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A Study On The Screening Of Congenital Heart Disease Using Pulse Oximetry In Asymptomatic Newborns Delivered In Tertiary Care Centre.

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Abstract:
Introduction: Congenital Heart Disease is the most common congenital abnormality in newborns and has been recognized as one of the leading causes of death in the first year of life. The global incidence of CHD is estimated at 8 per 1000 live births. Using pulse oximetry critical and many of the asymptomatic CHD can be identified in the immediate post natal period. This strategy will help in early identification and its intervention.
Objective: To assess the effectiveness of pulse oximetry as a screening tool for detection of CHD in asymptomatic newborn.
Methods: It was a Hospital based Cross sectional study conducted in the Department of Obstetrics and Gynaecology, in collaboration with the Department of Paediatrics, of a tertiary hospital in North Eastern State from May 2022 to April 2024.
Results: The mean birth weights of the neonates were2.93±0.29 Kg and the mean gestational age was 37.74±1.56 weeks. 4% of all neonates screened with pulse oximetry showed positive result. Among them 4 (2%) neonate were diagnosed with CHD. Out of the 4 neonates diagnosed with CHD, 3 were diagnosed with VSD and 1 with PDA.
Conclusion: Eight (8) i.e 4% of the neonates were screened with positive pulse oximetry and out of which four (4) were diagnosed with CHD. Proportion of neonates who were screened positive in pulse oximetry with positive echocardiographic findings were significantly higher than those who screened negative (p value <0.001). Therefore, the pulse oximetry screening for detection of CHD among asymptomatic neonates in our study showed a moderate sensitivity (75%), high specificity (97.4%) and negative predictive value (99.47%) and a reasonably low positive predictive value (37.5%), respectively.
Keywords:*Pulse oximetry, screening test, newborn, congenital heart disease.*

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I. Introduction

Congenital heart disease (CHD) is a structural abnormality in the heart or intrathoracic major blood vessel that is present at birth.[1] CHD is the most common congenital abnormality in newborns and has been recognized as one of the leading causes of death in the first year of life. The global incidence of CHD is estimated at 8 per 1000 live births.[2] The causes of CHD are multifactorial, involving genetic susceptibility and environmental factors. Maternal diabetes, rubella infection, alcohol, Down syndrome, Noonan syndrome, and phenylketonuria are some of the known etiologies of CHD. However, about 90% of CHD can occur without an underlying cause.[3]

Current routine screening methods for identifying babies with CHD include the newborn physical examination and antenatal anomaly ultrasound scanning, however both methods have relatively low detection rates. In one UK study, 15% of infants with CHDs who died before 12 months of age had a CHD that was undiagnosed prior to death.[4] Failure to diagnose a critical CHD prior to discharge from hospital occurred in up to 26% of infants in Swedish over an 8-year period, with an increase in infants discharged without diagnosis over the study period.[5] In UK studies, 25–30% of infants with potentially life-threatening conditions[6] and almost 80% of infants with obstructive left heart defects (the main causes of death from an undiagnosed CHD after discharge and before diagnosis) left hospital undiagnosed.[7] Similar data have been reported in the USA; 1 in 10 infants with a CHD dying in the first year of life did not have the malformation diagnosed before death and, of the infants who died in the first week of life, one-quarter did not have a diagnosis before death.[8] Death at home or in hospital emergency rooms occurred in 50% of infants with undetected critical CHDs.[9]

Although, prenatal sonograms can often identify structural heart disease; however, the sensitivity of CHD detection is highly variable, depending on operator expertise, gestational age, fetal position, and the type of cardiac defect. As a result, prenatal sonography will miss some patients with critical CHD and is known to miss many newborns with simple CHD. Newborns who might benefit from early treatment can often be identified in their first days of life through pulse oximetry screening—a painless, readily available noninvasive examination that is easy to incorporate into newborn assessments.[10]In recent years this practice has been widely introduced in various jurisdictions as it became evident that the number of late diagnosed infants can be reduced significantly when pulse oximetry is used in conjunction with other screening strategies.[11]The underlying principle is the ability of pulse oximetry in detecting clinically inapparent cyanosis. In many of the developed countries, the pulse oximetry screening among asymptomatic neonates for detection of critical congenital heart defects (CCHD) before discharge from hospital is being done universally.[12,13,14]

Although there is enough evidence for the routine use of pulse oximetry screening of CHD in many parts of the world, the situation in India regarding universal implementation of pulse oximetry screening is complex and needs deliberation.[15]

Considering the deficiency of manpower and facilities in terms of pediatric cardiac care facilities in our region and the cost of treatment, where many families are unable to afford healthcare outside of the region, the need for a cost-effective and simple screening test that can be conducted on all newborns after 24 hours of birth for the detection of CHDs as early as possible is vital. Therefore, keeping this background in mind, the present study was done to assess the effectiveness of pulse oximetry as a screening tool for detection of CHD in newborn infants.

II. **Method**

Hospital based cross sectional study conducted in the Department of Obstetrics and Gynaecology, in collaboration with the Department of Paediatrics. The study duration was for two calendar years from May 2022 to April 2024.

Inclusion criteria:
Healthy asymptomatic babies delivered in Department of Obstetrics and Gynaecology at>35 weeks of gestation

Exclusion criteria:
Antenatally diagnosed congenital heart disease
Newborns with congenital anomalies
Parents/Legal guardians not willing to give consent

Sample Size: Using the findings from a study by Gopalakrishnan S et al[15], where they found Sensitivity and Specificity to be 75% and 99% respectively and prevalence of CHD at 0.36%. Our calculated sample size (N) for the study was 200, using Buderer's formula at 10% precision and 95% Confidence Interval.

Buderer's Formula:
N for Sensitivity = $Z^2_{1-\alpha/2} \times S_N \times (1-S_N) / L^2 \times$ Prevalence
N for Specificity = $Z^2_{1-\alpha/2} \times S_P \times (1-S_P) / L^2 \times (1-\text{Prevalence})$
Sampling: 200Consecutive newborns in the Post-Natal Ward of Obstetrics and Gynaecology Department, who fulfilled the inclusion and exclusion criteria, were recruited for the study till sample size was reached.

Operational Definition:

A positive pulse oximetry screen was defined as an SpO2 < 90% in either the right hand or foot or an SpO2 between 90% and 94% in either site or a >3% difference between the two sites (repeated twice at 1-h intervals)

A negative pulse oximetry screen was defined as a SpO2≥95% in the right hand or foot and two sites and ≤3% difference between the two sites.

Procedure and data collection: As part of the screening, all asymptomatic neonates roomed-in with the mother were screened after 24h, 36h and 48h of life with a pulse oximeter after obtaining approval from the Research Ethics Board. At the time of screening the neonates were awake and calm or breastfeeding. The pulse oximetry screening was carried out twice a day in the morning and evening shifts. The SpO2 reading was recorded once a stable waveform was displayed on the monitor and the neonate who had a positive screen underwent a thorough clinical examination and a confirmatory 2D echocardiography.

Statistical Analysis: Data was collected using the pre-designed proforma. It was checked for consistency and completeness and then entered in IBM SPSS version 21 for Windows (IBM Corp. 1995, 2012). The data was analyzed and summarized using descriptive statistics like percentages, mean and standard deviation. Test accuracy using 2D echocardiography as the gold standard was studied using sensitivity, specificity, positive and negative predictive value. A p value of <0.05 was considered statistically significant.

III. **Results**

In this study, two hundred (200) neonates from the postnatal ward of the Department of Obstetrics and Gynaecology who fulfilled the inclusion and exclusion criteria were evaluated. The mean birth weights of the neonates were 2.93±0.29 Kg and the mean gestational age was 37.74±1.56 weeks (Table 1).4% of all neonates screened with pulse oximetry showed positive result and 96% showed negative pulse oximetry screen (Table 2). Only 4 (2%) neonate with positive pulse oximetry screening were diagnosed with CHD in this study (Figure 1). Out of the 4 neonates diagnosed with CHD, 3 were diagnosed with ventricular septal defect (VSD) and 1 with patent ductus arteriosus (PDA) (Figure 2). Proportion of neonates who were screened positive in pulse oximetry with positive echocardiographic findings were significantly higher than those who screened negative (p value <0.001) (Table 3). The sensitivity, specificity, positive predictive value and negative predictive value of pulse oximetry screening in the detection of CHD in asymptomatic neonates was 75%, 97.4%, 37.5% and 99.47% respectively (Table 4).

IV. **Discussion**

Congenital heart disease (CHD) causes significant morbidity in the neonatal population, comprising 24% of all birth defects, and is behind early infancy death rates.[16] Pulse oximetry has been utilised as a screening tool for the detection of congenital heart defects in newborn infants for more than a decade. Newborns that might benefit from early treatment can often be identified in their first days of life through pulse oximetry screening—a painless, readily available noninvasive examination that is easy to incorporate into newborn assessments.[10]The present study was done to assess the effectiveness of pulse oximetry as a screening tool for detection of CHD in newborn infants.

In the present study, two hundred neonates from the postnatal ward of the Department of Obstetrics and Gynaecology, who fulfilled the inclusion and exclusion criteria, were evaluated. Eight (8) i.e. 4% of the neonates screened with pulse oximetry showed positive result. Out of the 8 neonates, screened positive with pulse oximetry, 4 (2%) neonates were diagnosed with CHD in this study. 3 neonates were diagnosed with VSD and 1 neonate with PDA. Proportion of neonates who were screened positive with positive echocardiographic findings in pulse oximetry were significantly higher than those who screened negative (p value <0.001). Therefore, the pulse oximetry screening for detection of CHD among asymptomatic neonates in our study showed a moderate sensitivity (75%), high specificity (97.4%) and negative predictive value (99.47%) and a reasonably low positive predictive value (37.5%), respectively. These findings are in concordance with reported test accuracy from India[16] as well as meta-analysis reports by Plana MN et al,[17] and in the previous meta-analysis by Thangaratinam et al.[18] The high specificity reflected in our study, signifies the low false positive rate of pulse oximetry test. It also highlights the fact that a low pulse oximetry reading in asymptomatic newborns ‘‘rules in’’ congenital heart disease until proved otherwise.[18]

One of the strengths of our study is that it was a prospective study of healthy neonates using the Masimo motion-tolerant pulse oximeter which has the ability to read the pulse waveform in low perfusion states. Secondly, we used the standard algorithm for detection as endorsed by American Academy of Paediatrics (AAP) and American Heart Association (AHA) and screening was carried out as recommended. Also, the gold standard for positive pulse oximetry screen results was a 2D echocardiography performed by experienced pediatric cardiologist in the hospital. Clinical follow up for neonates with negative pulse oximetry screen results, along with the newly diagnosed CHD patients were also carried out in the pediatric cardiology OPD.

Our study is not without limitation in that, it was a hospital based study with a relatively small sample size. Thus, it is the inherent limitation of hospital-based study compared to community-based research. Another limitation of the study was that it was conducted in only one centre, necessitating the need for multicentre screening for more robust results.

To conclude, the results of the present study strongly indicates that pulse oximetry screening is an accurate and specific tool for detecting CHDs in clinically normal newborns. Pulse oximetry is a rapid, noninvasive, easily accessible and acceptable screening tool for detecting CHDs in asymptomatic newborns. Thus, in a resource-limited environment, pulse oximetry screening for CHD may contribute to its early diagnosis. We recommend that pulse oximetry screening should be included in the routine newborn examination at all nurseries. In addition, since CHD in the general population is a rare outcome we recommend larger and well-conducted studies to confirm the value of pulse oximetry as a screening test, in isolation or in combination with clinical examination to obtain precise estimates of its sensitivity.

Tables & Figures

Table 1. Distribution Of Respondents According To Birth Weight And Gestation (N=200)

Variables	Range	Mean ±SD)
Birth Weight (In Kg)	2.3 - 3.5	2.93±0.29
Gestational Age (In Weeks)	35 - 41	37.74±1.56

Table 2. Distribution Of Respondents According To Pulse Oximetry (N=200)

Pulse Oximetry Findings	Frequency (N)	Percentage (%)
Positive	8	4%
Negative	192	96%

Table 3. Association Of Pulse Oximetry Screening And Echocardiographic Findings (N=200)

Pulse Oximetry Screening	Echocardiographic Findings		P Value
	Positive	Negative	
Positive	3 (75%)	5 (2.6%)	***<0.001****
Negative	1 (25%)	191 (97.4%)	

***Fishers Exact Test**

Table 4. Accuracy Of Pulse Oximetry In Detection Of CHD

Accuracy Of Pulse Oximetry	Formula	Calculation	Diagnostic Accuracy
Sensitivity	$\frac{TP}{TP+FN}$	$\frac{3}{3+1} * 100$	**75%**
Specificity	$\frac{TN}{TN+FP}$	$\frac{191}{191+5} * 100$	**97.4%**
Positive Predictive Value	$\frac{TP}{TP+FP}$	$\frac{3}{3+5} * 100$	**37.5%**
Negative Predictive Value	$\frac{TN}{FN+TN}$	$\frac{191}{191+1} * 100$	**99.47%**

TP = True Positive; TN = True Negative; FP = False Positive; FN = False Negative

Figures & Legends

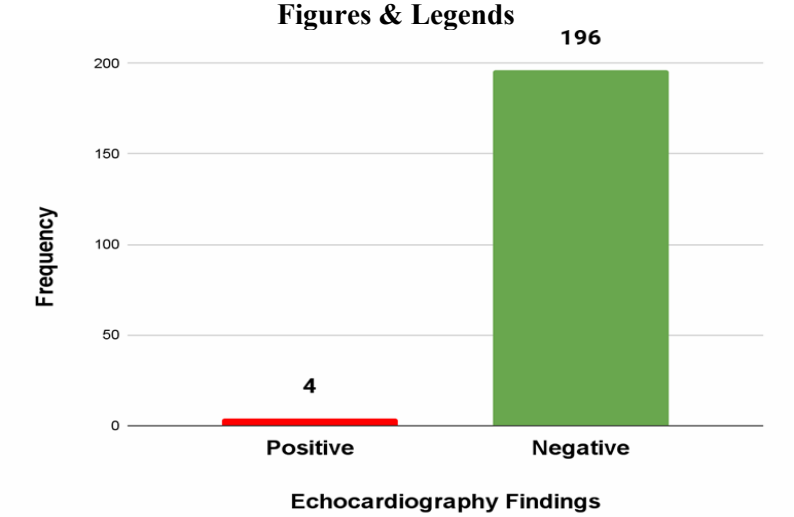

Figure 1. Distribution Of Respondents According To Echocardiography (N=200)

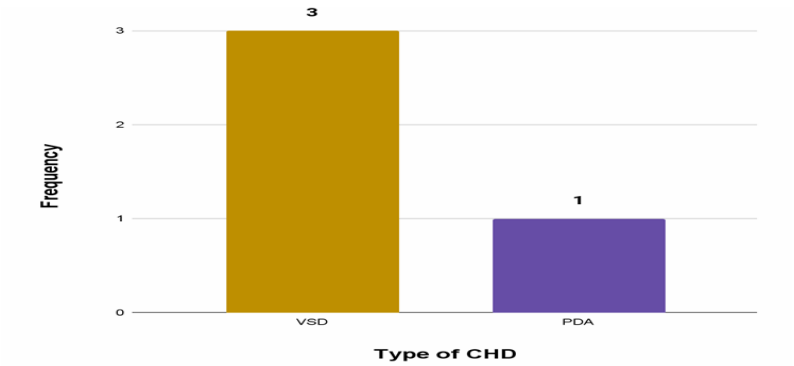

Figure 2. Distribution Of Participants According To types Of CHD (N=200)

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