Economic analysis of endovascular repair versus surveillance for patients with small abdominal aortic aneurysms

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Background: **The Positive Impact of EndoVascular Options for Treating Aneurysms Early (PIVOTAL) trial enrolled individuals with small (4.0- to 5.0-cm diameter) abdominal aortic aneurysms (AAA) and reported no difference in rupture or aneurysm-related death for patients who received early endovascular repair (EVAR) vs surveillance with serial imaging studies. We evaluated resource use, medical cost, and quality of life outcomes associated with the PIVOTAL treatment strategies.**

Methods: **This prospective economic and quality of life study was conducted within a randomized trial, with PIVOTAL sites participating in the quality of life (n = 67) and economic (n = 63) studies. The PIVOTAL trial randomized 728 patients (366 early EVAR and 362 surveillance). We used information from 701 quality of life (351 early EVAR and 350 surveillance) and 614 economic (314 early EVAR and 300 surveillance) study participants enrolled in the PIVOTAL trial. The main outcome measures were total medical costs and the aneurysm repair rate at 48 months.**

Results: **After 6 months, the rate of aneurysm repair was 96 vs 10 per 100 patients in the early EVAR and surveillance groups, respectively (difference, 86; 95% confidence interval [CI], 82-90; $P < .0001$), and total medical costs were greater in the early EVAR group ($33,471 vs $5520; difference, $27,951; 95% CI, $25,156-$30,746; $P < .0001$). In months 7 through 48, however, the rate of aneurysm repair was 54 per 100 patients in the surveillance group, and total medical costs were higher for patients in the surveillance vs the early EVAR group ($40,592 vs $15,197; difference, $25,394; 95% CI, $15,184-$35,605; $P < .0001$). At 48 months' follow-up, early EVAR patients had greater cumulative use of AAA repair (97 vs 64 per 100 patients; difference, 34; 95% CI, 21-46; $P < .0001$), but there was no difference in total medical costs ($48,669 vs $46,112; difference, $2557; 95% CI, −$8043 to $13,156; $P = .64$). After discounting at 3% per annum, total medical costs for early EVAR and surveillance patients remained similar ($47,765 vs $43,532; difference, 4232; 95% CI, −$5561 to $14,025; $P = .40$). There were no treatment-related differences in quality of life at 24 months.**

Conclusions: **A treatment strategy involving early repair of smaller AAA with EVAR is associated with no difference in total medical costs at 48 months vs surveillance with serial imaging studies. Longer follow-up is required to determine whether the late medical cost increases observed for surveillance will persist beyond 48 months. (J Vasc Surg 2013;58:302-10.)**

The decision for intervention in abdominal aortic aneurysm (AAA) is determined by whether the risk associated with rupture is greater than the risk associated with repair.[1] For open surgical repair, a threshold aneurysm diameter of 5.0 to 5.5 cm has been used to gauge risk. However, questions arise about whether a different threshold for intervention is appropriate for endovascular aneurysm repair (EVAR).

Two clinical trials evaluated the use of open surgery vs surveillance in patients with small aneurysms (4.0-5.5 cm).[2-4] Both studies, the Aneurysm Detection and Management (ADAM) and the United Kingdom Small Aneurysm Trial (UK-SAT), concluded that surveillance conveyed similar benefits as early open surgery with respect to all-cause mortality. However, the perioperative risk associated with EVAR was lower than that with open surgery, and EVAR clinical event rates varied with aneurysm diameter.[5-7] These results have led to speculation that the AAA diameter threshold for EVAR may be lower than that for open surgery.[8,9]

The Positive Impact of EndoVascular Options for Treating Aneurysms Early (PIVOTAL) study was a randomized, controlled clinical trial in which early EVAR was compared with surveillance with serial imaging

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studies in patients with small AAA.[10] From PIVOTAL, we prospectively evaluated long-term economic and quality of life outcomes associated with an early EVAR vs a surveillance treatment strategy using follow-up information through 48 months. Our objectives were to compare differences in medical resource use patterns, medical costs, and quality of life for EVAR vs surveillance patients by intention-to-treat.

METHODS

The PIVOTAL protocol was approved by each study site Institutional Review Board and is registered on clinicaltrials.gov (NCT00444821). All study patients consented to participate in the PIVOTAL study.

Overview of PIVOTAL trial design and clinical results. The PIVOTAL clinical trial randomly assigned 728 patients to receive surveillance (n = 362) or early EVAR (n = 366).[10] Patients were included if they were aged between 40 and 90 years, had infrarenal AAAs 4.0 to 5.0 cm in diameter, as assessed by computed tomography within 3 months of screening, and did not meet the study's exclusion criteria.[10] The primary clinical end point was the composite of rupture or aneurysm-related death. At a mean follow-up of 20 ± 12 months, the mortality rate was 4.1% in each group (unadjusted hazard ratio [HR] after early EVAR was 1.01; 95% confidence interval [CI], 0.49-2.07; $P = .98$). The rate of aneurysm rupture or aneurysm-related death was 0.6% in both groups (unadjusted HR, 0.99; 95% CI, 0.14-7.06; $P = .99$).

Overview of PIVOTAL economic study. We conducted a prospective economic study in PIVOTAL patients. Our original research plan included two components: (1) an intent-to-treat analysis comparing treatment-related differences in resource use, medical costs, and quality of life outcomes using empiric data collected during the PIVOTAL follow-up period, and (2) a cost-effectiveness analysis assessing incremental medical costs per incremental quality-adjusted life-year for an early EVAR vs a surveillance treatment strategy. However, the absence of a mortality and quality of life benefit for early EVAR limited our analysis to the first component.[11] The PIVOTAL Economic Study protocol was approved by Duke University School of Medicine's Institutional Review Board (Protocol ID: Pro00013065). Patients participating in the economic analysis provided informed consent for their inpatient bills to be collected by the Duke Economics and Quality of Life (EQOL) Coordinating Center in Durham, North Carolina.

Economic data. The study's economic information included data elements from the PIVOTAL case report form (CRF) and information collected by the Duke EQOL Coordinating Center. CRF information was collected during scheduled study visits that occurred at baseline, 6 months, 12 months, and annually thereafter and included AAA-related office visits, imaging studies (number and type), and EQ-5D (EuroQol Group, Rotterdam, The Netherlands) quality of life responses to the five dimension questions and a single-question visual analog scale (VAS) assessment. Site coordinators also collected patient-reported instances of inpatient care (emergent, observational stay, acute hospitalization, nursing home, and rehabilitation facility) and forwarded this information to the Duke EQOL Coordinating Center. Duke billing specialists then contacted the finance department at each inpatient care organization, obtained the appropriate patient bills, and abstracted key information. Duke personnel also collected Medicare Cost Reports from each hospital for relevant study years and abstracted their department-level costs-to-charges ratios.

Different methods were used to estimate the technical and professional components of each patient's outpatient and inpatient medical costs in the PIVOTAL economic analysis.[12] Medical costs for the technical and professional components of AAA-related office visits and imaging studies were estimated using reimbursements from the 2008 Medicare fee schedule as resource-based proxies for medical costs. The technical components of inpatient care were estimated from study patient billing information. For emergent, observational, and acute care, we multiplied hospital-specific departmental charges on study patient bills by their associated cost-to-charges ratios to derive cost estimates. For rehabilitation facility and nursing home care, we used per diems. Professional costs for AAA repair (EVAR and open surgery) were estimated using procedure descriptions from the CRF and Medicare fee schedule amounts. Professional costs for other inpatient care were estimated using previously described methods.[13,14] All costs were adjusted to 2008 values using the medical component of the consumer price index. For reporting of resource use and medical costs, inpatient care was grouped into the categories of AAA repair (EVAR device and open surgery) and other inpatient care, including secondary procedures, emergency department, other hospitalizations, and rehabilitation facility or nursing home.

We used standard methods in the coding of EQ-5D responses. This instrument has five dimensions, comprising mobility, self-care, usual activities, pain/discomfort, and anxiety/depression. Each dimension has three levels (no problems, some problems, and extreme problems). Dimension responses were collapsed into two levels (problems, yes or no) in this study's analyses.[15] The EQ-5D utility score uses responses to the five dimensions to compute a value on a scale of −0.54 to 1.00. A higher utility score indicates a better quality of life and a negative value indicates a health state worse than death that can be used to quality-adjust study patient survival time.[16] The final EQ-5D element, visual analog score (VAS), provides a one-question assessment of an individual's quality of life and ranges from 0-100, with a higher score indicating a better quality of life.

Statistical analysis. Baseline clinical characteristic and quality of life results are presented as percentages for discrete variables and as medians and 25th and 75th percentiles for continuous variables. Differences between dichotomous variables are assessed using the χ^2 statistic or the Fisher exact test, and differences between continuous variables are assessed using the Kruskal-Wallis test. Medical resource use, length of stay (LOS), and medical costs are presented as cumulative values by treatment with differences, 95% CIs, and *P* values. These values are presented within time periods of interest (0-6 months, 7-48 months, and cumulative). Analyses are performed for the entire population, for the prospectively defined subgroups of initial AAA diameter 4.0 to 4.5 cm and 4.6 to 5.0 cm, and for the investigative subgroups of patients with and without a history of coronary artery disease (CAD). Resource use, LOS, and medical cost analyses are performed on partitioned data using general linear models with inverse probability weighted adjustment for censoring and empiric standard errors.[17,18] Total medical cost analyses were performed with and without discounting at 3% per annum.[19] Statistical analyses were performed using SAS 8.2 or higher software (SAS Institute, Cary, NC).

RESULTS

Study population and baseline characteristics. The PIVOTAL clinical trial enrolled 728 patients (366 early EVAR and 362 surveillance).[10] Sites participating in the PIVOTAL quality of life study enrolled 710 patients, and sites participating in the economic study enrolled 666 patients. For the quality of life analyses, we eliminated patients who did not complete the EQ-5D instrument at time intervals of interest (baseline, 12 months, and 24 months). For the PIVOTAL economic analysis, we excluded 52 patients (27 early EVAR and 25 surveillance) who were enrolled at per diem hospitals that did not generate detailed patient bills, yielding 614 patients (314 early EVAR and 300 surveillance). The initial AAA diameter subgroup analysis was limited to 607 patients (310 early EVAR and 297 surveillance) because AAA diameter was not available for seven patients. Similarly, the CAD history subgroup analysis was limited to 611 patients (313 early EVAR and 298 surveillance) because CAD history was missing for three patients. Average follow-up time was similar for treatment groups (938 days for early EVAR and 934 days for surveillance).

Baseline characteristics. Economic study patients randomized to early EVAR and surveillance were well matched and similar to those in the PIVOTAL clinical trial (Table I).[10] Most patients were older white men with a history of hypertension and CAD.

Medical resource use. There were significant treatment-related differences in the use of EVAR and total repair at 0 to 6 months, 7 to 48 months, and overall (Table II). More early EVAR patients received AAA repair during the initial 6 months; whereas, more surveillance patients received AAA repair between 7 and 48 months. At the end of follow-up, almost all patients randomized to early EVAR and >60% randomized to surveillance had received AAA repair. There were no treatment-related differences in other types of inpatient care, and early differences in AAA visits and imaging studies reported at 6 months' follow-up did not persist.

Table I. Baseline characteristics for economic study patients

Variables[a]	*Surveillance (n = 300)*	*Early EVAR (n = 314)*	P
Demographics			
Age, years	70.0 (66.0, 76.0)	70.5 (65.0, 77.0)	.87
White race	283 (94.3)	289 (92.0)	.33
Male sex	251 (83.7)	275 (87.6)	.20
AAA diameter, cm	4.40 (4.20, 4.70)	4.50 (4.20, 4.70)	.61
Current tobacco use	87 (29.0)	87 (27.7)	.77
History of			
Family aneurysmal disease	70 (23.3)	55 (17.5)	.09
Coronary artery disease	169 (56.3)	170 (51.0)	.61
Peripheral vascular disease	79 (26.3)	89 (28.3)	.66
Hypertension	222 (74.0)	251 (79.9)	.11
Abdominal surgery	116 (38.7)	120 (38.2)	.95
Gastrointestinal disease	110 (36.7)	119 (37.9)	.84

AAA, Abdominal aortic aneurysm; *EVAR,* endovascular aneurysm repair.
[a]Categoric variables are presented as number (%) and continuous variables as median (25th, 75th).

Length of stay. Treatment-related differences in AAA repair LOS paralleled differences in the use of AAA repair procedures (Table III). Early EVAR patients had greater AAA repair LOS during months 0 to 6; whereas, surveillance patients had greater AAA repair LOS during the remaining study period. Although other hospitalizations and rehabilitation facility or nursing home care accounted for most LOS days for patients in both study arms (92% surveillance and 82% early EVAR), there was no treatment-related difference for this combined LOS category (surveillance, 1665.3 days/100 patients; early EVAR, 917.5; difference, 747.8; 95% CI, −583.0 to 2078.6; $P = .27$).

Medical costs. Treatment-related differences in medical costs were driven by differences in AAA procedure use and LOS (Table IV). Early EVAR patients had greater AAA repair costs during the initial 6 months and during the 0 to 48 months of follow-up; whereas, surveillance patients had greater AAA repair costs during months 7 to 48. Medical costs associated with other hospitalizations and rehabilitation facility and nursing home care for surveillance patients were nearly as large as those for AAA repair procedures, whereas those for early EVAR patients were much smaller. Nonetheless, there was no treatment-related difference for this combined medical cost category (surveillance, $20,507; early EVAR, $14,634; difference, $5873; 95% CI, −$2715 to $14,462; $P = .18$). Overall, there were no treatment-related differences in total medical costs at 48 months.

Discounting served to amplify treatment-related cumulative cost differences (Table V). However, these differences were not significant overall or for patients with smaller (4.0-4.5 cm) and larger (4.6-5.0 cm) diameter aneurysms.

Table II. Medical resource use per 100 patients[a]

Resource type	*Surveillance (n = 300)*	*Early EVAR (n = 314)*	*Difference (95% CI)*	P
0-6 months				
AAA repair				
Endograft device	9.7	94.9	−85.2 (−89.3 to −81.0)	<.0001
Open surgery	0.3	1.3	−0.9 (−2.4 to 0.5)	.19
Total repair	10.0	96.2	−86.1 (−90.2 to −82.0)	<.0001
Other inpatient care				
Secondary procedures	0.7	1.3	−0.6 (−2.2 to 0.9)	.44
Emergency department	1.7	2.9	−1.2 (−3.6 to 1.2)	.32
Other hospitalizations[b]	14.0	19.5	−5.5 (−13.8 to 2.9)	.20
Rehab facility/nursing home	1.0	1.9	−0.9 (−3.3 to 1.5)	.46
Outpatient care				
AAA visits	54.8	110.2	−55.4 (−63.2 to −47.6)	<.0001
Imaging studies	53.5	92.7	−39.2 (−45.5 to −32.8)	<.0001
7-48 months				
AAA repair				
Endograft device	52.3	0.8	51.6 (39.2 to 64.0)	<.0001
Open surgery	1.4	0.4	1.0 (−0.8 to 2.8)	.29
Total repair	53.7	1.2	52.6 (40.1 to 65.0)	<.0001
Other inpatient care				
Secondary procedures	1.6	2.0	−0.4 (−3.3 to 2.5)	.79
Emergency department	8.7	16.6	−7.9 (−21.5 to 5.7)	.25
Other hospitalizations[b]	124.7	92.1	32.6 (−18.4 to 83.6)	.21
Rehab facility/nursing home	20.1	7.0	13.0 (−17.8 to 43.8)	.41
Outpatient care				
AAA visits	635.6	595.3	40.3 (−5.1 to 85.6)	.08
Imaging studies	320.8	308.7	12.1 (−15.8 to 40.0)	.39
Total				
AAA repair				
Endograft device	62.0	95.6	−33.6 (−46.2 to −21.1)	<.0001
Open surgery	1.7	1.7	0.0 (−2.2 to 2.3)	.98
Total repair	63.8	97.4	−33.6 (−46.0 to −21.1)	<.0001
Other inpatient care				
Secondary procedures	2.3	3.3	−1.0 (−4.3 to 2.3)	.55
Emergency department	10.4	19.5	−9.1 (−22.9 to 4.7)	.20
Other hospitalizations [b]	138.7	111.6	27.1 (−24.9 to 79.2)	.31
Rehab facility/nursing home	21.1	9.0	12.1 (−18.8 to 43.0)	.44
Outpatient care				
AAA visits	690.4	705.5	−15.1 (−60.7 to 30.5)	.52
Imaging studies	374.4	401.4	−27.0 (−55.7 to 1.6)	.07

AAA, Abdominal aortic aneurysm; *CI,* confidence interval; *EVAR,* endovascular aneurysm repair.
[a]Cell values are rates per 100 patients.
[b]Includes non-AAA-related hospitalizations.

Quality of life. PIVOTAL patients reported problems with pain/discomfort and mobility and, to a lesser extent, with performing usual activities and anxiety/depression (Table VI). However, there were no treatment-related differences in the five EQ-5D quality of life dimensions or the utility score at baseline or at the 12-month and 24-month follow-up. Early EVAR vs surveillance patients reported lower VAS scores at 12 months; however, their scores were similar at baseline and at 24 months.

History of CAD. Although not statistically significant, medical costs for other hospitalizations were higher in surveillance vs early EVAR patients and other hospitalizations with a primary diagnosis of diseases of the circulatory system (International Classification of Diseases-9th edition, 390-459) accounted for $2349 (49%) of the $4773 treatment-related difference in other hospitalization medical costs. Patients with a history of CAD represented 55% of all study patients, 54% of those with smaller-diameter aneurysms (4.0-4.5 cm), and 58% with larger-diameter aneurysms (4.6-5.0 cm). Although there were no treatment-related differences in baseline characteristics, patients with vs without a history of CAD had greater history of peripheral vascular disease, hypertension, and gastrointestinal disease, with no differences in age or initial AAA diameter (Table VII). AAA repair-related medical costs appear to be driven by the rates of AAA repair in both patient groups. However, there also appears to be an interaction between CAD history and other hospitalizations (Table VIII). In patients with a history of CAD, medical costs for other hospitalizations and cardiovascular hospitalizations are significantly higher for surveillance vs early EVAR patients. Results for patients without a history of CAD show no treatment-related differences in other

Table III. Average length of stay per 100 patients[a]

Resource type	*Surveillance (n = 300)*	*Early EVAR (n = 314)*	*Difference (95% CI)*	P
0-6 months				
Total AAA repair[b]	18.1	166.1	−138.9 (−158.3 to 119.5)	<.0001
Secondary procedures	1.3	4.5	−3.1 (−8.7 to 2.5)	.27
Emergency department	2.7	3.5	−0.8 (−4.5 to 2.8)	.65
Other hospitalizations[c]	56.2	117.3	−61.1 (−130.3 to 8.0)	.08
Rehab facility/nursing home	26.8	69.9	−43.0 (−169.9 to 83.9)	.51
Total	105.0	361.2	−256.2 (−420.5 to −91.8)	.02
7-48 months				
Total AAA repair[b]	92.8	4.1	83.8 (54.6 to 113.0)	<.0001
Secondary procedures	8.1	2.9	5.2 (−8.6 to 18.9)	.46
Emergency department	9.9	16.6	−6.8 (−20.7 to 7.2)	.34
Other hospitalizations[c]	580.9	407.7	173.2 (−104.5 to 450.9)	.22
Rehab facility/nursing home	1001.5	322.7	678.8 (−529.4 to 1887.0)	.27
Total	1693.1	754.0	939.0 (−357.7 to 2235.8)	.16
Total				
Total AAA repair[b]	110.8	170.2	−55.1 (−89.6 to −20.5)	.02
Secondary procedures	9.4	7.4	2.0 (−12.8 to 16.8)	.79
Emergency department	12.6	20.1	−7.6 (−22.0 to 6.8)	.30
Other hospitalizations[c]	637.0	525.0	112.0 (−177.3 to 401.4)	.45
Rehab facility/nursing home	1028.3	392.5	635.8 (−590.3 to 1861.8)	.31
Total other inpatient care	1798.1	1115.3	682.8 (−650.3 to 2015.9)	.32

AAA, Abdominal aortic aneurysm; *CI,* confidence interval; *EVAR,* endovascular aneurysm repair.
[a]Cell values are days per 100 patients.
[b]The sum of EVAR and open surgery.
[c]Includes non-AAA-related hospitalizations.

hospitalization and cardiovascular hospitalization medical costs; however, there is a significant difference in total medical costs at 48 months that largely is driven by higher AAA repair-related medical costs in early EVAR vs surveillance patients.

DISCUSSION

The PIVOTAL research program provides the first randomized trial with the combination of clinical, economic, and quality of life components evaluating the use of an early EVAR strategy vs surveillance with serial imaging studies treatment strategy for patients with small AAAs. At the 48-month follow-up, there were no treatment-related differences in total medical costs, and at 24 months, there were no treatment-related differences in quality of life (EQ-5D five dimensions, utility score, and VAS). During the first 6 months, the use of early EVAR was associated with higher medical costs than surveillance; however, this trend was reversed in follow-up months 7 to 48. These results are driven by treatment-related differences in the rate and timing of AAA repair procedures.

Given the high variability inherent in medical costs data, results for the subgroups of patients with smaller-diameter (4.0-4.5 cm) and larger-diameter (4.6-5.0 cm) AAAs were remarkably consistent with the overall medical cost results. This was true for total medical costs at 48 months and for important cost drivers. AAA-related medical costs accounted for 46% of total medical costs for surveillance and 61% for early EVAR in all study patients. Similar cost distributions were observed for patients with smaller and larger aneurysms.

Results for surveillance patients with and without a history of CAD were quite different. Both groups had similar age, AAA diameter, and history of family aneurysm disease, but surveillance patients with vs without a history of CAD had greater history of cardiovascular disease (peripheral vascular disease and hypertension) and gastrointestinal disease. These differences were associated with higher rates of AAA repair, other hospitalizations, and cardiovascular hospitalizations. These differences in resource use led to higher AAA repair-related, other hospitalization, cardiovascular hospitalization, and total medical costs for patients with vs without a history of CAD and suggest that disease progression may be different for these two patient groups. Although there was no significant treatment-related difference in total medical costs for patients with a history of CAD, these results suggest that the economics of AAA repair may be quite different for different patient groups.

Few studies have investigated quality of life and medical cost differences for an early intervention (EVAR or open surgery) vs a surveillance treatment strategy in patients with small AAAs. The Comparison of surveillance vs Aortic Endografting for Small Aneurysm Repair (CAESAR) trial reported higher Medical Outcomes Study Short Form-36 scores (total, mental domain, and physical domain) for early EVAR vs surveillance at 6 months.[20] However, these differences rapidly diminished, such that there were no significant differences after 12 months. Although PIVOTAL used a different instrument (EQ-5D), our results at 12 and 24 months of follow-up also failed to demonstrate consistent treatment-related differences in quality of life.

Table IV. Average medical costs per patient[a]

Cost type	*Surveillance (n = 300)*	*Early EVAR (n = 314)*	*Difference (95% CI)*	P
0-6 months				
Inpatient				
Total AAA repair[b]	3095	29,491	−26,397 (−28,365 to −24,428)	<.0001
Secondary procedures	73	236	−163 (−467 to 141)	.29
Emergency department	48	31	17 (−41 to 74)	.57
Other hospitalizations[c]	1710	2642	−933 (−2590 to 724)	.27
Rehab facility/nursing home	285	178	107 (−333 to 547)	.63
Outpatient				
AAA visits	12	25	−12 (−14 to −11)	<.0001
Imaging studies	297	868	−570 (−629 to −512)	<.0001
Total medical costs	5520	33,471	−27,951 (−30,746 to −25,156)	<.0001
7-48 months				
Inpatient				
Total AAA repair[b]	18,189	351	17,838 (13,411 to 22,265)	<.0001
Secondary procedures	428	306	121 (−555 to 797)	.73
Emergency department	177	147	30 (−171 to 232)	.77
Other hospitalizations[c]	16,353	10,648	5706 (−1570 to 12,981)	.12
Rehab facility/nursing home	2159	1166	994 (−1505 to 3492)	.44
Outpatient				
AAA visits	141	132	9 (−1 to 19)	.08
Imaging studies	3144	2447	696 (357 to 1036)	<.0001
Total medical costs	40,592	15,197	25,394 (15,184 to 35,605)	<.0001
Total				
Inpatient				
Total AAA repair[b]	21,284	29,842	−8558 (−13,224 to −3893)	.0003
Secondary procedures	501	542	−41 (−780 to 698)	.91
Emergency department	226	178	47 (−162 to 257)	.66
Other hospitalizations[c]	18,063	13,290	4773 (−2702 to 12,247)	.21
Rehab facility/nursing home	2445	1344	1101 (−1454 to 3655)	.40
Outpatient				
AAA visits	154	157	−3 (−14 to 7)	.52
Imaging studies	3441	3315	126 (−222 to 474)	.48
Total medical costs	46,112	48,669	−2557 (−13,156 to 8043)	.64

AAA, Abdominal aortic aneurysm; *CI,* confidence interval; *EVAR,* endovascular aneurysm repair.
[a]Medical costs are presented as dollars per patient.
[b]Sum of EVAR and open surgery.
[c]Includes non-AAA-related hospitalizations.

Table V. Average medical costs by initial aneurysm diameter per patient[a]

Variables	*Ultrasound surveillance (n = 300)*	*Early EVAR (n = 314)*	*Difference (95% CI)*	P
All patients				
Undiscounted	46,112	48,669	−2557 (−13,156 to 8043)	.63
Discounted	43,532	47,765	−4232 (−14,025 to 5561)	.40
AAA 4.00-4.50 cm	(n = 191)	(n = 197)		
Undiscounted	48,017	47,229	788 (−16,943 to 18,520)	.93
Discounted	45,121	46,457	−1336 (−17,502 to 14,831)	.87
AAA 4.51-5.00 cm	(n = 106)	(n = 113)		
Undiscounted	46,733	51,008	−4276 (−20,294 to 11,742)	.60
Discounted	44,295	49,918	−5623 (−20,576 to 9330)	.46

AAA, Abdominal aortic aneurysm; *CI,* confidence interval; *EVAR,* endovascular aneurysm repair.
[a]Medical costs are presented as dollars per patient. Discount rate is 3% per annum.

Two analyses used information collected in the UK Small Aneurysm Trial (UK-SAT). Because this study reported no survival advantage for open surgery, the UK-SAT investigators conducted a cost-minimization study to examine treatment-related differences in medical costs and quality of life at the 12-month follow-up.[4] Medical costs for the early surgery group were 25% higher than those for surveillance. However, early surgery patients reported better outcomes for current health perceptions and less negative change in bodily pain. Although this was a well-conducted study, limiting follow-up to 12 months meant that only 34% of surveillance patients had undergone aneurysm repair.

Table VI. EQ-5D quality of life per patient[a]

Variables	*Ultrasound surveillance, No.*	*Early EVAR, No.*	P
Respondents			
Baseline	350	351	
12 months	308	318	
24 months	197	205	
	No. (%)	*No. (%)*	
Mobility problems			
Baseline	151 (43.1)	130 (37.0)	.099
12 months	114 (37.0)	119 (37.4)	.915
24 months	73 (37.1)	80 (39.0)	.684
Self-care problems			
Baseline	16 (4.6)	11 (3.1)	.322
12 months	20 (6.5)	17 (5.3)	.542
24 months	13 (6.6)	16 (7.8)	.640
Usual activity problems			
Baseline	114 (32.6)	101 (28.8)	.275
12 months	93 (30.2)	114 (35.8)	.132
24 months	57 (28.9)	78 (38.0)	.053
Pain/discomfort			
Baseline	191 (54.6)	183 (52.1)	.518
12 months	144 (46.8)	154 (48.4)	.674
24 months	80 (40.6)	94 (45.9)	.288
Anxious/depressed			
Baseline	86 (24.6)	94 (26.8)	.503
12 months	82 (26.6)	82 (25.8)	.811
24 months	36 (18.3)	41 (20.0)	.660
	Mean ± SD (n)	*Mean ± SD (n)*	
Utility score			
Baseline	0.783 ± 0.2 (349)	0.805 ± 0.1 (348)	.397
12 months	0.794 ± 0.2 (299)	0.799 ± 0.2 (311)	.713
24 months	0.817 ± 0.2 (191)	0.797 ± 0.2 (203)	.391
Visual analog scale			
Baseline	78.2 ± 15 (350)	77.8 ± 14 (351)	.382
12 months	78.1 ± 16 (308)	75.4 ± 17 (318)	.030
24 months	76.5 ± 18 (197)	76.2 ± 17 (205)	.669

EVAR, Endovascular aneurysm repair; *SD*, standard deviation.
[a]Cell values per patient are presented.

Table VII. Baseline characteristics by history of coronary artery disease (*CAD*)

Variable[a]	*Ultrasound surveillance*	*Early EVAR*	P
History of CAD	(n = 169)	(n = 170)	
Demographics			
Age, years	70.0 (66.0, 75.0)	71.0 (65.0, 76.0)	.77
White race	162 (95.9)	164 (96.5)	.77
Male sex	151 (89.4)	152 (89.4)	.99
AAA diameter	4.40 (4.20, 4.70)	4.50 (4.20, 4.70)	.31
Current tobacco use	40 (23.7)	42 (24.7)	.82
History of			
Family history of AA	41 (24.3)	30 (17.7)	.14
Peripheral vascular disease	41 (24.3)	63 (37.1)	.18
Hypertension	139 (82.3)	145 (85.3)	.45
Abdominal surgery	71 (42.0)	68 (40.0)	.71
Gastrointestinal disease	70 (41.4)	71 (41.8)	.95
No history of CAD	(n = 129)	(n = 143)	
Demographics			
Age, years	71.0 (67.0, 76.0)	70.0 (65.0, 77.0)	.48
White race	119 (92.3)	124 (86.7)	.14
Male sex	98 (76.0)	122 (85.3)	.053
AAA diameter	4.40 (4.20, 4.70)	4.45 (4.20, 4.70)	.69
Current tobacco use	47 (36.4)	45 (31.5)	.39
History of			
Family history of AA	29 (22.5)	25 (17.5)	.30
Peripheral vascular disease	28 (21.7)	26 (18.2)	.47
Hypertension	83 (64.3)	106 (74.1)	.08
Abdominal surgery	45 (34.9)	52 (36.4)	.80
Gastrointestinal disease	40 (31.0)	48 (33.6)	.65

AA, Aortic aneurysm; *AAA*, abdominal aortic aneurysm; *EVAR*, endovascular aneurysm repair.
[a]Categoric clinical variables are presented as number (%) and continuous variables as median (25th, 75th).

To extend the work of the UK-SAT investigators, Schermerhorn et al[21] used a Markov model to investigate the potential economic attractiveness of open surgery in patients with lower operative mortality defined by younger age and larger AAA diameter. This study assumed 61% of surveillance patients eventually underwent open surgery and assigned a utility weight of 0.86 for both treatment groups. A small quality-adjusted survival advantage was reported for early open surgery at a small incremental cost. However, whether the model included all cost types is unclear.

Young et al[22] used a Markov model to evaluate the cost-effectiveness of early EVAR for small AAA vs elective repair (EVAR or open surgery). Results from this model predicted that the use of early EVAR vs surveillance was associated with fewer quality-adjusted life-years and greater medical costs. This assessment was based on a 0.05 reduction in quality-adjusted life-years and an increased cost of $3000 (2007 US$) with early EVAR. This model assumed utility weights of 0.75 for surveillance, 0.70 for EVAR in the first year, and 0.71 for EVAR in the second year. Medical costs for a number of events are included in this model, but the list is not exhaustive.

Our study methods differed from these previous efforts in several ways that had important implications for our findings. First, we prospectively collected patient-level medical cost data at the episode-of-care level. Although outpatient care typically follows patterns that are captured relatively well in Medicare reimbursements, this is not the case with inpatient care that varies in the volume, type, and price of resources that are used for similar cases. Thus, studies not capturing this level of detail may underestimate the true variability inherent in their study results.

Second, we collected data for all inpatient care, and did not limit this work to certain types of cases. Models are able

Table VIII. Economic outcomes at 48 months by history of coronary artery disease (*CAD*)

Variable	*Ultrasound surveillance*	*Early EVAR*	*Difference (95% CI)*	P
History of CAD	(n = 169)	(n = 170)		
Resource use[a]				
AAA repair[b]	71.3	97.6	−26.3 (−44.8 to −7.9)	.005
Other hospitalizations[c]	180.8	119.2	61.6 (−23.3 to 146.5)	.16
Other cardiovascular	34.4	17.1	17.3 (−1.3 to 35.8)	.069
Medical costs,[d] $				
AAA repair[b]	23,239	29,351	−6112 (−12,876 to 651)	.076
Other hospitalizations[c]	22,062	10,822	11,240 (860 to 21,619)	.034
Other cardiovascular	4761	2128	3222 (85 to 6360)	.044
Total	52,336	45,343	6994 (−8352 to 22,339)	.37
No history of CAD	(n = 129)	(n = 143)		
Resource use[a]				
AAA repair[b]	55.2	96.9	−41.7 (−57.7 to −25.7)	<.0001
Other hospitalizations [c]	88.8	110.1	−21.3 (−70.4 to 27.7)	.39
Other cardiovascular	12.0	27.6	−15.6 (−32.4 to 1.2)	.069
Medical costs,[d] $				
AAA repair [b]	19,188	30,325	−11,137 (−17,438 to −4837)	.0005
Other hospitalizations[c]	13,200	16,679	−3479 (−13,911 to 6954)	.51
Other cardiovascular	2196	4675	−2479 (−5843 to 886)	.15
Total	38,921	52,890	−13,969 (−27,920 to −18)	.050

AAA, Abdominal aortic aneurysm; *CI,* confidence interval; *EVAR,* endovascular aneurysm repair.
[a]Presented as rates per 100 patients.
[b]The sum of EVAR and open surgery.
[c]Includes non-AAA-related hospitalizations.
[d]Presented as dollars per patient.

to show the implications of known variables but are not able to inform decision making when key relationships are not known in advance. Collecting data on all-cause inpatient care is an important consideration because it can be difficult to distinguish disease-related from non–disease-related resource use.

Third, the combination of above factors allowed us to represent results with confidence limits, not as point estimates. This is important because medical costs typically have extreme variability.

Fourth, we collected quality of life results over a sufficient period of time to determine that early treatment-related differences did not persist.

Our study has important limitations. First, PIVOTAL was not designed to investigate possible interactions between treatment and baseline clinical characteristics. Thus, although our analyses of patients with vs without a history of CAD are interesting, they are not definitive and will need to be replicated in future studies. Second, our study results are limited to the population of patients enrolled in the PIVOTAL clinical trial. We believe that our results accurately reflect the long-term resource use, medical costs, and quality of life outcomes for this population, but they may not be transferrable to other populations of patients with small AAAs.

CONCLUSIONS

A treatment strategy involving early repair of smaller AAA with EVAR is associated with no difference in total medical costs at 48 months and no difference in quality of life at 24 months vs surveillance with serial imaging studies. Longer follow-up is required to determine whether the late medical cost increases observed for surveillance will persist beyond 48 months.

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AUTHOR CONTRIBUTIONS

Conception and design: EE, LD, KO
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