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Comparison of Cerebral Oxygen Saturation between Midazolam and Propofol as Post Craniotomy Sedation

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Abstract

Introduction: Cerebral oxygen saturation reflects tissue perfusion in the cerebrum. Decreases in cerebral oxygen saturation are linked to longer hospital stays and cognitive impairment. Midazolam and propofol can decrease cerebral blood flow through decreasing the cerebral oxygen metabolic rate. The purpose of this research is to analyze the comparison of changes in cerebral oxygen saturation after midazolam and propofol administration in post-craniotomy patients in the ICU of Haji Adam Malik General Hospital Medan.
Subject and Method: This is a randomized control trial study. Patients were divided into, Midazolam group, that given an initial dose of 0.05 mg/kg followed by a maintenance dose of 0.02-0.10 mg/kg/hour and Propofol group that given sedation with a dose of 0.3-3mg/kg/hour, with the target of the 2 groups being a Richmond Agitation-Sedation Scale (RASS) value of 0 to -2. Data analysis using unpaired T test.
Results: The results for cerebral regional oxygen saturation and RASS between groups showed significant differences in right and left value ($p < 0.001$), but there was no significant difference in RASS ($p>0.05$) between each group at each measurement time. The results of the analysis of cerebral regional oxygen saturation and RASS between times, there was no significant difference in right and left value ($p>0.05$), but there was a significant difference in RASS ($p<0.001$) at each measurement time. Based on the results of the analysis carried out, it is known that there is no statistically significant difference in changes in cerebral regional oxygen saturation both right and left in changes in RASS because it is found that all data have $p>0.05$.
Conclusion: There is no change in right and left for cerebral regional oxygen saturation after administration of propofol and midazolam groups with RASS value 0 to -2 in post-craniotomy patients in the ICU of Haji Adam Malik General Hospital Medan.

Keywords: ICU, craniotomy, midazolam, propofol, cerebral regional oxygen saturation

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I. Introduction

Craniotomy is a neurosurgical technique that is performed by opening the skull bone to provide direct access to the brain.[1] Craniotomy can be performed infratentorially or supratentorially or in combination, where the procedure is carried out in a hospital that has neurosurgical facilities and an Intensive Care Unit (ICU).[2] Of the 38,058 post-craniotomy patients in America in 2017, 14.3% of them experienced complications in the form of airway complications (5%), cardiovascular complications (4%) and neurological complications (3%). Where as many as 73% of these patients were treated in the ICU.[3]

Current methods of monitoring patients who have had craniotomies offer valuable insights into the physiology and metabolism of the brain. Maintaining intracranial pressure (ICP),

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means arterial pressure (MAP), and oxygenation can be accomplished with the use of brain physiology monitoring.[4] In addition to keeping an eye on hemodynamics in the intensive care unit, managing stress and anxiety is also crucial. One of the things that can raise brain metabolism and cerebral blood flow (CBF) is stress (CMRO2). With the use of a ventilator machine, post-craniotomy patients in the ICU can avoid tension and anxiety by using sedative medications like propofol and midazolam.[5] At clinical dosages, propofol can lower cerebral reactivity, CBF, and brain metabolism.[6] Although midazolam is a straightforward medication with minimal impact on hemodynamics, reports have indicated that it build up in the body and rose the risk of delirium in patients receiving intensive care units. Many studies have been done to examine the effects of propofol and midazolam,[6,7] but none have compared the effects of midazolam and propofol on cerebral rSO_2 levels. Propofol and midazolam both lower CBF by slowing down the brain's oxygen metabolism.

A non-invasive monitoring method called cerebral regional oxygen saturation measures thoxygen saturation of the superficial brain cortex region—one of the areas most susceptible to hypoxia ischemia injury—using near infrared spectroscopy (NIRS).[8,9] If tissue and organ oxygenation changes slightly, the pulse oximetry (SpO_2) is still normal but the cerebral regional oxygen saturation value can change significantly. The more decreasing in cerebral regional oxygen saturation showed more serious the hypoxia in brain tissue, which can be used to assess prognosis. Cerebral regional oxygen saturation monitoring can be done using the bedside method continuously and monitoring oxygen levels "real-time". Therefore, cerebral regional oxygen saturation is widely used as a monitor in clinical practice in major operations that affect cerebral circulation.[10] NIRS is a non-invasive monitoring method that may be used to evaluate cerebral regional oxygen saturation while continuously monitoring changes in blood volume and cerebral oxygenation. NIRS can assess oxygen saturation in the body and brain tissue through sensors placed on the head or areas of the body (thenar muscles, kidney tissue). The prognosis of head injuries and the degree of the disease have been demonstrated to be correlated with cerebral regional oxygen saturation.[11] Research has demonstrated a potential correlation between cerebral oxygen desaturation events and postoperative neurocognitive dysfunction. Additionally, treating and monitoring these episodes may reduce the occurrence of postoperative neurocognitive dysfunction.[12] Thus, research on the importance of cerebral saturation in post-craniotomy patients with propofol and midazolam sedation is crucial given the high death and morbidity associated with anesthesia, particularly in patients undergoing craniotomies, and the efforts to prevent secondary brain injury. This research compared the effects of midazolam and propofol in the ICU at RSUP. Haji Adam Malik Medan on changes in cerebral saturation as measured by cerebral regional oxygen saturation values in post-craniotomy patients.

II. Subject and Methods

The study used a randomized control trial research design to determine the comparison of changes in cerebral regional oxygen saturation with midazolam and propofol sedation in post-craniotomy patients in the ICU at H. Adam Malik Hospital. The research was conducted in the Intensive Care Unit of H. Adam Malik Hospital, Medan. The study population was all post-craniotomy patients who used ventilators in the ICU at Haji Adam Malik Hospital, Medan. The research sample was the research population that met the inclusion and exclusion criteria. The technique for obtaining samples was by consecutive sampling, where samples that come and meet the inclusion and exclusion criteria were included in the study until the required number of subjects was met.The inclusion criteria for this study were patients aged 18–65 years, patients who underwent craniotomy surgery where post-operatively the patient was treated in the ICU with a mechanical ventilator attached, the patient or family was willing to take part in the research by filling out informed consent. Meanwhile, the exclusion criteria were patients whose families refused to be taken part in the research, pregnant women, patients with

heart defects, treatment patients who received vasopressor and inotropic drugs before surgery, patients who experienced shock after surgery, patients who experienced coagulation disorders, and patients with lung disease. The drop out criteria was that the patient experienced cardiac arrest after craniotomy surgery before the 6th hour of sampling. From the calculation results for the sample size, a minimum of 31 people are needed for the sample size in this study. Research samples were collected in accordance with the inclusion and exclusion criteria after receiving approval from the Universitas Sumatera Utara's Health Research Ethics Committee and H. Adam Malik Hospital Medan. The subject's family signed an informed consent form in the ICU of the hospital. All study participants had their identities (age, gender, weight, and height) recorded, as well as their anamnesis (either auto- or allo-anamnesic), physical examination, and supporting examinations (full blood tests, electrolyte levels, blood gas analysis, kidney function, and instant blood sugar levels) performed.

The patient was positioned head up 30°, then cerebral regional oxygen saturation value assessment was taken when the patient arrived at the ICU using INVOS® (T0) with ventilator settings $FiO_2 \leq 50\%$ by anesthesia residents at the Neuroanesthesia stage or ICU stage. Advanced ventilator settings were adjusted to the results of post-operative blood gas analysis. Monitoring and recording of blood pressure, heart rate and cerebral regional oxygen saturation using INVOS® was carried out again at the 3rd hour (T1) and 6th hour (T2) after the patient received sedation therapy in the ICU. Patients were divided into 2 groups which had been grouped by randomization using the randomizer.org application. The Midazolam (M) group was given sedation via a syringe pump with an initial dose of 0.05 mg/kg followed by a maintenance dose of 0.02 – 0.10 mg/kg/hour with a target RASS value of 0 to -2. The Propofol (P) group was given sedation via a syringe pump at a dose of 0.3 – 3mg/kg/hour with a target Richmond Agitation-Sedation Scale (RASS) value of up to -2. The comparison of cerebral regional oxygen saturation between group M and group P was assessed and statistical analysis was carried out.

Statistical Analysis

SPSS software was used to analyze the data. The demographic information about the subjects, such as age, gender, height, weight, BMI, PS-ASA, and length of operation, will be shown in tabular form. To determine the traits and frequency distribution of the participants, descriptive analysis was used. The presentation of numerical data involves the use of mean (mean) ± SD (standard deviation) and median (minimum-maximum). Categorical data, on the other hand, is shown as percentages. The unpaired T test was utilized for data analysis. A significant 95% confidence interval was defined as a p value less than 0.05.

III. Results

The research sample was taken at the Haji Adam Malik Central General Hospital, Medan. There were 40 samples obtained in this research, but only 32 samples met the inclusion and exclusion criteria and were the subjects of this research. In table 1, it is known that the age of group 1 has a mean±SD value of around 42±12.48 years with a range of 18-62 years and group 2 has a mean±SD value of around 41.67±13.84 years with a range of 18–65 years. The distribution according to gender in group 1 is known to be 11 male subjects and 6 female subjects, while in group 2 it is known that there are 9 male subjects and 6 female subjects.

The weight distribution of group 1 has a mean±SD value of 64±12.23 kg with a range of 38–78 kg and group 2 has a mean±SD value of 63.13±5.89 kg with a range of 52–72 kg. The height distribution of group 1 has a mean±SD value of 163.12±3.43 cm with a range of 157–168 cm and group 2 has a mean±SD value of 162±3.70 cm with a range of 154–168 cm. The BMI distribution for group 1 has a mean±SD value of 24.85±3.06 kg/m2 with a range of 20.79–29.30 kg/m2 and group 2 has a mean±SD value of 24.11±2.26 kg/m2 with range 19.92–28.46 kg/m2. The distribution of PS-ASA in group 1 is known to be 12 people in PS-ASA III and 5 people in IV, while in group 2 it is known that there are 13 people in PS-ASA III and 2 people in IV. The distribution of operation duration in group 1 had a mean±SD value of 414.41±140.48 minutes with a range of

Table 1. Data Characteristics

Characteristics	Group 1 Propofol (N = 16)	Group 2 Midazolam (N = 16)	P-value Normality[a]	p-value
Age (years)				
- Mean±SD	42±12.48	41.67±13.84	0.587	0.943[b]
- Median	40	43		
- Min-Max	18-62	18-65		
Gender				
- Male	11	9	p<0.001 (Categorical)	0.784[c]
- Female	6	6		
Body weight (kg)				
- Mean±SD	64±12.23	63.13±5.89	0.004	0.478[d]
- Median	65	64		
- Min-Max	38-78	52-72		
Height (cm)				
- Mean±SD	163.12±3.43	162±3.70	0.415	0.382[b]
- Median	164	163		
- Min-Max	157-168	154-168		
BMI (kg/m^2)				
- Mean±SD	24.85±3.06	24.11±2.26	0.323	0.448[b]
- Median	24.8	24.71		
- Min-MaX	20.79-29.30	19.92-28.46		
PS-ASA				
- III	12	13	p<0.001 (Categorical)	0.402[e]
- IV	5	2		
Duration (minutes)				
- Mean±SD	414.41±140.48	428.33±131.99	p<0.001	0.551[d]
- Median	375	380		
- Min-Max	300-840	345-790		

[a]Shapiro-Wilk Test; [b]Independent T-test; [c]Chi-Square Test; [d]Mann-Whitney Test; [e]Uji Fisher Exact

300-840 minutes and group 2 had a mean±SD value of 428.33±131.99 minutes with a range of 345–790 minutes. Based on normality data, it was known that age, height and BMI data were normally distributed, while gender, body weight, PS-ASA and duration data were not normally distributed. In the test analysis, the Independent T test was carried out on data that was normally distributed and the Mann-Whitney test on data that was not normally distributed.The Chi-Square test was also carried out on categorical data and Fisher's alternative test was carried out if it was known that the expected count was <5. If a p-value <0.05 is found in the characteristic data, it can be concluded that there is a difference or relationship between groups. Based on the results of the analysis carried out, it was known that all characteristic data did not find any differences or relationships between groups so that it did not affect the parameters to be assessed.

Haemodynamic of Patient

Table 4.2 shows the hemodynamic characteristics of the research subjects. In the group with propofol, the mean systolic blood pressure was 145.55 ± 14.10, the mean diastolic blood pressure was 83.83 ± 9.19, the mean MAP was 104.44 ± 8.03, the mean pulse rate was 81.11 ± 12.44, the mean breathing rate was 20.33 ± 1.94, the mean SpO_2 was 97.72 ± 0.95. Table 4.2 shows the hemodynamic characteristics of the research subjects. In the group with midazolam, the mean systolic blood pressure was 150 ± 21.76, the mean diastolic blood pressure was 80.38 ± 8.92, the mean MAP was 103.50 ± 9.93, the mean pulse rate was 81.27 ± 11.18, the mean breathing rate was 20.72 ± 2.13, the mean SpO_2 was 98 ± 1.02. Results of Cerebral Regional Oxygen Saturation

Table 2. Hemodynamic Patient

Hemodynamic	Group 1 Propofol (N = 16)	Group 2 Midazolam (N = 16)	P-value
Systolic Blood Pressure	145.55±14.10	150±21.76	0.472*
Diastolic Blood Pressure	83.83±9.19	80.38±8.92	0.283**
Mean Arterial Pressure	104.44±8.03	103.50±9.93	0.756*
Heart Rate	81.11±12.44	81.27±11.18	0.967*
Respiratory Rate	20.33±1.94	20.72±2.13	0.571*
Oxygen Saturation	97.72±0.95	98±1.02	0.345**

*T Independent Test; * Mann-Whitney Test

and RASS. In this study, changes in cerebral regional oxygen saturation and RASS were assessed at three measurement times, T0 before treatment, T1 after 3 hours, and T2 after 6 hours. Based on normality data (Tabel 3), it was known that all right rSO_2 T1–T2 and left rSO_2 T0–T2 data were normally distributed, except for right cerebral regional oxygen saturationT0 data and RASS data. In the test analysis, the Independent T-test was carried out on data that was normally distributed and the Mann-Whitney test on data that was not normally distributed. If a p-value <0.05 was found in the data, it can be concluded that there were differences between groups. Based on the results of the analysis carried out, it was found that there were statistically significant differences in cerebral regional oxygen saturation both right and left between groups at each measurement time. However, it was inversely proportional to the RASS where no significant differences were found between groups at any measurement time. Then, to determine whether there were any changes in cerebral regional oxygen saturation and RASS at each measurement period, an analysis of changes in these parameters was also performed (Table 4). The analysis's findings showed that, at each measurement time, there were no statistically significant variations in cerebral regional oxygen saturation on the left or right side. Nonetheless, statistically significant variations in RASS were discovered for every measurement interval. Then an analysis of changes in cerebral regional oxygen saturation and RASS (Δ cerebral regional oxygen saturation and ΔRASS) was also carried

Table 3. Analysis of Cerebral Regional Oxygen Saturation and RASS between Groups

Data	Times	Group 1 Propofol (Mean±SD)	Group 2 Midazolam (Mean±SD)	P-value Normality[a]	P-value
Right	T0	64.59±8.07	56.33±7.08	0.011	0.005[d]
	T1	64.94±6.22	55.20±7.59	0.086	P<0.001[b]
	T2	65.53±4.17	56.53±5.36	0.222	P<0.001[b]
Left	T0	63.47±5.29	52.87±5.73	0.245	P<0.001[b]
	T1	63.94±5.61	55.07±4.03	0.612	P<0.001[b]
	T2	63.29±5.21	55.73±4.86	0.495	P<0.001[b]
RASS	T0	-4.29±0.69	-4.13±0.74	P<0.001	0.576[d]
	T1	-2.29±0.69	-2.33±0.82	P<0.001	0.970[d]
	T2	-1.47±0.62	-1.80±0.86	P<0.001	0.313[d]

[a]Shapiro-Wilk Test; [b]Independent T-test; [d]Mann-Whitney Test

Table 4. Inter-Time Cerebral Regional Oxygen Saturation and RASS Analysis

Data	Time	Δ	P-value
	T0-T1	0.34±5.53	0.727[f]
Right	T0-T2	0.59±5.84	0.569[f]
	T1-T2	0.94±5.43	0.336[f]
	T0-T1	1.28±4.19	0.094[f]
Left	T0-T2	1.25±5.59	0.216[f]
	T1-T2	0.03±5.769	0.976[f]
	T0-T1	1.91±0.86	P<0.001[g]
RASS	T0-T2	2.59±0.84	P<0.001[g]
	T1-T2	0.69±0.69	P<0.001[g]

[f]Dependent T-test; [g]Wilcoxon Test

Table 5. Analysis of Changes in rSO_2 and RASS between Groups

Data	Time	Group 1 Propofol (Mean±SD)	Group 2 Midazolam (Mean±SD)	P-value Normality[a]	P-value
	T0-T1	-0.35±6.58	1.13±4.12	0.238	0.457[b]
Right	T0-T2	-0.94±6.52	-0.20±5.16	0.596	0.726[b]
	T1-T2	-0.59±5.34	-1.33±5.69	0.214	0.7051[b]
	T0-T1	-0.47±4.61	-2.20±-3.59	0.051	0.250[b]
Left	T0-T2	-0.18±6.23	-2.87±4.45	0.861	0.127[b]
	T1-T2	0.65±6.69	-0.67±4.62	0.194	0.529[b]
	T0-T1	-2.00±0.94	-1.80±0.77	0.003	0.502[d]
RASS	T0-T2	-2.82±0.73	-2.33±0.89	0.001	0.165[d]
	T1-T2	-0.82±0.64	-0.53±0.74	P<0.001	0.331[d]

[a]Shapiro-Wilk Test; [b]Independent T-test; [d]Mann-Whitney Test

out between the intervention groups to find out whether there were differences in the effect of the intervention on changes in cerebral regional oxygen saturation and RASS (Table 5). This was done because based on Table 4 it was known that there were differences in cerebral regional oxygen saturation values since the initial measurement (T0) so the researchers took a change approach so that the results obtained were certain and bias was eliminated. Based on normality data, it is known that all cerebral regional oxygen saturation data, both right and left, are normally distributed, except for RASS data. Based on the results of the analysis carried out, it was found that there were no statistically significant differences in changes in cerebral regional oxygen saturation, both right and left, and in changes in RASS because it was found that all data had p>0.05.

IV. Discussion

In this study, patients who received propofol or midazolam for anaesthesia following a craniotomy had their cerebral oxygenation levels compared. Cerebral regional oxygen saturation is a non-invasive monitoring method that measures the oxygen saturation of the superficial cerebral cortex area–one of the areas most susceptible to hypoxia ischemia injury–using near infrared spectroscopy (NIRS).[8,9] While the cerebral regional oxygen saturation value can fluctuate dramatically, the pulse oximetry (SpO_2) remains normal in the event of modest alterations in tissue and organ oxygenation. The degree of hypoxia in brain tissue can be utilised

to determine prognosis; the more marked the reduction in cerebral regional oxygen saturation, the more severe the hypoxia. It is possible to do continuous bedside technique cerebral regional oxygen saturation monitoring and "real-time" oxygen level monitoring. As a result, in clinical practice, cerebral regional oxygen saturation is frequently utilised as a monitor for major surgeries that impact cerebral circulation.[10] Failure to monitor blood oxygen saturation in the brain can damage brain tissue and function and even cause irreversible complications.[13]

This study consisted of 32 patients who were grouped into two different groups (propofol and midazolam, with the number of propofol and midazolam patients each being 16 individuals). The basic characteristics of patients can cause bias if it is known that there is a statistically significant relationship ($p<0.05$), however in this study all patients did not find significant results ($p>0.05$) so it was stated that all patients had homogeneous characteristics. In this study the mean age was 42 ± 12.48 years and 41.67 ± 13.84 years respectively, analysis of the intervention given to the two groups was carried out (comparable baseline characteristics) which showed there was no difference ($p=0.943$). Gender distribution found more males in both groups, namely propofol 64.71% and midazolam 60% and no relationship was found with gender in the intervention group ($p=0.784$). Then the average body weight was found to be heavier in the propofol group 64 ± 12.23 compared to the midazolam group 63.15 ± 5.89, but there was no difference between the intervention groups ($p=0.478$). In the height data, it was found that the propofol group was taller based on a mean of 163.12±3.43 cm compared to the midazolam group 162 ± 3.70, but there was also no difference found in the intervention group ($p=0.382$). Likewise, BMI was slightly higher in the propofol group 24.85 ± 3.06 kg/m2 compared to the midazolam group 24.11 ± 2.26 kg/m2, but there was also no difference in the intervention group ($p=0.448$). The classification of patients based on ASA showed that group III was the largest group in the two intervention groups, namely 70.59% for propofol and 86.67% for midazolam, but there was no correlation with the intervention group ($p=0.402$). Apart from that, the duration of surgery can be biased if the duration of the operation is too long, thereby worsening the patient's overall condition, so an assessment is carried out. In midazolam patients the duration was found to be longer with a mean of 428.33 ± 131.99 minutes compared to propofol 414.41 ± 140.48 minutes, but there was no difference ($p=0.551$) between intervention groups so that duration could not be a confounding variable (proposing bias). Based on previous studies, it is known that basic characteristics are very important not to be different because they can influence the overall research process and results. Differences in baseline characteristics between intervention groups can lead to systematic differences, imbalance in intervention response, and failure of randomization to be assessed. In this study, the comparison of basic characteristics was considered to have been successfully achieved and the randomization carried out was achieved so that the results of the subsequent assessment were considered relevant and accountable.[14,15]

In this study, an analysis was carried out between cerebral regional oxygen saturation between groups, it turned out that in the initial measurement of right and left cerebral regional oxygen saturation between the propofol and midazolam groups, it was found that the baseline of right propofol was 64.59±8.07 and right midazolam was 56.33±7.08, then left propofol was 63.47±5.29 and left midazolam 52.87±5.73 which were both significantly different ($p = 0.005$; $p < 0.001$). Because of this, additional analysis was carried out to assess changes in right and left cerebral regional oxygen saturation between times using Δcerebral regional oxygen saturation which then showed Δcerebral regional oxygen saturation both right and left between T0 and T1 ($p = 0.457$; 0.250), T0 and T2 ($p = 0.726$; 0.127), T1 and T2 ($p= 0.705$; $p =0.529$) found no statistically significant difference ($p > 0.05$). Researchers also carried out additional analysis of cerebral regional oxygen saturation between measurement times which supports the previous results where the right and left cerebral regional oxygen saturation between T0 and T1 ($p=0.727$;

0.094), T0 and T2 (p = 0.569; p = 0.216), T1 and T2 (p= 0.336; 0.976) which also shows there is no statistically significant difference (p > 0.05). Basically, both groups of propofol and midazolam have the same mechanism of action, namely GABA-R agonists, where both also reducecerebral metabolic rate of oxygen consumption ($CMRO_2$) and reduce cerebral blood flow (CBF), then both are also able to reduce ICP even though propofol is known to reduce ICP more than midazolam, but overall propofol has more benefits than midazolam because of the rapid onset and duration of action as well as independent excretion and no significant drug interactions, although with midazolam there are fewer cases of hemodynamic instability which can prevent reduction cerebral perfusion pressure (CPP). As is known, propofol and midazolam are the first choice of sedation in patients with regular sedation, sedation with increased ICP, sedation with targeted temperature management, and status epilepticus. Propofol is also recommended in patients with liver and kidney dysfunction, while midazolam is recommended in patients with hemodynamic instability.[16]

Ten human clinical trials were included in a systematic review research by Logan in 2020, which led to the conclusion that, in tests where pCO_2 and MAP were controlled, there were no appreciable variations in the cerebrovascular responses following the administration of propofol or midazolam.[17] In research conducted by Tanguy in 2018 in comparing propofol and midazolam on ICP, pO_2, pCO_2, CPP, MAP, and CBF showed that both gave identical results on cerebrovascular response and cerebral oxygen perfusion.[18] A research found that whereas propofol and midazolam can reduce CBF in similar ways, their effects on the autonomic nervous system and endothelial relaxation are different. Propofol predominantly produces parasympathetic reactions, whereas midazolam largely induces sympathetic responses. Furthermore, midazolam has no effect on endothelium relaxation and can constrict cerebral arterioles, whereas propofol suppresses endothelium relaxation. While there are variations in the cerebral autoregulation dynamics leading to a comparable decline in CBF, midazolam is thought to be superior in enhancing the cerebral autoregulation dynamics.[6]

V. Conclusion

Following the administration of propofol and midazolam groups with RASS values 0 to -2 in post-craniotomy patients in the ICU of Haji Adam Malik General Hospital Medan, there is no change in the regional oxygen saturation of the right and left cerebral areas.

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