ORIGINAL RESEARCH PAPER
Volume - 12 | Issue - 06 | June - 2023 | PRINT ISSN No. 2277 - 8179 | DOI : 10.36106/ijsr
INTERNATIONAL JOURNAL OF SCIENTIFIC RESEARCH

SCREENING OF TERM INTRAMURAL NEWBORNS FOR CRITICAL CONGENITAL HEART DISEASE BY USING PULSE OXIMETRY

Cardiovascular

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ABSTRACT

Background: Congenital heart defects (CHDs) constitute the most common group of congenital malformations, with an estimated incidence of 4 to 10 cases per 1000 live births. Approximately 25% of children with CHD have critical CHD (CCHD)(1) a structural defect associated with a significant risk of morbidity and mortality that requires surgical or catheter intervention before one year of age. Early diagnosis of Critical Congenital heart disease is required a better outcome any delay in diagnosis can lead to complications like cardiac failure or collapse and even death. **Aim & Objective:** To estimate the yield of pulse oximetry as a screening tool to diagnose critical congenital heart disease. **Methods:** It is a prospective observational study. Healthy-term intramural newborns were screened in post-natal wards and during immunization between 24-48 hours of life. AAP Algorithm was followed in which positive screening babies were taken for echocardiography for confirmation. **Settings and Design:** This study is a prospective observational study. It was done in a Government Medical College Hospital in Madhya Pradesh. **Results:** Among 6000 healthy term babies who were screened out of 10920 live births during the study period, 58% were male and 48% were low birth weight. In 66 (1.1%) babies, the screening showed failed results with mean oxygen saturation levels (SPO2) 82%. 2 D echocardiography results of these 66 babies revealed structurally normal heart in 34 (51.5%), CCHD in 4(6%) and non-CCHD in 28 (42.4%). The prevalence of CCHD was 1 per 1000 healthy term babies. The positive predictive value of screening for CCHD with pulse oximetry in this study was 39% when oxygen saturation was 90-94% and PPV was 47% when oxygen saturation was less than 90% **Conclusion:** The prevalence of CCHD in healthy-term neonates was 1 per 1000 in our hospital. Pulse oximetry before hospital discharge was useful for early detection of CCHD hence we recommend the inclusion of pulse oximetry of healthy term babies before discharge. Normal oxygen saturation doesn't rule out a-cyanotic CHD. While taking oxygen saturation we should look for acrocyanosis, Hypothermia, and Motion artefacts to avoid false positive results

KEYWORDS

Congenital Heart Defects, CHD, Congenital Malformations

INTRODUCTION

The best protection is early detection. Screening for congenital heart disease (CHD) in newborn babies is crucial and not only in early recognition but timely intervention with the prospect of improved outcome. Congenital heart defects (CHDs) constitute the most common group of congenital malformations, with an estimated incidence of 4 to 10 cases per 1000 live births with significant geographical differences. Asia reported the highest prevalence, i.e. 9.3 per 1000 live births compared with 8.2 and 6.9 per 1000 live births in Europe and North America, respectively (2). Approximately 25% of children with CHD have critical CHD (CCHD)(1), a structural defect associated with a significant risk of morbidity and mortality that requires surgical or catheter intervention before one year of age.CCHD account for more deaths than any other congenital malformation and up to 10% of all infant deaths are due to them.(3,4)

Prior to the widespread introduction of CCHD screening, it was estimated that up to one-third of infants with a potentially life-threatening CCHD lesion left the hospital undiagnosed. It has been shown that infants with CCHD who receive a delayed diagnosis have significantly higher mortality than those recognised prior to hospital discharged, with up to 40% presenting in cariogenic shock (5,6,7)and resulting in the deaths of 70-100 infants annually(8,9,10). These data underscore the importance of early recognition of CCHD in neonates. Further, most of them return to hospital in a circulatory collapse, but around five percent of the babies die in the community without a diagnosis.

CCHD may not be clinically obvious prior to the closure of the ductus arteriosus .early in the postnatal period. Cardiac murmurs are often not present in CCHD, particularly early on. The clinical detection of cyanosis in neonates may not always be possible or reliable. More than 50% of cases are missed by clinical examination. Most of the babies are discharged and they get readmitted with cardiac failure. These raise the need for screening program for early detection of heart disease. Ideas for how to improve the poor results were proposed. The need for an additional tool to improve early detection of critical congenital heart defects was obvious. Screening with POx in asymptomatic newborns has been shown to reduce the diagnostic gap that is left by prenatal ultrasound and physical exam alone, and has been shown to increase early diagnosis of CCHD by up to 30%. A recent study by Abouk et al. revealed that the implementation of mandatory screening has been associated with a 33.4% reduction in deaths due to critical congenital heart disease, translating to an absolute decline of 3.9 deaths per 100,000 births(11). This increase in early detection has also been predicted to achieve diagnosis prior to significant physiologic compromise for an additional 900-1,100 infants per year(12). Given that hypoxia and hypo-perfusion associated with cardio-vascular collapse have been associated with worse outcomes, POxS has the potential to reduce potential morbidity for hundreds of infants annually.

A simple and reliable screening method would be ideally suitable at all centres for early screening in CCHD cases. Pulse oximetry screening is a beneficial and cost-effective adjunct to prenatal ultrasound and postnatal physical examination to detect CCHD. Pulse oximetry can also detect significant non-CCHD conditions that require treatment in the newborn period; therefore, it should be regarded as a screening test for neonatal wellbeing in apparently healthy-looking infants.

AIM OF THE STUDY

- To estimate the yield of pulse oximetry as a screening tool to diagnose critical congenital heart disease.

MATERIALS AND METHODS

Study Design – prospective observational study

Study Setting- The study was carried out in postnatal world of MYH Hospital and MTH hospital, INDORE.

Duration of Study- It was done for one year after approval from the ethical committee,

Study Population- after taking written informed consent from parents all asymptomatic intramural then newborns word evaluated further with echocardiography for confirmation of congenital heart disease.

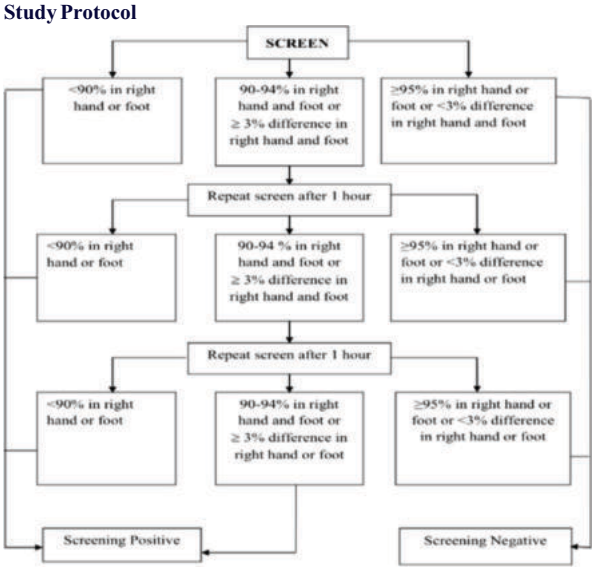
Inclusion Criteria - all symptomatic intramural newborns who were born from March 2021 to March 2022

Exclusion Criteria - those new ones who were diagnosed antenatally and those who were symptomatic at the time of screening.

We have divided study population in 3 groups:
- Group A where oxygen saturation was less than 90%
- Group B where oxygen saturation world 90-94%.
- Group C where oxygen saturation was more than 94%.

We followed AAP algorithm in this study.

Study Protocol



RESULTS

CHD is 3.6 in 6000 live birth that is 0.7 in 1000 live birth who was born in this hospital. The prevalence of congenital heart disease in the present study on the basis of location saturation and subsequent echocardiography was 22 in 6000 cases and the prevalence of critical Out of 6000 babies, 58% of the babies were male while 42% of babies for female.

Out of 6000 babies 52% of the babies were having weight in the range of 2.5-3 kg while 28% of the babies were having low birth weight.

When we compared the birth weight with echocardiographic findings they were significant relation between birth weight and echocardiography funding. Congenital heart disease in babies with having birth weight less than 2.5 kg was 1.3 times higher in babies with Birth weight more than 2.5 kg.

Table 1: Association of Screening Findings with Weight in Various Groups.

Weight Range	Number of Babies with Positive Screening	Group A (<90%)	Group B (90-94%)	%	Total Abnormal ECO Cardiography	P Value
<2.5 kg	37	21	16	56%	22	.037
>2.5 kg	29	9	20	44%	10	
Total	66	30	36	100%	32	

- When birth weight was compared with echocardiography findings a significant difference Chai square value = 4.338, df = 1, and P value is equal to 0.037 was found in babies with birth weight more than 2.5 kg and those with less than 2.5 kg, it can be inferred that there is a significant association between birth weight and presence of congenital heart disease i.e. birth weight less than 2.5 kg was 1.3 times more chance of developing congenital heart disease than those who birth weight was more than 2.5 kg.
- In this study, most of the babies were less than 2.5 kg which is 56% of total screened-positive babies.

Table 2: Positive screening with oxygen saturation 90-94%.

Heart diseases	Number	%
Critical CHD	0	0
Acyanotic CHD	14	38.8
NAD	22	61.2
Total	36	100

- Among group B only 38.8% babies were having acyanotic heart disease on echocardiography while most of them (61.2% babies had structurally normal heart.

Table 3: When oxygen saturation less than 90%

Heart diseases	Number	%
Cyanotic CHD	4	13.3
Acyanotic CHD	14	46.6
NAD	12	40.1
Total	30	100

- Among 30 babies with saturation less than 90%, 46% babies were having acyanotic heart disease.
- Only 13.3% babies were having cyanotic heart disease, while 40% babies having normal cardiac function.

Table 4: Summary of screening

Number of babies screened	Positive screening	ECHO positive results	Critical CHD	Non Critical CHD	Structurally normal heart
6000	66	32	4	28	34

- Out of all 6000 babies 1.1 % babies had positive screening results.
- Out of 66 screening positive babies 48.48% were having cardiac lesion. In which 6.06% babies were having critical CHD & 42.4% babies were having non critical CHD.
- Out of all screened-positive babies 51.5% were having a structurally normal heart.

Table 5: Cardiac lesion with saturation <90% cyanotic CHD

Cardiac Lesion	Mean Saturation	Number
Large VSD with PS	80 ± 5	4
Mild TR With Pulmonary HTN	86 ± 3	5
Interrupted Aortic Arch	85 ± 2	3
Tricuspid Regurgitation with PFO	88 ± 1	2
Total		14

Table 6: Cardiac lesion with saturation 90 -94 %

Cardiac Lesion	Mean Saturation (%)	Number
ASD	93 ± 1.5	4
ASD with PDA	92 ± 2	3
Pulmonary Stenosis with VSD	90 ± 0.5	3
Small VSD with PDA	91 ± 1	4

- In group B mean oxygen saturation of all acyanotic heart disease was 91.5%.

Table 7: Positive predictive value for detecting CHD when oxygen saturation less than 90%

Oxygen saturation	Echocardiography positive findings	Echocardiography negative findings	Total
Positive pulse oximetry screening	18	12	30

- Positive predictive value for detecting CHD oxygen saturation less than 90% PPV = TP/ TP+FP

= 18/30
= 60%

Table 8: Association of Group A with congenital heart disease on echocardiography

Variable	Congenital heart disease		Total
	Present	Absent	
SPO2 less than 90%	14	16	30
SPO2 more than 90%	14	22	36

PPV = TP/ TP+FP = 14/30 = 46.6% NPV = TN/TN+FN = 22/22+14 = 61.1%.
Sensitivity = TP/TP+FN = 14/28 = 50%
Specificity = TN/ TN+FP = 22/38 = 57.6%

DISCUSSION

In the present study, all congenital heart diseases with different hemodynamics were detected using a pulse oximetry screen. The sensitivity and negative predictive values of pulse oximetry screening to detect cyanotic heart disease and critical congenital heart disease were high..

The majority of the studies done in well-infant nurseries had used the saturation cut-off of less than 95% for abnormal pulse oximetry

[15,16,17]. The working group [5] recommended any saturation below 90% as abnormal for pulse oximetry screening in well infant nursery and recommended three repeated saturations taken hourly if the saturation is between 90% and 95%. In our study, all cases of critical cyanotic heart disease had a saturation persisting less than 90% . Considering a persistent saturation value of <95% as criteria for positive pulse oximetry screen would have led to 66 additional referrals for echocardiography.

The limitations of the present study include single center-based enrolment, Also, echocardiography was done only on selected controls rendering calculations of sensitivity, specificity, and predictive values inaccurate

To conclude, pulse oximetry screening is useful in detecting cyanotic heart diseases in a setting catering to sick out born neonates. Negative predictive value of pulse oximetry is high, making it useful to reliably rule out critical congenital heart disease or PPHN among sick neonates, thus avoiding need for an urgent echocardiography.

CONCLUSION

This study indicates that pulse oximetry is a noninvasive, reliable and useful screening tool for the early detection of congenital heart diseases especially cyanotic congenital heart diseases.

The normal oxygen saturation (negative pulse oximetry screening) does not rule out CHD, especially cyanotic congenital heart disease.

This study concludes that the use of pulse oximetry results in the early detection of CHD. Pulse oximetry has an additive effect and results in more efficient screening.

Funding-None.

Conflict of interest- The author declares that the research was conducted in absence of any commercial or financial relationship that could be constued a potential conflict of interest recommendations

This study suggests that pulse oximetry can be used as a screening method for early detection of congenital heart disease.

So we can recommend mandatory pulse oximetry screening in all newborns before discharge from the post-natal ward.

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