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**Research Article**

# Role of pulse oximetry in screening of critical congenital heart disease in asymptomatic neonates

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## ABSTRACT

**Background:** Neonatal screening for critical congenital heart disease can aid in early recognition and improved outcome of critical congenital heart diseases. Our aim was to assess the performance of pulse oximetry as a screening tool for the detection of critical congenital heart diseases in asymptomatic neonates.
**Methods:** Our study was a hospital based prospective study conducted on all asymptomatic neonates brought to neonatology section of tertiary care hospital. Pulse oximetric screening was performed by a single determination of postductal oxygen saturation in all asymptomatic newborns that fulfilled the inclusion criteria. To ensure universal screening, the timing of pulse oximetric determination was >24 hrs age. All newborns found to have a post-ductal saturation ≤95% underwent additional evaluation by echocardiography. Data regarding true and false positives as well as negatives was collected and sensitivity, specificity and predictive values of pulse oximetry for screening of asymptomatic newborns with congenital heart disease were determined.
**Results:** 2600 neonates were screened and 7 cases of CCHD were diagnosed, giving a prevalence of 0.27 %. Sensitivity, specificity, positive predictive value and negative predictive value of pulse oximetry for detection of CCHD were 77.78%, 99.92%, 77.78% and 99.92%, respectively.
**Conclusions:** We conclude that pulse oximetry is safe, easily available and reasonably accurate for screening of CCHD with sensitivity better than antenatal screening and clinical examination. Its specificity and negative predictive value are very high, making second stage confirmatory echocardiography highly cost-effective. Thus, the results of this study add to the already growing body of evidence that strongly supports introduction of pre discharge pulse oximetry screening as a routine procedure in healthy newborn babies.

**Keywords:** Pulse oximetry, Congenital heart disease, Screening

## INTRODUCTION

Most newborns with critical congenital heart disease CCHD, a group of morphologically heterogeneous disorders which have in common that early surgical or catheter interventional therapy is mandatory to achieve survival, can be diagnosed by echocardiography, palliated with prostaglandin infusion, and treated with surgery or transcatheter interventions. In the current era, congenital heart surgery allows for repair or palliation of nearly all types of congenital heart malformations. Congenital heart surgery, together with transcatheter interventions, has resulted in a marked improvement in survival for those with CCHD.[1]

Intervention is typically performed in the first weeks of life to optimize hemodynamics and prevent end-organ injury associated with delayed diagnosis. Because timely recognition of CCHD could improve outcomes, it is important to identify and evaluate strategies to enhance

early detection. Pulse oximetry has been proposed as one such strategy, and legislation has been proposed to support this practice.[2]

Currently, children with CCHD are diagnosed by a variety of mechanisms. Neonates with CCHD may be diagnosed in the newborn nursery on the basis of physical examination findings, such as heart murmurs, tachypnoea or overt cyanosis. These findings are not always evident before hospital discharge, which may occur before 48 hours of life.

A number of children with CCHD are so severely compromised at presentation that they die before surgical intervention. For example, investigators have reported that between 3% and 6% of neonates with dextro-transposition of the great arteries died because of hemodynamic compromise before surgical intervention could be offered.[3,4] Another preliminary study from California reported 2.0 deaths per 100000 live births related to delayed diagnosis of CCHD.[5] Presumably, earlier recognition of CCHD in these patients could have prevented death in at least some of these cases.

Although physical examination, electrocardiogram and chest radiograph are useful in identifying many cases of serious congenital heart disease postnatally, they do not have sufficient sensitivity and specificity to detect all cases. Echocardiography, although an essential diagnostic tool, has serious limitations as a universal screening too, particularly its cost.[6] Therefore there is considerable interest in improving the detection of CCHD with novel diagnostic techniques and our study explores the role of pulse oximetry as one such modality.

## METHODS

This was a hospital based prospective study conducted in the Neonatology department of a tertiary care hospital in North India, with the catchment area of both rural and urban populations.

### *Inclusion criteria*

All asymptomatic newborns who were brought to Neonatology OPD for a routine neonatal examination and did not manifest cyanosis, tachypnea (respiratory rate >60/min), grunting, flaring, retractions, murmur, active precordium, or diminished pulses were screened with pulse oximetry.

### *Approach*

Pulse oximetric screening for critical congenital heart disease was performed by a single determination of postductal saturation on all asymptomatic newborns that fulfilled the inclusion criteria. Nellcor io2 pulse oximeter was used to determine postductal saturation. The probe was placed over right or left foot. To ensure universal screening, the timing of pulse oximetric determination was >24 hrs age. All newborns found to have a post-ductal saturation ≤ 95% underwent additional evaluation by echocardiography. Data regarding true and false positives as well as negatives was collected and sensitivity, specificity and predictive values of pulse oximetry as a screening tool for congenital heart disease in asymptomatic newborns were determined.

### *Statistical analysis*

Our study involved descriptive statistics. True positive were defined as those newborns that were screened with pulse oximetry to have a spo2 ≤95% and echocardiography revealed congenital heart disease.

True negative were defined as those newborns who were screened with pulse oximetry to have a spo2 >95% and were put on clinical follow up, as CCHD will manifest over a period of time (mean age 6 wks).[7]

False positive were defined as those newborns that were found to have spo2 ≤95% with pulse oximetry and echocardiography revealed structurally normal hearts.

False negative were defined as those newborns who were found to have spo2 >95% with pulse oximetry but clinical follow up with echocardiography revealed cardiac illness and congenital heart disease.

## RESULTS

We screened 2600 neonates with pulse oximetry**.** Out of 2600 neonates who were screened nine cases were found with spo2 saturation less than 95% (Table 1).

**Table 1: Distribution of cases as per Post-ductal $spo_2$ saturation.**

| Post ductal saturation | ≤95% | 96% | 97% | 98% | 99% | 100% | Total |
|---|---|---|---|---|---|---|---|
| Number of patient | 9 | 671 | 618 | 936 | 319 | 47 | 2600 |
| % | 0.35% | 25.8% | 23.8% | 36% | 12.3% | 1.8% | 100% |

Out of these nine, echocardiography in seven cases revealed critical congenital heart disease (Table 2), while as the other two had structurally normal hearts. Forty two cases were lost on clinical follow-up. Two cases who had $spo_2$ saturation greater than 95% at the time of screening were detected with CCHD on clinical follow-up (Table 3). From our study the sensitivity of screening of CCHD by pulse oximetry is 77.78%, Specificity is 99.92%,

Positive Predictive Value is 77.78% and Negative Predictive Value is 99.92% (Table 4).

**Table 2: Echocardiography results in all cases with spo2 ≤ 95%.**

| Sr. no. | Post-ductal saturation | Echocardiography findings |
|---|---|---|
| 1 | 89% | TGA/VSD |
| 2 | 86% | Truncus Arteriosus |
| 3 | 87% | Tricuspid Atresia/VSD |
| 4 | 93% | TOF |
| 5 | 87% | TGA |
| 6 | 88% | HLHS |
| 7 | 94% | TAPVD |
| 8 | 93% | Normal study |
| 9 | 94% | Normal study |

**Table 3: Cases detected on clinical follow-up.**

| Sr. no. | Post-ductal saturation at the time of screening | Day of life at admission | Echocardiography findings done at the time of admission |
|---|---|---|---|
| 1 | 96% | 5 | TGA/VSD |
| 2 | 98% | 20 | TOF |

TGA-Transposition of Great Arteries TOF-Tetralogy of Fallot HLHS-Hypoplastic Left Heart Syndrome TAPVD-Total Anomalous Pulmonary Venous Drainage

**Table 4: Sensitivity/specificity/PPV & NPV of pulse oximetry.**

| True positive | False positive | True negative | False negative |
|---|---|---|---|
| 7 | 2 | 2549 | 2 |
| Sensitivity | Specificity | PPV | NPV |
| 77.78%, | 99.92%, | 77.78%, | 99.92%, |

## DISCUSSION

Congenital heart defects are the most common group of congenital malformations with a prevalence of 5-10 in every 1000 live births.[8] Early detection of major congenital heart defects (i.e. those leading to death or requiring invasive intervention before 1 year of age) might improve the outcome of newborn babies.[9] Improvement with early detection is particularly true for critical, duct-dependent lesions in which closure of the ductus arteriosus can result in acute cardio vascular collapse, acidosis and death.[10-12] Screening for congenital heart defects relies on mid trimester ultrasound scan in which the fetal heart is imaged, and postnatal physical examination that includes assessment of pulses and heart sounds and inspection for cyanosis. Both screening methods have a fairly low detection rate and substantial number of babies are discharged from hospital before congenital heart disease are diagnosed.[13-17] Some of these babies die or present in such a poor clinical state that the outcome despite treatment is poor.

Pulse oximetry is well established, accurate, noninvasive test for objective qualification of hypoxemia. Use of this screening method for early detection of congenital heart defects is based on the rationale that clinically undetectable hypoxemia is present, to some degree, in most potentially life threatening cases. Pulse oximetry has been assessed as a screening method for congenital heart defects in newborn babies in many studies.[18-23] Our study was also conducted to evaluate usefulness of pulse oximetry in screening CCHD in asymptomatic newborns.

Out of 2600 asymptomatic newborns screened by pulse oximetry only 9 cases were found $SpO_2$ ≤95%. These 9 cases further underwent echocardiography to confirm the findings of screening test. 7 out of 9 cases were detected to have CCHD. Thus, prevalence of CCHD in asymptomatic newborns was found to be 1 in 372 (0.27%). Tautz et al found that CCHD was identified using pulse oximetric screening in 1 in 1000 asymptomatic newborn (0.1 %).[24] Another study conducted by Arlettaz et al in 3262 newborns found that there were 11 cases of CCHD in asymptomatic neonates with $SpO_2$ <95% giving the prevalence of 1 in 297 (0.33%).[21]

The sensitivity was found to be 77.78% which is comparable to the results obtained by Rosati, et al, Meberg et al, Richmond et al and Riede FT et al (66.7%, 69.2%, 77.1%, 77.7% respectively).[19,22,25,26] Nine out of ten studies in a review by Mahle, et al found sensitivities to be less than 90% ranging from 0% to 87%.[27] This is explained in part by the fact that hypoxemia is not present in some forms of CCHDs.

In our study, specificity of pulse oximetry as a screening tool was found to be 99.9% which is again comparable to the studies conducted by other workers.[20,25,28]

The positive predictive value of 77.78% was comparable to that obtained by Koppel et al who obtained a PPV of 75%; however, it is higher than that obtained by other workers like Rosati et al, Richmond et al and Hoke et al but less than that obtained by Arlettaz, et al.[18,19,21,25,28]

The negative predictive value of 99.9% is comparable to all other studies which have reported it to be between 98% to 100%.[18-21,25,28,29]

The false positive rate was to be found to be 0.08% and was comparable to that obtained by Reich, et al, who reported it to be 0.09% at >24 hour.[29] A low false positive rate reduces the number of unnecessary echocardiograms.

## CONCLUSION

We conclude that pulse oximetry is safe, easily available and reasonably accurate for screening of CCHD with

sensitivity better than antenatal screening and clinical examination. Its specificity and negative predictive value are very high, making second stage confirmatory echocardiography highly cost-effective. Thus, the results of this study add to the already growing body of evidence that strongly supports introduction of pre discharge pulse oximetry screening as a routine procedure in healthy newborn babies.

Limitations of study were we lost 42 patients during follow up. It is quite possible that some of them may have died suddenly due to CCHD and were not included in calculations giving erroneous results.

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