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 is recognized as a standard monitoring tool for patients in the operating room and the intensive care unit. 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 ICU.

Methods

Following IRB approval, patients with CCCL were studied while in the ICU. In addition to routine monitoring which included our standard pulse oximeter sensor, (Masimo LNOP), 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 with LoSat was placed on the thumb of the left hand, or the great toe of either foot, as recommended by the manufacturer. Arterial blood gases (ABG), including CO-oximetry (SaO2), the gold standard, were obtained as clinically indicated. SpO2, from the three oximeters, and SaO2 were compared using linear regression analysis 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 12 patients (7 males; 5 females) were enrolled and studied. The mean (+ SD) age and weight were 6.5 (+ 7.0) months (range 7 days to 23 months) and 5.2 (+ 2.5) kg, respectively. A total of 60 ABGs were compared (mean + SD = 4.9 + 2.4 per patient) in this patient population. The mean (+ SD) of the SaO2 was 72.3% (+ 7.3%) and the range of the SaO2 85% - 56.1%. Table 1 shows the distribution of SaO2 values, the bias, precision, ARMS and the regression analysis.

Discussion

Accurate pulse oximetry monitoring provides a valuable clinical tool. One potential explanation for the observed differences in sensor performance involves the method of calibration used by the manufacturers. The Nellcor LoSat claims are obtained from healthy volunteers in the laboratory, while the Masimo Blue Sensor claims are obtained from data collection in actual patients suffering from CCCL. Despite advances in technology, only the new Masimo Blue sensor demonstrates acceptable accuracy as demonstrated by a smaller bias, precision, and ARMS.[table1]

	SaO2 (CO-oximetry)	Masimo SET Radical with Blue Sensor	Nellcor N600 with Lo-Sat and Max-I sensor	LNOP Sensor
Mean (±SD)%	72.3 (7.4)	70.5 (7.5)	75.9 (5.6)	75.2 (6.4)
Range %	85 - 56.1	87 - 52	89 - 61	91 - 57
Bias	-	-1.91	3.81	1.86
Precision	-	3.50	5.26	6.24
ARMS	-	3.97*	6.49	6.51
R^2 value	-	.886	.698	.60
Regression Equation	-	=6.60 + 0.886(x)	=37.7 + 0.531(x)	=37.2 + 0.526(x)

Table 1- The bias, precision, ARMS and regression analysis for the new sensors with low saturation accuracy claims, and the LNOP sensor in 12 children with congenital cyanotic cardiac lesions. Paired t-test of the ARMS shows a significant difference between the Masimo LNOP Blue and the other sensors, $p < 0.001$.