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Comparison of NIRS Technology Performance During Acute Hypoxia and Hemorrhagic Shock

Katherine E. Liu, PhD[1], Ulf Borg[2]

[1]Clinical Research, Patient Monitoring, Medtronic; [2]Medical Science, Patient Monitoring, Medtronic

Background

Near infrared spectroscopy (NIRS) is used to measure regional oxygen saturation, including both cerebral and somatic oximetry as a marker of perfusion.[1] Understanding cerebral and tissue oxygenation can assist clinicians in managing patients' hemodynamics. For example, cerebral desaturation events during surgery can lead to cognitive decline, major organ morbidity and mortality, renal failure, and stroke.[2-6] In cardiopulmonary bypass surgery, cerebral desaturation events are common, occurring in up to 61% of patients.[7] Previous Medtronic-independent, randomized prospective studies have shown that use of the INVOS™ monitoring system quickly identifies cerebral desaturation during surgery, allowing for interventions which can reduce patient ICU length of stay, decrease major organ morbidity, and reduce the odds of post operative cognitive decline.[2,5]

Importantly, although NIRS devices are commercially available from several manufacturers, multiple studies have reported that the devices' clinical performance differs. For example, in a Medtronic-sponsored prospective healthy volunteer study, Tomlin et al found that during controlled desaturation, there were significant differences between Medtronic, Nonin, and Edwards monitors, with the INVOS™ regional oximeter meeting a 20% relative decrease threshold, defined as cerebral desaturation, in all 10 healthy volunteers, compared to 1 or 2 healthy volunteers with EQUANOX and FORE-SIGHT, respectively.[8] The INVOS™ regional oximeter also detected a 10% relative decrease in cerebral oxygenation an average of 28 seconds earlier than EQUANOX, and 43 seconds earlier than FORE-SIGHT.[8] Other Medtronic-independent, prospective, healthy volunteer and patient studies have confirmed that the rates of desaturation and resaturation are significantly different between Medtronic, Nonin, and Masimo NIRS devices.[9-11] Due to differences in sensor designs, algorithms, and device performance, multiple groups have concluded that clinicians should be cautious in generalizing the findings of one NIRS device to all NIRS devices.[8,11-14] This is supported by multiple prospective, Medtronic-independent studies,[2,11,14] and by the American Society for Enhanced Recovery and Perioperative Quality Initiative Joint Consensus.[15]

The purpose of this study was to compare the performance of multiple NIRS devices in a pre-clinical setting designed to reflect relevant clinical scenarios, including acute hypoxia and hemorrhagic shock.

Methods

Test Devices

4 NIRS devices were tested, including the INVOS™ 7100 Regional Oximeter (Medtronic), EQUANOX 7600 (Nonin), FORE-SIGHT ELITE (Edwards), and Root O3 (Masimo) monitors.

Procedure

Healthy porcine weighing between 30-35lb were assessed. Each animal underwent anesthesia during the procedures. The study was performed at a lab accredited by the Association for Assessment and Accreditation of Laboratory Animal Care, and the protocol was approved by the site Animal Care and Use Committee.

Monitoring Procedures

NIRS sensors were placed between the ears, in front of the Nuchal crest, and over the peri-renal area on the left side. During each clinical scenario, one adult sensor from the Medtronic system and one adult sensor from either the Nonin, Edwards, or Masimo system were placed on the head simultaneously. The somatic sensors were placed over the peri-renal area with the emitters of each sensor facing in opposite directions, to avoid interference.

Acute Hypoxia

To induce acute hypoxia, the ventilator FiO_2 was rapidly decreased from 1.0 (baseline) to 0.08. When the animal reached SpO_2 of 40% ± 10%, this was held for 2 minutes, during which $CrSO_2$ and $RrSO_2$ were noted, and then FiO_2 was returned to baseline. This procedure was repeated once for each animal. After the repeat hypoxia procedure, the animal was allowed to recover to baseline.

Hemorrhagic Shock

Hypovolemia was induced by removing a total of 60% of the animal's calculated blood volume, in 3 steps of 20% blood volume reduction. At each step, physiological parameters were noted. To resuscitate the animal, the procedure was reversed, with blood volume restored in the same stepwise manner. At each step, physiological parameters were recorded.

Results

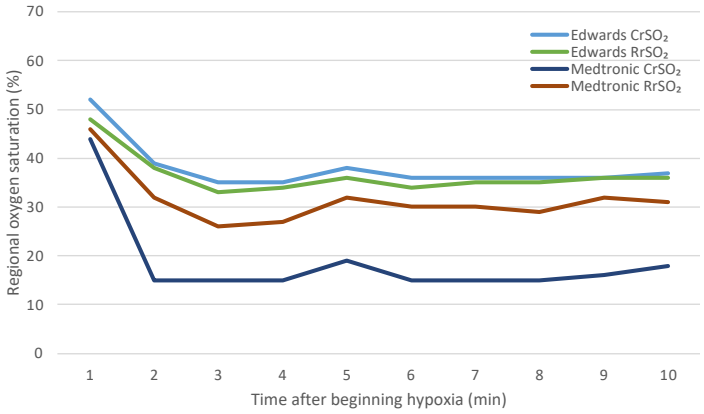
Across the procedures, the Nonin device exhibited signal interference, and was excluded from the analysis.

Acute Hypoxia

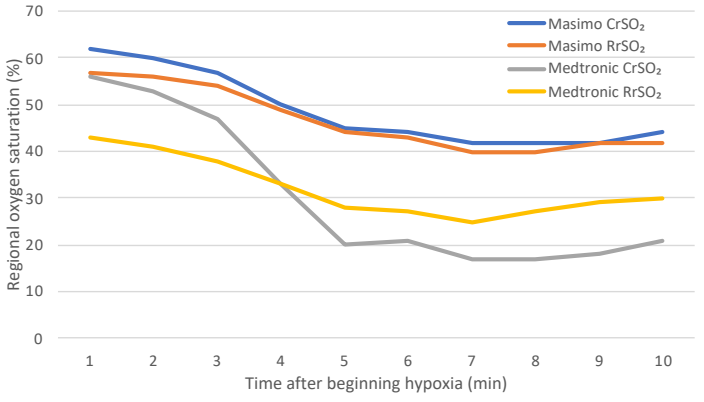
Compared to the Edwards device, the Medtronic device measured a large, rapid decrease in $CrSO_2$ within the first 2 minutes of hypoxia, dropping from 44% to 15% (66% decrease from baseline). In contrast, the Edwards device measured a drop from 52% to 39% (25% decrease from baseline) during the same time period. A similar pattern was observed in $RrSO_2$ measurements. While the Edwards device detected a decrease in both cerebral and peri-renal oxygen saturation, the magnitude of the change was consistently smaller (Figure 1A). The same trend occurred when comparing the responses of the Masimo and Medtronic devices during acute hypoxia. Relative to the baseline reading for each system, the Medtronic device measured $CrSO_2$ and $RrSO_2$ decreases of 70% and 42%, while the Masimo device measured decreases of 32% and 30%, respectively (Figure 1B).

Figure 1. Cerebral and peri-renal oxygen saturation during hypoxia, measured using A) Edwards and Medtronic devices, and B) Masimo and Medtronic devices.

A)



B)

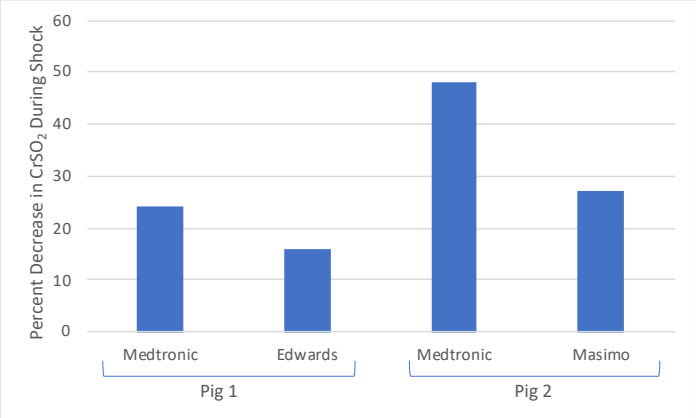


Hemorrhagic Shock

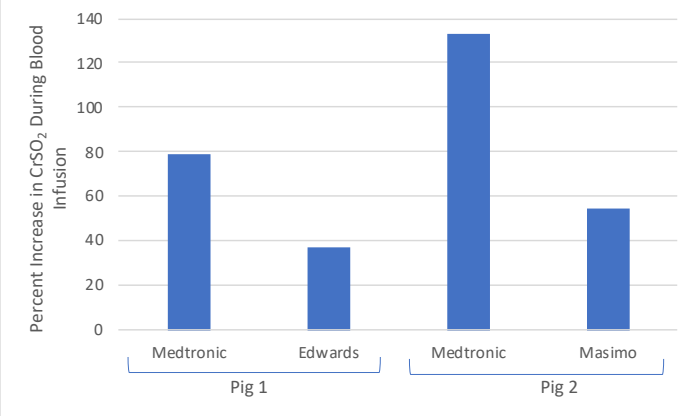
During induction of hemorrhagic shock, the Medtronic device had a more dynamic change in both $CrSO_2$ and $RrSO_2$ (24% and 10% from baseline, respectively), compared to the Edwards device (16% and 5% from baseline, respectively) (Figure 2A). The percent decrease in $CrSO_2$ was also larger for the Medtronic device (48%), compared to the Masimo device (27%) (Figure 2A). The Medtronic device also had a larger magnitude response in $CrSO_2$ during blood re-infusion, compared to either the Edwards (79% vs 37% increase from baseline, respectively) or Masimo (133% and 55% increase from baseline, respectively) devices (Figure 2B).

Figure 2. Percent change in cerebral oxygen saturation during A) shock, and B) during blood re-infusion.

A)



B)



Discussion

During acute hypoxia and hemorrhagic shock, the Medtronic, Edwards, and Masimo devices all detected changes in cerebral and peri-renal oxygen saturation. Importantly, the Medtronic INVOS™ 7100 regional oximeter showed greater responsiveness in regional oxygen saturation, including both $CrSO_2$ and $RrSO_2$, compared to the Edwards and Masimo devices. This is consistent with a previous Medtronic-sponsored animal study of acute hypoxia comparing the INVOS™ 5100C regional oximeter to NIRS devices from other manufacturers, where the Medtronic device demonstrated a faster response time, a greater magnitude change in regional oxygen saturation, and strong correlation to SpO_2 during the transition from normal oxygenation to hypoxia.[16] The results of this study are also consistent with prospective healthy volunteer studies, both MDT-sponsored and MDT-independent, which have reported that the INVOS™ regional oximetry system detects deoxygenation faster and has a more dynamic range compared to other NIRS devices, such as those from Nonin, Edwards, and Masimo.[8,11]

In circumstances where a patient experiences cerebral or tissue desaturation, the regional oximetry system needs to respond quickly in order to alert the clinician and allow adequate time for intervention. Combined with existing literature, this new data supports the conclusion that other NIRS devices do not respond the same as the INVOS™ regional oximetry system during critical physiological challenges, such as hypoxia or shock.[9,13,17] Care should be taken when selecting a regional oximeter, to ensure clinicians can achieve the best outcomes for their patients.

The INVOS™ monitoring system should not be used as the sole basis for diagnosis or therapy and is intended only as an adjunct in patient assessment. Reliance on the INVOS™ system alone for detecting cerebral desaturation events is not recommended.

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