



ASNR Career Center

The Go-To Job Site for Neuroradiology Employers and Job Seekers
Start here: careers.asnr.org

AJNR

Current Evaluation of the Safety and Efficacy of Aneurysm Treatment with the WEB Device

L. Pierot, A. Arthur, L. Spelle and D. Fiorella

AJNR Am J Neuroradiol 2016, 37 (4) 586-587

doi: <https://doi.org/10.3174/ajnr.A4702>

<http://www.ajnr.org/content/37/4/586>

This information is current as of December 6, 2023.

Current Evaluation of the Safety and Efficacy of Aneurysm Treatment with the WEB Device

L. Pierot, A. Arthur, L. Spelle, and D. Fiorella

We read with interest the recent review of 6 European studies of the Woven EndoBridge (WEB) aneurysm embolization system (Sequent Medical, Aliso Viejo, California) for the treatment of wide-neck bifurcation aneurysms (WNBA).¹ The WEB was introduced in 2010 in Europe and has undergone important evolution during the past 5 years. The devices involved have moved from dual-layer to single-layer construction, with a reduction in the size of the microcatheter used to deliver the device. This technique has been evaluated in several retrospective and prospective good clinical practice (GCP) studies with independent monitoring of all patient data, independent analysis of all adverse events, and independent adjudication of all anatomic results by a core laboratory. No other endovascular treatment for intracranial aneurysms has been so thoroughly evaluated immediately after its commercialization.

The results of 2 early prospective, multicenter studies (WEB Clinical Assessment of IntraSaccular Aneurysm Therapy [WEBCAST] and the French Observatory) were recently published, demonstrating that the treatment with the WEB is both feasible and safe.^{2,3} Because the study protocols were homogeneous, an analysis of the combined population of these 2 studies was conducted.⁴ In this population of 113 patients with 114 aneurysms treated with WEB, the treatment was successfully performed in 96.5% of aneurysms. Thromboembolic events and intraoperative rupture were observed in 15.0% and 0.9% of patients, respectively. However, these adverse events were not associated with permanent clinical worsening in most cases. One-month morbidity was 2.7%, and there was no mortality. At 1 year, delayed morbidity was 0.0% and mortality (unrelated to the treatment) was 3.9% (mostly related to cancer or cirrhosis). These safety numbers are comparable with those reported for aneurysm coiling.^{5,6}

In the same population, anatomic results were evaluated at 1 year, and adequate occlusion was reported in 82.0% (including complete occlusion in 56.0% and neck remnant in 26.0%). The rate of neck remnant was low compared with standard coiling as reported in the Clinical and Anatomical Results in the Treatment of Ruptured Intracranial Aneurysms (CLARITY) series: 46.0% in aneurysms treated with bare coils and 49.0% in aneurysms treated with Matrix detachable coils (Stryker, Kalamazoo, Michigan).⁷ Certainly longer follow-up is needed to evaluate the anatomic stability of this treatment, and very long-term follow-up (5 years) is foreseen in these prospective GCP studies. In a retrospective European series, anatomic results were reported stable between midterm (mean, 13 months) and long-term (mean, 26 months)

follow-up, with adequate occlusion at long-term in 84.2% of aneurysms, including complete occlusion in 68.4% and neck remnant in 15.8%.^{8,9}

The stability of occlusion after WEB treatment is probably related to appropriate device sizing. The frequency and the role of the so-called “compression” phenomenon in the long-term stability of aneurysm occlusion remain unknown. Further analysis of the combined WEBCAST and French Observatory cohorts will provide further insight into these 2 points. Moreover, as the device itself and our understanding of the procedure continue to evolve, it is likely that early and long-term occlusion rates will be even better in future studies.

It is probably not feasible and not ethical to evaluate the WEB in a randomized trial versus other aneurysm treatments. The WEB device is dedicated to a very specific subgroup of intracranial aneurysms (WNBA). Against which technique should the WEB be evaluated in a randomized trial (surgical clipping, balloon-assisted coiling, stent-assisted coiling, or flow diversion)? The safety and efficacy of these techniques for treatment of WNBA have not been evaluated in prospective, GCP studies—probably an essential first step before designing and powering a randomized controlled trial.

In summary, the WEB device is the first to be precisely and extensively evaluated for safety and efficacy since the beginning of its clinical use. Initial results have shown good safety and efficacy at midterm follow-up in comparison with the published literature for coil embolization of similar aneurysms. Further efficacy evaluation is foreseen in long-term follow-up of existing studies and new studies, which will be conducted to evaluate the latest generation of the device (WEBCAST2) and its efficacy in ruptured aneurysms (CLARITY). A prospective GCP trial is also underway in the United States with more than 100 of 150 planned patients already enrolled.

Disclosures: Laurent Pierot—RELATED: Consulting Fee or Honorarium: Sequent Medical; UNRELATED: Consultancy: Medtronic, MicroVention, Neuravi; OTHER: Principal Investigator for WEB studies (WEBCAST, French Observatory, WEBCAST2). Adam Arthur—UNRELATED: Consultancy: Codman,* Medtronic,* MicroVention,* Penumbra,* Sequent Medical,* Silk Road,* Stryker*; Grants/Grants Pending: Sequent Medical,* Siemens,* Penumbra*; OTHER: investor: Valor Medical; research support: Codman, Penumbra, Sequent Medical, Siemens; OTHER: Principal Investigator for the WEB Intrasaccular Therapy study (WEB-IT). Laurent Spelle—RELATED: Consulting Fee or Honorarium: Sequent Medical; UNRELATED: Consultancy: Medtronic, Stryker; OTHER: Principal Investigator for WEB study (CLARITY). David Fiorella—RELATED: grant: Siemens,* Sequent Medical,* MicroVention*; Consulting Fee or Honorarium: Medtronic, Johnson & Johnson, MicroVention, Penumbra; Support for Travel to Meetings for the Study or Other Purposes: MicroVention, Penumbra, Codman/Johnson & Johnson, Medtronic; OTHER: Consultancy: Medtronic/eV3, Sequent Medical, MicroVention, Penumbra, Johnson & Johnson/Codman; research support: Siemens, Penumbra, Sequent Medical, MicroVention; OTHER: Principal Investigator for WEB-IT. *Money paid to the institution.

REFERENCES

1. Armoiry X, Turjman F, Hartmann DJ, et al. Endovascular treatment of intracranial aneurysms with the WEB device: a systematic review of clinical outcomes. *AJNR Am J Neuroradiol* 2015 Nov 19. [Epub ahead of print] CrossRef Medline
2. Pierot L, Costalat V, Moret J, et al. Safety and efficacy of aneurysm

- treatment with WEB®: results of WEBCAST Study.** *J Neurosurg* 2015 Sep 18. [Epub ahead of print] Medline
3. Pierot L, Moret J, Turjman F, et al. **WEB treatment of intracranial aneurysms: clinical and anatomic results in the French Observatory.** *AJNR Am J Neuroradiol* 2015 Oct 29. [Epub ahead of print] CrossRef Medline
 4. Pierot L, Spelle L, Molyneux A, et al; WEBCAST and French Observatory Investigators. **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).** *Neurosurgery* 2016;78:133–41 CrossRef Medline
 5. Pierot L, Spelle L, Vitry F; ATENA Investigators. **Immediate clinical outcome of patients harboring unruptured intracranial aneurysms treated by endovascular approach: results of the ATENA study.** *Stroke* 2008;39:2497–504 CrossRef Medline
 6. Cognard C, Pierot L, Anxionnat R, et al; Clarity Study Group. **Results of embolization used as the first treatment choice in a consecutive nonselected population of ruptured aneurysms: clinical results of the Clarity GDC study.** *Neurosurgery* 2011;69:837–41; discussion 842 CrossRef Medline
 7. Pierot L, Cognard C, Ricolfi F, et al; CLARITY investigators. **Mid-term anatomic results after endovascular treatment of ruptured intracranial aneurysms with Guglielmi detachable coils and Matrix coils: analysis of the CLARITY series.** *AJNR Am J Neuroradiol* 2012;33:469–73 CrossRef Medline
 8. Lubicz B, Klisch J, Gauvrit JY, et al. **WEB-DL endovascular treatment of wide-neck bifurcation aneurysms: short- and midterm results in a European study.** *AJNR Am J Neuroradiol* 2014;35:432–38 CrossRef Medline
 9. Pierot L, Klisch J, Liebig T, et al. **WEB-DL endovascular treatment of wide-neck bifurcation aneurysms: long-term results in a European series.** *AJNR Am J Neuroradiol* 2015;36:2314–19 CrossRef Medline