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EVALUATION OF PULSE OXIMETRY IN NEONATES AS A SCREENING TOOL FOR EARLY DETECTION OF CONGENITAL HEART DISEASES

Paediatrics

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ABSTRACT

The study is designed as prospective observational study conducted at tertiary health care centre, To evaluate the diagnostic accuracy of pulse oximetry as a screening tool in neonates for early detection of congenital heart diseases. Total 5000 new-borns are screened as per inclusion criteria and screening algorithm. Ethical clearance and consent taken before inclusion in study as per format. A standardised table top neonatal wrap around Y type probe will be used to record oxygen saturation and 2D echo done by consultant paediatrician (trained for echocardiography). Results were analysed with help of standard statistical test. Pulse oximetry result failed in 5.9% subjects (n=298), out of which, 15 cases are true positive {Critical CHDs 5 are TOF, 3 TGA, 3 HLHS, 2 PA, 2 TAPVC}. Out of 283 false positive, 233 are cases of pulmonary pathology, significant but noncritical CHDs and others (sepsis) that required urgent intervention, 50 cases have negative screening before 24 hours of life, but no CHD and not required intervention. 4 cases are false negative {noncritical CHDs}. Rest 93.9% (n=4981) are true negative. There is strong association between low pulse oximetry and CHD (chi square value 181.28 and P value 0.00001 at 95% CI). There is a strong association between low pulse oximetry and CHD, so we can use pulse oximetry as screening tool for detection of critical CHD with 78.9% sensitivity, 94.3% specificity and 94.2% accuracy by pulse oximetry.

KEYWORDS

Critical CHD, Pulse Oximetry

INTRODUCTION

Congenital heart disease (CHD) is the most frequently occurring congenital disorder, 25% of them are Critical CHDs, responsible for 28% of all congenital birth defects [1]. The birth prevalence of CHD is reported to be 8-12/1000 live births [2,3]. Considering a rate of 9/1000, about 1.35 million babies are born with CHD each year globally [4].

More than 50% of Critical CHD deaths could be attributed to late or missed neonatal diagnoses. Therefore, survival of neonates with Critical CHD depends on early diagnosis and treatment of the defect. In recent years, detecting mild cyanosis has been made much easier using pulse oximetry in asymptomatic new-borns. We want to check diagnostic accuracy of pulse oximetry for detection of CHDs.

Pulse oximetry screening has been shown to be effective in narrowing this diagnostic gap in CCHD. In a multicentre study in Germany, 60% of CCHDs were diagnosed prenatally, 20% by postnatal physical examination and clinical observation, and a further 15.6% by pulse oximetry screening[4].

In a community hospital in India where most pregnancies were without prenatal follow-up, physical examination detected 11.5% of CCHDs, but the majority (84.6%) were detected by pulse oximetry screening alone[5]. This implies that pulse oximetry screening may be even more important in settings where periodical prenatal follow-up or fetal ultrasound screening is lacking.

Following 7 specific lesions have been identified as primary targets for pulse oximetry screening because they are consistently associated with some degree of hypoxia in the neonatal period:

1. Hypoplastic left heart syndrome
2. Pulmonary atresia
3. Tetralogy of fallots
4. Total anomalous pulmonary venous return
5. Transposition of the great arteries
6. Tricuspid atresia
7. Truncus arteriosus

Two screening sites comprising the right hand (pre ductal) and one foot (post ductal) either in parallel or in direct sequence

A "pass" or "negative" screening result refers to oxygen saturation ≥ 95% in either extremity with ≤ 3% absolute difference between the 2 sites

A "fail" or "positive" screening result refers to:

- Any oxygen saturation < 90%, or
- Oxygen saturation < 95% in both sites on 3 measures with 1 hour between each measure, or
- Absolute difference in oxygen saturation > 3% between the 2 sites on 3 measures with 1 hour between each measure.

AIMS AND OBJECTIVE

To evaluate the diagnostic accuracy of pulse oximetry as a screening tool in neonates for early detection of congenital heart diseases.

MATERIAL AND METHOD

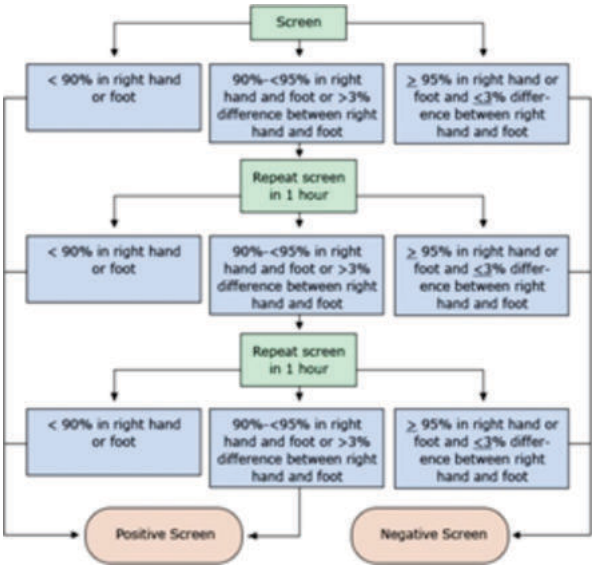
Ethical clearance for the study was obtained from the Government Medical College's ethical committee on the human subject on. Informed consent was taken from parents/guardians for enrolment of the patient for study. It is Prospective observational cohort study with Sample size – 5000 neonates done over a Period of 8 month at tertiary level referral teaching hospital (Government Hospital) attached to Government College.

- Inclusion criteria - All neonates born or referred to tertiary health care centre within 24 hours irrespective of gestational and sex are eligible for the study.
- Exclusion criteria - Pre -Diagnosed cases of CHD during the antenatal period, Neonates for whom consent will not obtained and Weight <1.8 kg
- Standard disinfection protocol will be maintained throughout the procedure
- 2D Echo – done by consultant paediatrician trained in echocardiography.
- Spo2 – A standardised tabletop neonatal wrap around type Y probe will be used to record oxygen saturation from right upper limb (preductal) and either foot (post ductal) at 12, 24 and 36 hours of life.
- Test Results

A "pass" or "negative" screening result refers to oxygen saturation ≥ 95% in either extremity with ≤ 3% absolute difference between the 2 sites

A "fail" or "positive" screening result refers to: – Any oxygen saturation < 90%, or – Oxygen saturation < 95% in both sites on 3 measures with 1 hour between each measure, or – Absolute difference in oxygen saturation > 3% between the 2 sites on 3 measures with 1 hour between each measure

The Screening Algorithm



RESULTS

Total 5,000 Newborn Screened as per Screening Algorithm followed by 2-D ECHO. Males were 2447 and females were 2553. Birth weight ranged from kg to 4.3kg. Average birth weight was 2.7kg. Babies delivered by normal delivery are 3253 and LSCS 1747. Term babies are 3367 and Preterm babies 1633.

Table - In true positive cases average Spo2

Average Spo2 At	Pre-Ductal	Post Ductal	Difference
12 Hol	97.45	95.96	1.48
24 Hol	97.51	95.98	1.52
36 Hol	97.4	95.9	1.47

298 CASES have failed pulse oximetry screening, out of which 56 cases failed at 12 HOL, 100 at 24 HOL and 142 at 36 HOL. POS failed in 5.9%(n=298) subject out of which 15 cases are true positive (pulse oximetry screening failed and 2D Echo also suggestive of CCHDs).

Out of 15 true positive cases (pulse oximetry screening failed and 2D Echo also suggestive of CCHDs), pulse oximetry failed at 12 HOL in 6 cases, at 24 HOL in 6 cases and at 36 HOL in 3 cases. 283 cases are False positive (pulse oximetry failed but 2D Echo suggestive of noncritical CHDs or either normal). 233 are cases of Pulmonary pathology, Significant but non critical CHDs and others (sepsis) required urgent intervention. 50 cases have Negative Screening before 24 hours of life, but no CHD as 2D Echo normal and not required intervention.

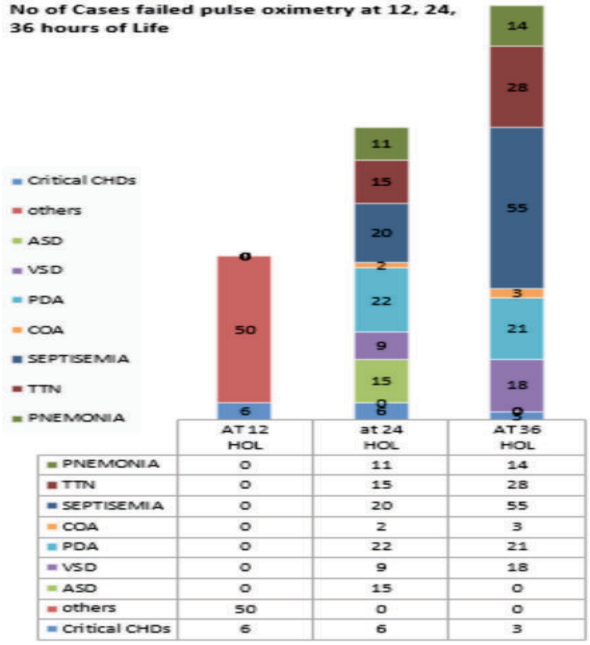


Table -True positive cases with critical CHDs

Critical CHD	NUMBER	PERCENTAGE
TOF	5	33.3
TGA	3	20
HLHS	3	20
PA	2	13.3
TAPVC	2	13.3
TOTAL	15	100

4 cases are False Negative (pulse oximetry result pass, but 2D Echo suggestive of critical CHDs).

Rest 93.9% (n=4698) are True Negative (pulse oximetry result pass and 2D Echo also normal).

Table -False positive result with noncritical CHDs

Non-critical Chds	No. Of Cases
PDA	43
ASD	15
VSD	27
COA	05
TOTAL	90

Table- False positive result with respiratory and other condition

Other Condition	No. Of Cases
Pneumonia	25
Septicaemia	75
TTN	43
Total	143

Table- Pulse Oximetry and 2D Echo Results.

Pulse Oximetry Result	2-D Echo Suggestive Of Chds	Normal 2-D Echo Finding	Total
Failed	15	283 (233+50)	298
Passed	4	4698	4702
Total	19	4981	5000

- Chi Square Value 181.28
- P Value 0.00001 at 95 % Cl
- Sensitivity 78.9 %
- Specificity 94.3%
- Negative predictive value 99.9 %
- False positive rate 5.6%

Table - Comparison with other study

Study Name	Sensiti-Vity	Specifi-City	NPV	False Positive Rate
Present Study	78.9	94.3%	99.9%	5.6%
Koppel et al; 2003	60%	99.95%	99.98%	-
Saxena A, et al. 20155	84.6%	68.3%	-	-
Thangaratinam S, et al. 20126	76.5%	99.9%	-	0.14%
Turska-Kmiec A, et al. 20127	78.9%	99.9%	-	0.026%
Zhao QM, et al. 20148	77.4%	97.1%	-	0.3%

From the above, present study have comparable outcome with other study in term of sensitivity and specificity.

CONCLUSIONS

There is strong association between low pulse oximetry and CHD, so we can use pulse oximetry as screening tool for detection of critical CHD with 78.9% sensitivity, 94.3% specificity and 99.9% NPV.

False positive cases occur due to pulmonary pathology and non-critical CHDs which required urgent intervention.

False negative cases occur in 0.08% (n=4) cases due to late presentation of Critical CHDs.

Recommendation

At periphery where 2D Echo and trained personnel not available, we can use pulse oximetry as screening tool for early detection critical CHDs. Before discharge or at around 24 hours of life screening with pulse oximetry is advisable for early detection of CHDs.

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