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Smartphone-based automatic assessment of left ventricular ejection fraction with a silicon chip ultrasound probe: a prospective comparison study in critically ill patients

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Editor—The portability and cost of ultrasound devices, and operator skills, remain significant barriers to the adoption of point-of-care echocardiography.[1–3] Recent hardware and software ultrasound innovations include crystal-free pocket probes and algorithms designed to facilitate and automate echocardiographic measurements, and connectivity to smartphones.[3,4] We designed the present study to compare automatic measurements of left ventricular ejection fraction (LVEF) taken with a silicon chip ultrasound probe and a smartphone ($LVEF_{SMART}$) to reference manual measurements ($LVEF_{REF}$) taken with a high-end ultrasound device.

We prospectively studied patients who required an echocardiographic evaluation during their ICU stay and in whom it was possible to obtain transthoracic images with a cart-based high-end ultrasound device (institutional review board approval # TI 71/2021). $LVEF_{SMART}$ measurements were taken with a software application (Butterfly IQ - Ultrasound, Butterfly Inc., Burlington, MA, USA) installed on a smartphone (iPhone 7, Apple, Cupertino, CA, USA) connected to a silicon chip ultrasound transducer (IQ, Butterfly Inc.) (Fig 1). The IQ transducer stands out in handheld ultrasound technology by replacing traditional piezoelectric crystal-based transducers with a single silicon chip containing a 2D array of capacitive micromachined ultrasound transducers. Each single microtransducer consists of a thin, conductive membrane that, when a voltage is applied, acts like a small drum to generate and receive ultrasound vibrations.

The software application (App) detects left ventricular endocardial borders on 3-s video clips of apical four-chamber images (Fig 1). The end-diastolic and end-systolic frames are detected automatically by the App (Fig 1 and Supplementary online video at https://doi.org/10.1016/j.bja.2023.02.032) and $LVEF_{SMART}$ is calculated using the monoplane Simpson formula (fully automatic mode). When images do not meet sufficient quality, a message is displayed and the user has to review images from the video clip to select end-diastolic and end-systolic images. Then the App calculates $LVEF_{SMART}$ (semi-automatic mode).

$LVEF_{SMART}$ measurements were compared with $LVEF_{REF}$ measurements taken by the same echocardiographic expert with manual tracing of endocardial borders on apical four-chamber images obtained with a high-end ultrasound device (Venue, GE HealthCare, Chicago, IL, USA). Both $LVEF_{SMART}$ and $LVEF_{REF}$ measurements were taken in triplicate and averaged for comparisons. Intra-operator reproducibility was assessed by calculating intraclass correlation coefficients.

We studied 95 patients over a 9-month period; 32 (34%) were mechanically ventilated at the time of the ultrasound evaluation (Supplementary Table S1). $LVEF_{REF}$ and $LVEF_{SMART}$ ranged from 26% to 80% (mean 54% [12%]) and from 28% to 79% (mean 54% [12%]), respectively. The intraclass correlation coefficients were 0.80 (95% confidence interval [CI] 0.74–0.86) and 0.86 (95% CI 0.81–0.90) for $LVEF_{REF}$ and $LVEF_{SMART}$, respectively. We observed a significant relationship (r=0.75, P<0.001) between $LVEF_{REF}$ and $LVEF_{SMART}$ (Supplementary Fig. S1). The average difference (bias) between $LVEF_{SMART}$ and $LVEF_{REF}$ was 0% (8%) with 95% limits of agreement of −17% to +16% (Supplementary Fig. S1). Thirty patients (32%) had $LVEF_{REF}$ <50% (left ventricular systolic dysfunction). The sensitivity and specificity of $LVEF_{SMART}$ to detect systolic dysfunction were 70% and 89%, respectively.

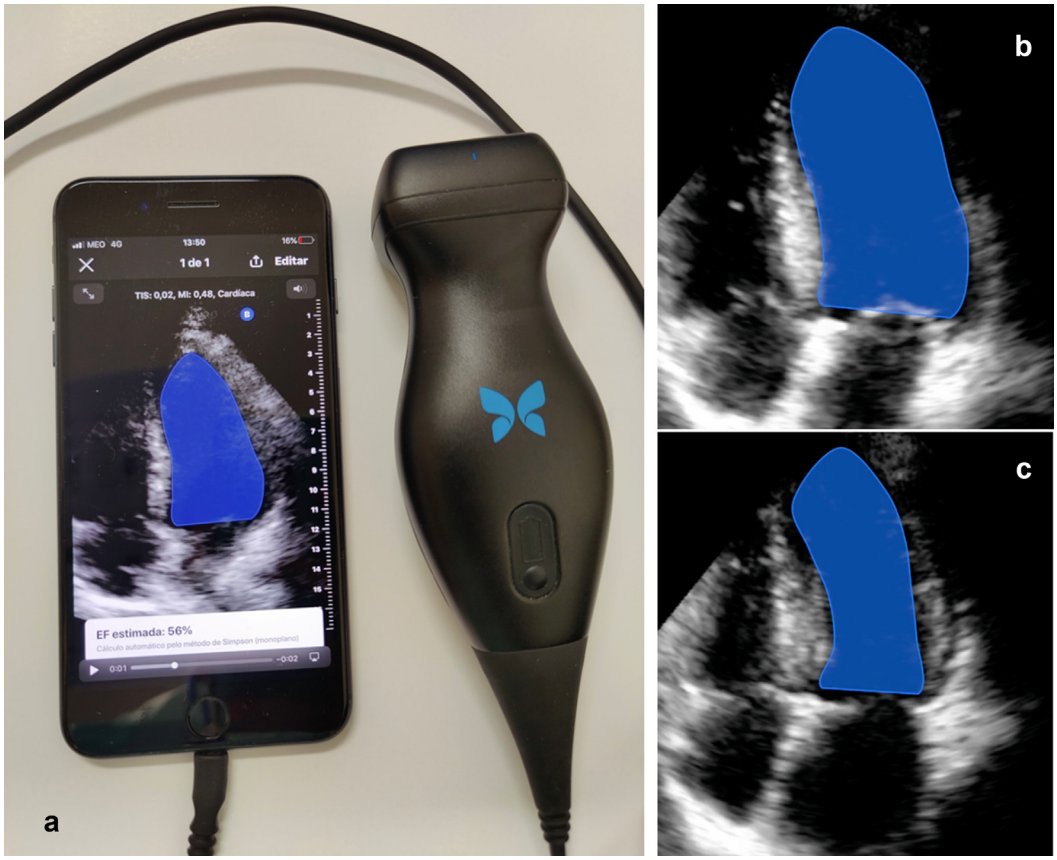

Fig 1. Smartphone-based ultrasound system used. The silicon chip probe is connected to a smartphone (a). The left ventricular (LV) ejection fraction is calculated (Simpson monoplane formula) by the software application installed on the smartphone from the automatic detection of LV end-diastolic (b) and end-systolic (c) area on a four-chamber apical view.

With the high-end ultrasound device, the quality of images was classified as good, fair, and poor in 41, 43, and 11 patients, respectively. Results did not change significantly after excluding the 11 patients with poor image quality (correlation coefficient r=0.76, average difference −1% [8%]). The App was able to provide fully automatic $LVEF_{SMART}$ measurements in 45 patients. The agreement between $LVEF_{SMART}$ and $LVEF_{REF}$ was slightly but not significantly better for fully automatic than for semi-automatic measurements (Supplementary Table S2).

The innovative smartphone-based ultrasonography system tested in the present study was appealing for several reasons. Firstly, the silicon chip of the probe is constructed using a widely used technology for making integrated circuits. It is therefore less expensive than classical ultrasound probes containing piezoelectric crystals. Secondly, the opportunity to use a smartphone for image acquisition and calculation enables clinicians to perform echocardiographic evaluations without the need to bring a bulky device to the bedside. Nevertheless, image quality was not good enough to enable fully automatic measurements by the smartphone App in more than half of our study patients. This finding is consistent with the recent evaluation of four handheld ultrasound systems where image quality was rated <3/5 for the Butterfly device and >4/5 for the other devices.[4] Of note, our LVEF measurements were taken in critically ill patients, in whom transthoracic echocardiography is sometimes challenging, in particular when patients are mechanically ventilated. However, the high-end ultrasound system enabled good and fair image quality recordings in 88% of patients.

Quantitative assessment of cardiac function remains challenging for many clinicians.[1,2] In this respect, several software applications and algorithms have recently been developed to facilitate, automate, and decrease the variability of echocardiographic measurements.[5–7] They include machine learning algorithms trained to recognise specific ultrasound images and to measure LVEF automatically.[8–10]

Comparison studies published so far have been performed almost exclusively in ambulatory cardiac patients, and yielded promising results with limits of agreement of 11%–13%.[8–10] We report wider limits of agreement, in particular when fully automatic measurements were not possible (−19% to +18%), unlikely to be acceptable from a clinical standpoint.

Our study has limitations. We studied haemodynamically stable patients to ensure comparability between measurements done at each step of the evaluation (LVEF measurements were first taken with the smartphone and then manually with the high-end system). We did not assess the ability of the smartphone method to track changes in LVEF. Future studies will need to assess the potential clinical value of the smartphone method in haemodynamically unstable patients and during changes in systolic function. Also, whether bradycardia (video clips were only 3 s long) and wall motion abnormalities could impact our results remains to be determined. Finally, LVEF is only one measurement among many for the assessment of cardiac function in critically ill patients.

In summary, the accuracy of LVEF measurements taken with a silicon chip transducer connected to a smartphone was excellent (bias 0%), and the specificity to detect left ventricular dysfunction was high (89%). However, the sensitivity could be improved, and limits of agreement were wide, particularly for semi-automatic measurements. Fully automatic measurements of LVEF were possible in less than half of the patients. Therefore, the smartphone method cannot be recommended to quantify LVEF in critically ill patients and further studies are warranted to clarify whether software or probe upgrades are necessary to improve it. Nevertheless, a qualitative evaluation of cardiac function with the smartphone method may remain clinically useful.

Authors' contributions

Study design: FAG, AF, FM
Study supervision, patient enrolment and data collection: JB, FAG, RV, JL, CM
Data analysis and interpretation: FAG, FM
Drafted the manuscript: FM
Revised the manuscript and approved the final version: all authors.

Declarations of interest

FM is the founder and managing director of MiCo, a Swiss consulting and research firm. MiCo does not sell medical devices and FM does not own shares and does not receive patent royalties from any medical device company. Other authors declare that they have no conflicts of interest. Butterfly Inc. and GE HealthCare were not involved with the planning, execution, data analysis, or writing of the manuscript.

Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.bja.2023.02.032.

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