ORIGINAL ARTICLE

Comparison of UVC with PICC Line for Reducing Central Line Associated Blood Stream Infections in Preterm Neonates with Birth Weight < 1250g: An Open-Label Randomized Controlled Trial

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ABSTRACT

Objective: To compare the incidence of central line associated blood stream infections (CLABSI) with the use of umbilical venous catheters (UVC) or peripherally inserted central cathethers (PICC) as primary vascular access in preterm neonates.

Method: This was an open-label, two parallel-arm, randomized controlled trial which included hospitalized neonates with birth weight <1250g who required a central venous access on day 1 of life. The neonates were randomized to either UVC or PICC groups and evaluated for the incidence of CLABSI.

Results: Of the total 238 eligible neonates, 128 and 110 neonates were randomized to the UVC and PICC groups, respectively. The baseline characteristics were comparable in both groups. There was no significant difference in the incidence of CLABSI among the UVC and PICC groups (21.1% vs 18.2%; *P* = 0.57). Neonates in the PICC group needed multiple attempts at insertion compared to those in the UVC group (43% vs 12%, *P* = 0.01); more time was needed for PICC line insertion [median (IQR) 20 (15, 40) vs 10 (5, 15) minutes], but had longer duration of the primary line [7 (4, 10) vs 5 (3, 7) days]. Early removal of the line for leakage was higher in the UVC group and local signs of inflammation were higher in the PICC group. The overall incidence of complications was similar between the groups (53% vs 45%, *P* = 1.00).

Conclusion: In preterm infants with a birth weight of less than 1250g, the incidence of CLABSI was similar in the UVC and PICC groups when used as a primary central line. The overall complication rates were comparable in the UVC and PICC groups.

Keywords: *Central line, CLABSI, Line removal, Malposition, Sepsis, Umbilical line*

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INTRODUCTION

Central venous catheters (CVC) are preferred over peripheral venous catheters for preterm neonates who need prolonged parenteral nutrition, larger fluid volumes, hyperosmolar fluids and medications such as inotropes [1]. The umbilical, internal jugular, antecubital and saphenous veins are the preferred sites for central venous access in neonates. Neonatologists routinely use the umbilical venous catheter (UVC) or peripherally inserted central catheter (PICC) for securing central venous access [2,3]. The insertion of the UVC requires less expertise compared to PICC lines. While UVCs are usually inserted on the first day of life when the umbilical stump is soft and can be easily manipulated [2], PICC can be inserted through the peripheral vein at any time during the stay in neonatal intensive care unit (NICU) and even after failure of UVC insertion.

The incidence of central line associated blood stream infection (CLABSI) usually ranges from 3-36% depending on the diagnostic criteria and the population demographics [4,5]. In a recent metanalysis, UVC insertion was associated with a higher risk of malposition (41%), migration (36%) and CLABSI (4%) [6]. The common complications associated with PICC include extravasation and sepsis [3]. Most studies comparing the performance of UVC with PICC in neonates are retrospective and observational [5,7-10]. In a single randomized controlled trial (RCT), the success rates and line-related complications were similar in both groups [11]. Considering the limited evidence comparing UVC with PICC as a primary central line, this RCT was planned to compare UVC with PICC line for the risk of CLABSI among preterm neonates, with birth weight less than 1250g.

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METHODS

This parallel group open-label randomized controlled trial was conducted from December 2018 to December 2020 at an intramural level-3 NICU of a tertiary care hospital in India. The study was approved by the Institute Ethics Committee. The study compared the UVC and PICC central venous lines as the choice of primary line on the first day of life with respect to incidence of CLABSI and complication rates.

Neonates with birth weight less than 1250g were eligible. Neonates with major congenital malformations and those with maternal chorioamnionitis were excluded. An informed consent was obtained from one of the parents or guardians after explaining about the study in the local language. The enrolled newborns were randomized to either UVC or PICC insertion. Random numbers were computer generated and stratified for birth weight (less than 1000g and 1000-1250g), by a person not involved in the study. Allocation concealment was achieved with serially numbered opaque envelopes. For twins and multiples, individual randomization was done for each infant. Blinding was not done considering the obvious nature of the intervention; however, the outcome was assessed by a senior neonatologist who was blinded to the study group. Appropriate size UVC (4 Fr or 5 Fr, Vygon India Pvt Ltd) or PICC (1Fr/28G and 200mm length, Premicath Vygon India Pvt Ltd) was inserted in the umbilical vein or peripheral vein, respectively, following a specially designed standard operating procedure. The central line was inserted by the senior resident on duty who had received appropriate training and experience (for at least a year) for the procedure. The length for UVC to be inserted was determined by modified Shukla's formula [3 x (weight of child) + 9/2] [12]. The length of the PICC line was calculated from the site of catheter insertion to the xiphisternum when the catheter was inserted from a lower limb, and up to the sternal angle when the catheter was inserted from the upper limb. Fixation of the UVC was done by bridging the catheters using protective skin adhesive and without the use of stitches. The PICC was secured using a sterile gauze piece and covered by a transparent adherent dressing (Tegaderm). The time needed for insertion of the catheter was determined by the time taken from the starting of the insertion procedure to fixation. A digital stopwatch was used for recording the time. The position of the catheter tip was confirmed by digital radiographs. A contrast dye, urograffin, was used for the localization of the PICC line tip at the time of taking the radiograph. The positioning of the line was confirmed in all babies by an independent observer (senior neonatologist). The tip of the UVC was adjusted to the upper level of the diaphragm (radio-logically T8-T9 vertebrae). The tip was of PICC was adjusted to the level of the diaphragm when inserted from the lower limb to T4 vertebrae or above the reflection of pericardium when inserted from the upper limb. All central lines were used for providing total parenteral nutrition (TPN) or medications as needed. A continuous flow of heparin at a dose of 0.5-1U/mL and a flow rate of 1mL/hour was used to maintain the line patency. Both the types of central lines were single lumen and were not used for the transfusion of any blood products.

The central line was removed when the newborn was not in need of TPN or medications needing lines at the discretion of the treating team. TPN was stopped when the neonate was able to tolerate at least 90% of enteral feeds. The unit policy allowed a maximum duration for the UVC as 10 days from the day of insertion, although no maximum duration for an indwelling PICC line was specified. This was in consonance with the Infusion Therapy Standards of Practice (INS) guidelines [13]. The decision for the reinsertion of a second central line and the type of line was at the discretion of the treating physician. In most cases, the second line was usually a PICC except when there was a failure to insert PICC on the first day after birth in the PICC group.

The primary study outcome was the incidence of CLABSI defined as clinical signs of sepsis at least 48 hours after insertion of a line, or within 48 hours after removal of the line with a positive blood culture (a single blood culture for an organism not commonly present on the skin and two or more blood cultures for an organism commonly present on the skin) [14]. Blood cultures where skin commensals were detected were concluded as true infection only if similar organism was found to be positive in two consecutive samples. The neonates in the study were monitored for the signs of infection every four hours from the time of enrolment until the line was in situ and for 48 hours after the removal of the line. Sepsis was defined by the presence of clinical signs of infection (temperature instability, cold peripheries, fever, lethargy, new onset tachypnoea or respiratory distress, abdominal distension, feed intolerance, altered aspirates, apneas, seizures, prolonged capillary filling time, shock) and positive blood or cerebral spinal fluid culture. Blood cultures were obtained in all neonates with clinical signs of sepsis and in those where antibiotics were started empirically.

The secondary outcomes included incidence of line-related complications such as malposition, occlusion, thrombus formation, migration or displacement, bleeding at local site or at the tip of line, pleural and pericardial effusion, line failure rate, probable sepsis, commom neonatal morbidities and in hospital mortality.

Malposition was defined as the tip of central line is not at appropriate place and displacement was defined as migration of the catheter tip after initial correct position. Hemorrhage was defined as estimated blood volume loss > 2mL (2 or more fully soaked gauze pieces). Probable sepsis was defined as the presence of clinical signs of sepsis and two or more positive sepsis screen parameters (total leucocyte count < 4000 per mm^3, absolute neutrophil count < 1500 per mm^3, the ratio of immature to mature neutrophil ratio > 0.2, and serum C-reactive protein > 1mg/dL), with a sterile blood culture. Line success was elective removal of the line after completing the intended use. If the line was removed before the indented use for any other reasons, it was considered a line failure. In infants with CLABSI if either the general condition was very unstable, or the infant was near full feeds the removal of the primary line and insertion of a secondary line were deferred. Infants were followed-up on a regular shift basis for all primary and secondary outcomes from enrolment till hospital discharge. A monitoring sheet specially designed for the study was used for listing all outcomes. Neonates completing 48 hours study duration were assessed for the primary outcome and those transferred out of the hospital or who died within 48 hours of enrollment were considered as lost to follow-up.

Based on hospital records, the baseline incidence of late-onset sepsis (LOS)/ CLABSI was 25% when UVC used as the primary central venous line. Assuming an expected absolute reduction of CLABSI by 10% using PICC as the primary central line, with a type I error of 0.05, power of 80%, with the allocation ratio of 1:1.2 (PICC vs UVC group), a sample size of 226 in the PICC group and 283 infants in the UVC group was needed. With an expected procedure failure rate of 20% in the UVC group, and assuming no failure in the PICC group, an allocation ratio of 1:1.2 was considered between PICC and UVC groups. Interim analysis was planned to assess the safety after 50% recruitment.

Statistical analysis: Statistical analysis was performed using Statistical Package for Social Sciences (SPSS) version 28. Descriptive statistics were used for baseline variables. Categorical outcomes were expressed as proportions and analyzed by the Chi-square test. Estimates of the strength of association were deduced by calculating relative risks with their respective 95% confidence intervals (CI). Continuous variables were expressed as mean (standard deviation) or median (interquartile range)

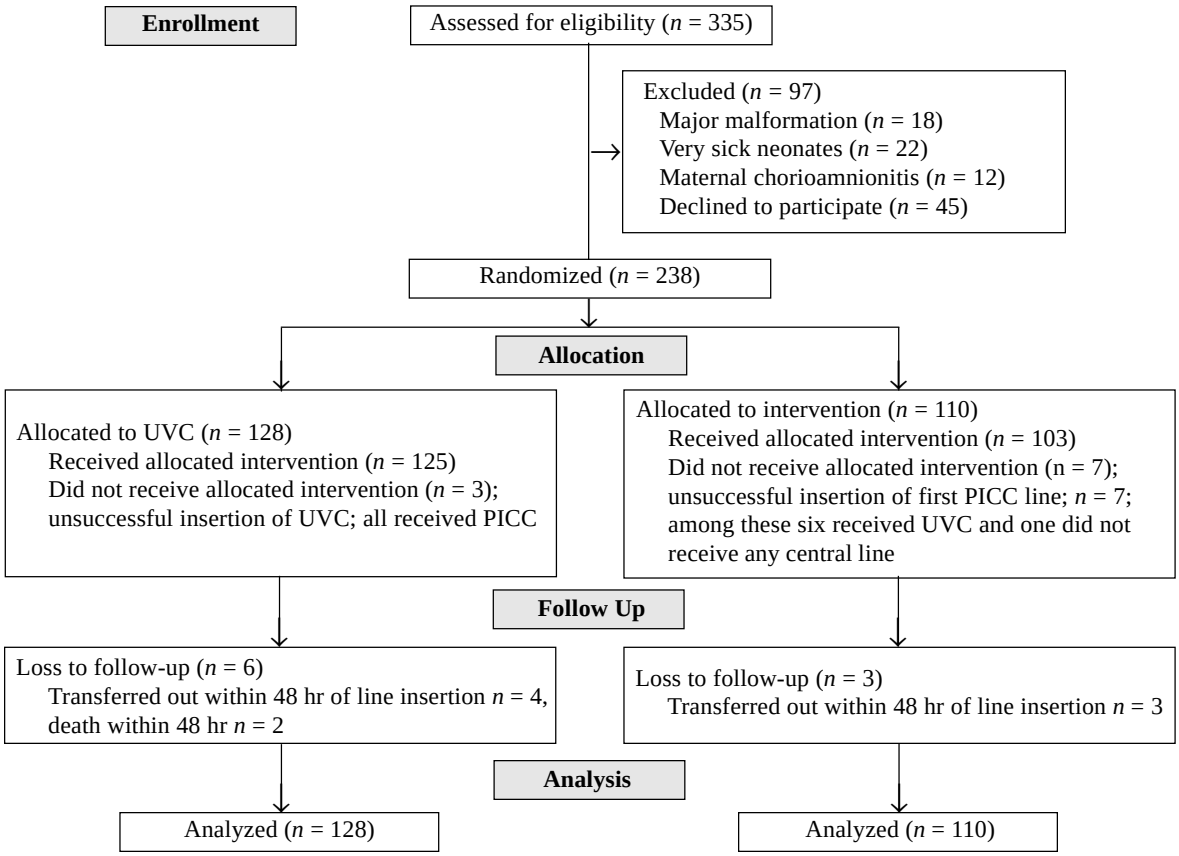

Fig.1 Flow of participants in the study

based on their distribution. These variables were tested for normality utilizing the Kolmogorov–Smirnov test and analyzed by the student t-test or Mann-Whitney U test. *P* value less than 0.0054 was considered as significant (O'Brien-Fleming approach) for the primary outcome. Intention to treat analysis was used for the primary outcome (CLABSI) and neonatal morbidities, and per protocol analysis was used for line-related outcomes. Subgroup analysis of incidence of CLABSI among infants less than 1000g and ≥1000g were analyzed. Predictors of CLABSI were evaluated using logistic regression analysis with the type of central line inserted, number of central lines, duration of the primary central line and total line duration as the dependent variables.

RESULTS

The flow of study participants is shown in **Fig. 1**. A total of 128 neonates were enrolled in UVC, and 110 neonates in the PICC groups. Among the 128 neonates in the UVC group, 125 received the UVC line and 3 neonates received the PICC line after failure to secure UVC. Of the 110 neonates in PICC group 103 neonates received PICC line, six received UVC line after failure to secure PICC line and one neonate received neither UVC nor PICC. The number of neonates lost to follow-up was 6 and 3 in UVC and PICC groups, respectively. The baseline characteristics of neonates included in the two groups were similar (**Table I**).

The incidence of CLABSI and other outcomes between the UVC and PICC groups was 27/128 (21.1%) and 20/110 (18.2%), respectively [*P* = 0.57, relative risk (RR): 0.8; 95% confidence interval (CI) 0.4, 1.6] **(Table II)**. On weight-based subgroup analysis, the incidence of CLABSI between UVC and PICC groups was 21% (10/48) vs 27% (13/47); *P* = 0.43 for birth weight < 1000g and 21% (17/80) vs 11% (7/63); *P* = 0.1 for birth weight ≥ 1000g. In both the groups, the predominant organisms causing CLABSI were gram negative bacteria.

The line-related outcomes and neonatal morbidities are shown in **Table II**. The proportion of neonates with sepsis (both CLABSI and probable sepsis) and other neonatal morbidities were similar between the two groups**.** *Klebsiella spp and Acinetobacter spp* were the commonest gram-negative organisms seen in eleven and six neonates in UVC, and three and two in PICC groups. Coagulase negative *Staphylocuccus spp* were seen in three and four neonates in UVC and PICC group, respectively and *Staphylococcus aureus* in one neonate in the UVC group. The incidence of complications between the two study groups is shown in **Table III.** The use of multiple lines, primary line duration (≥ 7days) and total line duration (≥ 11days) were the predictors for CLABSI on multivariate regression analysis (**Table IV**). PICC lines were inserted predominantly into lower limb veins (*n* = 90, 85%). However, the central line related complications were similar in both upper limb and lower limb groups of PICC line insertion (CLABSI: 19% vs 19%; *P* = 0.98).

DISCUSSION

In this RCT that compared the UVC and PICC groups when inserted as the primary line on day 1 of life among neonates with birth weight < 1250g, no statistical difference was found in the incidence of CLABSI between the two groups. In the sub-group of infants with birth weight > 1000 g, the incidence of CLABSI was lower in the PICC group by 10% that was clinically relevant, but did not reach statistical significance due to inadequate sample size. CDC definition was used to diagnose CLABSI in this study as it was standardized, practical and was used in various studies for surveillance of central line infection in neonates**.**

Table I Comparison of Baseline Characteristics between UVC and PICC groups

Characteristics	*UVC group (n= 128)*	*PICC group (n= 110)*
Birth weight (g)[a]	1035 (152)	1010 (166)
Gestational age (wk)[a]	29 (1.8)	29 (2.2)
Male	65 (51)	55 (50)
Length (cm)[a]	37 (2.7)	36 (2.6)
ANS	124 (97)	103 (94)
SGA	41 (32)	34 (31)
Resuscitation at birth	32 (25)	29 (26.4)
Multiple births	86 (67)	73 (66)
APGAR score at 5 min[b]	8 (7,8)	8 (7,8)
SNAPPE-II score[b]	10 (0,18)	10 (0,18)
Cesarean delivery	110 (86)	99 (90)
PROM	28 (22)	22 (20)
AREDF	25 (19.5)	28 (25)
GDM	16 (12.5)	23 (21)
PIH	38 (29)	39 (35)
EOS	3 (2.3)	1 (0.9)
RDS	102 (80)	77 (70)
Surfactant requirement	92 (72)	73 (66)
UAC	26 (20)	25 (22)

Data presented as n (%), [a]mean (SD) or [b]median (IQR)
ANS Antenatal steroids, AREDF Absent or reversal of end diastolic flow in umbilical artery, g Grams, GDM Gestational Diabetes Mellitus, EOS Early onset sepsis, PIH Pregnancy induced hypertension, PICC Peripherally inserted central catheter, PROM Premature rupture of membranes, RDS Respiratory distress syndrome, SGA Small for gestational age, SNAPPE-II Score for neonatal acute physiology with perinatal extension-II, UAC Umbilical arterial catheter, UVC Umbilical venous catheter, Wk Weeks

Table II Comparison of Central Line-Related and Neonatal Outcomes

Outcomes	*UVC group (n = 128)*	*PICC group (n = 110)*	*RR/ MD[b] (95% CI)*
CLABSI	27 (21.1)	20 (18.2)	0.8 (0.4, 1.6)
Gram negative	22 (81.4)	12 (60)	
Gram positive	4 (14.8)	6 (30)	
Candida spp	1 (3.7)	2 (10)	
Any sepsis	38 (29.7)	26 (23.6)	0.7 (0.3, 1.7)
Mortality	9 (7)	12 (10.9)	1.6 (0.4, 6.3)
NEC stage IIA or more	4 (3.1)	4 (3.6)	1.2 (0.1, 9.7)
Duration of hospital stay (d) [a]	29.5 (15.5, 45)	32.5 (23, 45)	3 (-4.5, 11.5)[b]
	UVC group (n = 131)	*PICC group (n = 106)*	
Successful in primary line insertion	125 (95)	102 (96)	0.8 (0.1, 4.8)
Multiple attempts for insertion	16 (12)	46 (43)	3.2 (1.35, 6.8)
Time for line insertion (min)[a]	10 (5,15)	20 (15,40)	15 (8.9, 16.1)[b]
Hemorrhage >2 mL	8 (6)	4 (4)	0.6 (0.1, 3.1)
Malposition	52 (39)	29 (27)	0.6 (0.3, 1.2)
Early removal of line	74 (56)	42 (39)	0.7 (0.5, 1.01)
Need for secondary line	49 (38)	20 (18)	0.5 (0.2, 1.04)
Primary line duration (d) [a]	5 (3,7)	7 (4,10)	2 (0.6, 3.4) [b]
Total line duration (d) [a]	7 (5,10)	8 (5,10)	1 (-1.6, 2.6) [b]
Line migration	14 (10)	3 (2)	0.2 (0.03, 1.5)

Data presented as n (%) or [a]median (IQR) with RR or MD[b] median difference (95%CI) using the Hodge-Lemann estimator
CLABSI Central line-associated bloodstream infection, PICC Peripherally inserted central catheter, UVC Umbilical venous catheter; One infant had failed insertion of both lines and was not included.

The overall reduction in the culture positive sepsis rate from 25% based on previous hospital records to 19% in the study center reflected an improvement in the quality of care and the use of standardized line protocol for insertion and maintenance. The incidence of CLASBI was similar in most of the previous observational studies that compared neonates with UVC and PICC lines [5, 8-11]. In an observational study with a larger sample size, the incidence of CLABSI was higher in the UVC group when controlled for dwell time [7]. Another retrospective study observed that PICC lines were associated with more CLABSI compared to UVC [15]. Both these studies evaluated the PICC lines which were inserted not as primary line and included mature neonates.

Gram negative bacteria such as *Klebsiella pneumoniae* and *Acinetobacter species* were the frequent CLABSI isolates in both the UVC and PICC groups in our study in contrast to the earlier studies where coagulase negative Staphylococci were predominantly isolated [5,7,9, 15-18]. This organism profile is similar to the other reports on neonatal sepsis from India [19-21].

The success rate of primary line insertion was similar in both groups, but the number of attempts and time required for insertion were higher in PICC group which is possibly due to the greater difficulty in localization of vein during the PICC line insertion compared to UVC insertion. This difference did not result in any untoward clinical outcomes as morbidities were similar and strict CLABSI bundle was maintained in both the groups. Similar to previous studies, the total duration of the central line was higher in the PICC group by 2-5 days compared to the UVC group [5,7-10]. PICC line may be preferred as the primary line as it had better longevity with fewer line-related complications necessitating the line removal. The common complications reported were displacement, leakage, blockage, malposition, local bleeding, and infections similar to other studies [5, 8-11]. The overall complication rate in these studies varied from 16.2% to 43% in the UVC group and 14.3% to 39% in the PICC group. Line leakage was higher in the UVC group in this study as sutures were not used to secure the UVC and/or UAC. Local inflammatory signs like erythema and induration were more common in PICC group, attributed

Table III Comparison of Line-Related Complications

Variable	*UVC group (n=131)*	*PICC group (n=106)*	*RR (95% CI)*
Reasons for early removal of line			
Limb edema	1 (0.7)	1 (0.9)	1.2 (0.02, 77.2)
Line occlusion	9 (7)	14 (13)	1.9 (0.6, 6.5)
Malposition	17 (13)	7 (6)	0.5 (0.1, 1.8)
Leakage	18 (14)	2 (1)	0.1 (0.01, 0.8)
Any sepsis	13 (9)	3 (3)	0.2 (0.03, 1.2)
Displacement	3 (2)	1 (0.9)	0.4 (0.01, 12)
Death	3 (2)	8 (7)	3.2 (0.4, 23.9)
Line thrombus	1 (0.7)	1 (0.7)	1.2 (0.02, 77.2)
Pleural effusion	0 (0)	2 (1.8)	6 (0.05, 726)
Pericardial effusion	0 (0)	1 (0.9)	3.7 (0.02, 575.3)
Other line related complications			
Local inflammation	8 (6)	20 (18)	3.0 (1.03, 8.7)
Atrial thrombus	2 (1.5)	1 (0.9)	0.6 (0.02, 17)
Liver hemorrhage	1 (0.8)	1 (0.9)	1.2 (0.03, 55.1)
Limb ischemia	1 (0.8)	0 (0)	0.4 (0.004, 44.4)
Overall complications	70 (53)	48 (45)	0.8 (0.53, 1.2)

Data presented as n (%)
CI Confidence interval, PICC Peripherally inserted central catheter, RR Relative risk, UVC Umbilical venous catheter
Analysis was done as per protocol; An infant can have more than one reason for line removal

to the use of breakaway needle as catheter introducer during insertion. These local complications were managed with warm compresses and were transient, as seen earlier [5]. The difference in the complication rates may result from differences in the definitions, gestational age, post-natal age, line duration, and protocols for the removal of central lines.

The neonates in the PICC group had lower gestational age with a higher degree of sickness [9, 11]. The average successful line usage rate for the PICC line and UVC line in this study was similar to that reported previously in two studies [9,11], but was lower than two other studies [5, 8]. This may be attributed to CLABSI as a non-uniform criterion for the line removal. The incidence of CLABSI was not associated with the type of central line in this study, as seen earlier [10]. Earlier studies have shown increased incidence of CLABSI with increase in UVC line duration and suggested replacing the UVC line electively after 5-7 days [4,5, 16, 22, 23].

The main strengths of the study are its randomized controlled study design with uniform protocol for line insertion and maintenance, standardized definitions for CLABSI and other complications, and daily assessment for early removal of the line. Due to slow rate of recruitment of the study population during the COVID-19 pandemic, the study was terminated before completion of the sample size. Early trial termination, limited sample size overall and for the a-priori stated sub-groups, and a high rate of transfer-outs before completion of study duration were the main limitations of the study. To conclude, in preterm infants with a birth weight of less than 1250g, incidence of CLABSI was not lower in the PICC group compared to UVC group when used as a primary central line. UVC was associated shorted line duration, early removal for line leakage but lesser signs of local inflammation.

Table IV Predictors of CLABSI

Parameter	*CLABSI (n = 47)*	*No CLABSI (n = 191)*	*OR (95% CI)*	*aOR* (95% CI)*
Multiple lines	25 (53.2)	44 (23)	3.8 (1.95, 7.38)	3.55 (1.35, 9.36)
Type of line				
UVC only	8 (17)	71 (37.2)	Ref	
PICC only	14 (29.8)	76 (39.8)	1.63 (0.65, 4.13)	
Required both	20 (42.6)	36 (18.8)	4.93 (1.98, 12.28)	
PICC followed by PICC	5 (10.6)	8 (4.2)	5.55 (1.46, 21.08)	-
Multiple attempts	16 (34)	46 (24.1)	1.63 (0.82, 3.24)	
Total line duration ≥ 11 d	30 (63.8)	28 (14.7)	10.27 (5.01, 21.05)	5.27 (2.28, 12.15)
Primary line duration ≥ 7 d	28 (59.6)	71 (37.2)	2.49 (1.3, 4.78)	2.7 (1.04, 7.03)
UAC	12 (25.5)	39 (20.4)	1.34 (0.63, 2.81)	-

CLABSI Central line associated blood stream infection, PICC Peripherally inserted central catheter, UAC Umbilical arterial line, UVC Umbilical venous catheter.
** Only those variables found statistically significant in univariable analysis were considered for multivariable analysis. Due to multicollinearity between "type of line" and "multiple lines", "type of line" is not taken into multivariable analysis.*

WHAT THIS STUDY ADDS?

- UVC was easy to insert with similar CLABSI incidence as compared to PICC line but was associated with shorter line duration in preterm infants with birth weight less than 1250g.

Contributors: SA, SrM, TPO: Conceptualized the study; SA, ShM, PRV: Collected data; SrM, SKD: Provided important inputs to the study design, data collection and manuscript. SrM, TPO, VV, SKD: Supervised the study conduct; SA, VV, SrM: Analyzed data. All authors prepared the manuscript with important inputs and approved the final version of the manuscript.

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