



The late complications of totally implantable central venous access ports: The results from an Italian multicenter prospective observation study[☆]

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A B S T R A C T

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Purpose: The principal aim of this study is to analyze the incidence of late complications in oncologic patients with totally implanted central venous access ports.

Methods: A prospective multicenter observational study was conducted in 26 Italian oncologic outpatient clinics. 1076 cancer patients with Totally Implanted Central Venous Access Ports (TIAP) were observed. 515 devices were observed in patients under treatment and 561 in patients who went to the outpatient clinic only for flushing.

Results: Late complications observed in patients under treatment were: 3 pocket infections (0.09/1000 days of port observation), 1 cutaneous infection (0.03/1000 days of port observation), 8 occlusions (0.24/1000 days of port observation) and 12 others.

In patients using the device only for flushing we observed 4 cases of device related bacteremia (0.04/1000 days of port observation), 1 pocket infection (0.01/1000 days of port observation), 1 cutaneous infection (0.01/1000 days of port observation), 3 occlusions (0.03/1000 days of port observation) and 7 other complications.

Conclusions: The low incidence of complications suggests that TIAP is safe and reliable for long term intermittent venous access. Our results support the use of TIAP in the oncology patients.

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Introduction

The totally implanted central venous access (TIAP), also called port, is a small reservoir connected to a venous catheter and positioned in subcutaneous tissue. Its use started in early 1980 in oncologic patients (Niederhuber et al., 1982) and nowadays these devices are an integral part of daily clinical routine (Vescia et al., 2008).

Compared to the externally venous access, TIAPs have a lower risk of infection (Maki et al., 2006), a lower interference with daily activities (e.g. swimming and bathing) and allow a better self image (RNAO, 2004; Halderman, 2000; O'Grady et al., 2002).

The use of this device, according to US Center for Disease Control and Prevention (CDC) Guidelines, is reserved for patients who require long term intermittent vascular access (O'Grady et al., 2002). In most cases TIAPs have one chamber, two chambers are used in patients undergoing bone marrow transplantation or in patients who require infusion of non-compatible drugs and fluids (Gallieni et al., 2008).

TIAPs may be associated with some complications, most of whom can be effectively prevented by adequate procedures of insertion and management.

Complications can occur early, as a consequence of catheter insertion. These include pneumothorax, arterial perforation and arrhythmias. Late complications include mechanical problems (such as pinch off, fractures and catheter migration), infections, extravasations, occlusions and vein thrombosis (Gallieni et al., 2008).

In one retrospective study (Yildizeli et al., 2004), the rate of late complications in 225 patients was 6.6%. They were: infections (2.2%), thrombosis (1.3%), extravasations (1.3%) and catheter ruptures (1.8%).

Proper nursing management of TIAPs is important to prevent, to detect and to treat late complications (Arch, 2007; Dougherty, 2006,1998).

Objective

The principal aim of this study is to analyze the incidence of late complications in oncologic patients with TIAP.

Methods

Setting and participants

This is a prospective multicenter observational study on adult oncologic patients with TIAP.

The study started on 19th February 2008 and finished on 21st August 2009 and it was conducted in twenty–six Italian oncology outpatient clinics.

The patients were divided into two groups: those under treatment and those that went to the clinic only for flushing the device.

Eligibility criteria were: patients with TIAP, ≥ 18 years old, able to understand and provide consent for participation. If the device had some complications in progress, the patient could not be included.

Authorization/approval by the Local Ethics Committee for each Hospital involved in the study was obtained.

Procedures

Nurses and physicians did not modify the usual care of the TIAP.

After enrollment, data about the device and its history were collected. Thereafter, at each patient's visit to the center, device management data (such as the type of antiseptic applied to the skin, the frequency of TIAP flushing and solution used) and the

possible presence of actual complications were recorded. If complications were observed, data on intervention carried out for their resolution were collected.

Definitions

In our study we observed the late complications:

“Cutaneous infection” was defined as induration and erythema around the site of needle insertion (Biffi et al., 1998).

“Pocket infection” was defined as induration and erythema around the TIAP, with culture-positive material aspirated from the pocket (Biffi et al., 1998).

For diagnosis of “device related bacteremia” two sets of blood samples for culture, one from a peripheral vein and one from the catheter, had to be obtained. Diagnosis was accepted with a 10-fold increase in colony-forming units of bacteria per ml from blood obtained through the device in comparison to peripheral blood culture (Biffi et al., 1998). If qualitative culture has been made, the diagnosis of bacteremia was accepted when the positivity of blood culture obtained through the TIAP was before than culture obtained from peripheral vein (Pittiruti, 2009).

Infection diagnosis was defined by the physician.

Furthermore we observed the occlusion (defined as an impossibility of flushing and drawing of blood) and other complications such as ‘withdrawal occlusion’ (impossibility to draw blood).

Analysis of data

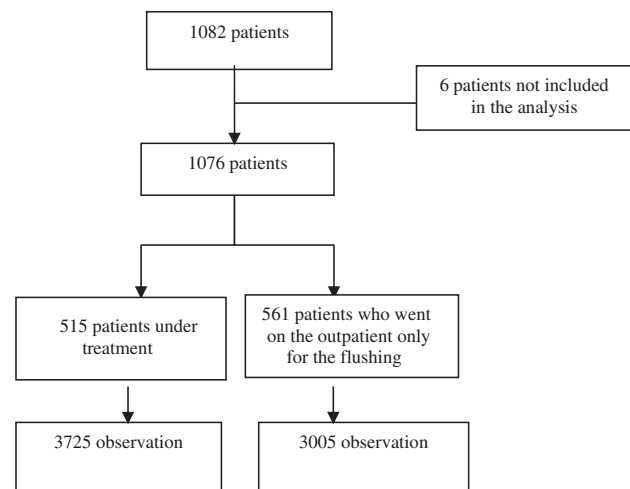
Data were stored in a Microsoft Access 2000 database and analysis was performed with the MedCalc Version 10.3.2.0 and Microsoft Excel 2007.

Complications are reported in terms of frequency for each type and expressed as 1000 days-observation-device.

Results

1082 patients were recruited. Analysis was conducted in 1076 patients (498 male and 578 female), since in six cases some important information were missing (see Graph 1). Patients' characteristics are summarized in Table 1. The age group most represented was 51–70 years.

515 devices were observed in patients under treatment, for a total of 32695 days (median 72 days, range 1–217). 561 devices



Graph 1. Study design.

Table 1
Patients' characteristics.

N. of Patients	1076		
Sex (male/female)	498/578		
Age (years)			
18–30	21 (2%)		
31–50	223 (20.7%)		
51–70	679 (63.1%)		
71–90	153 (14.2%)		
Type of cancer			
Solid cancer	964 (89.6%)		
Hematologic cancer	112 (10.4%)		
N. of patients under treatment	515	N. of patients who went on the outpatient only for the flushing	561
Gender (male/female)	249/266	Sex (male/female)	249/312
Age (years)		Age (years)	
18–30	14 (2.7%)	18–30	7 (1.2%)
31–50	124 (24.1%)	31–50	99 (17.7%)
51–70	302 (58.6%)	51–70	377 (67.2%)
71–90	75 (14.6%)	71–90	78 (13.9%)
Type of cancer		Type of cancer	
Solid cancer	465 (90.3%)	Solid cancer	499 (89.9%)
Hematologic cancer	50 (9.7%)	Hematologic cancer	62 (11.1%)

were observed in patients who went to the outpatient clinic only for flushing, for a total of 106173 days (median 211 days, range 1–395).

TIAP features are summarized in Table 2.

Late complications in patients under treatment

Late complications in patients under treatment are indicated in Table 3.

Infections occurred in 4 cases: 3 pocket infections (0.09/1000 days of port observation; 95% CI 0.065 to 0.115) and one of this had associated with cutaneous infection. One device was removed after pocket infection (34 days after the placement). Cutaneous site infection occurred in 1 case.

We observed eight occlusions (0.24/1000 days of port observation; 95% CI 0.203 to 0.277), two of them in the same device: the

Table 2
TIAP features.

Number of chamber			
One/two		1040/36	
Location of reservoir			
Thoracic area		1075 (99.9%)	
Data not available		1 (0.1%)	
Vein used			
Jugular		267 (24.8%)	
Subclavian		800 (74.4%)	
Other		8 (0.7%)	
Data not available		1 (0.1%)	
Type of catheter			
Open – ended catheter		728 (67.7%)	
Closed – ended catheter		348 (32.3%)	
TIAP in pt under treatment = 515		TIAP in pt that went on the outpatient only for the flushing N = 561	
Number of chamber		Number of chamber	
One/two	501/14	One/two	539/22
Vein used		Vein used	
Jugular	128 (24.8%)	Jugular	139 (24.8%)
Subclavian	383 (74.4%)	Subclavian	417 (74.3%)
Other	3 (0.6%)	Other	5 (0.9%)
Data not available	1 (0.2%)		
Type of catheter		Type of catheter	
Open – ended catheter	378 (73.4%)	Open – ended catheter	350 (62.4%)
Closed – ended catheter	137 (26.6%)	Closed – ended catheter	211 (37.6%)

Table 3
Late complication in pt under treatment.

Complication	N.	/1000 days of port observation	Port removal
Pocket infection	3	0.09 (95% IC 0.065 to 0.115)	1 case
Cutaneous site infection	1	0.03 (95% IC 0.015 to 0.045)	
Occlusion	8	0.24 (95% IC 0.203 to 0.277)	1 case
Other complication	12	0.37 (95% IC 0.328 to 0.412)	2 cases (pocket haematoma and withdrawal occlusion associate to dislocation)
Total	24	0.73 (95% IC 0.692 to 0.768)	

first resolved, but the device had to be removed after the second (89 days after the placement). In the other cases the return to the catheter patency was achieved through pressure flushing or with heparin or fibrinolytic agent. The median between TIAP positioning and the occlusion complications was 85 days (range: 13–1083).

Twelve others complications were observed. Among these, one withdrawal occlusion associated with dislocation of the device, one pocket haematoma (after 58 days of the TIAP positioning). This complication was not resolved and the device was removed.

Four devices (0.77%) were removed due to complications.

Late complications in patients that went to the outpatient only for flushing the device

Late complications observed in this group are indicated in Table 4.

Bacteremia was observed in 4 TIAP (0.04/1000 days of port observation; 95% CI 0.024 to 0.056). The median number of days between the positioning of TIAP and these complications was 588 days (range 410–2042). In three cases the devices were removed (median 650 days; range 434–2042).

Other infectious complications comprised one pocket infection (0.01/1000 days of port observation; 95% CI 0.002 to 0.018), which imposed the removal of the device (1132 days after placement), and one cutaneous infection (0.01/1000 days of port observation; 95% CI 0.002 to 0.018).

Three occlusions were observed (0.03/1000 days of port observation; 95% CI 0.016 to 0.044); in two cases the device was removed (after 510 and 2206 days of positioning).

Seven others complications occurred: one device was dislocated after a trauma and was removed (1685 days after positioning); in two cases infusion was difficult (subsequently in one case an occlusion occurred and in the other an infection was associated with occlusion); one case of strong pain near the pocket; two cases of withdrawal occlusions and difficulty of aspiration in one case.

The rate of removal due to complications was 1.25% (N = 7).

Nursing management

In all patients the access to the device was performed with Huber needles (Needle size ranged from 19 to 22 gauges). Nurses had difficulties in positioning the Huber needle in 18 cases: eight in patients under treatment and ten in the others.

In all cases the access was performed with sterile gloves or with “no-touch” technique. Skin antiseptics used were povidone iodine or chlorhexidine in isopropyl alcohol or, in some cases, an aqueous solution of chlorhexidine gluconate.

Table 4
Late complication in patients that went to the outpatient only to flushing the device.

Complication	N.	/1000 days of port observation	Port removal
Device related bacteremia	4 ^a	0.04 (95% IC 0.024 to 0.056)	3 cases (1 case associated with occlusion)
Pocket infection	1	0.01(95% IC 0.002 to 0.018)	1 case
Cutaneous site infection	1	0.01(95% IC 0.002 to 0.018)	
Occlusion	3	0.03 (95% IC 0.016 to 0.044)	2 cases
Other complication	7	0.07 (95% IC 0.049 to 0.091)	1 case (TIAP dislocation)
Total	16	0.15 (95% IC 0.120 to 0.179)	

^a in one case the bacteremia was associated to the occlusion.

In patients under treatment the devices were used mostly for delivering chemotherapy; in nine cases for blood products infusions and in seven cases for parenteral nutrition.

In 270 patients the median number of days between device flushes was more than 40; among them, in one hundred and sixty seven the median time was 40–60 days, in twenty-two 61–80 days and in eighty-one more than 80 days. Five complications were observed in the first group (40–60 days): 2 occlusions (1 TIAP was removed), 1 device related bacteremia (TIAP removed), 1 cutaneous infection and 1 pain near the TIAP pocket. No complications occurred in the other groups.

Discussion

In this large multicenter study TIAP appears to be safe and reliable for long term intermittent venous access. This conclusion is in accordance with the literature (Gallieni et al., 2008; Vescia et al., 2008; Biffi et al., 1997, 1998, 2004).

More complications were observed in the group of patients under treatment rather than those who accessed the device only for flushing. On the other hand, removal rate was greater in the second group (0.77% vs 1.24%). This may be due to the easier decision of removing the catheter when it is no longer used.

In one recent review, the mean of catheter related infections in patients with TIAP was 0.1/1000 days (Maki et al., 2006). This data is confirmed by our study, where the incidence of this complication is very low.

Incidence of pocket infection in our study is 0.09/1000 days in the group of patients under treatment and 0.01/1000 days in the other group. Other studies reported an incidence of 0.010/1000 days (Biffi et al., 2004) and 0.031/1000 days (Biffi et al., 1997). In order to reduce the complications, care of the device is very important and the role of nursing is crucial. In our study the access to the TIAP was performed with sterile gloves or with “no-touch” technique and before the accessing the skin was cleaned with povidone iodine or with chlorhexidine in isopropyl alcohol or in some cases with an aqueous solution of chlorhexidine gluconate. The aseptic techniques do not necessarily require sterile gloves, but if a “no-touch” technique is adopted, clean non-sterile gloves may be used. Recent Guidelines (Pittiruti et al., 2009; Marschall et al., 2008; Pratt et al., 2007; O’Grady et al., 2002) indicates that skin must be cleaned with a chlorhexidine preparation to reduce contamination. The Epic2 guideline (Pratt et al., 2007) points out that 2% chlorhexidine gluconate in 70% isopropyl alcohol is the preferred disinfectant. Povidone iodine should be used, but it must remain on the skin for at least 2 min, or longer if it is not yet dried before insertion (O’Grady et al., 2002). The NICE Guideline (2003) indicates that an alcoholic chlorhexidine gluconate solution should be used, while an aqueous solution of chlorhexidine gluconate should be used if the manufacturer’s recommendations prohibit the use of alcohol with their product.

Access to the TIAP must be performed using Huber needles, which should stay in place for no more than 7 days. Adhesive transparent dressing must be used for securing the needle to the

TIAP (RCN, 2010). In our study the access was always performed with the Huber needle.

Occlusions were observed in both groups of patients. In the first group the incidence was 0.24/1000 days while in the other 0.03/1000 days. In order to reduce the risk of occlusive complications appropriate flushing and locking procedures are indicated (Gallieni et al., 2008). Flushing must be performed using turbulent flush technique to prevent fibrin buildup or accumulation of precipitate medication inside the catheter lumen. Turbulent flush technique is achieved with a push-pause method (RNAO, 2008). In order to prevent blood reflux from the vein into the lumen of the catheter, positive-pressure locking techniques must be used (RCN, 2010). A previous explorative study has shown that not all centers used the positive-pressure technique (Dal Molin et al., 2009). In this study we did not recorded data about flushing technique.

Most manufacturers indicate that flushing must be performed every 4 weeks when the device is not in use (Vescia et al., 2008). However, one retrospective study suggests that less frequent flushing could be safe and feasible (Kuo et al., 2005).

Results of one explorative study indicate that flushing in some Italian Oncologic Center, when TIAP is not in use, is performed at intervals greater than 30 days (Dal Molin et al., 2009). In our study, in twenty-two devices flushing was performed between 61 and 80 days and in eighty-one cases more than 81 days. These data, according to Kuo, suggest the possibility of flushing the TIAP at intervals greater than 4 weeks. However, we believe that further studies are needed in this area to define the most appropriate time to flush the TIAP, when it’s not in use.

In conclusion, the low incidence of complication suggests that TIAP is safe and reliable for long term intermittent venous access. Our results support the use of TIAP in the oncology patients.

Conflict of interest statement

There are not any personal interest, but only scientific interest by the principal investigator and other researchers involved.

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