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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.

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