

WEB Treatment of Intracranial Aneurysms: Clinical and Anatomic Results in the French Observatory

^{id}L. Pierot, ^{id}J. Moret, ^{id}F. Turjman, ^{id}D. Herbreteau, ^{id}H. Raoult, ^{id}X. Barreau, ^{id}S. Velasco, ^{id}H. Desal, ^{id}A.-C. Januel, ^{id}P. Courtheoux, ^{id}J.-Y. Gauvrit, ^{id}C. Cognard, ^{id}A. Molyneux, ^{id}J. Byrne, and ^{id}L. Spelle

ABSTRACT

BACKGROUND AND PURPOSE: Flow disruption with the WEB device is a new technique for the endovascular treatment of wide-neck bifurcation aneurysms. To obtain precise data regarding the safety and efficacy of this treatment with high-quality methodology, the prospective French Observatory study was conducted. Analysis of these data is presented, including 1-year follow-up.

MATERIALS AND METHODS: Patients with bifurcation aneurysms for which WEB treatment was indicated were included in this prospective, multicenter Good Clinical Practice study. Clinical data, including adverse events and clinical status at 1 month and 1 year, were collected and independently analyzed by a medical monitor. An independent core laboratory evaluated the anatomic results at 1 year following the procedure.

RESULTS: Ten French neurointerventional centers included 62 patients (39 women), 33–74 years of age (mean, 56.6 ± 9.80 years) with 63 aneurysms. Aneurysm locations were the middle cerebral artery in 32 aneurysms (50.8%), anterior communicating artery in 16 (25.4%), basilar artery in 9 (14.3%), and internal carotid artery terminus in 6 (9.5%). Morbidity and mortality at 1 month were, respectively, 3.2% (2/62 patients) and 0.0% (0/62). Morbidity and mortality (unrelated to the treatment) at 1 year were, respectively, 0.0% (0/59) and 3.4% (2/59 patients). At 1 year, complete occlusion was observed in 30/58 aneurysms (51.7%); neck remnant, in 16/58 aneurysms (27.6%); and aneurysm remnant, in 12/58 aneurysms (20.7%).

CONCLUSIONS: This prospective French Observatory study showed very good safety of aneurysm treatment with the WEB, with a high rate of adequate aneurysm occlusion at 1 year (79.3%).

ABBREVIATIONS: DL = Dual-Layer; SL = Single-Layer; SLS = Single-Layer Spherical; WEBCAST = WEB Clinical Assessment of IntraSaccular Aneurysm Therapy

Endovascular treatment is now the first-line therapy for both ruptured and unruptured aneurysms, but aneurysms with a complex anatomy (especially wide-neck aneurysms) are, in some cases, untreatable or difficult to treat with standard coiling.^{1,2}

Thus, more complex endovascular techniques have been developed, such as balloon-assisted coiling, stent-assisted coiling, and flow diversion.^{3–9}

Flow disruption is a new endovascular approach, which involves placement of an intrasaccular device (Woven EndoBridge [WEB] aneurysm embolization system; Sequent Medical, Aliso Viejo, California), which modifies the blood flow at the level of the neck and induces aneurysmal thrombosis. The WEB was designed to treat wide-neck and bifurcation aneurysms. The device has been progressively developed from a Dual-Layer version (WEB DL) to Single-Layer (WEB SL) and Single-Layer Spherical (WEB SLS) versions. Treatment with the WEB has been evaluated in several retrospective series showing good safety results.^{10–13} In addition, midterm and long-term anatomic results have been evaluated in retrospective series showing good stability of the treatment.^{14,15}

To have a more rigorous evaluation of the safety and efficacy, 2 prospective, Good Clinical Practice series were initiated simultaneously in Europe (WEB Clinical Assessment of IntraSaccular

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From the Department of Neuroradiology (L.P.), Hôpital Maison-Blanche, Université Reims-Champagne-Ardenne, Reims, France; Hôpital Beaujon, (J.M., L.S.), Assistance Publique-Hôpitaux de Paris, Clichy, France; Centre Hospitalier Universitaire de Lyon (F.T.), Lyon, France; Centre Hospitalier Universitaire de Tours (D.H.), Tours, France; Centre Hospitalier Universitaire de Rennes (H.R., J.-Y.G.), Rennes, France; Centre Hospitalier Universitaire de Bordeaux (X.B.), Bordeaux, France; Centre Hospitalier Universitaire de Poitiers (S.V.), Poitiers, France; Centre Hospitalier Universitaire de Nantes (H.D.), Nantes, France; Centre Hospitalier Universitaire de Toulouse (A.-C.J., C.C.), Toulouse, France; Centre Hospitalier Universitaire de Caen (P.C.), Caen, France; and Oxford Neurovascular and Neuroradiology Research Unit (A.M., J.B.), Oxford Radcliffe Hospital, Oxford, UK.

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Please address correspondence to Laurent Pierot, MD, PhD, Department of Neuroradiology, Hôpital Maison-Blanche, 45, Rue Cognacq-Jay 51092 Reims Cedex; e-mail: lpierot@gmail.com

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Aneurysm Therapy [WEBCAST]) and in France (French Observatory). The short-term (6-month) results of the WEBCAST trial and a comparison of safety between the WEB DL and WEB SL/SLS in the French Observatory were published previously.^{16,17} These initial analyses confirmed the good safety and efficacy of the device in the short-term. This article reports the clinical and anatomic results of the French Observatory study with midterm (1-year) follow-up.

MATERIALS AND METHODS

The French Observatory is a single-arm, prospective, consecutive, multicenter, French study dedicated to the evaluation of WEB treatment for bifurcation aneurysms.

The study received national regulatory authorization (Comité Consultatif sur le Traitement de l'Information en matière de Recherche dans le domaine de la Santé), Reims institutional review board approval, and Commission Nationale Informatique et Libertés approval. Written informed consent was obtained for all patients.

Trial Design and Procedural Modalities

Trial design and procedural modalities have already been described in a previous publication.¹⁶ Briefly, inclusion criteria were ruptured (Hunt and Hess 1, 2, or 3), unruptured, and recanalized bifurcation aneurysms located in the basilar artery, middle cerebral artery, anterior communicating artery, and internal carotid artery terminus. In each center, the indication for endovascular treatment was decided by a local multidisciplinary team, which included neurosurgeons and neuroradiologists. The selection of aneurysms treated with the WEB device was performed autonomously in each center by the interventional neuroradiologists according to aneurysm characteristics (aneurysm status, aneurysm location and size, neck size) and when other therapeutic options like stent placement or flow diversion were deemed technically difficult or impossible.

The treatment of aneurysms with the WEB was performed with techniques similar to those used in the treatment of aneurysms with coils. Pre-, intra-, and postoperative antiplatelet therapy was managed in each center as indicated for typical endovascular treatment with coils or stents and coils. The study protocol did not specify the antiplatelet regimen to be followed. Triaxial access was recommended. Appropriate device sizing was selected on the basis of 2D and 3D digital subtraction angiography. According to the size of the WEB device, different microcatheters were used to catheterize the aneurysm, including Rebar-27 (Covidien, Irvine, California), DAC 038 (Stryker Neurovascular, Kalamazoo, Michigan), and, from late 2012 to the end of the trial, microcatheters dedicated to WEB treatment, including VIA-27 and VIA-33 (Sequent Medical). Treatment with ancillary devices (balloon, coils, and stents) could be performed if deemed necessary by the treating physician.

Data Collection

Each center completed a patient file with the following data: patient age and sex; aneurysm rupture status; aneurysm characteristics, including location, size, and neck size; date of the

procedure; type of device used (DL or SL/SLS); perioperative antiplatelet medications; occurrence of complications during or after the procedure; and use of additional devices during the procedure (coils, remodeling balloons, stents, or flow diverters). The preoperative Hunt and Hess grade was collected in case of ruptured aneurysms. The modified Rankin Scale score was collected before treatment (unruptured/recanalized aneurysms) and at 30 ± 7 days and 12 ± 3 months for all patients. Vascular imaging at 1 year was collected.

Data Analysis

Clinical data were independently monitored and analyzed, including all adverse events (A.M.). Morbidity was defined as an mRS of 2 when the preoperative mRS was ≤ 2 (or in case of a ruptured aneurysm). When the preoperative mRS was > 2 , morbidity was defined as an increase of 1 point.

An expert interventional neuroradiologist (J.B.) independently evaluated aneurysm occlusion by using the previously validated 3-grade scale: complete occlusion, neck remnant, and aneurysm remnant. According to previous publications, opacification of the proximal recess of the WEB device was considered complete occlusion.^{14,18}

Statistical Analysis

Continuous variables were described as mean \pm SD. Categorical data were described numerically as a categorical total and as a percentage of the population analyzed. Binomial data were described as a ratio of the true value and the population analyzed (x/n). Confidence intervals for binomial data were calculated by the Clopper-Pearson method, and *P* values were calculated by the Fisher exact test. Analyses were conducted by using SPSS statistical software (IBM, Armonk, New York) and StatXact-8 (Cytel, Cambridge, Massachusetts) for confidence intervals and *P* values.

RESULTS

Patient and Aneurysm Population

Between November 2012 and January 2014, 10 French centers included 62 patients (39 women, 62.9%), 33–74 years of age (mean, 56.6 ± 9.80 years) with 63 aneurysms.

Seven (11.1%) aneurysms were ruptured, 51 (81.0%) were unruptured, and 5 (7.9%) were previously treated but recanalized. Aneurysm locations were the MCA in 32 aneurysms (50.8%), anterior communicating artery in 16 (25.4%), basilar artery in 9 (14.3%), and ICA terminus in 6 (9.5%). The aneurysm neck was ≥ 4 mm in 57/63 aneurysms (90.5%). Fifty-two aneurysms (82.5%) were < 10 mm in size.

Thirty patients with 31 aneurysms were treated with the WEB DL; and 32 patients with 32 aneurysms, with the WEB SL/SLS.

Before the procedure, 10 patients had no antiplatelet treatment, 26 patients had 1 antiplatelet medication (clopidogrel or aspirin), and 25 patients had 2 antiplatelet medications. For 1 patient, the antiplatelet therapy regimen could not be confirmed. He was excluded from further analysis regarding this point because he had no thromboembolic event.

Treatment Feasibility, Adjunctive Treatments, and Adverse Events

Treatment was successfully performed in all except 1 patient treated with the WEB DL (98.4%). In this patient, it was impossible to deploy the WEB, which was stuck in the microcatheter. The aneurysm was treated with coils. Clinical follow-up was uneventful.

Adjunctive devices were used in 7/62 aneurysms treated with the WEB (11.3%): coils in 4 aneurysms and a stent in 3 aneurysms.

Nine thromboembolic events were reported in 8/62 patients (12.9%), and 1/62 was associated with a permanent deficit (1.6%). Five patients had no antiplatelet agent before the procedure, 1 patient had 1 antiplatelet agent, and 2 had 2 antiplatelet agents. All thromboembolic events were treated by antiplatelet medication, including tirofiban or abciximab. In 3 patients, a remodeling balloon was used in combination with antiplatelet treatment to reopen the vessel. No stent retriever or stent was used.

Intraoperative rupture was reported in 1/62 patients (1.6%) and was not symptomatic. Intracranial hemorrhage was detected in 1/62 patients (1.6%) on a control CT performed 24 hours after the procedure and was asymptomatic. Anatomically, it was not connected with the aneurysm. Because there was no other cause, it was interpreted by the medical monitor as being related to the antiplatelet treatment used in this patient. The clinical evolution was uneventful.

Mortality/Morbidity at 1 Month

At 30 days, all patients enrolled in the study had a clinical evaluation with mRS scoring.

There was no mortality at 1 month. Morbidity was observed in 2/62 patients (3.2%) related to a thromboembolic event in 1 patient (mRS 3) and to worsening of pre-existing aneurysm mass effect in 1 patient (this patient had a partially thrombosed large aneurysm of the basilar artery with progressive brain stem compression, mRS 3). When we looked at the conventional mRS score cohorts of mRS 0–2 and mRS 3–6, the confidence intervals essentially overlapped; this finding implied no difference in the rates of mRS 0–2 and mRS 3–6 from the procedure to 12 months.

Mortality/Morbidity at 1 Year

At 12 months, 59 of the 62 patients enrolled in the study were clinically evaluated with mRS scoring. Three patients included in the 30-day mortality/morbidity analysis were not included in the 1-year mortality/morbidity (1 patient not treated with WEB, 1 patient retreated before 1 year, and 1 patient lost to follow-up were not evaluated).

Two patients died between 1-month and 1-year follow-up: 1 unrelated to aneurysm disease or treatment and 1 from worsening of pre-existing mass effect described previously. All-cause mortality was 2/59 (3.4%), and neuro-related mortality was 1/59 (1.7%). The 2 patients who had an mRS of >2 at 1 month were improved at 1 year (mRS 1 and 2); this outcome led to no morbidity at 1 year.

Retreatment

One patient with aneurysm recanalization was retreated at 6 months by using a flow diverter. One patient had an attempted

retreatment at 10 months with a flow diverter, which was unsuccessful.

Anatomic Results at 1 Year

Of the 63 aneurysms in the intention-to-treat population, aneurysm occlusion was evaluated in 58 aneurysms at 1 year. The vascular imaging technique was digital subtraction angiography in 50/58 (86.2%) cases, CTA in 3 cases (5.2%), and MRA in 5 cases (8.6%). Aneurysm occlusion was not evaluated in 1 patient who was not treated with a WEB, 1 patient who had retreatment before 1 year (see above), 1 patient lost to follow-up, and 2 patients who died before 1 year (see above).

Complete occlusion was observed in 30/58 aneurysms (51.7%) in the global population, in 14/28 (50.0%) patients treated with WEB DL, and in 16/30 (53.3%) patients treated with WEB SL/SLS.

Neck remnant was observed in 16/58 aneurysms (27.6%) in the global population, in 8/28 (28.6%) patients treated with WEB DL, and in 8/30 (26.7%) patients treated with WEB SL/SLS.

Aneurysm remnant was observed in 12/58 aneurysms (20.7%) in the global population, in 6/28 (21.4%) patients treated with WEB DL, and in 6/30 (20.0%) patients treated with WEB SL/SLS.

DISCUSSION

The WEB French Observatory is, to date, the largest multicenter, prospective, Good Clinical Practice series dealing with WEB aneurysm treatment. Short and midterm follow-ups confirm the safety and efficacy of this treatment. At 1 month and 1 year, there was no mortality related to the treatment. Low morbidity was reported at 1 month (3.2%), with clinical improvement at 1 year leading to no morbidity at that time point. At 1 year, complete aneurysm occlusion was observed in 51.7% of aneurysms, with adequate occlusion (complete occlusion and neck remnant) in 79.3%.

New technologies for the endovascular treatment of intracranial aneurysms must be carefully evaluated for safety and efficacy; this evaluation has not always been performed in the past. For aneurysm treatment with the WEB device, careful evaluation of safety and efficacy has been built through a series of prospective, Good Clinical Practice clinical studies (French Observatory, WEBCAST, and WEBCAST 2 and the ongoing WEB Intracranial Therapy study under an FDA investigational device exemption). The French Observatory study was conducted during the early phase of clinical use of the WEB and included the learning curve with the WEB in terms of procedural technique, WEB sizing, and the approach to antiplatelet therapy. It shows that WEB treatment permits the management of ruptured, unruptured, recanalized, and complex wide-neck bifurcation aneurysms located at the MCA, anterior communicating artery, ICA terminus, and basilar artery with a very high success rate (98.4%). Despite the use of a relatively large microcatheter, the treatment appears to be feasible in the most cases.

The current results confirm the great safety of WEB treatment as has been reported in retrospective series and WEBCAST.^{10–17} The rate of thromboembolic events with the WEB (14.5%) was quite similar to that reported in the Analysis of Treatment by Endovascular Approach of Nonruptured Aneurysms (ATENA)

and Clinical and Anatomical Results In the Treatment of Ruptured Intracranial Aneurysms (CLARITY) series (respectively, 7.3% and 13.3%).^{1,2} Only 1 patient (1.6%) had a permanent deficit. Most patients treated in this study had wide-neck aneurysms (90.5% compared with 30.9% in ATENA), and the rate of TE events was higher in wide-neck aneurysms.¹⁹ The rate of intraoperative rupture was low (1 patient, 1.6%) and comparable with the 2.0% observed in ATENA and 3.7% in CLARITY.^{1,2} Moreover, the intraoperative rupture was not symptomatic.

Safety is also confirmed at 12 months with 2 deaths unrelated to the treatment, no new morbidity, and clinical improvement of patients who had morbidity at 1 month. No significant delayed adverse events were observed, as is the case with flow diverters. Remarkably, no delayed aneurysm rupture or intracranial parenchymal hemorrhage was reported.^{20,21}

The present results also highlight the high quality of aneurysm occlusion obtained with this technique, confirming the data from 6-month follow-up in the WEBCAST and from an already published retrospective European series.^{14,15,17} Complete occlusion, neck remnant, and aneurysm remnant were observed at 1 year in, respectively, 51.7%, 27.6%, and 20.7%. The clinical impact of neck remnant after WEB treatment is unknown and probably not different from that observed after coiling. However, long-term follow-up is clearly needed to evaluate this point and is foreseen for 2 years in the French Observatory and 5 years in other Good Clinical Practice studies (WEBCAST, WEBCAST 2).

In the European series, similar to these French Observatory results, complete and adequate occlusion was reported at mid-term follow-up (median, 13 months) in, respectively, 69.0% and 89.7%.^{14,15} This series also confirmed the long-term (median, 27 months) stability of WEB aneurysm treatment, showing complete and adequate occlusion in, respectively, 68.4% and 84.2%. There was no worsening of aneurysm occlusion between the mid- and long term. Comparison with other techniques is difficult because no series really focused on wide-neck bifurcation aneurysms. In the Matrix and Platinum Science trial, a subgroup analysis was conducted showing that in unruptured aneurysms with wide necks (not necessarily bifurcation), the rate of complete and adequate occlusion (at 12 months) was, respectively, 20.3% and 49.1% with coils and 45.7% and 78.6% with stent placement and coiling.²² If anatomic results with stent placement and coiling are relatively similar to those observed with the WEB, safety is worse with stent placement and coiling.

In a recent article, Cognard and Januel²³ reported on their initial experience with WEB aneurysm treatment. At short-term follow-up, among 14 aneurysms, 1 was completely occluded (7.2%) and neck and aneurysm remnants were observed in, respectively, 9 (64.3%) and 4 (28.6%) aneurysms. Long-term follow-up (mean, 18.6 months) was obtained in a very limited number of 7 patients and showed worse results. Indeed, this series was a very small, monocenter, self-analyzed report, dealing with complex aneurysms treated at the very beginning of the WEB experience. However, it introduces the concept of WEB shape modification with time, a parameter that was not analyzed in the French Observatory series.

Patients included in the French Observatory study were treated with Dual- or Single-Layer devices. Previous analyses

showed a similar safety of treatment with the devices, with a trend toward less thromboembolic events in patients treated with Single-Layer devices.¹⁶ Anatomically, results were similar in both groups of patients, with complete occlusion in 50.0% of patients treated with WEB DL, 53.3% of patients treated with WEB SL/SLS, and adequate occlusion in, respectively, 78.6% and 80.0%.

This study has several limitations. First, the population was relatively small (62 patients). However, it is the first prospective, multicenter study evaluation with high-quality methodology evaluating the midterm safety and efficacy of this treatment. Second, it was not a randomized study, and comparison with other techniques was not easy. However, safety data are excellent and quite comparable with those observed in large coiling series. Efficacy data are more difficult to compare with those in historical series because most were mixed sidewall and bifurcation and narrow- and wide-neck aneurysms. Third, the potential WEB “compression” phenomenon has not been evaluated, to our knowledge. Further work will be conducted on this topic.

CONCLUSIONS

This study, with independent analysis of clinical events and anatomic results, confirms the very good safety profile of WEB treatment for bifurcation aneurysms, with rates of thromboembolic events and intraoperative rupture comparable with those observed with standard coiling and very low morbidity and mortality rates. A high rate of complete (51.7%) and adequate occlusion (79.3%) was obtained at 1-year follow-up.

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