Comparison of Two Methods of Removing Totally Implantable Vascular Access Devices- A Single-Center Experience

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Research Article

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Abstract
In recent years, totally implantable vascular access devices (TIVADs) are widely used for infusion of high-concentration chemotherapeutic drugs and total parenteral nutrition solution, mainly in cancer patients. While there is no definite optimal time and detailed surgical procedures for the removal of TIVADs. The purpose of the study was to investigate the effects and complications of different removal approaches of totally implantable vascular access devices (TIVADs). A retrospective analysis was performed on 205 breast cancer patients who underwent TIVAD removal between June 2019 and November 2019. The patients were randomly divided into two groups. There were 102 cases in group A, in which the port was removed before the catheter. There were 103 cases in group B, in which the catheter was removed before the port. The systematic analysis focused on operation time and postoperative complications (pain, local skin infection, and hematoma). There were no significant differences in postoperative pain, wound infection, and hematoma between the two groups ($P > 0.05$). The operation time was significantly shortened in group A ($P < 0.01$). There were no significant differences in postoperative complications between the two groups. The operation time could be significantly reduced by adopting the strategy of removing the port before the catheter.

Introduction
Totally implantable vascular access devices (TIVADs), first introduced in 1982,¹ are widely used for infusion of high-concentration chemotherapeutic drugs and total parenteral nutrition solution, mainly in cancer patients. It is an implantable and long-term indwelling central venous infusion device embedded in subcutaneous tissue, which can be divided into two parts: a port and a catheter. Several studies have confirmed that the merits of the TIVAD are a safe route to the central vein, long-term maintenance, and comfort for the patients in clinical application.²–⁵ At the end of treatment, the removal of TIVADs is a basic and important procedure. Historically, removal of TIVADs is usually conducted by an interventional radiologist or a surgeon. There is already a routine procedure for interventional radiologists, nurse practitioners, and physician assistants who remove these devices daily. However, the removal sequence of port and catheter is per operator preference. To date, a related Medline search restricted to the English language has found little pertinent citations describing the surgical technique and postoperative complications.⁶–⁸ In the present study, we aimed to compare the TIVAD removal approaches based on our single-institution technical experience.

Methods
Patients
This prospective cohort study was conducted at Breast Disease Center of the Fourth Hospital of Hebei Medical University (Shijiazhuang, China), and 205 adult female patients with breast cancer who underwent of TIVAD removal between June 2019 and November 2019 were enrolled in the current analysis. Eligible patients were females with breast cancer and older than 18 years, who were scheduled...
for TIVAD removal at more than 3 months after chemotherapy. Exclusion criteria were set as follows: (1) patients who were unable to sign informed consent, (2) inability to stand for a preoperative chest X-ray, (3) history of diabetes or abnormal white blood cell count and clotting tests (international normalized ratio >2, or platelet count <40,000/mm$^3$ or >1,000,000/mm$^3$), (4) patients taking antiangiogenic drugs (such as anti-vascular endothelial growth factor antibody).

The patients were randomly and evenly assigned into two groups following the simple randomization procedures (computerized random numbers). There were 102 cases in group A, in which the port was removed before the catheter. There were 103 cases in group B, in which, in contrast to group A, the catheter was taken out first, and then the port was removed.

This retrospective study was approved by the Hospital Ethics Committee and patients’ informed consent.

**Type of port systems**

All the TIVADs used consisted of a silastic port with a silicone membrane connected to a silicone rubber catheter (8F, Groshong catheter, BARD X-Port isp™, CR Bard Inc., Murray Hill, NJ, USA). All the TIVADs were inserted in the internal jugular vein, and the ports were embedded in the lowest part of the deltopectoral groove about two fingers under the inferior border of the clavicle with no suture and fixation.

**Procedure for TICVAD removal**

The removal of TIVADs was performed in the central catheter room by the same surgeon under local anesthesia without the use of electrocautery. The operative procedure was as follows:

(1) The patient was placed in a supine position with his head tilted to the opposite side and arm slightly abducted.

(2) The operation area was disinfected with iodine and ethanol, and sterile sheets were laid. In addition, 1% lidocaine was used for local anesthetic infiltration.

(3) Two different strategies were used to remove TIVADs.

In group A, the port seat was taken out first, and then the catheter was removed (Fig. 1). After administration of local anesthesia with 1% lidocaine on the previously labeled landmarks, the skin was incised along the previous scar, subcutaneous tissue was dissected, and the position of the catheter lock was determined by palpation. The scalpel blade was inserted parallel to the catheter lock toward the port fibrous capsule to prevent cutting the catheter (Fig. A1). After the port was exposed (Fig. A2), hemostatic forceps were used to bluntly enlarge the opening of the fibrous capsule, the port was flipped (Fig. A3), and the TIVADs were removed with careful manual compression on the insertion point of the catheter (Fig. A4). At last, the catheter surrounded by the fibrous capsule was removed from the location within the vein and tunnel through blunt dissection.
In group B, the catheter was removed before the port seat (Figure 2). After the skin and subcutaneous adipose tissue were incised along the original incision, the fibrous capsule was opened with a scalpel blade along the long axis of the catheter lock to expose the catheter lock (Fig. B1). After blunt dissection, the catheter surrounded by the capsule was mobilized, and the deep side of the catheter lock was fixed by mosquito-type vascular forceps to lift the catheter lock and connect the catheter (Fig. B2). Then the catheter was dissected from the enveloping capsule without damaging it (Fig. B3), the opening of the fibrous sinus around the catheter was ligated, and the port was removed in the same way (Fig. B4).

(4) After the port was removed, the fibrous capsule was slightly punctured with the tip of the blade, which facilitated the growth of granulation tissue into the closed residual cavity. The next step was to vigorously irrigate the pocket with 10−20 mL of sterile saline.

(5) For skin closure, a discontinuous suture for deep tissue was performed with 3-0 non-absorbable suture (Johnson & Johnson, SA84G, USA), and then a subcuticular continuous intradermal suture was performed with 4-0 sterile absorbable multistrand suture (Johnson & Johnson, VCP422H USA). A bandage was applied using sterile excipients.

(6) The integrity of the catheter was examined.

**Main outcome measurement**

After the operation, all patients were given a Visual Analogue Score (VAS) for pain and asked to fill it under the guidance of the assistant doctor. These patients were also instructed to have a wound check within 7 days to ensure proper healing. A team consisting of a physician assistant and an attending physician followed the patients and collected the information.

The operation time and postoperative complications (pain, local skin infection, and hematoma) were measured. The operation time was determined from the time when the patient received local anesthetics to the time when the aseptic dressing was applied after skin closure. Patient pain was evaluated after the surgery using a VAS ruler as follows: 0 point, no pain, 1−3 points, mild pain, and >3 points, moderate-to-severe pain. Local skin infection was defined by the presence of erythema and/or tenderness over the skin sack and along the tunneled catheter to the vein access. All patients consented to complete the questionnaire and volunteered for this assessment.

**Statistical analysis**

All data were analyzed with SPSS for Windows, Version 21.0 (IBM Corp., Armonk, NY, USA). The data of age, retention time of TIVADs, and operation time were analyzed using an independent sample t-test. The incidence of postoperative pain, hematoma, and wound infection were analyzed using a chi-square test. When the sample size was less than 40 or the theoretical frequency was less than 1, they were analyzed using a Fisher’s exact test. A two-tailed \( P<0.05 \) was considered statistically significant.
Results

A total of 205 cases were enrolled in the present analysis. Primary malignant tumors were breast cancer. The mean age was 49.4 years (range, 26–75 years). The mean retention time of TIVADs was 259 days (range, 226–456 days). The catheterized vein was the right internal jugular vein in 108 cases (52.7%) and the left internal jugular vein in 97 cases (47.3%) (Table I). Baseline characteristics were well balanced between the two groups, and no statistical difference was found in terms of age, the retention time of TIVADs, the catheterized vein, and BMI ($P > 0.05$).

TIVADs were removed intact in all 205 cases. There were no cases of air embolism, uncontrolled hemorrhage, or catheter fragmentation. Table II summarizes the complication rate. During the intraoperative pain assessment using the VAS, 1.96% of patients in group A reported moderate-to-severe pain. In contrast, 2.91% of patients reported moderate-to-severe pain in group B. Bleeding and infectious complications were very low, and there were no significant differences between the two groups. In our current study, nine cases (4.4%) had local skin infection (swelling, pyorrhea, or fissuration) after 7 days of surveillance, which were then treated with antibiotics. A slight hematoma was found in nine cases after port removal, which recovered after hemostatic compression (Table II).

There was a significant positive correlation in the operation time between the two groups ($P < 0.01$). The average operation time in group A was 6.49 min, and 8.09 min in group B. However, the incidence of intraoperative pain, hematoma, and local skin infection was not significantly different between the two groups ($P > 0.05$).

Discussion

TIVADs have been used for more than 40 years in clinical practice. It is one of the commonly used techniques for breast cancer patients who need adjuvant chemotherapy delivery, and one of the primary procedures that surgical residents need to learn. At present, there is no definite optimal time and detailed surgical procedures for the removal of TIVADs. TIVADs need to be removed for certain clinical reasons. TUN et al. have reported that the rate of removal due to complications is 1.34% (27/2007). The device should be removed if a TIVAD-related infection occurs. At our institution, the main reason to remove the TIVADs is the completion of therapy. However, few studies have been conducted to determine the best removal method. In the specific procedural process, the preference for a procedure can be different. In a previous study by Murthy et al., 57 intact TIVADs were removed using the catheter removal first strategy. In this study, two different methods of TIVAD removal were compared in patients with breast cancer.

Efficacy and safety

A skilled surgeon can successfully remove a TIVAD within 10 min. However, it remains unclear which part should be extracted first. The 8F port is smooth without open suture holes, and there is no fixed base during the implantation process. For patients implanted with 8F TIVADs, it seemed that taking out the port first might be better according to our investigation. After the opening of the fibrous capsule was
enlarged, the hemostatic forceps went deep into one end of the port to lift and hold the reversed port, and then the TIVADs could be removed easily. We showed that the operation time could be significantly shortened in group A. Although only 1.5 min was saved, the difference was statistically significant ($P<0.05$).

The routine surgical procedure for TIVAD implantation generally requires an incision for port insertion on the anterior part of the thorax.\textsuperscript{11-12} The incision is usually higher than the port. In this study, the incision was made between the port seat and the upper edge of the catheter lock. Care should be taken to prevent cutting off the catheter during the operation. In group B, if the catheter was removed first, the capsule around the catheter lock would be free, which not only prolonged the operation time but also increased the risk of cutting off the catheter. Therefore, it was safer to remove the port first. Ultimately, the wound should be closed with absorbable monofilament 3-0 sutures.

**Limitations**

There are several limitations to the present study. First, all the cases enrolled were breast cancer patients implanted with 8F TIVADs. Second, all TIVADs in our study were inserted in the internal jugular vein, and the ports were not sutured to the surrounding tissues. This data bias may affect the observational results, and this method was only applicable to certain special populations.

**Conclusions**

To the best of our knowledge, we, for the first time, investigated the removal approaches of TIVADs. Although both the port and catheter could be removed easily under local anesthesia, based on our findings, the operation time was significantly shortened by removing the port before the catheter.

**Declarations**

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Availability of data and material: The datasets used or analysed during the current study are available from the corresponding author on reasonable request.

Code availability: N/A

Authors’ contributions:

Conception and design: Yan-shou Zhang, Yun-jiang Liu,

Analysis and interpretation: Yan-shou Zhang, Yun-jiang Liu,

Data collection: Yan-shou Zhang, Lei Han,
Writing the article: Yan-shou Zhang,

Critical revision of the article: Yun-jiang Liu,

Final approval of the article: Yan-shou Zhang, Yun-jiang Liu, Lei Han,

Statistical analysis: Yan-shou Zhang.

Ethics approval: The experimental protocol was established, according to the ethical guidelines of the Helsinki Declaration and was approved by the Human Ethics Committee of the Fourth Hospital of Hebei Medical University.

Consent to participate: Written informed consent was obtained from individual or guardian participants.

Consent for publication: N/A

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### Tables

**Table 1** Characteristics of patients

| Characteristic       | Group A       | Group B       | t / χ² | P value |
|----------------------|---------------|---------------|--------|---------|
| Age (yr) (mean + SD) | 49.32+8.23    | 49.51+8.37    | -0.17  | 0.87    |
| Retention time (day) | 257.75+34.28  | 260.19+41.02  | -0.46  | 0.65    |
| Catheterized vein    |               |               |        |         |
| Left                 | 46            | 51            |        |         |
| Right                | 56            | 52            |        |         |
| BMI ≥24              | 35            | 30            | 0.64   | 0.46    |
| BMI <24              | 67            | 73            |        |         |

**Table 2** Operation time and complications of the TIVADs
| Type of complication       | Group A     | Group B     | t / χ² | P value |
|----------------------------|-------------|-------------|--------|---------|
| Operation time (min)       | 6.49±1.28   | 8.09±1.00   | -9.98  | 0.00    |
| (mean + SD)                |             |             |        |         |
| Pain (>3 points)           | 2(1.96)     | 3(2.91)     | 0.33   | 0.77    |
| No. (%)                    |             |             |        |         |
| Hematoma                   | 3(2.94)     | 6(5.83)     | 1.02   | 0.50    |
| No. (%)                    |             |             |        |         |
| Local skin infection       | 5(4.90)     | 4(3.88)     | 0.13   | 0.75    |
| No. (%)                    |             |             |        |         |

**Figures**

**Figure 1**

(A1) Free parallel to the catheter lock toward the port fibrous capsule. (A2) Enlarge the opening of the fiber capsule. (A3) Flip the port. (A4) Remove the catheter after the port was removed.

**Figure 2**

(B1) Open the capsule along the long axis of the catheter lock. (B2) Lift the catheter lock and connect the catheter. (B3) Remove the catheter. (B4) Remove the port after the catheter was removed.