PULSE OXIMETRY AS A SCREENING TEST FOR CRITICAL CONGENITAL HEART DISEASE IN TERM NEWBORNS

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ABSTRACT

Background: Pulse oximetry has been suggested as a screening test for congenital heart disease (CHD) in asymptomatic newborns. However, most newborns in Mexico are discharged from the hospital without this evaluation. Objective: To evaluate pulse oximetry as a screening test for critical congenital heart disease (CCHD) in term newborns. Methods: We conducted a cross-sectional study in term newborns between July 2010 and April 2011. Pulse oximetry was determined before hospital discharge; in case of post-ductal oxygen saturation < 95%, a Doppler echocardiogram was performed. Results: From 1,037 newborns screened, two had CCHD, one had pulmonary atresia and ventricular septal defect, and one Ebstein’s anomaly. Minor CHD was present in 10 babies. The overall prevalence of CHD was 11.5 per 1000 live births, and the prevalence of CCHD was 3.9 per 1000 live births. For those with critical disease, pulse oximetry had a sensitivity of 100%, specificity 98.8%, positive predictive value 14.2%, negative predictive value 100%, and positive likelihood ratio of 86.2. In regression analysis, oxygen saturation, respiratory frequency, and postnatal age were related with CCHD. Conclusions: Pulse oximetry had a good sensitivity and specificity for the identification of critical congenital heart disease in term newborns. Low oxygen saturation, higher respiratory frequency, and early postnatal age were related with congenital heart disease. (REV INVES CLIN. 2015;67:130-4)

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BACKGROUND

Congenital heart disease (CHD) is the most common class of birth defects. From 1998 to 2005, the overall prevalence of CHD in the USA was 81.4/10,000 births¹. In Latin America, the reported prevalence is 2.3/1000 live newborns². Clinical examination is usually the initial method for diagnosis of heart disease, particularly in the presence of a heart murmur. However, the presence of heart murmurs in newborns in the first week of life varies from 0.6 to 77.4%, and most murmurs are known to be related to the circulatory...
changes occurring after birth\textsuperscript{3,4}. Also, their detection may depend on the experience of the examiner, postnatal age, and the study population\textsuperscript{3-6}.

The American Heart Association, American Academy of Pediatrics, and clinical studies suggest performing pulse oximetry as a routine test to detect CHD in asymptomatic newborns, combined with clinical examination\textsuperscript{7,9}. Pulse oximetry offers a reliable, noninvasive method for continuous assessment of arterial oxygen pressure (PaO\textsubscript{2}) and heart rate\textsuperscript{10,11}, based on the physiological principle that oxygenated and deoxygenated hemoglobin have different absorption spectra\textsuperscript{9,12}. In some studies, a saturation difference between right upper extremity (ductal) and lower extremity (post-ductal) of $\geq 7\%$ in the first six hours of life or a lower extremity saturation of $< 92\%$ are considered abnormal\textsuperscript{13}. In Mexico, performing pulse oximetry is not a universal policy for newborn screening, although early detection of CHD is crucial for survival in these newborns. Thus, the aim of this study was to evaluate pulse oximetry as a screening test for critical congenital heart disease (CCHD) in term neonates.

**METHODS**

**Study design and population**

The study was approved by the research and ethics committees of the hospital. In July 2010 to April, 2011 we conducted a prospective, cross-sectional study of newborns of $> 6$ hours of age. The study included consecutive infants born at our hospital, irrespective of mode of delivery, in whom no CHD was suspected and who were available during the working hours of the investigators. We excluded newborns with lung diseases or whose parent or guardian did not sign the informed consent. Due to a policy of early discharge in our hospital, the mean age at pulse oximetry screening was 12 hours. The clinical records of all newborns were reviewed at six months of age to identify whether any heart disease was diagnosed after hospital discharge.

**Pulse oximetry screening**

Saturation of peripheral oxygen (SpO\textsubscript{2}) was measured using a portable Rad-5\textsuperscript{™} handheld pulse oximeter with multisite sensor that prevents the pulse wave from changing with the neonate’s movements. This pulse oximeter signal is obtained by subtraction, making it more reliable than other equipment (Nellcor N-395, Novametrix MARS, and Philips Viridia 24C Rev BO), and has higher sensitivity and specificity\textsuperscript{14}. The measurement was taken during two minutes in the left lower extremity (post-ductal) until the reading remained the same in two determinations; the measurement was performed under physiological sleep and by only one member of the study team.

**Echocardiography**

In case the SpO\textsubscript{2} was $< 95\%$, Doppler echocardiography was performed in the Pediatric Cardiology Department to detect a probable CHD. Patients with CCHD were admitted to the neonatal intensive care unit and were followed until discharge from the hospital. We included a control group of 28 healthy newborns with normal clinical examination and SpO\textsubscript{2} $> 95\%$ for evaluation by Doppler echocardiography.

**STATISTICAL ANALYSIS**

We used descriptive statistics and analysis of quality of statistical test: sensitivity, specificity, positive predictive value, negative predictive value, and likelihood ratio. A logistic regression analysis was performed to identify variables related with all CHD and CCHD. Statistical analyses were performed using Statistica 6.0 software.

**RESULTS**

We evaluated 1,037 neonates, of whom 42.1\% were delivered by caesarean section. Mean birth weight was 3,000 g, and mean age at pulse oximetry screening was 12 hours (range, 6-48) (Table 1).

Fourteen (1.35\%) patients were referred to pediatric cardiology because of a SpO\textsubscript{2} $< 95\%$. These newborns also had a heart murmur at auscultation. Only 12 were true positives; of them, two had CCHD: one had pulmonary atresia and a ventricular septal defect, and the other one had Ebstein’s anomaly. The remaining 10 babies had mild CHD: five had patent ductus arteriosus (PDA) and foramen ovale (FO), two had PDA + FO + pulmonary hypertension (PH), one had PDA + PH + mild mitral insufficiency, and two had an atrial septal...
had cyanosis, one with pulmonary atresia and one with Ebstein’s anomaly.

Of the 12 patients with CHD, two (16.6%) underwent surgery, eight (66.6%) received follow-up in pediatric cardiology, and two (16.6%) were admitted to the neonatal intensive care unit, but there were no deaths.

As the purpose of the study was early diagnosis of CCHD, minor CHD in 10 children was classified as false positive for screening by pulse oximetry, thus obtaining a very good sensitivity, specificity, and negative predictive value, but low positive predictive value for this procedure in CCHD. However, these values increased when we considered screening for all CHD (Table 3).

In logistic regression analysis we found that oxygen saturation, respiratory frequency, and temperature were associated with all CHD, while oxygen saturation, respiratory frequency, and postnatal age were the variables associated with CCHD (Table 4).

**DISCUSSION**

Pulse oximetry proved to be a useful screening tool for the identification of congenital heart disease in the first hours after birth, as other studies have reported\(^{15-17}\).

From the 14 neonates with a murmur at auscultation, 12 had CHD and in eight of them (all with PDA) this abnormality was detected in their pulses. Two babies had cyanosis, one with pulmonary atresia and one with Ebstein’s anomaly.

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Table 3. Pulse oximetry screening for the detection of congenital heart disease in term newborns

<table>
<thead>
<tr>
<th></th>
<th>Values for all congenital heart diseases</th>
<th>Values for critical congenital heart diseases</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sensitivity (%)</td>
<td>100 (73.5-100)</td>
<td>100 (15.8-100)</td>
</tr>
<tr>
<td>Specificity (%)</td>
<td>99.8 (99.3-99.9)</td>
<td>97.9 (98.2-99.4)</td>
</tr>
<tr>
<td>Likelihood ratio</td>
<td>512 (128-2,046)</td>
<td>86.2 (49.1-151.3)</td>
</tr>
<tr>
<td>Positive predictive value (%)</td>
<td>85.7 (57.1-98.2)</td>
<td>14.2 (1.7-42.8)</td>
</tr>
<tr>
<td>Negative predictive value (%)</td>
<td>100 (99.6-100)</td>
<td>100 (99.6-100)</td>
</tr>
</tbody>
</table>

Values are shown as mean (95% CI).

The prevalence of all CHD (11.5 per 1000 live births) was similar to other populations\(^{18-20}\) and PDA was the single most common defect, followed by atrial septal defect.

There were no deaths from CCHD in this cohort. Although false positives of pulse oximetry represented 0.19%, similar to the results of Granelli, et al., who reported 0.17\(^{21}\), this screening test proved essential because mortality in early versus late detection of CCHD could be as different as 0.9 and 14.8%, respectively\(^{10,13,22,23}\). A delayed diagnosis has been estimated between 13.8 and 29.5% of live-born infants with nonsyndromic CCHD who could have benefited from routine screening at birth hospitals\(^{24,25}\).

Newborns with CCHD had an oxygen saturation of < 95%. This is consistent with data from Tapia-Rombo, et al.\(^{15}\), who reported that oxygen saturation of term infants at sea level is 97-100%, and in preterm infants, it is 95-100%; oxygen saturation below these values is considered abnormal in the first 24 hours of life\(^{25}\). De-Wahl Granelli, et al., in a study of 39,530 patients, reported similar sensitivity and specificity values after including non-cyanogenic CHD\(^{21}\).

In regression analysis, we found that low oxygen saturation and low temperature, but high respiratory frequency, were related to all CHD. High respiratory frequency could be related to peripheral airway obstruction that occurs in children with pulmonary hypertension associated to CHD\(^{24}\). Furthermore, in children with CHD, even after surgical repair of the malformations, pulmonary function is often abnormal and there is ventilatory limitation to exercise\(^{27}\). We do not have a clear explanation of the high body temperature found in this study because it was related with all CHD but not with CCHD alone when these were analyzed separately. Finally, low oxygen saturation, high respiratory frequency, and early postnatal age were the variables associated with CCHD, demonstrating the accuracy of pulse oximetry in this diagnosis.

Limitations of our study are that we performed only post-ductal measurement, and we did not perform Doppler echocardiography on all newborns. However, this study included a large sample size, and all patients were followed for six months to allow for detection of CCHD that may have been diagnosed after the screening test. Another advantage of our study is that the pulse oximeter used in this study precluded changes in oxygen saturation readings caused by the neonate’s movements. Furthermore, other studies have also performed only post-ductal measurement\(^{28}\).

Although many studies have shown that pulse oximetry is useful in the diagnosis of CHD\(^{29-32}\), few studies...
have been conducted in Latin American populations. According to our results, we consider that pulse oximetry must be implemented as a routine screening test in all newborns, as proposed by the American Heart Association and the American Academy of Pediatrics.

REFERENCES

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