Aswan University Medical Journal volume 1 / No.2/ December 2021 (47-52) Online ISSN: **2735-3117**

Pulse oximetry for diagnosis of Critical Congenital Heart Disease

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ABSTRACT

Keywords:

pulse oximeter, CCHD, newborn, Screening.

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Background: Critical Congenital heart disease (CCHD) includes severe disorders that require early identification to enhance early detection of CCHD, and early interference to optimize neonatal outcomes. **Objective:** To evaluate the accuracy of pulse oximeter in detecting CCHD in neonates. **Patients and methods**: all neonates delivered at Aswan University Hospital were recruited. The screening was performed by (Pulse oximetry) PO and echocardiography (ECHO) between 24 and 72 hours of age. **Results:** Among the 100 screened newborn, it was found that 5 true positive and 95 true negative cases. PO test for CCHD had a sensitivity of 100%, a specificity of 100%, a positive predictive value of 100%, and a negative predictive value of 100%. **Conclusion:** PO is a noninvasive and harmless, practicable tool to screen CCHD and diagnose clinically undetectable CCHD in newborns.

INTRODUCTION

Congenital heart disease (CHD) is a major cause of neonatal death (1),(2). In addition, it is not uncommon disease, the incidence of CHD were reported between 0.3% & 0.8% (3),(4). Critical Congenital heart diseases (CCHDs), have a strong impact on mortality and morbidity in childhood (5). CCHD embraces severe lesions that necessitate interference timely in life to enhance health outcomes and are commonly duct dependent (6). It was estimated that approximately 2 of every 1000 live births could have CCHD (7) (8); which necessitates early intervention in the first year of life by catheter or surgery (7). Late diagnosis of CCHDs leads to increase the morbidity and mortality (9).

Usually, CCHD present asymptomatically at birth without cyanosis, and as a result of early discharge of babies, *Khoshnood et al.* (10) reported that we might miss about 25 % of infants with CCHD as clinical pictures of CCHD may does not appear in early life. Cyanosis is apparent clinically only when there is SpO2 of <80% (11). The gold standerd test to detect CCHD is fetal echocardiogram (12).

Pulse oximeter (PO) has been studied as a newborn screening test to enhance the detection of CCHD (6). PO measures blood oxygen saturation and is a well-established, accurate, non-invasive method of detecting low oxygen levels (hypoxemia) (13). The degree of desaturation is often comparatively mild and may be clinically undetectable, even by experienced clinicians (14). So, CCHDs screening by PO has to be enhanced in newborns to reduce the occurrence of acute collapse in babies (13).

An easy to perform and a rapid test to detect CCHD in newborn infants would be highly desirable, so our aim in this study was to evaluate the accuracy of PO in comparison to

echocardiogram in neonates born in Aswan University Hospital (AUH).

METHODS

From October 2019 to March 2020, we collected asymptomatic full and post-term neonates (gestational age ≥ 37 weeks) delivered in AUH as a part of cross-sectional screening study. We excluded preterm neonates ≤ 36 weeks, prenatally CHD diagnosis, those with an obvious congenital anomaly, and non-compliant patients. Informed consent was obtained from one of the parents before the initial screening and the purpose of the screening was explained to them.

Screening of CCHD was done according to the American Academy of Pediatrics (AAP) algorithm (15). The screening was performed between 24 to 72 hours of age for babies, who are under observation in nursery clinic before being discharged, if the baby was to be discharged early from the hospital, the screening was performed at a follow-up visit at the same age.

All neonates were screened with PO via a highly trained nurse then Echocardiography (GE T8, Prope S6) by pediatric cardiologists. For the screening using PO *(Drägerwerk AG & Co. KGaA Moislinger Allee 53-5523542 Lübeck, Germany),* it was performed by; an adhesive sensor placed on the baby's skin with infant breathing room air. Initially, it was placed on the right-hand. Then, it was placed either on the left or right foot. Oxygen saturation (SpO2) was recorded when the PO showed stable waveforms.

A negative PO result: SpO2 in the right hand (Preductal) or foot (postductal) was >95% and Max 3% difference between pre- and postductal SpO2. Positive POS if preductal or postductal SpO2 was <90%, or if Preductal and postductal SpO2 were between 90% and 94%, or if the difference between Preductal and postductal SpO2 more than 3% after three repeated screenings separated by at least 1 hour. Positive Screen if the abnormality persisted till the last reading.

The study was approved by the ethical committee of Aswan Faculty of Medicine, Egypt (IRB number: aswu /239/5/18).

Statistical Analysis: Data were analyzed using Statistical Program for Social Science (SPSS) version 24. Quantitative data were expressed as mean ± standard deviation (SD). Qualitative data were expressed as frequency. The diagnostic accuracy of pulse oximetry for detecting the CCHD was measured by computing sensitivity, specificity, positive predictive values and negative predictive values.

RESULTS

The study involved 100 newborns, 45 % of them were males and 60% were delivered by cesarean section. The mothers' mean age were (26.34 ± 4) years, the mean gestational age was (37.72 ± 0.8) weeks. There was positive consanguinity in 5 neonates, and no one had family history of CHD.

Echocardiography test results: of the 100 included neonates, five of them had CCHD by Echo. Result showed as in table (1): 1 patient (1%) had pulmonary atresia, 3 patients (3%) had transposition of great arteries in, 1 patient (1%) had single ventricle double-outlet right ventricle. The results of PO reveals that out of 100 patients 5 patients were positive screening test as their pulse oximetry were as follow; in the right hand 97.07 ± 1.2 with Min 88 % and Max 99 %, in right foot 97.05 ± 1 with Min 88 % and max 98 % and After 1 hour 96.56 ± 1.2 with Min 88 % and max 99 %.

In the present study Diagnostic evaluation of pulse oximetry in relation to ECHO reviled 5 patients true positive & 95 patients true negative with a diagnostic sensitivity of 100%, the specificity of 100%, PPV of 100% & NPV of 100%, as regard CCHD. Figure 1

As regards the outcome of our patients, out of 5 patients with CCHD 3 were operated on, one patient was discharged and one patient with pulmonary atresia died 7 days postoperative.

DISCUSSION:

Antenatal diagnosis of CCHD is still a shortage in our country, so we need a simple noninvasive method to screen CCHD in all newborns as we still have a high percentage of consanguine marriage and other risk factors existing in our patients. Early diagnosis of CCHD continues to be important because delay in diagnosis increases morbidity, mortality, and disability, and emphasizes the need to improve the process for timely diagnosis. PO has been studied as a newborn screening test to enhance the detection of CCHD (6). It measures blood oxygen saturation and is a well-established, accurate, non-invasive method of detecting low oxygen levels (hypoxemia) (13). Therefore, to detect those babies with hypoxemia, we can use PO for this.

Our results showed that PO had a sensitivity of 100%, a specificity of 100%, a positive predictive value of 100%, and a negative predictive value of 100% in comparison to Echocardiography as a gold standard test. In line with our results *Lightfoot et al.,* the specificity was 99.4% while the sensitivity were not applicable (16). In contrary *Danworapong et al* found the sensitivity of PO was 42.86% and a specificity of 99.96% (17), the sensitivity was lower than that in our studies because of a high percentage of cases diagnosed as coarctation of the aorta (COA) (57.1%) in this study; it is known that COA has a low sensitivity of POS for CCHD (36%–53.3%). In *Riede et al.,* study sensitivity and specificity was 77.78% and 99.90%, respectively (18)

The false-positive rate in our study was zero, because sick and hypoxemic newborns from other causes were already excluded before the screening.

Our study was challenged by some limitations, one of the major limitations of this study was that low sample size and its limitation to AUH live born and that not all of our cases undergo ECHO screening for assessment of PO truthfulness and specificity as well as we didn't face other cases of positive PO test due to non-cardiac causes.

We recommend further studies to clarify the risk factors associated with CCHD and meticulous antenatal care for early diagnosis of CCHD is really to be considered in imminent studies.

CONCLUSIONS

Pulse oximeter is a rapid, accurate, effective and applicable method test for screening of CCHD, and spreading POS as a routine in all of our live births will have positive impacts on infant mortality and morbidity.

Abbreviations:

CHD: Congenital heart diseases; CCHD: critical Congenital heart diseases; POS: Pulse Oximetry screening; PO: Pulse Oximetry; AUH :Aswan University Hospital; AAP: American Academy of Pediatrics; SpO2:Oxygen saturation; SPSS: Statistical Program for Social Science; IRB: Institutional Review Board; SD: standard deviation; Min: minimum; Max: maximum; ECHO: echocardiography; ASD: atrial septal defect ;VSD: ventricular septal defect; PDA: patent ductus arteriousus; TR: tricuspid regurge; TGA: transposition of great arteries; PA: pulmonary atresia; COA: coarctation of the aorta; AVC: atrioventricualr septal defect; DORV: double outlet right ventricle; NVDs: normal vaginal delivery; CS: caesarian section;

Authors' contributions

AMI was the principal investigator, formulated the idea, and wrote the first draft of discussion. IHA were responsible for patient's interview and data collection, responsible for data acquisition, collected the data, formulated the results, and edited the final draft and revision. HMA review search. The manuscript has been read and approved by all the authors.

Ethics approval and consent to participate

The Research Ethics Committee at the Faculty of Medicine, Aswan University, has approved the study (IRB number: aswu/239/5/18). and all patients provided written informed consent before participation.

Consent for publication

The manuscript has been read and approved by all the authors.

Competing interests

The authors declare that they have no competing interests.

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Table 1: baseline characteristics for the included participants

		Number = 100
Gender	Female	55
	Male	45
Mode of delivery	C-section	60
	NVD	40
Consanguinity	Positive	5
	Negative	95
+ve family history of CHD		0
CCHD	+ve	5
	-ve	95
City		
Komombo		27
Edfu		24
Nasr Elnoba		16
Aswan		16
Daraw		11
		Mean (SD) / Median [Min- Max]
gestational age (weeks)		37.72 (0.8) / 37 [37-40]
Age of mother		26.34 (4)/ 26 [18- 39]

Table 2: Characteristics of the 5 neonates has CCHD

characters	Case 1	Case 2	Case 3	Case 4	Case 5
Gender	Male	male	male	male	female
Birth weight (kg)	2.7	2.9	3.3	3	3.2
Gestational age by (weeks)	38	39	38	38	38
Examination					
HR (b/min)	135	140	155	150	140
RR(cycle/min)	49	48	47	50	55
Blood Pressure (mmhg)	80/45	80/50	79/45	78/47	80/45
Color	Pink	pink	Pink	Dusky	Dusky
Investigation					
PO_2 at birth (%) Right hand Right foot PO_2 after one hour Right hand Right foot	 92% 91% 92 91	 92 92 92 92	 89 89 89 89	 86 86 86 86	 88 ٨٦ 88 86
ECHO	DTGA, ASD, VSD, PDA	D-TGA, ASD, VSD, PDA	DTGA, VSD, PFO, PDA	PA intact IVS PDA	single ventricle, DORV, TAPVR, ASD, , PDA
Outcome	Operated and discharged	Operated and discharged	operated	Died postoperative	Operated and discharged

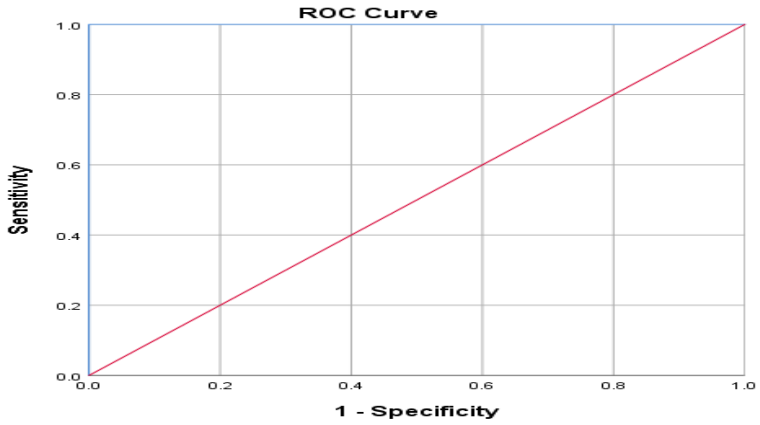

Figure 1: ROC Curve for PO