Role of pulse oximetry as a screening tool for detection of critical congenital heart diseases in newborns in Southern India

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ABSTRACT

Background: Timely diagnosis of critical congenital heart disease (CrCHD) is challenging but critical. Although echocardiography is the gold standard for diagnosis of CrCHD, it cannot be used as a screening tool. Pulse oximetry is a non-invasive, cost-effective screening tool, which can be used to detect CrCHDs in newborns. **Objective:** The main objective of the study was to assess the usefulness of pulse oximetry as a screening tool for early detection of CrCHD in otherwise asymptomatic newborns. **Materials and Methods:** This study was a hospital-based prospective observational study carried out at the Department of Paediatrics at a Tertiary Hospital of Southern India over a period of 12 months from January 2016 to December 2016. A total of 1000 asymptomatic newborns of >35 weeks of gestation born in the hospital were enrolled in the study. The screening was considered positive if pulse oximetry saturation (SpO_2) <90% in right hand (RH) or foot (F) or three readings of SpO2 of 90–94% in RH and F or >3% SpO_2 difference between RH and F at three readings. Echocardiography was performed in those with clinical suspicion of CHD and/or positive pulse oximetry screening. **Results:** In the present study, the sensitivity of pulse oximetry for detection of CrCHD was 100% and specificity was 98.5%. **Conclusion:** Pulse oximetry screening is an effective and reliable test which significantly increases the detection rate of CrCHDs compared to the current practice of clinical examination alone as a screening tool. This study reinforces the importance of pulse oximetry screening in newborns.

Key words: *Asymptomatic newborns, Critical congenital heart disease, Pulse oximetry*

Congenital heart disease (CHD) is the most common group of congenital malformations and affects 7–8/1000 newborns [1]. Approximately one-quarter of these children would have critical CHD (CrCHD), which, by definition, requires surgery or catheter intervention in the 1st year of life [2,3]. Timely diagnosis of CrCHD is challenging but critical. Children with such life-threatening defects may not initially show symptoms or they may be vague and the condition is not detected on routine clinical examination in the majority of cases [4]. Delayed or missed diagnosis leads to significant morbidity and mortality.

There is no effective screening tool for the detection of CrCHDs condition. Pre-natal ultrasound, performed by those with specific training in detecting CHD, can identify a variety of CrCHD lesions; however, numerous studies have reported that even when fetal ultrasound is routinely performed during pregnancy, fewer than 50% of cases of CrCHD are identified [5]. Echocardiography (echo) is the gold standard for the detection of CHD. However, it is impractical to use it as a screening tool in all newborns. Pulse oximetry can pick up the desaturation of blood objectively. It has been used to screen for CHD in newborns. It is a non-invasive procedure and has shown high specificity in the detection of CHD [1,6]. The objective of the study was to assess the usefulness of pulse oximetry as a screening tool for early detection of CrCHD in otherwise asymptomatic newborns.

MATERIALS AND METHODS

This study was a hospital-based prospective observational study carried out at the Department of Paediatrics at a Tertiary Hospital of Southern India over a period of 12 months from January 2016 to December 2016. Institutional ethical committee clearance was obtained. A total of 1000 asymptomatic newborns of >35 weeks of gestation were enrolled in the study. All newborns <35 weeks of gestation, all symptomatic newborns, and antenatally detected CHDs were excluded from the study. A pre-designed and pre-tested pro forma was used to collect information. Informed consent was obtained from parents or guardians for the enrolment of their babies in the study. Data related to antenatal risk factors, antenatal scan, gestational age, sex, birth weight were noted and detailed newborn examination was done and documented.

All the babies were clinically examined between 24 and 72 h of life with an emphasis on the peripheral pulse, cyanosis, tachypnea, cardiac pulsations, murmur, and external markers of CHDs (flat

nasal bridge, ear lobe anomalies, pre-auricular tag, hypertelorism, epicanthal folds, polydactyly, syndactyly, clinodactyly, abnormal creases, etc.), and pulse oximetry saturations were documented. Pulse oximetry readings were analyzed as follows:

The screening was considered positive ifSpO_2< 90% in the right hand (RH) or foot (F) at any time, three readings of SpO_2 of 90–94% in RH and F, and >3% SpO_2 difference between RH and F at three readings. The screening was considered negative ifSpO_2 ≥95% in RH or F and ≤3% difference between RH and F (Figure 1). In all suspected cases of CHD, 2D echo was done either by clinical examination or pulse oximetry screening to confirm the presence of CHD.

Data were entered in Microsoft excel sheet. Tests of an association such as kappa and Chi-square test were used for statistical analysis and $p<0.05$ was taken as statistically significant using SPSS software (version 20).

RESULTS

A total of 1000 asymptomatic newborns were screened. The mean time of screening was 36 h of life. The total number of CHDs suspected in the study group was 23. Among which, CHDs suspected using clinical examination alone were 5, by pulse oximetry screenings alone were 12 and 6 had both clinical and pulse oximetry abnormalities. Echo detected CHDs in 19, accounting to 82% of the suspected group and 2% of the total study group. None of the CHDs were detected antenatally. Among newborns with CHDs, the majority were males (13, 68.4%) with male to female ratio of 2:1.

In the present study, 16% (3/19) of newborns with CHDs were CrCHDs, accounting to 0.3% of the study group. CrCHDs detected were transposition of great arteries (TGA), supracardiac total anomalous pulmonary venous connection (TAPVC), and tetralogy of Fallot (TOF). The clinical examination was unremarkable in these newborns. Among 11 clinically suspected CHDs, all had murmur, 2 of them had abnormal respiration, and 3 had an abnormal heart rate. There were no other external markers of CHDs on clinical examination. 2D echo confirmed CHDs in 72% of clinically suspected babies (n= 8/11), accounting for 42% of total CHDs detected in the study (n=8/19).

Pulse oximetry screening was positive in a total of 18 babies, of which CHD was confirmed in 17 babies (94.4%), accounting for 89% of total CHDs (17/19) detected in the study. Clinical examination was unremarkable in all three cases of CrCHDs detected. Pulse oximetry was abnormal in all 3 cases of CrCHDs (100%). The sensitivity of pulse oximetry for detection of CrCHD was 100% and specificity was 98.5% (p=0.000) (Table 1).

DISCUSSION

Early recognition of CHD is important, especially the CrCHDs, as many children with undetected CrCHD die at presentation or before their first surgical intervention. Pulse oximetry has been tried as a screening tool for the early detection of CHD in asymptomatic newborns because the clinical examination alone appears to be insufficient and detection rate by antenatal scan is also low.

In our study, the majority of the newborns (56.6%) were males. The total number of CHDs suspected using clinical examination and/or pulse oximetry screenings was 23. Among them, 2D echo confirmed CHDs in 19, accounting to 82% of the suspected group and 2% of the total study group. None of the CHDs were detected antenatally in our study. Recently, two health technology assessment reports show the detection rate for an antenatal scan to be low [8]. Hence, pre-natal diagnosis should not be overestimated.

In the present study, 16% (3/19) of newborns with CHDs were CrCHDs (TAPVC, TOF, and TGA), accounting to 0.3% of the study group. Only 72% of babies with murmur had CHDs and none of the babies with CrCHD had any murmur. A study by Ainsworth *et al*. showed that about 54% of babies with murmur on routine newborn examination had CHD [9]. In a study by Arlettaz *et al*., 73% of babies with CHD had murmur [10]. Out of them, only 35% of cyanotic CHD presented with a murmur. These results show that routine newborn examination is important, but yet not sufficient to detect all CHDs. This also proves that the presence of a murmur does not correlate well with the severity of the lesion. In our study, the sensitivity of pulse oximetry for

Table 1: Association of positive pulse oximetry screening with critical congenital heart disease detection

SpO_2	CrCHD		Total
	Present	Absent	
<95%	3	15	18
>95%	0	982	982
Total	3	997	1000

p=0.000(significant), sensitivity 100%, specificity 98.5%, PPV-16.67%. PPVC: Positive predictive value

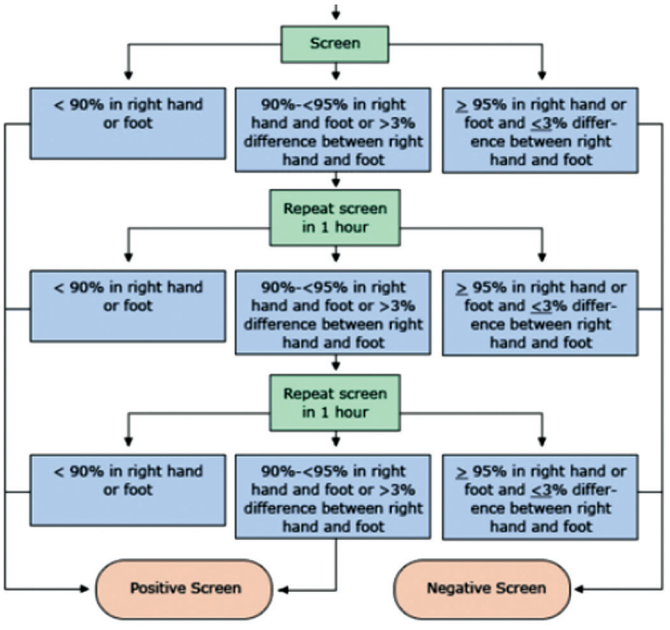

Figure 1: Pulse oximetry screening algorithm [7]

Table 2: Comparison of sensitivity, specificity, and PPV of various studies in the detection of CrCHDs

Study	Sample Size	Time (h)	Site	Cut off (%)	Sensitivity (%)	Specificity (%)	PPV
de-Wahl Granelli *et al*. [5]	39821	>24	RH&F	≥95	65.5	99.8	NA
Ewer *et al*. [11]	20055	<24	RH&F	≥95	75	99.1	84.9
Bakr *et al*. [12]	5211	31.7	RH&F	≥94	60	99.9	75
Nuntnarumit *et al*. [13]	10603	>24	RH&F	≥95	82.3 and 100	99.9	-
Hoke *et al*. [14]	2876	<24	RH&F	≥92	100	100	75
Taksande *et al*. [15]	4926	<4	RH&F	≥90	90	99.9	75
Saxena *et al.* [16]	19009	<24	RH&F	≥95	84.6	68.3	-
Present study	1000	24-72	RH&F	≥95	100	98.5	16.7

RH: Right hand, F: Foot, PPV: Positive predictive value

detection of CrCHD was 100%, specificity was 98.5% which was similar to studies by Hoke *et al*. [14] and Taksande *et al*. [15].

Our findings showed that pulse oximetry was a highly specific test for the detection of CrCHDs in asymptomatic newborns. Similar observations were made in various studies, as shown in Table 2, except in the study by Saxena *et al*., where the specificity was only 68.3% [16]. The reason given was the high prevalence of infection and respiratory issues in their cohort.

The sensitivity ranged from 60% to 100% and positive predictive value from 16.7% to 87.5% in various studies (Table 2) and also in other studies using single post-ductal values [17-19]. The factors which influenced this wide range of sensitivity were timing and repetition of pulse oximetry after initial low readings. In addition to these, the definitions of the severity of CHDs varied in different published works. The terms such as major, critical, severe, complex, and serious CHDs were used. We used the term CrCHDs for those who required surgery or catheter intervention in the 1st year of life [2,3]. The clinical examination was unremarkable in these newborns. Corrective surgeries were done for these children on days 4, 21, and 8 months, respectively. All three infants were thriving well on follow-up at 1 year.

The study had a few limitations. It was a single-center study. The echo could not be done for the complete study sample, which would have reflected the true incidence of CHDs and hence, define the real value of pulse oximetry screening in all newborns.

CONCLUSION

Pulse oximetry screening is an effective and reliable test which significantly increases the detection rate of CrCHDs compared to the current practice of clinical examination alone as a screening tool. As this is a simple, non-invasive, and inexpensive technique, it is worth considering as a part of routine newborn screening in developing countries.

AUTHORS' CONTRIBUTIONS

Swathi P M-Data collection, compilation, and analysis.
Pushpalatha K and Udayakumar S: Analysis and Review.

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