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Invited Commentary

Commentary on 'Early Results from the ENGAGE Registry: Real World Performance of the Endurant Stent Graft for Endovascular AAA Repair in 1262 Patients'

E.L.G. Verhoeven*, A. Katsargyris

Department of Vascular and Endovascular Surgery, Klinikum Nürnberg, Breslauer Strasse 201, 90471 Nürnberg, Germany

The Endurant (Medtronic, Santa Rosa, California, USA) Stent Graft Natural Selection Global Postmarket Registry (ENGAGE) is unprecedented because of its magnitude. In this report, the authors describe early results in 1262 patients treated with the Endurant stent-graft in 79 sites around the world. This large registry clearly demonstrates the commitment of the manufacturer to provide 'real world' data to the vascular community. We seem to move away from randomised trials comparing open and endovascular repair (EVAR) to focus on advances in EVAR. Clearly, we have reached a point of acceptance between two validated techniques in the treatment of infrarenal abdominal aortic aneurysms.

The authors document perioperative (30 days) outcomes for the total patient cohort, but also provide 1-year follow-up results for 39.6% (500/1262) of the patients. It is no surprise that the results are excellent. Most of the currently available third-generation stent-grafts would probably match these outcomes. Complications leading to higher re-intervention rates compared to open repair usually occur after the first year or even only after 3–5 years postoperatively.[1–3] We do not contest the quality of the results, and the authors do acknowledge that longer-term results need to be awaited, but the conclusion is overrated. As mentioned, we completely agree with the magnitude of the effort (unprecedented), but not that the results are (already?) promising (what?) or that the graft is safe and effective yet. Not that we doubt on the quality of the graft, but technically speaking we just need longer-term outcomes before having proven safety and effectiveness. Unfortunately, such premature conclusions are drawn too easy with new generation stent-grafts (or with current new concept stent-grafts).

The ENGAGE registry aims at reporting 'real world' results, by its magnitude and the many centres throughout the world. Nevertheless, we would argue that these are still larger and experienced centres. It actually positively surprises us that only 17.9% of the patients were treated outside instructions for use (IFU) criteria, in contrast to a recent published overview in the United States.[4] On the other hand, the inclusion criteria for the Endurant are very liberal, based on extensive bench testing by the manufacturer. Necks as short as 10 mm length, and/or severe angulations are part of the IFU's. To demonstrate effectiveness and safety, patients with adverse anatomy (inside the liberalised IFU's and outside IFU's) treated with the Endurant should be studied separately and in the long term. In addition, one has to be careful not to send the wrong message to the community, because in the real 'real world', most cases are performed in low volume centres.[5,6] Before treating patients outside these already liberal and not clinically proven IFU's, one needs to balance the risks of EVAR with the Endurant in challenging anatomy with other therapeutic options, such as open repair, fenestrated stent-grafting or even chimney techniques. Broadening eligibility is not a goal in itself and, more than ever, with so many options around, we must try hard to find the best solution for each individual patient, and not for the doctor.

In conclusion, we absolutely recognise the magnitude of the registry and congratulate both the manufacturer and all investigators. We eagerly await longer-term results that could demonstrate safety and effectiveness of the Endurant, especially in challenging anatomy.

Competition of Interest

Eric Verhoeven has received educational grants and is a consultant for Cook Inc., W.L. Gore & Associates, Siemens and Atrium-Maquet.

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* Corresponding author. E.L.G. Verhoeven, Department of Vascular Surgery, Klinikum Nürnberg, Breslauer Strasse 201, 90471 Nürnberg, Germany. Tel.: +49 9113982650; fax: +49 9113982984, +31 503611745.

E-mail address: Eric.Verhoeven@klinikum-nuernberg.de (E.L.G. Verhoeven).

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