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Comparison of Flow Impairment during Carotid Artery Stenting Using Two Types of Eccentric Filter Embolic Protection Devices

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Abstract

We investigated the angiographic findings and the clinical outcomes after carotid artery stenting (CAS) using two different, eccentric filter embolic protection devices (EPDs). Between July 2010 and August 2015, 175 CAS procedures were performed using a self-expandable closed-cell stent and a simple eccentric filter EPD (FilterWire EZ in 86 and Spider FX in 89 procedures). The angiographic findings (i.e., flow impairment and vasospasm) at the level of EPDs, neurologic events, and post-operative imaging results were compared between the FilterWire EZ and the Spider FX groups. The CAS was angiographically successful in all 175 procedures. However, the angiographs were obtained immediately after CAS-detected flow impairment in the distal internal carotid artery (ICA) in 11 (6.3%) and ICA spasms at the level of the EPD in 40 cases (22.9%). The incidence of these complications was higher with FilterWire EZ than Spider FX (ICA flow impairment of 10.5% vs. 2.2%, $P = 0.03$; vasospasm 30.2% vs. 15.7%, $P = 0.03$). There were nine neurologic events (5.1%); five patients were presented with transient ischemic attacks, three had minor strokes, and one had a major stroke. New MRI lesions were seen in 25 (29.1%) FilterWire-group and in 36 (40.4%) Spider-group patients. The neurologic events and new MRI lesions were not associated with the type of EPD used. Although the ICA flow impairment may result in neurologic events, there was no significant association between the FilterWire EZ and the Spider FX CAS with respect to the incidence of neurologic events by the prompt treatment such as catheter aspiration.

Key words: carotid artery stenting, filter embolic protection device, flow impairment, vasospasm

Introduction

The choice of embolic protection devices (EPDs) used during carotid artery stenting (CAS) procedures depends on the status of the carotid lesion and the preference of the interventional surgeon.[1–4] Although most CAS procedures are performed with the aid of such devices to prevent embolic neurological complications;[5,6] their use may result in complications, including vasospasms and dissection, and increase the complexity of the procedure.[7,8]

To address these problems and to obtain technical success, the surgeons must be proficient in the use of an appropriate combination of devices.[9,10] Hence, in this study, we retrospectively compared the incidence of flow impairment and investigated the associated clinical outcomes after CAS using two different eccentric filter EPDs, currently used in Japan.

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Materials and Methods

Our single-center registry shows that between July 2010 and August 2015, 199 patients with a diagnosis of carotid atherosclerotic disease or stenosis underwent CAS with the aid of various EPDs. The informed consent was obtained from all patients after the nature of the procedures had been fully explained. The approval was obtained from the relevant ethics committee. The degree of stenosis was determined angiographically using North American Symptomatic Carotid Endarterectomy Trial (NASCET) measurement criteria.[11] The indications for intervention were the presence of >50% stenosis

in symptomatic and >80% stenosis in asymptomatic high-risk patients.[6]

All patients underwent magnetic resonance (MR) plaque imaging before the procedure. On black blood T_1-weighted, black blood T_2-weighted, and time-of-flight images, the signal intensity of the plaque within the carotid artery was compared with that of the ipsilateral sternocleidomastoid muscle. Plaques with intraplaque hemorrhage and a lipid-rich necrotic core were defined as vulnerable and those with fibrous tissue and calcification were defined as stable.

For at least 3 days before the CAS, each patient received oral antiplatelet treatment consisting of aspirin (100 mg daily) and clopidogrel (75 mg daily) or of cilostazol (200 mg daily). The 24 patients with almost complete occlusion who underwent CAS using proximal or multiple EPDs were excluded from this study. Consequently, our final study population consisted of 175 patients treated with CAS using a simple distal eccentric EPD.

All patients were placed under general anesthesia and a bolus injection of heparin was delivered to achieve an activated clotting time >300 s. All procedures were performed with the aid of an eccentric filter design EPD. The FilterWire EZ (Boston Scientific, Natick, MA, USA), the first to be approved for use in Japan, was employed in 86 cases. The Spider FX (Medtronic, Minneapolis, MN, USA), approved subsequently, was used in 89 cases. The 175 patients underwent standard CAS after EPD placement. During the Spider FX delivery, if the microguidewire could not be advanced through a tortuous stenotic lesion, the microguidewire was passed through a microcatheter across the stenosis. The Spider FX was navigated to the distal ICA after the microcatheter was exchanged for a delivery sheath (Fig. 1). The procedure included predilation angioplasty, placement of an 8–10 mm diameter self-expandable closed-cell stent (Carotid Wallstent; Boston Scientific), and, when necessary (residual stenosis >20%), post-dilation angioplasty. All findings made in the course of CAS were recorded.

We used lateral intraoperative angiograms immediately after CAS to evaluate flow impairment. When anterograde flow in the internal carotid artery (ICA) ceased at the level of the filter EPD or was slower than that in the external carotid artery, ICA flow impairment was recorded. The distal ICA spasms at the level of the filter EPD were also recorded immediately after CAS.

All patients underwent diffusion-weighted MR imaging (DW-MRI) before and within 5 days after CAS to check for new microembolic lesions. After CAS, the patients' vital and neurologic signs were monitored and neurologic events were recorded and categorized as transient ischemic attacks (TIAs, neurologic deficit lasting for <24 h), minor stroke (neurologic deficit lasting for >24 h with a National Institutes of Health Stroke Scale score (NIHSS) <4), and as major stroke (neurologic deficit lasting for >24 h, NIHSS >4).

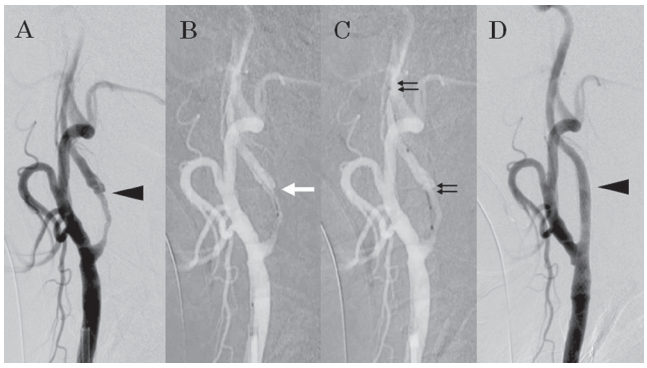

Fig. 1 Pre-operative right carotid angiograph showing tortuous ICA stenosis (A: *arrow head*). A 0.014-inch microguidewire and a microcatheter cross the stenosis (B: *arrow*). The Spider FX is navigated to the distal ICA after the microcatheter is exchanged for a delivery sheath (C: *small arrows*). The stenosis was restored immediately after stent placement (D: *arrow head*).

The baseline characteristics and the treatment outcomes were compared between the FilterWire EZ (n = 86) and the Spider FX (n = 89) groups. The continuous variables were expressed as the mean ± 1 standard deviation, and categorical variables as percentages. The Fisher's exact test was used for categorical and Mann–Whitney's U-test for continuous variables. A P-value <0.05 was considered statistically significant.

Results

As shown in Table 1, the study population comprised of 146 men (83.4%) and 29 women (16.6%); their mean age was 74.0 ± 8.0 years. Among the lesions, 91 (52.0%) were symptomatic and 84 (48.0%) were asymptomatic. Based on the NASCET criteria, the overall mean stenosis rate was 70.0 ± 13.9%, and the mean length of stenosis was 16.6 ± 5.4 mm. The vulnerable plaque was observed in 98 (56.0%) patients in the entire study. The patient's age, sex, degree of stenosis, and vulnerable plaque were not significantly different between the FilterWire and the Spider groups.

The CAS was angiographically successful in all 175 patients. We defined operative time as the interval between artery puncture and the removal of the sheath after CAS. The overall mean operative

Table 1 Comparison of baseline demographics, angiographic findings, and treatment outcomes between patients treated with CAS and the two types of eccentric filter EPDs

	Eccentric filter EPD			
	All (*n* = 175)	FilterWire EZ (*n* = 86)	Spider FX (*n* = 89)	*P*-value
Age (mean ± SD, *y*)	74.0 ± 8.0	73.0 ± 8.5	75.0 ± 7.5	0.33*
Male, *n* (%)	146 (83.4)	73 (84.9)	73 (82.0)	0.69†
Female, *n* (%)	29 (16.6)	13 (15.1)	16 (18.0)	0.69†
Symptomatic lesion, *n* (%)	91 (52.0)	44 (51.2)	47 (52.8)	0.88†
Asymptomatic lesion, *n* (%)	84 (48.0)	42 (48.8)	42 (47.2)	0.88†
Pre-operative stenosis				
Rate (mean ± SD %)	70.0 ± 13.9	69.5 ± 14.7	73.0 ± 13.0	0.44*
Length (mean ± SD mm)	16.6 ± 5.4	17.5 ± 5.4	16.0 ± 5.3	0.14*
Vulnerable plaque, *n* (%)	98 (56.0)	47 (54.7)	51 (57.3)	0.76†
Operative time (mean ± SD min)	46.0 ± 16.8	47.0 ± 15.4	45.0 ± 18.2	0.83*
Flow impairment, *n* (%)	11 (6.3)	9 (10.5)	2 (2.2)	**0.03**†
Distal ICA spasm, *n* (%)	40 (22.9)	26 (30.2)	14 (15.7)	**0.03**†
Neurologic events, *n* (%)	9 (5.1)	5 (5.8)	4 (4.5)	0.74†
TIA, *n* (%)	5 (2.9)	3 (3.5)	2 (2.2)	0.68†
Minor stroke, *n* (%)	3 (1.7)	1 (1.2)	2 (2.2)	>0.9†
Major stroke, *n* (%)	1 (0.6)	1 (1.2)	0	0.49†
Patient with new DW-MRI lesions, *n* (%)	61 (34.9)	25 (29.1)	36 (40.4)	0.15†

CAS: carotid artery stenting, DW-MRI: diffusion-weighted magnetic resonance imaging, EPD: embolic protection device, ICA: internal carotid artery, *n*: number of procedures, SD: standard definition, TIA: transient ischemic attack, *by Mann–Whitney's *U*-test, †by Fisher's exact test.

time was 46.0 ± 16.8 min; the mean operative time was 47.0 ± 15.4 min in the FilterWire and 45.0 ± 18.2 min in the Spider groups. The difference was not statistically significant.

The ICA flow impairment was observed in 11 patients (6.3%) immediately after angioplasty. The incidence of flow impairment was higher in the FilterWire group than in the Spider group (9/86, 10.5% vs. 2/89, 2.2%; $P = 0.03$). The distal ICA spasms at the level of the filter EPD were observed in 40 cases (22.9%); of these, 26 (30.2%) were in the FilterWire and 14 (15.7%) in the Spider groups ($P = 0.03$). The mild vasospasms were gradually resolved after EPD retrieval and did not result in flow impairment. However, five ICA spasms were observed after the treatment of flow impairment.

The neurologic events occurred after 9 of the 175 procedures (5.1%). A total of five patients (2.9%) experienced TIA, 3 (1.7%) suffered a minor stroke, 1 (0.6%) had a major stroke, and none developed cardiovascular events. There was no significant association between the neurologic events and the type of EPD used.

The DW-MRI detected new microembolic lesions after 61 of 175 (34.9%) CAS procedures; 52 patients (29.7%) were asymptomatic. New emboli were seen in 25 of 86 (29.1%) cases in the FilterWire group and in 36 of 89 (40.4%) cases in the Spider group; the difference was not statistically significant.

Table 2 shows the relationship between the ICA flow impairment and carotid lesions, neurologic events, or new lesions on DW-MRI. The mean pre-operative stenosis rate was 85.0 ± 13.1% in the flow impairment and 70.0 ± 13.8% in the normal flow group ($P = 0.05$). The mean pre-operative length of stenosis was 15.0 ± 6.2 mm in the flow impairment and 16.7 ± 5.3 mm in the normal flow group ($P > 0.5$). The five cases of flow impairment involved distal ICA spasms at the level of the filter EPD; ICA spasms without flow impairment were observed in 35 normal flow cases. The neurologic events occurred in two patients with flow impairment and in seven patients with normal flow. Although there were no significant differences in the rate of ICA spasms and neurologic events between the two groups,

Table 2 Relationship between flow impairment and carotid lesions, neurologic events, or new MRI lesions

	Flow impairment (n = 11)	Normal flow (n = 164)	P-value
Pre-operative stenosis			
Rate (mean ± SD %)	85.0 ± 13.1	70.0 ± 13.8	0.05*
Length (mean ± SD mm)	15.0 ± 6.2	16.7 ± 5.3	0.57*
Vulnerable plaque, n (%)	8 (72.7)	90 (54.9)	0.35†
Distal ICA spasm, n (%)	5 (45.5)	35 (21.3)	0.13†
Neurologic events, n (%)	2 (18.2)	7 (4.3)	0.10†
Patient with new DW-MRI lesions, n (%)	4 (36.4)	57 (34.8)	> 0.9†

ICA: internal carotid artery, DW-MRI: diffusion-weighted magnetic resonance imaging, n: number of procedures, SD: standard definition, *by Mann–Whitney's U-test, †by Fisher's exact test.

Table 3 Predictors of flow impairment after CAS from the multivariate regression model

Variable	Odds ratio (95% CI)	P-value
Filter EPD	5.5 (1.1–26.7)	0.025
Stenosis rate (%)	1.05 (1.00–1.11)	0.039

CI: confidence interval, EPD: embolic protection device.

Table 4 Association between ICA flow impairment and the FilterWire EZ.

	Flow impairment (n = 9)	Normal flow (n = 77)	P-value
Pre-operative stenosis			
Rate (mean ± SD %)	85.0 ± 13.4	67.0 ± 14.7	0.10*
Length (mean ± SD mm)	15.0 ± 6.3	17.5 ± 5.3	0.45*
Vulnerable plaque, n (%)	6 (66.7)	41 (53.2)	0.50†
Neurologic events, n (%)	1 (11.1)	4 (5.2)	0.43†
Patient with new DW-MRI lesions, n (%)	4 (44.4)	21 (27.3)	0.44†

DW-MRI: diffusion-weighted magnetic resonance imaging, n: number of procedures, SD: standard definition, *by Mann–Whitney's U-test, †by Fisher's exact test.

the incidence was higher in the flow impairment group than in the normal flow group (flow impairment group: ICA spasm, 45.5%, neurologic events, 18.2%; normal flow group: 21.3% and 4.3%, respectively). The new DW-MRI lesions were detected in 4 (36.4%) patients with flow impairment and 57 (34.8%) patients with normal flow; the difference was not statistically significant.

The flow impairment was analyzed using multiple logistic model including filter EPD, stenosis rate, stenosis length, and vulnerable plaque as covariates (Table 3). A stepwise method was applied for variable selection: filter EPD and stenosis rate remained significant.

Table 4 shows the association between ICA flow impairment and FilterWire EZ. The mean stenosis rate was 85.0 ± 13.4%, the mean length of stenosis was 15.0 ± 6.3 mm, and the incidence of vulnerable plaques was 66.7% in the flow impairment group. The degree of stenosis and the incidence of post-procedural events were not significantly different between the flow impairment and normal flow groups.

Discussion

Hart et al.,[12] who examined the effect of device characteristics on the clinical treatment outcomes, reported a statistically significant decrease in embolic events when eccentric filter EPDs were used during CAS procedures. Although these devices may engage the vessel wall more firmly than concentric filter EPDs, thereby providing better protection from embolization; ICA flow impairment is caused occasionally in CAS performed using filter EPD.[13,14] Iko et al.[15] and Roffi et al.[14] reported that the incidence of flow impairment was lower in the Spider FX than in the other filter EPD groups. However, the difference was not statistically significant because the number of patients treated using the Spider FX was relatively small. Of the 175 procedures in this study, more than half involved the use of Spider FX; the rate of ICA flow impairment was significantly lower in the Spider FX group than in the FilterWire group. This difference may be explicable by the differences in the design of the filter EPDs. Roffi et al.[14] reported that the degree of debris obstruction varies with the pore size/mesh density. The pore size of FilterWire EZ is smaller than that of Spider FX (110 μm vs. <200 μm) and the latter is heparin coated to prevent thrombosis in the filter. The ICA stenoses with greater volume of debris and/or vulnerable plaque may result in a higher incidence of flow impairment after CAS. In our study, the stenosis rate, not vulnerable plaque, was predictive of flow

impairment. However, we could not demonstrate whether greater plaque volume was associated with flow impairment, because the length of stenosis was not statistically different between the flow impairment and normal flow groups.

If flow impairment is partially caused by factors other than filter obstruction, flow-limiting vasospasm and arterial dissection also must relate to ICA flow impairment. The previous studies have shown severe vasospasms requiring pharmacologic treatment or filter removal in patients treated with CAS.[7,8,14,16] We encountered 40 spontaneous improved ICA spasms at the level of the filter EPD. Of these, five vasospasms were observed after the treatment of flow impairment. In our study, although there was no significant difference in the rate of ICA spasm between the flow impairment and normal flow groups, a higher incidence of vasospasm was recorded in the flow impairment group. Furthermore, the incidence of ICA spasm was significantly higher in the FilterWire EZ than in the Spider FX group. The Spider FX features independent wire movement that keeps the EPD in place during procedural manipulations and allows for longitudinal and rotational filter movement. We suggest that this decreases the friction between the EPD and the vessel wall and may reduce the risk of vasospasm and arterial dissection. Consequently, the lower rate of ICA spasm could prevent the flow impairment in patients treated with CAS using the Spider FX.

The previous literature reported a significantly higher incidence of neurologic events in patients with ICA flow impairment, compared to patients with normal flow.[17] We encountered flow impairment in 11 patients; this complication was resolved by catheter aspiration before EPD removal. Of them, two patients experienced a post-procedural minor stroke (FilterWire and Spider, n = 1 each). Although our study recorded a higher rate of neurologic events in patients with ICA flow impairment, the difference was not significant. Moreover, the incidence of ICA flow impairment was lower after Spider than after FilterWire CAS procedures; however, there was no significant association between the types of filter used and the incidence or severity of post-CAS neurologic events. The cause of flow impairment can be filter obstruction and/or vasospasm. Although vasospasm must be restored by EPD removal, it is difficult that we discriminate the cause of flow impairment before EPD removal. Therefore, the catheter aspiration was useful to exclude the possibility of filter obstruction. We consider that prompt treatment such as catheter aspiration can prevent neurologic events even when FilterWire, which may cause ICA flow impairment more frequently, are used.

The DW-MRI detected new embolic lesions after 61 of 175 CAS procedures (34.9%); this incidence was the same as that reported in the literature.[3,18–21] Theoretically, due to its larger pore size, the Spider FX may have a lower capture efficiency and may elicit more embolic complications than other eccentric filter EPDs.[22] The different capacity of each filter may also affect distal debris migration between the filter and vessel wall. However, in our series, there was not a statistically difference between the FilterWire and the Spider FX groups with respect to the incidence of post-CAS MRI lesions. We think that the placement of a Carotid Wallstent reduced the incidence of causal plaque rupture because this stent was designed from a closed-cell and a lower outward radial force.[12,23] The inconsistency between the incidence of flow impairment and post-CAS MRI lesions may be explained by the fact that flow impairment is not caused solely by filter obstruction.

As more devices are developed, the placement of EPDs and stents may add complexity and additional instrumentation to the CAS procedure. The exchange of the microguidewire for the EPD via the delivery sheath is a necessary step in the deployment of the Spider FX that prolongs the operative time. We found that the mean operative time was somewhat shorter in the Spider FX group, although the difference was not significant. According to Powell et al.,[16] the filter EPD occasionally failed to cross critically stenotic or tortuous carotid bifurcation stenoses due to an abrupt change between its floppy distal wire and the filter basket, and that this decreased trackability. We also found that it was difficult to cross carotid stenoses with proximal tortuosity with the FilterWire EZ. On the other hand, with the Spider FX, we were able to cross all lesions because the microguidewire, which is more trackable and flexible than the distal wire of the EPDs, crossed the lesion before navigation of the EPD delivery sheath. Especially in the presence of high-grade tortuous stenoses, it was relatively easy to exchange the Spider FX after the initial combined use of a microguidewire and a microcatheter to cross the lesion. Consequently, smooth crossing of the stenosis compensated for the prolonged operative time encountered with the Spider FX and the lower incidence of flow impairment may eliminate the need for pharmacologic treatment or aspiration.

Our study has some limitations. First, the selection of filter EPD was not random. The first series of patients were treated with the FilterWire EZ and the subsequent series with the Spider FX. This may affect the different outcomes by improved skills or lesion characteristics in the CAS procedure. However, the patients' characteristics were not significantly

different between the two groups. Furthermore, we believe that the increase in technical proficiency by the learning curve would have had only a small impact on the outcomes of CAS because the Spider FX deployment necessitates more steps than the FilterWire EZ. Second, our patients underwent CAS with a self-expandable closed-cell stent. The Carotid Wallstent was used as a first choice because in our experience, stent placement has been successful even in patients with severely calcified ICA lesions.[24] However, the use of different stent types and sizes must be recommended depending on the length and shape of the lesion in individual patients.[25,26] To determine whether various combinations of filter EPDs and stents exert a significant influence on the development of flow impairment, we are in the process of carrying out a prospective study.

In conclusion, we suggest that the cause of flow impairment during CAS is not only filter obstruction, but also vasospasm by the filter EPD. Although the incidence of flow impairment was higher in CAS using FilterWire EZ, the prompt catheter aspiration therapy prevented post-procedural neurologic events. The incidence of flow impairment including vasospasm was lower in CAS using the Spider FX; however, larger pores in this device may result in higher incidence rates of MRI lesions. We consider that the interventionalists must be familiar with the characteristics and pitfalls regarding each filter EPDs to provide safer CAS procedures.

Conflicts of Interest

The authors have declared that they have no personal financial or institutional interest in any of the drugs, materials, or devices used in this study. All authors are the members of The Japan Neurosurgical Society and all have registered self-reported COI Disclosure Statement Forms online.

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