scientific reports



OPEN

Clinical efficacy and safety of a new single-incision axillary vein puncture technique for totally implantable venous access ports

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To assess the clinical efficacy of a new single-incision axillary vein puncture technique for implanting totally implantable venous access ports (TIVAPs). A retrospective review of patient data from January 2023 to June 2023 at The Affiliated Suzhou Hospital of Nanjing Medical University was conducted. The study included adult patients with solid malignancies scheduled for intravenous chemotherapy and TIVAPs implantation. Patients were categorized into single-incision group (Group S) and dualincision group (Group D) based on different venous access approaches. Baseline information, primary tumors, immediate adverse events, indwelling time, and early and late adverse events were collected. A total of 338 patients were included in the analysis, with 117 in Group S. and 221 in Group D. Baseline characteristics were comparable between the groups. The technical success rate was 99.1% in Group S and 98.6% in Group D, demonstrating similarity. The mean operative time was 26 min in Group S, significantly shorter than the 36 min in Group D (p < 0.05). Group D experienced more occurrences of localised ecchymosis and painful. Overall, Group S exhibited superiority over Group D in terms of immediate adverse events (p < 0.05). Follow-up data revealed comparable adverse events rates between the two groups. In conclusion, the study indicates that the single-incision axillary vein puncture technique can be safely implemented by an experienced team with a low incidence of adverse events. This approach can serve as a valuable alternative for clinical TIVAPs placement.

Keywords TIVAPs, Axillary vein puncture, Single-incision

Since the seminal work by Niederhuber et al. introducing totally implantable venous access ports (TIVAPs) in 1982, these devices have become essential in treating patients needing chemotherapy, parenteral nutrition, or infusion therapy solutions^{2,3}. Subsequent research has generated abundant data confirming the safety and reliability of TIVAPs. Starting from the era of surgical cut-down access via the cephalic vein at the deltoidpectoralis groove¹, and advancing through the subsequent adoption of percutaneous methodologies, notably the modified Seldinger technique^{4,5}, the primary approach predominantly utilized in clinical practice remains insertion via the internal jugular vein or the subclavian vein^{6,7}. This procedural approach usually involves dual discrete incisions and the creation of subcutaneous tunnels. Challenges encountered during this technique include nociceptive manifestations at the tunnel site due to tissue traction, cutaneous ecchymosis over the subcutaneous tunnels—more noticeable in older individuals with reduced subcutaneous adipose tissue—along with potential errors in catheter length determination and related aesthetic concerns⁸⁻¹¹. This study adopted a new percutaneous puncture method proposed by Zhang et al.¹². This method involved puncturing the axillary vein and placing the port directly at the puncture site, bypassing the subcutaneous tunnels and dual incisions used in the conventional approach. This article describes and evaluates the feasibility, technical success, and adverse events of this new procedure, comparing its clinical effectiveness with the traditional method of port placement via the internal jugular vein.

Materials and methods

A retrospective analysis was performed on patient data collected from The Affiliated Suzhou Hospital of Nanjing Medical University. The study exclusively examined adult individuals with solid malignancies who underwent

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intravenous chemotherapy and port placement procedures from January 2023 to June 2023. Ethics Committee of The Affiliated Suzhou Hospital of Nanjing Medical University granted a waiver of the requirement for written informed consent from participants due to the retrospective nature of the research and use of anonymized clinical data.

Axillary vein puncture procedure for TIVAPs placement

The ports were inserted via axillary vein puncture in a controlled environment within an angiographic suite, with strict adherence to meticulous sterile barrier precautions. The procedure followed a systematic approach, utilizing the established protocol introduced by Zhang et al. ¹². Real-time ultrasound imaging was employed to assist in guiding the procedure.

Line a was identified as the deltoid-pectoralis major interosseous groove. Point A was designated as the first inflection point along the trajectory of the clavicle from the suprasternal fossa tracing. A parallel Line b was drawn through Point A, with Point B marked approximately 4 cm distal from Point A along Line b. Point B served as the entry site for the puncture needle, as depicted in Fig. 1. Following local anesthesia administration, the puncture needle was cautiously inserted at an angle of α parallel to Line a or b until it encountered resistance from the clavicle. After retracting the needle by approximately 1 cm, we deliberately increased the insertion angle while applying negative pressure at an angle of β . Successful puncture was confirmed by retrieving dark red blood, indicating penetration of the axillary vein. Figure 2 categorizes this approach as the single-incision group (Group S).

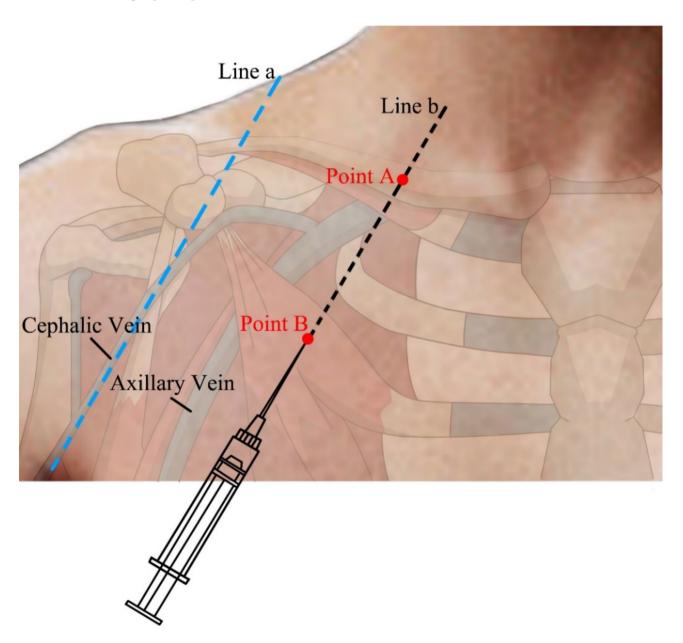


Fig. 1. Schematic diagram of axillary vein puncture procedure.

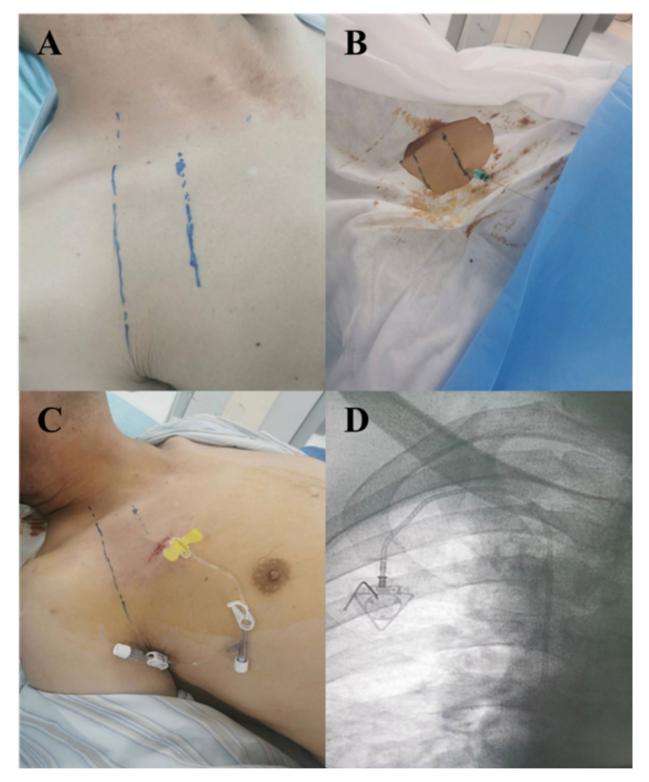


Fig. 2. Sequential stages of axillary vein puncture for TIVAPs placement. **(A)** Anatomical landmarks for axillary vein puncture. **(B)** Guidewire insertion into the axillary vein. **(C)** Full subcutaneous implantation of the TIVAPs. **(D)** X-ray visualization of the TIVAPs.

Internal jugular vein puncture procedure for TIVAPs placement

Puncture of the internal jugular vein under real-time ultrasound guidance categorized this approach as the dual-incision group (Group D).

Data compilation and definitions

A thorough retrospective review of patients' medical records was conducted, covering a range of essential data points. These encompassed demographic details like age and gender, relevant preoperative information including medical history, intraoperative observations such as immediate adverse events and operative time, and detailed follow-up data covering port indwelling duration, identification, and assessment of any early and late adverse events. Patients were followed until August 20, 2023, or until port removal due to complications or other reasons. Port indwelling duration was defined as the period from port implantation to removal due to any cause, occurrence of a fatal event, or patient's inability to attend follow-up appointments. Early and late adverse events were defined as those occurring within the first 30 days post-procedure and those occurring beyond 30 days post-procedure, respectively. Infectious adverse events were further classified into local infections and catheter-related bloodstream infections (CRBSIs).

Statistical analysis

All data were processed and analyzed using Statistical Package for Social Sciences version 26.0 for Windows (SPSS Inc., Chicago, IL, USA). The sample sizes were estimated based on preliminary experiments to ensure that the expected differences in the primary outcome indicators could be detected with 80% power at a two-sided α level of 0.05. Quantitative data conforming to a normal distribution were presented as median and interquartile range (IQR) [median, IQR], and a t-test was employed for the comparison of means between two samples. Qualitative data were expressed as frequency (n) and percentage (%), with the application of either the chisquare test or Fisher's exact test. A significance level of p < 0.05 was deemed statistically significant.

Results

A comprehensive retrospective analysis was conducted on a cohort of 345 cases involving TIVAPs that were percutaneously placed. This study spanned from January 1, 2023, to June 20, 2023, encompassing cases exclusively dedicated to intravenous chemotherapy for distinct malignant conditions. Out of the total, four cases exhibited a surgical information gap, and an additional case involved the upper extremity access procedure for bilateral breast cancer accompanied by axillary lymph node metastasis. Upon meticulous evaluation, the final sample included 117 patients in Group S and 221 patients in Group D, as depicted in Fig. 3. Remarkably, the mean age of patients in both cohorts converged at 63 years (p = 0.395). Gender distribution exhibited similar proportions between males and females (p = 0.101), and Body Mass Index (BMI) comparisons yielded 23.0 kg/m² for Group S and 22.9 kg/m² for Group D (p = 0.155). Thereby demonstrating statistical equivalence. Predominantly, the primary diagnoses comprised breast cancer (29%) and colorectal cancer (18%). Puncture access primarily favored the right side (86%), reflective of surgical preferences. Notably, instances of opting for a left-sided approach were occasionally influenced by the patient's surgical history. Detailed data are summarized in Table 1.

Table 2 presents a comprehensive overview of the challenges encountered by both study cohorts during the procedural interventions. These challenges encompassed instances of artery puncture, haemopneumothorax, obstruction of catheter advancement, localised ecchymosis, and painful. The mean procedural duration for Group S was notably shorter at 26 min, signifying a statistically significant difference compared to Group D, which exhibited a mean procedural time of 36 min (p<0.05). Pain symptom feedback provided by patients during the procedures showcased a notable contrast, with only three cases reporting pain in Group S, in contrast to the 14 cases in Group D. Furthermore, Group D experienced a higher incidence of localized ecchymosis. In Group D, one case experienced arterial puncture, while two other cases encountered unsuccessful attempts. Consequently, Group D achieved final technical success rate of 98.6%. Within Group S, there was one case of arterial puncture, resulting in a technical success rate of 99.1%. Collectively, the findings underscore the supremacy of Group S over Group D in terms of immediate adverse events (p<0.05).

During the follow-up period, the indwelling time of the TIVAPs were observed to be 154 days (93–171 days) and 130 days (90.5-163.5 days), respectively. In Table 3, Early adverse events manifested abnormally in 5 out of 338 patients, accounting for 1.5% of the total cases. Predominantly, these adverse events were characterized by localized incisional infections. Notably, in one case within Group S, discontinuation of TIVAPs usage was necessitated due to thrombotic occurrences.

Among the occurrences of late adverse events, thrombosis was identified in 5 cases (1.5%), with one patient in Group S experiencing axillary vein stenosis attributed to tumor progression. Suspected cases of catheter-related blood stream infection (CRBSI) were identified in 3 cases, marked by unexplained fever, which exhibited improvement following the removal of the TIVAPs. In Group D, catheter tip displacement was observed in 2 patients, both of which were rectified through surgical intervention to restore the recommended positioning.

Discussion

The percutaneous placement of TIVAPs via internal jugular vein puncture remains the prevailing clinical practice due to the superficial location and larger diameter of the right internal jugular vein, facilitating ease of venipuncture. However, previous studies have highlighted its inherent limitations, encompassing concerns related to cosmetic appearance, tunnel-related adverse events such as subcutaneous infections, discomfort in the neck area, challenges in advancing tunneling devices, inaccurate catheter length measurement, and catheter-associated venous thrombosis¹³. Despite the administration of local anesthesia, patients have reported experiencing discomfort during the creation of the subcutaneous tunnel, occasionally accompanied by localised

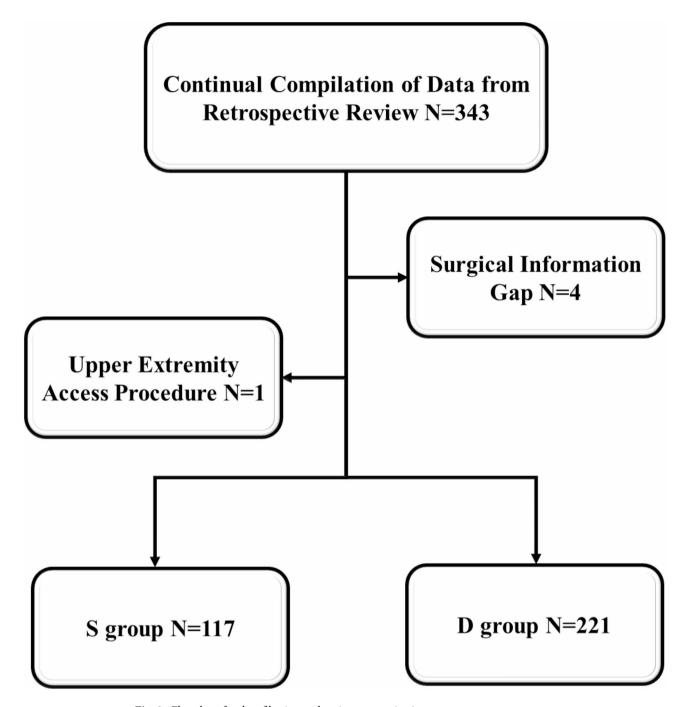


Fig. 3. Flowchart for data filtering and patient categorization.

ecchymosis¹⁰. The creation of subcutaneous tunnels and the use of dual-incisions for the puncture site and port placement are the primary drawbacks associated with this approach.

This study demonstrating the advantages of an alternative single-incision technique for TIVAPs placement. Utilizing the axillary vein puncture method, several of the aforementioned challenges were minimized. Some studies have proposed several advantages of using the axillary vein approach for TIVAPs implantation: (1) When accessed via the axillary vein, the catheter enters the vessel before passing through the gap between the clavicle and the first rib, avoiding compression and preventing the occurrence of pinch-off syndrome^{14,15}. In the study, Group S did not experience pinch-off syndrome. (2) The proximity of the axillary vein to the proximal segment of the artery reduces the likelihood of arterial puncture. Even in cases of accidental puncture of the axillary artery, effective hemostasis can be promptly achieved due to the absence of bony structures obstructing compression¹¹. In the study, there were only 1 case (0.85%) in Group S and 1 case (0.45%) in Group D with arterial mispenetration, all of which were corrected through adequate compression.

In this research, a new percutaneous axillary vein port placement technique was employed¹². In this method, the authors introduced several critical parameters: $AB = (3.89 \pm 0.40)$ cm, $\alpha = (25.84 \pm 5.54)^{\circ}$, and β

	S group (N=117)	D group (N=221)	P-value			
Age (year, median, IQR)	63.0 (54.0-68.5)	63.0 (54.5-70.0)	0.395			
Gender (%)						
Man	58 (49.6)	89 (40.3)	0.101			
Female	59 (50.4)	132 (59.7)				
BMI (kg/m², median, IQR)	23.0(20.9-26.0)	22.9 (20.8–25.0)	0.155			
Malignancies (%)						
Breast cancer	30 (25.6)	69 (31.2)				
Colorectal cancer	23 (19.7)	39(17.6)				
Lung cancer	21 (17.9)	36(16.3)				
Stomach cancer	12 (10.3)	35(15.8)				
Pancreatic cancer	5 (4.3)	9(4.1)				
Nasopharyngeal carcinoma	8 (6.8)	1(0.5)				
Other malignancies	18 (15.4)	32(14.5)				
Puncture access (%)						
Left	16 (13.7)	30 (13.6)	0.980			
Right	101 (86.3)	191 (86.4)				

Table 1. Demographic and clinical characteristics of two groups.

	S group (N=117)	D group (N=221)	P-value
Operative time (min, median, IQR)	26 (25–30)	36 (34–37)	<0.05
Immediate adverse events (%)	7 (6.0)	53 (24.0)	< 0.05
Artery puncture	1	1	
Haemopneumothorax	0	0	
Obstruction of catheter advancement	2	17	
Localised ecchymosis	1	21	
Painful	3	14	
Success# (%)	116(99.1)	218 (98.6)	1.000

Table 2. Demonstrates the Obstacles encountered by both groups at the time of the procedure. *Number of cases requiring ultrasound-guided re-puncture due to arterial puncture and other reasons.

	S group (N=117)	D group (N=221)	P-value
Indwelling time (days, median, IQR)	154 (93–171)	130 (90.5-163.5)	0.056
Early (%)	2 (1.7%)	3 (1.4%)	1.000
Local infection	1	3	
Thrombosis	1	0	
Late (%)	4 (3.4%)	7 (3.2%)	1.000
CRBSI#	1	2	
Stenosis	1	0	
Thrombosis	2	3	
Migration	0	2	

Table 3. Early and late adverse events. *CRBSI = catheter-related blood stream infection.

= $(66.18 \pm 10.26)^\circ$, which can be adjusted under ultrasound guidance. In the study, relying on reliable surface markings and ultrasound, a technical success rate of 99.1% was achieved, which aligns closely with data reported in previous studies 16,17 , demonstrating a high rate of success. This underscores the feasibility of utilizing this new method for axillary vein puncture.

In fact, during the surgical procedures, Group Sdid not incur severe adverse events such as haemopneumothorax or air embolism, indicating the safety of implementing the axillary vein puncture based on this new method.

The mean procedural time for the single-incision axillary vein puncture method we utilized was 26 min, notably shorter than the duration required for the conventional internal jugular vein approach. A distinct benefit observed in Group S was the absence of localised ecchymosis, attributed to the avoidance of subcutaneous tunneling. This highlights one of the advantages of the single-incision axillary vein puncture method over

the traditional internal jugular vein approach. Conversely, other facets of immediate adverse events did not demonstrate disparities with Group D. It is plausible that in elderly patients with limited subcutaneous tissue, surgeons deliberately lean towards the single-incision approach, steering clear of subcutaneous tunnels, which could contribute to a lower recorded incidence of immediate adverse events in Group D compared to the actual occurrences.

Infectious adverse events represent a prevalent cause for TIVAPs explantation¹⁸, with reported incidences ranging from 5.6–8%^{19,20}. The multifaceted nature of its risk factors encompasses aspects such as procedural mishandling during implantation, neutropenia in patients, a history of malignancy, and prolonged usage of glucocorticoid medications. Nonetheless, in the investigation, a total of 7 (2.1%) cases of infectious adverse events were encountered, encompassing instances of local infection and CRBSI. Robust maximum barrier protection protocols were implemented throughout the procedures, ensuring that surgeries were conducted, and TIVAPs were subsequently employed. Given that the majority of patients were undergoing intravenous chemotherapy for malignant tumors, implying an immunosuppressed and malignant state, the demand for comprehensive exploration into the risk factors associated with infectious adverse events and the establishment of standardized treatment protocols becomes all the more pressing.

Another critical adverse events to address is catheter-related thrombosis (CRT). Prior investigations have identified risk factors associated with CRT, encompassing factors like vascular trauma (such as the implantation of multiple TIVAPs, repeated catheter insertion attempts, employment of large-diameter or multilumen catheters), and improper catheter tip positioning within the superior vena cava^{21,22}. Thromboembolic adverse events rates have displayed a wide spectrum in earlier studies, ranging from 0.3–28.3%²³. Notably, this rate escalates to 27-66% when routine doppler ultrasound evaluations are conducted on patients²⁴. In this study, the incidence of CRT was even lower (1.8%), a trend which might be attributed to the utilization of TIVAPs featuring narrower catheter diameters.

Moreover, a pragmatic aspect that warrants attention is the potential oversight of asymptomatic thrombus cases during the follow-up period. Consequently, the statistical representation of patients encountering CRT might be lower than the actual occurrence. Given that individuals with malignancies inherently possess heightened susceptibility to CRT²³, the necessity of routine doppler ultrasound assessments for this patient population necessitates further exploration.

This study is subject to certain limitations that merit consideration. Retrospective in nature, it potentially missed certain statistical nuances between the two groups. The surgical approach was inherently non-randomized, as surgeons tailored their choice of approach based on individual preferences and patient-specific conditions, possibly introducing selection bias. Furthermore, patient satisfaction was not systematically assessed, and a quantitative benchmark for the optimal solution was lacking. The abbreviated duration of follow-up may curtail the evaluation of CRT and infectious adverse events, given their propensity to escalate over extended monitoring periods. Nonetheless, it's worth noting that adverse events themselves are relatively infrequent, and the instances of TIVAPs persisting for exceptionally long or short durations are limited. Consequently, a follow-up duration that strikes the optimal balance between benefits and limitations necessitates careful consideration.

Conclusion

In conclusion, the study indicates that the single-incision axillary vein puncture technique can be safely implemented by an experienced team with a low incidence of adverse events. This approach can serve as a valuable alternative for clinical TIVAPs placement.

Data availability

The datasets generated and/or analysed during the current study are not publicly available due the patient privacy agreement and further research but are available from the corresponding author on reasonable request.

Received: 8 April 2024; Accepted: 24 February 2025 Published online: 01 March 2025

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Acknowledgements

We appreciated clinical departments for data support to the manuscript.

Author contributions

C.M.,L.C. and Y.J.: concept and design of the study, C.M.,Z.Z. and D.M.:interpretation of results, writing of manuscript and final revision. C.M.,Z.Z. and Q.W.: data collection, data analysis. All authors approved the final version of manuscript.

Declarations

Competing interests

The authors declare no competing interests.

Ethics approval and consent to participate

This research study was conducted retrospectively from data obtained for clinical purposes. This study was approved by the Ethics Committee of The Affiliated Suzhou Hospital of Nanjing Medical University (K-2023-041). All methods were performed in accordance with the relevant guidelines and regulations.

Additional information

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