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Original Research Article

The prevalence of congenital heart disease in newborn detected by pulse oximeter screening test at 24 hours of birth and its correlation with clinical findings and ECHO

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ABSTRACT

Background: Detecting congenital heart disease (CHD) early is crucial for better outcomes, but most newborns show no symptoms. Newborn screening for CHD can identify such cases preventing serious consequences. This study aims to determine CHD prevalence and evaluate the effectiveness of pulse oximeter screening and clinical examination, correlating them with echocardiography findings.
Methods: A cross-sectional study was conducted to screen for CHD in all newborns born in our institution over a period of 3 months. A sample of 660 newborns were screened by pulse oximeter screening and clinical examination after random sampling.
Results: Comparison of baseline data like age distribution in mothers, gender and gestational age were comparable between newborns with CHD and those without CHD. A total of 8 CHDs were picked up after screening 660 newborns screened during a period of 3 months. CHDs that were picked up included hypoplastic left heart syndrome, pulmonary atresia, bicuspid aortic valve, transposition of great arteries, coarctation of the aorta, and other complex CHDs. It was found that either clinical examination or pulse oximeter screening has higher sensitivity than pulse oximetry screening or clinical examination alone.
Conclusions: For identification of a CHD in newborns after 24 hours of birth the order of preference for screening based on sensitivity is as follows-either pulse oximeter screening or clinical examination >clinical examination >pulse oximeter screening >pulse oximeter screening and clinical examination.

Keywords: Clinical examination, Congenital heart disease, Echocardiography, Pulse oximeter screening

INTRODUCTION

Each year, India sees the birth of over 200,000 children afflicted with congenital heart disease, with roughly 20% requiring early medical intervention. However, the existing healthcare services are inadequate to meet this demand. While there are more than 60 CHD centres across India, the majority are concentrated in the southern regions. Addressing the pressing need for enhanced care for these children presents a formidable challenge that cannot be delayed.[1-4]

Congenital heart defects are the most common birth defect in newborns, affecting about 8 out of every 1000 live births. Approximately a quarter of these defects are severe, necessitating surgery or catheter intervention within the first few days of life. Early detection of these CHDs before cardiovascular symptoms appear is crucial for reducing illness and death rates. Prenatal screening methods can identify roughly 50-80% of congenital heart defects, but postnatal diagnosis is challenging due to the absence of clear clinical signs in the first days after birth. Including pulse oximetry in routine screening alongside prenatal ultrasound and postnatal examination could help

reduce cases of late or missed diagnoses. Recognizing CHD promptly significantly improves the likelihood of a positive outcome.[1]

Following birth, the closure of the ductus arteriosus and other physiological adjustments might affect the results of pulse oximeter screening. Recent research found that the typical time for ductal closure is approximately 27 hours for boys and 45 hours for girls. However, many studies typically use a 24-hour cut-off, coinciding with the discharge time of healthy newborns without maternal complications. This timing prompts the performance of neonatal examination and screening within the initial 24 hours of life.[2]

There is a need for a cost-effective and simple screening test that can be conducted on all newborns after 24 hours of birth for the detection of CHDs as early as possible.[5]

This study aims at considering pulse oximetry and clinical examination which are cost-effective means to screen for congenital heart diseases which would aid in early diagnosis and early referral to higher centers for early intervention and surgery.

METHODS

Source of data

All normal neonates born during three months i.e. January to March 2023 at Cheluvamba hospital, a teaching tertiary care hospital attached to Mysore medical college and research institute, Mysore were enrolled for the study.

Sample size

All normal neonates born at Cheluvamba hospital were screened for the presence of any CHD after 24 hours of birth

$n = Z^2pq/d^2$

$=1.96\times1.96\times19.14\times80.86/3\times3$

$=660$

Where,

n=Sample size (cases)

Z=Z score corresponds to degree of confidence (1.96)

p=Prevalence of 0.01[6]

q=1-p (0.99)

d=Allowable error i.e. desired precision (5%)

Sampling method

Simple random sampling method was used.

Type of study

Cross-sectional study conducted from between January 2023 and March 2023.

Statistical methods

Newborns fulfilling the inclusion criteria and born at Cheluvamba hospital, Mysore were selected for the study, and consent for enrolment was obtained from the parents.

Inclusion criteria

All normal neonates born at Cheluvamba hospital attached to Mysore medical college and research institute, Mysore were enrolled for the study, and the following neonates were subjected to ECHO.

Newborns having positive screen after pulse oximeter screening test as mentioned below Or newborns having abnormal clinical examination findings on cardiovascular examination i.e. Abnormal precordial activity, abnormal pulse, apex beat, cardiac murmurs on auscultation.

Exclusion criteria

Neonates with respiratory pathology causing cardiac dysfunction were excluded from study.

Procedure

After obtaining approval by the institutional ethical committee and informed consent from parents/caregivers all newborns after 24 hours of life were screened by pulse oximeter screening as per the recent CDC guidelines. A screen is considered failed if any oxygen saturation measure is <90% (in the initial screen or repeat screens), Oxygen saturation is <95% in the right hand and foot on three measures, each separated by one hour, or >3% absolute difference exists in oxygen saturation between the right hand and foot on three measures, each separated by one hour. A screen is considered passed if any screening with an oxygen saturation measure that is ≥95% in the right hand or foot with a ≤3% absolute difference between the right hand or foot is considered a passed screen and screening would end. The algorithm for screening is depicted in Figure 1.

After the initial pulse oximeter screening test clinical and systemic examination was done on the newborns after 24 hours of life. The newborns with a positive pulse oximeter screening test or those with abnormal clinical findings suggestive of critical CHD were followed up with ECHO. Those with CHD identified by pulse

oximeter screening, clinical examination, and ECHO findings were recorded.[1,7,9,10]

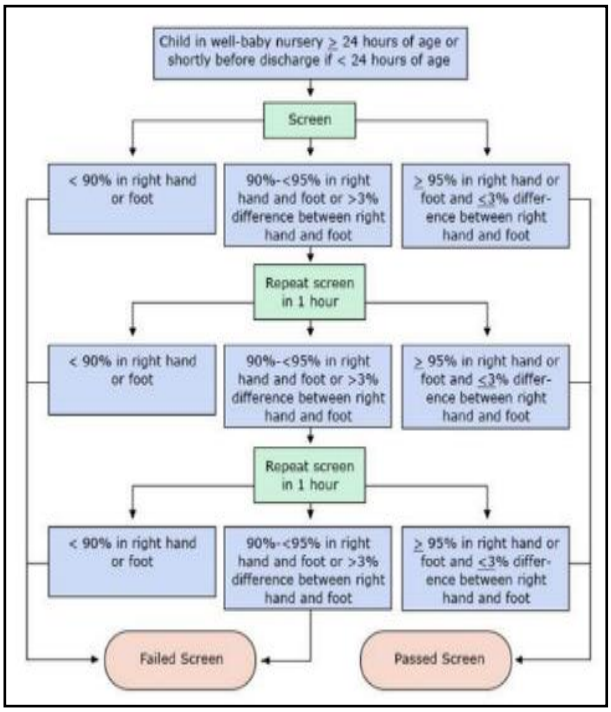

Figure 1: Algorithm for pulse oximeter screening in newborns.

Data collection and interpretation

Data was entered into Microsoft excel (Windows 10; Version 2010) and analyses were done using the statistical package for social sciences (SPSS) for the Windows software (version 22.0 and the SPSS Inc, Chicago).

RESULTS

After analysis of baseline parameters as shown in Table 1, there was no significant association of occurrence of CHD with maternal age, gender, or gestational maturity of the neonate.

After screening 660 neonates by simple random sampling 9 CHDs were picked up by pulse oximeter screening alone (1.4%), 9 (1.4%) CHDs were picked up by clinical examination of the neonate, 3 (0.5%) neonates had both clinical findings and failed the pulse oximeter screen. Those with abnormal clinical examination or failed pulse oximeter screen were followed up with 2D ECHO and 8 CHDs (1.2%) were confirmed by ECHO.

Table 3 shows a sensitivity of 50% for pulse oximeter screening alone but a specificity of 99.2%.

Table 4 shows the sensitivity of clinical examination alone for the detection of CHD is 75% and the specificity is 99.5%.

Tables 5 and 6 show the sensitivity and specificity of pulse oximeter screening and clinical examination taken together inclusive and exclusive respectively. When taken inclusively the sensitivity is 100% and specificity is 98.3%.

Table 1: Comparison of demographic characteristics with occurrence of CHD.

Parameters	Diagnosis		Total
	Normal	CHD	
Age of mother (in years)			
<30	600	7	607
	98.8%	1.2%	100.0%
≥30	52	1	53
	98.1%	1.9%	100.0%
P value	0.490		
Sex			
Female	272	3	275
	98.9%	1.1%	100.0%
Male	380	5	385
	98.7%	1.3%	100.0%
P value	1.000		
Delivery details			
Pre-term	149	0	149
	100.0%	0.0%	100.0%
Term	503	8	511
	98.4%	1.6%	100.0%
P value	0.209		
Total	652	8	660
	98.8%	1.2%	100.0%

Table 2: Diagnosis and clinical parameters among study subjects.

Parameters	Frequency	Percentage (%)
Diagnosis		
Normal	652	98.8
CHD	8	1.2
Pulse oximeter criteria		
Failed	9	1.4
Pass	651	98.6
Clinical examination		
Abnormal	9	1.4
Normal	651	98.6
Both clinical examination and the pulse-oximeter positive		
No	657	99.5
Yes	3	0.5
Either clinical examination or the pulse-oximeter positive		
No	645	97.7
Yes	15	2.3
2D echo finding		
Abnormal	8	1.2
Normal	7	1.1
Not done	645	97.7
Total	660	100.0

Table 3: Comparison of pulse-oximeter screening test in diagnosing CHD.

Pulse-oximeter screening test	Diagnosis		Total
	Normal	CHD	
Failed	5	4	9
	55.6%	44.4%	100.0%
Pass	647	4	651
	99.4%	0.6%	100.0%
P value	<0.001		
Sensitivity	50.0%		
Specificity	99.2%		
PPV	44.4%		
NPV	99.4%		

Table 4: Comparison of clinical examination in diagnosing CHD.

Clinical examination	Diagnosis		Total
	Normal	CHD	
Abnormal	3	6	9
	33.3%	66.7%	100.0%
Normal	649	2	651
	99.7%	0.3%	100.0%
P value	<0.001		
Sensitivity	75.0%		
Specificity	99.5%		
PPV	66.7%		
NPV	99.7%		

Table 5: Comparison of clinical examination and pulse-oximeter findings in diagnosing CHD.

Variables	Diagnosis		Total
	Normal	CHD	
No	651	6	657
	99.1%	0.9%	100.0%
Yes	1	2	3
	33.3%	66.7%	100.0%
P value	<0.001		
Sensitivity	25.0%		
Specificity	99.9%		
PPV	66.7%		
NPV	99.1%		

Table 6: Comparison of either clinical examination or pulse-oximeter findings in diagnosing CHD.

Variables	Diagnosis		Total
	Normal	CHD	
No	645	0	645
	100.0%	-	100.0%
Yes	7	8	15
	46.7%	53.3%	100.0%
P value	<0.001		
Sensitivity	100.0%		
Specificity	98.3%		
PPV	53.3%		
NPV	100.0%		

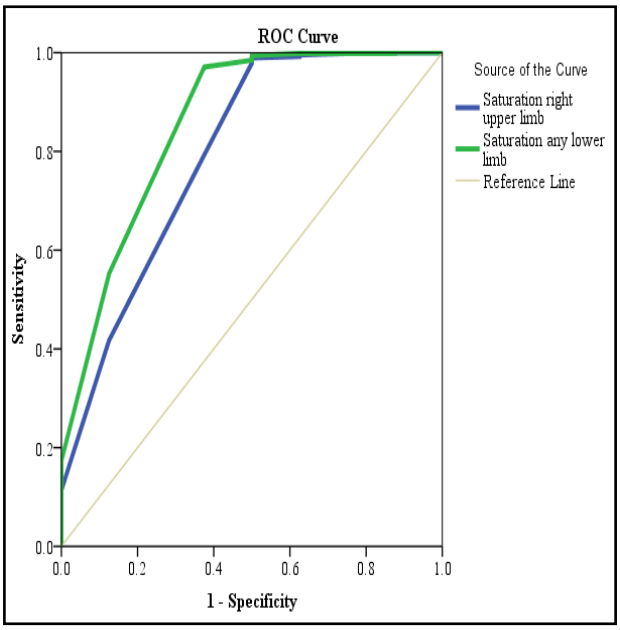

Figure 2: ROC curve for pulse-oximeter as predictor of CHD.

Table 7: Cut off saturation of upper limb and lower limb, sensitivity and specificity at cut off saturation.

Parameters	Ar	95 % CI		P value
		Lower bound	Upper bound	
O_2 saturation right upper limb	0.794	0.610	0.977	0.004
O_2 saturation any lower limb	0.857	0.702	1.000	0.001
Co-ordinates of the curve	SpO_2	Sensitivity	Specificity	
O_2 saturation right upper limb	95%	97.9%	50.0%	
O_2 saturation in any lower limb	95%	97.1%	62.5%	

Figure 2 depicts the ROC curve for saturation recorded by pulse oximeter in the right upper limb and any lower limb which is statistically significant with a p=0.004 and 0.001 respectively. From the ROC curve, we can derive the cut-off saturation of the test to be 95%. At the above cut-off saturation, the sensitivity of oxygen saturation of the upper limb and lower limb is 97.8% and 97.1% respectively, whereas the specificity is 50% and 62.5% respectively

DISCUSSION

Screening for critical congenital heart defects helps to identify some babies with critical congenital heart disease

before they go home from the hospital after birth. This allows these babies to be referred early to a cardiologist and may prevent disability or death early in life.[11-14,18]

This study was undertaken to identify and diagnose congenital heart diseases after 24 hours of life in newborns. This would help in early diagnosis and referral of babies born with congenital heart diseases to higher centres for further management.

Many studies have been done on the identification of congenital heart disease in newborns by pulse oximetry screening but this study combines both pulse oximeter screening and clinical findings together for identification of congenital heart disease.

During screening new-borns during the study congenital heart diseases which were picked up by pulse oximetry screening and clinical examination included pulmonary atresia, hypoplastic left heart syndrome, mitral atresia, Interrupted aortic arch, transposition of great arteries, coarctation of aorta, truncus arteriosus, tetralogy of Fallot with conoventricular ventricular septal defect. These newborns were referred to a cardiologist for further management early intervention and follow-up.

It was observed from this study that if the cut-off of saturation at 95% in both the upper limb and lower limb the sensitivity increases whereas the specificity decreases. According to the centre for disease control and prevention (CDC) guidelines the cut-off saturation is 95% in any of the limbs or a saturation difference of >3% between the right hand and either foot, the screen is repeated thrice with a gap of 1 hours if it's a failed screen at any point.

However, according to the American heart association guidelines, a pulse oximetry screen is considered positive if the measured oxygen saturation is <90% and no repeat testing is necessary. The threshold is saturation <95% or a difference of ≥4% in saturation between the right hand and either foot saturation.[10]

The American academy of pediatrics has revised congenital heart disease screening, opting for the lower extremity measurements only, lowering the saturation cut-off to 95%, eliminating the second retest, and standardizing the saturation difference to 2%. Screening now occurs within the first 24 hours of life. These changes aim to streamline the process, enhance sensitivity, and ensure prompt detection and treatment for affected infants.[9,16]

The closure of the ductus arteriosus and other physiological alterations following birth can influence the results of pulse oximeter screening. Recent investigations have estimated the median time for ductal closure to be approximately 27 hours in boys and 45 hours in girls. Nonetheless, numerous studies typically utilize a 24-hour threshold, coinciding with the discharge time for newborns deemed healthy without maternal complications. This underscores the significance of conducting neonatal assessments and screenings within the initial 24 hours of life to guarantee timely evaluation and necessary interventions.[2]

The goal of critical CHD screening in newborns is to reduce mortality and morbidity associated with delayed diagnosis by identifying newborns with CHD promptly. There is evidence that universal newborn pulse oximeter screening along with clinical examination improves the identification of patients with CHD compared with physical examination alone and will help in reducing mortality and morbidity among infants with congenital heart diseases.

Strengths

Pulse oximetry is an easy and affordable way to screen newborns for congenital heart diseases. This study combines clinical examination findings with pulse oximetry screening thus increasing the sensitivity of detection of congenital heart disease. If the cut-off for saturation of both upper limb and lower limb is taken as 95% it improves the sensitivity of the test.

Limitations

All children who failed the screen were followed up by a 2D ECHO for confirmation of diagnosis but those who passed the test were not followed up by the 2D ECHO.

CONCLUSION

For identification of a CHD in newborns after 24 hours of birth, the order of preference for screening based on sensitivity is as follows-either pulse oximeter screening or clinical examination >clinical examination > pulse oximeter screening>pulse oximeter screening and clinical examination. Pulse oximeter screening when taken as inclusive with clinical examination has higher specificity as compared to clinical examination and pulse oximeter screening alone and the cut-off for saturation of upper limb and lower limb of 95% will increase the sensitivity of the test but will reduce the specificity.

Recommendations

Pulse oximeter screening combined with clinical examination should be made a routine part of screening all newborns after 24 hours of birth. Pulse oximeter screening can be made a part of screening in all medical institutions for the identification of critical congenital heart diseases.

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Ethical approval: The study was approved by the Institutional Ethics Committee

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