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The Woven EndoBridge for unruptured intracranial aneurysms: Results in 95 aneurysms from a single center

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The Woven EndoBridge for unruptured intracranial aneurysms: Results in 95 aneurysms from a single center

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Abstract

Background and purpose: The Woven EndoBridge (WEB) is an intrasaccular flowdisruptor that is increasingly used for the treatment of (wide-necked) aneurysms. We present our experience with the WEB for unruptured aneurysms.

Materials and methods: Between April 2014 and August 2019, 93 patients with 95 unruptured aneurysms were primarily treated with the WEB. There were 69 women and 24 men, mean age 61 years (median 58, range 37–80).

Results: Of 95 aneurysms, 86 had been discovered incidentally, 3 were symptomatic and 6 were additional to another ruptured aneurysm. Location was anterior communicating artery 33, middle cerebral artery 29, basilar tip 19, carotid tip 8, posterior communicating artery 4, posterior inferior cerebellar artery 1, superior cerebellar artery 1. Mean aneurysm size was 6 mm (median 6, range 3–13 mm).

In one aneurysm additional coils were used and in another, a stent was placed. There was one procedural rupture without clinical sequelae. There were two thrombo-embolic complications leading to permanent deficit in one patient (mRS 2). Morbidity rate was 1.0% (1 of 93, 95%CI 0.01–6.5%) and mortality was 0% (0 of 93, 95%CI 0.0–4.8%). Angiographic follow-up at six months was available in 85 patients with 87 aneurysms (91%). Of 87 aneurysms, 68 (78%) were completely occluded, 14 (16%) had a neck remnant and 5 were incompletely occluded. Four aneurysms were retreated. Retreatment rate was 4.5% (4 of 87, 95%CI 1.7–13.6%).

Conclusion: WEB treatment of unruptured aneurysms is safe and effective. Additional devices are needed only rarely and retreatment at follow-up is infrequent.

Keywords

Aneurysm, flowdisruptor, endovascular treatment

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Introduction

The endovascular treatment of wide-necked intracranial aneurysms with coils mostly requires the use of a temporary protection balloon or a stent. However, this makes the procedure more complicated with a higher chance of complications.[1–4] With stents, peri-procedural dual antiplatelet therapy is obligatory and has to be prolonged for three to six months. This anti-aggregation regimen results in an inherent higher risk if stent-assisted coiling is used in ruptured aneurysms.[5] In the last decade, flow diverters are increasingly used for the treatment of wide-necked unruptured aneurysms. Flow diverters require the use of dual antiplatelet therapy and thus have high risks when used for the treatment of ruptured aneurysms. Although in recent years coated flowdiverters are available (for example P64/P48 HPC en PED Shield) which could potentially reduce the need for dual antiplatelet therapy. However very promising, these coated devices are still in an early stage and more research is still needed.[6–9] Many meta-analyses have been published on the use of flow diverters.[10] Morbi-mortality with flow diversion has been described with a broad range from almost 2–10% depending on the publication. This large range can be largely explained due to high variable risk of flow-diversion depending on the treatment difficulty of the

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target lesion. The efficacy at one year is also largely variable with means of around 80%.[11–16]

Recently, the intrasaccular flow disruptor Woven EndoBridge (WEB, MicroVention, Tustin, CA, USA) device has been developed, primarily for the treatment of (bifurcation) wide-necked aneurysms without the need for adjunctive devices and antiplatelet medication. The first clinical results of the WEB device show good safety and efficacy profiles. Most of the published series comprised wide-necked, unruptured aneurysms.[17–24]

In this paper, we present our clinical and angiographic results of WEB treatment of unruptured aneurysms in a single center.

Materials and methods

Woven EndoBridge

The WEB device is a self-expanding, spherical (WEB-SLS) or pumpkin-shaped (WEB-SL), braided mesh of platinum cored nitinol wires that can be deployed in the aneurysm sac. The WEB-SL device is available in diameters ranging between 4 and 11 mm and heights ranging between 3 and 9 mm. The WEB-SLS is available in diameters ranging between 4 and 11 mm, each with a fixed height ranging between 2.6 and 9.6 mm. Depending on the size of the WEB, they can be delivered through an 0.033; 0.027 or 0.021-in. microcatheter (Via 21, 27 or 33, Microvention) A lower profile range of WEBs is compliant with an 0.017-in. microcatheter (VIA 17) since 2016.

Placed in the aneurysm, the WEB modifies the blood flow at the level of the neck and induces aneurysmal thrombosis. The WEB can be fully retrieved until final detachment by an electrothermal detachment system.

Patients and aneurysms

A retrospective review was performed on medical records and angiographic studies of patients treated with a WEB device between April 2014 and August 2019 in our institution. We included all patients treated with a WEB device during this period. Patients with recurrent aneurysms after previous endovascular treatment or ruptured aneurysms were excluded. In this period, 93 patients with 95 unruptured aneurysms were primarily treated with the WEB device, ruptured aneurysms were excluded. Two patients had two aneurysms treated with WEB.

Each patient was discussed in a multidisciplinary neurovascular team. Patients were informed about the nature of their disease, the intended treatment and potential alternatives, with informed consent obtained at least 24 h before the procedure. General indication for treatment was unruptured intradural wide-necked aneurysms suitable for the WEB device. Smaller aneurysms in the anterior circulation were treated either because of familial history, high blood pressure, harboring previously ruptured aneurysm or multiplicity of aneurysms; or due the psychological stress of having an untreated aneurysm for the patient.

Endovascular procedure

Procedures were performed with the patient under general anesthesia on a biplane or a single plane Philips Allura angiographic system (Philips Healthcare, Best, the Netherlands). Either a 6 F guide catheter alone or triaxial access was used. After a suitable working projection was identified from 3D angiographic imaging, the target aneurysm diameter and height were measured in two directions. A VIA microcatheter was placed over a 0.014- or 0.016-in. micro guidewire in the aneurysmal sack.

The selection of the diameter and length of the WEB was made with the aid of computer simulation on the 3D workstation. From 3D rotational images, the aneurysm is measured in three dimensions. Oversizing the WEB is imperative to assure anchoring the device on the aneurysm walls. In general, the WEB is oversized with 1–2 mm from the mean of the width of the aneurysm in two perpendicular planes. In recent studies an oversizing of 2 mm is preferred to obtain less compaction risk of the WEB at follow up.[25] We tended to oversize the WEB as much as possible in our patients. When a good WEB position is confirmed, the device is detached and the procedure terminated, despite the possible presence of some flow inside the WEB and aneurysm.

Anticoagulation protocol

Patients were not preloaded with antiaggregating therapy before treatment. In general, no antiplatelet medication was given after treatment. Periprocedural medication included systemic heparinization with ACT values aimed at 250.

Follow-up

Patients were scheduled for clinical and angiographic follow-up at six months and two and five years. Clinical assessment was performed according to the modified Rankin Scale. Angiographic results were graded as complete occlusion, neck remnant, or persistent flow. Also, aneurysm occlusion was graded according to the Web Occlusion Scale (WOS), based upon the modified Raymond Scale as a standard assessment scale for reporting aneurysm occlusion[26] (Table 1).

Data collection and statistics

Patient demographics and treatment- and aneurysm characteristics were collected. A retrospective review was performed on medical records and radiographic

studies of all patients with unruptured aneurysms primarily treated with the WEB between April 2014 and August 2019. Quantitative variables were expressed with descriptive statistics, and categorical variables were expressed as frequencies or percentages with 95% CIs.

Results

Demographic characteristics of patients and aneurysms

There were 69 women and 24 men with a mean age of 61 years (median 58, range 37–80 years). Of 95 aneurysms, 86 had been discovered incidentally, 3 were symptomatic by mass effect ($n = 2$) or stroke ($n = 1$), and 6 were additional to another ruptured aneurysm. Aneurysm location was anterior communicating artery 33, middle cerebral artery 29, basilar tip 19, carotid tip 8, posterior communicating artery 4, posterior inferior cerebellar artery 1, and superior cerebellar artery 1 (Table 2). Eighty-eight aneurysms (92%) had a wide neck, defined as 4 mm or a dome to neck ratio 1.5. The mean aneurysm size was 6 mm (median 6 mm, range 3–13 mm) with a mean neck size of 4.5 mm (median 4.3 mm; range 2.5–8.1 mm). Mean dome to neck ratio was 1.26 (median 1.23; range 1.00–2.11).

Initial results and procedural complications

In general, after measurement one Web-device was sufficient to obtain an adequate sealing of the aneurysm. In 2% of aneurysms treated a second device with a different sizing was needed. The position of the WEB was considered as optimal when the neck was covered, ideally showing contrast stasis inside the aneurysm. Depending on the size of the aneurysm and the WEB we used a VIA-catheter ranging from 21 to 33, newer smaller profile WEB's delivered with a 17-catheter were also used (Table 3).

An additional 2% of patients the use of adjuctive devices was required during the embolization treatment. In one aneurysm additional coils were placed to completely occlude the aneurysm. In one aneurysm an additional stent was placed because of protrusion of the WEB into the parent vessel.

Periprocedural complications occurred in 3% of patients. In a 60-year-old woman with an unruptured 3 mm middle cerebral artery aneurysm, the aneurysm ruptured by the microcatheter during attempted WEB placement. Slack on the microcatheter due to vessel tortuosity made the microcatheter jump forward during the advancement of the WEB. This resulted in a perforation at the dome of the aneurysm. The WEB was removed and a second microcatheter was placed in the aneurysm to start coiling and subsequently withdrawing the Via after initial coil placement. An adequate occlusion was obtained following remodeling and stent placement. The patient outcome was excellent after three months (mRS 0). This patient is excluded from follow-up analysis.

There were two thrombo-embolic complications leading to a permanent deficit in one patient (mRS 2). Both thrombo-embolic complications occurred in a distal branch, probably due to the necessity of replacing the WEB a few times before obtaining an adequate position in the aneurysm. There was no mortality. Morbidity rate was 1.0% (1 of 93, 95%CI 0.01–6.5%), and mortality was 0% (0 of 93, 95%CI 0.0–4.8%).

Clinical and imaging follow-up

Angiographic follow-up at six months was available in 85 patients with 87 aneurysms (92%).

Of 87 aneurysms, 68 (78%) were completely occluded (Figures 1 and 2) (7 with proximal recess filling), 14 (16%) had a neck remnant and 5 (6%) were incompletely occluded. According to the WOS, 61 were completely occluded type A and 7 were occluded with a neck remnant type B (Table 4). Of five incompletely occluded aneurysms, four were retreated: three with a flowdiverter after 3, 24, and 24 months, respectively (Figure 3), and one with

Table 1. Web Occlusion Scale (WOS).

A	Complete occlusion
B	Complete occlusion. Visible collection of contrast within the marker recess
C	Residual neck filling. Contrast opacification of the aneurysm neck extending beyond the marker recess
D	Residual aneurysm filling. Contrast beyond the aneurysm neck and into the fundus. Either deep to the proximal recess or around the periphery of the device.

Table 2. Aneurysm location and aspect ratio breakdown.

	Anterior circulation ($n = 70$)	Mean neck	Mean width to neck ratio	Posterior circulation ($n = 25$)
ACA	33 (47%)	4.5	1.33	
ACM	29 (41%)	4.15	1.22	
Carotid tip	12 (12%)	5.00	1.17	
Basilar tip		4.94	1.25	19 (76%)
PCA/SCA		4.6	1.14	4/1 (20%)
PICA		4.6	1.74	1 (4%)

Table 3. Via-size used partial breakdown per aneurysm type.

	ACA		ACM		BASILAR	
Via size	*N*	Max mean size (mm)	*N*	Max mean size (mm)	*N*	Max mean size (mm)
17	4	4.6	8	3.6	3	4.8
21	19	5.6	10	4.6	7	5.2
27	6	7.4	11	6.5	8	7.2
33	3	12			1	9.0

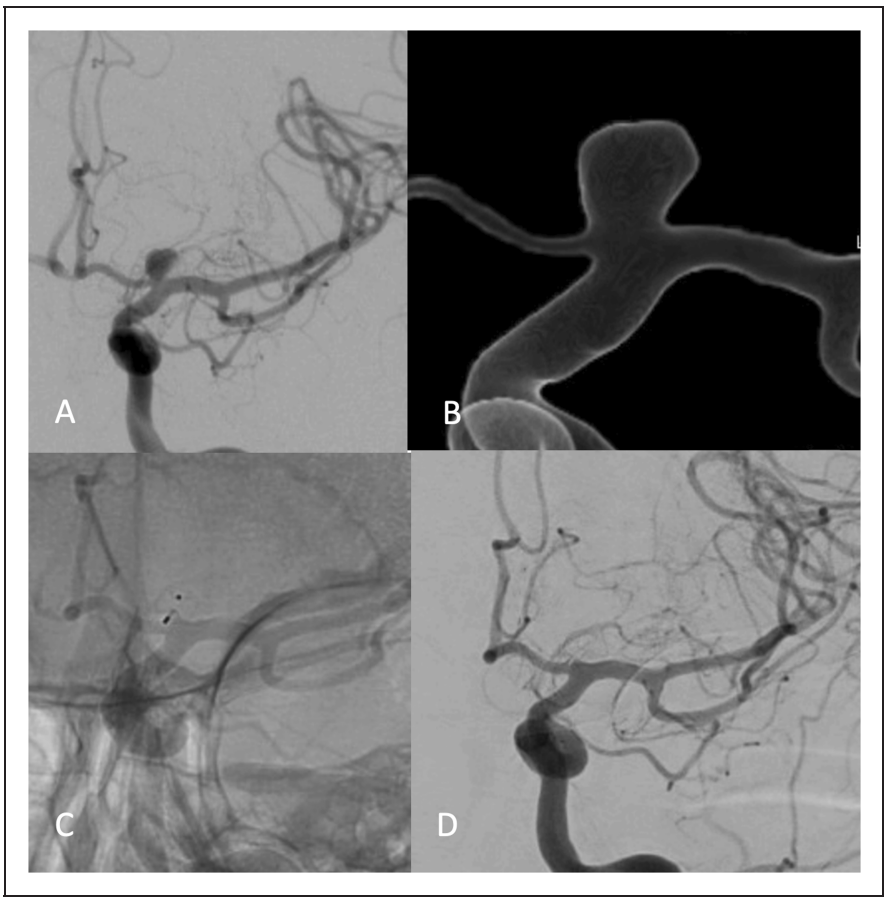

Figure 1. 49-year-old woman with an incidental carotid tip aneurysm: (a, b) 2D (a) and 3D (b) angiogram demonstrates wide-necked aneurysm; (c) WEB position after placement; (d) 5-years follow-up angiogram with stable complete occlusion.

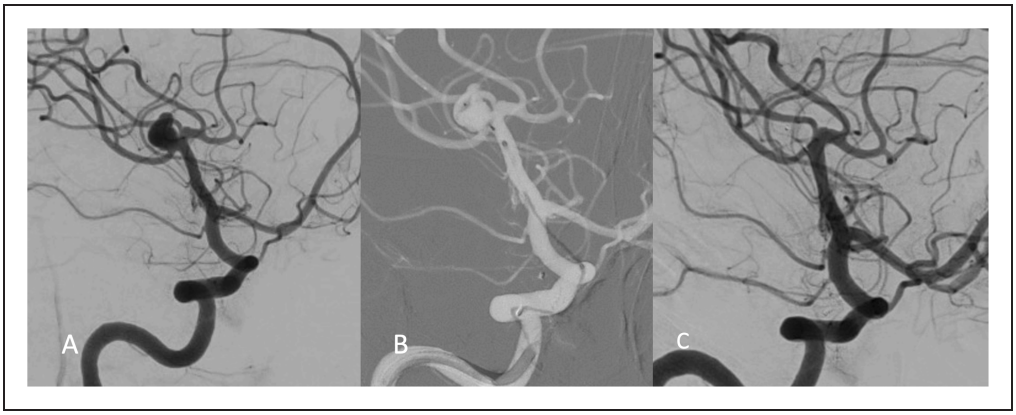

Figure 2. 55-year-old woman with an unruptured middle cerebral artery aneurysm additional to another ruptured aneurysm: (a) oblique right internal carotid angiogram shows wide-necked middle cerebral artery aneurysm; (b) immediately after WEB placement; (c) complete occlusion on two years follow-up angiogram.

Table 4. Results of follow-up angiography according to the Web Occlusion Scale (WOS).

Aneurysm occlusion	Six months	Two years	Five years
WOS A	61 (70%)	41 (78%)	4 (100%)
WOS B	7 (8%)	4 (8%)	
WOS C	14 (16%)	5 (10%)	
WOS D	5 (6%)	2 (4%)	
Total patients with follow-up ($n = 95$)	87 (92%)	52 (55%)	4 (4%)

Y-stenting and coiling after 12 months. Eligibility for retreatment was decided after multidisciplinary discussion. In general, we retreat aneurysms with evolutive remnants on second angiography or with a neck remnant of more than 3 mm. At follow-up, occlusion was complete in all four additionally treated aneurysms. Retreatment rate was 4.5% (4 of 87, 95%CI 1.4–11.6%). Angiographic follow-up at two years was already done in 55% of treated aneurysms, these revealed no impaction of the WEB device.

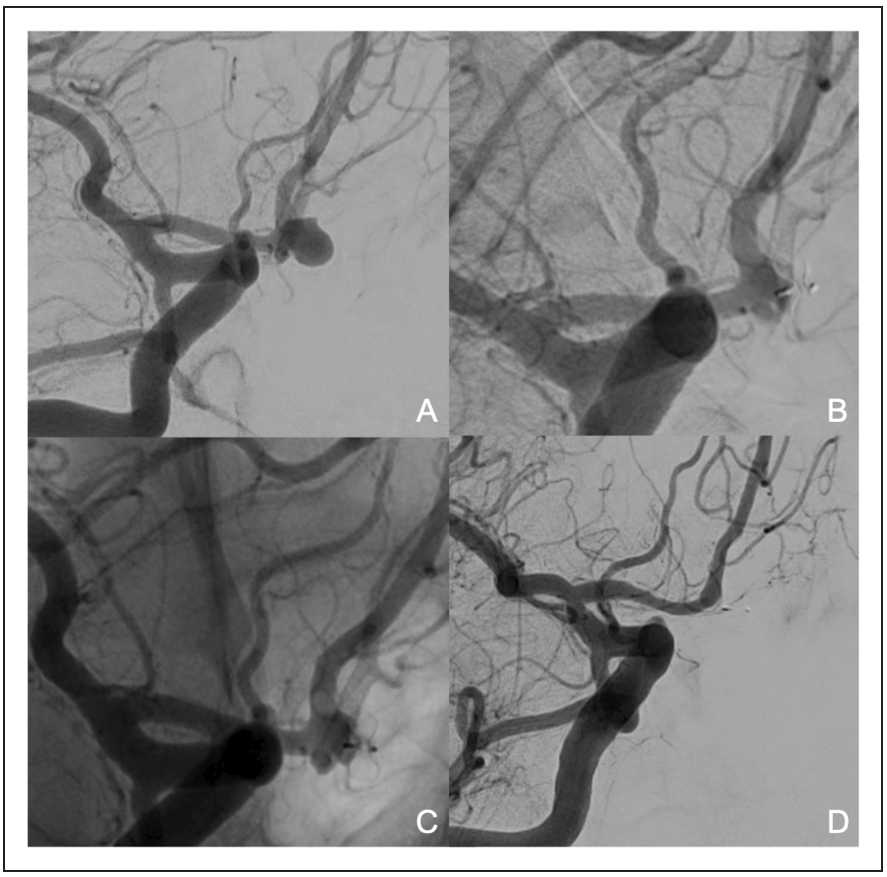

Figure 3. 51-year-old female patient with an incidental A1–A2 aneurysm: (a) aneurysm in oblique view with visible Acom. Good A1 on the left side; (b) Six months after treatment revealing impaction with a neck remnant of 2 mm; (c) control angiogram two years after initial treatment with further growing neck remnant to 3 mm. At that time, the decision was made to treat with a flow diverter (P48) to occlude the remnant; (d) control angiogram at six months shows a good occlusion of the remnant and occlusion of the Acom connection.

There were no hemorrhagic complications during the follow-up period.

Discussion

In this study of WEB treatment of wide-necked unruptured aneurysms, the safety and efficacy of the treatment were excellent. Morbidity was 1% and there was no mortality. At six months follow-up, 92% of aneurysms were adequately occluded and the retreatment rate was 4.5%. These results were generally obtained with the use of a single WEB device without additional devices. No antiplatelet therapy was needed in the peri- and postprocedural period.

Although confidence intervals are relatively wide in our study, results compare favorably with recent meta-analyses of WEB treatment of intracranial aneurysms.[20,21,24] In the WEB single-layer review,[24] cumulative morbi-mortality was almost 4% and the retreatment rate was over 8%. In a meta-analysis by Armoiry et al.,[20] permanent morbidity and mortality were 2.2–6.7% and 0–17%, respectively. The adequate occlusion rate varied between 65 and 85% at midterm follow-up. In another meta-analysis,[21] midterm complete and adequate occlusion rates after a median of seven months were 39% (95% CI, 26–52%) and 85% (95% CI, 78–91%), respectively. Perioperative morbidity and mortality rates were 4% (95% CI, 1–8%) and 1% (95% CI, 0–2%), respectively.

The safety of WEB treatment for unruptured (wide-necked) aneurysms is comparable with simple coiling but is better than both stent- or balloon-assisted coiling[5,27–29] and flow diversion.[10,14–16] In a meta-analysis by Algra,[29] compared with standard coiling, the pooled OR for complications in stent-assisted coiling was 1.82 (95% CI, 1.16–2.85%) and in balloon-assisted coiling 1.25 (95% CI, 0.71–2.20%).

Between February 2013 and January 2020, 19 meta-analyses concerning the treatment of cerebral aneurysms with flow diverters have been published.[10,15,16] Morbi-mortality of flow diversion has a broad range from almost 2–10% depending on the series. This large range can be largely explained due to high variable risk of flow diversion depending on the treatment difficulty of the target lesion. The efficacy at one year is also largely variable with means of around 80%.[11,12,30]

Since its introduction a decade ago, the WEB has proven to be a safe and effective device for both

ruptured and unruptured (wide-necked) aneurysms. The WEB is increasingly used for all types of aneurysms, bifurcation or sidewall, wide-necked, or small-necked.[26–28] The WEB may be used as an alternative for stent-assisted coiling or flow diverters in wide-necked unruptured aneurysms. The major advantage of the WEB is that peri-procedural and longstanding anti-platelet medication is not necessary. Moreover, the technique of WEB placement is relatively straightforward and comparable with standard coiling. Once the microcatheter is inside the aneurysm, WEB placement is relatively easy and quick. The WEB device is an innovative endovascular treatment device originally designed for wide-neck and bifurcation aneurysms that are technically challenging for endovascular treatment. With the progressive technical improvement of the WEB with lower profiles, smaller sizes, and low-profile catheters, indications are no longer limited to wide-neck bifurcation aneurysms. Also, sidewall aneurysms and aneurysms on distal locations are now more and more treated with the WEB.

A major concern is the retreatment rate after the use of WEB devices.[30–32] Previous long-term series reported a rate in between 11.5 and 16.3%, however Lylyk et al recently reported a retreatment rate up to 19.5%.[33–35] In our series we had a rather low retreatment rate of 4.5%. This lower retreatment rate can partly be explained due to our tendency to oversize the WEB as described recently by Guenego et al.[26] However, Herbretau et al.[36] did not find a relation between sizing and occlusion status. Unruptured aneurysms, location of the aneurysm in the anterior circulation and a wide neck size of 4-10 mm were shown to be more prone to aneurysmal remnants and the need for retreatment.[37] Initial partial aneurysm thrombosis, recurrent aneurysms and combination treatment of WEB with coils seem to be associated with higher aneurysm reoccurrence.[38] Kabbasch et al.[38] described a higher recurrence rate in relation to the height of a treated aneurysm. The mean neck size (4.5–5 mm depending on the aneurysm location) of treated aneurysms in our series was rather low and this could be a reason for our lower retreatment rate.

Lately new "neck-reconstructing" devices emerged and are available for the treatment of wide necked and bifurcation aneurysms (Contour, P-Conus, PulseRider, eCLIPse, Medina ea.).[39–47] These devices could be promising in those patients with a potential higher recurrence risk when using WEB treatment. However, the occlusion rate ranges from 50 to 83% depending on the device used.

Our results confirm the excellent safety and efficacy profiles, comparable with standard coiling, for the WEB in the treatment for unruptured aneurysms. Our study lacks the long-term follow-up to confirm our low retreatment rates. In our view, the WEB should be considered as a safe option for wide-necked, sidewall or bifurcation aneurysms. However, further research should be done to provide details concerning the best suited aneurysms to be treated with WEB and to determine the reasons for higher retreatment rates in some patients.

Declaration of conflicting interests

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