Cost–Effectiveness at Two Years in the VA Open versus Endovascular Repair Trial

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ABSTRACT

Background: Long-term clinical outcomes have been similar for endovascular and open repair of abdominal aortic aneurysm (AAA), increasing the importance of comparing cost–effectiveness.

Methods: We compared data to two years from a multicenter randomized trial of 881 patients. Quality-adjusted life years (QALYs) were calculated from EQ-5D questionnaires. Healthcare utilization data were obtained from patients and from national VA and Medicare sources. VA costs were obtained using methods previously developed by the VA Health Economics Resource Center. Costs for non-VA care were determined from Medicare or billing data.

Results: Mean life-years were 1.78 in the endovascular and 1.74 in the open repair group (P = 0.29), and mean QALYs were 1.462 in the endovascular and 1.461 in the open group (P = 0.78). Although graft costs were higher in the endovascular group ($14,052 vs. $1363; P < 0.001), length of stay was shorter (5.0 vs. 10.5 days; P < 0.001), resulting in lower cost of AAA repair hospitalization in the endovascular group ($37,068 vs. $42,970; P = 0.04). Costs remained lower after 2 years in the endovascular group but the difference was no longer significant ($5019; 95% CI: $16,720 to $4928; P = 0.35). The probability that endovascular repair was both more effective and less costly was 70.9% for life-years and 51.4% for QALYs.

Interpretation: Endovascular repair is a cost-effective alternative to open repair in the US VA healthcare system for at least the first two years.

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Introduction

Several randomized trials have compared endovascular with open repair for abdominal aortic aneurysm (AAA). These trials have generally reported reduced peri-operative mortality with endovascular repair, but mid- and long-term outcomes have been similar for the two procedures.1–3 The need is therefore increased for accurate comparison of costs, particularly in view of the high cost of endovascular grafts.1,4,5

The US Department of Veterans Affairs (VA) Open Versus Endovascular Repair (OVER) trial reported a comparison of clinical outcomes of the two procedures at two years after randomization.3 We summarize here, for the same two-year period, total healthcare costs and comparative cost–effectiveness of elective open and endovascular repair of AAA in the VA OVER trial.

Methods

Patients and clinical outcomes

Methods and two-year clinical outcomes were reported previously.3 In summary, eligible patients had AAA with (1) a maximum external diameter of at least 5.0 cm, (2) an associated iliac aneurysm with a maximum diameter of at least 3.0 cm, or (3) a maximum diameter of at least 4.5 cm plus either rapid enlargement or saccular morphology. Patients also required to be candidates for both procedures, and were excluded if they had previous abdominal aortic surgery, needed urgent repair, or were unable or unwilling to give informed consent or follow the protocol. Follow-up visits were scheduled 1 month after aneurysm repair, 6 and 12 months after enrollment, then yearly. All follow-up visits after endovascular repair included a computed tomogram and
plain radiography of the abdomen. For visit after open repair, only a computed tomogram at one year was specified.

The primary outcomes of this cost–effectiveness analysis were mean total healthcare cost per life year and per quality-adjusted life year (QALY). This report, like the clinical report, includes follow-up data to two years after randomization as of October 15, 2008. 881 patients were randomized between October 2002 and April 2008 at 42 VA medical centers, 444 to endovascular repair and 437 to open repair. Mean follow-up was 1.8 years, and 80% of patients had either completed two years of follow-up or died before two years. As described in the clinical paper, peri-operative mortality (30 days or inpatient) was lower for endovascular repair (0.5% vs. 3.0%; P = 0.004), but there was no statistically significant difference in mortality at 2 years (7.0% vs. 9.8%, P = 0.13). Nor were there statistically significant differences at two years between the two groups in major morbidity, procedure failure, secondary therapeutical procedures, aneurysm-related hospitalizations, or health-related quality of life.

Assessment of utilization and costs

All healthcare costs were included in this analysis and were adjusted to 2008 US dollars with the Consumer Price Index. Costs for the hospitalizations during which the AAA repair operation was performed were obtained from the VA Decision Support System (DSS) National Data Extracts.6 In the DSS, costs are compiled from intermediate products that make up the encounter, such as a radiologic test, a day in a ward, or a 15-min block of time in an operating room. A hospital stay is divided into segments based on the bed section, such as a medical care or surgical ward or a long-term care unit.

Within each bed section, DSS allocates costs among six mutually exclusive categories: surgery, nursing, laboratory, radiology, pharmacy, and ‘other’. The ‘surgery’ cost category could thus be included whether or not a patient is on the surgery bed section, and encompasses pre-operative care, the operating suite and the recovery room on the day of surgery. ‘Nursing’ includes the operating costs of regular acute-care wards and long-term care units, excluding physician costs. The category ‘other’ includes daily physician costs, ward clerks, respiratory therapy, dietetics, social work, etc. Each of these six categories includes fixed direct costs (those directly attributable to that category but incurred regardless of the volume of services provided) and fixed indirect costs (overhead departments such as housekeeping, engineering, and administration), allocated by formulae based on intermediate product use. Craft components used for each patient were recorded on OVER study forms, and prices were obtained from the VA’s National Patient Prosthetics Database.

Other VA utilization data, including other hospital stays, outpatient visits, contract care, and outpatient medications acquired from VA, were obtained from the VA Medical SAS Inpatient and Outpatient Datasets, which capture all utilization from the electronic record system of local VA medical centers, and from the Fee Basis files, which report care provided to VA patients by contract providers outside of VA facilities.9

For VA utilization other than the hospitalization for the AAA procedure, costs were obtained from the VA Health Economics Resource Center (HERC) average cost datasets.10-15 These are more directly comparable to the Medicare costing used for non-VA healthcare utilization than is the DSS method.

Non-VA healthcare utilization was obtained from Medicare claims data (available for 67% of the patient-months in the study period) and from patient self-reported data verified with billing data from the facilities where care was received. Costs were estimated by multiplying the healthcare charges in the Medicare claims or billing data by the hospital-specific cost-to-charge ratios obtained from cost reports submitted to Medicare annually.11

Assessment of effectiveness

Measures of effectiveness were life-years from randomization and quality-adjusted life years (QALYs), which incorporate health-related quality of life and medical outcomes into a single measure.13 Health-related quality of life was assessed using the EQ-5D questionnaire (EuroQol, Rotterdam, the Netherlands). EQ-5D index scores obtained at baseline, six months, and annually were converted into utility weights.14 The utility weights were connected with straight lines to construct the quality-adjusted survival curve. QALYs were computed from the area under the curve using the trapezoid rule.

Analysis

Cost and effectiveness (measured in life-years and QALYs) was compared on an intention-to-treat basis, regardless of the occurrence or type of the actual AAA repair. We discounted costs, life-years, and QALYs at 3% per year starting with the date of randomization.13

Bootstrap methods were used to examine the distribution of the incremental cost (i.e., mean total costs of the endovascular group minus mean total costs of the open repair group) and incremental effectiveness (i.e., mean life-years or QALYs for the endovascular group minus mean life-years or QALYs for the open repair group) across regions of the cost–effectiveness plane.5,15

Results

The mean cost of the hospital admission for AAA repair was lower for the endovascular repair group at $37,068 vs. $42,970 for the open repair group (difference −$5901, 95% CI: −$12,135 to −$821; P = 0.04) (Table 1). This was despite the surgical procedure itself being more expensive in the endovascular group ($23,618 vs. $11,594; P < 0.001) due to the high costs of the grafts ($14,052 vs. $1363; P < 0.001). However, the endovascular group had shorter stays in the hospital (mean 5.0 vs. 10.5 days; P < 0.001) and intensive care unit (mean 1.9 vs. 5.6 days; P < 0.001). Other costs of the AAA repair hospitalization were therefore higher in the open group, including nursing, pharmacy, laboratory, and fixed direct and indirect costs (as shown for nursing in Table 1).

From hospital discharge to two-years, costs were similar between the two groups (Table 2). Total mean costs after two years were $75,325 in the endovascular group and $80,344 in the open group, a non-significant difference of −$5019 (95% CI: −$16,720 to $4928; P = 0.35).

Cost–effectiveness analysis

Mean life-years during the study period were 1.78 for the endovascular group and 1.74 for the open group (difference 0.04, 95% CI −0.03 to 0.09; P = 0.29). Health-related quality of life as measured by the EQ-5D did not differ significantly between the two groups at baseline, 6 months, one year, or two years. Combining this quality of life information with life-years, the endovascular group had a mean of 1.462 quality-adjusted life year (QALYs) while the open group had 1.461 QALYs (difference adjusting for baseline EQ-5D score: 0.006, 95% CI: 0.038 to 0.052; P = 0.78). Endovascular repair was the dominant strategy with lower costs and more life-years, so we did not calculate an incremental cost–effectiveness ratio (i.e., the cost per year of life saved).

To characterize the precision of our cost–effectiveness estimates, a bootstrap analysis conducted by 2000 samplings (with replacement) of the 881 observations from trial participants is plotted in Fig. 1. Measuring effectiveness in life-years, the
See Methods for explanation of items.

Costs are in US dollars and are means except when median (IQR) is specified.

### Table 1
Costs of hospitalization for abdominal aortic aneurysm repair.

<table>
<thead>
<tr>
<th>Item</th>
<th>Endovascular repair (N = 444)</th>
<th>Open repair (N = 437)</th>
<th>Cost difference (95% CI)</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Surgery bed section</td>
<td>35,695</td>
<td>40,169</td>
<td>-4474 (-10,265 to -67)</td>
<td>0.04</td>
</tr>
<tr>
<td>Nursing cost category</td>
<td>6193</td>
<td>16,007</td>
<td>-9815 (-12,857 to -7833)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Intensive care units</td>
<td>2349</td>
<td>6466</td>
<td>-4118 (-7,575 to -3,089)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Wards</td>
<td>830</td>
<td>1317</td>
<td>-486 (-766 to -233)</td>
<td>0.0005</td>
</tr>
<tr>
<td>Other (recovery room, stepdown, etc)</td>
<td>412</td>
<td>1274</td>
<td>-862 (-1,372 to -575)</td>
<td>0.001</td>
</tr>
<tr>
<td>Fixed indirect total</td>
<td>2482</td>
<td>6579</td>
<td>-4097 (-5,615 to -3,206)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Fixed direct total</td>
<td>119</td>
<td>371</td>
<td>-252 (-444 to -156)</td>
<td>0.0002</td>
</tr>
<tr>
<td>Surgery cost category</td>
<td>23,618</td>
<td>11,594</td>
<td>12,024 (10,852 to 13,187)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Operating room</td>
<td>3219</td>
<td>3902</td>
<td>-683 (-1,070 to -280)</td>
<td>0.001</td>
</tr>
<tr>
<td>Surgical implants</td>
<td>14,052</td>
<td>1363</td>
<td>12,689 (12,227 to 13,099)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Anesthesia</td>
<td>1184</td>
<td>1528</td>
<td>-344 (-526 to -158)</td>
<td>0.0003</td>
</tr>
<tr>
<td>Other</td>
<td>447</td>
<td>415</td>
<td>32 (-181 to -286)</td>
<td>0.79</td>
</tr>
<tr>
<td>Fixed indirect total</td>
<td>4389</td>
<td>3982</td>
<td>407 (-105 to -907)</td>
<td>0.11</td>
</tr>
<tr>
<td>Fixed direct total</td>
<td>327</td>
<td>405</td>
<td>-77 (-129 to -22)</td>
<td>0.005</td>
</tr>
<tr>
<td>Radiology cost category</td>
<td>1597</td>
<td>1253</td>
<td>343 (0 to -717)</td>
<td>0.06</td>
</tr>
<tr>
<td>Laboratory cost category</td>
<td>796</td>
<td>2034</td>
<td>-1238 (-1,612 to -958)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Pharmacy cost category</td>
<td>895</td>
<td>2733</td>
<td>-1,838 (-3,446 to -1,129)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Other cost category</td>
<td>2597</td>
<td>6548</td>
<td>-3951 (-5,254 to -3,003)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Other bed sections</td>
<td>1373</td>
<td>2802</td>
<td>-1429 (-2,804 to -50)</td>
<td>0.04</td>
</tr>
<tr>
<td>Total cost</td>
<td>37,068</td>
<td>42,970</td>
<td>-5091 (-12,135 to -821)</td>
<td>0.04</td>
</tr>
<tr>
<td>Total, per randomized patient</td>
<td>32,094 (26,306, 40,038)</td>
<td>30,506 (21,785, 42,768)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

IQR = interquartile range.

Costs are in US dollars and are means except when median specified.

See Methods for explanation of items.

The probability of endovascular repair being both less costly and more effective than open repair was 70.9% (Fig. 1(A)). Measured in QALYs, this probability dropped to 51.4% (Fig. 1(B)). The proportions of observations from the bootstrap analyses below the diagonal lines indicate the observations that would favor endovascular repair if the decision maker were willing to pay $50,000 or $100,000 per life year or QALY. From these observations, if willing to pay $50,000, the proportions are 90.4% and 83.3%, respectively.

### Discussion
We observed no significant differences in survival, quality of life, or costs after two years between endovascular and open repair of AAA in this multicenter randomized trial. The hospitalization for AAA repair was less expensive in the endovascular repair group due to shorter hospital and intensive care stay and despite the high cost of the endovascular grafts. Apart from the hospital admission for the AAA procedure, two-year costs were similar between the two groups.

Most previous randomized trials and observational studies have found endovascular repair to be the more expensive strategy despite shorter hospital and intensive care stay.1,4,7 In the Dutch Randomized Endovascular Aneurysm Management (DREAM) trial, endovascular repair cost significantly more than open repair after one year (<18,179 vs. <13,886) despite shorter hospital and intensive care stay.5 Similarly, in the United Kingdom Endovascular Aneurysm Repair Trial 1 (EVAR 1), a trend toward higher cost with endovascular compared with open repair ($19,698 vs. $17,917) became statistically significant when AAA-related costs to a median 6.0 years were included ($23,153 vs. $18,586).1 Endovascular repair also led to higher hospital charges than open repair in a 20% sample of US 2001 hospital admissions ($50,346 vs. $47,009).16

### Table 2
Healthcare costs to 2 years after randomization in US dollars.

<table>
<thead>
<tr>
<th></th>
<th>Endovascular repair (N = 444)</th>
<th>Open repair (N = 437)</th>
<th>Cost difference (95% CI)</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Before AAA repair</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total</td>
<td>2292</td>
<td>2064</td>
<td>227 (-646 to 1198)</td>
<td>0.63</td>
</tr>
<tr>
<td>Median (IQR)</td>
<td>576 (102, 1425)</td>
<td>582 (89, 1317)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>AAA repair in year 1</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total, per randomized patient</td>
<td>37,068</td>
<td>42,338</td>
<td>-5269 (-11,591 to -518)</td>
<td>0.03</td>
</tr>
<tr>
<td>Discharge after AAA repair to 30 days</td>
<td>2344</td>
<td>2700</td>
<td>-355 (-1272 to -554)</td>
<td>0.44</td>
</tr>
<tr>
<td>Median (IQR)</td>
<td>1085 (337, 2115)</td>
<td>409 (132, 1051)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>30 days to 1 year</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total</td>
<td>18,348</td>
<td>16,149</td>
<td>2199 (-2,536 to 6435)</td>
<td>0.33</td>
</tr>
<tr>
<td>Median (IQR)</td>
<td>90990 (5,799, 16,895)</td>
<td>6183 (3,163, 13,718)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total at 1 year</td>
<td>60,053</td>
<td>63,252</td>
<td>-3199 (-12,939 to 5054)</td>
<td>0.48</td>
</tr>
<tr>
<td>Median (IQR)</td>
<td>47,705 (37,315, 64,809)</td>
<td>43,633 (30,782, 65,479)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total, 1 year to 2 year</td>
<td>15,272</td>
<td>17,091</td>
<td>-1820 (-6,105 to 2425)</td>
<td>0.42</td>
</tr>
<tr>
<td>Median (IQR)</td>
<td>6511 (2,772, 16,322)</td>
<td>5810 (2,356, 16,002)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total at 2 years</td>
<td>75,325</td>
<td>80,344</td>
<td>-5019 (-16,720 to 4928)</td>
<td>0.35</td>
</tr>
<tr>
<td>Median (IQR)</td>
<td>59,782 (43,666, 82,568)</td>
<td>55,153 (38,262, 85,369)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

AAA = abdominal aortic aneurysm; VA = Department of Veterans Affairs; IQR = interquartile range.

Costs are in US dollars and are means except when median (IQR) is specified.

See Methods for explanation.
Possible explanations for the difference between our findings and these earlier reports include: (1) timing—we entered patients 2002–2007, compared with 1999–2003 for EVAR-1 and DREAM and 2001 for the US sample, and expenses per inpatient day increased by more than 50% in the US from 1999 to 2007; (2) lower costs for hospital days, but similar costs for endovascular grafts, in Europe compared with the US; and (3), the VA cost accounting methods used in our study may have captured hospitalization costs more thoroughly than previous studies.

Figure 1. Cost-effectiveness planes. Bootstrap replications showing the differences in costs and/or life-years (LYs) (A) or quality-adjusted life year (QALYs) (B) on the cost-effectiveness plane between patients randomized to endovascular or open repair at 2 years of follow-up. The large dot indicates the point estimate from the study.
Our study has several limitations. First, our use of fixed direct costs distributes among both groups some costs that might seem to apply to only one group, such as disposable supplies and items bought for repeated use. Second, some pre-operative costs were not included because patients had to be candidates for both procedures prior to randomization, which required some evaluation beforehand. Third, there were a few protocol-driven practices that could distort costs, such as the required computed tomogram one year after open repair. Fourth, quality of life data were not collected in the first 6 months, during which a transient difference favoring endovascular repair has been reported.

Fifth, our study was conducted at VA medical centers using VA accounting methods, included only 5 women, and benefited from VA pricing for endovascular grafts. Our results therefore may not apply to other settings, particularly those in which endovascular grafts costs are substantially different from the mean $14,052 per patient we observed. Finally, we reported all healthcare costs, rather than only those related to AAA repair. While this might be considered a limitation, assessment of all healthcare costs, rather than only those related to AAA repair. Furthermore, the majority of costs in this 2-year analysis were clearly intervention-related.

Our findings suggest that endovascular repair is a cost-effective alternative to open repair in the US VA healthcare system for at least the first two years.

Appendix

The Open Versus Endovascular Repair (OVER) Veterans Affairs Cooperative Study Group includes: Investigators and site coordinators at participating Veterans Affairs Medical Centers — 

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