

Outcome in Men with a Screen-detected Abdominal Aortic Aneurysm Who are not Fit for Intervention

J. Lim, J. Wolff, C.D. Rodd, D.G. Cooper, J.J. Earnshaw*

Department of Vascular Surgery, Cheltenham General Hospital, Cheltenham GL1 3NN, UK

WHAT THIS PAPER ADDS

This study includes prospectively collected data on men with a large screen-detected abdominal aortic aneurysm who are unfit for, or decline, surgery. It provides a benchmark for turn-down rates in this population, and offers strategies to deal with patients in whom the risk of intervention outweighs the potential benefits because of poor general health.

Objective/Background: Abdominal aortic aneurysm (AAA) screening in Gloucestershire has been ongoing for 25 years. The aim of this study was to review the outcome of a cohort of men with a large (> 5.4 cm) screen-detected AAA who did not have early intervention for their AAA.

Methods: A prospectively maintained database was interrogated for a 10-year interval from 2001 to 2011. Men who did not have their large AAA repaired within 3 months of the diagnosis were identified. The reasons for initial nonintervention and subsequent outcomes were identified from a combination of hospital case notes and general practitioner records.

Results: Of 334 men referred, 59 (median age 71 years, range 62–83 years) did not have intervention within 3 months (initial nonintervention rate 17.6%). The reasons included placed back on surveillance after assessment ($n = 34$); immediately discharged ($n = 12$); required further investigations ($n = 5$); died before complete assessment ($n = 3$); and incomplete follow-up ($n = 5$). Sixteen men had delayed AAA repair with no perioperative mortality. Overall mortality in the study was 14/34 (nine from ruptured AAA, the rest from medical conditions). Two further men survived repair of a ruptured AAA. The overall rate of ruptured AAA was 11/59 (18.6%).

Conclusion: Information from studies such as these can be used to help plan treatment of men with a large AAA and to compare performance of vascular units.

© 2015 European Society for Vascular Surgery. Published by Elsevier Ltd. All rights reserved.

Article history: Received 31 March 2015, Accepted 22 July 2015, Available online 11 September 2015

Keywords: Aortic aneurysm, Aortic aneurysm screening, Outcomes research

INTRODUCTION

Rupture of an abdominal aortic aneurysm (AAA) causes around 4,000 deaths per year in England and Wales.¹ The National Health Service AAA Screening Programme (NAAASP) was started in 2009 and now covers all of England. Men aged 65 years are invited for an ultrasound scan to measure the diameter of their abdominal aorta.² A single ultrasound scan has been shown to reduce the risk of AAA-related mortality by nearly 50% at 10 years.³ Elective treatment for AAA detected by screening has lower 30-day mortality rates than repair of incidentally detected AAA.⁴ It is generally agreed that an AAA with a diameter > 54 mm should be referred for consideration of intervention; the Small Aneurysm Trial and a

subsequent randomized trial of early intervention for small AAA suggest surveillance is as safe as intervention for AAA below the 5.5 cm threshold.^{5,6}

AAA screening has been ongoing in Gloucestershire in the UK for nearly 25 years.⁷ The results of interventions for men with screen-detected AAA have been reported. In brief, men are invited to attend their general practitioner's (GP) surgery for ultrasound screening in the year that they are 65 years of age (all surgeries in Gloucestershire are visited at least annually). Men with an aorta < 2.6 cm are reassured and discharged. Those with a small or medium AAA (2.6–5.4 cm) are offered regular ultrasound surveillance. Patients in the present study all came from this screening programme.

Once patients with a large (> 5.4 cm) diameter AAA have been referred to a vascular service, consideration is given to whether the risks of intervention outweigh the risk of continued surveillance. After investigation and risk assessment, a number of patients do not go on to have intervention for their AAA. The proportion that does not have early surgery

* Corresponding author.

E-mail address: jonothan.earnshaw@glos.nhs.uk (J.J. Earnshaw).

1078-5884/© 2015 European Society for Vascular Surgery. Published by Elsevier Ltd. All rights reserved.

<http://dx.doi.org/10.1016/j.ejvs.2015.07.035>

is termed elsewhere the “turn-down” rate. However, this may include patients who do not have early surgery for a variety of reasons, and is better termed the initial nonintervention rate. This rate may vary between individual surgeons and vascular units. It would be expected that men with screen-detected AAA would be younger than those with AAA detected incidentally and might have lower initial nonintervention rates. The Vascular Society of Great Britain and Ireland (VSGBI) AAA Quality Improvement Programme in the UK identified this as an area of concern and recommended that turn-down rates be monitored in order to provide a more complete picture of interventions and outcomes.⁸

No initial nonintervention rates for a screened population of AAA exist in the published literature. Conway et al. reported on 106 patients turned down for AAA repair over 10 years,⁹ and Western et al.¹⁰ described the outcomes in 72 patients, but neither paper reported on the denominator treated, or how many screened patients were assessed in total. A questionnaire survey conducted by the VSGBI suggested that the initial nonintervention rate for elective AAA surgery is around 26% in the UK.⁸

The aim of the present study was to examine men from the Gloucestershire Aneurysm Screening Programme (GASP) referred to the local vascular service with an AAA of > 5.4 cm in diameter, in order to determine how many went on to have treatment, and to determine the outcome in men who did not have early treatment.

METHODS

GASP has a prospectively maintained database in Microsoft Access (Microsoft, Redmond, WA, USA) of all patients screened for AAA, since its inception in 1990, in the Cheltenham and Gloucestershire area, and including the transition to the NAAASP in 2009. The database was interrogated to identify all men with a screen-detected AAA referred to the vascular service at Gloucestershire Royal Hospital over the 10-year period from 2001 to 2011. Before 2010, men with an AAA > 4 cm were referred to the vascular service, and their surveillance was taken over by a hospital consultant. After becoming part of the NAAASP in April 2009, men were only referred to the vascular service if their AAA was > 5.4 cm.

Men who did not have treatment for their AAA within 3 months of the diagnostic scan suggesting it was over 5.4 cm in diameter were identified from the screening database. The reasons for the nonintervention and their subsequent outcomes were determined from a wide variety of sources: hospital case notes; GP records, both paper and electronic; and death certificates. Outcomes were collected up to the end of February 2013 when the study ceased, in order to identify 1-year mortality data for men assessed at the end of 2011. Data were recorded on an Excel spreadsheet (Microsoft) and analysed with SPSS version 21.0 (IBM, Armonk, NY, US).

RESULTS

From 2001 to 2011, 334 men with an AAA > 5.4 cm were assessed by the vascular service for management of their

large AAA. A total of 59 men (median age 71 years; range 62–83 years) did not have intervention within 3 months and formed the study group: initial nonintervention rate 17.6% (Fig. 1).

The following were the reasons why the men did not undergo prompt repair of their AAA: placed back on surveillance after assessment ($n = 34$); immediately discharged ($n = 12$); required further investigation and optimization ($n = 5$); died before complete assessment ($n = 3$); and incomplete follow-up ($n = 5$). Further details of these groups are recorded below.

Continued surveillance (34 men)

This was the largest group, containing nearly two-thirds of men turned down for early intervention. It was considered that the risks of intervention outweighed the risk of rupture at that time, often because the AAA had only just reached 5.5 cm in diameter, and the men were elderly (median age 77 years; range 64–84 years). Some had been under ultrasound surveillance for over a decade. Seventeen men were in poor health, and not suitable for any form of intervention; 12 would have been fit for endovascular aneurysm repair (EVAR) but, unfortunately, had aortic anatomy deemed unsuitable, on computed tomography angiography (CTA), for conventional EVAR. Five men declined repair after counselling but wished to be kept under surveillance.

In this group of 34 patients, nine underwent subsequent AAA repair a median of 23.0 months later (range 12.7–64.1 months). There were seven elective procedures: three EVAR and four open AAA repairs. Two patients had emergency AAA surgery for rupture (both survived). The only death in this group followed elective open AAA repair and was from colon cancer 58 months later. Median overall survival in this group of nine patients was 38.5 months (range 13.7–85.2 months).

At the end of the study interval, 14/34 men had died: nine from a ruptured AAA, one from myocardial infarction (MI), one following a stroke, one from pneumonia, one from urosepsis, and one from unknown reasons. Death occurred a median of 34.9 months (range 6.0–52.0 months) after the initial decision not to intervene. The remaining men alive at the end of the study had a median survival of 16.6 months (range 4.63–59.1 months). The two men with < 1 year of follow-up had incomplete data.

Discharged (12 men)

Twelve patients were discharged without any further AAA follow-up after their initial hospital consultation: seven men owing to their poor health precluding repair, four at their own choice, and one who was found to have inoperable lung cancer on work-up for EVAR and died shortly afterwards from pneumonia.

Six patients in this group subsequently died after a median of 26.9 months (range 5.1–49.2 months). Causes of death were pneumonia ($n = 2$), old age ($n = 1$), stroke ($n = 1$), and cardiac arrhythmia ($n = 1$); one probably from dilated cardiomyopathy, although this could not be

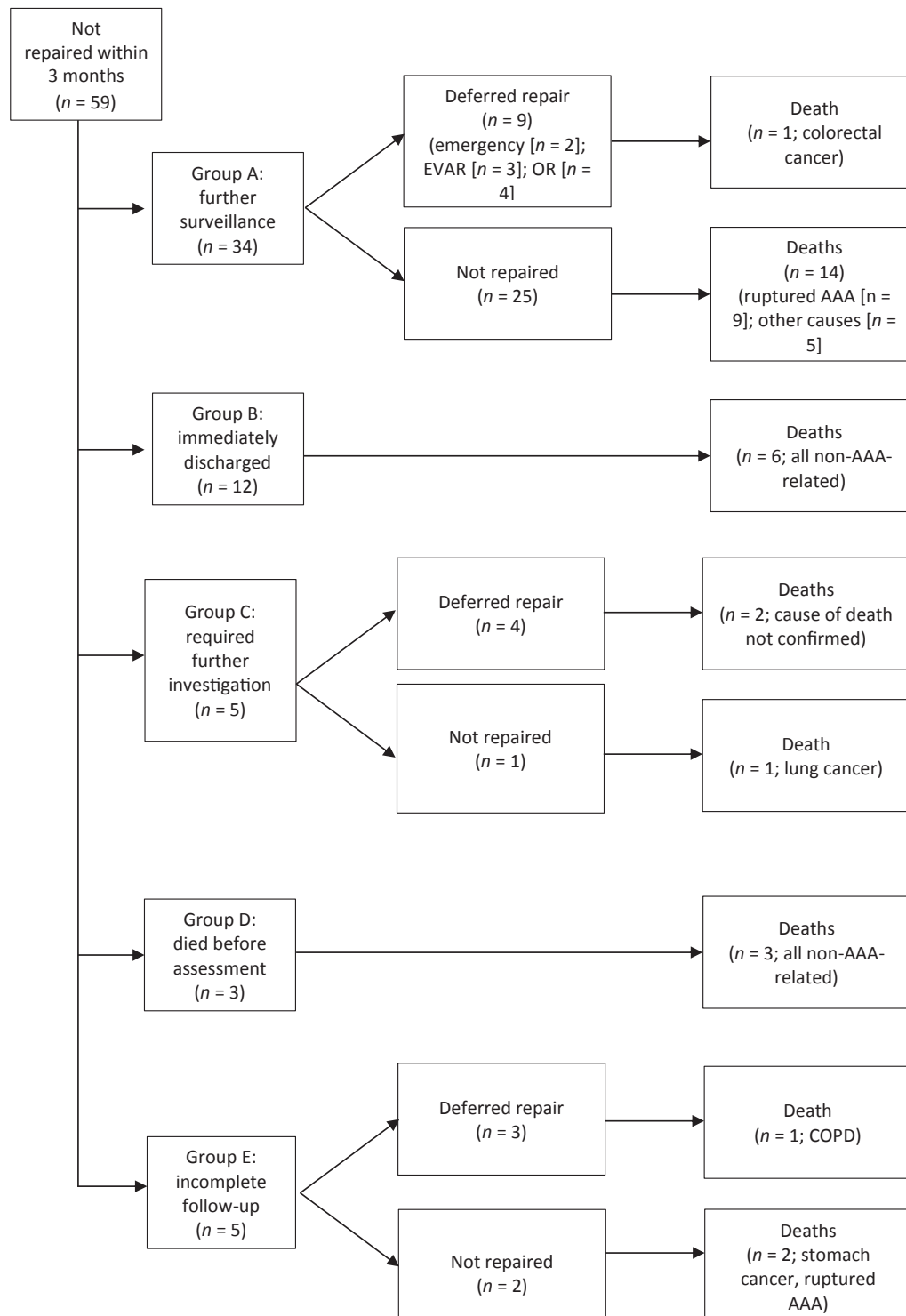


Figure 1. Flowchart of outcomes in men with a large abdominal aortic aneurysm (AAA) not repaired within 3 months of diagnosis. Note. EVAR = endovascular aneurysm repair; OR = open repair; COPD = chronic obstructive pulmonary disease.

confirmed from hospital or GP records. There were no AAA ruptures in this group.

At the end of the study, six men were still alive after a median of 25.4 months (range 3.0–43.0 months).

Further investigation and optimization (five men)

Five men had AAA repair deferred pending further investigation or optimization. Two required cardiology review (one

for severe cardiovascular comorbidities and one following collapse with unknown cause); one required optimization for severe chronic obstructive pulmonary disease (COPD); and one had investigation of an incidental pulmonary nodule. These four men underwent elective AAA repair (three EVAR, one open repair) a median of 19.4 months later (range 8.5–30.9 months). The last man in this group was diagnosed with lung cancer on work-up for his EVAR

and had his AAA repair delayed while he had radiotherapy. He died 6.6 months later (without AAA repair) from lung cancer.

Two other men died within the study interval, 70.4 and 71 months after elective AAA repair, respectively. Causes of death were not available from hospital or GP records.

Died before decision (three men)

Three men were intended for AAA repair but died before assessment was completed. One patient was diagnosed with lung cancer after CTA to assess his AAA, and died from the cancer after 4 months. One man was due to undergo open AAA repair but died of an MI before returning to the clinic to discuss his planned operation (time to death from referral was 1.9 months). The last man died 26 days after being referred for consideration of AAA repair from disseminated carcinomatosis with an unknown primary.

Incomplete follow-up (five men)

Information on outcome was incomplete for five men. Three patients' hospital and GP paper notes were unavailable, while two patients did not attend their hospital appointment to discuss their AAA when it had enlarged beyond 5.4 cm. The three patients whose notes were unavailable had their AAA repaired (two EVAR, one open repair) at a 14.4, 15.6, and 42.1 months after referral. One of the men died from COPD 18.7 months following EVAR.

With regard to the two men who failed to attend their hospital appointments, one died from a ruptured AAA 17.6 months after referral and the other died from stomach cancer 37.9 months after referral.

AAA-related mortality and repair

In total, in this group of 59 men who did not undergo intervention for AAA soon after their AAA reached the 5.5 cm threshold or above, 10 subsequently suffered ruptured AAA (16.9%). Nine ruptures occurred in men under surveillance and one in a man with incomplete follow-up. With regard to the 47 men not immediately turned down for treatment, this represents a rate of 21.3%. The median time from referral for repair to rupture was 32.8 months (range 9.5–44.5 months), and the median pre-rupture AAA diameter was 6.4 cm (range 5.7–7.4 cm).

Non-AAA-related causes of death included cancer ($n = 6$), MI ($n = 3$), pneumonia ($n = 3$), stroke ($n = 2$), and old age ($n = 1$); four were unknown owing to unavailable records. Kaplan–Meier survival analysis from time of referral to death (from all causes) showed an overall 1-year survival of 76.3% and 5-year survival of 22.0%.

Of 59 men studied here, 16 had deferred AAA repair (eight open repair, eight EVAR). There were no perioperative deaths, and all survived at least 1 year; four deaths occurred after 58.1, 95.1, 60.8, and 101.3 months, respectively. This gave a cumulative median survival from referral of 81.4 months (range 37.0–115.2 months). The remaining 43 men did not have their AAA repaired and 25 patients had

died by the end of the study; cumulative median survival in this group was 24.3 months (range 0.9–59.1 months).

DISCUSSION

This study offers a detailed insight into the fate of men with a large screen-detected AAA who do not undergo repair shortly after the diagnosis is made. This effect is an inevitable consequence of a screening programme for a disease that carries significant risks to repair. It is difficult to avoid, as men in screening programmes are not assessed for fitness before screening, or even during surveillance. It can be particularly traumatic if a man has been under surveillance for many years, and is then unfit when his AAA finally crosses the treatment threshold. Handling these sensitive issues requires information about the risks and consequences of both active treatment and nonintervention.

In this study the initial nonintervention (or turn-down) rate was 17.6%—not very different from the rate of 26.0% in all elective AAA in the VSGBI audit.⁸ It might be expected that screen-detected AAA would have a lower initial nonintervention rate, as the men are generally younger and potentially fitter than men with AAA detected incidentally. However, men aged 65 years with an AAA often have significant other comorbidities. Also, the Gloucestershire men with a large AAA contained a mix of 65-year-old men with an AAA detected at initial screen and men from the surveillance programme, who may be much older.

The second observation from this study is that there was a group of men with a large AAA who were deemed unsuitable for immediate repair. Sixteen out of 59 patients had deferred repair (two for rupture). Some were deemed unsuitable immediately, on the basis of the risks of elective repair compared with its benefit; this balance changed as the AAA enlarged. Another cohort required medical treatment either of a second condition, such as a lung cancer, or cardiac treatment to reduce the risk of perioperative cardiac complications. Outcomes in this group were good. Others such as Lederle et al. report a similar strategy:¹¹ they collected data on patients who were deemed unfit for AAA repair from 47 separate hospitals over 5 years. Their study found a rupture rate of 22.7% (45/198 patients) and a delayed AAA repair rate of 10.6% (21/198 patients). At the end of the present study, 30 out of 59 patients (i.e., a little over half) had died, but only 10 died from AAA rupture.

The NAAASP has access targets for intervention: 2 weeks from diagnosis to outpatient appointment with a specialist, and 8 weeks to intervention.¹² This accelerated investigation and treatment requires revision of the AAA pathways in many hospitals, but is designed to minimize the risk of rupture after diagnosis by screening. Data collected to monitor these NAAASP targets will enable the calculation of initial nonintervention rates at each vascular centre, something that has not been available previously. Whereas there may be good reason to defer intervention from AAA in some men, calculation of initial nonintervention rates by hospitals will ensure surgeons are not discouraged from taking on difficult procedures. The initial nonintervention

rate in NAAASP may well start low, as the programme initially detects AAAs in 65-year-old men, but may increase as the programme matures and more men are diagnosed with a large AAA during surveillance. The first reports from NAAASP suggest the initial nonintervention rate is 13.5%, but numbers are small (unpublished data).

The strengths of the present study include the use of a prospectively maintained screening database and > 90% complete follow-up (only 5/59 patients had incomplete follow-up) over a median of 24.1 months (range 0.87–59.1 months). Weaknesses include that it comes from a single vascular centre, albeit one with a long pedigree in AAA screening. Indications for treatment, and indeed interventions, for large AAA may have evolved during the study.

Information from studies such as this can be used to help plan treatment in men with a large AAA. A small initial nonintervention rate may be inevitable, and sensible. Also, a policy of not always intervening on men with a large AAA when it reaches 5.5 cm is probably widespread; many surgeons would not intervene at this stage for an 80-year-old man with comorbidity, as the risks of intervention may outweigh the benefits. However, continued surveillance with intervention later if the AAA continues to expand seems justified by the present data, where 16 of the 59 men (27.0%) underwent delayed intervention, with low morbidity and mortality.

It has been argued that focusing on individual surgeon outcomes has discouraged the highest-risk procedures, which may be one of the reasons for improving outcomes from elective AAA surgery. Performing high-risk preventive interventions is unlikely to be an effective use of resource in men with multiple comorbidities. The publication of results from other units will help determine whether the initial nonintervention rate of 17.6% reported here is reasonable.

CONFLICT OF INTEREST

None.

FUNDING

None.

REFERENCES

- 1 Anjum A, von Allmen R, Greenhalgh R, Powell JT. Explaining the decrease in mortality from abdominal aortic aneurysm rupture. *Br J Surg* 2012;**99**:637–45.
- 2 Davis M, Harris M, Earnshaw J. Implementation of the National Health Service abdominal aortic aneurysm screening programme in England. *J Vasc Surg* 2013;**57**:1440–5.
- 3 Thompson SG, Ashton HA, Gao LA, Buxton MA, Scott RAP. on behalf of the Multicentre Aneurysm Screening Study (MASS) Group. Final follow-up of the Multicentre Aneurysm Screening Study (MASS) randomized trial of abdominal aortic aneurysm screening. *Br J Surg* 2012;**99**:1649–56.
- 4 Lindholt JS, Norman PE. Meta-analysis of postoperative mortality after elective repair of abdominal aortic aneurysms detected by screening. *Br J Surg* 2011;**98**:619–22.
- 5 The UK Small Aneurysm Trial Participants. Mortality results for randomised controlled trial of early elective surgery or ultrasonographic surveillance for small abdominal aortic aneurysms. *Lancet* 1998;**352**:1649–55.
- 6 Filardo G, Powell JT, Martinez MA-M, Ballard DJ. Surgery for small asymptomatic abdominal aortic aneurysms. *Cochrane Database Syst Rev* 2012;**3**:CD001835.
- 7 Darwood RJ, Earnshaw JJ, Turton G, Shaw E, Whyman MR, Poskitt KR, et al. Twenty year review of abdominal aortic aneurysm screening in men in the county of Gloucestershire, UK. *J Vasc Surg* 2012;**56**:8–13.
- 8 Abdominal Aortic Aneurysm Quality Improvement Programme Team. National abdominal aortic aneurysm quality improvement programme interim report. Available from: <http://www.vsqip.org.uk/wp/wp-content/uploads/2013/06/National-AAA-QIP-Interim-Report.pdf> [accessed 01.10.13].
- 9 Conway KP, Byrne J, Townsend M, Lane IF. Prognosis of patients turned down for conventional abdominal aortic aneurysm repair in the endovascular and sonographic era: Szilagyi revisited? *J Vasc Surg* 2001;**33**:752–7.
- 10 Western CE, Carlisle J, McCarthy RJ, Currie IC. Palliation of abdominal aortic aneurysms in the endovascular era. *Eur J Vasc Endovasc Surg* 2013;**45**:37–43.
- 11 Lederle FA, Johnson GR, Wilson SE, Ballard DJ, Jordan WD, Blebea J, et al. Rupture rate of large abdominal aortic aneurysms in patients refusing or unfit for elective repair. *JAMA* 2002;**287**:2968–72.
- 12 NHS Abdominal Aortic Aneurysm Screening Programme. Screening for AAA. Available from: <http://aaa.screening.nhs.uk/screening> [accessed 01.05.14].