Clinical Evaluation of the Accuracy of Masimo SET and Nellcor N-595 Oximeters in Children with Cyanotic Congenital Heart Disease.

Whitney G.M., Tucker L.R., Hall S.R., Chang A.C. Anesthesiology. 2005;103:A1344.

Introduction

Several studies have demonstrated the relative inaccuracy of pulse oximetry in patients with low oxygen saturations. In patients with congenital heart disease, this proves to be a frequent shortcoming of pulse oximetry monitoring. The Blue Sensor probe developed by Masimo, Inc. is specifically designed to monitor low oxygen saturation in patients with hypoxemia.

This prospective, observational study was designed to assess the bias and precision of Nellcor N-595 using the OxiMax Max-I sensor and Masimo SET Radical Blue Sensor pulse oximeters in children with cyanotic congenital heart disease admitted to the pediatric cardiac intensive care unit.

Methods

Seven patients with cyanotic congenital heart disease with SaO2 <90% were enrolled. Measurements of SaO2 of whole blood were compared with simultaneous pulse oximetry saturations (SpO2) obtained using both Nellcor N-595 using the OxiMax Max-I sensor and Masimo SET Radical Blue Sensor. Data were analyzed to determine the precision and bias of the Nellcor N-595 pulse oximeter when compared to the Masimo SET pulse oximeter using the Blue Sensor probe.

Results

A total of 22 SaO2 measurements were recorded; the mean SaO2 was 75.8 % +/- 9.3% (60.9% - 91%). There was a significant difference in bias (SaO2 – SpO2) and precision (+/- 1 SD) detected in patients with cyanotic congenital heart disease. (p=0.0001)

Bias and Precision of the Nellcor N-595 v.	Bias and Precision of the Nellcor N-595 v. Masimo SET Radical Blue Sensor	
	Bias	Precision
Masimo SET Blue Sensor	0.17	2.51
Nellcor N-595	5.63	5.24

Discussion

Masimo SET Blue Sensor technology offers improved accuracy in the monitoring of SaO2 when compared to the Nellcor N-595 pulse oximeter in patients with cyanotic congenital heart disease. This represents a significant advance in the care of this complicated group of patients.