# Carotid artery stenting without using any embolic protective device

## A single Centre experience

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**Carotid artery stenting without using any embolic protective device. A single Centre experience**

INTRODUCTION: *Despite the use of embolic protective devices in the majority of cases applied with carotid stenting to prevent embolic neurological complications related to the carotid stenting procedure, this procedure is applied to some cases without protection. The aim of this study was to present the clinical outcomes of carotid artery stent application without a cerebral embolism protective device.*
MATERIAL AND METHOD: *A retrospective examination was made of a total of 171 patients applied with a stent between 2014 and 2017. The patients included in the study were applied with a stent because they were symptomatic and determined with >50% narrowing in the carotid artery on angiography or asymptomatic with >60% narrowing. The degree of carotid artery narrowing was determined with Doppler ultrasonography before angiographic examination and with the North American symptomatic carotid endarterectomy trial measurement criteria during angiography. After stenting the carotid artery, patients were observed at the hospital for 24 hours*
RESULTS: *In 10 (5.8%) patients, there was a mid cerebral artery branch infarct ipsilateral to the stent. No reperfusion bleeding was observed in any patient. In 5 (2.9%) patients, encephalopathy and agitation not exceeding 24 hours was observed. Hypotension was determined in 8 (4.6%) patients and headache lasting <24 hours in 53 (31%) patients. 1 (0.5%) patient, rectus abdominis bleeding developed one week after the procedure and within 24 hours, the patient was exitus.*
CONCLUSION: *Revascularisation interventions to be able to prevent the development of stroke are evaluated as important treatment options in patients with symptomatic or severe carotid stenosis. With careful patient selection in experienced centres and a multi-disciplinary approach both before and after the procedure, pleasing results can be obtained without the use of embolic protective devices.*

KEY WORDS: Carotid artery stenting, Embolic protective device, Stroke

## Introduction

Stroke is a significant cause of hospitalisation and death in western societies and is the second leading cause of death worldwide. Endovascular treatment for carotid artery disease has become a potentially safer and less invasive alternative method compared to endarterectomy. As carotid stenting is minimally invasive, it could be a more reliable treatmnt option, especially in the high-risk patient group [1-4]. Despite the use of embolic protective devices (EPD) in the majority of cases applied with carotid stenting to prevent embolic neurological complications related to the carotid stenting procedure, this procedure is applied to some cases without protection [5,6]. EPDs provide protection to reduce the risk of stroke, but even with this, procedural cerebral embolisation casts a shadow onthe success of carotid arterial stenting. Moreover, some studies have reported various complica-

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tions related to the used of EPD [7-10]. The aim of this study was to present the clinical outcomes of stent application without using a cerebral embolism protective device in 171 patients who presented at our centre and were deemed suitable for revascularisation because of carotid artery narrowing.

## Material and Method

A retrospective examination was made of 171 patients who were applied with a stent in the Interventional Vascular Neurology Clinic of Gaziantep University Medical Faculty Hospital between 2014 and 2017. The patients included in the study were applied with a stent because they were symptomatic and determined with >50% narrowing in the carotid artery on angiography or asymptomatic with >60% narrowing. For the patients planned to undergo stenting, paired anti-aggregant treatment (acetylsalicylic acid 300mg+ clopidogrel 75mg) was started one week before the procedure and was continued for 6 months. If there was no significant thrombus in the internal carotid stenosis segment, stenting was performed without the use of protection devices.

Thirteen patients with symptomatic or severe stenosis were treated with carotid endarterectomy because of contraindication of antiaggregation use, anatomic non-compliance for stenting (internal carotid artery carotid artery separation at right angle, inappropriate aortic arch) or self-wish. Nine patients underwent stenting using proximal or distal preservation methods because of the clotted appearance in the stenosis of the internal carotid artery. Patients with endarterectomy and protection devices were not included in the study. The demographic features of the patients, such as age and gender and vascular risk factors such as hypertension, hyperlipidemia and smoking were obtained from the hospital records. Symptomatic carotid artery narrowing was defined as a permanent or transient ischemic attack experienced within 6 months prior to the procedure.

A transient ischemic attack was evaluated as a stroke that recovered without sequelae within 24 hours. All the patients included in the study were examined with electrocardiogram and laboratory blood tests. The degree of carotid artery narrowing was determined with Doppler ultrasonography before angiographic examination and with the North American symptomatic carotid endarterectomy trial measurement criteria during angiography (NASCET collaborators) [11].

Before the procedure, the patients were evaluated with cranial computed tomography (CT) or magnetic resonance imaging (MRI). After stenting the carotid artery, patients were observed at the hospital for 24 hours. If new neurological dysfunction is present, CT or MRI is repeated. Otherwise imaging was not taken. After one week and one month after discharge, the patients were recalled and the examinations repeated. If there are new complications, it is recorded. In the angiographic procedures, a 7F sheath was placed on the right or left femoral artery and throughout the procedure, heartrate and blood pressure were monitored. A 70 U/kg bolus of unfractioned heparin was administered intravenously. As none of the carotid arteries could be visualised selectively, a diagnostic vertebral catheter (Cordis, USA), a right Judkins coronary catheter (Cordis, USA) and/or a 5F Simmon catheter (Cordis, USA) was used according to the variative status of the vascular structure. Under road-map guidance and with the aid of the diagnostic catheter, a 0.035 hydrophilic wire was placed in the external carotid artery. Leaving the wire in place, the diagnostic catheter was removed. Then, a 6F-7F wide lumen envoy catheter (Cordis, USA) was placed over the wire in the main carotid artery and the wire was removed. Before the procedure, the cranial vessels were evaluated on anterior and lateral images. Embolism protective devices were not used in any of the patients in the study. Balloon pre-dilatation (Simpass) was applied to patients with severe narrowing or with complex lesions where it was thought that the stent may not be able to be easily advanced. Then the stent was placed with appropriate localisation (Precise Cordis, USA, Boston Scientific Wall stent, USA). When residual narrowness was determined, post-dilatation with a balloon of appropriate dimensions was applied. During and after the stenting procedure, patients who developed bradycardia (pulse <40 or a reduction of ≤ 50% up to 24 hrs) or hypotension (systolic blood pressure <90 mmHg or mean arterial pressure < 50 mmHg) were recorded. At the end of the procedure, anterior posterior and lateral cranial angiographic images were taken again and the procedure was concluded. (Angiogram images of the patient with bilateral carotid artery stenosis before and after stenting. Angiogram images [1-3].

## Results

The study included 171 patients applied with carotid stent. The patients comprised 110 males and 60 females with a mean age of 67 years (range, 25-82 years). Vascular isk factors were determined as a history of stroke in 97 (56.7%) patients, hypertension in 112 (65.49%), hyperlipidemia in 47 (27.4%), diabetes in 66 (38.59%), smoking in 96 (56.1%), heart failure in 13 (7.6%), atrial fibrillation in 4 (2.3%), coronary artery disease in 58 (33.9%), and cardiac valve disease in 5 (2.9%) (Table I). Anti-aggregants had been previously used for other reasons by 146 (85.3%) patients and anticoagulants by 6 (3.5%).

The localisation of the applied stents was right-side internal cerebral artery (ICA) in 83 (48.5%) patients, left-side ICA in 96 (56.1%) and bilateral ICA in 8 (4.6%). A total of 16 (9.3%) stents were placed in the intracranial carotid segment. Pre or post balloon dilatation was

TABLE I - *Vascular risk factors*

| Risk factor | Male n =110 | Female n =61 | Total n =171 |
|---|---|---|---|
| Stroke history | 68(%61.8) | 29(%47.5) | 97(%56.7) |
| Hypertension | 70(%63.6) | 42(%68.8) | 112(%65.4) |
| Diabetes | 39(%35.4) | 27(%44.2) | 66(%38.5) |
| Hyperlipidemia | 19(%17.2) | 28(%45.9) | 47(%27.4) |
| Cigaret | 67(%60.9) | 29(%47.5) | 96(%56) |
| Heart failure | 11(%10) | 2(%3.2) | 13(%7.6) |
| Atrialfibrilasyo | 2((%1.8) | 2(%3.2) | 4(%2.3) |
| Coronary artery disease | 43(%39) | 15(%24.5) | 58(%33.9) |
| Heart valve disease | 3(%2.7) | 2(%3.2) | 5(%2.9) |
| Antiplatelet Anticoagulant | 98(%88.1) 5(%4.5) | 48(%78.6) 1(%1.63) | 146(%85.3) 6(%3.5) |

TABLE II - *Patients' intracranial and extra cranial stenosis grades*

| Angiographystenosis level | Left ICA origin | Left ICA intracranial | Right ICA origin | Right ICA intracranial |
|---|---|---|---|---|
| No stenosis | 42(%24.5) | 157(%91.8) | 50(%29.2) | 160(%93.5) |
| Less than 50% | 19(%11) | 3(%1.7) | 19(%11) | 4(%2.3) |
| 50-69% | 5(%2.9) | 3(%1.7) | 14(%8) | 1(%0.58) |
| 70-99% | 58(%33.9) | 6(%3.5) | 44(%25.7) | 4(%2.3) |
| Near occlusion | 41(%23.9) | 2(%1.1) | 34(%19.8) | 2(%1.1) |
| Occlusion | 6(%3.5) | 0(%) | 10(%5.8) | 0(%) |

TABLE III - *Complications during and after the procedure*

| Complications | Total 171% |
|---|---|
| Cerebral embolism | 10 %5.8 |
| Bradycardia | 42 %24.5 |
| Asystole | 10 %5.8 |
| Contrast agent encephalopathy | 5 %2.9 |
| HeadacheRectus muscle hematoma | 53% 393 %1.7 |
| Intra-stent restenosis | 3 %1.7 |
| Thick chillsMortality | 46% 26,91 %0.58 |

applied to the carotid lesion on the right side in 41 (23.9%) cases and to the left side in 44 (25.7%) (Table II). Post balloon dilatation was applied to vessels which had not opened sufficiently after the stent was opened. During the post-dilatation procedure, asystole developed in 10 (5.8%) patients and bradycardia developed in 42 (24.5%) during stent opening. Normal rhythm was regained following intravenous administration of 1 mg atropine.

In 10 (5.8%) patients, there was a mid cerebral artery (MCA) branch infarct ipsilateral to the stent. In these patients, dysarthria and/or hemiparesis was observed which lasted for <24 hours. Reperfusion bleeding was not observed in any patient. In 5 (2.9%) patients, encephalopathyand agitation not exceeding 24 hours was observed. Hypotension was determined in 8 (4.6%) patients and headache lasting <24 hours in 53 (31%) patients. The complaint of cold and shivering lasting up to 6 hours was seenin 46 (26.9%) patients after the procedure. Within the first week, local hematoma in the rectus abdominis muscle was seen in 3 (1.7%) patients. In 1 (0.5%) patient, rectus abdominis bleeding developed one week after the procedure and within 24 hours, the patient was exitus because of the development of disseminated intravascular coagulation (DIC). In the colour Doppler ultrasonography examinations of the carotid artery at 6 and 12 months, findings of re-stenosis were observed in the stent region in 3 (1.7%) patients (Table III).

## Discussion

Endovascular treatment of carotid pathologies has been reported to be correlated to a risk of cerebrovascular event in several recent studies [12,13]. Kastrup et al compared carotid artery stenting with and without the use of embolic protective devices (EPD) and reported that the incidence of minor and major stroke was significantly lower in the group where EPD was used and that complication rates related to embolisation were up to 5% lower with the use of a protective device during stenting. In the current study, without the use of pro-

tection, the rate of complications related to embolisation was 5.8%. In literature, while hemodynamic instability (bradycardia, hypotension) developing after carotid artery stenting has been reported to vary from 7% to 80%, the rate of persistent hemodynamic instability has been reported as 64% (14). In a study by Wu et al, the incidence of bradycardia was found to be 17.6% [15]. In studies related to carotid stenting, rates of asystole seen in patients vary between <1% and 33% [16]. In the current study, the rates of asystole determined at 5.8% and

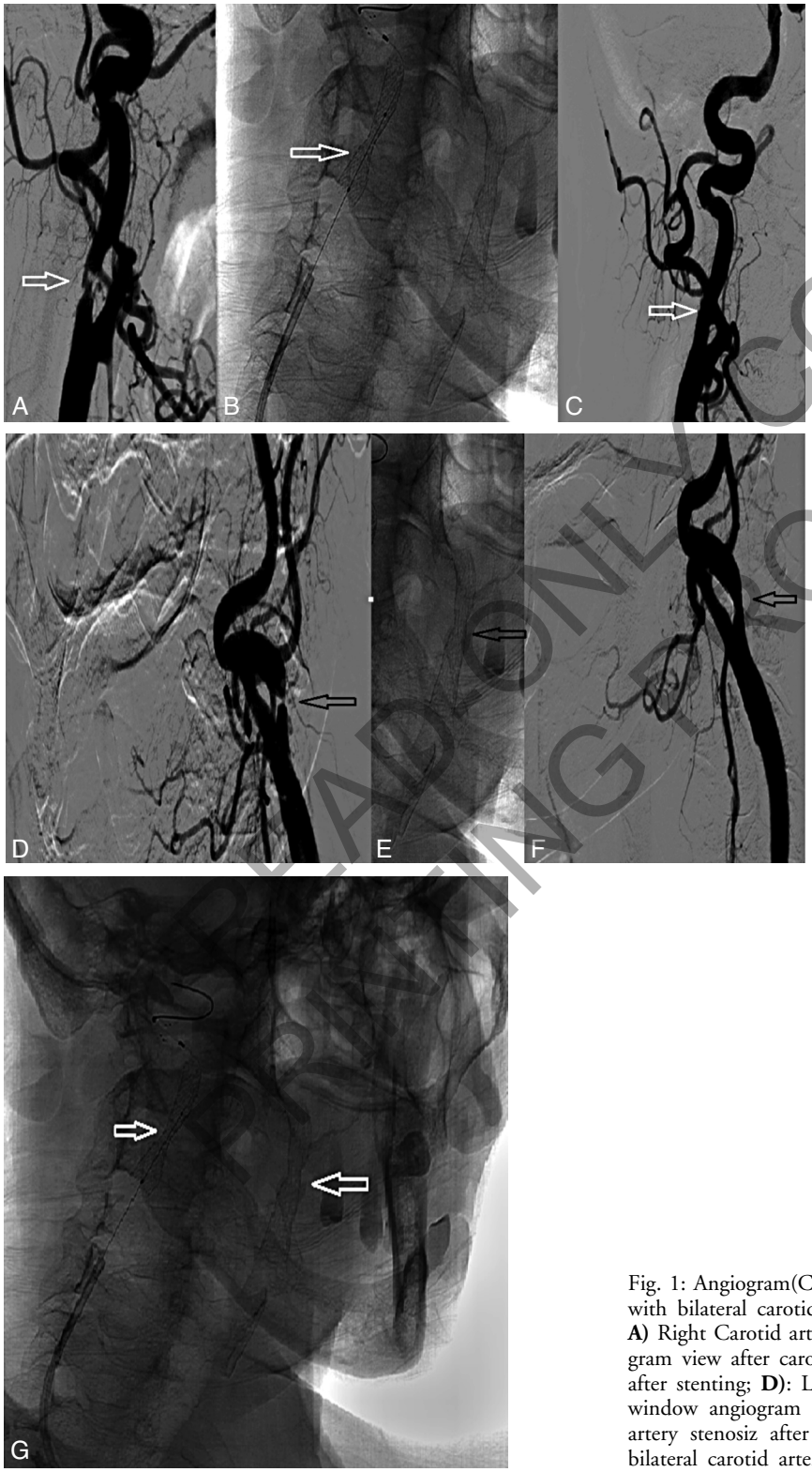




Fig. 1: Angiogram(Carotid artery stenting example) images of the patient with bilateral carotid artery stenosis before and after stenting.
**A)** Right Carotid artery stenosis before stenting; **B)** Bone window angiogram view after carotid artery stenting; **C)**Right Corotid artery stenosiz after stenting; **D)**: Left Carotid artery stenosis before stenting; **E)** Bone window angiogram view after carotid artery stenting; **F)** Left Corotid artery stenosiz after stenting; **G)** Bone window angiogram view after bilateral carotid artery stenting.

bradycardia at 24.5%were seen to be consistent with literature. Although the incidence of contrast encephalopathy varies between 0.3% and 1%, when hyperosmolar iodine contrast substance is used, this rate can reach 4% [17]. In 2.9% of the current study patients, impaired consciousness not exceeding 24 hours was observed. In a study of 56 patients by Marti et al, headache was observed in 12 (21.4%) patients [18]. In another study by Gunduz et al, headache which recoveredwithin 110 mins was seen at the rate of 39% [19]. Headache lasting <24 hours was observed at 31% in the current study. Moulakakis et al reported intracerebral hemorrhage incidence of 0.74% in carotid stent cases [20], and Abou-Chebl reported this rate as 0.67% [21]. This complication was not observed in any patient of the current study. Abdominal wall hematoma is a rarely seen but life-threatening complication following carotid artery stenting. In a 2007 case study by Çil et al, spontaneously developing rectus muscle hematoma following carotid stenting was reported for the first time and the reason given was the use of anticoagulants. In the current study, local rectus muscle hematoma was observed to develop spontaneously in 3 (1.7%) cases. In another case study by Fukunaga et al, a tear in the superficial circumflex iliac artery was shown to be the reason for the development of abdominal wall hematoma following carotid stenting [22]. Due to inconsistencies in definitions, determination of measurements and follow-up plans, a great variation is seen in the incidence of re-stenosis in the stent reported after carotid stenting. In the current study, re-stenosis was observed to develop in the stent in 3 (1.7%) cases. Carotid stenting and carotid endarterectomy remain the basic treatment approaches in re-stenosis cases.

Embolic protective devices constitute a mechanism to reduce the risk of embolism. International record analyses and a combined meta-analysis seem to confirm this [23,24]. However, despite the limitation of size and extent, low stroke rates have been reported from unprotected stenting [25]. In the majority of cases in the USA, carotid stenting is made using a distal filter protective device. Giri et al reported that stenting without using an EPD was applied to higher risk patients compared to those where EPD was used. Patients selected for unprotected carotid stenting had high rates of pre-procedural neurological risk factors. There was not reported to be any evidence of damage or significant benefit related to the use of distal protection in elective carotid stenting patients [26]. Barbato et al compared 36 randomised patients applied with stenting using or not using a distal filter, and on diffusion-weighted MRI taken after the procedure, no difference was determined in respect of evidence of cerebral embolism [27]. In the current study, the rates of symptoms and complications seen procedurally and in the postoperative follow-up showed no significant difference from those of studies conducted using embolic protective devices.

## Conclusion

Stroke is a significant cause of morbidity and mortality and one of the leading causes of atherosclerotic carotid artery disease. Revascularistion interventions are evaluated as important treatment options to be able to prevent the development of stroke. In recent years, the application of stenting has become important in the treatment of carotid stenoses. The low rates of stroke during and after treatment with a stent are encouraging, especially in patients with many vascular risk factors. With careful patient selection in experienced centres and a multi-disciplinary approach both before and after the procedure, pleasing results can be obtained without the use of embolic protective devices.

The low rates of severe complications associated with carotid artery stenting determined in the selected patients of the current study demonstrate that carotid stenting applications can be successfully applied without the use of EPD. Further studies made with and without EPDs will be able to confirm these success rates.


## Riassunto

Nonostante che nella maggiornaza dei casi lo stenting carotideo venga eseguito con l'adozione di dispositivi protettivi nei confronti delle complicazioni neurologiche di natura embolica, in alcuni casi la procedura viene eseguita senza strumenti di protezione. Con questo studio vengono presentati i risultati di stentin carotideo eseguito senza dispositivi di protezione nei confronti dell'embolia cerebrale.

Si tratta di uno studio retrospettivo su un totale di 171 pazienti sottoposti a stenting carotideo tra il 2014 e il 2017. L'indicazione allo stenting è stata per pazienti sintomatici con restringimento carotideo > 50% valutato angiograficamente, o su pazienti asintomatici con restringimento > 60%. Il grado del restringimento carotideo è stato valutato con US Doppler preliminare allo studio angiografico, e con i criteri di misurazione nel corso dell'angiografia della North American symptomatic carotid endarterectomy trial. Dopo lo stenting carotideo i pazienti sono stati trattenuti in osservazione ospedaliera per 24 ore.

N. 10 pazienti (5,8%) si è verificato un infarto di un ramo dell'arteria cerebrale media omolaterale allo stent. In nessun paziente è stata osservato un sanguinamento da riperfusione. n 5 pazienti (2,9%) è stata osservata encefalopatia ed agitazione per una durata non superiore alle 24 ore. n 8 pazienti (4,6%) si è manifestata ipotensione e in 53 pazienti (31%) cefalea persistente. Un paziente ha manifestato un'emorragia del retto addominale una settimana dopo la procedura, seguita dal decesso entro 24 ore.

Si conclude che gli interventi di rivascolarizzazione per la prevenzione dell'ictus sono considerati importanti

opzioni di trattamento in pazienti con stenosi carotidea grave o sintomatica. Con un'attenta selezione dei pazienti in centri esperti e un approccio multidisciplinare sia prima che dopo la procedura, è possibile ottenere risultati soddisfacenti senza l'uso di dispositivi di protezione nei confronti dell'embolia.

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