

The Effects of Carotid Endarterectomy Surgery on Cerebral Oxygenation, Randomized Clinical Trial

Karotis Endarterektomi Cerrahisinin Serebral Oksijenizasyon Üzerine Etkileri, Randomize Klinik Çalışma

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ÖZ

Amaç: Bu çalışmanın amacı kross-klemp (KK) süresi ile Near Infrared Spektroskopi (NIRS) değerlerinin Karotis Endarterektomi cerrahisi (KEA) sırasında nasıl değiştiğini gözlemlemektir.

Araçlar ve Yöntem: Çalışmaya 30 hasta dahil edildi. Genel anestezi indüksiyonu öncesi sistolik kan basıncı (SKB), diyastolik kan basıncı (DKB), ortalama arter basıncı (OAB), kalp atım hızı (KAH) ve periferik oksijen saturasyonu (SpO_2) ve bölgesel oksijen saturasyonu (rSO_2) değerleri sağ ve sol taraf olarak kaydedildi. Aynı parametreler karotis KK öncesi, karotis KK başlangıcının 3. dakika, 5. dakika, 10. dakikasında, kros klemp kalktıktan sonra 1. ve 5. dakikada ve postoperatif olarak kaydedildi.

Bulgular: Çalışmaya alınan ve sağ taraftan cerrahi geçiren (n:11) hastaların sağ taraf ortalama rSO_2 değerleri arası farklılık anlamlı bulundu ($p<0.05$). Çalışmaya alınan ve sol taraftan cerrahi geçiren (n:19) hastaların sol taraf ortalama rSO_2 değerleri arası farklılık anlamlı bulundu ($p<0.05$). Çalışmaya alınan hastaların hiçbirinde postoperatif nörolojik komplikasyon izlenmemiştir.

Sonuç: Sonuç olarak genel anestezi altında KEA cerrahisi yapılan hastalarda KK sırasında serebral oksijen saturasyonunda belirgin bir düşüş olduğunu, KK açılmasının ardından serebral oksijen saturasyonun basal değere tekrar ulaştığını veya basal değerin de üzerine çıktığını gözlemediğimiz.

Anahtar Kelimeler: carotis endarterectomy; near-infrared spectroscopy; cerebral ischemia

ABSTRACT

Purpose: The aim of this study is to assess how NIRS values changed with cross-clamp (CC) duration in carotid endarterectomy (CEA) surgeries.

Materials and Methods: The study included 30 patients. Before induction of general anesthesia, systolic blood pressure (SBP), diastolic blood pressure (DBP), mean arterial pressure (MAP), heart rate (HR), peripheral oxygen saturation (SpO_2), and regional oxygen saturation(rSO_2) values were recorded as right and left sides. The same parameters were recorded before the carotid CC, at the 3rd, 5th, and 10th minutes of the carotid CC, and at the 1st and 5th minutes after the cross-clamp removal postoperatively.

Results: When the rSO_2 values of the study participants were measured at different times, there was a significant difference ($p<0.05$) between the right-sided mean rSO_2 values of the patients who underwent right-sided surgery (n=11). There was also a significant difference ($p<0.05$) between the left-sided mean rSO_2 values of the patients who underwent left-sided surgery (n=19).

Conclusion: We discovered that there was a significant decrease in cerebral oxygen saturation during CC in patients who had CEA surgery under general anesthesia and that cerebral oxygen saturation reached or exceeded the basal value after the CC was opened.

Keywords: carotid endarterectomy; cerebral ischemia; near-infrared spectroscopy

Received: 01.11.2021; Accepted: 13.01.2022

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How to cite: Kaya Mert G, Avcı O, Gündoğdu O, İsbir AC, Özdemir Kol İ, Gürsoy S, Kaygusuz K. The effects of carotid endarterectomy surgery on cerebral oxygenation, randomized clinical trial. Ahi Evran Med J. 2022;6(2):143-149. DOI: 10.46332/aemj.1017231

INTRODUCTION

Carotid artery stenosis is one of the leading causes of cerebrovascular disease, accounting for 20-25 percent of all strokes.¹ There are three options for treating carotid artery stenosis. These are as follows: medical, endarterectomy, and endovascular stenting. Conditions such as symptomatology, degree of stenosis, and risk factors are considered in treatment selection.

Carotid endarterectomy (CEA) is a surgical procedure used to reduce the risk of cerebral infarction in patients with carotid artery stenosis.² In the works of the North America Symptomatic Carotid Endarterectomy Trial (NASCET) and the European Carotid Surgery Trial (ECST), it is indicated that carotid endarterectomy is superior to medical treatment in terms of preventing ischemic stroke in patients with symptomatic internal carotid artery (ICA) stenosis greater than 70% on Doppler ultrasonography (USG).^{3,4} Carotid endarterectomy procedures can be performed under general or regional anesthesia. It has not been demonstrated that the anesthesia technique used causes a significant difference in the proportion of patients who have a stroke or die within 30 days of surgery. Studies revealed that in selecting anesthesia techniques, surgeons could choose the appropriate anesthesia technique based on their personal preferences and the patients' clinical conditions.⁵

The most serious complication of CEA surgeries is stroke, which occurs as a result of cerebral embolism or hypoperfusion during intra-operative carotid artery cross-clamping (CC) and is reported to occur at a rate of 2-3%.^{6,7} Thus, early diagnosis of cerebral hypoperfusion or embolism that may occur during the CC process is critical in avoiding potential neurological damage and more severe cerebral damage.⁸ For this purpose, in CEA surgeries, various cerebral monitoring methods such as electroencephalogram (EEG), which evaluates brain perfusion and functions, somatosensory evoked potentials (SSEPs), Transcranial Doppler (TCD), which directly evaluates cerebral blood flow, jugular venous oxygen saturation ($S_{jv}O_2$), which provides information about cerebral oxygen metabolism and regional cerebral oximetry (NIRS), have been used.

The aim of this study is to monitor the changes in cerebral oxygen saturation using NIRS monitoring in carotid endarterectomy cases performed under general anesthesia and research how NIRS values changed with CC duration in CEA surgeries.

MATERIALS and METHODS

This randomized clinical trial was approved by Sivas Cumhuriyet University Ethics Committee with the decision dated 19.03.2019 and numbered 2019-03/08.

The study included thirty adult ASA (American Society of Anesthesiologists) II – III patients who will undergo carotid endarterectomy surgery under general anesthesia. Patients with uncontrolled cardiovascular, respiratory, and metabolic diseases, any intracranial pathology, and difficult airway criteria, patients with preoperative hemoglobin value less than 10 g/dl and greater than 17 g/dl, and patients who refused to participate in the study were excluded.

Prior to the study, the participants were informed verbally and in writing about all aspects of the study, and an informed consent document was regulated. This study was designed in accordance with the 2008 Declaration of Helsinki.

Age, weight, gender, ejection fraction, hemoglobin values, and carotid stenosis grades of the patients who were evaluated preoperatively were recorded. Premedicated patients who will undergo carotid endarterectomy surgery under general anesthesia are taken to the operating table and after respiratory and cardiac monitoring are provided, systolic blood pressure (SBP), diastolic blood pressure (DBP), mean arterial pressure (MAP), heart rate (HR), and peripheral oxygen saturation (SpO_2) and regional oxygen saturation (rSO_2) values were recorded as right and left sides. The patient was intubated with the appropriate endotracheal tube and connected to the anesthesia device after 2 minutes of preoxygenation, and the end-tidal carbon dioxide ($etCO_2$) value was also recorded. These values were taken as baseline values. The same procedures were measured and recorded prior to the carotid CC, at the 3rd, 5th, and 10th minutes during the carotid CC, 1 minute after the CC was removed, 5 minutes after the CC was removed,

and postoperatively.

Thiopental sodium (Pental Sodium İbrahim Etem Ulaga 1gr/1flk) at a dose of 5-7 mg/kg was used in the induction of anesthesia and fentanyl (Talinat Vem, 0.5mg/10ml) at a dose of 1-1.5 microgram/kg was used in suppressing the stress response in patients who had been premedicated by intramuscular administration of midazolam (Midolam Pharmada, 5 mg/1ml) at a dose of 0.025-0.05 mg/kg half an hour before the surgery. As a muscle relaxant, 0.5 mg/kg rocuronium bromide (Myocron Vem 50 mg/5 ml) was used. In the maintenance of anesthesia, 2% sevoflurane was used. Following standard anesthesia induction and muscle relaxant administration, the patients were intubated with the appropriate endotracheal tube. Afterward, anesthesia was maintained. Tidal volume was set to 6 ml/kg, etCO₂ values to 30-45 mmHg, and PEEP (Positive End Expiratory Pressure) values to 5 cmH₂O on the mechanical ventilator. Sugammadex (Bridion Schering-plough 100 mg/ml) was administered to the patients after the operation at a dose of 2 mg/kg to antagonize the effect of the muscle relaxant.

Hemodynamic and respiratory data of the study were obtained from the Drager brand XL model monitor. A Somanetics Invos Oximeter brand device was used to assess the rSO₂ values of the patients.

Statistical Analysis

When the obtained data were uploaded into the SPSS program and the parametric test assumptions were met in the data evaluation (Kolmogorov-Smirnov), the significance test of the difference between two means in independent groups, variance analysis for repeated measurements, the Bonferroni test to determine which measurement or measurement groups make a difference when an important decision is made as a result of the analysis, when Friedman test that parametric test assumptions could not be met, the Wilcoxon test was applied, the margin of error was set to 0.05.

RESULTS

The study included 12 female and 18 male patients. Of the

patients, 11 had surgery on the right side and 19 had surgery on the left side. The demographic data of the participants are presented in Table 1.

There was no significant correlation found between pre-operative hemoglobin values, ejection fractions, systolic and diastolic blood pressures, mean arterial pressure, heart rates, end-tidal carbon dioxide, and cerebral oxygen saturation in the study participants.

Table 1. Demographic data of the patients.

Variables	n	Minimum	Maximum	Mean ± SD
Age (year)	30	40.00	81.00	68.43 ± 8.67
Weight (kilogram)	30	56.00	110.00	74.23 ± 12.53
Preoperative hgb (g/dL)	30	10.90	15.50	13.30 ± 1.12
EF (%)	30	45.00	58.00	53.86 ± 2.73
Cross-clamp duration (minute)	30	7.00	14.00	9.96 ± 1.94

EF: ejection fraction

hgb: hemoglobin

SD: Standard deviation

There was a significant difference ($p<0.05$) between the participants' MAP values that were measured at different times. The mean baseline MAP value was found to be 106.00±14.24 mmHg, mean MAP value before cross-clamp was found to be 95.43±13.98 mmHg, mean MAP value at 3 minutes was found to be 88.06±15.05 mmHg, mean MAP value at 5 minutes was found to be 83.73±12.31 mmHg, mean MAP value at 10 minutes was found to be 83.00±11.78 mmHg, mean MAP value after cross-clamp1 was found to be 85.16±14.95 mmHg, mean MAP value after cross-clamp5 was found to be 94.03±15.40 mmHg, and postoperative mean MAP value was found to be 95.43±16.65 mmHg.

The mean HR value of study participants was measured postoperatively as 84.10 beats/min at the highest and 78.06 beats/min at the lowest at the fifth minute of cross-clamp. The difference in heart rate values measured at different times in the study participants was found to be insignificant ($p>0.05$).

When the right-sided rSO₂ values of the study participants measured at different times were compared, there was a significant difference ($p<0.05$). The mean right-sided rSO₂ values of all patients are shown in Table 2.

Table 2. Right-side cerebral oxygen saturation values (rSO₂)*

Variables	n	Minimum	Maximum	Mean ± SD
BSLrSO ₂	30	43.00	85.00	66.90 ± 9.70
BCCrSO ₂	30	44.00	86.00	68.43 ± 9.37
3.min. rSO ₂	30	40.00	79.00	64.96 ± 9.52
5.min. rSO ₂	30	41.00	96.00	65.00 ± 11.31
10.min. rSO ₂	17	49.00	76.00	63.52 ± 9.28
ACC1.min. rSO ₂	30	51.00	79.00	67.16 ± 7.08
ACC5.min. rSO ₂	30	56.00	79.00	68.96 ± 6.86
POSTOP.rSO ₂	30	58.00	80.00	69.70 ± 5.80

BSL: basal value,

BCC: Before cross-clamp,

3. min., 5.min., 10.min.: 3rd, 5th and 10th minutes of cross-clamp,

ACC1.min and ACC5.min.: 1st and 5th minutes after cross-clamp,

POSTOP: end of the operation,

SD: Standard deviation

*(p<0.05)

When the left-sided rSO₂ values of the study participants measured at different times were compared, there was a significant difference between basal rSO₂ and other measurements (p<0.05). The mean left-sided rSO₂ values of all patients are shown in Table 3.

Table 3. Left-Side cerebral oxygen saturation (rSO₂)*

Variables	n	Minimum	Maximum	Mean ± SD
BSLrSO ₂	30	49.00	81.00	65.70 ± 8.27
BCCrSO ₂	30	48.00	79.00	67.06 ± 7.93
3.min. rSO ₂	30	35.00	79.00	61.93 ± 8.95
5.min. rSO ₂	30	32.00	77.00	61.40 ± 8.83
10.min. rSO ₂	17	38.00	73.00	61.11 ± 8.27
ACC1.min. rSO ₂	30	44.00	80.00	67.16 ± 7.71
ACC5.min. rSO ₂	30	59.00	83.00	70.10 ± 6.48
POSTOP.rSO ₂	30	59.00	83.00	70.90 ± 6.00

BSL: basal value,

BCC: Before cross-clamp

3. min., 5. min., 10. min.: 3rd, 5th and 10th minutes of cross-clamp,ACC1.min and ACC5.min.: 1st and 5th minutes after cross-clamp,

POSTOP: end of the operation,

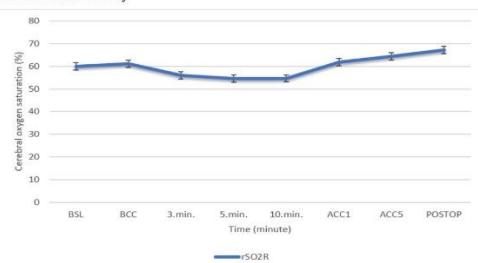
SD: Standard deviation

*(p<0.05)

The lowest mean rSO₂ value of the study participants at the 10th minute of the cross-clamp on the right was 663.52±9.28% and 61.11±8.2% at the 10th minute of the cross-clamp on the left. The difference in mean right and left rSO₂ values measured at different times in the study participants was found to be insignificant (p>0.05).

There was a significant difference (p<0.05) between the

right-sided mean rSO₂ values of the study patients who underwent right-sided surgery (n=11) (Figure 1).

Figure 1. Mean values of right-side cerebral oxygen saturation (rSO₂) of the patients had right carotis endarterectomy*

BSL: basal value,

BCC: Before cross-clamp,

3. min., 5. min., 10. min.: 3rd, 5th and 10th minutes of cross-clamp,ACC1 and ACC5: 1st and 5th minutes after cross-clamp,

POSTOP: end of the operation,

rSO₂R: Right cerebral oxygen saturation (%)

*(p<0.05)

Figure 1. Mean values of right-side cerebral oxygen saturation (rSO₂) of the patients who had right carotis endarterectomy

The lowest mean rSO₂ values on the right side of the patients included in the study who underwent right-sided surgery were measured as 54.67±5.99% at the 10th minute of cross-clamp, and the highest mean rSO₂ value was measured as 67.09±5.92% postoperatively (Table 4).

Table 4. Right-side cerebral oxygen saturation of the patients had right carotis endarterectomy*

Variables	Minimum	Maximum	Mean ± SD
BSLrSO ₂	43.00	78.00	59.82 ± 10.58
BCCrSO ₂	44.00	76.00	61.00 ± 10.15
3.min. rSO ₂	40.00	70.00	55.91 ± 8.84
5.min. rSO ₂	41.00	68.00	54.64 ± 8.02
10.min. rSO ₂	49.00	65.00	54.67 ± 5.99
ACC1.min. rSO ₂	51.00	74.00	61.73 ± 5.95
ACC5.min. rSO ₂	56.00	79.00	64.36 ± 6.45
POSTOP.rSO ₂	60.00	80.00	67.09 ± 5.92

BSL: basal value,

BCC: Before cross-clamp

3. min., 5. min., 10. min.: 3rd, 5th and 10th minutes of cross-clamp,ACC1.min and ACC5.min.: 1st and 5th minutes after cross-clamp,

POSTOP: end of the operation,

SD: Standard deviation

*(p<0.05)

There was an insignificant difference (p>0.05) between the left-sided mean rSO₂ values of the patients who underwent right-sided surgery (n=11).

There was a significant difference (p<0.05) between the left-sided mean rSO₂ values of the patients who underwent left-sided surgery (n=19) (Figure 2).

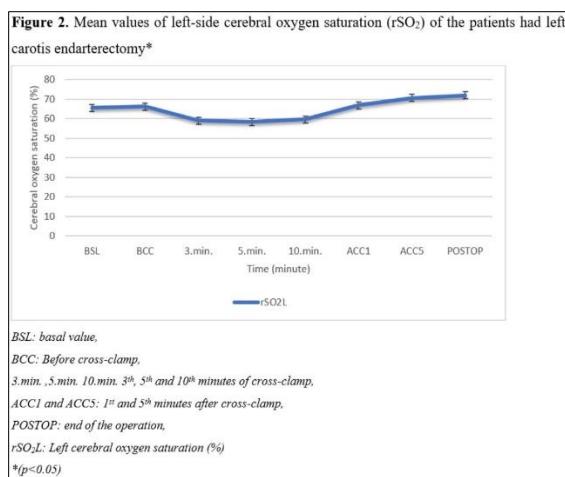


Figure 2. Mean values of left-side cerebral oxygen saturation (rSO₂) of the patients who had left carotis endarterectomy

The lowest mean rSO₂ values on the left side of the patients included in the study who underwent left-sided surgery were measured as $58.26 \pm 8.45\%$ at the 5th minute of cross-clamp, and the highest mean rSO₂ value was measured as $71.89 \pm 6.77\%$ postoperatively (Table 5).

Table 5. Left-side cerebral oxygen saturation of the patients had left carotis endarterectomy*

Variables	Minimum	Maximum	Mean \pm SD
BSLrSO ₂	49.00	80.00	65.47 ± 8.85
BCCrSO ₂	48.00	79.00	66.11 ± 8.61
3.min. rSO ₂	35.00	68.00	58.89 ± 8.65
5.min. rSO ₂	32.00	67.00	58.26 ± 8.45
10.min. rSO ₂	38.00	68.00	59.55 ± 8.71
ACC1.min. rSO ₂	44.00	76.00	66.74 ± 8.67
ACC5.min. rSO ₂	59.00	79.00	70.58 ± 6.52
POSTOP.rSO ₂	59.00	83.00	71.89 ± 6.77

BSL: basal value,
BCC: Before cross-clamp
3. min., 5. min., 10. min.; 3rd, 5th and 10th minutes of cross-clamp,
ACC1.min and ACC5.min.: 1st and 5th minutes after cross-clamp,
POSTOP: end of the operation,
SD: Standard deviation
*(p<0.05)

There was an insignificant difference ($p>0.05$) between the right-sided mean rSO₂ values of the patients who underwent left-sided surgery ($n=19$).

There was no statistically significant correlation between the calculated decrease percentages of rSO₂ and the surgical side stenosis degrees of the patients included in the study.

The differences between the baseline rSO₂ values measured on the surgical side of the patients included in the study and the lowest rSO₂ values measured during the cross-clamp were calculated. (ΔrSO_2 :baseline rSO₂-lowest measured rSO₂)/baseline rSO₂x100). The calculated difference is 27.8% at most, while it is 2.89% at the minimum. There was no decrease in rSO₂ during the cross-clamp in one patient according to baseline. The mean rSO₂ decrease was discovered to be 10.9%. There was a decrease of more than 20% in 3 of the patients included in the study compared to baseline. The lowest rSO₂ percentages measured during baseline and cross-clamping in these 3 patients were found to be 24.5%, 27.02%, and 27.8%, and the cross-clamp times of these patients were reported as 10 minutes, 8 minutes, and 11 minutes, respectively. None of the cases required shunt decision intraoperatively.

DISCUSSION

In this study, we used NIRS monitorization to assess the changes in cerebral oxygenation with CC duration in CEA surgeries. It is obvious that rSO₂ decreases when the CC duration increases. But this increase in ΔrSO_2 was not efficient for making a shunt decision by the surgeon.

General anesthesia applications have been preferred for the majority of patients as the choice of anesthesia in patients undergoing CEA surgery in recent years. Choosing general anesthesia applications provides advantages such as airway control, control of blood pressure and heart rate, especially in patients with coronary artery disease, providing comfort for the patient and surgeon, and providing brain protection with sodium thiopental.⁵ Regardless of anesthesia used, the use of monitoring methods that provide information about the cerebral status and early detection of neurological deficits is an essential and basic principle during CEA surgeries.⁵

All procedures performed under general anesthesia have the potential to impair brain perfusion, particularly in elderly patients.^{9,10} However, the brain is rarely monitored in routine practice. Monitoring cerebral oxygen saturation during the intraoperative period has been shown in numerous studies to be an appropriate and useful method. NIRS monitoring is a non-invasive analysis method that demon-

strates regional cerebral oxygenation offering brain oxyhemoglobin and deoxyhemoglobin tissue concentrations and weighted venous values.^{11,12}

In their study titled "Use of NIRS in Awake Carotid Endarterectomy Surgery," Robert et al.¹³ included 16 patients. The surgical side rSO₂ values of patients were observed to be baseline 69.1 ± 1.8 before the cross-clamp, to be 64 ± 1.2 at the 1st minute of cross-clamp, to be 63 ± 1.4 at the 5th minute of cross-clamp, to be 64 ± 1.5 at the 10th minute of cross-clamp, to be 63 ± 1.3 at the 15th minute of cross-clamp, and to be 67 ± 1.6 post-cross-clamp. rSO₂ values during CC decreased statistically significantly according to baseline rSO₂ values, but they returned to their former levels after CC. Unlike Robert et al., our study calculated basal systolic blood pressure as 154.1 ± 13.3 mmHg, basal diastolic blood pressure as 77.0 ± 11.5 mmHg, and mean basal blood pressure as 106.0 ± 14.2 mmHg. SBP in patients decreased significantly according to baseline at all times measured ($p < 0.05$), except for the difference between the postoperative measured value and the baseline value, which was insignificant ($p > 0.05$). We believe that the difference between our study and the study of Robert et al. is because, in the study of Robert et al., the patients were awake during the surgery, whereas, in our study, the patients were under general anesthesia. In addition, in our study, the MAP values of the patients were found to be 95.43 ± 13.9 mmHg pre-cross-clamp, to be 83.73 ± 12.3 mmHg during CC, to be 85.16 ± 14.9 mmHg post-cross-clamp and there was no correlation found between these values and rSO₂.

Pedrini et al.¹⁴ investigated the effectiveness of NIRS monitoring in predicting ischemia and shunt requirement during CEA surgery in their study with 473 patients in 2012. In this study, a 20% decrease in rSO₂ in NIRS monitoring was used as a reference for shunt indication, and a shunt was required in 41 of 473 patients. The study concluded that the use of NIRS can be a guide in the decision of ischemia and shunt requirements in CEA surgery.

Radak et al.¹⁵ argued in their 2012 study of 94 patients that the use of NIRS could be used to predict the need for a shunt in CEA cases, and they predicted that the decrease in the baseline rSO₂ value should be 20% or more during CC for shunt indication.

The mean rSO₂ decrease in our study was found to be 10.9%. While the calculated difference is 27.8% at most, it is 2.89% at the lowest. No significant correlation between the calculated decrease percentages of rSO₂ and the surgical side stenosis degrees of the patients was observed in our study. We believe this is due to the effect of contralateral stenosis on the decrease in the rSO₂ value.

In their study conducted in 2004 and included 594 patients, Mille et al.¹⁶ investigated which rSO₂ threshold value is critical in NIRS monitoring in carotid endarterectomy cases. In the study, the mean baseline rSO₂ value before the cross-clamp was 67.9 ± 6.8 , while the lowest mean rSO₂ value during CC was found to be 59.5 ± 7.2 . The mean rSO₂ value after removing the cross-clamp was found to be 67.7 ± 6.7 , which was close to the baseline value. The highest decrease in this study was around 12% during CC according to the baseline rSO₂ value, and no patient required a shunt. Neurological incidents did not occur in any of the patients preoperatively or postoperatively. As a result, Mille et al. concluded that using NIRS in CEA surgery would be a guide for patients.

In our study, the decreases in rSO₂ values during cross-clamp according to the surgical-sided baseline values were found to be statistically significant ($p < 0.05$). (CC 3rd min. p:0.021, CC 5th min. p:0.009, CC 10th min. p=0.024). It was observed that rSO₂ values returned to the baseline values after cross-clamp. A 20% decrease in rSO₂ in NIRS monitoring was considered a critical value for cerebral desaturation in our study. The mean rSO₂ decrease of the patients included in the study was found to be 10.9%. A decrease of 20% or more in rSO₂ was observed in 3 of the 30 patients included in the study. The need for a shunt in surgery was discussed, but since the cross-clamp time was anticipated to be short and the potential risks of shunt application were considered, the surgical procedure was completed without implementing shunt on the patients. The shunt helps minimize cerebral hypoperfusion during carotid cross-clamping in CEA, but it complicates the procedure, prolongs the duration, and may increase the risk of stroke.¹⁷ In our study, the rSO₂ decreased percentages of these three patients, calculated using the lowest rSO₂ measured during baseline and cross-clamping, were 24.5 percent, 27.02 percent, and 27.8 percent, respectively, and

their cross-clamp times were 10 minutes, 8 minutes, and 11 minutes, respectively. But even if there is an increase in ΔSO_2 higher than 20%, shunt decision was not made by the surgeon. Because the surgeries were made under general anesthesia, neurological symptoms can not appear. There was no neurological deficit observed when the patients were evaluated after the operation.

In this study, we discovered that there was a significant decrease in cerebral oxygen saturation during cross-clamping in a small number of patients undergoing carotid endarterectomy under general anesthesia and that cerebral oxygen saturation returned to or exceeded baseline value after the opening of cross-clamping. We believe that the percentage of decrease in the rSO_2 during CC and the duration of the CC is effective in making the shunt decision in patients under general anesthesia. In our study, we concluded that changes in the rSO_2 value do not correspond to changes in hemodynamics.

Conflict of Interest

The authors declare that they have no conflict of interest.

Acknowledgment

We thank all the members of the anesthesiology departments.

Ethics Committee Permission

This randomized clinical trial was approved by Sivas Cumhuriyet University Ethics Committee with the decision dated 19.03.2019 and numbered 2019-03/08.

Authors' Contributions

Concept/Design: GKM, OA, OG. Data Collection and/or Processing: Cİ, İÖK, SG, KK. Data analysis and interpretation: GKM, OA, OG. Literature Search: Cİ, İÖK, SG. Drafting manuscript: GKM, OA, OG. Critical revision of the manuscript: Cİ, İÖK, OG.

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