

# Effectiveness of endo-vascular treatment in carotid artery stenosis: A single center study

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## Abstract

**Aim:** To investigate the safety and effectiveness of endo-vascular stents to treat carotid artery stenosis (CAS).

**Material and Methods:** One-hundred fourteen patients who underwent selective endo-vascular stenting following selective carotid angiography between 2000 and 2014 were analyzed retrospectively. Demographic characteristics; stenosis degree; stent type; use of anti-coagulants and embolism protection system (EPS) during the procedure; pre-dilation and post-dilation during the procedure; use of a vascular occlusion device after the procedure; early complications (<30 days); prevalence of re-stenosis of the stent; sixth-month, first-year, second-year, and fifth-year controls; radiologic imaging results; and discharge time were analyzed.

**Results:** Among the patients, 83 (72.8%) were males and 31 (27.2%) were females, and the age range was 41–86 years (mean age: 69 ± 8.7 years). The proportion of concurrent hypertension was higher among females with CAS ( $p < 0.01$ ). The proportion of early complications was higher among the patients with the Nitinol stent than among those with the Wall stent ( $p = 0.062$ ). Embolic events and infarct development were observed in 13 (11.4%) patients within the first 30 days. Occlusion was detected in 4 of 97 patients (4.1%) who represented controls. While less than 50% stenosis that did not require intervention developed in four (4.1%) patients, more than 50% stenosis was detected in three (3.09%) patients. The likelihood of not developing stenosis was found to be 98% at the end of the first year, 96% at the end of the second year, and 87% at the end of the fifth year. The mean duration of stenosis was 4.86 ± 0.11 years.

**Conclusion:** The proportions of potency and early complications in endo-vascular treatment applied for CAS were similar to those in the literature. Further studies with a larger patient number and a longer duration of follow-up would provide better data concerning the effectiveness of treatment and complications.

**Keywords:** Carotid artery; stenosis; stenting.

## INTRODUCTION

Carotid artery stenosis (CAS) is among the most important causes of cerebrovascular diseases and is responsible for 20–25% of strokes (1). The prevalence of carotid artery diseases varies between 1 and 10% in the literature (2). Endo-vascular treatment of CAS is less invasive than surgery, and as such, has become more popular during the recent two decades. Carotid artery stenting is gradually replacing endarterectomy due to its technical ease and safety (3), and is being used more frequently, as it minimizes blood loss and has lower mortality and morbidity, a shorter duration of intensive care unit and hospital stays, and may be used in elderly patients who have other systemic problems. Thus, our aim was to investigate the effectiveness and complications in the

practice of carotid artery stenting at a single-center hospital that treated 114 patients between 2000 and 2014.

## MATERIAL and METHODS

The study was conducted after local ethics committee approval had been obtained from Baskent University (KA 14/99). One-hundred fourteen patients who underwent carotid endo-vascular stenting after selective carotid angiography at the Department of Interventional Radiology between January 1, 2000 and February 1, 2014 were analyzed retrospectively. Among the patients, 83 (72.8%) were male and 31 (27.2%) were female, and the age range was 41–86 years (mean age: 69 ± 8.7 years).

Demographic characteristics; stenosis degree; stent type; use of anti-coagulants and the embolism protection

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system (EPS) during the procedure; pre-dilation and post-dilation during the procedure; use of a vascular occlusion device after the procedure; early complications (<30 days); prevalence of re-stenosis of the stent; sixth-month, first-year, second-year, and fifth-year controls; radiologic imaging results; and discharge time were analyzed.

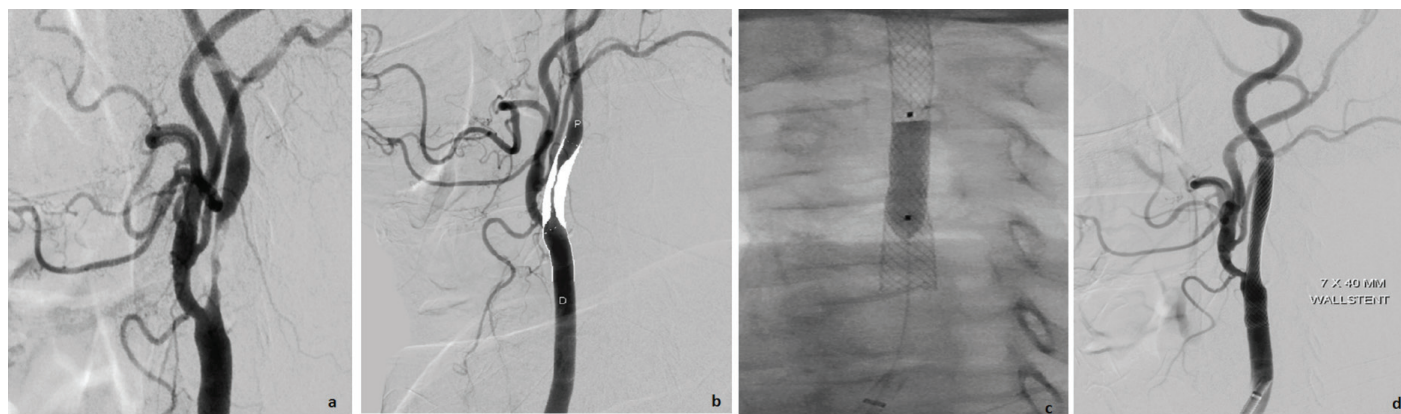
Comorbid diseases were detected (hypertension, coronary artery disease, diabetes mellitus, hyperlipidemia, and chronic renal failure). Symptomatic or asymptomatic data were recorded with clinical findings (e.g., visual disturbances, speech disorder, fatigue, imbalance, headache, and dizziness). Carotid Doppler ultrasound (US) and/or computed tomography (CT) and magnetic resonance (MR) angiography images were evaluated, and the stenosis type and plaque type were defined. The proper treatment method was selected after a consensus had been made among cardio-vascular surgeons, neurologists, and interventional radiologists, depending on the plaque type, degree of stenosis, comorbid diseases, and patient history. Stent type was selected after the stent feasibility was evaluated. Written and verbally informed consent was obtained after the patients were informed of the possible complications.

#### Technique

After the patients were positioned on the angiography table and standard sterile conditions were provided, US-guided local anesthesia was applied at the entrance site of the main femoral artery, and the vascular lumen was accessed with an 18-gauge needle through a single-wall puncture. A 4-F or 5-F short vascular sheath was placed with a guide wire for diagnostic purposes. Next, 5000–10000 IU of intra-vascular heparin was administered to reach the optimum clotting time (250–300 s). The arcus aorta was displayed using a 4-F or 5-F pigtail catheter in patients who did not undergo diagnostic angiography. The arcus aorta anatomy was determined, and the 4-F or 5-F diagnostic catheter, which had a proper angulation, was chosen. Davis, Simmons 1, and Simmons 2 catheters are the most commonly used catheters for diagnostic angiography. Both the main carotid arteries and vertebral

arteries were selectively catheterized, and the presence of stenosis, size, location, degree of stenosis, and the presence of an ulcer were evaluated through images. The degree of stenosis was determined depending on the area and diameter; stenosis diameter was taken as the main criterion.

After obtaining diagnostic images, the distal end of the external carotid artery was catheterized normally or selectively with a stiff glide wire and diagnostic catheter (4F-5F). A 0.035-inch Amplatz® Super Stiff Guidewire (Boston Scientific, Corp, Watertown, MA, USA) was placed at the distal end of the external carotid artery. A short diagnostic vascular sheath was removed over this sheath, and a long (90 cm) 6-F to 7-F vascular sheath was placed up to the distal end of the main carotid artery. The common carotid artery could be accessed with a larger (7-8 F), short vascular sheath and guide catheter (6-7 F) in patients whose arcus aorta anatomy did not enable the placement of a long vascular sheath. After the common carotid artery was accessed, the filter (Spider TM; Ev3 Inc, Plymouth, MN, USA) and carrier system were washed with heparinized saline, and the risk of embolism was eliminated. Nimodipine was administered as a vasodilator for the prevention of vascular spasms before filtering. A 0.014-inch atraumatic ended Extra Support wire (Boston Scientific, Corp, Watertown, MA, USA) was used to carry the filter by providing a proper angle to the distal edge, as we considered that the 0.014-inch carrier wire of the filter was not sufficient and atraumatic during the passage of the stenotic segments. The filter was opened in a smooth segment in the distal end of the internal carotid artery (ICA) stenotic segment. The filter was selected based on the diameter of the vascular segment. Pre-dilation was performed using 2- to 4-mm balloons, as progression of the stent was a concern in high-grade stenosis (90–95%). Self-expandable stents were used in all patients (Wall stent, Nitinol stent). A self-expandable stent was placed to include the stenosis site. Balloon dilation was repeated when a sufficient opening could not be obtained (post-dilation). Control angiography was performed to display the inside of the stent and cerebral flow (Figure 1).



**Figure 1.** Radiographic view of a 72-year-old patient treated with stenting due to carotid artery stenosis (a; before the procedure, b; calculation of occlusion rate, c; peroperative view, d; after the procedure)

Partial thromboplastin time (PTT) and activated partial thromboplastin time (aPTT) were controlled for 24 h after the procedure, and IV heparin infusion was performed. Early complications were evaluated using cerebral diffusion MRI. Clopidogrel use was recommended for 6 months after discharge. Outpatient clinic controls were performed by the same neurology, cardio-vascular surgery and radiology team using US, CT angiography, and MR angiography at 6 months, in the first year, in the second year, and in the fifth year. The patients were evaluated regarding potential complications.

**Statistical analysis**

The relationships between filter use, anticoagulant use, pre-dilation procedure, plaque type, early complications, stent type, and re-stenosis development were evaluated using the chi-squared test. The re-stenosis rates and standard deviations of the carotid stents were calculated using the Kaplan–Meier test. Statistical analyses were performed using Statistical Package for the Social Sciences (SPSS ver. 21.0 (IBM Corporation, Armonk, NY, USA). A p-value < 0.05 was accepted as statistically significant in the log-rank test.

**RESULTS**

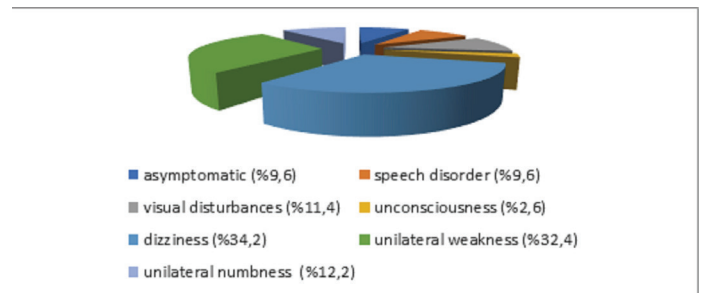
Patients who underwent stenting at our clinic were evaluated based on age and concurrent diseases. Among the patients, 83 (72.8%) were male and 31 (27.2%) were female, and the age range was 4–86 years (mean age: 69 ± 8.7 years).

Hypertension was the most common co-morbid disease. While hypertension was present in 52 of 83 males (65%), this proportion was 25/31 (80.6%) for females. The proportion of concurrent hypertension was higher in females among patients who developed CAS, and the difference was statistically significant (p < 0.01). When long-term occlusion and re-stenosis risk after stenting was evaluated in the presence of hypertension, the latter was detected in 8 of 11 patients who developed varying degrees of stenosis (p > 0.05). (Table 1)

Table 1. Distribution of comorbid conditions					
	DM	HT	HL	CAD	CRD
Patients (n=114)	51 (44.7%)	80 (70.2%)	20 (17.5%)	33 (28.9%)	5 (4,3%)

(DM : Diabetes mellitus, HT; Hypertension, HL; Hyperlipidemia, CAD; Coronary artery disease CRD; Chronic renal disease)

When pre-procedural symptoms were evaluated, CAS was detected incidentally during routine examination and tests in 11 of 114 patients (9.6%); in the remaining 103 patients, it was detected on admission to the neurology clinic due to various symptoms, including speech disorder (lisping) in 11 (9.6%) patients, visual disturbances in 13 (11.4%) patients, dizziness in 39 (34.2%) patients, unilateral weakness in 37 (32.4%) patients, unconsciousness in 3 (2.6%) patients, and unilateral numbness in 14 (12.2%) patients. Fourteen (12.2%) patients had more than one symptom on admission. (Figure 2)



**Figure 2.** Distribution of symptoms

The pre-procedural stenosis rates were analysed and were found to be between 50 and 99%, based on the diameter; the mean stenosis value was 80.8% ± 11.5.

When the plaque type was analyzed, 42% were detected to be calcified, 31% were of the mixed type, and 27% were of the fibro-fatty type. Sixteen (14%) of these plaques had ulcers. Ulcerated plaques were observed in 3 (18.8%) female patients and in 13 (81.2%) male patients. While 14 (87.5%) of the patients with ulcerated plaques were symptomatic, 2 (12.5%) were asymptomatic. A statistically significant difference was not detected between stenting success and post-procedure complication rates. Early complications were detected in 3 (18.8%) of the patients with ulcerated plaques. A statistically significant difference was not detected between early complication development and the presence of ulcerated plaques (p > 0.05).

When the stent types were analyzed, 90 (78.9%) patients had the Wall stent and 24 (21.1%) used the Nitinol stent. When early complications and plaque type were analyzed, early complications were detected in six (25%) patients who used the Nitinol stent and in nine (10%) patients who used the Wall stent (p = 0.062); the early complication rate was higher in patients who used the Nitinol stent than in patients who used the Wall stent. When the patients who developed varying degrees of stenosis in the late period after the procedure were analyzed, stenosis developed in two (8.3%) patients in the Nitinol stent group and in nine (10%) patients in the Wall stent group (Table 2).

Table 2 : Complications

	Early complications (< 30 day)	Late complications (> 30 day)		
		Stenosis 0-50%	Stenosis 50 -99%	Occlusion (99- 100% stenosis)
Nitinol Stent (n= 24)	6 (Infarct: 6)	6	-	2
Wall Stent (n= 90)	9 (Hemorrhage : 1 Infarct :8)	4	1	4

Stenosis of more than 50% that requires intervention and stent type were compared. More than 50% stenosis development was observed in two (8.3%) patients who used the Nitinol stent and in one (0.9%) patient who used the Wall stent (Table 2). The proportion of stenosis development was higher in the Nitinol stent group, although the difference was not statistically significant ( $p= 0.051$ ).

The cerebral protective system was applied to 112 (98.2%) patients during the procedure. Two patients did not use the EPS because it was not available at the time of the procedure. An embolic event leading to an acute infarct developed within the first 30 days in one (50%) patient who did not use a filter. This patient developed an acute infarct and died. However, statistical significance was not detected due to an insufficient number of patients ( $p > 0.05$ ). Early complications did not develop in 98 of 112 patients (87.5%) who used the EPS. An infarct was observed in 14 (12.5%) patients.

While pre-dilation was applied during the procedure in 23 (20.2%) patients, it was not required in 91 (79.8%) patients. The stenosis degree was above 90% in all patients who underwent pre-dilation. No complications developed after pre-dilation.

Post-dilation was applied to 113 (99.1%) of 114 patients. The post-dilation procedure was preferred when sufficient blood flow could not be achieved after stent opening. A new stent was required in one patient after post-dilation, although the target dilation could not be achieved.

When the peri- and post-procedural early complications (<30 day) were evaluated, hematoma was detected at the vascular intervention site in three (2.6%) patients, and pseudo-aneurysm was detected in one of these patients. The pseudo-aneurysm was embolised with percutaneous thrombin injection. Complications were not detected during the stenting procedure. Cerebral haemorrhage developed in one (0.8%) patient, and gastro-intestinal hemorrhage developed in one patient within 30 days after the procedure. A seizure developed soon after the procedure in one patient that was controlled with medical treatment; it was considered to be related to minimal embolic events.

The complications were evaluated as early (within the first 1 month) and late (after the first month) complications. Embolic events and infarction developed in 13 (11.4%) patients within the first 30 days. These patients developed speech disorder, fatigue, dizziness, and mental problems after the procedure. Intensive care was required due to

cardiac and respiratory problems, independently from the procedure; one patient died from embolic events. The patients who underwent carotid artery stenting were discharged from the hospital within  $2.00 \pm 1.99$  (range, 1–12) days.

All patients were followed up after the procedure; however, late controls could not be performed in 17 patients. The mean duration of follow up was  $1.00 \pm 1.75$  year.

Different degrees of stenosis developed in the late period in 11 of 97 (11.3%) patients who had controls. Complete occlusion developed in four (4.1%) patients. While four (4.1%) patients had less than 50% stenosis that did not require intervention, three (3.09%) had more than 50% stenosis. Balloon dilation was applied after diagnostic angiography in three patients who developed more than 50% stenosis; re-vascularization could be achieved in these patients. The likelihood of not developing stenosis was 98% at the end of the first year, 96% at the end of the second year, and 87% at the end of the fifth year. The mean duration of stenosis was  $4.86 \pm 0.11$  years (Figure 3).

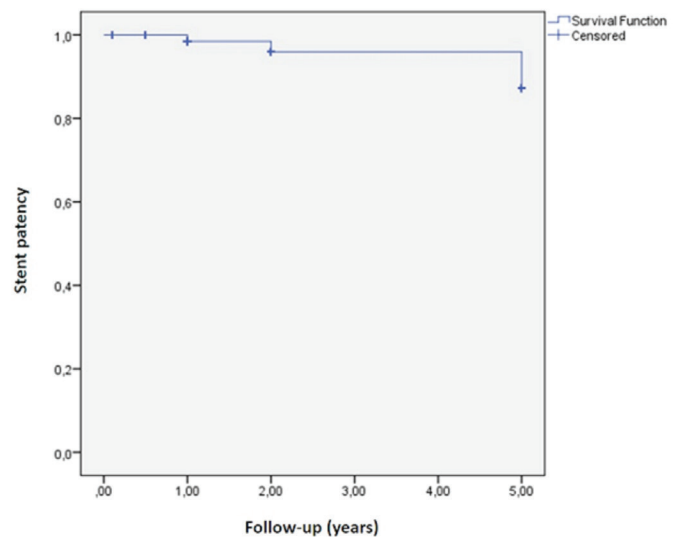


Figure 3. The mean duration of stent patency ( full patency: 1.0; full occlusion: 0.0)

## DISCUSSION

When we evaluated the demographic characteristics of the patients who developed CAS, gender was the most prominent feature. CAS was more frequent in males. Peripheral vascular stenosis was reported in 0.35% of females and 0.71% of males (4). The low frequency of vascular diseases among females is related to the protective effect of estrogen and is accepted worldwide (5).

The most common comorbid disease was hypertension. Animal tests have revealed that hypertension is a significant risk factor for atherosclerosis, and plaque formation begins together with elevated plasma cholesterol levels (6). Despite the absence of sufficient data in the literature concerning hypertension and stenosis development in females, we may assume that hypertension impairs estrogen-dependent vascular protection, leading to deformity and increases in stenosis development.

When pre-procedural symptoms are evaluated, 45% of patients were observed to be asymptomatic in a study of Kim et al. comparing 47 patients who underwent carotid endarterectomy and carotid stent (7). In a multi-center study including 47,403 patients from 278 centers, only 4,826 patients were symptomatic; 89% were asymptomatic (8). The proportion of asymptomatic patients was lower in the present study than in the literature. Carotid stenosis was detected incidentally in 9.6% patients. This may arise from all asymptomatic patients not being referred to our clinic.

In the NASCET trial, the most common clinical findings were unilateral numbness (38%), sensory defects (33%), headache (25%), aphasia (20%), visual field defects (14%), unconsciousness (5%), and dysarthria (3%) in anterior circulation disorders (9). In our study, 11 (9.6%) patients were admitted with speech disorder (lisp), 13 (11.4%) with visual disorders, 39 (34.2%) with dizziness and headache, 37 (32.4%) with unilateral fatigue, 3 (2.6%) with unconsciousness, and 14 (12.2%) with unilateral numbness. Fourteen (12.2%) patients had more than one complaint. The proportion of clinical findings was consistent with that of the literature.

When the stent type was analyzed, the Wall stent was used in 90 (78.9%) patients, and the Nitinol stent was used in 24 (21.1%) patients. The proportion of early complications was higher in patients who used the Nitinol stent. The proportion of more than 50% stenosis was higher in patients who used the Nitinol stent, although not statistically significant. We found no data concerning this issue in the literature. By contrast, it was reported that a significant difference was not detected between the Nitinol and Wall stents regarding embolic events, death, or stroke (10). The number of stent types used in our study was not equal. Long-term re-stenosis rates could be evaluated better in prospective studies conducted by equalizing all parameters, which could lead to differences before and during the operation.

Mortality independent of time was reported to be 0.6%, and proportion of stroke was reported to be 2.5% in the Prospective Registry of Carotid Artery Angioplasty and Stenting (Pro-CAS), which was conducted with 3,267 patients from 38 centers using EPS in 64% patients (11). An optimal comparison could not be performed with our study due to the absence of a time classification. However, we found the results to be similar when a comparison was made regarding the early mortality rate.

The rate of early mortality is between 0.5 and 2% in the literature (12-14). Our results were found to be consistent with that in the literature. The proportion of major stroke is reported to be between 0.5 and 4% (12-14). In the early studies, the complication rates were significantly higher than those currently, given the technical failure arising from the absence of EPS use and that the stents were newly introduced to the market. When the outcomes of the early technique, EPS and stent use were compared with endarterectomy, the former was found to be superior to the latter regarding early and late complications.

When the long-term re-stenosis rates were analyzed, we observed that the definition of "re-stenosis" was used for the patients who developed more than 50% stenosis according to the diameter. The proportion of re-stenosis varies between 2.7 and 6% in the literature (15-18). In a study of Gianmarco et al., the likelihood of re-stenosis was calculated as 98.4% in the first year, 93.3% in the third year, and 91.9% in the fifth year (19). Different levels of stenosis developed in 1-, 2-, and 5-year follow-ups of the patients in our study. Re-stenosis did not develop in most (88.7%) of our patients; thus, we conclude that our results are consistent with those in the literature.

Re-stenosis development proportion was reported as 6% in one year in a summary of 34 studies with endarterectomy (20). In another study, this proportion was 14% in the CAVATAS group (21). Stent application seems undisputedly superior to endarterectomy according to the results of our study and those in the literature.

Carotid artery stenting is a less invasive and less fearful procedure for patients than carotid endarterectomy, and patients can be mobilized earlier. In the study of Brooks et al., the hospital stay duration was  $1.8 \pm 0.58$  days in the carotid artery stenting group and  $2.7 \pm 1.2$  days in the carotid endarterectomy group, provided that no complications developed during the procedure. In the early period, these proportions were  $13.3 \pm 21$  days and  $3.8 \pm 3.5$  days in the stenting group and endarterectomy group, respectively (22). Eleven patients were followed up at the intensive care unit after stenting and were transferred to the ward thereafter in our study. The mean duration of hospital stay was  $2.00 \pm 1.99$  days (range, 1-12 days) for patients who underwent carotid stenting. Carotid artery stenting is presented to clinicians and patients as a preferable method due to the short hospital stay duration, low cost, and good patient satisfaction.

Our study has several limitations. First, it does not provide technical standardization due to its retrospective nature. Other limitations include the lost to follow up of some patients and absence of long-term follow ups.

## CONCLUSION

In conclusion, carotid stenting has gained popularity with technological developments. Endovascular stenting for CAS has been shown to reduce the peri-operative mortality rates and duration of hospital stay as a safe

and technically successful method, particularly for the elderly and high-risk patients. While the outcomes of early studies were discouraging due to the absence of EPS and anticoagulant use, less complicated outcomes can be obtained today than with endarterectomy. Therefore, carotid artery stenting is becoming the first choice in CAS treatment.

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