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Population screening for abdominal aortic aneurysm: evaluating the evidence against screening criteria

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Abstract

Screening for abdominal aortic aneurysm (AAA) has been initiated in the United Kingdom and United States. Screening using abdominal ultrasound scans allows AAAs to be detected and electively repaired before rupture. There is currently no policy for AAA screening in New Zealand (NZ). We reviewed literature to assess current evidence for AAA screening against standard criteria used to evaluate population-based screening programmes.

AAA rupture has high mortality, and people of Māori ethnicity are disproportionately affected. Abdominal ultrasound is a valid screening tool, and elective repair is an effective treatment. Screening reduces AAA-related mortality by about 40% in elderly men. However, the age and comorbidities of AAA patients means rupture risk has to be weighed against elective repair risk. Overtreatment is likely, given most individuals with AAA will not experience rupture in their lifetime. AAA screening appears to be cost-effective. It is unclear if the health system could support all the elements of a AAA screening pathway.

AAA appears to be an appropriate condition for which to consider population screening. We recommend research into the prevalence of AAA in NZ, the comorbidity profile of individuals with AAA, drivers of high mortality among Māori, and acceptability of AAA screening to the New Zealand public.

Abdominal aortic aneurysms (AAAs) are dilatations of the abdominal aorta, present in 5 to 10% of men aged 65 to 79 years.[1] AAAs expand asymptomatically until rupture, unless the individual dies of an unrelated cause before rupture occurs. Rupture carries a high mortality of 80 to 90%,[2–6] both due to individuals dying before emergency repair can be performed, and because emergency repair itself has a high mortality (30 to 65%).[3,7,8]

Detection of AAAs before rupture by abdominal ultrasound scans allows elective repair, which has a lower mortality (up to 10%).[9–14] Currently, detection of AAAs before rupture is largely incidental or opportunistic. Population-based AAA screening has been shown to reduce AAA-related mortality in older men,[15] with acceptable cost-effectiveness in international studies.[16]

In the United Kingdom, the National Screening Committee approved AAA screening in men aged 65 in 2007, and screening began in 2009.[17,18] In the United States, the United States Preventive Services Task Force (USPSTF) recommended AAA screening in male ever-smokers aged 65 to 75 in 2005. Since 2007, Medicare has covered one-time ultrasound screening in this group (and in women with a family history of AAA).[19,20]

Currently, there is no policy for AAA screening in New Zealand, although "awareness of the research evidence for screening is high".[21] The National Health Committee (NHC) has developed eight screening assessment criteria by which potential screening programmes can be evaluated.[22]

The purpose of this paper is to examine how contemporary knowledge about AAA stands in relation to these criteria, within a New Zealand context. It also identifies critical areas where knowledge is lacking or uncertainty remains. This is the second of two articles relating to AAA, the first article describes the epidemiology and burden of AAA in New Zealand between 2002–2006.

Criterion 1: The condition is a suitable candidate for screening

The NHC considers a condition to be suitable for screening if it is important in terms of mortality and morbidity, if there is adequate understanding of the natural history of the condition, and if there is a detectable disease marker and pre-symptomatic stage.[22]

AAA prevalence ranges from 4.5 to 7.7% in men aged 65 to 73 years in developed countries.[9,23–26] There are no population-based studies of AAA prevalence in New Zealand.

AAA is a cause of death in 1 to 3% of men aged over 65 years old in industrialised countries.[27,28] In New Zealand, there were approximately 236 AAA-related deaths per year between 2002 and 2006. However, this is likely to represent an underestimate. About 90% of these deaths were in New Zealand Europeans, and 7% in Māori.

Although absolute numbers were low, AAA event rates were 1.5 times higher in Māori than in New Zealand Europeans between 2002 and 2006. AAA mortality was twice as high, and Māori also presented at younger ages.

Similar to other countries, in New Zealand, rates of AAA events in women are considerably lower (about 23% of male rates between 2002 and 2006). Because AAA is more common among males, the bulk of AAA research is focused on males. However, females appear to have a higher rupture rate, higher case fatality in general, and higher mortality from emergency repair specifically than males.[6,29–31] Despite this, due to a dearth of AAA research in females, this review is limited to AAA screening in males.

The pathophysiology of AAA disease is well understood. It is usually related to atherosclerosis, and shares a similar pool of risk factors: age, male sex, smoking, and family history.[3,4,6,27,32,33] Aneurysmal size predicts likelihood of rupture.[34,35] For example, a AAA measuring between 5.1 and 5.9 cm has a rupture risk of 4% in the subsequent year, compared to 20% for a AAA measuring between 6.0 and 7.0 cm.[4,36]

If rupture does occur, overall mortality can be as high as 80 to 90%.[2–5] This is because less than half of rupture patients reach the hospital alive,[37] diagnosis is difficult,[38,39] fitness for surgery is often problematic,[4,40] and mortality from emergency repair is high.[3,7,8] However, a significant proportion of individuals with AAAs may never experience any problems from them during their lifetimes.

AAA is asymptomatic until rupture, and so a pre-symptomatic stage is clearly present. The 'disease marker' is an infrarenal aortic diameter of ≥3 cm on abdominal ultrasound, diagnostic of a AAA.[4]

Criterion 2: There is a suitable test

The abdominal ultrasound scan is non-invasive, and poses no physical risk to the patient. The test usually takes no longer than 10 minutes.[41,42] It is relatively inexpensive compared to other imaging modalities such as computed tomography (CT) and magnetic resonance imaging (MRI). CT and/or MRI are usually performed for anatomic mapping if aneurysm repair is clinically indicated.

The sensitivity of abdominal ultrasound scans in detecting AAAs is high, ranging from 92 to 99%. Its specificity is almost 100%.[43–45] The positive predictive value has been estimated at 97% and the negative predictive value at 99.9%,[43] which means that false positive rates are minimal. These are extremely high values, compared to screening tools used in other programmes.[46–48]

Scanning technique is susceptible to both intra and inter-observer variability, both reported as less than 4 mm in several studies. Intra-observer variability has been shown to change with scanning personnel, with less intra-observer variability reported in radiologists as compared to sonographers. [43,49,50]

Criterion 3: There is an effective and accessible treatment or intervention for the condition identified through early detection

The mainstay of effective treatment for screen-detected AAAs is elective repair. However, the majority of screen-detected AAAs will be of a size that does not warrant immediate elective repair. These individuals will require ultrasound surveillance. The frequency of surveillance is dependent on aneurysmal diameter and there is significant variation in recommended protocols.[9,12,13,23,24,51,52]

Overall mortality for AAA rupture is very high, and among those that undergo emergency repair, the 30-day operative mortality is 30 to 65%.[3,7,8] In contrast, the 30-day mortality from elective repair of an intact AAA is much smaller, between 3 and 10%.[9–14] Framed differently, for an individual with AAA, the risk of dying once AAA rupture has occurred is eight times higher than the risk of dying from elective repair. If an individual with AAA rupture makes it to surgery, the risk of dying during or after emergency repair is between three and six times higher than the risk of from elective repair.

This ‘better outcome’ from elective repair needs to be considered alongside the fact that a proportion of AAAs will never rupture, that is, people die with them instead of them. Estimating this proportion is problematic as there are very few population-based autopsy studies available. From our interpretation of a Finnish autopsy study conducted between 1959–1979[53] (which has the most comprehensive data on this issue) with about 400 cases, the ‘natural’ lifetime rupture rate was at least 30% and possibly up to 50%.

Using these estimates, about 50% to almost 70% of AAAs may not be problematic during an individual’s lifetime. It is clear that AAA screening has the potential to result in overtreatment in a cohort where AAA rupture would never have occurred.

Determining when the risk of rupture outweighs the risk of elective repair is thus a key issue in AAA management.[6] There is good consensus that elective repair should

be considered at an aneurysmal diameter of ≥5.5 cm.[4,6] As important as *when* to offer elective repair is the question of to *whom* it should be offered.

Older age and the presence of comorbidities are directly related to higher elective repair risk.[54–57] For example, between 2002 and 2006, elective repair mortality in New Zealand was almost 12% for individuals aged ≥85 years (compared to the national average of 6.7%). This means more than 2 deaths for every 20 individuals aged ≥85 years undergoing elective repair. Procedural factors such as type of approach (open or endovascular) as well as hospital volumes also affect elective repair mortality rates.[6,11,58–60]

Criterion 4: There is high quality evidence, ideally from randomised controlled trials, that a screening programme is effective in reducing morbidity and mortality

Four large population-based screening randomised controlled trials (RCTs) have been conducted: two in the UK (the MASS[9,61,62] and Chichester studies),[23,63,64] 1 in Denmark (the Viborg study),[24,65] and one in Australia (the Western Australia study).[25] All four studies primarily assessed the effect of invitation to AAA screening on all-cause mortality and AAA-related mortality, among other outcomes. (The details of the study design and results of each of these studies are available in a web appendix). Meta-analyses of these results have been conducted by the Cochrane Collaboration,[15] the USPSTF,[2] and Lindholt and Norman.[66] In each of these, the MASS study contributed the most weight to the pooled results, being the largest study.

There was no significant reduction in all-cause mortality. This is unsurprising as the contribution of AAA to all-cause mortality is small. There was a 40% reduction in AAA-related mortality at 3 to 5 years, and sustained up to 15 years. The Cochrane meta-analysis concluded that this benefit applied to males aged 65 to 79 years.[15] The USPSTF concluded benefit in males aged 65 to 74 years.[2] In terms of surgical workload, the Lindholt and Norman meta-analysis reported two to three-fold increases in elective repair rates in the short and long term. A decrease in emergency repair rates by about 50% was also noted.[66]

Each of the four screening RCTs also highlighted the variables upon which the benefits of AAA screening depend. One of these is overall AAA prevalence. The prevalence of AAAs in the Western Australia study population was relatively high at 7.2%.[25] New Zealand may have similar prevalence, although no data exist on this. Other variables include the background level of incidental detection and treatment, the exclusion of 'ineligible' individuals from screening, adequate screening uptake, minimising delays in the screening pathway, and maintaining low operative mortality from elective repair.

Criterion 5: The potential benefit from the screening programme should outweigh the potential physical and psychological harm (caused by the test, diagnostic procedures, and treatment)

AAA screening refers to not just a test but a pathway: from the invitation and ultrasound, through to surveillance and/or elective repair. The potential physical and psychological benefits and harms at each stage should be considered.

The main physical benefit of AAA screening at a population level is the reduction in rupture-related mortality. The screening process also presents opportunities for medical optimisation, in particular cardiovascular risk management.[6] The MASS study found a possible small reduction in deaths from ischaemic heart disease among those screened for AAA.[62]

As the abdominal ultrasound scan is non-invasive, the main physical harm from AAA screening lies in elective repair. Advanced age and the presence of comorbidities mean that the majority of AAA patients are high-risk for adverse postoperative events. Cardiac complications are the most common, occurring in approximately 11% of elective repair patients. Others include respiratory and renal failure, ischaemic colitis, spinal cord ischaemia, and prosthetic graft infections. Mortality from elective repair has already been discussed under Criterion 3.[67]

The psychological benefits of AAA screening may be in the form of reassurance after a negative scan. Individuals with a family history of AAA may derive significant benefit from having a feared condition confirmed/refuted, and from accessing elective repair if appropriate.

Four main studies considered psychological harms associated with AAA screening.[9,68–70] There appears to be some distress associated with attending a scan. This is transient if the scan is negative, but may not be so if the test is positive. After this point, there is conflicting evidence as to whether surgery or surveillance (or both) is associated with psychological distress. Reassuringly, the MASS study found that all scores were within population norms at all times.[9]

Overall, the majority of individuals screened by a screening programme will not have a AAA and can be 'reassured and discharged'. For those diagnosed with AAA, the benefit-harm balance requires clarification. Firstly, it is unclear how 'acceptable' the not insubstantial risk of elective repair is to the New Zealand public. Secondly, there is insufficient information on the comorbidity profile of AAA patients in New Zealand, and how this translates into fitness for surgery. There is also lack of research on the psychological impact of not being fit for surgery despite having a AAA of operable size.

Criterion 6: The health care system will be capable of supporting all necessary elements of the screening pathway, including diagnosis, follow-up and programme evaluation

A major practical issue in implementing AAA screening will be in identifying an eligible population. In New Zealand, the likely best source for recruitment is primary care registers. This is associated with good uptake and the ability to exclude genuinely ineligible candidates.[9,25,71] Adequate uptake of AAA screening in Māori will be vital given their disproportionate burden from AAA. Other key issues include where scans should be done (hospital or community) and who does them (ultrasonographers or other trained personnel). Alongside this is the need to consider who holds responsibility for explaining results to patients, and for arranging surgical referral or surveillance.

Identifying potential 'bottlenecks' in health services is dependent on scoping existing services and estimating the projected burden of AAA screening on these services. For

example, a national screening programme will increase elective and decrease emergency vascular surgical workload. Two meta-analyses estimate an approximate doubling in elective repairs,[15,66] which by 2002–2006 data would equate to a total of 534 elective repairs annually (based on an annual average of 267 elective repairs).

Estimates of vascular surgical workload, ultrasound surveillance, and other health service requirements as a result of population screening are highly dependent on AAA prevalence, the proportion of AAAs that are of operable size, the proportion of individuals with operable AAAs that are fit for surgery, and the levels of incidental detection.

There is lack of local data in each of these areas. Using MASS study figures and treatment protocols,[9] if 10,000 men aged 65 to 74 years were scanned, a AAA would be detected in about 490 men. Of these, about 431 men would require further surveillance at intervals ranging from 3 months to yearly depending on aneurysmal diameter (348 men would have AAAs between 3 and 4.4 cm, 83 men would have AAAs between 4.5 and 5.4 cm). About 59 would have AAAs ≥5.5 cm, thereby requiring referral for elective repair.

AAA screening will impact on a wide range of health services. These include radiological services, vascular outpatient and pre-assessment clinics, theatres, intensive care units, surgical and medical wards, rehabilitation and allied health services, nursing homes and community support services. Ability to screen will depend on workforce capacity and infrastructure in all these areas.

Coordination, monitoring, and evaluation is mandatory for a screening programme to be both efficient and effective. A central agency with mandate and oversight will be required,[72] along with appropriate information systems. A quality assurance framework will need to be established from the outset in order to deliver promised benefits and minimise harms. An important component of this will be to ensure that operative mortality and morbidity rates are consistently low, and there is a pre-determined system for managing surgical outliers.[6,73]

Criterion 7: There is consideration of social and ethical issues

There is an ethical obligation to convey potential harms and benefits to the individual, to allow them to make an informed decision about whether screening is right for them. Critical to the informed consent process is how evidence is framed, as it determines how harms and benefits are perceived.[74] For example, the reduction in rupture-related mortality could be presented as a relative risk reduction, an absolute risk reduction, or as numbers needed to screen (NNS).

MASS study figures for these are 42% (the risk of dying from a AAA is 42% lower in a group invited to be screened), 0.14% (the risk of death from a AAA drops from 0.33% in a group not invited to screening to 0.19% in an invited group, a 0.14% reduction), and 714 (714 men need to be screened in order to avoid one death from AAA) respectively. The expression of benefits and harms in a variety of forms allows for a more balanced informed consent process.[74 75]

The limitations of AAA screening should be made evident. The chances of falsely negative or positive scans are small but not negligible. The potential participant should understand that a positive scan is by no means a guarantee of elective repair, as

the latter is dependent on both aneurysmal size and fitness for surgery. An individual who normally considers himself healthy could then be in a situation where he knows he harbours a potentially dangerous disease but cannot access definitive treatment.

Offering population screening when a significant proportion of individuals with AAA (10 to 25% by some estimates) will be considered unfit for elective repair is a major ethical issue.[42] Additionally, the majority of AAAs may not rupture within the individual's lifetime. There is a significant probability of overtreatment for a condition that may never have manifested. This is especially important when the treatment in question has a mortality rate of up to 10%.

An equity focus is important if a screening programme is to avoid exacerbating existing inequalities. It is appropriate for AAA screening to be targeted to males in view of their higher prevalence. However, concerns have been raised about a possible gender bias (against females) in AAA diagnosis and selection for surgical treatment.[76] It is also worth noting that existing screening programmes do not appear to serve Māori particularly well,[77,78] and AAA disease has a higher mortality for Māori. Specific strategies to ensure high uptake and good access to treatment will be vital.

Criterion 8: There is consideration of cost-benefit issues

The cost of a population-based AAA screening programme is clearly far greater than the cost of the screening tool alone. Cost components include the invitation to screening process, ultrasonography, hospital costs (from pre-assessment to rehabilitation after surgery), community care, and costs to the patient and family. There is also significant cost associated with coordinating, monitoring, and evaluating a screening programme.

A systematic review considered the results of 16 cost-effectiveness studies, a mixture of decision analytic modelling as well as those 'piggybacked' to clinical trials.[79] Comparison was limited due to different methodology (types of models, time frames, screening strategies) as well as different assumptions (cost assumptions and discounting rates).

The highest quality trial, the MASS trial,[61,80] had an incremental cost-effectiveness ratio (ICER) of £36,000 per gained quality-adjusted life year (QALY) at four years. The National Institute for Health and Clinical Evidence (NICE) uses a threshold of below £25,000 to £30,000 per QALY to determine if an intervention is cost-effective.[81,82] By this measure, the MASS trial was on the margin of cost-effectiveness at 4 years, and improved over time.

There was wide discrepancy in ICERs , but in general, AAA screening appears to be cost-effective. Extrapolation to the New Zealand setting is limited due to large variations in cost assumptions. There are no local cost-effectiveness studies to date. Additionally, uncertainty about AAA prevalence in New Zealand limits the cost assumptions that can be made.

Conclusion

On the whole, AAA screening appears to be an appropriate condition for which to *consider* population screening. AAA screening fulfils five out of the eight NHC screening criteria. The remaining three criteria (benefit-harm balance, health system

capacity, and cost-effectiveness) are areas which lack New Zealand data, and where extrapolation from international studies is of limited value. Four core recommendations are proposed, arising from these gaps in knowledge.

Firstly, it is recommended that a population-based prevalence study be undertaken in New Zealand. Findings from this study will be essential in assessing true burden of disease, evaluating benefit-harm balance, forecasting health system requirements, and assessing cost-effectiveness.

Secondly, further research should be done on the comorbidity profile of individuals with AAA, particularly in terms of fitness for elective repair. This has significant implications for benefit-harm balance, and is also an ethical issue.

Thirdly, it is recommended that the drivers of high mortality in Māori be investigated further. This will be important in ensuring the benefits of AAA screening are evenly distributed between population groups.

Finally, it is recommended that further research be done on the acceptability of AAA screening to the New Zealand public. The perceived acceptability of AAA screening will influence uptake of both the screening test and any consequent treatment.

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