Articles

Mortality results for randomised controlled trial of early elective surgery or ultrasonographic surveillance for small abdominal aortic aneurysms

*The UK Small Aneurysm Trial Participants**

Summary

Background Early elective surgery may prevent rupture of abdominal aortic aneurysms, but mortality is 5–6%. The risk of rupture seems to be low for aneurysms smaller than 5 cm. We investigated whether prophylactic open surgery decreased long-term mortality risks for small aneurysms.

Methods We randomly assigned 1090 patients aged 60–76 years, with symptomless abdominal aortic aneurysms 4·0–5·5 cm in diameter to undergo early elective open surgery (n=563) or ultrasonographic surveillance (n=527). Patients were followed up for a mean of 4·6 years. If the diameter of aneurysms in the surveillance group exceeded 5·5 cm, surgical repair was recommended. The primary endpoint was death. Mortality analyses were done by intention to treat.

Findings The two groups had similar cardiovascular risk factors at baseline. 93% of patients adhered to the assigned treatment. 309 patients died during follow-up. The overall hazard ratio for all-cause mortality in the early-surgery group compared with the surveillance group was 0·94 (95% CI 0·75–1·17, p=0·56). The 30-day operative mortality in the early-surgery group was 5·8%, which led to a survival disadvantage for these patients early in the trial. Mortality did not differ significantly between groups at 2 years, 4 years, or 6 years. Age, sex, or initial aneurysm size did not modify the overall hazard ratio.

Interpretation Ultrasonographic surveillance for small abdominal aortic aneurysms is safe, and early surgery does not provide a long-term survival advantage. Our results do not support a policy of open surgical repair for abdominal aortic aneurysms of 4·0–5·5 cm in diameter.

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*Trial members and participants listed at end of paper

Correspondence to: Prof J T Powell, Department of Vascular Surgery, Imperial College School of Medicine, Charing Cross Hospital, London W6 8RF, UK
(e-mail: j.powell@ic.ac.uk)

Introduction

Abdominal aortic aneurysms commonly remain symptomless until they rupture. Aneurysms are an important cause of sudden death[1] and form a large part of the vascular surgical caseload.[2] Necropsy studies and clinical studies have suggested that the risk of rupture accelerates with increasing aortic diameter.[3,4] Surgeons, therefore, generally recommend prophylactic repair of aneurysms of more than 6·0 cm in diameter (which is about three times larger than the normal aortic diameter). There is, however, uncertainty about whether prophylactic repair is the best management for smaller symptomless aneurysms of 4·0–5·9 cm in diameter. Ultrasonographic screening studies of the general population in the UK show that 1·5–3·0% of men older than 60 years have occult aneurysms in this size range.[5–8]

There is currently no medical therapy that can prevent aneurysm growth and decrease the risk of rupture. The only available treatment for smaller abdominal aortic aneurysms is the insertion of a prosthetic aortic graft. Traditionally, surgery has been an elective open procedure with a 30-day operative mortality risk of 5–6%.[9,10] Endovascular repair has been introduced, but this technique is still under development and also has a high risk of procedure-associated mortality.[11] Elective aneurysm surgery is, however, safer than emergency repair of a ruptured aortic aneurysm, for which the 30-day mortality is 40–50%.[12,13]

It is not clear whether a policy of open surgical repair of small abdominal aortic aneurysms is preferable to a policy of surveillance, which has an higher risk of aneurysm rupture and death. Vascular surgeons in the UK, Canada, and the USA have been participating in three separate randomised trials to test the hypothesis that early, prophylactic elective surgery decreases the long-term mortality for patients with small abdominal aortic aneurysms (4·0–5·5 cm). This diameter range was selected by vascular surgeons in the UK, where the first trial started.[14] The Canadian trial ended early because of inadequate recruitment (C William Cole, personal communication) and the US trial[15] is continuing (Frank Lederle, personal communication). In the UK Small Aneurysm Trial,[16] 1090 patients were randomised between 1991 and 1995 to undergo early elective open surgical repair or regular ultrasonographic surveillance of aortic diameter. We report on the all-cause mortality results of the UK trial.

Methods

The methods have been described elsewhere.[16] In 93 UK hospitals between September, 1991, and October, 1995, 1276 patients aged 60–76 years who were fit for elective surgery were identified as having symptomless (non-tender), infrarenal,

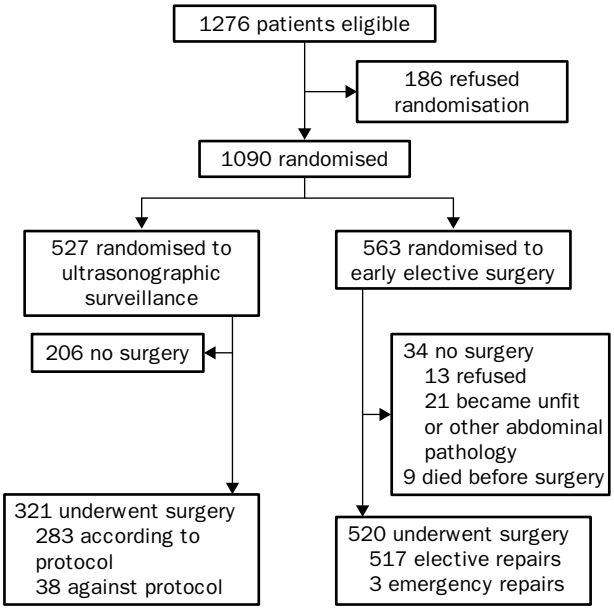
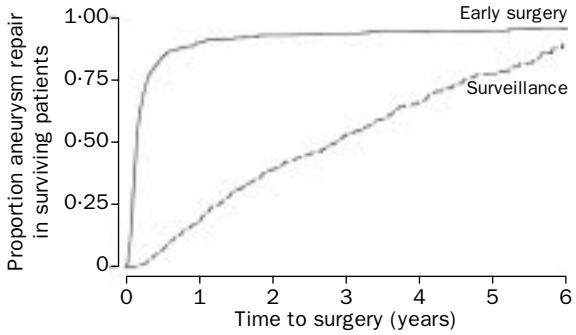


Figure 1: **Trial profile**



Number at risk

Early surgery	563	54	38	32	14	9	1
Surveillance	527	409	292	197	77	29	6

Figure 2: **Cumulative proportion of surviving patients undergoing surgery for aneurysm repair according to time since randomisation, by treatment group**
Kaplan-Meier estimates, with deaths taken as censoring.

abdominal aortic aneurysms of 4·0–5·5 cm in diameter. About half of these patients (610) were referred to vascular surgeons from another hospital clinic, 288 by their family physicians, 234 from screening programmes, 111 from hospitals not participating in the trial, and 33 patients from other sources. We excluded patients who were unfit for elective surgery, had symptoms associated the aneurysm, were unable to attend for follow-up, were unable to give informed consent, or in whom the aneurysm was tender. We obtained informed consent before randomisation from 1090 patients (85%).

Patients were randomly assigned to undergo surgery or ultrasonographic surveillance of aneurysm diameter. Randomisation was done centrally over the telephone by computer-generated simple random numbers. We recruited vascular surgeons by open invitation and obtained approval from local research ethics committees. Only one committee declined approval and the surgeon involved did not participate in the trial. Five specially trained regional trial coordinators reviewed eligible patients with the local vascular surgeon. At randomisation, the trial coordinators collected data on characteristics of the patients, previous medical history, diameter of abdominal aortic aneurysm (maximum anterior-posterior diameter by ultrasonography with an Aloka SSD500 with a 3·5 MHz transducer, Keymed, Southend, UK), lung function (forced expiratory volume in 1 s [FEV_1] and forced vital capacity [FVC]), electrocardiography at rest, ankle/brachial pressure index, quality of life (SF20 questionnaire), and laboratory blood tests. The regional trial coordinators met every 6 months to ensure uniformity of measurements, data collection, and coding procedures. The repeatability of measurement of aneurysm diameter was ±0·2 cm.

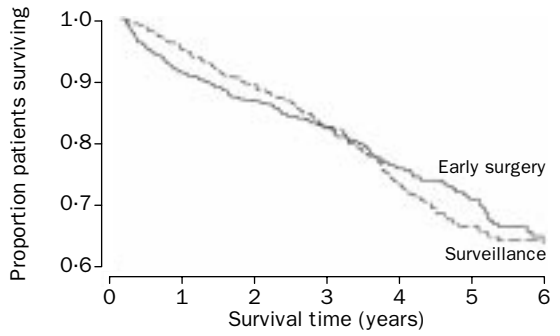
Treatment and follow-up

Surgery was performed according to normal local procedures. Patients randomised to ultrasonographic surveillance were reviewed at regular intervals by the trial coordinators, who measured aneurysm diameter and reported to the local surgeon. Patients with aneurysms of 4·0–4·9 cm in diameter were reviewed every 6 months, and those with aeurysms of 5·0–5·5 cm in diameter were reviewed every 3 months. If diameter of the aortic aneurysm exceeded 5·5 cm, the growth rate was more than 1 cm per year, the aneurysm became tender, or iliac or thoracic repair of an aneurysm was needed, elective surgical repair was recommended to the patient. 1 month after surgery, patients were reviewed by the participating surgeon. All randomised patients were flagged at the Office of National Statistics to enable us to obtain automatic notification of emigration, death, and underlying cause of death. All deaths that occurred within 2 weeks of elective surgery were attributed to abdominal aortic aneurysm. At the end of the trial, we contacted all remaining patients directly, to check survival status.

Variable*	Surveillance (n=527)	Early surgery (n=563)	Refused randomisation (n=186)
Mean (SD) age (years)	69·2 (4·4)	69·3 (4·4)	70·3 (4·3)
Sex (M/F)	434 (82%)/93 (18%)	468 (83%)/95 (17%)	146 (78%)/40 (22%)
Smoking status (2)			
Current	182 (34%)	222 (40%)	76 (43%)
Ex	314 (60%)	306 (54%)	92 (51%)
Never	31 (6%)	33 (6%)	11 (6%)
History of diabetes (2)	16 (3%)	14 (2%)	9 (5%)
History of hypertension (4)	209 (40%)	210 (38%)	71 (40%)
Ischaemic heart disease on ECG (19)			
Probable	66 (13%)	82 (15%)	25 (16%)
Possible	146 (28%)	143 (26%)	45 (29%)
Unlikely	305 (59%)	329 (59%)	85 (55%)
Aneurysm diameter (cm)	4·61 (0·37)	4·63 (0·40)	4·53 (0·41)
Body-mass index ([kg/m^2] 12)	25·2 (3·8)	24·8 (3·5)	25·2 (3·9)
Systolic blood pressure ([mm Hg] 3)	156·7 (26·6)	154·7 (26·4)	158·3 (25·0)
Cholesterol ([mmol/L] 15)	6·18 (1·18)	6·13 (1·20)	6·26 (1·17)
Fibrinogen ([g/L] 32)	4·42 (1·38)	4·45 (1·30)	NA
Right ABPI (18)	0·95 (0·22)	0·96 (0·21)	0·94 (0·24)
Left ABPI (19)	0·95 (0·22)	0·95 (0·21)	0·94 (0·23)
FEV_1 ([L] 27)	2·13 (0·75)	2·20 (0·73)	2·07 (0·78)
FVC ([L] 27)	3·08 (0·81)	3·19 (0·85)	3·01 (0·89)
Aspirin use	152 (29%)	147 (26%)	44 (24%)
β-blocker use	82 (16%)	83 (15%)	30 (17%)

ECG=electrocardiography; ABPI=ankle/brachial pressure index; NA=not available. *Numbers in brackets=number missing values for 1090 randomised patients.

Table 1: **Baseline characteristics of patients in randomised groups and those refusing randomisation**



Number at risk

Surveillance	527	497	468	412	229	125	52
Early surgery	563	513	489	450	302	187	63

Figure 3: **Overall survival by treatment group**
Kaplan-Meier estimates, log-rank test p=0·56.

Our primary endpoint was death. Other outcome measures were aneurysm rupture and death from surgical repair of abdominal aortic aneurysm.

Statistical analysis

The trial was designed to have 80% power to show a significant difference at the 5% level in 5-year all-cause mortality between the two treatments, estimated at 29% and 38% for early elective surgery and ultrasonographic surveillance, respectively. The required recruitment was 1000 patients with 5 years of follow up.[16] The date for the end of trial was June 30, 1998, which gave a mean of 4·6 years of follow-up per patient (range 2·6–6·9).

The independent data monitoring and ethics committee reviewed the data after every 70 deaths, focusing on 30-day mortality after elective surgery and comparing mortality in the two groups. Monitoring boundaries based on the O'Brien and Fleming rule[17] were used for decision making about continuation of the trial.

Analysis was done according to a plan drawn up before the mortality results were revealed. The main mortality analyses were done by intention to treat. We included deaths occurring up to June 30, 1998, provided they were recorded by Sept 30, 1998. We compared Kaplan-Meier survival curves for time since randomisation with a log-rank test. We used Cox's proportional hazards regression to estimate hazard ratios and to adjust for sex, smoking status, initial aneurysm diameter, mean of left and right ankle/brachial pressure index, FEV_1, use of aspirin, source or referral, regional centre, type of hospital (teaching or district), and treatment group. All non-categorical covariates were kept as continuous variables in the analysis (linear terms provided adequate fits to the data), but we present results as tertile groups. Because non-proportional hazards were anticipated, we calculated risk differences between the two randomised groups at 2 years, 4 years, and 6 years. We separated the first 6 months after randomisation from the subsequent follow-up for descriptive purposes. Whether age, sex, and initial aneurysm size affected the overall hazard ratio was assessed by tests of interaction in the Cox's regression analysis. We did secondary analyses of the time from randomisation until aneurysm surgery and the time after surgery for each group. Aneurysm growth rates were calculated by linear regression analysis.

Results

Of the 1090 patients (902 men and 188 women) who consented to randomisation, 563 (52%) were assigned to undergo early elective surgery and 527 (48%) to undergo ultrasonographic surveillance. Of the 563 patients in the early-surgery group, elective aneurysm repair with a prosthetic inlay graft was done in 517. In 452 (87%) of these patients, the operation was done within 5 months of randomisation. The median time to surgery was 1·8 months (IQR 1·1–3·6). In two further patients, emergency aneurysm repair for rupture was performed within 4 months of randomisation. At laparotomy, two further patients were found to have other abdominal pathology and the aneurysm repair was not completed. Of the remaining 42 patients assigned to early surgery, nine died before admission for surgery, 19 became unfit for elective surgery before admission, and 14 refused surgery after randomisation. One of those who refused underwent emergency repair of a ruptured aneurysm 18 months after randomisation.

Of the patients assigned to ultrasonographic surveillance, 489 patients adhered to trial protocol and did not undergo surgery until the diameter or the abdominal aortic aneurysm was more than 5·5 cm, increased by more than 1 cm per year, or became tender

Group	Number of deaths/number of patients (rate per 100 person-years)		Hazard ratio (95% CI)*	p
	Surveillance	Early surgery		
Patient-years of follow-up	2022	2262	. .	. .
Overall				
Unadjusted	150/527 (7·4)	159/563 (7·0)	0·94 (0·75–1·17)	. .
Adjusted†	. .	. .	0·91 (0·72–1·16)	. .
Adjusted‡	. .	. .	0·94 (0·74–1·19)	. .
By time period				
Months 0–6 adjusted‡§	12/527 (4·6)	31/563 (11·4)	2·52 (1·20–5·33)	. .
Months >6 adjusted‡	138/515 (7·8)	128/532 (6·4)	0·82 (0·64–1·06)	. .
By subgroup‡				
Age ([years], tertile groups)				
60–66	42/181 (5·8)	36/183 (4·7)	0·76	0·10‖
67–71	60/180 (8·9)	51/183 (6·8)	0·80	. .
72–76	48/166 (7·6)	72/197 (9·5)	1·25	. .
Sex				
Men	123/434 (7·3)	131/468 (6·9)	0·90	0·42‖
Women	27/93 (7·9)	28/95 (7·7)	1·16	. .
Aneurysm diameter ([cm], tertile groups)				
4·0–4·4	53/213 (6·5)	63/214 (7·4)	1·14	0·26‖
4·5–4·8	45/169 (6·8)	45/175 (6·3)	0·88	. .
4·9–5·5	52/145 (9·5)	51/174 (7·4)	0·79	. .

*For early-surgery group relative to surveillance group. †Adjusted for baseline factors, sex, smoking status, initial aneurysm diameter, mean of left and right ankle/brachial pressure index, forced expiratory volume in 1 s, as well as aspirin use. ‡Adjusted for baseline factors (as †) and source of referral (general practice, other clinic, other), regional centre, and type of hospital (teaching, district general). §Rates/6 months of 2·3 and 5·7 per 100 patients.‖ Test of interaction.

Table 2: **Overall mortality by randomised group, and by prespecified time periods and subgroups**

Factor	Number of deaths / number of patients	Crude death rate (per 100 person-years)	Adjusted hazard ratio (95% CI)*	Adjusted p*
Age ([years] tertile groups)				
60–66	78/364	5·3	. .	. .
67–71	111/363	7·8	1·04 per year (1·01–1·07)	. .
72–76	120/363	8·7	. .	0·01
Sex				
Men	254/902	7·1	1·13 (0·81–1·57)	. .
Women	55/188	7·8	1·0†	0·47
Smoking status				
Current	133/404	8·7	1·26 (0·98–1·61)	. .
Ex	159/620	6·4	1·0†	. .
Never	17/64	6·5	1·09 (0·63–1·87)	0·21
Aneurysm diameter ([cm] tertile groups)				
4·0–4·4	116/427	6·9	. .	. .
4·5–4·8	90/344	6·6	1·55 per cm (1·14–2·10)	. .
4·9–5·5	103/319	8·3	. .	0·005
ABPI (tertile groups)‡				
0·2–0·9	134/354	9·9	. .	. .
0·9–1·1	85/354	5·9	0·50 per unit (0·27–0·93)	. .
1·1–1·9	76/354	5·4	. .	0·03
FEV_1 ([L], tertile groups)				
0·3–1·8	127/377	9·1	. .	. .
1·9–2·5	102/373	6·9	0·74 per L (0·63–0·88)	. .
2·6–4·4	62/313	4·6	. .	0·001

ABPI=ankle/brachial pressure index.
*Adjusted for baseline factors listed in footnote ‡ to table 2, as well as randomised treatment group.†Reference category.‡Mean of left and right ABPI.

Table 3: **Crude death rates and adjusted hazard ratios and p values for baseline factors**

or ruptured. Five patients had an aortic graft inserted at the time of iliac or thoracic aneurysm repair. The remaining 38 patients underwent surgery against trial protocol: 25 requested surgery, 12 underwent imaging by alternative methods, which showed that the aneurysm had grown to more than 5·5 cm in diameter, and one had surgery performed by a surgeon not participating in the trial. Therefore, 93% of patients adhered to their assigned treatment (figure 1). In the last year of the trial, 94% of the patients in the surveillance group were still compliant with the protocol.

The baseline characteristics of the patients in the two groups were similar (table 1). There were slightly fewer current smokers in the surveillance group than in the early-surgery group, but the early-surgery group had slightly higher average lung function. We compared randomised patients with the 186 patients who refused randomisation (table 1). Although the latter group were slightly older, had slightly higher mean blood pressure, and smaller aneurysms than those who entered the trial, the differences were small.

	Deaths in surveillance group (n=150)	Deaths in early surgery group (n=159)
Cardiovascular deaths		
Total	105	94
Myocardial infarction	30	24
Stroke	7	5
Ruptured thoracic aneurysm	6	2
Ruptured abdominal aortic aneurysm*	17	6
After abdominal aortic aneurysm repair†	18	26
Other cardiovascular deaths	27	31
Cancer deaths		
Total	27	40
Lung cancer	10	14
Other cancer deaths	17	26
Other	17	23
Unknown‡	1	2

*Ten (43%) of 23 ruptured abdominal aortic aneurysm had diameter >5·5 cm.
†Underlying cause of death, within 14 days of operative repair.
‡Patient died abroad, cause of death not known.

Table 4: **Numbers of deaths according to reported underlying cause on the death certificate by treatment group**

For patients in the surveillance group, the median time to surgery was 2·9 years (figure 2). Only 38 patients (7%) underwent surgery against trial protocol (figure 1); these surgical interventions occurred at a constant rate during the trial. 104 patients (20%) remained alive and were still undergoing ultrasonographic surveillance for aneurysms of 5·5 cm or less in diameter at the end of the trial.

Overall survival in the two groups did not differ significantly (p=0·56, figure 3), and by 6 years about a third of patients in each group had died. For early surgery compared with surveillance, the unadjusted hazard ratio was 0·94 (95% CI 0·75–1·17); after adjustment for two sets of baseline covariates the hazard ratios were similar at 0·91 and 0·94 (table 2). Survival was worse initially in the early-surgery group, and subsequently worse in the surveillance group. The curves crossed over at about 3 years (figure 3). There were non-proportional hazards over time between the two groups, shown by the interaction between log time and hazard ratio in a time-dependent Cox's model (p=0·004). In the first 6 months after randomisation, the rate of death in the early-surgery group was about 2·5 times that in the surveillance group; among patients who survived at least 6 months, it was about 80% of that in the surveillance group (table 2). The estimated absolute differences in risk of death by 2 years, 4 years, and 6 years were, respectively, 1·9% more, 3·0% less, and 0·3% more in the early-surgery group than in the surveillance group (no significant difference from 0, p=0·33, p=0·29, and p=0·94).

The estimated hazard ratios showed a possible benefit of surgery for younger patients and those with larger aneurysms, with a possible corresponding benefit of surveillance in older patients and those with smaller aneurysms (table 2). None of the tests of interaction between treatment group and age, sex, or aneurysm diameter were significant, so associations are very weak.

Older age, larger aneurysm diameter, lower ankle/brachial pressure index, and poorer lung function (lower FEV_1) at baseline were independently related to an increased risk of death. Sex and smoking status were not independently related to mortality (table 3).

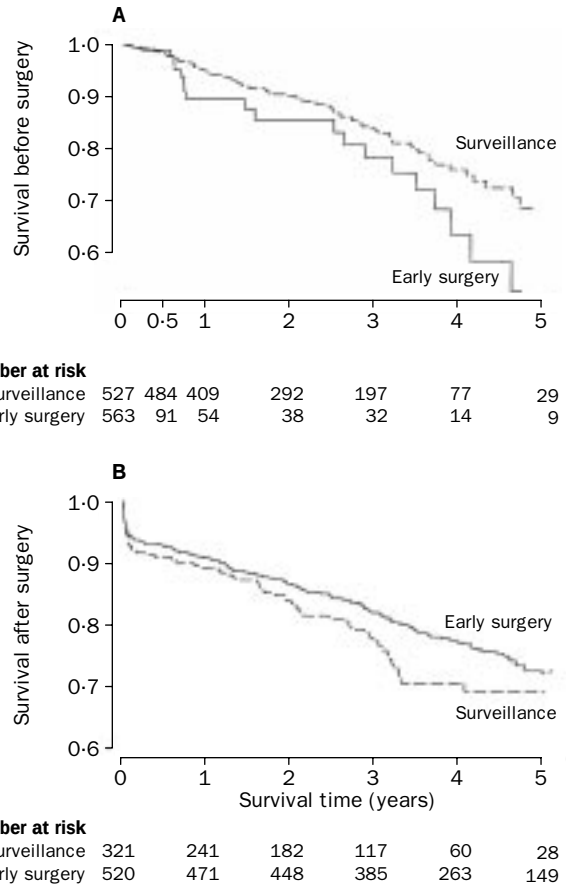


Figure 4: **Survival by randomised treatment group, up to time of surgery (A) and after surgery (B)**
Kaplan-Meier estimates, with surgery taken as censoring. Log-rank values p=0·05 (A), p=0·14 (B).

The number of deaths by reported underlying cause on the death certificate is shown in table 4. Necropsies were done on 89 (29%) patients who died. More deaths were reported to be from ruptured aneurysms in the surveillance group than in the early-surgery group. Other causes of death were distributed evenly between the two groups.

We also analysed survival by treatment received rather than by treatment assigned. Survival in the few patients in the early-surgery group who continued under surveillance was slightly worse than in those who continued under surveillance in the surveillance group (p=0·05, figure 4). Survival after surgery in the early-surgery group was slightly better than for patients in the surveillance group, but this difference was not significant, (p=0·14, figure 4). In particular, the 30-day operative mortality (adjusted for age and sex) was 5·8% in the early-surgery group and 7·1% in the surveillance group. (5·8% and 7·2%, respectively, for in-hospital mortality). These results should, however, be interpreted cautiously since the groups were not directly comparable, because of differences in age, aneurysm size, and number of tender or ruptured aneurysms at the time of surgical repair.

In the surveillance group the median aneurysm growth rate was 0·33 cm per year (IQR 0·20–0·53).

25 aneurysms ruptured, of which ten (40%) had a diameter more than 5·5 cm when last recorded. In these ten patients, four had become unfit for elective surgery, two had refused surgery, two were awaiting surgery, and in two the planned repair had not been completed because of other abdominal pathology. For the other ruptured aneurysms, the last recorded diameter of abdominal aortic aneurysm was 4·0–4·9 cm in seven patients and 5·0–5·5 cm in eight patients. Only eight of the patients with ruptured aneurysms were sent for emergency repair, two of whom survived beyond 30 days. The mean risk of rupture of aneurysms of 4·0–5·5 cm in diameter was 1·0% per year.

Discussion

Our results show that elective surgical repair was not associated with a long-term survival advantage for patients with small, symptomless abdominal aortic aneurysms. Ultrasonongraphic surveillance provided a safe alternative method of management. The survival curves (figure 3) reflect the early attrition rate in the early surgery group, in which the 30-day surgical mortality was 5·8%. After 3 years, the survival curves crossed, but at 6 years the survival was 64% in both groups, which is similar to survival after elective surgery in other studies.[9,18] The 5-year survival of patients undergoing surgery for small aneurysms was 62% in Rochester, USA,[18] and the 6-year survival in Canada was 60%.[9] Both of those studies found that the survival of these patients was significantly worse than in the general population of the same age and sex. There are no studies with which our neutral findings can be compared, although the results of the US trial (Aneurysm Detection and Management)[15] will be reported in the future.

The 30-day mortality rate (5·8%) for patients who underwent elective surgery in our trial was similar to other UK studies[10] and the Canadian Aneurysm study,[9] in which mortality rates were reported for an unlimited range of aneurysm diameters. Although this 30-day mortality rate was more than twice the rate used in the power calculations for the trial design,[16] it is about half the national in-hospital mortality rate for elective repair of abdominal aortic aneurysms.[19] The mortality rate we used in the power calculations (2%) was obtained from the selective published series of major vascular surgical centres, whereas national rates include operations done by general surgeons and for tender or symptomatic aneurysms of all diameters. In total, 321 (61%) of 527 patients who underwent surveillance eventually underwent elective surgical repair. The 30-day operative mortality in these patients was 7·1%. This slightly higher operative mortality may reflect the large proportion of tender or ruptured larger aneurysms in this group. The length of hospital stay after aneurysm repair was similar in the two groups (median 11 [IQR 9–13] days and 11 [9–15] days for early surgery and surveillance, respectively), which suggests a similar prevalence of complications after surgery in each group.

309 patients died before the end of the trial, about two-thirds of whom had cardiovascular-associated causes. The ankle/brachial pressure index, which is a measure of atherosclerosis,[20] was an important prognostic indicator for mortality. Death from rupture of abdominal aortic aneurysms was reported more commonly in patients in the surveillance group (17 deaths) than in the early-surgery group (six deaths). This information must be viewed with caution, however, since necropsies confirmed the cause of death in only 29% of all patients. Lung function was another important prognostic indicator of mortality, and 8% of the deaths were from lung cancer.

Coronary artery disease and lung cancer are recognised as common causes of death in patients with abdominal aortic aneurysm.[9,18]

Only 25 aneurysm ruptures were reported during the trial, and only 15 of these ruptures occurred in patients with aneurysms of less than 5·5 cm in diameter. In ten patients, the last recorded aneurysm diameter had been more than 5·5 cm. The total number of deaths attributable to aneurysms was low, but similar in the two groups.

We have considered whether a longer trial would show a different result. In the patients randomised to ultrasonographic surveillance, the rapid expansion of the aneurysm or expansion to more than 5·5 cm had already led to elective surgery being performed in 208 (39%) patients by June 30, 1998. In a further 65 patients, surgery had been performed because the aneurysm had become tender, and by the end of the trial aneurysm repair had been performed in 321 (61%) patients randomised to surveillance. With increasing length of follow-up, only a small proportion of patients with aneurysms of 5·5 cm or less would remain. In addition, investigation of the role of endovascular repair might mean that many patients whose aneurysms expand to more than 5·5 cm in diameter may not be managed by open surgical repair. Continuation of the trial would, therefore, be unlikely to show different results.

Recommendation of endovascular repair of aneurysms 4·0–5·5 cm in diameter would not be justified unless it was shown to have a significant advantage over open repair in a similar cohort to our study. 30-day mortality for repair of abdominal aortic aneurysms by the open elective surgery and endovascular methods is similar,[11,21] although the results of endovascular repair may improve as techniques and technology advance.

Our results are relevant to aneurysm screening programmes. Most aneurysms detected in population screening programmes are less than 5·5 cm in diameter. There is currently no effective therapy to offer these patients, other than advice to stop smoking.[22] Screening programmes can, however, yield important information about the epidemiology of abdominal aortic aneurysms. Until more results are available on endovascular repair, patients with aneurysms detected in screening programmes should undergo ultrasonographic surveillance until the diameter exceeds 5·5 cm.

Our trial was pragmatic in its approach to recruitment and fitness for surgery. The patients who were recruited from diverse referrals may not be representative of the general population of patients with abdominal aortic aneurysms, although this case is unlikely. Fitness for surgery was assessed locally and is probably representative of nationwide practice. Measurements were more precise and the ability of the specially trained trial coordinators to measure aneurysms diameter more reliably than reported previously[23] confirmed the diameter range of 4·0–5·5 cm with only a 0·2 cm error margin. The high rate of compliance with ultrasonographic surveillance is likely to have contributed to the safety of this management policy.

Surgeons were willing to cooperate, test a hypothesis, and provide the evidence on which contemporary vascular surgical practice should be based. The neutral result of this trial also may lead to comparison of management by endovascular repair, open repair, or ultrasonographic surveillance in large aneurysms.

Members of the UK Small Aneurysm Trial

Writing Committee—J T Powell, A R Brady, L C Brown, J F Forbes, F G R Fowkes, R M Greenhalgh, C V Ruckley, S G Thompson.
Steering Committee— R M Greenhalgh, J F Forbes, F G R Fowkes, J T Powell, C V Ruckley.
Monitoring Committee—P A Poole-Wilson, N Browse, C J Bulpitt, K Burnand, E C Coles, A Fletcher.
Trial Coordinators—S Blair, R Clark, C Devine, K Ferguson, S Hearn, E Kerracher, S Logan, A McCabe, R Meer-Baloch, M Mossa, A Rattray, K Wilson.
Data Management and Analysis—A R Brady, L C Brown, P J Franks, S G Thompson.
ECG Coding—N Keen, C Rose.
Blood Analysis—R Mir Hassaine.

Trial participants

South west England and South Wales—M Horrocks (Regional Trial Director); J Budd, M Horrocks (Royal United Hospital); R N Baird, P Lamont (Bristol Royal Infirmary); D C Wilkins, S Ashley (Derriford Hospital); K Flowerdew (Dorset County Hospital); A Baker (Frenchay Hospital); J Earnshaw, B Heather (Gloucester Royal Infirmary); C Gibbons (Morriston Hospital); R L Blackett (Neville Hall Hospital); S D Parvin (New Royal Bournemouth General Hospital); D R Harvey (North Devon District General Hospital); R Hedges (Princess of Wales Hospital); D Finch, D B Hocken (Princess Margaret Hospital); G E Morris, C P Shearman (Southampton General Hospital); P Lear (Southmead Hospital); P Lewis (Torbay Hospital); R J Clarke (Yeovil District General Hospital). *Scotland and north east England*—C V Ruckley (Regional Trial Director); A M Jenkins, C V Ruckley (Edinburgh Royal Infirmary); G G Cooper, J Engeset, R Naylor (Aberdeen Royal Infirmary); G Stewart (Ayr Hospital); J Cumming (Dryburn Hospital); J McCormick (Dumfries and Galloway Royal Infirmary); A Howd, A Turner (Dunfermline and West Fife Hospital); D R Harper, R C Smith (Falkirk and District Infirmary); J Chamberlain, A G Jones, M G Wyatt (Freeman Hospita); A J McKay (Gartnavel General Hospital); J C Forrester, P McCollum, P A Stonebridge (Ninewells Hospital); A I G Davidson (Perth Royal Infirmary); R Baker (Queen Elizabeth Hospital); J L R Forsythe, D Lambert (Royal Victoria Infirmary); J L Duncan (Royal Northern Infirmary). *The Midlands*—P R F Bell (Regional Trial Director); P R F Bell, D Ratliff (Leicester Royal Infirmary); K G Callum, J R Nash (Derbyshire Royal Infirmary); D S McPherson (Glenfield General Hospital); R E Jenner, R Stewart (Kettering and General District Hospital); P R Armitstead (Kidderminster General Hospital); W W Barrie (Leicester General Hospital); D B Hamer, S Powis (Northampton General Hospital); L D Coen, J Michaels C L Welsh (Northern General Hospital); B R Hopkinson, P W Wenham (Nottingham Queen's Medical Centre); J Beard (Royal Hallamshire Hospital); A Auckland (Sandwell District General Hospital); J Black, R Downing, N C Hickey (Worcester Royal Infirmary). *London and south east England*—R M Greenhalgh (Regional Trial Director); A H Davies, R M Greenhalgh, D Nott (Charing Cross Hospital); A R L May (Colchester General Hospital); R McFarland (Epsom District Hospital); P Taylor (Guy's Hospital); J W P Bradley, T Paes (Hillingdon Hospital); A E P Cameron (Ipswich Hospital); A McIrvine (Joyce Green Hospital); D Negus, P R Taylor (Lewisham Hospital); C M Butler, R W Hoile (Medway Hospital); B Pardy (Newham General Hospital); J Ackroyd (Princess Alexandra Hospital); G Hamilton (Royal Free Hospital); R Lane (Royal Hampshire County Hospital); A E B Giddings (Royal Surrey County Hospital); J Dormandy, R Taylor (St Georges's Hospital); M Thomas (St Peter's Hospital); K J Burnand (St Thomas's Hospital); M Adiseshiah (University College Hospital); P Pattison (West Middlesex Hospital); J Clarke, J Colin (West Norwich Hospital); P Rutter (Wexham Park Hospital); S Brearley, M Pietroni (Whipps Cross Hospital). *North England and North Wales*—C N McCollum (Regional Trial Director); C N McCollum (University Hospital South Manchester); M G Greaney, D Reilly (Arrowe Park Hospital); W G Paley (Blackburn Royal Infirmary); M Lambert (Blackpool, Victoria Hospital); R Hughes (Burnley General Hospital); S Blair (Clatterbridge Hospital); J E G Shand (Cumberland Infirmary); L A Donaldson (Grimsby District General Hospital); J M D Galloway, A R Wilkinson (Hull Royal Infirmary); M Gough (Leeds District General Hospital); J Mosley (Leigh Infirmary); D M Matheson (Macclesfield General Hospital); M Walker (Manchester Royal Infirmary); N Hulton (Oldham Royal Hospital); M I Aldoori, C K Yeung (Pontefract General Infirmary); A R Hearn (Royal Preston Hospital); J Kelly (Royal Lancaster Infirmary); D Durrans, B Gwynn (Stafford General Hospital); G B Hopkinson (Stoke City General Hospital); R G M Duffield (Telford General Hospital); I G Schraibman (The Infirmary Rochdale); R Hall, S H Leveson (York District Hospital); J Clark, O Klimach (Glan Clwyd Hospital, Rhyl).

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References

1 Manfredini R, Portaluppi F, Grandi E, Fersini C, Gallerani M. Out-of-hospital sudden death referring to an emergency department. *J Clin Epidemiol* 1996; **49:** 865–68.

2 Budd JS, Reid A, Thompson M, Sayers R, Naylor R, Bell PRF. The changing workload of a surgical unit with a vascular interest. *Eur J Vasc Endovasc Surg* 1995; **9:** 176–80.

3 Darling RC. Ruptured arteriosclerotic abdominal aortic aneurysms: a pathologic and clinical study. *Am J Surg* 1970; **119:** 397–401.

4 Glimaker H, Holmberg L, Elvin A, et al. Natural history of patients with abdominal aortic aneurysms. *Eur J Vasc Surg* 1991; **5:** 125–30.

5 Collin J, Walton J, Araujo L, Lindsell D. Oxford screening programme for abdominal aortic aneurysm in men aged 65 to 74 years. *Lancet* 1988; ii: 613–15.

6 Scott RAP, Ashton HA, Kay DN. Abdominal aortic aneurysm in 4237 screened patients: prevalence, development and management over 6 years. *Br J Surg* 1991; **78:** 1122–25.

7 Lucarotti ME, Shaw E, Heather BP. Distribution of aortic diameter in a screened male population. *Br J Surg* 1992; **79:** 641–42.

8 Smith FC, Grimshaw GM, Paterson IS, Shearman CP, Hamer JD. Ultrasonographic screening for abdominal aortic aneurysm in an urban community. *Br J Surg* 1993; **80:** 1406–09.

9 Johnston KW. Nonruptured abdominal aortic aneurysm: six-year follow-up results from the multicenter prospective Canadian aneurysm study. *J Vasc Surg* 1994; **20:** 163–70.

10 Bradbury AW, Adam DJ, Makhdoomi KR, et al. A 21 year experience of abdominal aortic aneurysm operations in Edinburgh. *Br J Surg* 1998; **85:** 645–47.

11 May J, White GH, Yu W, et al. Concurrent comparison of endoluminal versus open repair in the treatment of abdominal aortic aneurysms: analysis of 303 patients by life table method. *J Vasc Surg* 1998; **27:** 213–21.

12 Johnson KW. Ruptured abdominal aortic aneurysm. 6 year follow-up results of a multicenter prospective study: Canadian Society for Vascular Surgery Aneurysm Study Group. *J Vasc Surg* 1994; **19:** 888–900.

13 Bradbury AW, Makhdoomi KR, Adam DJ, Murie JA, Jenkins AMcL, Ruckley CV. Twelve-year experience of the management of ruptured abdominal aortic aneurysm. *Br J Surg* 1997; **84:** 1705–07.

14 Powell JT, Greenhalgh RM, Ruckley CV, Fowkes FGR. Prologue to a surgical trial. *Lancet* 1993; **342:** 1473–74.

15 Lederle FA, Wilson SE, Johnson GR, et al. Design of the abdominal aortic aneurysm detection and management study. *J Vasc Surg* 1994; **20:** 296–303.

16 The UK Small Aneurysm Trial Participants. The UK Small Aneurysm Trial: design, methods, progress. *Eur J Vasc Endovasc Surg* 1995; **9:** 42–48.

17 O'Brien PC, Fleming TR. A multiple testing procedure for clinical trials. *Biometrics* 1979; **35:** 549–56.

18 Hallett JW, Naessens JM, Ballard DJ. Early and late outcome of surgical repair for small abdominal aortic aneurysms: a population-based analysis. *J Vasc Surg* 1993; **18:** 684–91.

19 Department of Health. Hospital Episode Statistics 1989–1996. London: Department of Health, 1997.

20 Newman AB, Siscovick DS, Manolio TA, Polak J, Borhani NO, Wolfson SK. Ankle-arm index as a marker of atherosclerosis in the Cardiovascular Health Study: Cardiovascular Heart Study (CHS) Collaborative Research Group. *Circulation* 1993; **88:** 837–45.

21 Woodburn KR, May J, White GH. Endoluminal abdominal aortic aneurysm surgery. *Br J Surg* 1998; **85:** 435–43.

22 MacSweeney STR, Ellis M, Worrell PC, Greenhalgh RM, Powell JT. Smoking and growth rate of small abdominal aortic aneurysms. *Lancet* 1994; **344:** 651–52.

23 Ellis M, Powell JT, Greenhalgh RM. The limitations of ultrasonography in surveillance of abdominal aortic aneurysms. *Br J Surg* 1991; **78:** 614–16.