

# Clinical and Anatomical Follow-up in Patients With Aneurysms Treated With the WEB Device: 1-Year Follow-up Report in the Cumulated Population of 2 Prospective, Multicenter Series (WEBCAST and French Observatory)

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**BACKGROUND:** Flow disruption with WEB is an innovative endovascular approach for wide-neck bifurcation aneurysms. Initial series have shown a low complication rate with good efficacy.

**OBJECTIVE:** To report clinical and anatomical results of the WEB treatment in the cumulated population of WEBCAST (WEB Clinical Assessment of Intracranial Aneurysm) and French Observatory series.

**METHODS:** WEBCAST and French Observatory are single-arm, prospective, multicenter, Good Clinical Practice studies dedicated to the evaluation of WEB treatment. Ruptured and unruptured bifurcation aneurysms located in the basilar artery, middle cerebral artery, anterior communicating artery, and internal carotid artery terminus were included in both studies. Clinical data were independently evaluated. Postoperative, 6-month (in WEBCAST), and 1-year aneurysm occlusion was independently evaluated with a 3-grade scale: complete occlusion, neck remnant, and aneurysm remnant.

**RESULTS:** The cumulated population was 113 patients (74 female, 65.5%) 33 to 74 years of age with 114 aneurysms with a mean neck size of 5.6 mm. There was no mortality at 1 month, and morbidity was 2.7%. A statistically significant difference in the rate of occurrence of thromboembolic events was observed between the use of any antiplatelet agent and the use of no antiplatelet agent ( $P < .001$ ). At 1 year, complete aneurysm occlusion was observed in 56.0%, neck remnant in 26.0%, and aneurysm remnant in 18.0%. Worsening of aneurysm occlusion between the procedure and 12 months was observed in 2.0% and between 6 months and 1 year in 7.1%.

**CONCLUSION:** The analysis in this large cumulated population of studies confirms favorable safety and efficacy of WEB treatment.

**KEY WORDS:** Aneurysms, Endovascular treatment, Flow disruption, WEB device

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If endovascular treatment is now the first-line treatment for both ruptured and unruptured aneurysms, wide-neck aneurysms are some-

times untreatable or difficult to treat with standard coiling.<sup>1,2</sup> The limitations of standard coiling have driven the development of different endovascular techniques such as balloon-assisted coiling, stent-assisted coiling, and flow diversion.<sup>3-9</sup>

Flow disruption is another new endovascular approach that involves placement of an intrasaccular device (WEB, Sequent Medical, Aliso Viejo, California). Placed in the aneurysm, the device will modify the blood flow at the level of the neck and induce aneurysmal thrombosis. The WEB shape was designed to treat wide-neck

**ABBREVIATIONS:** **ATENA**, Analysis of Treatment by Endovascular Approach of Non Ruptured Aneurysms; **CLARITY**, Clinical and Anatomic Results in the Treatment of Ruptured Intracranial Aneurysms; **DSA**, digital subtraction angiography; **GCP**, Good Clinical Practice; **HELPS**, HydroCoil Endovascular Aneurysm Occlusion and Packing Study; **MAPS**, Matrix and Platinum Science; **mRS**, modified Rankin Scale

bifurcation aneurysms. The device has been developed progressively from a dual-layer version (WEB DL) to single-layer versions (WEB SL and WEB SLS [single-layer spherical]). Several retrospective series have shown this treatment to have very good safety results.<sup>10-13</sup>

Midterm and long-term anatomical results evaluated in retrospective series have shown good stability of the treatment.<sup>14,15</sup>

To conduct a more rigorous evaluation of the safety and efficacy of the WEB device, 2 prospective, Good Clinical Practice (GCP) series were initiated simultaneously in Europe (WEBCAST) and in France (French Observatory). The short-term (6 months) results of the WEBCAST trial and a comparison of safety between WEB DL and WEB SL/SLS in the French Observatory were published previously.<sup>16,17</sup> Midterm clinical and anatomical results of the French Observatory were also recently reported.<sup>18</sup> This article reports the clinical and anatomical results of the WEB treatment in the cumulated population of WEBCAST and French Observatory series, including midterm (1-year) follow-up.

## METHODS

The WEBCAST and French Observatory are both single-arm, prospective, consecutive, multicenter studies dedicated to the evaluation of WEB treatment for bifurcation aneurysms conducted in Europe and France.

Both studies received national regulatory authorization, including approval from the Consultative Committee of Information Processing in Healthcare Research program, Reims Institutional Review Board approval, and National Commission for Data Processing and Freedom approval in France. For WEBCAST centers outside France, national or institutional approval was obtained according to the regulations of each country. Written informed consent was obtained for all patients.

### Trial Design and Procedural Modalities

Trial design and procedural modalities have already been described in previous publications.<sup>16,17</sup> Briefly, inclusion criteria for both studies were ruptured (Hunt and Hess grade I, II, or III) and unruptured aneurysms located in the basilar apex, middle cerebral artery bifurcation, internal carotid artery terminus, or anterior communicating artery complex. In the French Observatory, recanalized aneurysms were also included. In each center, the indication for endovascular treatment was decided by a local multidisciplinary team that included neurosurgeons and neuroradiologists. The selection of aneurysms treated with the WEB device was performed autonomously in each center by the interventional neuroradiologists and was based on aneurysm characteristics (aneurysm status, aneurysm location and size, neck size).

The treatment of aneurysms with the WEB was performed with techniques similar to those used in the treatment of aneurysms with coils. Preoperative, intraoperative, and postoperative antiplatelet therapy was managed in each center as indicated for typical endovascular treatment with coils or stents and coils. Antiplatelet activity testing was not required in the French Observatory and WEBCAST protocols. Triaxial access was recommended. Appropriate device sizing was determined based on 2- and 3-dimensional digital subtraction angiography (DSA). Depending on the size of the WEB device to be used, different microcatheters were used to catheterize the aneurysm, including Rebar-27 (Covidien Neurovascular, Irvine, California), DAC038 (Stryker, Fremont, California), and from late 2012 until the end of the trials, microcatheters dedicated to WEB

treatment, the VIA-27 and VIA-33 (Sequent Medical). Treatment with ancillary devices (balloon, coils, and stents) could be performed in French Observatory if deemed necessary by the treating physician. In WEBCAST, use of ancillary devices was authorized as a rescue treatment, not as an initial planned treatment strategy.

### Data Collection

Each center completed a patient file with the following data: demographic information, including patient age and sex; aneurysm information, including rupture status, location, size, and neck size; and procedure information, including date, 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).

Preoperative Hunt and Hess grade was collected in cases of ruptured aneurysms. Modified Rankin Scale (mRS) score was collected before treatment (unruptured/recanalized aneurysms), at 30 days ( $\pm 7$  days), and at 12 months ( $\pm 3$  months) for all patients. Vascular imaging was collected at 6 months in WEBCAST and at 1 year in both studies.

### Data Analysis

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

An expert interventional neuroradiologist (J.B.) independently evaluated aneurysm occlusion using the previously validated 3-grade scale: complete occlusion, neck remnant, and aneurysm remnant. According to a previous publication, opacification of the proximal recess of the WEB device was considered complete occlusion.<sup>14,19</sup>

In both studies, postoperative and 1-year aneurysm occlusion was evaluated. In WEBCAST, 6-month anatomical results were also evaluated.

Direct comparison of postoperative and 1-year aneurysm occlusion was performed with a simple 3-grade scale: stable, improved, or worsened. The same scale was used in WEBCAST to compare 6-month and 1-year aneurysm occlusion.

### 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 the Fisher exact test. Analyses were conducted with SPSS statistical software and ExactX Software for confidence intervals and *P* values.

## RESULTS

### Patient and Aneurysm Population

In WEBCAST, between December 2011 and February 2014, 10 European centers included 51 patients (35 female, 68.6%) 33 to 74 years of age (mean,  $55.6 \pm 10.8$  years) with 51 aneurysms.

In French Observatory, between November 2012 and January 2014, 10 French centers included 62 patients (39 female, 62.9%)

**TABLE 1. Patient and Aneurysm Population<sup>a</sup>**

Characteristic	Combined
<b>Age, yr</b>	
Mean	56.1 ± 10.22
Range	33-74
<b>Male sex, n/N (%)</b>	39/113 (34.5)
<b>Hunt and Hess grade (ruptured), n/N (%)</b>	
1	2/10 (20.0)
2	5/10 (50.0)
3	3/10 (30.0)
<b>mRS score (unruptured), n/N (%)</b>	
0	85/103 (82.5)
1	14/103 (13.6)
2	2/103 (1.94)
3	1/103 (1.0)
4	1/103 (1.0)
<b>Core laboratory measurements at the index procedure</b>	
Maximum sac width, mm	
Mean	8.04 ± 2.41
Range	3.9-16.70
Maximum neck width, mm	
Mean	5.57 ± 0.44
Range	2.40-13.80
<b>Aneurysm location, n/N (%)</b>	
Anterior communicating	21/114 (18.4)
Basilar	21/114 (18.4)
Internal carotid artery	12/114 (10.5)
Middle cerebral artery	60/114 (52.6)
<b>Antiplatelet therapy before or during the procedure, n/N (%)<sup>b</sup></b>	
No antiplatelet	16/112 <sup>b</sup> (14.3)
1 antiplatelet	50/112 <sup>b</sup> (44.6)
2 antiplatelets	46/112 <sup>b</sup> (41.1)

<sup>a</sup>mRS, modified Rankin Scale.<sup>b</sup>Information about antiplatelet treatment was not available for 1 patient.

33 to 74 years of age (mean, 56.6 ± 9.80 years) with 63 aneurysms.

The cumulated population was 113 patients with 114 aneurysms (Table 1).

Ten of 114 aneurysms (8.8%) were ruptured, 99 of 114 (86.8%) were unruptured, and 5 of 114 (4.4%) were previously treated but recanalized.

Eighty-one patients harboring 82 aneurysms were treated with WEB DL, and 32 patients harboring 32 aneurysms were treated with WEB SL/SLS.

Antiplatelet treatment before and during the procedure is reported in Table 1. Antiplatelet activity testing was not performed in all participating centers and was not analyzed.

### Treatment Feasibility, Adjunctive Treatments, and Adverse Events

Treatment was successfully performed in 110 of 114 aneurysms in which treatment was attempted with WEB

**TABLE 2. Adverse Events, Morbidity, and Mortality at 1 Month<sup>a</sup>**

Event Type	Combined Patients, n/N (%)
<b>Thromboembolic events</b>	17/113 (15.0)
Asymptomatic	9/113 (8.0)
Symptomatic without sequelae	6/113 (5.3)
Symptomatic with sequelae	2/113 (1.8)
<b>Intraprocedural rupture</b>	1/113 (0.9)
<b>Intracranial hemorrhage</b>	1/113 (0.9)
<b>Morbidity</b>	3/113 (2.7)
mRS >2 if baseline ≤2	
mRS +1 or more if baseline >2	
mRS >2 and ruptured at baseline	
<b>Mortality</b>	0/113 (0.0)

<sup>a</sup>mRS, modified Rankin Scale.

(96.5%). Causes for failure were protrusion and subsequent retrieval of the device in 2 aneurysms, lack of appropriate device sizing in 1 aneurysm, and inability to deploy the WEB in 1 aneurysm.

Among aneurysms treated with WEB devices, adjunctive devices were used in 11 of 110 aneurysms treated with WEB (10.0%), coils were used in 7 aneurysms, and stents were used in 3 aneurysms. Adverse events are reported in Table 2.

In comparing the rate of thromboembolic events and prophylactic antiplatelet regimen before or during the procedure, of the 16 patients with no antiplatelet therapy, 9 (56.3%) had a thromboembolic event; of the 50 patients with one antiplatelet agent, 6 (12%) had a thromboembolic event; and of the 46 patients with 2 antiplatelet agents, 2 (4.4%) had a thromboembolic event. There was a statistically significant difference between the use of any antiplatelet agent and the use of no antiplatelet agent ( $P < .001$ ). There was no statistically significant difference between the use of 1 or 2 antiplatelet agents ( $P = .27$ ).

Intraoperative rupture (1 of 113 patients, 0.9%) and intracranial hemorrhage (related to antiplatelet treatment, 1 of 113 patients, 0.9%) were asymptomatic.

The mean fluoroscopy time was 38.7 minutes (range, 3.4-103.0 minutes).

### Mortality/Morbidity at 1 Month

There was no mortality at 1 month (Table 2). Morbidity was observed in 3 of 113 patients (2.7%), related to initial aneurysm rupture in 1 patient (mRS score, 3), a thrombotic event in 1 patient (mRS score, 3), and worsening of pre-existing aneurysm mass effect in 1 patient (this patient had a partially thrombosed large aneurysm of the basilar apex with progressive brainstem compression; mRS score, 3).

The mRS scores at 30 days and at 12 months are reported in Table 3.

**TABLE 3. Modified Rankin Scale Score at 30 days and 12 Months<sup>a</sup>**

mRS Score	At 30 d, n/N (%)	At 12 mo, n/N (%)
0-2	108/113 (95.6)	96/103 <sup>b</sup> (93.2)
3-5	5 <sup>c</sup> /113 (4.4)	3 <sup>d</sup> /103 <sup>b</sup> (2.9)
6	0/113 (0.0)	4 <sup>e</sup> /103 <sup>b</sup> (3.9)

<sup>a</sup>mRS, modified Rankin Scale.

<sup>b</sup>Ten patients were not evaluated with mRS at 12 months.

<sup>c</sup>Two patients had mRS scores >2 (3 and 4) before the treatment because of a previous subarachnoid hemorrhage. Three patients had mRS worsening after the procedure (because of subarachnoid hemorrhage, 1; because of a thromboembolic event, 1; and because of an increase in mass effect, 1).

<sup>d</sup>Two patients had mRS scores >2 (3 and 4) before the treatment. One patient retreated with a flow diverter had a delayed complication (parent artery occlusion) with clinical worsening (mRS score, 4) at 1 year.

<sup>e</sup>Three patients died of unrelated causes (2 cancer, 1 cirrhosis). One patient described above died as a result of worsening mass effect.

**Mortality/Morbidity at 1 Year**

At 12-month follow-up (mean, 12.6 ± 2.2 months), 103 of the 113 patients (91.2%) enrolled in the study were clinically evaluated with mRS scoring.

Four of 103 patients (3.9%) died between the 1-month and 1-year follow-up: 3 unrelated to aneurysm disease or treatment (cancer, 2; cirrhosis, 1) and 1 of worsening of pre-existing mass effect described previously (this patient had an mRS score of 3 at 1 month). All-cause mortality, neuro-related mortality, and procedure-related mortality were 4 of 103 (3.9%), 1 of 103 (1.0%), and 0 of 103 (0.0%), respectively.

Among the 3 patients who had an mRS score >2 at 1 month related to the procedure, 1 died between 1 month and 1 year (see above) and 2 were improved at 1 year (mRS score, 1 and 2), resulting in a 0.0% morbidity at 1 year.

**Anatomical Results at 1 Year**

Anatomical results at 1 year were evaluated in 99 patients with 100 aneurysms (Table 4).

Vascular imaging technique was DSA in 92 of 100 (92.0%) aneurysms, computed tomographic angiography in 3 of 100

**TABLE 4. Anatomical Results Postoperatively and at 6 and 12 Months**

Status	Postoperative		Aneurysms at
	Aneurysms, n/N (%)	Aneurysms at 6 mo, <sup>a</sup> n/N (%)	12 mo, <sup>b</sup> n/N (%)
Complete	15/114 (13.2)	24/44 (54.5)	56/100 (56.0)
Neck remnant	20/114 (17.5)	13/44 (29.5)	26/100 (26.0)
Sac remnant	79/114 (69.3)	7/44 (15.9)	18/100 (18.0)

<sup>a</sup>Six-month data available only for the WEBCAST study.

<sup>b</sup>Twelve-month results were not evaluated in 4 patients not treated with WEB, 4 patients who died, 3 patients lost to follow-up, and 3 WEB patients retreated before 1 year.

aneurysms (3.0%), and magnetic resonance angiography in 5 of 100 aneurysms (5.0%).

**Evolution of Aneurysm Occlusion Between the Procedure and 12 Months**

This evolution was evaluated in the 99 patients (100 aneurysms) with 1-year follow-up. There was improvement in aneurysm occlusion in 64 of 100 aneurysms (64.0%), stability in 34 aneurysms (34.0%), and worsening in 2 of 100 aneurysms (2.0%). Postoperative anatomical results are reported in Table 4.

**Evolution of Aneurysm Occlusion Between 6 and 12 Months**

This evaluation was feasible in the WEBCAST study (In French Observatory, the patients had no vascular imaging at 6 months). Anatomical results at 6 months are reported in Table 4.

Among the 51 patients, 9 were not included in this evaluation (no WEB treatment, 3; death, 2; lost to follow-up, 2; retreatment before 1 year, 1; no 6-month follow-up, 1). Ultimately, evolution of aneurysm occlusion was evaluated in 42 patients (42 aneurysms). There was improvement of aneurysm occlusion in 3 of 42 aneurysms (7.1%), stability in 36 of 42 aneurysms (85.7%), and worsening in 3 of 42 aneurysms (7.1%).

**Retreatment**

Retreatment was performed with a flow diverter in 2 patients, with stent and WEB in 1 patient, and with stent and coil in 1 patient (Table 5). One patient treated with a flow diverter had a delayed parent artery occlusion with clinical worsening (mRS score, 4). One patient had attempted retreatment with flow diverter, but placing it properly was not possible for anatomical reasons (coverage of perforators).

**DISCUSSION**

Combining the data and results of the 2 GCP studies WEBCAST and French Observatory has created the largest prospective and multicenter cohort of patients with aneurysms treated with WEB and permits a rigorous evaluation of safety. Moreover, because follow-up at 1 year is now completed in both series, it provides an opportunity to analyze precisely the efficacy of the treatment.

**TABLE 5. Retreatment Completed, Attempted, and Planned at 12 Months**

Index Procedure	Retreatment	Combined Aneurysms, n/N (%)
Retreatment completed by 12 mo		4/110 <sup>a</sup> (3.6)
Retreatment attempted by 12 mo		1/110 <sup>a</sup> (0.9)
Retreatment planned at 12 mo		2/110 <sup>a</sup> (1.8)

<sup>a</sup>Number of aneurysms effectively treated with WEB at the index procedure.



## Feasibility and Safety of WEB Aneurysm Treatment

Analysis of the cumulated population confirms data from previous series showing excellent feasibility of the treatment (96.5%), the relatively limited use of adjunctive devices (10.0%), and good safety at 1 month and 1 year.<sup>10-17</sup> Thromboembolic events, including asymptomatic appearance of thrombus during the procedure, were observed in 15.0% of patients, with permanent deficit in only 1.8% of patients. These are very good results, considering that the risk of thromboembolic events is higher in wide-neck bifurcation aneurysms.<sup>20</sup> Analysis of the rate of thromboembolic events in relation to preoperative and intraoperative antiplatelet treatment indicated fewer thromboembolic events associated with the use of any (1 or 2) antiplatelet medication ( $P < .001$ ). However, the small size of the group of patients without antiplatelet treatment must be considered in the interpretation of this statistic.

Intraoperative rupture was reported in 1 patient (0.9%) and was asymptomatic. Notably, no delayed adverse events were observed, as have been occasionally reported for such other devices as flow diverters.<sup>21,22</sup> Finally, morbidity and mortality at 1 month were 2.7% and 0.0%, respectively, confirming the high degree of safety of the treatment. At 1 year, mortality was 3.9% (4 deaths), with 3 deaths unrelated to aneurysm disease or treatment (cancer and cirrhosis) and 1 neurological death related to the increased mass effect of a large, partially thrombosed aneurysm. These results compare favorably with previous series of patients with aneurysms treated with coils like Analysis of Treatment by Endovascular Approach of Non Ruptured Aneurysms (ATENA) and Clinical and Anatomic Results in the Treatment of Ruptured Intracranial Aneurysms (CLARITY).<sup>1,2</sup>

## Efficacy of WEB Aneurysm Treatment

In this large, cumulated population with 1-year follow-up, the most important point to analyze was treatment efficacy. Complete aneurysm occlusion was observed in 56.0% of aneurysms, neck remnant in 26.0%, and aneurysm remnant in 18.0%, with adequate occlusion (complete occlusion or neck remnant) in 82.0% of aneurysms. These results are very similar to results reported in a retrospective European series, with complete and adequate occlusion of 69.0% and 89.7%, respectively, at the midterm follow-up (median, 13 months).<sup>14</sup> In the same series, complete occlusion and adequate occlusion were observed in 68.4% and 84.2%, respectively, at the long-term follow-up (median, 27 months).<sup>15</sup>

The stability of aneurysm occlusion in the midterm and long term is probably the key factor in terms of treatment efficacy. The evolution of aneurysm occlusion between the end of the procedure and 1 year is probably not an optimal indicator because it is well known that there is a rapid change of intra-aneurysmal flow after the deployment of the WEB that can be missed by postoperative DSA if delayed acquisitions are not performed. Thus, it is not surprising to have a high rate of aneurysm occlusion improvement during this period of time (64.0%). Interestingly, the rate of

aneurysm occlusion worsening between end of the procedure and 1 year was very low (2.0%).

Evolution of aneurysm occlusion between 6 months and 1 year was analyzable only in WEBCAST because 6-month follow-up was not required in French Observatory. Again, the rate of aneurysm occlusion worsening was very limited (7.1%), with stable or improved aneurysm occlusion in a high percentage of aneurysms (91.8%).

Anatomical results observed in this cumulated population are difficult to compare with previous series dealing with other endovascular approaches because WEB treatment is used in a relatively precise group of aneurysms (wide-neck bifurcation aneurysms that are prone to recurrence).<sup>23</sup> In the CLARITY series, which contained both narrow- and wide-neck aneurysms, complete occlusion and adequate occlusion were obtained in 34.4% and 80.4% of aneurysms, respectively, at the midterm follow-up (16.7 months). Moreover, stability of treatment was low, with aneurysm occlusion worsening observed in 51.1% of aneurysms between the postoperative period and midterm.<sup>24</sup> In Matrix and Platinum Science (MAPS) Trial, a subgroup analysis was conducted showing that in unruptured aneurysms with a wide neck (not necessarily bifurcation), the rates of complete and adequate occlusion (at 12 months) were 27.1% and 57.6%, respectively, with coils.<sup>25</sup> With stenting and coiling, higher rates of complete and adequate occlusion (45.7% and 62.8%, respectively) were obtained, albeit at the price of a higher rate of complications. Finally, efficacy of WEB treatment is difficult to compare with flow diverters because indications are not the same and the use of flow diverters in bifurcation aneurysms remains controversial.

Retreatment was performed in a limited percentage of aneurysms treated with the WEB (3.6%). It is difficult to compare retreatment rates from 1 series to another because indications for retreatment are not well established and are quite variable from 1 center to another.<sup>26</sup> However, the very low retreatment rate observed with WEB is absolutely comparable to the lowest rate of retreatment reported in the large coiling series. In the HydroCoil Endovascular Aneurysm Occlusion and Packing Study (HELPS), the retreatment rate was 3.0% with both bare and hydrogel coils.<sup>27</sup> In the CLARITY study, the retreatment rate was 3.3% for aneurysms treated with bare coils but 9.5% in the Matrix group.<sup>28</sup> In the Cerecyte Coil Trial, retreatment rate was 3.5% in the bare coils group and 7.7% in the Cerecyte coils group.<sup>29</sup> In the MAPS wide-neck aneurysm subset, the retreatment rate was 13.7% for coils alone and 14.1% for stent and coils.<sup>25</sup>

## WEB Aneurysm Treatment vs Surgery (Clipping)

Comparison of WEB treatment with surgery (clipping) is difficult because no surgical series is specifically dedicated to wide-neck bifurcation aneurysms. Certainly, in some cases reported in the present series, surgical clipping would have been a therapeutic option, but in all centers participating in WEBCAST and French Observatory, endovascular treatment was selected by multidisciplinary teams

that included neurosurgeons. Recent series reporting the treatment of unruptured intracranial aneurysms (the majority of aneurysms treated in the present series) have shown good safety of aneurysm clipping.<sup>30</sup> From the data we have from the literature comparing clipping and coiling (International Subarachnoid Trial and Barrow Ruptured Aneurysm Trial), it is clear that the short-term and midterm safety is higher with coiling, and the present series shows that WEB treatment has a safety similar to that of coiling.<sup>31,32</sup> Regarding efficacy, it is difficult to compare WEB treatment with clipping because surgical series usually do not report 1-year anatomical results evaluated with DSA by an independent core laboratory.

## Limitations

This study has several limitations. First, it is not a randomized study, and comparison with other techniques is difficult. However, safety data are excellent and quite comparable to those observed in large coiling series. Moreover, efficacy data also show the high rate of complete and adequate occlusion at 1 year with stable occlusion in most cases. Second, a recent series has outlined the potential phenomenon of so-called WEB “compression,” which was not analyzed in the present series.<sup>33</sup> WEB compression is a decrease in the height of the device owing to the deepening of the proximal and distal concave device recesses during follow-up. Because both the proximal marker (near the aneurysm neck) and the distal marker (near the aneurysm apex) move toward the center of the device over time, one hypothesis is that the mechanism responsible for this phenomenon is likely associated with clot organization/clot retraction. Further work will be conducted on this topic.

## CONCLUSION

This analysis of the cumulated population of 2 GCP studies dealing with wide-neck bifurcation aneurysm treatment with WEB (WEBCAST and French Observatory) confirmed the high safety of this treatment with no mortality and low morbidity at 1 month (2.7%). Moreover, this treatment is associated with a good efficacy with limited worsening of aneurysm occlusion between postoperative DSA and 1 year (2.0%) and between 6 months and 1 year (7.1%). With a complete and adequate occlusion rate of 56% and 82%, respectively, the long-term protective effect of the WEB device is comparable to that of other endovascular series.

## Disclosures

Clinical Trial Registration: URL: <http://www.clinicaltrials.gov>. French Observatory: unique identifier: NCT18069. WEBCAST: unique identifier: NCT01778322. Drs Pierot, Spelle, Molyneux, and Byrne are consultants for Sequent. Dr Pierot is principal investigator for the WEBCAST and French Observatory studies.

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## APPENDIX

WEBCAST Investigators: National Institute of Neurosciences, Budapest (Hungary): Istvan Szikora; Helios Klinikum, Erfurt (Germany): Joachim Klisch; Universität Koeln, Koeln (Germany): Thomas Liebig; CHU Maison-Blanche, Reims (France): Laurent Pierot; CHU Purpan, Toulouse (France): Christophe Cognard, Anne-Christine Januel; CHU Beaujon, Clichy (France): Jacques Moret, Laurent Spelle; CHU Gui De Chauliac, Montpellier (France): Alain Bonafé, Vincent Costalat, Paolo Macchi, Omer Eker, Riquelme; CHU Bretonneau, Tours (France): Denis Herbreteau; Rikshospital, Copenhagen (Denmark): Markus Holtmannspötter; Klinikum Vest, Recklinghausen (Germany): Werner Weber. French Observatory Investigators: CHU Maison-Blanche, Reims (France): Laurent Pierot; CHU Bretonneau, Tours (France): Denis Herbreteau; CHU Ponchaillou, Rennes (France): Jean-Yves Gauvrit, Hélène Raoult; Hôpital Laennec, Nantes (France): Hubert Desal; CHU Pellegrin, Bordeaux (France): Xavier Barreau; CHU Poitiers, Poitiers (France): Stéphane Velasco; CHU Purpan, Toulouse (France): Christophe Cognard, Anne-Christine Januel; CHU Beaujon, Clichy (France): Jacques Moret, Laurent Spelle; CHU Côte de nacre, Caen (France): Patrick

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## COMMENTS

The authors present the clinical and anatomical outcomes for intracranial bifurcation aneurysms treated with the WEB device in the WEBCAST Trial and the French Observatory Series. Both are single-arm, prospective, multicenter, Good Clinical Practice studies. The entire population included 113 patients with 114 aneurysms, of which 91% were unruptured. Aneurysm locations included the middle cerebral artery (52%), anterior communicating artery complex (18%), basilar apex (18%), and internal carotid artery terminus (11%). Successful device deployment was achieved in 97% of cases, and adjunctive treatment with coils or stents was needed in 10% of cases. The thromboembolic event rate was 15%, resulting in 2% morbidity, and was significantly associated with the use of no antiplatelet agents. There were 1 intraoperative rupture and 1 intracranial hemorrhage, both clinically silent. There was no mortality at the 1-month follow-up and 4 mortalities at the 1-year follow-up (only 1 of which was neurologically related). At 1 year, complete occlusion was observed in 56%, neck remnant in 26.0%, and aneurysm remnant in 18.0%. Between the procedure and 1-year follow-up, the occlusion status improved in 64%, remained stable in 34%, and worsened in 2% of cases. Retreatment was required in 3.6%.

The combination of these 2 prospective studies represents the largest series of WEB cases in the literature. The authors have demonstrated an excellent safety profile and a very low recurrence rate of 2%. In fact, in 64% of cases, the occlusion classification improved, suggesting progressive thrombosis.

These data are certainly encouraging. However, as with any early technology, the results should be taken with caution. Complete aneurysm occlusion at 1 year was observed in only 56% of patients. In the subarachnoid hemorrhage population, incomplete aneurysm occlusion has been shown to increase the risk of future rupture in the Cerebral Aneurysm Rupture After Treatment (CARAT) study.<sup>1</sup> Additionally, a recent systematic review evaluating the predictive nature of the Raymond grading scale (which is used in the present study) found an increased risk of aneurysm rupture for class II (residual neck) and class III (residual dome) aneurysms.<sup>2</sup> This review included both ruptured and unruptured aneurysms. The present study quotes an “adequate” occlusion rate of 82%, defining both class I and Class II as adequate. Although our experience at Mount Sinai is that class II aneurysms have a long-term outcome profile similar to that of class I aneurysms,<sup>3</sup> this is not universally agreed on, and there is certainly contradictory evidence.<sup>2</sup> The concept that class II aneurysms should be lumped with class I aneurysms into an “adequately occluded” class is reasonable but also debatable. Finally, we must always consider the excellent clinical and anatomical outcomes for microsurgical clipping of aneurysms, especially of the middle cerebral artery.<sup>4</sup> All of these factors must be taken into consideration when counseling and treating patients with unruptured intracranial aneurysms.

Despite these cautions, the addition of a new technology to the armamentarium of treatments available for difficult, wide-necked aneurysms should be welcomed. For it is only through continued innovation and technique refinement that we can hope to offer future patients better care than that which is available today.

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This article presents the 1-year clinical and angiographic results of endovascular treatment of a combined patient population with intracranial aneurysms from 2 multicenter, single-arm, prospective Good Clinical Practice trials, the WEBCAST and French Observatory studies, both conducted in Europe. The trial evaluated the efficacy and safety profile of the Woven EndoBridge (WEB) device, a novel intrasaccular aneurysm occlusion device, in the treatment of wide-necked bifurcation aneurysms in both the anterior and posterior circulation. Among a total of 114 aneurysms in 113 patients, the authors demonstrated a very high rate of successful device deployment (96.5%), complete occlusion or neck remnant (“adequate occlusion”) in 30.7% immediately postoperatively, a thromboembolic complication rate of nearly 2% (total, 15%) with significant correlation to no antiplatelet therapy, and no immediate mortality. One-month morbidity was 2.7%. Additional endovascular devices (stent and coils) were required in 10% of the procedures. At 1 year, the adequate occlusion rate increased to 82%, and there were 4 deaths, 3 unrelated to treatment. The retreatment rate was 3.6% at the conclusion of trial with about 2% planned for retreatment. Recurrence rate was 2%. The data suggest very impressive aneurysm treatment rates with the device with very high safety. Despite the above, there are some finer aspects of deliberation that demand attention.

Foremost is the disproportionate number of patients with unruptured aneurysms (99 of 114, 87%), which makes the study biased toward an assessment of endovascular management of unruptured aneurysms. Only 8.8% (10 of 114) were ruptured, and even those were in the relatively better Hunt and Hess grades I to III. This essentially morphs the concept of vasospasm-related morbidity and overall effect of subarachnoid hemorrhage on the modified Rankin Scale. The results are therefore more or less important as purely technical accomplishments of angiographic aneurysm occlusion, which nonetheless are important in determining risk-benefit aspects in managing patients with unruptured aneurysms.

The follow-up period of 1 year is obviously a very short interval in a disease as dynamic as intracranial aneurysms because recurrences are very well documented to occur in a delayed fashion.<sup>1</sup> The fact that about 10% of the aneurysms still required additional stent and/or coil devices implies that not all aneurysms have the anatomical configuration amenable to an exclusively intrasaccular strategy of occlusion. The characteristics of those aneurysms are not elaborated.

A critical factor in this study that is not apparent is the basic case selection process, which should have been described more clearly beyond the mention of “endovascular treatment was selected by multidisciplinary

teams that included neurosurgeons.” Toward this end, the inclusion of angiographic images and brief clinical details of a few illustrative case examples would have been illuminating to the reader. Natural questions that arise would be why some of these aneurysms would not be amenable to clipping with or without bypass. The issue of microsurgery becomes more immediate because more than half of the treated aneurysms in the study were in the middle cerebral artery location. Several studies have repeatedly demonstrated excellent long-term results with microsurgical management of middle cerebral artery bifurcation aneurysms.<sup>2-4</sup> Other aneurysm characteristics such as location of perforators and the presence of thrombosis are also not described.

The other endovascular means of managing wide-necked bifurcation aneurysms is the Y-stent assisted coiling techniques, which have been reported to show encouraging results. It would have been interesting if the authors had analyzed the WEB device with this perspective.<sup>5-7</sup>

Despite the above, this study is an important advance in the management of the difficult situation of a patient with a wide-necked bifurcation aneurysm. It demonstrates the safety and efficacy of a novel device that is conceptually elegant. It would be exciting to learn how the WEB device compares with contemporary new devices such as the pCONus (Phenox, Bochum, Germany) and PulseRider (Pulsar Vascular, San Jose, California), which target exactly the same aneurysm morphology.<sup>8-10</sup> Indeed, we should never lose sight of those unfortunate patients who suffer the devastating complication of subarachnoid hemorrhage from an aneurysm. Continuing investigation into the pathophysiology of aneurysm formation and rupture and innovation in methods to treat the consequences of a rupture are crucial to developing effective techniques in aneurysm occlusion. Toward this goal, neurosurgeons are uniquely equipped to spearhead the efforts in basic science and clinical methodology research, as well as patient care above all.

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