ORIGINAL ARTICLE

Totally Implantable Venous Access Devices Implanted Surgically

A Retrospective Study on Early and Late Complications

Isidoro Di Carlo, MD; Stefano Cordio, MD; Gaetano La Greca, MD; Giuseppe Privitera, MD; Domenico Russello, MD; Stefano Puleo, MD; Ferdinando Latteri, MD

Background: The techniques used for the implantation of totally implantable venous access devices (TIVADs) are the percutaneous approach and surgical cutdown; however, the choice is still controversial.

Hypothesis: The surgical cutdown approach may be beneficial to reduce the rate of complications.

Design: Retrospective review.

Setting: A university hospital and a tertiary referral center.

Patients: Patients undergoing a TIVAD implant at the First Surgical Clinic of the University of Catania in Catania, Italy, between January 1995 and December 1999, were considered for the study. All of the devices were implanted in an operating room under fluoroscopic control. The vein of choice was the cephalic vein. When the cephalic vein was not suitable for implantation, the external jugular vein or the axillary vein and its branches were used. The percutaneous approach to the subclavian vein or internal jugular vein was considered a last resort to implant a catheter.

Results: During the study period, 346 TIVADs were implanted in 344 patients. The procedure was performed with local anesthesia in 341 cases (98.5%), and only 2 patients (0.6%) required sedation for psychological reasons. Three patients (0.9%) had their TIVAD placed during a laparotomy. In 326 patients (94.2%), the devices were implanted in the cephalic vein. In the remaining cases, other veins were used with surgical cutdown. The mean time for the procedure was 15 minutes. Percutaneous access was never used, and no early mechanical complications were recorded. Only 6 patients (1.8%) in our study group had late complications (1 case of migration of the catheter, 2 cases of infection, and 3 cases of withdrawal occlusion). The catheter life ranged from 6 to 1487 days (mean time, 348 days).

Conclusion: Our results confirm the safety, speed, and low cost of the open cutdown technique. This surgical procedure avoids both early and late complications that frequently occur with percutaneous access. Surgical cutdown should be considered the technique of choice to implant the TIVAD, especially in cancer patients.

Arch Surg. 2001;136:1050-1053

From the First Surgical Clinic (Drs Di Carlo, La Greca, Russello, Puleo, and Latteri) and the Department of Radiology (Dr Privitera), University of Catania; and the Department of Clinical Oncology, San Luigi Hospital (Dr Cordio), Catania, Italy.

PERIPHERAL vascular access represents a significant problem in the administration of chemotherapy because of venous irritation and the need for multiple venipunctures. Totally implantable venous access devices (TIVADs) have become an important tool in the treatment of patients with malignant neoplasms.[1] With the expanding use of the TIVAD, however, complications are being encountered more frequently. The percutaneous approach and surgical cutdown are the techniques used for TIVAD implantation. The relationship between both early and late mechanical complications and the technique of placement is reported in the literature.[2,3] The purpose of this retrospective study was to analyze our experience with the TIVAD and to point out the factors influencing complications related to the technique of placement.

RESULTS

From January 1995 to December 1999, 346 TIVADs were implanted in 344 patients. In all patients, the devices were inserted to infuse chemotherapy, in 98.9% for solid tumors and in 1.1% for hematologic disease (**Table 1**). Two hundred fifty-six TIVADs (74.1%) were implanted by a highly experienced surgeon, 40 (11.5%) were inserted by other surgeons, and 50 (14.4%) were implanted by fellows in surgery. The procedure was performed with local anesthesia in 341 cases (98.5%), and only 2 patients (0.6%) required sedation for psychological reasons. Three patients (0.9%) had their TIVAD placed in the vena

PATIENTS AND METHODS

Between January 1995 and December 1999, at the First Surgical Clinic of the University of Catania in Catania, Italy, 346 TIVADs were implanted in 344 patients. The group consisted of 203 men and 141 women between the ages of 31 and 79 years. The indication for implantation was the infusion of intravenous chemotherapy in patients with solid tumors or hematologic disease. The only laboratory studies determined absolutely necessary were a complete blood cell count, including a platelet count, and coagulation tests. Bacteremia, septicemia, and disseminated intravascular coagulation were considered absolute contraindications for implantation.

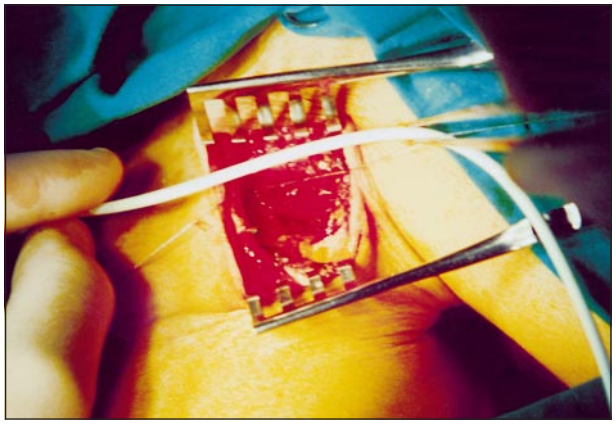
In the present study, 62.1% of the TIVADs were of the same type (Port-a-Cath; SIMS Deltec Inc, St Paul, Minn). In the remaining 131 cases (37.9%), 2 different kinds of products (BardPort; Bard Access Systems, Salt Lake City, Utah, and Celsite; B/Braun Celsa, Chasseneuil, France) were used. The material of the injection port was titanium in all cases. In 246 cases (71.1%), the TIVAD catheters were made of silicone rubber; in 100 cases (28.9%), they were made of polyurethane.

All of the devices were implanted in the operating room under fluoroscopic control, even if the patient was treated and monitored in a day hospital setting. Those performing the procedure were surgeons or fellows in surgery. Perioperative antibiotic prophylaxis was performed as a single dose of cephalosporin given 10 minutes before the operation. All TIVADs were implanted using local anesthesia (usually 10 mL of 2% mepivacaine hydrochloride); sedation was reserved for patients for whom local anesthesia was not suitable. General anesthesia was used for the patients in whom TIVADs were placed during a major surgical procedure. The preferred method of implantation was to use the cephalic vein with a single skin incision at the Mohrenheim fossa. When the cephalic vein was absent or had been destroyed by previous chemotherapy and thus was not suitable for implantation, the external jugular vein or the axillary vein and its branches were used instead. The external jugular vein was used if clinically evident; otherwise the axillary vein and its branches were chosen. The percutaneous approach to the subclavian vein or internal jugular vein was considered a last resort to implant a catheter. Correct positioning of the distal tip of the catheter in the superior vena cava was carried out in all cases by fluoroscopic control. In particularly overweight patients, we eliminated half of the subcutaneous tissue to better localize the port for future punctures. Finally, a test puncture was performed to check patency and flow through the system. At the end of the procedure, a chest radiograph was obtained. Flushing with a solution of heparin sodium (5000 IU of heparin in 10 mL of isotonic saline) was performed every month.

cava and right gonadal vein during a laparotomy for colon cancer. In 326 patients (94.2%) the devices were implanted in the cephalic vein. In 15 patients (4.3%) the

Table 1. Diagnosis of Cancer in 344 Patients

Diagnosis	Patients, No. (%)
Breast cancer	118 (34.3)
Colorectal cancer	97 (28.1)
Lung cancer	38 (11.8)
Ovarian cancer	33 (9.5)
Gastric cancer	26 (7.5)
Hepatic cancer	9 (2.6)
Pancreatic cancer	6 (1.7)
Lymphoma	4 (1.1)
Esophageal cancer	3 (0.8)
Gallbladder cancer	2 (0.5)
Cancer of the cardia	2 (0.5)
Sarcoma	2 (0.5)
Miscellaneous	4 (1.1)



Narrowed cephalic vein not usable for catheter insertion.

cephalic vein was not used: in 11 of these the vein was narrowed because of previous chemotherapy (**Figure**), in 2 patients the vein was hypoplastic, and in the remaining 2 the vein was absent. In these cases the catheter was surgically inserted using, respectively, the external jugular vein in 9 patients (2.6%), the axillary vein in 3 (0.9%), the coracobrachial vein in 2 (0.6%), and the internal jugular vein in 1 (0.3%). Percutaneous access was never used. The mean time for the procedure was 15 minutes (range, 9-45 minutes). A progressive increase in the number of implants was recorded from 1994 to 1999. In 36 patients (11.1%) we eliminated half of the subcutaneous tissue to better localize the port for its puncture. No early or late complications concerning the subcutaneous pocket were recorded in these subjects. Retrospective analysis of our study population showed that the catheter life ranged from 6 to 1487 days (mean time, 348 days). No early mechanical complications were recorded.

Only 6 patients (1.8%) in our study had late complications. Six days after implantation, 1 patient's TIVAD would not infuse; a chest x-ray showed a migration of the catheter into the subcutaneous pocket. The catheter was replaced, and the patient has used the TIVAD since then. Two patients (0.52%) experienced infection of the subcutaneous pocket, and after curative antibiotic therapy, the system was removed and a new TIVAD was implanted. The causative agent was coagulase-negative *Staphylococcus aureus* in both patients. Finally, in 3 pa-

Table 2. Early and Late Complications Due to the Percutaneous Approach*

Authors	Pneumothorax Cases/ Patients, No. (%)	Arterial Puncture Cases/ Patients, No. (%)	Embolization Cases/ Patients, No. (%)
Biffi et al[5]	10/333 (3)	4/333 (1.2)	5/333 (1.5)
Ballarini et al[3]	1/99 (1)	. . .	3/99 (3)
Kincaid et al[7]	11/589 (1.9)	. . .	. . .
Aldrighetti et al[6]	8/192 (4.1)	16/192 (8.3)	1/174 (0.5)
Poorter et al[2]	6/149 (3.6)	. . .	. . .

*Ellipses indicate not applicable.

tients (0.87%) withdrawal occlusion was recorded; x-rays never localized malposition of the tip of the catheter or a fibrin sleeve. Because these patients required only infusion, the systems were left in place. The TIVAD was treated with a heparin solution flush without specific anticoagulant treatment. One patient died after 210 days with the system in place; 2 patients have continued to use the TIVAD 378 and 679 days after implantation, respectively. The catheters of 2 of these TIVADs are made of silicone, and 1 of polyurethane.

COMMENT

Vascular access for patients requiring long-term drug delivery was a serious and challenging problem until the development of TIVADs. Since the first implant, performed by Niederhuber and colleagues[4] in 1982, these systems have increasingly been used in the field of oncology. They achieve safe and less painful vascular access, facilitate treatment of many medical disorders, and improve patients' quality of life by giving them unrestricted mobility and freedom in their activities. These devices can be implanted through either a surgical or percutaneous procedure.[1-3] Although many surgical teams use percutaneous access for placement of the TIVAD, both early and late complications are frequently observed (**Table 2**). Pneumothorax is the most frequent complication and has the greatest clinical, economic, and psychological implications. The best time to implant the TIVAD is during the principal oncologic surgical procedure, but this decision must often be delayed until after the pathologist and oncologist consult. In this case a second surgical step is required, with consequential psychological effects on the patient. Therefore, the surgeon who performs the TIVAD implantation should use a technique with a low rate of complications to avoid further psychological trauma. In our experience no early mechanical complications occurred; we particularly want to stress the absence of pneumothorax, a clinical condition related to the percutaneous approach. Patients who undergo the percutaneous approach for TIVAD implantation and develop pneumothorax increase the costs of their procedure by US $535 if they are managed with observation; when tube thoracostomy is required, the cost for each patient becomes much higher (US $1827).[5] Pneumothorax occurs during the subclavian vein puncture, and the percutaneous approach with the internal jugular vein has been suggested by some authors to avoid this complication.[6,7] However, arterial puncture and related complications have been reported with this method. In our opinion, the physician performing the implant should be fully versed in the alternative puncture technique, but the impossibility of using the superficial venous system should not be considered justification for the percutaneous approach, as suggested by others.[1] With our patients, it was always possible to use the surgical technique with a vein and avoid the risk of complications related to the percutaneous approach.

Some authors use the learning curve to explain the incidence of pneumothorax with the percutaneous method.[2,5] Cancer patients should be treated with particular care on the basis of their often negative clinical course. For this reason, surgery fellows should be taught the surgical method, and the percutaneous approach should be reserved for other diseases.

Last but not least, the surgical approach prevents "pinch-off" and its relatively disastrous complications due to the migration of the fractured catheter. On the basis of a radiographic scale, Klotz et al[8] suggest the removal of the catheter system within 6 months when confronted with the typical sign of a pinch-off. In our opinion, when the pinch-off sign is present, the catheter should be removed immediately to avoid fatal complications.[9]

Migration of the catheter tip during insertion is a consequence of not using fluoroscopy during the surgical implant. The use of fluoroscopy during catheter placement seems important not only to avoid immediate migration of the catheter but also to prevent malfunction. In fact, malfunction (defined as resistance to flush or infuse a substance, complete inability to infuse a substance, or resistance to blood aspiration) may occur whenever the catheter is in place and is related to the anomalous position of the catheter tip.[10] Placement of TIVADs in an operating room or outpatient clinic setting without a means to localize the tip of the catheter should be avoided.[11] In our 3 patients with malfunction, the tip of the catheter was correctly positioned. It appears that the withdrawal occlusion was due to long-lasting total parenteral nutrition infusion without adequate postinfusion treatment.

There are 2 types of catheter-associated thrombosis: small thrombosis limited to the tip of the catheter, characterized by an inability to withdraw blood from the system with unimpaired infusion into the system, and large thrombosis of the catheterized veins.[12] The incidence of this complication is not reported in the literature because it usually is not clinically relevant. In our experience, no clinical evidence of thrombosis was recorded, and only 1 case of tip occlusion was found. The clinical course of this patient was particularly benign and did not include therapy. This catheter tip thrombosis is currently considered the first step toward fibrin sleeve formation along the catheter, caus-

ing withdrawal occlusion. Experimental results suggest that the sleeve around a central venous catheter is not a fibrin sleeve but a stable cellular-collagen tissue covered by the endothelium, mainly formed by smooth muscle cells migrating from the injured vein wall into the early pericatheter thrombus.[13] For this reason, anticoagulants such as warfarin sodium need further investigation before standardization for clinical use.[1]

Port pocket infection, caused by gram-positive cocci, suggests either direct inoculation or migration of the organism along the access needle as the primary mechanism. Two of our patients developed this complication during a long period in which the system was implemented in a different department and flushing with a heparin solution was performed by another team of medical nurses. With a standardized technique and correct care and maintenance, the rate of infectious complications could be zero.

Our results confirm the safety, speed, and low cost of the open cutdown technique. This surgical procedure avoids both early and late complications that frequently occur with percutaneous access. The surgical cutdown should be considered the preferred technique to implant the TIVAD, especially in cancer patients. The pathological composition of the fibrin sleeve needs further investigation before standardization of anticoagulants for clinical use. Further reduction of complication rates is feasible through the combined efforts of medical oncologists, surgeons, and nursing staff.

Corresponding author: Isidoro Di Carlo, MD, via Regina Margherita n 180, 98034 Francavilla (ME), Italy (e-mail: idicarlo@mbox.unict.it).

Reprints: Isidoro Di Carlo, MD, First Surgical Clinic, University of Catania, 95100 Catania, Italy.

REFERENCES

1. Kock HJ, Pietsch M, Krause U, Wilke H, Eigler FW. Implanted vascular access systems: experience in 1500 patients with totally implanted central venous port systems. *World J Surg.* 1999;22:12-16.
2. Poorter RL, Lauw FN, Bemelman WA, Bakker PJ, Taat CW, Veenhof CH. Complications of an implantable venous access device (Port-a-Cath) during intermittent continuous infusion of chemotherapy. *Eur J Cancer.* 1996;32:2262-2266.
3. Ballarini C, Intra M, Pisani Ceretti A, et al. Complications of subcutaneous infusion port in the general oncology population. *Oncology.* 1999;56:97-102.
4. Niederhuber JE, Ensminger W, Gyves JW, Liepman M, Cozzi RN. Totally implanted venous and arterial access system to replace external catheters in cancer treatment. *Surgery.* 1982;92:706-711.
5. Biffi R, de Braud F, Orsi F, et al. Totally implantable central venous access ports for long-term chemotherapy: a prospective study analyzing complications and costs of 333 devices with a minimum follow-up of 180 days. *Ann Oncol.* 1998; 9:767-773.
6. Aldrighetti L, Paganelli M, Caterini R, Catena M, Ronzoni M, Ferla G. Safety and efficiency of totally implantable devices for prolonged venous access: a prospective study. *J Chemother.* 1996;8:393-396.
7. Kincaid EH, Davis PW, Chang MC, Fenstermaker JM, Pennell TC. "Blind" placement of long-term central venous access devices: report of 589 consecutive procedures. *Am Surg.* 1999;65:520-524.
8. Klotz HP, Schopke W, Kohler A, Pestalozzi B, Largiader F. Catheter fracture: a rare complication of totally implantable subclavian venous access device. *J Surg Oncol.* 1996;62:222-225.
9. Di Carlo I, Fisichella P, Russello D, Puleo S, Latteri F. Catheter fracture and cardiac migration: a rare complication of totally implantable venous device (TIVD) placement. *J Surg Oncol.* 2000;73:172-173.
10. Petersen J, Delaney JH, Brakstad MT, Rowbotham RK, Bagley CM Jr. Silicone venous access devices positioned with their tips high in the superior vena cava are more likely to malfunction. *Am J Surg.* 1999;178:38-41.
11. Gladwin MT, Slonim A, Landucci DL, Gutierrez DC, Cunnion RE. Cannulation of the internal jugular vein: is postprocedural chest radiography always necessary? *Crit Care Med.* 1999;27:1819-1823.
12. De Cicco M, Matovic M, Balestreri L, et al. Central venous thrombosis: an early and frequent complication in cancer patients bearing long-term silastic catheter: a prospective study. *Thromb Res.* 1997;86:101-113.
13. Xiang DZ, Verbeken EK, Van Lommel AT, Stas M, De Wever I. Composition and formation of the sleeve enveloping a central venous catheter. *J Vasc Surg.* 1998; 28:260-271.

IN OTHER AMA JOURNALS

ARCHIVES OF INTERNAL MEDICINE

Assessing Clinical Probability of Pulmonary Embolism in the Emergency Ward: A Simple Score

Jacques Wicki, MD; Thomas V. Perneger, MD, PhD; Alain F. Junod, MD; Henri Bounameaux, MD; Arnaud Perrier, MD

Objective: To develop a simple standardized clinical score to stratify emergency ward patients with clinically suspected pulmonary embolism (PE) into groups with a high, intermediate, or low probability of PE to improve and simplify the diagnostic approach.
Methods: Analysis of a database of 1090 consecutive patients admitted to the emergency ward for suspected PE in whom diagnosis of PE was ruled in or out by a standard diagnostic algorithm. Logistic regression was used to predict clinical parameters associated with PE.
Results: A total of 296 (27%) of 1090 patients were found to have PE. The optimal estimate of clinical probability was based on 8 variables: recent surgery, previous thromboembolic event, older age, hypocapnia, hypoxemia, tachycardia, band atelectasis, or elevation of a hemidiaphragm on chest x-ray film. A probability score was calculated by adding points assigned to these variables. A cutoff score of 4 best identified patients with low probability of PE. A total of 486 patients (49%) had a low clinical probability of PE (score ≤4), of which 50 (10.3%) had a proven PE. The prevalence of PE was 38% in the 437 patients with an intermediate probability (score of 5-8; n=437) and 81% in the 63 patients with a high probability (score ≥9).
Conclusions: This clinical score, based on easily available and objective variables, provides a standardized assessment of the clinical probability of PE. Applying this score to emergency ward patients suspected of having PE could allow a more effective diagnostic process. (*2001;161:92-97*)

Corresponding author and reprints: Arnaud Perrier, MD, Medical Clinic 1, Department of Internal Medicine, Geneva University Hospital, 24 Rue Micheli-du-Crest, CH-1211 Geneva 14, Switzerland (e-mail: Arnaud.Perrier@medecine.unige.ch).