CEREBRAL OXIMETRY IN HEALTHY ADULTS: A COMPARISON OF THREE COMMERCIAL NEAR-INFRARED SPECTROPHOTOMETERS

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Abstract

Background: Cerebral oximetry is increasingly becoming a desirable form of monitoring in anaesthesia and critical care. Familiarity with normal values for each device is therefore important. We compared NIRO 300 and INVOS 5100 with the novel MASIMO O3 cerebral oximeter.

Methods: Regional cerebral oxygen saturations ($rScO_2$) of nine healthy volunteers were measured using NIRO 300, INVOS 5100, and MASIMO O3 under various conditions of hyperoxia, hypocapnia, and change in head position. Changes in vital signs and $rScO_2$ were compared. Reliability analyses of the NIRS devices were performed using Intraclass Correlation Coefficients (ICC) estimates at 95% confidence interval based on 2-way mixed-effects model, multiple rater, and absolute-agreement and consistency selections. $P < 0.05$ was considered statistically significant for this study.

Results: The mean (SD) baseline values from NIRO 300 and INVOS 5100 were comparable [73.8% (4.2%) vs 73.4% (5.6%) respectively, ($p = 0.84$)]. The baseline from MASIMO O3 [66.8% (3.9%)] was significantly lower compared to NIRO 300 ($p = 0.002$), and INVOS 5100 ($p = 0.011$). Changes in head position were not associated with statistically significant changes in NIRS values ($p > 0.05$). Significant increases were recorded for each of the NIRS devices at $FiO_2 = 0.45$ and $FiO_2 = 1$ ($p = 0.0001$) and during supine hyperventilation ($p = 0.0001$). The Intraclass Correlation Coefficients (ICC) estimates based on 2-way mixed-effects model suggested poor absolute-agreement (0.63; 95% CI = 0.16 - 0.81), but good consistency (0.81; 95% CI = 0.77 - 0.85). Absolute-agreement and consistency tests for NIRO 300 and INVOS 5100 pairs were moderate (0.74; 95% CI = 0.68 - 0.79).

Conclusion: Findings of this study affirm that different NIRS devices give different estimates but similar trends during various interventions. Values from the novel MASIMO O3 were generally lower than NIRO 300 and INVOS 5100.

Keywords: Cerebral oxygenation; Measurement; Techniques; Near-infrared spectroscopy.

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Introduction

Adequate oxygen delivery to vital organs particularly the brain is of fundamental importance during anesthesia and critical care. Cerebral hypoxia may lead to neurological complications like stroke, organ dysfunctions, and increased hospital length of stay.[1] Unfortunately, satisfactory global oxygen delivery which can be ensured with traditional patient monitoring may not translate to sufficient oxygen supply to the brain.[2] Therefore, it is essential to monitor tissue oxygenation. Cerebral oximetry is a non-invasive monitoring of the oxygen balance of the brain. The equipment uses the Near-infra-red spectroscopy (NIRS) to measure tissue oxygenation non-invasively. Though introduced first by Jobsis in 1977, cerebral oximetry was not available commercially until the 1990s.[3] Presently, it has become an invaluable means of minimizing the risk of hypoxic brain damage particularly in high risk patients. Potentially disastrous neurologic incidents that would have been missed by other conventional monitoring are now readily detected and avoided with the use of NIRS.[4] Cerebral oximetry is progressively becoming a basic monitor for patients undergoing open heart surgeries due to improved outcomes established with its use.[2,4,5,6] Furthermore, emerging data suggests better outcomes with its use in the management of patients undergoing non-cardiac procedures including vascular surgery, neurosurgery, and trauma.[7]

Contrary to the pulsatile flow dependent nature of the traditional peripheral pulse oximeter, cerebral oximeter is not pulsatile flow dependent.[1] Unlike the earlier designs, modern cerebral oximeters display absolute cerebral oxygen saturation for ease of interpretation and decision making.[8] Among the commonly used commercially available brands of regional tissue oximeters are: NIRO 300 (Hamamatsu Photonics, Hamamatsu City, Japan), INVOS 5100 (Somanetics/Covidien, Inc., Boulder, CO), and the more recently introduced MASIMO O3 (Masimo International, Puits-Godet 10, 2000 Neuchatel, Switzerland)**.** Regional cerebral oxygen saturation ($rScO_2$) is measured as tissue oxygenation index (TOI) on NIRO 300, and regional tissue oxygen saturation (rSO_2) on INVOS 5100 and MASIMO O3. Despite improvement in performance of cerebral oximeter technology over the years, a significant variability in accuracy within and between the devices has been reported by many researchers.[9,10] These findings are believed to be related to the different methodologies and assumptions used to calculate the cerebral oxygenation indices of the various brands of this equipment. The current lack of reference standard for calibration of cerebral oximeters from regulatory agencies poses a major challenge to resolving this drawback.[9] Therefore, correlation and comparison of results from these different monitors remain ill-defined. The aim of this study was to evaluate and compare the ability of NIRO 300, INVOS 5100, and MASIMO O3 to detect changes in cerebral oxygenation during hyperoxia, hypocapnia, head down position, and head up position in healthy adult volunteers, and assess the variability of these monitors.

Methods

This study was approved by the Ethics Committee of Yamagata University Faculty of Medicine where the study was conducted (approval number: 2017-140), and registered at UMIN.org; www.umin. ac.jp/ctr/index.htm (registration number: UMIN000029059). Formal written informed consent was obtained from the nine (9) healthy volunteers enrolled into this study.

This is a prospective study conducted on healthy volunteers. Exclusion criteria were individuals younger than 18 years, body mass index >30 kg/m^2, pregnancy, non-white race, local skin disease affecting the face, history of chronic medical illnesses (diabetes, hypertension, and peripheral vascular disease).

The default manufacturers' settings of the devices were used. The averaging measurement time of NIRO, INVOS, and MASIMO O3 were 10, 1, and 8 seconds respectively. With the volunteers in supine position on the operating room (OR) table, the adhesive optodes of NIRO, INVOS, and MASIMO O3 were placed sequentially one after the other on the left side of the forehead 1cm above the eyebrow and 1cm lateral to the midline. The study had 7 sequential stages with each lasting 5 minutes, followed by a 3 minute period for equilibration before the next stage (Figure 1). Each volunteer went through each of the 7 stages for each of the sensors in a sequence of

NIRO to INVOS to MASIMO. A transition period of 5 minutes for change of sensor to the next NIRS monitor was observed. Each volunteer went through a total of 21 stages. The volunteers were instructed to breathe normally in room air (Control - A), then 20 degrees head down, 20 degrees head up, then supine with the volunteers breathing hyperoxic gas mixtures with fraction of inspired oxygen (FiO_2) of 45% followed by FiO_2 of 100% administered via Drager anesthesia machine. Volunteers were returned to room air in supine position (Control - B) before they were finally instructed to hyperventilate in room air until an E_TCO_2 value of 22.5mmHg (3.0 kPa) was achieved for the hyperventilation stage. The angle of the OR table was standardised using a digital angle meter. Oxygen analyzer on the anaesthesia machine was used to ensure delivery of the desired oxygen concentration. Gas delivery was through a single use disposable circle breathing system attached to a properly fitting mask. Main streaming E_TCO_2 unit was connected between the HME filter and the Y-piece of the breathing system. For each of the interventions, vital parameters were recorded over the 5 minute period.

Data collected from each of the subjects after proper medical history for exclusion of inappropriate volunteers included demographic data (age, weight, height). The heart rate (HR), peripheral oxygen saturation (SpO_2), systolic blood pressure (SBP), diastolic blood pressure (DBP), stroke volume (SV), cardiac Index (CI) and regional cerebral oxygen saturation ($rScO_2$) were measured continuously after obtaining baseline values. Recordings were manually extracted and entered into the study proforma at intervals of 1 min throughout the study period.

Statistical analyses

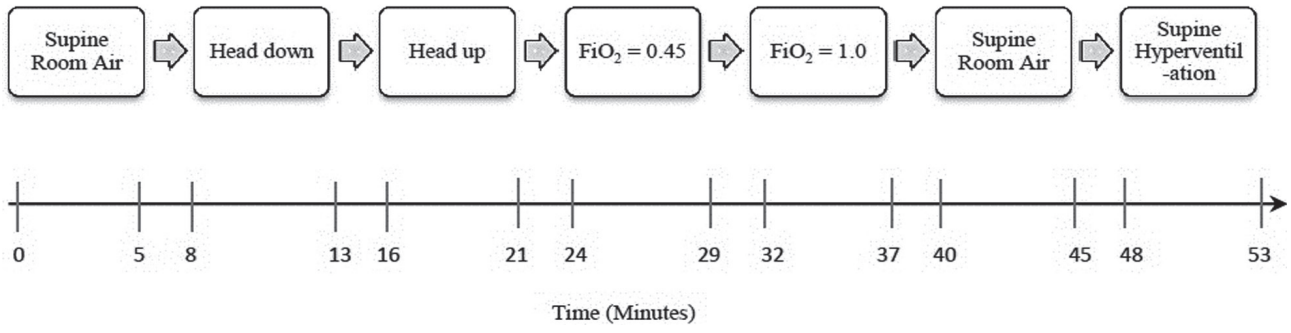
The collected data were entered into SPSS Statistics for Windows, version 25. (IBM Corp., Armonk, N.Y., USA) for statistical analyses. The mean value of the recorded parameters during data capturing periods for each of the interventions was used as the summary value.[11] Results are presented as means ± standard deviation (S.D). Analysis of variance (ANOVA) was used to detect significant difference in the mean values of measured variables, and for comparison of mean $rScO_2$ of the 3 NIRS devices. Comparison of HR, SpO_2, SBP, DBP, SV, and CI changes during interventions were performed using independent samples test in pair-wise manner. Changes in $rScO_2$ from the NIRS devices during interventions were also compared to the baseline using independent samples test. Reliability analyses of the NIRS devices were performed using Intraclass Correlation Coefficients (ICC) estimates at 95% confidence interval based on 2-way mixed-effects model, multiple rater, and absolute-agreement and consistency selections. Based on the 95% confidence interval of the ICC estimate, values < 0.5, between 0.5 and 0.75, between 0.75 and 0.9, and > 0.90 were interpreted as poor, moderate, good, and excellent reliability, respectively.[12] P <0.05 was considered statistically significant.

Results

A total of 972 NIRS measurements were taken from 9 adult (7 males and 2 female) volunteers who

Fig. 1

Data acquisition flow chart showing the 7 sequential stages (5 minutes each) of data acquisition followed by periods for equilibration (3 minutes each) for volunteers after connection of each test NIRS device



participated in the study. Six baseline measurements [Supine on room air (A)] were taken per volunteer per monitor and five measurements per volunteer per monitor at the 6 other stages of the study. The mean (SD) age was 27 (2) years with a range of 25 – 30 years. The mean (SD) weight and height were 64 (10) kg and 167 (10) cm respectively, while the body mass index (BMI) ranged from 19.4 to 26.0 kg/m^2 with a mean (SD) 22.5 (2.5) kg/m^2. The mean (SD) of HR, SpO_2, SV, and CI during the interventions were significantly different from the baseline (Table 1). The mean SBP and DBP were statistically comparable to the baseline throughout the study period.

Following change to head down position, there was a statistically significant reduction in mean HR (p=0.039); other hemodynamic variables were not significantly different. All hemodynamic variables remained statistically the same following change to head up position (p > 0.05). Increasing FiO2 to 45% was associated with a significant increase in SpO_2 (97% vs 99%, p<0.0001), and a decrease in cardiac index (2.40 vs 2.22 L/min/m^2, p=0.011); other variables were comparable to the baseline. Further increase in FiO_2 to 1 was associated with significant reduction in HR (59 vs 53 beat/min, p<0.0001), rise in SpO_2 (97.0 vs 99.3%, p<0.0001), and further reduction in cardiac index (2.40 vs 2.13 L/min/m^2, p<0.0001). During supine on room air (B), the SpO_2 remained significantly higher than the baseline (97 vs 98 %, p<0.0001), and the cardiac index was significantly lower (2.40 vs 2.26 L/min/m^2, p=0.03). Supine hyperventilation phase was associated with a significant increase in HR (59 vs 61 beat/min, p – 0.024), SpO_2 (97.0 vs 99.2 %, p<0.0001), cardiac index (2.4 vs 2.7 L/min/m^2, p<0.0001), and SV (69.0 vs 72.3 mL, p=0.041) compared to the baseline.

The mean (SD) rScO2 during the various interventions for the three devices are reported in table 2. The differences in baseline mean rScO2 of MASIMO O3 compared to NIRO 300 and INVOS 5100 were significantly lower (p < 0.05). Change in mean cerebral saturation from each individual's baseline for the NIRS devices in response to the various interventions is shown in figure 2. The ICC estimates of the three NIRS devices based on 2-way mixed-effects model for absolute-agreement was 0.63 (95% CI = 0.16 - 0.81), but for consistency, the estimates was 0.81 (95% CI = 0.77 - 0.85). The estimates for both absolute-agreement

Table 1

Mean (Standard deviation) of the haemodynamic variables against interventions

Variables (Unit)	Supine on room air (A)	Head down	Head up	F_IO_2 = 0.45	F_IO_2 = 1.0	Supine on room air (B)	Supine hyperve-ntilation	P – value*
SBP (mmHg)	113.20 (18.56)	112.94 (17.92)	110.70 (15.55)	109.90 (16.10)	109.96 (16.02)	110.31 (15.80)	112.85 (17.29)	0.336
DBP (mmHg)	65.52 (13.10)	64.56 (12.67)	65.2 (11.49)	62.68 (12.09)	63.16 (13.15)	62.71 (13.58)	64.30 (13.29)	0.303
HR (/min)	58.83 (10.47)	56.47 (8.76)	58.61 (7.46)	58.79 (43.64)	53.28 (6.97)	57.10 (7.14)	61.40 (8.79)	0.014**
SPO_2 (%)	97.04 (1.56)	97.25 (1.98)	97.25 (1.63)	98.96 (1.11)	99.29 (0.89)	97.98 (1.55)	99.15 (1.18)	0.0001**
CI (L/min/m^2)	2.40 (0.61)	2.33 (0.64)	2.37 (0.49)	2.22 (0.57)	2.13 (0.53)	2.26 (0.49)	2.71 (0.80)	0.0001**
SV (mL)	69.02 (11.45)	69.88 (13.37)	69.56 (12.40)	68.24 (13.00)	67.16 (12.48)	67.29 (11.08)	72.35 (15.67)	0.016**

* Analysis of variance (ANOVA) statistics

** - Statistically significant

SBP - Systolic blood pressure, DBP – Diastolic blood pressure, HR – Heart rate,

SPO_2 - Peripheral oxygen saturation, CI – Cardiac index, SV – Stroke volume

Table 2
The mean (SD) regional cerebral oxygenation ($rScO_2$) from the different devices

	Mean (SD) regional cerebral oxygenation		
Intervention	NIRO 300	INVOS 5100	MASIMO O3
Supine on room air (A)	73.83 (4.21)*	73.35 (5.64)*	66.76 (3.94)**
Head down	74.67 (5.87)	73.33 (5.67)	68.00 (5.23)
Head up	72.96 (4.16)	71.36 (4.27)	65.76 (3.49)
FiO_2 = 0.45***	75.87 (4.44)	77.91 (3.93)	69.31 (3.96)
FiO_2 = 1.0***	77.67 (3.89)	81.04 (2.95)	70.87 (3.64)
Spine on room air (B)	74.07 (3.98)	74.67 (4.46)	66.42 (3.91)
Supine hyperventilation***	70.13 (4.56)	68.07 (4.85)	61.67 (3.99)

The mean of seven measurements in each of nine subjects (n = 63).
* Comparable (p = 0.84).
** Significantly lower compared to NIRO 300 (p = 0.002), and INVOS 5100 (p = 0.011).
*** Significantly higher compared to baselines (p = 0.0001).

and consistency tests for NIRO 300 and INVOS 5100 pairs were the same - 0.74 (95% CI = 0.68 - 0.79). The estimates for NIRO 300 and MASIMO O3 pair for absolute agreement was 0.43 (95% CI = -0.21 to 0.74); for the consistency test, the estimate was 0.74 (95% CI = 0.67 - 0.79). Estimates for INVOS 5100 and MASIMO O3 were similar to those for NIRO 300 and MASIMO O3 (absolute agreement = 0.48; 95% CI = -0.21 to 0.77; for consistency = 0.75, 95% CI = 0.68 - 0.80).

Discussion

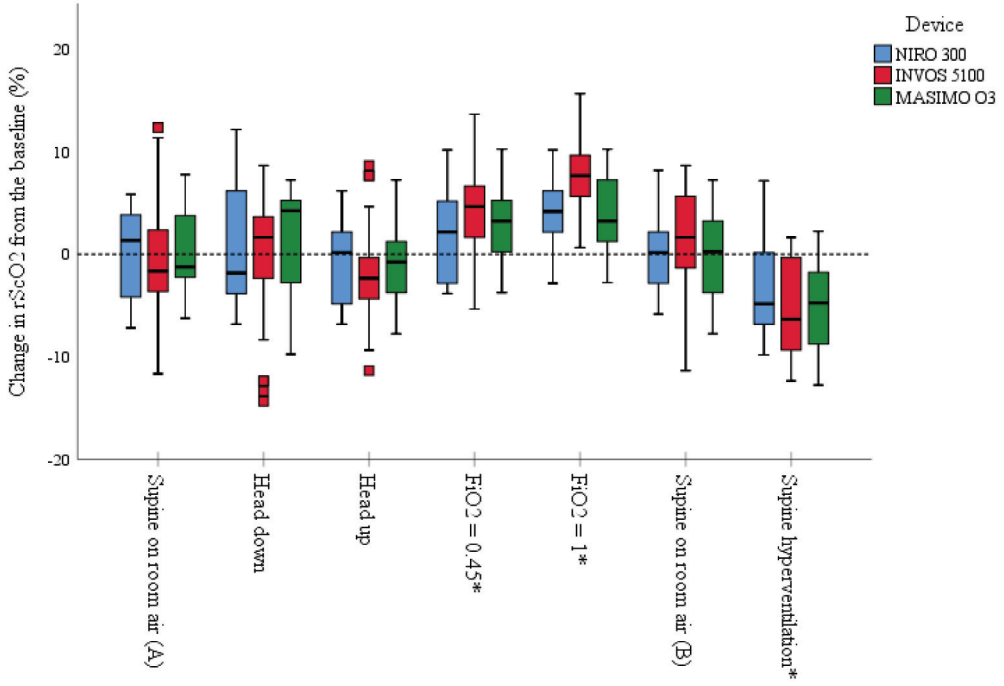
The results of this study show that the three cerebral oximeters detected changes in cerebral oxygenation during hyperoxia, hypocapnia, and supine hyperventilation in healthy adult volunteers. Though the three devices showed similar trends in detecting changes during the different interventions, the values obtained from NIRO 300 and INVOS 5100 were comparable while values from MASIMO O3 were significantly lower. There were large variances in measurements from the devices. Our results affirm that the absolute values and dynamic responses to hyperoxia, hypocapnia, and hyperventilation differ among the different devices. Familiarity with the performance of specific device (and sensor) in use, including the normal ranges and responses to interventions is therefore important for efficient and safe use of the device for optimal benefit.

The ICC estimates for measurements from the three NIRS devices showed good correlation from consistency test results but poor absolute agreement due to very low lower limit of the confidence interval for agreement test. Agreement between NIRO 300 and INVOS 5100 in this study was moderate. Similar but lower baseline mean cerebral oxygen saturation values were reported for NIRO 300 and INVOS by Thavasothy et al.[8], with both monitors demonstrating similar changes in response to hyperoxia and hypocapnia. The wide difference in baseline reported by Thavasothy et al.[8] compared to ours may be due to differences in the methodology used in both studies. Though, the wide margin of difference remains a pointer to the fact that absolute values for cerebral oxygen saturation may be too broad for clinical decisions, the role of the three evaluated devices as trend monitors is clearly defined by the similar responses to the various interventions explored in the current study as previously reported by several others.[8,9,13,14]

Dullenkopf et al.[13] in their comparative study of INVOS 5100 adult and pediatric sensors with NIRO 300 found a mean difference of 10% or more between values from paediatric sensors and adult INVOS sensors and NIRO 300. The cerebral oxygenation values derived by INVOS adult sensor and NIRO

Fig. 2

Boxplot showing the minimum, first quartile, median, third quartile, and maximum of change in cerebral oxygen saturation from each individual's baseline value measured with the different devices in response to the various interventions (n = 9)



Interventions

* - Statistically significant ($p < 0.05$)

300 at interoptode distance of 4 cm were however comparable in agreement with our findings on INVOS and NIRO.

Our result shows that the monitors individually demonstrated ability to detect increase in cerebral oxygenation following hyperoxia at FiO2 of 0.45 and 1.0. They equally detected decreases in cerebral oxygenation individually following hypocapnia, presumably related to cerebral vasoconstriction as previously reported by others.[8]

Following head-down and head-up positions, the NIRS devices did not show statistically significant changes in values. Contrary to our findings, Kurihara et al.[15] in a study of five healthy male subjects during 90° head-up tilt and 6° head-down tilt observed a significant reduction in cerebral oxygenation following head up tilt but no significant change in NIRS values during head down tilt, and suggested that cerebral oximeter could be a reliable and sensitive technique for cerebral oxygenation monitoring during postural changes. Mol et al.[16] measured cerebral oxygenated haemoglobin (O2Hb), deoxygenated haemoglobin (HHb) and tissue saturation index (TSI) bilaterally on the forehead of 15 healthy individuals and observed that O2Hb showed the most prominent decline on standing up compared to other parameters. They suggested it as a preferred parameter in the assessment of cerebral oxygenation responses to postural changes. However, O2Hb was not measured in the current study.

In another study evaluating the relationship between central venous pressure (CVP), cerebral tissue oxygen saturation and outcome in post-cardiac arrest patients, Ameloot et al. observed that venous cerebral congestion due to elevated CVP impairs cerebral oxygenation.[17] Application of positive end-expiratory pressure (PEEP) in victims of traumatic brain injury leading to elevated CVP has also been associated with raised intracranial pressure (ICP), and reduced cerebral perfusion pressure, blood flow in the middle cerebral artery and cerebral desaturation.[17]

To the best of our knowledge, MASIMO O3 has not been previously compared clinically with NIRO 300 and INVOS 5100. A recent study compared peripheral somatic rSO_2 values from EQUANOX 7600 device (Nonin Medical Inc., Plymouth, Mn) with MASIMO O3 device derived from 20 adult patients who had cardiac surgery under cardiopulmonary bypass, and observed no significant difference between both monitors - EQUANOX median rSO_2 60% (95% CI 57–62) versus MASIMO O3 median rSO2 62% (95% CI 61–64), p = 0.103.[18] Significant correlations were observed between the two devices. In a study on absolute and trend accuracy of MASIMO O3 determined by comparing regional cerebral oxygen saturation with reference cerebral oxygen saturation calculated by combining arterial and venous saturations of oxygen in the blood samples, Redford et al.[1] reported an absolute root-mean-squared error of 4%, and trends with relative root-mean-squared error of 2.1%. Benkreira et al.[19] conducted a retrospective study and a prospective study in adult patients undergoing cardiac surgery. The retrospective cohorts were patients who had portal vein Doppler imaging during routine care in the intensive care unit; patients who had cognitive and echocardiographic evaluations the day pre-surgery and daily for additional 3 days post-surgery formed the prospective cohort. A significant association between portal pulsatility, post-operative delirium, and cerebral desaturations measured with MASIMO O3 was reported (OR, 2.23; CI, 1.12-4.71; p = 0.02). Results of the current study showed that MASIMO O3 demonstrated similar trend response to head up and head down positions, hyperoxia, and hypocapnia compared to NIRO 300 and INVOS 5100. Its outputs also correlated well with the two NIRS devices but the absolute agreement is poor.

Limitations of this study include the fact that this study was conducted on healthy young adult volunteers, and the results may not be reflective of the responses of the extremes of age or patients who are sick with chronic medical conditions. The small sample size used for the study is another limitation that reduced the ability of the study to detect smaller differences among the evaluated devices. The NIRS sensors were used in a consecutive order, and non-randomisation of the sensors could have introduced bias in the data acquired. The degree of head up and head down position to which volunteers were exposed was limited to 20 degree, and does not represent the full range of motion to which patients may be exposed. The discomfort that may be associated with large range of angles particularly in head-down position for an awake volunteer was a major consideration for limiting the range of angle used in this study. Therefore, changes in $rScO_2$ following changes in position reported here may not adequately reflect changes that may occur during surgery. Finally, the MASIMO O3 is a new generation device which also displays HHb and HbO2 which were not reported in this study.

Conclusion

NIRS values from healthy individuals suggested good consistency and poor agreement for NIRO 300, INVOS 5100 and MASIMO O3. Significantly lower values were recorded form MASIMO O3 compared to the other two devices. Trend values in an individual on any particular device may be more indicative of cerebral well-being than an absolute value. Absolute values and dynamic responses to hyperoxia, hypocapnia, and change in head position differ among the different devices, and familiarity with the performance of specific device (and sensor) in use, including the normal ranges and responses to interventions is therefore important for efficient and safe use of the device for optimal benefit. It is desirable to further improve on regional oximetry technology to strengthen clinical confidence and reinforce utilization in clinical management of patients.

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Conflicts of interest: None.

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