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# Carotid endarterectomy in awake patients: safety, tolerability and results

***Endarterectomia de carótida em pacientes acordados: segurança, tolerabilidade e resultados***

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*Abstract*

***Objective:*** **To analyze the results of 125 carotid endarterectomies under loco-regional anesthesia, with selective use of shunt and bovine pericardium patch.**

***Methods:*** **One hundred and seventeen patients with stenosis ≥ 70% in the internal carotid artery on duplex-scan + arteriography or magnetic resonance angiography underwent 125 carotid endarterectomies. Intraoperative pharmacological cerebral protection included intravenous administration of alfentanil and dexametasone. Clopidogrel, aspirin and statins were used in all cases. Seventy-seven patients were males (65.8%). Mean age was 70.8 years, ranging from 48 to 88 years. Surgery was performed to treat symptomatic stenosis in 69 arteries (55.2%) and asymptomatic stenosis in 56 arteries (44.8%).**

***Results:*** **A carotid shunt was used in 3 cases (2.4%) due to signs and symptoms of cerebral ischemia after carotid artery clamping during the operation, and all 3 patients had a good outcome. Bovine pericardium patch was used in 71 arteries ≤ 6 mm in diameter (56.8%). Perioperative mortality was 0.8%: one patient died from a myocardial infarction. Two patients (1.6%) had minor ipsilateral strokes with good recovery, and 2 patients (1.6%) had non-fatal myocardial infarctions with good recovery. The mean follow-up period was 32 months. In the late postoperative period, there was restenosis in only three arteries (2.4%).**

***Conclusion:*** **Carotid artery endarterectomy can be safely performed in the awake patient, with low morbidity and mortality rates.**

***Descriptors:*** **Endarterectomy, Carotid. Anesthesia, Local. Stroke.**

*Resumo*

***Objetivo:*** **Analisar os resultados de 125 endarterectomias carotídeas, realizadas sob anestesia loco-regional com uso seletivo de shunt e remendo de pericárdio bovino.**

***Métodos*****: Cento e dezessete pacientes com estenose na artéria carótida interna ≥ 70% ao ecoDoppler colorido +**

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| Abbreviations, acronyms & symbols | |
|---|---|
| CVAs | Cerebrovascular accidents |
| ECG | Electrocardiogram |
| EEG | Electroencephalography |
| MAP | Mean arterial pressure |

**arteriografia ou angiorressonância magnética foram submetidos a 125 endarterectomias carotídeas. As medidas de proteção farmacológica intraoperatória incluíam a administração endovenosa de alfentanil e dexametazona. Clopidogrel, aspirina e estatinas eram utilizadas em todos os casos. Setenta e sete pacientes eram do sexo masculino (65,8%). A idade média foi de 70,8 anos, variando de 48 a 88 anos. A operação foi indicada por estenose sintomática em 69 artérias (55,2%), e por estenose assintomática em 56 artérias (44,8%).**

***Resultados:*** **O shunt de carótida foi necessário em 3 casos (2,4%) devido a sintomas de isquemia cerebral após a colocação do clampe carotídeo durante o ato cirúrgico, e os três pacientes tiveram boa evolução. Remendo de pericárdio bovino foi utilizado em 71 artérias ≤ 6 mm de diâmetro (56,8%). A mortalidade perioperatória foi de 0,8%: um paciente faleceu devido a infarto agudo do miocárdio. Dois pacientes (1,6%) tiveram infartos cerebrais isquêmicos ipsilaterais menores com boa recuperação, e 2 pacientes (1,6%) tiveram infartos do miocárdio não-fatais com boa recuperação. O tempo médio de seguimento foi de 32 meses. No pós-operatório tardio, houve reestenose significativa em apenas três artérias (2,4%).**

***Conclusão:*** **A endarterectomia carotídea no paciente acordado é uma técnica segura, sendo realizada com baixas taxas de morbimortalidade.**

***Descritores:*** **Endarterectomia das Carótidas. Anestesia Local. Acidente Vascular Cerebral.**

## INTRODUCTION

Ischemic cerebrovascular accidents (CVAs) are the third most common cause of death in the United States[1]. Up to 52% of all ischemic cerebral infarctions are caused by extracranial atherosclerotic cerebrovascular disease, that is, by stenoses in the internal carotid arteries caused by cholesterol plaque attached to thrombus[2]; it is known that the prevalence of carotid artery stenosis is high in patients with coronary disease and hypertension[1].

The first carotid endarterectomy was performed by Dr. Michael E. DeBakey in 1953 (and published in 1959)[3]. After a period of initial enthusiasm, followed by another period of concern due to high rates of complications reported in the 1970s and 1980s[4], prospective and randomized studies with large number of patients have been performed in the United States and Europe to investigate more objectively which patients would benefit from this procedure[5-8]. These studies were published from 1995 to 2004, and demonstrated that carotid endarterectomy plus medical therapy were superior to medical therapy alone in preventing ischemic strokes and death in selected patients with hemodynamically significant stenosis (≥ 70%) in the internal carotid artery[5-8].

It is estimated that more than 103,000 carotid endarterectomies are performed each year in the United States[1] with the aim of preventing ischemic strokes. However, there are still controversies regarding the type of anesthesia, cerebral monitoring and cerebral protection during the surgery, the use of a patch in closing the carotid artery and the criteria to use a carotid artery shunt.

The aim of this study is to describe and assess the results of carotid endarterectomy under loco-regional anesthesia, with selective use of a carotid artery shunt and bovine pericardium patch.

## METHODS

From April 1996 to November 2012, 125 consecutive carotid endarterectomies were performed on 117 patients under loco-regional anesthesia at the Vascular Surgery and Cardiovascular Surgery Services in the Red Cross University Hospital of Paraná, Curitiba. All patients were included in a prospective registry, and signed a written informed consent form before surgery. This study was approved by the Research Ethics Committee of the Positivo University.

All patients received perioperative acetylsalicylic acid (325 mg/day), clopidogrel (75 mg/day) and statins (simvastatin 20 mg/day or rosuvastatin 10 mg/day). This medication was started 15 days before the procedure and maintained for 1 year or more. There were 8 bilateral procedures. Six of the bilateral carotid endarterectomies were performed with an interval ranging from 4 to 5 weeks and 2 were performed at a later date when the contralateral carotid artery became symptomatic. There were 77 male (65.8%) and 40 (34.2%) female patients. The mean age of patients was 70.8 years, ranging from 48-88 years. Comorbidities of this group of patients were: diabetes (n=99 or 84.6%), smoking (n=97 or 82.9%), hypertension (n=92 or 78.6%), peripheral artery disease (n=64 or 54.7%), dyslipidemia (n=63 or 53.8%), ischemic coronary artery disease (n=62 or 53%), chronic obstructive pulmonary disease (n=14 or 11.9%) and chronic renal failure (n=5 or 4.3%).

The carotid arteries of all patients were assessed by color Doppler ultrasound along with digital subtraction angiography or magnetic resonance angiography with gadolinium. The arteriography and magnetic resonance were performed to confirm the presence of hemodynamically significant stenosis (seen on Doppler ultrasound) and to calculate the degree of stenosis. For this calculation, we used the method

described in the NASCET study[7]. Carotid endarterectomy was indicated when the degree of stenosis in the internal carotid artery was greater than or equal to 70%.

The surgery was indicated for symptomatic stenosis in 69 arteries (55.2%), and asymptomatic stenosis in 56 arteries (44.8%). The indications for operation are listed in Table 1. Among symptomatic patients, 42 had suffered transient ischemic attacks (33.6%), and 14 (11.2%) had experienced small cerebral infarcts. Thirteen patients (10.4%) had monocular blindness: 10 of them had experienced transient symptoms (amaurosis fugax), and 3 had permanent visual field defects. Three patients had total occlusion of the contralateral internal carotid artery. All asymptomatic lesions underwent surgery before coronary artery bypass grafting (31 cases), open repair of abdominal aortic aneurysms (14 cases), or major abdominal surgery (11 cases).

Table 1. Indications for carotid endarterectomy (125 procedures).

| Signs and symptoms | N | % |
|---|---|---|
| Transient ischemic attack | 42 | 33.6 |
| Cerebral infarction | 14 | 11.2 |
| Monocular blindness | 13 | 10.4 |
| Transient (amaurosis fugax) | 10 | |
| Permanent visual field defect | 3 | |
| Asymptomatic carotid stenosis | 56 | 44.8 |

The technique used by our anesthesiology service was superficial and deep cervical plexus block, seeking to provide conditions for neurological assessment of the patient during the procedure in the operating room since, in our view, consciousness is the best parameter to know whether the patient's brain is suffering or not from ischemia. During pre-anesthetic assessment, we confirmed the possibility of performing the procedure and the patient was oriented regarding the loco-regional anesthesia. The patients were on continuous oxygen mask and were monitored with ECG, invasive blood pressure and strict control of heart rate; their brain function was monitored by the level of consciousness and motor activity in the upper and lower limb in the contralateral side of the body.

Before loco-regional anesthesia, we administered a dose of 2 mg of dexamethasone intravenously. The superficial cervical plexus block was performed with subcutaneous injection of 5 to 10 ml of 0.5% ropivacaine along the posterior border of the sternocleidomastoid muscle. The deep cervical plexus block was performed with injection of the same anesthetic solution in the transverse processes of C2, C3, and C4 respectively located 2, 4 and 6 cm below the mastoid process, in a straight line drawn between the mastoid process and the C6 transverse process (Chassaignac's tuber). The needle was inserted perpendicular to the skin up to the transverse process and, after aspiration, 5 ml of solution was injected in each transverse process. The patient was maintained without sedation for improved neurological monitoring, and we used short-term opioids, such as alfentanil at a dose of 5 mg/kg if the patient had postural or emotional discomfort.

The operating table was adjusted so that the patient stayed in a semi-upright position (at an angle of 45°). When necessary, sodium nitroprusside in a dosage of 0.05 micrograms per kilogram of body weight per minute was administered using an infusion pump in order to keep the mean arterial pressure (MAP) at the level of the measures that had been obtained in the pre-anesthetic assessment (MAP between 100 and 120 mmHg). Five minutes before placing the arterial clamps to do the carotid occlusion test (during 3 minutes), 5000 international units of unfractionated heparin were administered intravenously. Intraoperative cerebral monitoring consisted of neurological examination and observation for signs or symptoms of cerebral ischemia, such as changes in level of consciousness, seizures, slurred speech or motor deficit in the upper and lower limbs on the contralateral side of the body.

The techniques used in our service were conventional carotid endarterectomy with primary closure and conventional endarterectomy with closure using a bovine pericardium patch (Figures 1-4). The carotid shunt was used when the patient under loco-regional anesthesia and undergoing cerebral monitoring showed symptoms of cerebral ischemia.

At the end of the procedure a careful review of hemostasis was performed and heparin was not reversed. A continuous suction drain was inserted by contraincision, the incision was sutured in layers and the patient was taken to the intensive care unit.

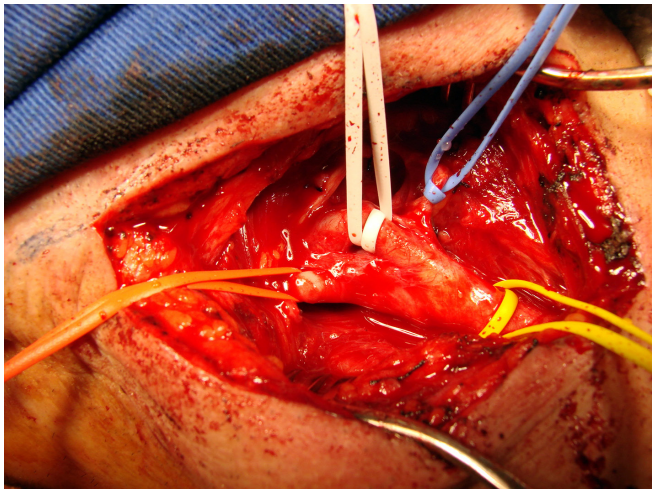

*Fig. 1 - Surgical dissection: common carotid artery (yellow strip), external carotid artery (white strip) and internal carotid artery (red strip).*

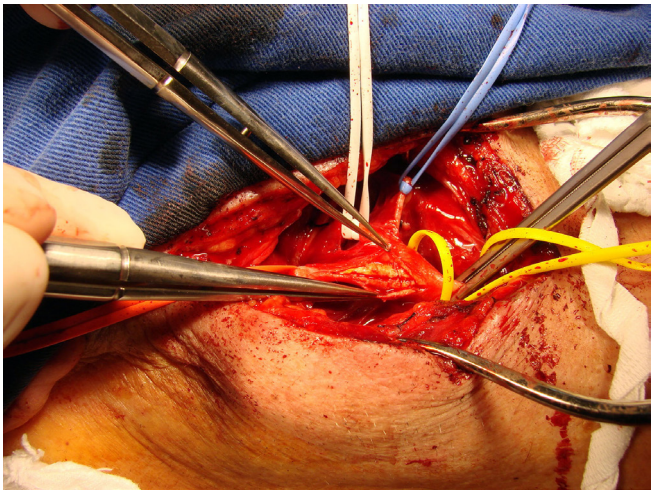

*Fig. 2 - Arteriotomy of the internal carotid artery with a view of the cholesterol plaque.*

*Fig. 3 - Example of cholesterol plaque removed from the internal carotid artery.*

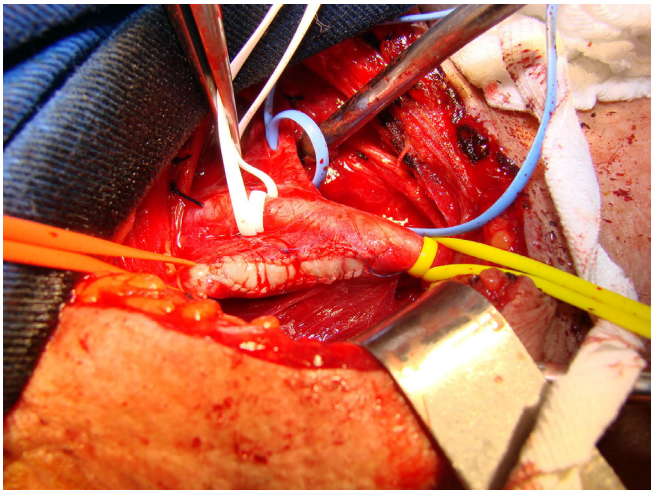

*Fig. 4 - Closing the internal carotid artery with elliptical patch of bovine pericardium.*

Patients underwent neurological assessments looking for signs or symptoms of cerebral ischemia in the immediate postoperative period, on the seventh postoperative day, and 30, 90 and 180 days after the procedure; after this period, the neurological assessments were annual. In patients where neurological examination was abnormal, realization of Doppler ultrasound was indicated; in neurologically normal patients, the Doppler was performed 6 months after the surgery. When the Doppler ultrassound showed a hemodynamically significant stenosis, the patient underwent arteriography or magnetic resonance angiography to confirm the lesion.

## RESULTS

The carotid endarterectomies were performed with loco-regional anesthesia in 117 patients undergoing 125 surgeries: no patient required conversion to general anesthesia. The carotid endarterectomy with conventional primary closure was used when the diameter of the internal carotid artery was > 6 mm[9,10] and was performed in 54 arteries (43.2%). When the diameter of the internal carotid artery was ≤ 6 mm, which was observed in 71 arteries (56.8%), the chosen technique was conventional endarterectomy and closure with an elliptical bovine pericardium patch[10]. The patch was used in 95% of female patients (n=38), and 42.8% of male patients (n=33).

It was necessary to use intraoperative shunt in 3 cases (2.4%). The first patient had stenosis of approximately 80% in the carotid being operated, and contralateral carotid occlusion; its circle of Willis was complete, and he had mental confusion followed by contralateral motor deficit in the arm and leg during the crossclamping test of the carotid artery. The second patient had 70% stenosis in the carotid being operated and stenosis of approximately 10% in the contralateral carotid artery, with a complete circle of Willis, and presented motor deficit in the contralateral upper limb during removal of the atherosclerotic plaque. The third patient had stenosis of approximately 80% in the carotid being operated, and 20% in the contralateral carotid artery, and its circle of Willis showed absence of the anterior cerebral artery; this patient showed mental confusion and motor deficit in the contralateral arm and leg during the crossclamping test. In those 3 cases, the neurological symptoms disappeared immediately after insertion of the shunt and the patients had a normal outcome.

The average crossclamping time of the internal carotid artery was 19 minutes, ranging between 13 and 31 minutes. Perioperative mortality was 0.8%: one patient died of an acute myocardial infarction on the 2nd day after the procedure. Two patients (1.6%), both symptomatic, had a small ipsilateral ischemic cerebral infarct with good recovery, and 2 patients (1.6%) had nonfatal myocardial infarction with good recovery. In three surgeries (2.4%) there was excessive bleeding through the drain, and the incision was reopened for

revision of hemostasis. The average hospital stay was 3 days (2-6 days). The average follow-up time was 32 months (6-192 months). Doppler ultrasound follow-up was performed in all patients, and significant restenosis (stenosis ≥ 70%) was found in three arteries (2.4%); the 3 cases with significant restenosis after carotid endarterectomy underwent angioplasty with stent implantation in the carotid artery, with a good outcome. During the late postoperative period, there were no cases of ischemic stroke.

## DISCUSSION

The natural history of atherosclerotic carotid artery disease is very worrying. Roederer et al.[11] showed that in equal to or greater than 80% stenosis in the internal carotid artery, the incidence of ischemic symptoms or total occlusion of the affected artery was 46% in 12 months. Aldoori et al.[12] showed that in equal to or greater than 75% stenosis in the internal carotid artery, the incidence of ischemic cerebral infarction was 50% in 3 years, with a mortality rate of 83%.

Despite carotid endarterectomy has shown its efficacy in preventing ischemic strokes in both symptomatic and asymptomatic patients with hemodynamically significant stenosis in the internal carotid artery[5-8], ischemic cerebral infarction is still the most feared complication after this surgery. For this reason, particular attention has been paid to technical details of this procedure, in particular the preservation and monitoring of brain function during the crossclamping of the internal carotid artery.

Numerous nonrandomized studies have been performed trying to establish what the best anesthesia would be to perform the surgical treatment of carotid disease: general or loco-regional. Although several clinical studies have suggested potential advantages of loco-regional anesthesia[9], the only prospective randomized study comparing the two techniques was published recently, and concluded that the combined rates of cerebral infarction, myocardial infarction and perioperative death were similar for both techniques. However, the loco-regional anesthesia has shown better outcomes in patients who had occlusion of the contralateral internal carotid artery[13].

The main reason why loco-regional anesthesia is preferred in our service, in spite of general anesthesia, is the fact that we can observe the neurological status of the patient during carotid artery crossclamping[14]. The fact that a small but significant group of patients will present intolerance during crossclamping of the internal carotid artery, and consequently require the carotid shunt for cerebral protection during endarterectomy, causes a serious dilemma for surgeons who choose to perform this surgery using general anesthesia. In order to make sure that an unconscious patient will not suffer an ischemic stroke while the surgery is performed, one of two methods should be used: routine use of a shunt (in all patients), or some monitoring technique to differentiate patients who are at risk to develop an ischemic stroke and the need to use the shunt selectively.

Historically, no monitoring technique showed good correlation with the neurological status of the awake patient, which is considered the "gold standard" (to which all other techniques should be compared). The main direct (electroencephalography, response to evoked potentials) and indirect methods (stump pressure of the internal carotid artery, transcranial Doppler) for the detection of cerebral ischemia during carotid crossclamping showed, at some point, low sensitivity or low specificity when compared to the neurological status of the awake patient[15-17].

Electroencephalography (EEG), despite being the most accurate and used method to monitor brain function, can lead to a high incidence on the use of shunt (up to 28%); in addition, the incidence of false negative and false positive results reported is 4.5% and 6.7%, respectively[18]. Another worrying fact is that intraoperative ischemic strokes have clearly occurred in the absence of any changes in EEG[18]. Lawrence et al.[19] demonstrated that the incidence in the use of shunts in patients operated under loco-regional anesthesia was approximately 4.5%, a result comparable to our study (incidence in the use of shunt of 2.4%). As the routine use of a carotid shunt may lead to an incidence of up to 3% of iatrogenic complications (such as embolization of air or cholesterol particles to the brain, and lesions of the carotid intima causing early thrombosis and late stenosis)[14], we opted for its selective use in our service.

It has been shown that routine use of a bovine pericardial patch (and other materials such as polyester, polyurethane and autologous veins) to close the internal carotid artery is more effective than primary closure in decreasing the incidence of perioperative ischemic strokes, perioperative carotid thrombosis and late restenosis[20]. However, some surgeons believe that the use of a patch for closing the internal carotid arteriotomy may prolong the operative time and the clamping time, making the procedure technically more complex and may be unnecessary in certain patients[21,22]. In our service, we chose to use the patch in arteries of small diameter (≤ 6 mm), because we believe that they would have greater chances of having complications if they were closed primarily. Recently, Mannheim et al.[23] performed a randomized controlled study comparing 216 patients undergoing carotid endarterectomy with primary closure versus 206 patients who had their arteriotomies closed with patch; the incidence of restenosis >70% in this study were significantly lower in patients who received patch compared to patients with primary closure (2.2% versus 8.6%, *P*=0.01). In our study, where we used the patch selectively[10], the incidence of significant restenosis in the internal carotid artery after 32 months of mean

follow-up was 2.4%, and the incidence of perioperative carotid thrombosis was 0%.

Regarding the use of hypnoanalgesics, alfentanil calms the patient, improves his tolerance to operation time, and does not hamper his responses to verbal commands of the surgical team. If the MAP increases during surgery (increase of arterial pressure up to 15% compared to the initial pressure of the patient, or MAP greater than 120 mmHg) we use sodium nitroprusside, because this medication provides an accurate and immediate control of the blood pressure. The use of corticosteroids (dexamethasone) before the surgery aims to inhibit cerebral edema caused by the mechanism of ischemia/reperfusion, which may compromise the outcome of carotid endarterectomy.

When we assess our perioperative rates of ischemic stroke and death (1.6% and 0.8%), we found comparable results to the most recent prospective randomized study on this subject, recently published in the literature (CREST study)[24]. In the group undergoing carotid endarterectomy in the CREST study, the rates of ischemic stroke and death in the perioperative period were 2.3% and 0.3%, respectively. In the group of patients undergoing treatment of carotid stenosis with stenting in the CREST study, the rates of perioperative ischemic stroke were significantly higher when compared to the group undergoing carotid endarterectomy (4.1% versus 2.3%, *P*=0.01). Mas et al.[25] recently demonstrated in a multicenter, randomized prospective study, that the incidence of ischemic strokes and death in symptomatic patients with carotid stenosis ≥60% were significantly lower in patients undergoing endarterectomy when compared to patients undergoing stenting in carotid arteries. In this study, the incidence of ischemic strokes or death in 30 days was 3.9% after endarterectomy and 9.6% after stenting (*P*=0.01) and after a 6 months follow-up period, the incidence was 6.1% after endarterectomy and 11.7% after stenting (*P*=0.02). At the moment, due to a higher incidence of ischemic strokes when opting for stenting[24,25], carotid endarterectomy seems to be the most appropriate technique for treatment of extracranial atherosclerotic cerebrovascular disease.

One limitation of this study was a retrospective analysis of data. On the other hand, we emphasize the fact that no patient in this series have been lost during the mean 32 months follow-up period.

## CONCLUSION

We conclude that in our service, carotid endarterectomy performed on awake patients with selective use of a shunt and bovine pericardium patch is a very well tolerated, safe and effective technique to treat internal carotid artery stenosis ≥70% in symptomatic and asymptomatic patients. This procedure can be performed with very low morbidity and mortality rates.

| **Authors' roles & responsibilities** | |
|---|---|
| CTM | Analysis and/or interpretation of data, statistical analysis, final approval of manuscript conception and study design, conduct of procedures and/or experiments, writing of the manuscript or review of its content |
| JAFJr | Sudy design, analysis and interpretation of data, approval of final version of the manuscript |
| CAC | study design, analysis and interpretation of data, approval of final version of the manuscript |
| JW | Study design, analysis and interpretation of data, approval of final version of the manuscript |
| ORMF | Data collection, analysis and interpretation of data; approval of the final version of the manuscript |
| FFR | Data collection, analysis and interpretation of data; approval of the final version of the manuscript |
| LPB | Study design, analysis and interpretation of data, approval of final version of the manuscript |

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