



● *Clinical Note*

ARTIFICIAL INTELLIGENCE-POWERED MEASUREMENT OF LEFT VENTRICULAR EJECTION FRACTION USING A HANDHELD ULTRASOUND DEVICE

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Abstract—The aim of this study was to assess the accuracy of an algorithm for automated measurement of left ventricular ejection fraction (LVEF) available on handheld ultrasound devices (HUDs). One hundred twelve patients admitted to the cardiology department underwent assessment performed with an HUD. In each case, the four-chamber apical view was obtained, and LVEF was calculated with LVivo software. Subsequently, during the examination performed with the use of the stationary echocardiograph, the 3-D measurement of LVEF was recorded. The average LVEFs measured with LVivo and the 3-D reference method were $46 \pm 14\%$ and $48 \pm 14\%$, respectively. The correlation between the measurements obtained with the HUD and 3-D evaluation was high ($r = 0.92$, 95% confidence interval: $0.87-0.95$, $p < 0.0001$). The mean difference between the LVEF obtained with LVivo and the 3-D LVEF was not significant (mean difference: -0.61% , 95% confidence interval: -1.89 to 0.68 , $p = 0.31$). The LVivo software despite its limitations is capable of the accurate LVEF measurement when the acquired views are of at least good imaging quality. (E-mail: dominika.filipiak@gmail.com) © 2020 World Federation for Ultrasound in Medicine & Biology. All rights reserved.

Key Words: Handheld ultrasound devices, Left ventricular ejection fraction, Automated echocardiographic assessment.

INTRODUCTION

Left ventricular systolic function evaluation is an essential part of all transthoracic echocardiographic examinations, including bedside assessment (Lancellotti et al. 2015; Lang et al. 2015; Neskovic et al. 2018; Cardim et al. 2019). Despite the fact that according to the European Association of Cardiovascular Imaging guidelines Simpson's modified rule is a recommended method of left ventricular ejection fraction (LVEF) calculation from 2-D echocardiography, LVEF assessment on the basis of the 3-D echo is gaining significance (Lang et al. 2015). Such a modality is obviously inaccessible in the case of handheld ultrasonographic devices (HUDs)—previously introduced appliances were limited to only visual LVEF assessment, based on 2-D views. Visual analysis can be described as easy and prompt, but very operator dependent.

Having been in use for more than 10 y, HUDs have found their niche in the clinical medicine. Despite the apparent technical constraints, their ultraportability is appreciated, particularly because these devices can be used to perform partial focused exams, in any clinical setting, extending and improving physical examination beyond the stethoscope (Egan and Ionescu 2008; Fukuda et al. 2009; Culp et al. 2010; Kimura et al. 2012; Filipiak-Strzecka et al. 2013, 2014, 2017, 2018; Colclough and Nihoyannopoulos 2017; Wejner-Mik et al. 2019). The viewpoint of potential operators has also changed - from the exclusive application of ultrasonography by experienced cardiologists in the echocardiography laboratories, toward its use by a wide range of medical professionals, often with only basic training in ultrasonography (DeCara et al. 2003, 2005; Martin et al. 2009; Filipiak-Strzecka et al. 2013; Gulić et al. 2016; Colclough and Nihoyannopoulos 2017). It is important to remember, that echocardiography is a highly operator-dependent technique. Although it has been confirmed that skills can be improved relatively rapidly, enabling the reliable identification of specific

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pathologic findings, which are dichotomous and most often very apparent (e.g., pericardial effusion or gross chamber enlargement), other tasks may still prove challenging (e.g., moderately impaired systolic function or mild valvular disease). Quantification of systolic function typically requires long-term learning and training (Moss et al. 2002; Bristow et al. 2004; Hunt et al. 2005; McMurray et al. 2012; Frederiksen et al. 2015). What is more, HUDs offer very limited quantification capabilities, which does not help in reducing subjectivity.

Cooperation between ultrasonographic device manufacturers and developers of artificial intelligence (AI)-based cardiac analysis tools has resulted in enhancing the capabilities of the latest generation of HUDs through the installation of LVivo software, which provides completely automated endocardium detection of the left ventricular wall and the modality for calculating end-systolic and end-diastolic left ventricular volumes and LVEF using the apical four-chamber (4CH) view. Software can be either pre-installed or purchased later and downloaded *via* the Internet. LVivo EF App shares the same algorithm as LVivo EF Desktop software, enabling automated calculation of ejection fraction from 4CH and/or 2CH views and biplane. Analysis can be performed on recordings from all types of echocardiographs (Bienstock et al. 2020). The clinical feasibility of the described software was previously suggested by Lai et al. (2020a, 2020b), who found that in a consecutive non-selected population, algorithm-calculated LV volumes correlate with magnetic resonance imaging (MRI)-derived measurements. Furthermore, these

volumes are not significantly different from physician-derived LV volumes measured with the use of ultrasound-enhancing agents. Unpublished results confirming significant agreement between LVivo-calculated LVEF (assessing a single-plane 4CH apical view) and MRI-estimated LVEF in the form of an abstract can be found on the manufacturer's page in the Publications Section (Bienstock et al. 2020; Lai et al. 2020b). The difference that downloading the LVivo EF App directly into HUD memory makes is the instant access to the software during bedside examination with immediate analysis results. Because HUDs are becoming more commonly acknowledged by medical professionals other than echocardiographers, the addition of automated measurement capability can possibly improve the diagnostic accuracy of echocardiographic examinations performed by non-expert sonographers (DeCara et al. 2003, 2005; Martin et al. 2009; Gulić et al. 2016; Colclough and Nihoyannopoulos 2017). On the other hand, the question of whether current algorithms are reliable in the different settings in which

bedside HUDs are used to perform point of care in ultrasound examinations remains to be addressed. For this reason, the aim of this study was to validate an automated measurement of LVEF by means of aforementioned algorithm available on HUD.

METHODS

In a group of 112 consecutive patients admitted to the cardiology department, additional assessment was performed with a HUD (Vscan Extend, GE Vingmed Ultrasound, Horten, Norway). The device featured a dual probe, which combined a phased array probe (frequency range of 1.7–3.8 MHz, image sector limited to 70°, maximum depth 24 cm, aperture size 13 × 19 mm) with a linear probe (frequency range of 3.4–8.0 MHz). Vscan Extend enables 2-D gray-scale as well as color Doppler mode. The 4CH apical view was obtained, and LVEF was calculated with the LVivo App EF software (DiA Imaging Analysis Ltd, Be'er Sheva, Israel), an artificial intelligence-augmented application, which is able to operate in the low-memory and processing-power environments of mobile ultrasound. The 4CH apical view was registered with the predefined cardiac setting by a fifth-year cardiology resident after 6 mo of training in the Echocardiography Laboratory. In accordance with manufacturer's recommendations, the view was optimized on the left ventricle, and a heart cycle lasting at least two beats was recorded. The interventricular septum was aligned parallel to the image plane. Depth was adjusted so that two-thirds of the view was occupied by the left ventricle. After the clip of the cardiac cycle was recorded, the software algorithm almost instantly traced the endocardial border and calculated LVEF, end-systolic volume and end-diastolic volume (Fig. 1).

Should the device indicate that the automated algorithm failed to calculate the LVEF, the image acquisition is repeated. After three subsequent failures, it was concluded that LVivo software is not capable of calculating LVEF. Imaging quality was assessed on a four-grade scale created for the purpose of this study: 1 = optimal, border of all endocardial segments visible during systole and diastole; 2 = good, endocardial border of a single segment difficult to define; 3 = acceptable, two to five segments of endocardium not visible; 4 = poor, six or more segments of endocardium difficult to define.

Shortly after HUD examination, full-volume 3-D echocardiography was performed with a high-end system (E9, GE Vingmed Ultrasound, Horten, Norway) by an accredited echocardiographer. Dedicated LVQ software was used for the computer-assisted LVEF calculation based on a 3-D data set. The endocardial border contour was manually corrected when considered necessary by visual judgment. If the data set quality was not sufficient

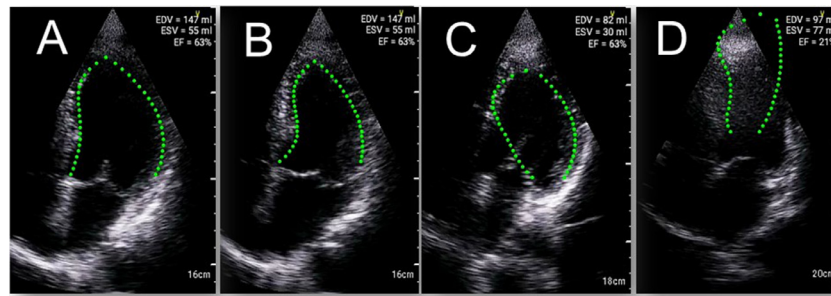


Fig. 1. Four-chamber apical views acquired with use of handheld ultrasound devices. (a, b) Left ventricular ejection fraction measurements with LVivo software in (a) diastole and (b) systole), with good tracing of the endocardium. (c, d) Examples of LVivo software failure in endocardial border detection: (c) the entire septal endocardium border was traced incorrectly; (d) the highlighted endocardial borders do not match the actual outline of this structure.

for LVEF 3-D evaluation, the patient was excluded from the study.

Signed informed consent was obtained from each patient. The study protocol was approved by the ethics committee of our institution.

RESULTS

Ultimately, 96 (53 men, mean age: 63 ± 11) of 112 patients were enrolled into the study group. In the remaining 16 cases (14%), 3-D image quality was not sufficient to allow calculation of the LVEF. LVivo software was unsuccessful in calculating LVEF in a total of 36 patients: the aforementioned 16 patients and in an additional 20 patients who remained in the study group because of satisfactory 3-D image quality.

The indications for echocardiographic examination are summarized in Table 1. Forty patients (42%) in the study group were either hospitalized for myocardial infarction or had a history of myocardial infarction.

The quality of images acquired with the use of HUD was assessed as optimal in 25 (22%) patients, good in 37 (33%), acceptable in 24 (21%) and poor in 26 (23%). LVivo EF was unable to calculate LVEF in all of the patients with poor image quality (including those 16 patients ultimately excluded from the analysis), 9 patients with acceptable image quality and 1 patient in whom image quality was assessed as good. The average

LVEF value was $46 \pm 14\%$ with 3-D LVQ measurements and $48 \pm 14\%$ using LVivo software. The correlation coefficient between the LVEF values obtained with LVivo and those obtained with the reference 3-D method was $r = 0.92$ ($p < 0.0001$, 95% confidence interval (CI): 0.87–0.95). Using the paired sample *t*-test, we found that the difference between the mean LVivo and 3-D LVEF values was not significant (mean difference = 0.61%, 95% CI: -0.68 to 1.89 , $p = 0.35$). On Bland–Altman analysis, the lower and upper limits of agreement were -10.40 and 11.61 , respectively. However, it should be underlined that in individual cases, the plot revealed relatively large discrepancies between both methods of LVEF measurements exceeding 1.96 standard deviations (SD) (Fig. 2).

Table 1. Indications for echocardiography

Indication	No. of patients (% n = 96)	No. of patients excluded for insufficient 3-D quality
Ischemic heart disease	57 (59.3%)	11
Hypertension	9 (9.4%)	2
Idiopathic cardiomyopathy	11 (11.5%)	—
Syncope	2 (2.1%)	—
Valvular heart disease	6 (6.2%)	3
Arrhythmia	11 (11.5%)	—

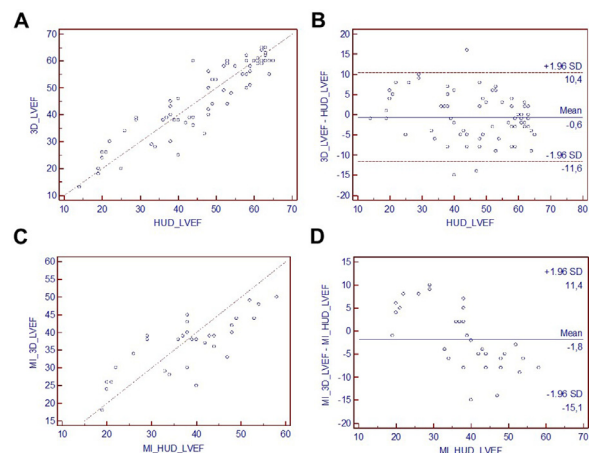


Fig. 2. Comparisons of LVivo and 3-D left ventricular ejection fraction (LVEF) measurements. Graphs are correlation and Bland–Altman plots of LVEF assessed with LVivo software and reference 3-D measurements. (a, c) correlation plots. (a) Entire study population. (c) Patients with a history of myocardial infarction (MI). (b, d) Bland–Altman analysis for the (b) whole study population and (d) patients with a history of myocardial infarction (MI).

LVivo software EF assessment is based on a single apical view, and for this reason we have assumed that the differences in EF can be larger in patients with regional wall motion abnormalities, in whom LVEF values derived from different apical views can significantly vary. For this reason, we analyzed the group of patients with history of myocardial infarction separately and found that the difference between Lvivo and 3-D LVEF was also not statistically significant (mean difference = 1.81%, 95% CI: -0.63 to 4.25 , $p = 0.14$, lower limit of agreement [LoA] = -15.07 , upper LoA = 11.45). The correlation coefficient r was 0.78 ($p < 0.0001$, 95% CI: $0.59-0.89$).

DISCUSSION

To the best of our knowledge, our study is the first to assess the clinical feasibility and accuracy of automated LVEF measurement with the use of a HUD.

One of the ongoing trends in echocardiography development is the tendency to automate the assessment of acquired data sets. Zhang et al. (2018) experimentally trained and evaluated convolutional neural network models for fully automated assessment of echocardiographic examination with promising results.

Despite constant validation of algorithms designed for automated echocardiographic assessment, the question remains: Can the results of studies performed with high-end systems also be relevant in cases of HUD usage in various settings? There are specific features of the HUD echocardiographic examinations, such as small screen dimensions and lower image quality, compared with the high-end stationary devices. On the other hand, HUDs are more easily used by non-expert echocardiographers. HUD examination should be perceived rather as a part of the physical examination than a standalone procedure. The main expectations for the AI-powered HUD algorithm differ from those for algorithms designed for postprocessing of the previously acquired data set, with particular emphasis on improving time-effectiveness and providing immediate feedback for an operator with little experience in echocardiography. Software needs to be optimized for the limited memory capacity and processing power of the HUD in comparison with stationary stations. For the reasons mentioned above, it appeared to us that software should be tested in the “natural” HUD setting—in real time during bedside examination. Study populations consisted of consecutive patients with a wide array of cardiologic ailments. The HUD was operated by the non-expert sonographer with basic experience; automated assessment can possibly prove most vital in this scenario,

With all probability, the greatest effort was expended on development of the automated LVEF

assessment algorithms. This parameter plays a vital role in echocardiographic assessment, as it remains a key criterion for different pharmacologic and invasive treatment strategies. Fredriksen et al. (2015) confirmed that even a novice echocardiographer using high-end stationary systems with the aid of algorithm for the automated LVEF assessment is capable of obtaining results comparable with those of manual planimetry performed by an experienced echocardiographer. It is important to underline that in the Fredriksen et al. study, the inexperienced operator was allowed to use manual border editing. Manual editing of endocardium borders appears to be crucial for reliable measurement, which is supported by the significant differences observed in the results of studies assessing automated EF assessment. Rhamouni et al. (2008) obtained a moderate correlation ($r = 0.64$) between visual assessment by an expert and automated reading of LVEF and a similar correlation (0.63) between AutoEF measurements and MRI-derived EF values. In this study, fully automated LVEF assessment was used. On the other hand, Cannesson et al. (2007), who allowed manual editing of automatically traced endocardium borders in their study methodology, obtained a good correlation ($r = 0.98$) between the automated EF assessment and results of manual biplane Simpson’s rule and MRI. The LVivo software used in our study did not offer manual editing, which may explain the observed discrepancies in some cases.

The ability of LVivo software to calculate LVEF values successfully was strictly related to the acquired imaging quality. Thirty-five of 36 failures occurred in patients with either poor or acceptable image quality. One patient with image quality classified as “good” had severe mitral valve insufficiency and a significantly increased left atrium diameter. Thus, it can be hypothesized that distorted heart geometry is another reason for algorithm failure; this, however, was beyond the scope of our study.

The software used in our study provides the LVEF assessment based on 4CH apical views only. Over the years, the LVEF biplane Simpson method, as well as 3-D derived LVEF assessment, has been confirmed as advantageous (Scollan et al. 2016; Heinen et al. 2018). St. John Sutton et al. (1998) reported that single-plane based measurement tends to underestimate LVEF value in comparison with the biplane Simpson method. This may prove particularly important in patients with regional wall motion abnormalities, for example, patients post-myocardial infarction. This was reflected in the results of our study, in which the correlation between LVEF measurements performed by both methods was lower in the group of patients who had previously had a myocardial infarction.

Limitations

This was a single-center study with a limited study population. The scale of image quality assessment was not based on any official guidelines and was created for the purposes of the study. All examinations with the HUD were performed by the same cardiology resident; thus, inter-rater agreement could not be assessed, and the results of this study may to a limited extent reflect individual diagnostic skills. The 3-D LVEF assessment was performed by other examiners; however, this was in compliance with our study goals attempting to simulate realistic clinical settings in which automated LVEF measurements with the HUD would be used by less experienced clinicians, whereas the actual EF in 3-D echo requires an advanced diagnostic skill set. For this reason 3-D measurements were performed by experienced echocardiographers.

Inter-rater agreement pertaining to 3-D LVEF assessment was not evaluated in our study. However, the high-end conventional echocardiographic examinations were performed by accredited specialists with significant clinical experience. Furthermore, agreement between their findings had been confirmed in both clinical and research scenarios.

CONCLUSIONS

Despite its limitations, LVivo software, is capable of accurate LVEF assessment when the calculations are based on views of at least good imaging quality. Such expanded capabilities of HUDs can potentially lead to overall improvements in the diagnostic quality of ultrasonographic examinations, particularly when in the hands of non-echocardiographers.

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