



Shanghai expert consensus on totally implantable access ports 2019



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ABSTRACT

Totally implantable access ports (TIAPs) are used for patients with poor peripheral vascular support requiring central venous access. In recent years, TIAPs have been gradually accepted and promoted by patients, doctors, and nurses owing to their advantages of convenient carrying, a long maintenance period, low complications, and a high quality of life for patients. Currently, medical personnel that handle TIAP implantation and management in China are from different areas of healthcare, including surgery, internal medicine, radiology, nurse anesthesia, vascular access, etc., and many only handle TIAP as a part of their duties. Therefore, the operating procedures and steps for the diagnosis and treatment of complications of TIAP vary from person to person, resulting in different incidence and treatment methods for complications in the implantation and use of TIAP in different medical units. Based on this, we have updated the Shanghai expert consensus on TIAPs from 2015 and explored the diagnosis and treatment procedures of related complications while continuing to emphasize standardized implantation and maintenance.

1. Introduction

In 2015, the first Chinese expert consensus on intravenous implantable venous access ports was released.¹ After the consensus was released, the resulting attention and recognition by relevant medical peers effectively promoted the development and popularization of standardized procedures for the implantation and maintenance of access ports. During the communication and study that followed, we found that a specific diagnosis and treatment process for the complications related to intravenous access ports was needed. Therefore, we updated the Shanghai expert consensus on access ports and continued to emphasize the standardization of the implantation and maintenance procedures and explored the diagnosis and treatment process for related complications.

2. Selection of port location and access port standards

At present, the chest wall and the upper arm are the most common port locations, using a chest wall port and an upper arm port, respectively.

The body of the chest wall port is implanted into the superficial fascia of the pectoralis major. The appropriate pouch size with a thickness of 0.5–1 cm should just be able to accommodate the appropriate port body. A flat place should be selected for the location of the pouch so that it is not easily squeezed and rubbed through normal activities, avoiding skin with radiotherapy or tumor invasion and areas with lymph node metastasis. The privacy of the patient should be considered as much as possible.

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The body of the upper arm port is implanted on the inner side of the upper arm, and the incision of the pouch is located more than 7 cm from the medial epicondyle of the humerus of the elbow joint.² It is recommended that a subcutaneous short tunnel of about 3 cm be made to accommodate. Upper limbs with an axillary lymph node dissection should be excluded.

An upper arm port is currently recommended as an alternative option to patients who are unable to be implanted in the chest wall or who have special requirements for the position of the pouch.

In selecting the size of the access port, the thickness of the subcutaneous tissue should be fully considered, and it should be easy for nurses to touch the pins. For thin patients, a small access port should be selected to alleviate skin tension of the pouch and a finer catheter should be selected under the premise of meeting the normal requirements.³

3. Access vein selection and guidance

Currently, the options for vein access for the chest wall port mainly include the internal jugular vein, the subclavian vein, and the third segment of the axillary vein, etc. The options for vein access for the upper arm port mainly include the basilic vein, the first segment of the axillary vein, the brachial vein, etc. In making the vascular selection, the diameter ratio of catheter/vein must be less than 45%.⁴

It is easy to cause complications such as a pneumothorax, hematoma, nerve damage, and pinch-off syndrome when puncturing a vein based on body landmarks; therefore, ultrasound-guided percutaneous puncture catheterization is recommended.^{5,6}

4. Options of implanted catheter for access port under special conditions

In patients with obstruction of the superior vena cava or a neck or chest that is not suitable to make a pouch, lower extremity veins (e.g., the femoral vein) could be considered for access. The end of the catheter should not be placed at the confluent level of the bilateral common iliac veins or below (due to a high incidence of thrombus or fibrin sheath). It is recommended that the port be placed above the level of the renal vein opening (not currently due to evidence-based data, but only opinions of experts based on experience). The main problems with venous catheterization of lower extremity veins include a high incidence of thrombosis, catheter displacement, or infection. However, whether prophylactic anticoagulant therapy is needed is still inconclusive. For some high-risk populations with limited activity and the long-term bedridden, prophylactic anticoagulant therapy may be beneficial.

5. Aseptic operations

Access port implantation should strictly follow the principles of surgical aseptic operations, including:

- a. The largest sterile barriers include wearing a surgical hat, mask, sterile gloves, and sterile surgical gown and using a sterile cloth to cover the entire body of the patient.⁷
- b. Air treatment in the operating room and the cleaning of environmental surfaces.
- c. Skin preparation for the implantable surgical area; skin disinfection and drape; disinfection range more than 15 cm from the surgical incision; waiting for the natural drying of disinfectant on the skin.^{8–10}
- d. Disinfectant use: If there is no contraindication, it is recommended to routinely disinfect the skin with alcohol-containing disinfectants before surgery. Povidone-iodine-ethanol, chlorhexidine (>0.5%) ethanol may be the best option at present.^{8–10}
- e. Decrease tissue damage, bleeding, and dead space during surgery.
- f. Dressing covers the wound after surgery.
- g. Prophylactic antibiotic use is not recommended.

6. End position of the catheter

The end of the catheter should be located in the cavoatrial junction of the superior vena cava and the right atrium to decrease the incidence of catheter dysfunction during indwelling. Intraoperative X-ray is recommended for proper positioning. An effective X-ray localization method includes that the catheter can be located under the tracheal carina (40.3 ± 13.6 mm)¹¹ or 2.4 vertebral body units,¹² and 2.9 cm below the right main bronchus.¹³ Intracardiac electrocardiogram localization is a recommended alternative option when intraoperative X-ray positioning cannot be used.¹⁴

7. Standardized maintenance of access ports

The maintenance and use of an access port, complication monitoring, and patient education should be carried out by personnel who have received relevant training and assessment.¹ Key points of access port maintenance and use include:

- 6.1 Strictly perform aseptic procedures.¹⁵
- 6.2 Evaluate by observing, touching, and actively asking the patient: determine whether there is redness, swelling, pain, or exudation in the area of the port body and the surrounding skin, whether the port body and the catheter have separated, whether the port body is turned over, and check the chest and neck of the same side for swelling, whether the ipsilateral arm circumference is thickened and other suspected thrombosis symptoms, and understand the thickness of the port body and the depth of insertion to provide a reference for the selection of non-invasive needle models.^{1,15}
- 6.3 A 2% chlorhexidine gluconate solution (with caution regarding use with an infant less than 2 months of age) is preferred for skin disinfection, while iodophor (with the effective concentration of iodine not less than 0.5%) or 2% of iodonium solution and 75% ethanol can also be used. Once the skin is completely and naturally dried, the needle can be inserted.
- 6.4 Use a non-coring needle or Huber needle for the puncture.^{15,16} 1) A needle with appropriate size and length should be selected according to the purpose of needle, the nature of the infusion, the physique of the patient, and the placement depth of the port body. In general, the minimum size of non-invasive needle should be used under the premise of meeting treatment needs, and the needle should be safely located at the bottom of the injection seat. Guideline recommendations¹⁷ include the following: When used for intravenous infusion including antibiotics and chemotherapy drugs, the size of non-invasive needle should be 20–22 G; when used for blood product infusion and parenteral nutrition, the selected needle size should be 19–20 G. The commonly used length is 19 mm. 2) Before the needle is inserted, patients need to be assessed for pain relief requirements and wishes, including the possible use of a local anesthetic such as a freezing spray, lidocaine, etc. 3) The non-invasive needle bevel face is opposite to the interface of the injection seat catheter lock to maximally and effectively flush the injection seat reservoir and catheter. 4) For patients with continuous infusion, the needle location should be replaced in a planned manner to help skin heal and prevent local infection. 5) When removing the needle, the non-dominant hand can be used to secure the access port body. The dominant hand gently removes non-invasive needle to prevent needle stick injury. After disinfecting the puncture point, a sterile dressing is applied for local skin healing.
- 6.5 In the continuous infusion, non-invasive needles, transparent dressings, and infusion joints should be replaced every 7 days.¹⁸ The gauze dressing should be changed every 2 days; when the dressing is wet, loose, contaminated, or damaged, it should be replaced immediately; when the joint is detached, contaminated, or damaged, it should be replaced immediately. If the gauze

dressing pad is under the non-invasive needle and transparent semipermeable membrane dressings and does not interfere with observation of the puncture site, the replacement frequency is the same as that of the semipermeable membrane dressings.¹⁵

- 6.6 Before each infusion, a syringe of at least 10 mL should be used for testing; the function of the catheter is evaluated by withdrawing and rinsing. If there are any catheter dysfunctions such as pumping without blood return and/or pushing with resistance, they should be treated immediately.
- 6.7 After infusion of a drug solution, blood product, or nutrient solution and between incompatible drugs, normal saline (unless there are drug contraindications) should be used for pulse tube flushing; after the infusion is flushed with saline flushing, 0–100 U/mL of heparin saline is used for positive pressure sealing of the tube. The prefilled flushing device is the first option for flushing and sealing.¹⁵
- 6.8 Pay attention to any complaints from the patient during the infusion. If any of the following conditions occur, it should be treated immediately: 1) The infusion speed changes; 2) The patient has pain, burning, swelling, or other discomfort, or dampness or leakage at the puncture site; or 3) The dressing is loose, damaged, etc.
- 6.9 During the treatment interval, it is recommended that the access port undergo regular maintenance every 4 weeks.^{15,18}
- 6.10 For pressure injection, a high-pressure-resistant access port and non-invasive needle should be used. At the time of the pressure injection and after the injection, the risk of catheter rupture or ectopy should be guarded.¹⁵
- 6.11 Patients and/or caregivers are provided with individualized education according to age, education level, cultural factors, etc., including: the type of access port, identification and treatment of potential complications, and precautions for daily activities, etc.^{19–21} It should be emphasized that medical staff should be informed immediately when any of the following conditions occur at home: 1) body parts around the port appear red or swollen or if there is any feeling of burning or pain; 2) unexplained fever (body temperature over 38°C), chills, or hypotension, etc.; 3) discomfort such as swelling or pain in the shoulders, neck, or upper limbs of the catheterization side.

8. Implantable access ports for children

Access port implantation and maintenance methods are basically the same for children as they are for adults. For children who cannot cooperate with surgery, they need to be assisted by sedation anesthesia. Ultrasound-assisted lower internal jugular vein puncture is preferred for vessel puncture.²² Intraoperative X-ray-assisted positioning is recommended, and the positioning method follows the adult procedure. If conditions permit, real-time positioning by esophageal ultrasound can be used intraoperatively. Echocardiography and ECG positioning can also be used for neonates.²³ For children with a relative lack of subcutaneous fat, it is recommended to place the pouch in the pectoralis major to avoid the port body wearing on the skin to form pressure ulcers. As children are active, it is recommended that the port body is sutured in-place to the surrounding tissue to prevent the port body from turning over.

9. Common complications of access ports

It is critical to work to prevent access port-related complications. If complications do occur, in view of the access port being an invasive implant device, if the patient needs to continue to use the port, relevant measures can be taken to preserve port access as much as possible; if treatment is not effective or the patient no longer needs to continue to use access port, it should be taken out as time permits.

9.1. Infection

Infection is a complication that seriously affects the lifespan of the access port, including the skin, the tunnel, the pouch, and infection in the port body.

- 9.1.1 When skin, pouch, or tunnel infection occurs, the use and maintenance of the access port should be terminated; if drainage occurs, bacterial culture and drug sensitivity tests should be performed with local debridement and systemic anti-infective therapy; it can be reused and maintained once the infection has been controlled. If the pouch skin has been damaged, the port body can be transferred nearby after the local infection is controlled; another pouch can be made while the original one can be sutured.
- 9.1.2 The typical manifestations of infection in the access port body include chills and high fever accompanied with elevated white blood cell counts after the use or maintenance of the access port. If infection of the access port is suspected, use of the access port should be suspended; blood sampling, cultures, and drug sensitivity tests should be simultaneously carried out in the port body and the peripheral blood. Sensitive antibiotics should be used for systemic treatment according to the results of the drug sensitivity tests. The port body uses the "antibiotic lock" technology for sealing (different types of antibiotics, concentration, sealing time, and number of repetitions are still under investigation, please refer to Ref. 24).

After anti-infective treatment is demonstrated to be ineffective, or when the infected bacteria are identified as *Staphylococcus aureus* or *Candida albicans*, the access port should be taken out as time permits.

9.2. Intravenous thrombosis

Venous thrombosis occurs in the vein of the implanted catheter and is classified as either asymptomatic or symptomatic thrombosis. Asymptomatic venous thrombosis is usually identified incidentally through examination while patients with symptomatic thrombosis have relevant clinical symptoms including discomfort in the catheterization location or ipsilateral upper limb, pain in the ipsilateral shoulder, swelling and congestion in the face or neck, headache or head swelling; signs on the body: veins-nets occur in the neck, upper limbs or chest, while the catheterization location and the limbs incur swelling, fever, erythema, tenderness, edema, and induration along the vein accompanied with pain.^{25,26} Ultrasound is recommended as a preferred diagnostic method, along with venography if necessary.²⁷

Treatment consists of the use of an anticoagulant for 3–6 months, such as low-molecular-weight heparin or rivaroxaban^{28,29}; thrombolytic therapy can only be an option for patients with anticoagulation therapy whose symptoms cannot be alleviated or whose symptoms are aggravated. Patients with anticoagulation and thrombolytic therapy have a risk of bleeding and should be thoroughly informed.

After treatment, if the symptoms of the patient are relieved and the catheter still needs to be used, anticoagulant therapy should be continued until the access port is taken out. If the patient's symptoms are not relieved, or the patient has no further need for the use of the catheter, the access port should be removed and anticoagulant therapy should be continued for at least 3 months after the removal of the access port.²⁶

9.3. Catheter occlusion

Catheter occlusion manifests as the dysfunction of the bolus injection and the withdrawal of blood. After mechanical catheter compression factors are excluded, occlusion of the catheter content is considered, and thrombus is the most common indication followed by drug precipitation. Treatment method: For thrombotic occlusion, the administration of

urokinase 5000–10000 U/mL, or alteplase (rt-PA) 1 mg/mL, positive pressure sealing, extraction after 30–120 min, and repeating the above steps.

9.4. Fibrin sheath

A fibrin sheath is vascularized fibrous connective tissue that is further developed by a fibrin-containing thrombus covering the surface of the implanted catheter. A fibrin sheath envelops the outer wall of the catheter and the end hole of the catheter, which may result in a loss of function of the catheter, and may also result in infection, thrombosis, and even pulmonary embolism after pulling out.^{30,31} For a fibrin sheath, difficulty in withdrawing blood is the main problem, but bolus injection is normal or slightly resistant and patients have no discomfort during bolus injection. Wall-sticking of the catheter end and the three-way valve need to be excluded. Venography is an imaging method commonly used and recognized internationally to see whether there is still contrast of a tubular sheath-like image at the location of the catheter.³²

Transcatheter thrombolysis is a common treatment method for a fibrin sheath,^{33–35} but the contraindications of thrombolysis need to be excluded. Urokinase, streptokinase, and alteplase (rt-PA) are commonly used drugs. Common methods: 1) 15000 IU of urokinase is dissolved in 1.5 mL of normal saline (0.25 million units of urokinase and physiological saline dissolved into 25 mL, with 1.5 mL extracted) and injected into the access port.³⁶ 2) 2.5 mg of alteplase (rt-PA) is dissolved in 50 mL of normal saline and injected at a rate of 17 mL per hour for 3 h.^{34,37} Other methods include changing the catheter³⁸ or pulling the fibrin sheath through the femoral vein through the arrester.^{39–41}

9.5. Catheter end displacement

Displacement of the catheter tip can occur in surgery because the catheter is not implanted into the superior vena cava, but into another vein during catheter implantation. The occurrence of catheter tip displacement is mainly associated with very superficial implantation into the superior vena cava, strenuous activity of the arm and shoulders, or repeated vomiting and coughing during catheterization. After the end of the catheter is displaced, it can cause complications such as thrombosis and a fibrin sheath which can affect catheter function and needs to be adjusted as soon as possible. Interventional radiology techniques can be used to correct displacement of the catheter by using the arrester, or the catheter can be adjusted to the upper cavity veins under incision fluoroscopy.

9.6. Damage or rupture of catheter

The causes of catheter damage or rupture²⁰ include: 1) pinch-off syndrome⁴²; 2) some uncertain external force, such as seat belts, overly tight clothing, or squeezing that can lead to catheter damage, a common problem with the subcutaneous tunnel catheter position across the front of the collarbone⁴³ as well as the fold location of the catheter; 3) a small diameter of syringe is used with a high-pressure injection; 4) at the connection of catheter body and the port body, if the two are at an angle, damage can occur, typically associated with chronic stress and improper operation.

Most patients have no obvious symptoms. During maintenance or use, patients have discomfort such as distending pain and cold at the location of the pouch and the running area of the catheter. The catheter rupture is often discovered through maintenance, when the blood cannot be drawn back, or it is incidentally discovered on chest radiograph.⁴⁴ A few patients have symptoms such as heart palpitations and arrhythmia. The ruptured catheter may drop into the superior vena cava, the right atrium, the right ventricle, or the pulmonary artery, which may lead to myocardial perforation, thrombosis, or even pulmonary pseudoaneurysm. The most common drop location of the catheter is between the vena cava and the right atrium.⁴⁵

Imaging examinations are the primary method for diagnosing catheter damage and rupture with chest radiography being the most common diagnostic tool for catheter rupture. If catheter damage is suspected, angiography is necessary, which could identify that the contrast agents pass through the broken catheter and extravasate to the area surrounding the catheter.

If a catheter crack is found, the catheter should be pulled out immediately to avoid the catheter from rupture and serious complications such as embolism. If a catheter breaks off, the preferred method is to remove it under X-ray fluoroscopy by the arrester.^{46–48}

10. Comprehensive management of access ports⁴⁹

Intravenous access ports are for long-term central venous access. In order to ensure the safety of this access, comprehensive tracking and management should be performed from the time of implantation, throughout the port's lifespan, and through to removal. All relevant information of patients receiving venous access ports should be electronically recorded. The relevant information during implantation, use, and maintenance should be recorded, especially the time, cause, diagnosis, and treatment of patient complications and results, so as to track each patient through the follow-up system, analyze the complications, identify the problems, and implement an improvement plan, thus continuously improving the safety of the access. Comprehensive management also needs the cooperation of a multidisciplinary team including implantation physicians, access nurses, nurses using the access port, as well as the departments of radiology, interventional radiology, ultrasound, and laboratories, to identify complications in time with early diagnosis and treatment and prevent serious complications.

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