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Original Research Article

A STUDY ON USE OF PULSE OXIMETRY IN EARLY DETECTION OF CONGENITAL HEART DISEASE IN CYANOTIC NEWBORN

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ABSTRACT

Background: To detect the Usefulness of pulse oximetry monitoring in early detection of CHD in newborns with cyanosis.

Materials and Methods: This study was an observational, prospective study conducted in Department of Paediatrics, Siddhartha Medical College, Vijayawada - a tertiary care centre with well-equipped facilities. Study was conducted for 12 months from APRIL 2021–MARCH 2022. 100 cyanotic newborn babies aged 12-48 hours admitted in NICU, department of Paediatrics, were included. The usefulness of pulse oximetry monitoring in early detection of Congenital heart disease (CHD) in newborns with cyanosis is studied.

Results: Out of 100 newborns with cyanosis, only 45% were male babies. Majority (57%) of the babies included were delivered by normal vaginal delivery. Majority (78%) of the newborn's included were born to couples who were distantly related to each other.19% of the newborns were first born child. Nearly one fifth of the newborns were first born child in their family. The mean birth weight is 2.8±0.37kg. 20 % of the newborns were LBW babies. (≤2.5kg) The mean time of oxygen saturation recording was 31.4±3. 6hours. Frequency of newborns with positive result by pulse oximetry were 60%. 80 % of the newborns with cyanosis with positive pulse oximetry result included were having normal study in the echocardiogram. One cyanotic new born had Epstein's anomaly. The frequency of TA, and TOF group were two each. Three newborns with cyanosis were having TAPVC and four newborns with cyanosis were having TGA as per the echocardiogram. Out of 100 new-borns with cyanosis included, twelve newborns were cyanotic due to cyanotic CHD. Five newborns were cyanotic due to hypothermia. Eight new-borns were cyanotic due to PPHN. Sixty newborns were cyanotic due to respiratory causes and 15 newborns were cyanotic due to CNS related reasons. There is no significant association between CHD and consanguinity in the study.

Conclusion: This study indicates that pulse oximetry is a non-invasive, reliable and useful monitoring tool for a nearly detection of CHD especially cyanotic CHDs.

Keywords: CHD, Newborns, Pulse oximeter, TGA, TAPVC.

INTRODUCTION

Congenital Heart Disease (CHD) is among the common birth defects, with incidence of around 9 in 1,000 live births.[1] Challenges faced in the management of CHD includes factors like delayed diagnosis, low availability of paediatric cardiac centres and transporting sick neonates to health care Centre. Diagnosis of many children is too late which adds to morbidity or death significantly.[2] Delayed diagnosis is common, in around 25% of infants being missed in newborns when identification is based on clinical symptoms or signs of heart disease even in settings with routine prenatal sonograms.[2] Approximately 40% of these infants with missed diagnoses at birth present with cardiogenic shock at a

medical facility and 5% are diagnosed at autopsy [3,4]. Studies in Europe and the US have suggested that newborn screening with pulse oximetry testing prior to discharge from the nursery can decrease the number of missed diagnoses by ~30%.[1]

Pulse Oximetry Screening (POS) for Cyanotic CHD was added in 2011, to the Recommended Uniform Screening Panel by the Health and Human Services Secretary.[5] In the subsequent years, many states have implemented their own protocols to comply with this recommendation. Pulse oximetry is the mainstay procedure for detecting hypoxemia indirectly in medically ill patients since 1980s. The screening of Cyanotic CHD by pulse oximetry has the advantage of its ability to detect clinical and subclinical levels of hypoxemia which raises the suspicion of Cyanotic CHD. However, pulse oximetry does not offer information about stroke volume, which is decreased and a crucial physiologic feature of several Cyanotic CHDs that could be detectable during the neonatal transition.

The existing pulse oximetry monitoring protocol to detect critical CHD, is restricted to neonates 24 to 48 hours of age in well infant nursery.[6] A simple algorithm for units catering to sick newborns is challenging because of heterogeneity of underlying conditions; need of studies across a broad range of newborn delivery systems has been expressed. Pulse oximetry as a screening test for Cyanotic CHD has been evaluated among well neonates, but not in sick neonates.[6]

The present study was designed to evaluate the utility of Pulse oximetry monitoring in detecting CHD among newborns with cyanosis in a tertiary care hospital.

Aim & Objectives

Aim

To detect the Usefulness of pulse oximetry monitoring in early detection of CHD in newborns with cyanosis.

Objective

To evaluate use of pulse oximetry as a method for identifying CHD in newborns with cyanosis.

MATERIAL AND METHODS

Patients and methods

The current study was conducted in the department of Paediatrics among the cyanotic new born babies aged 12-48 hours admitted in NICU, department of Paediatrics, Old government hospital, Siddhartha Medical College, Vijayawada.

Study period: 12 months from APRIL 2021–MARCH 2022.

Data collection: 10 months

Type of study: This observational prospective open-label study was done to study usefulness of pulse oximetry monitoring in early detection of congenital heart disease

Source of data: After getting approval from the Institutional Ethics Committee, cyanotic new born babies aged 12-48 hours admitted in NICU, department of Paediatrics, were included.

Inclusion Criteria

New born babies with cyanosis admitted in NICU.

Exclusion Criteria

- Babies with saturation ≥95% in both upper and lower limbs
- Babies with sepsis

Methodology

This study was a hospital based open labeled prospective study. In this study we monitored newborn babies with cyanosis in the NICU for CHD using pulse oximetry between April 2021 and March 2022.

Babies with saturation ≥95% in both upper and lower limbs, and babies with sepsis were excluded from this study. Newborn babies with cyanosis were monitored by pulse oximetry using WITLEAF

WIT-S300 HAND HELD NEW GENERATION PULSE OXIMETER. Pulse oximetry

Readings were taken in a quiet or sleeping new born from right hand and foot. The probe was cleansed with alcohol swab before each use.

The readings were recorded after stabilization for one minute, according to the manufacturer instructions. The functional oxygen saturation of ≥95% was accepted as normal. If the new born baby had oxygen saturation below 90%, echocardiography was performed. In the case of a new born with oxygen saturation between 90%-94%, a second measurement was performed six hours later. If the oxygen saturation remained below 95%, echocardiography was performed.

Imageno:1 Hand held new generation Pulse Oximeter

New born babies who underwent echocardiography were categorized as having either a normal heart or a structurally malformed heart.

RESULTS

Out of 100 new-borns with cyanosis,55% were female babies and 45% were male babies. [Table 1]

Mode of Delivery

Majority (57%) of the babies included were delivered by normal vaginal delivery. 34% of the babies were delivered by LSCS. 7% of the babies were delivered by instrumentation namely outlet forceps. 2% of the babies were delivered by breech. [Table 2]

Consanguinity

Majority (78%) of the newborns included were born to couples who were distantly related to each other. [Table 3]

Birth order

19% of the newborns were first born child. Nearly one fifth of the newborns were first born child in their family. 57% of the newborns were second born child. 24% of the newborns were third born child. [Table 4]

Birth weight

The mean birth weight is 2.8±0.37kg. The minimum birth weight is 2 kg.

The maximum birth weight is 3.8kg.

Most of the babies included were of weight 2.8kg. [Table 5]

LBW

20% of the newborns were LBW babies. (≤2.5kg) 80% of the newborns were of normal weight. [Table 6]

Time of Oxygen saturation recording:

The mean time of oxygen saturation recording was31.4±3.6hours. Oxygen saturation was recorded at the earliest at 25 hours of life. Oxygen saturation was recorded at the late at 40 hours of life. Oxygen saturation was recorded at 30 hours of birth in most of the study newborns. [Table 7]

Pulse oximetry monitoring

Frequency of newborns with positive result by pulse oximetry were 60%. Frequency of newborns with negative result by pulse oximetry were 40%. [Table 8]

Diagnosis

Out of 100 newborns with cyanosis included,12 newborns were cyanotic due to cyanotic CHD.

5 newborns were cyanotic due to hypothermia and 15 newborns due to CNS related reasons. 60 newborns were cyanotic due to respiratory causes. 8 newborns were cyanotic due to PPHN [Table 9]

Positive Pulse oximetry newborns and characters

Among the newborns with cyanosis with positive pulse oximetry results, 18(30%) of them were born to couples who has consanguinity.

Among the newborns with cyanosis with positive pulse oximetry results, 42(70%) of them were born to couples who married from distant relation. [Table 10]

Echocardiogram in newborns with positive pulse oximetry

Among the newborns with cyanosis with positive pulse oximetry results, echocardiogram showed normal study in 48 newborns with cyanosis.

Among the newborns with cyanosis with positive pulse oximetry results, echocardiogram showed abnormality in 12 newborns with cyanosis. [Table 11]

Birth weight and heart disease

Among12 newborns with cyanosis having congenital cyanotic heart disease, LBW is noticed in 2 newborns. [Table 12]

Association between Consanguinity &CHD in new born with cyanosis

Among 22 babies born out of consanguineous marriage, 4(18.18%) babies were having cyanotic congenital heart disease.

Among 78 babies born out of nonconsanguineous marriage,8 (10.25%) babies were having cyanotic congenital heart disease.

The chi-square statistic with Yates correction is 0.4081. The p-value is 0.522912. Hence no significant association is present between CHD and consanguinity in the study. [Table 13]

Consanguinity & ECHO Association

Among 22 babies born out of consanguineous marriage,4 (18.18%) babies had abnormal Echocardiogram findings.

Among 78 babies born out of non-consanguineous marriage, 8 (10.25%) babies were having abnormal Echocardiogram findings.

The chi-square statistic with Yates correction is 0.4081. The p-value is 0.522912. Hence no significant association is present between ECHO findings and consanguinity in the study. [Table 14]

Table 1: Gender distribution of newborns

Gender	Frequency	Percent
Female	55	55.00%
Male	45	45.00%
Total	100	100.00%

Table 2: Mode of delivery

Mode of Delivery	Frequency	Percent
BREECH	2	2.00%
LSCS	34	34.00%
NVD	57	57.00%
Outlet Forceps	7	7.00%
Total	100	100.00%

Table 3: Frequency of consanguinity in the parents of newborns

Consanguinity	Frequency	Percent
YES	22	22.00%
NO	78	78.00%
Total	100	100.00%

Table 4: Frequency of birth order of newborns

Birth order	Frequency	Percent
1	19	19.00%
2	57	57.00%
3	24	24.00%
Total	100	100.00%

Table 5: Mean Birth weight of newborns

Mean Birth weight	Standard deviation
2.8310	0.3700

Table 6: Frequency of low-birth-weight babies

LBW	Frequency	Percent
NO	80	80.00%
YES	20	20.00%
Total	100	100.00%

Table 7: O2 recording time of babies

Mean time of recording	Std Dev
31.4200	3.6131

Table 8: Pulse oximetry monitoring

Pulse oximetry monitoring	Frequency	Percent
Negative	40	40.00%
Positive	60	60.00%
Total	100	100.00%

Table 9: Diagnosis of newborns with cyanosis

	Frequency	Percent
CCHD	12	12.00%
Hypothermia	5	5.00%
PPHN	8	8.00%
Respiratory	60	60.00%
CNS related	15	15.00%
Total	100	100.00%

Table 10: Frequency of consanguinity in the newborns with Positive Pulse oximetry

Consanguinity	Frequency	Percent
Yes	18	30%
No	42	70%
Total	60	100.00%

Table 11: Echocardiogram results in newborns with positive pulse oximetry

ECHO Result	Frequency
EA	1
Normal Study	48
TA	2
TAPVC	3
TGA	4

TOF	2
Total	60

Table 12: LBW in newborns with cyanosis with heart disease

LBW	EA	TA	TAPVC	TGA	TOF	Total
NO	1	2	2	3	1	9
YES	0	0	1	1	1	3
TOTAL	1	2	3	4	2	12

Table 13: Consanguinity &CCHD association

	Consanguinity	Non- Consanguinity	Total
CCHD	4	8	12
Normal Heart	18	70	88
Total	22	78	100

Table 14: Consanguinity & CCHD association

ECHO	Consanguinity	Non- Consanguinity	Total
Abnormal	4	8	12
Normal	18	70	88
Total	22	78	100

DISCUSSION

This study was an observational, prospective study conducted in Department of Paediatrics, Siddhartha Medical College, Vijayawada - a tertiary care canter with well-equipped facilities.

Study was conducted for 12 months from **APRIL2021–MARCH2022**.

100 cyanotic new born babies aged 12-48 hours admitted in NICU, department of Paediatrics, were included. The usefulness of pulse oximetry monitoring in early detection of Congenital heart disease(CHD) in newborns with cyanosis is studied.

Chi-square analysis was used for association between the qualitative data. Most of the variables were expressed using frequency and percentages.

Principles of pulse oximetry and its limitations:

Oxygenated blood absorbs the red light at a wavelength of 660 nm, and deoxygenated blood absorbs light in the infrared spectrum at 940 nm.[7] Computation of oxygen saturation is done by using calibration algorithms, based on the amount of signals from non-pulsatile (venous, capillary, bone, and skin) and

Pulsatile arterial blood flow. Continuous signal from the non-pulsatile vessels and tissues is removed by microprocessor which allows the pulsatile signal to be displayed as a plethysmographic wave form on pulse oximeter monitor.[7]

For the safe use of pulse oximetry, knowledge of its limitations is required. There are multiple sources of potential artifacts, that cause false readings relevant for neonates especially. These include poor perfusion, motion artifacts, and cold skin at the site of measurement, ambient light, phototherapy, irregular rhythms, skin pigmentation and jaundice, inappropriate probe positioning (penumbra effect), intravenous dyes, venous pulsation, and presence of abnormal haemoglobin molecules.[7]

Pulse oximeters recommended for screening for CHD should capture functional oxygen saturation (haemoglobin that transports oxygen), be validated for low perfusion states, be motion "tolerant", and have a 2% root-mean-square accuracy.[6] A pulse oximeter's performance is optimized for oxygen saturations (SpO2) particularly in the range of 80%–100%. The modern pulse oximeters are developed based on healthy, fit adult individuals who were exposed to different degrees of sub ambient oxygen with SpO2 ranging between 80% and 100%. Therefore, any SpO2<80%is extrapolated by a computer program[8]. Most new pulse oximeters are able to detect motion and label it as artifact or perform calculations quickly in a way that renders them motion tolerant. The SpO2 value is not a continuous assessment. The pulse oximeter takes the average readings over a period of time

For the sake of accurate measurement, the average is taken over a shorter period of time. For a pulse oximetry measurement to be accurate, the adequate pulse volume and pressure in peripheral tissue is pre-requisite. In situations like septic shock, the pulse oximeter cannot assess the oxygen saturation[9,10] due to cool extremities.

Pulse Oximetry in neonates

Levesque et al,[11] in 2000 evaluated oximetry values of newborns from day of admission to discharge. They considered gender, birth weight, gestational age, Apgar scores, mode of delivery, measurement site, and infant condition while measuring (quiet, sleeping, or crying). Measurements were done at admission to nursery, after 24 hours of birth, and discharge. The oxygenation saturation was 97.2%.[11] They observed an increase in saturation if measured with right hand (preductal). Difference in age postnatally was not clinically relevant.[11] Infant's activity caused significant differences in values, fussy or crying versus sleeping.[11]

Use Oximetry in Cyanotic CHD screening:

De Wahl, Granelli et al[12,13] measured oxygen saturations in new-borns and compared with Cyanotic CHD. Atleast two of three newborns with Cyanotic CHD were missed during physical examination[13].By including POS rate of diagnosis is

around 82%. Many studies from Europe had similar findings.[14,15,16] Sensitivity was 76.5% and specificity was 99.9% POS for detecting CHD.[16]
Pulse oximetry is great tool to identify hypoxemia present sub-clinically, present in certain CHD like truncus arteriosus, TGA, TA, hypoplastic left heart syndrome, TO, TAPVC.

Gender

Male gender, consanguinity, family history of smoking and history of pregnancy induced hypertension were significant predictor of CHD. Out of 100 new-borns with cyanosis in the present study, 55% were female babies, only 45% were male babies. Mathur MD,[17] conducted a study to evaluate pulse oximetry for detection of CCHD in sick neonates using echocardiography as gold standard.65% of the newborns included were males. This is in contradiction to the present study, in which majority of them were females numerically.

Weight of the babies

The mean birth weight is 2.8 ±0.37 kg. The minimum birth weight is 2 kg. The maximum birth weight is 3.8 kg. Most of the babies included were 2.8 kg weight.
Mathur MD,[17] conducted a study to evaluate pulse oximetry in the detection of CCHD in sick neonates using echocardiography. Among 210 new borns with a CHD, the mean birth weight was observed to be 2.5 kg.

EFFECTIVENESSOFPULSEOXIMETRYMONITORING

In the present study abnormal pulse oximetry was found in 51 babies of which 10 had CCHD on echocardiography. One cyanotic new born had Ebstein's anomaly.
The frequency of TA, TOF and TAPVC group were two each. Three newborns with cyanosis were having TGA as per the echocardiogram.
This study showed that pulse oximetry can detect CCHD in cyanotic new born babies. Notably pulse oximetry identified cases of life threatening complex cyanotic CHD such as Transposition of great arteries (TGA), Tricuspid Atresia (TA), none of which had been detected clinically.

TIME OF PULSE OXIMETRY MONITORING

If Pulse oximetry monitoring is performed after a few days of life, there will be a reduced incidence of false positives, because of the physiologic decrease in the pulmonary vascular resistance, but a new born with a ductal-dependant CHD could deteriorate rapidly if the ductus arteries us had already closed. Measurements performed shortly after birth may lead to an increased number of false positives18
In this study the babies were monitored between12-48 hours of age in the view of early detection of CHD and to decrease the number of false positive results. This higher false positive rate is due to early screening of healthy babies with delayed transitional circulation. The mean time of oxygen saturation recording was 31.4± 3.6 hours. Oxygen saturation was recorded at the earliest at 25 hours of birth newborns. Oxygen saturation was recorded at the late at 40 hours of birth new-borns. Oxygen saturation was recorded at 30 hours of birth in most of the study newborns.

SATURATION CUT-OFF

Our decision to use a 95% cut-off was based on published normal pulse oximetry values in healthy newborns,[19] and saturation differences observed in infants with left obstructive heart disease and obligate right to left shunt across the ductus arteriosus58.Pulse oximetry is known to overestimate arterial oxygen saturation at low saturations and under estimate it at high saturation.[20] The sensitivity and specificity remained quite stable using a cut-off ranging from 92% to 95%, whereas a cut-off below 92% led to a rapid decrease of sensitivity.
Accordingly, frequency of newborns with positive screening by pulse oximetry were 20%. Frequency of new-borns with negative screening by pulse oximetry was 80%.

Echocardiogram result

80 % of the new-borns with cyanosis with positive pulse oximetry result were having normal study in the echocardiogram. One cyanotic new born had Ebstein's anomaly. The frequency of TA and TOF group were two each. Three newborns with cyanosis were having TAPVC and 4 were having TGA as per the echocardiogram

Consanguinity in cyanotic newborn with heart disease

Consanguinity is often considered as a significant predictors of cyanotic heart disease.
Majority (78%) of the newborns included were born to couples who were distantly related to each other. Among the newborns with cyanosis with positive pulse oximetry results,[18] (30%) of them were born to couples who married consanguineously. Among the newborns with cyanosis with positive pulse oximetry results, 42 (70%) of them were born to couples who married from distant relation.
In a study done by Mathur MD,[17] new-borns with cyanosis with CCD history of consanguineous marriage in the parent's were 200 times more prone than to poses CHD. (OR=0.03)

Diagnosis

Out of 100 newborns with cyanosis included, twelve newborns were cyanotic due to cyanotic CHD. Five newborns were cyanotic due to hypothermia. Eight newborns were cyanotic due to PPHN. Sixty new-borns were cyanotic due to respiratory causes and 15 newborns due to CNS related reasons.

CONCLUSION

This study indicates that pulse oximetry is a non-invasive, reliable and useful tool for an early detection of congenital heart diseases especially cyanotic congenital heart diseases. This study concludes that using pulse oximetry as an additive tool to clinical examination can result in more efficient screening. Most common congenital heart disease in newborns with cyanosis is TGA followed by TAPVC.

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