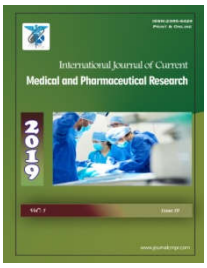
Research Article

INTERNATIONAL JOURNAL OF CURRENT MEDICAL AND PHARMACEUTICAL RESEARCH

ISSN: 2395-6429, Impact Factor: 4.656
Available Online at www.journalcmpr.com
Volume 5; Issue 10(A); October 2019; Page No. 4623-4627
DOI: http://dx.doi.org/10.24327/23956429.ijcmpr201910758



ROLE OF CLINICAL EXAMINATION AND PULSE OXIMETRY IN SCREENING FOR CONGENITAL HEART DISEASE IN NEWBORNS

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ARTICLE INFO

Article History:
Received 06th July, 2019
Received in revised form 14th August, 2019
Accepted 23rd September, 2019
Published online 28th October, 2019

Key words:

Congenital heart disease, Clinical examination, Pulse oximetry, Asymptomatic newborns.

ABSTRACT

Background and objective: This study was designed to evaluate the effectiveness of routine postnatal clinical examination and pulse oximetry screening in detecting congenital heart disease in newborns. The aim of this study is to determine whether a pulse oximetry screening combined with clinical examination is superior in the diagnosis of congenital heart disease to clinical examination alone.

Methods: 1000 term newborn babies born in tertiary Hospital during the study period of 18 months (Feb 2017 to May 2018) 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. Echocardiogram was 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 of combined screening was 95.65%, whereas it was 26% for oximetry alone and60% for clinical examination alone. Specificity for combined screening was 99.89%, 99.8% for pulse oximetry alone, 98% for clinical examination alone. The positive predictive value of the combined tool was 95.65%.

Conclusion: Combining pulse oximetry and clinical examination can enhance the clinician's ability to detect life threatening CHD in a timely manner.

INTRODUCTION

Among all congenital malformations, cardiac lesions are the most common, with a prevalence of approximately 6-8/1,000 live births.[1] Clinical diagnosis of heart disease in the newborn can be quite challenging. Clinical examination alone fails to detect more than 50% of babies with congenital heart disease[2](CHD). Early diagnosis of CHD is important because delay in diagnosis can lead to cardiac failure, cardiovascular collapse and even death.[1]

Pulse oximetry has been used as a screening method for CHD in newborn period. It is a non invasive and specific screening tool for an early detection of critical congenital cardiovascular malformations.[3]

Approximately one quarter of these children will have critical congenital heart disease, which by definition requires surgery or catheter intervention in the first year of life. Because timely recognition of CCHD could improve outcomes, it is important to identify and evaluate strategies to enhance early detection. Pulse oximetry has been proposed as one such strategy[4].

Echocardiography is the gold standard for detecting CHD, however it is impractical to use echocardiography as a screening tool in newborns.

In the Indian context with a high birth rate, the absolute number of babies with CHD may be enormous. If they are not detected in the newborn period it will cause lot of morbidity and even mortality. Hence there is a need to improve the screening methods to increase the detection of CHD in neonates. This study is an attempt to increase the effectiveness of screening of CHD by combining clinical examination and pulse oximetry in newborns[5].

Objectives of the Study

1. To evaluate the effectiveness of routine postnatal clinical examination in detecting structural heart disease in newborns.
2. To determine the effectiveness of a pulse oximetric screening for the detection of congenital heart disease in otherwise healthy newborn.
3. To determine if a pulse oximetry screening combined with clinical examination is superior in the diagnosis

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of congenital heart disease to clinical examination alone.

MATERIALS AND METHODS

1000 newborn babies born in tertiary hospital during a period of 16 months (Feb 2017 to May 2018) underwent a thorough clinical examination on day 2 of life with emphasis on peripheral pulses, cyanosis, tachypnea, cardiac pulsations and murmurs. Chest X ray and ECG were done if any abnormality was detected. Echocardiography was done for further confirmation. 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 Pulse oximetry 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 term newborn babies delivered in a tertiary care hospital.

Exclusion Criteria

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

Statistical Analysis

A total of 1000 term newborn babies were screened. Newborns with respiratory distress syndrome, premature babies(less than 37weeks), 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 below 95% were evaluated with 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 Double Outlet Right Ventricle 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 echocardiography, 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.

Comparing Clinical Examination with Presence of Congenital Heart Disease

Table 1 Association of respiratory rate with CHD (ACHD, CCHD)

		Respiratory Rate		Total
		<60/min	>60/min	
Normal	Count	976	1	977
	%	97.8%	50.0%	97.7%
Acyanotic Heart Disease	Count	17	1	18
	%	1.7%	50.0%	1.8%
Cyanotic Heart Disease	Count	5	0	5
	%	0.5%	0%	0.5%
Total	Count	998	2	1000
	%	100%	100%	100%

The P value is 0.1,suggesting that there is no significant relationship between respiratory rate and congenital heart disease. Among thousand babies 2 had abnormal respiratory rate. One had acyanotic heart disease and one had severe PPHN.

Table 2 Association of peripheral pulse and CHD (ACHD, CCHD)

		Peripheral Pulse		Total
		Normal	Abnormal	
Normal	Count	977	0	977
	%	97.8%	0%	97.7%
Acyanotic	Count	17	1	18
	%	1.7%	100.0%	1.8%
Cyanotic	Count	5	0	5
	%	0.5%	0%	0.5%
Total	Count	999	1	1000
	%	100.0%	100.0%	100.0%

P value was 0.1. suggesting no significant relation between peripheral pulse and CHD. The one case with abnormal peripheral pulsation was PDA with bounding pulse.

Table 3 Cyanosis vs Congenital Heart disease

		Cyanosis		Total
		Absent	Present	
Normal	Count	977	0	977
	%	98.0%	0%	97.7%
Acyanotic	Count	18	0	18
	%	1.8%	0%	1.8%
Cyanotic	Count	2	3	5
	%	0.2%	100%	0.5%
Total	Count	997	3	1000
	%	100.0%	100.0%	100.0%

The p value is less than 0.005 suggesting a quite significant relation between cyanosis and cyanotic congenital heart disease

Table 4 Murmur vs CHD

		Murmur		Total
		Absent	Present	
Normal	Count	976	1	977
	%	99.6%	5.0%	97.7%
Acyanotic	Count	1	17	18
	%	0.1%	85.0%	1.8%
Cyanotic	Count	3	2	5
	%	0.3%	10.0%	0.5%
Total	Count	980	20	1000
	%	100.0%	100.0%	100.0%

P value is 0.001 (showing significant relationship)

Comparing Pulse Oximetry with Presence of Congenital Heart Disease

Table 5 SpO_2 < 4 HRS VS CHD

			Acyanotic	Cyanotic	Total
spo2<4hr	>95%	Count	11	0	11
		%	66.7%	0%	50.0%
	<95%	Count	6	5	11
		%	33.3%	100.0%	50.0%
Total		Count	17	5	22
		%	100.0%	100.0%	100.0%

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 within 4 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).Sensitivity = 47.8% Specificity = 99.8% Positive predictive value = 91.66

Table 6 SpO_2 within 48-72 hrs vs CHD

SpO2			Acyanotic	Cyanotic	Total
Spo2 within 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%

One baby who had SpO2<95 % was detected to have PPHN, without any CHD. Out of the 18 acyanotic CHDs, only 1 showed abnormal spo2 within 48-72 hrs while all the cases(5) with Cyanotic CHD showed abnormal spo2 within 48-72 hrs. The one with abnormal spo2 and no significant CHD turned out to be PPHN. One acyanotic heart disease with low SpO2 was associated with severe PPHN (large VSD with PPHN). P value is 0.000 (highly significant). Sensitivty =100% Specificity = 99.7% Positive Predictive Value =71.42%

Table7 ECHO Vs congenital heart diseases

ECHO	Number	Percent
Not done	975	97.5
Normal	2	0.2
Abnormal	23	2.3
Total	1000	100.0

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

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

Comparing Combined Clinical and Pulse Oximetry with Presence of Congenital Heart Disease

Table 8 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%

Table 9 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 Predictive Value	91.66	85.71	95.23	95.65

RESULTS

1. In this study, antenatal scan could detect only 8% of CHDs
2. Respiratory rate, heart rate, abnormal pulses have no significant correlation for CHD in this study.
3. Cyanosis has significant correlation with cyanotic heart disease. Sensitivity in detecting CCHD is 60%, specificity is 100%
4. Sensitivity of murmur for CHD is 82.6%, specificity is 99.8%
5. For CCHD sensitivity is 40%, specificity is 98%
6. Sensitivity for combined cyanosis and murmur for detecting CHD is 86.9%, specificity is 99.89%, and Positive predictive value (PPV) of 95.23%, for CCHD, sensitivity is 60%, specificity is 98% and PPV of 14.62%.
7. Pulse oximetry screening within 4hrs of birth for CHD, sensitivity is 47.8%, specificity is 99.8% and PPV is 91.66%. For CCHD, sensitivity is 100%, specificity is 99.2% and PPV of 41.6%.
8. Pulse oximetry screening within 48-72hrs of birth shows sensitivity for CHD as 35.2%, specificity as 99.8%, and positive predictive value as 85.71%
9. For CCHD, sensitivity is 100%, specificity is 99.7% and positive predictive value is 71.42%
10. Early pulse oximetry screening leads to false positive results due to PPHN
11. Combined clinical and pulse oximetry screening for CHD shows sensitivity of 95.65%, specificity of99.89% and positive predictive value of .65% For CCHD, sensitivity is 100%,specificity is 97.98% and PPV is 20%.

DISCUSSION

According to Mitchell and colleagues[6] definition, congenital heart disease is a gross structural malformation of the heart disease or great intrathoracic vessels with a real or potential functional importance. Early recognition of Congenital Heart Disease (CHD) is of crucial importance because clinical presentation and deterioration may be sudden. Clinical examination for the early signs of CHD is an essential part of routine neonatal examination and can identify some asymptomatic newborns. 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.

In Sendelbach and colleagues[7]study, only 28% of CHD were detected prenatally[7].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 to dangerous overconfidence.

A study by Ainsworth and colleagues showed, about 54% of babies with murmur on routine clinical examination had structural heart disease[8] Arlettaz and colleauges[1] study also proved the importance of clinical examination. In their study, 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. Ainsworth[8] and Richmond's[9] studies also proved that the presence of murmur does not correlate with severity of the lesion.

Baker and Habib[10] study showed a sensitivity of 6% for clinical examination. Specificity was 100%.Vaidyanathan and colleagues study had 57 patients 2.9% with positive clinical examination, the most common being murmur 84 patients,.6%).Clinical evaluation was positive in only 3 patients (17.6%) with major and 32 patients (7.8%) with minor

CHD. The sensitivity for clinical examination in their study was 9.26%.

Clinical examination for the early signs of CHD is an essential part of routine clinical examination.

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, Respiratory rate and abnormal pulsus showed no significant relationship with CHD. One baby with bounding peripheral pulse was detected to have PDA in echocardiography. 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.

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%.

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 fullterm newborns before 12hrs of age, in 50% of newborns by about 24hrs,and in 81% of newborns by 48hrs[11].Performing pulse oximetry screening at less than 6hrs of age when some newborns may still have persistent ductal shunting, could result in false positives.
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 and neurological sequelae. In our study pulse oximetry screening within 4hrs had sensitivity of 47.8%, specificity of99.8%, and positive predictive value of 91.66%.Screening after48 hours showed a sensitivity of 26%, specificity of 99.8%, and PPV of 85.71%.

Richmond and colleagues[9] study demonstrated that pulse oximetry in the first 24 hrs of life can result in timely recognition of serious cyanotic congenital heart disease Sendelbach and colleagues[7] did pulse oximetry screening at 4hrs of age and before discharge. 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 was0.99.Their study did not support recommending routine Pox screening in seemingly healthy neonates.

Koppel and colleagues[12] study calculated a detection rate of 60%, a false positive rate of 0.05% and a positive predictive value of 75% for pulse oximetry screening. Vaidyanathan and colleauges[13] study reported poor sensitivity for pulse oximetry for the detection of CHD. Their study showed sensitivity of 11.4%, specificity of 90.9% and PPV of 9.4% for Pox screening.

Habib and Baker[10] study showed sensitivity of 31%, specificity of 100% for Pox screening for congenital heart disease. Richmond and colleagues[9] reported sensitivity of 26% and specificity of 100%.Hoke and colleauges's[14] case control study had relatively low specificity of 88% and high false positive rates compared with other studies.

In this study, we examined the effectiveness of clinical examination and pulse oximetry in detection of CHD in newborns. We evaluated the effectiveness of combined screening also. This study showed that pulse oximetry can detect cyanotic CHD in asymptomatic newborns 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, 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. Similar study by Baker and Habib[10] showed Sensitivity for combined method was 77%. Specificity was 100% . The positive predictive value for combined method was 66.7%[10]. Vaidyanathan and colleagues[13]study showed a sensitivity of 19%, specificity of 88%,and PPV of 12 % for combined screenings

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 colleagues[1] study showed that routine clinical examination at 6-8weeks of life led to the diagnosis of 31% of CHDs in the study population.

CONCLUSION

Pulse-oximetry screening offers an effective and reliable means for detecting cyanotic CHD in asymptomatic newborns. Though routine clinical examination is effective in detection of congenital heart disease in newborns, combining pulse oximetry and clinical examination after birth had a higher sensitivity for detection of congenital heart diseases in newborns.

Combining clinical examination and pulse oximetry can enhance the clinician's ability to detect life-threatening congenital heart disease in a timely manner.

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How to cite this article:

Shiv Narayan Panda and Mahesh Awariwar (2019) ' Role of Clinical Examination and Pulse Oximetry in Screening for Congenital Heart Disease in Newborns', *International Journal of Current Medical and Pharmaceutical Research,* 05(10), pp 4623-4627.

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