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Research Article

ROLE OF PULSE OXIMETRY SCREENING FOR DETECTION OF CRITICAL CONGENITAL HEART DISEASE IN ASYMPTOMATIC TERM AND NEAR-TERM NEWBORN

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Abstract

Introduction: Pulse oximetry test is an inexpensive, non-invasive, painless test that can be life-saving, particularly in the diagnosis of right to left shunt and critical congenital heart disease. **Objective:** To determine the role of pulse oximetry screening for early diagnosis of CCHD in asymptomatic term and near-term newborn. **Methodology:** This cross-sectional study was carried out in ICMH, Dhaka. Total 1057 healthy term and near-term newborn, age between 24 and 72hourswere screened. If the oxygen saturation measurement<90% in right hand/ foot, and/or oxygen saturation measurement<95% in both extremities on three consecutive measurement, and/or there is a >3% absolute difference in oxygen saturation between the right hand and foot on three consecutive measurement were considered as pulse oximetry screening positive. An echocardiography was done in all neonates. Statistical analysis was done by using SPSS-23 software. **Results:** Among 1057 neonate 43(4.06%) had CHD. Among these 43 neonates 31(72.09%) had screening positive and 12(27.90%) had screening negative. The validity of CHD for screening positive cases was correlated by calculating sensitivity, which was 72.1%, specificity 99.9%, accuracy 98.8%, PPV 96.9% and NPV 98.8%. The validity of critical CHD for screening positive was correlated by calculating sensitivity that was 90.9%, specificity 99.8%, accuracy 99.5%, PPV 93.8% and NPV 99.7%. **Conclusion:** The validity of CHD for screening positive is higher in specificity and show high accuracy. The validity of critical CHD for screening positive reveal high sensitivity, specificity and high accuracy.

Keywords: Pulse oximetry, Critical congenital heart disease, Oxygen saturation, Echocardiography

INTRODUCTION

Any structural abnormality in the heart or intrathoracic major blood vessel that is present at birth, recognized as congenital heart disease (CHD)[1]. CHD is one of the most common congenital abnormalities in newborns and has been recognized as one of the leading causes of death in infancy. The approximate incidence of CHD is 0 .8% of 1000 live birth[2], among them 25% of these defects are critical congenital heart disease[3]. The prevalence of congenital heart disease in Bangladesh is 25/1000 live birth[4]. Physical examination is insufficient to detect all pathologies during birth or hospitalization. The mortality rate of late detection is twice of those detected early[5]. Critical CHD require intervention from very first weeks of life to optimize hemodynamic stability and prevent end-organ dysfunction. Pulse oximetry can detect mild hypoxemia, which is characteristic for many forms of CCHD, and may not be recognized by clinical examination[6]. Pulse oximetry was developed in the early 1970s based on the different absorption spectra between oxygenated and deoxygenated hemoglobin[7]. It is a quick, painless, non-invasive and reliable method used to determine arterial oxygen saturation levels. Pulse oximetry screening may allow detection of infants who have missed by other screening methods before they are discharged from hospital, and give opportunity for any urgent cardiac intervention before the onset of life-threatening cardio respiratory collapse. Eventually it improves child survival, reduces cost and declines childhood mortality. The aim of this study was to determine the reliability of this test by applying it to newborn babies and then performing echocardiography on all those neonates, and to determine the proportion of CHD among asymptomatic term and near term newborn.

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METHODOLOGY

This cross-sectional study was conducted in department of pediatrics and department of obstetrics in Institute of Child and Mother Health (ICMH), Dhaka from July 2020 to June 2021. Healthy term and near term newborn, aged between 24 and 72 hours, born in ICMH obstetrics ward and visited to ICMH neonatal out patient department were enrolled into the study. Babies with prenatal diagnosis of CHD and co-morbidities such as preterm delivery, respiratory distress syndrome, dysmorphic syndromes, multiple congenital anomalies, sepsis, perinatal asphyxia were excluded from the study. Data were collected in pretested structured questionnaire from parents of the selected cases in a face-to-face interview. Prior informed written consent was taken. Medical records including history, physical examination, investigation during birth were reviewed. Oxygen saturation was measured purposively in healthy term and near-term newborns at the postpartum ward, whose age was within 24 to 72 hours before being discharged to home and visited the ICMH pediatric neonatal out patient department for various reasons. Contec CMS60D USA FDA approved pulse oximeter with neonatal soft sensor probe was

used. The probe was initially placed on the right hand and then on either the left or right foot. Oxygen saturation was recorded until the pulse oximetry showed stable waveforms and was recorded for at least 3 minutes. Screening was considered positive if presence of at least one or both of the following

1) Oxygen saturation measurement was <90% in right hand or foot, or
2) Oxygen saturation measurement was <95% in both extremities on three consecutive measurement at one hour interval, or
3) If there was a >3% absolute difference in oxygen saturation between the right hand and foot on three consecutive measurement at one hour interval.

An echocardiography was done in each neonate by a single Pediatric Cardiologist in ICMH to rule out CHD. Data were checked and cleaned before incorporating into statistical software (SPSS -version 23) and analyzed. Descriptive analytical techniques including percentage, mean, SD etc were used. For the validity of study outcome sensitivity, specificity, accuracy, positive predictive value and negative predictive value of CHD and critical CHD in the evaluation of screening positive was calculated.

RESULTS

Among 1057 neonates, 32 were found pulse oximetry screening positive. Among this 32 screening positive neonates 31 were confirmed CHD by echocardiography and among them 30/31 were CCHD. On further echocardiography investigation 12 screening negative neonates were found to have CHD and among them 3/12 were suffering from CCHD.

Table I. Postnatal history of the study neonate (n=43)

Postnatal history	Frequency	Percentage
Temperature		
Normal	31	72.1
High	12	27.9
Heart rate		
Tachycardia present	4	9.3
Absent	39	90.7
Respiratory rate		
Tachypnoea present	2	4.7
Absent	41	95.3
Murmur		
ESM	1	2.3
PSM	10	23.3
Others	14	32.6
No	18	41.9
Length (cm)		
<50	30	69.8
≥50	13	30.2
Occipitofrontal circumference (cm)		
<35	25	58.1
≥35	18	41.9

Table II. Oxygen Saturation level of the study neonates (n=32), who are screening positive

Oxygen Saturation Level	Frequency	Percentage
Right hand		
<90	6	18.75
90-95	26	81.25
Mean±SD	92.5±2.7	
Lower limb		
<90	7	21.88
90-95	25	78.13
Mean±SD	92.1±2.9	

So final analysis was done on this 43 (32+12) neonates with CHD. Most of the studied neonates that is 30 (69.8%) presented in between 49-72 hours of age while the remainders 13 (30.2%) presented before 48 hours. Slight male dominance (1.4:1) was observed. 22 (51.2%) neonates had birth weight in between 2500-4000 grams, 18 (41.9%) were below2500 grams and only 3 (7%) babies were above 4000 grams. Majority (38; 88.4%) of the neonates were term born and only 5 (11.6%) babies were near term.

Table III. Distribution of study neonates by color doppler echocardiography finding (n=43)

Color doppler echocardiography finding	Frequency	Percentage
VSD	5	11.6
ASD	5	11.6
TOF	5	11.6
Complete AV cannal defect	2	4.7
DIRV	1	2.3
DILV	1	2.3
ASD+VSD	1	2.3
VSD+ severe valvular PS	1	2.3
Tricuspid atresia	2	4.7
DTGA	2	4.7
Large VSD	5	11.6
VSD+ASD+Pulmonaryatresis	2	4.7
Large PDA	4	9.3
Large ASD	3	7.0
ASD+VSD+PDA	1	2.3
VSD+PDA	1	2.3
Medium VSD+ mild PS	2	4.7

Table IV. Distribution of study neonates by color doppler echocardiography finding, who were screening positive (n=31).

Color doppler echocardiography finding	Frequency	Percentage
VSD	1	3.2
TOF	5	16.1
Complete AV cannal defect	2	6.5
DIRV	1	3.2
DILV	1	3.2
ASD+VSD	1	3.2
VSD+ severe valvular PS	1	3.2
Tricuspid atresia	2	6.5
DTGA	2	6.5
Large VSD	3	9.7
VSD+ASD+Pulmonaryatresis	2	6.5
Large PDA	3	9.7
Large ASD	3	9.7
ASD+VSD+PDA	1	3.2
VSD+PDA	1	3.2
Medium VSD+ mild PS	2	6.5

Table V. Distribution of critical congential heart disease by color doppler echocardiography finding among screening positive neonates (n=30)

Color doppler echocardiography finding	Frequency	Percentage
TOF	5	16.7
Complete AV canal defect	2	6.7
DIRV	1	3.3
DILV	1	3.3
ASD+VSD	1	3.3
VSD+ severe valvular PS	1	3.3
Tricuspid atresia	2	6.7
DTGA	2	6.7
Large VSD	3	10.0
VSD+ASD+Pulmonaryatresis	2	6.7
Large PDA	3	10.0
Large ASD	3	10.0
ASD+VSD+PDA	1	3.3
VSD+PDA	1	3.3
Medium VSD+ mild PS	2	6.7

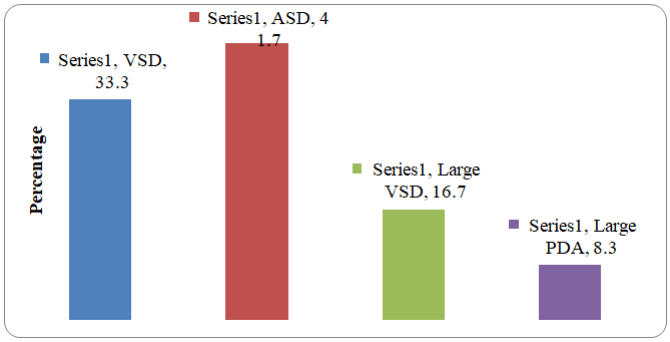

Figure 1: Color doppler echocardiography finding in pulse oximeter screening negative cases (n=12)

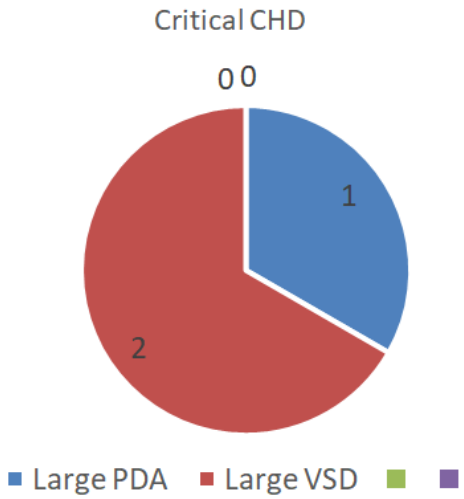

Figure2. Distribution of Critical Congential Heart Disease by color doppler echocardiography finding among screening negative neonates (n=3)

Table VI. Value of pulse oximeter in identifying CHD

Pulse oximetry	CHD found in color doppler echocardiography	CHD not found in color Doppler echocardiography	Total
Screening positive	31 (TP)	1 (FP)	32
Screening negative	12 (FN)	1013 (TN)	1025
Total	43	1014	1057

TP=True positive; FP=False positive
FN=False negative; TN=True negative

Table VII. Value of pulse oximeter in identifying critical CHD

Pulse oximetry	Critical CHD found in color doppler echocardiography	Critical CHD not found in color doppler echocardiography	Total
Screening positive	30 (TP)	2 (FP)	32
Screening negative	3 (FN)	1022 (TN)	1025
Total	33	1024	1057

TP=True positive; FP=False positive
FN=False negative; TN=True negative

Table VIII. Sensitivity, specificity, accuracy, positive and negative predictive values of the CHD and critical CHD evaluation of screening positive in study population

Test parameter	Congenital heart disease (CHD)	Critical congenital heart disease
Sensitivity	72.1	90.9
Specificity	99.9	99.8
Accuracy	98.8	99.5
Positive predictive value	96.9	93.8
Negative predictive value	98.8	99.7

DISCUSSION

In this study we observed that majority (69.8%) patients belonged to age 49-72 hours group. The mean age was found 56.17±12.89hours. More than half (58.1%) of the patients were male, 18(41.9%) had birth weight <2500 gram, 20(46.5%) mother belonged to age 31-40 years. Manjunath, *et al.* reported in a study that CHD, the majority of were males (13, 68.4%) with male to female ratio of 2:1.[8] Al Mamun, *et al.* observed in another study that the mean age at screening was 34.92±8.65 hours.[9] Screening was done within 24 to 30 hours in 38.43% neonate, 31 to 36 hours in 16.47% cases, 37 to 42 hours in 21.96% cases and 43 to 48 hours in 23.14% cases. Male were 322(63.1%) and female were 188(36.9%). Klausner, *et al.* reported 8802(83.0%) babies had birth weight 2500-4000 gram, 980(9.3%) were of > 4000 gram and 807(7.6%) were <2500 gram[3]. Tekleab and Sewnet study[10] also observed the mean gestation age and birth weight of the study subjects were 39.4±1.6 weeks and 3,076.8±490.5 g respectively. The present study observed that 38(88.4%) patients were term, 20(46.5%) were delivered by cesarean section. Klausner *et al.* (2017) observed 9584(90.5%) patients were term (>37 weeks of gestation), 559(5.3%) were late preterm (35-37 weeks) and 446(4.2%) were preterm (<35 weeks)[3]. Tekleab and Sewnet observed cesarean section was the mode of delivery for 484 (51.4%) of the study subjects. 414(44.0%) patients had gestational age 39-40 weeks, 284(30.2%) were 37-38 weeks and 243(25.8%) were 41-44 weeks[10]. The present study showed that 12(27.9%) showed raised temperature, 4(9.3%) had tachycardia, 2(4.7%) had tachypnoea, 10(23.3%) had PSM, 30(69.8%) was length <50 cm and 25(58.1%) was OFC <35 cm. Manjunath *et al.* reported[8] among 11 clinically suspected CHDs, all had murmur, 2 of them had abnormal respiration, and 3 had an abnormal heart rate. A study[11] by Ainsworth *et al.* showed that about 54% of babies with murmur on routine newborn examination had CHD. In a study by Arlettaz *et al.* (2006) 73% of babies with CHD had murmur[12].

In current study the mean right hand oxygensaturatation was found to be 92.5±2.7 percent and lower limb oxygensaturation was found as 92.1±2.9 percent. Tekleab and Sewnet reported [10] the 941 study subjects, 123 (13.1%) and 70 (7.4%) of them had foot and right arm SPO2 readings <95% respectively, during the initial screening. The mean foot and right arm SPO2 readings of the study population were 95.8% (SD 2.3) and 96.0% (SD 2.2) respectively. In studies of healthy populations, the distribution of SpO2 measured in a lower extremity at 24 hours was reported to be 97.3±.3%[13].One study that examined newborns with known CCHD suggested that the addition of upper and lower measurements would increase sensitivity from 89.4% to 92.4% without a decrease in specificity[14]. Regarding color doppler echocardiography, 31 cases were found CHD who were pulse oximeter screening positive, and among them (30/31) of newborn with CHD were CCHD. Among them 5(16.1%) had TOF, 3(9.7%) had large VSD, 3(9.7%) had large PDA and 3(9.7%) had large ASD. Manjunath *et al.* (2020) in their study observed that 16% (3/19) of newborns with CHD were CCHD (TAPVC, TOF, and TGA), accounting to 0.3% of the study group[8]. Al Mamun *et al.* reported color doppler echo cardiography showed TGA with shunt lesion (14.29%) and TOF (10.72%) were the commonest CCHD among pulse oximetry screening positive cases[9].Tekleab and Sewnet, reported the echocardiographic findings were: PDA: eleven (19.6%), PPHN: ten (17.9%), ASD: two (3.6%), and no

abnormality was detected in 33 (58.9%)[10]. No case of CCHD was detected among the screened newborns. In this study color doppler echocardiography showed that among the pulse oximetry screening negative babies, 12 babies had CHD, and among them (3/12) of the neonates with CHD were CCHD. Among them 5(41.7%) in ASD, 4(33.3%) in VSD, 2(16.7%) in large VSD and 1(8.3%) in large PDA. Al Mamun *et al.* showed that among the pulse oximetry screening negative babies 20 had CHD. ASD (20%), VSD (20%) and PDA (12%) were the commonest acyanotic CHD. TGA with shunt lesion (12%) and TOF (12%) were the commonest CCHD[9]. This study showed that out of all cases 31 were diagnosed as screening positive by pulse oximetry and confirmed congenital heart disease by color doppler echocardiography finding. They were true positive. One case was diagnosed as screening positive by pulse oximetry scan but not confirmed congenital heart disease by color doppler echocardiography. They were false positive. Of 1025 cases of screening negative, which were diagnosed by pulse oximetry, 12 were confirmed as congenital heart disease and 1013 were normal findings by color doppler echocardiography. They were false negative and true negative respectively. Manjunath *et al.* (2020) reported 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[8]. Al Mamun *et al.* (2016) observed CHD were found in 24 cases out of 28 who were screening positive in first 48 hours[9]. CHD were also found in 20 cases who were screening negative. This study showed out of all cases 30 were diagnosed as screening positive by pulse oximetry and confirmed critical CHD by color doppler echocardiography finding. They were true positive. Two cases was diagnosed as screening positive by pulse oximetry scan but not confirmed critical CHD by color doppler echocardiography finding. They were false positive. Of 1025 cases of screening negative, which were diagnosed by pulse oximetry, 12 were confirmed as CHD and among them 3 were CCHD, and 1013 were normal findings by color doppler echocardiography. They were false negative and true negative respectively. Manjunath *et al.* reported clinical examination was unremarkable in all three cases of CCHD detected[8]. Pulse oximetry was abnormal in all 3 cases of CCHD (100%). The sensitivity of pulse oximetry for detection of CCHD was 100% and specificity was 98.5% (p=0.000). Al Mamun *et al.* (2016) observed critical CHD were found in 21 cases out of 28 who were screening positive. Critical CHD were also found in 6 cases that were screening negative[9].

The present study showed that the validity of congenital heart disease for screening positive was correlated by calculating sensitivity that was 72.1%, specificity was 99.9%, accuracy was 98.8%, PPV was 96.9% and NPV was 98.8%. The validity of critical congenital heart disease for screening positive was correlated by calculating sensitivity was 90.9%, specificity was 99.8%, accuracy was 99.5%, PPV was 93.8% and NPV was 99.7%. Manjunath *et al.* also observed the sensitivity of pulse oximetry for detection of CCHD 100%, and specificity 98.5% which was similar to studies by Hoke *et al.* and Taksande *et al.*[8,15,16]. Al Mamun *et al.* also reported Sensitivity of pulse oximetry to identify CHD was 54.54%, specificity was 99.14%, PPV was 95.85%, NPV was 80%[9]. Sensitivity of pulse oximetry to identify Critical CHD was 77.77%, specificity was 98.55%, PPV was 75%, NPV was 98.75%. Hoke *et al.* detected 81% neonate with critical CHD with pulse oximetry screening[15]. de Wahl Granelli *et al.* found abnormal pulse oxymetry result in 66% apparently well baby with duct dependent CHD[17]. A recent meta-analysis of 13 eligible studies included 229,491 infants who underwent pulse oxymetry screening detected CCHD in 77.2% cases[18]. Kar in Bangladesh found sensitivity 75% and specificity 65.5% in his study[19]. Thangaratinam *et al.* recently estimated similar sensitivity and specificity of pulse oxymetry screening[20].de Wahl Granelli *et al.* found pulse oximetry as an effective adjunct to clinical examination and the combined detection rate of CCHD was 92%[17]. In the subsequent year, a German study by Riede *et al.* screened over 40,000 babies using only postductal saturations between 24 hours and 72 hours of age[6]. They reported the sensitivity of 78% and specificity of 99.9% and a false positive rate of 0.1%. Our study also concluded with the similar findings and proved the necessity of pulse oximetry test in detecting CCHD in newborn.

Conclusion

Pulse oximetry is a good screening test for early detection of critical CHD for those who have no obvious feature. The validity of congenital heart disease for screening positive is higher in specificity and show high accuracy. The validity of critical congenital heart disease for screening positive show high sensitivity, specificity and high accuracy.

Declaration

The authors received no funding, grant or financial help from any source. They declare no conflict of interest.

Authors Contribution

TM, MAA conceived the idea, contributed in designing the study, sample taking and data analysis. MIH performed echocardiography, reviewed discussion writing. UKD, BB and MAH contributed in data analysis and discussion writing.

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