A Novel Device to Measure Cerebral Oxygen Saturation in Neonates, Infants and Children

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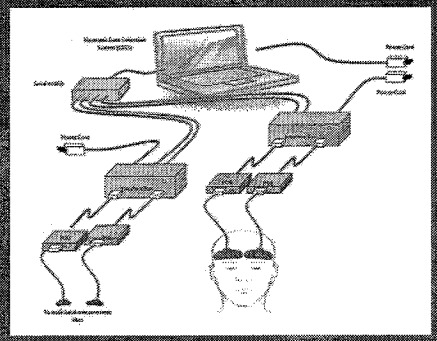
Introduction: Neurological sequelae following states of hypoperfusion occur in children as a result of cerebral hypoxia-ischemia. Near-infrared spectroscopy (NIRS), a non-invasive optical technology, can be utilized at the bedside to monitor brain oxygenation to detect tissue hypoxia-ischemia, allowing for early intervention and potential prevention of permanent injury. The purpose of this study was to calibrate and validate an advanced technology NIRS regional cerebral oximeter for use in neonates, infants and children.

Methods: 100 children aged <12 years weighing <40 kg with cardiovascular disease and no neurologic, hematologic or craniofacial disease undergoing cardiac catheterization using general anesthesia were enrolled. Arterial and jugular bulb venous blood were obtained for co-oximetry simultaneously with the NIRS optical signal from each patient to calculate a weighted average cerebral oxygen saturation ($SavO_2$= 0.7 SjO_2 + 0.3 SaO_2). The NIRS optical signals were calibrated against $SavO_2$ to create an algorithm to determine NIRS regional cerebral oxygen saturation ($rScO_2$). Device accuracy was assessed by correlation, bias, precision, A_{rms}, linear regression and Bland- Altman analysis.

NIRS Device:

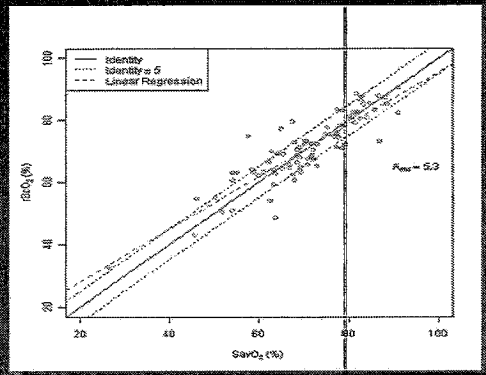
- Dual emitter/dual detector configuration
- Four wavelengths of light (730, 760, 810, 880 nm) from light emitting diodes (LEDs)
- Dynamic compensatory algorithms
- One common sensor



Results: 86 patients were included in the analysis, while 14 were excluded for protocol violations (incomplete blood draws or processing errors). There were 7 neonates, 44 infants, and 35 children; of these, 54% were female, 79% Caucasian, and 40% with cyanotic disease (table).

Subject Demographics	Results (n=86 subjects)
Age (years)	
Neonates (0-30 days)	7/86 (8.1%)
Infants(31 days -2 years)	44/86 (51.2%)
Children (2-12 years)	35/86 (40.7%)
Gender	
Male	39/86 (45.3%)
Female	47/86 (54.7%)
Weight (kg)	8.4 ± 8.3
Skin Tone	
very light	14/86 (16.3%)
Light	47/86 (54.7%)
Light Intermediate	14/86 (16.3%)
Dark Intermediate	5/86 (5.8%)
Dark	6/86 (7.0%)
Cyanosis	
Cyanotic	35/86 (40.7%)
Acyanotic	51/86 (59.3%)

Arterial saturation, $rScO_2$, and $SavO_2$ ranged from 34 to 100%, 34 to 91% and 26 to 91% respectively. Hemoglobin concentration ranged from 8-23 g/dL and bilirubin from 0.2 to 6.2 mg/ml. Arterial pCO_2 ranged from 28-61 mmHg. The A_{rms}, bias and precision between $SavO_2$ and $rScO_2$ were 5.3%, 0 ±5.3% and 5.3%, respectively (figure). $SavO_2$ and $rScO_2$ were related linearly (y=0.85x+11, r=0.88). Relationships between age, skin color, bilirubin, hemoglobin and arterial saturation with accuracy were not detected.



Conclusions: This NIRS regional cerebral oximeter accurately measures cerebral oxygen saturation in children over a wide range of age, skin color, oxygenation, and hemoglobin. It offers advantages over other NIRS devices by using one common sensor to measure the absolute value of cerebral oxygen saturation in a more diverse population as might be encountered clinically in an operating room or intensive care unit.

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