



## TO STUDY THE ROLE OF PRE-DISCHARGE PULSE OXIMETRY SCREENING IN TERM/NEAR TERM NEONATES FOR CRITICAL CONGENITAL HEART DEFECTS

### Neonatology

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### ABSTRACT

**Objective :** To evaluate the effectiveness of pre-discharge pulse oximetry as screening for critical congenital heart disease (CCHD) in Term and near term newborns.

**Methods :** This was a prospective case control study conducted in the Neonatal intensive care unit and postnatal wards of a tertiary hospital, Delhi. The study period was from June 2014 to November 2015, and followed up to 3 months. Inclusion criteria :-Healthy near term (35 to 37 completed weeks of gestation) and term (37 to 42 completed weeks of gestation) neonates. Exclusion criteria :-Neonates with any congenital malformation detected antenatally, Neonates requiring care in the neonatal intensive care unit., Severe IUGR and Maternal intake of drugs apart from the nutritional supplements. The pulse Oximetry Probes were applied to right upper limb (Preductal) and right lower limb (Postductal) in a calm /awake baby for about 3 min for saturations and their difference was recorded. A mean of three readings were taken. Oxygen saturation  $SpO_2 < 95%$  or differential saturation  $> 3%$  was considered screen positive and sent for echocardiography for confirmation.

Statistical analysis : Data was entered in a predesigned proforma in Microsoft Excel. The data was then analyzed statistically using Stata software version 11 (Stata Corp, College Station, TX). Continuous data with normal distribution was analyzed by student t test and non-normally distributed data by Wilcoxon rank sum test (Mann-Whitney). Categorical data was analyzed by chi-square or Fisher exact test. A P value of  $< 0.05$  was taken as significant.

**Results :** Of the 4100 term and near term neonates screened 427 (10.4%) babies were screen positive and 3273 (89.6%) babies screen negative with pulse oximetry. Total of 42 newborns screen positive for detection of CCHD by  $SPO_2$  constituted 9.8% (42/427). out of 42 screen positive newborns for  $SPO_2$ . Echocardiography examination in these newborns revealed congenital heart disease in 59.5% (25/42). The sensitivity and specificity of  $SPO_2$  for detection of CCHD was 80% and 99% respectively, whereas positive predictive value (PPV) and negative predictive value (NPV) was 9.5% and 100% respectively. P value was significant ( $< 0.0001$ ).

**Conclusion :** The technique of pulse oximetry is simple, reliable and an effective method of screening for detection of CCHD.

### KEYWORDS

screening, newborn, congenital heart disease, pulse oximetry

#### Introduction

Congenital Heart Disease (CHD) is one of the most common birth defects affecting nearly 8 newborns every 1000 births annually. Among these, 2.5-3 are severe CHD (Critical CHD: CCHD). There is no uniform definition of CCHD. Paediatric cardiologists usually define CCHD as a condition that is either; duct-dependent or requires surgery/intervention during the first month of life for the survival [1]. On the other hand, Mellander and Sunnergardh defined, critical as 'a heart defect that most likely would have caused circulatory collapse or death if surgery or catheter intervention was not performed before 2 months of age [2]. In spite of diagnosis, 43% of cases of CCHDs report to the Neonatal Intensive Care Unit (NICU) in state of shock at the time of readmission after hospital discharge [2].

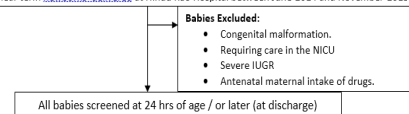
#### Method

The study was conducted in the Post natal wards and the Neonatal Intensive Care unit of Hindu Rao Hospital, Delhi and the discharged neonates were followed up telephonically and physically in the Well Baby Clinic of the Neonatal Division Hindu Rao Hospital. Neonates for the study were enrolled from June 2014 to November 2015 and followed up to 3 months. The total study period was one and a half year. This was a Prospective Case Control study. Inclusion criteria :-Healthy near term (35 to 37 completed weeks of gestation) and term (37 to 42 completed weeks of gestation) neonates born during the study period were included in the study. Exclusion criteria :-Neonates with any congenital malformation detected antenatally, Neonates requiring care in the neonatal intensive care unit., Severe IUGR, Maternal intake of drugs during the antenatal period apart from the nutritional supplements. The pulse Oximetry screening OXI-SAT 2060 (2 in number) Probes were applied to right upper limb (Preductal) and right

lower limb (Postductal) in a calm /awake baby for about 3 min, and thus pre-ductal saturation and post-ductal saturations and their difference was recorded. A mean of three readings were taken. If  $SpO_2$  in RUL or in RLL was  $< 95%$  or differential saturation  $> 3%$  it was considered screen positive and neonate sent for echocardiography (done by ENVISOR-C Model-2000 colour doppler using pediatric probe size-8). The babies were followed for 3 months by regular telephonic contact, and any critical illness requiring admission were recorded.

Statistical analysis: Data was entered in a predesigned proforma in Microsoft Excel. The data was then analyzed statistically using Stata software version 11 (Stata Corp, College Station, TX). Continuous data with normal distribution was analyzed by student t test and non-normally distributed data by Wilcoxon rank sum test (Mann-Whitney). Categorical data was analyzed by chi-square or Fisher exact test. A P value of  $< 0.05$  was taken as significant.

Normal term or near term newborns delivered at Hindu Rao Hospital between June-2014 and November-2015



- Babies Excluded:**
- Congenital malformation.
  - Requiring care in the NICU
  - Severe IUGR
  - Antenatal maternal intake of drugs.

All babies screened at 24 hrs of age / or later (at discharge)

**PULSE OXIMETER SCREENING: Equipment:** OXI-SAT 2060 (2 in number)  
**Method :** By monitoring for 3 min in a calm / awake baby at pre-ductal (Right upper limb) and post-ductal location (Right lower limb): Mean of 3 recordings  
**Data Collected: (4100)**  
 (1) Preductal Saturation (2) Postductal saturation (3) Differential saturation (4) Time for recording

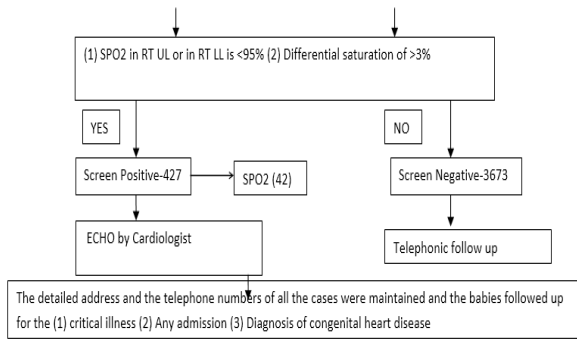


Figure -1: Method of screening for pulseoximetry.

**RESULTS:**

In our study from June 2014 to November 2015, total deliveries were 12493. Among these 4100 were screened, 427 were screen positive and 3673 were screen negative as shown in the figure (2).

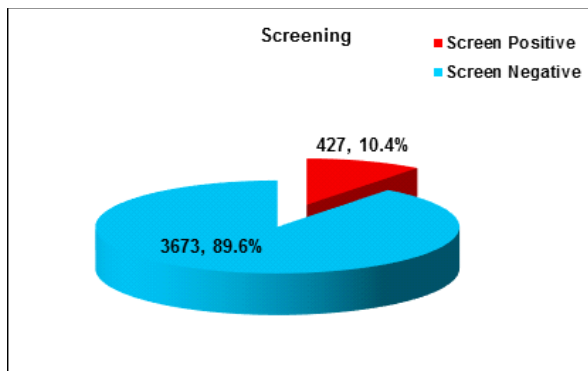


Figure2: Screen positive and Screen negative cases.

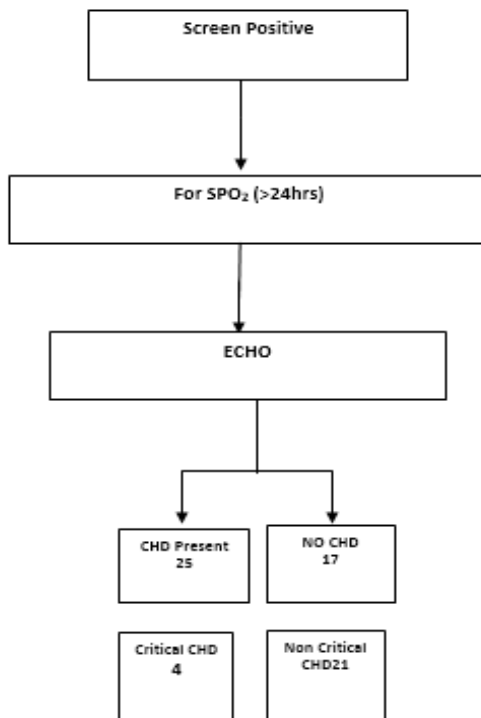


Figure (3) Showing screen positive CHD cases by pulse oximetry and echocardiography based CCHD detected cases .

TABLE(1). LIST OF ECHO DIAGNOSIS

Among screen positive cases, following critical and non-critical CHDS were found.

CRITICAL CHD'S	NUMBER
Total Anomalous Pulmonary Venous Drainage	2
Transposition Of Great Arteries	1
Pulmonary Atresia with VSD	1
NON CRITICAL CHD'S	NUMBER
VSD	8
ASD	2
PFO	4
PDA	5
ASD + VSD	2

In our study, the screen positive newborns for detection of CHD by SPO2 constituted 9.8% (42/427). All forty two screen positive newborns for SPO2 > 24 hrs i.e those newborns who had SPO2 <95 in right upper limb or right lower limb or differential saturation >3% underwent echocardiography. Echocardiography examination in these newborns revealed congenital heart disease in 59.5% (25/42)

TABLE (2) Detection of CCHD by SPO2 and its p value

SPO2 (>24hrs)	CCHD Present		CCHD Absent		P value
	Frequency	%	Frequency	%	
Abnormal	4	80.0%	38	1.0%	<0.0001
Normal	1	20.0%	3731	99.0%	
Total	5	100%	3769	100%	

TABLE (3) Sensitivity, Specificity, PPV, NPV of SPO2 for detection of CCHD

Sensitivity	80.0%
Specificity	99.0%
PPV	9.5%
NPV	100.0%

In our study, the sensitivity of SPO2 for detection of CCHD was 80%, specificity 99%, PPV 9.5% and NPV 100%. P value is significant (<0.0001) indicating important role of SPO2 monitoring in detection of CCHD

**DISCUSSION**

Our study was conducted in the division of Neonatology at Hindu Rao Hospital, Delhi. Total number of deliveries during this period were 12493, out of which 4100 newborns were screened randomly. Among 4100 newborns screened, 10.4% (427/4100) were screen positive and 89.6% (3673/4100) were screen negative for detection of CHD by pulse oximetry. In our study screen positive cases for SpO2 were 1.02% (42/4100). In a study done by Andrew K Ewer et al[3] they had similar proportion of screen positive cases for SpO2 0.97% (195/20055). In our study, the screen positive newborns for CHD by pulse oximetry 9.8% (42/427). Newborns who had SPO2 <95% in right upper limb or right lower limb or differential saturation >3% were considered screen positive for CHD and these accounted for 9.8% (42/427). Echocardiography examination in these newborns revealed congenital heart disease in 59.5% (25/42), out of which critical CHD constituted 16% (4/25). In study done by Riede[4] SPO2 was performed between 24 hrs -72 hours in term and post term babies and a cut off value of 95% was used for doing ECHO as against near term and term in our study with a same cutoff value of 95%. Among overall screen positive newborns, 0.94% (4/427) had CCHD and among overall screen negative newborns 0.02% (1/3673) had CCHD thus making 0.146% (6/4100) incidence of CCHD in the study population. This is comparable to 0.186% incidence of CCHD in the study done by Riede[4]. Most common CCHD in screen positive newborns in our study was Total Anomalous Pulmonary Venous Drainage (2 cases) and Transposition of Great Arteries (TGA) (1 case) followed by 1 case of Pulmonary Atresia with VSD. However only one case of Critical Coarctation of Aorta was detected on telephonic follow up at 3 months among screen negative newborns. This is comparable to the study done by Riede[4] in which most commonly detected CCHD was Total Anomalous Pulmonary Venous Drainage followed by TGA. All four screen positive cases for CCHD were referred to higher center for operative intervention and were alive till last follow up at 3 months of

age. In our study, the sensitivity of SPO2 for detection of CCHD was 80%, specificity 99%, PPV 9.5% and NPV 100%. P value was significant (<0.0001) indicating important role of SPO2 monitoring in detection of CCHD. Study done by Ewer [5] mentions that it is important to consider sensitivity, specificity, false positive and false negative rates. Meta analysis [6] of studies done for screening of newborns for congenital heart disease also indicates that sensitivity is 76.5% and specificity is 99.9% which is comparable with our study.

**Table. Results of Studies Examining Oximetry Screening for CCHD**

Study's First Author	N	Age at Screening, H	Probe Location	Cutoff for Normal	FP	FP Rate %	TP	FN	TN	PPV %	NPV %	Sensitivity %	Specificity %
Hoke [7](2006)	287	<24	H+F	92/7	53	1.84	4	0	281	7.0	98.1	100.0	100
Richmond [8](2002)	562	11.7	F	95	51	0.91	9	4	562	15.0	99.9	69.2	99.8
Koppel [2](2008)	112	72	F	96	1	0.01	3	2	112	75.0	99.9	60.0	99.9
Reich [9](2004)	211	>24	H+F	95/4	2	0.09	1	1	211	33.3	99.9	50.0	99.9
Bakr [10](2005)	521	31.7	H+F	94	1	0.02	3	2	521	75.0	99.9	60.0	99.9
Rosati [1](2005)	529	72	F	96	1	0.02	2	1	528	66.7	100	66.7	100
Arlotta [11](2006)	326	8	F	95	7	0.21	17	3	323	70.8	99.9	85.0	99.8
Kawalec [12](2006)	27	26	F	95	13	0.05	7	1	271	35.0	99.9	87.5	99.9
Meberg [13](2009)	50	6	F	95	32	0.65	43	NA	NA	11.7	NA	NA	NA
Sendelbach [14](2008)	10	4	F	96	63	4.5	0	1	103	0	99.9	0	95.5
Riede [4](2010)	42	24-72	F	96	40	0.094	14	4	413	25.9	99.9	77.8	99.9
Present Study (2016)	410	>24	H+F	≥95/ <3	38	0.92	4	1	376	9.5	100	80	99
Shahzad [15](2017)	138	Upto 7 days	H+F	≥95/ <3	NA	NA	16	NA	NA	45.7	95.1	76.1	83.7

- FP indicates false-positive; TP, total positive; FN, false-negative; TN total negative; PPV, positive predictive value; NPV, negative predictive value; H+F, hand and foot; F, foot; and NA not available.
- \*Excludes study by Meberg et al[13] because false-negative data were not included.

**CONCLUSION**

The prevalence of CCHDs among asymptomatic newborns is high (1.46/1000) particularly in places where facilities for fetal echocardiography is not available. The technique of pulse oximetry is simple and reliable with specificity of 100%. Asymptomatic newborns with positive screen may be further evaluated for specific diagnosis of

CCHDs before discharge. Early diagnosis of CCHDs prepares the parents psychologically, physically and financially for timely intervention in their precious child. To conclude Pulse oximetry is an ideal neonatal screening programme that can be taken up at national level for the screening of CCHDs, in asymptomatic newborns at birth. Conflict of interest; None Funding -None

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