Endovascular Abdominal Aortic Aneurysm Repair

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The early 1990s ushered in the era of endovascular aneurysm repair (EVAR). Diffusion of this technology, although widespread, has been met with enthusiasm by some and caution by others. Advocates of traditional open surgical techniques maintain that EVAR is costly and that long-term outcomes for patients are inferior. The objectives of the present review are to use a case scenario to highlight the clinical problem, examine current data on the use of EVAR, and to describe the principles behind the safe application of this therapy to patients.

Case Scenario

A 78-year–old white man involved in a motor vehicle crash is evaluated in the emergency department and is found to be without serious injury. Computerized tomography (CT) reveals the incidental finding of a 4.8-cm infrarenal abdominal aortic aneurysm. He has been unaware of the aneurysm but recalls an older brother who had undergone repair of an aneurysm previously. He smokes 2 packs of cigarettes daily, has moderate chronic obstructive pulmonary disease, and has hypertension that is well controlled on a β-Blocker. He is referred to a vascular surgeon, who recommends ultrasound surveillance with a 6-month follow-up visit. The subsequent visit reveals aneurysm growth to 5.6 cm, which is confirmed by repeat CT. The patient remains asymptomatic and endovascular aneurysm repair is offered.

Clinical Impact of Abdominal Aortic Aneurysm

Abdominal aortic aneurysm (AAA) is a significant health risk in older populations, representing the 14th-leading cause of death for the 60- to 85-year-old age group in the United States. Necropsy studies from Europe and the United States suggest an overall prevalence of the condition of 2% to 4% for men and 1% to 2% for women. The prevalence is greatly affected by case definition, however, with less stringent definitions of AAA in population-based screening studies demonstrating a prevalence of nearly 9% in men and 2% in women. Universally noted are the graded increase in prevalence with advancing age and the increased prevalence with male gender.

Noninvasive screening programs and a dramatic rise in the elderly population have led to an overall increased incidence of asymptomatic AAA. Despite an aggressive surgical posture toward elective repair before rupture, the incidence of ruptured AAA has also continued to increase. Annually 35,000 to 40,000 aneurysms are repaired surgically in the United States. A steady upward trend in stent graft use reflected in administrative databases implies that EVAR now represents the majority of cases. With Markov modeling of hospital costs ranging from $16,016 to 18,484 for open repair and $20,083 to 20,716 for EVAR, AAA represents a considerable economic burden.

Pathophysiology and Current Therapies

AAAs are conventionally defined as a ≥50% increase in aortic diameter compared with the normal proximal aorta. The inciting events leading to AAA formation are not well understood. Some common themes of maturing aneurysms include 1) proteolytic degradation of aortic wall connective tissue, 2) transmural inflammation, 3) immune responses, and 4) increased biomechanical wall stresses. Once AAA formation is initiated, a slow steady growth of the aneurysm until rupture is typical, although on an individual basis this growth rate may be quite variable. Larger-diameter aneurysms in particular, along with female gender, advanced age, smoking, and hypertension have been associated with rapid growth. Rapid growth has consequently been associated with increased risk of rupture, although initial aneurysm size at diagnosis has the strongest association with rupture.
aneurysm repair, initially using homografts, has successfully been employed to prevent rupture since the 1950s. The traditional open surgical approach in the modern era is performed either via a retroperitoneal or transperitoneal exposure to obtain proximal and distal aortic control. The aneurysm is then opened, back-bleeding branch arteries are ligated, and a prosthetic graft is sutured from the normal proximal aorta to the normal distal aorta or iliac segments. Flow is then restored to the lower extremities and the aneurysm sac is closed over the newly placed synthetic graft. Although effective and durable in treating aneurysms and preventing rupture, this operation has been associated with national mean mortality rates >4% since the 1980s.

The excessive mortality associated with open aneurysm repair and a strong trend in surgery toward minimally invasive techniques led to the concept that a covered stent graft might be delivered endoluminally, effectively sealing off the aneurysm wall from systemic pressures, preventing aneurysm rupture, and decreasing associated mortality. In 1991, the first published report of stent graft implantation for AAA in humans suggested that this approach was feasible. Subsequent years have seen a tremendous surge in both the number of endovascular aneurysm repairs performed and technological improvements in stent graft design. Four Food and Drug Administration (FDA)–approved devices, each with a slightly different design, are currently being marketed (Figure 1). Rather than relying on sutures to provide fixation, as in open repair, endovascular stent grafts rely on radial forces of self-expanding stents for fixation or self expand in concert with active fixation using hooks or barbs at the proximal aorta fixation site. One FDA-approved device uses bare-wire suprarenal support, as well. With appropriate positioning and adequate fixation, each of these devices redirects the transmission of aortic pulsatile flow and shear forces from the wall of the aneurysm sac to the graft itself. The responses of aneurysm sacs to these changes are variable. The great majority will cease growth or shrink over time. With longer follow-up now being achieved after EVAR, >97% 5-year and >94% 9-year rupture-free survival has been observed.

Evidence for Endovascular Repair

Two randomized European trials comparing EVAR to open surgery (OS) and 1 randomized trial comparing EVAR to no intervention were published in 2005. The first was the Dutch Randomized Endovascular Aneurysm Management (DREAM) trial, randomizing 351 patients with asymptomatic AAAs >5 cm in diameter with suitable stent graft anatomy to OS or EVAR. This study suggested a 30-day benefit in mortality favoring EVAR (1.2% EVAR versus 4.6% OS; P = 0.10). The trend toward an early mortality advantage was lost, however, 12 months into the 2-year study follow-up.

The second trial, from the United Kingdom, labeled EVAR trial 1 (EVAR 1) was similar to DREAM in comparing EVAR to OS in patients with suitable stent graft anatomy and aneurysm size ≥5.5 cm. This study randomized a large group of patients (1082), with 94% receiving their allocated treatment. EVAR 1 more clearly demonstrated an early perioperative mortality benefit for EVAR (1.7% EVAR versus 4.7% OS; P = 0.009). Blood product use and length of hospital stay also favored EVAR. In contrast, the primary end point of all-cause mortality did not show a lasting benefit for EVAR at the 4-year study conclusion, although aneurysm-related death was decreased (3.5% EVAR versus 6.3% OS; P = 0.02). Complication rates (17.6 per 100 person-years EVAR versus 3.3 per 100 person-years OS; P < 0.0001) and reintervention rates (6.9 per 100 person-years EVAR versus 2.4 per 100 person-years OS; P < 0.0001) were much higher for stent graft repair than for open repair.

EVAR trial 2 (EVAR 2) randomized 338 patients >60 years of age with aneurysms ≥5.5 cm who were deemed unfit for open surgical repair to EVAR or no intervention. Between the 2 arms of the study, 142 patients died during follow-up, which correlated to a 64% overall mortality by Kaplan–Meier estimates at 4 years. This study was complicated by long delays in EVAR after randomization and a 27% patient crossover rate from the no intervention group. In the final analysis, no benefit to EVAR over medical management was detected in either overall mortality or aneurysm-related mortality for patients unfit for open surgery.

Ongoing in the United States is the Open Versus Endovascular Repair (OVER) trial, a 9-year study that be-
gan in 2002 comparing endovascular aneurysm repair with standard open surgery using a multicenter randomized trial through the Department of Veteran Affairs (VA) Cooperative Study Group.32

Clinical Use

The FDA approved the transluminal stent graft treatment of abdominal aortic aneurysms in 1999.33 Whereas 2 devices were initially approved, AneuRx by Medtronic (Minneapolis, Minn) and Ancure by Endovascular Technologies Inc (EVT; Menlo Park, Calif), the Ancure device was removed from the market in 2001 after the company failed to submit >2500 medical device reports to the FDA.34 Three additional devices now also hold FDA approval, including the Zenith (Cook Inc, Bloomington, Ind), Excluder (W.L. Gore and Associates, Flagstaff, Ariz), and Powerlink (Endologix Inc, Irvine, Calif) systems. Multiple other stent grafts bearing the CE (Conformité Européenne) mark are employed in Europe after demonstrating safety for their intended use. Many stent grafts have undergone modification, with resulting technologies in the third generation and beyond. Despite the diversity among the devices, a generalized discussion of device implantation is indicated.

Preprocedural planning is the most critical component of a technically successful endovascular abdominal aortic aneurysm repair. CT provides the backbone for evaluating patient candidacy. In addition to the indications of either an asymptomatic aneurysm of appropriate maximal diameter, or a small aneurysm with features putting it at increased risk of rupture, patients being considered for EVAR must fulfill several anatomic criteria. These include 1) iliofemoral access vessels that will allow safe insertion and deployment of the device, adequate seal, and sufficient length to provide axial support for the graft and 2) an infrarenal aortic neck of adequate length, limited angulation, and appropriate diameter. These anatomic features, as well as the presence or absence of thrombus and calcium at each level, can be evaluated using CT.

Cardiac complications are the most common serious perioperative complication of EVAR30 and the most common cause of late death.28 Patient selection must therefore also include careful risk stratification of patient comorbidities. The Society for Vascular Surgery has recommended a medical comorbidity grading system for EVAR that emphasizes cardiac, pulmonary, and renal status but also includes hypertension and patient age as relevant factors.35 This scoring system aids in patient selection and provides a framework for uniform data collection patterns intended to facilitate analysis of outcomes for EVAR.

When a decision is made to proceed with EVAR, it can be performed under general anesthesia, local anesthetic with conscious sedation, epidural, or spinal block. The patient is prepped from nipples to knees for the very small but present risk of needing immediate conversion to open surgery. Control of both femoral arteries is typically obtained through small groin incisions, although a totally percutaneous approach has been reported with low complication rates and high incidence of technical success.36 After bilateral access is obtained, a marking angiogram is typical to confirm preoperative CT measurements and identify the exact location of the lowest renal artery. Most devices follow with ipsilateral main body insertion and deployment at the infrarenal neck, wire cannulation of the contralateral “gate,” contralateral limb deployment, balloon angioplasty to fully expand the device, and completion angiography (Figure 2). Technical success is achieved when there has been successful access to the arterial system using a remote site, successful deployment of the stent graft with secure proximal and distal fixation, absence of either a type I or type III endoleak (see adverse effects), and a patent stent graft without significant twist, kinks, or obstruction by intraoperative measurements.37

Patients who undergo EVAR need regular clinical follow-up with appropriate imaging for the remainder of their lives because of the potential for stent graft migration and other causes.
of sac repressurization that put the patient at risk of aneurysm rupture. CT is the gold standard for follow-up imaging. Concerns with this method include the cumulative effects of radiation exposure and the effect of repetitive administration of intravenous contrast on renal function. Magnetic resonance imaging/angiography is an alternative for follow-up of most devices but is costly, time consuming, and not universally available. Duplex ultrasound is another option that bears the limitations of relatively small numbers of accredited vascular ultrasound technicians to perform exams and the risk of interoperator variability. Wireless pressure monitoring of the aneurysm sac using a small sensor implanted at the time of EVAR has been proposed as an alternative to other imaging modalities, but no long-term studies currently demonstrate the efficacy of pressure-sensing devices in preventing AAA rupture after EVAR.\(^1\)\(^2\) Efforts to find the optimal method for minimizing the frequency and inconvenience for the patient of follow-up visits while maximizing freedom from aneurysm-related death are ongoing.

### Complications of Endovascular Aneurysm Repair

The numbers of adverse events possible with EVAR are many, because it is a technically complex procedure typically performed on a high-risk patient population. One of the most common adverse events is the need for a secondary intervention of some type. Data from the EUROpean collaborators on Stent/graft Techniques for aortic Aneurysm Repair (EUROSTAR) registry of 2846 patients treated from December 1999 until December 2004 revealed that EVAR resulted in a cumulative incidence of secondary interventions of 6.0%, 8.7%, 12%, and 14% at 1, 2, 3, and 4 years, respectively.\(^3\) Secondary interventions are typically performed when the aneurysm sac has become repressurized because of incomplete exclusion of blood flow from the sac. The term “endoleak” was created to describe this complication in 1996, and a classification scheme has been adopted (Figure 3). Type I and type III endoleaks are treated with immediate intervention to halt peri-graft flow or flow between modular components. Type II endoleaks are typically managed expectantly with intervention reserved for persistent endoleaks in the presence of aneurysm sac enlargement. The presence of a persistent type II endoleak for \(>6\) months, however, has been associated with aneurysm enlargement, increased rate of secondary interventions, and even aneurysm rupture.\(^4\)\(^5\) Type IV endoleaks rarely occur with modern stent graft design, and type V endoleaks (endotension), although still reported, are much less frequent after modification of the Gore Excluder device in 2004 to a low-permeability expanded polytetrafluoroethylene layer.\(^6\)\(^7\) Secondary interventions occur in a spectrum ranging from diagnostic angiography to endograft removal with conversion to open repair, although the majority are percutaneous treatment of type II endoleaks with source embolization.

A related cause of endoleak and potential complication of EVAR is device failure. The integrity of stent graft materials and maintenance of proper positioning within the aneurysm are critical in preventing pressurization of the aneurysm sac and rupture. Material failure includes fracture of any of the metallic components of the stent graft, including stents, hooks, or bars, or tears in the fabric component of the stent graft. Loss of proper stent graft position can occur for many reasons. Material failure, inadequate proximal or distal seal zone, aneurysm remodeling after EVAR, or features of the vessel, such as thrombus or calcium, that limit stent purchase, have all been implicated in the migration of stent grafts. Each of these modes of failure needs to be analyzed within the context of their clinical significance. A stent fracture that leaves the graft fabric intact and is not in a critical region for maintaining fixation would likely need only follow-up, whereas modular component separation resulting in a large type III endoleak will require urgent intervention to restore stent graft integrity.

### Approach to the Small Abdominal Aortic Aneurysm

Whereas randomized clinical trials have focused on establishing the proper use of EVAR for larger aneurysms, its application for the treatment of small aneurysms is still an area of controversy. Early open aneurysm repair for aneurysms \(<5.5\) cm in diameter does not confer a long-term survival advantage.\(^8\)\(^9\) However, retrospective analysis of the large EUROSTAR database revealed that EVAR for aneurysms with diameters between 4.0 cm and 5.4 cm had lower incidence of type I endoleak and improved cumulative freedom from aneurysm-related death relative to 2 comparison groups with aneurysms diameters of 5.5 to 6.4 cm and \(>6.5\) cm.\(^10\) Level 1 evidence is lacking at this time, but the Positive Impact of EndoVascular Options for Treating Aneurysms EarLy (PIVOTAL) and Comparison of surveillance versus Aortic Endografting for Small Aneurysm Repair (CAESAR) trials were initiated in an attempt to provide such evidence.\(^1\)\(^1\) Both are device specific, randomize patients with smaller aneurysms to EVAR or surveillance, and use an FDA-approved Medtronic device or the Cook Zenith device, respectively. Until the results of these trials are published, the optimal management of small aneurysms remains ambiguous and a patient-specific approach that takes into account aneurysm morphology, biology, and patient comorbidities should be used.

### Published Clinical Guidelines

The 2005 American College of Cardiology/American Heart Association practice guidelines for the management of patients with peripheral arterial disease (lower extremity, renal, mesenteric, and abdominal aortic) states that it is reasonable to offer EVAR of infrarenal aortic and/or com-
mon iliac aneurysms in patients at high risk of complications from open operations because of cardiopulmonary or other associated diseases and that repair may be considered in patients at low or average surgical risk.53 Whereas this document proposes a treatment algorithm setting the threshold for surgical repair at $\geq 5.5$ cm except in cases of rapid expansion, it also states, “Ultimately, once an infrarenal aortic aneurysm reaches an appropriate size for graft replacement, a choice must be made between a traditional open operation or endovascular repair. Like all other aspects of aneurysm management, this decision requires a balanced judgment of relative risks.” Other features, such as saccular aneurysm morphology, patient gender, heredity, uncontrolled hypertension, and chronic obstructive pulmonary disease may also be important considerations.54

**Conclusions**

The patient described in the vignette meets all the recommended criteria for aneurysm repair. His age, ethnic background, and heavy smoking history are typical of patients with this disease process. The absolute aneurysm size and history of rapid expansion suggest that repair would offer a mortality benefit. Before offering EVAR, however, anatomic suitability must be confirmed by an experienced clinician using accurate imaging. Once it is established that the patient is an appropriate candidate for endovascular repair, the risks and benefits of both open and endovascular approaches should be discussed. Given the advanced age and pulmonary morbidity

**Figure 3.** Schematic demonstrating the different types of endoleak after endovascular aneurysm repair. Type I endoleaks occur because of inadequate graft seal resulting in perigraft flow and include (Ia) perigraft flow occurring proximally, (Ib) perigraft flow occurring distally, and (Ic) perigraft flow around an iliac artery occlusion device. Type II endoleaks occur when branch arteries backbleed because of collateral flow. These endoleaks include (IIa) backbleeding inferior mesenteric artery and (IIb) backbleeding lumbar artery. Type III endoleaks occur when flow persists between the segments of a modular graft and include (IIIa) leaks between iliac limbs or an iliac limb and main body component and (IIIb) leaks between main body components. Type IV endoleaks (IV) occur when flow is present through endograft material (graft porosity). Type V endoleak, or, “endotension” (V), occurs when persistent or recurrent pressurization of the aortic aneurysm exists in the absence of demonstrable endoleak. Drawings prepared by H. Fischer, MFA.
of this patient, endovascular repair would be appropriate therapy.

Disclosures
None.

References


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Circulation. 2008;117:1738-1744
doi: 10.1161/CIRCULATIONAHA.107.747923
Circulation is published by the American Heart Association, 7272 Greenville Avenue, Dallas, TX 75231
Copyright © 2008 American Heart Association, Inc. All rights reserved.
Print ISSN: 0009-7322. Online ISSN: 1524-4539

The online version of this article, along with updated information and services, is located on the World Wide Web at:
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