

Radiologic placement of totally implantable venous access devices: Outcomes and complications from a large oncology cohort

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ABSTRACT

Introduction: Totally implantable venous access devices (TIVADs) or ports are increasingly used in oncology settings to provide long-term, easy venous access. This study reports our experience and results with 1180 cases in Singapore.

Method: Data from January 2019 to January 2022, obtained from a hospital-approved secure database application called the Research Electronic Data Capture registry, were reviewed and analysed retrospectively.

Results: A total of 1180 patients underwent TIVAD implantation with a 100% technical success rate. The mean age of the cohort was 61.9 years. The mean dwell duration was 342 days (standard deviation [SD] 223; range 3–1911). By 1 February 2022, 83% of patients were still using the TIVAD, 13.6 % underwent removal after completion of treatment, 2.1% were removed due to infection, 0.6% due to malfunction, 0.6% due to port extrusion and 0.1% at patient's request. The right internal jugular vein (IJV) was the most commonly accessed site (83.6%), followed by the left IJV (15.6%). The early post-procedure complications were pain (24.7%), bruising (9.2%), swelling (3.6%), bleeding (0.5%), fever (0.4%), itchiness (0.2%) and allergic dermatitis (0.1%). The delayed post-procedure complications were TIVAD site cellulitis (3.80%); discharge (1.10%); skin erosion with device extrusion (0.60%); malpositioned catheter (0.33%), which was successfully repositioned, catheter-related bloodstream infections (0.25%); migration of TIVAD leading to catheter dislodgement (0.25%); venous thrombosis (0.25%); fibrin sheath formation requiring stripping (0.10%) and TIVAD chamber inversion (0.10%).

Conclusion: TIVAD implantation via the jugular vein under radiological guidance provides a safe, reliable and convenient means of long-term venous access in oncology patients. By sharing our experience and acceptable outcomes from a large oncology cohort, we aim to increase the awareness and adoption of TIVAD usage in oncology patients, especially in Asia.

Ann Acad Med Singap 2025;54:27-35

Keywords: complications, long-term venous access, oncology, ports, totally implantable venous access device, TIVAD

CLINICAL IMPACT

What is New

- Adoption of totally implantable venous access devices (TIVADs) in oncology patients remains poor despite improved device construct and implantation techniques.
- To the best of the authors' knowledge, this study is the first from Singapore to share the experiences and results of TIVAD implantation in a large cohort.

Clinical Implications

- Radiologically guided insertion of TIVADs is a safe and reliable procedure with a high technical success rate and acceptably low complication rates.
- Apart from chemotherapy administration, TIVADs can be used for parenteral nutrition, obtaining blood samples and contrast media injections for imaging.

INTRODUCTION

Long-term intermittent venous access has proven to be indispensable for oncology patients who require frequent intravenous (IV) infusions and repeated phlebotomies apart from facing the discomfort of frequent venepuncture.¹ Totally implantable venous access devices (TIVADs) or ports are preferred to external catheters, especially in these patients, due to their low complication rates and high patient comfort and satisfaction.²

Historically, surgeons implant ports under general anaesthesia with venous cut-down. However, radiologically guided port placement has become increasingly popular and a routine since the first port implantation performed by Morris et al.³ in

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Accepted: 3 December 2024

1992 using interventional radiology techniques with higher technical success rates and lower complications.^{4,5}

Due to the improved construct of the TIVADs currently available, apart from administering chemotherapy, it can be utilised for parenteral nutrition, withdrawing blood samples and withstanding high-pressure contrast media injections during cross-sectional imaging, which is routinely performed for oncology patients.

Although different veins at various sites can be used, the internal jugular vein (IJV) is the ideal vessel for primary venous access, with higher success rates and lower short- and long-term complication rates.⁶ Hence, the most popular technique for port placement under radiological guidance is the creation of a tunnel between the venepuncture site and the port pocket in the infraclavicular region after IJV puncture. This study presents our experience and results in patients who underwent TIVAD implantation using this technique. Apart from having heterogeneous sample groups, most large cohort studies currently available are from the West, suggesting a higher adoption rate. Specific data involving the adoption rate of TIVADs and large-scale studies from Asia remain sparse. Therefore, we aim to bridge this gap and augment the adoption scale of TIVAD in Asian patients.

METHOD

The SingHealth Centralised Institutional Review Board (CIRB 2021/2357) approved this study, where the requirement for informed consent was waived due to retrospective anonymisation. Patients' data were obtained from a hospital-approved secure database application called the Research Electronic Data Capture (REDCap) registry. Data of all TIVADs placed at Singapore General Hospital from January 2019 to January 2022 were anonymised and used for this review.

Pre-procedure considerations

Written informed consent was obtained from all patients. Procedural details, including the options, advantages and expected complications, were relayed to all patients during this process. Relevant clinical histories, such as previous mastectomy and axillary dissection, prior or planned radiation therapy to the chest, presence of indwelling cardiac pacemaker and the assessment of the amount of subcutaneous tissue and condition of the skin over the infraclavicular region, were also performed. Alternative options for long-term venous access, such as peripherally inserted central catheter (PICC) or tunnelled venous catheters like Hickman,

were offered to patients deemed unsuitable for TIVAD implantation.

Haemoglobin (Hb), platelet, absolute neutrophil count (ANC), international normalised ratio (INR) and partial thromboplastin time (PTT) values were obtained from all patients. The procedures were deferred if the patient has an ANC of <1500/mcL, Hb is <8.0 mg/dL, platelet is <50,000 mcL or INR and PTT are >1.5 times the normal value.

All patients were administered IV prophylactic antibiotics before the procedure: 1 g cefazolin or 600 mg clindamycin for patients with a history of penicillin allergy or 1 g vancomycin for patients with a history of methicillin-resistant *Staphylococcus aureus* infection.

Sedoanalgesia with IV midazolam and fentanyl was administered in selected cases (at operators' discretion) for patient comfort and anxiolysis, with strict continuous physiologic monitoring (with pulse oximetry, electrocardiography and non-invasive blood pressure) carried out by the nursing staff. As most TIVAD implantations were performed in an outpatient setting, patients who received IV sedation were monitored for at least 4 hours post-procedurally until they were deemed safe for discharge.

Implantation techniques

Single-lumen power that are able to withstand high-pressure contrast media injections TIVADs were implanted in the chest. IJV was the preferred venous cannulation site, followed by the external jugular vein (EJV). Smaller profile ports were usually reserved for thin cachectic patients with minimal subcutaneous fat in the infraclavicular region, with the ultimate choice left to the operator.

The following steps were universally adopted during the insertion procedure with minor technical variations between the operators: (1) Preparation. Preliminary ultrasound examination was done to assess the target veins' patency. Surgical skin preparation was performed with ChloraPrep One-Step (2% chlorhexidine gluconate/70% isopropyl alcohol; BD, Wokingham, UK) followed by sterile draping of the procedural field. Povidone iodine was used instead of ChloraPrep in cases of allergy to chlorhexidine or alcohol. (2) Venous access. Venous access was obtained under ultrasound guidance using an 18G needle. A 0.035-inch wire was introduced, and the needle was exchanged for a peel-away sheath. (3) Creation of the subcutaneous port pocket and tunnel. Subcutaneous pocket was created approximately 3 cm below the clavicle, generally

along the mid-clavicular line or slightly lateral. Ideal depth of the pocket should be 5 mm beneath the skin and superficial to the pectoral fascia. (4) Preparation and fixing of the port catheter system. The catheter was pulled through the subcutaneous tunnel with the help of a tunneller. One end of the catheter was connected to the port's exit stem. Anchoring sutures were used (at operators' choice) to anchor the port to the pectoralis fascia with non-resorbable sutures (Prolene; Ethicon, Bridgewater, NJ, US). (5) Introduction of the catheter. The other end of the catheter was trimmed to an appropriate length using fluoroscopic guidance and advanced through the peel-away sheath to the desired position under fluoroscopy. The port system was flushed and locked with 5 mL of 100 units/mL of concentrated heparin sodium solution (terminal flushing). Sodium citrate (4%) was used in patients who were hypersensitive to heparin or had a history of heparin-induced thrombocytopenia. (6) Skin closure. The port pocket was closed either with a bi-layered technique using simple interrupted deep dermal suturing with 2-0 polyglactin resorbable suture (coated Vicryl; Ethicon), followed by running subcuticular sutures with 4-0 polyglactin resorbable suture (coated Vicryl; Ethicon) with application of octyl cyanoacrylate tissue adhesive (Dermabond, Ethicon) for skin closure. However, some operators would forgo the subcuticular sutures and would close the skin with Dermabond after deep dermal suturing with 2-0 polyglactin resorbable suture (coated Vicryl). Steristrips were applied instead of tissue adhesive in cases with a history of cyanoacrylate allergy. The venotomy site was closed with Dermabond or steristrips.

A final fluoroscopic image was obtained to ensure and document the correct positioning of the system and to exclude any catheter-port dissociation or kinking.

Follow-up

A nurse clinician contacted all patients via phone on postoperative day 1 with a standardised questionnaire to check on early complications such as pain, fever, swelling, bruising and bleeding. Video consultations mostly replaced physical attendance during the pandemic, and patients were encouraged to send a photograph of their wounds, especially if there was cause for concern. Any patients who showed symptoms or signs of complications were physically evaluated at a later date.

A standardised workflow was implemented for cases where any issues or complications were encountered during the TIVAD usage. A nurse clinician would initially assess the problem and escalate to a consultant accordingly if a second opinion was

required. All consultations, findings and results, including the date and reason for explantation, were recorded on the REDCap registry.

RESULTS

A total of 1180 patients underwent TIVAD implantation between January 2019 and January 2022, with a 100% technical success rate. These patients' baseline demographics are presented in Table 1. The mean dwell duration for the TIVAD was 342 days (SD 223 days; range 3–1911). At the time of data collection (1 February 2022), 83% of patients (n=980) were still using the TIVAD, i.e. in-situ, 13.6 % (n=160) had their TIVAD removed after completion of treatment, 2.1% (n=25) had their TIVAD removed due to infection, 0.6% (n=7) of the TIVAD were removed due to malfunction, 0.6% (n=7) were removed due to port extrusion and 0.1% (n=1) was removed at patient's request.

Table 1. Patients' baseline characteristics.

Characteristics (n=1180)	n	%
Age (years)		
Range	20–90	
Mean	61.9	
Sex		
Female	732	62
Male	448	38
Race		
Chinese	940	79.7
Malay	118	10.0
Indian	66	5.6
Others	56	4.7

The right IJV was the most commonly accessed site (n=986, 83.6%), followed by the left IJV (n=184, 15.6%). The left and right EJV were accessed in 6 (0.5%) and 4 (0.3%) patients, respectively. The mean number of ultrasound-guided passes for accessing the vein was 1.07 ± 0.3 , with the majority (94%) successful with a single pass.

The most common position of the catheter tip was the cavoatrial junction (58.4%), followed by the right atrium (36.8%) and then the superior vena cava (SVC) (4.8%).

Anchoring suture was utilised in 37.3 % (n=440) of the cases, with a curvilinear trend in the diminished use of anchoring suture from 63.3% in 2019 to 27.8% in 2021 ($P=0.03$).

Sedoanalgesia using IV midazolam and fentanyl was administered in 562 patients (47.6%). The rest (n=618, 52.4%) was performed with local anesthesia (LA) only. The range of IV midazolam administered was 0.5–5 mg, with an average dose of 1.2 mg and an SD of 2.3. For IV fentanyl, the range was 10–100 mcg, with an average dose of 15.0 mcg and an SD of 19.1.

The complications related to TIVAD implantation were divided into early (≤ 30 days after implantation) (Table 2A) and delayed (>30 days) (Table 2B). The most common early post-procedure complications were pain (24.7%), bruising (9.2%) and swelling (3.6%). These were treated symptomatically with analgesics and reassurances that they would resolve with time. Six patients (0.5%) presented with persistent bleeding post-procedure, which resolved with manual compression. Five patients had fevers after the procedure; they were presumed to be due to early TIVAD site infection and treated empirically with broad-spectrum oral antibiotics. One case presented with erythema and mild blistering around the site where Dermabond adhesive was applied. The vigilant attending removed the adhesive cast, and the symptoms resolved with antihistamines and steroid ointment. A patch test later confirmed that the patient had allergic contact dermatitis to the Dermabond adhesive.

Table 2A. Early (≤ 30 -day post-implantation) complications related to TIVAD implantation.

Early related complications	n	%
Early related complications	291	24.7
Bruising	108	9.2
Swelling	42	3.6
Bleeding	6	0.5
Fever	5	0.4
Itchiness	2	0.2
Allergic dermatitis	1	0.1

Infection and failure to use TIVADs were the dominant delayed complications. The spectrum of infection ranged from TIVAD site cellulitis, which was the most common complication presenting with erythema and pain/discomfort (n=45, 3.8%), to catheter-related bloodstream infections (CRBSIs) (n=3, 0.25%). Aggressive antibiotic therapy was instituted in these cases to salvage the TIVAD system. Twenty-five (2.1%) TIVADs were removed due to infection, including those with progressive symptoms of infection, including discharge (n=13,

Table 2B. Delayed (>30 -day post-implantation) complications related to TIVAD implantation.

Delayed related complications	n	%
TIVAD site cellulitis	45	3.80
Discharge	13	1.10
Skin erosion with device extrusion	7	0.60
Malpositioned catheter (successfully repositioned)	4	0.33
Catheter-related bloodstream infections	3	0.25
Migration of TIVAD leading to catheter dislodgement	3	0.25
Venous thrombosis	3	0.25
Fibrin sheath formation requiring stripping	1	0.10
TIVAD chamber inversion	1	0.10

TIVAD: totally implantable venous access device

1.1%) despite antibiotic therapy and those with CRBSIs.

In our cohort, failure to use the TIVAD was mainly due to migration of the catheter (n=7, 0.6%) and skin erosion with extrusion of the TIVAD's septum and reservoir (n=7, 0.6%) (Fig. 1). The catheter was successfully repositioned with the aid of endovascular snares in 4 migration cases, as the tip was still intraluminal (Fig. 2). The other 3 were removed, and a new TIVAD was implanted as the catheter tip had migrated extraluminally.

Venous thrombosis around the catheter was encountered in 3 cases (0.25%). All 3 cases had significant pericatheter thrombus formation; hence, the TIVADs were explanted rather than a trial of thrombolytic agent administration. These patients were started with anticoagulation with low molecular weight heparin, and other means of venous access were obtained. One patient (0.1%) presented with the ability to infuse but could not withdraw blood (withdrawal occlusion due to ball-valve effect). Linogram confirmed the presence of fibrin sheath formation, which was successfully treated with endovascular stripping (Fig. 3). We also report a case of the TIVAD chamber inversion/flip of the TIVAD (0.1%), which happened 50 days after implantation (Fig. 4). The TIVAD was explanted for this case, and a new TIVAD was implanted on the contralateral side with anchoring sutures.

DISCUSSION

TIVAD guarantees a long-term, reliable means of venous access to oncology patients undergoing regular chemotherapy, in whom peripheral venous

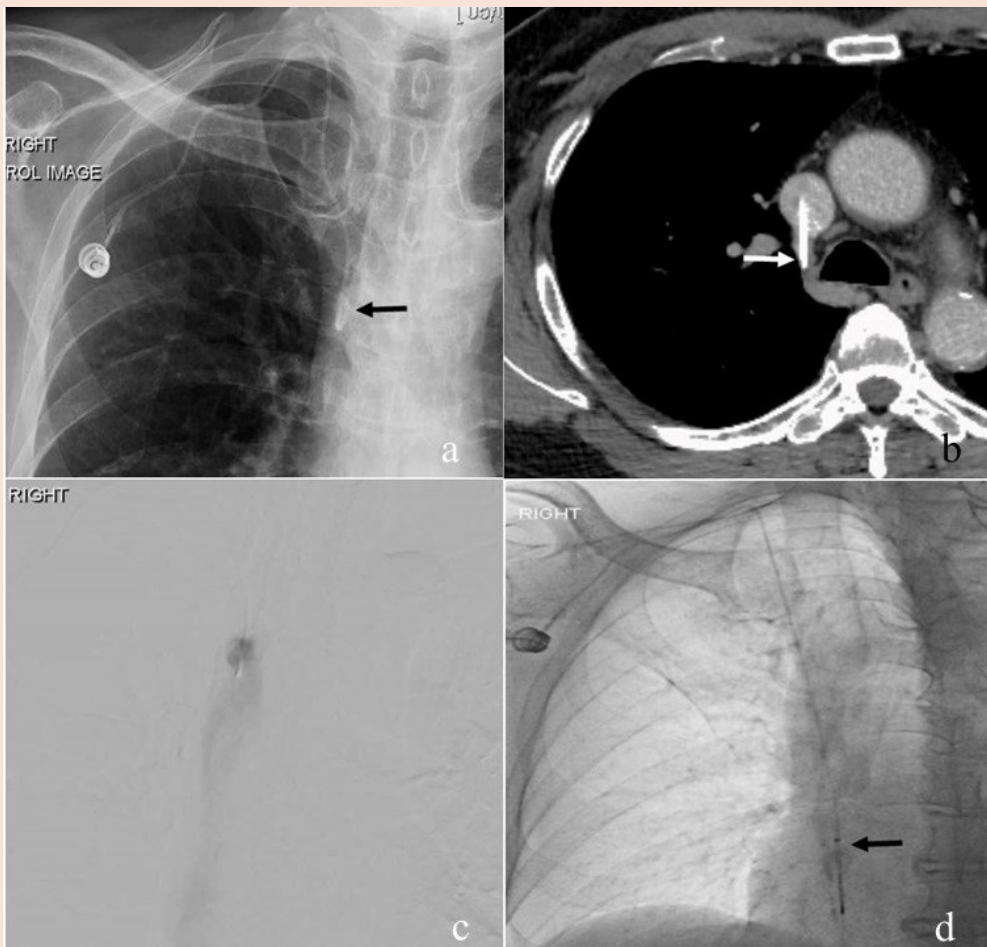
Fig. 1. Skin erosion with resultant partial exposure of the Bard PowerPort's septum and reservoir.



access often becomes increasingly difficult during the regimen. TIVAD provides better patient comfort and quality of life, offering more freedom of activity, requiring less maintenance, having a lower infection rate, longer dwell time and greater cost-effectiveness compared to external venous access catheters.^{7,8}

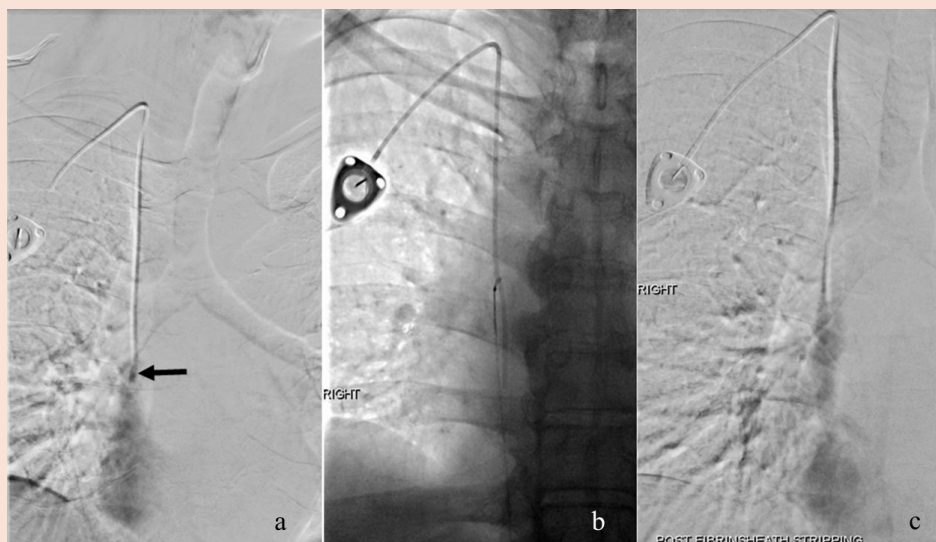
The subcutaneous pocket creation is a critical step in TIVAD implantation, and the operator must ensure that the TIVAD access site, i.e. septum, is not over the skin incision to reduce the probability of skin erosion caused by repeated punctures before adequate healing.⁹ Although the reported incidence of skin erosion in literature is up to 1%,¹⁰ this complication necessitates device explantation, as it should be considered infected even when no signs are present. The TIVAD septum should ideally be approximately 5–20 mm beneath the skin, as there is a risk of skin erosion if placed too superficial and an increased risk of difficulty in cannulation

Fig. 2. Migration of the catheter.



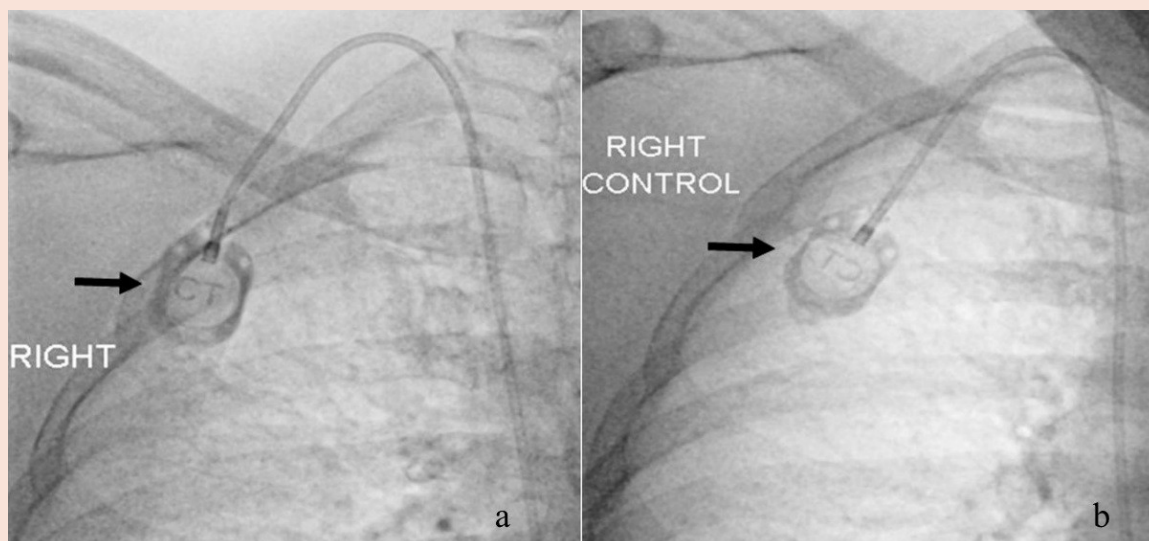
(A) The chest radiograph of a Braun Celsite Babyport shows the distal end of the catheter looping cranially and making a U-turn (arrow). (B) Contrast-enhanced computed tomography (CT) shows the catheter tip has malpositioned into the azygos vein (arrow). (C) Linogram demonstrated a patent catheter within the azygos vein, which was partially opacified. (D) The catheter tip was successfully repositioned back into the cavoatrial junction with an endovascular snare (arrow).

Fig. 3. Pericatheter fibrin sheath formation.



The patient presented with withdrawal occlusion. (A) Control linogram showed a sleeve of fibrin sheath (arrow) around the catheter with opacification of the SVC and right atrium. (B) Endovascular stripping of the fibrin sheath was performed with the aid of a loop snare catheter inserted via a right femoral venous approach. Stripping was accomplished by pulling the closed-loop snare catheter caudally. (C) Post-stripping linogram demonstrates a successful result with the disappearance of the fibrin sheath sleeve and the withdrawal occlusion.

Fig. 4. Inversion of the TIVAD chamber.



(A) Final fluoroscopic image of a Medcomp Dignity CT port. The initials "CT" were printed in reverse with radiopaque ink at the base of the TIVAD chamber (arrow) to signify that it is compatible with power injection for contrast agents. (B) On post-implantation day 50, the attending nurse could not palpate the TIVAD septum for puncture. A subsequent control radiograph demonstrated the reversal of the initials "CT" in keeping with an inversion of the TIVAD chamber. It was explanted, and a new TIVAD was inserted on the contralateral side with fixation sutures.

if placed too deep.¹¹ Choosing an appropriately sized device is crucial to reducing the risks of skin erosion and subsequent extrusion, as implanting a larger profile device in a thin patient may lead to overstretching of the overlying skin, which eventually thins out due to repetitive punctures.¹²

The right IJV is the most preferred site of access in our cohort. This is due to the straight course that the catheter takes from the point of venous access to the target position of the catheter tip with minimal points of contact to the vessel wall by the catheter, thereby reducing the risk of

venous thrombosis.^{6,13} Additionally, jugular access precludes complications unique to subclavian venous access, like pinch-off syndrome, pneumothorax, haemothorax, thoracic duct or brachial plexus injury.¹⁴

The cavoatrial junction is the optimal location for the catheter's tip as it has a reduced risk of causing arrhythmias compared to the right atrium¹⁵ and a reduced risk of catheter migration/flicking into the contralateral brachiocephalic vein (BCV), IJV or the azygos vein, which can potentially occur when the catheter tip is in the SVC. Technically, we would suggest trimming the catheter slightly longer than the target site when inserting from the left side due to the acute angulations between the left BCV and the SVC and in patients with abundant subcutaneous fat at the pocket site, as the TIVAD system will retract when the patient stands up, and the subcutaneous fat surrounding the TIVAD pocket gravitates inferiorly.¹⁶

Some earlier conventional techniques for TIVAD placement entail the use of anchoring sutures to prevent TIVAD inversion or rotation.^{3,5} We noted a curvilinear trend in the reduced use of such anchoring sutures, with 1 case (0.1%) of port inversion and 3 cases (0.25%) of TIVAD migration leading to complete catheter dislodgement. This exceedingly low incidence of TIVAD inversion is similar to the findings described by McNulty et al.,¹⁷ which stated an incidence ranging between 0 and 1.6% with or without suture fixation and suggested creating an optimal-sized subcutaneous pocket that snugly accepts the port to avert this issue. Sánchez LY et al. even encountered 3 cases of rotations (0.53%) despite using anchoring sutures.¹⁸ From the authors' perspective, avoiding anchoring sutures during TIVAD explantation offers the potential advantages of shorter procedure time and less extensive dissection, as it eliminates the need to ensure complete removal of these nonresorbable sutures similar to other groups.¹⁷

TIVAD implantation can be performed comfortably with only LA. However, it can be associated with some discomfort and a source of anxiety in some patients. Therefore, monitored conscious sedation and IV analgesia were given for some patients.

Post-procedure pain and minor bruising/ecchymosis around the implantation site are usually expected and will resolve with time. Minor haematomas have been reported in up to 8%.¹⁹ However, the presence of palpable haematoma is more significant as it can lead to difficulties in needling the TIVAD due to the inability to palpate the TIVAD septum. It can also potentially lead to issues with wound healing due

to the increased tension in the pocket caused by the accumulation of blood, which also increases the likelihood of abscess formation.¹¹ Hence, palpable haematomas causing tension at the incision site warrant evacuation by reopening the incision. Therefore, meticulous haemostasis before closure of the TIVAD pocket is paramount to prevent this complication.

A technique employed to minimise bleeding during pocket creation involves using a local anaesthetic combined with a vasoconstrictor, usually adrenaline. Although this reduces the amount of lignocaine needed to get the desired anaesthetic effect, it has effectively reduced bleeding at the operative site. This combination has effectively reduced bleeding and facilitated a safe and efficient surgical experience.²⁰

Several studies have investigated the timing of initial chemotherapy administration after TIVAD insertion. A recent study published in the Korean Journal of Clinical Oncology found that chemotherapy administration within 2 days of implantation was safe.²¹ Currently, our institution allows TIVAD usage as early as the day following the procedure, provided there are no complications. The duration between TIVAD insertion and the first access for chemotherapy was recorded for 52.6% of the cohort, with a mean duration of 3.4 days and an SD of 2.1. There have been reports of poor wound healing in patients receiving antineoplastic agents targeting the vascular endothelial growth factor (VEGF) signalling pathway. As VEGF-mediated angiogenesis in wound healing mainly occurs 4–14 days after administration, an interval of 14 days has been suggested between administration of VEGF-targeted therapy and TIVAD placement.²²

The use of prophylactic antibiotics before the implantation of the TIVAD remains controversial. Although these procedures are generally considered clean surgeries, some studies have suggested that prophylactic antibiotics may reduce the risk of surgical site infections.²³ However, other studies have found that the prevalence of surgical site infections following TIVAD implantation is low and that prophylactic antibiotics are unnecessary.^{24,25} Nezami et al.,²⁶ a study in a large cohort of 5967 patients, concluded that prophylactic antibiotics did not prevent short-term implantation-related infection; however, there was a statistically significant risk of infection when TIVADs were placed in an inpatient setting. This was thought to be due to an increased frequency of TIVAD access and a more pathogenic hospital ecosystem.

At Singapore General Hospital, prophylactic antibiotics are routinely administered during TIVAD implantation procedures, which is still perceived as the standard of care. Implantation is avoided in patients with neutropenia (ANC <1500/mcL).²⁷ Although we should strive to achieve an ideal outcome with a 0% infection rate, our reported infection rate is still low, 3.8% for TIVAD site cellulitis and 0.25% for CRBSIs. These are comparable to the reported incidence of TIVAD-associated infection in literature, ranging from 0.6% to 27%.²⁸ Besides prophylactic antibiotics and neutrophil counts, we believe that there are other clinical factors, such as diabetes mellitus; type and stage of malignancy, i.e. haematological malignancy; microbial colonisation at the insertion site; and type of chemotherapy used, may play a role in TIVAD-related infection. We hope that a dedicated trial with a detailed subgroup analysis of these factors can be considered as a prospective study in the future.

Catheter-related thrombosis is a known complication of long-term venous access. In an extensive series of 51,049 cancer patients with TIVAD insertion, 1.81% of the patients developed venous thrombosis.²⁹ Unfortunately, cancer patients have an increased risk of developing venous thrombo-occlusive disease due to their underlying prothrombotic state, with a host of them receiving potentially venotoxic medications, which can lead to endothelial damage. Other factors for increased risk of venous thrombosis are the type of central venous catheters used, insertion into the subclavian vein, longer catheter dwell time, catheter-to-vein ratio and post-insertion care of the catheter system.³⁰ A systematic review and meta-analysis have also shown that TIVADs are associated with a decreased risk of thrombosis compared to PICCs or external catheters like Hickman catheters.³²

Our group did not encounter other complications, such as accidental arterial puncture, air embolism, pneumothorax or haemothorax, due to the routine and meticulous use of ultrasound and fluoroscopic guidance during these procedures.

Study limitations

There are some limitations to our study. The patient cohort was from a single tertiary academic institution with a dedicated interventional radiology service and a high volume of TIVAD referrals, which may limit the generalisation of the results. Procedures were performed by a large number (>20) of consultants (with experience varying from <1 year to >25 years) and supervised trainees with

a diverse range of skills and knowledge, which can influence the outcome. Further statistical analysis beyond descriptive statistical analysis was not performed due to the low incidence of complications, which limits the capability of this study despite the large sample size.

CONCLUSION

TIVAD or port inserted via the jugular vein under radiological guidance is a safe, convenient and reliable means of long-term venous access, with an acceptable rate and severity of complications and a low rate of device explantation due to these complications.

We aim to increase the awareness and adoption of TIVAD in oncology patients, particularly in Southeast Asia, by sharing these findings and favourable outcomes, and look forward to more robust TIVAD studies from Asia.

Ethics statement

This study was approved by the SingHealth Centralised Institutional Review Board (CIRB 2021/2357).

Declaration

The authors declare they have no affiliations or financial involvement with any commercial organisation with a direct financial interest in the subject or materials discussed in the manuscript.

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