Evaluation of the Accuracy of Aorta Scan BVI 9600 in Screening for Abdominal Aortic Aneurysm

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WHAT THIS PAPER ADDS
Attempts have been made to reduce the cost of ultrasound equipment, operators, and their training, which make up a significant proportion of the cost of abdominal aortic aneurysm (AAA) screening programmes. With this in mind, the BVI 9600 promised to be a cost-effective automated ultrasound device to detect AAA without a trained operator. Prior reports are equivocal about its suitability, and this study evaluates the accuracy of this device for the purpose of detecting AAA as part of a low-cost AAA screening programme. We describe some critical limitations of this device and recommend improvements required before it or other similar devices could be used in screening.

Objectives: Despite a decreasing incidence of abdominal aortic aneurysm (AAA), the cost-effectiveness of AAA ultrasound screening can be improved by reducing the screening costs and increasing the uptake rates. The BVI 9600 (BVI) is a promising tool for this purpose as it is inexpensive and can detect AAA without a trained operator. This study aims to investigate whether the BVI can be used to detect AAA for the purpose of a low-cost outreach screening approach.

Methods: A total of 142 subjects had their abdominal aortae measured by five sonographers using the BVI and a conventional ultrasound machine. The examination included four anterior—posterior measurements at four equally spaced scanning locations from the xiphisternum to the umbilicus. The measurements produced by each machine were compared using Bland—Altman plots, followed by an analysis of the AAA detection performance.

Results: The BVI measured the aortic diameter to within 0.88–1.56 cm of the true diameter, exceeding the 0.5 cm “clinically acceptable difference” (CAD). Its accuracy was poorer when measuring the aneurysmal aortae (mean difference −0.56 cm, variability 1.72 cm) than normal aortae (mean difference 0.02 cm, variability 0.76 cm). Nine out of 52 aneurysms were not detected due to undersizing measurement and non-visualization of the aortae.

Conclusions: At present, the BVI is not sufficiently accurate to detect AAA for screening purposes. A number of technical features require improvement.

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INTRODUCTION
National screening programmes for abdominal aortic aneurysm (AAA) are being implemented based on the results from several randomized trials in the 1990s.1 These trials suggested that AAA prevalence and the expected number of AAA detected by ultrasound screening were sufficiently high to justify the benefits and cost-effectiveness of screening. Although the benefits of AAA screening remain significant,2 the cost-effectiveness of screening in the future is uncertain. Such uncertainty emerged after the observation that incidence of AAA is decreasing3 and current screening programmes have low yield.4,5 Lederle6 suggested that such low yield could be due to low uptake rates by populations with high risk of AAA, many of whom are socially deprived and living in rural areas.7 In addition, the current screening approach is expected to be costly in the long term due to expensive ultrasound equipment8 and the ongoing training costs of screeners with high turnover rates.9 In order to maintain the cost-effectiveness of screening in the future, it is necessary to have a different screening model that costs less and produces a higher uptake. With this in mind, the BVI 9600 (Verathon Medical UK Ltd, High Wycombe, UK) has been trialled for AAA screening with some promising results.10 This device is inexpensive and can be used by operators without training in ultrasound imaging. Therefore, screening can potentially be provided at low cost by
practice nurses in primary care settings regardless of the geographical location, thus potentially increasing the uptake rate of rural dwellers.

In addition to being cost-effective, a successful screening programme needs to be safe. This relies on the accuracy of the ultrasound device at measuring the aortic diameter. Two previous studies in this topic provided conflicting results; Flu et al.\textsuperscript{10} concluded that the device demonstrated acceptable sensitivity whereas Abbas et al.\textsuperscript{11} suggested that the device lacks adequate sensitivity for screening. Our aim was to investigate further whether the BVI 9600 (BVI) is sufficiently accurate and with sufficiently low variability to be used in AAA screening. The BVI was compared with a conventional ultrasound (US) machine for accuracy of aortic measurements and AAA detection performance.

**METHODS**

*Settings and patient recruitment*

This study was conducted over a 4-month period, with participants recruited from patients referred to the Otago Vascular Diagnostics Laboratory in Dunedin. Inclusion criteria was people aged 50 years and above. There were no exclusion criteria other than age < 50 years. Some participants had existing known AAA and were either under surveillance or awaiting treatment. Written, informed consent was obtained having ethical approval from the regional Ethics Committee.

*Equipment*

The BVI has a 3.0-MHz circular transducer of 18 cm penetration depth capacity. It generates a three-dimensional (3D) scan of the aortic region using ultrasound reflections on multiple planes in order to construct a 3D geometry of the aorta. Subsequently, the diameter of the aorta is directly deduced.\textsuperscript{10} If the diameter is deemed 3.0 cm or larger, its specific measurement is shown with a “result display” (which shows a B-mode cross-sectional image of aorta) and an “aiming display” (which shows the position of the aorta relative to the US probe). If the diameter is deemed to be less than 3.0 cm, the measurement and “aiming display” will not be shown, in which case the operator manually measured the diameter on the “result display” using electronic callipers.

Comparison US evaluation of the aortic diameters was performed by a conventional US device (Toshiba Alipo XG, Zoetmeer, The Netherlands) with a 3.5-MHz abdominal transducer of 28 cm penetration depth capacity, used routinely in the clinical setting.

*Operators*

The operators were five experienced vascular sonographers. A training session was provided by the device manufacturer, including an instruction booklet for revision. None of the operators had used this device prior to this study.

*Scanning process*

Each aorta was measured by one sonographer using the BVI first, followed by a second blinded sonographer using the conventional US machine. Four anterior—posterior aortic diameter measurements were taken on the transverse plane at four equally spaced segments marked along the midline between the xiphisternum and the umbilicus as per the manufacturer’s instructions (Fig. 1). Measurements using the BVI and conventional US were made at the same marked points. The aortic diameter was measured from inner-to-inner (ITI) sides of the wall using the BVI, whereas using conventional US the aortae were measured from the outer-to-outer (OTO) sides of the walls as in the clinical setting. We defined an AAA as one with a diameter of 3.0 cm or more at any aortic segment, measured from the OTO of the aortic walls. Patients found to have a previously undiagnosed AAA by the conventional US machine were referred back for formal evaluation in the vascular laboratory.

*Statistical analysis*

The repeated measurements from both machines were compared. The variability, calculated as 1.96 times the standard deviation of the mean difference, signifies how much the BVI measurements varied from those of the conventional US system. This variability was compared with a clinically acceptable difference (CAD) of 0.5 cm, described by Jaakola et al.\textsuperscript{12} The 95% limits of agreement (LOA), calculated by the sum of the mean difference and the variability, is the range within which 95% of the differences between the BVI and the US measurements lie. The above statistical measures are illustrated using Bland—Altman plots in which the differences between measurements of each BVI—US pair are plotted against the averages of those
measurements. The proportion, measured in percentages of the BVI measurements that were within ±0.5 cm of the US measurements, was calculated as described by Lederle et al. Kappa statistics were calculated to determine the inter-observer agreement of the AAA detection between the BVI and US. An analysis of the sensitivity, specificity, positive predictive value (PPV), and negative predictive value (NPV) was performed to enable a direct comparison with the literature. However, the conclusion of our data was drawn from the measurement of variability and the Bland—Altman plots for comparing two clinical methods. Visualisation proportion was defined as the proportion of aortic segments that were visualised adequately to enable aortic diameter measurements by each device. An analysis of the aneurysms that the BVI failed to detect was performed with regard to the likely accountable factors. These statistical analyses were applied to measurements of individual segments of the aorta (A, B, C, and D) and the maximal aortic diameter (the largest measurement out of these four measurements).

**RESULTS**

During the study period, 142 participants were scanned. The mean maximal aortic diameter of all the aortae was 3.02 cm (range 1.39—9.46 cm); that of normal aortae was 2.11 cm and of aneurysmal aortae 4.63 cm. Conventional US detected 52 aneurysms (size 3.10—9.46 cm); the BVI detected 43 aneurysms (83%), including eight of the 12 large aneurysms (>5.5 cm, 67%) and 35 of the 40 small and medium aneurysms (3.0—5.4 cm, 88%).

**Inter-device differences**

The measurement mean differences, variability, and LOA for the BVI—US pairs of each aortic segment are presented in Table 1. The BVI measurements were within the CAD in 75—87% of the time. However, the variability was large, ranging between 0.88 and 1.56 cm (Table 1), and increased as aortic diameter increased (Fig. 2). Measurements at the distal segments (C and D) were less accurate than those of the proximal segments (A and B), though a systemic measurement bias was present with the BVI consistently under-measuring aortic diameters (Fig. 2). The distal aortic segments were found to associate with more aortic dilatations over 3.0 cm than the proximal counterparts (32 and 42 aneurysms at C and D respectively, compared to 3 and 10 at A and B).

**Measurement accuracy of the aneurysmal aortae and non-aneurysmal aortae**

The measurement accuracy of the BVI when measuring aneurysmal aortae was distinctly inferior to that of normal aortae (Fig. 2). This was also demonstrated by a lower percentage of measurements that achieved the CAD (59% vs. 88%, p < .05), a larger systematic bias (mean difference −0.56 vs. 0.02 cm) and a larger variability (1.72 cm vs. 0.76 cm) (Table 2). Consequently, the BVI failed to detect three aneurysms (3.1 cm, 3.56 cm, and 5.74 cm) due to an under-measurement by 0.9—3.9 cm compared to conventional US equipment.

**Table 1.** BVI compared with conventional ultrasound: mean differences, variabilities, limits of agreement (LOA), proportion of measurements within the clinically acceptable difference (CAD), and the number of missed images for measurements of the abdominal aorta taken in the transverse plane at location A, B, C, and D and the maximal measurement from 142 subjects.

<table>
<thead>
<tr>
<th>A</th>
<th>B</th>
<th>C</th>
<th>D</th>
<th>Maximum</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean difference (95% CI)</td>
<td>Variability</td>
<td>LOA</td>
<td>Proportion within CAD (%)</td>
<td>n² (total = 142)</td>
</tr>
<tr>
<td>−0.02 (−0.11 to 0.07)</td>
<td>0.88</td>
<td>−0.90, 0.86</td>
<td>77</td>
<td>101</td>
</tr>
<tr>
<td>−0.03 (−0.12 to 0.06)</td>
<td>0.94</td>
<td>−0.97, 0.91</td>
<td>81</td>
<td>112</td>
</tr>
<tr>
<td>−0.12 (−0.25 to 0.02)</td>
<td>1.48</td>
<td>−1.59, 1.36</td>
<td>80</td>
<td>120</td>
</tr>
<tr>
<td>−0.27 (−0.41 to −0.13)</td>
<td>1.56</td>
<td>−1.83, 1.29</td>
<td>77</td>
<td>123</td>
</tr>
<tr>
<td>Maximum −0.19 (−0.31 to −0.08)</td>
<td>1.32</td>
<td>−1.48, 1.10</td>
<td>78</td>
<td>135</td>
</tr>
</tbody>
</table>

a Number of BVI—US pairs. Scans from which no measurement could be obtained were excluded from the analysis and thus the numbers of BVI—US pairs are different at each aortic segment. CAD: difference <0.5 cm.
Table 2. BVI compared with conventional ultrasound: mean differences, variabilities and limits of agreement (LOA), proportion of measurements within the clinically acceptable difference (CAD), and the number of missed images of the maximum normal and aneurysmal aortae diameters with BVI.

<table>
<thead>
<tr>
<th></th>
<th>Mean difference (95% CI)</th>
<th>Variability</th>
<th>LOA</th>
<th>Proportion within CAD (%)</th>
<th>n²</th>
<th>Number of non-visualised segments (BVI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Normal aortae</td>
<td>0.02 (−0.06 to 0.10)</td>
<td>0.76</td>
<td>−0.73, 0.76</td>
<td>88</td>
<td>86</td>
<td>4 (4.4%)</td>
</tr>
<tr>
<td>Aneurysmal aortae</td>
<td>−0.56 (−0.81 to −0.32)</td>
<td>1.72</td>
<td>−2.25, 1.11</td>
<td>59</td>
<td>49</td>
<td>3 (5.8%)</td>
</tr>
</tbody>
</table>

a Number of BVI—US pairs. Scans from which no measurement could be obtained were excluded from the analysis. CAD: difference <0.5 cm.

Non-visualisation of the aorta

Non-visualisation occurred more frequently among aortic scans by the BVI (18% of all scan measurements) than the conventional US system (6%) (Table 1). Complete non-visualisation (i.e., involving all four aortic segments) occurred in seven aortae examined by the BVI; whereas this issue was not encountered by the conventional US. Similarly, non-visualisation of the distal segments (C or D) occurred in 19 aortae examined by the BVI, compared to eight by conventional US. Consequently, the BVI failed to detect three aneurysms (size 3.7, 5.47, and 6.17 cm) due to complete non-visualisation and another three aneurysms (size 3.4, 4.0, and 5.6 cm) due to non-visualisation of the distal segments.

Aneurysm detection

The BVI had modest levels of agreement with US in the diagnosis of AAA, having a kappa coefficient of 0.83 (95% CI 0.73−0.92). The sensitivity was 83% (70−92%), specificity 98% (92−100%), positive predictive value 96% (85−99%), negative predictive value 90% (82−96%), false positive rate 2% and false negative rate 17%.

DISCUSSION

The BVI is a promising tool, suitable for a low-cost and easily accessible AAA screening outreach approach. Unfortunately, its accuracy in AAA detection has not received much attention from the screening literature. This study evaluated the measurement accuracy of the BVI against that of a conventional US machine in 142 subjects. We conclude that, at present, the BVI is not sufficiently accurate to detect AAA for the purpose of screening. This is consistent with the conclusion by Abbas et al., where the AortaScan AMI 9700 was compared with CT in 91 subjects (excluding large AAAs and participants with BMI >35 kg/m²). The authors concluded that the device lacked adequate measurement sensitivity (81%) to be used in screening. In contrast, Flu et al., comparing the BVI 9600 with conventional US in 150 subjects clinically suspected of AAA, concluded that the BVI 9600 demonstrated a sensitivity (90%) acceptable for screening. It is difficult to interpret these results, as the specific ultrasound measurement variability of the aortic diameter was not reported in either study. Other studies comparing CT and US measurements of the abdominal aorta commonly regard differences of less than 0.5 cm (the CAD) between the equivalent methods clinically acceptable..

The operators were highly skilled which suggests that the poor performance of the BVI in this study is mainly the result of its technical shortcomings. Because the BVI demands minimal operator skills, it is doubtful that more training of the operators can improve the AAA detection accuracy without substantial technical improvement to the device. Hartshorne et al. suggested the same, and that the accuracy achieved should be within the CAD before it could be used in AAA screening.

Aneurysm detection

Out of 52 aneurysms detected by conventional US, the BVI failed to detect nine aneurysms, three due to measurement inaccuracy, three due to non-visualisation of all four segments of the aorta, and three due to non-visualisation of the distal segments. Reliable identification of aneurysm is of course the goal of screening. The manufacturer of the BVI stated that the device was designed to simply detect aortic diameters over 3.0 cm, not to accurately measure the diameters. However, inaccurate measurements of the aneurysmal aortic diameters by the BVI around this point may have led to its failure to detect a proportion of aneurysms in this study. The aneurysmal aortae were less accurately measured than the normal ones, evident by a larger systematic under-measurement bias (−0.56 cm) and measurement variability (1.72 cm). Consequently, the BVI failed to detect three aneurysms (3.1 cm, 3.56 cm, and 5.74 cm) due to an under-measurement by 0.9 to 3.9 cm compared to US. Abbas et al. have suggested that the BVI would be more accurate for larger aortae, but this issue remains controversial in studies comparing different conventional US devices. Failure of the BVI to detect a significant proportion (33%) of large aneurysms (4 of 12 aneurysms measuring over 5.5 cm) is particularly serious with significant imminent risk of rupture and the lost opportunity for immediate repair. The failure to detect 12% of the smaller AAA while having fewer immediate consequences for the patients still may significant clinical implications.

There are several possible factors accounting for the poorer performance of the BVI. They include the systematic bias produced by the difference in measuring the OTO wall of the vessel with conventional US compared to an ITI wall technique with the BVI. This would have lead to a systematic under-measurement by the BVI and the failure to detect borderline aneurysms. Automatic adjustment for this systematic bias is attractive however the size of this effect was too variable. The effect would be accentuated when
there is poorer resolution of the BVI to automatically detect the inner margin as may occur in aneurysms burdened by mural thrombi. From this study we considered it to be preferable for the further development of the BVI or any other upcoming non-conventional ultrasound devices designed for AAA screening to follow the more widely used conventional OTO wall measurement of the aortae. It would make comparison with current criteria of AAA easier. However, the measurement technique for the abdominal aorta remains controversial.21 A recent study by Hartshorne et al.20 found that the ITI wall method was more reproducible and it is used in at least one screening programme. The large measurement variability of aneurysmal aortae with the BVI protocol may be contributed to by the difficulties in assessing the aortic diameter in the presence of vessel tortuosity. Tortuosity makes the detection of the true cross sectional image difficult. Tortuosity is present in most ectatic aortae21 and in a significant number of aortae going on to expand into aneurysms.22 The ability to cope with vessel tortuosity to insure true cross sectional measurement should be a development priority in the technical improvement of the BVI, as also recommended by Hartshorne.8

**Non-visualization**

Non-visualization of the whole aorta or the distal segments led to failure of the BVI to detect six aneurysms (size range 3.4–6.47 cm). Non-visualization is a well-recognized challenge in ultrasound scanning of the abdominal aorta, commonly due to bowel gas and participant obesity.23 This was no different in this study although it was not quantified. Real-time scanning and adequate depth of US penetration are both needed to minimize these impediments to visualization. Unfortunately, the BVI lacks real-time imaging and has a penetration of only 18 cm. As obesity is associated with AAA,24 it would be advantageous if real-time scanning and greater penetration depth could be incorporated into the BVI. These technical improvements could particularly minimise the risk of the BVI failing to detect large aneurysms, four out of 12 large aneurysms (>5.5 cm) in this study, due to non-visualisation of the aorta, or its misidentification.

**Strength of measurement agreement**

A reasonable kappa score of AAA detection was achieved, signifying an agreement between the BVI and conventional US in regard to detection. In contrast, the sensitivity of detecting AAA is consistent with the results by Abbas et al.,11 who concluded that the BVI was not sufficiently sensitive for AAA screening. However, these statistical measures may be misleading due to AAA being a disease of relatively low prevalence, a statistical issue reported by Meehl and Rosen.25

**Implications for screening**

The conventional US screening cut off for an AAA is 3.0 cm but the BVI device using an ITI measurement may under estimate this by as much as 2–3 mm and exclude significant numbers of small aneurysms for further surveillance. Hartshorne et al.1 suggested that a screening programme using an automated device like the BVI could select a diameter threshold below 3.0 cm for participants to have a follow up conventional US re-evaluation for additional safety. Such an approach with many additional conventional US scans may offset the cost-effectiveness of screening programmes. The minimal operator skill requirement of the BVI eliminates the need to train staff extensively and bypasses the requirement of sophisticated ultrasound operator skills. Therefore, this remains an important potential advantage of the BVI. However, only with further technical development of the BVI scanning technology is this strategy with a low-cost automated device likely to succeed. Another shortcoming of the BVI currently is its lack of ability to detect iliac artery aneurysms (IAAs). IAAs share similar risk factors with AAAs yet are underdiagnosed and more lethal when rupturing; thus, there has been suggestion to screen for isolated and coexisting IAA during AAA screening.26 However, further studies into the cost-effectiveness of such approach are required due to the low incidence of isolated IAA and the unreliable diagnostic accuracy of ultrasonography in detecting co-existing IAA.27

Limitations of the study include the use of the criteria of less than 0.5 cm as the acceptable measure of variability. This is based on inter-observer and intra-observer variability using conventional US.15,28 However these inter-observer and intra-observer measures may be different for BVI and was not analysed in this study. It is expected that such variability may have contributed to the measurement variability between the BVI and US system. This does not detract from the overall reasonable basis for this criteria.

The sonographers in this study had never used the BVI prior to the study. However, because of their prior experience in ultrasonography they had a considerable advantage over inexperienced prospective screeners in the community for whom the device is designed. We suggest that the generalisability of the study findings would apply. Larger studies in the future are recommended to test the accuracy of an improved device when used by novices.

**CONCLUSION**

At present the BVI is not sufficiently accurate to detect AAA for the purpose of screening. The BVI requires significant technical development before it can be considered for screening in the future. However, were it possible to make these improvements to make the BVI more accurate while maintaining a low-cost profile by eliminating the need for extensively trained ultrasound operators, it could suit a screening model that aims for low-cost and easy accessibility to residents of rural areas and other settings where capture rates of current screening models are low.

**FUNDING**

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