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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 (SpO_2) 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 atrioventricular 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. O_2 saturation (SpO_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 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 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 O_2 saturation of normal newborns ($SpO_2 \geq 95\%$) was 98.1% and was 82.5% in the low SpO_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).

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Figure 1 Lists of patients, type of CCHD, and method of detection

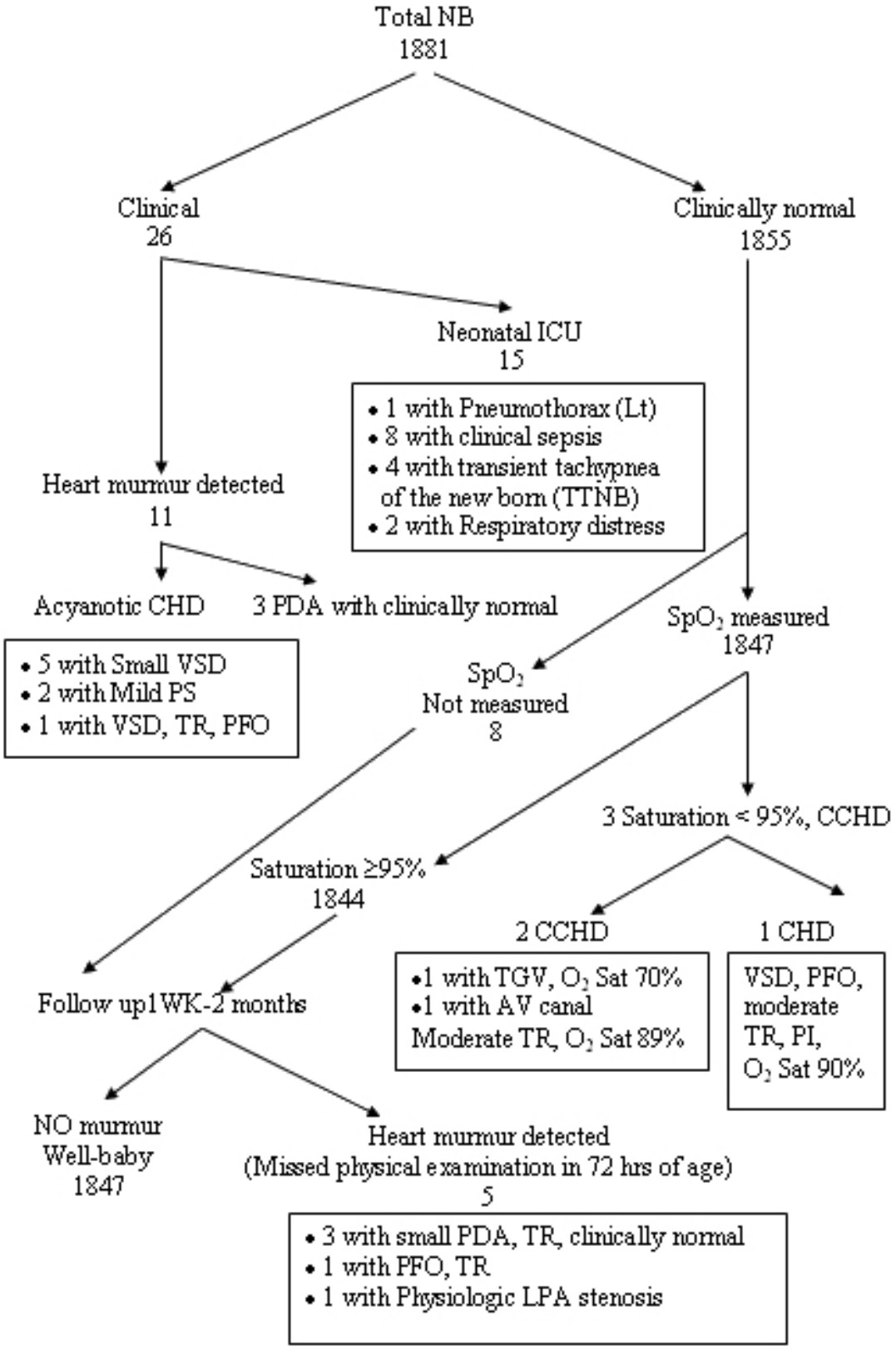

Table 1 Comparision of Results of Pulse Oximetry Screening between well Saturation (≥95%) and low Saturation (<95%) groups

Data	Well Saturation (≥ 95%)	Low Saturation (< 95%)
Population	1,844	3
Mean gestational age	38.3 Wk	38.1Wk
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.[1,2,3,4,5] The incidence CCHD is agreeable with the previous study.[13] 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%).[13] 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%).[15] Our efficacy

data is very closed to the number of other study.[15] 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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