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Validation of the FORE-SIGHT® Pediatric NIRS Cerebral Oximeter

Barry D. Kussman, M.B.B.Ch., Peter C. Laussen, M.B.B.S., Paul B. Benni, Ph.D., Doff B. McElhinney, M.D., Francis X. McGowan, Jr., M.D.
Anesthesiology, Perioperative & Pain Medicine, Children's Hospital Boston and Harvard Medical School, Boston, Massachusetts

Introduction:

Near infrared spectroscopy (NIRS) is increasingly used to monitor cerebral O₂ balance. Near-infrared light propagation is affected by differences in the anatomy of adult and pediatric foreheads and with source-detector spacing¹. The FORE-SIGHT® (CASMED, Branford, CT) uses a laser diode and 4 wavelengths of light to measure cerebral tissue oxygen saturation. FDA clearance has been received for clinical use of the FORE-SIGHT® cerebral oximeter in human adult (>40 kg) and neonatal/infant (2.5-8 kg) subjects. The aim of this study was to validate the FORE-SIGHT® cerebral oximeter in pediatric subjects (>4-< 50 kg) using a pediatric sensor with a source-detector separation of 40 mm.

Methods:

With IRB approval and written informed consent, 53 pediatric subjects with congenital heart disease undergoing elective cardiac catheterization were enrolled. FORE-SIGHT® pediatric sensors were applied bilaterally to the forehead to measure cerebral oxygen saturation (SctO₂) by NIRS. Reference blood samples were obtained simultaneously from the aorta or femoral artery (SaO₂) and the internal jugular vein bulb (SjvO₂) and analyzed by co-oximetry. As the arterial fraction of cerebral blood volume is estimated at 30%², a reference for SctO₂ was determined as REF SctO₂ = (0.3*SaO₂) + (0.7*SjvO₂)³. SctO₂ was compared to REF SctO₂ using linear regression, with determination of bias and precision (1SD). Regression techniques were used to evaluate the effects of age, weight, and head circumference on NIRS accuracy.

Results:

Forty subjects (0.4-16 yr; 4.6-49.5 kg, head circumference 38.0-54.6 cm, male 58%) completed the study protocol; technical difficulties during jugular bulb sampling resulted in exclusion of 13 subjects from analysis. A total of 218 samples were analyzed. Baseline saturation data (%) were SaO₂ 77.0-99.2, SjvO₂ 44.0-84.6, SctO₂ 55.9-85.4, REF SctO₂ 54.3-87.2. An initial analysis of SctO₂ accuracy using adult calibration of the pediatric sensor showed a bias of -2.56 and precision (1SD) of 5.55%. Linear regression of the SctO₂ error (SctO₂ - REF SctO₂) was statistically significant (P=0.001) for weight, age, and head circumference, with the SctO₂ error greatest for the lower weight subjects (Figure 1a). A correction factor modeled into the FORE-SIGHT® calibration as a function of weight <30 kg improved the SctO₂ bias and precision to -0.04 and 5.36%, respectively (Figure 1b).[figure1]

Discussion:

This study validates the pediatric FORE-SIGHT® cerebral oximeter to accurately measure cerebral tissue oxygen saturation. The improvement in accuracy of the FORE-SIGHT® in pediatric patients after adjusting the calibration was related to weight, age, and head circumference; this may reflect the shift in the relative ratio of brain gray and white matter and extracerebral tissue during development¹.

References: 1. Applied Optics 2003;42:2881. 2. Ann Nucl Med 2001;15:111. 3. Adv Exp Med Biol 2005;566:195.

From Proceedings of the 2009 Annual Meeting of the American Society Anesthesiologists.

Figure 1

Figure 1(a): NIRS SctO2 error due to weight using fixed calibration

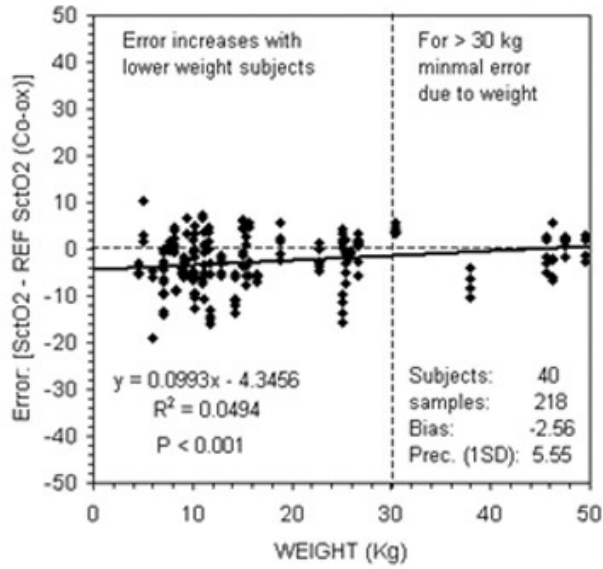


Figure 1(b): NIRS SctO2 with weight corrected calibration

