

CLINICAL RESEARCH

Interventional Cardiology

Microembolization During Carotid Artery Stenting in Patients With High-Risk, Lipid-Rich Plaque

A Randomized Trial of Proximal Versus Distal Cerebral Protection

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- Objectives** The goal of this study was to compare the rate of cerebral microembolization during carotid artery stenting (CAS) with proximal versus distal cerebral protection in patients with high-risk, lipid-rich plaque.
- Background** Cerebral protection with filters partially reduces the cerebral embolization rate during CAS. Proximal protection has been introduced to further decrease embolization risk.
- Methods** Fifty-three consecutive patients with carotid artery stenosis and lipid-rich plaque were randomized to undergo CAS with proximal protection (MO.MA system, n = 26) or distal protection with a filter (FilterWire EZ, n = 27). Microembolic signals (MES) were assessed by using transcranial Doppler during: 1) lesion wiring; 2) pre-dilatation; 3) stent crossing; 4) stent deployment; 5) stent dilation; and 6) device retrieval/deflation. Diffusion-weighted magnetic resonance imaging was conducted before CAS, after 48 h, and after 30 days.
- Results** Patients in the MO.MA group had higher percentage diameter stenosis ($89 \pm 6\%$ vs. $86 \pm 5\%$, $p = 0.027$) and rate of ulcerated plaque (35% vs. 7.4% ; $p = 0.019$). Compared with use of the FilterWire EZ, MO.MA significantly reduced mean MES counts ($p < 0.0001$) during lesion crossing (mean 18 [interquartile range (IQR): 11 to 30] vs. 2 [IQR: 0 to 4]), stent crossing (23 [IQR: 11 to 34] vs. 0 [IQR: 0 to 1]), stent deployment (30 [IQR: 9 to 35] vs. 0 [IQR: 0 to 1]), stent dilation (16 [IQR: 8 to 30] vs. 0 [IQR: 0 to 1]), and total MES (93 [IQR: 59 to 136] vs. 16 [IQR: 7 to 36]). The number of patients with MES was higher with the FilterWire EZ versus MO.MA in phases 3 to 5 (100% vs. 27%; $p < 0.0001$). By multivariate analysis, the type of brain protection was the only independent predictor of total MES number. No significant difference was found in the number of patients with new post-CAS embolic lesion in the MO.MA group (2 of 14, 14%) as compared with the FilterWire EZ group (9 of 21, 42.8%).
- Conclusions** In patients with high-risk, lipid-rich plaque undergoing CAS, MO.MA led to significantly lower microembolization as assessed by using MES counts. (Carotid Stenting in Patients With High Risk Carotid Stenosis [“Soft Plaque”] [MOMA]; NCT01274676) (J Am Coll Cardiol 2011;58:1656–63) © 2011 by the American College of Cardiology Foundation

Despite the lack of randomized controlled trials, cerebral protection appears to have reduced neurological complications during carotid artery stenting (CAS) (1,2). However, distal protection with filters did not fully prevent embolic complications. Potential reasons include unprotected lesion crossing, suboptimal apposition of the device to the arterial wall, emboli smaller than filter porous size, and loss of

debris during filter recapture. These limitations have been confirmed by previous studies with diffusion-weighted magnetic resonance imaging (DW-MRI), which revealed a 37% mean rate of post-CAS new embolic lesions, mainly silent and ipsilateral (3).

Proximal endovascular occlusion (PEO) is an alternative approach that uses balloons to occlude both the external carotid artery (ECA) and common carotid artery (CCA) leading to blood flow arrest in the target internal carotid artery (ICA). This technique may provide better protection during all procedural steps and may be particularly indicated for lesions at high risk of embolization, such as those with high lipid content and irregular surfaces (4,5). Potential drawbacks of PEO are patient intolerance to occlusion,

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Manuscript received February 4, 2011; revised manuscript received July 13, 2011, accepted July 19, 2011.

balloon-induced ECA dissection, and the need for a large sheath (8-F/9-F). Favorable results have been reported in nonrandomized studies and single-center experiences with 30-day stroke and death rates as low as 1.4% (6–9). Moreover, a lower rate of microembolic signals (MES) with proximal occlusion compared with filter protection has been demonstrated with transcranial Doppler (TCD) in unselected patients undergoing CAS (10). Thus, the aim of this study was to randomly compare PEO versus filter protection during CAS in patients with lipid-rich stenosis deemed at potential high risk of embolic complications.

Methods

Study patients. From February 2009 to March 2010, a total of 120 consecutive patients were scheduled for CAS because of carotid artery stenosis $\geq 50\%$ (according to Doppler ultrasound) in symptomatic patients and $\geq 75\%$ in asymptomatic patients. Fifty-three patients had a lipid-rich plaque at computed tomography angiography (CTA) defined as a plaque with ≤ 50 Hounsfield units (HU) (11,12) and were enrolled into the study and randomly assigned to receive distal protection using the FilterWire EZ (Boston Scientific Corporation, Santa Clara, California) ($n = 27$) or proximal protection with the MO.MA system (Invatec, Roncadelle, Brescia, Italy) ($n = 26$). Exclusion criteria were: myocardial infarction 72 h before CAS, major neurological deficit (scores on the National Institutes of Health stroke scale ≤ 15 or the modified Rankin Scale > 3), stroke or retinal embolism within 1 month before the index procedure, contralateral ICA occlusion, severe disease of the ipsilateral ECA, and intracranial stenosis of the ipsilateral CCA requiring treatment.

The carotid Wallstent (Boston Scientific Corporation) was used in all patients. The study endpoint was the MES load, as a surrogate of cerebral embolization, assessed by TCD during CAS.

Informed written consent was given by all patients, and the protocol was approved by the local ethical committee.

CAS protocol. In the FilterWire EZ group, the device was positioned in the distal ICA through a standard guide/sheath. The MO.MA (9-F in 19 patients and 8-F in 7 patients) was positioned in the CCA with the single marker of the distal balloon located in the ECA, aiming at fully excluding all side branches. After ECA occlusion was confirmed by using contrast injection, the CCA balloon was inflated. A second injection of contrast in the CCA was performed to test proximal occlusion to look for contrast stagnation. Clinical status and hemodynamic parameters (ICA back pressure) were monitored for 30 s. If occlusion intolerance did not occur, a 0.014-inch guide wire was advanced through the lesion and positioned in the distal ICA. Pre-dilation was left to the operator's discretion and performed with 4.0×40 mm coronary balloons. After deployment, all stents were dilated with a 5.0 or 5.5 mm Sterling balloon (Boston Scientific Corporation). Filter-

Wire EZ was retrieved through a 4.3-F dedicated catheter; in the MO.MA group, aspiration of 60 ml of blood was performed through the guiding catheter and, if no debris was found in the last basket, the occlusion balloon was deflated. An additional 20 ml of blood aspiration was performed if debris were found in the last basket.

All patients were treated with aspirin 100 mg/day plus clopidogrel 75 mg/day or ticlopidine 250 mg for at least 10 days before CAS and 1 month afterward. Statins were given to all patients (81% were receiving statins before study enrollment). During CAS, patients received intravenous heparin (5,000 U) to maintain the activated clotting time > 250 s. Atropine (0.5 to 1 mg) was injected intravenously immediately before stent dilation.

In all patients, a neurological examination was conducted by a neurologist before and after CAS and at 30 days.

Computed tomography angiography. Scanning was performed with a 64-slice multidetector computed tomography (CT) scan (VCT XT, GE Medical System, Milwaukee, Wisconsin). Image datasets were analyzed using volume-rendering, multiplanar reconstruction and vessel analysis software. Carotid stenosis severity and composition were assessed using magnified cross-sectional CT images obtained at the most severe narrowing site. Their density was measured in HU using a fixed pixel lens averaging 3 measurements. A lesion with ≤ 50 HU was defined as a lipid-rich plaque (11–13).

Transcranial Doppler. Two 2-MHz transducers connected to TCD equipment (MultiDop T, DWL, Sipplingen, Germany) fitted on a headband and placed on the temporal bone window were used for bilateral continuous measurement of flow velocity in the ipsilateral M1 segment of the middle cerebral artery and contralateral A1 segment of the anterior cerebral artery. Assessment of MES was carried out from the ipsilateral middle cerebral artery, whereas flow velocity assessment of the contralateral anterior cerebral artery was used for detecting activation of the collateral pathway via the anterior communicating artery during proximal occlusion. Assessment of MES was performed in the ipsilateral middle cerebral artery (14,15) during the following CAS steps: 1) lesion crossing with the FilterWire EZ or with a standard 0.014-inch wire in the MO.MA group after CCA occlusion; 2) lesion pre-dilation; 3) lesion crossing with the stent; 4) stent deployment;

Abbreviations and Acronyms

CAS = carotid artery stenting
CCA = common carotid artery
CT = computed tomography
CTA = computed tomography angiography
DW-MRI = diffusion-weighted magnetic resonance imaging
ECA = external carotid artery
HU = Hounsfield unit
ICA = internal carotid artery
IQR = interquartile range
MES = microembolic signals
PEO = proximal endovascular occlusion
STA = superior thyroid artery
TCD = transcranial Doppler

5) stent dilation; and 6) device retrieval or deflation. Contrast injection during CAS in the FilterWire EZ group increased Doppler signal intensity, leading to a possible uncorrected evaluation of MES. Therefore, these signals were excluded from final analysis. Some Doppler signals could not be counted individually in the specific procedural steps. Thus, 1 s of microembolic shower was considered as 10 MES. Macroemboli (emboli that partially or completely obstructed the middle cerebral artery [16]) were also assessed.

Radiological assessment. Cerebral DW-MRI, including T1-weighted and T2-weighted fluid attenuated inversion recover and diffusion-weighted sequences, was assessed by an experienced neuroradiologist aware of the study purpose but blinded to neurosonological and clinical data. All magnetic resonance scans were performed the day before CAS, within 48 h after CAS, and at 30 days. New cerebral lesions were evaluated and categorized according to maximal diameter (<5, 5 to 10, and >10 mm), number, and location (inside or outside the vascular territory of the target artery).

Statistical analysis. A sample size of at least 24 patients per group was calculated to assess as significant ($p < 0.05$) a difference in MES between groups equal to 1 SD (corresponding to about 84 counts [10]) with a power >90% by using the Student *t* test. Numerical data are summarized as mean \pm SD or median (interquartile range [IQR]) as specified. Categorical data are summarized as numbers and percentages. Clinical characteristics and MES counts during CAS steps were compared between groups by using the Student *t* test. Due to the skewed MES distribution, the results were confirmed by using the Wilcoxon rank sum test. For comparing MES in each CAS step, the Bonferroni correction for multiple testing was applied, thus considering p values <0.008 as significant. Categorical data were compared by using the chi-square test or Fisher exact test, as appropriate. Predictors of MES were assessed by multivariate covariance analysis considering age, high-risk surgical status, lesion length, lesion eccentricity and severity, lesion pre-dilation, and type of protection device. MES values were log-transformed before analysis. All tests were 2-sided, and p values <0.05 were considered significant, unless otherwise specified. All analyses were performed using SAS version 9.13 (SAS Institute Inc., Cary, North Carolina).

Results

Patients' clinical characteristics are reported in Table 1. The only difference in clinical variables was a significantly higher rate of hypertension in the filter group. Lesion characteristics and CAS procedural variables are reported in Table 2 and Figure 1. In the MO.MA group, CTA showed a higher stenosis area (89% vs. 86%; $p = 0.027$) by using the ECST method and rate of ulcerated plaque (7.4% vs. 35%; $p = 0.019$). Technical success (<30% post-CAS diameter stenosis) was achieved in all patients.

Table 1 Patient Characteristics

Characteristic	FilterWire EZ (n = 27)	MO.MA (n = 26)	p Value
Age (yrs)	69.4 \pm 4	68.2 \pm 7	0.673
Age \geq 80 yrs	3 (11)	2 (7.7)	0.990
Male	20 (74)	22 (85)	0.344
Hypertension	23 (85)	15 (58)	0.026
Diabetes	7 (26)	6 (23)	0.890
Hypercholesterolemia	25 (92)	25 (96)	1.000
Smoking	7 (26)	11 (42)	0.208
Coronary artery disease	19 (70)	13 (50)	0.129
Previous CABG	9 (33)	4 (15)	0.230
Previous PTCA	8 (30)	8 (31)	0.928
Symptomatic patients	2 (7)	4 (15)	0.420
High surgical-risk patients	14 (51)	8 (31)	0.119

Values are mean \pm SD or n (%).

CABG = coronary artery bypass graft; PTCA = percutaneous transluminal coronary angioplasty.

Clinical outcome. Two major complications occurred: 1 intraprocedural ipsilateral retinal embolism in the filter group and 1 cardiac death due to acute myocardial infarction 25 days after CAS in the MO.MA group. A transient mild gait disorder occurred in 1 patient in the filter group 48 h after the procedure. The PEO was well tolerated in all but 1 patient who showed the lowest mean back pressure (32 mm Hg) and developed transient aphasia and right sensory deficit during debris aspiration, which immediately resolved after CCA balloon deflation. In the MO.MA group, the mean back pressure was 50.8 \pm 11 mm Hg.

Microembolic signals. The percentage of patients with at least 1 MES during all CAS phases ranged from 81% to 100% in the FilterWire EZ group and from 27% to 96% in the MO.MA group (Table 3). Overall, there were a significantly lower number of patients with at least 1 MES in the MO.MA group compared with the FilterWire EZ group in phases 3, 4, and 5.

In the MO.MA group, the mean number of MES was significantly lower ($p < 0.0001$) in phase 3 (23 [IQR: 11 to 34] vs. 0 [IQR: 0 to 1]), 4 (30 [IQR: 9 to 35] vs. 0 [IQR: 0 to 1]), and 5 (16 [IQR: 8 to 30] vs. 0 [IQR: 0 to 1]), and significantly higher ($p = 0.0036$) in phase 6 (2 [IQR: 1 to 6] vs. 8.5 [IQR: 3 to 17]), whereas no difference was found in phase 2 as compared with the FilterWire EZ group (7 [IQR: 6 to 12] vs. 0 [IQR: 0 to 1]) (Fig. 2).

By multivariate analysis, the type of embolic protection was the only significant independent predictor of the mean number of MES (Table 4). Patients in the MO.MA group had an estimated 80% reduction in total MES number compared with the FilterWire EZ group (–81.7 [95% confidence interval: –88.6 to –70.7]; $p < 0.0001$).

In the MO.MA group, carotid vessel anatomy did not allow for inflation of the ECA balloon proximal to the superior thyroid artery (STA) in 22 of 26 patients, 31% of whom had residual flow from the ECA into the ICA as demonstrated by using contrast injection (Fig. 3). No

Characteristic	FilterWire EZ (n = 27)	MO.MA (n = 26)	p Value
Stenosis assessment by Doppler ultrasound			
PSV (m/s)	3.1 ± 0.9	3.3 ± 0.8	0.143
EDV (m/s)	1.1 ± 0.3	1.2 ± 0.4	0.493
Diameter stenosis (%)	82 ± 6	88 ± 6	0.199
Stenosis assessment by CTA			
MLA (mm ²)	3.88 ± 1.28	3.57 ± 1.81	0.342
MLD (mm)	2.01 ± 0.41	1.89 ± 0.3	0.431
Diameter stenosis (ECST, %)	86 ± 5	89 ± 6	0.027
Diameter stenosis (NASCET, %)	70 ± 8.8	74 ± 12	0.179
Hounsfield units	31.7 ± 8.8 (19-50)	31.7 ± 11.7 (14-50)	1.000
Long lesion (>15 mm)	13 (48)	14 (54)	0.678
Lesion eccentricity (>1.2)	18 (67)	17 (65)	0.922
Ulceration/thrombus	2 (7.4%)	9 (35%)	0.019
Type I aortic arch	20 (74)	22 (87)	0.344
Variants of Willis circulation	7 (26)	10 (38)	0.328
Stenosis pre-dilation	7 (26)	10 (38)	0.328
Procedural time (s)*	928 ± 236	—	—
Occlusion time (s)	—	602 ± 223	—
Macroscopic evidence of debris	7 (26)	7 (27)	0.934

Values are mean ± SD, mean ± SD (range), or n (%). *Procedural time defined as the time interval between guide/sheath positioning below the bifurcation and its retrieval.

CTA = computed tomography angiography; ECST = European Carotid Surgery Trial; EDV = end-diastolic velocity; MLA = minimal lumen area; MLD = minimal lumen diameter; NASCET = North American Symptomatic Carotid Endarterectomy Trial; PSV = peak systolic velocity.

correlation was found between ECA patency and MES count. The 2 patients with retinal embolism and gait disorder had the highest MES count during stent crossing. No macroemboli were observed during all procedures.

Radiological assessment. Cerebral DW-MRI, performed in 35 of 53 patients (66% [21 and 14 in the FilterWire EZ and MO.MA group, respectively]) at 48 h and 30 days after CAS, showed 45 new lesions in 11 of 35 patients (31.4%)

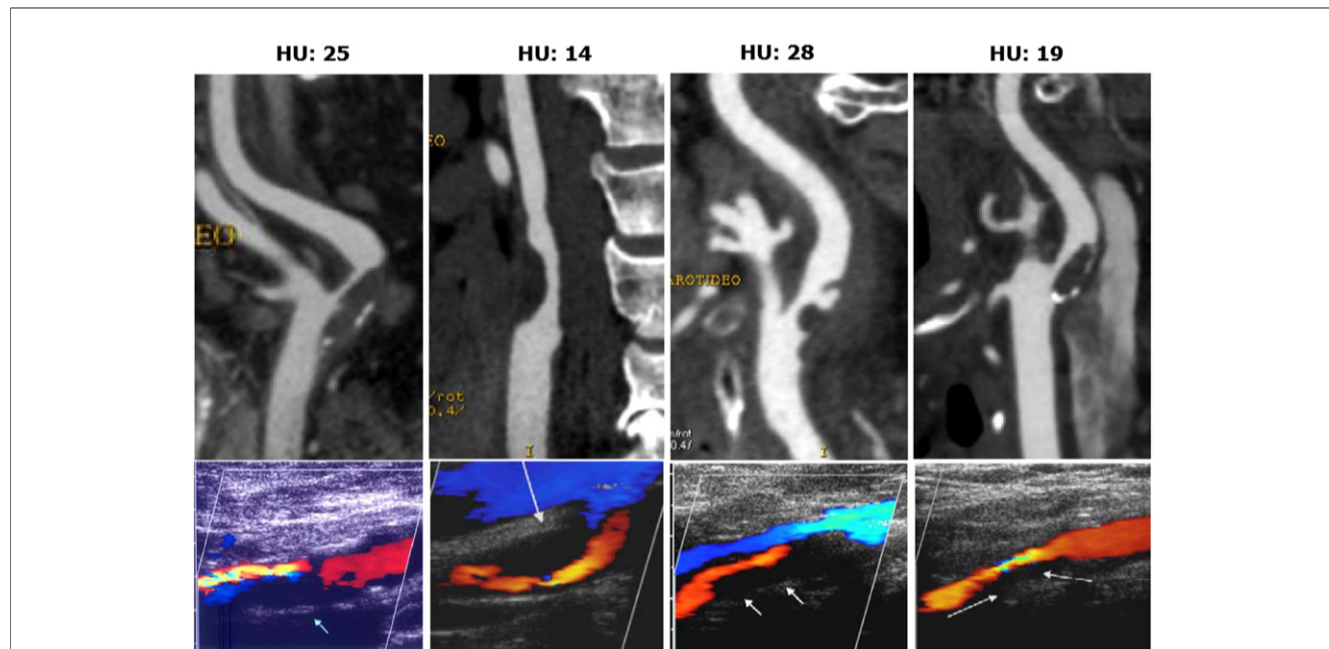


Figure 1. Carotid Vessel Evaluation by CTA and Doppler Ultrasound

Computed tomography angiography (CTA) curved multiplanar reconstruction of carotid bifurcation (**upper strip**) and corresponding color Doppler ultrasound imaging (**lower strip**) in 4 study patients. **Arrows** indicate soft plaques. HU = Hounsfield units.

Steps	FilterWire EZ (n = 27)	MO.MA (n = 26)	p Value
Lesion wiring	26 (96%)	19 (73%)	0.145
Pre-dilation*	6/7 (86%)	4/10 (40%)	0.578
Stent crossing of the lesion	27 (100%)	7 (27%)	<0.0001
Stent deployment	27 (100%)	7 (27%)	<0.0001
Stent post-dilation	26 (96%)	7 (27%)	<0.0001
Device retrieval/deflation	22 (81%)	25 (96%)	0.721

Values are n (%). *Pre-dilation: n = 7 patients in the FilterWire EZ group and n = 10 in the MO.MA group.

CAS = carotid artery stenting; MES = microembolic signals.

at 48 h. No further lesions were detected at 1-month follow-up in either group. Thirty-eight new lesions were found in 9 of 21 patients (42.8%) in the filter group, while 7 new lesions were detected in 2 of 14 (14.3%) MO.MA group patients (Fisher exact test: p = 0.14). Most (78%) of the new lesions occurred in the target vessel territory and were silent in all but 1 case. Forty-one of 45 (91.1%) lesions had a diameter ≤10 mm. The FilterWire EZ patient with retinal embolism had a negative DW-MRI study, whereas the patient with gait disorder showed bilateral lesions involving the anterior and posterior circulation.

Discussion

This is the first randomized study comparing 2 different brain protection devices in patients with high-risk, lipid-

Variable	Estimated Effect (%)	95% CI	p Value
Age (1-yr increment)	-0.4	-3.4 to 2.8	0.822
HSR versus LSR	-12.2	-52 to 60.9	0.677
Lesion length (>15 vs. ≤15)*	-16.6	-49.6 to 37.9	0.482
Lesion eccentricity (>1.2 vs. <1.2)*	52.7	-10.6 to 161	0.128
Stenosis diameter by ECST (1% increment)*	-0.5	-4.6 to 3.8	0.826
Pre-dilation (yes vs. no)	-18.4	-51.4 to 36.9	0.445
Protection device (MO.MA vs. FilterWire EZ)	-81.7	-88.6 to -70.7	<0.0001

Evaluated by using multivariate analysis of covariance. *Lesion length, lesion eccentricity, and percentage diameter stenosis were assessed using computed tomography angiography.

HSR = high surgical risk; LSR = low surgical risk; other abbreviations as in Tables 2 and 3.

rich lesions undergoing CAS. Plaque composition was assessed with CTA, and 50 HU was considered an established cutoff point for high lipid content (11,12). Given the low rate of clinically manifest embolic complications during CAS (1,2), the number of MES detected by TCD was used as a surrogate of cerebral embolization. The Wall-stent was used in all patients to standardize treatment strategy and reduce confusing factors. This stent was chosen because of its closed design with the smallest cell area that may achieve better lesion coverage and reduce plaque prolapse.

Our study found that CAS with PEO was associated with a significantly lower MES rate compared with the FilterWire EZ, suggesting better brain protection. The

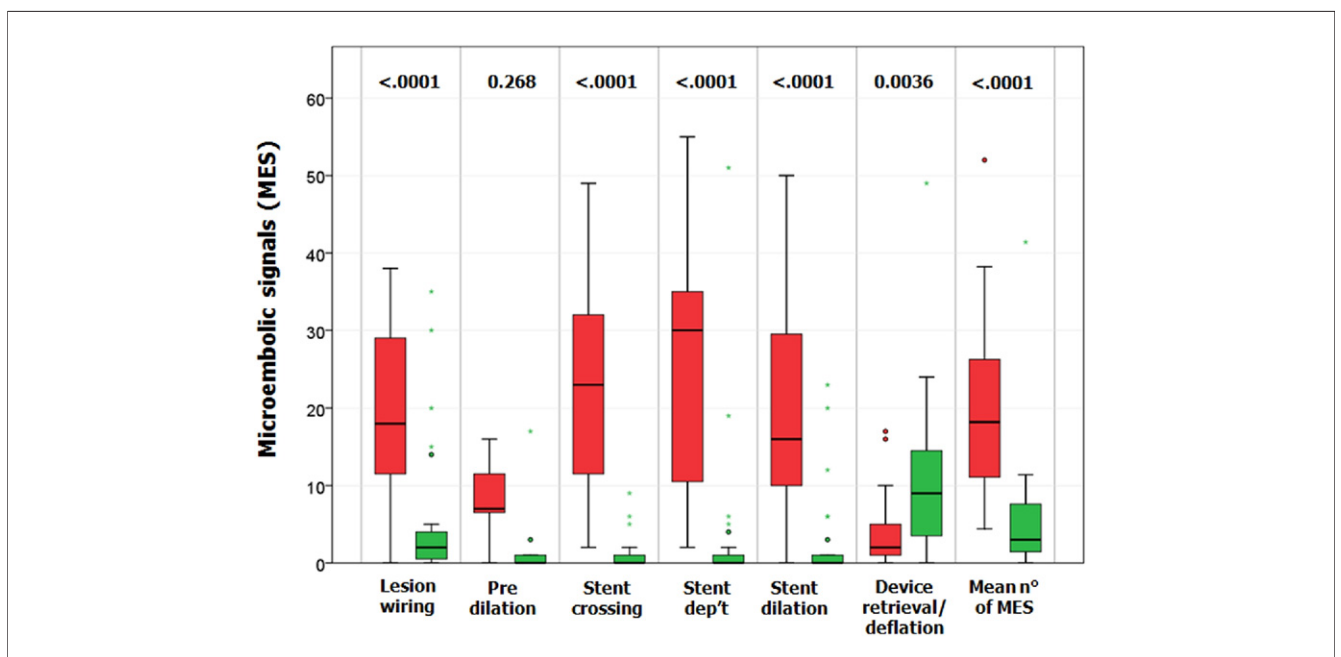


Figure 2 MES Counts During Carotid Stenting Phases

The median and interquartile range of each phase microembolic signals (MES) count are reported in the MO.MA group (green box plots) and in the FilterWire EZ group (red box plots). Statistical significance is indicated for each phase. dep't = deployment.

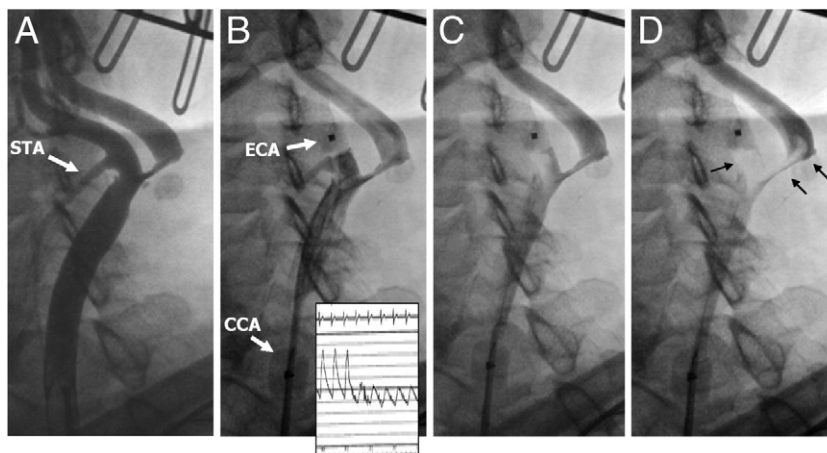


Figure 3 Angiographic Sequence of Carotid Stenting Performed with MO.MA (Patient #3)

(A) Baseline angiography (arrow indicates superior thyroid artery [STA]). (B) Inflation of external carotid artery (ECA) and common carotid artery (CCA) balloons. Flow arrest is confirmed by blood pressure drop (frame) and contrast stagnation. Note that STA is still patent due to its origin close to ECA ostium. (C and D) Progressive contrast dilution indicating collateral flow from STA to ICA (black arrows).

MES count was significantly lower with PEO in phases 1 through 4, similar in both groups in phase 2, and significantly lower in the filter group in phase 6.

Lesion crossing. If a filter is used, lesion crossing with a standard coronary wire or the device itself is performed without any protection. This method may be associated with a substantial embolization risk, especially in tight and soft/ulcerated plaques (17,18). The finding that MES number in the FilterWire EZ group was similar to that reported in unprotected CAS or in CAS performed with different distal protection devices (10,19–21) confirms that this phase is a clear source of embolization. On the contrary, PEO has the advantage of significantly reducing risk before any device is advanced through the lesion. This may explain the significantly lower number of MES in the MO.MA group compared with the FilterWire EZ group.

Stent deployment and dilation. Previous TCD studies showed that stent deployment and dilation are the steps with higher embolization risk (10,19–21). Because we used the same type of stent and implantation technique, MES count difference in these phases should be largely attributed to the type of brain protection. Use of MO.MA almost abolished MES compared with FilterWire EZ, thus confirming the superiority of the former device. Similar results have been reported by Ribo et al. (22), who used reversal flow technique during transcervical CAS although they did not report any quantitative data. We separately assessed the role of stent crossing and deployment and found that both steps cause a similar rate of microembolization. Interestingly, the 2 FilterWire EZ patients with clinical events had the highest MES counts during stent crossing. It is noteworthy that MES number in the FilterWire EZ group was somewhat less than that reported with the first-generation

device (FilterWire XL) (10,20). This finding may be due to improvement in the filter design.

Lesion pre-dilation. Lesion pre-dilation is performed in 30% to 70% of CAS procedures (2) and is generally preferred in cases of severe stenosis and calcified vessel to facilitate stent crossing and deployment. This phase has also been shown to be at risk of embolization (19–21). Only a trend in favor of the MO.MA was found during this phase, which may be due to the small number of patients receiving balloon pre-dilation in both groups.

Device retrieval/deflation. Differently from the other CAS phases, device retrieval/deflation was associated with a significantly higher MES count in the MO.MA group and a surprisingly small number of MES in the FilterWire EZ group. A similar trend, although not statistically significant, was reported by Schmidt et al. (10); Ribo et al. (22) described short clusters of microemboli at balloon deflation. Potential explanations include suboptimal debris aspiration before balloon deflation, atherosclerotic disease of the common carotid artery at the site of balloon inflation, and “washout” of plaque debris prolapsing through the stent at the time of blood flow restoration.

Role of ECA exclusion. Occlusion of the ECA by balloon inflation is a key step of PEO. Parodi et al. (23) reported that when the CCA only was occluded, ICA flow from the ECA was observed in most patients, potentially leading to debris embolization. Because the STA is the first ECA branch, the balloon should be inflated before its take-off to achieve ECA exclusion. In this study, STA was not excluded in 84% of cases because it took off from the ECA ostium or distal CCA (24). Indeed, angiography demonstrated residual flow from STA to ICA in 30% of these cases. However, neither significant MES during CAS nor

new cerebral lesions at DW-MRI were detected in these patients, suggesting a minor clinical role of STA patency. **Diffusion-weighted MRI.** New cerebral ischemic lesions, mainly silent, have been found by using DW-MRI after either diagnostic or interventional procedures of extracranial carotid arteries (25). A systematic review by Schnaudigel et al. (3), which included 1,363 patients undergoing CAS, reported a 37% mean rate of new ischemic lesions. These lesions were found both in and outside the target vessel territory, suggesting suboptimal brain protection in the former case and a role of complex anatomy, and diffuse disease of the aortic arch and supra-aortic vessels as sources of embolization in the latter case. We found new ischemic lesions in 31% of patients (42.8% in the FilterWire EZ group and 14.3% in the MO.MA group). This difference was not statistically significant. The lesions were ipsilateral in 78% of patients, underlining the CAS-associated risk and the need of further cerebral protection improvement. Similar data were reported by Faraglia et al. (26) and Leal et al. (27), who found new lesions in 13.9% and 12.5% of patients undergoing trans-cervical CAS under flow reversal protection, respectively.

Predictors of total number of MES. Several clinical and angiographic variables (age, high-risk surgical status, stenosis severity, length and eccentricity, lesion predilation, and type of protection device) have been found to predict neurological CAS complications and may have influenced our results. Interestingly, by multivariate analysis, the only predictor of MES count was the type of brain protection. Indeed, CAS with MO.MA was associated with an 80% reduction in TCD-detected cerebral embolization.

Clinical implications. Although there is evidence that MES represent microemboli, the clinical impact of cerebral microembolization during CAS is not established. However, cerebral microemboli have been involved in cognitive decline after heart surgery, carotid endarterectomy, and CAS (28,29). Multiple risk factors, including age, hypertension, and/or diabetes affecting cerebral microcirculation, may increase brain vulnerability to ischemic injury from microemboli in patients undergoing CAS. If this holds true, MES reduction during CAS should be pursued to improve clinical outcome.

Study limitations. All CAS were performed by experienced operators and only one type of filter was used. Thus, our results should be interpreted with caution and may be different with other distal protection devices.

Conclusions

Microembolization was significantly reduced by MO.MA compared with FilterWire EZ during CAS of high-risk, lipid-rich lesions, suggesting that PEO may provide better brain protection.

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Key Words: carotid stenting ■ cerebral embolization ■ embolic protection.