The use of handheld ultrasound devices (HUD): a position statement of the European Association of Cardiovascular Imaging (2018 update)

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Abstract

Recent technological advances in echocardiography, with progressive miniaturization of ultrasound machines, have led to the development of handheld ultrasound devices (HUD). These devices, no larger than some mobile phones, can be used to perform partial, focused exams as an extension to the physical examination. The European Association of Cardiovascular Imaging (EACVI) acknowledges that the dissemination of appropriate HUD use is inevitable and desirable, because of its potential impact on patient management. However, as a scientific society of cardiac imaging, our role is to provide guidance in order to optimize patient benefit and minimize drawbacks from inappropriate use of this technology. This document provides updated recommendations for the use of HUD, including nomenclature, appropriateness, indications, operators, clinical environments, data management and storage, educational needs and training of potential users. It also adresses gaps in evidence, controversial issues and future technological developments.

Introduction

Ultrasound is the most versatile imaging method in medicine. Its unique characteristics (availability, portability, low cost, and absence of side effects) make it suitable for use in different clinical settings and environments, by operators with different backgrounds, to assess different structures of the human body. Additionally, the fast acquisition and the possibility for immediate image interpretation can provide relevant clinical information with direct impact on patient management.

Recent technological advances have led to progressive miniaturization of ultrasound machines, with devices now ranging from stationary high-end systems (able to deploy the full range of cutting edge ultrasound technology) to small devices, no larger than many mobile phones, that can be easily used to perform partial, focused exams, extending and improving physical examination beyond the stethoschope [1,2]. The latter are referred to as handheld ultrasound devices (HUD).

The availability of HUD has the potential to transform the world of cardiac ultrasound: from the initial, exclusive use of the technique by cardiologists to scan the heart in echocardiography laboratories, towards its use by a wide range of operators outside echocardiography laboratories, assessing the heart and other structures. However, the advent of these new tools also brings new challenges, such as proficiency in image acquisition, analysis, interpretation, and reporting, which typically requires long-

term learning and training [3-5]. These challenges should be properly addressed and overcome, as they are fundamental to ensure quality in cardiac imaging. Additionally, quantification of image data [6], which helps to reduce subjectivity and decrease operator-dependence, is often desired in echocardiography, but HUD only offer limited quantification capabilities.

The mission of the European Association of Cardiovascular Imaging (EACVI) is to promote excellence in clinical diagnosis, research, technical development, and education in cardiovascular imaging, with the ultimate goal of better patient care. Whilst we acknowledge that dissemination of appropriate HUD use is inevitable and desirable because of its potential positive impact on patient management, it is the role of the EACVI as a scientific society of cardiac imaging to provide guidance, in order to optimize patient benefit and to minimize drawbacks from inappropriate use of this new technology. Accordingly, this document provides recommendations for the use of HUD, including nomenclature, appropriateness, indications, clinical environments, data management and storage, educational needs and training of potential users. It also adresses gaps in evidence (several recommendations are based on expert consensus only), controversial issues and future technological developments. This position statement provides an update of the previous one [5], which was finalized when HUD had just entered the clinical arena. Since then, numerous studies on their clinical application have been published, mainly concerning feasibility and reliability of these devices, but also randomized clinical trials assessing outcomes. [7,8]

Recommendation 1: Scope of the use of HUD

The EACVI recommends the appropriate use of HUD since it may have a significant positive impact on patient management.

Nomenclature and definitions

The classification of the currently available echocardiography machines according to their size, mobility and functions is shown in Table I [5]. Although in the medical literature the most frequently used expression to describe these devices is "pocket size echocardiography devices", the EACVI position is that this term should be substituted by handheld ultrasound devices (HUD), utilized in this document. The use of other terms, such as "limited cardiac ultrasound" "echoscope", "echoscopy", or "ultrasound/visual stethoscope" is discouraged. In addition, the different types of echocardiographic studies are similarly defined in Table II [9-16]. Remarkably, the intrinsic technological capabilities of each type of machine define the types of examination that can be performed. Accordingly, a *POCUS/ FoCUS* examination may be performed with any type of ultrasound machine, but a *standard/conventional echocardiography* can only be performed with fully equipped machines, and not

with HUD. In other words, HUD can only perform *POCUS*/ *FoCUS* examinations and this principle should be always kept in mind when discussing education, training and competence in HUD.

Devices

Although the number of available HUD models is increasing and the appearance and capabilities of the devices vary among the different types, HUD share some common characteristics. They consist of a display unit and of a generic or dedicated probe, which usually provides two-dimensional grey-scale images with lower spatial and temporal resolution than high-end systems. Most systems comprise the option for color-Doppler imaging, with similar limitations. There are a limited number of basic controls, including those for adjusting depth and gain, as well as an image freeze and a store function for still frames and loops. Available measurements are usually limited to simple distance and area assessments. While early devices allow data storage only in generic image or movie formats, some more recent machines support basic DICOM standards for downloading patient information and uploading images. Spectral Doppler function is not currently implemented in any HUD. Furthermore, M-mode technology is not available in any, and simultaneous ECG is lacking, so that ECG triggering and precise end-diastole identification is not feasible.

Diagnostic performance

HUD can be used to assess cardiac *structure and function*, in different *settings* by different *operators.*

Cardiac structures

Feasibility is excellent for imaging most cardiac structures and for the pleura, and satisfactory for the abdominal great vessels [17,18]. Linear measurements of most cardiac structures and vessels (left atrium (LA), left ventricle (LV), wall thickness, LV outflow tract diameter, aortic root ascending aorta, aortic arch, right atrium and right ventricle, abdominal aorta and inferior vena cava (IVC) and its respiratory variation) can be performed reliably and the concordance with measurements from high-end systems (performed by appropriately trained operators) is usually good, with some limitations regarding LA and RV size as well as vena cava dimensions. There is an overall good concordance with conventional echocardiography in the detection and assessment of pericardial and pleural effusion, as well as of large intra cardiac masses. [17-30]

Cardiac function

Apart from the possibility to post-process DICOM images from HUD with external software to calculate LV ejection fraction (EF) [6], the online assessment of LV systolic function is qualitative, based on visual estimation of LVEF and regional wall motion. No significant bias has been reported between HUD and high-end systems for visual estimation of LVEF [19]. Accordingly, LV global and regional systolic dysfunction can be detected with good sensitivity and specificity [17-19,21-33] Variable correlations between HUD and high-end systems to identify RV dysfunction have been reported [17,24,31,33,34]

The quantitative assessment of diastolic function with HUD is impossible due to the absence of spectral Doppler. [35]. However, the presence of LA dilatation and of ultrasound lung comets may point to increased LA pressures. [36,37].

Valve Assessment

The lack of spectral Doppler prevents a comprehensive quantitative assessment of valve disease severity and of systolic pulmonary artery pressure. However, the detection of morphological abnormalities and indirect signs of severity are feasible, allowing an initial qualitative analysis of valvular function. Valve morphology, and presence/absence of turbulent flow are features that can be detected by HUD and may lead further patient assessment.

The agreement between HUD and high-end echo systems to diagnose significant aortic, mitral and tricuspid valve dysfunction ranges from modest to good. Heterogeneity of the results in different studies is related to the valve examined and to predominant disease mechanism (stenosis or regurgitation). [17-19,21,24,38]

TABLE III summarizes HUD indications and potential imaging targets.

Recommendation 2: Diagnostic performance of HUD

HUD provide accurate morphological and functional data and may be used to assess cardiac structure and function. Technical limitations must be recognized and accepted. In particular, HUD cannot currently be used for a quantitative assessment of valve disease, for the assessment of diastolic function and for the quantification of pulmonary artery pressure.

Settings

Clinical setting

Out of hospital use

The previous European Association of Echocardiography position paper had already acknowledged the potential usefulness of HUD in out-of-hospital settings [5]. There is evidence that these devices can be used in screening for structural heart disease, especially in low- and middle-income and developing countries, [39-46] and that screening with HUD can be associated with improved outcomes in patients with structural heart disease in remote areas [7]. Other potential indications have been proposed, including screening for LV systolic dysfunction and hypertrophic cardiomyopathy [47] or in pre-participation screening for competitive sports [48,49]; however, data are only derived from small studies and expert consensus opinion.

The use of HUD in pre-hospital emergency medicine has not been widely tested, but is promising in well-defined circumstances (e.g. cardiac tamponade, acute myocardial infarction). [50]

Other out of the hospital applications of HUD have been reported, such as their use in different land, sea, and sky environments, including on the battlefield [51-54], and to characterise cardiopulmonary adaptations to outer space. [55]

In-hospital use

There is evidence that HUD is accurate for in-hospital use, both in the inpatient and in outpatient setting, where it has been used as a screening tool for determining need for performing a standard/conventional echocardiography [9,17,19,31,56-58]. Accordingly, it can be apropriate to use HUD within the hospital by trained operators, providing answers to well-defined clinical questions, which arise from the clinical assessment. Typical use is the assessment of cavity size, wall thickness, global and regional ventricular systolic function, pericardial or pleural effusion, IVC respiratory variation, and the detection of gross valvular abnormalities. Also, after a first conventional/standard echocardiogram in the echocardiography laboratory, the use of HUD may reliably replace conventional echocardiography in the basic qualitative follow-up of LV systolic function, pericardial effusion and IVC collapse. [56] Because of the current availability of HUD with dual probe (phased-array and linear), an additional use of these devices is the assessment of intravascular flow at bedside, useful to guide vascular invasive procedures such as central venous catheter insertion and intraarterial line placement.

In cases of nondiagnostic or uncertain HUD findings the threshold to request image review /conventional echocardiography should be low and a comprehensive examination should be performed without delay as clinically indicated .

HUD may be used for FoCUS in emergency departments (ER) in intensive care units (ICU) and in intermediate care settings, and the specific use of these devices in these environments have confirmed their feasibility and accuracy [10,11,22,24,59-61].

HUD may also be useful as an adjunct in resuscitation management, and algorithms involving limited ultrasound examination of the heart, with these or other types of machines have been suggested in this context [62-66].

Recommendation 3: HUD as a clinical tool in cardiology

HUD can be used for FoCUS, to complement physical examination, to triage candidates for standard echocardiography, and as a screening tool for cardiac pathology. The threshold to request image review or conventional echocardiography should be low.

Recommendation 4: HUD in the out-of-hospital setting

HUD can be used to screen for cardiac pathology or to extend physical examination in order to obtain a tentative diagnosis and support patient management.

Recommendation 5: HUD in the hospital setting

HUD can be used to extend physical examination in different hospital clinical scenarios and environments in order to obtain an overview of cardiac structure and function and to follow-up previously diagnosed pathologies.

Teaching

HUD are currently used as a part of a structured educational program in some medical schools [67-71]. In the USA, the "national ultrasound curriculum" outlines areas for which ultrasound examination should be taught to medical students, and emerging programmes for ultrasound are already being integrated into the undergraduate medical education in a number of countries [72].

Though evidence regarding teaching and training is still limited [73], the EACVI supports the integration of the use of HUD in medical curricula as an extension to traditional physical examination (inspection, palpation, percussion, auscultation and insonation by HUD [74]

Recommendation 6: HUD as a teaching tool

HUD should be incorporated as a teaching tool in pre- and post-graduate medical curricula.

Operators

Only appropriately trained operators, familiar with the technical characteristics of the devices (including awareness of their diagnostic limitations) should use HUD in clinical settings. Under these conditions, operators with different backgrounds (e.g. cardiologists, other physicians, residents, medical students, sonographers, technicians, nurses, others) and well-defined expertise may use these devices.

Recommendation 7: HUD operators

Only appropriately trained operators may use HUD, independently of their background.

Education, training and competence

Important differences in diagnostic accuracy of examinations performed with HUD by trainees compared with expert operators have been reported, confirming that previous experience in image acquisition and interpretation play important roles in the skilledand safe use of these devices in clinical practice. [31,75,76].

Accordingly, sufficient knowledge and skills are mandatory to avoid inappropriate use of HUD and diagnostic errors. The process of education, training and achievement of competence in HUD application should include two major steps: 1-competence in imaging acquisition and interpretation, and 2-specific education and training in HUD (Figure 1).

In cardiology, competence in imaging acquisition and interpretation can be achieved by fulfilling current requirements for training and competence in echocardiography or FoCUS, described in detail in the respective EACVI and other documents [10-13,77-79].

This knowledge should always be complemented by additional specific education and training in HUD (Figure 1). In this context, the feasibility and clinical accuracy of HUD in the assessment of different cardiovascular structures, their inherent technical limitations, and particular training on the specific system in use are important educational issues.

The EACVI on-line program of basic training and certification for HUD may be used as the first step in this specific training process. This program consists of an on-line course, which introduces the principles of cardiac ultrasound, explains echocardiographic image interpretation and covers relevant cardiology topics from the daily routine (http://learn.escardio.org/eacvi-pocket-size-programme). It also includes instructional lectures with interactive media, pattern-recognition cases, references for further reading, multiple-choice questions for self-assessment, and teaching cases. This basic certification can be obtained by correctly answering the self-assessment test and by submitting a proof of hands-on

practical training. In line with the current update document, the EACVI on-line program, first developed in 2011, will be revised and updated.

The EACVI on-line course is just a part of the initial basic training-certification process, and should be complemented by additional practical HUD training.

Recommendation 8: Education, training and competence in HUD

Education, training and competence in HUD use/application are mandatory and include two steps: 1 - Competence in image acquisition and interpretation, 2 - Specific education and training in HUD use.

Reporting and storage

As stated in the first position statement from our association [5], HUD examinations should be reported as a part of the physical examination.

Accordingly, results of HUD examinations should always be written in the patient chart/records. The information should be provided in a clear and comprehensive way, integrated with clinical data, and with the identification of the operator. It should be objective and concise and include the answer to the question raised after clinical evaluation. Additional findings with potential clinical impact should also be reported.

Images should be stored according to the applicable national rules for technical examinations for later review as a clinical baseline reference, as well as for medico-legal issues and quality control.

Ideally, HUD examination images (still frames and clips) should be DICOM (digital imaging and communications in medicine) compatible and be systematic and automatically stored retrieved, and visualized through hospital's PACS or cloud-based computing systems. Both non-cloud and cloud-based storage systems should respect the new general data protection regulation(GDPR).

Recommendation 9: HUD results - reporting, storage and review

The results of HUD examinations should be documented in the patient records. Images should be stored for later review and reference.

Controversial issues

Cost-Benefit

As a consequence of their relative low cost and potential beneficial impact on patient management, HUD may impact cost-benefit ratios. HUD allow screening for structural heart disease, provide a rapid and accurate diagnosis and treatment of several major cardiac conditions and facilitate triage of

candidates for a standard echocardiogram, with the potential to reduce waiting lists for comprehensive echocardiographic examinations [9,31,33,34,61,80-82].

However, despite all these theoretical advantages, no large- scale cost-benefit study has been undertaken in this area [28,81,83].

Reimbursement in EU countries

The EACVI´s mission is to provide better patient care. In this setting, to advocate for the patient and to defend patients' best interest may be considered part of this goal. Although reimbursement could be potentially linked to proof of training, skills and continuing education of the user, the EACVI does not currently recommend reimbursement for examinations performed with HUD. This position is based on the current role of these devices only as an extension of the physical examination. However, the future incorporation of technological developments in these devices may lead, in the future, to revised recommendations from EACVI regarding reimbursement issues.

Gaps in evidence

Most HUD studies are proof-of- concept studies, showing feasibility and accuracy of HUD examinations but little/no evidence on hard end-points, outcomes and cost-benefit ratio has been shown.

Recommendation 10: Research priorities on HUD

Further studies with HUD evaluating outcomes and cost-benefit in different clinical scenarios are warranted.

Future directions

The clinical implementation of HUD is still in its infancy, but with further technical developments their use is likely to increase rapidly. Smarter software tools will guide the users of these devices and might contribute to a wider clinical use, both inside and outside hospitals, by cardiologists and non-cardiologists. Improved image quality and optimized image storage and retrievement will be important for a more comprehensive use of HUD. If implemented, the incorporation of spectral Doppler will increase significantly their technical capabilities.

In the future, industry also will play an important role, helping to overcome the above mentioned current technical limitations of HUD, contributing for its dissemination and full adoption in clinical practice .

The decision not to include spectral Doppler (and other more advanced imaging features) in HUD depends more on marketing strategies than on technological challenges. Since pulsed-wave (PW) spectral Doppler is based on the same basic principles as colour Doppler, adding a PW Doppler mode to current HUD is mainly a matter of software implementation. Continuous wave spectral Doppler displays have additional demands on beam forming and power supply, but are within the limits of current technology. However, inclusion of spectral Doppler technology in HUD may create a strategic problem for vendors as they could be considered as "small high-end echocardiography machines" available at a fraction of the cost of full platforms.

The inherent limitations of technical quality [19] and the risks of use by not fully trained operators [75] provide the potential for a decrease in diagnostic accuracy and renders HUD controversial in the echocardiography community. Accordingly, the EACVI recommends that also in this case the use of these devices should remain limited to the extension of the clinical assessment.

Conclusions

HUD have the potential to transform the world of cardiac ultrasound [84]. Though currently probably underutilized, it seems likely that in the near future, improved image quality and technical developments will increase their usage by operators with different backgrounds and in different environments. The EACVI's guidance for the use of HUD is provided in order to achieve maximal benefit for patients in terms of optimal care and safety.

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