Original Research Article

A Prospective Study to evaluate the Validity of Pulse Oxymeter Screening for early detection of Congenital heart disease

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Abstract

Background: This study was designed to evaluate the effectiveness of routine postnatal clinical examination and pulse oximetry screening in detecting congenital heart disease in new-borns. **Aim:** To evaluated the accuracy of pulse oximetry screening for early detection of congenital heart disease.**Subjects and Methods:** The term new-born babies born during the study period of 12 months had a thorough clinical examination on day 2 of life with emphasis on peripheral pulses, cyanosis, tachypnea, cardiac pulsations and murmurs. Pulse oximetry screening was done within 4hrs of birth and at 48-72hrs of life. Chest X- ray, ECG and Echocardiogram were done for those babies with either abnormal clinical examination or pulse oximetry reading. Clinical examination was done again 2 weeks after discharge. **Results:** The sensitivity 26% for oximetry alone and 60% for clinical examination alone. Specificity was 99.8% for pulse oximetry alone, and 98% for clinical examination alone. **Conclusion:** Pulse oximetry can enhance the clinician's ability to detect life threatening CHD in a timely manner.

Keywords: Congenital heart disease, Clinical examination, Pulse oximetry, Asymptomatic new-borns.

Introduction

Congenital heart disease (CHD) is one of the commonest structural abnormalities found in newborns and remains a leading cause of morbidity and mortality. The birth prevalence of CHD is estimated to be 9.1 per 1000 live births with significant geographical differences. Asia reported the highest prevalence, that is 9.3 per 1000 live births compared with 8.2 and 6.9 per 1000 live births in Europe and North America, respectively[1].Critical congenital heart disease (CCHD) is a subset of CHD that requires invasive intervention or results in death within the first month (or first year by some definitions) of life. This definition is rather arbitrary because some cases of CCHD may be diagnosed or require intervention only after the first year. In the literature, CCHDs have also been categorized as serious and life threatening or major CHD. In general, these are cardiac defects that are dependent on the ductus arteriosus for pulmonary or systemic circulation, or are mixing lesions. CCHD occurs in 1 to 3 per 1000 live births, and comprises up to a third of all CHDs[2-5]. Timely diagnosis of CCHD contributes favorably to morbidity and mortality. Even with diagnostic capabilities improving over time, not all CCHDs can be diagnosed prenatally or presymptomatically. Universal echocardiographic screening for all newborns is not practical or cost-effective[6].

In recent years, pulse oximetry has been evaluated extensively as a screening tool for detecting CCHD and many centers worldwide have included pulse oximetry in their newborn screening programs. In this study, we evaluated the accuracy of pulse oximetry screening for early detection of congenital heart disease.

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Materials and Methods

This prospective study was conducted at Department of Pediatrics and neonatology, at Nalanda Medical College and Hospital, Patna. The study was conducted over a period of 2 year from June 2015 to May 2017.The study was approved by institutional research and ethical research committee. Informed consent was taken from all the participants after explaining the study protocol.100 new-born babies born were observed. Pulse oximetry was done within first 4 hours of life and after 48hrs (48-72hrs). It was performed on either right or left foot of the baby while the baby was quiet after feeding. As soon as the PO measurement showed a good pulse wave, the maximal value was noted. SpO2 of 95% or more was considered as normal.In the case of an asymptomatic infant with borderline values (90 - 94%) a second measurement was performed within 1hr. If the saturation remained below 95%, echocardiography was performed. If the saturation is <90%, echocardiography was performed immediately by the cardiologist.A follow up for all babies was done after 2 weeks in their first post neonatal visit. In this follow up clinical examination was done to rule out CHD.

Results

A total of 1000 new-born babies were screened. New-borns with respiratory distress syndrome, premature babies(less than 37weeks), and extremely low birth babies were excluded. In all babies, SpO2 reading is initially measured within 4hrs of delivery. All babies underwent clinical examination on day 2. Those who had murmur and those with SpO2 values were below 95% were evaluated with chest X-ray, ECG and ECHO. SpO2 measurements were repeated 48hrs after birth.Antenatal scan detected 2 cases of congenital heart disease. One was severe pulmonary stenosis. Other one was DORV with pulmonary atresia.Gestational complications were seen in 5 babies. One mother had fever with rash. Baby had bounding peripheral pulses, murmur, SpO2 within normal limits. On echo, PDA was diagnosed. In 4 babies mothers had gestational diabetes. 2 were taking insulin treatment. One baby had large VSD with left ventricular hypertrophy, whose mother was not on treatment.

One baby who had SpO2<95 % was detected to have PPHN, without any CHD. Out of the 18 acyanotic CHDs, only 6 showed abnormal spo2 within4 hrs while all the cases (5) with Cyanotic CHD showed abnormal spo2 within 4 hrs. The one with abnormal spo2 and no significant CHD turned out to be PPHN. Six acyanotic heart disease with low SpO2 was associated with severe PPHN (large VSD with PPHN) . P value is 0.000 (highly significant) [Table 1].

Table 1: SpO2< 4 hrs vs CHD

			Acyanotic/Cyanotic			Total
			Acyanotic	Cyanotic	PPHN	
1.00	Count	11	0	0	12	
	% w	66.7%	.0%	.0%	50.0%	
2.00	Count	6	5	1	12	
	% w	33.3%	100.0%	100.0%	50.0%	
Total		Count	18	5	1	24
		% w	100.0%	100. 0%	100.0%	100.0%

Among the 11 abnormal values 5 were CHD, 6 were acyanotic heart disease with PPHN [Table 2].

Table 2: SpO2 within 4 Hrs Vs CHD

SpO2<4hrs	Number	Percent
Normal	12	52.18
Abnormal	11	47.82
Total	23	100.0

Table 3: Sensitivity and specificity of SpO2 (within 4hrs) for CHD

SpO2<4 hrs	CHD	
	Present	Absent
Abnormal	11	1
Normal	12	976
Sensitivity = 47.8%	Specificity = 99. 8%	
Positive predictive value = 91.66%		

Table 4: SpO2 Within 4 hrs Vs CHD.

SpO2<4hr	Number	Percent
Normal	0	0.00
Abnormal	5	100.0
Total	5	100.0

Table 5: Sensitivity and specificity of SpO2<95% within 4 hours vs. cyanotic heart disease

SpO2 value within 4hrs	CCHD	
	Present	Absent
SPO2 <95%	5	7
SPO2>95%	0	988
Sensitivity = 100%	Positive predictive value =41.6%	
Specificity = 99.2%		

Five babies had CCHD, one ACHD with severe PPHN, one with severe PPHN [Table 6].

Table 6: SpO2 within 48-72 hrs.vs. CHD

SpO2 within 48 -72hrs	Number	Percent
>95%	993	99.3
<95%	7	.7
Total	1000	100.0

Table 7: SpO2 between 48-72 hrs. vs CHD.

SpO2 within 48-72 hrs.'	Number	Percent
Normal	17	73.91
Abnormal	6	26.09
Total	23	100.0

After 48 hrs 7 babies had SpO2 less than 95%, 5 had cyanotic heart disease, 1 had acyanotic heart disease with severe PPHN. One had only severe PPHN [Table 7].

Table 8: Sensitivity and specificity of SpO2 within 48-72hrs for CHD

SpO2 within 48- 72hrs	CHD Present	Absent
Spo2 >48 hrs.' <95%	6	1
>95%	17	976
Sensitivity = 35.2%	Positive predictive value = 85.71%	
Specificity=99.8%		

Table 9: SpO2 within 48-72 hrs vs. CCHD

SpO2			Cyanotic	Cyanotic	Total
Spo2 within n 48-72 Hrs.	>95%	Count	17	0	17
			94.4%	.0%	70.8%
	>95%	Count	1	5	6
			5.6%	100.0%	29.2%
Total		Count	18	5	23
			100.0%	100.0%	100.0%

Table 10: Sensitivity and specificity of SpO2 within 48-72hrs for cyanotic congenital heart disease

SpO2 within 48-72hrs	CCHD	
	Present	Absent
Spo2< 95%	5	2
Spo2 > 95%	0	993
Sensitivity y =100%	Specificity = 99.7%	
Positive Predictive Value =71.42%		

Table 11: Chest x-ray vs. congenital heart diseases

CXR	Number	Percent
Not done	975	97.5
Normal	19	1.9
Abnormal	6	.6
Total	1000	100.0

Chest x-ray was abnormal in 4 cyanotic congenital heart disease and 2 acyanotic heart disease.

Table 12: ECHO Vs. congenital heart diseases

ECHO	Number	Percent
Not done	975	97.5
Normal	2	.2
Abnormal	23	2.1
Total	1000	100.0

One baby with murmur had no CHD in echo. One with severe PPHN.

Discussion

According to literature congenital heart disease is a gross structural malformation of the heart disease or great intrathoracic vessels with a real or potential functional importance.[11,12] Early recognition of Congenital Heart Disease (CHD) is of crucial importance because clinical presentation and deterioration may be sudden. Many children with undetected complex CHD die at presentation or before their first surgical intervention. Clinical examination for the early signs of CHD is an essential part of routine neonatal examination and can identify some asymptomatic new-borns. Pulse oximetry has been suggested as a screening tool for the early detection of CHD in asymptomatic new-borns, because the physical examination alone appears to be in-sufficient. In our study two (8%) cyanotic CHD were antenatally detected by scan. Twenty congenital heart diseases were missed by antenatal scan. Thus prenatal diagnosis should not be overestimated and could lead todangerous overconfidence. In a study, only 28% of CHD were detected prenatally technology assessment reports, shows the rate for antenatal scan is low.[13]

Two babies with acyanotic heart disease were found to have gestational complications for mother. One had gestational diabetes mellitus, echocardiography for the new-born showed large VSD and LVH. Other one had fever and rashes during pregnancy, clinical examination for the baby showed bounding peripheral pulses and systolic murmur. Echo showed PDA.

All non cyanotic CHD except one were detected by murmur. We couldn't detect murmur within 48hrs of birth, but on follow up murmur was present. In our study, clinical examination showed a sensitivity of 60%, specificity of 98%, and PPV of 95. 23%. For CCHD, sensitivity was 60%, specificity was 98% and of PPV of 14.62%. A study showed,[14] about 54% of babies with murmur on routine clinical examination had structural heart disease. Another study also proved the importance of clinical examination. In their study,[15] 73% of infants with CHD (29/40) had a murmur at the time echocardiography was performed. Out of them, only 35% of cyanotic CHD (6/17) presented with a murmur, whereas all non-cyanotic CHD (23/23) were detected by means of a murmur. These results confirm the importance of clinical examination, but also that the presence of a murmur does not correlate well with the severity of the cardiac lesion. Certain studies also proved that the presence of murmur does not correlate with severity of the lesion.[15,16]

Clinical examination for the early signs of CHD is an essential part of routine clinical examination. Respiratory rate and abnormal pulses showed no significant relationship with CHD. One baby with bounding peripheral pulse was detected to have PDA in echocardiography. Cyanosis presented in 3 cyanotic heart diseases. This study suggests that the presence of abnormal clinical signs like murmur should warrant a prompt cardiac evaluation. In our study, 82% of babies with murmur had structural heart disease. In our study we detected murmur in twenty babies. Two babies had cyanotic CHD. One baby with murmur showed no CHD in Echo. Murmur was not present in three cyanotic heart diseases. One baby had no murmur in clinical examination but SpO2 was below 95 in two readings. Echo done showed PPHN and ASD. On follow up after 2 weeks, murmur was detected.

A recent study showed a sensitivity y of 46% for clinical examination.[11] Specificity was 100%.Vaidyanathan and colleagues study had 157 patients (2.9%) with positive clinical examination, the most common being murmur (84 patients, 1.6%).Clinical evaluation was positive in only 3 patients (17.6%) with major and 32 patients (7.8%) with minor CHD. The sensitivity y for clinical examination in their study was 9.26%. Pulse oximetry has been suggested as a

screening tool for the early detection of CHD in asymptomatic new-born.

We took the saturation cut off as 95% as this reflects published normal Pox values in healthy new-borns. We measured only leg saturation as both upper-limb and lower limb measurements are time consuming. A study measured oxygen saturation in upper and lower limbs of 22 babies with known cyanotic congenital heart disease and found out that the difference in saturation between upper and lower limbs in babies with obligatory right to left ductal shunts was at least 7%, implying a post ductal saturation of at most 93% in these cases.[17]

The optimal measurement time remains uncertain. We did pulse oximetry screening within 4hrs of birth and between 48-72 hrs.' of birth. In our study after 48 hrs of birth the average age at screening was about 52 hrs. Echocardiography studies have shown that complete closure of the ductus arteriosus occurs in less than 10% of full-term new-borns before 12hrs of age, in 50% of new-borns by about 24hrs, and in 81% of new-borns by 48hrs. Performing pulse oximetry screening at less than 6hrs of age when some new-borns may still have persistent ductal shunting, could result in false positives. If Pox screening is performed after a few days of life, there will be reduced incidence of false positives, because of the physiologic decrease in the pulmonary vascular resistance, but a new-born with a ductal dependent CHD could deteriorate rapidly if the DA has already closed.

Measurement performed shortly after birth may lead to increased number of echocardiograms.[18] But this would allow the anticipation of clinically critical situations, which can result in higher morbidity and neurological squeal. False positive Pox readings due to pulmonary hypertension can be of benefit because they lead to careful clinical examination and echocardiography, and ,therefore ,to correct management of the patient with no delay. In order to shorten the hospital stay, there is a tendency to do SpO2 screening on the first day of life that can lead to false positives and unnecessary interventions in some cases. In our study pulse oximetry screening within 4hrs had sensitivity of 47.8%, specificity of 99.8%, and positive predictive value of 91.66%. Screening after 48 hours showed a sensitivity of 26%, specificity of 99.8%, and PPV of 85.71%.

Conclusion

The combination of arterial-pulse oximetry (APO) and clinical examination (CE) is crucial in the detection of congenital heart defects (CHD). Despite lower results in CHD detection, the APO is essential in the diagnosis of CCHD.

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