PORTUGUESE JOURNAL OF PEDIATRICS

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ORIGINAL ARTICLE

Neonatal screening for critical congenital heart disease: five-year experience of a tertiary hospital

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Abstract

Introduction: Congenital heart disease (CHD) is the most prevalent congenital anomaly and a leading cause of neonatal morbidity and mortality. Approximately 25% of CHD cases are classified as critical congenital heart disease (CCHD), which requires percutaneous or surgical intervention within the first year of life. Pulse oximetry (POx) has been proposed as an effective, non-invasive screening tool for CCHD, particularly in tertiary hospitals where high-risk newborns are often managed. This study aimed to evaluate the implementation, effectiveness, and outcomes of a neonatal CCHD screening program at hospital discharge in a tertiary hospital. **Methods**: A retrospective observational study was conducted over five years at a tertiary hospital, following the 2017 adoption of a POx-based CCHD screening protocol. Newborns with abnormal POx results underwent echocardiographic evaluation. Data were collected on screening adherence and screening results, including positive test rates and positive predictive value (PPV). **Results**: Out of 11,800 newborns admitted to the postnatal ward, 94% (n = 11,094) were screened for CCHD using POx. Abnormal POx results were observed in 0.5% of cases (n = 56), prompting echocardiographic follow-up. No cases of CCHD were identified, yielding a false-positive rate of 0.5%. Out of the referred cases, six newborns were diagnosed with non-critical CHD and two with non-cardiac conditions. The PPV was 0% for CCHD, 0.05% for non-critical CHD, and 0.02% for non-cardiac conditions. **Conclusion**: While this screening program was effectively implemented, no CCHD cases were identified. The findings highlight the need for further research to evaluate the role of POx screening across different hospital levels.

Keywords: Congenital heart disease. Neonatal screening. Pulse oximetry.

Rastreio neonatal de cardiopatias congénitas críticas: experiência de cinco anos num hospital terciário

Introdução: As cardiopatias congénitas (CC) são o grupo mais comum de anomalias presentes ao nascimento e uma das principais causas de morbilidade e mortalidade dos recém-nascidos. Cerca de 25% dos casos são cardiopatias congénitas críticas (CCC), que requerem intervenção percutânea ou cirúrgica no primeiro ano de vida. A oximetria de pulso (POx) foi proposta como uma ferramenta de rastreio eficaz e não invasiva CCC, particularmente em hospitais terciários, referência de casos de alto risco. Este estudo teve como objetivo avaliar a implementação, a eficácia e os resultados de um programa de rastreio neonatal de CCC, à data da alta hospitalar, num hospital terciário. **Método**: Foi realizado um estudo observacional

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Received: 22-12-2024
Accepted: 04-05-2026
https://pjp.spp.pt

Available online: 15-06-2026
Port J Pediatr. (Ahead of print)
DOI: 10.24875/PJP.24000097

retrospetivo ao longo de cinco anos num Hospital de terciário, após a adoção, em 2017, de um protocolo de rastreio de CCC baseado em POx. Recém-nascidos com resultados anormais no POx foram submetidos a avaliação ecocardiográfica. Foram recolhidos dados sobre a adesão ao rastreio, taxas de resultados positivos e valor preditivo positivo. **Resultados**: Durante o período de estudo, dos 11.800 RN admitidos no alojamento conjunto, 94% (n = 11.094) realizaram o rastreio de CCC por POx. 56 RN (0,5%) apresentaram resultados anormais pelo que realizaram ecocardiograma. Não foram detetadas cardiopatias congénitas críticas, 6 recém-nascidos foram diagnosticados com cardiopatia congénita não crítica e 2 apresentaram condições não cardíacas. O valor preditivo positivo foi de 0% para o diagnóstico de CCC, 0,05% para cardiopatia congénita não crítica e 0,02% para condições não cardíacas. **Conclusão**: Este programa de rastreio mostrou-se exequível e amplamente implementado. No entanto, não foram detetadas cardiopatias congénitas críticas. Estudos adicionais poderão explorar o papel do rastreio por oximetria de pulso em diferentes contextos de diferenciação hospitalar.

Palavras-chave: Cardiopatia congénita. Oximetria de pulso. Rastreio neonatal.

Key points

"What is known"
- CHD is the most common group of anomalies present at birth, with nearly 25% being critical.
- In 2011, the American Academy of Pediatrics and American Heart Association recommended the use of POx as a screening method for CCHD.
- In 2014, in Portugal, the universal implementation of CCHD screening was recommended, even though there is no national protocol.

"What is added"
- At our hospital, since the implementation of CCHD screening with POx in 2017, no cases of CCHD were detected by screening over a five-year period.
- CCHD screening had a positive predictive value of 0%.

Introduction

Congenital heart disease (CHD) is the most prevalent birth anomaly, affecting about 8 – 10 per 1,000 live births. Almost 25% are classified as critical congenital heart disease (CCHD), which requires surgical or percutaneous intervention within the first year of life. CCHD contributes to 40% of infant deaths from congenital anomalies. Advances in prenatal diagnosis and neonatal care have improved outcomes, and early detection plays a critical role in survival and treatment success[1–4].

Neonatal screening using pulse oximetry (POx) has been widely endorsed as a means to improve early detection and outcomes for CCHD. Tertiary hospitals play a key role in implementing such screenings due to their focus on high-risk newborns[5].

Since 2011, the American Academy of Pediatrics (AAP) and the American Heart Association (AHA) have recommended POx screening after 24 hours of life or prior to discharge. This recommendation was subsequently incorporated into the Recommended Uniform Screening Panel (RUSP) guidelines in the United States and then adopted into national screening guidelines in the United States and several European countries[6,7].

What we know about POx

Pulse oximetry (POx) is widely regarded as an accessible, non-invasive, painless, cost-effective method for screening for critical congenital heart disease (CCHD), as most CCHD cases involve some degree of hypoxemia.

How: POx measures peripheral oxygen saturation by emitting light through the skin and analyzing the light absorption differences between oxygenated and deoxygenated hemoglobin[6].

Goals: The American Academy of Pediatrics (AAP) and the American Heart Association (AHA) identified 13 common congenital heart defects as primary targets for CCHD screening, focusing on conditions that often lead to neonatal hypoxemia (see Table 1)[8]. POx alone has shown a sensitivity of 75% and a specificity of 99.3% for detecting CCHD, improving to around 90% sensitivity when combined with additional diagnostic tools such as fetal echocardiography and physical examination[2,4].

False negatives: Certain CCHDs, such as coarctation of the aorta, may be missed by POx, particularly conditions with no initial hypoxemia. Non-CCHD cases that lack hypoxemia may also go undetected[3].

False positives: False-positive results often stem from non-cardiac conditions such as sepsis,

Table 1. Primary and secondary targets of the CHD screenings defined by the AAP and the AHA in 2009

Primary targets
Hypoplastic left heart syndrome
Pulmonary atresia
Total anomalous pulmonary venous drainage
d-Transposition of the great arteries
Tricuspid atresia
Truncus arteriosus
Tetralogy of Fallot
Secondary targets
Coarctation of the aorta
Double-outlet right ventricle
Ebstein anomaly
Interrupted aortic arch
Single ventricle
Other non-specified cyanotic lesions

pneumonia, or hemoglobinopathies. However, these conditions may still benefit from early detection and timely medical intervention[9].

A complementary tool, the peripheral perfusion index (PPI), may enhance the detection of certain CCHDs, especially those involving obstructed blood flow from the heart that POx may miss. The PPI assesses peripheral blood flow and has shown potential in detecting cases such as coarctation of the aorta. Combining both POx and PPI may improve overall screening effectiveness, especially for conditions that are not always accompanied by low oxygen saturation[10–12].

In Portugal, a 2014 study from Centro Hospitalar Universitário de Coimbra was the first to describe the incorporation of CCHD screening into a Portuguese maternity setting, advocating for its widespread implementation[13]. However, Portugal currently lacks a standardized national protocol for CCHD screening, resulting in varied practices across healthcare centers.

The impact of CCHD screening on infant mortality remains debated, with some studies suggesting a mortality reduction of up to 33%, while others report a minimal effect on CCHD-related mortality[14,15]. In Portugal, research on the effectiveness of CCHD screening is scarce, underscoring the importance of studies to assess the feasibility and outcomes of POx screening for early identification and management of newborns with CCHD.

This study aimed to assess the feasibility and outcomes of a neonatal CCHD screening program performed at discharge in a tertiary hospital.

Methods

A retrospective observational study was conducted at Hospital Santa Maria, ULSSM, a tertiary care hospital in Lisbon, Portugal. The study evaluated the implementation and outcomes of a neonatal screening program for Critical Congenital Heart Disease (CCHD) using pulse oximetry (POx) and peripheral perfusion index (PPI). Data were collected from hospital records between April 1, 2017, and December 31, 2022.

A consecutive sample of newborns admitted to the postnatal ward was included. Eligible participants were asymptomatic term and late preterm infants (≥ 34 weeks of gestation). Newborns were excluded if they were symptomatic, had a prenatal diagnosis of congenital heart disease, or were directly admitted to the Neonatal Intensive Care Unit (NICU), as they did not undergo routine screening.

Screening was performed by the nursing team using the Masimo® oximeter (model FKF-RDS7A, Irvine, USA). Measurements were taken at 48 hours of life or prior to discharge, with some screenings occurring up to 72 – 96 hours postnatally. The POx measured oxygen saturation (SpO_2) on the right hand (pre-ductal) and one foot (post-ductal). Simultaneously, PPI values were recorded at both sites.

The screening protocol followed a stepwise approach: immediate failure if SpO_2 < 90% or PPI < 0.5 in either limb; repeat failure if SpO_2 between 90 and 94%, or pre- and post-ductal difference ≥ 3%, or PPI < 0.7 after up to two additional measurements spaced one hour apart. Newborns with a positive screening result were referred to Pediatric Cardiology for further evaluation, including echocardiography. The full hospital screening protocol is outlined in Fig. 1.

Collected data included: sample characteristics (date of birth, sex, gestational age, and birth weight), screening data (date and result of POx screening, need for retesting, and number of repetitions), and clinical outcomes (referral to Pediatric Cardiology, transfer to other services, and neonatal mortality).

All data were analyzed using Microsoft Excel®. Continuous variables (e.g., gestational age and birth weight) were expressed as means, while categorical variables (e.g., screening outcome and referral status) were presented as frequencies and percentages.

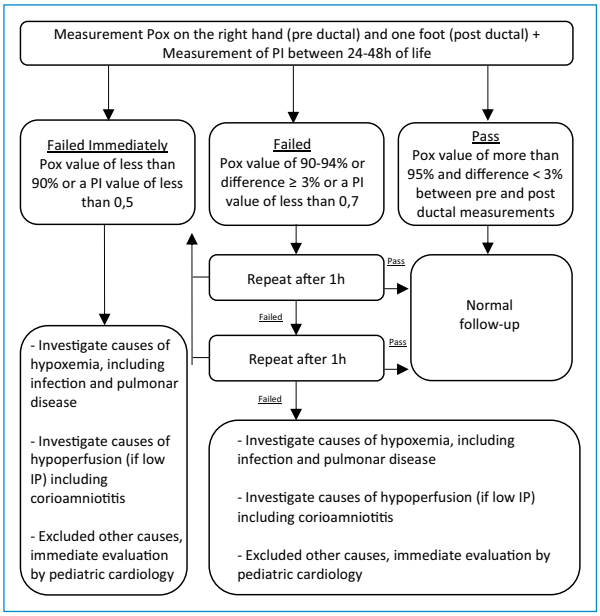

Figure 1. Algorithm for neonatal screening of CCHD implemented at Hospital Santa Maria since 2017.
PI > 4,5 can result from vasodilatation related tp crying (for example), justifying a repitition of the measurement.

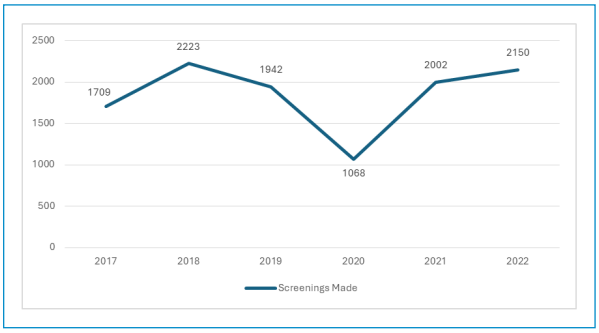

Figure 2. Number of CCHD screenings carried out between 2017 and 2022.

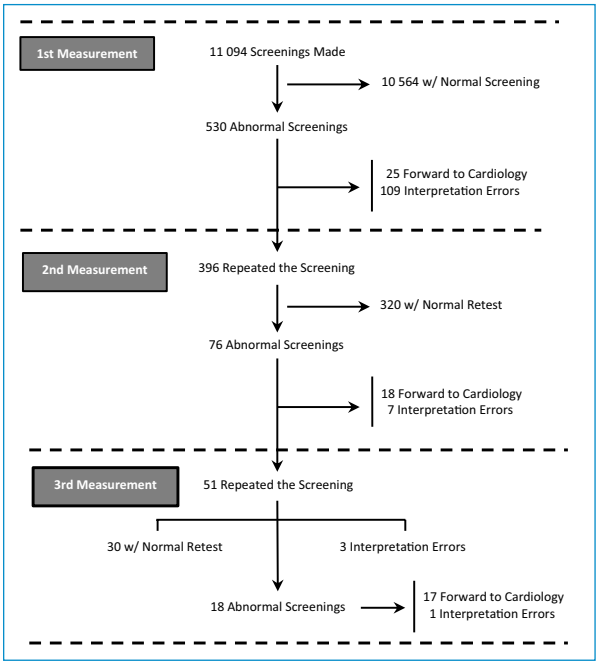

Figure 3. Diagram showing CCHD screening between 2017 and 2022.

Results

Data on CCHD screening

During the study period, a total of 11,800 newborns were admitted to the postnatal ward at Hospital Santa Maria, with 94% (n = 11,094) undergoing CCHD screening using pulse oximetry and the peripheral perfusion index. Annual screening numbers ranged from 1,068 to 2,223. Lower numbers were observed during the initial implementation phase in 2017 and during the COVID-19 pandemic, which suspended routine screenings.

Among the 11,094 newborns screened, 530 (4.7%) failed the initial screening performed at 48 hours of life or immediately prior to discharge, occasionally up to 72 – 96 hours postnatally. Of these, 396 newborns (74%) underwent at least one repeat screening: 345 (64%) were retested once, and 51 (10%) twice. A total of 60 newborns were referred to Pediatric Cardiology, including 25 (5%) referred immediately after the initial screening and 35 (7%) referred following abnormal repeat test results.

A subset of neonates with abnormal initial screening outcomes did not undergo repeat evaluation. Early in the protocol's adoption, several misinterpretations were noted, often linked to PI values < 0.7 and oxygen saturations at the borderline threshold of 94%. Moreover, an elevated PPI and reversed saturation differentials —where post-ductal values exceeded pre-ductal by ≥ 3%— were inaccurately labeled as pathological.

The most common abnormal findings on POx screening included a pre- and post-ductal oxygen saturation difference ≥ 3% (n = 322), oxygen saturation values < 95% (n = 143), and PPI values < 0.7 (n = 110). Of the 60 referrals to Pediatric Cardiology, only five met the criteria for immediate failure, defined as oxygen saturation < 90% or PPI < 0.5. Fig. 3 presents a summary diagram of these screening outcomes.

Positive screenings

Out of the 60 newborns who screened positive, either due to an initial screening failure or positive retesting,

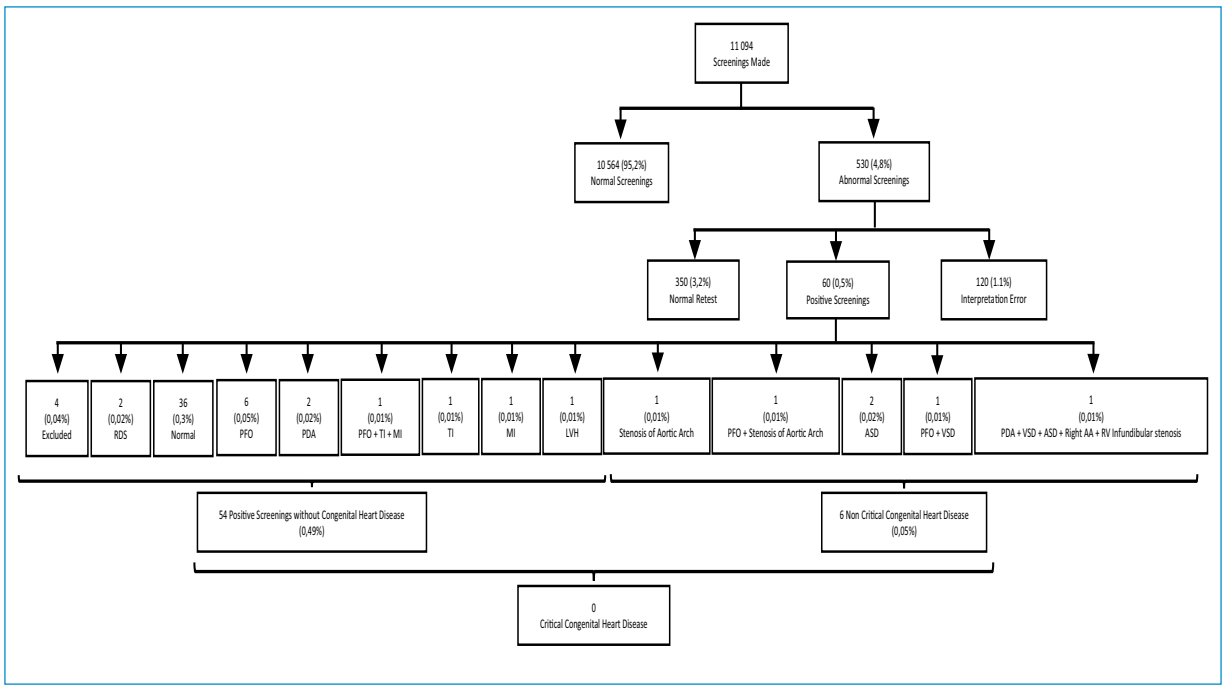

Figure 4. Overview of the results of neonatal CCHD screening between 2017 and 2022, at Hospital Santa Maria.
Abbreviations: AA Aortic Arch; ASD Atrial Septal Defect; LVH Left Ventricular Hypertrophy; MI Mitral Insufficiency; PDA Patent Ductus Arteriosus; PFO Patent Foramen Oval; RDS Respiratory Distress Syndrome; RV Right Ventricular; TI Tricuspid Insufficiency; VSD Ventricular Septal Defect.

clinical records were accessible for 56 infants, all of whom underwent echocardiography.

The cohort was 52% female and 48% male. The mean birth weight was 3,186 grams (SD ± 608 g) and the mean gestational age was 39 weeks (SD ± 1.5 weeks).

No cases of critical congenital heart disease were diagnosed. However, 18 infants presented with findings on cardiac ultrasound: six had non-critical congenital heart defects, and 10 had transient cardiac alterations (Fig. 4). According to follow-up data, both cases of stenosis of the aortic arch remained stable with no echocardiographic progression observed. The referral reasons included pre-ductal saturation below 93% and a 3% differential between pre- and post-ductal saturations. Two additional cases of transient respiratory distress were recorded, one of which required short-term hospitalization in the NICU with supplemental oxygen.

In total, no cases of CCHD were diagnosed, the false-positive rate for the screening was 0.5%, with a positive predictive value of 0% for CCHD, 0.05% for non-critical CHD, and 0.02% for non-cardiac conditions.

Discussion

This study assessed the implementation and outcomes of a five-year neonatal screening program for critical congenital heart disease (CCHD) using pulse oximetry (POx) at discharge in a tertiary care hospital setting. Despite a high screening adherence rate of 94%, no cases of CCHD were detected, raising questions about the added value of POx screening in environments where prenatal diagnosis is frequently available and comprehensive.

The absence of CCHD diagnoses aligns with previous findings in similar tertiary settings, such as those reported by Schena et al.[11]. However, the inability to verify the prenatal care status of each newborn in our sample limits our capacity to evaluate the extent of overlap between prenatal and postnatal detection. This limitation is particularly relevant in assessing the incremental value of postnatal POx screening in high-resource hospitals.

While no CCHD cases were found, the screening program identified six cases of non-critical CHD and two non-cardiac conditions, consistent with previous reports from Portugal[16,17]. These findings, while not immediately life-threatening, suggest that POx screening may confer secondary benefits through the early detection of clinically relevant conditions. However, in tertiary care environments, with well-established prenatal screening, the cost-effectiveness and clinical

utility of universal POx screening warrant critical evaluation.

The observed false-positive rate of 0.5% was higher than that reported in U.S. studies (approximately 0.05%) but like rates in the United Kingdom, where earlier screening (at 24 hours) has been associated with increased false positives[1–3,18]. Since our screenings were performed after 48 hours of life, early transitional circulation is an unlikely explanation. Instead, the elevated false-positive rate may be attributed to protocol deviations, such as referring newborns based on a single abnormal reading, and the relatively easy access to echocardiography during weekdays, which may have lowered the threshold for referral. These findings highlight the importance of strict protocol adherence and ongoing staff training to minimize unnecessary interventions and maintain screening accuracy.

The inclusion of the peripheral perfusion index (PPI) as an adjunct to POx was a key methodological component of this study. PPI has been suggested to aid in detecting cardiac anomalies not typically associated with hypoxemia, such as left ventricular outflow tract obstructions[19]. However, in our sample, two cases of aortic arch stenosis presented with normal PPI values. Moreover, PPI was frequently misinterpreted, contributing to inconsistent decisions regarding repeat testing and referrals. These results underscore the need for international consensus on validated PPI thresholds and further research to determine its value when used alongside POx.

Several limitations should be considered. First, we lacked complete data on prenatal follow-up, which likely impacted our ability to detect new CCHD cases. Additionally, high-risk neonates, such as those admitted to the NICU, were excluded from screening, potentially leading to missed diagnoses. Variability in staff experience and deviations from the screening protocol may also have influenced the outcomes. Finally, incomplete post-discharge follow-up raises the possibility of undetected false negatives.

In conclusion, while POx screening remains a widely endorsed, cost-effective tool for CCHD detection[19–21], its diagnostic yield in tertiary care settings with high prenatal detection rates may be limited. POx may offer more benefit in lower-level healthcare facilities with restricted access to prenatal screening[22–23.] The addition of tools such as PPI holds promise, but requires further validation. Future efforts should focus on national-level evaluations of cost-effectiveness, the refinement of protocols, and the incorporation of adjunctive methods to optimize neonatal cardiac screening programs.

Conclusion

This study demonstrates the feasibility of incorporating pulse oximetry-based screening for critical congenital heart disease (CCHD) into routine clinical workflows within a tertiary care setting. Despite high screening adherence, the absence of confirmed CCHD cases and a relatively elevated false-positive rate underscore the need to critically reassess the effectiveness of such programs in high-resource environments with established prenatal diagnostic systems.

Future research is warranted to evaluate the clinical usefulness, cost–benefit ratio, and optimal strategies for implementing CCHD screening across different healthcare settings, particularly where prenatal detection is limited or unavailable.

Author contributions

M. Ruivo: bibliographic search, study design, data collection, analysis and interpretation of results, and drafting of the article; F. Carmo: data collection, analysis and interpretation of results, and drafting of the article; C. Ferreira Gonçalves: data collection, analysis and interpretation of results, and drafting of the article; A. Andrade: data collection, and analysis and interpretation of results; M. Ferreira: data collection; M. Rebelo: critical reviewing of the content of the article; A. M. Graça: critical reviewing of the content of the article; A. Berenguer: drafting of the article and critical reviewing of the content of the article.

Funding

None.

Conflicts of interest

None.

Ethical considerations

Protection of human subjects and animals. The authors declare that no experiments on humans or animals were performed for this research.

Confidentiality, informed consent, and ethical approval. The authors have obtained approval from the Ethics Committee for the analysis of routinely collected and anonymized clinical data; therefore, individual informed consent was not required. Relevant ethical recommendations have been followed.

Declaration on the use of artificial intelligence (AI). The authors declare that no generative artificial intelligence was used in the writing or creation of the content of this manuscript.

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