Original Article

Totally implantable venous access devices in cancer chemotherapy: A retrospective analysis of 8421 catheter days in a tertiary cancer center

ABSTRACT

Background: The management of several malignancies requires prolonged venous access and repeated injections. While totally implantable venous access devices (TIVADs) can help circumvent many difficulties related to repeated venous cannulation, these devices are associated with their own share of complications.

Objectives: In this study, we report our experience with TIVADs, the complications associated with them and their salvage rate.

Materials and Methods: This retrospective study of adult patients who underwent TIVAD insertion for cancer cytotoxic chemotherapy between January 2016 and December 2020 was conducted at Malabar Cancer Center, a tertiary cancer center in Kerala, India. The majority of the catheters were inserted using the modified Seldinger's technique into the right internal jugular vein under ultrasonographic guidance. Local anesthesia was used for pain relief during the procedure in the majority of patients. The number of catheter days, rate of complications associated with the use of TIVADs and their nature, and the salvage measures undertaken along with their outcomes were recorded.

Results: A total of 37 catheters were inserted in 34 patients during the study period. The total number of catheter days was 8421, and the average number of catheter days was 227.6 days per patient. Postoperative complications developed after the insertion of 7 catheters (18.9%), the most common complication being infection. Three catheters (42.9%) could be salvaged after complications. Twenty-eight (87.5%) catheters were available for use till the end of the planned chemotherapy. Five patients are currently receiving chemotherapy and their catheters are *in situ*.

Conclusion: TIVADs are convenient for long-term venous access in patients with cancer and provide safe and continuous venous access till the completion of chemotherapy.

Keywords: Central venous access, chemoports, complications of venous access devices, venous access devices

INTRODUCTION

Cancer treatment involves prolonged administration of systemic cytotoxic chemotherapy, nutritional support, and administration of intravenous fluids, drugs, blood, and blood products. With a few exceptions, prolonged systemic chemotherapy plays a significant role in the treatment of most hematological as well as solid cancers.[1,2] Hence, long-term venous access is essential during the treatment of most cancers.

Repeated cannulation of the peripheral veins for long-term venous access is painful and is associated with high failure rates and complications.[3-5] Certain chemotherapeutic agents,

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parenteral nutritional agents, and vasopressors are not suited for peripheral venous administration, and hence, central venous access is mandatory in such cases.[6-8] Therefore, in a patient undergoing cancer treatment, the ideal venous access is central rather than peripheral.

Devices that provide long-term, central venous access include peripherally inserted central catheters (PICCs), tunneled external catheters, and totally implanted venous access devices (TIVADs). Currently, there are no evidence-based guidelines for choosing one venous access device over the other. Nevertheless, TIVADs are generally preferred in patients requiring long-term intermittent venous access, as is often required during the treatment of solid tumors.[8,9] TIVADs in their currently used form were first introduced in 1982 by Niederhuber *et al*.[10] Although TIVADs are used in several conditions that require long-term venous access, such as cystic fibrosis,[11-13] cancer chemotherapy is by far the most common indication. Hence, TIVADs are also called chemoports. Their introduction has helped circumvent many difficulties associated with long-term venous access in patients with cancer.[14] However, these devices are also associated with occasional complications such as infection, venous thrombosis, wound gape, and migration[15-18] which sometimes warrant their removal before the completion of chemotherapy. In this study, we aimed to assess the complication rates for TIVADs used during chemotherapy in a tertiary cancer center. We also aimed to assess their salvage rates and the availability of chemoports for venous access until the completion of chemotherapy.

MATERIALS AND METHODS

General study details

This retrospective cohort study was conducted in the surgical oncology department of Malabar Cancer Center, a tertiary cancer center in Kerala in South India, between January 2016 and December 2020. The study was approved by the Institutional Review Board (IRB)-Scientific Review Committee [Supplementary Appendix 1]. In view of the retrospective design, the requirement for individual patient consent was waived by the IRB. The study was not registered with any public clinical trials registry. The study was conducted according to the ethical guidelines outlined in the Declaration of Helsinki and the Indian Council of Medical Research guidelines for ethical research. No funding was obtained for conducting this research.

Participants

We evaluated the data of patients with cancer aged more than 18 years who underwent TIVAD insertion for chemotherapy at our center between January 2016 and December 2020. There were no specific exclusion criteria.

Variables

The primary endpoint of the study was the incidence of complications associated with the use of TIVADs. The secondary endpoints included their salvage rate and the availability of chemoports for venous access until the completion of chemotherapy.

Study methodology

Data for the study were obtained from case records, surgical notes, anesthesia notes, multispecialty board discussion records, digital radiology records, and telephonic inquiry wherever required. Details related to the patient demographics, size of the catheter, number of catheter days, completion of chemotherapy, complications, and interventions were obtained.

Patient counseling

Patients were counseled about the various forms of central venous access by the nurse-in-charge of the Central Venous Access Devices (CVAD) clinic. PICCs were the preferred form of central venous access at our institute; they were inserted and maintained by trained nurses in the CVAD clinic. TIVADs were selectively used in patients with solid tumors where peripheral venous access was not available for PICC insertion; PICCs were not used in cases of bilateral axillary dissection for breast cancer or when the patient preferred other methods over PICC.

Technique

The procedure of insertion was carried out by the surgical oncologists. The patients received local anesthesia during the procedure in the majority of the cases. General anesthesia (GA) was used if the procedure was clubbed with another oncological procedure that required GA; the catheter was inserted at the same sitting. Local anesthesia was used in stand-alone procedures, whenever the patient was willing for the same. Catheter insertions into the left internal jugular vein (IJV) were routinely performed under GA.

All patients were counseled in detail about the nature of the procedure, its benefit as well as the common complications associated with it by the clinicians and nurses who had received special training in the maintenance of chemoports. Initially, we used the percutaneous anatomic landmark technique for venous access. However, we soon switched to the ultrasonography-guided technique to visualize the IJV for all the cases. Injection amoxicillin-clavulanic acid 625 mg was injected intravenously preoperatively, approximately 30 min before the procedure. Local anesthetic was infiltrated at the site of venous access, at the site of chamber insertion, and over the entire length of the skin where tunneling was planned. The

modified Seldinger's technique was used for insertion. Devices with a catheter size of 9.6 Fr were used in all patients. After securing the guidewire into the vein, a subcutaneous pouch was created just below the clavicle, superficial to the pectoral fascia, and the radio-opaque port reservoir (chamber) was placed in the pouch. Deep biting sutures were used to fix the chamber on the pectoral fascia. The catheter was tunneled till the site of venous access using a metallic tunneler and brought out of the skin incision at the site of venous access.

The catheter was trimmed with a sharp knife such that the cut edge reached the sternal angle of Louis from the site of insertion when placed on the body. This helped to keep the catheter close to the cavo-atrial junction when placed in the vein. In the case of a Groshong tip catheter, tunneling was performed in the retrograde direction as the catheter tip could not be cut. The breakable dilator (peel away sheath) was carefully inserted into the vein. Once the dilator was completely inserted till the hub, the catheter was threaded into the dilator. The hub of the dilator was broken, and the dilator was withdrawn by peeling it away. While slowly withdrawing the dilator, the catheter was pushed into the vein with the index finger. Care was taken to avoid kinking the catheter at the insertion site. The backflow of venous blood was confirmed, and heparin solution was injected into the port to prevent clotting.

Some variation in the catheter tip position (i.e. entry into the right atrium or placement in the superior vena cava [SVC]) was generally accepted. C-arm was used to confirm the position of the guidewire before catheter insertion whenever the procedure was performed on the left side. In case of malpositioning of the guidewire, it was corrected before inserting the dilator. Digital chest radiography was performed after the procedure in all cases.

The catheters were used for administering intravenous chemotherapy as well as for the transfusion of intravenous fluids, blood, blood products, and total parenteral nutrition when indicated. The catheters were also used in emergencies.

Catheter removal

Once the chemotherapy course was completed, the devices were removed within a month, except in patients who required prolonged therapy with trastuzumab, where the ports were maintained for a longer period. The ports were usually removed using local anesthetic infiltration for pain control. The previous incision was recreated, and the chamber was moved out of the subcutaneous pouch. Finger pressure was applied for several minutes at the site of venous access to prevent bleeding and hematoma formation. The wound was sutured after ensuring hemostasis.

Catheter care

The patients were offered regular catheter care in a CVAD clinic by nurses trained in the procedure. The access needle was inserted before the administration of each cycle of chemotherapy and was removed on the same day after the administration. When the port was in use, regular flushing was not required. However, when not in use, the port was flushed with 10 mL of 0.9% saline and locked with heparin saline once every 4 weeks. In case of catheter blocks, the patients were treated in the CVAD clinic with saline injection and aspiration technique. If this did not work, urokinase or alteplase injection was used to relieve the block.

Definitions

The complications were categorized as intra-operative, early postoperative (occurring within 2 weeks of insertion) and late (occurring 2 or more weeks after the insertion). Complications associated with infections were further categorized as those caused by catheter chamber infection or catheter-related bloodstream infection. The number of catheter days was calculated as the time in days from the date of catheter insertion till the date of removal and the average of these values was also obtained.

Statistics

No sample size calculation was performed for this study, and all patients fulfilling the eligibility criteria were included. The Statistical Package for the Social Sciences (SPSS) version 20.0. (Armonk, NY, USA: IBM Corp.) was used for data analysis. Descriptive statistics were used to summarize the data. Fisher's exact test was used for analyzing the correlation between the number of catheter days and the incidence of complications. A $P < 0.05$ was considered statistically significant.

RESULTS

During the study period, 34 adult patients underwent TIVAD insertion [Figure 1]. During the same period, 245 patients underwent PICC insertion. With 3 patients undergoing reinsertions, the total number of TIVAD insertions was 37. There were a total of 8421 catheter days, with an average catheter days of 227.6 days per patient. The demographic details, cancer diagnoses, method of insertion, site of insertion, and catheter size are described in Table 1.

Intra-operative events

The procedures were uneventful in most cases. However, we encountered intra-operative difficulties in two cases. In one

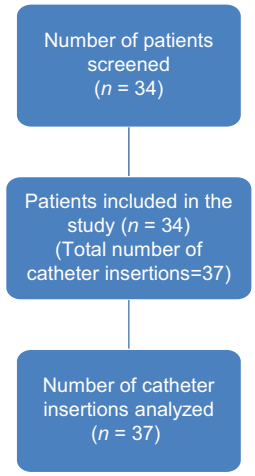

Figure 1: Patient recruitment flowchart

case where we used the anatomical landmark-based method of venous access, we had an accidental arterial puncture. We controlled the situation by applying pressure on the area and managed to avert the formation of a hematoma. In the other case, we encountered difficulty in inserting the guidewire after gaining access to the vein using the ultrasound-guided method. We failed to pass the guidewire despite reconfirming the venous access. We used the open technique to visualize the vein and directly inserted the catheter into it. The venotomy wound was sutured using 5-0 polypropylene.

Post-operative complications

We encountered one case of chamber site infection during the immediate postoperative period. All other complications occurred two weeks after the date of insertion and were classified as late complications. All infectious and non-infectious complications encountered are described in Table 2.

To date, 32 catheters have been removed; 28 (87.5%) catheters were removed after the completion of chemotherapy, while 4 were removed before the completion of intended chemotherapy because of complications. Five patients are currently receiving chemotherapy. There was no mortality attributable to catheter-related complications in this study. The average number of catheter days for patients who developed catheter-related complications was 126. A total of 6 out of 7 catheter-related complications in our study occurred in the initial 200 catheter days. Fisher's exact test revealed a higher risk of developing a complication during the initial 200 days of catheter use ($P = 0.014$).

In one patient who developed a wound gape at the surgical site, a local random rotation flap was used to cover it. The wound healed and the chemotherapy could be completed. However, in another patient who developed a wound gape, despite re-suturing the wound, the chamber got infected and had to be removed. Three patients developed port-related infections. They were treated with culture-guided antibiotics, vancomycin or linezolid, and one catheter could be salvaged.

In some cases, we observed that the catheter chamber migrated towards the site of incision due to gravity and with repeated passing of the access needle, the overlying skin got thinned out and damaged. A wound gape developed at or close to the incision site when performing high insertion of the chamber, in which we created an incision well below the clavicle on the chest and placed the chamber in the subcutaneous pouch created above the incision. We later adopted the technique of low insertion of the chamber, in which the incision was made close to the clavicle, and the chamber was placed below the incision after creating an adequately sized subcutaneous pouch. This prevented the migration of the chamber towards the incision and the subsequent skin damage.

Table 1: Patient demographics, cancer diagnoses, and details of the central venous access device insertion procedure

Variable	Categories	*n* (%)
Age (years)	<40	5 (13.51)
	40-50	12 (32.43)
	>50	20 (54.05)
Sex	Female	34 (91.89)
	Male	3 (8.11)
Cancer diagnosis	Bilateral breast cancer	24 (64.86)
	Unilateral breast cancer	8 (21.62)
	Others	5 (13.51)
Anesthesia	Local anesthesia	31 (83.78)
	General anesthesis	6 (16.21)
Site of insertion	Right IJV	35 (94.59)
	Left IJV	2 (5.40)
Mode of venous access	Ultrasonogram-guided	33 (89.18)
	Anatomical landmark-based	3 (8.11)
	Open	1 (2.70)

IJV: Internal jugular vein

Table 2: Incidence of immediate and late postoperative complications and outcome of salvage measures

Type of complication	Incidence (number)	Per 1000 catheter days	Outcome, i.e., the number of catheters salvaged
Infection			
Chamber site infection	2 (5.41)	0.36	1
CRBSI	1 (2.70)		
Wound gape	2 (5.41)	0.24	1
Flipping of catheter chamber	1 (2.70)	0.12	1
Venous thrombosis	1 (2.70)	0.12	0
Total	7 (18.92)	0.83	3

CRBSI: Catheter-related blood stream infection

The chamber flip (chamber inversion) was corrected by re-exploration and re-fixing of the catheter to the pectoral fascia. In most cases, blocked catheters could be salvaged using the saline push aspiration technique or by using one of the thrombolytic agents. However, in two cases, the blocks could not be reversed and the catheters had to be removed. IJV thrombosis was treated with anticoagulation after the removal of the catheter. Four catheters were removed before the completion of chemotherapy due to complications, and three patients underwent reinsertion at a later stage.

DISCUSSION

In our study, 37 TIVADs were inserted in 34 patients. The majority of the patients underwent insertions in the right IJV under ultrasound guidance using local anesthesia for pain relief. Seven patients (18.9%) had complications, the most common being infection. Other complications included wound gape, flipping of the chamber, and venous thrombosis. Three catheters could be salvaged despite complications. A total of 32 catheters have been removed so far, of which 28 (75.7%) were removed after the completion of chemotherapy and 4 (19.8%) were removed before the completion of the planned chemotherapy due to various complications. Statistical analysis showed that catheter-related occurred more frequently in the initial 200 days of use than later. However, this finding needs to be cautiously interpreted because of the small number of participants in the study. The port was available for venous access till the completion of chemotherapy in 87.5% of the patients.

Most of the complications that we encountered, including infection, wound gape, flipping of the chamber, and catheter block, have been extensively reported in the literature.[16,19-23] Other complications that have been described include catheter rupture, migration or embolization, and pinch-off syndrome. Potentially serious complications such as SVC erosion and perforation, cardiac perforation, and tamponade are extremely rare and have not been reported in recent literature. The overall infection rate in our study was 0.36 per 1000 catheter days. In the published literature, the infection rate varies from 0.12 to 1.96 per 1000 catheter days.[15,23-26] In a study on the long-term availability of TIVADs in 204 adult patients undergoing cancer chemotherapy with a total of 183,328 catheter days, the authors reported the long-term availability of the TIVAD in 91.7% of the patients at a median follow-up of 21.9 months.[27]

We believe that ultrasound-guided access helped us to reduce intraoperative complications like vascular injury, hemothorax, and pneumothorax. Several studies have shown an improvement in the outcomes with the routine use of ultrasonography for guiding venous access in the form of fewer failed attempts and intraoperative complications and reduction in the overall cost from the averted adverse events.[28-32] This technique has, therefore, become the standard of care, especially in the case of pediatric patients.

In our study, the right IJV was cannulated in most cases as we were more familiar with this procedure. The left IJV was used when the right IJV was not available due to the tumor location, thrombosis from the previous cannulation, or infection. While a large, randomized trial from Turkey showed no difference in the complication rate based on the site of venous access,[33] a recent prospective, randomized study from China has shown a reduced rate of complications and improved patient satisfaction with subclavian vein access compared to IJV; the authors recommended the routine use of the left subclavian vein for venous access in children undergoing implantable port insertions.[34]

The importance of local anesthesia for pain relief during insertion of TIVADs is well recognized. Proper counseling of the patients and allaying their anxiety is extremely important for a smooth and comfortable procedure. In a study comparing lignocaine, buffered lignocaine (alkalinized), and chloroprocaine for local analgesia during central venous access in 62 patients, no statistically significant difference was observed in the pain scores at the time of injection or catheter placement.[35] In a recent prospective, randomized study, the authors compared anatomical landmark-based venous access using local anesthesia with ultrasound-guided access under superficial cervical plexus block with local infiltration anesthesia in 100 patients undergoing port insertion. The ultrasound-guided access under SPCB provided better pain control, reduced the number of attempts at venous access, and provided more comfort to both the patient and the surgeon.[36]

The catheter tip position after the insertion of CVAD is a matter of continuing debate. The cavo-atrial junction is traditionally considered the ideal site for placement, and former guidelines firmly recommended it.[37] However, ensuring the presence of the catheter tip at this anatomic location is difficult, and previous studies have demonstrated the safety of intra-atrial placement of the catheter.[38] Some studies have shown a better performance of the catheter placed in the right atrium, with a reduced rate of thrombosis and catheter block compared to placement in the SVC.[39,40]

Our study was limited by its small sample size and a homogenous population, where the vast majority of the

patients were adult female patients with breast cancer. Hence, it can be difficult to generalize some of our results. However, we found that the ultrasound-guided technique for venous access and catheter insertion under local anesthesia were feasible and safe and was associated with the availability of the catheter for chemotherapy in an overwhelming majority of the patients when supported by a dedicated catheter care clinic.

CONCLUSION

TIVADs are convenient for long-term venous access in patients with cancer and provide safe and continuous venous access till the completion of chemotherapy. The overall complication rate with TIVADs is low when trained staff associated with a dedicated catheter care clinic help in maintaining these devices.

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Conflicts of interest
There are no conflicts of interest.

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Supplementary Appendix 1-Study protocol

Longterm central venous access in cancer patients: Experience from a Tertiary Care Cancer Institute

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INTRODUCTION

As there is need of frequent administration of chemotherapy, blood components, antibiotics and TPN in cancer patients long term venous access is necessary. Chemoport (CPs), otherwise known as subcutaneous venous access device, is used for long term venous access. It is usually inserted in right internal jugular vein or right subclavian vein. Neiderhuber*et al*. was the first to demonstrate CPs placement in 1982.[1]

There are various types of central venous access devices that is open-ended tunneled catheters, tunneled valve catheters, implantable subcutaneous CPs, non cuffed non tunneled CVCs, and peripherally inserted central catheters.

Central venous access have greater longevity, lower infection rates, multiple lumens for simultaneous administration of drugs, a route for administration of antibiotics, blood components and central venous pressure monitoring.[2]

CP has advantages as puncture needle can be removed; skin acts as a barrier, and prevents infection compared to open tunneled central venous catheter systems which can transmit infection. Even though expensive finally with prevention of multiple punctures, long life and prevention sepsis they are better than peripheral venous access devices. As patients with malignancy has multiple thromboembolic risk factors due to age, malignancy, hypercoagulability, chemotherapy, infections, immobility catheter material, multiple placement attempts, catheter size and length, number of lumens, and catheter tip localization, which can be solved by using CPs.[3]

Surgical technique - Under aseptic precaution first ultrasound guided puncturing of internal jugular vein is done, guide is placed, catheter is flushed with heparin zed saline, subcutaneous space is created 2–3 cm below ipsilateral clavicle, port is placed and fixed. Catheter is tunneled subcutaneously catheter tip is placed at level of the cavo-atrial junction or 2–3 cm below the carina correlating with second intercostal space. Aspiration of blood was done to check its function and flushed with heparinized saline. Post procedure chest radiograph us taken.

Complications can be divide in to early that is within 30 days and late after 30 days, they include pneumothorax, malposition, arterial puncture, pinch-off syndrome due to nerve plexus injury (occur only in SCV access blood stream infection).[3]

Research question

What is the outcome of CPs that is subcutaneous venous access device in cancer patients from 2015 to 2017 at Malabar cancer centre?

Aim

To evaluate the outcome of CPs in cancer patients from 2015 to 2017 at Malabar cancer centre.

Objectives

Among the patients who got CPs inserted at Malabar cancer centre. The objectives are:

1. Assess intra op immediate and late complications

2. To assess the salvage rate and availability of chemo ports till completion of chemotherapy.

METHODOLOGY

Study setting

- Malabar Cancer Centre is a tertiary cancer care centre in Northern part of Kerala. It is an autonomous institution under the department of Health and Family welfare, Government of Kerala. This centre is situated in Kodiyeri, in Thalassery municipality. The centre caters around 4000 new cancer patients every year
- Patients who require long-term venous access or with difficult peripheral venous access e.g. paediatric cancer patients and patients in whom peripheral upper arm venous aaccess is avoided like bilateral breast cancer will undergo CPs insertion at our centre

Study design

- This is a retrospective cohort study of patients who undergo CPs insertion during the period of June 2015–2017 at Malabar Cancer Centre.

Study population

- Patients who underwent CPs insertion at Malabar Cancer Centre during the period of June 2015–2017.

Inclusion criteria

1. All patients who underwent CPs insertion at MCC
2. All patients having the complete records and regular follow up.

Exclusion criteria

1. Patients who underwent CPs insertion elsewhere
2. Patients who are not on follow-up.

Study period

December 2018 to January 2019

Data variables

- Demographic variables, clinical variables, and follow-up details
- Input variable: Type venous access, site of venous access
- Outcome variable: Complications, patient satisfaction, and premature CPs removal.

Source of data collection

The demographic profiles, details of cancer, details of treatment will be collected from the case record of the patients from the medical records department.

Procedure for collecting the data

The demographic, clinical, and treatment details of all the patients undergoing treatment at Malabar Cancer Centre are recorded routinely in the case record. This data will be collected from the medical record department.

Data entry and analysis

Data will be entered in a pro forma and validated by the principal investigators and the co-investigators. All the discrepancies in the data will be corrected by checking the case records. The statistical analysis will be done using The Statistical Package for the Social Sciences (SPSS) version 20.0. (Armonk, NY, USA: IBM Corp.).

Ethics considerations

- The permission from the IRB/institutional scientific committee will be obtained for the study
- The process of data collection will not pose any risk or harm to the subjects as no kind of intervention or any interference with treatment is undertaken in this study
- Data confidentiality: The names of the patients will not be entered anywhere in the study.

DISSEMINATION OF RESULTS

The results will be published in peer-reviewed national and international journals and conferences, increasing the body of

knowledge, and informing the larger scientific/medical body.

Project Management

	December 2018	December 2018	January 2019	January 2019	January 2019
Finalization of protocol					
Data abstraction and validation					
Data entry					
Data analysis					
Report writing					
Report dissemination					

Pro forma

Name
Age
Sex
Hosp number
DOR
Contact number
Co morbid
DOS
decision to put chemoports
From insertion to chemotherapy interval
Insertion interval
Re-exploration rates
Catheter blockade
Intraoperative complications
Early complications
Infectious complications
Noninfectious complications
Reason for catheter removal

Late complications
Chemotherapy
Catheter days

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