



Near-infrared spectroscopy device selection affects intervention management for cerebral desaturation during cardiopulmonary bypass surgery

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Abstract

Objective Currently, several near-infrared spectroscopy oximetry devices are used for detecting cerebral ischemia during cardiopulmonary bypass (CPB) surgery. We investigated whether two different models of near-infrared spectroscopy oximetry devices affect the assessment of cerebral ischemia and its management during CPB.

Methods From January 2017 to August 2017, 70 adult cardiovascular surgery cases were randomly assigned to 1 of 2 different near-infrared spectroscopy oximetry devices. The devices were INVOS 5100C (Medtronic, Minneapolis, MN, USA) (group I; $n = 35$) and FORE-SIGHT ELITE (CAS Medical Systems, Branford, CT, USA) (group F; $n = 35$).

Results There were no significant differences in patient characteristics. The rSO_2 values were significantly higher for patients in group F than for patients in group I. Scalp–Cortex distance showed negative correlations with the mean rSO_2 values in group I ($P = 0.01$). Interventions for low rSO_2 during CPB for groups I and F were increase perfusion flow (13:5; $P = 0.03$), blood transfusion (7:1; $P = 0.02$), and both (6:1; $P = 0.04$), respectively. The Scalp–Cortex distance in group I was significantly longer in patients who required intervention than in patients who did not (17.1 ± 2.5 vs 15.1 ± 1.6 mm; $P = 0.007$).

Conclusions It is inappropriate to use the same intervention criteria for different near-infrared spectroscopy oximetry devices. Moreover, brain atrophy influence rSO_2 values depending on device selection. It is important to note that inappropriate device selection may misguide perfusionists into performing unnecessary or excessive intervention during CPB.

Keywords Near-infrared spectroscopy · Cerebral ischemia · Cardiopulmonary bypass · Fore-sight elite · INVOS 5100C

Introduction

There are currently several near-infrared spectroscopy (NIRS) oximetry devices commercially available and used for detecting cerebral ischemia during cardiopulmonary bypass (CPB). These devices may help surgeons and anesthesiologists avoid poor cerebral perfusion, which can result in perioperative neurological adverse events. These devices operate on the same measurement principles; however, their algorithms of detection and calculation of regional cerebral

oxygen saturation (rSO_2) value are different, and it is inappropriate to compare values measured by such different devices directly. Thus, measured values and trends fluctuate depending on devices.

Our previous retrospective evaluation of 223 adult patients undergoing cardiac surgery has revealed that brain atrophy, poor left ventricular ejection function, anemia, and hemodialysis had significant correlations with low initial cerebral rSO_2 values measured by INVOS 5100C (Medtronic, Minneapolis, MN, USA) [1]. In clinical settings, these fluctuations of measured values affect the decision making for intervention during CPB.

In this study, 70 patients were randomly assigned to 1 of 2 groups in which surgery was performed using 2 different devices: the INVOS 5100C and the FORE-SIGHT ELITE (CAS Medical Systems, Branford, CT, USA). We prospectively evaluated intraoperative rSO_2 values in each group and the presence or absence of intervention for low rSO_2 value during CPB.

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Subjects

From January 2017 to August 2017, 96 patients underwent elective cardiac surgery at Kitasato University Hospital. Patients ≤ 12 years of age; patients who did not undergo preoperative brain magnetic resonance imaging; and patients with a medical history of acute cerebral infarction, intracranial hemorrhage or neurosurgery, surgery performed in a nonsupine position, off-pump coronary artery bypass surgery, and/or with left ventricular assist devices were excluded from the study. Finally, 70 patients were enrolled.

Methods

Each patient was randomly assigned to 1 of 2 groups utilizing either the INVOS 5100C (group I; $n = 35$) or the FORE-SIGHT ELITE (group F; $n = 35$). This research was conducted with the approval of the Kitasato University Medical Ethics Organization (approval number: KMEO B16-96). All patients gave informed consent before inclusion in the study.

Scalp–Cortex distance

Preoperative brain magnetic resonance imaging was routinely evaluated for detection of cerebrovascular disease. Scalp–Cortex distance (SCD) was measured on a T1-weighted image of the mid-sagittal plane as the distance from the surface of the scalp on the upper forehead, at 4 cm from the superciliary arch, to the frontal cerebral cortex (Fig. 1).

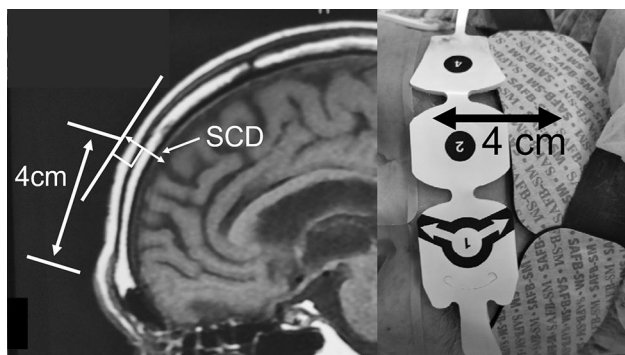


Fig. 1 Scalp–Cortex distance (SCD) was defined as the distance between the scalp surface of the forehead at 4 cm from the superciliary arch and the frontal cerebral cortex in reference to a midsagittal plane of a T1-weighted magnetic resonance image

Cerebral rSO₂ monitoring

From anesthetic induction to the end of surgery, continuous monitoring of cerebral rSO₂ was carried out in each group. Optodes of each device were placed on the patient's forehead, at 4 cm from the superciliary arch, to avoid the frontal sinus [2]. The values were recorded at anesthetic induction, CPB start, aortic cross clamp, and CPB end.

Interventions during CPB

Interventions for low rSO₂ during CPB were defined as approaches to improve rSO₂ values such as increasing perfusion flow rate, increasing inspired oxygen fraction, and blood transfusion. Increasing perfusion flow should be considered as primary intervention method, and the others as supplemental. Since there is no established value of rSO₂ that should be maintained during CPB to avoid postoperative cognitive disorder, the thresholds for intervention were set as an absolute drop to below 40% or a 10% relative decrease from the initial baseline value. These thresholds were based on the recommendation by the manufacturer of INVOS 5100C, Medtronic, with clinical modifications.

Data collection

Patient medical records were reviewed for preoperative clinical and demographic characteristics according to the hospital information system.

Data analysis

Continuous variables were presented as mean \pm standard deviation. For each group, odds ratios for the presence of intervention and correlations between rSO₂ value and SCD were evaluated.

Differences with $P < 0.05$ were considered statistically significant. Statistical analyses were performed using JMP Software, version 12.0 (SAS Institute, Carey, NC, USA).

Results

Patient characteristics

Patient characteristics including age; sex; body surface area; medical history (stroke, hypertension, diabetes mellites, and hemodialysis); preoperative left ventricular ejection fraction; hemoglobin concentration (Hb); and SCD are shown

Table 1 Patient characteristics

	Group I (35)	Group F (35)	P value
Age (year)	68.6 ± 15.4	68.4 ± 11.4	0.58
Sex (male)	0.57 ± 0.50	0.63 ± 0.49	0.63
BSA (m ²)	1.62 ± 0.23	1.60 ± 0.20	0.64
Past history			
Stroke	0.09 ± 0.28	0.17 ± 0.38	0.29
HT	0.63 ± 0.49	0.17 ± 0.38	0.80
DM	0.17 ± 0.38	0.17 ± 0.38	1.00
HD	0.20 ± 0.06	0.09 ± 0.06	0.18
LVEF (%)	59.6 ± 12.6	60.6 ± 15.2	0.76
Hb (g/dL)	13.0 ± 2.3	13.1 ± 1.7	0.83
SCD (mm)	15.6 ± 12.6	15.1 ± 2.0	0.32

BSA body surface area, HT hypertension, DM diabetes mellitus, HD hemodialysis, LVEF left ventricular ejection fraction, Hb hemoglobin concentration, SCD Scalp–Cortex distance

in Table 1. There were no significant differences between the 2 groups.

Operative outcomes

Surgical procedures, CPB time, perfusion index, minimum core temperature, blood transfusion during CPB, and postoperative neurological adverse events are shown in Table 2. In group I, 1 patient of aortic valve replacement experienced convulsions and 1 patient of aortic valve replacement, tricuspid valve annuloplasty, coronary

Table 2 Operative outcome

	Group I (35)	Group F (35)	P value
Procedure			
CABG	5 (14.3)	8 (22.9)	0.36
Valve	18 (51.4)	16 (45.7)	0.63
Aortic	2 (5.7)	4 (11.4)	0.39
CABG + Valve	7 (20.0)	3 (8.6)	0.17
CABG + Aortic	0	2 (5.7)	0.15
Valve + Aortic	0	1 (2.9)	0.31
Miscellaneous	3 (8.6)	1 (2.9)	0.30
CPB time (min)	167.4 ± 65.3	177.4 ± 67.0	0.53
Perfusion index (L/min/m ²)	2.42 ± 0.19	2.35 ± 0.14	0.14
minimum CT (°C)	33.4 ± 0.3	33.5 ± 0.5	0.57
BT (mL)	297.7 ± 415	238.9 ± 297.4	0.49
Stroke	0	0	–
Convulsion	1 (2.9)	0	0.31
Delayed emergence (> 24 h)	1 (2.9)	0	0.31

CABG coronary artery bypass grafting, CPB cardiopulmonary bypass, CT core temperature, BT blood transfusion during cardiopulmonary bypass

artery bypass and maze procedure experienced delayed emergence. However, there were no significant differences between the 2 groups.

Intraoperative rSO₂ values

The rSO₂ values were recorded at anesthetic induction, CPB start, aortic cross clamp, and CPB end. The values for group F are significantly higher than those for group I. However, there were no significant differences in mean mixed venous oxygen saturation value in the 2 groups (Table 3).

Interventions for low rSO₂ value

Interventions for low rSO₂ during CPB for group I and group F were increase perfusion flow (13:5; P = 0.03), blood transfusion (7:1; P = 0.02), and both (6:1; P = 0.04), respectively. Interventions were significantly more frequent in group I, despite similar patient backgrounds (Table 4). The cases of high perfusion pressure of > 400 mmHg at the inlet of the artificial lung were managed only with blood transfusion without increasing perfusion flow.

SCD and rSO₂ values

In group F, there was no correlation between the mean rSO₂ value and SCD. In contrast, the mean rSO₂ value in group I had a significant negative correlation with SCD (Fig. 2). In group I, in which mean rSO₂ and SCD were significantly correlated, the relationship between SCD and the presence or absence of intervention was examined. The mean SCD of interventions were significantly longer than that of noninterventions (17.1 ± 2.5 vs 15.1 ± 1.6 mm; P = 0.007). A cutoff value of SCD for group I was determined by ROC analysis. The area under the curve was 0.75, and a cutoff value for intervention was SCD > 17.6 mm (Table 5) (Fig. 3).

Table 3 Intraoperative rSO₂ values

rSO ₂ (%)	Group I (35)	Group F (35)	P value
Anesthetic induction	61.0 ± 10.5	70.7 ± 6.3	< 0.0001**
CPB start	61.2 ± 11.2	70.5 ± 6.5	< 0.0001**
AOX	57.5 ± 9.2	68.8 ± 7.3	< 0.0001**
CPB end	65.5 ± 10.8	73.3 ± 5.0	0.0002**
Mean	61.4 ± 9.3	70.9 ± 5.3	< 0.0001**
S _v O ₂ (%)	82.7 ± 4.1	81.5 ± 3.7	0.18

rSO₂ regional cerebral oxygen saturation, CPB cardiopulmonary bypass, AOX aortic cross clamp, S_vO₂ mixed venous oxygen saturation **P < 0.01

Table 4 Intraoperative intervention for low rSO₂ value

	Group I (35)	Group F (35)	Odds	95 % CI	P value
Increase PF	13 (37.1)	5 (14.3)	3.5	1.1–11.4	0.03*
Increase FiO ₂	0	0	–	–	–
BT	7 (20.0)	1 (2.9)	8.5	1.0–73.3	0.02*
Increase PF and BT	6 (17.1)	1 (2.9)	7.0	0.8–61.8	0.04*

rSO₂ regional cerebral oxygen saturation, PF perfusion flow, FiO₂ inspired oxygen fraction, BT blood transfusion *P < 0.05

Fig. 2 There is a significant negative correlation between mean rSO₂ value and Scalp–Cortex distance (SCD) in group I. In group F, measured mean rSO₂ value is not affected by SCD

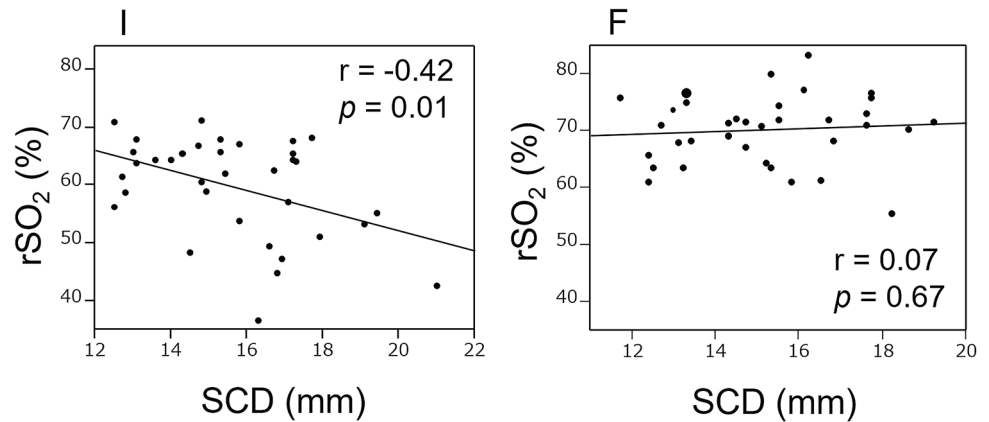


Table 5 Intervention and Scalp–Cortex distance of Group I

SCD (mm)	Intervention (-)	Intervention (+)	Cutoff value	AUC	P value
Group I	15.1 ± 1.6	17.1 ± 2.5	17.6	0.75	0.01**

SCD Scalp–Cortex distance, AUC area under the curve **P < 0.01

Discussion

Since CPB surgery was first introduced, perioperative stroke emerged as a serious adverse event. In 1965, Pillsbury et al. reported their 450 consecutive open-heart surgeries. The incidence of stroke was 2.0% (n = 9), and the mortality rate was 55.6% (n = 5) [3]. Recent meta-analysis revealed that the incidence of perioperative stroke after cardiac surgery was 2.03%. The operative and late mortality were 21.3 and 10.9%, respectively [4]. It is inappropriate to compare these studies with studies reported by clinicians with different historical and clinical backgrounds. However, despite much innovative progress, perioperative stroke remains a complication that concerns surgeons.

Real-time, noninvasive monitoring of tissue oxygenation using an NIRS oximetry device was first reported in 1977 [5]. Today, clinical utility of such devices has been established and commonly applied to detect cerebral ischemia during CPB surgery. In 184 Japanese medical

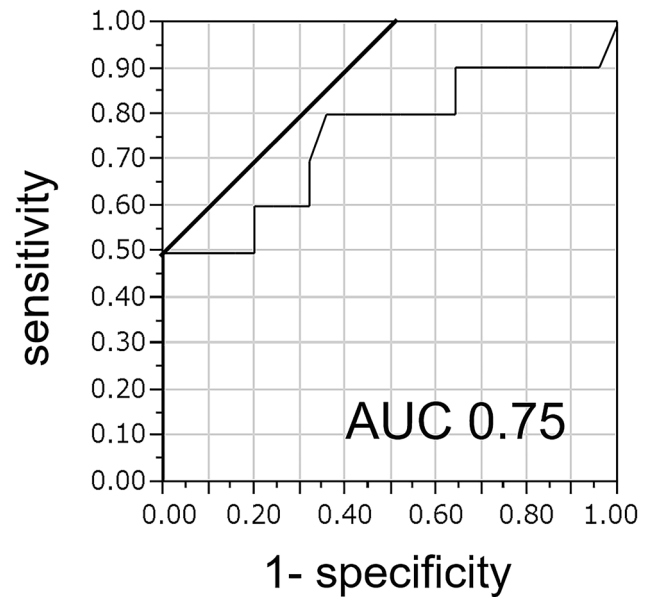


Fig. 3 Result of receiver operating characteristic analysis for the evaluation of decision making for intervention for desaturation during CPB in group I. Area under the curve (AUC) was 0.75. Cutoff values for intervention was Scalp–Cortex distance of > 17.6 mm

centers in which cardiac surgery was performed, 155 (84%) used intraoperative NIRS oximetry monitoring, and 70 (38%) used it routinely [6]. Although several NIRS oximetry devices are commercially available, their algorithms

of detection and calculation of rSO_2 value are different. Thus, measurement results may vary, and factors that influence measurements must be weighed differently [6].

Fluctuations in measured rSO_2 values with the INVOS 5100C during cerebral desaturation are reportedly significantly wider than those with the EQUANOX 7600 (Nonin Medical Inc, Plymouth, MN, USA), and a similar but non-significant trend was observed for the INVOS 5100C compared with the FORE-SIGHT ELITE [7]. Greenberg et al. reported that the FORE-SIGHT ELITE was significantly less affected by extracranial contamination such as dermal ischemia than the INVOS 5100C [8]. These reports suggest that vulnerability of noise-tolerance specifications of INVOS 5100C. In addition, recent report suggests that rSO_2 alone is insufficient in describing cerebral metabolism and predicting neurological outcome [9].

In our study, intraoperative interventions for lower rSO_2 value were performed more frequently in group I than in group F. Measured decreasing rSO_2 values in group I were significantly affected by longer SCD, which means that brain atrophy may influence rSO_2 values, depending on device selection. Inappropriate intervention for pseudo-lower rSO_2 values may have been performed without the presence of actual ischemia. In particular, SCD of longer than 17.6 mm in group I may misguide perfusionists to perform unnecessary or excessive interventions. In such cases, INVOS 5100C should not be used. An appropriate application of the intervention threshold such as decreasing rSO_2 value of 40% assumes that the value is less affected by non-ischemic parameters. It is unlikely that there were more cases of cerebral ischemia in group I than in group F in a similar clinical populations. Moreover, it is inappropriate to use the same intervention criteria for different NIRS oximetry devices during CPB. Further study will be required to determine optimal value of rSO_2 to be maintained for each NIRS device.

Study limitations

The limitation of this study is small sample size (≤ 100 patients) in a single-center design. Moreover, thresholds for intervention against desaturation may vary depending on each clinical team. Additional multicenter studies should be carried out in larger patient populations to investigate device selection and measured cerebral rSO_2 values during CPB surgery and the impact on the need for interventions.

Conclusion

We report a prospective study to investigate the relationship between NIRS oximetry device selection and measured cerebral rSO_2 values during CPB and its influence on whether

interventions to improve desaturation should be performed. In the INVOS 5100C group (group I) in our study, SCD longer than 17.6 mm may compel clinicians to perform excessive interventions. In such cases, INVOS 5100C should not be used. Moreover, it is inappropriate to use the same intervention criteria for different NIRS oximetry devices during CPB. Device selection affect intervention for desaturation during CPB. Appropriate device selection should be considered for safe and minimally invasive cardiac surgery.

Declarations

Conflict of interest We have no conflict of interest.

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