

# Outcomes of carotid artery stenting in high-risk patients; a single center retrospective review

Ahmet Kırbaş (\*), Nurşen Tanrıku (\*), Mutlu Cihangiroğlu (\*\*\*), Ömer Işık (\*)

## SUMMARY

In our study, we evaluated the safety and efficacy of carotid artery stenting(CAS) in high surgical risk patients. 22 consecutive patients who underwent carotid artery stenting(CAS) between March 2009 and December 2011 were eligible. Only symptomatic stenosis were studied in high surgical risk patients as defined by the SAPHIRE(Stenting and Angioplasty with Protection in Patients at High-Risk for Endarterectomy) trial. The mean age was 77.8 (range 67-87). Of the study group, 17 male(77.27%) and 5 female(22, 72%). Procedural success was achieved in 21 patients(95.4%). The mean stenosis in patients was 90.68 ±5.4%. Reasons for stenting included cardiac/pulmonary risk(63%), contralateral carotid artery occlusion(72%), age older than 75(72%). None of the patients suffered from major stroke, MI or death due to CAS during their hospital stay. The overall rate of in-hospital adverse events (TIA, permanent bradycardia, hypotension) was 18.1 %(4 of 21). Bradycardia in 2(9.5%), hypotension in one(4.7%) and transient ischemic attack in one(4.7%) were observed during procedures. Our results support the use of CAS in high surgical risk patients with significant symptomatic carotid artery disease.

**Key words:** Carotid artery stenting, stroke, symptomatic carotid stenosis, complications

## ÖZET

**Yüksek riskli hastalarda karotis arter stent sonuçları ; tek merkezli retrospektif inceleme**

Bu çalışmada, yüksek cerrahi riskli hastalarda karotis arter stent güvenliği ve etkinliği değerlendirildi. Mart 2009 ile Aralık 2011 tarihleri arasında 22 hastaya ardişık olarak karotis arter stent uygulandı. SAPHIRE(Endarterektomi için Yüksek Riskli Hastalarda Stent ve Anjiyoplasti ile koruma) çalışmasında tanımlandığı gibi yüksek cerrahi riski bulunan, semptomatik darlıkları olan hastalarda çalışıldı. Hastaların ortalama yaşı 77(dağılım 67-87), 17'si erkek(%77, 27), 5'i kadın(%22, 72) idi. İşlem 21 hastada başarı ile uygulandı. (%95.4). Hastaların ortalama stenoz oranı %90, 68 ± 5.4 idi. Stent uygulama nedenleri, kardiyak ve solunumsal risk (% 63), diğer taraf karotis arterde tıkanıklık (% 72), 75 ve daha ileri yaş (%72) idi. Hastaların hiçbirinde hastanede kalış süresince karotis stent işleminde bağlı inme, miyokard infarktüsü ve ölüm gelişmedi. İşlem sonrası beklenmeyen olay oranı (bradikardi, geçici iskemik atak, hipotansiyon)%18.1 idi. İşlemler sırasında iki hastada kalıcı bradikardi (%9.5), bir hastada hipotansiyon(%4.7), bir hastada geçici iskemik atak gelişti. Sonuçlarımız yüksek riskli semptomatik karotis arter darlığı bulunan hastalarda karotid arter stent (KAS) kullanımını desteklemektedir.

**Anahtar kelimeler:** Karotis arter stentleme, inme, semptomatik karotis stenozu, komplikasyon

## Introduction

Atherosclerotic disease at the carotid bifurcation has been seen to be responsible for greater than 20 to 25% of all strokes(1). The treatment of extracranial carotid artery occlusive disease is intended to decrease the risk of stroke. Prospective randomized controlled trials have provided level I evidence to support the use of carotid endarterectomy(CEA) as standard therapy for achieving durable freedom from stroke in symptomatic and asymptomatic patients(2,3). However, these trials excluded patients that exhibited risk factors associated with increased complication rates for patients undergoing CEA. These risk factors included clinically significant cardiopulmonary disease, contralateral carotid artery occlusion, recurrent carotid artery stenosis, previous neck surgery, and age greater than 80 years old. Carotid angioplasty and stenting(CAS) is a percutaneous procedure for treating patients with carotid stenosis, and it has emerged as a potential alternative therapy for patients that are at increased risk for CEA(4,5). This study sought to evaluate whether patients at increased perioperative risk for CEA may be treated with CAS while maintaining equivalent outcomes.

## Material and Methods

An institutional review board approved retrospective review of the clinical variables. A total number of 22 patients with high risk had undergone the procedure from January 2009 to November 2011. Only high surgical risk patients with clinically significant cardiac disease (congestive heart failure, abnormal stress test, or the need for open-heart surgery), severe pulmonary disease, contralateral carotid occlusion, recurrent stenosis after CEA, and an age older than 80 as defined by the SAPHIRE trial(5).

\* Department of Cardiovascular Surgery, Medicana Camlica Hospital

\*\* Department of Anesthesiology and Reanimation, Medicana Camlica Hospital

\*\*\* Department of Radiology, Medicana Camlica Hospital

**Reprint request:** Dr. Ahmet Kırbaş, Medicana Camlica Hospital, Department of Cardiovascular Surgery, Istanbul, Turkey

**E-mail:** ahmetkiras@gmail.com

**Date submitted:** February 05, 2012 **Date accepted:** March 19, 2012 **Online publication date:** December 27, 2012

Indications for CAS include >60% stenosis, symptomatic, and >80% stenosis, asymptomatic. All patients were subjected to neuroimaging, either CT or MRI. Carotid Doppler or CTA (computed tomography angiography) or MRA (magnetic resonance angiography) were the initial screening tools for evaluating carotid artery disease. Patients suspected to have carotid stenosis from the initial evaluation were selected for digital subtraction angiography (DSA). Informed consent was obtained from all patients before the procedure. Patients who chose to undergo CAS but did not meet SAPHIRE criteria for high surgical risk were excluded from the study. Data concerning both patient demographics and stenting factors were reviewed. The patient demographic data points included the age and sex of patient as well as the clinical risk factors. The treatment factors included the presence of symptoms, pre and postprocedure stenosis, deployment success, and stent location. The primary outcome measures were overall rate of in-hospital adverse events (transient ischemic attack (TIA), hemorrhage, minor stroke, major stroke, myocardial infarction (MI), and death and the 30-day stroke/death / MI risk. These data were stratified for both symptomatic and asymptomatic stenoses. Patients were treated with 100 mg aspirin OD, combined with 75 mg clopidogrel bisulfate OD for five days, before CAS. At discharge patients were advised to continue clopidogrel for a period of four months and aspirin life long. Statistical analysis was performed using the Fisher exact test.

Carotid artery angioplasty and stenting was performed in the operating room utilizing a digital fluoroscopic imaging system (Axiom Artis, Siemens, Europe) under local anesthesia. Entry access was achieved by placing a 5F introducer sheath in the femoral artery using the Seldinger technique. After selective DSA, the introducer sheath was replaced with a 7F sheath. A 7F guiding catheter (Mach1, Boston Scientific, USA) was then placed in the distal common carotid artery. A filterable cerebral protection device, AngioGuard Spider Fx EV3 (Minnesota, USA) were used. Protection devices were used in all patients. An over-the-wire angioplasty balloon (Terumo, Rx Muso, USA) was used to pre-dilate stenosis with a pressure of 6 – 8 atmospheres if indicated. At the time of balloon angioplasty, 0.6 mg IV atropine was routinely given to counter any significant bradycardia. A self-expanding carotid stent Protégé EV3 (North Plymouth, Minnesota, USA) was deployed

across the stenosis. Post-stenting balloon angioplasty was performed depending on the appearance of the completed angiogram. Clinical success was defined as maximal residual stenosis of less than 30%. In cases of any abnormality being monitored, patients were sent to the cardiovascular care unit.

## Results

Males were 17 and females 5 in number. Hypertension was an important risk factor (86.3%) in our study group. Other details are mentioned in Table I. All the patients who presented to us were symptomatic, and the mean stenosis in symptomatic patients was 90.6% with a range of 80% to 99% stenosis. The reasons for stenting included cardiac/pulmonary/medical risk (49.5%), contralateral internal carotid artery occlusion (72.7%), recurrent stenosis after CEA (4.5%), age older than 80 (40.9%) (Table II). The clinical picture at presentation was TIA 22.7%, minor stroke 18.1%, and major stroke 59.0%. Other angiographic findings are mentioned in Table III. The overall rate of in-hospital adverse events (TIA, permanent bradycardia, hypotension) was 18.1% (4/22). Of these events, 1 patient (4.5%) had a hemispheric TIA (neurological symptoms that resolved within 24 hours), and two (9.5%) had severe bradycardia (despite routine prophylactic atropine before stent placement) and 1 patient (4.7%) had hypotension. One had transient hypotension lasting for few minutes. Stenting was performed in 95.4% of the cases, except in one patient. She was a 82-year-old female who presented with TIA, and had 80% stenosis of the right internal carotid artery (RICA). Carotid artery structure was not suitable for processing because all segment of carotid artery was tortuous. Hemodynamic disturbances were encountered in 3 patients. Post stenting residual stenosis was less than 10%.

## Discussion

Atherosclerotic carotid artery disease has been implicated in 8% to 29% of all ischemic strokes (6). Traditionally, CEA has been the procedure of choice for selected symptomatic and asymptomatic patients (7). Carotid artery angioplasty was introduced in 1979, and the first carotid stent in 1989 (8,9). As newer techniques in endovascular therapy evolve, such as the use of distal cerebral protection devices, and with more experience, CAS has been proposed as an alternative to CEA particularly in patients at high surgical risk (10,11).

The European Carotid Surgery Trialist Collaborative Group concluded that surgery in asymptomatic patients with 70% to 99% stenosis would have to be performed with a very low complication rate because of the only 5.7% 3 year risk of stroke in that group(12). The initial indications were some of the key exclusion criteria from NASCET/Veterans Affairs Cooperative Studies Program/ACAS including restenosis after CEA, contralateral internal carotid artery occlusion, previous neck irradiation, advanced age, and severe cardiopulmonary disease. Recently studies suggest that a role of CAS in the treatment of extracranial carotid atherosclerotic disease, particularly in patients at high surgical risk(13,5) Single Center experiences with carotid angioplasty and stenting(CAS) across the globe suggest good, immediate, and intermediate results and a low rate of complications.(14) Advantages to CAS include the avoidance of general anesthesia, the elimination of a neck incision and a potential reduction in periprocedural hemodynamic fluctuation. Disadvantages to CAS include the risk of stroke, sparse data on long-term durability, and access site complications(15).

Patients with factors determined to increase the perioperative risk of standard CEA surgery such as prior carotis surgery, and an elevated modified Goldman Cardiac Risk Score can be treated successfully with CAS while achieving complication rates equivalent to CEA. This was partially demonstrated in the Stenting and Angioplasty with Protection in Patients at High Risk for Endarterectomy(SAPPHIRE) trial, which compared CAS with cerebral protection to endarterectomy in patients with moderate-to-severe stenosis and associated cardiopulmonary comorbidities. The SAPPHIRE trial demonstrated improved periprocedural outcomes for patients treated using CAS with cerebral protection compared with standard CEA surgery in high surgical risk patients with respect to the outcomes of MI, stroke and mortality. The inclusion criteria for the prospective, randomized study was symptomatic stenosis greater than 50% or asymptomatic stenosis greater than 80% in patients meeting at least 1 criterion for high risk. Of note, only 29.9% of patients in the CAS group and 27.7% of patients in the CEA had from symptomatic stenosis. The study was designed as a noninferiority study and demonstrated that CAS was not inferior to CEA in the patients studied(5).

Successful use of CAS is predicated on avoiding specific procedural risk factors including age greater

than 80 years old, aortic arch calcification, aortic arch elongation or distortion, innominate or common carotid artery stenosis, and common carotid or internal carotid artery tortuosity(16,17). Tortuosity of the internal carotid artery may increase the difficulty of positioning the emboli protection device, preventing complete vessel wall apposition and decreasing the efficacy of the device at capturing embolic particles. Lesions evaluated by B-mode ultrasound and determined to have echolucent plaque with a gray-scale median score of less than 25 have been reported to be more friable and prone to dislodgement of emboli.(18) Increased lesion length has also been associated with an increased risk for stroke in patients treated with CAS(19). Here we review our experience with CAS in symptomatic patients. The overall early mortality 0%. The overall rate of in-hospital adverse events(TIA, permanent bradycardia, hypotension) was 18.1%(4/22). Of these events, one patient(4.5%) had a hemispheric TIA(neurological symptoms that resolved within 24 hours), and two(9.5%) had severe bradycardia (despite routine prophylactic atropine before stent placement) and one patient(4.7%) had hypotension. We report a retrospective case series of symptomatic patients who were deemed high risk of underwent CAS. The low periprocedural 30-day stroke/TIA/MI/death rate in symptomatic patients(4.7%) compares favorably with rates of other published studies in other prospective studies CAVATAS (Carotid and Vertebral Artery Transluminal Angioplasty Study(9.9%) and SPACE trial(6.5%)(13,20).

Our study has limitations because it was a retrospective chart review; however, all of the patients were part of several prospective carotid stent trials. Also, the sample size in this study may not be large enough for strong conclusions. With more patients and a longer follow-up, our conclusions might have been different. However, until we have a randomized prospective study, the data from our present study can be useful.

Given the relatively low risk of morbidity and mortality in symptomatic patients in our series, CAS is still a viable alternative to best medical management in patients who are high surgical risk of CEA. Further randomized studies are warranted to compare the safety and efficacy of the use of CAS in high-risk patients with symptomatic carotid artery disease.

The authors disclose no conflict of interest.

## References

1. Veith F, Amor M, Ohki T, Beebe H, Bell P, et al. Current status of carotid bifurcation angioplasty and stenting based on a consensus of opinion leaders. *J Vasc Surg* 2001;33:S1116.
2. North American Symptomatic Carotid Endarterectomy Trial Collaborators. Beneficial effect of carotid endarterectomy in symptomatic patients with high-grade carotid stenosis. *N Engl J Med* 1991;325:445-53.
3. Mayberg MR, Wilson SE, Yatsu F, Weiss DG, Messina L, et al. Carotid endarterectomy and prevention of cerebral ischemia in symptomatic carotid stenosis. Veterans Affairs Cooperative Studies Program 309 Trialist Group. *JAMA* 1991;266:3289-94.
4. Carotid Revascularization Using Endarterectomy or Stenting Systems (Ca-RESS) phase I clinical trial: 1-year results. *J Vasc Surg* 2005;42:213-9.
5. Yadav JS, Wholey MH, Kuntz RE, Fayad P, Katzen BT, et al. Protected carotid-artery stenting versus endarterectomy in high-risk patients. *N Engl J Med* 2004;351:1493-01.
6. Meyers PM, Schumacher HC, Higashida RT, Leary MC, Caplan LR, et al. Use of stents to treat extracranial cerebrovascular disease. *Annu Rev Med* 2006;57:437-54.
7. Executive Committee for the Asymptomatic Carotid Atherosclerosis Study. Endarterectomy for asymptomatic carotid artery stenosis. *JAMA* 1995;273:1421-8.
8. Mathias K, Mittermayer C, Ensinger H, Neff W. Perkutane Katheterdilatation von Karotisstenosen. *Rofo* 1980;133:258-61.
9. Mathias K, Jager H, Hennings S, Gissler HM. Endoluminal treatment of internal carotid artery stenosis. *World J Surg* 2001;25:328-36.
10. Van der Vaart M, Meerwaldt R, Reijnen M, Tio R, Zeebregts C. Endarterectomy or carotid artery stenting: the quest continues. *Am J Surg* 2008;195:259-69.
11. Gray WA, Hopkins LN, Yadav S, Davis T, Wholey M, et al. Protected carotid stenting in high-surgical-risk patients: the ARCHeR results. *J Vasc Surg* 2006;44:258-69.
12. The European Carotid Surgery Trialists Collaborative Group. Risk of stroke in the distribution of an asymptomatic carotid artery. *Lancet* 1995;345(8944):209-12.
13. Endovascular versus surgical treatment in patients with carotid stenosis in the Carotid and Vertebral Artery Transluminal Angioplasty Study (CAVATAS): a randomised trial. *Lancet* 2001;357(9270):1729-37.
14. Stankovic G, Liistro F, Moshiri S, Briguori C, Corvaja N, et al. Carotid artery stenting in the first 100 consecutive patients: results and follow up. *Heart* 2002;88:381-6.
15. Henry M, Polydorou A, Klonaris C, Henry I, Polydorou AD. Carotid angioplasty and stenting under protection. State of the art. *Minerva Cardioangiol* 2007;55:19-56.
16. Hobson RW, Howard VJ, Roubin GS, Brott TG, Ferguson RD, et al. Carotid artery stenting is associated with increased complications in octogenarians: 30-day stroke and death rates in the CREST lead-in phase. *J Vasc Surg* 2004;40:1106-11.
17. Lin SC, Trocciola SM, Rhee J, Dayal R, Chaer R, Morrissey NJ. Analysis of anatomic factors and age in patients undergoing carotid angioplasty and stenting. *Ann Vasc Surg* 2005;19:798-04.
18. Biasi GM, Froio A, Diethrich EB, Deleo G, Galimberti S, et al. Carotid plaque echolucency increases the risk of stroke in carotid stenting: the Imaging in Carotid Angioplasty and Risk of Stroke (ICAROS) study. *Circulation* 2004;110:756-62.
19. Krapf H, Nagele T, Kastrup A, Bühring U, Grönewäller E, et al. Risk factors for periprocedural complications in carotid artery stenting without filter protection: a serial diffusion-weighted MRI study. *J Neurol* 2006;253:364-71.
20. Ringleb PA, Allenberg J, Bruckmann H, et al. 30 day results from the SPACE trial of stent-protected angioplasty versus carotid endarterectomy in symptomatic patients: a randomised non-inferiority trial. *Lancet* 2006;368(9543):1239-47.