Endovascular aneurysm repair versus open repair in patients with abdominal aortic aneurysm (EVAR trial 1): randomised controlled trial

*EVAR trial participants**

Summary

Background **Although endovascular aneurysm repair (EVAR) has a lower 30-day operative mortality than open repair, the long-term results of EVAR are uncertain. We instigated EVAR trial 1 to compare these two treatments in terms of mortality, durability, health-related quality of life (HRQL), and costs for patients with large abdominal aortic aneurysm (AAA).**

Methods **We did a randomised controlled trial of 1082 patients aged 60 years or older who had aneurysms of at least 5·5 cm in diameter and who had been referred to one of 34 hospitals proficient in the EVAR technique. We assigned patients who were anatomically suitable for EVAR and fit for an open repair to EVAR (n=543) or open repair (n=539). Our primary endpoint was all-cause mortality, with secondary endpoints of aneurysm-related mortality, HRQL, postoperative complications, and hospital costs. Analyses were by intention to treat.**

Findings **94% (1017 of 1082) of patients complied with their allocated treatment and 209 died by the end of follow-up on Dec 31, 2004 (53 of aneurysm-related causes). 4 years after randomisation, all-cause mortality was similar in the two groups (about 28%; hazard ratio 0·90, 95% CI 0·69–1·18, p=0·46), although there was a persistent reduction in aneurysm-related deaths in the EVAR group (4% *vs* 7%; 0·55, 0·31–0·96, p=0·04). The proportion of patients with postoperative complications within 4 years of randomisation was 41% in the EVAR group and 9% in the open repair group (4·9, 3·5–6·8, p<0·0001). After 12 months there was negligible difference in HRQL between the two groups. The mean hospital costs per patient up to 4 years were UK£13 257 for the EVAR group versus £9946 for the open repair group (mean difference £3311, SE 690).**

Interpretation **Compared with open repair, EVAR offers no advantage with respect to all-cause mortality and HRQL, is more expensive, and leads to a greater number of complications and reinterventions. However, it does result in a 3% better aneurysm-related survival. The continuing need for interventions mandates ongoing surveillance and longer follow-up of EVAR for detailed cost-effectiveness assessment.**

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Introduction

Endovascular aneurysm repair (EVAR) offers a short-term benefit over open repair for the management of large abdominal aortic aneurysms (AAA).[1,2] However, data from registries—eg, EUROSTAR (European Collaborators Registry on Stent-graft Techniques for AAA Repair) and RETA (Registry for Endovascular Treatment of Aneurysms)[3,4]—indicate the need for close surveillance of endografts over many years, since complications arise in 25–40% of patients who often need additional interventions or conversion to open surgery.[5,6] As the technology of EVAR develops, graft durability should improve and the number of complications reported should fall.[7]

Trials with a similar protocol to EVAR trial 1 are underway in the Netherlands (DREAM), France (ACE), and the USA (OVER).[8] The most advanced of these, the Dutch DREAM trial,[2,9] has focused on short-term combined mortality and morbidity outcomes, and preliminary results suggest that EVAR is not associated with an enduring improvement in health-related quality of life (HRQL) at 12 months.[9] Other studies[10] suggest that EVAR is more expensive than open repair.

Our aim was to assess longterm survival, generalisability, graft durability, HRQL, and hospital costs associated with both EVAR and open repair. Midterm results are presented.

Methods

The detailed methods for EVAR trial 1 have been published.[11] Briefly, recruitment into the trial began on Sept 1, 1999, with 13 eligible UK hospitals. We regarded hospitals as eligible when they had completed 20 EVAR procedures and submitted the data to RETA.[4] During the subsequent 4 years the number of hospitals that had sufficient experience with EVAR increased to 41, though only 34 of these had entered patients into EVAR trial 1 by the end of planned recruitment on Dec 31, 2003. Trained trial coordinators at every centre were responsible for recruitment of patients and data collection. Data were collated centrally and confidentially at the main trial office based at Charing Cross Hospital, Imperial College, London.

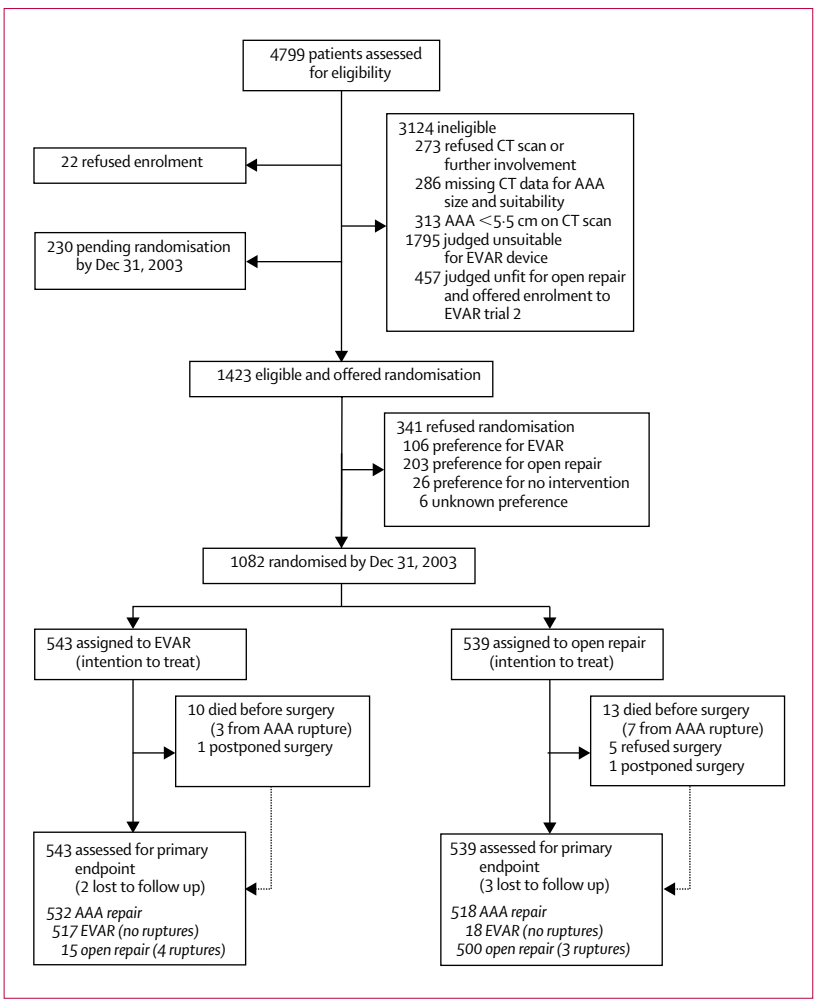

Figure 1: **Trial profile**

Patients

During recruitment, we asked every centre to register all consecutive male and female patients into the EVAR study if they were aged 60 years or older and had an aneurysm that was suspected to measure at least 5·5 cm in diameter in any plane, according to a computed tomography (CT) scan. An interventional radiologist assessed patients for aneurysm diameter and anatomical suitability for EVAR. Patients who were suitable were assessed locally for fitness—ie, anaesthetically and medically well enough—for elective (non-emergency) open repair; we provided guidelines for cardiac, respiratory, and renal status. Patients judged fit for both procedures were offered entry into EVAR trial 1. Patients who were unsuitable for EVAR were offered open repair or surveillance. Patients considered unfit for the open procedure were offered entry into EVAR trial 2.[12]

All patients provided written informed consent, and the study was approved by the North-West Multicentre Research Ethics Committee.

Procedures

The trial manager, independently of the participating centres, undertook randomisation to EVAR or open repair, using a one-to-one ratio in randomly sized permuted blocks stratified by centre. We encouraged centres to do surgery within 30 days of randomisation. All patients were flagged for mortality at the Office for National Statistics and all death certificates were reviewed by an endpoint committee, without knowledge of randomisation, to agree cause of death and assign an *International Classification of Diseases* (ICD) code.[13] Aneurysm-related mortality was defined as all deaths within 30 days of any surgery for AAA unless overruled by post-mortem findings or if a separate procedure (unrelated to the aneurysm) took place between aneurysm repair and death and was attributed as the cause of death. Deaths for which the underlying cause was attributed to ICD10 codes I713–19 were also classified as aneurysm related. We categorised deaths that arose within 30 days of any aneurysm surgery as procedure-related. We also recorded late complications of aneurysm repair (more than 30 days after operation), such as aortoduodenal fistula or aortic rupture after endografting, as procedure-related aneurysm deaths.

After aneurysm repair, we saw patients at 1, 3, and 12 months, and yearly thereafter. To monitor graft durability, we collected CT scan data yearly for all patients in both treatment groups. Patients treated with EVAR had additional CT scans at 1 and 3 months after the procedure. Follow-up for HRQL included completion of the Short Form 36 (SF36)[14] and EuroQol 5-D (EQ5D) weighted index score[15] at 1, 3, and 12 months after surgery. For the main hospital admission, we obtained data on key resource use, including length of hospital stay, duration of procedure, type of device or graft, and the resource implications of complications. We also obtained data on adverse events, such as myocardial infarction, stroke, amputation, or the need for chronic renal dialysis. We recorded postoperative complications relating to the aneurysm and hospital admissions (with associated resource use) for secondary interventions, but not details about use of community-based health services, pharmaceuticals, and hospital stay for reasons other than those listed above. We did not include costs associated with diagnostic tests or imaging before declaration of suitability for EVAR. An independent data monitoring and ethics committee monitored data during the course of the trial. One interim analysis was done in May, 2003, after the first 100 deaths had occurred, but stopping rules did not need to be implemented.

Our primary outcome was all-cause mortality, with secondary outcome measures of aneurysm-related mortality, incidence of postoperative complications of aneurysm repair and secondary interventions, HRQL, and hospital costs.

Statistical analysis

Our recruitment target was 900 patients. With an average follow-up of 3·3 years, this number of patients would yield 80% power to detect at the 5% significance level a reduction in all-cause mortality from 7·5% to 5% per year (174 deaths in total).[11] All analyses were done in accordance with a predefined analysis plan, which was agreed before any outcome data were made available. Patients randomised up to Dec 31, 2003, were included and follow-up was truncated on Dec 31, 2004. All primary and secondary endpoints were analysed by intention to treat.

We used Kaplan-Meier methods to construct survival curves for all-cause and aneurysm-related mortality, and Cox regression to calculate hazard ratios with 95% CIs; hazard ratios of less than 1 favoured the EVAR group. We calculated crude hazard ratios and adjusted them first for age, sex, forced expiratory volume in 1 sec (FEV_1), AAA diameter, log (creatinine), and statin use at baseline, with secondary adjustments for body-mass index (BMI), smoking status, systolic blood pressure, and serum cholesterol concentrations. We selected primary covariates because they are predictors of survival after an open AAA repair,[16] and the secondary covariates because they are known prognostic indicators for cardiovascular mortality.[17,18] We used the missing indicator method—including a dummy variable for every missing baseline covariate—for the adjusted analyses.[19] Patients lost to follow-up were included in all intention-to-treat analyses but censored at their last date known to be alive. We assessed interactions for age, sex, aneurysm diameter, and creatinine, with the last variable dichotomised at its median value.

We established classifications for graft-related complications at the start of the trial, according to the modified guidelines of White and May.[20] In some instances, patients had more than one type of graft complication, but for the purposes of analysis we categorised patients by their most serious complication—for example, if a patient had a type 1 endoleak followed for a period of time, which then deteriorated to graft migration, we classified the patient under migration. Thus, the number of complications is greater than the number of patients. We analysed time from randomisation to first complication and to first secondary intervention with Kaplan-Meier methods, and used Cox regression to calculate hazard ratios between the two randomised groups. We censored patients who did not have a complication or secondary intervention at death, loss to follow-up, or on Dec 31, 2004.

We assessed HRQL after surgery with the EQ5D and SF36 questionnaires, and classified the results into three timepoints from randomisation: 0–3 months, 3–12 months, and 12–24 months. HRQL was summarised by three outcomes: the EQ5D weighted index score and the SF36 physical and mental component summary scores. We did a secondary HRQL analysis at 1, 3, and 12 months after the operation. Differences were adjusted for baseline scores with analysis of covariance.

We calculated hospital costs up to 4 years from randomisation. We based costs on resource-use data collected in the trial case record forms and in questionnaires sent to 41 trial centres (21 completed forms returned by May, 2004), which sought information on centre-specific resource use, such as staffing of procedures, equipment, and consumables used, and routine outpatient follow-up outside of the trial. We costed resource use with local unit costs taken from the questionnaire when possible, or otherwise with national unit costs from routine UK National Health Service (NHS) sources, for the financial year 2003–04·[21–23] We used the method of inverse weighting to estimate mean total costs in each group, and the

	EVAR (n=543)	Open repair (n=539)	Hazard ratio from Cox regression model (95% CI; p)		
			Crude	Primary adjusted*	Secondary adjusted†
Aneurysm-related deaths‡	19	34	0·55 (0·31–0·96; 0·04)	0·55 (0·31–0·96; 0·04)	0·51 (0·29–0·92; 0·02)
Deaths from all causes	100	109	0·90 (0·69–1·18; 0·46)	0·90 (0·69–1·19; 0·46)	0·88 (0·67–1·16; 0·36)

*Adjusted for age, sex, FEV_1, AAA diameter, log (creatinine), and statin use. †Adjusted for variables in primary adjustment plus BMI, smoking, systolic blood pressure, and serum cholesterol. ‡Deaths within 30 days of surgery for AAA plus deaths with underlying cause given as ICD10 codes I713–19.

Table 1: **Aneurysm-related and all-cause mortality (intention-to-treat analysis)**

	EVAR	Open repair
Before operation (n=543 and 539)		
AAA rupture	3	7
Coronary heart disease	1	2
Stroke	0	1
Cardiovascular, other	1	0
Cancer, other	5	1
Respiratory	0	1
Other	0	1
Total	10	13
<30 days after primary operation (n=532 and 518, respectively)		
Procedure related AAA (elective)	7	23
AAA rupture and emergency repair	1	1
Died of rupture after elective AAA repair	1	0
Cardiovascular, other	0	1
Total	9	25
>30 days after primary operation (n=523 and 493, respectively)		
Procedure related AAA (elective)	1	1
Late in-hospital death after AAA rupture	1	0
Died of rupture after elective AAA repair	5	1
Coronary heart disease	22	16
Stroke	9	6
Cardiovascular, other	6	3
Cancer, lung	10	10
Cancer, other	11	17
Respiratory	4	13
Renal	4	1
Other	8	3
Total	81	71

Table 2: **Causes of death by group**

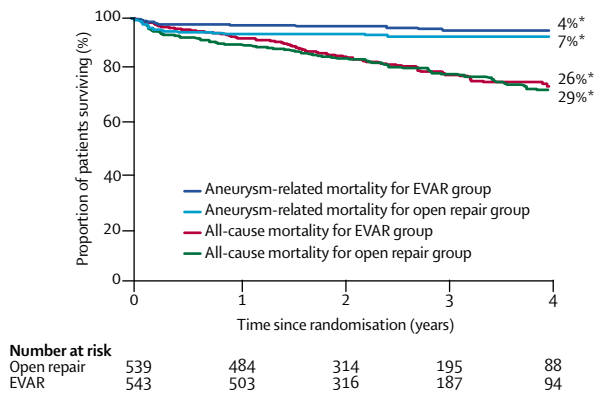

Figure 2: **Kaplan-Meier curve of survival and survival free from aneurysm-related death**
*Mortality 4-year point estimates.

difference in cost, taking into account censoring.[24] We used bootstrap methods to obtain the standard error for the difference in mean costs.[25] We used mean imputation, conditional on treatment group, to impute missing resource-use data. We discounted costs by 3·5% per year.[26]

Role of the funding source

The sponsor of the study had no role in study design, data collection, data analysis, data interpretation, or writing of the report. The corresponding author had full access to all the data in the study and had final responsibility for the decision to submit for publication.

Results

Between September, 1999, and December, 2003, 34 centres registered 4799 patients for consideration for entry into either EVAR trial 1 or 2. Figure 1 shows the trial profile. 1423 patients were eligible; 341 refused to be randomised. Patients who refused were similar to those randomised in terms of their mean age (74 years, SD 7) and the proportion who were men (89%, n=302), but their aneurysm diameter was slightly greater (median 64 cm, IQR 5·9–7·0, p=0·02).

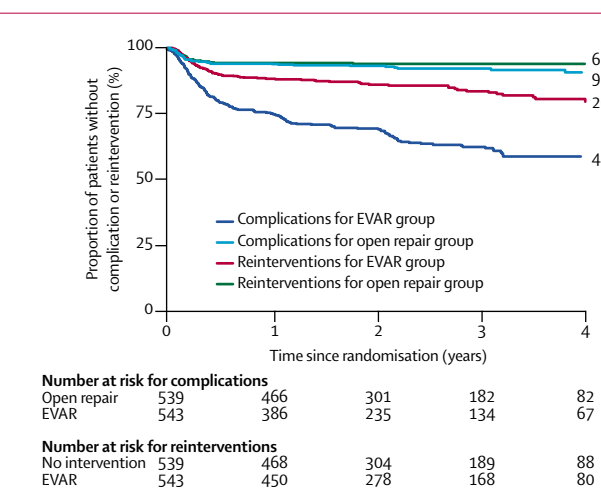

Figure 3: **Kaplan-Meier curve of postoperative complications and reinterventions**
*4-year point estimates for patients with complications or reinterventions.

Table 1 of the first EVAR report[1] shows the baseline characteristics of the two randomised groups, which were similar: mean age 74 years (SD 6), 91% (n=983) men, and median aneurysm diameter 6·2 cm (IQR 5·8–7·0). The median time from randomisation to surgery was 43 days (28–70) for the EVAR group and 36 days (20–59) for the open repair group and, by December, 2004, the median follow-up was 2·9 years (1·9–4·0) with five patients lost to follow-up. More than 99% (n=533) of endovascular repairs used commercially available devices: 272 (51%) Zenith (Cook, Copenhagen, Denmark); 177 (33%) Talent (Medtronic, Minneapolis, MN, USA); 35 (7%) Excluder (Gore, Flagstaff, AZ, USA); 19 (4%) AneuRx (Medtronic); 15 (3%) Quantum or Teramed (Cordis, Waterloo, Belgium); six (1%) Edwards Lifepath (Edwards Lifesciences, Saint-Prex, Switzerland); four (<1%) EVT (Guidaut, Indianapolis, IN, USA); two (<1%) Bard device (Bard, New Jersey, NJ, USA); one (<1%) Anson Aorfix (Lombard Medical, Oxford, UK); one (<1%) Endologix (Endologix, Irvine, CA, USA); one (<1%) Baxter device (Baxter, Deerfield, IL, USA). 90% (n=481) of these grafts were bifurcated and the remainder were aortouni-iliac.

By Dec 31, 2004, 100% of patients had been followed up for 1 year, 70% for 2 years, 47% for 3 years, and 24% for 4 years. There were 209 deaths; 53 aneurysm-related (table 1) and 68 from other cardiovascular disorders (table 2). All-cause mortality at 4 years after randomisation was similar in the two groups (table 1, figure 2). However, there was a persistent difference in aneurysm-related mortality (table 1, figure 2). There were no significant interactions, for either all-cause or aneurysm-related mortality, with age, sex, aneurysm diameter, or creatinine concentration (all p>0·2).

In a post-hoc analysis, we divided the follow-up into the first 6 months after randomisation and the period after 6 months. The hazard ratios for aneurysm-related mortality, comparing the EVAR and open repair groups, were 0·42 (95% CI 0·21–0·82) and 1·15 (0·39–3·41) in the two periods, respectively, the latter having a wide CI because of the few deaths included. The corresponding hazard ratios for total mortality were 0·55 (0·33–0·93) and 1·10 (0·80–1·52).

Analysis by intention to treat for the time from randomisation to first complication and first secondary intervention is shown in figure 3. During the first 4 years of follow-up, the overall rates of complications and reinterventions seemed to diverge between groups. By 4 years, the proportion of patients with at least one complication after AAA repair was 41% in the EVAR

	Successful EVARs completed (n=529)†		Open repairs completed (n=519)†	
	Number of patients with complication	Number of patients with reintervention	Number of patients with complication	Number of patients with reintervention
Graft rupture (9)	9	3	0	0
Graft infection (3)	1	1	2	0
Graft migration (EVAR specific; 14)	12	7		
Endoleak type 1 (EVAR specifc; 29)‡	27	17		
Endoleak type 3 (EVAR specific; 10)‡	8	4		
Graft kinking (EVAR specific; 9)	6	2		
Endotension (EVAR specific; 6)§	6	0	1 (confirmed after open repair)	0
Endoleak type 2 (EVAR specific; 100)‡	79	17	1 (confirmed after open repair)	0
Technical deployment problems (EVAR specific; 2)	2	2		
Unspecified endoleak (EVAR specific; 4)	4	4		
Graft thrombosis (14)	12	10	1	1
Graft stenosis (4)	2	0	1	0
Distal embolisation from graft (2)	1	0	0	0
Renal infarction (3)	3	0	0	0
Anastomotic aneurysm (2)	0	0	1	1
Iliac dilatation (6)	1	1	5	2
Re-exploration of open repair (16)	-	-	16	16
Other surgery required (29)	13 (13)	13	16	16
Total (262 complications in 230 patients)	186 of 529 (35%; 95% CI 31–39)	81 of 529 (15%; 95% CI 12–19)	44 of 519 (8%; 95% CI 6–11)	36 of 519 (7%; 95% CI 5–9)

*In some cases patients have had more than one type of complication. In these cases most serious complication has been used for classification. Complications are listed in order of severity. Total numbers of complications are given in brackets in first column. †535 EVARs attempted: four conversions in theatre, two procedures abandoned. 515 open repairs attempted: four conversions from EVAR to open repair in theatre. ‡Type 1=presence of blood leaking either from top or bottom of graft; type 2=other arteries backbleeding into aortic sac; type 3=structural fault of graft or its limbs. §Continued sac expansion after repair without observed endoleak.

Table 3: **Postoperative complications* after leaving theatre by operation received (not intention to treat)**

group, compared with 9% in the open repair group. Overall rates of complications were 17·6 per 100 person years in the EVAR group and 3·3 per 100 person years in the open repair group (hazard ratio 4·9, 95% CI 3·5–6·8, p<0·0001). Similarly, the proportion of patients with at least one reintervention by 4 years was 20% in the EVAR group and 6% in the open repair group. The rate of at least one reintervention was 6·9 per 100 person years in the EVAR group and 2·4 per 100 person years in the open repair group (2·7, 1·8–4·1, p<0·0001).

The types of postoperative complication and number of reinterventions that arose after EVAR and open repair are shown in table 3. By December, 2004, 186 (35%) of all patients who received EVAR had reported one or more postoperative complications, of whom 81 (44%) needed a secondary intervention, 19 of these during the primary hospital admission. Among the remaining 62 readmissions, two patients (both presenting with graft rupture) died within 30 days of their secondary intervention. In total, there were 14 conversions to open repair after EVAR deployment; four during the primary

	EVAR (n=543): mean (SD) (number of patients)	Open repair (n=539): mean (SD) (number of patients)	Crude difference: mean (SE)	Difference adjusted for baseline score: mean (SE) (number of patients)	p
EQ5D weighted index score*					
Baseline	0·75 (0·22) (541)	0·74 (0·23) (531)	0·01 (0·01)	Ref	
0–3 months	0·73 (0·21) (238)	0·67 (0·25) (245)	0·06 (0·02)	0·05 (0·02) (482)	0·01
3–12 months	0·71 (0·25) (476)	0·73 (0·23) (414)	−0·01 (0·02)	−0·01 (0·01)(885)	0·37
12–24 months	0·74 (0·24) (398)	0·75 (0·25) (371)	−0·01 (0·02)	−0·02 (0·02) (764)	0·29
SF36 physical component summary*					
Baseline	39·92 (5·92) (533)	39·83 (5·90) (534)	0·08 (0·36)	Ref	
0–3 months	37·82 (5·92) (225)	36·14 (5·45) (242)	1·68 (0·53)	1·66 (0·50) (462)	0·001
3–12 months	37·77 (5·73) (466)	37·81 (5·84) (394)	−0·05 (0·40)	0·04 (0·37) (849)	0·91
12–24 months	38·17 (5·83) (359)	38·33 (5·78) (339)	−0·16 (0·44)	−0·15 (0·40) (692)	0·71
SF36 mental component summary*					
Baseline	43·59 (6·79) (533)	43·95 (6·73) (534)	−0·35 (0·41)	Ref	
0–3 months	43·86 (7·02) (225)	44·04 (7·31) (242)	−0·18 (0·66)	−0·05 (0·66) (462)	0·94
3–12 months	44·64 (6·67) (466)	44·18 (6·81) (394)	0·46 (0·46)	0·41 (0·45) (849)	0·36
12–24 months	44·54 (6·43) (359)	44·76 (6·81) (339)	−0·22 (0·50)	−0·29 (0·49) (692)	0·56

*Higher scores indicate better quality of life.

Table 4: **Comparison of HRQL at different timepoints from randomisation**

	EVAR (n=532)*	Open repair (n=518)†
Preoperative embolisation	58 (11%)	4 (1%)
EVAR device	517 (97%)	18 (3%)
Additional EVAR parts (number, number of patients)		
Extenders	114 (88)	3 (3)
Cuffs	16 (15)	0
Metallic non-covered stents	18 (18)	0
Theatre occupation time (min) (mean, SD)	182 (61)	205 (69)
Blood products used (mL) (mean, SD)	164 (520)	896 (1060)
Contrast agent (mL) (mean, SD)	195 (107)	6 (34)
Postoperative interventions	38 (7%)	29 (6%)
Length of stay (days) (mean, SD)		
Preoperative ward	1·9 (2·5)	2·2 (3·1)
Intensive therapy, intensive care, or cardiac intensive care units	0·7 (3·8)	2·4 (5·9)
High dependency or coronary care units	0·9 (2·4)	1·9 (2·8)
Postoperative ward	6·9 (14·6)	9·2 (13·6)
Total length of stay	10·3 (17·8)	15·7 (16·9)
Postoperative dialysis	5 (1%)	11 (2%)

Data are number (%) unless otherwise indicated. *11 and †21 died before, postponed, abandoned, or refused primary procedure.

Table 5: **Resource use during primary hospital admission for patients who had AAA repair**

	EVAR (n=543)	Open repair (n=539)	Mean difference	SE of difference
Primary hospital admission				
Main procedure	7569	2811	4757	108
Hospital stay	3015	6304	−3290	568
Other	235	89	146	34
Total	10 819	9204	1613	607
Secondary procedures, adverse events, scans				
Secondary AAA procedures	1056	200	856	227
Other adverse events	294	359	−65	169
Outpatients/CT scan/ultrasound scan*	1089	182	907	37
Total	2439	741	1698	631
Total cost including 4-year follow up	13 258	9945	3313	690

*Average number of outpatient follow-up appointments, CT and ultrasound scans estimated from a survey of trial centres.

Table 6: **Estimated costs (UK£) over 4 years follow-up based on intention to treat**

theatre procedure, two more during the primary admission, and eight after initial discharge from hospital. By contrast, complications and reinterventions were rare in open repair patients.

At baseline, the EQ5D scores were similar in both groups and to age-matched and sex-matched population norms (table 4).[27] Although the open repair group had a diminished HRQL at 0–3 months, it had recovered by 3–12 months and at 12–24 months after randomisation there was no difference between the groups (table 4). Secondary analyses based on time from surgery did not alter these findings (data not shown).

Mean resource use is shown in table 5. The costs per patient of the primary procedure and hospital admission, on an intention-to-treat basis, were higher in the EVAR group than in the open repair group (table 6).

Discussion

Our midterm results for all-cause and aneurysm-related mortality, together with post-operative complications and reinterventions, HRQL, and hospital costs begin to provide the information from which clinical guidelines might emanate. After 4 years, all-cause mortality did not differ between patients randomised to EVAR and those randomised to open repair of AAA, despite an initial postoperative benefit of EVAR. However, there was a significant difference in the aneurysm-related mortality at 4 years (4% *vs* 7%). This finding accords with the 3% operative mortality difference that we reported for the same patients at 30 days.[1] These favourable results for EVAR in fit patients contrast starkly with the much less favourable results noted in patients considered unfit for open repair and discussed later in this issue of *The Lancet*.[12]

This benefit of aneurysm-related mortality in the EVAR group of EVAR trial 1 persisted despite the presence of a higher number of complications and reinterventions in this group than in the open repair group. Nevertheless, even after exclusion of the fairly benign type 2 endoleaks, late complications are much greater after EVAR than open repair, a fact that has important implications for surveillance and costs. Longterm surveillance does not seem necessary for open-repair patients, but is required after EVAR. Although we priced surveillance in accordance with routine clinical protocols, rather than the more rigorous trial protocol, it added to the increased hospital costs of EVAR versus open repair. We will do a follow-up analysis when more data are available to ascertain whether the rates of complications and reinterventions will diminish over time, or with newer generations of endografts or different types of graft.

There is no clear suggestion that the need for continued surveillance in the EVAR group has affected HRQL scores. Neither SF36 nor EQ5D identified any strong differences between the groups up to 2 years after randomisation. The deterioration of HRQL early after open repair echoes the findings of the DREAM trial.[9] However, though the DREAM trial reported an improved HRQL (EQ5D) for open repair versus EVAR patients after 6 months, our trial showed no difference between the two groups at either 3–12 or 12–24 months.

Of the patients assessed for eligibility, we considered just over half of those with aneurysms of at least 5·5 cm in diameter anatomically suitable for EVAR. Others[28,29] have reported similar degrees of suitability for EVAR. Despite its benefit on 30-day operative mortality EVAR cannot, therefore, displace open repair, and the skills of open repair should be maintained in the training of vascular surgeons.

Midterm results show a 3% aneurysm-related survival benefit for EVAR in fit patients, with increased need for reinterventions and constant surveillance, which increase hospital costs. There is no midterm evidence of all-cause mortality or HRQL benefit from EVAR. Therefore, we have begun a detailed longterm cost-effectiveness evaluation to contribute to guidelines for the use of EVAR in routine clinical practice.

EVAR trial participants

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Conflict of interest statement

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