A Sustained Mortality Benefit from Screening for Abdominal Aortic Aneurysm

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Background: Longer-term mortality benefit and cost-effectiveness for abdominal aortic aneurysm (AAA) screening are uncertain.

Objective: To estimate the benefits, in terms of AAA-related and all-cause mortality, and cost-effectiveness of ultrasonography screening for AAA in a group that was invited to screening compared with a group that was not invited at a mean 7-year follow-up.

Design: Randomized trial.

Setting: 4 centers in the United Kingdom.

Patients: Population-based sample of 67 770 men age 65 to 74 years.

Intervention: Patients with an AAA detected at screening had surveillance and were offered surgery after predefined criteria were met.

Measurements: Mortality data were obtained after flagging on the national database. Unit costs obtained from large samples were applied to individual event data for the cost analysis.

Results: The hazard ratio was 0.53 (95% CI, 0.42 to 0.68) for AAA-related mortality in the group invited for screening. The rupture rate in men with normal results on initial ultrasonography has remained low: 0.54 rupture (CI, 0.25 to 1.02 ruptures) per 10 000 person-years. In terms of all-cause mortality, the observed hazard ratio was 0.96 (CI, 0.93 to 1.00). At the 7-year follow-up, cost-effectiveness was estimated at $19 500 (CI, $12 400 to $39 800) per life-year gained based on AAA-related mortality and $7600 (CI, $3300 to ∞) per life-year gained based on all-cause death. (All values are reported in U.S. dollars [U.K. £1 = U.S. $1.58]).

Limitation: Inclusion of deaths from aortic aneurysm at an unspecified site, which may include some thoracic aortic aneurysms, may have underestimated the treatment effect.

Conclusions: These results from a large, pragmatic randomized trial show that the early mortality benefit of screening ultrasonography for AAA is maintained in the longer term and that the cost-effectiveness of screening improves over time.

A fast-growing body of literature is providing evidence in favor of screening men for abdominal aortic aneurysm (AAA). Several large, randomized trials published in the past few years (1–4) have consistently shown that screening reduces AAA-related mortality. A few observational studies of programs under way in localized areas have established the feasibility of systematic screening and have explored its practical implementation (5–7). In addition to the mortality benefit, evidence indicating that screening is highly cost-effective is increasing (8–11). In light of this evidence, national screening programs are now being considered in many countries (12–14).

However, there is little evidence regarding long-term outcomes after AAA screening; almost all of the evidence from randomized trials is limited to the first 4 years after screening (1–4). Moreover, long-term cost-effectiveness has been estimated only through health economic modeling (10). We describe cost-effectiveness based on 7-year follow-up from the largest of the 4 trials of AAA screening—the Multicentre Aneurysm Screening Study (MASS) (2). The trial randomly assigned approximately 67 800 men age 65 to 74 years to receive an invitation to screening or to not receive an invitation. At 4-year follow-up, the trial reported a substantial relative reduction of 42% (95% CI, 22% to 58%) in AAA-related mortality and an incremental cost-effectiveness ratio of $44 900 (CI, $24 000 to $231 000) per life-year gained (9), which is at the border-line of the commonly accepted threshold for interventions. All values are reported in U.S. dollars (U.K. £1 = U.S. $1.58) (15). The costs of AAA screening are primarily incurred at the start of the program, but benefits continue to accrue in terms of life-years gained in patients in whom AAA rupture is avoided through elective surgery. It is therefore expected that cost-effectiveness of screening will improve over time. The mid-term results of MASS provide reliable, trial-based information regarding clinical outcomes and cost-effectiveness over a longer period.

METHODS

The details of the MASS protocol were described previously (2), but a brief summary is provided (**Figure 1**).

Context

Is it cost-effective to screen older adults for abdominal aortic aneurysm (AAA)?

Contribution

This 7-year follow-up report of a large randomized trial in the United Kingdom found that men age 65 to 74 years who were invited to have ultrasonography and surveillance for AAA had lower mortality rates than did those who were not invited (hazard ratio, 0.53 [CI, 0.42 to 0.68]). Cost-effectiveness for AAA-related deaths, based on costs applied to the events experienced by the men, was estimated at $19 500 (CI, $12 400 to $39 800) per life-year gained.

Cautions

Only men were studied. Actual costs of screening and surveillance may vary substantially in different settings.

—*The Editors*

Between 1997 and 1999, a population-based sample of 70 495 men age 65 to 74 years from 4 centers in the United Kingdom was identified by obtaining records for every man in this age range who was registered with a family physician (registered persons account for approximately 98% of the population). Persons who were ineligible for the trial (incorrect details, known AAA, previous AAA surgery, or terminal illness) were excluded before randomization. The remaining 67 770 men were randomly assigned to receive an invitation to ultrasonography for AAA or to not receive an invitation to ultrasonography. At screening, men with an aortic diameter of 3.0 cm or greater were defined as having an AAA and were subsequently invited for recall scans to monitor growth of the aneurysm. Men with an aortic diameter of 3.0 to 4.4 cm were rescreened every year, and those with an aortic diameter of 4.5 to 5.4 cm were rescreened every 3 months. Participants were considered for elective surgery when the aortic diameter reached 5.5 cm, aortic expansion was 1.0 cm or more in 1 year, or they experienced symptoms attributable to the aneurysm. Men with an aortic diameter less than 3.0 cm on the initial scan were not rescreened. Blood pressure was also measured; although family physicians were informed of these measurements, no further intervention was provided through the screening program. We obtained approval from local ethics committees at each center, and all patients who had screening provided signed informed consent.

Additional data on follow-up scans and AAA surgeries were collected from hospital records. Deaths up to 31 March 2005 were confirmed by the U.K. Office of National Statistics after matching of the unique National Health Service number for each person. Follow-up ranged from 5.9 to 8.2 years (mean, 7.1 years). The primary outcome of interest, AAA-related mortality, is defined as all deaths within 30 days of any AAA surgery (elective or emergency) plus all deaths with International Classification of Diseases, Ninth Revision, codes 441.3 (ruptured abdominal aortic aneurysm), 441.4 (abdominal aortic aneurysm without mention of rupture), 441.5 (ruptured aortic aneurysm at unspecified site), or 441.6 (aortic aneurysm at unspecified site without mention of rupture). The use of codes 441.5 and 441.6 may result in inclusion of some thoracic aortic aneurysm deaths. Investigation of the accuracy of cause-of-death coding on the death certificates was done by an independent mortality working party that was blinded to group allocation. The results of this analysis showed that inaccuracies in coding did not have an important impact on study outcomes (2).

Statistical Analysis

All analyses were done by using Stata, version 9 (Stata Corp., College Station, Texas). Deaths related to AAA (primary analysis) and all-cause mortality (secondary analysis) were compared between the 2 randomized groups by using unadjusted Cox regression by intention-to-treat analysis. Adjustment for age at baseline did not influence the results. The proportional hazards assumption was tested by using Schoenfeld residuals. An unbiased randomization-based estimate of the benefit of screening was also obtained (16). This estimate is calculated by subtracting from the control group a subgroup that is equivalent in terms of survival to the nonadherent subgroup in the invited group. Thus, the remaining controls are comparable to the group of invited patients who attended screening. Life-years gained are estimated as the area between the Kaplan–Meier curves for both groups (17).

The cost-effectiveness of screening is estimated from a health service perspective for follow-up truncated at 7 years, with adjustment for censoring (18). Details of the costing exercise in the trial at 2000–2001 prices were reported previously (9). The unit costs obtained (U.K. £1 = U.S. $1.58 for the year 2000 [15]) are inflated to the 2004–2005 financial-year level by using annual hospital and community health services pay and price inflation indices (19). Costs are applied to the following events on the basis of individual resource use: invitation to screening ($2.46), reinvitation after nonresponse ($2.42), initial scan ($35.95), recall scan ($86.74; done in the hospital rather than in the community and including costs for periodic routine meetings with a consultant), consultation for elective surgery ($583.79), elective AAA surgery ($13 015.74), and emergency AAA surgery ($21 054.32). Costs relating to scans of incidentally detected AAAs in the control group are not included (data not available), but costs relating from resultant AAA repair surgery are included. Sensitivity analyses were done by using 1) costs retained at the 2000–2001 financial-year level for comparison with previous publications, 2) quality-adjusted life-years based on age-related reductions, 3) U.S.-based unit cost estimates for

Figure 1. Study flow diagram.
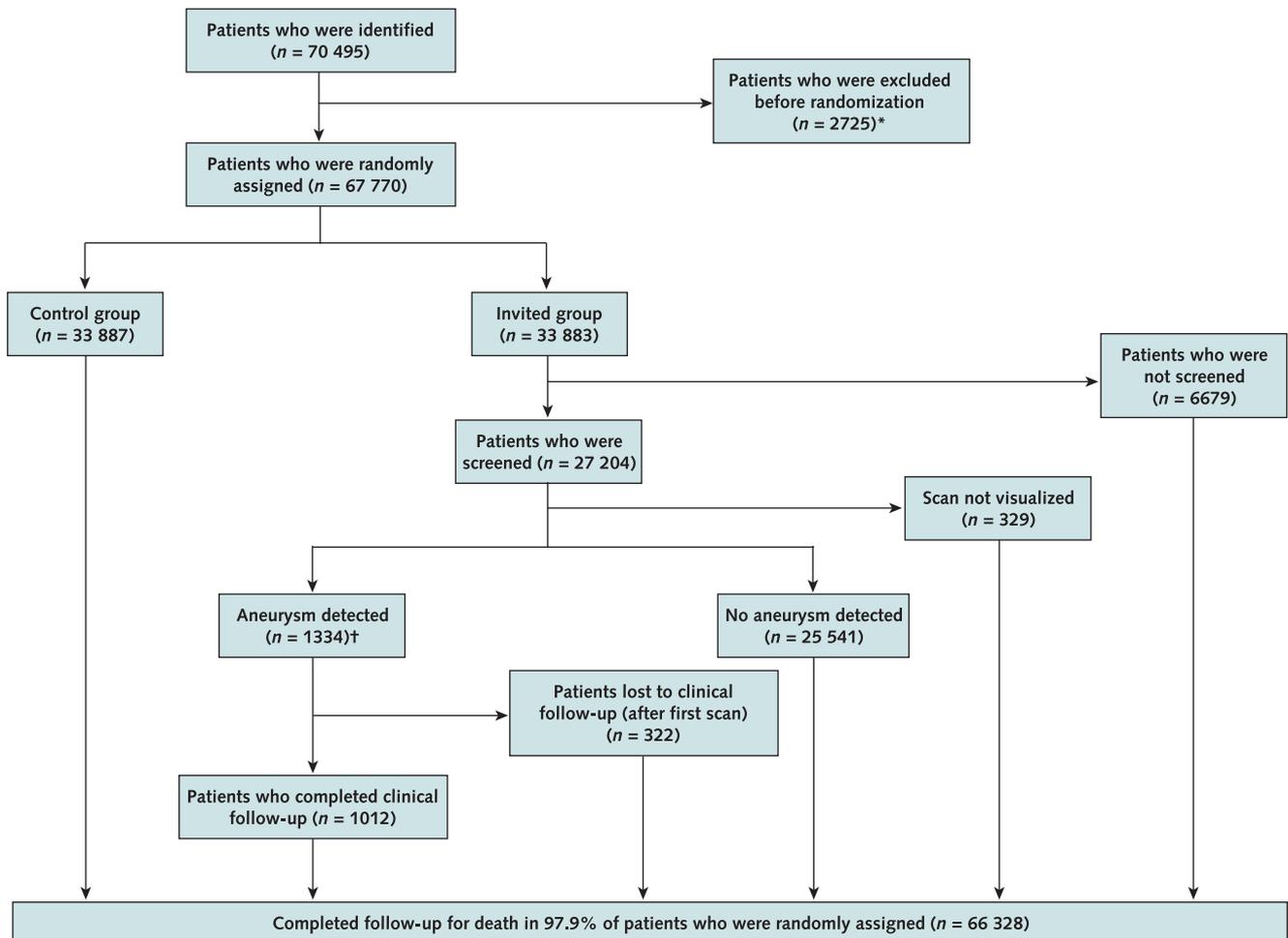
*Patients who should not have been included in the sample because they did not meet the inclusion criteria for the study (for example, because of age or because they were no longer registered at a participating practice). †Aneurysm was defined as an aortic diameter ≥30 mm.

scans and surgeries, 4) an increase of 50% in the cost of a consultation (a U.S.-based estimate was not available, but this analysis reflects possible additional assessments), 5) 3 and 4 combined. Quality-of-life adjustments are made only on the basis of age, with an adjustment of 0.78 for life-years gained between the ages 65 and 74 years and an adjustment of 0.75 for life-years gained at ages older than 75 years (20). The U.S.-specific estimates for scans (initial and recall) are based on Medicare reimbursement for AAA screening at $90.95 (Current Procedural Terminology code G0389) (21), and U.S.-specific costs for surgeries are based on previously published estimates (22, 23) that were inflated to 2004 prices (24): $18 160 for elective procedures and $31 106 for emergency procedures.

Discounting is applied at the current recommended values of 3% per annum for costs and effects (25). Estimates of AAA-related costs and effects take into account the rate of non–AAA-related deaths across both groups

over time. The Fieller method is used to calculate bounds for the CI for cost-effectiveness (26, 27).

Role of the Funding Source

This study was funded by the Medical Research Council. The funding source had no role in the design, implementation, or analysis of the study.

RESULTS

Figure 1 shows the flow of participants through the trial. Numbers differ slightly from earlier publications because of identification of a few duplicate records in the database. Of 67 770 randomly assigned men, 33 883 were invited to be screened: 27 204 (80%) attended and 1334 (4.9%) AAAs were identified. The mean age at randomization was 69.2 years in both groups. Loss to follow-up because of death was 2.1% overall (2.2% in the control group and 2.1% in the invited group). Loss to clinical follow-up

Table 1. **Deaths Related to Abdominal Aortic Aneurysm, Ruptured Abdominal Aortic Aneurysm, and Other Causes***

Variable	Control Group (*n* = 33 887)	Invited Group (*n* = 33 883)
Follow-up, *person-years*	216.0	216.6
Deaths within 30 days of elective surgery, *n*†	12	18
Deaths from ruptured AAA, *n*‡	153	67
Deaths from ruptured aortic aneurysm at unspecified site, *n*§	31	20
Total AAA-related deaths, *n (n per 1000 person-years)*	196 (0.91)	105 (0.48)
Hazard ratio (95% CI)	1.00‖	0.53 (0.42–0.68)
Nonfatal ruptured AAA, *n*	61	30
Total ruptured AAA, *n (n per 1000 person-years)*¶	257 (1.18)	135 (0.62)
Hazard ratio (95% CI)	1.00‖	0.52 (0.42–0.64)
Non-AAA cardiovascular deaths, *n*		
Ischemic heart disease	1805	1690
Stroke	403	416
Other	508	522
All cardiovascular deaths, *n***	2912	2723
Deaths from cancer, *n*	2409	2386
Deaths from other causes, *n*††	1797	1774
All deaths, *n (n per 1000 person-years)*	7119 (32.8)	6882 (31.6)
Hazard ratio (95% CI)	1.00‖	0.96 (0.93–1.00)

* AAA = abdominal aortic aneurysm; ICD-9 = International Classification of Diseases, Ninth Revision.
† Patients with ICD-9 codes 441.3–441.6 who died within 30 days of elective surgery are included.
‡ Patients with ICD-9 codes 441.3–441.4 and all patients who died within 30 days of emergency AAA surgery are included.
§ Patients with ICD-9 codes 441.5–441.6 are included.
‖ Reference group.
¶ AAA-related deaths plus the incidence of nonfatal ruptured AAA.
** Includes AAA-related deaths.
†† Includes 12 deaths of unknown cause (7 patients in the control group and 5 patients in the invited group), 10 of which occurred outside of the United Kingdom (7 patients in the control group and 3 patients in the invited group) with fact-of-death notifications and 2 general practitioner–notified deaths in the invited group.

(nonattendance at recall scans) was 19% at 4 years and 24% at 7 years. The **Appendix Table** (available at www.annals.org) shows surgeries and deaths within 30 days in each of the randomly assigned groups. A few endovascular operations are included in these figures—6 in the control group and 14 in the invited group. As expected, the total number of elective procedures is greater in the invited group than in the control group (5% overall 30-day mortality), whereas the number of emergency surgeries is greater in the control group (35% overall 30-day mortality). Although the 30-day mortality after elective surgery is 4% in the invited group and 8% in the control group, there is only limited evidence of a difference between the groups (*P* = 0.067).

There were 301 AAA-related deaths and 14 001 deaths overall (21% of all men) (**Table 1**). **Figure 2** shows cumulative AAA-related mortality; the hazard ratio is 0.53 (CI, 0.42 to 0.68) for the group invited to be screened. The test for proportional hazards was not statistically significant (*P* = 0.208). Nine AAA-related deaths and 1 nonfatal rupture have been recorded in patients with normal results on

the initial scan over the mean follow-up period of 7.1 years, for a rate of 0.54 (CI, 0.25 to 1.02) per 10 000 person-years. Five of the 10 ruptures occurred more than 4 years after the initial scan. Of 57 AAA-related deaths in patients with an AAA detected on the initial scan, 12 were in persons who were lost to clinical follow-up, 14 were in patients with contraindications for elective surgery (declined or unfit), 8 were in patients awaiting consultation or elective surgery (1 patient had an aortic diameter of 5.3 cm and was referred for expansion only; the AAA diameters of the other patients were 5.6 cm, 5.8 cm, 5.8 cm, 5.9 cm, 6.4 cm, 6.7 cm, and 8.3 cm at last scans), 5 were in patients who had not yet met the criteria for elective surgery, and 1 was in a patient who had only a suprarenal AAA on the initial scan. The 17 remaining deaths in patients in this group occurred after elective surgery (including 4 patients who died more than 30 days after the operation). In the group invited to be screened, the overall incidence of nonfatal ruptured AAA was approximately half that of the control group (**Table 1**).

The estimated hazard ratio is 0.96 (CI, 0.93 to 1.00) in terms of all-cause death. In addition to the reduction in AAA-related mortality in the invited group, there is a possible reduction in deaths from ischemic heart disease (hazard ratio, 0.93 [CI, 0.87 to 1.00]) (**Table 1**).

The rates of AAA events and all-cause death were about twice as high in patients in the invited group who did not have screening as those in patients who were screened, reflecting the fact that they are in a self-selecting, less-fit group. The unbiased randomization-based hazard ratio is 0.42 (CI, 0.33 to 0.55) for benefit in persons who had screening in terms of AAA-related mortality.

The incremental cost-effectiveness ratio at 7 years is estimated to be $19 500 (CI, $12 400 to $39 800) per life-year gained. **Table 2** shows the specific costs and effects for each randomized group, and **Figure 3** shows the cost-effectiveness acceptability curve. For example, if a health service provider were willing to pay $40 000 per life-year gained, the probability that AAA screening would be cost-effective is 98%. When costs for the 2000–2001 financial year were used, the cost-effectiveness is estimated to be $16 400 (CI, $10 400 to $33 400) per life-year gained. Cost-effectiveness based on all-cause death rather than AAA-specific death is estimated to be $7600 (CI, $3300 to ∞) per life-year gained at 2004–2005 prices. The upper CI bound cannot be estimated because the CI for the difference in all-cause death includes 0; hence, the CI for the cost-effectiveness estimate (difference in costs/difference in effects) includes infinity (28). **Table 3** shows the results for the sensitivity analyses.

DISCUSSION

Our study provides evidence regarding longer-term outcomes for men after screening for AAA. The relative benefit in terms of AAA-related mortality observed at 4

Figure 2. Cumulative abdominal aortic aneurysm (*AAA*)–related mortality.
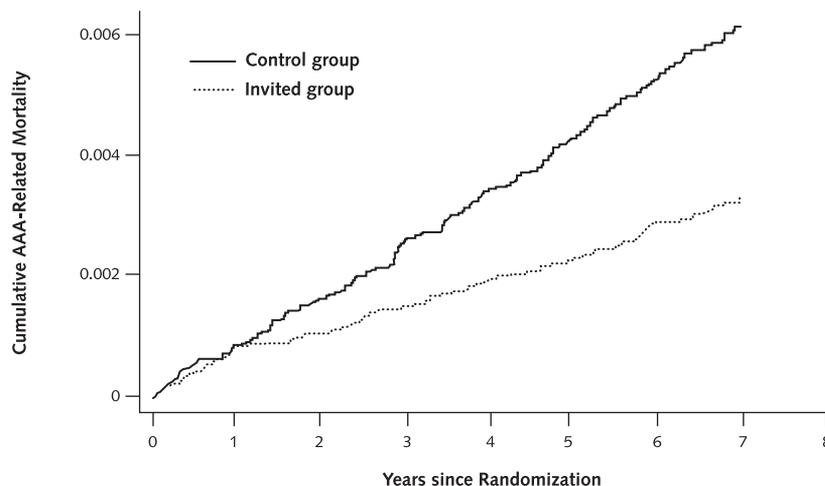
Men at risk, *n*								
Control group	33 887	33 046	32 100	31 049	29 979	28 850	27 630	15 456
Invited group	33 883	33 016	32 073	31 117	30 094	28 992	27 828	15 634

years is maintained at 7 years: The group invited to be screened had approximately half the risk. The risk reduction was even greater in patients who attended the screening. These results are derived from a large population-based, randomized trial yielding narrow CIs. The loss to follow-up was small, the accuracy of death certification has been shown to be sufficient (2), and any misclassification of deaths from thoracic aortic aneurysm would only render the results conservative.

The AAA mortality curves (**Figure 3**) diverge at a constant rate after 1 year, and the life-years gained (the area between the curves) are therefore substantially greater for years 5 to 7 than for years 1 to 4. Because the cost difference (**Table 2**) is similar at 4 and 7 years, cost per life-year gained improves markedly. On the basis of 2004–2005 prices and discounting costs and effects at 3%, 4-year cost-effectiveness for AAA screening was previously estimated at around $55 300 per life-year gained, with a wide CI ($29 700 to $295 300) (9). Conservative estimates presented along with this individual patient analysis suggested that cost-effectiveness may decrease to around $12 600 per life-year gained by 10 years of follow-up. Our study supports this estimate: 7-year cost-effectiveness was estimated at $19 500 per life-year gained. Furthermore, the CI is now much narrower, at $12 400 to $39 800. These estimates take into

Table 2. Discounted Mean Costs and Effects at 7-Year Follow-up per Randomly Assigned Patient*

Variable	AAA-Related Death			All-Cause Death		
	Years 1–4	Years 5–7	Total	Years 1–4	Years 5–7	Total
Life-days						
Control group	1336.65	806.65	2143.30	1327.20	797.76	2124.96
Invited group	1337.42	808.40	2145.82	1328.69	802.79	2131.48
Difference	0.77	1.75	2.52	1.49	5.03	6.52
Costs, $						
Control group	75.95	40.77	116.72	75.94	40.69	116.63
Invited group	189.49	62.05	251.54	189.50	62.15	251.65
Difference	113.54	21.28	134.82	113.56	21.46	135.02
Cost per life-year gained (95% CI)			19 500 (12 400–39 800)			7600 (3300–∞)

* Costs were calculated in 2004–2005 prices and are reported in U.S. dollars. Results for years 1 to 4 differ slightly from those of previous publications because of discounting at 3% rather than at 1.5% (effects) and 6% (costs), adjustment due to non–AAA-related death, and updating of 4-year data on deaths and number of patients at risk. Costs differ slightly between the 2 outcomes because of an assumption of deaths of other common causes in both groups during adjustment for this in the analysis of AAA-related deaths. AAA = abdominal aortic aneurysm.
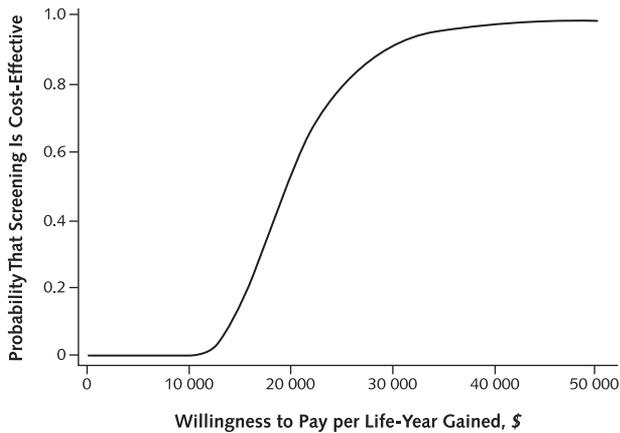
account competing mortality risks (that is, deaths due to causes other than AAA). This issue can also be addressed by considering all-cause death as the outcome in the cost-effectiveness analysis. This provides a cost-effectiveness estimate of $7600 per life-year gained, but the upper bound of the CI is infinite.

The sensitivity analyses confirm that using U.S.-based cost estimates does not substantially influence cost-effectiveness estimates. The most extreme result, produced by using U.S.-based costs and increasing the cost of a consultation by 50%, still indicates favorable cost-effectiveness at $30 800 (CI, $19 700 to $62 600) per life-year gained. Increasing these screening-related costs further, which may be required for generalization to some settings, will inevitably increase the cost-effectiveness estimate. Because increases in the cost of elective surgery is generally offset by increases in the cost of emergency surgery, it is unlikely that differences in surgical costs similarly influence the

Table 3. Cost-Effectiveness Estimates from Sensitivity Analyses*

Analysis	Cost per Life-Year Gained (95% CI), $
Base-case analysis	19 500 (12 400–39 800)
2001 costs	16 400 (10 400–33 400)
Quality-adjusted life-years	24 600 (15 700–49 700)
U.S.-based costs for scans and surgeries	29 600 (18 900–60 200)
Consultation cost increased by 50%	20 700 (13 200–42 200)
Consultation cost increased by 50% and U.S.-based costs for scans and surgeries	30 800 (19 700–62 600)

* All sensitivity analyses are 1-way unless otherwise stated. Costs (in U.S. dollars) and effects are discounted at 3% per annum. Details regarding the analyses are given in the Methods section.

cost-effectiveness of the program. Furthermore, our estimates show that AAA screening is favorable in terms of cost-effectiveness based on a 7-year follow-up period, but it is expected that the cost-effectiveness will continue to improve over time (29). The age-based, quality-of-life sensitivity analysis also shows only a limited influence on results. Changes in quality of life relating to reassurance or anxiety associated with AAA screening or surgery have not been included; such adjustments might make the cost-effectiveness estimate more or less attractive. However, results from MASS suggested only small changes in quality of life relating to the screening program (2), which may be related to pre-invitation differences in health perceptions (30). All cost-effectiveness results refer to a policy of population screening for men rather than one of selective screening of high-risk groups, such as persons who have ever smoked. Although data are not available to enable relevant subgroup sensitivity analyses to be conducted, it might be expected that the cost-effectiveness for high-risk groups would be more favorable because of the increased prevalence of AAA. However, the potential benefits are diminished under a selective screening strategy because approximately 10% of AAAs occur in persons who never smoked (7, 31).

In addition to these principal results, our analysis provides further information regarding ruptures in patients who had normal results on initial screening. Because of the rarity of events in such persons, there is little published information on this key quantity. However, it is required to inform models of the long-term cost-effectiveness of screening and to address whether (and when) to rescreen patients with a normal aortic diameter (<3.0 cm) at the first scan. In MASS, after 7 years of follow-up, the rupture rate in patients with an initial aortic diameter less than 3.0 cm remains low—0.54 rupture per 10 000 person-years. That this low rupture rate has continued to 7-year follow-up suggests that early rescreening of this large group would yield only very limited further benefit. However, although the rupture rate in this group was 0.40 rupture per 10 000 person-years in the first 4 years, it increased to 0.75 rupture per 10 000 person-years in years 5 to 7. Continued follow-up data from MASS will enable this rate to be more adequately assessed to inform rescreening policy.

The continuing divergence of the AAA mortality curves between 4- and 7-year follow-up (**Figure 3**) arises for several reasons. As discussed, there is not a major increase in numbers of ruptures between 4 and 7 years in patients with an initial normal aortic diameter. Second, benefits from elective surgery after incidental detection of AAAs have not increased in the control group. There were 93 elective surgeries in the control group in years 1 to 4, compared with 59 elective surgeries in years 5 to 7. Third, benefits have continued to accrue in the invited group among patients with an initial small or medium AAA who have undergone elective surgery in years 5 to 7. There were

170 elective surgeries in this subgroup in years 1 to 4 and 114 elective surgeries in years 5 to 7.

Fewer all-cause deaths were also observed in the invited group. This arises not only as a result of decreased AAA-related mortality but also from a difference in ischemic heart disease–related deaths. The latter may be due to AAA-related deaths being misclassified as ischemic heart disease–related deaths. Another explanation may be that the difference is a result of lifestyle changes (diet, smoking, and exercise) among patients who were screened (although no specific advice was given) or treatment of high blood pressure given by the family physician after measurements taken with the scan. Further benefit may have occurred in patients in the invited group who were considered for elective surgery, including those who were unfit for the procedure who received other treatments and advice relating to their general cardiovascular health. Costs relating to non–AAA-related medications and interventions that may arise after averting AAA-related deaths through the screening program were not collected in the trial. Exclusion of such costs may partially explain why the estimated cost-effectiveness is more favorable when based on all-cause death, because these additional costs will have occurred predominantly in the invited group. However, the inclusion of such costs in cost-effectiveness analyses is the subject of ongoing debate (25, 32, 33).

In conclusion, these longer-term results from MASS provide trial-based confirmation that the cost-effectiveness of AAA screening is well below the commonly accepted thresholds for interventions (34) and compares favorably with other screening programs (35–37). It is expected that the lifetime cost-effectiveness of screening will be highly favorable (10, 29). Furthermore, these results show that the mortality benefit of an approximate 50% reduction in AAA-related death in patients invited to be screened is maintained at 7-year follow-up. The risk for AAA rupture remains low in patients with normal results on initial screening.

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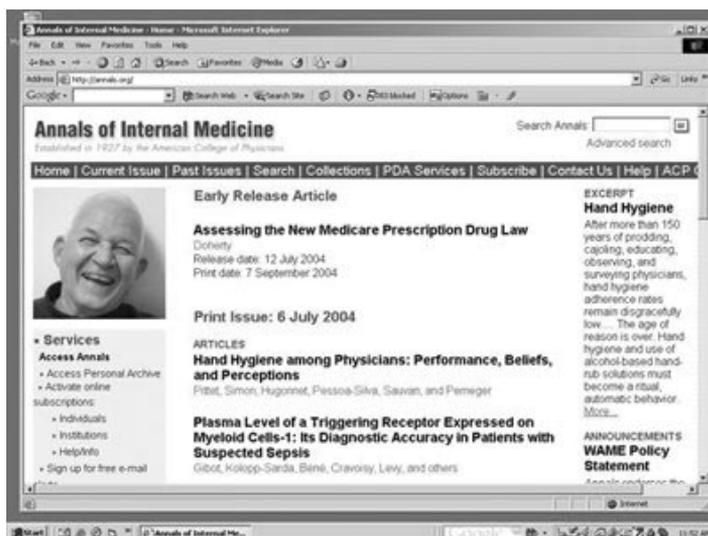
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Appendix Table. **Surgeries for Abdominal Aortic Aneurysm and Subsequent 30-Day Deaths***

Variable	Control Group (n = 33 887), n		Invited Group (n = 33 883), n	
	Surgeries	Deaths	Surgeries	Deaths
Elective surgery				
Through the screening program	NA	NA	414	13
Not through the screening program	156	12	36	5
Total†	156	12 (8)	450	18 (4)
Emergency surgery				
For ruptured AAA	92	39	33	10
For symptomatic but unruptured AAA	19	2	12	3
Total†	111	41 (37)	45	13 (29)
Other‡	2	0	11	0

* AAA = abdominal aortic aneurysm; NA = not applicable.
† The numbers in parentheses are percentages.
‡ Primary surgery for iliac aneurysm.