A PROSPECTIVE STUDY ON PULSE OXIMETRY AS A TOOL FOR EARLY DETECTION OF CONGENITAL HEART DISEASES

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ABSTRACT

Background: Cardiac malformations represent the most prevalent congenital anomalies. Pulse oximetry emerges as a valuable asset for the prompt identification of Congenital Heart Diseases (CHD) in regions lacking comprehensive cardiology infrastructure, particularly rural areas. This study aimed to assess the efficacy of pulse oximetry, in conjunction with clinical parameters, for detecting CHD in newborns, with echocardiography serving as the reference modality.

Materials and Methods: A prospective observational study was carried out at an Indian tertiary care center. The study encompassed 731 newborns born after 35 weeks of gestation, who underwent pulse oximetry and physical examination within 0-48 hours post-birth. Pulse oximetry assessment was performed on the left foot of each newborn for a minimum of 2 minutes, using BPL portable monitor. Statistical analysis was executed utilizing SPSS software, with a significance threshold set at $p<0.05$.

Results: Among the participants, 57 newborns exhibited SPO2 levels <95%, with 11 presenting cyanosis. Conversely, among the 678 infants with SPO2>95%, no cases of cyanosis were observed. A significant discrepancy in cyanosis prevalence was evident between the two groups. Furthermore, 7.02% of subjects with SPO2<95% manifested a murmur, while murmurs were absent in those with SPO2>95%, indicating a significant difference in murmur occurrence between the groups.

Conclusion: Pulse oximetry emerges as a pivotal tool for the early detection of congenital heart diseases, complementing clinical assessment parameters effectively.

Keywords: Congenital Heart Disease, Echocardiography, Pulse Oximeter, Oxygen Saturation

INTRODUCTION

Cardiac anomalies stand out as the most prevalent among congenital malformations, with an estimated prevalence of 6-8 per thousand live births, and the incidence of congenital heart disease (CHD) ranging from 8-10 per 1000 live births [1-4]. CHDs contribute to 9% of all infant mortality, with 40% of these deaths attributed to congenital malformations. Infants with CHD face a twelvefold higher risk of mortality within their first year of life. Notably, routine neonatal examinations overlook approximately half of infants with CHD [5,6]. Despite the efficacy of routine fetal echocardiography in detecting CHD, its widespread application is hindered by associated costs.

Byrne *et al*. [7] demonstrated the utility of simultaneous upper and lower extremity pulse oximetry in identifying desaturation indicative of hypoplastic left heart syndrome, coarctation, and tetralogy of Fallot in asymptomatic newborns. Pulse oximetry, a standard method for monitoring blood oxygenation in newborns, provides accurate and reliable measurements of oxygen saturation (SPO2) without the need for instrument calibration. The noninvasive probes are easy to apply and cause minimal skin injury, even in neonates. SPO2 measurements exhibit rapid responsiveness to changes in blood oxygenation and demonstrate significant correlations with arterial blood oxygen saturation (SaO2), arterial oxygen pressure (PaO2), and transcutaneous oxygen (tcPO2) within the normal range of blood oxygenation. Consequently, pulse oximetry has been coined the "fifth vital sign" [8,9].

While pulse oximetry has been proposed as a screening tool in the early neonatal period to identify CHDs and prompt intervention, the primary method of screening asymptomatic newborns for CHD in many settings remains physical examination, which has shown limited effectiveness [10]. In resource-limited settings with inadequate medical personnel, pulse oximetry offers a valuable means of early CHD detection. Additional advantages include its rapid response to changes in oxygen saturation, provision of continuous noninvasive information, and absence of calibration requirements. This study aimed to assess the effectiveness of pulse oximetry in conjunction with clinical parameters for CHD detection.

MATERIALS AND METHODS

The investigation was conducted in a prospective, observational manner, encompassing neonates at a tertiary care facility. Inclusion criteria comprised neonates born with a gestational age surpassing 35 weeks, as determined by maternal records and New Ballard Score assessment within 48 hours of delivery. Neonates born with a gestational age below 35 weeks and those whose parents declined participation were excluded.

The examination procedure involved pulse oximetry assessment on the left foot of neonates for a minimum duration of 2 minutes, while maintaining a stable position, utilizing BPL portable monitor. This device monitors oxygen saturation, pulse rate, displays plethysmograph with a perfusion bar indicator, and integrates principles of spectrophotometric oximetry and plethysmography. Concurrently, a clinical examination was conducted. Neonates exhibiting oxygen saturation levels below 95% underwent echocardiographic evaluation. All echocardiographic assessments, including M-mode and 2-D imaging, were performed using the advanced technology laboratory echocardiography machine. Statistical analyses were executed utilizing SPSS software. Discrete variables were presented as percentages, while continuous variables were expressed as mean ± standard deviation. The distribution variance of discrete variables was assessed using the chi-square test, and the significance of differences in continuous variables was determined through Student's t-test, with a significance threshold set at a p-value of < 0.05.

RESULTS

In **Table 1,** it is evident that 57 newborns exhibited SPO2 levels below 95%, among whom 11 displayed cyanosis. Conversely, among the 678 patients with SPO2 levels exceeding 95%, none exhibited cyanosis. This discrepancy in cyanosis prevalence between the two groups was statistically significant. Additionally, within the subset of subjects with SPO2 levels below 95%, 7.02% presented with murmurs, whereas murmurs were absent in subjects with SPO2 levels above 95%, indicating a significant difference in murmur occurrence between the two groups. However, no significant variances were observed in the remaining baseline clinical parameters.

Table 2 compares the baseline clinical characteristics of newborns with and without congenital heart disease among those with SPO2 levels below 95%. Cyanosis was absent in all normal infants, whereas 25 infants with congenital heart disease presented with cyanosis, indicating a significant difference between the two groups in terms of cyanotic infants. Murmurs were absent in all normal subjects, whereas 11.11% of infants with congenital heart disease exhibited murmurs. However, there was no significant difference in the occurrence of murmurs between the two groups, as delineated in **Table 2.**

Echocardiography was conducted on the 57 newborns demonstrating oxygen saturation levels below 95%. Out of these, 38 newborns (66.66%) exhibited abnormal echocardiographic findings suggestive of congenital heart diseases. The majority of these abnormalities were ventricular septal defects, followed by atrial septal defects, as illustrated in **Table 3** and **Figure 1.**

Table 1: Pulse oximetry and Baseline clinical variables in the study newborns

Variables	SPO2<95%		SPO2>95%		P-value
	n	%	n	%	
Apgar at 1 min. <3	0	0	3	0.44	0.71
Apgar at 1 min. 3-6	1	1.75	30	4.42	
Apgar at 1 min. >6	56	98.25	645	95.13	
Apgar at 5 min. <3	0	0.00	0	0.00	0.39
Apgar at 5 min. 3-6	0	0.00	13	1.92	
Apgar at 5 min. >6	57	100.00	665	98.08	
Heart rate <120 beats/min	3	5.26	74	10.91	0.25
Heart rate 120-140 beats/min	50	87.72	540	79.65	
Heart rate >140 beats/min	4	7.02	64	9.44	
Respiratory rate <40/min	6	10.53	57	8.41	0.65
Respiratory rate 40-60/min	50	87.72	594	87.61	
Respiratory rate <60/min	1	1.75	27	3.98	
Cyanosis Present	11	19.30	0	0.00	<0.05
Cyanosis Abesent	46	80.70	678	100.00	
Murmur Present	4	7.02	0	0.00	<0.05
Murmur Abesent	53	92.98	678	100.00	

Table 2: Baseline variables in study newborns with SPO2< 95% (57 cases)
Table 3: Echocardiographic results in the study newborns

Variables	Normal (n=21)		CHD (n=36)		P-value
	n	%	n	%	
Gestational age 35-38 wks	7	33.33	16	44.44	0.33
Gestational age >38 wks	14	66.67	20	55.56	
Male gender	11	52.38	20	55.56	0.49
Female gender	10	47.62	16	44.44	
Birth weight 1500-2500 gms	8	38.10	14	38.89	0.58
Birth weight >2500 gms	13	61.90	22	61.11	
Apgar at 1 min. <3	-	-	-	-	0.59
Apgar at 1 min. 3-6	-	-	1	2.778	
Apgar at 1 min. >6	21	100.00	35	97.22	
Apgar at 5 min. <3	-	-	-	-	-
Apgar at 5 min. 3-6	-	-	-	-	
Apgar at 5 min. >6	21	100.00	36	100	
Heart rate <120 beats/min	-	-	4	11.11	0.19
Heart rate 120-140 beats/min	21	100.00	2	5.556	
Heart rate >140 beats/min	-	-	30	83.33	
Respiratory rate <40/min	2	9.52	12	33.33	0.27
Respiratory rate 40-60/min	18	85.71	24	66.67	
Respiratory rate <60/min	1	4.76	-	-	
Cyanosis Present	-	-	25	69.44	<0.05
Cyanosis Absent	21	100.00	11	30.56	
Murmur Present	-	-	4	11.11	0.22
Murmur Absent	21	100.00	32	88.89	
Blood Group A	5	23.81	7	19.44	0.65
Blood Group B	6	28.57	12	33.33	
Blood Group AB	2	9.52	3	8.33	
Blood Group O	8	38.10	14	38.89	
Haemoglobin (gms/dl); Mean ± SD	15.12 ± 2.14		14.07 ± 2.57		0.91

Type of CHD	n	%
Normal	19	33.33
VSD	12	21.05
ASD	6	10.53
VSD + PDA	5	8.77
ASD + PDA	4	7.02
Isolated PDA	3	5.26
ASD + VSD	1	1.75
VSD + Pulmonary atresia	1	1.75
Coarctation of Aorta + PDA	1	1.75
Tetralogy of Fallot + PDA	1	1.75
Coarctation of Aorta	1	1.75
Ebstein Anomaly	1	1.75
Isolated Pulmonary atresia	1	1.75
PPHN	1	1.75
Total	**57**	**100.00**

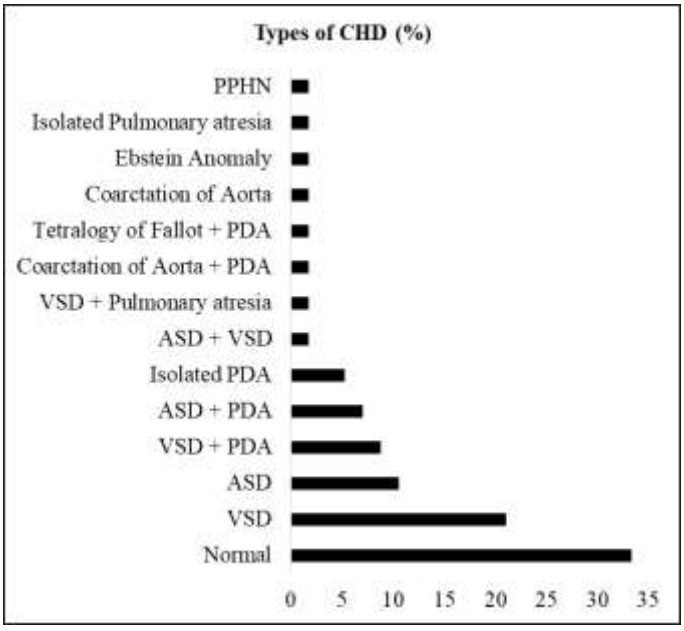

Figure 1: % Distribution of echocardiography results in screened population

DISCUSSION

In India, the majority of research on congenital heart disease (CHD) is predominantly clinically focused, primarily due to cost constraints and the limited availability of echocardiography. Relying solely on clinical diagnosis for CHD can be erroneous, lacking data on pulse oximetry utilization for early CHD detection in Indian studies. This investigation established a threshold of oxygen saturation below 95% for assessing normal pulse oximeter values in healthy newborns.

However, it's acknowledged that oximetry may overestimate arterial oxygen saturation at lower levels and underestimate it at higher saturations [11-13]. Comparing findings with existing literature is challenging due to the lack of standardization in study design and methodology [14-16]. Nevertheless, this study yields valuable insights into the role of pulse oximetry in early CHD detection in India.

Among 731 screened newborns, 57 exhibited SPO2 levels below 95%, with 4 of them presenting murmurs, later confirmed to have CHD. Ainsworth SB *et al*. identified murmurs in 0.6% of infants examined, with 54% diagnosed with CHD. Discrepancies may arise due to murmur detection within 48 hours of birth in this study, contrasting with examinations repeated within 2-14 days in another [17]. Notably, 11 newborns displayed cyanosis, all with arterial saturation below 95%, highlighting a significant association between cyanosis and CHD. Khalil, A. *et al*., observed cyanosis in 5 newborns, all diagnosed with CHD [18]. Our study noted a higher incidence of cyanosis, likely influenced by concurrent pulse oximetry usage, sample size variation, and methodological differences. Pulse oximetry, alongside clinical evaluation, plays a crucial role in early CHD detection, especially when murmur and cyanosis are present, offering a cost-effective alternative in resource-limited settings like India.

Griebsch L *et al*. reported varying diagnostic yields for clinical examination, pulse oximetry, and screening echocardiography [19]. Bakr, A.F. *et al*., concluded that combining pulse oximetry with clinical examination enhances timely life-threatening CHD detection [20]. Pulse oximetry emerges as a simple, noninvasive, and cost-effective screening tool, recommended for routine use in newborn CHD detection [21]. Timing is crucial, with optimal performance observed within 8-24 hours post-birth [22]. This study underscores the significant relationship between combined pulse oximetry and cyanosis in early CHD detection ($p<0.05$). Utilizing pulse oximetry alongside clinical examination pre-discharge can facilitate early CHD detection.

CONCLUSION

Pulse oximetry has become increasingly recognized as a crucial instrument in the early identification of congenital heart diseases (CHDs), serving as a valuable adjunct to conventional clinical evaluation metrics. Its utilization enhances the efficiency and accuracy of screening processes, thereby facilitating timely intervention and management strategies**.**

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