

Carotid artery stenting without embolic protection device: a single center experience

Emboli koruyucu cihaz kullanmadan karotid arter stentleme: tek merkez deneyimi

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Abstract

Purpose: Carotid artery stenting (CAS) is a frequently used method in carotid artery stenosis. There are many publications in the literature regarding whether or not embolic protection devices (EPD) should be used during carotid stenting. In this study, we reported the short- to mid-term results of our patients in whom we did not use EPDs during carotid stenting procedure.

Materials and methods: We retrospectively analyzed patients who underwent carotid artery stenting between June 2022 and June 2025 in our clinic. The patient's clinical characteristics and procedural data were obtained by scanning patient files.

Results: Sixty patients were included in the study. The average age of the patients was 70±9. Fifty five patients underwent stenting under local anesthesia and 5 under general anesthesia. Right carotid artery in 12 patients, left carotid artery in 40 patients, and bilateral carotid artery stenting was performed in 8 patients. Self-expandable stents were used in all patients. But, EPDs were not used in any of the procedures. Patients were followed up for 11±5 (minimum 1-maximum 24) months for recurrent stroke and death. No recurrent stroke or death was detected in any patient during the follow-up period. Transient ischemic attack (TIA) was only seen in a patient.

Conclusion: CAS is successfully performed without the use of embolic protection devices in experienced centers.

Keywords: Carotid artery stenosis, carotid artery stenting, anti-embolic device.

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Öz

Amaç: Karotis arter stentleme (KAS), karotis arter stenozunda sık kullanılan bir yöntemdir. Literatürde karotis stentleme sırasında emboli koruyucu cihazların kullanılıp kullanılmayacağı konusunda birçok yayın vardır. Bu çalışmada, karotis stent işlemi sırasında emboli koruyucu cihaz kullanmadığımız hastalarımızın kısa-orta süreli sonuçlarını bildirdik.

Gereç ve yöntem: Kliniğimizde Haziran 2022 ile Haziran 2025 arasında karotis arter stenti uygulanan hastaları retrospektif olarak analiz ettik. Hastaların klinik özellikleri ve prosedürel verileri, hasta dosyaları taranarak elde edildi.

Bulgular: Çalışmaya 60 hasta dahil edildi. Hastaların yaş ortalaması 70±9 idi olup 55 hastaya lokal anestezi ve 5 hastaya genel anestezi altında işlem yapıldı. 12 hastada sağ karotis arter, 40 hastada sol karotis arter ve 8 hastada bilateral karotis arter stentleme yapıldı. Tüm hastalarda kendi açılabilir stentler kullanıldı. Hiçbir prosedürde emboli koruyucu cihaz kullanılmadı. Hastalar tekrarlayan inme ve ölüm açısından 11±5 (minimum 1-maksimum 24) ay takip edildi. Takip süresi boyunca hiçbir hastada tekrarlayan inme veya ölüm tespit edilmedi. Sadece bir hastada geçici iskemik atak (GİA) tespit edildi.

Sonuç: Deneyimli merkezlerde KAS, emboli koruyucu cihaz kullanılmadan başarıyla gerçekleştirilebilir.

Anahtar kelimeler: Karotis arter stenozu, karotis arter stentleme, emboli koruyucu cihaz.

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Introduction

Stroke is the third leading cause of death and the most important cause of long-term disability [1]. Approximately 20% of ischemic strokes are caused by carotid artery stenosis [2]. Carotid artery endarterectomy (CAE) together with medical treatment was previously the main treatment option in the past, but today, carotid artery stenting (CAS) has begun to be used with increasing frequency with technological advances [3]. In parallel with these developments, there are different approaches in different centers that treat CAS. The most important of these differences is the use of embolic protection devices (EPD). In this study, we tried to present the short- to mid-term clinical results, such as transient ischemic attack (TIA), stroke or death, of stent application without the use of EPD in patients diagnosed with carotid artery disease who applied to our clinic and were decided to undergo revascularization.

Materials and methods

Between June 2022 and June 2025, sixty patients who were symptomatic (ischemic stroke or TIA within the last 6 months) and had angiographically >50% stenosis in the carotid artery or were asymptomatic and had >60% stenosis in the carotid artery were included in the study. The degree of internal carotid artery stenosis was measured according to NASCET (North American Symptomatic Carotid Endarterectomy Trial) criteria. This study was approved by Non-Interventional Clinical Research Ethics Committee of Pamukkale University. All patients were informed in detail about the intervention and written informed consent was obtained from the patients.

Patients with total stenosis detected on imaging were not included in the study. In addition, patients with intracranial lesions and in whom dual antiplatelet therapy is contraindicated were excluded from the study. Clinical characteristics of all patients, such as age, gender, hypertension, diabetes, hyperlipidemia and smoking, were obtained from patient files and hospital records.

Study protocol

Carotid artery doppler ultrasonography (USG) was performed before carotid angiographic examination to determine the degree of carotid artery stenosis in all patients included in the study. The patients included in the study underwent a full neurological examination by an independent neurologist before and within 24 hours after the procedure. Patients underwent cranial Computed tomography (CT) or Magnetic Resonance Imaging (MRI) before the procedure, and these procedures were repeated for patients who described any neurological changes after the carotid artery stenting procedure. All patients were loaded with 300 mg acetylsalicylic acid (ASA) and 450 mg clopidogrel before the procedure and given dual antiplatelet therapy for 6 months, then continued with 100 mg ASA. Then, all patients were evaluated with carotid doppler USG at 3, 6 and 12 months.

Angiographic procedures

After the patients were prepared for the procedure, a 6F vascular sheath was placed in the femoral artery. Heart rate and blood pressure were monitored throughout the procedure. Unfractionated heparin was administered intravenously at a bolus dose of 70 U/kg. A vertebral catheter and/or 5F Simmon catheter were used to selectively visualize each of the carotid arteries. A 0.035-inch hydrophilic wire with a diagnostic catheter was guided into the external carotid artery using a roadmap. The wire was left in place and the diagnostic catheter was removed. Afterwards, an 8F long sheath catheter (Boston Scientific, USA) was placed in the common carotid artery and the hard wire was removed.

Before the procedure, cranial vessels were evaluated in anterior and lateral views and the venous phase was visualized. Then, a 0.014-inch micro wire was inserted into the distal part of the stenosis in the internal carotid artery and a self-expandable stent (Protégé™ RX Tapered, Medtronic) suitable for the appropriate vascular structure was placed over it. Afterwards, correct stent placement was evaluated with contrast

injection. Then, if residual stenosis was detected to be more than 30%, balloon angioplasty was performed. 1 mg atropine administered intravenously to the patients before balloon inflation and/or stent placement to prevent the development of hypotension and bradycardia. At the end of the procedure, AP and lateral

cranial imaging were performed again and the procedure was concluded (Figure 1). In patients with bilateral stenosis, the steps were started on the side with the greater degree of stenosis, and then these steps were repeated for the other side.

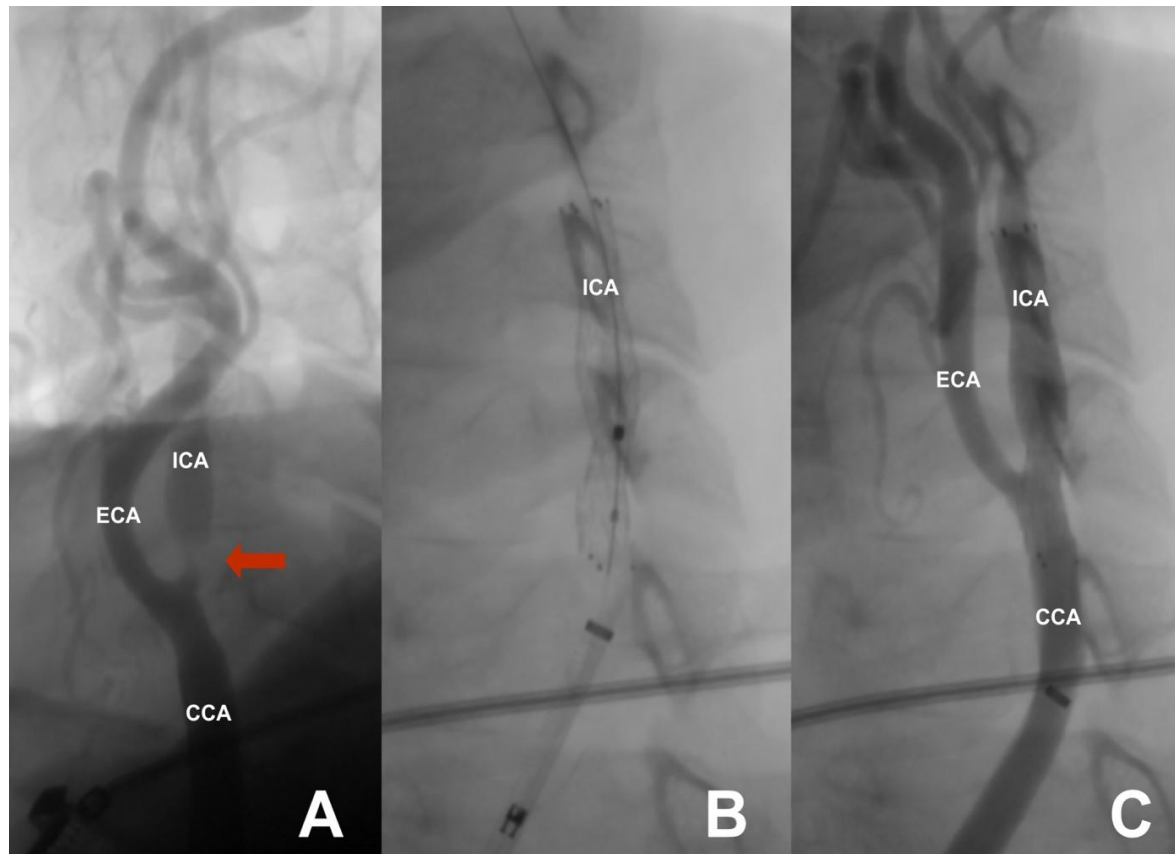


Figure 1. Carotid artery stenting performed using self expandable-stent. A) Highly stenotic internal carotid artery (Red Arrow). B) Balloon-assisted angioplasty without embolic protection device. C) Final result with revascularized carotid artery

(CCA: Common Carotid Artery, ICA: Internal Carotid Artery, ECA: External Carotid Artery)

Statistical analysis

Data analysis was done using the SPSS 28 package program. The conformity of the variables to normal distribution was determined using the Kolmogorov-Smirnov test. Continuous variables showing normal distribution were expressed as mean $\pm$ standard deviation, those not showing normal distribution were expressed as median (minimum and maximum values). Categorical data were expressed as

percentages. Comparative analyses were not performed because there was no control group.

Results

A total of 60 patients, 44 male and 16 female, were included in the study. The average age of these patients was 70 ± 9 . Hypertension was found in 70% of the patients, diabetes mellitus in 37%, hyperlipidemia in 23%, coronary artery disease in 27% and active smoking in 23% (Table 1).

Table 1. Clinical characteristics of the patients

Parameter	Number / Percentage
Age (mean $\pm$ SD)	70 $\pm$ 9
Male	44 (73%)
Female	16 (27%)
Smoking	14 (23%)
Coronary Artery Disease	16 (27%)
Hypertension	42 (70%)
Hyperlipidemia	14 (23%)
Diabetes Mellitus	22 (37%)
Cerebrovascular Disease*	44 (73%)

* Symptomatic patients with ischemic stroke or TIA within 6 months preceding intervention

55 patients underwent the procedure under local anesthesia, and 5 patients under general anesthesia because they could not cooperate. Self-expandable stents were used in all patients. A total of 68 successful carotid stenting procedures were performed in 60 patients, including 40 left, 12 right and 8 bilateral carotid stenting in the same session (Table 2). EPDs were not used in any of the procedures (including 8 bilateral same-session cases). There was no stroke or death during and after the procedure (0/60 patients, 0%; 0/68 procedures, 0%). Only one patient who received general anesthesia had unilateral upper extremity weakness while the patient was extubating. Angiographic imaging was performed immediately again. Although no vascular occlusion was detected,

tirofiban (Agrastat, 12.5 mg/50 ml) irrigation was performed and the procedure was terminated. When the patient completely recovered from the effects of anesthesia, the weakness also improved. We accepted this condition as a TIA. Thus, the TIA rate of 1.47% (1/68 procedures) was found to be consistent with the literature. No significant diffusion restriction was detected in the control diffusion MRI. Procedure-related bleeding complications or hypotension requiring inotropic support were not observed in the patients and all patients were discharged alive. Patients were followed up for 11 $\pm$ 5 (minimum 1-maximum 24) months for recurrent stroke and death. Thromboembolism was not detected in any patient during the follow-up period, except the patient who had periprocedural TIA.

Table 2. Features related to carotid artery stenting procedure

Parameter	Value
Degree of stenosis (mean), %	70%
Side (Left, Right, Bilateral), n	40 / 12 / 8
Stent length, mm	40
Stent proximal diameter, mm	8
Stent distal diameter, mm	6
Type of stent	Self expandable

Discussion

Atherosclerosis is the most common cause of carotid artery stenosis. Various cranial thromboembolisms that occur as a result of this stenosis in the carotid artery cause mortality and permanent disabilities [4, 5]. For this reason, various treatment options have been developed. CAE is still one of the most frequently used treatment methods today. However, patients with carotid artery stenosis have high risk of surgery because they are elderly and have comorbid diseases. In our study, the average age of the patients was 70 years, with 70% having hypertension, 27% having coronary artery disease and one in three patients having diabetes mellitus. Most part of patients (73%) had a stroke or TIA attack before the procedure. Alternative treatment options have been developed due to comorbid diseases and older age. For this purpose, the first carotid artery balloon angioplasty was performed in 1980 [6]. Later, CAS treatment was preferred only in patients with high surgical risk. However, later studies conducted in parallel with the developments in medical treatment, device technology and interventional radiology showed a significant decrease in mortality and recurrent ischemic stroke (from 7% to 2%) risk in CAS treatment [7-10]. Therefore, the use of CAS in carotid artery stenosis is increasing in daily practice [11]. As a result of all these, it has been stated in various guidelines that CAS treatment is an alternative treatment for CAE, especially in high-risk patients [12].

Cranial thromboembolism is one of the important complication associated with carotid artery stenting which may occur during or after the procedure [13]. In addition, complications related to the access site, bleeding, myocardial infarction and death are other important complications. Although most patients in our patient group were symptomatic and had lesions that increased the risk of thromboembolism, such as severe thrombosed stenosis, none of the our patients had thromboembolism. Only one of our patients who underwent the procedure under general anesthesia had upper extremity weakness when he is extubating at the

end of the procedure. The weakness improved, when the patient completely recovered from the effects of anesthesia. We did not use an EPD in any of our patients. Restenosis was observed in a control angiogram 6 months after stenting in one of our patients. An EPD was used only in this patient who underwent in-stent balloon angioplasty for restenosis.

When we look at the literature, there are many studies comparing the use of EPD or not [14-16]. Although the use of EPD seems theoretically logical, but the results may vary in practice. In particular, in their 279-patient multicenter CASWEP trial published in 2022, Gorgulu et al. [17] showed that CAS without carotid protection device (CPD) was not associated with a higher rate of periprocedural TIA, stroke, and death or new ischemic brain lesions on postprocedural DW-MRI compared to CAS with CPD [17]. Additionally, anti-embolic devices require more maneuvering, especially in cases of vascular tortuosity and severe atherosclerosis so this situation may increase emboli release or other complications such as dissection or vasospasm [18-20]. Therefore, we believe that the experience in the CAS procedure and the use of the correct medication before and during the procedure are very important.

Limitations of the study

It should be noted that the most important limitation of this study is that it is a single-center, retrospective study and the number of patients is significantly small. Another important limitation is the lack of comparative data on CAS with EPD and without EPD. The lack of post-procedural DW-MRI control is also a limitation. Moreover, we report outcomes per-patient as primary analysis; per-procedure rates are identical in our series but may differ in larger studies with bilateral procedures.

In conclusion, as a result, CAS is successfully applied in our center. When CAS is performed by an experienced operator with the right medication, also without using distal embolism protection devices, the procedure may be performed safely. The short- to mid-term clinical results of the procedure are satisfactory.

Declaration of Conflicting Interests and Ethics: The authors declare that they have no known competing financial or personal relationships that could be viewed as influencing the work reported in this paper and the Pamukkale University Non-Interventional Clinical Research Ethics Committee approved this study (approval reference date and number: 12.12.2024 and E-60116787-020-623324).

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