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Association between periprocedural cerebral desaturation during transcatheter aortic valve implantation and postprocedural delirium: a prospective observational study

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Abstract

Background The aim of this study was to investigate whether the level of decrease in cerebral oxygen saturation during the valve placement phase of the transcatheter aortic valve implantation (TAVI) procedure under sedation has an effect on postoperative delirium (POD).

Methods The study initially assessed 50 patients between the ages of 50 and 90 years with an indication for TAVI by the cardiac team. Regional cerebral oxygen saturation (rScO2) was measured using Near-infrared spectroscopy (NIRS) before the procedure (T1), during surgical field sterilization (T2), catheter placement (T3), wire manipulation (T4), valve placement (T5) and access site artery repair (T6). Confusion Assessment Method for The Intensive Care Unit (ICU-CAM) test was performed on intensive care unit and the presence of POD was questioned. Patients were divided into two groups as those without POD (Group 1) and those with POD (Group 2).

Results The study was completed with 41 patients in total. While POD was present in 12 (29.3%) of the patients evaluated intensive care unit, POD was not observed in 29 (70.7%) patients. The rScO2 value measured at T5 was significantly lower in Group 2 compared to Group 1 ($p < 0.001$).

Conclusions In our study, the rate of POD after TAVI was as high as 29.3%. Low rScO2 during valve placement was associated with delirium. Our findings indicate that NIRS devices could be a useful tool for assessing the risk of POD during the TAVI procedure; however, further research is needed to validate their routine clinical use.

Keywords Postoperative delirium, Transcatheter aortic valve implantation, Near-Infrared spectroscopy

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Background

Since 2002, transcatheter aortic valve implantation (TAVI) has been performed in patients with severe aortic stenosis in whom the surgical risk is moderate to high [1]. Overall, the incidence of complications after TAVI has decreased significantly due to increased experience of the operator performing the procedure, better sizing experience on computed tomography, significant technological advances in the design of the prostheses, and reduced size of the sheaths, although the rate of delirium is still high [2].

Delirium is a syndrome that develops over a short period of time and tends to fluctuate, characterized by inattention and cognitive impairment, and occurs as an acute change in cognitive function [3, 4]. Postoperative delirium is the decompensation of cerebral function in response to one or more pathophysiologic stress factors such as major surgery [5, 6]. Post-procedure delirium is a common complication after TAVI procedure due to the elderly and frail patient population. Patients with post-procedure delirium after TAVI have a doubled length of hospital stay and an almost 3-fold increased risk of post-procedure readmission and death [7, 8].

Near-infrared spectroscopy (NIRS) devices have the capacity to measure tissue oxygenation non-invasively and have been used to evaluate the relationship between cerebral oxygenation and cognitive function [9]. In studies conducted with major orthopedic surgeries, it has been reported that the occurrence of post-procedure delirium in the postoperative period increases in patients with perioperative cerebral desaturation [10, 11].

The aim of this study is to evaluate the relationship between the level of cerebral oxygen desaturation during valve deployment and the incidence of post-procedure delirium. We hypothesize that a significant decrease in cerebral oxygen saturation during the valve deployment phase of the TAVI procedure under sedation increases the likelihood of developing post-procedure delirium.

Methods

The study was conducted prospectively at Istanbul University-Cerrahpaşa, Institute of Cardiology, between 2021 and 2023 after obtaining ethics committee approval (Date: 31.03.2021 Number: E-69291215-900-65040). The study initially planned to assess 50 patients for eligibility, all of whom provided written informed consent to participate in the research. All patients were graded by the cardiac team (cardiologist, cardiovascular surgeon and anaesthetist) according to the aortic stenosis criteria of the of the "2021 ESC/EACTS Guidelines for the management of valvular heart disease" (Fig. 3 in the guideline). Patients with high-gradient aortic stenosis (AS) with a peak velocity (Vmax) ≥ 4 m/s, low-gradient aortic stenosis (AS) with a peak velocity (Vmax) < 4 m/s, and an aortic valve area (AVA) < 1 cm^2 were considered to have severe aortic stenosis. Patients were also assessed for TAVI using the patient-based assessment in the same guideline (Table-6 in the guideline) [12].

Patients who had no indication for TAVI, who had neurological or psychological diseases (dementia, alzeimer, cerebrovascular disease, etc.), who had a history of allergy to ketamine, midazolam, fentanyl, or who were at a sociocultural level where they could not answer the psychological and neurological tests were excluded from the study. Consent for the study was obtained from each patient and the Mini-Mental State Examination test was performed after pre-anesthetic examination [13]. Patients with Mini-Mental State Examination scores below 24 were excluded from the study.

To minimize selection bias, all patients undergoing TAVI during the study period were systematically screened based on predefined inclusion criteria, including severe aortic stenosis meeting the 2021 ESC/EACTS Guidelines, approval for TAVI through patient-specific assessment, and Mini-Mental State Examination (MMSE) scores ≥ 24. Exclusion criteria encompassed neurological or psychological conditions, allergies to anesthetic agents, and communication barriers. Data collection was standardized using validated NIRS devices for rScO2 measurement and the Confusion Assessment Method for The Intensive Care Unit (ICU-CAM) test, which was applied uniformly by trained clinicians to ensure consistency and reduce potential confounding.

Patients who were admitted to the catheterization laboratory for the procedure were monitored with electrocardiogram, oxygen saturation (SpO_2), invasive arterial, NIRS, bispectral index. After monitoring, oxygen support was provided to each patient with a 6 L/min mask. A standard anaesthesia protocol with midazolam 2 mg and ketamine 0.5 mg/kg, fentanyl 1 mg/kg was then administered to each patient. In case of the need for an additional anesthetic dose during the procedure (patient agitation, movement that would disrupt the procedure, etc.), 0.25 mg/kg ketamine was administered as an IV bolus. Moderate sedation (conscious sedation), a form of sedation defined by the American Society of Anesthesiologists in which the patient can respond significantly to verbal and tactile stimuli, was applied [14]. Right and left regional cerebral oxygen saturation (rScO2) was monitored by placing two NIRS probes on each side of the patients' forehead. The same rSCO2 meter (Medtronic, Somanetics, Covidien, Cerebral/Somatic Oximeter, Mansfield, MA 02048 USA) was used for all rScO2 measurements. Right and left rScO2 values were averaged for analysis.

Age, gender, weight, height, current diseases, arterial blood gas (partial oxygen saturation (pO2), partial carbon dioxide (pCO_2), SpO_2, base exclusion, lactate,

hemoglobin, hematocrit, platelet values were recorded. Bispectral index, heart rate, mean arterial pressure (MAP), respiratory rate, SpO_2 were measured continuously. rScO2 was measured at 6 different times: baseline monitoring phase (without supplemental oxygen) (T1), post-sedation phase, during surgical field sterilization (T2), catheter insertion (T3), wire manipulation (T4), valve placement (T5) and during access site artery repair (T6).

All TAVI procedures were performed by the same cardiology team to ensure standardization and used the transfemoral approach. Oxygen flow was increased from 6 L/min to 8 L/min at the beginning of the T5 phase (valve deployment and rapid ventricular pacing). If the duration of T5 was prolonged (more than 30 s) or if post-procedural hemodynamic instability occurred, vasopressors and inotropic agents were administered to stabilize cerebral perfusion. Specifically, ephedrine (5 mg IV) was used for transient hypotension, and dopamine infusion was initiated if multiple boluses of ephedrine were required.

At the end of the procedure, the patient was transferred to cardiology intensive care unit after neurologic examination and Modified Alderate Scoring System (MASS) was questioned. The ICU-CAM [15] Test was performed at 12 and 24 h in the intensive care unit and the presence of post-procedural delirium was questioned. Patients were divided into two groups as those without post-procedure delirium (Group 1) and those with post-procedure delirium (Group 2).

During the postoperative ICU stay, sedation was avoided unless deemed absolutely necessary to minimize its impact on the incidence of postoperative delirium. No patients required sedation postoperatively, and as per the study protocol, any patient requiring sedation would have been excluded. The treatment regimen for patients diagnosed with postoperative delirium was adjusted only after the diagnosis, ensuring that medications did not confound the results.

Sample size calculation

An a priori power analysis was conducted to determine the appropriate sample size for this study. We anticipated that the groups might not be of equal size and that a high effect size would be expected based on preliminary data. Using G*Power (3.1.9.7) [16] software, we set the alpha level at 0.05, the desired power at 0.80, and an allocation ratio of 2:1. According to the power analysis, the minimum required sample sizes were 25 participants for Group 1 (no delirium) and 13 participants for Group 2 (delirium). These parameters were chosen to ensure sufficient power to detect significant differences while accounting for the anticipated effect size. Our study included 29 participants in Group 1 and 12 participants in Group 2, which we believe is adequate based on the power analysis results.

Statistical analysis

Statistical analyses were performed using IBM© SPSS© Statistics version 29 (IBM© Corp. Armonk, NY, USA). Categorical and continuous variables are presented as frequencies, percentages, means, and standard deviations (SD). Normality of the data was assessed using the Shapiro–Wilk test. Depending on the distribution, categorical variables were analyzed using Pearson's chi-square test or Fisher's exact test, and continuous variables were analyzed using independent samples t-test or Mann-Whitney U test. For repeated measures, differences between groups were evaluated using Mixed-design ANOVA, with Greenhouse-Geisser correction applied when necessary to adjust for sphericity violations. To account for multiple comparisons, pairwise comparisons were performed using the Bonferroni correction method. All statistical tests were two-sided, and a p-value of < 0.05 was considered statistically significant.

All participants completed the data collection process without any missing data, ensuring that all variables were fully available for analysis. As there were no concerns regarding variability or potential confounders, sensitivity analyses were not deemed necessary for this study.

Results

A total of 50 patients who underwent TAVI procedure under sedation participated in the study. No missing data were observed for any of the variables collected in this study. All participants who met the inclusion criteria completed the data collection process in full, ensuring the completeness and accuracy of the dataset. A total of 9 patients were screened out prior to the study: 4 patients were deemed not eligible (2 with dementia, 1 with a history of Alzheimer's disease, and 1 with a history of cerebrovascular disease), and 5 patients were excluded after screening (3 with a Mini-Mental State Examination score lower than 24 and 2 with communication difficulties). The study was completed with 41 patients in total (Fig. 1). 20 (48.8%) of the patients were female and 21 (51.1%) were male. The mean age was 79.32 ± 7.9 years and BMI was 27.97 ± 5.18 kg/m². The mean Mini-Mental State Examination score was 26.39 ± 1.83 points. Patients' demographic and chronic disease data are shown in Table 1. The mean procedure time was 106.41 ± 16.72 min.

One patient (2.4%) died (within 1 week). The follow-up period in the intensive care unit (ICU) ranged from 1 to 5 days, the mean duration of intensive care unit stay was 1.78 ± 1.13 days. The mean MASS score was 9.17 ± 0.70. 12(29.3%) patients were diagnosed with delirium in intensive care unit.

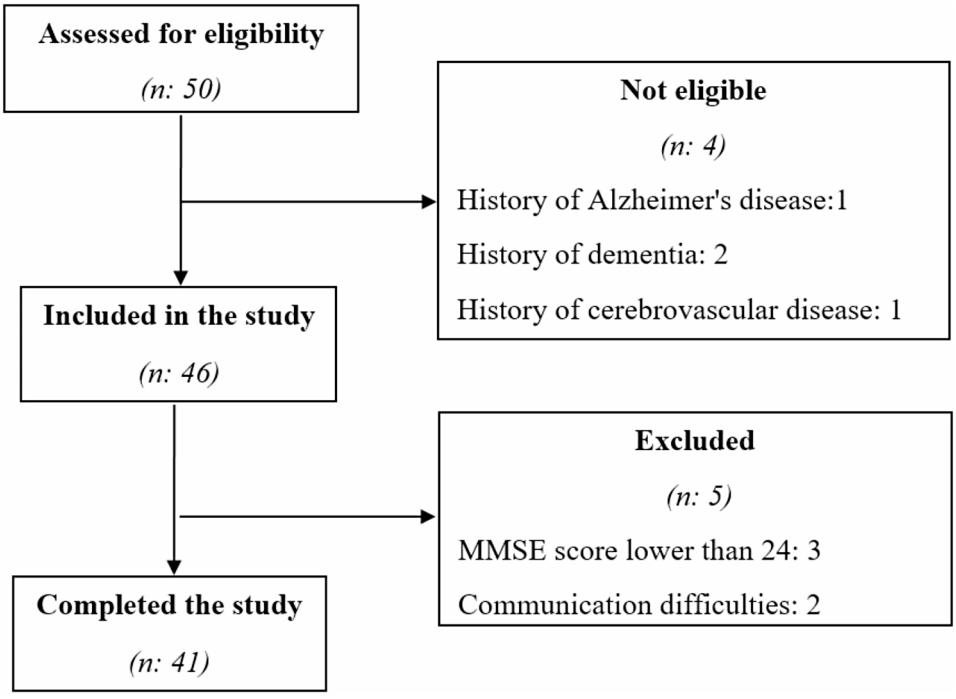

Fig. 1 CONSORT flow diagram summarizing study participant disposition. Abbreviations: MMSE Mini-Mental State Examination

Demographic data were similar between the groups ($p > 0.05$). Duration of procedure (min) and duration of intensive care unit stay (day) did not differ between groups ($p > 0.05$) (Table 2).

In Table 1, baseline demographics and comorbidities were compared between Group 1 (non-delirium) and Group 2 (delirium). No statistically significant differences were found between the groups for variables such as age, gender, or comorbidities ($p > 0.05$). However, as presented in Table 2, the baseline MMSE scores were significantly lower in the delirium group compared to the non-delirium group ($p < 0.001$).

No significant difference was observed in the duration of rapid ventricular pacing between Group 1 (non-delirium) and Group 2 (delirium) ($p = 0.621$). This finding indicates that the duration of pacing did not have a differential impact on the cerebral oxygenation levels or the incidence of postoperative delirium in our cohort (Table 2).

While post-procedure delirium was present in 12(29.3%) of the patients evaluated in intensive care unit, post-procedure delirium was not observed in 29(70.7%) patients. While post-procedure delirium was observed in 9 (22%) patients on day 1 in intensive care unit, post-procedure delirium was encountered in 3(7.3%) patients on day 2. When rScO2 values measured at 6 different times were compared, T1, T2, T3, T4 values did not show statistically significant difference between the groups ($p > 0.05$). The rScO2 value measured at T5 was significantly lower in Group 2 compared to Group 1 ($p < 0.001$). Similarly, the rScO2 value at T6 was lower than group 1 ($p = 0012$) (Table 2).

The cut-off value of the rScO2 value was determined as 43 (Fig. 2). When we made a separate grouping as those with rScO2 values below 43 and above 43, the delirium rate was significantly higher in those with rScO2 values below 43 ($p < 0.001$). The absolute risk increase for developing post-procedure delirium was 76.4% for patients with rScO2 values below 43% compared to those with values above this threshold. No significant correlation was observed between low rScO2 and postoperative atrial fibrilation, arrhythmia rate, intensive care unit stay and death ($p > 0.05$). Sensitivity analyses were not performed, as the primary analysis was deemed robust, and there were no concerns regarding the variability or potential confounders that would necessitate further analyses. In patients with delirium, the difference in rScO2 low between T1 and T5 times was 38.79% (Table 3).

At T5, the relative percentage reduction in rScO2, calculated by normalizing each patient's T1 value to 100%, was significantly greater in the delirium group compared to the non-delirium group ($p < 0.001$). This normalization allowed for a standardized comparison of percentage reductions across patients, emphasizing the critical association between marked cerebral desaturation and the development of postoperative delirium during valve deployment (Fig. 3).

The results revealed a significant main effect of time on rScO2 values ($F\ (5, 195) = 38.943$, $p < 0.001$), indicating that rScO2 values significantly varied across the six time

Table 1 Summary of patient demographics and medical histories

	Group 1 (No delirium) *n* = 29		**Group 2 (Delirium present) *n* = 12**	***p***
	***n* (%)**		***n* (%)**	
Gender	Male	17 (81%)	4 (19%)	0.181
	Female	12 (60%)	8 (40%)	
Smoking	None	20 (64.5%)	11 (35.5%)	0.231
	Present	9 (90%)	1 (10%)	
Chronic Alcohol Consumption	None	24 (68.6%)	11 (31.4%)	0.651
	Present	5 (83.3%)	1 (16.7%)	
Substance Use Disorder	None	29 (100%)	100%	N/A
Diabetes Mellitus	None	18 (78.3%)	5 (21.7%)	0.307
	Present	11 (61.1%)	7 (38.9%)	
COPD	None	26 (68.4%)	12 (31.6%)	0.543
	Present	3 (100%)	0 (0%)	
	Oxygen Dependent	0 (0%)	0 (0%)	
Peripheral Artery Disease	None	29 (100%)	12 (100%)	N/A
Previous Cardiac Surgery	None	24 (68.6%)	11 (31.4%)	1.000
	CABG	4 (80%)	1 (20%)	
	Heart Valve Surgery	1 (100%)	0 (0%)	
Previous PCI	None	20 (69.0%)	9 (31.0%)	1.000
	Present	9 (75.0%)	3 (25.0%)	
Kidney Failure	None	28 (71.8%)	11 (28.2%)	0.505
	Non-dialysis dependent	1 (50%)	1 (50%)	
	Dialysis Dependent	0 (0%)	0 (0%)	
Heart Failure	None	26 (70.3%)	11 (29.7%)	1.000
	Present	3 (75.0%)	1 (25.0%)	
Hypertension	None	11 (68.8%)	5 (31.3%)	1.000
	Present	18 (72.0%)	7 (28.0%)	
Active Endocarditis	None	29 (100%)	12 (100%)	N/A
Chronic Atrial Fibrillation	None	25 (67.6%)	12 (32.4%)	0.302
	Present	4 (100%)	0 (0%)	
Permanent Pacemaker Use	None	29 (100%)	12 (100%)	N/A
Pulmonary Hypertension	None	25 (73.5%)	9 (26.5%)	0.398
	Present	4 (57.1%)	3 (42.9%)	
NYHA Class	Class 3	16 (66.7%)	8 (33.3%)	0.493
	Class 4	13 (76.5%)	4 (23.5%)	
Liver Disease	None	29 (100%)	12 (100%)	N/A
MI	None	26 (72.2%)	10 (27.8%)	0.620
	Present	3 (60.0%)	2 (40.0%)	

Abbreviations: COPD Chronic obstructive pulmonary disease, CABG Coronary artery bypass grafting, PCI Percutaneous coronary intervention, NYHA New York Heart Association, MI Myocardial Infarction

points. Additionally, the interaction between time and group was significant (F (5, 195) = 3.567, $p < 0.001$), suggesting that the differences in rScO2 between the groups varied over time. The main effect of group was also significant (F (1, 39) = 1397.034, $p < 0.001$). Comparisons of rScO2 values across time points, adjusted for multiple comparisons, revealed significant differences. Specifically, rScO2 values at T5 were significantly lower compared to T1 ($p < 0.001$), T2 ($p < 0.001$), T3 ($p < 0.001$), T4 ($p < 0.001$), and T6 ($p < 0.001$). rScO2 values at T5 were significantly lower than at other time points, indicating notable variations over time. These findings are illustrated in Fig. 4.

While oxygen saturation did not differ between groups, respiratory rate was higher in Group 1 only at T1 ($p = 0.013$). MAP was significantly lower in Group 2 at T5 ($p = 0.003$). At other times, MAP was similar between the groups.

Discussion

In this study, we tested the hypothesis that rScO2 levels are associated with the development of post-procedure delirium during TAVI under sedation. The results supported our hypothesis. The results showed that lower rScO2 values were significantly associated with higher post-procedure delirium rates. In particular, patients with low rScO2 values measured at the time of valve

Table 2 Intergroup comparison of demographic data, laboratory values, and rScO2 measured at six different times during the procedure

	Group 1 (No delirium)			Group 2 (Delirium present)			*p*
	Mean ± SD			Mean ± SD			
Age	78.86	±	8.45	80.42	±	6.86	0.767
BMI	27.70	±	5.20	28.64	±	5.28	0.342
Processing Time	104.72	±	15.09	110.50	±	20.28	0.470
Intensive Care Unit Length of Stay (days)	1.93	±	1.25	1.42	±	0.67	0.328
Preoperative Hb	11.77	±	1.70	11.29	±	1.35	0.262
Preoperative Hct	34.02	±	4.82	33.00	±	3.92	0.488
Preoperative Plt	230.90	±	67.54	225.92	±	57.38	0.832
Intraoperative Hb	10.46	±	1.12	10.78	±	1.06	0.403
Intraoperative Hct	32.38	±	3.38	32.31	±	3.31	0.877
MMSE	27.24	±	1.46	24.33	±	0.49	**< 0.001**
RPV duration	29.62	±	5.89	31.83	±	9.21	0.621
T1 rScO2	60.50	±	9.84	58.75	±	8.69	0.877
T2 rScO2	62.12	±	9.56	56.17	±	6.54	0.127
T3 rScO2	63.14	±	9.35	55.46	±	8.65	0.088
T4 rScO2	59.24	±	15.03	56.00	±	6.89	0.506
T5 rScO2	56.29	±	11.75	35.96	±	9.26	**< 0.001**
T6 rScO2	60.17	±	10.04	54.46	±	9.54	**0.012**

Abbreviations: BMI Body Mass Index, Hb hemoglobin, Hc Hematocrit, Plt Platelets. MMSE Mini-Mental State Examination, RPV Rapid Ventricular Pacing, T1Baseline monitoring phase (without supplemental oxygen), T2 Post-sedation phase, during surgical field sterilization, T3 During catheter insertion, T4 During wire manipulation, T5 During valve placement, T6 During access site artery repair, rScO2 Regional cerebral oxygen saturation, HR Heart rate, RR Respiratory rate, MAP Mean arterial pressure, SpO_2 Oxygen saturation

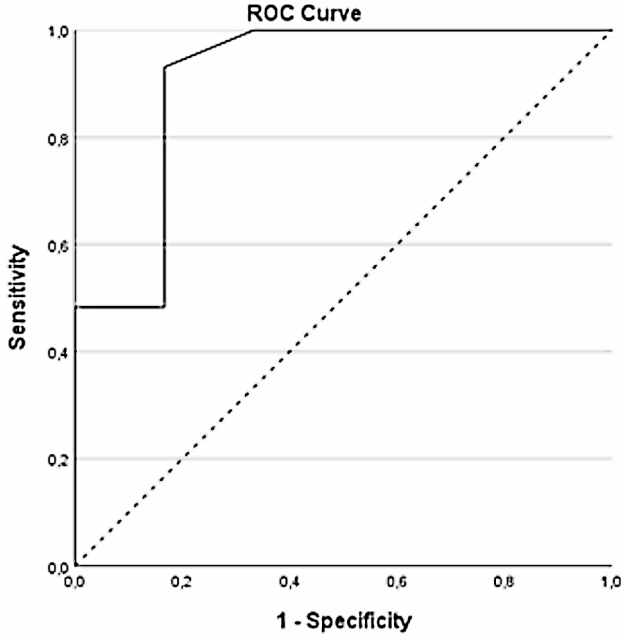

Fig. 2 ROC curve for rScO2 values measured at T5 predicting the presence of POD

implantation had higher rates of post-procedural post-procedure delirium. The rScO2 cut-off value identified by the ROC analysis was 43, and patients with values below this threshold exhibited a higher incidence of post-procedure delirium. However, further studies are required to validate this threshold and assess its applicability in broader populations.

Post-procedure delirium is one of the complications that can be seen with a rate of 17–61% after major surgical procedures, especially in elderly patients [17, 18]. Cognitive decline, prolonged hospitalization, decreased functional and physical independence, and increased risk of dementia have been associated with increased caregiver burden, health care costs, morbidity and mortality [19]. Therefore, post-procedure delirium is a major burden on both the patient's health and quality of life and the healthcare system in general.

The mean age of the patients in our study was 79.32 ± 7.9, consisting predominantly of elderly individuals. It is known that cognitive tests such as the MMSE are used to predict postoperative delirium, especially in elderly patients [20, 21]. In our study, we excluded patients with MMSE scores below 24 in order not to influence the course of our study. However, when the MMSE scores of the two groups were compared, the MMSE rate was lower in the group with delirium. This shows the effect of lower MMSE scores, albeit above 24, in predicting delirium.

In some studies conducted in the intraoperative period in elderly patients, low MAP and fluctuations in MAP were found to be associated with post-procedure delirium [22, 23, 24]. In a study conducted in TAVI patients, no significant relationship between low MAP and post-procedure delirium in the intraoperative period was

Table 3 Comparison of patients above and below the cut-off value of rScO2 in terms of morbidity and mortality

	Group 1 (No delirium)			Group 2 (Delirium present)			*p*
	Mean ± SD / *n* (%)			Mean ± SD / *n* (%)			
Delirium	None		27 (93.1%)			12 (16.7%)	**0.001<**
	Present		2 (6.9%)			10 (83.3%)	
Postoperative AF	None		26 (89.7%)			9 (75.0%)	0.334
	Present		3 (10.3%)			3 (25.0%)	
Postoperative arrhythmia	None		23 (79.3%)			12 (100%)	0.156
	Present		6 (20.7%)			0 (0%)	
Mortality	None		28 (96.6%)			12 (100%)	1
	Present		1 (3.7%)			0 (0%)	
Intensive Care Unit Length of Stay (days)	1.83	±	1.26	1.67	±	1.67	0.899

Abbreviation: AF Atrial fibrillation

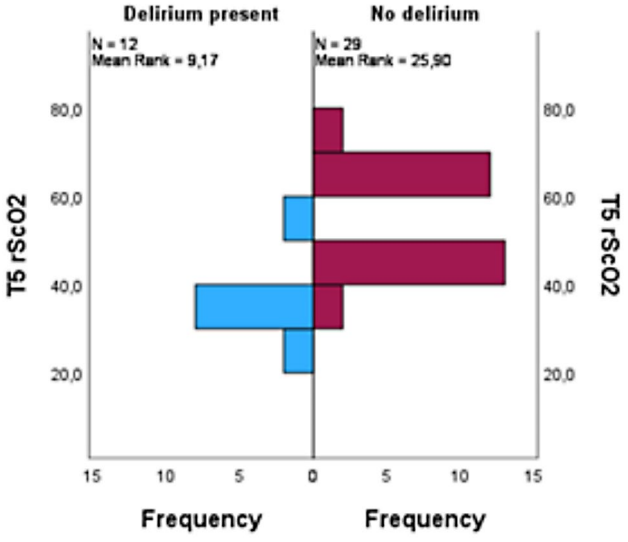

Fig. 3 Comparison of relative percentage reductions in rScO2 at T5 between delirium and non-delirium groups

demonstrated [25]. In our study, post-procedure delirium was associated with MAP values measured at T5, but not with overall mean MAP. The low MAP here also explains the low rScO2.

In order to estimate cerebral perfusion and cerebral blood flow, rScO2 has been measured non-invasively with the NIRS meter and its routine use in the clinic has become frequent. The level of decrease in the rScO2 value in the NIRS device used in various types of surgeries, which is thought to cause neurological complications, varies in studies and a clear percentage is not given. Mille et al. suggested that postoperative neurologic complications may increase after more than 20% decrease in rScO2 [26], while Rigamonti et al. suggested that at least 15% decrease in rScO2 is associated with neurologic, cardiac or renal postoperative complications [27]. In other similar studies, a decrease in rScO2 of more than 10% from baseline is dangerous in terms of neurologic complications, especially post-procedure delirium, but a decrease of less than 5% is considered a safe range [11, 28, 29]. The ROC analysis in our study identified an rScO2 cut-off value of 43%, which was associated with an increased risk of post-procedural delirium. The decrease between T1 and T5 was 38.79%, which is a high rate in patients with delirium.

In a recent study in TAVI patients, Seppelt et al. found decreased 1-year survival in patients with baseline rScO2 levels < 56. They found the post-procedure delirium rate to be 26%. The post-procedure delirium rate was 29.3%, which was similar to Seppelt et al. [30] In our study, unlike Seppelt et al. the duration of intensive care unit stay did not differ between groups.

Our study demonstrates that low rScO2 values during valve placement are significantly associated with a higher incidence of post-procedure delirium in patients undergoing TAVI. While previous studies have highlighted the general perioperative risk factors for post-procedure delirium, our research suggests a specific threshold (rScO2 < 43%) that correlates with increased risk. These findings suggest that cerebral oxygenation monitoring during TAVI procedures may help identify patients at higher risk for post-procedural delirium. However, further studies are required to determine whether NIRS devices can reduce its incidence. This adds a new dimension to existing literature by providing a clear, actionable parameter for clinicians to improve patient outcomes in the context of TAVI.

It is important to recognize that absolute rScO2 thresholds may vary between NIRS devices due to differences in calibration and measurement techniques. Consequently, monitoring trends in rScO2 may provide more clinically relevant insights than relying solely on specific cut-off values.

Our study suggests a cut-off value for cerebral saturation to assess its impact on post-procedure delirium during TAVI and highlights its potential as a useful parameter in clinical practice. These findings underscore the importance of cerebral oxygenation monitoring in evaluating the risk of post-procedural delirium and contribute to the current body of knowledge. While the

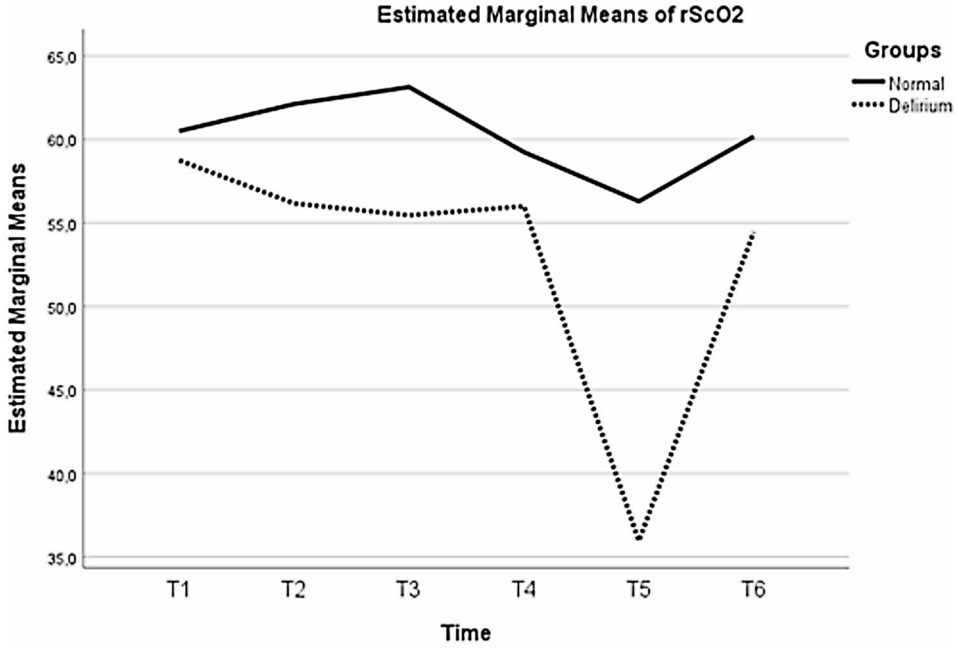

Fig. 4 Association of rScO2 measured at 6 different times with delirium

identified rScO2 threshold of 43% is significantly associated with post-procedural delirium, its interpretation should be contextualized within the specific methodology and conditions of this study. Future research with larger and more diverse populations, as well as comparisons across different NIRS device platforms, is essential to validate this threshold and establish its broader clinical utility.

Limitations

There are very few prospective studies similar to ours. However, our study has several limitations. Firstly, the sample size was limited, which may affect the generalizability of our findings. Although we recognized the potential impact of frailty and functional status on delirium, we could not conduct a frailty test that would systematically evaluate these parameters. Another limitation is that laboratory parameters, known to influence postoperative delirium, as well as medications administered during the ICU stay, were not systematically recorded. While our study focused on predefined rScO2 measurements during this phase, we acknowledge that continuous monitoring of low rScO2 durations during T5 could enhance our understanding of its implications on postoperative delirium. Moreover, since a single NIRS device was used, device-specific variability must be considered when interpreting the results. While emphasizing the critical role of hypoperfusion on neurocognitive outcomes during TAVI, we should also have accounted for factors such as embolization and wire manipulation. Future studies should utilize advanced tools, such as intraoperative transcranial Doppler for embolization monitoring, and adopt multimodal approaches in larger cohorts to better understand these multifactorial processes.

Conclusions

TAVI is usually the procedure of choice for high-risk patients who cannot undergo AVR. Although not as risky as open heart surgery, the TAVI procedure may involve complications such as rhythm disturbances, hypotension, and decreased rScO2, especially during valve implantation. Our study revealed that low rScO2 values during TAVI were associated with a higher risk of post-procedure delirium, and an rScO2 cut-off value of 43% was an effective cut-off to determine this association. These findings highlight the potential importance of cerebral oxygenation monitoring in clinical settings, but further studies are needed before its widespread implementation. Additional research is needed to better understand how the results obtained can be used in clinical practice and the role of NIRS.

Abbreviations

AS	Aortic stenosis
AVA	Aortic valve area
ICU-CAM	Confusion assessment method for the intensive care unit
MASS	Modified Alderate scoring system
MMSE	Mini-mental state examination
NIRS	Near-infrared spectroscopy
POD	Postoperative delirium
TAVI	Transcatheter aortic valve implantation

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Author contributions
HYA contributed to the conception, design, methodology, supervision, and data curation of the manuscript. She drafted the original manuscript and critically revised it. BS participated in formal analysis, software usage, and visualization. YO participated in the acquisition, analysis, and interpretation of data. ZS Participated in the acquisition, analysis, and interpretation of data. Also provided supervision and critical revisions. AY, EET, and MY contributed to the acquisition, analysis, and interpretation of data, as well as manuscript review and editing. MAY, KE contributed to data curation, manuscript review, and editing. All authors read and approved the final manuscript.

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Data availability
The datasets used and/or analysed during the current study are available from the corresponding author on reasonable request.

Declarations

Ethics approval and consent to participate
All study protocols were carried out in accordance with relevant guidelines and regulations and were approved by the Ethics Committee of Istanbul University-Cerrahpaşa (Date: 31.03.2021, Number: E-69291215-900-65040), Istanbul, Turkey, prior to the initiation of the study. Patients were verbally informed about the data acquisition protocol, and written informed consent was obtained from all participants and/or their legal guardians. The study adhered to the principles of the Declaration of Helsinki, with no violations during the informed consent and data acquisition process.

Consent for publication
Not Applicable.

Competing interests
The authors declare no competing interests.

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