In this issue of *Circulation*, a report from the GLOBAL collaborators on Advanced Stent-graft Techniques for Aneurysm Repair (GLOBALSTAR) describes the results of a multicenter clinical experience of fenestrated endovascular repair for juxtarenal/pararenal aneurysms. It is estimated that 50% of patients with abdominal aortic aneurysms are not candidates for endovascular repair (EVAR) with the use of the currently commercially available devices because of unfavorable anatomy. This includes patients with short or angulated necks, aneurysmal extension into either internal iliac artery or complex aneurysmal involvement of the juxtarenal, paravisceral, and thoracoabdominal aorta. A number of advanced endograft technologies have been developed to extend the use of EVAR in circumstances of complex anatomy, eg, fenestrated EVAR. The feasibility of such techniques has been established, and a number of centers have begun to accumulate clinical experience. But, as in the early days of EVAR, enthusiasm and optimism for these techniques has not been matched by evidence, which is essential before the techniques can be advocated for day-to-day clinical practice. The biggest hurdle to develop evidence arises from the fact that fenestrated EVAR and similar advanced techniques can be applied to a relatively small number of patients in each of the centers using them; therefore, it takes a long time to establish a substantial cohort even in the busiest of the centers. A collaborative project is ideal to develop a database of advanced techniques that is large enough to allow conclusions to be drawn in a shorter span of time. The aim of GLOBALSTAR Registry Collaborators project is to provide an investigative vehicle to provide evidence to characterize the applicability of advanced endovascular techniques to clinical practice.

Article see p 2707

In this report, the authors strive to present a real-world experience for the use of fenestrated endografts, which has the potential to be different from the experience in single centers of excellence or from investigators who possess Investigator Device Exemptions. To achieve this goal, the authors included patients from 14 different centers at which they assessed the outcome in a range of 11 to 59 patients per center. The authors took care to avoid inclusion of the learning curve associated with the use of fenestrated stent grafts by excluding centers that had performed <10 fenestrated stent graft cases, yet they were able to evaluate 316 patients over a 4-year period. This approach is radically different from published experience to date, which typically provides data on small numbers of patients.

These authors report a 30-day mortality of 4.1%, which is surprising when one considers other series that report 1.8% mortality for endovascular repair, and 2.8% for open repair of juxtarenal aneurysms. The GLOBALSTAR study used a multicenter approach with a variety of endovascular specialists at different centers, and this may explain, to a certain degree, what initially appears to be a significantly higher mortality rate. To put the GLOBALSTAR Registry Data results in perspective, one must consider recent analysis of the results of open infrarenal (2600 patients) and complex aortic aneurysm repair (nearly 600 patients) in the National Surgical Quality Improvement Program (NSQIP) database. The NSQIP is the leading nationally validated, risk-adjusted, outcomes-based program to measure and improve the quality of surgical care in the private sector. It was modeled after work that started in the Veterans Administration to quantify and characterize quality care in surgical patients. In this multicenter study, in which the data are obtained prospectively, the mortality associated with complex open aneurysm repair was not substantially different from the mortality associated with infrarenal aneurysm repair (5.7% versus 5.1%). The mortality associated with complex open aneurysm repair in the NSQIP database review may actually be worse (5.7% NSQIP versus 4.1% GLOBALSTAR) than fenestrated EVAR, thereby favoring the endovascular approach. A comparison between these study data may not be valid, because the demographics of the patient population in the NSQIP and GLOBALSTAR registry may not be comparable.

There appears to be a substantial missing link to the understanding the clinical relevance of the data in this report from the GLOBALSTAR investigators. The authors do not include either a historical or a contemporary control for the results of open repair of complex juxtarenal aneurysms. The authors recognize this, and used the Vascular-Physiological and Operative Severity Score for the enUmeration of Mortality and Morbidity (V-POSSUM), which is a risk-adjusted scoring system for predicting 30-day mortality in patients undergoing elective vascular surgery. It has been used to assess surgical outcome by comparing predicted deaths.
with observed deaths.11,12 There is, however, no consensus on the best risk prediction model for mortality following elective abdominal aortic aneurysm repair. A recent analysis of 5 risk prediction models has been undertaken by using the UK National Vascular Database.13 The Medicare, V-POSSUM, and Vascular Biochemical and Hematologic Outcome Model models were found to accurately predict risk in 3, 2, and no risk-group quintiles, respectively. Although these authors concluded that the Medicare and Vascular Governance North West models contain similar risk factors and showed good discrimination when applied to the UK National Vascular Database, there was no evidence to suspect that the V-POSSUM score would not be applicable to patients undergoing complex aortic aneurysm repair. Nevertheless, the estimated predicted mortality rate of 11% seems quite high. The GLOBALSTAR authors’ only explanation for this is that they believe their patients may be sicker than those described in other reports, but this assertion unfortunately cannot be verified.

A substantial advantage of the data presented in this article is the fact that the grafts used were off the shelf and all made by the same manufacturer. These characteristics of the study support the concept that these results provide insight into the real-world experience with this approach to endovascular aneurysm repair, in contrast to modified stent grafts prepared on the back table in the operating room.14,15

A significant finding in this series is the 5 patients whose procedure was complicated by spinal ischemia, a well-recognized complication with thoracoabdominal repairs, but less well described in the fenestrated literature or in association with repair for type IV or juxtarenal aortic aneurysms. There is concern that endovascular repair associated with fenestrated grafts in the juxtarenal aorta result in coverage of both lumbar vessels in the visceral aorta and concomitant closure/obstruction of the hypogastric vessels, which might increase the risk of spinal cord ischemia by interruption of collateral pathways in the pelvis.16 Unfortunately, the GLOBALSTAR database did not have detailed information on the distal fixation sites, so this possibility cannot be confirmed or excluded. The fact that 4 of these 5 patients had endografts extending to the celiac artery is noteworthy, and it leads one to speculate as to whether standard spinal cord protection protocols should be routinely instituted in this subset of patients.

In summary, this report is a valuable addition to the literature in the sense that it does illustrate real-world experience with a commercially available device and points out areas in which new information must be obtained. The report also identifies gaps in the data gleaned from vascular specialty databases, such as the GLOBALSTAR and V-POSSUM, in comparison with the NSQIP. The vascular/endovascular community will be well served if the many isolated reports from single-center studies are analyzed in collaborative efforts such as demonstrated by the GLOBALSTAR Investigators. It is possible that newer databases established to achieve regional collaboration such as the Vascular Study Group of New England will fill the gaps identified in this article.17

Disclosures

None.

References


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Endovascular Repair of Juxtarenal Aneurysms: Real-World Experience
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