Woven EndoBridge case series

2022

A multicenter study attempts to explore the changes in trends and treatment outcomes over time for WEB embolization of intracranial aneurysms. The WorldWideWEB consortium is a retrospective multicenter collaboration of data from international centers spanning from January 2011 and June 2021, with no limitations on aneurysm location or rupture status. Both bifurcation and sidewall aneurysms were included. These patients were stratified based on treatment year into five treatment intervals: 2011-2015 (N = 66), 2016-2017 (N = 77), 2018 (N = 66), 2019 (N = 300), and 2020-2021 (N = 173). Patient characteristics and angiographic and clinical outcomes were compared between these time intervals. This study comprised 671 patients (median age 61.4 years; 71.2% female) with 682 intracranial aneurysms. Over time, we observed an increasing tendency to treat patients presenting with ruptured aneurysms and aneurysms with smaller neck, diameter, and dome widths. Furthermore, we observed a trend towards more off-label use of the WEB for sidewall aneurysms and increased adoption of transradial access for WEB deployment. Moreover, the proportion of patients with adequate WEB occlusion immediately and at last follow-up was significantly higher in more recent year cohorts, as well as lower rates of compaction and retreatment. Mortality and complications did not differ over time. This learning curve study suggests improved experience using the WEB for the treatment of intracranial aneurysms and has yielded higher rates of adequate occlusion over time [1)]

A retrospective study of 31 patients with intracranial aneurysms who were treated with WEB at a single institution in the USA in 2019-2021. Data were collected via chart review on patient demographics, aneurysm characteristics, procedural details, and occlusion status at six months follow up. Bivariate analyses were performed comparing completely occluded aneurysms with neck remnants and residual aneurysms.

16 (52%) had completely occluded aneurysms while 11 (35%) patients had a neck remnant, and 4 (13%) patients had a residual aneurysm at follow-up. Patients with neck remnants and residual aneurysms had aneurysms with larger diameters. A large aneurysm diameter is an independent risk factor for incomplete occlusion (OR 4.23 95% CI 1.08-16.53 P-value = 0.038). Patients with residual aneurysms had an average difference between the aneurysm width and WEB diameter of -0.08mm compared to 1.2 mm in patients with occluded aneurysms. 75% of patients with a residual aneurysm presented with a ruptured aneurysm. Lastly, more patients with a residual aneurysm had an immediate angiographic outcome of incomplete occlusion.

Larger aneurysms are at risk for incomplete occlusion status post WEB treatment. Larger, ruptured aneurysms with minimal difference in aneurysm and WEB diameter that fail to occlude immediately post-treatment are more likely to present as residual aneurysms at short-term follow-up [2)].

Siddiqui FM, Pandey AS. Commentary: Post-Market American Experience With Woven EndoBridge Device: Adjudicated Multicenter Case Series. Neurosurgery. 2021 Jun 16:nyab203. doi: 10.1093/neuros/nyab203. Epub ahead of print. PMID: 34133743.

Data of all patients with proven SAH who were either treated with a WEB device, coil embolization, or neurosurgical clipping between March 2015 and August 2018 was systematically reviewed. Clinical parameters on intensive care unit (ICU), medical history and mortality rates were evaluated and compared between the different treatment approaches.

Of all 201 patients included, 107 patients received endovascular coil embolization, 56 patients were treated with clipping and in 38 cases a WEB device was placed. The overall mortality was 17.9%. Thirteen patients (34.2%) in the WEB group had a Hunt and Hess grade > 3. Essential medical factors showed no clinically relevant differences between the treatment groups, and the analyzed blood parameters were predominantly within physiological limits without any relevant outliers. The Hunt and Hess grade but not the treatment modality was identified as independent risk-factor associated with ICU-mortality in the overall cohort ($p < 0.001$).

In this study, there was no difference in the early clinical course between those treated with WEB embolization, coil embolization, or neurosurgical clipping. Since WEB embolization is a valuable treatment alternative to coiling, it seems not justified to exclude this procedure from upcoming clinical SAH trials, yet the clinical long-term outcome, aneurysm occlusion, and retreatment rates have to be analyzed in further studies [3)].

Between April 2013 and July 2018, 47 (ruptured, 12; 25.5%) intracranial aneurysms treated only with WEB and a follow-up of at least 3 months were included in the study. Angiographic outcome at follow-up, peri-procedural complication rate, and rate of retreatment were recorded.

Of the 47 aneurysms, 12 (25.5%) were ruptured. The mean size of the aneurysms was 6.3 mm (ruptured, 5.4 mm; unruptured, 6.6 mm). Median follow-up period was 9 months. Complete occlusion was observed in 26/47 aneurysms (55.3%; ruptured, 66.6%; unruptured, 51.4%). Thirteen aneurysms (27.6%; ruptured, 16.6%; unruptured, 31.4%) showed a neck remnant. In 4/47 aneurysms (8.5%; ruptured, 8%; unruptured, 8.5%), persistent contrast enhancement inside the WEB was recorded. In 4/47 patients (8.5%; ruptured, 8%; unruptured, 8.5%), an aneurysm remnant was noted. Adequate occlusion (complete occlusion and neck remnant) was observed in 43/47 aneurysms (91.4%; ruptured, 91.6%; unruptured, 91.4%). Retreatment rate was 6.3% (ruptured, 8%; unruptured, 5.7%). Six (12.7%; ruptured, 25%; unruptured, 8.5%) thromboembolic events were recorded. Hemorrhagic complications occurred in two patients (4.2%; ruptured, 16.6%; unruptured, 0%).

WEB enables adequate occlusion of ruptured and unruptured intracranial aneurysms mostly without requirement of long-term antiplatelet therapy. The benefit is seen especially by the wide-necked aneurysms, but indications should be extended to include narrow-necked, smaller, and side-wall aneurysms [4)].

2015

Data from all consecutive patients treated with a single-layer WEB device, in 10 European centers from June 2013 to May 2014 were included. Clinical presentations, technical details, intra- and perioperative complications, and outcomes at discharge were recorded. Clinical and angiographic data at last follow-up were also analyzed when available. RESULTS:

Ninety patients with 98 WEB-treated aneurysms were included in this study. In 93 cases (95%), WEB placement was possible. Complete occlusion at the end of the procedure was obtained in 26 instances (26%). Additional treatment during the procedure (coiling and/or stent placement) was necessary in 12 cases (12.7%). Procedure-related complications occurred in 13 cases, leading to permanent neurologic deficits in 4 patients (4.4%). Early vascular imaging follow-up data were available for 44 patients (57%), with an average time interval of 3.3 months. Treatment-related morbidity and mortality rates at last follow-up were 2.2% and 1.1%, respectively.

In this study, the feasibility and safety of the single-layer WEB device was comparable with that of the double-layer. However, further studies are needed to evaluate long-term efficacies [5].

Fifteen patients (15 aneurysms) were consecutively treated in our center by 2 operators for a large-neck bifurcation aneurysm between March 2012 and February 2014. Results were evaluated by assessing WEB cage position at the aneurysm neck on angiography and high-resolution contrast-enhanced flat-panel detector computed tomography, contrast medium stagnation within the WEB and aneurysm on intraprocedural angiography, and 1-day time-of-flight magnetic resonance angiography. All aneurysms were followed up by angiography. Results at follow-up were graded as complete occlusion, neck remnant, or residual aneurysm. The 2 operators compared postprocedural and follow-up images and classified them as better, same, or worse. Subtracted images were compared in different projections to assess any WEB device compression or shape changes. RESULTS: A worsening was observed between the postprocedural and first follow-up angiography in 10 of 14 (71.5%) and in 4 of 7 (57.2%) between the first and second control angiography. Compression of the WEB cage was observed at first follow-up in 8 of 14 (57.2%) and in an additional 3 of 7 cases (42.8%) at second control. Last angiography showed complete occlusion in 1 of 14 (7.2%), neck remnant in 8 of 14 (57.2%), and residual aneurysm in 5 of 14 (35.7%) cases. CONCLUSION: This article draws attention to the risk of WEB compression and aneurysm recanalization. Future prospective studies should evaluate delayed WEB shape changes with different types of WEB devices (dual layer, single layer, single layer spherical) [6].

Fifty-five aneurysms in 52 patients, including 14 ruptured aneurysms, underwent treatment with the WEB device. The median age of patients was 55 years (range, 30-75 years); 19/55 (37%) were men. The device could be deployed in all patients and was implanted in 51/55 (93%) cases. Procedural complications occurred in 6/51 (12%), comprising 2 thromboembolic events, 2 thrombus formations, 1 high-grade posterior cerebral artery stenosis, and 1 aneurysm rupture. None of these had clinical sequelae. Angiographic follow-up at 3 months was available for 44/51 (86%) aneurysms. A favorable angiographic result at 3 months was achieved in 29/44 (66%) cases, whereas the percentage of good anatomic results increased from 40% in 2012 to 75% in 2014.

The WEB device proved to be safe. Acceptable occlusion rates can be achieved but seem to require wide experience with the device [7].

Ten patients with unruptured anterior communicating artery aneurysms with a mean neck diameter of 5.4 mm were treated with the WEB. Treatment failed in 3 of the 10 aneurysms without further clinical complications. One patient developed a procedural thromboembolic event, and the other 6 had normal neurologic examination findings at 1-month follow-up. Immediate anatomic outcome

evaluation showed adequate occlusion (total occlusion or neck remnant) in 6 of 7 patients. Angiographic control was obtained in all patients, including 6 adequate aneurysm occlusions (3 complete occlusions and 3 neck remnants) at short-term follow-up.

In this small series, treatment of wide-neck anterior communicating artery aneurysms with the WEB device was feasible and safe. However, patient selection based on the aneurysm and initial angiographic findings in the parent artery is important due to the limitations of the WEB device navigation [8].

Seven experienced neurovascular specialists were trained. These physicians independently reviewed angiographic image sets from 30 patients treated with the WEB under blinded conditions. No additional clinical information was provided. Raters graded each image according to the WOS (complete occlusion, residual neck or residual aneurysm). Final statistics were calculated using the dichotomous outcomes of complete occlusion or incomplete occlusion. The interobserver agreement was measured by the generalized κ statistic.

In this series of 30 test case aneurysms, observers rated 12-17 as completely occluded, 3-9 as nearly completely occluded, and 9-11 as demonstrating residual aneurysm filling. Agreement was perfect across all seven observers for the presence or absence of complete occlusion in 22 of 30 cases. Overall, interobserver agreement was substantial (κ statistic 0.779 with a 95% CI of 0.700 to 0.857) [9].

Eight patients with 8 unruptured wide-neck aneurysms were enrolled in a study. Average dome width was 7.5 mm (range, 5.4-10.7 mm), and average neck size was 4.9 mm (range, 2.6-6.5 mm). One-year angiographic follow-up obtained in all aneurysms included 1 complete aneurysm occlusion (12.5%), 6 neck remnants (75%), and 1 aneurysm remnant (12.5%). Of 8 aneurysms, worsening of aneurysm occlusion was observed in 2 (25%) by compression of the WEB device. There was no angiographic recurrence of initially totally occluded aneurysms. No bleeding was observed during the follow-up period.

Endovascular therapy of intracranial aneurysms with the WEB-SL device allows treatment of wide-neck aneurysms with a high rate of neck remnant at 1 year, at least partially explained by WEB compression. Initial size selection and technologic improvements could be an option for optimization of aneurysm occlusion in WEB-SL treatment [10].

2014

Eighty-three patients with 85 aneurysms were included in this series. Technical success was achieved in 77 patients with 79 aneurysms (92.9%). Periprocedural complications were observed in 9 patients (10.8%), leading to permanent neurologic deficits in 3 (3.9%). Morbidity and mortality at 1 month were 1.3% and 0.0%, respectively. Angiographic follow-up was performed for 65/79 aneurysms (82.3%) 3-24 months after treatment (mean, 5.3 months). Complete aneurysm occlusion was observed in 37/65 aneurysms (56.9%); neck remnant, in 23/65 (35.4%); and aneurysm remnant, in 5/65 (7.7%).

In this large prospective series of patients, WEB flow disruption was a safe and efficient technique [11].

2013

Nineteen patients with 20 unruptured wide-neck bifurcation IAs were treated by WEB placement. Technical issues, immediate posttreatment angiographic findings, and clinical and imaging follow-up at 3, 6, and 12 months were assessed.

Failure of WEB placement occurred in 1 case because of unavailability of a suitably sized device. Embolization was successful in 18 patients with 19 IAs, and it required additional stent placement and/or coiling in 3 cases at the acute phase and in 1 case at follow-up. Two patients experienced a symptomatic complication, and 16 patients had normal neurologic examination findings at discharge. Immediate anatomic outcome showed 1 complete occlusion, 13 near-complete occlusions, and 5 incomplete occlusions. At follow-up, 17 patients had normal neurologic examination findings and 1 retained a hemiparesis. Angiographic controls were obtained in all patients (mean, 6 months), and they showed stable or improved results in all except 4 cases, including 2 complete occlusions, 15 near-complete occlusions, and 2 incomplete occlusions.

In this initial series of patients, EVT of wide-neck bifurcation IAa with the WEB was feasible. Further studies are needed to evaluate the indications, safety, and efficacy of this new technique [12)].

2012

Twenty patients with 21 aneurysms were treated by using the WEB in 3 European centers. The ability to successfully deploy the WEB, immediate posttreatment angiographic results, adverse events, clinical outcome, and angiographic follow-up results were recorded.

Aneurysm location was the ICA (4/21, 19.1%), MCA (8/21, 38.1%), AcomA (5/21, 23.8%), and BA (4/21, 19.1%). No treatment failures were reported. Treatment was performed exclusively with the WEB in 16/21 (76.2%) patients. Additional treatment (coiling and/or stent placement) was used in 5/21 (23.8%) patients. One patient (4.8%) experienced transient clinical worsening (mRS 1 at 1 month, mRS 0 at 3 months) related to a thromboembolic event. Inadvertent detachment of the WEB was observed, and the WEB was retrieved in 1 patient, without adverse effects. In the short-term follow-up (2-8 months), adequate occlusion (total occlusion or neck remnant) was observed in 80.0% of aneurysms.

Intrasaccular flow disruption is a new endovascular approach for aneurysm treatment. In our preliminary experience, this treatment was feasible and mostly used in bifurcation aneurysms (MCA, BA, ICA) with unfavorable anatomy. Further studies are needed to precisely evaluate the indications, safety, and efficacy of this new technique [13)].

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