Evaluation of a Novel Cerebral Oximeter for Congenital Heart Disease

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Disclosures

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Introduction

• Neurologic sequelae following congenital heart surgery are not uncommon
  – Stroke rate 5.4 in 1000 patients
  – Seizures reported in 2.3% of patients
• Neurodevelopmental issues not apparent until later in life
• Cerebral hypoxia-ischemia identified as a contributor
• Potential for early intervention if recognized

Near infrared spectroscopy (NIRS)
What Does NIRS Measure?

- O₂ Supply
  - CBF
  - SaO₂
  - Hct
  - P₅₀

- O₂ Demand
  - CMRO₂

How Does NIRS Work?

- Spectrophotometer
  - oxy & deoxy hemoglobin (SO₂)
  - Log (I/I₀) = SO₂

- Probe
  - sits on head
  - scalp, skull, brain

Light Source (I₀)

Detector (I)
NIRS Summary

- Similar to pulse oximetry
  - Measures hemoglobin saturation with light
  - Non-invasive, continuous, bedside

- Different from pulse oximetry
  - Gas exchanging vessels (capillaries, venules, arterioles)
  - Tissue oxygen supply/demand
  - 1000 fold greater signal
  - Monitors for tissue hypoxia-ischemia

Study Aim

- Calibrate and validate an advanced technology NIRS device to measure cerebral tissue oxygen saturation in children with cardiovascular disease
Patient Population

- Inclusion criteria
  - Neonates, infants and children
  - Weight < 40 kg
  - Cardiovascular disease
  - Various oxygen saturations
  - Undergoing cardiac catheterization

- Exclusion criteria:
  - Adhesive allergy or skin condition
  - Craniofacial disease
  - Hemoglobinopathy
  - Cerebrovascular disease/acute neurologic injury
  - Life threatening condition

Measurements

- NIRS
  - rScO₂

- Co-oximetry
  - Arterial and jugular bulb venous saturation
  - Total hemoglobin concentration and hematocrit
  - Blood gas (pH, pCO₂, pO₂, SaO₂)
  - Carboxyhemoglobin and methemoglobin

- Chemistry
  - Serum bilirubin
Study Design

• 2 phases:
  – Calibration
    • Calibrate a NIRS regional cerebral saturation (rScO₂) to weighted average cerebral saturation
    • SavO₂=0.7 SjO₂+0.3 SaO₂
  – Validation
    • Compare arterial and jugular venous blood samples to calculate SavO₂ with NIRS rScO₂ from algorithm
Protocol

• Bilateral cerebral sensors placed after induction of anesthesia
• Arterial and venous catheters placed by cardiologist
• Arterial and jugular bulb venous samples drawn at beginning of catheterization
• Simultaneous recording of cerebral oximetry during blood draws

Statistics

• Accuracy of device determined through $A_{rms}$ statistic
  – Estimates agreement between a test device and an accepted reference device
• Device considered accurate if $A_{rms}$ less than 6%
• Bland-Altman analysis performed to determine limits of agreement
Results

- 100 enrolled patients
- 86 included in analysis
- 89% of patients ASA 3 or 4
- 62% of patients with cyanotic cardiac defects
- 59% neonates and infants
- 79% Caucasian

Results continued

- Room air pulse oximetry
  - <80% in 16.5%
  - <90% in 24.7%
- Arterial pCO\textsubscript{2} 28-61 mmHg
- Hemoglobin 8-23 g/dL
- SaO\textsubscript{2}: 34-100%
- rScO\textsubscript{2}: 34-91%
- SavO\textsubscript{2}: 26-91%
- Bilirubin 0.2-6.2 mg/ml
- No appreciable methemoglobin or carboxyhemoglobin
**Absolute rScO₂ accuracy**

**Ipsilateral**
- $A_{\text{rms}}$ 5.3%
- Mean bias $0 \pm 5.3$
- Precision 5.3%

**Contralateral**
- $A_{\text{rms}}$ 5.5%
- Mean bias $1.1 \pm 5.3$
- Precision 5.42%

No statistically significant difference between adhesive and non-adhesive sensors.

No effect from bilirubin and total hemoglobin.

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**Figure 2: rScO₂ versus SavO₂**

- Slope = 0.85
- Intercept = 11
- $R = 0.88$
Summary

- Device accurately measures rScO₂
  - Absolute
  - Precision 5%
  - Ages 4 days to 11 years
  - Light and dark complexions
  - Arterial oxygen saturation range of 34-100%
  - Hgb 8-23 g/dL
Advantages of device

- Dual emitter/dual detector:
  - Measures absolute cerebral oxygen saturation
  - Uses one common sensor
  - Accurate over wide range of ages and cerebral oxygen saturations
- Dynamic compensation:
  - 4 wavelength construct better accounts for variation in light scattering in age, brain development and cerebral vasodilation

Limitations of device

- Error from arterial to venous ratio not constant among patients
  - Ratio of arterial to venous 30:70 utilized
  - Studies show a range for the ratio
- Not thoroughly tested under extreme conditions
  - Only 2 patients with rScO2 <45%
**Intervention thresholds for rScO₂**

- **Luxury**: 100%
- **Normal**: 80%
- **Disturbed**:
  - 60%
  - 45%
  - 30%
  - 0%

- **Damage**:
  - ATP
    - EEG flat
  - Lactate
    - Δ EEG

**Discussion**

- Cerebral hypoxia-ischemia is a perioperative issue for children with cardiovascular disease
- Neurodevelopmental issues not detected until later in life
- Significant health care cost
- Need real time detection of hypoxia-ischemia in order to intervene before injury occurs