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Oxygen Saturation Screening Test: A Useful Method for Predicting Complex Congenital Heart Disease in Newborns

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Abstract

Background: Critical congenital heart diseases (CCHDs) are the most common group of congenital malformations in newborns, the mortality and morbidity of which may be prevented by early diagnosis. As a simple and noninvasive technique in detecting hypoxemia, pulse oximetry can help us in the early diagnosis of complex congenital heart diseases. This study aims to provide information for future clinical and health policy decisions for making a Uniform Screening Panel in the early detection of CCHDs in newborns.

Methods: In this study, we determine the prevalence of congenital heart disease in newborns with Oxygen Saturation in the Maternity ward of Imam-Reza Hospital in Mashhad, Iran.

Material and Methods: This is a prospective clinical study which was conducted in the Maternity ward of Imam-Reza hospital between March 2018 and March 2019. We recorded Spo2 of the newborns between 4 to 24 hours after delivery by a trained general practitioner using RS232C/NOVAMETRIX Pulse Oximetry device. The newborn also underwent a comprehensive clinical examination by a neonatologist, and further cardiological evaluation was performed afterward. A pediatric cardiologist performed Echocardiography for the final diagnosis if there was no evidence of other non-cardiac pathologies. Statistical analysis of data was done by SPSS version 24.

Results: Out of a total of 418 newborns screened by a pulse oximetry device, four newborns were screen-positive, and had pulse oximetry tests with Spo2 results. Two of these patients were reported to have complex congenital heart diseases, subsequently. The remaining two newborns with positive screening tests had no congenital heart disease in echocardiography evaluation.

Conclusion: This study revealed that a pulse oximetry screening test could be beneficial for detecting many of the newborns with CCHDs before hospital discharge. However, further research studies with larger sample sizes are necessary for a definitive result.

Key Words: Complex congenital heart diseases, Pulse oximetry, Spo2.

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1- INTRODUCTION

The most common group of congenital malformations are congenital heart diseases (CHDs) which occur in 0.9 percent of live births affecting ~40 000 newborns per year in the United States. One-fourth of this group is estimated as Complex CHDs (CCHDs) who require surgery and/or catheterization early in their lives (1-3).

Screening methods for CHDs are now limited to perinatal ultrasound scanning and postnatal physical examination performed by skilled specialists, which still have a low detection rate for many of CHDs and may lead to undetected CCHDs after discharge. So undiagnosed congenital heart diseases remain a significant concern in public health; since early detection may considerably prevent morbidity and mortality (4).

Pulse oximetry is a feasible and noninvasive screening test for quantifying hypoxemia and can help detect hypoxemia in those CCHDs with cyanosis (2, 3). Screening for CCHDs by the use of pulse oximetry was added to the US Recommended Uniform Screening Panel in 2011 (1). Although the need for pulse oximetry is accepted worldwide for predicting congenital heart disease, it is not yet a clinical protocol for newborn screening tests in Iran, and there are still some controversies among medical policy makers regarding its cost-benefits. So it seems necessary to scientifically determine its importance and its benefits. Therefore, this prospective study was designed to evaluate the utility of the Pulse Oximetry Screening test in the early detection of CCHDs in newborns and assess the impact of this test in identifying the patients with an acute heart disease to provide information for future clinical and health policy decision makers, so that they can make a Uniform Screening Panel accordingly.

2- MATERIALS AND METHODS

The newborns who were born at Imam-Reza Hospital between March 2018 and March 2019 were prospectively enrolled in our study. A trained general practitioner performed the pulse oximetry screening. The demographic data includes maternal age, weight, and history of gestational diabetes, drug history, smoking, addiction, and any assisted reproductive technique infertility. The newborns' characteristics such as sex, age (at the time of checking Spo2), birth weight, gestational age, history of NICU admission, Spo2, and the presence of any accompanied anomaly, were also checked.

Cyanotic CCHDs as the "primary" targets of screening were: Hypoplastic Left Heart Syndrome (HLHS), Pulmonary Atresia, Transposition of the Great Arteries, Truncus Arteriosus, Tetralogy of Fallot (TOF), Tricuspid Atresia, and Total Anomalous Pulmonary Venous Return (TAPVR), Severe Coarctation of the Aorta with Pulmonary Hypertension (PH), Double Outlet Right Ventricle (DORV) with Pulmonary Stenosis (PS), Ebstein Anomaly, Interrupted Aortic Arch and Single Ventricle.

All enrolled newborns underwent a pulse oximetry test using the Covidien Pulse Oximetry device. We considered the newborns with Spo2<95% as the screen positive group.

In this screening, post ductal Spo2 measurements were performed from the left foot in all newborns.

2-1. Inclusion and Exclusion Criteria

The inclusion criteria were the newborns being born at Imam-Reza Hospital between March 2018 and March 2019, with a birth weight of more than 2000 grams without any perinatal diagnosis of cardiac defects, gross anomaly, or any need for being hospitalized in the neonatal intensive care unit (NICU). All newborns

with a gestational age of <34 weeks were excluded from this study.

2-2. Data Analysis

A standard workup was performed for all the neonates with SpO2<95%, consisting of a pediatric cardiologist visit, chest X-ray, ECG, and Echocardiography; and the treatment measures were planned accordingly. Newborns with positive pulse oximetry screening tests were rechecked 6 hours later, and if their Spo2 was less than 95% again, they were referred to a neonatologist. A pediatric cardiologist consultation was done if the neonatologist excluded other non-cardiac reasons. Comprehensive Echocardiography by a pediatric cardiologist was the final step for the definitive diagnosis. Descriptive analyses of the data, including frequency percentage, mean and standard deviation, and inferential analyses including Pearson correlation coefficient, Chi-square, and Student t-test were performed by SPSS software for Windows, version 24. All tests were two-tailed, and $p<0.05$ was considered statistically significant.

3- RESULTS

Out of the 418 newborns screened in our study, the mean gestational age was 38.99±1.51 weeks, and birth weight was 3138.08±464.6 (Mean±SD) grams. Spo2<95 was considered as the positive group.

Four newborns were pulse oximetry screen-positive (0.9%). Two patients had CCHD diagnosis; one patient PDAVSD and the other pulmonary atresia (TOF anatomy); the remaining two newborns were diagnosed as normal in the echocardiography.

Based on the results, the sensitivity for Pulse Oximetry CCHD screening was calculated as 100%, and the specificity was 99.5%.

There were no statistical differences between maternal factors (Diabetes, assisted reproductive technology, smoking, and addiction, and using alcohol) with Newborn Spo2 (shown in **Table 1**).

Table-1: Maternal factors and the newborn Spo2

Maternal Factor	Spo2 +	Spo2 -	P-value
DM	96.7±1.4	96.6±1.7	>0.99
ART	95.7±0.6	96.7±1.4	>0.99
DH (Alcohol)	96	96.6±1.8	NA
DH (Other)	97.1±1.3	96.6±1.8	NA
Smoking	96.2±1.3	96.7±1.7	>0.99
Addiction	96.1±0.8	96.7±1.7	>0.99

DM, Diabetes Mellitus; ART, Assisted Reproductive Technology; DH, Drug History; NA, Non- Applicable

As shown in **Fig. 1**, Newborn Spo2 was significantly correlated with birth weight (P=0.001).

4- DISCUSSION

In this study, we hypothesized that pulse oximetry screening and physical examination might be helpful in the early detection of CCHDs. CCHDs are responsible for 20% of neonatal deaths, which is a considerable amount in comparison to other malformations (3). Consequently, having a screening protocol for early detection of CCHDs can help prevent the increase in morbidity and mortality.

In various studies, the threshold for further evaluation was Spo2<95% (similar to what we used) or any difference in upper and lower extremity oxygen saturation greater than 3% (5, 6). Mawson et al. demonstrated the benefits of heightening the threshold and, as a result, the proportion of false positives for prompt diagnosis of non-cardiac pathology (7, 8).

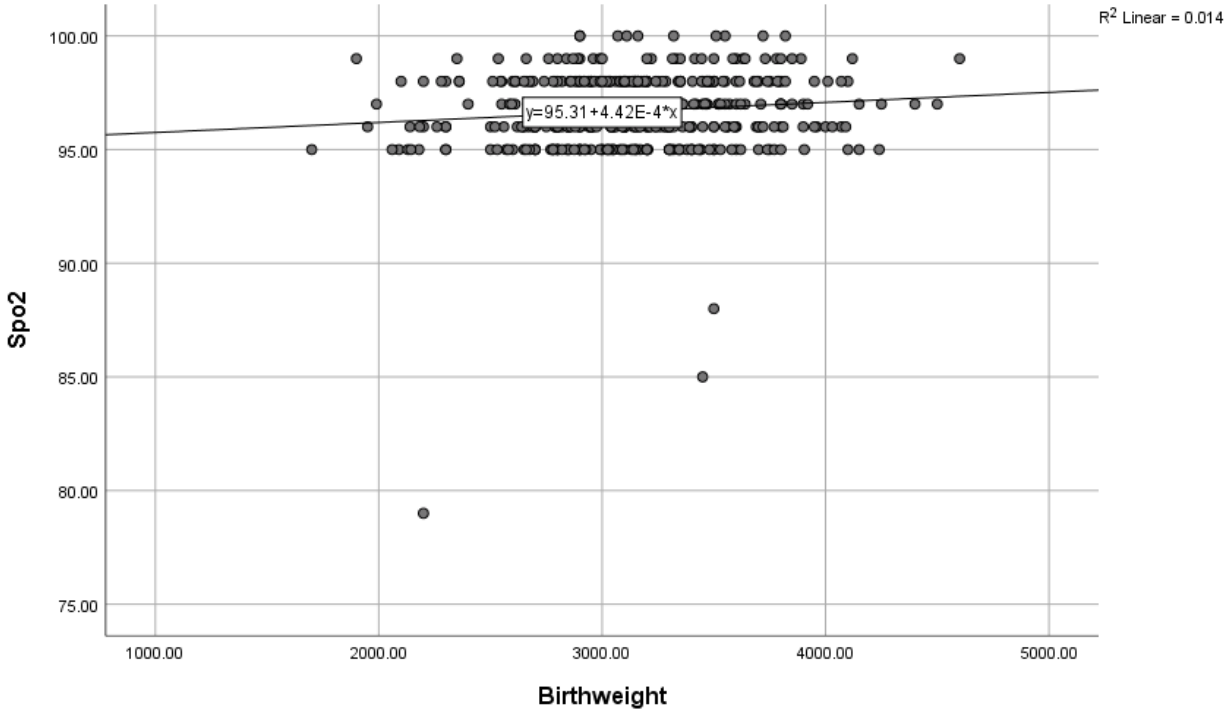

Fig. 1: Correlation between Newborn Spo2 and birth weight

We screened the newborns during 4 to 24 hours after birth because normal newborns were discharged after this period, and we no longer had any access to them. Although lower rates of false-positive results in later screenings (>24h) were reported in published studies (9, 10), in a study in Poland, an average age of 7 hours was selected for screening, and surprisingly, it provided one of the lowest false positive rates (0.026% of the total population) (11). Meanwhile, Narayen et al. did not find any difference in false-positive rates between early and late (1 hour vs. day 2-3 after birth) screenings. They observed a normal range of SpO2 within the first 60 minutes (12).

Some studies such as the one by Uygur et al. investigate the additional value of peripheral perfusion (index (PPI) measurements accompanied by pulse oximetry screening for detecting CCHDs (3), which is a method for diagnosing early CCHDs that is being used in many parts of the world. Although these steps are known to be beneficial for early diagnosis of CCHD, even the Spo2 screening test is controversial practice among our country's Screening Panel. Considering several large studies that used SpO2 as the screening method for congenital heart defects in newborns (1, 13, 14, 15) and comparing them with our results, we can state that the addition of pulse oximetry into our Screening Panel can be lifesaving; though the Lack of extended follow-up data is our limitation for newborns with normal SpO2 reading.

5- CONCLUSION

This study revealed that the pulse oximetry screening test is a feasible method for detecting many newborns with CCHDs before hospital discharge. However, further research with larger sample sizes are necessary for a definitive result.

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