

Totally Implantable Venous Access Port Catheters For Cancer Patients

Kanser Hastaları için Tamamen İmplant Edilebilir Venöz Port Kateterler

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Abstract

The increase in the number of cancer patients and the advances in chemotherapy have increased the use of port catheters. They reduce vascular complications of chemotherapy in patients particularly with inappropriate veins and provide comfort for both patients and users. The aim of this article is to define the most frequently used surgical approach for port catheter implantation in our hospital, possible early and late complications and the principles of use and maintenance. Port catheter implantation to right shoulder via right subclavian vein access, which is the most frequently used one, was defined with original images. 71 interventions in 61 patients were summarized in the light of literature. Continuous variables defined as mean \pm standard deviation, categorical variables defined as percentages. Of the patients, 47.54%(n=29) were female, 52.45%(n=32) were male. Mean ages were 55.89 \pm 11.69 for female, 62.56 \pm 8.69 for male. 56 interventions out of 71 were implantation, 15 were removal. Subclavian vein was the most frequently used vein (85.71%(n=48)). Colon adeno carcinoma was the leading reason for implantation (39.28%(n=22)). 51.78%(n=29) of the patients had metastasis. Liver was the most metastatic organ (44.82%(n=13)). Leading additional disease was hypertension (32.78%(n=20)). The only early complication was pneumothorax (2.08%(n=1)). Occlusion/thrombosis was the most common cause of removal (40%(n=6)). The most isolated microorganism on infected ports was Staphylococcus Aureus (75%(n=3)). Port catheters can be easily implanted with Seldinger's technique and simple surgical intervention. They provide comfort for both patients and users. Due to serious early and late complications, attention should be given during implantation and use. Periodic maintenance should not be neglected.

Keywords: Malignancy, Chemotherapy, Vascular Access Ports, Nursing Management, Maintenance

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Introduction

Totally implantable venous access port catheters (TIVAP) were first described in 1982 by Niederhuber in cancer patients (1). Since then, with the increasing number of the cancer patients, they have become the preferred way of chemotherapeutic treatment which reduces the vascular complications of the chemotherapy and improves the quality of life (2). They have also used for parenteral nutrition and/or antibiotic therapy to prevent the recurrent venous insertions and the related complications.

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Öz

Son yıllarda, kanser hastalarındaki artış ve kemoterapi protokollerindeki ilerlemeler, venöz port kateterlerin kullanımını da arttırmıştır. Özellikle periferik venleri uygun olmayan hastalarda kemoterapinin vasküler komplikasyonlarını azaltmakta ve hem hastalar hemde kullanıcılar için konfor sağlamaktadır. Bu yazının amacı, hastanemizde port kateter implantasyonu için sıklıkla kullanılan cerrahi yaklaşımı, olası erken ve geç komplikasyonları, kullanım ve bakım esaslarını kullanıcılara tanımlamaktır. Hastanemiz kardiyovasküler cerrahi kliniğinde port kateter implantasyonu için en sık kullanılan sağ subklavyen ven girişi ile sağ omuz bölgesine port yerleştirilmesi işlemi özgün resimlerle tanımlanmış, kliniğimizde port kateterler ile ilgili 61 hastada yapılan 71 girişimin sonuçları literatür eşliğinde özetlenmiştir. Sürekli değişkenler ortalama \pm standart sapma, kategorik değişkenler yüzde olarak belirtilmiştir. Hastaların %47.54'si (n=29) kadın, %52.45'i (n=32) erkekti. Kadınların yaş ortalaması 55.89 \pm 11.69, erkeklerin ki 62.56 \pm 8.69 idi. 71 müdahalenin 56'sı implantasyon, 15'i çıkarılma işlemiydi. Kolon adenokarsinomu %39.28 (n=22) ile en sık implantasyon nedeniydi. %51.78 (n=29) hastanın metastazı mevcuttu. En sık metastaz olan organ %44.82 (n=13) ile karaciğerdi. Hastaların %75.41'i (n=46) ek hastalıklara sahipti. En sık görülen ek hastalık %32.78 (n=20) ile hipertansiyondur. Implantasyon için en çok kullanılan %85.71 (n=48) ile subklavyen vendi. Karşılaşılan tek erken komplikasyon %2.08 (n=1) ile pnömotoraksdi. Oklüzyon/tromboz %40 (n=6) ile en sık çıkarılma nedeniydi. Enfekte portlarda en sık izole edilen mikroorganizma %75 (n=3) ile staphylococcus aureusdu. Port kateterler, Seldinger tekniği ve basit cerrahi müdahale kombinasyonu ile kolayca implante edilebilirler. Hem hastalar hem de kullanıcılar için büyük kolaylık sağlarlar. Gelişebilecek olası ciddi erken ve geç komplikasyonlar nedeniyle implantasyonları ve kullanımları sırasında maksimum özen gösterilmeli, periyodik bakımları ihmal edilmemelidir.

Anahtar Kelimeler: Malignite, Kemoterapi, Vasküler Giriş Portları, Hemşirelik Yönetimi, Bakım

This device consists of a reservoir with a silicone septum and a radiopaque silicone line entering to the central vein and is totally implanted under the skin. They are used with specially designed needles named "Huber Needle" which do not harm the silicone septum of the reservoir (Figure 1A-B). In this way, the silicone septum is resistant to about 3000 punctures.

For the reason that the implantation of TIVAP is a combination of Seldinger's technique and a simple surgical intervention that can be performed under local anesthesia, many different clinics such as anesthesiology, general surgery, thoracic surgery, pediatric surgery, radiology and cardiovascular surgery are undertaken this intervention by using varying methods and accessing sites.



Figure 1A. The prepared TIVAP for implantation.



Figure 1B. The specially designed Huber Needle for TIVAP.

Despite its severe peri-interventional complications such as pneumothorax, hemothorax and arterial puncture (also bleeding and hematoma related with arterial puncture), accessing through the subclavian vein is the most preferred approach because of its better long-term outcome. Also, there are a number of studies that show accessing through the internal jugular vein is considered to be safer compared to accessing through the subclavian vein (3,4). Moreover, implanting the TIVAP to the upper arm or forearm and accessing through the basilic, cephalic or axillary veins have been performed with the thought of safer puncture procedures. It may be concluded that it could be suitable for long-term usage with minimal complications (5).

However, the TIVAP is still associated with a series of possible severe complications. These complications can be examined as early and late complications. Pneumothorax, hemothorax, arterial puncture, hematoma, bleeding and arrhythmias, which can occur during implantation, are the early complications. Infections, extravasations, vein thrombosis, catheter thrombosis/occlusion, catheter fracture and migration are seen as late complications (6). Most of these early and late complications can be prevented by doctors by using proper implantation technique under antisepsis rules and can be prevented by nurses with proper nursing management (7,8).

The aim of this article is to define the most frequently used surgical approach in our

cardiovascular surgery clinic for the implantation of TIVAP, possible early and late complications, principles of their use and maintenance to the users. We also summarized our hospital's cardiovascular surgery clinic results in 71 interventions, in 61 patients in the light of literature.

Material and Method

As the definition of the most frequently used surgical approach, we defined right subclavian vein accessed the TIVAP implantation to right shoulder which is the most preferred site and side all over the world. We defined the technique with original images that were captured in an intervention which was performed by our hospital's cardiovascular surgery clinic. In accordance with the Helsinki Declaration Principles, the patient was informed and a written approval had been taken for using the images that show the implantation stages.

Also, as our clinical experience, 61 patients, who were admitted to the cardiovascular surgery clinic of our hospital between 2014 and 2017 with the request of the TIVAP implantation or related complications, were evaluated retrospectively. Patients' admission files and/or hospital's electronic system were used for data collection. Demographic data, implantation site, side, comorbid diseases of the patients, reason for the TIVAP implantation (malignancies), presence of metastasis and complications were evaluated.

Implantation Technique

For the right subclavian vein accessed TIVAP, after the patient is monitored and positioned (the shoulders should be extended, face should look to the opposite side (left) in light Trendelenburg position), right part of the patient's (from nipple to neck and from sternum to mid-axillary line) is prepped and draped for simple surgical intervention. The procedure is performed under local anesthesia (prilocaine hydrochloride). A horizontal incision of 3-4 cm. is performed about 10 cm. under the clavicle, on the mid-clavicular line and a subcutaneous pocket for the reservoir is created with sharp and blunt dissection.

When a large enough pocket is created and the bleeding is controlled, the next stage, which includes the subclavian vein puncture with the commonly used technique of Seldinger, begins. The guide wire is placed in the subclavian vein with the puncture by taking the mid-1/3 down side of the clavicle curvature as a landmark (Figure 2).

The needle of the injector should be advanced under the clavicle towards the sternal notch. With the placement of guide wire, the TIVAP should be prepared. In our clinic, usually a 20 cm. of line is left from the reservoir (Figure 1A).

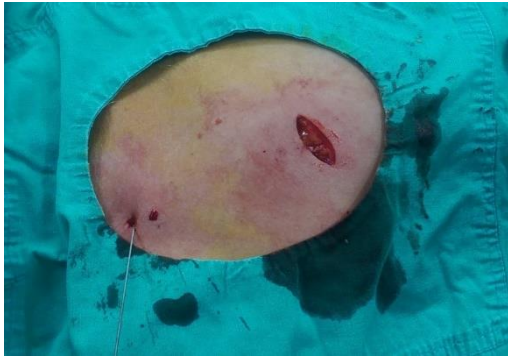


Figure 2. The passed line from subcutaneous pocket to puncture site with the help of tunneller.

After performing a 0,5 cm. of incision to guide wires entrance site on the skin, firstly the line is passed under the skin from subcutaneous pocket to guide wire entrance with the help of tunneler and the reservoir is placed in to the subcutaneous pocket. Then the sheet is inserted with a dilatator through the guide wire, to the subclavian vein (Figure 3A-B).



Figure 3A. The placed guide wire in the subclavian vein from the mid-1/3 down side of the clavicular curvature as landmark.



Figure 3B. Insertion of the sheet through the guide wire to the subclavian vein.

The dilatator is pulled back and the line is advanced inside through the sheet (Figure 4A).

The procedure is accomplished with the removal of the sheet by tearing it in to two pieces and leaving the line in the subclavian vein. In its final position we control the port catheter with Huber needle and a 10 ml injector. If it is OK, we fix the port with non-absorbable suture in the subcutaneous pocket and fill

the port catheter with heparinized saline. After a last bleeding control we close the incisions with subcutaneous suture (Figure 4B).



Figure 4A. Insertion of the line through the sheet to subclavian vein.



Figure 4B. Last position of the implanted TIVAP before the closure.

Results

In our hospital's cardiovascular surgery clinic a total of 71 TIVAP interventions were made in 61 patients. Of the patients, 47.54% (n=29) was female and 52.45% (n=32) was male. Mean age of the female patients was 55.89 ± 11.69 , mean age of the male patients was 62.56 ± 8.69 . Of these 71 interventions, 56 were TIVAP implantation and 15 were TIVAP removal. Colon adeno carcinoma took the first place in primary reasons (malignancies) of implantation (39.28% (n=22)). Invasive ductal carcinoma was the second with 16.07% (n=9) and squamous cell larynx carcinoma and pancreas ductal carcinoma were sharing the third place with 8.92% (n=5). In the examination of malignancies according to gender, colon adeno carcinoma and invasive ductal carcinoma were sharing the first place in female patients with 36.0% (n=9) while colon adeno-carcinoma was taking the first place alone in male patients with 41.93% (n=13) (Table 1).

24.59% (n=15) of the patients had no comorbid diseases, while the remaining 75.41% (n=46) patients had comorbid diseases accompanying with the malignancies. Hypertension 32.78% (n=20), diabetes 14.75% (n=9) and hypothyroid 14.75% (n=9) were the first three of these comorbid diseases (Table 2). Of the 56 patients, which the TIVAP were implanted, 48.21% (n=27) had no metastasis and

51.78 (n=29) had metastasis. Liver was taking the first with 44.82% (n=13), lung was taking the second with 34.48% (n=10) and bones were taking the third place with 17.24% (n=5). Brain (10.34% n=3), surrenal gland (6.89% (n=2)), appendices (3.44% (n=1)), colon (3.44% (n=1)) and orbita (3.44% (n=1)) were the other metastatic organs respectively in the examination of metastasis localizations. The

most frequently used access site for the TIVAP was right subclavian vein in both gender (Female 32.14% (n=18) and male 41.07% (n=23)). Left subclavian vein (12.49% (n=7)), right internal jugular vein (10.71% (n=6)) and right common femoral vein (3.57% (n=2)) were the other venous access sites. Pneumothorax was the only early complication (2.08% (n=1)).

Table 1. The primary reasons (malignancies) for the TIVAP implantation.

Primary Causes (malignancies)	Male (n=31)		Female (n=25)		Total (n=56)	
	n	%	n	%	n	%
Stomach Adeno Ca.	3	9.67	-	-	3	5.35
Non-small Cell Lung Ca.	4	12.90	-	-	4	7.14
Colon Adeno Ca.	13	41.93	9	36	22	39.28
High Grade Urothelial Ca.	1	3.22	-	-	1	1.78
Endometrium Ca.	-	-	1	4	1	1.78
Invasive Ductal Ca.	-	-	9	36	9	16.07
Squamous Cell Larynx Ca.	5	16.12	-	-	5	8.92
Prostate Ca.	2	6.45	-	-	2	3.57
Hodgkin Lymphoma	-	-	1	4	1	1.78
Pancreas Ductal Adeno Ca.	3	9.67	2	8	5	8.92
Maxillary Sinus Mucoepidermoid Ca.	1	3.22	-	-	1	1.78
Over Musinoz Ca.	-	-	3	12	3	5.35
Squamous Cell Parotis Ca.	1	3.22	-	-	1	1.78

Table 2. Additional diseases accompanying with the malignancies in patients that intervention performed to their TIVAP.

Comorbiddiseases in 61 patients	n	%
Patients those haveno comorbiddiseases	15	24.59
Patients those have comorbiddiseases	46	75.41
Hypertension	20	32.78
Diabetes	9	14.75
Hypothyroid	9	14.75
Pepticulcus	8	13.11
Depression	6	9.83
Coronary artery disease	4	6.55
Hyperlipidemia	4	6.55
Renal insufficiency	3	4.91
Chronic obstructive pulmonary disease	3	4.91
Carotid artery disease	2	3.27
Epilepsy	2	3.27
Anemia	2	3.27
*Others (each)	1	1.63

*Others: Obesity, venous insufficiency, hyperparathyroidism, malign hypercalcemia, stroke, myomauteri, drug abuse, nefrolithiazis, hepatitis.

The TIVAP removals were also examined. Of the 15 removed ones, 93.33% (n=14) was subclavian and 6.66% (n=1) was femoral accessed TIVAP. Occlusion/thrombosis was the leading reason of removals with 40% (n=6). Infection (26.66% (n=4)), psychological-patient's request (26.66% (n=4)) and mechanical complication (6.66% (n=1)) were the other TIVAP removal reasons. 66.66% (n=4) of the patients, who have occluded/thrombosed TIVAP, had metastasis. The malignancies of the patients, who had infected TIVAP, were colon adeno carcinoma 75% (n=3) and invasive ductal carcinoma

25% (n=1). In the culture-antibiogram of these infected TIVAP, the pathogenic microorganisms were 50% (n=2) Staphylococcus Aureus alone, 25% (n=1) Staphylococcus Aureus and Staphylococcus Epidermidis and 25% (n=1) Gr (-) diphteroid bacillus.

Discussion

In recent years, with the increasing use of folinic acid, 5-fluorouracil, irinotekan and oxaliplatin in different treatment regimens like FOLFIRI,

FOLFOX or FOLFIRINOX as continuous systemic chemotherapy, particularly for advanced colorectal and metastatic pancreatic cancer, the need of TIVAP and their use have increased (9). The subclavian vein accessed TIVAP, has been the most preferred one because of lower infection incidence and good stabilization on the chest wall (5). Because of the angulations of innominate vein to superior vena cava and the risk of thoracic duct damage, right side has been preferred more than left side (10).

However, the possibility of severe early complications such as pneumothorax, hemothorax, arterial puncture or hematoma has forced clinicians to use alternative access sites and imaging devices. Today, ultrasound-guided, internal jugular vein access is also widely accepted, too. Venography or fluoroscopy as guides and femoral, basilic or cephalic veins as access sites are also used (9,11). In our hospital's cardiovascular surgery clinic, mostly the worldwide accepted access sites and sides are used (85.71% subclavian vein, 73.21% right side and 12.50% left side). No imaging device is used during the intervention and the punctures are performed by land-mark guided technique. Pneumothorax was the only early severe complication with 2.08% (n=1), while it was 1% to 2.5% for interventional radiologic implantation and 2.4% to 4.3% for land-mark guided implantation (12,13). On the other hand, interventional radiologists determine that blind (land-mark guided) puncture of the subclavian vein is also feasible but would certainly raise the risk of peri- and post-interventional complications. Therefore, they did not opt for a blind venous puncture (14).

Infection is another important complication of the TIVAP with the rate varying from 1.5% up to 13% in the literature (15). Accompanying diseases, suppressed immune system of the patients, deterioration of the skin integrity, frequency of use, thrombus in the line or reservoir, parenteral nutrition, metastasis and poor autonomy of the patients have been determined as the risk factors for infection (16,17). The infection mostly occurs as a result of repeated puncture of the reservoir septum (18). Blood borne contamination (i.e sepsis, translocation of the pathogenic microorganisms from digestive system in neutropenic patients) and misuse of the TIVAP against the antisepsis rules (i.e. using nonsterile substances for injection or using without cleaning the skin) are other reasons of infection. The previous studies had determined that *Staphylococcus Aureus* and coagulase-negative staphylococci were the most frequent pathogenic microorganisms. An increasing number of gram-negative bacilli infections have also been reported (19). In case of infection, one of the two therapeutic options should be chosen. 1- removal of the TIVAP and systemic antibiotics (conventional treatment), 2- retention of the TIVAP and systemic antibiotics (conservative treatment) (20). In our study, we

observed that 7.14% (n=4) of the 56 TIVAP implanted patient had infection and the pathogenic microorganisms were also *Staphylococcus Aureus*, *Staphylococcus Epidermidis* and gram-negative diphtheroid bacillus as it was determined in literature. Conventional treatment was chosen for our patients with the thought of biofilm production of the pathogenic microorganisms on the surface of TIVAP. In most of the patients removal of the TIVAP can be catastrophic; at least treatment protocol cannot be maintained. Obeying antisepsis rules sharply can prevent the early peri-procedural infection complication.

However, nursing management is very important for the late TIVAP infections. There are a number of studies that determine the insufficient knowledge of the users about the catheter related infections and as the result of this, high presence of catheter infections (21). Using them without cleaning the skin, using non-sterile injectors or staff, not washing the TIVAP with saline after each use and not filling the reservoir and the line with heparinized saline can easily cause the infection or thrombosis/occlusion of the device. Thrombosis of the line or reservoir occur 60-70% in the first 15-30 days of the implantation. It may also occur in any time between the 15th day and 2nd year (22). For preventing the thrombosis in TIVAP, filling the system with 100U/ml heparinized saline at the end of the implantation, cleaning with saline and filling with 100U/ml heparinized saline after each use is recommended. This procedure must be repeated in every 4-6 weeks when the TIVAP is not use. Any prophylactic anticoagulant is not recommended for the TIVAP implanted patients.

Thrombosis/occlusion was the leading and another cause for TIVAP removal with 40% (n=6) (9.83% of the patients) in our study.

Pinch-off Syndrome, which can be described as "transection and embolisation of the TIVAP", is an uncommon complication that users should pay attention. For subclavian vein accessed TIVAP the incidence is reported as 1.1-5.0 % (23). Detecting the breakage or separation of the TIVAP and collection of the drug under the skin or its irritation can prevent the further severe complications and give the chance of early intervention to the doctors. Lin et al had stated they determined Pinch-off Syndrome in 73 of the 3358 TIVAP implanted patients (24). However, Ustuner et al. had stated that they determined none in 68 patients (25). In our study, we determined 1 interesting Pinch-off Syndrome case in 56 TIVAP implanted patients. The reservoir and the locker were found in the subcutaneous pocket but there was no line. The subcutaneous pocket closed and chest radiography was taken. The line was seen in the portal vein and it was taken out successfully with conventional angiographic method in a nearby center's cardiology department. We think that it could be taken out from the subcutaneous pocket easily if she referred to cardiovascular surgery clinic

directly when the collection of the drug under the skin was determined.

We also determined that cancer patients who have been TIVAP implanted, establish psychological relations with the device. In our study we had 4 patients who insist on the removal of the TIVAP without any medical requirements, just because of the presence of the device always reminds her/him bad days that they lived during the diagnosis and treatment period.

In conclusion; TIVAP are increasingly used and helpful devices both for cancer patients and the users. Beside all its benefits, implantation procedure consists a simple surgical intervention. This intervention which we call "simple" can be so complex and some early or late major complications can be so severe that they may cause to death. TIVAP can be the only chance of treatment for some patients. So the implantation and maintenance of the TIVAP deserve high attention.

We suggest that not all departments, only the experienced ones and the ones, who will able to treat these complications, should perform the implantation. Effective nursing management and practice are very important for preventing the late complications. In case of complication, early detection of the symptoms by the users can give the chance of early intervention to save the TIVAP, to maintain the patient's and user's comfort.

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