### **REVIEW ARTICLE**

Kenneth Ouriel, MD, Review Section Editor

## Screening for abdominal aortic aneurysm in Canada: Review and position statement of the Canadian Society for Vascular Surgery

Tara M. Mastracci, MD, FRCSC, a,b and Claudio S. Cinà, MD, Spec Chir(lt), FRCSC, MSc (HRM), a,b on behalf of the Canadian Society for Vascular Surgery, Hamilton, Ontario, Canada

#### BACKGROUND AND RATIONALE

#### Significance of the problem

Abdominal aortic aneurysms (AAA) are found in 6% (95% confidence interval [CI] 5-6) of men over the age of 64<sup>1-4</sup> and 1% (95% CI 1-2) of women in the same age group.5 AAAs confer a risk of spontaneous rupture and death, which is related to the diameter of the aneurysm: a risk of rupture of 0.5%, 1%, 11%, and 26% per year has been associated with a diameter of <4 cm, 4.0 to 4.9 cm, 5.0 to 5.9 cm, 6.0 to 6.9 cm, respectively.<sup>6-8</sup> Population based studies show that 66% (95% CI 58-73) of patients with ruptured aneurysms die before reaching the hospital or in the hospital before operative repair.9 For those who undergo surgery, the operative mortality for ruptured AAAs is reported to be 41% (95% CI 40-42) in a recent large observational study<sup>10</sup> and 48% (95% CI 46-50) in a metaanalysis of cohort studies. 11 The 30-day perioperative mortality for elective open repair of AAAs is reported in most series and randomized controlled trial it is 5% to 8%. 12-24

#### The screening tool

Ultrasonography has the characteristics of the ideal screening tool (simplicity, safety, reliability, validity, cost effectiveness and acceptance to the public<sup>25</sup>) and has been used in previous RCTs of screening programs. 1-4 It is able to define the diameter of the infrarenal aorta in 98% (95% CI 92-94) of individuals, 26 with a sensitivity and specificity of 100% and 98%, respectively.<sup>27</sup> The correlation between observers for ultrasound measurements of the abdominal

From the Department of Surgery, a Division of Vascular Surgery and the Department of Clinical Epidemiology and Biostatistics, b McMaster Uni-

Additional material for this article may be found online at www.jvascsurg.org. Correspondence: Claudio S. Cinà, MD, 304 Victoria Ave N, Suite 305, Hamilton, ON L8L 5G4 Canada (e-mail: cinacs@mcmaster.ca).

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aorta is high (Spearman coefficient = 0.99), but abdominal girth reduces the precision of the measurement.<sup>28</sup>

A focused physical examination has been investigated as a screening tool to identify AAA. Sensitivity has been reported in the range of 76% to 85% and specificity 85% for AAA > 5 cm  $^{29,30}$  with moderate interobserver agreement (kappa = 0.5).<sup>31</sup> The diagnostic properties of physical examination require further investigation.

#### The evidence for screening

Outcome mortality. Several large population based studies<sup>32-38</sup> and four RCTs of men over 65 years old<sup>1-5</sup> investigated the effect of screening programs on AAA related mortality. The pooled estimate of the effect of screening based on the meta-analysis of four RCTs showed a relative risk (RR) of 0.60 (95% CI 0.45-0.80; P = .0004) in favor of screening men >65 years of age (Fig 1).39 The absolute risk reduction (ARR) for the outcome mortality was 0.13% (95% CI 0.07-0.21), which corresponds to a number needed to screen (NNS) of 769 (95% CI 476-1428) over 3.4 years. If only trials that screened patients 65 to 75 years old are considered, the ARR reduction for the outcome mortality was 0.16% (95% CI 0.13-0.2), which corresponds to a number needed to screen (NNS) of 625 (95% CI 500-769) over 4 years. The details of the screening protocols used in these RCTs are presented in Table I (online only).1-4

Rescreening. Two of the RCTs looked at the need for rescreening in individuals with <3 cm AAA: the Viborg trial<sup>1</sup> repeated an ultrasound examination (USE) 3 to 5 years after the first one and found that new AAA > 3 cm occurred in 28% (95% CI 21-35), but none were clinically significant (the largest <48 mm)<sup>1</sup>; and the Chichester trial rescreened patients with aortic diameter <3 cm every 2 years and identified 4.1% AAA, which were all <3.8 cm in

Age. Age affects the magnitude of benefit from screening. Males over the age of 75 were included in two of the four RCTs<sup>3,4</sup>; and the pooled RR for mortality was 0.76

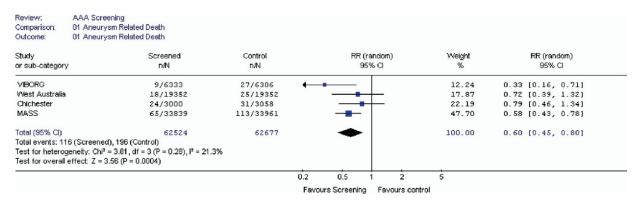


Fig 1. Pooled relative risk abdominal aortic aneurysm related death (men >64 years old). 1-4

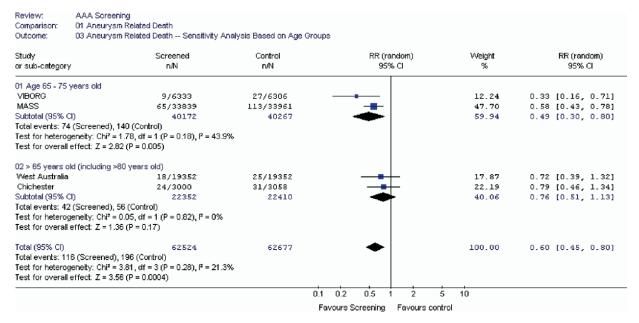


Fig 2. Pooled relative risk of abdominal aortic aneurysm related death stratified by age. 1-4

(95% CI 0.51-1.13, P = .17), in those studies, which excluded older men a larger benefit was identified (RR 0.49; 95% CI 0.3-0.8, P = .005) (Fig 2). The reduced benefit of screening elderly males is due to the reduced life expectancy and to the demonstrated increased mortality after AAA repair (odds ratio [OR] 2.11; 95% CI 1.03-4.32, for each 10-year increase in age).

**Women.** One of the RCTs<sup>5</sup> included 9342 women. The prevalence of AAA >3 cm was 1% (95% CI 1-2) and of AAA >5 cm was 0.1% (95% CI 0.3-2.3); screening did not reduce mortality (RR = 1.49, 95% CI 0.72-3.10).<sup>5</sup>

Data from the ADAM screening program shows that female sex is a negative risk factor for the presence of AAA (OR 0.17, 95% CI 0.07-0.48).<sup>42</sup> In this study, the strongest risk factor associated with AAA was a smoking history: the prevalence of AAA >3 cm was 0.4% (95% CI 0.08-0.7) in nonsmokers and 1.5% (95% CI 1-2) in women who ever smoked.<sup>42</sup> This corresponds to a four-fold greater risk in

smokers than nonsmokers (OR 3.8, 95% CI 1.57-9.20). In women with aneurysms, however, other risk factors were similar to men. Of these, the presence of cerebrovascular disease (OR 3.20, 95% CI 1.48-6.92), family history of AAA (OR 2.6 95% CI 1.1-6.0) and age (OR 1.8, 95% CI 1.2-2.6) were statistically significant, while coronary artery disease was not (OR 1.38, 95% CI 0.68-2.81). <sup>42</sup> Given the low (0.1%) baseline prevalence of clinically significant (>4 cm) AAA in women, from a population based perspective, even in women smokers the prevalence of AAA is still very low (0.4%, 95% CI 0.16-0.92).

In the United Kingdom Small Aneurysm Trial, the hazard ratio (HR) for risk of rupture was four times higher in women compared with men (HR 4.0, 95% CI 2.0-7.9; P < .001), but the HR for the primary outcome of all-cause mortality was worse for immediate repair in women (0.99) than in men (0.80), although this did not achieve statistical significance. <sup>43</sup> Ruptured aneurysms seem also to occur at

an older age in females compared with males: the Chichester trial found that 53% (95% CI 47-60) of ruptured aneurysms occurred in men younger than 80 years, and 72% (95% CI 62-81) in females older than 80 years.<sup>5</sup>

Family history. The ADAM study found that a family history positive for presence of AAA is associated with a two-fold increase in the risk of having an AAA (OR 1.9; 95% CI 1.6-2.3) with no difference between men (OR 1.96, 95% CI 1.77-2.16) and women (OR 2.6, 95% CI 1.12-6.01). In the West Australia RCT a sister with an AAA was associated with an OR of 2.7 (95% CI 1.4-5.3), and in a population study in Sweden, a first degree relative with an AAA was associated with OR 4.4 (95% CI 1.5-13.0).

Quality of life. Five trials used the SF-36 scale<sup>46-51</sup> and one the General Health Questionnaire,<sup>48</sup> and found no difference between patients with AAA and those without, participating in a screening program. The negative results found in these studies are not surprising since the SF-36 is not a good tool to measure anxiety (personal communication with D.L. Streiner, Feb 5, 2006). In addition, they did not compare individuals entering a screening program vs those who did not. One RCT, using a scale specifically designed to assess changes in quality of life caused by screening programs, found a significantly worse score in individuals with AAA compared with those without.<sup>52</sup> Invitation to screening is associated with anxiety in all participants, which disappears with time.<sup>48</sup>

#### The cost of screening

The Viborg trial studied the cost effectiveness of the screening program and estimated that the cost per life year gained was €9057 (95% CI 5872-20,063 [C\$12,736.29, 95% CI 8257-28,213, conversion rate €1 = C\$1.41]) after 5 years. The cost effectiveness improves over time with a reduction in cost of 20% after 15 years (€1825, 95% CI 1185-4063, [C\$2566, 95% CI 1666-5713]). Likewise, the 7-year follow-up data for the MASS trial also found AAA screening to be cost effective (£12,500 [95% CI £8000-25,700] per life year gained). Calculate the screening to be cost effective (£12,500 [95% CI £8000-25,700] per life year gained).

Using decision analysis, Wanhainen et al found that the costs per life year gained ranged from US\$8309 to \$14,084, according to the type of AAA screening strategy,55 and Montreuil et al estimated a quality adjusted cost utility ratio of C\$6194 (95% CI 1892-10,837).<sup>56</sup> Kim et al, in a cost analysis of the MASS trial, demonstrated that the societal cost of providing surgery for patients with AAA increases by 47% if a screening program is implemented.<sup>57</sup> This increased cost is due to the increased number of elective procedures generated by the screening program, which is not completely offset by the reduction in surgeries done for ruptured AAA.<sup>57</sup> The cost of screening increases if compliance falls,58 perioperative mortality for urgent AAA repair decreases, or perioperative mortality for elective AAA repair increases.<sup>59</sup> This is due to the relative decreases in the number of lives saved in these scenarios.

Different imaging modalities have been investigated to reduce the cost of screening programs. Lee et al studied the accuracy of an ultrasound examination (USE) performed by a vascular technician, who was instructed to examine the aorta as fast as possible, to a maximum of 5 minutes (a "quick scan"). When the two methods were compared using decision analysis, the "quick scan" was associated with a 39% cost saving per quality adjusted life year (QALY) (\$11,215 with conventional ultrasound to \$6850 with the quick scan).60 In another study, a cohort of patients referred for assessment of vascular diseases at a tertiary center, a portable ultrasound unit operated by a physician during the physical examination was compared with a conventional USE performed by technicians. The portable unit had a sensitivity of 93% (95% CI 79-96), a specificity of 97% (95% CI 93-99), a positive predictive value of 89% (95% CI 78-96), and a negative predictive value of 98% (95% CI 95-100).61 The current average cost of a focused aortic USE in Canada (Table II, online only) is C\$63 (SD 20); the use of a "quick scan", as described above, will reduce this cost.

Using information from RCTs, 1-4 a population based study,9 and a metaanalysis,11 we projected the effect that a screening program will have on the Canadian population. Without a screening program, the aneurysm related mortality over 41 months is 5664 patients or 3283 patients if we consider men >65 years or men 65 to 75 years old, respectively (Table III, online only). During the same period, 7014 or 4065 surgeries respectively, will be done following the routine care of patients identified incidentally to have an AAA or because of rupture. If a screening program is implemented, the aneurysm related mortality over 41 months is 2094 for men >65 years and 1214 for men 65 to 75 years old; the number of surgeries that would be performed 15,158 and 8784, respectively (generated by screening and, in nonparticipants, by AAA identified by standard care or because of rupture) (Table IV, online only). This translates to 3570 or 2069 lives saved (according to the age group of individuals involved in the screening program) over 41 months. This corresponds to an ARR of 30% and a NNT of 3. This means that we need to operate on three AAA to save one life at an additional cost of additional 8144 or 4719 surgeries, respectively.

We used the cost for elective and ruptured aneurysm repair at the Hamilton Health Sciences (a tertiary vascular university referral center) to generate an estimate of the cost of treatment of AAAs (Table VIII, online only). We estimate that the cost of treatment of AAAs in all men >65 years old over a 41-month period, in the current system in Canada is C\$173,239,065 and if only men 65 to 75 years of age are considered, the current costs are C\$100,400,160. If a screening program were implemented the cost would be C\$313,874,682 or C\$181,883,889 for screening all men >65 years of age or only men 65 to 75 years of age, respectively.

Finally, the cost of repeated USE in patients with 3.4 to 4.4 cm AAA and in 4.5 to 5.4 cm AAA should be considered. Since AAAs grow at a rate of 2 mm per year, 6-8 a base case patient with a 3.5 cm AAA will require on average, 10 years of follow-up before the AAA becomes >5.5 cm and

therefore considered for surgery. If an ultrasound per year is done, the cost of 10 additional tests must be added.

#### STANDARD OF CARE OUTSIDE OF CANADA

The United States Preventative Services Task Force (USPSTF) recommends one time screening for AAAs in men 65 to 75 years of age who have ever smoked. EThe Screening Abdominal Aortic Aneurysms Very Efficiently (SAAAVE) Act was introduced into the Senate in 2005. This supports an AAA screening program that will start in January 2007, and provide screening ultrasounds to male ever-smokers when they turn 65 years old. The American Society for Vascular Surgery (SVS) and the Society for Vascular Medicine and Biology have a consensus statement that adds women with cardiovascular risk factors (such as smoking, hypertension, and peripheral vascular disease), age 60 to 85 years and both men and women 50 years and older with family history of aneurysm.

The Vascular Society of Great Britain and Ireland has organized a working group to examine the evidence existing for advocating population based screening, but no screening guidelines have been suggested.<sup>65</sup> There are currently no formal guidelines or screening programs in Australia and New Zealand (personal communication with the President of the Australia and New Zealand Vascular Society discussing their Society's stance on AAA screening). In Sweden, programs for AAA screening are considered investigational until further evidence is available (personal communication from the President of the Swedish Vascular Society discussing their Society's stance on AAA screening).<sup>66</sup>

#### DISCUSSION

The goal of screening programs is to use a diagnostic test in apparently healthy individuals to identify those at risk of morbidity and mortality from a disease.<sup>67</sup> Individuals at-risk will then be offered a treatment to divert the risk. Screening programs are most effective in conditions which are prevalent, have a detectable risk factor and for which a safe and cost effective treatment exists. 25 RCTs have shown that AAA screening is effective in reducing AAA related mortality in patients 65 to 80 years of age (RR 0.60; 95% CI 0.45-0.80). The benefit increases if only patients 65 to 75 years old are enrolled (RR 0.49; 95% CI 0.30-0.8). The inclusion of older males reduces the benefit and cost effectiveness of screening because of the shorter life expectancy and higher perioperative mortality. 41 Women have risk factors for AAA similar to men and they appear to have a greater risk of rupture. The benefit of screening in women, however, is uncertain given the low prevalence of disease, and that rupture occurs later in life and results of surgery may be worse.

A screening program at a population level, and screening of a particular individual, are two related, but different concepts. The former requires a careful examination of the benefits at the population and the individual levels, and of the societal cost. The latter requires an evaluation of the constellation of risk factors which, in that particular indi-

vidual, increases the probability of the presence of an aneurysm.

The Geoffrey Rose "prevention paradox" applies to mass screening programs, which may provide benefits to the population at large, but provide minimal or no benefit to the individual patient being screened.<sup>68</sup> The individual risk of participating in a screening program is an important consideration when the intervention offered is associated with 5.5% (95% CI 4-8)22 mortality and a 26% (95% CI 20-33) moderate to severe systemic complications.<sup>23</sup> The screening program will save the lives of those patients who would have died because of rupture; however, it is also associated with the perioperative mortality of elective surgery (in our estimate of scenarios in the Canadian population, 638 deaths if screening is applied to >65 year, or 370 deaths if applied to 65- to 75-year-old men, respectively). Although the population of patients who would have died because of rupture and the population of patients who die because of complications of elective surgery may somewhat overlap, they are not necessarily the same. This means that some people who may have never ruptured their AAA may be killed by the screening program. Considering the individual risk of a patient in the context of the available evidence is crucial when determining the benefit of screening for AAA.

At a population level, our analysis of a screening program of men >65 or 65 to 75 years of age implemented in the Canadian system, we have shown that it will reduce aneurysm related mortality by 30%, corresponding to an NNT of 3. This means that, to save one life, we will need to screen 625 individuals and operate on three. Without a screening program, patients would be generally operated upon for AAA with a diameter of 5 to 5.5 cm according to the results of RCTs and suggested guidelines. 43,57,69 The implementation of a screening program will increase the number of surgeries, not only because of increased number of AAAs identified by screening but also because a number of individuals would be operated upon for AAAs of borderline diameter, rapid change in size, patient preference, patient and physician anxiety, or growth of the aneurysm during follow-up. This effect is shown in Table IV where the expected number of patients with AAA >5.5 cm (8176) for males >65 and 4739 for males 65 to 75) is smaller than the actual number of individuals who will receive surgery (13,355 for males > 65 and 7740 for males 65 to 75). The combination of these factors explains why the cost of the screening program increases two-fold if implemented in the male population >65 years (\$140,635,617 vs \$81,483,727). An analysis of the risk reduction of the available RCTs also suggests that the benefit of screening is greater if only individuals 65 to 75 years are considered (Fig 2).

RCTs have shown that in men >65 years of age, the NNS to prevent one AAA related mortality is 769 (95% CI 1428-476).<sup>1-5</sup> This is comparable to screening strategies of fecal occult blood testing in colorectal cancer (NNS = 808, 95% CI 563-1648) and mammography in breast cancer (NNS = 1887, 95% CI 1343-3505).<sup>70</sup> A cost analysis of

AAA screening found a cost per life year gained of US\$8309 to \$14,084.55 This compares with colon cancer screening (ie, fecal occult blood testing) that has a cost per life year gained of US\$10,000-US\$25,00071 and with breast cancer screening (ie, mammography), which has a cost per life year gained of US\$16 000 - US\$20 000.<sup>72</sup> The interventions associated with these conditions, however, have lower mortality and morbidity than open AAA repair. In addition, these cost analysis studies were done in non-Canadian health care system models. Over a 41-month cycle (the average duration of the RCTs of screening programs), we estimated that the cost for treating of AAA in Canada for people 65 to 75 years, in the current system, is C\$100,400,162. If a screening program were applied to the same group of individuals, the cost would increase by C\$81,483,727 (Table VIII, online only). Considering that the screening program will save 2069 patients (Table III and Table IV, online only), the cost of treating AAA within the screening program is C\$39,383 per life gained. Our review and meta-analysis of the literature shows that the NNS for this age group is 625. At an average cost of C\$60 for USE, this translates to an average screening cost per life gained of C\$37,500 over 41 months. The overall additional cost of the screening program is therefore C\$110,813 per life saved. Assuming that the average life expectancy of patients undergoing AAA repair is 6 years, <sup>73</sup> the cost per life year gained is C\$18,469, which is in the range of what is considered cost effective. This is in keeping with similar studies of the effect of screening in a Canadian setting.74

The majority of cost associated with AAA screening is secondary to the additional elective surgeries produced by the screening program. However, the number of ultrasounds performed adds to the cost of screening. There is currently no evidence to guide the exact screening program model that would be best applied to the Canadian Health Care system, and further research will be needed to devise a Canadian model that is both cost effective and efficient. For example, in the four RCTs, ultrasounds were used to detect patients with AAA >3 cm: the majority (74%, 95% CI 73-76) had small AAA (<4.4 cm),<sup>2,3</sup> which may never reach the operative threshold during the patient's life span, and 11% (95% CI 10-13) had >5 cm AAA in whom further follow-up or surgery may be indicated to prevent rupture. If screening were focused only on those patients at risk of a large AAA (>5 cm), the number of non useful USE could be reduced with improved cost effectiveness. A focused physical examination with a sensitivity for aneurysms >5 cm in diameter of 82% to 98%<sup>30,75</sup> followed by an USE in only those patients identified to have an AAA, may represent a strategy to reduce cost. This was supported by the Canadian Task Force on Preventative Health.<sup>76</sup> RCTs of screening have not evaluated the use of physical exam before USE for AAA screening. A review of the topic by Frame et al<sup>77</sup> suggests that the cost per life year for a screening program is US\$41,550 if USE alone is used and US\$28,741 if a preliminary physical examination is used to screen those who are candidate for an US.

Several factors influence the need and effectiveness of a screening program for aneurysms. Decreasing the perioperative mortality of elective aneurysm repair will increase the benefit of a screening program. Endovascular AAA repair with an anticipated perioperative mortality of 1% to  $2\%^{23,24}$  offers promise as a better intervention, but further studies of its impact on long-term costs and mortality are necessary. Sensitivity analyses have shown that decreasing the operative mortality of ruptured aneurysm repair decreases the cost effectiveness and benefit of a screening program.<sup>59</sup> It is therefore possible that if endovascular technology are proven to improve the perioperative mortality of ruptured AAA, 78-90 the effectiveness of a screening program will require reassessment. Imposing a strategy that subjects an asymptomatic population to a 5.5% risk of death might not be justified if the perioperative mortality for ruptured AAA were lower than the current 48%.

While the above arguments pertain to a population based screening, an individual physician may elect to use USE as a screening tool based on the anticipated individual risk for AAA of a particular patient. A screening program at a population level and screening of a particular individual are related, but different concepts. The former requires a careful examination of the benefits at the population and the individual levels, and of the societal cost. The latter requires an evaluation of the constellation of risk factors, which in that particular individual, increases the probability of the presence of an aneurysm. Age >70 years (OR 1.7), family history (OR 1.9), smoking (OR 1.9), and cerebrovascular disease (OR 1.3) are powerful determinants of the probability of having an AAA and are similar in men and women.<sup>69</sup> Since the odds ratio associated with these risk factors are of similar magnitude, the effect of multiple risk factors can be assumed to be additive. This means that in an individual who is >70 years, with a positive family history, a smoker and has cerebrovascular disease, we should anticipate a six-fold increase in the risk of AAA. In this particular individual, either man or woman, performing a USE is justified and acceptable.

In conclusion, RCTs have shown benefit of implementing a screening strategy at a population level in high risk individuals. The cost effectiveness of these programs needs to be carefully considered by governing health care agencies and health care providers.

# POSITION STATEMENT OF THE CANADIAN SOCIETY FOR VASCULAR SURGERY FOR SCREENING OF ABDOMINAL AORTIC ANEURYSM

The Canadian Society for Vascular Surgery recommends the following guidelines for screening patients for AAA. This is based on a review of the evidence conducted in 2006. These guidelines should be revised as new evidence becomes available through a systematic review commissioned by the CSVS every 5 years. Levels of evidence are based on the GRADE recommendations (Fig 3, Table V, Table VI, Table VII, online only).

- 1. A population based screening program is recommended for men 65 to 75 years of age who are candidates for surgery (anticipated low perioperative mortality and morbidity) and are willing to participate.
  - Evidence grade HIGH (RCT). Rationale: Relative risk of AAA related mortality 0.49 (95% CI 0.3-0.8, P=0.005) in screened men 65 to 75 years old compared with nonscreened.<sup>1,2</sup>
- 2. Screening provides borderline to no benefit for men 75 to 80 years old.
  - Evidence Grade HIGH (RCT). Rationale: Relative risk of AAA related mortality 0.76 (95% CI 0.51-1.13, P = 0.17) in screened men >65 years old compared with nonscreened.<sup>3,4</sup>
- Population based screening of women >65 years old is not recommended
  - Evidence Grade HIGH (RCT). Rationale: Relative Risk of AAA related mortality 1.49 (95% CI 0.72-3.10) in screened women compared with nonscreened.<sup>5</sup>
- 4. Individualized investigation with USE of women >65 years old with multiple risk factors for AAA (smoking history, cerebrovascular disease, family history of AAA) may be beneficial.
  - Evidence Grade MODERATE (Cohort data from RCTs, <sup>44,69</sup> population-based study). <sup>45</sup> Rationale: In women, these factors increase the risk of AAA one- to seven-fold, but the baseline prevalence of >4 cm AAA is 0.1% (95% CI 0.03-0.3).
- Ultrasound is an effective imaging modality for AAA screening.
  - Evidence Grade HIGH. (RCT Data, <sup>1-4</sup> Cohort Studies <sup>26-28</sup>). Rationale: All screening RCTs employ ultrasound in their screening strategy. Ultrasound has 100% sensitivity and 98% specificity.
- 6. In participants found by screening to have an aortic diameter <3 cm, no follow-up ultrasound is necessary before 3 to 5 years.
  - Evidence Grade HIGH (Cohort study of RCTs<sup>1,4</sup>). Rationale: A new AAA >3 cm was identified at 3- to 5-year follow-up, in 28% and 4.1% of patients with an aortic diameter of <3 cm at the first ultrasound. All new AAA were <4 cm.<sup>1,4</sup>
- 7. For individuals with aneurysms 3.0 to 4.4 cm, a yearly abdominal ultrasound is an acceptable practice. The true effective interval of re-screening is unknown for this group and it is likely that every 2 years is also acceptable for the smaller aneurysms.
  - Evidence grade MODERATE (population based study, 6 cohort study of tertiary referral centers<sup>7</sup>). Rationale: Based on available evidence regarding growth rates and risk of rupture: mean 0.21 cm growth rate for aneurysms 3.0 to 4.4 cm SD 0.45 cm.
- 8. Screening individuals with popliteal artery aneurysms is likely beneficial.
  - Grade Low (Systematic Review<sup>94</sup>). Rationale: 37% (95% CI 35-39) of patients with popliteal aneurysms in

- observational studies have concurrent abdominal aortic aneurysmal disease.
- 9. Screening men or women <65 years old is not likely to be beneficial.
  - Grade HIGH (RCT<sup>95</sup> and Population based studies<sup>33</sup>). Rationale: The incidence of AAA in individuals 50 to 65 years of age is 0.9% (95% CI 0.8-1.0)<sup>95</sup>to 1.7% (95% CI 1.2-2.3).<sup>33</sup>
- 10. Screening men 65 to 75 years old may be cost effective.
  - Evidence grade MODERATE (Cost analysis of RCT data, <sup>57</sup> a systematic review of studies of screening costs <sup>55</sup> and projections from real cost data at a Canadian tertiary care center (unpublished data from Mc-Master University). Rationale: The cost per life year gained is estimated to be \$12,813.
- 11. A strategy including physical examination and USE needs to be investigated to screen AAA.
  - Grade Low (Metaanalysis of cohort studies<sup>29,77</sup> and Cohort studies of tertiary referral center<sup>31,75</sup>). Rationale: Sensitivity 82% for AAA >5 cm; cost of screening program 30% lower.
- 12. The cost effectiveness of screening programs for AAA should be re-evaluated if advances in vascular surgery or endovascular techniques improve the mortality of urgent or elective operative intervention for AAA.
  - Grade HIGH (Decision analysis of RCT data<sup>96</sup>). Rationale: Cross tabulation of perioperative mortality for ruptured and elective surgery for AAA using cost of the screening program as dependent variable, demonstrates that the cost improves if elective mortality is reduced and ruptured mortality increases, and vice versa.

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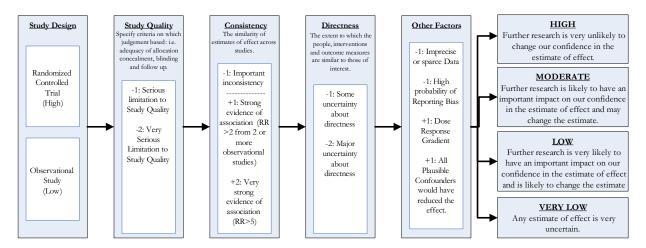
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**Fig 3.** Online only. GRADE Recommendations for Quality Assessment of Evidence. The GRADE recommendations address shortcomings of existing quality assessment systems that put weight on study design, but exclude other factors such as study quality (defined as adequacy of allocation concealment, blinding, and follow-up), consistency (defined as the similarity of estimates of effect across studies), and directness (defined as the extent to which the people, interventions and outcome measures are similar to those of interest). <sup>91</sup>

Table I. (Online only) Screening protocols of four RCTs of AAA screening.

	1-year follow-up	3-month follow-up	Referral to surgeon
MASS <sup>2</sup> Chichester <sup>4</sup> VIBORG <sup>1</sup> West Australia <sup>3</sup>	3-4.4 cm 3.0-4.4 cm 3-5 cm All results referred to family physician for standard management	4.4-5.4 cm 4.4-5.9 cm	>5.5 cm >6 cm >5 cm

Table II. (Online only) Cost of sonographic imaging of abdominal aorta

Jurisdiction	Cost <sup>†</sup> ultrasound examination of abdominal aorta	Source
United Kingdom	£23.23	97
Sweden	€42.78	98
Canada*		
Ontario	\$ 53.80	Ontario Hospital Insurance Plan (OHIP) Website
Alberta	\$ 76.88	Alberta Ministry of Health Website
British Columbia	\$ 98.04	British Columbia Health Website
Manitoba	\$ 32.50	Manitoba Health Website
Newfoundland	\$ 54.19	Newfoundland Health
Prince Edward Island	\$ 42.72	PEI Health Website
Saskatchewan	\$ 85.50	Saskatchewan Health website.

<sup>\$,</sup> Canadian Dollar.

**Table III.** (Online only) Anticipated aneurysm related mortality in the male population in Canada without a screening program

	Males > 65	Males 65-75	Derivation
Population	1,834,100	1,063,017	Census 2005 <sup>100</sup>
Individuals with AAA (>3 cm)	110,046	63,781	6% total population <sup>1-4</sup>
Individuals with AAA (5 - 5.5 cm)	11,005	6378	0.6% total population <sup>1-4</sup>
Individuals who receive elective surgery by standard care	4769	2764	0.26% of total population <sup>1-4</sup>
Individuals who will rupture over 41 months	6603	3827	0.36% total population <sup>1-4</sup>
Individuals with ruptured AAA who will die before reaching the hospital or in hospital without receiving surgery	4358	2526	66% individuals who will rupture over 41 months <sup>9</sup>
Individuals with ruptured AAA who will undergo emergency surgery	2245	1301	34% individuals who will rupture over 41 months <sup>9</sup>
Perioperative mortality for individuals with ruptured AAA	1078	625	48% individuals with ruptured AAA who will undergo emergency surgery <sup>11</sup>
Perioperative mortality for individuals undergoing elective repair	229	133	4.78% Individuals who receive elective surgery by standard care <sup>1-4</sup>
Total mortality	5664	3283	Deaths from rupture AAA not undergoing surgery + perioperative mortality of ruptured and elective AAA repair over 41 months

The calculations are based on the natural history of the disease assuming that patients are left to standard care and for a 41-month follow-up (from randomized controlled trials of screening programs<sup>1,3,51,99</sup> and population based studies<sup>9,11</sup>). Results are presented for the entire male population older than 65 and 65 to 75 years of age

<sup>\*</sup>Includes physician and technical component, where available.

 $<sup>^{\</sup>dagger}$ If possible, fees for limited examinations of the abdominal aorta were recorded preferentially.

**Table IV.** (Online only) Anticipated aneurysm related mortality in the male population in Canada with a screening program in place

	Males > 65	Males 65-75	Derivation
Population eligible for screening	1,834,100	1,063,017	Census 2005 <sup>100</sup>
Individuals expected to have >3 cm AAA	110,046	63,781	6% total population <sup>1-4</sup>
Individuals expected to have 5 - 5.5 cm AAA	11,005	6378.0	0.6% total population <sup>1-4</sup>
Participating population			1.4
Population participating in screening (compliers)	1,362,736	789,822	74.3% total population <sup>1.4</sup>
Number of individuals who will require at least one USE required for screening*	1,362,736	789,822	
Number of patients identified by USE with >3 cm AAA	81,764.2	47,389.3	6% of number of US <sup>1-4</sup>
Number of patients identified by USE with >5.5 cm AAA	8176	4739	0.6% number of US <sup>1-4</sup>
Individuals who receive elective surgery because of screening	13,355	7740	0.98% number of US <sup>1-4</sup>
Perioperative mortality for individuals undergoing elective repair  Nonparticipating population	638	370	4.78% total number of elective surgery <sup>1-4</sup>
Nonparticipating population	471,363	273,195	25.7% of total population <sup>1,3,51,99</sup>
Number of patients >3 cm AAA	28282	16392	6% noncomplier population <sup>1-4</sup>
Number of patients >5.5 cm AAA	2829	1639	0.6% noncomplier population <sup>1-4</sup>
Individuals who receive elective surgery by standard care	1226	710	0.26% of nonparticipating population <sup>1-4</sup>
Individuals who will rupture over 41 months	1697	984	0.36% of nonparticipating Population <sup>1-4</sup>
Individuals with ruptured AAA who will die before reaching the hospital or in hospital without receiving surgery	1120	649	66% of nonparticipating who will rupture <sup>9</sup>
Individuals with ruptured AAA who will undergo emergency surgery	577	334	34% of nonparticipating who will rupture <sup>9</sup>
Perioperative mortality for individuals with ruptured AAA	277	161	48% of patients who will undergo emergency surgery <sup>11</sup>
Perioperative mortality for individuals undergoing elective repair	59	34	4.78% total number of elective surgery <sup>1-4</sup>
Total mortality	1456	844	Death from RAAA before reaching hospital or in hospital without receiving surgery + perioperative mortality
Total mortality of strategy	2094	1214	without receiving surgery + perioperative mortality

USE, ultrasound examination.

The calculations are based on the natural history of the disease assuming that patients are left to standard care and for a 41-month follow-up (from randomized controlled trials of screening programs<sup>1,3,51,99</sup> and population based studies<sup>9,11</sup>). Results are presented for the entire male population older than 65 and 65 to 75 years of age. Data are given for the proportion of the same population, which will not participate in the screening program. In the latter we assume that the risk of rupture is similar to the one of those participating in the screening program.

Table V. (Online only) Quality of evidence of randomized controlled trials of AAA screening 101

Trial	Allocation concealment	Randomization	Outcome assessors blinded	Intention to treat analysis	Protocolized follow-up	Grade <sup>91-93</sup>
Viborg <sup>1,96</sup> MASS <sup>2</sup>	No	No	Yes	Yes	Yes	High
MASS <sup>2</sup>	No	Yes	No	Yes	Yes	High
West Australia <sup>3</sup>	No	No	Yes	Yes	No	High
Chichester 4,5	No	Yes	No	Yes	Yes	High
ADAM 69	Yes	Yes	Yes	Yes	Yes	High
UKSAT <sup>22</sup>	Yes	Yes	No	Yes	Yes	High

<sup>\*</sup>In a 41-month screening cycle patients invited to the screening program may require multiple USE (Table I).

 $\textbf{Table VI.} \ \ (\textbf{Online only}) \ \ \textbf{Quality of evidence of meta-analysis of AAA screening} ^{102}$ 

Author	Search strategy reported	7 L J	More than one database searched	Data extraction done in duplicate	J	Funnel Plot or measure of publication bias	Description of the population	Precision of estimate of effect	
Lederle FA <sup>29</sup>	Yes	Nonrandomized studies	No	No	Yes	No	Yes	Moderate	Moderate
Dawson I <sup>94</sup>	No	Case series and retrospective hospital based	ND	ND	No	No	Yes	High	High
Frame PS <sup>77</sup>	No	Nonrandomized studies	No	ND	No	No	Yes	Moderate	Moderate

ND, not described.

Table VII. (Online only) Quality of evidence for observational AAA screening studies 103

Author	Study design	Multicenter trial	Details of coding and classifying data	Outcome Assessors Blinded	Size of the estimate	Precision of the estimate	Grade <sup>91-93</sup>
Singh K <sup>26</sup>	Population based	No	NA	NA	NA	High	Moderate
Bengtsson H <sup>9</sup>	Population based	Yes	Yes	NA	Large	High	High
Reed WW <sup>6</sup>	Population based	No	Yes	NA	NA	Moderate	Moderate
Tayal VS <sup>27</sup>	Prospective non- randomized	No	NA	NA	Large	High	Moderate
Pleumeekers HJCM <sup>28</sup>	Population based	No	NA	Yes	Large	High	Moderate
Bernstein EF <sup>7</sup>	Population based	No	No	No	NA	Moderate	Low
Morris GE <sup>33</sup>	Population based	No	NA	No	NA	High	Low
Fink HA <sup>31</sup>	Cohort study	No	NA	Yes	Large	High	Moderate
Venkatasubramaniam AK <sup>75</sup>	Cohort study	No	NA	Yes	Large	High	Moderate

NA, not applicable.

**Table VIII.** (Online only) Anticipated operative costs in the male population in Canada with and without a screening program in place

	Current status		Screening program	
	>65 yrs	65 – 75	>65 yrs	65 – 75
Individuals who receive elective surgery by standard care	4769	2764	1226	710
Cost	\$96,181,192	\$55,744,352	\$24,725,968	\$14,319,280
Individuals with RAAA who will undergo emergency surgery	2245	1301	577	334
Cost	\$77,057,873	\$44,655,810	\$19,805,075	\$11,464,289
Individuals who receive elective surgery because of screening	'	1	13355	7740
Cost			\$269,343,640	\$156,100,320
Total Operative Costs	\$173,239,065	\$100,400,162	\$313,874,682	\$181,883,889

The methodology of this cost analysis is as follows: Costing data was collected at the level of each functional center, with breakdowns for staffing, drugs, and other supplies and expenses. Nursing costs for the ICU and vascular ward were derived on the basis of an average hour per patient day value, based on recorded work load. Laboratory and diagnostic imaging costs were averaged across the entire cohort of patients treated for elective and ruptured abdominal aortic aneurysms. Finally, an indirect (overhead) cost allocation was made at a rate of 23%. Costing for allied health care was not considered.

The calculations are based on the natural history of the disease assuming that patients are left to standard care and for a 41-month follow-up (from randomized controlled trials of screening programs<sup>1,3,51,99</sup> and population based studies<sup>9,11</sup> see tables 3 and 4). Projections for the current systems are for the entire male population older than 65 years of age. Projections in the screening group are presented for the entire male population older than 65 and 65 to 75 years of age. Calculations are based on data from a costing study at a Canadian tertiary care center, which found the average cost of conventional open repair of AAA is \$20,168.00, and the average cost of a repair for ruptured AAA is \$34, 324.22.