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ORIGINAL ARTICLE

Early screening with pulse oximetry for the detection of critical cyanotic congenital heart defects. Diagnostic test study

Tamizaje temprano con oximetría de pulso para la detección de cardiopatías congénitas críticas cianóticas. Estudio de pruebas diagnósticas

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What do we know about the subject matter of this study?

Critical congenital heart disease affects about 8 per 1000 live births. Early screening with pulse oximetry is a potential tool for detection.

What does this study contribute to what is already known?

This prospective observational study evaluated early screening for congenital heart disease in neonates using pulse oximetry, which contributed to reducing the length of hospital stay of the mother-infant dyad without affecting patient safety since the rate of false negatives during clinical follow-up was not increased.

Abstract

Cyanotic critical congenital heart defects (CCHD) are severe malformations that manifest as cardiocirculatory collapse during the first month of life, with high mortality without timely treatment. **Objective:** To evaluate the performance of the American Academy of Pediatrics (AAP) protocol for the use of pulse oximetry for the early detection of critical congenital heart defects in neonates. **Patients and Method:** Prospective study of diagnostic tests in neonates older than 34 weeks and 2000 grams of birth weight between 6 to 48 hours of age, between August 2021 and January 2022. Clinical variables were collected from a review of medical records. Those with a prenatal history of CCHD detected by prenatal ultrasound were excluded. According to the AAP protocol, any saturation value less than 90% was considered a positive screening. The oximetry result was evaluated against a reference standard consisting of echocardiography or clinical follow-up. **Results:** A total of

Keywords:
Congenital Heart Disease; Neonatal Screening; Oximetry; Echocardiography; Clinical Protocols; Diagnostic Test.

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609 neonates underwent pulse oximetry testing with a median of 15.4 hours of life; 6.9% of patients had a positive screening and underwent echocardiography. Outpatient follow-up was conducted on 520 neonates with a mean of 96 days of life. No patients with critical congenital heart disease were detected. Screening identified non-critical congenital heart diseases with a sensitivity of 70.7% (95% CI 55.6 - 85.9) and a specificity of 97.6% (95% CI 96.1 - 99.0). **Conclusions:** Most early screenings were true negatives during outpatient follow-up. A positive screening allowed for the identification of non-critical congenital heart disease detected by echocardiography or another cause of non-cardiac hypoxemia.

Introduction

It is estimated that congenital heart disease in general has a global incidence of approximately 8-12 per 1,000 live births, which is equivalent to 1% of births. Of all congenital heart diseases, 25-30% correspond to critical cyanotic forms, resulting in an incidence of 2-3 per 1,000 live births[1-2].

Between 18% and 25% of patients affected by critical cyanotic congenital heart disease (CCHD) die within the first year of life, and up to 60% face long-term complications. Early detection of critical CCHD is essential due to its high mortality rate and the morbidity associated with late diagnosis. Tools such as obstetric ultrasound and clinical evaluation detect about 68% of cases during the prenatal stage, but fetal cardiovascular physiology hinders diagnosis, thus increasing mortality[3-5].

The American Academy of Pediatrics (AAP) proposes universal screening with pulse oximetry, preferably performed around 24 hours of life, since, before this period, the transition from fetal circulation to extrauterine life may generate greater variability in oxygen saturation, which could result in more false positives. There are discrepancies about the optimal time for its application. Studies conducted in Spain and the United Kingdom suggest that it could be more effective around twelve hours of life, without significantly increasing the rate of false positives or modifying false negatives. In Colombia, the possibility of performing it around twelve hours of life is justified by the limitations in health services and the need for early discharge[3-10].

Pulse oximetry screening allows rapid, noninvasive, and low-cost detection, with an impact on neonatal morbidity and mortality. In addition, it allows the identification of other non-cardiac hypoxemia conditions such as respiratory distress syndrome, hypoglycemia, sepsis, or non-critical CHD requiring outpatient follow-up. These false positives are considered "cost-effective" since the timely diagnosis of these conditions contributes to the reduction of neonatal morbidity and mortality [6,8,11].

The objective of this investigation was to evaluate the performance of the AAP protocol[3] of the use of pulse oximetry for early detection of critical CCHD in term and near-term newborns, performed from six hours and before 48 hours of life using echocardiography or clinical follow-up as the reference standard.

Patients and Method

Study design

Prospective study of diagnostic tests in neonates at the *Clínica Universitaria Bolivariana*, Medellín, Colombia, a center specialized in the mother-infant dyad, located at 1510 meters above sea level between August 1, 2021, and January 31, 2022.

Inclusion/Exclusion Criteria

All newborns who underwent critical CCHD screening with pulse oximetry between six and 48 hours of life were consecutively included, recruited from the hospitalization service in rooming-in with their mother or from the basic neonatal care unit, who they were born at more than 34 weeks of gestation, had a birth weight over 2000 grams, and had prior informed consent signed by their caregivers before the test was performed. Those with a prenatal history of critical CCHD detected by obstetric ultrasound were excluded.

The AAP considers transposition of great the arteries, pulmonary atresia with intact ventricular septum, hypoplastic left ventricle syndrome, tetralogy of Fallot, truncus arteriosus, and total anomalous pulmonary venous return as critical CCHD and pulse oximetry was considered the index test to detect them. The performance of the pulse oximetry test was evaluated against a reference standard composed of echocardiography or clinical follow-up by telephone contact 21 days after birth. This work was written following the recommendations for reporting the results of diagnostic test studies (STARD)[12].

Data collection process

In the institution, all newborns meeting the eligi-

bility criteria for critical CCHD routinely underwent pulse oximetry screening according to the institutional protocol; and those who, in addition to meeting the inclusion criteria, the guardian signed informed consent, participated in the study.

The pulse oximetry screening for the detection of critical CCHD consists of measuring pre-ductal oximetry in the right upper limb and post-ductal oximetry in the left lower limb, using the Masimo SET® Rad-97 oximeter with the EVE™ application. The first measurement was made after six hours of the patient's life and with a maximum of 48 hours of life.

The interpretation of the results was based on the algorithm recommended by the AAP in 2020[3], which is widely accepted in the literature for the interpretation of the screening test:

- Any saturation value < 90% is considered a positive screening.
- An oxygen saturation ≥ 95% in both the right hand and foot, a saturation variability ≤ 3%, and a pulsatility index of both pre- and post-ductal > 0.4 is considered a negative screen.
- Saturation values between 90-94.9% or a variability > 3% or a pulsatility index of both pre- and post-ductal > 0.4 are indications to repeat the measurement at the time of the first measure (second screening attempt), and if these findings persist, the screening is considered positive.

The screening test was performed by a university nurse or pediatrician previously trained in the use of the equipment and interpretation of the results. A positive screening result indicated in-hospital echocardiography, which is the standard reference test to exclude the diagnosis of critical CCHD. In addition, echocardiography was performed in patients with symptoms or clinical signs suggestive of heart disease according to the treating physician's criteria.

Echocardiography was performed by a pediatric cardiologist trained in echocardiography who was not blinded to the critical CCHD screening test result or the patient's clinical information. Echocardiography findings were evaluated by the treating pediatrician.

In case the screening result was negative in an asymptomatic neonate, the neonate was discharged according to the usual observation protocol for healthy neonates in the institution, which is usually between 12 and 18 hours of life. During the COVID-19 pandemic period, such observation was reduced to 6-8 hours postnatal in healthy neonates without risk factors.

Given the high cost and limited availability of echocardiography, the gold standard test for patients with negative pulse oximetry screening was clinical follow-up by telephone contact after 21 days of life in which a single semi-structured interview was conducted to inquire about the presence of any signs suggestive of CHD (Appendix 1, supplementary material available online version). Patients with any clinical signs were referred for priority clinical review and echocardiography. Otherwise, when in the telephone interview all the answers were negative, it was considered absence of symptoms of critical CCHD and these patients were classified as true negatives of the screening test.

Statistical analysis

Qualitative variables were expressed as absolute and relative frequencies, while quantitative variables were expressed as means and standard deviation (SD) or median with their respective interquartile range (p25-p75) according to whether or not the assumption of normality of the data evaluated by the Kolmogorov-Smirnov test was met.

To evaluate the performance of the pulse oximetry test, the results were compared with those obtained with a reference standard consisting of echocardiography and clinical follow-up of the patients at 21 days. The validity index or percentage of agreement observed between the two tests, sensitivity, specificity, and the positive or negative likelihood ratio with their respective 95% confidence intervals were estimated. The analyses were performed in the IBM SPSS 27 statistical package.

Ethical considerations

The study was considered minimum risk according to resolution 8430 of 1993 of the Colombian Ministry of Health and had the approval of the Health Research Ethics Committee of the institution by Act No. 13 of 2021 and with the informed consent of the caregivers, following all the established ethical regulations.

Results

During the study period, 609 neonates were included and underwent different diagnostic tests according to the algorithm described in Figure 1.

Most of the patients were full-term and 11 (1.8%) had clinical manifestations of heart disease such as murmur, dyspnea, and tachycardia at the initial evaluation (Table 1).

Table 2 describes the pulse oximetry screening values. The first screening attempt was performed on 206 patients in the first 12 hours of life, on 233 patients between 12 and 18 hours, and on 170 patients after 18 hours of birth. In total, 42 (6.9%) patients had a positive pulse oximetry test for critical CCHD (33 detected by first and second screening, and 9 detected only by first screening).

The 42 positive results were detected in the first

screening, five in the first 12 hours, 14 between 12 and 18 hours, and 23 in a time greater than 18 hours after birth.

54 (8.9%) patients required echocardiography (42 due to positive screening and 12 due to pathological findings in obstetric ultrasound or clinical manifestations during the initial evaluation suggestive of heart disease). However, one patient with clinical symptoms did not undergo this test because the pulse oximetry screening was negative, and he remained asymptomatic during the clinical follow-up by telephone call.

In the 53 echocardiographies performed, the most frequent abnormal findings were: interatrial septal defect (n = 3, 5.7%), interventricular septal defect (n = 1, 1.9%), and partial anomalous pulmonary venous connection (n = 1, 1.9%). In addition, other physiological alterations were observed such as patent foramen ovale (n = 36, 67.9%), patent ductus arteriosus (n = 24, 45.3%), and pulmonary hypertension (n = 5, 9.4%).

During the hospital stay, no patient was diagnosed with critical CCHD, 582 (95.6%) were discharged after the usual postnatal observation, while 12 (4.4%) were hospitalized due to other pathologies such as sepsis risk, neonatal sepsis, hypoglycemia, and hyperbilirubinemia.

Telephone follow-up was made to 520 neonates because it was not possible to contact the remaining 89. Three patients with cardiovascular symptoms were identified and underwent outpatient echocardiography with negative results for critical CCHD. The minimum time of telephone contact during follow-up was 49 days; the latest call was made 312 days after birth, with a mean of 96 days. It is important to highlight that considering this wide range of follow-up periods, no patient with critical CCHD was detected.

Thirteen patients were identified as requiring echocardiography during follow-up due to altered birth echocardiography, of which three had an abnormal result showing aberrant subclavian artery, patent ductus arteriosus, and patent foramen ovale, but without the presence of CCHD; the remaining ten patients had normal follow-up echocardiography.

The outcome of non-critical CHD, defined for this study as abnormal echocardiography (performed at birth or during outpatient follow-up in the presence of cardiac symptoms after day 21 of birth), was evaluated in an exploratory manner and it was observed that screening with pulse oximetry detected 70.7% (n=29) of these non-critical heart diseases. These positive screening results are considered "cost-effective" false positives. In addition, the specificity of screening for non-critical CHD was 97.6% (95% CI 96.1- 99.0) (Table 3).

No deaths were reported during the follow-up of the 520 patients in whom clinical telephone follow-up was obtained, 12 mothers reported that their children had been hospitalized due to a cause other than heart disease, and no patient was hospitalized at the time of telephone contact.

Discussion

The usefulness of screening for CHD in newborns has been widely studied during the last decade, which has led to the routine implementation of tests such as pulse oximetry in the initial evaluation of neonates. In this study performed in a high-complexity institution, the results obtained were consistent with those expected and described in other studies. Most of the pulse oximetry results were negative for critical CCHD, and in those that were positive, no critical heart disease was detected in the echocardiogram or the clinical follow-up, as previously proposed by authors such as Wong KK et al, who detected alterations with non-cardiac causes that explain the altered screening result such as the presence of neonatal sepsis and hypoglycemia, as well as the presence of non-critical CHD[13-14].

It is important to note that in our study, screening was performed shortly before the usual time, in contrast with other studies and with the recommendations of the AAP, which suggests performing it around 24 hours of life but also endorses its performance before 24 hours if the patient is going to be discharged. This decision was made because of the need for early discharges due to the health context caused by the COVID-19 pandemic and the reduced supply of maternity services in the city, which led to a higher occupancy of services during the post COVD-19 pandemic period[15-17].

Most healthy newborns in our study had a negative first test which is similar to that reported in other institutions, suggesting that early CHD screening should be implemented in middle-income countries with high birth rates, without affecting the quality of care and patient safety[13].

Similar to a previous study performed at the same institution (unpublished data), it was observed that in the second screening, most were negative and those positive did not present any critical CCHD based on the frequency of heart disease in this population. The absence of critical CCHD could be explained by the relatively small sample size for the incidence of critical CCHD and the exclusion of patients with prenatal diagnosis of critical CCHD compared to previous studies[18-19]. However, this study shows the experience of a high-complexity center in the use of pulse oximetry as a screening tool for these CHDs.

Our findings are also similar to those described by other authors such as Schena et al, who screened 42169

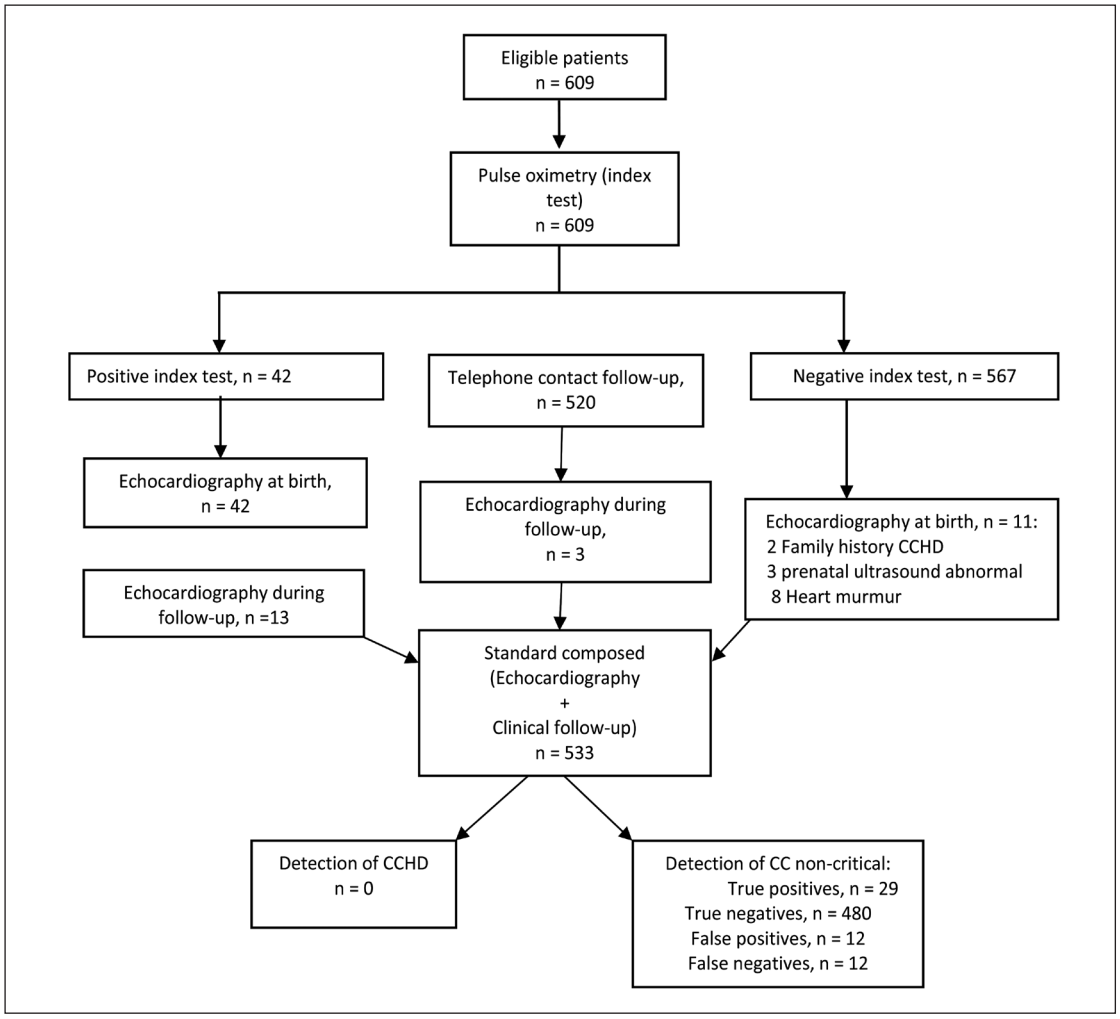

Figure 1. Flowchart.

Table 1. Sociodemographic and Clinical Characteristics of Neonates (n = 609)

Características	N (%)
Sex Male n (%)	323 (53)
Gestacional age (weeks)*	39 (38-39.6)*
Preterm n (%)	38 (6.2)
Term (%)	571 (93.8)
Weight at birth (grams)†	3.080 (411)†
SAG n (%)	47 (7.7)
AGA n (%)	557 (91.5)
LGA n (%)	5 (0.8)
Family history of heart disease n (%)	4 (0.7)
Symptoms of heart disease n (%)	11 (1.8)
Murmur	4
Dyspnea	4
Tachycardia	3
Fetal echocardiography n (%)	11 (1.8)
Abnormal result, n=11 n (%)	3 (27.3)

*Median (percentile 25-75) †Media (Standard deviation). †SGA: small weight for gestational age; AGA: appropriate weight for gestational age; LGA: large weight for gestational age.

Table 2. Performance of the Screening Variables with Pulse Oximetry

Characteristics	Median (p25-p75)
First screening, n = 609	
Pre-ductal saturation (%)	97 (96-98.3)
Post-ductal saturation (%)	97 (96-98.4)
Pulsatility index in the right hand	1.4 (1.0-2.0)
Pulsatility index in the lower limb	1.1 (0.8-1.6)
Saturation difference	1.1 (0.5-2.0)
Second screening, n = 50	
Pre-ductal saturation (%)	95 (93. 1-97)
Post-ductal saturation (%)	95.5 (93.2-97.1)
Pulsatility index in the right hand	1.6 (1.1-2.3)
Pulsatility index in the lower limb	1.3 (0.8-1.9)
Saturation difference	1.7 (0.7-3.5)
Overall screening results	n/N (%)
Negatives	567 /609 (93.1)
Positives	42/609 (6.9)

Table 3. Performance of Pulse Oximetry for the Detection of Non-Critical Congenital Heart Diseases (CHD) Compared to a Composed Standard (Echocardiography and Outpatient Clinical Follow-up), n = 533 Patients

	Detection of non-critical CHD (n = 41) n (%)	No detection of non-critical CHD (n=492) n (%)
Positive pulse oximetry	29 (70.7)	12 (2.4)
Negative pulse oximetry	12 (29.3)	480 (97.6)
Parameter (Confidence interval 95%)		
Accuracy, %	95.5 (93.6-97.4)	
Sensitivity, %	70.7 (55.6 -85.9)	
Specificity %	97.6 (96.1 -99.1)	
Positive predictive value %	70.7 (55.6-85.9)	
Negative predictive value %	97.6 (96.1 -99.1)	
Positive likelihood ratio	29 (16.0-52.5)	
Negative likelihood ratio	0.3 (0.2-0.5)	

patients, and only 0.46% had a positive result in the second screening, of which most patients had normal echocardiography and only in three (1.5%) patients did they detect critical CCHD such as tetralogy of Fallot, coarctation of the aorta, and Cor triatriatum dexter. It is also important to mention that, although not many echocardiograms were performed, the follow-up through telephone calls covered a sufficiently long time frame for detecting symptoms of critical CCHD. No such symptoms were found during follow-up, and those patients who required an echocardiogram during the follow-up had either a normal result or a non-critical CHD[20].

The main objective of screening with pulse oximetry is the detection of critical CCHD, however, measuring pre- and post-ductal saturation is one of the tools for early detection of other non-cardiac pathologies that compromise systemic perfusion, such as respiratory pathologies and sepsis, as shown in different studies where oximetry allowed the detection of other non-cardiac causes in positive screening as in 0.24% in Malaysia, 0.84% in the United Kingdom, and up to 17.9% in Ethiopia[11,15,15,23-23].

Regarding biases, these were controlled in the selection of the population by including all patients who met the eligibility criteria of the study. However, information biases could have occurred due to the sample size. Although it is a considerable number that reflects the clinical practice of our center in a given period, perhaps not all the analyses that were intended with respect to the performance of the tests were achieved, in addition to the fact that due to costs it was not possible to perform the most accepted reference standard (echocardiography) on all participants, but only on symptomatic neonates or those with positive screening (partial verification bias). It should be clarified that this diagnostic strategy was a similar design to that used in the study by Ewer et al. in the United Kingdom where 20,055 screenings with pulse oximetry were performed and only 192 echocardiographies during immediate postnatal hospitalization[23].

In our study, the strategy of using clinical follow-up through telephone contact as the reference standard was due to the high costs of echocardiography, and this may have limited the results by increasing the overestimation of the index test sensitivity. The impact of this bias was reduced since long-term outpatient follow-up by structured telephone interview to alert to the presence of critical CCHD symptoms performed on 85.4% (520/609) of patients ruled out critical CHD in those patients with negative screening, thus confirming these results as true negatives of the pulse oximetry test.

Additionally, in a real clinical scenario in a Maternal and Child Unit in a middle-income country, according to data from an exploratory analysis of this study and considering the limited availability of echocardiography in our context, the combination of pulse oximetry screening and clinical follow-up detected non-critical CHD with a sensitivity and a specificity of 70.7% and 95%, respectively. These non-critical CHD that are usually asymptomatic in the absence of screening may go undetected in the neonatal period which may indicate that screening adds useful and relevant information. However, it should be noted that a negative screening does not exclude the presence of a non-critical CHD; and the result of this exploratory analysis should be corroborated in subsequent studies where echocardiography is performed in all patients, which is the reference standard for the detection of these pathologies.

The main finding of this research is that, according to the data obtained, early screening (within the first 12 hours of life) with pulse oximetry could be considered with the aim of rapid discharge in those neonates without risk factors, reducing the length of hospital stay of the mother-infant dyad and reducing health system costs without affecting patient safety, given that the negative results were corroborated as true negatives during follow-up. However, studies with long-term follow-up and larger sample sizes are required to evaluate the performance of the pulse oximetry screening test for the detection of critical CCHD and to include cost-effectiveness data to provide information to implement this test in our health system. Additionally, it was found in this sample that screening early does not increase false positives.

Conclusion

We were unable to evaluate the performance of early screening with pulse oximetry for the detection of these critical CCHDs. Despite the limitations of the study, it is important to highlight the extensive outpatient follow-up performed on most participants, during which alarm signs or symptoms that could indicate the presence of critical CCHD were identified. In addition, it was evidenced that early screening probably does not affect patient safety since long-term follow-up ruled out the presence of critical CCHD in those neonates with negative screening, thus confirming these results as true negatives.

Future challenges

To conduct a prospective multicenter study in Colombia of the pulse oximetry screening test to achieve a sufficient sample size to evaluate the incidence of these CHDs in our sphere and the performance of this test in the detection of critical CCHD given the low incidence of these conditions in the general population.

Ethical Responsibilities

Human Beings and animals protection: Disclosure the authors state that the procedures were followed according to the Declaration of Helsinki and the World Medical Association regarding human experimentation developed for the medical community.

Data confidentiality: The authors state that they have followed the protocols of their Center and Local regulations on the publication of patient data.

Rights to privacy and informed consent: The authors have obtained the informed consent of the patients and/or subjects referred to in the article. This document is in the possession of the correspondence author.

Conflicts of Interest

Authors declare no conflict of interest regarding the present study.

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