Original Article

Does Masimo Signal Extraction Technique Pulse-Oximeter Improve the Detection Rate of Congenital Heart Diseases of Newborn? - An Observational Study

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Abstract

Introduction: Congenital heart diseases (CHDs) are common congenital anomalies, which if left untreated account for higher mortality and morbidity. Early detection and surgical correction of CHDs are the best treatment measures. The current study aims to test whether Masimo signal extraction technique (SET) pulse-oximeter, which uses signal extraction technology improves the detection rate of CHDs with its overall sensitivity, specificity, and accuracy. **Subjects and Methods:** The current prospective, observational study was conducted at a tertiary medical center over a period of 2 years. All the neonates' pre- and post-ductal oxygen saturation along with clinical examination was performed within 24 h of life. Postductal reading of ≤ 95% and/or with difference between pre- and postductal of > 5% was considered to be positive for CHDs. Infants with clinical symptoms or test positive for pulse oximetry were referred for echocardiographic confirmation. **Results:** A total of 2213 infants were observed. Seventeen CHD cases were detected during the study period. Four hundred and fifteen infants tested positive with the pulse oximeter. Ten of them had minor or major CHD and two of the infants had critical CHD. The overall sensitivity of pulse oximetry screening was 70.59% (95% CI), specificity of 81.65%, and a diagnostic accuracy of 81% for any CHDs. **Conclusion:** Masimo SET pulse oximeter is a sensitive tool for detecting CHDs. A pulse oximeter in combination with clinical examination aids in the better detection rate of CHD. Echocardiography must be considered in all infants who test positive with pulse oximeter or any abnormal findings in the clinical examination.

Keywords: Congenital heart disease, masimo, preterm, pulse oximetry

Introduction

Congenital heart diseases (CHDs) are a common congenital anomaly, which left untreated accounts for higher mortality and morbidity. Over the years, advancement in medical management and surgical correction improved the patient outcome but missed or delayed diagnosis still attributes to the higher mortality rates.[1] The worldwide prevalence of CHDs is 8 per 1000 live births with geographical variations.[2] The Asian population has the highest prevalence for CHD of 9.3 per 1000 live births.[3] One in every four infants with CHD has a critical congenital heart defect which presents with severe hypoxia and cyanosis, requiring medical intervention within the 1st month of life.[4] Critical CHD includes coarctation of aorta, transposition of great artery, hypoplastic left heart syndrome (HLHS), pulmonary atresia, tetralogy of Fallot (TOF), total anomalous pulmonary venous return (TAPVC), tricuspid atresia, and truncus arteriosus. Critical CHD with duct-dependent defects may not always present with visible cyanosis and may be easily missed out in clinical examination.[5]

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How to diagnose?

Echocardiography (ECHO) is the gold standard for the confirmation of CHDs.[6] Prenatal and postnatal ECHO helps in the early identification and timely initiation of the treatment. The major limitation of ECHO is not the technique, but the unavailability of trained physicians and equipment in low- and middle-income countries. The routine physical examination (including family history, auscultation, presence of other anomaly, echocardiogram, chest X-ray, and four limb blood pressure) still remains as a sole diagnostic tool in such developing countries although it lacks sensitivity and specificity.[7,8]

Pulse oximetry testing is a sensitive tool, which measures oxygen saturation (SpO_2) and it is widely accepted as most reliable noninvasive method of assessing oxygenation. A major flaw associated with conventional pulse oximeter is that it only measures the pulsating component of arterial blood. Therefore, in low perfusion states, it may show a false low SpO_2. To overcome this limitation, Masimo signal extraction technique (SET) pulse oximeter uses conventional red and infrared photoplethysmographic signals along with a combination of light shielded optical sensors, adaptive filtration, and digital signal processing which claims to have a better ability to measure SpO_2 accurately in motion or low perfusion states.[9,10]

The current study aims to find the sensitivity, specificity, positive predictive value, negative predictive value, and diagnostic accuracy of Masimo SET pulse oximeter and also to compare the pulse oximeter testing with clinical examination in detecting critical CHDs of new-borns.

Subjects and Methods

A single center, prospective observational study was conducted in a multidisciplinary tertiary care centre. Infants who were subjected to pulse oximeter testing within first 24 h. Of life and had a gestational age (GA) more than 34 weeks were enrolled in the study. Informed consent was obtained from the parents. The study was approved by the Institutional Ethical Committee IEC 165/2017.

A postductal reading of ≤95% SpO_2 or with a difference of >5% between pre- and post-ductal SpO_2 was considered as test positive and referred for ECHO for further evaluation. Routine clinical examination was also performed. The presence of any symptoms such as cyanosis, respiratory distress, blood pressure fluctuations, heart murmurs, chest X-ray abnormality, or overlapping anomaly was considered as abnormal. The child was then referred to a senior physician following which ECHO was taken. Postnatal ECHO was performed in all the infants irrespective of pulse oximeter test positive or abnormal clinical examination before discharge. Irrespective of pulse oximeter test positive or abnormal clinical examination a postnatal ECHO was performed in all the infants before discharge. The assessments such as clinical examination, pulse oximetry testing, and ECHO were performed accordingly by a neonatologist, respiratory therapist (specialized in neonatal respiratory care), and a cardiologist, respectively.

Echocardiography classification of congenital heart disease[7]

Normal

No echocardiographic abnormality or any of the following: Patent ductus arteriosus (PDA) <2 mm in size without volume overload of left ventricle, interatrial communication (patent foramen ovale or atrial septal defect [ASD]) <5 mm without volume overload of right ventricle and mild turbulence at branch pulmonary arteries. Very small muscular ventricular septal defects (VSDs), which are likely to close spontaneously.

Minor congenital heart disease

ASD >5 mm with right ventricle volume overload, PDA >2 mm with left ventricle volume overload, restrictive VSD, valvular aortic/pulmonary stenosis with gradients <25 mm Hg.

Major congenital heart disease

These were subdivided into two subgroups.

Serious congenital heart disease

Any CHD that was likely to require intervention within the 1st year of life, but was not defined as critical.

Critical congenital heart disease

Any CHD that was likely to require an intervention within the first 28 days of life. ECHO was performed with Philips CX50 POC system.

Statistical analysis

A predetermined sample size was calculated with an expert dependent sample size calculation assuming the test sensitivity of 60%, specificity of 99%, and the prevalence rate of CHD (8 per 1000 live births). On an average, 7 live births occur per day in our center. Based on these data, we estimated a sample size of 2500. We calculated the sensitivity, specificity, positive and negative predictive values, positive and negative likelihood ratio, and diagnostic accuracy of pulse oximetry and clinical examination. The categorical variables are expressed in n (%). Data were analyzed using IBM (SPSS Statistic version 20, South Asia, Bangalore, Karnataka, India).

The data were collected using an expert validated pro forma. Maternal data such as gravida, parity, antenatal complications, labor, fetal ECHO findings, prenatal steroid administration, and infant data such as mode of birth, GA, gender, birth weight, APGAR score, physical examination and Pre- Post ductal SpO_2 and ECHO findings were recorded. SpO_2 was measured from the right hand (preductal) and right lower limb (postductal) between 2 and 24 h of life. Masimo SET pulse oximeter was used to measure SpO_2 and Philip CX50 general imaging ultrasound system was used for ECHO.

Results

A total of 3120 newborn admissions occurred during the study period, of which 2213 infants were enrolled in the

study. This was 89% of the calculated sample size. Baseline characteristics of the study population were 52% of them were males. Seventy percent of them were born after 37 weeks of gestation. 86% of them had APGAR score of more than 7 at 5 min of birth. Sixty-five percent of them had birth weight of more than 2500 g. Only 1.4% of the infants had familial history of CHD. Pulse oximetry testing was positive for 415 infants and 102 infants had abnormal clinical findings [Figure 1].

Table 1: Demographic details of study population

Variable	*n* (%)
Gender	
Males	1145 (52)
Females	1068 (48)
Gestational age (weeks)	
≥37	1549 (70)
≥34≤36	664 (30)
APGAR score at 5 min	
≥7	1915 (86)
<7	298 (14)
Birth weight (g)	
≥2500	1452 (65)
<2500	761 (35)
Family history of CHD, *n* (%)	33 (1.4)
Average SpO_2 in CHD mean (SD)	90.7 (2.8)

CHD: Congenital heart diseases, SD: Standard deviation, SpO_2: Oxygen saturation

A total of 17 CHD cases were diagnosed with ECHO giving a prevalence rate of 7.6 per 1000 live births. Fourteen of them had minor or major CHD and 3 of them had critical CHD (prevalence rate of 1.3 per 1000 live births). Only 1.4% of the infants 7 had familial history of CHD [Table 1]. Critical CHD included TOF, HLHS, and TAPVC [Table 2] and the rest were noncritical CHDs including ASD, 10 PDA, and 3 VSD. The average SpO_2 in all the CHD's detected was 90.7% (2.8) mean and standard deviation. Diagnostic accuracy of Masimo SET pulse-oximeter and clinical examination in detecting CHDs.

The sensitivity of pulse oximetry for detecting any CHDs was 70.59% (95% confidence interval [CI] 44.04–

Table 2: Details of newborns with critical congenital heart diseases (*n*=3)

Critical CHDs detected	Pulse oximetry	Clinical examination
Tetralogy of Fallot (*n*=1)	True positive	Normal
Hypoplastic left heart syndrome (*n*=1)	False negative	Normal
Total anomalous pulmonary venous connection (*n*=1)	True positive	Abnormal

CHDs: Congenital heart diseases

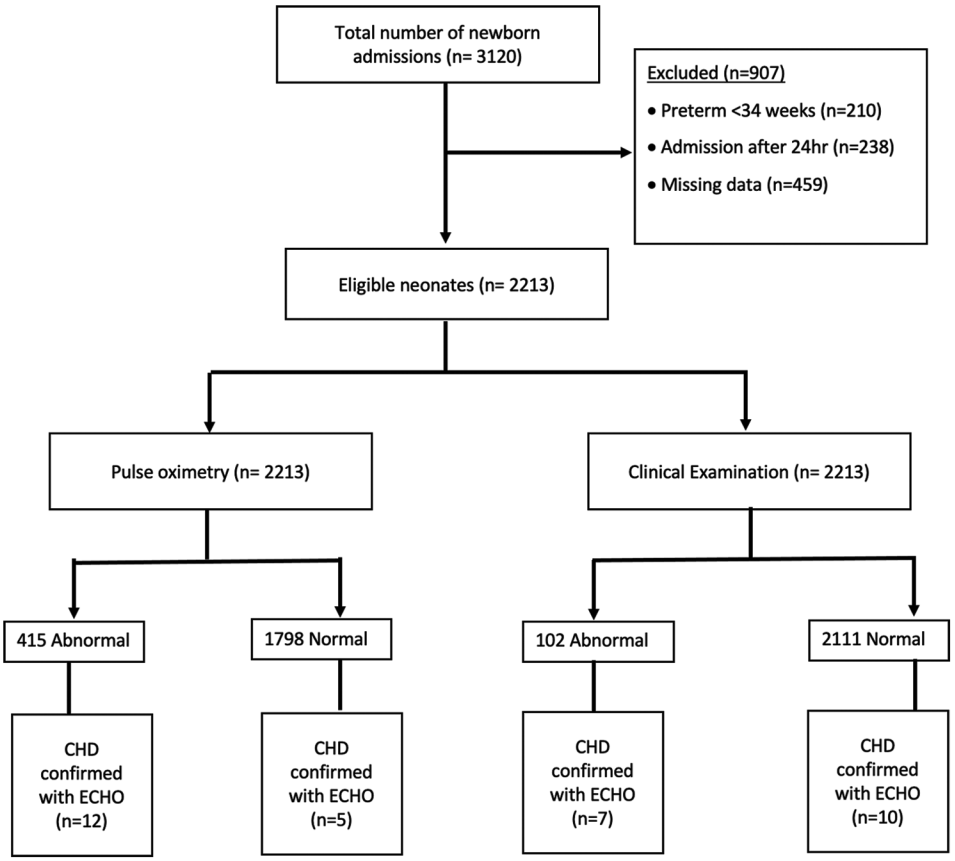

Figure 1: Study characteristics

Table 3: Accuracy of masimo signal extraction technique pulse ox and clinical examination in detecting congenital heart diseases (*n*=17)

Parameters	Pulse oximetry (*n*=2213)	Clinical examination (*n*=2213)
True positive	12	7
False negative	5	10
False positive	403	95
True negative	1793	2101
Sensitivity (95% CI) (%)	70.59 (44.04-89.69)	41.18 (18.44-67.08)
Specificity (95% CI) (%)	81.65 (79.96-83.25)	95.67 (94.74-96.49)
Positive predicted value (95% CI) (%)	2.89 (2.12-3.94)	6.86 (3.88-11.85)
Negative predicted value (95% CI) (%)	99.72 (99.42-99.87)	99.53 (99.30-99.68)
Diagnostic accuracy (95% CI) (%)	81.56 (79.88-83.16)	94.49 (93.45-95.40)
Positive likelihood ratio (95% CI) (%)	3.85 (2.80-5.29)	9.52 (5.22-17.37)
Negative likelihood ratio (95% CI) (%)	0.36 (0.17-0.75)	0.61 (0.41-0.92)

CI: Confidence interval

89.69) compared to physical examination 41% (95% CI 79.96–83.25). The specificity of the pulse oximeter was 81.65% (95% CI 79.96–83.25) versus 95.67% (95% CI 94.74–96.49) for clinical examination [Table 2]. Out of the 3 critical CHD cases, the pulse oximeter detected two cases and only 1 case had abnormal findings in clinical examination [Table 3]. The sensitivity for pulse oximeter and clinical examination were 66.7% (95% CI 9.43–99.16) versus 33.33% (95% CI 0.84–90.57), respectively, and specificity was 100% (95% CI 99.83–100) for both the tests in detecting critical CHDs [Table 4].

Discussion

The prevalence of CHD in the current study was 7.6 per 1000 live births which was slightly lesser than the reported prevalence.[2,3] The possible reason can be the overall higher percentage of term infants (70%) and the inclusion criteria of GA above 34 weeks by which the nonsignificant and minor CHDs associated with preterm infants are less reported. The prevalence of critical CHD was 1.3 per 1000 live births.

Since 1990s, pulse oximeter has been used as a reliable test for measuring SpO_2 in infants. Hoke *et al*. first reported the use of pulse oximeter in asymptomatic newborns with CHD and showed a reasonable sensitivity and specificity for the test.[11] Over the years, pulse oximetry has been extensively studied.[10-15] Recent Cochrane review showed a moderate evidence of using pulse oximeter in detecting the CHD.[16] The overall sensitivity and specificity of Masimo SET pulse oximeter in the current study were 70.59 (95% CI 44.04–89.69) and 81.65 (95% CI 79.96–83.25), respectively. For critical CHDs, the sensitivity was 66.7 (9.43–99.16) and specificity of 100 (99.83–100). The reported critical CHDs in the study were 3 out of 2213, and this rate may attribute to the lowest sensitivity of the pulse oximeter testing.

Clinical examination which is still used as a stand-alone tool for detecting CHDs had a much lower sensitivity compared to pulse oximeter 41 (95% CI 79.96–83.25). If clinical examination was used as stand-alone tool, then three critical CHDs and 10 minor or major CHDs would have been missed and left the hospital undiagnosed.

The infants with critical CHD such as duct-dependent lesion are mostly asymptomatic in first 72 h of life till the PDA closes.[12] The early diagnosis and prompt medical management decide the morbidity and mortality in these cases. Hence, the pulse oximeter testing was performed within 24 h of life in the current study.

Conventional pulse oximeters assume that the pulsating blood is arterial blood. Misinterpretation can occur with motion artifacts. Multiple studies reported low oximetric reading compared to normal arterial oxygenation in newborns.[17,18] Numerous factors such as low peripheral perfusion, motion artefact, probe placement or partial probe placement and hyperbilirubinemia or dyshemoglobinemias affect this measurement. Masimo SET pulse oximeter earned its popularity by its filtration capability of motion artefacts and also by giving accurate measurement in lower profusion states. Shah *et al*. compared the effect of motion on SpO_2 and heart rate measurement made with Masimo SET and Nellcor N-200 pulse oximeter and their data suggested the Masimo SET may offer improvement in pulse oximetry performance, particularly in clinical situation in which extreme artefacts are likely.[9]

The current evidence from developed countries recommends the use of routine pulse oximetry screening in neonates but in developing countries such as India, where population outnumbers the trained health-care professionals, it is challenging. A successful implementation of routine screening will occur only with repeated training and workforce planning.[14,16]

Conclusion

Masimo SET pulse oximeter is a sensitive tool in detecting critical CHD of new-borns. ECHO must be considered in all infants who test positive with pulse oximeter or any abnormal findings in clinical examination.

Table 4: Accuracy of masimo signal extraction technique pulse oximeter and clinical examination in detecting critical congenital heart diseases (*n*=3)

Parameters	Pulse oximetry (*n*=2213)	Clinical examination (*n*=2213)
True positive	2	1
False negative	1	2
False positive	0	0
True negative	2210	2210
Sensitivity (95% CI) (%)	66.7 (9.43-99.16)	33.33 (0.84-90.57)
Specificity (95% CI) (%)	100 (99.83-100)	100 (99.83-100)
Positive predicted value (95% CI) (%)	100	100
Negative predicted value (95% CI) (%)	99.95 (99.78-99.99)	99.91 (99.80-99.96)
Diagnostic accuracy (95% CI) (%)	99.95 (99.75-100.00)	99.91 (99.67-99.99)
Negative likelihood ratio (95% CI) (%)	0.33 (0.07-1.65)	0.67 (0.30-1.48)

CI: Confidence interval

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Conflicts of interest

There are no conflicts of interest.

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