International Journal of Science Academic Research
Vol. 02, Issue 01, pp.739-741, January, 2021
Available online at http://www.scienceijsar.com

ISSN: 2582-6425

Research Article

TO STUDY THE EFFECTIVENESS OF PULSE OXIMETRY AS A SCREENING TOOL FOR THE DETECTION OF CONGENITAL HEART DISEASE IN NEWBORNS

[1,] *Dr. Preeti Sharma, [2]Dr Alok Raina, [3]Dr Mohit Sharma and [1]Dr Sonam Chalotra

[1]Department of pediatrics GMC Jammu, India
[2]Consultant Pediatrician at District hospital Udhampur, Jammu, India
[3]Department of medicine, GMC Jammu, India

Received 16th November 2020; **Accepted** 25th December 2020; **Published online** 13th January 2021

Abstract

Background: Congenital heart diseases are the most common congenital malformation with an incidence of approximately 8 per thousand live births. Congenital heart disease account for 6 to 10% of all infant deaths. Approximately 25% of children with congenital heart disease have critical congenital heart disease. Pulse oximetry in newborn screening can detect mild hypoxemia that may not be recognized by clinical examination. Thus pulse oximetry can help to identify babies that may be affected with critical congenital heart disease before they leave the newborn nursery. The objective of the present study were to determine the role of pulse oximetry as a screening tool for detection of congenital heart disease in newborns on the first day of life. **Methods:** This prospective study was conducted in the postnatal ward of department of Gynecology and obstetrics in SMGS Hospital Jammu over a period of one year from November 2016 to October 2017. In this study pulse oximetry and clinical examination were used as screening and echocardiography as a diagnostic/confirmatory tool for detection of congenital heart disease. Neonates were first subjected to clinical examination followed by pulse oximetry. Neonates having either or both of these screening methods positive were subjected to echocardiography. A total of 3213 newborns were screened. **Results:** Neonates with clinical examination suggestive of congenital heart disease (but normal pulse oximetry screening) were 16. On echocardiography, 7 were found to be normal and remaining 9 had CHD. Neonates with pulse oximetry screening suggestive of congenital examination (but normal clinical findings) were 9 and on echocardiography, among these 9 subjects, 7 had CHD and 2 had persistent pulmonary artery hypertension. 7 cases were both screening tests positive and all of these were detected with congenital heart disease on echocardiography. Thus total congenital clinical examination cases detected in our study were 23. The sensitivity, specificity, PPV and NPV of pulse oximetry was 60.87%, 77.78%, 87.50% and 43.75% respectively. The sensitivity, specificity, PPV and NPV of clinical examination was 69.57%.22.22%, 69.57% and 22.22% respectively. **Conclusion:** Pulse oximetry is an effective, non invasive and feasible screening tool for detection of congenital heart disease. Combining pulse oximetry screening and clinical examination can enhance clinician ability to detect life threatening CHD in a timely manner and this screening method should become a part of discharge policy of every newborn.

Keywords: Newborn, Pulse oximetry, Clinical examination, Congenital heart disease, Critical congenital heart disease.

INTRODUCTION

Congenital heart disease are the most common congenital malformation with an incidence of approximately 8 per thousand live births (Pradat *et al.,* 2003; Sendelbach *et al.,* 2008) Congenital heart disease account for 6 to 10% of all infant deaths (Wren *et al.,* 2008). Congenital heart disease can range from mild, never requiring surgery to more severe ones requiring major heart surgeries. Approximately 25% of children with congenital heart disease have critical congenital heart disease (Wren *et al.,* 2008; Vaidyanathan *et al.,* 2011). If critical congenital heart diseases are not diagnosed early after birth, it leads to delay in referral and early mortality and morbidity. Currently, congenital heart disease are diagnosed by a variety of mechanisms. Neonates with congenital heart disease may be diagnosed in newborn nursery on the basis of physical examination findings, such as heart murmurs, tachypnea or overt cyanosis. These findings are not always evident before hospital discharge, which may occur before 48 hours of life. Also these methods are subjective and require skilled and trained workers. Since 1980 prenatal ultrasonography has been used for identifying congenital anamolies. However numerous studies have shown that even when fetal ultrasonography routinely performed during pregnancy, fewer than 50% of cases of critical congenital heart disease were identified (Mahle *et al.,* 2002).

***Corresponding Author: Dr. Preeti Sharma,**
Department of pediatrics GMC Jammu, India.

Pulse oximetry in new born screening is a non invasive test that can detect mild hypoxemia that may not be recognized by clinical examination. Thus pulse oximetry can help to identify the babies that may be affected with critical congenital heart diseases before they leave the newborn nursery. The life threatening congenital heart diseases that can be detected through pulse oximetry are pulmnory atresia, tetralogy of fallot, total anomalous pulmonary venous return, transposition of great arteries, single ventricle, tricuspid atresia and hypoplastic left heart syndrome. We carried out the study to determine the role of pulse oximetry as a screening tool for detection of congenital heart disease in newborns.

MATERIALS AND METHODS

The study was conducted in the post natal ward of department of Gynecology and obstetrics in SMGS Hospital over a period of one year from November 2016 to October 2017. In this study pulse oximetry and clinical examination was used as screening and echocardiography as a diagnostic/ confirmatory tool for detection of congenital heart disease. Newborns with gestational age $\geq$ 35 weeks and birth weight $\geq$ 2kg were included in this study. Neonates with congenital heart diseases detected in antenatal period and neonates admitted in NICU were excluded from the study. This study was approved by Institutional Ethics Committee of GMC Jammu. A written consent was taken from the parents and purpose of study was explained to them.

Table 1. Sensitivity, specificity, positive predictive value, negative predictive value and accuracy of pulse oximetry in detecting CHD

True positive No.	False negative No.		False positive No.	True negative No.
14	9		2	7
Sensitivity (%)	Specificity (%)	PPV (%)	NPV (%)	Accuracy (%)
(TP/TP+ FN) × 100	(TN/FP+ TN) × 100	(TP/TP+ FP) × 100	(TN/FN+ TN) × 100	(TP+TN) / (TP+FN+FP+TN)
60.87	77.78	87.50	43.75	65.62

Table 2. Sensitivity, specificity, positive predictive value, negative predictive value and accuracy of clinical examination in detecting CHD

True positive No.	False negative No.		False positive No.	True negative No.
16	7		7	2
Sensitivity (%)	Specificity (%)	PPV (%)	NPV (%)	Accuracy (%)
(TP/TP+ FN) × 100	(TN/FP+ TN) × 100	(TP/TP+ FP) × 100	(TN/FN+ TN) × 100	(TP+TN) / (TP+FN+FP+TN)
69.57	22.22	69.57	22.22	56.25

Clinical examination followed by pulse oximetry screening was performed in all the enrolled newborns. Subjects were considered clinical examination positive if they had anyone of these findings -Central cyanosis, abnormal peripheral pulses, abnormal precordium murmur (Grade II and above). Echocardiography was done on all subjects with positive clinical examination. SPO2 measurement with pulse oximeter was performed on right hand (preductal) and either foot (postductal) when infant was quiet. The oxygen saturation cut off value in this study was 95%. Newborns with oxygen saturation below 90% by pulse oximetry or a saturation difference of more than 3% between right hand (preductal) and either foot (postductal) were subjected to echocardiography. Newborns with saturation < 95% but ranging between (90-94%) were subjected to repeat pulse oximetry measurement after 4 hours. If the repeat saturation value remain below 95%, echocardiography was performed. If the repeat saturation was ≥ 95%, the newborn was considered as normal and echocardiography was not performed.

RESULTS

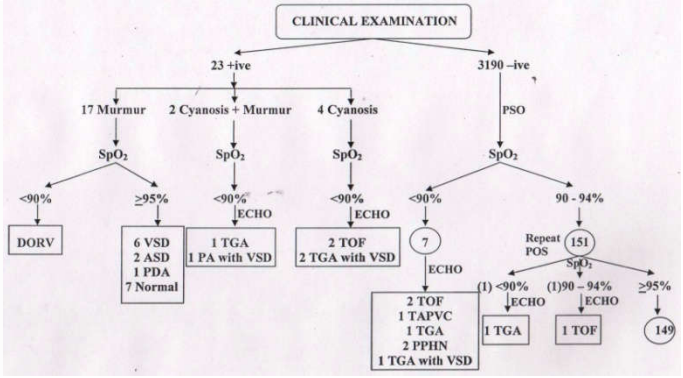
A total of 3213 newborns were screened. On clinical examination, murmur alone was detected in 17 newborns, cyanosis alone was detected in 4 subjects and 2 subjects had both cyanosis and murmur. A total of 23 subjects had clinical findings suggestive of congenital heart disease while the remaining 3190 subjects were clinically normal. All these 23 newborns when subjected to pulse oximetry screening, spo_2 was less than 90% in 7 subjects and remaining 16 have $spo_2 \geq$ 95 %.None of these subjects have spo_2 between 90 to 94 %. Echocardiography was performed on all these 23 subjects in whom clinical findings were suggestive of congenital heart disease. Out of these, 6 (26.09%) had ventricular septal defects (VSD), 2 (8.70%) each had transposition of great arteries with ventricular septal defects (TGA with VSD), tetralogy of fallot (TOF) and atrial septal defect (ASD), while 1 (4.35%) each had transposition of great arteries (TGA), double outlet right ventricle (DORV), patent ductus arteriosus (PDA) and pulmonary atresia with VSD (PA with VSD) respectively and 7 (30.43%) subjects were normal. The remaining 3190 subjects that were clinically normal were subjected to pulse oximetry screening. Spo_2 was less than 90% in 7 subjects.Spo_2 was 90 to 94% in 151 subjects in whom repeat pulse oximetry was performed after 4 hours and only 2 out of these 151 were pulse oximetry positive in repeat screening, 1 having spo_2 less than 90% and 1 having Spo2 between 90 to 94% again. Thus total of 9 subjects were pulse oximetry screening positive alone and subjected to echocardiography.

On echocardiography 3 (33.34%) newborns had tetralogy of fallot (TOF), 2 (22.22%) each had transposition of great arteries (TGA) and persistent pulmonary hypertension (PPHN), while 1 (11.11%) newborn each had TGA with VSD and total anomalous pulmonary venous connection (TAPVC). Thus, Positive clinical examination (but normal pulse oximetry) cases were 16. On echocardiography, 7 were found to be normal and remaining 9 had CHD. Positive pulse oximetry screening (but normal clinical findings) cases were 9 and on echocardiography, among these 9 subjects 7 had CHD and 2 had persistent pulmonary artery hypertension. 7 cases were both screening tests positive and all of these were detected with congenital heart disease on echocardiography. Congenital heart disease cases detected in our study were 23. The sensitivity, specificity, PPV and NPV of pulse oximetry was 60.87%, 77.78%, 87.50% and 43.75% respectively. The sensitivity, specificity, PPV and NPV of clinical examination was 69.57%.22.22%, 69.57% and 22.22% respectively.

DISCUSSION

The present study reviewed the sensitivity, specificity, positive predictive value and negative predictive value of pulse oximetry and clinical examination. The sensitivity, specificity, PPV and NPV of pulse oximetry in present study was 60.87%, 77.78%, 87.50% and 43.75% respectively. The sensitivity, specificity, PPV and NPV of clinical examination in present study was 69.57%.22.22%, 69.57% and 22.22% respectively. Study conducted by Kalita *et al.* 2016 showed sensitivity and specificity of pulse oximetry 48.18% and 98.04% respectively. In their study, sensitivity and specificity of clinical examination was 82.34% and 98.22% respectively. Fernanda Cruz *et al.* 2015 showed 44.4% sensitivity and 99.53% specificity of pulse oximetry for detection of congenital heart disease whereas sensitivity and specificity of clinical examination in their study was 88.89% and 99.55%.In both these studies sensitivity of pulse oximetry was lower than in present study. Although both these studies showed higher sensitivity and specificity of clinical examination than in our study, but pulse oximetry when combined with clinical examination showed better results than clinical examination alone and these results were comparable with present study. Similarly in study conducted by Fernanda Cruz *et al.* 2015, when clinical examination was combined with pulse oximetry showed 100 % sensitivity and 99.5% specificity. Further the specificity of pulse oximetry in present study is lower than the studies mentioned above. The reason behind this may be the fact that we did pulse oximetry screening within 24 hours of life and high number of false positive cases due to pulmonary

hypertension is certainly influenced by early time of measurement. Study conducted by Arlettaz *et al.* 2006 showed 100% sensitivity and 99.7% specificity of pulse oximetry for detection of CHD. The reason for such high sensitivity and specificity in their study was because the study calculated the sensitivity and specificity of pulse oximetry only for detection of cyanotic CHD. According to study conducted by Taksande *et al.* 2013, a pulse oximetry cut off value of below 90% for detecting critical CHD showed 100% sensitivity, 99.95% specificity, 87.50% positive predictive value and 100% negative predictive value. Again study considered results only for detection of critical CHD. The study done by Koppel *et al.* 2003 reported the effectiveness of pulse oximetry screening for detection of CHD in asymptomatic newborns. According to the study the sensitivity, specificity, positive and negative predictive value of pulse oximetry for detection of CHD was 60%, 99.95%, 75% and 99.98% respectively. The results were comparable with the present study. Although infant mortality has decreased over the past 3 decades for children with all forms of CHD, many children are still diagnosed too late to avoid significant morbidity or death (Schultz *et al.,* 2018; Mahle *et al.,* 2012). Delayed diagnosis of CCHD is unfortunately all too common, with up to 25% of infants with these defects being missed in newborns when identification is based on clinical symptoms or signs of heart disease even in settings with routine prenatal sonograms (Wren *et al.,* 2008; Mahle *et al.,* 2012; Ng and Hokanson, 2010). Approximately 40% of these infants with missed diagnoses at birth present in cardiogenic shock at a medical facility and 5% are diagnosed at autopsy (Mahle *et al.,* 2012; De-Wahl Granelli *et al.,* 2009). 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% (Mahle *et al.,* 2009; Kemper *et al.,* 2011). In 2011, pulse oximetry screening for CCHD was added to the Recommended Uniform Screening Panel by the Health and Human Services Secretary. In the present study, among 9 subjects positive for pulse oximetry alone, 7 were found to have CHD and of them 6 were having critical CHD. These cases were clinically negative and were detected by pulse oximetry alone. This showed the importance of pulse oximetry for detection of critical congenital heart disease. If in present study clinical examination alone was used as screening tool for detection of congenital heart disease, these cases would have missed and detected later on when the neonate become symptomatic and critically sick. These cases in present study were detected earlier before they become symptomatic .These cases along with other critical CHD (detected by clinical examination and later on found to be pulse oximetry positive also) that were detected in present study before they become seriously ill were referred to cardiology center for early intervention.



Conclusion

Pulse oximetry is an effective, non invasive and feasible screening tool for detection of cyanotic congenital heart disease. It has an important role for early detection of critical. CHD that can be missed by routine physical examination of newborns. Pulse oximetry combined with clinical examination is more effective screening tool for detection of congenital heart disease than clinical examination alone .Combining pulse oximetry screening and clinical examination can enhance clinician ability to detect life threatening CHD in a timely manner and this screening method should become a part of discharge policy of every newborn.

REFERENCES

De-Wahl Granelli A, Wennergren M, Sandberg K *et al.* 2009. Impact of pulse oximetry screening on the detection of duct dependent congenital heart disease: A Swedish prospective screening study in 39,801 newborns. *BMJ,* 338: a3037.

Kemper AR *et al.* 2011. Strategies for implementing screening for critical congenital heart disease. *Pediatrics*, 128(5):e1259-67.

Mahle WT, Martin GR, Beekman RH *et al.* 2012. Section on Cardiology and Cardiac Surgery Executive Committee Endorsement of Health and Human Services recommendation for pulse oximetry screening for critical congenital heart disease. *Pediatrics*., 129(1):190–192.

Mahle WT, Newburger JW, Matherne GP. *et al*. 2009. American Heart Association Congenital Heart Defects Committee of the Council on Cardiovascular Disease in the Young. Council on Cardiovascular Nursing; Interdisciplinary Council on Quality of Care and Outcomes Research. American Academy of Pediatrics Section on Cardiology and Cardiac Surgery. Committee on Fetus and Newborn Role of pulse oximetry in examining newborns for congenital heart disease: a scientific statement from the American Heart Association and American Academy of Pediatrics. *Circulation*, 120(5):447–458.

Mahle WT, Tavani F, Zimmerman RA *et al.* 2002. An MAGNETIC RESONANCE IMAGING study of neurological injury before and after congenital heart surgery. *Circulation,* 106 (suppl I): 1-109-1-114.

Ng B, Hokanson J. 2010. Missed congenital heart disease in neonates. *Congenit Heart Dis.*, 5(3):292–296.

Pradat P, Francannet C, Harris JA, Robert E. 2003. The epidemiology of cardiovascular defects, part I: a study based on data from three large registries of congenital malformations. *Pediatr Cardiol.,* 24(3):195-221.

Riehle-Colarusso T, Strickland MJ, Reller MD *et al.* 2007. Improving the quality of surveillance data on congenital heart defects in the metropolitan Atlanta congenital defects program. *Birth Defects Res A Clin Mol Teratol.,* 79 (11):743–753.

Schultz AH, Localio AR, Clark BJ, Ravishankar C, Videon N, Kimmel SE. 2008. Epidemiologic features of the presentation of critical congenital heart disease: implications for screening. *Pediatrics,* 121(4):751–757.

Sendelbach DM, Jackson GL, Lai SS, Fixler DE, Stehel EK, Engle WD. 2008. Pulse oximetry screening at 4 hours of age to detect critical congenital heart defects. *Pediatrics,* 122(4):e815-820.

Vaidyanathan B, Satish G, Mohanan ST *et al.* 2011. Clinical screening for congenital heart disease at birth: a prospective study in a community hospital in kerala. *Ind Pediatr*., 48(l):25-30.

Wren C, Reinhardt Z, Khwaja K. 2008. Twenty - year trends in diagnosis of life threatening neonatal cardiovascular malformations. *Arch Dis Child Fetal. Neonatal. Ed*., 93(1): F33-F35.

****