

Screening of Newborn by Pulse Oximetry at Birth for the Critical Congenital Heart Disease

Ravindra S. Sonawane¹, Ripal Dipak Shah², Sagar Sonawane³ and Rajendra Gaikwad^{4*}

¹Professor and Head, Department of Paediatrics, Dr. Vasanttrao Pawar Medical College Hospital and Research Centre, Nashik – 422003, Maharashtra, India

²Former PG Resident, Department of Paediatrics, Dr. Vasanttrao Pawar Medical College Hospital and Research Centre, Nashik – 422003, Maharashtra, India

³Associate Professor, Department of Paediatrics, Dr. Vasanttrao Pawar Medical College Hospital and Research Centre, Nashik – 422003, Maharashtra, India

⁴Professor, Department of Paediatrics, Dr. Vasanttrao Pawar Medical College Hospital and Research Centre, Nashik – 422003, Maharashtra, India; peditrics@drvasanttraopawarmedicalcollege.com

Abstract

Background: Early diagnosis of congenital heart disease is important for a good clinical outcome. Unrecognized or delayed diagnosis of some severe congenital heart diseases can lead to cardiac failure, cardiovascular collapse, and even death. Pulse oximetry screening (POS) in newborns has been shown to enhance the detection of critical congenital heart disease (CCHD). Clinical evaluation is likely to miss the diagnosis in first few hours of hospital stay after birth due to absence of signs and symptoms of CCHD. In the absence of clinical findings during early neonatal period, the best parameter that can be assessed, is the detection of hypoxemia by pulse oximetry screening. **Aims and Objectives:** Usefulness of pulse oximetry in newborn for early detection of Critical Congenital Heart Disease (CCHD). **Material and Methods:** This Prospective Observational Study was conducted on 125 newborn babies in postnatal ward at tertiary care centre for a period of 2 years satisfying the inclusion and exclusion criteria. Evaluation was done between 24 to 48 hours of birth with pulse oximeter. Institutional ethics committee permission was taken prior to study. **Results and Conclusion:** Total 125 neonates were screened by pulse oximeter, 2 were detected to have positive screen for Congenital Heart Disease (CHD) of which 1 had CCHD confirmed by echocardiography. Study revealed that Pulse Oximetry screening can be an important screening tool in routine neonatal care for early detection of CCHD.

Keywords: Critical Congenital Heart Disease, Pulse Oximetry

1. Introduction

Pulse Oximetry Screening (POS) in newborns has been shown to enhance the detection of CCHD¹. Congenital Heart Disease (CHD) is one of the most common birth defects, with an incidence of nine out of every 1,000 live births², of this 25% will have critical congenital heart disease³. Critical CHD refers to lesions requiring surgery or catheter-based intervention in the first year of life⁴. Congenital heart disease account for about 10% of infant deaths⁵. Early diagnosis of congenital heart disease is important for a good clinical outcome. Unrecognized or delayed diagnosis of some severe congenital heart diseases can lead to cardiac failure, cardiovascular collapse, and

even death⁶. However, diagnosis of congenital heart disease in the first few days of life is difficult because of an initial lack of specific clinical signs⁵.

Clinical examination remains the most frequently used method to diagnose congenital heart disease in newborns. In particular the presence of a heart murmur can raise the suspicion of congenital heart disease. But routine neonatal clinical examination fails to detect more than 50% of infants with congenital heart disease⁷. More than 55% of them have no murmur⁸ and most of them are discharged before a diagnosis can be made and readmitted with severe heart failure or cardiovascular collapse⁷.

*Author for correspondence

Therefore, there is a need for effective screening program for early detection of congenital heart disease. This disease would be ideally suited for a screening program if simple and reliable method were available. Recently pulse oximetry has been suggested as a screening tool for detection of congenital heart disease especially cyanotic and critical congenital heart diseases in asymptomatic newborn⁹. These babies have a decreased oxygen saturation due to right to left shunt which is either intracardiac or at Patent Ductus Arteriosus (PDA) level. This can be measured by pulse oximetry.

2. Aim and Objectives

To detect usefulness of pulse oximetry screening in newborn for diagnosis of CCHD.

3. Material and Methods

This prospective observational study was conducted on 125 newborn babies in postnatal ward at tertiary care centre. Institutional ethics committee permission was taken prior to study.

$$n > \frac{Z^2 (\text{sensitivity}) \times (1 - \text{sensitivity})}{d^2 \times (1 - \text{prevalence})}$$

$$z = 1.96$$

Sensitivity is 76%, prevalence is 0.225%, d is 0.16. Therefore, sample size is 125.

Study included all neonates in the post-natal ward during the period of 2018 August to 2020 December. Consent was obtained from parents or legally acceptable representative.

3.1 Eligibility Criteria

Inclusion Criteria

Asymptomatic newborn babies in postnatal ward.

Exclusion Criteria

- Babies who are admitted in NICU at birth
- Antenatally diagnosed as having congenital heart disease on ultrasonography
- Neonates whose parents or legally acceptable representative has not given the consent.

3.2 Methodology

This study was a hospital based prospective observational study. In this study we screened asymptomatic newborn

babies in the post-natal ward for congenital heart disease using pulse oximetry. Pulse oximetry readings were taken in a quiet or sleeping newborn from all four limbs. The probe was cleansed with alcohol swab before each use. The readings were recorded after stabilization for one minute. The functional oxygen saturation of $\geq 95\%$ was accepted as normal. If the newborn baby had oxygen saturation below 90%, echocardiography was performed. In the case of a newborn with oxygen saturation between 90% – 94%, a second measurement was performed six hours later. If the oxygen saturation remained below 95%, echocardiography was performed. Cardiac clinical examination screening was also performed for all babies simultaneously with pulse oximetry screening. We looked for central cyanosis and cardiac murmur. Echocardiography was performed for babies having cardiac murmur or central cyanosis. The cardiac clinical examination and pulse oximetry screening were carried out between 24 to 48 hours of age. Newborn babies who underwent echocardiography were categorized as having either a normal heart or a structurally malformed heart.

4. Results

Table 1 shows that, the total number of patients screened in our hospital was 125 (100%) and the total number of babies with congenital heart disease was 2 (1.6). The critical congenital heart disease amongst study population was 0.8% i.e., 1 patient out of 2 congenital heart disease.

Table 1. Incidence of critical congenital heart disease amongst study population

Incidence	Frequency	Percent
Total number of patients screened	125	100
Total number of babies with congenital heart disease	2	1.6
Total number of babies with critical congenital heart disease	1	0.8

In the newborns, amongst study population, 52% mothers were multigravida and 48% were primigravida, 69.6% were term deliveries and 30.4% were late preterm. Most common birth weight was 2.5 To 3.9 Kg (82.4%) followed by less than 2.5 Kg (17.6%).

Table 2 shows that, right upper limb and left lower limb O₂ saturation was ≥ 95 (98.4%), 90-94 (0.8%) and 0.8% had O₂ saturation less than 90%.

Table 2. Right upper limb and left lower limb O₂ saturation amongst study population

O ₂ saturation	Frequency	Percent
≥ 95	123	98.4%
90-94	1	0.8%
< 90	1	0.8%
Total	125	100%

Congenital heart disease amongst the study population was Ventricular Septal Defect with Pulmonary Stenosis in 1 patient and 1 case of Transposition of Great Arteries with Intact Ventricular Septum i.e., CCHD.

Table 3. Sensitivity and specificity amongst the study population

Screening test (SpO ₂)	CCHD (2D-ECHO)		Total
	Present	Absent	
< 95	1	1	2
≥ 95	0	123	123
Total	1	124	125

Parameter	Estimate
Sensitivity	100%
Specificity	99%
Positive Predictive Value	50%
Negative Predictive Value	100%

Table 3 shows that Sensitivity amongst the study population consists of 100%, Specificity 99%, positive predictive value 50% and negative predictive value consists of 100%.

5. Discussion

Congenital heart disease occurs in 9 of every 1000 livebirths¹⁰. Approximately one quarter of these children will have critical congenital heart disease (CCHD), which by definition requires surgery or catheter intervention in the first year of life¹¹. Congenital malformations are one of the leading causes of infant death in the United States and other developed nations and CCHD is responsible for more deaths than any other type of

malformation.^{12,13} Most newborns with CCHD 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 CCHD¹⁴. 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 practice¹⁵.

Pulse oximetry screening for congenital cardiac diseases has been approved in United states in 2011, with proven sensitivity and specificity it has been recommended as a useful screening tool for CCHD in neonates in developed countries such as United Kingdom, Canada, Germany but still awaiting its due recognition and inclusion in the panel of neonatal screening tests in India^{16,17}. Globally, pouring support on its implementation as a screening tool in early identification of CCHD make an un-ignorable potential candidature in the panel^{18,19}. It has been reported to be a safe, useful tool to screen neonates for cardiac malformation particularly in rural areas with limited infrastructure.

In our study, the total number of patients screened was 125 (100%) and the total number of babies with congenital heart disease was 2 (1.6). The critical congenital heart disease amongst study population was 0.8% (Table 1). Among them 51.2% were males and 48.8% were females. In the newborns, amongst study population, 52% mothers were multigravida and 48% were primigravida, 69.6% were term deliveries and 30.4% were late preterm. Most common birth weight was 2.5 To 3.9 Kg (82.4%) followed by less than 2.5 Kg (17.6%). Most of the study population had right upper limb and left lower limb O₂ saturation of ≥ 95 (98.4%), 90-94 (0.8%) and 0.8% had O₂ saturation less than 90%. Congenital heart disease consists of Transposition of Great Arteries with Intact Ventricular Septum in 1 patient and 1 case of Ventricular Septal Defect with Pulmonary Stenosis. From which Critical Congenital heart disease consists of only 1 case i.e., Transposition of Great Arteries with Intact Ventricular Septum.

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