**ORIGINAL RESEARCH** 



# Can NIRS be a surrogate indicator of elective shunt in carotid endarterectomy? A single-center observational retrospective study says no

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#### Abstract

**Background** Neuromonitoring during carotid endarterectomy (CEA) under general anesthesia is desirable and may be useful for preventing brain ischemia, but the selection of the most appropriate method remains controversial.

**Purpose** To determine the effectiveness of near infrared spectroscopy (NIRS) compared to multimodality intraoperative neuromonitoring (IONM) in indicating elective shunts and predicting postoperative neurological status.

**Methods** This is a retrospective observational study including 86 consecutive patients with CEA under general anesthesia. NIRS and multimodality IONM were performed during the procedure. IONM included electroencephalography (EEG), somatosensory evoked potentials (SSEPs) and transcranial motor-evoked potentials (TcMEPs). Sensitivity, specificity, and positive and negative predictive values (PPV and NPV) were calculated for each neuromonitoring modality.

**Results** NIRS presented a sensitivity and a specificity for detecting brain ischemia of 77.7% and 89.6%, respectively (PPV = 46.6% and NPV = 97.2%). In contrast, a 100% sensitivity and specificity for multimodality IONM was determined (PPV and NPV = 100%). No significant difference (in demographical or clinical data) between "true positive" and "false-positive" patients was identified.

Among the methods included in multimodality IONM, EEG showed the best results for predicting postoperative outcome after CEA (PPV and NPV=100%).

**Conclusion** NIRS is inferior to multimodality IONM in detecting brain ischemia and predicting postoperative neurological status during CEA under general anesthesia.

Keywords Carotid endarterectomy · Intraoperative neuromonitoring · Near infrared spectroscopy · Brain ischemia

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# 1 Background

Carotid endarterectomy (CEA) is the treatment of choice to prevent future cerebrovascular events in symptomatic patients with high-grade stenosis of the internal carotid artery [1]. However, this procedure can be associated with an increased risk of stroke. Strokes with an onset during CEA are mainly caused by thrombosis, embolism, or intraoperative ischemia related to hypoperfusion during crossclamping (CC) of the carotid artery [2, 3].

Cerebral ischemia during CC may be prevented by the placement of an intraluminal shunt, which may reduce the duration that blood flow is interrupted [4]. Nevertheless, not every patient would need a shunt, and this procedure may be associated with complications. Routine shunting may be unnecessary in approximately 85% of patients because most of them have sufficient collateral cerebral perfusion during CC [4]. There are some complications related to shunt placement, and it may also limit the exposure of the distal portion of the plaque [4]. Therefore, selecting those patients who truly would need the shunt is essential to avoid taking unnecessary risks associated with the placement of a shunt.

Bearing this in mind, neuromonitoring for detecting brain ischemia during CEA is normally used to decide when the performance of a shunt is indicated or if it is necessary to activate a stroke protocol [5]. Different monitoring modalities with different evidence of utility have been described for this purpose: awake procedures, electroencephalography (EEG), bispectral index (BIS), near infrared spectroscopy (NIRS), somatosensory and motor-evoked potentials (SSEP & MEP) and transcranial Doppler (TCD). The use of regional anesthesia to perform CEA in an awake patient is considered the gold standard for neurological monitoring during the procedure [6-8]. However, awake procedures are associated with some disadvantages, such as patient anxiety, airway obstruction, the need to switch to general anesthesia or inadvertent nerve or vascular injury during regional block placement [4, 9]. Recently, it has been demonstrated that awake procedures in vascular surgery are not associated with a benefit in mortality, length of hospital stay, death or quality of life when compared with general anesthesia [10]. Thus, the lack of superiority of regional anesthesia has led to the replacement of this monitoring modality in some countries by other monitoring techniques that can be performed under general anesthesia (GA) [11].

Selection of the most appropriate neuromonitoring method during CEA under general anesthesia is critical but controversial. In fact, neuromonitoring methods during CEA has been reported to be widely diverse among centers and countries [12]. In any case, EEG, SSEPs, MEPs and NIRS are the most commonly used.

EEG has demonstrated a high positive predictive value (PPV) and high negative predictive value (NPV) for detecting brain ischemia [13–15]. The main advantage of this kind of monitoring is real-time evaluation of cortical blood flow integrity [11]. Nevertheless, it is associated with high procedural costs; its accuracy relies on high expertise in neurophysiology interpretation, and preexisting EEG abnormalities in patients with previous strokes or anesthetic-induced changes make interpretation of the EEG more difficult [16]. Some anesthetic agents can mimic ischemia in EEG (mainly halogenated agents) [11], and it is important to note that EEG primarily monitors activity in the cerebral cortex but not in deep brain structures such as the brainstem [9].

The presence of SSEP changes has also been demonstrated to be a good predictor of perioperative neurological deficits [17, 18]. SSEPs, when used without MEPs, allow neuromuscular blockade (which must be avoided after intubation for MEPs). No significant complications were reported for this neurophysiological monitoring. MEPs are normally used in combination with SSEPs, but their role in neuromonitoring for carotid endarterectomy is controversial. MJ Malcharek et al. (2020), in a retrospective study of 571 patients, concluded that MEPs presented an unacceptably high number of false-positives [19]. However, its use in combination with SSEPs has been recommended by some authors [20, 21]. It is important to emphasize that the use of MEPs determines the anesthetic agents that can be used because many common anesthetic agents interfere with them [11, 22]. It must also be mentioned that SSEPs and MEPs are very sensitive to hypotension, mechanical compression of neural tissue, hypocapnia and hypothermia [11]. Furthermore, as stated for EEG, this kind of monitoring also needs to be interpreted by experienced clinical neurophysiology experts.

The use of cerebral oximetry in vascular surgery has increased in recent decades. This kind of monitoring was initially considered very useful in cardiac surgery, but in 2017, the authors of a meta-analysis concluded against the use of NIRS in cardiac surgery due to its lack of clinical significance and its cost and limitations [23]. Regarding CEA, NIRS data have shown a good correlation with the mean flow velocity obtained by measuring stump pressures, and they have been proposed as an adequate tool for predicting the need for shunts [24, 25]. Nevertheless, some limitations have also been reported. There is no consensus on the threshold value of regional cerebral oxygen saturation (rSO2) to define the risk for cerebral hypoperfusion [26]. Moreover, rSO2 cutoff values reported in previous studies have been compared with EEG, TD, and single SSEP or MEP [27] but not with multimodality IONM, defined as using EEG, SSEPs and MEPs. In fact, clinical studies that specifically analyze the correlation between cerebral oximetry and EEG and SSEP/MEPs monitoring are needed [11].

Therefore, the aim of the present work is to describe the effectiveness of cerebral oximetry (NIRS) in detecting cerebral ischemia for indicating elective shunt and predicting the postoperative neurological status and to compare its results with simultaneous multimodality (EEG, SSEPs and transcranial MEPs [TcMEPs]) intraoperative neuromonitoring (IONM). The endpoint considered in the present work is the postoperative neurological status.

## 2 Methods

#### 2.1 Type of study

This study consisted of a retrospective analysis of data from a single-center cohort of patients who were treated with CEA.

#### 2.2 Ethics

All participants signed an informed consent form, and the study was approved by the local Ethics Committee in January 2017 (code 2017\_76).

#### 2.3 Patients

Eighty-six consecutive patients with indications for CEA (from 2017 to 2020) were included in the study (14 women; mean age 69.96 years old [SD=8.6]). The mean percentage of stenosis in the ipsilateral carotid artery was 80.2% (SD=8.85%), while the mean percentage of stenosis in the contralateral carotid artery was 63.0% (SD=20.80%). Only 5 patients (5.8%) had a history of contralateral CEA. Other clinical variables of the selected cohort of patients are shown in Table 1.

#### 2.4 Anesthesia

All patients underwent CEA under GA. All patients were monitored with invasive blood pressure (radial artery) to record baseline values before anesthetic induction. Total intravenous anesthetic (TIVA) was induced with a standardized protocol of propofol and remifentanil, which was maintained at 4–7 mg/kg/h and 0.05–0.5 mcg/kg/ min, respectively, guided by the bispectral index (40–60).

Table 1 Clinical features of the patients included in the study
-----------------------------------------------------------------

1		2
Age		68.96 (SD=8.60)
Sex		72:14
Symptoms		76 (88.4%)
Diabetes		41 (47.7%)
Hypertension		71 (82.5%)
Coronary disease		25 (29.1%)
Smoking status	Current	32 (37.2%)
	Past	31 (36.0%)
Statin use		63 (73.2%)
Ipsilateral carotid stenosis (%)		80.3 (SD = $8.85$ )
Contralateral carotid stenosis (%)		63.0 (SD = 20.80)
Contralateral CEA		5 (5.8%)
Preoperative mRankin Scale	0-1	80 (93.0%)
	2–3	6 (6.9%)
Postoperative mRankin Scale	0-1	79 (91.9%)
	2–3	7 (8.1%)
<b>SD</b> : Standard Deviation		

**SD**: Standard Deviation

Rocuronium was given for intubation purposes only (0.5– 0.6 mg/kg) and was reversed with sugammadex (2–4 mg/ kg) when needed (i.e., during an inability to monitor MEP). Oxygen saturation was kept above 95%, and CO2 partial pressure was maintained between 35 and 40 mmHg [28]. Mean arterial pressure was kept at 20% above baseline during clamping if a warning was identified [29] by vasopressors such as phenylephrine or norepinephrine. The temperature was maintained above 35 °C.

#### 2.5 NIRS monitoring

Cerebral oximetry was performed using two sensors placed on the forehead, and measurements were continuously taken with an INVOS 5100c or 7100 Regional Oximeter (Medtronic), which recorded the baseline value before administering sedative drugs or supplementary oxygen.

Regional oximetry monitoring and the use of protocols for dealing with desaturations are useful for improving postoperative results. However, in carotid surgery, no consensus has been established on the threshold for shunt placement (between 9 and 20%) [30–33]. This is probably due to the heterogeneity of the study protocols and the monitoring with which it is compared (stump pressure, transcranial Doppler, EEG, SSEP, MEP) and above all to the technical limitations of regional oximetry, which is mainly related to the extracerebral contamination of the external carotid artery, but above all to being a regional monitor of the blood flow of the frontal lobes. This is the main difference from multimodal IONM, which allows monitoring of the entire sensory and motor pathway as well as the cerebral cortex.

In the present work, the 20% threshold was used, we must emphasize that this NIRS warning criterion was not used to decide whether to implement a shunt or not. Instead, the decision was based on the warning criteria of multimodal neurophysiological monitoring and its interpretation by the surgical team.

#### 2.6 Multimodal IONM

Multimodal IONM was performed using Cadwell IOMAX® (Kennewick, USA) hardware. Monitoring was performed as follows:

- EEG was recorded using corkscrew electrodes in positions Fp1, F7, C3, P3, T3, O1, Fp2, F8, C4, P4, T4, O2, Fz, Cz in a double banana montage with filters of 0.5–70 Hz.
- SSEPs were recorded after stimulation of the bilateral median nerve at the wrist and posterior tibial nerve at the internal malleolus, with a varying intensity of 15–45 mA, 3.7–5.1 Hz interleaving stimulation frequency and

a pulse width of 0.2 ms. Peripheral SSEPs were recorded at the axillary point and at Cv–Fz, with filters 1-750 Hz. Cortical SSEPs were recorded at C3, C4, Cz, and Fz, with filters of 30-300 Hz.

• TcMEPs were evoked using anodal transcranial pulses at position C3–Cz/C4–Cz using corkscrew electrodes (train of 5–7 pulses, 0.5 ms, ISI 4 ms). Thresholds to elicit MEPs were calculated, such as the minimal intensity to evoke a reliable response and minimize cephalic movement that could disrupt the surgery. We used twisted bipolar needle electrodes bilaterally on the extensor digitorum communis, abductor pollicis brevis and abductor hallucis muscles to record the MEPs, with filters of 100–1500 Hz.

Warning criteria were the same as those that were previously published [22], and they included any of the following criteria indicated below:

- a decrease in amplitude of the EEG of 50% or marked change (delta) in the background frequency ipsi- or bilateral to the surgery,
- a drop of 50% or more of the amplitude of SSEPs, or.
- a 90% drop in amplitude of the MEPs.

The presence of any warning criteria was indicated to the surgeon and to the anesthesiologist.

## 2.7 Statistics

Postoperative neurological evaluation was performed within the first 30 min after the surgery and was evaluated each hour during the first postoperative 24 h. To calculate the sensitivity, specificity, positive and negative predictive values of each monitoring modality, we categorized each patient as follows:

- "True positives" were considered when a warning occurred in any of the monitoring methods, and the neurological status was compatible with the monitoring (note that shunt placement allowed us to recover monitoring warnings in most of the cases).
- "False-positives" were considered when a warning occurred and there was no change in the postoperative neurological status compared to the preoperative status.
- "True negatives" were considered when there was no warning and there was no change in the postoperative neurological status compared to the preoperative status.
- "False-negatives" were considered when no warning occurred, and the neurological status was not compatible with the monitoring (note that shunt placement allowed recovery of monitoring warnings in most of the cases).

Sensitivity, specificity, and positive and negative predictive values were calculated for each modality of IONM.

A comparison between "true positives" and "false-positives" in terms of demographic and clinical data was performed by using nonparametric statistical tests (chi-square and Mann–Whitney U). Statistical significance was considered when the p value was < 0.05.

## **3 Results**

Fifteen patients (17.4%) showed significant changes in NIRS monitoring, but only seven patients (8.1%) also presented warning criteria in multimodal IONM. A shunt was performed in all patients with changes in both monitoring modalities, and 6 patients showed a complete recovery of the IONM baselines, while one patient did not. That patient presented neurological deficits after the surgical procedure.

Apart from the patients who presented changes in both monitoring modalities, 2 patients (2.3%) only showed changes in IONM (with normal NIRS monitoring). All of them recovered their basal registries after shunt placement, and no neurological deficits were found after surgery.

Furthermore, 8 patients (9.3%) presented changes in NIRS monitoring that were maintained until the end of the surgery but without IONM warning. In none of these patients was a shunt placed, and none of the patients suffered from postsurgical neurological deficits. In two of these cases, a preoperative brain computed tomography (CT) scan was available. In one case (patient 18), a large frontal sinus was identified. In the other case (patient 68), marked brain atrophy was evident. Both conditions could have contributed to the NIRS changes.

Regarding all these results, one can consider that, in the present work, NIRS monitoring had 7 patients who were "true positives" (warning in NIRS and IONM), 8 patients who were "false-positives" (warning in NIRS but not in IONM), and 2 patients who were "false-negatives" (warning in IONM but not in NIRS). Regarding these data, NIRS monitoring had a sensitivity and specificity for detecting significant cerebral ischemia of 77.7% and 89.6%, respectively, and a positive and negative predictive value of 46.6% and 97.2%, respectively (Table 2).

A comparison between "true-positive" and "false-positive" patients was performed. Different distributions in sex (100% of males in the "false-positive" group) were identified (p=0.038). No other variables showed statistically significant differences between groups (Table 3).

Finally, the IONM consisted of three different techniques (i.e., TcMEP, SSEP and EEG), and an individual evaluation was performed for each of them (Table 4). EEG showed the

 Table 2
 Evaluation of NIRS and IONM as diagnostic tests for cerebral ischemia

	NIRS	IONM
True Positives	7	9
False-Positives	8	0
True Negatives	69	77
False-Negatives	2	0
Sensitivity	77.7%	100%
Specificity	89.6%	100%
Positive Predictive Value	46.6%	100%
Negative Predictive Value	97.2%	100%

highest levels of sensitivity and specificity (100%). In contrast, TcMEP showed the lowest sensitivity (11.1%).

## 4 Discussion

The present study consisted of a retrospective analysis of prospectively collected brain oximetry (NIRS) and neurophysiological (multimodal IONM) intraoperative data during CEA. NIRS showed a lower PPV and NPV than multimodal IONM. No clear differences were identified between "true positive" and "false-positive" patients. Finally, among the different modalities of IONM, EEG showed the best results for predicting postoperative outcome after CEA. All these results will be discussed below.

Cerebral oximetry showed a high NPV but a low PPV. This agrees with previously reported data. In a recent Cochrane metanalysis of 15 studies (1822 patients), the authors concluded that there was uncertainty about the effect of NIRS monitoring in preventing postoperative stroke [34]. Furthermore, another meta-analysis showed no difference in terms of neurological deficits between groups selecting shunts with or without NIRS monitoring [35]. Finally, when comparing NIRS with awake monitoring, a low sensitivity and high specificity to identify intraoperative ischemia was reported for NIRS monitoring [36]. In any case, most

 Table 4 Evaluation of each IONM modality as a diagnostic test for cerebral ischemia

	TcMEP	SSEP	EEG
True Positives	1	6	9
False-Positives	0	0	0
True Negatives	77	77	77
False-Negatives	8	3	0
Sensitivity	11.1%	66.6%	100%
Specificity	100%	100%	100%
Positive Predictive Value	100%	100%	100%
Negative Predictive Value	90.6%	96.2%	100%

authors agree on the need for better-quality data to be able to make stronger recommendations about the use of NIRS monitoring during CEA [34–36].

One of the main issues in NIRS monitoring is the threshold criteria for considering brain ischemia. A recent metaanalysis stated that the most common NIRS threshold value for brain ischemia used in most of the studies was  $\Delta 20\%$ rSO2, but those studies performed under general anesthesia varied considerably in the value of this threshold and, consequently, in shunt criteria indication [36]. Apart from the uncertainty about which is the best rSO2 threshold, several studies have reported that NIRS signals show contamination from extracranial sources [37–39].

The low PPV of NIRS can be considered an important aspect when deciding which brain ischemia monitoring during CEA should be used. In the present work, 8 patients would have received a shunt without a real need for it, and they would have been exposed to the complications of this procedure. On the other hand, two patients ("false-negatives") would have been at risk of suffering from postoperative neurological deficits if a shunt had not been placed due to the multimodal IONM warning. Therefore, NIRS should not be used as a single monitoring method for cerebral ischemia in CEA procedures.

Interestingly, no differences (apart from different sex distributions) were identified between patients with

Table 3 Comparison between patients with "false-positi	ive" and "true-positive" NIRS changes
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		NIRS changes		
		False-Positives (n=8)	True Positives (n=7)	p value
Age		65.0 (SD = 12.07)	70.1 (SD = 6.36)	0.486
Sex (male:female)		8:0	4:3	0.038
Diabetes		4 (50.0%)	5 (71.4%)	0.398
Hypertension		6 (75.0%)	6 (85.7%)	0.605
Coronary disease		3 (37.5%)	2 (28.6%)	0.714
Smoking status	Current	3 (37.5%)	3 (42.9%	0.253
	Past	4 (50.0%)	1 (14.3%)	0.605
Statin use		6 (75.0%)	6 (85.7%)	
Ipsilateral carotid stenos	is (%)	80.0% (SD=0.07)	78.8% (SD = 0.013)	0.595
Contralateral carotid ster	nosis (%)	59.0% (SD=0.25)	84.0% (SD = 0.076)	0.076
Contralateral CEA		-	1 (14.3%)	0.268

true-positive and those with false-positive NIRS changes. Thus, we can assume that the presence of vascular risk factors is not associated with a decrease in NIRS capacity to detect cerebral ischemia. However, morphological features of the cranium and/or the brain might influence the utility of NIRS in monitoring cerebral ischemia. As shown in two of the "false-negative" cases, a large frontal sinus and significant brain atrophy were present. Both conditions are associated with a larger distance between the brain surface and the NIRS detector; thus, the signal obtained in such situations might not be used with confidence. A possible recommendation in CEA cases where NIRS is going to be used is to perform a preoperative brain CT or MRI scan to evaluate the morphology of the cranium and the brain. In any case, future studies should also focus on this aspect.

On the other hand, it is also interesting to highlight that EEG was the modality of multimodal IONM with the greatest predictive capacity. This finding agrees with previous reports where EEG showed high reliability to determine the need for shunting during CEA [13, 14]. It should be noted that no significant correlation between rSO2 and EEG changes has been reported [40]; thus, one cannot consider that these monitoring methods may be interchangeable. Nevertheless, Thirumala et al. (2015), in a metanalysis, concluded that the sensitivity and specificity of EEG in predicting postoperative strokes were 52% and 84%, respectively [41], figures much lower than those reported here. Similar sensitivity and specificity of EEG were reported in an updated review by the same research group [42]. However, those authors included those events that occurred up until 30 postoperative days. In the present work, we have only focused on the intrasurgical and immediate postsurgical (24 h after the surgery) events and not those that could occur up until 30 days after the procedure; thus, it would not be accurate to compare the present and referenced works [41, 42].

As EEG data has been proposed as a biomarker of brain hypoperfusion [43, 44], a recent meta-analysis reported that EEG was the monitoring method used in the largest number of patients [3]. However, one of the most critical points for the use of EEG is the need for expert interpretation. In any case, the use of quantitative EEG (a procedure that processes the EEG recorded signal and is represented in a color code, which is an easier method of interpretation) has been demonstrated to be useful in the detection of cerebral ischemia [45].

Despite the utility of EEG in detecting brain ischemia, it has been previously reported that the diagnostic accuracy of multimodality IONM is higher than that of an approach using single IONM during CEA [46]. As stated in the introduction section, SSEPs and MEPs are very sensitive to many intraoperative situations, but SSEPs are also widely accepted as good biomarkers of brain hypoperfusion [43, 44], and TcMEPs are able to detect subcortical ischemia, while EEG and SSEPs are not [47, 48]. Therefore, we consider that multimodal IONM is the most suitable technique for detecting brain ischemia during CEA.

## 4.1 Limitations

This work has some limitations that should be noted. The retrospective nature of the analysis and the fact that the data were obtained from a single institution are the most significant. Most of the published literature about brain ischemia monitoring during CEA shares these limitations. Thus, future observational, prospective, multicenter studies should be performed to elucidate the role of cerebral oximetry in CEA procedures.

## 5 Conclusion

NIRS presented lower sensitivity and specificity than multimodality IONM in detecting brain ischemia and, therefore, in predicting the postoperative neurological status during CEA under general anesthesia. EEG showed the best predictive capacity among the different methods included in multimodality IONM. Therefore, we consider that NIRS cannot be used as a single neuromonitoring method for brain ischemia during CEA procedures. Rather, it should always be accompanied by any type of neurophysiological monitoring technique and always include EEG.

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#### Declarations

**Ethics approval** The study was approved by the local Ethics Committee in January 2017 (code 2017 76).

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