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Original research

Aneurysm treatment with the Woven EndoBridge (WEB) device in the combined population of two prospective, multicenter series: 5-year follow-up

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ABSTRACT

Background Evaluating a new endovascular treatment for intracranial aneurysms must not only demonstrate short-term safety and efficacy, but also evaluate longer-term outcomes (eg, delayed complications, anatomical results, retreatment). The current analysis reports the 5-year clinical and anatomical results of Woven EndoBridge (WEB) treatment in two European combined trial populations (WEBCAST (WEB Clinical Assessment of Intracranial Aneurysm Therapy) and WEBCAST-2).

Methods All adverse events occurring between the procedure and 5-year follow-up were independently evaluated by an expert. Aneurysm occlusion was evaluated by an independent core laboratory using a three-grade scale: complete occlusion, neck remnant, and aneurysm remnant. In cases where data were not available at 5-year follow-up, the last observation carry forward (LOCF) method was used.

Results The safety and efficacy populations comprised 100 patients and 95 aneurysms, respectively. No adverse event related to the device occurred after the procedure during the 5-year follow-up period. Mortality at 5 years was 7.0% (7/100 patients) including mortality related to the WEB (0/100, 0.0%), the procedure (1/100, 1.0%), and another condition (6/100, 6.0%). At 5 years, complete aneurysm occlusion was observed in 49/95 (51.6%) aneurysms, neck remnant in 25/95 (26.3%), and aneurysm remnant in 21/95 (22.1%). Retreatment rate at 5 years was 11.6% (11/95 aneurysms).

Conclusions This analysis conducted in a population of patients with wide-neck bifurcation aneurysms confirms WEB's safety profile. Additional evidence demonstrates good stability of aneurysm occlusion with adequate occlusion (complete occlusion or neck remnant) at 5 years in 77.9% of aneurysms with a low retreatment rate (11.6%).

Clinical trial registration WEBCAST and WEBCAST-2: Unique identifier: NCT01778322.

INTRODUCTION

Evaluating an intracranial aneurysm (IA) treatment must determine its safety and efficacy in the short-, mid-, and long-term. The experience we have with flow diversion shows that complications such as

WHAT IS ALREADY KNOWN ON THIS TOPIC

- ⇒ Studies (including WEBCAST, WEBCAST-2, and French Observatory) have shown the great safety and good efficacy of wide-neck bifurcation aneurysm treatment with the WEB device at mid- and long-term follow-up (1, 2 and 3 years).
- ⇒ The importance of studying complications and occlusion stability at very long term for complex aneurysms.

WHAT THIS STUDY ADDS

- ⇒ 5-year analysis in WEBCAST and WEBCAST-2 confirms the high safety of WEB aneurysm treatment with no adverse event related to the device occurring after the procedure during the 5-year follow-up period.
- ⇒ This analysis also shows good stability of aneurysm occlusion at 5-year with a low retreatment rate.

HOW THIS STUDY MIGHT AFFECT RESEARCH, PRACTICE OR POLICY

- ⇒ This analysis confirms the high safety and good efficacy of WEB aneurysm treatment at very long-term follow-up, which might induce further adoption in real life practice.

remote hematomas or parent artery thrombosis can occur several months after the initial treatment.¹⁻³ Aneurysm recanalization is a well-known phenomenon after aneurysm coiling: it can be associated with aneurysm bleeding or rebleeding, and can occur and worsen several months or years after the initial treatment.⁴ Therefore, short- and mid-term evaluations alone cannot precisely evaluate the results of a new aneurysm treatment: instead, long-term evaluation is mandatory to draw evidence-based conclusions about treatment efficacy.

Treatment of wide-neck aneurysms and, more specifically, wide-neck bifurcation aneurysms (WNBA), is technically difficult and has led to the development of new techniques such as balloon-assisted coiling (BAC), stent-assisted coiling (SAC), flow diversion, and intrasaccular flow disruption.⁵



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Currently, only one flow disrupter has been widely clinically evaluated: the Woven EndoBridge (WEB) device (Microvention, Aliso Viejo, California, USA). Since its introduction into clinical practice in Europe in 2010, the device's design has significantly evolved from the initial dual layer (DL) version (WEB-DL) to the single layer (SL) versions (WEB-SL and WEB-SLS (single layer spherical)). The device evolution improved with the integration of DFT (drawn filled tubing) wires made from nitinol and platinum, which heightened visibility and led to EV (enhanced visualization) device versions. Additionally, the delivery microcatheter has also evolved, with the development of microcatheters dedicated to WEB device placement: VIA microcatheters (Microvention).

Since WEB's introduction, this treatment has been extensively evaluated in several Good Clinical Practice (GCP) studies conducted in Europe (WEB Clinical Assessment of Intracranial Aneurysm Therapy (WEBCAST) and WEBCAST-2); in the United States (WEB Intracranial Therapy (WEB-IT)); and in France (French Observatory).⁵⁻¹¹ Additional WEB trials have recently been published (CLinical Assessment of WEB Device in Ruptured aneurYSms (CLARYS)), are under analysis (CLinical Evaluation of WEB 0.017 Device in Intracranial AneurYSms (CLEVER)), or are currently recruiting (WEB-IT China).¹²

The present study analyzes the clinical outcomes and anatomical results at 5 years of WEB aneurysm treatment in the combined WEBCAST and WEBCAST-2 trial populations.

METHODS

The article has been prepared in accordance with the STROBE statement.

WEBCAST and WEBCAST-2 are prospective, consecutive, multicenter, single-arm European trials dedicated to evaluating WEB treatment for WNBA. Both trials received national regulatory authorization according to each country's regulations. In France, the study was approved by the Consultative Committee of Information Processing in Healthcare Research Program (CCTIRS), the Reims Institutional Review Board, and the National Commission for Data Processing and Freedom (CNIL). In Germany, the study was approved by local ethics committees of participating centers. Written informed consent was obtained from all patients. Enrollment took place from December 2011 to February 2014 for WEBCAST and from July 2014 to May 2015 for WEBCAST-2.

WEB devices

The WEB is a self-expanding, retrievable, electrothermally detachable, braided device, which is placed within the aneurysm sac. During the study time frame, the device existed in several iterations (see Introduction). In WEBCAST, patients were treated with WEB-DL, while WEBCAST-2 patients were treated with WEB-SL-EV and WEB-SLS-EV. The WEB device exists in different sizes as defined by their width and height.

In tandem with device developments, the microcatheters used to deliver these devices also evolved with the development of microcatheters dedicated to WEB treatment: VIA microcatheters (Microvention) now exist in different sizes according to the WEB size, which will be placed in the aneurysm sac (VIA 17, VIA 21, VIA 27, and VIA 33).

Trial design and procedural modalities

Trial design and procedural modalities have been described in previous publications, and both studies were conducted following GCP guidelines.⁵⁻¹⁰ Inclusion criteria for the two studies were:

ruptured (Hunt and Hess I to III) and unruptured aneurysms located in the basilar artery (BA) apex, middle cerebral artery (MCA) bifurcation, internal carotid artery terminus (ICAt), or anterior communicating artery complex (Acom).

A local multidisciplinary team (neurosurgeons and neuroradiologists) selected participants with aneurysms treated by endovascular treatment. Selection of aneurysms treated with the WEB device was performed autonomously in each center by interventional neuroradiologists based on aneurysm characteristics.

Data collection

Each center completed a patient file with the following data:

- ▶ Demographics: age and sex;
- ▶ Aneurysm: rupture status, location, aneurysm size (width and height), and neck size; and
- ▶ Procedure: date, device type used (DL or SL/SLS), and complications occurring during or after procedure.

Preoperative Hunt and Hess grade was collected with ruptured aneurysms. Modified Rankin Scale (mRS) score was gathered before treatment for unruptured aneurysms. In addition to clinical follow-up at 30 days (± 7 days), clinical and imaging follow-up was expected at 6 months, 1, 3, and 5 years. For patients without vascular imaging follow-up at 5 years, the reason for not performing this examination was collected. Before considering the patient as being lost to follow-up, at least three attempts to contact the patient and/or the general physician were done.

Data analysis

All adverse events were independently and blindly monitored and analyzed by a single medical monitor (AM), including events that occurred after retreatment if any. Morbidity was defined by mRS greater than 2, evaluated by a neurosurgeon, a neurologist, or a neuroradiologist not involved in the patient's treatment. Aneurysm occlusion was evaluated by an independent expert interventional neuroradiologist (JVB) using a three-grade scale: complete occlusion, neck remnant, and aneurysm remnant. This evaluation was performed on postoperative digital subtraction angiography (DSA), and at each yearly follow-up between 1-year and 5-year vascular imaging (DSA, magnetic resonance angiography (MRA), or computed tomography angiography (CTA)), which was selected autonomously by the centers. Based on previous work, opacification of the WEB device's proximal recess was considered complete occlusion.¹³ Aneurysm occlusion and its evolution between 1 and 5 years were also evaluated in the subgroup of patients having a 5-year follow-up. Evolution of aneurysm occlusion was made using a threegrade scale: worse, stable, and improved. Worsening and improvement were defined as a grade change in the three-grade occlusion scale.

Per protocol, patients in whom a WEB was intended but not placed (not deployed or not implanted) were included in the safety analysis up to 30-day follow-up and they were excluded afterwards. For patients who were retreated after the initial WEB procedure, the follow-up for aneurysm occlusion was not collected after the time of retreatment as the goal of WEBCAST/WEBCAST-2 was to evaluate the efficacy (aneurysm occlusion) after WEB treatment alone. The last evaluation used for these patients was the occlusion evaluation before retreatment.

An analysis based on last observation carry forward (LOCF) method was used for the results at 5 years, to replace any data not available with the last data available.

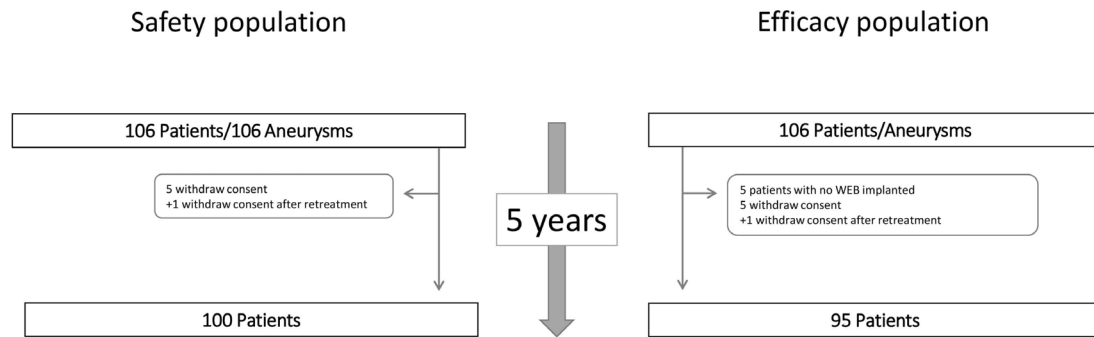


Figure 1 Population flow chart for the two studies for safety and efficacy at 5 years. 'Lost to follow-up' means that the centers were unable to contact the patients using different techniques (telephone call, email, letter, etc.) so the patient exited the study.

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 analyzed population. Binomial data were described as a ratio of the true value and the analyzed population (x/n). Confidence intervals for binomial data were calculated by the Clopper-Pearson method, and P values were calculated by Fisher's exact test. Analyses were conducted using SPSS statistical software (SPSS, Chicago, Illinois, USA).

RESULTS

Patient and aneurysm population

The two trials combined population initially included 106 patients. After removing patients having withdrawn consent (6), 100/106 patients (94.3%) potentially had 5 years follow-up. According to the study flow chart (figure 1), this safety group comprised 100/106 patients (94.3%), including 68 females (68.0%), with an age range of 27–77 years (mean: 54.6 \pm 10.5 years). The mean for safety follow-up was 50.4 \pm 20.7 months after initial procedure.

After excluding patients for whom WEB efficacy could not be evaluated (no WEB implanted (5), consent withdrawn (6)), the percentage of aneurysms with 5 years anatomical follow-up was 89.6% (95/106 aneurysms) (figure 1). The mean for efficacy follow-up was 53.0 \pm 17.7 months after initial procedure. Aneurysm status was ruptured in 7/95 (7.4%) and unruptured in 88/95 (92.6%) patients. Aneurysm locations per core laboratory analysis were MCA in 49/95 aneurysms (51.6%), Acom in 20/95 (21.1%), BA in 17/95 (17.9%), and ICAt in 9/95 (9.5%). Maximum aneurysm size ranged from 2.8 to 17.0 mm (mean: 7.3 \pm 2.6 mm). The neck was wide (\geq 4 mm) in 79/95 (83.2%) aneurysms.

Mortality and morbidity at 5 years

Mortality at 5 years in patients treated exclusively with WEB was reported in 7/100 patients (7.0%). There were no deaths during the procedure and in the month following the initial procedure, three deaths between 1 month and 1 year (3.0%), one death between 1 year and 2 years (1.0%), two deaths between 2 and 3 years (2.0%), and one death between 3 and 4 years (1.0%). No deaths occurred between 4 years and 5 years. Of the seven deaths, 1 (1.0%) occurred 74 days after the initial WEB treatment and was related to the initial procedure (retroperitoneal hematoma) not the device. Four deaths were unrelated to the initial procedure (skin cancer at 126 days, lung cancer at 166 days and 743 days, and pneumonia at 780 days). Two deaths occurred after the retreatment of the aneurysm (see later) but were unrelated to the initial procedure and retreatment (pulmonary cancer at

840 days of the initial WEB procedure and respiratory failure at 1219 days).

At 5 years, 1/100 (1.0%) patients had morbidity unrelated to the initial procedure (alcoholic neuropathy) that occurred more than 2 years after the initial procedure. Finally, mortality and morbidity related to the WEB were 0.0% and 0.0% at 5 years, respectively, while procedure-related mortality and morbidity were 1.0% and 0.0%, respectively.

Anatomical results at 5 years

Five-year follow-up was analyzed in 95 patients/aneurysms including 11 who were retreated (see table 1). Some 46/95 (48.4%) patients had no follow-up at 5 years and their last follow-up performed was taken into account according to the LOCF methodology and were as follows: 4 (4.2%) at the index procedure, 2 (2.1%) at 6 months, 14 (14.7%) at 1 year, 6 (6.3%) at 2 years, 10 (10.5%) at 3 years, and 10 (10.5%) at 4 years. Vascular imaging techniques included DSA in 27/95 aneurysms (28.4%), MRA in 51/95 (53.7%) aneurysms, CTA in 8/95 (8.4%) aneurysms, and type of images not specified in 9/95 (9.5%) aneurysms. At 5 years, complete occlusion was observed in 49/95 (51.6%) aneurysms, neck remnant in 25/95 (26.3%), and aneurysm remnant in 21/95 (22.1%). Adequate occlusion (complete occlusion or neck remnant) was observed in 74/95 (77.9%) aneurysms. Importantly, no neck or aneurysm remnant was associated with bleeding/rebleeding during the follow-up period.

Excluding 46 patients not having a follow-up at 5 years with images to evaluate the occlusion (lost to follow-up (8), follow-up without images (22), deaths (7), retreatment (9)), 49 patients had a 5-year follow-up (mean: 60.0 \pm 3.2 months). Complete occlusion was observed in 28/49 (57.1%) aneurysms, neck remnant in 15/49 (30.6%), and aneurysm remnant in 6/49 (12.2%). Adequate occlusion was observed in 43/49 (87.8%) aneurysms. Compared with 1-year aneurysm occlusion, occlusion at 5 years was improved in 7/49 (14.3%) aneurysms, stable

Table 1 Aneurysm occlusion at 5 years in aneurysms treated with Woven EndoBridge dual layer (WEB-DL) and Woven EndoBridge single layer/single layer spherical (WEB-SL/SLS)

Aneurysm Occlusion	WEB-DL (n=44)	WEB-SL/SLS (n=51)	Total (n=95)
Complete occlusion*	20 (45.5%)	29 (56.9%)	49 (51.6%)
Neck remnant	13 (29.5%)	12 (23.5%)	25 (26.3%)
Aneurysm remnant	11 (25.0%)	10 (19.6%)	21 (22.1%)
P=0.585.			
*Opacification of the proximal recess considered as complete occlusion.			

Table 2 Aneurysm occlusion at 5 years according to aneurysm location

Aneurysm Occlusion	MCA (n=49)	Acom (n=20)	BA (n=17)	ICAt (n=9)
Complete occlusion*	25 (51.0%)	10 (50.0%)	10 (58.8%)	4 (44.4%)
Neck remnant	14 (28.6%)	5 (25.0%)	3 (17.6%)	3 (33.3%)
Aneurysm remnant	10 (20.4%)	5 (25.0%)	4 (23.5%)	2 (22.2%)

*Opacification of the proximal recess considered as complete occlusion.
Acom, anterior communicating artery; BA, basilar artery; ICAt, internal carotid artery terminus; MCA, middle cerebral artery.

in 36/49 (73.5%), and worsened in 6/49 (12.2%). Worsening of aneurysm occlusion evolved from complete occlusion to neck remnant in 5/49 (10.2%) aneurysms, complete occlusion to aneurysm remnant in 0/49 (0.0%) aneurysm, and neck remnant to aneurysm remnant in 1/49 (2.0%) aneurysm.

Anatomical results at 5 years in aneurysms treated with WEB-DL and WEB-SL/SLS

No significant differences were observed in anatomical results for aneurysms treated with WEB-DL and WEB-SL/SLS (table 1).

Anatomical results at 5 years in different aneurysm locations

No significant differences were observed in anatomical results based on aneurysm location (table 2).

Retreatment

Retreatment rate was evaluated in 95 aneurysms. Five aneurysms untreated with WEB (one protrusion, one subsequent retrieval of device, three lack of appropriate device sizing) and six patients who withdrew consent were excluded from this analysis.

The retreatment rate at 5 years was 11.6% (11/95 aneurysms). Retreatment rate was statistically not different when the device used in the index procedure was WEB-DL in 4/44 (9.1%) compared with WEB-SL/SLS in 7/51 (13.7%) ($P=0.537$). Retreated aneurysm locations per core laboratory analysis were MCA in 6/49 aneurysms (12.2%), Acom in 2/20 (10.0%), BA in 3/17 (17.6%), and ICAt in 0/9 (0%) ($P=0.750$). Retreatment was mainly performed during the first 2 years post-treatment: 3 (3.2%) between index procedure and 1 year, 5 (5.3%) between 1 and 2 years, 0 (0.0%) between 2 and 3 years, 2 (2.1%) between 3 and 4 years, and 1 (1.1%) between 4 and 5 years. Aneurysm occlusion status at retreatment time was neck remnant in 2 (2.1%) aneurysms and aneurysm remnant in 9 (9.5%) aneurysms. Retreatment modalities were stent (with coils: 3, with WEB: 2, without coils or WEB: 1) in 6 (6.3%), WEB alone in 1 (1.1%) aneurysm, clipping in 2 (2.1%) aneurysms (clipping failed in one case), and flow diverter in 2 (2.1%) aneurysms.

DISCUSSION

This analysis reports the combined population of two European GCP WEB trials (WEBCAST, WEBCAST-2) at 5-year follow-up. This long-term analysis confirms the high safety of WEB aneurysm treatment. Mortality at 5 years was 7.0%, including 0.0% mortality related to the WEB device, 1.0% related to the initial procedure, and 6.0% related to other diseases (mostly cancer and infection). Morbidity at 5 years was 1.0% unrelated to WEB or initial procedure (alcoholic neuropathy). Complete occlusion was observed in 51.6%, neck remnant in 26.3%, and aneurysm remnant in 22.1% with adequate occlusion in 77.9%. Finally, retreatment was performed in 11.6% of cases at 5 years.

The value of long-term follow-up is to determine whether a given treatment is associated with delayed complications and if aneurysm occlusion is stable or unstable. In our series, no delayed adverse events were reported after 1 year, in contrast to what has been observed with flow diversion.^{1-3 14} The current analysis confirms the very high safety of WEB aneurysm treatment. Morbidity and mortality at 5 years (1.0% and 7.0%, respectively) were mostly due to unrelated diseases (alcoholic neuropathy for morbidity, cancer and infection for mortality). No morbidity or mortality at 5 years was related to the WEB device. At 5 years, mortality related to the initial procedure was low (1.0% induced by a retroperitoneal hematoma related to femoral puncture) and morbidity related to the initial procedure was 0.0%. Comparing long-term safety of WEB aneurysm treatment with other endovascular approaches is not an easy task given that very few studies report follow-up beyond 1 year, and the global mortality is not exclusively related to the aneurysm or its treatment, but can be due to unrelated conditions. This unrelated mortality is different from one series to another depending on several patient factors such as age, sex, risk factors, and associated diseases. Furthermore, the longer the follow-up, the greater the chance of outcomes from unrelated conditions (cancer, infection, etc.).

Regarding coiling, the Matrix and Platinum Science (MAPS) trial reported a 5-year follow-up showing 49 deaths in 477 followed-up patients (10.3%).¹⁵ In a large meta-analysis that included 14 634 aneurysms treated by coiling, all-cause mortality was 2.8% at 5 years and 4.3% at 7 years.¹⁶ In these two series, causes of death were not reported, which makes comparison with our series difficult. Regarding flow diversion, 3.7% (4.6% if patients with no 5-year follow-up are excluded) 5-year mortality is reported in the Pipeline for Uncoilable or Failed Aneurysms (PUFS) trial with no details regarding cause of death.¹⁶

Evaluation of long-term stability of aneurysm occlusion is the main reason for having long-term follow-up when evaluating a new endovascular treatment for IAs. Coiled aneurysms often reopen after coiling. In the recent ARETA publication dealing with 908 patients harboring 945 aneurysms treated by coiling (including BAC), the rate of aneurysm recanalization at 1 year was 29.5%.¹⁷ If recanalization often occurs in the first year post-procedure, it can also be encountered after 1 year or the remnant can continue to grow after 1 year. Thus, it is not only important to assess stability of aneurysm occlusion at mid-term but also in the long term. In the combined WEBCAST and WEBCAST-2 population, anatomical results were also analyzed at 3 years, showing complete aneurysm occlusion in 50.8%, neck remnant in 32.8%, and aneurysm remnant in 16.4% with adequate occlusion (complete occlusion and neck remnant) in 83.6%.¹⁸ These results are quite similar to what is reported at 5 years, demonstrating the stability of aneurysm treatment with WEB. Occlusion stability obtained with WEB treatment is also confirmed by the evolution between 1 year and 5 years post-procedure, analyzed in the subgroup of patients with 5-year follow-up. Aneurysm occlusion was stable and improved in 43/49 aneurysms (87.8%) and worsened in 6/49 (12.2%). Moreover, worsening occurred in the vast majority of aneurysm evolution from complete occlusion to neck remnant (5/49, 10.2%). In only one aneurysm (2.0%) worsening led to aneurysm remnant with the potential risk of bleeding.

Comparing long-term anatomical results with different endovascular techniques in the subpopulation of WNBA is not easy given that most series do not follow up after 1 year and also mix wide- and narrow-neck aneurysms, and bifurcation and sidewall aneurysms. A recent series analyzed aneurysm occlusion in 108

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