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REVIEW ARTICLE

Effectiveness of pulse oximetry as screening for congenital heart disease in newborns

Efectividad de la oximetría de pulso como tamizaje de cardiopatías congénitas en recién nacidos

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Abstract

Neonatal screening (NT) is one of the most widely used pediatric preventive practices globally; it has also been recognized as one of the ten most valuable achievements in public health. Within this screening process, pulse oximetry has proven to be an effective, non-invasive and low-cost method, which is also well tolerated by newborns to detect congenital heart disease in the first hours of birth. Given that,the aim of this study was to identify the effectiveness of pulse oximetry as a screening for congenital heart disease in newborns.A systematic review of controlled clinical trials and observational studies on congenital heart diseases was carried out in MEDLINE via PubMed, EMBASE via Ovid, LILACS and CENTRAL. Risk of bias assessment was performed with QUADAS-2. A narrative synthesis of the findings was made. A total of 18,345 articles were found, of which 15 met the inclusion criteria. The data were analyzed in a sample of 286,731 newborns in all the included studies. The results of the studies were published between 2015 and 2021, covering European countries,the Middle East, and the United States. The reported diagnostic accuracy analyzes indicate a specificity greater than 95%. Sensitivity had greater variability. To conclude, Pulse oximetry is a non-invasive, inexpensive and useful tool that helps in the detection of congenital heart disease in newborns. Early diagnosis can lead to more effective interventions and better neonatal outcomes.

Keywords: *Neonatal screening. Oximetry. Heart diseases. Congenital anomalies.*

Resumen

El tamizaje de cardiopatía congénita neonatal por oximetría de pulso es una práctica preventiva utilizada en todo el mundo y reconocida como un logro de la salud pública, que ha demostrado ser un método eficaz, no invasivo y de bajo costo, que, además, es bien tolerado por los recién nacidos para detectar cardiopatías congénitas en las primeras horas del nacimiento Por lo anterior, el objetivo de este trabajo fue identificar la efectividad de la oximetría de pulso como tamizaje de cardiopatías congénitas en recién nacidos. Por ello, se realizó una búsqueda sistemática de estudios clínicos controlados y estudios observacionales sobre cardiopatías congénitas en MEDLINE vía PubMed, EMBASE vía Ovid, LILACS y CENTRAL. La valoración de riesgo de sesgo se realizó con QUADAS-2. Se hizo síntesis narrativa de los hallazgos. La búsqueda arrojó 18 345

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títulos; en total quince estudios cumplieron con los criterios de inclusión. Los datos se analizaron en una muestra de 286 731 recién nacidos en todos los estudios incluidos. Los resultados de los estudios fueron publicados entre 2015 y 2021, abarcando países europeos, Medio Oriente y Estados Unidos. Los análisis de precisión diagnóstica reportados, indican una especificidad superior al 95%. La sensibilidad tuvo una mayor variabilidad. Como conclusión, se tiene que la oximetría de pulso es una herramienta no invasiva, económica y útil que coadyuva en la detección precoz de cardiopatías congénitas en recién nacidos, la cual es altamente específica, y tiene una sensibilidad moderada y una tasa general baja de falsos positivos.

Palabras clave: *Tamizaje neonatal. Oximetría. Cardiopatías. Anomalías congénitas.*

Introduction

Congenital heart diseases (CHDs) account for 20% of neonatal deaths, which is why several mechanisms and procedures (including a history and physical exam, chest x-ray, electrocardiogram and echocardiogram) have been validated in clinical practice for early detection of this type of diseases. These are considered part of basic neonatal screening (NS), since their use can provide a reasonable assessment of the functional manifestations of heart disease, allowing an appropriate diagnosis and initiation of the respective treatment measures[1]. However, these types of procedures can only detect 27% of the most serious cases[2]. The most effective method has turned out to be neonatal echocardiography, but it is relatively expensive and is not available at all healthcare centers[3].

In addition, some heart diseases do not produce signs and symptoms to identify them in the first days of life[4], and in cyanotic newborns, other types of pulmonary diseases must be ruled out[5]. Likewise, systematic measurement of oxygen saturation 24-48 hours after birth is appropriate, since this can detect hypoxemia, one of the first indicators of structural congenital heart defects, which could allow early detection of these diseases[6]. This is done with a pulse oximeter with an appropriately sized sensor for the right hand and one foot, keeping in mind the reference values adapted to the altitude of the place where the test is performed[6].

Pulse oximetry screening helps promptly identify critical congenital heart diseases (CCHDs) such as hypoplastic left heart syndrome, pulmonary atresia, tetralogy of Fallot, anomalous pulmonary venous return, transposition of the great arteries and tricuspid atresia, prior to discharge from the maternity ward and in children born outside of the hospital setting[7]. A sensitivity and specificity of 98.5 and 98%, respectively, have been reported for the detection of CCHDs, which justifies its routine use in all departments caring for newborns, and its incorporation in the group of mandatory NS tests in many countries; however, its practice has not yet become widespread[8].

Accordingly, the objective of this study was to identify the effectiveness of pulse oximetry as screening for CHD in newborns.

Materials and method

The review followed the standard protocol for systematic reviews, and therefore was based on the methodological manuals of the items contained in the Preferred Reporting Items for Systematic reviews and Meta-Analyses extension for Scoping Reviews (PRISMA-ScR) checklist.

Studies were selected if the title or abstract contained information on pulse oximetry in newborns to screen for CHD. The review included controlled clinical trials and observational studies to identify the sensitivity and specificity of pulse oximetry as screening for CHD in newborns, which also performed echocardiograms as a confirmatory test for participants with a positive screening. Studies which did not meet the inclusion criteria and for which it was not possible to obtain the required data were excluded. Studies on infants or adults were not considered.

Furthermore, a database search was conducted on MEDLINE via PubMed, EMBASE via Ovid, LILACS and CENTRAL for articles published from January 2015 to January 2022. The terms used were adjusted to each of the databases: MeSH, Emtree, DeCS, Bireme and free-text terms (Table 1). A manual search of the article references was also done. The articles could be in any language, as long as the abstract and text were also available in English.

One investigator (IM) screened the studies by title and abstract to find potential candidates. The full text of selected studies was screened by another investigator (RD). A third evaluator (CV) was consulted to reach a consensus on the inclusion of a given study in the two described stages. Duplicate articles were eliminated after transferring the search results to EndNote®

Web (Clarivate Analytics, Philadelphia, PA, USA). Following this, two reviewers independently evaluated the titles and abstracts of the articles to identify highly eligible studies. These underwent full-text evaluation. Finally, a narrative synthesis of the findings was done by type of study. Two authors extracted data independently. The data extracted to a matrix included: country, type of study, population (n), pulse oximetry tool, false positives, false negatives, true positives, true negatives, specificity and sensitivity (Table 2).

As per the protocol, the methodological quality and risk of bias of the studies was determined using QUADAS-2.

For the synthesis of the information, the absolute values of the studies that correspond to the sensitivity and specificity data of pulse oximetry as a screening test for congenital heart disease are described. The qualitative analysis was done through a descriptive synthesis of pulse oximetry and the setting in which it was applied.

The collected data was synthesized in a table which includes the information found in the studies for each variable. The information is also presented as a meta-summary. The PRISMA-ScR checklist was used to report the results and draft the manuscript.

Table 1. Search strategy

Database	Strategy
MEDLINE via PubMed	("congenital heart defects"[All Fields]) AND (Pulse oximetry) AND (newborn)
EMBASE via Ovid	(AllFields: congenital heart defects) AND (AllFields: Pulse oximetry) AND (AllFields: newborn)
Lilacs	congenital heart defects AND pulse oximetry AND newborn AND (db:["LILACS"])
CENTRAL	(congenital heart defects) AND (Pulse oximetry):ti,ab,kw AND (newborn):ti,ab,kw

Results

Characteristics of the included studies

A total of 18,345 records were obtained. After applying filters, 1,588 articles were identified for title review. The full text of 98 articles was reviewed due to their high eligibility, with 15 articles ultimately included in the systematic review (Fig. 1). The results of these studies were published between 2015 and 2021 and covered European and Middle Eastern countries as well as the United States.

Sensitivity and specificity

The data was extracted from the selected studies[9-23] (Table 2). Only two studies were retrospective, those by Song[11] and Jones[19], and the total evaluated population was 286,731 newborns.

The analyses of diagnostic precision performed in all the evaluated studies indicated a specificity greater than 95%. Likewise, sensitivity in the studies by Jawin, Gómez, Cubells and Jones[13,14,17,19] reached 100%. The lowest percentages were found in the studies by Narayen[9] and Van Niekerk[22], with 50% each, and Ozalkaya[21], with 60%, due to the number of true positives in their studies. It should also be noted that the articles by Van Niekerk[22] and Zuppa[23] indicated human error in the application of the protocol and interpretation of the algorithm, which led to the recording of false negatives, since in some cases saturations of 90-94% were accepted as approved, and in others a difference ≥ 4% was accepted as approved, with arm-leg saturations of 96-100% (n = 4), 95-99% (n = 1), 95-100% (n = 1), 100-95% (n = 3) and 99-95% (n = 1) (Table 2).

The sensitivity of the 15 studies ranged from 50 to 100% and the specificity from 95 to 100%. Regarding the detected heart diseases, the studies by Ozalkaya[21] and Jones[19] indicated that after employing pulse oximetry and an echocardiogram, newborns were diagnosed with transposition of the great arteries, coarctation of the aorta, total anomalous pulmonary venous connection, and pulmonary stenosis and hypoplasia. Zuppa[23] and Albuquerque's[24] studies found aortic, mitral and pulmonary valve dysplasias as well as atrial and ventricular septal defects.

In Narayen's[9] study, two out of seven children had a delayed CCHD diagnosis and died before surgery due to circulatory failure, which emphasizes the importance of a timely assessment.

Environmental characteristics that can affect the screening results

The environmental characteristics that can affect the screening results in newborns include the timing of the test, altitude of the geographic area where the test is performed, and the specific pulse oximeter used. The clinical characteristics could not be analyzed since the entire population of the included studies consisted of healthy, asymptomatic newborns. In all the studies, the

Table 2. Characteristics of the included studies

#	Author/Year/ Reference	Country	Type of study	Population	Measurement tool	False positive	False negative	True positive	True negative	Specificity %	Sensitivity %
1	Song, 2021[11]	China	Observational (retrospective)	3,327	PM-50	47	126	139	3,015	95	64.7
2	Bin-Nun, 2021[12]	Israel	Observational (cross-sectional)	19,763	Not specified	48	0	1	19,714	99.9	76.3
3	Narayen, 2018[9]	Netherlands	Observational (cross-sectional)	23,959	Not specified	221	5	5	23,728	99.1	50
4	Hu, 2017[10]	China	Observational (longitudinal)	167,190	Not specified	292	10	34	166,864	99.8	77.3
5	Taksande, 2017[15]	India	Observational (prospective)	4,926	Masimo RAD 7M SET	0	3	9	4,914	99.4	90
6	Klausner, 2017[16]	USA	Observational (cross-sectional)	10,320	Not specified	4	1	0	10,315	99.8	87.5
7	Cubells, 2017[17]	Spain	Observational (prospective)	8,856	Not specified	5	2	3	8,846	99.9	100
8	Jones, 2016[19]	United Kingdom	Observational (retrospective)	10,260	Not specified	0	0	23	10,237	99.8	100
9	Van Niekerk, 2016[22]	South Africa	Observational (prospective)	2,256	Nelicor	1	1	1	998	99.9	50
10	Ozalkaya, 2016[21]	Turkey	Observational (cross-sectional)	10,200	Nelicor	1	4	6	8,197	100	60
11	Jawin, 2015[13]	Malaysia	Observational (prospective)	5,247	Masimo RAD-7M SET	13	18	15	5,201	99.7	100
12	Gómez, 2015[14]	Mexico	Observational (cross-sectional)	1,037	Belicor N395	10	2	12	1,013	99.8	100
13	Alburquerque, 2015[24]	Brazil	Observational (cross-sectional)	4,027	PM-60 Mindray	34	0	9	3,984	99.5	88.9
14	Oakley, 2015[20]	United Kingdom	Observational (prospective)	9,613	Nelicor NPB40	7	1	7	6,314	100	88
15	Zuppa, 2015[23]	Italy	Observational (cross-sectional)	5,750	Ohmeda 3900	0	51	247	5,452	99.8	77.8

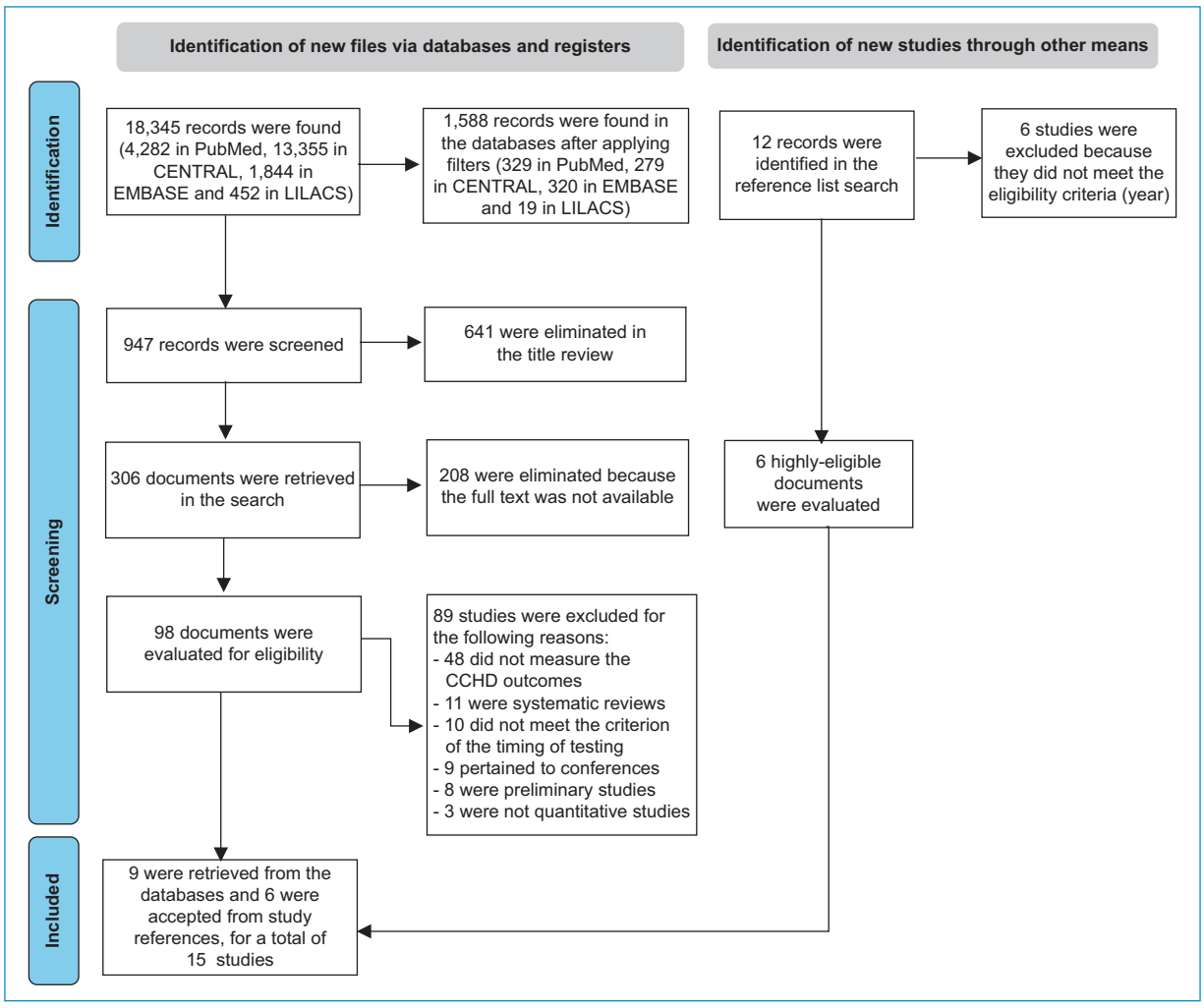

Figure 1. Preferred Reporting Items for Systematic reviews and Meta-Analyses (PRISMA) diagram.
Source: own elaboration.

newborns underwent a cardiovascular physical exam (CPE) and pulse oximetry within the first 24 hours of life and between 48 and 72 hours of life. The American Academy of Pediatrics working group recommends that screening not be started until after 24 hours of life (or as late as possible, if an earlier discharge is expected), and that it be completed on the second day of life. Dawson et al.[25] have established reference data for oxygen saturation in healthy, term infants during their first 24 hours of life.

The time needed to reach a stable saturation > 95% is generally 20 minutes in healthy infants (range: 3 to 90 min), and therefore a 24-hour wait is cautious. Earlier screening can result in more false positives due to the transition from fetal to neonatal circulation and stabilization of the systemic oxygen saturation. Therefore, six of the fifteen studies chose to apply the test after 24 hours after birth[16,19-23]. The study by Bin-Nun[12] altered the interpretation of the test results (oxygen saturation) due to difficulties attributed specifically to altitude, based on the fact that the mean SaO_2 levels, both pre- and post-ductal, were 0.4% lower in infants born in Jerusalem (approximately 780 meters above sea level) than in those born in Tel Aviv (approximately at sea level). While this difference may seem to be minimal and clinically insignificant, it significantly increases the rate of false positives, resulting in 3.5 times more echocardiograms.

Methodological quality

The quality of the primary diagnostic accuracy studies was evaluated using the QUADAS-2 tool. Patient selection risk (QUADAS-2, Domain 1) was evaluated,

Table 3. Risk of bias assessment

Author	Patient selection	Index test	Reference standard	Flow and timing
Narayen, 2018[9]	Low	Low	Low	Low
Hu, 2017[10]	Low	Low	Low	Low
Song, 2021[11]	Low	Low	Low	Low
Bin-Nun, 2021[12]	High	Low	Low	Low
Jawin, 2015[13]	Low	Low	Low	Unclear
Gomez, 2015[14]	Low	Low	Low	Low
Taksande, 2017[15]	Low	Low	Unclear	Low
Klausner, 2017[16]	Low	Low	Low	Low
Cubells, 2017[17]	Low	Low	Low	Unclear
Alburquerque, 2015[24]	Low	Low	Low	Low
Jones, 2016[19]	Low	Low	Low	Unclear
Oakley, 2015[20]	Low	Low	Low	Low
Ozalkaya, 2016[21]	Low	Low	Low	Low
Van Niekerk, 2016[22]	Low	Low	Unclear	Low
Zuppa, 2015[23]	Low	Low	Low	Low

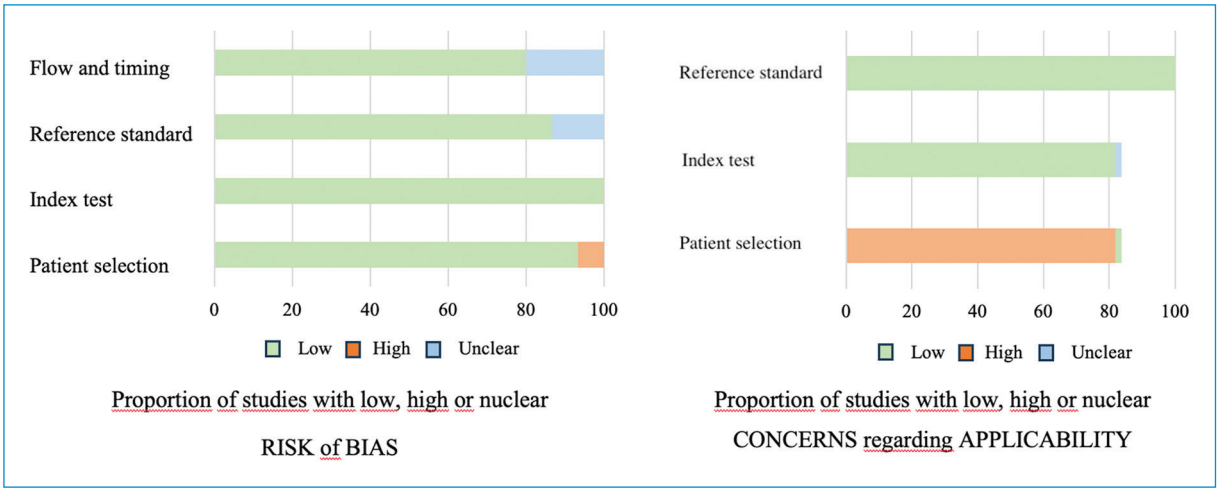

Figure 2. Overall QUADAS-2 risk of bias.

obtaining a low risk of bias in 14 studies and high risk in only one which provided little information on the selection process[12] (Table 3).

For the index test (QUADAS-2, Domain 2), all of the studies had a low risk of bias and few concerns regarding applicability. Most of the studies had a prospective design with consecutive participant enrollment and included an adequate description of the index test (Fig. 2). There was a low risk of bias in reference standard performance or interpretation (QUADAS-2, Domain 3). The risk of two studies was considered uncertain because they used an incomplete reference standard to identify false negatives[15,22]. The risk of differential verification bias was inevitable, as the diagnosis of those with positive test results was determined by echocardiography, while cases with negative tests

were generally confirmed through clinical follow up. It should be noted that only one study used echocardiography to obtain positive and negative pulse oximetry results[21]. For flow and timing assessment (QUADAS-2, Domain 4), 12 studies had a low risk of bias and the remaining three had an unclear risk due to insufficient information[13,17,19]. The studies showed an unclear risk of bias for the "flow and timing" domain. It is important to mention that most of the studies had no aspects that might hinder the feasibility of screening, either in selecting the study population or in applying the reference standard for screening. Likewise, the protocol implementation adhered to the American Academy of Pediatrics guidelines.

Discussion

The objective of this study was to identify the sensitivity and specificity of pulse oximetry as screening for CHDs in newborns. We present a review of 15 articles with a total of 286,731 individuals. The primary analysis was restricted to studies with thresholds around 95% (< 95% and ≤ 95%), except for the study by Bin-Nun[12] which used 93-94%. The analysis of these studies showed that pulse oximetry is a highly specific detection test with moderate sensitivity and a low false-positive rate.

The average overall sensitivity of the 15 studies included was 81.5%, the specificity was 99.4% and the false-positive rate was 0.24%. The inclusion of studies which used different saturation thresholds than those of the primary analysis slightly improved the sensitivity of the test. The exclusion of studies with high risk of bias did not significantly alter the sensitivity or specificity. Most of the studies were done in high-income countries (USA, Europe); however, studies in middle-income countries were also included. Methodological differences were found between the studies regarding the inclusion or exclusion of newborns with a presumptive prenatal diagnosis, the timing of the test (before or after 24 hours of life), the site of the test (only post-ductal or pre- and post-ductal), the measurement of functional or fractional saturation, and the study design (prospective or retrospective). An analysis of these aspects showed no effect on sensitivity or specificity among these variables[26,27].

The present review presents a larger number of included infants compared to other reviews with similar reviews evaluating the accuracy of pulse oximetry as a screening test for CCHD, compared to the reviews by Plana[28] and Aranguren[29], the authors of this review selected a significantly greater number of references and included data from more than 400,000 newborns, allowing greater precision in the test accuracy estimates. However, the results are still similar to those of our review. The strengths of this review include an exhaustive literature search to identify all relevant studies, a rigorous assessment of the risk of bias of the included studies using the QUADAS-2 tool, removal of duplicate data and a sensitivity analysis to investigate the differences in estimates of pulse oximetry accuracy between studies with high, low or uncertain risk of bias.

Two studies[13,23] included more than 100 CCHD cases, and nine studies included fewer than 10[9,12,15-18,20-22]. The relatively low number of CCHD cases included in this review indicates that the sensitivity accuracy continues to be low. We also found that the use of different strategies to confirm negative pulse oximetry cases might well have affected the sensitivity results. However, specificity was affected by the timing of the test and the risk of bias due to the flow and timing domain on the QUADAS-2 tool. The false-positive rates were 0.16% and 0.11% for newborns examined before and after 24 hours after birth, respectively. The absolute difference was 0.05%, with more false positives in the early detection group than in the late detection group. This means, in relative terms, that there were five times more false positives in the early detection group than in the late detection group.

Regarding the effect of altitude on pulse oximetry measurements, the findings of a study in Bolivia showed a difference in oxygen saturation between newborns in La Paz (3,640 MASL) and Cochabamba (2,558 MASL) ($p = 0.000$). In La Paz, the oxygen saturation of clinically healthy newborns was 86% at 10 minutes, 88% at 12 hours and 89% at 24 hours. In Cochabamba, it was 88% at 10 minutes, 89% at 12 hours, and 91% at 24 hours[30]. However, it is important to keep in mind that the reference values for pulse oximetry may change according to the altitude at which the test is performed[31].

The limitations include the fact that most of the studies had a prospective design with consecutive participant enrollment and included an adequate description of the index test. All of the studies efficiently reported the exclusion criteria. However, our review included relevant studies that met the inclusion criteria. The included studies were mainly considered to have a low or uncertain risk of bias in the QUADAS-2 domains. Data was complete and available for all the included studies. The risk of bias in QUADAS Domain 3 was low, as the diagnosis was established by echocardiography in cases

with positive test results. However, the cases with negative tests were generally confirmed through clinical follow up or a review of the congenital malformation registries and mortality databases. Likewise, the studies considered to have an uncertain risk of bias for the "flow and timing" domain had greater specificity.

No clinical studies were found within the search window. This is partially due to the limited number of controlled clinical trials on this topic in the current literature.

Practice implications and clinical relevance

These findings have substantial implications because they confirm the importance of pulse oximetry in screening for CHD in newborns.

Conclusions

This review provides a description of the sensitivity and specificity of pulse oximetry as a screening test for CHD in newborns. Pulse oximetry is highly specific, with moderate sensitivity and a low overall false-positive rate. Pulse oximetry is a non-invasive, inexpensive and useful adjunct tool for early detection of CHD in newborns.

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Conflicts of interest

The authors declare no conflicts of interest.

Ethical considerations

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

Data confidentiality. The authors declare that no patient data appear in this article. Furthermore, they have acknowledged and followed the recommendations as per the SAGER guidelines according to the type and nature of the study.

Right to privacy and informed consent. The authors declare that no patient data appear in this article.

Use of artificial intelligence for generating text. The authors declare that they have not used any type of generative artificial intelligence for the writing of this manuscript, nor for the creation of images, graphics, tables, or their corresponding captions.

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