

Non-Invasive Cerebral Oximetry as Predictor of Cerebral Blood Flow Cessation in Potential Brain-Dead Donors

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Abstract: The determination of brain death in adult organ donors usually includes confirmation with an instrumental test after the clinical diagnosis. The time interval between these two diagnostic steps varies widely and represents a significant source of stress for patients' families. We aim to explore whether cerebral oximetry monitoring using near-infrared spectroscopy (NIRS) is useful for predicting the absence of cerebral blood flow in potential organ donors after brain death, with the aim of providing more accurate information to families regarding waiting times. Case series presentation: Eight cases were included over a one-year period. Patients diagnosed with brain death whose relatives consented to organ and/or tissue donation. Acquisition of data on the temporal evolution of regional cerebral oxygen saturation between clinical diagnosis of brain death and its instrumental confirmation. The mean regional cerebral oxygen saturation was $66.8 \pm 2.03\%$ eight hours before the clinical diagnosis, $68.4 \pm 1.0\%$ at the time of clinical diagnosis, and $68.6 \pm 1.5\%$ at the time of instrumental confirmation. Cerebral oximetry using NIRS monitoring in this study was not useful for predicting the absence of cerebral blood flow in brain-dead organ donors. In clinical practice, monitoring organ donors with this technology is not relevant, as it does not contribute to reducing the family's waiting time.

Keywords: Cerebral regional oximetry, organ donation process, brain dead.

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Introduction

Diseases of the central nervous system (CNS) are the most frequent cause of brain death (BD), with a prevalence in Spain of 16.5 cases per 1,000 inhabitants (Ministry of Health, 2024a), and they constituted the second leading cause of mortality in 2022 (National Statistics Institute, 2024). Approximately 120,000 people suffer a stroke each year in Spain, and around 25,000 individuals die because of this condition (Ministry of

Health, 2024b). Several studies have reported a prevalence of BD in Spanish intensive care units (ICUs) ranging from 14% to 24% (Escudero et al., 2009; Bodi et al., 2015). A substantial proportion of patients who die from CNS diseases become organ and/or tissue donors. In 2024, Spain reported a total donation rate of 52.6 donors per million population, including 25.6 donors per million corresponding to BD, and an overall rate of

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49.7 donors per million population (National Transplant Organization, 2024).

BD is defined as the irreversible cessation of all intracranial neurological functions, involving both the cerebral hemispheres and the brainstem, and its diagnosis is based on clinical criteria (Escudero, 2009). An instrumental test for BD confirmation is not recommended as confirmatory tests for brain death in the most recent Death by Neurological Criteria Consensus Guideline published by the American Academy of Neurology (Greer et al., 2023). However, in patients whose family or legally responsible representative consents to organ donation, certain clinical situations require the use of an instrumental test for the confirmation of BD in addition to clinical diagnosis. Many Spanish protocols include instrumental tests in this process, with more than 87% doing so, as reported in the study by Mahillo et al. (2018) These tests can demonstrate the absence of cerebral blood flow---such as computed tomography angiography, conventional arteriography, cerebral scintigraphy, and transcranial Doppler ultrasonography---or the absence of cortical electrical activity, as assessed by electroencephalography (EEG).

The interval between the clinical diagnosis of death and its confirmation through instrumental testing compatible with BD is highly variable and unpredictable. This period can be particularly distressing for families who have consented to organ donations, as one of their most frequent requests is to minimize the waiting time. At the same time, it is sometimes necessary to perform multiple instrumental tests to confirm death, which increases the consumption of medical resources.

Current neurocritical care management includes several methods for monitoring cerebral oxygenation, such as hemoglobin saturation in the internal jugular vein bulb (S_{jvO_2}), brain tissue oxygen pressure (P_{tiO_2}), and non-invasive regional cerebral tissue oxygenation. The latter, measured as regional oxygen saturation (rSO_2) using near-infrared spectroscopy (NIRS), is one of the most widely employed techniques in ICU and others hospital settings (Zhong et al., 2021).

The supply of O_2 to the brain tissue is the product of the arterial O_2 content and cerebral blood flow, which, according to Hagen-Poiseuille's equation, correlates directly with cerebral perfusion pressure, which is the difference between mean arterial pressure (MAP) and intracranial pressure (De Georgia et al., 2015). Based on the emission of near-infrared light photons, NIRS technology can detect changes in cerebral O_2 metabolism by analyzing the relative absorbance of oxyhemoglobin and deoxyhemoglobin by means of two sensors (both hemispheres) placed on the patient's

forehead (Eyeington et al., 2019). It measures venous (75–80%), capillary (5%), and arterial (20–25%) blood oxygen saturation in small cortical vessels, providing a percentage value of rSO_2 .

We hypothesize that rSO_2 , measured using Masimo Regional Oximetry O3® NIRS technology, may be a useful tool for assessing changes in, and the absence of, cerebral blood flow in potential brain-dead organ donors. This approach could allow for the prediction of waiting times, thereby facilitating the organ donation process for families.

The primary aim of this study was to explore changes in non-invasive cerebral regional oximetry between the clinical diagnosis of brain death and the confirmation via instrumental testing in potential organ and tissue donors. The secondary objectives were: (a) to evaluate the evolution of cerebral regional oximetry during the period preceding and following the clinical diagnosis of brain death, and (b) to assess the timing of changes in cerebral regional oximetry across the different phases of the donation process, starting from the occurrence of brain death.

Method

The report of this study is in accordance with the STROBE checklist for cross-sectional studies guidelines (Strengthening the Reporting of Observational studies in Epidemiology) (von Elm et al., 2008). A case series study involving neurocritical patients admitted to the ICU of a tertiary hospital (Madrid, Spain), whose pathological process led them to BD, and whose relatives or responsible person agreed to organ and/or tissue donation. Exclusion criteria: patients with a clinical diagnosis of BD that were not donors, either due to medical contraindications or family refusal.

Since the population of interest consisted of potential organ donors, data were collected from the time the patient was identified as having catastrophic brain injury with no further therapeutic options. Study data were recorded hourly in the patient's daily chart until discharge from the ICU. Routine patient monitoring (Mx/800 multiparametric monitor, Philips) included invasive blood pressure, surface electrocardiography (ECG), and peripheral oxygen saturation (SpO_2). Regional cerebral oxygen saturation (rSO_2) was monitored using the unit's standard device, Masimo Regional Oximetry O3®. The primary endpoint was the assessment of rSO_2 in both cerebral hemispheres (expressed as absolute regional cerebral saturation values, i.e., percentage of hemoglobin saturation) over time, from the suspected onset of brain death to its confirmation via isoelectric EEG or any other test demonstrating absent cerebral blood flow. Secondary data collected included demographic and clinical

characteristics, hemodynamic parameters, SpO₂, and ventilator settings.

A descriptive analysis was performed to characterize the study population and to evaluate the temporal evolution of rSO₂, using baseline values recorded at least 8 hours prior to the diagnosis of brain death. Reference values reported in healthy individuals, as described in the literature using the same NIRS technology, are approximately 65–67% in both cerebral hemispheres (Eyeington et al., 2019).

The study was approved by the Drug Research Ethics Committee (CEIm 05/23, Registration No. 5093). To obtain the required data, it was not necessary to subject the donor to any monitoring or extraordinary examination. The data were collected from the patient medical records according to standard practice. The processing, communication, and transfer of the personal data of all participating subjects complied with the provisions of Organic Law 3/2018, of December 5, on Personal Data Protection and Guarantee of Digital Rights, and the application of Regulation (EU) 2016/679 of the European Parliament and of the Council of April 27, 2016, on Data Protection. No personal data of the subjects were recorded except for the variables of interest for the study, and the ethical principles of the Declaration of Helsinki and the Oviedo Convention on Human Rights and Biomedicine were followed.

Result and Discussion

Table 1. Characteristics of The Cases Studied

Case	Age	Gender	Apache II	ADM_D	INT_TT	INS_D	Time
1	79	F	28	IPH	NO	EEG	6
2	54	F	8	MCA_S	NO	EEG	3
3	78	F	26	MCA_S	P_TBT	EEG	4
4	63	M	29	CPR_A	NO	EEG (x2)	26
5	79	F	25	IPH-SAH	NO	EEG (x2)	11
6	43	M	9	CPR_A	NO	CTA (x2)	14
7	46	F	25	CPR_A	NO	EEG	7
8	62	M	14	IPH	NO	EEG	4

APACHE II: APACHE II score; ADM_D: admission diagnosis; INT_TT: interventional treatment; INS_D: instrumental confirmatory diagnosis; TIME: hours between clinical diagnosis of brain death and instrumental confirmation; IPH: intraparenchymal hemorrhage; MCA_S: Medial Cerebral Artery stroke; CPR_A: post cardiopulmonary resuscitation anoxia; SAH: subarachnoid hemorrhage; EEG: electroencephalogram; (x2): performed twice; P_TBT: percutaneous thrombectomy; CTA: Computed tomography angiography.

Of eleven potential brain-dead donors identified over a one-year period, nine ultimately became organ and tissue donors. The study includes six cases that were continuously monitored at least from 8 hours prior to the clinical diagnosis of brain death (BD) until the completion of the instrumental test, and two additional patients monitored from 2–4 hours before death until the instrumental test. Data from three donors were not recorded correctly and were therefore excluded from the analysis. The characteristics of the included cases are summarized in Table 1.

Throughout the measurement period, rSO₂ values remained within the same range as baseline measurements (prior to BD), with no significant changes observed in either hemisphere in any of the cases. Figure 1 presents the individual data for six cases, illustrating the trend of rSO₂ in both hemispheres alongside pulse oximetry, recorded at 2-hour intervals from 8 hours before the clinical determination of BD to the performance of the instrumental test.

The mean rSO₂ of both hemispheres 8 hours prior to the clinical diagnosis was $66.8 \pm 2.03\%$ ($n = 6$), at the time of clinical diagnosis it was $68.4 \pm 1\%$ ($n = 8$), and at the time of instrumental confirmation it was $68.6 \pm 1.5\%$ (Figure 2, $N=8$).

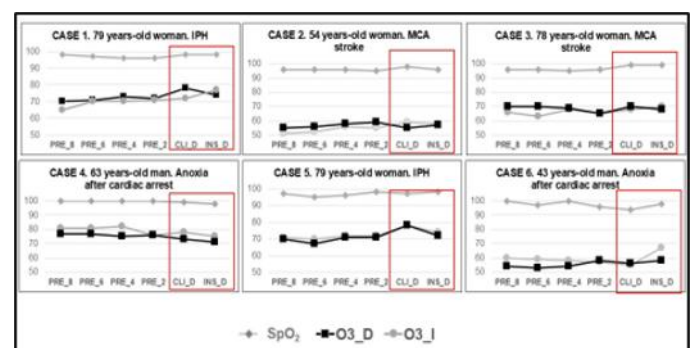


Figure 1. Trend values of rSO₂ and SpO₂ at 2-hour intervals, from 8 hours prior to the clinical diagnosis of BD until confirmation by instrumental testing, from the 6 cases. SpO₂: pulse oximetry saturation; O3_D: right cerebral regional oximetry; O3_I: left cerebral regional oximetry; IPH: intraparenchymal hemorrhage; MCA: Medial Cerebral Artery; Pre_8,6,4 and 2: 8,6,4 and 2 hours prior to clinical diagnosis of BD. CLI_D: time of clinical diagnosis of BD; INS_D: time of instrumental confirmation of BD.

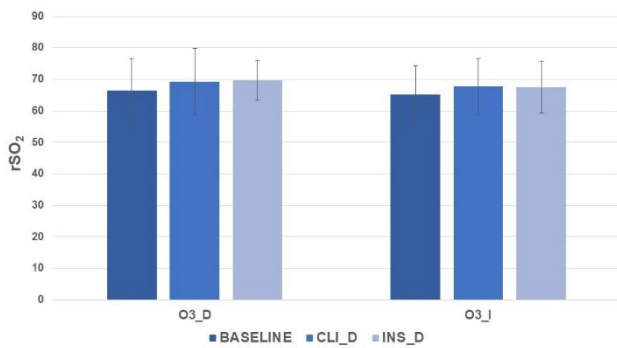


Figure 2. Regional oximetry values in both cerebral hemispheres prior to the BD, at the time of clinical diagnosis of BD (CLI_D), and at the time of instrumental confirmation (INS_D). Mean and standard deviation of all cases included; (O3_D: right cerebral regional oximetry, O3_L: left cerebral regional oximetry).

As expected, the time intervals between measurement points varied considerably. The mean duration between clinical diagnosis and instrumental confirmation of BD was 9.4 ± 7.7 hours, with a maximum of 26 hours and a minimum of 3 hours. Instrumental confirmation was performed by electroencephalography (EEG) in seven patients, two of whom required a second test showing isoelectric traces at 11 and 27 hours after clinical diagnosis. In one case, confirmation was achieved using computed tomography angiography.

In this case series of patients with severe brain damage, cerebral regional oxygenation values monitored with NIRS technology did not change during the evolution of such damage until the BD was confirmed by instrumental testing. As expected, highly variable evolution times to death have also been observed, as well as the time elapsed between clinical and instrumental diagnosis. Since instrumental testing is not performed during night shifts, these intervals may be overestimated in certain cases. Nevertheless, in three cases included in the study with longer intervals (4, 5 and 6), a first non-confirmatory test was performed close to the clinical diagnosis of BD, with a second test being necessary.

The most significant limitation of this study is the short number of cases included. However, the trend in rSO_2 from the onset of catastrophic brain damage to confirmation of BD by instrumental diagnosis has been recorded, showing a total absence of changes in all cases, and values like normal ranges for healthy individuals.

A previous study in neurocritical patients examining the absence of cerebral blood flow in brain death reported results like ours, despite using different NIRS devices than the Masimo system. Soehle et al. using the INVOS 5100C/7100 and Foresight Elite systems, observed that normal rSO_2 values persisted in

12 organ donors up to the time of aortic cross-clamping (Soehle et al., 2024).

Kerz et al. compared NIRS technology with other monitoring modalities in a series of 11 patients, reporting findings consistent with those observed in our study. They evaluated the ability of NIRS to detect ischemic events, defined as a $PtIO_2$ value ≤ 15 mmHg, and assessed the correlation between cerebral tissue oxygenation measured invasively and rSO_2 values. No correlation was found between $PtIO_2$ and NIRS readings, so they concluded that NIRS monitoring did not reliably detect ischemic episodes (Kerz et al., 2016).

Others previous publications evaluating cerebral oxygenation in individuals with severe brain damage who die in the ICU identified, include case studies using invasive technologies other than NIRS. Palmer et al. used a Clark polarographic microcatheter, which measures an area of approximately 17 millimeters (Integra Neurosciences, Plainsboro, NJ), to assess cerebral tissue oxygenation, determining that it was equal to 0 in the 8 patients who suffered BD (Palmer & Bader, 2005). Another study using the same monitoring in 6 cases of BD, it was observed that a decrease in cerebral tissue oxygenation toward 0 mmHg as ICP increased and CPP decreased, reaching 0 only when there was clinical evidence of BD. Furthermore, it remained at 0 for the next 12 hours until the second examination and without response to oxygen administration (Smith et al., 2007).

NIRS monitoring, using sensors placed on the patient's forehead at both midlines, targets regions perfused by the middle and anterior cerebral arteries. However, the findings of this study indicate that NIRS does not reliably capture the absence of cerebral blood flow, prompting consideration of possible underlying causes.

First, superficial tissues may significantly influence the measurement of various parameters, including tissue oxygenation (Amendola et al., 2023). In this regard, Soehle et al. concluded that under conditions of normal extracerebral oxygenation, the NIRS devices used in their study were unable to detect cerebral hypoxia due to extracerebral contamination (Soehle et al., 2024).

Second, several studies have highlighted the utility of NIRS technology for the early detection of cerebral perfusion deficits in various clinical scenarios, including cardiopulmonary resuscitation (Shin et al., 2022), cardiac surgery with extracorporeal circulation (Escudero et al., 2019), vascular and thoracic surgery (Ali et al., 2022), and pulmonary endarterectomy (Catalan et al., 2014). In our case series, flow through the external carotid artery remained uncompromised, meaning that the extracranial contribution to the NIRS signal is highly

variable, which can account for up to 50% of the measured signal (Khan et al., 2021) when systemic arterial oxygenation is within normal ranges.

Conclusion

Regional cerebral oximetry values measured using NIRS technology remained stable during the progression to brain death and up to the time of instrumental diagnosis in all cases studied. Therefore, NIRS is not a reliable tool for assessing the absence of cerebral blood flow, nor can it be used to predict the interval between clinical and instrumental confirmation of brain death in organ and tissue donors.

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Author Contributions

Design, conceptualization, data acquisition, methodology, formal analysis: DRH, ADF and MJRA. Data acquisition: MDR, MJRA. Writing of the paper: DRH, ADF and IMB. Validation and visualization of the article: JASG, BAS, NVG and SRD.

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Conflicts of Interest

The author declares no conflict of interest.

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