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Original Scientific Paper

HEMATOLOGY PATIENTS ARE AT A HIGHER RISK OF LATE COMPLICATIONS OF TOTALLY IMPLANTABLE VENOUS ACCESS PORTS – A SINGLE CENTER RETROSPECTIVE COHORT STUDY

Bruno Lovreković[1], Delfa Radić Krišto[2,4], Njetočka Gredelj Šimec[2] and Helena Jerkić[3,4]

[1]Division of general and sport traumatology and orthopoedics, Department of surgery, Merkur University Hospital Zagreb, Croatia;
[2]Division of hematology, Department of internal medicine, Merkur University Hospital, Zagreb, Croatia;
[3]Department of Cardiology, Sestre milosrdnice University Hospital Centre Zagreb, Croatia;
[4]School of Medicine, University of Zagreb, Zagreb, Croatia

SUMMARY – Totally implantable venous access ports (TIVAPs) are central venous devices for long-term intravenous treatment, most commonly used in oncology patients. Despite many benefits, their usage can be associated with severe complications. The purpose of this study was to determine early and late complications of TIVAPs insertion.

Methods: We performed a single-center retrospective study in University Hospital Merkur and enrolled 90 hematology and 7 oncology patients who had TIVAPs inserted in the period between November 2013 and May 2018. The procedure of insertion was performed by a cardiologist under fluoroscopy through the right subclavian vein in local anesthesia. Our main focus was on early and late complications of TIVAPs insertion. Early complications occurred in the first 30 days of insertion and late complications beyond 30 days after insertion.

Results: Complications of TIVAPs insertion occurred in 26 patients (26.8 %); all of them were hematology patients. Early complications were found in 8 (8.2%) patients and late complications in 18 (18.5%) patients. Pneumothorax as an early complication was found in 2 (2.1%) patients. Early infections were found in 5 (5.1%) patients and all were classified as bloodstream infections. One (1.03%) patient exhibited wound healing problems and required TIVAP extraction. Late complications were found in 18 (18.5%) patients: one (1.03%) port pocket infection, 16 (16.5%) bloodstream infections and one (1.03%) late catheter related venous thrombosis (1.03%).

Conclusion: The implantation and use of TIVAPs is a valuable method in the treatment of oncology and hematology patients. However, in view of the number of TIVAPs complications observed in our study, we can conclude that hematology patients are at a higher risk for developing TIVAPs-related late infections.

Keywords**:** *totally implantable venous access port; complication of insertion; hematology patients*

Correspondence to: *Assist. Prof. Helena Jerkić, MD, PhD*, Department of Cardiology, Sestre milosrdnice University Hospital Centre Zagreb, Croatia
e-mail: helenajerkic@yahoo.com

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Introduction

Totally implantable venous access ports (TIVAPs) are subcutaneously implanted devices for long-term intravenous treatment in oncology and hematology patients undergoing intensive chemotherapy[1,2]. They serve not only for a safe administration of chemotherapy, but also for prolonged administration of fluids, blood and blood products, antibiotics, parenteral nutrition and frequent blood sampling[3]. In modern medicine, TIVAPs used in combination with other vascular access devices, such as peripherally inserted central catheters (PICC), provide adequate care and quality of life. Although they are a complex system, TIVAPs are now used most commonly because of their safety, low infection rates, and easy implantation and use[4]. Literature data on catheter-related complications in oncological patients and a lack of data on hematology patients were our main motive for performing this retrospective study in University Hospital Merkur, Zagreb.

TIVAPs consist of a subcutaneously implanted port and central venous catheter, which provide a simple and safe vascular access. These devices are made of a silicone or polyurethane material with different characteristics. While silicone has a better biocompatibility and lower risk of provoking thrombosis, polyurethane catheters have thinner walls with a larger internal lumen diameter, resulting in a lower risk of obstruction. The catheters have a diameter under 10 Fr and they are percutaneously inserted via the subclavian or internal jugular vein using the Seldinger technique over a guide wire with split sheath technology. The proper position of the catheter tip at the junction of the superior vena cava and right atrium must be confirmed by fluoroscopy. If the catheter tip is in the subclavian vein rather than the right atrium, a high rate of thrombotic complications can occur.

During the subclavian vein puncture and catheter insertion, life-threatening periprocedural complications can occur, such as pneumothorax, hemorrhage from the subclavian vein, hemothorax, catheter malposition, arrhythmias, air embolism, venous wall perforation or tamponade.

Postprocedural complications of TIVAPs insertion are catheter malfunction, catheter-related venous thrombosis, pocket or bloodstream infection, drug extravasation injury, wound healing problems or skin necrosis and catheter embolization[5,6].

Methods

This study retrospectively included all 97 patients with hematological and oncological malignancies who received TIVAPs at University Hospital Merkur in Zagreb, Croatia, in the period between November 2013 and May 2018.

Preoperative evaluation included a medical history and physical examination focusing on previous venous thrombosis and previous vascular access complications. Blood samples were collected before and 24 hours after the procedure. A platelet count below $50x10^9$/L was considered a relative contraindication. Absolute contraindications were international normalized ratio (INR) >1.5, fever or sepsis and hereditary thrombophilia or acquired hypercoagulability states. If the platelet count was below $50x10^9$/L and the TIVAP was needed urgently, a platelet transfusion was performed before the procedure.

TIVAPs insertion was performed via the right subclavian vein using the Seldinger technique. All devices were implanted in adult patients requiring chemotherapy or hematopoietic stem cell transplantation.

After properly positioning the catheter, the next step is to place the port or reservoir. Ports are made from titanium or plastic and may have a single chamber or double chambers. Some ports have a valve which reduces the occurrence of malfunction caused by intracatheter thrombi by preventing a reflux of blood. The port is implanted 2-3 cm below the clavicle, under the subcutaneous tissue and above the pectoral fascia. When the catheter and port are connected, the system must be flushed with an anticoagulant. The skin above the port must be intact so that the sutures are not at the future puncture site. The most important feature of the whole procedure is strict adherence to sterile technique. The TIVAPs are ready to be used after implantation and must be flushed with heparin during the next four to six weeks of the outpatient's follow up.

Immediately after implantation and 4-6 hours after the procedure, a chest radiograph was performed for a routine follow-up of catheter position and a possible diagnosis of pneumothorax.

If the patients developed a fever above 38 °C after implantation, two sets of blood cultures were obtained from the port catheter and peripheral vein twice in a 1-hour interval.

The primary endpoint of this study was the incidence of complications of TIVAPs insertion. Complications were classified into two categories: early (intraoperative and postoperative period within 30 days) and late complications (more than 30 days after insertion). All complications which we followed in the early and late period were: pneumothorax, hemorrhage from the subclavian vein, hemothorax, pocket or bloodstream infection, catheter-related venous thrombosis, catheter malposition or malfunction, catheter embolization, arrhythmias, air embolism, venous wall perforation, pericardial tamponade, drug extravasation injury, wound healing problems and skin necrosis.

Pocket infection was defined by erythema, induration or tenderness around the port with culture positive material from the port pocket. Port-related bloodstream infections were defined as positive blood cultures obtained through the device or positive catheter tip culture with symptoms of systemic inflammation. Catheter-related venous thrombosis was detected with ultrasound or venography when arm or facial swelling were present.

Statistical analysis

After collecting and analyzing the data, the results were presented in tables and figures. Following the distribution normality analysis, appropriate tests were selected for a comparison of variables between groups. The patients were divided into two groups: one with complications after TIVAPs insertion and the other without complications after TIVAPs insertion. The differences between these two groups in continuous variables were tested with the Student's t-test in normally distributed variables or with Mann Whitney's U test in non-normally distributed variables. The differences in categorical variables were tested with Pearson's chi square test. Statistical significance was considered at a P value of < 0.05. All statistical analyses were performed with the Statistica for Windows 12.0 software (Statsoft, Tulsa, OK).

Results

We investigated 97 patients; 56 (57.7%) were women and 41 (42.3%) were men. The baseline characteristics are shown in Table 1. Mean age was 51.2 years with a range of 19-80 years of age. Total catheter stay time was 20 720 days with a mean time of catheter usage of 269.09 days. The majority of patients in our study had a hematological malignancy (90; 92.7%) with lymphomas (63; 64.9%) (Non-Hodgkin Lymphoma 49, Morbus Hodgkin 14) as the most common ones, followed by acute lymphatic leukemia (19; 19.6%). Only 7 (7.2%) patients had solid organ cancer. A total of 10 (10.3%) patients had thrombocytopenia and they received a platelet transfusion before the procedure, while 7 (7.2%) patients had previous venous thromboembolic incidents.

Table 1. Baseline characteristics of the study participants

No of patients	97
Male, n (%)	41 (42.3%)
Age, years	51.25 mean
BMI>30 kg/m^2 (%)	10.3%
Diabetes mellitus, n (%)	13 (13.4%)
Current smoker, n (%)	6 (6.2%)
Thrombocytopenia < 50x10^9/L, (platelet transfusion before the procedure), n (%)	10 (10.3%)
Leukopenia during procedure, n (%)	20 (20.6%)
Previous thromboembolic incidents, n (%)	7 (7.2%)
Hematologic malignancy, n (%)	90 (92.7%)
Solid organ cancer, n (%)	7 (7.2%)
Disease: AML, n (%) ALL, n (%) NHL, n (%) MH, n (%) CLL, n (%) MM, n (%) Ovary cancer, n (%) Breast cancer Leiomyosarcoma Colon cancer	 5 (5.1%) 19 (19.6%) 49 (50.5%) 14 (14.4%) 1 (1.0%) 2 (2.1%) 2 (2.1%) 3 (3.1%) 1 (1.0%) 1 (1.0%)

AML — Acute Myeloid Leukemia, ALL – Acute Lymphocytic Leukemia, NHL — Non-Hodgkin Lymphoma, MH — Morbus Hodgkin, CLL — Chronic Lymphocytic Leukemia, MM — Multiple Myeloma

TIVAP was removed in 44 (45.3%) patients and the most common reason for removal was death, which occurred in 22 (22.7%) patients. The second most frequent indication for removal was infection, which was present in 13 (13.4%) patients and occurred as early infection in 1 (1.03%) patient and late infection in 12 (12.3%) patients. Aside from this, one patient (1.03%) with a wound healing problem required TIVAP extraction and one patient had catheter-related venous thrombosis and died soon after TIVAP was removed (Table 2). The infections were caused by *Staphylococcus epidermidis* (5 cases), *Staphylococcus haemolyticus* (2 cases), Coagulase-negative *staphylococci* (3 cases), *Pseudomonas aeruginosa* (1 case) and *Enterococcus faecalis* (2 cases). In 8 (8.2%) patients, the indication for removal was termination of chemotherapy.

Early complications occurred in 8 (8.2%) patients and the most common were infections, which were present in 5 (5.15 %) patients. All these infections were bloodstream infections and there were no early pocket infections. We also found 2 (2.06%) patients with pneumothorax and 1 (1.03%) patient with a wound healing problem. Late complications occurred in 18 (18.5%) patients with the most common being infections. Late infections occurred in 17 (17.5%) patients; 16 (16.5%) were bloodstream infections and only one was a pocket infection. We also found one late catheter-related venous thrombosis (Table 3).

Table 2. TIVAP indications of removal

Total ports removed, n (%)	44 (45.3%)
Completion of treatment, n (%)	8 (8.2%)
Complications, n (%)	14 (14.4%)
Early complications, n (%) 1. Wound healing problem 2. Early infection	2 (2.1%) 1 (1.03%) 1 (1.03%)
Late complications (all infections), n (%)	12 (12.3%)
Death, n (%)	22 (22.7%)

Table 3. TIVAP early and late complications

Early complications n (%)	**8 (8.2%)**
1. Pneumothorax, n (%)	2 (2.06%)
2. Early bloodstream infections, n (%)	5 (5.15%)
3. Early wound healing problems, n (%)	1 (1.03%)
Late complications n (%)	**18 (18.5%)**
1. Late pocket infection, n (%)	1 (1.03%)
2. Late bloodstream infections, n (%)	16 (16.5%)
3. Late catheter related venous thrombosis, n (%)	1 (1.03%)

We found a total of 21 (21.6%) bloodstream infections, among which 12 patients (57%) had a port bloodstream infection which required catheter removal. Only 2 patients had an early port bloodstream

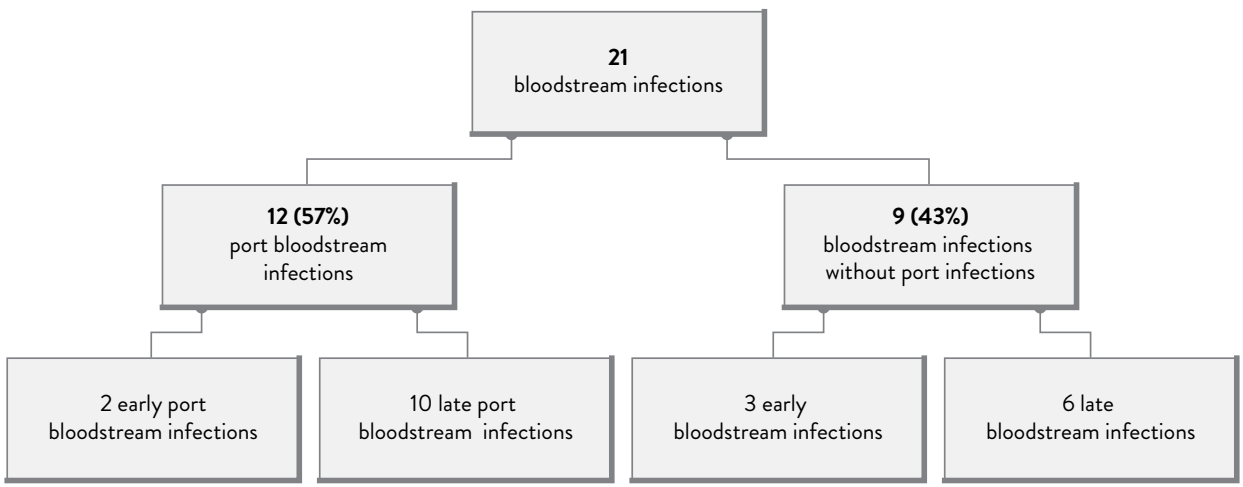

Figure 1. Incidence of port infections and bloodstream infections among all patients

Table 4. Analysis of factors affecting complications

Factors		Complications		*P*-value
		No. 71 (73.2%)	**Yes 26 (26,8%)**	
1. Age (yr)		50.78	51.45	0.95
2. Sex	a) Male	33(46.48%)	11(42.31%)	0.89
	b) Female	38(53.52%)	15(57.69%)	
3. Laboratory	a) White blood cell count	7.39	7.33	0.64
	b) Hemoglobin	109.90	109.78	0.59
	c) Partial thromboplastin time	1.14	1.04	0.66
	d) Activated partial thromboplastin time	22	20	0.51
	e) Platelet count	211.88	223.36	0.70
4. Previous thromboembolic incidents before TIVAPs insertion		6 (8.4%)	1 (3.8%)	0.09

infection in the first 30 days after the insertion procedure, and 10 patients had late port bloodstream infections. The most common pathogen in port bloodstream infections was *Staphylococcus epidermidis*, which was isolated in 66.6% of the patients, while the most common pathogen in bloodstream infections without port infections were coagulase-negative *staphylococci*, which were isolated in 60% of the patients (Figure 1).

We enrolled 97 patients, among which 26 (26.8%) had complications and 71 (73.1%) did not have complications during and after the procedure (Tables 3 & 4). Baseline characteristics (age and sex) in both groups were similar. There were no significant differences in laboratory findings before TIVAPs insertion between these two groups. We also found that previous thromboembolic incidents had no influence on early or late complications of TIVAPs insertion (Table 4).

Discussion

Previous studies have shown that TIVAPs provide important and useful vascular access for patients on chemotherapy, but could be associated with several complications[7].

In our study, complications occurred in 26 patients (26.8%) out of 97 implantations. Most of them were late complications, which appeared 30 days after insertion. Only in 14 cases out of these 26 complications were TIVAPs removed, with the main reasons for removal being port and bloodstream infections. The rate of complications in our study was higher than it is reported in the literature[8]. The aforementioned more frequent complications were infections. The rate of other complications, such as pneumothorax, hemothorax, catheter malposition or malfunction, hematoma, wound healing problems and catheter-related venous thrombosis, were in line with the literature[9,10]. A possible reason for these results might be the fact most of our subjects had an active hematological disease. Unfortunately, there are no randomized studies with higher proportions of hematology patients; the majority of studies on TIVAPs have included patients with solid organ cancer.

A recently published study with 1391 oncology patients, including 103 hematology patients (7%), showed that patients with hematological malignancies had a higher incidence of TIVAPs-related infections (31.2%) compared to patients with solid tumors (9.4%)[11].

Also, in a prospective study, Mollee *et al.* have reported that hematological malignancies may confer a greater risk for TIVAPs infections than solid tumors[12]. Long lasting neutropenia, immunosuppression and frequent catheter manipulations were major risks factors contributing to the increased risk of infections in these patients[12].

All our hematology patients included in this study were treated with different chemotherapy protocols that resulted in secondary immunodeficiency and neutropenia with increased susceptibility to infections. They also needed more frequent transfusion support than patients with solid organ cancer, so their port catheters were used more frequently. Also, hematology patients were treated not only with more intensive chemotherapy protocols than the patients with solid organ cancer, but also with allogenic and autologous transplantation, which increase the risk for secondary immunodeficiency and significantly increase the risk for infections.

In our study, we included only 7 (7.2%) patients with solid organ cancer and they had no complications after TIVAPs insertion. The proportion of these patients was too small to compare with results from other studies.

A retrospective study by Ignatov et al. showed that on a total of 561 implantation cases, complications occurred in 18%[3]. In that study, there were no hematological patients and all of the included patients had solid organ cancer, breast or gynecological malignancies. They reported that age, the type of solid organ cancer and the presence of metastases were not patient-related risk factors for complications. Another prospective study of 793 patients with TIVAPs showed an overall morbidity rate of 16.1%, with an infection rate of 5.6%[13]. Only 12.5% of the included patients had a hematological disease and all others had solid tumors (87.5%). They have shown that early first use of an implanted device within 7 days from placement and a jugular vein approach were factors significantly related to complications.

A recently published study with 1747 oncology patients, 8.5% of them being hematology patients, found that hematological malignancy and palliative chemotherapy were independent risk factors for TIVAPs-related infections for the same reasons that we noticed[14]. In that study, the overall incidence of TIVAPs infections was 2.5% and the incidence of late bloodstream infections was significantly higher in patients with hematological diseases than in patients with solid organ tumors.

Also, many previously published papers were done by surgeons or intervention radiologists who inserted TIVAPs, but did not clinically detect catheter-related bloodstream infections and were not notified of them, so the incidence of infections could in reality be underestimated[15,16].

The higher proportion of late infections in our study might be due to insufficient port catheter care. In University Hospital Merkur in Zagreb, we inserted port catheters to patients from other hospitals from all over Croatia. After we inserted the port catheters, the patients returned to their local hospitals, where catheter care was resumed and performed. In other words, the reason for a higher incidence of late infections might be insufficient education for port catheter care in local hospitals. It is very important that patients and medical staff members confirm their knowledge of the methods for TIVAPs care at certain intervals.

The incidence of pocket infections in our study was compatible with previous reports[17].

The rate of catheter-related venous thrombosis in our study was significantly lower than it is reported in the literature[18]. We only had one case of catheter-related venous thrombosis after 30 days of insertion (1.03%) and the reason for this result might be the fact that we inserted and positioned TIVAPs only in the subclavian vein. Data from the literature have shown that the internal jugular vein and veins of the upper arm have a higher risk of developing thrombotic complications[19]. We also tried to put the tip of catheter at the cavo-atrial junction using fluoroscopy to confirm the appropriate position. Previous data have shown that a high rate of thrombotic complications can occur if the catheter tip is in the subclavian vein rather than the cavo-atrial junction[19–21].

A study by Pejsa et al. found that the use of a peripherally inserted central catheter (PICC) in 90 patients with hematological malignancies was complicated by thrombosis in four patients (3.8%). In 39 patients (37%) PICC was removed before the end of treatment due to suspected or proven infection[22]. The authors used peripheral veins for PICCs insertion, mostly *v. basilica* or *v. cephalica*, which might be the reason for the higher incidence of thrombotic complications they reported.

In our study, the rates of pneumothorax (2.06%) were similar to the ones reported in the literature (0.1-3.2%)[23] and we did not observe other complications, such as severe arrhythmia, cardiac perforation, hemothorax, catheter dysfunction and catheter malposition.

Conclusion

The implantation and use of TIVAPs is a valuable method in the treatment of oncology and hematology patients. However, in view of the number of TIVAPs-related complications observed in our study, we can conclude that hematology patients are at a higher risk for TIVAPs-related late infections.

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Sažetak

HEMATOLOŠKI PACIJENTI IZLOŽENI SU VIŠEM RIZIKU OD KASNIH KOMPLIKACIJA UZROKOVANIH POTPUNO IMPLANTIRANIM VENSKIM PORT KATETERIMA – RETROSPEKTIVNA KOHORTNA STUDIJA U JEDNOM KLINIČKOM CENTRU

B. Lovreković, D. Radić Krišto, N. Gredelj Šimec i *H. Jerkić*

Potpuno implantirani venski port kateter je centralni venski kateter koji se koristi za dugotrajno intravensko liječenje, najčešće kod onkoloških bolesnika. Unatoč brojim prednostima, korištenje venskih port katetera može biti uzrokom i teških komplikacija. Cilj je ove studije odrediti rane i kasne komplikacije ugradnje venskih port katetera.

Metode: Ovo je monocentrično, retrospektivno ispitivanje napravljeno u Kliničkoj bolnici Merkur, Zagreb, koje je uključilo 90 hematoloških bolesnika i 7 onkoloških bolesnika koji su imali tumore solidnih organa. Bolesnici su uključeni u ispitivanje u periodu od studenog 2013. do svibnja 2018. godine. Venski port kateter ugrađen je u desnu ili lijevu potključnu venu, u lokalnoj anesteziji i pod kontrolom rendgenskog uređaja. Praćene su rane i kasne komplikacije ugradnje venskog port katetera. Rane komplikacije javile su se unutar 30 dana od ugradnje, a kasne nakon 30 dana.

Rezultati: Komplikacije ugradnje venskih port katetera javile su se kod 26 bolesnika (26,8 %) i svi su bili hematološki bolesnici. Kod 8 (8,2 %) bolesnika javile su se rane komplikacije, a kod 18 (18,5 %) kasne komplikacije. Najčešća rana komplikacija bila je infekcija, kod 5 (5,1 %) bolesnika, a prezentirala se bakterijemijom, kod 2 (2,1 %) bolesnika razvio se pneumotoraks. Kod jednog bolesnika (1,03 %) bilo je potrebno odstraniti venski port kateter zbog neprikladnog cijeljenja rane. Kasne komplikacije bile su prisutne kod 18 bolesnika (18,5 %). Isto tako, najčešća kasna komplikacija bila je infekcija koja se kod 16 bolesnika (16,5 %) prezentirala bakterijemijom, a kod jednog bolesnika (1,03 %) infekcijom mjesta insercije port katetera. Kod jednog bolesnika (1,03 %) se razvila venska tromboza potencirana kateterom.

Zaključak: Ugradnja i primjena potpuno implantiranih venskih port katetera vrijedna je metoda u liječenju hematoloških i onkoloških bolesnika. No, prema zastupljenosti ranih i kasnih komplikacija u našem ispitivanju, možemo istaknuti da su infekcije najčešće komplikacije ugradnje ovih katetera i da je zastupljenost infekcija veća u skupini hematoloških bolesnika u odnosu na onkološke bolesnike sa solidnim tumorima.

Ključne riječi*: potpuno implantirani venski port kateter; rane i kasne komplikacije; hematološki pacijenti*