Aortic Aneurysm Sac Enlargement After EVAR

Analyzing instructions-for-use compliance and its effect on patient outcomes.

BY ANDRES SCHANZER, MD

The most dramatic shift in the surgical management of abdominal aortic aneurysms (AAAs) occurred in 1991 when Juan Parodi reported the first endovascular aneurysm repair (EVAR).[1] This transformative moment paved the way for minimally invasive AAA repair as an alternative to open surgical repair. In 2006, only 15 years after the initial EVAR report, 21,725 EVAR procedures were performed in the United States, for the first time exceeding the number of open surgical AAA repairs.[2] Currently, more than 80% of elective AAA repairs in the United States are performed via EVAR.[3]

RECENT DATA

Results from the three largest prospective randomized trials (EVAR, DREAM, and OVER) that compared early and late outcomes after open and endovascular repair of AAAs were remarkably consistent in all major outcomes.[4-6] In aggregate, the findings can be summarized as follows: (1) perioperative morbidity and mortality are significantly lower after EVAR than after open repair; (2) the short-term survival advantage of EVAR diminishes during long-term follow-up such that if patients survive beyond approximately 2 years, the long-term survival of patients is similar for both groups; and (3) although the reintervention rate after EVAR is higher than after open repair, most of these reinterventions are performed with catheter-based techniques, albeit at overall higher costs.

Rates of AAA sac enlargement after EVAR are not negligible. In a large university series, the rate of aortic sac enlargement after EVAR was reported to be 21% at 5 years.[7] A more recent study that analyzed 478 patients who underwent EVAR demonstrated a 42% rate of aneurysm sac enlargement at 5 years.[8] In another study, in patients treated for type II endoleaks based on surveillance-detected AAA sac enlargement, 55% continued to show expansion > 5 mm 5 years after treatment.[9]

RETROSPECTIVE ANALYSIS OF POST-EVAR AAA SAC ENLARGEMENT

To better understand the predictors of AAA sac enlargement after EVAR, we conducted a study using data from a large, multicenter cohort CT scan database to determine the degree of compliance with anatomic guidelines in the instructions for use (IFU) for the EVAR device, examine changes in compliance with the IFU over the last decade, and determine the relationship between baseline aortic and iliac artery anatomic characteristics and the incidence of AAA sac enlargement after EVAR.[10]

Data from patients who underwent EVAR between January 1, 1999, and December 31, 2008, were obtained from a medical imaging repository at M2S (West Lebanon, NH). For the purposes of this study, M2S provided de-identified data on all patients in their prospectively acquired database who underwent a CT scan before EVAR and had at least one CT scan after EVAR. Using these criteria, 10,228 patients were identified. The primary limitation of this study was that the clinical characteristics of the patients were not available, and thus the generalizability of this population to those undergoing EVAR in the United States could not be established.[11] Similarly, no information was available regarding which interventions, if any, were performed in response to the findings of the CT scan.

This study demonstrated that the incidence of AAA sac enlargement after EVAR was 41% at 5 years in this cohort of patients—a rate that increased during the time period of the study. When all EVAR-treated patients were classified according to compliance with IFU criteria, 5,983 (58.5%) were found to be outside the most conservative IFU, and 3,178 (31.1%) were outside of the most liberal IFU available in the United States market. This indicates the presence of liberal interpretation of the anatomic characteristics deemed suitable for EVAR. Our analysis has shown that several of these factors, including aortic neck diameter, aortic neck angle, and common iliac artery diameter, were independently associated with

TABLE 1. SIGNIFICANT INDEPENDENT PREDICTORS FOR AAA SAC ENLARGEMENT AS IDENTIFIED VIA MULTIVARIABLE COX PROPORTIONAL HAZARDS ANALYSIS

Covariates	Hazard Ratio (95% Confidence Interval)	*P* Value
Age (y)		
< 60	Reference	–
60–69	0.8 (0.6–1.05)	.11
70–79	0.87 (0.67–1.14)	.31
≥ 80	1.32 (1.03–1.75)	.05
Female sex	0.96 (0.82–1.13)	.64
AAA diameter		
Maximum AAA diameter ≥ 55 mm	0.97 (0.86–1.13)	.62
Aortic neck length		
> 15 mm	Reference	–
10–15 mm	0.87 (0.71–1.07)	.19
< 10 mm	0.94 (0.77–1.15)	.53
Aortic neck diameter at lowest renal artery		
< 28 mm	Reference	–
28–32 mm	1.8 (1.44–2.23)	< .0001
> 32 mm	2.07 (1.46–2.92)	< .0001
Conical neck	1.17 (0.97–1.42)	.1
Aortic neck angle		
< 45°	Reference	–
45°–60°	1.04 (0.9–1.21)	.58
> 60°	1.96 (1.63–2.37)	< .0001
Iliac diameter		
Both common iliac arteries ≤ 20 mm	Reference	–
Only one common iliac artery > 20 mm	1.46 (1.21–1.76)	< .0001
Both common iliac arteries > 20 mm	1.31 (0.99–1.74)	.06
Endoleak during follow-up	2.7 (2.4–3.04)	< .0001

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AAA sac enlargement (Table 1). These observations raise the question as to whether such liberal selection of anatomic criteria is justified when using current endovascular device designs.

MOVING FORWARD

This analysis of M2S data was meant to be a starting point for a critical conversation in the evolving field of EVAR, rather than a conclusion. It has now been unambiguously established that the risk of late rupture after EVAR is higher than initially believed.[12] A consensus exists that the primary anatomic determinant of late AAA rupture after EVAR is aortic sac enlargement.[12,13] It is likely that the rate of aortic sac enlargement after EVAR will be dependent on the specific patient population and endovascular device studied. Based on this analysis of patients undergoing EVAR in the M2S database, EVAR is frequently performed in patients outside of industry-recommended anatomic guidelines, and this practice increases the risk of late aortic sac enlargement.

Undoubtedly, EVAR represents a tremendous advance in the treatment of AAA and has provided significant benefit to many patients. However, if the widespread application of this technique continues to grow in patients with unfavorable anatomy, the benefits of EVAR may be offset by increased rates of treatment failure, costly reinterventions, and the potential for late aneurysm rupture. Endovascular technologies must continue to evolve so that patients with anatomy that is not optimal for currently available devices can be treated more effectively.

Next-generation fenestrated and branched EVAR devices appear to offer a repair option that is more durable than standard EVAR devices in patients with compromised sealing zones. However, these devices are only available at select sites through clinical trials or early postapproval rollout programs.[14-19] Furthermore, it is important to note that these devices are typically more complex and require larger doses of radiation and prolonged procedure times.

In summary, within the last 2 decades, countless patients have benefitted from a minimally invasive approach to the treatment of AAAs. In an exceptionally brief span of time, vascular surgeons have developed and implemented the necessary skill set required to safely provide EVAR to patients, with extremely low perioperative mortality. Continued device development with a focus on durability in treating patients with more complex anatomy and in preventing late AAA sac enlargement and rupture is an imperative. Next-generation EVAR devices, such as the highly promising branched and fenestrated solutions, will expand the suitable anatomic criteria for successful EVAR; however, with standard EVAR technology, careful patient selection is critical for successful long-term patient outcomes. ■

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