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Pulse Oximetry Screening for Detecting Congenital Heart Disease in Neonates – Experience from Tertiary Referral Children's Hospital in South India

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Abstract

Background: Congenital heart disease is the most common type of birth defect in infancy with incidence of 8 to 12 per 1000 live births in India. Pulse oximetry has emerged as a good screening tool in the recent past in many countries being noninvasive and cost effective. This study aimed at estimating the accuracy of pulse oximetry as a standard screening method to detect congenital heart diseases (CHD) in neonates.

Methods: This prospective observational study was conducted in a tertiary referral medical college hospital from December 2018 to June 2020. Pulse oximetry readings were taken of 1603 asymptomatic neonates breathing in room air from right hand and either foot after 24 hours of birth. Pulse oximetry was considered positive if oxygen saturation in room air measured <95% or difference between right hand and foot was more than 3% persistently for 3 readings as per the standard American Academy of Pediatrics algorithm. Neonates with positive pulse oximetry or those with persistent abnormal clinical examination underwent echocardiography.

Results: Of the term neonates (n=1603) screened, incidence of CHD was 0.7 per 1000 live births and critical CHD was 0.3 per 1000 live births. The sensitivity, specificity, positive predictive value, and negative predictive value of pulse oximetry to detect any CHD were 70.6%, 98.8%, 38.7%, and 99.7%, major CHD was found to be 60%, 98.4%, 19.4%, and 99.7%, and critical CHD to be 85.7%, 98.4%, 19.4%, and 99.9%, respectively. Pulse oximetry had significant positive correlation with abnormal clinical examination (R=0.29, p<0.001) and ECHO findings in detecting CHD (R=0.49, p<0.001). Regression model to evaluate whether abnormal clinical examination and positive pulse oximetry are significant predictors of CHD detected by ECHO was statistically significant (R2 =0.34, p value <0.001) and both were significant independent predictors (p<0.001).

Conclusion: Pulse oximetry screening is a useful tool for detecting congenital heart diseases in newborns.

Key Words: Congenital heart disease, Neonate, Pulse oximetry, Screening.

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1- INTRODUCTION

Congenital Heart Disease (CHD) is the leading cause of mortality and morbidity both in developed as well as developing countries. It is the most common type of birth defect in infancy (1). Some infants are born with complex forms of congenital heart defects and need surgery to survive. In some cases, the defect may be mild and goes unnoticed at birth, but is diagnosed later. The incidence of the congenital heart disease in India is 8 to 12 per 1000 live births (2). 25% of the congenital cardiac defects are life threatening and require early interventions (3). It encompasses a broad and diverse range of conditions that manifest from prenatal period to late adulthood.

Congenital heart disease may present with a variety of symptoms ranging from being asymptomatic to those with severe failure that need intensive supportive management. Most babies manifest the illness only when the compensatory mechanism of the body fails. Survival of infants with CHD depends on the severity of the defect, age of diagnosis and the treatment (4).

About 97% of babies born with a non-critical CHD are expected to survive up to one year of age and 95% of these babies survive up to 18 years of age (5). About 75% of babies born with a critical CHD are expected to survive up to one year of age and 69% of these are expected to survive up to 18 years of age (6). The survival rate has also increased with the significant improvement in medical and surgical care. This improved survival rate is the result of early detection and correction of the defects at the optimal time. Various screening methods as well as diagnostic tools have added to such improvements.[7] Echocardiography, prenatal ultrasonography, cardiac MRI, CT angiography, X-ray, and pulse oximetry are the different modalities of screening and diagnostic tools (7, 8). Although newer tools like 2D ECHO and cardiac MRI have a high specificity and sensitivity in detecting the diseases, these investigations are a privilege to only the developed nations due to their higher cost and availability (9). The incidence of heart defects is higher in lower and middle socioeconomic population (10).

In developing nations like India, there is a need for low cost and easily available screening tools to detect heart diseases early in life, which leads to a higher cost benefit ratio and good accuracy. Pulse oximetry has emerged as a good screening tool in the recent past in many countries owing to its feasibility, accuracy, non-invasiveness and specificity; hence the study aimed to estimate the accuracy of pulse oximetry as a standard screening method to detect congenital heart diseases in neonates.

2- MATERIALS AND METHODS

2-1. Sampling and population

This study was conducted in hospitals attached to tertiary level referral medical college hospitals in South India from December 2018 to June 2020. All neonates born in these hospitals were included in the study. Antenatal newborns with detected CHDs were excluded. Informed consent was taken from parents prior to enrolment. Institutional ethical committee approval was taken before commencing the study.

2-2. Procedure

Enrolled neonates were examined by a resident doctor. Examination was considered as abnormal and suggestive of CHD if neonates had central cyanosis, tachypnea (RR >60/min), intercostal retractions, precordial pulsations, poor femoral pulses, hepatomegaly, or murmur (9). Neonates breathing in room air were evaluated through measuring oxygen saturation by pulse oximeter (BPL Excello oximeter, BPL Medical Technology Inc,

India) after 24 hours of birth from right hand and either foot. Once stable signals were obtained, the recordings were noted. Pulse oximetry readings were analyzed as follows:

Pulse oximetry was considered positive if the oxygen saturation at room air was measured as <95% or there was more than 3% difference between right hand and foot. Neonates with positive pulse oximetry were screened one hour later and were considered positive only if the abnormality persisted on two more consecutive attempts. Saturation of ≥ 95 % in the right hand and foot, and ≤ 3% difference between the two sites was considered negative (11). All neonates with <95% were subjected to emergency echo-cardiography (GE Vivid S6). ECHO was done on all neonates with positive pulse oximetry and amongst neonates with negative pulse oximetry in those who had persistent abnormal clinical examination. Echocardiography (ECHO) was performed by a trained cardiologist, blinded to clinical examination findings and pulse oximetry results. In our study, major CHD was defined as any CHD that was likely to require intervention within the first year of life and critical CHD was defined as any CHD that was likely to require an intervention within the first 28 days of life.

2-3. Data analysis

Data was analyzed using SPSS version 21 (USA Inc). Student-t test was used for continuous variables and Chi-square test for comparing proportions. Sensitivity, specificity, positive and negative predictive value of pulse oximetry in detecting cyanotic heart disease in sick neonates were calculated. In view of skewed distribution of the variables, Spearman correlation was done to find correlations among pulse oximetry, abnormal clinical examination, and CHD detected by ECHO.

3- RESULTS

During the study period from December 2018 to June 2020, there were 2160 live births of which 1603 were eligible for the study. Study flow is depicted in **Fig 1.** In the study population, prevalence of CHD was 0.7 per 1000 live births and critical CHD was 0.3 per 1000 live births. Baseline characteristics of the study population is given in **Table 1**.

Table-1: Comparison of baseline characteristics

Characteristics	Positive pulse oximetry (n=31)	Negative pulse oximetry (n=1572)
Male*	19(61)	890(57)
Birth weight (kg)[#]	2.46(± 0.54)	2.38(±0.56)
Gestational age (wk)[#]	38(±1.8)	37(± 2.2)
Clinical signs*		
Tachycardia >160/min	29(93)	17(10)
Tachypnea >60/min	25(80)	17(10)
Central cyanosis	14(45)	0
Murmur	2(6)	14(8)
Feeble peripheral pulses	1(3)	4(2)

*** n (%),** [#] Mean ±SD

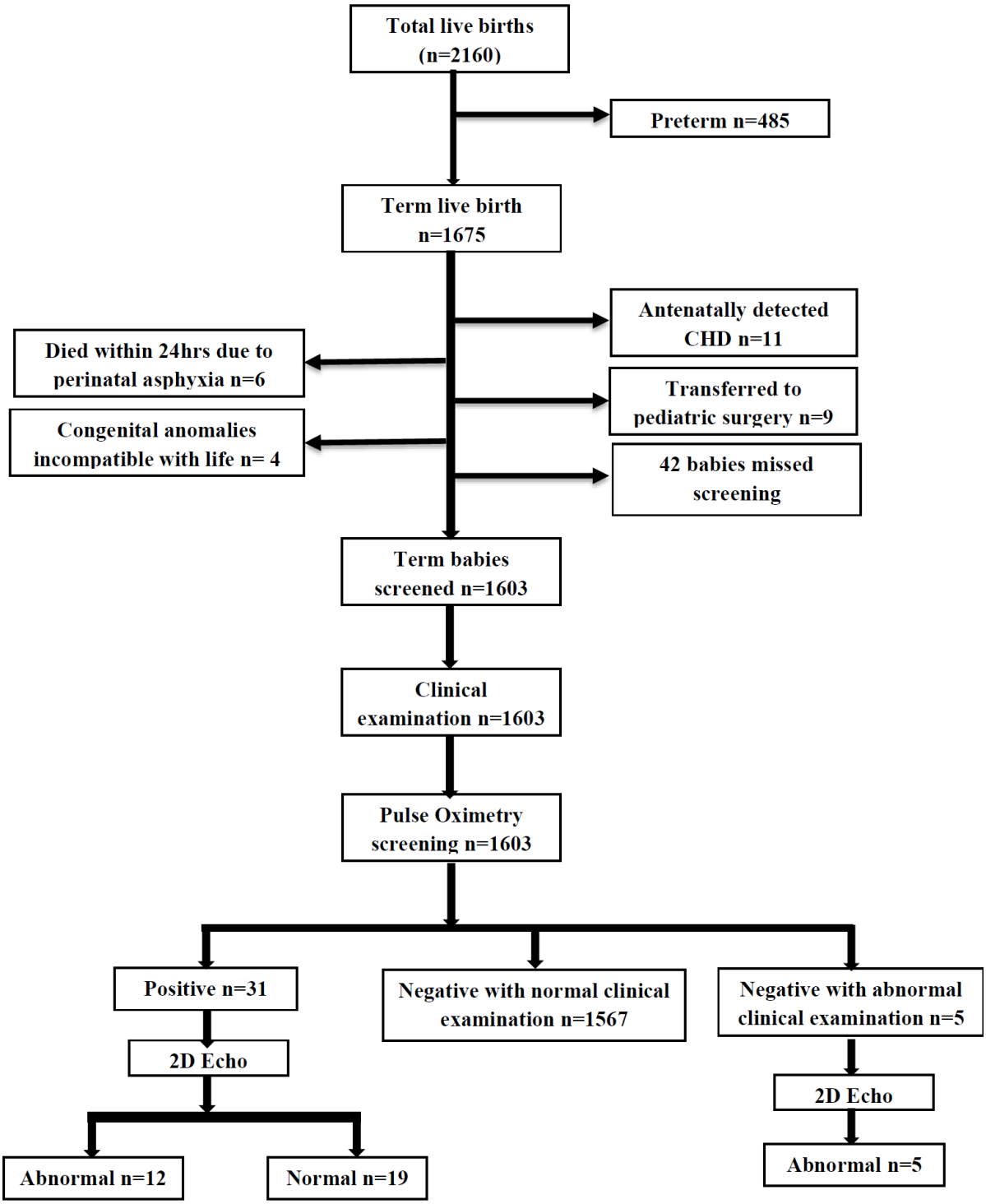


Fig. 1: Flow of participants in the study

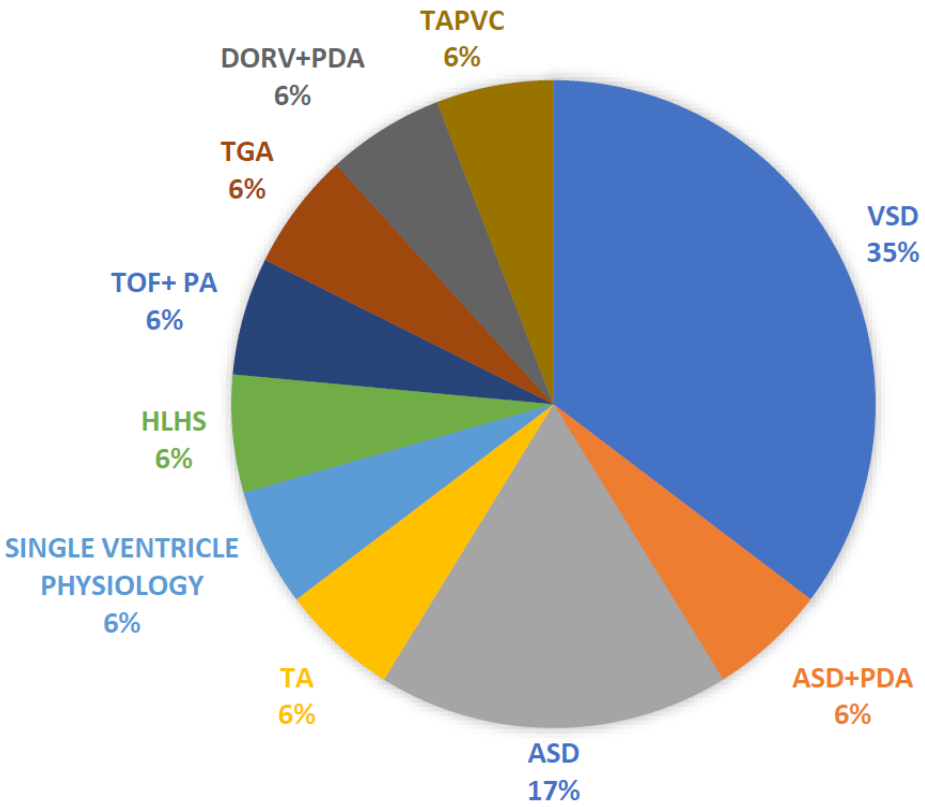
The sensitivity, specificity, positive predictive value and negative predictive values of pulse oximetry to detect any CHD were 70.6%, 98.8%, 38.7% and 99.7%, those of major CHD were 60%, 98.4%,19.4% and those of 99.7%, critical CHD were 85.7%, 98.4%, 19.4% and 99.9%, respectively, as shown in **Table 2**. Pulse oximetry had a significant positive correlation with abnormal clinical

examination (R=0.29, p<0.001) and ECHO findings detecting CHD (R=0.49, p<0.001). The different CHDs detected are depicted in **Fig 2**.

Table-2: Sensitivity, Specificity and Predictive accuracy of Pulse Oximetry

Variable	TOTAL CHD@		MAJOR CHD		CRITICAL CHD	
Pulse oximetry	2DECHO		2D ECHO		2D ECHO	
	YES	NO	YES	NO	YES	NO
Positive	12	19	6	25	6	25
Negative	5	1567	4	1568	1	1571
Sensitivity	70.60%		60%		85.70%	
Specificity	98.80%		98.40%		98.40%	
PPV*	38.70%		19.40%		19.40%	
NPV#	99.70%		99.70%		99.90%	

@CHD: Congenital heart disease *PPV: Positive predictive value #NPV: Negative predictive value



VSD: Ventricular septal defect, ASD: Atrial septal defect, PDA: Patent ductus arteriosus, TA: Tricuspid atresia

HLHS: Hypoplastic left heart syndrome, TOF: Tetralogy of Fallot, TGA: Transposition of great arteries, DORV: Double outlet right ventricle, TAPVC: Total anomalous pulmonary venous circulation

Fig. 2: Distribution of CHD in the study population

Regression model was used to evaluate whether abnormal clinical examination and positive pulse oximetry are significant predictors of CHD detected by ECHO; and it led to statistically significant results R^2 0.36, f=2(df-3,1468) ($p<0.001$). Both were, thus, significant independent predictors with beta coefficients of 0.26 and 0.38, respectively, and with p values of <0.001.

4- DISCUSSION

In the present study, the majority of congenital heart diseases with different hemodynamics were detected using pulse oximetry screens. The sensitivity and negative predictive values of pulse oximetry screening to detect major heart disease and critical congenital heart disease were high. Many studies done in well infant nurseries have used the saturation cut-off of less than 95% for positive pulse oximetry (12-14).

The prevalence of CHD was 0.7 per 1000 live births and critical CHD was 0.3 per 1000 live births which is similar as reported by Indian studies (2, 3, 10).

A study conducted by Nandakishor Palve et al. (15), showed sensitivity, specificity, and negative predictive values of 100%, 99.9% and 100%, respectively for detection of critical CHD in newborns which is comparable to our study. Another study by Caiju Du et al. (16), showed diagnostic sensitivity and specificity values of 69% and 99%, respectively, which is similar to the values found in our study. Thus, implying pulse oximetry screening may serve as a valuable diagnostic tool with high accuracy for CHD. Gopalkrishnan et al. (17) also showed that sensitivity, specificity, positive and negative predictive values of pulse oximetry screening for detection of critical CHDs in asymptomatic neonates were 75%, 99.29%, 18.75%, and 99.94%, respectively, confirming that pulse oximetry screening of asymptomatic neonates improved the detection of CHDs. Yohen et al. reported high sensitivity of 85.7 % to detect any CHD (13). A cochrane meta-analysis by Plana et al. confirmed Pulse oximetry as a tool with high specificity and moderate sensitivity with low false positivity (18).

Our study showed that Pulse oximetry had significant positive correlations with abnormal clinical examination (R=0.29, $p<0.001$) and ECHO findings detecting CHD. Regression model also confirmed that abnormal clinical examination and positive pulse oximetry are significant predictors of CHD. Studies by Gunarathne[19] and Albuquerque[20] have shown that detection of critical CHD by Pulse oximetry screening is better than physical examination alone and both combined could detect all the critical CHD cases.

4-1. Strengths and limitations of the study

Strengths of the study include good sample size and cost effectiveness, along with a reliable and pragmatic design. The limitations of study include single centre based enrolment.

5- CONCLUSION

To conclude, pulse oximetry screening is useful in detecting congenital heart diseases. Negative predictive value of pulse oximetry is high, making it useful to reliably rule out critical congenital heart disease.

5-1. What does this study add?

In a developing country like India, it is the need of the hour to inculcate accurate, feasible, non-invasive, good cost-benefit ratio screening methods to detect congenital heart disease and this study concludes that pulse oximetry screening is very useful in detecting congenital heart diseases in neonates.

6- AUTHORS' CONTRIBUTIONS

MGP conceived the study, planned and designed the study protocol, SKK collected data, ARC contributed to statistical analysis and interpretation, drafted and edited manuscript, SS drafted the manuscript. All authors approved the final manuscript.

7- Conflict of interest

None.

8- FUNDING

None.

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