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Totally implantable venous access ports: A prospective randomized study comparing subclavian and internal jugular vein punctures in children☆

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ABSTRACT

Background and objectives: Totally implantable venous access ports (TIVAPs) are essential in children who require long-term intermittent intravenous therapy.
Methods: Patients who needed to undergo TIVAP implantation were randomly assigned to the internal jugular vein group or the subclavian vein group. The medical histories, operative details and major complications from the time of port implantation to 48 h after port removal were collected.
During the use of TIVAPs, satisfaction surveys were regularly conducted for the children and guardians and compared in the two groups.
Results: A total of 216 patients in the subclavian vein group and 199 patients in the internal jugular vein group were included. TIVAPs were successfully implanted in all children. The incidence of postoperative venous access occlusion in the subclavian vein group and internal jugular vein group was 1.5% and 5%, respectively, and the difference was statistically significant ($P < 0.05$). The average satisfaction score of the children and guardians in the subclavian vein group was 9.6 ± 0.3, and that in the internal jugular vein group was 8.3 ± 0.8. There was a significant difference between the 2 groups ($P < 0.05$).
Conclusions: Subclavian vein should be the first choice for TIVAP implantation in children.
The level of evidence rating: Treatment study level I.

Totally implantable venous access ports (TIVAPs) are essential in patients, especially in children, who need long-term yet intermittent infusions, such as the case of chemotherapy. A suitable TIVAP not only provides children with safe vascular access for treatment but also protects their vessels from repeated puncture injuries. Puncture and catheterization are the two core technologies of TIVAP implantation. In subclavian vein TIVAP placement, the catheter only passes through the chest wall, which is more comfortable than the neck or groin. The risk of infection and symptomatic thrombosis is reduced [1–3]. However, some articles do not recommend subclavian vein TIVAP placement as the first choice in children [4,5]. To further explore the best implantation path for TIVAP placement in children, a randomized controlled study of two vein catheterization approaches was simultaneously conducted in the Department of Oncology, Children's Hospital of Chongqing Medical University. The research is summarized as follows.

1. Materials and methods

1.1. Patients

From April 2015 to January 2018, patients who underwent TIVAP implantation in the Department of Oncology, Children's Hospital of Chongqing Medical University were included in this study. The study was approved by the Human Research Ethics Committee. All patients underwent surgery in the same surgical group. All children were identified by the expert group before surgery according to the indications for TIVAP implantation [5]. Preoperative routine examinations showed no abnormal blood coagulation, PLT $\geq 50 \times 10^9$/L, an absolute neutrophil value $\geq 0.5 \times 10^9$/L, no evidence of infection in the surgical area or other parts of the body, and no other surgical contraindications [5]. The catheterization path was determined according to the situation of the child

Abbreviations: TIVAPs, Totally implantable venous access ports; PLT, platelet count; EMR, electronic medical records; HIS, hospital information system; IJ, internal jugular vein; SC, subclavian vein.

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during the operation, and multiple vascular punctures were sometimes required; information which was given to the parents and guardians during the informed consent of the operation. If both vein catheterizations (internal jugular and subclavian veins) were suitable for catheter placement, a random number table was used to randomly assign eligible patients to the internal jugular or subclavian vein group. Patients were not included in this study if their parents refused to participate or if only one vein was suitable for catheterization. Venous access ports were Braun products (5F epoxy resin catheter, port weight 3 g).

1.2. Surgical technique

The patients were anesthetized via an inhalation cannula, and routine disinfection of the bilateral neck, chest and shoulder was carried out. All ports and puncture supplies were rinsed in 10 U/ml heparin saline.

1.2.1. Subclavian vein TIVAP placement

The percutaneous Seldinger technique was used [6]. Left subclavian vein puncture was performed first: The puncture point was located below the middle and outer 1/3 of the left clavicle, and puncture was performed with negative pressure along the line connecting the coracoid process and the upper edge of the ipsilateral sternal bone of the clavicle towards the clavicle and first rib space (see Fig. 1). The angle between the needle and the skin was less than 30°. After confirming the smooth return of blood, a guide wire was inserted, and a bedside X-ray film or an esophageal ultrasound was performed to confirm that the guide wire was in the superior vena cava or right atrium (see Fig. 2). A 0.2 cm incision was made with a pointed blade at the puncture point, and then the expansion sheath was inserted. If the left subclavian vein puncture was unsuccessful or if the guide wire was difficult to insert, the procedure was changed to a right subclavian vein puncture. If the right subclavian procedure still failed, the procedure was changed to an ultrasound-guided internal jugular vein puncture and placement, and the right internal jugular vein was preferred.

A catheter filled with 10 U/ml heparin saline was inserted into the superior vena cava along the catheter sheath, and the length of the catheter was calculated according to a formula [7]. X-ray films or esophageal ultrasound confirmed that the catheter tip was located at the entrance of the superior vena cava (Fig. 2). All procedures consisted of catheter placement in the central venous circulation followed by subcutaneous pocket creation and port attachment to the catheter with fixation, as well as closure of the pocket. After reviewing the bedside X-ray (see Fig. 2) to confirm the success of the operation, aspiration and injection via the noncoring needle were provided to verify the function of the port; then, the port was locked with 10 U/ml heparin.

1.2.2. Internal jugular vein TIVAP placement

According to previous studies [5,8], we used ultrasound-guided internal jugular vein puncture to implant the TIVAPs. The right internal jugular vein was preferred.

1.3. Postoperative use and maintenance

After the operation, the port could be used immediately. The TIVAPs were maintained according to the consensus of Chinese experts [5] and American guidelines for the prevention of catheter-related infections [9]. The occurrence of complications related to surgery, such as postoperative blood pneumothorax, was closely observed. The catheter was flushed and sealed according to the operating program, and the sealed heparin concentration was 10 U/ml [10]. When using the venous access port, if the catheter was occluded, X-ray examination was performed except for cases of pinch-off syndrome or mechanical obstruction caused by other reasons. The catheter was flushed once every 4 weeks during the infusion interval.

1.4. Data collection and analysis

The operative details and the major complications from the time of port implantation to 48 h after port removal were collected by EMR and HIS. The satisfaction surveys of the children and their guardian were conducted regularly during the use of the venous access port. With reference to the method of scoring pain [11], the most satisfactory score was 10 points, and the least satisfactory score was 0 point. Continuous variables such as age, operation time, and child or parent satisfaction in the two groups were analyzed using t-tests. Categorical data were tested using the chi-square test or Fisher's exact test. $P < 0.05$ was considered statistically significant.

2. Results

A total of 415 patients were randomly divided into two groups, 199 patients in the internal jugular vein group and 216 patients in the subclavian vein group (Fig. 3). All patients' TIVAPs were removed. The minimum age was 4 months, and the maximum age was 17 years and 1 month. Patients in both groups could use their TIVAPs normally after the operation (some patients shown in Fig. 4). The demographics, disease types, and basic conditions before surgery were similar between the two groups of children. The average operation time in the subclavian

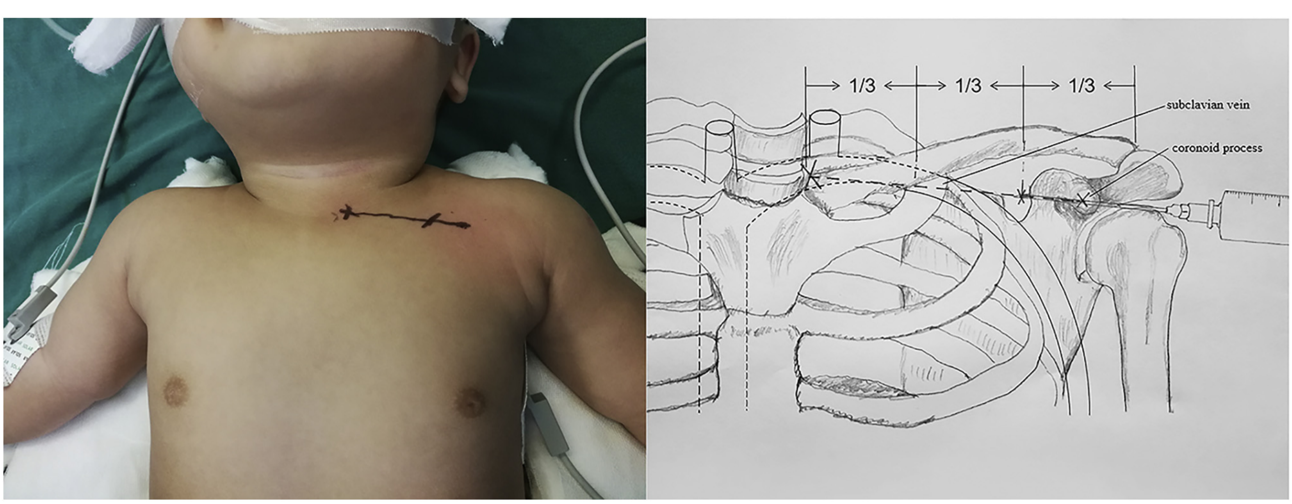

Fig. 1. Preoperative body surface positioning of the puncture line and schematic view of the subclavian vein puncture.

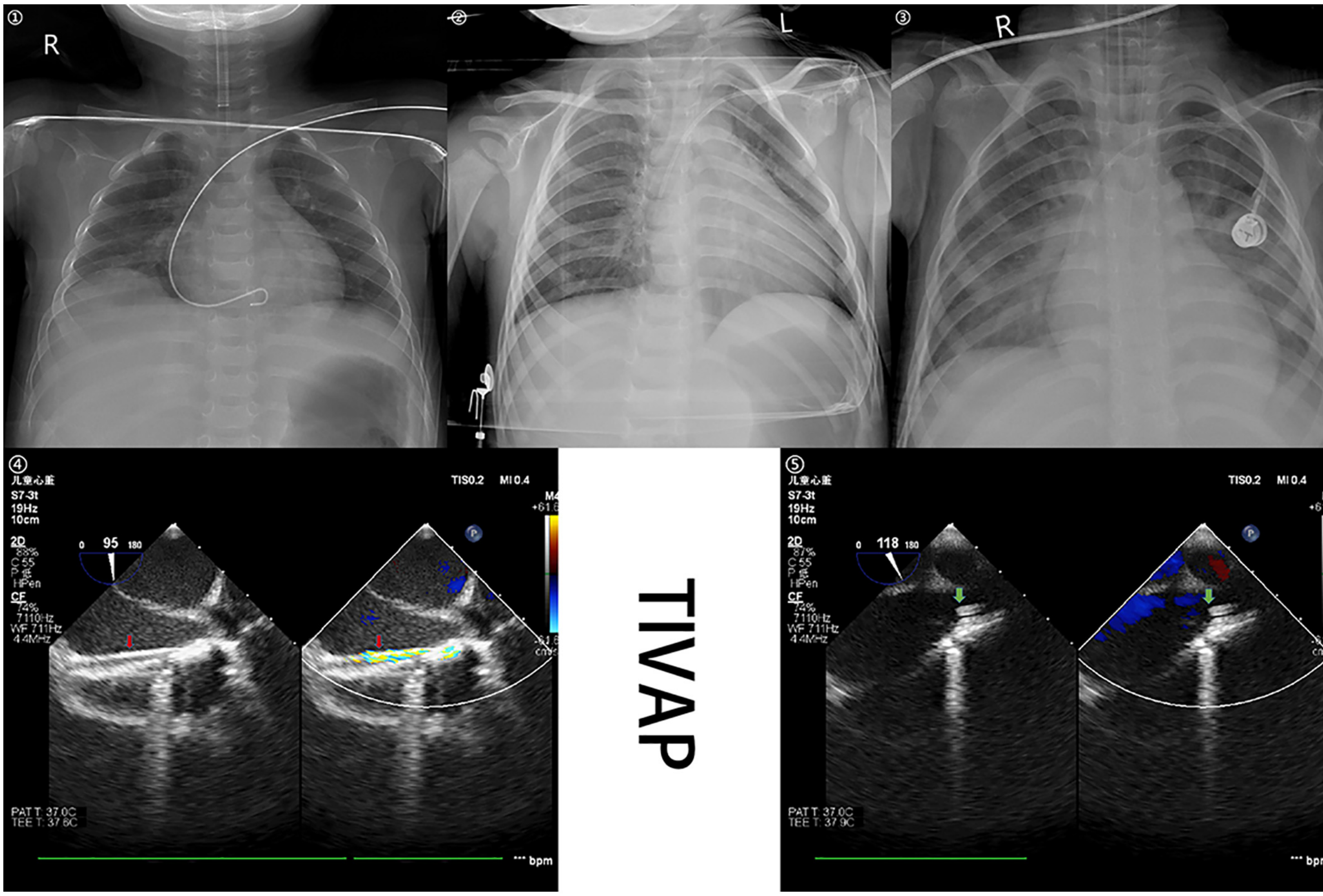

Fig. 2. X-rays and esophageal ultrasound examinations during subclavian venous access port implantation. (1) X-ray film of the guide wire entering the right atrium through the left subclavian vein puncture, (2) X-ray film of the catheter tip at the entrance of the superior vena cava during left subclavian vein puncture, (3) X-ray film after successful port implantation of the left subclavian vein puncture, (4) esophageal echocardiogram of the guide wire into the right atrium through the left subclavian vein puncture (red arrow marks the guide wire), and (5) echocardiography (the green arrow marks the catheter tip) showing that the catheter tip was located at the entrance of the superior vena cava during the left subclavian vein puncture.

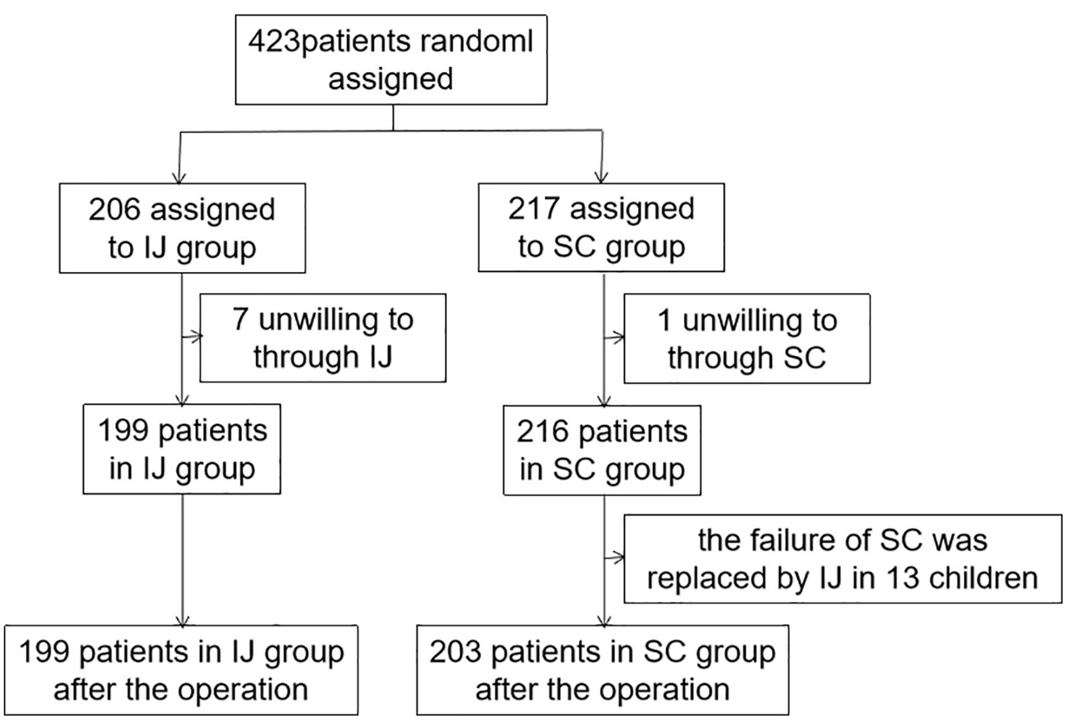

Fig. 3. Consort diagram.(IJ: internal jugular vein; SC: subclavian vein).

Fig. 4. (1-3) Patients in the internal jugular vein group (black arrow marks the subcutaneous catheter seen on the surface). (4–6) Patients in the subclavian vein group.

vein group was shorter than that in the internal jugular vein group ($P < 0.05$). The average time of use of the venous access ports was basically similar between the two groups. The satisfaction of patients and their families in the subclavian vein group was significantly higher than that in the internal jugular vein group ($P < 0.05$). See Table 1 and Table 2 for details.

All of the 415 children's TIVAP implantations were successful. The success rate was 100%. A total of 13 of the 216 children in the subclavian vein group experienced failure during the subclavian vein catheterization at first but underwent successful placement with the internal jugular vein. The success rate of subclavian vein catheterization was 93.98% and the internal jugular vein was 100% ($P < 0.001$). But catheter embolism occurred in 1.5 and 5% (P = 0.044) of patients with subclavian and jugular catheters, respectively. The intraoperative and postoperative complications of all children are shown in Table 1, Table 2 and Fig. 5. In the subclavian vein group, 5 patients experienced accidental puncture of the subclavian artery, and 1 patient experienced lung puncture (intraoperative radiographs suggested pneumothorax). However, none of them had hemopneumothorax requiring closed chest drainage. No cases of chyle leakage or pinch-off syndrome were found in these patients. A total of 13 children in the two groups had catheter embolism: 5 cases of mechanical obstruction and 8 cases of thrombosis blockage (two thrombosis blockages in one child). Thrombolysis was successfully performed in 7 patients with 5000 U/ml urokinase solution, and 2 patients underwent port removal owing to thrombolysis failure. A total of 12 patients in both groups were diagnosed with catheter-associated bloodstream infections. After the ports were subjected to antibiotic lock therapy, 5 cases were cured, and 7 ports were removed. Five patients with skin infections around the port were cured through debridement and negative pressure drainage surgery (see Fig. 6).

Table 1
Comparison of patients' operative details when performing TIVAPs implantation in SC group and IJ group.

Categorical variables	SC group (n = 216)		IJ group (n = 199)		χ^2	P-value
	n	%	n	%		
Success of original plan	203	93.98	199	100	12.364	<0.001
Misinsertion of artery	5	2.31	1	0.50	2.387	0.128
Insert the chest by mistake	1	0.46	0	0	0.919	0.522
Continuous variables	$\bar{x}$	SD	$\bar{x}$	SD	t-value	P- value
Times of puncture[a]	1.65	1.43	1.23	0.89	3.527	<0.001
Operation time (min)[a]	45.7	23.1	75.9	32.4	−10.777	<0.001

[a] Including the times of ultrasound-guided internal jugular vein puncture after the failure of subclavian vein catheterization.

3. Discussion

The subclavian vein is a continuation of the axillary vein. It is closely connected to structures such as the intrinsic fascia of the neck, the first rib anadesma, the anterior oblique muscle, and the subclavian fascial sheath. It has a constant position and is not easily shifted, which is conducive to puncture [12]. The success rate of subclavian vein catheterization in our research was 93.98%, which was a relatively high level

Table 2
Comparison of patients' information when performing TIVAPs implantation in SC group and IJ group.

Categorical variables	SC group (n = 203)		IJ group (n = 199)		χ^2	P-value
	n	%	n	%		
Gender					0.003	0.957
Male	128	63.0	126	63.2		
Female	75	37.0	73	36.8		
Disease					/	0.736[a]
Hematological malignancies	108	53.2	99	49.8		
Extracranial malignant solid tumor	79	38.9	85	42.7		
Intracranial malignancy and retinoblastoma	4	2	2	1		
Nonmalignant tumor	12	5.9	13	6.5		
Complication						
Catheter-related bloodstream infection	5	2.5	7	3.5	0.386	0.534
Catheter occlusion	3	1.5	10	5	4.041	0.044
Skin infections around the port	3	1.5	2	1	/	>0.999[a]
Reasons of removing port					/	0.236[a]
Non-need	198	97.5	189	95		
Suspected infection	3	1.5	4	2		
Catheter clot occlusion	0	0	2	1		
Mechanical obstruction (catheter displacement, fold, or adherence)	2	1	4	2		
Continuous variables	$\bar{x}$	SD	$\bar{x}$	SD	t- value	P-value
Average age (months)	23.5	19.4	23.6	20.12	−0.051	0.960
Preoperative chemotherapy course	1.2	0.6	1.3	0.7	−1.539	0.125
Preoperative blood routine						
Hb (g/L)	113.2	20.7	115.1	21.6	−0.901	0.368
WBC ($\times 10^9$/L)	8.3	7.6	8.4	6.3	−0.144	0.886
PLT ($\times 10^9$/L)	243.3	192.8	256.1	194.5	−0.663	0.508
Average in-port time (months)	18.3	6.3	18.2	6.8	0.153	0.878
Satisfaction	9.6	0.3	8.3	0.8	21.652	<0.001

[a] Fisher exact test.

compared with other reports [13,14]. This means that the bony landmark-based puncture method our team used was suitable for children. The subclavian vein and brachiocephalic vein of children are shorter than those of adults, and the angle between the left subclavian vein and the brachiocephalic vein is larger than that on the right side, so it is easier to insert the catheter through the left subclavian vein in children. These are the reasons why the left subclavian vein has been the first choice for this group of children.

The internal jugular vein, external jugular vein, and subclavian vein are commonly used to insert central venous catheters in children. The method of external jugular vein port implantation is not frequently currently used because of the additional surgical incision, the long operation time and the high catheterization failure rate [5]. In this study, the other two paths were compared. We found that the operation time was shorter and the incidence of catheter obstruction was lower in the subclavian vein group than in the internal jugular vein group. We hypothesize that the long operation time of the internal jugular vein group was related to intraoperative ultrasound preparation and the longer tunneling times. We believe the reason for the lower incidence of blockage in subclavian venipuncture catheter implantation than in internal jugular vein implantation is that children's longitudinal growth rate is much faster. Additionally, neck puncture catheterization requires running the catheter twice along the longitudinal axis of the human body. The rapid growth of children may be one of the reasons for the high incidence of catheter displacement in the internal jugular vein group. The subclavian vein TIVAP is relatively fixed and does not shift with children's neck movement. The incidence of catheter folding is reduced. Repeated catheter shifting may also damage the lining of blood vessels and increase the incidence of intravascular thrombosis [3,15–17].

A statistical difference was seen in the total number of catheter embolism, which occurred in 1.5 and 5% ($P = 0.044$) of patients in the subclavian and in the jugular groups, which would support the view that subclavian vein should be the first choice for children's TIVAPs [1–3]. However, Rodrigo [18] reported that catheters implanted in the subclavian vein present greater risk of infection and embolism and did not recommend subclavian vein TIVAP placement as the first choice in children. We speculate that this difference may be related to their subclavian vein puncture methods. After all, their success rate of subclavian vein puncture is relatively low and the number of cases is relatively small. Because subclavian puncture may cause hemopneumothorax and pinch-off syndrome, some surgeons prefer internal jugular or external jugular vein catheterization. However, in this group of 203 children who underwent subclavian vein catheterization, none had pinch-off syndrome. We hypothesize that the first reason is age: The junction of the clavicle and the first rib in children is mainly cartilage (as can be seen from the chest film in Fig. 2), which does not easily pinch off the tube; the puncture method we used limited pinch-off syndrome. In these children, the puncture point was located below the middle and outer 1/3 of the left clavicle. Most of the catheter entered the subclavian vein outside the clavicle and the first rib fascial segment. Because of the protection of the subclavian vein, this method can effectively avoid pinch-off syndrome caused by the compression of the clavicle and the first rib (as seen in Fig. 7).

No pneumothorax or hemothorax requiring closed chest drainage was found in this group. Bedside X-rays or esophageal ultrasonography was performed after the guide wires were inserted. After confirming that the guide wires were in the superior vena cava, vascular dilation sheaths were inserted, and catheters were placed. Both the puncture needle and the guide wire were thin, and the damage was slight. When needles or guide wires are mistakenly inserted into the subclavian artery or thoracic cavity, the surrounding connective tissue can normally close the puncture cavity; if we discovered this phenomenon, we immediately removed the instrument. Serious pneumothorax or hemothorax can be avoided. Sometimes children's venous blood is red, and the pressure is high. Whether the subclavian artery is mistakenly punctured is often difficult to determine. If we cannot confirm this, the guide wire can also be inserted, and X-ray or esophageal ultrasound can be performed at the bedside for identification.

If the skin around the port or pocket is infected, the port should usually be removed [19,20]. Our institution adopted a new surgical method for the treatment of children's soft tissue infections [21] and performed

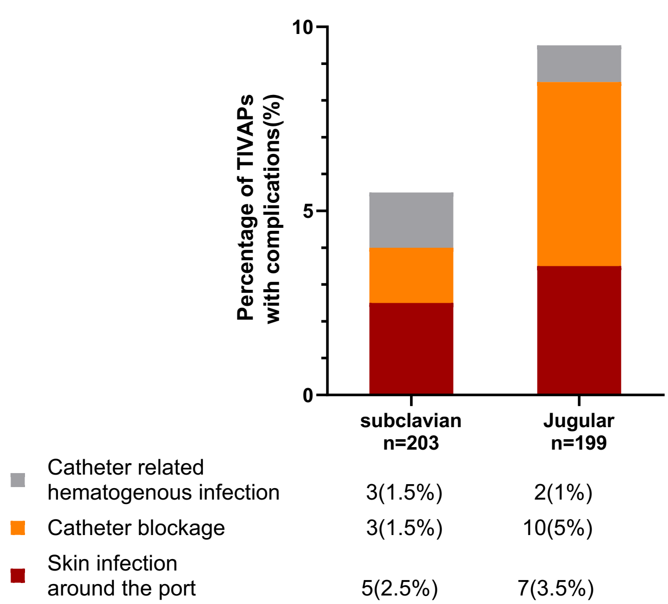

Fig. 5. Postoperative complications in the two groups of children.

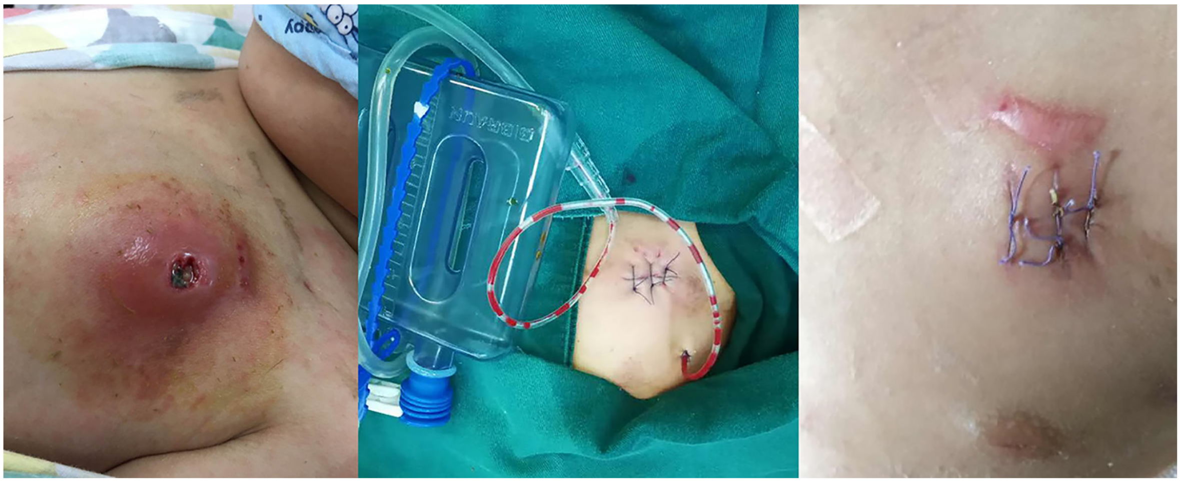

Fig. 6. Children with preoperative, intraoperative and postoperative skin infections around the port.

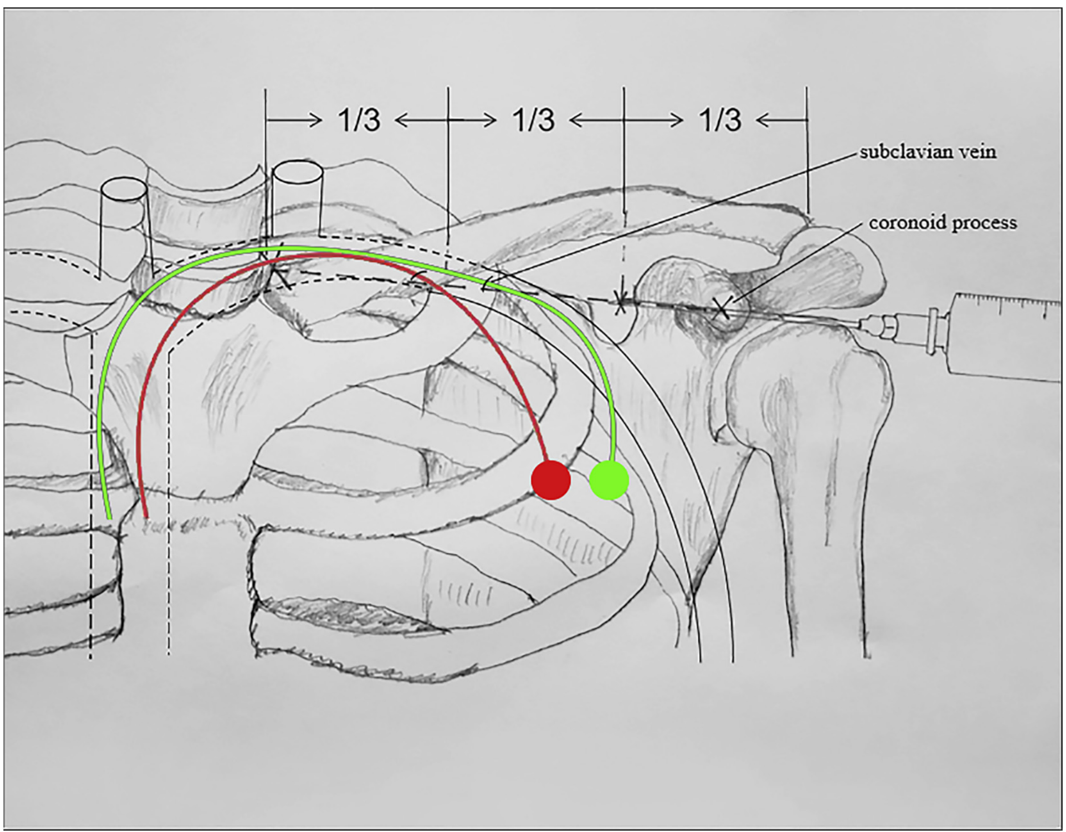

Fig. 7. Green indicates the TIVAPs implanted by the puncture method adopted by our team. The catheter enters the subclavian vein outside the clavicle and the fascial segment of the first rib. Because of the protection of the subclavian vein, this method can effectively avoid pinch-off syndrome caused by compression of the clavicle and the first rib. Red indicates the TIVAPs implanted by other methods. The catheter enters the subclavian vein after the clavicle and the fascial segment of the first rib. The catheter at the contact site of the clavicle and the first rib is not in the subclavian vein, which may cause pinch-off syndrome.

thorough debridement, disinfection and negative pressure drainage in the infected pocket. All 5 cases of children with skin or pocket infection around the ports were cured. The ports were successfully maintained and their use was continued after the wound healed. Therefore, we believe this method is worth promoting.

The satisfaction survey results of children or parents in this group showed that the satisfaction in the subclavian vein group was significantly higher than that in the internal jugular vein group, which is consistent with the conclusions of other researchers [1–3]. We believe that the main reason for the high satisfaction in the subclavian vein group is that there is no catheter in the necks of children in this group (as shown in Fig. 3), and there is no need to worry about the displacement of the catheter when the neck is twisted. Therefore, the safety and comfort are higher in this group than in the internal jugular vein group. This means that children and parents may prefer to have ports imported through the subclavian vein, if they have the chance to choose.

4. Conclusion

Subclavian vein TIVAPs have few postoperative complications and demonstrate high postoperative comfort in children. The technique we used can effectively avoid complications such as hemopneumothorax and pinch-off syndrome. The left subclavian vein should be the first choice for TIVAP implantation in children.

Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.jpedsurg.2020.04.021.

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