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Expert consensus on the clinical application of totally implantable venous access devices in the upper arm (2022 Edition)

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ABSTRACT

With the widespread adoption of ultrasound guidance, Seldinger puncture techniques, and intracardiac electrical positioning technology for the placement of peripherally inserted central catheters in recent years, an increasing number of medical staff and patients now accept peripheral placement of totally implantable venous access devices (TIVADs) in the upper arm. This approach has the advantage of completely avoiding the risks of hemothorax, pneumothorax, and neck and chest scarring. Medical specialties presently engaged in this study in China include internal medicine, surgery, anesthesiology, and interventional departments. However, command over implantation techniques, treatment of complications, and proper use and maintenance of TIVAD remain uneven among different medical units. Moreover, currently, there are no established quality control standards for implantation techniques or specifications for handling complications. Thus, this expert consensus is proposed to improve the success rate of TIVAD implantation via the upper-arm approach, reduce complication rates, and ensure patient safety. This consensus elaborates on the technical indications and contraindications, procedures and technical points, treatment of complications, and the use and maintenance of upper-arm TIVAD, thus providing a practical reference for medical staff.

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Totally implantable venous access devices (TIVADs) are primarily used for chemotherapy or parenteral nutritional support in patients with malignant tumors.[1] In China, the subclavian, internal jugular, and axillary veins are common puncture sites for TIVAD implantation. The upper arm TIVAD, also called the upper arm port (UAP), was first proposed by Starkhammar et al.[2] in a multicenter study on UAP implantation using percutaneous or venous cutdown techniques. As a result of the differences in the vascularity and anatomy of the upper limb and chest wall, upper arm TIVAD has the advantages of avoiding the risk of hemothorax and pneumothorax and preventing scarring in the neck and chest compared to chest wall TIVAD implanted via the subclavian or internal jugular vein.[3–5] Upper arm TIVAD has a wide range of applications and is easy to perform; it may be an important alternative in patients with head and neck tumors, cervicothoracic burns, bilateral breast prostheses, and severe thoracic lordosis/torsion, and in patients receiving cervicothoracic radiotherapy or molecular targeted therapy, or undergoing tracheostomy or esophagostomy.

The wide acceptance of upper-arm TIVAD has been driven by the recent success of ultrasound guidance, Seldinger puncture techniques, and intracardiac electrical positioning technology in placing peripherally inserted central catheters (PICC lines). The insertion of a UAP completely avoids the risk of hemothorax and pneumothorax and prevents neck and chest scarring. In China, TIVADs are used in various medical disciplines, including internal medicine, surgery, anesthesiology, and interventional departments. However, the command of implantation techniques, treatment of complications, and use and maintenance of TIVAD are uneven among different medical units. Moreover, no established quality control standards exist for implantation technologies or specific protocols for handling complications. Thus, this expert consensus is proposed to improve the success rate of upper-arm TIVAD implantation, reduce the complication rate, and ensure patient safety by providing a practical reference for medical staff.

1. Indications and contraindications

Indications:

- Indicate in long-term intermittent intravenous infusions, including intravenous chemotherapy and total parenteral nutrition.
- Recommend for the infusion of hypertonic or irritating fluids.

Contraindications:

- Local infection in the upper limb intended for device implantation or symptoms or evidence of bloodstream infection.
- Venous thrombosis in the upper limb intended for implantation.
- History of allergies to port and catheter materials.
- Diagnosis of superior vena cava (SVC) syndrome.
- History of radiation therapy to the upper limb or axillary area.
- Vascular occlusion, thrombosis, or previous vascular surgery at the intended implantation site.
- Severe coagulation dysfunction.

2. Preoperative assessment and informed consent

Survival assessment: Implantation of an upper-arm TIVAD could be considered for patients with an expected overall survival of over 3 months. Alternative infusion routes are generally recommended for patients with an expected overall survival of no longer than 3 months; however, the patient's preferences should be considered.

Medical history assessment: To understand the risk factors for catheter-related complications, including the history of central venous line placement and catheter-related infections, thrombosis, diabetes, and underlying cardiac diseases.

Medication assessment: To evaluate whether the patient has recently used antiplatelet, anticoagulant, or anti-angiogenic targeting drugs or has a history of medication allergy.

Laboratory assessment: To include complete blood count, coagulation, and D-dimer levels, coagulation and fibrinolytic function could provide baseline data to analyze catheter-related thrombosis. The procedure is recommended to be safer in patients with a leukocyte count $\geq 3.5 \times 10^9$/L, platelet count $\geq 50 \times 10^9$/L, and prothrombin time/international normalized ratio ≥ 1.5.[6] Otherwise, the risk of bleeding and infection may increase, and appropriate treatment should be administered before the procedure.

Imaging assessment: For patients with lung cancer or mediastinal masses, assessments should focus on the presence of SVC compression, stenosis, or SVC syndrome.

Vascular and skin assessment: To measure the subcutaneous fat thickness of the arm intended for device implantation, confirm the absence of cutaneous ulceration or infection at the puncture site, and evaluate the diameter and elasticity of the target vessel. A catheter outer diameter-to-vessel inner diameter ratio of $\leq 45\%$ is recommended. Various types and sizes of TIVAD are available; therefore, there is no particular restriction on arm circumference or subcutaneous fat thickness as long as the port can be properly accommodated.

Catheter selection: The smallest diameter catheter with fewer lumens should be selected as long as the treatment needs are met.

Informed consent: Patients and their families should be informed regarding the purpose and manner of the procedure, intraoperative cooperation tips, postoperative precautions, possible complications, and their incidence. The patient and/or a family member must be informed of the study and sign the informed consent form.

3. Places and conditions for implantation

We recommend performing TIVAD implantation in an interventional procedure room or standard operating room. Otherwise, the procedure should be completed in a dedicated central venous line placement room that meets the requirements of a Class II environment per the Sterile and Hygiene Standards for Healthcare Facilities.

Medical equipment should include but not be limited to vascular ultrasound, heart monitoring, and X-ray positioning/fluoroscopy.

TIVAD implantation is currently a Class III interventional procedure not graded in other disciplines. There is no standard *trans*-upper-arm access procedure. Trained physicians or nurses with intermediate- or high-level expertise in intravenous therapy are recommended to perform this procedure. Operators should also be familiar with alternative techniques for TIVAD implantation via the chest wall and lower limbs.

4. Sites and methods of placement

Arm selection: In the presence of breast cancer, the UAP should be placed contralateral to the side of the breast involved. Port placement should be avoided on the side of the previous axillary lymph node dissection or intended axillary radiotherapy. The UAP should be contralateral to the pacemaker or dialysis fistula. An arm with an obstructed venous pathway, which causes difficulty delivering a PICC line, should be avoided. The specific placement site depends on the patient's condition, limb status, and activity requirements.

Vessel selection: The basilic, brachial, cephalic, or the first segment of the axillary vein can be selected as the access vessel. According to the zone insertion method[7,8] (Fig. 1), the target vessel for puncture should be in the yellow or green zones because of its larger diameter and increased blood flow.

Location of the port hub: The tail of the catheter and the port hub should be placed in the green zone to facilitate patient activity, catheter use, and maintenance.[8]

Placement of TIVAD: A short-axis, out-of-plane approach with ultrasound guidance is recommended using the Seldinger technique.

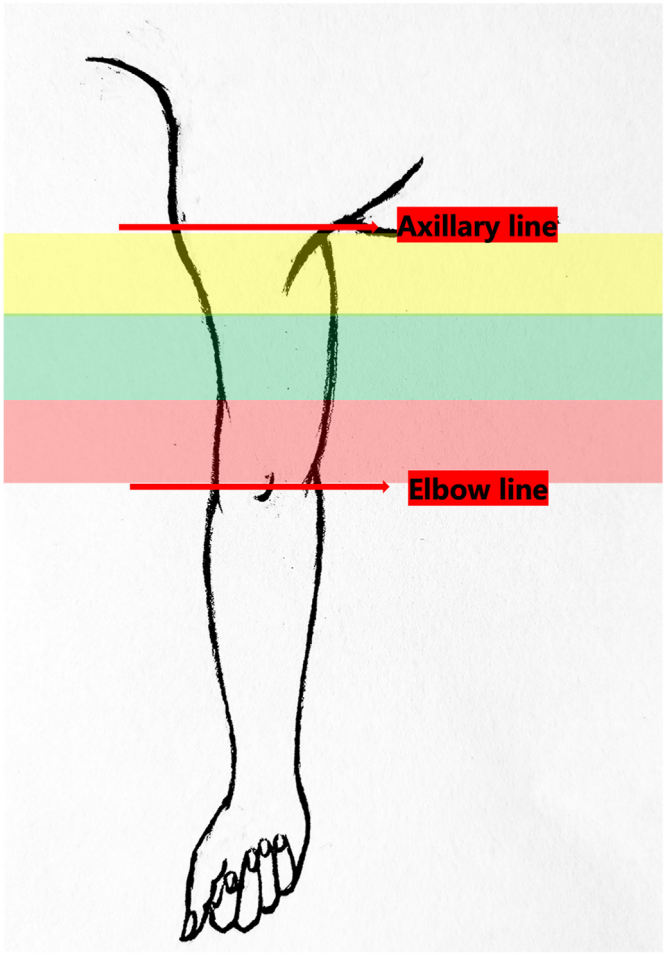

Fig. 1. ZIM partitions.
The area between the elbow and the axilla is divided into 3 equal zones: the middle 1/3 (green zone), the proximal 1/3 of the axilla (yellow zone), proximal 1/3 of the elbow (red zone).

5. Operative procedure

Step 1: Skin is cleaned from the wrist to the shoulder joint. The patient is placed in the supine position on the operating table with the upper arm exposed, abducted, and externally rotated. The entire upper arm is prepared and draped in a sterile fashion. Operators disinfect both hands and wear surgical masks, caps, and gowns, following the principle of a maximal sterile barrier.
Step 2: Local anesthesia is induced with 1–2% lidocaine. Ultrasound-guided puncture of the target vein is performed with a 21G fine needle, a 0.018-inch guidewire-exchanged micropuncture sheath is deployed using the Seldinger technique, and the guidewire is removed. The guidewire exchange requirement is determined according to the situation, and if necessary, a 0.035-inch guidewire is advanced via the micropuncture sheath. The peel-away sheath is exchanged again using the Seldinger technique, and the guidewire is removed.
Step 3: The catheter is fed through the peel-away sheath into the vessel, reaching the middle and lower thirds of the SVC, 1 cm below the carina, or the point where the catheter meets the right main bronchus under fluoroscopy. The peel-away sheath is withdrawn, and local pressure is applied to the puncture site to prevent bleeding.
Step 4: Depending on the size of the port hub, a 1.5–2 cm transverse incision is made 3–5 cm diagonally below the puncture site beside the punctured vein. The port pocket is created by the blunt separation of the subcutaneous fat. For the port pocket, it is preferable to maintain the subcutaneous tissue and fat content on the surface of the port hub. An in situ incision for direct port pocket creation is generally not recommended. However, a port pocket can be created near the puncture site in a small number of patients if space is limited. The size of the port pocket should be proportional to that of the port hub, and the skin should be sutured without tension at the wound edge so that the port hub can move slightly after suturing.
Step 5: A guiding needle is introduced into the catheter through a subcutaneous tunnel from the puncture site to the incision site. The catheter is trimmed to the appropriate length and attached to the port hub. A non-coring needle is used to puncture the port septum, draw blood, and flush with a 0.9% sodium chloride solution to confirm that the device system is unobstructed.
Step 6: Implantation of the port base into the port pocket. The port hub is usually not fixed with sutures; however, fixing the port base to the subcutaneous tissue for patients with lax tissues may avoid port-hub migration and catheter kinking.
Step 7: The subcutaneous tissue is reapproximated with interrupted or continuous sutures, preferably with absorbable sutures. A topical skin adhesive can close the skin incision and puncture site, eliminating the need to remove stitches or change dressings.
Step 8: The port should be punctured to confirm that blood can be drawn back and the injection can be pushed smoothly. X-ray images of the TIVAD are obtained immediately after surgery.

6. Catheter tip positioning

Unlike in thoracic wall access, the catheter tip in UAP is significantly affected by the motion of the upper limb. The catheter tip tends to move caudally by approximately 2 cm when the arm is adducted from an abduction position.[9,10] We recommend that the catheter tip be positioned at the middle and lower thirds of the SVC or at least 2 cm above the cavoatrial junction (CAJ) with the arm abducted intraoperatively using one of the following techniques. (1) Body-surface positioning: Body-surface measurements are commonly used in China. With the catheterized arm abducted, the distance from the puncture site to the point below the right sternoclavicular joint is measured along the course of the catheter. The measurement is reversed down to the right edge of the third sternocostal joint. This method is simple and easy to perform but is unsuitable for patients with inconspicuous body surface markings or passive body positions. (2) Electrocardiogram (ECG) positioning: The catheter is advanced until the P-wave peaks, indicating that the tip has reached the CAJ. The catheter is advanced further until a negative wave appears, indicating that it has entered the right atrium. The catheter is then retracted back to the P-wave peak and withdrawn backward for another 2–3 cm, where the length of the retained catheter is determined. (3) Positioning under X-ray fluoroscopy: The catheter is directly advanced under fluoroscopy to reach the middle and lower thirds of the SVC, specifically 1 cm below the carina or at the intersection of the right main bronchus and the SVC. (4) Electromagnetic tracking positioning: A Y-shaped thoracic body surface electromagnetic signal acquisition device is used to track the position of the magnetic guidewire tip inside the catheter in real-time, thereby tracing the entire path of the catheter tip in real-time. Although the accuracy of the combined application of this device and ECG positioning is not as high as that of positioning using fluoroscopy, radiation can be avoided.[11]

7. Common complications and management

The risks of hemothorax and pneumothorax are completely avoided by choosing the upper arm as the TIVAD puncture site. The overall complication rate and incidence of catheter-related infections and thrombosis with upper arm access are not significantly different from those with chest wall TIVADs.[4] Complications are classified according to the time of occurrence as early ($\leq$30 days after TIVAD implantation) and late (>30 days after TIVAD implantation).[11]

7.1. Common early complications

Nerve and artery injuries: TIVAD in the upper arm may cause adjacent nerve and artery injuries with an incidence of 0.2–0.6%.[12] Vascular ultrasound can distinguish between arteries (veins are easily compressed, whereas arteries are elastic and hardly compressed) and nerves (images of which are generally hyperechoic) to avoid injuries. The basilic vein is preferred because it is free of the arterial and median nerve collaterals.[13] The brachial vein is accompanied by the median nerve and brachial artery, and nerve injury during puncture may manifest as transient numbness of the forearm and fingers. When this occurs, the surgeon re-punctures by changing the puncture direction or site.

Port pocket bleeding: Port pocket bleeding is a relatively uncommon complication of upper arm TIVAD implantation, occurring in <1% of cases because the pocket can be easily compressed to stop bleeding. Risk factors for port-pocket hemorrhage include preoperative coagulopathy, inadequate intraoperative hemostasis, postoperative use of anticoagulant medications, and accidental puncture of the superficial vein. Bleeding can be effectively avoided by adequate intraoperative compression and by creating a pocket next to the puncture route. If bleeding occurs, the TIVAD should be temporarily discontinued until it stops due to compression. If bleeding worsens progressively, timely reoperation should be performed. Antithrombotic drugs should be reasonably discontinued perioperatively, depending on the patient's specific thrombotic risk.

Cardiac arrhythmia: Stimulation of the sinus node following the entry of a guidewire or catheter into the right atrium can lead to arrhythmias, which are usually transient. Patients may also experience palpitations or chest tightness. Nevertheless, hemodynamic changes are rarely observed, and arrhythmias are usually relieved by the prompt withdrawal of the guidewire or catheter. The incidence of arrhythmias ranges from 0.1% to 0.9%, including atrial fibrillation, supraventricular tachycardia, and in severe cases, ventricular fibrillation.[14,15] The use of real-time ultrasound, electrocardiographic guidance, or real-time positioning with digital subtraction angiography (DSA) during upper-arm TIVAD implantation can accurately confirm the position of the catheter tip and prevent this complication.[16]

Catheter line displacement: Displacement of the catheter into the subclavian vein, a branch of the SVC, or upward into the internal jugular vein may cause difficulty in injection, blood collection, and catheter insertion. Intraoperative ultrasound monitoring of the internal jugular vein, followed by localization of the catheter tip using electrocardiographic techniques, may exclude catheter displacement. Deep inspiration, pushing with 0.9% sodium chloride solution, head rotation, and neck compression may assist in correcting the displacement. If repeated attempts fail to reposition the catheter, adjustments should be made using fluoroscopy or DSA.

Port-hub rotation: The incidence of port-hub rotation in the upper arm is 0.4–0.5% and usually occurs within 1 month of TIVAD implantation.[17] The probability of port-hub rotation may increase with the laxity and mobility of the upper arm skin. Port-hub rotation is mainly associated with an oversized subcutaneous pocket, absence of suture fixation, strenuous activities, or external forces. Once the port-hub rotation is identified, the port can be repositioned by gently lifting the body with the surrounding skin and repositioning the port hub inside the pocket. If manual repositioning fails, an incision is required. The upper-arm TIVAD port body should generally be placed on the myofascial surface to avoid injury, and local fixation should be performed to reduce port-hub rotations. However, there is a risk of nerve damage from suture fixation, which can also make it difficult to remove the port later.[12]

7.2. Common late complications

TIVAD-related infection: TIVAD placement in the upper arm and thoracic wall share a similar risk of infectious complications[18], which are the leading causes of unplanned removal of the port hub. Local infections include skin and subcutaneous soft tissue infections at the port pocket, subcutaneous tunnel, and puncture site, while systemic infections include bacteremia and fungemia. Gram-positive cocci are the most common pathogens. TIVAD use and maintenance should be stopped once an infection is confirmed. The most effective treatment strategy for upper-arm TIVAD-associated bloodstream infections is device removal and prompt rational antibiotic therapy. Prophylactic antibiotics are generally not recommended after TIVAD implantation but may be required in immunocompromised and bone marrow-compromised patients.[19] Prophylactic antimicrobial sealants may be considered in patients who experience multiple catheter-associated bloodstream infections, despite maximum adherence to the principles of the sterile technique. Continued emphasis should be placed on training and quality control of healthcare providers regarding TIVAD implantation, use, and maintenance.

Venous thrombosis of the upper limb: This typically presents with unilateral swelling and pain in the limb on the side of the TIVAD, and varicose veins may also develop in the arm, neck, and shoulders. The incidence of symptomatic thrombosis in upper arm TIVAD does not increase compared to that in thoracic wall TIVAD. The routine removal of TIVAD is generally not recommended in the presence of catheter-associated venous thrombosis of the upper limb. Anticoagulation is the primary treatment; thrombolytic therapy can be added if necessary. Even after TIVAD removal, patients with catheter-associated thrombosis still require anticoagulation for at least 3 months to dissolve the thrombus and maintain endothelial coverage to prevent the recurrence of thrombosis.[20] For central venous access devices to remain in place after thrombosis, the duration of treatment should be appropriately extended during the retention period. Central venous catheter-associated thrombosis prevention by routine anticoagulation therapy is not recommended. Whenever possible, patients should be encouraged to use non-pharmacological means, such as early limb activity, normal activities of daily living, proper limb exercises, and adequate hydration to prevent thrombosis.[21]

Catheter occlusion: Catheter occlusion manifests as a poor infusion or injection and difficulty drawing blood. Common causes include catheter twisting or fracturing, displacement or occlusion of the butterfly needle, fibrin sheath formation, and catheter occlusion by blood or medication. When the catheter system is obstructed, incorrect needle positioning and occlusion of the port needle, or external connections should be ruled out. If catheter occlusion is suspected, normal catheter alignment and tip position should be confirmed by chest radiography. If there is no migration, the presence of a thrombus or fibrin sheath is evaluated using angiography or ultrasonography. Mechanical occlusion requires examination of the entire infusion system and repositioning of the catheter tip or the patient before recanalizing the catheter. Pharmacological occlusion requires a review of the patient's medication history and the selection of an appropriate lysis agent based on the medication's properties. Treatment with thrombolytic urokinase is preferred for thrombotic occlusion. Timely and properly flushing and sealing the catheter to reduce drug or blood residues in the catheter and port base can effectively prevent occlusion. The solution strategy for catheter occlusion should be based on the three main causes (mechanical, pharmacological, and thrombotic) –to achieve recanalization promptly and avoid delay and treatment interruption.

Secondary migration: Secondary displacement can occur at any time during catheter retention. It may be associated with sudden changes in intrathoracic pressure (e.g., violent coughing and vomiting), high position of the original tip in the SVC, congestive heart failure, or significant arm movement and tumor location (i.e., lung cancer).[22,23] Secondary catheter migration may be asymptomatic or manifest as infusion dysfunction and can be diagnosed using radiography or DSA. Displacement can be corrected using interventional techniques or reoperations under DSA.

Port-hub exposure: The leading causes of port-hub exposure are too small a port pocket, too shallow subcutaneous implantation of the port hub, or skin breakage induced by local infection or drug extravasation.[24]

The port pocket should be sized according to the port hub size during the initial operation. If infection or extravasation causes skin breakage at the port pocket, relocation of the port hub to a new, nearby pocket can be considered once local infection or injury is controlled.

Drug extravasation: The incidence of extravasation of infused chemotherapeutic agents is 0.01–6%. The reasons for this include migration of the non-coring needle due to improper arm positioning on the port side, loosening due to poor fixation, failure to pierce the bottom of the injection base, formation of a fibrin sheath in the TIVAD, detachment of the catheter lock, damage to the membrane of the port hub, and rupture of the catheter.[25] The non-coring needle should be of an appropriate length for the implanted device to ensure that the puncture is in place and properly fixed. High-pressure injections are prohibited in non-high-pressure-resistant catheters. A syringe of 10 mL should be used to flush and seal the catheter, and patients should be well informed. Patients must be carefully monitored during infusion, and complaints should be taken seriously.

Upper-limb motor limitation: Catheter-associated upper-limb motor limitation is a unique late complication of TIVAD in the upper arm, with an incidence of approximately 1.1%. Affected patients usually complain of shoulder joint pain, difficulty in upper arm elevation and abduction, and an inability to fully extend the forearm 2–3 months after TIVAD implantation. The exact cause remains unclear and may be related to local vascular fibrostriatal changes, asymptomatic thrombosis, restriction of limb movement on the port side, and the patient's fear of movement after port placement.[26]

7.3. Rare complications

Anesthetic allergy: Although TIVAD in the upper arm is less invasive and requires only local anesthesia, patients should be routinely asked about their drug allergy history before surgery. Anesthetics should not be injected into a vein or artery during surgery. Anesthesia should be administered with extra caution if patients receive additional sedation or analgesic treatment, and patients should be monitored carefully during the procedure. If pallor, decreased blood pressure, urticaria, or other allergic symptoms are noted immediately after the infiltration of local anesthesia, allergic reactions should be considered.

Catheter breakage or fracture: Breakage or fracture of the catheter in the upper arm TIVAD is rare and may be related to factors such as the compromised connection between the catheter and port hub, angled catheter, improper activity, or improper operation. Patients may have no apparent symptoms, and breakage may be detected incidentally during catheter obstruction or chest scanning. The preferred treatment method is endovascular removal using a grasper under fluoroscopy.[27]

Upper limb venous reflux disorder: This can occur 4–5 months after TIVAD implantation and manifests as swelling and bruising of the arm on the side of the port after occasional exertion or heavy lifting. In some cases, the congestion and engorgement of the forearm veins diminish over time. Once thrombosis is excluded by ultrasound and D-dimer testing, causes such as local vascular compression, slow blood flow, and transient compensatory insufficiency of blood flow should be considered.

Lymphatic leakage: The lymphatic network is rich in the upper limbs. Surgical trauma involving the implantation or removal of an upper-arm TIVAD may cause lymphatic leakage from the port pocket and wound. Local pressure or suturing may be effective if necessary.

8. Use and maintenance of the upper arm port

Proper and standardized use and maintenance are crucial to prevent complications and extend the life of TIVAD.[28,29] Specifically, they include the following:

- Strict adherence to the principles of sterile technique.
- Chlorhexidine disinfects the port hub and surrounding skin more than dressing.
- Choice of the proper type of non-coring needle and assurance that the fluid outlet of the non-coring needle faces away from the port-catheter junction.
- Blood is drawn to assess catheter function. If blood return or hard pressure is not required, the cause should be determined.
- Application of positive pressure flush techniques using 0.9% sodium chloride or heparin sodium as a locking solution[30];
- Avoid injecting radiocontrast agents with a high-pressure syringe pump unless using high-pressure-resistant catheters.
- Routine monthly flushing and maintenance of the catheter between treatments. Some studies have suggested that flushing once every 3 months is safe and effective, but further evidence is still pending.[30,31]

9. Patient education

Careful education of patients and their families can effectively reduce the risk of complications associated with upper arm TIVAD. In particular, patients should.

- Protect the wound and avoid contact with water when bathing for 2 weeks postoperatively.
- Wear loose tops during port placement to avoid needle slipping by pulling.
- Engage in unrestricted daily activities but avoid strenuous arm-waving movements and exercise of the arm with the port.
- Routine monitoring of the complete blood count during chemotherapy, particularly for early detection and management of myelosuppression and to prevent severe infectious complications.
- Promptly contact their healthcare provider with the port in cases of unexplained high fever, localized redness, swelling, pain, or arm swelling.
- Careful tracking of the device maintenance manual and medical team contact details

10. Removal of the upper arm port

10.1. Indications and timing for removal of the TIVAD in the upper arm include

- Conservative measures cannot resolve complications, including infection, thrombosis, and catheter rupture.
- The patient requests it, even when treatment is not completed and the port is in normal use.
- Treatment completion and confirmation that no further intravenous fluid therapy is required in the short term.

10.2. Removal steps are as follows

Step 1: The patient is placed in the supine position with sterile preparation of the operative field.
Step 2: Infiltration with local anesthesia is followed by an incision of the skin and subcutaneous tissues along the original incision at the port pocket site. The fibrous adhesive tissue on the surface of the port is bluntly separated using forceps.
Step 3: The catheter is slowly withdrawn, the proximal end is lifted, and the port is removed smoothly to confirm that the entire TIVAD device is intact and undamaged.
Step 4: The pocket is compressed to ensure hemostasis, and the incision is closed with stitches.

Author contributions

All authors contributed to the paper. The first draft of the manuscript was written by Xiaoxia Qiu, Guangxin Jin, and Xuebin Zhang, and all authors commented on the versions of the manuscript. Xiaoxia Qiu, Guangxin Jin, and Xuebin Zhang contributed equally to this work.

Xiaoxia Qiu, Xuebing Zhang, and Lichao Xu are all responsible for the revision and editing of the article and their contributions are equal. All authors read and approved the final manuscript.

Declaration of competing interest

Lujun Shen is an youth editorial board member for Journal of Interventional Medicine and was not involved in the editorial review or the decision to publish this article. All authors declare that there are no competing interests.

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