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Complications of blind placement technique in 980 subcutaneous infusion ports

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ABSTRACT: ***Purpose:*** **Subcutaneous Infusion Ports (SIPs) for prolonged venous access are useful tools for drug administration in a wide range of chronic diseases. An extensive use of these devices has to be balanced against the potential complications worsening the length and the quality of life of frequently compromised patients. The aim of the present study is the prospective evaluation of early and late complications of the technique for the blind placement of totally implantable devices for prolonged venous access.**
Methods: **Between April l, 1991 and September 30, 1999, 980 SIPs were implanted in 967 patients. Thirteen patients received 2 SIPs. The surgical procedure, the *catheter through peel-away* technique after infraclavicular approach to the right or left subclavian vein, was performed without intraoperative fluoroscopy (blind placement technique) in the operating room under local anaesthesia. A postoperative chest radiography to rule out any procedure-related complications and to check the position of the catheter tip was obtained in all cases. For the purpose of the study, intraoperative complications as well as all SIP-related complications were recorded during the follow-up period and classified as major and minor complications.**
Results: **The study population consisted of 524 males/443 females, with a mean age of 56.3 ± 11.4 years (range 19-85 years). Primary diagnosis was malignancy in 916 patients (94.7%), acquired immunodeficiency syndrome (AIDS) in 44 patients (4.5%), and short gut syndrome secondary to subtotal small bowel resection in 2 cases (0.2%), others in 5 cases (0.5%). Perioperative complications were recorded in 12.9% of the 980 insertion procedures, including 77 cases of arterial puncture (7.8%) of the subclavian artery, 1 case of hemoptysis (without clinical and radiological evidence of pneumothorax) (0.1%), 23 cases of pneumothorax (2.3%), 20 of which (86.9%) required chest drainage, 10 cases of unsuccessful progression of the J-wire after the venepuncture (1%), 16 cases of catheter malposition (1.6%). As for the follow-up, 919 patients (95.0%) who had received 942 SIPs turned out to be suitable for long-term analysis, while 48 patients (5.0%) were excluded due to missing data. Seventy-seven SIPs (8.2%) were removed during the follow-up period, 13 of which received a second SIP. Long-term complications were recorded in 9.5% of the 942 SIPs, including mechanical complications (2.9%), infections (4.4%) and venous thrombosis (1.2%). Minor and major complication rates were 7.3% and 2.2% respectively. The overall incidence of SIP-related complications was 22.1%, including 44 major complications (4.5%) and 173 minor complications (17.6%).**
Conclusions: **Given the low rate of major complications, SIPs should be considered safe and effective devices, representing the first choice approach for prolonged venous access. Blind placement technique performed by full-trained operators yields adequate success rate to be suggested as a routine procedure.**

KEY WORDS: *Subcutaneous infusion ports, Devices for prolonged venous access, Complications, Technique*

INTRODUCTION

During the last decade, the use of totally implantable devices for prolonged venous access (Subcutaneous Infusion Ports - SIPs) has been widely adopted for the administration of chemotherapy, total parenteral nutrition (TPN), antibiotics, analgesics, and blood products. With the expanding use of SIPs, however. new and more frequent complications are being encountercd. We describe the results of a prospcctive study performed to assess the safety and the efficiency of these devices.

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MATERIALS AND METHODS

Between April 1, 1991 and September 30, 1999, 980 SIPs were implanted in 967 patients. Thirteen patients received 2 SIPs. Inclusion criteria were the need for central venous access and life expectancy more than 1 month in the presence of (1) prolonged/repeated therapy including phlebotoxic drugs or (2) continuous infusion therapy or (3) unsuitability of peripheral venous accesses. Exclusion criteria were (1) life expectancy less than 1 month or (2) patient refusal. At the time of enrollment, demographic data, primary diagnosis and indication for SIP placement, as well as all intraoperative complications, were recorded.

The surgical procedure was performed in the operating room under local anaesthesia (lidocaine 2%, 10 ml) with continuous EKG monitoring. The same device (B. Braun, Celsite, ST201-ST301) was implanted in all cases. The *catheter through peel-away* technique was performed in all cases. Intraoperative fluoroscopy was not used at the time of the insertion (blind placement procedure), while all patients received a postoperative chest radiography to rule out any pneumo-hemothorax and to verify the correct position of the catheter tip in the superior vena cava (SVC). SIP management included flushing with 10 ml of normal saline solution with heparin at 100 U/ml, to be repeated monthly or after any drug administration. The Huber needle was always used to enter the port.

For the purpose of this study, the follow-up period was extended through December 31, l999. During the follow-up period, patient survival and all SIP-related complications were recorded. Perioperative and long-term complications were classified as mechanical, septic and thrombotic complications. All cases of malposition or displacement, defined as location of the catheter tip in any vein other than the SVC, respectively at the time of insertion or at any time during the follow-up period, were conservatively treated through an angiographic approach, consisting in a transfemoral access to the vein using a guide-wire to hook the catheter and retrieve its tip in the SVC. SIP removal was considered only after an unsuccessful angiographic procedure of interventional radiology. Both local and systemic septic complications were treated with antibiotics against gram-positive bacteria (vancomycin 1 g every 12 hours) until the results of serial blood coltures allowed a specific treatment against the isolated microrganism. SIP removal was planned only for persistent (> 7 days) septic features (fever, leucocytosis), or hemodynamic instability with hypotension or shock, or fungal infection. Venous thrombotic complications were treated with anticoagulants and SIP removal, while injection of thrombolytic agents (urokinase, 5000 U) through the port was performed in case of catheter occlusion. All perioperative and long-term complications were classified as major and minor complications. According to a previously reported classification (6), major complications included pneumothorax, hemothorax, sepsis, venous thrombosis, and catheter tip pulmonary embolism; minor complications included arterial puncture, local infection, catheter malposition and displacement, subcutaneous extravasation of chemotherapeutic agents or TPN, and catheter occlusion.

RESULTS

The study population consisted of 524 males/443 females, with a mean age of 56.3 ± 11.4 years (range 19-85 years). Primary diagnosis was malignancy in 916 patients (94.7%), acquired immunodeficiency syndrome (AIDS) in 44 patients (4.5%), short gut syndrome secondary to subtotal small bowel resection in 2 cases (0.2%), others in 5 cases (0.5%). Indications for SIP placement were chemotherapy in all neoplastic patients, 37.6% of them receiving continuous infusion chemotherapy through an external infusion pump, TPN and antiviral/antimycotic drugs in AIDS patients, and TPN in short gut syndrome. SIPs were used for chemotherapy in 867 cases (88.5%), TPN in 112 cases (11.4%), antiviral/antimycotic drugs in 44 cases (4.5%), and blood transfusions (2-11 units of PRBC) in 33 cases (3.4%). Venous access for SIP insertion was obtained with an infraclavicular approach to the right (39.2%) or left (60.8%) subclavian vein in all cases. Patients who underwent SIP placement by cutdown of the cephalic vein were excluded from this study.

Perioperative complications were recorded in 127 (12.9%) of the 980 insertion procedures, consisting in 77 cases of arterial puncture (7.8%) of the right (32 cases) or left (45 cases) subclavian artery, 1 case of hemoptysis (without clinical and radiological evidence of pneumothorax) (0.1%), 23 cases of pneumothorax (2.3%), 20 of which (86.9%) required chest tube for 48-72 hours, 10 cases of unsuccessful progression of the J-wire after the venepuncture (1.0%), 16 cases of catheter malposition (1.6%), in the contralateral innominate vein (2 cases), ipsilateral jugular vein (12 cases), azygous vein (1 case), and inferior thyroid vein (1 case) (Tab. I). All cases of catheter malposition, once recognised by postoperative chest radiography, underwent the angio-

graphic procedure, which allowed the correct placement of the catheter tip in the SVC in the 14/16 cases (87.5%). Two cases of unsuccessful procedure required the removal of SIP and its subsequent contralateral reinsertion. In 3 cases (0.3%), the procedure was interrupted because of the patient's request and was then successfully repeated a few days later.

As for the follow up, 919 patients (95.0%) who had received 942 SIPs turned out to be suitable for long-term analysis, while 48 patients (5.0%) were excluded due to missing data. Seventy-seven SIPs (8.2%) were removed during the follow-up period, 13 of which received a second SIP.

Long-term complications were recorded in 9.5% (90 cases) of the 942 SIPS, including 29 cases of mechanical complications (2.9%), 42 cases of infection (4.4%) and 11 cases of venous thrombosis (1.2%). Minor and major complication rates were 7.3% and 2.2%, respectively. Mechanical complications included 18 cases of catheter displacement in the right (6 cases) or left (12 cases) ipsilateral internal jugular vein, 14 of which where successfully treated through an angiographic approach, 1 case of catheter kinking, 2 cases of catheter breakage with pulmonary embolism by the distal fragment, that was successfully removed through an angiographic transfemoral approach, 1 case of hydrothorax (2000 ml) secondary to the catheter tip displacement with TPN extravasation, 1 case of intravenous clustering of the catheter which required SIP removal, 2 cases of catheter tip displacement in the soft tissues (without secondary morbidity), which required SIP removal, 1 case of port inversion in the subcutaneous pocket, 1 case of catheter occlusion and 2 cases of catheter fissuration. Infections included 35 cases (83.3%) of local infections (due to *Staphilococcus epidermidis* and *aureus*) 15 of which (42.8%) were successfully treated with antibiotics while the other 20 (57.2%) re-

TABLE I - COMPLICATIONS OF BLIND PLACEMENT TECHNIQUE IN 980 SUBCUTANEOUS INFUSION PORTS

PERIOPERATIVE COMPLICATIONS-(12.9% OUT OF 980 PROCEDURES)		
Subclavian artery puncture		7.8%
Pneumothorax		2.3%
Catheter malposition		1.7%
Unsuccessful progression of the J-wire after the venepuncture		1.0%
Hemoptysis without evidence of pneumothorax		0.1%
LONG-TERM COMPLICATIONS (9.5% OUT OF 942 SIPS)		
Infections (4.4%)	Local infection	3.7%
	Sepsis	0.7%
Mechanical complications (2.9%)	Catheter displacement	1.9%
	Catheter breakage with pulmonary embolism of the distal fragment	0.2%
	Catheter displacement in the soft tissues	0.2%
	Catheter fissuration	0.2%
	Hydrotorax for TNP extravasation	0.1%
	Catheter kinking	0.1%
	Intravenuos clustering of the catheter	0.1%
	Port inversion in the subcutaneous pocket	0.1%
	Catheter occlusion	0.1%
Venous thrombosis		1.2%
Extravasation of chemotherapy with local phlogosis		0.8%
Persistent chest pain		0.1%

quired SIP removal, and 7 cases (16.7%) of sepsis, all of which were successfully treated with antibiotics. Thrombosis of ipsilateral subclavian vein (9 cases), of innominate vein (1 case), and of subclavian, axillary and brachial veins (1 case) required SIP removal and anticoagulant prolonged treatment. Other complications (0.8%) included 7 cases of extravasation of chemotherapy (5-FU) with local phlogosis, and 1 case of persistent chest pain (4 months after the placement), which required SIP removal.

The overall incidence of SIP-related complications was 22.1% (217 SIPs), including 44 major complications (4.5%) and 173 minor complications (17.6%).

DISCUSSION

According to the literature (1-4), the most common indication for long-term venous access devices is the infusion of chemotherapeutic agents (51-97%), other indications are administration of TPN (3.9-8.5%), long-term antibiotics, insulin and blood products. In our series, SIPs were most frequently used for chemotherapy (88.5%), while TPN and antimycotic/antiviral therapies were the main indication for SIP placement in 11.4% and 4.5% of the cases, respectively. SIPs allowed the chemotherapy to be administred through infusion pumps in 37.6% of our neoplastic patients, who therefore received domiciliary chemotherapy while attending their daily activities and reducing at the same time the current congestion of day-hospital facilities (5). Continuous infusion has been also suggested to optimize the antineoplastic effects of chemotherapy, when compared with traditional administration per intermittent bolus.

As for the placement procedure, the *catheter through peel-away* technique was used in all cases after a percutaneous access to the subclavian vein according to the Aubaniac and Wilson technique. Our preference for the subclavian vein is consistent with the literature (6), since jugular and femoral veins are considered as second choice approaches for SIP insertion. Complications of the venepuncture procedure were self-limiting subclavian artery lesions (7.8%) and pneumothorax (2.3%), that required chest drainage in most of the cases (86.9%). The incidence of pneumothorax in our series was consistent with literature (0.4%-12.4%) (6-8).

Furthermore, our 2.3% incidence may be explained by the fact that at our institution SIP insertion is considered as a training procedure for subclavian venepuncture prior to the involvement of residents in critical patient care. Our incidence of intraoperative complications is, therefore, comprehensive of a learning curve for this type of procedure, as attested by the fact that only one case of pneumothorax was recorded when the procedure was performed by an experienced operator. We believe that the percutaneous approach is a safe procedure, with a complication rate mainly related to the experience of the operator. Surgical venous cutdown, as asserted by other authors (7, 9, 18), is a time consuming procedure that should be reserved for those cases of unsuccessful percutaneous venepuncture. Catheter malposition was recorded only in 1.6% of the cases (16 patients), 87.5% of which were then corrected through an angiographic procedure. These results support our approach to the SIP placement without intraoperative fluoroscopy (8, 16).

As for the follow-up period, mechanical complications occurred in 2.9% of the cases. Out of 29 cases, catheter displacement in the ipsilateral jugular vein was the most frequent event (18 cases, 62.1%). Catheter displacement from the SVC is a well-recognized risk factor for venous thrombosis, especially in patients receiving sclerogenic drug infusions, i.e. chemotherapy. This adverse event needs, therefore, to be promptly corrected before any further drug administration. In our experience, the correction of catheter displacement was achieved in all cases through an angiographic approach, which we suggest as the treatment of choice for any catheter displacement (as well as malposition) from the SVC, avoiding a new surgical procedure with potential further morbidity. It is worthwhile to underline that catheter displacement from the SVC can potentially occur at any time from the SIP insertion, requiring close monitoring of the catheter tip position before drug infusions. Catheter displacement is reported in all major series, with an incidence ranging from 2.5% to 2.6% (5-8, 15). No clear risk factors have been identified, even if both turbulent flow in SVC and specific characteristics of catheter material can play a role in promoting this event. Infectious complications were recorded in 4.4% of the cases, 52.3% of which were successfully treated with antibiotics alone. This result is lower than the reported 70% rate of successful conservative treatment of SIP-related infections (10). In our experience, all systemic infections were successfully treated with antibiotics, while 57.2% of local infections required SIP removal. This observation suggests that no correlation between the type (local or systemic) of infection and the need of SIP removal exists, meaning that all SIP-related infections deserve a preliminary attempt of conservative manage-

ment, the SIP removal being reserved to persistent sepsis (> 7 days of antibiotics) or hemodynamic septic fealures (hypotension or shock).
The overall incidence of complications (22.1%) was at the high end of the reported range (4%-39%) (1-9, 11-15, 17-19). However, with reference to the severity of complications, more than two thirds of them (78.7%) were classified as minor complications. We believe that these results represent an acceptable price when compared with the positive impact of SIPs on the quality of life of our patients, thus encouraging our choice of extensive application of these devices. Subcutaneous infusion ports are safe and effective devices, representing the first choice approach for prolonged venous access in patients receiving TPN or chemotherapy. Blind placement technique performed by full-trained operators yields adequate success rate to be suggested as a routine procedure.

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