Pulse oximetry for diagnosis of Critical Congenital Heart Disease

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ABSTRACT

**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 asymptptomatically 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 standard 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...
The abnormality persisted till the last reading.

Separation of at least 1 hour. Positive Screen if
than 3% after three repeated screenings
between 90% and 94%, or if the difference
if

Preductal
Postductal

A negative PO
result: SpO2 in the right
hand (Pre ductal) or foot
(post ductal) was
>95% and Max 3% difference between pre-
and post ductal SpO2. Positive POS if
preductal or post ductal SpO2 was <90%, or
if Pre ductal and post ductal SpO2 were
between 90% and 94%, or if the difference
between Pre ductal and post ductal 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 arteriosus; TR: tricuspid regurge; TGA: transposition of great arteries; PA: pulmonary atresia; COA: coarctation of the aorta; AVC: atrioventricular septal defect; DORV: double outlet right ventricle; NVDs: normal vaginal delivery; CS: cesarian 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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**References**


Table 1: baseline characteristics for the included participants

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<tr>
<td>Negative</td>
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<td>+ve family history of CHD</td>
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<td>Daraw</td>
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<tr>
<td>Mean (SD) / Median [Min- Max]</td>
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<td>gestational age (weeks)</td>
<td>37.72 (0.8) / 37 [37-40]</td>
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<td>Age of mother</td>
<td>26.34 (4) / 26 [18-39]</td>
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Table 2: Characteristics of the 5 neonates has CCHD

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<td>Gestational age by (weeks)</td>
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<td>Examination</td>
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<td></td>
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<tr>
<td>Right hand</td>
<td>92%</td>
<td>92</td>
<td>89</td>
<td>86</td>
<td>88</td>
</tr>
<tr>
<td>Right foot</td>
<td>91%</td>
<td>92</td>
<td>89</td>
<td>86</td>
<td>88</td>
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<tr>
<td>PO2 after one hour</td>
<td></td>
<td></td>
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<tr>
<td>Right hand</td>
<td>92</td>
<td>92</td>
<td>89</td>
<td>86</td>
<td>88</td>
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<tr>
<td>Right foot</td>
<td>91</td>
<td>92</td>
<td>89</td>
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<td>D-TGA, ASD, VSD, PDA</td>
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<td>PA intact IVS PDA</td>
<td>single ventricle, DORV, TAPVR, ASD, , PDA</td>
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<td>Operated and discharged</td>
<td>operated</td>
<td>Died postoperative</td>
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Figure 1: ROC Curve for PO