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Evaluation of Critical Congenital Heart Disease Screening Results with Pulse Oximetry

Nursu Kara[1], Didem Arman[1], Adem Gül[1], Türkan Şimşek[1], Özben Ceylan[2], Serdar Cömert[1]

[1]University of Health Sciences Turkey, İstanbul Training and Research Hospital, Clinic of Pediatrics, Division of Neonatology, İstanbul, Turkey
[2]University of Health Sciences Turkey, İstanbul Training and Research Hospital, Clinic of Pediatric Cardiology, İstanbul, Turkey

ABSTRACT

Introduction: The early diagnosis and treatment of critical congenital heart diseases (CCHD), which require surgery or intervention during the 1st year of life, is an important issue. Screening of CCHD with pulse oximetry increases early diagnosis rates. Therefore, our study aimed to evaluate the results of CCHD screening with pulse oximetry among babies born in our hospital.

Methods: The results of the CCHD screening with pulse oximetry of the babies with a gestational age of ≥34 weeks that were born in our hospital between January 1, 2018, and December 31, 2020, were retrospectively evaluated.

Results: Among the 14,766 babies born during the study period, the screening results of 11,892 babies were evaluated; 5,826 of whom were female (48.9%), and 6,066 (51.1%) were male. The number of babies who passed the screening test was 11,871 (99.8%), whereas 21 (0.2%) failed. Among 21 babies who failed the screening test and were evaluated by echocardiography, 7 (33.3%) babies were found to have CCHD. Preductal and postductal saturation values were found to be significantly lower in patients with the positive screening test and in whom CCHD was detected, compared with those without CCHD.

Conclusion: Early diagnosis of CCHD before discharge is possible with pulse oximetry screening. Better prognosis and lower mortality rates are targeted with early diagnosis in these babies. Therefore, arrangements should be made for the screening of all newborn babies with pulse oximetry.

Keywords: Critical congenital heart disease, screening, pulse oximetry

Introduction

Congenital heart disease (CHD) is one of the most common congenital anomalies (1). The incidence of CHD is around 8-10 per 1,000 live births. Critical congenital heart disease (CCHD) is a disease that requires surgical intervention or catheterization within the first year of life. This group constitutes 25% of CHDs (2,3). The diagnosis of these anomalies in the prenatal period is vital in terms of reducing morbidity and mortality in the neonatal period. It was reported that early treatment of CHD with antenatal diagnosis or detected in the early postnatal period improves prognosis and decreases mortality (4-6). It is challenging to diagnose CCHD in the early postpartum period by physical examination alone. Physiological haemodynamic changes, absence of cyanosis in the early period, and absence of significant murmur are the most important reasons for delayed diagnosis. The echocardiographic examination is the gold standard in diagnosis, but it is impossible to screen every newborn with echocardiography. Oxygen saturation measurement with pulse oximetry is used for CCHD screening.

Pulse oximetry is a non-invasive device that measures the oxygen saturation in arterial blood. Changes in the absorption of red and infrared light passing through tissues by oxyhemoglobin and deoxyhemoglobin form the basis of the evaluation. Because of measuring the absorption of light through the sensor, the oxygen value in the blood is determined, and hemoglobin saturation is called oxygen saturation. Oxygen saturation measurement with pulse oximetry is an easy, painless, and reliable method (7). Additionally, with the dissemination of the CCHD screening program with pulse oximetry in the postnatal period, the rate of early diagnosis before these infants become symptomatic has increased (8,9).

Our study evaluates the pulse oximetry results of babies born in our hospital over three years.

Methods

In our study, CCHD screening test results of all healthy newborns above 34 weeks of gestation who were born in our hospital between January 1, 2018, and December 31, 2020, were evaluated retrospectively. All the babies were found to be normal in the physical examination and were rooming in with their mothers. Newborns with antenatal diagnosis, hospitalized in the intensive care unit, referred to an external center for any reason, and those with additional anomalies were excluded from the study.

Address for Correspondence: Nursu Kara MD, University of Health Sciences Turkey, İstanbul Training and Research Hospital, Clinic of Pediatrics, Division of Neonatology, İstanbul, Turkey
Phone: +90 505 648 45 50 **E-mail:** nursukara@gmail.com **ORCID ID:** orcid.org/0000-0002-1466-7848

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CCHD screening was performed in our hospital as follows; all newborn babies were examined before the measurement, and in case of any symptoms such as cyanosis, tachypnea, and murmur in their physical examination, these patients were considered symptomatic and evaluated in terms of echocardiographic examination. Preductal and postductal oxygen saturation were measured with the Masimo Radical 7® pulse oximeter device in babies who were asymptomatic and had no abnormal findings in the physical examination. Measurements were made from the right hand for preductal measurement and the right or left foot for postductal measurement. The test result was determined as "positive" (fail the test) and "negative" (pass the test). According to this screening result, if one or more of the following criteria were present in at least two measurements, the result was considered positive.

- Passed the test if both measurements were above 95% or above and the preductal-postductal SaO_2 difference was ≤3%.

- If any measurement was between 90 and 95% and/or the preductal-postductal SaO_2 difference was more than 3%, the test was repeated one hour later. If both measurements were 95% and above and the preductal-postductal SaO_2 difference was ≤3% on repetition, patients were considered negative (passed the test); further evaluation was performed when the result was positive.

- If any measurement was <90%, the measurement failed, and further evaluation was performed (10,11), (Figure 1).

An echocardiographic was examined on babies who failed the screening test. Additionally, cardiac anomalies detected because of the examination were evaluated.

The study was approved by the University of Health Sciences Turkey, İstanbul Training and Research Hospital Local Ethics Committee (approval number: 2742, date: 19.02.2021).

Statistical Analysis

SPSS (Statistical Package for Social Sciences, 23rd version, USA) program was used to analyze the findings. The distribution of variables was measured with the Kolmogorov-Smirnov test. While evaluating the study data, in addition to descriptive statistical methods (mean, standard deviation, median, frequency, ratio, minimum, maximum) in the comparison of quantitative data, Student's t-test was used for two-group comparisons of normally-distributed parameters, and Mann-Whitney U test was used for two-group comparisons of non-normally-distributed parameters. The Pearson's chi-square test, Fisher's exact, and Yates continuity correction test (Yates corrected chi-square) were used to compare qualitative data. Significance was evaluated at $p<0.01$ and $p<0.05$ levels.

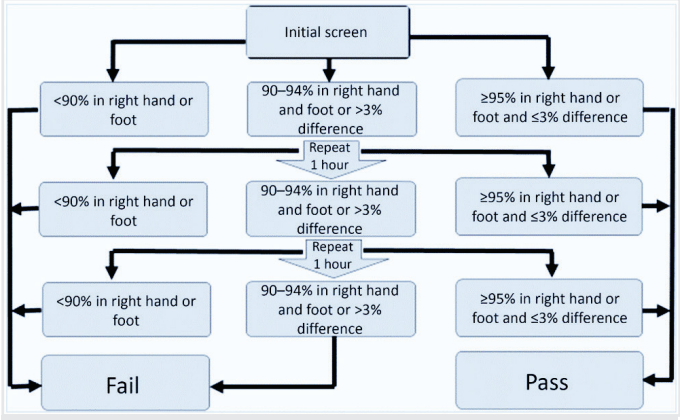

Figure 1. Neonatal congenital heart disease screening chart (10,11)
RH: Right hand, F: Foot

Results

Fourteen thousand seven hundred and sixty-six babies were born in our hospital during the study period. Screening results of 11,892 babies who met the inclusion criteria were evaluated retrospectively. Five thousand eight hundred and twenty-six (48.9%) of the cases were female, and 6,066 (51.1%) were male. While the number of infants passing the screening test was 11,871 (99.8%), the remaining failed number of infants was 21 (0.2%) (Figure 2). Seven (33.3%) out of 21 infants who failed the screening test had CCHD and underwent echocardiographic examination; patent foramen ovale (PFO) was found in 1 (0.04%), PFO and pulmonary hypertension in 1 (0.04%), and sepsis in 1 (0.04%) baby. Pulmonary atresia (28.5%) was the most common etiologic cause in those seven patients with CCHD (Table 1). The positive predictive value of the test was 33.3%. While there was no statistically significant difference in terms of gestational age and gender between the cases with the positive screening test and cases with and without CCHD, the saturation values were found to be significantly lower in infants with CCHD ($p<0.001$) (Table 2).

Discussion

In our study, 11,892 babies were screened for CCHD. While 11,871 (99.8%) of the babies passed the screening test, 21 (0.2%) babies failed. CCHD was present in 7 (33.3%) of 21 babies. The most common etiologic cause was pulmonary atresia (28.5%).

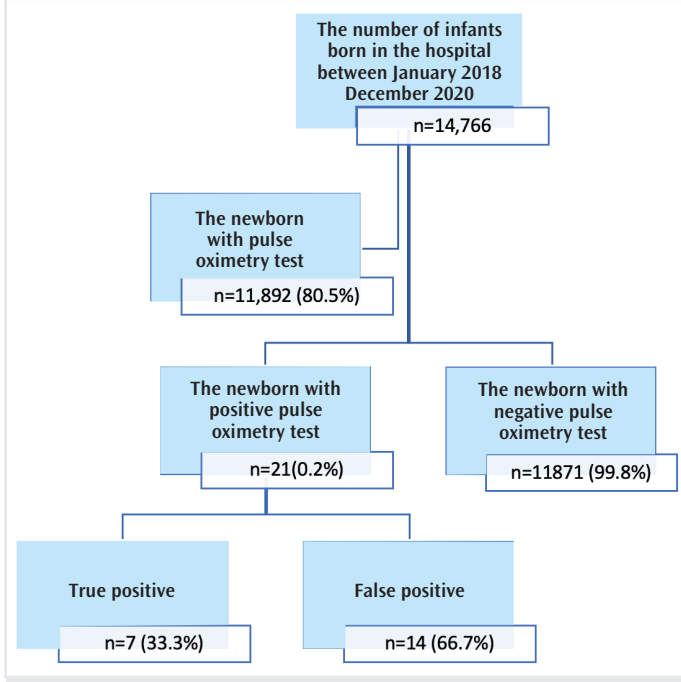

Figure 2. Screening test results of newborns screened with pulse oximetry

Table 1. Cases with positive pulse oximetry screening test and echocardiographic diagnoses

Case no	Gender	Gestation week	Preductal-postductal saturation measurement	Echocardiography
1	Male	38.14	88-89	Pulmonary atresia
2	Female	39.42	84-84	Great artery transposition
3	Male	38.28	90-91	Tricuspid atresia
4	Male	37.14	91-89	Total abnormal pulmonary venous return
5	Female	39.42	85-86	Pulmonary atresia
6	Male	37.57	87-88	Single ventricle, aortic coarctation
7	Female	38.57	91-95	Aortic coarctation
8	Female	38.28	93-92	Normal
9	Female	37.85	93-95	Normal
10	Male	39.57	94-95	Normal
11	Female	38.14	93-93	Normal
12	Female	40.42	94-92	Normal
13	Male	38.14	93-95	Normal
14	Female	39.14	91-94	Normal
15	Male	38.85	92-94	PFO, pulmonary hypertension
16	Male	39.42	91-94	Normal
17	Female	37.14	94-98	Normal
18	Female	38.85	92-90	Normal
19	Male	36.57	87-91	PFO
20	Male	40.14	91-93	Normal (early sepsis)
21	Male	39.14	91-94	Normal

Table 2. Comparison of cases with a positive screening test

Cases with a positive screening test, (n=21)		Cases with critical congenital heart disease, (n=7)	Cases without critical congenital heart disease, (n=14)	p
Gender	Female (n, %)	n=3, 43%	n=7, 50%	0.799[b]
	Male (n, %)	n=4, 57%	n=7, 50%	
Gestation week (median) (min.-max.)		38.28 (37.57-39.4)	38.85 (38.06-39.4)	0.488[a]
Preductal saturation (median) (min.-max.)		88 (85-91)	92.5 (91-93.25)	0.001[a]
Postductal saturation (median) (min.-max.)		89 (86-91)	94 (92-95)	0.006[a]

[a]Mann-Whitney U Test, [b] Fisher's exact test, min.: Minimum, max.: Maximum

Preductal and postductal saturation values of patients with positive screening tests were significantly lower in patients with CCHD than in those without.

CCHD is defined as a disease requiring surgical intervention or catheterization within the first year of life (12-16). Approximately 30% of newborns with CCHD are discharged from the hospital without being diagnosed, and these discharged newborns may present with a haemodynamic disorder, cardiovascular collapse, metabolic acidosis, and even death (17,18). Additionally, various postnatal hemodynamic changes reduce the chance of an early diagnosis of CCHD in newborn babies. It is known that one of the most important factors affecting the prognosis is the time of diagnosis (19-21). In a meta-analysis in which studies on the subject were evaluated, it was reported that the mortality risk of patients diagnosed in the antenatal or postnatal early period decreased with appropriate treatment and approach (22). Hence, it is essential to screen babies without an antenatal diagnosis for CCHD before being discharged from the hospital.

Oxygen saturation measurement with pulse oximetry is a non-invasive, easy, and applicable screening method (7,12,23,24). It is effective and reliable in critical CHD screening (25-27). The American Academy of Pediatrics and the American Heart Association have developed a CCHD screening algorithm, in which preductal-postductal saturation measurement is performed, and the difference is evaluated using pulse oximetry after the postnatal 24th hour (28,29).

In our country, since 2016, CHD screening has been performed with pulse oximetry in pilot hospitals. In our hospital, since November 2017, all babies have been screened with pulse oximetry after the 24th hour of their life or before discharge. In the last three years, 14,766 babies were born in our hospital, and 11,892 babies were screened with pulse oximetry. While 21 (0.2%) of 11,892 babies screened with pulse oximetry failed the screening, the rest (99.8%) passed. Because of the

echocardiographic examination of 21 babies who failed the screening, seven babies were diagnosed with CCHD. Two of the seven babies were diagnosed with pulmonary atresia, whereas the others were diagnosed with tricuspid atresia, aortic coarctation, single ventricle-isthmus hypoplasia, transposition of the great arteries (TGA), and total abnormal pulmonary venous return (TAPVR) anomaly (Table 1). The American Academy of Pediatrics has specified the priority disease group to be diagnosed by screening as hypoplastic left heart syndromes, pulmonary atresia, tetralogy of Fallot, total pulmonary venous return anomaly, TGA, tricuspid atresia, and truncus arteriosus (29). de-Wahl Granelli et al. (17) reported that the most common causes in cases who could not pass the screening test were TGA, pulmonary atresia, hypoplastic left heart syndromes, and aortic coarctation, respectively.

However, Riede and Schneider (24) detected the most common duct-dependent and cyanotic diseases such as TGA and TAPVD by screening (30). Dilli et al. (31) reported that 6 (0.12%) out of 34 babies with positive screening tests were diagnosed with CCHD, and the most common etiologic cause was TAPVR anomaly. In our study, the diagnoses of the cases detected by screening were compatible with the literature.

Although the measurement of oxygen saturation with pulse oximetry is useful in detecting CCHD, the false-positive rate in the literature varies between 0.14% and 0.87% (12). In a study conducted in our country in 2018, the false positivity rate was 3.7% (32), and this rate was found to be 0.12% in another study by Özalkaya et al. (33) The reason for the false-positive rate in both studies being different from the literature was associated with the scanning time. It was reported that the rate of false positivity decreased from 0.87% to 0.035% in cases screened after the postnatal 24th hour (30). In our study, the rate of false positivity was also 0.11%. We think that the false positivity rate is low because the screening time of the babies was after the postnatal 24th hour per the discharge protocol of our hospital. PFO was present in one patient, and PFO and pulmonary hypertension was present in one patient out of the fourteen false positive patients. Another patient, who was not screened and whose echocardiographic evaluation was normal, received treatment with the diagnosis of early sepsis. Scanning with pulse oximetry also enables the incidental detection of non-critical cardiac defects such as atrial septal defect, ventricular septal defect, in which right-left shunt continues, PFO who has not yet closed, and persistent pulmonary hypertension. Also, non-cardiac pathologies that may decrease the oxygen saturation value, such as sepsis, intracranial bleeding, circulatory failure, lung infection, and hereditary hemoglobinopathies, can be detected (29,34,35).

In our study, preductal and postductal saturation measurements were significantly lower in the group with CCHD among the patients with the positive screening test than without CCHD. In the literature studies conducted, no finding was found in which saturation values were compared between the two groups.

Study Limitations

The limitation of our study is that we could not include the cases whose screening test was found to be negative and had been diagnosed in the late infancy period because of its retrospective nature.

Conclusion

Early diagnosis of CCHD before discharge is possible with pulse oximetry screening. Better prognosis and lower mortality rate are aimed with early diagnosis in these babies. Therefore, necessary arrangements should be made to screen all newborn babies with pulse oximetry.

Ethics Committee Approval: The study was approved by the University of Health Sciences Turkey, İstanbul Training and Research Hospital Local Ethics Committee (approval number: 2742, date: 19.02.2021).

Informed Consent: Retrospective study.

Peer-review: Externally peer-reviewed.

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