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Original article

Neonatal Pulse Oximetry Screening for Congenital Heart Disease

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Abstract:

Background: Lower respiratory tract infections, sepsis, and congenital heart disease are still the main causes of new-born death, but most of these issues are curable with early detection and treatment. It has been established that pulse oximetry screening (POS) is a non-invasive investigation that can identify 50–70% of congenital heart defects (CHDs) that have not been identified before. The aim of this study is to count the number of participants with congenital heart disease who were found through early screening- using pulse oximetry. **Methods:** A prospective study was conducted on new-borns 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 were 41 patients had pulse oximetry≤90 (27.7%), 73 patients had pulse oximetry≤92 (49.3%) and 114 patients had pulse oximetry≤95 (77.0%). Also, the initial pulse oximetry different was ranged (3.00-6.00) with mean (3.88±1.02) and the second pulse oximetry different was ranged (2.00-7.00) with mean (4.01±1.22). **Conclusion:** Even in the first hour of life, oxygen saturations were found to be abnormal in the majority of CCHD patients. The proportions of anomalous results were highest with the highest oxygen saturation threshold (95%).

Keywords: congenital heart disease, hypoxemic, pulse oximetry screening, respiratory conditions.

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Introduction

Congenital heart disease (CHD) is the most common congenital ailment in neonates [1]. About 25% of cases of CHD are classified as critical CHD, which is defined as "requiring surgery or catheter-based intervention during the first year of life" [2]. Some babies with severe congestive heart failure are not detected until they are released from the birth hospital, despite the fact that many of them exhibit symptoms and are identified soon after delivery [3, 4]. The risk of morbidity and death rises in infants with significant cardiac abnormalities that are not diagnosed promptly [5]. Due to birth defects, congenital heart illness has been connected to 30–50% of neonatal deaths [6]. Between 1999 and 2006, the number of child deaths in the US reported as a result of congenital cardiac abnormalities exceeded 13,000 [7].

Due to the paucity of CHD screening programs, a sizable fraction of neonates with CCHDs go undiagnosed before being released from the hospital [8]. Only around half of all CHDs can be detected by foetal anomaly screening using prenatal ultrasonography at 20 weeks [9]. Although only 22% of CCHDs, such as coarctation of the aorta, can be detected early in pregnancy [10]. Similarly ineffective, post-natal clinical assessment only detects 31% of severe CHDs when it comes to heart sounds and visual cyanosis inspection [11, 12].

A 75–90% increase in CCHD detection can be achieved by using pulse oximetry screening (POS) [11, 13]. Prior studies have demonstrated that POS is reliable, affordable, and well-liked by medical staff and parents [14, 15, 16]. The premise behind pulse oximetry screening is that children with congenital heart defects who do not exhibit symptoms would likely have a fluctuation in oxygen content between their pre- and post-ductal circulations, or a degree of hypoxemia that may not be clinically noticeable [17, 12]. Significant hypoxemic non-cardiac disorders like sepsis or respiratory issues can also be detected by it [18]. All patient groups- including neonates- can be evaluated for hypoxemia (low blood oxygen levels) using pulse oximetry, which is a reliable and well-established technique [14, 19, 20]. The index test, which may be run either before or after the clinical examination, enables screening to lower the number of kids who are released from the hospital without receiving a CCHD diagnosis [15]. As a result, the purpose of this study was to identify the number of participants with congenital heart disease who were discovered through early screening with pulse oximetry.

Methods

A prospective study was carried out on newborns with congenital heart disease- who were admitted to the well-baby nursery and NICU of implementation at two tertiary hospitals (Dubai hospital in the United Arab Emirates and Benha university hospital in Egypt) on all deliveries- born between June 2014 and December 2016.

Ethical consideration:

Their parents and caregivers who opted to participate completed informed consent forms- after receiving approval from the local ethics commission and being informed of the trial's advantages and disadvantages. All procedures were conducted in accordance with the ethical guidelines established by the institutional and/or national research committee, as well as the 1964 Helsinki Declaration and any updates thereto or similar ethical standards. The Qalyubia College of Medicine and the Dubai Hospital's Ethical Council both gave their approval to the study {M.D.6.2016}.

Inclusion criteria:

Women who are term or late preterm (>35 weeks gestation) may be assessed with pulse oximetry. There are no dysmorphic traits or symptoms of cardiovascular problems, such as cyanosis, abnormal vital signs, or a heart murmur, because there is

no prenatal diagnosis of congenital cardiac disease.

Methodology:

Between 12 and 24 hours prior to discharge from the nursery, the right hand and right foot's pulse oximetry was taken. A disposable low noise cable sensor and a Masimo Radical-7 pulse oximeter- were used to screen each baby. Disposable sensors were part of the study grant, which helped allay worries about reusable probes potentially spreading infections. The person in charge of screening verified the accuracy of the measurement by looking at all confidence indicators, such as the perfusion index and signal identification quality- before reporting saturations.

There was no time limit for screening each extremity because confidence indicators were used to demonstrate if readings were accurate. The person in charge of the screening took note of the newborn's age (measured in hours), the start and end times of the pulse oximetry screening, any difficulties the staff or family had using the equipment, and the amount of time needed to get past obstacles. The test was deemed negative and the baby 'passed' screening if the oxygen saturation in both the right hand and right foot was greater than 95%, with a 3% difference. Unless there was a need for additional cardiac evaluation in the well-baby nursery, it was not necessary to do so.

A newborn will be deemed positive and 'referred' to their physician if the oxygen saturation was 95% for any measurement or if there was a 3% discrepancy between the two saturations. The test will be repeated in one hour. The baby's doctor was informed and in charge of all subsequent choices about assessment and care. It was suggested that neonates who were "referred" have echocardiogram to assess the structure of their hearts, and that if their oxygen saturation level was 90%, they be admitted to the neonatal intensive care unit (NICU) for further observation and assessment. Decisions regarding echocardiography, additional consultation, and transfer to the NICU- were decided by the attending physician.

Diagnostic Strategies:

A complete assessment for the causes of hypoxemia should be performed on any infant with a positive screen result. Using a diagnostic echocardiogram, CCHD must be ruled out if there are no other possible causes for hypoxemia [21].

Statistical Analysis:

A personal computer was used to tabulate and statistically analyze the data using Microsoft Excel 2017 and SPSS 25 (SPSS Inc., Chicago, IL, USA). The following terminology were used in the statistical evaluation: Descriptive data includes things like mean, standard deviation, and percentage (%). Analytical techniques include the t, paired t, Mann-Whitney, and chi-squared (x2) tests. A p value of less than 0.05 was used to assess statistical significance.

Results

A total of 148 neonates had congenital heart disease, with 58 patients (39.2%) having TOF, 23 (15.5%) having PS, 14 (9.5%) having TGA, 13 (8.8%) having HLHS, 9 (6.1%) patients having CoA, 8 (5.4%) having plum atresia and PA, 6 (4.1%) patients having IAA, 5 (3.4%) patients having TAPVD, and 4 (2.7%) patients having AS, Table (1).

Also, there were 45 patients who had ventilated at admission (30.4%) and 29 patients requiring oxygen at admission (19.6%), Table (2).

There were also 41 patients who had pulse oximetry90 (27.7%), 73 patients who had pulse oximetry92 (49.3%), and 114 patients who had pulse oximetry95 (77.0%). Furthermore, the initial pulse oximetry difference was (3.00-6.00) with a mean (3.881.02) and the second pulse oximetry difference was (2.00-7.00) with a mean (4.011.22), Table (3).

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Table (1) Diagnosis of disease among the studied cases (n=148).

Diagnosis	The studied cases (n=148)	
	N	%
HLHS	13	8.8
TGA	14	9.5
Plum atresia	8	5.4
CoA	9	6.1
TAPVD	5	3.4
IAA	6	4.1
AS	4	2.7
PA	8	5.4
PS	23	15.5
TOF	58	39.2

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**.**

Table (2) Ventilated at admission and requiring oxygen among the studied cases (n=148).

	The studied cases (n=148)	
	N	%
Ventilated at admission.		
No	103	69.6
Yes	45	30.4
Requiring oxygen at admission		
No	119	80.4
Yes	29	19.6

Table (3) Pulsox among the studied cases (n=148).

Pulsox	The studied cases (n=148)	
	N	%
Pulsox ≤ 90		
No	107	72.3
Yes	41	27.7
Pulsox ≤ 92		
No	75	50.7
Yes	73	49.3
Pulsox ≤ 95		
No	34	23.0
Yes	114	77.0
	Mean± SD	**Range**
Initial Pulsox different	3.88±1.02	3.00-6.00
Second Pulsox different	4.01±1.22	2.00-7.00

Pulsox: Pulse oximetry

Furthermore, gestational age was substantially higher in HLHS patients than in TOF, TGA, Plum atresia, CoA, TAPVD, PA, PS, and AS patients (P0.001). While birth weight was considerably higher in TOF patients than in HLHS, TGA, Plum atresia, CoA, TAPVD, PA, PS, and AS patients (P0.001), Figure (1, 2).

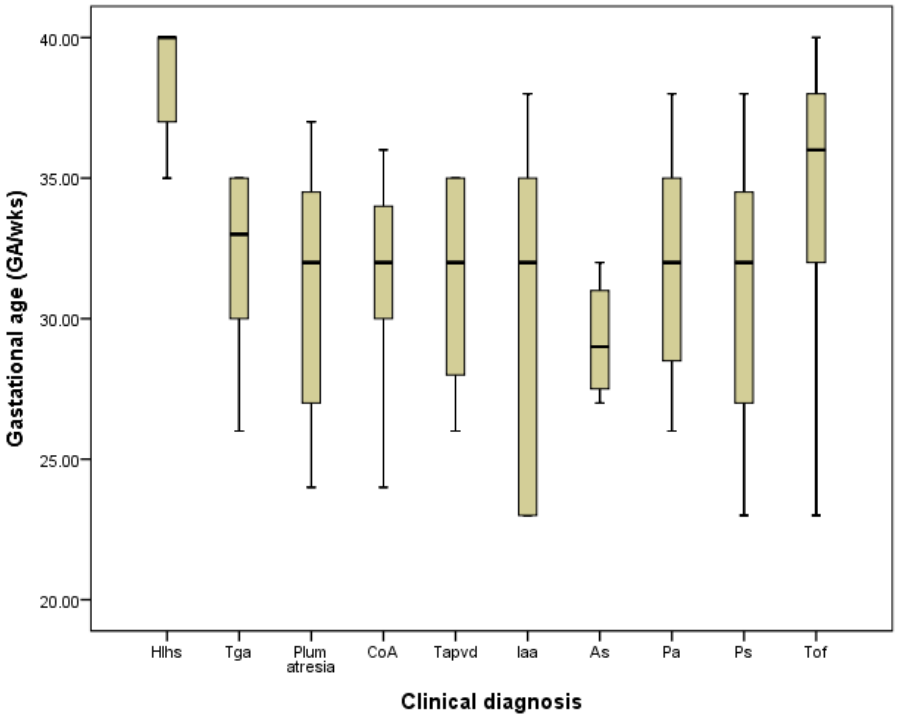

Figure (1) Gestational age distribution in relation to clinical diagnosis.

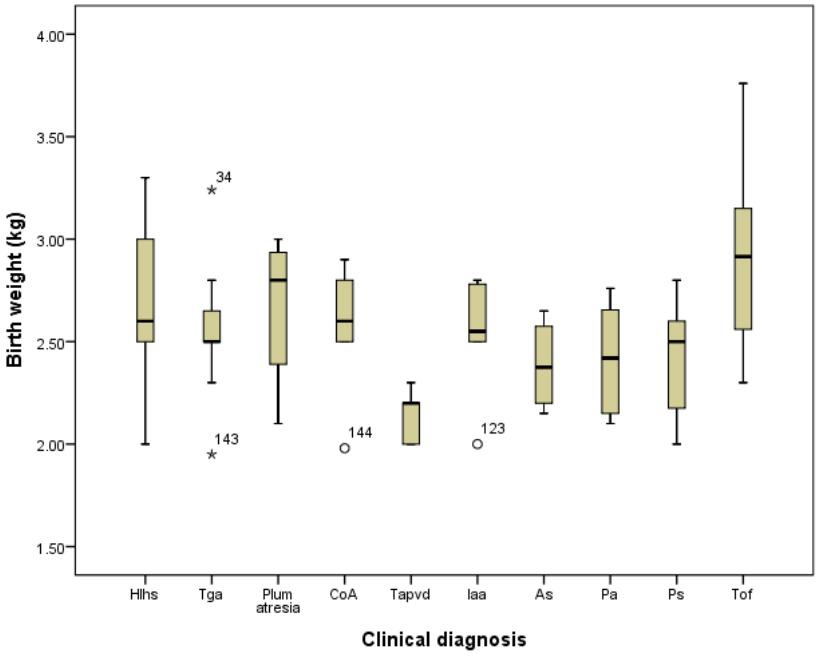

Figure (2) Birth weight distribution in relation to clinical diagnosis.

Furthermore, there was a statistically significant variation in Admission pulse oximetry oxygen saturation thresholds among the infants with different diseases ($p< 0.05$). Also, a significant increases between the 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), Figure (3).

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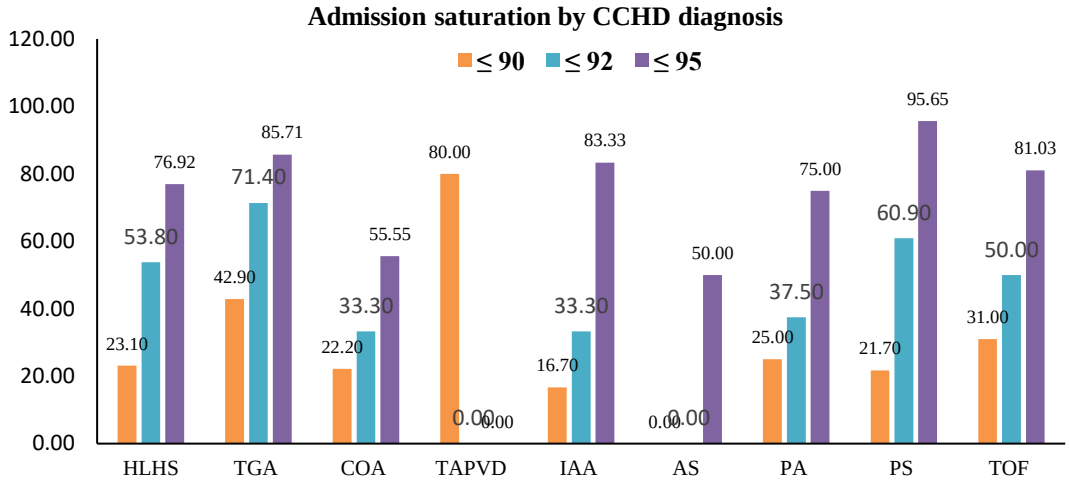

Figure (3) Distribution of neonates with admission saturation by CCHD diagnosis (n=148).

Discussion

According to the findings of the current study, 45 patients were ventilated at the time of admission (30.4%) and 29 patients required oxygen at the time of admission (19.6%). Name of the author **[22]** Discovered that upon admission, 31 patients (12%) needed oxygen, while 31 patients (11%) needed ventilation. At the time of admission and hence when oxygen saturations were assessed, none were receiving a prostaglandin E infusion. In addition, Name of the author **[8]** observed that during their stay, 103 patients (66%) needed oxygen therapy for a median of 2 days (range 1–18 days). Eighty-one (51%) newborns required non-invasive respiratory support (CPAP or high flow nasal cannula (HFNC) therapy; median 2 days, range 1-18 days), 34 (22%) required low flow oxygen therapy (median 2 days, range 1-5 days), and seven (4.5%) infants required mechanical ventilation (median 3 days, range 1-6 days).

According to the current study, 41 patients had pulse oximetry 90 (27.7%), 73 patients had pulse oximetry92 (49.3%), and 114 patients had pulse oximetry95 (77.0%). Also, Name of the author [22] discovered that, Preductal pulse oximetry has a 46–72% sensitivity to diagnose congestive cardiac heart disease (CCHD) in newborns without co-morbidities. Furthermore, Name of the author [23] discovered that the consensus Pulsox screening criterion for further exploration is 95%. Furthermore, Name of the author [22] found that when compared to the two lower criteria, adopting the 95% criterion improved pulse oximetry's sensitivity to identify CCHD. This was not the case for all cardiac anomalies, either.

While applying a higher threshold can result in a greater percentage of false-positives needing to be examined, recent research has shown that such false-positives may nevertheless benefit from quick therapy (for example, earlier detection of newborns with sepsis and pneumonia [11]. Furthermore, Name of the author [24] observed that 164 (2.79%) of 5874 neonates tested positive for hypoxemia on pulse oximetry. Those with severe hypoxia (saturation of peripheral oxygen (SPO2) 90%) underwent 2D echocardiography. CHD was found in approximately 28.5% of infants. In the group where there was a greater than 3% variation in saturation between the upper and lower extremities, three out of six instances (or 50%) of Cr CHD were seen. Additionally, they found that the pulse oximetry readings of 144 newborns ranged from 90% to 95%.

After six hours, hypoxemia was still present in 78 (54.16%) of the newborns who were observed again. Of these 78 newborns, five (6.4%) tested positive for a critical congenital heart defect (Cr CHD). That Name of the author [15] found that PO provides good diagnostic, moderate sensitivity, and low false positive rates for detecting Cr CHD. They advocate it as a screening tool in asymptomatic babies prior to hospital discharge. Furthermore, Name of the author [25] discovered that Pulse oximetry (PO) offers 100% sensitivity, 100% specificity, 100% positive predictive value, and 100% negative predictive value- when compared to echocardiography, the gold standard test. That was by Name of the author [26] reported that the sensitivity was not applicable, and the specificity was 99.4%. On the other hand, Name of the author [27] discovered that the specificity was 99.96% and the sensitivity of PO was 42.86%. The reason for the lower sensitivity compared to previous studies was the substantial number of cases in this study that were classified as coarctation of the aorta (57.1%); COA has a poor sensitivity of POS for CCHD (36%-53.3%). In the study conducted by Name of the author [28], the corresponding values for sensitivity and specificity were 77.78% and 99.90% in the investigation by Name of the author [28].

In the following disorders, this study discovered statistically significant increases in the proportion of neonates with low entry saturations and no co-morbidities by threshold for 95 compared to 90 and 92, respectively: Transposition of the major arteries (85.71% vs 42.9% and 71.4%), hypoplastic left heart syndrome (76.92% vs 23.1% and 53.8%), and coarctation of the aorta (55.55% vs 22.2% and 33.3%). In the same vein, Mawson et al. [22] observed that the percentage of neonates in the various Pulsox threshold groups varies based on the diagnosis of congestive cardiomyopathy, even after clinically unstable neonates are eliminated. A significant proportion of their PA, TGA, and TAPVD population had aberrant values, even at the lowest pulse oximetry threshold (89%). These conditions can be identified by duct-dependent pulmonary blood flow (PA), excessive right to left shunting of blood at the atrial level, or absence of mixing of oxygenated and deoxygenated blood (TGA) (TAPVD). Additionally, Granelli et al. [13] noted that, while coarctation of the aorta was not found in most cases in a large Swedish analysis that relied on weak femoral pulses for identification, a combination of preductal and post ductal saturation tests may be beneficial. Moreover, Mawson et al. [22] found that the proportion of neonates with an abnormal result was low (20, 36, and 42%, respectively) for different CCHD lesions, AS, PS, and CoA, even with a higher saturation threshold (95%). Prior research by [29, 30] revealed that pulse oximetry screening for CoA had a lower sensitivity. Additionally, [29] revealed that the sensitivity of pulse oximetry screening for pulmonary stenosis (PS) is lower. Also, Name of the author [8] found that 0.8% of 23,614 newborns had a positive POS result, which is consistent with previous research [12, 11]. A total of 64 babies, including 7 cases of CCHDs, received postnatal diagnoses for CHDs. With a specificity of 99.3%, POS sensitivity varied from 85.7% to 33% in the detection of CCHD (severe and serious). Pulse oximetry screening revealed 6/7 (85.7%) cases of CCHD prior to hospital discharge. The rate of post-discharge CCHD diagnosis was nearly doubled in neonates without pulse oximetry screening, according to a different study by **[31];** it was 7/100,000 in cohorts with POS screening compared to 13/100,000 in cohorts without POS screening (relative risk 0.52, CI 0.2 to 1.42). The small number of CCHDs in the big cohort study may have contributed to the difference's lack of statistical significance.

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Conclusion

Even in the first hour of life, the majority of people in a cohort with CCHD diagnoses had abnormal oxygen saturation levels. The proportions of anomalous results were highest with the highest oxygen saturation threshold (95%). The percentage of inaccurate results varied based on the CCHD diagnosis, suggesting hemodynamic differences specific to the lesion.

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