Comparison of endovascular aneurysm repair with open repair in patients with abdominal aortic aneurysm (EVAR trial 1), 30-day operative mortality results: randomised controlled trial

*The EVAR trial participants**

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Summary

Background **Endovascular aneurysm repair (EVAR) is a new technology to treat patients with abdominal aortic aneurysm (AAA) when the anatomy is suitable. Uncertainty exists about how endovascular repair compares with conventional open surgery. EVAR trial 1 was instigated to compare these treatments in patients judged fit for open AAA repair.**

Methods **Between 1999 and 2003, 1082 elective (non-emergency) patients were randomised to receive either EVAR (n=543) or open AAA repair (n=539). Patients aged at least 60 years with aneurysms of diameter 5·5 cm or more, who were fit enough for open surgical repair (anaesthetically and medically well enough for the procedure), were recruited for the study at 41 British hospitals proficient in the EVAR technique. The primary outcome measure is all-cause mortality and these results will be released in 2005. The primary analysis presented here is operative mortality by intention to treat and a secondary analysis was done in per-protocol patients.**

Findings **Patients (983 men, 99 women) had a mean age of 74 years (SD 6) and mean AAA diameter of 6·5 cm (SD 1). 1047 (97%) patients underwent AAA repair and 1008 (93%) received their allocated treatment. 30-day mortality in the EVAR group was 1·7% (9/531) versus 4·7% (24/516) in the open repair group (odds ratio 0·35 [95% CI 0·16–0·77], p=0·009). By per-protocol analysis, 30-day mortality for EVAR was 1·6% (8/512) versus 4·6% (23/496) for open repair (0·33 [0·15–0·74], p=0·007). Secondary interventions were more common in patients allocated EVAR (9·8% *vs* 5·8%, p=0·02).**

Interpretation **In patients with large AAAs, treatment by EVAR reduced the 30-day operative mortality by two-thirds compared with open repair. Any change in clinical practice should await durability and longer term results.**

Introduction

Rupture of an abdominal aortic aneurysm (AAA) is usually fatal. For more than 50 years aortic aneurysms have been treated with prophylactic open surgical repair,[1] a major surgical procedure done under general anaesthesia, usually consisting of a midline laparotomy and cross-clamping of the aorta for at least 30 min. This technique has an associated 30-day mortality of 4–12%;[2] however, graft durability is generally for 20–30 years and sees most patients through to the end of their lives.

In the early 1990s, Volodos in the Ukraine[3] and Parodi, Palmaz, and Barone in Argentina[4] introduced a less invasive endovascular method for AAA repair. Over time, these pioneering devices were improved, and commercial development of the technology has meant that the technique has spread worldwide. Briefly, the endovascular aneurysm repair (EVAR) procedure can be done percutaneously but usually consists of two small incisions in the groin to expose the femoral arteries. The sheathed Dacron or PTFE (polytetrafluoroethylene) graft and stents are fed through these arteries with catheters and guidewires until the graft is positioned correctly at the top and bottom of the aneurysmal segment of aorta. Removal of the sheath with or without balloon expansion allows barbs or other fixing mechanisms to attach to the artery wall and hold the graft firm, allowing blood to pass through it and remove pressure from the diseased aortic wall.

Two open voluntary registries have proved successful at monitoring the progress and development of EVAR over the past 8 years. The UK Registry for Endovascular Treatment of Aneurysms (RETA) was started in 1996,[5] and the European EUROSTAR initiative in 1999.[6] These registries have indicated that the 30-day mortality after EVAR could be as high as 2·9% and 3·1%,[7,8] but findings of other studies have estimated lower mortalities.[9] Even though technological development of endovascular grafts continues, durability remains uncertain, and therefore the evolving technology should be tested in a randomised trial.

The EVAR 1 trial started recruitment in September, 1999. The underlying hypothesis, based on annual mortality rates of 7·5% and 5%, allows the possibility that EVAR may improve survival after 3 years from 79% to 86%. Subsequently, other similar trials, including the Dutch DREAM trial,[10] have commenced, but most of these studies are powered on shorter-term combined mortality and morbidity outcomes. Here, we report the first results from EVAR 1 of 30-day operative mortality.

The important long-term outcomes of all-cause mortality, graft durability, quality of life, and cost-effectiveness for EVAR 1 and the associated EVAR 2 trial (a randomised trial of EVAR with best medical treatment versus best medical treatment alone in patients unfit [anaesthetically and medically not well enough] for open repair) are scheduled for release in 2005.

Methods

Detailed methods for the EVAR 1 trial have been published elsewhere.[11] In summary, recruitment into the trial began on Sept 1, 1999, with just 13 eligible UK centres. During the subsequent 4 years, the number of centres that showed sufficient experience with EVAR rose to 41, although only 34 of these had entered patients into the trial by the end of planned recruitment in December, 2003. National experience was monitored by the RETA registry in Sheffield and centres were invited to submit their EVAR experience to this registry, who informed the EVAR trial management committee once a hospital had done at least 20 EVAR procedures satisfactorily. At this point, the centre was invited to participate in the EVAR trials and, if accepted, a vascular surgeon, interventional radiologist, and trial coordinator were nominated, with responsibility for patients' recruitment and follow-up. Full training of the trial coordinator was needed before any patients could be recruited. Ethics approval for the studies was granted by the northwest multicentre research ethics committee and local approval was arranged at every centre.

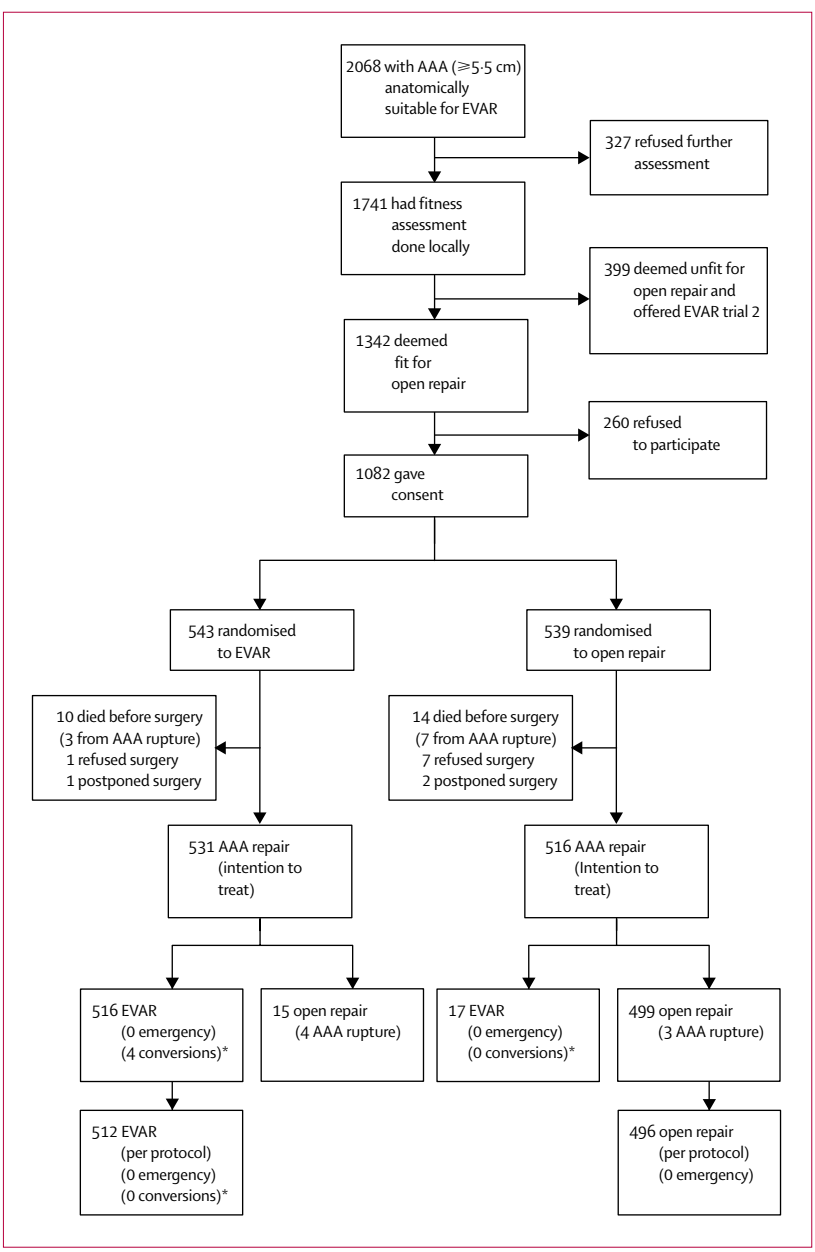

Figure: **Trial profile**
*Conversion from EVAR to open repair in theatre during primary admission.

Patients

During the recruitment phase (September, 1999, to December, 2003), eligible patients of both sexes aged at least 60 years were identified in whom computed tomography had indicated the presence of an aneurysm 5·5 cm or more in diameter, which was regarded as anatomically suitable for EVAR. After clinical assessment, patients were assessed locally for their fitness (ie, anaesthetically and medically well enough) for elective (non-emergency) open aneurysm repair, with guidelines provided for recommended levels of cardiac, respiratory, and renal function.[11] Patients deemed unfit for open repair were considered for a separate trial, EVAR 2.[11] We obtained signed consent for randomisation from patients eligible for EVAR 1.

Procedures

We randomly allocated patients to either open AAA repair or EVAR. Randomisation used a 1/1 ratio in randomly permuted block sizes constructed by the STATA version 8 (Stata Corporation, TX, USA). Randomisation was stratified by centre and was done centrally by the trial manager only when all necessary baseline data had been received at the trial coordinating centre at Imperial College, London, UK.

Surgery was done according to typical local procedures, and we encouraged centres to undertake the aneurysm repair within 1 month of randomisation. The excess treatment costs of EVAR were provided by the UK NHS Executive triggered by randomisation or by private insurers—British United Providential Association and AXA Private Patient Plan Healthcare—who funded only on the basis of a randomised controlled trial. Patients were flagged at the Office for National Statistics for mortality and cause of death. An operative case record form was obtained that included perioperative data, length of hospital stay, and mortality information. All patients were followed up at 30 days.

Statistical analysis

The primary outcome measure for EVAR 1 is all-cause mortality with target recruitment of 900 patients.[11] The trial also had 90% power, at the 5% significance level, to detect a difference in 30-day operative mortality of 5·8% for open repair versus 1·5% for EVAR.

During the course of the trial, a closed and confidential data monitoring and ethics committee reviewed results and, to date, stopping rules have not been implemented. Neither the trialists nor any other person had access to the results. The writing committee saw operative mortality data 4 weeks before manuscript submission.

We analysed data according to a plan drawn up before the mortality results were available. We included all operations undertaken up to July 1, 2004. The main analysis compared the groups by intention to treat, only including those who underwent aneurysm repair. A further per-protocol analysis was done, comparing outcomes by randomised group for patients who received the allocated elective treatment. This analysis excluded emergency AAA repairs (all open repairs) and patients who converted from EVAR to open repair in theatre during the primary procedure.

We used logistic regression modelling to compare the treatment groups in terms of 30-day operative mortality and in-hospital mortality. We calculated odds ratios that were crude and adjusted for age, sex, FEV_1 (forced expiratory volume in 1 s), AAA diameter, log[creatinine], statin use, and time between randomisation and surgery. These variables were selected because they are known predictors of survival after open surgical repair[12] and statins have been implicated in offering a potential survival benefit for patients undergoing vascular surgery.[13]

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, 2068 patients were identified with an aneurysm measuring at least 5·5 cm that was judged anatomically suitable for EVAR and 1342 (65%) of these were regarded as fit for elective open aneurysm repair (figure). Signed consent for randomisation was obtained from 1082 (81%) patients. 543 were randomised to EVAR and 539 to open repair. 512 (94%) patients in the EVAR group received their intended elective treatment compared with 496 (92%) in the open repair group. Aneurysm rupture leading to death before surgery or emergency open repair happened in 17 patients, seven in the EVAR group and ten in the open repair group (figure). 15 patients randomised to EVAR underwent an open repair (four by patient preference, four altered aneurysm anatomy, four ruptured aortic aneurysm, and three unknown) and 17 allocated open repair underwent EVAR (12 by patient preference, four unfit for open repair, and one unknown). In total, 35 (3%) patients had not undergone aneurysm repair by July 1, 2004. Of these, eight had refused surgery after randomisation, three became unfit and the operations were postponed, and 24 had died before AAA surgery.

The two groups were well matched for baseline characteristics (table 1). The median number of days between randomisation and surgery was 43 days (IQR 28–69) in the EVAR group and 35 (IQR 19–55) in the open repair group (logrank test p=0·0004), but patient age at surgery did not differ. More than 99% of endovascular repairs used commercially available devices: 51% Zenith (Cook, Copenhagen, Denmark), 33% Talent (Medtronic, Minneapolis, MN, USA), 7% Excluder (Gore, Flagstaff, AZ, USA), 4% AneuRx (Medtronic), 2% Quantum or Teramed (Cordis, Waterloo, Belgium). 90% of these grafts were bifurcated and the remainder were aorto-uni-iliac.

The intention-to-treat analysis showed that 30-day and in-hospital mortality were two-thirds lower in the EVAR group than in the open repair group, and adjustment for baseline covariates did not alter the benefit of EVAR (table 2). Nine deaths happened within 30 days in the EVAR group, including one after emergency open repair for AAA rupture and two from aneurysmal rupture after repair; two further in-hospital deaths arose, including one after emergency open repair of AAA rupture. 24 deaths arose within 30 days in the open repair group, including one after emergency open repair for

	EVAR (n=543)	Open repair (n=539)
Age at randomisation (years)	74·2 (6·0)	74·0 (6·1)
Men	494 (91%)	489 (91%)
Body-mass index (kg/m²)	26·4 (4·6)	26·4 (4·4)
AAA diameter (cm)	6·5 (0·9)	6·5 (1·0)
Diabetes	49 (9%)	62 (12%)
Current smokers	115 (21%)	117 (22%)
Past smokers	367 (68%)	380 (70%)
Never smoked	61 (11%)	41 (8%)
Previous history of cardiac disease*	234 (44%)	229 (43%)
Aspirin use	292 (54%)	280 (52%)
Statin use	177 (33%)	181 (34%)
Systolic blood pressure (mm Hg)	148 (22)	147 (22)
Diastolic blood pressure (mm Hg)	82 (12)	82 (13)
Ankle-brachial pressure index (mean of both legs)	1·01 (0·18)	1·03 (0·18)
FEV_1 (L)	2·1 (0·7)	2·1 (0·7)
Serum creatinine (μmol/L)†	102 (91–118)	102 (90–119)
Serum cholesterol (mmol/L)	5·1 (1·2)	5·1 (1·1)

Data are mean (SD) or number of patients (%), unless otherwise indicated. Numbers do not always add up to totals in group because of occasional missing values. *Cardiac disease classified as history of any of the following: myocardial infarction, cardiac revascularisation, angina, cardiac valve disease, significant arrhythmia, and uncontrolled congestive cardiac failure. †Creatinine was positively skewed and data are presented as median (IQR).

Table 1: **Baseline characteristics**

	EVAR	Open repair	Odds ratio (95% CI)				p
			Crude	p	Adjusted*	p	
Outcome by intention to treat (number of patients)	531	516					
30-day mortality (number of deaths)	1·7% (9)	4·7% (24)	0·35 (0·16–0·77)	0·009	0·37 (0·17–0·83)	0·016	
In-hospital mortality (number of deaths)	2·1% (11)	6·2% (32)	0·32 (0·16–0·64)	0·001	0·30 (0·14–0·62)	0·001	
Median (IQR) length of hospital stay (days)†	7 (5–10)	12 (9–16)					<0·0001‡
Median (IQR) length of operation (min)†	180 (140–215)	200 (155–240)					<0·0001‡
Secondary interventions either during 30 days or during the primary admission							
Conversion to open repair	10	0					
Correction of endoleak	18	1					
Re-exploration of open repair	1	15					
Other surgery	21	14					
Unknown	2	0					
Total	52 (9·8%)	30 (5·8%)					0·02§
Outcome by per protocol (number of patients)	512	496					
30-day mortality (number of deaths)	1·6% (8)	4·6% (23)	0·33 (0·15–0·74)	0·007	0·34 (0·15–0·78)	0·011	
In-hospital mortality (number of deaths)	1·6% (8)	6·0% (30)	0·25 (0·11–0·54)	0·001	0·24 (0·11–0·54)	0·001	

*Adjusted for age, sex, FEV_1, AAA diameter, log[creatinine], statin use, and time from randomisation to surgery. †For primary procedure only. ‡Mann-Whitney test. §χ^2 test.

Table 2: **Outcome by intention-to-treat and per-protocol analysis**

aneurysmal rupture and one from AAA rupture after open repair; eight further in-hospital deaths happened after open repair, including one after emergency repair for rupture. Compared with the open repair group, both the time spent in theatre and length of stay in hospital were lower in the EVAR group (table 2). During the primary EVAR procedure, four patients converted to an open repair. However, almost 75% more secondary interventions were undertaken either within 30 days of the procedure or within the same admission in the EVAR group than in the open repair group (table 2).

Per-protocol analysis showed that 30-day mortality was two-thirds lower and in-hospital mortality three-quarters lower in patients who had received EVAR. Adjustment for baseline covariates did not alter by much the benefit of EVAR (table 2).

Discussion

We have shown a clear short-term survival benefit of EVAR, with 1·7% of patients dying by 30 days compared with 4·7% of those allocated open repair. EVAR had at least two-thirds lower 30-day and in-hospital mortality compared with open repair. Whether this early benefit will be sustained is not yet known, particularly since (according to EUROSTAR)[6] further interventions might be needed in at least 25% of patients who have undergone endovascular repair, and a 1% annual risk of AAA rupture remains after endografting.[14,15] Even with short-term follow-up, secondary interventions were more usual in the EVAR group than the open repair group.

The EVAR 1 trial over-recruited, with 1082 patients (81% of those eligible), making it one of the largest of the planned trials of endovascular versus open AAA repair.[16] To our knowledge, this trial is one of the first randomised comparisons of EVAR and open repair, all previous reports being based on cohort and retrospective comparisons.[9,17] Only patients with large aneurysms (⩾5·5 cm) were considered for EVAR 1. Although many published series for endovascular AAA repair included patients with small AAA, findings of randomised trials showed that early elective open AAA repair did not improve 5-year patient survival.[18–20]

We should recognise that patients recruited into EVAR 1 were a subgroup of all AAA patients in whom the aortic anatomy seemed to be suitable for EVAR. Suitability varies between both devices and manufacturers; the generalisability of our findings is still uncertain, with estimates for the proportion of aneurysm patients in whom EVAR is possible ranging from a third to two-thirds.[21–23] Favourable anatomical selection criteria, such as defined aneurysm neck, might have had additional effects to facilitate the placement of an inlay graft at open repair.

30-day mortality for EVAR (1·7%) was lower than that reported by the registries (RETA[5] and EUROSTAR[6]), perhaps because the EVAR 1 trial only included patients judged fit for open surgery.[11] 30-day mortality for open surgery (4·7%) also was lower than that reported in prospective population studies,[2,12] possibly because of the technical factors discussed above; however, the results in both arms of the trial compare well with a large observational comparison based in the USA.[17] Open repair 30-day mortalities that are lower than ours have been quoted in some university centres, but ours is a multicentre trial, with patients from university hospitals and regional centres, representing institutions at which EVAR is done in the UK today, and therefore they are very applicable to the real clinical setting. Too few deaths occurred to comment on any possible heterogeneity by recruitment date or other factors. In addition to the benefits on mortality, patients allocated EVAR were discharged from hospital much earlier after the procedure than were those assigned open repair.

Although the time between randomisation and surgery was longer for patients allocated EVAR, this difference did not result in an increase in the number of

AAA ruptures before the planned surgery. Furthermore, if preoperative deaths are added to the 30-day postoperative mortality, yielding a mortality rate of 3·5% (19/543) in the EVAR group and 7·1% (38/539) in the open repair group, the absolute difference in death rates between the groups remains similar to that for 30-day mortality alone.

The choice of endografts used was made by the individual centres. The technology of endovascular repair continues to develop, and during the course of the trial new endografts reached the market (and were used in the trial); safety alerts have been issued about some devices.[24] This finding only underscores the importance of waiting for long-term survival, durability, and other outcomes before changing any policies of clinical practice; these results will become available in 2005.

These early results with EVAR, applied to large aneurysms in patients judged fit for open repair, provide justification for continued use of this technique in controlled or trial settings; however, the early promise of endovascular repair cannot be guaranteed and might not endure in the long term. The 30-day mortality results are a licence to continue scientific evaluation of EVAR, but not to change clinical practice.

Contributions

The authors of this paper are the EVAR trial participants, who include all trial committee members and vascular surgeons, radiologists, and trial coordinators from all trial centres and supporting hospitals. The responsibility of the running of the trial was in the hands of the trial management committee, which was chaired by R M Greenhalgh. The writing committee shared responsibility for drafting the paper according to their disciplines, and all drafts and changes were passed through L C Brown, the trial manager. J T Powell contributed greatly to the quality of the manuscript. S G Thompson is the lead statistician for the trial. G P S Kwong undertook analyses. R M Greenhalgh was responsible for the final content of the manuscript.

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Conflict of interest statement

RMG has benefited from research support from manufacturers of endovascular grafts, Cook, Boston Scientific, and Bard. These companies, with W L Gore, Medtronic, and Edwards Lifesciences, are major sponsors of the annual international Charing Cross Symposium. None of the other members of the writing committee have a conflict of interest.

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