Evaluation of Pulse Oximetry in the Early Detection of Congenital Heart Diseases in Newborns

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ABSTRACT

Background: Congenital heart diseases, which are asymptomatic at birth, are the most important causes of infant mortality. This study aimed to evaluate the role of pulse oximetry in the early detection of congenital heart diseases among newborns.

Methods: In this cross-sectional descriptive study, 1230 newborns who were born in university hospitals in an urban area of Iran were placed under the pulse oximetry of right hand and right foot. The neonates with peripheral oxygen saturation (SPO2) of less than 95% in the right hand or right foot underwent pulse oximetry of the hands and feet again after two hours. Finally, the newborns with an SPO2 of less than 95% in the second stage were subjected to diagnostic echocardiography. The results were analyzed in SPSS software (version 18).

Results: Out of 1230 neonates who underwent pulse oximetry, 417 newborns had an SPO2 of less than 95%, and their SPO2 was rechecked two hours later. Finally, echocardiography was performed for 32 newborns who had an SPO2 of less than 95%, of whom 24 infants were healthy and 8 infants (6 females and 2 males) had congenital heart disease. The sensitivity of the pulse oximetry to detect congenital heart disease was 100%, and its specificity was 98.04%.

Conclusion: The results of this study highlighted the high sensitivity of pulse oximetry in the diagnosis of critical congenital heart disease which can be used at birth.

Keywords: Arterial oxygen saturation, Congenital heart diseases, Newborn, Pulse oximetry

Introduction

Congenital Heart Diseases (CHD) are among the most common congenital anomalies. These diseases account for 3% of neonatal mortalities and 46% of deaths due to congenital anomalies occurring in the first year of life. The prevalence rate of these disorders is 5-8 per 1000 live births, of which about 25% are associated with cyanosis (1).

About 50% of newborns with congenital heart diseases are asymptomatic in the first few days of birth and are not diagnosed with primary examinations. Up to 39% of newborns with a critical CHD leave the hospital before a diagnosis could be made (2). Moreover, 25% of the newborns who die of CHDs during the first week cannot be diagnosed with these diseases.

Furthermore, out of 10 children who die of congenital heart anomalies during the first year of life, one case is found suffering from these disorders (3).

Early diagnosis and timely treatment of CHD shortly after birth will prevent sudden cardiopulmonary collapse and death of these newborns (4). Pulse oximetry is a simple, inexpensive, non-invasive, and fast method that can show the percentage of oxygen saturation in the blood. In many types of heart diseases, there is some degree of hypoxemia, which may not be visible to the eye; therefore, it seems that pulse oximetry can be used to detect these conditions (5).

Accoring to the results of a study by Ewer et

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al., pulse oximetry is a very cost-effective method for the early diagnosis of congenital heart disease (6). Bhola et al. have confirmed pulse oximetry as a standard method for the evaluation and detection of congenital heart diseases in infants (7). Additionally, the results of studies conducted by Abbasi et al. (8) and Movahedian et al. (2) in Iran showed that pulse oximetry was useful in the diagnosis of congenital heart diseases; however, Valmari (9), who reviewed 10 articles, stated that screening with a pulse oximetry was not sufficiently sensitive. Accordingly, due to the importance of the issue, this study aimed to evaluate the role of pulse oximetry in the early detection of CHD among newborns.

Methods

This descriptive cross-sectional study included all neonates who were born in university hospitals in an urban area of Iran. The sample size was considered equal to the statistical population. The newborns were enrolled in the study using a census sampling method. The inclusion criteria were: 1) gestational age of more than 37 weeks, 2) being healthy, and 3) parents’ willingness to participate in the study.

The data were collected using a researcher-made checklist for assessing the newborn’s demographic characteristics, such as age, gender, initial pulse rate and two hours later, and the result of echocardiography. A checklist was prepared based on a review of the literature, and its content validity was confirmed by experts. The checklist was completed by interviewing the newborn’s parents and the use of neonatal medical records. Pulse oximetry was performed with a Pulse Oximeter named Nemoxi using a neonatal probe.

The procedure was as follows: Pulse oximetry of right hand and right foot was performed for all of the healthy term newborns at least 2 hours after birth by the experienced personnel of the nursery (first phase). Peripheral oxygen saturation (SP02) of equal to or greater than 95% was considered normal. The SP02s of less than 95% were rechecked after 2 hours (second phase). When the SP02 was equal to or greater than 95%, it was considered normal, and otherwise, the newborn was referred to a pediatric cardiologist (first author) for echocardiography and more detailed examinations on the same day. The result of the echocardiography determined the presence or absence of congenital heart disease, cyanotic, or its type.

The study protocol was approved by the Ethics Committee in the Bioethics Research Center of Rafsanjan University of Medical Sciences, Rafsanjan, Iran (IR.RUMS.REC.1394.206). It should be noted that all parents were informed of the confidentiality of the data. Finally, the data were analyzed in SPSS software (version 18) through descriptive and analytical statistics. A p-value of less than 0.05 was considered statistically significant.

Results

A total of 1230 newborns met the eligibility criteria for pulse oximetry screening. The majority of the neonates were male (n=625, 50.8%). Moreover, the mean age of the newborn was 18.77±6.14 (age range: 2-24 hours). Totally, 417 newborns had an SP02 of less than 95%, and their SP02 was rechecked two hours later. Finally, echocardiography was performed for 32 newborns who had an SP02 of less than 95%, of whom 24 infants were healthy and 8 infants (6 males and 2 males) suffered from CHD (Table 1).

The normality of the data was examined using the Kolmogorov-Smirnov test and non-parametric tests were used due to the nonnormal distribution of the data (P<0.001).

Based on the results, the mean SP02 score of the right hand of the newborns in both phases of measurement was significantly higher than that of the right foot of the newborns (P<0.001, Mann-Whitney U). Furthermore, the mean SP02 score of

### Table 1. Neonatal characteristics and SP02 in the newborns with CHD in echocardiography

<table>
<thead>
<tr>
<th>Number</th>
<th>Gender</th>
<th>Age (hours)</th>
<th>SP02 (First phase)</th>
<th>SP02 (Second phase, 2 hours later)</th>
<th>Type of CHD</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td>Right Hand</td>
<td>Right Foot</td>
<td>Right Hand</td>
</tr>
<tr>
<td>1</td>
<td>Girl</td>
<td>8</td>
<td>96</td>
<td>94</td>
<td>96</td>
</tr>
<tr>
<td>2</td>
<td>Girl</td>
<td>10</td>
<td>96</td>
<td>93</td>
<td>96</td>
</tr>
<tr>
<td>3</td>
<td>Girl</td>
<td>4</td>
<td>90</td>
<td>91</td>
<td>92</td>
</tr>
<tr>
<td>4</td>
<td>Girl</td>
<td>4</td>
<td>90</td>
<td>90</td>
<td>92</td>
</tr>
<tr>
<td>5</td>
<td>Girl</td>
<td>4</td>
<td>91</td>
<td>90</td>
<td>91</td>
</tr>
<tr>
<td>6</td>
<td>Girl</td>
<td>23</td>
<td>85</td>
<td>87</td>
<td>85</td>
</tr>
<tr>
<td>7</td>
<td>Boy</td>
<td>2</td>
<td>92</td>
<td>91</td>
<td>94</td>
</tr>
<tr>
<td>8</td>
<td>Boy</td>
<td>2</td>
<td>90</td>
<td>89</td>
<td>93</td>
</tr>
</tbody>
</table>

ASD, Atrial Septal Defect; PFO, Patent Foramen Ovale; LVH, Left Ventricular Hypertrophy; MR, Mitral Regurgitation; PDA, Patent Ductus Arteriosus.
the right arm at two phases in 24 neonates who did not have a cardiac problem in echocardiography was significantly higher than that of the right foot (P<0.001, Mann-Whitney U). However, these results were not observed in pulse oximetry of 8 newborns who had CDH disorders (P<0.05, Mann-Whitney U test). Additionally, the mean SPO2 score of the right hand of 32 neonates was significantly higher than that of their right foot (P<0.001, Mann-Whitney U test) (Table 2).

Based on the findings, the results of two hours of pulse oximetry test also indicated a disorder in 100% of the actual patient cases. Accordingly, the sensitivity (the number of correctly diagnosed patients) will be high for the diagnosis of congenital heart diseases. In computing the specificity for testing, the results indicated an elevated value of the specificity, (98.04%) which is indicative of the high number of non-diseased people identified by the correct test (Table 3).

### Discussion

Based on the results of this study, out of 1230 neonates, 8 cases had a CHD (6.5 cases per 1000 neonates). In this regard, the outbreak of CHD was 4 per 1000 in the study performed by Movahedian et al. (2). In the same line, Hoke et al. carried out a study to assess the oxygenation of the hands and feet as a screening test for the early diagnosis of ducital dependent heart diseases on 2876 newborns. The results led to the diagnosis of 4 cases suffering from CHD (an incidence rate of 0.7 per 1,000 live births) (10).

Critical CHD, which is the severe type of CHD, has an incidence rate of approximately 2.5 to 3 per 1000 live births (11). The higher prevalence of these disorders in our study could have been affected by some factors, such as the higher prevalence of consanguineous marriage in the study population, which needs to be further investigated. In another Iranian study, the incidence rate of CHD was evaluated in newborns admitted to the neonatal department over a four-year period. The results revealed that about 41.3% of the newborns with CHD had consanguineous parents (12). Moreover, in another study conducted on children with CHD, the parents of about 44.4% of the children had a consanguineous marriage (13).

According to the results of this study, the mean SPO2 score of the right hand of the newborns in both phases of measurement was significantly higher than that of their right foot. This result is consistent with the findings of a study carried out by Movahedian et al. (2). Therefore, based on the results obtained from the present study, only the pulse oximetry of feet can be performed instead of hands in the beginning.

The results of two hours of pulse oximetry test also revealed that 100% of the actual patient cases suffered from a disorder. Consequently, the sensitivity of this test was high for the diagnosis of CHD. Regarding the calculation of specificity, the results indicated a high value of the specificity (98.94%). The sensitivity of pulse oximetry for the diagnosis of CHD was determined at 100% in the studies conducted by Arlettaz et al. (14) and Reich et al. (15) on 3262 and 2124 neonates, respectively. This result is consistent with the findings obtained from this study.

Furthermore, based on the results of a study carried out by Abbasi et al., the maximum

### Table 2. Comparison of the mean and standard deviation of SPO2 (Second phase, 2 hours later) in newborns based on the results of echocardiography

<table>
<thead>
<tr>
<th>Result of Echocardiography</th>
<th>Number</th>
<th>SPO2</th>
<th>Mean ± SD</th>
<th>*P-Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Normal</td>
<td>24</td>
<td>Right Hand</td>
<td>95.52±1.54</td>
<td>0.001</td>
</tr>
<tr>
<td></td>
<td>24</td>
<td>Right Foot</td>
<td>93.69±1.23</td>
<td></td>
</tr>
<tr>
<td>Abnormal</td>
<td>8</td>
<td>Right Hand</td>
<td>92.83±3.50</td>
<td>0.328</td>
</tr>
<tr>
<td></td>
<td>8</td>
<td>Right Foot</td>
<td>91.50±2.27</td>
<td></td>
</tr>
<tr>
<td>Total</td>
<td>32</td>
<td>Right Hand</td>
<td>94.35±2.47</td>
<td>0.034</td>
</tr>
<tr>
<td></td>
<td>32</td>
<td>Right Foot</td>
<td>93.43±1.86</td>
<td></td>
</tr>
</tbody>
</table>

*Mann-Whitney U Test

### Table 3. Sensitivity and specificity of pulse oximetry and final test (echocardiography)

<table>
<thead>
<tr>
<th>CHD based on echocardiography</th>
<th>SPO2 (First phase)</th>
<th>SPO2 (Second phase, 2 hours later)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Healthy N (%)</td>
<td>Sick N (%)</td>
</tr>
<tr>
<td>NO</td>
<td>813 (100)</td>
<td>409 (98.1)</td>
</tr>
<tr>
<td>Yes</td>
<td>0 (0)</td>
<td>8 (1.9)</td>
</tr>
<tr>
<td>Total</td>
<td>813 (100)</td>
<td>417 (100)</td>
</tr>
</tbody>
</table>

Sensitivity 100% Specitivity 66.53 %
sensitivity and specificity of the pulse oximetry for detecting oxygen saturation was obtained at 88%. They concluded that the pulse oximetry was a useful tool to estimate the arterial oxygen saturation in children with CHD, and it was also a noninvasive method, compared to the cardiac catheterization (8).

According to the results of the aforementioned studies, it is possible to use pulse oximetry to diagnose CHD, which is also cost-effective. In line with the results of this study, Griebsch et al. revealed the cost-effectiveness of pulse oximetry as a screening test, whereas echocardiography would not be a cost-effective screening method (16). De-Wahl Granelli et al. also reported that the implementation of pulse oximetry prior to discharge was simple, cheap, as well as fast, and would result in a diagnosis of about 92% of the disease cases. Moreover, due to early diagnosis and treatment, this economical method would also prevent human casualties (17). This finding was also confirmed in other studies (7, 18).

Dangerous heart diseases that require urgent action and begin from the uterus can be diagnosed from birth. These disease include tricuspid atresia with pulmonary atresia along with a small patent ductus arteriosus (PDA) that require an emergency PDA stent implantation, D-transposition of the great arteries with intact ventricular septum, which requires a Rashkind emergency surgery, and coarctation of the aorta, which requires an angioplasty balloon, ventricular failure and ventricular defect or hypertrophic cardiomyopathy in the newborns of diabetic mothers (which are also common).

However, pulse oximetry is essential for the immediate referral of dangerous diseases in other neonates because of the limitations in performing echocardiography. Moreover, it can be very helpful to prevent unnecessary referrals of the neonates.

The study of newborns on the first day of birth was one of the limitations of this study. Therefore, it is suggested that further studies conduct similar research in other centers and the second day afterward, especially with larger sample sizes.

**Conclusion**

Based on the results of this study, pulse oximetry is highly sensitive to the diagnosis of critical CHD. Therefore, it can be used as a simple, effective, and cost-effective screening method for newborns in hospitals. Moreover, it can be selected as a basis for decision making in investigations, such as echocardiography.

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**Conflicts of interests**

None declared.

**Financial Disclosure**

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