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Implementing Pulse Oximetry Screening for Congenital Heart Disease

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Abstract

Background: identifying newborn infants with congenital heart disease before they suffer cardiovascular collapse is of paramount importance in optimizing outcome following surgical or catheter intervention. Pulse oximetry screening of all newborns is being considered for national implementation in the UK with the aim of detecting affected infants at an early stage, particularly those in whom pulmonary or systemic blood flow will be duct dependent.

Objective: is to determine the number of participants with congenital heart disease identified by early screening using pulse oximetry. Patients and methods: a prospective study was conducted on newborns patients with congenital heart disease who admitted to the well-baby nursery and neonatal intensive care unit (NICU) of implementation was performed at 2 tertiaries hospitals, (Dubai hospital in United Arab Emirates and Benha university hospital in Egypt) on all deliveries born from June 2014 through December 2016.

Results: There was a statistically significant difference between Admission pulse oximetry oxygen saturation threshold among the studied neonates with different disease ($p \leq 0.05$). There were statistically significant increases between the percentage of neonates with low admission saturations, without co-morbidities, by threshold for ≤ 95 compared ≤ 90 and ≤ 92 respectively in different diseases.

Conclusion: In conjunction with antenatal fetal anomaly screening and physical examination of newborn, pulse oximetry screening can play an important role in early detection of critical congenital heart defects, as well as non-cardiac conditions such as sepsis, pneumonia, and other significant pathologies.

Keywords: Congenital Heart Disease; Neonatal Intensive Care Unit; Pulse Oximetry Screening; Cyanosis; Pulmonary stenosis

Abbreviations: CHD: Congenital Heart Disease; CCHD: Critical CHD; AHA: American Heart Association; APP: American Academy of Pediatrics; NICU: Neonatal Intensive Care Unit; HLHS: Hypoplastic Left Heart Syndrome; PA: Pulmonary Atresia; PS: Pulmonary Valve Stenosis; AS: Aortic Stenosis; IAA: Interruption of the Aortic Arch; CoA: Coarctation of the Aorta; TOF: Tetralogy of Fallot; TGA: Transposition of the Great Arteries; TAPVD: Total Anomalous Pulmonary Venous Drainage; PO: Pulse Oximeter

Introduction

Congenital heart disease (CHD) is the most common birth defect and affects approximately 8 per every 1000 newborns born each year. Critical CHD (CCHD), severe types of CHD, has an incidence of approximately 2.5 to 3 per 1000 live births [1]. These more serious defects cause significant morbidity and mortality, accounting for nearly 40% of deaths in children with congenital anomalies in the first year of life [2]. Over the past two decades numerous advances in care have resulted in a significant reduction in mortality secondary to CCHD; however, timely diagnosis remains an issue for these newborns. Despite prenatal diagnosis and newborn examinations, as many as 39% of infants diagnosed with CCHD are diagnosed only after discharge from the newborn nursery [3]. Delay in diagnosis may have significant adverse implications; one study showed that 43% of cases diagnosed after hospital discharge from the nursery were in shock at the time of readmission [4]. Pulse oximetry has been recommended as a potential newborn screening test for CCHD. Early efforts provided the conceptual basis for pulse oximetry in the detection

of CCHD [5]. Subsequent work has provided additional evaluation of the sensitivity, specificity, and diagnostic gap of pulse oximetry screening [6].

In 2009, the American Heart Association (AHA) and American Academy of Pediatrics (AAP) released a statement on the potential use of pulse oximetry screening to detect CCHD [7]. The statement recognized that the most favorable outcomes are realized when screening on the right lower extremity is conducted after 24 h of age, using 95% as the cutoff value for additional consultation and evaluation. The AHA and AAP concluded that pulse oximetry screening could potentially improve detection of CCHD [8]. However, universal screening was not endorsed at the time and the authors recommended that 'future studies in larger populations and across a broad range of newborn delivery systems are needed to determine whether this practice should become standard of care in the routine assessment of the neonate' [9].

Aim of the Study

The aim of this study is to determine the number of participants with congenital heart disease identified by early screening using pulse oximetry.

Patients and Methods

A prospective study was conducted on newborns patients with congenital heart disease who admitted to the well-baby nursery and neonatal intensive care unit (NICU) of implementation was performed at 2 tertiaries hospitals, (Dubai hospital in United Arab Emirates and Benha university hospital in Egypt) on all deliveries born from June 2014 through December 2016.

Ethical Consideration: After obtaining approval from the local ethics committee, their parents and care givers who agreed to participate gave their signed informed consent after explanation of the trial benefits and hazards. All procedures were carried out in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Declaration of Helsinki and its later amendments or comparable ethical standards. The study received the approval of the ethical committee of Dubai hospital and Qalyubia faculty of medicine.

Inclusion Criteria: Eligible for pulse oximetry screening: term or late preterm (>35 weeks gestation), Absence prenatal diagnosis of congenital heart disease, Absence dysmorphic features and No signs of cardiovascular abnormalities, such as cyanosis, abnormal vital signs, or a cardiac murmur.

Methodology: The pulse oximetry of the right hand and the right foot was conducted between 12, 24 hours of age and discharge from the nursery. The Masimo Radical-7 pulse oximeter and a disposable low noise cable sensor were used to screen each newborn. Disposable sensors were provided by the study grant and used to avoid concerns regarding potential for transmission of infection with reusable probes. To ensure accuracy of the reading obtained, the individual responsible for screening verified all confidence indicators, including the signal identification quality and perfusion index, before reporting saturations. A time requirement for performing screening on each extremity was not specified, since confidence indicators were used to indicate readings as accurate. The individual responsible for screening recorded age (in hours) of newborn, time that pulse oximetry screening began and ended, obstacles encountered with equipment, newborn, family or staff and time spent overcoming obstacles. If the oxygen saturation was >95% for both the right hand and the right foot and there was <3% difference between the two, the test was considered negative, and the newborn 'passed' screening; no further cardiac evaluation in the well baby nursery was necessary unless indicated by subsequent physical exam or clinical condition. If the oxygen saturation was ≤ 95% for any measurement or if there was ≥ 3% difference between the two saturations, the test will be repeated after 1 hour twice before considering it positive and the newborn 'referred' to his or her physician. The newborn's physician was informed and responsible for all future decisions regarding care and evaluation. For newborns who were 'referred', it was recommended that echocardiography be obtained to evaluate cardiac anatomy and if the oxygen saturation was <90% that he or she be transferred to the NICU for further monitoring and evaluation. Decisions regarding echocardiography, additional consultation, or transfer to the NICU were made at the discretion of the physician caring for the newborn.

Diagnostic Strategies: Any newborn with a positive screen results first requires a comprehensive evaluation for causes of hypoxemia. In the absence of other findings to explain hypoxemia, CCHD needs to be excluded based on a diagnostic echocardiogram [7].

Statistical Analysis

The results were tabulated and statistically assessed using SPSS 25 (SPSS Inc., Chicago, IL, USA) and Microsoft Excel 2017 on a personal computer. It underwent statistical evaluation using: The terms percentage (%), mean, and standard deviation are examples of descriptive data. Analytical methods include the t, paired t, Mann-Whitney, and chi-squared (x^2) tests. A P value less than 0.05 was used to determine statistical significance.

Results

A flowchart of the study population shown in Figure 1. Of the 472 newborns patients with congenital heart disease. 324 patients were excluded from the study (61 patients declined consent and 263 patients did not meet the inclusion criteria, 148 patients were willing to participate and divided into 132 patients in ICU and 16 patients in postnatal. A total of 148 patients, 100 (67.56%) of them were females and 48 (32.44%) patients were males, (Figure 2). Among 148 neonates, 93 (62.8) of neonates were diagnosed with preterm and 55 (37.2) were diagnosed with full-term (Figure 3). There was significant relation among full-term and preterm groups regarding diagnosis (P<0.001). The most diagnoses in full-term were TOF, HLHS and TGA (74.5%,

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16.4%, 5.5%) respectively, and the most diagnosis in preterm were PS, TOF and TGA (23.7%, 18.3%, 11.8%) respectively (Table 1). Among ventilated at admission, there was significant relation among patients under ventilated and without ventilated groups regarding diagnosis (P<0.001). PS, TGA and HLHS were most diagnoses in patients under ventilated (22.2%, 24.4%, 17.8%) respectively. While there was no significant relation among patients requiring oxygen and non-requiring oxygen groups regarding diagnosis (P=0.188), (Table 2) Gestational age was significantly increased among patients with HLHS than patients with TOF, TGA, Plum atresia, CoA, TAPVD, PA, PS and AS (P<0.001). While birth weight was significantly increased among patients with TOF than patients with HLHS, TGA, Plum atresia, CoA, TAPVD, PA, PS and AS (P<0.001), (Table 3).

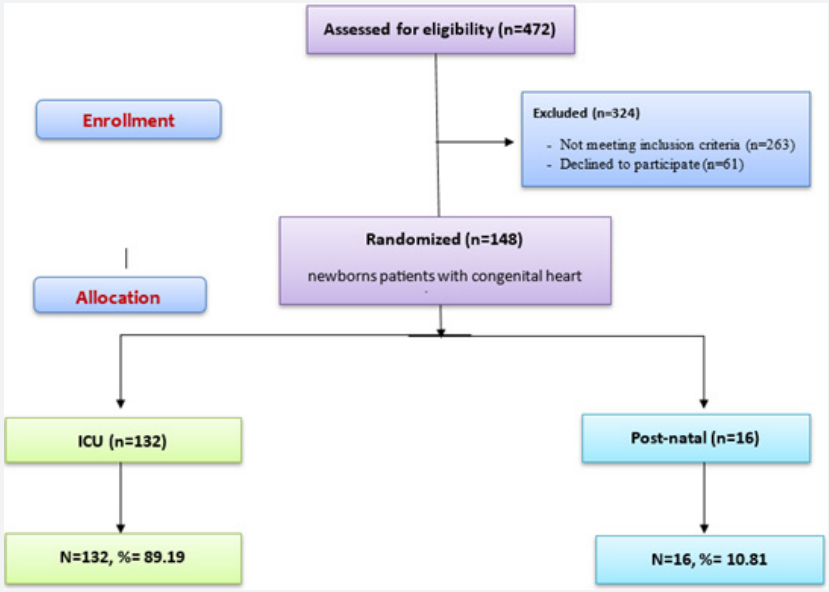

Figure 1: Flowchart of newborns patients with congenital heart disease.

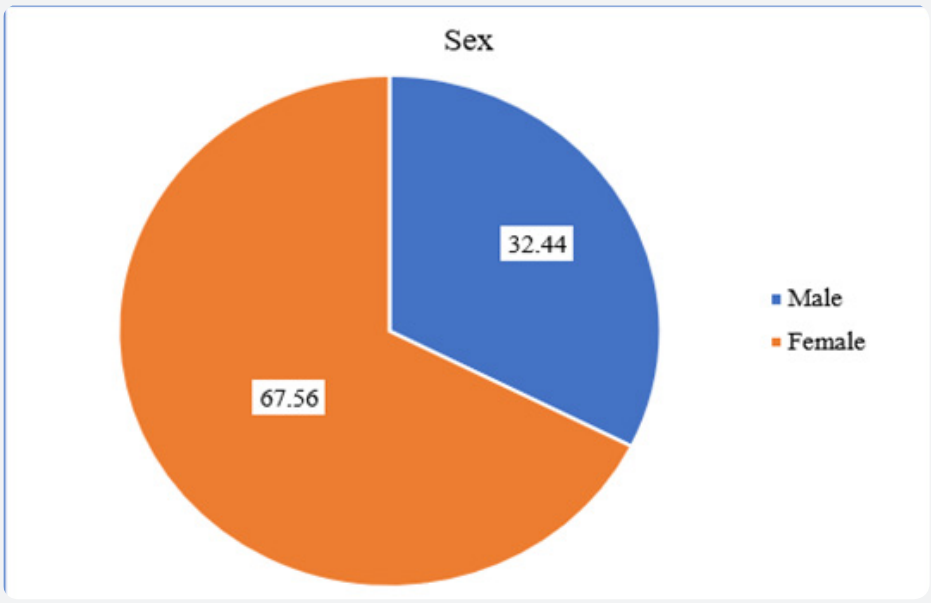

Figure 2: Sex distribution among the studied cases.

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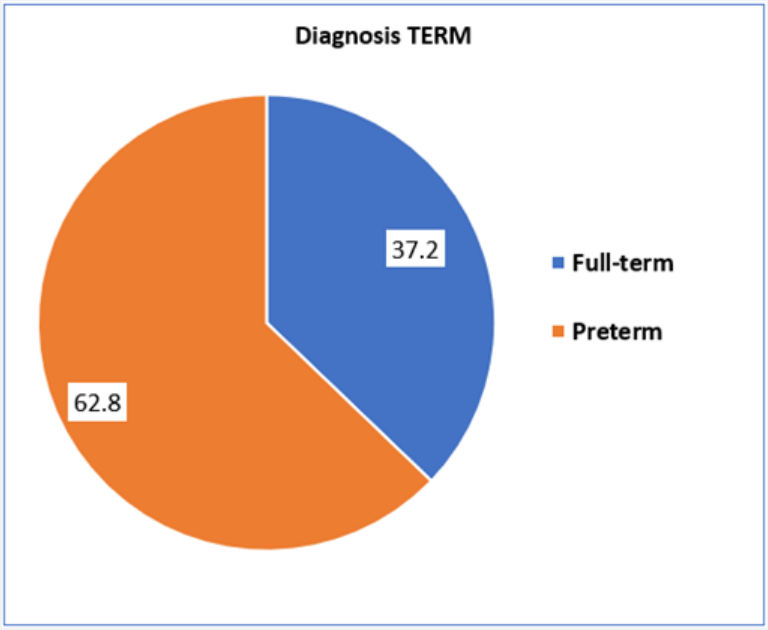

Figure 3: Diagnosis TERM distribution among the studied cases.

Table 1: Diagnosis in relation to diagnosis TERM among the studied cases (n=148).

Diagnosis	Diagnosis TERM				P value
	Full-term (n=55)		Preterm (n=93)		
	N	%	N	%	
HLHS	9	16	4	4.3	
TGA	3	5.5	11	12	
Plum atresia	1	1.8	7	7.5	
CoA	0	0	9	9.7	
TAPVD	0	0	5	5.4	<0.001*
IAA	0	0	6	6.5	
AS	0	0	4	4.3	
PA	0	0	8	8.6	
PS	1	1.8	22	24	
TOF	41	75	17	18	

HLHS: Hypoplastic left heart syndrome, PA: Pulmonary atresia, PS: Pulmonary valve stenosis, AS: critical aortic stenosis, IAA: interruption of the aortic arch, CoA: coarctation of the aorta, TOF: tetralogy of Fallot, TGA: transposition of the great arteries, TAPVD: total anomalous pulmonary venous drainage, *: Significant.

Table 2: Percentages of neonates requiring ventilation and/or oxygen at admission by CCHD diagnosis (n=148).

Diagnosis	At Admission							
	Ventilated				Requiring oxygen			
	No		Yes		No		Yes	
	(n=103)		(n=45)		(n=119)		(n=29)	
	N	%	N	%	N	%	N	%
HLHS	5	4.9	8	18	10	8.4	3	10

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TGA	3	2.9	11	24	11	9.2	3	10
Plum atresia	8	7.8	0	0	8	6.7	0	0
CoA	8	7.8	1	2.2	4	3.4	5	17
TAPVD	3	2.9	2	4.4	4	3.4	1	3.4
IAA	5	4.9	1	2.2	5	4.2	1	3.4
AS	4	3.9	0	0	4	3.4	0	0
PA	3	2.9	5	11	6	5	2	6.9
PS	13	13	10	22	17	14	6	21
TOF	51	50	7	16	50	42	8	28
P value	<0.001*				0.188			

HLHS: Hypoplastic left heart syndrome, PA: Pulmonary atresia, PS: Pulmonary valve stenosis, AS: critical aortic stenosis, IAA: interruption of the aortic arch, CoA: coarctation of the aorta, TOF: tetralogy of Fallot, TGA: transposition of the great arteries, TAPVD: total anomalous pulmonary venous drainage, *: Significant.

Table 3: Demographics data by specific CCHD diagnosis (n=148).

Diagnosis	N	Gestational age (GA/wks.)		Birth weight (kg)	
		Mean± SD	95% CI	Mean± SD	95% CI
HLHS	13	38.62±1.76	37.55-39.68	2.67±0.38	2.44-2.90
TGA	14	32.07±3.22	30.21-33.93	2.55±0.28	2.39-2.71
Plum atresia	8	31.00±4.99	26.83-35.17	2.67±0.35	2.38-2.96
CoA	9	31.78±3.67	28.96-34.60	2.60±0.28	2.39-2.82
TAPVD	5	31.20±4.09	26.13-36.27	2.14±0.13	1.97-2.31
IAA	6	30.50±6.22	23.97-37.03	2.53±0.29	2.22-2.84
AS	4	29.25±2.22	25.72-32.78	2.39±0.23	2.02-2.75
PA	8	31.88±4.05	28.49-35.26	2.41±0.27	2.19-2.64
PS	23	30.74±4.39	28.84-32.64	2.43±0.25	2.32-2.54
TOF	58	34.43±4.83	33.16-35.70	2.93±0.37	2.83-3.02
P value		<0.001*		<0.001*	

HLHS: Hypoplastic left heart syndrome, PA: Pulmonary atresia, PS: Pulmonary valve stenosis, AS: critical aortic stenosis, IAA: interruption of the aortic arch, CoA: coarctation of the aorta, TOF: tetralogy of Fallot, TGA: transposition of the great arteries, TAPVD: total anomalous pulmonary venous drainage, *: Significant.

There was a statistically significant difference dmission pulse oximetry oxygen saturation threshold among the studied neonates withdifferent disease (p≤0.05). There statistically significant increases betwee the percentage of by threshold for ≤ 95 compared ≤ 90 and ≤ 92 respectively in different diseases as follows for: Hypoplastic left heart syndrome (76.92% vs 23.1% and 53.8%), Transposition of the great arteries (85.71% vs 42.9% and 71.4%), Coarctation of the aorta (55.55% vs 22.2% and 33.3%), Interruption of the aortic arch (83.3% vs 16.7% and 33.3%), Pulmonary atresia (75.00% vs 25% and 37.5%), Pulmonary valve stenosis (95.65% vs 21.7% and 60.9%), Tetralogy of Fallot (81.3% vs than 31% and 50%) (Table 4).

Table 4: Number and percentage of neonates with admission saturation by CCHD diagnosis (n=148).

Diagnosis	Admission pulse oximetry oxygen saturation threshold (%)									Sig. tes
	≤ 90			≤ 92			≤ 95			
	N	%	95% CI	N	%	95% CI	N	%	95% CI	P value
HLHS (13)	3	23	0.07-0.50	7	54	0.27-0.81	10	76.9	0.50-0.93	0.013*
TGA (14)	6	43	0.18-0.70	10	71	0.45-0.92	12	85.7	0.64-0.95	0.044*
COA (9)	2	22	0.08-0.50	3	33	0.11-0.67	5	55.6	0.25-0.86	0.051*
TAPVD (5)	4	80	0.33-0.89	--	--	--	--	--	--	---

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IAA (6)	1	17	0.09-0.67	2	33	0.13-0.74	5	83.3	0.50-0.91	0.001*
AS (4)	--	--	--	--	--	--	2	50	0.20-0.80	---
PA (8)	2	25	0.10-0.60	3	38	0.13-0.75	6	75	0.38-0.91	0.06*
PS (23)	5	22	0.07-0.40	14	61	0.41-0.80	22	95.7	0.84-0.97	0.001*
TOF (58)	18	31	0.19-0.44	29	50	0.37-0.63	47	81	0.70-0.91	0.001*

HLHS: Hypoplastic left heart syndrome, PA: Pulmonary atresia, PS: Pulmonary valve stenosis, AS: critical aortic stenosis, IAA: interruption of the aortic arch, CoA: coarctation of the aorta, TOF: tetralogy of Fallot, TGA: transposition of the great arteries, TAPVD: total anomalous pulmonary venous drainage. Comparison between the studied diseases done using Kruskal Wallis test (H), *Significant

Discussion

Congenital heart disease (CHD) is a major cause of neonatal death. In addition, it is not an uncommon disease, the incidence of CHD was reported between 0.3% & 0.8% [10]. Most newborns with a CCHD are asymptomatic at birth and detection prior to the onset of symptoms usually involves routine screening by antenatal ultrasound scan and postnatal clinical examination of the cardiovascular system. Unfortunately, both have a variable, and often low, detection rate [11] and up to 30% of infants born with CCHD are discharged home before the diagnosis has been established with reported mortality rates as high as 50% [12]. Pulse oximeter (PO) has been studied as a newborn screening test to enhance the detection of CCHD [13]. PO measures blood oxygen saturation and is a well-established, accurate, non-invasive method of detecting low oxygen levels (hypoxemia), [14]. The degree of desaturation is often comparatively mild and may be clinically undetectable, even by experienced clinicians [15]. So, CCHDs screening by PO must be enhanced in newborns to reduce the occurrence of acute collapse in babies [14]. Thus, the aim of this study is to determine the number of participants with congenital heart disease identified by early screening using pulse oximetry.

In our study, there was significant relation among full-term and preterm groups regarding diagnosis (P<0.001). The most diagnoses in full-term were TOF, HLHS and TGA (74.5%, 16.4%, 5.5%) respectively, and the most diagnosis in preterm were PS, TOF and TGA (23.7%, 18.3%, 11.8%) respectively. Among ventilated at admission, there was significant relation among patients under ventilated and without ventilated groups regarding diagnosis (P<0.001). PS, TGA and HLHS were most diagnoses in patients under ventilated (22.2%, 24.4%, 17.8%) respectively. While there was no significant relation among patients requiring oxygen and non-requiring oxygen groups regarding diagnosis (P=0.188). In a study by Mawson et al. [16] reported that thirty-eight (14%) had co-morbidities including preterm delivery, respiratory distress syndrome, intra-uterine growth retardation (birth weight < 3rd centile) and other congenital anomalies. Twenty-two (8%) had respiratory co-morbidities at admission. Thirty-one (12%) were ventilated on admission, and 30 (11%) were requiring oxygen on admission. None were receiving a prostaglandin E infusion at the time of admission and therefore at the time oxygen saturations were measured.

In this concern a study by Jain et al. [17] reported that most of the neonates were born full-term (73%). Both critical and non-critical CHD were noticed in full-term neonates, i.e., 58.3% and 85.29%, respectively. Out of the total 164 2D echocardiographs, 120 did not show any cardiac defect. The high number of false positive cases was because we performed pulse oximetry before 24 hours of life. Many studies noticed that false positives are far less when screening is done between 24 to 48 hours of life [18,19]. The present study showed that, there were statistically significant increases between the percentage of neonates with low admission saturations, without co-morbidities, by threshold for ≤ 95 compared ≤ 90 and ≤ 92 respectively in different diseases as follows for: Hypoplastic left heart syndrome (76.92% vs 23.1% and 53.8%), Transposition of the great arteries (85.71% vs 42.9% and 71.4%), Coarctation of the aorta (55.55% vs 22.2% and 33.3%), Interruption of the aortic arch (83.3% vs 16.7% and 33.3%), Pulmonary atresia (75.00% vs 25% and 37.5%), Pulmonary valve stenosis (95.65% vs 21.7% and 60.9%) and Tetralogy of Fallot (81.3% vs than 31% and 50%). In the same line, Mawson et al. [16] reported that, even after removal of clinically unstable neonates, the proportion in the different Pulsox threshold groups varies according to the CCHD diagnosis. Even at the lowest pulse oximetry threshold of ≤ 90%, most of their cohort with PA, TGA, and TAPVD had abnormal values. The hemodynamics of these lesions are characterized by duct-dependent pulmonary blood flow (PA), failure of mixing of oxygenated and deoxygenated blood (TGA) or obligate right to left shunting of blood at atrial level (TAPVD).

Additionally, they found a statistically significant increment in sensitivity of pulse oximetry for CoA, HLHS, and TOF was noted when the saturation threshold was increased from ≤ 90% or ≤ 92% to ≤ 95%. The data for CoA and HLHS is clinically important because the systemic arterial circulation is duct-dependent, and a benefit of presentation prior to onset of heart failure or circulatory collapse has been reported [20, 21]. In HLHS, there is an obligatory left to right shunt at atrial level and the systemic arterial circulation is maintained by blood flow from the right ventricle into the pulmonary artery and right to left through the arterial duct. The systemic arterial oxygen saturations are equal in the upper and lower limbs and reflect the pulmonary to systemic flow ratio. Even with oxygen saturations measured early after birth in their study, only the highest threshold (≤ 95%) was associated

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with an abnormal result in most cases. With the continued fall in pulmonary vascular resistance during the first days after birth, oxygen saturations increase so that the sensitivity of detection by pulse oximetry is also likely to fall.

In coarctation of the aorta, in contrast to HLHS, there is antegrade flow of blood through the left heart, so that it would be expected for preductal saturations to be normal or near normal in the first hours after birth and even after the arterial duct begins to constrict. Also, Granelli et al. [22] reported that, the combination of measurement of both preductal and post ductal saturation may be useful, but coarctation of the aorta was not detected in most cases in a large Swedish study and depended for the most part on weak femoral pulses for detection. Moreover, Mawson et al. [16] observed that, for certain CCHD lesions, AS, PS and CoA, even with the use of a higher saturation threshold (≤ 95%), the proportion of infants with an abnormal result was low (20, 36 and 42%, respectively). The lower sensitivity of pulse oximetry screening for CoA has previously been recognized by Valmari, [23] and Meberg et al. [24]. Valmari, [23] also noted the lower sensitivity of pulse oximetry screening for Pulmonary stenosis (PS).

In study by Singh and Chen, [25] of 23,614 newborns, 0.8% had a positive POS result, consistent with previous studies [6,26]. In total, 64 infants had a postnatal diagnosis of CHDs, including 7 cases of CCHDs. Sensitivity of POS varied from 85.7% for detection of CCHD to just 33% for detection of major (critical and serious) CHD, and specificity was 99.3%. Pulse oximetry screening was able to identify 6/7 (85.7%) cases of CCHDs prior to discharge from hospital. When used in conjunction with physical examination of the newborn, 65.6% of major CHDs were diagnosed prior to discharge from the hospital. Another study by Banait et al. [27] reported that the rate of post-discharge diagnosis of CCHDs was almost doubled in infants with no pulse oximetry screening; 7/100,000 in cohorts with POS screening versus 13/100,000 in populations without POS screening (relative risk 0.52, CI 0.2 to 1.42). However, this difference was not statistically significant which could be because of the small number of CCHDs in the large cohort study.

Conclusion

In conjunction with antenatal fetal anomaly screening and physical examination of newborn, pulse oximetry screening can play an important role in early detection of critical congenital heart defects, as well as non-cardiac conditions such as sepsis, pneumonia, and other significant pathologies. Our study adds further evidence for implementation of routine pulse oximetry screening to detect critical CHDs.

Data Sharing Statement

All data and materials included in this work are available.

Ethics Approval and Consent to Participate

Our local Ethics Committee approved our study and a written consent for participation was obtained from all patients.

Human and Animal Rights

No animals were used for studies that are the basis of this research. All the humans were used in accordance with the Helsinki Declaration of 1975.

Authors' Contributions

All authors made a significant contribution to the work reported, whether that is in the conception, study design, execution, acquisition of data, analysis and interpretation, or in all these areas; took part in drafting, revising or critically reviewing the article; gave final approval of the version to be published; have agreed on the journal to which the article has been submitted; and agree to be accountable for all aspects of the work.

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