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A study to asses pulse oximetry as a screening tool for detecting congenital heart disease

[1]Mahtab Alam, [2]Manjunath GM, [3]Gowhar Iqbal Wani, [4]Dr. Nikhil Gupta

[1,4]Senior Resident, Department of Pediatrics, VMMC and Safdarjung Hospital, New Delhi, India
[2]Senior Resident, Department of Pediatrics, Mandya Institute of Medical Sciences, Mandya, Karnataka, India
[3]Registrar, Department of Pediatrics, Government Medical College, Jammu & Kashmir, India

Corresponding Author:
Dr. Nikhil Gupta

Abstract

Background: The incidence of congenital heart defect is 8-10/1000 live-births according to various reports from the different parts of the world.[3] this incidence has remained constant worldwide.[4] It is responsible for significant morbidity and mortality in infants worldwide. These account for about 30% of the total congenital abnormalities. Neonates with CHD presents with low oxygen saturation which can be screened with the help of pulse oximetry. Pulse oximetry is an easy and non-invasive method for measuring arterial oxygen saturation in newborns with a high level of accuracy.
Objective: To asses the role of Pulse Oximetry as a Screening Tool for Detecting Congenital Heart Disease.
Materials and Methods: The present prospective observational study was conducted by the Department of Paediatrics (Post Natal Ward) at Government Multi-specialty Hospital, Sector-16 and Chandigarh from December 2015 to June 2016.
Results: Among the study out of 528 study subjects nearly 5 (0.9%) of them were found to be positive and 523(99.1%) of them were found to be negative. The mean value of spo2 in positive screened cases of the upper limb was noted to be 91.20 which ranged from 89-94. In the lower limb, the mean value was found to be 90.20, which ranged from 84-94. The mean value of hand-foot difference was 3.00. The mean SpO_2 Saturation in the upper and lower Limb between screen positive and Screen Negative was found to be statistically Significant with P Value of less than <0.0001.
Conclusion: Early diagnosis of CHD is crucial to reduce the significant morbidity and mortality of CHD as the first manifestation of CHD may be associated with circulatory collapse or death. Pulse oximetry can detect mild hypoxemia which is characteristic of CHD. Therefore, pulse oximetry screening should be implemented in routine post natal examination of neonates.

Keywords: Heart disease, congenital, pulse oximetry, screening tool

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Introduction

Congenital heart disease means child is born with an abnormally structured heart or large vessels, such that heart may have incomplete or missing parts, may be put together wrong ways, may have holes between chamber partitions or may have narrow or leaky valves or narrow vessels [1]. It may manifest at birth or any time after birth. These are primarily present in neonates, infants and children; although in our country it is not uncommon to see adult patients with uncorrected congenital heart defect due to limited diagnostic facilities [2].

The incidence of congenital heart defect is 8-10/1000 live-births according to various reports from the different parts of the world [3]. This incidence has remained constant worldwide [4]. It is responsible for significant morbidity and mortality in infants worldwide. These account for about 30% of the total congenital abnormalities [5]. Nearly 27.5% of still-births occur due to this congenital heart defect [6]. In India, approximately 10% of infant mortality is solely due to congenital heart defect [7, 8].

Advanced diagnostic technology and progress in therapeutic management have increased the life expectancy of the CHD patients in the western countries, but in developing countries like India, there is a quite different situation [9]. In India, CHD is a major health burden because of its high birth rate. Crude birth rate in India is approximately 21.8/1000 according to 2011 census data [10]. At this crude birth rate, total live-births per year are approximates as 26,382,216. If birth prevalence of CHD is considered as 8/1000 live-births, then nearly 211,058 children are born with congenital heart defect each year [11]. This number further increases if spontaneous abortions and still-births are taken into account [12]. The common lesions of the CHD that account for approximately 85% of all the cases are ventricular septal defect, atrial septal defect, patent ductus arteriosus, pulmonary and aortic valve stenosis, coarctation of aorta, tetralogy of Fallot and transposition of the great vessels. Although CHD occurs with equal frequency in males and females, but there are some lesions in which male have preponderance. They are aortic stenosis, coarctation of aorta and transposition of the great vessels. Defects which are more commonly observed in females are patent ductus arteriosus, atrial septal defect and Ebstein's anomaly [13, 14].

Neonates with CHD presents with low oxygen saturation which can be screened with the help of pulse oximetry. Pulse oximetry is an easy and non-invasive method for measuring arterial oxygen saturation in newborns with a high level of accuracy. Pulse oximetry is feasible and cost-effective screening test for cardio-respiratory function and for quantification of hypoxemia [14]. Pulse oximetry measures SpO_2 continuously, without the need for calibration and correlates closely with arterial oxygen saturation.

Objective: To Assess the role of Pulse Oximetry as A Screening Tool for Detecting Congenital Heart Disease.

Materials and Methods

The present prospective observational study was conducted by the Department of Pediatrics (Post Natal Ward) at Government Multi-Specialty Hospital, Sector- 16, and Chandigarh from December 2015 to June 2016.

Sample size was estimated on previous studies by Zhao Q M *et al*, with a sensitivity of 93.2% and specificity of 97.1% and prevalence of 4% the sample size was found to be 478 subjects with a power of 80% and confidence interval of 95% for possible attrition it was decided to include a sample of 528 in the present study.

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Inclusion criteria

- All neonates born at GMSH 16 and between 24-72 hrs. of life were included in the study.

Exclusion criteria

- Neonates with birth asphyxia.
- Neonates with significant illness (Temp >37.5 or 60 or severe chest in drawing).

The neonates who fulfil the criteria for inclusion in the study were enrolled after obtaining written informed consent from one of the parents after completely explain all the details of study. Patient information sheet was provided to the parent while taking consent to make process of obtaining consent easy and transparent. Basic detail was recorded as per preform attached. Cardiovascular examination of all neonates was done followed by pulse oximetry. Babies with positive findings in CVS examination will be subjected to echocardiography.
SpO_2 of all the subjects was checked. Children having saturation 3% between the right and or either foot was considered as positive cases. These positive cases were further evaluated by Echocardiography. Position of the child Screening was performed following 24 hours of birth and before discharge i.e. 3% between right hand and either foot, repeat of the test was done twice at one-hour interval, persistence off in ding will be labelled as positive. Baby with positive finding on clinical examination and pulse oximetry will be subjected to Chest X-ray and Echocardiography for further evaluation and confirmation of congenital heart disease.

Machine: Echocardiography Philips Echocardiography machine was used and Model no was Model: MCMD02AA.

Statistical methods: Chisquare test was used to compare the proportion of positive cases with different variables. Discrete categorical data was represented in the form of either a number or a percentage (%); continuous data assumed to be normally distributed, was written as either in the form of its mean and standard deviation or in the form of its median and interquartile. All the statistical tests were two-sided and was performed at a significance level of α=.05. Analysis was conducted using IBM SPSS Statistics (version22.0).

Results

The prospective study was conducted in Department of Pediatrics, Government Multi-Specialty Hospital, Sector 16, and Chandigarh. The observations recorded in the present study entails the use of pulse oximetry in the neonates for detecting the congenital heart disease before discharge from the hospital. The study was also focused on further exploration of the positive screened neonates by chest X-ray and echocardiography.
The present study was carried out for a period of six months from the month of 18 December 2015 to 17 June 2016. During the study period, 528 healthy asymptomatic neonates were examined for the detection of congenital heart disease with the help of pulse oximetry.

Table 1: Baseline profile of cases

parameters	Value (n=528)
Birth weight (Mean ± SD) kg	2.81± 0.42
Gestational Age (Mean ± SD) weeks	38.31± 1.65
Term babies no (%)	457(86.6%)
Pre term no (%)	64(12.1%)
Post term no (%)	7(1.3%)

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AGA no (%)	454(86%)
SGA no (%)	22(4.2%)
LGA no (%)	52((9.8%)

The mean gestational age of the present study population was 38.3106 ± 1.65132 weeks. It ranges from 32.00-43.00 weeks. Out of 528 cases examined 64(12.1%) were pre term, 457(86.6%) were term, 7(1.3%) were post term neonates. The positive screened cases were term infants in the present study. This might be due to relatively small number of preterm and post terms were included in the study.

In the present study, mean birth weight of the neonates was 2.81 ± .425 kg, with a range of 1.8 to 3.9 kg. Out of 528 neonates, 22(4.2%) were small for gestational age (SGA), 454 (86.0%) were appropriate for gestational age (AGA), 52 (9.8%) were large for gestational age (LGA).

The mother of the neonates under the study was also examined for the presence of any complications or infections. In the present study, maternal infections were found to be present in three of the cases. These three cases were found positive for the pulse oximetry screening test for CHD. They were further evaluated by echocardiography and these cases were diagnosed as the case of atrial septal defect.

Table 2: Pulse oximetry status of cases

Total no of cases	**Screen status**	
	Positive	**Negative**
528	5(0.9%)	523(99.1%)

Among the study out of 528 study subjects nearly 5 (0.9%) of them were found to be positive and 523(99.1%) of them were found to be negative.

Table 3: SpO_2 of upper and lower limb among study subjects

	Upper Limb		**Lower Limb**	
Spo2 (%)	**Frequency**	**Percentage**	**Frequency**	**Percentage**
<95	5	0.9	5	0.9
95	17	3.2	37	7
>95	506	95.8	486	92

Screening was done in all 528 enrolled cases, in 523 cases, spo2 in right upper limb (pre ductal) and foot was ≥ 95%.and difference of spo2 between two limbs was ≤ 3%. In 5 cases, spo2 in both right upper limb and foot were less than 95%, the difference saturation between two limbs in two cases was >3%and three was <3%. In the present study, out of 528 cases examined, 506(95.8%) cases showed the oxygen saturation > 95%, 17(3.2%) cases had the spo2 of 95%, whereas 5(0.9%) cases had the oxygen saturation of < 95% measured in the upper limb (right hand).

In the lower limb, the oxygen saturation was found to be > 95% in 486(92%) cases, 95% in 37(7%) cases, whereas < 95% in 5(.9%) cases. These five cases were considered positive and were further referred for echocardiography for the confirmation of congenital heart disease.

Table 4: Comparison of Spo2 of Screen positive and Negative cases

Spo2 Mean ±SD	**Screen status**		**P value**
	Positive (5)	**Negative (523)**	
Upper limb	91.2±2.2	98.34±1.21	<0.0001
Lower limb	90.2±3.9	97.34±1.24	<0.0001
difference	3±2	1.04±0.9	

The mean value of spo2 in negative screened cases of the upper limb was found to be 98.34. It ranged from 95-100, whereas in the lower limb, mean value was found to be 97.34, range being the same as the upper limb, from 95-100. The mean value of hand-foot difference was 1.04.

The mean value of spo2 in positive screened cases of the upper limb was noted to be 91.20 which ranged from 89-94. In the lower limb, the mean value was found to be 90.20, which ranged from 84-94. The mean value of hand-foot difference was 3.00.

The mean SpO_2 Saturation in the upper and lower Limb between screen positive and Screen Negative was found to be statistically Significant with P Value of less than <0.0001.

Table 5: Profile of screen positive neonates

Patient characteristics	1	2	3	4	5
B.wt	2.7	3	3	2.9	2.76
Gestation	38	40	37	39	39
Age of baby	32	40	40	66	48
Spo2(UL)	89	94	89	92	92
Spo2(LL)	84	93	94	91	89
difference	5	1	5	1	3
Peripheral pulse	Absent	Present	present	present	absent
CFT	>3 sec	<3 sec	<3 sec	< 3 sec	>3 sec
cyanosis	Present	Absent	absent	absent	present
CVS	Murmur+nt	WNL	WNL	WNL	Murmur+nt
CXR	Cardiomegaly	WNL	WNL	WNL	Murmur+nt
echo	ASD+TR	ASD	ASD	NO CHD	ASD+TR

In the present study, two neonates had ASD along with TR, two suffered only with ASD. A pulse oximetry cut-off value of below <95% for detecting CHD showed 100% sensitivity, specificity 99.8%, positive predictive value of positive value 80% and negative predictive value negative value was 100%. Incidence of CHD is 0.76% (7/1000), incidence of ASD is 0.38% (3.8/1000), incidence of ASD with TR is also 3.8% (3.8/1000).

Discussion

Congenital heart disease (CHD) is also known as a congenital heart anomaly or congenital heart defect, is a problem in the structure of the heart that is present at birth. 10 Heart defects are the most common birth defect. 27 In 2013 they were present in 34.3 million people globally. 28 Congenital cardiovascular malformations are the leading cause of infant deaths with a prevalence of about 5-10/1000 live-births. Due to great advances in surgical techniques over the last few decades, most congenital defects can be repaired which increases the long term survival of the patients. Therefore, the early diagnosis of congenital heart disease is mandatory to achieve the better survival rate of the patients [15].

Pulse oximetry screening is an effective non-invasive and inexpensive tool for detecting CHD. It helps in earlier diagnosis of the neonates suffering from CHD which may not recognize either by prenatal ultrasonography or by post-natal clinical examination. Delay in diagnosis is associated with hemodynamic compromise due to hypoxia and hypo perfusion leading to end-organ damage which will result in cardio-vascular collapse/death. Congenital heart defects were considered critical if the infants received the interventional catheterization, undergone corrective surgery or died as a result of the defect within twelve months of the birth. Henceforth, if CHD is diagnosed as early as possible, timely intervention can be performed to increase the survival rate of the infants.

Earlier studies have emphasized the screening of neonates using pulse oximetry for detection of CHD. The first abstract which evaluated pulse oximetry as a screening tool for CHD was

published in 1995 [16].
In the study done by Rosati E *et al*. [17] the usefulness of pulse oximetry for screening detection of CHD was done and median age of the study subjects was 72 hours.
In the present study based on the screening tool it was found that 0.9% of the subjects were positive by the screening test and the cut off value of < 95% for detecting the CHD had 100% sensitivity and 99.8% specificity and 80% was positive Predictive value and 100% negative predictive value.
In the present study Meberg A *et al*. [18] the pulse oximetry had a sensitivity of 77.1%, specificity of 99.4% which is much lesser than our study findings. In another study Riede FT *et al*. [19] the pulse oximetry had a sensitivity of 77.78% and specificity was 99.9%, Positive Predictive Value of 25.9% and negative predictive value of 99.9% which is almost comparable to our study findings.
Thangaratinam *et al*. [20] in 2012 found that pulse oximetry is a highly specific tool in detecting critical congenital heart disease with a very low false positive rate. They estimated the sensitivity rate of 63%, specificity rate of 99.8% and false positive rate of 0.2%. Turska A *et al*. [21] the sensitivity of the test was 78.9% and specificity rate was 99.9%. The positive predictive value was 51.7% and negative predictive value was 99.9% and concluded that pulse oximetry screening can be an effective tool in diagnosing CHD.
In another study done by Taksande AM *et al*. [22] the Pulse oximetry showed the sensitivity of 100%, specificity of 99.95%, and positive predictive value of 87.5% and negative predictive value of 100%. They concluded that pulse oximetry is safe, feasible and non-invasive test for detecting CHD in clinically normal neonates.

Conclusion

Congenital heart disease can be prevented partly through rubella vaccination, using iodized salt and folic acid. Some defects do not need treatment while others can be effectively treated with surgical intervention as soon as it is diagnosed.
Early diagnosis of CHD is crucial to reduce the significant morbidity and mortality of CHD as the first manifestation of CHD may be associated with circulatory collapse or death. Pulse oximetry can detect mild hypoxemia which is characteristic of CHD. Therefore, pulse oximetry screening should be implemented in routine post-natal examination of neonates.

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