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Combining Pulse Oximetry and Clinical Examination in Screening for Congenital Heart Disease

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Abstract. The objective of this study was to evaluate combined pulse oximetry and clinical examination as a screening method for congenital heart disease (CHD) in asymptomatic newborns. Asymptomatic newborns were screened for CHD using pulse oximetry and clinical examination before their discharge from the nursery. Oxygen saturation ≥94% was considered normal. Echocardiography was done for newborns with abnormal readings and for those with significant murmurs. Data concerning undetected cases were collected from the pediatric referral hospital. A total of 5211 cases were screened. Echocardiographic evaluations were done based on low pulse oximetry in five cases and on murmur detection in ten others. The sensitivity of the combined method of screening was 77%, whereas it was 31% for oximetry alone and 46% for clinical examination alone. Specificity was ∼100% for all methods. The positive predictive value of the combined tool was 66.7%. We conclude that combining pulse oximetry and clinical examination can enhance the clinician's ability to detect life-threatening CHD in a timely manner. This screening method should become a part of the discharge plan for every newborn.

Key words: Congenital heart disease — Pulse oximetry — Clinical examination — Neonatal screening — Asymptomatic newborns

Neonatal screening has been universally accepted for the past 3 decades; it is currently an essential part of medical service in >26 countries worldwide. Initially, neonatal screening was aimed at the diagnosis of metabolic disorders, but currently it is performed for a wide variety of genetic and acquired disorders [13]. Neonatal screening aims at the earliest possible recognition of disorders so that intervention with effective treatment can prevent their serious consequences.

Congenital heart disease (CHD) is a relatively common problem, with an incidence of five to ten in every 1000 live births [9]. Routine neonatal examination fails to detect >50% of infants with CHD. More than 55% of these have no murmur in the nursery, and ≤82% of them are discharged before a diagnosis can be made [17]. Unrecognized neonatal heart disease carries a serious risk of mortality, morbidity, and handicap [2, 4, 14, 16]. Therefore, there is a need for an effective screening program for CHD. This disorder would be ideally suited for a screening program if simple and reliable methods were available. Recently, pulse oximetry has been suggested as a screening tool for CHD in asymptomatic newborns [7, 11, 12]. In view of the preliminary results, we decided to evaluate the efficacy of combining pulse oximetry and clinical examination as a screening method for CHD in asymptomatic newborns before their discharge from the nursery.

Materials and Methods

This study was conducted in the neonatology department of King Abdel-Aziz Specialist Hospital, Taif, Saudi Arabia, which is the largest maternity hospital and nursery in the area. A program to screen asymptomatic, well newborns for CHD using pulse oximetry and routine cardiac clinical examination was initiated in January 2004.

All newborn babies in the well-baby nursery were screened by pulse oximetry before discharge using a Digioxi PO 920 pulse oximeter (Digicare Biomedical Technology, West Palm Beach FL, USA). Sick babies admitted to the neonatal intensive care unit (NICU) at birth were excluded. Before the study, the two assigned nurses received training in the proper use of the pulse oximeter. Clinical examination during this period was done by the same two pediatricians assigned to this task.

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The screening was done daily, including weekends. Pulse oximetry readings were taken, in a quiet setting with the infants in a calm state, from right upper and lower limbs. The probe was cleaned with alcohol swabs before each use. The reading was recorded after stabilization for 1 minute, according to the manufacturer's instructions. A fractional (as opposed to functional) oxygen saturation of ≥94% was accepted as normal [6, 10, 15]. Any infant who had an oxygen saturation < 90% from either limb was examined by echocardiography. Saturations between 90% and 94% were verified by three readings; if they persisted in this range, echocardiography was also done. Echocardiography was also performed for cases having cardiac murmurs of grade II or greater.

The study lasted for 6 months (January–July 2004). In the meantime, data were collected from the cardiology service of the only pediatric hospital in the region to identify patients who had been diagonsed with CHD after their discharge from the well-baby nursery. Sensitivity, specificity, and positive predictive values of the screening methods were calculated (95% confidence interval). The chi-squared test was used to compare categorical data. A p value < 0.05 was considered statistically significant.

Results

During the 6 months of the study, 5211 asymptomatic newborns were screened by pulse oximetry and clinical examination before discharge. The average age at screening was 31.7 hours. Fifteen echocardiographies were done for newborns in the well-baby nursery; five of these were done based solely on the low saturation. The other ten were done based on detection of murmurs during routine clinical examination. None of these ten underwent echocardiography based on the saturation criteria. Of the 545 NICU admissions during the period of the study, 19 cases of CHD were diagnosed. All NICU admissions were excluded from this study.

Among the five infants examined because of low pulse oximetry, one had a saturation of 92% and was diagnosed with total anomalous pulmonary venous return (TAPVR). Another infant with a saturation of 85% was diagnosed with pulmonary atresia (PA). The third had a large ventricular septal defect (VSD) and a saturation of 93%. In the fourth case, the saturation was 89% and the echocardiography revealed a truncus arteriosus (TA). The fifth infant, who had a saturation of 93%, showed a normal heart apart from a persistent foramen ovale shunting left to right. Ten echocardiograms were done based on murmur detection only. Four of them showed normal hearts. The other six detected two cases of patent ductus arteriosus (PDA), three cases of VSD, and one case of atrial septal defect (ASD).

Records from the main pediatric referral hospital in the region were revised for the same time frame of the study. Three patients were diagnosed with CHD while being investigated for failure to thrive and respiratory symptoms. One had corrected transposition of the great arteries, the second had pulmonary stenosis, and the third had a VSD. These disorders had not been detected by the oximetry screening or by the initial routine examination.

Table 1 summarizes the results of pulse oximetry and clinical examination. Table 2 shows the number of patients either identified or missed by the combined method of screening. Table 3 shows a statistical analysis of the screening methods. Pulse oximetry, which was very specific (nearly 100%), detected four CHD of 13 cases (sensitivity of 31%) and had a positive predictive value of 80%. Screening by pulse oximetry alone missed all the cases that were detected clinically. Clinical examination alone identified six CHD of 13 (sensitivity of 46%) and was also very specific (100%), with a positive predictive value of 60%. Screening by clinical examination alone also missed all of the cases that were identified by oximetry. The combined screening tool had a sensitivity of 77% and a positive predictive value of 66.7%, as well as a 100% specificity. The findings by chi-squared test were statistically significant for the three screening tools. Calculating the incidence of CHD is beyond the scope of this study.

Discussion

Early recognition of CHD is of crucial importance because clinical presentation and deterioration may be sudden. Furthermore, many children with undetected complex CHD die at presentation or before their first surgical intervention [8, 17]. Clinical examination for the early signs of CHD is an essential part of routine neonatal examination and can identify some asymptomatic newborns [5]. Pulse oximetry has been suggested as a screening tool for the early detection of CHD in asymptomatic newborns, because the physical examination alone appears to be insufficient [7, 11]. Oximetry screening has never been proposed as a substitute for careful physical examination, and the value of combining the two methods has not been assessed heretofore.

In this series, we evaluated the efficacy of combining pulse oximetry with clinical examination in screening for CHD. Our study showed that pulse oximetry can detect CHD in asymptomatic newborns after it has been missed by routine clinical examination. Clinical examination also picked up another group of cases that were missed by pulse oximetry. The combined approach had an additive effect and resulted in more efficient screening.

Contrary to the findings reported by Reich et al. [11], routine pulse oximetry did increase the number of echocardiograms performed. However, it also increased the total number of children diagnosed with

Table 1. Pulse oximetry and clinical examination as individual screening tests

	Positive	Negative	Total
Pulse oximetry			
CHD	4	9	13
NoCHD	1	5195	5196
Total	5	5206	5211
Clinical examination			
CHD	6	7	13
NoCHD	4	5194	5198
Total	10	5201	5211

CHD, congenital heart disease.

Table 2. Combined clinical examination and pulse oximetry as a screening method

	Positive	Negative	Total
CHD	10	3	13
NoCHD	5	5193	5198
Total	15	5196	5211

CHD, congenital heart disease.

Table 3. Statistical analysis of the different screening methods

	Pulse oximetry (%)	Clinical exam (%)	Combined (%)
Sensitivity	30.8	46	77
Specificity	99.9	99.8	99.7
Positive predictive value	80	60	66.7

CHD. Notably, pulse oximetry identified cases of complex CHD as PA, TAPVR, and TA, none of which had been detected clinically. The patient who had large VSD had an oxygen saturation of 93%. The fact that murmurs were absent in these cases, or that they were missed by human error, makes the combination of oximetry with clinical examination very valuable. Cases picked up by clinical examination alone did not occur in patients with low saturations. Indeed, these cases were simple acyanotic defects (VSD, PDA, and ASD).

In screening for metabolic disorders, high sensitivity is considered to be essential because the incidence is very low. For congenital cardiac diseases, which have a higher incidence, specificity is important because a test with a low specificity would generate costly follow-up testing and would make screening prohibitively expensive [3]. Similar to what was shown in other studies [7, 11], we demonstrated that pulse oximetry alone had an almost 100% specificity, while its sensitivity was relatively low (31%). The positive predictive value was also comparable. The sensitivity, specificity, and positive predictive value of clinical examination alone for detection of CHD matched those reported by Ainsworth et al. [1]. When pulse oximetry and clinical examination were combined, the sensitivity was more than doubled (77%), while the specificity remained around 100%. The relatively low sensitivity may limit the ability of this screening method to identify all cases of CHD. However, the high specificity would diminish parent anxiety and obviate unnecessary echocardiograms and costly follow-ups. This factor makes the combined approach the best available screening method for CHD in asymptomatic newborns.

The inability to trace infants who moved out of our region so that we could record the outcomes of the CHD cases was a limitation of this study. Another limitation is that postmortem examination is not routinely practiced; in our area, hence, some infants who died with undiagnosed CHD could have been missed. The fact that antenatal diagnosis for CHD is currently not available in our center is an important point that needs to be taken into consideration when comparing our results with those of others who had this facility [11].

The age of screening is a factor that might affect the results. In our facility, the average hospital stay for babies born vaginally is 1 day vs 4 days for babies born by cesarean section. The average age at screening was 31.7 hours. In other studies that evaluated oximetry as a screening tool [7, 11], the average age at screening was ≥2 days. We can assume that if our combined screening method had been used at a comparable age, the final diagnostic yield would have been much better.

We recommend that future studies examine the combined screening method carefully over a longer time frame. They should also look into the long-term cardiovascular and neurodevelopmental outcomes of infants with CHD. In addition, the costs and benefits should be considered.

We conclude that combining pulse oximetry and clinical examination can enhance the clinician's ability to detect life-threatening CHD in a timely manner. This screening program should become a part of discharge plan for every newborn.

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