The Bias and Precision of a New Generation of Pulse Oximeter.

Gehring H., Hornberger C., Matz H., Schäfer R., Konecny E., Schmucker P. *Respir Care* 2000; 45(8):019.

Introduction

A new generation of pulse oximeter (PO) has addressed requirements for an improved performance during motion (1) and low perfusion (2,3) artefact simulation. However, the validation of screening accuracy, bias and precision against the gold standard oximetry has yet to be proven.

Methods

Nine healthy volunteers participated after written informed consent and approval by the Ethics Committee of the Medical University of Luebeck were obtained. A 24 gauge radial artery cannula was placed in the non-dominant hand for arterial blood sampling using a dry heparinized 2 ml Monovette® LH (Sarstedt, Germany). The reference oximeters were an OSM-3 (Radiometer, Copenhagen) and a 270 CO-Oximeter (Ciba-Corning), where SaO2 samples were measured in a random fashion. The PO battery consisted of a Datex-Ohmeda 3900, Agilent Technologies (formerly Hewlett-Packard) CMS monitor software Rev. B.0, a Nellcor/Mallinckrodt N-395, and a Schiller OX-1 (identical to the IVY 2000) incorporating Masimo SET technology. 3 Nellcor/Mallinckrodt N-3000s served to represent the established generation of pulse oximeter and provided a control for the desaturation procedure. The SpO2 data of all devices were recorded continuously during a desaturation procedure where the monitored saturation was between 70 and 100%. To allow stable conditions for all the pulse oximeters, plateaus were established at saturation steps of 5%.

Results

Table 1 shows the bias (mean of differences between SaO2 and SpO2) and precision (± 1sd) as well as the Pearson's correlation coefficient r and the R2-values from the data of the tested PO battery.

	N 3000	N 3000	N 395	Agilent	D-O 3900	IVY 2000
N	274	274	274	274	262	274
Mean	-0.6	-0.1	-0.9	1.2	-1.5	0.8
±1 sd	1.4	1.2	1.8	1.6	1.7	1.8
r	0.98	0.98	0.97	0.97	0.97	0.98
R^2	0.96	0.97	0.94	0.94	0.95	0.96

Conclusions

All PO tested in this investigation fulfilled the high standard of accuracy within the range -2 £ D Sa-pO2 £ 2.

References: 1. Barker SJ et al.: Anesthesiology 1999; 91:A581 ; 2. Russel GB et al.: Anesthesiology 1999; 91:A582; 3. Russel GB et al.: Anesthesiology 1999; 91:A584