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Study of Pulse Oximetry and Clinical Examination in Screening for Congenital Heart Disease in neonatal unit of tertiary care hospital in North India

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Abstract

Objective: Neonatal screening for critical congenital heart disease can aid in early recognition and improved outcome of critical congenital heart diseases. The objective of this study was to evaluate combined pulse oximetry and clinical examination as a screening method for congenital heart disease (CHD) in asymptomatic newborns

Methods: Our study was conducted on all asymptomatic neonates brought to neonatology section of Department Of Paediatrics Government Medical College Srinagar tertiary care hospital for period of six months from January 2018 to June 2018 to asymptomatic newborns were screened for CHD using pulse oximetry and clinical examination before their discharge from the nursery. All newborns found to have a post-ductal saturation ≤95% and abnormal cardiac examination underwent additional evaluation by echocardiography. Data regarding true and false positives as well as negatives was collected and sensitivity, specificity and predictive values of pulse oximetry for screening of asymptomatic newborns with congenital heart disease were determined.

Results: Among the 3575 newborns screened,41 had CHDs at birth . Pulse oximetry detected 18 CHD (sensitivity 43.90 %, specificity 99.86%.Clinical examination detected 10 casesof CHD with sensitivity of 24.39 % and specificity of 99.69%.Addition of pulse oximetry to clinical examination significantly improved sensitivity for CHD to 68.29% and specificity to 99.63% .

Conclusions: Pulse oximetry is a sensitive screening tool for detecting major CHDs in Indian newborns. It adds significant value to the current practice of using clinical examination as a sole screening tool for detecting CHDs.

Keywords: Pulse oximetry, Congenital heart disease, Screening

Introduction

Congenital heart defects (CHDs) are a leading cause of neonatal and infant mortality in the developed world[1] CHDs are among the commonest congenital malformations with nearly 15% being life threatening during the neonatal period, and almost one-third to half requiring surgical

or transcatheter intervention within the first year of life.[2] The birth prevalence of CHDs worldwide is regarded as 8 per 1000 live births.4. Of these, nearly 60,000-90,000 suffer from critical CHDs that require early intervention[3]Missed and delayed diagnosis of these critical defects account for a significant increase in morbidity and mortality.[4] This is especially true for newborns with duct-dependent critical defects where closure of the duct leads to acute cardiovascular decompensation and death.[5]Routine clinical examination of newborns lacks sensitivity for detecting CHDs[6]. Pulse oximetry is an accurate, non-invasive test used for quantifying hypoxemia that has been used in several large-scale studies to screen for CHDs[7]Most of these studies , are from high-income countries. The rationale for using pulse oximetry is that most critical CHDs produce some degree of hypoxemia that is detectable by oximetry, but does not produce clinically visible cyanosis.[8]Pulse oximetry has been reported as a highly specific test with moderate sensitivity for detecting critical CHDs, making it an ideal test for CHD screening.[9] Also, it has a lower false-positive rate for detecting critical CHDs when testing is done after 24 h of birth.[9]Though echocardiography remains the gold standard for CHD diagnosis, using pulse oximetry with clinical examination as a screening regimen can aid in the early detection of critical CHDs.In view of the preliminary results, we decided to evaluate the efficacy of combining pulse oximetry and clinical examination as a screening method for CHD in asymptomatic newborns before their discharge from the nursery.

Materials and methods

This was a Prospective Clinical Study conducted in the Neonatology Department of a Department of Paediatrics Government medical college Srinagar for period of six months from January 2018 to June 2018. All asymptomatic newborns who were brought to Neonatology OPD for a routine neonatal examination and did not manifest cyanosis, tachypnea (respiratory rate>60/min), grunting, flaring, retractions, murmur, active precordium, or diminished pulses were screened for congenital heart disease with thorough clinical examination and pulse oximetry. Clinical examination was recorded in a proforma that included the following clinical parameters: central cyanosis, cardiac murmur and respiratory distress.

Pulse oximetry readings were taken using wall mounted pulse oximeter Edan I M50 in a quiet setting with the infants in a calm state, from right upper and lower limbs. The probe was cleaned with alcohol swabs before each use. The reading was recorded after stabilization for 1 minute, according to the manufacturers instructions. The timing of pulse oximetric determination was >24 hours age.

Echocardiography was done in all neonates with abnormal clinical examination and newborns found to have a postductal saturation ≤ 95% .Echocardiography was done by single pediatric cardiologist on Seimens Accuson S 2000 machine using 8 MHZ paediatric probe.

Normal echocardiographic finding was either;

No echocardiographic abnormality or any of the following:

- Patent ductus arteriosus <2 mm in size without volume overload of left ventricle.
- Interatrial communication (patent foramen ovale or atrial septal defect) <5 mm without volume overload of right ventricle
- Mild turbulence at branch pulmonary arteries.

An informed consent sheet with details of the study protocol was provided to the parents, and newborns were recruited into the study after one of the parents signed this sheet. None of the parents refused to provide consent for the study.

***Statistical analysis*:** We calculated the sensitivity, specificity, positive and negative predictive values, and diagnostic accuracy of pulse oximetry and clinical examination and their combination for detecting CHD.

Results

During the 6 months of the study, 3575 asymptomatic newborns were screened by pulse oximetry and clinical examination before discharge. A CHD was diagnosed by echocardiography in 41 newborns. Out of 3575 neonates who were screened 23 cases were found with SPO_2 saturation less than 95%. Out of these 23, echocardiography in 18 revealed congenital heart disease while the 5 cases had structurally normal hearts.23 cases who had spo2 saturation greater than 95% at the time of screening revealed congenital heart disease on clinical follow-up.From our study the sensitivity of screening of CHD by pulse oximetry is 43.90 %, Specificity is 99.86%,Positive Predictive Value is 78.26.% [58.40% to 90.25% CI] and Negative Predictive Value is 99.35%[99.15% to 99.51% CI]

Abnormal clinical examination as cause for echocardiography was present in 21 cases. Of them 10 had CHD. 11 cases had no structural heart disease.31 cases who had normal clinical examination at the time of screening revealed congenital heart disease on clinical follow-up. From our study the sensitivity of screening of CHD by clinical examination is24.39 %, Specificity is 99.69%,.Positive Predictive Value is 47.62.% [29.02 % to 66.90% CI] and Negative Predictive Value is 99.13% [98.96% to 99.27% CI]

The combination of pulse oximetry and clinical examination detected 28 patients with CHD of total 41 patients (68.29%); hence, adding clinical examination to pulse oximetry significantly increased the sensitivity to 68.29% and specificity to 99.55%with Positive Predictive Value of 63.64.% [50.70 % to 74.86% CI] and Negative Predictive Value of 99.63%[99.42% to 99.76% CI]. But the combination still failed to diagnose 13 cases (31.70%). [Table 1, Table 2 and Table 3]

Table 1: Pulse oximetry and clinical examination as individual screening tests.

	Positive	Negative	Total
PULSE OXIMETRY			
CHD	18	23	41
NO CHD	5	3529	3534
TOTAL	23	3552	3575
CLINICAL EXAMINATION			
CHD	10	31	41
NO CHD	11	3523	3534
TOTAL	21	3554	3575

Table 2: Combined clinical examination and pulse oximetry as a screening method.

	Positive	Negative	Total
CHD	28	13	41
NO CHD	16	3518	3534
TOTAL	44	3531	3575

Table 3: Statistical analysis of the different screening methods.			
	PULSE OXIMETRY%	**CLINICAL EXAMINATION%**	**COMBINED%**
SENSITIVITY	43.90%	24.39%	68.29%
SPECIFICITY	99.86%	99.69%	99.55%
POSITIVE PREDICTIVE VALUE	78.26%	47.62%	63.64%
NEGATIVE PREDICTIVE VALUE	99.35%	99.13%	99.63%

Discussion

Early recognition of CHD is of crucial importance because clinical presentation and deterioration may be sudden. Furthermore, many children with undetected complex CHD die at presentation or before their first surgical intervention [10,11]. Clinical examination for the early signs of CHD is an essential part of routine neonatal examination and can identify some asymptomatic newborns [12]. Pulse oximetry has been suggested as a screening tool for the early detection of CHD in asymptomatic newborns, because the physical examination alone appears to be insufficient [13,14]. Oximetry screening has never been proposed as a substitute for careful physical examination, and the value of combining the two methods needs to be emphasized.

Out of 3575 asymptomatic newborns screened by pulse oximetry and clinical examination 44cases were found SpO2 ≤95% and abnormal clinical examination. These 44 cases further underwent echocardiography to confirm the findings of screening test. 41 out of 44 cases were detected to have CHD. Thus, prevalence of CHD in asymptomatic newborns was found to be 1 in 88(1.1%). Our high prevalence can be due to fact that our study was hospital based study and main referral unit for all high risk mothers which have high incidence of fetal abnormalities Furthermore our prevalence values are more suggestive because of small sample size .Tautz et al found that CHD was identified using pulse oximetric screening in 1 in 1000 asymptomatic newborn (0.1 %).[15].In study conducted by Arlettaz et al[16] in 3262 newborns found that there were 11 cases of CCHD in asymptomatic neonates with SpO2 <95% giving the prevalence of 1 in 297 (0.33%).Further we included clinical examination as additional screening tool which increased rate of detection of CHD in asymptomatic neonates. From our study the sensitivity of screening of CHD by pulse oximetry is 43.90 %, Specificity is 99.86%.Similar to what was shown in other studies [13,14], we demonstrated that pulse oximetry alone had an almost 100% specificity, while its sensitivity was relatively low (43.90%). The positive predictive value was also comparable. The sensitivity, specificity, and positive predictive value of clinical examination alone for detection of CHD matched those reported by Ainsworth et al. [17].

Clinical examination had a significantly lower sensitivity (24.39%) than pulse oximetry for detecting any CHD. This is low when compared with the best potential (sensitivity above 90%) of using clinical examination alone as a tool for detecting CHDs[18] Detection of a clinical examination abnormality has been suggested as a predictor of CHD, warranting a prompt echocardiographic evaluation.[19]

When pulse oximetry andnclinical examination were combined, the sensitivity

was increased from 43.90 to 68.29 while the specificity remained around 100%. The relatively low sensitivity may limit the ability of this screening method to identify all cases of CHD. However, the high specificity would diminish parent anxiety and obviate unnecessary echocardiograms and costly follow-ups. This factor makes the combined approach the best available screening method for CHD in asymptomatic newborns.

Conclusion

The increasing availability of treatment opportunities for newborns with major CHDs makes early detection crucial to decrease mortality and long-term morbidities. The results of our study indicate that pulse oximetry is a sensitive tool for detecting major CHDs in Indian newborns. Adding pulse oximetry to clinical examination significantly increases the detection of newborns with major CHDs before they are discharged from the hospital.

Limitations

Our study is hospital based study. Our hospital is main referral unit for all high risk pregnancies both for fetal or maternal causes. Hence more neonates with congenital heart disease are screened here.Also sample size is less. Considering the low prevalence rate of CHD sample size should be more.

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