Reliability of cardiac dimensions and valvular regurgitation assessment by sonographers using hand-carried ultrasound devices

Claudio Coletta, Elettra De Marchis, Monica Lenoli, Stefano Rosato, Marco Renzi, Augusto Sestili, Patrizia Romano, Tommaso Infusino, Roberto Ricci, Vincenzo Ceci

Cardiology Department, S. Spirito Hospital, Rome, Italy
Istituto Superiore di Sanità, Rome, Italy

Received 5 March 2005; received in revised form 21 May 2005; accepted 1 June 2005
Available online 6 July 2005

Abstract

Aim: We sought to assess the reliability of some basic echocardiographic data obtained by trained sonographers using a hand-held ultrasound device.

Methods: One hundred and twelve consecutive patients (mean age 61, 64 males) referred for in-hospital or ambulatory routine echocardiography were considered. All patients underwent two-dimensional and colour Doppler examination performed by a trained sonographer equipped with a hand-held ultrasound device and by a certified cardiologist equipped with a standard platform, in random order. Indexed left ventricular end-diastolic and end-systolic transverse diameters, aortic root, end-systolic left atrium transverse diameter, end-diastolic interventricular septum and posterior wall thickness were calculated by two-dimensional left parasternal long-axis view in blind conditions. Mitral and aortic valve regurgitation were investigated by colour-Doppler imaging on parasternal and apical views and compared using a 0 to 4 semi-quantitative score.

Results: Overall feasibility was high for both settings (sonographers: 93%; cardiologists: 95%; P not significant). Excellent concordance of end-diastolic diameter (kappa 0.75), left atrium (kappa 0.76) and interventricular septum thickness (kappa 0.77) results was found. Good concordance was observed for end-systolic diameter (kappa 0.66), aortic root (kappa 0.64) and posterior wall thickness (kappa 0.67) results. A high linear correlation between the couples of results was present for all parameters. A good agreement of the mitral (kappa 0.66) and aortic (kappa 0.84) regurgitation scores was also found, with a low prevalence of
discordant results (mitral regurgitation: 22%, aortic regurgitation: 9%) and no ≥2-point discrepancies.

**Conclusion:** In a general population referred for Doppler echocardiography, basic cardiac linear dimensions and valvular regurgitation severity assessment by trained sonographers using hand-held ultrasound devices appear accurate and reliable for routine clinical use.

© 2005 The European Society of Cardiology. Published by Elsevier Ltd. All rights reserved.

**Introduction**

The recent availability of hand-held ultrasound devices gave new opportunities to the physician for improving bedside diagnostic possibilities in a large spectrum of clinical conditions and in different settings. In spite of their technical limitations, the use of small portable machines is becoming attractive because of their size, portability and favourable cost–benefit ratio. Recent investigations have demonstrated that these hand-held ultrasound devices give reliable information in cardiac patients when used by certified personnel. In a recent positional paper, the American Society of Echocardiography recommended the level 1 of competence in clinical echocardiography for the routine use of portable ultrasound machines by physicians, underscoring the assumption of individual responsibility for the final diagnostic report.

Cardiac sonographers routinely use high-level ultrasound devices for the diagnostic application, and the quantitative data obtained by these operators are trustfully utilized by physicians in the clinical management of patients both in the ambulatory and in-hospital setting. However, no data are still available concerning the reliability of morphologic and functional information obtained by non-medical operators equipped by hand-portable ultrasound devices in cardiology.

The aim of our study was thus to determine the reliability of some basic cardiac linear measurements and of valvular regurgitation severity assessment as performed by specifically trained sonographers with hand-held ultrasound devices, using as a reference standard the corresponding data reported by certified cardiologists equipped with a high-level machine.

**Methods**

One hundred and twelve consecutive patients referred for routine Doppler echocardiography in our laboratory between April 2003 and June 2003 were considered for the study. Each subject underwent two-dimensional and colour Doppler echocardiographic evaluation by a hand-carried ultrasound device and a standard platform for echocardiography, in the same session and in a pre-defined random order. The only exclusion criteria were the presence of a mitral or aortic prosthetic valve and any other clinical situation contraindicating a prolonged echocardiographic session, comprehensive of severe cardiac failure, resting chest pain and life-threatening arrhythmias. The design of the study was approved by the local Hospital Ethical Committee, and all patients gave written informed consent.

**Echocardiography protocol**

A complete two-dimensional and colour Doppler examination was performed in each subject by trained cardiac sonographers (E.D.M., M.L.) using a commercially available, battery-powered portable platform (Opti-Go Philips MS) equipped by a 2.5 MHz phased-array transducer giving digital fundamental imaging on a 5.5 inch liquid crystal display. Both operators had more than 100 complete examinations performed on the portable device of the study, and more than 5 years of full-time activity in clinical adult echocardiography. Repetitive linear measurements on the freeze-frames were obtained by means of scrolling capability, and power-encoded colour Doppler imaging of mitral and aortic valve was obtained in left parasternal long axis and apical views. Area and volume calculation software was not available on the hand-held device of the study, as time-motion and spectral Doppler analysis. In the same session, a complete two-dimensional and velocity-encoded colour Doppler examination was performed by cardiologists (C.C., M.R.) on a state-of-the-art, fully digital echocardiography device (Sonos 5500, Philips MS) equipped by a 1.8/3.6 MHz second harmonic fusion imaging transducer and a 15-inch high definition screen. Measurements on this machine were routinely performed using second-harmonic, ECG-guided two-dimensional freeze frames.
The order of examinations was preventively determined in a random sequence.

The left parasternal long-axis view was utilized for linear measurements at end-diastole and end-systole. Linear dimensions were calculated following the American Society of Echocardiography recommendations, averaging 3–5 measurements for end-diastolic and end-systolic frames. The electrocardiographic signal was not available on the hand-carried platform, and the end-diastole and the end-systole were identified as the frames with the largest and the smaller left ventricular areas, as visually estimated by the sonographers. The operators were aware of clinical status of the patients, but echocardiographic examinations and measurements were performed in blind conditions.

A head-to-head comparison of each couple of measurements was performed for the following linear dimensions: (a) indexed end-diastolic left ventricular transverse diameter (upper normality value: 30 mm/m²); (b) indexed end-systolic left ventricular transverse diameter (upper normality value: 20 mm/m²); (c) interventricular septum thickness at end-diastole (upper normality value: 12 mm); (d) posterior wall thickness at end-diastole (upper normality value: 12 mm); (e) indexed aortic root at end-diastole (upper normality value: 18 mm/m²); (f) indexed left atrium transverse diameter at end-systole (upper normality value: 22 mm/m²). In order to minimize confounding procedural pitfalls, the operative method was preventively discussed and definitively established by dedicated meetings. Each parameter was singly considered, and calculation procedures were discussed and approved by all operators in keeping of the current guidelines. In particular, sites of linear measurements were carefully specified in relation to well-defined anatomic sites of reference on the two-dimensional images (Fig. 1a). M-Mode dimensions on the standard echo machine were not calculated for the purpose of the study.

Mitral and aortic valve anatomy and function were inspected by two-dimensional examination in parasternal long-axis, apical four-chamber, two-chamber and long-axis views. Valvular regurgitation was assessed by power-encoded colour Doppler modality on the portable device, and by velocity-encoded colour Doppler on the standard echo machine.

Figure 1 Head-to-head comparison of end-systolic left ventricular diameter determination (a) and of colour-Doppler mitral regurgitation assessment (b) by portable devices and standard echocardiography. ESD, end-systolic diameter. Other abbreviations as in Fig. 2.
Severity of valvular regurgitation at colour Doppler was subjectively scored in a 1- to 4-point scale (1 = absent or trivial regurgitation, 2 = mild, 3 = moderate, 4 = severe) using two parameters: (a) dimensions of regurgitant jet; (b) thickness of regurgitant flow at vena contracta. The ratio between colour jet and left atrium areas was not considered for the software limitations of the portable device. Colour Doppler gain, filters and velocity scale (where available) were subjectively established by the single operator for the best image quality (Fig. 1b).

Moreover, two-dimensional and colour Doppler image quality of each examination was subjectively defined on a 4-grade scale (0 = not feasible, 1 = poor quality, 2 = average quality, 3 = high quality).

Intra- and inter-observer variability for left ventricular end-diastolic and end-systolic transverse diameters and for mitral valve regurgitation severity score as defined by sonographers equipped with the portable device was investigated in the first 20 patients of the study.

Statistical analysis

All corresponding measurements between the portable device and the traditional machine were assessed by linear regression analysis for correlation coefficient and by Bland–Altman plots for 95% limits of agreement. Cohen’s kappa coefficient values and weighted kappa values of agreement between the two diagnostic settings were determined for all parameters (agreement, based on Fleiss’s classification: <0.40, poor; 0.40–0.59, moderate; 0.60–0.75, good; >0.75, excellent). The sensitivity, specificity and overall accuracy of the results obtained by sonographers in the detection of abnormal linear dimensions and valvular regurgitation scores 3 and 4 were also determined. Results from continuous data are given as mean ± standard deviation. Comparison between normally distributed continuous data were performed using the paired Student’s t-test. The Chi-squared test was used to compare categorical groups. Data were elaborated and analysed using the SPSS for Windows statistical package, version 8.0 (SPSS Inc., Chicago, IL, USA).

Results

Population of the study

Mean age was 61 ± 11 years; 64 were male (57%) and 54 were in-hospital patients (48%). Clinical questions for the echocardiographic referral are reported in Table 1. The more frequent indications for the study were the assessment of left ventricular function (22 patients, 20%) and the regional wall motion analysis in patients with proven or suspected coronary artery disease (19 patients, 17%). Seven patients had atrial fibrillation during the ultrasound diagnostic procedures (6%).

Reproducibility

Intra-observer reproducibility (EDM) was high for linear measurements (end-diastolic diameter mean difference: 2%, 95% limits of agreement −9% to +7%; end-systolic diameter mean difference: 3%, 95% limits of agreement −11% to +13%) and for mitral regurgitation severity assessment (5% of discordant results, absence of ≥2 points discrepancy). Inter-observer reproducibility data demonstrated a good concordance for linear measurements (end-diastolic diameter mean difference: 4%, 95% limits of agreement −13% to +9%; end-systolic diameter mean difference, 5%, 95% limits of agreement −13% to +8%) and for mitral regurgitation severity assessment (10% of discordant results, absence of ≥2 points discrepancy).

Feasibility and image quality (Fig. 2)

The sonographers defined the examination as technically inadequate in seven patients, and this evaluation was confirmed by cardiologists in five using the standard device. No other patients were excluded by the cardiologists due to poor technical quality, and the overall feasibility of examination was comparable between the two diagnostic approaches (94% vs. 96%; P not significant).

<table>
<thead>
<tr>
<th>Clinical question</th>
<th>N</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Suspected left ventricular dysfunction</td>
<td>22</td>
<td>20</td>
</tr>
<tr>
<td>Chest pain or suspected acute coronary syndrome</td>
<td>19</td>
<td>17</td>
</tr>
<tr>
<td>Hypertensive heart disease</td>
<td>18</td>
<td>16</td>
</tr>
<tr>
<td>Valvular disease or cardiac murmurs</td>
<td>13</td>
<td>12</td>
</tr>
<tr>
<td>Previous myocardial infarction</td>
<td>11</td>
<td>10</td>
</tr>
<tr>
<td>Dyspnoea, signs of congestive heart failure</td>
<td>7</td>
<td>6</td>
</tr>
<tr>
<td>Atrial fibrillation</td>
<td>7</td>
<td>6</td>
</tr>
<tr>
<td>Previous coronary surgery</td>
<td>6</td>
<td>5</td>
</tr>
<tr>
<td>Previous coronary angioplasty</td>
<td>5</td>
<td>4</td>
</tr>
<tr>
<td>Pericarditis or pericardial effusion</td>
<td>4</td>
<td>4</td>
</tr>
</tbody>
</table>
examination was considered of poor quality in 20 patients either by sonographers and by cardiologists (18%) and this low score was coincident in 14 of these subjects. The examination was defined of high technical quality in 27 patients by sonographers and in 34 patients by cardiologists (24% vs. 30%; P not significant), whereas average quality was found in 58 patients by sonographers and in 53 patients by cardiologists (52% vs. 47%, P not significant).

Linear dimensions

The direct comparison of linear dimensions was possible in the 105 patients with sufficient technical quality of examination (Table 2).

A good concordance was found for aortic root diameter (kappa = 0.642, R = 0.931), end-systolic diameter (kappa = 0.662, R = 0.964) and posterior wall (kappa = 0.668, R = 0.886). An excellent concordance was observed for end-diastolic diameter (kappa = 0.755, R = 0.959), left atrium transverse diameter (kappa = 0.762, R = 0.964) and interventricular septum thickness (kappa = 0.770, R = 0.927). Linear correlation and Bland–Altman plots of end-diastolic and end-systolic left ventricular transverse diameters are represented in Fig. 3.

Values of sensitivity, specificity and overall accuracy of hand-held linear measurements related to the normal or abnormal results obtained by the cardiologist were assessed for each parameter, and are reported in detail in Table 2. The best accuracy of the portable platform in the detection of abnormal results was observed for the posterior wall thickness (94%) and for the end diastolic transverse diameter (94%). Determination of left atrium transverse diameter by portable device had the weakest accuracy for screening normal and abnormal values (90%). A slight overestimation of linear dimensions by sonographers was observed for both end-diastolic and end-systolic transverse diameters, with relatively lower values of specificity (65% and 70%, respectively).

Valvular regurgitation

A good concordance was found for the semi-quantitative assessment of mitral regurgitation severity (kappa = 0.639, R = 0.841), while the concordance of the aortic regurgitation assessment appeared excellent (kappa = 0.882, R = 0.949). The mitral and aortic regurgitation severity score was coincident in 78% and 90% of patients, respectively, and score discrepancies superior to 1 point were not observed. Considering as clinically relevant any regurgitation score 3 or 4 as defined by the cardiologist on the standard platform, the diagnostic procedure on the portable device showed a good accuracy for the detection of significant

<table>
<thead>
<tr>
<th>Variable</th>
<th>K</th>
<th>Weighted K</th>
<th>R</th>
<th>R²</th>
<th>Sens (%)</th>
<th>Spec (%)</th>
<th>Acc (%)</th>
<th>95% CI of Diff.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Aorta</td>
<td>0.642</td>
<td>0.658</td>
<td>0.931</td>
<td>0.867</td>
<td>92</td>
<td>83</td>
<td>91</td>
<td>−2.5/ + 4.1</td>
</tr>
<tr>
<td>Left atrium</td>
<td>0.762</td>
<td>0.761</td>
<td>0.964</td>
<td>0.930</td>
<td>95</td>
<td>80</td>
<td>90</td>
<td>−3.6/ + 2.8</td>
</tr>
<tr>
<td>IV septum</td>
<td>0.770</td>
<td>0.547</td>
<td>0.927</td>
<td>0.859</td>
<td>97</td>
<td>79</td>
<td>93</td>
<td>−1.6/ + 1.9</td>
</tr>
<tr>
<td>P. wall</td>
<td>0.668</td>
<td>0.478</td>
<td>0.886</td>
<td>0.785</td>
<td>97</td>
<td>70</td>
<td>94</td>
<td>−1.7/ + 1.7</td>
</tr>
<tr>
<td>LV EDD</td>
<td>0.755</td>
<td>0.568</td>
<td>0.959</td>
<td>0.920</td>
<td>100</td>
<td>65</td>
<td>94</td>
<td>−4.4/ + 3.3</td>
</tr>
<tr>
<td>LV ESD</td>
<td>0.662</td>
<td>0.574</td>
<td>0.964</td>
<td>0.930</td>
<td>100</td>
<td>70</td>
<td>93</td>
<td>−3.5/ + 4.2</td>
</tr>
<tr>
<td>Mitral reg</td>
<td>0.639</td>
<td>0.663</td>
<td>0.841</td>
<td>0.707</td>
<td>70</td>
<td>92</td>
<td>86</td>
<td>−0.89/ + 0.95</td>
</tr>
<tr>
<td>Aortic reg</td>
<td>0.882</td>
<td>0.837</td>
<td>0.949</td>
<td>0.900</td>
<td>98</td>
<td>89</td>
<td>94</td>
<td>−0.67/ + 0.51</td>
</tr>
</tbody>
</table>

Acc, Accuracy; CI, confidence intervals; K, Cohen’s kappa coefficient; Weighted K, Cohen’s weighted kappa coefficient; IV, Interventricular; LV EDD, left ventricular end-diastolic diameter; LV ESD, left ventricular end-systolic diameter; P. wall, posterior wall; R, regression coefficient; reg, regurgitation; Sens, sensitivity; Spec, specificity; 95% CI of Diff., 95% confidence intervals of the difference between the two measurements.
mitral and aortic valve regurgitation (86% and 94%, respectively).

### Discussion

Our study demonstrates that cardiac linear dimensions and subjective mitral and aortic regurgitation severity assessment as performed by specifically trained sonographers equipped with hand-carried ultrasound platforms give reliable results. In our investigation, data obtained by experienced cardiologists with a high-level device were considered as the reference gold standard. Even though we did appreciate minor discrepancies between the two diagnostic settings, accuracy of the hand-carried device results proved to be acceptable for the clinical use. In particular, this study found portable echocardiography to be a reliable approach for the detection of left atrial and left ventricular dilatation, wall hypertrophy, aortic root enlargement and valvular regurgitation in the hands of certified sonographers. Considering the relationship between end-diastolic and end-systolic dimensions, the left ventricular ejection fraction should be detectable in patients without segmental wall motion abnormalities. However, cardiac function was not an end point of the study, and further investigations should assess this particular feature.

Two other important issues were raised by our study:

(a) On a head-to-head comparison, the technical quality of examinations, as defined by sonographers on the hand-carried machine and by cardiologists on the high-level platforms, was comparable. A slight trend toward a better quality in the reference setting was obviously recorded, but in only two patients the examination was considered unfeasible by sonographers and not by cardiologists.

(b) A high intra- and inter-observer reproducibility was found in a group of non-selected, consecutive patients using the portable device. Notably, we admitted to the study consecutive, non selected patients, representative of the real daily activity of an ultrasound diagnostic laboratory.

The present study first demonstrates that trained sonographers equipped with hand carried
ultrasound platforms can perform two-dimensional and colour Doppler examinations with reliable results. Analogously to the routine operative modalities of the diagnostic activity, using portable ultrasound platforms sonographers could perform measurements (linear dimensions, areas or volumes depending on the implemented software), consider valvular regurgitation severity, and acquire the best images and clips for the final medical report, where technically possible.

Considering the technical limitations of portable ultrasound devices, their main use in clinical cardiology has to remain as an integration to the physical examination, just like an ‘imaging stethoscope’ in the hands of physicians. However, the results of our study open new interesting possibilities in the diagnostic management of in-hospital and ambulatory patients.

Previous clinical studies already demonstrated the diagnostic reliability of certified cardiologists and trained physicians equipped with hand-carried devices for the assessment of various cardiac abnormalities,10,11 and for the diagnosis of abdominal aortic aneurysm.12,13 when compared with a technologically high-level platform. In the hands of trained operators, a low inter-observer variability for the visual determination of left ventricular ejection fraction was also demonstrable (2%), in spite of the recognized difficulty of this particular task.4 A less favourable impact of small portable ultrasound devices was found in the hands of resident internists without formal training in echocardiography,14 but a diagnostic improvement in comparison with the physical examination alone was detected in the assessment of left ventricular dysfunction,15–17 and in the outpatient clinical setting.18 Finally, sub-optimal diagnostic results have been described testing portable devices in critically ill patients,19 but more favourable data were reported in another study on patients admitted for acute cardiac care.20

Left ventricular hypertrophy diagnosis based on the indexed mass, as assessed on a portable ultrasound device by an experienced investigator, was highly reliable, suggesting the possibility of a first step screening of hypertensive heart disease with a low-cost technology.3 Similar results are reported in our study, where the accurate interventricular septum and posterior wall thickness values obtained with hand-carried platforms confirmed the availability of low-cost information on left ventricular hypertrophy in the general population. Moreover, the high concordance found in our study for left atrium and left ventricle transverse diameters opens new diagnostic possibilities in some clinical conditions, as in patients with atrial fibrillation for the assessment of cavity dimensions, or in the first-step diagnostic screening of patients with low functional capacity in the absence of known cardiac diseases.

High reproducibility of valvular regurgitation severity score has been demonstrated in previous studies by portable ultrasound devices in the hands of trained or certified cardiologists.5,10,21 Our study confirms the possibility of reliable information on valvular regurgitation severity by trained sonographers equipped with portable platforms. In the routine diagnostic setting, the severity of valvular regurgitation has to be defined by the responsible physician, and any evaluation by non-medical personnel could be considered useless or redundant. However, such a high concordance of valvular regurgitation severity scores warrants the reliability of colour Doppler examination in the hands of trained sonographers, in spite of the poorer Doppler technologies (power-encoded vs. velocity-encoded signal), the lower screen areas (5 vs. 15–17 inches) and the worse image definition of portable ultrasound devices.

The American Society of Echocardiography, in a recent positional paper,9 has defined the human requisites for operating in clinical echocardiography with portable devices, establishing a level 1 of competence as a minimum standard for any independent diagnostic activity. In that document, the need of the assumption of responsibility by a certified physician (cardiologist, anaesthesiologist, etc.) has been also stressed, establishing solid rules in view of the probable, enormous expansion of these low-cost diagnostic tools. Our study validates the diagnostic data obtained by dedicated, non-medical personnel, but their application in the routine clinical environment requires constant revision by a certified physician. Currently, one of the major limits of state-of-the-art portable echocardiography is the lack of high-capacity digital storage systems for the off-line analysis of images and clips.

Limitations of the study

Our study acknowledges some limitations. By design, analysis of cardiac dimensions was restricted to a group of linear data obtained by the left parasternal approach, and alternative basic information, as the left ventricular areas and volumes, have been neglected. This was due to the well-known technical limitations of hand-carried ultrasound platforms, with absence of two-dimensional calculations packages in most cases. Moreover, using the apical approach in patients with poor
left parasternal acoustic window, more reproducible linear dimensions would have been obtained.

We compared the accuracy of quantitative data made by sonographers on a portable platform with the results of certified cardiologists equipped with a standard echocardiographic machine. In this way we introduced a combined variable influencing the results, i.e. the human and the technical factor. However, the aim of the study was to validate a new, easily available diagnostic strategy in comparison with the best reference golden standard, and the high concordance found in our study seems to reduce the weight of possible methodological bias.

Finally, the operative time required for the two alternative approaches has not been calculated, so that a real cost-effectiveness analysis is still lacking, and we cannot exclude that the high concordance between the two strategies would be attributable to the unpractical, time-consuming method of the study, not easily applicable in routine clinical activity.

Conclusions

The recent introduction of portable, largely accessible and low-cost ultrasound devices determines a new problem regarding the clinical reliability of this new diagnostic approach. In addition to the validated use as an integration into the physical examination by physicians, these technically limited devices, in the hands of trained sonographers, could give accurate information about cardiac dimensions, wall thickness and valvular regurgitation severity. This appears useful for a better clinical management of in-hospital patients at the bedside or in the ambulatory setting, particularly as an aid to non-echocardiography-certified cardiologists.

Analogously to the routine ultrasound diagnostic activity, the results obtained by sonographers need the final validation of a responsible physician, thus the presence of a digital storage support for clips or images, still lacking in most of hand-carried devices for a cost- and weight reduction policy, appears to be a necessary further step for the full utilization of portable echocardiography.

References

18. Vourvouri EC, Poldermans D, Deckers JW, Parharidis GE, Roelandt JR. Evaluation of a hand carried cardiac ultrasound