

Role of Pulse Oximetry For the Early Detection of Congenital Heart Diseases: A Prospective Observational Study

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ABSTRACT

Background: Cardiac lesions are the most common congenital deformities. Pulse oximeter is a valuable tool for early detection of Congenital Heart Diseases in the rural areas, which do not have a well-equipped cardiology set up. The aim of the present study was to study the efficaciousness of pulse oximeter along with the clinical parameters in detecting congenital heart diseases in the newborns with echocardiography as the investigative modality.

Materials and Methods: A prospective observational study was conducted in the Department of Pediatrics at Kamla Nehru State Hospital for Mother and Child (KNSHM & C), newborn unit and Department of Cardiology, Indira Gandhi Medical College, Shimla, which is a tertiary care hospital. The study involved 3464 consecutive newborns with gestation more than 35 weeks who underwent pulse oximetry and physical examination from 0-48 hours of life. Pulse oximetry examination was performed on the left foot of newborns for at least 2 minutes in a stable position with Comet BPL and T medical's new dual parameter colour TFT portable monitor. The results were analysed using SPSS software, and the probability value of less than 0.05 was considered significant.

Results: The study enrolled a total of 3580 newborns. A total of 3464 (96.76%) infants were enrolled in the study and the rest 116 (3.24%) were excluded from the population of the study as they did not meet the inclusion criteria. 45 newborns with $SPO_2 < 95\%$, 9 (0.26%) had cyanosis. Amongst

the 3419 patients with $SPO_2 > 95\%$, cyanosis was absent (100%). There was a significant difference in cyanosis amongst both the groups. There were 6.7% subjects with $SPO_2 < 95\%$ who had a murmur and the murmur was absent in the subjects with $SPO_2 > 95\%$. There was a significant difference in the murmur amongst both the groups.

Conclusion: Pulse oximetry is an important tool for early detection of congenital heart diseases along with the clinical parameters.

Keywords: Pulse Oximeter, Oxygen Saturation, Echocardiography, Congenital Heart Diseases.

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INTRODUCTION

Among all congenital malformation, cardiac lesions are the most common with a prevalence of approximately 6-8 per thousand live births and the incidence of congenital heart disease is 8-10/1000 live births.¹⁻⁴ Congenital Heart Diseases account for 9% of all infant deaths out of which 40% of deaths are due to congenital malformations. Children with CHD are, approximately, at twelve times higher risk of mortality in the first year of life. Routine neonatal examination fails to detect approximately 50% of infants with CHD.^{5,6} The costs associated with routine fetal echocardiography would make it impractical as a screening modality. Byrne et al reported the detection of desaturation

secondary to hypoplastic left heart syndrome, coarctation and tetralogy of Fallot in a group of asymptomatic newborns through the use of simultaneous upper and lower extremity pulse oximetry.⁷ Pulse oximetry is a standard method of monitoring blood oxygenation in newborn infants. Pulse oximetry measurements (SPO_2 -the estimated percent oxygen saturation of pulsatile arterial blood) are accurate and reliable. Instrument calibration is not required. The probes are noninvasive and easy to apply and do not cause significant cutaneous injuries even among the smallest babies. SPO_2 measurements respond, within seconds, to changes in blood oxygenation. There are significant correlations of SPO_2

with arterial blood oxygen saturation (SaO₂), arterial oxygen pressure (PaO₂), and transcutaneous oxygen (tcPO₂) over the normal range of blood oxygenation.⁸ The pulse oximetry has therefore become the 'fifth vital sign'.⁹

Pulse oximetry has been suggested as a method to screen newborns in the early neonatal period to detect these lesions and initiate therapy before they become life-threatening, but in our set up, the only method used for screening large number of asymptomatic newborns for congenital heart diseases is the physical examination which has been shown to be ineffective.¹⁰ In the developing countries with inadequate medical personnel, pulse oximetry can be very useful in early detection of CHD. Other advantages of pulse oximetry are rapid response time to changes in oxygen saturation, provision of continuous information non invasively and absence of the need to calibrate before use. This study was conducted to evaluate the effectiveness of pulse oximetry along with the clinical parameters to detect the Congenital Heart Diseases.

MATERIALS AND METHODS

All consecutive newborns in Kamla Nehru State Hospital for Mother and Child (KNSHM & C) and newborn nursery in department of Paediatrics, Indira Gandhi Medical College (IGMC), Shimla (Tertiary care hospital) in the study population were examined in the prospective, observational manner. In this study, all the newborns with more than 35 weeks of gestation,

determined by maternal record and New Ballard Score within 48 hours of birth were included. The newborns with less than 35 weeks of gestation and with parents unwilling to participate were excluded from the study. The study protocol was approved by ethical review committee of Indira Gandhi Medical College, Shimla. Informed written consent was obtained from the parents before enrollment of the newborns in the study.

Procedure

Pulse oximetry examination was performed on the left foot of the newborns for at least 2 minutes in a stable position with Comet BPL and T medical's new dual parameter colour TFT portable monitor. It monitors oxygen saturation, pulse rate, displays plethysmograph along with perfusion bar indicator and combines the principles of spectrophotometricoximetry and plethysmography. Simultaneously, the clinical examination was done. The newborns with oxygen saturation less than 95% were subjected to echocardiographic examination. All echocardiographic studies, M-mode and 2-D were on advanced technology laboratory ultramark-7 echocardiography machine with facilities of 2-D, M-mode and colour flow Doppler. Statistical analyses were done with SPSS. All discrete variables were expressed as percentages and continuous variables as mean \pm SD. The difference in distribution of discrete variables was analysed using chi square test. Significance of difference in continuous variables was analysed using students t test, and p value of < 0.05 was considered as statistically significant.

Table 1: Baseline clinical characteristics in relation to pulse oximetry in the study population

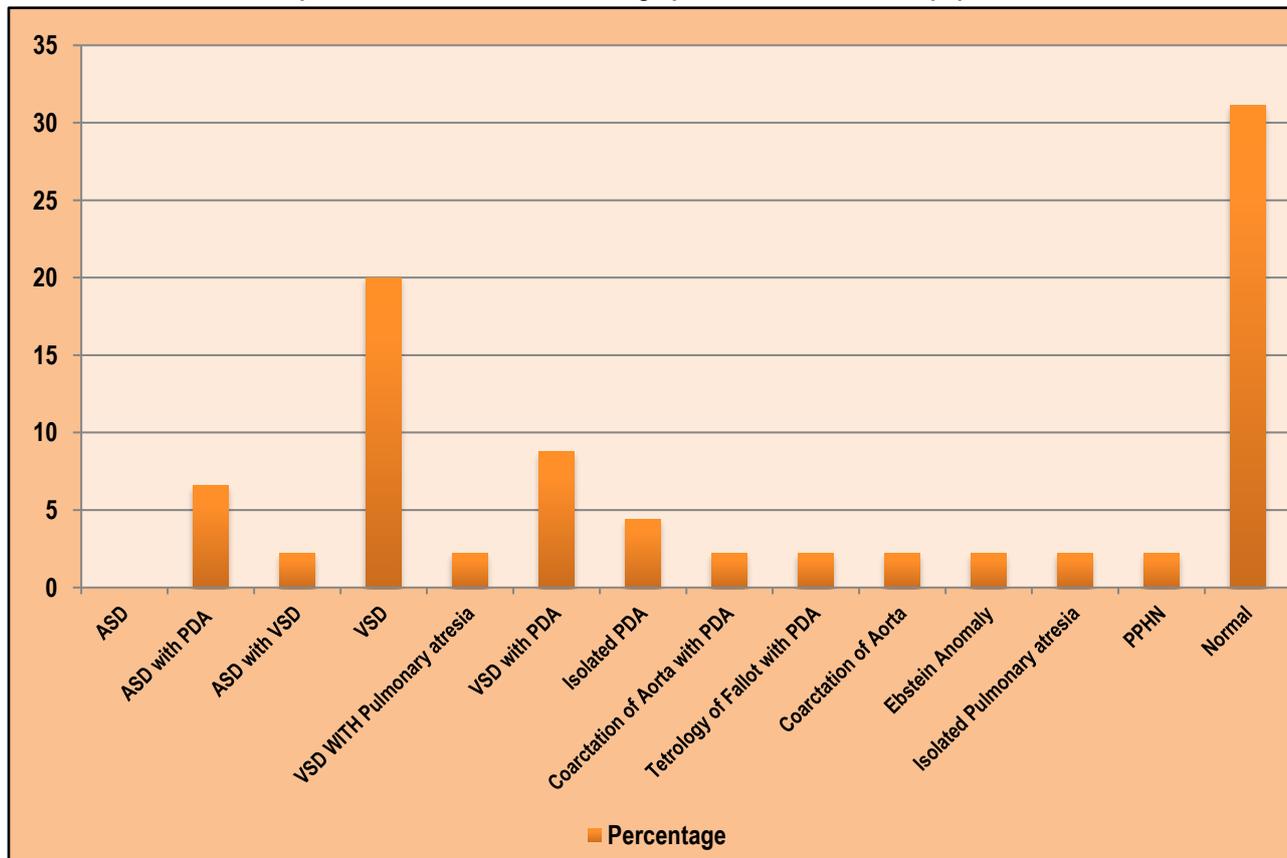
Characteristics	SPO ₂ <95% n=45(%)	SPO ₂ >95% n=3419(%)	p-value
Cyanosis			
- Present	9 (20)	0(0)	0.000*
- Absent	36 (80)	3419 (100)	
Murmur			
- Present	3 (6.7)	0	0.000*
- Absent	42 (93.3)	3419 (100)	
APGAR at 1 min.			
- <3	0	14 (0.4)	0.69
- 3-6	1 (2.2)	152 (4.4)	
- >6	44 (97.8)	3253 (95.2)	
APGAR at 5 min.			
- <3	0	0	0.42
- 3-6	0	64 (1.9)	
- >6	45 (100)	3355 (98.1)	
Respiratory rate			
- <40	5 (11.1)	288 (8.4)	0.70
- 40-60	39 (86.7)	2997 (87.7)	
- >60	1 (2.2)	134 (3.9)	
Heart rate			
- <120	2 (4.4)	374 (10.9)	0.27
- 120-140	40 (88.9)	2722 (79.7)	
- >140	3 (6.7)	323 (9.4)	

*p value is significant.

Table 2: Distribution of echocardiographic results in screened population of SPO₂< 95%

LESION	No. of patient(n=45)	Percentage(%)
TOTAL	45	100
ASD	5	11.1
ASD with PDA	3	6.6
ASD with VSD	1	2.2
VSD	9	20
VSD WITH Pulmonary atresia	1	2.2
VSD with PDA	4	8.8
Isolated PDA	2	4.4
Coarctation of Aorta with PDA	1	2.2
Tetrology of Fallot with PDA	1	2.2
Coarctation of Aorta	1	2.2
Ebstein Anomaly	1	2.2
Isolated Pulmonary atresia	1	2.2
PPHN	1	2.2
Normal	14	31.1

Graph 1: Distribution of echocardiographic results in screened population



RESULTS

The study enrolled a total of 3580 newborns. A total of 3464 (96.76%) infants were enrolled in the study and the rest 116 (3.24%) were excluded from the study population as they did not meet the inclusion criteria.

From Table 1, we can see 45 newborns had SPO₂<95%, 9 (0.26%) had cyanosis. In all 3419 patients with SPO₂ > 95%; cyanosis was absent (100%). There was a significant difference in cyanosis amongst both the groups. There were 6.7% subjects with SPO₂ < 95% who had a murmur and, the murmur was absent in

the subjects with SPO₂ >95%. There was a significant difference in murmur amongst both the groups. There was no significant difference in the rest of baseline clinical parameters.

Echocardiography was performed in 45 newborns that had oxygen saturation less than 95%. A total of 30 (68.88%) newborns had abnormal echocardiographic results suggestive of congenital heart diseases. Atrial septal defect was detected in 5 patients (11.1%), there were 9 patients (20%) who had ventricular septal defect. Both atrial and ventricular septal defects were detected in 1

subject. Ventricular septal defect with pulmonary atresia was detected in 1 patient. Atrial septal defect with PDA was seen in 6.6% patients. Coarctation of aorta was seen in 1 patient. Tetralogy of fallot with PDA was also seen in 1 patient. Isolated pulmonary atresia and Ebstein anomaly were seen in 1 patient each respectively. The distribution of congenital heart diseases is depicted in Table 2.

Table 3 compares the baseline clinical characteristics of newborns with and without congenital heart disease with $\text{SPO}_2 < 95\%$. There were 5 normal subjects with gestational age of 35-38 weeks and 13 patients of congenital heart disease. Gestational age of 10

normal subjects and 17 with congenital heart disease was more than 38 weeks. There was no significant difference in the gestational age amongst both the groups. There were 17 males and 13 females who had congenital heart disease.

Cyanosis was absent in all the normal infants whereas 9 infants with congenital heart disease had cyanosis and 21 didn't have cyanosis. There was significant difference in the cyanotic infants amongst both the groups. Murmur was absent in all the normal subjects but 10% of infants with congenital heart disease had murmurs. There was no significant difference in murmur amongst both the groups.

Table 3: Baseline characteristics of newborns with or without congenital heart disease with $\text{SPO}_2 < 95\%$ (45 cases)

Characteristics	Normal (%) (n=15)	Congenital heart disease (%) (n=30)	P - value
Gestational age			0.3
- 35-38 wks	5(33.3)	13(43.3)	
- >38 wks	10(66.7)	17(56.7)	
Sex distribution			0.5
- Male	8(53.3)	17(56.7)	
- Female	7(46.7)	13(43.3)	
Birth weight			0.6
- 1500-2500 g	6(40)	12(40)	
- >2500 g	9(60)	18(60)	
Apgar at 1 min.			0.6
- < 3	-	-	
- 3-6	-	1(3.3)	
- >6	15(100)	29(96.7)	
Apgar at 5 min			-
- <3	-	-	
- 3-6	-	-	
- >6	15(100)	30(100)	
Heart rate (beats/min)			0.2
- <120	-	2(6.7)	
- 120-140	15(100)	25(83.3)	
- >140	-	3(10)	
Respiratory rate (per min)			0.3
- <40	1(6.7)	10(33.3)	
- 40-60	13(86.7)	20(86.7)	
- >60	1(6.7)	-	
Cyanosis			0.01*
- Present	-	9(30)	
- Absent	15(100)	21(70)	
Murmur			0.2
- Present	-	3(10)	
- Absent	15(100)	27(90)	

*p value significant

DISCUSSION

It is essential to recognize congenital heart disease in the early stages as the deterioration is sudden and, most of the children with complex heart disease die at presentation or before any surgical intervention is made for their correction.^{4,11} Though the clinical examination is essential for early signs of CHD which can identify asymptomatic newborns, pulse oximetry has been suggested as a screening tool for early detection of CHD in asymptomatic newborns as physical examination alone is insufficient.

In India, most of the studies done on CHD are purely clinically oriented due to cost effectiveness and non-availability of echocardiography. The diagnosis of CHD can be fallacious, if diagnosed clinically only. There is no data pertaining to pulse oximetry use for early detection of CHD from the Indian studies. The present study was done with oxygen saturation less than 95% as the cut off value, as it is considered to be normal pulse oximeter value in healthy newborns and overestimates arterial oxygen saturation at low values and underestimates at higher

saturation.^{12,13} Comparison with the literature is arduous because the design and method of studies are not standardised¹⁴⁻¹⁶, nevertheless from this study, valuable information is obtained regarding the role of Pulse oximeter in early detection of congenital heart disease in Himachal Pradesh. Out of 3464 newborns screened, 45 cases with SPO₂ <95% were observed and 3 cases had a murmur, who were later found to have congenital heart disease. Ainsworth SB et al, detected the murmur in 0.6 % of the total babies examined out of which 54% of the newborns had congenital heart disease. The variation is attributed to the fact that murmur detection in the present study was within 48 hours of life, whereas in this study, clinical examination was repeated within 2-14 days.¹⁷ 9 (0.26%) of the newborns had cyanosis, and all of them had arterial saturation < 95%. The relation of cyanosis was significant with congenital heart disease (p<0.01). Khalil, A. et al., noted cyanosis in 5 (0.04%) newborns and all them had congenital heart disease.¹⁸ We noted high percentage of cyanosis, which can be attributed to the fact that pulse oximeter was used alongside and also to the different sample size and the method of study used. The pulse oximeter has a significant role in early detection of congenital heart diseases along with the clinical parameters especially if murmur and cyanosis is observed alongside. It is also a cost effective measure in country like India where echocardiography is not easily accessible.

Griebsch L et al¹⁹ reported that clinical examination alone, pulse oximetry, and screening echocardiography achieved 34.0, 70.6, and 71.3 timely diagnoses per 100,000 live births, respectively. Bakr, A.F. et al.,²⁰ concluded that combining pulse oximetry and clinical examination can enhance the clinician's ability to detect life-threatening CHD in a timely manner.

Pulse oximetry has been found to be a simple, noninvasive, and inexpensive test and should be routinely used for screening of newborns for the detection of congenital heart disease.²¹ In another study by Amir Hosein Movahedian et al.,²² the best time to perform pulse oximetry is within 8-24 hours of the infant's birth. In this study, it was observed that combined pulse oximetry and cyanosis has a significant relation in the early detection of congenital heart disease in the newborns.(p<0.05). Pulse oximeter along with clinical examination may be used as a pre-discharge measure for early detection of congenital heart diseases.

CONCLUSION

The pulse oximeter has a definite role as a screening tool for the early detection of congenital heart disease in the newborns prior to the development of critical manifestations of the disease. Along with pulse oximeter, the other parameters like cyanosis have a significant relation with the early detection of congenital heart disease in the newborns (p<0.05).

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