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Studying the use of pulse oximetry in early detection & reducing diagnostic gap of CHD in neonates

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Abstract

Background: Among all Birth defects, Congenital Heart disease (CHD) is most common congenital anomalies with preponderance of around 6 to 8 per 1000 live births. Children born with CHD in India is more than 200,000 per year out of which one- fifth are likely to have Critical congenital heart disease(CCHDs). Methodology that have been proposed to work on early identification of congenital heart disease includes prenatal ultrasound screening, prolonged hospital stay after delivery. Pulse oximetry (SpO2) has presented as one such strategy. Pulse Oximetry is the first, relatively simple approach has been used for universal screening of congenital heart diseases. **Methodology**- The study was conducted on 600 neonates visiting paediatric outpatient department (OPD) and admitted in Neonatal Intensive Care Unit (NICU) at tertiary care centre between January 2020 to December 2021. All relevant information was recorded in case record form (CRF). All neonates were examined for vital parameters including Tachycardia, Tachypnea (RR>60/Min), Murmur. Pulse oximetry readings (after stable signals) were taken for right upper limb. All neonates with abnormal Pulse oximetry were subjected to observations at 6 hours after birth. Any of the readings at 6 hours were taken as positive. **Results**- Mean Gestational age of the newborns was 38.11 ± 0.86944 days. mean birth weight of the newborns was 2.66 ± 0.38 kg. The SpO2 levels for four limbs at 6 hrs for right upper limb were 97% ± 3.81%. Distribution of newborn according to heart rate was, 99.6% were normal while only 0.4% had tachycardia, 97.6% had normal respiratory rate, while 2.4% had tachypnoea. 0.4% babies had Murmur. **Conclusion**- The study concludes that use of pulse oximetry results in early detection of CHD. Pulse oximetry has an additive effect and results in more efficient screening.

Keywords: Pulse oximetry, neonates, CCHD, heart disease, Spo2.

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Introduction

Birth defects are referred as structural or functional abnormalities, including metabolic disorders, which occurs from birth.[1] The term congenital disorder also have same definition and can be used interchangeably.[2] Birth defects are under recognized cause of mortality and morbidity among infants and children. They can be life threatening and have negative impact on individuals, families, health care systems and societies. The etiology of nearly 50% birth

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defects is unknown.[3] A meta-analysis showed may be as many as 472,177(421,652 to 522,676) congenital malformations affected births in India each year.[4] Among all birth defects, Congenital Heart disease (CHD) is most common congenital anomalies with preponderance of around 6 to 8 per 1000 live births. These diseases account for 1% of neonatal and 30 to 40% of mortalities due to congenital anomalies happening in first year of life. In consideration of birth prevalence of CHD, Children born with CHD in India is more than 200,000 per year out of which one- fifth are likely to have Critical congenital heart disease(CCHDs). CCHD is defined as lesion which require corrective treatment in 1 year of life. Prenatal ultrasound in some studies still detects fewer than 50% cases of CCHDs. Early diagnosis is crucial for good clinical result. Cardiovascular collapse, heart failure and even death may result from late or missed diagnosis resulting in significant morbidity and 12 times higher mortality during early infancy and over 80% deaths in early neonatal period.[5] Even if "a thorough physical examination of each newborn is now universally accepted as good practice, many times during routine clinical examination congenital heart diseases are not detected. The most probably reason is not that examination is poorly performed,but many babies with cardiac malformation have no signs that can be detected by clinical examination.[6] Due to persistence of fetal circulation in first initial days of life, physical findings like murmur, cyanosis and tachypnoea may not be determined before discharge from hospital, which may occur 48-hours of life.[7] If diagnosis in these babies is being missed because they have no clinically noticeable physical signs, it becomes clear that obviously an alternate procedure ought to be utilized to diagnose the disease.[6] Methodology that have been proposed to work on early identification of congenital heart disease includes prenatal ultrasound screening, prolonged hospital stay after delivery one or more post discharge examinations during the first or the following two weeks of life training clinicians to recognize silent CHD.[8]

Pulse oximetry (SpO2) has presented as one such strategy, and in 2011 SpO2 screening for critical congenital heart disease was added to "Recommended Uniform Screening Panel for Newborns in United States".[7] Pulse Oximetry is the first, relatively simple approach used for universal screening of congenital heart diseases. It is a simple, harmless, easy, painless and accessible method that measures oxygen saturation and allows detection of lesions which usually presents with hypoxemia. It is recommended that the estimation of oxygen saturation recognizes infants with mild cyanosis who do not have an audible murmur or other indicators of cardiac abnormality and are not identified on routine clinical examination.[9] Recently, Pulse oximetry has been suggested as screening tool for detection of congenital heart diseases among asymptomatic new-borns.

Therefore, the above study was conducted to assess the use of pulse oximetry in early diagnosis of congenital heart diseases in new-borns.

Materials And Methods

Study place- The study was conducted on Neonates visiting Paediatric Out Patient Department (OPD) and admitted in Neonatal Intensive Care Unit (NICU) at tertiary care centre between January2020 to December 2021.

Study design- Prospective Observational Study.

Inclusion criteria- Neonates visiting Pediatric Out Patient Department (OPD) and admitted in Neonatal Intensive Care Unit (NICU) having birth weight >/=1.8kg whose parents were ready to give informed written consent.

Exclusion criteria- Those who were found to be diagnosed case of CHD in USG done during ANC period, neonates weighing <1.8kg, and whose parents were not ready to give informed written consent.

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Sample size- 600 neonates visiting Pediatrics Out Patient Department (OPD) and admitted in Neonatal Intensive Care Unit (NICU).

Data analysis- The findings were recorded in case record form and the same was entered in SPSS 20 version. The information was represented in the form of frequencies, proportions, tables etc. Graphs, charts figures were drawn wherever necessary.

Ethical consideration- The study was approved from Institutional Ethical Committee. All ethical considerations and necessary approvals were taken.

All neonates at admission were evaluated clinically for temperature, heart rate, respiratory rate, chest retraction, capillary refilling time, and cyanosis. Tachycardia, Tachypnoea (RR>60/Min), Cyanosis, Murmur was considered as positive findings suggestive of CCHD. Pulse Oximetry readings (after stable signals) were taken for Right upper limb. Pulse oximetry was considered abnormal if oxygen at room air or on oxygen therapy was <90%. All neonates with abnormal pulse oximetry were subjected to observations at 6 hours after birth. Any of the readings at 6 hrs were taken as positive. And echocardiography was done by paediatric cardiologist.

Results

Table 1: Gender Distribution of babies

Gender	Number	Frequency
MALE	260	43.33%
FEMALE	340	56.66%
TOTAL	600	100%

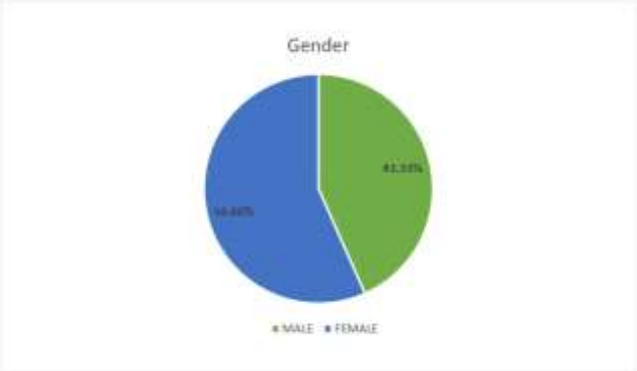

Figure 1

In the above study,43.33% of babies were male and 56.66% were female.

Table 2-GESTATIONAL AGE

Gestational age	Number	Percent
PRETERM	27	4.5%
TERM	573	95.5%
TOTAL	600	100%

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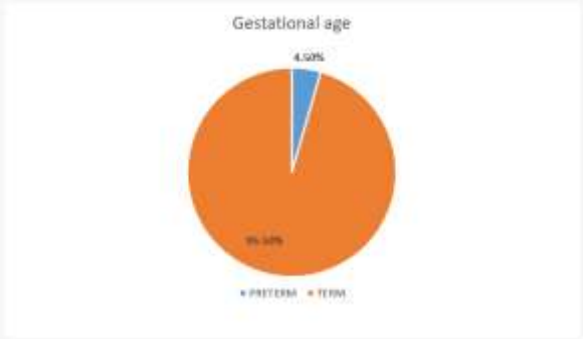

Figure 2

Of our study population 95.5% babies belongs to term gestation and 4.5% babies were preterm.

Table 3- Mode of delivery vs SpO2 screening results SpO2 Screening

Mode of delivery	**<90%**	**90 – 95%**	**>95%**
Normal Vaginal delivery	8(80%)	56(60.2%)	279(56.1%)
LSCS	2(20%)	37(39.7%)	217(43.3%)
Instrumental	0	0	1(0.2%)
Total	10(100%)	93(100%)	497(100%)

Table 4- Distribution of birth weight

Weight	**Frequency**	**Percent**
1.8 to 2.5kg	175	29.2%
2.5 to 3.5kg	404	67.3%
> 3.5kg	21	3.5%
Total	600	100%

Of our study population, 29.2% babies belong to 1.8 to 2.5kg birth weight,67.3% of newborn fall in weight range of 2.5 to 3.5kg and 3.5% of newborn were above 3.5kg birth weight.

Table 5- Distribution of new-borns according to presence of murmur

Murmur	**Frequency**	**Percent**
Absent	598	99.6
Present	2	0.4
Total	600	100

Among our study group 0.4% babies had murmur on clinical examination and 99.6% of babies had no murmur.

Table 6- 2D echo findings

SpO2 in Rt UL	**Echo findings**	**Diagnosis**
72%	HLHS	Cyanotic CHD
78%	ASD	Acyanotic CHD
68%	TOF + PS	Cyanotic CHD
82%	PPHN	PPHN
90%	PPHN	PPHN
88%	PPHN	PPHN
85%	Large VSD+ ASD+PDA	Acyanotic CHD
85%	Tricuspid atresia	Cyanotic CHD

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64%	TOF + PA	Cyanotic CHD
91%	Normal	Normal

Positive predictive value of SpO2 predicting heart disease
= no. of confirmed case of CHD by 2Decho

No. of cases with SpO2 <90%
= 6/10
=60%

Discussion

A total of 600 newborns were studied out of which 260 (43.33 %) were males and 340 (56.66%) were females. Study by Taksande A *et al.*[10] showed that male was 50.95% and females were 49.05%. Study by Atef El-Sayed Donia *et al.*[11] showed that 55.0% were males and 45.0% were females. In study done by Saxena *et al.*[12] out of 19009 new-borns 10183(53.5%) were males and 8826(46.4%) were females.

Mean Gestational age of the newborns was 38.11 ± 0.86944 days. Study by Tekleab AM *et al.*[7] showed that mean gestation age and birth weight of the study subjects were 39.4 weeks (SD 1.6). Study by Qu-ming-Zhao *et al.*[13] studied with mean gestational age 38.9 weeks. Study by Fernanda Cruz de lira *et al.*[14] studied with gestational age >37weeks.

In our study mean birth weight of the newborns was 2.66 ± 0.38 kg. Study by Tekleab AM *et al.*[7] showed that mean birth weight was 3,076.8 g (SD 490.5). Study by Atef El-Sayed Donia *et al.*[11] showed that mean birth weight was 3.19 ± 0.29 kg. Study by Taksande A *et al.*[10] showed mean birth weight 2.7kg ± 0.43kg. Study by Saxena *et al.*[12] mean birth weight was 2.74 ± 0.46 kg. Study by Qu-ming-Zhao *et al.*[13] study shows, mean birth weight 3.23 ±0.54kg.

In above study postnatal age of screening was 6hrs after birth. Study by Atef El-Sayed Donia *et al.*[11] showed that mean postnatal age of initial POx testing was 3.3 ± 1.1 h (range: 2.5–13.0 h).

The SpO2 levels for four limbs at 6 hrs were at 6 hrs for right upper limb 97% ± 3.81%. Study by Tekleab AM *et al.*[7] showed that of the 941 study subjects, 123 (13.1%) and 70 (7.4%) right arm SpO2 readings <95% respectively, during the initial screening. The mean foot and right arm SpO2 readings of the study population were 95.8% (SD 2.3) and 96.0% (SD 2.2) respectively. One hundred and forty- two (15.1%) study subjects had either initial foot/right arm SpO2 reading <95% or foot to right arm SpO2 reading difference of >3%. Study by Taksande A *et al.*[9] considered pulse oximetry cut-off value <90% for detecting CCHD. Study by Bakr *et al.*[15] accepted >94% saturation as normal and for screening <90% in either limb. Saturation between 90%-95% were verified by 3 readings. Study by Arelattaz *et al.*[17] considered >95% saturation as normal and for screening <90% saturation immediate 2-Decho to be done and saturation ranging between 90 – 95% second measurement to be performed after 4 to 6hrs.

Distribution of newborn according to heart rate was, 99.6% were normal while only 0.4% had tachycardia i.e. heart rate >160, 97.6% had normal respiratory rate, while 2.4% had tachypnoea (>60). 0.4% babies had Murmur while 99.6% didn't. In this study Mean respiratory rate 46.9± 4.4/min and Mean Heart rate 146.0935 ± 4.29 bpm. Study by Atef El-Sayed Donia *et al.*[11] showed that the mean respiratory rate was 45.0 ± 2.0/min, heart rate was 133 ± 7 bpm, and temperature was 36.81 ± 0.14 °C.

Total no. of 2D echo done is 10. 2D Echo was done in 1.6% cases, in which 10% had Mitral atresia, 30% had PPHN, 20% had TOF, 10% had Tricuspid Atresia, 10% had VSD + Distal

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COA, 10 % had ASD and 10% had Normal. Study by Tekleab AM *et al.*[7] showed that echocardiographic findings were: PDA: eleven (19.6%), PPHN: ten (17.9%), ASD: two (3.6%), and no abnormality was detected in 33 (58.9%). No case of CCHD was detected among the screened newborns. Study by Atef El-Sayed Donia *et al.*[11] showed that 20.8% had PDA, 4.2% had PDA, PFO and pulmonary hypertension, 4.24 had PDA, PFO, VSD etc. Study by Koppel *et al.*[16] showed that diagnostic echocardiogram was performed in infants with oxygen saturation <95% within first 24hrs of life. 3 babies with CHD identified (but none had critical left – heart obstructive lesion). 2 patients with negative screens were later admitted; 1 with coarctation of aorta and 1 with hypoplastic left pulmonary artery with aorto-pulmonary collaterals. Study by Bakr *et al.*[15] studied 5,211 infants, five babies were identified with an oxygen saturation <94% which was considered to be abnormal. One infant had TAPVC, one had pulmonary atresia, one had large ventricular septal defect and another child had Truncus arteriosus. The fifth child had a normal heart. Three babies were later diagnosed with CHD that was not detected by pulse oximetry when being investigated for failure to thrive & respiratory symptoms.

57.2% babies were delivered by Normal Vaginal Delivery, 42.1% by LSCS, and 0.2% by Instrumental delivery. Study by Tekleab AM *et al.*[7] showed that Cesarean section was the mode of delivery for 484 (51.4%) of the study subjects. Study by Atef El-Sayed Donia *et al.*[11] showed that 68.3% were delivered by cesarean section and 31.7% vaginally. All had negative family history and the mean maternal age was 28.7± 4.8 years.

Pulse oximetry screening was done at 6-hrs at bed-side and any value <90% was taken as positive pulse oximetry screening. Saturation in Right upper limb was taken.10 new-borns were found positive for pulse oximetry screening. Presence of critical congenital heart disease was confirmed by echocardiogram. Pulse oximetry screening at 6 hrs had positive predictive value 60%. In a study conducted by Arlettaz *et al.*[17] show PPV 63%. Study done by Palve *et al.*[18] calculated 2 different positive predictive for Critical CHD which is 80% and CHD which is 100%. Study conducted by Koppel *et al.*[16] shows PPV of 75%. Study done by Taksande *et al.*[10] for detecting CCHD with cut off saturation <90% showed Positive predictive value 75% and with cut off value <95% showed positive predictive value 52.84%.

Conclusion

The normal oxygen saturation (negative pulse oximetry screening does not rule case of CHD especially acyanotic congenital heart diseases. The absence of murmur does not exclude serious heart disease. A comprehensive study required to validate the results of this study. The study concludes that use of pulse oximetry results in early detection of CHD. Pulse oximetry has an additive effect and results in more efficient screening.

References

1. The global burden of disease: 2004 update.Geneva WHO 2008.
2. Management of birth defects and haemoglobin disorders: report of a joint WHO – march of dimes meeting, Geneva Switzerland 17-19 May 2006.
3. Anita Kar. Birth defects in India: Magnitude, Public health impact and prevention. JKIMSU, Vol.3, No.2, July-dec 2014.
4. Bhide P, Kar A. A national estimate of the birth prevalence of congenital anomalies in India: systematic review and meta- analysis. BMC Pediatr. 2018;18(1):175
5. C R Gunratane, Indika Hewage, Anula Foneska, Sampath Thennakoon. Comparison of pulse oximetry screening versus routine clinical examination in detecting critical congenital heart disease in newborns. Srilanka journal of child health, 2021:50(1):04-11.
6. Richmond S, Reay G, Abu Harb M. Routine pulse oximetry in the asymptomatic newborn. Arch Dis Child Fetal Neonatal Ed. 2002; 87: F83–F88

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7. Tekleab AM, Sewnet YC. Role of pulse oximetry in detecting critical congenital heart disease among newborns delivered at a high altitude setting in Ethiopia. Pediatric Health Med Ther. 2019; 10:83-88.
8. Pekka Valmari. Should pulse oximetry be used to screen for congenital heart disease ? Arch Dis Child Fetal Neonatal ed 2007 ;92: F219 – F224
9. Sophie Jullien. Newborn pulse oximetry screening for critical congenital hearts defects. Jullien BMC Paediatrics 2021,21(suppl 1):305.
10. Tekleab AM, Sewnet YC. Role of pulse oximetry in detecting critical congenital heart disease among newborns delivered at a high altitude setting in Ethiopia. Pediatric Health Med Ther. 2019; 10:83-88.
11. Taksande A, Meshram R, Lohakare A. An update work of pulse oximetry screening for detecting critical congenital heart disease in newborn. Images Paediatr Cardiol 2017 Jul – Sep ;19(3):12 – 18.
12. Saxena A, Mehta A, Ramakrishnan S. Pulse Oximetry as a screening tool for detecting major congenital heart defects in Indian newborns. Arch Dis Child Fetal Neonatal ed 2015;0:F1-F6.
13. Zhao QM, Ma XJ, Ge XL, Liu F, Yan WL, Wu L *et al.*; Neonatal Congenital Heart Disease screening group. Pulse oximetry with clinical assessment to screen for congenital heart disease in neonates in China: a prospective study. Lancet. 2014; 384(9945):747-54.
14. Lira Albuquerque FC, Maia ET, de Figueiredo VL, Mourato FA, da Silva Mattos. Clinical examination and pulse oximetry to detect congenital heart defects. Int J Cardiovasc Sci. 2015; 28:148–151.
15. Bakr AF, Habib HS. Combining pulse oximetry and clinical examination in screening for congenital heart disease. Pediatr Cardiol. 2005; 26:832– 835.ss
16. Koppel R, Romen A, Nitzan M. Pulse oximetry: fundamentals and technology update 2014.
17. Arlettaz R, Bauschatz A, Monkhoff M. The contribution of pulse oximetry to the early detection of congenital heart disease in newborns. Eur J Pediatric (2006) 165 ; 94- 98.
18. Palve N, Utture A, Nanavati R. Pulse oximetry screening for critical congenital heart disease – Experience in public hospital in India. India J child Health Vol 4 | Issue 2 | Apr – Jun 2017.