

ORIGINAL ARTICLE

A prospective observational study on 249 subcutaneous central vein access ports in a Swedish county hospital

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Abstract

Background. Reliable central vein access is a fundamental issue in modern advanced oncological care. The aim of this study was to determine the incidence of complications and patient perception regarding central vein access ports. **Methods.** We prospectively studied 249 single lumen access ports implanted between 1 July 2008 and 15 March 2010 in a mixed patient population at a 500-bed secondary level hospital in Sweden. We determined the number of catheter days, infection rate and mechanical complications, as well as patient satisfaction regarding the access port, over a six-month follow-up period. **Results.** Two hundred and forty-four different patients received 249 ports yielding a total of 37 763 catheter days. Ultrasound and fluoroscopic guidance was used in 98% of procedures. Vein access was obtained percutaneously by an anaesthesiologist in all cases. There was no case of pneumo- or haemothorax. The incidence of catheter-related bloodstream infection, was 0.05/1000 catheter days and the incidence of pocket/tunnel infection was 0.39/1000 catheter days. Clinically apparent deep vein thrombosis occurred in four patients (1.6%). Patient satisfaction was overall high. **Conclusion.** These results confirm that our team-based approach with written easily accessible evidence-based guidelines and a structured education programme leads to a very low complication rate and a high degree of patient satisfaction.

A reliable and safe access to the central circulation is essential in most fields of modern advanced healthcare. The first long-term vascular access catheterisation techniques were described in the early 1970s by Hickman [1] and Broviac [2], and the use of a totally implantable central vein access port was introduced by Niederhuber [3] in 1982. Access ports are widely used in medical practice for the administration of cytotoxic drugs, parenteral nutrition and blood sampling. Implantation and use of access ports offer a safe, reliable and well-tolerated route to the patient's bloodstream, but may be associated with complications such as infection, vascular perforation, thrombotic and mechanical problems all of which may be severe and even life-threatening.

Since 1999, a structured educational programme on the use and care of central vein catheters has been in use in all units at our 500-bed hospital and

associated outpatient clinics. Our routines are based on the recommendations of the Centre for Disease Control and Prevention (CDC) [4].

Our research group has previously demonstrated a low infection rate with both short-term central vein- [5] and arterial [6] catheters.

In order to further evaluate our routines, we conducted a prospective observational survey with the primary aim of determining the incidence of all access port-related complications, and patient perception of the port.

Materials and methods

Setting

The hospital is a 500-bed general county hospital including most medical, oncological and surgical

specialties except neurosurgery and cardiac surgery. No solid organ or stem cell transplantations are performed. All nursing staff handling central vein access ports received special training, and about 150–200 ports are implanted each year by the Department of Anaesthesia and Intensive Care.

Patients

Patients ≥ 18 years of age and with a predicted survival of more than six months were invited to take part in the study. Exclusion criteria were: ongoing severe infection; severe coagulation disorder at the time of implantation; or inability to communicate in English or a Scandinavian language.

Port implantation

Two different central vein port systems were used; the Bard® port with a silicone Groshong catheter and B.Brauns Celsite® port ST301 with an open-ended silicone catheter. Prior to surgery the patients received a total body wash using a sponge containing 4% chlorhexidine. Antibiotic prophylaxis was not routinely administered. All port systems were implanted in an operating theatre with maximal sterile precautions (cap, mask, gown, gloves and a large drape). The implanting physician was assisted by a theatre nurse. All procedures were carried out by either a resident or specialist anaesthesiologist using the Seldinger percutaneous technique, and the catheter inserted via a spilt sheath. The surgical area was prepared with a solution containing 70% ethanol and 0.5% chlorhexidine, and the skin passively dried for 1–2 minutes before sterile draping. The procedure was routinely carried out under local anaesthesia, but in some cases intravenous propofol sedation was also used. Ultrasound-guided venepuncture and fluoroscopy was used, and the internal jugular vein was the first choice because of the minimal risk for pinch-off syndrome and its good ultrasound accessibility compared to the subclavian vein. The catheter was then tunnelled towards the right infraclavicular area where a pocket just large enough for the port reservoir was prepared using a single sharp skin incision and subsequent blunt dissection. After correct tip positioning, with the help of fluoroscopic guidance, in the right atrium or distal superior vena cava, the catheter was connected to the port reservoir. No reservoir-anchoring sutures were applied. Subcutaneous tissue was adapted with two to three subcutaneous sutures and the skin closed with a continuous intracutaneous suture (Ethicon, Vicryl™, Johnson & Johnson). The port reservoir was then punctured and system function verified. Finally 40 ml 0.9% saline was flushed

through the system. The wound over the port reservoir was covered with a semi-transparent dressing (Hartmann Hydrocoll®) and the puncture site over the internal jugular vein covered with an absorbant film dressing (Tegaderm™ + Pad). Post-implantation chest x-rays were not routinely performed and the patient was able to use the port immediately after implantation.

Port care

All port handling was carried out by nursing staff with specific training in port handling stressing the importance of hygiene precautions. Written instructions for port care and problem-solving were easily available through the hospital IT-system. CVC-team support (anaesthesiologist/intensive care nurse) was available on a 24-hour basis from the Department of Anaesthesiology and Intensive Care. Prior to puncture of the reservoir membrane, the skin was disinfected with a solution containing 70% ethanol and 0.5% chlorhexidine. During this procedure, sterile or high purity gloves were used. Intravenous positioning was verified by blood aspiration prior to use. After use 40 ml of 0.9% saline was flushed through the system. When the port needle was left in situ, it was covered with a semi-permeable transparent dressing (Tegaderm™ HP). During continuous use intravenous positioning was verified once a day. When indwelling, the port needle was changed once a week. Intermittent injections were performed through a needleless injection membrane attached to the needle, NIM, (Smartsite®). NIMs are disinfected with ethanol/chlorhexidine before use. Dressing and NIMs were changed and the area around the puncture site disinfected every three days. Resting ports were not routinely flushed. Routine use of antithrombotic and intraluminal or subcutaneous heparin was not used.

Port problem-solving

When catheter occlusion occurred the first step was to try to flush the system with a 10 cm³ syringe containing isotonic saline. If this failed, a 2.5–5 cm³ syringe was tried with caution by an anaesthesiologist. Alteplase 0.2 mg/ml, ethanol 70% or hydrochloric acid 1 mmol/ml was used to restore catheter patency if flushing with saline was unsuccessful, depending on the probable cause of occlusion. Prior to installation of ethanol or hydrochloric acid, a chest x-ray was obtained to rule out catheter fracture or disconnection.

Data collection

Patients were invited to take part in the study on the day of scheduled surgery. Written and verbal

information about the study was provided and patient consent obtained. At implantation we collected the following data: patient characteristics (age, gender, disease, laboratory results); implantation characteristics (vessel choice, procedural time, use of antibiotics, anaesthetic method, implantation difficulties, use of ultrasound/fluoroscopy, anaesthetist training level); and patient perception during the procedure. One week after port implantation patients were interviewed and the information cross checked with the patient's notes as regards port-related complications. Interviews were performed by telephone. This procedure was repeated once a month for the entire follow-up period of six months. All interviews and chart reviews followed a specific protocol. Two research nurses and the main author conducted the interviews and chart reviews.

Microbiological methods

When an infection was suspected, swab cultures from the area around the reservoir and tunnel as well as blood cultures drawn from the port and a peripheral vein, were obtained. Swabs were transported in Amies medium with charcoal. Identification and antibiotic susceptibility testing were performed by standard methods at our local microbiology laboratory (www.srga.org, accessed < <http://www.srga.org> accessed / > January 1, 2007). A culture from the reservoir pocket, and the catheter tip were taken from all systems removed. The tip was then cultured using a standardised semi-quantitative method [7] for up to two days. The tip culture results were categorised as follows: > 15 colony forming units (CFU); 1–15 CFU; and negative culture. When blood cultures were performed, a minimum of 10 ml was injected into an aerobic and an anaerobic bottle, respectively. The bottles were incubated for up to six days using an automated blood culture system (BacT/ALERT, bioMérieux, Inc., Durham, NC, USA). Identification and antibiotic susceptibility testing were performed using standard methods for all colonies detected.

Definitions

Catheter colonisation was defined as a positive tip culture in the absence of clinical symptoms of systemic inflammatory response syndrome (SIRS) [4]. Port pocket and/or tunnel infection was defined as local signs of inflammation around the port/tunnel with culture-positive fluids from the port pocket/tunnel [4]. Catheter-related infection, CRI, was defined as a positive tip culture in a patient with at least two of four SIRS symptoms and no other source of infection [8]. CRBSI was defined as isolation of the same microorganism from tip culture and from

a blood culture drawn from another vessel, together with at least two of the four SIRS criteria [4]. The criteria for 'difficult implantation' were more than four attempts to puncture the vessel and/or necessity to change access vein [5]. Catheter-related deep venous thrombosis, DVT, was defined as occlusion (partial or total) of the vein into which a catheter had been placed. Catheter occlusion was defined as inability to aspirate or flush via the catheter. Procedural time was defined as the time from the application of local anaesthetic to completion of the last suture.

Statistical methods

Descriptive analyses were performed to characterise the patient population. The significance of differences between groups was determined using the χ^2 -test for categorical variables and Student's t-test for continuous variables. Two-tailed tests of significance were used. A number of univariate logistic regression analyses were performed to estimate the risk for port-related colonisation and infection. We used multivariate regression models controlling for catheterisation time. All analyses were conducted using a statistical software package (SPSS, version 13.0. for Windows, SPSS Inc., Chicago, IL, USA).

Ethics

The study was approved by the Regional Ethics Review Board at the University of Linköping (reference number: M207-07).

Results

Patient and catheter characteristics

Two hundred and fifty patients were included. One patient left the study after one month and was excluded. Swab-, tip- and blood cultures were missing in three patients with suspected pocket infection and in two patients with catheter-related deep vein thrombosis, whose access port was removed at another hospital. The median patient age was 62 years (range 20–88) and 60% of patients were female. A total of 37 763 catheter days were studied and the median follow-up time was 180 days (range 1–225). Forty-four patients (18%) died during the follow-up period. No patient death could be related to access port complications. At the end of follow-up 174 patients (70%) still had their access port in place. Drop-outs are shown in Figure 1. Bard® ports with Groshong silicone catheters were used in the first 69 cases (28%) and the BBraun® Celsite ST301 open-ended silicone catheter was used in the remaining 180 cases.

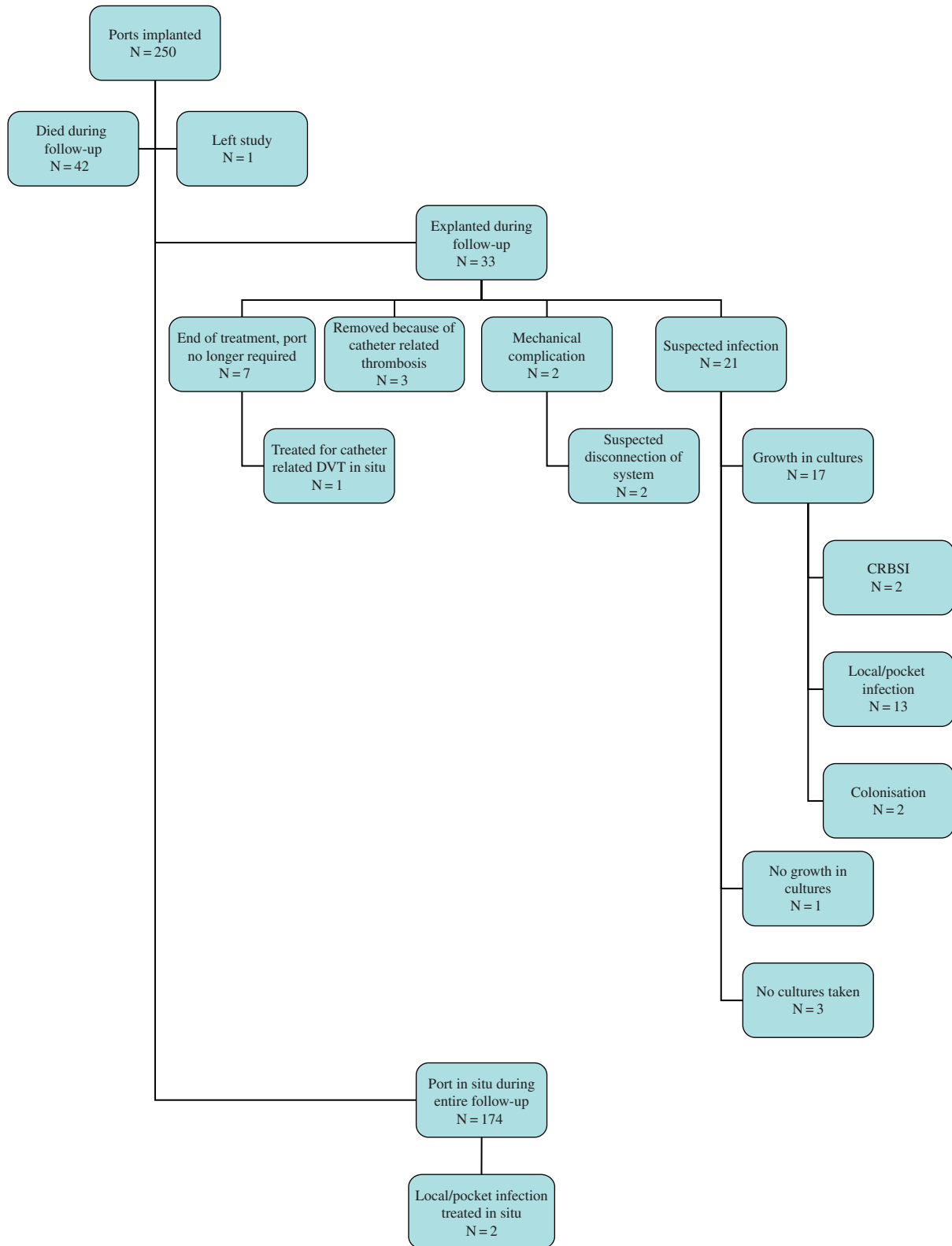


Figure 1. Study outline.

Implantation characteristics

Vein choice, tip positioning and the use of ultrasound/fluoroscopic guidance are outlined in Table I.

Antibiotic prophylaxis was administered in 10 cases (4%) and an additional five patients were under antibiotic treatment at the time of port implantation. Vancomycin was the most frequently used antibiotic for prophylaxis (five of 10 cases).

In 238 cases (96%) the inserting physician was a specialist anaesthesiologist. Median procedure time was 25 minutes (range 9–75). One hundred and

sixty-eight patients (68%) received local anaesthetic only, 79 patients (32%) received light propofol sedation in addition to the local anaesthetic. In one case general anaesthesia was required. Patient peri-procedural perceptions are outlined in Table II. The proportion of patients with moderate to severe procedural discomfort was 25% in both the group receiving local anaesthetic only and the propofol sedation group.

Arterial puncture occurred seven times (2.8%), but no intra-arterial guidewire or dilator placement occurred. In eight cases (3%) the inserting physician had to change access vein due to inability to place the catheter in the first-choice vein.

Table I. Patient and insertion characteristics.

	n	%
Gender		
Female	150	60.2
Male	99	39.8
Indication for implantation		
Cytotoxic drugs	238	95.6
Parenteral nutrition	5	2
Difficult iv access	6	2.4
Disease		
Haematological malignancy	29	11.6
Colorectal cancer	55	22.1
Upper GI cancer	12	4.8
Breast cancer	67	26.9
ENT cancer	3	1.2
Urogenital cancer	18	7.2
Lung cancer	11	4.4
Sarcoma	2	0.8
Pancreatic cancer	20	8
Hepatocellular cancer	1	0.4
Malignant melanoma	5	2
Gynaecological cancer	11	4.4
Unknown tumour	3	1.2
Other	12	4.8
Competence level of inserting doctor		
Specialist	238	95.6
Resident	11	4.4
Vein choice		
Right internal jugular	214	85.9
Left internal jugular	24	9.6
Right subclavian	4	1.6
Left subclavian	6	2.4
Femoral	1	0.4
Use of ultrasound		
Yes	244	98
No	5	2
Tip position		
Superior vena cava	170	69.4
Right atrium	71	29
Brachiocephalic vein	3	1.2
Inferior vena cava	1	0.4
Antibiotics		
Not administered	234	94
Prophylaxis	10	4
Ongoing	4	1.6
Ongoing and prophylaxis	1	0.4
Anaesthetic		
Local infiltration	170	68.2
Local infiltration and sedation	78	31.3
General anaesthesia	1	0.4

Early mechanical (up to one month after implantation) complications

No case of pneumo- or haemothorax was recorded. One patient had a port-related haematoma appearing a few hours after surgery that was treated conservatively. Two systems (0.8%) had to be removed due to suspected disconnection between the catheter and reservoir; in one case a faulty radiological diagnosis led to port removal and in the other case suspected handling error during implantation caused disconnection.

For comparison of adverse events with those in other recent studies, see Table III.

Occlusive and thrombotic complications (from implantation up to six months)

On 36 occasions (0.95/1000 catheter days) we registered catheter occlusion and/or failure to draw blood

Table II. Patients' perceptions.

	n	%
Grade of procedural discomfort		
No discomfort	68	27.4%
Light discomfort	116	46.8%
Moderate discomfort	58	23.4%
Severe discomfort	6	2.4%
Moderate to severe discomfort and...		
Local anaesthetic only	42	25.7%
Local anaesthetic and sedation	20	25.6%
Does port influence everyday life ¹		
Much influence	24	9.6%
Little to no influence	182	73.1%
No data ²	43	17.3%
Does port facilitate during treatment ¹		
Yes	202	81.1%
No	2	0.8%
No data ²	45	18.1%
Are you satisfied with your port ¹		
Yes	199	79.8%
No	7	2.8%
No data ²	43	17.3%

¹Median values during follow-up; ²Patient dead or unable to answer at first follow-up.

Table III. Port-related adverse events in recent studies.

Author (year)	Method	No. of catheters	Catheter-days	Arterial puncture N (%)	Pneumothorax N (%)	Haemothorax N (%)	Local haemorrhage N (%)	Local infection N per 1000 catheter-days (%)	Catheter-related bloodstream infection N per 1000 catheter-days (%)	Catheter-related deep vein thrombosis N per 1000 catheter-days (%)
Teichgräber (2011) [10]	Retrospective	3160	922 599	5 (0.16)	0 (0)	NA	3 (0.11)	0.016 (0.57)	0.15 (5.1)	0.11 (3.7)
Barbetakis (2011) [13]	Retrospective	700	156 800	3 (1.6)	16 (2.2)	NA	19 (2.6)	0.19 (4.4)	NA	0.21 (4.7)
Peris (2010) [16]	Prospective*	3951	1 642 402	176 (4.4)	109 (2.8)	NA	205 (5.2)	0.186 (7.3)□	0.186 (7.3)□	0.261 (10.2)
Heibl (2010) [11]	Prospective	140	29 107	NA	3 (2.1)	NA	1 (0.7)	0.17 (3.8)	0.27 (5.6)	0.03 (0.7)
Biffi (1997) [12]	Prospective	178	32 089	3 (1.6)	6 (3.37)	0	0	0.031 (0.56)	0.124 (2.24)	0.062 (1.12)
Present series (2013)	Prospective	249	37 763	7 (2.8)	0 (0)	0 (0)	1 (0.4)	0.39 (6)	0.05 (0.8)	0.1 (1.6)

*Both ports and tunneled catheters included. □ No differentiation between local and systemic infection.

through the catheter. No catheter had to be removed because of occlusion. Four (1.6% or 0.1/1000 catheter days) clinically apparent catheter-associated deep vein thromboses (DVT) were diagnosed by computerised tomography (CT), ultrasound or phlebography. All these patients received anticoagulant therapy and three patients (1.2%) required catheter removal because of their DVT. One patient had pocket infection and a DVT simultaneously. No clinically evident pulmonary embolisation occurred in patients with a catheter-related thrombus.

Catheter colonisation and port-related infections (from implantation up to six months)

Twenty-four of 249 (9.6%) had a suspected local pocket infection associated with the access port. In 15/249 (6% or 0.39/1000 catheter days) local pocket infection was verified by culture. *Staphylococcus aureus* and coagulase-negative staphylococci were the most common microorganisms responsible for local pocket infections, 26% and 53%, respectively. As regards the three patients with missing culture results and suspected pocket infection, whose port was removed at another hospital, we chose not to include these since a positive culture is mandatory according to the definitions used. Had these been included, the pocket infection rate would have been 7.2% or 0.47/1000 catheter days. A CRBSI was recorded on two occasions (0.8% or 0.05/1000 catheter days). Both patients had local signs of infection around the reservoir and *S. aureus* sepsis. These patients had their port removed immediately and the infections were successfully treated with antibiotics. The two CRBSIs occurred on days 7 and 37 after

implantation, respectively. Characteristics of infected ports are outlined in Table IV.

There were no statistically significant differences between the port infection group and patients without infection with regard to age, gender, primary diagnosis or neutrophil count. No statistically significant differences were found between groups with regard to anaesthetist training level, use of antibiotics, complicated procedure, long procedural time (> 40 minutes) or choice of vein for insertion.

Patient perception

During the implantation procedure, 25% of patients experienced moderate (23.4%) to severe discomfort (2.6%). There were no significant differences between patients receiving local anaesthetics only or with propofol sedation.

The vast majority of patients (202/249 (81%)) felt that the access port facilitated their treatment. One hundred and eighty-two (73%) patients reported that the port had little or no effect on their daily life (Table II).

Discussion

In modern advanced oncological medicine, a reliable and safe central vein access is of great importance. Ever since the 1970s when Broviac and Hickman [1,2] first described implanted catheters, indwelling vascular access devices have been developed and refined. Since the introduction of the totally implanted central vein access port in the 1980s [3] several models have become commercially available.

Major findings in this study were that a low overall complication rate may be achieved by implementing

Table IV. Infected ports.

Infected access port	Clinical signs	On day	Wound/pocket swab	Cultures Tip	Blood	Interpretation	Misc.
1	Local infectious	30	<i>S. aureus</i> *	–	–	PI	Treated in situ
2	Blister, thin skin covering reservoir	86	CoNS*	–	–	PI	CVC-DVT
3	Small skin wound over reservoir	35	CoNS [§]	–	–	PI	
4	Rubor and some pus	25	<i>E. coli</i> *	–	–	PI	
5	Discoloration of skin over reservoir	142	<i>Propionibacterium</i> *	–	–	PI	CVC-DVT
6	Wound over reservoir	136	Peptostreptococci [§] CoNS*	–	–	PI	
7	Local infectious	21	<i>Klebsiella</i> [§] <i>Enterococcus faecalis</i> *	–	–	PI	Treated in situ
8	Wound over reservoir	119	<i>S. aureus</i> *	<i>S. aureus</i> * (1–14 CFU)	–	PI	No systemic symptoms, catheter tip contaminated during explantation
9	Rubor over reservoir	26	<i>S. aureus</i> *	<i>S. aureus</i> * (1–14 CFU)	–	PI	No systemic symptoms, catheter tip contaminated during explantation
10	Local infectious	35	CoNS [§]	CoNS [§] (1–14 CFU)	–	PI	No systemic symptoms, catheter tip contaminated during explantation
11	Reservoir covered by thin epithelial layer	82	–	CoNS* [§] (1–14 CFU)	–	–	Tip colonisation Two different strains with different resistance patterns
12	Wound gap, pus over reservoir	34	CoNS*	CoNS* (15–50 CFU)	–	PI	No systemic symptoms, catheter tip contaminated during explantation
13	Wound rupture	89	CoNS*	CoNS* (> 50 CFU)	–	PI	No systemic symptoms, catheter tip contaminated during explantation
14	Local infectious	154	CoNS*	CoNS* (> 50 CFU)	–	PI	No systemic symptoms, catheter tip contaminated during explantation
15	Small wound	63	CoNS [§]	CoNS [§] (1–14 CFU)	–	PI	Fever as only systemic symptom, tip contamination
16	Sepsis	15	<i>S. aureus</i> *	–	<i>S. aureus</i> *	PI	Complex interpretation, multiple skin ulcerations, not CRBSI according to definition
17	Sepsis and local infectious	7	<i>S. aureus</i> *	<i>S. aureus</i> *	<i>S. aureus</i> *	CRBSI	
18	Sepsis and local infectious	37	<i>S. aureus</i> [§]	<i>S. aureus</i> [§]	<i>S. aureus</i> [§]	CRBSI	
19	High fever, light rubor around reservoir	68	–	CoNS [§] (1–14 CFU)	Lactobacillus [§]	–	Tip colonisation

CFU, colony forming units; CoNS, coagulase negative Staphylococci; CRBSI, catheter-related blood stream infection; CVC-DVT, central venous catheter-related deep venous thrombosis; PI, pocket/local infection,

*Sensitive to all tested antibiotics; [§]Antibiotic resistance to some degree, no methicillin resistant *S. aureus* (MRSA) recorded.

evidence-based guidelines concerning the implantation and care of subcutaneous vascular access ports. The strength of this study was our rigorous follow-up protocol with monthly medical record reviews and patient interviews, and that only one patient was lost to complete follow-up. Since the majority of the patients had their port in place at the end of the follow-up period, late (>6 months) complications may have occurred after the follow-up period without our knowledge. Another weakness in this study was that our threshold for removal of suspected infected ports was low. It is noteworthy that we did not have any patients with acute leukemia in our study population, which should be taken into consideration when comparing our infection and thrombosis complication figures with those in other studies.

During follow-up interviews with the patients there could have been a risk for bias. Compared to short-term and tunneled central vein catheters (TCVC), the totally implanted access port may, according to meta-analyses, offer the lowest risk for infectious complications [9]. From recent publications the incidence of port-related blood stream infection lies between 0.127 to 0.27/1000 catheter days [10–12] (see Table III). In comparison, the CRBSI incidence in this material was 0.05/1000 catheter days. Our study group has previously found low CRBSI rates on both short-term CVCs and arterial catheters [5,6] indicating well-established routines intravascular catheter care at our hospital. However, the incidence of port pocket infection 15/249 (6%) was slightly higher than in recent publications [11,13].

One of 19 (5%) of the port infections became clinically apparent during the first week after implantation. This finding supports the recent findings of others authors, questioning the use of routine antibiotic prophylaxis [14,15]. Both of our patients with CRBSI had local pocket infection at the same time indicating that bacterial spread occurred on the external surface of the port system.

Several studies have shown that the implantation procedure can be performed with a low rate of mechanical complications [10,16,17]. The present study supports these results with regard to the use of ultrasound-guided venepuncture and fluoroscopy, both of which should be mandatory when inserting long-term CVCs.

Symptomatic catheter-related DVT is a frequent complication in up to 28% of adults [18]. The corresponding figure in our material was 1.6% but we could not find any relationship between port-related infection and catheter-related DVT. This relationship has previously been demonstrated in haematological patient populations [19,20]. Some

bacteria often responsible for catheter-related infections are thrombogenic [21,22] and the pathophysiological mechanism behind this is thought to be bi-directional, with infection causing thrombosis and vice versa [19]. The low incidence of clinically apparent DVTs in this study could be linked to the low incidence of infection or vice versa. When dealing with catheter-associated DVTs we have adapted the approach suggested by Baskin *et al.* [18] leaving more catheters in situ for continual use without any adverse events occurring as a result.

There are no convincing guidelines as to the proper time-interval between resting port catheter flushing. A recent publication [23] suggests that flushing intervals may be extended for up to four months without compromising medical safety. The results in our series support this, and further questions the regular interval flushing practice in oncology patients with a port.

Subcutaneous central vein access ports are well-tolerated and offer a high degree of satisfaction among users [24–26]. Procedural distress during implantation has been reported to be as high as 30% [24] similar to the results in this study. Noteworthy is that 25% of patients completing the implantation procedure under local anaesthesia with or without sedation, experience the same procedural distress. An overwhelmingly high proportion of patients, however, have a high degree of satisfaction regarding their port, and patients state that the port has minimal influence on their daily life.

In conclusion, we have found that our team-based approach with written, easily accessible evidence-based guidelines and a structured education programme contribute to a low complication rate and a high degree of satisfaction in patients with a subcutaneous central vein access port.

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