Incidence of Nonelective Removal of Single-Lumen Silicone and Dual-Lumen Polyurethane Percutaneously Inserted Central Catheters in Neonates

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Abstract

Objective: *To compare the incidence of nonelective removal of single-lumen silicone and dual-lumen polyurethane percutaneously inserted central catheters (PICCs).*

Study Design: *A prospective cohort study was conducted with neonates in whom 247 PICC lines had been successfully inserted. Patients were assigned to either the single-lumen silicone group or the dual-lumen polyurethane group and nonelective removal incidence was compared using a logistic regression model.*

Results: *Incidence of nonelective removal in dual-lumen polyurethane PICCs ($n = 91$) was 48.3% versus 34% in single-lumen silicone PICCs ($n = 156$). Thus, dual-lumen polyurethane catheters had a significantly increased chance of nonelective removal compared with single-lumen silicone PICCs ($P = .004$). The most usual complication in dual-lumen polyurethane PICCs was suspected catheter-related bloodstream infection; in single-lumen silicone PICCs it was external rupture.*

Conclusions: *Dual-lumen polyurethane PICCs are associated with higher rates of nonelective removal and complications such as suspected catheter-related bloodstream infection. Cautious nursing care is necessary to prevent complications.*

Keywords: *central venous catheterization, critical care, newborn, nursing*

Introduction

A peripherally inserted central catheter (PICC) is a device inserted into a peripheral vein and threaded into the central venous circulation.[1] PICCs can vary in gauge size, material, and number of lumens. The PICCs used in neonatal intensive care units (NICUs) are usually 2F (24 gauge) and 3F (20 gauge), silicone or polyurethane catheters, with single or dual lumens. PICCs made of silicone have a slower gravity flow rate and thicker catheter walls. Using polyurethane provides PICCs with greater wall strength thereby allowing the production of a small-sized, high-flow catheter with greater luminal capacity.[2] Single-lumen catheters are generally preferred, unless multiple lumens are essential for patient management because they appear to be less likely to induce complications.[3]

The incidence of major complications associated with PICC lines is low.[1] However, mechanical and infectious

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complications occur in 13%-63.6% of inserted catheters. These complications include occlusion, phlebitis, thrombosis, catheter site inflammation, leakage, rupture, extravasation, pericardial effusion, and catheter-related sepsis.[4,5] Catheter material and number of lumens are associated with the incidence of complication such as phlebitis, occlusion, and catheter-related bloodstream infection.[2] A study[6] that evaluated and compared the relative durability and complications of proximal valve polyurethane and distal valve silicone PICCs in 326 adult patients demonstrated that polyurethane PICCs were more durable. In addition, a study[3] that identified the frequency and types of complications associated with PICCs used in pediatric patients for parenteral antimicrobial therapy showed that the use of dual-lumen catheters was associated with a higher incidence of complications.

Some risk factors, such as the material and number of lumens of PICCs, have been studied independently.[3,6] However, the relationship between different types of PICCs made from different materials and having a different number of lumens and the incidence of nonelective removal in the neonatal population remains unclear. The advent of PICC technology requires evidence to inform clinical practice. The aim of our study was to compare the incidence of nonelective removal of single-lumen silicone and dual-lumen polyurethane PICCs in neonates.

Methods

Study Design and Setting

This was a prospective cohort study of infants admitted to a tertiary-level NICU of a private hospital in the city of São Paulo, Brazil, between August 2010 and August 2012. The indications for PICC insertion were determined by an attending neonatologist and included the need for parenteral nutrition with dextrose concentration $> 12.5\%$, continuous infusion of vesicant medications, therapies with variations in osmolarity or pH, and prolonged antibiotic therapy.[7] Two types of catheters were included in this study: 1.9F (26 gauge) single-lumen silicone PICC (BD First PICC; Beckton, Dickinson and Company, Franklin Lakes, NJ) and 2.0F (24 gauge) dual-lumen polyurethane PICC (Nutriline Twinflo; Vygon, Aachen, Germany). A single-lumen silicone PICC was inserted for single-agent therapy, such as antibiotics only or intravenous fluid only. A dual-lumen polyurethane PICC was inserted for the delivery of multiple intravenous infusates such as parenteral nutrition and antibiotics. No blood products were administered through PICCs because it is not recommended to administer these through PICC lines smaller than 3F.

PICCs were inserted by a team of 2 nurses under sterile conditions. Nurses were encouraged to participate in a training program that consisted of didactic and practical development of clinical skills for PICC insertion, maintenance, and removal. The procedure of insertion was considered successful when the position of the catheter tip was confirmed and approved for use after assessment of a supine-position radiograph by the attending neonatologist and the nurses.[7] The catheter tip could be located in veins such as the brachiocephalic, jugular, subclavian, axillary, iliac, saphenous, superior or inferior vena cava, and cavoatrial junction. Details of catheter insertion, maintenance care, and removal were documented in patients' charts. The catheter hub was disinfected before access using an alcohol swab and new clean gloves. Transparent semipermeable membrane dressings, sterile tapes, and surgical strips were changed every 7 days or earlier in the case of loss of adhesion. Dwell time and PICC removal were determined by an attending neonatologist according to a patient's clinical condition, type of intravenous therapy, and functionality of the device.[7]

Participants and Data Collection

The study sample comprised neonates who were born at the hospital and underwent successful insertion of PICC lines (single-lumen silicone or dual-lumen polyurethane PICC), had no other central venous catheter inserted, and no congenital anomalies. The exclusion criteria were death of the infant, transfer to another hospital during follow-up, and no record of the type of the catheter or reason for removal in the medical chart.[7] A statistical power analysis was used to calculate the required sample size. Based on the study by Ong et al,[6] assumptions were made as follows: $\alpha = 0.05$, power $= 0.80$, nonelective removal incidence in polyurethane PICCs of 26.8% and in silicone PICCs of 47.9%, and ratio of sample sizes was 1:1. The sample size necessary for a 2-tailed test was estimated as 182 catheters, 91 in the single-lumen silicone group and 91 in the dual-lumen polyurethane group. Medical records of neonates were examined, and patients were assigned to either the single-lumen silicone group or the dual-lumen polyurethane group. Data were collected until the number of dual-lumen polyurethane catheters was reached, resulting in a sample of 247 catheters. All neonates were monitored daily from PICC placement until removal, which was the main outcome variable.

Definitions

The following variables were collected: date of PICC insertion, main medical diagnosis, weight at the time of PICC insertion, postnatal and corrected gestational age at the time of PICC insertion, sex, catheter type (single-lumen silicone or dual-lumen polyurethane PICC), intravenous therapy indicating the need for PICC (eg, parenteral nutrition, antibiotic, or general intravenous access), initial tip position, date of removal, reason for removal, and dwell time of the catheter (ie, time interval between insertion and removal of the catheter in days). The following definitions were used: elective removal of the catheter occurred when it was no longer required (eg, end of therapy) and nonelective removal occurred when there were complications.[7] Suspected catheter-related bloodstream infection was bacteremia or fungemia in a neonate who had an intravascular device if the neonate had ≥ 1 positive blood culture results (from samples drawn from the peripheral vein or central access) or clinical manifestations of infection (fever or hypotension) with no other apparent sources of bloodstream infection.[1,8] Catheter occlusion was the inability to flush the catheter with 1 mL saline solution using a 10-mL syringe.[1] External catheter rupture was a rupture of an external segment of the device due to high pressure generated by using a small-

volume syringe for infusion or flushing against resistance.[1] Accidental dislodgement was an inadvertent partial or complete removal of the catheter from the infant's body.[1] Tip migration was spontaneous movement of the tip of the catheter at any time while in situ leading to a peripheral location identified on the radiograph.[1] Extremity edema was the identification of a mild to severe edema in the area surrounding the catheter insertion site or in the extremity associated with the catheter.[1] Thrombosis was identified by medical diagnosis. Extravasation was the escape of potentially injurious solutions from the walls of the vein causing skin redness, edema, and discoloration.[9] Phlebitis was an inflammatory reaction in the vein associated with the placement and dwell time of a catheter, identified by erythema or palpable venous cord at the vein.[1,8]

Outcome Measures

The primary outcome was the comparison of incidence of nonelective removal in single-lumen silicone and dual-lumen polyurethane PICCs. The secondary outcome was the risk factors of nonelective removal in the cohort.

Ethics

The study protocol was approved by the Ethics Committee of the institution (No. 238/2010).

Statistical Methods

The analysis was performed using R: A Language and Environment for Statistical Computing (version 2.15.2, 2013, R Foundation for Statistical Computing, Vienna, Austria). The univariate analysis compared baseline characteristics of the neonates and characteristics of the PICC insertion procedure of single-lumen silicone and dual-lumen polyurethane PICCs. A χ^2 test or Fisher exact test was used for discrete variables, and Student *t* test was used for continuous variables. The same analysis was used to identify the risk factors of nonelective removal. A logistic regression was carried out with the variables that could contribute to increase the risk of nonelective removal, such as postnatal age, PICC indication, medical diagnosis, and type of PICC. The final model was selected using a stepwise algorithm by Akaike information criterion statistic. For all statistical analyses, $P \leq .05$ with a 95% confidence interval was considered statistically significant.

Results

Of the 275 PICCs recorded in this study, data collection was completed for 247 catheters (Figure) and for 191 neonates. Of the PICCs inserted, 156 (63.2%) were single-lumen silicone PICCs and 91 (36.8%) were dual-lumen polyurethane PICCs. The majority of newborns, 146 (59.1%), were boys. The newborns had a mean corrected gestational age of 34.1 weeks, 10.2 days of life, and weighed 1,909 g. The most common diagnosis of the newborns was prematurity, which accounted for 77.7% of PICC insertions, and respiratory distress syndrome, which accounted for 66% of PICC insertions. Significant differences were observed between the single-lumen silicone group and the dual-lumen polyurethane group with regard to the diagnosis of sepsis (Table 1).

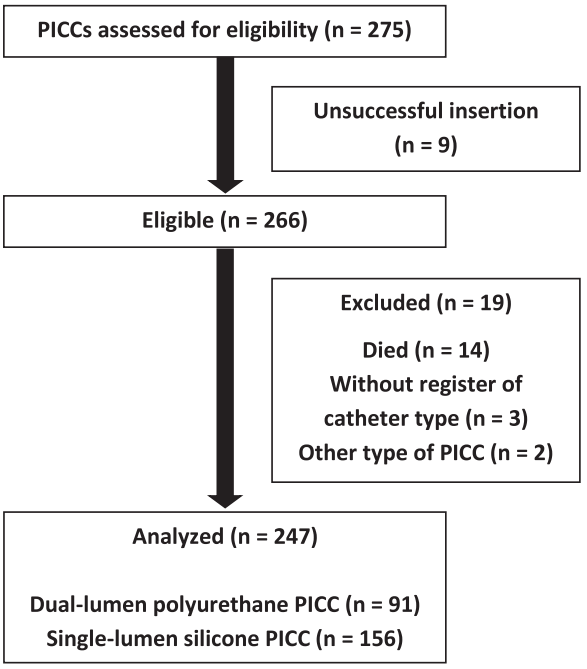

Figure. **Flowchart for included infants with peripherally inserted central catheters (PICCs) and their type of catheter.**

The distal tips of 211 (86.5%) catheters were placed in central veins, such as the superior or inferior vena cava, cavoatrial junction, and right atrium. Most of the single-lumen silicone PICCs, 134 (85.9%), had a central tip position. A similar proportion, 87.5%, was found in the dual-lumen polyurethane group with no significant differences ($P = .7$). The site of insertion was the upper extremity in 186 (76.7%) PICC insertions, lower extremity in 32 (13.2%) PICC insertions, followed by the neck and head in 18 (7.4%) and 6 (2.5%) PICC insertions, respectively. There were no differences in the site of insertion between the groups ($P = .9$). Regarding the veins used for PICC insertion, in the upper extremity the most common veins were the axillary, followed by the basilic. In the lower extremity, the saphenous vein was often used, and the jugular and temporal veins were used frequently to insert catheters in the neck and in the head insertion sites.

Considering that each PICC can have > 1 intravenous fluid, PICC placement was indicated for antibiotic infusion in 205 patients (83%), parenteral nutrition in 148 patients (59.9%), dextrose-based solutions in 88 patients (35.6%), and dopamine or dobutamine in 56 patients (22.7%). There were significant differences between the groups with regard to PICC indication for parenteral nutrition and dopamine or dobutamine (Table 1).

One hundred fifty (60.7%) catheters were removed because they were no longer required. Nonelective removal occurred in 34% of single-lumen silicone PICC group patients and 48.3% in dual-lumen polyurethane PICC group patients. If the PICC line was indicated to infuse dopamine or dobutamine, the incidence of nonelective removal increased among single-lumen silicone PICCs to 64% and among polyurethane dual-lumen catheters to 48.4%. Because the 2 types of PICC showed

Table 1. **Comparison of Baseline Characteristics and Indication of Single-Lumen Silicone and Dual-Lumen Polyurethane Peripherally Inserted Central Catheters (PICCs)**

	Single-lumen silicone PICC (n = 156)	Dual-lumen polyurethane PICC (n = 91)	*P*
Infant characteristic			
Corrected gestational age (wk)	34.4 ± 4.6	33.7 ± 4.1	.19
Postnatal age (d)	10.6 ± 19.3	9.6 ± 14.3	.66
Weight (g)	1,978.1 ± 855.1	1,790.1 ± 847.8	.09
Diagnosis of prematurity			.38
Yes	124 (79.5)	68 (74.7)	
No	32 (20.5)	23 (25.3)	
Diagnosis of respiratory distress syndrome			.56
Yes	105 (67.3)	58 (63.7)	
No	51 (32.7)	33 (36.3)	
Diagnosis of sepsis			.02
Yes	28 (17.9)	28 (30.8)	
No	128 (82.1)	63 (69.2)	
Sex			.31
Male	96 (61.5)	50 (54.9)	
Female	60 (38.5)	41 (45.1)	
PICC indication			
Antibiotics			.11
Yes	125 (80.1)	80 (87.9)	
No	31 (19.9)	11 (12.1)	
Parenteral nutrition			.02
Yes	82 (52.6)	66 (72.5)	
No	74 (47.4)	25 (27.5)	
Dopamine or dobutamine			.01
Yes	25 (16)	31 (34.1)	
No	131 (84)	60 (63.9)	
Dextrose-based solution			.13
Yes	61 (39.1)	27 (29.7)	
No	95 (60.9)	64 (70.3)	

Note: Values are given as mean ± SD or n (%).

Table 2. Multivariate Logistic Regression Model for Nonelective Removal of Peripherally Inserted Central Catheters (PICCs)

Predictor	Odds ratio	95% Confidence interval Low	Superior	*P*
Postnatal age	1.033	1.016	1.053	< .001
Polyurethane PICC	2.653	1.378	5.153	.004
Silicone PICC with dobutamine or dopamine	5.356	2.176	13.947	.000
Polyurethane PICC with dobutamine or dopamine	0.987	0.407	2.394	.977

significant differences due to the diagnosis of sepsis, and PICC indication for parenteral nutrition and use of dopamine or dobutamine, a logistic regression model was conducted to predict which variables influenced the incidence of nonelective removal. The predictors of nonelective removal were the use of dual-lumen polyurethane PICC, single-lumen silicone PICC with dobutamine or dopamine infusion, and an increase of each day of life in postnatal age (Table 2).

The most frequent reasons for nonelective removal were suspected catheter-related bloodstream infection in 27 PICCs (27.8%), and catheter occlusion and rupture in 18 PICCs (18.6%). Complications such as occlusion and rupture were more common in single-lumen silicone PICCs. Occurrence of suspected catheter-related bloodstream infection and catheter dislodgement was more common in dual-lumen polyurethane PICCs (Table 3).

The average dwell time for PICCs was 11.6 days (range 1-70 days). The mean ± SD dwell time was 13.9 ± 9.1 days for dual-lumen polyurethane PICCs and 10.3 ± 9.7 days for single-lumen silicone PICCs. This difference was statistically significant ($P = .004$).

Table 3. Reasons for Nonelective Removal in Single-Lumen Silicone and Dual-Lumen Polyurethane Peripherally Inserted Central Catheters (PICCs)

Reason	Single-lumen silicone PICC (n = 53) n	%	Dual-lumen polyurethane PICC (n = 44) n	%
Suspected catheter-related bloodstream infection	12	22.6	15	34.1
Catheter occlusion	13	24.5	5	11.4
Catheter rupture	14	26.4	4	9.1
Catheter dislodgement	8	15.1	7	15.9
Tip migration	0	—	5	11.4
Extremity edema	2	3.8	6	13.6
Extravasation	2	3.8	2	13.6
Infiltration	1	1.9	0	—
Thrombosis	1	1.9	0	—
Total	53	100	44	100

Discussion

The role of health care professionals in NICUs includes the selection of the appropriate type of catheter to accommodate a patient's vascular access needs based on the prescribed therapy or treatment regimen, length of treatment, dwell time, vascular integrity, ability, and resources available to care of the device.[8] PICCs have different characteristics, such as material (eg, polyurethane or silicone) and number of lumens, which can affect their performance. Nonelective removal incidence seems to be higher among dual-lumen polyurethane PICCs. The results suggest a 2.6 times greater chance of complications in this group with a statistically significant difference compared to single-lumen silicone PICCs ($P = .004$). However, it is important to emphasize that dual-lumen polyurethane PICCs had a significantly longer dwell time, which ensures central vascular access for almost 2 weeks. They also allow 2 independent routes for intravenous infusion and represent a technology that is potentially less invasive than a surgically placed central venous access. Furthermore, many catheter-related complications can be prevented by careful bedside nursing care and the type of catheter will influence the nursing care of PICC lines.

The overall incidence of nonelective removal of 39.3% found in this study was lower than that found in previous studies with PICCs in neonates. A retrospective study that included 167 infants who underwent 241 PICC insertions in a Brazilian NICU reported a nonelective removal rate of 47.7%.[10] A prospective study conducted with 226 neonates requiring surgical treatment who underwent 302 PICC insertions at a tertiary-level NICU in London reported a nonelective removal rate of 46.3%.[11]

In terms of number of lumens, similar results for dual-lumen PICCs were found in a study that showed the frequency and types of complications with PICCs inserted in pediatric patients for parenteral antimicrobial therapy. Complications occurred in > 30% of PICCs and dual-lumen PICCs had a higher rate of complication (30.8 per 1,000 catheter-days) and 1.8 times (95% confidence interval [1.34-2.53]) greater risk of complications compared with single-lumen PICCs.[3] A retrospective study conducted with 61 newborns who had dual-lumen polyurethane 3F PICCs reported nonelective

removal in only 23 PICCs (37.7%). Local edema and phlebitis were the most common complications and affected 21.3% of newborns.[12] However, our study evaluated PICCs with a smaller inner diameter, which may have contributed to a higher incidence of complications. A nested case-control study conducted with 647 adult patients showed a 2.4 times greater risk of catheter-related bloodstream infection when the dual lumen PICC was placed compared with single-lumen catheters.[13] In our study, suspected catheter-related bloodstream infection was the most common reason for nonelective removal of dual-lumen polyurethane PICCs. Meticulous, sterile insertion techniques for PICCs can reduce the risk of this complication. Decreasing catheter manipulation is also a key to prevention of nonelective removal. Staff should wash their hands before every line entry, and hubs or intravenous injection sites should be cleaned with antiseptic and allowed to air-dry before the line is entered.[14] The adoption of a PICC team, including members of the nursing staff who are considered to be experts, is also a helpful strategy. The team's role could be inserting and removing PICC lines, changing dressings, maintaining skills competency, and providing familiarity with standards of practice, and developing educational activities for nursing staff.[15]

Analysis of the material of the catheter showed that the nonelective removal rate of silicone PICCs was lower. The results suggest a 5.3 times greater chance of complications if the catheter was indicated to deliver dopamine or dobutamine. It is recommended that a dual-lumen polyurethane PICC be used if newborns need infusion of these drugs. A randomized trial assessed the performance of PICCs made from different material and with different tip designs: a 4F single-lumen silicone catheter with distal side slits and a 4F single-lumen polyurethane catheter with open-end tip. The study evaluated 26 adult patients who had a PICC inserted for chemotherapy and/or perioperative intravenous nutritional support. The completion rate was 81.8% in the silicone group and 92.9% in the polyurethane group, with no significant differences between them. The total complication rate was also not different between the groups (9.1% and 14.3%).[16]

Other studies found similar results relating to reasons for nonelective removal of silicone PICCs. A retrospective cohort study conducted in a 49-bed NICU teaching hospital in Taiwan analyzed 518 silicone 2F single-lumen PICCs and showed incidence of rupture of 2.5% and occlusion of 7.1%. The overall complication rate was 26.1%.[5] The higher incidence of rupture on the external portion of silicone PICC lines suggests that lower pressure is needed to rupture a silicone catheter than a polyurethane catheter. This complication can be caused by the high pressure created by the use of small volume syringes for infusion, flushing against resistance, and failure to stabilize the catheter. Catheter occlusion is a mechanical complication that results from clotted blood or precipitated infusion products within the lumen, or fibrin sheath or thrombus formation at the catheter tip.[17] Steps to decrease this complication include flushing the catheter before each infusion as part of the assessment of catheter function and after each infusion to clear the infused medication from the catheter lumen, which will prevent contact between incompatible medications.

Our results suggest that the catheter material and the number of lumens of PICC lines may affect the incidence of nonelective removal. Dual-lumen polyurethane 2F PICCs had a significantly higher incidence of nonelective removal compared with 1.9F single-lumen silicone PICCs and lasted significantly longer.

Although our study analyzed a cohort of 247 PICCs, some limitations should be considered. The nonelective removal incidence in our study was different from the study used to estimate the sample size. In our study complications were more frequent in polyurethane PICCs. Further studies should be conducted with a larger sample of neonates. Other types of PICCs should also be assessed, possibly comparing them with surgically inserted central venous catheters. These studies would contribute to conclusions about the most appropriate choice of central vascular access device for the neonatal population. Finally, the results of our study represent the use of PICC lines in a single private hospital with a specific nursing team.

Conclusions

Dual-lumen polyurethane PICCs are associated with higher rates of nonelective removal than single-lumen silicone catheters. However, these catheters lasted for almost 2 weeks, which can represent a useful vascular access option for neonates. The incidence of nonelective removal was related to the type of catheter inserted, the use of dopamine or dobutamine, and the newborn's postnatal age. Cautious nursing care is necessary to prevent catheter-related complications in both types of PICCs.

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