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ORIGINAL ARTICLE

The Role of Pulse Oximetry in the Diagnosis of Congenital Heart Disease Screening

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Abstract

Introduction: Congenital heart defects (CHD) are common congenital malformations and cause mortality and morbidity in the neonatal period. Therefore, the diagnosis of critical CHDs is important. In this study, we aimed to present our critical congenital heart disease screening results with pulse oximetry and to emphasize the importance of screening.

Methods: All newborns born in our hospital between January 2020 and January 2021 and with a gestational age >34 weeks were included in the study. A total of 1605 newborns were screened with pulse oximetry device.

Results: The median birth weeks of 1605 newborns screened to detect critical congenital heart disease were 38 weeks (34–41 weeks), and their birth weight was 3065 g (2035–5040 g). Of the newborns included in the study, 767 (47.8%) were male and 838 (52.2%) were female. While 1591 (99%) of the babies included in the study passed the screening, 14 (1%) remained. False negativity was detected in one of the babies who underwent the screening. Critical CHDs were observed in three (21.4%) of the patients, while false positivity was detected in 11 (78.6%) of the infants who failed the screening. The false positive rate of the screening test in all babies was 0.6%. In our study, the sensitivity of CHD screening with pulse oximetry was 75%, the specificity was 99.3%, the positive predictive value was 21.4%, and the negative predictive value was 99.9%.

Discussion and Conclusion: We thought that since its incidence is not low, it is a life-threatening condition, and early diagnosis and effective interventions are available, CHD screening with pulse oximetry should be performed on all newborns and included in the newborn screening program.

Keywords: Critically congenital heart disease; newborn; pulse oximetry.

Congenital anomalies are structural and functional anomalies that occur during intrauterine life, and approximately 2% of all babies are born with any congenital anomaly [1]. The prevalence of congenital heart diseases (CHD), which is one of the most common congenital anomalies in the neonatal period, is approximately 8 per 1000 live births [2-4]. Critical congenital heart diseases (CCHDs), on the other hand, account for approximately one-quarter of all CHD and occur in approximately two of 1000 newborns. These babies are at risk for serious complications in the first few days or weeks of life and require catheter-based interventions or cardiac surgery in the neonatal period [5-7].

Ultrasonography and fetal echocardiography (echo) are used in the prenatal period in the diagnosis of congenital heart diseases. However, the chance of diagnosis of these babies may be low due to the experience of the practitioner,

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the unsuitable fetal position, and the fact that fetal echo is not routinely performed on every baby [8]. Since most of these babies are asymptomatic, they may be missed during postnatal physical examination [3,7,9]. Postnatal echo is the gold standard in the diagnosis of congenital heart disease, but it is applied to babies with pathology in physical examination. Pulse oximetry is an easy-to-use, low-cost and non-invasive device that measures oxygen saturation and heart rate in newborns, and is used for screening in the early diagnosis of babies with CCHD in many centers [6]. Our aim in this study is to emphasize the importance of CCHD screening with pulse oximetry, to summarize the studies on this subject and to present the results of our clinic.

Materials and Methods

All newborns born in our hospital between January 2020 and January 2021 and with a birth week greater than 34 weeks of gestation were included in the study. Patients with congenital heart disease detected in the prenatal period, patients with symptoms thought to be of cardiac origin in the postnatal period, and patients admitted to the neonatal intensive care unit were excluded from the study.

Systemic examinations of all newborns were performed before screening. All asymptomatic newborns were screened with a pulse oximetry device (Covidien Nellcor) at the latest within 24-48 hours after birth. In babies who were discharged earlier than the 24th hour at the request of the family, screening was performed as soon as possible, that is, just before leaving the hospital. Oxygen saturation was measured by applying the pulse oximetry probe to the right hand in the upper extremity and to any of the feet in the lower extremities, and the values were recorded in a separate file for each baby. If both saturation measurements were ≥95% and the saturation difference between both extremities was ≤3%, the baby was considered to have passed the test; if any of the measurements was <90%, the baby was considered to have failed the test and echo was performed. In babies with 90-94% difference in any of the measurements or >3% difference between the two extremities, the test was repeated one hour later. In cases where both measurements were ≥95% and the difference between both extremities was ≤3% on repetition, the baby was considered to have passed the test; the baby was considered to have failed the test if any of the measurements were found to be <90%; if any of the measurements was between 90-94% or the difference between the two extremities was >3%, the test was repeated one hour later. In the third test; the baby was considered to have passed the test if both measurements were ≥95% and the difference between both extremities was ≤3%; if any of the measurements was <90%, or any of the measurements was between 90-94%, or the difference between the two extremities was >3%, the baby was considered to have failed the test and echo was performed. Screening was performed according to the American Academy of Pediatrics CCHD newborn screening algorithm (Fig. 1). The patients who underwent echo were divided into two groups as CCHD (+) and CCHD (-), according to the criteria defined in the literature according their echo result [6].

Data analysis and descriptive statistics were performed using the IBM SPSS version 23.0 statistical package program. Numerical variables in the study were expressed as mean, standard deviation, median, minimum and maximum values, and categorical variables were expressed as numbers and percentage. Sensitivity, specificity, positive predictive value and negative predictive value were calculated for pulse oximetry screening. Our study was approved by the ethics committee (Protocol no: 2021-03/32) and informed consent was obtained from the parents before screening.

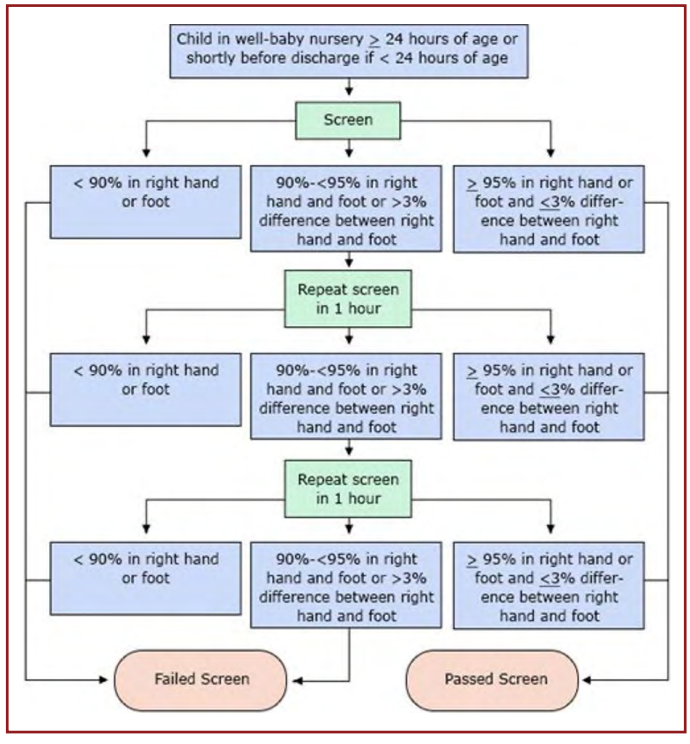

Figure 1. American Academy of Pediatrics CCHD screening algorithm. Adapted from: Kemper AR, Mahle WT, Martin GR, et al. Strategies for implementing screening for critical congenital heart disease. Pediatrics. 2011;128(5).

Can be found at: www.pediatrics.org/cgi/content/full/128/5/e1259

Results

A total of 1825 babies were born in the hospital within one year. The prevalence of CCHD among babies was 2.1 per 1000 live births (4/1825). One hundred and eighty three of all born babies were excluded from the study. Three of these babies who were not included in the study had prenatal CCHD diagnosis. Thirty-seven of the remaining 1642 patients could not be included in the study because screening could not be performed for reasons such as early discharge. The flow chart of the study is shown in Figure 2. The median birth week of 1605 newborn babies screened to detect CCHD was 38 weeks (34-41 weeks), and their median birth weight was 3065 grams (2035-5040 grams). Of the infants included in the study, 767 (47.8%) were male and 838 (52.2%) were female. The descriptive characteristics of the babies are shown in Table 1.

Of the babies included in the study, 1591 (99%) passed the screening, while 14 (1%) failed (Table 2, Fig. 2). In the echo performed to the babies who failed the screening, CCHD was detected in three (21.4%) of the babies, and false positivity was detected in 11 (78.6%) of the babies. The false positivity rate of the screening test in all babies was 0.6%. False negativity was detected in one of the babies who underwent screening (Table 2). Birth characteristics and diagnoses of four patients with CCHD are given in Table 3. CCHD was detected within the first 15 days follow up after birth, in one of the 1591 babies who passed the screening. Three of the four patients (75%) diagnosed with CCHD were detected during the screening performed with a pulse oximetry device, while one (25%) patient missed the screening. In our study, the sensitivity of CHD screening with pulse oximetry was 75%, the specificity was 99.2%, the positive predictive value was 21.4%, and the negative predictive value was 99.9%.

Table 1. Descriptive characteristics of babies

Male/Female (n,%)	767/838 (47.8/52.2)
Gestational week (weeks)	38 (34-41)
Birth weight (g)	3065 (2035-5040)

Table 2. Pulse oximetry screening results

	CCHD -, n	CCHD +, n	Total, n
Passed screening, n(%)	1590 (99)	1 (0,06)	1591
Failed screening, n(%)	11 (78,6)	3 (21,4)	14
Total, n(%)	1601 (99,7)	4 (0,3)	1605

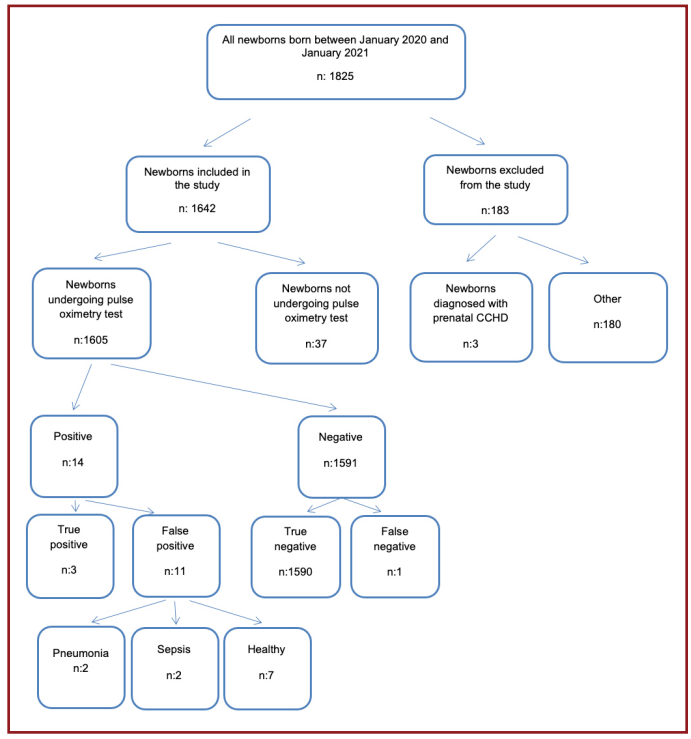

Figure 2. Flow chart of the study.

Discussion

Babies born with CCHD may appear healthy in the early postnatal period and may not be diagnosed. This can cause the baby to deteriorate suddenly, to have a poor clinical picture despite treatment, and to have poor cardiopulmonary and neurologic outcomes after surgery [7]. For these reasons, early diagnosis of babies with CCHD is important. CCHD screening with pulse oximetry should be performed on all newborns at the latest within 24-48 hours after birth. In babies who are discharged earlier than 24 hours at the request of the family, it should be performed at its latest, that is, just before leaving the hospital. The pulse oximeter device to be used must be approved for newborns and motion-tolerant. Newborns should not be discharged until the underlying cause or hypoxemia has been identified and the hypoxemia has been resolved. It should be noted that these babies usually appear normal and do not show clinical signs other than low oxygen saturation.

According to the results of the Cochrane meta-analysis, which included 457202 infants and examined 21 studies on CCHD screening with pulse oximetry in 2018, screening with pulse oximetry showed moderate sensitivity (76.3%) in detecting CCHD, but high specificity (99.9%), and had low false positivity rate (0.14%). In addition, when the pulse oximetry screening was performed after 24 hours, the false positivity rate was found to be lower compared to the first

Table 3. Birth characteristics and diagnoses of four patients with CCHD

Gender	Birth time, week	Birth weight, g	Screening result	Echocardiography result
Male	37	3470	Failed	Transposition of the great arteries
Male	37	2020	Passed	Total anomalous pulmonary venous return
Female	38	2920	Failed	Transposition of the great arteries
Female	38	2950	Failed	Truncus arteriosus

24 hours [5]. Narayen et al.[10] in their study, found the sensitivity as 50% and specificity as 99.1% in the screening of CCHD with pulse oximetry, and Song et al.[11] found the sensitivity as 89.9% and specificity as 94.7% in their study. In another study, the sensitivity and specificity of pulse oximetry in the diagnosis of CCHD were found to be 78.9% and 99.9% [12]. In our study, similar to previous studies, the sensitivity was 75% and the specificity was 99.2%.

Studies have shown that the majority of false positivities are caused by non-cardiac causes such as pulmonary disorders and infection. In the study by Meberg et al. [13], 50008 newborns were screened and 134 (41%) of the positive test results were found to be caused by pneumonia, sepsis, transient tachypnea of the newborn (TTN), persistent pulmonary hypertension of the newborn (PPHN), pneumothorax and meconium aspiration syndrome. In a study conducted in Germany, Riede et al.[14] reported that 28 (70%) of 40 false positive results were due to either PPHN or sepsis. In the United Kingdom, Singh et al. [15] screened 25859 newborns with pulse oximetry. Of 208 false positive results, 9 were diagnosed as CCHD, 103 (49.5%) had respiratory tract diseases such as congenital pneumonia, meconium aspiration syndrome, oxygen-requiring TTN, 2 babies had culture-positive sepsis and 28 had culture-negative sepsis, and eight babies had CHD that did not meet the CCHD criteria. In our study, pneumonia and sepsis were diagnosed in 4 patients with false positivity. These findings may be considered an additional benefit of screening with pulse oximetry, as many of these findings can result in serious disease, including cardiovascular collapse, and may benefit from early detection and intervention. Based on these results, pulse oximetry screening may be considered a highly specific and moderately sensitive test with very low false-positive rates for detecting CCHD. Based on the meta-analysis, available evidence supports routine screening for CCHD in healthy and asymptomatic newborns prior to discharge from the nursery [5]. It has also been accepted by the American Heart Association (AHA) and the American Academy of Pediatrics (AAP) that pulse oximetry screening has a reliability of over 75% when performed in accordance with the application protocol [7]. It is routinely performed within the scope of newborn screening program in America and in many European countries.

In conclusion, because of its incidence, severity and life-threatening condition, and the availability of effective interventions with early diagnosis, CCHD screening with pulse oximetry should be performed in all newborns and included in the newborn screening program.

Ethics Committee Approval: The Acibadem Mehmet Ali Aydinlar University Medical Research Ethics Committee granted approval for this study (date: 11.02.2021, number: 2021-03/32).

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References

1. Corsello G, Giuffrè M. Congenital malformations. J Matern Fetal Neonatal Med 2012;25(1 Suppl):25–9. [CrossRef]
2. van der Linde D, Konings EE, Slager MA, Witsenburg M, Helbing WA, Takkenberg JJ, et al. Birth prevalence of congenital heart disease worldwide: A systematic review and meta-analysis. J Am Coll Cardiol 2011;58:2241–7. [CrossRef]
3. Hoffman JI. It is time for routine neonatal screening by pulse oximetry. Neonatology 2011;99:1–9. [CrossRef]
4. Wright J, Kohn M, Niermeyer S, Rausch CM. Feasibility of critical congenital heart disease newborn screening at moderate altitude. Pediatrics 2014;133:e561–9. [CrossRef]
5. Plana MN, Zamora J, Suresh G, Fernandez-Pineda L, Thangaratinam S, Ewer AK. Pulse oximetry screening for critical congenital heart defects. Cochrane Database Syst Rev 2018;3:CD011912. [CrossRef]
6. Ewer AK. Pulse oximetry screening for critical congenital heart defects: A life-saving test for all newborn babies. Int J Neonatal Screen 2019;5:14. [CrossRef]
7. Mahle WT, Newburger JW, Matherne GP, Smith FC, Hoke TR, Koppel R, et al. Role of pulse oximetry in examining newborns for congenital heart disease: A scientific statement from the AHA and AAP. Pediatrics 2009;124:823–36. [CrossRef]
8. Narayen IC, Blom NA, Ewer AK, Vento M, Manzoni P, te Pas AB.

Aspects of pulse oximetry screening for critical congenital heart defects: When, how and why? Arch Dis Child Fetal Neonatal Ed 2016;101:F162–7. [CrossRef]
9. Ewer AK, Middleton LJ, Furmston AT, Bhoyar A, Daniels JP, Thangaratinam S, et al. Pulse oximetry screening for congenital heart defects in newborn infants (PulseOx): A test accuracy study. Lancet 2011;378:785–94. [CrossRef]
10. Narayen IC, Blom NA, van Geloven N, Blankman EIM, van den Broek AJM, Bruijn M, et al. Accuracy of pulse oximetry screening for critical congenital heart defects after home birth and early postnatal discharge. J Pediatr 2018;197:29–35.e1.
11. Song J, Huang X, Zhao S, Chen J, Chen R, Wu G, et al. Diagnostic value of pulse oximetry combined with cardiac auscultation in screening congenital heart disease in neonates. J Int Med Res 2021;49:3000605211016137. [CrossRef]
12. Turska Kmieć A, Borszewska Kornacka MK, Błaż W, Kawalec W, Zuk M. Early screening for critical congenital heart defects in asymptomatic newborns in Mazovia province: Experience of the POLKARD pulse oximetry programme 2006-2008 in Poland. Kardiol Pol 2012;70:370–6.
13. Meberg A, Brügmann-Pieper S, Due R Jr, Eskedal L, Fagerli I, Farstad T, et al. First day of life pulse oximetry screening to detect congenital heart defects. J Pediatr 2008;152:761–5.
14. Riede FT, Wörner C, Dähnert I, Möckel A, Kostelka M, Schneider P. Effectiveness of neonatal pulse oximetry screening for detection of critical congenital heart disease in daily clinical routine--results from a prospective multicenter study. Eur J Pediatr 2010;169:975–81. [CrossRef]
15. Singh A, Rasiah SV, Ewer AK. The impact of routine predischarge pulse oximetry screening in a regional neonatal unit. Arch Dis Child Fetal Neonatal Ed 2014;99:F297–302. [CrossRef]