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**Pulse oximetry screening for clinically unrecognized critical congenital heart disease in the newborns**

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**Abstract**

**Aim:**

To determine the incidence of clinically unrecognized critical congenital heart disease (CCHD) in the newborns by using pulse oximetric screening.

**Methods:**

Pulse oximetry was performed on clinically normal newborns at 24-48 hours of age. If screening oxygen saturation (SpO2) was below 95%, echocardiography was then performed. Data regarding true and false positives as well as negatives were collected and analyzed.

**Results:**

Pulse-oximetric screening was performed on 1847 clinically normal newborns. Low SpO2 (<95%) was found in three babies two of them had CCHD, including one with transposition of the great vessels, one with complete atroventricular canal with moderate tricuspid regurgitation (sensitivity: 100%; specificity: 99.8%; positive predictive value: 100%; negative predictive value: 100%; accuracy: 99.8%).

**Conclusions:**

In addition to routine physical examination in the newborn infants pulse oximetry may improve the early diagnosis CCHD in the newborn. If oxygen saturation in clinically normal newborns is below 95% at 24-48 hours of age, referral to a cardiology unit is suggested.

**MeSH:** Heart Defects, Infant, Newborn, Neonatal Screening/methods, Congenital/complications/diagnosis Oximetry
Introduction
The incidence of congenital heart diseases (CHD) is 8-10 per 1,000 live births.\(^1,2,3,4,5\) Early diagnosis of CHD is important because the delayed diagnosis of severe CHD can lead to cardiac failure, cardiovascular collapse and even death. Many infants died without the diagnosis of CHD.\(^6\) Routine neonatal examinations fails to detect more than 50% of infants with CHD.\(^7,8,9,10,11\) Many neonates with CHD have no signs that can be detected by clinical examination. Critical congenital heart diseases (CCHD) in the newborn may have borderline low oxygen saturations unrecognized clinically. This fact has led some to explore the possibility of screening all newborn babies with pulse oxygen oximetry in addition to the usual routine physical examination.\(^12,13,14\) In developing countries with inadequate medical personnel, this method can be very helpful in early detection of CCHD. Our study is designed to determine the incidence of clinically unrecognized CCHD by using pulse oximetric screening.

Methods
All infants born aged 24-48 hours at Synphaet Hospital during September 2004 to September 2006 were clinically evaluated. Only clinically normal newborns were included in the study. Exclusion criteria were any of the following abnormalities on physical examination: cyanosis, tachypnea, grunting, nasal flaring, chest retraction, significant heart murmur, active precordium, and diminished pulse. Pulse oximetry was performed using the Masimo Set pulse oximeter model Radical. Measurements were performed by the nurses on the right hand and one foot. \(\text{O}_2\) saturation (Sp\(\text{O}_2\)) below 95% underwent additional evaluation by echocardiography. CCHD was defined as a lesion that would likely require surgical correction during the first few months of life.

Results
During the study period there were 1,881 live born infants at Synphaet Hospital. Twenty-six neonates who met the exclusion criteria were excluded. Eight of these neonates had CHD (Figure 1). There were 8 neonates no \(\text{SpO}_2\) measurement. All of them were well on our well baby follow up record. Oximetry screening was performed on 1,847 clinically normal born infants. There were three infants with \(\text{SpO}_2\) below 95%. Two of them had CCHD, including one patient with transposition of the great vessels (TGV), one patient with complete atrioventricular canal (AV canal) & moderate tricuspid regurgitation (TR). The mean \(\text{O}_2\) saturation of normal newborns (Sp\(\text{O}_2 \geq 95\%\)) was 98.1% and was 82.5% in the low Sp\(\text{O}_2\) group (Table 1). There were 11 infants with congenital heart disease in this group of infant during this study period, the incidence of CHD was 5.8 per 1000 live births and CCHD was 1.08 per 1000. A pulse oximetry cut-off value of below 95% showed 100% sensitivity, 99.8% specificity, 100% positive predictive value, 100% negative predictive value and accuracy of 99.8% in identifying CCHD (Table 2).
Figure 1 Lists of patients, type of CCHD, and method of detection

- Total NB 1881
  - Clinical 26
    - Neonatal ICU 15
      - 1 with Pneumothorax (Lt)
      - 8 with clinical sepsis
      - 4 with transient tachypnea of the newborn (TTNB)
      - 2 with Respiratory distress
    - Heart murmur detected 11
      - A cyanotic CHD
        - 3 PDA with clinically normal
          - SpO₂ measured 1847
            - 3 Saturation < 95%, CCHD
              - 2 CCHD
                - 1 with TGV, O₂ Sat 70%
                - 1 with AV canal
                  - Moderate TR, O₂ Sat 89%
              - 1 CHD
                - VSD, PFO, moderate TR, PI, O₂ Sat 90%
          - Saturation ≥ 95% 1844
            - Follow up 1WK-2 months
              - NO murmur
                - Well-baby 1847
              - Heart murmur detected (Missed physical examination in 72 hrs of age) 5
                - 3 with small PDA, TR, clinically normal
                - 1 with PFO, TR
                - 1 with Physiologic LPA stenosis
        - 2 CCHD
          - SpO₂ measured 1847
            - Not measured 8
              - 3 Saturation < 95%, CCHD
                - 2 CCHD
                  - 1 with TGV, O₂ Sat 70%
                  - 1 with AV canal
                    - Moderate TR, O₂ Sat 89%
                - 1 CHD
                  - VSD, PFO, moderate TR, PI, O₂ Sat 90%
            - SpO₂ measured 1847
              - Not measured 8
                - 3 Saturation < 95%, CCHD
                  - 2 CCHD
                    - 1 with TGV, O₂ Sat 70%
                    - 1 with AV canal
                      - Moderate TR, O₂ Sat 89%
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            - Follow up 1WK-2 months
              - NO murmur
                - Well-baby 1847
              - Heart murmur detected (Missed physical examination in 72 hrs of age) 5
                - 3 with small PDA, TR, clinically normal
                - 1 with PFO, TR
                - 1 with Physiologic LPA stenosis
            - SpO₂ measured 1847
              - Not measured 8
                - 3 Saturation < 95%, CCHD
                  - 2 CCHD
                    - 1 with TGV, O₂ Sat 70%
                    - 1 with AV canal
                      - Moderate TR, O₂ Sat 89%
                  - 1 CHD
                    - VSD, PFO, moderate TR, PI, O₂ Sat 90%
            - SpO₂ measured 1847
              - Not measured 8
                - 3 Saturation < 95%, CCHD
                  - 2 CCHD
                    - 1 with TGV, O₂ Sat 70%
                    - 1 with AV canal
                      - Moderate TR, O₂ Sat 89%
                  - 1 CHD
                    - VSD, PFO, moderate TR, PI, O₂ Sat 90%
    - Acyanotic CHD 3 PDA with clinically normal
      - SpO₂ measured 1847
        - Not measured 8
          - 3 Saturation < 95%, CCHD
            - 2 CCHD
              - 1 with TGV, O₂ Sat 70%
              - 1 with AV canal
                - Moderate TR, O₂ Sat 89%
            - 1 CHD
              - VSD, PFO, moderate TR, PI, O₂ Sat 90%
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Table 1 Comparision of Results of Pulse Oximetry Screening between well Saturation (≥95%) and low Saturation (<95%) groups

| Data                      | Well Saturation (≥ 95%) | Low Saturation (< 95%) |
|---------------------------|-------------------------|------------------------|
| Population                | 1,844                   | 3                      |
| Mean gestational age      | 38.3 Wk                 | 38.1 Wk                |
| Mean body weight          | 3,168 Gm                | 2,196 Gm               |
| Total Mean oxygen sat     | 98.1%                   | 82.5%                  |
| Mean oxygen sat of Rt hand| 98.2%                   | 83%                    |
| Mean oxygen sat of foot   | 98.1%                   | 82%                    |

Table 2 Results of Pulse Oximetry Screening for CCHD. Synphaet Hospital

| SpO2 not measured 8     |
| Number screened 1,847   |
| CHD cases in clinical infants 8   |
| CCHD cases in clinically normal newborns 2 |
| CHD cases in clinically normal newborns 1 |
| Incidence of CHD in total population 5.8/1,000 |
| Major CCHD detected by screening 1000 number screened 1.08/1,000 |
| True positive 3         |
| False positive 0        |
| True negative 1,844     |
| False negative 0        |
| Sensitivity 100%        |
| Specificity 99.8%       |
| Positive predictive value 100% |
| Negative predictive value 100% |
| Accuracy 99.8%         |

Discussion
The reported incidence of CHD was 8-10 per 1000 live births. The incidence CCHD is agreeable with the previous study. To determine the sensitivity, specificity, predictive value, and accuracy of a program of pulse oximetry screening in asymptomatic newborns for CCHD, the previous study reported of the effectiveness of pulse oximetry screening for CHD in asymptomatic newborns (Sensitivity: 60%; specificity: 99.95%; positive predictive value: 75%; negative predictive value: 99.98%; accuracy: 99.97%). The low sensitivity in this study was because they had included non critical CHD in their calculation. However, other study revealed that systematic screening for CCHD with high accuracy required a new generation oximeter, and comparison of saturation values from the right hand and one foot substantially improves the detection of CCHD (Sensitivity: 98.5%; specificity: 96.0%; positive predictive value: 89.0%; negative predictive value: 99.5%). Our efficacy
data is very close to the number of other study. The cost of pulse oximetry screening is minimal. Although the same disposable probe was used on multiple cases, alcohols cleaning between cases were emphasized and yet no evidence of infection was found. One limitation of the study is that the number of screened neonates are too small and no case of coarctation of aorta to validate the difference of oxygen saturation in the right arm and leg.

**Conclusion**

This study demonstrated the use of noninvasive, cost-effectiveness tool which is pulse oximetry screening adjunct to routine neonatal examination for detecting CCHD in clinically normal newborns that were born at Synphaet Hospital during 24 months period.
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