New Pulse Oximetry Sensors with Low Saturation Accuracy Claims - A Clinical Evaluation
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Introduction

Despite the recognized inaccuracies of pulse oximetry at oxyhemoglobin saturations below 70%, pulse oximetry has been recognized as a standard monitoring tool for patients in the operating room and the intensive care unit. Despite advances in pulse oximetry technology in other areas such as motion resistance and low perfusion sensitivity, monitoring low oxyhemoglobin continues to be a problem. Recently, both Masimo and Nellcor have introduced sensors with accuracy claims for saturation levels below 70%. Patients with congenital cyanotic cardiac lesions (CCCL) have low oxyhemoglobin saturation levels. Careful maintenance of these low saturations, within very narrow limits, is required to ensure adequate cardiac output and peripheral perfusion prior to surgical correction of certain CCCL. For this reason, these patients present specific problems for pulse oximeters. We set out to test the accuracy of a traditional pulse oximeter sensor and these new sensors in CCCL patients in the Critical Care unit.

Methods

Following IRB approval, patients with CCCL were studied while in the ICU. Monitoring for the postoperative care of these patients was routine, and included our standard pulse oximeter sensor, (Masimo LNOP). In addition to the standard sensor, a Masimo LNOP Blue sensor attached to a Masimo SET Radical pulse oximeter and a Nellcor Max-I attached to a Nellcor N600 pulse oximeter equipment with LoSat was placed on the thumb of the left hand, or 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, the Bland Altman technique of calculating bias and precision and the ARMS, an accuracy statistic used by the FDA. Additionally, paired t-testing was used to compare the ARMS (accuracy) from each of the three sensors.

Results

A total of 8 patients (4 males) were studied. The mean (+ SD) age and weight were 33 (+ 34) days and 5.8 (+ 2.8) kgs, respectively. A total of 41 ABGs (mean + SD = 5 + 2.7 per patient) were obtained. The mean (+ SD) and range of the SaO2 was 72.5% (+ 7.6%) and 85% - 56.1%. The bias, precision and the regression analysis are presented in Table.

	SaO2	Masimo Blue Sensor	Nellcor N 600 Max-I sensor	LNOP sensor
Mean (+SD) %	72.5 (7.6)	70.6 (8.1)	75.9 (7.0)	74.3 (7.0)
Range %	85 - 56.1	87 - 52	89 - 61	91 - 57
Bias	-	-1.91	3.38	1.82
Precision	-	3.32	4.60	6.31
ARMS		3.83 *	5.71	6.57
R2 value	-	.832	.638	.399
Regression equation	-	= 0.854 + 0.962(x)	= 32.178 + 0.603(x)	= 32.264 + 0.580(x)

Table - The bias, precision, A_{RMS} and regression analysis for the new sensors with low saturation accuracy claims, and the LNOP sensor in 8 children with congenital cyanotic cardiac lesions. Paired t-test of the A_{RMS} shows a significant difference between the Masimo LNOP Blue and the other sensors, $p < 0.001$.

Discussion

Accurate pulse oximetry monitoring provides a valuable clinical tool. Despite advances in technology, only the new Masimo Blue sensor demonstrates acceptable accuracy as demonstrated by a smaller bias, precision, and A_{RMS}.