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Absolute and Trending Accuracy of FORE-SIGHT and INVOS Cerebral Oximeters in Healthy Volunteers

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Introduction: The purpose of this study is to compare simultaneous measurements from two FDA-approved near-infrared spectroscopy (NIRS) cerebral oximeters: FORE-SIGHT® (CAS Medical Systems, Branford CT), and INVOS® 5100C (Somanetics Corp., Troy MI) against the commonly used gold standard of weighted co-oximetry jugular bulb and arterial oxygen saturation values during episodes of deliberate oxygen desaturation.

Methods: Healthy adult subjects were enrolled in this IRB-approved volunteer study after obtaining written informed consent. A right internal jugular bulb catheter and a left radial arterial line were placed. FORE-SIGHT and INVOS adult sensors were placed on the right & left forehead respectively. A Sequential Gas Delivery system (Respiract, Thornhill Research, Toronto) was used to deliver gas mixtures following a protocol of step changes of room air, 21%, 8%, 21%, & 50% inspired oxygen at five minute intervals. Oxygen saturation (S_pO_2) was maintained > 70% when measured at the finger. Blood samples were drawn simultaneously from the jugular bulb ($S_{jv}O_2$) and radial arterial (S_aO_2) catheters and analyzed for oxygen tension using a co-oximeter (GEM 4000, IL, Lexington MA). Co-oximeter reference values, CX(F) and CX(I), were calculated based upon previous validation studies of each monitor:

$$CX(F) = [0.3 \times S_aO_2] + [0.7 \times S_{jv}O_2]$$

$$CX(I) = [0.25 \times S_aO_2] + [0.75 \times S_{jv}O_2]$$

Absolute and trending NIRS-derived cerebral tissue oxygen saturation values determined by the FORE-SIGHT ($S_{ct}O_2$) and INVOS (rSO_2) monitors were modeled as a function of CX(F) and CX(I) using linear regression. Bias and precision (1 standard deviation) were also determined.

Results: 12 subjects (8 male/4 female; 9 Caucasian/3 African American; Age: 21-34 y; weight 56-95 kg) completed the study protocol. A total of 58 samples were analyzed. PaO_2 ranged from 38 - 449 mmHg; $P_{jv}O_2$ ranged from 23 - 63 mmHg and P_aCO_2 ranged from 31 - 53 mmHg. The range of baseline room air values for FORE-SIGHT $S_{ct}O_2$ was 68-76% and for INVOS rSO_2 was 48-89%. The range of baseline room air reference values for CX(F) was 69.7-80.0% and for CX(I) was 67.6-78.7%. Regression lines for absolute cerebral tissue oxygen saturation values against co-oximeter reference values are shown in Figure 1. Regression lines for trending changes of cerebral tissue oxygen saturation values are shown in Figure 2. For 2/12 subjects, the change in INVOS rSO_2 from room air baseline to hypoxic challenge (F_iO_2 8%) exceeded the change in CX(I) by 2 standard deviations (9.16%), giving the appearance that cerebral oxygen saturation was falling more rapidly than it really was. This did not occur for transitions of $S_{ct}O_2$ for FORE-SIGHT. **Conclusion:** The results demonstrate that the FORE-SIGHT cerebral oximeter monitor has much greater precision with respect to measuring both absolute and trend changes in cerebral tissue oxygen saturation than the INVOS cerebral oximeter monitor.

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Figure 1



