The Use of Handheld Ultrasound Devices – An EFSUMB Position Paper

Die Anwendung handgeführter Ultraschallgeräte – Ein EFSUMB Positionspapier

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ABSTRACT

The miniaturization of ultrasound equipment in the form of tablet- or smartphone-sized ultrasound equipment is a result of the rapid evolution of technology and handheld ultrasound devices (HHUSD). This position paper of the European Federation of Societies in Ultrasound and Medicine (EFSUMB) assesses the current status of HHUSD in abdominal ultrasound, pediatric ultrasound, targeted echocardiography and heart ultrasound, and we will report position comments on the most common clinical applications. Also included is a SWOT (Strength – Weaknesses – Opportunities – Threats) analysis, the use for handheld devices for medical students, educational & training aspects, documentation, storage and safety considerations.

ZUSAMMENFASSUNG

Die Verkleinerung von handlichen zu handgeführten Ultraschallgeräten mit einer Größe und Form von Tablets bzw. Smartphones ist das Ergebnis einer rasanten Technologieentwicklung. Dieses Positionspapier der Europäischen Ultraschallgesellschaft (EFSUMB, European Federation of Societies in Ultrasound and Medicine) beschreibt aktuelle Anwendungen von kleinen und kleinsten Ultraschallgeräten am Thorax und Abdomen. Häufige angewandte Applikationen werden beschrieben. Das Positionspapier beinhaltet auch eine SWOT-Analyse (Strength – Weaknesses – Opportunities – Threats). Anwendungen durch Medizinstudenten sowie Ausbildungs- und Trainingsaspekte, Dokumentation, Speicherung von Daten sowie Sicherheitsaspekte werden beleuchtet.

Introduction

The miniaturization of ultrasound equipment is a result of the rapid evolution of technology. Today it is possible to use portable handheld scanners that work wirelessly using battery power to perform B-mode scanning and often Doppler as well [1 – 7]. The European Federation of Societies for Ultrasound in Medicine and Biology (EFSUMB) has observed the use of handheld ultrasound devices (HHUSDs). In this position paper we consider handheld ultrasound devices to be tablet- or smartphone-sized scanners (pocket-sized) and we will report position comments on the most common clinical applications.

SWOT analysis

A SWOT (Strengths – Weaknesses – Opportunities – Threats) analysis aims to identify the key internal and external factors that are important for achieving an objective, in this case the use of handheld ultrasound devices (▶ **Table 1**).

The parties involved in the medical application of handheld devices are mainly new users of ultrasound scanners, such as residents of internal medicine, pulmonology, rheumatology, surgery and anesthesiologists. Other groups of health care personnel may also be trained to perform specific ultrasound examinations with handheld devices. This may be ambulance staff, primary care physicians, nurses and physiotherapists.

The strengths of handheld ultrasound devices are that they are easy to transport in a pocket both in in-hospital and other settings. They are cheaper than high-end ultrasound devices and use less power. Accordingly, they may be readily available for many users in various clinical settings.

The weaknesses of HHUSDs are that the screen is small, and it may be difficult to find a suitable position for the device/screen while using one hand to hold the transducer. This may result in inadequate scans since small lesions can be missed or areas can be overlooked because of small screen sizes and difficult positioning. The small size also makes the HHUSD easier to misplace. HHUSDs may have limited features and limited possibilities for fine tuning the image using the on-screen buttons.

The strengths of handheld devices result in several opportunities: ultrasound may be performed by a wider range of health care providers with varying levels and with different types of education. Handheld devices may also facilitate the use of ultrasound for teaching purposes, e. g., in anatomy and physiology. This may result in easier and faster diagnostics particularly for simple questions with a yes/no answer in the emergency setting. The expected gain is that a patient's diagnosis is recognized rapidly, and treatment can be changed accordingly, which may lead to better health care and even a shorter hospital stay. Some studies have been undertaken to support this [8 – 10]. With the increased usage of ultrasound amongst healthcare providers, the prices of ultrasound equipment may fall, enabling even more users to acquire HHUSDs. However, lower prices may result in people with less ultrasound training using handheld devices to maximize profit when ultrasound examinations are reimbursed. Furthermore, ultrasound examinations without a clinical indication may be performed more frequently, e. g. in obstetrics. Lack of education may result in an increase in both false-positive and false-negative diagnoses, thus increasing the need for a second ultrasound examination by qualified health care personnel.

Common uses

Abdominal handheld ultrasound

Abdominal ultrasound examination covers a range of different diseases and organs and is performed in various clinical settings ranging from acute examinations to routine and follow-up examinations. In addition, physicians from a wide range of specialties including pediatrics, emergency care medicine, gastroenterology, urology and gastrointestinal surgery perform abdominal ultrasound. This stresses the need for systematic and well-considered implementation of HHUSDs in abdominal ultrasound to achieve comparable and reliable information between different patients, diseases and physicians.

The clinical trials published on abdominal HHUSDs generally fall into one of four groups: gastroenterology, gynecology, urology and abdominal aortic ultrasound. Most of the articles on HHUSDs in gastroenterology and related fields focus on tentative diagnosis and triage of acutely ill patients or on assessments of ascites for paracentesis [8, 9, 11, 12].

In a study performed by residents in 199 recently admitted medical patients [8], the diagnosis of ascites, liver metastases, abdominal tumors, hydronephrosis and cholelithiasis could be confirmed but not ruled out by HHUSD, when compared to standard ultrasound examination performed by an experienced radiologist. This finding is confirmed by a study on 28 medical ward patients [13], which suggests that even though the specificity of HHUSDs is high for hepatic, biliary, renal and ascites evaluation, the sensitivity is insufficient when conventional ultrasound devices are

▶ **Table 1** SWOT analysis for handheld ultrasound devices.

strengths	weaknesses
easy to carry low cost low power supply flexible and versatile in use	small screen – insufficient for diagnostics difficult to place the screen/device while scanning limited possibilities for documentation limited features available
opportunities	**threats**
more widespread use of ultrasound by different health care professionals easier and faster diagnoses, particularly in emergencies possibility of using ultrasound for teaching medical students, for instance	insufficient training of people performing ultrasound (more false-positive/-negative diagnoses) unwarranted scanning caused by an interest in profit

used as the gold standard. One feasibility study on known focal lesions with a focus on HHUSD image quality and ability to reliably evaluate abdominal lesion size and vascularization showed satisfactory results and overall high diagnostic accuracy and value for determining the puncture site for paracentesis among other things [7]. In 216 trauma patients, HHUSD FAST-scanning had an NPV of 99.5 %, signifying that HHUSDs could be used to rule out free abdominal fluid [12]. Concordantly, in patients clinically suspected of ascites, HHUSDs successfully confirmed the diagnosis in 96 % of cases, while the diagnosis was only missed in mild cases as assessed by conventional ultrasound or computed tomography (CT) [14]. In the same study HHUSD-guided paracentesis of ascites was feasible in 38 of 40 patients, with no severe complications. In another study performed in an outgoing palliative care unit, an HHUSD was successfully used to both diagnose ascites and guide paracentesis when necessary in terminally ill patients [15]. In a study of patients in a cardiology ward, experienced physicians successfully used HHUSD examination to screen for abdominal aortic aneurysms [16].

In a study of 196 medical patients [9], an HHUSD was used to confirm cardiac, lung and abdominal findings, which resulted in a changed primary diagnosis in 18.4 % of patients, a confirmed diagnosis in 19.4 % of patients, and an additional diagnosis in 9.2 % of patients. These results are similar to another study showing either a confirmed or altered primary diagnosis or an important secondary diagnosis following HHUSD examination in roughly 40 % of patients admitted to the emergency ward [17]. In another study focusing mainly on abdominal ultrasound performed by general practitioners and specialists in internal medicine and gastroenterology, there was agreement between the initial clinical hypothesis and the latter HHUSD examination in 66 % of cases. In the remaining 34 %, the initial hypothesis was not confirmed by the HHUSD examination. Gastroenterologists had higher agreement between their clinical hypothesis and HHUSD examinations (92.4 %) than specialists in internal medicine (67.1 %), who again had higher agreement than general practitioners (47.0 %) [18].

HHUSDs have also been applied for urologic US evaluations. Different hand-held bladder scan devices have been commercially available for bladder volume evaluation for many years [19]. Most of these devices are dedicated to this purpose and exceed the scope of this review. With respect to general purpose HHUSDs, a few studies have been published concerning kidney and bladder diagnostics. One study in 36 patients found that the evaluation of quantitative parameters such as kidney length, renal-pelvis length, renal cyst size and post-void bladder and prostate volume was feasible with only small variations between observers and compared with a standard US device [20]. In addition, correlation with standard US was moderate to substantial for evaluation of the presence of hydronephrosis, the number of renal cysts and the presence of the ureter jet sign. In another study concerning the evaluation and grading of hydronephrosis in 200 kidneys and with high-end US as the gold standard, HHUSDs were found to have an NPV between 96 % and 98 % depending on the threshold for hydronephrosis [21]. In a recent study, a modified HHUSD device was successfully used for ultrasound-guided percutaneous nephrolithotomy in 31 patients with kidney stones verified by CT scans [22].

A few studies have been performed using HHUSDs in gynecology and obstetrics. Studies in women with vaginal bleeding or pelvic pain in first-trimester pregnancies showed good ability of HHUSDs to triage for further treatment, except in cases of ectopic pregnancy [23, 24]. For routine third-trimester or antenatal examinations, HHUSDs have been successfully applied to assess fetal growth and wellbeing, placental location and fetus presentation [24, 25]. In gynecological patients, HHUSDs could assess the presence or absence of pelvic masses either using abdominal transducers [24] or a modified transvaginal transducer [26], while the latter also allows for reliable assessment of focal mass sizes and vascularization compared with conventional ultrasound.

The published studies vary considerably in size and study setup. The number of included patients range from small cohorts to a few hundred patients [7, 11 – 13]. The published studies involve physicians from a great variety of medical specialties and with experience ranging from medical students to highly experienced sonographers, making interpolation between studies difficult. Also, the quantity of pre-study ultrasound training varies between studies.

The published studies also vary with respect to their design as some evaluate the impact on clinical decision making, while others compare the diagnostic accuracy of HHUSDs with conventional ultrasound or other imaging modalities. For all of the above-mentioned reasons, the overall level of evidence for HHUSDs in abdominal ultrasound is still modest, but the amount of data is steadily growing.

Position Comment

Handheld ultrasound devices are rapidly becoming a part of everyday clinical practice for the evaluation of abdominal disease. HHUSDs should primarily be used in POCUS with few and clear examination objectives, such as the assessment of the presence of ascites, guidance of paracentesis, and the assessment of hydronephrosis or gall-bladder calculi. Furthermore, the ability of HHUSDs to alter or support clinical decision making at a very early point during patient hospitalization should be further explored.

Echocardiography and Lung Ultrasound

The use of HHUSDs in the initial bedside evaluation of the acute patient is increasing viewed as a natural extension of the traditional physical examination of the cardiovascular system [27].

Several studies have evaluated the performance of handheld devices for the assessment of specific clinical questions, either in the daily assessment of the acute patient in a variety of environments (admissions ward, emergency room, intensive care) or in the follow-up of patients with an established diagnosis at outpatient clinics. Many of these studies have determined the performance of a HHUSD cardiac scan by measuring the agreement with an independently performed high-resolution echocardiogram. Left ventricular (LV) size, LV systolic function, regional wall motion abnormalities and pericardial effusion have all been detected using HHUSDs with good to high levels of accuracy [27]. In one study with trained cardiologists performing bedside ultrasound with HHUSDs in 104 acute cardiac care patients, the level of agreement for systolic function and pericardial effusion had a kappa of 0.89 and 0.81, respectively [28]. Agreement was less robust for assessing aortic, mitral and tricuspid valve function (kappa: 0.55 – 0.66). In a more recent study, 82 patients admitted with acute myocardial infarction were initially scanned with a, HHUSD by an experienced sonographer, who tried to perform as comprehensive examination as possible, including the use of color Doppler (average time 10 minutes). Correlation coefficients between the initial scan and a subsequent standard echo were good for LV ejection fraction and global wall movement (the wall motion index) score of 0.75 and 0.69, respectively. The levels of agreement for left ventricular enlargement, right ventricular dysfunction, pericardial effusion and inferior vena cava (IVC) distention were less robust with highly variable agreement in the assessment of segmental regional wall motion, dependent upon which part of the myocardium was being evaluated. This was assumed to be due to the limited field of view offered by the HHUSD that was used [29]. The evaluation of filling pressures using HHUSDs by measuring IVC diameter during the respiratory cycle has been evaluated in a number of studies again with variable agreement with respect to the reference scan [27]. As with the previous study, a feasibility study of 108 inpatients initially scanned with an HHUSD by an experienced cardiologist followed by a departmental echo found reduced correlation between exams for IVC diameter compared to that for LV and RV function, valvular function, atrial size and pericardial effusion [30]. Although the authors speculated that this may reflect the time interval between the two scans, satisfactory visualization of the IVC was scored at only 85 % and this again may be due to the limited field range of HHUSDs [27].

Despite some of the current HHUSDs lacking either color or spectral Doppler, the assessment of valve disease, both stenosis and regurgitation (only those with color Doppler), is possible with these devices. In a study of 130 patients with suspected or known aortic stenosis (AS), an additive scoring system was applied based upon a grayscale assessment of the level of restriction in the opening of each valve cusp using an HHUSD. This was then compared with aortic valve area indices calculated using high-end echocardiography. The receiver operating curves for diagnosing severe and moderate to severe stenosis using the calculated AS score were 0.946 and 0.936, respectively. Although not significantly better than skilled clinical examination, this performed better than aortic calcium scores obtained using the HHUSD [31]. Using an HHUSD equipped with color Doppler in the assessment of acute coronary patients, trained cardiologists were able to identify aortic stenosis and regurgitation to a good level of agreement compared with subsequent high-end echocardiography. However, agreement was only moderate for mitral and tricuspid regurgitation ($k = 0.55 – 0.56$), with a tendency to overestimate regurgitation using the HHUSD [28]. In another study comparing inter- and intra-observer agreement between HHUSDs and standard echocardiography in 320 patients, the level of agreement for grading mitral and aortic regurgitation was at least moderate ($r > 0.6$), while the detection of mitral regurgitation was less favorable, with milder cases being missed by the HHUSD [32].

With reference to some of the above studies, the perceived limitations of HHUSDs for cardiac ultrasound when compared to even portable echo machines were highlighted in a position statement by the European Association for Echocardiography in 2011. Based on the technical performance of units at that time, the listed indications were: complement to clinical examination, screening tool in the emergency room or ambulance, initial evaluation in outreach clinics, triage tool for determining who should undergo fully comprehensive echocardiogram and teaching tool [33]. One study evaluated the spontaneous use (not part of a clinical trial) of HHUSDs by non-specialist hospital residents who had undergone appropriate training [34]. The use of an HHUSD by 24 residents admitting 542 patients overnight was retrospectively analyzed. The residents elected to scan 42 % of patients as part of their initial assessment and not to scan 58 % of patients, with lack of clinical indication, time constraints and poor patient cooperation as the main reasons for the latter choice. There was, however, a wide variation in the percentage use of the HHUSD by individual residents (17 – 85 %), despite all receiving the same level of training. A number of factors may account for this variation, including comfort with use of the device, time and efficient data collection, i. e., information already available from previous patient tests and imaging.

The identification of fluid overload within the lungs by the visualization of multiple ring-down artifacts in the image known as B-lines or “lung rockets” has been shown to be reliably achievable with HHUSDs and can be taught to other members of the patient care team [35]. In a prospective study using HHUSDs for the assessment of 185 outpatients with established heart failure (HF), 8 chest zones were scanned by skilled investigators for a median of 2 minutes, with all recorded clips reviewed offline. 32 % of patients had ≥ 3 B-lines, yet 82 % had no findings at auscultation. At follow-up these patients had a four-fold increase in hospital admission for heart failure and death than patients with < 3 B-lines. HHUSD assessment may therefore allow optimization of patients with HF [36]. In another study, however, a potential discrepancy with HHUSDs in the assessment of B-lines in patients with HF was highlighted due to their limited clip store capacity. When comparing an HHUSD with 2-second clip store with a high-end system able to record at least 6 seconds, there was a significant difference in the number of B-lines observed during a standardized scanning protocol, with a higher number being seen using the longer recorded clips [37].

HHUSDs have also been successfully employed for the detection of B-lines in other interstitial lung conditions. In a study of 39 patients with rheumatoid arthritis comparing HRCT with standardized lung ultrasound, a subset of 29 patients were also scanned using an HHUSD by a physician with limited training in B-line recognition at ultrasound. In this subset, the sensitivity and specificity for interstitial lung disease with respect to HRCT were 89 % and 50 %, respectively, while the concordance with standard ultrasound was good (k = 0.78) [38]. The value of lung ultrasound performed by operators with limited experience using HHUSDs has also been demonstrated in the acute assessment of patients with dyspnea. Five junior doctors performed 69 scans using HHUSDs combined with clinical assessment of patients with breathlessness. The final diagnosis was determined by the senior admitting physician at discharge and this was used to calculate receiver operator curves for clinical and ultrasound performance. The resultant area under the curve was significantly higher for ultrasonic diagnosis (chronic obstructive lung disease, pulmonary edema, pneumonia, pleural effusion) than clinical assessment: 0.87 vs. 0.81 [39]. Notably, two of the doctors who underwent extended training demonstrated increased diagnostic accuracy compared to their peers. In the further management of pleural effusion (PE), HHUSDs may offer an ideal solution for bedside quantification and guidance of thoracentesis for the resolution of respiratory compromise. In a study of 73 people with an abnormal chest radiograph suggestive of PE, a single experienced ultrasound operator performed pleural ultrasound with an HHUSD. Significant PE was diagnosed by single-point measurement in 46 patients in whom successful aspiration of the effusion was performed using ultrasound guidance. On review of the measured inter-pleural distance, the authors determined that a value of > 6.3 cm predicted an effusion volume > 1000 ml with a sensitivity of 91.7 % and a specificity of 99.9 % [40].

Incorporating both lung and cardiac ultrasound into the initial assessment of the acutely dyspneic patient with an HHUSD can enhance the diagnostic performance of this point of care approach. In 68 patients presenting at an emergency department with breathlessness, an HHUSD was used to evaluate the lung to look for B-lines and pleural effusions, the heart to look for pericardial effusion and assess ejection fraction, and the IVC to look for increased distention. Patients were divided into cardiogenic and non-cardiogenic causes of dyspnea, with the final diagnosis determined by a senior physician reviewing all investigations and patient response to treatment. Two-by-two contingency tables were used to calculate sensitivity and specificity data for differing combinations of the ultrasound exam compared with the final diagnosis. As with other studies, lung ultrasound alone showed good sensitivity and specificity of 92.6 % and 80.5 %, respectively, for detecting cardiogenic edema, but the overall accuracy was best (90 %) when this was combined with either the cardiac or IVC findings [41].

Position Comment

There are now a number of good quality studies with a reasonable number of patients, comparing HHUSDs with high-quality echocardiograms, thereby establishing the value of these devices in the initial assessment of both the acute and non-acute patient. Initial assessment of LV enlargement, LV function, pericardial effusion and valve function (to some extent) is possible, with good levels of agreement with departmental echocardiograms. However, some limitations have been highlighted: namely the field of view offered by these units, which can prevent reliable evaluation of the IVC. HHUSDs can also reliably be used to determine the presence of both pulmonary edema and pleural effusions and guide thoracentesis in the latter. This can be performed without the need for departmental ultrasound and there is good evidence to indicate that this can be reliably performed by clinicians with limited ultrasound training.

Handheld Devices for Pediatric Ultrasound

The use of handheld ultrasound is particularly attractive when it comes to pediatric applications given that the body habitus of children is well-suited for ultrasound. The low proportion of fat and lower examination depth allow for acquisition of excellent quality images, requiring no high-end technology. Consequently, pediatric ultrasound applications could be potentially performed using less sophisticated devices, such as portable devices or even HHUSDs. Moreover, the reduced size of such devices may be better tolerated by the pediatric patient, allowing for a calmer and more effective examination. The notion of point-of-care ultrasound has been endorsed and efforts have been made to incorporate this into pediatric practice [6, 42, 43]. As seen in all aspects of US, HHUSDs can be used for initial evaluation and diagnosis, follow-up and procedural guidance in pediatric imaging.

There is limited evidence regarding HHUSDs in general pediatric applications, but there are some reports of use for cardiac applications. The added value of an HHUSD in a neonatal intensive care unit was illustrated in a pictorial paper and includes the early identification of intraventricular hemorrhage, hydrocephalus and ovarian cysts. The availability of an HHUSD allowed serial monitoring of an intraventricular thrombus over multiple frequent examinations, demonstrating thrombus evolution to a cystic area following central liquefaction. This interpretation would have been problematic if the patient was only examined once in the radiology department [44]. A major part of the available literature deals with cardiac applications. A study enrolled neonates and children < 6 years old, comparing the quality of cardiac ultrasound images acquired with an HHUSD and a conventional device. The diagnoses in question included various heart abnormalities: patent ductus arteriosus, atrio-ventricular canal, peripheral pulmonary valve stenosis, aortic coarctation, atrial septal defect, ventricular septal defect, preoperative or postoperative tetralogy of Fallot and mitral regurgitation. It was concluded that the image quality of cardiac anatomic structures did not differ significantly based on the readers' evaluation between the HHUSD and the conventional device. Only 9 % of findings, none of which were critical, were missed by the HHUSD, showing the value of such a device, especially in remote areas with poor access to medical care [45]. In keeping with these results, another study investigated the diagnostic accuracy of HHUSDs handled by critical care physicians for the diagnosis of pericardial effusion, decreased cardiac function and left ventricular enlargement in pediatric patients. The reference method used in this study was a standard echocardiogram and the examined population included patients aged 3 months to 20

years. It was found that HHUSDs accurately detected effusions in more than 90 % of cases and correctly calculated left ventricular size and systolic function in 96 % of patients [46].

Rheumatic heart disease (RHD) is another field where HHUSDs have been evaluated in pediatric patients [47 – 49]. In a field study taking place in a deprived region and involving more than 1000 children, HHUSDs had a sensitivity of 78.9 % and a specificity of 87.2 % for the diagnosis RHD, although the sensitivity was even higher for definite RHD. The inter- and intra-observer agreement ranged from 66 % to 83 % and 71.4 % to 94.1 %, respectively. In light of these results and the low cost of HHUSDs, these devices can be used as an initial screening tool for RHD, especially in remote areas, but a standard ultrasonographic device should be used to confirm the findings in suspicious cases [47]. Similarly, another team investigated the diagnostic accuracy of an HHUSD used by trained nurses for diagnosing RHD with a sensitivity of more than 77 % and a specificity of 90 %. The percentage of agreement between the different observers was 91.4 % [48]. Another study concluded that HHUSD echocardiography has a sensitivity of 90.2 % and a specificity of 92.9 % for RHD and even higher diagnostic accuracy for definite RHD [49]. A similar approach of screening for RHD with HHUSDs has also been tested in school students, revealing a significant number of children with previously undetected abnormalities [50].

HHUSDs have also been tested for the detection of patent ductus arteriosus in premature infants. When the images were evaluated by a neonatologist after short training, the examination had a sensitivity of 69 % and specificity of 88 %, but when interpreted by an experienced cardiologist, the sensitivity increased to 87 %. As a result, such applications should only be endorsed after proper training or if there are no specialists available [51]. The same hypothesis was tested in a study where the HHUSD exams were evaluated by pediatric cardiologists. It was found that HHUSDs could detect patent ductus arteriosus in neonates with false-positive rates around 11 % and false-negative rates of less than 6 %. The results were better for neonates weighing more than 1000 g and having a gestational age > 37 weeks [52].

Another longstanding application of HHUSDs in children is US-guided urine collection by suprapubic aspiration. Initial results have shown that suprapubic aspiration is more frequently successful if guided by an HHUSD and fewer attempts are required [53]. One recent study showed that using an HHUSD to determine urine bladder volume prior to urethral catheterization increased the success rate of the procedure and avoided unsuccessful repeated attempts [54].

A case series presents 3 patients with head trauma where portable ocular ultrasound detected increased intracranial pressure by measuring the diameter of the optic nerve sheath [55]. Another proposed application for portable ultrasonography, but with limited evidence, is the measurement of thyroid volume in children in an attempt to define the prevalence of goiters and thus detect the status of iodine deficiency disorders [56].

Position Comment

There is currently limited evidence regarding the incorporation of HHUSDs in pediatrics. However, HHUSDs have provided promising results in the detection of RHD and other cardiac applications and are strongly recommended as an initial screening tool, especially in remote areas or developing countries. Although there are limited reports available regarding other applications, it is expected that HHUSDs could greatly assist minimally invasive procedures, like vein cannulation, which are commonly performed under the guidance of a portable ultrasonographic machine in intensive care units or emergency departments. Given the lower quality of HHUS images compared to conventional ultrasonographic machines, it remains to be addressed whether it is better for the examination to be performed by an experienced radiologist or a clinician.

Handheld Devices for Medical Students

Compared with standard ultrasound devices, the lower costs and handiness make HHUSDs an attractive training tool for medical students in the preclinical and clinical setting. The need and demand for ultrasound training will grow with the expanded use of these devices. The training of medical students will therefore be of outmost importance to meet these needs. In the preclinical setting, ultrasound training will also improve the understanding of anatomy [57] and allow a more rapid diagnosis and decision-making process during clinical training.

There are few studies reporting on the use of handheld devices for educational purposes, with most of them focusing on intrathoracic organs. One randomized trial assessed the efficacy of different ultrasound training programs involving the use of HHUSDs for teaching focused cardiac ultrasound. 45 third-year medical students were allocated to one of three educational programs: (a) lecture-based approach with scan training by a sonographer, or (b) coupled electronic education modules with sonographer scan training, or (c) self-directed program, combining electronic modules with scan training on a high-fidelity ultrasound simulator. Image interpretation skills and scanning technique were evaluated after each program. It was found that all three programs were associated with a significant improvement in image interpretation (mean improvement 1.3-fold), but the quality scores of self-directed students were lower than those of students taught by sonographers [58].

At Mayo Medical School, 42 first-year students participated in 3 weeks of echocardiography training, using each other as training subjects. The aim of the program, which was implemented in their standard anatomy curriculum, was to identify cardiovascular structures at a parasternal long-axis plane. The rate of correct identification of anatomical structures increased from 3.7 % pretraining to 91.0 % at the completion of the program [59], suggesting that teaching on handheld devices is effective.

A Hong Kong study assessed the use of handheld devices by fourth-year medical students as means for their introduction to point-of-care transthoracic echocardiography during their 2-week anesthesiology rotation [60]. The students were allocated to groups of 8 – 9 subjects. Each student received a booklet on basic transthoracic echocardiography before training, which included lectures and practice. The aim was to teach identification of cardiac structures using the parasternal long axis, parasternal short axis, apical and subcostal views. At the end of their training, students achieved a mean success rate of 82 %.

At the University of California, Irvine, a study assessed the feasibility of point-of-care diagnostic ultrasound training in the four-year medical school curriculum using handheld ultrasound devices. The program was introduced to first-year students in 2010 and involved web-based lectures, peer-to-peer training supervised by faculty members, and performance assessments. Although this study did not provide efficacy data, it postulates that early training of medical students with handheld devices will enhance their understanding of anatomy and physiology, and may promote the growth of predictive, preventative, participatory and personalized medicine [57].

A systematic review of the literature in 2017 found it possible to teach medical students to use HHUSDs for a limited number of pathologies mainly cardiac. There was no consensus on the protocols best-suited for the educational needs of medical students and no data on long-term skills retention [61].

Position comment

To date, a limited number of studies have been published, indicating that the use of handheld devices in medical education may be feasible as an adjunct in teaching anatomy and clinical examination. However, teaching ultrasound in general to undergraduate students is still not officially included in the standard curriculum of many medical schools and the evidence on handheld devices comes mostly from retrospective studies. We expect the need and demand for ultrasound training will grow with the use of handheld devices and early training will be of outmost importance. Further investigation of the optimal learning scenarios and implementation methods with a critical eye on study design and educational research method is needed [62].

Education and practical training

As with any other medical training, the use of HHUSDs needs dedicated education and practical training [63 – 66]. To our knowledge, there are currently no prospective trials investigating handheld ultrasound training.

The importance of appropriate training in POCUS was addressed by a statement of the American College of Radiology (ACR) which recognized point-of-care ultrasound as an adjunct to the physical examination [67]. The ACR also pointed out that training and credentialing as well as quality assurance are of paramount importance. There is a clear risk that without adequate training POCUS can be harmful to patient care [67].

To address these concerns, many large medical societies request formal training in POCUS. US is now an integral part of training in many medical specialties. Likewise, emergency ultrasound training from the American College of Emergency Physicians (ACEP) requires formal didactic and experiential components in POCUS training [68]. Formal training can be accomplished either by attending a residency curriculum covering emergency ultrasound or by attending an introductory emergency ultrasound course [68]. Residents are also required to gain practical experience in emergency ultrasound, since the certification concluding training must follow the guidelines of the ACEP. Similar training courses and numbers of supervised examinations are also requested by other societies.

So far, little is known regarding the adequacy of short introductory courses and limited examinations for achieving the necessary expertise. Most studies investigating learning curves in POCUS suffer from methodological issues [64]. The impact of a 16-hour course including 8 hours of hands-on training on POCUS skills was investigated in a study by Mandavia et al. [70]. During a 10-month follow-up period, they found that the 18 second-year emergency medicine residents were able to perform POCUS studies considered to be adequate in 96.1 % of cases and the diagnosis was accurate in 94.6 % [70].

The number of required examinations to reach a level of expertise was investigated in a retrospective study by Blehar et al. [71]. Based on 52 408 US examinations, they investigated the learning curve of 191 emergency physicians to learn 18 predefined examination types (i. e., FAST, aorta, right upper quadrant) [71]. The authors concluded that a range of 50 to 75 examinations sufficed to reach excellent interpretation skills for most of the examination types [3]. This opinion was not shared by Jang et al., who prospectively investigated the learning curve of 127 emergency physicians to reach a sufficient expertise level [72]. This study showed no major impact on the accuracy of US examinations of the right upper quadrant after performance of the first 50 examinations [72]. The authors concluded that "rather than simply requiring an arbitrary number of examinations, another method of competency assessment may be necessary" [72].

One method to improve US skills could be the use of simulators. However, the data on the optimal use of simulation-based training is still sparse [73]. A systematic review performed by Østergaard et al. could only identify 17 studies investigating simulation-based abdominal US training [74]. However, among these 17 studies, no studies used tests with established evidence of validity and 11 studies were identified to be at high risk for bias [69]. Based on the present literature, it was concluded that simulation appears to be "equally good or better than no training or than existing training methods" [74]. Recently the same group published the first simulation-based test for abdominal ultrasound skills with a pass/fail standard [75].

Position Comment

POCUS education and training is needed no matter what equipment is used. There is no consensus on the number of cases to be performed or the time required for reaching a safe and acceptable level. Possibly competency-based assessment and training methods such as ultrasound simulation training and simulation-based tests may be preferred.

Documentation, image storage and safety

Both and European and American ultrasound societies recommend that retrievable image documentation and written reports should be supplied for US examinations [76]. The use of HHUSDs mainly by non-radiologists in a clinical, often acute setting challenges the way ultrasound images and reports are documented and stored. In most cases, operators will use HHUSDs without ac-

cess to a PACS (Picture Archiving and Communication System) or RIS (Radiology Information System). Furthermore, the clinician recommending the examination and the operator performing the HHUSD exam will most likely be the same person. The majority of HHUSD examinations will be undertaken as part of the clinical examination, and the documentation thereof should be done in the hospital or clinic patient journal record system. The documentation should preferably include the reason for performing the HHUSD exam, the outcome/conclusion, the name of the operator performing the scan and the time and date of the examination.

When an HHUSD is used for ultrasound-guided interventional procedures, a description of the procedure should be supplied in the patient's medical record as with a surgical procedure. If possible, US images should also be saved within the patient journal. Image documentation in HHUSDs can pose a problem. If a patient identifier can be attached to the images and the HHUSD can send pictures to digital storage at the institution, this should be preferred. Some HHUSDs consist only of a transducer connected to a personal mobile device and care should be taken not to violate patient confidentiality and data safety and local rules must be followed carefully.

All of the above stresses the need for well-considered, simple diagnostic inquiries for HHUSD examinations, which could be answered with yes/no. In addition, HHUSDs are already used in low- and middle-income countries as well as in rural areas and in catastrophe settings. In these settings, documentation, image storage and data safety may be less crucial than in first-world hospital settings [77, 78]. Conversely, online and/or cloud-based data management may well be implemented to perform ultrasound examinations with HHUSDs, where qualified ultrasound specialists are not readily available [79].

Position Comment

US with an HHUSD performed mainly by non-radiologists challenges the conventional ways of storing and describing US images. In the implementation of HHUSDs, care should be taken that documentation is performed and preferably standardized but should not overrule the need for immediate US assessments and subsequent clinical interventions in acutely ill patients. Data safety should be considered at all times.

Future Perspectives and conclusion

We define handheld ultrasound devices as devices with a screen the size of a smartphone or a small tablet that can be easily carried by a physician [80]. The advantages of such miniaturized scanners are clear and straightforward, as they can answer simple and focused medical questions regarding organ or symptom-related issues.

Studies involving HHUSDs have mainly been about POCUS which is not a replacement for comprehensive ultrasound, but rather offers immediate access to clinical imaging for rapid and direct solutions [33, 68, 81, 82]. HHUSDs will likely extend the user base of medical ultrasound since a handheld device is already less expensive than a full conventional ultrasound system. Users will range from medical students to medical specialists. Primary care physicians are also likely to benefit from using HHUSDs in many point-of-care cases. Specialized training and formal certification are crucial. The proper use of HHUSDs is preceded by an understanding of the use of POCUS and the use of conventional ultrasound. As there is still little evidence on the acquisition of ultrasound skills using HHUSDs only, training in conventional US examinations should continue to be the mainstay of US education with the possible addition of HHUSDs for specific predefined applications.

In conclusion, HHUSDs should primarily be used in point-of-care ultrasound with few and clear examination objectives. The integration of HHUSD for focused ultrasound examinations in the daily acute and critical care workflow is safe and easily applied to patient admissions, but there is still limited evidence in this field.

Also, the legal aspects of using a personal phone or tablet to obtain medical images will have to be addressed in the future. Documentation and reporting should be performed in a clear, uniform language using commonly accepted terminology. EFSUMB, working continuously to build the European ultrasound community, is also dedicated to ultrasound education and training within the field of HHUSDs.

Conflict of Interest

The authors declare that they have no conflict of interest.

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ERRATUM

The Use of Handheld Ultrasound Devices – An EFSUMB Position Paper

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In the above article, the name of the co-author was misspelled. Right: Alexandros Sotiriadis.