Complications Associated with Central Venous Catheters*  
A Survey  
Walter L. Scott, Ph.D.†

The Federal Food and Drug Administration has a system for reporting problems with medical devices that requires manufacturers of medical devices to report medical complications or equipment malfunction that causes, or could cause, death or serious injury. In a two-year period, central venous catheters were associated with 170 complications: tissue perforation, loss of catheter integrity, (including: catheter separation, severance, break, rip, puncture, or leak), and other problems. Causes of the complications were related to device failure (12 percent), health care professionals (55 percent), patients (3 percent), or pathologic or physiologic aspects (3 percent); causes of 28 percent of the complications were indeterminable. Further analysis indicated that complications (especially tissue perforation) were primarily health professional technique-related. There were no reports of complications related to infection. Data support the need for more education in catheter application and the need to modify the system by which these data are reported to more reliably detect infection. (Chest 1985; 94:1221-24)

M = medical device reporting, HCP = healthcare professional, PRS = Practitioner Reporting System.

Medical care has become technologically sophisticated and depends on devices that have their own risks. Because of this, the federal government has implemented regulations that mandate a system for reporting device-related complications. The Medical Device Reporting (MDR) regulations became effective Dec 13, 1984. The regulation requires manufacturers and importers of medical devices (including in vitro diagnostic devices) to report to FDA required information when such information is received that reasonably suggests that one of their devices (1) may have caused or contributed to a death or serious injury, or (2) has malfunctioned, and if the malfunction recurs, is likely to cause or contribute to a death or serious injury. As a result of this regulation, an MDR database has been established that contains the collected data.

For editorial comment see page 1125

The data for the MDR are collected by telephone and written report by FDA’s Office of Compliance and are transferred to computer files by an outside contractor. There are no standard forms for reporting, but there are certain specified items that must be included in the report if the information is available.

For long-term use, central venous catheters (CVCs) are used for chemotherapy and for parenteral nutrition. In intensive care, CVCs are essential for monitoring, modifying fluid and pressure balances, and administering therapeutic substances such as drugs and antibiotics. Therefore, these devices play an important role in the treatment of the seriously ill. However, use of these catheters requires training, supervision, and meticulous caution or life-threatening complications can result.1-5 For example, malpositioned catheters, depending on anatomic location and catheter technique, have led to cardiac perforation and tamponade,2,4 hydrothorax,5,6 hemothorax,5 pneumothorax,7,8 chylothorax,9,10 and hydromediastinum;11,13 other problems associated with positioning include mural thromboses,11 venous dissection,15 knotted catheters,5,13 and cardiac arrhythmias.9,16,17

The purpose of this study was to determine, from the MDR system, the cause and types of complications that result with CVCs and the incidence of the complications.

METHODS

The Federal Food and Drug Administration has a system for reporting problems with medical devices (MDR), which requires manufacturers and importers to report complications or malfunctions that cause, or could cause, death or serious injury. The data collected from the MDR from December 13, 1984, to December 18, 1986, were analyzed to determine the incidence of death and serious injury from complications involving central venous catheters and the incidence and causes of these complications.

The MDR reports were surveyed for information about CVCs, flexible or nonflexible and single- or multiple-lumen, used for nontraumatic functions and not involving anatomic alteration of formed tissue. Also included was tubing whose functional ends were intended to be located within the vena cava (inferior or superior) or within proximate central veins, excluding the heart chambers. Catheter guidewires, Swan-Ganz flow-directed catheters, and angioplasty catheters were not included.

Reports involving CVCs were categorized by type of complication.
Table 1—Reports of Death or Injury Related to Complications of Central Venous Catheterization with Various Causes*

<table>
<thead>
<tr>
<th></th>
<th>Death (D)</th>
<th>Injury (I)</th>
<th>Total (D &amp; I)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Reports</td>
<td>Patients (%)</td>
<td>Reports (%)</td>
</tr>
<tr>
<td>Health Care Professional Patient</td>
<td>32</td>
<td>32 (62)</td>
<td>56 (48)</td>
</tr>
<tr>
<td>Device failure</td>
<td>3</td>
<td>3 (6)</td>
<td>2 (2)</td>
</tr>
<tr>
<td>Pathologic/physiologic</td>
<td>2</td>
<td>2 (4)</td>
<td>3 (3)</td>
</tr>
<tr>
<td>Indeterminable (all causes)</td>
<td>12</td>
<td>12 (23)</td>
<td>39 (33)</td>
</tr>
</tbody>
</table>

*Reports were made between December 1984 through December 1986 as part of the Medical Device Reporting (MDR) system administered by the Food and Drug Administration.

Values in excess of 100 percent due to rounding of fractions.

as follows: perforation of tissue, separation (loss of catheter integrity), infection, and other. Infection was defined as contamination of the catheter while it was under the management of a health care professional (HCP), and did not include contamination of a catheter before its use; such as would occur with unsealed packages. Other causes of complications included such problems as thromboembolization, induced supraventricular arrhythmias, and ventricular arrhythmias.

The most likely cause of the complication was determined (the author) from the circumstances and nature of the complication and from any follow-up information. When information was conflicting, absent, or deemed inadequate, the cause was classified as indeterminable. Probable causes were categorized as catheter failure (a break in the integrity of the catheter), or related to the health care professional, patient (such as pulling out or cutting a catheter), or pathologic or physiologic influences (such as thrombosis or thromboembolism).

RESULTS

Of the 170 reports of death or injury from CVCs involving 185 patients, the probable cause of 52 percent of complications was related to an HCP (Table 1); of 52 deaths, causes of 62 percent were related to an HCP. The most common complication related to the HCP was tissue perforation (94 percent of fatalities and 54 percent of injuries) (Table 2), which was substantially more frequent than other HCP-related complications. Catheter separation occurred about half as often as perforation. Infection and other causes of complications related to HCP were negligible. The second most frequent cause of all CVC complications was indeterminable (30 percent of reports), followed by device failure (12 percent). Patient and pathophysiologic/physiologic influences together accounted for 6 percent of the reports.

In most reports of separation (loss of catheter integrity), a cause could not be ascertained (indeterminable); however, when it could be determined, the problem usually resulted from using excessive force—either in pulling on a catheter to remove or dislodge it or in forcing positive or negative pressure from a syringe into the catheter to open an occlusion in it, not following directions on the device label or insert, shearing the catheter during surgical implantation as with an insertion needle, and puncturing the catheter with a suture needle. Also in this category, a few reports involved separation of a catheter at the hub, which resulted in its sliding into the circulation and requiring retrieval. Manufacturing defect, use of incompatible catheter components or inappropriate procedures to insert a catheter, or resterilization and reuse of disposable catheters were reported to result in separation.

There were four reports of air embolization. Embolization of catheter-fragments was reported 63 times and resulted from all the possible categories of cause. Few reports indicated that fragments that remained

Table 2—Health Care Professionals—Related Central Venous Catheter Complication Reports*

<table>
<thead>
<tr>
<th></th>
<th>Death (D)</th>
<th>Injury (I)</th>
<th>Total (D &amp; I)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Reports</td>
<td>Patients (%)</td>
<td>Reports (%)</td>
</tr>
<tr>
<td>Perforation</td>
<td>30</td>
<td>30 (94)</td>
<td>29 (52)</td>
</tr>
<tr>
<td>Separation</td>
<td>1</td>
<td>1 (3)</td>
<td>26 (46)</td>
</tr>
<tr>
<td>Infection</td>
<td>0</td>
<td>0 (0)</td>
<td>0 (0)</td>
</tr>
<tr>
<td>Other</td>
<td>1</td>
<td>1 (3)</td>
<td>1 (2)</td>
</tr>
<tr>
<td>TOTAL</td>
<td>32</td>
<td>32 (100)</td>
<td>56 (100)</td>
</tr>
</tbody>
</table>

*Reports were made between December 1984 through December 1986 as part of the Medical Device Reporting (MDR) system administered by the Food and Drug Administration.

1222

Complications from Central Venous Catheters (Walter L. Scott)
caused no further problems to the patient; most indicated that surgical or other retrieval techniques were required. Causes of catheter fragment emboli in this study were predominantly indeterminable, which may reflect problems associated with materials, design, or misuse of catheter or other variables.

**Discussion**

The 1986 market for all types of CVCs has been estimated at 2.75 million CVCs, and CVC complications resulting in death of, or injury to, patients continue to be reported in the MDR. The predominant cause of complication was related to HCPs. An inverse relationship between HCP experience and rate of complication has been demonstrated. Also, inexperienced physicians have been noted to fail significantly more often than experienced physicians in attempting catheterization and to cause complications more often in conscious patients than in unconscious patients.

Therefore, HCPs may not fully understand the venous anatomy. It has been suggested that before HCPs use this technique, they undergo supervised experience and gain experience first on a mannequin or cadaver and subsequently (under experienced supervision) on anesthetized or unconscious patients.

The medical literature includes many reports indicating that infection, thrombosis, and thromboembolic complications are common problems associated with CVC use. Catheter-fragment embolism has been described as a serious complication with a mortality of about 30 percent when the catheter fragment was not removed. These complications should be reflected in the MDR databases; however, there were no reports of infection and only four reports of thromboembolism associated with CVCs in the MDR database.

A possible explanation for no reports of infection may be that the physician who prescribes catheterization delegates responsibility for its management to a different member of the HCP team, who may perceive a report of infection as an admission of questionable technique, and thus, might be reluctant to report the complication. Also, infection may not be as obvious as other complications and would require confirmation by laboratory analysis, which may not clarify the cause of the infection.

Perforation, the most common cause of death or injury, can be prevented by proper selection of the percutaneous venous entry site, which determines the structures through which the catheter must pass, and the angle of vessel wall impingement as the catheter courses through the vessels. Manufacturers have recommended that a left side insertion of the CVC should be avoided when possible. In addition to the problems of catheter tip impingement angle within the central veins discussed earlier, the left side approach has been associated with damage to the thoracic duct, sometimes followed by chylothorax.

The percutaneous site can influence the juxta positional attitude that the catheter and the tip finally make with respect to the vessel wall. Roentgenographically, the tip should appear parallel to the vessel wall. The latter is critical, in that excursions of a catheter tip associated with normal respiration, heart beat, and movement of the head, extremity, or other body part could produce vessel wall erosion, associated thrombosis, and eventual perforation. Every effort should be made to ascertain the position of the catheter tip initially, verifying it roentgenographically, and thereafter on a routine basis. Electrocardiographic (ECG) monitoring may also be useful in ascertaining catheter tip placement and is the MDR has been demonstrated that tall peaked P-waves can be identified as the catheter tip enters the right atrium.

The influence of patient position on vena caval size, area, and configuration has been ultrasonically assessed and found to vary significantly in the supine, right and left lateral positions. This may be a further consideration during insertion, as well as long-term retention of CVCs. Selection of the appropriate catheter or cannula length and rigidity is also important, with attention paid to the linear markings (distance from tip) and the specific anatomic and pathologic requirements for each patient. Excess push or torque force administered upon insertion could lead to perforation.

Air embolization may occur upon CVC insertion, especially in hypovolemic patients. Catheters should be inserted with the patient horizontal, or for hypovolemia, with patients in the Trendelenburg position, or as a general precaution, the 10 to 15° head-down tilt with special consideration for patients at risk of spontaneous bleeding from elevated venous pressure or elevated intracranial pressure, in the head-down tilt position. Air embolism has also been described after CVC removal, the air entraining along the residual catheter track.

The CVC users are urged to report to the Practitioner Reporting System (PRS) incidents of infection and infection-related complications, thrombosis and thromboembolic events. Such information could provide valuable information for improvements in materials, design, and technique for CVC use, all of which would ultimately improve patient care.

---

*The PRS is a voluntary information reporting activity, coordinated by the United States Pharmacopeia (USP) under FDA contract, to provide a mechanism for practitioners to report their concerns about medical products. Unless the reporter specifically requests otherwise, the USP forwards a copy of the report to the manufacturer. Reports may be submitted by contacting: The United States Pharmacopeia, Practitioner Reporting System, 12601 Twinbrook Parkway, Rockville, Maryland 20852-1790; or by calling toll-free 800-838-6725; in Maryland call collect (301) 881-0256.
The predominant complication reported to the MDR database for CVC use was related to HCPs and, therefore, to techniques of insertion and management. The most common HCP-related complication was tissue perforation, representing 67 percent of all MDR-reported, HCP-related complications. Second to perforation as the most common HCP-related complication was loss of catheter integrity, which represented 31 percent of the HCP-related complications in MDR. Device failure also represented a significant cause (12 percent) of CVC complications reported. Infection and thrombogenicity were under-reported in the MDR compared with the medical literature; this discrepancy requires further investigation of the circumstances of and attitudes toward these two CVC-related complications.

REFERENCES
2. Langston CS. The aberrant central venous catheter and its complications. Diag Radiol 1971; 100:55
36. Nakao S, Come PC, McKay RG, Bansil BJ. Effects of positional changes on inferior vena cavai size and dynamics and correlations with right-sited cardiac pressure. Am J Cardiol 1987; 59:125