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Impact of Pulse Oximetry Screening on the Detection of Duct Dependent Critical Congenital Heart Disease in Neonate

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Abstract

Background: *Screening for congenital heart diseases (CHD) in newborn babies aid in early recognition, with the prospect of improved outcome. Currently there is no effective screening protocol for this condition. Pulse oximetry is highly specific for detection of critical CHD with moderate sensitivity that meets criteria for universal screening.*

Objective: *To evaluate the use of pulse oximetry as a screening tool in early detection of critical CHD specially duct dependent critical CHD in asymptomatic newborn babies.*

Methodology: *A cross sectional study conducted in Dhaka Shishu (Children) Hospital from October 2014 to June 2015. Newborns attended outpatient department or admitted in different wards with having gestational age >35 weeks and age between 24-48 hours were included and pulse oximetry screening was done. Oxygen saturation measurement <90%, or oxygen saturation measurements <95% in both extremities on three consecutive measurements separated by one hour, or a >3% absolute difference in oxygen saturation between the right hand & foot on three consecutive measurements was considered as pulse oximetry screening positive. Routine neonatal examination was done and clinical evidence of CHD was noted. Echocardiogram was done to rule out CHD. Data were analyzed by using SPSS and sensitivity, specificity and predictive values were calculated.*

Result: *Total 510 neonate were screened during the data collection period. Mean age at screening was 34.99±8.4 hours, male were 322(63.1%) and female were 188(36.9%). Among the neonates 28(5.49%) were found pulse oximetry screening positive and 25(4.90%) were suspected as CHD by routine neonatal examination. Critical CHD were found in 21 cases out of 28 screening positive cases among them duct dependent critical CHD was found in 11 cases. Sensitivity of pulse oximetry to identify critical CHD was 77.77% and specificity was 98.55%. Sensitivity of pulse oximetry to identify duct dependent critical CHD was 78.57% and specificity 96.57%.*

Conclusion: *Pulse oximetry is a good screening test for early identification of duct dependent critical CHD for those who have no obvious feature. So in resource poor country like Bangladesh if all neonatal health setup use pulse oximetry screening within 24-48 hours of life, it will increase early identification of duct dependent critical CHD.*

Key wards: *Pulse oximetry screening, duct dependent critical congenital heart disease, neonate.*

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Introduction

CHD is the most common congenital malformations and accounts for about 8-10 per 1000 live births.[1-7] Approximately one quarter of these children have critical CHD and may manifest before the first routine clinical examination and responsible for more deaths than any other type of malformation.[6,8] About 1.8 babies per 1000 live births have duct dependent critical CHD with a persistent ductus arterious being necessary for the survival.[7,8] With advances in perinatal care, congenital malformations are emerging as one of the

leading cause of neonatal and infant mortality, even in developing countries and majority death occur during first month of life.[9] Now a days, even complex CHD can be treated with the appropriate surgical or catheter intervention. Timely recognition is crucial for a good outcome and delayed diagnosis of severe CHD can lead to cardiac failure, cardiovascular collapse and even death. Many infants die without diagnosis of CHD.[10] Routine neonatal examination fails to detect more than 50% of infants with CHD as signs of CHD may not become evident in early period.[5,11,12] A study from United Kingdom showed that 25% of the infants with critical CHD were not diagnosed until after discharge from the newborn nursery.[13] Critical CHD, which by definition required surgery or catheter intervention in the first year of life and duct dependent critical CHD includes CoA, Interrupted aortic arch, HLHS, Pulmonary Atresis, Tetralogy of Fallot with severe PS etc.[14] These congenital heart diseases may manifest with sudden and profound worsening clinical status in the first days and weeks of life corresponding to changes in pulmonary vascular resistance and closure of the ductus. Critical CHD in the newborn may have borderline low oxygen saturation with unrecognized cyanosis clinically. Pulse oximetry has the potential to identify hypoxemia that might not otherwise produce visible cyanosis. Pulse oximetry is highly specific for detection of critical congenital heart defects with moderate sensitivity that meets criteria for universal screening. As such, some have proposed that pulse oximetry be considered as a vital sign equivalent in importance to pulse, respirations, and blood pressure.[15] Pulse oximetry monitoring is also capable of detecting other conditions that include hypoxia including some lung conditions and persistent pulmonary hypertension of newborn. The investigators observed that pulse oximetry is much more effective in identifying infants with critical CHD and is more accurate and much less expensive than screening all newborns with echocardiography. Using a cutoff of 95% in lower-extremity saturation, Hoke et al[16] found that 81% of neonates with critical CHD could be identified. It should be done within 24-48 hours of life. Earlier screening can lead to an increased rate of false positive results due to the transition from fetal to neonatal circulation and the stabilization of systemic oxygen saturation levels.[15] Later screening can miss an opportunity for intervention for defects that are impacted by the closing of the ductus arteriosus. Thus screening all newborn babies with pulse oximetry in addition to the usual routine physical examination is an essential aid to identify CHD and can be used as universal screening for CHD.[17-18]

Neonates with CHD can be diagnosed on the basis of physical findings. But these findings are not always evident before hospital discharge or within 1st 48 hours of life. Newborns with CHD, especially critical CHD are susceptible to sudden worsening in clinical status without accurate diagnosis. As because timely recognition of CHD can improve outcomes, it is important to identify and evaluate strategies to enhance early detection. The association of delayed diagnosis of CHD with mortality, morbidity and disability provides a rationale for strategies such as pulse oximetry assessment to improve early detection and outcome.[17]

In developing countries like Bangladesh this method can be very helpful in early detection of CHD as fetal echocardiograpgy is not routinely done here. Very few data are available in Bangladesh regarding pulse oximetric screening for the detection of CHD in Bangladesh. This study was conducted to assess the use of pulse oximetry in early detection of critical CHD specially duct dependent critical CHD in asymptomatic newborn babies and to determine the sensitivity, specificity, and predictive values of pulse oxymetry for early detection of CHD.

Materials and Methods

This cross sectional study was conducted in Dhaka Shishu (Children) Hospital from October 2014 to June 2015. Newborns attended at Dhaka Shishu (Children) Hospital for various reasons or admitted in different wards who's gestational age was >35 weeks and age between 24 to 48 hours were included purposively and pulse oximetry screening was done. Newborn prenatally diagnosed as CHD, critically ill having, cyanosis respiratory distress and getting O_2 and already had echocardiographic evaluation were excluded from the study. Informed written consent was taken from the parents of the selected neonate. Appropriate sensor for the newborn hand and foot was used. Sensor was placed on the right hand and either foot. In cases of poor perfusion, local rewarming of sensor sites was done. The site was cleaned of debris and dry before sensor placement. In the presence of sources of bright light, covering the sensor site with

an opaque material was done. Preductal (right hand) and post ductal (foot) oxygen saturation was observed with the help of pulse oximeter (NT1A, Solaris Medical Technology, Inc. USA). If the oxygen saturation measurement <90%, or oxygen saturation measurements <95% in both extremities on three consecutive measurements separated by one hour, or there is a >3% absolute difference in oxygen saturation between the right hand and foot on three consecutive measurements separated by one hour were considered as pulse oximetry screening positive. Routine neonatal examination was done and clinical evidence of CHD like cardiac murmur, weak pulse and abnormal 4 limb BP was noted. Echocardiogram was done to rule out CHD. Data were analyzed by using SPSS version 21. Sensitivity, specificity and predictive values were calculated.

Results

Total of 510 babies were enrolled with a mean age at screening of 34.92±8.65 hours. Screening was done within 24 to 30 hrs in 38.43% neonate, 31 to 36 hrs in 16.47% cases, 37 to 42 hrs in 21.96% cases and 43 to 48 hrs in 23.14% cases. Mean weight was 2898.43±216.85 gm and mean gestation was 38.22(±1.33) wks (Table-I).

Table- I

Distribution of the age in hours during screening of the study population (n=510)

Age in hours	Frequency	Percent
24-30 hrs	196	38.43
31-36 hrs	84	16.47
37-42 hrs	112	21.96
43-48 hrs	118	23.14
Mean age in hrs ±SD	34.92±8.65	
Mean weight in gm ±SD	2898.43±216.85	
Mean gestational age in wk ±SD	38.22±1.33	

Among the neonates 28(5.49%) were pulse oximeter screening positive (Fig.-1).

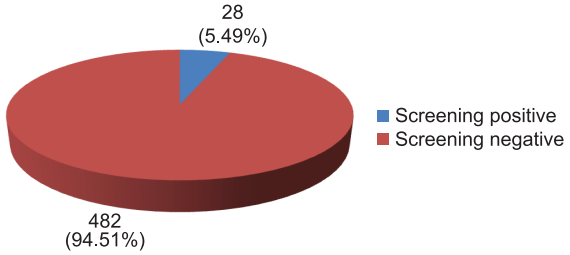

Fig.-1 *Frequency of pulse oximeter screening positive cases among study neonate*

Among the neonates 25(4.90%) were suspected as CHD by routine neonatal examination (Fig.-2).

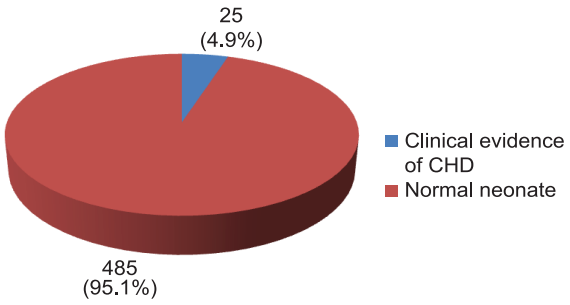

Fig.-2: *Frequency of neonate of suspected CHD detected by routine neonatal examination*

Color dopplar echo cardiography showed that TGA with shunt lesion (14.29%) and TOF (10.72%) were the commonest CCHD among pulse oximetry screening positive cases. Pulmonary atresia (10.72%), severe pulmonary stenosis (7.14%), TOF with severe pulmonary stenosis (7.12%) and CoA (7.12%) were common duct dependent CCHD (Table-II).

Table-II

Distribution of color doppler echocardiography finding in pulse oximeter screening positive cases (n=28)

Color Doppler Echocardiography findings	Frequency	Percent
Pulmonary atresia	3	10.72
Severe Pulmonary stenosis	2	7.14
HLHS	1	3.57
TOF with severe Pulmonary stenosis	2	7.14
CoA	2	7.14
Interrupted Aortic arch	1	3.57
TGA with VSD	1	3.57
TGA with VSD+ASD	3	10.72
TOF	3	10.72
VSD	1	3.57
PDA	1	3.57
ASD	1	3.57
Normal study	4	14.29

*HLHS: Hypoplastic Left heart Syndrome, TOF: Tetralogy of Fallot, CoA: Coarctation of Aorta, TGA: Transposition of Great Arteries, VSD: Ventricular Septal Defect, ASD: Atrial Septal Defect.

Colour dopplar echocardiography 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 (Table-III).

Table-III

Distribution of color doppler echocardiography finding in pulse oximetry screening negative cases (n=29)

Color doppler echocardiography findings	Frequency	Percent
TOF	1	5
TOF with severe Pulmonary stenosis	2	10
TGA with PDA	2	10
TGA with VSD	1	5
VSD	5	25
ASD	5	25
PDA	3	15
CoA	1	5

*TOF: Tetralogy of Fallot, TGA: Transposition of Great Arteries, CoA: Coarctation of Aorta, PDA: Patent Ductus Arteriosus, VSD: Ventricular Septal Defect, ASD: Atrial Septal Defect.

CHD were found in 24 cases out of 28 who were screening positive in first 48 hours. CHD were also found in 20 cases who were screening negative. Sensitivity of pulse oximetry to identify CHD was 54.54%, specificity was 99.14%, PPV was 95.85%, NPV was 80%.

Critical CHD were found in 21 cases out of 28 who were screening positive. Critical CHD were also found in 6 cases who were screening negative. Sensitivity of pulse oximetry to identify cyanotic CHD was 77.77%, specificity was 98.55%, PPV was 75%, NPV was 98.75% (Table-V).

Total duct dependent critical CHD was found in 14 cases. Among them 11(78.57%) were identified by pulse oximetry out of 28 who were screening positive. Duct dependent critical CHD were also found in 3(21.43%) case who were screening negative. Sensitivity of pulse oximetry to identify duct dependent critical CHD was 78.57%, specificity was 96.57%, PPV was 39.28%, NPV was 99.37% (Table-VI).

Table-IV

Value of pulse oximeter in identifying CHD

Pulse oximetery	CHD found in color doppler echocardiography	CHD not found in color doppler echocardiography	Total
Screening positive	24	4	28
Screening negative	20	462	482
Total	44	466	510

Sensitivity 54.54%, Specificity 99.14%, PPV 95.85%, NPV 8%

Table-V

Value of pulse oximeter in identifying critical CHD

Pulse oximetery	Critical CHD found in color doppler echocardiography	Critical CHD not found in color doppler echocardiography	Total
Screening positive	21	7	28
Screening negative	6	476	482
Total	27	483	510

Sensitivity 77.77%%, Specificity 98.55%, PPV 75%, NPV 98.75%

Table-VI

Value of pulse oximeter in identifying duct dependent critical CHD

Pulse oximetery	Duct dependent critical CHD found in color doppler echocardiography	Duct dependent critical CHD not found in color doppler echocardiography	Total
Screening positive	11	17	28
Screening negative	3	479	482
Total	14	496	510

Sensitivity 78.57%, Specificity 96.57%, PPV 39.28%, NPV 99.37%

Discussion

Congenital heart defects are a leading cause of infant death, accounting for more deaths than any other type of malformation.[19] Screening for critical congenital heart defects in newborn babies can aid in early recognition. This study assessed the performance of pulse oximetry as a screening method for the detection of critical CHD specially duct dependent critical CHD in asymptomatic newborn babies.

Pulse oximetry has been identified as a potentially useful screening test for congenital heart disease in asymptomatic newborns. Pulse oximetry is a non-invasive, readily available, relatively cheap, well-validated test and carried out by either a nurse or a doctor.[19] Currently, pulse oximetric screening has been proposed by some authors as one such strategy for early detection of cyanotic CHD in newborns. In this study, among 510 cases, mean screening age was 34.99±8.4 hours. Color doppler echocardiography in 28 pulse oximetry screening positive neonate should 21(75%) asymptomatic new-born had critical CHD. Hoke et al[16] detected 81% neonate with critical CHD with pulse oximetry screening. de Wahl Granelli et al[20] found abnormal pulse oxymetry result in 66% apparently well baby with duct dependent CHD. A recent meta-analysis of 13 eligible studies included 229,491 infants who underwent pulse oxymetry screening detected CCHD in 77.2% cases.[21] In this study pulmonary atresia (10.72%), severe pulmonary stenosis (7.14%), TOF with severe pulmonary stenosis (7.12%) and CoA (7.12%) were common duct dependent critical CHD. TGA with shunt lesion (14.29%) and TOF (10.72%) were the commonest cyanotic CHD and 4 neonate showed low saturation but normal echocardiographic findings. Pure left to right shunts such as VSD, ASD, or PDA should not be detected by pulse-oximetry as there is no mixing of deoxygenated blood. But in this study, 3 asymptomatic newborn was detected by pulse oximetric screening. This happened probably due to bidirectional shunting during early postnatal pulmonary hypertension.

In this study, three newborn with TOF and three newborn of TGA with shunt were screened as negative as in large shunt oxygen saturation can be maintained in TGA cases so they were missed by pulse oximetry screening.

In this study sensitivity of pulse oximetry was 54.54% and specificity 99.14% for the detection of CHD. In detecting critical CHD sensitivity was 77.77% and specificity was 98.55%. Sensitivity was similar in detecting duct dependent critical CHD and was 78.57% and specificity is 96.57%. So, this study demonstrated the use of pulse oximetry screening adjunct to routine neonatal examination for detecting critical CHD in clinically normal newborns. Hoke et al[16] and Goldman et al[22] showed low specificity (88%, 12%). Kar et al[23] in Bangladesh found sensitivity 75% and specificity 65.5% in their study. Thangaratinam et al[24] recently estimated similar sensitivity and specificity of pulse oxymetry screening.

The majority of studies involved a relatively small number of patients and were underpowered to address test accuracy. Recently, two studies examining test accuracy have been reported from Scandinavia, recruiting large cohorts of 50 000 (in a Norwegian study) and 40,000 subjects (in a Swedish study).[20,25] The studies reported sensitivities of 77.1% and 62.07% and specificities of 99.4% and 99.82%, respectively. The studies used different pulse oximetry test methods; one used postductal saturations alone[25] and the other used pre and postductal saturations[20] with similar thresholds of this study. Testing was generally early in the Norwegian study (median age, 6 hours)[25] and later in the Swedish study (median age, 38 hours).[20] The highly specific nature of the test also signifies that a low pulse oximetry reading in asymptomatic newborns ''rules in'' congenital heart disease until proved otherwise.[24] The validity of the findings is dependent on the methodology of the systematic review and the quality of the individual studies included.[26,27] This study, therefore, reports a sensitivity and specificity that is similar to that of the Swedish study and Norwegian study in detecting cyanotic CHD. Sensitivity and specificity was also similar in detecting duct dependent critical CHD.

Majority of the study did pulse oximetry screening in well baby nurseries.[14,20,25] But this study was a hospital based study, neonates who were brought with some problems other than respiratory distress and cyanosis were included. Mathur et al[28] found sensitivity 95.2% and specificity 52.4% in neonates who were admitted in NICU. Their specificity was low because screening was also positive in respiratory distress, acyanotic CHD with heart failure, shock and persistent pulmonary hypertension of newborn.

This study was a hospital bases single centered study. Large multicenter study including well baby maternities should be carried out for better evaluation of the effect of screening and its acceptability to parents and healthcare professionals specially with the possibility of non-significant lesions being detected during echocardiogram and the cost and cost-effectiveness of screening program for health care services.

Conclusion

Pulse oximetry is a good screening test for early identification of duct dependent critical CHD for those who have no obvious feature. So in resource poor country like Bangladesh if all neonatal health setup use pulse oximetry screening within 24-48 hours' of life, will increase early identification of CHD, specially duct dependent critical CHD.

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