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Evaluation of the Newborn Heart Screening Test as a Screening Method for Congenital Heart Disease in a Public Hospital in Western São Paulo

Evaluation Of The Newborn Heart Screening Test As A Screening Tool For Congenital Heart Disease In A Public Hospital In Western São Paulo

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Summary

Congenital heart defects are structural defects of the heart and represent approximately 30% of all congenital malformations, with an incidence of 9.4 cases per 1000 live births, being the most common congenital disease in newborns. Critical considerations include heart defects manifesting in the neonatal period and complications from surgical intervention or interventional catheterization in the first days of life or up to the end of the first month of life, approximately 2 per 1000 live births. In these cases, there is a mixing of systemic and pulmonary blood circulation with reduced peripheral oxygen saturation; therefore, routine pulse oximetry measurement allows for early detection and referral for specific tests. Objective: To evaluate the incidence of positive newborn heart screening tests at the Regional Hospital of Presidente Prudente - SP from July 2022 to June 2024 and compare it with data found in current literature. Methodology: This was a retrospective cross-sectional study using medical record review, examining newborns who underwent echocardiography before hospital discharge with a gestational age of 35 weeks or greater, who were asymptomatic, in a rooming-in setting, and who underwent pulse oximetry between 24 and 48 hours of life with a positive result. Results: 2057 newborns were evaluated, 4 presented with an abnormal newborn heart screening test, corresponding to an incidence of 0.19%. After follow-up and reassessment, the final diagnosis was normal in 100% of cases. Discussion: Evaluating the diagnosis of the identified heart conditions, none were described as critical, all presenting around 1 year of age as simple heart conditions without clinical repercussions. Their identification in the newborn heart screening test contributed to early referral to a specialist physician. Conclusion: Pulse oximetry testing is a mandatory assessment for both screening and diagnosis of critical congenital heart disease as well as non-critical congenital heart disease.

Keywords: Congenital heart disease. Neonatal screening. Newborn heart screening test.

Abstract

Congenital heart defects are structural defects of the heart and represent approximately 30% of all congenital malformations, with an incidence of 9.4 cases per 1000 live births, being the most common congenital disease in newborns. Critical considerations include heart defects manifesting in the neonatal period and complications from surgical intervention or interventional catheterization in the first days of life or up to the end of the first month of life, approximately 2 per 1000 live births. In these cases, there is a mixing of systemic and pulmonary blood circulation with reduced peripheral oxygen saturation; therefore, routine pulse oximetry measurement allows for early detection and referral for specific tests. Objective: To evaluate the incidence of positive newborn heart screening tests at the Regional Hospital of Presidente Prudente - SP from July 2022 to June 2024 and compare it with data found in current literature. Methodology: This was a retrospective cross-sectional study using medical record review, examining newborns who underwent echocardiography before hospital discharge with a gestational age of 35 weeks or greater, who were asymptomatic, in a rooming-in



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setting, and who underwent pulse oximetry between 24 and 48 hours of life with a positive result. Results: 2057 newborns were evaluated, 4 presented with an abnormal newborn heart screening test, corresponding to an incidence of 0.19%. After follow-up and reassessment, the final diagnosis was normal in 100% of cases. Discussion: Evaluating the diagnosis of the identified heart conditions, none were described as critical, all presenting around 1 year of age as simple heart conditions without clinical repercussions. Their identification in the newborn heart screening test contributed to early referral to a specialist physician. Conclusion: Pulse oximetry testing is a mandatory assessment for both screening and diagnosis of critical congenital heart defects as well as non-critical congenital heart defects.

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1 INTRODUCTION

Congenital heart diseases are structural defects of the heart that are present at birth. fetal and birth defects, which account for approximately 30% of all congenital malformations. (ZAIDI *et al.*, 2017), with an incidence of around 9.4 cases per 1000 live births according to A recently published study (LIU *et al.*, 2019) makes the most common congenital disease in newborns. It represents a heterogeneous group of diseases, ranging from heart conditions. ranging from simple heart conditions with no clinical repercussions to complex heart diseases with a high potential for severity, being responsible for the majority of deaths resulting from congenital malformations, accounting for 10% infant mortality accounts for 15% of deaths (WREN *et al.*, 2007), but can represent up to 30% of deaths. resulting from congenital malformations. (SILVA *et al.*, 2022)

Critical congenital heart diseases (CCHs) are defined as those that manifest during the period... neonatal patients with hypoxia, heart failure, or low systemic output who require surgical intervention or interventional catheterization in the first few days of life or up to the end of the first month of life (SCIENTIFIC DEPARTMENT OF CARDIOLOGY AND NEONATOLOGY, 2022), representing about 25% of all cases (approximately 2:1,000 live births (GRANELLI *et al.*, 2005). Critical congenital heart diseases include those cyanotic and duct-dependent (the ductus arteriosus is responsible for maintaining circulation) pulmonary or systemic, or allows a mixture between these circulations in heart diseases in which the neonatal circulation is maintained in parallel) (SILVA *et al.*, 2022), and its functional closure This occurs in the vast majority of newborns (NB) within the first 72 hours of life. At the time of Hospital discharge, between 24 and 48 hours after birth for most newborns, may not yet present with clinical signs. It is common for the physical examination to be unremarkable, including on cardiac auscultation. apparently normal, and hypoxemia may not yet have clinical manifestations, especially if the Oxygen saturation is greater than 80% or there is associated anemia (COCAM, 2021). When diagnosed, The treatment needs to be carried out in specialized cardiology and cardiac surgery centers. neonatal units, which are generally located geographically far from maternity wards, make it... Treating these babies is a major challenge for our healthcare system, given that we have to



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to be able to quickly identify a newborn with heart disease, stabilize their clinical condition and hemodynamic monitoring is necessary, and after that, the patient can be transferred to a referral center. cardiological. The diagnosis of these heart conditions should preferably be made in the pre- or post-cardiological period. immediate postnatal care, since the risk of morbidity and mortality increases when there is a delay in... diagnosis (SCHULTZ *et al.*, 2008). Currently, it is estimated that about 30% of patients with Critical congenital heart disease is still only diagnosed after discharge from the nursery. (MELLANDER *et al.*, 2006).

In the CCC group, there is a mixing of blood between the systemic and pulmonary circulations. which leads to a reduction in peripheral oxygen saturation. Therefore, pulse oximetry measurement Routine testing allows for the detection of low oxygen levels and referral of the newborn for evaluation. specialized clinic, as well as for carrying out specific tests aimed at diagnosis. definitive (COCAM, 2021). Thus, the use of pulse oximetry is considered as A "screening" tool for detecting these heart conditions before discharge from the nursery could increase Early diagnosis allows for more appropriate initial management. (SILVA *et al.*, 2022)

In August 2022, the scientific departments of cardiology and neonatology of the Society The Brazilian Society of Pediatrics published a scientific document that systematizes the care of newborns. Born with suspected or diagnosed congenital heart disease. Pulse oximetry should be performed. routinely in all newborns with a gestational age of 35 weeks or more and who They are clinically well, asymptomatic, and living in a shared accommodation setting. The test should be Ideally performed between 24 and 48 hours of life, with oximetry measurement at two sites: hand right (pre-ductal measurement) and in one of the lower limbs (post-ductal). This is considered normal. SpO2 greater than or equal to 95% and a difference in SpO2 between the right upper limb and one of the Lower limb oxygen saturation less than or equal to 3%. If SpO2 is less than or equal to 89%, it is considered a test. The test result is positive and a cardiological and echocardiographic evaluation should be performed; discharge is not expected. Hospitalization is required before this assessment is performed. If SpO2 is between 90% and 94% or a difference If the difference between the measurements of the right upper limb and the lower limb is greater than or equal to 4%, the test should... The test should be repeated after one hour, up to two times. If the measurements remain the same, the test... It will be considered positive and the newborn should undergo cardiological/echographic evaluation (SCIENTIFIC DEPARTMENT OF CARDIOLOGY AND NEONATOLOGY, 2022) . Changes found when using pulse oximetry to diagnose suspected congenital heart disease. Critical tests in newborns showed a sensitivity of 76% and specificity of 99% for the definitive diagnosis (PLANA *et al.*, 2018).

With the aim of analyzing the incidence of a positive heart screening test (oximetry) in a Public Hospital in Western São Paulo, as well as the pathologies diagnosed through the performance of Echocardiogram, we will perform this study.



1.1 Justification

There is a scarcity of records of analyses evaluating the use of pulse oximetry as a screening tool of critical congenital heart diseases in Western São Paulo, as well as its correlation with data from current literature.

2. OBJECTIVE

2.1 General objective

To assess the incidence of positive newborn heart screening tests at the Regional Hospital of Presidente Prudente - SP during the period from July 2022 to June 2024 and compare with the data found in current literature.

2.2 Specific objective

Analyze the pathologies found in positive tests, incidence of clinical pathologies and Surgical procedures were found and followed up with a final diagnosis.

3. METHODOLOGY

Retrospective cross-sectional study using electronic medical record review. searching all newborns with a gestational age equal to or greater than 35 weeks and who They were clinically well, asymptomatic, living in a shared accommodation setting, and that They underwent pulse oximetry between 24 and 48 hours of life, without a prior diagnosis of heart disease. during prenatal care from July 2022 to June 2024 at the Regional Hospital of Presidente Prudente - SP, a public hospital and a reference center for medical care for 45 municipalities in the West. Paulista. The inclusion criteria are patients with a gestational age equal to or greater than 35 weeks. weeks ago, they were clinically well, asymptomatic, and in a residential setting. The group consisted of infants who underwent pulse oximetry between 24 and 48 hours of life, without a prior diagnosis. The diagnosis includes heart disease during prenatal care and a positive pulse oximetry test result. A positive test is indicated when oxygen saturation is less than or equal to 89% in the right upper limb or in the... lower limb in the first measurement, or saturation between 90% and 94%, or a difference between the measurements of the right upper limb and lower limb greater than or equal to 4% after 2 retests with each interval is 1 hour. The exclusion criteria are newborns younger than 35 weeks.



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Newborns diagnosed with heart disease during prenatal care but with incomplete medical records.

Patient data as well as information regarding clinical progress will be obtained.

through a review of electronic medical records from July 2022 to June 2024.

The gestational age, as determined by the New Ballard method, will be assessed along with the initial physical examination.

complete information, birth weight, sex, and the result of the pulse oximetry test. Based on the test...

If a positive result is obtained, the diagnoses found through echocardiography will be evaluated.

Thus, the primary outcome is the measurement of positive newborn heart screening tests and their correspondence with current literature, and identifying the diagnosed pathologies. The risks

They understand the risk of data leaks, and the benefits are knowing the local reality.

The research will follow the guidelines of the Ethics and Research Committee of the Regional Hospital.

Project approval. Registration on the Brazil Platform and the Management System will also be carried out.

Research Group (SGP) of the University of Western Paulista.

3.1 Statistical Analysis

The statistical analysis was performed using the Action Stat software, integrated with Microsoft Excel and based on the R programming language. Initially, a descriptive analysis of the data was performed with the aim of characterizing the studied sample. For the quantitative variables, the following were calculated Descriptive measures (mean, minimum, maximum, standard deviation, and coefficient of variation). The variables Qualitative data were described using absolute and relative frequencies.

4. RESULTS

The results were organized into two stages, according to the nature of the variables. analyzed: initially, the findings regarding the categorical variables are presented and discussed. followed by the analysis of quantitative variables, described by means of descriptive measures. The data The clinical and diagnostic findings presented were obtained from the analysis of medical records and results. of the echocardiographic examinations performed after the abnormal screening, as shown in Table 1.

Among the 2057 newborns evaluated, 4 presented with abnormal heart screening results. corresponding to an incidence of 0.19%. This value is consistent with the literature, which describes a low rate of positive tests, especially in general populations, reinforcing the character of screening for the exam.

With regard to sex, a predominance of males was observed, with 75% ($n = 3$) of the cases, while 25% ($n = 1$) were female. Although the sample is small, this finding This is consistent with some of the literature, which describes a higher prevalence of certain heart conditions.

congenital conditions in males.

Regarding prematurity, half of the newborns with abnormal test results were premature (50%). while the remaining 50% were born at term. Prematurity is described as a factor associated with higher chance of false-positive results in pulse oximetry, due to adaptations physiological changes in the cardiorespiratory system during the neonatal period.

Regarding birth weight, 75% (n = 3) had adequate weight and 25% (n = 1) They were classified as low birth weight. This finding reinforces the clinical heterogeneity of newborns. born with abnormal test results.

Regarding the initial echocardiographic diagnoses, abnormalities were identified. Non-critical conditions without clinical repercussions, such as patent foramen ovale, mild valvular insufficiency. and small cardiac communications, each accounting for 25% of cases.

After follow-up and reassessment, the final diagnosis was normal in 100% of cases. showing that all the altered heart tests in this study corresponded to results. False positives, without confirmation of a definitive critical congenital heart disease.

For the quantitative variables, measures of central tendency and measures of... were calculated. dispersion, as shown in Table 2.

Table 1 - Analysis of categorical variables described by descriptive measures

VARIABLE	CATEGORIES	N %
SEX	Masculine	3 75%
	Feminine	1 25%
PREMATURE?	Yes	2 50%
	No	2 50%
TERMS	Yes	2 50%
	No	2 50%
DIAGNOSIS HOME	Patent foramen ovale + Mild right ventricular hypertrophy	1 25%
	Small ostium secundum type atrial septal defect	1 25%
	Size + Trabecular muscular ventricular communication + Mild mitral regurgitation	
	Moderate tricuspid regurgitation.	1 25%
	Patent foramen ovale + Aortic shelf with aortic isthmus measuring at smallest diameter 4.5mm (-1.0oz)	1 25%
DIAGNOSIS	Normal	4 100%

END		
WEIGHT	Adequate	3 75%
	Low weight	1 25%

Source: Medical records analyzed

Table 2 - Descriptive measures for quantitative variables with their respective coefficients of variation

	AGE GESTATIONAL (DAYS)	WEIGHT BIRTH (G)	OF POSTNATAL AGE OF ECO REALIZATION (DAYS) (OF LIFE)
MINIMUM	247	2120	2
MAXIMUM	270	3460	3
AVERAGE	258	2856.25	2.5
Standard Deviation	11.50	671.09	0.50
COEFFICIENT of VARIATION	4.46%	23.50%	20.00%

Source: Medical records analyzed

Gestational age ranged from 247 to 270 days, with a mean of 258 days and a standard deviation of 11.5 days and a coefficient of variation of 4.46%, indicating low variability among newborns. evaluated. In clinical terms, these values correspond to a range of 35 weeks and 2 days. 38 weeks and 4 days of gestation, with an average of 36 weeks and 6 days and a standard deviation of 1.6 weeks. predominantly characterized by late preterm or borderline newborns. late prematurity and term prematurity.

Birth weight ranged from 2120 g to 3460 g, with an average of 2856.25 g. standard deviation of 671.09 g. The coefficient of variation of 23.5% suggests moderate dispersion, reflecting a data distribution that is reasonably consistent with balance between the samples.

The postnatal age at the time of the echocardiogram ranged between 2 and 3 days. life expectancy, with an average of 2.5 days and a coefficient of variation of 20%, indicating a relatively high distribution. homogeneous across cases.

In general, descriptive measures of quantitative variables indicate a sample. small, but clinically diverse, consistent with the expected profile of newborns.

Patients were submitted for investigation after an abnormal heart screening test.

5. DISCUSSION

This study sought to identify asymptomatic newborns without a diagnosis.



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previous diagnosis of congenital heart disease during prenatal care, who had a positive newborn heart screening test, as well as the identified pathologies, clinical profile with variables of weight, gestational age and sex, and the outcome. with a final diagnosis after outpatient follow-up. The Regional Hospital is the health center.

A reference for the western region of São Paulo state, allowing access to a broad database for analysis.

2057 live births were evaluated, of which 4 presented with the newborn heart screening test. altered, corresponding to an incidence of 0.19%. In one of the largest studies to investigate the The accuracy of pulse oximetry testing in detecting congenital heart disease in the United Kingdom was 20,055 newborns were investigated in six maternity hospitals in the United Kingdom who were All babies were asymptomatic and underwent pulse oximetry screening before discharge. followed up until 12 months of age, in which 53 presented severe congenital heart disease (24 critical cases), with a prevalence of 2.6 per 1000 live births, presenting false-positive in 0.8% of newborns. Therefore, if these results were replicated in a In a population of 100,000 babies, approximately 264 would present with severe congenital heart defects. of which 130 would be identified by means of pulse oximetry (EWER et al., 2011).

Another study conducted in Brazil analyzed 10,053 newborn heart screening tests, of which 42 Newborns presented with abnormalities, which corresponds to 0.41% of the total. In this study, of those who 15 had abnormal test results, 15 repeated the heart test with normal results, and 11 presented Echocardiogram result of heart disease. Of the 11 babies considered, 6 presented this result. Normal and 5 remained with the test abnormal. Of those that remained abnormal, congenital heart disease. Criticism was identified in 1 patient (NASCIMENTO; ROSA; FARIAS, 2024).

In a 2017 systematic review for evidence on the use of pulse oximetry for To detect critical congenital heart disease in newborns, 19 studies with 436,758 participants were analyzed. newborns, noting in the review that for every 10,000 apparently healthy babies Of those examined, approximately six will present with critical congenital heart disease. The newborn heart screening test... will correctly identify five of these newborns. Thus, current evidence supports the Use of pulse oximetry testing as a method for diagnosing critical congenital heart disease in newborns. asymptomatic newborns before hospital discharge (PLANA et al., 2018)

Evaluating the diagnosis of the identified heart conditions, none were characterized as critical, all being diagnosed around 1 year of age as simple heart conditions without Clinical impact. Echocardiogram findings show non-critical congenital heart disease. such as patent foramen ovale, mild right ventricular hypertrophy, atrial septal defect type "ostium secundum" of small size, trabecular muscular interventricular communication, Mild mitral regurgitation. Although these are acyanotic heart diseases, their identification... The screening for the newborn heart test contributed to early referral to a doctor. A specialist is needed for follow-up and monitoring. The limitations of the study are based on the sample size.



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small in identifying tests for critical heart disease, and in not evaluating the follow-up of newborns who tested normal.

6. CONCLUSION

Pulse oximetry testing is an essential assessment for both screening and diagnosis of critical congenital heart disease as well as non-critical congenital heart disease. This allows the patient to be referred for evaluation by a specialist as early as possible. This is possible for follow-up and monitoring. This work demonstrates the importance of the examination. For this purpose, further studies and new research may complement and fill gaps not yet identified. These are covered by the current analysis.

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