Infectious Port Complications Are More Frequent in Younger Patients with Hematologic Malignancies than in Solid Tumor Patients

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Abstract

Background: We assessed longevity and complications of totally implantable venous access devices in oncology patients. Methods: 197 patients received a total of 201 port devices via the subclavian vein for delivery of chemotherapy between January 1, 2005, and December 31, 2006. We reviewed the patient charts for port-related complications and risk factors until July 31, 2007. Results: A total of 47,781 catheter days were analyzed (median, 175 days; range, 1-831). Forty-six different complications occurred (0.96 complications/1,000 catheter days). The only risk factor significantly associated with a higher complication rate was younger age. Older patients had a lower risk for developing complications with a risk reduction of 2.4% for each year. There were no differences regarding underlying tumor, gender, access side, method of placement (subclavian/cephalic vein) or implanting team (thoracic versus visceral surgery). A trend was seen for shorter port longevity in hematologic patients compared to oncologic patients (p = 0.059). The former developed significantly more port-associated infections than solid tumor patients [11/53 cases (21%) versus 2/148 cases (1.4%); p < 0.0001]. Conclusions: Port-associated infections were mostly observed in younger patients with hematologic neoplasms. Prospective trials should be performed to evaluate the benefit of a prophylactic antimicrobial lock in these selected patients.
Infectious Port Complications Are More Frequent in Younger Patients with Hematologic Malignancies than in Solid Tumor Patients

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Key Words
Port system \cdot Central venous access \cdot Central venous catheter infection

Abstract

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Introduction

Totally implantable port systems have been widely used in the last two decades for delivery of long-term medical therapy like antibiotics, parenteral nutrition or anticancer drugs in oncology patients [1]. They succeeded the subcutaneously tunneled catheter systems like Hickman or Groshong lines, which had been developed for long-term use in the 1970s [2]. Implantable port devices have numerous advantages over conventional central venous catheters (CVCs). They can be used over long periods of time after one-time implantation thus avoiding repeated insertions of a CVC. They can be implanted in local anesthesia in an outpatient setting. Patient compliance is excellent since peripheral venipunctures can be

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avoided and quality of life is not impaired [3]. The high purchase and insertion costs are redeemed by low maintenance costs [4].

Generally, implantation of a port system is considered when a medical therapy is planned to exceed 2 months or if peripheral vascular access is difficult to achieve.

Different studies have evaluated the usefulness and reliability of totally implantable catheter devices with particular interest for the most common complications occurring during or after implantation [5–11]. As a measure of quality control at our center, we performed a retrospective analysis to identify complications in our patients with implanted port systems.

Patients and Methods

We performed a retrospective analysis of 197 oncology patients who received a total of 201 port systems for delivery of chemotherapy between January 1, 2005, and December 31, 2006. The study was approved by the ethics committee, and patients gave written informed consent for the scientific analysis of their data. A single type of port system (BardPort™ implantable titanium device with a self-sealing rubber septum and an open-ended silicone catheter; Bard Access Systems, Salt Lake City, Utah, USA) was used. Patients who received intra-abdominal port systems for regional hepatic chemotherapy or other types of central venous access devices like Shaldon’s catheters for stem cell apheresis were excluded from the present study. The ports were placed by the team of either the department of thoracic surgery (n = 153) or of the department of visceral and transplantation surgery (n = 48) in the operating room under general or local anesthesia. Peri-insertional antibiotics were given in selected patients only. In 59 of the 201 cases (29%) either β-lactam antibiotics or quinolones were applied as prophylaxis. The port system was implanted in the right (n = 160) or left (n = 41) pectoralis fascia after formation of a subcutaneous pocket in the infraclavicular area. Two techniques were used for venous access: direct puncture of the subclavian vein (n = 62; 31%) or surgical cut-down to the cephalic vein (n = 139; 69%), depending on the patient’s anatomy. When the surgeon could not access the subclavian vein by advancing the guide wire through the cephalic vein, the procedure was changed to a direct puncture of the subclavian vein. The correct catheter position in the superior vena cava was checked peripherally by fluoroscopy and postoperatively by chest radiography. Immediate use of the system was permitted after radiological control of the catheter position. Patients were treated in an outpatient and/or inpatient setting by specially trained oncology nursing staff. The same team took care of the ports according to the recommendations of the manufacturer. Lock with heparin solution was performed after every access and every 4–12 weeks if the system was not in use. Patients did not routinely receive oral anticoagulants or heparin for prevention of thrombosis.

Ninety (47%) patients were female and 107 (53%) male. The median patient age was 58 years (range, 18–86).

In 148 cases, the underlying disease was a solid tumor, and in 53 cases a hematologic malignancy. Underlying diagnoses are shown in figure 1. We analyzed the electronic patient charts of our digital clinical information system (KISIM version 4.813, CISTEC AG, Zurich, Switzerland) and the patient charts of the oncology department to determine the incidence of port-related complications up to July 31, 2007, and evaluated possible risk factors. An event leading to censoring of the data was defined as the occurrence of either a complication, death of any cause, end of analysis or port removal. All complications that occurred in the observation period were considered for analysis if they were presumably associated with the port system. Early postoperative complications like pneumothorax or hematoma were also included. Deep venous thrombosis was defined as occlusion of the large veins as seen with Doppler ultrasound, phlebography or CT scan. Occlusions of the catheter by a fibrin sleeve without radiographic proof of thrombosis were defined as thrombotic complication only if flushing with urokinase did not result in patency of the system. Infections of the catheter or needle insertion site, pocket infections and catheter-related blood stream infections (CRBSI) were defined as port-associated infections. Fever of unknown origin (FUO) was defined as port related if persistent symptoms under antibiotic therapy necessitated port removal.

Neutropenia was defined as less than 1,000 neutrophils per cubic micrometer of blood.

Statistical calculations were performed with the Statistical Analysis Software SPSS 13 for Mac OS X (SPSS Inc., Chicago, Ill., USA). The log rank test was used to compare two groups in regard to the time to port-related complications. In order to determine risk factors for complications, a Cox regression analysis was performed. The significance of an association between two variables was assessed by Fisher’s exact test or Student’s t test. p values <0.05 were considered statistically significant.

Results

One hundred and ninety-seven patients received a total of 201 port systems. A total of 47,781 catheter days were documented (median, 175 days; range, 1–831). For-
ty-six (23%) complications occurred until the cut-off date of July 31, 2007 (0.96 complications/1,000 port days). The complications and actions taken are listed in Table 1. The most common complications were thrombosis (n = 12; 6%; 0.25 complications/1,000 port days), port-associated infection (n = 13; 6.5%; 0.27) and catheter malposition (n = 9; 4.5%; 0.19). Other complications were hematoma (n = 5; 2.5%; 0.1), pneumothorax (n = 4; 2%; 0.08), arterial puncture (n = 1; 0.5%; 0.02), FUO (n = 1; 0.5%; 0.02) and unsuccessful port placement (n = 1; 0.5%; 0.02). Nineteen complications required port removal and one implantation failed (n = 20; 10%; 0.42). In 22 of the 46 cases with documented complications, port function was preserved and the system remained in use. Four port systems remained in situ without further use. After detection of a deep venous thrombosis, the port system remained functional in 7 of 12 cases, two ports had to be removed, and three remained in situ without further use. Port-associated infections consisted of four catheter or port needle insertion site infections, two pocket infections and seven CRBSI. Infections and one case of FUO resulted in removal of 12 of the 14 devices. In two cases of insertion site infection, the systems could be rescued by systemic antibiotics and vancomycin lock. Identified pathogens were coagulase-negative Staphylococcus (n = 4), Staphylococcus aureus (n = 2), Escherichia coli (n = 1), Pseudomonas aeruginosa (n = 1) and Corynebacterium amycolatum (n = 1). The underlying diagnoses in patients with infectious complications were aggressive non-Hodgkin’s lymphomas (n = 6), acute lymphocytic leukemia (n = 2), Hodgkin’s lymphoma (n = 2), multiple myeloma (n = 1), nonseminomatous germ cell tumor (n = 1), small cell lung cancer (n = 1) and colorectal cancer (n = 1). These patients received the following treatments: Hyper-CVAD (cyclophosphamide, vincristine, doxorubicin, dexamethasone, cytarabine, methotrexate) with (n = 1) or without (n = 2) rituximab, EPOCH (etoposide, vincristine, doxorubicin, cyclophosphamide, prednisone; n = 2), ICE (ifosfamide, carboplatin, etoposide) with rituximab (n = 1), CHOP (cyclophosphamide, doxorubicin, vincristine, prednisone) with rituximab (n = 1), cytarabine/etoposide (n = 1), Mini-BEAM (carmustine, etoposide, cytarabine, melphalan; n = 1), docetaxel/ifosfamide (n = 1), topotecan monotherapy (n = 1) and dose-intensive chemotherapy (cy-

Table 1. Complications

<table>
<thead>
<tr>
<th></th>
<th>All cases (n = 201)</th>
<th>Events/1,000 port days</th>
<th>Solid (n = 148)</th>
<th>Hem (n = 53)</th>
<th>Actions taken</th>
</tr>
</thead>
<tbody>
<tr>
<td>Unsuccessful placement</td>
<td>1 (0.5)</td>
<td>0.02</td>
<td>0</td>
<td>1 (2)</td>
<td>–</td>
</tr>
<tr>
<td>Hematoma</td>
<td>5 (2.5)</td>
<td>0.1</td>
<td>3 (2)</td>
<td>2 (4)</td>
<td>hematoma excision (n = 2) port functional, left in situ (n = 5)</td>
</tr>
<tr>
<td>Arterial puncture</td>
<td>1 (0.5)</td>
<td>0.02</td>
<td>1 (1)</td>
<td>0</td>
<td>port removal</td>
</tr>
<tr>
<td>Pneumothorax</td>
<td>4 (2)</td>
<td>0.08</td>
<td>4 (3)</td>
<td>0</td>
<td>chest tube (n = 3) port functional, left in situ (n = 4)</td>
</tr>
<tr>
<td>Port-associated infection</td>
<td>13 (6.5)</td>
<td>0.27</td>
<td>2 (1)</td>
<td>11 (21)</td>
<td>port removal (n = 11) antibiotic lock, rescue (n = 1) systemic antibiotics, rescue (n = 1)</td>
</tr>
<tr>
<td>Port-associated bacteremia</td>
<td>1 (0.5)</td>
<td>0.02</td>
<td>1 (1)</td>
<td>0</td>
<td>port removal</td>
</tr>
<tr>
<td>Deep venous thrombosis</td>
<td>12 (6)</td>
<td>0.25</td>
<td>9 (6)</td>
<td>3 (6)</td>
<td>port removal (n = 2) port nonfunctional, left in situ, anticoagulation (n = 3) port functional, left in situ, anticoagulation (n = 7)</td>
</tr>
<tr>
<td>Malposition</td>
<td>9 (4.5)</td>
<td>0.19</td>
<td>6 (4)</td>
<td>3 (6)</td>
<td>port removal (n = 4) port not used, left in situ (n = 1) port functional, left in situ (n = 2) port revision (n = 2)</td>
</tr>
<tr>
<td>Total</td>
<td>46 (23)</td>
<td>0.96</td>
<td>26 (18)</td>
<td>20 (38)</td>
<td>–</td>
</tr>
</tbody>
</table>

Figures in parentheses indicate percentages. Solid = Patients with solid tumors; Hem = patients with hematologic neoplasms.
clophosphamide/total body irradiation and high-dose melphalan, respectively) with autologous stem cell transplantation (n = 2). At the time of infection, 6 patients were neutropenic and 4 patients had just recovered from neutropenia. The median duration of neutropenia in patients with an infection was 5 days (range, 0–25 days).

The median port survival time was not reached at the end of the study, exceeding 831 days. The risk of an event was highest in the first month due to inclusion of perioperative and early postoperative complications in the analysis and leveled off thereafter (fig. 2a). The only significant risk factor associated with a higher complication rate in the Cox regression analysis was younger age (multiplicative effect on the hazard ratio per year, 0.976; 95% CI, 0.957–0.996; p = 0.019). Older patients had a lower risk for developing port complications with a calculated risk reduction of 2.4% for each year. While the median age of the whole patient population was 58 years (range, 18–86), patients with port-related infections had a median age of 45 years (range, 18–74), whereas patients with thromboses were 52 years (range, 22–65) and patients with catheter malpositions 64 years (range, 31–74) old.

There were no significant differences regarding the underlying tumor, gender, placement side (left versus right), access method (subclavian versus cephalic vein) or implanting team (from the department of thoracic surgery versus the department of visceral surgery). When the patients were divided into two groups, i.e. as having hematologic neoplasms or solid tumors, a trend was seen for shorter event-free port longevity in patients with hematologic malignancies compared with solid tumor patients (p = 0.059 in the log rank test). The hazard ratio for an event was 0.572 in favor of solid tumor patients (95% CI, 0.318–1.03; p = 0.063; fig. 2b). Patients with hematologic malignancies were significantly younger than solid tumor patients (mean 47.3 ± 15.2 years versus 58.6 ± 12.2 years; p < 0.001 in the Student’s t test; 95% CI for the difference in age, 7.17–15.39 years; fig. 3).

When analyzed in reference to port-associated infections, patients with hematologic diseases developed significantly more complications compared to patients who had solid tumors [11/53 cases (21%) versus 2/148 cases (1.4%); p < 0.0001 in the Fisher’s exact test].

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Fig. 2. a Kaplan-Meier analysis of the event-free port longevity measured from the day of placement. b Event-free port longevity in patients with solid tumors compared to patients with hematologic neoplasms. Marks represent censored data, i.e. day of port removal, patient’s death, end of study period or occurrence of complication. Perioperative complications (pneumothorax and hematoma) were included in the analysis.

Fig. 3. Boxplot showing the difference in age between patients with solid tumors (solid) and patients with hematologic malignancies (nonsolid).
Discussion

Totally implantable venous access devices have proved to be less susceptible to complications than tunneled catheter systems [10, 12, 13]. The reported event rate ranged from 0.45 to 1.16 events/1,000 port days [5–11]. Our study showed comparable results with 0.96 overall events/1,000 port days. The main complications observed were port-associated thrombosis (0.25 events), port-associated infection (0.27 events) and catheter malposition (0.19 events). A comparison of the published literature and our data is presented in Table 2 showing similar results. Rare complications were puncture of the artery, port placement failure and hematoma in the early postoperative period. Four cases of pneumothorax occurred after puncture of the subclavian vein. This complication could be avoided by using the surgical cut-down technique to the cephalic vein. An option to reduce the rate of complications and to improve the success rate with the percutaneous approach may be the use of two-dimensional ultrasound for guidance of the cannulation [14, 15].

Six percent of our patients developed catheter-related thrombosis. No predisposing risk factors were observed in our study. Other trials have identified significant variables for the development of arm vein thrombosis: catheter tip position, side of catheter insertion (right versus left), platelet count, female gender and underlying lung cancer [11, 16–18]. One study tested treatment with low molecular weight heparin (LMH) for prevention of catheter-related thrombosis after port placement and found a significant reduction in the incidence of thrombotic complications. However, this study had a very high thrombosis rate in the untreated arm (62% of the patients) [19]. High rates of thrombotic complications were also observed in two other trials with indwelling CVCs using LMH or low dose warfarin for prophylaxis [20, 21]. The main reason for these high rates reported may be the systematic search for thromboses by using phlebography in all study patients. We performed phlebography only in case of suspected thrombosis based on clinical symptoms. But even if only the symptomatic patients who received a prophylaxis were considered for comparison, we found a low rate of thrombosis without any anticoagulation (6%). In more recent trials, the thrombosis rate was in the range of our study, ranging from 3.5 to 18%, and no significant reduction of the thrombosis incidence was seen with LMH or warfarin administration compared with placebo [22–25]. Apparently, thorough system care by flushing the port system at regular intervals with a heparin solution may be sufficient for maintaining these low rates of thrombotic complications. Therefore, the use of LMH or oral anticoagulants for prevention of port-related thrombosis is not generally recommended.

Twenty-nine percent of the patients received peri-insertional antibiotics. In our series, only 4 of the documented 14 infectious complications occurred within the first month with the earliest occurring at day 15 after implantation. One of these 4 patients had received prophylactic antibiotic treatment. We suggest that the applied prophylaxis with β-lactam antibiotics or quinolones did not have a relevant impact on the infection rate.

Patients with hematologic malignancies developed significantly more infectious complications than patients with solid tumors. Coagulase-negative Staphylococcus was the main pathogen isolated. This observation has been made in previous studies as well [11]. The difference in the incidence of infections may be attributable to more intense chemotherapy, resulting in prolonged neutropenia, and also to a direct impairment of the immune system by the disease itself. Lack of immunocompetence is a main risk factor for infections, as seen in patients with

<table>
<thead>
<tr>
<th>Study</th>
<th>Cases</th>
<th>Days in situ</th>
<th>Events/1,000 port days</th>
<th>Infections/1,000 port days</th>
<th>Thrombosis/1,000 port days</th>
</tr>
</thead>
<tbody>
<tr>
<td>Biffi et al., 1997</td>
<td>178</td>
<td>180</td>
<td>0.65</td>
<td>0.16</td>
<td>0.06</td>
</tr>
<tr>
<td>Brown et al., 1997</td>
<td>158</td>
<td>270</td>
<td>0.62</td>
<td>0.35</td>
<td>0.14</td>
</tr>
<tr>
<td>Kock et al., 1998</td>
<td>1,500</td>
<td>284</td>
<td>0.45</td>
<td>0.17</td>
<td>0.11</td>
</tr>
<tr>
<td>Lyon et al., 1999</td>
<td>205</td>
<td>169</td>
<td>1.16</td>
<td>0.21</td>
<td>0.27</td>
</tr>
<tr>
<td>Wolosker et al., 2004</td>
<td>519</td>
<td>353</td>
<td>0.5</td>
<td>0.23</td>
<td>0.07</td>
</tr>
<tr>
<td>Caers et al., 2005</td>
<td>448</td>
<td>366</td>
<td>0.85</td>
<td>0.19</td>
<td>0.35</td>
</tr>
<tr>
<td>Present study</td>
<td>201</td>
<td>238</td>
<td>0.96</td>
<td>0.27</td>
<td>0.25</td>
</tr>
</tbody>
</table>

Table 2. Literature comparison
HIV, who develop significantly more port infections than cancer patients (1.5 vs. 0.96 infections/1,000 port days) [26]. The pathogens described in the literature are predominantly Gram-positive cocci with coagulase-negative Staphylococcus accounting for 50% of all cases [13, 26–28]. Our treatment usually comprised the removal of the colonized port system. However, while pocket infections are always an indication for device removal, a combined local and systemic antibiotic therapy may be considered to preserve the port in CRBSI if risk factors for treatment failure like heart valve prosthesis or concurrent thrombosis are absent, according to guidelines for the treatment of catheter-related infections [29, 30]. The strategy is also dependent on the isolated pathogen. Removal is always necessary in infections with S. aureus and Candida spp., while a preservation of the system may be successful with coagulase-negative Staphylococcus, Corynebacterium jeikeium and P. aeruginosa [31]. By applying antibiotics intraluminally in high concentrations – the so called antibiotic lock technique – 80% of the colonized catheter lines may be rescued [32, 33]. The antibiotic-lock technique was superior to systemic treatment alone with regard to preservation of infected ports in immunocompromised patients [34, 35]. Numerous antibiotics were tested for the lock technique, but the agent most extensively studied is vancomycin [36]. The use of vancomycin has various advantages: it targets Gram-positive pathogens, it is compatible with heparin in effective concentrations, and it remains chemically stable and biologically active for at least 25 days in vivo [37–39]. Since hematologic patients are at high risk for developing infectious complications, prophylaxis with a vancomycin-heparin lock was studied to reduce the incidence of port-associated infections. A prophylactic vancomycin-heparin lock was tested in pediatric populations and proved effective in reducing CRBSI [40, 41]. In one study of 117 adult hematology patients, local application of vancomycin and heparin led to significantly less colonization of the catheter system with Gram-positive bacteria and also significantly less bacteremias [42]. Despite good results in a few prospective trials with this approach, the widespread use of a vancomycin-heparin lock for prevention of CRBSI is not generally recommended because of concerns regarding the emergence of vancomycin-resistant pathogens [31, 43]. As of today, the appearance of antibiotic resistance has not been described after a vancomycin lock. This may be related to the fact that the solution does not reach the circulation if applied properly. We think that prophylaxis with a vancomycin-heparin lock could be considered an option in selected hematologic patients who are at high risk for developing CRBSI. Another promising approach to circumvent this problem may be the prophylactic application of ethylenediaminetetraacetic acid (EDTA), a chelating, nonantibiotic agent to remain in the port system. More recent studies have demonstrated its efficacy in reducing CRBSI due to its antimicrobial properties against various pathogens, either alone or combined with other agents [44, 45]. In addition, EDTA prevents coagulation by binding calcium and is therefore an adequate agent to preserve patency of the catheter system.

The only patient-related risk factors for the development of port-related complications identified in the Cox regression analysis were younger age and underlying hematologic malignancy. These two factors are related to each other, since patients with hematologic neoplasms were significantly younger than solid tumor patients (mean, 47.3 ± 15.2 years vs. 58.6 ± 12.2 years). Here, infections were the main type of complication. This is most likely attributable to the more intense chemotherapy causing prolonged neutropenia. We observed that 10 of the 14 patients who developed infectious complications were neutropenic or had recovered from neutropenia shortly before the complication occurred. A direct correlation between the degree of neutropenia and infectious complications was demonstrated 40 years ago [46]. The risk for a patient to develop catheter-related infections is elevated during neutropenic periods compared to nonneutropenic periods [47, 48]. Patients who receive dose-intensive chemotherapy might therefore be treated with granulocyte colony-stimulating factor to reduce the length of neutropenia and the incidence of infectious complications [49].

In conclusion, in our series of 201 port placements, thrombotic complications were observed rarely. Patients with hematologic malignancies were younger and had a higher risk of developing port-associated infections than solid tumor patients, resulting in a trend to shorter event-free port longevity.

Therefore, we suggest that trials be performed to evaluate the benefit of a catheter lock with antimicrobial agents at regular intervals in younger patients with hematologic malignancies.
References


