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Effects of three peripherally inserted central catheters insertion techniques on catheterization outcomes: A randomized controlled trial

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ABSTRACT

Background: Catheterization methods for peripherally inserted central catheters (PICC) mainly include the traditional method, one-needle subcutaneous tunnel catheterization, and two-needle subcutaneous tunnel catheterization, all of which are widely used in clinical practice. Researchers focus heavily on complications after these PICC catheterizations but ignore the effect of PICC catheterization process, such as one-time puncture success rate, patient experience, bleeding, and related issues.

Methods: This was a three-arm, parallel, randomized controlled trial. Patients were recruited from Zhongshan Hospital of Xiamen University in China between January and April 2025. Patients who met the inclusion criteria were randomly categorized into three groups. Primary indicators were the one-time puncture success rate, pain intensity, and total bleeding volume during catheterization. Secondary indicators included the blood oozing rate within 24 h after catheterization and catheterization operating time.

Results: In total, 681 patients were recruited. 226 in the traditional non-tunnel catheterization group, 232 in the one-needle subcutaneous tunnel catheterization group, and 223 in the two-needle subcutaneous tunnel catheterization group. The one-needle and two-needle subcutaneous tunnel catheterization groups demonstrated significantly better outcomes compared to the traditional non-tunnel catheterization group in terms of one-time puncture success rate (RD = 6.3 %, 95 % CI: 1.6 % to 11.1 %, $P = 0.014$; RD = 6.6 %, 95 % CI: 1.8 % to 11.3 %, $P = 0.011$) and blood oozing rate within 24 h after catheterization (RD = −7.8 %, 95 % CI: −13.5 % to −2.0 %, $P = 0.012$; RD = −8.3 %, 95 % CI: −14.1 % to −2.5 %, $P = 0.007$). Both the traditional non-tunnel catheterization group and the one-needle subcutaneous tunnel catheterization group demonstrated significantly lower values compared to the two-needle subcutaneous tunnel catheterization group in terms of total bleeding volume (MD = −0.2, 95 % CI: −0.3 to 0.0, $P = 0.026$; MD = −0.2, 95 % CI: −0.4 to −0.1, $P = 0.002$), pain intensity (MD = −0.2, 95 % CI: −0.3 to −0.1, $P = 0.006$; MD = −0.2, 95 % CI: −0.3 to −0.1, $P = 0.003$), catheterization operating time (MD = −0.9, 95 % CI: −1.6 to −0.2, $P = 0.011$; MD = −1.0, 95 % CI: −1.7 to −0.3, $P = 0.006$).

Conclusion: One-needle subcutaneous tunnel catheterization was superior to the other two methods and did not cause nerve or blood vessel damage. It is recommended for clinical use.

Registration: Registered in the Chinese Clinical Trial Registry (ChiCTR2400094988, www.chictr.org.cn). The first recruitment was conducted in January 2025. https://www.chictr.org.cn/bin/project/edit?pid=242304.

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What is already known

- In contemporary clinical practice, there are three main PICC catheter insertion techniques: traditional non-tunnel catheterization, one-needle subcutaneous tunnel catheterization, and two-needle subcutaneous tunnel catheterization.
- Existing studies have focused on the impact of the three PICC catheterization methods on complications after insertion.
- In the catheter placement process, while existing studies have compared the two-needle subcutaneous tunnel method with the traditional non-tunnel method, the effectiveness of the widely used one-needle subcutaneous tunnel method remains unclear.

What this paper adds

- One-needle and two-needle subcutaneous tunnel catheterization demonstrated significantly better outcomes compared to traditional non-tunnel catheterization in terms of one-time puncture success rate and blood oozing rate within 24 h after catheterization.
- Both one-needle subcutaneous tunnel catheterization and traditional non-tunnel catheterization demonstrated significantly lower values compared to two-needle subcutaneous tunnel catheterization in terms of total bleeding volume, pain intensity, and catheterization operating time.
- To sum up, one-needle subcutaneous tunnel catheterization is superior to traditional non-tunnel and two-needle subcutaneous tunnel catheterization methods, without causing nerve or blood vessel damage, it is recommended that one-needle subcutaneous tunnel catheterization be promoted in clinical practice.

1. Introduction

Peripherally inserted central catheters (PICC) are a widely used venous access for chemotherapy in patients with cancer and for resuscitative treatments in patients who are critically ill (Hu et al., 2022; Li et al., 2024). With ongoing practice and research in PICC insertion techniques, the tunneled PICC method has been introduced as an alternative to the traditional non-tunneled approach. The US Standard of Practice for Infusion Therapy proposes to support the implementation of PICC catheterization through tunnel creation in order to optimize medical practice and reduce catheter-induced complications (Nickel et al., 2024). However, the manner in which tunnels are created has not been clearly defined (Nickel et al., 2024). The “Expert Consensus on Tunneling Peripheral Central Venous Catheter Placement Technology (2022)” proposed two main types of tunnel methods in China: one-needle subcutaneous tunnel catheterization and two-needle subcutaneous tunnel catheterization. One-needle subcutaneous tunnel catheterization is defined as the establishment of a tunnel and puncture completed directly with a puncture needle. After a subcutaneous tunnel is established, the puncture needle enters the blood vessel directly, and the catheter outlet corresponds to the puncture point. Two-needle subcutaneous tunnel catheterization involves the use of a puncture needle to complete the puncture and a tunnel needle to establish the subcutaneous tunnel. A subcutaneous tunnel is formed between the puncture point and the skin outlet (Professional Committee of Oncology Nursing and China Anti-Cancer Association, 2023). Two large-scale surveys have shown that 12.1 % - 13.9 % of PICC catheterizations were performed using the tunneled PICC method in China (Yang et al., 2024; Li et al., 2025). Therefore, clinical practice has established three commonly used catheterization methods. The modified Seldinger technique (MST) under ultrasound guidance is widely used in clinical practice, including the traditional catheterization method, one-needle subcutaneous tunnel catheterization, and two-needle subcutaneous tunnel catheterization (Professional Committee of Oncology Nursing and China Anti-Cancer Association, 2023).

Over time, research on the three PICC insertion techniques has primarily focused on their impact on catheter-related complications. Findings consistently indicate that tunneled PICC catheterization is associated with a reduced incidence of complications during catheter dwell time, such as blood oozing at the puncture site, catheter-related infection, catheter-related thrombosis, phlebitis, and catheter displacement (Hong and Mao, 2024). However, the evaluation indicators for PICC catheterization include not only complications but also the patient experience and bleeding during the procedure, with particular emphasis on the one-time puncture success rate, an important concern among experts worldwide (Nickel et al., 2024; Sheng et al., 2024). Additionally, it has been emphasized that repeated venipuncture, pain, and bleeding during the catheterization process can intensify adverse patient experiences, such as tension and fear (Dong et al., 2023). A recent retrospective study by Duncanson et al. confirmed that needle fear is highly prevalent among adults with chronic diseases, especially in patients with malignant tumors, with an incidence rate of 17 % - 52 %, significantly impacting patients' medical decision-making and adherence to catheterization (Duncanson et al., 2021).

Currently, there is still no consensus on the optimal indications for the three PICC catheterization methods regarding the catheterization process. Research on the effectiveness of the catheterization process has only compared the two-needle subcutaneous tunnel catheterization method with the traditional non-tunnel method (Dai et al., 2020; Sheng et al., 2024). Studies indicate that while the two-needle tunnel catheterization method improves catheter stability and success rates, it is markedly more complex (Dai et al., 2020; Sheng et al., 2024). Repeated punctures traumatize tissue, significantly increase bleeding, and prolong insertion time (Dai et al., 2020; Sheng et al., 2024). As for the one-needle subcutaneous tunnel method, which is also widely used in clinical practice, is deemed by expert consensus to be relatively easier to perform. However, its catheterization success rate may be lower than that of the non-tunneling method (Oncology Nursing Special Committee and Chinese Anti-Cancer Association, 2023). However, a descriptive study on the one-needle subcutaneous tunnel method reported a high puncture success rate of 96 % with no significant pain experienced by patients during the procedure (Ostroff and Moureau, 2017). To date, the effects of these three PICC catheterization methods during the catheterization process remain unclear.

Based on this, it is necessary to compare these three catheterization methods to determine which one has the best effect during the catheterization process. Therefore, this randomized controlled trial (RCT) aimed to compare the effects of the three widely used clinical catheterization methods on one-time puncture success rate, pain, and bleeding during the catheterization process to provide better guidance for implementing PICC catheterization in the clinic and facilitate its management.

2. Methods

2.1. Study design

This was a three-arm, parallel RCT registered at the Chinese Clinical Trial Registry on December 24, 2024. The trial was conducted in accordance with the trial registration protocol with no major deviations.

2.2. Study patients

All patients were recruited at the intravenous therapy specialty clinic of a tertiary hospital in Xiamen, China, between January and April 2025. The inclusion criteria were: (a) aged $\geq$18 years; (b) undergoing PICC catheterization for the first time; (c) complete language expression and comprehension; and (d) provision of informed consent and voluntary participation. The exclusion criteria were: (a) history of bilateral breast cancer resection or inability to undergo upper extremity venous catheterization due to superior vena cava obstruction; (b) puncture site infection or history of vascular surgery; and (c) critically illness

requiring resuscitation within 24 h, such as cardiac arrest, shock, or post-major major surgery. The recruited patients were assessed by two researchers. The enrollment and assessment process is illustrated in Fig. 1.

The sample size was calculated based on the primary outcome measure of the one-time puncture success rate. According to the selected reference, the one-time puncture success rates were 96 % for one-needle (Ostroff and Moureau, 2017) and 95.3 % for two-needle subcutaneous tunnel catheterization (Xiao et al., 2021), respectively. Combined with previous clinical practice, the success rate of a one-time puncture success rates using traditional non-tunnel PICC was 88 %. Power analysis was performed to calculate the effect size. The sample size was determined with 90 % power ($\beta = 0.1$, representing a 90 % probability of avoiding a Type II error) to detect significant effects at a two-sided significance level ($\alpha = 0.05$). The Power Analysis and Sample Size software, Version 15.0.5 (Uone-Tech, Beijing, China) was used for sample size estimation, and the required sample size was calculated to be at least 622 cases. Considering a dropout rate of 5 %, the minimum required sample size was 655 cases.

2.3. Randomization and masking

This study used computer-generated random numbers. Participants were assigned to groups according to the remainder when each number was divided by three. Using Microsoft Excel 2016 software (Microsoft, Seattle, WA, USA), 1000 random integers were generated. Then, a non-study group member placed each integer in sequence into a sealed and opaque envelope to ensure allocation concealment. Patients who met the eligibility criteria and consented to participate were assigned by the same non-research team member, who used a calculator to divide each integer by three and allocated them according to the remainder. Those with a remainder of zero when divided by three were allocated to the traditional non-tunnel catheterization group; those with a remainder of one were allocated to the one-needle subcutaneous tunnel catheterization group; and those with a remainder of two were allocated to the two-needle subcutaneous tunnel catheterization group. In this study, only the data processors were blinded, as the operators, patients, and outcome evaluators were aware of the differences among the three catheterization procedures.

2.4. Intervention

2.4.1. Catheterization nurses

All PICC procedures were implemented following the standardized protocols outlined in the textbook "*Training Materials for Intravenous Therapy Nurses in the Specialty of Intravenous Infusion Therapy*," published by the People's Health Publishing House in 2021 (Wu et al., 2021). Four catheterization nurses who performed the PICC procedures were certified as intravenous therapy specialists by the Chinese Nursing Association and had over 10 years of experience in PICC placement.

2.4.2. Materials

Disposable central venous catheter insertion care package (SENTURIAN, Shanghai, China), 4F single-lumen open-ended polyurethane

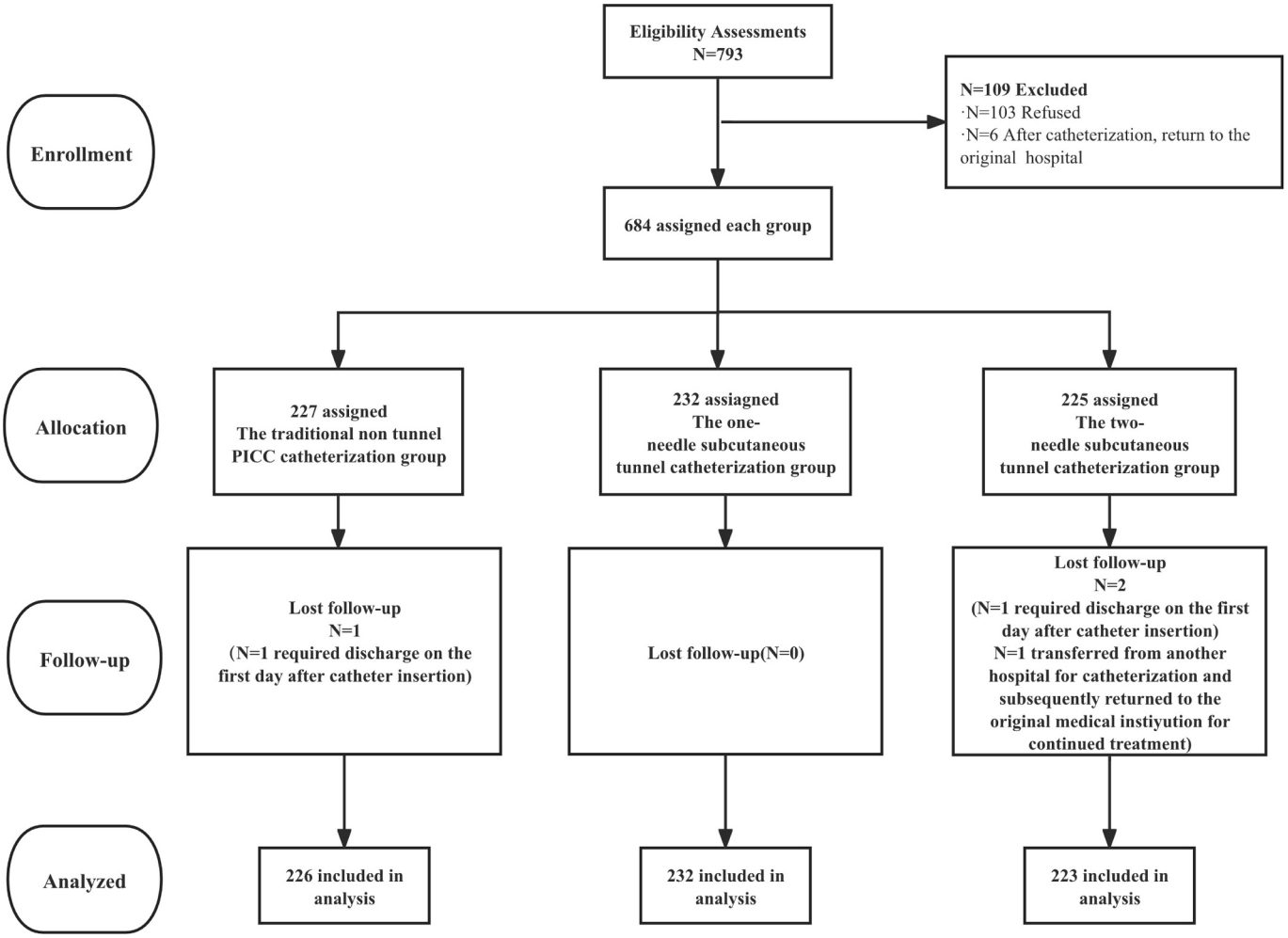

Fig. 1. Consort diagram profile flow.

PICC catheter and kit (BARD, Inc., Salt Lake City, Utah, USA) such as metal puncture needle with a length of 7 cm, outer diameter of puncture needle core 0.9 mm and catheter sheath in the dilator/introducer kit with a length of 7 cm. Doppler ultrasonic blood stream detector, 2 % lidocaine, and disposable subcutaneous tunneling needle (length 14 cm, diameter 2 mm). All patients in this study used the same brand and model of materials.

2.4.3. Procedure

All three groups received standardized health education before and after catheterization. Catheter maintenance during the initial 24 h after insertion was performed following a standardized operating procedure. A combination of verbal education, PICC catheter brochures, and electronic videos was used to educate patients and their families on: (a) the advantages and disadvantages of catheter placement, and key points for cooperation during the catheter placement process; and (b) precautions for daily life while wearing the catheter, recognition of complications, ways to seek medical assistance, and catheter maintenance during the wearing period after catheterization.

The PICC catheterization procedure was as follows: First, the skin surrounding the puncture site was disinfected, and a sterile field was thoroughly established to maximize sterile barriers. This step was consistent across all three catheterization methods. Second, different catheter insertion methods were implemented based on patient group allocation. All participants in the three groups underwent puncture using the MST under ultrasound guidance.

2.4.3.1. Traditional non-tunnel catheterization group. The specific methods were as follows: Step 1: The puncture point on the mid-upper arm was selected (Brescia et al., 2024). Step 2: Local anesthesia with lidocaine was used, and the puncture was performed under ultrasound guidance to advance the guidewire and expand the skin. Step 3: The dilator components and trimmed catheter were inserted. Step 4: The catheter was positioned and secured.

2.4.3.2. One-needle subcutaneous tunnel catheterization group. The specific methods were as follows: Step 1: A vein puncture point was identified, and the puncture was performed in the upper one-third or upper

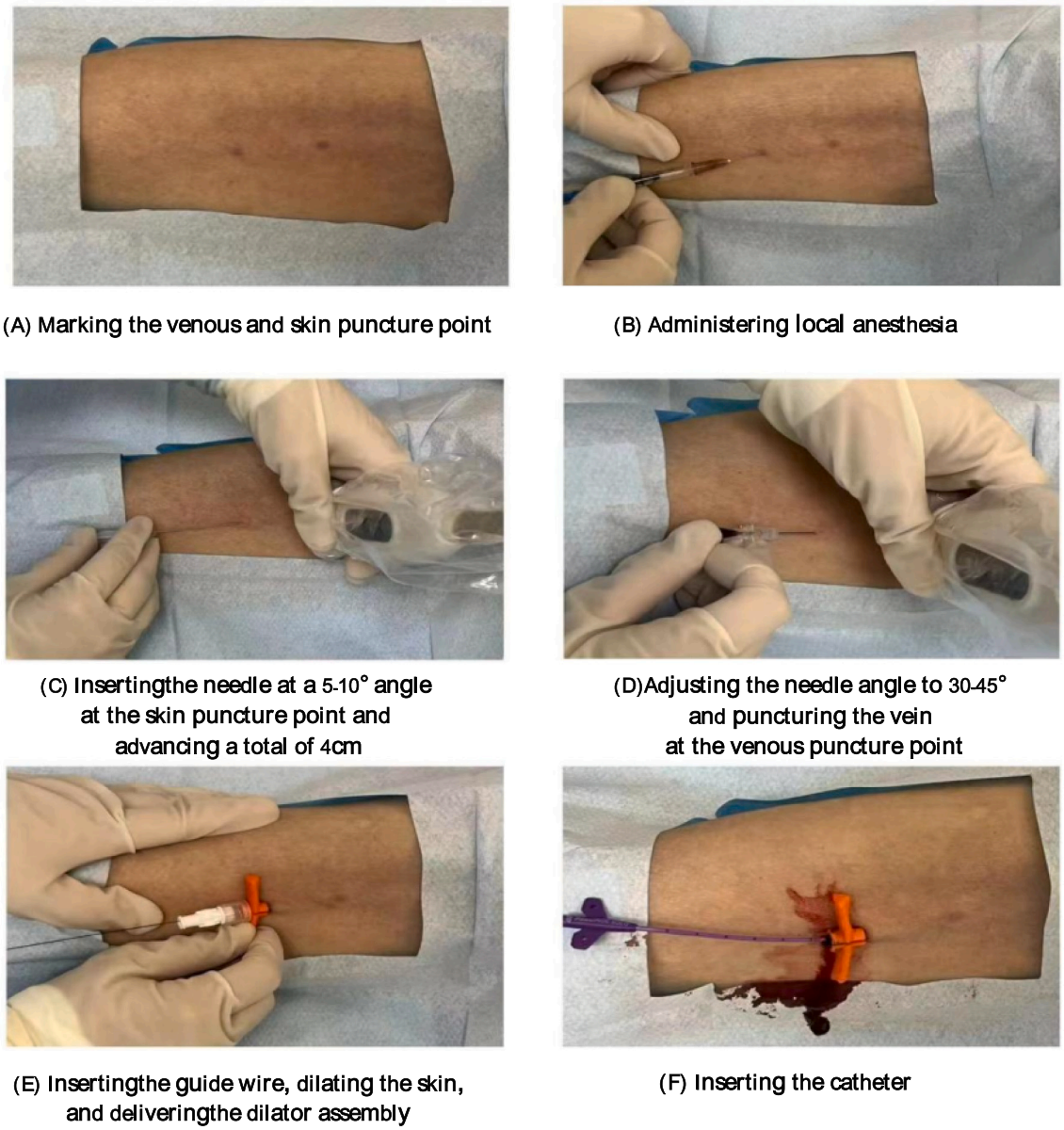

Fig. 2. Image of the one-needle subcutaneous tunnel catheterization method.

segment of the mid-upper arm. Step 2: The skin puncture point was marked 4 cm below the identified vein puncture site. Step 3: Safe penetration of the puncture needle into the predetermined target vein was ensured by using ultrasound to examine the vascular direction and nerve distribution between the skin and vein puncture sites, avoiding contact with vessels or nerves. Local anesthesia was administered at the skin puncture site. Step 4: The puncture needle was inserted at a 5–10° angle from the skin puncture point into the subcutaneous tissue and advanced a total of 4 cm.

The needle angle was then adjusted to 30–45° once ultrasound confirmed its position at the vein puncture site, ensuring accurate venous entry (Wang et al., 2019). Step 5: The guidewire was inserted, the skin at the puncture site was expanded, and the dilator components were introduced. Step 6: The trimmed catheter was inserted, positioned, and secured. See Fig. 2 for detailed procedural steps.

2.4.3.3. Two-needle subcutaneous tunnel catheterization group. The specific methods were as follows: Step 1: the vein puncture point and the catheter exit point (4 cm below the vein puncture point) were marked. Step 2: The vein was punctured at the vein puncture point, the guidewire was inserted, and the skin was expanded, including the skin at the catheter exit point. All surgeries were performed under local anesthesia. Step 3: Normal saline was used to separate the subcutaneous tissue between the vein puncture point and the catheter exit point, causing the skin to bulge (Wu et al., 2022). Step 4: The blunt end of the tunneling needle was advanced along the skin bulge from the catheter exit site to the vein puncture site until the needle tip emerged from the skin at the vein puncture location. Step 5: The catheter end was attached to the tunneling needle's interface at the exit site, and the tunneling needle was pulled out from the vein puncture site, guiding the catheter (Xiao et al., 2021). Step 6: The dilator components were inserted, and the catheter was trimmed, positioned, and secured.

2.5. Outcome variables and measures

2.5.1. Primary indicators

The primary outcome measures included one-time puncture success rate, pain intensity, and total bleeding volume during catheterization.

One-time puncture success refers to the insertion of the puncture needle into the target vein with smooth guidewire advancement in only one attempt. If the puncture needle fails to enter the vein on the first attempt and is withdrawn from the subcutaneous tissue for further exploration, it is considered a second puncture (Li et al., 2012).

Pain is assessed using a Numeric Rating Scale (Karcioglu et al., 2018) immediately after catheterization. This scale comprises 11 numbers ranging from 0 to 10. Patients were asked to rate the highest level of pain experienced during the catheterization process using these numbers, with higher numbers indicating more severe pain: 0 for no pain, 1–3 for mild pain, 4–6 for moderate pain, 7–9 for severe pain, and 10 for excruciating pain.

The total bleeding volume during catheterization is determined by weighing the sterile gauze before and after catheter placement using a precise electronic scale with an accuracy of 0.1 g (Xiao et al., 2021).

2.5.2. Secondary indicators

The secondary outcome measures included the blood oozing rate within 24 h after catheterization and catheterization operating time.

When changing dressings within 24 h after catheterization, the proportion of patients with blood oozing at the catheter site relative to the total number of patients with catheter placement is calculated (Liu et al., 2022). Active oozing refers to the continued oozing of fresh blood from the catheter exit or the vein puncture site (Wu et al., 2021). Catheterization operating time is determined by the total time elapsed from the start of the puncture to the completion of catheter tip placement and fixation (Xiao et al., 2021).

2.5.3. Safety indicator

Incidents of arterial and/or nerve injuries.

2.6. Data collection

Data on the evaluation indicators were collected and recorded by two trained clinical nurses who were not involved in the study. The catheterization nurses recorded the patient's basic information and laboratory test values closest to the time within one week before catheterization.

2.7. Statistical analysis

All data were double-checked before entry, and IBM SPSS Statistics Version 26.0 (IBM, Inc., Armonk, NY, USA) was used for data analysis. Descriptive statistics were employed for normally distributed continuous variables, expressed as mean ± standard deviation. Descriptive statistics were used for non-normally distributed continuous variables, expressed as median and interquartile range. Count data are described using frequencies and percentages. Three groups of normally distributed measurement data were compared using analysis of variance. The F-test and Welch test were used for the homogeneity and heterogeneity of variances, respectively. If $P < 0.05$, further pairwise comparisons were conducted using the least significant difference method for homogeneous variances and the Tamhane method for heterogeneous variances. Statistical significance was set at $P < 0.05$. For the three groups of non-normally distributed measurement data, the Kruskal–Wallis test was used for intergroup comparisons. The chi-square test was used to compare the counting data among the three groups. If $P < 0.05$, the α-partition method was used to conduct additional pairwise comparisons, and statistical significance was set at P value <0.017.

2.8. Ethics considerations

This project was approved by the Ethics Committee of Zhongshan Hospital affiliated with Xiamen University, China (XMZSYKY Ethical Approval, No. 2024-158). Detailed information about the purpose of this study was provided to patients who met the inclusion and exclusion criteria, and informed consent was obtained from them or their families. The study was conducted in accordance with the Declaration of Helsinki of the World Medical Association (World Medical Association, 2013), and all participant data were kept confidential.

3. Results

3.1. Participants

In total, 684 patients were included in the study and randomized. Among them, 227 patients were included in the traditional non-tunnel catheterization group, 232 in the one-needle subcutaneous tunnel catheterization group, and 225 in the two-needle subcutaneous tunnel catheterization group. Among these, one patient in the traditional non-tunnel catheterization group requested discharge on the first day after catheter insertion. In the two-needle subcutaneous tunnel catheterization group, one patient requested discharge on the first day after catheter insertion, whereas another patient was transferred from another hospital for catheterization and subsequently returned to the original medical institution for continued treatment. Neither patient could undergo the 24 h postoperative bleeding indicator assessment. Therefore, three participants were withdrawn from the study. A total of 681 participants completed the study. The overall loss to follow-up was 0.4 % (Fig. 1).

3.2. Patient characteristics

A total of 681 patients were enrolled, and general data were

analyzed. The differences among the three groups in age, gender, and clinical characteristics, including type of illness, catheterization vein, body mass index (BMI), activated partial thromboplastin time (APTT), and platelet count were comparable and not statistically significant ($P > 0.05$). See Table 1.

3.3. Primary outcome

3.3.1. Comparison of one-time puncture success rate among the three groups

The one-time puncture success rates for the traditional non-tunnel, one-needle subcutaneous tunnel, and two-needle subcutaneous tunnel catheterization groups were 88.5 %, 94.8 %, and 95.1 %, respectively ($\chi^2 = 9.416$, $P = 0.009$). Pairwise comparisons revealed that both the one-needle and two-needle subcutaneous tunnel catheterization groups had higher one-time puncture success rates than the traditional non-tunnel catheterization group (risk difference [RD] = 6.3 %, 95 % confidence interval [CI]: 1.6 % to 11.1 %, $P = 0.014$) and (RD = 6.6 %, 95 % CI: 1.8 % to 11.3 %, $P = 0.011$) respectively. However, no significant difference was observed in the one-time puncture success rate between the one-needle and two-needle subcutaneous tunnel catheterization groups (RD = −0.2 %, 95 % CI: −5.0 % to 4.5 %, $P = 0.907$). See Table 2.

3.3.2. Comparison of pain intensity during catheterization among the three groups

The pain intensity scores during catheterization for the traditional non-tunnel catheterization, one-needle subcutaneous tunnel catheterization, and two-needle subcutaneous tunnel catheterization groups were 1.6 (standard deviation [SD]: 0.7), 1.6 (SD: 0.7), and 1.8 (SD: 0.8), respectively. Statistically significant differences were observed between the groups (F = 5.546, $P = 0.004$). Pairwise comparisons revealed no significant difference in pain intensity scores between the one-needle subcutaneous tunnel catheterization group and the traditional non-tunnel catheterization group during catheterization (mean difference [MD] = 0.0, 95 % CI: −0.2 to 0.1, $P = 0.817$). However, both the traditional non-tunnel and one-needle subcutaneous tunnel catheterization groups had significantly lower pain scores than the two-needle subcutaneous tunnel catheterization group, respectively (MD = −0.2, 95 % CI: −0.3 to −0.1, $P = 0.006$), (MD = −0.2, 95 % CI: −0.3 to −0.1, $P = 0.003$). See Table 2.

3.3.3. Comparison of total bleeding volume during catheterization among the three groups

The total bleeding volumes during catheterization for the traditional non-tunnel, one-needle subcutaneous tunnel, and two-needle subcutaneous tunnel catheterization groups were 2.8 (SD: 0.6) ml, 2.8 (SD: 0.5) ml, and 3.0 (SD: 0.7) ml, respectively. Statistically significant differences were observed between the groups (F = 6.238, $P = 0.002$). Pairwise comparisons revealed no significant difference in intraoperative blood loss between the one-needle subcutaneous tunnel catheterization group and the traditional non-tunnel catheterization group (MD = −0.0, 95 % CI: −0.2 to 0.1, $P = 0.881$). However, both the traditional non-tunnel and one-needle subcutaneous tunnel catheterization groups had significantly lower intraoperative blood loss than the two-needle subcutaneous tunnel catheterization group, respectively (MD = −0.2, 95 % CI: −0.3 to 0.0, $P = 0.026$), (MD = −0.2, 95 % CI: −0.4 to −0.1, $P = 0.002$). See Table 2.

3.4. Secondary outcomes

3.4.1. Comparison of blood oozing rate within 24 h after catheterization among the three groups

The blood oozing rates within 24 h after catheterization for patients in the traditional non-tunnel catheterization, one-needle subcutaneous tunnel catheterization, and two-needle subcutaneous tunnel catheterization groups were 16.4 %, 8.6 % and 8.1 %, respectively. Statistically significant differences were observed among the groups ($\chi^2 = 9.945$, $P = 0.007$). Pairwise comparisons revealed that both the one-needle and two-needle subcutaneous tunnel catheterization groups had significantly lower blood oozing rates within 24 h after catheterization compared to the traditional non-tunnel catheterization group (RD =

Table 1
Baseline characteristics of the research sample ($N = 681$).

Variable	The traditional non tunnel PICC catheterization group ($n = 226$)		The one-needle subcutaneous tunnel catheterization group ($n = 232$)		The two-needle subcutaneous tunnel catheterization group ($n = 223$)		Total ($n = 681$)	
	n	%	n	%	n	%	n	%
Gender								
Man	143	63.3	133	57.3	134	60.1	410	60.2
Female	83	36.7	99	42.7	89	39.9	271	39.8
Type of illness								
Malignant tumor	180	79.6	193	83.2	189	84.8	562	82.5
Craniocerebral disease	20	8.8	18	7.8	16	7.2	54	7.9
Infection	14	6.2	9	3.9	9	4.0	32	4.7
Other	12	5.3	12	5.2	9	4.0	33	4.8
Cathererization vein								
Right basilic vein	147	65.0	166	71.6	138	61.9	451	66.2
Right brachial vein	34	15.0	24	10.3	38	17.0	96	14.1
Left basilic vein	36	15.9	30	12.9	33	14.8	99	14.5
Left brachial vein	9	4.0	12	5.2	14	6.3	35	5.1

	Mean	SD	Mean	SD	Mean	SD	Mean	SD
Age	60.5	13.1	63.4	12.5	62.0	13.2	62.0	13.0
BMI	21.5	3.4	22.0	3.5	22.0	3.4	21.8	3.5

	M	P_{25}	P_{75}	M	P_{25}	P_{75}	M	P_{25}	P_{75}	M	P_{25}	P_{75}
APTT	31.4	27.9	34.4	31.1	27.6	34.10	30.9	27.3	33.9	30.9	27.6	34.2
Platelet count	255.5	208.0	335.0	268.0	211.3	335.0	266.0	215.0	329.0	266.0	212.0	335.0

Note. BMI = body mass index; APTT = activated partial thromboplastin time.

Table 2
Differences in one-time puncture success rate, blood oozing rate within 24 h after catheterization, pain intensity, total bleeding volume during catheterization and catheterization operating time ($N = 681$).

Variable	The traditional non tunnel PICC catheterization group ($n = 226$)		The one-needle subcutaneous tunnel catheterization group ($n = 232$)		The two-needle subcutaneous tunnel catheterization group ($n = 223$)		Total ($n = 681$)		x^2	P
	n	%	n	%	n	%	n	%		
One-time puncture success rate									9.416	0.009[a]
Yes	200	88.5	220	94.8	212	95.1	632	92.8		
Blood oozing rate within 24 h after catheterization									9.945	0.007[b]
Yes	37	16.4	20	8.6	18	8.1	75	11.0		
	Mean	SD	Mean	SD	Mean	SD	Mean	SD	F	P
Pain intensity	1.6	0.7	1.6	0.7	1.8	0.8	1.7	0.7	5.546	0.004[c]
Total bleeding volume during catheterization	2.8	0.6	2.8	0.5	3.0	0.7	2.8	0.6	6.238	0.002[d]
Catheterizaton operating time	11.1	3.0	11.0	3.2	12.0	4.9	11.4	3.8	4.659	0.010[c]

Note.
[a] Use α-partition method for pairwise comparison: The traditional non tunnel PICC catheterization group < The one-needle subcutaneous tunnel catheterization group = The two-needle subcutaneous tunnel catheterization group.
[b] Use α-partition method for pairwise comparison: The traditional non tunnel PICC catheterization group > The one-needle subcutaneous tunnel catheterization group = The two-needle subcutaneous tunnel catheterization group.
[c] Use method LSD for pairwise comparison: The traditional non tunnel PICC catheterization group = The one-needle subcutaneous tunnel catheterization group < The two-needle subcutaneous tunnel catheterization group.
[d] Use method Tamhane for pairwise comparison: The traditional non tunnel PICC catheterization group = The one-needle subcutaneous tunnel catheterization group < The two-needle subcutaneous tunnel catheterization group.

−7.8 %, 95 % CI: −13.5 % to −2.0 %, $P = 0.012$), (RD = −8.3 %, 95 % CI: −14.1 % to −2.5 %, $P = 0.007$). However, no significant difference was observed in the blood oozing rate within 24 h after catheterization between the one-needle and two-needle subcutaneous tunnel catheterization groups (RD = 0.5 %, 95 % CI: −5.2 % to 6.3 %, $P = 0.832$). See Table 2.

3.4.2. Comparison of catheterization operating time among the three groups

The catheterization operating time for the traditional non-tunnel catheterization, one-needle subcutaneous tunnel catheterization, and two-needle subcutaneous tunnel catheterization groups was 11.1 (SD: 3.0) min, 11.0 (SD: 3.2) min, and 12.0 (SD: 4.9) min, respectively. Statistically significant differences were observed among the groups ($F = 4.659$, $P = 0.010$). Pairwise comparisons showed no significant difference in the catheterization operating time between the one-needle subcutaneous tunnel catheterization group and the traditional non-tunnel catheterization group (MD = −0.1, 95 % CI: −0.8 to 0.6, $P = 0.858$). However, both the traditional non-tunnel catheterization group and the one-needle subcutaneous tunnel catheterization group had shorter catheterization operating time compared to the two-needle subcutaneous tunnel catheterization group (MD = −0.9, 95 % CI: −1.6 to −0.2, $P = 0.011$), (MD = −1.0, 95 % CI: −1.7 to −0.3, $P = 0.006$). Details are presented in Table 2.

3.5. Occurrence of accidental artery injury and nerve injury among the three groups

No accidental arterial or nerve injuries occurred in any of the three catheterization groups.

4. Discussion

This study showed that the one-needle and two-needle subcutaneous catheterization groups were superior to the traditional non-tunnel catheterization group in terms of the one-time puncture success rate and the blood oozing rate within 24 h after catheterization. The total bleeding volume during catheterization, pain intensity, and catheterization operating time in the one-needle catheterization group were lower compared to those in the two-needle catheterization group.

The results of this study showed that the one-time puncture success rates of the one-needle and two-needle subcutaneous tunnel catheterization groups were 94.8 % and 95.1 %, respectively, both significantly higher compared to those of the traditional non-tunnel catheterization group. These rates were comparable to the 96 % reported for one-needle subcutaneous tunnel catheterization (Ostroff and Moureau, 2017) and the 95.3 % reported for two-needle subcutaneous tunnel catheterization (Xiao et al., 2021). The one-time puncture success rate was positively correlated with the vessel diameter (Ostroff and Moureau, 2017). Establishing the tunnel shifts the venous puncture point from the middle of the mid-arm to the upper mid-arm or upper arm, where the vessel diameter is typically larger. Furthermore, the 2024 Infusion Therapy Practice Standards in the United States explicitly state that the catheter to vessel diameter ratio must be <45 % (Nickel et al., 2024). Currently, 4F is one of the most widely used catheter types globally, with an outer diameter of 1.43 mm (Swaminathan et al., 2022; Sun et al., 2025), indicating that the target vessel diameter should be >3.2 mm. Therefore, the increased diameter of the blood vessels improved the one-time puncture success rate of the two subcutaneous catheterization methods. The traditional non-tunnel catheterization method makes it challenging to find suitable vessels in patients with poor vascular conditions in the middle of the mid-arm, resulting in a lower one-time puncture success rate.

Presently, professionals recognize that the one-time puncture success rate in two-needle subcutaneous catheterization is higher than that of traditional non-tunnel catheterization. There are differing views on the success rate of one-needle subcutaneous catheterization compared to traditional non-tunnel catheterization. It has been proposed that the one-needle subcutaneous tunnel catheterization method is challenging to perform and has a low success rate (Professional Committee of Oncology Nursing and China Anti-Cancer Association, 2023). However, results from this study demonstrated higher success rates in the one-needle subcutaneous catheterization group compared to the conventional non-tunneled PICC placement group. This may be attributed to the fact that all three PICC catheterization methods in this study utilized the freehand technique, without using a needle guide. Take the one-needle subcutaneous tunnel catheterization procedure as an example. During this procedure, when the puncture needle tip reaches beneath the ultrasound probe along the tunnel, a bright spot appears in the subcutaneous tissue under the probe on ultrasound. The operator gently moves the puncture needle. If the fluctuation in subcutaneous tissue caused by the light touch occurs exactly at the center of the target vessel under the probe without deviation, the operator can determine the

puncture direction. Then, adjust the puncture angle according to the vessel depth. When a white spot appears in the vessel on the ultrasound screen and blood flows slowly from the puncture needle hub, it indicates successful vessel entry. All of this occurs without the use of a needle guide. The freehand technique requires operators to independently adjust needle insertion angles based on ultrasound-detected vessel depth and subcutaneous tissue thickness without relying on needle guides to position the puncture needle within the vessel. Multiple studies have demonstrated that the freehand technique eliminates the need for hand-switching during needle guide separation, prevents resistance between needle guides and puncture needles, and reduces needle displacement and vessel dislodgement, thereby enhancing first-attempt success rates (Li et al., 2019; Yue et al., 2020). This change in operating habits may be an influential factor in determining success rates.

The results of this study showed that one-needle subcutaneous catheterization reduced pain and bleeding compared to two-needle subcutaneous catheterization, but was similar to traditional non-tunnel catheterization. In the process of catheterization, compared to traditional non-tunnel catheterization, one-needle subcutaneous tunnel catheterization does not change the procedural steps or catheterization tools, but only adjusts the angle and path of the puncture needle entering the blood vessel. Specifically, a thin metal needle (0.9 mm in diameter) is used to build a tunnel through the subcutaneous tissue and then puncture the vein. Therefore, one-needle subcutaneous tunnel catheterization was similar to traditional non-tunnel catheterization in terms of pain and bleeding.

The two-needle subcutaneous catheterization increased pain and bleeding compared with one-needle subcutaneous catheterization. Based on the analysis of these results, this may be related to the following factors: First, an additional metal tunnel needle is required to establish a subcutaneous tunnel after successful venous puncture with a metal needle in two-needle subcutaneous tunnel catheterization. To successfully guide the catheter out and prevent it from dislodging within the subcutaneous tunnel during two-needle subcutaneous tunnel formation, the diameter of the metal tunnel needle must be larger than that of the catheter. Consequently, the thicker metal tunnel needle causes more damage to subcutaneous tissue, microvessels, and peripheral nerves. Additionally, the injury site is rich in nerve terminals and a two-layer microvascular network (Liu et al., 2022), which increases pain and bleeding. Second, whereas one-needle subcutaneous catheterization involves only one incision, two-needle subcutaneous catheterization requires two incisions, one at the skin exit of the catheter and the other at the vascular puncture site. This, in turn, increased pain and bleeding. Similarly, the two-needle subcutaneous tunnel method produces more pronounced discomfort than traditional non-tunnel catheterization for the same reasons. However, the results of this study are not entirely consistent with those of Li (Li et al., 2024). The study reported that the pain score for the two-needle subcutaneous tunnel catheterization method was 1.4 (SD: 0.9), while the pain score for the traditional non-tunneled catheterization method was 1.2 (SD: 0.8). Although there was no statistically significant difference between the two groups, the numerical values for the two-needle subcutaneous tunneled catheterization group were higher compared to those for the traditional non-tunneled catheterization group. Further exploration in this area is warranted.

The results of this study indicate that blood oozing within 24 h after catheterization with both the one-needle and two-needle subcutaneous tunnel catheterization methods results in less blood loss compared to that of traditional non-tunnel catheterization, which is consistent with the findings of previous studies (Wang et al., 2019; Xiao et al., 2021). Based on these result analysis, it may be related to the following factors: firstly, in the traditional non-tunnel catheterization method, tearing the puncture sheath after catheterization can easily cause blood exudation along the periphery of the catheter because the puncture points of the skin and blood vessels are located along the same straight line, and the puncture sheath diameter is larger compared to that of the PICC catheter (Xiao et al., 2021). Secondly, establishing a subcutaneous tunnel creates a distance between the vascular and skin puncture points equal to the length of the tunnel, which increases the frictional force of catheter sliding compared to the traditional non-tunnel catheterization method. Furthermore, the presence of connective and muscle tissues under the skin at the tunnel site puts pressure on the vascular puncture point and accelerates hemostasis, thereby reducing the occurrence of post-catheterization blood oozing. Finally, the improved success rate of one-needle and two-needle subcutaneous tunnel catheterization reduces the number and area of skin wounds, thereby decreasing the incidence of oozing blood.

These results indicated that the catheterization operating time was comparable between the one-needle subcutaneous tunnel catheterization group and the traditional non-tunnel catheterization group but shorter than that of the two-needle subcutaneous tunnel catheterization group. The main reason is that the two-needle subcutaneous tunnel catheterization method involves additional steps, including local anesthesia at the catheter exit site, skin dilation, separation of subcutaneous tissues with saline, and the use of a metal tunnel needle to guide the catheter in establishing the tunnel, thereby increasing the operation time.

No accidental arterial or nerve injury occurred during the three catheterization methods, indicating that all methods were safe and feasible. All three catheterization methods were performed using the ultrasound-guided modified Seidinger technique. The one-needle and two-needle subcutaneous tunneling methods included ultrasound examinations in accordance with the 2024 American Infusion Therapy Practice Standards before tunnel establishment, emphasizing the importance of using vascular visualization methods (Nickel et al., 2024). This approach enables the prompt detection of arteries and nerves during needle or tunnel needle insertion, thereby preventing inadvertent damage to these structures and ensuring the safety and viability of the procedure.

4.1. Limitations and implications

Despite the positive findings, this study had some limitations. First, all samples in this study were from Chinese patients. The average BMI of the included participants was 21.8 kg/m^2, placing it within the moderate range for the Chinese population according to national weight standards (normal BMI range: 18.5–23.9 kg/m^2) (National Clinical Practice Guideline on Obesity Management Editorial Committee, 2024). According to the World Health Organization's body weight classification criteria, a BMI exceeding 25 kg/m^2 is defined as overweight or obese (Factshee WHO, 2023). Although 24.2 % of the participants had a BMI exceeding 23.9 kg/m^2 and 11.2 % had a BMI exceeding 26.9 kg/m^2, the prevalence of obesity or super-obesity remained limited. Future research could explore the issues related to overweight or obese populations. Secondly, to avoid bias and ensure comparability of the research results, this study uniformly set the tunnel length and catheter material during the procedure. For cases where a longer tunnel or a longer dilator/catheter sheath kit might be required, this study did not include a discussion. Future research could also target such populations. Thirdly, the results were based on the operator's proficiency in freehand operation under ultrasound guidance, rather than on the original use of an additional needle guide device. This was beneficial in improving the success rate of one-time puncture, thereby reducing bleeding and pain. It suggests that professional personnel should strengthen the training and practice of freehand operation to improve the technique of PICC catheterization. Fourthly, this was a one-center study, which needs to be further verified by a multicenter, large-sample RCT in the future. Lastly, future research may also explore the effectiveness and safety of combining the one-needle subcutaneous tunnel technique with ultrasound-guided MST for other types of vascular catheterization, such as central venous catheterization.

5. Conclusions

The results of this study showed that one-needle subcutaneous tunnel catheterization was superior to two-needle subcutaneous tunnel catheterization and traditional non-tunnel catheterization methods, without causing nerve or blood vessel damage. Based on previous studies, the tunneling method for PICC catheterization can reduce the incidence of complications associated with indwelling catheters. Therefore, one-needle subcutaneous tunnel catheterization deserves to be recommended in clinical practice.

CRediT authorship contribution statement

Lan Li: Writing – review & editing, Writing – original draft, Project administration, Investigation, Data curation, Conceptualization. **Xinlei Wu:** Writing – review & editing, Writing – original draft, Project administration, Investigation, Conceptualization. **Lihui Lin:** Project administration, Data curation. **Zhiyun Cai:** Project administration, Data curation. **Xijun Ye:** Project administration, Data curation. **Yufeng Lin:** Project administration, Investigation. **Yajiao Wang:** Writing – review & editing, Project administration. **Liu Yang:** Writing – review & editing, Writing – original draft, Project administration, Investigation, Conceptualization.

Ethics considerations

This project was approved by the Ethics Committee of Zhongshan Hospital Affiliated with Xiamen University in China (xmzsyyky ethical approval, No. 2024-158).

Declaration of competing interest

The authors declare no potential conflicts of interest and sources of funding with respect to the research, authorship and/or publication of this article.

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Data availability

The datasets used and/or analyzed in the current study are available from the corresponding author upon reasonable request.

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Update

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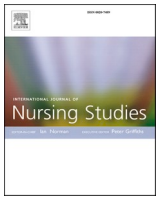

Corrigendum

Corrigendum to "Effects of three peripherally inserted central catheters insertion techniques on catheterization outcomes: A randomized controlled trial" [Int. J. Nurs. Stud. 172 (2025) 105209]

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The authors regret that they have identified some small mistakes (mainly due to accidental presentation of incorrect ethical numbers at the end of the article) that do not affect any conclusions of the work but are deemed sufficiently important to require correction. The authors would like to apologize for any inconvenience caused.

The corrected sentence should read: 'This project was approved by the Ethics Committee of Zhongshan Hospital of Xiamen University in China (xmzsyyky ethical approval, No.2024-158).'.

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