Pulse Oximetry as a Screening Test for Congenital Heart Defects in Newborn Infants: A Test Accuracy Study with Evaluation of Acceptability and Cost-Effectiveness

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Background

Screening for congenital heart defects (CHDs) relies on antenatal ultrasound and postnatal clinical examination; however, life-threatening defects often go undetected. **Objective**

To determine the accuracy, acceptability and cost-effectiveness of pulse oximetry as a screening test for CHDs in newborn infants.

Design: A test accuracy study determined the accuracy of pulse oximetry. Acceptability of testing to parents was evaluated through a questionnaire, and to staff through focus groups. A decision-analytic model was constructed to assess cost-effectiveness. **Setting :** Six UK maternity units. **Participants:** These were 20,055 asymptomatic newborns at ≥ 35 weeks' gestation, their mothers and health-care staff. **Interventions:** Pulse oximetry was performed prior to discharge from hospital and the results of this index test were compared with a composite reference standard (echocardiography, clinical follow-up and follow-up through interrogation of clinical databases). **Main Outcome Measures:** Detection of major CHDs - defined as causing death or requiring invasive intervention up to 12 months of age (subdivided into critical CHDs causing death or intervention before 28 days, and serious CHDs causing death or intervention between 1 and 12 months of age); acceptability of testing to parents and staff; and the cost-effectiveness in terms of cost per timely diagnosis.

Results

Fifty-three of the 20,055 babies screened had a major CHD (24 critical and 29 serious), a prevalence of 2.6 per 1000 live births. Pulse oximetry had a sensitivity of 75.0% [95% confidence interval (CI) 53.3% to 90.2%] for critical cases and 49.1% (95% CI 35.1% to 63.2%) for all major CHDs. When 23 cases were excluded, in which a CHD was already suspected following antenatal ultrasound, pulse oximetry had a sensitivity of 58.3% (95% CI 27.7% to 84.8%) for critical cases (12 babies) and 28.6% (95% CI 14.6% to 46.3%) for all major CHDs (35 babies). False-positive (FP) results occurred in 1 in 119 babies (0.84%) without major CHDs (specificity 99.2%, 95% CI 99.0% to 99.3%). However, of the 169 FPs, there were six cases of significant but not major CHDs and 40 cases of respiratory or infective illness requiring medical intervention. The prevalence of major CHDs in babies with normal pulse oximetry was 1.4 (95% CI 0.9 to 2.0) per 1000 live births, as 27 babies with major CHDs (6 critical and 21 serious) were missed. Parent and staff participants were predominantly satisfied with screening, perceiving it as an important test to detect ill babies. There was no evidence that mothers given FP results were more anxious after participating than those given true-negative results, although they were less satisfied with the test. White British/Irish mothers were more likely to participate in the study, and were less anxious and more satisfied than those of other ethnicities. The incremental cost-effectiveness ratio of pulse oximetry plus clinical examination compared with examination alone is approximately £24,900 per timely diagnosis in a population in which antenatal screening for CHDs already exists.

Conclusions

Pulse oximetry is a simple, safe, feasible test that is acceptable to parents and staff and adds value to existing screening. It is likely to identify cases of critical CHDs that would otherwise go undetected. It is also likely to be cost-effective given current acceptable thresholds. The detection of other pathologies,

such as significant CHDs and respiratory and infective illnesses, is an additional advantage. Other pulse oximetry techniques, such as perfusion index, may enhance detection of aortic obstructive lesions.