Pulse oximetry screening for critical congenital heart defects in asymptomatic newborn babies: a systematic review and meta-analysis

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CRD summary
The authors concluded that pulse oximetry was highly specific for the detection of critical congenital heart defects in asymptomatic newborn babies, with moderate sensitivity. This was generally a well-conducted review and the authors' conclusion is likely to be reliable.

Authors' objectives
To assess the performance of pulse oximetry to screen for critical congenital heart defects in asymptomatic newborn babies.

Searching
MEDLINE, EMBASE, SciSearch and The Cochrane Library were searched, from 1951 to 2011 without restrictions on language or publication status. Some search terms were reported. The reference lists of relevant articles and reviews were scanned to identify further studies.

Study selection
Eligible for inclusion were studies of pulse oximetry (index test) as a screening method for critical congenital heart defects in asymptomatic newborn babies during the first 28 days of life.

Included studies were reported to have been conducted in a variety of newborn-care settings. Pulse oximetry was conducted as single and multiple readings. Over half of included studies used the foot alone (post ductal) to measure oxygen saturation; other studies used both right hand and foot (pre ductal and post ductal). Various reference standards were used to verify the test results, including echocardiography (for positive results), and use of congenital anomaly registers, mortality data and clinical follow-up (for negative results). Definitions of congenital heart defects varied and several individual cardiac lesions were reported.

Two reviewers independently selected studies for inclusion in the review. Disagreements were resolved by consensus and following discussion with a third reviewer.

Assessment of study quality
Study quality was assessed using QUADAS criteria. Studies were considered to be good if they demonstrated prospective consecutive recruitment; adequate description of the population, test and reference standard; blinding of test and reference standard; full verification of the test with the reference standard; and with more than 90% follow-up.

Two reviewers carried out the quality assessment.

Data extraction
Data were extracted into 2x2 tables to enable the calculation of sensitivity, specificity, and 95% confidence intervals (CI). Thresholds were applied as defined in the primary studies.

Two reviewers carried out the data extraction. Authors were contacted for data clarification, where necessary.

Methods of synthesis
True-positive and false-positive rates for various thresholds were plotted in receiver operating characteristics space. Summary estimates were presented in a hierarchical summary receiver operating curve (not presented in the paper). Cohort and case-control studies were analysed separately. Forest plots were used to investigate heterogeneity. Covariates were added to the model to explore the influence of timing of the test (less than 24 hours versus 24 or more hours after birth); test method (pre ductal and post ductal versus post ductal only); oxygen saturation (functional versus fractional); or antenatal screening (inclusion or exclusion of cases screened positive for congenital heart defects).
Sensitivity analysis was conducted to explore the effect of study design. Publication bias was assessed using a funnel plot.

**Results of the review**

Thirteen studies (229,421 babies) comprising 12 cohort designs and one case-control design were included in the review. Most studies scored well on the criteria considered (above) to represent good quality, with the exception of blinding of the index test which was carried out in only one study. One cohort study was excluded from the meta-analysis because it included no newborn babies with critical congenital heart defects.

Overall sensitivity for pulse oximetry was moderate at 76.5% (95% CI 67.7 to 83.5; $I^2=25\%$); overall specificity was high at 99.9% (95% CI 99.7 to 99.9; $I^2=98.5\%$, which indicated high heterogeneity). The false-positive rate was low (0.14%; 95% CI 0.06 to 0.33) and this was particularly the case (p=0.0017) when pulse oximetry was carried out after 24 hours (0.05%; 0.02 to 0.12) compared to within 24 hours from birth (0.50%; 0.29 to 0.86).

False-positive rates were significantly increased when newborn babies suspected to have congenital heart defects were included (0.73%; 95% CI 0.50 to 1.05; p<0.0001). There were no other significant differences in sensitivity between subgroups in terms of timing of the test, test method or antenatal screening.

Substantial publication bias was reported.

**Authors' conclusions**

Pulse oximetry was highly specific for the detection of critical congenital heart defects in asymptomatic newborn babies, with low false-positive rates and moderate sensitivity.

**CRD commentary**

The review question was clear. Inclusion criteria were specific and potentially replicable. Several relevant data sources were accessed and attempts were made to minimise publication and language biases. Publication bias was assessed and was substantial. The review process was conducted with efforts to minimise error and bias. An appropriate quality assessment tool was applied and the included studies generally scored well.

Some study details were presented and the method of synthesis seemed appropriate. There was little detail on patient characteristics or care setting, which meant that the generalisability of the results was unclear. A high level of statistical heterogeneity was noted for overall specificity. The authors acknowledged that the verification of negative test results varied in robustness, which raised the possibility of missed false negatives. This was generally a well-conducted review and the authors' conclusion is likely to be reliable.

**Implications of the review for practice and research**

**Practice:** The authors stated that there was strong evidence to support the clinical practice of pulse oximetry as a screening method to detect critical congenital heart defects in asymptomatic newborn babies.

**Research:** The authors stated that further research was unlikely to provide substantially different findings to this review, due to the number of babies now being tested with pulse oximetry. However, specific research was warranted into cut-off levels for screening at high altitude, as was the cost implication of pulse oximetry when applied outside the hospital setting.

**Funding**

No funding.

**Bibliographic details**


**PubMedID**

22554860
DOI
10.1016/S0140-6736(12)60107-X

Original Paper URL
http://www.thelancet.com/journals/lancet/article/PIIS0140-6736%2812%2960107-X/abstract

Other publications of related interest

Indexing Status
Subject indexing assigned by NLM

MeSH
Heart Defects, Congenital /diagnosis; Humans; Infant, Newborn; Neonatal Screening; Oximetry

AccessionNumber
12012020804

Date bibliographic record published
08/05/2012

Date abstract record published
06/07/2012

Record Status
This is a critical abstract of a systematic review that meets the criteria for inclusion on DARE. Each critical abstract contains a brief summary of the review methods, results and conclusions followed by a detailed critical assessment on the reliability of the review and the conclusions drawn.