Endovascular Repair of Abdominal Aortic Aneurysm
No Cause for Alarm

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In the now 20 years since it was initially described, endovascular repair of abdominal aortic aneurysm (EVAR) has matured to the point where some 70% to 80% of potentially eligible patients are treated with this modality. Furthermore, the majority of patients managed with conventional open operation are those in whom anatomic considerations disallow EVAR. In the current issue of Circulation, Schanzer et al detail anatomic characteristics of a large patient cohort treated with EVAR, indicating that the primary study end point of abdominal aortic aneurysm (AAA) sac enlargement may be alarmingly high (40% at 3 years); such sac enlargement is considered a surrogate in their report for threat of late AAA rupture, representing, of course, EVAR treatment failure. Although the implications of this study referable to appropriate patient (anatomic) selection for, and close follow-up after EVAR are both evident and emphasized elsewhere, the authors’ concerns relative to late performance of EVAR are, at this point in the evolution of this technology, refuted by a substantial body of literature. To wit, in consideration of the clinically relevant outcomes of late AAA rupture and/or freedom from AAA-related mortality, EVAR has perhaps exceeded the expectations of even its more aggressive proponents. A surfeit of literature encompassing single-center cohort studies, registries/trials, and even randomized trials of EVAR versus open repair for AAA has verified the clinical effectiveness of EVAR. In the 7000 EVAR-treated patients represented in these studies, reflecting the above-noted different study designs, freedom from AAA-related mortality averages a minimum of 95% even out to 5 years with actuarial methods. A large longitudinal study of EVAR in Medicare beneficiaries (with a time interval identical to that in the Schanzer study) found late AAA rupture after EVAR to be a rare event (1.8% at 4 years). These data, combined with the Level 1 evidence verifying the perioperative advantages of EVAR, doubtlessly account for the rapid dissemination of EVAR and its enthusiastic adoption by both patients and vascular surgeons.

How, then, are the data of Schanzer et al reconciled with the preponderance of favorable literature referable to late performance of EVAR?

The initial consideration is the primary end point of the study, late AAA sac enlargement after EVAR, detailed at 17% and an alarming 41% at 3 and 5 years, respectively. The data are incomplete because the study inclusion criteria indicated the presence of a single postoperative study and the reader is not informed of the temporal clustering of such follow-up studies. As the authors concede, these data could have been influenced by the use of devices (which are no longer in use) known to be associated with an up to 40% rate of sac enlargement. Yet, the authors’ data on late sac enlargement are in conflict with the bulk of extant literature on studies that detail this parameter. For example, in our experience, only 8% of sequentially imaged post-EVAR patients demonstrated sac enlargement at 3 years. In the Eurostar registry, the corresponding number is in the 10% range and in device-specific trials (in which inclusion criteria mandate adherence to specific instructions for use [IFU]), the rate of sac enlargement ranged from 5% to 12%. Indeed, the significance (or, more properly stated, the lack thereof) of AAA sac diameter increase after EVAR has been doubted by some investigators as a result of poor correlation with clinically relevant outcomes. An important proviso in this regard is the amply demonstrated ominous significance of AAA sac enlargement associated with endoleak, i.e., cases in which incomplete exclusion of the AAA sac from the bloodstream is noted. Accordingly, sac enlargement associated with endoleak, although occurring in <10% of cases, is a legitimate indication for secondary intervention. Schanzer et al note that AAA sac enlargement was strongly correlated with late endoleak (hazard ratio, 2.7), a finding that is both intuitively logical and repeatedly demonstrated in the literature. Yet, the authors’ data on the overall incidence of late sac enlargement, being widely discrepant with the bulk of the literature, are easily explained by the constraints of their study design. This study considers only patients whose surgeons chose to obtain postprocessing computed tomography models after EVAR; such studies, in turn, are typically obtained only when some question about the technical results of EVAR arises. Stated differently, the report of Schanzer et al is a study of patients whose surgeons sought further information about a post-EVAR computed tomography scan result. M2S reconstructions are not routinely obtained (there are cost considerations) outside clinical trials. Accordingly, the denominator in the Schanzer et al study is unknown, and herein lies the explanation for their AAA sac enlargement data.

The data on surgeons’ adherence (or lack thereof) to recommended IFU are intriguing, particularly as they relate to
trends over time. The manner in which the authors have grouped the individual AAA anatomic features and IFU into liberal and conservative applications, ie, in a binary fashion, tends to overestimate the numbers of procedures performed outside of IFU. It is both expected and demonstrated\(^4\) that a particular EVAR device will perform optimally when applied in the appropriate anatomy; the converse is also true. Yet, in the realities of clinical practice, any particular anatomic feature (eg, AAA neck length, angulation, quality, iliac vessel diameter) or constraint can frequently be overcome by selection of a particular EVAR device or, for example, by placement of an iliac surgical conduit to introduce the device. Because none of these data are available in the Schantzer et al study, there is no way to assess the potential mitigation of the authors’ data on IFU adherence by such maneuvers. Furthermore, in high-risk (for open repair) patients, surgeons frequently and intentionally compromise on IFU guidelines simply because that is appropriate clinical decision making. Indeed, we have studied this issue in our own experience and found that, in some 40% of our patients, at least 1 IFU parameter was violated, but in 90% of these cases, it was indeed a single anatomic feature that was not ideal for EVAR. This was true across a variety of devices; freedom from AAA-related mortality at 5 years was 95%, and was independent of strict adherence to IFU.\(^14\) Thus, although a general recommendation to adhere to IFU considerations in EVAR is appropriate, favorable results have been achieved when less stringent criteria are applied in accordance with individual patient considerations. Otherwise, the authors’ data indicative of the fact that more challenging AAA anatomy has been treated in recent years reflect both increasing surgeon experience and better EVAR devices.

A final anatomic parameter that the authors emphasize is the average AAA size at treatment, which in their study was a bit under the 5.5-cm threshold for treatment indication emanating from 2 large randomized trials. In my view, this size threshold number is hardly absolute, and the article’s tone is overly harsh in its implication that the 60% of EVAR patients treated with AAAs ≤5.5 cm were incorrectly managed. Society for Vascular Surgery Practice guidelines clearly indicate that a variety of clinical and/or anatomic features (not to mention patient preference) clearly influence the decision to proceed with treatment, particularly for AAAs in the 5.0- to 5.5-cm range.\(^2\) In our experience, the average size at EVAR treatment in nearly 1000 patients was a shade under 57 mm, nearly identical to Eurostar registry data.\(^1,5,11\) The fear that minimally invasive EVAR would engender a stangpade to needless repair very small AAAs has, in fact, been refuted. Just after commercial approval of several EVAR devices in 1999, overall AAA repair in Medicare beneficiaries was flat (through 2004), although EVAR became the predominant mode of AAA repair with a significant reduction in perioperative mortality\(^12\) compared with open operation. Many features likely influenced the data on size at treatment reported by Schantzer et al, and it is worth emphasizing that larger AAAs are less likely to be anatomically suitable for EVAR.

The data reported by Schantzer et al, albeit constrained by the serendipity of follow-up imaging data, highlight elements of patient selection and follow-up in the practice of EVAR that have been repeatedly emphasized. Their report, by its nature, considers only anatomic data, whereas both the decision to treat and the technical mode of treatment must consider the totality of patient presentation. The concerns raised in the Schantzer et al report are, in a sense, legitimate, yet the preponderance of evidence has verified the clinical efficacy of EVAR.

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References


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