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## Role of Pulse Oximetry in Detection of Congenital Heart Disease in Children.

### **ABSTRACT:**

**Background:** Congenital heart diseases are an important causes of morbidity & mortality of children. Pulse oximetry is used routinely in neonatal intensive care and emergency units. This study was aimed to evaluate the results of oxygen saturation measured by pulse oximetry with the purpose of use it to detect congenital heart diseases in children as it is readily available, relatively cheap and easily done.

**Patients and Method:** This is a cross- sectional, comparative study. It was done at al- Batool Teaching Hospital for Maternity & Children- Diyala province/ Iraq from Sept 2011 – Mar 2012. Children who were suspected to have congenital heart disease was examined by echocardiography and pulse oximetry together, a cut- off value of oxygen saturation (Spo2) measured by pulse oximetry below 95% was considered low and compared to echocardiography results. Sensitivity, specificity, false positive rate, false negative rate, predictive values, & accuracy rate were calculated.

**Results:** A ninety five children had enrolled, 45 ( 47%) of them had congenital heart diseases and 50 child ( 53%) had normal echocardiography results. Pulse oximetry showed a decreased Spo2 in 13 of 45 children with CHD ( sensitivity = 29 %) and it was normal in 44 from 50 normal children ( specificity = 88 %). The results were rather similar after comparing the results of Spo2 of acyanotic CHD children versus the normal children. Spo2 of cyanotic CHD of children to the normal group showed high sensitivity and specificity, 100 % & 88 %, respectively.

**Conclusion:** Pulse oximetry was found to be specific & sensitive tool to detect cyanotic defects, so routine pulse oximetry may detect a child who might not have been detected otherwise. In acyanotic subtypes, pulse oximetry had a limited role in detection of the defect & in spite of good specificity to exclude them in normal babies.

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## INTRODUCTION

Congenital heart diseases are the commonest group of congenital malformation; it affects 7-8/1000 newborn. It contributed to 3% of all infant mortality & 46% of deaths from all congenital malformations, most deaths occur in the 1st year of life and a large proportion of these children require surgery in the 1<sup>st</sup> year.<sup>[1]</sup>

Clinical experience & epidemiological observations suggest that although physical examination, electrocardiogram, & chest radiography are useful in identifying many cases of serious congenital heart diseases, they do not have sufficient sensitivity & specificity to detect all cases, echocardiography, although an essential diagnostic tool, has many limitations as a universal screening tool, especially its cost.<sup>[2]</sup>

A common feature of many forms of congenital heart diseases is hypoxemia which results from the mixing of systemic & venous circulation or parallel circulation as one might see in dextro-position of great arteries. It may result in obvious cyanosis.<sup>[3]</sup> In general, to detect central cyanosis, it requires 4 g or more of reduced hemoglobin; this corresponds to a systemic oxygen saturation of

80% to 85% (depending on the patient's hemoglobin level). If the systemic oxygen saturation is 85% or more, detecting cyanosis with the "eye oximeter " is very difficult.<sup>[4]</sup>

Pulse oximetry was developed in the early 1970s based on different absorption spectra between oxygenated & deoxygenated hemoglobin.<sup>[5]</sup> Deoxygenated hemoglobin absorb light in the red band (600 to 750 nm), whereas oxygenated hemoglobin absorbs light in the infrared band (850 to 1000 nm). The ratio of light absorbance at these two wavelengths correlates with the saturation of hemoglobin in the capillaries.<sup>[6]</sup> It has the potential to identify hypoxemia that might not otherwise produce visible cyanosis, especially among darkly pigmented newborns.

Pulse oximetry is used routinely in the assessment of the young children in neonatal intensive care units & emergency departments.<sup>[7]</sup> As such, some have proposed that pulse oximetry be considered as a vital sign equivalent in importance to pulse, respiration, & blood pressure.<sup>[8]</sup> It has gained wide acceptance as a noninvasive method to determine oxygen saturation (Spo<sub>2</sub>). The method

does not require calibration & is able to provide instantaneous data that correlate well with blood gas measurement.<sup>[9]</sup> It is readily available, relatively cheap, and well-validated test currently

carried out by either a nurse or a doctor.<sup>[10]</sup>

This study was aimed to evaluate the results of oxygen saturation measured by pulse oximetry with the purpose of use it to detect CHD in children.

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## PATIENTS & METHOD

This is a cross-sectional, comparative study, conducted at al- Batool Teaching Hospital for Maternity & Children from 1st of September 2011 – 1st of March 2012. Al- Batool Teaching Hospital is the alone hospital for children at Baquba city (center of Diyala province/ eastern Iraq), it receives patients from the city itself, in addition to referred cases from peripheral districts.

### Patients inclusion and Identification of Children with CHD

Children who suspected to have congenital heart disease were enrolled in the study, those were either hospitalized, outpatients, or referred children from peripheries for echocardiography study, a care was taken to enroll each patient once a time in spite of many follow up echocardiography examinations might be done during the study period. The diagnosis of congenital heart disease was determined by echocardiography because it is now considered the definitive

diagnostic modality.<sup>[11]</sup> All children were examined by pulse oximetry, followed by by echocardiography, these were done separately & blindly. CHD were divided according to the types of CHD into acyanotic and cyanotic subtypes.<sup>[3]</sup>

### Pulse Oximetry & Its Measures

The pulse oximetry equipment type which had been used was [ 2 sat, Infinium Medical Inc., FL 33773 USA, Serial no. was ( O2 sat. 1007- 00142), manufactured at 7/7/ 2010]. It is well known that the peak performance of the commercially available oximeters occurs in the range of 92 % to 97%, therefore, in the critical range of oximetry screening ( 94% to 97%), the variability will be negligible.<sup>[12]</sup> Thus, the available pulse oximetry can be in the study confidently.

The oxygen saturation (Spo2) measured by pulse oximetry below 95 % was considered as the cut-off level in most studies &

suggested by American Academy of Pediatrics (AAP) & Scientific Statement of the American Heart Association (AHA), both of these institutes recommend positioning of the probe of pulse oximetry at the foot.<sup>[13]</sup> To avoid movement artifacts, the pulse was observed until a good waveform was obtained, it is usually require 3- 5 minutes.

#### *Exclusion Criteria*

Patients who had any suspected cause of hypoxia or low Spo<sub>2</sub> other than congenital heart disease were not included in the

study, those were children with anemia & respiratory distress whatever the cause, furthermore, nail staining had been avoided on measuring pulse oximetry.

#### **Statistics Analysis**

It was carried out manually with electronic calculator. Sensitivity, specificity, false positive rate, false negative rate, predictive values, & accuracy rate of pulse oximetry were calculated by comparison of its measure in cases of CHD and its subtypes (acyanotic and cyanotic ) with normal children.

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## **RESULTS**

A ninety five children were included in the study, 45 ( 47 %) children of them have different congenital heart diseases and 50 ( 53 %) children have no congenital heart diseases. CHD detected in the study were distributed into: 1) Acyanotic CHD: ventricular septal defect VSD (n=25, 55.5 %), atrial septal defect ASD (n=11, 24.5 %), and aortic stenosis (n=2, 4.5 %). 2) Cyanotic CHD: Tetralogy of Fallot TOF (n=7, 15.5 %) only. Most of the children with CHD were below 6 month old; male to female ratio was 1.4:1, table 1.

Echocardiography study was requested by a pediatrician due to a diverse group of manifestations in the study children, cardiac murmur was the commonest, followed by

dyspnea and central cyanosis, table (2). Pulse oximetry showed a decreased Spo<sub>2</sub> in 13 of 45 children with CHD ( sensitivity = 29%) and normal readings in 44 of 50 normal children ( specificity = 88%). The results were rather similar after comparing the results of Spo<sub>2</sub> of acyanotic CHD children against the normal children, table. The state was dissimilar when distribute the results of Spo<sub>2</sub> of cyanotic CHD of children to the normal children showing high sensitivity and specificity, 100% and 88%, respectively, tables (3-5).

Regarding the level of decrement of Spo<sub>2</sub>, children who had positive pulse oximetry and acyanotic CHD were having Spo<sub>2</sub> located at 90-94%, whereas Spo<sub>2</sub> of children with cyanotic CHD were below 90%.

**Table(1): The age to gender distribution of children with congenital heart disease.**

Age \ Gender	Male Number (%)	Female Number (%)	Total Number (%)
Birth- 6 mo	19(42)	13 (29)	32 (71)
> 6 mo- 1 yr	4 (9)	2 (4)	6 (13)
> 1 yr- 3 yr	3 (7)	4 (9)	7 (16)
Total	26 (58)	19 (42)	45 (100)

**Table (2): Requests for echocardiography examination of children in the study.**

Requests	Congenital heart disease		Total Number (%)
	Present Number (%)	Absent Number (%)	
Cardiac murmur	24 (25)	10 (11)	34 (36)
Dyspnea	0 (0)	19 (20)	19 (20)
Cyanosis	5 ( 5)	7 (7.5)	12 (12.5)
Fatigue	1 (1)	3 (3)	4 (4)
Follow up for previous CHD	9 (9.5)	0 (0)	9 (9.5)
Follow up for hemolytic diseases.	0 (0)	6 (6.5)	6 (6.5)
Mixed (fatigue, cyanosis, dyspnea)	6 (6.5)	5 (5)	11 (11.5)
Total	45 (47)	50 (53)	95 (100)

**Table (3): Pulse oximetry results in the study groups.**

Oximetry Results	Congenital heart disease		Total Number (%)
	Present Number (%)	Absent Number (%)	
Low Spo2	13 (14) <sup>a, e</sup>	6 (6) <sup>c</sup>	19 (20)
Normal Spo2	32 (33) <sup>d</sup>	44 (47) <sup>b, f</sup>	76 (80)
Total	45 (47)	50 (53)	95 (100)

Table 3 showed the following statistical results for Pulse oximetry in CHD:

<sup>a</sup> Sensitivity = 29 % , <sup>b</sup> Specificity = 88 % , <sup>c</sup> False positive rate = 12 %

<sup>d</sup> False negative rate = 71 % , <sup>e</sup> Positive predictive value = 68.4 %

<sup>f</sup> Negative predictive value = 57.8 % , Accuracy = 57/95 = 60 %

**Table (4): Results of pulse oximetry of acyanotic congenital heart disease children distributed to the normal babies.**

Oximetry Results	Congenital heart disease (CHD)		Total no. (%)
	Acyanotic CHD Number (%)	No CHD Number (%)	
Low Spo2	6 (6.8) <sup>a, e</sup>	6 ( 6.8) <sup>c</sup>	12 (13.6)
Normal Spo2	32 (36.4) <sup>d</sup>	44 ( 50) <sup>b, f</sup>	76 (86.4)
Total	38 (43.2)	50 ( 56.8)	88 (100)

Table 4 showed the following statistical results for Pulse oximetry in acyanotic CHD::

<sup>a</sup> Sensitivity = 15.7 %., <sup>b</sup> Specificity = 88 %., <sup>c</sup> False positive rate = 12 %

<sup>d</sup> False negative rate = 84 % , <sup>e</sup> Positive predictive value = 50 %

<sup>f</sup> Negative predictive value = 57.8 % , Accuracy = 50 /88 = 56.8 %

**Table (5): Results of oximetry of cyanotic congenital heart disease distributed to the normal children.**

Oximetry results	Congenital heart disease (CHD)		Total Number (%)
	Cyanotic CHD Number (%)	No CHD Number (%)	
Low Spo2	7 (12) <sup>a, e</sup>	6 (11) <sup>c</sup>	13 (23)
Normal Spo2	0 <sup>d</sup>	44 ( 77) <sup>b, f</sup>	44 (77)
Total	7 (12)	50 (88)	57 (100)

Table 3 showed the following statistical results for Pulse oximetry in cyanotic CHD:

<sup>a</sup> Sensitivity = 100 % , <sup>b</sup> Specificity = 88 % , <sup>c</sup> False positive rate = 12 %

<sup>d</sup> False negative rate = 0 % , <sup>e</sup> Positive predictive value = 53.8 %

<sup>f</sup> Negative predictive value = 100 % , Accuracy = 51 /57 = 89.4 %

## Discussion

Congenital heart diseases are important causes of morbidity & mortality of children. Their detection may be challenging, perhaps many difficulties might obscure the diagnosis, such as lack of cardiac murmur & subclinical cyanosis, on other

hand, physical examination skills are on decline in current trainers. Echocardiography, although an excellent diagnostic tool, it needs for special cardiologist or a trainer staff. This study was aimed to evaluate the results of oxygen saturation measured by pulse

oximetry with the purpose of use it to detect congenital heart diseases as it is readily available and well-validated test currently carried out by a nurse or a doctor.

Many studies had been done world-widely regarding accuracy of pulse oximetry as a screening test for congenital heart disease at the neonatal period, whereas this study was planned to evaluate the accuracy of pulse oximetry at different age groups of children.

The results showed that pulse oximetry had low sensitivity to detect CHD (29 %), but when it was detected, there was 68.4 % (positive predictive value) chance of being have the malformation, on the other hand, it was found that the test had high specificity (88 %), so the test was more reliable to exclude CHD but this exclusion is precise in 57.8% only (negative predictive value) because 32 child had acyanotic CHD. In general, the accuracy of the test to diagnose CHD was 60 %.

Many studies showed a sensitivity varied between 25 % & 98.5 %. [14,15] Hoke et al showed that pulse oximetry had a specificity of 88 % with 12 % false positive results., other studies showed specificity of 98-100 % with false positive rate 0%

to 2%.<sup>[15-21]</sup> It is well known that oxygen saturation decreased in cases of presence of right to left shunt (cyanotic CHD or acyanotic CHD with Eisenmenger syndrome), so it was reasonably to find normal Spo<sub>2</sub> in cases of acyanotic CHD with left to right shunt making the sensitivity of the test low. Results of the current study were slightly different from other mentioned studies, this might be due the lower proportion of cyanotic heart diseases.<sup>[7,19]</sup>

This is very obvious when applying the statistical analysis for cyanotic heart diseases and normal children which showed high sensitivity (100%) with specificity of 88% and negative predictive value 100 % with good accuracy (89.4 %), thus, pulse oximetry as a potentially useful screening test for cyanotic heart disease. A study showed specificity to detect cyanotic heart diseases nearly 100 % and other demonstrate sensitivity & specificity of pulse oximetry in 69% & 89%, respectively.<sup>[15,22]</sup>

The results of the current study were compatible with these measures, but the rate of detection (sensitivity) was somewhat higher than that recorded, this is logical but the difference might be due to conditions of each study like the

small sample size of cyanotic defects in the current study.

Many other studies evaluate the issue of physical examination together with pulse oximetry results, it yielded a sensitivity of 76.9% and specificity of 99.9% to detect CHD; other study reported that the clinical examination alone had sensitivity of 58% to detect CHD.<sup>[15,18]</sup> Therefore, limitation of pulse oximetry in certain situation, e.g. acyanotic CHD, might be over-come by taking the clinical examination in consideration, this possibly will support the idea of admitting pulse oximetry to the clinical practice.

### **Conclusion**

Pulse oximetry was found to be specific & sensitive tool to detect cyanotic CHD, so routine pulse oximetry may detect a child who might not have been detected otherwise. In a cyanotic CHD,

pulse oximetry had a limited role in detection of the defect & in spite of good specificity to exclude the defect.

### **Recommendations**

The major weakness of our study was the small number sample of the study, so we recommend to do another large well- conducted study to evaluate the pulse oximetry for every type of CHD with higher precision, in isolation or in combination with clinical examination. Further research is also required to evaluate the acceptability and consequences of the screening program to parents and medical professionals concerning rarity of the congenital heart disease in the general population versus the cost-effectiveness and the possibility of non-significant lesions being detected during echocardiography.

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