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Research article

EARLY DETECTION OF CRITICAL CONGENITAL HEART DISEASE IN NEWBORNS USING PULSE OXIMETRY SCREENING

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ABSTRACT

Background: Congenital heart diseases which are dependent on the ductusarteriosus to maintain adequate oxygenation or systemic blood flow are termed as a critical congenital heart disease (CCHD). Delay in the diagnosis of CCHD is the major cause leading to morbidity and mortality in newborn infants. 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. **Objectives:** To record the value of Pulse Oximetry within 24 hours of birth and evaluate Pulse Oximetry as screening tool for early diagnosis of CCHD. **Methods:** Longitudinal descriptive study was conducted on total 700 intramural neonates, satisfying the inclusion and exclusion criteria, who were evaluated within 24 hours of birth with currently available pulse oximeter, after the Institutional Ethical Committee approval. The study was conducted over a period of 4 months. Part-A: Neonatal Case Record, Part-B: Pulse Oximetry Screening Record, Part-C: Clinical Examination Record, Part-D: Echocardiography Record. **Results and Conclusion:** Total 700 neonates were screened by pulse oximeter with consecutive sampling method. 4 (0.57%) subjects were detected to have positive screen and the diagnosis was confirmed by echocardiography. Study revealed that Pulse Oximetry Screening can be an important primary screening tool in routine neonatal care for early detection of Critical Congenital Heart Diseases particularly in rural setup.

Keywords: Pulse Oximetry Screening, Neonates, Critical Congenital Heart Disease, Neonatal Heart Disease

INTRODUCTION

Congenital heart diseases (CHD) are a group of morphologically heterogeneous disorders occurring in 6 to 8 per 1000 live births. Down's syndrome, Turner's syndrome, Noonan syndrome, maternal diabetes, alcohol intake during pregnancy, rubella infection and phenylketonuria are the known etiological factors whereas up to 90% of CHDs occur in pregnancies without any predisposing cause. One fourth of the pregnancies with CHD after full term delivery will have infants presenting with critical congenital heart disease (CCHD).[1]

The fetal patent ductus is a major anatomic component of an intrauterine great artery consisting of pulmonary trunk or ductus or aortic continuity that delivers 85% of right ventricular output into the descending aorta.[2] Many forms of CHD that depend on the ductusarteriosus to maintain adequate oxygenation or systemic blood flow are termed as

CCHD. Neonates with such unrecognized CCHD can manifest with profound metabolic acidosis, intracranial hemorrhage, hypoxic-ischemic encephalopathy, necrotizing enterocolitis, cardiac arrest or death if the ductus constricts or closes. Effective strategies are available for stabilizing neonates with known CCHD until intervention can be performed, most notably continuous infusion of prostaglandin E1 to maintain patency of the ductus. These strategies cannot be used effectively unless CCHD is diagnosed or at least suspected.[3]

Early surgical or catheter interventional therapy is mandatory to achieve survival in case of CCHD.[4] With advances in both palliative and corrective surgery, the number of children with congenital heart disease surviving to adulthood has increased dramatically.[5] Despite increased use of prenatal diagnostic modalities for detection of CCHD is increased over the last few decades, a significant proportion of affected new-borns are still not diagnosed before discharge after birth.[6]CCHD remains the leading cause of death in children with congenital malformations despite these advances.

Conventionally, in the first few hours after birth, diagnosis of CCHDs is dependent on physical examination findings such as heart murmurs, tachypnea or overt cyanosis. These findings are not always evident during first few hours of hospital stay.[6] Heart murmurs are one of the hallmarks of non-critical heart disease typically diagnosed later in life. Many times these may be absent or misleading because of the underlying anatomy, prolonged decline of pulmonary vascular resistance or reduced ventricular function.[4] Recent trends of earlier discharge within 24-48 hours and other changes in postnatal care may aggravate this problem.

Majority of CCHD lesions in the newborns present with some degree of hypoxemia resulting from the mixing of systemic and venous circulations or parallel circulations which may cause obvious cyanosis. Importantly, newborn shaving mild hypoxemia, with arterial oxygen saturation of 80% to 95%, will not have visible cyanosis. Early detection of such cases may be enhanced by pulse oximetry, if performed on asymptomatic new-borns within 24 hours of life.[6]

Early diagnosis in the first few days of life is difficult. Prenatal diagnosis of CHD routinely is carried out by ultrasonography in antenatal period, but it picks up only less than half of all cases. Limitations of prenatal fetal echocardiography are related to: Availability of expertise and experience (paediatric cardiologist). Availability of echocardiography machine, Image quality, Subtle lesions, such as small ventricular septal defects, Developing or progressive lesions, Lesions which are undetectable before birth[7]

Delayed diagnosis of CCHD can lead to cardiac failure, cardiovascular collapse and even death. Clinical evaluation though mandatory can miss out the diagnosis as the findings may not be obvious or may be too subtle in the initial 24 hours of life. So detection of CCHD without unnecessary delay should be the task for providers of primaryneonatal care. In the absence of clinical findings, the best parameter that can be assessed is the detection of hypoxemia by pulse oximetry screening.

Aim& Objectives:

1. To study the value of pulse oximetry within 24 hours after birth for predicting CCHD in new-borns.
2. To study the clinical profile of new-borns detected with abnormal pulse oximetry screening.
3. To confirm the diagnosis by echocardiography in positively screened new-borns.

METHODOLOGY

This descriptive longitudinal (prospective) study was conducted at the Neonatology Unit of Pravara Rural Hospital, Pravara Institute of Medical Sciences, Loni. Intramural neonates who were evaluated within 24 hoursage with currently available pulse oximeter (EMCO 4040 NP NIBP Oximeter, India) were enrolled in study.[8]

Inclusion criteria: Singleton, Inborn neonates (intramural), Including neonates with extreme low birth weights as well i.e. weight<1000gms

Exclusion criteria: Multiple gestations, Out born neonates, Neonates with a life threatening congenital anomalies, Neonates with lethal malformations, Neonates requiring any surgical intervention

Sample Size & Study Period: The study was conducted on approximately 700 neonates according to inclusion and exclusion criteria, during 4 months period starting from 8th February 2013 to 9th June 2013 after informed written consent and approval from the Institutional Ethical Committee, Pravara Institute of Medical Sciences, Loni.

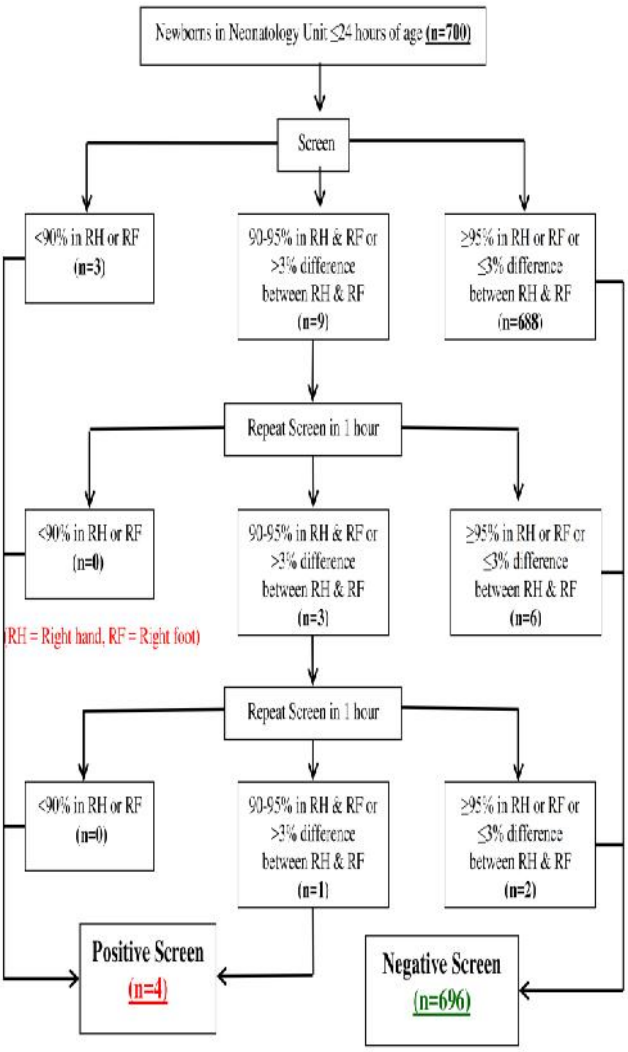

Fig 1: Screening protocol for pulse oximetry

Study conduct: The study was conducted in 4 parts as follows:

Part A: Neonatal Case Record

Part B: Pulse Oximetry screening Record

Part C: Clinical Examination Record

Part D: ECHO Record

Pulse Oximetry Screening was done using the protocol displayed in Fig. 1. Oxygen saturation is a relative measure of the amount of oxygen that is dissolved or carried in blood. It is an indicator of the percentage ofhemoglobin saturated with oxygen at the time of themeasurement.Normal oxygen saturation values are 97% to 99% in the healthy individual. An oxygen saturation value of 95% is clinically accepted in a patient with a normal hemoglobin level.[9] Proper care was taken to rule out any interference with pulse oximetry like agitation of the infant, proper placement of the probe, human error or equipment malfunction. Probe was placed at on right hand and right foot.

Screening was considered positive if :

(1)Any oxygen saturation measure was <90% (in the initial screen or in repeat screens)

(2) Oxygen saturation was <95% in the right hand and foot on three measures, each separated by one hour.

(3) A >3% absolute difference existed in oxygen saturation between the right hand and foot on three measures, each separated by one hour. Any screening that was ≥95% in the right hand or foot with a ≤3% absolute difference in oxygen saturation between the right hand or foot is considered a negative screen and screening was ended. **Statistical Analysis:** The analysis was carried out with OpenEpiopen source software version2. Sensitivity, specificity, positive predictive value and negative predictive values for pulse oximetry screening were calculated.

RESULTS

Table 1: On first Screening

Screen	No. of neonates (n)	SpO_2	
		Right Hand	Right Foot
Negative	688	>95%	>95%
Direct Hypoxemic (SpO_2<90%)	3	<90%	<90%
Indirect Hypoxemic (SpO_2 90-95%)	9	90-95%	90-95%
TOTAL	**700**	-	-

Table 2: Screening of neonates in Indirect Hypoxemic Cases after Providing Oxygen

Screen	No of neonates (n)	SpO_2	
		Right Hand	Right Foot
Negative	688	>95%	>95%
Non-Hypoxemic	8	>95%	>95%
Persistent Indirect Hypoxemic	1	90-95%	90-95%
Direct Hypoxemic	3	<90%	<90%
TOTAL	**700**	-	-

Table 3: Pulse Oximetry and Echocardiographic findings of Positive Cases

SpO_2		Echocardiographic Findings	Final Diagnosis
Right Hand	Right Foot		
52	55	Single valve present at atrio-ventricular junction, enlarged heart chambers	Complete atrio-ventricular septal defect
75	77	Transposition of great arteries, Small PFO, small PDA, Severe Pulmonary hypertension	Transposition of Great Arteries
82	89	TAPVC-Supracardiac type, ostiumsecundum patent 7mm, persistent left SVC draining into coronary sinus, All 4 pulmonary veins drain anomalously in vertical vein through innominate vein	Total Anomalous Pulmonary Venous Connection
94	91	Coarctation of aorta, preductal type, bicuspid aortic valve	Coarctation of Aorta

DISCUSSION

Critical congenital heart diseases are fatal if prompt medical or surgical intervention is not provided. Prenatal diagnosis with the help of an ultrasound is not easily available in India particularly in rural areas. Early detection of CCHD enables us for prompt intervention which may save patient's life as many of the CHDs are duct dependent and closure of ductusarteriosus at around 72 hours may lead to sudden deterioration or death. Moreover, recent trend of early discharge from the hospital also adds to the problem.

Present study was carried out with screening time within 24 hours of birth, on a total 700 neonates at Neonatology Unit of Pravara Rural Hospital, Loni. Most of the patients being from rural areas insist for early discharge, within 24 hours after birth. Moreover, literature suggests that many studies have been carried out for screening after 24 hours of birth. So it was thought prudent to evaluate the pulse-oximetry findings within 24 hours of birth in an attempt to provide a non-invasive screening tool which can be easily performed and helpful in the early diagnosis in rural setup.

95% SpO_2 level was used as a cutoff value, at which pulse oximetry screening has the best overall performance. [1,10,11,12] On first screening, 12 neonates were found to have abnormal SpO_2levels. **(Table 1)** Out of these, 3 neonates had SpO_2 values <90% and followed directly by clinical examination and echocardiography and 9 having SpO_2 levels 90-95%, were provided oxygen and rescreened according to the protocol. SpO_2 level of only 1 neonate remained <95% and was subjected to clinical examination and echocardiography. **(Table 2)** Rest all were considered negative in screening and no further actions were taken.

POS in order to detect CCHD showed a very good sensitivity, specificity and negative predictive value (NPV), but positive predictive value(PPV) was less than optimal. Results of present study were comparable to the study done by Arlettaz*et al* but there were some differences in terms of sensitivity and NPV with recent study done by Granelli*et al*.[1,10] This variation in the PPV might be due to difference in prevalence of the disease amongst the population under study or use of movement-artifact resistant pulse oximetry e.g. Masimo Technology.

Table 4: Comparison with other studies

Parameters	Arlettaz *et al*[1]	Granelli *et al*[10]	Present Study
Sensitivity	100%	62.07%	100%
Specificity	99.7%	99.82%	98.85%
NPV(Negative Predictive Value)	100%	20.69%	100%
PPV (Positive Predictive Value)	63%	99.97%	33.33%

In present study, pulse oximetry had detection rate of 0.57% (4 out of 700) which was followed by clinical examination and echocardiography.**(Table 3)** The positive cases were diagnosed as: 1. Complete atrio-ventricular septal defect 2. Transposition of great arteries 3. Total anomalous pulmonary venous connection4. Coarctation of aorta

It has been well documented that POS sometimes does not detect left heart obstructive lesions. In some cases, there is right to left shunting via a patent ductusarteriosus which may not get detected by POS.[13]

POS is a complementary tool and should not be used as an alternative to thorough physical examination. Complex cyanotic lesions can also be missed by POS alone, especially in the context of high pulmonary blood flow. However, concomitant clinical examination may detect tachypnea and prompt further evaluation.[4]

The rate of false-positive results in our study was 1.14%. Riede*et al* reported 0.10% false-positive rate.[4]Higher false positive rate in present study might be due to pulmonary hypertension, sepsis and other conditions like human error or equipment malfunction.

POS has been mentioned as a cost-effective tool in the detection of CCHDs.[14] With results of present study and its comparison to already published literature, it can be very well stated that the currently available pulse oximeters as an adjunct to clinical examination can substantially improve detection rate of CCHDs and enables us to prevent burden of death and sequelae of neurologic impairment or disability, which may result from late diagnosis of CCHD.

CONCLUSION

The problem of late diagnosis of Critical Congenital Heart Diseases and its potential sequelae has major health impact. Pulse Oximetry Screening can be an important primary screening tool in routine neonatal care for early detection and effective management of Critical Congenital Heart Diseases particularly in rural setup.

Limitations of the study: The sample size is small and makes the calculation of the effectiveness of POS difficult. Extensive research for authentication and standardization is still required.

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