Elective treatment of abdominal aortic aneurysm with endovascular or open repair: The first decade

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Objectives: The development of endovascular aneurysm repair (EVAR) as an alternative to open repair of abdominal aortic aneurysms (AAA) has led to an increasing number of patients being treated by this less-invasive technique. It was anticipated that EVAR would reduce the operative mortality and morbidity compared with open repair. This study examined the initial 10-year experience in one center when both techniques were available to determine if there were advantages to one technique or the other, putting the results into the perspective of routine clinical care of patients with infrarenal AAA.

Methods: From June 1996 to May 2005, 677 patients underwent elective repair of their infrarenal AAA, of which 417 were treated with open repair and 260 by EVAR. Demographic and aneurysm-specific data, comorbidities, operative morbidity, mortality, and late outcome were analyzed.

Results: Open repair patients were 2 years younger (71 vs 74 years, P < .001), had larger aneurysms (6.01 ± 1.38 cm vs 5.45 ± 0.99 cm, P < .001), greater familial predisposition, a higher incidence of current smokers, and a higher incidence of chronic obstructive pulmonary disease than the EVAR group. There were no differences in renal function, hypertension, coronary artery disease, or heart failure between the two groups. Overall operative mortality was 3.1%; operative mortality per group was 3.5% for open and 2.7% for EVAR (P = .627). Procedure-related outcomes showed significant differences in operative blood loss and length of hospital stay in favor of EVAR, and 95% of the EVAR patients were discharged home vs 83% in the open repair group (P < .001). A Kaplan-Meier log-rank analysis showed no difference in early or long-term survival between open repair and EVAR (P = .20), but did show a difference in mid-term (3-year) survival favoring open repair (P < .002). Survival analysis by age (<70 and ≥70 years) showed no difference between treatment groups.

Conclusions: Open repair and EVAR are both performed safely in patients treated for elective infrarenal AAA. EVAR has the perioperative advantages of reduced blood loss, reduced length of intensive care unit and hospital stay, and increased number of patients discharged to home. The mid-term survival advantage of open repair has been observed in other reports and deserves further study. (J Vasc Surg 2007;45:258-62.)

The past decade has brought about a major change in the approach to patients with aortic aneurysms. The ongoing enthusiasm to find less-invasive means of managing all forms of vascular disease has resulted in the evolution of catheter-based techniques that can be applied to every major vascular bed.

Open repair of abdominal aortic aneurysms (AAA) has always been considered among the most major of surgical procedures, and the potential complications, which are decreasing in frequency, are highly morbid. It is not surprising that endovascular aneurysm repair (EVAR) was a welcome addition to the procedural armamentarium of the vascular surgeon. Vascular disease, however, is a lifelong problem and most often associated with significant comorbidities that frequently will determine the outcome of major vascular reconstructions.

Unquestionably, operative management has improved, and the advances in critical care have reduced operative morbidity and mortality. EVAR has reduced the need for intensive care unit stay and blood transfusions, shortened hospital stays, and in some studies, decreased procedure-related and aneurysm-related mortality. The reduction in operative mortality observed in randomized trials has not been observed in all studies, however, and has not yet translated into better survival during longer term follow-up.

Many centers became involved with EVAR as part of registration trials for new devices. Such trials had specific guidelines for graft implantations. Once devices received United States Food and Drug Administration approval, guidelines for use continued but physician judgment became more prominent in patient selection.

During the last 10 years, the Jobst Vascular Center has offered endovascular and open repair to patients undergoing elective treatment of their infrarenal AAA. This study reviewed the procedure-related morbidity and mortality of open and EVAR and investigated the effect of these procedures on mid-term and long-term survival.

PATIENTS AND METHODS

All patients undergoing elective repair of an infrarenal AAA between June 1996 and May 2005 were reviewed. Patients were identified from the Jobst Vascular Registry, which prospectively records patients undergoing vascular procedures at The Toledo Hospital. The operating room database and individual surgeon case lists were also used to
corroborate the findings. Patient-related and AAA-related information were recorded from these databases in addition to lab records, operative notes, physician notes, and radiology records. The study was approved by the hospital’s Institutional Review Board.

Patients with ruptured aneurysms or aneurysms involving the renal arteries were excluded from this analysis. Elective repair of infrarenal AAA was performed in 677 consecutive patients. The type of repair was decided by the primary vascular surgeon and patient preference. Devices used for the EVAR group included EVT (Endovascular Technologies, Menlo Park, Calif), Vanguard (Boston Scientific, Natick, Mass), Lifepath (Baxter, Morton Grove, Ill), Lifepath (Edwards, Irvine, Calif), Zenith (Cook, Bloomington, Ind), Talent and AneuRx (Medtronic, Santa Rosa, Calif), AnCure (Guidant, Indianapolis, Ind), and Excluder (W. L. Gore & Associates, Flagstaff, Ariz).

Computed tomography (CT) scans and arteriography were obtained in nearly every case of EVAR early in the study. CT scans were the predominant imaging method for patients having open repair.

Main outcome measures were operative death (defined as death ≤30 days of the procedure or during the hospitalization, whichever was longer), blood loss, length of hospital stay, status at discharge, and long-term mortality.

The EVAR group was monitored with physical examination and serial CT scans and plain abdominal radiographs at 1, 6, 12, 18, and 24 months, and yearly thereafter. Patients in the open repair group were monitored at 1, 6, and 12 months with physical examination and generally every 6 to 12 months thereafter. Postoperative imaging was not routinely performed in patients having open repair. Follow-up data were retrieved from the hospital database, the inpatient and outpatient data systems, and the Social Security Registry.

Statistical analysis. Cumulative event rates were determined with Kaplan-Meier survival analysis, and the probability difference between patients undergoing open and EVAR repair was compared using log-rank analysis. Characteristic differences between open and EVAR groups were compared using $\chi^2$ or the Fisher exact test for categorical variables and the Student $t$ test for continuous variables; data that were not normally distributed were analyzed using the Mann-Whitney rank sum test. Data are expressed as the mean value ± SD or as frequencies and percentages. A value of $P < .05$ was considered statistically significant. Statistical analyses were performed with the use of commercially available software (NCSS, Kaysville, Utah).

Results

Patient characteristics. Of the 677 patients who underwent elective infrarenal AAA repair, 417 had conventional open repair and 260 had EVAR. Demographic characteristics and comorbidities of the patients are listed in Table I. Compared with the EVAR group, the patients undergoing open repair were 3 years younger (71 vs 74 years, $P < .001$) but had larger aneurysms (6.01 ± 1.38 vs 5.45 ± 0.99, $P < .001$), greater familial predisposition ($P = .039$), and more current smokers ($P = .011$), which likely contributed to more chronic obstructive pulmonary disease ($P = .001$).

There were no differences in renal function, hypertension, coronary artery disease, or heart failure between the two groups. The open repair group had 324 men (77.7%) and 93 women (22.3%), and the EVAR group had 207 men (79.6%) and 53 women (20.4%), with no differences in gender distribution. Most patients in both groups were in their eighth decade of life. The mean follow-up time was 1078 ± 52 days for the EVAR group and 1665 ± 41 days for the open repair group ($P < .0001$).

Gender analysis. A significant gender difference was found in our patient population with regards to age, with women being 4 years older than men (75 vs 71 years, $P < .004$) at the time of intervention. This observation persisted for each treatment group. Women also presented with smaller aneurysms (5.5 cm) than men (6.2 cm, $P < .001$).

Aneurysm specifics. Aneurysms were larger in the open repair group (mean, 6.01 ± 1.38 cm) compared with the EVAR group (mean, 5.45 ± 0.99 cm, $P < .001$). In the open repair group, both tube grafts and bifurcated grafts were used as dictated by aneurysm morphology and surgeon preference. The devices used in the EVAR group were 183 Anurex, 24 Vangard, 15 Zenith, 12 Excluder, 9 AnCure, 7 Lifepath, 6 Baxter, and 4 Talent.

Operative mortality. Overall operative mortality was 3.1%. Operative mortality was 3.5% for the open repair group and 2.7% for the EVAR group ($P = .627$; Table II). A perceptible difference was found in operative mortality by age (Table II). Only three patients <70 years died from elective AAA repair (1.3%), and all had open repair. For patients ≥80 years of age, operative mortality increased to

Table I. Demographics and comorbidities of abdominal aortic aneurysm patients

<table>
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<tr>
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<th>Open*</th>
<th>EVAR*</th>
<th>P</th>
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<tbody>
<tr>
<td>Males</td>
<td>324 (77.7)</td>
<td>207 (79.6)</td>
<td>.555</td>
</tr>
<tr>
<td>Females</td>
<td>93 (22.3)</td>
<td>53 (20.4)</td>
<td>.555</td>
</tr>
<tr>
<td>Age (years)</td>
<td>71.6 ± 7.9</td>
<td>73.7 ± 7.6</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>Aneurysm size (cm)</td>
<td>6.01 ± 1.58</td>
<td>5.45 ± 0.99</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>Creatinine (mg/dL)</td>
<td>1.13 ± 0.41</td>
<td>1.13 ± 0.49</td>
<td>.642</td>
</tr>
<tr>
<td>Family history</td>
<td>39 (9.3)</td>
<td>13 (5)</td>
<td>.039</td>
</tr>
<tr>
<td>Past smoker</td>
<td>227 (54.4)</td>
<td>165 (63)</td>
<td>.027</td>
</tr>
<tr>
<td>Current smoker</td>
<td>134 (32.1)</td>
<td>60 (23.1)</td>
<td>.011</td>
</tr>
<tr>
<td>COPD</td>
<td>170 (40.8)</td>
<td>50 (19.2)</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>Hypertension</td>
<td>293 (70.3)</td>
<td>178 (68.5)</td>
<td>.620</td>
</tr>
<tr>
<td>CAD</td>
<td>203 (48.7)</td>
<td>141 (54.2)</td>
<td>.160</td>
</tr>
<tr>
<td>CHF</td>
<td>38 (9.1)</td>
<td>35 (13.5)</td>
<td>.076</td>
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COPD, Chronic obstructive pulmonary disease; CAD, coronary artery disease; CHF, congestive heart failure.

*Data are presented as n (%) for categoric variables and mean ± standard deviation for continuous variables, where appropriate.
9.5% in the open repair group and 6.6% in the EVAR group (P = NS).

**Other operative outcomes.** Statistically significant differences, all in favor of EVAR (Table III), were seen in the amount of estimated blood loss (2532 ± 1982 mL vs 536 ± 708 mL, P < .001), length of stay (9 ± 9.7 days vs 3.4 ± 3.7 days, P < .001), and patients discharged to home (83% vs 95%, P < .001).

**Mid-term and long-term survival.** Operative mortality was similar between the two treatment groups. Long-term mortality at 1, 3, and 5 years for each group is shown in Table IV. Only one aneurysm-related death in the current series occurred after the postoperative period. An overall Kaplan-Meier log-rank survival analysis showed no difference between the two treatment groups (P = .20); however, χ² analysis of the long-term mortality results indicates that there was a mid-term (3-year) survival benefit favoring open repair (P < .002; Fig 1). Since many believe the benefit of EVAR may be greater in older patients, we analyzed operative and long-term survival for patients ≥70 years (Fig 2) and found no difference.

**DISCUSSION**

EVAR is rapidly developing as the technique of choice for elective repair of infrarenal AAA. Although distinct short-term advantages to this less-invasive approach have been demonstrated, no definitive guidelines have been established to determine which patients should undergo EVAR vs open repair, assuming anatomy is appropriate for both.

Procedure-related and long-term mortality are appropriately considered the primary focus for comparing these two techniques. Although others have shown a significant short-term survival benefit of EVAR, reducing operative mortality by up to 66%, that was not observed in this clinical series. Interestingly, when EVAR demonstrated benefit compared with open repair, the mortality in patients undergoing open repair approached 5%. If an operative mortality of <4% can be achieved, it is likely that procedure-
related mortality will not be different between the two techniques. This point is illustrated by the current series in which the mortality of open repair was substantially lower than that observed in patients enrolled in randomized trials. One cannot exclude clinical judgment and surgeon bias as influencing results in any nonrandomized trial. Intuitively, physician bias would seem to favorably affect open repair by selecting higher-risk patients for EVAR. That did not appear to be the case in this series because, with the exception of age, open repair patients had more comorbidities than EVAR patients.

Trials reporting early survival benefit of EVAR have yet to demonstrate a sustained survival advantage. Mortality results reported here are surprisingly similar to those reported in the Lifeline registry. EVAR patients were older than those undergoing open repair, women were older than men, and women had smaller aneurysms than men. Freedom from aneurysm-related rupture remained excellent in both groups throughout follow-up. The survival curves in our patients and in those of the Lifeline registry (Fig 3) have a striking similarity. Although there is no difference in procedure-related or long-term mortality, there is a significant separation of mid-term (3-year) mortality favoring those who have open repair. The reasons for this observation are speculative, but may include more intense patient evaluation and better control of cardiovascular risk factors over the mid-term in open repair patients.

Operative mortality is usually associated with age and is no different in this series. We were gratified to find that no patient <60 years of age died as a result of elective operation for their AAA, and only three patients <70 years old died. Although a much higher procedure-related mortality occurred in patients ≥80 years (9.5% open, 6.5% EVAR), the differences were not significant. Sicard et al reported similar findings, with postoperative mortality no different for open and EVAR groups. They also noted that the subgroup of patients ≥80 years had an overall higher mortality, but less so in patients undergoing EVAR.

Reduced procedure-related length of stay in the intensive care unit and in the hospital is a consistent observation of EVAR-treated patients compared with open repair. This advantage is muted by the increasing number of repeat procedures over time in EVAR patients, which are associated with requisite hospitalization. Carpenter et al reported that the procedure-related length-of-stay advantage to EVAR was lost during the first year of follow-up owing to the readmissions required for subsequent aneurysm-related procedures. When total hospital days were compared at 12 months, no difference existed between EVAR and open repair patients. As follow-up continues over the long term, the additional procedures required may actually place EVAR patients at a disadvantage in a length-of-stay analysis.

Patients undergoing EVAR have a significant reduction in blood loss and the need for transfusions. Translating the short-term benefit into a long-term advantage relates to the risk of blood-borne diseases. This risk in the United States is miniscule compared with other comorbidities facing patients and is unlikely to translate into meaningful clinical observations.

CONCLUSION

Open repair and EVAR can both be performed safely in patients treated for elective infrarenal AAA. Owing to the low operative mortality of open repair in patients <70 years old, open repair should be liberally applied in younger patients with AAA. EVAR clearly has perioperative advantages of reduced blood loss, decreased length of hospital stay, and an increased number of patients discharged to home. Early and late survival curves are similar; however, the long-term follow-up in EVAR patients is limited. The midterm survival advantage in open repair patients noted here and in other reports deserves greater study. If specific factors can be identified that correlate with this midterm survival advantage, perhaps improved survival over the long term can be enjoyed by both treatment groups.

We recognize the contributions of Steven Dosick, MD, Steven Gale, MD, Andrew Seiwert, MD, and Ralph Whalen, MD, who were responsible for much of these clinical data, and gratefully acknowledge the editorial and technical assistance of Marilyn Gravett and Victor Cantu.
REFERENCES


INVITED COMMENTARY

Peter L. Faries, MD, New York, NY

Chahwan and colleagues have provided a valuable analysis of their single-center experience with abdominal aortic aneurysm (AAA) repair. Their review analyzes the short-term and intermediate-term results of standard open repair and endovascular repair (EVAR) performed using a wide variety of stent grafts and highlights several important areas that are of interest. Of particular note, the authors are to be congratulated on obtaining excellent results—particularly with open AAA repair—where they achieved a mortality rate of 3.5% compared with 2.7% for EVAR (P = NS).

With this low perioperative mortality rate for open repair and the relatively small sample size, the authors were able to negate any significant perioperative survival advantage for EVAR. This mirrors the results of the pivotal trials reported for the AneuRx1 (Medtronic, Minneapolis, Minn), Excluder,2 (W.L. Gore and Associates, Flagstaff, Ariz) and Zenith3 (Cook, Bloomington, Ind) devices. Only in studies that evaluated much larger patient populations could significantly lower perioperative mortality be demonstrated for endovascular repair.4

The current study did demonstrate significant advantages with respect to operative blood loss and hospital length of stay, again similar to the previously reported pivotal trials. These findings reinforce previously published analyses that indicate success in preventing aneurysm-related death can be achieved in appropriately selected patients using conventional open repair techniques. The increase in perioperative morbidity associated with open repair may ultimately be balanced by its increased durability. This is suggested by the authors’ finding of increased survival at the 3-year time point. Although this could not be related to increased aneurysm-related mortality in the EVAR group, and the overall survival curves did not vary significantly, the finding is interesting. Whether it implies the patients who underwent open repair received more thorough management of cardiac and other comorbid medical conditions or another more difficult-to-define cause cannot be determined from the current study.

Of concern in the analysis is the selection of the type of repair procedure performed. Although the authors suggest that they favored open repair for patients who were generally younger (on average 71 vs 74 years old), the patients treated with open repair did not appear to have an increased number of comorbid medical conditions. Whether this reflects a limitation of the analysis of comorbid factors that limits the ability to distinguish the extent of the comorbid disease or whether it is an accurate reflection of a truly equal distribution of disease between the two groups cannot be distinguished in the current analysis.

It is also interesting that average size of the aneurysms treated by standard open repair was significantly larger (6.0 cm) than the size of aneurysms treated using EVAR (5.4 cm). It is possible that the authors have different thresholds for performing aneurysm repair according to the technique that is going to be used. For patients in whom open repair is being considered, the threshold for repair with respect to maximum aortic diameter may be higher. Alternatively, larger aneurysms may not have anatomy suitable for endovascular repair and consequently open repair is necessary.

Ultimately, the equivalent survival curves between the open and endovascular repair groups suggest that patients can undergo EVAR and thereby reduce the perioperative blood loss, hospital length of stay, and recovery time, and still maintain longer-term survival that is equal to patients treated by open repair. This appears to be of particular relevance for octogenarians, in whom the increase in perioperative mortality for open repair appears to be most significant.

REFERENCES


