Clinical Trial Of New Pulse Oximetry Sensor Designed For Use On Children With Congenital Cyanotic Cardiac Disease.

Cox P.N., Fernandes K. *Respir Care*. 2005;50(11):1517.

Introduction

Pulse oximetry has been recognized as a standard monitoring tool for patients in the operating room and the intensive care unit. This wide acceptance of the technology has occurred despite the recognized inaccuracy of the technology at saturations below 70%. This continues to be a problem despite advances in pulse oximetry technology in other areas such as motion resistance and low perfusion sensitivity. As patients with congenital cyanotic cardiac lesions (CCCL) have low oxyhemoglobin saturation levels, they present specific problems for pulse oximeters. Masimo Corporation has developed a sensor, the "Blue" sensor, specifically designed for use in patients with chronically low saturations. We set out to test the accuracy of a traditional pulse oximeter sensor and a new Blue sensor in CCCL patients in the Critical Care unit.

Methods

Following IRB approval, patients with CCCL were studied while in the ICU. Monitoring included all monitoring routine for the postoperative care of these patients, including our standard pulse oximeter sensor, a Masimo LNOP sensor. In addition to the standard sensor, a Blue sensor was placed on the thumb of the left hand and the great toe of either foot, as recommended by the manufacturer. Data from all 3 pulse oximetry sensors was recorded on a laptop computer. Arterial blood gases (ABG), including CO-oximetry (SaO2), the gold standard were obtained as clinically indicated. The time the ABG was obtained was noted in the computer record. SpO2, from the three oximeters, and SaO2 were compared using linear regression analysis and the Bland Altman technique of calculating bias and precision. Additionally, paired t-test was used to compare the errors (bias) from each of the three sensors.

Results

A total of 21 patients (12 males) were studied. The mean (± SD) age and weight were 50 (± 58) days and 4.1 (± 1.1) kgs, respectively. A total of 160 ABGs (mean ± SD = 7.6 ± 4.7 per patient) were obtained in this patient population. The mean (± SD) and range of the SaO2 was 71.9% (± 6.6%) and 85.8% - 53.3%. The bias, precision and the regression analysis are presented in Table.

	SaO2 (CO-oximetry)	Blue Sensor on Thumb	Blue Sensor on Toe	LNOP Sensor
Mean (±SD) %	71.9 (6.6)	71.8 (7.7)	71.4 (7.6)	76.6 (5.3)
Range %	85.8 - 53.3	93 - 50	92 - 47	92 - 61
Bias	-	-0.22	-0.56	4.7 *
Precision	-	3.82	3.47	5.2
R2 value	-	.755	.792	.408
Regression equation	-	= -1.155 + 1.013(x)	= -2.065 + 1.021(x)	= 39.65 + 0.514(x)

Table: The bias, precision and regression analysis for the new Blue sensor placed on either the thumb or toe and the LNOP sensor in 21 children with congenital cyanotic cardiac lesions. Paired t-test of the bias shows a significant difference between the LNOP and the Blue sensor, on either site, $p < 0.001$.

Discussion

Accurate pulse oximetry monitoring provides a valuable clinical tool. Despite advances in technology, previous oximeters were inaccurate in the range of saturations found in this patient population. The new Masimo Blue sensor, designed for use specifically in this patient population, is more accurate as demonstrated by a smaller bias and precision, than the standard LNOP sensor.