Original Article

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A Comparative Study of Pulse Oximetry Screening and Clinical Examination in Diagnosis of Congenital Heart Disease

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Abstract

Background: Pulse oximetry is a reliable and non-invasive method for measuring oxygen saturation and has a rapid response. During the past several years pulse oximetry has gained wide spread use in the neonatal oxygen monitoring. The present study was done to determine if a pulse oximetry screening combined with clinical examination is superior in the diagnosis of congenital heart disease to clinical examination alone. **Subjects and Methods:** The term new-born babies born in NARAYANA medical college and Hospital during the study period of 12months (February 2018 to January 2019) 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:** Though routine clinical examination is effective in detection of congenital heart disease in new-borns, combining pulse oximetry and clinical examination after birth had a higher sensitivity for detection of congenital heart diseases in new-borns. **Conclusion:** Combining clinical examination and pulse oximetry can enhance the clinician's ability to detect life-threatening congenital heart disease in a timely manner. This issue requires the formulation of national policy that will make screening for CCHD a priority.

Keywords: Pulse oximetry screening, clinical examination, congenital heart disease.

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Introduction

The principal rationale for new-born screening lies in the pre-symptomatic identification of congenital heart defects that are either immediately life threatening or become so as a consequence of physiological changes occurring as the infant adapts to postnatal life.[1] It is difficult to identify clearly the time when clinical examination of the cardiovascular system was introduced into routine practice ,but it is likely to that this happened as an integral part of the clinical new-born examination which became more widespread in the 1950s with the rise in hospital deliveries. As with other new-born screening based on the routine new-born examination, the distinction between good clinical practice and screening can be a fine one. Current guidance published in Health for all children includes recommendations to examine the cardiovascular system of all infants' shortly after birth and again at 6-8 weeks of age.[2,3]

In the past, new-born examinations were carried out twice before discharge, once within 24 hrs of birth and again few days later. Clinical clues are often subtle. In view of relative lack of sensitivity of the routine clinical examination for detection of CHD and the potential implications is not diagnosing critical CHD at birth, recent studies have focused on the use of pulse oximetry for detection of CHD.[4]

In new-borns, ECG and chest X-ray changes may take a few days to evolve. For the new-born, particularly in the first few days a normal ECG and normal chest X- ray does not rule out serious heart disease. Hyperoxia test is frequently used to rule out critical CHD.[5,6] When doubts persist whether a patient has CHD or not despite a thorough clinical exam and chest X-ray, ECG, and hyperoxia test, an echocardiogram should be arranged.

Two commonest causes being infections sustained in the early months of pregnancy and the administration of drugs to mother. Maternal rubella is a known cause commonly resulting in persistent ductus arteriosus and the next common lesion is peripheral pulmonary artery stenosis. Other virus infections in early pregnancy may similarly affect the foetus including mumps, influenza, measles, chicken pox, herpes zoster, infective hepatitis and poliomyelitis. Drugs which can cause CHD are cytotoxic drugs, corticosteroids, fertility drugs, warfarin, folic acid antagonists, dextroamphetamine, certain anticonvulsants and lithium.[7]

Prenatal ultrasound, performed by those with specific training in congenital heart defects, can identify a variety of CCHD lesions; however, numerous studies have reported that even when foetal ultrasound is routinely performed during pregnancy, fewer than 50% of cases of CCHD are

identified. Most of the published literature comes from European countries, which tend to have more centralized health care systems and uniform practices and may represent the best –case scenario for population prenatal ultrasound screening. In the United States, many congenital surgery referral centers have reported prenatal detection rates >50% for functional single ventricle lesions, although the detection rate is generally <30 % for CCHD lesions with 2- ventricle circulation. The quality of anatomic ultrasounds varies considerably.[8,9]

Pulse oximetry is a reliable and non-invasive method for measuring oxygen saturation and has a rapid response. During the past several years pulse oximetry has gained wide spread use in the neonatal oxygenmonitoring.[10]

Pulse oximetry is a method of measuring oxygen saturation from a light signal transmitted through the tissue, taking into account the tissue pulsatile nature of volume changes with blood flow. It is a non-invasive means of obtaining information regarding saturation continuously. The pulse oximeter has 2 signal components, AC signal component represents absorption of light by the pulsating arterial blood, and the DC signal component represents absorption of light by the tissue level, including venous, capillary and non-pulsatile arterial blood. Pulse oximeters differentiate the absorbance of incidence of light by pulsatile arterial component from the static component. Hence they are called pulse oximeters. Measurement of arterial haemoglobin oxygen saturation is accurate and reliable in new-born.[4,11]

The present study was done to determine the effectiveness of a pulse oximetric screening for the detection of congenital heart in otherwise healthy new-born and to determine if a pulse oximetry screening combined with clinical examination is superior in the diagnosis of congenital heart disease to clinical examination alone.

Subjects and Methods

1000 new-born babies born in Narayana medical college and hospital during a period of 12 months 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.

Inclusion criteria

1000 new-born babies delivered in Narayana Medical College Hospital.

Exclusion criteria

1. New-born with respiratory disorder.
2. Premature babies less than 37 weeks of gestation.
3. Extremely low birth weight babies

Results

Table 1: Combined clinical and pulse oximetry screening for CHD.

Clinical/pulse oximetry >48 hrs	CHD Present	Absent
Abnormal	22	1
Normal,	1	976

Sensitivity = 95.65%, Specificity = 99.89%, Positive predictive value = 95.65%

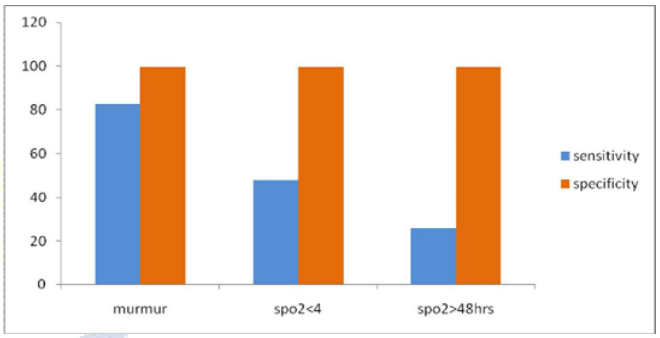

Figure 1: Showing Sensitivity and specificity of clinical examination and pulse oximetry screening for CHD.

Table 2: Combined clinical and pulse oximetry in cyanotic heart disease.

Combined Clinical/ pulse oximetry>48 hrs	CCHD	
	Present	Absent
Abnormal	5	20
Normal	0	975
Sensitivity = 100%	Positive predictive value =20%	
Specificity = 97.98%		

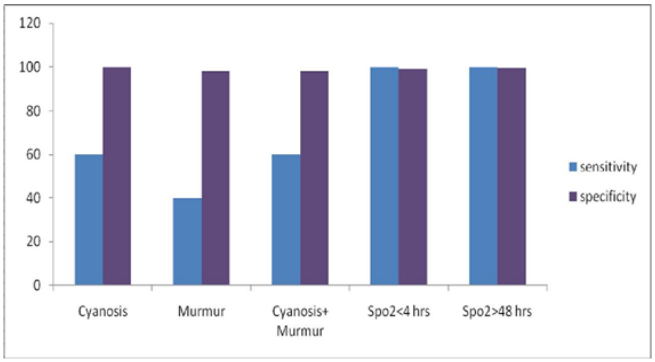

Figure 2: Showing Sensitivity and specificity of clinical examination and pulse-oximetry screening for CCHD.

A common feature of many forms of congenital heart disease is hypoxemia. Hypoxemia may result in obvious cyanosis. However, generally 4-5gm of deoxygenated haemoglobin is needed to produce visible central cyanosis,

independent of haemoglobin concenteration. For the typical new-born with a haemoglobin concentration of 20 g/dl, cyanosis will only be visible when arterial oxygen saturation is <80%.If the infant has a haemoglobin concentration of 10 g/dl, the saturation must be less than 60% before the cyanosis to be apparent. Importantly, those children with mild hypoxemia, with arterial oxygen saturation of 80% to 95%, will not have visible cyanosis. Pulse oximetry was developed in the early 1970s based on the different absorption spectra between oxygenated and deoxygenated haemoglobin. Deoxygenated haemoglobin absorbs light in the red band (600 to 750nm), whereas oxygenated haemoglobin absorbs light in the infrared band (850 to 1000nm). The ratio of light absorbance at these two wavelengths correlates with the saturation of haemoglobin in the capillaries. 4 7At the near infrared range, the light absorbance of oxygenated haemoglobin is different from that of reduced haemoglobin .The absorbance of both wavelengths has a pulsatile component which is due to fluctuation in the volume of arterial blood between the source and detector.[12]

Table 3: Statistical analysis of different screening methods for detection of congenital heart diseases.

	Pulse oximetry within 4 Hrs.'	Pulse oximetry after 48 Hrs.'	Clinical exam	Combined
Sensitivity	47.8	26	60	95.65
Specificity	99.8	99.8	98	99.89
Positive	91.66	85.71	95.23	95.65
Predictive				
Value				

Table 4: Statistical analysis of different screening methods for detection of cyanotic congenital heart diseases.

	Pulse oximetry within 4 Hrs.'	Pulse oximetry after 48 hrs	Clinical exam	Combined
Sensitivity	100%	100%	60	100%
Specificity	99.2%	99.7%	98	97.98%
Positive	41.6%	71.42%	14.62	20%
predictive				
value				

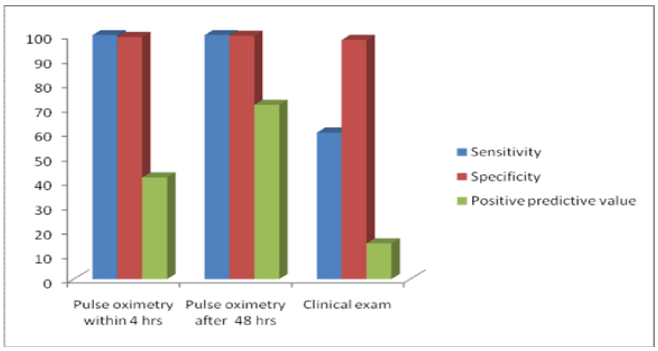

Figure 3: Showing sensitivity, specificity and PPV of combined Screening for CCHD.

Discussion

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.

Baker and Habib,[13] study showed a sensitivity y of 46% for clinical examination. 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. Hoke and colleagues had done both arm and leg saturation in their studies but it is time consuming.[14] Byrne and colleagues measured oxygensaturation 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.[15]

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-termnew-borns before 12hrs of age, in 50% of new-borns by about 24hrs, and in 81% of new-borns by 48hrs7 4 .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. But this would allow the anticipation of clinically critical situations, which can result in higher morbidity y 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%.

Richmond and colleagues study demonstrated that pulse oximetry in the first 24 hrs of life can result in timely recognition of seriouscyanotic congenital heart disease Sendelbach and colleagues did pulse oximetry screening at 4hrs of age and before discharge.[16,17] In their study considering only the initial 4 hour Pox screening, sensitivity was 0.75 and specificity was 0.94. Of 859 neonates with abnormal Pox screening results, 3 had CCHD (clinically apparent soon after the 4 hour Pox screening) and 856 were false positive screens. When considering both the initial 4 hour Pox screening coupled with the repeat Pox screening at discharge (for neonates for whom both Pox results were available),sensitivity was 0.00 and specificity was 0.99. Their study did not support recommending routine Pox screening in seemingly healthy neonates.

Koppel and colleagues study calculated a detection rate of 60%,[18] a false positive rate of 0.05% and a positive predictive value of 75% 5 9 for pulse oximetry screening. In their study a new-born with TAPVC was notdetected by pulse oximetry.

Arlettaz and colleauges had reported in their study that post ductal pulse-oximetric screening in the first few days of life is an effective means for detecting cyanotic CHD in otherwise healthy new-borns. Their study showed sensitivity of 100%, specificity of 99.7% and PPV of 63% for the detection of cyanotic heart disease.[1]

In this study, we examined the effectiveness of clinical examination and pulse oximetry in detection of CHD in new-borns. We evaluated the effectiveness of combined screening also. This study showed that pulse oximetry can detect cyanotic CHD in asymptomatic new-borns after it has been missed by routine clinical examination. Clinical examination picked many acyanotic CHD where pulse oximetry failed to detect it. The combined approach had an additive effect and resulted in more efficient screening of CHDs.

The sensitivity of combined method in our study is 95.65%, 26% for pulse oximetry alone, and 60% for clinical examination alone. Specificity for combined method is 99.89%, and 99.8%, 98% for pulse oximetry and clinical examination alone. Positive predictive value for the combined method is 95.65%.We took the SpO2 value within 48-72 hours for sensitivity detection of combined method as it had less false positive findings.

Vaidyanathan and colleagues study showed a sensitivity of 19%, specificity of 88%, and PPV of 12 % for combined screening.[19] To evaluate the effectiveness of combined clinical examination and pulse oximetry screening, a large prospective study is needed. As pulse oximetry is non-invasive and safe, this screening programme can be included in the discharge plan for every new-born.

In our study 2 cases clinical examination and antenatal scan were normal but pulse oximetry value in first 4hrs were below 95 and echocardiography had done and found to be TGA. Two babies were antenatally diagnosed to have CHD. One had pulmonary stenosis and the other had DORV. Among the five babies with cyanotic heart disease, 3 babies were found to have murmur and cyanosis.

Table 5: Showing specificity, sensitivity and PPV of clinical examination, Pox screening and combined method by various studies.

	Clinical		P Ox				Combined		
	SENS	SPEC	PPV	SENS	SPEC	PPV	SENS	SPEC	PPV
Vaidyanathan And Colleagues19	9.26	97.4	23.3	11.4	90.9	9.4	19	88	12
Arletaz and Colleagues1				100	99.7	63			
Baker and Habib13	46	100		31	100		77	100	66.7

Seven babies (0.7%) were found to have PPHN. One term baby with tachypnea had persistent low SpO2 found to have severe PPHN without any CHD. All babies with PPHN had SpO2 less than 95% within 4hrs. Six (26% of CHDs) babies were associated with acyanotic heart diseases one had low SpO2 after 48 hrs also and found to have severe PPHN with large VSD. So SpO2 measurement within first 4hrs can lead to false positive detection of cyanotic CHDs due to PPHN. Sendelbach and colleauges study showed that the high number of false positive cases due to pulmonary hypertension is certainly influenced by their early measurement.[17]

Chest X-ray, ECG and echocardiogram were done for those babies who had abnormal clinical finding or Pox reading. Chest X-ray was abnormal in 4 cyanotic congenital heart diseases and 2 acyanotic, heart diseases.ECG was abnormal

in 4 cyanotic heart disease and 2 acyanotic heart disease.
Echocardiogram showed structural heart disease in 23 babies.[18] babies with acyanotic heart disease and 5 cyanotic heart disease.
In our study follow up at 2 weeks of life did not get any newly detected murmur. Gregory and colleague20 study showed that routine clinical examination at 6-8weeks of life led to the diagnosis of 31% of CHDs in the study population.

Conclusion

Though routine clinical examination is effective in detection of congenital heart disease in new-borns, combining pulse oximetry and clinical examination after birth had a higher sensitivity for detection of congenital heart diseases in new-borns.
Combining clinical examination and pulse oximetry can enhance the clinician's ability to detect life-threatening congenital heart disease in a timely manner. This issue requires the formulation of national policy that will make screening for CCHD a priority.

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