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Original Article

Feasibility of Pulse Oximetry as a Screening Tool for Early-Onset Neonatal Sepsis at Tertiary Care Teaching Hospital in India

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Abstract

Introduction: Sepsis is a serious infection in neonates. It usually presents with non-specific symptoms, making early diagnosis difficult. In India, with an incidence of sepsis 30 per 1,000 live births, early detection is very important. Hypoxia is a one of the important findings seen in sepsis. Pulse oximetry is a simple, reliable way to measure oxygen saturation. The primary objective of this study was to assess the feasibility of utilizing pulse oximetry as a means of detecting hypoxia in asymptomatic neonates with early-onset neonatal sepsis (EONS).

Methods: A prospective observational study was conducted among 282 asymptomatic neonates. Pulse oximetry was performed thrice: within six hours, within 24 hours of life and one to two hours before discharge. Newborns with oxygen saturation below 90% within six hours or with readings between 90 - 94% within 24 hours on repeat screening were considered as test-positive. Full sepsis screening including blood cultures, chest X-ray was performed in test positive asymptomatic neonates. Echocardiography was also performed to exclude any cardiac problems. Neonates who tested negative were observed until they were discharged from the hospital to detect any possible development of sepsis.

Results: Out of 282 neonates, five (1.8%) tested positive by pulse oximetry. All of them were confirmed to have probable EONS. All those neonates who tested-negative by pulse oximetry, remained free of EONS during follow-up.

Conclusions: Pulse oximetry can be a useful screening tool for detecting EONS.

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Introduction

Early-onset neonatal sepsis (EONS) is a potentially life-threatening condition that occurs in neonates within the first 72 hours of life. It is the major factor responsible for neonatal morbidity as well as mortality, especially in preterms and in resource limited regions of the world. EONS can lead to various complications such as meningitis, pneumonia, and even death. In India, it poses a serious problem, especially in health care facilities where a large number of deliveries are conducted.[1]

Early diagnosis is necessary for effective treatment. As the neonates display vague symptoms and signs, the clinical diagnosis is very difficult. If the diagnosis is early, then treatment is effective and can lead to dramatic improvement.[2] In EONS,

hypoxemia is an important clinical feature and seen in nearly 30% neonates with sepsis.[3] Pulse oximetry is a non-invasive and readily available technique for measuring blood oxygen saturation.[4] Recent studies suggest a potential link between low oxygen saturation and the presence of EONS in neonates.[5] This has led to growing interest in exploring the feasibility of using pulse oximetry as a screening tool for EONS in resource-limited setting.

This study was undertaken to investigate the feasibility of implementing pulse oximetry as a screening tool for EONS in neonates admitted to a tertiary care hospital in India. By evaluating the effectiveness of pulse oximetry in identifying potential EONS cases, we hope to contribute valuable insights for improving early detection and management strategies for this life-threatening condition.

Methods

A prospective observational study was conducted at tertiary care teaching hospital of northern Karnataka, India. The study was undertaken over a period of 18 months (November 2018 - May 2020) after getting clearance from Institutional Ethics Review Committee. The study included asymptomatic neonates born after 35 weeks gestation, delivered at the hospital (both Caesarean sections and vaginal deliveries), with parental consent. Newborns with pre-existing signs of sepsis or those admitted to the neonatal intensive care unit were excluded. Using expected incidence of sepsis as 30%, expected sensitivity as 99% and expected specificity 85%, and desired precision as 5%, the minimum sample size was 282.[6] The primary outcome was to identify hypoxia potentially caused by EONS. Masimo Radical-7 pulse oximetry with a reusable probe was used to measure peripheral oxygen saturation (SpO_2) on both the right hand and foot of each neonate. The probe was secured with tape until consistent readings were obtained. Pulse oximetry screenings were conducted three times: within six hours of delivery, 24 hours of delivery, and one to two hours before discharge. Each screening took about five minutes on average. Hypoxaemia (Test positive): Peripheral capillary oxygen saturation (SpO_2) < 90% within six hours or repeat readings between 90 - 94% within 24 hours. Normoxaemic (Test Negative): (SpO_2) > 90% at six hours and repeat readings > 94% within 24 hours.[6] Test-positive neonates with abnormal oxygen saturation underwent a comprehensive workup for EONS, including complete blood count, C-reactive protein (CRP), I / T ratio, blood cultures, chest radiography, and 2D echocardiography to exclude cardiac etiology. Diagnosis of EONS was established by at least one of the following criteria: serum CRP > 10 mg / dL, I / T ratio > 0.2, positive blood cultures, or chest X-ray findings suggestive of pneumonia.[7] We followed up with test-negative newborns until discharge to monitor for any potential development of infections.

Results

The study enrolled 282 neonates born after 35 weeks gestation who were asymptomatic. Table 1 depicts the baseline characteristics of enrolled neonates. Table 2 shows the peripheral oxygen saturation (SpO_2) between neonates with probable sepsis and non-sepsis. Table 3 shows the vital characteristics (Heart rate, respiratory rate, temperature and SpO_2) between neonates with probable sepsis and non-sepsis.

Table 1: Baseline characteristics of newborns (N = 282)

Variables	Characteristics	Frequency (%)
Maternal age (Years)	< 20	13.5
	21 - 25	56.4
	26 - 30	25.9
	> 30	4.3
Parity	Primipara	64.2
	Multipara	35.8
Delivery mode	LSCS#	52.8
	Normal vaginal delivery	47.2
Maternal Conditions	Anemia	9.9
	Hypermesis gravidarum	7.4
	Hypertension	3.6
	MSAF##	0.7
Gestational age (Weeks)	Term (> 37)	90.4
	Late preterm (35 - 37)	9.6
Sex	Male	54.6
	Female	45.4
Weight (Kg)	< 2.5	26.6
	≥ 2.5	73.4
Birth weight as per age	AGA*	95.4
	SGA**	4.6
PROM ^	Yes	1.1
	No	98.9

#Lower Segment Caesarean Section,*Appropriate for Gestational Age, ** Small for Gestational Age, ##Meconium stained Amniotic Fluid, ^ Premature Rupture of Membranes

Table 2: SpO_2 between probable sepsis and non-sepsis neonates

SpO^2	Probable Sepsis		Non-Sepsis		P-value
	N	%	N	%	
85 - 89%	5	100.0%	0	0.0%	< 0.001*
90 - 94%	0	0.0%	8	2.9%	
95% or above	0	0.0%	269	97.1%	
Total	5	100.0%	277	100.0%	

*Peripheral capillary oxygen saturation

There is a strong association between low SpO_2 (85 - 89%) and probable sepsis in newborns. All babies with probable sepsis had low SpO_2. Patients with suspected sepsis have significantly higher heart rate, respiratory rate, temperature and lower SpO_2 compared to those without sepsis

Table 3: Heart rate, respiratory rate, temperature and SpO_2 of sepsis and non-sepsis groups

Parameters at six hours	Probable sepsis		Non sepsis		P-value
	Mean	SD	Mean	SD	
Heart rate (per min)	172.0	7.6	133.1	7.6	< 0.001
Respiratory rate (per min)	64.0	1.9	44.7	4.0	< 0.001
Temperature (°C)	37.8	0.2	36.7	0.2	< 0.001
SpO_2 (%)	89.2	0.8	97.5	1.2	< 0.001

Discussion

EONS is a devastating condition in neonates. It is the most important contributor of neonatal morbidity as well as mortality, especially in preterms and in the developing regions of the world, including Southeast Asia, Africa and South America. Neonatal sepsis which occurs within 72 hours is termed as EONS. This is a dreaded condition also in our country, India, especially those centres where significant number of deliveries are conducted. As the clinical features which the neonates develop is very subtle and difficult to pick up, diagnostic modality has to be improved upon. With early diagnosis, the recovery is remarkably good and outcome can be dramatically improved.

In developing countries, EONS is major contributor to high neonatal mortality rate. Various researches have stated that neonatal sepsis, specifically EONS is important reason of neonatal mortality in underdeveloped countries like India. EONS contribute for 30% to 50% of total neonatal mortality.[8,9] The diagnosis of EONS is very difficult due to complex nature of the conditions as newborn transition from intrauterine to extra uterine life, usually presenting with nonspecific symptoms like respiratory distress, poor feeding, or lethargy, requiring high index of suspicion.[10] It has been found that hypoxemia can weaken immune response, increasing vulnerability to infection leading to damage of tissues, which ultimately make environment favorable for sepsis.[11]

We found positive association between maternal age and EONS risk. Our findings on maternal age and EONS risk (highest prevalence in 21 - 25 year old) partially align with Soman et al who reported a positive association.[12] However, Salem et al found the opposite.[13] Further investigation is needed to clarify this relationship.

For the detection of hypoxemia, pulse oximetry is a simple, reliable and accurate technique.[4] In developed countries, pulse oximetry is used as a screening tool for detecting congenital heart diseases.[14] But pulse oximetry is less commonly used in low-income or underdeveloped countries for screening of congenital heart diseases as it contributes to a small number of neonatal deaths and very few and costly treatment options. However, neonatal sepsis can be easily identified as a secondary condition while screening for congenital heart diseases.[15] In low-income countries, pulse oximetry has been shown to decrease neonatal and child deaths by early detection of hypoxaemia-associated conditions such as pneumonia and urgent oxygen therapy.[16,17]

This study was planned to investigate the feasibility of

implementing pulse oximetry as a screening tool for EONS. As this test is non invasive, economical and easily done by all health care personnel, this test has the potential of becoming an important screening test for detecting EONS.

Similar to other studies, our study found a predominance of primipara mothers and a high rate of C-sections (52.8%). While Adatara et al linked Caesarean sections to EONS risk, others argue these deliveries don't necessarily expose newborns to vaginal bacteria, a potential risk factor.[18] Similar to our study, Swamy et al found that none of the test negative neonates had EONS and demonstrated pulse oximetry can be used as a screen for early onset sepsis in asymptomatic newborns[6] where in their study 213 neonates were screened with pulse oximeter out of which two were EONS which is comparable to our study.[6] Elsa etal in their study found that 13% neonates were sepsis positive out of which eight were detected by pulse oximeter screening.[5]

The strengths of the present study are that it tries to address the problem of missed diagnoses of EONS resulting from early discharge. It has also examined the use of pulse oximetry as a non-invasive, easily accessible tool which has the potential for the early detection of EONS. It also analyses different factors related to both the mother and the newborn that could potentially be associated with EONS. The limitation of the present study is that it is a relatively moderate sample size study conducted at a single centre. This fact can potentially limit the generalizability of our results. For the diagnosis of EONS, we had to depend upon lab reports as all the suspected sepsis cases had sterile blood cultures, raising questions about the definitive diagnosis of EONS. Although high CRP and other indicators indicate a potential infection, additional research is needed to ascertain whether pulse oximetry alone can help to diagnose EONS. If further research validates the effectiveness of pulse oximetry as a screening tool, it could have significant implications for improving the identification of EONS as pulse oximetry is a simple, painless, and cost-efficient method that is readily available in most healthcare settings.

Conclusions

The present study concludes that the pulse oximetry does have the potential to be valuable screening tool for detecting EONS. However, the usefulness of pulse oximetry as a stand-alone screening method for EONS in this study requires further validation in larger, multi centric studies encompassing more varied population. The usefulness needs to be proven by further studies using blood culture-confirmed sepsis cases and a bigger, more varied population.

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