Clinical Decision Making for Endovascular Repair of Abdominal Aortic Aneurysm

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Case presentation: Mr JG is a 78-year-old retired banker who was referred for evaluation and treatment of a 6-cm abdominal aortic aneurysm (AAA), seen on a recent surveillance abdominal ultrasound, that had expanded 9 mm since an earlier study (8 months previous). His comorbidities for vascular disease include hypertension, non–insulin-dependent (type 2) diabetes mellitus, moderate obstructive pulmonary disease, and coronary artery disease. He underwent coronary bypass surgery 5 years ago. Moderate residual congestive heart failure was managed medically. A CT scan obtained to better assess the arterial anatomy demonstrated an infrarenal AAA measuring 6.2 cm in maximal diameter (Figure 1A). Should AAA repair be recommended to this patient, and if so, AAA repair by what method?

Abdominal aortic aneurysm (AAA) is defined as a permanent localized dilation of the aorta that has at least a 50% increase in diameter as compared with the expected normal diameter of the aorta, which may vary according to age, sex, and body size.1 Numerous possible etiologies for AAA have been investigated, including degenerative processes affecting connective tissue integrity, inflammatory disorders, genetic susceptibility, and infectious causes. Risk factors include advanced age, smoking, male gender, and family history. Other factors that are associated with an increased prevalence of AAA include hypertension, hypercholesterolemia, and atherosclerotic diseases.2–9 Initial development and subsequent growth of AAA is a complex interaction of many of these factors.

The majority of patients with AAAs are asymptomatic. AAAs frequently are detected incidentally during imaging studies for another pathology. In people 60 years and older, AAAs are found in 4% to 8% of men and 1% to 3% of women.7,10–19 The incidence increases 2- to 5-fold in the presence of cardiovascular risk factors and a family history of aneurysm.20,21

Each year, ≈15,000 people in the United States die from a ruptured abdominal aneurysm, rendering it the 15th leading cause of death in this country.22 Thirty percent to 75% of patients with a ruptured AAA die before they ever reach a hospital.23–29 Even with surgery, an average 48% (95% CI 46% to 50%) perioperative mortality rate is associated with a ruptured AAA repair.30 The overall mortality rate in patients with ruptured AAA ranges from 67% to 89%.23–29 Therefore, detection of AAAs before rupture and elective repair can prolong survival and decrease the periprocedural complication rate. Evidence suggests that screening patients for AAAs resulted in an ≈45% reduction in the incidence of ruptured AAA16,18 and a 21% to 68% decrease in aneurysm-related deaths.13,15,16,18,31

These observations have led a group of experts to recommend screening of AAA for all men 60 to 85 years of age, all women 60 to 85 years of age with cardiovascular risk factors, and all men and women >50 years of age with a family history of AAA.19

The primary goal in AAA treatment is to prolong survival through the prevention of rupture. The treatment options include the following:

1. Open surgical repair
2. Endovascular repair
3. Continued surveillance

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Making a decision among the above options is based on the following factors:

1. Patient factors
2. Aneurysmal factors
3. Resources

**Patient Factors**

**Comorbidities and Operative Risk**
Independent risk factors for perioperative mortality of AAA repair have been identified by Steyerberg et al.\(^{32}\)
These factors include elevated creatinine \(>1.8\) mg/dL (OR 3.3, 95% CI 1.5 to 7.5), congestive heart failure (OR 2.3, 95% CI 1.1 to 5.2), electrocardiographic evidence of ischemia (OR 2.2, 95% CI 1.0 to 5.1), pulmonary dysfunction (OR 1.9, 95% CI 1.0 to 3.8), older age (per decade: OR 1.5, 95% CI 1.2 to 1.8), and female gender (OR 1.5, 95% CI 0.7 to 3.0).

**Life Expectancy**
A patient’s life expectancy is a critical factor in deciding whether to proceed with the repair. Age, sex, and known comorbidities are taken into account in determining life expectancy. In the United States, life expectancy for individuals aged 60, 65, 70, 75, 80, and 85 years and older, adjusted for sex and ethnicity, are 13, 11, 10, 8, 6, and 5 years, respectively.\(^{33}\) For patients who undergo AAA repair, the 5-year survival rate is reduced compared with age- and sex-matched individuals—60% to 65% as compared with 75% to 80%. Excess mortality in this patient group is substantially attributable to the associated comorbidities, particularly coronary artery disease.\(^{34}–^{38}\)

Elements further complicating decision making include coexistent treatable malignancies, as well as other conditions that, although not associated with vascular disease, have an impact on recovery and outcome.

**Patient Preference**
Although the physician may recommend a course of action in many instances, the decision to repair or observe aneurysms of borderline size (4.5 to 5.4 cm) should be made with informed input from the patient and family.\(^{39}\) Assessment should take into account less quantifiable elements such as quality of life, aneurysm-related anxiety, and anticipated level of function after intervention. When aneurysm repair is indicated, the choice to proceed with an endovascular procedure instead of conventional repair may be made with the patient’s involvement after an adequate understanding of each procedure’s benefits and shortcomings have been evaluated.

**Aneurysmal Factors**

**Risk of Rupture**

1. Diameter of the aneurysm. This is the most reliable predictor of rupture. Risk of rupture increases appreciably with each increase in diameter. For aneurysms \(<4\) cm in diameter, the annual risk of rupture approaches 0%, whereas for aneurysms with a diameter of 4 to 4.9 cm, 5 to 5.9 cm, 6 to 6.9 cm, 7 to 7.9 cm, and 8 cm and larger, the annual risk of rupture ranges from 0.5% to 5%, 3% to 15%, 10% to 20%, 20% to 40%, and 30% to 50%, respectively.\(^{30,39,40}\)

2. Expansion. Rapid expansion of AAA (\(>1\) cm/year) is associated with increased rupture risk.\(^{39}\)

3. Smoking. Cigarette smoking may augment risk of rupture by 1.5- to 2.4-fold.\(^{41,42}\)

4. Hypertension. Elevated blood pressure has been associated with an increased risk of rupture.\(^{42}\)

5. Family history. The risk of rupture was shown to be higher in patients with a positive family history of AAA, and risk increases with the
number of first-degree relatives affected.\textsuperscript{43,44}  
6. Chronic obstructive pulmonary disease.\textsuperscript{42,45}  
7. Female gender. The risk of rupture is 3 times higher in women than it is in men.\textsuperscript{42}  
8. Aneurysmal shape. Saccular aneurysms were found to carry a higher risk of rupture.\textsuperscript{46,47}

**Anatomic Characteristics**  
Aorto-iliac anatomy and vessel wall characteristics may influence the risks anticipated with conventional AAA repair, as well as the suitability for endovascular exclusion. Proximal aneurysm extension to the visceral aorta may exclude the endovascular option and necessitate temporary renal or mesenteric ischemia during operative repair. Special anatomic considerations in determining feasibility of endovascular aneurysm repair (EVAR) include aorto-iliac dimensions, aortic angulation, iliac artery tortuosity, distal aneurysm extension, and location of branch vessels. Classification and guidelines have been published to guide the eligibility of AAAs for EVAR on the basis of anatomic features.\textsuperscript{48} Although standard criteria are increasingly breached to accommodate the highest-risk patients, ongoing changes in design and material technology will continue to expand the proportion of treatable aneurysms.\textsuperscript{49}

**Resources**  
Resource availability has been an underemphasized element of the decision-making process for aneurysm repair, particularly when EVAR was considered. Recommendations for intervention in AAAs of borderline size may be similarly affected. For example, the widespread use of EVAR in the United States as compared with Canada, in our opinion, is in great part attributable to the differences in funding of the 2 health systems. This disparity parallels those previously documented for percutaneous coronary procedures.\textsuperscript{50,51} In such instances, the patient should be informed of treatment options and referred to a center with endovascular expertise.

**Endovascular Aneurysm Repair**  
Since the introduction of EVAR for AAA in 1991,\textsuperscript{52} catheter-based technology has evolved substantially, accommodating many changes in materials and design to achieve greater procedural success and durability in a larger proportion of aneurysms. Vascular centers worldwide have integrated the new technology for the treatment of AAAs into mainstream patient care, and their short- and intermediate-term experiences have been accrued for comparison to conventional open surgical repair (OPEN). There is only 1 published randomized clinical trial showing early results comparing the outcomes of EVAR to OPEN for AAAs.\textsuperscript{53} In addition, there are 2 such studies in progress (the Dutch Randomized Endovascular Aneurysm Management [DREAM] trial in the Netherlands and Open Versus Endograft Repair at US Department of Veterans Affairs Medical Centers).\textsuperscript{54}

**Outcomes**  
With the minimally invasive nature of EVAR, perioperative mortality and morbidity had been expected to be lower as compared with OPEN. Although the perioperative mortality rates range from 0.8% to 5.6%,\textsuperscript{55-61} most of these studies did not show a statistically significant difference in the perioperative mortality between these 2 treatment modalities. A lack of survival benefit in these studies may be explained by the bias in selecting higher-risk patients for EVAR as compared with OPEN. Stratification of EVAR patients according to severity of comorbid factors by Verzini et al\textsuperscript{62} showed that the EVAR perioperative mortality was 7.8% in patients with American Society of Anesthesiologists’ (ASA) physical status classification IV (ASA-IV) compared with only 0.3% in patients grouped as ASA-I through ASA-III. In addition, ASA-IV was independently associated with increased perioperative mortality (HR 17.8; 95% CI 1.6 to 188; \(P=0.016\)). Furthermore, when the propensity score–based analysis was used to reduce the bias caused by the surgeon’s decision making and to control for systemic differences between EVAR and OPEN, Teufelsbauer et al\textsuperscript{63} found that in ASA-IV patients, the in-hospital mortality rate was significantly lower in the EVAR group as compared with the OPEN group (4.7% compared with 19.2%; \(P<0.02\)). In addition, the 900-day mortality rate was significantly lower in the EVAR group.

The first randomized comparison of EVAR and OPEN appears to confirm the benefits of the less invasive technology.\textsuperscript{53} In this multicenter trial, 1082 patients with an AAA measuring at least 5.5 cm in diameter that was judged anatomically suitable for EVAR and patients who were regarded fit for elective OPEN were randomized to EVAR (543 patients) and OPEN (539 patients). The in-hospital mortality for the EVAR group was 2.1% compared with 6.2% in the OPEN group (\(P=0.001\)), and the 30-day mortality rate for the EVAR group was 1.7% compared with 4.7% in the OPEN group (\(P=0.009\)). Unlike previously published reports, this trial showed a clear early survival benefit for EVAR.

The perioperative morbidity has been reduced substantially in EVAR as compared with OPEN. The absolute reduction in complications ranges from 30% to 70%, primarily in cardiac, pulmonary, and gastrointestinal systems.\textsuperscript{39} One of the striking outcomes of EVAR, as compared with OPEN, is early recovery.\textsuperscript{59,64} In addition, the length of hospital stay and use of the intensive care unit are reduced in EVAR as compared with OPEN. In contrast, non–life-threatening vascular complications such as groin hematoma and femoral artery injury have been shown to be higher in EVAR as compared with OPEN.\textsuperscript{54}

A broader view of the use and outcomes of EVAR has been obtained in a published population-based study examining statewide experience in New York.\textsuperscript{65} In this study, the use of EVAR increased significantly after the year 2000, coinciding with the implementa-
tion of training programs in EVAR. The number of hospitals performing EVAR had also increased, likely reflecting broader acceptance and geographic dissemination of this technology. By 2002, there were more EVAR than OPEN being performed. EVAR patients had more comorbidities; however, they suffered fewer complications and had a shorter length of hospital stay. In-hospital mortality was significantly less in the EVAR group as compared with the OPEN group (1.14% versus 3.55% in 2001 and 0.8% versus 4.2% in 2002).

Specific sequelae of EVAR have been defined in the literature. These include endoleak, continued aneurysmal growth in the absence of a leak (endotension), structural failure of the device, migration of the device, and AAA rupture. The need for secondary procedures in 10% of patients per year has been well documented. In addition, experience in device explantation is gradually being accrued.

Procedure
The primary technical goal of EVAR is to exclude the aneurysm from the circulation by introducing a covered stent (stent graft) into the aneurysm intraluminally. To assess the feasibility of a successful repair, preprocedural imaging (eg, spiral CT with 3D reconstruction, magnetic resonance angiogram, or aortogram) is required to assess the following:

1. The aneurysm extent and shape
2. The landing zones for the proximal and distal attachment of the stent graft to the vessel wall
3. The vascular access for the passage of the delivery system
4. The branches of the aorta and iliac arteries

The procedure should be performed in a suite equipped for digital subtraction angiography to guide the procedure under fluoroscopy and to obtain intraoperative angiographic imaging. The steps for the procedure in brief are as follows (see Figure 2):

a. Surgical exposure of the common femoral arteries.
b. Gaining guide wire access: Fluoroscopically guided passage of a guide wire through the aneurysmal segment into the thoracic aorta
c. Device delivery: The stent graft is advanced over a stiffer guide wire through the aneurysmal lumen.
d. Graft deployment: After angiographic localization of the major branch vessels, the device is optimally positioned and then deployed. When necessary, additional components for extension to the iliac arteries may be introduced via the ipsilateral femoral artery access and then deployed.
e. Completion angiogram: After deploying the stent graft, a completion angiogram is performed to verify the appropriate position of the device and confirm the exclusion of the aneurysm from direct pulsatile flow. Any flow outside the device but within the aneurysm is considered an endoleak and may need to be evaluated further.

Limitations
Several factors may limit the use of AAA EVAR. Anatomic features of the AAA by far are the most important factor. Unsuitable anatomy (eg, short neck, poor vascular access) is considered to be a potential contraindication to EVAR. Chronic renal insufficiency not requiring dialysis is another potential contraindication because of the intraprocedural use of potentially nephrotoxic contrast media. In addition, this technology requires trained personnel, special equipment, and long-term clinical and radiological follow-up, which may be limited by the availability of resources in some health systems. The advantages and disadvantages of AAA EVAR are summarized in the Table.

Choosing Between Different Modalities
In general, OPEN may best serve a younger healthier patient, whereas older, higher-risk patients may benefit from EVAR. This conclusion was supported by a decision analysis model analyzing the EUROSTAR (EUROpean cobalt chromium STent with Antiproliferative for Restenosis) data.

The accepted size threshold for intervention is a diameter of 5.5 cm in an average patient, and the use of EVAR should not change this threshold. For borderline AAA (4.0- to 5.5-cm aneurysm), watchful waiting (ultrasonographic surveillance) may be a safe strategy, particularly if significant co-morbidities are present. Ultimately, the patient’s preference should play a significant role in choosing between these modalities with an understanding of the short- and long-term consequences.

Conclusion
In our case study, Mr JG’s risk of aneurysm rupture was estimated at >10% over the next year. It was felt
that this risk was accentuated by his documented rapid expansion, poorly controlled hypertension, and known obstructive pulmonary disease. We therefore recommended aneurysm repair. As he was deemed to be at higher risk for perioperative complications associated with his cardiac status and concurrent pulmonary disease, an endovascular repair was performed under a local anesthetic with adjunctive sedation uneventfully (Figures 1B and C). He was observed in the intermediate care unit overnight and subsequently discharged home on the second postoperative day. One month postoperatively, he reported having resumed all of his baseline activities. At the 12-month follow-up visit, the routine surveillance CT scan (Figure 1D) showed a successful repair, with a decrease in the diameter of the aneurysm to 4.3 cm.

Note Added in Proof

During the review process, a second randomized clinical trial comparing the early outcomes of EVAR with OPEN in AAA was published (the Dutch Randomized Endovascular Aneurysm Management [DREAM] trial). In this multicenter trial, 345 patients with AAA at least 5 cm in diameter who were considered suitable candidates for both techniques were randomized in EVAR (171 patients) and OPEN (174 patients). The operative (30-day) mortality rate for the EVAR group was 1.2% compared with 4.6% in the OPEN group (P = 0.10). The composite end point of operative mortality and severe complications was 4.7% in the EVAR group and 9.8% in the OPEN group (P = 0.10). The combined rate of operative mortality and moderate or severe complications was 18.1% in the EVAR group and 23.6% in the OPEN group (P = 0.23).

The results of the DREAM trial mirror those of the recent EVAR-1 trial in that both show a clear early survival benefit of EVAR. However, the long-term outcomes of EVAR have yet to be defined in randomized clinical trials.

References


