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ORIGINAL INVESTIGATION

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Accuracy of left ventricular ejection fraction determined by automated analysis of handheld echocardiograms: A comparison of experienced and novice examiners

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Abstract

Background: Handheld ultrasound devices have been developed that facilitate imaging in new clinical settings. However, quantitative assessment has been difficult. Software algorithms have recently been developed with the aim of providing rapid measurements of left ventricular ejection fraction (LVEF) with minimal operator input.

Methods: We prospectively enrolled a cohort of 70 patients scheduled to undergo echocardiography at the University of California, San Diego. Each patient underwent a standard echocardiography examination by an experienced sonographer as well as a handheld ultrasound with automated software by both the sonographer and an inexperienced resident.

Results: There was a positive correlation between the LVEFs obtained from the standard transthoracic echocardiogram and handheld device in the hands of a novice (r = 0.62; 95% CI 0.45-0.75) and experienced sonographer (r = 0.69; 95% CI 0.54-0.80). The sensitivity and specificity to detect a reduced LVEF (<50%) were 69% and 96% for the novice and 64% and 98% for the experienced sonographer. The sensitivity and specificity to detect a severely reduced LVEF (<35%) were 67% and 97% for the novice and 56% and 93% for the experienced sonographer, but when limited to recordings of at least adequate quality, improved to 100% and 100% for the novice and 100% and 98% for the experienced sonographer, respectively.

Conclusion: These data demonstrate that the handheld ultrasound device paired with novel software can provide a clinically useful estimate of LVEF when the images are of adequate quality and yield results by novice examiners that are similar to experienced sonographers.

KEYWORDS

diagnostic imaging tools, echocardiography, hand-carried ultrasound, heart failure, left ventricular ejection fraction

1 | INTRODUCTION

The echocardiogram has become a centerpiece in the evaluation of patients with known or suspected heart disease. It is able to noninvasively provide excellent images of the heart without contrast material or ionizing radiation.[1,2] However, standard echocardiography requires the use of a large ultrasound instrument and a highly skilled technologist. Recent technical advances have enabled the development of small handheld ultrasound devices that can be carried in a pocket and applied in a broad spectrum of clinical situations by a variety of clinical specialties.[3] Although good quality recordings can generally be obtained, easily applied technology has not yet been available to derive quantitative data from these images. Such quantitative methodologies would be of particular value for the inexperienced examiner.

Among the various parameters measured by echocardiography, the left ventricular ejection fraction (LVEF) has become paramount as it has important implications in the diagnosis, management, and prognosis of an array of cardiac diseases.[4-13] Novel software algorithms have recently been developed that can provide automated measurements of LVEF from the apical 4-chamber view with a single keystroke without further operator input (LVivo, DiA Imaging Analysis Ltd, Beersheba, Israel). This capability may be of particular importance to the novice examiner. The objective of this study was to validate the diagnostic accuracy as the correlation coefficient and sensitivity/specificity of the new software when applied to images derived by a small handheld ultrasound device in the hands of both an experienced and novice sonographer.

2 | METHODS

2.1 | Study population

We prospectively enrolled a cohort of 70 consecutive patients who consented to be a part of the study after clinical echocardiogram at the University of California, San Diego.

Each patient signed a consent form and the study was approved by the University of California, San Diego Institutional Review Board. Outpatient, inpatient, and emergency room patients were included. We excluded patients <18 years of age, patients on ventilators or in the intensive care unit, patients who could not be rotated into a lateral decubitus position, and those with chest wall incisions.

2.2 | LV Ejection fraction measurements

The comprehensive transthoracic echocardiogram examination was performed as per the guidelines set forth by the American Society of Echocardiography.[14] Echocardiograms were obtained in the standard manner from a full-feature echocardiography by an experienced sonographer and served as the gold standard. LVEF was calculated from these recordings by manual tracking of the left ventricular endocardial border in apical four and two chamber views and applying Simpson's rule method of disks.[2] A second-year internal medicine resident served as the novice sonographer and was trained with 2 hours of lectures followed by practice using a handheld device (V-scan, GE Inc, Boston, Massachusetts) to examine three patients prior to participating in the study. Patients were placed in the lateral decubitus position. The transducer was then placed at the point of maximal impulse or at the fifth intercostal space at the midclavicular line. The probe was then adjusted until appropriate apical 4-chamber landmarks were identified, and optimal images were obtained. The experienced and novice sonographers would alternate who would obtain the apical 4-chamber view with the handheld device first. They were separated and blinded to the ejection fraction determination by the other examiner and the best transducer position to obtain the apical view. Once the apical 4-chamber view was obtained, a single keystroke was then used to activate the LVivo software. LVivo is a fully automated proprietary method for LV border detection and tracking. The algorithm uses local contrast enhancement for separating walls from blood to detect the endocardial borders. The algorithm tracks the endocardium, and volume is calculated for each frame. From the volume curve, the end-diastolic and end-systolic frames are detected for each beat and the EF is calculated. The default beat for presentation is the second. One tap on the screen of the handheld device would trigger the software to calculate and display an LVEF (Figure 1).

Contrast agents were used at the discretion of the ultrasound technician to enhance the endocardial borders if needed while performing the standard transthoracic echocardiogram. Image quality was determined on a scale of 1 to 5 by the ultrasound technician on images obtained using the standard transthoracic echocardiogram, where 1 = poor, 2 = marginal, 3 = adequate, 4 = good, and 5 = excellent (Figure 2).

2.3 | Outcome

The primary outcome of our study was the Pearson correlation coefficient between the LVEF calculated by the standard transthoracic echocardiogram, and the LVEF calculated when the novice used the handheld device paired with the software. We also compared the results obtained by the experienced sonographer with those of the novice. Second, we evaluated the diagnostic accuracy as the sensitivity/specificity of the handheld device and software to detect both any reduction in LVEF (<50%) and a severe reduction in LVEF (<35%) in novice and experienced sonographer.

2.4 | Statistical analysis

We summarized continuous variables as mean and standard deviation and categorical data using absolute counts and proportions. Pearson correlation coefficients (r) and 95% confidence intervals (CI) were calculated between LVEFs obtained from the standard

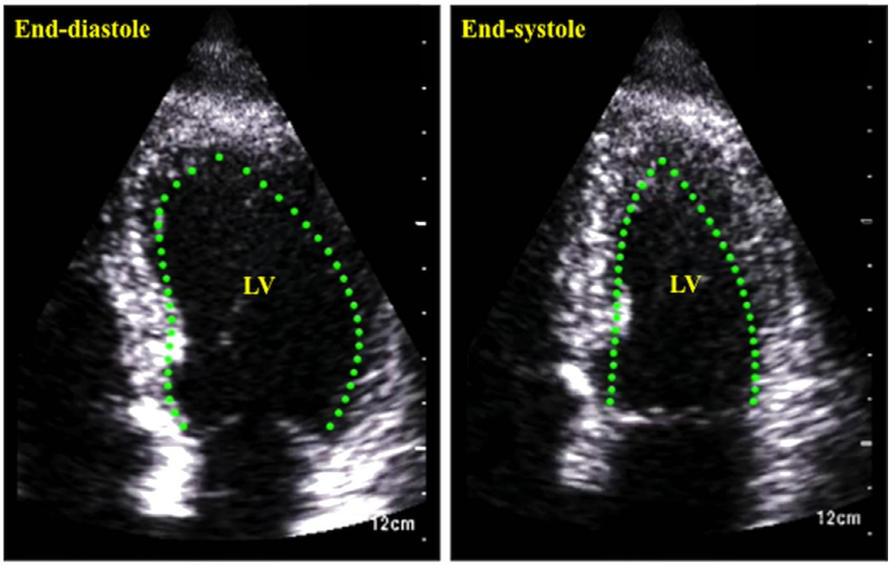

FIGURE 1 Images obtained using the handheld V-scan device with the left ventricular ejection fraction calculated using the LVivo software. Ultrasound images obtained by the V-scan handheld ultrasound device with ejection fractions calculated using the LVivo software. Left image is in end-diastole and right image is in end-systole. LV = left ventricle

transthoracic echocardiogram and handheld device paired with the software.[15] We separately evaluated this correlation for the LVEFs obtained by the experienced and novice sonographers. Sensitivity and specificity to detect left ventricular dysfunction were calculated, first for the ability to identify a LVEF less than 50% and then to detect a LVEF less than 35%. We repeated this analysis for a subgroup in which images were of at least adequate quality (ie, greater than 2). Analyses were performed using Stata 13 (StataCorp LLC; College Station, TX) statistical software.

3 | RESULTS

Patient demographics and characteristics are summarized in Table 1. Two patients were excluded, as no clinically usable images could be obtained. Patients were divided evenly by gender and had mean age of 61 ± 18 years and an average BMI of 28 ± 6 kg/m^2. The most common reasons for which a transthoracic echocardiogram was ordered were congestive heart failure (19%), dyspnea or hypoxia (17%), and valvular pathology or murmur (16%). There were 25 (36%) patients who were inpatient. The image quality obtained by the standard instrument was deemed at least adequate in 80% of patients, as shown in Table 1. Contrast agents were used in 23 patients at the discretion of the experienced sonographer. Patients with heart failure comprised a third of patients. Among these, 9 (13%) had a preserved ejection fraction ≥50%, 5 (7%) had a mild or moderately reduced ejection fraction of 35%-49%, and 9 (13%) had a severely reduced ejection fraction of <35%.

For all patients, there was a significant correlation between the ejection fractions obtained from the standard transthoracic echocardiogram and the handheld device in the hands of both the novice (r = 0.62; 95% CI 0.45-0.75) and experienced sonographer (r = 0.69; 95% CI 0.54-0.80) (Figure 3). In a subgroup analysis that excluded images that were not at least of adequate (image quality > 2) quality, the positive correlation strengthened between the standard transthoracic and handheld echocardiograms in the hands of both novice (r = 0.68; CI 0.51-0.80) and experienced sonographers (r = 0.82; CI 0.71-0.89) (Figure 4).

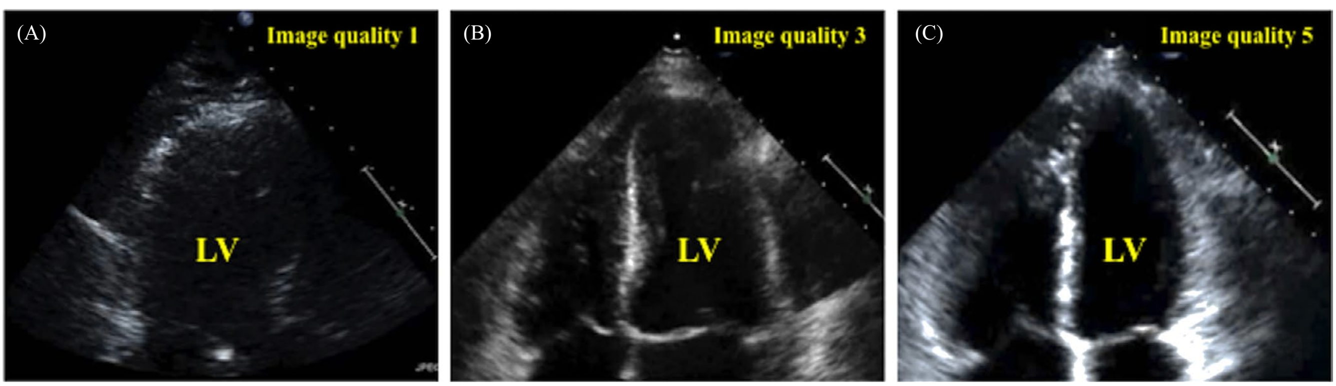

FIGURE 2 Quality of images obtained by standard transthoracic echocardiogram. Examples of various quality of images obtained by standard transthoracic echocardiogram. A, Poor quality image corresponding to an image quality of 1; B) Adequate quality image corresponding to image quality of 3; C) Excellent quality image corresponding to image quality of 5. LV = left ventricle

TABLE 1 Patient characteristics

Parameters	n = 70
Age, years	61 ± 18
Male, n (%)	35 (50)
Anthropometric values	
Height, m	1.69 ± 0.11
Weight, kg	78.9 ± 20.0
BMI, kg/m^2	27.6 ± 6.3
Comorbidities, n (%)	
COPD	10 (14)
Congestive heart failure	23 (33)
Preserved EF (≥ 50%)	9 (13)
Mild/mod reduced EF (35%-49%)	5 (7)
Severely reduced EF (<35%)	9 (13)
Indication for Echocardiogram, n (%)	
Congestive heart failure	13 (19)
Dyspnea or hypoxia	12 (17)
Valvular pathology or murmur	11 (16)
Drug monitoring	7 (10)
Prior to procedure/operation	6 (9)
Acute coronary syndrome	6 (9)
Other indication[a]	15 (21)
Image Quality, n (%)	
Poor	2 (3)
Marginal	12 (17)
Adequate	27 (39)
Good	16 (23)
Excellent	13 (19)
Patient Location, n (%)	
Outpatient	42 (60)
Emergency department	3 (4)
Inpatient	25 (36)

Note: Values are presented as mean ± SD or n (%).

Abbreviations: COPD = chronic obstructive pulmonary disease; EF = ejection fraction.

[a]The other indications included evaluation of chest pain other than acute coronary syndrome (n = 4), new-onset atrial fibrillation (n = 3), pericardial effusion (n = 2), syncope (n = 2), abnormal ECG (n = 2), endocarditis (n = 1), and congenital defects (n = 2).

The sensitivity and specificity to detect any reduction in ejection fraction (<50%) and a severely reduced ejection fraction (<35%) when all images were included or only images of at least adequate quality were included are summarized in Table 2. The sensitivity and specificity to detect a reduced ejection fraction when the novice sonographer obtained the image were 69% and 96%, respectively. Similarly, when an experienced sonographer obtained the image the sensitivity was 64% and the specificity was 98%. When images that were not of adequate quality were excluded, the sensitivity for both the novice and experienced sonographers improved to 75% and the specificity improved to 100% for the novice while remaining 98% for the experienced sonographer. When images of less than adequate quality were excluded, the sensitivity to detect a severely reduced ejection fraction improved from 67% and 56% for the novice and experienced sonographers, respectively to 100%.

4 | DISCUSSION

This study evaluated the use of a small handheld ultrasound device paired with automated quantitative software in the evaluation of left ventricular systolic function. There was a positive correlation between this novel technology and the standard transthoracic echocardiogram for both examiners, which strengthened when only images of adequate quality were included. This is potentially a consequence of inaccurate tracking of the endocardial borders when the software was presented with poor quality images. This most commonly occurred in patients with significant lung disease, or very dilated cardiomyopathy for whom the sector width of the handheld device was not wide enough to fully capture the endocardial borders and apex. Additionally, the correlation was similar regardless of whether an experienced sonographer or novice obtained the images. This similar correlation is likely a result of the software streamlining the measurement of LVEF to a single keystroke. This is important, as this new technology requires virtually no operator input and would potentially enable clinicians in a variety of specialties with varying experience to gather information on systolic function in a broad range of clinical settings. Furthermore, the handheld device and software were able to detect a reduction in ejection fraction, especially when severely reduced, with excellent sensitivity and specificity when the images were of at least adequate quality.

Although the echocardiogram has become a cornerstone in the assessment of left ventricular systolic function, acquisition of diagnostic images is a complex skill to master, requiring both motor and cognitive skills. Still, the standard of care continues to be a formal transthoracic echocardiogram performed by an experienced ultrasound technician and interpreted by a cardiologist. However, an ultrasound technician is not always readily available, especially outside of standard work hours. In addition, although it is possible to obtain an "eyeball" estimation of the ejection fraction, this suffers from the intrinsic limitation of a subjective evaluation.[16] Handheld device is increasingly being performed outside the echocardiography laboratory by individuals with limited experience. Novices can differentiate a severe LV dysfunction from normal (ie, LVEF 60% and 10%) by "eyeball" method. It would be much more difficult for a novice to evaluate a borderline LVEF. Therefore, both noncardiologists and cardiologists who are very early in their training are "novice sonographers" that could potentially benefit from this technology.

While the introduction of handheld ultrasound devices has opened up the possibility of obtaining images in a wide variety of settings, images are generally not as good as those obtained by the standard instrument. Additionally, the quantitative capabilities of handheld devices are typically limited. However, the recently

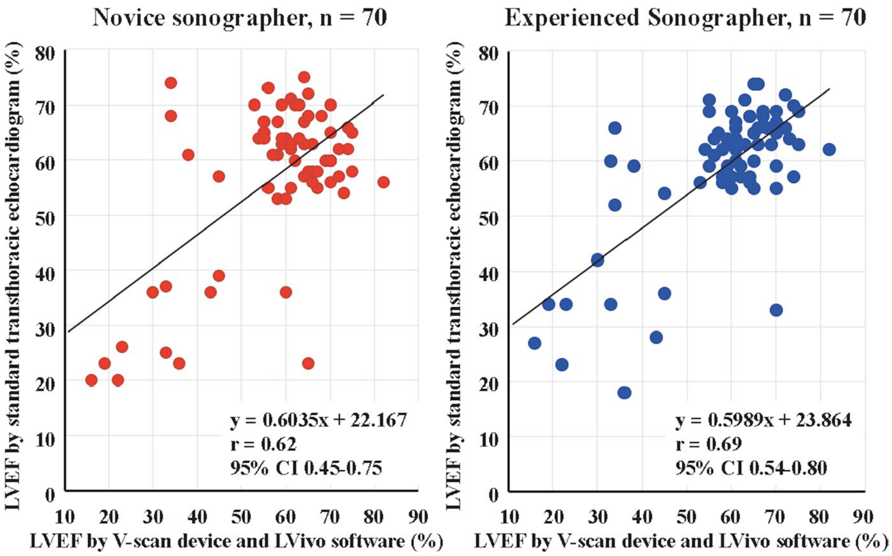

FIGURE 3 Scatter plot of ejection fractions obtained by novice and experienced sonographers using the V-scan device and LVivo software against the ejection fraction obtained by a standard transthoracic echocardiogram, all images

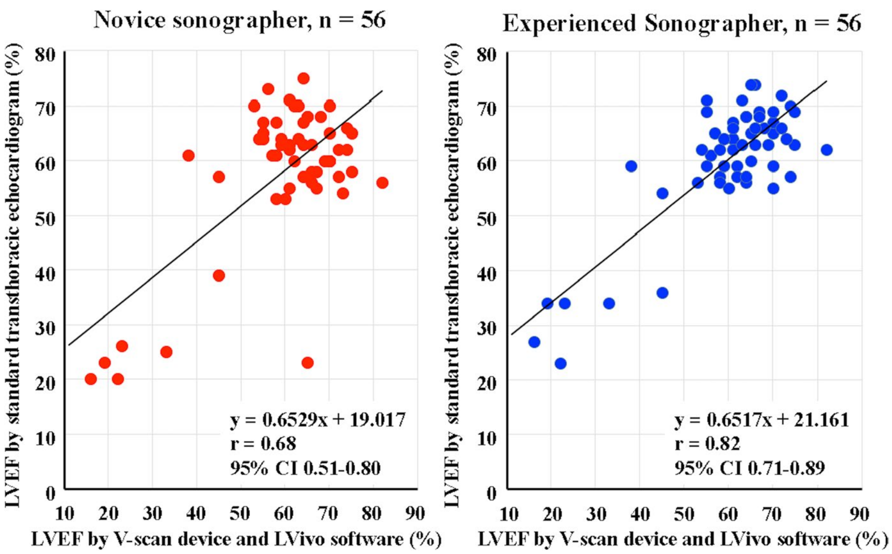

FIGURE 4 Scatter plot of ejection fractions obtained by novice and experienced sonographers using the V-scan device and LVivo software against the ejection fraction obtained by a standard transthoracic echocardiogram, image quality >2

TABLE 2 Sensitivity and specificity of the V-scan and LVivo software

		Novice Sonographer (%)	Experienced Sonographer (%)
Detection of any reduction (<50%) in ejection fraction All images (n = 14)	Sensitivity	69	64
	Specificity	96	98
Detection of severe (<35%) reduction in ejection fraction All images (n = 9)	Sensitivity	67	56
	Specificity	97	93
Detection of any reduction (<50%) in ejection fraction Image quality > 2 (n = 8)	Sensitivity	75	75
	Specificity	100	98
Detection of severe reduction (<35%) in ejection fraction Image quality > 2 (n = 5)	Sensitivity	100	100
	Specificity	100	98

developed software used in this study overcomes this limitation, thereby rendering this technology better suited for not only a wider range of applications, but also a wider range of examiners. These data demonstrate that it is reasonable to include handheld ultrasound instruments equipped with these software algorithms in the clinician's toolkit for evaluation of systolic function. With such high specificity, regardless of image quality or sonographer experience, it could be helpful in distinguishing heart failure with reduced EF (HFrEF) from HF with preserved EF (HFpEF) in patient with the clinical syndrome of HF but unknown EF.

However, there are significant limitations to this device and study that need to be considered. First, the image needs to be of at least adequate quality in order for the software to accurately track the endocardial borders. In our study, the experienced sonographer rated the majority of patients (80%) as having at least adequate quality image based on the standard echocardiogram. We could not evaluate the image quality of the handheld device. Therefore, the results can appropriately applied only to good quality images. This will be difficult in certain patient populations, such as those with significant pulmonary disease or left ventricular assist devices. Contrast can be used in patients with suboptimal images to enable more accurate measurements and was applied in the examinations obtained by the full-feature instrument, but contrast cannot yet be used for the handheld device and software, representing a limitation of this technology and a disadvantage in this study. It is likely that the correlations would strengthen if contrast-enhanced images were used on images obtained by both the standard instrument and the handheld paired with the software. Second, as already mentioned, the vector width is not sufficiently wide to capture the endocardial borders and apex of very dilated left ventricles. Third, there were only three emergency department patients and no intensive care unit patients included in the study, so it is unanswered whether these results apply to this population. Furthermore, only 14 patients had a reduced ejection fraction, introducing the potential for spectrum bias. Our study is limited sample size. However, given that this is novel technology, and there are no data regarding the expected effect size, we used Cohen's effect sizes for Pearson's r, where a large effect size is set at 0.50 with alpha set to 0.05 and beta to 0.2 between LVEF by LVivo for the novice and that of standard echocardiogram (corresponding to a power of 80%), the required sample size is 29. The estimated effect size of 0.50 is conservative and actually very similar to correlation coefficients seen comparing the standard transthoracic echocardiogram to angiography in patients with suboptimal images.[17] Fourth, there was only a single inexperienced examiner that served as the novice. In addition, this examiner did not receive any special training prior to the study other than that which was outlined above. Other novice examiners may not obtain comparable results, although this examiner was representative of the medical residency class at the University of California, San Diego. Fortunately, many of these limitations can be easily addressed. Future iterations of the handheld device can be updated to have larger vector widths. To address the problem with poor quality images, the software could potentially be modified to be able to trace the endocardial borders after contrast enhancement. The software could also be modified to allow users to manually adjust the tracing when it is clearly erroneous secondary to poor image quality. It is reasonable to anticipate that results would be improved with more extensive training of novice sonographers.

5 | CONCLUSION

These data demonstrate that the use of a handheld ultrasound device paired with a novel software algorithm can provide a clinically useful estimate of LVEF when images are of adequate quality, and yields results by novice examiners that are similar to experienced sonographers.

CONFLICTS OF INTEREST

This study was performed using instruments and software produced by General electric and DiA Imaging Analysis. The authors do not have any other conflicts of interest to disclose.

AUTHOR CONTRIBUTIONS

Omar M. Aldaas: Concept/design, data collection, statistics, data analysis/interpretation, and drafting article. Ajit Raisinghani: Concept/design, critical revision of article. Sachiyo Igata: Data collection, data analysis/interpretation. Megan Kraushaar: Concept/design, Data collection. Anthony N. DeMaria: Concept/design, data analysis/interpretation, critical revision of article, approval of article.

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