Cukurova Medical Journal
ÇUKUROVA ÜNİVERSİTESİ TIP FAKÜLTESİ

Cukurova Med J 2024;49(3):744-750
DOI: 10.17826/cumj.1493108

RESEARCH

Periprocedural clinical outcomes of stenting and endarterectomy in patients with carotid artery stenosis

Karotis arter darlığı olan hastalarda uygulanan stent ve endarterektominin işlem sürecindeki klinik sonuçları

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Abstract

Purpose: To identify the chief pathological cause of extracranial cerebrovascular disease, which is atherosclerosis, we analyzed and compared the early and 6-month morbidity and mortality rates of patients who underwent carotid endarterectomy (CEA) and carotid artery stenting (CAS) for carotid artery stenosis.

Materials and Methods: We retrospectively included patients who had undergone surgical endarterectomy and endovascular carotid stent implantation for carotid artery stenosis between April 2019 and August 2022. We evaluated neurological examinations, routine blood tests, neurological and systemic complications, mortality rates, and follow-up colour Doppler ultrasonography 6 months post-discharge.

Results: The study included a total of 300 patients, with 52.7% (n = 158) undergoing CEA and 47.3% (n = 142) undergoing endovascular stent implantation (CAS). The patients' average ages were 66±8 years in the CEA group and 70±7.4 years in the CAS group, suggesting that those undergoing CAS were generally older. Notably, there were significantly more instances of congestive heart failure and a history of cerebrovascular disease within the CAS group compared to the CEA group. However, no significant difference was observed in the rates of postprocedural complications. Furthermore, there were no cases of mortality reported in either group.

Conclusion: The preferred method for treating severe carotid artery stenosis should be determined by considering patient characteristics and preferences, as well as the complication rates in the centre.

Keywords:. Carotid endarterectomy, carotid artery stenting, carotid artery stenosis, restenosis.

Öz

Amaç: Ekstrakraniyal serebrovasküler hastalığın primer patolojik nedeni aterosklerozdur. Karotis arter darlığı nedeniyle karotis endarterektomi (CEA) ve karotis arter stentleme (CAS) yapılan hastaların erken ve ilk 6 aylık morbidite ve mortalite sonuçlarını karşılaştırdık.

Gereç ve Yöntem: Nisan 2019 ile Ağustos 2022 tarihleri arasında karotis arter darlığı nedeniyle cerrahi endarterektomi ve endovasküler karotis stent implantasyonu uygulanan 300 hasta retrospektif olarak çalışmaya dahil edildi. Nörolojik muayeneler, rutin kan testleri, nörolojik ve sistemik komplikasyonlar, mortalite oranları ve taburcu olduktan 6 ay sonraki renkli doppler ultrasonografi takipleri retrospektif olarak değerlendirildi.

Bulgular: Karotis endarterektomi (CEA) uygulanan %52,7 (n = 158) ve endovasküler stent implantasyonu (CAS) uygulanan %47,3 (n = 142) olmak üzere toplam 300 hasta çalışmaya dahil edildi. Hastaların yaş dağılımı CEA grubunda 66±8 yıl ve CAS grubunda 70±7,4 yıl olup, CAS uygulanan hastalar daha yaşlıydı. Konjestif kalp yetmezliği tanısı ve serebrovasküler hastalık öyküsü CAS grubunda CEA grubuna göre anlamlı olarak daha yaygındı. İşlem sonrası komplikasyon oranlarında anlamlı bir fark yoktu. Her iki grupta da mortalite gözlenmedi.

Sonuç: Ciddi karotis arter stenozunun tedavisinde seçilecek yöntemin hasta özellikleri ve tercihinin yanı sıra merkezdeki komplikasyon oranları da göz önünde bulundurularak yapılması uygun olacaktır.

Anahtar kelimeler: Karotis endarterektomi, karotis arter stentleme, karotis arter darlığı, restenoz.

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Received: 31.05.2024 Accepted: 08.09.2024

INTRODUCTION

Cerebrovascular diseases are a significant cause of illness and death among adults[1]. The main pathological cause of extracranial cerebrovascular diseases is atherosclerosis. Around 75–80% of all strokes are ischemic, and about 20% of ischemic strokes are due to extracranial cerebrovascular diseases. Carotid endarterectomy (CEA) reduces stroke risk in patients with moderate to severe (>50%) symptomatic carotid artery narrowing[2,3]. The North American Symptomatic Carotid Endarterectomy Trial (NASCET) and European Carotid Surgery Trial (ECST) confirm the superiority of endarterectomy over medical treatment in severe carotid artery stenosis[4,5].

Carotid artery stenting (CAS) presents an alternative to CEA developed to treat surgically inaccessible carotid bifurcation lesions. It avoids the general and local complications of surgery. Yet, fragments of atherosclerotic plaque might dislodge more frequently during CAS, causing an embolic stroke. Multiple studies have compared the mortality and morbidity outcomes of these two procedures[6-10]. After CEA, 5% of patients suffer minor or major strokes[8]. Large-scale randomised trials, such as the International Carotid Stenting Study (ICSS) and the Carotid Revascularisation Endarterectomy vs. Stenting Trial (CREST), reported higher stroke, death, and peri-procedural heart attack (MI) rates in the CAS group than the CEA group (8.5% and 5.2%)[6,9]. Initially, CAS was a treatment modality used where surgical treatment could not be performed. However, due to its less invasive nature, it corresponds more with anatomical suitability. Therefore, a clear evaluation of the indications and complications is vital for accurate patient selection for CAS or CEA. The guides for the CEA option propose acceptable 30-day morbidity and mortality rates of fewer than 6% in symptomatic patients and fewer than 3% in asymptomatic patients[10].

While previous studies have primarily focused on endarterectomy, minimally invasive endovascular techniques have gained popularity, particularly within the last two decades. There is a pressing need for studies that compare these two techniques. In our research, we compared the early and 6-month morbidity and mortality outcomes of patients who underwent CEA and CAS for carotid artery stenosis at our clinic. Our goal was to determine which of these two treatment modalities should be selected, under what circumstances, and possible complications. We examined which treatment is optimal in relation to short-term complications in patients with carotid artery stenosis, with the intention of sharing our clinic's experiences.

MATERIALS AND METHODS

Study design and sample

We retrospectively included 300 patients who met the follow-up criteria and underwent either surgical endarterectomy (n = 158) or endovascular carotid stent implantation (n = 142) for carotid artery stenosis at Adana City Training and Research Hospital between April 2019 and August 2022. Approval was obtained from the Ethics Committee of Adana City Training and Research Hospital (no.2310, date: 15.12.2022). In this single-centre retrospective cross-sectional study, individual consent was waived due to the retrospective observational nature of the study. Patient information was sourced from the unalterable hospital database. The group sample sizes of 158 and 142 achieved an 82% power to detect a difference of 6.0 between the null hypothesis that both group means are 87.0 and the alternative hypothesis that the mean of group 2 is 81.0. Known group standard deviations were 16.0 and 19.0, and a significance level (alpha) of 0.05000 was used in the two-sided Mann-Whitney test assuming a normal distribution.

Patients with carotid artery stenosis were diagnosed using colour Doppler ultrasound, followed by CT angiography or MR angiography. Their degree of stenosis was evaluated based on the North American Symptomatic Carotid Endarterectomy criteria. Symptomatic carotid artery stenosis was defined as patients who suffered a stroke, transient ischemic attack, or amaurosis fugax in the last 6 months and had carotid stenosis between 50% and 99%. Asymptomatic carotid artery stenosis was characterized as 70% to 99% carotid disease. Neurointerventionalists and cardiovascular surgeons –considering the patient's demographic characteristics, comorbidities, and procedure-related risks together – determined the treatment approach. The neurointerventional team comprised one certified cerebral endovascular therapy practitioner and three trainees. The cardiovascular surgeon was an experienced professional who had conducted

numerous carotid endarterectomies. CAS was performed on patients with significant comorbidities, such as stage III/IV congestive heart failure, recent myocardial infarction, and severe lung diseases, as well as cases with anatomical challenges, including prior neck surgery, a history of radiotherapy to this region, restenosis post-CEA, and exceedingly high lesion placement (above the 2nd cervical vertebra). The age range for patients included was 40–85 years.

Therapeutic protocol and surgical technique

All patients underwent general anaesthesia for surgical endarterectomy. The neck incision was made parallel to the sternocleidomastoid muscle, or parallel to the skin line, 5–6 cm below the clavicular angle, depending on the length of the neck. All patients received 5000 U intravenous heparin before clamp placement, which occurred 3 min later. The clamp sequence was as follows: internal carotid artery (ICA), common carotid artery (CCA), and external carotid artery. Arteriotomy was performed from the CCA to the ICA bulb. The plaque was removed first by classical endarterectomy up to the bulb, and then by eversion. The plaque endpoint was inspected. The arteriotomy was closed using 6/0 prolene. Complete plaque removal was confirmed and no patient required a shunt. Patients were roused and extubated postoperatively. Post-discharge treatment comprised clopidogrel (75 mg/day) or acetylsalicylic acid (100 mg/day).

For endovascular stent implantation, a loading dose (300–300 mg) of clopidogrel and acetylsalicylic acid is administered on the procedure's day. During the procedure, oxygen saturation, blood pressure, and cardiac rhythm are monitored. After administering local anaesthesia, an 8F sheath is inserted into the main femoral artery. Subsequently, a pigtail catheter is advanced to the aortic arch, followed by aortography. All patients receive 5000 U intravenous heparin during the procedure. The guiding catheter is then advanced to the anterior bifurcation. For embolism risk, a distal embolus protection device is situated in the petrous segment of the ICA in scenarios of patients with a mixed plaque image. Depending on the necessity of the angiography images, angioplasty balloon pre-dilatation is conducted. Care is exerted to ensure that the self-expandable stent incorporates the 1–2-cm normal segment proximal and distal to the lesion. In case of necessary circumstances based on the control angiography images, post-dilatation of the residual stenosis is conducted using an angioplasty balloon. Patients with severe bradycardia receive an intravenous atropine (1.0 mg). If a distal embolus protection device is used, it is removed. Post-discharge treatment includes clopidogrel (75 mg/day) and acetylsalicylic acid (100 mg/day) for the initial 6 months. After 6 months, either clopidogrel (75 mg/day) or acetylsalicylic acid (100 mg/day) is recommended.

Patient selection and follow-up

Neurological examinations, both before and after the procedure, were conducted to identify new strokes or cranial nerve damage. Additionally, routine blood tests (haemoglobin, haematocrit, urea, creatinine, glomerular filtration rate) were carried out, mortality rates were assessed, and follow-up colour doppler ultrasonography at the 6-month mark post-discharge was evaluated retrospectively. Carotid stenosis of 70% or more was deemed significant for restenosis. For this study, the presence of factors such as contrast nephropathy, inguinal/operative site haematoma, periprocedural ipsilateral minor/major stroke, cranial nerve damage, and residual stenosis after 6 months were recorded as neurological and systemic complications. Only patients whose procedures and subsequent follow-ups were conducted by the same team were included in the study. Four patients who were not treated by the same team and whose 6-month follow-up carotid Doppler ultrasound images were unavailable were thereby excluded from the study.

Statistical analysis

The patient data collected in the study was analyzed using the IBM Statistical Package for the Social Sciences (SPSS) for MacOS 29.0 (IBM Corp., Armonk, NY). Descriptive statistics such as frequency and percentage were used for categorical data and means, standard deviations, median, minimum, and maximum values were employed for continuous data. Intergroup comparisons were assessed using an independent sample t-test, while a chi-square or Fisher's exact test was used to compare categorical variables. The results were deemed statistically significant if $P < 0.05$.

RESULTS

The study included a total of 300 patients, with 52.7%

(n= 158) undergoing CEA and 47.3% (n= 142) undergoing CAS. The patients' demographic characteristics are presented in Table 1. The average age of patients in the CEA group was 66±8 years, compared to 70±7.4 years in the CAS group – indicating that patients undergoing CAS were significantly older (P ≤ .001). Diabetes Mellitus (DM) was present in 60.1% (n = 95) of the CEA cases and 35.2% (n = 50) of the CAS cases, a difference which was statistically significant (P < 0.001). The diagnosis of Congestive Heart Failure (CHF) and history of Cardiovascular Disease (CVD) were significantly higher in the CAS group than in the CEA group (P = 0.008, P < 0.001) (Table 1).

Table 1. Distribution of demographic characteristics according to the procedures performed on the patients

Variables (N=300)	**CEA (n=158)**			**CAS (n=142)**			**p-value**
	n (%)	Mean±SD	Median (Min-Max)	n (%)	Mean±SD	Median (Min-Max)	
Age (years)		66±8	66 (41-81)		70±7.4	71 (44-85)	<0.001[a]
Gender							0.985[b]
Woman	48 (30.4)			43 (30.3)			
Male	110 (69.6)			99 (69.7)			
Smoking	63 (39.9)			56 (39.4)			0.938[b]
HT	138 (87.3)			130 (91.5)			0.321[b]
DM	95 (60.1)			50 (35.2)			<0.001[b]
CAD	111 (70.3)			85 (59.9)			0.059[b]
Bypass history	35 (22.2)			27 (19)			0.503[b]
CHF	2 (1.3)			12 (8.5)			0.008[b]
COPD	25 (15.8)			26 (18.3)			0.675[b]
CRF	0 (0)			2 (1.4)			0.223[b]
CKD	9 (5.7)			9 (6.3)			1.000[b]
Hyperlipidemia	80 (50.6)			68 (47.9)			0.650[b]
CVD history	58 (36.7)			84 (59.2)			<0.001[b]
TIA history	26 (16.5)			13 (9.2)			0.088[b]
Carotid artery stenosis		87±9.5	90 (60-99)		88.3±7.1	90 (60-99)	0.152[a]
Right	73 (46.2)			70 (49.3)			0.592[b]
Left	85 (53.8)			73 (51.4)			0.679[b]
Contralateral carotid occlusion	5 (3.2)			16 (11.3)			0.012[b]
Contralateral carotid stenosis 50-99%	46 (29.1)			20 (14.1)			0.002[b]

[a] Independent Sample t-test; [b] Chi-square or Fisher's Exact test.; CEA= carotid endarterectomy, CAS= Carotid artery stenting, HT=hypertension, DM=diabetes mellitus, CAD=coronary artery disease, CHF=congestive heart failure, COPD=Chronic Obstructive Pulmonary Disease, CRF=Chronic renal failure, CKD=chronic kidney disease, CVD=Cerebrovascular disease, TIA=transient ischemic attack.

In patients who underwent CEA, the average operative time ranged from 30 to 70 min, with a mean time of 50 min. Similarly, the average cross time spanned from 8 to 25 min, with a mean time of 14 min.In the CAS group, pre-dilation was performed on 8.5% (n = 12) of patients, and post-dilation was performed on 7% (n = 10) of patients. Balloon-expandable stents were used in 22.5% (n = 32) of patients, and self-expandable stents were used in 77.5% (n = 110). There was no significant difference in postprocedural complication rates ($P = 0.714$) (Table 2). Mortality was not observed in either group.

Table 2. Distribution of complications according to the procedures performed on patients

Variables (N=300)	CEA (n=158)	CAS (n=142)	p-value
	n (%)	n (%)	
Complication	14 (8.9)	10 (7)	0.714[a]
Contrast nephropathy	0 (0)	2 (1.4)	0.223[a]
Inguinal/Operation site hematoma	9 (5.7)	3 (2.1)	0.198[a]
Periprocedural ipsilateral minor stroke	4 (2.5)	4 (2.8)	1.000[a]
Periprocedural ipsilateral major stroke	0 (0)	1 (0.7)	0.473[a]
CN damage	2 (1.3)	0 (0)	0.500[a]
6. month residual stenosis	1 (0.6)	4 (2.8)	0.193[a]

CEA= carotid endarterectomy, CAS= Carotid artery stenting, CN=cranial nerve; [a] Chi-square or Fisher's Exact test.

DISCUSSION

We found no statistically significant difference in restenosis or neurological complications in the immediate or 6-month follow-up after revascularisation for severe carotid stenosis between the CEA and CAS groups.

Clinically, severe carotid stenosis can lead to transient ischemic attack, ischemic stroke, risk of ischemic cerebrovascular events including retinal ischemia, and risk of hemodynamic damage to the brain. This results in reduced local perfusion and accelerated progression of cognitive function decline[11,12]. According to a recently updated review of evidence from the Society for Vascular Surgery, CEA is superior to medical therapy in the long-term prevention of stroke or death. Additionally, CEA is more effective than CAS in reducing long-term stroke or death in symptomatic low-risk surgical patients[13].

The literature recommends CEA for severe (≥70%) symptomatic carotid stenosis if an operative stroke/death rate of <6% can be maintained[14-16]. The benefit is less evident, but most guidelines suggest considering CEA for symptomatic stenosis ranging from 50–69%[14-16]. For patients with asymptomatic carotid artery stenosis ≥60–70%, CEA is endorsed as long as operative stroke/death rates <3% can be upheld[14-16].

Although CEA remains the preferred option for patients with severe symptomatic or asymptomatic carotid artery stenosis, recent studies suggest that CAS is equally suitable for the majority of such patients[17-19]. In certain situations, such as for those with high surgical risk or where CEA cannot be performed due to technical reasons, CAS is the preferred option[19]. The benefits of CAS include better cosmetic outcomes, avoidance of cranial nerve injury, and shorter hospital stays[20]. The ICSS randomised trial found no clear superior procedure[21]. According to the study, CAS was just as effective as CEA in preventing fatal or disabling stroke (6.4% versus 6.5%, respectively). The ICSS linked CAS to a higher risk of procedure-related and minor strokes but found no difference in neurological outcomes. As with the ICSS, our findings also could not definitively discern which procedure was more effective.

CAS appears to be a safe and effective alternative in patients younger than 70. In our study, the average age of patients who underwent CAS was higher than that of the CEA group, which was attributed to the increased risk of comorbidities and surgery with advancing age. Indeed, the diagnosis of CHF and history of cerebrovascular disease were significantly more common in the CAS group than in the CEA group.

Randomised controlled trials have consistently shown a higher procedural stroke rate in patients treated with CAS compared to those treated with CEA. In our study, minor stroke rates were similar (2.5% in CEA vs. 2.8% in CAS), but major stroke was only observed in the CAS group (0.7%); however, this difference was not statistically significant. CAS had a lower risk of procedural myocardial infarction and local problems such as cranial nerve injuries and surgical site hematoma. Procedural myocardial infarction was not seen in any of our patients, while cranial nerve injuries occurred in 1.3% of the CEA group but were absent in patients undergoing CAS. CAS also appears to be as durable as CEA in providing long-term protection against ipsilateral stroke and maintaining low restenosis rates[20,22].

In a review of 34 studies that lasted on average 13 months (ranging from 6 to 31 months), Gröschel et al. found a 50% stenosis rate of 6% at 1 year and 7.5% at 2 years, as well as a >70% stenosis rate of 4%[23]. According to the Stent Protected-Angioplasty versus Carotid Endarterectomy (SPACE) study, albeit both groups had equivalent stroke risk at the 2-year mark, restenosis (>70%) was more prevalent in the CAS group (11.1% vs. 4.6%)[24,25]. In our research, Doppler ultrasound imaging performed at 6 months revealed no significant difference in restenosis rates (>70% stenosis) between CEA and CAS (0.6% and 2.8%, respectively). For young female patients with DM, hyperlipidaemia, or who smoke and develop carotid restenosis (particularly post-CEA), re-intervention is advisable to lower the risk of potential cerebrovascular events[26].

The refinement of patient selection criteria for CAS and the development of new technologies such as advanced embolism protection devices and double-layer stents have further reduced periprocedural complications[27]. As is the case with surgical procedures, there is a positive correlation between more experienced operators and improved CAS outcomes. The utilization of embolism protection devices, CAS techniques like balloon sizing, and referrals of patients with attributes such as advanced age, aortic arch tortuosity, lesion tortuosity, and lesion calcification to CEA are significant factors in avoiding periprocedural complications[27].

This study has several limitations. Changes due to ongoing technological developments during the retrospective case inclusion period may have influenced the accuracy of the results. Additionally, this research only encompasses cases from one institution with an average patient count, suggesting a potential for selection bias due to the absence of randomisation. Operator preferences might have also affected the results. Further, a 6-month follow-up period was used, but a more extended period is necessary to ascertain the risk of restenosis.

In recent years, options such as lifestyle modifications, blood pressure control, and statin therapy have emerged as attractive treatments. These are particularly favoured for asymptomatic patients with a low risk of stroke[28].

There was no statistically significant difference between the CEA and CAS groups regarding mortality and neurological complications in the early or first 6-month follow-up after revascularisation for severe carotid stenosis. Nevertheless, as the number of cases increases, more information concerning the treatment's effectiveness and potential complications will emerge, which could shape recommendations. The choice of method for treating severe carotid artery stenosis should be based on patient characteristics, preferences, and the treatment centre's complication rates. We predict that advancements in surgical strategies, and the use of new materials and equipment during the endovascular procedure, will likely reduce potential complications. In addition, tailoring the treatment method to the patient's clinic emerges as a logical solution.

Author Contributions: Concept/Design : DÖ, CCÖ, ZA; Data acquisition: DÖ, IÖ, CCÖ, BA; Data analysis and interpretation: DÖ, OKU, ZA; Drafting manuscript: DÖ, OKU, İÖ; Critical revision of manuscript: DÖ, OKU, ZA; Final approval and accountability: DÖ, OKU, İÖ, CCÖ, BA, ZA; Technical or material support: DÖ, OKU, İÖ, CCÖ, BA, ZA; Supervision: DÖ, OKU, ZA; Securing funding (if available): n/a.
Ethical Approval: The study has been approved by the ethics committee at 15.12.2022 with protocol number 2310.
Peer-review: Externally peer-reviewed.
Conflict of Interest: There is no specific funding related to this research.
Financial Disclosure: There is no specific funding related to this research.
Informed consent: All procedures followed were in accordance with the ethical standards of the responsible committee on human experimentation (institutional and national) and with the Helsinki Declaration of 1975, as revised in 2008. Informed consent was obtained from all participants.

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