Original article

Comparison of outcomes after endovascular and open repair of abdominal aortic aneurysms in low-risk patients

J. J. Siracuse[1], M. L. Schermerhorn[3], A. J. Meltzer[4], M. H. Eslami[1], J. A. Kalish[1], D. Rybin[2], G. Doros[2], A. Farber[1] and the Vascular Study Group of New England

[1]Division of Vascular and Endovascular Surgery, Boston Medical Center, and [2]Department of Biostatistics, Boston University, School of Medicine, and [3]Division of Vascular and Endovascular Surgery, Beth Israel Deaconess Medical Center, Harvard Medical School, Boston, Massachusetts, and [4]Division of Vascular and Endovascular Surgery, New York-Presbyterian Hospital, Weill Cornell Medical College, New York, USA

Correspondence to: Dr J. J. Siracuse, Division of Vascular and Endovascular Surgery, Boston University, School of Medicine, 88 East Newton Street, Boston, Massachusetts 02118, USA (e-mail: jeffrey.siracuse@bmc.org)

Background: **In randomized trials endovascular aortic aneurysm repair (EVAR) has been shown to have superior perioperative outcomes compared with open aneurysm repair (OAR). However, outcomes in patients at low risk of complications are unclear and many surgeons still prefer OAR in this cohort. The objective was to analyse perioperative and longer-term outcomes of OAR and EVAR in this low-risk group of patients.**

Methods: **All elective infrarenal EVARs and OARs in the Vascular Study Group of New England database were reviewed from 2003 to 2014. The Medicare scoring system was used to identity patients at low risk of perioperative complications and death. Perioperative and longer-term outcomes were analysed in this cohort. A Kaplan–Meier plot was constructed for evaluation of longer-term survival. Further propensity matching and multivariable analysis were performed to analyse additional differences between the two groups.**

Results: **Some 1070 patients who underwent EVAR and 476 who had OAR were identified. Mean(s.d.) age was 67·3(5·7) and 65·1(6·3) years respectively ($P < 0·001$). EVAR was associated with a lower overall perioperative complication rate (4·2 *versus* 26·5 per cent; $P < 0·001$). There was no difference in 30-day mortality (0·4 *versus* 0·6 per cent; $P = 0·446$). Overall survival at 3 years was similar after EVAR and OAR (92·5 *versus* 92·1 per cent respectively; $P = 0·592$). In multivariable analyses there was no difference in freedom from reintervention (odds ratio 1·69, 95 per cent c.i. 0·73 to 3·90; $P = 0·220$) or survival (hazard ratio 0·85, 0·61 to 1·20; $P = 0·353$).**

Conclusion: **In patients predicted to be at low risk of perioperative death following aneurysm repair, EVAR resulted in fewer perioperative complications than OAR. However, perioperative mortality, reinterventions and survival rates in the longer term appeared similar between endovascular and open repair.**

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Introduction

Endovascular aortic aneurysm repair (EVAR) has become an accepted treatment for an increasing proportion of patients with an infrarenal abdominal aortic aneurysm (AAA)[1]. The increasing use of EVAR is driven mainly by improved perioperative outcomes that are associated with a less invasive repair[2–4]. This benefit has been particularly noted in high-risk and elderly patients[5–7]. However, concerns about the long-term durability of EVAR persist and many patients require further reinterventions[4,7,8]. The perioperative benefit in the overall population diminishes over time as patients with EVAR require more reinterventions, and long-term survival rates have been shown to be equivalent after EVAR and open aneurysm repair (OAR)[7–11].

Although the advantages of EVAR over OAR are well established for higher-risk patients, the benefit in patients who are at low risk of perioperative morbidity and mortality remains unclear[3,6,10]. Data from the American College of Surgeons National Surgical Quality Improvement Program (NSQIP) has shown that even lower-risk patients have lower rates of perioperative morbidity and mortality following EVAR[7,12].

However, this study was limited to perioperative outcomes and was unable to assess aneurysm- or procedure-specific details[12]. Balancing this perioperative benefit against repair durability is important because vascular surgeons continue to debate whether EVAR should be offered to otherwise healthy patients who are expected to have a long lifespan and could tolerate OAR. As such, many vascular surgeons may preferentially offer OAR to younger, lower-risk patients because of perceived advantages in perioperative mortality, morbidity and long-term durability.

The objective of this study was to compare perioperative and longer-term outcomes in low-risk patients with AAA identified using the Medicare aneurysm scoring system in the database of the Vascular Study Group of New England (VSGNE)[13].

Methods

Vascular Study Group of New England database

A retrospective review was undertaken of all patients with an infrarenal AAA undergoing index EVAR and OAR from 2003 to 2014 and registered in the VSGNE database. The VSGNE is a regional collaboration between 30 academic and community hospitals in the six New England states. Data on commonly performed vascular procedures from each participating institution are collected and maintained in a prospective registry. It was founded in 2001 by vascular surgeons in northern New England, and has subsequently been expanded to include vascular surgeons, radiologists and cardiologists in all six New England states. The VSGNE's collaborative mission is to use collected information to improve the quality, safety, effectiveness and costs associated with the care of patients with vascular disease[14].

A number of preoperative and intraoperative variables are recorded within the VSGNE database, along with perioperative complications. In the present study, reinterventions recorded within 1 year for EVAR included endovascular interventions for endoleak, sac growth, graft migration, limb occlusion and rupture, and open interventions for endoleak, sac growth, graft migration, graft infection and rupture. Reinterventions for OAR included procedures for incisional, graft and intestinal complications, and leg ischaemia. Follow-up in person was required for the assessment of reinterventions. However, follow-up for mortality was based on data abstracted from social security records.

Medicare aneurysm score

The Medicare aneurysm score is a validated risk prediction tool for perioperative death following EVAR and open repair of intact AAA[13]. Variables included in the model are: age, sex, presence of congestive heart failure, peripheral arterial disease, chronic renal insufficiency and cerebrovascular disease, with points assigned based on degree of influence on the risk. After assignment of a cumulative point score, patients were risk-stratified into low-, moderate- and high-risk categories. Only low-risk patients, defined by male sex, age less than 75 years, and no diagnosis of renal insufficiency, congestive heart failure, peripheral arterial disease or cerebrovascular disease, were included in this analysis. For the Medicare aneurysm score, co-morbidities were determined based on medical history and coding.

To eliminate high-risk characteristics further, any patients who were not judged locally to be candidates for open vascular surgery or general anaesthesia, or who had a history of aortic surgery, were excluded. Preoperative aneurysm morphology was not available for analysis. Patients with surrogate markers of more complicated or extensive aneurysm disease were excluded. These included patients having OAR who required a suprarenal or supracoeliac aortic clamp, internal iliac artery ligation, or concurrent infrainguinal bypass, renal artery bypass or thromboembolectomy. Patients having EVAR who required preoperative or concurrent internal iliac artery embolization, common femoral endarterectomy, femoral to femoral artery bypass, iliofemoral bypass or renal artery stenting were also excluded.

Statistical analysis

Patient characteristics were compared between EVAR and OAR groups using Student's *t* test and gamma regression for continuous variables, and Fisher's exact test for categorical variables. Postoperative complications were compared across the intervention groups using Fisher's exact test. For survival analysis, Kaplan–Meier plots were constructed and 3-year postoperative survival was compared between EVAR and OAR by means of the log rank test.

Multivariable Cox proportional hazards regression was used to compare mortality for EVAR and OAR groups while adjusting for possible confounders. The co-variables included in the model were: age, smoking, diabetes, hypertension, and use of statins and beta-blockers. These variables were selected based on bivariable analysis comparing EVAR and OAR groups. The association was expressed as a hazard ratio (HR) with corresponding 95 per cent confidence interval. Multivariable logistic regression was used to compare 1-year reintervention in the EVAR and OAR groups while adjusting for the same possible confounders as in the Cox regression model. The association was expressed as an odds ratio (OR) with 95 per cent confidence interval. All analyses were performed

Table 1 Demographics and co-morbidities of low-risk patients with an abdominal aortic aneurysm

	Overall ($n = 1546$)	EVAR ($n = 1070$)	OAR ($n = 476$)
Demographics			
Age (years)			
31–55	78 (5·0)	37 (3·5)	41 (8·6)
56–65	510 (33·0)	316 (29·5)	194 (40·8)
66–75	958 (62·0)	717 (67·0)	241 (50·6)
Caucasian	1506 (97·4)	1041 (97·3)	465 (97·6)
BMI < 30 kg/m^2	1004 (64·9)	685 (64·0)	319 (67·0)
Smoking status			
Previous smoker	770 (49·8)	555 (51·9)	215 (45·2)
Current smoker	677 (43·8)	437 (40·8)	240 (50·4)
Medical funding			
Primary Medicare	228 of 457 (49·9)	199 of 367 (54·2)	29 of 90 (32)
Primary Medicaid	20 of 457 (4·4)	15 of 367 (4·1)	5 of 90 (6)
Primary private insurance	197 of 457 (43·1)	146 of 367 (40·0)	51 of 90 (57)
Living at home	1540 (99·6)	1065 (99·5)	475 (99·8)
Medical history			
Diabetes	266 (17·2)	207 (19·3)	59 (12·4)
Hypertension	1236 (79·9)	871 (81·4)	365 (76·7)
Coronary artery disease	444 (28·7)	309 (28·9)	135 (28·4)
COPD	432 (27·9)	298 (27·9)	134 (28·2)
Preoperative aspirin	1164 (75·3)	810 (77·7)	354 (74·4)
Preoperative statin	1107 (71·6)	779 (72·8)	328 (68·9)
Preoperative beta-blocker	1093 (70·7)	716 (66·9)	377 (79·2)

Values in parentheses are percentages. EVAR, endovascular aneurysm repair; OAR, open aneurysm repair; BMI, body mass index; COPD, chronic obstructive pulmonary disease.

using SAS® version 9.3 (SAS Institute, Cary, North Carolina, USA), and for all tests the significance level was set at 0·05.

Sensitivity analyses were performed in a propensity-matched sample (1 : 1 matching). This was performed to eliminate further any differences between the groups that existed after classification as low risk based on the Medicare aneurysm scoring system. The propensity score was calculated based on age, smoking, diabetes, hypertension, and use of statins and beta-blockers. A matching calliper was set to 20 per cent of the standard deviation of the propensity score. The quality of matching was assessed using standardized difference in means.

Results

Among low-risk patients with an AAA, 1070 who underwent EVAR and 476 who had OAR met the criteria for inclusion in the analysis (*Table 1*). Their mean(s.d.) age was 67·3(5·7) and 65·1(6·3) years respectively ($P < 0·001$). OAR was performed through a midline incision in 375 patients (78·8 per cent). A tube graft was used in 276 patients (58·0 per cent). General anaesthesia was used in 988 EVARs (92·3 per cent) and in all open repairs. The mean(s.d.) total procedure time was 136(58) min for EVAR and 202(81) min for OAR ($P < 0·001$). Estimated blood loss was lower for EVAR (189(190) *versus* 1293 (1108) ml; $P < 0·001$).

The EVAR cohort had a lower overall complication rate (4·2 *versus* 26·5 per cent; $P < 0·001$) and a lower composite major adverse cardiac event rate (death, myocardial infarction, stroke) (1·2 *versus* 3·8 per cent; $P < 0·001$) (*Table 2*). However, there was no difference in 30-day mortality (0·4 *versus* 0·6 per cent; $P = 0·446$). Median duration of follow-up in person was 300 (range 0–3701) days for EVAR and 370 (0–2888) days for OAR. The total median follow-up with regard to mortality was 795 (0–3972) and 1571 (0–3979) days respectively.

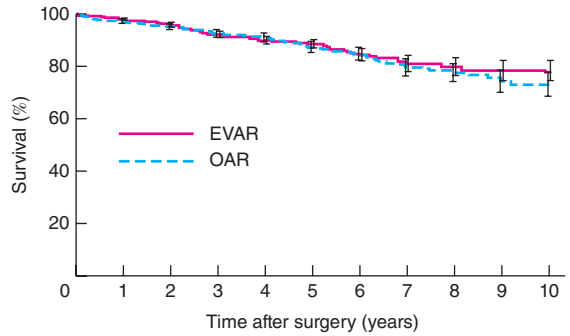
In the EVAR group, 38 patients (3·6 per cent) had reinterventions within 1 year, including 25 for endoleaks, 12 for sac growth, two for graft migration and one for aneurysm rupture. There were no conversions to open repair. In the OAR group, nine patients (1·9 per cent) had reinterventions within 1 year, including two for incisional complications, two for graft complications, two for intestinal complications and three for limb complications.

Long-term survival rates were similar after EVAR and OAR: 98·0 *versus* 97·1 per cent respectively at 1 year, 92·5 *versus* 92·1 per cent at 3 years, 89·0 *versus* 87·7 per cent at 5 years and 77·7 *versus* 72·8 per cent at 10 years ($P = 0·592$) (*Fig. 1*). On multivariable analysis EVAR did

Table 2 Postoperative complications among low-risk patients with an abdominal aortic aneurysm

	Overall ($n = 1546$)	EVAR ($n = 1070$)	OAR ($n = 476$)	P‡
ICU stay (days)*	0 (0–41)	0 (0–16)	2 (0–41)	< 0·001§
Myocardial infarction	23 (1·5)	7 (0·7)	16 (3·4)	< 0·001
Congestive heart failure	15 (1·0)	6 (0·6)	9 (1·9)	0·021
Pulmonary complications	35 (2·3)	8 (0·7)	27 (5·7)	< 0·001
Renal complications	49 (3·2)	14 (1·3)	35 (7·4)	< 0·001
Leg ischaemia	10 (0·6)	4 (0·4)	6 (1·3)	0·078
Bowel ischaemia	9 (0·6)	1 (0·1)	8 (1·7)	< 0·001
Wound complication	20 (1·3)	4 (0·4)	16 (3·4)	< 0·001
Return to operating theatre	27 (1·7)	8 (0·7)	19 (4·0)	< 0·001
Any postoperative complication	171 (11·1)	45 (4·2)	126 (26·5)	< 0·001
Postoperative LOS (days)†	3·2(3·6)	1·7(2·0)	6·7(3·8)	< 0·001§
Discharged to facility	56 (3·6)	21 (2·0)	35 (7·4)	< 0·001
30-day mortality	7 (0·5)	4 (0·4)	3 (0·6)	0·446
Postoperative stroke	3 (0·2)	3 (0·3)	0 (0)	0·999
MACE	31 (2·0)	13 (1·2)	18 (3·8)	< 0·001
Reintervention within 1 year	47 (3·0)	38 (3·6)	9 (1·9)	0·220

Values in parentheses are percentages, unless indicated otherwise; *values are median (range) and †mean(s.d.). EVAR, endovascular aneurysm repair; OAR, open aneurysm repair; ICU, intensive care unit; LOS, length of stay; MACE, major adverse cardiac event. ‡Fisher's exact test, except §gamma regression.



No. at risk

EVAR	1070	781	572	390	292	209	154	100	59	26	13
OAR	476	413	349	303	252	215	186	140	99	60	32

Fig. 1 Kaplan–Meier analysis of survival after open (OAR) *versus* endovascular (EVAR) abdominal aortic aneurysm repair. $P = 0·592$ (log rank test)

not independently influence mortality (adjusted HR 0·85, 95 per cent c.i. 0·61 to 1·20; $P = 0·353$). There was no difference between EVAR and OAR in rates of freedom from reintervention within 1 year of AAA repair (odds ratio 1·69, 95 per cent c.i. 0·73 to 3·90; $P = 0·220$). Sensitivity analyses based on a propensity-matched sample (473 patients who had EVAR successfully matched 1 : 1 with 473 who had OAR) resulted in similar findings. There was no significant difference between EVAR and OAR in survival (HR 0·82, 0·56 to 1·20; $P = 0·298$) or freedom from reintervention within 1 year (OR 1·90, 0·79 to 4·60; $P = 0·153$).

Discussion

This study has reaffirmed the superior short-term outcomes of EVAR compared with OAR in low-risk patients. EVAR was associated with lower rate of major perioperative complications. However, there was no difference in perioperative and longer-term mortality, or in freedom from reintervention by 1 year. These data can help guide clinicians in providing an evidence basis for informed consent for the patients. The mortality results in the present low-risk group have notable similarities with those in the UK EVAR-1 trial[8], which showed that EVAR was associated with fewer perioperative complications and had a lower perioperative mortality rate for the overall cohort; however, the survival benefit did not extend to the longer term.

The perioperative outcomes in this study are similar to those of previous studies of high-risk and elderly patients, which showed lower morbidity rates after EVAR than OAR; however, unlike in these populations, there was no difference in perioperative mortality in the low-risk cohort[3,6,10]. This may be reflective of an overall healthier population able to tolerate and survive perioperative complications. Traditionally, patients having EVAR have been shown to have a higher rate of reintervention than those undergoing OAR[3,8,9]. The analysis of reinterventions in the present study is limited because the follow-up for reintervention was restricted to 1 year; it is quite possible that many reinterventions occur during longer-term follow-up[11,15]. Although the rates of reintervention are similar, it is not possible to determine the

scale of reintervention for either technique. There were no conversions to open surgery. Similar to findings for higher-risk and older patients[3,6,10], the present study did not show a difference in long-term survival. Data supporting the long-term benefit and durability of EVAR include the result of the Open *versus* Endovascular Repair (OVER) trial, which showed no difference in overall survival between patients treated with EVAR and OAR at 9 years, with an increased long-term survival benefit for EVAR in patients aged less than 70 years[16]. However, there were more aneurysm-related deaths in the EVAR group. This has also been confirmed in the Medicare population[7]. Analysis of the long-term cause of death after AAA repair revealed that death from co-morbidities rather than aneurysm complications is more common[17]. Long-term follow-up of this low-risk population with lower co-morbidities is required to assess the long-term durability of repair and causes of death[18].

Previous analysis of the NSQIP database[12] showed improved perioperative outcomes for EVAR compared with OAR. However, this administrative database does not include details about the procedure, except that the repairs are for infrarenal aneurysm[13]. Specifically, clamp location is not addressed and concurrent procedures are not eliminated. Here, it was possible further to eliminate patients deemed unfit for open repair as this variable is included in the VSGNE database. The VSGNE database provides information on clamp location as well as details about adjunct procedures that would make the repair more complex and potentially more likely to cause morbidity[19]. Although the present results confirmed that EVAR has a lower perioperative complication rate, there was no difference in mortality. This may be explained by the exclusion of patients who had a suprarenal clamp placed for an infrarenal aneurysm, as well as elimination of concomitant procedures that can increase morbidity and mortality, and exclusion of patients unfit for open repair and for general anaesthesia. These data were not present in the NSQIP database and could not be accounted for.

Limitations of this study include those inherent to using a large regional database. Potential bias may exist because the data are collected by the institutions and each case is not adjudicated independently. However, the cases are audited and mortality is followed up independently. Another limitation is that it was not possible to stratify by region or vascular units to take into account practice variations. Overall numbers are relatively low owing to the strict inclusion and exclusion criteria applied to make the groups comparable for simple infrarenal aneurysm repair in low-risk patients. A further issue is the limited long-term individualized follow-up for the assessment of durability of AAA repair. It is also possible that patients could have had other reinterventions at institutions that did not contribute to the VSGNE. It is not possible to determine the specific reintervention performed from the database; however, it is possible to establish whether it was an endovascular or open reintervention. Missing reintervention data were treated as missing completely at random in the secondary analysis.

The VSGNE regional database demonstrated that, even among patients at lowest risk, EVAR is associated with reduced perioperative morbidity, but similar rates of perioperative mortality and reintervention at 1 year. OAR did not appear to offer improved long-term survival.

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