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Evaluation of the association between silent ischemic lesions and stent design in carotid stenting applications

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SUMMARY

OBJECTIVE: Minor ischemic events and silent ischemic lesions are more common in carotid stenting than in endarterectomy. These silent ischemic lesions are also associated with stroke risk and cognitive impairment, so it is important to understand the factors that increase the risk and develop strategies to reduce the risk. We aimed to evaluate the association between carotid stent design and silent ischemic lesion development.

METHODS: The files of the patients who underwent carotid stenting between January 2020 and April 2022 were scanned. Patients with diffusion MR images taken within the postoperative 24 h were included in the study, while those undergoing acute stent placement were excluded. The patients were divided into two groups: those with open-cell stents and those with closed-cell stents.

RESULTS: A total of 65 patients, including 39 patients undergoing open-cell stenting and 26 patients undergoing closed-cell stenting, were included in the study. There was no significant difference in demographic data and vascular risk factors between the groups. New ischemic lesions were detected in 29 (74.4%) patients in the open-cell stent group and 10 (38.4%) patients in the closed-cell stent group and were significantly higher in the open-cell group. There was no significant difference between the two groups in terms of major and minor ischemic events and stent restenosis at the 3-month follow-up.

CONCLUSION: The rate of new ischemic lesion development was found to be significantly higher in carotid stent procedures performed with an open-cell Protégé stent than in those performed with a closed-cell Wallstent stent.

KEYWORDS: Embolism. Carotid stenosis. Diffusion MRI. Stent. Stroke.

INTRODUCTION

One of the common causes of stroke is carotid atherosclerosis. Current guidelines recommend carotid stenting (CAS) as an alternative treatment to endarterectomy (CEA), especially in high-risk patients for endarterectomy[1-3]. Multicenter randomized studies reported that periprocedural disabling stroke and death rates historically declined from 4.4 to 0.8% as the materials used began to change, the techniques employed improved, and the experience in this field increased[4,5]. Despite such decreasing rates, the frequency of minor strokes in the treatment of CAS is still slightly higher compared to CEA[4]. In recent years, studies have reported that the transcarotid artery revascularization (TCAR) method has a lower risk of periprocedural stroke and death compared to transfemoral carotid stenting (TFCAS), but no clear recommendation has been found in the guidelines to date[1,6]. In the ESVS 2023 guideline, which is in the process of publication, it is recommended that the transradial access or TCAR method should be considered in patients who are planned for carotid stenting and that the transfemoral access may increase the risk of complications, as class IIa level B[2]. However, in many centers, including our center, TCAR still cannot be performed and TFCAS is widely applied. Therefore, improvements are needed to reduce complications after CAS.

Cerebral infarction as a perioperative complication related to CAS is an issue, and previous studies reported that risk factors for cerebral infarction included emboli protection devices (EPD), the operator's skill, patient age, plaque properties, stent design, and statin use[2,7-11]. EPD, balloon angioplasty, and stent design are material-related factors that may affect procedural complications. Although current guidelines recommend the use of EPD, numerous studies have found no significant difference between the clinical outcomes and newly detected ischemic lesions on diffusion-weighted magnetic resonance imaging (DWI) images of patients for whom an EPD has been used or not[12-14]. Even there are reports in the literature that new ischemic lesion development as detected in DWI is more

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common in patients for whom a distal protection type EPD has been used[13].

Carotid stents include open-cell stents with fewer interconnections and larger empty cells and closed-cell stents with more frequent interconnections. There are also controversial results on the effect of stent design on clinical outcomes, and the guidelines have not made a clear decision on this subject yet[12]. While some studies have reported a higher risk of stroke in patients using open-cell stents, there are also studies reporting the opposite result[7,15-17]. There are a relatively small number of studies evaluating the association between stent design and post-stenting microembolization. Therefore, we wanted to evaluate whether the stent design has any effect on the microembolic lesions as detected in DWI and on the 3rd month clinical outcome in patients on whom we performed CAS in our own clinic.

METHODS

The data of the patients who underwent CAS in our Interventional Neurology clinic at Bolu Abant Izzet Baysal Training and Research Hospital between January 2020 and April 2022 were evaluated retrospectively after obtaining the approval of the ethics committee. (Ethics Committee of Bolu Abant Izzet Baysal University (2022-236) 27/09/2022). Patients older than 18 years of age who had a DWI check within 24 h (16–32 h) after the procedure were included in the study. Those undergoing acute CAS were excluded from the study. DWI scans were performed on the same 1.5-T device (Signa Explorer, GE Healthcare, Chicago, IL, USA) in all patients who underwent CAS before and at least 24 h (16–32) after the procedure. Patients who could not undergo follow-up imaging due to reasons such as failure to make an appointment, device malfunction, or maintenance were excluded from the study. The files of 104 patients to whom we applied CAS during the study date range were scanned. A total of 65 patients who met the inclusion and exclusion criteria were included in the study (Figure 1). The patients were divided into two groups: those with open-cell stents and those with closed-cell stents. The patients' age, gender, vascular risk factors, antiaggregant treatments, rate of stenosis in the ICA, and contralateral ICA, which side was operated on, and arch types were noted. Residual stenosis rates, complications during the procedure, and cardiac and cerebrovascular events in the postoperative 3-month follow-up, patients with more than 50% residual stenosis on the 3rd month Doppler USG were noted. It was noted whether predilatation or postdilatation was performed in the procedure and whether EPD was used or not.

Procedure

All patients were operated on under local anesthesia with acetylsalicylic acid and clopidogrel treatment. After an 8F 11-cm sheath was placed, the bilateral extracranial and intracranial vessels were evaluated using a diagnostic catheter in at least two planes. A 6F guide catheter was placed in the CCA. There was no operator preference bias in the stent selection since the stent design available in the hospital on the day of the procedure applied to the stenosis segment was used. The reason for the change in the type of stent used was the purchase from the company that gave the lowest bid in the tender held by the hospital. An open-cell Protégé (Medtronic Corp.; Minneapolis, MN, USA) stent was available in our hospital between January 2020 and March 2021 and a closed-cell Wallstent (Boston Scientific, Marlborough) between March 2021 and April 2022. After stenting, images of ipsilateral intracranial vessels and the ICA were obtained from at least two planes. Residual stenosis rates were noted.

Statistical analysis

Data were evaluated by the SPSS 21.0 (IBM Corp., Armonk, NY, USA) software.

Categorical variables were expressed as numbers and percentages, and countable variables as mean±SD. Between the two independent groups, countable variables showing normal distribution were evaluated by the independent sample T test, and variables not showing normal distribution were evaluated by the Mann–Whitney U test. Chi-square test was used when comparing categorical variables. $p<0.05$ was considered significant.

RESULTS

The data of a total of 65 patients, including 39 patients undergoing open-cell stenting and 26 patients undergoing closed-cell stenting, who met the inclusion criteria, were evaluated. Age, gender, and vascular risk factors in both groups are given in Table 1. There was no difference in terms of demographic data and vascular risk factors.

Pre-procedural stenosis rates, contralateral stenosis rates, residual stenosis rates, which side ICA was treated, arch types, balloon angioplasty rates, balloon sizes, distal filter usage rates, and symptomatic/asymptomatic patient rates are given in Table 2. Preoperative stenosis rates were found to be significantly higher in the closed-cell stent group (80.69±12.37% vs. 73.0±11.0% respectively; $p=0.011$). The rate of predilatation and double dilatation was found to be higher in the closed-cell stent group (for all, $p<0.01$). There was no difference in the other data between the two groups.

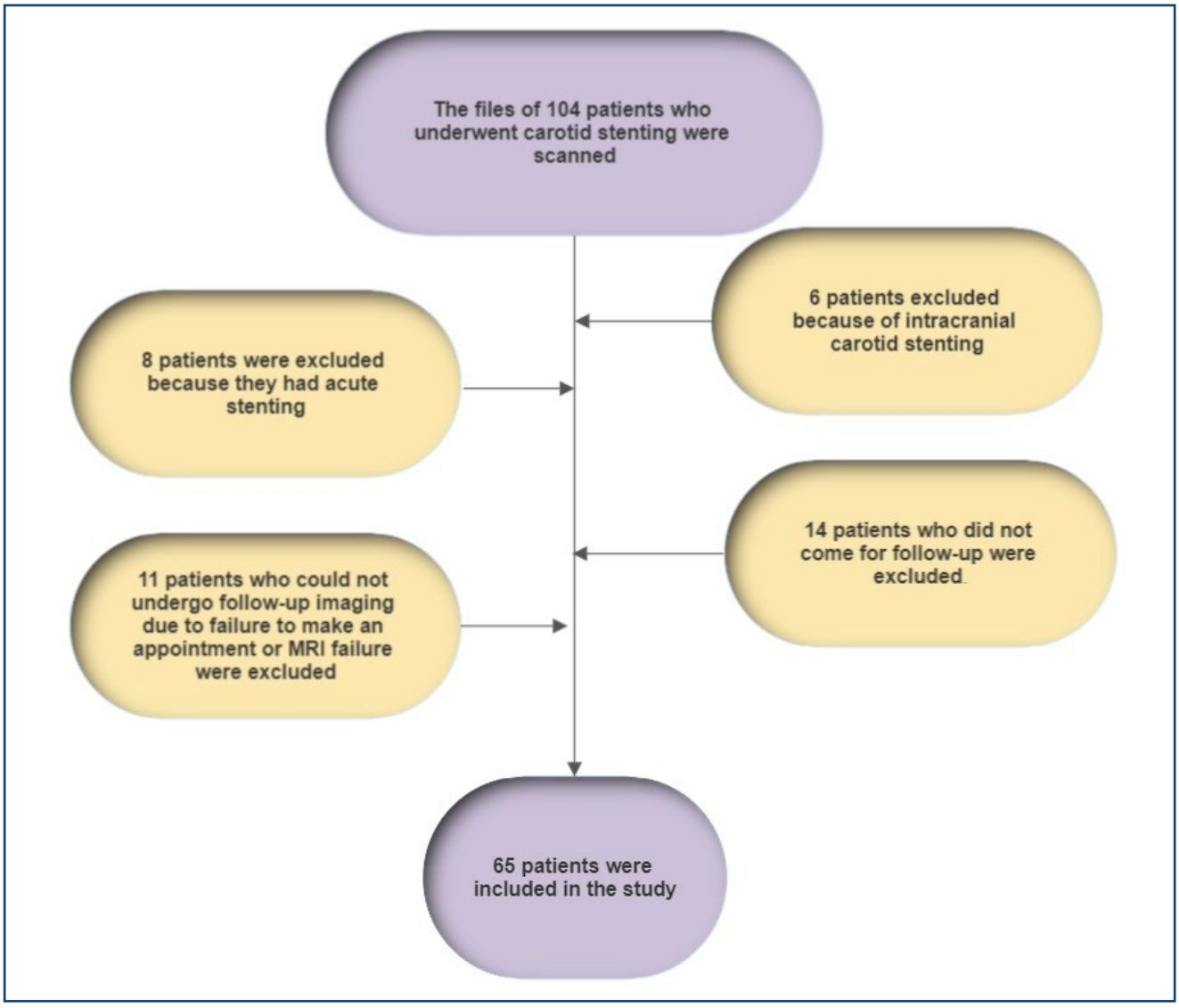

Figure 1. Flowchart.

Table 1. Comparison of patients' demographic data and vascular risk factors.

	Open-cell stent n=39	Closed-cell stent n=26	p
Age	68.02±11.45	67.42±9.08	0.82
Gender M/F	25/14	20/6	0.27
HT n (%)	28 (71.8)	19 (73.1)	0.91
DM	18 (46.2)	13 (50)	0.76
HL	26 (66.7)	20 (76.9)	0.37
CAD	17 (43.6)	11 (42.3)	0.91
Previous stroke	14 (35.9)	11 (42.3)	0.60
Smoker	20 (51.3)	12 (46.2)	0.68

HT: hypertension; DM: diabetes mellitus; HL: hyperlipidemia; CAD: coronary artery disease.

New ischemic lesions were detected in 29 (74.4%) patients in the open-cell stent group and 10 (38.4%) patients in the closed-cell stent group, and they were significantly higher in the open-cell group (p=0.004). No significant difference was identified between the two groups in terms of stent thrombosis, restenosis, and major cardiac and cerebrovascular events within the first 3 months postoperatively (Table 3).

DISCUSSION

In this study, we found that the rate of new ischemic lesion development in diffusion MRI was significantly lower in patients undergoing closed-cell stenting.

Table 2. Comparison of patients' radiological data.

	Open-cell stent (39)	Closed-cell stent (26)	p
Stenosis rate	73.0±11.04	80.69±12.37	**0.011**[a]
Contralateral stenosis rate	20.28±25.43	30.76±34.57	0.16
Leftf (%)/Right (%)	25 (64.1)/14(35.9)	16 (61.5)/10 (38.5)	0.83
Symptomatic/Asymptomatic (%)	29 (74.4)/10 (25.6)	21 (80.8)/5 (19.2)	0.54
Residual stenosis	14.69±10.67	11.11±11.6	0.19
Balloon angioplasty (%)	27 (69.2)	21 (80.7)	0.30
DF (%)	22 (56.4)	14 (53.8)	0.83
Predilatation (%)	6 (15.3)	17 (65.3)	**0.00**[b]
Postdilatation (%)	25 (64.1)	18 (69.2)	0.66
Double angioplasty vs others (%)	4 (10.2)	13 (50)	**0.001**[b]
Prediltatation balloon diameters (n)	2 mm (2) 3 mm (4)	2 mm (1) 2.25 mm (1) 2.5 mm (2) 2.75 mm (3) 3 mm (5) 3.5 mm (5)	
Posdiltatation balloon diameters	3 mm (1) 3.5 mm (2) 4 mm (2) 4.5 mm (3) 5 mm (18)	4 mm (2) 4.5 mm (11) 5 mm (11)	

DF: distal filter; [a]Independent sample T test; [b]Chi square test; p<0.05.

Table 3. Comparison of clinical outcome data of patients during 3-month follow-up.

	Open-cell stent (39)	Closed-cell stent (26)	p
Stent thrombosis	1 (2.5)	0	0.41
Restenosis>50%	0	0	–
Minor ischemic stroke	2 (5.1)	1 (3.8)	1.00
Major ischemic stroke	2 (5.1)	0	0.51
Intracerebral hemorrage	0	0	–
Death	1 (2.5)	0	0.41
MACCE	2 (5.1)	0	0.51
Silent ischemic lesion	29 (74.3)	10 (38.4)	**0.004**[a]

[a]Chi square test; p<0.05. MACCE: major adverse cardiac and cerebrovascular events.

Carotid stents consist of cascading rings connected in a helical fashion by bridges. The free cell area between the bridges varies according to the bridge density between the rings. Stents with a free cell area of less than 5 mm^2 are called closed-cell stents, while those with a free cell area of more than 5 mm^2 are called open-cell stents. Closed-cell stents provide a higher level of support to the vessel wall, and the radial force applied by the stent reduces the likelihood of thrombogenic material passing into the circulation. Open-cell stents, on the other hand, have fewer bridges, allowing them to be more flexible and to be applied to tortuous vessels[15]. In our study, a Wallstent (Boston Scientific, Marlborough) stent with a free cell spacing of 1.08 mm^2 from the closed-cell stent group and a Protégé (Medtronic Corp., Minneapolis, MN, USA) stent with a free cell spacing of 10.71 mm^2 from the open-cell stent group were employed.

Timaran et al.'s randomized controlled study conducted on 40 high-risk patients for endarterectomy reported that new ischemic lesions were detected in 53% of the patients in the open-cell group and 47% in the closed-cell group and that no difference was found between microembolic signals detected by transcranial Doppler and the rates of new ischemic lesion development of the two groups[15]. Bijuklic et al.'s observational study identified new ischemic lesions in 26% of the patients in both the open-cell and closed-cell stent groups[18]. Leal et al.'s study evaluating 45 patients undergoing closed-cell stenting and 19 patients undergoing open-cell stenting detected new ischemic lesions in 18% and 37% of patient, respectively[19]. Park et al.'s study evaluating 91 CAS cases reported a significantly higher number of new ischemic lesions for the open-cell stent group[17]. In a meta-analysis of 930 cases in total, which evaluated the data of 8 studies assessing postoperative MR images, the probability of developing both ipsilateral and contralateral new ischemic lesions was found to be significantly higher in the open-cell stent group. It has been reported that the probability of developing a new ischemic lesion is 25% higher when CAS is performed with an open-cell stent (RR, 1.25 95%)[7]. In our study, a new ischemic lesion was identified in 74.4% of the

open-cell stent group, which is significantly higher, than the 38.5% of the closed-cell stent group. In our study, a higher rate of new ischemic lesions was found in the open-cell stent group compared to previous studies. In the study conducted by Park et al., it was reported that 51.1% of new ischemic lesions were detected in which the Precise stent was used[17]. This may be related to the wider free cell spacing of the Protégé stent (10.71 vs. 5.89 mm^2).

Hart et al.'s observational study conducted on 701 CAS patients found a significantly low rate of new neurological event development in patients undergoing closed-cell stenting (3.4% vs. 1.3%)[20]. A study by Bosiers et al. investigating 3,179 stent cases reported a new neurological event and death within 30 days in 3.4% of the patients undergoing open-cell stenting and 1.2% of the patients undergoing closed-cell stenting[11]. A meta-analysis including 46728 CAS cases identified no significant association with stent design in terms of major events at 30-day and 1-year follow-ups[7]. In another meta-analysis evaluating only 1,557 CAS cases performed on symptomatic patients, the risk of stroke within 30 days was found to be 10.3% in those undergoing open-cell stenting and 6% in those undergoing closed-cell stenting[16]. In our study, a major cerebrovascular event developed within 90 days in two (5.1%) patients in the open-cell group but in none (%0) in the closed-cell group.

Today, hybrid and dual-layer mesh-covered stents (DLS) are also available. Although hybrid stents are thought to theoretically combine the advantages of both stents, a meta-analysis that included 4,182 cases of stroke and death within 30 days found no difference between open-cell and closed-cell stents, nor did it find any significant difference between the two groups in the comparison of hybrid stents and closed stents involving 5,987 cases[7]. It was reported by Montorsi et al. that less microembolic signal was detected in cases using DLS than those using closed-cell stents[21]. In the ESVS 2023 guideline, consideration of DLS in cases of elective carotid stenting has been added as a new recommendation at Class 2b level C[2]. Hybrid or DLS stents were not used in our study. In DLSs, the very small cell sizes of the inner mesh cover the plaque better and reduce the risk of prolapse. DLS may be preferred, especially in cases where plaque structure is more risky, but its higher cost is a factor limiting its use.

De Viries et al.'s meta-analysis identified no significant difference between the rates of restenosis and stent fracture between open-cell and closed-cell patients; however, they reported a rate of restenosis of 5% for open-cell patients and 3.2% for closed-cell stent patients[7]. In our study, stent fractures and significant restenosis were not observed in the 3-month follow-up of the patients. Acute stent thrombosis developed in one patient in the open-cell stent group.

Balloon angioplasty is another factor that may be associated with complications in carotid stenting. It is thought that the plaque may break up with the effect of a "cheese grater" and cause embolism, especially in the postdilatation stage. In the meta-analysis study conducted by Ziapour et al., it was determined that avoidance of postdilatation reduces the risk of hemodynamic instability and that both postdilatation and predilatation do not have an independent effect on the development of new neurological events or mortality. However, it has been reported that the risk of developing neurological events is higher in patients who have undergone two dilatations, regardless of the type of dilatation[22]. In our study, although the proportion of patients who underwent two dilatations was higher in the group receiving closed-cell stents, the number of silent ischemic lesions was lower. In the ESVS guideline, it is recommended to prefer a balloon size of <5 mm if predilatation is to be made and to avoid postdilatation if residual stenosis is <30%. In our study, balloons with sizes between 2 and 3.5 mm were used for predilatation and between 3 and 5 mm for postdilatation, in accordance with the recommendations of the guidelines[2]. New ischemic lesions developing after carotid stenting are clinically important, even if they do not give any signs. In a long-term follow-up study conducted by Gensicke et al. on 62 patients who developed new ischemic lesions after CAS and 62 patients who did not, the 5-year risk of TIA or stroke was found to be significantly higher in those with new ischemic lesions, as shown on DWI (22.8 vs. 8.8%)[23]. It has also been reported that silent ischemic lesions increase the risk of cognitive decline and dementia[24]. During carotid revascularization procedures, iatrogenic and atherosclerotic microemboli and cerebral blood flow variability could cause cognitive deficits. The RAVLT (Rey Auditory Verbal Learning Test) test the success of total volumes of microemboli developing after CAS was found to be negatively correlated in short- and long-term follow-ups. Localization of silent ischemic lesions has also been noted to be important[25]. Therefore, it is critical to develop techniques that will reduce the possibility of silent ischemic lesion development in the CAS procedure. In our study, no cognitive evaluation was made, and both patients who had a stroke within a month had a silent ischemic lesion in the postoperative DWI scan.

The limitations of our study include its retrospective nature, a relatively small number of cases, and short follow-up periods. Although ours is a retrospective study, there was no bias in stent preference because the stent design available in the hospital at that time was used. Further randomized controlled studies with

high case numbers and long follow-up periods, also involving patients with hybrid and DLS stent designs and making cognitive evaluations, are needed.

CONCLUSION

Although it is thought that silent ischemic lesions don't show any clinical signs, such lesions are known to be associated with long-term stroke risk and cognitive impairment[23,24]. Therefore, it is essential to develop strategies aimed at reducing the development of silent ischemic lesions. In this study, we evaluated the effect of stent design, a factor that might influence procedural complications, on new ischemic lesions in DWI, and the rate of new ischemic lesion development was found to be significantly higher in CAS with an open-cell Protégé stent than in those performed with a closed-cell Wallstent stent.

AUTHORS' CONTRIBUTIONS

AY: Conceptualization, Data curation, Formal Analysis, Writing – original draft, Writing – review & editing. **MY:** Formal Analysis, Investigation, Writing – original draft, Writing – review & editing.

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