Journal of The Cardiovascular Thoracic Anaesthesia and Intensive Care Society

GKDA Derg 2023;29(4):211-217
DOI: 10.14744/GKDAD.2023.37640

RESEARCH ARTICLE

Totally Implantable Venous Access Devices: Study of 1,613 Patients and Complication Management

Nadide Örs Yıldırım

Department of Anesthesiology and Reanimation, Sincan Training and Research Hospital, Ankara, Türkiye

ABSTRACT

Objectives: Totally implantable venous access devices (TIVADs) are crucial for treating patients with malignancy. However, reaching the intravenous route is rendered difficult owing to the consequences of chemotherapy. This retrospective study aimed to investigate the early and late complications associated with percutaneous insertion and TIVAD use.

Methods: A total of 1,647 TIVAD procedures in 1,613 patients between 2010 and 2023 were retrospectively analyzed. All TIVADs were placed in the cardiovascular surgeon operating room under sedation. A C-arm fluoroscopy machine and ultrasound were used during the procedure.

Results: A total of 1,613 patients were included in the study, of which 1,085 were males and 528 were females. The mean age of these patients was 49.8±19.2 (16–86) years. At the right side, 1,403 devices were implanted (791 right subclavian vein and 612 right internal jugular vein), while 210 were implanted at the left side (128 left subclavian vein and 82 left internal jugular vein). During the study period, 285 early and 142 late complications were detected. TIVAD insertions were performed successfully, with no recorded deaths.

Conclusion: This study revealed that TIVADs are relatively safe procedures. Majority of the early complications are related to the implantation technique, whereas late complications are associated with catheter fatigue or the use of inlabrate. These complications can be prevented by adhering to rules of the procedure and employing the appropriate technique. Although C-arm fluoroscopy is crucial for these procedures, a risk of accumulated radiation exposure exists but can be reduced with utmost care.

Keywords: Complication, fluoroscopy, internal jugular vein, subclavian vein, totally implantable venous access devices

Please cite this article as: "Örs Yıldırım N. Totally Implantable Venous Access Devices: Study of 1,613 Patients and Complication Management. GKDA Derg 2023;29(4):211-217".

Introduction

Since the introduction of totally implantable venous access device (TIVAD) in 1982, significant progress has been made in its application.[1] Over the years, TIVADs have gained prominence in oncology care, significantly enhancing the quality of life and treatment of patients with cancer. These devices eliminate the need for repetitive venipuncture procedures when administering chemotherapy, parenteral nutrition, antibiotics, fluids, and blood sampling, rendering them particularly valuable for prolonged intravenous (IV) access requirements.[2]

TIVADs comprise of catheters with the distal end positioned at the atriocaval junction and the proximal end connected to a port chamber, usually located in the subcutaneous tissue of the anterior thoracic wall.[3] The choice of entry sites for TIVADs mainly includes the internal jugular and subclavian veins. In certain cases, alternatives such as the cephalic vein, axillary vein in the deltopectoral groove, or lower extremity veins may be considered when the upper venous routes are not feasible.[2]

Although the internal jugular vein can be readily cannulated with the aid of ultrasonography (USG), occasionally, it may not be the preferred option. Despite several disadvantages associated with subclavian vein catheterization, its location in a cosmetically and easily accessible area makes it a viable option. However, in patients with cancer, these sites carry a relatively higher risk of complications, including thrombosis, catheter

Address for correspondence: Nadide Örs Yıldırım, MD. Sincan Eğitim Araştırma Hastanesi, Anesteziyoloji ve Reanimasyon Kliniği, Ankara, Türkiye

Phone: +90 536 265 01 71 **E-mail:** orsnadide@gmail.com

Submitted: September 27, 2023 **Revised:** September 28, 2023 **Accepted:** November 23, 2023 **Available Online:** December 19, 2023

The Cardiovascular Thoracic Anaesthesia and Intensive Care - Available online at www.gkdaybd.org

fatigue, vein stenosis, and pneumothorax during insertion, leading to a range of early and late complications.[4]

Early complications include introductory sheath kinking, difficult vessel access, arterial puncture, pneumothorax, and cardiac arrhythmia. Late complications include bloodstream infections, catheter malposition, thrombotic occlusion, superior vena cava syndrome (SVCS), "pinch-off" syndrome, extravasation, and pocket and catheter infections.[5] Therefore, understanding and addressing these complications are pivotal in optimizing the use of TIVADs in patient care.

This study aimed to retrospectively analyze 1,613 TIVADs implanted at a single medical center. Both early and late complications associated with device placement are evaluated, providing insights into the challenges posed by TIVAD use and offering recommendations for their prevention and management.

Methods

This study was conducted in accordance with the Declaration of Helsinki guidelines. Local ethics committee approval was obtained from the University of Health Sciences, Scientific Research Ethics Committee (no: 2023/327). This study retrospectively analyzed 1,613 TIVAD procedures performed on 1,647 patients between 2010 and 2023 at a single medical center. These patients were undergoing chemotherapy for the treatment of solid tumors, a clinical indication that enhances the quality of life of these patients.

An experienced anesthesiology team performed all procedures. Two different TIVAD models were utilized: the 9.6-F TIVAD (BardPort Titanium Implantable Port, USA) and the 8.0-F open-ended silicone single-lumen TIVAD (Polysite® 4,008 ISP, adult standard portsilicone catheter, France). The patients received detailed information regarding the procedure prior to TIVAD implantation, and written consent was obtained from the patients.

Preoperative assessments included a thorough medical history and physical examination, underscoring the potential anatomical issues such as chest wall tumors, fractures, cervical or mediastinal adenopathy, rotational flaps, SVCS, and body structure. This evaluation aided in preventing complications and facilitated vascular access. Before surgery, chest radiographs were obtained to assess anatomical structures, and complete blood counts and coagulation tests were performed.

The exclusion criteria included bilateral upper extremity vein stenosis due to prior catheterization or disease, signs of skin infection at the implantation site, fever of unknown origin, and any systemic infection or sepsis. Patients with platelet counts lower than 50,000/mm^3 received platelet transfusion prior to TIVAD placement. Furthermore, patients with International Normalised Ratio (INR) levels exceeding 1.5 received vitamin K or fresh frozen plasma before TIVAD placement.

In the operating room, TIVADs were inserted under strict aseptic conditions with procedural sedation supported by tumescent local anesthesia. Continuous monitoring were performed using electrocardiogram, noninvasive arterial blood pressure, and pulse oximetry. All patients received premedication with IV 0.03 mg/kg midazolam. Procedural sedation was maintained with 0.05–0.15 mcg/kg/min remifentanil infusion. Patients were administered 2 L/min oxygen via a facemask during the procedure, and their sedation level was evaluated using the Ramsay Sedation Scale (RSS), targeting an RSS of 3–4.

Initially, the right subclavian vein entry was the preferred approach until 2017. However, owing to several introductory sheath-kinking incidents, the right lower internal jugular vein was used for cannulation, in line with the widespread adoption of USG and echocardiography guidance, as recommended by the guidelines. In challenging cases with difficult venous access, the left internal jugular or left subclavian vein was used as the primary vein. The subclavian vein was also selected in instances where the jugular vein access was not feasible.

The neck and upper chest vessels were evaluated using USG to confirm patency before patient preparation and draping. Patients were positioned supine with Trendelenburg positioning, and their necks were turned to the opposite side of the procedure. The neck and upper chest were sterilized three times with 10% povidone iodine, and sterile towels were draped over the patient. The operator wore a mask, cap, and lead apron.

Before starting the procedure, all necessary tools were prepared on the process table. Sterility was maintained for the micropuncture sheath, needle, and peel-away sheath, and these were flushed with sterile saline. The wires required for the procedure were placed in an easily accessible location. A sterile drape was applied over the ultrasound probe.

The vein access site was marked using USG guidance, and for subclavian vein attempts, the Seldinger technique was employed without USG. The infraclavicular approach was used when USG was preferred. For internal jugular vein access, the ultrasound transducer was placed just above the collarbone, allowing entry to the vein and lateral puncture to keep the access point low.

Once the needle entered the vein, its position was confirmed by the inflow of blood and USG. A guidewire was then inserted through the needle, and its path is verified using C-arm fluoroscopy. A skin incision was made where the guidewire entered the skin, followed by blunt tissues dissection to create space for the catheter and reduce the risk of catheter bending. Next, a suitable location for the port pocket was determined in the infraclavicular space between the nipple and midline of the clavicle. Tumescent anesthesia

(1% lidocaine with epinephrine 1:100,000, sodium bicarbonate) was administered to this area. A transverse incision was made, and a subcutaneous pocket was created via blunt dissection, with concurrent hemostasis.

A tunnel was prepared, and the catheter was advanced through the tunnel formed between the pocket and guidewire. The intraducer sheath was introduced into the vein over the guidewire. After guidewire removal, the catheter was advanced through the sheath to the atriocaval junction, and its position was confirmed via C-arm fluoroscopy.

To avoid serious complications, proper catheter tip positioning is crucial, including thrombosis and pleural effusion. The catheter tip should ideally be located between the tracheal bifurcation area and the cavoatrial junction, with a distance of approximately 3.5–5 cm between them. Hence, positioning the catheter tip 2–3 cm from the tracheal bifurcation toward the side of the heart was deemed appropriate.

Using an injector, venous return was confirmed through aspirating blood. Following a final assessment, the catheter was connected to the port chamber, which was then implanted and secured to the lower part of the pocket using two anchoring sutures to prevent postoperative displacement. To confirm its functionality, blood aspiration from the port chamber was performed. The catheter lumen was flushed initially with approximately 60 mL of physiological saline, followed by a low-dose solution of 100 U/mL unfractionated heparin.

After completion of the implantation, the subcutaneous and skin incisions were sutured, and sterile gauze was applied for dressing the TIVAD incisions. Patients were transferred to the intensive care unit for recovery, and a chest X-ray was conducted prior to clinic discharge to rule out procedure-related complications.

Visualization of the TIVAD implantation procedure from our clinic is provided in the Appendix section as a video link. It encompassed the entire detailed process of TIVAD placement.

Patient follow-up was conducted throughout their treatment and until catheter removal. Complications and patient demographics were recorded both before and after the procedure, and the data were retrospectively reviewed. These complications were categorized as early (perioperative and up to the first use) and late (occurring after the first catheter use).

Results

During the study period, 1,647 TIVADs were implanted. Among them, 26 patients required TIVAD removal due to various complications and underwent reinsertion for treatment continuation. Data from eight patients were deemed insufficient, resulting in study exclusion. Thus, the study was ultimately completed with 1,613 patients. The mean age of the patients was 49.8±19.2 years (range, 16–86). Of the patients, 1,085 were males and 528 were females. The majority of TIVADs (1,403) were implanted on the right side, whereas 210 were implanted on the left side. Patient demographics and the TIVAD insertion side are summarized in (Table 1). Importantly, no deaths occurred because of TIVAD insertion during the study period.

Table 1. Demographic characteristics

Demographic characteristics	n	%
Sex		
Male	1.085	67
Female	528	33
Median age (years)	49.8±19.2	
Age range (years)	16–86	
Right subclavian vein	791	49
Right jugular vein	612	38
Left subclavian vein	128	8
Left jugular vein	82	5

The most common early complication noted was procedure-related technical difficulties (4.6%). In cases where preferred vascular access was unattainable, the contralateral site was selected for vascular access. Introductory sheath kinking (4.2%) was another frequently encountered early complication, whereas arterial puncture, although common, did not lead to major complications.

In five patients, pinch-off syndrome was identified as a late complication. The broken catheter segments were immediately extracted from the right ventricle via percutaneous intervention, and the TIVADs were repositioned to the contralateral side to ensure continuous treatment.

While platelet infusions were administered to three (0.2%) patients with platelet counts below 50,000/mm^3, minor bleeding occurred in these cases. However, these nonserious bleeding events were successfully managed through conservative measures. Eight cases (0.5%) demonstrated user-related TIVAD pocket infections. Six of these cases responded well to antibiotic treatment, whereas two cases with bacteremia necessitated the removal of port catheters, coupled with surgical intervention alongside antibiotic therapy. Nine patients experienced pocket hematomas that spontaneously resolved without the need for treatment. Skin necrosis occurred in six patients, leading to port catheter removal followed by surgical correction.

Pneumothorax, a significant early complication, was detected in eight patients (0.5%) via chest X-ray. Among these patients, six were managed with 24 h of oxygen

Table 2. Key points for radiation safety

Minimize fluoroscopy time.
Minimize the number of images taken.
Use a C-arm fluoroscopic machine with a laser-aiming line.
Do not take images with an image intensifier (or flat panel detector) underneath.
Use available patient dose reduction technologies (e.g., pulsed mode or low-dose mode).
Use collimation.
Use all available information (e.g., MRI, CT) to plan the interventional procedure.
Position yourself in a low-scatter area.
Use shielding devices.
For a lead apron, wear a wraparound type rather than a front type.
Once a year, lead aprons and thyroid protectors should be assessed for damage.
Wear your dosimeter and know your dose.
Use eye shields to protect the lens.
Obtain appropriate training.
Keep the lead apron and thyroid protector on a hanger, ensuring that they do not get wrinkled.

MRI: Magnetic resonance imaging; CT: Computed tomography.

support without any further procedures. Two patients required closed tube thoracostomy and were treated in the intensive care unit for 48 h before discharge without complications.

SVCS, a severe complication requiring immediate attention, was noted in 12 patients. The port catheters were cautiously removed, and treatment with low-molecular-weight heparin (LMWH) was initiated, resulting in the absence of serious complications in these patients.

In 12 patients, imaging revealed incorrect catheter positioning toward the internal jugular vein. This was promptly corrected under C-arm fluoroscopy guidance (Table 2).

Thrombotic occlusion, the most common late complication, was documented in 97 patients. Of these, 93 were effectively treated with thrombolytic agents, whereas the TIVADs of the remaining four patients were removed.

Notably, no radiation-related complications were observed throughout the study. Table 3 provides a summary of the early and late complications identified in this research.

Table 3. List of port catheter complications

A. Early complications	n	%
a. Introductory sheath kinking	68	4.2
b. Difficult vessel access	75	4.6
1. Access site change	61	4.8
2. Venography	14	0.9
c. Arterial puncture	29	1.8
d. Pocket hematoma	9	0.6
e. Pneumothorax	8	0.5
f. Cardiac arrhythmia	16	1
g. Guidewire bending	5	0.3
h. Post-procedural bleeding	3	0.2
B. Late complications		
1. Catheter malposition	12	0.7
2. Overlying skin erosion	6	0.4
3. Thrombotic occlusions	97	6
4. Pinch-off syndrome	5	0.3
5. Superior vena cava syndrome	12	0.7
6. Infection	8	0.5
7. Twiddler's syndrome	1	0.06
8. Catheter release	1	0.06

As comprehensively stated in the article, careful manipulation of the tissues at the puncture site will prevent kinking of the catheter tubing after placement.

Discussion

TIVADs have become indispensable tools for treating patients with cancer, remarkably improving their quality of life by eliminating the need for repeated venipuncture during chemotherapy and other medical procedures. However, similar to any medical intervention, TIVAD placement is not devoid of complications. In this discussion, we elucidate the various complications encountered in our study and provide insights into their management and prevention.

One of the most common early complications observed in our study was kinking of the introductory sheath, occurring in approximately 4.6% of cases. While Barbetakis et al.[3] reported a lower incidence (0.9%) in their study, our findings suggest a higher prevalence, particularly among patients with subclavian vein access. This issue can impede TIVAD implantation; however, we highlight the utility of fluoroscopy in resolving this complication. In this case, the sheath is slowly withdrawn under fluoroscopy and the catheter is easily passed through the sheath when the fracture disappears.

Extreme caution must be exercised to ensure that the sheath does not exit the vein during this process.

Accidental arterial puncture occurred in 1.8% of our patients, a relatively lower rate than the 6–8% reported in central vein catheterization.[6] Fortunately, these punctures did not result in complications. Pneumothorax, a serious complication, was documented in 0.5% of cases in our series, corroborating with existing data, with a rate of 0.5%–6%. Management of pneumothorax varies according to severity, ranging from observation to tube thoracostomy. Follow-up chest X-rays are crucial in suspected cases even if not initially detected during discharge. Six of our patients were on oxygen support during a 24-h follow-up. Although pneumothorax was not initially detected on the X-ray at the time of discharge, conducting follow-up X-ray examinations in patients with suspected pneumothoraxis is important. In this study, pneumothorax was radiologically observed 10 h after the procedure in one of the two patients who had a strong suspicion of pneumothorax. A precise needle tip placement at the suprasternal notch and angle optimization, along with USG guidance, can help minimize this risk. Aiming the needle tip at the suprasternal notch and ensuring vessel access at an angle of <10° is recommended.

Serious cardiac arrhythmias due to mechanical stimulation of the heart wall during catheterization were noted in 1% of the study group. This complication can be avoided through meticulous catheter tip positioning using C-arm fluoroscopy.

Pocket hematoma, a common early complication, is more likely to occur in patients receiving anticoagulant or antiplatelet therapy. Poor surgical techniques are also responsible for these complications. Although often treated conservatively, in case of an event, it is essential to avoid using the ports to prevent further complications, such as infection.

In our study, late complications, including TIVAD pocket infections, occurred in 0.5% of cases, consistent with rates reported in the literature (0.67–4.1%).[1,3] A strict aseptic technique during insertion and access, along with the use of 2% chlorhexidine for preparation, as recommended in the recent guidelines, can help minimize contamination.[7]

Although rare, SVCS is a life-threatening complication. Early diagnosis is crucial, and immediate catheter removal and anticoagulant therapy with LMWH are essential for management. Patients who develop SVCS have nonspecific symptoms such as chest pain, dyspnea, unilateral pleural effusion, and hemodynamic collapse. Predisposing factors include large-diameter catheters, left-sided placement, and hypercoagulable states, particularly in patients with cancer.[2,8] The catheters should immediately be removed from patients who develop this syndrome, and anticoagulant therapy such as LMWH should be initiated.

Skin necrosis, secondary to port diaphragm pressure on the overlying skin, can be exacerbated by radiation or chemical exposure.[9] Prevention involves avoiding port placement in areas with minimal subcutaneous tissue and fat and considering smaller-sized ports with reduced tissue pressure. Subfascial port placement is an option for patients with limited subcutaneous fat.

Necrosis, defined as tissue death due to insufficient blood supply, can occur if the port diaphragm exerts excessive pressure on the overlying skin.[10] This can also be caused by radiation or chemicals. Reversal of necrosis is not possible. Overlying skin necrosis is more common in situations where there is loss of subcutaneous fat.[10] Thus, port placement should be avoided in areas with minimal subcutaneous tissue and fat to prevent this complication. If ports must be placed, small-sized ones should be preferred, and less pressure should be applied to the tissue. Adhering to this rule during the tunneling process is necessary. Ports can also be placed in the subfascial region for this group of patients.

"Pinch-off" syndrome, caused by compression between the first rib and clavicle, is another important but often overlooked complication.[11,12] This can be induced by swimming and vigorous arm movements. Compression may cause temporary occlusion, complete embolization, or catheter rupture. Regular chest X-ray imaging should be considered in patients experiencing difficulties with drug administration and blood aspiration from TIVADs. Patients with TIVADs should be examined using chest X-rays at regular intervals. If distortion or catheter bending is noted on imaging, the possibility of "pinch-off" syndrome should be considered. In the literature, there is paucity of information regarding "pinch-off" syndrome. We noted five (0.3%) patients with symptoms suggestive of "pinch-off" syndrome. Silicon catheter parts were completely separated from the port housing. Four patients were treated via percutaneous intervention. Owing to further localization of the silicon catheter, one patient underwent surgical intervention.

Thoracic outlet syndrome should be investigated via chest X-ray performed before the procedure. Providing access to the subclavian vein away from the ligament connecting the clavicle and the first rib is considered as the most important factor to prevent this problem.

Another important late complication is catheter malposition. Short catheters left in the subclavian vein or in the upper third of the superior vena cava are the primary causes of migration.[13,14] It can result from excessive arm or shoulder movement, vomiting, coughing, or congestive heart failure.[13] In our study, we detected five malpositions

in the internal jugular vein, and these were corrected via C-arm fluoroscopy imaging. Patients with catheter malposition may present with symptoms of neck, ear, and shoulder area pain or unusual sensations during drug administration.[13,14] Careful examination of patients with pain or unusual sensations during drug administration is therefore essential. In our study, we encountered a catheter in the right ventricle without signs of "pinch-off" syndrome in chest X-ray imaging, likely secondary to forceful flushing or drug administration.

Thrombotic occlusions, which are a frequent occurrence, can often be managed effectively through thrombolytic drug administration. However, in the existing literature, there is a notable dearth of comprehensive information concerning the resolution of occluded catheters via this method. Our study provides a notable contribution to this gap in knowledge. Of the 97 patients in our sample who presented with intraluminal thrombosis, 85 were successfully treated without requiring catheter replacement. We achieved this by employing a combination of a thrombolytic agent and the innovative three-way tap technique. This approach not only offers a viable solution to the problem but also represents a cost-effective means of preserving catheters, which is particularly valuable in resource-constrained healthcare settings.

Additionally, our investigation shed light on an infrequently discussed complication known as Twiddler syndrome, which is primarily associated with cardiac pacemakers but can also manifest in ports.[15] Twiddler syndrome arises from the device rotation within its fibrous capsule. [15] To prevent this issue, ports are typically secured with sutures. However, in our study, we encountered a case in which the sutures had become dislodged, resulting in port rotation. This observation underscores the importance of meticulously securing ports to prevent rotation, thereby averting the risk of inadvertent subcutaneous drug administration. We emphasize the necessity of confirming proper functionality and blood flow from the port prior to drug administration as a precautionary measure.

Wound dehiscence, occurring in 1%–3% of cases, is typically managed via TIVAD removal. Poor suture technique and delayed wound healing due to chemotherapy are common contributing factors. In our practice, we implemented additional support sutures using nonabsorbable materials, which were subsequently removed after a period of 2 weeks. This simple precautionary measure has been proven effective in preventing premature wound dehiscence in our patients.

Over the past 5 years, our clinical practice has witnessed a shift in our approach to vascular access. In our routine practice since 2017, we have leveraged intraoperative USG and venography guidance to reduce the rate of unsuccessful attempts in our clinic. This adjustment aligns with the findings of Silberzweig et al.,[16] who reported the successful use of venography guidance for vascular catheterization procedures. In cases where subclavian vein cannulation proves challenging, we employ venography to evaluate the vein prior to cannulation. This approach minimizes the risk of unnecessary punctures and enhances patient safety.

It is of paramount importance to note that when performing surgical procedures under C-arm fluoroscopy, measures must be taken to mitigate potential biological hazards posed by radiation exposure. All personnel involved in the procedure should be equipped with appropriate personal protective gear, including aprons, thyroid shields, gloves, glasses, and caps, to ensure their safety.

Conclusion

The surgical TIVAD insertion has considerably improved the quality of life of patients requiring long-term IV treatments, with added cosmetic benefits. Although these procedures are generally secure, early and late complications remain a possibility. The use of imaging modalities can facilitate vascular access and reduce the risk of unnecessary punctures.

Overall, a meticulous surgical technique and a cautious approach can help prevent early complications. Thrombosed port catheters can often be effectively treated with thrombolytic therapy, allowing continued treatment without the need for catheter replacement. During catheterization, continuous patient follow-up and expert care can mitigate the risk of later complications.

Notably, Biffi et al.[17] conducted a study involving 403 patients and demonstrated that early and late complication rates remain unaffected by cannulation techniques and sites. Despite the undeniable utility of port catheters, recognizing that they can pose serious and potentially fatal complications is essential. Therefore, a thorough understanding of these devices and vigilant monitoring throughout their use is imperative to ensure patient safety and treatment efficacy.

Disclosures

Online Appendix File: https://drive.google.com/file/d/10HFH2kym75yBCoAe5GSdJwo6lcxx3Q1h/view?usp=sharing

Ethics Committee Approval: The study was approved by The University of Health Sciences Gülhane Scientific Research Ethics Committee (Date: 26/09/2023, No: 2023/327).

Informed Consent: Written informed consent was obtained from all patients.

Peer-review: Externally peer-reviewed.

Conflict of Interest: None declared.

Financial Disclosure: The authors declared that this study has received no financial support.

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