EDITORIAL

There is No Substitute for Human Intelligence

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Artificial intelligence (AI) algorithms and handheld devices are two quantum jumps, which have brought point-of-care ultrasound (POCUS) to the forefront, facilitating bedside use by frontline medical personnel. Handheld machines now provide better quality images, while AI improves image acquisition and diagnostic yield. Handheld ultrasound is the new norm driving portability to the bedside, and these small "pocket rockets" are poised to be the next best friend forever (Bff) of frontline doctors after their cell phones. Using handheld device increases portability, reduces machine turnaround time, facilitates rapid diagnosis with reasonable accuracy, makes infection control easier, reduces number of personnel exposed, and reduces diagnostic cost, all this with an acceptable picture quality.

Put together, these developments guide beginners to acquire diagnostic quality images better than their skill set and provide analysis for yielding information more than their knowledge. Even if the user is a trained emergency physician, intensivist, and anesthesiologist, the addition of AI software will ensure consistent diagnostic quality images with automated analysis so that a diagnosis is not missed. While the human mind consciously scans and analyzes images, the AI algorithms are trained for the same by deep learning and perform the task with equal if not better alacrity. Deep learning is a form of machine learning, which is the science of training computers to perform tasks not by being explicitly programmed, but rather through enabling them to study patterns within data.[1]

On February 7, 2020, the US FDA authorized the marketing of the first AI-based software that guides users in real time to acquire diagnostic quality echocardiography images. "Today's marketing authorization enables medical professionals who may not be experts in ultrasonography, such as a registered nurse in a family care clinic or others, to use this tool. This is especially important because it demonstrates the potential for artificial intelligence and machine learning technologies to increase access to safe and effective cardiac diagnostics that can be life-saving for patients"—accompanying statement by Robert Ochs, Ph.D., deputy director of the Office of *In Vitro* Diagnostics and Radiological Health in the FDA's Center for Devices and Radiological Health.[2]

The approved software, Caption Guidance, was developed based on images acquired by 15 registered sonographers across a range of body mass index (BMI) and cardiac pathologies and validated by experts including cardiologists. The software algorithms were trained by more than 5,000,000 hand movements of cardiac sonographers enabling the machine to understand the impact of ultrasound probe position and movement on image quality. The software guides users to acquire 10 standard transthoracic echocardiography (TTE) views of the heart. The software monitors image quality continuously, and it calculates 6D geometric distance between the current probe location and probe location anticipated to optimize the image and applies corrective probe manipulations to improve image quality. The software recognizes image of diagnostic quality by a quality meter. When the quality meter exceeds a certain threshold, the video clip gets captured automatically (auto-capture). If auto-capture is not achieved in 2 minutes, then the user has the option to save the best clip. The software thus converts a suboptimal image into one of diagnostic quality. The software also has the capability to automatically calculate ejection fraction (auto-EF) without calculating chamber volumes with reasonable accuracy. The software is compatible with multiple machines.[3]

This approval was based on two studies, one of which is the study by Narang et al. subsequently published online in JAMA Cardiology on February 18, 2021.[3] Narang et al. studied the use of this AI-guided software (Caption Guidance, Caption Health) guiding novice users (8 nurses) in conducting 240 scans capturing 10 transthoracic echocardiography views after minimal training (1-hour didactic lecture on familiarity with ultrasound machine and AI software, followed by 9 practice scans on volunteers). These AI-guided scans were compared with expert sonographer scans of the same patients done on the same machine without using AI guidance. The primary endpoints were qualitative estimation of LV size, LV function, RV size, and presence of nontrivial pericardial effusion. The FDA agreement required that at least 80% of scans be of acceptable quality for particular assessment. Secondary endpoints included six more parameters: qualitative assessment of RV function; left atrium size; structural assessment of the aortic, mitral, and tricuspid valves; and qualitative assessment of IVC size. The scans were reviewed by a panel of five expert echocardiographers. They reported adequate quality in 98.8% of nurse scans for primary endpoints—LV size, LV function, and presence of nontrivial pericardial effusion—and 92.2% adequacy for assessment of RV size; more than 90% adequacy for secondary

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endpoints except IVC size—57.5% and tricuspid valve—83.3%. They concluded that the integration of AI with medical imaging would allow use by novice users and in settings which do not have access to ultrasound. The study was adequately powered but did not enroll intensive care or emergency room patients.

The study by Harish M Maheshwarappa compares the use of a handheld ultrasound machine (Vscan Extend™, General Electric Healthcare [GE]) with a traditional ultrasound machine (Vivid, GE). The handheld machine also has an AI-based software for objectively calculating LVEF from end-systolic and end-diastolic volumes by Simpson's method (LVivo application). The users are trained intensivists in both groups in contrast to the study by Narang et al. where users were novices. The handheld machine has a phased array probe (1.5–3.8 MHz) and a linear probe (3.5–8 MHz), whereas multiple probes were used in assessment by conventional machine. Maheshwarappa et al[4] studied 96 patients admitted to the intensive care unit with COVID-19 infection. The primary endpoint was time taken for the assessment of these patients by POCUS vis-a-vis traditional method. POCUS arm included scanning of lungs, heart, diaphragm, abdomen, and deep veins, using handheld AI-enabled ultrasound machine, while the traditional arm included clinical examination, review of ECG and CXR, plus an ultrasound of lungs, heart, and diaphragm by the traditional machine. As is obvious no clinical examination or input from ECG and CXR was integrated when patients were examined by handheld ultrasound machine; rather, the operator was blinded to the clinical findings. The median duration of bedside examination in POCUS arm using handheld ultrasound was 9 (8.0–11.0) minutes, compared to 20 (17–22) minutes in traditional arm—the latter included clinical examination and ECG and CXR interpretation ($P < 0.001$). They also studied the efficacy and safety profile of handheld ultrasound machine compared to traditional machine. The agreement between intensivists' findings in both groups was perfect for LV systolic function with a Cohen kappa coefficient of 1.0, moderate for regional wall motion abnormality (RWMA) with a coefficient of 0.53 [0.37, 0.69], fair for inferior vena cava (IVC) collapsibility, with a coefficient of 0.37 [0.25, 0.49], and poor for RV systolic function and pericardial effusion with a coefficient of 0.07 and −0.01, respectively. Cohen kappa coefficient showed a good agreement for lung parameters between the two groups. Hence, the authors concluded that the use of handheld ultrasound machine reduces the time to diagnosis, which is efficacious and safe. They postulate that bedside ultrasound is a useful tool to help a primary physician or an intensivist screen the patient. If the diagnosis and management need expert advice and consultation, experts can be called over. This approach reduces the chances of spread of infection among the healthcare workers and the burden on an exhausted healthcare system during the pandemic.

The study raises several questions. Is a handheld machine actually superior to the conventional machine for point-of-care ultrasound? Definitely so for basic ultrasound and initial screening involving qualitative assessments, but definitely not a substitute for conventional machine. Handheld machines are limited by the absence of color (present in some machines as in the one used in this study), pulse, and continuous-wave Doppler. Conventional machines rule the roost for objective measures or quantitative assessments, which become increasingly important during follow-up scans. The image quality of a conventional machine is undoubtedly superior to the handheld one despite technical advances in this field.[5] Is the use of AI a silver lining? Should we sell out AI-guided machines? Definitely not, AI is not the panacea for quality improvement in POCUS. The value addition of AI software to calculate LVEF by volume-based method for use in intensive care is questionable. Firstly, the image acquisition needs to be proper to avoid foreshortening for using this automation correctly; hence, only a trained user can acquire images for this purpose. Secondly, if a trained user is acquiring images, then LVEF by eyeballing is comparable to that acquired by Simpson's method; hence, the addition of AI software is not essential. Thirdly, visualization of most portion of endocardial border is a prerequisite for the calculation of end-systolic and end-diastolic volumes by Simpson's method; critically ill patients especially those on ventilator have poor echo windows, and hence, border visualization is mostly suboptimal. AI algorithms are available, which accurately calculate EF automatically without delineating borders and calculating volumes.[6] Lastly, LVEF in critical care has its limitations—it is preload- and afterload-dependent so changes in LVEF may represent changes in loading conditions and not changes in contractility. The calculation of stroke volume by LVOT VTI obtained from apical five-chamber view and LVOT diameter obtained from a zoomed PLAX view with the aortic leaflets opened and parallel to the aortic wall in systole will be a superior target for hemodynamic assessment, and its automation by AI software in the future will definitely be a more lucrative option.

The most intriguing aspect of the study is the prescribed lack of clinical examination and interpretation of ECG and CXR in the handheld ultrasound group. The reduction in total duration of examination comes at a cost of no clinical examination and no laboratory adjuncts, something that defies good clinical practice and rational clinical decision-making and precludes human connect, compassion, and empathy, even if the patients are sedated and ventilated. We need to work in a way that POCUS does not lose its focus, and this may well be a reason that POCUS has universally not been shown to improve patient outcomes.

The introduction of handheld and AI-integrated machines is definitely a welcome step toward bringing and using technology to patients across the healthcare system. Like all technology, there needs to be training, credentialing, privileging, and regulation to ensure correct medical, legal, and ethical use. Handheld machines need to have color and Doppler package, while AI algorithms need to build on image quality, view classification and segmentation of cardiovascular structures, measure and quantify the morphological structure, and detect abnormalities.[7]

Above all, we humans as holders of handheld machines and users of AI software need to decide about our imaging requirements and challenges, machine users, machine deployment, imaging protocols, and the anticipated diagnostic yield to choose an appropriate machine for a particular unit. What works best in ER may not be suitable for operation theater or surgical intensive care. So let us choose wisely and remain the master rather than becoming a slave to new technology.

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