Screening for abdominal aortic aneurysms using a dedicated portable ultrasound system: early results

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Aims Abdominal aortic aneurysms (AAA) are often diagnosed at time of (impending) rupture leading to a dramatic increase of morbidity and mortality. A simple screening device might be the key solution for widespread AAA screening. This study evaluated the diagnostic accuracy of a new portable ultrasound scanner (Aortascan BVI 9600) developed for automatic AAA detection.

Methods and results A total of 150 patients with presumed aneurysmatic peripheral atherosclerotic disease were included in the study. Patients were first scanned with conventional ultrasound (US), serving as reference technique. An infra-renal abdominal aorta diameter of ≥30 mm was defined as an AAA. Hereafter, the aorta was scanned using the Aortascan BVI 9600. Statistical analyses were performed using SPSS version 15.0 statistical software. Abdominal aortic aneurysms were detected with conventional US in 78 (52%) patients, compared with 74 (49%) AAA’s detected with Aortascan BVI 9600. The Aortascan BVI 9600 demonstrated a sensitivity, specificity, positive and negative predictive value of 90, 94, 95, and 89%, respectively, in the detection of AAA’s.

Conclusion The Aortascan BVI 9600 automatically detects the aortic diameter with a 90% sensitivity without the need for a trained operator. Because of these unique capabilities, it can be used for AAA screening outside the hospital.

KEYWORDS Abdominal Aortic Aneurysm; Ultrasound; Screening

Introduction

The prevalence of abdominal aortic aneurysm (AAA), in patients aged above 55 years, ranges from 4.1 to 14.2% in men and from 0.35 to 6.2% in women. The incidence of AAA is known to increase, due to an increased life expectancy. Effective screening programs for detecting AAA are currently not available. Therefore, AAAs are often diagnosed at time of (impending) rupture which leads to a dramatic increase of morbidity and mortality. Abdominal ultrasound (US) and computerized tomography (CT) are the most frequently used non-invasive imaging tests to detect or exclude the presence of an AAA. These imaging techniques are expensive and require trained staff. In case of CT, the patient is exposed to a fair amount of radiation. Hence these techniques are not ideal for screening purposes. A simple screening device, which is less expensive and offers the possibility for use outside the hospital, might be the key solution for widespread AAA screening. In 2006, a pilot study conducted by Vidakovic et al. demonstrated the diagnostic potential of an automatic bladder volume scanner (BVI 6400, Verathon Medical, Bothell, USA) to detect AAA. The current study evaluated the diagnostic accuracy of a new portable ultrasound scanner [Aortascan BVI 9600 (BVI 9600), Verathon Medical] developed for automatic AAA detection.

Methods

Study population

The study population consisted of 150 consecutive patients referred to the outpatient clinic of the Department of Vascular Surgery of the Erasmus Medical Center (Rotterdam, The Netherlands) for presumed aneurysmatic peripheral atherosclerotic disease. Patient enrolment was performed from January until December 2008, after approval of the

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hospital’s Ethics Committee. All patients gave informed consent at time of inclusion. Patients with abdominal aortic stents or a previous open aortic reconstruction were excluded from the study.

Baseline characteristics
A detailed history was obtained from every patient and the following characteristics were recorded: age, gender, body mass index, heart failure (defined as the presence of heart failure symptoms according the New York Heart Association classification or previous hospital admission for decompensated heart failure), ischaemic heart disease (defined as history of angina pectoris, coronary revascularization or myocardial infarction), cerebrovascular disease (defined as a history of ischaemic or haemorrhagic stroke), lower extremity arterial disease (defined as ankle brachial index <0.9), renal dysfunction (defined as creatinine clearance >2.0 mg/dL), diabetes mellitus (fasting blood glucose ≥7.0 mmol/L or requirement for insulin and/or anti-diabetic medication), hypertension (blood pressure was measured during pre-operative evaluation at the outpatient clinic and hypertension was defined as systolic blood pressure ≥140 mmHg, diastolic blood pressure ≥90 mmHg in non-diabetics, systolic blood pressure ≥130 mmHg, diastolic blood pressure ≥80 mmHg in diabetics or the use of antihypertensive medication), hypercholesterolemia (LDL cholesterol >3.5 mmol/L and the requirement of lipid-lowering medication), chronic obstructive pulmonary disease (according to the GOLD classification), and smoking status.

Measurement of the abdominal aortic diameter
All patients were first scanned with conventional US and measurements obtained with conventional US served as the reference value. An infra-renal abdominal aorta diameter (either anterior–posterior or transverse) of ≥30 mm was defined as an AAA.5 Hereafter, the aorta was scanned using the Aortascan BVI 9600. The examinations were performed and reviewed by two physicians, both skilled and experienced in abdominal US. The inter-observer variability between the two echocardiographists was up to 95% for the measured aortic diameter.

Conventional abdominal ultrasound
A handheld US device (SonoSite Titan, SonoSite Inc., Bothell, Washington) with a C11/8-5 MHz broadband slightly curved array transducer was used for US evaluation of the abdominal aorta. Both anterior–posterior and transverse diameters at the largest portion of the abdominal aorta were measured. The aortic diameters were obtained using on-screen callipers from the outer edge to edge of the aortic wall, including intraluminal thrombus if present. The maximal obtained diameter, measured in the xiphoid to umbilical tract, was used for analysis.

Aortascan BVI 9600
The Aortascan BVI 9600 was developed to measure the abdominal aorta diameter using US (Figure 1), based on technology of the BVI 9400 BladderScan®, a portable 3D scanner used for bladder volume measurements. The Aortascan BVI 9600 measures the aortic diameter by interrogating a three dimensional region containing the aorta and performing automated image analysis. After pressing the scan button, results are displayed within 10 s (Figure 2). The three dimensional scan is obtained as a set of 12 mechanically rotated 2D scans, 15 degrees apart. Each planar scan is obtained by mechanically sweeping a single element transducer through a 120° arc. The transducer is used for transmission and reception of ultrasonic waves at 3.7 MHz. Echoes originating from a depth up to 20 cm were included for analysis. Dedicated detection software uses the data obtained from the 3D scan to create a 3D geometry of the abdominal aorta. From this 3D geometry, the maximum diameter is deduced and displayed as result for the user. The user is also provided with a B-mode image representing the cross-sectional scan plane. Electronic callipers are provided to manually redefine the maximum diameter when necessary. Each Aortascan BVI 9600 assessment consisted of four consecutive scans, located at the midline of the abdomen, starting ~2.5 cm below the xiphoid. Scanning locations are shown in Figure 3. Abdominal aortic diameter measurements <30 mm were displayed solely as being <3.0 cm. An estimated diameter in mm was provided by the Aortascan, when the abdominal aorta diameter was assumed to be ≥30 mm. The maximal abdominal aorta diameter was used for the hypothesis on the presence of AAA.

Statistics
Dichotomous data are described as numbers and percentages. The continuous variables age and BMI are described as mean ± SD. Differences in baseline characteristics between patients with abdominal aorta diameter <30 mm or ≥30 mm, detected with conventional US, were evaluated using χ² tests for categorical data. Continuous data were compared using one-way ANOVA. For all tests, a P-value less than 0.05 (two sided) was considered significant. All analyses were performed using SPSS version 15.0 statistical software (SPSS Inc., Chicago, IL, USA).

Results
A total of 150 patients with presumed aneurysmatic peripheral atherosclerotic disease were included in the study.
Abdominal aortic aneurysms were detected with conventional US in 78 (52%) patients, compared with 74 (49%) presumed AAA’s detected with Aortascan BVI 9600. Mean abdominal aortic size was 39 mm, measured with conventional US. Patients with aneurysmatic disease were older (70 vs. 65 years), more likely to be male (89 vs. 59%, \(P < 0.01\)) and had more often a BMI >25 compared with patients with normal abdominal aortic size. Other factors associated with an AAA were heart failure, renal dysfunction, and smoking. Baseline characteristics are shown in Table 1.

In total, 70 (90%) AAA patients measured with conventional US were detected with the Aortascan BVI 9600 as well. Furthermore, 68 (95%) patients with normal abdominal aorta observed with conventional US had a normal abdominal aorta, measured with the Aortascan BVI 9600 as well. False-positive measurements, i.e. a presumed AAA detected with the Aortascan BVI 9600, which was not present with conventional US was observed in four patients (5%). False-negative measurements, i.e. an AAA detected with conventional US and missed with the Aortascan BVI 9600 was present in eight (10%) patients. We have found sensitivity, specificity, positive-predictive value and negative-predictive values of 90, 94, 95, and 89%, respectively (Table 2). Furthermore, the correlation, in measured AAA
The prevalence and incidence of AAA has been widely investigated and a population-based study including 6386 patients showed a prevalence of AAA in 263 (8.9%) men and 74 (2.2%) women. From 0.35 to 6.2% in women with all patients aged above 55 years. In patients with symptomatic atherosclerotic disease, the prevalence of aneurysmatic disease is much higher, as data of our own population showed prevalence up to 25%. Therefore, the use of a quick and efficient AAA screening tool in this high-risk population, could add significantly to complete the patients risk profile.

Patients with ruptured AAA have a worse prognosis, as up to 55% of the patients that reach the hospital alive will still die in the first 30 post-operative days. Therefore, screening of patients at increased risk for developing AAA and subsequent elective surgical interventions may improve outcome. As noted by Hailey et al., the non-availability of an echo-system and/or operator at the point-of-care may lead to a delay in diagnosis and patient management. Although the first portable echo devices were developed in the 1970s, portable echo has become commercially available since 1996. In 2003, for instance, portable cardiac US (or echo-stethoscope) broadened the application of echocardiography to the patient’s bedside. The use of portable US for AAA detection was first described by Vidakovic et al., using the automatic BVI 6400 system.

Ultrasonography provides the possibility to diagnose or rule-out AAA rapidly and accurately. However, finding the correct cross-sectional scan plane with the maximum aortic diameter remains the most difficult part in AAA screening. Small errors in the angle of cross-section causes direct errors in the found diameter and may lead to wrong diagnosis. Therefore, only well-trained echocardiographists should perform conventional US for the detection of AAA. Hence Vidakovic et al. proposed to use the automatic BVI 6400 system for AAA screening because of (i) potential widespread availability, (ii) low costs (~10,000 €) compared with expensive conventional US equipment, and (iii) steep learning curve compared with more intensive training required for conventional US. They concluded that the BVI 6400 is simpler for use, requires a less intensive training period and therefore can be used by a nurse or a technician. Furthermore, the BVI 6400 is roughly four times less expensive compared with conventional US. In the pilot study conducted by Vidakovic et al., volume measurements of the infrarenal abdominal aorta were performed with the BVI 6400 and compared with conventional US. On the basis of the technical characteristics of the BVI 6400, they estimated that a volume of 14 mL measured with the BVI 6400 corresponds with an abdominal aortic diameter of 30 mm, which is considered an AAA. Using the cut-off value of >14 mL for the presence of AAA, they demonstrated a sensitivity of 94% and specificity of 82% of the BVI 6400 in the detection of AAA. Furthermore, positive and negative predictive values for the BVI 6400 to detect AAAs were 88 and 92%, respectively. However, although these data look promising, the use of volume measurements, which have to be recalculated, remains questionable.

In our study, the Aortascan BVI 9600 directly measured the maximum abdominal aortic diameter and therefore, we did not have to estimate a volume cut-off value corresponding with the abdominal aortic diameter in mm. Consequently, results obtained from the Aortascan BVI 9600 can be directly compared with conventional US. With the use of these new types of measurements, we found a sensitivity of 90% and an increased specificity of 94% compared to the BVI 6400.
Furthermore we found a negative predictive value of 89% and an increased positive predictive value of 95% compared to the BVI 6400. The Aortascan BVI 9600 provides a scan depth of 20 cm, which was sufficient for the patient population. Hence, no false negatives occurred due to a limited field of view. However, although the Aortascan BVI 9600 seems to detect AAA with a sufficient accuracy, the use of the system should not be extended as a replacement for conventional US. Patients with AAA detected by the Aortascan BVI 9600 should be referred to a radiologist to perform a conventional abdominal US.

Although we have used conventional US as the reference technique, we are aware that the sensitivity and specificity of conventional US is not 100%. This is mainly due to the difficulty of finding the right cross-sectional plane and location of the aorta, even for experienced operators. The 3D acquisition of the Aortascan BVI 9600 is likely to overcome the problems associated with 2D US. This was demonstrated in a patient with a curved aortic shape (including an AAA) not located at the midline of the abdomen. The measurement with conventional US initially produced a false-negative result, where the Aortascan BVI 9600 did detect an AAA. The presence of a true AAA was confirmed with a second conventional US measurement. This case underlines the need for future studies, evaluating the accuracy of the Aortascan BVI 9600, using angio-CT as the reference technique.

In conclusion, the Aortascan BVI 9600 automatically detects and calculates the aortic diameter with a 90% sensitivity without the need for a trained operator. Because of these unique capabilities, it can be used for AAA screening outside the hospital and allows for AAA detection in patients who would not have been examined otherwise. However, final diagnosis and subsequent treatment requires additional medical examination.

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