

Original Research Article

RCT to analyse efficacy of double port extension tubing connection to peripheral IV cannula in prevention of neonatal late onset sepsis

Vinit Malik*, Archana Agrawal, Abhishek Singh, Navratan Gupta, Alpa Rath

Department of Pediatrics, Lala Lajpat Rai Memorial Medical College, Meerut, Uttar Pradesh, India

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*Correspondence:

Dr. Vinit Malik,

E-mail: malikvinit88@gmail.com

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ABSTRACT

Background: Late-onset sepsis (LOS), defined as sepsis occurring after 72 hours of age, causes substantial mortality and morbidity in neonates admitted in NICU. These neonates depend significantly on vascular access to administer fluids, nutrition, blood products and medication. This typically relies on the use of Peripheral Intravenous Cannula (PIVC) however, problems associated with IV infusion therapy include contamination of fluid with bacteria, endotoxins and particulates. Despite strict adherence to hygienic protocols, the incidence of nosocomial sepsis remains high. Incorporating an intravenous cannula with double port extension may be an effective strategy to reduce LOS. So, we did an open-label randomized controlled trial (RCT) to determine if the addition of a double port extension to an intravenous cannula can help in the prevention of LOS.

Methods: Open label randomized controlled trial was conducted in 300 newborns admitted in the Department of pediatrics, LLRM Medical college, Meerut from April 2023 to March 2024. Admitted neonates underwent a sepsis screen. Those with a negative sepsis screen were enrolled and then randomly assigned to the groups. Group A: Babies with an intravenous cannula with a double port extension; Group B: Babies with an intravenous cannula without double port extension

Results: 150 babies from each group were analysed. 13.34% and 43.34% were blood culture positive in each group respectively (p -value<0.001). 10% and 30% were sepsis screen positive in respective groups. 142 (94.67%) discharged, 1 (0.66%) expired and 133 (88.67%) discharged, 10 (6.66%) expired out of 150 babies in each group respectively.

Conclusions: The addition of a double port extension in the IV cannula shows a reduction in LOS when compared to the control.

Keywords: Double port extension, Intravenous cannula, Late onset sepsis, NICU, Randomized control trial

INTRODUCTION

Neonates admitted to neonatal intensive care units (NICUs) depend significantly on vascular access to administer fluids, nutrition, blood products and medication. Intravenous therapy (IVT) involves delivering therapeutic solutions directly into a vein, serving as the quickest and most dependable method for administering fluids, electrolytes, chemotherapy, medications, blood transfusions and certain nutritional

provisions like total parenteral nutrition (TPN).^{1,2} It's important to note that PIVC therapy carries inherent risks, including complications like clotting, occlusion, leakage, infiltration, extravasation, phlebitis and infection.³

Peripheral venous catheters are a critical risk factor for nosocomial sepsis among newborns. Various factors contribute to an increased risk of catheter-related infections, such as the type of intravenous (IV) fluids

used (e.g., D10, N/2 D10, Isolyte-P) and the type of medications administered (e.g., various antibiotics, inotropes). Additionally, reports indicate that the contamination of IV administration sets with gram-negative bacteria can lead to the rapid proliferation of endotoxins, exacerbating the risk of infection.⁴

A strategy for the prevention of intravascular catheter-related infections may effectively reduce complications associated with peripheral line usage.⁵ Sepsis is a critical medical condition triggered by widespread infections in the body, leading to a series of potentially deadly inflammatory immune reactions. Neonatal sepsis specifically refers to sepsis occurring within the first 28 days after birth.

Neonatologists differentiate between early-onset sepsis (EOS) and late-onset sepsis (LOS) based on when the infection begins. EOS typically occurs within 48-72 hours after birth, while LOS includes infections that manifest 72 hours after birth and during the neonatal intensive care unit (NICU) stay.⁶ Late-onset sepsis (LOS) is primarily associated with acquiring pathogens horizontally or nosocomially, often through exposure in hospital or community settings. This exposure can result from contamination or colonization of invasive medical devices, contact with healthcare providers or other environmental sources.

Therefore, in light of the limited data available in the pediatric population and the absence of Indian studies investigating the therapeutic efficacy of intravenous cannulas with extensions in neonates, we have designed an open label randomized controlled trial (RCT) to assess the influence of intravenous cannulas with extensions on neonatal mortality and morbidity. The extension sets may offer cost-effectiveness, easy accessibility, a shorter training curve, simplified monitoring, enhanced drug delivery, reduced risk of dislodgement and potentially lowers rates of cannulation, thereby potentially contributing to the prevention of neonatal late-onset sepsis.

METHODS

Ethical clearance from our institutional ethical committee was taken and an informed consent was taken from the guardian of each newborn prior to the enrollment in our study.

Participants

All neonates admitted in NICU of LLRM Medical college who needs IV access from April 2023 to March 2024.

Study design

Open label randomized controlled trial.

Study sample

To achieve a reduction in the infection rate from 25% to 12% using a double port extension, with a power of 95% and a significance level of 5%, at least 300 infants needed to be enrolled (150 in each group). The prevalence of culture-positive late-onset sepsis (LOS) in the LLRM Medical College NICU from April to August 2022 was 25% taken from our hospital records.

Sample size= $4pq/d^2=4 \times 25 \times 75/25=300$, P=Prevalance
Q=(1-p d2=max allowable error (20% of p)

Inclusion criteria

Babies meeting any criteria were included like intramural babies (32-40 weeks) admitted to the NICU and delivered by mothers without antenatal risk for early onset sepsis. Extramural babies less than 24 hours old without a history of previous hospitalization and antibiotic therapy and without antenatal risk factor for EOS.

Exclusion criteria

Babies with any of the following criteria were excluded. Babies born with major congenital anomalies. Very preterm babies or extremely low birth weight babies. Babies delivered by mothers with antenatal risk factors for sepsis, including febrile illness in the mother with evidence of bacterial infection within 2 weeks prior to delivery. Foul-smelling liquor. Rupture of membrane >24 hours.

Single, unclean or >3 sterile vaginal examinations during labour. Prolonged labour (sum of 1st and 2nd stages >24 hours). Positive sepsis screen or first blood culture positive on admission. Extramural babies more than 24 hours old or with a history of previous hospitalization and antibiotic therapy.

Intervention

Babies meeting the inclusion criteria and requiring IV cannula placement for management underwent a sepsis screen. These babies were then randomly assigned to one of two groups. Those with a negative sepsis screen were enrolled in the study and later analysed after obtaining informed consent from their parents in their local language.

Group A

Babies with an intravenous cannula with a double port extension.

Group B

Babies with an intravenous cannula without double port extension.

All healthcare personnel involved in the insertion and fixation of cannulas in the NICU were provided with instructions on the proper techniques for the insertion and fixation of double port extension to the peripheral IV cannula. A blood culture and sepsis screen were sent at admission and at 96 hours. Only those patients were included in the study whose blood culture and sepsis screen at the time of admission were negative. Blood culture and other laboratory investigations were sent at 96 hours. Babies were clinically assessed every 12 hours for signs of sepsis, including heart rate, respiratory rate, temperature, pulse, capillary refill time (CRT) and systemic examinations.

Data collected included the total duration of antibiotic therapy, number of catheter days, number of IV catheters required, total duration of hospital stay and patient outcomes in terms of morbidity or mortality. If any extra PIVC was introduced, that can be counted in the number of catheterization and number of catheter days. After written informed consent from the patient's parents, detailed history, demographic data was recorded and clinical examination findings and laboratory findings were noted on pre-designed proforma.

Statistical analysis

Data was entered in MS Excel. Analysis was conducted in R software version 4.3.2. Graphs and charts are created in MS Excel. Statistical report prepared in MS word. Categorical Variables were expressed in frequencies and percentages. Further Association between categorical variables was checked using Chi-square test and Unpaired t test. All the assumptions for chi-square test were checked before analysis. A p value of <0.05 is considered statistically significant.

RESULTS

Demographic data

Out of 300 participants enrolled in specified time interval. 150 in each group. Out of 300, Majority of patients were admitted for respiratory distress n=122, low birth weight (LBW) n=138, intramural n=276, female patients n=171, Term babies n=150 and delivered via lscs n=183 (Table 1).

In Group A, 13.34% were blood culture positive and 86.66% were blood culture negative (p value<0.05). In Group B, 43.34% were blood culture positive and 56.66% were blood culture negative (Table 2).

In Group A, 94.67% were discharged, 0.66% were expired and 4.67% were left against medical advice. In Group B, 88.67% were discharged, 6.66% were expired and 4.66% were left against medical advice (Table 3). C-reactive protein values were positive in 12.66% of Group A and 40% of Group B (p value<0.05). In Group A, 10% were positive for the sepsis screen and 90% were negative for the sepsis screen. In Group B, 38% were positive for the sepsis screen and 72% were negative for the sepsis screen (Table 4).

In Group A, 38.66% had a platelet count less than 1.5 lakh cells/mm³ and in Group B, 53.34% had a platelet count less than 1.5 lakh cells/mm³. In Group A, 88% had less than or equal to 5 catheterizations and 12% had more than 5 catheterizations. In Group B, 14% had less than or equal to 5 catheterisations and 86% had more than 5 catheterisations. In Group A, 68.66% had less than or equal to 10 catheter days and 31.34% had more than 10 catheter days.

In Group B, 37.34% had less than or equal to 10 catheter days and 62.66% had more than 10 catheter days. In Group A, 70.66% had less than or equal to 10 days of antibiotic therapy and 29.34% had more than 10 days of antibiotic therapy. In Group B, 37.34% had less than or equal to 10 days of antibiotic therapy and 62.66% had more than 10 days of antibiotic therapy. In Group A, 68% had less than or equal to 10 days of hospital stay and 32% had more than 10 days of hospital stay. In Group B, 38% had less than or equal to 10 days of hospital stay and 62% had more than 10 days of hospital stay (Table 5).

The cannula related localized complication were less in Group A compared to Group B. In Group A Infiltration/Extravasation were in 40.90%, Localized Phlebitis in 22.72%, Blockage in 15.15% and Dislodgement in 21.21% compared to Group B infiltration/extravasation were in 53.84%, localized phlebitis in 25.27%, blockage in 8.79% and dislodgement in 12.08% (Table 6).

Table 1: Distribution of neonates as per indication of admission, gender, gestation, birth weight, type of admission and mode of delivery.

Variable	Sub variable	Group A (n=150)	Group B (n=150)	Total (n=300)
Indication for admission	Prematurity	42 (28%)	28 (18.67%)	70
	Respiratory distress	46 (30.67%)	76 (50.67%)	122
	Perinatal asphyxia	39 (26%)	29 (19.33%)	68
	Neonatal jaundice	18 (12%)	14 (9.33%)	32
	Difficulty in feeding	5 (3.33%)	3 (2%)	8
Gender	Male	59 (39.34%)	70 (46.66%)	129
	Female	91 (60.66%)	80 (53.34%)	171
Gestation	≤34 weeks	42 (28.00%)	28 (18.66%)	70

Continued.

Variable	Sub variable	Group A (n=150)	Group B (n=150)	Total (n=300)
	35-36 weeks	36 (24.00%)	44 (29.34%)	80
	≥37 weeks	72 (48.00%)	78 (52.00%)	150
Birth weight	≤1500 g	36 (24.00%)	32 (21.33%)	68
	1501-2499 g	78 (52.00%)	60 (40.00%)	138
	≥2500 g	36 (24.00%)	58 (38.67%)	94
Type of admission	Intramural	136 (90.66%)	140 (93.34%)	276
	Extramural	14 (9.34%)	10 (6.66%)	24
Mode of delivery	LSCS	92 (61.34%)	91 (60.66%)	183
	NVD	58 (38.66%)	59 (39.34%)	117

Table 2: Association of blood culture and intervention used for prevention of neonatal LOS.

Blood culture	Group A (n=150)	Group B (n=150)	P value
Positive	20 (13.34%)	65 (43.34%)	<0.001
Negative	130 (86.66%)	85 (56.66%)	

Table 3: Association of outcome and intervention used for prevention of neonatal LOS.

Outcome	Group A (n=150)	Group B (n=150)	P value
Discharged	142 (94.67%)	133 (88.67%)	0.021
Expired	1 (0.66%)	10 (6.66%)	
Lama	7 (4.67%)	7 (4.67%)	

Table 4: Association of sepsis screen and intervention used for prevention of neonatal LOS.

Sepsis screen	Group A (n=150)	Group B (n=150)	P value
Positive	15 (10.00%)	57 (38.00%)	<0.001
Negative	135 (90.00%)	93 (62.00%)	

Table 5: Comparison of Outcome, Blood Culture, CRP, TLC, I/T ratio, Sepsis screen, Platelet count, number of catheterization, number of catheter days, duration of antibiotic therapy and duration of hospital stay and intervention used for prevention of Neonatal LOS.

Variable	Sub variable	Group A (n=150)	Group B (n=150)	P value
Outcome	Discharged	142 (94.67%)	133 (88.67%)	0.021
	Expired	1 (0.66%)	10 (6.66%)	
	Lama	7 (4.67%)	7 (4.67%)	
Blood culture	Positive	20 (13.34%)	65 (43.34%)	<0.001
	Negative	130 (86.66%)	85 (56.66%)	
CRP	Positive	19 (12.66%)	60 (40.00%)	<0.001
	Negative	131 (87.34%)	90 (60.00%)	
TLC	Positive	5 (3.34%)	13 (8.66%)	.051
	Negative	145 (96.66%)	137 (91.34%)	
I/T ratio	Positive	17 (11.34%)	60 (40.00%)	<0.001
	Negative	133 (88.66%)	90 (60.00%)	
Sepsis screen	Positive	15 (10.00%)	57 (38.00%)	<0.001
	Negative	135 (90.00%)	93 (62.00%)	
Platelet count (<1.5 lakh/ml)	Yes	58 (38.66%)	80 (53.34%)	.010
	No	92 (61.34%)	70 (46.66%)	
No. of catheterization	≤5	132 (88.00%)	21 (14.00%)	<0.001
	>5	18 (12.00%)	129 (86.00%)	
No. of catheter days	≤10	103 (68.66%)	56 (37.34%)	<0.001
	>10	47 (31.34%)	94 (62.66%)	
Duration of antibiotic therapy (days)	≤10	106 (70.66%)	56 (37.34%)	<0.001
	>10	44 (29.34%)	94 (62.66%)	
Duration of Hospital stay (days)	≤10	102 (68.00%)	57 (38.00%)	<0.001
	>10	48 (32.00%)	93 (62.00%)	

Table 6: Comparison of Cannula related localized complications between two groups.

Cannula related localized complication	Group A (n=150)	Group B (n=150)	Total (n=300)	P value
Infiltration/extravasation	27 (40.90%)	49 (53.84%)	75 (25%)	0.003
Localized phlebitis	15 (22.72%)	23 (25.27%)	38 (12.66%)	0.164
Blockage	10 (15.15%)	8 (8.79%)	18 (3%)	0.626
Dislodgement	14 (21.21%)	11 (12.08%)	25 (8.33%)	0.530
Total	66 (44%)	91 (60.66%)	157 (52.33%)	

DISCUSSION

The study demonstrated that neonates using double port extension tubing had a lower incidence of late-onset sepsis compared to those without the extension. Wax DB et al, tested the usability and efficacy of a novel passive shielding device to prevent contamination even in the absence of hand hygiene or port disinfection.⁷ The usability of the device was acceptable to practitioners.⁷ In our study we tried to determine/analyse various parameters related to neonatal LOS and outcomes and their association with intervention (addition of double port extension tubing to iv cannula) used for preventing neonatal late-onset sepsis (LOS).

In the current study population 43% were male and 57% of them were female which were nearly equal, in both groups. In a study conducted by Wuni et al, 276 neonates were enrolled.⁸ In this study, males comprised 55.1% (152 neonates) while females accounted for 44.9% (124 neonates) similarly in Al-Momani et al, More males (56.4%) than females (43.6%) male-dominant population, study by Ismail et al, shows care-seeking rates for female neonates are lower than males, Parents are more likely to pay more and seek care from providers perceived as higher quality, for males than females.^{9,10}

The majority of the neonates were intramural admissions (92%), with a small percentage being extramural (8%). This high percentage of intramural admissions could reflect the study's focus on neonates already within the hospital system, potentially indicating a population at higher risk for LOS. Similar, in previous study a high proportion of inborn/intramural admissions were present.⁹ In the study by Saranappa, et al, Inborns were 73.3% (2311) and 26.7% (841) were outborn.¹¹

In the study by Al-Momani et al, to analyze the elements and factors that link with newborn deaths at Neonatal Intensive Care Unit (NICU), 62.2% of neonates were term, 17.5% were near term and 20.3% were preterm.⁹ In, our study found that 50% of neonates were term, 26.67% were near term and 23.33% preterm. In a previous study, 75% were term and 25% were preterm.^{10,11} Similar findings were reported in a study conducted in Ethiopia in which 34.9% were preterm neonates and 63.6% were full-term neonates.¹² The birth weight distribution showed that nearly half (46%) of the neonates had a birth weight between 1500 to 2499 grams. The study

population had a higher proportion of low-birth-weight neonates compared to typical populations. In comparison, by Al-Momani et al, 74.2% of full-term neonates had a birth weight of 2500 grams or more, 20.9% had a birth weight between 1500 and 2499 grams.⁹ The percentage of ≤ 2500 g (25.8%) is comparable with studies from Ethiopia (35%) and Pakistan (37.7%).^{12,13}

The majority of deliveries were via LSCS (61%), indicating a higher incidence of cesarean sections in this study. In the study by Al-Momani et al, 62.8% of deliveries were by Caesarian-section and 37.2% were normal vaginal deliveries.⁹ This distribution is consistent with modern practices in obstetrics where LSCS is often performed for various medical reasons. It might also be due to better resources at tertiary level referral centers to deal with various complications. So, more LSCS deliveries were performed at tertiary level referral centers.

The study reported a high discharge rate (87.66%) with a relatively low mortality rate (3.66%). In the study by Al-Momani et al, 91.9% of patients were discharged and 8.1% expired.⁹ In a study by Ogundare et al, neonatal deaths occurred in 32% of babies with EOS while all babies with culture positive LOS survived.¹⁴ The significant association between the intervention and the outcome suggests that the type of IV cannula used may impact the likelihood of discharge, potentially influencing the neonatal LOS rate.

In the current study, out of 300 blood cultures analyzed, 85 (28.34%) were positive, whereas 215 (71.66%) were negative. Similarly, in a study conducted by Ali et al, a cohort of 71 infants diagnosed with sepsis was assessed.¹⁵ Among these cases, 32 infants (45%) were confirmed to have sepsis, based on both positive blood culture results. In the study done by Gowda Harsha et al, out of 6340, 146 (6.4%) positive blood cultures were thought to represent true bacteremia.¹⁶

In the current study, among the 300 patients analyzed for C-reactive protein (CRP), 79 (26.33%) tested positive, while 221 (73.67%) tested negative. In contrast, the study conducted by Ali et al, reported positive CRP results in 40 (55.3%) patients with confirmed sepsis and 31 (44.7%) patients with probable sepsis.¹⁴ This difference in CRP positivity between the confirmed and probable sepsis groups was statistically significant ($p=0.020$).

Harsha et al, elevated C-reactive protein was consistently associated with late-onset Gram-negative sepsis ($p < 0.05$).¹⁶ The study observed a significant association between positive blood culture, c-reactive protein and the intervention used. Group A, which used IV cannulas with double port extension, showed lower rates of positive blood culture (13.34%) and c-reactive protein (12.66%) compared to Group B. This suggests that the intervention in Group A may be more effective in preventing infections or inflammation.

The total leukocyte count (TLC), immature to total neutrophil (I/T) ratio, sepsis screen and platelet count results showed significant differences between the two groups. Harsha et al.¹⁶ Thrombocytopenia, was consistently associated with late-onset Gram-negative sepsis ($p < 0.05$). Of 200 patients with culture-proven nosocomial sepsis, 119 (59.5%) patients developed thrombocytopenia (platelet count $< 150 \times 10^9/l$) in study by Charoo et al.¹⁷ In our study thrombocytopenia found in 46% of population. Group A had notably better results in these markers, indicating that the intervention could be reducing the risk of sepsis or inflammatory responses.

Group A had significantly fewer catheterization indicating the average life span for intravenous cannula was significantly prolonged. In previous studies, Smith AB et al, reports different average lifespans for pive in neonates (10 to 50 hours) and children (15 to 276 hours).¹⁸ Birhane et al showed in critically ill neonates can maintain PIVC for upto 144 hours with adequate monitoring.¹⁹ Group A had significantly shorter durations of catheter days, with a mean hours of cannula 241.28 hours with SD of 74.08 hours compared to Group B mean hours of cannula 291.68 hours with SD of 86.58 hours and a lower total duration of antibiotic therapy compared to Group B. These results underscore the potential benefits of using a double port extension IV cannula in reducing the frequency and duration of catheter use, which could contribute to fewer infections and shorter hospital stays.

The length of hospital stay was significantly shorter in Group A, which is consistent with the other findings indicating that the intervention with double port extension may contribute to improved overall outcomes, including reduced LOS.

The cannula related localized complication were less in group A compared to Group B. In the study by Marsh et al. the infiltration incidence was 23%, phlebitis 12% and dislodgement 7% of catheters.²⁰ In our study incidence of Infiltration was 25%, phlebitis 12.66%, blockage 3% and dislodgement 8.33% of catheters. The findings from this study provide a background to conduct further clinical trials and to consider for the integration of double port extension tubing in neonatal care protocols to prevent late-onset sepsis in practice. By reducing infection rates, decreasing hospital stay durations and lowering antibiotic usage, the double port extension tubing offers a

multifaceted approach to improving neonatal outcomes. Healthcare providers may consider adopting this intervention as part of their standard practice, particularly for neonates with lower birth weights who are at increased risk for sepsis. Furthermore, ongoing education and training for NICU staff on the implementation and maintenance of such devices are crucial to ensure their effectiveness and sustainability. There has been no previous research conducted specifically on the efficacy of double port extension tubing connections to peripheral IV cannulas in the prevention of neonatal late-onset sepsis, highlighting the need for future studies on this topic.

Strength of our study was including its large sample size of 300 participants, which boosts statistical power and reliability. It utilizes both descriptive and inferential statistics for a thorough analysis of outcomes and interventions. The comparison between two intervention groups provides insights into effective strategies for preventing neonatal late-onset sepsis (LOS). By employing various diagnostic markers like blood culture and C-reactive protein, the study offers a comprehensive view of clinical status.

The study's limitations include several factors that may affect the interpretation of results. Despite a sample size of 300, the division into two groups of 150 participants each may not fully capture the variability within the broader population. The potential for bias exists in group allocation, as the intervention-based division could introduce confounding factors. The cross-sectional design restricts the ability to infer causality and the findings may not be generalizable beyond the study's single-center setting.

While statistical significance was achieved for several outcomes, the clinical relevance of these findings remains unclear. Additionally, the study lacks long-term follow-up, limiting insights into the lasting effects of interventions. There was also a lack of previous studies for comparison, which constrained the ability to contextualize the current data against established findings. Finally, the absence of control for all potential confounding factors, such as underlying health conditions, may influence the observed outcomes.

CONCLUSION

This study comprehensively evaluated the impact of using IV cannulas with double port extension (Group A) versus standard IV cannulas (Group B) on neonatal outcomes. The results demonstrate that the use of IV cannulas with double port extension is associated with notably improved outcomes for neonates. The findings indicate that Group A had significantly better metrics in several critical areas, including infection rates, inflammatory markers and overall hospital-related outcomes. Specifically, Group A showed a lower incidence of positive blood cultures, reduced levels of c-reactive protein and better total leukocyte count and

immature to total neutrophil ratios. These differences suggest that the double port extension cannulas are more effective in preventing infections and managing inflammatory responses, thereby mitigating some of the risks associated with neonatal late-onset sepsis (LOS). The observed reduction in the number of catheterizations, total catheter days and duration of antibiotic therapy further supports the conclusion that this intervention is beneficial in minimizing the frequency and impact of invasive procedures, which are often associated with increased infection risk.

In conclusion, the use of IV cannulas with double port extension represents a promising advancement in neonatal care. By significantly reducing infection rates, minimizing the need for invasive procedures and shortening hospital stays, this intervention has the potential to substantially improve neonatal outcomes. Continued research and implementation of evidence-based practices will be essential in enhancing the quality of care for neonates and achieving optimal health outcomes.

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