CLINICAL EVALUATION OF NEAR-INFRARED CEREBRAL OXIMETRY IN THE AWAKE-PATIENT CAROTID ENDARTERECTOMY

JACEK WOJCIECHOWSKI1, MAGDALENA SIDOROWICZ2, KRZYSZTOF SZYNDLER1, ŁUKASZ ZNANIECKI1, MARCIN TRENKNER1, GRZEGORZ HALENA1, MACIEJ BRZEZIŃSKI1, JAN ROGOWSKI1

Department of Cardiovascular and Vascular Surgery, Medical University in Gdańsk1
Kierownik: prof. dr hab. J. Rogowski
Anaesthesiology and Intensive Therapy Unit, Medical University in Gdańsk2
Kierownik: prof. dr hab. M. Wujtewicz

The aim of the study was to evaluate the usefulness of continuous monitoring of regional cerebral oxygen saturation (rSO2) for detection of brain ischemia during carotid endarterectomy.

Material and methods. We performed 44 carotid endarterectomies using regional anesthesia, with simultaneous regional cerebral oxygen saturation monitoring in both hemispheres of the brain.

Results. Oxygen saturation in the hemisphere ipsilateral to the operated carotid artery dropped from 65.1±8.1 to 58.2±10.7 after carotid artery cross-clamping. The difference was statistically significant (p<0.005). Oxygen saturation in the hemisphere contralateral to the operated artery did not demonstrate a difference between that before or after carotid artery closure (65.7±9.2 and 66.1±10.2, respectively, p=0.1). In five patients (11.4%) carotid artery clamping was associated with the appearance of neurological deficits. Shunt usage was necessary in four cases; the rSO2 decreased by 19.2±14% in this group. In the group without neurological deficit during carotid clamping, the rSO2 decreased by 9.7±10.3% (the difference between groups with and without neurological deficit was not statistically significant, p=0.5). In patients with a rSO2 drop above 20%, the sensitivity of the cerebral oximetry was 20% and specificity 97.5%, while the negative predictive value was 90.7%.

Conclusions. Continuous cerebral oximetry is a simple and non-invasive method of patient monitoring during carotid endarterectomy. The rSO2 decreases significantly after the ICA clamping. The sensitivity of cerebral oximetry in prediction of neurological deficit during the procedure is low. Defining the threshold value of rSO2 decrease after ICA clamping as an indication for shunt was not possible with the results of this study.

Key words: cerebral oximetry, carotid artery, endarterectomy, near-infrared refracted spectroscopy, cerebral ischaemia

Carotid endarterectomy is one of the most popular vascular surgical procedures, and is commonly used as a prophylactic procedure for the prevention of stroke. Patients with symptomatic as well as asymptomatic carotid artery stenosis are qualified for the surgery. The benefit of surgical treatment of carotid stenosis was proved in multinational, multicenter studies such as NASCET and ECST (1, 2). In order to provide benefit, the procedure complication rate has to be appropriately low. In the NASCET and ECST studies, the combined perioperative stroke and death ratio reached 6.5% and 7.5%, respectively.

In order to decrease the perioperative stroke ratio, it is advised to use one of the multiple methods available for monitoring of cerebral perfusion. Internal carotid artery back pressure monitoring, EEG analysis, evaluation of somatosensory evoked potentials (SSEPs), as
well as continuous neurological state monitoring in patients operated on using regional anesthesia are methods used in cerebral perfusion monitoring.

Cerebral hypoperfusion may be associated with the occurrence of a new cerebral ischemic focus or an increase in previous pathologies of the brain.

In order to maintain an appropriate level of cerebral perfusion, shunting may be used (3). However, the use of a shunt may be associated with additional complications such as arterial dissection, thrombosis or embolism.

Regional cerebral oxygen saturation monitoring by means of near-infrared refracted spectroscopy (NIRS) was first described in 1977 by Jobsis et al. (4). NIRS is a method of non-invasive continuous measurement of cerebral perfusion, which may be performed during the carotid endarterectomy. However, previous publications concerning this method are sparse and often divergent (5, 6).

The aim of the study was to evaluate whether a decrease in cerebral oxygen saturation measured by NIRS during carotid endarterectomy may serve as an indicator of neurological complication risks. As a consequence, it would allow us to set the threshold value for saturation decrease, below which shunt use would be obligatory. A secondary aim was to evaluate the influence of carotid clamping on cerebral saturation in the hemisphere contralateral to the operated side, which would reflect brain perfusion by collateral circulation. Answers to above questions would allow us to evaluate the usefulness of NIRS cerebral saturation monitoring in carotid artery surgery.

MATERIAL AND METHODS

Forty-four consecutive patients treated surgically for the indication of symptomatic or asymptomatic carotid stenosis in our department between July 2005 and December 2006 were enrolled into the analysis. Male sex consisted of 59.1% of the group; age range was 51 to 83 years. Characteristics of the studied cohort are presented in tab. 1. Symptomatic carotid stenosis was defined if a history of previous stroke, transient ischaemic accidents (TIA) or amaurosis fugax was present. Doppler ultrasonography was used to diagnose the carotid stenosis. In cases of diagnostic doubts, digital subtraction angiography was performed. All surgical procedures were performed using local anesthesia by various surgeons. All patients received intramuscular petidine (1 mg/kg body mass) 1 hour prior to the surgery. Beside oscillometric blood pressure measurement, ECG monitoring and pulsoximetry, and continuous cerebral oximetry measurement by means of near-infrared refracted spectroscopy were routinely used.

Prior to arterial clamping, heparin was administered intravenously in each case (100 j/kg body mass). After ICA clamping, the patient’s neurological state was evaluated by examination of spoken response and motor function of the upper limb contralateral to the operated carotid artery. If the neurological state did not diminish after 3 minutes of observation, carotid endarterectomy was performed with simple arterial closure. In cases of neurological symptoms during trial ICA clamping, shunting was used (Javid shunt). Neurological state was then examined each 4-6 minutes during the procedure, and after the procedure was completed.

Cerebral oximetry

Invos 4100 (Somanetics Inc., Troy, MI) was used to perform continuous cerebral oximetry measurement. Measurement protocol consisted of bi-hemispheric reading of data (in 1 minute periods) from two electrodes placed on the patient’s forehead. Data were recorded for offline analysis. Cerebral saturation was calculated for the following intervals:

1. Saturation mean value of the last 10 minutes prior to ICA clamping (rSO2-0).
2. Saturation mean value of the first 3 minutes after ICA clamping (rSO2-1).
3. Saturation mean value of the whole period of ICA clamping (rSO2-2).

Table 1. Group characteristics

<table>
<thead>
<tr>
<th>Feature</th>
<th>n=44</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Male</td>
<td>26</td>
<td>59.1</td>
</tr>
<tr>
<td>Symptomatic stenosis</td>
<td>23</td>
<td>52.2</td>
</tr>
<tr>
<td>Asymptomatic stenosis</td>
<td>21</td>
<td>47.7</td>
</tr>
<tr>
<td>Coronary artery stenosis</td>
<td>22</td>
<td>50</td>
</tr>
<tr>
<td>Arterial hypertension</td>
<td>31</td>
<td>70.4</td>
</tr>
<tr>
<td>Chronic obstructive pulmonary disease</td>
<td>4</td>
<td>9.1</td>
</tr>
<tr>
<td>PAD</td>
<td>7</td>
<td>15.9</td>
</tr>
<tr>
<td>Glaucoma</td>
<td>2</td>
<td>4.5</td>
</tr>
<tr>
<td>Thrombocytopenia</td>
<td>1</td>
<td>2.2</td>
</tr>
<tr>
<td>Contralateral ICA occlusion</td>
<td>6</td>
<td>13.6</td>
</tr>
</tbody>
</table>
4. Saturation mean value of 10 minutes after ICA de-clamping (rSO₂-3).

The measurements were performed for both hemispheres, i.e. ipsilateral and contralateral to the treated artery. The percentage of saturation drop was calculated according to the following formula:

\[ \Delta rSO_2 = \frac{(rSO_2-0)-(rSO_2-1)}{(rSO_2-0)} \times 100 \]

Statistical analysis

Quantitative data were expressed as mean±standard deviation, while qualitative data was expressed as a frequency of occurrence in percentages. The null hypothesis was rejected at the statistical relevance of level p<0.05. Normal distribution analysis for quantitative variables was performed by means of the W test of Shapiro-Wilk, while variation homogeneity was assessed by Leven’s test. In cases of significant differences, post-hoc tests were used to analyze differences between particular pairs.

Cerebral saturation mean value comparison between groups of patients who were either neurologically symptomatic or asymptomatic during cross-clamping was performed by means of the Mann-Whitney U test for two independent groups and by means of ANOVA/ANOVA for repeated measures designs.

All statistical analyses were performed using STATISTICA version 7.1pl software (Statsoft inc, 2004).

RESULTS

In the studied group we reported neither death nor stroke. We reported one case of postoperative bleeding, requiring wound revision on the day of surgery. Another patient required a second surgical procedure in the third postoperative week due to false aneurysm of the common carotid artery.

Intraoperative cerebral oximetry analysis

There was a statistically significant drop in the cerebral oximetry in the hemisphere ipsilateral to the operated artery noted after ICA cross-clamping (from 65.1±8.1 [rSO₂-0] to 58.2±10.7 [rSO₂-1], p<0.005). After flow restoration, a significant increase in cerebral saturation was noted in the ipsilateral hemisphere (to 68.3±8.9 [rSO₂-3], [p<0.005]). The saturation values before the procedure (rSO₂-0) and after declamping (rSO₂-3) did not reach statistical significance (p=0.46) (fig. 1).

Oxygen saturation in the hemisphere contralateral to the operated artery did not change after ICA cross-clamping (65.7±9.2 [rSO₂-0] and 66.1±10.2[rSO₂-1], before and after clamping, respectively).

Graphical presentation of cerebral saturation for both hemispheres during the procedure can be found in fig. 2.

Comparison based on the occurrence of neurological symptoms during ICA cross-clamping

Neurological deficit after ICA cross-clamping occurred in 5 patients (11.4%). In 4 cases, these symptoms occurred during the first 2 minutes after cross-clamping. Those cases were performed with shunt use. One patient presen-
tected with neurological deficits in ninth minute after cross clamping; this procedure was performed without shunt use. After flow restoration the entire neurological deficit withdrew.

Table 2 presents characteristics of patients with neurological deficits during cross-clamping. In this group, the cerebral saturation decreased by 19.2±14%, while in the asymptomatic group, it decreased by 9.7±10% (the difference did not reach statistical significance, p=0.2). The average age of the asymptomatic group was 68.5±8 years; the symptomatic group was 77.4±4 years. This difference was statistically significant (p=0.01).

Neurological symptoms after ICA clamping occurred in 19% (4 patients) of patients that presented with a symptomatic stenosis; this occurred in 4.3% of asymptomatic patients (p=0.14).

ICA clamping time was shorter in the group with neurological deficit, however this difference was not statistically significant (p=0.28). Table 3 presents values of cerebral saturation in particular time ranges for patients with deficits as well as those who were asymptomatic.

Sensitivity, specificity and predictive values are presented for selected values of saturation decrease (ΔrSO₂) in tab. 4. In cases of saturation drops of 20% of the initial value, the sensitivity of cerebral oximetry was estimated to 20%, and specificity to 97.5%. Positive and negative predictive values were 50% and 90.5%, respectively.

DISCUSSION

Carotid endarterectomy is an established preventive surgical procedure for cerebral stroke (1, 2). However a prophylactic procedure should not be a threat itself to the patient. The struggle to diminish the complication rate has been a target of many studies for years. Cerebral saturation measurement by NIRT is a simple, noninvasive method and may show disturbances in cerebral blood flow (7-10).

The majority of studies evaluating cerebral oximetry as a tool for diagnosing acute cerebral hypoperfusion has been performed on patients treated using general anesthesia. In these conditions, it is impossible to evaluate the neurological status of the patient directly. Other methods used to evaluate cerebral blood flow, such as EEG (11), transcranial Doppler-ultrasonography (8), or measurement of somatosensory evoked potentials (SSEPs) (6), are indirect methods of neurological status evaluation. Those methods have several limitations and conclusions drawn upon them may be burdened with error.

Regional or local anesthesia in carotid endarterectomy is used routinely in many centers. As a fact, it is considered the “golden stan-

Table 2. The characteristics of patients with positive “test clamping” of ICA

<table>
<thead>
<tr>
<th>Sex</th>
<th>Age</th>
<th>Symptomatic stenosis</th>
<th>rSO₂-0</th>
<th>rSO₂-1</th>
<th>ΔrSO₂ %</th>
<th>Shunt use</th>
</tr>
</thead>
<tbody>
<tr>
<td>M</td>
<td>73</td>
<td>no</td>
<td>42.9</td>
<td>30.33</td>
<td>29.30</td>
<td>yes</td>
</tr>
<tr>
<td>K</td>
<td>80</td>
<td>yes</td>
<td>64.8</td>
<td>58.33</td>
<td>9.98</td>
<td>yes</td>
</tr>
<tr>
<td>M</td>
<td>81</td>
<td>yes</td>
<td>58.8</td>
<td>56.66</td>
<td>3.63</td>
<td>yes</td>
</tr>
<tr>
<td>K</td>
<td>80</td>
<td>yes</td>
<td>76.5</td>
<td>65.33</td>
<td>14.63</td>
<td>no</td>
</tr>
<tr>
<td>M</td>
<td>73</td>
<td>yes</td>
<td>62.8</td>
<td>38.66</td>
<td>38.34</td>
<td>yes</td>
</tr>
</tbody>
</table>

Table 3. The value of cerebral saturation as measured by NIRS and ICA and the cross-clamp time in patients subjected to CEA

<table>
<thead>
<tr>
<th>Group (n)</th>
<th>Clamp time</th>
<th>Operated side</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>rSO₂-0 pre-clamp</td>
<td>rSO₂-1 3 min cross-clamp</td>
</tr>
<tr>
<td>No neurological deficit (n=39)</td>
<td>26.6±6.3</td>
<td>65.2±7.9</td>
</tr>
<tr>
<td>Neurological deficit (n=5)</td>
<td>22.6±6.2</td>
<td>61.2±12.1</td>
</tr>
<tr>
<td>p</td>
<td>0.28</td>
<td>0.49</td>
</tr>
</tbody>
</table>
standard” and the best method for being able to monitor cerebral perfusion by many surgeons. Therefore in our opinion, the best way to evaluate a new method of cerebral perfusion monitoring is to compare it to the “golden standard”. Moreover, local anesthesia allows for severely ill patients to undergo surgery when general anesthesia would be contraindicated.

A significant decrease in cerebral saturation after ICA clamping in all studied individuals confirms the fact that cerebral oximetry reflects a change of perfusion in the studied cerebral region. A question arises concerning whether it is possible to foresee cerebral hypoperfusion and the threat of stroke based only on the value of saturation decrease during ICA clamping. In our material, the incidence of neurological deficit during ICA clamping was an indication for use of a shunt. Neither stroke nor persistent neurological deficit was observed postoperatively in the studied group; this could result from a simple borderline decrease in cerebral perfusion. In studies where the cerebral saturation was measured during general anesthesia procedures, it was possible to assert only after the procedure whether the saturation decrease resulted in damage to the brain.

The saturation change associated with ICA clamping in the hemisphere contralateral to the operated carotid artery was only modest. Increases in saturation from 65.7±9.2 (\(\Delta rSO_2\)) to 66.1±10.2 (\(rSO_2\)) and finally after flow re-establishment to 67.7±9.6 (\(rSO_2\)) was not significant statistically. It is difficult to conclude that there was a compensative cerebral flow increase in the contralateral hemisphere based on these results; Hirofumi made similar observations (14). In our study we measured saturation changes associated with ICA end ECA clamping simultaneously, which deemed it impossible to measure saturation changes resulting from collateral flow through the ECA.

So called “test clamping” of the ICA for the initial three minutes is done to verify whether the collateral blood flow is sufficient and whether it is necessary to use shunting. The use of shunting may itself be a source of neurological complications; therefore, it is advised to use it only in situations where it absolutely indicated (3, 15). In our study, the average saturation decrease in the group of patients with neurological symptoms during “test clamping” was 19.2% and it was higher than that of a group with negative “test clamping”, however the difference was not statistically significant. Moreover, individual values of saturation decrease in the group with positive test clamping was of great variation; \(\Delta rSO_2\) ranged from 3.6 to 38.3 (tab. 2). Therefore, the result of saturation decrease could not clearly indicate the need for shunting. The \(rSO_2\) measurement is taken from the forehead region, which theoretically may indicate the blood flow in anterior and middle cerebral arteries. However, it may not reflect the saturation in each part of the brain. The group of 5 patients with positive “test clamping” was older than those with the negative test.

Many authors have tried to establish the value of cerebral saturation change after ICA clamping that would still be safe for the patient. Mille et al. showed that a drop in cerebral saturation higher than 20% of initial values was a threat of cerebral hypoperfusion (13). However this hypoperfusion does not always result in neurological complications. In his study performed on 594 patients, neurological complications appeared both in cases with a saturation decrease below and above the level of 20% of initial values. In our study there were no neurological complications, however first symptoms of cerebral hypoperfusion appeared at various levels of saturation.

Setting the threshold value of saturation decrease at the level of 20%, Mille et al. estimated the sensitivity of cerebral oximetry at the level of 30% and specificity at 98%; positive and negative predictive values were 37% and 98%, respectively (13).

Beese et al. performed a study on 317 patients operated using general anesthesia and monitored by SSEPs and set the same cut off value at 20%; they estimated sensitivity at the level of 7% and specificity at the level of 99%, with positive and negative predictive values of 60% and 91%, respectively (6).

Table 4. NIRS sensitivity and specificity

<table>
<thead>
<tr>
<th>(\Delta rSO_2)</th>
<th>Sensitivity</th>
<th>Specificity</th>
<th>PPV</th>
<th>NPV</th>
</tr>
</thead>
<tbody>
<tr>
<td>&gt;5</td>
<td>100</td>
<td>47.5</td>
<td>19.2</td>
<td>100</td>
</tr>
<tr>
<td>&gt;10</td>
<td>80</td>
<td>70</td>
<td>25</td>
<td>96.6</td>
</tr>
<tr>
<td>&gt;15</td>
<td>20</td>
<td>82.5</td>
<td>12.5</td>
<td>89.2</td>
</tr>
<tr>
<td>&gt;20</td>
<td>20</td>
<td>97.5</td>
<td>50</td>
<td>90.5</td>
</tr>
</tbody>
</table>

PPV – positive predictive value, NPV – negative predictive value.
Samra evaluated brain oximetry in patients operated using local anesthesia with selective shunt use. Setting the saturation cut off value at level of 20%, he estimated sensitivity at the level of 80% and specificity at 82.2%, whereas positive and negative predictive values were 33.3% and 97.4%, respectively (5).

In our study, selecting the same cut off value, we have estimated sensitivity at 20% and specificity at 97.5% with positive and negative predictive values of 50% and 97.5%, respectively.

Rigamonti et al. also presented results of NIRS monitoring of patients treated using local anesthesia. In cases with a saturation decrease higher than 15%, the sensitivity of this method was 44%; specificity was 82% and the negative predictive value was 94%. However, patients with contralateral occlusion and a history of neurological deficit were excluded from the analysis (16). Caudra et al. concluded that it is the group of patients with symptomatic stenosis that shows higher saturation decreases during ICA clamping compared to asymptomatic patients (17). It seems that narrowing the analyzed group may diminish the value of the study. In our analysis, patients with symptomatic stenosis required shunt use more frequently compared to asymptomatic patients.

After ICA clamping, significant changes in cerebral saturation occur. Despite the fact that rSO₂ monitoring is a simple and noninvasive method, it may not be a basic method of cerebral flow monitoring during CEA. Saturation measurement is read from the frontal area, and it seems that saturation measurement taken from various brain regions would be a more sensitive method and thus hypoperfusion assessment would be more accurate.

CONCLUSIONS

One has to take into consideration that it is very difficult to define the "normal" reference value. It mainly results from the great variability of absolute saturation values between the tested individuals throughout the surgical procedure. We found that the most credible value would be the proportional saturation decrease value resulting from ICA clamping.

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Adress correspondence: 80-210 Gdańsk, ul. Dębinki 7