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Off-Label Use of The WEB Device

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Abstract

Introduction: We present our initial experience with the off-label use of the WEB device.

Methods: We performed a retrospective study from 2 institutions of patients with intracranial aneurysms who underwent treatment with WEB device alone or in conjunction with stenting and/or coiling in an off-labeled location.

Results: Eleven patients with 12 aneurysms were included. Four (30.8%) aneurysms presented ruptured. Off-labeled locations included 3 aneurysms in the posterior communicating artery (PCOM), 3 supraclinoid ophthalmic artery (OA), 2 pericallosal artery, 2 posterior inferior cerebellar artery (PICA), 1 vertebrobasilar junction, and 1 cavernous internal carotid artery (ICA). Mean dome-to-neck ratio was 1.91 ± 0.9 . Average duration of the procedure was 63.9 ± 29.6 min. Femoral route was used in 61.5% and radial access in 48.5% of cases. Five procedures (41.7%) were performed under monitored anesthesia care. We had 1.33 attempts per aneurysm. WEB embolization was supplemented with coiling in 2 cases (16.67%) and stenting in 1 case (8.3%). Based on the 'OKM' grading scale, we report a rate of 0% for grade 1, 33.3% for grade 2 and

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33.3% for grade 3. Post-procedural occlusion was complete in 4 (33.3%) and adequate in 8 (66.6%) patients. No procedure-related deaths or symptomatic complications were reported.

Conclusion: The WEB device was successfully deployed in off-labeled locations, including PCOM, OA and pericallosal aneurysms. The efficacy of this usage must be evaluated in multicenter prospective studies, but our preliminary results are promising. Correct characterization of the aneurysm size/morphology, as well as awareness of possible adjunct treatments, are crucial for successful intervention.

Keywords

WEB; endovascular; aneurysm; off-label; embolization; subarachnoid hemorrhage

INTRODUCTION

The Woven EndoBridge (WEB; Sequent Medical, Aliso Viejo, California) has emerged as an alternative to treat complex aneurysms. It is an intrasaccular flow-diverter that does not require long-term antiplatelet use.¹⁵ The WEB was FDA approved for the treatment of saccular, wide-necked, bifurcation intracranial aneurysms with dome diameters from 3 mm to 10 mm, a neck size ≤ 4 mm or a dome-to-neck ratio between 1–2. The WEB device has been previously used as a stand-alone device or in conjunction with other endovascular tools.²⁰ We present our initial experience with deployment of the WEB device in off-labeled locations. We used the WEB if patient was indicated for endovascular procedure and needed an adjunct to coiling (stent or flow diverter). The rationale to use the WEB is to avoid antiplatelet therapy when an adjunct to coiling is needed, and the aneurysm-patient characteristics is not suitable for microsurgical clipping.

METHODS

Patient Selection

This is a retrospective study of a prospectively maintained database from 2 separate institutions. IRB approval was obtained from both institutions. Patients (or legal representatives) consented for the off-label use of the device. The study period was from September 2018 to August 2019. The study included patients with intracranial aneurysms who underwent treatment with the WEB device only in off-labeled locations, in conjunction with stenting and/or coiling. Demographic, clinical and procedural data were collected from electronic medical charts, including age, gender, rupture status, Hunt-Hess Grade (HHG), duration of the operation, presence of complications, aneurysm characteristics (location, height, width, neck size and dome-to-neck ratio), size of the WEB device, number of attempts, catheters used, occlusion rate and O'Kelly-Marotta novel grading scale for flow-diversion.⁹ Aneurysm height was measured as the longest diameter perpendicular to the parent artery. Aneurysm width was defined as the longest diameter perpendicular to the height.

Indication: We used the WEB if patient was indicated for endovascular procedure and needed an adjunct to coiling (stent or flow diverter) that require antiplatelet agents. We treat all aneurysm in one setting if they all can be treated with one modality, and if they all

require treatment based on: rupture status, size > 7mm, family history of ruptured aneurysm and high-risk features on vessel wall imaging.

Technical considerations

One institution used femoral access while the other used trans-radial approach for all patients. The technical details are described elsewhere.²⁰ If stent placement was not planned but was deemed necessary intraoperatively, or if there was flow limitation (from stent occlusion) or WEB herniation, intravenous Tirofiban infusion was initiated prior to stent deployment and continued during 4 hours postoperatively. Our antiplatelet management regimen is described elsewhere.^{3-5,8,17} The infusion is followed by administration of dual antiplatelet therapy. If there is any concern of device herniation, aspirin therapy is maintained for 6 weeks. A tri-axial system was used to deliver the WEB device (6 Fr Neuron Max 088 as large-bore guide catheter, 6 Fr Sofia 070 as an intermediate catheter, and VIA as microcatheter). Based on the size of the WEB device, one of three available VIA microcatheters (21, 27 or 33 Fr) is used for deployment.

RESULTS

Patients and Aneurysms Characteristics

We treated 12 patients in this study. The mean age was 61 ± 13.2 years. The proportion of females was 91.7%, and 30.8% of aneurysms presented ruptured. We encountered one case of sentinel headache and 1 case of diplopia from a cavernous internal carotid artery (ICA) aneurysm. The mean dome-to-neck ratio was 1.91 ± 0.9 . Specific aneurysm features in this sample included: mean aneurysm width of 8.0 ± 6.8 mm, mean aneurysm height of 9.51 ± 7.2 mm and mean neck width of 5.0 ± 2.5 mm. We treated 3 aneurysms located in the posterior communicating artery (PCOM), 3 supraclinoid ophthalmic artery (OA), 2 pericallosal artery, 2 posterior inferior cerebellar artery (PICA), 1 vertebrobasilar junction and 1 in the cavernous segment of the ICA. Additional information regarding complications, catheters and adjunct coiling/stenting of the aneurysms is presented in Table 1.

Outcomes

The average duration of each procedure was 63.9 ± 29.6 minutes. We had 1.33 attempts per aneurysm. A 6Fr Cook (with 6F Sofia as intermediate catheter) was used mostly, except in some cases where a 6Fr Envoy was used and exchanged with a 5F Bernstein. We used the femoral route in 61.5%, and the radial in 48.5%. We performed 5 procedures (41.7%) under monitored anesthesia care. WEB devices ranged between 4×3 mm and 11×9 mm, and were delivered through VIA 21, 27, and 33 microcatheters (Sequent Medical, Inc, Aliso Viejo, California, USA).

One patient had 2 aneurysms in off-labeled locations (PCOM and pericallosal arteries) that were both treated in a single setting (Figure 1). One patient had a giant supraclinoid ICA aneurysm with a 360 ICA loop (Figure 2). We were unable to navigate through the loop; however, deployment of the WEB device made navigation easier and secured the neck. The aneurysm was then packed with adjunct coiling. One patient had an OA aneurysm treated with WEB, and an additional cavernous ICA aneurysm treated with a pipeline embolization

device (PED, Figure 3). The vertebrobasilar junction aneurysm was treated with simultaneous stenting with the LVIS device, given the size and the unfavorable shape. This was complicated by an asymptomatic angiographic decrease in flow that resolved with intra-arterial Tirofiban. One of the PICA aneurysms presented with rupture and had a favorable morphology for WEB deployment. The angiographic run post web deployment dislodged the WEB (likely due to high pressure and malposition of the device), which landed in the right VB junction. This patient had codominant vertebral arteries and the VA was reconstructed distal to PICA with onyx and coils. We managed in to secure the PICA aneurysm eventually with coils. Thus, our final complication rate was 16.7%, with all cases remaining asymptomatic. No patients developed permanent complications or clinical deficits after WEB embolization. No procedure-related mortalities were reported. One death occurred after withdrawal of care in a patient who presented with HHG of 4 and showed no improvement in the neurological exam.

Based on the 'OKM' scale,⁹ we report an occlusion rate of 0% for grade 1, 33.3% for grade 2 and 33.3% for grade 3. Complete and adequate occlusion was achieved in 4 (33.3%) and 8 (66.7%) cases, respectively. Patients with stents remained on dual antiplatelet therapy for 6 weeks, followed by monotherapy only. No aneurysm recurrences were reported in this cohort. All patients were followed-up at least during 6 weeks, with most having 6-month follow-up.

DISCUSSION

We present our initial experience with the off-label use of the WEB device, with an early success rate of 66.7% and no mortality or symptomatic complications. In the clinical study that led to FDA approval of the WEB device,¹ 54.77% of 148 treated aneurysms achieved complete occlusion within 1-year post-procedure without re-treatment, recurrent subarachnoid hemorrhage or clinically significant parent artery stenosis. Adequate occlusion was achieved in 121/143 (84.6%) subjects. The FDA then approved the WEB for adults with saccular, wide-necked, bifurcation aneurysms in the following locations: middle cerebral artery bifurcation, ICA terminus, anterior communicating artery complex, and basilar artery tip.¹⁶ The approved metrics were the following: dome diameter from 3 mm to 10 mm, neck size 4 mm or dome-to-neck ratio between 1–2. Since then, multiple studies have shown WEB embolization to be feasible and compare well with coiling.^{2,7,10–12,15} Previously reported complication rates range from 13–17%,^{12–14} with very low treatment-related mortality and serious complications.¹² The success of the WEB, combined with the development of the new single-layer WEB, provided enough rationale to propose its deployment for treatment of additional aneurysms.¹⁸

This is the first case-series describing the off-label use of the WEB device. All included aneurysms were in the approved dome-to-neck ratio, except for the giant ICA aneurysm and the vertebrobasilar aneurysm that required adjunct treatment. Although an important metric, the dome-to-neck ratio alone is not sufficient to predict complications as the aneurysm shape can be irregular leading to herniation. This was the case of one of the PICA aneurysms, which required parent vessel reconstruction, and the vertebrobasilar aneurysm, which required stenting. Of note, both aneurysms had an appropriate D/N ratio. The WEB is

diverse and can be used in adjunct to coiling, stenting or both. It can help with neck reconstruction which can facilitate navigation and secure the neck for treatment. In addition, the WEB assisted us in treating a patient with OA aneurysm at the same time as treating the cavernous aneurysm with a flow-diverter. Although the flow-diverter could have been used to treat the OA aneurysm, we believed that this could increase the risk of thrombosis of the ICA (using 2 stents) and place the ophthalmic artery at risk.

There was a difference in the endovascular access and anesthesia care between the two institutions. One institution used general anesthesia with transradial access, based on the institution cumulative experience.⁶ The second institution used a transfemoral route and monitored anesthesia care for most of the elective cases, following a strict protocol that has been implemented to provide same-day discharge for patients with aneurysms treated with the pipeline embolization device.¹⁹

Limitations

Although our success and complication rates using WEB in off-labeled locations are similar to those reported for aneurysms with approved indication, the small sample size and short duration of our study does not allow for a meaningful comparison. We consider using the WEB device in off-labeled locations when the anatomy and/or patient comorbidities favor endovascular intervention, such as when treatment of multiple aneurysms is planned in one session. One of the rationals of using WEB is to avoid using antiplatelet agents but in one case only we had to salvage the WEB with the stent. Although the WEB was used in locations that are currently not FDA-approved, the dome-to-neck ratio and neck width were in the approved range. These metrics must be considered carefully, as supplementing a WEB with a stent loses the benefit of avoiding antiplatelet therapy. Finally, these aneurysms could be dealt with via other endovascular alternatives (balloon assisted coiling or balloon + WEB, other stents or neck bridging devices, etc.) or surgical alternatives (clipping or bypass) depending on the interventionists/surgeon practice and expertise.

CONCLUSION

The WEB device was successfully deployed in different off-labeled locations, including PCOM, OA and pericallosal aneurysms. The efficacy of this usage must be evaluated in multicenter prospective studies, but we believe that our preliminary results are promising. Correct characterization of the aneurysm size and morphology, as well as awareness of possible adjunct treatments, are crucial for successful intervention.

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None

ABBREVIATIONS:

WEB	Woven EndoBridge Device
PCOM	posterior communicating artery

OA	ophthalmic artery
PICA	posterior inferior cerebellar artery
ICA	internal carotid artery
OKM	O'Kelly-Marotta Scale
FDA	Food and Drug Administration
HHG	Hunt & Hess Scale
PED	Pipeline Embolization Device

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Figure 1.

(A) Patient harboring 2 aneurysms in different off-labeled locations: PCOM (black arrowhead) and pericallosal artery (white arrowhead). (B) Anteroposterior and lateral unsubtracted views showing the WEB device deployed in the PCOM aneurysm. that were both treated in a single setting using the WEB device. (C) With the first WEB already in the PCOM aneurysm (black arrowhead), a second WEB is advanced through the microcatheter into the pericallosal aneurysm (white arrowhead). (D) Anteroposterior subtracted and unsubtracted views showing WEB devices in place. (E) Post-operative angiography showing late intrasaccular flow.

Figure 2.

(A) Giant high-flow cavernous aneurysm with difficult 360 ICA loop. (B) A WEB device is placed to secure the neck, divert the flow and facilitate navigation. (C) Post-deployment angiography shows decreased aneurysm filling (white arrowhead pointing to distal WEB marker), with improved flow in the ipsilateral MCA (when compared to A). (D) Adjunct coiling of the aneurysm.

Figure 3.

(A) Patient harboring 2 aneurysms in different off-labeled locations: OA (white arrowhead) and cavernous ICA (black arrowhead). (B) A WEB device was deployed in the OA aneurysm (white arrowhead pointing to distal WEB marker), reducing intrasaccular flow. (C) A PED was used to reconstruct the ICA at this level and exclude the cavernous aneurysm (black arrowheads). (D) Post-operative anteroposterior and lateral angiography showing almost complete occlusion of the OA aneurysm (white arrowhead, reduced intrasaccular flow compared to B) and reduced flow in the cavernous aneurysm (black arrowhead).

Table 1

Aneurysms characteristics and outcomes.

Location	Number of patients	Adjunct treatment	D/N ratio	Complications	OKM scale
VB junction	1	Coiling and Stenting	1.11	Asymptomatic decrease in distal flow	0
PCOM	3	None	3.0 1.9 1.4	None	3 3 0
OA	3	None	1.6 1.10 1.11	None	2 2 2
PICA	2	None	2.13 1.24	Web herniation None	3 3
Pericallosal	2	None	1.6 1.6	None	2 0
Cavernous ICA	1	Coiling	2.5	None	0

D/N= dome-to-neck; ICA = internal carotid artery; OA = ophthalmic artery; OKM = O'Kelly-Marotta grading scale; PCOM = posterior communicating artery; PICA = posterior inferior cerebellar artery; VB = vertebrobasilar.