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SCREENING OF CYANOTIC CONGENITAL HEART DISEASE BY PULSE OXIMETRY

Paediatrics

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ABSTRACT

Background: Congenital heart disease (CHD) is the most common congenital malformation. Early detection of CHD in asymptomatic newborns immediately after birth will help in timely intervention and reduce mortality. **Objective:** To evaluate pulse oximetry as a screening tool for critical congenital heart disease in asymptomatic newborns **Intervention:** It was a single centre hospital based prospective study. Apparently healthy term, near- term newborns who did not require hospitalization were screened clinically and with pulse oximeter at 24 to 48 hours of age. preductal and postductal SPO2 reading >95% was taken as a negative screening. Positive screening was defined as SPO2<90% or a persistent equivocal SPO2 (90-95%) in three readings. Subsequent confirmatory echocardiography examination was done for those who screened positive by clinical or pulse oximeter examination. Data were analysed statistically. **Results:** Study population comprised of 6940 apparently healthy babies. 9(15.25%) babies with oxygen saturation below 90% had Critical CHD, out of which 4 cases had pulmonary stenosis/atresia and 4 had transposition of great arteries and 1 case had Tetralogy of Fallot. 35 babies with saturation 90-95% were found to be having acyanotic CHD. Out of which majority of cases were of VSD and other cases were AVSD, dextrocardia and PDA. Sensitivity, specificity PPV, NPV for detecting CCHD in this study was100%. **Discussion:** Clinical examination alone can miss the CHDs in newborn babies so pulse oximetry should be supplemented in newborn screening protocol.

KEYWORDS

Congenital heart disease (CHD), Screening, Pulse oximetry

INTRODUCTION:

Critical congenital heart diseases (CCHD) are the malformation of the heart or large blood vessels associated with the heart, affecting various parts or function. It is one of leading cause of mortality in the first year of life.[1]

Congenital heart disease (CHD) occurs in approximately 0.8% of live birth. the incidence is higher in stillborn 3 to 4%, spontaneous aborts 10 to 25%, and in premature infants approximately 2% excluding patent ductus Arteriosus.[2]

CHD are generally classified by severity: mild CHD are most common, often asymptomatic and with spontaneous resolution; moderate CHD are also benign, but require drug therapy; critical CHD (CCHDs) are characterized by sever alteration of cardiac anatomy and they require nonsurgical and surgical interventions during the first year of life.[3]CCHD accounts for approximately 1/3rd of all major congenital defect.[4]

CCHD is a wide spectrum of severity in infants: approximately 2 to 3 in 1000 newborns infants will be symptomatic with heart disease in the 1st year of life. The diagnosis established at 1 week of age in 40 to 50 % of patient with CCHD, and at one month of age in 50 to 60 % babies.[2]

Cyanosis is a common presenting sign of the CCHD in neonates. Physical examination is insufficient to detect all pathologies during birth hospitalization because of mild hypoxemia, ventricular dysfunction, and patent duct as well as the absence of murmur.[6]

Babies with a duct-dependent pulmonary circulation, who often present with a visible cyanosis only 4 % were missed; while babies with ductus-dependent systemic circulation, often with a subnormal arterial oxygen saturation (SpO2) without visible cyanosis, 30% were missed [6]. Routine neonatal inspection fails to detect about 50% of CCHD infants [7]. Approximately 20%–30% of CCHD cases are undiagnosed during birth hospitalization.[8]

These babies if left untreated deteriorate rapidly in hours so early diagnosis and appropriate management is the key in reducing mortality and morbidity.

Prenatal ultrasound or screening 2D ECHO can identify a variety of CCHD lesion; however numerous studies have reported that even when fetal ultrasound is routinely performed during pregnancy, fewer than 50% cases of CCHD are identified.[9]

Echocardiography is gold standard for detection of CCHD. However, it is impractical to use it as a screening tool in all newborns[9].

Pulse oximetry is a non-invasive procedure can pick up the desaturation of blood objectively so we can use it as screening tool for CCHD in newborns.[9]

England Wren et al found that one third of infants with a potentially life-threatening heart defect were discharged with disorder undetected, and that 5% of these died with the condition first recognized by autopsy.[8]

In CCHD serious morbidity and mortality normally result from hemodynamic compromise which comes in form of cardiovascular collapse and end organ damage.

Nowadays palliative and corrective interventions are available in treatment of CCHD. So, with the help of early neonatal screening programs babies diagnosed early & referred for interventions early. This approach helps in decrease neonatal mortality and increase surviving of babies. The mortality rate of late detection is twice of those detected early.

MATERIALS AND METHODS:

The study was conducted in the postnatal ward of PDZH Udaipur. This was a single centre prospective observational study. All term, near term neonates admitted to the postnatal ward were included in the study. Infants with multiple congenital malformations and antenatally diagnosed CHD were excluded. Infants were recruited over a period of 12 months from august 2021 to July 2022. Informed consent was obtained by parents before enrolment in the study. The study was cleared by the Hospital Ethics Committee. Pulse oximeter saturation of all infants included in the study was recorded between 24 and 48 h of life by applying pulse oximeter probe on preductal (right hand) and postductal (any foot) site by the investigator and concurrently clinical examination was done. Neonatal reusable pulse oximeter was used to document the saturations. Results were said to be positive if SpO2 saturation on pulse oximeter was < 90% in right hand and foot, 3 readings were taken 1 h apart before labelling it positive. Results were said to be negative if SpO2 saturation on pulse oximeter was ≥95% in right hand or foot and the difference between right hand and foot was ≤3%. The diagnostic accuracy of pulse oximetry was measured by computation of sensitivity, specificity, positive and negative predictive values. If as per protocol the screening was positive, then the baby was evaluated further by chest X-ray, and two-dimensional echocardiography (2D ECHO) and other causes of desaturation by temperature, CBC, RBS. ECHO was performed by a cardiologist in positive screened babies.

RESULTS:

Our study was single centered hospital based prospective study,

conducted in postnatal ward of PDZH Udaipur. A total number of 14896 deliveries were conducted in our institute, out of which by excluding abortus, early discharged babies, not consenting mothers, sick newborns and premature newborn 6940 babies were screened in our study. The male female ratio in this study was 1.2 and most of babies 63.2% were delivered by NVD. Majority of babies 72.80% were come under 37-40 weeks of gestation age, and 83.3% were > 2.5 kg as we excluded premature babies **(Table 1).**

Table 1: Study Population by Gestation Age & Birth Weight

Gestation age	Babies
34-36 week	1888 (27.20%)
37-40 weeks	5052 (72.80%)
Birth wight (gram)	Babies
1500-2500	1143 (16.7%)
>2500	5797(83.3%)

Babies were screened according to AAP protocol **(Figure 1).** 6264 (90.2%) babies consider negative screened as their saturation was more than 95 percent. Nine (0.12%) babies had saturation below 90 percent so they were considered positive screened in first screening and they all were diagnosed as cyanotic congenital heart disease and they all required urgent surgical interventions. A number of six hundred sixty-six (9.59%) babies were screened as equivocal in first screening are undergone second screening out of which 144 (2.07%) saturation came >95% came under negative screening and remaining 522 (7.52%) babies were further undergone for third screening in which 472 (6.80%) babies saturation were more than ninety five percent and remaining 50 babies whose saturation between 90 to 95 percent in all three screening were also considered as positive screened in which 40 babies were diagnosed as acyanotic congenital heart diseases and 10 had false positive result. Forty five babies were diagnosed as acyanotic CHD during the study period which is negative by pulse oximetry **(Table 2).** The result of the study analysed statistically. The Sensitivity, specificity, PPV, and NPV of pulse oximetry for diagnosis of overall CHD were 55.68%, 68.75%, 83.05% and 36.07%. The sensitivity, specificity, PPV, and NPV of pulse oximetry for detecting cyanotic congenital heart disease was 100% as no CCHD was missed by the study **(Table 3).**

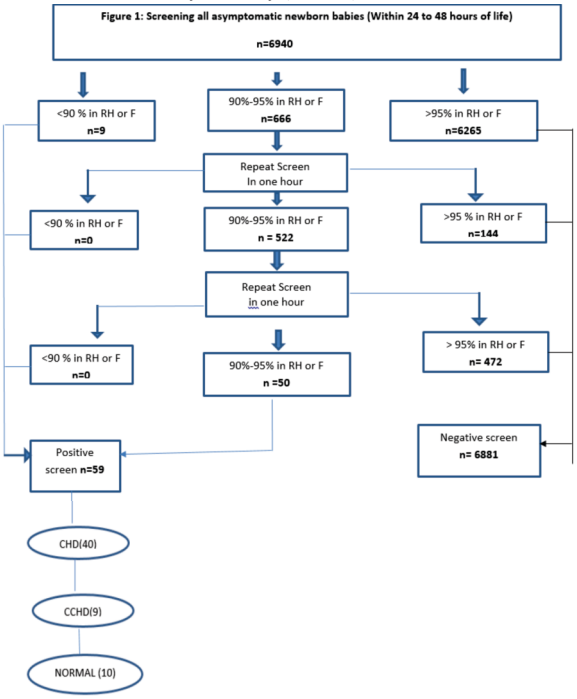

Table 2: Diagnosis in positive screened babies (pulse oximetry and clinical examination)

S. No.	Pulse oximetry result	Clinical examination	Diagnosis	Number	Percent (%)
1	Positive	Negative	TGA	4	3.33%
2	Positive	Negative	Severe PS/ Pulmonary Atresia	4	3.33%
4	Positive	Negative	AVSD	15	12.50%
5	Positive	Negative	ASD with VSD Dextrocardia	3	2.50%
6	Positive	Negative	PDA	2	1.67%
7	Positive	Negative	VSD	15	12.5%
8	Positive	Negative	Polycythemia	2	1.67%
9	Positive	Negative	Normal baby	8	6.67%
10	Negative	Positive	ASD	3	2.50%
11	Negative	Positive	ASD with VSD	6	5.00%
12	Negative	Positive	ASD with VSD Dextrocardia	2	1.67%
13	Negative	Positive	COA	3	2.50%
14	Negative	Positive	PDA	2	1.67%
15	Negative	Positive	PFO	2	1.67%
16	Negative	Positive	VSD	21	17.50%
17	Negative	Positive	Hypo glycemia	3	2.50%
18	Negative	Positive	Hypothermia	4	3.33%
19	Negative	Positive	Congenital-heart block	1	0.83%
20	Negative	Positive	Normal babies	14	11.66%
21	Positive	Positive	TOF physiology	1	0.83%
22	Positive	Positive	AVSD	1	0.83%
23	Positive	Positive	PDA	1	0.83%
24	Positive	Positive	Dextrocardia with VSD	3	2.50%
			Total	120	100%

Table 3: Statistical result of pulse oximetry for critical cyanotic congenital heart disease

Sensitivity	100%
Specificity	100%
PPV	100%
NPV	100%
Test accuracy	100%

DISCUSSION:

Congenital heart disease is the (CHD) is the most common congenital malformation. [10] Morbidity and mortality vary with the severity of the congenital heart disease and can be serious. [11] Early detection of congenital heart disease in the asymptomatic period immediately after birth will reduce clinical deterioration by instigation of appropriate, timely management. Pulse oximetry has been proposed as an alternative screening method for the detection of congenital heart defects. [12] It is a simple, non-invasive investigation which measures the percentage of hemoglobin in blood that is saturated with oxygen. It is proposed that the measurement of oxygen saturation identifies infants with mild cyanosis who do not have an audible murmur or other signs of cardiac abnormality and are not detected by routine clinical examination. [13] **Ailes et al** estimated that approximately 875 newborns with critical CHD could be identified at birth hospitals in the U.S. each year by using pulse oximetry newborn screening. **Koppel RI et al 2003.** "Effectiveness of pulse oximetry screening for congenital heart disease in asymptomatic newborn" studied 11,281 asymptomatic newborns in two hospitals. Diagnostic echocardiogram was performed in infants with oxygen saturation ≤ 95% within the first 24 hours of life. Three babies with CHD were identified (but none had a critical left-heart obstructive lesion). Two patients with negative screens were later readmitted; one with aortic coarctation and one with hypoplastic left pulmonary artery with aorto-pulmonary collaterals. The sensitivity of the screening test was calculated to be 60%, with a specificity of 99.95%, a positive predictive value of 75% and a negative predictive value of 99.98%. [14] A multicentric study did by **Engel M S et al 2016** "Pulse oximetry screening: a review of diagnosing critical congenital heart disease in newborns" sensitivity of screening (69.9 %), specificity (99.9%), PPV (47%). [13]

Arlettaz et al screened 3,262 babies in their study out of which 24(0.7%) babies positive with pulse oximetry, of which 17 (71%) had CHD: 11 cases (28%) had CCHD. Diagnosed by prenatally and they showed only low pulse oximetry value. They diagnosed HLHS in 3 babies, 2 with TGA, 2 with DORV, 1Case of COA, 1 with TAC, 1 with AVSD, 1 with VSD. The sensitivity and specificity of study were100% and 99.7% respectively. The PPV and NPV were 63% and 100 %respectively [15].

In 2011 the US Secretary of Health and Human Services recommended universal screening of newborns for critical congenital heart defects using pulse oximetry. As in 2015 at least 43 states have passed a law or regulation that requires hospitals to screen newborns for critical CHDs.

AHA protocol evaluates the pulse oximetry reading of the infant on a hand and foot after 24 hours of age. To avoid the problem of multiple false positives it was decided to repeat the screen twice prior to declaring the infant a failure.

Seven key lesions which would be expected to have a low saturation were targeted by the AHA.

These included hypoplastic left heart, pulmonary atresia, Tetralogy of Fallot, total anomalous venous return, transposition of the great arteries, tricuspid atresia and truncus arteriosus.

CONCLUSIONS:

In this study pulse oximetry screening offered good results for detecting CCHD with high sensitivity, specificity and test accuracy. Hence it can be concluded that Pulse oximetry screening added to clinical examination enhance the diagnosis rate of CHDs.

We recommend that clinical examination must be supplemented with pulse oximetry for all newborn screening protocols

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