Cogitare Enfermagem

ORIGINAL ARTICLE

RANDOMIZED CONTROLLED TRIAL ON CUTTING THE PERIPHERALLY INSERTED CENTRAL CATHETER IN NEONATES

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ABSTRACT

Objective: To compare the complications between the Peripherally Inserted Central Catheter with length adjustment with cut and without cut. Method: Randomized controlled trial. Composed the sample 46 neonates admitted to a Neonatal Intensive Care Unit service in Paraná, Brazil, between April and July 2021, with catheter indication. Participants were electronically randomized and divided into a control group, whose catheter length was adjusted by cutting it, and an experimental group, whose catheter was kept uncut. Data were analyzed by Mann-Whitney test and Fisher's test. Results: The mean length of catheter stay was ten days in both groups (p=0.79). No relevant difference was identified regarding complications, such as infiltration, obstruction, and infection. Conclusion: Catheter cutting for length adjustment does not interfere in the complications presented. REBEC Register: RBR-2w4dpg5.

DESCRIPTORS: Catheterization, Central Venous; Nursing; Clinical Trial; Infant, Newborn.

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INTRODUCTION

Vascular access is frequently used in hospitals to provide an infusion therapy route, which is often invasive and uncomfortable for the patient.[1]

The Peripherally Inserted Central Catheter (PICC) provides a venous access for long lasting infusion, with reduced risks of complications when compared to other central catheters, besides protecting the patient from exposure to multiple access puncture attempts.[1] The PICC is a device for insertion in veins in the distal extremities that follow anatomically up to the vena cava, whose insertion is a private activity of the nurse/doctor with specific technical training for the procedure.[2]

The PICC is widely used in newborns (NBs) and has advantages, such as the length of stay and reduction of invasive procedures. It has disadvantages, such as the need for specialized training for device insertion and the need for calibrated and intact veins for insertion, as well as the need for constant surveillance during its use, for prevention and/or identification of related complications.

PICC indications must be made early by the multi-professional team, to consider factors associated with the patient and intravenous therapy. Factors such as difficulty of venous access, treatment time, characteristics of the solutions infused, clinical characteristics, type of material available in the hospital, patient preference and level of training of the team responsible for daily care should be scored.[3]

The proper location of the PICC tip is in the cave-atrial junction, with decreased risk of complications related to this device. To this end, it is a protocol of the procedure to measure the length of catheter to be introduced.[4]

This measurement is performed from the point of catheter insertion (puncture site) to the estimated site of the cave-atrial junction. When puncturing the upper limbs, neck or head, this measurement is taken from the puncture site to the right clavicle-sternal junction and from this point to the third intercostal space. If the chosen puncture site is in the lower limbs, the measurement is considered from the puncture site up to the inguinal region and following the umbilical scar up to the xiphoid appendix.[4]

After the measurement, there is the possibility to cut the catheter to adjust the size to be inserted or to count the length, in which the rest of the PICC (excess length) is left outside the catheter's entry orifice. This is because neonatal PICCs are usually 30 to 50 cm long, and insertion measurements vary from 4 to 35 cm. Institutional protocols vary, as does the presentation of the PICC by the industry, and this is a practice whose basis is variable.[4]

Given this, the aim of the study is to compare the complications between length-adjusted PICC with cut and uncut.

METHOD

This is a randomized controlled trial, with newborns admitted to the Neonatology Service and Neonatal Intensive Care Unit (NICU) of a reference hospital for high-risk pregnancy located in Curitiba-PR, Brazil.

The sample was composed of 100% of NBs admitted to the NICU during data collection, with indication for PICC insertion in the period from April to July 2021. The size was estimated based on the average of 200 insertions per year, intending to reach 25% of the annual insertions, seeking quantitative and qualitative representativeness about the

population seen at the NICU. We included 46 RNs, with no loss to follow-up.

The eligibility criterion was the indication for PICC insertion by the multi-professional team. After eligibility, the NB was included in the randomized group and had the catheter inserted. NBs with unsuccessful catheter insertion were excluded.

The NBs were divided into two groups, electronically randomized (randomization), by the Random.org® program: Control Group (CG), NB with PICC, whose length was adjusted by cutting the catheter according to the institutional protocol, and Experimental Group (EG), whose catheter was kept in its integrity. Recruitment was carried out by the nurses of the service after identification of the need for PICC insertion. The randomization generated by the program was available in a folder, at the nursing station, when, after indicating the PICC, the nurse in charge of the procedure checked whether to cut the catheter. Regardless of the patient's size, the established sequence was followed. After inclusion in the randomization, the catheter was inserted by the nurse of the service and daily follow-up was performed by the researchers.

The standardized indication and randomization ensured the random inclusion of NBs with different pathologies, weights, and gestational age, ensuring the uniformity of the sample. Smaller NBs with larger catheters only could lead to a doubtful conclusion, which was ensured by electronic randomization and application of the Informed Consent Form (ICF) before the identification of the inclusion group.

The research followed the institutional protocol for indication, insertion, and maintenance of the PICC, changing only the adjustment of its length for the EG. The PICC is indicated, following the Infusion Nursing Society (INS) protocol, for infusion of intravenous therapy for a period longer than seven days, Total Parenteral Nutrition (TPN), dextrose higher than 10% and pH lower than 5 and higher than 9. PICC insertion and dressing changes were performed by the nurses responsible for the Neonatology Service, and maintenance was performed by the nursing team.

The insertion protocol included prior measurement of the catheter, from the insertion site to the estimated point of the cave-atrial junction, and cutting of the PICC with a scalpel, scissors, or guillotine. For the research, all catheters were cut with a scalpel, to avoid a bias of non-standard tip change. The insertion was performed by direct, blind puncture, with a limit of 3 punctures in the attempts. In this technique, the catheter is migrated according to the standardized technique and the positioning confirmed by radiography after its stabilization.

The dressings were made with transparent film and gauze for the first 24 hours, and changed, followed by transparent film. The dressings were changed as needed - if dirty, or loose, or after 14 days of stay. All catheters, in both groups, were stabilized, close to the insertion, with stabilizing tape, followed by covering with transparent film, avoiding that the spare portion of the EG composed a traction risk bias, if fixed only with film. On the film, a secondary Chevron technique was performed, with adhesive tape, according to the institution's standard.

The included patients were followed-up during the entire data collection period daily, using a specific instrument with the following data: gender, days of life, gestational age (GA), birth weight and weight at PICC insertion, main diagnosis, continuous and intermittent infusion solutions, concomitant venous accesses, catheter insertion site, catheter tip position, exteriorized catheter length, complications presented during PICC maintenance, and the reason for removal (outcome).

Based on the assumption that there could be differentiation in the tip of the catheter from its cut and differentiation in the maintenance of the longer catheter, we sought to verify the reason for removing the studied PICCs (primary outcome) and the differences in complications during their use (secondary outcome).

Based on the survey from previous years, which indicates the insertion of 100 to 200 catheters per year, the sample estimate collected from April to July 2021 was 35 to 60 catheters. The proposal was to include all patients who used PICC, so no sample calculation was performed.

The procedure for PICC insertion at the institution already had a standardized form in which data on the patient and on PICC insertion, catheter location, dressings, traction, and removal were included. The daily care of the PICC was performed by the nursing team, while the protocol change was performed by qualified nurses, in pairs, according to the institutional protocol. All PICCs were stabilized, and the insertion site covered according to the INS guidelines, 2021.[5]

The first dressing change was performed 24 hours after insertion, or earlier if necessary to reposition the catheter. Consecutive changes were performed routinely, every seven days, or when the dressing was dirty or loose. The standard dressing was transparent film with gauze on the first day, and only film on the remaining dressings.

The exteriorization of the PICC was followed by the researchers and by the qualified nurses, considering that, at each dressing change, the exteriorized portion of the catheter should be counted and recorded to follow up whether accidental traction occurred, since this incident results in the migration of the PICC tip. The follow-up was carried out until the catheter was removed, with a record of the outcome of the final PICC use.

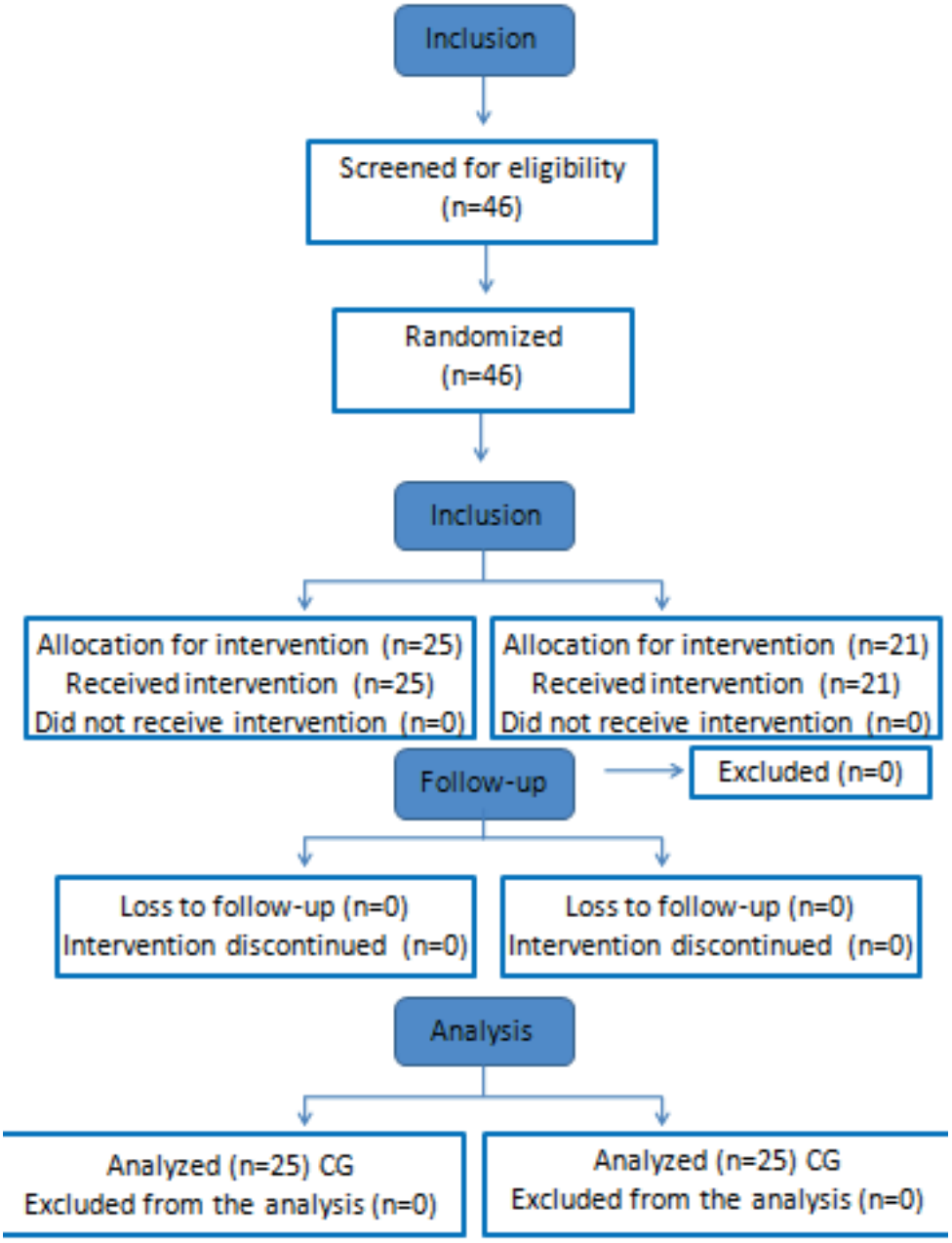
Data were tabulated in a specific Excel® spreadsheet, and statistical analysis was performed after importing the data from the program. The analyses were performed using the Mann-Whitney test for continuous variables and Fisher's test for categorical variables. The confidence interval adopted was 95%. The comparison was made based on the current literature pertinent to the theme, aiming at establishing the possible relationships existing among the variables, outcome, and characteristics of the processes involved in the practice studied.

The present study was approved by the Ethics Committee of the Hospital, under opinion CAAE 42324921,2,0000,0096, following the criteria contained in Resolution 466/2012 as well as with registration in REBEC (RBR-2w4dpg5).

RESULTS

The inclusion criteria were met for 46 NBs with indication and success of PICC insertion. There was no loss to follow-up or exclusions and, according to the randomization, 25 NBs were included in the CG and 21 in the EG (Figure 1).

Figure 1 - Flowchart for obtaining the sample. Curitiba, PR, Brazil, 2021



Source: Elaborated by the authors (2021)

The sample was composed of 46 neonates, 25 in the CG, predominantly male (76.3%), and 21 NBs in the EG, mostly female (64%). Prematurity was the predominant diagnosis, with eight NBs (32%) in the CG and 12 (57.1%) in the EG (p=0.42). The gestational age (GA) of the newborns in the CG group was 38 weeks or more, while in the EG group the newborns were distributed into three more recurrent GA ranges: 28 to 29+6 weeks, 34 to 35+6 weeks, and 38 weeks or more, with no significant differences between the groups. The time of life at the PICC insertion ranged from one to seven days, mostly in both groups, and the most found birth weight was 1801 to 2200g in the CG and EG (Table 1).

Table 1 - Characterization of NBs from the CG and EG. Curitiba, PR, Brazil, 2021

Variables	CG n=25 (%)	EG n=21 (%)	p-value

Gender			
Male	16 (76.2)	9 (36)	
Female	5 (23.8)	16 (64)	0.09
Diagnosis			
Prematurity	8 (32)	12 (57.1)	0.42
Asphyxia	2 (8)	1 (4.8)	1.00
Respiratory disorders	3 (12)	0 (0)	0.25
Hypoglycemia	3 (12)	1 (4.8)	0.62
Other	9 (36)	7 (33.4)	0.77
Gestational age			
≤ 27+6 weeks	2 (8)	3 (14.3)	0.66
28 to 29+6 weeks	2 (8)	5 (23.8)	0.25
30 to 31+6 weeks	2 (8)	1 (4.8)	1
32 to 33+6 weeks	5 (20)	1 (4.8)	0.22
34 to 35+6 weeks	0 (0)	5 (23.8)	0.05
36 to 37+6 weeks	5 (20)	1 (4.8)	0.22
≥ 38 weeks	9 (36)	5 (23.8)	0.55
Age at insertion date			
≤ 7 days old	20 (80)	16 (76.2)	1.00
8 to 14 days old	1 (4)	1 (4.8)	1.00
15 to 21 days old	2 (8)	1 (4.8)	1.00
≥ 28 days	2 (8)	3 (14.3)	0.66
Birth Weight			
600 to 1000g	3 (12)	4 (19)	0.69
1001 to 1400g	2 (8)	2 (9.6)	1.00
1401 to 1800g	1 (4)	4 (19)	0.19
1801 to 2200g	6 (24)	4 (19.0)	1.00
2201 to 2600g	4 (16)	3 (14.3)	1.00
2601 to 3000g	3 (12)	1 (4.8)	0.62
3001 to 3400g	4 (16)	2 (9.6)	0.68
≥ 3401g	2 (8)	1 (4.8)	1.00

Source: Prepared by the authors (2021)
Note: Mann-Whitney and Fisher's test.

Elective removal occurred in 16 (64.0%) of the PICCs in the CG and eight (38.1%) in the EG. The most identified PICC insertion site in the groups was in the upper limbs, with 19 PICCs (76.0%) in the CG and ten (47.6%) in the EG. The location of the PICC tip in the superior vena cava represented more than 80% of the catheters in both groups (Table 2).

Table 2 - Characterization of the PICC in the CG and EG. Curitiba, PR, Brazil, 2021

Variables	CG n=25 (%)	EG n=21 (%)	p-value
Reason for removal			
Elective removal	16 (64)	8 (38.1)	0.44
Non-elective removal	6 (24)	11 (52.3)	0.28
Removal due to death	3 (12)	2 (9.6)	1.00
Place of insertion			
Upper limbs	19 (76)	10 (47.6)	0.47
Inferior limbs	2 (8)	5 (23.8)	0.25
Cephalic region	2 (8)	6 (23.8)	0.25
Jugulars	2 (8)	1 (4.8)	1.00
Staying Time			
1 to 7 days	10 (40)	11 (52.4)	0.79
8 to 14 days	9 (36)	7 (33.3)	1.00
15 to 21 days	4 (16)	2 (9.6)	0.68
over 21 days (21 to 42 days)	2 (8)	1 (4.8)	1.00
Tip Location			
Central	21 (84)	17 (81)	1.00
Peripheral	4 (16)	4 (19)	1.00

Source: Prepared by the authors (2021)
Note: Mann-Whitney test.

The length of stay ranged from one to 21 days in the CG and from 1 to 14 days in the EG. The average length of stay of the catheters with cut (EG) was equal to 10.6 days, while for the catheter without cut (CG), this mean was 8.9 days (p=0.46).

Regarding complications, it was observed that obstruction was present in three (12%) catheters in the CG and in one (4.8%) in the EG (p=0.34). Infiltration occurred in one (4%) in the CG and in four in the EG (19%) (p= 0.26). Regarding traction, one catheter (4%) in the CG and two (9.6%) in the EG, with no difference between groups (p=0.53). Infection was present in three (14.2%) catheters in the CG and in two (9.6%) in the EG (p = 1.0) (Table 3).

Table 3 - Complications of PICC in the CG and EG. Curitiba, PR, Brazil, 2021

Complications	CG n=25	EG n=21	value of p
Obstruction	3 (12)	1 (4.8)	0.34
Infiltration	1 (4)	4 (19)	0.26
Accidental traction	1 (4)	2 (9.6)	0.53
Infection	3 (12)	2 (9.6)	1.00

Source: Elaborated by the authors (2021)
Note: Mann-Whitney and Fisher's test.

Analyzing the characteristics of the dressing, it was observed, during the days the catheters remained in the study, that 86.1% were clean in the CG and 94.1% in the EG (p=0.009). Change of the dressing was performed on 13.9% of the days the PICCs remained in the CG compared to 17.5% in the EG (p=0.35). The stay of the gauze dressing in the first hours of PICC insertion represented 13.7% of the days in the CG and 19.7% in the EG (p=0.67) (Table 4).

Table 4 - PICC dressings in the CG and EG. Curitiba, PR, Brazil, 2021

Dressing	CG n=25	EG n=21	value of p
Dressing characteristics			
Clean	86.09	94.15	
Dirty/loose	13.91	5.85	0.09
Change of dressing			
Yes	13.91	17.55	
No	86.09	82.45	0.35

Source: Elaborated by the authors (2021)
Note: Mann-Whitney test.

DISCUSSION

For the nursing performance regarding the PICC, it is necessary to develop appropriate care practices that aim to meet the specific needs of the NB, since this population is more vulnerable to greater complications from the use of devices such as the PICC.

The most identified diagnosis of NBs admitted to the studied NICU was prematurity in both groups, a reality like that of the national literature. Studies in Brazilian NICUs show an average of 80% of the population with a prematurity diagnosis, and the most observed gestational age range is 29 to 36 weeks, corresponding to 60% of the sample.6-9 In this sample, the NBs with gestational age over 38 weeks were admitted due to respiratory distress, hypoglycemia, or perinatal asphyxia. The remainder had a gestational age below 29 weeks, which was expected, considering that the NICU studied is a reference in high-risk pregnancy, where the most extreme preterm infants are seen. This reality is also consistent with the extensive use of PICC to minimize the manipulation of premature NB to obtain venous access. The preterm population is the one that needs the use of this device according to the INS indications.[5]

In a study on the birth weight of NBs performed in Minas Gerais, 49% of these had a weight below 2500 grams, another study conducted in São Paulo in 2019 showed that the average birth weight was 1182 grams, a result like those presented in this study.[8,10] The weight of the NB interferes in the exteriorized portion of the blunt catheter, which will be smaller in NB with larger size while in premature NB the exteriorized portion will be larger. Randomization allowed a homogeneous sample, to eliminate a possible bias arising from the exteriorized portion of the catheter in each group studied.

Regarding the length of stay of the PICC, in this study we obtained results compatible with studies conducted in Minas Gerais and São Paulo, whose average length of stay was 11.3 to 12.5 days.[7,9]

Regarding tip location, a study carried out in Paraná demonstrated that 74.1% of catheters were in central position after radiography, another study carried out in Ceará

showed 73.8% of catheters in central position, both studies with results like the present study, which obtained more than 80% of its catheters in central position.[6,8]

During the use of the PICC, the reason for removal is a relevant predictor of care failures related to care with the catheter. Nursing professionals are primarily responsible for maintaining safety, since they provide direct patient care; however, there are many errors and adverse events, making patient safety a health challenge.[11]

In a study carried out in Minas Gerais, among the complications that led to removal of the PICC, 5.6% were due to obstruction and 10.69% to infiltration, compared to 9.7% of removals due to obstruction, 2.1% accidental removal, 0.8% infiltration, and phlogistic signs in 2.9%, in a service in Paraná.[6,12] In this study, the predominant complications were obstruction, extravasation, traction, and infection.

The predominant site of PICC insertion was the upper limbs, which is similar to the reality found in the study conducted in São Paulo, with 41.6% of catheters inserted in the upper limbs, as well as in Fortaleza, with 66.7% of insertions in this site.[7,13] A randomized study conducted in 2010 identified the association between complications and the site of insertion, and the results showed no association between the vein used, body hemisphere and the occurrence of complications, similar to the results presented in the current study, in which it was not possible to establish any correlation.[14]

Another factor that may influence the complications presented, still discussed in a scarce and superficial way in the literature, so that there is no consensus to guide the current professional practices, is the cutting of the PICC, the main objective of this research. Pettit[15] analyzed the cutting of the PICC with scissors, scalpel blade, and the manufacturer's own guillotine, and it was identified that all the catheters cut had irregularities, so that the study identified that cutting alters the tip of the catheter. Moreover, the author did not identify any correlation between catheter cutting and the occurrence of complications and cites that it is essential to carry out further studies to allow a relationship between clinical results and the tip of the trimmed catheter. In the present study, the complications presented do not show any difference that may have been associated with the catheter clipping in the EG. Obstructions that could be facilitated by the increased length of the uncut PICC were evaluated, with no difference between the groups studied. The permanence of a larger portion of the catheter could also facilitate traction, in such a way that the previous stabilization of the PICC close to the exit orifice equalized the groups in what concerns this risk.

Another study in Ottawa (2019) evaluated 338 literatures on the safety of cutting the PICC in neonatal patients, not enough scientific evidence was identified to publish guidelines on this practice.[16]

In 2019, a study was conducted in Iowa that shows that catheters with centimeters exteriorized were significantly associated with a higher bloodstream infection rate, although promising, the safety of cutting the PICC for newborns is unknown.[17] The overall PICC-related infection rates in the CG and EG were equal in the statistical evaluation. However, this analysis requires much more evaluation that was not performed in the current study. It is pertinent to assess patient risk, maternal infection, cause of preterm birth (and cases of prematurity), catheter treatment by antibiotic infusion in the catheter route, signs of clinical sepsis, dressing changes, number of catheter route manipulations, among others. Thus, due to the existence of several factors interfering in this result that were not evaluated, it is not possible to infer that uncut catheters have the same risk of infection as the others, constituting a limitation in the analysis of this study.

Still on the risks of PICC manipulation, stabilization of the device and changing the dressing are the entire responsibility of the nurse. The catheter dressing is changed in situations, such as detachment, bleeding, or dirtiness.[18] A study carried out in Sergipe showed that the change of dressing was evaluated in 2,937 actions of change, and all performed by nurses with periodicity.[19] Changes of dressing could have an influence

in relation to the complications presented, such as infection, traction, obstruction, and infiltration, a correlation that was not established in this study.

CONCLUSION

In the present study, we observed that cutting the catheter to be inserted for size adjustment or leaving the catheter in its integrity according to the manufacturer had no correlation with the occurrence of the complications presented.

The most frequent complications were obstruction, accidental traction, infiltration and infection, whose percentages are like those found in the literature. It is essential to conduct research to support practices performed and established without adequate theoretical basis, due to the lack of data to guide decision-making. Thus, we aimed to explore this theme to increase the professional practice related to the PICC cutting, contributing to improve the population's health care.

The potential contribution of this study is to provide professionals with guidelines for the construction of protocols that group together manufacturers' guidelines allied to studies on clinical practice, to promote safe care for the patients assisted. This topic is of fundamental relevance to neonatology due to the characteristics of NBs as well as the difference between the sizes of premature and full-term NBs. The permanence of a 5 cm spare catheter in an adult is very different when compared to a neonate, so the study has a fundamental contribution for neonatal nurses.

It is necessary to evaluate larger samples and catheters of different materials and lumens, as this modifies their characteristics. Therefore, the results provide academic and literature support for the practice of cutting the PICC, but further studies on the subject are needed, to provide greater scientific evidence to promote nursing care practices and thus ensure patient safety.

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Substantial contributions to the conception or design of the work; or the acquisition, analysis, or interpretation of data for the work - Wosnes T dos R, Giacomozzi CM; Drafting the work or revising it critically for important intellectual content - Wosnes T dos R, Giacomozzi CM, Giacomozzi LM, Silva RPVC; Agreement to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved - Wosnes T dos R, Giacomozzi CM, Giacomozzi LM, Silva RPVC. All authors approved the final version of the text.

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