

Pulse oximetry screening for critical congenital heart disease - Experience in a public hospital in India

Nandkishor Palve¹, Alpana Utture¹, Ruchi Nanavati¹, Akshay Hire¹, Prafulla Kerkar²

From Departments of ¹Neonatology, and ²Cardiology, Seth GS Medical College and KEM Hospital, Parel, Mumbai, Maharashtra, India

Correspondence to: Dr Alpana Utture, 303, Sushila Sadan, Dr. M. B. Raut Road, No. 2, Shivaji Park, Dadar, Mumbai - 400 028, Maharashtra, India. Phone: +91-9820042059, Tel: 02224450190. E-mail: utture.alpana@gmail.com

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ABSTRACT

Background: Critical congenital heart disease (CCHD) if undiagnosed in the first few days of life is associated with high morbidity or and mortality. Pulse oximeter screening for CCHDs in newborn babies can aid in early recognition with the prospect of improved outcome. Routine pulse oximetry screening of asymptomatic infants for CCHD is prevalent in developed countries but not in India. **Aims:** To estimate the diagnostic accuracy of screening for CCHD with a new generation pulse oximeter in a setting of a public hospital in India. **Materials and Methods:** A prospective observational study including all term neonates (>37 weeks) admitted to the postnatal ward. **Results:** 1594 term newborns were screened by pulse oximetry. Of these, 1589 (99.69%) neonates passed the screening and 5 failed the test. For CCHD, sensitivity was found to be 100% with a specificity of 99.94% and positive and negative predictive value was 80% and 100%, respectively. Peripheral perfusion index (PPI) was 2.04 in infants who passed the test in comparison to 0.65 in those who failed the test. **Conclusion:** Pulse oximetry has a high sensitivity, specificity, and negative predictive value for detection of CCHD in newborn infants. PPI is a good predictor of systemic hypoperfusion in CCHD.

Key words: Critical congenital heart disease, Peripheral perfusion index, Pulse oximeter, Screening

Congenital heart defects (CHD) account for nearly one-third of all major congenital anomalies. Reported birth prevalence of CHD is 8 per 1000; although, it varies widely among the studies worldwide [1,2]. Critical CHD (CCHD) is a potentially life-threatening cardiac abnormality, which means that either the systemic or the pulmonary circulation, is dependent on the patent ductus arteriosus and it often requires invasive procedures in the first 28 days of life [3,4]. CCHD occurs at a frequency of 1.2-1.7 per 1000 live births and accounts for 10-15% of all cases of CHD [5]. Early diagnosis of CCHD is an important since the risk of morbidity and mortality increases when there is a delay in the diagnosis and referral to a tertiary center with expertise to treat such cases [6,7]. The previous research has shown that delay in identifying critical congenital disease increases mortality and may also increase morbidity post operatively [8,9].

Traditionally screening for CHDs included clinical assessment of pulses, heart sounds, and presence of cyanosis. However, clinical assessment alone has a fairly low detection rate, and a substantial number of babies are discharged from the hospital before CHDs are diagnosed [10]. This deficiency in detection is because of limitations in physical examination, such as difficulty in identifying cyanosis, especially in anemic or dark-pigmented neonates, early hospital discharge in duct-dependent lesions if the duct has not yet closed, and lack of murmurs in infants with CCHD. Prenatal USG at 18 weeks of gestation can detect many major congenital cardiac malformations. However, prenatal

detection of CHD is only 57%, and isolated defects are detected even less frequently [11-13].

In the last 10-15 years, noninvasive transcutaneous pulse oximetry has provided the means and impetus for blood oxygen saturation screening as an adjunct to traditional screening methods. Pulse oximetry screening can identify newborns with CCHD who are missed by routine prenatal ultrasound and by pre-discharge examination [14,15]. Pulse oximetry is easily available and screening after 24 h of life can lead to the detection of CCHD during a critical period when potentially life-saving intervention can be undertaken. Numerous studies have shown that routine pulse oximetry is highly sensitive and specific for identifying CCHD [16-18]. Although pulse oximetry is a good tool for screening CCHDs with hypoxemia, its sensitivity for detection of left heart obstructive disease (LHOD) is low. Pulse oximetry-derived peripheral perfusion index (PPI) has been proposed as a tool to detect critical left heart obstruction but has never been studied prospectively [19]. Further studies of infants with various cardiac lesions are needed before incorporating PPI in the screening process for CCHD.

In 2011, the American Academy of Pediatrics and the American Heart Association recommended screening all asymptomatic babies with pulse oximetry to detect CCHD [20]. However, routine pulse oximetry screening for CCHD is not widely used in India, and there are only a few studies for the same. In the studies conducted in India, some have shown good sensitivity

and specificity, while others have not shown the same [21,22]. We undertook this study to find out the feasibility, utility and diagnostic accuracy of screening for CCHD with a new generation pulse oximeter in neonates delivered in a public hospital in India.

MATERIALS AND METHODS

The study was conducted in the postnatal ward of a tertiary hospital in Mumbai. This was a single center prospective observational study. All term neonates (>37 weeks) admitted to the postnatal ward were included in the study. Infants with multiple congenital malformations and antenatally diagnosed CHD were excluded. Infants were recruited over a period of 3 months from September 2015 to November 2015. Informed consent was obtained before enrolment in the study. The study was cleared by the Hospital Ethics Committee.

Pulse oximeter saturation of all infants included in the study was recorded between 24 and 48 h of life by applying pulse oximeter probe on preductal (right palm) and postductal (any foot) site by the investigator while clinical examination was done by the registrar in the postnatal ward. The Masimo model radical 7 pulse oximeter was used to document the saturations. Results were said to be positive if SpO₂ saturation on pulse oximeter was <90% in right hand or foot. If SpO₂ was 90% to <95% or there was >3% difference between right hand and foot, 3 readings were taken 1 h apart before labeling it positive [23].

Results were said to be negative if SpO₂ saturation on pulse oximeter was ≥95% in right hand or foot and the difference between right hand and foot was ≤3% [23]. The PPI was noted for all the babies in either foot. The algorithm for pulse oximetry screening has been shown in Fig. 1. The diagnostic accuracy of pulse oximetry was measured by computation of sensitivity, specificity, positive and negative predictive values. If as per protocol the screen was positive, then the baby was evaluated further by chest X-ray, electrocardiogram and two-dimensional echocardiography (2D ECHO). ECHO was performed by a cardiologist who was blinded about the pulse oximetry results.

RESULTS

During our study period, there were total 2006 live births and 1652 term live births. 1594 term newborns were screened by pulse oximetry. Fig. 2 shows the flow chart of screening. Nine infants with CHD were diagnosed on prenatal ultrasound scan. Table 1 shows the diagnosis of antenatally detected CHDs. Of the 1594 babies screened, 1589 (99.69%) neonates passed the screening and 5 failed the test. A total of 9 newborns (including 5 on antenatal USG and 4 from postnatal pulse oximeter screening) had CCHDs, with incidence of 4.4 per 1000 live births. Seven neonates had a false negative test as they were subsequently diagnosed by clinical examination and 2D ECHO to have heart disease. Out of these babies, 2 babies were diagnosed to have small patent foramen ovale with patent ductus arteriosus (PDA), 1 baby had a small atrial septal defect (ASD) with PDA, 3 babies had small to moderate ASD while one had tiny ASD with VSD.

Table 1: Spectrum of congenital heart diseases in newborns who were diagnosed on antenatal scan

S. No.	Congenital heart disease
1	Left hypoplastic heart with moderate ASD with large PDA
2	Left hypoplastic heart type A, large PDA, large ASD with hypoplastic aorta
3	d-TGA with VSD
4	Congenital heart block with VSD and PDA
5	Intracardiac TAPVC
6	Complete congenital heart block with VSD
7	OS ASD with bicuspid aortic valve
8	Dysplastic tricuspid valve
9	Tricuspid atresia

TGA: Transposition of great arteries, PDA: Patent ductus arteriosus, ASD: Atrial septal defect, VSD: Ventricular septal defect, OS: Ostium secundum, TAPVC: Total anomalous pulmonary venous connection

Five neonates (0.31%) who failed the screening test had positive findings on clinical examination. Out of these babies, 4 were diagnosed on 2D ECHO to have critical heart disease, which are shown in Table 2. One baby, who failed the screening test, had absent bilateral femoral pulsations on clinical examination and oxygen saturation could not be recorded in the lower limb. This baby died before a 2D ECHO could be done, and postmortem examination revealed interrupted aortic arch.

Sensitivity of pulse oximetry for CHDs was found to be 41.67% (95% confidence interval [CI] 15.17-72.33%) with specificity of 100% (95% CI 99.77-100%). Positive predictive value was 100% (95% CI 47.82-100%) and negative predictive value was 99.56% (95% CI 99.09-99.82%). Negative likelihood ratio was 0.58 (95% CI 0.36-0.94). For CCHD, sensitivity was found to be 100% (95% CI 39.76-100%), with specificity of 99.94% (95% CI 99.65-100%) and positive predictive value of 80% (95% CI 28.36-99.49%), with negative predictive value of 100% (95% CI 99.77-100%). Positive likelihood ratio was 1590 (95% CI 224.10-11280.97) and negative likelihood ratio was 0.

PPI ranged from 1.2 to 3.6 with a mean of 2.04 in infants who passed the test. In cases of failed test, they ranged from 0.8 to 0.9 with mean a of 0.65. In the infant with IAA, no PPI values could be recorded at postductal site.

DISCUSSION

Out of the 1652 live births, 21 babies were diagnosed to have CHDs, with incidence of 10.4 per 1000 live births. Nine newborns had CCHDs, with incidence of 4.4 per 1000 live births, which is about twice the reported incidence. Out of these 9 babies, 5 were diagnosed on antenatal scan while remaining 4 failed pulse oximetry screening and were subsequently diagnosed on 2D ECHO and postmortem examination. Sensitivity was 41% for all CHD and 100% for CCHD. Specificity was 99.94% and false-positive rate of 0.06%.

In 2011, Ewer et al. reported the results of a prospective assessment of the accuracy of pulse oximetry as a tool for screening

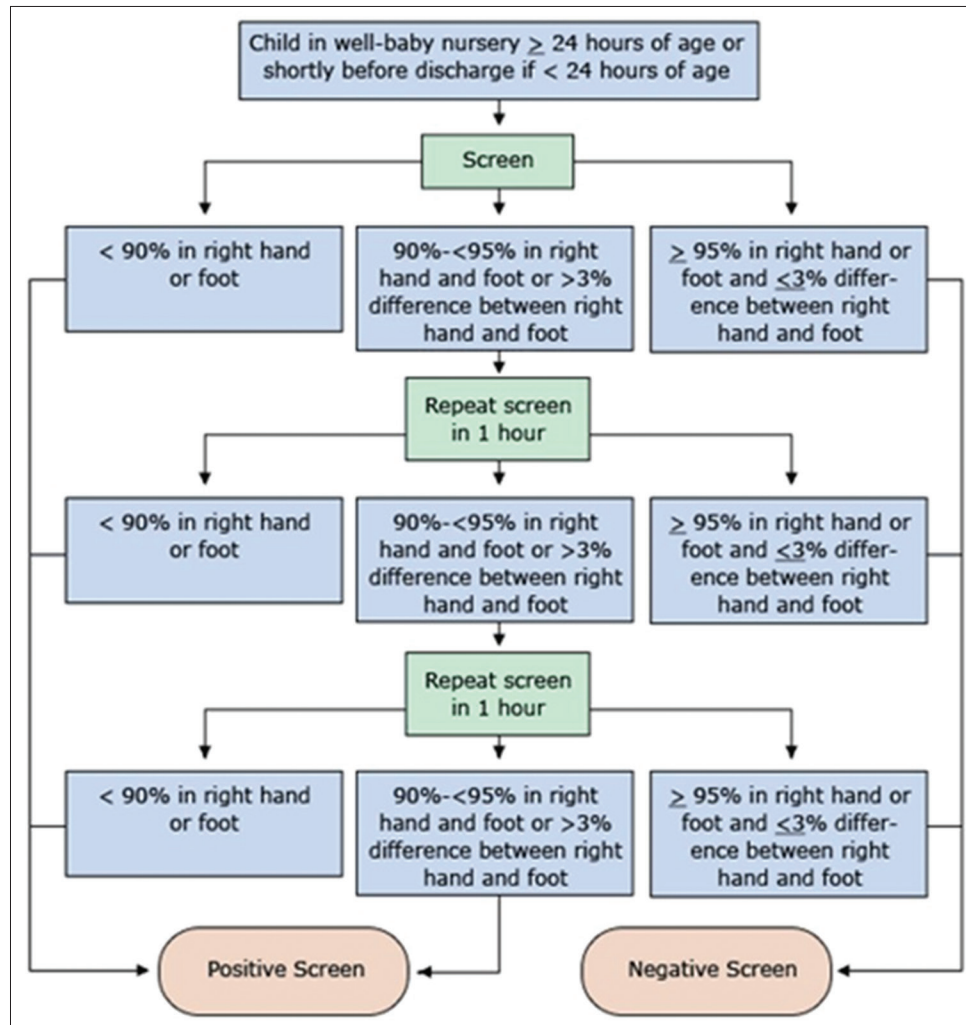


Figure 1: Critical congenital heart defect screening algorithm [23] (percentages refer to oxygen saturation as measured by pulse oximeter)

Table 2: Clinical features and 2D ECHO findings of neonates who failed pulse oximetry screening

S. No.	CVS examination	Screening pass/fail	2D ECHO findings	Postmortem finding
1	Cyanosis, tachypnea, PSM	Failed	D-TGA with intact IVS with large non-restricted PDA with large ASD with left to right shunt	
2	PSM	Failed	Tricuspid atresia type IB with large OS ASD with R to L shunt, 3 mm subaortic VSD with L to R shunt	
3	PSM	Failed	PDA 2.5 mm restrictive, L to R shunt	
4	Cyanosis, tachypnea	Failed	Supracardiac TAPVR	
5	Absent bilateral femoral pulsations	Failed		IAA

PSM: Pan systolic murmur, TGA: Transposition of great arteries, IVS: Interventricular septum, PDA: Patent ductus arteriosus, ASD: Atrial septal defect, VSD: Ventricular septal defect, TAPVR: Total anomalous pulmonary venous return, IAA: Interrupted aortic arch, 2D ECHO: Two-dimensional echocardiography, CVS: Cardiovascular, OS: Ostium secundum

for CCHD in 2005 neonates of >34 weeks' gestational age. The study group here was quite large as compared to 1594 babies in our study. Major CHD was found in 53 neonates and CCHD in 24. Sensitivity was 58% for critical cases and 29% for all major heart disease which was less as compared to the sensitivity of 41% for all CHDs and 100% for CCHD in our study [16]. False-positive results were seen in 0.8% of newborn babies in this study, as compared to 0.06% for CCHD in our study.

Qu-ming Zhao et al. in a prospective multicenter study screened 122,738 consecutive newborn babies and detected

CHDs in 1071. In babies screened for CCHD with pulse oximetry alone, sensitivity was 78.4%, specificity 99%, and false-positive rate was 0.29%. In addition of pulse oximetry to clinical assessment improved sensitivity for detection of CCHD from 77.4% (95% CI 70.0-83.4) to 93.2% (87.9-96.2) [24]. Compared to this, we had a sensitivity of 100%, specificity of 99.94% and a false-positive rate of 0.06% in our study. Taksande et al. in a similar study in a hospital in rural India screened 2110 asymptomatic neonates for CCHDs and found 100% sensitivity, 99.95% specificity, 87.50% positive predictive value, and 100%

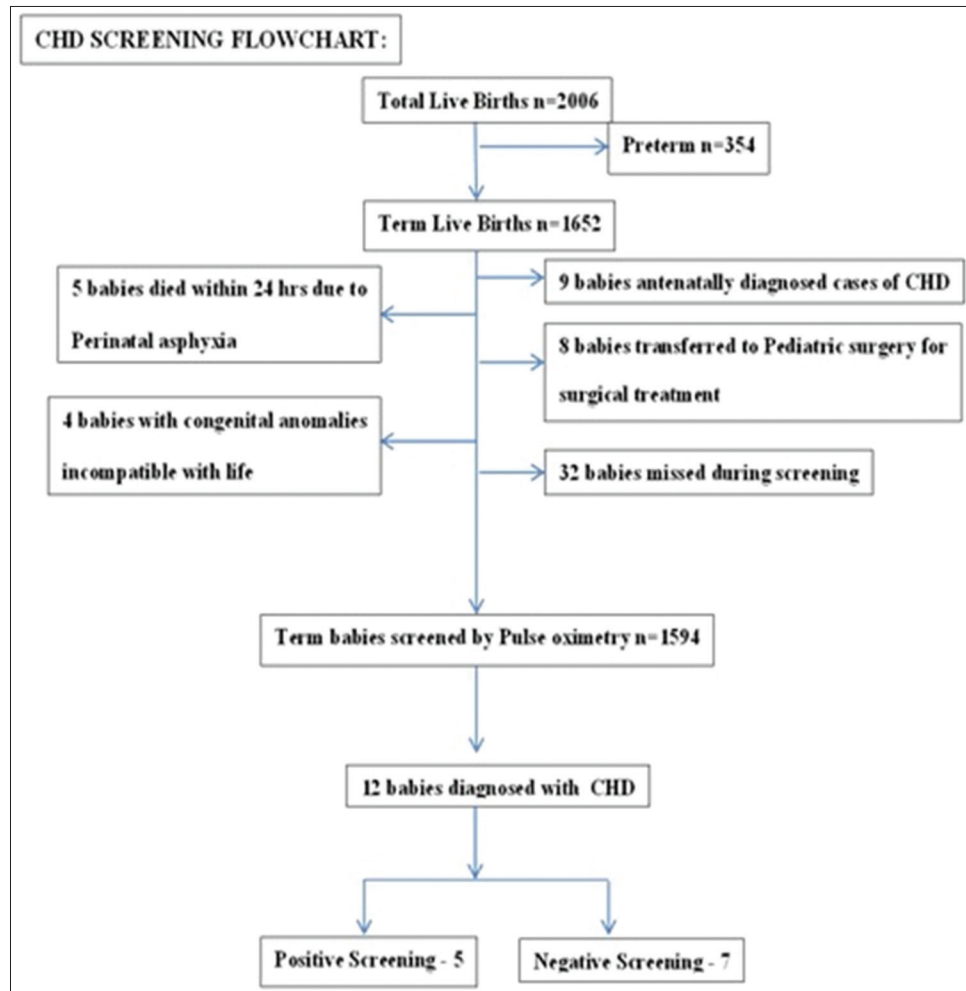


Figure 2: Flow chart showing recruitment of cases

negative predictive value [21]. This compares very well with our results.

Thangratinam et al. in a systematic review and meta-analysis screened 552 studies and identified 13 eligible studies with data for 229,421 newborn babies. The overall sensitivity of pulse oximetry for detection of CCHDs 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 CCHDs 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]; $p=0.0017$) [25].

In our study, all the 5 infants who failed the pulse oximeter screening also had signs suggestive of cardiac disorder in the form of pansystolic murmur, cyanosis, and absent pulses. Schena et al. studied 50244 infants and found that in tertiary hospitals, 95% of CCHDs were identified before pulse oximeter screening either antenatally or on clinical examination. However, in 1-2 level units, only 28% were detected clinically, and perfusion index and pulse oximetry screening added a 46% sensitivity to the sole physical examination [26]. This compares with our findings that a good antenatal ultrasound examination and detailed physical examination can identify most of the heart diseases.

Bradshaw et al. in their study found that the average screening time for pulse oximetry was 3.5 min (0-35 min). They

concluded that pulse oximetry can be implemented successfully in community hospitals without an excessive number of false positives or additional nursing staff [27].

Granelli et al. studied 10,000 normal newborns and 9 infants with left LHOD and found PPI value <0.70 giving an odds ratio for LHOD of 23.75 (95% CI 6.36-88.74). They concluded that PPI values lower than 0.70 may indicate illness and a value <0.50 (1st percentile) indicates definite underperfusion [11]. In our study, PPI in infants who passed the test was mean of 2.04 as compared to 0.65 in those who failed the test suggesting reduced systemic perfusion. Thus, PPI values might be a useful additional tool for early detection of LHOD. In our study, 2D ECHO could not be done on all neonates due to practical difficulties in doing, so however, all infants were followed up clinically through infancy.

CONCLUSION

Pulse oximeter screening for CCHD is a sensitive test with high specificity and negative predictive value. Incorporation of pulse oximetry to the routine assessment of the newborn infant can enhance detection of CCHD. Since not all CCHD are associated with hypoxemia, addition of PPI is a promising technique to detect impaired perfusion in the case of left LHODs and may cover the diagnostic gaps of this screening test.

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