



Fixation of the short-term central venous catheter. A comparison of two techniques¹

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Abstract

Purpose: To compare the fixation of the central venous catheter (CVC) using two suture techniques.

Methods: A clinical, analytical, interventional, longitudinal, prospective, controlled, single-blind and randomized study in adult, intensive care unit (ICU) patients. After admission and indication of CVC use, the patients were allocated to the Wing group (n = 35, catheter fixation with clamping wings and retainers) or Shoelace group (n = 35, catheter fixation using shoelace cross-tied sutures around the device). Displacement, kinking, fixation failure, hyperemia at the insertion site, purulent secretion, loss of the device, psychomotor agitation, mental confusion, and bacterial growth at the insertion site were evaluated.

Results: Compared with the Wing group, the Shoelace group had a lower occurrence of catheter displacement (n=0 versus n=4; p = 0.04), kinking (n=0 versus n=8; p=0.001), and fixation failure (n=2 versus n=8; p=0.018). No significant difference was found in bacterial growth (n=20 versus n=14; p=0.267) between groups.

Conclusion: The Shoelace fixation technique presented fewer adverse events than the Wing fixation technique.

Key words: Catheters. Vascular Access Devices. Suture Techniques. Microbiota. Blood Circulation.

■ Introduction

The short-term central venous catheter (CVC) is placed in large venous vessels for the administration of solutions into the superior vena cava or right atrium. It is designed for continuous use in patients hospitalized for days or weeks¹. CVC is mainly indicated for patients with difficult access to peripheral veins, delivery of intravenous chemotherapy, potentially sclerosing medications, and total parenteral nutrition, repeated administration of blood products or blood components, repeated collection of blood samples, and hemodynamic monitoring^{2,3}.

The CVC is inserted by percutaneous puncture and has been associated with a number of complications². The level of physician experience of more than 50 punctures performed reduces complication risk^{4,5}. The CVC is placed using the Seldinger technique, in which the vessel is punctured with a long needle, whereby a guidewire is advanced to the appropriate position for subsequent insertion and positioning of the catheter^{2,6}.

According to the American Society of Anesthesiologists (ASA) task force on central venous access, the use of sutures is the preferred CVC fixation technique to minimize the risk of infection, but the use of sutures, clamps or tapes for CVC fixation is based on local or institutional practices⁷.

The CVC insertion site in adults should be based on clinical needs and located in an uncontaminated area, preferably at the upper end of the body to minimize the risk of infection⁷. Catheter-related bloodstream infections occur by migration of the skin microbiota through the percutaneous insertion site, suggesting that sutureless securement devices may prevent lesions around the insertion site, thus reducing bacterial colonization⁸. The use of chlorhexidine is recommended for hand antisepsis prior to

venipuncture and dressing changes⁷. The costs of catheter-related complications are high. A single catheter-related infection costs from US\$4.000 to US\$56.000 and complications resulting from inadequate positioning may affect the reimbursement rates of medical centers⁹.

Unplanned removal of the CVC and the need for reinsertion has received little attention, but carries a potential life-threatening risk¹⁰. CVC should be fixed to the skin and should not move into or out of large veins, as this may lead to failure of the venous line, causing support interruption (i.e., delivery of inotropic drugs and vasopressors) and hemorrhagic shock¹¹. The risk of unplanned removal of the CVC is greater in patients with agitation and delirium¹².

The literature on CVC remains inconclusive whether the most appropriate method of CVC fixation is the use of devices based on suture securement, which are available as commercial kits, or the use of sutureless securement devices, which are more expensive and not available in public health services. The present study addressed this problem and evaluated two CVC fixation techniques used in two hospitals in Southern Minas Gerais (Brazil), where the procedures are not standardized.

■ Methods

The study was approved by the Research Ethics Committee of UNIVÁS (approval no. 1.372.730) and performed in accordance with the Resolution 466/2012 of the Brazilian National Health Council (CNS) on research involving human beings. Written informed consent was obtained from all patients or their representatives prior to their inclusion in the study, and anonymity was assured.

This clinical, analytical, interventional,

longitudinal, prospective, controlled, single-blind, randomized trial was conducted from January to August 2016 in adult clinical and surgical intensive care units (ICUs) of the Samuel Libânio General Hospital at the Universidade do Vale do Sapucaí (UNIVÁS) and ICUs of the Santa Paula Hospital and Maternity Center, both located in Pouso Alegre-MG, Brazil.

A pilot study with 14 patients with short-term CVC was conducted to define the size of the sample. Adverse events were evaluated and loss of catheter fixation to the skin was used as the primary endpoint. The Fleiss method with continuity correction was applied to determine the sample size, assuming a sample size ratio of 1.0, percentage of positive non-exposed patients of 50.0% (Wing fixation), and percentage of positive exposed patients of 14.0% (Shoelace cross-tied fixation). Participants were selected by simple random sampling. Setting the significance level α at 0.05 (5%) and the power of the sample (1- β) at 80%, the sample size of 62 participants (31 patients per group) would be required to detect differences between groups. Anticipating some missing data, 35 patients were randomly allocated to each group, for a total of 70 patients.

Adult patients of both sexes, with indication for CVC insertion into jugular or subclavian veins, admitted to an ICU in the participating institutions were selected to participate in the study.

Exclusion criteria were break in asepsis during the placement of the device; multiple puncture attempts (i.e., more than 3 puncture sites in the chosen access route) resulting in excessive local trauma; need for device repositioning due to an anomalous route or catheter malpositioning after insertion, verified by chest radiography; CVC removal before the minimum period of three days; and patient death before the minimum period of three days.

Randomization

The allocation sequence was generated using a computer-generated randomization chart (<http://www.randomization.com>). The patients were randomly allocated to 2 groups: the Wing group (n = 35, catheter fixation with clamping wings and retainers) and Shoelace group (n = 35, catheter fixation using shoelace cross-tied sutures around the device).

Procedure

The team responsible for CVC insertions was composed of three physicians with training and experience of more than 50 punctures using the Seldinger technique¹³.

The physician, already wearing a mask and a cap, performed hand wash with 4% chlorhexidine solution with surfactants (a skin degerming agent) and dressed the sterilized gown and gloves to perform antisepsis of the patient's skin⁷. A Foerster clamp and sterile gauze were used for applying a 4% chlorhexidine solution from the puncture site to the opposite direction, repeating the procedure three times and then removing the excess solution. Next, 0.5% alcoholic chlorhexidine was also applied three times from the puncture site to the opposite direction using a Foerster clamp and sterile gauze. Fenestrated areas were positioned to ensure a sterile barrier. Before the catheter puncture was performed, a minimum of 2 minutes was allowed to elapse after application of the antiseptic to the skin⁸.

The Seldinger technique was used for the percutaneous puncture of central venous vessels, including internal jugular veins and subclavian veins. The catheter used was the Arrow double-lumen 7Fr 20 cm CVC (Arrow International Inc, Cleveland, OH). After the puncture and catheter insertion, the device was secured to the skin with a 3-0 nylon thread. Catheter fixation was performed according to group allocation, using either the Wing or

Shoelace fixation technique, as described below.

Wing fixation technique

The catheter was fixed to the skin with a single stitch and triple knots were tied to each perforation lateral to the securing wings (rubber clamp and retainer), leaving a distance of 2 cm between the securing wings and puncture site for visualization of the ostium. The catheter was fixed to the skin with a single stitch and triple knots were tied to each perforation of the distal wings (Figure 1).



Figure 1 – Wing fixation of a short-term CVC with securing wings in an ICU patient.

Shoelace fixation technique

The catheter was first fixed to the skin with a U-shaped stitch placed around the puncture site, cross-tied with stitches known as “shoelace sutures” until the threads passed through the perforations of the distal wings, and secured with triple knots. Next, the catheter was secured to the skin with a single stitch and triple knots were tied to each perforation of the securing wings, leaving a distance of 2 cm between the securing wings and puncture site for visualization of the ostium (Figure 2).

Gauze and micropore tape dressings were applied¹⁴ and 0.5% alcoholic chlorhexidine

solution was used to clean the insertion site during daily dressing changes⁸.

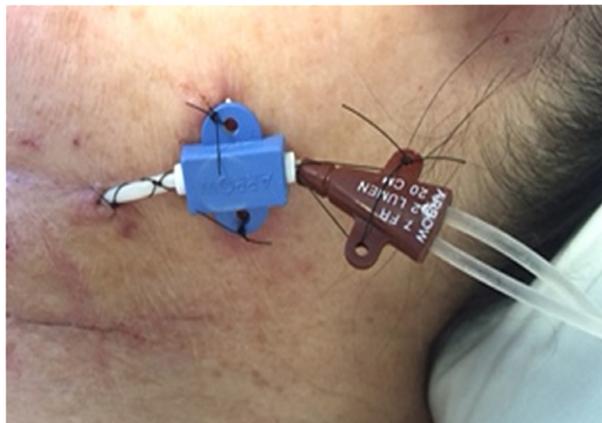


Figure 2 – Shoelace fixation of a short-term CVC with securing wings in an ICU patient.

Data collection

Data were collected 3 and 5 days after CVC insertion, immediately before the daily dressing change. ICU nurses on duty, with more than 5 years of experience, completed a standardized data collection form. The presence of adverse events related to catheter fixation was indicated with an “X” in the form, according to the following items:

1. Catheter displacement - defined as the displacement of the device of more than 2 cm due to tensile forces, measured by a graduated scale on the catheter (Figure 3A).
2. Catheter kinking - folding of the catheter on itself (Figure 3B).
3. Loss of fixation - loss of sutures that held the catheter in place (Figure 3C).
4. Hyperemia at the insertion site - redness around the ostium (Figure 3D).
5. Purulent-looking secretion - presence of a yellowish, thick secretion at the insertion site (Figure 3D).
6. Loss of device - “pulling out” of the catheter or damaging one of the lumens of the device by traction (Figure 3F).

7. Psychomotor agitation - presence of involuntary and purposeless movements associated or not with aggressive behavior¹⁵.

8. Mental confusion (delirium) - disturbance of consciousness characterized by acute onset and fluctuating course of inattention, accompanied by change in cognition or perceptual disturbance¹⁶.

Disease severity was assessed using APACHE II, a severity of disease classification system¹⁷. APACHE II uses a point score based on 12 routine physiologic measurements, age, and previous health status to provide a general measure of disease severity. An increasing score (range 0-71) is associated with increased risk of hospital death.

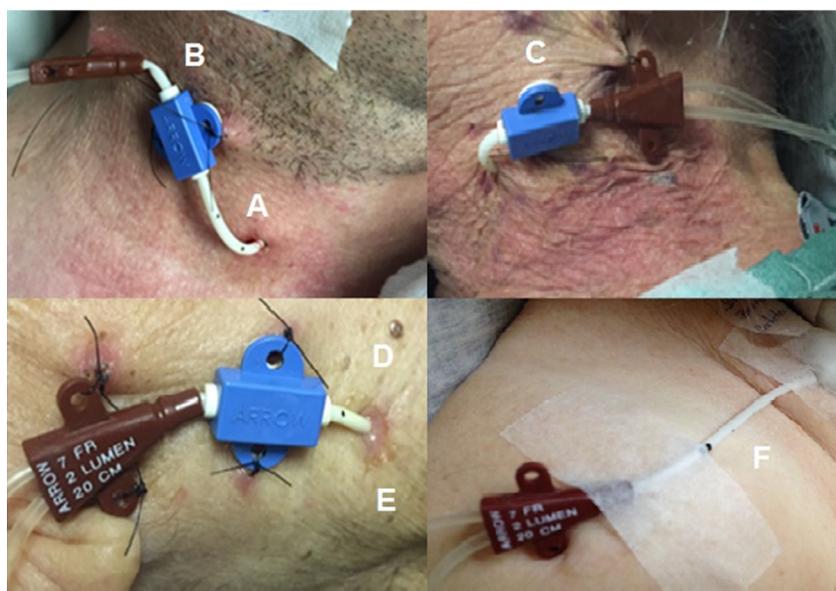


Figure 3 – Examples of adverse events observed in ICU patients associated with the use of a short-term CVC. Catheter displacement (A); Catheter kinking (B); Loss of fixation (C); Hyperemia at insertion site (D); Purulent-looking secretion (E); Loss of the device (F).

Evaluation of the microbiological culture

After completing the data collection form, samples were collected at the catheter insertion site for microbiological culture. Sample collection was performed 3 and 5 days after CVC insertion, before dressing changes, using sterile and disposable swabs packaged in individual swab containers (Absorve[®], Carl, São Paulo, Brazil). The swab was previously moistened in a sterile phosphate-buffered saline (PBS buffer) containing 3% Tween-80¹⁸, and rubbed for 30 seconds with uniform up and down movements in a 5 cm² area delineated by

a sterile filter paper template (Nalgon[®], Nalgon Equipamentos Científicos Ltda, São Paulo, Brazil)¹⁹. The swab was then placed in sterile tubes containing 1 ml of 0.9% saline solution and 8 glass beads, and transported in a thermal box to the Laboratory of Basic Research of the School of Health Sciences at UNIVÁS.

To count the isolated microorganisms, 0.1 ml of the obtained material was placed in Petri dishes with plate count agar (PCA) and spread with a sterile Drigalski spatula. The plates were incubated at 35°C for 24 hours and the colonies were counted.

Statistical analysis

Descriptive analysis was conducted to determine the central tendency (means and medians) and standard deviation (SD) for quantitative variables; proportions were used for categorical variables. Categorical variables were compared using the Chi-square test. Normal distribution was investigated using the Kolmogorov-Smirnov test. A *t*-test was used for comparing data with parametric distribution. Data that were not normally distributed were compared using the Mann-Whitney U test.

Statistical analysis was carried out using the Predictive Analytics Software (PASW) 18.0 for Windows (IBM Corp., Armonk, NY, USA) and the Microsoft Office Excel software (Microsoft Corp., Redmond, WA, USA).

All statistical tests were performed at a significance level α of 0.05 ($p < 0.05$). Data were expressed as mean \pm SD.

Results

Of the 70 patients recruited from January to August 2016, 67 of them agreed to participate in the study, 2 were excluded because of catheter malpositioning, 2 patients died and an elective removal of the device occurred before the minimum period of 3 days.

Considering 2 accidental CVC losses, 60 patients were evaluated for catheter displacement, kinking, loss of fixation, hyperemia at the insertion site, purulent secretion, and loss of the device, and 62 patients were assessed for psychomotor agitation and mental confusion on the day-3 assessment. On the day-5 assessment, 2 more accidental losses and one elective removal of the device had occurred, and 3 patients had died, resulting in a sample of 54 patients; for the items psychomotor agitation and mental confusion, 55 patients were evaluated. Considering patient deaths, CVC losses, elective removals and accidental losses of collected samples, 57 cultures were evaluated for day 3 and 53 cultures were evaluated for day 5.

The mean age of patients was 59.8 ± 18.6 years in the Shoelace group ($n=32$) and 61.1 ± 20.8 years in the Wing group ($n=30$), with no significant difference between groups ($p=0.803$). No significant difference in gender distribution ($p=0.640$) was found between groups (Figure 4).

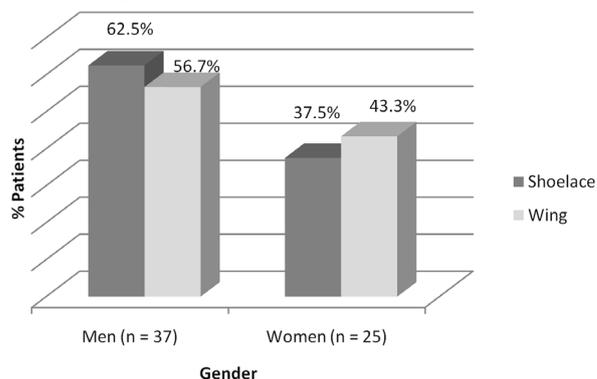


Figure 4 – Frequency distribution by gender of ICU patients with short-term CVC, according to the fixation technique. Chi-square test, $p=0.640$.

The mean disease severity score for the whole sample ($n=62$) was 19.89 ± 5.90 . For the Shoelace group ($n=32$), the mean score was 19.81 ± 5.214 (median, 20.0) and for the Wing group ($n=30$), the mean score was 19.97 ± 6.651 (median, 18.0). The groups were similar ($p=0.919$), showing no significant difference in disease severity.

The subjective assessment of mental status was also performed and showed no significant difference between groups on day 3 and (Table 1) and day 5 (Table 2).

Table 1 - Frequency distribution of the mental state (agitation and confusion) of ICU patients with CVC on day 3 for both groups.

Mental State		Shoelace group	Wing group	p-value*
Agitation	N	6.0	5.0	0.830
	%	18.8%	16.7%	
Mental confusion	N	8.0	4.0	0.245
	%	25%	13.3%	

*Chi-square test ($p < 0.05$).

Table 2 - Frequency distribution of the mental state (agitation and confusion) of ICU patients with CVC on day 5 for both groups.

Mental State		Shoelace group	Wing group	p-value*
Agitation	N	6.0	5.0	0.893
	%	20.7%	19.2%	
Mental confusion	N	8.0	6.0	0.702
	%	27.6%	23.1%	

*Chi-square test (p<0.05).

The subclavian vein was used in 15 (24.2%) patients, with the Shoelace technique being used in 6 (9.68%) of them and the Wing technique, in 9 (14.52%). The internal jugular vein was used in 47 patients (75.8%), with the Shoelace technique being used in 26 (41.94%) of them and the Wing technique, in 21 (33.87%). There was no significant difference (p=0.301) in the distribution of the access vein between the two techniques.

Overall, adverse events occurred in 45.16% of cases. Adverse events in general occurred in 8 (25%) patients in the Shoelace group compared to 20 (66.7%) patients in the Wing group (Table 3).

Table 3 - Frequency distribution of adverse events in general related to catheter insertion in ICU patients with CVC on day 5 for both groups.

Technique		Adverse Events		
		No	Yes	Total
Shoelace	N	24	8	32
	%	75%	25%	100%
Wing	N	10	20	30
	%	33.30%	66.70%	100%
Total	N	34	28	62
	%	54.84%	45.16%	100%

Chi-square test, p=0.001.

The occurrence of the different types of adverse events during the study period was compared between both techniques. On day 3, a significant difference between groups was found only for catheter kinking (Table 4). On day 5, significant differences between groups were found for catheter displacement, kinking and loss of fixation (Table 5). No significant differences were observed in loss of device, hyperemia and purulent-looking secretion at insertion site on day 3 (Table 4) and day 5 (Table 5) between groups.

Table 4 - Frequency distribution of adverse events in ICU patients with CVC on day 3, according to the fixation technique used.

Adverse Events		Shoelace group	Wing group	p-value*
Displacement > 2 cm	N	0	2	0.214
	%	0%	7.1%	
Kinking	N	0	4	0.042
	%	0%	14.3%	
Loss of fixation	N	2	6	0.130
	%	6.3%	21.4%	
Los of device	N	0	2.0	0.230
	%	0%	6.7%	
Hyperemia	N	3	3	1.0
	%	9.4%	10.7%	
Purulent secretion	N	1	1	1.0
	%	3.1%	3.6%	

*Fisher's exact test (p<0.05); Numbers in bold indicate statistical significance.

Table 5 - Frequency distribution of adverse events in ICU patients with CVC on day 5, according to the fixation technique used.

Adverse Events		Shoelace group	Wing group	p-value
Displacement > 2 cm	N	0	4	0.04 *
	%	0%	16%	
Kinking	N	0	8	0.001 *
	%	0%	32%	
Loss of fixation	N	2	8	0.018 **
	%	6.9%	32%	
Los of device	N	1	3	0.344 *
	%	3.3%	10.7%	
Hyperemia	N	4	5	0.718*
	%	13.8%	20%	
Purulent secretion	N	0	1	0.463*
	%	0%	4%	

*Fisher's exact test (p<0.05); **Chi-square test (p<0.05); Numbers in bold indicate statistical significance.

The microbiological analysis of samples collected at the insertion site on day 3 (Figure 5) and day 5 (Figure 6) showed no significant differences between groups.

No significant difference was found in bacterial count in samples collected at the catheter insertion site on days 3 and 5 of the study period (Table 6).

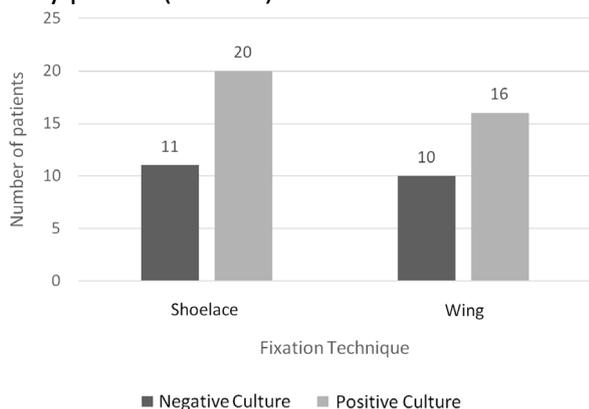


Figure 5 - Microbiological analysis of samples collected at the insertion site in ICU patients with CVC on day 3, according to the fixation technique. Fisher's exact test; p=1.0.

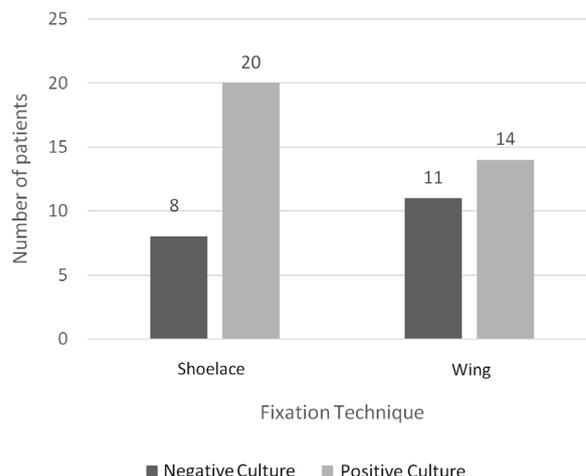


Figure 6 - Microbiological analysis of samples collected at the insertion site in ICU patients with CVC on day 5, according to the fixation technique. Fisher's exact test; p=1.0.

Table 6 - Bacterial count in positive samples collected at the insertion site in ICU patients with CVC on days 3 and 5, according to the fixation technique.

Fixation technique	Day 3	Day 5
	Bacterial count (CFU/ml)	Bacterial count (CFU/ml)
	Median	Median
Shoelace group	100	2250
Wing group	100	100
Mann-Whitney test	p= 0.792	p= 0.129

CFU/ml, colony forming units per milliliters.

Discussion

No study describing the catheter fixation technique using shoelace cross-tied sutures was found in the literature. However, it resembles the Chinese Finger Trap technique described for the fixation of biliary catheters. In this technique, the thread is passed through the skin near to the insertion of the biliary catheter, and the suture ends are tensioned for equal lengths. The suture is then tied around

the catheter near its insertion point into the skin. The ends of the sutures are crossed around the catheter up to 6 cm from the insertion point. A triple knot is firmly secured at the distal end of the catheter and the suture ends are crossed over each other several times in the reverse direction on the way back to the skin. The thread is then sutured to the skin next to the catheter²⁰.

The fixation technique using securing wings consisted of a rubber clamp and retainer, chosen as the control procedure in the present study, was that recommended by the catheter manufacturer (Arrow International Inc.) and provided with the catheter kit.

The incidence of adverse events in ICUs, semi intensive units and inpatient units of a private tertiary hospital with 250 beds in São Paulo (Brazil) was evaluated in 2006²¹. A total of 229 adverse events were reported during a period of 4 months; 21 (9.17%) of them were associated with the use of CVCs and included obstruction, extravasation, dislodgement, incorrect fixation, unplanned removal, bleeding, and clamping²¹. In the present study, 45.16% of patients experienced adverse events, including catheter displacement, kinking, loss of fixation and loss of device, what is a high percentage of adverse events associated with CVC compared to the findings of Nascimento *et al.*²¹.

In the study by Bevc *et al.*²² on hemodialysis catheters, 33.7% of them were removed because of complications, such as CVC occlusion, decreased blood flow, loss of fixation, displacement, CVC malpositioning, fever, signs of infection, and bleeding at the insertion site²⁶. In the present study, a reduced occurrence of catheter displacement, kinking and loss of fixation was obtained with the use of the Shoelace fixation technique.

Jaber *et al.*²³ conducted a study describing the incidence, risk factors, and characteristics and consequences of agitation in a mixed clinical-surgical population of critically ill patients. Agitation was associated

with an unplanned CVC removal rate of 16% compared to 1% in the non-agitated group²³. In the present study, 23.1% of patients in the Wing group showed mental confusion and 19.2% had agitation on day 5, resulting in an CVC (unplanned removal) loss rate of 10.7%. In the Shoelace group, 27.6% patients showed mental confusion and 20.7% had agitation, corresponding to an unplanned removal rate of 3.3%, but without significant difference between groups.

A previous literature review compared the use of gauze and tape with that of transparent polyurethane dressings to secure CVCs. The use of gauze and tape was associated with lower rates of catheter-related bloodstream infections¹⁴. In the present study, gauze and micropore tape were chosen for the dressings because of the possibility that the transparent film could interfere with the stability of the catheter. Catheter stabilization is an important intervention that may reduce the risks of phlebitis and catheter displacement, and may also contribute to prevent bloodstream infection⁸. The most common pathway in the pathophysiology of CVC infection is the migration of skin microorganisms from the insertion site through the tunnel created by the insertion of the catheter²⁴. The total displacement of the tip of a CVC inserted in a patient during flexion and maximum extension of the head and neck ranges from 1.5 to 3.0 cm²⁵. Thus, it was chosen to assess displacements greater than 2 cm with the head in a neutral position relative to the thorax.

Sixty catheters were analyzed during a period of 5 months in a previous study evaluating the combination of skin culture with the culture in CVC connectors for stratification of the negative predictive value in catheter colonization and catheter-related bloodstream infection²⁶. ICU patients undergoing cardiac surgery were enrolled in the study when the CVC remained for at least 7 days after insertion. Skin and/or needleless connector and/or hub

cultures were positive in 51.7% of the samples after removal of the device²⁶. In the present study, the skin and catheter complex sample was collected at the CVC insertion site during the study period. The microbiological culture was positive in 64.5% of the samples on day 3 and in 71.4% of the samples on day 5 among the patients in the Shoelace group, and in 61.5% of the samples on day 3 and 56% of the samples on day 5 among patients in the Wing group, without significant differences between groups.

■ Conclusion

The Shoelace fixation technique resulted in fewer adverse events than the Wing fixation technique.

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