International Journal Dental and Medical Sciences Research
Volume 3, Issue 1, Jan-Feb 2021 pp 92-98 www.ijdmsrjournal.com ISSN: 2582-6018

"An observational study to screen for clinically unrecognized critical congenital heart disease in the newborns using pulse oximetry"

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Date of Submission: 15-12-2020 Date of Acceptance: 30-12-2020

Contributor Credit:

- KA- Conceptualize and design the study, Design of project, Data collection and analysis.
- JS – Manuscript first draft and study writing, Data collection.
- SB – Guide-idea incubation, design, supervision of data collection, analysis, intellectual inputs.
- AG - Approval of study and manuscript, manuscript review, , and gave critical inputs to the manuscript.
- MC – Critical inputs, guided the entire process, data analysis, and intellectual inputs.

Funding source: None

Conflict of Interest: None of the authors has to declare any conflict of interest.

I. INTRODUCTION:

Congenital heart disease (CHD) is defined as an abnormality in cardiovascular structure or function that is present at birth, even if it is discovered much later. CHD is the most common congenital disorder in newborns with a birth prevalence of approximately 8-10 per 1000 live births [1-3]. Critical CHD (CCHD), defined as requiring surgery or catheter-based intervention in the first year of life, occurs in approximately 25 percent of those with CHD [4]. Many newborns with CCHD are asymptomatic and usually not diagnosed until discharge, and up to 25% of infants with these defects, being missed in the newborn stage, even in settings with routine prenatal sonograms [5-11]. Approximately 40% of these infants with missed diagnosis at birth present with cardiogenic shock to a medical facility and 5% are diagnosed at autopsy [12]. Thus the risk of morbidity and mortality increases with delay in diagnosis [13-15]. The seven classifications for CCHDs are 1.Hypoplastic left heart syndrome 2.Pulmonary atresia (with intact septum) 3.Tetralogy of Fallot 4.Total anomalous pulmonary venous return 5.Transposition of the great arteries 6.Tricuspid atresia 7.Truncus arteriosus.

Many asymptomatic neonates with CHD/CCHD may have borderline low oxygen saturation. This fact has led to exploring the possibility of screening all the newborn babies with pulse oximetry in addition to the usual routine physical examination. Pulse oximetry is a simple, well established, non-invasive, and painless test that is used to measure the percentage oxygen saturation of hemoglobin in the arterial blood and the pulse rate. Pulse oximetry was recommended as a screening tool to detect critical CHD in 2011 by the American Academy of Pediatrics and the American Heart Association. Due to its ease of application to the patient, providing results promptly, pulse oximetry offers many advantages as a screening tool. In developing countries with inadequate medical personnel, the method mentioned above can be very helpful in the early detection of CCHD.

II. AIMS AND OBJECTIVES:

1. To determine the incidence of clinically unrecognized critical congenital heart disease in the newborns by using pulse oximetry.
2. To find Sensitivity, Specificity, Positive Predictive Value, and Negative Predictive Value of pulse oximetry for detection of Critical CHD in clinically normal newborns.

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III. MATERIALS AND METHODS:

Study site: This study was conducted at JAIPUR GOLDEN HOSPITAL, Sector-3, Rohini, New Delhi -110085

Study population: Newborns admitted to the postnatal ward of Jaipur golden hospital.

Study design: Cross-sectional Observational Study.

Sample size

Based on hospital admission data and considering the incidence of CCHD is 8-10 per 1000 live births. Taking this value as reference, the minimum required sample size with 0.7% margin of error and 5% level of significance is 593 patients. So roundoff the total sample size taken is 600.

Duration of study: The study was conducted from December 2016 to November 2017.

Inclusion Criteria:

1. All healthy newborns (inborn) admitted to the postnatal ward and NICU.

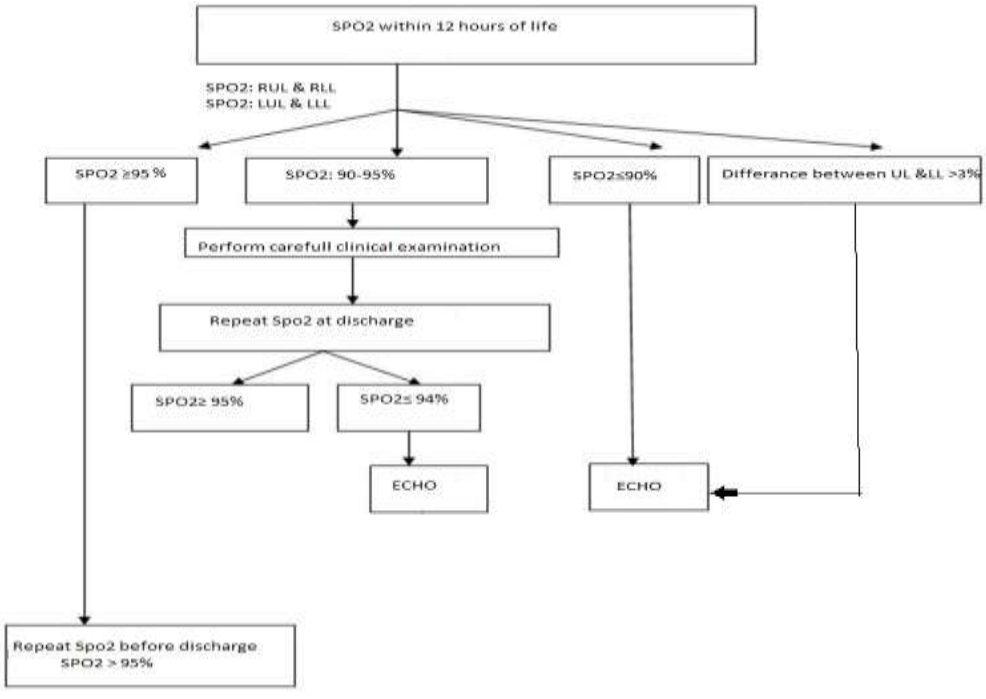
Exclusion Criteria:

1. Patients with a prenatal diagnosis of duct dependent circulation by fetal echocardiography.
2. Following abnormalities on physical examination: cyanosis, hypotension, tachypnoea, grunting, nasal flaring, chest retraction, significant heart murmur, active precordium, and diminished pulse.

IV. METHODOLOGY:

The measurements of SpO2 were performed using a DatexOhmeda 3800 pulse oximeter with a neonatal Nellcor™ reusable SpO2 sensor probe. For each newborn, SpO2 was measured in all the four limbs of the newborn within the first 12 hours of life. The probe was held manually at the wrist or palm and the sole, following a random order. Each screening attempt was conducted with the infant in the supine position after cleaning the probe with spirit swab, and measurement was considered complete once the waveform on the plethysmograph was stable. A SpO2 result of ≥95% was considered normal. If theSpO2 difference between the right upper limb and lower limb (preductal and postductal) was ≥3%, then echocardiography was done. If the SpO2 was between 90-94%, clinical examination was performed carefully. If CHD was suspected, the neonate was referred for echocardiography. If no suspicion of CHD was made clinically, then a measurement of SpO2 was repeated at the time of discharge and, echocardiography was done if SpO2 ≤95%persisted. When the SpO2 reading was ≤90%, bedside echocardiography was done. For normal babies, a follow-up evaluation (Spo2 and clinical evaluation) was performed at the time of discharge. At this point of evaluation, if the newborn had abnormal cardiac examination including a finding of SpO2 <90%, echocardiography was done.

V. FLOW CHART OF STUDY DESIGN



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Statistical Methods:

Categorical variables were presented in number and percentage (%) and continuous variables were presented as mean ± SD and median. A diagnostic test was used to calculate the sensitivity and specificity of Pulse oximetry screening for clinically unrecognized critical congenital heart disease in the newborns. A p-value of <0.05 was considered statistically significant. The data was entered in MS EXCEL spreadsheet and analysis was done using Statistical Package for Social Sciences (SPSS) version 21.0.

VI. RESULTS:

A total of the seven hundred and fifty-six babies were born in Jaipur golden hospital during a study period of one year out of that Spo2 screening was done on six hundred newborns. Study outline described in the flowchart.

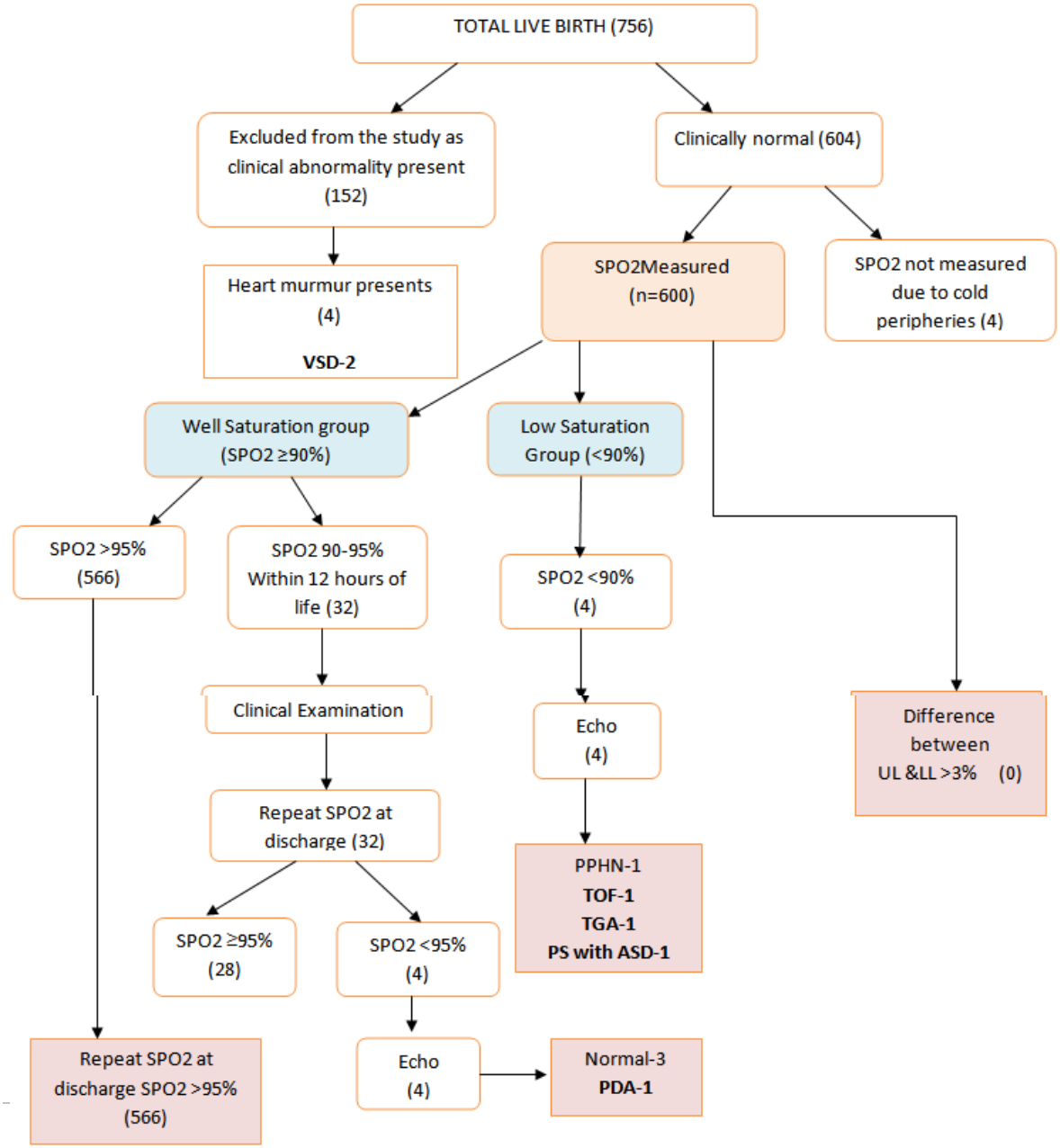

Figure 2: Outline of study Observations and Results:

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The mean gestational age of both the groups (well saturation and low saturation) was 38.49± 1.61 and 38.00± 0.70 respectively. The male and female ratios in both groups were similar. So, in both the groups baseline characteristics were comparable. Comparison of saturation in all limbs at 12 hours and discharge between both the groups showed mean saturation of different limbs in the well saturation group is 97.22% ± 0.75% and in the low saturation group is 84.37% ± 0.98% with a significant p-value is < 0.001. In our study 152 newborns were excluded according to the exclusion criteria of the study but to find the incidence of CHD per 1000 live birth, clinical examination and auscultation were done. A heart murmur was present in 4 of them; later 2 of them were diagnosed as PDA, 1 as VSD, and 1 as mild PS. The incidence of CHD per 1000 live births in the present study is 10.6.

Evaluation of pulse oximetry screening test in terms of Sensitivity, Specificity, Positive predictive value and negative predictive value with a cutoff value of saturation below 90% in identifying CCHD showed 100% sensitivity, 99.8% specificity, 75% positive predictive value, 100% negative predictive value and accuracy of 99.9%

Table 1: Results of Pulse Oximetry Screening for CCHD in Jaipur Golden Hospital

Total Live Birth	756
Excluded	152
SpO2 not measured	4
Number Screened	600
CHD cases in clinical infant	4
CCHD cases in clinically normal newborns	3
CHD cases in clinically normal newborns	4
Incidence of CHD/1000 live birth	10.6
Incidence of CCHD/1000 live birth	3.9
CCHD detected by screening/1000 number screened	5

Table 2: Comparison of Gestational age between Well Saturation group and low saturation group

Variable	**GROUP 1 – Well Saturation ($SpO_2 \geq 90$ %) (n=596) Mean± SD**	**GROUP II - Low Saturation ($SpO_2 < 90$%) (n=4) Mean± SD**	**p-value**
Gestational age (weeks)	38.49± 1.61	38.00± 0.70	0.50
Body weight (kg)	2.62 ± 0.30	2.37± 0.14	< 0.001
Male	302	2	-
Female	294	2	-
12 hours saturation in left upper limb	96.30% ± 1.30%	83.00% ± 0.70%	<0.001
At discharge saturation in left upper limb	97.93% ± 0.91%	85.00% ± 1.73%	0.001
12 hours saturation in right upper limb	97.21% ± 1.41%	85.00% ± 0.70%	< 0.001
At discharge saturation in right upper limb	98.51% ± 0.65%	86.00% ± 1.87%	0.001

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12 hours saturation in left lower limb	96.09% ± 1.30%	84.00% ± 2.82 %	0.001
At discharge saturation in left lower limb	97.92% ± 0.79%	85.00% ± 1.73%	<0.001
12 hours saturation in right lower limb	96.36% ± 1.34%	83.00% ± 0.70%	0.001
At discharge saturation in right lower limb	97.46%± 0.54%	84.00% ± 2.82%	0.001
Mean saturation	97.22% ± 0.75%	84.37% ± 0.98%	< 0.001

Table 3: Evaluation of screening test (pulse oximetry) in terms of Sensitivity, Specificity, Positive predictive value, and negative predictive value with a cutoff value of saturation below 90% in identifying CCHD.

Screening test results SpO2 <90%	Diagnosis by ECHO		Total
	CCHD positive	negative	
Positive	3	1	4
Negative	0	596	596
Total	3	597	600

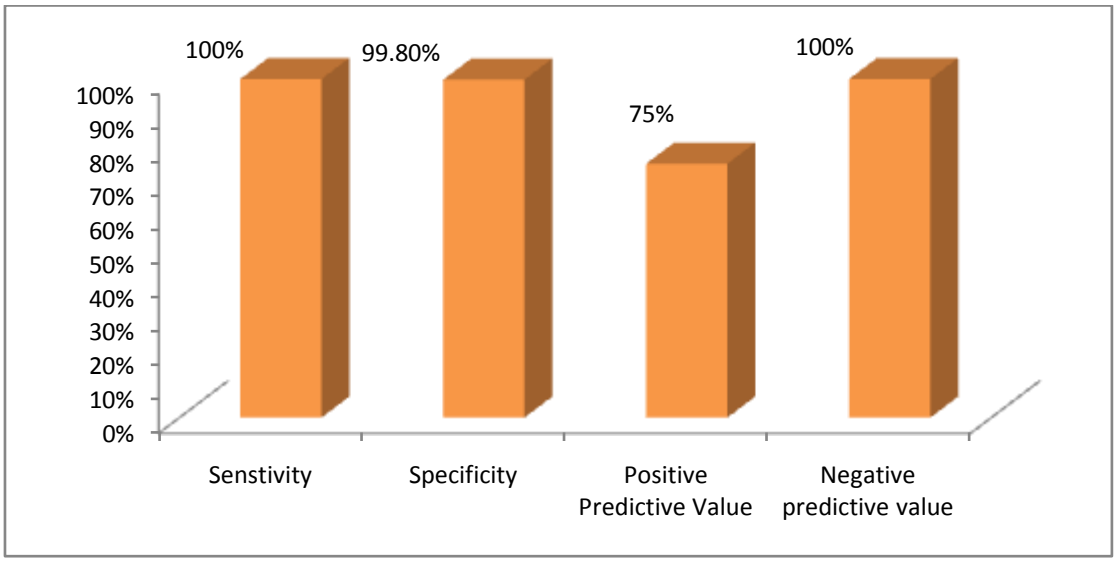

Figure 1: Sensitivity, Specificity, Positive predictive value, and negative predictive value of pulse oximetry with a cutoff value of saturation below 90% in identifying CCHD.

VII. DISCUSSION:

CHD is the most common congenital disorder, however, many newborns are asymptomatic even the ones with Critical congenital heart diseases (CCHD) and hence lead to delay in diagnosis which increases morbidity and mortality. Many neonates with CHD have no clinical signs and may have borderline low oxygen saturation. This fact has led to exploring the possibility of screening all newborn babies with pulse oximetry.

A study by **Hanning CD**[16] **and Moyle JT**[17] reported that for a pulse oximetry measurement to be accurate, the peripheral tissue needs an adequate pulse volume and pressure. In situations such as septic shock, where the extremities are cool and have low perfusion, the pulse oximeter may not reliably assess the oxygen saturation. In the present study also, in 4 patients, it was not possible to measure SpO2 due to cold extremities and low perfusion.

In the present study, the incidence of CHD per 1000 live births in the present study is 10.6 that is comparable to various previous studies that report it to be 8-10 per live births [1,2,3].

A study by **Oster ME et al** [4] reported that Critical CHD occurs in approximately 25 percent of those with CHD. In our study, the

incidence of CCHD is 3.9 that is more than the previous studies. The reason for this can be the small study size in this study in comparison to others.

A study by **Thangaratinam S et al** [18] did a meta-analysis of 13 studies (all of which used a cutoff SpO2 threshold of <95 percent), and found the sensitivity of pulse oximetry for detection of critical CHD to be 76.5 percent (95% CI 67.7-83.5) and specificity to be 99.9 percent (95% CI 99.7-99.9) with the average false-positive rate for these infants being 0.14%. In the present study, with a cutoff value of saturation below 90% in identifying CCHD, sensitivity is 100% and the specificity is 99.8%. There was no false-negative case while there was 1 case of false positive. In the present study, specificity is comparable to the above-mentioned study but sensitivity is more because the cutoff taken in our study is 90% as compared to 95% in the above-mentioned study.

The characteristics of the screening test will depend on which algorithm is being used. The New Jersey algorithm, which considers SpO2 <95 percent in either extremity on three measurements to be a positive screen, has a higher sensitivity but lower specificity than the AAP algorithm. The Tennessee algorithm, which initially tests only the lower extremity and considers an initial SpO2 of at least 97 percent to be a negative screen, has lower resource utilization than the AAP algorithm but may have lower sensitivity[19]. As the SpO2 threshold is decreased, the sensitivity of pulse oximetry to detect critical CHD decreases, and the specificity increases [20,21].

Zhao QM et al [22] found in a large multicenter prospective study of 1,22,738 newborn infants born between 2011 and 2012, the sensitivity of detecting critical CHD was greatest using the combination of pulse oximetry plus clinical assessment (93 percent) compared with either pulse oximetry alone (84 percent) or clinical assessment alone (77 percent). In our study also the screening of CCHD was done by using both pulse oximetry and clinical assessment.

In most of the Indian institutions, pulse oximetry before discharge from the newborn nursery is not performed routinely. And even screening for CCHD is also not done regularly. Pulse oximetry is safe, noninvasive, inexpensive, and has an excellent detection rate with reasonable sensitivity that will detect many cases of CCHD. Due to its ease of application to the patient, providing results promptly and without the need for calibrating the sensor probe, pulse oximetry offers many advantages as a screening tool.

VIII. CONCLUSION AND RECOMMENDATIONS:

The goal of critical CHD screening in newborns is to reduce mortality and morbidity associated with delayed diagnosis by identifying infants with critical CHD in a timely manner. There is evidence that universal screening with pulse oximetry improves the identification of patients with critical CHD compared with physical examination alone.

CHD lesions targeted by pulse oximetry screening include defects which typically a) require intervention in the first year of life, and b) present with hypoxemia some or most of the time.

Pulse oximetry is a safe, feasible, and noninvasive screening tool for detecting CCHD in clinically normal newborns.

It could be suggested that critical CHD screening using pulse oximetry be performed in all newborns after 12 hours of life or as late as possible if an early discharge is planned. Oxygen saturation (SpO2) should be measured in the right hand (preductal) and either foot (postductal).

Infants with positive screening results using pulse oximetry should undergo an evaluation to identify the cause of hypoxemia. If critical CHD is identified on echocardiography, urgent consultation with a pediatric cardiologist and/or transfer to a medical facility with pediatric cardiology expertise is warranted.

Limitations:

The main limitation of the present study was that the number of screened neonates was too small and from a single centre.

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