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Original Article

Paediatrics Section

Neonatal Pulse Oxymetry Screening for Detection of Congenital Heart Disease in Asymptomatic Newborns: A Cross-sectional Study from a Tertiary Care Hospital

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ABSTRACT

Introduction: Screening for Congenital Heart Diseases (CHD) depends on the antenatal ultrasonography and clinical examination of the newborn, however both these methods have low detection rates and often life-threatening congenital heart diseases are missed. Pulse Oximetry (PO) is an easy, accurate, rapid, non invasive method of detecting hypoxaemia. The purpose of using PO to identify Critical Congenital Heart Disease (CCHD) is that clinically non detectable minimal hypoxaemia can be detected by pulseoximetry.

Aim: To study the accuracy of pulse oxymetry as a screening tool for early detection of critical congenital heart diseases in asymptomatic newborns.

Materials and Methods: This cross-sectional study was conducted in the Department of Paediatrics and the Postnatal Ward of Obstetrics and Gynaecology at Sri Venkateswara Medical College, Tirupathi, Andhra Pradesh, India, from January 2017 to December 2020. All the term asymptomatic newborns of age more than 24 hours were screened using PO. Screening was positive if a: PO was <90% in right hand or foot at any stage of screening, b was 90% to <95% on both; there was >3% absolute difference in oxygen saturation between the right hand and foot on three consecutive measures (each separated by one hour). All the screen positive babies were subjected to 2D echocardiography. All statistical analyses were performed using OpenEpi website epicalculator, and Chi-square's test was used to calculate the p-value.

Results: The mean gestational age (weeks) was 38±4 days. Out of 14,400, PO screening was positive in 45 babies, and subsequent echocardiography detected CHD in 30 babies. The sensitivity was 66.67%, positive predictive value was 66.67%, negative predictive value was 99.90%, with a diagnostic accuracy of 99.79%. On 2D electrocardiography, 30 were true positive cases, whereas, false positives and false negatives were 15 each. Remaining 14340 newborns were true negatives.

Conclusion: Pulse oximetry is a safe, accessible, feasible test that can be used for early detection of CCHD's that are often undetected on antenatal ultrasonography.

Keywords: Critical congenital heart disease, Echocardiography, Hypoxaemia, Oxygen saturation, Term newborn

INTRODUCTION

Congenital Heart Diseases (CHD) are the most common group of birth anomalies, with a prevalence of around 6 to 11 per 1000 live births [1-3]. They account to 10% of all infant deaths, and 46% of deaths related to congenital anomalies [2,4]. Of those children with CHD, 25% have Critical Congenital Heart Disease (CCHD) [1]. The CCHD is defined as cardiac lesions that require surgery or cardiac catheterization within the first month (or within the first year by different definitions) of life to prevent death or severe end organ damage [5].

Screening strategies to detect congenital heart defects include antenatal ultrasound and physical examination of the newborn baby. Both techniques have a fairly low detection rate for isolated defects and many babies are discharged from hospital before diagnosis [2,3].

Most early deaths due to undiagnosed cardiac malformations occur in babies with obstructions of the left ventricular outflow tract, with majority likely to have appreciable right to left ductal flow at some stage [6]. The diagnosis in these babies is missed as they have no clinically detectable physical signs, depicting the need for formulating a different strategy for early detection of CCHDs. Although healthcare systems and governments worldwide are considering pulse oximetry as a screening strategy for newborn babies, uncertainty exists about false-positive rates and test accuracy. In 2011, the Secretary's Advisory Committee on Heritable Disorders in Newborns and Children (SACHDNC), in collaboration with the American Academy of Pediatrics, the American College of Cardiology Foundation, and the American Heart Association, convened a work group to outline implementation strategies for pulse oximetry screening in newborns for CHD [8]. After reviewing data from existing large studies in Sweden and the United Kingdom, the work group proposed a screening protocol based on results of measurements from the right hand (preductal) and either foot (postductal) [6-8].

Routine clinical examination of newborns lack sensitivity for detecting CHDs [9,10]. Pulse oximetry is an accurate, non invasive test used for quantifying hypoxaemia that has been widely used in many large scale studies as screening tool for detecting CHDs [6-11]. The purpose of the present study was to determine the diagnostic accuracy of pulse oximetry for early detection of CCHD in asymptomatic term newborns.

MATERIALS AND METHODS

This cross-sectional study was conducted in the Department of Paediatrics and the Postnatal Ward of Obstetrics and Gynaecology at Sri Venkateswara Medical College, Tirupathi, Andhra Pradesh, India, from January 2017 to December 2020. The Institutional Ethics Committee approval was obtained (Letter No. 73/2016, dated 11/10/2016). An informed consent was obtained from parents before initial screening.

Sample size calculation: The sample size was calculated based on the prevalence of CHDs [1-3] and relative precision by using formula [12]: 4 pq/l^2

where, prevalence 9 per 1000 live births and the maximum allowable error as 10.

Inclusion criteria: All the asymptomatic term newborn babies delivered in the study institution were included in this study.

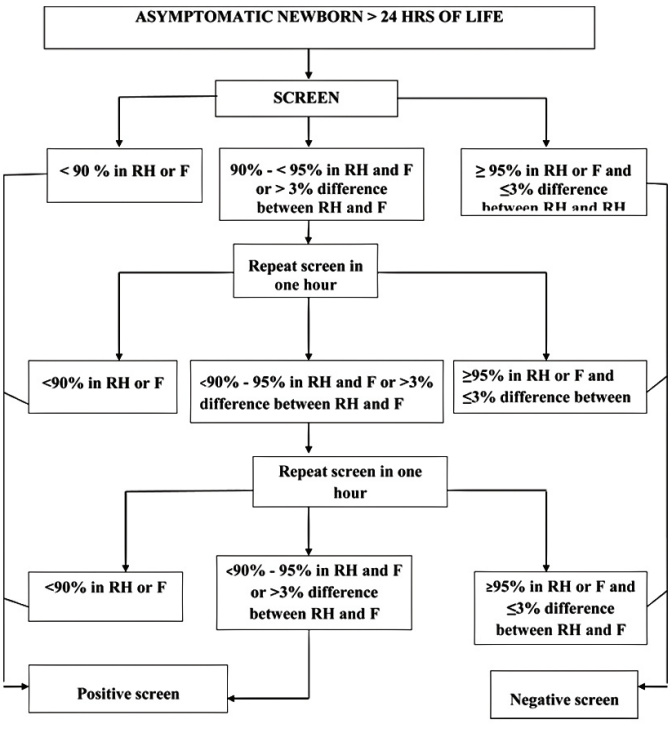
Exclusion criteria: Newborns with respiratory disorders, babies who were antenatally diagnosed with CHDs, premature babies less than 37 weeks of gestation, those who had cardiac signs on examination, and parents who refused to give consent were excluded from this study.

Study Procedure

Pulse oximetry screening was done using motion-tolerant pulse oximeter (masimo SET radical 7) and probes were cleaned with alcohol swab before each use. Pulse oximetry was conducted on a quiet or sleeping newborn and recorded on right upper extremity and either right or left foot of all the asymptomatic newborns who met the inclusion criteria.

- Negative screen- If pulse oximetry was ≥95% in right hand or either foot with ≤3% absolute difference in oxygen saturation between right hand and foot.
- Positive screen-
    a. If pulse oximetry was <90% in right hand or foot at any stage of screening,
    b. If pulse oximetry was 90% to <95% on both,
    c. If there was >3% absolute difference in oxygen saturation between the right hand and foot on three consecutive measures each separated by one hour.

All the newborns tested positive were subjected to 2D echocardiography to confirm the cardiac disease [Table/Fig-1] [13].



[Table/Fig-1]: Screening protocol based on the results of Right Hand (RH) and Foot (F) [13].

STATISTICAL ANALYSIS

All statistical analyses were performed using OpenEpi website epicalculator, and Chi-square's test was used to find p-value. Collected data was analysed for specificity, sensitivity, 95% confidence interval, diagnostic accuracy, prevalence of CHD's, positive and negative predictive values. Statistical significance was defined as p-value <0.05.

RESULTS

Out of 28,800 live newborns delivered in the Maternity Ward, 9840 preterm newborns were excluded and out of 18,960 term newborns, 4560 term newborns were excluded due to early discharge, who had respiratory distress, antenatally diagnosed CHDs, parents not giving consent, insufficient data and who underwent pulseoximetry but refused for 2D echocardiography. A total of 14,400 asymptomatic term newborns who met the inclusion criteria were screened by pulse oximetry. Mean gestational age (weeks) was 38±4 days, and male to female ratio was 1.2:1 [Table/Fig-2]. Among 14,400 newborns screened, 30 newborns were true positive (both 2D echocardiograpy and pulse oximetry positive), 15 were false positive (2D echocardiograpy negative and pulse oximetry positive), 15 were false negative (2D echocardiography positive and pulse oximetry negative) and remaining 14340 were true negatives (p-value <0.001). Pulse oximetry positive rate was 0.31%, with a true positive rate of 0.20%, false positive rate of 0.10%, and false negative rate of 0.10%. All the 15 false negative babies were detected to have small Ventricular Septal Defect (VSD), on echocardiography [Table/Fig-3].

Characteristics	Total screened newborns	Newborns with heart disease
Gestational age in weeks (mean)	38±4 days	37±6 days
Birth weight, in grams	2800	2600
Gender		
Male	7903	20
Female	6497	10
Type of delivery		
Normal vaginal delivery	6765	10
Lower section caesarean section	7635	20

[Table/Fig-2]: Epidemiological parameters of screened newborn (n=14,400).

Test	Disease present (n)	Disease absent (n)
Positive	True positive (30)	False positive (15)
Negative	False negative (15)	True negative (14340)

[Table/Fig-3]: Results of pulseoximetry screen (considering 2D echocardiograpy as standard).

Among 14,400 asymptomatic newborns screened, 12.7% newborns had family history of consanguinity. About 15 out of 45 newborns with CHD had family history of consanguinity accounting for 33.33%.

Specificity of pulse oximetry screening was 99.90%, sensitivity was 66.67%, positive predictive value was 66.67%, negative predictive value was 99.90% with a diagnostic accuracy of 99.79%. Prevalence of CHD in asymptomatic term new borns was 0.3% [Table/Fig-4,5].

Type of CHD	No. of cases
Mild PS + VSD	15 (0.1%)
TGA	15 (0.1%)
Small VSD	15 (0.1%)
Total	45 (0.31%)

[Table/Fig-4]: Type of Congenital Heart Diseases among screened newborns (N=14,400).
PS: Pulmonary stenosis; VSD: Ventricular septal defect; TGA: Transposition of great arteries

Statistics	Value	95% CI
Sensitivity	66.67%	41.71%-84.82%
Specificity	99.90%	99.76%-99.96%
Disease prevalence	0.31%	0.22%-1.30%
Positive predictive value	66.67%	41.71%-84.82%
Negative predictive value	99.90%	99.76%-99.96%
Diagnostic accuracy	99.79%	99.62%-99.89%

[Table/Fig-5]: Analysis of pulse oximetry screening test results.

DISCUSSION

Congenital heart defects are the foremost common group of congenital malformations. Early detection of major congenital heart defects (i.e., those resulting in death or requiring invasive intervention before 1 year of age) might improve the end result of newborn babies. Improvement with early detection is especially true for critical, duct-dependent lesions during which closure of the ductus arteriosus can result in acute cardiovascular collapse, acidosis, and death [14].

Among 14,400 newborns screened 1830 babies (12.7%) had history of consanguinity, 15 out of 45 newborns with CHD's had history of consanguinity (33.33%). The sensitivity of pulse oximetry in screening CHD in asymptomatic term newborns was 66.67%, positive predictive value was 66.67%, with adiagnostic accuracy of 99.79%. All the 15 false negative babies were found to have small ventricular septal defect. In the present study, the pulse oxymetry screening had low sensitivity, as half of the babies with CHDs were noncritical,and also low false positivity was seen as measurements were recorded in term babies after 24 hours of life.

Koppel RI et al., performed pulse oximetry screening for identifying critical CHD by one-time measurement of postductal saturation (saturation <95% at >24 hours) on all asymptomatic newborns (n=11,281) in the well-infant nurseries of two participating hospitals in New Hyde Park, New York. This study concluded 60% sensitivity; 99.95% specificity; 75% positive predictive value, 99.98% negative predictive value, and accuracy of 99.97%. These results were comparable with the present study [14].

Mahle WT et al., conducted a systematic review of the literature about current screening methods for CCHD, burden of missed and/or delayed diagnosis of CCHD, rationale of oximetry screening, and clinical studies of oximetry inotherwise asymptomatic newborn. The analysis of pooled studies performed after 24 hours of life showed the estimated sensitivity was 69.6%, and the positive predictive value was 47.0%; however, sensitivity varied widely from 0% to 100%. False-positive screens were seen in 0.035% [5].

Saxena A et al., did cross-sectional observational study on a cohort of 19,009 babies. Sensitivity of pulse oximetry for identification of CHD was 47.2% (95% CI 39.6% to 54.9%). The sensitivity of clinical assessment for identification of CHD was 25.2% (95% CI 19.1% to 32.4%). The combination of pulse oximetry andclinical assessment enhanced the sensitivity to 65.4% (95% CI 57.7% to 72.4%) and this was statistically more significant when compared to pulse oximetry screening alone (p-value <0.01) or performingclinical assessment alone (p-value <0.01). The specificities for oximetry, clinical assessment and for both combined were 68.3% (95% CI 67.7% to 69%), 97.3% (95% CI 97.1% to 97.6%) , 66.7% (95% CI 66% to 67.4%) respectively. Sensitivity of this study ishigher than the present study, as the combination of physical examination and pulse oximetry screening had added benefits [11].

Ruangritnamchaiet C et al., conducted pulse oximetry on 1,847 clinically normal newborns at 24-48 hours of age at Synphaet Hospital, Bangkok and a SpO_2 value below 95% was considered positive.In this study,the sensitivity was 100%, the specificity was 99.8%, positive predictive value was 100%, negative predictive value was 100% with a diagnostic accuracy of 99.8% in detecting CCHD. Both sensitivity and positive predictive values of the study is higher than the present study, because only CCHD were considered during analysis (but the specificity and negative predictive values are comparable) [15].

Zhao QM et al., conducted a large scale, prospective, multicentered study in the newbornsof age 6-72 hrs at 18 hospitals in China during the period August 2011 and November 2012. Total 1,22,738 consecutive newborn babies were screened (1,20,707 asymptomatic and 2,031 symptomatic) with 157 critical and 330 major CHD were detected [16]. In the asymptomatic newborns, the sensitivity of pulseoximetry plus physical examination was 93.2% for critical congenital heart disease and 90.2% for major disease. The combination of pulse oximetry and clinical assessment enhanced thesensitivity from 77.4% to 93.2%. The false positive percentage for identification of CCHD was 2.7% (3298 of 120,392) for clinical assessment alone and 0.3% (394 of 120,561) for pulse oximetry screening alone. False positive percentage was 0.1%. Sensitivity of pulse oxymetry screening in this study is more than the present study, but false positive rates of present study is comparable [16].

Taksande AM et al., [17], studied accuracy of pulse oximetry screening for detecting critical congenital heart disease in the newborns at arural hospital of Central India. In this study pulse oximetry screening was performed on 2110 newborns within 4 hours of life. When SpO_2 value of less than 90% was considered positive the pulse oximetry screening had 100% sensitivity, 99.95% specificity, 87.50% positive predictive value, 100% negative predictive value, and when SpO_2 value below 95% was considered positive, the pulse oximetry screening had 100% sensitivity, 95.08% specificity, 6.36% positive predictive value, 100% negative predictive value. The present study had specificity which is comparable to the findings of Taksande AM et al., [17]. The positive predictive value of the present study is high when compared to this study, as the screening was done after 24 hrs in the present study, positive predictive value is higher than the present study when Spo_2 cut-off was taken as less than 90%.

Turska Kmieć A et al., did screening for critical congenital heart defects in 51,908 asymptomaticnewborns. The CCHD was diagnosed solely by pulse oximetry in 15 newborns, which constituted 18.3% of all CCHD; 14 (0.026%) were false positives and four were false negative. The sensitivity of the test was 78.9% and specificity 99.9%. The positive predictive value was 51.7% and negative 99.9% [18]. The sensitivity was higher than the present study due to large sample size and specificity was similar.

Prevalence of CHD in asymptomatic newborns was found to be three in 1000 newborns (0.3% disease prevalence) with 0.34% and 0.23% prevalence seen male and female babies respectively. Male babies had a higher risk of CHD than female babies. SGA babies had high probability of congenital heart disease when compared to AGA babies. The prevalence of CHD in the present study is lower when compared to those by Saxena A et al.,(0.83%), Zhao QM et al., (0.87%),Taksande AM et al.,(2.18%), Ruangritnamchai C et al., (0.58%) [11,15-17]. The reason may be the inclusion of only asymptomatic (both term and preterm) newborns in all these studies.

In the present study, CHDs were detected in 30 babies who were screen positive. Mild pulmonary stenosis with ventricular septal defect was seen in 15 babies, and Transposition of Great Arteries (TGA) was seen in 15 babies.

Limitation(s)

The study was conducted in only one centre and it necessitates the need for multicentre screening.

CONCLUSION(S)

Pulse oximetry is a rapid, non invasive, easily accessible and acceptable screening tool for detecting CHDs in asymptomatic newborns.The results of the present study strongly indicate that pulse oximetry screening is an accurate, sensitive and specific tool for detecting CHDs in clinically normal newborns. The increasing availability of treatment modalities for newborns with major CHDs warrant early detection crucial to reduce mortality and long-term morbidities. Hence, authors recommend pulse oximetry screening should be included in the routine newborn examination at all nurseries.

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