Pulse Oximetry Screening Update

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Why do we need to use Pulse Oximetry screening (POS)?

- Incidence of life-threatening Congenital Heart Disease(CHD) – 2-3/1000 live births.
- Antenatal ultrasound – Low detection rate (35-86%), limited by availability of expertise.
- Clinical findings - not always apparent before discharge.
- Proportion discharged with undiagnosed defect - 25-39%, even in the most recent era, even in developed countries.

Acharya G, et al. Acta Obstet Gynecol Scand 2004; Brown KL, et al. Heart. 2006
Wren C, et al. Arch Dis Child Fetal Neonatal Ed. 2008; Randall P, et al. BJOG. 2005

Why do we need to use POS?

- Echocardiography – Gold standard, but Universal Echo is not practicable.

- Search for a tool which is easy to use, doesn't need a lot of expertise, relatively cheap, with high specificity and sensitivity.

Does Pulse Oximetry Screening (POS) satisfy these criteria?

- Pulse Oximetry is a well established test for objective quantification of hypoxemia.
- Most critical CHDs have some degree of hypoxemia.
- POS to complement existing methods for early detection was first reported over 10 years ago.

Richmond S Reay G, et al. Arch Dis Child Fetal Neonatal 2002

Existing studies using POS

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

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Summary

Background Screening for critical congenital heart defects in newborn babies can aid in early recognition, with the prospect of improved outcome. We assessed the performance of pulse oximetry as a screening method for the detection of critical congenital heart defects in asymptomatic newborn babies.

Methods In this systematic review, we searched Medline (1951–2011), Embase (1974–2011), Cochrane Library (2011), and Scisearch (1974–2011) for relevant citations with no language restriction. We selected studies that assessed the accuracy of pulse oximetry for the detection of critical congenital heart defects in asymptomatic newborn babies. Two reviewers selected studies that met the predefined criteria for population, tests, and outcomes. We calculated sensitivity, specificity, and corresponding 95% CIs for individual studies. A hierarchical receiver operating characteristic curve was fitted to generate summary estimates of sensitivity and specificity with a random effects model.

Findings We screened 552 studies and identified 13 eligible studies with data for 229 421 newborn babies. The overall sensitivity of pulse oximetry for detection of critical congenital heart defects was 76·5% (95% CI 67·7–83·5). The specificity was 99·9% (99·7–99·9), with a false-positive rate of 0·14% (0·06–0·33). The false-positive rate for detection of critical congenital heart defects was particularly low when newborn pulse oximetry was done after 24 h from birth than when it was done before 24 h (0·05% [0·02–0·12] *vs* 0·50 [0·29–0·86]; p=0·0017).

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Existing studies using POS

Pulse oximetry with clinical assessment to screen for congenital heart disease in neonates in China: a prospective study

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Summary

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

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What do these studies indicate?

POS has moderately high sensitivity

- Sensitivity - 76.5% (95% CI 67.7-83.5).
  - About three quarters of those with critical CHD can be diagnosed using POS alone.

- POS combined with clinical examination further increase its sensitivity (up to 93.2%)
  - More than 90% of these babies can be diagnosed using POS plus clinical examination.

Thangaratinam S, et al. Lancet 2012; Zhao QM, et al. Lancet 2014

POS has very high specificity

- Specificity – 99.9% (95% CI 99.7-99.9).
  - Most patients who do not have a critical CHD demonstrate normal saturation.

Thangaratinam S, et al. Lancet 2012

Accuracy of POS

With high specificity and very good sensitivity

POS satisfies the criteria for a screening test

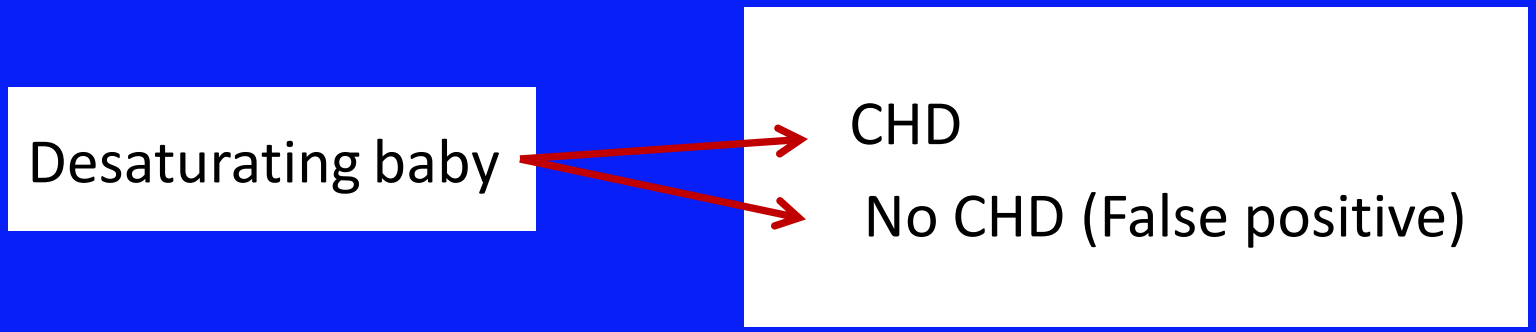
Thangaratinam S, et al. Lancet 2012

What do we mean by Critical CHD?

- Any duct-dependent CHD from which infant is likely to die or undergo invasive procedures (surgery or cardiac catheterisation) in the first 28 days of life.
  - Left-sided obstruction - Hypoplastic left heart, aortic stenosis, coarctation, interrupted aortic arch
  - Right-sided obstruction - Pulmonary atresia/stenosis
  - TGA, TAPVC and Tetralogy of Fallot

Thangaratinam S, et al. Lancet 2012

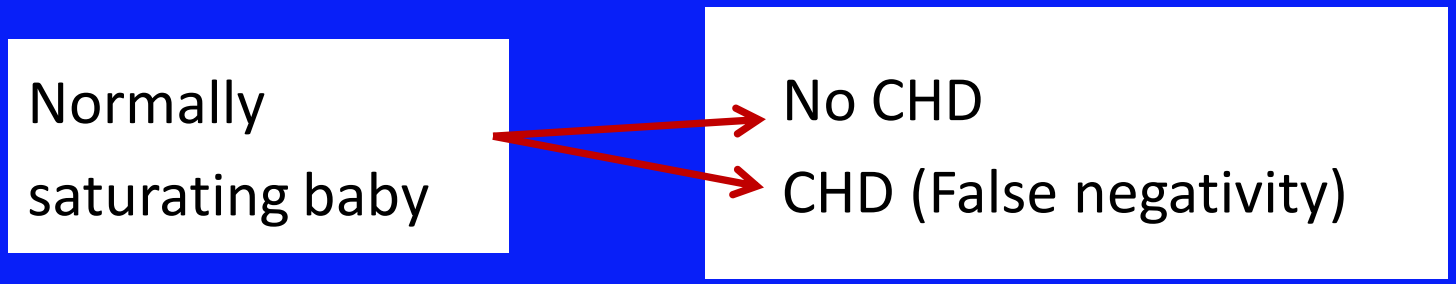
POS has false positivity



- Earlier in life the screening is performed greater is the false positivity

Thangaratinam S, et al. Lancet 2012

POS has False negativity



- About a quarter of critical CHDs may not be picked up by POS alone.
- CHDs likely to be missed - Left sided obstructive lesions, especially Coarctation of aorta.

How should screening be performed?

POS – ideal time?

Early Screening (<24 hours of age)

- False positivity with early screening is 10 times higher than late screening (0.5% vs 0.05%).
- Greater clinical load and parental anxiety.
- About 75% of false positivity is due to conditions such as pneumonia, TTN, PPHN etc.

Ewer AK., et al. Lancet 2011; de-Wahl Granelli A, et al. BMJ 2009
Ewer AK, et al. Early Hum Dev 2012

POS – ideal time?

Late Screening (>24 hours of age)

- Delay in discharge.
- Risk of missing babies who present early.
  - Nearly 50% of critical CHD present in first 24 hrs and 20% of them present in cardio-respiratory collapse.

de-Wahl Granelli A, et al. BMJ 2009; Ewer AK, et al. Curr Opin Cardiol 2013

POS – ideal time?

Early (<24 hrs) vs late (>24 hrs)

- Benefits of early screening needs to be balanced against risk of increased false positivity.

- Pragmatically each Hospital needs to adapt the timing of screening to suit local circumstances, based on discharge policy and follow up availability.

Timing of Screening

- AAP recommendation –
  - No earlier than 24 hours after birth

    OR
  - Just before discharge if discharged within 24 hrs.

- Nepean Hospital –
  - 24 to 48 hours or at discharge, whichever is early.

Kemper AR, et al. Pediatrics 2011

Cut-off value of positive test

- Different studies have used cut-off limits from 92% to 96%.
- AAP recommendation…. < 95%.
- SPO_2 value of 95% is estimated to be 2.5^{th} centile for healthy newborns.
- No recommended cut-off value for high altitude.

Jegatheesan, et al. Pediatrics 2013

Post ductal SPO_2 alone OR both pre and post

Post ductal SPO_2 seems logical

- Post ductal region has the lowest saturation (R-L shunt across PDA).
- Meta-analysis – Sensitivity using post ductal alone is as good as pre-post ductal SPO_2.
- Quicker

Thangaratinam S, et al. Lancet 2012

Post ductal SPO_2 alone OR both pre and post

Both Pre and postductal SPO_2 may have added benefit

- Individual studies that used both pre and post SPO_2 have picked up CHDs which would have been missed by post ductal SPO_2 alone.
- Results of the meta-analysis may have been skewed by larger number of studies that used post ductal SPO_2 alone.

Thangaratinam S, et al. Lancet 2012; De-Wahl Granelli A, et al. BMJ 2009
Ewer AK. Et al. Lancet 2011; Lannering K, et al. Pediatrics 2015

Post-ductal SPO_2 alone OR both pre and post

- Weighing up benefits and risks, each Hospital needs to decide on the protocol based on individual circumstances.

- AAP recommendation – use both pre and post.

  screening is negative if $SPO_2 \geq 95\%$ AND

  Pre-post difference ≤ 3%.

- In Australia, guidelines differ in different Hospitals.

Mahle WT, et al. Circulation 2009. Kemper AR, et al. Pediatrics 2011

Single or multiple measurements

- Repeating measurement if the first one is borderline (SPO_2 is 90-94%) reduces false positivity.

- Repeating the test in babies who are asymptomatic and have SPO_2 90-94% is a pragmatic way to further reduce false positives.

- AAP recommendation - 2 repeat tests at a gap of 1 hour in asymptomatic babies before considering positive.

de-Wahl Granelli A, et al. BMJ 2009; Kemper AR, et al. Pediatrics 2011

What should be done after a positive test?

- Ideal approach -Echocardiography to rule out CHD
  - Driving factors – parental anxiety, physician anxiety.
  - Limiting factors - limited cardiac services.
- Pragmatic approach - clinical exam, X-ray, blood gas, septic work up to identify non-cardiac causes of desaturation.
- Unexplained, persistent hypoxemia....echocardiogram.

What should be done after a negative test?

- With sensitivity of over 90% with clinical exam and POS, less than 10% babies go home undiagnosed.

- Parental counselling (parent information sheet) regarding limitations and usefulness of the test avoids false reassurance as well as reduces anxiety.

Ewer AK, et al. Health Technol Assess 2012;
Powell R, et al. Arch Dis Child Fetal neonatal 2013

POS – other considerations

- Which type of Pulse Oximeter?
  - Motion-tolerant pulse oximeters that perform better in low perfusion state (Eg: Masimo)
- Which type of Probe?
  - Reusable …cost effective
- Who performs the test?
  - Midwife, doctor, dedicated screener

Take home message

- POS acts as an adjunct (not a replacement) for existing methods, reduces the diagnostic gap and acts as a safety net.
- POS identifies babies with non-cardiac conditions such as GBS pneumonia.
- Screening protocol needs to be tailored to individual Health care facility.
- Parental counselling reduces anxiety as well as avoids false reassurance.

Thank you