Journal of Surgical Oncology

Totally Implantable Central Venous Access Ports. Analysis of 700 Cases

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Background and Objectives: Vascular access has great importance in the treatment of patients submitted to prolonged chemotherapy. Purpose of this study is to assess the efficacy and safety of the percutaneous insertion and use of totally implantable central venous access ports (TICVAP).

Methods: During a 10-year period, 700 TICVAP were inserted into cancer patients for chemotherapy. Early and late complications and their management were recorded and analyzed.

Results: Of the 700 catheters implanted, 126 (18%) presented one or more types of early and late complication. Removal of 262 catheters was performed, of which 216 (82.4%) were elective indications due to the termination of the treatment and 46 (17.6%) resulted from complications that could not be controlled using clinical measures. In 280 patients (40%), the catheter remained functional until the patient's death, and 158 patients (22.5%) are still making use of their catheters for clinical treatment.

Conclusions: The low rate of complications according to this study confirms the safety and convenience of the percutaneous insertion and use of TICVAP in patients undergoing prolonged chemotherapy regimens and explains the increasing use of these devices in current medical oncology practice.

J. Surg. Oncol. 2011;9999:1–3.

KEY WORDS: device; chemotherapy; complications

INTRODUCTION

Cancer patients who require long-term chemotherapy and/or total parenteral nutrition need safe and reliable central venous access. The introduction of a totally implantable central venous access port (TICVAP) has made a significant contribution to the treatment of these patients as it has enabled them to resume their normal daily activities, while permitting a complete subcutaneous access.

Totally implantable catheters consist of silicone catheters whose distal extremity is positioned at the junction of the superior vena cava with the right atrium and whose proximal extremity is connected to a pocket inserted into subcutaneous tissue, usually in the anterior wall of the thorax.

The aim of this study was to investigate, in a retrospective way, the early and late complications due to percutaneous insertion and use of TICVAP, analysing the relevant number of 700 consecutive patients treated at a single cancer institution, after Institute's Ethics Committee approved the study.

MATERIALS AND METHODS

From January 2001 to October 2010, 700 totally implantable catheters were inserted into cancer patients for chemotherapy. Their ages ranged from 17 to 76 years, with an average of 54.7 years; 498 were female and 202 were male (Table I). The main clinical indications for the implantation of the catheters were chemotherapy for the treatment of solid tumors and haematological diseases (Table II).

All the implantation procedures were performed in the operating room, with the participation of an anaesthetist monitoring the operation despite the use of local anaesthesia. The totally implantable catheters utilized consisted of 8 or 9Fr silicone catheters and titanium or silicone ports.

Preoperative evaluation included a history and physical examination that focused on possible anatomic pitfalls (clavicle fracture, cervical or mediastinal adenopathy, chest wall tumors, presence of rotation flaps as part of head and neck reconstructive surgery), body habitus, and vascular access history (side used and pneumothorax history, previous line infection). The only laboratory studies requested as absolutely necessary were a complete blood count, including platelet count, and coagulation tests. All patients had chest radiographs for preoperative identification of mass lesions or anatomic anomalies.

No catheter was introduced while there was presence of fever of indeterminate origin, any systemic infectious condition (bacteremia or septicemia), or signs of skin infection, in the proximity of the location for implanting the port. Each patient underwent placement of a single type of TICVAP, constructed from titanium and silicone rubber, connected to an 8 or 9Fr polyurethane catheter inserted percutaneously (Seldinger technique) in the subclavian or the internal jugular vein, without using ultrasound guidance. At the end of the procedure, flow and reflux (back flow) were always tested via the pocket. When these were unsatisfactory, the catheter was repositioned until adequate function was obtained.

A confirmatory chest X-ray was always performed after the placement and all patients were checked by a physician before discharge.

Our hospital policy restricts the use and maintenance of ports to specialized nursing staff. To prevent clot formation and catheter blockage TICVAPs were flushed with 20 ml normal saline and then filled with sterile heparinized saline after each infusion of medication or blood withdrawal (15 ml of a solution containing 5,000 IU of heparin). The maximal interval between episodes of flushing of the catheters was a month.

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Received 2 April 2011; Accepted 20 May 2011

DOI 10.1002/jso.21990

Published online in Wiley Online Library (wileyonlinelibrary.com).

TABLE I. Demographics of the Study Population

Number of patients	n = 700
Median age (years)	54.7
Age range (years)	17–76
Male/female ratio	202/498
Right subclavian vein	284 (40.5%)
Left subclavian vein	341 (48.7%)
Right internal jugular vein	48 (6.9%)
Left internal jugular vein	27 (3.9%)

The patients were followed up until the time of catheter removal or death. All patients were seen routinely by the surgeons placing the device. Complications were divided into two main categories according to Biffi et al.'s [1] classification: early (intraoperative and post-implantation period to first use) and late complications (occurring after the first chemotherapy course given through the device).

Blood screening for bacteremia has not been performed at regular intervals, since blood sampling for microbiology was obtained when clinically suggested (unexplained fever and/or signs of sepsis). Criteria for the diagnosis of device-related bacteremia were defined as [2]: (a) greater than a 10-fold increase in colony-forming units (CFU) of bacteria per milliter of blood obtained through the device in comparison to peripheral blood cultures; (b) greater than 1,000 CFUs of bacteria obtained through the device, in the absence of peripheral blood cultures. Device-related bacteremia or fungaemia was considered cured when culture results were negative at the termination of antibiotic therapy and no evidence of clinical infection had been seen by 2 weeks later.

Port pocket infection was defined as induration, erythema, and tenderness around the port with culture-positive material aspirated from the port pocket. Cutaneous site infection was defined as induration, erythema, or tenderness and exudate at the port surface needle access site. Thrombosis was identified with ultrasound and/or venography when clinically suggested by progressive arm or facial swelling.

RESULTS

Of the 700 catheters implanted, 126 (18%) presented some type of complication. Removal of 262 catheters was performed, of which 216 (82.4%) were elective indications due to the termination of the treatment and 46 (17.6%) resulted from complications that could not be controlled using clinical measures. In 280 patients (40%), the catheter remained functional until the patient's death, and 158 patients (22.5%) are still making use of their catheters for clinical treatment. The total catheter use was 22,400 weeks, ranging from 1 to 214 weeks per patient, with an average of 32 weeks.

There were no related deaths to the insertion process. Early and late complications following percutaneous insertion of TICVAPs are shown in Tables III and IV.

TABLE II. Tumor Types for Patients Underwent Insertion of a Totally Implantable Central Venous Access Port

Tumor type	Number (n = 700)
Breast cancer	386
Gynecologic cancer	124
Lung cancer	93
Lymphoma	47
Gastrointestinal tract cancer	17
Urinary tract cancer	17
Other	16

TABLE III. List, Exact Number, and Percentage of Early Complications

Early complications	Number/700	%
Pneumothorax	16	2.2
Hematoma	16	2.2
Cardiac arrhythmia	15	2.1
Arterial puncture	11	1.6
Guide wire bending	7	1
Introductory sheath kinking	6	0.9
Bleeding	3	0.4
Pocket early infection	2	0.3

Ten out of 16 patients, in whom a pneumothorax was seen as a complication of the TICVAP placement, underwent a tube-thoracostomy, with no additional morbidity. The other 6 had a marginal pneumothorax (<20%) and they were followed up for 24 hr without the need for thoracostomy. Fifteen patients were diagnosed with rapid atrial fibrillation and treated with intravenous amiodarone with 100% sinus rhythm restoration after a few hours.

Regarding late complications catheter-association venous thrombosis was the most frequent (4.7%). Ipsilateral arm swelling or facial swelling was the more frequent clinical sign. In all cases triplex ultrasonography yielded a positive result. Low molecular weight heparin subcutaneously was started in therapeutic doses for a week, followed by oral anticoagulation for 3 months.

Infectious complications occurred in relation to 29 of the catheters (4.1%). Non-complicated primary bacteremia (persistent fever only) occurred in all cases. Patients were treated using peripheral intravenous antibiotic therapy (vancomycin or teicoplanin) for the first 48 hr, followed by infusion of this drug via the catheter. Antibiotic treatment was changed if needed, according to blood culture's results. The catheter had to be removed in 16 cases because the fever continued (infection rate requiring removal of the catheter: 16/700 or 2.3%). In the remaining 13 cases there was an improvement in the clinical condition, with the catheters preserved (preservation rate of 44.8%, 13/29 patients).

Pinch-off syndrome (obstruction of the catheter because of compression between the clavicle and the first rib) was diagnosed in 18 cases (2.5%) and the catheters were immediately removed. Catheter rupture was noticed in 3 cases, while in 2 cases catheter migration and embolization of the pulmonary artery was observed. One patient underwent sternotomy, while the other had catheter removal through the femoral vein by means of interventional radiology.

Finally, 41 patients (5.9%) escaped follow-up and no data are available.

DISCUSSION

Vascular access has great importance in the treatment of patients submitted to prolonged chemotherapy. Since the introduction of the partially implantable catheter described by Broviac and modified by Hickman during the 1970s, handling oncological patients has become much easier due to the increased safety in relation to the

TABLE IV. List, Exact Number, and Percentage of Late Complications

Late Complications	Number/700	%
Catheter-associated venous thrombosis	33	4.7
Port pocket infection	29	4.1
Pinch-off syndrome	18	2.5
Skin erosion	6	0.8
Catheter rupture	3	0.4
Catheter migration and embolization	2	0.3

previously performed peripheral or temporary vein accesses [3,4]. With the introduction of totally implantable catheters in the 1980s, the choices have become even greater.

Because this equipment is totally implantable, without any of its components brought to the surface through the skin, it offers advantages over partially implantable systems: low infection rates and no restrictions on patients' physical activities [5]. These advantages have been leading to increasingly frequent use of such systems, especially for outpatient chemotherapy treatment.

An obvious disadvantage of these devices is the fact that they are much more expensive than tunneled catheters; moreover, the crude cost of the commercially available devices does not take into account the additional costs of catheter maintenance and the treatment of possible complications [2].

The results of this large case-series show that TICVAP placement, despite the low percentage of complications, is not free from incidents some of them potentially dangerous. This study recorded every unintentional event during and after port placement to point out all the difficulties associated with this procedure. The small number of complications during the operations can be attributed to the preoperative care, standardized surgical techniques, and the specialized team. The absence of fluoroscopy during insertion is a great disadvantage. The lack of imaging guidance during the percutaneous procedure is difficult to justify clinically and ethically.

There is a debate concerning the insertion method. Our surgical team favors the percutaneous access route with very good results. Others propose the open cut-down technique as more safe, reliable, and low-cost procedure [6].

The subclavian is the vein used most frequently whenever the percutaneous approach is performed, because the distance to the vena cava and the right atrium is shorter and no tunneling is necessary, so it results in a shortened procedure time; moreover this approach does not require a second incision of the neck that might be disadvantageous especially in cachectic patients. Other authors prefer to access through the internal jugular vein, especially the right one, because the straight course from this vein to the superior vena cava minimizes the contact of the catheter with the wall of the vessel, so the related risk of thrombosis is decreased [7].

The factors that predict complications are: previous major surgery, radiation therapy in the region of access, prior catheterization, prior attempts of catheterization, lack of experience, high body mass index, and more than two needle's passages (defined as separated skin punctures). If only one needle's passage is attempted, the rate of complications is of 1.6%, compared with 10.2% for two passages and 43.2% for three or more passages. Of course, combinations of risk factors are associated with higher rates of complications [8].

Pneumothorax's rate in literature comprised between 0.5% and 6% of cases. This is the most life-threatening complication, with heavy clinical, economic, and psychological consequences when it occurs. In our series a percentage of 2.2% was recorded.

Atrial fibrillation is a complication reported in literature whose rate is between 0.1% and 0.9%. This complication occurs when the catheter is pushed up to the right atrium. There are only a few cases reported, and the patients usually require pharmaceutical or electrical intervention, in addition to the prompt removal of the catheter [9]. In our series a percentage of 2.1% is higher compared to the literature but probably the lack of intraoperative imaging guidance is responsible for this.

Infection is the most common complication of venous access catheters and the leading reason for their removal. Catheter-related infections are reported in 11–45% of patients with Hickman catheters, 0–22% of patients with TICVAP, and 7–32% of patients with Groshong catheters [2,10]. In our series port-related bacteremia was calculated 4.1%. In many cases of bacteremia related to the catheter, antibiotic therapy without catheter removal is an option since the patient is stable and without signs of sepsis. The antibiotic we utilized empirically was vancomycin, because of the high incidence of infection by coagulase-negative *Staphylococcus* [11]. In the literature, the catheter preservation rate is between 60% and 80% [12] while in our sample we obtained therapeutic success in 44.8% of the cases.

The most important non-infectious complication was the catheter-related venous thrombosis. In the literature the rates range from 7% to 50% [6]. In our series we observed 33 cases (4.7%). The clinical suspicions of deep vein thrombosis were based on the presence of oedema, pain, erythrocyanosis, and presence of collateral circulation. Diagnostic confirmation of deep vein thrombosis was obtained by triplex scanning. Systemic anticoagulation was performed, initially using heparin of low molecular weight and subsequently using acenocoumarol for 3 months. Cases of pulmonary thromboembolism were not recorded.

CONCLUSIONS

The low rate of complications according to this study confirms the safety and convenience of the percutaneous insertion and use of TICVAP in patients undergoing prolonged chemotherapy regimens and explains the increasing use of these devices in current medical oncology practice. J. Surg. Oncol © 2011 Wiley-Liss, Inc.

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