ORIGINAL ARTICLE

Efficacy and safety of carotid artery stenting: Experience of a single center

Karotis arter stentlemesinin etkinliği ve güvenliği: Tek merkez deneyimi

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ABSTRACT

Objective: Moderate and severe carotid artery stenosis in the internal carotid artery causes 10% to 15% of all strokes. The aim of this study was to evaluate the safety and short-term efficacy of carotid artery stenting (CAS) performed at a tertiary referral center.

Methods: The records of patients who underwent CAS between January 2017 and May 2018 at a tertiary care center were analyzed retrospectively and a total of 145 patients were included in the study.

Results: The mean age of the patients was 70.1±8.6 years, 75.2% of the study group was male, and 37.9% had hypertension. Of the patients evaluated, 81 (55.9%) were classified as symptomatic and 64 (44.1%) were classified as asymptomatic. A percutaneous coronary intervention was performed after CAS more often in symptomatic patients (38.9%), while it was observed at the same rate both before (25.9%) and after (25.9%) CAS in the asymptomatic group, but the difference between the groups was not statistically significant. A distal embolic protection device (EPD) was used in symptomatic patients (59.2%) and in the asymptomatic group (78.7%); however, a proximal EPD was used significantly more often in symptomatic patients (45.6%) compared with asymptomatic patients. No patient death was recorded while in hospital, and stroke/transient ischemic attack (TIA) development was observed in 5 (3.4%) patients. Stroke was seen in 2 patients (2.4%) and TIA in 3 patients (3.7%) in the symptomatic group; TIA or stroke was not seen in the asymptomatic group.

Conclusion: The results of this study revealed that CAS was a safe and practical procedure with an acceptable complication rate. In the appropriate patients, experienced interventionists can achieve good results when aggressive risk modification is applied and an EPD and optimal medical therapy are used.

ÖZET

Amaç: İnternal karotis arterdeki orta ve şiddetli darlıklar tüm inmelerin %10–15'ine neden olmaktadır. Bu çalışmada, üçüncü basamak bir referans merkezde karotis arter stentlemesinin (KAS) güvenliğini ve kısa dönem etkinliğini değerlendirmeyi amaçladık.

Yöntemler: Üçüncü basamak merkezimizde Ocak 2017 ile Mayıs 2018 arasında KAS uygulanan hastalar geriye dönük olarak değerlendirildi. KAS uygulanan 145 hasta çalışmaya dahil edildi.

Bulgular: Hastaların ortalama yaşı 70.1±8.6 yıl idi ve tüm grubun %75.2'si erkek olup %37.9'unda hipertansiyon mevcuttu. Hastaların 81'i (%55.9) semptomatik, 64'ü (%44.1) asemptomatik olarak gruplandırıldı. Semptomatik hastalarda koroner girişimler daha çok KAS sonrası (%38.9) yapılırken, asemptomatik grupta ise KAS öncesi (%25.9) ve sonrasında (%25.9) benzer oranlarda yapıldığı görüldü ama gruplar arasında istatistiksel fark yoktu. Semptomatik hastalarda (%59.2), asemptomatik hastalarda (%78.7) olduğu gibi distal emboli koruyucu cihaz (EKC), proksimal EKC'ye göre daha fazla kullanıldı. Ancak proksimal EKC, semptomatik hastalarda asemptomatik hastalara kıyasla anlamlı olarak daha fazla kullanıldı. Hastane içi ölüm görülmedi ve tüm popülasyonda 5 (%3.4) hastada inme veya geçici iskemik atak (GİA) gözlendi. Asemptomatik grupta GİA veya inme gözlenmedi, semptomatik grupta 2 hastada (%2.4) inme ve 3 hastada (%3.7) GİA görüldü.

Sonuç: Bu çalışma kabul edilebilir komplikasyon oranları ile KAS'ın güvenirliğini ve uygulanabilirliğini ortaya koymuştur. KAS prosedürü, deneyimli girişimciler tarafından optimal tıbbi tedavi altında, agresif risk modifikasyonu ile EKC kullanılarak, uygun hastalarda en az komplikasyonla gerçekleştirilmelidir.

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Stroke is the second-leading cause of death with about 6.5 million strokes occurring worldwide each year.[1] Atherosclerotic carotid artery stenosis, which typically occurs in common carotid artery bifurcation, is responsible for approximately 20% of all strokes.[2] Since carotid stenosis is typically not symptomatic prior to a potentially disabling stroke, potential carotid artery disease should be considered in patients with atherosclerotic risk factors.[3]

Abbreviations:

ASA	*Acetylsalicylic acid*
CAS	*Carotid artery stenting*
CEA	*Carotid endarterectomy*
EPD	*Embolic protection device*
ESC	*European Society of Cardiology*
ICA	*Internal carotid artery*
MI	*Myocardial infarction*
TIA	*Transient ischemic attack*

According to the European Society of Cardiology (ESC) guidelines, carotid artery intervention is advised with a Class 2a recommendation in patients with asymptomatic carotid artery stenosis of >60%, and a Class 1 indication in patients with symptomatic carotid artery stenosis of >50%.[4] The choice of a carotid endarterectomy (CEA) or carotid artery stenting (CAS) should be determined according to the risk presented by periprocedural complications, anatomical features, and patient comorbidities. Carotid stenosis in the internal carotid artery (ICA) is considered symptomatic if the patient has a recent history (<6 months) of ischemic stroke or transient ischemic attack (TIA).[5]

Following the emergence of endovascular treatment for carotid artery stenosis, there has been much discussion of the preferred means of management. Numerous randomized controlled trials have compared CEA and CAS. These studies have shown that periprocedural stroke was more frequent in CAS procedures (especially in symptomatic patients), while and myocardial infarction (MI) was more often seen in CEA procedures. Clinically silent ischemic lesions were commonly associated with CAS, although the clinical significance is a subject of debate.[6,7] According to the guidelines, the two most essential criteria for a decision between CEA and CAS are the experience of the center and operator, the risk of complications, and the anatomical features of the patient. Even though this recommendation is underpinned by many large-scale, randomized clinical studies, including the Carotid Revascularization Endarterectomy vs. Stenting Trial (CREST),[8] long-term outcome data for CAS are still lacking.[9] The aging population and increasing life expectancy call for real-life, long-term results that reflect stent restenosis and other complications after CAS in order to decide on the proper treatment strategy.

The objective of the present study was to retrospectively evaluate the safety and short-term efficacy of CAS as performed at a tertiary referral center.

METHODS

Study population

A total of 145 patients who underwent CAS between January 2017 and May 2018 at a single institution were retrospectively enrolled. Carotid stenosis was confirmed in all of the patients with noninvasive tests, such as Doppler sonography, computed tomography, or magnetic resonance angiography. Selective carotid angiography was performed to assess the severity of stenosis once neurological stability was established. The degree of stenosis was calculated according to the North American Symptomatic Carotid Endarterectomy Trial (NASCET) criteria.[10] The patients in the symptomatic group were primarily patients who were referred from the neurology unit. The timing of the procedure for these patients was a joint decision made with the neurologist according to an assessment of the risk of hemorrhagic transformation. However, since some patients did not present for up to 6 months after the stroke, there is a recognized difference in the interval between diagnosis and intervention in the symptomatic patients. The choice of revascularization strategy (CAS vs. CEA) was based on both the ESC guidelines and team experience, considering morphological and clinical data, suitability, and least periprocedural risk.[4] All of the patients underwent a neurological examination before the CAS procedure and, if necessary, after the procedure. Written, informed consent was obtained from all of the patients before the procedure, and the Medicana International Ankara Hospital ethics committee approved the study protocol (08 Jan 2020-04). Baseline characteristics, laboratory and echocardiographic data, procedural data, and outcome data were subsequently collected and analyzed retrospectively.

Procedural details

All of the patients were treated with acetylsalicylic acid (ASA) 300 mg and clopidogrel 600 mg before the procedure, and ASA 100 mg daily and clopidogrel

75 mg daily was continued as maintenance. Routine clopidogrel resistance testing was not performed. The intervention was generally performed under local anesthesia through the right femoral artery. An 8-F sheath (9-F in cases of where a proximal embolism protection device [EPD] was used) and a 0.035-in. hydrophilic wire (Terumo Corp., Tokyo, Japan) was introduced into the aorta with fluoroscopic guidance. A multiple side-hole pigtail catheter (Cook Medical Inc., Bloomington, IN, USA) was placed over the guidewire and into the aortic arch. Given the complexity of the aortic anatomy, arcus aortography was performed with 25 cm^3 of contrast at 15 mL/second and the specific anatomy was considered in the catheter selection for the common carotid artery.

Anticoagulation was infused with a bolus of 100 IU/kg unfractionated heparin to achieve an activated clotting time of 250–300 seconds. All of the procedures were performed with a proximal or distal protection device, depending on the decision of the interventionist and the characteristics of the vascular conditions. A distal EPD (Emboshield NAV6, Abbott Vascular, Inc., Santa Clara, CA, USA; Angioguard, Cordis Corp., Santa Clara, CA; or EPI FilterWire, Boston Scientific Corp., Marlborough, MA, USA) was preferred in cases of unstable plaques, while a proximal EPD (MoMA, Invatec S.p.A., Roncadelle, Italy) was preferred for unilateral lesions with severe stenosis. In proximal EPD cases, 0.5–1 mg of atropine was used to protect against hypotension and bradycardia. In a case of 95% stenosis (according to NASCET criteria), the lesion was usually predilated and then postdilated as necessary according to the vessel diameter.

The stent selection was at the discretion of the interventionist. Hybrid stents were used frequently; however, closed-cell stents (Xact, Abbott Vascular Inc., Santa Clara, CA, USA; WallStent, Boston Scientific Corp., Marlborough, MA, USA) were used in lesions with a high thrombus load rather than open-cell stents (Rx Acculink, Abbott Vascular Inc., Santa Clara, CA, USA; Protégé Rx, Medtronic Inc., Minneapolis, MN, USA). Embolic material aspiration was continued in patients with the MoMa Proximal Flow Blockage Embolic Protection System (Medtronic Inc., Minneapolis, MN, USA) until at least 3 clear aspirates were observed. Before the retrieval of the protection device, a final biplane angiogram of the stent lesion and intracranial views were performed. At the end of the procedure, the arterial introducer was removed and hemostasis was achieved with manual compression or vascular closure devices. Patients were discharged after 24 hours of follow-up in the hospital. After 1 month of dual antiplatelet therapy, use of clopidogrel was discontinued.

Definitions

A stroke was defined as a neurological deficit of cerebrovascular cause that persisted beyond 24 hours or a new lesion observed with imaging. A TIA was defined as a focal neurological deficit that entirely resolved within 24 hours. No specific definitions were used for complications; they were categorized according to standard definitions. A neurologist evaluated all neurological complications.

Statistical analysis

Normally distributed data are shown as mean±SD and were compared with a t-test. Those without normal distribution are shown as median (25^{th}-75^{th} percentile) and were compared with the Mann-Whitney U test. Categorical variables are presented as frequencies and percentages and were compared using a chi-squared test. SPSS Statistics for Windows, Version 22.0 (IBM Corp., Armonk, NY, USA) was used to analyze all of the study data. A 2-tailed p value of <0.05 was considered statistically significant.

RESULTS

Among the analyzed patients, 81 (55.9%) were classified as symptomatic because they had a history of TIA or stroke within the 6 months prior to the stenting procedure and 64 (44.1%) were classified as asymptomatic. The baseline characteristics and laboratory parameters of the patients are summarized in Table 1. The mean age was 70.1±8.6 years, 75.2% were male, and 37.9% were hypertensive. One-third of the patients had previous coronary artery bypass grafting surgery, and 38.6% needed coronary revascularization. None of the baseline characteristics revealed a statistically significant difference between symptomatic and asymptomatic patients with the exception that the C-reactive protein level was higher in the symptomatic group. Among the symptomatic patients, percutaneous coronary intervention was more often performed after CAS (38.9%), whereas in the asymptomatic group, it performed at the same rate be-

Table 1. Baseline characteristics and laboratory parameters

Parameters	All patients (n=145)	Symptomatic (n=81)	Asymptomatic (n=64)	*p* value
Age (years)	70.1±8.6	70.0±9.2	70.2±7.9	0.896
Male gender, n (%)	109 (75.2)	57 (70.4)	52 (81.3)	0.132
BMI, kg/m^2	27.8±5.3	28.0±5.3	27.5±5.1	0.563
DM, n (%)	55 (37.9)	29 (35.8)	26 (41.3)	0.503
HT, n (%)	127 (87.6)	70 (86.4)	57 (90.5)	0.454
HL, n (%)	121 (83.4)	68 (84.0)	53 (84.1)	0.977
Previous CABG n (%)	45 (31.0)	22 (27.2)	23 (36.5)	0.230
Previous PCI, n (%)	40 (27.6)	19 (23.5)	21 (33.3)	0.189
CAD, n (%)				
1-vessel disease	44 (30.3)	26 (32.1)	18 (29.3)	0.214
2-vessel disease	30 (20.7)	17 (21.0)	3 (21.0)	
3-vessel disease	22 (15.2)	15 (18.5)	7 (11.3)	
Non-obstructive	39 (26.9)	17 (21.0)	22 (35.5)	
Normal	10 (6.9)	6 (7.4)	4 (3.2)	
Need for coronary revascularization, n (%)				
PCI	56 (38.6)	35 (43.2)	21 (33.3)	0.297
CABG	14 (9.7)	9 (11.1)	5 (7.9)	
No	75 (51.7)	38 (45.7)	37 (58.7)	
Timing of coronary revascularization, n (%)				
Before CAS	30 (20.7)	16 (22.2)	14 (25.9)	0.346
After CAS	42 (29.0)	28 (38.9)	14 (25.9)	
Simultaneous	1 (0.7)	1 (1.4)	–	
AF, n (%)	5 (3.4)	3 (3.7)	2 (3.2)	0.863
Laboratory parameters				
Serum glucose mg/dL median (25th-75th percentile)	110.5 (49.0–359.0)	111.0 (49.0–359.0)	110.0 (68.0–279.0)	0.457
HbA1c (%)	6.8±1.6	6.9±1.8	6.7±1.5	0.785
Creatinine (mg/dL)	0.95±0.26	0.94±0.28	0.96±0.23	0.665
Total cholesterol (mg/dL)	189.9±45.2	188.2±45.1	192.9±45.6	0.619
Triglyceride (mg/dL) median (25th-75th percentile)	158.0 (45.0–862.0)	153.5 (45.0–862.0)	165.0 (55.7–766.0)	0.123
LDL cholesterol (mg/dL)	113.3±36.2	112.6±35.2	114.2±37.7	0.792
HDL cholesterol (mg/dL)	39.0±11.7	38.9±11.5	39.2±12.0	0.860
Hemoglobin (mg/dL)	13.5±1.6	13.4±1.8	13.8±1.3	0.154
Platelet count (x10^3/L)	248.5±68.8	257.6±73.4	236.6±60.8	0.069
CRP	4.4±4.0	4.7±4.1	2.0±1.8	0.041

AF: Atrial fibrillation; CABG: Coronary artery bypass grafting; CAD: Coronary artery disease; CAS: Carotid artery stenting; CRP: C-reactive protein; DM: Diabetes mellitus; HbA1c: Glycated hemoglobin; HDL: High-density lipoprotein; HL: Hyperlipidemia; HT: Hypertension; LDL: Low-density lipoprotein; PCI: Percutaneous coronary intervention.

Table 2. Echocardiographic parameters

Parameters	All patients (n=145)	Symptomatic (n=81)	Asymptomatic (n=64)	*p* value
LVEF (%) median (25^{th}-75^{th} percentile)	60.0 (20.0–68.0)	57.5 (20.0–68.0)	60.0 (25.0–65.0)	0.076
LVEDD (cm)	4.7±0.6	4.8±0.5	4.6±0.7	0.074
LVESD (cm)	3.0±0.7	3.1±0.6	2.9±0.8	0.234
Septal thickness (cm)	1.2±0.23	1.2±0.25	1.1±0.18	0.118
Posterior thickness (cm)	1.1±0.14	1.1±0.15	1.1±0.14	0.536
LA (cm)	4.0±0.5	4.1±0.5	3.9±0.5	0.216
sPAP (mmHg) median (25^{th}-75^{th} percentile)	15.0 (15.0–70.0)	15.0 (15.0–70.0)	15.0 (15.0–45.0)	0.312

LA: Left atrium; LVEDD: Left ventricular end diastolic diameter; LVEF: Left ventricular ejection fraction; LVESD: Left ventricular end systolic diameter; sPAP: Systolic pulmonary artery pressure.

fore (25.9%) and after (25.9%) CAS, without a statistically significant difference between the groups. The echocardiographic parameters of the groups indicated no statistically significant difference (Table 2). The majority of the symptomatic group patients had experienced a stroke (76.5%), while the most common complaints in the asymptomatic group were vertigo, diplopia, and numbness (59.4%).

The procedural features are shown in Table 3. The most common first diagnostic method in both groups was Doppler ultrasonography. In total, 8.3% of the study patients had bilateral lesions, which represented 7.4% of the symptomatic group and 9.5% of the asymptomatic group. In symptomatic patients, CAS was performed within an average of 43.6 (32.0 days (6.0–180.0 days) after a stroke or TIA. A distal EPD was used in 59.2% of the symptomatic patients and in 78.7% of the asymptomatic group. Significantly more proximal EPDs were used in symptomatic patients (45.6%) compared with asymptomatic patients. Procedure-related TIA or stroke was not seen in the asymptomatic group, while stroke was recorded in 2 patients (2.4%) and TIA in 3 patients (3.7%) in the symptomatic group. Hypotension requiring positive inotropes was observed in 10 patients (6.9%) in the entire study population, with no significant difference between the groups. In-hospital death was not observed in any patient. Three of the patients who underwent a control Doppler examination had in-stent restenosis.

Clinical and procedural comparisons of distal and proximal EPDs are shown in Table 4. The severity of stenosis was statistically greater in the proximal EPD group. The majority of patients in the proximal EPD group were symptomatic, and the most common symptom was a stroke. The stent diameter was smaller in the proximal EPD group, and the need for predilatation was greater in the proximal EPD group. No significant difference was observed between the groups in the occurrence of stroke, TIA, or hypotension.

DISCUSSION

The CAS results of our center analyzed in this study revealed a technical success rate of 100% with no in-hospital death and a stroke/TIA complication rate of 3.4%. More than half of the patients were symptomatic. The most common admission complaints in asymptomatic patients were vertigo, diplopia, and numbness. The plaque structure was fibro-fatty in one-third of the patients, and was more common in symptomatic patients. One-third of the patients had a history of coronary artery bypass grafting, and more than one-third of the patients underwent coronary revascularization. Although a distal EPD was used in the majority of the study patients, a proximal EPD was used more often in symptomatic patients.

Despite advances in medical and interventional therapies, stroke continues to be an important problem due to increased survival and the high incidence of vascular risk factors. Some 10% to 15% of all strokes are caused by thromboembolism with 50% to 99% stenosis in the ICA.[4,11] Peripheral vascular stenosis was reported in 0.35% of females and 0.71% of males.[12] Similar

Table 3. Procedural features

Parameters	All patients (n=145)	Symptomatic (n=81)	Asymptomatic (n=64)	*p* value
First symptom, n (%)				
Neurological	81 (55.9)	81 (100.0)	–	
Vertigo-diplopia- numbness	38 (26.2)	–	38 (59.4)	<0.001
Cardiac	13 (9.0)	–	13 (20.3)	
Syncope	3 (2.1)	–	3 (4.7)	
None	10 (6.9)	–	10 (15.6)	
Symptom, n (%)				
Stroke	62 (42.7)	62 (76.5)	–	<0.001
TIA	20 (13.7)	29 (24.5)	–	
None	64 (43.6)	–	64 (100.0)	
First diagnosis, n (%)				
USG	98 (67.6)	60 (74.1)	38 (59.4)	0.244
DSA	32 (22.1)	14 (17.3)	18 (28.1)	
CT	12 (8.3)	5 (6.2)	7 (10.9)	
MRI	3 (2.1)	2 (2.5)	1 (1.6)	
Plaque characteristics on USG, n (%)				
Fibro-fatty	16 (28.1)	13 (38.2)	3 (13.0)	0.115
Calcific	8 (14.0)	4 (11.8)	4 (17.4)	
Mixed	33 (57.9)	17 (50.0)	16 (69.6)	
Doppler velocity median (25^{th}-75^{th} percentile)	280.0 (133.0–600.0)	295.0 (137.0–600.0)	230.0 (133.0–600.0)	0.672
Target stenosis carotid artery, n (%)				
Right carotid artery	69 (47.6)	41 (50.6)	28 (44.4)	0.739
Left carotid artery	64 (44.1)	64 (42.0)	64 (46.0)	
Bilateral	12 (8.3)	6 (7.4)	6 (9.5)	
Lesion severity group, n (%)				
<70	15 (10.4)	9 (11.3)	6 (9.3)	0.221
70–90	42 (29.0)	21 (26.3)	21 (33.9)	
>90	47 (32.4)	30 (37.5)	17 (27.4)	
Bilateral	41 (28.3)	20 (25.0)	21 (33.9)	
Vertebral artery stenosis, n (%)	7 (10.9)	4 (10.5)	3 (11.5)	0.899
Time from stroke to diagnosis (days) median (25^{th}-75^{th} percentile)	–	28.0 (1.0–180.0)	–	NA
Time from stroke to CAS (days) median (25^{th}-75^{th} percentile)	–	32.0 (6.0–180.0)	–	NA
Embolic protection device, n (%)				
Proximal blockage (MoMa)	49 (33.8)	36 (45.6)	13 (21.3)	0.003
Distal filter	96 (66.2)	45 (59.2)	51 (78.7)	
Lesion stenosis, %, mean (SD)	85.2±10.1	85.0±10.9	85.5±9.1	0.764
Closure device, n (%)	63 (43.4)	34 (42.5)	29 (47.5)	0.551
Mean stent proximal diameter (mm)	8.9±1.2	8.8±1.3	9.1±1.0	0.333
Mean stent distal diameter (mm)	7.3±1.1	7.5±1.2	7.2±1.1	0.175
Mean stent length (mm)	37.2±4.4	37.9±4.0	36.3±4.8	0.032
Predilatation, n (%)	96 (66.2)	57 (72.2)	39 (63.9)	0.299
Postdilatation, n (%)	101 (69.7)	54 (68.4)	47 (77.0)	0.255
Complication, n (%)				
Stroke	2 (1.4)	2 (2.4)	–	0.060
TIA	3 (2.0)	3 (3.7)	–	
Hypotension, n (%)	10 (6.9)	6 (7.5)	4 (6.6)	0.156
Control USG, n (%) ISR	3 (7.9)	2 (8.6)	1 (6.7)	0.688

CAS: Carotid artery stenting; CT: Computed tomography; DSA: Digital subtraction angiography; ISR: In-stent restenosis; ISR: In-stent restenosis; MRI: Magnetic resonance imaging; TIA: Transient ischemic attack; USG: Ultrasonography. (MoMA; Invatec S.p.A., Roncadelle, Italy).

Table 4. Comparison of proximal and distal embolic protection devices

Parameters	Proximal EPD (n=49)	Distal EPD (n=96)	*p* value
Symptomatic, n (%)	36 (73.5)	44 (47.3)	0.003
Symptom, n (%)			
Stroke	27 (55.1)	33 (36.3)	0.017
Transient ischemic attack	9 (18.4)	11 (12.1)	
None	13 (26.5)	47 (51.6)	
Plaque characteristic on ultrasonography, n (%)			
Fibro-fatty	8 (36.4)	8 (22.9)	0.016
Calcific	6 (27.3)	2 (5.7)	
Mixed	8 (36.4)	25 (71.4)	
Target stenosis carotid artery, n (%)			
Right carotid artery	22 (44.9)	45 (49.5)	0.557
Left carotid artery	24 (49.0)	37 (40.7)	
Bilateral	3 (6.1)	9 (9.9)	
Lesion severity group, n (%)			
<70	4 (8.2)	7 (7.9)	<0.001
70–90	7 (14.3)	34 (38.2)	
>90	28 (57.1)	18 (20.2)	
Bilateral	10 (20.4)	30 (33.7)	
Lesion stenosis, %, (mean±SD)	88.0±11.2	83.9±8.9	0.023
Mean stent proximal diameter (mm)	8.6±1.4	9.1±1.0	0.010
Mean stent distal diameter (mm)	7.6±1.3	7.2±1.0	0.042
Mean stent length (mm)	37.9±4.0	36.8±4.6	0.179
Predilatation, n (%)	39 (79.6)	57 (62.6)	0.039
Postdilatation, n (%)	35 (71.4)	66 (72.5)	0.890
Complication, n (%)			
Stroke	1 (2.0)	1 (1.1)	0.480
Transient ischemic attack	–	4 (3.1)	
Hypotension	4 (8.2)	6 (6.6)	
Control ultrasonography, n (%)			
In-stent restenosis	3 (15.8)	–	0.196

EPD: Embolic protection device; SD: Standard deviation.

to reports in the literature, the majority of patients in our study were men. CAS and CAE are the current options for revascularization, and studies have shown that these methods have different safety profiles. Periprocedural minor stroke is seen more often in CAS, while higher rates of periprocedural MI and postoperative cranial nerve paralysis occur in CEA. The guidelines state that to perform CAS, the risk of complication should be <3% for asymptomatic patients and <6% for symptomatic patients.[4] In our study, the complication rate was 3.4% in the entire study population, with 6.1% in the symptomatic group and no stroke/TIA in the asymptomatic group. These rates are better than the results in most registry or single-center studies. In some national CAS registry studies, the stroke/death rates remained under 3%, while others had different results. In a review of large registries (more than 1.5 million CAS procedures), the stroke/death rates exceeded 3% in 40% of the studies, and more than 5% in 14%.[13–15]

The management of symptomatic patients is more precise, while the management of patients with as-

ymptomatic carotid artery stenosis is more controversial.[4] Recent guidelines and advances in the medical treatment of asymptomatic carotid stenosis highlight the need for a more cautious approach to revascularization.[4,5] The recommendations in the guidelines are based on studies conducted 2 to 3 decades ago. There are serious differences between the medical treatment used in early studies and current modern medical treatment. New pharmacological and technological developments have increased the practicability of CAS.[5] There is no randomized trial comparing CAS and medical therapy, and there is no clear standardization in CEA and CAS studies.[7,8] Technical factors, such as operator experience with stenting, the use of EPDs, and parameters like MI and cranial nerve injury at primary endpoints that could affect the results of the studies were not included. The Carotid Revascularization and Medical Management for Asymptomatic Carotid Stenosis Trial (CREST-2; CEA plus intensive medical therapy [IMT] vs. IMT alone and CAS plus IMT vs. IMT alone) and an accompanying registry, as well as the Stent-Protected Angioplasty versus Carotid Endarterectomy (SPACE-2) randomized controlled trial (best medical treatment [BMT] alone vs. CEA plus BMT vs. CAS plus BMT, ISRCTN 78592017) are examples of new research.[16,17] An important study related to the CREST-2 registry was published in late 2019.[18] In contrast to the CREST-2 registry, both symptomatic (44.9%) and asymptomatic patients (55.1%) were included in this study. The patients were provided with optimal medical treatment (hypertension, hyperlipidemia, dual antiplatelet) before the procedure, and attention was paid to technical details, such as proper blood pressure control, use of an EPD, short filter time, and the use of closed-cell stents. We have been performing CAS in our clinic since 2009 and have been applying most of these parameters for a long time. Since we are a teaching facility, some interventionists have been able to complete the learning curve at our center. All of these cases are considered the equivalent of cardiovascular disease, aggressive risk factor modification is performed, and concomitant diseases (such as diabetes mellitus, hypertension, hyperlipidemia, etc.) are treated according to the guidelines. In addition, all patients receive effective dual antiplatelet therapy before the CAS procedure. The CREST-2 registry, which included 2114 patients, had a stroke/death rate outcome of 2.8% among the 961 patients with symptomatic carotid stenosis, and 1.4% among the 1180 patients with asymptomatic carotid stenosis. These rates are seen as good results that have not been seen in randomized trials.

The use of an EPD has repeatedly been shown to prevent thromboembolism and subsequent strokes caused by the detachment of carotid plaque particles during CAS.[19,20] Various EPDs have been produced using filters and guidewire-appended balloons. Distal filter EPDs and proximal EPDs are the most commonly used. To date, the routine use of an EPD in

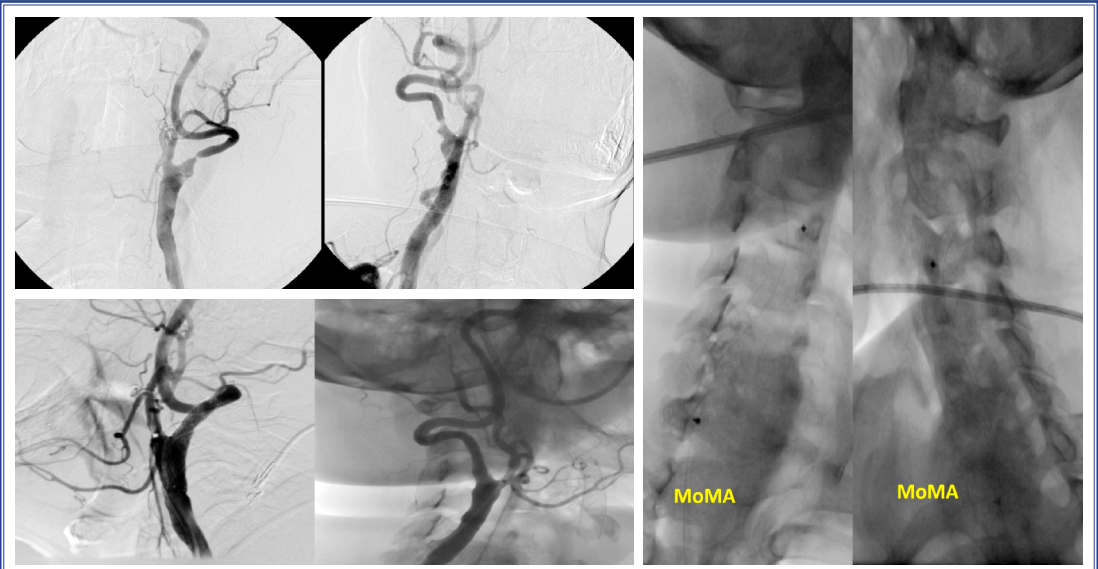

Figure 1. Bilateral carotid artery stenosis in a patient before and after stenting with a proximal embolic protection device (MoMA; Invatec S.p.A., Roncadelle, Italy).

CAS continues to be a subject of research, although the European Society of Cardiology/ European Society for Vascular Surgery 2017 guidelines suggest that an EPD should be considered in patients undergoing CAS (class IIa, level of evidence C).[4] Schmidt et al.[21] reported that compared with a distal EPD device, a proximal EPD system significantly decreased the microembolic signal count during the procedural phases of wire passage of the stenosis, balloon dilation, stent implantation, and overall. In practice, a proximal EPD is often not used sufficiently as a result of some related difficulties, but it was used without hesitation when necessary in our study (Fig. 1). Open-cell stents accommodate well to the shape of the vessel, making delivery easier, but physically cover less of the target lesion, potentially posing a higher risk of embolization as debris material may prolapse into the stent struts. Closed-cell stents can bend vessels if implanted inappropriately. Hybrid stents that merge features of open-cell and closed-cell stents are also available. There are not yet enough randomized studies of the different stent types. Hybrid stents were frequently used in our study, although we do not know the distribution between the groups in detail.

The main limitations of our study are the retrospective design and the relatively small numbers. Nonetheless, the results represent valuable real-word experience with all-comer patients treated for carotid artery disease at a tertiary center. The absence of post-processing brain magnetic resonance imagining, especially to detect silent ischemia, is another limiting factor.

Conclusion

To summarize, important points in a CAS procedure include the equipment, the multidisciplinary functioning capability of the facility, the education and experience of the interventionist, and patient selection. In addition, the use of an EPD, appropriate blood pressure control, stent selection, and close follow-up after the procedure are necessary to achieve low complication rates. Centers can manage the treatment of patients with carotid stenosis by observing these criteria and monitoring the complication rates with a registry system. The results of the present study suggest that CAS is a safe and effective alternative to CEA when performed in high-volume, experienced centers with an EPD and optimal medical therapy.

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REFERENCES

1. Benjamin EJ, Blaha MJ, Chiuve SE, Cushman M, Das SR, Deo R, et al; American Heart Association Statistics Committee and Stroke Statistics Subcommittee. Heart Disease and Stroke Statistics-2017 Update: A Report From the American Heart Association. Circulation 2017;135:e146–e603. [CrossRef]
2. Sardar P, Chatterjee S, Aronow HD, Kundu A, Ramchand P, Mukherjee D, et al. Carotid Artery Stenting Versus Endarterectomy for Stroke Prevention: A Meta-Analysis of Clinical Trials. J Am Coll Cardiol 2017;69:2266–75. [CrossRef]
3. Diao Z, Jia G, Wu W, Wang C. Carotid endarterectomy versus carotid angioplasty for stroke prevention: a systematic review and meta-analysis. J Cardiothorac Surg 2016;11:142. [CrossRef]
4. Aboyans V, Ricco JB, Bartelink MEL, Björck M, Brodmann M, Cohnert T, et al; ESC Scientific Document Group. 2017 ESC Guidelines on the Diagnosis and Treatment of Peripheral Arterial Diseases, in collaboration with the European Society for Vascular Surgery (ESVS): Document covering atherosclerotic disease of extracranial carotid and vertebral, mesenteric, renal, upper and lower extremity arteriesEndorsed by: the European Stroke Organization (ESO)The Task Force for the Diagnosis and Treatment of Peripheral Arterial Diseases of the European Society of Cardiology (ESC) and of the European Society for Vascular Surgery (ESVS). Eur Heart J 2018;39:763–816.
5. Mohler ER, Fairman RM. Management of asymptomatic carotid atherosclerotic disease. UpToDate, Wolters Kluwer. Available at: https:// www.uptodate.com/ contents/ management-of-asymptomatic-carotid-atherosclerotic-disease?search= management-of-asymptomatic-carotid-atherosclerotic%20disease,&source=search_result&selectedTitle=1~150&usage_type=default&display_rank=1 Accessed Oct 11, 2017.
6. Bonati LH, Jongen LM, Haller S, Flach HZ, Dobson J, Nederkoorn PJ, et al; ICSS-MRI study group. New ischaemic brain lesions on MRI after stenting or endarterectomy for sympto-

matic carotid stenosis: a substudy of the International Carotid Stenting Study (ICSS). Lancet Neurol 2010;9:353–62.
7. Kuliha M, Roubec M, Procházka V, Jonszta T, Hrbáč T, Havelka J, et al. Randomized clinical trial comparing neurological outcomes after carotid endarterectomy or stenting. Br J Surg 2015;102:194–201. [CrossRef]
8. Brott TG, Howard G, Roubin GS, Meschia JF, Mackey A, Brooks W, et al; CREST Investigators. Long-Term Results of Stenting versus Endarterectomy for Carotid-Artery Stenosis. N Engl J Med 2016;374:1021–31. [CrossRef]
9. Bonati LH, Dobson J, Featherstone RL, Ederle J, van der Worp HB, de Borst GJ, et al; International Carotid Stenting Study investigators. Long-term outcomes after stenting versus endarterectomy for treatment of symptomatic carotid stenosis: the International Carotid Stenting Study (ICSS) randomised trial. Lancet 2015;385:529–38. [CrossRef]
10. North American Symptomatic Carotid Endarterectomy Trial (NASCET) investigators. Clinical alert: benefit of carotid endarterectomy for patients with high-grade stenosis of the internal carotid artery. National Institute of Neurological Disorders and Stroke Stroke and Trauma Division. Stroke 1991;22:816–7. [CrossRef]
11. Roger VL, Go AS, Lloyd-Jones DM, Adams RJ, Berry JD, Brown TM, et al; American Heart Association Statistics Committee and Stroke Statistics Subcommittee. Heart disease and stroke statistics-2011 update: a report from the American Heart Association. Circulation 2011;123:e18–e209.
12. Kannel WB, McGee DL. Update on some epidemiologic features of intermittent claudication: the Framingham Study. J Am Geriatr Soc 1985;33:13–8. [CrossRef]
13. Kallmayer MA, Tsantilas P, Knappich C, Haller B, Storck M, Stadlbauer T, et al. Patient characteristics and outcomes of carotid endarterectomy and carotid artery stenting: analysis of the German mandatory national quality assurance registry - 2003 to 2014. J Cardiovasc Surg (Torino) 2015;56:827–36.
14. Werner N, Zeymer U, Hochadel M, Hauptmann KE, Jung J, Janicke I, et al; Arbeitsgemeinschaft Leitende Kardiologische Krankenhausärzte, Rheinland-Pfalz, Germany. Fifteen-year experience with carotid artery stenting (from the carotid artery stenting-registry of the Arbeitsgemeinschaft Leitende Kardiologische Krankenhausärzte). Am J Cardiol 2015;115:360–6.
15. Paraskevas KI, Kalmykov EL, Naylor AR. Stroke/Death Rates Following Carotid Artery Stenting and Carotid Endarterectomy in Contemporary Administrative Dataset Registries: A Systematic Review. Eur J Vasc Endovasc Surg 2016;51:3–12.
16. Howard VJ, Meschia JF, Lal BK, Turan TN, Roubin GS, Brown RD Jr, et al; CREST-2 study investigators. Carotid revascularization and medical management for asymptomatic carotid stenosis: Protocol of the CREST-2 clinical trials. Int J Stroke 2017;12:770–8. [CrossRef]
17. Eckstein HH, Reiff T, Ringleb P, Jansen O, Mansmann U, Hacke W; SPACE 2 Investigators. SPACE-2: A Missed Opportunity to Compare Carotid Endarterectomy, Carotid Stenting, and Best Medical Treatment in Patients with Asymptomatic Carotid Stenoses. Eur J Vasc Endovasc Surg 2016;51:761–5.
18. Lal BK, Roubin GS, Rosenfield K, Heck D, Jones M, Jankowitz B, et al. Quality Assurance for Carotid Stenting in the CREST-2 Registry. J Am Coll Cardiol 2019;74:3071–9.
19. Wholey MH, Al-Mubarek N, Wholey MH. Updated review of the global carotid artery stent registry. Catheter Cardiovasc Interv 2003;60:259–66. [CrossRef]
20. Mas JL, Trinquart L, Leys D, Albucher JF, Rousseau H, Viguier A, et al; EVA-3S investigators. Endarterectomy Versus Angioplasty in Patients with Symptomatic Severe Carotid Stenosis (EVA-3S) trial: results up to 4 years from a randomised, multicentre trial. Lancet Neurol 2008;7:885–92. [CrossRef]
21. Schmidt A, Diederich KW, Scheinert S, Bräunlich S, Olenburger T, Biamino G, et al. Effect of two different neuroprotection systems on microembolization during carotid artery stenting. J Am Coll Cardiol 2004;44:1966–9. [CrossRef]

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Anahtar sözcükler: Karotis arter stenozu; karotis arter stentlemesi; emboli koruma cihazı; inme.