



Validation of the CAS Adult Cerebral Oximeter During Hypoxia in Healthy Volunteers



David MacLeod FRCA, Keita Ikeda PhD, Eugene Moretti MD, John Keifer MD, Eugene Moretti MD, W. Ames.

Department of Anesthesiology • Duke University Medical Center • Durham, North Carolina

INTRODUCTION

Near-Infrared Spectroscopy (NIRS) Prototype Cerebral Oximeter (CAS Medical Systems, Inc.; Branford, CT USA)

- non-invasive
- optically-based
- continuous estimation of cerebral tissue oxygen saturation ($S_{ct}O_2$)

Pulse oximetry

- non-invasive
- optically-based
- continuous estimation of arterial oxygen saturation (S_pO_2)

METHODS

- 18 ASA 1 subjects (9 males / 9 females)
- 2 prototype NIRS sensors on forehead
- Desaturations to $S_pO_2 > 70\%$
 - O_2 : 21 - 8%
 - 5 min increments
 - normocarbida ET CO_2 40 mmHg
- Simultaneous blood samples
 - radial artery catheter
 - jugular bulb catheter
- NIRS validated by correlating optically determined $S_{ct}O_2$ with reference $S_{ct}O_2$ (derived from blood gas measurements using IL 682 co-oximeter)
- Equation 1: Reference $S_{ct}O_2 = 0.3 \times S_aO_2 + 0.7 \times S_{jb}O_2$

ABSTRACT

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 AUTHOR(S): D. B. MacLeod, K. Ikeda, F. Keifer, E. Moretti, W. Ames
 AFFILIATION(S): Duke University Medical Center, Durham, NC
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Introduction: Cerebral near-infrared spectroscopy (NIRS) is a non-invasive, optical-based technique to measure brain oxygenation continuously by determining the cerebral tissue oxygen saturation ($S_{ct}O_2$). Light from the NIRS forehead sensor passes through extracerebral tissue and backscatters from scattering sites and deoxyhemoglobin within cerebral vasculature, and returns to $S_{ct}O_2$ in a near-infrared optical emission pathway. The purpose of this study was to validate the new prototype NIRS $S_{ct}O_2$ with a reference $S_{ct}O_2$ derived from simultaneous radial artery and jugular bulb oxygen samples.

Methods: With informed consent, 18 healthy ASA I volunteers were recruited. Right arterial and jugular bulb oxygen and left radial arterial S_pO_2 were measured. The prototype CAS NIRS sensor (CAS Medical Systems, Inc., Branford, CT, USA) was placed on the right and left forehead. A Regional Gas Delivery system was used to achieve pre-specified an inspired oxygen fraction (21% to maintain P_iO_2 arterial oxygen partial pressure) and arterial CO_2 (range of 40 mmHg).

Upon completion the inspired oxygenation was decreased to 10%. The protocol was repeated if the mean $S_{ct}O_2$ value remained $> 70\%$. Each step was continued for 5 minutes. Blood samples were drawn continuously from the jugular bulb ($S_{jb}O_2$) and radial artery (S_aO_2) arteries and returned for oxygen saturation in a continuous (IL 682). The reference $S_{ct}O_2$ was calculated from the following equation:

$$\text{reference } S_{ct}O_2 = 0.3 \times S_aO_2 + 0.7 \times S_{jb}O_2$$

and was compared with the NIRS $S_{ct}O_2$ value distributed on the right and left forehead (NIRS sensor) using linear regression.

Results: 18 subjects completed the study. 253 samples were analyzed. The results are shown in Figure 1. The NIRS $S_{ct}O_2$ showed a strong correlation with the reference $S_{ct}O_2$ over the spectrum of $S_{ct}O_2$ values between 70 and 100%. Normative NIRS $S_{ct}O_2$ values ranged from values between 70 and 100% (range 69.1 - 100%).

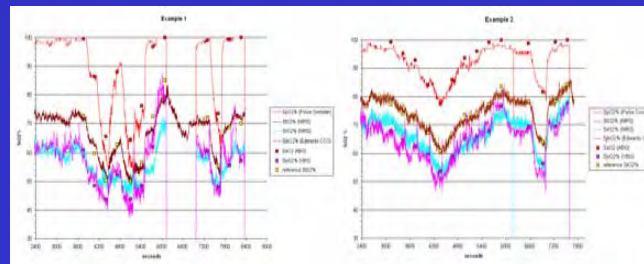
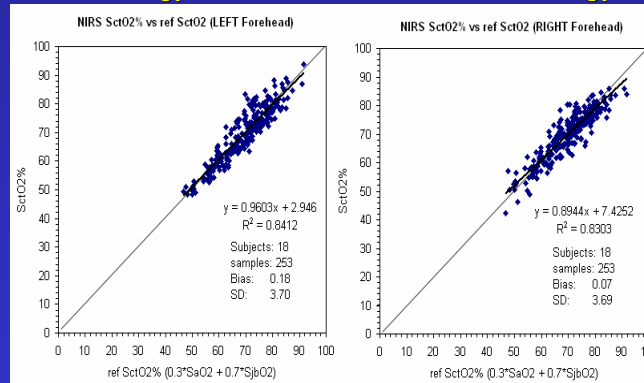
Conclusion: The study supports the validity of non-invasive NIRS $S_{ct}O_2$ as an estimate of cerebral tissue oxygenation during periods of oxygen desaturation. There was a strong correlation with the global indices of tissue oxygenation (arterial and jugular bulb oxygen saturation) and with small differences between the reference $S_{ct}O_2$ and NIRS $S_{ct}O_2$ may reflect inter-subject variability and differences in the regional blood flow of the cerebral tissue.

Reference: Adv Exp Med Biol. 2005;566:195-201.

REFERENCES

1. Benni PB, et al. Validation of the CAS neonatal NIRS system by monitoring VV-ECMO patients: Preliminary Results. Adv Exp Med Biol. 2005;566: 195-201.

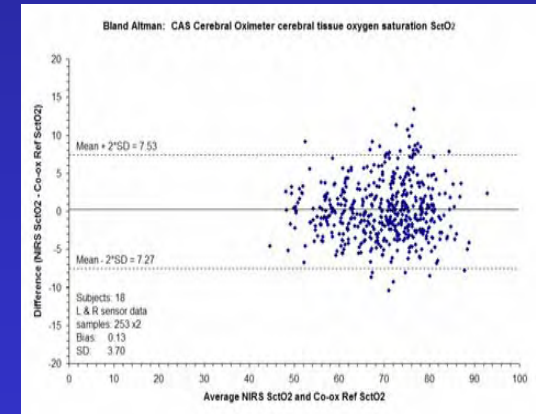
NIRS $S_{ct}O_2$ vs Co-oximetry Reference $S_{ct}O_2$



RESULTS

- 18 subjects completed study – no adverse events
- 253 samples analyzed
- NIRS $S_{ct}O_2$ showed a strong correlation with the Co-oximetry reference $S_{ct}O_2$ over the spectrum of S_pO_2 70 – 100%
- Normative NIRS $S_{ct}O_2$ (room air)
 - Average $73.6 \pm 3.2\%$
 - Range 66.6 – 79.7%
- Normative Co-oximetry reference $S_{ct}O_2$ (room air)
 - Average $74.6 \pm 2.8\%$
 - Range 70.0 – 80.0%

Bland-Altman Analysis



CONCLUSION

- The CAS Cerebral Oximeter $S_{ct}O_2$ strongly correlates with co-oximetry derived reference $S_{ct}O_2$ and demonstrates a high level of accuracy.

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SOFTWARE SCREEN

