

ORIGINAL ARTICLE

USE OF SINGLE- AND DOUBLE-LUMEN PERIPHERALLY INSERTED CENTRAL CATHETERS IN EXTREMELY PREMATURE NEWBORNS: A RANDOMIZED CLINICAL TRIAL*

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ABSTRACT

Objective: compare the rates of complications, infections and obstruction of single-lumen peripherally-inserted central catheters to those of double-lumen catheters in extremely premature infants.

Method: randomized clinical trial with 30 newborns with gestational age between 24 and 32 weeks. The variables collected were period of use, complications, handling of catheters and obtaining peripheral venous accesses. Analysis was performed using descriptive statistics.

Results: there were differences in rates regarding handling catheters ($p=0.001$) and obtaining concomitant venous accesses ($p=0.01$). However, there was no difference in complication ($p=0.14$), obstruction ($p=0.55$) and infection rates ($p=0.47$). Despite being more frequently handled, double-lumen catheters do not increase the risk of complications. They reduce the need for obtaining new peripheral accesses and, consequently, the pain of premature infants.

Conclusion: the use of double-lumen peripherally-inserted central catheters is beneficial for newborns that need multi-infusion therapy.

DESCRIPTORS: Central Venous Catheterization; Neonatal Intensive Care Units; Premature Infant; Nursing; Clinical Trial.

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UTILIZAÇÃO DO PICC MONO LÚMEN E DUPLO LÚMEN EM RECÉM-NASCIDOS PREMATUROS EXTREMOS: ENSAIO CLÍNICO RANDOMIZADO

RESUMO

Objetivo: comparar as taxas de complicações, infecção e obstrução do cateter central de inserção periférica mono lúmen com o duplo lúmen em prematuros extremos.

Método: ensaio clínico randomizado, com 30 recém-nascidos de idade gestacional entre 24 e 32 semanas. As variáveis coletadas foram tempo de duração, complicações, manipulação dos cateteres e obtenção de acessos venosos periféricos. A análise foi realizada por estatística descritiva.

Resultados: houve diferença nas taxas de manipulação do cateter ($p=0,001$) e obtenção de acessos venosos concomitantes ($p=0,01$). Contudo, não houve diferença nas taxas de complicações ($p=0,14$), obstrução ($p=0,55$) e infecção ($p=0,47$). O cateter duplo lúmen não eleva os riscos de complicações, porém é mais manipulado. Entretanto, reduz a obtenção de novos acessos periféricos, e conseqüentemente a dor dos prematuros.

Conclusão: a utilização do cateter central de inserção periférica duplo lúmen é benéfica para os recém-nascidos que necessitam de terapia infusional múltipla.

DESCRITORES: Cateterismo Venoso Central; Unidades de Terapia Intensiva Neonatal; Recém-Nascido Prematuro; Enfermagem; Ensaio Clínico.

USO DE PICC MONO Y DOBLE LUMEN EN RECIÉN NACIDOS PREMATUROS EXTREMOS: UN ENSAYO CLÍNICO ALEATORIZADO

RESUMEN:

Objetivo: comparar las tasas de complicaciones, infección y obstrucción del catéter central de inserción periférica mono lumen con las del doble lumen en bebés prematuros extremos.

Método: ensayo clínico aleatorizado con 30 recién nacidos en edad gestacional entre 24 y 32 semanas. Las variables recogidas fueron la duración, las complicaciones, la manipulación del catéter y la obtención del acceso venoso periférico. El análisis fue realizado por estadísticas descriptivas.

Resultados: una diferencia fue observada en las tasas de manipulación del catéter ($p=0,001$) y obtención de accesos venosos concomitantes ($p=0,01$). Sin embargo, no se observó diferencia en las tasas de complicaciones ($p=0,14$), obstrucción ($p=0,55$) e infección ($p=0,47$). El catéter doble lumen no aumenta el riesgo de complicaciones, pero es más manipulado. También reduce la obtención de nuevos accesos periféricos y, en consecuencia, el dolor de los bebés prematuros.

Conclusión: el uso del catéter central de inserción periférica doble lumen es beneficioso para los recién nacidos que requieren terapia de infusión múltiple.

DESCRIPTORES: Cateterismo Venoso Central; Unidades de Cuidado Intensivo Neonatal; Recién Nacido Prematuro; Enfermería; Ensayo Clínico.

INTRODUCTION

The use of venous accesses in premature newborns (PNs) encompasses different interconnected factors and events that lead to care excellence. Consequently, assertiveness is a fundamental aspect of professional practice in neonatal nursing and infusion therapy.

In the professional routine involving PNs, the requirement for multiple intravenous therapies is common, which calls for the need for more than one venous access, because of the variety and incompatibility of drugs and solutions. Therefore, different evaluations are carried out by teams in search of a device or a second alternative that meets the needs of PNs, taking into account the option's cost-benefit ratio.

Peripherally inserted central catheters (PICC) have proved one of the main alternatives for long-term infusion therapy and use in PNs because of their specific characteristics regarding the application in intravenous therapy, the benefits of pain reduction in this population, and the best cost-benefit ratio concerning duration and infection rates when compared with other catheters used in the neonatal segment⁽¹⁾.

The double-lumen PICC (DLPICC) is a device that was recently introduced into the Brazilian market and is less invasive than phlebotomy, deep vein puncture catheters, and repeated peripheral punctures. It has two independent routes for administering multiple intravenous therapies, which benefits the neonatal population⁽²⁾.

Considering the scarceness of the literature on DLPICC, its use must be assessed and discussed so professionals can come up with resources to offer the best venous access alternative for PNs. There are advantages related to keeping a safe route, with a potential reduction in the need to obtain venous accesses. Additionally, the second via allows the infusion of incompatible intravenous therapies. However, the presence of the second via is not free from risks, given that it increases the occurrence of infections and the risk of obstruction because of the reduction in the lumen gauge⁽³⁻⁵⁾.

The professional activity of nurses in face of the need to promote newborns' health, with care oriented toward reducing handling and promoting development, is decisive when the selection of neonatal infusion therapy devices and practices is concerned. This practice area is essential for the care to this population, which shows many specificities in the therapeutic approach they require, as well as for the social impact resulting from the newborns' stay at the neonatal intensive care unit (NICU). Consequently, the construction of knowledge must provide this population with better treatment and life conditions. The objective of the present study was to compare complication, obstruction, and infection rates observed in the use of mono-lumen PICC (MNPICC) and DLPICC in extremely preterm newborns.

METHOD

This was a randomized controlled trial carried out with 30 newborns whose gestational age ranged from 24 to 32 weeks who were admitted to the neonatology service and NICU at a teaching hospital in Curitiba, state of Paraná, Brazil. To meet the randomization required by the study design, the examined groups were called A and B, with the former referring to the control group (CG) and including the patients that used MLPICC and the latter designating the experimental group (EG), which included the patients that used DLPICC.

Randomization pairing was performed in blocks and had the following combinations: AABB, ABAB, BABA, ABBA, BAAB, and BBAA. The blocks were drawn by the professional team every four inclusions, after a professional drew a new available combination from an envelope with all the combinations and handed it to a researcher. Once the block with

four patients was complete, a new draw was carried out with all the possible combinations included. Every newborn that met the eligibility criteria was included in the drawn randomization and received the catheter corresponding to the group indicated in the draw (A or B). Both catheter types used were made of polyurethane, with French gauge 2, from Vygon®.

Data collection occurred between August 2013 and August 2015. This period was set to reach the study population, with daily monitoring of the use of the catheters. Over the study period, 126 PNs were born, of whom 47 met the eligibility criteria. Successful insertion was obtained for 40 PICC. Thirty PNs who had a central PICC positioning and completed the use of the catheter in the NICU at the hospital where the study was performed made up the study sample. The distribution of PNs was uneven in the groups, with 14 patients allocated in the CG and 16 in the EG (Figure 1).

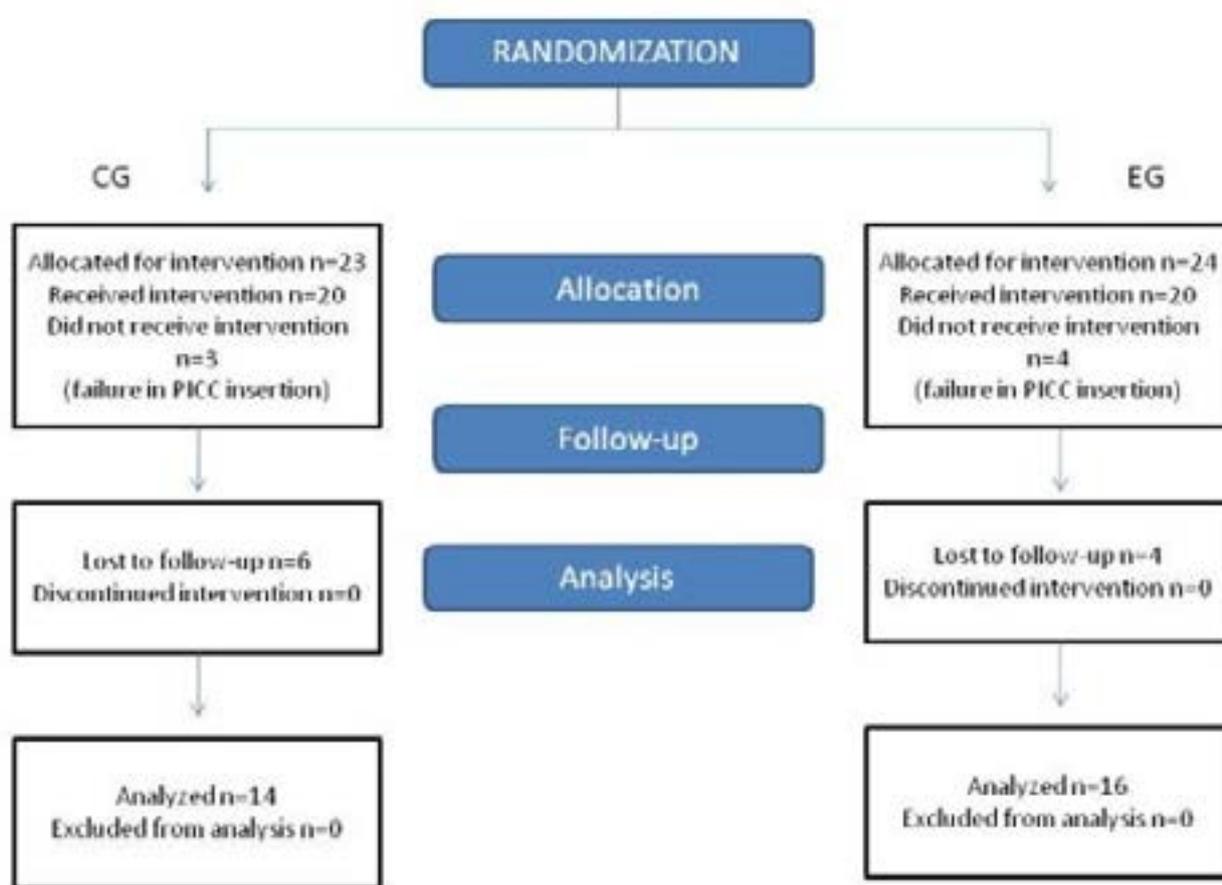


Figure 1 – Flow chart showing patient inclusion. Curitiba, Paraná, Brazil, 2017

The eligibility criteria were: gestational age under 32 weeks, indication for double-lumen central venous access (multiple intravenous therapy and use of total parenteral nutrition (TPN) in an exclusive via), use of PICC as the newborn's first central venous catheter, and signature of free and informed consent forms by the people responsible for the patients. The ineligibility criteria were: initial location of the catheter end in a peripheral region and discontinuity of the stay in the NICU in question during the period of PICC use.

Statistical analysis was carried out after data were imported from Excel to Statistica®

10.0, by Stat Soft. Continuous variables showed an asymmetric distribution. They were examined with analysis of the median by applying the Mann-Whitney test. For categorical variables measurements, absolute frequency values or frequency intervals were established, and Fisher's test and Pearson's chi-squared test were applied. The adopted level of significance was 5%, with a confidence interval of 95%.

Data were shown separately to emphasize the occurrence of similarities or differences between the groups. This type of presentation allowed to visualize and understand the variables involved in the use of the two types of catheter. It was not possible to determine the relative risk or correlations between the studied groups and variables because of the data asymmetry and the reduced number of participants.

The analyzed outcome variable was the elective or nonelective (prompted by complications) removal of the catheter. The variables that influenced catheter handling, TPN infusion, antibiotics, intravenous therapies, and concomitant peripheral venous accesses (PVA) were also controlled. Data were written in the nursing notes by the team that handled the catheters, with the register of the number of handlings, the number of TPN route breaches, the antibiotics administration route, and the number of new PVA obtained. Additionally, a researcher monitored the catheters daily, asking the team in case of a lack of records. The evaluated sample characterization variables were: gestational age, weight at birth, mortality risk score (Score for Neonatal Acute Physiology with Perinatal Extension II (SNAPPE II)), and gender at birth.

Ethical aspects were observed. The proposal was evaluated by the Research Ethics Committee at the Hospital de Clínica at the Federal University of Paraná as per report no. 172.382 of 11/20/2010 and registered with the primary ID number RBR-8y56jt on the Brazilian Registry of Clinical Trials platform.

RESULTS

The sample was 30 newborns with an average gestational age of 28.5+1.5 weeks for patients in the CG and 28.7+1.8 weeks for patients in the EG. The weight at birth ranged from 575 g to 1.750 g, with no difference between the groups. The female gender prevailed, with nine newborns in the CG (64.3%) and ten in the EG (62.5%). Three patients (21.4%) showed a fifth-minute Apgar score lower than seven in the CG, the same number (18.7%) found in the EG. Regarding the newborn mortality risk classification (SNAPPE II), the groups showed similar results. Ten newborns (71.5%) in the CG and 14 newborns (87.5%) in the EG had a SNAPPE II score lower than 47, as shown in Table 1. Data related to the use of PICC by the examined groups are shown in Table 2.

Table 1 – Characteristics of newborns in the control group and the experimental group. Curitiba, Paraná, Brazil, 2017 (continues)

Characteristics	CG (n = 14)	%	EG (n = 16)	%	p
Female gender	9	64.3	10	62.5	0.83*
Male gender	5	35.7	6	37.5	0.45*
Gestational age (weeks)	28.5+1.5	-	28.7+1.8	-	0.73*
Weight (g)	1134.3+336.9	-	1140.6+286.0	-	0.96*
Fifth-minute Apgar <7	3	21.4	3	18.7	0.52**
Fifth-minute Apgar >7	11	78.6	13	81.3	0.30**

SNAPPE II < 24	6	42.9	10	62.5	0.64**
SNAPPE II from 24 to 47	4	28.6	4	25	1.00**

NOTE: *Student's t-test; **Fisher's exact test

Table 2 – Use of PICC in the control group and the experimental group. Curitiba, Paraná, Brazil, 2017

	CG			EG			p value*
	median	minimum	maximum	median	minimum	maximum	
Time of PICC use (days)	13.5	3	26	14	5	26	0.98
Total number of PICC handlings	59	10	117	154	61	288	0.001
Total number of intravenous therapies	50.7	5	125	58.6	16	143	0.44
Flush	49.5	7	95	92.5	36	183	0.001
Days of TPN use	9	0	25	11.5	0	26	0.54
TPN route breaches	9.5	0	31	0	0	6	0.003
New venous accesses	1	3	11	1	0	3	0.01
Total number of PVA handlings	20.5	2	168	7	0	63	0.001

NOTE: *Fisher's exact test

The time of PICC use was similar in both groups, with a median of 14 days in the EG and 13.5 days in the CG. Regarding the total number of intravenous therapies prescribed for each group, no difference was found. The medians were 50.7 therapies in the CG and 58.7 in the EG over the period the catheter was used.

The use of TPN was similar in the groups, with a median of nine days of TPN in the CG and 11.5 days in the EG ($p=0.54$). The number of TPN infusion route breaches showed a median of 9.5 in the CG and zero in the EG ($p=0.003$).

The episodes of PICC handling occurred for the nurses to administer intravenous therapies and keep the catheter. The CG showed a median of 59 handlings, whereas the EG had a median of 154 handlings, with a significant difference between the groups ($p=0.001$).

Analysis of the interval between the times they were handled during the day indicated that the CG showed a higher concentration of occurrences in the interval from one to five handlings per days, whereas the EG had a higher concentration in the interval from 11 to 15 handlings per day and reached the interval from 16 to 20. The handlings recorded in the CG accounted for around half the total number of handlings, which also included those related to PVA. The newborns in this group were handled from two to 168 times, with a median of 20.5 handlings including all the accesses. In the EG, the number of handlings ranged from zero to 63, with a median of seven ($p=0.001$).

The patients in the CG and EG received a median of one new access, with a variation from three to 11 new punctures in the CG, whereas the patients in the EG received from zero to three new access ($p=0.01$). In addition to the handlings for administration of intravenous therapy, PICC handlings were also carried out to keep the device permeability with flushing, with a median of 49.5 in the CG and 92.5 in the EG. This difference occurred because each lumen receives a flush as a result of its characteristics. No failures related to

the inexecution of this care procedure was found, which was observed by checking the procedure in the nursing prescription as well as the register of its execution in the nursing notes.

The complication rates related to the use of catheters in the examined groups are shown in Table 3. The number of general complications was 13 cases (81.2%) in the EG and eight cases (57.1%) in the CG. The nonelective removal of the devices occurred in ten (62.5%) and seven (50%) PICC, respectively, in the EG and the CG.

Table 3 – Complications related to the use of PICC in the control group and the experimental group. Curitiba, Paraná, Brazil, 2017

Complications	CG		EG		p value*
	n	%	N	%	
General complications	8	57.1	13	81.25	0.14
Total obstruction	1	7.1	2	12.5	0.55
Partial obstruction	1	7.1	3	18.75	0.35
Blood culture +	5	35.7	7	43.75	0.47
Infiltration	2	14.3	3	18.75	0.56
Other complications	3	21.4	6	37.5	0.28

Legenda: *Teste exato de Fisher

The main complications found in the studied sample were: obstruction, infection, and infiltration, among others. The total obstruction rates observed in the CG and the EG were similar. There was one case (7.14%) in the former and two cases (12.5%) in the latter ($p = 0.55$), with no removal or via loss resulting from the problem. The infiltration rate was also similar in both groups, with two cases (14.3%) in the CG and three (18.7%) in the EG that culminated in the removal of the catheters. Catheter-related infection was assessed by verifying the occurrence of positive blood culture, the clinical condition, and the removal of PICC as a result of this complication. Positive blood cultures were obtained in five cases (35.7%) with MLPICC and seven (43.7%) with DLPICC.

All the five PICC with a positive blood culture (100%) were removed in the CG, whereas five out of seven PICC that showed a positive blood culture (71.4%) were removed in the EG. The other catheters were taken out because of different problems. Other complications occurred, with isolated cases in the examined groups, totaling three cases (21.4%) in the CG and six (37.5%) in the EG.

DISCUSSION

Insertion and maintenance of PICC are fundamental for extreme PNs. Consequently, the use of the catheter must meet the demands of these patients, complete the therapeutic process with the application of infusion therapy, and culminate in the elective removal of the device. Using PICC that way reduces the exposure of PNs to pain, reduces barriers, and the use of multiple venous accesses, increasing care quality.

The time of PICC use is a type of data that shows considerable variation in studies in the Brazilian and international literature. Studies carried out in Brazilian NICU have indicated an average use for seven days at a certain institution, 10.6 days at a second place, and 13 days at a third NICU⁽⁶⁻⁸⁾. A study performed in China reported a similar average time of use, with a period of 13.6 days⁽⁹⁾.

An investigation that evaluated neonatal MLPICC and DLPICC showed that the latter had longer time of use, with an average period of 14 days versus 10 days for MLPICC, a result similar to that found in the present study⁽²⁾. This variation indicates the possibility of improving the professional practices related to the application of these devices to optimize their elective removal and minimize the complications resulting from the use of different types of PICC.

Analysis of time of PICC use must be associated with the nonelective removal of these devices. An isolated interpretation does not include the relationship of differences in the indication for insertion and removal of these catheters, which vary according to the examined realities. In a study carried out in a NICU at a private hospital in São Paulo, state of São Paulo, Brazil, 37.2% of the PICC, including MLPICC and DLPICC, were removed because of complications⁽¹⁰⁾. There was a balance between elective and nonelective removals in a study performed in Maringá, totaling 48.8% of the PICC in each group, whereas 30.8% of the neonatal PICC were removed because of complications at a private hospital in São Paulo and 48.6% at a hospital in Fortaleza. Nonelective removal accounted for 43.8% of the procedures in another NICU in the South region of Brazil^(6-8,11). However, a study carried out in China showed that the nonelective removal rate corresponded to only 10.71% of neonatal PICC⁽⁹⁾. These results emphasize the urgent need to evaluate the Brazilian national scene of neonatal PICC approach, use, and use management.

In the present study, the nonelective removal rate reached 62.5% for DLPICC and 50% for MLPICC, and the removal occurred because of different complications. According to the score of risk for nonelective neonatal PICC removal, the newborns classified as having moderate risk reach up to 36% of nonelective removal, whereas in high-risk patients the percentage of nonelective PICC removal reach up to 64% of losses, which reinforces and justifies the findings described in the present study⁽¹²⁾.

When evaluated separately, neonatal PICC showed a similar incidence of complications (45.6% for DLPICC and 35.4% for MLPICC)⁽²⁾. In the present study, these rates were 81.2% and 57.1%, respectively, not all of which resulted in the catheter removal.

Both in the Northeast and the South regions of Brazil, PICC rupture was the most frequent complication described in the literature, followed by obstruction^(6,11). These situations differ from that observed in the present study, because no ruptures were found in the examined catheters. It is possible that PICC rupture is caused by an increase in the catheter intraluminal pressure, either because of increased infusion volumes or the use of positive pressure in cases of resistance and/or obstruction. Therefore, ruptures must be better explained when they occur in studies involving neonatal PICC to allow the prevention of this event, given that it may result from a flux limitation in the device or inadequate clearance practices.

Comparison of data on PICC-related complications in newborns must be deepened because of the presence of different approaches to the subject in the literature, whose results are shown by procedure or by patient, can describe a combination of silicone and polyurethane PICC, with mono or double-lumen catheters, and varied brands and gauges. Complication rates may include catheters in a noncentral position, complications related to the insertion of the device, calculations by incidence or prevalence, and the evaluation of complications that resulted in PICC removal or that were managed. These factors originate different rates for comparison, which must be interpreted.

According to this nonelective PICC removal risk score, the number of daily intravenous therapies is classified as a high risk factor, combined with the presence of double-lumen catheters, which increase the need for manipulation. Consequently, analyzing the

permanence of the catheter in combination with its therapeutic indication is relevant⁽¹¹⁾. Considering the homogeneity of the samples in the present study, it is important to stress that the practices carried out must be reviewed, with a reduction systems opened and lower associated risks. The difference in the number of daily handlings was remarkable (the median was 59 handlings in the CG and 154 in the EG over the period of PICC use), which implies risks involved in the application of neonatal DLPICC.

Additionally, other outcomes must be evaluated. The patients in the CG received more PVA, with which the handlings to administer intravenous therapies were distributed. The median in this group was 20.5 PVA handlings versus seven in the EG. The results regarding new accesses also differed. The maximum number of punctures was 11 in the CG and three in the EG.

Carrying on the analysis about the controlled risk factors, TPN infusion is a relevant factor for the development of PICC complications. Although the use of an exclusive via for TPN is recommended, the TPN infusion via in the studied catheters had via breaches because of the specificities of the NICU reality⁽⁴⁾. When double-lumen catheters are not available, there are the options of peripheral puncture and interruption of TPN infusion to administer other solutions, which distinguishes the practices. That resulted in the CG's having a median of 9.5 breaches, whereas the EG showed zero breaches.

Infiltration is not the most common complication associated with PICC use, but it can reach up to 12.4% of the complications⁽⁷⁾. This event possibly results from catheter migration, in a spontaneous movement of the device in the thoracic space of the patient, which may happen at any time when it is inserted. The identification of the event is radiographic⁽¹⁰⁾.

Different realities are found regarding the occurrence of PICC-related infections. A study carried out in Australia that examined DLPICC in low-weight PNs showed that the infection rate accounted for 10.3% of the catheters⁽¹³⁾.

Inserting a minimum number of lumens may help reduce the infection rate and the costs related to patient hospitalization. An increase of 5% in the use of MLPICC is associated with the prevention of 1.5 related blood infections⁽¹⁴⁾. When the number of DLPICC insertions was decreased and the primary bloodstream infection rates were evaluated in patients using MLPICC and DLPICC in a study carried out in Canada, it was found that the rates dropped and that the need for reinsertion was lower in the group that used MLPICC⁽¹⁵⁾.

An explanation about the number of lumens and its correlation with the occurrence of infections is the increase in the number of related handlings⁽²⁾. The use of concomitant PVA may distribute MLPICC therapies and handlings, influencing this occurrence. However, punctures also pose risks of infection and complications.

A prospective cohort study performed in Taiwan with 125 newborns in ICU concluded that the high number of punctures exposes these patients to an increased number of complications⁽¹⁶⁾.

It is important to consider that the similarity in the infection rates found for the two groups contradicts nearly all the backing material in the literature. This may result from the homogeneity that characterized the sample, material, catheter gauges and brands, and indications in the present study, which does not occur in investigations that do no control PICC indications and evaluate different populations. Differences in the groups that could be attributed to the results were not identified. With homogeneous groups, data may suggest that the number of lumens is not the only risk factor for catheter-related infections, indicating that the problem may have a relationship with care protocols.

When the differences between patients are better controlled, the relationship between the number of lumens and the occurrence of infections is weaker. That may be a consequence of a compensation of the convenience of indicating DLPICC according to the need of the patient⁽¹⁷⁾.

In face of that, the authors emphasize that the perspective of occurrence of complications is a fundamental condition to establish clinical guidelines for DLPICC use, given that different issues pertain to the use of this type of catheter.

It is important to stress the high specificity of the present study regarding the examination of a sample with extremely preterm newborns (to whom the results have primordial relevance), which may originate innovative data. Sample homogeneity is also a relevant element when factors such as risk of infection are addressed. This homogeneity includes similar time of PICC use, the total number of intravenous therapies, and the days of TPN use.

The choice of catheter type must meet the needs of the infusion therapy, with the evaluation of the use of concomitant venous accesses that may also cause complications. The number obtained for this access type was higher in the group that used MLPICC because of the need for more infusion vias.

Sample size is a relevant factor that can limit data inference power. Additionally, handling DLPICC was an unprecedented procedure for the care team, which may have influenced the way the professionals dealt with and cared for the patients considering the remarkable difference in the number of handlings in the device.

CONCLUSION

Using DLPICC is relevant for the treatment of PNs. Designing guidelines for this use aims to minimize the damages resulting from this practice, associated with pain reduction and handling of newborns.

The complication rates shown in the present study differ from those found in the literature. They may have been influenced by the reduced sample or its homogeneity. Carrying out a clinical trial with catheters made of the same material and controlling the intervening variables are uncommon actions in the field. The general complications and the obstruction and infection rates were similar, which directly impacts catheter selection.

Therefore, DLPICC can be beneficial to PNs, as long as the indication, insertion, and handling are conducted properly. Multiprofessional discussions are the fundamental point to choose one type of catheter in detriment of others, taking into account the associated risks and practices.

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