Clinical Report

Systematic Hospital-based Management to Maintain Safety of Central Venous Catheterization

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Abstract

After the occurrence of two cases of fatal complications associated with central venous (CV) catheterization, Tokyo Medical University Hospital formed a multidisciplinary panel tasked with developing a systematic plan aimed at preventing the occurrence of serious adverse events during this procedure. The purpose of this study was to clarify whether the system developed was successful in reducing the mechanical complication rate during CV catheterization. Systematic management was based on the following guidelines: (1) CV catheterization should be performed in a designated room; (2) only certified physicians are allowed to perform CV catheterization; (3) catheter insertion records should be made and collected; and (4) post-insertion management should be standardized. During the first 5 years 6 months, the complication rate was 4.9%. The management system devised by the panel resulted in a lower occurrence rate of complications than before. Further investigation will be conducted on risk factors for such complications. Improvement of the guidelines will enable safer CV catheterization.

Introduction

The use of central venous (CV) catheters was first reported by Aubaniac in 1952\textsuperscript{1}). Central venous catheters are used extensively worldwide\textsuperscript{2\textsuperscript{b}). This type of catheterization has been taught and implemented without any special manual or system since the beginning of the 2000s, and its simplicity has contributed to its widespread use. Many interns are instructed to place a CV catheter by a senior doctor. They often carefully and successfully insert the thick trocar, using their own individual method, in the corner of a large, shared room. Although arterial puncture or mild pneumothorax occasionally occurs, serious adverse events are rare, and few clinicians consider CV catheter insertion to be a potentially life-threatening procedure for patients.

On the other hand, mechanical complications following CV catheterization occur at rates of 6.2%-10.7% for subclavian vein puncture, 6.3%-11.8% for internal jugular vein puncture, and 12.8%-19.4% for femoral vein puncture\textsuperscript{3\textsuperscript{b}). One randomized, controlled trial found that the incidences of complications during CV insertion into the subclavian and femoral veins were 18.8% and 17.3%, respectively\textsuperscript{4\textsuperscript{b}). Once three or more puncture attempts have been made in the subclavian vein, the incidence of complications increased from 4.3% to 24.0%\textsuperscript{7}). Serious or fatal complications associated with CV catheterization have been reported\textsuperscript{3\textsuperscript{b}5\textsuperscript{b}6\textsuperscript{b}).

At Tokyo Medical University Hospital (TMUH), similar to other Japanese (tertiary) hospitals, physicians per-
form CV catheterization as a routine procedure. Two cases of fatal complications associated with CV catheterization occurred at TMUH over approximately 6 months between 2003 and 2004. Some measures are taken to prevent complications, and up to five puncture attempts or three actual punctures may be made at any one go. If CV insertion is still unsuccessful, the physician or puncture site should be changed[7]. Physician education using simulated CV insertion before insertion in a patient is useful in ensuring patient safety[7]. Therefore, TMUH decided to implement systematic management to prevent mechanical complications during CV catheterization.

Forming a multidisciplinary panel was the first step in preventing mechanical complications with this procedure. The aim of this report is to describe how this problem was tackled and how effective the procedures adopted were in achieving a reduction in complication rates.

Methods

Institutional information

Tokyo Medical University Hospital is a 1,015-bed teaching hospital. Approximately 10,000 surgical procedures are performed there annually, and 2,000-3,000 patients visit the outpatient department daily.

Forming a panel

Before the establishment of a new protocol for CV catheterization at TMUH, it was hard to determine the number of such procedures and associated mechanical complications as records were inadequate. In February 2004, however, a panel was established tasked with evaluating the current situation, preparing in-hospital guidelines, and designing a system of comprehensive management of CV catheterization. It was composed of 14 people, and included physicians, nurses, and radiologists. The panel required physicians who performed CV catheterization to submit a registration form. This form required the following to be recorded: the patient ID; the name of the physician performing the CV catheterization; the purpose of CV catheterization; the duration and location of the procedure; and the occurrence of any complications. According to these forms, CV catheterization was performed 153 times and complications occurred in 14 cases (9.2%) in April 2004.

Issues revealed

The panel identified the following issues in CV catheterization and post-insertion management at TMUH: (1) indications for CV catheterization were not strict, and where there were difficulties in maintaining peripheral venous lines, it was inserted without adequate consideration; (2) sufficient explanations were not being provided to the patient, and patient consent was not being obtained; (3) CV catheterization was being performed in various locations, including large shared rooms, so emergency trays could not be used when a patient’s condition changed suddenly; (4) since there were no qualification standards, any physician could perform this procedure, regardless of their level of experience; and (5) there were no standard procedures for managing patients during and after CV catheterization.

Systematic CV catheterization management

The panel prepared the following set of guidelines. (1) The main indications for CV catheter placement are intravenous high-calorie infusion, securing an intravenous route, administering cardiovascular agents, and others. Indications for CV catheterization should be strictly judged by the medical team rather than a single physician. (2) Written informed consent must be obtained from the patient after being given sufficient explanation of the procedure’s risks and benefits. (3) Planned or semi-emergent CV catheterization should be conducted between 9 AM and 5 PM at the Central Venous Catheter Center (a semi-clean room that had been previously used for coronary catheter intervention; blood gas analyzers and ultrasound testing equipment were installed in this room). (4) Central venous catheterization must be performed by more than two physicians, including at least one certified physician. Physicians who had experience with > 100 CV catheterizations were certified by the panel (this requirement was put into place because if two doctors and one nurse were present during CV catheterization, the practitioners could swap places and the minimum number of staff required to respond to an emergency would be present). (5) Physicians must perform CV catheterization according to the following guidelines (Table 1). (6) The physician must present

Table 1 Guidelines for managing patients during and after CV catheterization

| 1) Insert catheter at center of CV line |
| 2) Use ultrasonography before catheter insertion |
| 3) Do not attempt to puncture > 3 times |
| 4) Obtain blood gas measurements |
| 5) Obtain chest x-rays immediately after and at 4-8 hours after insertion |
| 6) Submit “CV line insertion record” to panel |

CV, central venous
the CV catheterization record and post-CV catheterization observation checklist to the panel. The panel will analyze these records and offer feedback to medical staff for safer CV catheterization. (7) The panel will regularly hold central venous catheter study sessions and workshops for staff so that they understand the CV catheterization management system and continue to closely monitor for possible CV insertion-related adverse events. (8) A CV catheterization training system (including certification testing for operating physicians) should be initiated, and new interns will be required to attend the training.

There rules were established in October 2004 and implemented immediately thereafter. The number of CV catheterizations and complications occurring between October 2004 and March 2010 were analyzed.

The protocol of this study was approved by the Tokyo Medical University Ethics Committee (no. 2009).

Results

The total number of procedures in the first month after commencing implementation of systematic management was 166. Complications reported during that period comprised 1 pneumothorax, 3 arterial punctures, and 1 puncture site hematoma (total: 5 complications; overall complication rate: 3.0%). Data for the first month and each 6 months following October 2004 are shown in Figure 1. During that period, 8902 CV catheterizations were performed, and 435 complications occurred (overall incidence, 4.9%).

Discussion

Several lessons were learned from the implementation of this project. First, systematic management of CV catheterization resulted in a reduction in the mechanical complication rate. The complication rate decreased to 4.9% after implementation of the new system. This rate is as good as that reported previously[3][4][8]. Systematic management enabled the head of the hospital to know the numbers of CV catheterizations and complications that occurred, and to prepare a standardized procedure for patient care during CV catheterization.

Second, at first, there was strong resistance to using the Central Venous Catheter Center. Some physicians were resistant to having a specified site where CV catheterization could be performed. However, the fact that the two previous serious adverse events resulted from a CV catheterization performed in a ward room strongly influenced the panel’s guidelines. In the Central Venous Catheter Center, the catheter position could be confirmed in real time on radiographs, blood gas analysis was available, and emergency carts were readily accessible. Eventually, physicians realized that the Central Venous Catheter Center was a convenient and efficient location to perform CV catheterization, and resistance to the guidelines decreased.

Finally, some practitioners did not follow the guidelines. However, practitioners who did not conform to the guidelines were encouraged to adhere to the guidelines at panel meetings held once every 2 months. The panel’s chairperson warned physicians that they would lose their license to perform CV catheterization if they did not follow the guidelines. No physician deviated from the guidelines after being warned.

This study had two limitations. First, it was conducted at a single center. Second, it was not designed to compare the complication rate between before and after introduction of systematic management.

Conclusions

Regardless of these limitations, the new system of management resulted in a lower rate of mechanical com-
complications. Using these data, further investigation will be conducted on the risk factors involved in such complications. Improvement of the guidelines will enable safer CV catheterization.

**Contributors**: MU, MS, and TM developed and conducted the study protocol. MU and YF analyzed data and synthesized the first drafts of the manuscript. YO, MT, JW and TM made the database.

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**References**

組織的管理による中心静脈カテーテル挿入の安全性維持

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【要旨】はじめに：東京医科大学病院は、中心静脈（CV）ライン挿入に関する2件の大きな合併症を経験した。再発防止のための第一歩として、多職種で構成される委員会を立ち上げ、具体的な方策の議論を始めた。この総説では、CVライン挿入の安全性を維持するために当院が取り組んできた組織的な一元管理を紹介するとともに、合併症発生率からみたこの取り組みの振り返りを行う。

方法：組織的管理は、以下のガイドライン含む。（1）CVライン挿入は、そのために特別に用意された部屋（CVラインセンター）で実施する。（2）病院から許可を与えられた医師のみが、CVライン挿入を実施できる。（3）CVラインを挿入した場合には、「実施記録」を記入し、これを提出する。（4）挿入後は観察チェックリストにて経時的に、CVラインに関する異常、合併症の有無を確認する。

結果：挿入ガイドラインの運用が始めて5.5年間のCVライン挿入は8,902件、合併症発生数は435件（合併症発生率4.9%）であった。

結論：CVライン挿入の組織的管理は、文献的に報告されているものと同程度の合併症発生率の維持に寄与している可能性がある。今後は、合併症発生のリスク因子を分析することでガイドラインを改善し、より安全なCVライン挿入の達成を目指す。

（キーワード）中心静脈カテーテル、CVライン、組織的管理、合併症、有害事象