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Comparative Results for the Carotid Artery Stenting Versus Carotid Artery Endarterectomy with Regional Anesthesia: Retrospective Analysis and Review of the Literature

Murat Günday, Mehmet Özülkü, Tonguç Saba, Erkan Yıldırım, Rafi Doğan, Ayşe Canan Yazıcı

Başkent University Konya Application and Research Center, Clinic of Cardiovascular Surgery, Konya, Turkey

ABSTRACT

Introduction: Carotid artery endarterectomy has already gained acceptance as the standard method for treating extracranial carotid artery stenosis. The last 2 decades have witnessed the increasing popularity of minimally invasive endovascular techniques.

Patients and Methods: This study involved a retrospective analysis of 41 patients undergoing stent placement in carotid artery and carotid artery endarterectomy between January 2005 and January 2012 due to carotid artery stenosis. The patients were divided into two groups, group 1 (surgery, n=20) and group 2 (stenting, n=21). The two groups were compared with respect to complications, length of hospitalization, and costs.

Results: The mean age was 68.35±8.21 years in group 1 and 66.76±9.16 years in group 2. The mean total cost was 2158.00±801.30 TL (Turkish Lira) for group 1 and 6927.86±2884.72 TL for group 2. The mean length of follow-up was 560.05±232.94/ days in the stenting group and was 933.85±505.45 /days in the surgery group. No statistically significant difference was found between the two groups in terms of age, gender, diabetes mellitus, restenosis, mean duration of hospitalization, and mortality ($p>0.05$). The only difference was observed in the average cost, which turned out to be lower in group 1 than in group 2 ($p<0.05$).

Conclusion: Recently, new alternative stent and filter types have become available, preferred especially in patients with recurrent internal carotid artery stenosis and in those with a history of radiotherapy on the neck. However, when compared with carotid endarterectomy under regional anesthesia is just as safe as stenting and it is also cheaper.

Key Words: Stents; carotid endarterectomy; anesthesia; regional

Bölgesel Anestezi Altında Karotis Endarterektomi ile Karotis Arter Stentin Karşılaştırmalı Sonuçları: Retrospektif Analiz ve Literatürün Gözden Geçirilmesi

ÖZET

Giriş: Karotis arter endarterektomi ekstrakranial karotis arter stenozunun standart tedavisinde kabul edilmiş bir yöntemdir. Son iki dekatta, minimal invaziv endovasküler teknikler daha popüler hale gelmiştir.

Hastalar ve Yöntem: Çalışmamızda Ocak 2005-Ocak 2012 yılları arasında karotis arter tıkanıklığı nedeniyle karotis arter endarterktomi ve karotis artere stent yerleştirilmesi yapılan 41 hasta retrospektif olarak analiz edildi. Hastalar grup 1 (cerrahi, n=20) ve grup 2 (stent, n=21) olarak iki gruba ayrıldı. Hastalar postoperatif komplikasyon, hastane kalış ve maliyet açısından karşılaştırıldı.

Bulgular: Ortalama yaş grup 1'de 68,35±8,21 yıl, grup 2'de ise 66,76±9,16 yıl idi. Ortalama toplam maliyet grup 1'de 2158,00±801,30 TL (Türk lirası), grup 2'de 6927,86±2884,72 TL idi. Ortalama takip süresi stent grubu için 560,05±232,94/gün ve cerrahi grup için 933,85±505,45/gün idi. Yaş, cinsiyet, diabetes mellitus, restenoz, ortalama hastanede kalış süresi ve mortalite açısından iki grup arasında fark yoktu. Sadece maliyet grup 1'de grup 2'den daha düşüktü ($p>0,05$).

Sonuç: Son zamanlarda yeni stent ve filtre tipleri rekürren internal karotis arter stenozu olan ve boyuna radyoterapi alan hastalarda tercih edilebilir. Ancak bölgesel anestezi altında karotis endarterektomi stent ile karşılaştırıldığında stent kadar güvenli olup üstelik stentden daha ucuzdur.

Anahtar Kelimeler: Stent; karotis endarterektomisi; bölgesel anestezi

Correspondence

Murat Günday

E-mail: gundaymurat@yahoo.com
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INTRODUCTION

Carotid endarterectomy (CEA) and carotid artery stenting (CAS) are two alternative methods accepted for the treatment of carotid artery stenosis. Although CEA is accepted to be the standard treatment method, the recent period has witnessed the emergence of percutaneous transluminal angioplasty (PTA) and CAS as less invasive alternatives. The first carotid balloon angioplasty took place in 1979, and the first stent was installed in 1989.

CAS has been offered as an alternative treatment method to CEA especially in surgical patients with a high level of risk (coronary artery disease, pulmonary disease, renal disease, restenosis, or inaccessible lesions above the C2 level)[1-3]. The outcomes of the randomized trials that compare the use of CAS vs. CEA in symptomatic patients remain controversial[4,5]. It has been reported recently by Liu et al.[6] that CAS is inferior to CEA as regards the incidences of periprocedural stroke and death, especially in symptomatic patients. On the other hand, CAS seemed to be associated with a lower ratio of myocardial infarction. This stemmed from the fact that most studies used general anesthesia, which rendered them quite limited in terms of CAS anesthesia[7,8]. In the present study, in contrast, the CAS results were compared with the results of CEA performed under regional anesthesia.

PATIENTS and METHODS

The study received the approval of the Institutional Review Board (Project no: KA11/263), and was supported by the Research Fund. It involved a retrospective analysis of the data of 41 patients with carotid artery stenosis who had been admitted to the Department of Cardiovascular Surgery between January 2005 and January 2012. The patients were divided into two groups, group 1 (surgery, n=20) and group 2 (stent, n=21). Considering the indications for stent, it was installed in symptomatic and asymptomatic patients under the age of 70 with a lesion of ≥70%, patients without ulcerated or dissected lesion, patients with a development of restenosis on account of a previous intervention, patients with a lesion in the distal internal carotid artery, patients with carotid bifurcation at a level higher than the C2 vertebra, and patients in a generally bad condition with additional risk factors for morbidity and mortality. Endarterectomy was performed on the other symptomatic (TIA, stroke etc.) and asymptomatic patients with a stenosis of 70%-99% in the carotid artery as well as on symptomatic patients with an ulcerated lesion of ≥50%. The exclusion criteria were as follows: claustrophobia, orthopnea, carotid body tumor, carotid artery aneurysm.

Preceeding surgery, all the patients underwent diagnostic carotid duplex scanning and/or angiography. The stenoses in the carotid arteries were assessed according to the North American Symptomatic CEA Trial (NASCET) criteria[9,10]. The definition of minor stroke adopted in the study was a new, non-disabling neurologic deficit resolved completely within 30 days[11]. The definition of major stroke, on the other hand, was a new neurologic deficit persisting for more than 30 days. The follow-up was carried out in both groups by Doppler ultrasonography, Magnetic resonance imaging (MRI) angiography and computed tomography (CT) angiography to check for post-endarterectomy patency as well as for the presence or absence of restenosis.

The Technique of Anesthesia

An hour before the operation, the patients were premedicated intravenously with 1 mg of midazolam. Patient follow-ups were performed using 5- lead electrocardiography, pulse oximetry and invasive blood pressure via radial artery cannulation. For superficial and deep cervical plexus block, patients were positioned supine with head turned to the opposite side. For the deep block, Chassaigne's tubercle and mastoid process were identified first, and a line joining the two points was drawn. Then three points were marked at the distances of 2, 4 and 6 cm respectively to the mastoid process. At these three points a 5 cm, 22-gauge needle was inserted until contact was established with the transverse process. Then the needle was drawn back 1 mm, and 10-15 mL (3-5 mL at each point) of 0.5% bupivacaine was slowly injected. For the superficial block, 10-15 mL 0.5% bupivacaine (3-5 mL for each point) was injected subcutaneously at the three points. The Verbal Pain Scale (VAS; 0: No pain 10: Irresistible pain) was used to evaluate the intraoperative pain. When the VAS score above 3, the patients were administered supplemental topical anesthesia with titrated 2% lidocaine.

Surgical Technique

As described above, regional anesthesia was applied to all patients before surgery. After the skin was incised, the common, external and internal carotid arteries were found. Then heparinization was performed and arteriotomy was carried out after clamping. A longitudinal incision was made anteriorly in the common carotid artery (CCA). Carotid artery shunt was placed selectively in patients. The only criterion considered in our clinic when deciding whether to use shunts is the development of a neurological deficit after the total clampage of the CCA. In the present study, a shunt was used in 9 patients (45%) who underwent CEA. Then the atheromatous lesions between the tunica arteria media and the tunica arteria adventitia in the external, internal and common carotid arteries were removed. The proximal and distal intimal endpoints were secured by tacking sutures and were used frequently in the internal and external carotid artery. In patients with internal carotid artery (ICA) diameter below 4 mm, an external jugular vein patch was used to close the arteriotomy. Primary repair (n=10, 50%) and patch closure (n=10, 50%) were the options for surgery.

After surgery all patients were routinely monitored with electrocardiogram and pulse oximeter, and were assessed hourly for levels of consciousness and neurologic status. The patients in the intensive care unite (ICU) were administered low-molecular-height heparin, aspirin (100 mg/day) and clopidogrel (75 mg/day). They were prescribed aspirin and clopidogrel for the rest of their life.

Stenting Technique

Beginning from the third day before the intervention, the patients were administered clopidogrel (75 mg/day) and aspirin (100 mg/day). All the patients were intravenously given 5 000-10 000 units of heparin during the procedure. The patients under regional anesthesia were covered in sterile conditions, and the Siemens Multistar T.O.P (Siemens, Erlangen, Germany) and the Philips Integris V (Philips Medical Systems, Amsterdam, The Netherlands) devices were used to perform the angioplasty at a

femoral or brachial puncture site. Under road map guidance, a balloon- or a self-expanding stent (Wallstent, Boston Scientific Inc., Watertown, and Ma, USA) was deployed in the stenosis region. In case a stented segment was not opened to the required degree, balloon dilatation was applied repeatedly in the stenosis region. Cerebral and carotid angiograms were performed after the procedure to document the vascular anatomy as well as to exclude the possibility of cerebral thromboembolism. For the protection of the brain, a filter system was used in all patients. Once the stenting procedure was completed, clopidogrel (75 mg/day) and aspirin (100 mg/day) were prescribed for life.

Statistical Analysis

The Shapiro-Wilk test was used in evaluating the normality of the distribution of the continuous variables, and Levene's test was used in evaluating the homogeneity of variance in the groups. The outcomes of the homogeneity and normality tests were used to determine the statistical methods to be applied in comparing the study groups. These test results revealed that the parametric test assumptions were not available for some of the variables, and therefore the two independent groups were compared using the Mann-Whitney U test. The groups that had normal distribution and homogeneous variance were compared using Student's t test and the Factorial Analysis of Variance. The results of these tests were expressed in the following form: the number of observations (n), mean ± standard deviation, median and min-max values. The Fisher Exact test was used for the statistical evaluation of the categorical variables. The results of this test were expressed in the following form: the number of observations (n) and ratio (%). The SPSS software (SPSS Ver. 10.0; SPSS Inc., Chicago IL, USA) was used to perform all of the statistical analyses. Values of $p<0.05$ were considered statistically significant.

RESULTS

Clinical Characteristics of the Study Population

CEA was performed by the same surgical team on 20 of the 41 patients (12 (60%) male, 8 (40%) female; mean age 68.35±8.21 years) and CAS was performed by the same invasive radiology team on 21 patients (13 (61.9%) male, 8 (38.1%) female; mean age, 66.76±9.16 years). Table 1 shows the preoperative demographic characteristics.

The patients' clinical findings were assessed before the procedure. They were given in Table 2. It was decided to operate on twelve asymptomatic patients, six in each group, because of coronary artery disease. In their preoperative examination, first a murmur was noticed through listening and then a serious stenosis was detected in their carotid artery through Doppler ultrasonography. For this reason, endarterectomy or stenting was applied to all of them before coronary bypass.

Cost: Information about the cost of the procedures was acquired from the finance department of the hospital. The average total cost was 2158.00±801.30 TL (Turkish Lira) for group 1 and 6927.86±2884.72 TL for group 2. Thus the average total cost turned out to be lower in group 1 than in group 2 ($p<0.05$) (Table 3).

Period of hospitalization: The average length of hospitalization was 2.50±1.40 days in group 1 and 1.62±1.77 days in group 2. There was no statistically significant difference between the groups as regards this parameter ($p>0.05$) (Table 3).

Mortality and Morbidity: No mortality occurred in any of the patients. Hemiplegia was observed in two (10%) patients in group 1. Hemiparesis was observed in one patient (4.7%) and speech disorder in another patient (4.7%) in group 2 (Table 3). These complications were not statistically significant ($p>0.05$).

Table 1. Demographic variables

Variables	Group 1	Group 2	p
Average age (year)	66.76±9.16	68.35±8.21	0.562
Male gender	12 (60%)	13 (61.9%)	0.902
DM	11(80.9%)	11 (55%)	0.868
HT	17 (52.3%)	17 (85%)	1
HL	14 (66.7%)	16 (80%)	0.341
Smoking	4 (19%)	6 (30%)	0.602
CRF	3 (14.3%)	3 (15%)	1

HT: Hypertension, DM: Diabetes mellitus, HL: Hyperlipidemia, CRF: Chronic renal failure

Table 2. Preoperative symptoms

Symptoms	Group 1	Group 2
Vertigo	4 (20%)	3 (14.3%)
Hemiparesis	1 (5%)	4 (19%)
Hemiplegia	6 (30%)	8 (38.1%)
Speech disorders	1 (5%)	0
Transient ischemic attack	2 (10%)	0
Asymptomatic	6 (30%)	6 (28.6%)

Table 3. Postoperative morbidity, cost, and length of hospital duration

Cost, morbidity and hospitalization	Group 1	Group 2	p
Cost (TL)	1853.37±533.94	5502.62±2101.08	0.001*
Duration of hospital stay (day)	2.50±1.40	1.62±1.77	0.085
Restenosis	3 (15%)	2 (9.5%)	0.597
Hemiplegia (symptom of stroke)	2 (10%)	0	0.306
Hemiparesis (symptom of stroke)	0	1 (4.7%)	0.329
Speech disorders (symptom of stroke)	0	1 (4.7%)	0.329

TL: Turkish Lira , *Significant

During the follow-up period, restenosis was observed in 3 patients (15%) in group 1 and in 2 patients (9.5%) in group 2 (Table 3). These were not statistically significant either (p>0.05).

A patch was used in two of the patients in the surgical group who had been diagnosed with restenosis (approximately 10 months after endarterectomy). All the patients were treated by percutaneous transluminal carotid artery (PTCA) and stent implantation. The average length of follow-up was 560.05±232.94/days in the stent group and 933.85±505.45/days in the surgical group.

DISCUSSION

The recent discussion on the treatment of carotid artery stenosis is centered on the question whether it is stenting or endarterectomy that constitutes a more effective method. The selection of the revascularization strategy should be made according to the patient's surgical risk profile as well as to the locally available expertise. A number of randomized controlled trials have been performed to compare the two procedures. Some of these have shown stenting to be as good as endarterectomy[4,12], while others have discovered points of inferiority[13]. Stenting has been put into use as an alternative method of treatment for high-grade stenoses in advanced age, occlusions of the contralateral carotid artery, congestive heart failure, restenoses stemming from carotid endarterectomy, and stenoses developing after radiotherapy. Two major studies touching on the subject, NASCET and the European Carotid Surgery Trial, have demonstrated that endarterectomy remains superior to medical treatment in preventing ischemic cerebral paralysis in symptomatic carotid artery stenoses over 70%[9,14]. It should be noted that the full implications these results would become clearer if a reassessment was done after the inclusion of regional anesthesia in the patients' anesthesia protocol. Neurologic evaluation of patients is essential under general anesthesia, and a number of techniques like electroencephalography (EEG), transcranial doppler (TCD), somatosensory evoked potentials (SSEP), and various combinations of these, have been developed with the purpose of intraoperative monitoring of cerebral perfusion[15]. The problem with most of these monitoring techniques is that they necessitate special equipment, technicians, and specialists to evaluate the results. Under regional anesthesia, on the other hand, it is possible to monitor cerebral activity with a high degree of sensitivity and specificity. If some changes in consciousness or motor function are observed after clamping, a carotid shunt may be used. Among the relevant literature, one should not overlook the GALA study, which compared the results of local and general anesthesia in carotid surgery[16]. GALA was an ambitious multicentre trial (comprising 95 centres in 24 countries) that brought together data from 3526 patients, gathered in 8 years. As regards the primary outcome (postoperative stroke, myocardial infarction, or death between randomization and 30 days after anesthesia), the GALA trial did not reveal any difference between patients undergoing CEA under LA local anesthesia (n ¼ 1773) and those undergoing it under general anesthesia (n ¼ 1753; 4.5% vs 4.8%, respectively; risk ratio (RR), 0.94; 95% confidence interval (CI), 0.70-1.27; p ¼ not significant). Moreover, there was no significant difference beteween the two groups as regards quality of life and length of stay in hospital[16].

There is a wide range of studies in the literature about the deployment of shunts during carotid endarterectomy. While some of the researchers recommend routine use of shunts, others argue for their use in selected cases only[17,18]. There is also the possibility of an embolism developing because of the installation of a shunt. The rate of utilization of shunts under regional anesthesia is reported to be between 5,3% and 19,2% in the literature[19,20]. In the present study, the rate in question was higher than in the literature (45%) because of the surgeon's preference in this direction. No embolism was observed in any of the patients included in the study.

The respective outcomes of the two methods, CEA by general anesthesia and CAS, are still a matter of debate. In their study, Rantner et al. determined that the risk of CAS, in comparison with CEA, is greatest in patients treated within 7 days of the symptoms. Accordingly early surgery remains the most effective method for stroke prevention in patients with symptomatic carotid artery stenosis[21]. Park et al. determined a statistically significant reduction in the length of hospitalization in CAS as against CEA (1.2 vs. 2.1 days), while CAS turned out to be associated with higher total procedural costs ($17.402 vs. $12.112; p<0.029) and direct costs ($10.522 vs. $7227; p<0.017). On the other hand, they found no statistically significant difference between the two groups as regards perioperative mortality (0% vs. 2%; p=NS), major adverse events (2% vs. 10%; p=0.36), strokes (2% vs. 4%; p=NS), myocardial infarctions (0% vs. 4%; p=0.49), and hypotension necessitating pressor support (21% vs. 18%; p=NS)[22]. In another study CAS was determined to be inferior to CEA as regards the periprocedural outcomes of stroke or death, especially in symptomatic patients, while it was found to be associated with a lower incidence of myocardial infarction[6]. Doig and Brown similarly argue that carotid endarterectomy, in combination with optimal drug therapy, remains the standard treatment for symptomatic stenoses of the internal carotid artery between 70%-99%. On the other hand, they agree that stenting could be an option for younger patients and patients unsuitable for endarterectomy[23].

In our study, the average length of hospitalization was 2.50±1.40 days in group 1 and 1.62±1.77 days in group 2. No mortality was observed in any of the patients. Hemiplegia was observed in two patients (10%) in group 1. As complications in group 2, hemiparesis was observed in one patient (4.7%) and speech disorder in another patient (4.7%). In the follow-up period, restenosis was found in 3 patients (15%) in group 1 and 2 (9.5%) patients in group 2. None of these were statistically significant (p>0.05).

Despite the drop observed in the last decade in stent prices, the surgery costs have remained on the same level. Despite

this, recent studies have revealed that surgery is still more advantageous than stenting in terms of the costs incurred[24]. In the present study, the average cost was calculated as 2158.00±801.30 TL for group 1 and 6927.86±2884.72 TL for group 2 ($p<0.05$).

It can be stated in conclusion that CEA remains a golden standard of treatment for both symptomatic and asymptomatic internal carotid artery stenoses, although the amount of data available on stenting remains limited. In the literature we have not encountered any comparison of CEA under regional anesthesia with CAS. We argue here that the former method continues to be a much cheaper and safer option than the latter. Further large-scale, long-term, randomized trials are likely to provide more detailed information on the two alternative treatments.

LIMITATIONS of the STUDY

The most important limitation of our study was that it was performed retrospectively and with a small patient group.

CONFLICT of INTEREST

The authors reported no conflict of interest related to this article.

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