The Least-Invasive Approach

Transitioning to a fast-track EVAR protocol.

BY BRANT W. ULLERY, MD, AND JASON T. LEE, MD

Since its introduction in 1991, endovascular aneurysm repair (EVAR) has been shown in multiple randomized controlled trials to be associated with reduced early morbidity and mortality and equivalent long-term clinical outcomes compared with conventional open surgery.[1,2] Although up to 50% of patients with abdominal aortic aneurysms (AAAs) have been historically considered anatomically unsuitable for standard EVAR, the combination of technological advancement and increased surgeon experience has allowed many of these initial anatomic constraints to be overcome, including those related to hostile proximal aortic neck anatomy and inadequate access site vessels. This extension of EVAR technology to a wider cohort of patients with challenging anatomy has been complemented by more recent procedural and engineering refinements aimed at further minimizing morbidity and enhancing cost effectiveness while preserving patient safety.

INCREASING UTILIZATION OF PEVAR

The widespread use of percutaneous EVAR (PEVAR) and the increasingly smaller profiles of currently available devices have served as the foundation for an even less-invasive, modern-day EVAR procedure. In observational reports of PEVAR and standard femoral exposure EVAR, benefits attributed to PEVAR included shorter procedure times, reduced need for general anesthesia, lower complication rates, fewer wound complications, and shorter hospital stays.[3,4] Nelson and colleagues[4] conducted the only multicenter, randomized controlled trial of PEVAR versus open femoral exposure for EVAR and demonstrated that PEVAR can be performed safely with > 90% technical success and a low incidence of access site–related complications. The study demonstrated significantly shorter times to hemostasis (10 vs 23 minutes) and procedural completion (107 vs 141 minutes) using the Perclose ProGlide closure device (Abbott Vascular) in a "preclose" technique. Additionally, favorable trends were noted with regard to procedural blood loss, groin pain, time to ambulation, and overall quality of life among those undergoing PEVAR. Successful PEVAR may also increase operator confidence by avoiding routine general anesthesia or postoperative intensive care unit admissions and, in some centers, even routine admission at all.

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REDUCING LENGTH OF HOSPITAL STAY AFTER EVAR

EVAR is associated with higher overall costs relative to open repair mainly as a result of up-front, device-related costs and, to a lesser extent, the accrual of long-term costs associated with more intensive imaging surveillance and the increased need for secondary procedures.[5,6] Although the adoption of less-aggressive postoperative imaging surveillance protocols and ultrasound-based (vs CT angiography) surveillance by many institutions is expected to yield some long-term improvement in the cost efficiency of EVAR, recent attention has focused on reducing hospital length of stay as a primary strategy to minimize the overall cost of EVAR, particularly given that devices represent a fixed cost that often remains outside immediate control of the implanting physician. In the European study by Al-Zhuir and colleages,[7] an increase in short-stay EVAR procedures (1 day vs >1 day) from 30% to 45% in the first and second half of a 21-month study period resulted in an overall cost reduction of nearly £2,000 per patient.

In an even more aggressive attempt at reducing length of stay, Lachat and colleagues[8] recently reported the first series of outpatient EVARs involving a cohort of 100 consecutive patients. Inclusion criteria for outpatient EVAR in their series included asymptomatic AAAs, the ability

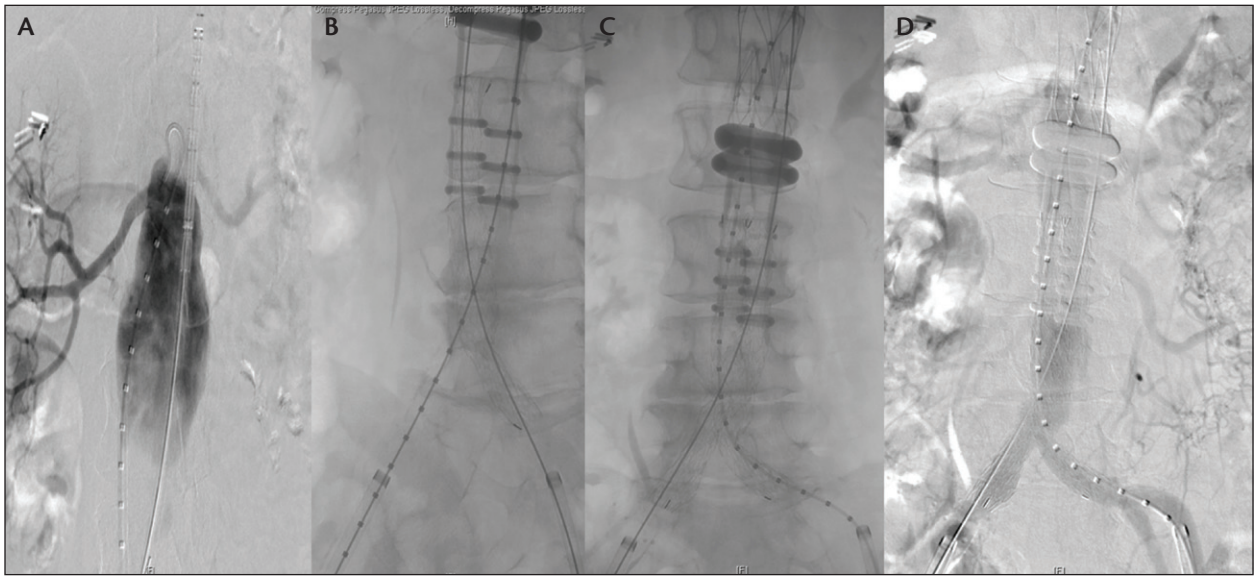

Figure 1. Intraprocedural images during EVAR with the Ovation Prime® System. Initial aortogram (A), cannulation of the contralateral gate and placement of iliac limbs (B, C), and completion aortogram (D).

to provide informed consent, technically uncomplicated EVAR procedures with an operative time of < 4 hours, adult observer assistance at home for the first 24 hours, and travel time to the hospital of < 1 hour if readmission was required. Per protocol, EVAR was generally performed under local anesthesia and with percutaneous access. Patients were discharged home after 4 to 6 hours of observation and checked the following morning and on the fifth postoperative day in the outpatient clinic.

Clinical results demonstrated 30-day mortality and readmission rates for this cohort of 0% and 4%, respectively, with all readmissions secondary to access vessel complications (stenosis, n = 2; pseudoaneurysm, n = 2). Renal function remained stable in all patients, and none of the outpatients developed any infections or perioperative delirium following same-day discharge. Satisfaction surveys performed on the fifth postoperative day and repeated at 3-month follow-up showed that 97% of the patients in the cohort would undergo outpatient EVAR again and recommend it to others. Moreover, financial analysis revealed significant cost savings in nursing fees, ward costs, management costs, and total costs in a cohort of 42 matched contemporary patients treated with a standard stent graft (21 outpatient EVARs vs 21 inpatient EVARs). The authors concluded that elective outpatient EVAR can be performed safely, provided that specific criteria are fulfilled and special precautions are taken.

Earlier this year, Dosluoglu and colleagues[9] also reported outpatient EVAR to be safe and feasible in a select group of patients undergoing elective procedures.

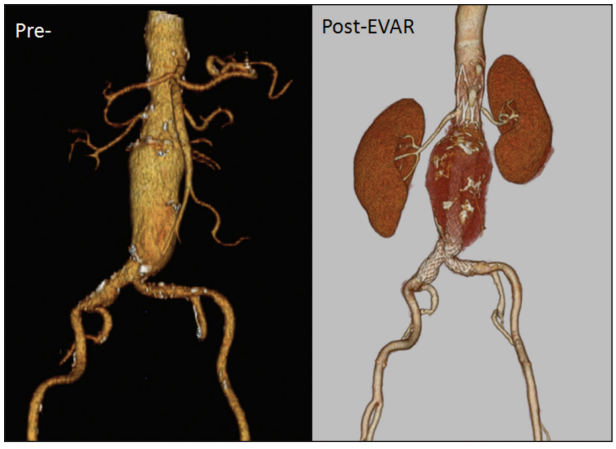

Figure 2. Pre- and postoperative CT angiography of a AAA after endovascular treatment using the Ovation Prime System.

The authors discussed the option of same-day discharge at the time of the preoperative clinical visit for patients with favorable anatomy, normal renal function, void of high-risk medical conditions, good functional capacity, and who had someone to stay with them the night of surgery. Patients opting for same-day discharge were permitted to do so following a 6-hour observational period if the physician had no concerns regarding the repair, closure, or postoperative clinical status.

Of the 64 elective EVARs performed over the 21-month study period, 84% were performed totally percutaneously, and 81% utilized general anesthesia. One-third of patients (n = 21) were discharged on the same day, whereas the remaining patients were dis-

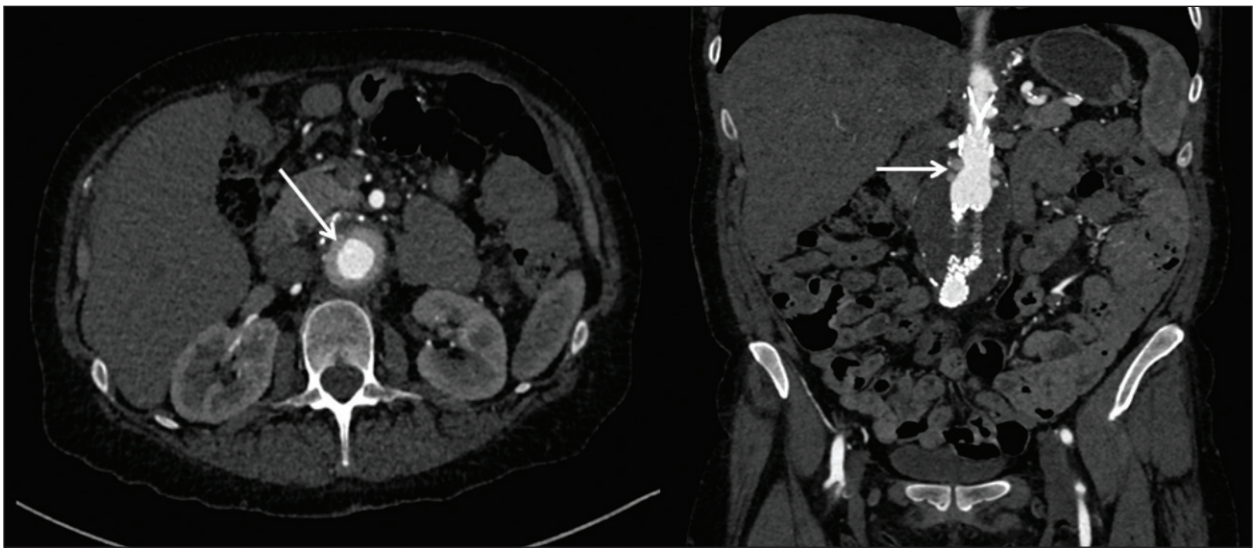

Figure 3. Routine postoperative CT angiography showing sealing rings of the Ovation Prime System.

charged on either postoperative day 1 (n = 23; 36%) or postoperative day 2 to 6 (n = 20; 31%) due to significant baseline comorbid status, transportation issues, patient preference, urinary retention, femoral cutdown, or baseline chronic renal insufficiency requiring periprocedural hydration. The only unplanned readmission occurred in the same-day discharge group because of severe postimplantation syndrome. No patients developed renal failure or any infectious complications. At a mean follow-up of 8.3 months, aneurysm-related mortality was 0%.

CLINICAL DATA WITH THE OVATION® STENT GRAFT

These early favorable clinical experiences demonstrate the viability of fast-tracking appropriate EVAR patients, and such efforts are likely to gain considerable momentum with the development of increasingly low-profile, highly versatile stent grafts. The Ovation Prime Stent Graft (TriVascular, Inc.) represents one of the most recent US Food and Drug Administration–approved devices and was specifically developed to accommodate a broader range of complex aortoiliac neck anatomy and difficult iliofemoral access vessels with a low-profile 14-F outer-diameter delivery system and a proximal aortic neck seal mechanism designed to conform to complex proximal infrarenal aortic neck morphology (Figures 1 through 3).

In a recent, prospective, multicenter trial, the Ovation® Stent Graft demonstrated excellent safety and effectiveness in the treatment of 161 patients with AAAs, particularly in the subgroup of patients with short aortic necks and small-caliber, heavily calcified access vessels.[10] Bilateral percutaneous access was performed in 43% of cases, with 34% of cases completed using locoregional anesthesia or conscious sedation. No stent graft migration or type I, III, or IV endoleaks were observed. At 1 year, AAA-related and all-cause mortality were 0.6% and 2.5%, respectively, along with an overall treatment success rate of 99.3%. Even in the 40% of patients with challenging anatomy (defined as access vessel < 6 mm in diameter and/or proximal neck length < 10 mm), the Ovation® Stent Graft yielded 100% technical success and 97% freedom from major adverse events through 1 year.

STANFORD EXPERIENCE WITH THE OVATION PRIME STENT GRAFT

Our experience with the Ovation Prime Stent Graft began after its US Food and Drug Administration approval in late 2012. Since this time, we have successfully implanted > 30 endografts. Technical success has been 100%, with the majority (91%) of these cases performed using bilateral percutaneous femoral access. We have not experienced any significant type I, III, or IV endoleaks, and there have been no limb occlusions or secondary interventions to date. Length of hospital stay has ranged from 1 to 2 days. Over time, and with increasing familiarity with the device and delivery system, we have found the Ovation Prime Stent Graft to be particularly useful for patients with challenging aortic anatomy and difficult access site vessels. Less trauma to the access site, increasing accommodation of the iliac vessels for smaller-profile devices, and relative ease of deployment contribute overall to the less-invasive approach that likely will have theoretical clinical benefits.

We recently performed successful percutaneous EVAR

STANFORD CRITERIA FOR FAST-TRACK EVAR

Preoperative Criteria

- Functionally independent, performing all activities of daily living
- Social support with someone available to stay with the patient for the first 24 hours postprocedure
- Absence of significant baseline comorbidities (unstable angina, congestive heart failure, severe chronic obstructive pulmonary disease)
- Normal renal function
- Favorable aortic anatomy (no angulated iliac or aortic portions or significant thrombus)

Periprocedural Criteria

- Uncomplicated PEVAR with a procedural duration < 2 hours
- Uneventful 4-hour observation period following the procedure
- Able to tolerate a regular oral diet
- Pain controlled with oral analgesics

using the Ovation Prime Stent Graft in two nonagenarians under local anesthesia only, with both patients being discharged approximately 12 hours postprocedure with minimal discomfort and the ability to return to full activities of daily living that day. One of the procedures was performed with routine cath lab nursing staff under monitored sedation, much like performing bilateral iliac stents in an outpatient setting, further amplifying the cost savings by avoiding anesthesia issues completely. Although these are only anecdotal reports, most experienced EVAR enthusiasts understand the challenges of treating patients in their 90s and that avoiding any time of anesthetic or access complication is paramount to long-term benefit when treating patients at advanced age.[11] More rigorous and controlled trials will be necessary to truly understand the benefits and potential disadvantages of such an approach. At Stanford, we are currently developing a fast-track EVAR protocol using the criteria noted in the *Stanford Criteria for Fast-Track EVAR* sidebar.

LIFE STUDY: LEAST INVASIVE FAST-TRACK EVAR

Due to single-center reports and surgeon interest in fast-tracking patients, there is now industry support to study these efforts to determine its place in modern EVAR practice. The Ovation Prime System represents the first device to explore the safety and feasibility of EVAR using a systematic, less-invasive protocol.

The company recently launched the LIFE study, a prospective, consecutively enrolling, nonrandomized, multicenter, postmarket registry to evaluate the clinical and cost benefits of the low-profile Ovation Prime System when used as part of a fast-track EVAR protocol featuring bilateral percutaneous access, no general anesthesia, no postoperative intensive care unit admission, and next-day discharge. The primary endpoint will be determined by evaluating the proportion of patients who experience a major adverse event within 30 days of the procedure and will be compared to a performance goal based on the previous Ovation Global Pivotal Trial. A host of secondary endpoints will also assist in demonstrating the benefits to the patient, physician, and hospital through improved clinical outcomes and reductions in health care system costs as compared to historical control data.

CONCLUSION

In summary, EVAR continues to evolve into an increasingly safe, less-invasive, and efficacious therapeutic alternative to open AAA repair. Led by the low-profile 14-F Ovation Prime Stent Graft, the trend toward lower-profile devices has enabled the transition toward a fast-track EVAR protocol characterized by routine percutaneous access and the potential to avoid general anesthesia. Results of the LIFE study will significantly contribute to the existing literature in the near future and add momentum to the inevitable transition toward a fast-track, next-day-discharge EVAR protocol. ■

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1. Lederle FA, Freischlag JA, Kyriakides TC. Outcomes following endovascular versus open abdominal aortic aneurysm repair. JAMA. 2009;302:1535-1542.
2. United Kingdom EVAR Trial Investigators, Greenhalgh RM, Brown LC, et al. Endovascular versus open repair of abdominal aortic aneurysms. N Engl J Med. 2010;362:1863-1871.
3. Malkawi AH, Hinchliffe RJ, Holt PJ, et al. Percutaneous access for endovascular aneurysm repair: a systemic review. Eur J Vasc Endovasc Surg. 2010;39:676-782.
4. Nelson PR, Kracjer Z, Kansal N. A multicenter, randomized, controlled trial of totally percutaneous access versus open femoral exposure for endovascular aortic aneurysm repair (the PEVAR trial). J Vasc Surg. 2014;59:1181-1193.
5. Dryjski M, O'Brien-Irr MS, Hassett J. Hospital costs for endovascular and open repair of abdominal aortic aneurysms. J Am Coll Surg. 2003;197:64-70.
6. Angle N, Dorafsjar AH, Moore WS, et al. Open versus endovascular repair of abdominal aortic aneurysms: what does each really cost? Ann Vasc Surg. 2004;18;612-618.
7. Al-Zhuir N, Wong J, Nammuni I, et al. Selection, thirty day outcome and costs for short stay endovascular aortic aneurysm repair (SEVAR). Eur J Vasc Endovasc Surg. 2012;43:662-665.
8. Lachat ML, Pecoraro F, Mayer D, et al. Outpatient endovascular aortic aneurysm repair. Ann Surg. 2013;258:754-759.
9. Dosluoglu HH, Lall P, Blochle R, et al. Ambulatory percutaneous endovascular abdominal aortic aneurysm repair. J Vasc Surg. 2014;59:58-64.
10. Mehta M, Valdes FE, Nolte T, et al. One-year outcomes from an international study of the Ovation abdominal stent graft system for endovascular aneurysm repair. J Vasc Surg. 2014;59:65-73.
11. Lee GK, Ullery BW, Lee JT. Elective EVAR in nonagenarians is safe in carefully selected patients [published online ahead of print April 3, 2014]. Ann Vasc Surg. doi: 10.1016/j.avsg.2014.03.026.