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**Original research article**

# Pulse Oximetry Screening For Critical Congenital Heart Defects In Asymptomatic Newborn Babies

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**Abstract**

Congenital heart disease (CHD) is a leading cause of infant mortality, accounting for more deaths than any other type of malformation. The incidence of CHD varies between 4-10/1000 live births in India.About 1 in every 4 babies born with a heart defect has a critical congenital heart defect (Critical CHD, also known as critical congenital heart disease).In Asymptomatic new borns measurement of oxygen saturations using pulse oximeter on the Right hand and foot was carried out after 24hrs of birth. Saturations above 95% was regarded as having negative screen. Out of total 400 neonates were screened and 7 cases of hypoxemia were identified. They were subjected to ECHO and4 had diagnosed to have critical congenital heart disease (TGA, TAPVC, DORV) and two cases had ASD and one was normal. Negative screen did not report back with any symptoms.

**Keywords:** CCHD, Pulse Oximetry, ECHO

## Introduction

Although for more than 30 years of standard practice has called for clinical examination of the cardiovascular system as the routine newborn examination, studies suggest that routine cardiovascular examination misses nearly half the newborns with significant CCHD. Even though a thorough physical examination of every neonate is now universally accepted as a good practice it is apparent that an appreciable proportion of babies with congenital cardiac malformations are not detected by this routine examination [1, 2].

Heart murmurs, one of the hallmarks of noncritical heart disease diagnosed later in life may be absent or misleading because of the underlying variation in anatomy, prolonged decline of pulmonary vascular resistance or reduced ventricular function [3].

For example, babies with an isolated interruption of the aortic arch may have no murmur while the ductus remains patent, would have normal femoral pulses. They would therefore be likely to pass a routine examination only to become rapidly and severely unwell within a few days as the duct closes.

Though Echocardiography is the gold standard for diagnosis of CCHD and can be performed by neonatologist or paediatric cardiologist with acceptable accuracy, it is not feasible as a routine screening test in most of the settings. Simple, cost effective, feasible, bedside screening test is thus required [4].

CCHD in the newborn may have low oxygen saturations unrecognized clinically.

Pulse oximetry is a well-established, non-invasive test for quantification of hypoxemia.

Use of this screening method for early detection of CCHD is based on clinically undetectable hypoxemia in potentially life-threatening cases. 30,18. Improvement with early detection is particularly true for critical, duct dependent lesions in which closure of the ductusarteriosus can result in acute cardiovascular collapse and death [5, 6].

Hence the need for a sensitive diagnostic tool at primary, secondary and tertiary care level units was long felt. The answer to this lies in screening of newborns with pulse oximetry after birth and confirmation with echocardiography. In this scenario, we planned to study the effectiveness of pulse oximetry screening in detection of CCHD at our tertiary care hospital.

## Methodology

**Study Setting:** The study was conducted in the post natal ward in the tertiary care hospital, S. Nijalingappa Medical College, Bagalkot .

**Study Design:** This was a hospital based prospective observational study. All neonates fulfilling selection criteria, born and admitted in postnatal ward during study period were included in the study.

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**Study Method**
In Asymptomatic new borns measurement of saturations using pulse oximeter on the Right hand and foot was carried out after 24hrs of birth.73 Saturations above 95% was regarded as having negative screen. Those with saturation below 90%were subjected to Echocardiography. Patients with saturations between 90 and 95% were subjected to a second pulse oximetry screen 6-12 hrs later. Screening was done after 24 hrs of birth.
Detailed clinical examination was done in all newborns after pulse oximetry.
Any positive findings in CVS was noted.

**Sample Size**
Therefore, a minimum of 342 cases were included in the study

**Inclusion criteria**
- All the asymptomatic newborn neonates (term and late preterm) delivered in the tertiary care hospital.
- Parents who gave informed consent.

**Exclusion criteria**
Newborn with respiratory symptoms and signs. Newborn with symptomatic cardiac diseases
All neonates with prenatal sonographic diagnosis of duct dependent circulation

**Data Collection**
Neonates included in the study were asymptomatic neonates (term and late preterm) delivered in the tertiary care hospital. The study was commenced after obtaining clearance from the institutional ethical committee. Parents of all neonates were given written informed consent forms for this study and neonates of those who were unwilling were excluded from the study. All those neonates who had a diagnosis of duct dependent circulation on antenatal sonogram were also excluded.

**Results**

**Table 1:** Distribution of the CCHD among Pulse Oximetry positive cases (N=7)

| CCHD | Frequency | Percent |
|---|---|---|
| POSITIVE | 4 | 57% |
| NEGATIVE | 3 | 43% |
| Total | 7 | 100% |

All 7 neonates with oxygen saturation of <90% in pulse oximetry were subjected to ECHO. It was found that 4 out of 7 neonates were diagnosed to be suffering from CCHD.

**Table 2:** Predictive Value of positive test

| | Pulse Oximetry Positive | Pulse Oximetry Negative | Total |
|---|---|---|---|
| CCHD positive | 4 | 0 | 4 |
| CCHD negative | 3 | 393 | 396 |
| Total | 7 | 393 | 400 |

True positive = 4 False positive = 0 True negative = 393 False negative = 3
True positive rate (Sensitivity)= TP/(TP+FN) =57.14%
False positive rate = FP/(FP+TN) =0.0%
The predictive value of a positive test of Pulse oximetry was found to be 57.1% in our study.

**Table 3:** Types of critical congenital heart diseases observed

| Critical congenital heart disease | Number of cases |
|---|---|
| Total anomalous pulmonary venous connection | 01 |
| Transposition of great arteries | 01 |
| Double outlet right ventricle | 02 |

**Discussion**
The first reports suggesting the use of pulse oximetry as a screening test for CCHD were published in 1995. After that many studies using pulse oximetry showed the usefulness of this test.
These were followed by single unit studies before several large cohort studies were undertaken.
Firstly, a cohort study of 39,821 newborns in a single region in Sweden recorded a sensitivity of 82.9% and a specificity of 98%. No infant who underwent oximetry died of duct dependent systemic or

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pulmonary circulation compared to 5 such deaths in regions without pulse oximetry.
This was followed by a German study of 3,364 term neonates who underwent pulse oximetry between 6 and 36 hours. Of the 18 neonates with abnormal results, 50% had critical congenital heart defects. Sensitivity was determined to be 82% and specificity 99.9%.
In a prospective multicentered trial in SAXONY, Germany, Pulse oximetry screening was performed in healthy term and post-term newborns at the age of 24-72 hours. In 42,240 newborns from 34 institutions during a 2 year period were included in a study 72 children were excluded due to prenatal diagnosis/or clinical signs of CCHD before pulse oximetry screening.795 newborns did not receive pulse oximetry screening, mainly due to early discharge after birth. In 41,445 newborns pulse oximetry screening was performed and showed true positive in 14,false positive in 40, true negative in 41,384 and false negative in 4 children. Sensitivity, specificity, positive and negative predictive value were 77.78%,99.9%,25.93% and 99.99% respectively [7].
A large multi-centre study was undertaken involving 20,555 newborn babies.This study reported an incidence of major congenital heart disease of 2.6:1 000 live births with 24 babies with a CCHD detected.
The sensitivity reported was 75% (95% Cl 53.29 - 90.23) for critical cases, 49.06% (95% Cl 35.06 - 63.16) for a major CHD with a specificity 99.16% (95%Cl - 99.28) and false positive rate of 0.8%.
When reviewed within a systematic review and meta-analysis, some key observations were described [8]:

- Pulse oximetry detected 30 additional cases of a CCHD per 100 000 live births.
- The false positive rate, if tested at >24 hours was 0.05 (0.02-0.12), which equates to a specificity of 99.95% and sensitivity of 77.5 (61.8-88.0). The cost effectiveness of this study was analyzed in terms of Quality Adjusted Life Years.

In this study of 400 neonates, babies with a prenatal diagnosis of duct dependent circulation on antenatal sonogram were excluded as we wanted to test result using pulse oximetry only.
The prenatal detection of congenital heart disease (CHD) in low risk pregnancies (For cardiac defects) ranges from 5 to 40%.
A study from Germany has reported 60% of CCHD diagnosed on antenatal ultrasonography.
Predictive value of a positive test indicates, the probability that a patient with a positive test result had the disease which is tested for. The predictive value of a positive test for CCHD was found to be 57.14%in our study which is better when compared to other study [9].
A study by Reide *et al* reported a positive predictive value of 25.93% for CCHD. Another study by Zhao *et al* found the analysis of both clinical evaluation and pulse oximetry as: Sn=932% (879-962); Sp=971% (971-972); PPV=38% (32-45);
NPV= 9999% (9998-100); LR+ = 326% (325- 326); LR- = 007% (006-009) and found that pulse oximetry adds to the current methods of diagnosing CCHD.
The results of this study bring out the inherent limitations of clinical screening for CCHD in newborns immediately after birth, especially in the context of limited resource environments. It is not feasible to do echocardiogram for every neonate especially in areas with high birth rate like India [10].
However, reports with good follow up data, higher coverage of echocardiography and better diagnostic value of antenatal ultrasonography have suggested sensitivity, specificity, positive and negative predictive value to be 77.78%, 99.90%, 25.93% and 99.99%, respectively.
In our study, within the setup of a tertiary based hospital, the incidence of critical congenital heart disease was found to be 1 per 1000 live births.
Thus, in resource limited environment, pulse oximetry screening for CCHD makes valuable contribution towards early diagnosis of CCHD. The added advantage is diagnosis of other morbidities and its utilization in further monitoring of those with hypoxemia.
In UK, a study looking at cost-effectiveness of screening determined that pulse oximetry required further testing within their setting in order to accurately determine costs based on primary data [11].
A study done in India introduced pulse oximetry screening as a tool to be used in a less resourceful setting. Its use is employed at the different cadres of healthcare practitioners: the on-site paediatrician performed clinical evaluation while pulse oximetry was performed by a study nurse.
Bedside echocardiography was performed by a research officer while only those babies with abnormal echocardiograms were reviewed by a paediatric cardiologist [12].
In this context, the sensitivity of pulse oximetry without clinical examination was low (<20%). This study explained the limitations of technical and human factors as well as limited skill to perform echocardiography.

**Conclusion**

- Critical congenital heart diseases are invariably associated with hypoxaemia and this principle is utilised while using a pulse oximeter for the screening.
- Many a times CCHD do not exhibit clinical signs or symptoms but deteriorate rapidly with fatal outcome.

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- Pulse oximetry is an effective adjunct to antenatal ultrasonography and appropriate clinical examination in the diagnosis of critical congenital heart diseases even in resource limited environment.

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