

Sensitivity and Specificity Performance during Motion Artifact in Three Pulse Oximeters Designed for Use in Motion.

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Introduction

Two new pulse oximetry signal processing methodologies (Nellcor/Oxismart XL® and Masimo SET®) have been introduced for the continuous and accurate reading of saturation (SpO₂) during patient motion. We evaluated and compared these two new devices with a third device (NPB-290/Oxismart®) that was designed to only accept and post values from qualified pulses during motion. This study targeted the effects of motion artifact on the alarm performance of these three pulse oximeter technologies in normal adult subjects during stable normoxic and hypoxic plateaus and rapid desaturation-resaturation epochs.

Methods

With IRB approval and informed consent, 24 healthy volunteers (8 men / 16 women) age 24-55 yr were separated into 3 groups of 8 and studied under 3 different protocols. Protocol 1 consisted of 4 mild motion periods (1 min) during both stable normoxia (SpO₂ = 93-97%) and stable hypoxia (SpO₂ = 73-77%). Protocol 2 consisted of 4 mild motion periods (2-3 min) each during rapid desaturation from 100 to 70% and resaturation from 70 back to 100%. Protocol 3 was the same as 2 except that the 4 motions were more severe. Each instrument on the motion hand was compared to a like instrument on the same digit of the non-motion hand, and sensor sites were rotated between subjects in a balanced design. Each protocol consisted of 32 normoxic [True Negative (TN)] motion events and 32 hypoxic [True Positive (TP)] motion events. Using a threshold of SpO₂ < 90% to denote hypoxia, detected hypoxia (TP), detected normoxia (TN), missed alarms (False Negative (FN)), false alarms [False Positives (FP)], Sensitivity [TP/(TP+FN)], and Specificity [TN/(TN+FP)] were calculated. Drop outs were attributed either to the false negative or false positive rates depending if they occurred during hypoxia or normoxia. A non-parametric chi square analysis was used to determine statistical differences at the p<0.05 level.

Results

The results are summarized in the table. p<0.05 = * for N-395 vs Ivy/Massimo, £ for N-395 vs NPB-290 and † for Ivy/Massimo vs NPB-290.

Discussion

The voluntary motions used in this study significantly affected the performance of all three pulse oximeters. The N-395/Oxismart XL® and Ivy/Masimo SET® had similar performance as measured by sensitivity and specificity for detecting induced hypoxic events in the presence of mild motion and was superior to the NPB-290/Oxismart®. However, during severe motion artifact the N-395/Oxismart XL® exhibited superior performance, Ivy/Masimo SET® intermediate, while the NPB-290/Oxismart® fared the worst in the motions utilized in this study. The newer oximeter signal processing algorithms appear to be a significant advance over the NPB-290/Oxismart® when pulse oximeters signals are corrupted by motion artifact.

Alarm state	←----- Mild Motion ----->			←----- Severe Motion ----->		
	N-395	Ivy 2000	NPB-290	N-395	Ivy 2000	NPB-290
True Pos.	64	61	63	30	26	19
False Neg.	0	3	1	2	6	13
True Neg.	63	62	56	29	25	22
False Pos.	1	2	8	3	7	10
£ Drop out	0	0	5	1	6	21
Sensitivity	1.00	0.95	0.98	0.94 * £	0.81 * †	0.59 £ †
Specificity	0.98 £	0.97 †	0.88 £ †	0.91 * £	0.78 * †	0.69 £ †