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A Prospective Study on Screening of Congenital Heart Diseases Using Combined Pulse Oximetry and Clinical Examination in Neonates

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Background: Congenital malformations are responsible for half of infant deaths, with congenital heart disease accounting for 10% of the fatalities. Clinical examination remains the primary method for diagnosing congenital heart disease in newborns.

Materials and Methods: The study was conducted in the postnatal ward involving 224 newborns. Asymptomatic term newborns underwent screening for cyanotic congenital heart disease using pulse oximetry and clinical examination. The pulse oximetry was performed using a GE MONITOR device.

Results: Pulse oximetry saturation levels were below 90% in 5.4%, between 91-94% in 2.2%, and above or equal to 95% in 92.4% of the newborns. The diagnoses included TOF (1; 0.5%), pulmonary stenosis (1; 0.5%), and tricuspid atresia (1; 0.5%). Among the newborns with positive pulse oximetry screening (oxygen saturation <95%), 17 were identified. Out of these, 3 had confirmed cyanotic congenital heart disease by echocardiography. Similarly, among the newborns with negative clinical examination screening (oxygen saturation ≥95%), 209 were identified. Out of these, 15 had positive clinical examination results, with 3 having confirmed cyanotic congenital heart disease by echocardiography.

Conclusion: Pulse oximetry is a valuable screening tool for the early detection of congenital heart diseases, particularly cyanotic congenital heart diseases. It emphasizes the importance of both pulse oximetry and clinical examination results for a comprehensive screening approach. The study highlights the need for further research to refine and optimize the screening process for congenital heart diseases.

Keywords: Pulse oximetry, congenital heart disease, clinical examination, screening tool, asymptomatic

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Introduction

Among all congenital malformations, congenital heart disease (CHD) is a relatively common problem with an incidence of 5-8 in every 1000 live births [1]. Critical congenital heart disease accounts for 25% of congenital heart diseases. Congenital malformations account for half of the infant deaths of which 10 % are due to congenital heart disease [2]. Ongoing advancements in diagnostic techniques and therapeutic interventions have markedly altered the prognosis for infants with congenital malformations. However, it is important to acknowledge that these structural anomalies continue to play a substantial role in the incidence of morbidity and mortality among this demographic [3]. In the majority of infants early detection of congenital heart disease is critical for achieving favourable clinical outcomes, as there are effective surgical repair or palliation options available. Failure to recognize or delay in diagnosing severe congenital heart diseases can lead to cardiac failure, cardiovascular collapse and even death [4].

Clinical examination remains the most commonly employed method for diagnosing congenital heart disease in newborns. Specifically, the detection of a heart murmur can indicate the presence of congenital heart disease. However, routine neonatal clinical examinations fail to identify more than 50% of infants with congenital heart disease [5]. This is because over half of these infants do not have a murmur and many are discharged before a diagnosis can be made, only to be readmitted with severe heart failure or cardiovascular collapse [6].

Hence, it is imperative to establish a comprehensive screening program aimed at the early identification of congenital heart disease. In recent years, pulse oximetry has been proposed as a screening instrument for the detection of congenital heart disease, particularly in cases of cyanotic and critical congenital heart defects in asymptomatic newborns [7]. These infants exhibit reduced oxygen saturation levels, attributed to either an intracardiac right-to-left shunt or a Patent ductus arteriosus (PDA) lesion which can be accurately assessed through pulse oximetry [8]. Since there are various stages of hypoxia in severe cyanotic heart disease that may not be apparent from the patient's outward appearance, pulse oximetry represents a significant improvement in this area [9].

Recent research, encompassing a comprehensive meta-analysis, has assessed implementation of routine pulse-oximetry testing in newborns before their discharge from hospital, aimed at facilitating identification of congenital heart disease [10] [11]. Pulse-oximetry is recognized as a non-invasive, simple, and cost-effective method that can be easily used after basic training [12]. Nonetheless, discrepancies in sensitivities have been observed, which have led to concerns regarding efficacy and reliability of test. The primary aim of this research is to evaluate effectiveness of combining pulse oximetry with clinical examination as a method for screening for cyanotic congenital heart disease in asymptomatic newborns. Additionally, study aims to determine value of pulse oximetry screening in early identification of cyanotic congenital heart disease.

Materials and Methods

Study Design: Prospective study.

Study Site: The present study was carried out in postnatal ward of Yashoda Hospital, Hyderabad.

Study Population: This study included 224 newborn babies from postnatal ward of Yashoda Hospital, Hyderabad.

Inclusion Criteria: Asymptomatic term newborn infants admitted to postnatal ward were included. A parental information leaflet was given to all eligible infants and written consent was obtained before enrolling in study. The examination was conducted after 24 hours unless infant's parents requested an earlier discharge.

Exclusion Criteria: Infants requiring admission to Neonatal Intensive Care Unit (NICU) at birth, preterm infants, newborns diagnosed with congenital heart disease before birth and infants presenting with external congenital anomalies were excluded.

Methodology

Asymptomatic term newborns underwent screening for congenital heart disease utilizing pulse oximetry with GE MONITOR in postnatal ward, in conjunction with a cardiac clinical examination. Pulse oximetry measurements were conducted on newborns in a quiet or sleeping state, typically from right hand, with probe thoroughly cleaned with an alcohol swab before each use, following manufacturer's instructions.

A functional oxygen saturation level of ≥5% was considered within the normal range. Should the newborn's oxygen saturation fall below 90%, an echocardiography was initiated.

For newborns with oxygen saturation levels between 90% and 94%, a subsequent measurement was scheduled for six hours later. Should the oxygen saturation levels persist below 95%, an echocardiography was also performed.

Cardiac clinical examination screening was performed for all babies simultaneously with pulse oximetry screening. We look for tachycardia, tachypnoea, central cyanosis and cardiac murmur.

Echocardiography was performed for babies having tachypnoea tachycardia cardiac murmur or central cyanosis. The cardiac clinical examination and pulse oximetry screening were carried out between 24 to 48 hours of age.

Newborn babies who underwent echocardiography were categorized as having either normal hearts or structurally malformed hearts. Following the initial 24-hour clinical examination, if any abnormalities were detected, an echocardiography was performed.

Statistical Analysis

Data entry was done using M.S. Excel and statistically analysed using Statistical Package for Social Sciences (SPSS Version 16) for MS Windows.

Descriptive statistical analysis was carried out to explore the distribution of several categorical and quantitative variables. Categorical variables were summarized with n (%), while quantitative variables were summarized by mean ± S.D.

Results

The demographic distribution revealed that females constituted 51.3%, while males accounted for 48.7%. The predominant method of delivery was through a lower segment caesarean section (LSCS), with 79.9% of mothers opting for this method, whereas 20.1% chose normal vaginal delivery (NVD).

All newborns were found to be of term gestation. The birth weights were,70.1% were within the 2.5 to 3 kg range, 25.4% had weights between 3.1 to 3.5 kg and 4.5% exceeded 3.5 kg. Parental consanguinity was observed in 8.5% of newborns.

Among the mothers, 12.1% were diagnosed with diabetes mellitus. There was no family history of congenital heart diseases reported in this study (Table 1). On clinical examination, 4% exhibited tachycardia, 3.6% presented tachypnoea, 4% showed cyanosis and 6.7% had murmurs.

Pulse oximetry readings were taken for all newborns, with 5.4% having saturation levels below 90%, 2.2% falling within the 91-94% range, and 92.4% achieving saturation levels of 95% or higher.

The timing of pulse oximetry measurements was recorded to be conducted after 24 hours of birth in all cases (Table 2).

Pulse oximetry screening results show that 92.4% of newborns had negative readings, indicating an oxygen saturation level of at least 95%. Conversely, 7.6% had positive readings, indicating an oxygen saturation level below 95%.

Among the newborns with positive readings, three cases of cyanotic heart diseases were confirmed through echocardiography.

Table 1: Distribution of newborns based on various parameters

Parameters		Frequency(n)	Percent(%)
Baby -Gender	Female	115	51.3%
	Male	109	48.7%
	Total	224	100%
Mode of delivery	LSCS	179	79%
	NVD	45	20.1%
	Total	224	100%
Gestation	Term	224	100%
Body weight (Kg)	2.5-3	157	70.1%
	3.1-3.5	57	25.4%
	>3.5	10	4.5%
	Total	224	100%
Consanguinity	Yes	19	8.5%
	No	205	91.5%
	Total	224	100%
Diabetes Mellitus in Mother	Yes	27	12.1%
	No	197	87.9%
	Total	224	100%
Mother-family H/O CHD	Absent	224	100%

Table 2: Distribution of newborns based on the clinical examination, pulse oximetry saturation, timing of pulse oximetry

		Frequency	Percent
Clinical examination	Tachycardia	9	4.0%
	Tachypnoea	8	3.6%
	Cyanosis	9	4.0%
	Murmurs	15	6.7%
	Clinical examination Positive	15	6.7%
Pulse-oximetry saturation	<90%	12	5.4%
	91-94%	5	2.2%
	>/=95%	207	92.4%
	Total	224	100%
Pulse-oximetry time (Hours)	24	10	4.5%
	25	161	71.8%
	26	38	17.0%
	27	7	3.1%
	28	6	2.6%
	29	1	.5%
	30	1	.5%
	Total	224	100%

Table 3: Comparison between Pulse oximetry screening and Cardiac clinical examination

Screening	Pulse Oximetry	Clinical Examination
Total number of babies screened	224	224
Total number of babies with negative screening (Oxygen saturation ≥95%)	207 (92.4%)	207 (92.4%)
Total number of babies with positive screening (Oxygen saturation <95%)	17 (7.6%)	15(6.69%)
Total number of CHD confirmed by Echocardiography in babies with positive screening.	15(6.69%)	15(6.69%)
Total number of Cyanotic heart diseases confirmed by Echocardiography in babies with positive screening	3(1.33%)	3(1.33%)
Total number of acyanotic heart diseases confirmed by Echocardiography in babies with positive screening	12(5.35%)	12(5.35%)
Total number of babies with positive screening but having normal heart confirmed by Echocardiography	2(0.89)	0(0.89)

Table 4: Correlation of clinical findings and 2D Echo Findings

2D Echo finding	Tachycardia	Tachypnea	Cyanosis	Murmur
Large OS ASD	Yes	Yes	No	Yes
Large PDA	No	No	No	Yes
Mid Muscular VSD	Yes	Yes	Yes	Yes
Moderate OS ASD	No	No	No	Yes
Moderate PDA	Yes	Yes	No	Yes
Small mid-muscular VSD	Yes	Yes	Yes	Yes
Small OS ASD	Yes	Yes	No	Yes
Small OS ASD with Moderate PAH	Yes	Yes	Yes	Yes
Small OS ASD with small PDA	Yes	Yes	Yes	Yes
Small OS ASD	Yes	Yes	Yes	Yes
Small PFO	Yes	No	No	Yes
Small VSD and small OS ASD	No	No	Yes	Yes
Pulmonary Stenosis	No	No	Yes	Yes
TOF	No	No	Yes	Yes
Tricuspid Atresia	No	No	Yes	Yes

Table 5: 2D Echo findings, oxygen saturation and echocardiography result of babies with positive clinical examination

	Saturation	Frequency
SATURATION <90%		
Large OS ASD	88%	1
Moderate PDA	88%	1
Small OS ASD with moderate PAH	88%	1
Mid Muscular VSD, small ASD	89%	1
Small mid muscular VSD	89%	1
Small OS ASD	89%	2
Small VSD and small OS ASD	89%	1
Pulmonary stenosis	86%	1
TOF	86%	1
Tricuspid atresia	86%	1
SATURATION 90-94%		
Small PFO	91%	1
Moderate OS ASD	91%	1
Large PDA	92%	1
Small OS OSD	92%	2
Small OS ASD with small PDA	93%	1

Table 6: Screening tests for Congenital heart diseases, Cyanotic heart diseases and confirmed by ECHO

Screening Method	Number of babies with CHD	CHD confirmed by ECHO	Normal heart confirmed by ECHO in CHD Babies	Number of babies with Cyanotic heart diseases	Cyanotic heart diseases confirmed by ECHO	Normal heart confirmed by ECHO in Cyanotic heart diseases
Positive only for cardiac clinical examination (A)	15	15	0	3	3	0
Positive only for pulse oximeter (B)	17	15	2	3	3	0
Positive for both screening tests (C)	15	15	0	3	3	0
Total No. of screening positive babies (A+B+C)	17	15	2	3	3	0

In terms of clinical examination screening, 93.3% of newborns had negative findings, while 15 6.7% had positive findings. Among newborns with positive findings, three cases of cyanotic heart diseases were confirmed through echocardiography. Specific cyanotic heart diseases identified included TOF (n=1; 0.5%), pulmonary stenosis (n=1; 0.5%), and tricuspid atresia (n=1; 0.5%) (Table 3). Table 4 shows a correlation between clinical findings and 2D Echo. In all cases of cyanotic heart diseases, symptoms such as murmur and cyanosis were identified on cardiac examination. Saturation levels for cyanotic heart diseases were as follows: TOF (86%), pulmonary stenosis (86%) and tricuspid atresia (88.6%) (Table 5). A total of 15 newborns had positive CHD in clinical examination screening, with 3 cases of cyanotic heart diseases confirmed through echocardiography. In babies with CHD and normal heart rate 2 were positive only for pulse oximeter and 2 were screened positive with all tests (Table 6).

Discussion

Congenital heart disease (CHD) can be diagnosed at any age, with certain conditions typically identified in newborns and others in infancy [13]. It is recognized as the leading cause of major congenital anomalies, posing a significant global health challenge. Pulse oximetry could be a helpful initial test for detecting heart defects in newborns who have no symptoms. The study conducted by Albuquerque et al. showed that out of 53 congenital heart disease (CHD) positive patients 27 were identified through cardiac echocardiography (CE) and 23 through cardiac allograft physiology (APO) testing [14].

Hypoxemia develops at birth and can cause cyanosis, a noticeable bluish discolouration of the skin [15]. In our study, a small number of patients with congenital heart disease (CHD) were cyanotic. The majority of these had a less serious condition, with almost half exhibiting symptoms. The findings of Surana et al., were similar to the current study, showing that the majority of children with heart defects were cyanotic, while a few were cyanotic [16]. In our study, we found no instances of consanguinity among the parents of the newborns, no family history of congenital heart defects and only a few mothers were diagnosed with maternal diabetes. According to the research conducted by Vaidyanathan B, few babies were found to have consanguinity among their parents (2%) some of their mothers (10%) had diabetes (10%), and very few parents (0.8%) had a family history of CHD [17]Top of FormBottom of Form. Tachycardia was the most frequently observed symptom, noted in the majority of CHD cases, followed by tachypnea, cyanosis, and cyanotic spells [18]. In our study tachycardia, tachypnea, and cyanosis follow murmurs.

In the current study, the most common heart defects in newborns were tetralogy of Fallot (TOF), pulmonary stenosis, and tricuspid atresia. The study conducted by Mathur et.al., on pulse oximetry screening to detect cyanotic congenital heart disease showed tetralogy of Fallot (TOF) in some children where the blood flow to the lungs is decreased [19]. The conditions included double outlet right ventricle with pulmonary atresia, severe pulmonary stenosis and pulmonary venous hypertension due to blocked blood vessels.

Pulse oximetry was negative in one newborn with tetralogy of Fallot and mild narrowing of the pulmonary artery, along a significant left-right blood flow. In this study, negative pulse oximetry screening (oxygen saturation ≥95%) outnumbered the positive results of which 3 were confirmed to have CHD cyanotic by echocardiography. The majority of studies conducted in well-baby nurseries have set the saturation threshold below 95% as the cutoff for abnormal pulse oximetry readings [20]. A working group suggested that any saturation below 90% should be considered abnormal for pulse oximetry screening in well-baby nurseries. They also recommend taking three consecutive saturation readings every hour if the saturation falls between 90% and 95% [21].

From this study, it was not possible to calculate sensitivity and specificity because echocardiography was not used on babies who tested negative to determine the true negative and false negative rates. Raju SPK et al. found that pulse oximetry was 90% sensitive, 55.58% specific, had a positive predictive value of 5.62%, a negative predictive value of 99.47% and an odds ratio of 11:3 for detecting cyanotic congenital heart disease [22]. The study conducted by Bakr et al. showed that the combined screening method had a sensitivity of 77%, oximetry alone had a sensitivity of 31% and clinical examination alone had a sensitivity of 46%. In our study, all screening methods had a specificity of around 100%. The positive predictive value for the combined method was 66.7% [23]. Present study limitations include a small sample size and the absence of a follow-up assessment for every participant. Consequently, the calculation of sensitivity and specificity was not possible, as echocardiography was not performed on the screening-negative babies to determine the true negative and false negative cases.

Conclusion

In conjunction with clinical examination, pulse oximetry is a non-invasive, reliable and efficient screening technique for the early identification of congenital heart diseases, especially those involving cyanosis thus highlighting its value addition in the diagnostic procedure. It is crucial that a normal pulse oximetry reading does not rule out congenital heart defects, especially those without cyanosis and lack of a murmur, thus highlighting its value addition in the diagnostic procedure.

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Declaration of competing interest: The authors declare no conflict of interest.

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