is "Real-time ultrasound-guided intervention" in which after a pre-scan the intervention is performed while the target vein and the catheterization needle are being observed in real time under the ultrasound tomographic imaging.

The internal jugular vein, subclavian vein, and femoral vein are used for CVC. The selection of the catheterization site depends on the case. However, in recent years, there is a tendency to select the internal jugular vein, which has a low risk of complications of pneumothorax, and a better operability. Among the target 10 cases analyzed this time, the internal jugular vein was selected in eight cases.

Of the eight cases where internal jugular vein catheterization was adopted, pre-scan were performed in six cases, and the landmark method (see Glossary) without a pre-scan was performed in two cases. Even among the six cases where a pre-scan was performed, there were cases in which a vertebral artery, a common carotid artery, or a subclavian artery was erroneously punctured.

In the case of the internal jugular vein catheterization, since the internal jugular vein and the common carotid artery overlap in the anatomical position (Fig. 1, Fig. 2, Fig. 3), it is necessary to pay particular attention to the positional relationship of the artery and the vein as well as the direction of catheterization. In a pre-scan, evaluate the diameter and depth of the vein, presence or absence of vein collapse, overlapping and its degree of the artery and vein, and constructs (arteriovenous and nerves) present around the target vein, which will become the risks for the procedure. Based on the obtained information, you can select the optimal catheterization site for the patient and recognize the safe direction and safe depth range, which leads to a more reliable catheterization.

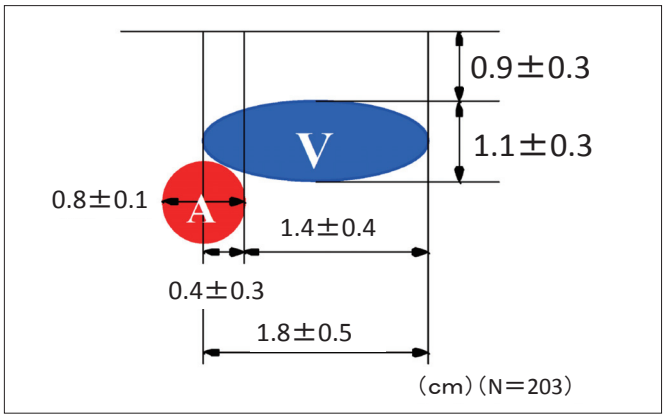
A pre-scan is available to consider what type of approach should be taken to avoid risks. Therefore, the pre-scan is recommended as one of the necessary measures to enhance safety.

Points of the catheterization procedures related to the Recommendation 3, Recommendation 4, Recommendation 5 and Recommendation 6

You can watch it in a movie.

URL https://www.medsafe.or.jp/movie/

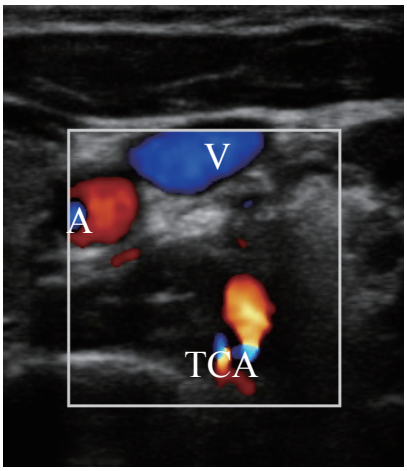
Figure 1
Positional relationship between internal jugular vein (V) and common carotid artery (A)



The internal jugular vein is located at a depth of about 1 cm. under the skin.

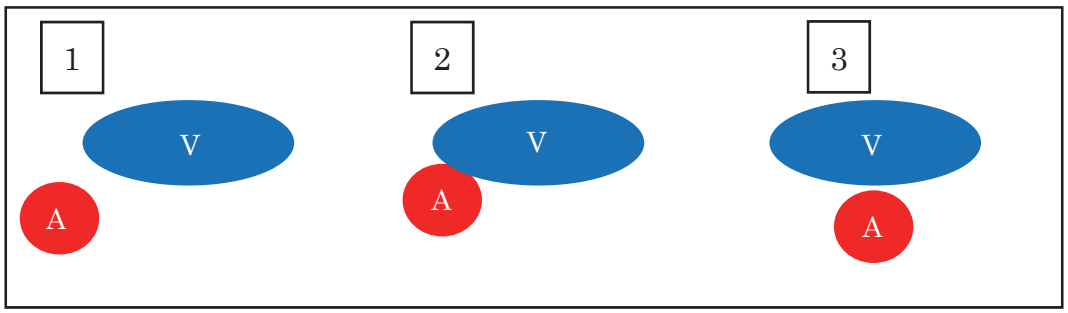
Joho Tokumine. "Detailed explanation I Internal jugular vein catheterization." *Ultrasound-Guided Central Venous Catheterization Method Manual*. Sogo Igaku Sha 2007, 28 (3): 44. (Reprinted with permission)

Figure 2
Color Doppler images of internal jugular vein and common carotid artery



On the dorsal side of the internal jugular vein (V), not only common carotid artery (A) but many arterioles such as transverse cervical artery (TCA) exist.

Figure 3 Positional relationship of internal jugular vein (V) and common carotid artery (A). [pattern classification]



		Right side	Left side
1:	Apart.	12% (22/186),	12% (2/17)
2:	Partly overlapped.	79% (147/186),	82% (14/17)
3:	Completely overlapped.	9% (17/186),	6% (1/17)

From 2 and 3, it is assumed that internal jugular vein (V) and common carotid artery (A) overlap by approximately 90%.

Joho Tokumine, Kenichi Nitta, Koji Teruya, et al. "Ultrasound-Guided Internal Jugular Venipuncture by Short-Axis Approach in 203 Cases at the University of the Ryukyus Hospital." *Journal of Japan Society for Clinical Anesthesia* 28 (3) 439-446, 2008. (Reprinted with permission)

【Intervention techniques】

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.

It has been reported that a real-time ultrasound-guided intervention has less failure of catheter placement than the conventional landmark method.

In the eight cases of internal jugular vein catheterization, six cases conducted a pre-scan and then underwent real-time ultrasound-guided intervention. Just in one case, we could confirm that the practitioner who used an ultrasound had undergone simulation training in real-time ultrasound-guided catheterization.

The real-time ultrasound-guided intervention is certainly an excellent method. However, since an image on ultrasound is a two-dimensional, there exists a pitfall that even if the catheterization needle has already penetrated through the target vein, the image appears as if the tip were inside the vein（Figs. 4 and 5）. Hence, the position of the catheterization needle is misidentified and the catheter is unexpectedly inserted deeper. It is recommended that the practitioners understand these characteristics and pitfalls of ultrasound and receive simulation training.（See the video referred to in Recommendation 3）

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

We hope that to a system will be constructed in the near future, where, under the consideration of the pitfalls of ultrasound, an education curriculum for simulation training of real-time ultrasound-guided catheterization will be established and medical practitioners will participate in the course.

Figure 4　Mechanism of misidentification of a needle tip which occurs under ultrasound-guided intervention.

The ultrasound information is displayed as a two-dimensional image on the screen, though it is obtained from the original three-dimensional information on the ultrasound 3-D field. The tip portion outside the ultrasonic detecting field is not depicted, which makes a phenomenon that the true needle-tip disappears [a], and false needle-tip [b] is on the screen, under the deviation of the two plains of the needle and the ultrasound. This is the cause of the false needle-tip displayed as the "Needle tip".

Figure 4-1　Ultrasound Detecting field

［3-Dimensional］

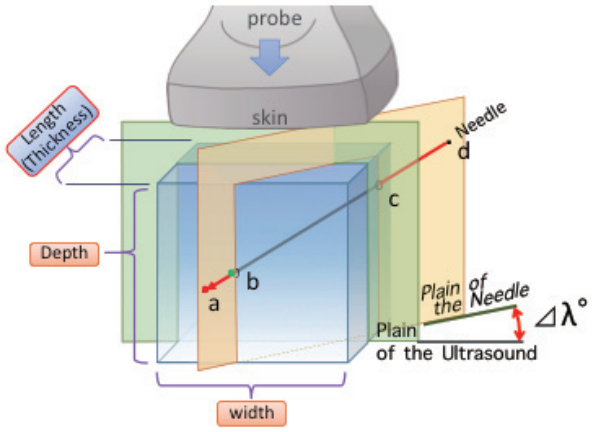
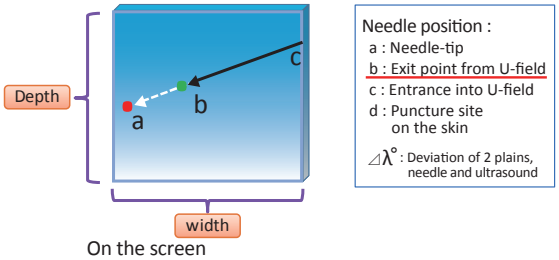


Figure 4-2　Ultrasound Display Screen

［2-Dimensional］

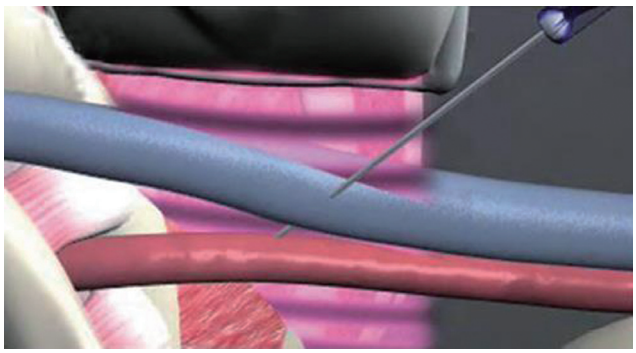


On the screen

[a] ●: Actual Needle-tip is out of sight

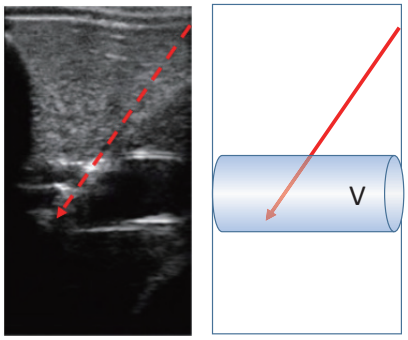
[b] ●: looks like the "Needle-tip"

Figure 5　Ultrasound images on Simulator



［Actual simulator model］

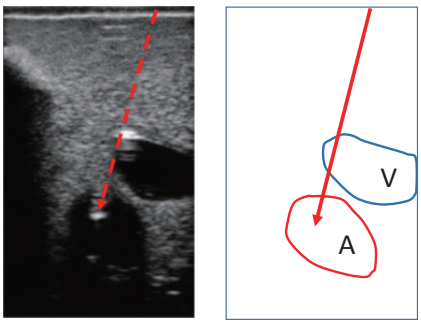
・The needle-tip is penetrated to the artery



・Misidentifying situation

［Long-axis view］

Needle-tip is in the vein



・Situation of no deviation between two plains

［Short-axis view］

Needle-tip in the artery detected

Tokumine J, Lefor A T, Yonei A, et al. "Three-step method for ultrasound-guided central vein catheterization." *BJA* 2013; 110（3）: 368-373.（Modified and reprinted with permission）

【Intervention techniques】

Recommendation 5 The needle in the "CVC kit" is mostly too long for the internal jugular vein. Therefore, do not insert beyond the reach of jugular vein. Especially in the case of emaciated patient, the operator should pay attention not to insert too deep.

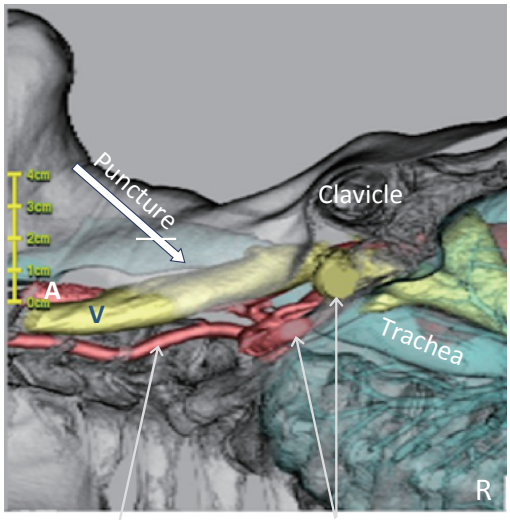
Of the eight cases where the internal jugular vein was selected, six were the thin (emaciated) patients with a BMI of 20 or less and five of them had injured arteries (suspect involved). In some cases a catheterization needle reached the vertebral artery or the common carotid artery and in the other case the subclavian artery was penetrated and the catheter was indwelled in the aorta. In particular, it was speculated that an important issue lies in the depth of the internal jugular vein catheterization for the patient in the emaciated status.

Anatomically, the internal jugular vein is located approximately 1 cm below the skin (Figs. 1 and 6), and the internal jugular vein and the common carotid artery are in an overlapped positional relationship (Fig. 1, Fig. 2, Fig. 3). Because of them, venous blood is typically aspirated by catheterization within 2 cm. You should be most careful not to stab too deeply and it is important not to puncture more than 3 cm. Furthermore, attention should be paid to the catheterization direction in consideration of the positional relationship of the artery and the vein. (Refer to the video in Recommendation 3)

In any of the cases, the length of the catheterization needles in the central venous catheter kit used was 6.0 to 8.9 cm. Thus, it was suggested that a length of needles longer than the depth of the vein was one of the factors of deep catheterization. In particular, caution should be paid to the insertion length of the catheterization needle in a thin patient. Some central venous catheter kits have needles that are devised so as not to be stabbed too deeply. They are ultrasound-assisted needles whose tip can be clearly seen with ultrasound and a short catheterization needle fitted to the internal jugular vein. For the medical safety improvement, to select such a central venous catheter kit should be considered.

● What we expect of (or what we want to propose to) academic societies and companies.
Currently, products of catheterization needles with a scale are very limited and are less common. For a safe catheterization procedure, development and technological innovation of the catheterization needle that can limit the depth of catheterization, and catheterization devices such as guide wires and dilators are expected.

Figure 6 Positional relationship between the internal jugular veins



When punctured at an angle of about 30 to 45 degrees against the skin from the apex of the submandibular triangle, the needle reaches the internal jugular vein within 2 cm of insertion in the average Japanese physique. It reaches the subclavian vein at approximately 4 cm deep and may cause pneumothorax at 5 cm deep. Furthermore, if you puncture the medial side 3–4 cm, the vertebral artery may be erroneously stabbed.

The 3D anatomy lecture for the anesthesiologist 5th class — Internal jugular vein paracentesis. Joho Tokumine, Tomoko Sekiguchi, Yoshimasa Takeda, et al. *LiSA. 2011; 18 (6): 590-598.* (Modified and reprinted with permission)

【Intervention techniques】

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, 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.

The procedure using a guide wire was performed in eight out of 10 cases. Among the five cases where ultrasound was used（in two cases X-ray fluoroscopy was used in addition）, some cases showed that the guide wire was placed in the blood vessel through ultrasound or X-ray fluoroscopy. Furthermore, during the internal jugular vein catheterization procedure, in two cases the guide wire was inserted 30 cm. In one of the cases a guide wire strayed into the venous branch to cause an injury, and in the other case the procedure was continued although there was resistance at the time of insertion.

In the case of a real-time ultrasound-guided catheterization, there is an advantage that you can confirm whether the guide wire is correctly indwelled in the vein during the intervention procedure. Even if the guide wire deviates out of the blood vessel, if it is noticed before insertion of the dilator, there is little possibility of serious complications. Therefore, it is important to confirm, at the time of inserting a guide wire, its presence in the blood vessel by ultrasound or X-ray fluoroscopy.（Refer to the video introduced in Recommendation 3）

In the case of internal jugular vein catheterization, the insertion length of the guide wire is about 13 to 15 cm to the sixth intercostal space. If you insert it deeply with a fear of its dropping out accidentally, there is a possible risk that it reaches the heart to affect the cardiac muscle, which can cause fatal cardiac arrhythmias. In addition, deep insertion of the guide wire increases risks where the guide wire deviates out of the vessel or strays into the vein branch and injures it, and so it is important not to insert the guide wire more than 20 cm. Also, in the case of insertion under the X-ray fluoroscopy as well, it is important to perform the procedure while paying attention to the straying of the guide wire tip into the branch and its position against the vein wall and heart.

Furthermore, currently the scale mark on the guide wire is not easy to read at the time of insertion. Thus, as indicated in Recommendation 5, the development and technological innovation of the catheterization devices including needles are anticipated.

【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.

Typically, after insertion of a catheter, intravascular placement is confirmed with reverse blood; furthermore, the position of the catheter is ascertained with the X-ray frontal view. 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.（Fig. 7）

In four of the 10 cases, a central venous catheter was used although reverse blood could not be confirmed. In two cases of them, an indwelling catheter for dialysis was inserted under X-ray fluoroscopy. Since infusion was possible with the catheter although blood removal was not possible, the catheter was used for returning blood and dialysis was started. But, the patient's condition changed suddenly. In the other two cases, it was judged that the tip of the catheter was touching the blood vessel wall because reverse blood was observed on the side 1 alone of the double lumen catheter. But, in actual fact, the tip was deviated from the blood vessel. In clinical settings, as factors when reverse blood cannot be confirmed, it may sometimes be judged that when the catheter tip enters the narrow vessel from the central vein, withdrawal of the catheter becomes difficult because of a collapse when negative pressure is applied, or the catheter tip is touching the vessel wall. However, if there is no reverse blood, it is essentially important not to use the catheter. Especially, in the case of an indwelling catheter for dialysis, since the probability of causing fatal complications is high when dialysis is initiated with extravascular erroneous placement. Therefore, when reverse blood cannot be confirmed, you should use contrast-enhanced CT and X-rays with a small amount of contrast agent to confirm that the catheter is placed in the target vein.

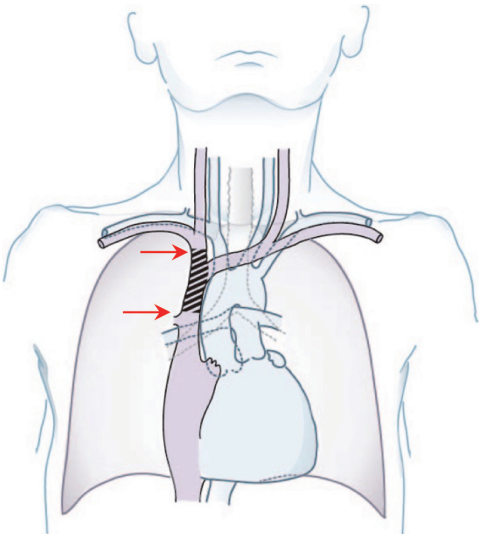
However, even if reverse blood is confirmed, it may actually draw a hematoma. Furthermore, in the situations of hypoxemia and anemia, arterial blood and venous blood cannot be distinguished by blood color alone. Consequently, it is necessary to recognize that there are situations in which you cannot say there is no problem with just a confirmation of reverse blood or the color and force of reversed blood（which can easily be sucked）. If you are not sure whether the reversed blood is venous blood or arterial one, it is also necessary to make sure by blood gas analysis and pressure waveforms.

In all the four cases in which central venous catheter was used, although the reverse blood could not be confirmed, the location of the tip of an inserted catheter was confirmed by X-ray frontal view, and it was judged that there was no problem. There was also a case where the catheter was judged to be indwelled in the blood vessel because it was close to the shadow of the superior vena cava on an X-ray view, but deviation into the thoracic cavity was confirmed by CT. For this reason, it was suggested that the X-ray frontal view alone could not confirm whether or not the catheter was deviated to the outside of the blood vessel. In the cases where catheter placement in the blood vessel is suspected, for such a reason as absence of reverse blood, it is necessary to take a side view（Fig. 8［8-2］）and perform CT scans, in addition to the X-ray frontal view（Fig. 8［8-1］）to reconfirm the position of the catheter.

●The points of chest X-ray findings after the insertion of a central venous catheter

- □ Localization of a catheter
- □ Intrathoracic fluid accumulation: Hemothorax due to vascular injury
- □ Pneumothorax
- □ Infiltrate images of the lung field: Pulmonary hemorrhage, injury to pulmonary artery
- □ Deviation of the mediastinum to the unaffected side: Tension pneumothorax
- □ Pneumomediastinum: Trachea, bronchial injury
- □ Cardiac shadows, enlargement of mediastinal shadows: Cardiac tamponade, mediastinal hematoma

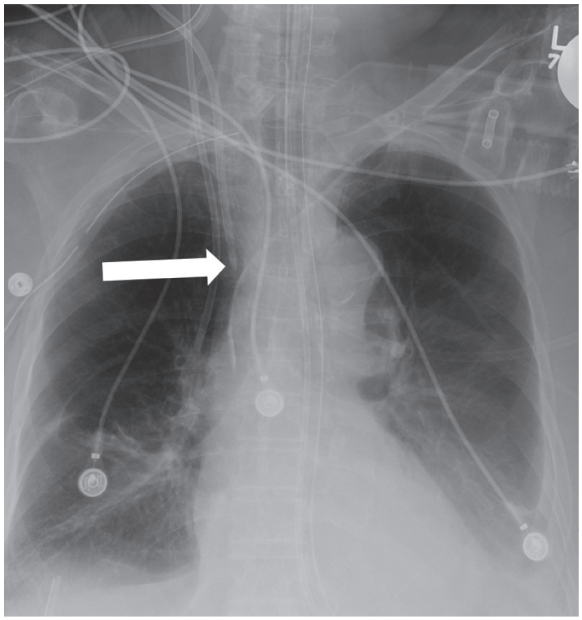
Figure 7　Ideal position of the central venous catheter tip



1）The central venous catheter tip should be between the inferior border of the clavicle and the inferior border of tracheal bifurcation.
2）The catheter should run parallel to the body axis and should not curve in the U-shape or run in the horizontal axis direction.
3）If there is any doubt that the catheter tip may be placed differently from the expected position of the superior vena cava, check it with the X-ray lateral view.

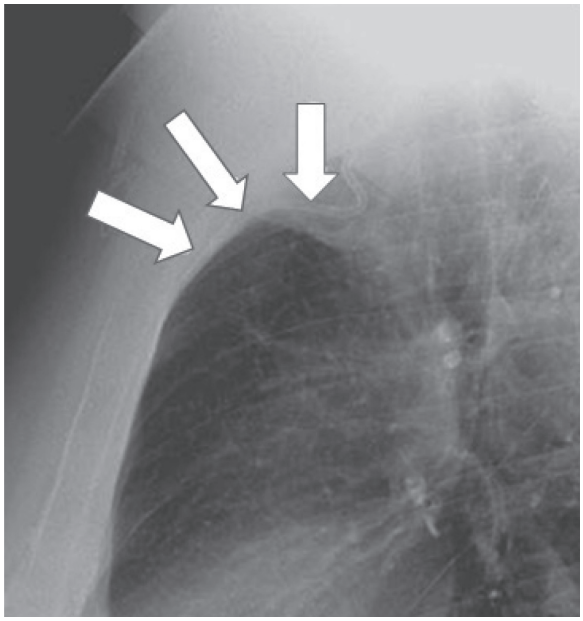
Figure 8　The example of central venous catheter not placed in the superior vena cava

［Fig. 8–1］ Chest X-ray frontal view



The chest X-ray frontal view taken with portable X-ray device. The tip of the catheter inserted into the right internal jugular vein was determined to be in an appropriate position in the superior vena cava.（Arrow）Meanwhile, reverse blood in the catheter was scarce.

［Fig. 8–2］ Chest X-ray lateral view



The X-ray lateral view revealed that the catheter was displaced forward and strayed into the right internal thoracic vein.（Arrow）

Roldan C J, Paniagua L. "Central Venous Catheter Intravascular Malpositioning: Causes, Prevention, Diagnosis, and Correction." *West JEM* 2015; 16（5）: 658-664.（Reprinted with permission）

【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.

In five out of 8 cases resulting in erroneous catheterization to the artery, vascular injuries, or pneumothorax, sudden drop in blood pressure and a decrease in percutaneous arterial oxygen saturation (SpO_2) were observed within one hour after the catheterization finished. When looking back, there were three cases where symptoms of restlessness, such as "moving restlessly" and "intense body motion," were observed prior to variability of the vital signs. In addition, there were three cases where difficulty in breathing and cyanosis of lip were observed after 7-12 hours of catheterization. The patient monitoring systems were not worn during and after catheterization in four out of 10 cases.

As described above, changes in patients appear in the vital signs and symptoms of restlessness, and so patient observation and utilization of monitoring are also important means for early detection of complications such as hemorrhage, pneumothorax and airway narrowing. In particular, if there are problems of erroneous catheterization to the artery or no backflow of blood, physicians and nurses should share the information with an awareness of the issues. If the patient's condition changes or an abnormal change occurs in infusion line, we believe that prompt examination and diagnosis will lead to the saving of their lives.

Furthermore, in the case where a catheter was indwelled in the artery, pulsatile backflow of blood was observed when the infusion pump was removed. In the case where a catheter was indwelled in the right ventricle, there was the backflow of blood that filled an infusion line without any use of infusion pump, and infusion resistance occurred when it was dealt with. If such abnormalities are found, you should positively suspect of the catheter straying into the arterial system or the heart chamber.

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

For the implementation of patient care and information sharing among the healthcare professionals, it is hoped that the standard specification of implementation record forms of the insertion of a central venous catheter and a patient observation checklist after the insertion of a central venous catheter will be prepared, which is available for many institutions.

● Observation points immediately after the insertion of a central venous catheter

- □ Changes in blood pressure, pulse, and percutaneous arterial oxygen saturation (SpO_2)
- □ Difficulty in breathing, reduction of breath sounds, and presence or absence of laterality
- □ Presence or absence of subcutaneous emphysema
- □ Cyanosis of lip
- □ Hematoma, hemorrhage of the catheterization site
- □ Restlessness symptoms
- □ Jugular venous distention

【Patient care】

Recommendation 9 In order to respond promptly to the event of complications, the cooperation with other departments including transfer to other hospitals should be designed in manual.

CVC is a medical intervention that has a risk of dying of complications. Among the reported cases, there was a death where the incorrect insertion was noticed after the insertion of a central venous catheter in the operating room, and even though multiple physicians examined, pleural hemorrhage occurred after the withdrawal, resulting in death. It is important to perform the CVC after establishing the in-hospital system assuming the occurrence of fatal complications.

In particular, if fatal complications occur in a high-risk patient, there may be the cases where the clinical department concerned alone cannot fully cope with the situation because they may require urgent open-chest surgery. If you are in a large medical institution, you should establish an in-hospital system that can obtain the cooperation of the specialized clinical departments, such as the cardiovascular surgery, anesthesiology, and the emergency department, in your hospital. In addition, if the life-saving response seems difficult in the hospitals such as clinics or small medical institutions, you should have an appropriate manual for cooperation, including the transfer system with local key hospitals or regional hospitals that have the specialized clinical departments for cardiovascular surgery, anesthesiology, and emergencies, etc.

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

As for the following items, the need for them has been mentioned in the in-hospital investigation reports, and in the review of the Expert Analysis Subcommittee, it was recognized that the development was important for the safer insertion of a central venous catheter. However, within the present review period, it was not possible to examine the issues thoroughly. It is hoped that specialized academic societies and companies will address the following challenges, which will lead to further improvement in medical safety in the future.

（1） **Explanation and informed consent forms of the insertion of a central venous catheter**

It is hoped that the standard specification of "Explanation and informed consent forms of the insertion of a central venous catheter" will be prepared, which is available for many institutions.

（2） **Educational curriculum about the real-time ultrasound-guided central venous catheterization**

We hope that a system will be constructed in the near future in which, under consideration of the pitfalls of ultrasound, an education curriculum for simulation training of the real-time ultrasound-guided catheterization will be established and medical practitioners will participate in the course.

（3） **Implementation record forms of the insertion of a central venous catheter and a patient observation checklist after the insertion of a central venous catheter**

For the implementation of patient care and information sharing among the healthcare professionals, it is hoped that the standard specification of implementation record forms of the insertion of a central venous catheter and a patient observation checklist after the insertion of a central venous catheter will be prepared, and that it is available for many institutions.

（4） **Development of the catheterization device**

For a safe catheterization procedure, development and technological innovation of the catheterization needle that can limit the depth of catheterization and catheterization devices such as guide wires and dilators are expected.

6. Conclusion

The Expert Analysis Subcommittee for Central Venous Catheterization delivered nine recommendations after analyses and examinations of the ten death cases caused by the complications of central venous catheterization（CVC）reported this time. Recommendation 1 was on the indication of CVC, Recommendation 2 on the informed consent, Recommendations 3-6 on the catheterization procedure, Recommendation 7 on the confirmation of catheter positioning, and Recommendations 8-9 were about patient care. These contents are never new but have been pointed out repeatedly in various guidelines. As a result of the examination of the ten cases, particularly from the viewpoint of what should be done to avoid situations leading to death, these nine items were highlighted and recommended among many recommendations in the guidelines.

The patients who require the CVC are normally in poor general condition. Among the ten target cases studied this time, blood coagulation disorder was observed in seven cases and BMI was lower than 20 in six cases. Therefore, the CVC is a high-risk medical intervention（risky procedure）that may cause fatal complications. This should be recognized firmly as the basic attitude to decide the indication, to obtain the Informed Consent, carry out the procedure and to undertake post-operative care. Further, if a problem occurs during procedure, the information should be disclosed actively, and the awareness of the problem should be shared among the medical team. These are the fundamental principles to avoid situations leading to death. We would like to expect that the reports of death caused by complications of CVC will decrease in the future. Additionally, we will revise the recommendations after evaluating their effect so as to make them more useful.

As is generally known, medical accidents are not as simple as will disappear just by physicians following guidelines or recommendations, but are rather caused by complex multiple factors when they overlap complicatedly. Until now, many medical professionals who hoped for medical safety have made constant efforts to improve the quality of medical care, and it has been promoted gradually while trial and error being repeated. This effort must be continued in the future.

We would like to express our deepest condolences to the patients who died due to accidents and to the bereaved families. We would also like to express our sincere gratitude to the medical institutions as well, who contributed to the investigation of the causes and to the prevention of recurrence, and cooperated in sharing the in-hospital investigation reports. We hope that the recommendations in this First Report will be of help to medical professionals as a step toward improving medical safety.

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7. Materials

Complications of CVC［Investigation items checklist］

Items		Viewpoints	Concrete items
Basic information	Patient information	Primary disease/Medical history	
		Age/Gender	Age:____year-old Gender : ☐ Male ☐ Female
		Body height/Weight	Height:_____cm Weight:_____kg
		Habitus	BMI
	Laboratory data information	Blood data	☐ Hemoglobin:_____g/dL ☐ Hematocrit:____% ☐ Platelets:_____ × 10^4 μL ☐ PT-INR:____ ☐ APTT:_____second ☐ D dimer:____ng/mL ☐ Fibrinogen:____mg/dL ☐ T-P:_____g/dL ☐ Albumin:_____g/dL ☐ Other
		Hemorrhage risk factors	☐ Blood coagulation disorder ☐ DIC ☐ End stage of liver cirrhosis ☐ Dialysis therapy ☐ Antiplatelet therapy（Bayaspirin, etc.） ☐ Anticoagulant therapy（warfarin, heparin, etc.） ☐ Other
		Signs indicating dehydration	☐ Present => ☐ Decreased urine output ☐ Dry skin ☐ Dry mouth ☐ Other ☐ Absent
		Edema	☐ Edema extremities ☐ Edema of lower extremities ☐ Anasarca ☐ Ascites
		Imaging findings	☐ Chest X-ray ☐ Contrast-enhanced CT
Cause of death	Autopsy Ai	Autopsy results	
		Ai results	
	Cause	Injured blood vessels	（Describe injured blood vessels: including suspect）
Diagnosis and Choice of treatment	Objectives	The aim of the insertion of a central venous catheter	☐ Electrolyte correction ☐ Improvement of nutritional status ☐ Whole body control ☐ Dialysis ☐ Other
	Decision	Decision of the insertion of the central venous catheter	☐ Council decision making ☐ Decision by the responsible person for the clinical department concerned ☐ Decision by the attending physician ☐ Other
		Options other than the central venous catheter	☐ Present ☐ Absent
Informed Consent	Details of explanation	Explanation sheet	☐ Present ☐ Absent
		Patient-specific risk explanation	☐ Present ☐ Absent
	Consent	Response of the patient and family	

Items		Viewpoints	Concrete items
Intervention procedures	About the Practitioner	Practitioner's position	☐ Attending physician ☐ Senior（instructing）physician ☐ Initial training residents ☐ Later training residents ☐ Responsible person for the clinical department ☐ Anesthesiologists ☐ Emergency department physicians ☐ Other hospitals
		Practitioner's implementation experiences of insertion of the CVC （number of cases）	_____cases（Dr.　　）
		Number of experiences in using the same kit employed	_____cases（Dr.　　）
		Practitioner's recognition of the risk	
	Employed devices	Specification of the catheterization kit employed	
		Length（cm）/diameter（mm, G）of the catheterization needle	_____cm/_____mm（　　G）
	Risk assessment during catheterization	Ultrasonic diagnostic equipment	☐ Present　　☐ Absent
		Evaluation of catheterization risk	☐ Confirmation of blood stream ☐ Arteriovenous positional relationship ☐ Vein description（diameter and collapse） ☐ Depth of the vein
	Confirmation of the needle position	Real time approach	☐ Short-axis crossover method ☐ Long-axis parallel method
		Method to confirm the needle position	☐ Short-axis image ☐ Long-axis image
	Insertion of a guide wire	Usage of a guide wire	☐ Used => ☐ Insertion with a metal needle（Seldinger method） ☐ Insertion with an outer cylinder needle（modified Seldinger method） ☐ Not used
		Insertion length of the guide wire	Insert_____cm from the skin
		Status during insertion	☐ With a sense of resistance ☐ No sense of resistance ☐ Other
		Confirmation of the guide wire	☐ Short-axis image ☐ Long-axis image

Items		Viewpoints	Concrete items
	Puncture	Puncture site	☐ The internal jugular vein（left, right） ☐ Subclavian vein（left, right）（supraclavicular approach） ☐ Subclavian vein（left, right）（subclavian approach） ☐ The femoral vein（left, right）
		Number of punctures	☐ One time ☐ Two times ☐ Three times ☐ Other（ ）times
	Confirmation of insertion	Reverse blood	
		Radiographic image for confirmation	☐ X-rays ☐ Simple CT ☐ Contrast-enhanced CT ☐ MRI
		Examination time	☐ 1._____ minutes/hours after insertion ☐ 2._____ minutes/hours after insertion ☐ 3._____ minutes/hours after insertion
		Interpretation results	
	Response at the time of arterial puncture	Bleeding control methods	☐ Manual astriction:_____minutes ☐ Gauze pressure immobilization:_____minutes ☐ Other
	Procedure discontinuation	Proposal situation for the discontinuation of procedure	☐ Present ☐ Absent
		The reason of no proposal	☐ There was no proposer ☐ Atmosphere where it was hard to propose ☐ Other
Patient care	Observation	Vital signs at ordinary times	☐ Blood pressure:____mmHg ☐ Respiration:___times/minute ☐ Pulse:____times/minute ☐ SpO_2:____% ☐ Consciousness level
		Vital signs at the time of accident	☐ Blood pressure:____mmHg ☐ Respiration:____times/minute ☐ Pulse:____times/minute ☐ SpO_2:____% ☐ Consciousness level
		Monitoring status	☐ ECG monitor ☐ SpO_2 monitor ☐ Blood pressure monitor ☐ A line ☐ Other ☐ Absent
	Abnormal signs and the provided actions	Abnormal signs	☐ Unrest ☐ Active body motion ☐ Cyanosis of lip ☐ Delirium ☐ Widely opened eyes ☐ Pain ☐ Shortness of breath ☐ Pulsatile or unnatural backflow in line ☐ Infusion resistance ☐ Other
		The time when abnormal signs recognized	☐ _____minutes after the start of paracentesis ☐ _____minutes after insertion
		Providing actions to abnormal signs	

Items		Viewpoints	Concrete items	
The management system of the medical institution	In-hospital system	The consensual decision-making system concerning CVC	☐ Present	☐ Absent
		The manual of CVC	☐ Present	☐ Absent
		Clear descriptions of progress observation items after insertion	☐ Present	☐ Absent
		The system of consultation with other departments	☐ Present	☐ Absent
	Education system	In-hospital certification system of CVC	☐ Present	☐ Absent
		Presence or absence of the training system for the ultrasound-guided CVC using the simulator	☐ Present	☐ Absent
	Response to the event of complications	The response system to the event of complication	☐ Present	☐ Absent
		Inter-Hospital/clinic cooperation and transfer system	☐ Present	☐ Absent

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Issued in March 2017

Edited and published by Japan Medical Safety Research Organization

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According to Article 6, paragraph 15 of the Medical Care Act, the Japan Medical Safety Research Organization was designated as the Medical Accident Investigation and Support Center, and is to perform the duties including investigation prescribed in each item of Article 6, paragraph 16 of the same Act（hereinafter referred to as “duties”）.

The contents to be published in this report were written based on the information reported in accordance with Article 6, paragraph 11 of the same Act. This information is based on the data obtained at the time of writing, and we will not guarantee the contents for the future. In addition, this report should be applied by those who use it with their free will, judgment, and choice based on their individual responsibility. It does not restrict the discretion of healthcare professionals or impose duties or responsibilities on them.