

Comparison of Ultrasound-Guided Umbilical Venous Catheter Insertion with Blind Method: A Randomized Controlled Trial

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Keywords

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Abstract

Introduction: Ultrasonography (USG) can be used in neonates to manipulate and place the umbilical catheter in the correct position. Although chest radiograph (CXR) is the gold standard, a noninvasive method like USG without radiation exposure may be an alternative bedside armamentarium to the clinician. The purpose of the study was to evaluate whether USG-guided umbilical venous catheter (UVC) insertion is superior to the conventional method for the successful insertion of UVC. **Method:** The neonates born between 25 and 42 weeks of gestation requiring parenteral fluids and admission to neonatal intensive care unit (NICU) between September 2020 and November 2022 were randomized in two weight-based strata: $\leq 1,200$ and $> 1,200$ g. USG-guided UVC insertion was done in the intervention group and blind UVC insertion was done in the control group. **Results:** Out of 112 enrolled neonates, 58 were in the USG-guided group and 54 in the blind group. There was no significant difference in the failure rate between the intervention and control groups (20% versus 29% [RR: 0.69, 95% CI: 0.36–1.33]). The sensitivity and specificity of USG in

locating tip position were 97 and 46.8%, respectively. The mean procedure time in USG and blind groups was 8.9 and 8.3 min, respectively (p value 0.56). **Conclusion:** USG does not reduce the failure rates during the insertion of umbilical catheters. However, being a safe, noninvasive procedure, it can be considered a rescue modality to CXR in NICUs equipped with portable USG for guiding UVC insertion.

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Introduction

Umbilical venous catheter (UVC) insertion is a commonly performed procedure in neonatal intensive care units (NICUs). The placement of the catheter through the umbilical vein is chosen because of the quick and easy access, especially in extremely preterm neonates where peripheral veins are thin and fragile with overlying immature skin. The complications associated with UVC insertion are primarily due to its malposition. Often, the umbilical vein is directly visualized, and the catheter is blindly inserted till a predecided length based on the

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measurement of body dimensions like birth weight or shoulder umbilical length [1–3]. An observational study was conducted to evaluate the accuracy of 5 different formulae for UVC insertion, and the predicted success rate varied between 44.9% and 55.7%. Also, approximately 50% of UVCs required manipulation to achieve the desired positions [1].

Confirmation of the UVC tip position is important as malposition can cause pleural effusion, liver haematoma, and intra-atrial positioning can cause arrhythmia, pericardial effusion, and cardiac tamponade. Traditionally, confirmation of the UVC tip position is done by X-ray. However, X-rays are time-consuming and are associated with radiation exposure. Also, anteroposterior (AP) radiographs were found to be less reliable than lateral radiographs for confirming the same [4]. Apart from radiography, ultrasonography (USG), electrocardiogram, and echocardiography have been used to identify the correct position of UVC at the cavoatrial junction [5–7]. Ultrasound is readily available in most intensive care units. It avoids radiation exposure and offers direct visualization of the catheter and the vessels both during insertion and after final positioning. It has been seen that the use of USG to guide UVC insertion can avoid its entry into the portal circulation [8]. When USG was compared with chest radiography to confirm the position of the central venous catheter tip in paediatric patients, the agreement between the two was 94% [9].

Limited studies are available using USG to confirm the correct position of the UVC in neonates [7, 8, 10–16]. Most studies except one [16] are observational studies with a small sample size. Hence, we conducted this randomized controlled study to evaluate the difference in failure rate between USG-guided and conventional insertion of UVC.

Materials and Methods

Study Design

This open-label randomized controlled trial was conducted in a tertiary NICU between September 2020 and November 2022. This study protocol was reviewed and approved by the Institute Ethics Committee, All India Institute of Medical Sciences, Bhubaneswar, and the trial was registered with the Clinical Trial Registry of India (CTRI/2020/09/027935).

Participants

All neonates born between 25 and 42 weeks of gestation who were admitted to the NICU and required umbilical venous access were included. UVC was inserted for the following indications: babies on mechanical ventilation for respiratory failure, severe birth asphyxia, total parenteral nutrition, shock, hypoglycemia needing glucose concentration >12.5%, and surgical conditions.

Exclusion criteria were congenital anomalies involving the abdominal wall, congenital diaphragmatic hernia, necrotizing enterocolitis, and peritonitis.

Randomization and Allocation Concealment

Stratification was done based on birth weight (<1,200 g). Subsequently, stratified variable block randomization (block size varying from 4–6) was done separately for each stratum into two groups, one being interventional (USG group) and the other being the control group (blind group). The randomization sequence was generated independently by a third person not involved in the study using web-based randomization (sealed.envelop.com) [17]. The randomization sequence in each stratum was kept in a serially numbered sealed opaque envelope in two different colours (white form for <1,200 g and orange for >1,200 g strata).

Intervention Group

In the intervention group, USG was used to direct UVC insertion, as well as locate the tip position. During insertion, pressure was given on the liver (upper abdomen) by the transducer to align the umbilical vein with the ductus venosus. The length of insertion was predetermined as per the nomogram based on shoulder umbilical length [18]. We used an umbilical catheter of size 3.5 French for infants weighing less than 1,500 g and size 4–5 French for infants weighing more than 1,500 g. UVC was inserted by residents working in the NICU, and USG was done by the principal investigator. Ultrasound was done with the in-house Fujifilm Sonosite (M Turbo) ultrasound machine (Washington, USA) available in our department. Scans were performed by placing the probe in a sagittal and transverse plane on the right abdominal wall on the mid-abdomen. The cardiac probe of frequency 4–8 MHz was used for this purpose. Wherever necessary, 0.5-mL normal saline injection was administered for better visualization of the tip. Passage of the umbilical catheter beyond the ductus venosus in the inferior vena cava or inferior vena cava-right atrial junction was taken as the correct position. On X-ray, desired location corresponds to the tip being 0.5–1 cm above the diaphragm [19]. If the position was incorrect as per both USG and X-ray, then alternate vascular access (PICC line) was placed (online suppl. Fig. S1; for all online suppl. material, see <https://doi.org/10.1159/000535096>). Online supplementary Figures S2–S5 show the correct and incorrect position of UVC on CXR and USG.

Control Group

In the control group, UVC was inserted by the conventional method by a predetermined formula. An X-ray was done to confirm the tip position. The findings of the X-ray were confirmed by another neonatologist (blind to the allocation group) and were compared with ultrasound findings. If the position of the UVC tip was incorrect on X-ray, then UVC was removed and insertion was tried again in the blind group under aseptic precautions with ultrasound guidance. Ultrasound was used to trace the UVC as it passed through the umbilical vein, left portal vein, ductus venosus, and inferior vena cava. With the help of USG, manipulation was done so that the final position of UVC reached the IVC or cavoatrial junction. Therefore, the success rate with ultrasound guidance was evaluated.

No cross-over occurred in the USG group, whereas in the control group with failed attempts, USG-guided insertion was tried, but primary outcome was considered prior to cross-over. All demographic details and other in-hospital outcomes (sepsis, complications, and mortality) were collected in both groups.

Outcomes

The primary outcome was the difference in the failure rate of USG-guided UVC insertion with the conventional method. Failure was defined as malposition, inability to negotiate the catheter to the correct position, or inability to locate the catheter by USG. Secondary outcomes included sensitivity and specificity of USG with X-ray in determining the tip position of UVC, the mean duration of the procedure of catheter insertion in both groups, the correlation between shoulder umbilical length and USG-determined length, and difference in complications related to UVC insertion between groups.

Quality Control

The person doing the ultrasound was trained in the radiology department for 15 days. Ten cases of umbilical insertion and its tip position were supervised by a radiologist. Out of 10 cases, findings in 8 cases were in complete agreement between the investigator and the radiologist. USG was done by the principal investigator prior to CXR to reduce bias, and CXR finding was interpreted by the managing clinician.

Statistical Analysis

Considering the failure rate of UVC insertion by a conventional method to be 50% [1, 4] and assuming a decrease in the failure rate with the help of ultrasound to be 25%, with the power at 80% and the α -error taken as 0.05, the sample size was calculated to be 112. We had aimed to enrol the entire sample in two strata of <1,200 g (36 babies) and >1,200 g (76 babies). It was decided based on UVC requirements among babies admitted to our NICU in the previous year.

Data collection was done on a structured proforma and entered in Microsoft Excel 2016, Version 15.26 (Redmond, WA, USA)TM. Statistical analysis was done using STATA/IC Version 14.2 (StataCorp, TX, USA). Categorical data were analysed by the χ^2 test. An independent *t* test was used for analysing continuous data with normal distribution and the Mann-Whitney U test for skewed distribution. The correlation between USG-based length estimation, chest X-ray-based length, and shoulder umbilical length was compared using Pearson's correlation coefficient. A *p* value <0.05 was taken as statistically significant.

Results

A total of 650 NICU admissions occurred between September 2020 and November 2022 (shown in Fig. 1). Hundred and twelve neonates were recruited for the study and 40 babies were excluded. Fifty-four babies were randomized to the blind group and 58 babies were randomized to the USG group. The mean (\pm SD) gestation age was 33.7 (\pm 4.5) and 33.5 (\pm 4.3) weeks in SG and blind groups, respectively. Median (IQR) birth weights were 1,672 (1,060–2,365) and 1,445 g (1,020–2,245) in USG and blind groups, respectively. The age of neonate (median [IQR]) at the insertion of the umbilical line was 5 (2–14) hours in the USG group and 2 (2–12) hours in the blind group. The remaining baseline characteristics were comparable in both groups (Table 1).

Primary Outcome

There was no difference in failure rates between the USG group and the blind group (RR: 0.69, 95% CI: 0.36–1.33, *p* value 0.27) (online suppl. Table S1). Failure rates were lower in the USG group versus the blind group (20% vs. 29%), but the difference was not statistically significant.

Secondary Outcomes

Out of 112 cases, USG findings were in complete agreement with CXR findings in 84 cases (75.8%). The sensitivity and specificity of USG were 96.9% and 46.8%, respectively (Table 2). Area under the ROC curve using USG as a diagnostic modality is 0.71 (online suppl. Fig. S6).

UVC was successfully inserted in 80% of cases in babies weighing less than 1,200 g and 72% of cases in babies weighing >1,200 g. There was no difference in failure rates between the 2 groups on subgroup analysis (RR: 0.72, 95% CI: 0.35–1.46, *p* value 0.35, Table 3).

USG-guided reinsertion was tried in failed cases, and it was successful in 6 cases in the blind group. In 10 cases among the USG group, USG could reposition the catheters and correct position could be attained before confirming with chest X-ray. The procedure duration of catheter insertion was similar in both groups, with a mean duration of 8.9 min in the USG-guided group and 8.3 min in the blind group (*p* value 0.56).

The median duration of time taken for USG to detect the tip position was 8 minutes (IQR 5.5–12 min) and for CXR was 37 minutes (IQR 33–44 min). The maximum time taken for USG and CXR was 20 and 125 min, respectively.

The correlation between shoulder umbilical length (Dunn's formula) and USG-guided length was good (correlation coefficient 0.81). Dunn's formula and Shukla's formula were compared with USG length. Correlation with Dunn's formula was better than Shukla's formula (correlation coefficient 0.81 and 0.64, respectively).

A Bland-Altman plot was made with USG length and CXR length to look for agreement between these 2 measurements (shown in Fig. 2). The majority of the values lie within the 2SD of the mean difference. The mean difference was 0.15 cm, stating that USG length exceeded CXR length by 0.15 cm.

The only complication noted was central line-associated bloodstream infection. Central line-associated bloodstream infection occurred in 9 out of 98 cases. There was no difference between USG and blind groups (RR: 0.46, 95% CI: 0.12–1.76, *p* value 0.248).

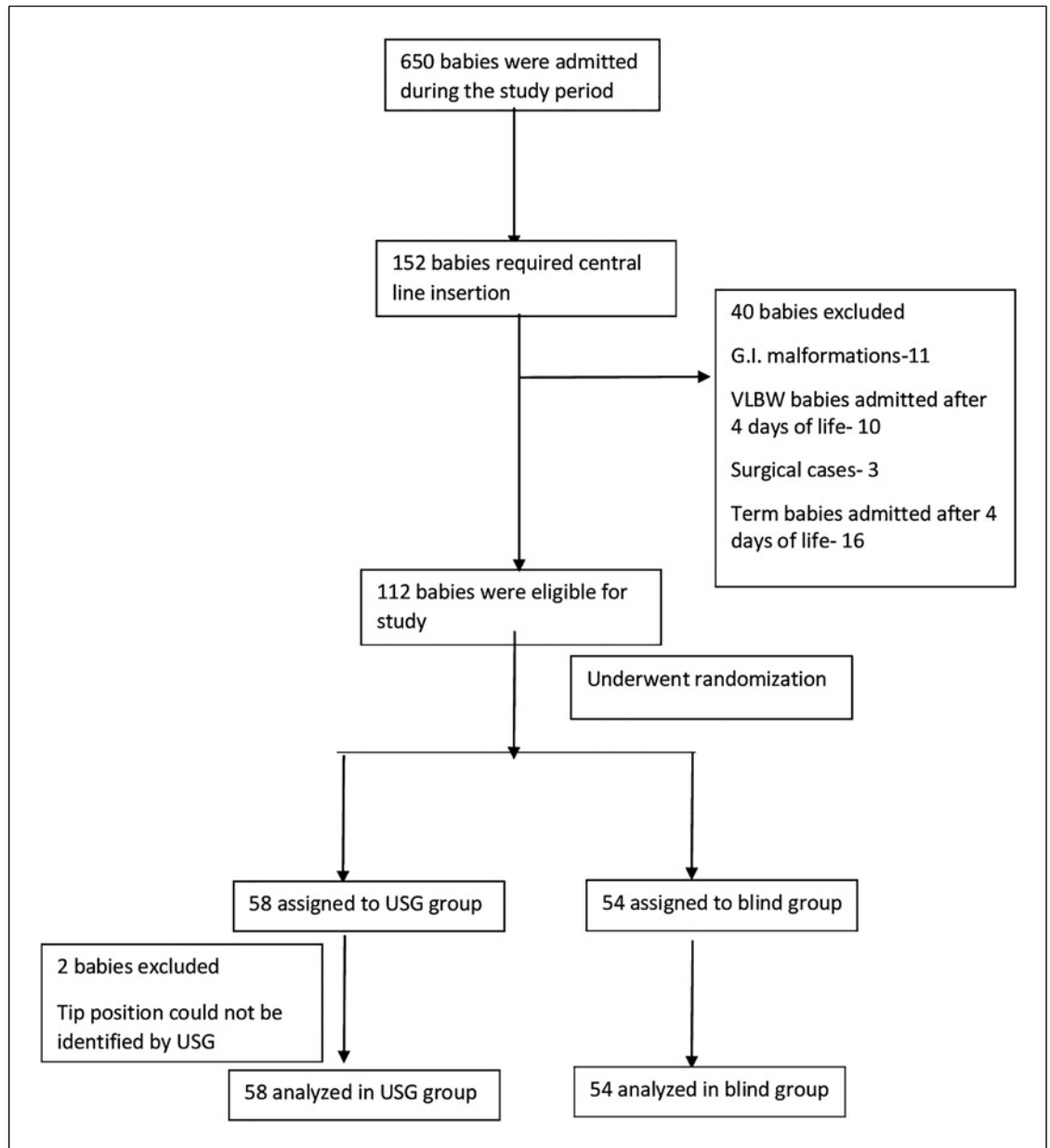


Fig. 1. CONSORT flow diagram. A total of 650 NICU admissions occurred in the study period. Hundred and twelve neonates were recruited for the study and 40 babies were excluded. Fifty-four babies were randomized to the blind group and 58 babies were randomized to the USG group.

Discussion

In this study, we compared the difference in failure rate in UVC insertion between USG-guided technique and conventional technique and found that there was no statistical difference between both groups. Similar findings were observed in subgroup analysis, and failure rates did not change with variation in birth weight. The lack of

statistical difference in failure rate by USG may be due to the low failure rate (25%) in our study as compared to the predicted failure rate (50%).

In our study, the failure rate decreased from 29% to 20% with the use of ultrasound. No previous studies have compared the difference in failure rates across different gestational ages. An increase in successful insertion can be attributed to direct visualization of the anatomy and

Table 1. Baseline characteristics in both groups

Baseline characteristics	USG group (n = 58)	Blind group (n = 54)	p value
Gestational age, weeks*	33.7 (±4.5)	33.5 (±4.3)	0.78
Birth weight, grams ^a	1,672 (1,060–2,365)	1,445 (1,020–2,245)	0.57
Males, n (%)	28 (48)	32 (59)	0.24
Age at UVC insertion, hours ^a	5 (2–14)	2 (2–12)	0.22
Mode of delivery, n (%)			
Caesarean	41 (70)	42 (77)	0.39
Inborn, n (%)	45 (77.5)	47 (87)	0.59
Small for gestational age (SGA), n (%)	31 (53)	21 (39)	0.12
Indication of insertion, n (%)			0.79
Respiratory failure	12 (20.6)	10 (0.2)	
Nutrition	20 (34.5)	19 (0.3)	
Hypoglycaemia	7 (0.1)	7 (0.1)	
Surgical	3 (0.1)	1 (0.0)	
Perinatal asphyxia	8 (0.1)	11 (0.2)	
Polycythaemia	5 (0.1)	2 (0.0)	
Septic shock	3 (0.1)	3 (0.1)	
Cardiogenic shock	0 (0)	1 (0.0)	
Respiratory support at admission, n (%)			0.69
Room air	14 (24)	10 (18)	
CPAP/HFNC	30 (52)	32 (60)	
Intubated	14 (24)	12 (22)	

n, number; %, percentage; CPAP, continuous positive airway pressure; HFNC, high-flow nasal cannula.
^aMedian (IQR). *Mean (±SD).

Table 2. Sensitivity and specificity of USG compared with CXR

	Percentages (95% CI)
Sensitivity	96.9 (89.3–99.63)
Specificity	46.8 (32.11–61.92)
Positive predictive value	71.6 (65.76–76.78)
Negative predictive value	91.7 (73.10–97.80)
Positive likelihood ratio	1.8 (1.39–2.39)
Negative likelihood ratio	0.1 (0.02–0.27)
Accuracy	75.9 (66.90–83.47)

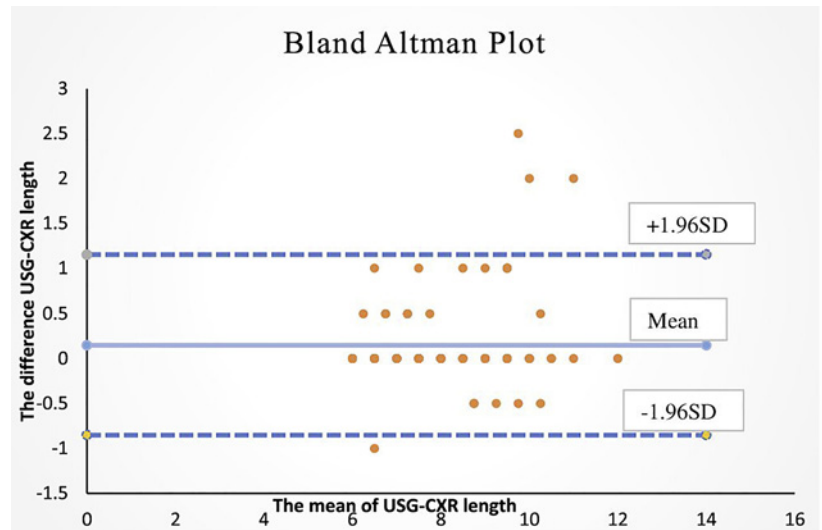
Table 3. Success and failure rates in stratified groups

	Failure	Success	Total
<1,200 g, n (%)	7 (19.4)	29 (80.5)	36
>1,200 g, n (%)	21 (27.6)	55 (72.3)	76
Total	28	84	112

alignment of the umbilical vein with the ductus venosus due to pressure by the USG transducer. Kishigami et al. [8] suggested that compression of the abdomen near the portal sinus improved the insertion rate to 93% by aligning the umbilical vein with the ductus venosus. The absence of benefit in a few cases by USG-guided insertion can be attributed to the formation of a false tract or of a less resistant pathway for the catheter into the portal vein or liver parenchyma owing to closing of the ductus venosus.

In the current study, USG-guided reinsertion was tried in cases with incorrect positions of catheters in the control group. In 30% of cases among the blind group, USG could be used to guide the catheter and negotiate it into the correct position. Thus, CXR can be avoided and frequent manipulations can be prevented by USG. On comparing ultrasound and no ultrasound groups, Rossi et al. [20] found a significant reduction of X-ray requirement by 19% in the USG group.

Fig. 2. Bland-Altman Plot showing agreement between USG-CXR length. The majority of the values lie within the 2SD of the mean difference. Mean difference was 0.15 cm, stating that USG length exceeded CXR length by 0.15 cm. Dotted line indicates the upper and lower limits of agreement and middle line indicates the mean difference (mean difference = 0.15 cm, upper LOA = 1.15 cm, lower LOA = -0.85 cm).



In our study, the sensitivity and specificity of USG in detecting the correct position of the catheter tip were 96.9 and 46.8%, respectively. The sensitivity and specificity of USG reported in the previous studies were 93–95% [10, 21]. However, both studies have used USG/echocardiogram as the gold standard to detect malpositions. Although specificity was low, USG could identify almost all catheter malpositions in the liver or the portal vein. Malpositions that could not be identified by USG were mostly inside the right atrium or in the inferior vena cava, just near the right atrial junction as per CXR. The target zone (desired position: IVC beyond ductus venosus) mentioned in previous studies ranges from 4 to 11 mm in length [22]. In most cases, our study showed a discrepancy between USG and CXR lengths from 5 to 10 mm. As IVC enters the right atrium in the sagittal plane, an AP radiograph with the diaphragm as a landmark might not detect the true cavoatrial junction. In our study, the appropriate position was taken as the tip position above the diaphragm. Thus, the low specificity of USG can be attributed to the poor localization of UVCs on AP CXR.

One of the demerits of X-ray is the time taken to perform it. In our study, the median time taken for ultrasound and X-ray was 8 and 37 min, respectively. Also, the maximum time taken for an X-ray in our study was 120 min. Time and logistic issues related to X-rays can delay the confirmation of tip position and prolong the administration of fluids. Thus, USG is a faster and noninvasive modality as compared to X-ray. A previous study has shown that the mean time to

obtain an X-ray was 40 min and USG reduced the time of line placement by 64 min [22]. Although portable X-rays provide immediate visualization, low sensitivity and radiation exposure limit its use and make USG a better modality.

Various formulae have been used to determine the length of UVC insertion [1, 3]. Zaghoul et al. [15] found the agreement coefficient between X-ray and USG for central line tip identification to be 0.87. In our study, good agreement was present between USG and CXR length, thereby emphasizing the fact that USG improves tip localization and decreases malposition rates.

Our study was one of the few randomized studies comparing the USG method of UVC insertion with the blinded method using a robust methodology. Our study had a few limitations. Studies have shown that lateral radiographs are better than AP radiographs in determining the tip position [23]. We could have done both AP and lateral X-rays to improve sensitivity to detect the tip position. Lack of blinding at the outcome assessment level was another limitation in our study. USG being an operator-dependent procedure requires training. It could have been possible that the detection rate of malposition improved gradually with more enrolment of cases. Future studies can be planned with lateral radiographs and the use of different views of echocardiogram (apical, 4 chambers, and subcostal) to improve the accuracy of USG.

Overall, our study revealed no benefit of USG on reduction in failure rate of UVC insertion. Being a safe, fast, and noninvasive alternative to chest X-rays, it can be used as a rescue modality to guide UVC insertion in cases with failed procedure.

Summary

What Is Already Known on the Topic?

- X-ray is the gold standard to determine the central venous catheter tip position in neonates.
- USG has good sensitivity and specificity to localize the UVC tip position.
- There is a high failure rate of UVC insertion and a majority required manipulation when inserted by the conventional method.

What This Study Adds?

- USG has good sensitivity to localize UVC tip position and can be used to guide catheter in cases with failed insertion.
- There is good agreement between CXR and USG catheter lengths.

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Statement of Ethics

The Institute Ethics Committee, All India Institute of Medical Sciences, Bhubaneswar, studied and approved the protocol (IEC/2020-21/25) prior to recruitment and the trial was registered with

the Clinical Trial Registry of India (CTRI/2020/09/027935). Written informed consent was taken from the parents to participate in the study.

Conflict of Interest Statement

The authors have no relevant financial or nonfinancial interests to disclose.

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Author Contributions

P.M. recruited participants, collected and analysed data, and formulated the manuscript; P.K.M. and T.K.S. participated in the design of the study and edited and revised the manuscript; T.S. and U.D. provided interpretation of the data and revised the manuscript; and N.D.B. edited and revised the manuscript.

Data Availability Statement

All data generated or analysed during this study are included in this article and its online supplementary material files. Further enquiries can be directed to the corresponding author.

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