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Original Research Article

Can pulse oxymetry be used as a routine screening tool in early diagnosis of critical congenital heart diseases in newborns?

Gomathi Chenna Reddy*, K. N. Devaraj

Department of Pediatrics, Shadan Institute of Medical Sciences, Hyderabad, Telangana, India

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***Correspondence:**
Dr. Gomathi Chenna Reddy,
E-mail: dr_gomathi@hotmail.com

ABSTRACT

Background: Unrecognition or delayed diagnosis of severe congenital cardiac diseases (CCD) can lead to cardiac failure, cardiovascular collapse and death. Pulse oximetry can be used as a screening tool for detection of critical CCD (CCCD) in newborns. We conducted this study to correlate pulse oximetry findings in asymptomatic newborns to detect CCCD and coarctation of aorta.
Methods: All babies delivered in our hospital were included; after clinical evaluation, pulse oximetry screening was done 12 hours after delivery, taken in three extremities (Right thumb, left thumb and left great toe). If the readings were <95% in any of the limbs, they were further evaluated to detect cardiac defects.
Results: Of 800 babies, 54.4% were males and 66.1% were delivered by normal vaginal delivery. Antenatal scan of all were normal. Mean±SD birth weight was 2.92 kg ±.29 ranging 2.14 Kgs-3.80 kgs. Oxygen saturation was >95% in 799 babies, there was no significant clinical findings, and were negative for pulse oxymetry screening; one baby had positive pulse oximetry screening (<95%) with 'ejection systolic murmur' over left 2nd and 3rd intercostal space. There was no evidence of cyanosis, oedema or tachypnoea. Pulse oximetry reading was 88% in right thumb, 90% in left thumb and 92% in left great great toe. Echocardiography showed Atrial Septal Defect, Ventricular Septal Defect with Pulmonary Stenosis.
Conclusions: Pulse oximetry is a non-invasive, reliable, and useful screening tool for an early detection of CCCD in newborns. The combination of pulse oximetry and clinical judgement is needed.

Keywords: Critical congenital heart disease, Early detection, Echocardiography newborns, Pulse oxymetry

INTRODUCTION

Congenital cardiac diseases (CCD) have a wide spectrum of severity in infants. About 2-3 in 1000 newborn infants with heart disease remain symptomatic in the 1st year of life. The diagnosis is established by the first week after birth in 40-50% of neonates with CCD and by 1 month of age in 50-60% of patients.[1] Saxena A et al., have reported the prevalence of major acyanotic and cyanotic CCDs as 23.2 and 20.1%, respectively, among Indian children.[2] Clinical skills is the centre stone of clinical diagnosis in many Critical CCD (CCCD), which later confirmed by echocardiography, palliated with prostaglandin infusion, and treated with surgery or transcatheter interventions. Interventions that are adjuvant and support diagnosis is typically performed in the first weeks of life to optimize hemodynamics and prevent end-organ injury associated with delayed diagnosis.

Timely recognition of CCCD known to improve outcomes, makes it crucial to identify and evaluate strategies to enhance early detection. With prenatal ultrasonography failing to detect CCDs, particularly that of ductal origin in few, pulse oximetry, a simple tool is in

the centre of focus recently as it has been proposed as one such strategy, and legislation has been proposed to support this practice.

The clinical significance of screening for CCCD in neonates is that on many occasions asymptoatic newborns discharged as normal only to return later with syptoms. Hence, it is important to detect congenital heart diseases before discharge from the hospital. Aamir T et al., reviewed hospital discharge records for infants and matched to the Electronic Birth Certificate records to identify newborns who were discharged as normal and later admitted with a diagnosis of critical congenital cardiovascular malformations.[3] They found that in addition to routine clinical examination, further examination with pulse oximetry oxygen saturation as a routine newborn screening service is warranted.

Pulse oximetry is used routinely in the assessment of neonates in neonatal intensive care units (NICU) and emergency departments. It has been proposed as an adjunct to the assessment of the newborn in the delivery room, and to consider it as a vital sign equivalent in importance to pulse, respirations, and blood pressure.[4] Contemporary use of pulse oximetry has thus already contributed to heightened recognition of congenital heart disease in neonates.[5]

Pulse oximetry has gained wide acceptance as a noninvasive method to determine oxygen saturation (SpO_2). The method does not require calibration and is able to provide instantaneous data that correlate well with blood gas measurements. A common feature of many forms of CCDs is hypoxemia, which if mild, may be missed during clinical examination, wherein pulse oxymetry is useful.

Pulse oximetry offers a reliable non-invasive, real-time objective method for monitoring oxygen saturation. Use of the pulse oximeter in the labor room has demonstrated the efficacy as well as the sensitivity of this tool in assessing the cardiopulmonary adaptation of the newborn.[6] In addition, difficulties in identifying cyanosis clinically in few cases (dark pigmented skin, anemia, absent cardiac murmers, failure of prenatal ultrosonography in picking up the malformations) that may prove expensive even few hours later, due to underlying life threatening conditions, have supported the use pulse oxymetry as a screening tool for early detection of hypoxemia in CCCD.

Many Indian studies detecting CCDs using pulse oximetry saturation is helpful and support its inclusion in the screening panel.[7,8] Palve N et al have shown that pulse oxymetry high sensitivity, specificity, and negative predictive value in Indian neonates.[9]

Saxena A et al too demonstrated its sensitivity in Indian neonates, but with low specificity; in contrast, Taksande AM et al proved it to be a reliable simple non-invasive tool with high sensitivity and specifity along with good positive predictive value and 100% negative predictive value.[10,11]

The purpose of this prospective study was to assess the reliability of pulse oximetry screening to detect cyanotic congenital heart defects in asymptomatic newborns.

METHODS

This prospective study was conducted by the Department of Pediatrics of Shadan Institute of Medical Sciences and Research Center, Hyderabad, India after obtaining approval from the Instittuitional Ethics Committee from May 2017 May to February 2018.

All live full-term babies delivered in our hospital during the study period, who were asymptomatic for CCHD and coarctation of Aorta were screened and enrolled after obtaining a written informed consent from the parents for participation and release of their medical information for the purpose of this research.

Newborns with cardiac defects previously detected by antenatal ultrasonography and those with hypoxaemia other than CHD were excluded. Included patients were assessed clinically and by pulse oximetry using mindray pm-60 hand-held pulse oximeter.

Pulse oximetry was conducted on a quiet or sleeping new born and recorded in three extremities (right thumb, left thumb and left great toe). The probe was cleansed with alcohol swab before each use. The same pulse oximeter was used for all the subjects of this study. The readings were recorded after stabilization for one minute.

To avoid movement artifacts, the pulse was observed until a good waveform was obtained. It required 3-5 minutes for all 3 measurements to be performed. If the pulse oximetry showed under saturation at 12hours of age further oximetry evaluation was done at 48 hours and 72 hours of life.

The functional oxygen saturation of $\geq$95% was accepted as normal, if the readings fall below 95% in any of the limbs, they are subjected echocardiography to detect cardiac defects.

Detailed clinical examination of cardiovascular system was performed for all the babies parallelly.

Statistic analysis

Descriptive and inferential statistical analysis has been carried out in the present study. p value estimation and Chi-square/ Fisher Exact test has been used to find the significance of study parameters on categorical scale between two or more groups.

p - value significance + Suggestive significance (p value: 0.05<p<0.10) *Moderately significant (p value: 0.01<p ≤0.05) ** Strongly significant (p value : p≤0.01).

The Statistical software namely Stata 10.1, MedCalc 9.0.1, were used for the analysis of the data and Microsoft word and Excel have been used to generate graphs, tables etc.

RESULTS

We enrolled 800 neonates subjected them to clinial evaluation and pulse oxymetry. There were 434 (54.4%) male babies and 366 (45.6%) female babies. Normal vaginal delivery was the preferred mode of delivery in 530 (66.1%) and 270 (33.9%) were delivered by caesarean section. Antenatal scan of all babies was normal. All mothers had normal uneventful trimesters. Mean±SD birth weight was 2.92 kg ±.29 ranging 2.14 Kgs-3.80 kgs. Table 1 tabulates the general demographic features of the study population. Oxygen saturation was >95% in 799 babies and one had <95% which was statistically significant (p= 0.001) (Table 2).

Table 1: Distribution of details of babies studied.

Details	n (N=800)	%	95%CI
Mode of delivery			
Normal	530	66.25	62.78-69.32
LSCS	270	33.75	30.68-37.22
Gender			
Male	434	54.25	50.91-57.80
Female	366	45.75	42.20-49.09
Birth Weight			
<2.5 Kgs	22	2.75	1.92-4.28
2.5-3.5 Kgs	754	94.25	92.27-95.66
>3.5 Kgs	24	3.0	2.02-4.43

Table 2. Distribution of oxygen saturation

O_2 saturation (pulse oxymetry) (%)	Right Thumb n (%)	Left Thumb n (%)	Left great toe
≤ 95	1(0.12)	1(0.12)	1(0.12)
96	89(11.1)	69(8.63)	79(9.88)
97	170(21.25)	124(15.5)	168(21.0)
98	326(40.75)	270(33.75)	280(35.0)
99	140(17.50)	196(24.5)	188(23.5)
100	74(9.25)	140(17.5)	84(10.5)

Table 3 tabulates the oxygen saturation recorded at different parts of the body.

Table 3. Mean SpO_2 values at different positions

Location	Range	Mean±SD
Right thumb	88-100	97.90±1.1
Left thumb	90-100	98.26±1.2
Left great toe	92-100	98.04±1.1

There were no significant clinical findings in 799 babies; None of these had tachycardia, tachypnoea, cyanosis, physical manifestations of congenital anomalies; all had well-felt peripheral pulses. Of 800 neonates, 799 were negative for pulse oxymetry screening; one baby had positive pulse oximetry screening (<95%) with cardiac murmur and confirmed by echocardiography to have CCCD (Table 4).

Baby with low oxygen saturation was a full-term female child delivered by LSCS had a birth weight of 3.6 Kgs, normal antenatal scan, with cyanosis; mean oxygen saturation was 88%, 90% and 92% for right thumb, left thumb and left great toe, respectively. Echocardiography revealed Atrial Septal Defect (ASD), Ventricular Septal Defect (VSD) with Pulmonary Stenosis(PS). There was no evidence of Coarctation Of Aorta (COA).

Table 4. Correlation of cardiac problems in relation to Pulse oximetry.

Pulse oxymetry	Right thumb		Left thumb		Left great toe	
	n	Patients with cardiac problems	n	Patients with cardiac problems	n	Patients with cardiac problems
<95%	1	1	1	1	1	1
≥95%	799	0	799	0	799	0
p	<0.001**		<0.001**		<0.001**	

DISCUSSION

Pulse oxymetry screening for congenital cardiac diseases has been approved in United states in 2011, with proven sensitivity and specificity it has been recommended as a useful screening tool for CCCD in neonates in developed countries such as United Kingdom, Canada, Germany but still awaiting its due recognition and inclusion in the panel of neonatal screening tests in India.[12-17] Globally, pouring support on its implementation as a screening tool in early identification of CCCD make an unignorable potential candidature in the panel.[18-23] It has been reported to be a safe, useful tool to screen neonates for cardiac malformation particularly in rural areas with limited infrastructure. Aksande AM et al reported that hypoxemia in neonates (SPO_2 <90%) after 4 hours of birth calls for further assessment including echocardiography.[11]

Implementation of pre-discharge pulse oximetry screening for newborns may improve the timely detection of asymptomatic critical congenital cardiovascular malformations.[3]

Timing is an important factor to be followed in assessment. Measurements performed shortly after birth may lead to an increased number of false positive results.[24-25] Readings obtained ≥24 hours have been associated with less false positivity, hence, it is suggested that readings be taken after 24 hours.[26] However, one has to be cautious of missing out life threatening symptom of hypoxemia due to severe and critical cardiac conditions requiring immediate attention. With studies revealing greater sensitivity at 6-12 hours post natally and specificity at 0-6 hours of birth, use of this screening test at the timings is justifiable.[27] We screened the babies at 12 hours after birth in the view of early detection of CCCD and to decrease the number of false positive cases. If the pulse oximetry showed under saturation at 12 hours of age further oximetry evaluation was done at 48 hours and 72 hours of life.

Previous studies used a 95% cut-off of normal pulse-oximetry values in healthy newborns and saturation differences observed in infants with left obstructive heart disease and obligate right to left shunt across the ductus arteriosus and Coarctation of aorta where the oxygen saturation was observed differentially in upper and lower limbs.[28,29]

Pulse oximetry estimations are known to vary with altitudes; overestimate arterial oxygen saturation at low altitudes and underestimate at high altitudes. Cut-off value ranging from 92%-95% was found to be ideal as the sensitivity and specificity remained quite stable, whereas a cut-off value below 92% led to a rapid decrease of sensitivity.[29-30]

Detection rate of CCCD with pulse oxymetry is varied ranging from 0.02%-0.13%.[31-34] In the present study, only one baby with oxygen saturation <95% was subjected to echocardiogram which was positive. Detection rate In the present study was 0.13%.

Arlettaz et al, reported a significantly higher rate of detection (0.46%) of CCCD by pulse oximetry than our study.[35] In contrast to our study, this study included babies with CCCD diagnosed prenatally. We excluded antenatally detected CCCD babies probably that is the reason for low detection rate in the present study. Ruangritnamchai et al, reported a lower rate (0.1%, 03/1847), similar to present study. Detection rates reported by Indian authors varies from 0.38% -2.73%, Mathur NB et al., reported a higher positive rate in cyanosed sick children in NICU detecting 95.2% of true positive cases.[36-38] This study concluded that high negative predictivity of pulse oxymetry makes it a useful tool in ruing out CCCD. Shenoy KD et al conclude that pulse oxymetry is helpful in identiifying those missed by the clinician during clinical examination and screen positives to be confirmed by echocardiography.[39]

The baby with low oxygen saturation was a full term female child had a normal antenatal scan; delivered by LSCS had a birth weight of 3.6 Kgs. Baby had cyanosis with mean oxygen saturation was 88%, 90% and 92% for right thumb, left thumb and left great toe, respectively. CCCD detected echocardiographically was ASD, VSD with PS. This patient did not show any evidence of COA.

Ease of use and not required extensive training is an added advantage with pulse oxymetry. Trained nurses, health assistants will find this easy to use as they are familiar with this skill and does not require extensive training making them capable of identifying hypoxemia and can alert the physician for the initiation of next level of assessments.

All said and done, none can replace the clinical skills and expertise. Hence, it is important that a clinician is alert and well trained to identify the signs of CCCD even in asymptomatic neonates. Identifying and eliminating false positive cases is dependent on treating physician's clinical judgement.

False positivity is one of the hindrances; Hamilçıkan Ş et al report a false positivity of 0.02%. Even respiratory problems can present with hypoxemia. Hence, hypoxemia confirmed by pulse oxymetry and thorough clinical examination for definite diagnosis is required before considering echocardiography, particularly in places with poor infrastructure.[40] In places with suboptimal diagnostic setups, interventions and management, pulse oxymetry can be an adjuvant to clinical expertise.

However, authors emphasize on training and developing clinical skills in identifying the early signs, with supporting diagnostic tools to aid in arriing at diagnosis. With various studies supporting its role in bridging the gap in the early diagnosis during the early neonatal

period, it is the high time that we adopt pulse oxymetry as a routine screening tool in our neonates to preserve many precious lives particularly in low infrastructure.

CONCLUSION

Authors conclude that pulse oximetry is a non-invasive, reliable, and useful screening tool for an early detection of congenital heart diseases especially cyanotic heart diseases which otherwise misses the attention of the pediatrician. In addition to prenatal ultrasonography and routine clinical examination, further screening with pulse oximetry is warranted to improve early detection of CCCD. The combination of pulse oximetry and clinical judgement is needed in many cases.

Pulse oxymetry can be a screening tool for early detection of CCCD, particularly in asymptomatic neonates in places with lack of diagnostic infrastructure, hence, it should be used as a screening method for detection of CCCD.

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