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REVIEW PROTOCOL

Accuracy of pulse oximetry for screening congenital heart disease: systematic review protocol

Acurácia da oximetria de pulso para triagem das cardiopatias congênitas: protocolo de revisão sistemática

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ABSTRACT

Objective: to determine the accuracy of pulse oximetry for screening congenital heart defects in newborns. **Method**: this is a Systematic Review of diagnostic accuracy that will consider premature, term and post-term newborns, without previous diagnosis of congenital heart disease, born in a hospital or home environment. The search will be performed in MEDLINE Complete (PubMed), CINAHL Complete, Embase, Scopus, Google Scholar, ProQuest Central and Trove databases. No delimitation of language or period of publication. Identified references will be managed through EndNote, and duplicates will be excluded. The selection will take place by two independent reviewers. Studies will be critically evaluated using a checklist for diagnostic test accuracy studies. Details on index tests, populations, study methods, and significant results for the review will be extracted. Whenever possible, sensitivity and specificity will be pooled in bivariate statistical meta-analysis. Registration number on the PROSPERO platform: CRD42021256286
Keywords: Systematic Review; Newborn; Oximetry.

RESUMO

Objetivo: determinar a acurácia da oximetria de pulso para triagem de cardiopatias congênitas em recém-nascidos. **Método:** trata-se de uma Revisão Sistemática de acurácia diagnóstica que considerará recém-nascidos prematuros, termo e pós-termo, sem diagnóstico prévio de cardiopatia congênita, nascidos em ambiente hospitalar ou domiciliar. A busca será realizada nas bases de dados MEDLINE *Complete* (PubMed), CINAHL *Complete*, Embase, Scopus, *Google Scholar*, ProQuest *Central and Trove*. Sem delimitação de idioma ou período de publicação. As referências identificadas serão gerenciadas por meio do EndNote e, as duplicações excluídas. A seleção ocorrerá por dois revisores independentes. Os estudos serão avaliados criticamente por meio de uma lista de verificação para estudos de acurácia de testes diagnósticos. Detalhes sobre os testes de índice, populações, métodos de estudo e resultados significativos para a revisão, serão extraídos. Sempre que possível, a sensibilidade e a especificidade serão agrupadas em meta-análise estatística bivariada. Número de registro na plataforma PROSPERO: CRD42021256286
Descritores: Revisão Sistemática; Recém-Nascido; Oximetria.

INTRODUCTION

Births of newborns with congenital heart disease (CHD) have increased over the last century, reaching an estimated 9 per 1000 live births over the past 15 years. CHD represents a public health priority with a prevalence of 1.35 million cases per year. Newborns with critical CHD - which require intervention in the first month of life - have an incidence between 2.5 and 3 per 1,000 live births and a mortality rate of 0.94 per 10,000 live births, when diagnosed after 24 hours of birth[1,2]. Converging with the fact that approximately 50% of the most severe cases are diagnosed during prenatal care and the others, on average, by the sixth week of life[3].

It is important to point out that, in view of the decrease in infant mortality due to communicable diseases, non-communicable diseases, such as congenital anomalies, especially CHD, began to appear significantly in the infant mortality scenario[4].

Critical CCs, according to their physiology, are dependent channels, resulting

in an association between systemic and pulmonary circulation with a reduction in peripheral saturation. In this sense, screening using the Pulse Oximetry Test (POT) is implemented as a strategy for early diagnosis in healthy newborns with more than 34 weeks of gestation and has a sensitivity and specificity of 75% and 99%, respectively[5,6-7]. However, POT may not indicate alterations in congenital heart diseases that do not affect saturation, such as in coarctation of the aorta or obstructions to the left side of the heart [1,5].

The implementation of accurate and economical technologies for the diagnosis of CHD is still a current challenge. In addition to POT, when caring for newborns in the maternity ward, cardiac auscultation is performed to identify adverse sounds such as a heart murmur, which is present in some CHDs. However, it is important to highlight that this practice in isolation is limited, and has an impact on the number of late diagnosed cases[3].

In POT, the positive result consists of a saturation value below 95% in the right upper limb and, in one of the lower limbs, or a difference greater than or equal to 3% between the two measurements. The newborn is screened again within an hour, and if the result persists, the newborn is referred for an echocardiogram. If the result is negative in the retest, the routine conduct is followed[5,8].

The protocol used for screening after birth aims to limit false positive cases. Although the POT has several advantages such as proven effectiveness, readily available equipment, minimally invasive monitoring and, as most parents and staff know, its implementation is not universal[9].

Internationally, Switzerland, Ireland and Poland were the first countries to recommend routine POT. And in 2011, in the United States of America, Indiana, Maryland, and New Jersey were the first states that approved Neonatal Screening as mandatory. In 2018, the mandatory requirement was expanded throughout the United States of America, with the possibility of verifying at least 120 lives saved per year[8,10].

The challenges for implementing POT include the preparation of the health system in terms of infrastructure, human resources trained to manage and monitor positive cases considering the functional, vital and economic sequelae for the family and institutions. The following are emphasized in the implementation process: limitations of screening; ability to detect other health conditions; updated and recommended algorithm[8,11].

A universal POT program will advance the detection of CHD and other serious conditions such as respiratory and sepsis. Regarding the algorithm used, there are divergences of recommendations according to the countries and states. It is important to have a definition to limit false-positive results, considering the time of discharge from the maternity hospital or the delivery environment[10].

Due to advancements in pediatric cardiology and technological resources for the survival of these patients, a greater number of chronically ill adolescents and adults is expected, who will require surgical treatments and continued health care throughout their lives[12]. Thus, it is essential to update health professionals in order to favor the diagnosis and monitoring of cases[13].

Thus, in order to search for existing studies, a preliminary search was carried out on the PROSPERO platform, on the Cochrane Database of Systematic Reviews and JBI Evidence Synthesis, and found: two records on PROSPERO, one being a systematic review of effectiveness in development and one review systematic diagnostic accuracy already finalized and published in the Cochrane Library[14]. No studies related to the topic of this research were identified in the JBI Evidence Synthesis.

In an analysis of a similar review publication, it was noted that there was a four-year interval between the last included study and the present review protocol. The publication recommended further research with evidence on routine newborn screening in Intensive Care Units [NICU] and in the home birth setting, as well as further analysis on the relative sensitivities of post-ductal versus pre-ductal saturation tests.[14].

In addition, a recent publication in the Pediatrics Journal[15] is highlighted with an update to the POT screening flowchart, with the aim of simplifying the interpretation and the screening process, which will impact the sensitivity of the test. An oxygen saturation of at least 95% is required in both evaluated limbs, performed in the first 24 hours or before, and a reassessment only after the newborn fails the first test. This publication also adds to the importance of a greater density of works and research aimed at understanding and improving screening effectiveness and efficiency.

Given the relevance of the subject to the obstetrics and pediatrics area, it is concluded that

it is pertinent to develop a systematic review of diagnostic test accuracy to enable the synthesis of evidence on the specificity, sensitivity and, consequently, accuracy of the TOP in the newborn. Being a reference method in the decision making of managers and for the practice of health professionals, in the context of implementing technologies and elaborating protocols. That said, this review will also enable the development of a survey on the budgetary impact of the TOP. Thus, the objective of this review is to determine the accuracy of pulse oximetry for screening congenital heart defects in newborns.

METHOD

This protocol and the future systematic review of diagnostic test accuracy is being developed in accordance with the JBI[16,17] and PRISMA[18] guidelines. The protocol was registered on the PROSPERO platform CRD42021256286.

Review question

The research question was developed from the mnemonic PIRD (Population, Index Test, Reference Test, Diagnosis of interest) specific for systematic reviews of diagnostic test accuracy. Thus, the following research question was elaborated: What is the diagnostic accuracy of the pulse oximetry test for the screening of congenital heart diseases in newborns?

Inclusion criteria

Participants

Studies with newborns up to 48 hours of life, regardless of gestational age at birth, who were not diagnosed with congenital heart disease during prenatal care and born in a hospital or home environment[19]will be included.

Interest test

This review will include studies presenting the POT as a test of interest; performed in the first 24 hours of life or between 24 hours and 48 hours; pre-ductal and post-ductal screening (upper limb and lower limb) or in lower limb only; with parameters for positive test < 95% or with > 3% difference between upper and lower limb for positive test and the need to retest after one hour[14].

Reference test

Studies on POT without comparison with other diagnostic tests will be included, as well as studies that compare pulse oximetry and cardiac auscultation performed during physical examination by the medical or nursing team. Cardiac auscultation is also indicated in the literature as a possibility to identify abnormal murmurs, such as heart murmurs, present in some congenital heart diseases[20].

Diagnosis of interest

Critical congenital heart disease, children who need care in the first month of life, classified as cyanotic or ductus arteriosus-dependent heart disease[2].

Types of studies

This review will select studies of diagnostic test accuracy with sensitivity and specificity outcomes or the variables of true positive, true negative, false positive and false negative. With emphasis on observational studies including cohort studies and case-control studies.

Search strategy

The search strategy will aim to locate published and unpublished studies. A three-step search strategy will be used in this review. An initial search limited to MEDLINE and CINAHL will be performed, which will be followed by an analysis of the text words contained in the title and abstract, and the index terms used to describe the article. A second search using all identified keywords and index terms will then be performed across all included databases. Thirdly, the reference list of all identified reports and articles will be searched for further study. Studies published in all languages will be considered for inclusion in this review, without time limitation. Figure 1 presents the complete strategy for the PubMed database carried out on May 15, 2021.

Sources of information

The databases to be searched include MEDLINE Complete (PubMed), CINAHL Complete, Embase, Web of Science, and Scopus. Sources of unpublished studies and grey literature to be researched include capes thesis bank, Open Access Theses and Dissertations and WorldWideScience.org.

Selection of studies

After the search, all identified citations will be collected and sent to EndNote and duplicates will be removed. Titles and abstracts will be selected by two independent reviewers for

Search	Strategy	Retrieved logs
#1	((((((((((infant, newborn[MeSH Terms]) OR (Newborn[Title/Abstract])) OR (Neonate[Title/Abstract])) OR (Infant, Postmature[MeSH Terms])) OR (Infant, Premature[MeSH Terms])) OR (Infant, Preterm[MeSH Terms])) OR (infant, newborn [MeSH Terms])) OR (Newborn [Title/Abstract])) OR (Neonate [Title/Abstract])) OR (infant, postmature [MeSH Terms])) OR (infant, premature [MeSH Terms])) OR (infant, premature [MeSH Terms])	703,210
#2	(((((Oximetry[MeSH Terms]) OR (Pulse oximetry[Title/Abstract])) OR (Pulse oximetry screening[Title/Abstract])) OR (oximetry [MeSH Terms])) OR (pulse oximetry [Title/Abstract])) OR (pulse oximetry screening [Title/Abstract])	18,992
#3	(((((((((Heart Defects, Congenital[MeSH Terms]) OR (Abnormality, Heart[Title/Abstract])) OR (Congenital Heart Defect[Title/Abstract])) OR (Malformation Of Heart[Title/Abstract])) OR (Congenital Heart Disease[Title/Abstract])) OR (heart defects, congenital [MeSH Terms])) OR (abnormality heart [Title/Abstract])) OR (congenital heart defect [Title/Abstract])) OR (malformation of heart [Title/Abstract])) OR (congenital heart disease [Title/Abstract])	170,376
#4	#1 AND #2 AND #3	489

Figure 1 - Search strategy developed for the Pubmed database. Curitiba, PR, Brazil, 2021
Source: Elaborated by the authors, 2021.

evaluation according to the inclusion criteria for the review. Potentially relevant studies will be retrieved. The full text of selected citations will be evaluated in detail against the inclusion criteria by two independent reviewers. Reasons for excluding full-text studies that do not meet the inclusion criteria will be recorded and reported in the systematic review. Any disagreements that arise between reviewers at each step of the study selection process will be resolved through discussion or with a third reviewer. Search results will be reported in full in the final systematic review and presented in a flowchart of Preferred Reporting Items for Systematic Reviews and Meta-analyses for Diagnostic Test Accuracy (PRISMADTA).

Evaluation of methodological quality

Articles selected for retrieval will be assessed by two independent reviewers for methodological validity, prior to inclusion in the review, using the QUADAS-2 review tool. Any disagreements that arise between reviewers will be resolved through discussion or with a third reviewer. The results of the critical evaluation will be reported in narrative form and in table form. All studies, regardless of their methodological quality results, will undergo data extraction and synthesis.

Data extraction

Data will be extracted from the studies included in the review by two independent reviewers and will be sent to Microsoft Word. Extracted data will include specific details about the population, index test, and diagnosis of significant interest for the purpose of the review. Any disagreements that arise between reviewers will be resolved through discussion or through a third reviewer. The authors of the articles will be contacted to request missing or additional data, when necessary.

Summary of data

Quantitative data will, where possible, be pooled in statistical meta-analysis using the JBI Systems for Assessing and Reviewing United Administration Information (JBI-SUMARI). All results will be subject to double data entry. Effect sizes will be expressed in a proportional forest plot expressed as Odds Ratio (for categorical data) and weighted mean differences (for continuous data) and their 95% confidence intervals will be calculated for analysis. Will be displayed in paired forest plots if the same diagnostic threshold values are used across studies; or on summarized receiver operating characteristic curves (SROC) if they vary. Heterogeneity will be statistically assessed using standard chi-square and also explored through subgroup analyzes based on the different study designs included in this review. When statistical grouping is not possible, results will be presented in narrative format, including tables and figures to aid in data presentation, where appropriate.

Evaluation of the recommendation of the findings

A summary of the findings will be created using GRADEpro GDT (McMaster University, ON, Canada). The GRADE approach to classifying the quality of evidence for the accuracy of the diagnostic test will be followed. The following result will be included in the Summary of Findings: estimates of accuracy (sensitivity and specificity).

CONFLICT OF INTERESTS

The authors have declared that there is no conflict of interests.

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Data analysis and interpretation:
Writing and/or critical review of the intellectual content: Saganski GF, Freire MHS, Santos WM
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