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Can Hospital Rounds With Pocket Echocardiography By Cardiologists Reduce Standard Transthoracic Echocardiography?

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Abstract

Background—Hospitalized patients are frequently referred for transthoracic echocardiograms (TTE). The availability of a pocket, mobile echocardiography (PME) device that can be incorporated on bedside rounds by cardiologists may be a useful and frugal alternative.

Methods—This was a cross-sectional study designed to compare the accuracy of PME images with those acquired by TTE in a sample of hospitalized patients. Each patient referred for echocardiography underwent PME acquisition and interpretation by a senior cardiology fellow with level II training in echocardiography. Subsequently, a TTE was performed by skilled ultrasonographers and interpreted by experienced echocardiographers. Both groups were blinded to the results of the alternative imaging modality. Visualizability and accuracy for all key echocardiographic parameters (ejection fraction, wall motion abnormalities, left ventricular end diastolic dimension, inferior vena cava size, aortic and mitral valve pathology, and pericardial effusion) were determined and compared between imaging modalities.

Results—240 hospitalized patients underwent echocardiography with PME and TTE. The mean age was 71 ± 17 years. PME imaging time was 6.3 ± 1.5 min. Sensitivity of PME varied by parameter; was highest for aortic stenosis (97%) and lowest for aortic insufficiency (76%). Specificity also varied by parameter; was highest for mitral regurgitation (100%) and lowest for left ventricular ejection fraction (92%). Equivalence testing revealed the PME outcomes to be significantly equivalent to the TTE outcomes with no discernible differences in image quality between the PME and TTE ($p=7.22 \times 10^{-7}$). All outcomes remain significant after correcting for multiple testing using the false discovery rate (FDR).

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Conclusion—The results from rapid bedside PME examinations performed by experienced cardiology fellows compared favorably with those from formal TTE studies. For hospitalized patients, this finding could shift the burden of performing and interpreting the echocardiogram to the examining physician and reduce the number and cost associated with formal echocardiography studies.

Keywords

Echocardiography; handheld echocardiography; pocket mobile echocardiography; bedside echocardiography

Introduction

Transthoracic echocardiography (TTE) is a remarkably popular imaging technique with over 20 million procedures performed each year in the United States.¹ However, a recent analysis of appropriateness indicated that 22% of TTEs performed were deemed unnecessary.² Hospitalized patients are often referred for echocardiography as they have signs or symptoms of cardiovascular disease or risk factors for cardiovascular disease. The recent availability of a high-resolution pocket, mobile echocardiography device (PME) provides a potential alternative to use in hospitalized patients on rounds instead of referral for a formal TTE. Others and we have performed studies to validate that the image quality of PME is comparable to TTE.³⁴⁵⁶⁷⁸⁹

Here we compared a rapid PME examination on bedside hospital rounds, performed and interpreted by senior cardiology trainees, with standard TTE, performed by skilled ultrasonographers and interpreted by senior cardiology imaging specialists. We assessed key echocardiographic parameters and major diagnostic findings.

Methods

Sample Population

The institutional review board at Scripps Clinic approved the study. A cohort of 240 inpatients referred for TTE were consecutively enrolled from 25 September 2012 to 12 March 2013. The patients were selected according to a "next available" model based on the consent of the patient, availability of the patient for imaging and availability of one of 3 senior cardiology fellows to perform the image acquisition. The exclusion criteria were only patients in the intensive care unit (ICU) or patients who were on positive pressure ventilation due to the inherent limitations of acquiring images in this patient population.

Study acquisition

Third year cardiology fellows at Scripps Clinic with greater than 6 months of training in echocardiography (level II competence) attempted to acquire standard echocardiography projections of parasternal (long axis and short axis); apical 2-, 3-, and 4- chamber; and subcostal views, along with color Doppler analysis of valvular blood flow with a PME (Vscan, GE Healthcare, Milwaukee, Wisconsin). On the same day, as close in time as

possible, a comprehensive TTE was performed by an ultrasonographer with the Philips iE33 Echocardiograph System (Philips Medical Systems, Andover, Massachusetts).

Blinding

Every PME study was assigned a number, and patients were identified by their medical record number only. The cardiology fellows and ultrasonographers acquiring the respective images were not blinded to the clinical indication for the study. The PME images were analyzed at the bedside by the cardiology fellow performing the study and findings were not modified once they had been interpreted. The cardiology fellow acquiring PME images was not aware of the findings on the TTE. The standard TTE images were interpreted by cardiologists with level III competence in echocardiography in accordance with standard clinical care and were blinded to the results of the corresponding PME examination. The cardiology-readers were also unaware that patients had undergone image acquisition with the PME device. An independent statistician who had no role in image acquisition or processing did comparison of PME findings and TTE findings.

Study Interpretation

The following elements were interpreted on images acquired by both the PME and TTE device: ejection fraction (normal or moderately reduced or severely reduced), segmental wall motion abnormality (present or absent), left ventricular end diastolic dimension (normal or enlarged), mitral valve appearance (normal or abnormal), mitral stenosis (present or absent), mitral regurgitation (present or absent), aortic valve appearance (normal or sclerotic or stenotic), aortic regurgitation (present or absent), aortic stenosis (present or absent), pericardial effusion (present or absent; small or large) and inferior vena cava (normal or dilated) size. Miscellaneous findings such as tricuspid valve appearance, right ventricular function and presence of pleural effusions were also recorded and were compared between the two devices.

Ejection fraction was graded as normal (55%), moderately reduced (>35% but <55%) or severely reduced (35%) by visual estimation. Segmental wall motion was considered abnormal if there was at least 1 segment with lack of translational motion toward the centerline or lack of normal systolic thickening in accordance with standard echocardiography guidelines. Left ventricular end diastolic dimension was measured in the parasternal long-axis view with electronic calipers built into the software of the PME device and was considered enlarged if greater than 5.3 cm for women or 5.9 cm for men. Pericardial effusion was considered significant if it was at least moderate or associated with evidence of hemodynamic changes and collapse of the right atrium or right ventricle during diastole as per accepted definitions. The mitral valve was considered structurally abnormal if it seemed to have moderate or severe mitral annular calcification, prolapse, flail, or at least moderately thickened leaflets or subvalvular apparatus according to accepted criteria.¹⁰ The aortic valve was considered stenotic if the valve was thickened or abnormally echodense with restricted leaflet opening in the representative views. The aortic valve was considered sclerotic if the valve was thickened or abnormally echodense but noted to have no restriction in leaflet opening. The inferior vena cava was considered dilated if its diameter was greater

than 2.1 cm and/or there was less than 50% collapse during inspiration (corresponding to a right atrial pressure 10 mm Hg).

Color Doppler flow mapping of mitral and aortic valves was performed in a systematic manner in their representative views. Physiologic and trace amount of regurgitation in the mitral and aortic positions was interpreted as the absence of any significant valvular regurgitation. Each clinical element could also be classified as "not well visualized" if the images were inadequate for interpretation. If a clinical element was not well visualized with the standard TTE machine, the interpretation of that element on the corresponding PME was excluded from further analysis. Finally, each PME and TTE study was classified as "technically adequate" or "technically difficult" based on the ease of image acquisition, echogenicity of the patient, the visualizability of key clinical elements and the overall quality of acquired images. Studies were deemed "technically adequate" especially if the image quality was satisfactory for making measurements and analyzing the key echocardiographic variables mentioned previously.

Statistical Analysis

Measurements outcomes were categorized based on clinical significance. Agreement between the TTE and PME was calculated as the proportion of observations in which both devices provided identical results. Logistic regression was performed to assess the relationship between device agreement and age, sex, and body mass index. Overall image quality, defined as either technically adequate or difficult, was similarly evaluated.

Equivalence testing between the echocardiogram and PME was performed by assessing the hypotheses:

$$\begin{array}{ll} H_{0,j} : D_j \geq \delta_j \\ H_{A,j} : D_j {<} \delta_j, \end{array}$$

Where D_j is the difference between the echocardiogram and PME of the *j*th outcome; and $\delta_j > 0$ is the margin of clinically acceptable difference, determined *a priori* as one-fourth of the standard deviation of the echocardiogram outcomes. The paired, two-sided test statistic for (1) is:

$$z_{j} = \frac{\frac{1}{n} \sum_{i=1}^{n} (PME_{i,j} - TTE_{i,j}) \pm \delta_{j}}{\left(\frac{\operatorname{Var}(PME_{i,j} - TTE_{i,j})}{n}\right)^{\frac{1}{2}}}, \quad (2)$$

Where $TTE_{i,j}$ and $PME_{i,j}$ are the outcomes from the TTE and PME for the *i*th study participant, respectively. Under $H_{0,j}$, z_j has a standard normal distribution. Thus, *P*-values were calculated as the area of the density function beyond the lower and upper bounds of z_j .

Results

Baseline Characteristics

The characteristics of the 240 patients that we evaluated are detailed in Table 1. All patients were admitted to the general medical, cardiac or surgical floors of Scripps Green Hospital. The indications for echocardiography are outlined in Table 1. The most common indications were chest pain, coronary artery disease, arrhythmia, congestive heart failure and shortness of breath. 105 studies (44%) were ordered by cardiologists and 135 (56%) were ordered by other specialists at our medical center.

Results

The mean duration of image acquisition using the PME device was 6.3 ± 1.5 minutes as compared with 46 minutes for the TTE studies. This included 2-D image acquisition and color flow Doppler imaging of the aortic, mitral and tricuspid valves. The findings for what was well visualized for PME and TTE are summarized in Table 2. There were no discernible differences in image quality between the TTE and PME ($p=7.22\times10^{-7}$). For what was deemed high image quality, there was agreement of 85.0% between devices. Due to suboptimal visualization of endocardial borders, 8 (3.3%) PME and 6 (2.5%) standard TTE images were not adequate for interpretation of wall motion abnormalities. Left ventricular end-diastolic dimension could not be measured in 15 (6.3%) PME images due to poor visualization of endocardial borders. The inferior vena cava was not well visualized in 67 (28%) of the PME images and 52 (22 %) of the TTE images. The aortic valve was not well visualized in 18 (7.5%) PME images and 8 (3.3%) TTE images. Echocardiography contrast (Definity, Lantheus Medical Imaging, North Billerica, Massachusetts) was required to assist interpretation of 24 (10%) of the TTE images.

Point of care diagnostic accuracy of PME

Accuracy of interpretation, including sensitivity, specificity, positive predictive value, negative predictive value, and overall agreement of PME images compared to standard TTE images are summarized in Table 3, using TTE as the reference standard. The sensitivity of PME ranged from 76% for detection of aortic insufficiency to 97% for aortic stenosis. The specificity of PME ranged from 92% for ejection fraction to 100% for mitral regurgitation. In general, there was a very high proportion of agreement between outcomes across the devices. Equivalence testing revealed the PME outcomes to be significantly equivalent to the TTE outcomes. The smallest *P*-value was obtained for aortic stenosis ($p=2.16\times10^{-57}$) while the largest *P*-value was obtained for aortic insufficiency (p=0.014). All outcomes remain significant after correcting for multiple testing using false discovery rate (FDR). For the most part, differences between the devices could not be attributed to age, sex, or body mass index (Table 4).

The incidence of missed diagnoses by PME varied by echocardiographic parameter and the majority of false negative findings on PME were clinically insignificant. The missed diagnoses with potential clinical relevance are detailed in Table 5. There were 13 (5.4%) cases in which a segmental wall motion abnormality was missed by PME. Left ventricular

ejection fraction was falsely read as normal in 5 patients (2.1%) with a moderately reduced ejection fraction (>35% but <55%) on TTE. There were 2 (0.8%) PME studies where a diagnosis of moderate aortic stenosis was missed. No moderate, large or hemodynamically significant pericardial effusions were missed by PME.

Discussion

In comparing PME and TTE imaging, we found remarkable concordance for all key parameters including ejection fraction, cavity dimensions, valve structure and function, the presence or absence of a pericardial effusion, and the size of the inferior vena cava. TTE proved to be more sensitive in the diagnosis of a wall motion abnormality, aortic insufficiency and the presence of small, trivial pericardial effusions. The proportion of technically adequate studies which were satisfactory for image interpretation was similar between the PME and TTE. However, the evaluation of both the inferior vena cava and the left ventricular end-diastolic dimension were diminished with PME due to suboptimal visualization. The diagnostic accuracy of PME with regards to left ventricular function, wall motion analysis and valvular lesions has been demonstrated to be equally concordant in a previous report.¹¹ The key difference in our study is that all PME examinations were performed and interpreted by cardiology fellows at the bedside making this a true "point of care" evaluation; while all examinations in the aforementioned report were performed by experienced cardiologists under optimal conditions and patient positioning in a dedicated echocardiography lab. Furthermore, in our study all images were analyzed on the smaller display of the PME device while they were uploaded to a computer work station and reviewed on a larger display in the prior report.

The logistics of the study strongly favored the superiority of TTE. Not only were such studies on average 46 minutes in duration, but they were also performed by skilled ultrasonographers and interpreted by senior cardiologists (as compared with trainees who performed and analyzed the PME studies) who are dedicated imaging specialists. Furthermore, the TTE study incorporates M-mode, spectral Doppler, tissue harmonic imaging, and tissue Doppler imaging. Such enhanced imaging allows for more extensive hemodynamic assessment such as pulmonary artery pressure along with the detection and quantification of intra- cardiac shunts. The spectral Doppler capabilities of TTE also make it a superior tool over PME to discern the causes of heart failure with preserved ejection fraction (diastolic heart failure, restrictive cardiomyopathy and constrictive pericarditis) and quantify the severity of valvular abnormalities. TTE studies also used intravenous contrast enhancement in 10% of the patients to improve endocardial border evaluation. Accordingly, the traditional echocardiographic laboratory examination is far more comprehensive and labor intensive. But it is also far more expensive, with an average combined technical and professional fee of \$800, which may not be appropriately justifiable in all hospitalized patients. In contrast, the routine use of PME is free except for the initial cost of a device, which is currently \$7900 and the additional 5-10 minutes spent per patient by a cardiologist in obtaining and interpreting the images. This is not an insignificant amount of time for a busy clinician and may dissuade many from performing PME examinations routinely on all patients, especially given the lack of established reimbursement for the study.

The upfront cost of the device and the time spent in imaging may be offset by practical advantages of PME on hospital rounds such as the avoidance of transporting the patient to an echo lab, which leads to additional personnel costs and potential compromise of safety during the time a patient is left without nursing surveillance or monitoring. PME also allows for a rapid, point of care assessment which helps in the early diagnosis and treatment of patients as compared to a median wait time of up to 24 hours for image acquisition and interpretation among inpatients referred for TTE.¹² This has the potential to improve hospital workflow and aid in the earlier discharge of patients which could potentially help reduce the costs associated with inpatient care. Additionally, there is the opportunity to directly share and discuss the results of the PME with the patient in real-time, an interaction that certainly does not occur during a TTE examination. On the other hand, our study begins to define the boundaries for PME as a screening tool. For clinical concerns about a regional left ventricular wall abnormality, or detailed color flow mapping of a valvular lesion, quantification of left ventricular diastolic function, or determination of right-sided pressures, current PME is limited without spectral Doppler capability or fully comparable endocardial visualization.

While attempts were made to simulate real practice for inpatients, the knowledge that the PME studies would be directly compared with TTE exams made for a longer acquisition and more quantitative analysis than might be necessary. This prolonged imaging time is also the likely explanation for the comparable image quality between PME and TTE. We believe that our patient cohort is fully representative of hospitalized patients who are not critically ill, in the intensive care unit, and that the inclusion of a sample of 240 patients can be considered definitive to recommend the widespread use of PME in this patient population. However, our design can be criticized by not eliminating any potential for sample bias. It would have been preferred to have every patient referred for TTE to be enrolled in the current study, but due to patient availability and/or cardiology fellow availability we were unable to perform a PME exam on every patient referred for TTE.

Another potential limitation of our study is that we did not use an independent core lab to assess all of the images, but instead performed the analysis in a blinded fashion with the data assessed by a biostatistician without any knowledge of what type of imaging was being compared. It is also possible that the use of a core lab would have detected a greater discrepancy in key echocardiographic parameters; especially the presence of wall motion abnormalities which can be subtle and easily missed on the small display of the PME device. It is vitally important to underscore that all examinations were performed by senior cardiology fellows with significant ultrasound experience and hence we cannot comment on the use of this device by medical professionals lacking echocardiography training. Furthermore, cardiology fellows performing imaging were aware of the clinical indication for the study, which may have biased them to pay particular attention to certain cardiac structures and improve the overall accuracy of the PME exam.

Notwithstanding these limitations, we interpret our findings as providing the evidence for the potential use of PME instead of TTE for many hospitalized patients who are referred for echocardiography. There is a possibility that widespread use of PME by unskilled clinicians may lead to false positive findings and actually increase diagnostic testing for patients and

we only support the increased use of PME by trained cardiologists for improving the diagnostic yield of the bedside clinical examination and to help reduce the growing number of unnecessary TTE studies. In the event of poor visualization with PME and for quantifying the severity of a valvular lesion or for particular questions that require Doppler assessment with hemodynamics, a TTE can be performed. There is the unaddressed, lingering question as to whether any echocardiographic examination is needed for many of these patients, but if a PME ultimately supplanted the stethoscope for bedside cardiac examination, that question would be pre-empted.

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Clinical Significance

- Overuse of cardiac imaging contributes to the exponential rise in healthcare associated costs.
- A new high-resolution, pocket mobile echocardiography device has excellent diagnostic accuracy and compares favorably with transthoracic echocardiography.
- Widespread and routine use of pocket mobile echocardiography by experienced cardiologists has the potential to decrease referrals for transthoracic echocardiography and minimize costs associated with cardiac imaging.

	Table 1
Patient and Echocardiography	Characteristics

Characteristic	Value
Patients (n = 240)	
Mean age (SD), years	71 (17)
Males (%)	128 (53)
Female (%)	112 (47)
BMI	
Mean (SD), kg/m ²	26 (5.0)
<18.5 kg/m ² , %	3
18.5-30 kg/m ² , %	75
>30 kg/m ² , %	22
Echocardiography	
Indication %	
Coronary artery disease, chest pain	27
Arrhythmia	18
Congestive heart failure	12
Shortness of breath	11
Valve evaluation	8
Syncope	6
Pericardial effusion	5
Hypotension	4
Endocarditis	4
CVA or TIA	4
Pre-operative evaluation	2.5
Left ventricular function evaluation	2
Pulmonary embolism	2
Other	1
Ordered by cardiologist %	44
Mean time to complete PME exam (SD), min	6.3 (1.5)
Patients with echocardiogram within 1 year, %	33
Ejection fraction [*] >0.55, %	70
Ejection fraction <0.35, %	11
Segmental WMA, %	39
Enlarged LVEDD, %	14
Abnormal aortic valve, %	23
Abnormal mitral valve, %	27
Dilated IVC, %	30
Pericardial effusion, %	10

Characteristic		Value
Technically adequate is	mages, %	56
Echocardiographic con	trast use, %	10

BMI = body mass index; CVA = cerebrovascular accident; TIA = transient ischemic attack; WMA = wall motion abnormality; LVEDD = left ventricular end diastolic dimension; IVC = inferior vena cava.

Data were not available for 1 patient

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Table 2Number of observations obtained from the TTE and PME

TTE Variable		TTE	PME
Ejection fraction	<35	27	32
	35-55	43	46
	>55	169	161
	Not visualized	1	1
LVEDD	Small	5	5
	Normal	197	189
	Enlarged	33	31
	Not visualized	5	15
WMA	No	140	147
	Yes	94	85
	Not visualized	6	8
Aortic valve	Normal	169	161
	Abnormal	56	61
	Not visualized	15	18
Aortic insufficiency	No	146	163
	Yes	90	71
	Not visualized	4	6
Aortic stenosis	No	193	191
	Yes	43	43
	Not visualized	4	6
Mitral valve	Normal	167	168
	Abnormal	65	65
	Not visualized	8	7
Mitral regurgitation	No	94	111
	Yes	142	125
	Not visualized	4	4
Mitral stenosis	No	223	221
	Yes	13	15
	Not visualized	4	4
IVC size	Normal	121	111
	Dilated	67	62
	Not visualized	52	67
Pericardial effusion	No	216	219
	Yes	24	21
	Not visualized	0	0

 $WMA = wall\ motion\ abnormality;\ LVEDD = left\ ventricular\ end\ diastolic\ dimension;\ IVC = inferior\ vena\ cava.$

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Table 3

agreement between TTE and PME was calculated as the proportion of observation in which both devices provided identical results. P-values represent Visualizability and Accuracy of Images Obtained by Using Pocket Mobile Echocardiography compared to Transthoracic Echocardiography. Overall statistical equivalence testing results.

TTE Variable	Visualized by PME, %	Sensitivity	Specificity	Specificity Pos. Pred. Value		Neg. Pred. Value Overall Agreement	P-value
Ejection fraction	66	0.93	0.92	0.84	0.97	0.90	1.81×10^{-9}
LVEDD	94	0.87	0.98	0.91	0.98	0.97	3.36×10 ⁻ 15
WMA	97	0.86	0.97	0.95	0.91	0.93	1.08×10^{-6}
Aortic valve	96	0.96	0.96	0.88	0.98	0.96	9.11×10-11
Aortic insufficiency	97	0.76	0.98	0.96	0.87	0.90	1.40×10^{-2}
Aortic stenosis	97	0.97	0.99	0.97	0.99	0.99	2.16×10-57
Mitral valve	98	0.95	0.98	0.97	0.98	0.98	1.88×10^{-29}
Mitral regurgitation	98	0.88	1.00	1.00	0.84	0.93	1.35×10^{-3}
Mitral stenosis	98	0.92	0.98	0.81	0.99	0.98	4.61×10 ⁻⁹
IVC size	72	0.93	0.98	0.98	0.95	0.97	2.16×10-57
Pericardial effusion	100	0.79	0.99	0.92	0.977	0.97	1.81×10^{-9}

Table 4

Logistic regression results between age, sex, and body mass index (BMI) and differences in outcomes from the TTE and PME. Results are presented as *P*-values with odds ratios, in parentheses, when p<0.05.

TTE Variable	Age	Sex	BMI
Ejection fraction	(1.04) 0.031	0.44	0.67
LVEDD	0.16	0.86	0.43
WMA	0.41	0.99	0.43
Aortic valve	(1.08) 0.034	0.25	0.87
Aortic insufficiency	0.15	0.55	0.75
Aortic stenosis	0.16	0.94	0.51
Mitral valve	0.60	0.74	0.99
Mitral regurgitation	0.76	0.99	0.72
Mitral stenosis	0.25	0.39	0.40
IVC size	0.22	0.16	0.69
Pericardial effusion	0.52	0.58	0.83

WMA = wall motion abnormality; LVEDD = left ventricular end diastolic dimension; IVC = inferior vena cava.

Table 5
Missed diagnoses with clinical significance on PME examination

TTE Variable	PME results	TTE results	Number of instances, %
Ejection fraction	>55%	>35% but < 55%	5, 2.1
WMA	Absent	Present	13, 5.4
Aortic valve	Normal	Moderate stenosis	2, 0.8