Established in 1871

Swiss Medical Weekly

Formerly: Schweizerische Medizinische Wochenschrift

An open access, online journal • www.smw.ch

Original article | Published 3 March 2017 | doi:10.4414/smw.2017.14412
Cite this as: Swiss Med Wkly. 2017;147:w14397

Ultrasound screening for abdominal aortic aneurysms

A feasibility study in selected male population attending the outpatient clinics of the Regional Hospital of Lugano, Switzerland

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Summary

QUESTIONS UNDER STUDY: This pilot study aimed to assess the feasibility, acceptance and costs of an ultrasound scan screening programme for abdominal aortic aneurysms (AAA) in the elderly male population resident in Canton Ticino, Switzerland.

METHODS: The target population were male patients aged 65–80 years who attended the outpatient clinics of the Lugano Regional Hospital in 2013. The patients showing interest were contacted by phone to verify their eligibility and fix the appointment for the ultrasound scan of the abdominal aorta. Patients with recent examinations suitable for AAA detection were excluded. Aneurysm was defined as an abdominal aorta with sagittal and/or axial diameter ≥ 30 mm. Patients' characteristics and study results were presented as descriptive statistics. The chi-squared test was used to compare categorical variables with $p < 0.05$ as a statistical significance threshold.

RESULTS: 1634 patients received the screening information leaflet and 745 (45.6%) underwent the ultrasound scan. Among the 1091 eligible patients, the acceptance rate was 68.3%. A previously unknown AAA was diagnosed in 31 patients (4.2%, 95% confidence interval 2.8–5.9%). Age and area of residence had a statistically significant impact on patient's acceptance rate ($p < 0.05$). The mean cost per screened patient was CHF 88.

CONCLUSIONS: AAA screening of male patients aged 65–80 years is feasible with limited financial and organisational effort. Adherence might be improved by a larger community-based programme and involvement of general practitioners.

Key words: *screening; ultrasound scan; abdominal aortic aneurysm; male population; Switzerland*

Introduction

Rupture of an abdominal aortic aneurysm (AAA) is associated with a high overall mortality rate of 65–85% [1]. This holds true despite the introduction of modern, less invasive (endovascular) treatment methods [2]. Prevention of rupture is therefore paramount and a more than appealing concept.

The vast majority of ruptured abdominal aortic aneurysms are larger than 55 mm in diameter. There is a strong male predominance of the disease, with men around four times more likely to have an AAA [3]. Normal aneurysm growth rate is around 1 cm in 3 years and the prevalence of the disease increases with age [4]. Before any rupture event, abdominal aortic aneurysms have a long asymptomatic latent phase.

According to Frame and Carlson, a meaningful medical screening programme should meet the following criteria [5]:

- The disease must have a significant impact on the quality of life.
- Acceptable methods of treatment are available.
- There must be a latent, asymptomatic period during which detection and treatment significantly reduce morbidity and/or mortality.
- The treatment in the asymptomatic phase must yield a therapeutic result higher than that obtained by delaying the treatment until symptoms appear.
- A low-cost detection method is needed and the incidence of the disease must be sufficient to justify the cost of screening.

Screening for AAA meets all these criteria. Several population-based randomised trials have evaluated ultrasound screening for AAA: two British studies (the Multicentre Aneurysm Screening Study [MASS] and the Chichester trial), and one each in Denmark (Viborg) and Western Australia [6–9]. The MASS trial probably provides the most robust evidence of a reduction in aneurysm-related mortality by almost 50% in the screened population of men aged from 65 to 75 years. In the cost-effectiveness analysis, AAA screening proved to be cost-effective for men from 65 to 75 years of age, which was also so in the long term follow up [7].

Based on this evidence, the World Health Organization has included AAA screening among the interventions that proved to be cost effective, and many countries have organised national AAA screening programmes, including the UK, Italy, Denmark and Australia. Switzerland has lagged behind and so far no established medical organisations or health authorities have promoted screening programmes on a cantonal or national level.

For this reason, we implemented the present pilot study in order to verify the feasibility, acceptance and costs of an AAA ultrasound scan screening programme in Canton Ticino, Switzerland as a contribution to the discussion on a national level. About 1800 male patients aged from 65 to 80 years every year attend the various outpatient clinics of the Regional Hospital of Lugano and we chose these patients as the target population for this study.

Methods

This was a pilot screening study assessing the feasibility, acceptance and costs of implementing an AAA screening programme at the Regional Hospital of Lugano, Switzerland.

Selection and enrolment of patients

The target study population consisted of all male patients aged from 65 to 80 years attending the outpatient clinics of the Regional Hospital of Lugano, from January to December 2013. Inpatients were not considered for the study, nor were patients who attended our emergency department.

As a criterion for eligibility, patients had to have undergone no prior examinations suitable for AAA diagnosis in the past (regardless of whether the result was positive or negative), had no prior aortic surgery, be able to understand the nature of the study and give informed consent, and be resident in Canton Ticino. Patients were invited to participate by the clinic clerks and received a leaflet with a summary of the information on the AAA screening programme. If there was no direct evidence of lack of eligibility and patients agreed to leave their contact details, the project secretary called patients by telephone two to three days later. The secretary informed patients by telephone about the details of the screening programme and checked their eligibility, as well as their willingness to participate. If the patient's feedback was positive, the secretary fixed an appointment for the ultrasound scan and sent a confirmation letter with the appointment details. No second calls were foreseen for patients who could not be reached on the first call. General practitioners were not involved in the recruitment or information, but were informed about the scan results of their patients.

Endpoints and methods of measurement

Aortic aneurysm was defined as an enlargement of the transverse or anterior-posterior diameter of the aorta by ≥30 mm [8]. Ultrasound scans were performed with a Logic 9 ultrasound machine (General Electrics®, Milwaukee, USA) by a single, specifically trained radiologist with 30 years of experience. The presence of aneurysm-related risk factors was investigated by the radiologist after completion of the ultrasound scan.

The following characteristics of patients recruited for the screening programme were recorded: the patient's age and aneurysm-related risk factors such as tobacco use, family history of AAA, dyslipidaemia, arterial hypertension, obesity and chronic pulmonary disease. The results of the ultrasound scan were documented in terms of maximal transverse and sagittal aortic diameter (outer-to-outer measurement). In the event of unwillingness to participate, the patient's reasons for refusal were documented. Possible exclusion criteria were documented, as were reasons for failure to contact the patient. Patients who were found to have an aneurysm between 3 and 5 cm in diameter were reported to their general practitioner with the recommendation to organise an ultrasound scan follow-up, whereas patients with an aneurysm diameter >5 cm were referred to a vascular surgeon. The pharmacological approach, risk factor management and vascular workup were referred to the patient's general practitioner.

Statistics

No statistical assumptions were made for the sample size as this was a feasibility study aiming at the inclusion of as many patients as possible over a given time. Descriptive statistics were used for demographic data, eligibility, risk factors, response to screening invitation, reasons for refusal, failure to perform the ultrasound scan, and ultrasound results. Proportions were reported with the relevant 95% confidence intervals (CI). The chi-square test was used to compare the distribution of categorical variables. A p-value of less than 0.05 was considered statistically significant.

Ethics

The study was reviewed and approved by the competent ethics committee and was conducted in accordance with the principles stated in the Declaration of Helsinki. Patients agreeing to participate were asked to sign the informed consent form for the study.

Results

The clinic clerks offered the summary information leaflet to 1634 patients attending the various outpatient clinics of the Regional Hospital of Lugano, Switzerland. Two hundred and forty-eight patients (15%) immediately refused any further contact and 295 (21%) of the remaining 1386 were ineligible for the study because of the availability of recent examinations allowing assessment of the aorta.

Three hundred and forty-six (32%) of the 1091 eligible patients contacted by telephone to arrange the appointment for the ultrasound scan did not confirm their participation or did not attend the scheduled visit; 745 (68%) underwent the planned ultrasound scan of the abdominal aorta. The study flow is summarised in figure 1. A previously unknown AAA was diagnosed in 31 screened patients (4.2%, 95% CI 2.8–5.9).

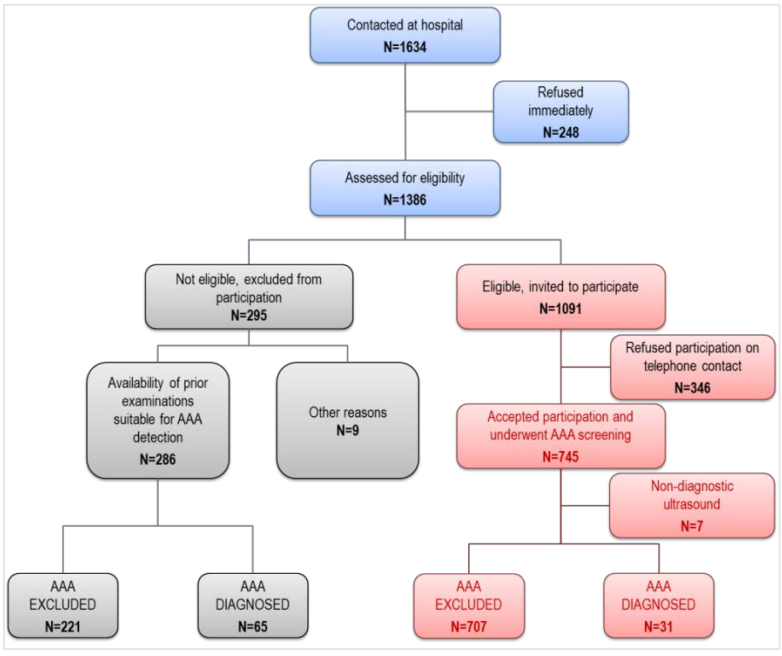

Figure 1: Study eligibility and recruitment. AAA = Abdominal aortic aneurysm.

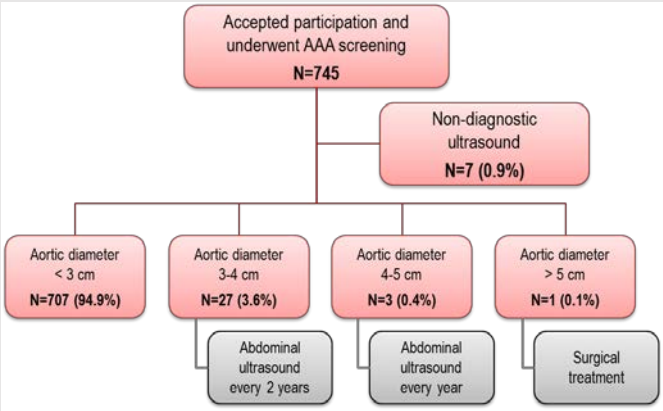

Figure 2: Aortic diameters and subsequent management strategy in the screened patients. AAA = Abdominal aortic aneurysm.

In 7 of the 745 patients examined with ultrasound, neither the sagittal nor the axial diameter of the infrarenal abdominal aorta could be assessed, because of meteorism or obesity. In 27 (3.6%) patients, an aortic diameter of 3–4 cm was detected. In three patients (0.4%) the infrarenal aorta had a diameter of 4–5 cm and one patient (0.1%) had an AAA of >5 cm in diameter. Ultrasound examination follow-up was recommended every two years for patients with aneurysms 3–4 cm in diameter, and every year for those with aneurysms of 4–5cm (fig. 2). The patient with an abdominal aortic diameter of more than 5 cm underwent open surgical repair with no postoperative complications.

The study was not designed to estimate AAA prevalence. However, for 1031 patients the information about presence/absence of AAA could be obtained, either from previous recent examinations or the study screening results; it could not be assessed in the remaining 603 patients because of early refusal or drop-out. The available data show a prevalence of AAA of 9.3% (96/1031, 95% CI 7.6–11.3%).

If the patients immediately declining the screening invitation on the first contact and those refusing to participate on the following phone call are considered, the overall refusal rate was 594/1634 patients (36%). Almost half of these patients (248/594, 42%) did not provide specific reasons for declining the invitation to undergo the AAA screening, and the most frequent justifications indicated were lack of interest (186/594, 31%), higher priority given to other health problems or medical investigations (59/594, 10%), being under constant medical oversight already (38/594, 6%), logistical problems (37/594, 6%), and decision subject to prior general practitioner's advice (27/594, 5%).

The impact of age and area of residence on patient participation in the screening programme, assessed in all 1634 patients, shows that older patients have a statistically lower probability of undergoing AAA screening and that patients living in the Lugano area had a higher probability of participating in the screening programme compared to other regions of the canton Ticino ($p<0.05$). The influence of age and area of residence is also apparent when only the drop-outs due to patient refusal are considered out of the 1091 eligible patients ($p = 0.0004$ and $p = 0.0001$, respectively) (tables 1 and 2).

Table 1: Abdominal aortic aneurysm screening acceptance rate by age category (eligible patients).

Age (years)	Patients undergoing AAA screening	Patients refusing AAA screening	Total
65–70	73.8% (335)	26.2% (119)	100% (454)
71–75	67.9% (247)	32.1% (117)	100% (364)
76–80	59.7% (163)	40.3% (110)	100% (273)
Total	745	346	1091

AAA = abdominal aortic aneurysm
p = 0.0004

Table 2: Abdominal aortic aneurysm screening acceptance rate by area of residence (eligible patients).

Area of residence	Patients undergoing AAA screening	Patients refusing AAA screening	Total
Lugano area	71.2% (597)	28.8% (241)	100% (838)
Locarno	48.2% (13)	51.8% (14)	100% (27)
Bellinzona area	65.6% (59)	34.4% (31)	100% (90)
Leventina	66.7% (6)	33.3% (3)	100% (9)
Mendrisio area	58.4% (59)	41.6% (42)	100% (101)
Riviera	58.3% (7)	41.7% (5)	100% (12)
Vallemaggia	33.3% (1)	66.7% (2)	100% (3)
Blenio	20.0% (2)	80.0% (8)	100% (10)
Other	100% (1)	–	100% (1)
Total	745	346	1091

AAA = abdominal aortic aneurysm
p = 0.0001 (Lugano compared with other areas of the canton)

The total cost of the screening programme, including information leaflets, letters to the general practitioners, administrative support, and medical and nursing staff involvement was 65 549 Swiss francs (CHF). The corresponding mean cost per screened patient was CHF 88. The number of patients to be screened to detect one previously unknown AAA was 24. The average cost of each new AAA diagnosis through the screening programme was CHF 2114.5.

Discussion

To date several randomised trials have demonstrated the efficacy of AAA screening in terms of reduction in AAA-related mortality at a reasonable cost and with a number needed to screen (NNS) amongst the lowest of all the existing screening programmes. As a result of the gathered evidence, several national societies of vascular surgery, such as the Canadian Society of Vascular Surgery, recommend AAA screening of the male population aged from 65 to 75 years [10]. Other countries started screening programmes years ago (Denmark, the UK, Germany, Italy).

In Switzerland, no abdominal aortic aneurysm screening programme has been implemented at a cantonal or national level so far. Meyer et al. published the initial results of a computer-based alert system that stimulated an ultrasound scan booking for male patients over 60 years of age each time a doctor accessed noninvasive arterial work-up data [11]. This method is not adopted throughout the whole country.

We conducted this pilot feasibility study with the aim of encouraging discussion on the advisability and implications of a large-scale screening programme, through the analysis of the technical and logistical requirements, the acceptance by the target population, and the associated costs.

Our enrolment system, basically including only the delivery of an information leaflet, one phone contact and possibly a later interview with a physician involved in the study, turned out to be effective, efficient and inexpensive. The employment of a secretary at 50%, a

radiologist at 10% and of a clerk for preparation of patients prior to echography, allowed us to manage a pool of 1386 potential candidates and to screen 745 patients in one year. In terms of time consumption, in the initial phase each ultrasound scan took approximately 7 to 8 minutes, whereas after a few months the screening rate increased to one patient every 5 minutes. Of course, the invitation only reached patients attending the outpatient clinics of our institution. This meant limited organisational effort, but it clearly does not allow the whole potential male target population to be reached. Our enrolment did not exclude patients with severe concomitant diagnoses that would exclude them from undergoing any kind of aortic surgery or intervention. Patients aged from 75 to 80 years were included in our study even if screening in this age group has shown fewer benefits [9]. These two factors in patient enrolment might reduce the potential benefit in terms of risk reduction of mortality of the screening. Higher age results in reduced life expectancy and higher perioperative mortality with a negative impact on screening benefit [12]. We did not include patients older than 80 years of age for this reason.

Considering all 1634 patients who were offered the information leaflet at the very first contact, the participation rate is 64%. In the literature, higher participation rates are reported for large multicentre studies such as the Viborg Vascular Screening (74.7%) and the MASS Multicentre Aneurysm Screening Study (80.3%) [6, 13]. The reason for the lower acceptance is probably multifactorial. From the analysis of the collected data we identified two factors having a statistically significant relationship with patient participation (area of residence and age); there are other probable causes that we have not been able to assess objectively, but which we feel should be considered. The delivery of the information leaflet by the clinic clerk did not allow personal explanation and emphasis on the usefulness of the screening programme by a doctor. This might have negatively influenced the uptake of our screening programme. Moreover, the invitation to our screening was based on a single call, whereas in most screening programmes patients might receive repeated calls. Another suspected limiting factor is the attitude of the general practitioners towards the screening programme: the lack of their direct involvement is likely to have resulted in a less supportive behaviour or even to have led some of them to perceive our invitation, addressed directly to the subjects, as interfering with their patient management. As we did not systematically seek further contact after a patient's refusal to participate, we received information about the general practitioner's reactions only occasionally. Therefore, we are unable to determine how many patients were discouraged from undergoing the proposed screening or how many benefitted from AAA screening anyhow, even if not through the participation in our study. A closer collaboration with the general practitioners would also have allowed the exclusion of patients with a severe concomitant diagnosis, who are unable to undergo any kind of aortic intervention.

If we consider all patients for whom the presence or absence of AAA could be determined, either by prior recent investigations or by the study screening, the resulting overall prevalence of AAA of 9.3% (95% CI 7.6–11.3%) appears higher than that reported in large studies such as the Western Australia [9] and the MASS [6] trials (7.2% and 4.9%, respectively) [6, 9]. This difference is probably due to the fact that the target population of our study consisted of medicalised subjects attending the hospital clinics, including cardiology and angiology. On the other hand, the AAA prevalence we observed in the 745 patients with no prior investigations suitable for AAA detection who had the ultrasound screening was 4.2% (95% CI 2.8–5.9%), in line with the published results from the MASS and Viborg trials [6, 8]. We are not aware of any recent studies describing the AAA prevalence in Switzerland. A recently published article from neighbouring northern Italy showed a AAA prevalence on ultrasound scan of 2.5% in a male invited group aged 60 to 85 years [14].

The average cost per screened patient was CHF 88. This cost includes the resources needed for contacting and selecting patients who were ineligible or eventually refused to participate. The cost of the ultrasound scan, which is, apart from the costs of elective aortic surgery in the screened population, the most important cost factor, seems comparable to the cost in other countries. In Canada, for example, the cost of the ultrasound scan ranged from 32 to 98 Canadian dollars [10]. Initial screening cost 83.75 Danish kroner in the Viborg trial [8]. Of course the overall costs might be different in our screening programme if it were more community based. We cannot make any assumptions about this at present.

The overall impression of the hospital staff involved in the study was that the AAA screening implied minimal organisational effort and very limited discomfort for the participating patients; however, patient discomfort was not included in the data collected and, therefore, it could not be objectively quantified.

As to cost-effectiveness, the advantage in preventing aneurysm rupture and the related potential risks and costs seem sufficient to justify the screening cost even if our study did not include a proper cost-effectiveness analysis. In contrast to other countries where AAA ultrasound screening programmes proved to be cost-effective [7], we do not have this analysis for the Swiss healthcare system. In order to validate cost-effectiveness of our screening programme, further studies would be necessary, including advanced calculation models.

In conclusion, AAA screening of the male population aged from 65 to 80 years is feasible with limited financial and organisational effort. Uptake might be improved by offering a more community-based programme and by getting more support from the general practitioners.

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Financial disclosure
The study was financed by a grant of the Advisory Board for Research of the Ente Ospedaliero Cantonale (ABREOC), Bellinzona, Switzerland.

Competing interests
No potential conflict of interest relevant to this article was reported.

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