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Effectiveness of subcutaneous tunneling technique in reducing PICC dislodgement and malposition: a pilot multicenter randomized controlled trial

Original article

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Abstract: **Objective:** To evaluate the impact of subcutaneous tunneling on peripherally inserted central catheters (PICCs) dislodgement and malposition. Dislodged or malpositioned PICCs can lead to improper treatment. The subcutaneous tunneling strategy may be effective, but there is insufficient evidence, and proximal movement has not been explored.
Methods: We randomized 630 patients who needed PICCs placement to either the tunneled PICCs (experimental group) or the non-tunneled PICCs (control group). Dislodgement and malposition of the catheter were the primary outcomes, and catheter-related infection (CRI) and catheter-related thrombosis (CRT) were the secondary outcomes.
Results: Subcutaneous tunneling does not significantly reduce distal catheter movement, but it significantly reduces proximal catheter movement (4.3% vs. 9.9%, $P = 0.007$), which may explain the lower incidence of CRI (2.0% vs. 5.3%, $P = 0.030$) and CRT (3.6% vs. 12.5%, $P < 0.001$).
Conclusions: Although subcutaneous tunneling does not significantly improve catheter prolapse, it should still be used clinically because proximal catheter movement can be a more serious problem associated with CRI and CRT.

Keywords: *catheterization • complications • peripheral adverse effects • randomized controlled trial • tunneled multicenter study*

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1. Introduction

Peripherally inserted central catheters (PICCs) are highly recommended for patients requiring chemotherapy, prolonged parenteral nutrition, and long-term antibiotic therapy due to their safety, convenience, versatility, and cost-effectiveness.[1–3] As with other central venous access devices (CVADs), there are some initial problems with PICCs. Approximately 14.4%–61.4% of catheters have complications, which increase patients' physical burden and lead to improper treatment.[4–6]

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Catheter dislodgement and malposition are common and serious problems associated with long-term indwelling. A catheter moved distally is more likely to cause blockage, thrombosis, and malfunctions, whereas a catheter moved proximally is more likely to cause arrhythmias, cardiac tamponade, and tricuspid valve dysfunction.[7] Several approaches have been made to securing PICCs, including sutureless devices, semi-permeable transparent dressings, and cyanoacrylate adhesives. However, these measures are estimated to be effective between 85% and 95%, and components should be changed regularly.[8–10] A bundled approach may be optional without considering economic costs, but more randomized controlled trials (RCTs) with appropriate sample sizes are needed to confirm it.[11]

Subcutaneous tunneling is a relatively mature technique that uses either a single puncture with the appropriate needle or a double puncture with a metallic device. As early as 2001, Selby et al.[12] first reported the subcutaneous tunneling technique for PICCs placement. After that, two Chinese scholars[13,14] independently conducted an RCT study and concluded that tunneled PICCs were more effective in preventing dislodgement and malposition than non-tunneled PICCs. However, the results of a multicenter case-control study[15] showed no statistical difference between the two groups ($P > 0.05$).

Differences in the results may be indirectly affected by the catheter material, the number of lumens, or the securement strategies. However, it is confirmed that the catheter can move under certain circumstances, including changes in position, arm movements, changes in chest pressure, etc.[16,17] Compared to distal movement, proximal movement has received less attention, possibly due to the application of sutureless devices. Approximately 1–2 cm away from the catheter exit, this device effectively limits PICCs' proximal movement. However, the clinical practice seems to ignore that a minor proximal movement of PICCs can introduce various bacteria into the blood vessels; distal movement may not cause serious health risks at the same distance. Therefore, a parallel, single-blinded, multicenter, and randomized controlled trial was conducted to evaluate the impact of the subcutaneous tunneling technique on catheter movement.

2. Methods

2.1. Design and setting

This study was a parallel, single-blinded, multicenter randomized controlled trial conducted over 6 months. All eligible participants were randomly (1:1 ratio) assigned to an experimental group (tunneled PICCs) or a control group (non-tunneled PICCs). Data were collected at the baseline around catheter placement and on days 1, 7 ± 3, 30 ± 7, 60 ± 7, 90 ± 7, 120 ± 7, 150 ± 7, and 180 ± 7 (if applicable). This study followed the CONSORT checklist[18] and was registered on the chictr.org website with the registration number (ChiCTR2100049855).

A 3-center RCT underwent a PICCs placement procedure in outpatient departments between August and December 2021 and was observed until May 2022. This study was conducted in 3 tertiary teaching hospitals in China: Qilu Hospital of Shandong University, Liaocheng People's Hospital, and Zaozhuang Municipal Hospital. The reference number of the Qilu Hospital of Shandong University Ethics Committee was 2021042, and the subcenters approved the permission for this clinical trial.

2.2. Participants

Eligible participants who were scheduled for PICC placement were recruited. The inclusion criteria were as follows: (1) aged ≥18 years, (2) conscious and able to understand and communicate in Chinese, (3) scheduled to return to our hospitals for maintenance or able to be contacted regularly via mobile phone, and (4) provided informed consent and participated voluntarily in this study. The following exclusion criteria were used: (1) having other types of central venous catheters, e.g., Centrally Inserted Central Catheters (CICCs), PICCs or CICCs ports, and dialysis catheter; (2) planned catheter dwelling time <7 d or life expectancy <1 month; and (3) lack of complete blood count (CBC) or coagulation action test. The eliminated criteria included: (1) missed two or more data collections for any reason and (2) voluntary withdrawal from trials due to exacerbation of illness or other reasons.

2.3. Randomization

This study adopted a type of block randomization stratified by the center with variable block size. A third-party statistician used SAS 9.3 software (SAS Inc., Cary, N.C., USA) to generate the random allocation sequence, and 1:1 random assignments were sealed in consecutive envelopes. Each hospital had an independent researcher to keep the opaque envelope, and the random allocation sequence was revealed after the patients were registered to enroll in the study. The care providers and participants were not blinded due to differences in wounds and surgical procedures between the two groups. However, data collectors and analysts were blinded to random assignments throughout the study.

2.4. Procedures

2.4.1. Catheter placement

All PICCs used in our study were 4Fr, open-ended silicone with a proximal valve (Branden Medical Scientific,

Inc., Dezhou, Shandong, China). In the control group, non-tunneled PICCs were inserted into the upper arm using the standard PICCs placement under a Doppler ultrasound device, including the function of ECG and Doppler Ultrasound Guidance devices (ECG-EDUG). In the experimental group, the PICCs were placed using metallic tunneling combined with the standard PICCs placement technique. Specifically, there are 3 points that we need to explain in more detail: (1) As for the distal trimming catheter, we created a tunnel in the opposite direction[19] after insertion, which prevented hidden problems associated with failed punctures. (2) Gauze is routinely used to reduce bleeding at the exit site following catheter placement in patients without significant bleeding problems. An octyl cyanoacrylate skin adhesive was used in the experimental group instead of gauze at the vein puncture site to achieve as much blinding as possible between the two groups. (3) During the experimental design stage, the sutureless devices recommended by the latest guideline[11] were not adopted because they were not universally and uniformly available in all centers. We used sterile transparent dressings and sterile tape fixation, which was widely practiced in our 3 centers. PICCs insertion follows the SIP protocol[20] and hospital policies as much as possible. Table 1 lists other components that are important for the PICC placement.

2.4.2. Catheter maintenance

PICCs were maintained according to established guidelines[11] and hospital policies by specially trained nurses (sterile gauze was removed after 24 h, dressing changed every 7 d, skin antisepsis with 2% chlorhexidine in alcohol, covered with transparent semipermeable membranes, and flushed and locked with saline only). After maintenance, nurses should strictly confirm the catheter's position and properly record catheter-related complications in a unified maintenance booklet. To meet regulatory requirements, nurses must sign their names.

- Follow the principle of the maximum sterile barrier during catheter placement and perform strict hand hygiene before surgery
- A modified Seldinger technique was used to insert PICCs under ultrasound guidance. The CVR ratio was calculated before catheter placement using the vein diameter at the venipuncture site without a tourniquet
- After inserting the catheter into the vein, a 12–15 cm tunneler with an end connecting the catheter and another end creates a subcutaneous tunnel from the vein puncture site to the tunnel exit site
- The tunnel length should be longer than 3 cm in the experimental group
- The exposure length in both groups is 5–7 cm
- The catheter exit sites were fixed with 2 cm × 2 cm gauze compression and then covered with a 10 cm × 10 cm sterile transparent dressing. A cross-section of sterile tape was used to affix the catheter and dressing, followed by tape used to secure the film's lower edge
- All catheter tips were checked using posteroanterior chest X-ray radiography

Note: CVR, catheter-to-vein ratio; PICCs, peripherally inserted central catheters.

Table 1. The key components of PICCs placement.

2.5. Data collection

We collected information on the patient's demographics, medical history, laboratory test results, and details related to catheter insertion at the time of catheter placement. After returning to our hospital, patients were screened for asymptomatic catheter-related thrombosis (CRT), followed by an appointment with an ultrasonographer. In addition to CRT, independent researchers assessed other outcomes through catheter maintenance or telephone follow-up, with termination dates of extubation for any reason (e.g., end of treatment, unplanned extubation, death, etc.) or 6 months post-insertion. The follow-up period lasted 6 months because many studies reported that the average catheter dwell time was <6 months.[4,5,10,21]

2.6. Measurements

Catheter dislodgement and malposition are the primary outcomes. When using PICCs, the catheter does not need to be replaced if it moves <2 cm distally; however, if the catheter moves >4–5 cm distally, it must be removed; if the catheter is in between, the patient should have an X-ray to confirm its position.[22] Considering this, we defined distal catheter movement as follows: catheter prolapse ≥2 cm (criterion 1) or catheter prolapse ≥5 cm (criterion 2). A shorter catheter exposure outside the skin indicates that the catheter is moving proximally. This is divided into two grades: catheter movement proximally 0.5–2 cm (grade 1) and catheter movement proximally ≥2 cm (grade 2). As secondary outcomes, we also included CRT and catheter-related infection (CRI), as previous studies had shown significant differences between the groups.[13–15] Local infections and central line-associated bloodstream infections (CLABSIs) that occur during the indwelling period or within 48 h after catheter removal were included.[23] CRT was defined as thrombosis detected by ultrasound occurring in the vein with a catheter, including symptomatic or asymptomatic.[11,24]

2.7. Statistical analysis

Statistical analysis was conducted using SPSS 25.0 (IMB SPSS Software, Chicago, IL, USA). Continuous variables are expressed as mean and standard

deviation (SD), and categorical variables are reported as percentages. Group comparisons were performed using the chi-square test or Fisher's exact test. The final analysis included all randomly assigned patients; missing data were excluded. The level of statistical significance was set at 0.05.

3. Results

3.1. Study procedure

A total of 630 participants were recruited and randomized between August and December 2021. We excluded 10 patients with failed PICCs insertions (n = 7) or catheter tips located in non-central veins (n = 3). The experimental group (n = 310) and control group (n = 310) were randomly assigned from 620 patients after this exclusion. In the 6-month follow-up period, 11 participants failed to follow up (missed two data collection sessions [n = 6], Coronavirus Disease 2019 (COVID-19) isolation interrupted treatment [n = 1], and no longer cooperate with follow-up [n = 4]), and 4 participants voluntarily withdrew due to illness exacerbation. Ultimately, 605 patients were analyzed (Figure 1).

3.2. Participant information

Of the 605 patients, 433 (71.57%) completed treatment, 45 (7.44%) underwent unplanned extubation, 39 (6.45%) died, and only 88 (14.54%) still had PICCs after 180 d. The mean age was 55.87 ± 13.94 years, with 83.0% of the participants being female. A total of 88.1% of patients had cancer, mostly pelvic, breast, or gastrointestinal. A total of 71.4% of the insertion bodies were in the right arm, and 85.3% of the insertion vessels were basilic veins. The average length outside the skin was 6.85 ± 0.61 cm, and most tips were located at T7 (52.7%) and T6 (28.8%). The catheter-to-vein ratio (CVR) at the puncture site of the experimental group was lower than that in the control group (P < 0.001). Other baseline and PICCs characteristics were similar between the two groups (Table 2).

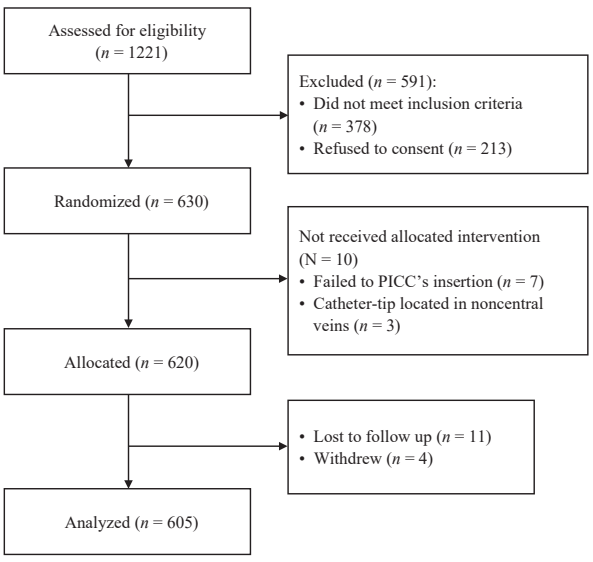


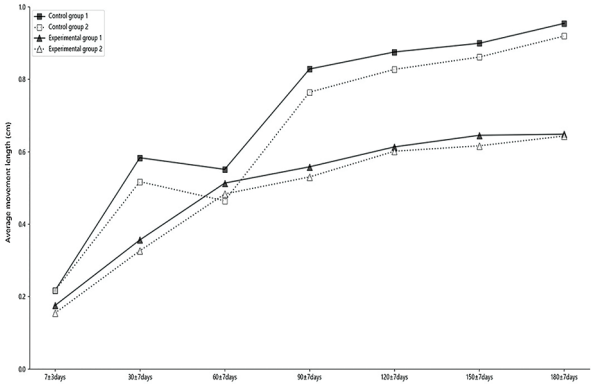
Figure 1. CONSORT flowchart of study participants. Abbreviations: CONSORT, consolidated standards of reporting trials; PICCs, peripherally inserted central catheters.

3.3. Movement characteristics of exposed PICCs with time

Figure 2 shows the average movement length of PICCs outside the skin. The solid line records the mean distal or proximal movement of the catheter using a scalar (has size but no direction), while the dotted line uses a vector (has both size and direction). The average movement lengths increased with time in both groups, but the changes in the control group were more significant than in the experimental group. Notably, a temporal turning point appeared in the control group at 60 ± 7 d. The vertical distance between the solid and dotted lines in the control group was more significant than in the experimental group.

3.4. Outcomes comparison of participants

As shown in Table 3, the results showed opposite characteristics when different criteria determined distal catheter movement, but neither group of results was statistically significant (P > 0.05). The difference in proximal catheter movement between the two groups was statistically significant, with a rate of 4.3% in the experimental group and 9.9% in the control group (P = 0.007).



Note: The latest follow-up data were used to fill in missing values caused by extubation. Abbreviation: PICCs, peripherally inserted central catheters.

Figure 2. Average movement length of exposed PICCs in both groups.

Characteristics and categories	Experimental group (n = 302)	Control group (n = 303)	t/χ^2	P
Age (years)	55.71 ± 13.46	56.03 ± 14.43	−0.286	0.775
BMI (kg/m²)	24.19 ± 0.21	23.81 ± 3.86	1.248	0.212
Gender				
Male	55 (18.2%)	48 (15.8%)	0.602	0.438
Female	247 (81.8%)	255 (84.2%)		
Cancer				
Yes	272 (90.1%)	261 (86.1%)	2.225	0.136
No	30 (9.9%)	42 (13.9%)		
Diagnosis body				
Head disease	14 (4.6%)	12 (4.0%)	2.202	0.9
Breast disease	57 (18.9%)	69 (22.8%)		
Respiratory disease	17 (5.6%)	16 (5.3%)		
Gastrointestinal disease	47 (15.6%)	52 (17.2%)		
Pelvic disease	142 (47.0%)	129 (42.6%)		
Blood disease	10 (3.3%)	10 (3.3%)		
Others	15 (5.0%)	15 (5.0%)		
Comorbidity				
Hypertension	41 (13.6%)	52 (17.2%)	1.495	0.221
Diabetes	19 (6.3%)	24 (7.9%)	0.608	0.435
CHD	6 (2.0%)	13 (4.3%)	2.639	0.104
History of DVT	11 (3.6%)	12 (4.0%)	0.042	0.838
History of CVADs	26 (8.6%)	24 (7.9%)	0.095	0.758
Coagulation function				
PLT	247.77 ± 108.48	249.94 ± 94.27	−0.263	0.793
TT	14.01 ± 1.69	13.78 ± 2.40	1.34	0.181
APTT	11.47 ± 1.61	11.54 ± 2.76	−0.402	0.688
PT	30.52 ± 4.67	29.66 ± 5.96	1.962	0.051
FIB	3.47 ± 0.95	3.53 ± 1.26	−0.687	0.492
D−dimer	1.13 ± 3.36	0.93 ± 1.72	0.897	0.37
Insertion arm				
Left	87 (28.8%)	86 (28.4%)	0.013	0.908
Right	215 (71.2%)	217 (71.6%)		
Insertion vein				
Basilic vein	248 (82.1%)	268 (88.4%)	4.86	0.088
Brachial vein	47 (15.6%)	30 (9.9%)		
Cephalic vein	7 (2.3%)	5 (1.7%)		
CVR at the puncture site	0.28 (0.26, 0.31)	0.34 (0.30, 0.43)	−11.224	<0.001
Average length outside the skin	6.84 ± 0.65	6.85 ± 0.57	−0.077	0.939
Tip position				
T5	9 (3.0%)	16 (5.3%)	2.64	0.451
T6	92 (30.5%)	82 (27.1%)		
T7	159 (52.6%)	160 (52.8%)		
T8	42 (13.9%)	45 (14.9%)		

Note: Data are presented as the mean ± SD, median Interquartile Range, and *n* (%); APTT, activated partial thromboplastin time; BMI, body mass index; CHD, coronary Heart Disease; CVADs, central venous access devices; CVR, catheter−to−vein ratio; DVT, deep venous thrombosis; FIB, fibrinogen; PLT, platelet; PT, prothrombin time; SD, standard deviation; T, thoracic vertebra; TT, thrombin time.

Table 2. Demographic and clinical characteristics at baseline.

Characteristics and category	Experimental group (n = 302)	Control group (n = 303)	χ^2	P
Distal movement				
Criteria 1			1.321	0.25
0–2 cm	251 (83.1%)	262 (86.5%)		
≥2 cm	51 (16.9%)	41 (13.5%)		
Criteria 2			1.327	0.249
0–5 cm	291 (96.4%)	286 (94.4%)		
≥5 cm	11 (3.6%)	17 (5.6%)		
Proximal movement				
Total	13 (4.3%)	30 (9.9%)	7.175	0.007
0.5–2 cm	8 (2.6%)	19 (6.3%)	7.185	0.028
≥2 cm	5 (1.7%)	11 (3.6%)		
CRI				
Total	6 (2.0)	16 (5.3)	4.683	0.03
Local infection	4 (1.3)	9 (3.0)		0.101[a]
CLABSI	2 (0.7)	7 (2.3)		
CRT				
Total	11 (3.6)	38 (12.5)	16.092	<0.001
Symptomatic	4 (1.3)	12 (4.0)	15.245	<0.001
Asymptomatic	7 (2.3)	25 (8.3)		

Note: Fisher's exact test; CLABSI, central line-associated bloodstream infection; CRI, catheter-related infection; CRT, catheter-related thrombosis.

Table 3. Outcomes of the participants.

For the second outcome, there were 6 (2.0%) cases of infection detected in the experimental group compared to 16 (5.3%) cases in the control group ($P = 0.030$). The incidence of CRT was also significant in comparison between the two groups (3.6% vs. 12.5%, $P < 0.001$).

Experimental/control group 1: Use the scalar ([has size but no direction] to record the average distal or proximal movement of exposed PICCs; Experimental/control group 2: Use the vector (has both size and direction) to record the average distal or proximal movement of exposed PICCs.

4. Discussion

PICC-related complications have been compared based on the subcutaneous tunneling technique,[15,25–27] but a detailed description of catheter dislodgement and malposition is lacking. Our results showed no significant difference in the incidence of distal catheter movement between the two groups, whether it was the 2 cm or the 5 cm criteria; however, the incidence of proximal catheter movement was significantly reduced in the experimental group, which was reported for the first time. Kim et al.[15] reported that this technique was ineffective in reducing distal movement, but the other two studies[13,14] reported its significance ($P < 0.05$). In PICCs placement, securement strategies might have contributed to this difference. In other words, the conventional group also had limited catheter movement if assisted securing was used, making it difficult to observe the difference.

Due to the pressure of tissue compression on catheter securement within the subcutaneous tunnel, tunneled PICCs were shown to minimize freedom of movement and provide fixation of the catheter position.[13] However, subcutaneous tunneling did not significantly affect the incidence of distal catheter movement. Still, as we increased the criteria from 2 cm to 5 cm, the tunneled PICCs became more advantageous (16.9% vs. 13.5%, 3.6% vs. 5.6%). We believe that there is another explanation for this result. In the formation of subcutaneous tunnels, the catheter may have slight folds or curls, and mild prolapse may occur due to the gravity of the catheter and the pulling force during maintenance. In the middle and late dwelling stages, subcutaneous tunneling became more advantageous for securing PICCs; therefore, it may be more suitable for patients with long-term PICCs needs. Furthermore, tunneled cuffed PICCs may be necessary.[28,29] It should be noted, however, that cuffed PICCs were relatively recently introduced, and the safety and efficacy of these devices cannot be compared to the currently prevalent cuffed CICCs. Hence, clinical research is still required to demonstrate their effectiveness.

In this study, the subcutaneous tunneling technique significantly reduced proximal movement ($P < 0.05$), and the difference between the solid and dotted distance between groups also illustrated this. A temporal turning point appeared at 60 ± 7 d after catheter placement in the control group, suggesting that this was a period when catheter proximal movement was most common, possibly due to increased arm movement after the patient was discharged from the hospital, but the exit site had not yet fully healed. We cannot also rule out the possibility that the proximal movement was caused by the weekly dressing changes performed by medical personnel. However, the results are clear: there is greater stability in the tunneled catheter since it sits tightly under the subcutaneous tissue at a longer distance from the puncture site. In addition to the securement strategy, our study also relied on adequate exposure length, which may have contributed to discovering the potential benefits of subcutaneous tunneling. It is significant because the proximal movement of the catheter allows bacteria to enter the blood vessels and even the catheter tip to enter the heart, which can result in more severe complications.

As mentioned in previous studies,[30,31] subcutaneous tunnels form a natural barrier that makes it difficult for

microbes to travel retrograde along catheters, thereby reducing the incidence of CRI ($P = 0.030$). This study, however, suggests that there may be another explanation. We compared the results from previous studies, which showed significant differences in CRI and proximal movement incidences[15,32,33]; however, there is evidence of a positive correlation between the studies, which suggests that the subcutaneous tunneling technique may reduce the incidence of infection by inhibiting proximal catheter movement.

In the experimental group, the incidence of CRT was significantly lower than in the control group (3.6% vs. 12.5%, $P < 0.001$), which is consistent with previous studies but may present new clinical implications.[13,14,27] There has been evidence that the CVR has an exponential rather than a proportional effect on CRT.[32] In reverse taper PICCs, the catheter size increases by 2 Fr (approximately 0.67 mm), allowing for tamponade and reducing catheter movement.[33] In our study, the tunneled PICCs with a non-reverse taper design obtained a larger vessel diameter by moving the puncture site proximally and reducing the CVR. In other words, subcutaneous tunneling may be a better solution to allow for tamponade and reduce catheter movement without affecting the CVR, reducing the risk of CRT.

At present, tunneled PICCs are not popular in clinical catheterization. However, high rates of CRI and CRT are indeed significant factors affecting the acceptance and promotion of PICCs. This study supports the benefit of subcutaneous tunneling for people with indwelling PICCs in reducing CRI and CRT. Thus, subcutaneous tunneling technology should be promoted in PICCs placement, particularly in patients at high risk of thrombosis and infection. This is the first study that indicates that low CRI and CRT may be related to catheter retraction movement, which may provide a fresh perspective on tunneled PICCs. We encourage more prospective, large-sample, and multicenter studies to explore changes in the incidence of CRI and CRT based on catheter retraction movement, thereby providing more sufficient evidence to support PICC innovation.

5. Conclusions

Our study explored the effectiveness of the subcutaneous tunneling technique in reducing catheter malposition and dislodgement. This study aimed to explore whether subcutaneous tunneling reduces catheter malposition and dislodgement. Based on the results, the incidence of distal catheter movement was not significantly different between the two groups. This may indicate that cuffed PICCs or sutureless devices are still better for reducing distal catheter movement. However, proximal catheter movement was significantly decreased in the experimental group, which was reported for the first time. In addition, the incidence of CRI and CRT also decreased, possibly as a result of proximal catheter movement. Accordingly, combining subcutaneous tunneling with sutureless devices in cuffed PICCs may be advisable.

Limitations

This study has several limitations. Firstly, the Infusion Therapy Standards (INS) of Practice 2021 recommend using sutureless devices to secure PICCs. Our experimental design phase did not achieve uniformity across all centers, which needs to be improved. From another perspective, our study demonstrated the necessity of sutureless devices in clinical settings, as the incidence of distal movement was higher than in other studies using sutureless devices.[13–15] In light of this, we recommend that hospitals in the same situation introduce sutureless devices as soon as possible. Secondly, catheter movement is significantly affected by insert location.[34,35] As a result of factors such as patient position, skin condition, and vascular condition, 50 (16.6%) exit sites in the experimental group and 66 (20.8%) exit sites in the control group were in the red zone, which may increase catheter dislodgement and malposition. However, the comparison between the two groups was not statistically significant ($\chi^2 = 2.665$, $P = 0.121$) and therefore had little influence on our results. Lastly, catheters made of soft materials are likely to move, affecting experimental judgments. Unlike our study, most polyurethane catheter tunnels are created before puncture. If tunnels are created using a unified approach, it would be interesting to investigate whether catheter material influences the results.

Trial registration

ChiCTR2100049855

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Ethical approval

The study was conducted with the approval of the Qilu Hospital Ethics Committee (Approval no. 2021042).

Conflicts of interest

All contributing authors declare no conflicts of interest.

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