CARDIAC IMAGING AND NON-INVASIVE TESTING

A hand-carried cardiac ultrasound device in the outpatient cardiology clinic reduces the need for standard echocardiography

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Objective: To assess the potential value and cost-effectiveness of a hand-carried ultrasound (HCU) device in an outpatient cardiology clinic.

Methods: 222 consecutive patients were prospectively enrolled in the study. When standard echocardiography (SE) was specifically indicated on the basis of clinical history, electrocardiogram and physical examination, the same cardiologist (level-2 or level-3 trained) immediately performed an HCU examination. The cardiologist then reassessed the clinical situation to confirm or cancel the SE request according to the information provided by HCU. The SE examination was performed by a sonographer and examined in a blinded fashion by a cardiologist expert in echocardiography. Findings from the two examinations were compared.

Results: HCU was performed in 108/222 patients, and a definite diagnosis was established in 34 of them (31%), making SE examination potentially avoidable. In the 74 patients with inconclusive HCU results and for whom SE was still indicated, the decision was mainly dictated by the lack of spectral Doppler modality in the HCU system. The overall agreement between HCU and SE for diagnosis of normal/abnormal echocardiograms was 73% ($\kappa=0.4$). On the basis of the potentially avoided SE examinations and the obviated need for a second cardiac consultation, a total cost saving of €2142 per 100 patients referred for echocardiography was estimated.

Conclusions: The use of a simple HCU device in the outpatient cardiology clinic allowed reliable diagnosis in one third of the patients referred for echocardiography, which translates into cost and time saving benefits.

At present, echocardiography is the most well-established and cost-effective diagnostic imaging tool in cardiology, and standard echocardiography (SE) is required whenever physical examination is inconclusive or doubtful or for evaluation of the severity of a known disease.¹ It has recently been shown in outpatient cardiology clinics that physical examination alone may lead to missed diagnoses of major unexpected abnormalities.² However, a complete echocardiographic examination is an expensive diagnostic test, which requires skilled personnel, and is usually performed several days after the first cardiology evaluation. This results in the need for a second patient–doctor encounter for possible revision of treatment, with consequent delay in diagnosis and treatment and high-cost outpatient cardiology clinic management.

Over the last few years, hand-carried ultrasound (HCU) devices have proved to be reliable tools for rapidly assessing the presence of cardiac abnormalities,³ with the potential for providing answers to the clinical questions raised after physical examination. Their use could lead to a reduction in the number of SE examinations, a decreased work load for echocardiographic laboratories, and prompt clinical decisions, with a positive impact on both patient management and financial arrangements.

With these concepts in mind, we designed this prospective study which aimed to assess the potential value and cost-effectiveness of HCU devices in reducing the need for SE in our outpatient cardiology clinic. The HCU findings were compared with the results of SE.

METHODS

Study population and design

From 15 September to 15 December 2004, 222 consecutive patients (mean (SD) age 63 (13) years) referred to our

outpatient cardiology clinic were screened and enrolled in the study. Table 1 gives their characteristics. Eight cardiologists (four level-2 and four level-3 trained in the performance and interpretation of echocardiograms, according to the American Society of Echocardiography requirements)⁴ took the clinical history, performed the electrocardiography and physical examination, and requested other diagnostic tests, when appropriate, for further information.

When SE was specifically indicated, a HCU examination was immediately performed by the same cardiologist using a commercially available system (OptiGo; Philips Medical Systems, Andover, Massachusetts, USA). The cardiologist then reassessed the clinical situation in order to confirm or cancel the SE request according to the information provided by the HCU examination. The SE (Sonos 5500; Philips Medical Systems) examination was performed for comparison, independently of the HCU results, by an echocardiographer (sonographer) and examined by a cardiologist expert in echocardiography blinded to the HCU results. Findings from the two examinations were compared.

The institutional medical ethics committee approved the study, and verbal informed consent was obtained from all patients.

The HCU device

The OptiGo portable device is equipped with a 2.5 MHz phased array transducer and operates on a rechargeable lithium ion battery or alternating current. The system is supplemented with

Abbreviations: HCU, hand-carried ultrasound; LV, left ventricular; SE, standard echocardiography

Table 1 Baseline characteristics of 222 patients referred to outpatient cardiology clinic

Characteristic	Number (%)
Men	104 (47)
1st evaluation/control (FU)	103 (46)/119 (54)
History of hypertension	91 (41)
Documented CAD	28 (13)
Chest discomfort	23 (10)
Dyspnoea	17 (8)
History of arrhythmia	13 (6)
Diabetes mellitus	11 (5)
Known valve disease	10 (5)
HF/dilated CMP	4 (2)
Syncope	6 (2)
High risk for CAD	2 (0.5)
ECG abnormalities	2 (0.5)
Other	15 (7)

CAD, coronary artery disease; CMP, cardiomyopathy; ECG, electrocardiogram; FU, follow-up; HF, heart failure.

two-dimensional imaging, colour flow Doppler imaging, and calipers for linear measurements.

Echocardiographic diagnosis

The HCU examination was performed to answer the questions raised by the cardiologist after the clinical evaluation. Thus a goal-directed echocardiography examination was performed using the HCU device according to the specific clinical question, but major unexpected cardiovascular findings, if detected, were also considered and recorded. All abnormalities that would affect decision-making for clinical patient management were defined as major.²

The protocol for HCU examination was flexible, and linear measurements were taken only if visually estimated as abnormal. In the case of suspected left ventricular (LV) hypertrophy, the interventricular septum and posterior wall measurements were noted. LV function was considered normal in the case of a visually estimated LV ejection fraction >50% in the absence of segmental wall motion abnormalities. The right ventricle was evaluated for both dimensions and function.

Valve regurgitation was qualitatively estimated using the colour degree on four steps and noted if more than mild. For valve stenosis, two-dimensional and colour Doppler aspects of the valve were described, and any stenosis, if present, was noted. Pericardial effusion was detected as an echo-free space between the pericardial layers.

The SE examination was performed in accordance with the American Society of Echocardiography recommendations,⁵ and second harmonic images were analysed according to departmental protocol. A clinically significant abnormal echocardiogram was defined as follows: LV end-diastolic dimension >56 mm; LV wall thickness >12 mm; LV ejection fraction ≤50% using the biplane Simpson's method; abnormal right ventricular dimensions and systolic function (qualitatively assessed); the presence of pericardial effusion; more than mild valvular regurgitation; any valvular stenosis. Furthermore, for both HCU and SE examinations, other pathological findings such as severe atrial enlargement and aortic dilatation, if detected, were also considered abnormal major findings.

Cost-effectiveness of the HCU device

The average cost of an SE examination is about €62, whereas the echocardiographic investigation performed using the HCU device, being considered part of the physical examination, is not charged for. However, considering that the capital investment of such a device is about €15 000 and the 5-year equipment depreciation of this amount is about €3000 a year, the cost of an HCU examination is €6.94, on the basis of the number of patients referred for echocardiography among those seen in our outpatient cardiology clinic (with an estimation of 432 patients per year). The cost of a cardiology consultation at our institution is about €13.

Statistical analysis

Descriptive statistics are reported as mean (SD) for continuous variables and as percentages for categorical variables. The agreement between HCU and SE examinations for the detection of major findings was assessed by 2×2 tables with weighted kappa statistics. κ Values <0.4, between 0.4 and 0.75, and >0.75 were considered to represent poor, fair-to-good, and

Figure 1 Allocation of patients to a hand-carried ultrasound (HCU) and/or a standard echocardiography (SE) examination.

Table 2 Ability of hand-carried ultrasound (HCU) examination to answer clinical referral questions and reasons for confirming standard echocardiography (SE)

	LVD/F	Valves	RV
Number (%)	84 (78)	17 (16)	7 (6)
Question answered by HCU	32/84 (38%)	6/17 (35%)	2/7 (29%)
Incidental findings	Valve abnormalities (4), LVOT obstruction (1)	PAP (1)	
SE confirmed	57/84 (68%)	12/17 (71%)	5/7 (71%)
Reasons for confirming SE	Diastole (38), WMA (8), poor quality (6)	Quantification (11)	PAP (5)

LVD/F, left ventricular dimension/function; LVOT, left ventricular outflow tract; PAP, pulmonary artery pressure; RV, right ventricle; WMA, wall motion abnormalities.

excellent agreement, respectively, on the basis of the Fleiss classification.⁶

RESULTS

General results

A total of 222 patients were enrolled in the study. As shown in table 1, this population had a heterogeneous pathology, but most reported a history of hypertension. Patients were also balanced for sex and type of evaluation (new patients or follow-up): about half had been referred by a primary care doctor or other specialist for an initial cardiac evaluation, and the rest were already under the care of a cardiologist and were having a follow-up examination. A few patients had been sent to the cardiology outpatient clinic from other departments of the hospital before planned admission for surgical interventions or other invasive manoeuvres.

Figure 1 shows the distribution of the patients in the study. An echocardiographic examination was requested in 110/222 (50%) patients. HCU was immediately performed in 108 patients (two were directly referred for SE for scheduled evaluation of LV function and thus excluded from the study). Reasons for referring the patients for echocardiography were evaluation of LV dimensions and function ($n = 84$), cardiac murmurs or valve assessment ($n = 17$), right ventricular dimensions and function ($n = 7$) (table 2). The mean examination time was <2 min (1.8 (0.6)), excluding report writing.

In 112/222 (50%) patients, SE was not performed because the cardiologist considered the available clinical information sufficiently accurate (32/112, 29%) or because the patient had recently undergone SE (80/112, 71%).

Questions answered using the HCU device

Satisfactory information was obtained using the HCU device for 40/108 clinical questions (37%), with similar percentages of questions answered by HCU (LV dimensions/function, 38%; cardiac murmurs/valves, 35%; right ventricle, 29%; table 2). The need for SE was confirmed in 74 patients: 68 patients with

inconclusive HCU and six patients for whom HCU answered the referring questions but revealed incidental findings requiring subsequent assessment with SE. Reasons for confirming the SE request were mainly related to the lack of spectral Doppler modality in the HCU device for patients requiring haemodynamic assessment (LV diastolic (dys)function, valve dysfunction, estimation of pulmonary artery pressure). Finally, HCU allowed us to cancel SE requests in 34/108 patients (31%) (fig 1).

Comparison between HCU and SE

In total, 71 patients had an SE examination performed at our department, whereas 37 patients were missed (fig 1). Figure 2 shows the comparison between HCU and SE in the patients in whom both examinations were performed ($n = 71$). For each patient, both HCU and SE results were classified as normal or abnormal, according to the presence/absence of ≥ 1 major abnormalities, and the agreement between the two devices was 73% ($\kappa = 0.4$). Figures 3 and 4 show examples. SE disclosed 29 major abnormalities in 21 patients, whereas HCU missed 10 major abnormalities in nine patients: nine LV hypertrophies and one mild pericardial effusion located posteriorly to the right atrium. For two of these patients, the echocardiogram was considered abnormal by both SE and HCU; however, the HCU examination missed LV hypertrophy among the detected abnormalities. In addition, the SE examination diagnosed eight patients with pulmonary hypertension, which was not detected with HCU.

A false-positive diagnosis by HCU occurred in 12 patients: 10 patients were considered to have mild LV hypertrophy (wall thickness 12–13 mm), and two patients showed right ventricular dilatation.

Cost-effectiveness analysis

According to the estimated costs (SE = €62, HCU = €6.94), the use of the HCU device allowed us to cancel SE for 34 of the 108 patients referred, resulting in a total cost saving of €1872 over the study period ($(62 - 6.94) \times 34$). Moreover, the introduction of the HCU in the physical examination session obviated the need for a second consultation in the same 34 patients. Therefore, taking into account the estimated costs for cardiology consultation, an additional cost saving of €442 was made. Thus the total cost saving was €2314 over the study period (ie €2142 per 100 patients referred for echocardiography).

DISCUSSION

The development of portable echocardiographic systems called “ultrasound stethoscopes” has allowed reliable bedside anatomical and functional information to be rapidly obtained. Thus specific cardiac abnormalities can be detected that would otherwise be missed at the time of clinical assessment. To this end, the HCU device has been designed for evaluation of LV hypertrophy and abdominal aortic aneurysm in hypertensive and older patients,^{7,8} and is a useful tool for assessing the

		SE	
		Normal	Abnormal
HCU	Normal	38	7
	Abnormal	12	14

Agreement 73%, $\kappa = 0.4$

Figure 2 Agreement between hand-carried ultrasound (HCU) and standard echocardiography (SE) in diagnosing normal/abnormal echocardiograms.

Figure 3 Apical four-chamber view obtained with hand-carried ultrasound (A, C) and standard echocardiography (B, D) in a 68-year-old woman with a history of rheumatic disease, showing mild-to-moderate mitral and tricuspid regurgitation. She was referred to the cardiologist for evaluation of dyspnoea and palpitations, and after consultation, including hand-carried ultrasound examination, was treated with high doses of diuretics.

prevalence of LV dysfunction in the community,⁹ quantifying valvular regurgitation,¹⁰ detecting pericardial effusion,¹¹ and assessing extravascular lung water and pulmonary oedema.^{12–13} Furthermore, its applicability has been proven in different clinical scenarios such as cardiology consultation rounds,¹⁴ cardiology inpatient¹⁵ and outpatient² clinics, emergency departments,¹⁶ and chest pain units.¹⁷ The potential advantages of using HCU include a brief examination time, simplicity of

use, availability at the patient's bedside, transportability, and relatively low costs.

In this study, we investigated the potential of a simple HCU device with limited Doppler capability in the daily management of patients referred to an outpatient cardiology clinic. We hypothesised that, in the outpatient clinic, it may reduce the need for SE without loss of important information. To this aim, this study was designed without altering the usual workflow in

Figure 4 Parasternal long axis (top) and apical four-chamber views (bottom) acquired with hand-carried ultrasound (A, C) and standard echocardiography (B, D), showing a dilated left ventricle in a 67-year-old man with a history of stroke. The patient was referred to the outpatient cardiology clinic by the neurologist for electrocardiographic abnormalities and dyspnoea on effort.

the daily outpatient clinic: cardiologists were not selected on the basis of their echocardiographic experience, HCU was available whenever needed, and SE was performed for diagnostic comparison and verification.

The main findings of this study can be summarised as follows.

- (1) Half of the patients need an echocardiographic investigation, most (78%) for evaluation of LV dimensions and function.
- (2) HCU may provide a reliable answer in one third of the patients referred for SE, with a considerable cost saving.
- (3) Agreement between HCU and SE is moderate, with the vast majority of discrepancies due to evaluation of LV hypertrophy.

In our study, 110 out of 222 patients (50%) were referred for SE examination. These data are similar to those reported by Vourvouri *et al*² if only the new patients are considered. In 34 of the 110 patients referred for SE (31%), a definitive diagnosis was made in the same clinical session using the HCU device, which raised the possibility of not performing SE. These results suggest the potential of the HCU device of saving on one third of the more expensive and time-consuming SE examinations, without the need for a second cardiology consultation for SE report reviewing and changes in medication, if needed.

The most common reason for the echocardiographic request (78%) was evaluation of LV dimensions and function. The HCU device provided conclusive evidence in 38% of cases, saving on about one third of the SE examinations initially requested for this clinical question. When an SE was confirmed (68% of the patients in the LV function group), this was mainly due to the need for an accurate assessment of LV diastolic (dys)function suggested by ≥ 1 consistent abnormal findings at HCU. Although the identification of diastolic dysfunction may reflect a particular interest in our centre, which negatively affects the results of this study, we believe that a complete evaluation of LV function is strongly indicated for a comprehensive haemodynamic assessment, especially in patients with hypertension and/or dyspnoea.

Among the reasons for inconclusive HCU results was that careful evaluation of wall motion abnormalities was requested in eight patients (11%). Obviously, the lack of harmonic imaging in the HCU device is a limitation; however, in our experience, the detection of wall motion abnormalities also depends on the skill of the operator. In fact, investigation of regional ventricular function is one of the most difficult tasks for echocardiographers and requires extensive experience. These eight patients were examined by three different cardiologists, all with level-2 experience, highlighting the need for appropriate training of the operators to increase confidence in the interpretation of LV wall motion.

Assessment of cardiac valves and the right ventricle (accounting for 22% of the indications for echocardiography) was satisfactorily dealt with by HCU in 35% and 29% of patients, respectively, demonstrating the capacity of the HCU device to avoid additional SE examinations when clinical suspicion of valve disease or right heart pathology is present. In this regard, when HCU and SE findings were compared, no valve dysfunction was missed with the portable device, for either significant regurgitation or stenosis of any degree, confirming the reliability of the HCU examination for gross evaluation of these cardiac structures. However, when accurate quantitative analysis of valvular lesions is needed, SE with spectral Doppler is obviously required.

The comparison of the 71 patients who had both HCU and SE examinations indicates agreement for the diagnosis of normal or abnormal echocardiograms in about three out of four

patients. Discrepancies lay mainly in the evaluation of LV hypertrophy. This finding is not completely unexpected, as the HCU equipment used in our study has a limited frame rate and no electrocardiographic recording for triggering, which affects the reliability of wall thickness estimation. Furthermore, these results are consistent with a previous study specifically designed to evaluate LV hypertrophy by HCU, with systematic measurements of LV wall thickness using calipers, which reports a sizeable proportion (10%) of wrong diagnoses.⁷

Finally, our data confirm that the HCU device may be very useful for reducing departmental costs and saving time to diagnosis. Estimation of the costs of the HCU examination according to the number of outpatients referred for echocardiography in the study period and the cancellation of 34 SE examinations resulted in a mean cost saving of €1872. With the incorporation of HCU into the physical examination, a second consultation to evaluate the SE examination and to modify clinical management would have been avoided in the same patients, leading to a further cost saving of €442. Thus the overall estimated cost saving was €2314 (€2142 per 100 patients referred for echocardiography).

Study limitations

The HCU device used in this study has limited (colour) Doppler facilities, which prevents a comprehensive echocardiographic examination. Indeed, the use of a portable machine in an outpatient clinic should be easy and practicable, and not limited to skilled (echo)cardiologists. Portable fully equipped systems require more experience and training, both in performing the examinations and interpreting the data, and we should be cautious in suggesting the widespread use of these systems in a clinical setting where immediate decision-making is required. Appropriate training is mandatory because of the complexity of the echocardiographic system, as recommended by the American Society of Echocardiography.⁴

Most of the patients evaluated were affected by arterial hypertension. Although the results of this study cannot be extrapolated to different clinical situations, they reflect the clinical spectrum of the population referred to our cardiology department.

CONCLUSIONS

The use of a simple HCU device in an outpatient cardiology clinic allows bedside diagnosis in one third of the patients referred for echocardiography, resulting in cost and time savings on SE examination and a second cardiology consultation. The proportion of clinical questions answered by HCU is similar for the assessment of LV function, cardiac valves and right ventricle. Most inconclusive HCU examinations are related to the limited Doppler capability of the device.

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IMAGES IN CARDIOLOGY .....

Giant left atrium and a right sided heart

A 21-year-old patient presented to the emergency department with symptoms of shortness of breath and leg oedema that had worsened in the previous six months. An ECG showed atrial fibrillation and a reverse progression of the R wave in the anterior leads, suggesting a diagnosis of dextrocardia (panel A). A chest radiograph revealed enlargement of the cardiac area, and magnetic resonance imaging (MRI) depicted a giant aneurysm (16.0 cm) of the left atrium with severe mitral and tricuspid regurgitation (panel B and video 1; to view video footage visit the *Heart* website—<http://www.heartjnl.com/supplemental>). The giant atrium pushed the heart into the right side of the thorax, changing the electrical axis of the heart and altering the ECG. During surgery, the patient was found to have a congenital cleft of the mitral valve, resulting in the unusual enlargement of the left atrium. After surgery, the previous ECG changes disappeared with return of a normal progression of the R wave (panel C). A follow-up MRI showed the heart had returned to its normal left-sided position with a reduction in size of the left atrium (panel D and video 2).

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To view video footage visit the *Heart* website—
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