Pulse Oximetry with Clinical Assessment to Screen for Congenital Heart Disease in Neonates in China: A Prospective Study

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Background

Several pioneering studies have provided evidence for the introduction of universal pulse oximetry screening for critical congenital heart disease. However, whether the benefits of screening reported in studies from high-income countries would translate with similar success to low-income countries is unknown. We assessed the feasibility and reliability of pulse oximetry plus clinical assessment for detection of major congenital heart disease, especially critical congenital heart disease, in China.

Methods

We did a pilot study at three hospitals in Shanghai to assess the accuracy of pulse oximetry plus clinical assessment for detection of congenital heart disease. We made a data collection plan before recruitment. We then undertook a large, prospective, and multicentre screening study in which we screened all consecutive newborn babies (aged 6–72 h) born at 18 hospitals in China between Aug 1, 2011, and Nov 30, 2012. Newborn babies with positive screen results (either an abnormal pulse oximetry or abnormal clinical assessment) were referred for echocardiography within 24 h of screening. We identified false-negative results by clinical follow-up and parents' feedback. We calculated sensitivity, specificity, positive and negative predictive values, and positive and negative likelihood ratios for pulse oximetry alone, and in combination with clinical assessment, for detection of major and critical congenital heart disease.

Findings

In the pilot study, 6785 consecutive newborn babies were screened; 46 of 49 (94%) cases of asymptomatic major congenital heart disease and eight of eight (100%) cases of asymptomatic critical disease were detected by pulse oximetry and clinical assessment. In the prospective multicentre study, we screened 122 738 consecutive newborn babies (120 707 asymptomatic and 2031 symptomatic), and detected congenital heart disease in 1071 (157 critical and 330 major). In asymptomatic newborn babies, the sensitivity of pulse oximetry plus clinical assessment was 93·2% (95% CI 87·9–96·2) for critical congenital heart disease and 90·2% (86·4–93·0) for major disease. The addition of pulse oximetry to clinical assessment improved sensitivity for detection of critical congenital heart disease from 77·4% (95% CI 70·0–83·4) to 93·2% (87·9–96·2). The false-positive rate for detection of critical disease was 2·7% (3298 of 120 392) for clinical assessment alone and 0·3% (394 of 120 561) for pulse oximetry alone.

Interpretation

Pulse oximetry plus clinical assessment is feasible and reliable for the detection of major congenital heart disease in newborn babies in China. This simple and accurate combined method should be used in maternity hospitals to screen for congenital heart disease.