Smyrna Tıp Dergisi ***Araştırma Makalesi***

Long–term Outcomes of Stent Application in Extracranial Carotid Artery Stenosis and the Effect of Stents on Treatment Ekstrakraniyal Karotis Arter Stenozunda Stent Uygulamasının Uzun Dönem Sonuçları ve Stentlerin Tedaviye Etkisi

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Summary
Objective: In recent years, carotid artery angioplasty and stenting (CAS) has been considered as an alternative to carotid endarterectomy (CEA), due to new antiplatelet agents and advances in endovascular therapy. Studies comparing CAS and CEA have shown that CAS is an effective and safe treatment method. In this research it was aimed to elucidate the benefits od CAS and positive outcomes of the cases.
Material and Methods: A total of 52 patients, 12 women (23%) and 40 men (77%) with transient ischemic attack, stroke, dizziness, imbalance, hemiplegia, tinnitus, and neck murmur, who were diagnozed carotid artery stenosis were included in the study. A total of 56 stent placement procedures were applied to 52 patients. All procedures were performed under local anesthesia and the patient was monitored. The main femoral artery was catheterized with Seldinger method, the initial ACT value was measured with before starting the procedure. Then, 5.000 IU heparin was given as a bolus and control ACT values were set to be between 250IU – 300IU.
Results: The degree of stenosis in DSA was over 70% in 30 cases (53.5%), and symptomatically 50% and above in 26 cases (44.6%) before the stent application. Endovascular treatment was applied to 56 carotid artery lesions (4 patients bilaterally, 1 patient after restenosis balloon angioplasty) in 52 patients included in the study. Angiographic success was defined as a residual stenosis of less than 30% in diameter after stenting. Technical success in stenting was achieved as 100%. Ipsilateral ICA occlusion constituted 5.7% of the patient population in our series.
Conclusion: Regarding the results of this study one can conclude that carotid artery stending is a safe and effective alternative to carotid endarterektomy in convenient cases. Additionally, administration of local anesthesia with a less invasive procedure also contributed to shorter hospitalisation and increased quality of life fort he patients.
Key words: Carotid artery stenting, carotid endarterectomy, digital subtraction angiography, internal carotid artery, stroke

Özet
Amaç: Son yıllarda, yeni antiplatelet ajanlar ve endovasküler tedavideki gelişmeler nedeniyle karotis arter anjiyoplastisi ve stentleme (CAS), karotis endarterektomiye (CEA) bir alternatif olarak düşünülmüştür. CAS ve CEA'yı karşılaştıran çalışmalar, CAS'ın etkili ve güvenli bir tedavi yöntemi olduğunu göstermiştir. Bu araştırmada, CAS'ın faydaları ve vakalardaki olumlu sonuçların açıklanması amaçlanmıştır.
Gereç ve Yöntem: Geçici iskemik atak, inme, baş dönmesi, dengesizlik, hemipleji, kulak çınlaması ve boyun üfürümü olan ve karotis arter stenozu tanısı konulan 12 kadın (%23) ve 40 erkek (%77) olmak üzere toplam 52 hasta çalışmaya dahil edildi. 52 hastaya toplam 56 stent yerleştirme prosedürü uygulandı. Tüm prosedürler lokal anestezi altında gerçekleştirildi ve hasta monitörize edildi. Ana femoral arter Seldinger yöntemi ile kateterize edildi, işleme başlamadan önce ilk ACT değeri ölçüldü. Daha sonra bolus olarak 5.000 IU heparin verildi ve kontrol ACT değerleri 250IU – 300IU arasında olacak şekilde ayarlandı.
Bulgular: Stent uygulamasından önce DSA'daki stenoz derecesi 30 olguda (%53,5) %70'in üzerinde, semptomatik olarak 26 olguda (%44,6) ise %50 ve üzerindeydi. Çalışmaya dahil edilen 52 hastada 56 karotis arter lezyonuna (4 hasta bilateral, 1 hasta restenoz balon anjiyoplasti sonrası) endovasküler tedavi uygulandı. Anjiyografik başarı, stentlemeden sonra çapı %30'dan az kalan rezidüel stenoz olarak tanımlandı. Stentlemede teknik başarı %100 olarak elde edildi. Hasta popülasyonunun %5,7'sinin ipsilateral ICA oklüzyonu vardı.
Tartışma: Bu çalışmanın sonuçlarına bakıldığında, karotis arter stentlemesinin uygun vakalarda karotis endarterektomisine güvenli ve etkili bir alternatif olduğu sonucuna varılabilir. Ek olarak, daha az invaziv bir

prosedürle lokal anestezi uygulanması da daha kısa hastanede kalış süresine ve hastaların yaşam kalitesinin artmasına katkıda bulunmuştur.
Anahtar kelimeler: Karotis arter stentleme, karotis endarterektomi, dijital subtraksiyon anjiyografisi, iç karotis arteri, inme

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Introduction

Carotid artery diseases are diagnosed more frequently due to the increase in the average life expectancy of the general population and the easy accessibility of imaging methods. Stroke is the most common cause of bedridden patients and is the third leading cause of death. Approximately, 80% of strokes are ischemic, and the etiology is extracranial carotid artery stenosis in 1/3 of the cases (1,2).

Many studies have proven the benefits of carotid endarterectomy (CEA), a method that has been used in selected patients for almost 60 years (3). In recent years, carotid artery angioplasty and stenting (CAS) has been considered as an alternative to CEA, due to new antiplatelet agents and advances in endovascular therapy. Studies comparing CAS and CEA have shown that CAS is an effective and safe treatment method (4,5).

Carotid artery stenosis is one of the common causes of stroke and is estimated to be responsible for approximately 20-25% of all ischemic events (6,7,8). Asymptomatic carotid artery stenosis over 50% is observed 2-8% in the population (6). Carotid artery stenosis is higher among patients with heart disease (18.2%), and this rate is even higher (22,1%) in the presence of heart disease and hypertension (9).

Carotid artery stenosis may be asymptomatic or may lead to stroke. Up to 60% of the carotid arterial stenosis can be detected in the doppler ultrasonography examination (10). Risk of stroke due to carotid artery stenosis depends on the degree of stenosis and the structural feature of the lesion. Symptomatic patients are defined as patients with a history of stroke or transient ischemic attack in the past 6 months (6). Symptomatic patients are at risk of stroke much higher than asymptomatic. Ipsilateral stroke in carotid disease typically results from distal embolism from ulcerated plaque, hemodynamic changes caused by occlusion or preocclusive stenosis, or a combination of these two mechanisms (11). The degree of stenosis, the hemodynamic changes caused by stenosis in the distal bed and the morphology of the atherosclerotic plaque (whether or not ulceration or intra-plaque bleeding) plays an important role in the treatment decision of stenosis.

The management of carotid artery stenosis may vary from patient to patient. Carotid artery stenosis can be treated by medical therapy, open surgery or revascularization with endovascular method, or can be followed-up only. Revascularization with carotid endartercteomy (CEA) is the accepted conventional treatment for symptomatic carotid artery stenosis. However, besides the patient-related factors such as comorbidity or inappropriate neck anatomy, a paradigm shift has occurred in the treatment of carotid artery stenosis recently with the development of neuro-interventional materials, techniques and experiences. Revascularization with endovascular method can be achieved with angioplasty or stenting. Angioplasty alone has some disadvantages because the rate of restenosis is higher than CEA (12). However, the majority of patients who develop restenosis remain asymptomatic. Dissection risk, elastic recoil of the artery, and distal embolization are other disadvantages. Carotid artery stenting (CAS) reduces the incidence of dissection, vascular recoil, and distal embolization (6). Today, endovascular carotid stenosis treatment is performed in selected suitable patients with the combination of stenting and angioplasty (7,12).

In parallel with technological developments, balloon angioplasty and stenting have emerged as an alternative to carotid endarterectomy. Studies conducted in recent years, have reported that endovascular therapy is equivalent to or even superior to CEA (13). While prophylactic treatment with anti-aggregant drugs was used for many years, the risk of ischemic stroke in symptomatic has been reduced by 65% and 83% via CEA in NASCET and ECST respectively.

The aim of this study was to elucidate the results of the patients we treated with CAS and to evaluate the treatment outcomes and possible complications with regard to the existing studies on this subject.

Material and Method

The patients included in this study applied to the Neurology Outpatient Clinic of Mersin University Faculty of Medicine with reasons such as TIA, stroke, dizziness, imbalance, hemiplegia, tinnitus, and neck murmur, and were referred to the radiology department with the suspicion of CAS as a result of their examinations or during the imaging procedure performed for other reasons. All individuals were diagnozed with hey were patients with carotid artery stenosis.

A total of 52 patients, 12 women (23%) and 40 men (77%), were included in the study. A total of 56 stent placement procedures were applied to 52 patients. The ethics committee approval has been granted and the study complied with the Declaration of Helsinki and informed consent has been obtained from all participants.

All procedures were performed under local anesthesia and the patient was monitored. The main femoral artery was catheterized with Seldinger method, the initial ACT value was measured with before starting the procedure. Then, 5.000 IU heparin was given as a bolus and control ACT values were set to be between 250-300.

Heparin infusion was continued for 24 hours after the procedure. Distal protection device was used in all procedures. The protection umbrella used in most of the cases in our series was FilterWire EZ (Boston Scientific), and a small number of Spider FX (ev3) and Emboshield (Abbott) were used. The filter was placed, predilatation was performed with balloons of 2,5 – 4 mm in diameter in cases to procced the stent. A final evaluation was conducted on the localization of the stent by injecting an opaque material through the guide catheter. The stent was passed through the guide catheter and the segment planned to be stented was entered. Having reached definitive localization, the stent was opened. In our series, most of the carotid stents were Wallstent (Boston Scientific; Galway, Ireland) and few Xact (Abbott), Protege (ev3) self-expandable stents were used. Control DSA (Digital Subtraction Angiography) was performed by removing the delivery catheter of the stent. The position of the stent and its degree of opening were determined.

In transverse views, the intra-stent lumen diameter was measured using three different window settings. Initially used values were 500 HU window width and 200 HU window level, used as standard for CT angiography. The second parameters used were window setting, which included a window width of 1500 HU and a window level of 400 HU. Third was the window setting, with a window width of 1500 HU and a window level of 1500 HU, in which the stent and the patient's bony cortex could be selected. In all patients, there was a well-defined boundary between the contrast-filled lumen and the stent with a higher attenuation than the lumen and surrounding the contrast. We made all our measurements at this level, as this limit was most clearly and best observed in the window with a window level of 1500 HU.

Inclusion criteria

- Presence of DSA data on extra-cranial carotid artery stenosis before stenting,
- The stent was applied to the extracranial ACA and/or ICA branch,
- The stent was applied in our institution,
- The control data in 1–6–12 months was available,
- Individuals who used their medication regularly.

Exclusion criteria

- Stents applied outside our institution,
- Imaging data in another hospital,
- Those who took their medication irregularly,
- Patients who underwent stenting in the main carotid artery and/or internal carotid arteries for reasons such as dissection, aneurysm other than stenosis.

Results

A total of 52 patients, 12 women (23%) and 40 men (77%), were included in the study. A total of 56 stent placement procedures were applied to 52 patients. The ages of the cases ranged from 48 to 91 years, with a mean age of 68,25 years. There were 9 patients (17.3%) over the age of 79, and 43 patients (82.7%) aged 79 and under. HT was detected in 34 patients (65.3%), DM in 15 patients (28.8%), dyslipidemia in 27 patients (51.9%), and 36 patients (69.2%) were smokers.

Before the stent application, the degree of stenosis in DSA was over 70% in 30 cases (53.5%), and symptomatically 50% and above in

26 cases (44.6%). Only 1 patient (1.92%) had undergone CEA operation before the procedure.

Endovascular treatment was applied to 56 carotid artery lesions (4 patients bilaterally, 1 patient after restenosis balloon angioplasty) in 52 patients included in the study. Stenting procedures for contralateral ICA (internal carotid artery) stenosis of 4 patients were performed in different sessions. Angiographic success was defined as a residual stenosis of less than 30% in diameter after stenting. Technical success in stenting was achieved as 100%. In cases where sinosal arrest and transient bradycardia developed during the post-dilatation procedure, normal rhythm was maintained by administering atropine. There was no hemodynamic change that caused significant distress in any of the cases. Ipsilateral ICA occlusion was detected in three patients. This constituted 5.7% of the patient population in our series. Stent occlusion was detected in two patients at the 1st and 6th months after treatment, and no neurological finding developed in these patients. Both patients had DM patients and one of them continued to smoke after the procedure.

Figure 1. *60% stenosis at the left ICA bulbus level in the upper left. The lumen was observed to be open in the control after the stent in the upper right. At the bottom, lumen open is observed in MIP, axial CT and volume rendering images in the 1st month CT control.*

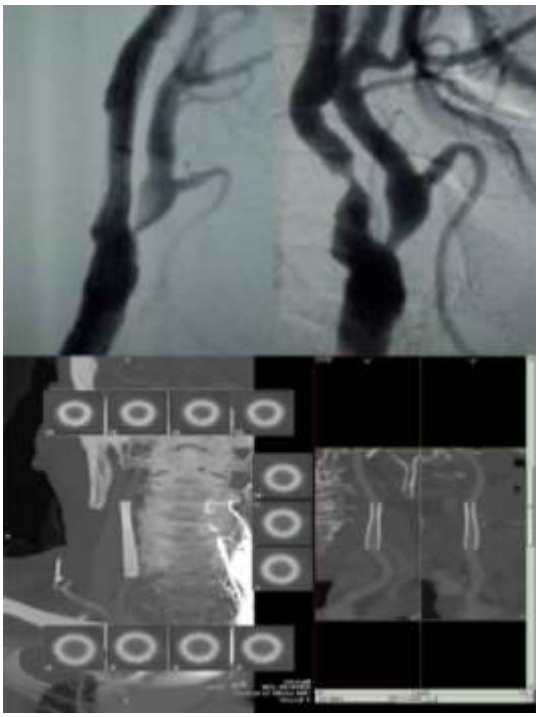
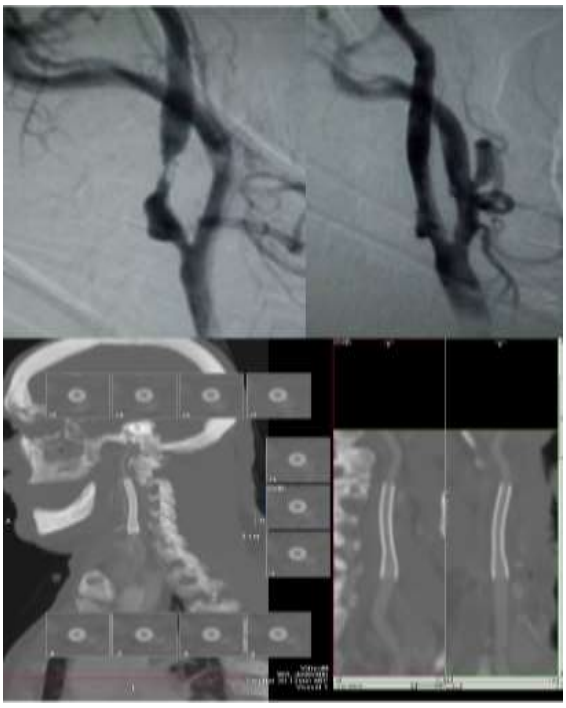


Figure 2. *Upper left right ICA bulbus and 70% stenosis at cervical level.*



The lumen was observed to be open in the control after the stent in the upper right. At the bottom, in the 12th month CTA control, lumen open is observed in MIP, axial CT and volume rendering images.

Figure 3: *Upper left right ICA bulbus and 70% stenosis at cervical level.*

The lumen was observed to be open in the control after the stent in the upper right. At the bottom, in the 12th month CTA control, lumen open is observed in MIP, axial CT and volume rendering images.

Discussion

Stroke ranks fourth among the causes of death and is one of the leading factors of long-term disability (15). Carotid artery stenosis is the cause of approximately 25% of ischemic strokes (16). Previously, carotid artery endarterectomy with medical treatment was the main treatment option, but nowadays, due to technological developments, carotid artery stenting has been used with increasing frequency (17). In fact, in current studies using a distal embolism protective device, it has been shown that CAS treatment is as much protective as CAE in recurrent ischemic stroke and the complication rate is similar or even lower (18, 19).

Many studies have shown that the carotid interventional method, in other words stenting, carries risks similar to surgery. As a result of the examination of 11243 patients from American records, the stroke and death rate was 4.7%. In addition, it has been shown that the complication rates in interventions that do not use any of the aforementioned protection systems were significantly higher than those in which the protection system was used (6.2% unprotected, 2.8% protected) (20). Another German-based study; Pro-CAS (Prospective Registry of Carotid Angioplasty and Stenting) revealed the risk of stroke and death as 2.4% in asymptomatic patients and 3.1% in symptomatic patients as a result of 3.853 interventions (21). In the ELOCAS (European Long-Term Carotid Artery Stenting Study) study, the recurrence rate of a milder stenosis within 5 years was shown as 3.4% (22).

New pharmacological and technological developments increase the applicability of CAS. CREST, SAPPHIRE, and EVA-3S are multicenter, randomized controlled trials to determine the better treatment option between CAS and CEA in symptomatic and asymptomatic patients (23,24,25). Until recently, no significant difference was found between CAS and CEA in CREST, which had the lowest risk among randomized controlled trials (mortality, stroke, and 30-day MI development), (7.2% and 6.8%, respectively) (24).

The four-year stroke/death rates for all patients were 6.4% for CAS and 4.7% for CEA (p=0.03). After the intervention period, the incidence of stroke was also low in both treatment branches (2% vs. 2.4%). In CREST study, patients younger than 70 years benefited from CAS, while CEA was more beneficial in patients over 70 years of age. These findings showed that increased vascular calcification is more risky for the CAS procedure. In the CREST study, the proportion of symptomatic patients was 52%, and 42% of the patients had a previous history of cardiovascular disease (24).

CAS is an alternative to CEA in symptomatic patients (Class I, evidence level B) with medium to low risk for endovascular intervention. The more experienced the operator and the center performing the procedure, the lower the rate of CAS complications. According to the guidelines, the complication rate of the center performing the procedure should be less than 6% in symptomatic patients and less than 3% in asymptomatic patients (26,27,28). CEA can be performed in asymptomatic patients with >70% stenosis of the internal carotid artery if the perioperative risk of stroke, MI, and death is low (Class IIa, Level of Evidence A) (28). CEA may be preferred over CAS in elderly patients with inconvenient arterial anatomy for endovascular intervention such as insufficient neck anatomy for surgery (proximal-distal stenosis, previous CEA in the same vessel, opposite vocal cord paralysis, open tracheostomy, radical surgery, radiation) (29). Due to the high rate of distal embolization observed during carotid artery stenting, many cerebral protective systems have been developed to capture and remove atheroma debris released during percutaneous intervention in the carotid arteries.

One of the problems encountered in stent treatment is is the development of re-stenosis. Stent placement on the vessel wall activates vascular smooth muscle cells and endothelial cells, initiating the inflammatory and proliferative phase of the wall repair process (30). Re-stenosis develops in stents due to intimal hyperplasia. The result is ipsilateral cerebral ischemia. In the study of Schillinger et al., 12 patients with stenosis between 50% and 60% remained asymptomatic in the first 6 months after stent treatment, while 2 out of 3 patients with stenosis of 70% or more had

a stroke (31). Therefore, it can be thought that 70% stenosis rate in the stent lumen for restenosis may be more clinically significant (32). Antiaggregant and anticoagulant therapy after endovascular therapy is vital for stent patency. Although the application of CEA in cases with contralateral ICA occlusion has a high risk of complications, we have applied CAS in these cases and our results was clearly successful. Re-stenosis rates after CAS were 6% at 1st month, 6% at 6th month, 8% at 12th month, and no significant difference was found between previous studies on CAS in the literature. End-stent stenosis was not observed in any of our cases, but smooth muscle cell proliferation and myointimal hyperplasia appeared to be the main reason for the re-stenosis rates in our research.

There are various opinions about medical treatment, the protocol we applied (acetylsalicylic acid and clopidogrel treatment) is one of the most recommended schemes in the literature (33).

In the review of Gröschel et al. investigating the rates of re-stenosis after CAS, including 34 studies, with an average of 13 months (6-31 months), 50% stenosis rate was 6% at 1 year, 7.5% at 2 years and the rate of >70% stenosis was found to be 4% (34). In our cases with re-stenosis and occlusion after CAS, diabetes emerged as a common risk. Ipsilateral stroke was rarely observed for CAS and CEA. Symptomatic status and gender did not differ significantly on treatment difference. While the results in CAS were better in young patients, CEA was evaluated as better in elderly patients.

The recommendations of the American Stroke Association's (2021) vary according to stenosis severity and vascular risk factors (35). CAS is an alternative to CEA in patients with a low/average complication rate with CAS diagnosed with stenosis >70% by symptomatic, noninvasive methods or >50% by digital substrate angiography (DSA) (category 1, evidence B). However, for this group, CEA was defined as category 1, evidence A. The National Institute for Health and Clinical excellence (NICE) guideline supports the use of stent in symptomatic carotid artery stenosis, while citing a lack of evidence, saying that CAS should only be used in asymptomatic patients in special circumstances (36). The most recently published guideline, the European Society for Vascular Surgery, states that CAS can be used as an alternative to CEA in patients with a high surgical risk and/or periprocedural risk of stroke/death <6% (37).

CAS performed under local anesthesia significantly reduced the hospital stay of the patients, and local complications such as nerve injury, pseudoaneurysm, and inguinal hematoma, which occur in CEA and prolong the hospital stay, were not observed in any of our cases.

In cases where sinosal arrest and transient bradycardia developed during the post-dilatation procedure, atropine was administered to maintain normal rhythm, and no hemodynamic changes that caused significant distress were detected in any of the cases. Being awake during the procedure is an important advantage over CEA in that it enables us to easily monitor the neurological status during the procedure. CAS has ceased to be an alternative treatment method for CAD and has become the main treatment modality in many cases.

Conclusion

Regarding the results of this study one can conclude that carotid artery stending is a safe and effective alternative to carotid endarterektomy in convenient cases. Additionally, administration of local anesthesia with a less invasive procedure also contributed to shorter hospitalisation and increased quality of life fort he patients.

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Competing interests
The authors declare that they have no competing interests.

Ethical Declaration
The ethics committee approval has been granted and the study complied with the Declaration of Helsinki and informed consent has been obtained from all participants.

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