Role of perfusion index in pulse oximetry screening for critical congenital heart disease in neonates

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ABSTRACT

Introduction: Screening for critical congenital heart diseases (CCHD) with oxygen saturation (SpO₂) by pulse oximeter often misses left-sided obstructive heart diseases. Objective: The role of perfusion index (PI) along with SpO₂ in CCHD screening was studied. Methodology: The Masimo, RADICAL-7 pulse oximeter was used to record the SpO₂ and PI in the right hand and left foot of asymptomatic babies at 24–72 h of life. Babies with SpO₂ <95% or PI <0.7 were rechecked at an hourly interval for three recordings. SpO₂ 90–94% or PI <0.7 in all three recordings or SpO₂ <90% at any one recording were considered as screen positive. An echocardiogram was done for screen-positive cases. Screen negative cases were clinically followed for 6 weeks. Result: Of 1011 screened babies, four were screen positive. One baby had PI <0.7 and SpO₂ <90%. This baby had single ventricle, transposed great vessels, and interrupted aortic arch. Other three cases had SpO₂ between 90% and 94% in all three recordings. Echocardiogram showed severe right ventricle outflow obstruction in 2 cases and normal heart in one baby. At follow-up, no baby had CCHD. Conclusion: In this study with small sample size, only one baby had left-sided obstructive lesion but also had single ventricle physiology. Hence, there was no difference in the diagnostic accuracy between SpO₂ alone and SpO₂ with PI in screening for CCHD. Thus, combining PI with SpO₂ may improve CCHD screening using pulse oximeter, but large-scale study is needed.

Key words: Critical congenital heart disease, Newborn screening, Oxygen saturation, Perfusion index, Pulse oximetry

Congenital heart diseases (CHD) requiring intervention in the 1st month of life to ensure survival is considered as critical CHD (CCHD). CCHD has an incidence of about 170 in 100,000 live births. Early diagnosis and timely therapy are crucial to prevent acute deterioration of the affected children [1]. CHD with right-sided obstruction or well-mixing lesion present predominately with cyanosis. These cyanotic CHD initially present with faint cyanosis which may be indistinguishable clinically. Thus, the clinical examination (CE) fails to identify about 50% of CHD in the neonatal period [2]. However, these babies can be identified with low oxygen saturation (SpO₂) in the pulse oximeter. Hence, American Academy of Pediatrics (AAP) has recommended SpO₂ measurement by pulse oximeter as a screening strategy to identify cyanotic CHD [3].

However, left-sided obstructive lesions such as hypoplastic left heart syndrome, interrupted aortic arch, and coarctation of aorta present initially with poor peripheral perfusion. SpO₂ may remain within normal limits at an early stage of the disease and can be missed by pulse oximeter screening [1]. Studies have shown that more than 3% difference in saturation (DSpO₂) between pre-ductal and post-ductal regions may give a clue to these left-sided obstructive heart diseases [4]. Granelli and Ostman-Smith have found that peripheral perfusion index (PI) measured with new generation pulse oximeter can help in screening for left-sided obstructive lesions [5]. PI is a measure of the pulsatile blood flow in the underlying tissues and is decreased in babies with reduced peripheral tissue perfusion [6]. PI below 0.7 was suggested as a screening tool for identifying left-sided obstructive heart diseases [5].

This study was planned with a hypothesis that combining PI with SpO₂ may improve CCHD detection. The primary objective was to compare the diagnostic accuracy of SpO₂ alone, with SpO₂ and PI in screening for CCHD among asymptomatic newborn babies at 24–72 h of life. The secondary objective was to find out the diagnostic accuracy of CE in screening for CCHD either alone or in combination with SpO₂ and PI.

METHODOLOGY

This prospective study was done in a tertiary care hospital in the Tamil Nadu state of India. The study was carried out over a period of 4 months from October 2011 to January 2012. The Institutional Ethics Committee approved the study. All babies born during the study period and asymptomatic at 24–72 h of life were included in the study. Asymptomatic babies under evaluation for sepsis due to various perinatal risk factors were excluded from the study.
Parents of all babies who satisfied the inclusion criteria were approached for the study. Written informed consent was obtained from the parents and basic demographic details were collected. Babies were then clinically examined for any dysmorphic features, central cyanosis, respiratory distress, apical impulse location, femoral pulses, and grade ≥3/6 precordial murmur.

The new generation pulse oximeter with signal extraction technology (Masimo, RADICAL-7, Signal extraction pulse Co-Oximeter with rainbow technology) was used for recording functional hemoglobin $\text{SpO}_2$ percentage and PI. The instrument displays the pulse waveform, heart rate, $\text{SpO}_2$, and PI. The reusable neonatal probe was applied in the right hand (Pre-ductal area) and the left foot (Post-ductal area) serially when the baby was calm and quiet. The $\text{SpO}_2$ and PI were recorded, once the monitor’s display panel showed regular pulse waves. The probe was cleaned with a compatible disinfectant solution between babies.

If PI was ≥0.7 with $\text{SpO}_2$ ≥95% in both tested limbs and $\text{DSpO}_2$ between the two limbs was ≤3%, the screening was considered negative. If anyone of these readings was abnormal, the test was repeated after 1 h. If the second recording result remained abnormal, it was reconfirmed by repeating the test 3rd time after another hour. Babies who consistently had $\text{SpO}_2$ <95% or PI <0.7 or $\text{DSpO}_2$ >3% in all three recordings were declared screen positive.

We had four screen positive cases: One at first recording and other three at the end of three recordings. The baby who was screen positive at first recording had $\text{SpO}_2$ <90% and PI< 0.7 in the right hand. This baby was antenatally diagnosed to have single ventricle. Postnatal echocardiogram of this baby showed transposition of great vessels (TGV), interrupted aortic arch, single ventricle, hypoplastic left atrioventricular valve, and patent ductus arteriosus. Three babies persistently had $\text{SpO}_2$ 90–94% by echocardiography. The parents of babies who did not come for follow-up were tracked through phone about the health status of the baby. For those parents who could not be contacted by phone, a letter enquiring the health status of their baby was posted to their mailing address. The babies who could not be contacted by phone or post were considered as dropouts.

Sensitivity, specificity, positive predictive value (PPV), and negative predictive value (NPV) for $\text{SpO}_2$, PI, and CE were calculated individually and in combination using OpenEpi, Version 2, open source calculator for diagnostic tests. Categorical data were analyzed with two-tailed Fisher’s exact test for small groups and Chi-square test for the large population using SPSS Version 16. p<0.05 was considered as significant.

RESULTS

A total of 1011 babies out of 1059 eligible babies were screened. 48 babies were discharged before 24 h of life due to various reasons and were not included in the study (Fig. 1).

Male to female ratio in the study population was 1.03:1. The babies were screened at a mean age of 34 h (±10.5), and their mean birth weight was 2850 g (±440) (Table 1).

Mean $\text{SpO}_2$ in the right hand and left foot was 97.42% (±1.35) and 97.58% (±1.44), respectively, with a mean $\text{DSpO}_2$ of 1.07% (±0.86). Mean PI in the right hand and left foot was 2.43 (±1.48) and 2.43 (±1.32), respectively (Table 2).

We had four screen positive cases: One at first recording and other three at the end of three recordings. The baby who was screen positive at first recording had $\text{SpO}_2$ <90% and PI< 0.7 in the right hand. This baby was antenatally diagnosed to have single ventricle. Postnatal echocardiogram of this baby showed transposition of great vessels (TGV), interrupted aortic arch, single ventricle, hypoplastic left atrioventricular valve, and patent ductus arteriosus. Three babies persistently had $\text{SpO}_2$ 90–94%
Table 1: Baseline characteristics of the study population

| Characteristics       | Observation     |
|-----------------------|-----------------|
| Male: female ratio    | 1.03:1 (p=0.687)|
| Mean birth weight     | 2850 (±440) g   |
| Mean age at screening | 34.03 (±10.5) h |
| Mode of delivery      | Labor naturale-453; Cesarean section-532; Assisted breech-3; Outlet forceps-17; Vacuum-6 |

Table 2: Study results

| Characteristics       | Observation     |
|-----------------------|-----------------|
| Mean \(\text{SpO}_2\) in right hand | 97.42% (±1.35) |
| Mean \(\text{SpO}_2\) in left foot    | 97.58% (±1.44) |
| Mean DS\(\text{SpO}_2\)              | 1.07% (±0.86)  |
| Mean PI in right hand  | 2.43 (±1.48)   |
| Mean PI in left foot   | 2.43 (±1.32)   |
| Number of babies with dysmorphism | 4 (down syndrome-1, Preauricular skin tag-3) |
| Number of babies with cardiac murmur | 4 (CCHD-1, VSD-3) |
| Number of screen positive cases | 4 (Low \(\text{SpO}_2\) and low PI-1, low \(\text{SpO}_2\)-3) |
| Number of confirmed CCHD | 3 (Antenatally detected-2, detected by screening-1) |

\(\text{SpO}_2\): Pulse oximeter saturation, \(\text{DSpO}_2\): Difference in pulse oximeter saturation between right upper limb and left lower limb, PI: Perfusion index, CCHD: Critical congenital heart disease, VSD: Ventricular septal defect

In this study, an attempt was made to study the role of combined \(\text{SpO}_2\) and PI screening in identifying the CCHD. The results are encouraging since PI has rightly identified one baby with the interrupted aortic arch. Interestingly, this baby also had \(\text{SpO}_2\) <90% due to TGV and single ventricle. It can be assumed that even if it had been an isolated interrupted aortic arch, this case would have been picked up by pulse oximeter when both \(\text{SpO}_2\) and PI were recorded in all babies. Thus, PI and \(\text{SpO}_2\) each have a unique role as a screening tool for identifying left-sided obstructive heart diseases and cyanotic heart diseases, respectively.

de-Wahl Granelli et al. have suggested that incorporating cutoff values for PI into routine pulse oximetry screening would probably increase sensitivity for detection of the left heart obstructive disease [4]. In our study, the PI <0.7 has a sensitivity of 33.33%, specificity of 100%, and PPV of 100% in identifying all CCHD. However, it has a sensitivity of 100% and specificity of 100% in identifying CCHD with the left-sided obstructive lesion since there was only one case with the interrupted aortic arch in the study population which was identified by low PI.

de-Wahl Granelli et al. stated that in a complex heart disease with a combination of TGV, arch obstruction and duct dependent circulation, the post-ductal saturation may well be >95%, and hence, >3% DSp\(\text{O}_2\) between pre-ductal and post-ductal regions was included as a screening tool in their study [4]. Although we had one baby with TGV and aortic arch obstruction, the DSp\(\text{O}_2\) was not significant. Probably this was due to the complex nature of the defect with single ventricle physiology which resulted in \(\text{SpO}_2\) <90% in both pre-ductal and post-ductal areas.

There were two babies in this study with antenatally detected CHD whose \(\text{SpO}_2\) screening was positive and echo later confirmed the critical cardiac lesions. This supports Richmond et al.’s comment that even if the antenatal diagnosis was not made in these babies, the screening saturation measurement would have triggered the evaluation for CHD [7]. Riede et al. stated that in babies with the prenatal diagnosis of CCHD, if medical treatment is initiated soon after birth, \(\text{SpO}_2\) will be spuriously high because of medical therapy [8]. Koppel et al. have noted that in a center where fetal echocardiography is readily accessible, many lesions will be diagnosed prenatally, and therefore, \(\text{SpO}_2\) screening may be less useful in detecting new CCHD. However, centers, where fetal echocardiography is performed less frequently, are likely to demonstrate higher yields from pulse oximetry screening [9].

Although CE is said to miss about 50% of CHD in infants, many studies on CHD screening have included the CE in their screening methods. CE had a sensitivity of 33.33%, specificity of 100%, and PPV of 100% in identifying all CCHD. However, it has a sensitivity of 100% and specificity of 100% in identifying CCHD with the left-sided obstructive lesion since there was only one case with the interrupted aortic arch in the study population which was identified by low PI.
In our study, PI was low in one baby with left-sided obstructive lesion, but due to coexisting single ventricle physiology, SpO₂ was also low. Hence, in this study, there was no difference in the diagnostic accuracy between SpO₂ alone and SpO₂ with PI in screening for CCHD. However, the study was limited by small sample size. Thus, combining PI with SpO₂ may improve CCHD screening using pulse oximeter but large-scale study is needed.

REFERENCES

1. Liske MR, Greeley CS, Law DJ, Reiche JD, Morrow WR, Baldwin HS, et al. Report of the Tennesse task force on screening newborn infants for critical congenital heart diseases. Pediatrics 2006;118:e1250.
2. Thangaratinam S, Daniels J, Ewer AK, Zamora J, Khan KS. Accuracy of pulse oximetry in screening for congenital heart disease in asymptomatic newborns: A systematic review. Arch Dis Child Fetal Neonatal Ed 2007;92:F176-80.
3. Mahle WT, Martin GR, Beckman III RH, Morrow WR, Rosenthal GL, Snyder CS, et al. Endorsement of health and human service recommendation for pulse oximetry screening for critical congenital heart disease. Pediatrics 2012;129:190.
4. de-Wahl Granelli A, Wennergren M, Sandberg K, Mellander M, Bejlum C, Inganäs L, et al. Impact of pulse oximetry screening on the detection of duct dependent congenital heart disease: A Swedish prospective screening study in 39,821 newborns. BMJ 2009;338:a3037.
5. Granelli AD, Ostman-Smith I. Noninvasive peripheral perfusion index as a possible tool for screening for critical left heart obstruction. Acta Paediatr 2007;96:1455-9.
6. Perfusion Index, Clinical Applications of Perfusion index-Summary; 2009. Available from: http://www.masimo.co.uk/pdf/whitepaper/LAB3410F.pdf. [Last accessed on 2012 Jan 23].
7. Richmond S, Reay G, Harb MA. Routine pulse oximetry in the asymptomatic newborn. Arch Dis Child Fetal Neonatal Ed 2002;87:F83-8.
8. Riede FT, Worner C, Dahmert I, Hokkel A, Kostelka M, Schneider P. Effectiveness of neonatal pulse oximetry screening for detection of critical congenital heart disease in daily clinical routine—results from a prospective multicenter study. Eur J Pediatr 2010;169:975-81.
9. Koppel RI, Druschel M, Carter T, Goldberg BE, Mehta NP, Talwar R, et al. Effectiveness of pulse oximetry screening for congenital heart disease in asymptomatic newborns. Pediatrics 2003;112:451.
10. Arlettas R, Bauschatz AS, Monkhoff M, Essers B, Baurleurs F. The contribution of pulse oximetry to the early detection of congenital heart disease in newborns. Eur J Pediatr 2006;165:94-8.
11. Valmari P. Should pulse oximetry be used to screen for congenital heart disease? Arch Dis Child Fetal Neonatal Ed 2007;92:F176-80.
12. Vaidyanathan B, Sathish G, Mohanan ST, Sundaram KR, Warrier KK, Kumar RK. Clinical screening for congenital heart disease at birth: A prospective study in a community hospital in Kerala. Ind Ped 2011;48:25-30.

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