International Journal of Science and Research (IJSR)
ISSN: 2319-7064
SJIF (2022): 7.942

# Clinical and Pulse Oximetry Screening to Detect Congenital Heart Diseases in Asymptomatic Newborns

**Santanu Ghosh*[1], Deepak Joshi[2], Sathish Kumar R[3], Avinash Singh[4]**

[1]PGT, Pediatrics, Command Hospital, Kolkata
Corresponding Author Email: *santanughosh2010.08[at]gmail.com*

[2]Professor, Department of Paediatrics, Command Hospital, Kolkata
Email: *deepakjoshi6562[at]yahoo.co.in*

[3]PGT, Paediatrics, Command Hospital, Kolkata
Email: *rskamc[at]gmail.com*

[4]PGT Paediatrics, Command Hospital, Kolkata
Email: *avirythm[at]gmail.com*

**Abstract:** ***Background: Congenital heart diseases (CHDs) are among one of the commonest congenital malformations encountered in clinical practice and remain an important cause of morbidity and mortality in infants and children. The prevalence of CHD ranges from 8 to 12 per 1000 live births.1, 2With 27 million live births every year, India has a huge burden of children with CHD. Life - threatening CCHD form around 10% - 25% of all CHD in the newborns and one third of these neonates are discharged home without a diagnosis.3Therefore, aim of this study is to assess all newborns in a Tertiary care hospital for congenital heart diseases (CHD) by clinical examination and pulse oximetry. Methods: As part of the screening, all asymptomatic newborns born between February 2021 to July 2022, underwent clinical examination for presence or absence of cyanosis, delayed or absence femoral pulses, cardiac murmur and Spo2 measurement with a pulse oximeter before discharge to home from the postnatal ward. Pulse Oximetry screen: Two separate sites, the right hand (preductal) and either foot (post ductal) were tested consecutively. Clinical screen: Any baby with apparent Cyanosis was confirmed by pulse oximetry and subsequent investigations. Any baby with absent/delayed femoral pulse underwent 4 - limb BP followed by Echocardiography. Any baby with cardiac murmur was evaluated by 2D echocardiography after comprehensive clinical exam. Results: In our study, a total of 350 babies were screened by pulse oximetry and clinical examination. Our study showed that combined screening method identified more number of cases with congenital heart diseases than any single method of screening. It was found to be statistically significant. (P value - 0.0001). Among total 7 cases with abnormal saturation 71.4% showed cardiac murmur and among 343 cases with normal saturation only 0.9% showed cardiac murmur. There is statistically significant association between abnormal saturation and cardiac murmur as p value is <0.0001. Conclusion: Pulse oximetry screening of asymptomatic neonates between 24 and 48 hours of life improved the detection of CCHDs with high specificity and negative predictive value, moderate sensitivity and a reasonably low false positivity rate.***

**Keywords:** critical congenital heart disease, CCHD, congenital heart disease newborns, echocardiogram, cost - effectiveness

## 1. Introduction

Congenital heart diseases (CHDs) are among one of the commonest congenital malformations encountered in clinical practice and remain an important cause of morbidity and mortality in infants and children. The prevalence of CHD ranges from 8 to 12 per 1000 live births.[1, 2]With 27 million live births every year, India has a huge burden of children with CHD. However, there are significant problems in the form of poor parental awareness, delayed diagnosis and late referrals to limited and unequally distributed paediatric cardiac care facilities in the public and private sector.[3] Life - threatening CCHD form around 10% - 25% of all CHD in the newborns and one third of these neonates are discharged home without a diagnosis.[4] The routine antenatal anomaly scan at 18 - 20 weeks is able to detect only around 50% of CHD.[5, 6, 7] The majority of the CHD are asymptomatic at birth and the degree of cyanosis is not clinically recognizable. Cyanosis is apparent clinically only when there is at least 5 g/dl of deoxygenated haemoglobin or an SpO2 of <80%.[8, 9] Pulse oximetry screening to detect CCHD was first studied in the beginning of the 21st century. The underlying principle is the ability of pulse oximetry in detecting clinically in apparent cyanosis. Pulse oximetry screening studies have come from the bench to bedside in the last few years with a moderate sensitivity of 76.3%, high specificity of 99.9% and low false positive rate of 0.14% in the detection of CHD among asymptomatic newborns in hospitals before discharge.[10]

## 2. Materials and Methods

Written informed consent was taken from participant's mother. As part of the screening, all asymptomatic newborns born between February 2021 to July 2022, underwent clinical examination for presence or absence of cyanosis, delayed or absence femoral pulses, cardiac murmur and Spo2 measurement with a pulse oximeter before discharge to home from the postnatal ward. The neonates were awake and calm or breastfeeding during the screening.

**Clinical screen**: Any baby with apparent **Cyanosis** was confirmed by pulse oximetry and subsequent investigations. Any baby with **absent/delayed femoral pulse** underwent 4 -

limb BP followed by Echocardiography. Any baby with **cardiac murmur** was evaluated by 2D echocardiography after comprehensive clinical exam.

**Pulse Oximetry screen**: Two separate sites, the right hand (preductal) and either foot (post ductal) were tested consecutively after ensuring that the hands and feet of the neonates are warm to touch. The SpO2 reading was recorded once a stable waveform was displayed on the monitor. Cut - off Pulse oximetry will be 95% or Pre and post - ductal saturation, difference >3%.

Screening was considered positive if:
1) Any oxygen saturation measure <90%
2) Oxygen saturation <95% in the right hand and foot on three measures, each separated by one hour.
3) A >3% absolute difference in oxygen saturation between the right hand and foot on three measures, each will be 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.

The neonate positive in screening underwent a confirmatory 2D echocardiography by the cardiologist in the Department of Cardiology for diagnosis or exclusion of CHD. (Reference Standard)

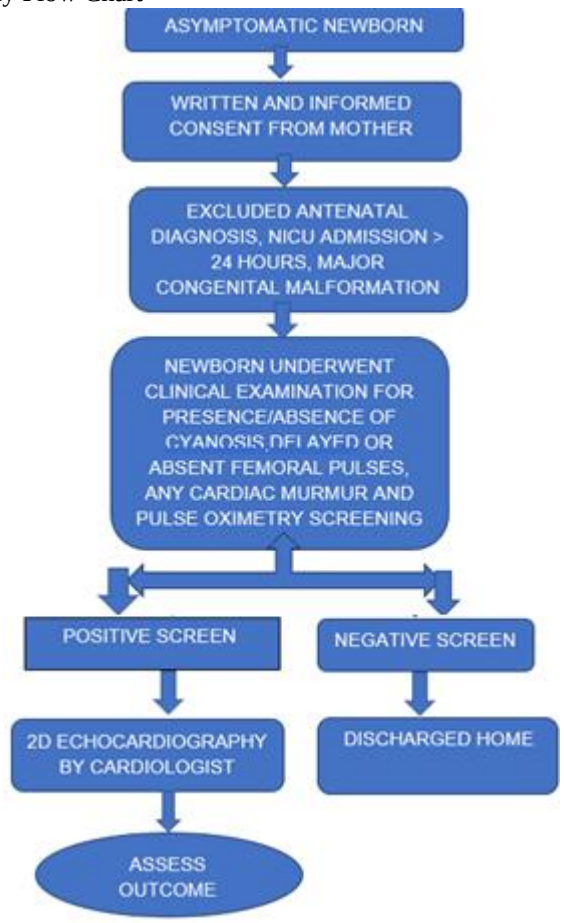
***Inclusion criteria*:**
a) All stable and asymptomatic Newborns delivered during the study period.

***Exclusion criteria*:**
a) Neonates with antenatal ultrasound/ echocardiographic diagnosis of CHD
b) Any neonate requiring Neonatal Intensive Care Unit (NICU) admission>24hrs
c) Any major congenital malformations.
d) Out born neonates.

**Tools and Technique:**
a) Stethoscope
b) Pulse Oximeter

***Data analysis***:
Data was recorded on a predesigned proforma and managed on an excel spread sheet. P - value of < 0.05 will be considered as statistically significant.

Study Flow Chart




**Statistical Analysis:** A total of 350 asymptomatic new - borns were enrolled in the study and screened by clinical examination and pulse oximeter. Males were 192 and females were 158.

**Table 1:** Distribution of the study population according to Gender (n=350)

| Gender | | Frequency | Percent |
|---|---|---|---|
| | Female | 158 | 45.1 |
| | Male | 192 | 54.9 |
| | Total | 350 | 100.0 |

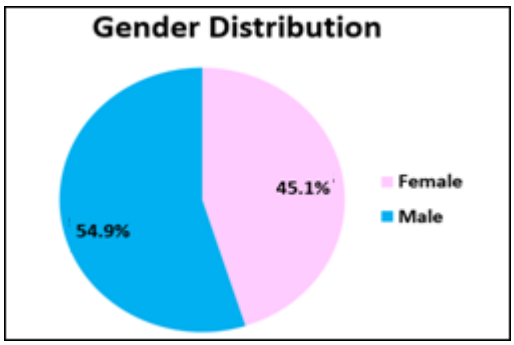



**Diagram 1:** Distribution of the study population according to Gender (n=350)

Among 350 participants 54.9% were male and 45.1% were female.

**Table 2:** Distribution of the study population according to Gestational age (n=350)

| Gestational age | | Frequency | Percent |
|---|---|---|---|
| | Preterm | 29 | 8.3 |
| | Term | 321 | 91.7 |
| | Total | 350 | 100.0 |

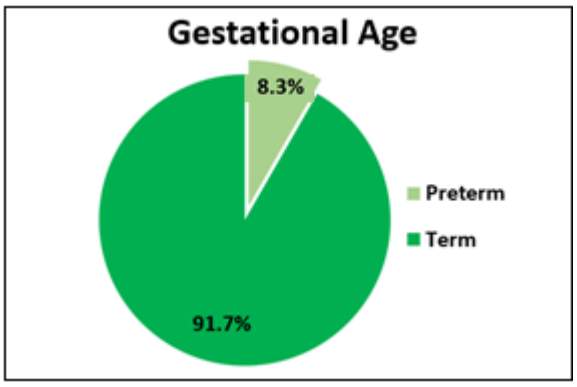
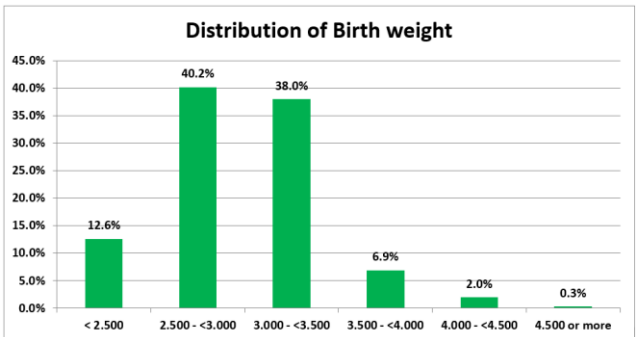



**Diagram 2:** Distribution of the study population according to Gestational age (n=350)

Above table and diagram showed that among 350 Participants, only 8.3% were preterm where 91.7% were term. MeanGestational age was 38.1± 1.52 weeks.

**Table 3:** Distribution of the study population according to Birth weight (n=350)

| Birth Weight in Kg | Frequency | Percent |
|---|---|---|
| <2.500 | 44 | 12.6 |
| 2.500 - < 3.000 | 141 | 40.3 |
| 3.000 - <3.500 | 133 | 38.0 |
| 3.500 - < 4.000 | 24 | 6.9 |
| 4.000 - < 4.500 | 7 | 2.0 |
| 4500 or more | 1 | 0.3 |
| Total | 350 | 100.0 |




Above table and diagram showed that among 350 babies 12.6% were LBW baby. And 2.3% were weighed more than 4kg. Rest had normal birth weight.

**Table 4:** Distribution of the study population according to Presence of Cardiac Murmur (n=350)

| Cardiac murmur | | Frequency | Percent |
|---|---|---|---|
| | Absent | 342 | 97.7 |
| | Present | 8 | 2.3 |
| | Total | 350 | 100.0 |

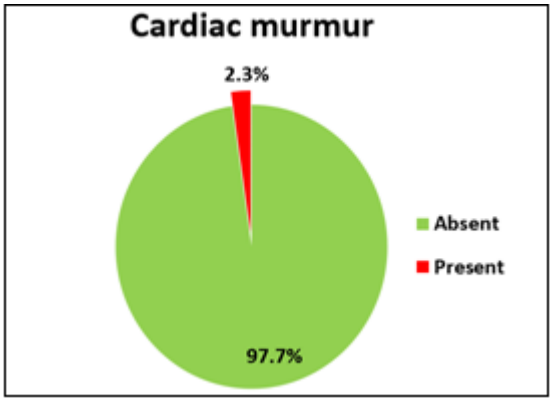



**Diagram 4:** Distribution of the study population according to Presence of Cardiac Murmur (n=350)

Above table and diagram showed that among 350 participants cardiac murmur present in 2.3% of the cases.

**Table 5:** Distribution of the study population according to 2D ECHO findings (n=350)

| 2D ECHO findings | Frequency | Percent |
|---|---|---|
| Closing PDA | 3 | 0.9 |
| PM VSD and OS - ASD | 1 | 0.3 |
| Obstructed infracardiac TAPVC with ASD | 1 | 0.3 |
| Ostium secundum ASD | 5 | 1.4 |
| Not required | 340 | 97.1 |
| Total | 350 | 100.0 |

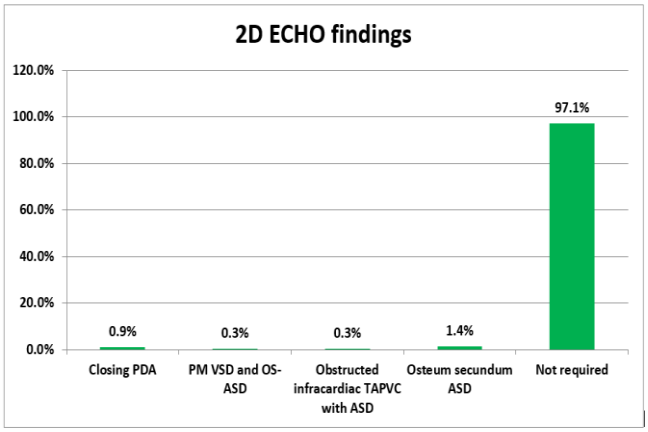



**Diagram 5:** Distribution of the study population according to 2D ECHO findings (n=350)

Above table and diagram showed that among 350 patient 97.1% did not require 2D ECHO. Among rest of the patient 0.9% had closing PDA, 0.3% had PM - VSD and OS - ASD, 0.3% had Obstructed infracardiac TAPVC with ASD and 1.4% had Ostium secundum ASD.

**Table 6:** Distribution of the CHD babies according to pulse oximetry (n=10)

| CHD babies | RUL pulse oximetry Screening | | RLL Pulse oximetry Screening | |
|---|---|---|---|---|
| | Positive | Negative | Positive | Negative |
| Ostium Secundum ASD | 1 (20%) | 4 (80.0%) | 2 (40.0%) | 3 (60.0%) |
| Closing PDA | 0 (0.0%) | 3 (100.0%) | 3 (100.0%) | 0 (0.0%) |
| PM - VSD and OS - ASD | 0 (0.0%) | 1 (100.0%) | 1 (100.0%) | 0 (0.0%) |
| Obstructed infra cardiac TAPVC with ASD | 1 (100.0%) | 0 (0.0%) | 1 (100.0%) | 0 (0.0%) |
| Total | 2 (20.0%) | 8 (80.0%) | 7 (70.0%) | 3 (30.0%) |

***Femoral pulse was present in all of the babies.**
***None of the babies had cyanosis.**
***Obstructed infracardiac TAPVC with ASD baby also had cleft lip, IUGR with microcephaly**

## 3. Discussion

Some babies with heart defects may appear normal soon after birth and discharged before cardiac defect is detected. These babies are at risk of developing serious heart defects and can have significant morbidity and mortality. Routine pulse oximetry screening can help in early diagnosis of these defects before they go for complications.

**Effectiveness of pulse oximetry screening:**
In this study, abnormal pulse oximetry was found in 10 cases. Out of 10 babies, 10 had congenital heart disease. Out of 10 cases only 8 cases had murmur.

This study shows that pulse oximetry can detect congenital heart disease in asymptomatic newborns who were normal on routine clinical examination.

Notably pulse oximetry identified cases of life threatening complex cyanotic CHD such as Transposition of great arteries (TGA), Tricuspid Atresia (TA), Pulmonary Atresia (PA), none of which had been detected clinically.

Pure left-to-right shunts such as ventricular septal defect, atrial septal defect, or patent ductus arteriosus should not be detected by pulse oximetry, but some of these defects (5 - 17%) proved to be screen positive.[11] This may be due to bidirectional shunting during early postnatal pulmonary hypertension.

**T**ime of pulse oximetry screening: If screening is done after a few days of life, there will be reduced incidence of false positives, because of physiological decrease in pulmonary vascular resistance.

In this study the babies were screened between 24 - 48 hours of age in the view of early detection of CHD and to decrease the number of false positive results.

**Saturation cut off:** Our decision to use 95% as cut off was based on AAP guidelines. Pulse oximetry is known to overestimate oxygen saturation at low saturations and underestimate at higher saturation. The sensitivity and specificity remained stable at a cut off of 92 - 95%, whereas cut off below 92% led to a rapid decrease in sensitivity.

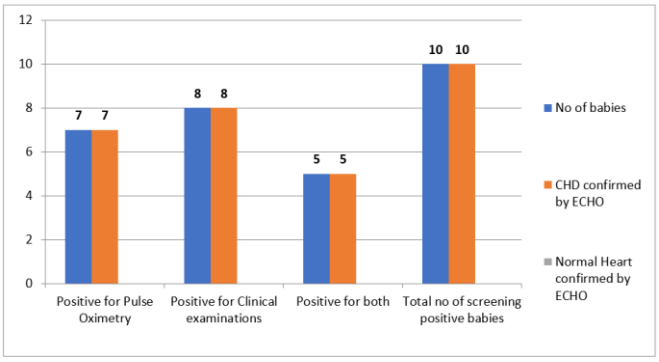
**Effectiveness of clinical examination screening:**
In our study 350 healthy new - born babies were screened. Out of the 350 babies 8 had heart murmur. The prevalence of murmur was 22.8 per 1000 of normal newborns during the period of study. The reported prevalence of heart murmur in neonate varies from 6 per 1000 to 42 per 1000. These variations may be due to the examiner's skills and experience, the timing and frequency of examination, the conditions under which examination takes place and the size of population studied**.** All those babies with murmur underwent echocardiography. CHD were detected in 8 (100%) babies. **Effectiveness of combined [pulse oximetry+ clinical examination] screening:** In this study, we evaluated the efficacy of combining pulse oximetry with clinical examination in screening for CHD. In our study, CHD was detected in 10 babies (8 babies by clinical examination screening +10 babies by pulse oximeter screening + 8 babies were positive for both screening test).

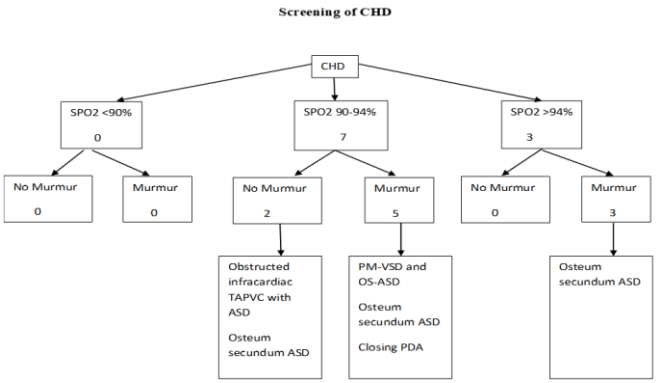
Our study showed that pulse oximetry can detect CHD in asymptomatic newborns which was missed by routine clinical examination especially life threatening cyanotic congenital heart disease. Clinical examination also picked up another group of cases that were missed by pulse oximetry. Most of the acyanotic heart diseases were detected by means of a murmur. So the combined approach had an additive effect and resulted in more efficient screening.

**Table:** Screening Result

| SCREENING METHOD | NUMBER OF BABIES | CHD CONFIRMED BY ECHO | NORMAL HEART CONFIRMED BY ECHO |
|---|---|---|---|
| Positive only for cardiac clinical examination(A) | 3 | 3 | 0 |
| Positive only for pulse oximeter(B) | 2 | 2 | 0 |
| Positive for both screening test(C) | 5 | 5 | 0 |
| TOTAL NO.OF SCREENING POSITIVE BABIES(A+B+C) | 10 | 10 | 0 |

**Diagram: Screening result:**






## 4. Conclusion

This study indicates that pulse oximetry is a non - invasive, reliable, and useful screening tool for an 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 acyanotic congenital heart disease.

The prevalence of murmurs detected at routine examination of neonates is 1.48%.

About 69.4% murmurs were due to an underlying cardiovascular malformation. So detection of a cardiac murmur may be a clue to the presence of an underlying heart disease particularly in asymptomatic new - born.

The absence of a murmur does not exclude serious heart disease.

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

This study suggests that combined screening (pulse oximetry + cardiac clinical examination) should be used as a screening method for detection of CHD.

## 5. Limitations

1) Small sample size.
2) For all babies, a follow up evaluation was not performed.
3) Sensitivity and specificity could not be calculated since echocardiography was not performed on screening negative babies to know the true negative and false negative cases.

## References

[1] Saxena A, Mehta A, Sharma M, et al. Birth prevalence of congenital heart disease: a cross - sectional observational study from North India. Ann PediatrCardiol.2016; 9 (3): 205e209.
[2] Saxena A. Congenital heart disease in India: a status report. Indian Pediatr.2018; 55 (12): 1075e1082.
[3] Saxena A. Pediatric cardiac care in India: current status and the way forward. Future Cardiol.2018; 14 (1): 1e4.
[4] Thangaratinam S, Brown K, Zamora J, Khan KS, Ewer AK. Pulse oximetry screening for critical congenital heart defects in asymptomatic newborn babies: a systematic review and meta - analysis. Lancet.2012; 379 (9835): 2459e2464.
[5] Chew C, Halliday JL, Riley MM, Penny DJ. Population - based study of antenatal detection of congenital heart disease by ultrasound examination. Ultrasound Obstet Gynecol.2007; 29 (6): 619e624.
[6] Westin M, Saltvedt S, Bergman G, et al. Routine ultrasound examination at 12 or 18 gestational weeks for prenatal detection of major congenital heart malformations? A randomised controlled trial comprising 36, 299 fetuses. BJOG.2006; 113 (6): 675e682.
[7] Tegnander E, Williams W, Johansen OJ, Blaas HG, Eik - Nes SH. Prenatal detection of heart defects in a non - selected population of 30, 149 fetuses–detection rates and outcome. Ultrasound Obstet Gynecol.2006; 27 (3): 252e265.
[8] Chew C, Halliday JL, Riley MM, Penny DJ. Population - based study of antenatal detection of congenital heart disease by ultrasound examination. Ultrasound Obstet Gynecol.2007; 29 (6): 619e624
[9] O'Donnell CP, Kamlin CO, Davis PG, Carlin JB, Morley CJ. Clinical assessment of infant colour at delivery. Arch Dis Child Fetal Neonatal Ed.2007; 92 (6): F465eF467.
[10] Plana MN, Zamora J, Suresh G, Fernandez - Pineda L, Thangaratinam S, Ewer AK. Pulse oximetry screening for critical congenital heart defects. Cochrane Database Syst Rev.2018; 3 (3). CD011912. Published 2018 Mar 1.

## Author Profile

**Dr. Santanu Ghosh** is a post - graduate student in the department of Paediatrics at the Command Hospital in Kolkata, India.

**Dr. Deepak Joshi** is a Professor, Department of Paediatrics, Command Hospital, Kolkata

**Dr. Sathish Kumar R** is a post - graduate student in the department of Paediatrics at the Command Hospital in Kolkata, India.

**Dr. Avinash Singh** is a final year post - graduate student in the department of Paediatrics at the Command Hospital in Kolkata, India.