RESEARCH ARTICLE

Pulse oximetry as a screening tool for critical congenital heart defects in newborns

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Abstract

Objective: To evaluate the effectiveness of pulse oximetry as a screening tool for critical congenital heart defects in newborns.

Methods: This cross-sectional study was conducted at the neonatology department of the Children's Hospital and the Institute of Child Health, Lahore, Pakistan, from January to June 2016, and comprised neonates aged up to 07 days. Babies with a prenatal diagnosis of heart defects and those whose parents refused to give consent were excluded. Oxygen saturation of enrolled patients was measured in right index finger (pre-ductal) and in the left big toe (post-ductal) subsequently. Echocardiography was done on all the enrolled babies to confirm the diagnosis. SPSS 19 was used for data analysis.

Results: Of the 145 babies initially enrolled, 138(95.2%) were included. The overall mean age of the babies was 2.17±1.62 days (range: <24 hours-07 days) whereas the mean birth weight was 2.95±0.47kg (range: <2.5->4kg). Babies with pre- and post-ductal oxygen saturation measurement difference of >3% showed a detection rate of 16(45.7%) for critical congenital heart defects. Sensitivity and specificity of this screening test was calculated to be 76.19% and 83.76%, respectively, while positive and negative predictive values were 45.71% and 95.15%, respectively.

Conclusion: The measurement of pre- and post-ductal oxygen saturation by pulse oximetry was an effective screening tool for the detection of critical congenital heart defects in newborns.

Keywords: Pulse oximetry, Congenital heart defects, Newborn. (JPMA 67: 1220; 2017)

Introduction

Cardiovascular anomalies are commonest congenital malformation (6-8/1000) responsible for majority of the deaths in the first year of life.[1] Critical congenital heart defect (cCHD) is defined as any serious congenital cardiac defect which causes neonatal mortality or need for cardiac catheterisation or surgery during first 28 days of life. Interrupted aortic arch, hypoplastic left heart syndrome, tetralogy of Fallot, transposition of great arteries, pulmonary atresia with intact septum, pulmonary or aortic valve stenosis, pulmonary atresia with ventricular septal defect, coarctation of aorta and total anomalous pulmonary venous drainage are included in this definition.[2]

The incidence of congenital heart defects (CHD) was found to be 5.8/1000 live births in an Asian study conducted in a tertiary care hospital at Kathmandu in 2008, while the incidence of duct-dependent cCHDs is 1-1.8/1000 live births.[3,4] Fewer than 50% cCHDs are diagnosed prenatally.[5] A multicentre study conducted in China in 2016 has shown that critical congenital heart defects have a mortality rate of 30% if left untreated.[6]

Routine neonatal examination fails to detect 30 to 50 % babies with cCHD and they are discharged home without a diagnosis.[7]

Clinical signs of cCHD in the neonates may be subtle or they may present with cyanosis, unexplained acidosis, and tachypnoea without respiratory concerns, shock or even sudden death.[8] One-sixth of the neonates with cCHD have persistent ductusarteriosus which is necessary for survival.[1]

Data from California reveals upto 30 deaths per year attributable to missed or late diagnoses of cCHD.[9] Delay in diagnosis worsens pre-operative clinical course and post-operative outcome. This is evident from the data of Fixler et al. that mortality from cCHD was found to be lower in newborns diagnosed before discharge compared with those diagnosed after discharge (0.9 % vs 18%).[10]

Pulse oximetry screening (POS) has been proposed as an effective, non-invasive, inexpensive tool allowing earlier diagnosis of cCHD in newborns with prospects of improved outcome.[11] False positive results for detection

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of cCHD was found to be lower when pulse oximetry was performed after 24 hours from birth versus when done before 24 hours (0.05% vs. 0.5%).[2]

With Pakistan having one of the highest neonatal mortalities in the world, i.e. 46/1,000 live births, early recognition of cCHD may lead to a reasonable reduction in this burden.[12] More so with a lack of universal availability of echocardiographic facility in most of our healthcare centres, pre- and post-ductal oxygen saturation measurement will help in early detection of cCHD in newborns. A number of studies have been carried out worldwide, but there is lack of locally published literature about the use of pulse oximetry as a screening tool to detect cCHD in newborns. The current study was planned to help determine the effectiveness of this screening method to detect cCHD.

Patients and Methods

This cross-sectional study was conducted at the neonatology unit of the Children's Hospital and the Institute of Child Health, Lahore, Pakistan, from January to June 2016, and comprised neonates. It was initiated after obtaining permission from the institutional review board. Informed written consent was obtained from parents or guardians. Term neonates of either gender admitted in the neonatal unit through neonatal outpatient (Emergency Department (OPD/ED) who presented within first week of life were included. Non-probability consecutive sampling technique was used. The sample size was calculated with 80% power of test and 5% level of significance by taking 1% of cCHD of newborn per 1,000 live births[4] by using thefollowing formula:

n=Z^2(p) (1-p)/d^2

Babies with a prenatal diagnosis of heart defects and those whose parents refused to give consent were excluded from the study. Biodata, history, pre- and post-ductal oxygen saturation measurement and echocardiographic findings were recorded on a pre-designed proforma.

Oxygen saturation of enrolled patients was measured in right index finger (pre-ductal) and in left big toe (post-ductal) subsequently with Masimo Set Rad 8 pulse oximeter (Model No. M80592, Masimo Corporation, California). It was chosen to measure the oxygen saturation because false bradycardia, data dropouts, and false desaturations were lowest with this device.[13] To avoid movement artefacts, the reading was ignored until the waveform was stable on pulse oximeter. Although the cut-off value of pre- and post-ductal oxygen saturation measurement difference is more than 3%, where probability of duct-dependent cCHD increases, but in our study echocardiography was performed on all babies by a paediatric cardiologist by using 5S or 7S probes with echocardiographic machine (Vivid7 model, General Electric) to detect any cCHD.[14]

SPSS 19 was used for data analysis. Qualitative variables like age and weight were presented as mean and standard deviation while quantitative variables (types of cCHD) were presented in frequency and percentages. Chi-square test (x2) was used to compare variables. Correlation test was applied to check the relationship of pre- and post-ductal oxygen saturation measurement difference for detection of cCHD. OpenEpi software was used to find the sensitivity and specificity of the study through 2x2 tables by using variables of pre- and post-ductal oxygen saturation measurement difference and echocardiographic findings. P $\leq$0.05 was taken as statistically significant.

Results

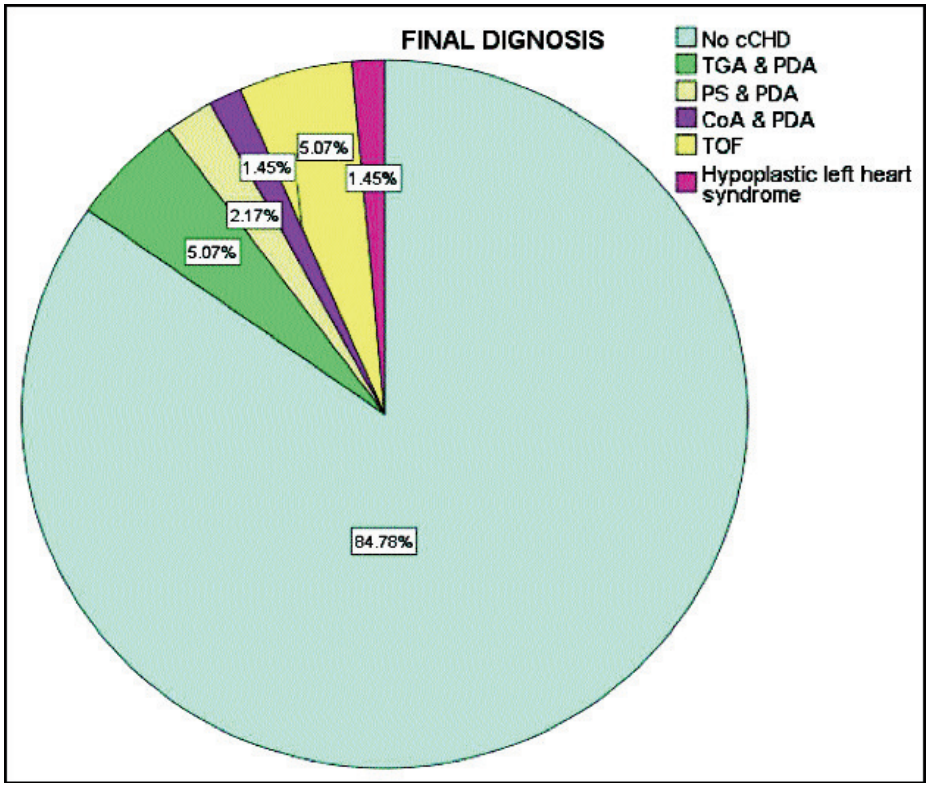
Of the 145 babies initially enrolled, 138(95.2%) were included as 7(4.8%) were excluded, of which 3(42.9%) had a prenatal diagnosis of heart defects and parents of 4(57.1%) neonates refused to give consent. Of those who were included, 97(70.3%) were males and 41(29.7%) females, with a males-to-female ratio of 2.3:1.

The overall mean age of the babies was 2.17±1.62 days (range: <24 hours to 07 days) whereas the mean birth weight was 2.95±0.47kg (range: <2.5 to >4kg).

Table: Correlation of pre and post ductal oxygen saturation measurement difference with cCHD.

Pre and Post ductal oxygen saturation measurement difference	Diagnosis on Echocardiography		Total
	With cCHD	No cCHD	
Up to 3%	5	98	103
	4.90%	95.10%	100.00%
More than 3%	16	19	35
	45.70%	54.30%	100.00%
Total	21	117	138
	15.20%	84.80%	100.00%

cCHD: Critical Congenital Heart Defect.



cCHD: Critical congenital heart defect
TGA: Transposition of great arteries
PDA: Patent ductusarteriosus
PS: Pulmonary stenosis
CoA: Coartation of
TOF: Tetralogy of fallot

Figure: Frequency of various types of cCHD detected by echocardiography.

Moreover, 103(74.63%) patients had normal pre- and post-ductal oxygen (O_2) saturation difference, i.e. up to 03%. Among these neonates, 5(4.9%) had a cCHD while 98(95.1%) had no cCHD.

Also, 35(25.36%) patients had abnormal pre- and post-ductal O2 saturation difference, i.e. more than 3%. Out of these, 16(45.7%) were found to have cCHD on echocardiography while 19(54.3%) were without cCHD (Table).

The most common cCHDs found were transposition of great arteries (TGA) and tetralogy of Fallot (TOF), both found in 7(5.07%) patients each, followed by pulmonary stenosis3(2.17%), hypoplastic left heart syndrome (HLHS) 2(1.45%) and coartation of aorta (COA)2(1.45%) (Figure).

Sensitivity and specificity of pulse oximetry was found to be 76.19% (95% confidence interval (CI): 52.45-90.88%) and 83.76% (95% CI: 75.54-89.70%), respectively, with positive predictive value of 45.71% (95% CI: 28.83-63.35%) and negative predictive value of 95.15% (95% CI: 89.03-98.41%). Chi-square test showed a value of 33.80 (p=0.0001).

Discussion

Diagnosis and treatment of cCHDs have changed dramatically over the last few decades. Clinical examination alone is unable to detect all forms of cCHD and up to 50% of babies with cCHD are discharged home without a diagnosis.[7] Although screening echocardiography is associated with the highest detection rate, it is an expensive modality. Pulse oximetry screening (POS) has been proposed as an effective, non-invasive, inexpensive and less time-consuming screening tool allowing earlier diagnosis of cCHD in newborns with prospects of an improved outcome.[15]

In a study conducted by Reich JD et al. the detection rate of cCHD was found to be 48.9%.[16] Similar results were observed in our study where the detection rate of cCHD was found to be 45.7%.

Sensitivity and specificity of our study were76.19% and 83.76%, respectively, with positive predictive value of 45.71% and negative predictive value of 95.15%. In a similar study conducted by Turska KA et al. in Poland, sensitivity and specificity were calculated to be 78.9% and 99.9%, respectively, with positive predictive value of 51.7% and negative predictive value of 99.9%.[17]

Meberg A. et al. and Riede FT et al. observed similar results in their studies as well. In the study conducted by Meberg A et al., the sensitivity and specificity were found to be 77.1% and 99%, respectively, whereas data by Riede FT et al. revealed a sensitivity of 77.8% and specificity of 99.8%.[18,19] However the results differed from the study conducted by Koppel RI et al. where sensitivity and specificity was found to be 60% and 99.9%, respectively.[20] The difference may be due to smaller sample size in our study and different demographic characteristics of two populations.

There is a positive correlation between the two variables

of pre- and post-ductal oxygen saturation measurement difference and detection of critical congenital heart defects in our study. Similar results were shown by studies conducted by Rosati E. et al. and Ewer A. et al.[21,22]

The current study had a few limitations. The number of enrolled patients was small, which can be attributed to the fact that the incidence of cCHD is low (1-1.8/1,000). Besides, it was a single-centre study, which limits the statistical power of the study.

Conclusion

The measurement of pre- and post-ductal oxygen saturation by pulse oximetry was an effective screening tool for the detection of critical congenital heart defects in newborns.

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References

1. Rüegger C, Bucher HU, Mieth RA. Pulse oximetry in the newborn: Is the left hand pre-or post-ductal? BMC Pediatrics 2010; 10: 35.
2. 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: 2459-64.
3. Shah GS, Singh MK, Pandey TR, Kalakheti BK, Bhandari GP. Incidence of congenital heart disease in tertiary care hospital. Kathmandu Univ Med J 2008; 6:33-6.
4. De-Wahl Granelli A, Wennergren M, Sandberg K, Mellander M, Bejlum C, Ingans L, et al. Impact of pulse oximetry screening on the detection of duct dependent congenital heart disease: a Swedish prospective screening study in 39821 newborns. BMJ 2009; 338: 3037.
5. Govindaswami B, Jegatheesan P, Song D. Oxygen Saturation Screening for Critical Congenital Heart Disease. Neo Reviews 2012; 13: e724-31
6. Zeng Z, Zhang H, Liu F, Zhang N. Current diagnosis and treatments for critical congenital heart defects. Exp Ther Med 2016; 11: 1550-54.
7. Kumar P. Universal Pulse Oximetry Screening for early detection of Critical Congenital Heart Disease. Clin Med Insights Pediatr 2016; 10: 35-41.
8. Yun SW. Congenital heart disease in the newborn requiring early intervention. Korean J Pediatr 2011; 54: 183-91.
9. Chang RK, Gurvitz M, Rodriguez S. Missed diagnosis of critical congenital heart disease. Arch Pediatr Adolesc Med 2008; 162: 969-74.
10. Fixler DE, Xu P, Nembhard WN, Ethan MK, Canfield MA. Age at referral and mortality from critical congenital heart disease. Paediatrics 2014; 134: e98-105.
11. Chamsi-Pasha MA, Chamsi-Pasha H. Critical Congenital Heart Disease Screening. Avicenna J Med 2016; 6: 65-8.
12. Pakistan. Pakistan Demographic and Health Survey 2012-13. Islamabad: National Institute of Population Studies; 2013.
13. Hay WW, Rodden DJ, Collins SM, Melara DL, Hale KA, Fashaw LM. Reliability of conventional and new pulse oximetry in neonatal patients. J Perinatol 2002; 22: 360-6.
14. De-Wahl Granelli A, Mellander M, Sunnegardh J, Sandberg K, Östman-Smith I. Screening for duct-dependent congenital heart disease with pulse oximetry: a critical evaluation of strategies to maximize sensitivity. Acta Paediatr 2005; 94: 1590-6.
15. Arlettaz R, Bauschatz AR, Monkhoff M, Essers B, Bauersfeld U. The contribution of pulse oximetry to the early detection of congenital heart disease in newborns. Eur J Pediatr 2006; 165: 94-8.
16. Reich JD, Miller S, Brogdon B, Casatelli J, Gompf TC, Huhta JC, et al. The use of pulse oximetry to detect Congenital Heart Disease. J Pediatr 2003; 142: 268-72.
17. Turska KA, Boryszewska MK, Blaze W, Kawalec W, Zuk M. Early screening for critical congenital heart defects in asymptomatic newborns in Mazovia province: experience of the POLKARD pulse oximetry 2006-08 in Poland. Kardiol Pol 2012; 70: 370-76.
18. Meberg A, Pieper SB, Due R, Eskedal L, Fagerli I, Farstad T, et al. First day of life pulse oximetry screening to detect congenital heart defects. J Pediatr 2008; 152: 761-65.
19. Riede FT, Worner C, DahnertI, Mockel A, Kostelka M, Schneider P. Effectiveness of neonatal pulse oximetry screening for detection of critical congenital heart disease in daily clinical routine. Eur J Pediatr 2010; 169: 975-81.
20. Koppel RI, Druschel CM, Carter T, Goldberg BE, Mehta PN, Talwar R et al. Effectiveness of Pulse Oximetry Screening for Congenital Heart Disease in Asymptomatic Newborns. Pediatrics 2003; 111: 451-5
21. Rosati E, Chitano G, Dipaola L, Felice CD, Latini G. Indications and limitations for a neonatal pulse oximetry screening of critical congenital heart disease. J Perinat Med 2005; 33: 455-57.
22. Ewer AK, Middleton LJ, Furmston AT, Bhoyar A, Daniels JP, Thangaratinam S, et al. Pulse oximetry screening for congenital heart defects in newborn infants: a test accuracy study. Lancet 2011; 378: 785-94.