

Screening for Duct-Dependent Congenital Heart Disease with Pulse Oximetry: A Critical Evaluation of Strategies to Maximize Sensitivity

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Introduction

Congenital heart disease (CHD) is relatively common, presenting in 5 to 10 of every 1,000 live births. Early diagnosis and treatment has improved outcomes in this population. Unfortunately, current screening practices still miss a number of infants with CHD who are sent home undiagnosed. Up to 30% of deaths due to CHD in the first year of life are due to unrecognized cases that die in the community. It has been suggested that pulse oximetry might be helpful in detecting infants who may have CHD.¹ This study was designed to find out the sensitivity that could be expected from arterial saturation monitoring by observing the differences in pre and postductal measurement of SpO₂ in a population of healthy infants and a population of infants with CHD. In addition, these researchers studied the differences in the ability to detect CHD (sensitivity) between conventional and new generation pulse oximetry.

Methods

Two hundred (200) healthy newborns and sixty-six (66) infants with CHD were studied. A Masimo SET Radical with LNOP-neo sensor and a convention pulse oximeter, the Datex-Ohmeda TuffSat, with the Flex II sensor were used on each infant. The measurements were carried out in the following manner. One sensor/pulse oximeter combination was placed on the right hand of the infants while the other sensor/pulse oximeter was placed on either foot. Once readings were obtained, the sensors were switched and readings were taken at the other site. The pulse oximeters were randomly placed with each infant.

Results

The Masimo SET Radical obtained readings in all CHD infants, while the Datex-Ohmeda TuffSat obtained readings in only 76%. In addition, many SpO₂ readings less than 95% (false positives) were recorded in the normal group with the Datex-Ohmeda TuffSat. Because of this false positive rate and inability to measure in numerous infants, this conventional pulse oximeter was excluded from further analysis. By defining a positive test for CHD as a SpO₂ of < 95% in the hand and foot or a hand-foot difference of > ±3%, the screening method with the Masimo SET Radical reaches a sensitivity of 98.5%, a specificity of 96.0%, a positive predictive value of 89%, and a negative predictive value of 99.5%.

N=200 CHD Infants	% of Patients Device was Able to Obtain a Reading	Sensitivity for Detecting CHD	Specificity for Detecting CHD
Masimo SET Radical	100%	98.5%	96%
Datex Ohmeda TuffSat	76%	<i>Not Usable</i>	<i>Not Usable</i>

Authors' Discussion and Conclusions

"This study shows that the sensitivity of screening for critical congenital heart disease with pulse oximetry can be very high if a high-performance new-generation oximeter is used, and if not only postductal saturation but saturation difference between the right hand and one foot is measured."

1. Koppel et al. Effectiveness of Pulse Oximetry Screening for Congenital Heart Disease in Asymptomatic Newborns. *Pediatrics* 2003;111:451-455.