Diagnostic accuracy of pocket-size handheld echocardiographs used by cardiologists in the acute care setting

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Aims	Pocket-size echographs may be useful for bedside diagnosis in acute cardiac care, but their diagnostic accuracy in this setting has not been well tested. Our aim was to evaluate this tool in patients requiring an urgent echocardiogram.
Methods	Trained cardiologists performed echocardiograms with a pocket-size echograph (Vscan) in consecutive patients requiring urgent echocardiography. The exams were then compared in a blinded manner with echocardiograms performed with a high-end standard echocardiograph.
Results	A total of 104 patients were studied. There was an excellent agreement between the Vscan and the high-end echocardiograph for the left ventricular systolic function and pericardial effusion (Kappa: 0.89 and 0.81, respectively), and the agreement was good or moderate for evaluating the aortic, mitral, and tricuspid valve function and the left ventricular size (Kappa: 0.55−0.66). Visualization of the Vscan images in full-screen format on a PC did not in general confer added value.
Conclusion	The Vscan used by a trained cardiologist has good diagnostic accuracy in the emergency setting compared with a high-end echocardiograph, despite small screen size and lack of pulse-wave and continuous Doppler.
Keywords	Pocket-size echocardiographs • Vscan • Acute cardiac care

Introduction

Echocardiography is a valuable tool for patient triage in the emergency care setting, allowing rapid bedside assessment of diagnostic parameters such as left ventricular (LV) ejection fraction, valve function, or the presence of pericardial effusion.[1,2] Until recently, however, echocardiographs were of consequent size and impractical to handle in the intensive care unit, emergency wards, or at a resuscitation scene. Smaller echocardiographs have become available, either in a mobile 'laptop' format, or more recently in a pocket-size handheld "PDA" format. Mobile echocardiographs have already shown good performance but remain inferior to standard systems, especially for quantification of valve disease or pulmonary hypertension.[3−5] Pocket-size handheld devices, such as the Acuson P10 (Siemens), offer 2D greyscale images; the Vscan (GE Healthcare Vingmed Ultrasound, Horten, Norway) also offers colour-Doppler imaging, but without pulsed-wave or continuous Doppler. The Vscan has already shown good results in a recent study conducted in unselected routine patients from an echocardiography lab.[6] Furthermore, it has been useful in out-patient consultations as an extension of physical examination[7,8] with good diagnostic accuracy in expert operators.[8] However, its potentially most useful application is in the emergency care setting, where the compact nature of the device makes it significantly more practical than standard or even portable echocardiographs. Nevertheless, the practical appeal of this device should not be offset by a loss of diagnostic accuracy, especially in a setting where important clinical decisions need to be made rapidly and may determine the immediate outcome of the patient. Use of the Vscan has not been well tested in the emergency care setting. Our aim was therefore to evaluate the

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diagnostic accuracy of the Vscan in the hands of trained cardiologists in patients requiring urgent echocardiography.

Methods

Patient recruitment and echocardiographic evaluation

We recruited consecutive patients at our institution (a tertiary referral centre) requiring an urgent echocardiogram for any reason. The study was approved by the institutional ethics committee, and all patients gave informed consent to participate in the study. The requested echocardiogram was performed using a Philips iE33 echocardiograph (Andover, MA, USA) with an S5 probe, and was then interpreted offline on an Xcelera workstation by an experienced cardiologist proficient in echocardiography (H.M, P.K, P.M, T.S, L.S., C.V, or H.B). This echocardiogram constituted the gold standard. A second echocardiogram was performed with the Vscan within 12 h of the initial examination by another cardiologist (A.T. or H.B). All physicians who participated in this study were certified cardiologists with over 4 years' experience in echocardiography. Patients were excluded if an interventional procedure (e.g. coronary angioplasty, pericardiocentesis etc.) had been performed between the two examinations, or if the clinical conditions had changed (e.g. introduction of inotropic drugs). The cardiologist performing the Vscan examination was blinded to the result of the iE33 exam, but aware of the clinical context of the patient. The cardiologists who interpreted the iE33 exams also interpreted the corresponding Vscan examinations on a PC in full-screen format, blinded to the identity of the patient and after a period of ≥3months to avoid a carry-over effect of the iE33 exam.

Description of the Vscan

The unit has a flip-screen and measures $135 \times 73 \times 28$ mm with a total weight of 390 g including the fixed probe (*Figure 1*). The screen diagonal is 8.9 cm with a resolution of 240×320 pixels. The field-of-view for greyscale 2D imaging has an angle of $75°$ and a maximum depth of 25 cm. Gain is automatically adjusted with varying depths, but can also be manually adapted. Colour Doppler is superimposed on the 2D images for real-time blood flow imaging with a $30°$ sector. The bandwidth of the phased-array probe is $1.7–3.8$ MHz. All controls can easily be manipulated by the thumb of the hand holding the unit. Acquisition is obtained through an 'Auto-Cycle' function that automatically detects a full cardiac cycle (without an ECG trigger), or in case of failure by storing of a 2-second loop. Voice recording and exam number are used for patient identification. The still images are stored on a 4-GB SD memory card along with the MP4 video files and can be reviewed on the display unit, or copied to a PC via the included docking station or directly from the SD-card.

Data analysis

iE33 exams were viewed on a 21′ PC screen using Xcelera software (Philips) with all routinely available parameters (2D and M-mode measurements, colour Doppler, continuous-wave, pulsed-wave and tissue Doppler quantifications). Vscan exam analysis was performed by the operator directly on the display unit and also by a separate examinator (who had interpreted the corresponding iE33 exam) in full-screen format on a 21′ PC screen, using QuickTime software (the Vscan comes with dedicated software for viewing on a PC but does not run video on Windows XP, and does not show full-screen views). The Vscan exams were analysed only by eyeball assessment (no measurements were performed in our study, but are available on the device for measuring chamber size with 2D images). The analysis constituted of image quality assessment (1 = excellent, 2 = good, 3 = moderate, 4 = poor); left and right ventricular (RV) size (1 = small, 2 = normal, 3 = dilated); LV ejection fraction (1 = hyperkinetic, 2 = normal, 3 = mild, 4 = moderate, 5 = severe reduction); RV systolic function (1 = normal, 2 = reduced); valve stenosis (1 = absent, 2 = present) of the mitral and aortic valves (based for the Vscan exams upon valve morphology and motion as well as assessment of colour Doppler); valve regurgitation (1 = absent/non-significant, 2 = mild, 3 = moderate, 4 = severe) of the mitral, aortic, and tricuspid valves; size of the inferior vena cava (1 = collapsed, 2 = normal, 3 = dilated) and the presence of pericardial effusion (1 = none, 2 = mild, 3 = moderate, 4 = severe). Finally all examinators had to assess the probability (classified as unlikely, possible or probable) of the following diagnoses: myocardial ischaemia, pulmonary embolism, heart failure, or shock due to systolic dysfunction, heart failure due to valvular dysfunction, shock due to hypovolaemia or tamponnade.

Statistical analysis

An agreement between the imaging techniques was evaluated by the weighted Kappa statistic (VassarStats, ©Richard Lowry 1998–2011). Kappa values of <0.2 were interpreted as poor, $0.21–0.4$ as fair, and $0.41–0.6$ as moderate, $0.61–0.8$ as good, and $0.81–1.00$ as excellent. Correlation between parameters was calculated by Pearson's correlation coefficient; differences between groups were evaluated by the paired Student's *t*-test. Statistics (other than the Kappa statistic) were performed using the IBM SPSS v.19 program (Chicago, IL, USA). Data are expressed as the mean $\pm$ SD. A two-tailed $P < 0.05$ was considered to be statistically significant.

Results

A total of 104 patients (66 males, aged 66 ± 19 years) were included. Indications for the echocardiogram were chest pain in 22 (21%), dyspnoea in 21 (20%), evaluation of the LV ejection fraction in 19 (18%), suspected tamponnade in 16 (15%), hypotension in 8 (8%), cardiac arrest in 2 (2%), and other in 16 (15%). The Vscan images were acquired within 3.6 ± 3.2 h of the iE33 exams and were performed in the intensive care unit in 73

Figure 1 Bedside use of the Vscan (GE Healthcare) in a patient admitted to the intensive care unit. All the controls may be accessed by the thumb of the hand holding the unit.

Table 1 Main results comparing Vscan, Vscan full-screen, and iE33 exams (the latter being considered as the 'gold standard')

Parameter (scoring)	Vscan score	Vscan FS score	IE33 score	P Vscan vs. iE33	P Vscan FS vs. iE33	κ Vscan vs. iE33	κ Vscan FS vs. iE33
LV systolic function, 1−5 (hyperdynamic/ normal/mild/moderate/severe)	2.8 ± 1.3	2.9 ± 1.2	2.9 ± 1.2	0.32	0.72	0.89	0.90
LV size, 1−3 (small/normal/dilated)	2.2 ± 0.5	2.1 ± 0.4	2.1 ± 0.5	0.016	0.23	0.59	0.59
RV systolic function, 1−2 (normal/ reduced)	1.1 ± 0.3	1.1 ± 0.3	1.2 ± 0.4	0.06	0.12	0.69	0.69
RV size 1−3 (small/normal/dilated)	2.1 ± 0.4	2.0 ± 0.4	2.2 ± 0.5	0.62	0.028	0.39	0.46
Aortic stenosis absent/present	—	—	—	—	—	0.66	0.88
Aortic regurgitation, 1−4 (NS/mild/ moderate/severe)	1.3 ± 0.5	1.3 ± 0.6	1.2 ± 0.5	0.07	0.013	0.62	0.69
Mitral stenosis absent/present	—	—	—	—	—	0.65	0.85
Mitral regurgitation, 1−4 (NS/mild/ moderate/severe)	1.6 ± 0.7	1.4 ± 0.7	1.4 ± 0.7	0.001	0.29	0.56	0.61
Tricuspid regurgitation, 1−4 (NS/mild/ moderate/severe)	1.7 ± 0.7	1.5 ± 0.7	1.4 ± 0.7	0.003	0.70	0.55	0.69
IVC size, 1−3 (small/normal/dilated)	2.3 ± 0.6	2.2 ± 0.5	2.2 ± 0.5	0.040	0.44	0.49	0.57
Pericardial effusion, 1−4 (none/mild/ moderate/severe)	1.2 ± 0.5	1.3 ± 0.7	1.3 ± 0.6	0.41	0.53	0.81	0.88

Mitral and aortic stenosis diagnoses are non-quantitative, and therefore without mean ± SD values.

NA, not available data due to suboptimal image quality; Vscan FS, Vscan.mpg images viewed on a computer in full-screen format; LV, left ventricle; RV, right ventricle; IVC, inferior vena cava; NS, no or non-significant regurgitation;

κ (Kappa statistic): ≤0.2 = poor; 0.21−0.40 = fair; 0.41−0.60 = moderate; 0.61−0.80 = good; >0.80 = excellent agreement.

(70%) cases, in the emergency room in 20 (19%) cases, on the wards in 9 (9%) cases and in the catheterization laboratory in 2 (2%) cases. The main results are summarized in *Table 1*.

Image quality

The quality of the echocardiograms was considered as being either excellent or good in 58/104 (56%) of the iE33 exams, in 49/104 (47%) of the Vscan exams, and in 40/104 (38%) of the Vscan full-screen images. There were no significant differences in the overall scores of image quality between the iE33 exams and the Vscan exams (2.4 ± 0.8 vs. 2.5 ± 0.9, P = 0.51). However, the Vscan full-screen images were scored as being of lesser quality (2.8 ± 0.8) than the iE33 images (P < 0.001). There were significant correlations between image quality of the iE33 and Vscan exams (r = 0.50, P < 0.001) as well as between the iE33 and Vscan full-screen exams (r = 0.55, P < 0.001). *Figure 2* illustrates differences in image quality between the two echocardiographs.

LV systolic function

Images were of insufficient quality to evaluate LV systolic function in 1/104 (1%) patients using the Vscan (and was also impossible in this patient using the iE33 echocardiograph). A total of 43 (41%) patients had reduced LV systolic function as evaluated by the iE33 echocardiograph. The agreement between the Vscan exams and the Vscan full-screen images with the iE33 exams was excellent, with no significant differences between the scores of LV systolic function. Correlations of LV systolic function between the iE33 and Vscan/Vscan full-screen images were good (r = 0.89

and 0.90 respectively, P < 0.001). Only three patients with reduced LV systolic function on the iE33 exam (all evaluated as mildly reduced) were diagnosed as having normal function by the Vscan exam.

RV systolic function

RV systolic function could not be assessed using the Vscan in 16 (15%) patients (essentially due to image dropout of the RV free wall in the apical four-chamber view) compared with 6 (6%) patients with the iE33 echocardiograph. Reduced RV systolic function was diagnosed in 18 (18%) of the patients by the iE33. Of these patients, six were diagnosed as having normal systolic function on the Vscan exam, although overall agreement between the exams was good.

Ventricular size

The agreement between the Vscan and iE33 exams for the RV and LV size was fair or moderate, but better for the LV size than for the RV size.

Valve stenosis

The agreement with the iE33 exams for diagnosis of valve stenosis was good with the Vscan images, and excellent with the Vscan full-screen images. Aortic stenosis was diagnosed in eight patients by the iE33 exam, among whom one patient with a bioprosthesis was missed by the Vscan exam (but diagnosed when using the Vscan full-screen images). Conversely, aortic stenosis was suspected in five patients with the Vscan images, but ruled out by
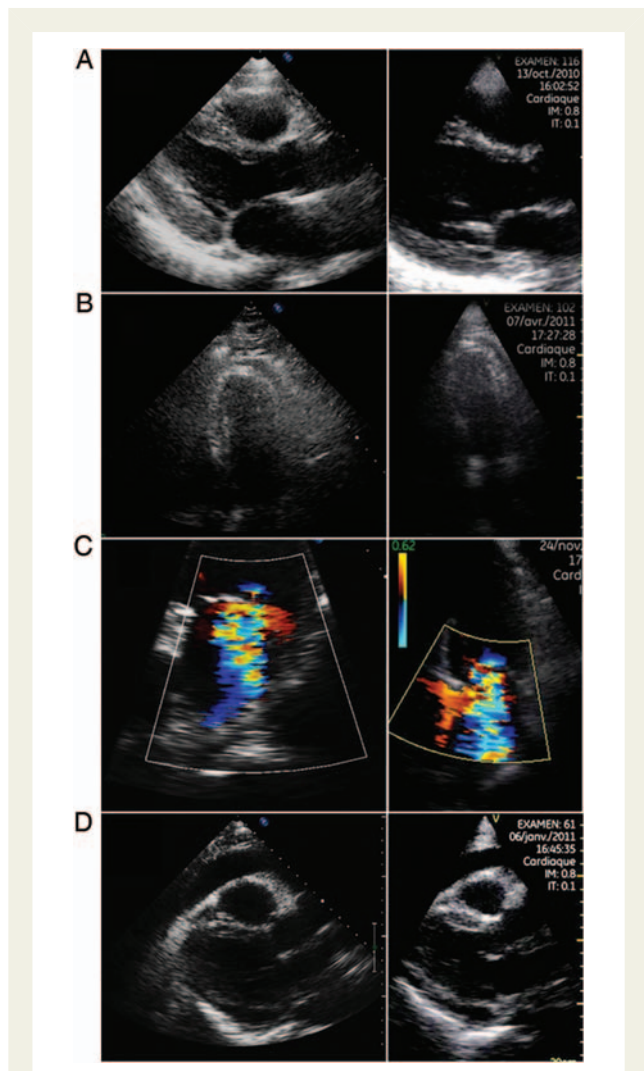
Figure 2 Each panel shows images obtained in the same patient with the iE33 (on the left) and with the Vscan (on the right). (*A*). Patient with good quality parasternal long-axis views (*B*). Patient with moderate quality apical views (*C*). Patient with mitral regurgitation. (*D*). Patient with pericardial effusion.

the iE33 exam. All these patients had thickened valve leaflets (valve sclerosis) that did not result in significant stenosis. Mitral stenosis was present in three patients, all of whom were diagnosed by the Vscan exam based on the extent of annular calcification and/or leaflet mobility. The Vscan exams suspected mitral stenosis in three additional patients, in whom the iE33 exams failed to show any significant transvalvular gradient.

Valve regurgitation

The agreement for quantification of valve regurgitation with the iE33 exams was moderate or good with the Vscan images, and slightly better with the Vscan full-screen images. The main reason for disagreement was due to the classification of regurgitation as 'mild' with the Vscan exams and 'absent or non-significant' with the iE33 exams in 25/51 patients with mitral regurgitation and

13/24 patients with aortic regurgitation. None of the patients with at least moderate valve regurgitation on the iE33 exams was missed by the Vscan exams.

Pericardial effusion

A total of 19 patients had pericardial effusion diagnosed by the iE33 echocardiograms. The agreement with the Vscan images was excellent, although two patients with mild effusion were missed by the Vscan exams (the effusion was judged as being minimal by the iE33 exams). Moderate or severe effusion was present in four patients, all of whom were also diagnosed by the Vscan exams. Of these, three patients had evidence of chamber compression on the iE33 exams, which was also seen on the Vscan images. Mild pericardial effusion was suspected with the Vscan or Vscan full-screen images in five patients, but not confirmed by the iE33 exams (due to interpretation of heterogenous pericardial space as being due to fat rather than effusion in four cases).

Clinical diagnoses

The agreement between the Vscan and iE33 exams was $\kappa = 0.61$ for myocardial ischaemia, 0.50 for hypovolaemia, 0.67 for heart failure due to systolic dysfunction, 0.87 for heart failure due to valvular dysfunction, 0.65 for pulmonary embolism, and 0.87 for tamponnade.

Discussion

Our study evaluated for the first time the handheld Vscan device for performing echocardiograms in the emergency care setting by experienced cardiologists. The main results can be summarized as follows: (i) image quality was good and not significantly different from a high-end standard echocardiograph; (ii) there was an excellent agreement between the Vscan and the high-end echocardiograph for LV systolic function and pericardial effusion (although mild effusion may be less accurately evaluated); (iii) The agreement was good or moderate for evaluating valve function and the chamber size; and (iv) visualization of the Vscan images in full-screen format on a PC does not in general seem to confer added value compared with visualization on the device itself.

The small-screen size of the Vscan did not compromise perception of exam quality and interpretation of the images. This is likely due to the high-resolution screen as well as the fact that the screen may be held close up for analysing details. Our data, showing good performance of the VScan for evaluating LV systolic function and the presence of pericardial effusion, are in agreement with a recent report using the Vscan in routine patients.[6] Also in agreement with this report is the slight overestimation of valve regurgitation, implying high sensitivity of the colour Doppler of the Vscan. The agreement in our study was, however, not as good for evaluating chamber size (that was evaluated on the Vscan using only visual assessment, whereas M-mode and 2D measurements were used with the iE33 exams). The agreement regarding the assessment of RV function was also limited, again probably because it was only assessed visually with the Vscan, whereas additional parameters such as tricuspid annular plane systolic excursion and TDI velocities were used with the iE33 echocardiographs.

There are few data on pocket-size ultrasound devices in acute care patients. A pilot study with the Acuson P10 device used by a novice echocardiographer in 22 stable intubated patients before cardiac surgery showed fair estimation of the ejection fraction.[9] In a recent study, 90 patients admitted to the cardiology ward were studied with a Vscan as well as with a high-end ultrasound machine by experienced echocardiographers.[10] The correlation between the two exams was good, although the patient population was more stable than in our cohort.

It is important to stress that the echocardiograms were performed by trained cardiologists. Use of handheld devices by cardiology trainees has shown limited diagnostic accuracy in evaluating ventricular systolic function.[9,11] Our results may therefore not be extended to less experienced examiners or to non-cardiologists (e.g. intensive care specialists) who have not followed specific training and certification. It is obvious that urgent bedside echocardiography may be technically difficult and requires sufficient operator training and experience to allow correct image acquisition and interpretation. It should also be underlined that the Vscan exam is not expected to substitute a complete echocardiographic examination. These concerns have led the European Association of Echocardiography to recently publish a position statement on the use of pocket-size imaging devices that stresses these points and indicates these devices as a 'complement to a physical examination in the coronary and intensive care unit' and as a 'tool for a fast initial screening in an emergency setting'.[12]

Study limitations

Delay between the iE33 and Vscan exams may have partly explained differences in results, due to rapid clinical evolution of acutely ill patients. However, the delay was relatively limited and we excluded patients in whom clinical conditions had changed significantly. We decided not to use the measurement tool of the Vscan device, which could have yielded better results in the assessment of chamber size. Finally, inter-observer variability may partly explain differences in results between the VScan and iE33 exams, as they were performed by different operators. This was however unavoidable in order to have an unbiased assessment of the Vscan.

Conclusions

The recent availability of affordable pocket-size echographs that are extremely practical to use in the acute care bedside setting is susceptible to facilitate patient management. Our study shows that this tool has good diagnostic accuracy compared with high-end standard echocardiographs, despite the lack of pulsed-wave and continuous-wave Doppler and small screen size. It may therefore be considered as a useful tool in first line evaluation and decision-making of critically ill patients, for whom an urgent treatment decision should be taken. However, it is mandatory that the operator performing echocardiograms (with any device) has sufficient expertise, especially in the emergency care setting where technical conditions may be difficult and misdiagnosis responsible for a fatal patient outcome.

Conflict of interest: None declared.

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