Abdominal Aortic Aneurysm Screening Using Non-imaging Hand-held Ultrasound Volume Scanner – A Pilot Study

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Background. Screening for abdominal aortic aneurysms (AAA) is cost-effective and timely repair improves outcome. Using standard ultrasound (US) an AAA can be accurately diagnosed or ruled-out. However, this requires training and bulk equipment.

Aim. To evaluate the diagnostic potential of a new hand-held ultrasound bladder volume indicator (BVI) in the setting of AAA screening.

Methods. In total, 94 patients (66 ± 14 years, 67 men) referred for atherosclerotic disease were screened for the presence of AAA (diameter >30 mm using US). All patients underwent both examinations, with US and BVI. Using the BVI, aortic volume was measured at 6 pre-defined points. Maximal diameters (US) and volumes (BVI) were used for analyses.

Results. In 54 (57%) patients an AAA was diagnosed using US. The aortic diameter by US correlated closely with aortic volume by BVI (r = 0.87, p < 0.0001). Using a cut-off value of ≥50 ml for the presence of AAA by BVI, sensitivity, specificity, positive and negative predictive value of BVI in detection of AAA were 94%, 82%, 88% and 92%, respectively. The agreement between the two methods was 89%, kappa 0.78.

Conclusion. The bladder volume indicator is a promising tool in screening patients for AAA.

Keywords: Abdominal aortic aneurysm; Screening; Ultrasound; Volume.

Introduction

Abdominal aortic aneurysm (AAA) requires both early detection and timely repair to reduce aneurysm-related mortality and improve outcome. The prevalence of AAA is strongly influenced by age and gender and can be detected in 5–8% of men and in 1% of women over the age of 65 years.1–4 Since effective screening programs are not established yet, diagnosis of an AAA is still frequently made at the time of rupture or impending rupture, which leads to a dramatic increase of postoperative mortality and morbidity.5

Cost-effectiveness of screening for AAA is highly dependent on the selection of the patient population.

Several diagnostic techniques, including ultrasound and computerized tomography, can be used for the detection of AAA. However, these techniques are expensive and usually require bulky equipment with a trained staff, which prevails the widespread use for screening purposes. Considering the increased incidence of AAA in the near future, a simple and inexpensive screening device that can also be used outside the hospital setting in the general population is useful.

This prospective study sought to evaluate the diagnostic potential and accuracy in AAA screening of a low cost hand-held ultrasound scanner for the three-dimensional measurement, originally intended as an automatic bladder volume indicator (BVI). As a reference, a standard ultrasound device (US) was used. The study was designed to test the hypothesis that BVI would be helpful in detection of AAA in a high-risk patient population.
Methods

Study population

The study population consisted of 94 patients referred because of atherosclerotic disease to the outpatient clinic of the Erasmus University Medical Center, Rotterdam, the Netherlands. Patients were screened for cardiovascular risk factors, including: age, hypertension, angina pectoris, previous myocardial infarction, heart failure, stroke, renal failure (serum creatinine >2 mg/dl), smoking, diabetes mellitus, hypertension, and hypercholesterolemia. Medical therapy was noted in all.

After informed consent was obtained, all patients underwent both examinations, with US and BVI. The examinations were performed by a physician skilled and experienced in abdominal ultrasonographic practice. Examinations with BVI were repeated by a second physician similarly skilled and experienced. Physicians were blinded for the previous findings. An abdominal aortic aneurysm was defined as an abdominal aorta of >30 mm.

Hand-held US scanner for the three-dimensional assessment of volumes (BVI)

The Mobile Bladderscan BVI 6400 (Diagnostic Ultrasound, Bothell, WA, USA) is a non-imaging volumetric ultrasound device that is designed for automatic measurement of bladder volume (Fig. 1a). It measures ultrasonic (3.7 MHz) reflections within the patient’s body on 12 rotational planes within a 120 degree sector, detects fluid-tissue borders, creates a 3-dimensional shape of the organ, and calculates the fluid volume.6 Transducer is slightly focused, with focus at 6–8 cm.

When imaging on the lower abdomen, a penetration depth of 14–16 cm is possible. An aiming icon on the instrument’s LCD screen guides the user to optimal positioning of the scan-head, to ensure accuracy of measurement. After pressing the scan button, the volume is reported on the LCD screen within 5 seconds (Fig. 1b). With the BVI, the aortic volume in milliliters was measured in every patient lying in supine position with elevated knees at six pre-defined symmetrical topographic points around the abdominal midline until the level of umbilicus. Maximal measured volume was used for the analysis.

Standard two dimensional duplex US device

The standard US device Sonos 5500 (Hewlett Packard, Andover, Massachusetts, USA) was used for examination of abdominal aorta. All ultrasound examinations were focused on the identification of the infrarenal aorta and assessment of its diameter in transverse (anterior–posterior) and sagittal (left-to-right) dimension at four levels. All diameters were measured from edge to edge of the aortic wall, including intraluminal thrombus, when present. The values of obtained measurements were expressed in centimeters, and maximal measured diameter was used for the analysis.

Statistical analysis

Descriptive statistics were reported as means (±SD) for normal distributions or as median (range) in case of a skewed distribution. A comparison of results between the groups obtained by both US and BVI was analyzed using the Student t test; the test results were considered significant at a p value of less than .05. BVI

Fig. 1. Bladder volume indicator (a) and principle of acquisition of measurements (b).
and US produce measures that cannot be compared directly (volumes and diameters, respectively). Therefore, correlation of results obtained by US and BVI was assessed by Spearman’s coefficient of rank correlation. The diagnostic accuracy and predictive value of BVI was compared with US, which was considered the standard tool for assessment of AAA diameter. The agreement for the measurements between the two examination techniques was assessed by 2 x 2 tables using weight kappa statistics. Kappa values <0.4, 0.4–0.75, and >0.75 were considered to represent poor, fair to good, and excellent agreement respectively, based on Fleiss’s classification. All analysis was performed using the statistical software SPSS for Windows 12.0.1 (SPSS Inc., Chicago, Illinois, USA).

Results

Patient’s characteristics of the study population are shown in Table 1. As shown patients presenting with an AAA were predominantly males. Patients with an aortic aneurysm also were older and more frequently had a history of myocardial infarction as compared to those without an aortic aneurysm. The US and BVI examinations were feasible in all patients. The median maximal aortic diameter in the total study population using US was 39 mm (range 14–85). A total of 54 (57%) patients had a abdominal aortic diameter >30 mm. The median maximal aortic volume measured by BVI was 71 ml (range 14–210 ml).

Table 1. Characteristics of study population

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>All patients (n = 94)</th>
<th>Patients with AAA (n = 54)</th>
<th>Patients without AAA (n = 40)</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age, years (SD)</td>
<td>66 ± 14</td>
<td>70 ± 11</td>
<td>62 ± 17</td>
<td>.009</td>
</tr>
<tr>
<td>Males (%)</td>
<td>67 (71)</td>
<td>45 (83)</td>
<td>22 (55)</td>
<td>.003</td>
</tr>
<tr>
<td>BMI (kg/m²)</td>
<td>25 ± 4</td>
<td>25 ± 4</td>
<td>25 ± 4</td>
<td>ns</td>
</tr>
<tr>
<td>Myocardial infarction (%)</td>
<td>20 (21)</td>
<td>16 (29)</td>
<td>4 (10)</td>
<td>0.04</td>
</tr>
<tr>
<td>Angina pectoris (%)</td>
<td>18 (19)</td>
<td>9 (16)</td>
<td>9 (23)</td>
<td>ns</td>
</tr>
<tr>
<td>Heart failure (%)</td>
<td>5 (5)</td>
<td>4 (7)</td>
<td>1 (3)</td>
<td>ns</td>
</tr>
<tr>
<td>Renal failure (%)</td>
<td>5 (5)</td>
<td>5 (9)</td>
<td>0</td>
<td>ns</td>
</tr>
<tr>
<td>Diabetes mellitus (%)</td>
<td>12 (13)</td>
<td>7 (13)</td>
<td>5 (13)</td>
<td>ns</td>
</tr>
<tr>
<td>Hypertension (%)</td>
<td>50 (53)</td>
<td>30 (56)</td>
<td>20 (50)</td>
<td>ns</td>
</tr>
<tr>
<td>Cerebrovascular disease (%)</td>
<td>15 (16)</td>
<td>7 (13)</td>
<td>8 (20)</td>
<td>ns</td>
</tr>
<tr>
<td>Current or former smoking (%)</td>
<td>76 (81)</td>
<td>47 (86)</td>
<td>29 (73)</td>
<td>ns</td>
</tr>
<tr>
<td>Hypercholesterolaemia (%)</td>
<td>43 (46)</td>
<td>21 (39)</td>
<td>22 (55)</td>
<td>ns</td>
</tr>
<tr>
<td>Aortic diameter by US, mm (SD)</td>
<td>39 ± 19</td>
<td>52 ± 16</td>
<td>21 ± 4</td>
<td>.001</td>
</tr>
<tr>
<td>Aortic volume by BVI, ml (SD)</td>
<td>71 ± 47</td>
<td>96 ± 48</td>
<td>37 ± 14</td>
<td>.001</td>
</tr>
</tbody>
</table>

AAA = abdominal aortic aneurysm; BMI = body mass index; US = standard ultrasound device; BVI = bladder volume indicator, ns = not significant (i.e. p > 0.05).

Maximal aortic diameter assessed by US correlated closely with the maximal aortic volume by BVI (r = 0.87, p < .0001, 95% CI = 0.81–0.91, Fig. 2). Using a cut-off value of ≥50 ml for the presence of AAA by BVI, sensitivity, specificity, positive and negative predictive value of the BVI in detection of AAA were 94%, 82%, 88% and 92%, respectively. The agreement between US and BVI in detecting an AAA was 89%, kappa 0.78 (Table 2). Inter- and intraobserver variability of BVI measurements were 93% and 94%.

Discussion

The prognosis for ruptured AAAs is poor. Therefore, screening of patients at risk and timely elective repair improves outcome. The preferred screening method is ultrasound imaging. It is cheaper than other imaging modalities and non-invasive. Ultrasonography can measure the size of AAA with accuracy of 2–3 mm, with sensitivity and specificity approaching 99%. With ultrasonography it is possible to diagnose or rule-out the AAA rapidly and accurately. At present, ultrasound screening with standard US devices requires training and bulky equipment. We hypothesized that the BVI can be used for the screening of AAA.

This study shows that BVI can be effectively used for the detection of AAA in high-risk individuals. To our knowledge this device has never been utilized...
for this purpose before. The sensitivity, specificity and accuracy for the detection of AAA are very similar to those of US. There is a good correlation between diameter obtained by US and volume obtained by BVI. Considering its low cost (about €8,000 for the BVI 6400), steep learning curve and potential widespread availability, screening for AAA using this device is promising.

Bladder volume indicator (BVI), presented for the first time in 1988, was originally designed for the estimation of postvoid residual volumes. The device is inexpensive and can effectively be used after a short training. Since now, several generations of BVIs were widely applied in clinical practice, and they proved to be a very useful tool in diagnosing and management of voiding dysfunction. A measurement method of bladder volume is different between BVI and US. Several reports in urological literature found that the BVI is as reliable and accurate as the standard US to measure postvoid residual urine.\(^{12,13}\)

Recently, it has been shown that portable US devices can also be successful in screening patients with risk-factors for AAA.\(^{2,14,15}\) Compared to the portable US devices, the BVI is simpler for use, requires a shorter training period, and is roughly four times cheaper. Because of this, it is presumable that BVI could be adopted in near future for the large screening programs for AAA, and that the examination could be performed by a nurse or a technician.

The BVI uses a three-dimensional ultrasound technique detecting volumes, in contrast to conventional ultrasound techniques measuring anterior—posterior or sagittal diameter. There are few publications regarding the volume measurements for detection and follow-up of aneurysmal disease of the aorta, and according to them the volumetric assessment has potential advantages. Being that a three dimensional change is reflected by a much smaller change in two dimensions, it might be concluded that volume measurements are more accurate than the measurements of diameter, because they will encounter changes in aneurysm size earlier.\(^{16}\) Currently, volumetric measurement using CT is suggested as diagnostic method of choice in follow-up of patients after endovascular AAA repair (EVAR), but this is time-consuming and requires specific and expensive hardware and software for acquiring data.\(^{17-19}\) We hypothesize that the BVI may play a role in the follow-up of patients after EVAR.

There are several factors influencing BVI results. The BVI has a 120 degrees angle of view for every of 12 rotational planes, and interpolates between planes creating a 3-dimensional reconstruction of differently shaped cavities for the volume measurement. In the case of tube-like cavity with open ends, such as the abdominal aorta, the BVI takes one sample (part) of that cavity, and calculates its volume. The size of that sample primarily depends on the depth at which the abdominal aorta lies and on the penetration depth of the US beam. This means that when the AAA is close to the anterior abdominal wall the sample taken by the BVI for the volume measurement will be smaller than the sample of the same AAA which is positioned deeper in the abdomen (Fig. 3). Taking into consideration technical characteristics of the BVI 6400, we have estimated that the volume of 50 ml corresponds with the AAA which diameter is 30 mm (by the definition, the lower diameter considered for the AAA), and which is positioned close to the anterior

![Fig. 3. Relation between the volumes measured by the BVI and position of the aorta to the anterior abdominal wall. Detailed explanation in the text.](image-url)

| Table 2. Agreement of diameter measured by ultrasound device (US) and volume measured by bladder volume indicator (BVI). Number of patients: 94. Values of ≥ 30 mm for US and ≥ 50 ml for BVI were considered suggestive for the presence of AAA |
|---------------------------------|-----|-----|
|                                | US  | BVI |
| <30 mm                         | 33  | 7   |
| ≥30 mm                         | 3   | 51  |

Agreement 89%; Kappa = 0.78.
abdominal wall. For this reason, we have decided to use this value as the cut-off point for the presence of the AAA. Also, sampling at several different points (in our study at six symmetrical predefined points) diminishes the chance to skip aneurysmatically changed part of the abdominal aorta.

Other possible problems, which could influence the BVI results, might be: extracted edges between aortic wall and blood, thickened aortic wall, irregular aortic wall, and confusing inferior vena cava or bowel for abdominal aorta. The later might be overcome by the addition of a Doppler measurement, identifying blood flow coming from the heart compared to venous return. Operator depending factors include the angle between BVI and the abdominal wall and compatibility between abdominal wall and ultrasound probe.

At present the BVI can not be used as a diagnostic tool. The results of this pilot study imply that a secondary examination by the standard US is recommended in patients with measured volumes larger than 50 ml.

Future directions. This study showed the potential of a hand-held automatic US bladder device to detect AAA in a high-risk patient population. It is interesting to determine its potential role in screening of medium-risk population, in follow-up of patients with known AAA, especially after EVAR (potential presence of endovascular leak), and in screening of first-degree relatives of patients with AAA. Future studies are needed to clarify these issues.

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