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ORIGINAL ARTICLE

Near Infrared Light Source Versus Naked Eye Visualization for Establishing Intravenous Access in Neonates: A Randomized Control Trial

Bichitrananda Raut,[1] Satish Saluja,[2] Arun Soni,[2] Manoj Modi[2]

1. Department of Neonatology, IMS and SUM Hospital, SOA Deemed to be University, Bhubaneswa Odisha, India.
2. Department of Neonatology, Sir Ganga Ram Hospital Marg, Old Rajinder Nagar, New Rajinder Nagar, New Delhi, India.

Correspondence to: Dr. Bichitrananda Raut, Email: drbichitraraut@gmail.com, ORCiD: 0000-0002-5963-8004

ABSTRACT

Objective: To compare efficacy of near infrared light (NIR) versus naked eye (NE) visualization for intravenous access in the neonates.

Methods: This was a randomized controlled trial carried out in a tertiary care center in New Delhi, India from 2015 to 2017. A total of 480 admitted neonates, who required placement of intravenous catheter were randomized to receive intravenous access attempt with NE group or using NIR source group. Primary outcome was first attempt success rate of establishing intravenous access. Secondary outcomes were to compare the time to establish intravenous access, number of pricks taken, and cost of consumables used.

Results: Of 240 neonates in each group the mean birth weight of neonates in NE group and NIR group being 1665 ± 820 grams and 1600 ± 778 grams, respectively (p-value = 0.363). Mean gestational age of neonates were 31.78 ± 3.9 weeks in NE group and 31.79 ± 3.9 weeks in NIR group (p-value= 0.972). First-attempt success rate in NE group and NIR group was 122 (50.8%) and 124 (51.7%) respectively. The median(IQR) of time taken to establish intravenous access was 37.5 (13- 134.7) sec and 43 (17-221.2) sec in the NE group and NIR group, respectively (p-value = 0.307). There was no significant difference between the groups for secondary outcomes.

Conclusion: Use of NIR source as compared to NE visualization, for establishment of intravenous access in neonates, does not improve first attempt success rate.

Keywords: Near Infrared Light, Neonate, Vein Viewer.

Clinical Trial Registry #: CTRI/2017/01/007693

INTRODUCTION

Most preterm and sick neonates admitted to neonatal intensive care unit (NICU) require intravenous access for administration of fluid, medications and parenteral nutrition. Intravenous access is usually established either by a peripheral venous cannula or by a peripherally inserted central catheter (PICC). Selection of vein for intravenous access is usually made by naked eye (NE) visualization and sometimes palpation.[1] NE visualization and establishment of intravenous access may be at times technically challenging and needs multiple attempts due to small size of the veins.[2] This not only leads to repeated punctures but also prolongs the procedure time. Vein Viewer is a device which utilizes a near infrared (NIR) light source to image the hemoglobin in red blood cells and processes the light reflected from moving blood cells and static surrounding tissues. Then the image of vein is projected back onto the skin in real time, showing the subcutaneous veins as black lines against a green background.[3] This Vein Viewer is sufficiently safe for both the patient and the operator. There is no ionizing radiation associated with its use and neither does it produce enough heat to cause heat burns. Intravenous cannulation with this technique has shown to improve first attempt venipuncture success in pediatric population.[4] To our knowledge there is only one study using NIR for central venous access in neonates by Phipps et al, 2011.[1]

There are limited studies evaluating the efficacy of NIR light source in establishing intravenous access in the neonatal population. Neonates usually have very small caliber veins which are difficult to visualise by the NE. Use of Vein Viewer for assessing intravenous access might help in visualisation of subcutaneous veins and hence reduce the number of pricks, thereby improving the success rate of intravenous access in neonates. This

might also result in a decrease in consumables used and hence cost of procedure. Till date, there is only one Randomized Control Trial on efficacy of NIR light source in securing intravenous access in neonates. There is paucity of data to support or refute the benefit of this device for securing intravenous access in this population. So we designed this study with an objective of comparing efficacy of NIR versus NE visualization for intravenous access in both preterm and term neonates. Here our aim is to compare first attempt success rate of establishing intravenous access (peripheral or PICC) with or without use of NIR light source in neonates.

METHODS

This randomized controlled study was conducted in the tertiary level NICU of Sir Ganga Ram Hospital, New Delhi, India with the neonates requiring intravenous access who were admitted to NICU during June 2015 to April 2017 after taking written informed consent. The Institutional Ethics committee cleared the study protocol prior to commencement and the same was registered with CTRI (Clinical Trial Registry of India) with reference number of CTRI/2017/01/007693. All neonates who were admitted to NICU and required an intravenous access (either a peripheral cannula or PICC line). Those neonates who had necessity of emergency resuscitation and conditions precluding the feasibility of obtaining an informed consent were excluded. During study period, total 1901 neonates were admitted to the NICU. Of these, 1222 neonates were assessed for inclusion and 742 neonates were excluded from study. Remaining 480 neonates were randomized into intervention as showed in consort flow chart of study in figure 1. Computer generated randomization sequence was prepared with a block size of four and was stored in sealed opaque envelopes. Neonates were further stratified for gestational age (<30wk, 30-34wk and >34wk), skin color (Dark or Fair as per Fitz Patrick Scale) and visibility of vein (Visible or non-visible).

Intervention: Enrolled neonates were randomized into one of the two intervention arm: naked eye cannulation (NE group) or NIR light source guided cannulation (NIR group). Intravenous cannulations on enrolled infants were done by Neonatal trainee resident staffs who were formally educated regarding study protocol and trained for 2 weeks for use of NIR light source. NIR light source, "Vein Viewer Flex, Christie" (Christie Medical Holdings Inc. Memphis, TN) was used for NIR guided cannulation. Allocation of intervention was done just before the procedure. The same manufacturer's intravenous cannula and PICC lines were used during the entire study period to eliminate any equipment bias. Neonates enrolled into NE group were cannulated as per the standard technique by the clinician. In the NIR group, the NIR light source was mounted on neonate's bed and NIR light was put over different parts of the limbs for visualization of appropriate vein. An attempt was considered as finished, when the needle first touches the skin until the needle was removed from skin. For peripheral cannula, successful placement was defined as backflow of blood as well as immediate easy push of 2 ml normal saline through the cannula without signs of extravasations. Similarly successful placement of PICC was defined as advancement of catheter to desired length with backflow of blood present coupled with radiological confirmation of central location of catheter tip. First attempt success was considered if peripheral cannula or PICC was successfully inserted in a single prick attempt. A nurse, not involved in procedure recorded the time taken for successful intravenous cannulation, using a stop watch with timing range of 1/100 sec (0.01 sec) and accuracy of 0.003%. After each procedure, the details of demographic characteristics, first attempt success, number of attempts, and consumables (number of cannula or PICC, syringes, gauze pieces, gloves, gown, mask, and eye sheets used) were recorded on proforma by the clinician.

Primary outcome was to measure the first attempt success rate of establishing intravenous access (peripheral or PICC). Secondary outcome variables were to measure time to establish intravenous access (peripheral or PICC), number of pricks made for peripheral intravenous cannula and PICC insertion and cost of consumables in peripheral intravenous cannula and PICC insertion. Data were recorded prospectively on a predesigned proforma and was entered in a MS Access form.

Statistical analysis was done by using SPSS version 17. Data were analyzed using standard statistical tests. First attempt success rate and overall success rate were compared using Chi-square test. Number of attempts in each group was compared using Independent t-test for those variables which were normally distributed and Mann–Whitney U test for those variables which were not normally distributed. Statistical significance was considered when p value ≤0.05 was obtained.

RESULTS

Out of 480 neonates, 240 neonates were allocated in each group the mean birth weight of neonates in NE group and NIR group was 1665 ± 820 grams and 1600 ± 778 grams, respectively (p-value 0.363). Mean gestati-

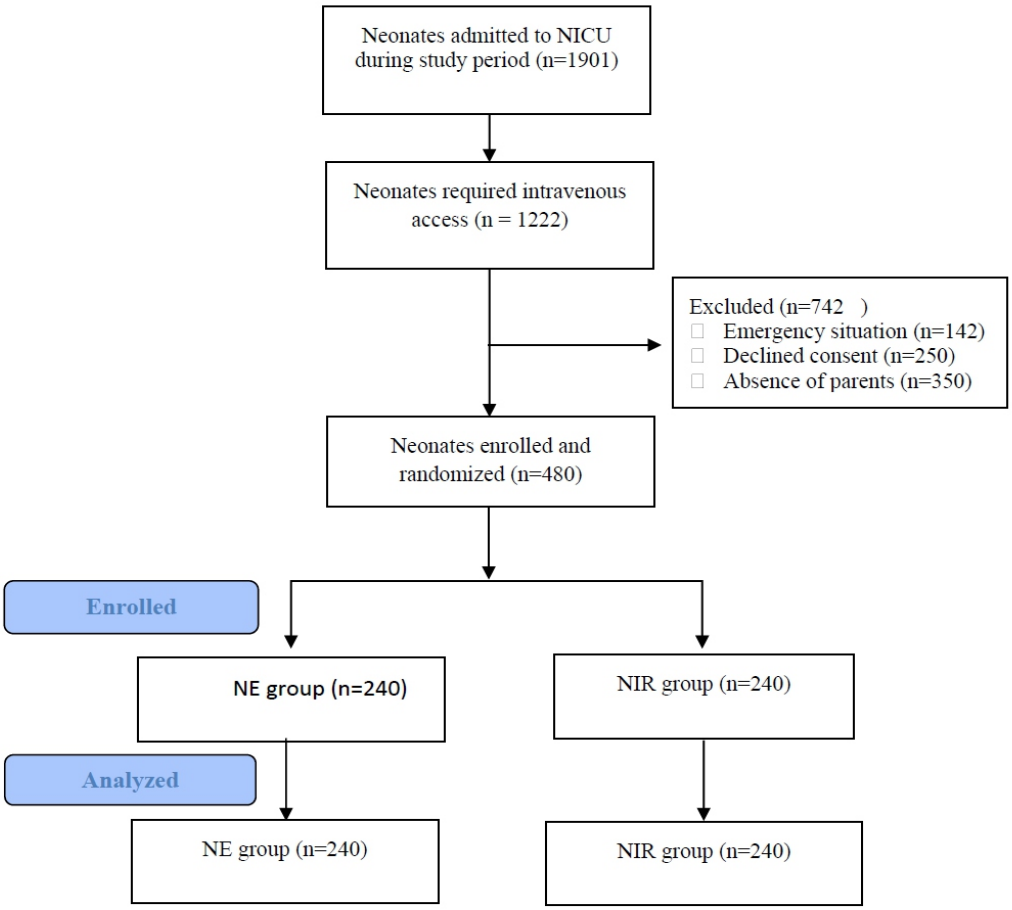

Figure 1: Consort flow diagram showing subject enrollment and intervention allocation

onal age of neonates was 31.78 ± 3.9 weeks in NE group and 31.79 ± 3.9 weeks in NIR group (p-value 0.972). Median age at enrollment was 11.0 (3-27.7) days in NE group and 8 (3-26.7) days in NIR group (p-value 0.068). Males were found significantly higher in NIR 167 (69.6%) group as compared to NE 145 (60.4%) group (p-value 0.044). (Table 1)

Overall, 246 intravenous cannulations were inserted successfully in first attempt. The first attempt success rate in NE group and NIR group was 122 (50.8%) and 124 (51.7%) (p-value 0.927) respectively. (Figure 2) An insignificant association of NE and NIR group was found with gestational age (p value 0.684), skin color (p value 0.526) and visibility of vein (p-value 0.442). (Table 2)

The secondary outcomes of enrolled subjects were illustrated in table 3. The median and interquartile range of time taken for first attempt success was 13.5 (10-20) sec and 18 (10-30) sec in the NE group and NIR group, respectively. The median and interquartile range of time taken to establish intravenous access was 37.5 (13-134.7) sec and 43 (17-221.2) sec in the NE group and NIR group, respectively. The median and interquartile range of number pricks required for an intravenous access was 1 (1-2) and 1 (1-3) in NE group and NIR group respectively. The mean and SD for cost of consumables was 333 (132.6) and 324 (100) in NE group and NIR group, respectively. There was no significant difference between the groups for secondary outcomes.

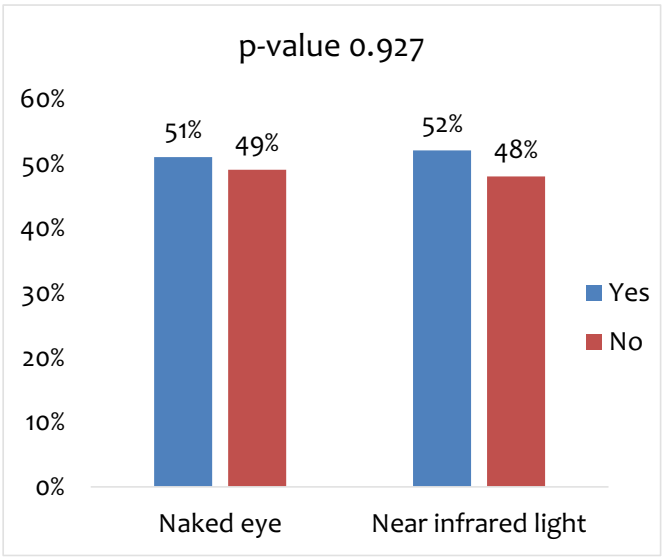

Figure 2: First attempt success rate of intravenous cannulations (n=480)

Table 1: Demographic parameters of enrolled subjects (n=480)

Parameters	NE Group (n=240)	NIR Group (n=240)	p- value
Gestational Age, Weeks	31.78 ± 3.9	31.79 ± 3.9	0.972$^{\$}$
Birth Weight, Grams	1665 ± 820	1600 ± 778	0.363$^{\$}$
Male Gender, n (%)	145 (60.4)	167 (69.6)	0.044$^{\wedge *}$
Age at Enrolment, Days*	11 (3-27.7)	8 (3-26.7)	0.068$^{\&}$
Jaundice Requiring Phototherapy, n (%)	23 (9.6)	21 (8.8)	0.752$^{\wedge}$
Dehydration, n (%)	2 (0.8)	2 (0.8)	0.999$^{\sim}$
Shock, n (%)	4 (1.7)	9 (3.8)	0.160$^{\wedge}$

-NE: Naked eye, NIR: Near infrared light
*Data expressed as mean (SD) unless specified. * Median (Interquartile range)*
$^{\wedge}$Chi-Square/$^{\sim}$Fisher Exact test applied, $^{\$}$Independent t-test applied, $^{\&}$Mann-Whitney U Test applied, *p-value ≤ 0.05

Table 2: First attempt success rate of establishing intravenous access in enrolled subjects (n=246)

Parameter	NE Group (n=122)	NIR Group (n=124)	p- value
Gestation, Weeks			
<30	46 (37.7)	41 (33.1)	0.684
30-34	43 (35.3)	50 (40.3)	
≥ 35	33 (27.0)	33 (26.6)	
Skin Color			
Dark	55 (45.1)	61 (49.2)	0.526
Fair	67(54.9)	63 (50.8)	
Visibility of Vein			
Visible	64 (52.5)	72 (59.0)	0.442
Non-visible	58 (47.5)	52 (41.9)	

-NE: Naked eye, NIR: Near infrared light
Data expressed as n (%)
Chi-Square test applied

Table 3: Comparison of time to establish intravenous access, number of pricks taken, and cost of consumables used in enrolled subjects (n=246)

Parameter	NE Group (n=122)	NIR Group (n=124)	p- value
Time to 1st Success, sec	13.5 (10-20)	18 (10-30)	0.123
Time to Establish Intravenous Access, Sec	37.50 (13-134.7)	43.00 (17-221.2)	0.307
Number of Pricks to Establish IV Access	1 (1-2)	1 (1-3)	0.491
Cost of Consumables*	55 ± 45.1	61 ± 49.2	0.526

-NE: Naked eye, NIR: Near infrared light
*Data expressed as median (Interquartile range), unless specified, * mean ± SD*
Mann-Whitney U Test applied

DISCUSSION

In the present study, we evaluated the efficacy of NIR light source in establishing intravenous access in neonates admitted to NICU. We observed no difference in the first attempt success rate with or without the use of NIR. Our overall first attempt success rate was 51.2%. First attempt peripheral intravenous cannula insertion success ranges from 65% to 86% in the pediatric and adult populations.[5-14]

Ultrasound and transillumination have been used to improve visualisation of veins for insertion of IV cannula.[15,16] Utility of vein viewer for intravenous access in pediatric and adult population has been described.[3,4,17] In our study, first attempt success rate did not improve significantly with use of NIR light source. There are no published studies in neonates which have reported success rates of peripheral intravenous cannula insertion. Several studies have reported utility of NIR for intravenous access in adult and pediatric age group with mixed results.[3-5,18-20] Hess et al in a prospective non-randomized study in children 0-17 years, found significant improvement in first attempt success rate by using NIR light (80% vs 49%) as compared to standard technique.[4] Other studies however, have not shown any benefit of this device in improving success rates for IV access in pediatric population.[5,18,19]

The success of NIR has also been evaluated by other parameters such as number of pricks and procedural time for cannulation. Most studies did not find any difference in these outcomes by use of NIR. We also observed that the number of pricks required and time to successful cannulation were comparable in both the groups. Conversely few studies have reported favorable results for these parameters.[4,21] Hess et al reported decrease in mean number of attempts and time of procedure with the use of NIR in pediatric population.[4] Sun et al in a randomized controlled trial (3months - 17 years pediatric age group) also observed similar benefits by use of NIR.[21]

Difficult venous cannulations are often due to lack of easily accessible veins. Scoring systems to quantify difficulty in venous access have been developed, DIVA score is one such scoring system which has been studied in pediatric population.[6] Kim et al in a subgroup analysis reported that use of NIR, in pediatric population with DIVA score ≥4 was associated with higher first attempt success rate, even though there was no difference in overall first attempt success rates.[3] DIVA score however, has not been validated in neonates, we used the applicable components of this score such as gestational age, skin color and visibility of veins to account for difficulty in venous access. Analysis of data in stratified groups based on these factors did not show any difference in success rates with or without use of NIR.

Multiple attempts to achieve intravenous access are likely to result additional use of consumables thus escalating the cost of procedure. We analyzed the cost of consumables for intravenous access with and without use of NIR. There was no difference in cost in the two groups. Hess et al reported a presumed cost saving of 7.2$ with use of NIR for the observed difference in first attempt success in their study.[4]

Strength of our study is that it's a randomized control trial with adequate sample size. We accounted for difficulty in visualizing the veins by stratifying the neonates by gestational age, skin color and availability of visible veins. Limitation of our study was inability to mask the intervention. Even though clinicians underwent an adaptation period of two weeks, we were unable to account for the influence proficiency of different users for handle the Vein Viewer. Users reported several technical challenges while using vein viewer like magnification of the vein image, poor image stabilization with movement of the limb and depth assessment issue for the two-dimensional nature of the image. Further multicenter randomized control trial with adequate sample size are needed to establish role of NIR light source in venous access in neonates.

CONCLUSION

Use of NIR light source as compared to NE visualization, for establishment of intravenous access in neonates, does not improve first attempt success rate. The time taken for intravenous access, number of pricks and the cost of consumables are comparable.

ETHICAL APPROVAL: Ethics Committee approval was obtained from the Ethics Committee of the Sir Ganga Ram Hospital New Delhi, India No. (EC/07/838, date: 14.07.2015).

AUTHORS' CONTRIBUTIONS: BR: Principal investigator and a major contributor in data collection, analysis and interpretation, manuscript writing, and literature search.

SS, AS & MM: Helped in drafting the work, data collection, and final approval of the version to be published. Approval of final version of the manuscript.

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