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ORIGINAL ARTICLE

Pulse oximetry test in a reference unit - evaluation after 3 years of implementation as a universal screening test

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Abstract

Introduction: The present study searched to evaluate the results of pulse oximetry test in the screening of critical congenital heart disease in a public maternity hospital in Brazil, especially regarding the rate of positive and false positive tests. **Methods:** A descriptive, retrospective and cross-sectional study was conducted by collecting data from the oximetry test logbook and from an electronic medical record from January to December 2018.The results were compared with the others described in the literature. **Results:** 1,976 pulse oximetry tests were performed, with 303 alterations initially. 52 newborns had kept the altered test after retest, and 39 newborns were excluded. Among the altered tests, 9 congenital heart defects were found, but no critical congenital heart defects, generating 2.6% of false positive tests. **Conclusion:** The pulse oximetry test as a neonatal screening tool was important for the diagnosis of newborns with congenital heart disease, even though no cases of critical congenital heart defects. The number of false positive tests observed was much higher than reported in the literature, causing indirect costs in length of hospital stay, unnecessary examinations and family anxiety.

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INTRODUCTION

Congenital heart disease is the most common congenital anomaly in newborns, and also the one with the highest mortality[1-3]. It has an estimated prevalence of between 6-8 per 1000 live births[3]. It is responsible for 6 to 10% of infant deaths, and for about 50% of infant mortality linked to congenital malformations[1].

About 1-2 in every 1000 live births will have critical congenital heart disease, a serious cardiac anomaly, requiring corrective or palliative surgical intervention with catheter placement within the first year of life[4]. These are heart diseases in which the systemic or pulmonary circulations are dependent on the patency of the ductus arteriosus, so that, if the latter is closed or flow restricted, there will be hemodynamic decompensation with shock, acidosis, neurological sequelae and death[3,5].

Up to 30% of newborns with CCC may be asymptomatic in the first days of life[6]. As the physical examination is able to detect only about 32% of CCC[5], performing a screening test is essential and can reduce morbidity and mortality related to the late diagnosis of a CCC[5,7].

Screening tests aim to detect a group of individuals most likely to have a particular pathology. Neonatal screening tests are performed on children between 0 and 30 days of life, aiming at the early diagnosis of metabolic, hematological, anatomical, infectious pathologies, among others, that may impair the somatic, neurological and/or psychological development of the newborn. born, enabling early intervention to improve the prognosis of these patients[8].

The pulse oximetry test is recommended by the American Academy of Pediatrics (AAP), the American Heart Association (AHA), and the American College of Cardiology[9]. The Brazilian Society of Pediatrics (SBP) recommends performing the test on all apparently healthy newborns over 34 weeks of gestational age, between 24 and 48 hours of life, respecting the guidelines for performance, to maintain the sensitivity of the test. at 75% and specificity at 95%[5].

There is still no consensus in the world about the ideal technique for performing the test, and studies using different techniques (location of oximetry and cut-off point) have been published over the years[10]. The technique recommended by the AAP and AHA differs from the one chosen as a protocol by the SBP, which requires a saturation difference of at most 2% between pre- and post- ductal oximetry for the test to be considered normal.

Despite satisfactory sensitivity and high specificity, if there are flaws in the technique of its performance or even in the equipment used, an unacceptable number of false positives can be generated[11]. It is important to emphasize that the finding of positive tests, whether true or false, brings anxiety and anguish to the newborn's family, in addition to requiring additional tests such as the echocardiogram, generating costs and longer hospital stay.

About 3 years ago, in a public maternity hospital in the Federal District, a study was carried out that detected the need to review protocols and processes, train teams and adapt the equipment used, due to the high rate of false-positives, about of 5%[12], contrasting with the world result, which varies around 0 to 1.8%[11].

The current work aimed to analyze the results of performing the test in the same service, especially regarding the rate of positive and false positive tests.

METHODOLOGY

This is a descriptive, retrospective and cross-sectional study, carried out by collecting data in the oximetry test record book from January to December 2018. This book records all tests performed on babies hospitalized in a regional public maternity hospital in the DF. When it was necessary to perform the echocardiogram according to the protocol or when there were doubts in the book record, the patient's electronic medical record was accessed.

All newborns born in this maternity hospital and admitted to the rooming-in sector of this hospital were included in the study, with a pulse oximetry test performed and duly noted in the examination record book.

The pulse oximetry test is performed between 24-48 hours of life, by the nursing technician responsible for the daily care of each NB, according to the shift schedule. The Dixtal Biomédica 2021® device is used, most of the time with only one sensor, which is initially positioned on the right upper limb of the newborn, recording the value obtained with a good oximetry curve, and then repositioned on the lower limb. , right or left. When a second device (of the same brand) is available, the measurement takes place simultaneously. When the test is altered, it is repeated in 24 hours (retest) also by the nursing technician assigned to patient care.

The flowchart used is that of the Brazilian Society of Pediatrics, and the cut-off point is the SpO2 value < 95% or a difference between pre- and post- ductal saturation ≥ 3%. In the protocol, it is oriented that, if the test is altered, a retest must be performed within 1 hour, and if the alterations are maintained, an echocardiogram must be performed before hospital discharge.

Patients with a gestational age of less than 34 weeks were excluded from this study; patients who did not complete the pulse oximetry test due to early discharge or by requesting an echocardiogram before the end of the test; patients with a lack of information in the exam record book or in the electronic medical record and even patients with a gestational diagnosis of critical congenital heart disease.

The following data were collected from the registry book: a) gestational age; b) value of the oximetry test; c) value of the retest when performed; d) result of the echocardiogram.

The data found were analyzed and compared with data reported in other literature on the subject.

RESULTS

In the period between January and December 2018, 1976 pulse oximetry tests were performed, 1673 of which were normal and 303 abnormal in the first test.

Of the 303 altered tests, 212 were considered normal after retest, 52 NB had altered retests and 39 were excluded from the study.

Among the altered tests, 39 tests were excluded, 10 due to misidentification of the medical record (SES), 6 due to being less than 34 weeks of gestational age, 6 due to being discharged without performing an echocardiogram, 10 children due to being discharged without the performing the retest after the first altered test and 7 newborns for performing the echocardiogram without performing the pulse oximetry retest.

No case of CCC was identified during the study period, among patients who underwent echocardiography, either before or after retest.

Of the 52 patients with altered retests who underwent echocardiography, 21 had a normal result, 21 had a patent foramen ovale, and 9 had identified, but not critical, congenital heart disease, all without cardiac or hemodynamic symptoms. (Table 1)

Table 1. Result of echocardiograms of patients with altered retest.

Result	The amount
Normal	21
Pervious foramen ovale	21
Interatrial Communication	3
Patent foramen ovale + ventricular septal defect	2
ductus arteriosus persistence	2
Patent foramen ovale + pulmonary hypertension	1
Patent foramen ovale + patent ductus arteriosus + pulmonary hypertension	1
Patent foramen ova + aortic hypoplasia	1
TOTAL	**52**

Nine newborns were found with congenital heart disease (0.46%), but none with critical congenital heart disease. Among the oximetry tests performed completely, according to the SBP flowchart, there were a total of 52 positive tests without the diagnosis of critical heart disease, which corresponds to a total of 2.6% false positives.

Seven patients underwent echocardiography before the retest, and in 4 of them the presence of congenital heart disease was identified, being 3 NB with atrial septal defect, 1 of these associated with patent ductus arteriosus and another with mitral and tricuspid regurgitation and 1 NB with communication interventricular, as shown in Graph 1.

DISCUSSION

In the present study, a screening test was performed in 1976 newborns, and 9 cases (0.46%) of congenital heart disease and no critical congenital heart disease were identified.

While Hu et al, in Shanghai, China, performed 167,190 tests and identified 206 cases of congenital heart disease (0.12%), 34 of which were critical congenital heart defects (0.02%)[13]. Hoke et al, found 4 CCC (0.13%) among a total of 2972 tests and did not differentiate other non-critical congenital heart diseases[14].

Regarding false positives, the current study found 2.6% of false positives, while Hu et al obtained a total of 0.19%[13] and Hoke et al 1.8%[14].

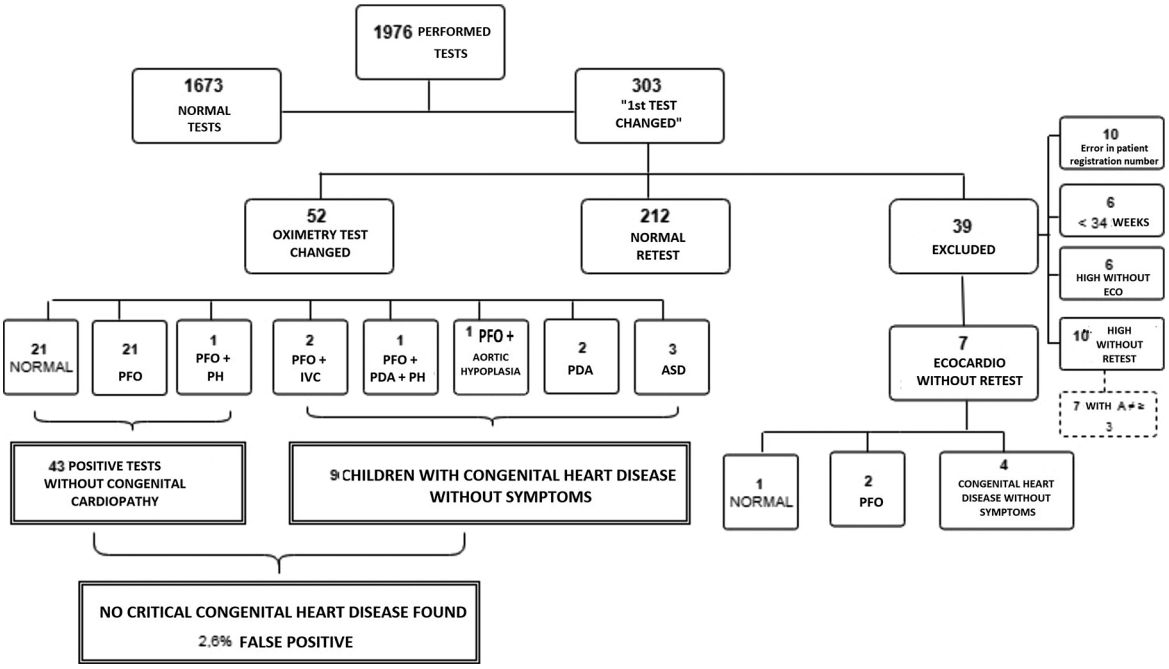
Both studies used different flowcharts from the one applied in this unit. Hoke et al used a flowchart with an echocardiogram indication if $SpO_2 \leq 92\%$ or difference between pre and post ductal saturation $\geq 7\%$, repeating the test at 6 and 24 hours of life[14], and Hu et al consider the same cut-off point as in the present study, but with greater tolerability of the difference between pre- and post- ductal saturation , accepting values up to 3%[13].

When comparing the present study with that of Lima, carried out at the same service in 2015, we observed that 1052 NB were evaluated with the oximetry test, finding 72 NB with a positive test, of which 35 had CC (3.32%), but none child was identified with CCC. It found a total of 5.4% false positives[12]. In Arkansas, Andrews et al, used a protocol with a cutoff point of < 95% or a difference of < 3%, evaluating a total of 1905 NB, with 3 positive tests that were later submitted to an echocardiogram, with a false positive (0.05%) with FOP and two newborns with atrial septal defect[15].

In Dallas, Texas, Sendelbach et al selected 15233 newborns for the study. During hospitalization, 77 children had physical examination findings that led directly to echocardiography, and of these, one had tetralogy of Fallot. 768 were evaluated by a repeat pulse oximetry test, and 767 tested negative. Only 1 NB persisted with a positive pulse oximetry, and had a normal echocardiogram, resulting in a total false positive of 0.06%[16].

Ewer et al, gathered data from 20055 newborns in the United Kingdom who were screened with pulse oximetry, of which 195 had abnormal results, and 192 underwent echocardiography for investigation, with 32 congenital heart diseases (0.15%) being found CCC (0.08%) and 163 NB with false positive results (0.8%)[17].

We can observe that between the two studies carried out in the same unit, in 2015, shortly after the implementation of the pulse oximetry test, and the current study, in 2019, there were some improvements, probably after training the initial team, resulting in a lower number of false positives after 3 years of screening. However, 2.6%



Graphic 1. Results of oximetry tests and echocardiograms. FOP: Pervious foramen ovale; HP: Pulmonary Hypertension; IVC: Interventricular Communication; PDA: Patent ductus arteriosus; ASD: Interatrial Communication.

is still a high number, which differs from all the literature described, being twice as high as the study with the highest number of false positives, carried out in John Hopkings Hospital and Baltimore Hospital, between 1993 and 1995, at which time the training and dissemination of pulse oximetry testing was not well established.

Table 2 describes the results of several studies carried out around the world regarding the oximetry test for the diagnosis of CC and CCC.

The high rate of false positives observed in the present study should be appreciated, since patients who need to wait for an echocardiogram have a prolonged hospital stay, in addition to suffering immeasurable stress and worries. In addition, the feasibility of applying the oximetry test could even be questioned, considering the high cost generated by it in prolonged hospitalizations and performing unnecessary echocardiograms.

In our unit, 2.6% of the patients who underwent the test were referred for echocardiography. In Ever 's study[17], 0.95% of patients were referred for echocardiography and in Andrews' study[15], only 0.15%.

A series of limitations were identified in the unit where the study was carried out that may explain the result different from that obtained in other places in the world: 1) there is no continuous training of the team members assigned to perform the oximetry test. Such training was carried out in the implementation of the test, but over the years new professionals joined the team and were not trained. It can also be observed that in some studies, the professional responsible for the screening test is directed only for this purpose, and in the study in question, the person who performs the test is the same professional responsible for the daily care of the patient; 2) the use of a single monitor to perform the test, and the use of a sensorless oximeter with motion control, which may contribute to the large number of false positives found.

In this study, some difficulties were encountered in data collection, due to the low standardization of the notes in the exam record book and in the medical record, with loss of some data.

It was also observed occasions of hospital discharge without performing an echocardiogram, especially when the test was positive due to a difference between pre- and post-ductal saturation >3%.

It should also be noted that it was not possible to carry out the follow - up of the newborns in this unit, making it impossible to carry out a prospective study and analysis of the clinic and findings after hospital discharge, which if it could be performed, could enrich the study with false-negative result data.

It is concluded that neonatal screening with the pulse oximetry test allowed the identification of patients with normal clinical examination , but who had congenital heart disease. Although we have not identified cases of CCC, the search for this pathology associated with high morbidity and mortality is still justified.

The training of teams in the execution, recording and interpretation of the pulse oximetry test is essential for its routine use to be useful and the direct and indirect costs reasonable for the health units and the families served by it.

Table 2. Oximetry tests.

Author	Lima (2015)[12]	Carvelo et al. (2019)	Hu et al. (2017)[13]	Hoke et al. (2002)[14]	Andrews et al. (2014)[15]	Sendelbach et al. (2009)[16]	Ewer et al. (2011)[17]
place of study	Brasília, Brasil	Brasília, Brasil	shanghai, china	Jonh Hopkings e Baltimore Hospitals	Arkansas, EUA	Dallas, EUA	Reino Unido
Total RN	1052	1976	167190	2972	1905	15233	20055
study period	January-June 15	January 18 - December 18	July 12 - Dec 14	August 93 - February 95	January 12 - December 12	March 06 - February 07	February 08 - January 09
Oximetry measurement	Pré e pós-ductal	pre and post ductal	pre and post ductal	pre and post ductal	pre and pos ductal	pre and post ductal	pre and post ductal
Saturation cut-off point	<95%	<95%	<95%	= 92%	<95%	<96%	<95%
Pre- and post-ductal difference	= 3%	= 3%	>3%	=7	>3%	-	=2%
retest number	1	1	1	1	1	1	1
responsible for the test	Team responsible for the patient	Team responsible for the patient	-	nursing team	trained nurses	Trained technicians not involved in daily care	trained health professionals
Equipment	Solo DC 2515 - Dixtal	Dixtal Biomedical 2021	-	Nelicor 50	motion tolerant oximeters	Nellcor N-395	Radical 7
CC	11	9	206	-	-	-	32
CCC	0	0	34	4	2	0	18
False positive	5%	2.60%	0.19%	1.80%	0.05%	0.06%	0.80%

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