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Smartphone interfaced handheld echocardiography for focused assessment of ventricular function and structure in children: a pilot study.

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Abstract

Introduction—Miniaturized echocardiographic machines improve availability and portability and can be particularly useful for underserved and resource-limited settings. The goal of this study was to compare left ventricular fractional shortening (FS) and left ventricular ejection fraction (LVEF) obtained by a newer handheld echo (HHE) machine to standard transthoracic echocardiogram (TTE) in children.

Methods—Pediatric outpatients (Birth –18 years) undergoing TTE were prospectively enrolled. HHE protocol included 2D and M-mode images from the parasternal long, short and apical-4 chamber views. HHE and TTE measurements were reviewed for agreement. Kappa statistic was used to analyze qualitative indices while FS and LVEF were analyzed with Lin's concordance correlation coefficient (CCC) and Bland–Altman limits of agreement (loa).

Results—Sixty children were enrolled; 55 were included in the quantitative analysis. Mean age was 7.5 ± 5.5 years; 67% males; median HHE image acquisition duration was 2.3(1-5) minutes. FS and EF by HHE showed good agreement with TTE [CCC = 0.82, 95%CI (0.73,0.90), mean bias -3.18%, loa (-7.00,6.44%) versus CCC = 0.81 (0.72,0.90), mean bias -0.87%, loa (-6.94,5.17%), respectively. In children ≤ 5 years, HHE FS (n=20) and EF (n=21) agreed with TTE measurement [0.59 (0.31,0.88), mean bias 0.30%, loa (-8.5,9.1%); 0.79 (0.63,0.96), mean bias 0.10%, loa (-5.99,6.14)]. Kappa values for RV size, function and LV function were 1.00 (p<0.05); 0.75 for LV size (p<0.05) and 0.66 for pericardial effusion (p<0.05).

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Authors contributions

BA was responsible for data collection, data analysis/interpretation and writing the initial manuscript draft. DP assisted with data analysis and JS assisted with data interpretation. BA, DP, TM, MA, and JS contributed to project design, and critical revisions of the manuscript drafts. All authors accept responsibility for and approve the final version of the manuscript.

Conclusion—HHE demonstrates good correlation with standard TTE for focused assessment of ventricular chamber sizes and function in children.

Keywords

Handheld ultrasound; Echocardiography; Children

INTRODUCTION

Since the 1970s, the concept of the ultrasonic stethoscope has engaged the attention of the medical community[1]. The development of the first generation of portable devices, in the 2000s, including laptop-sized ultrasound machines with full capabilities for standard echocardiography heralded improved ultrasound access to many and enabled the conduct of bedside ultrasonography. Further advances resulted in second-generation machines, including a hand-carried portable ultrasound weighing between 2 and 3 kg. These machines provided 2-dimensional (2D) imaging but lacked color and spectral Doppler and ECG synchronization. Recently, third generation handheld or pocket-sized machines that are lighter in weight and consist of just an ultrasound probe that works with mobile based technology for image display with wireless capabilities and full color flow Doppler imaging have been introduced[2]. The advent of these relatively cheaper and user-friendly miniaturized ultrasound scanners has improved overall enthusiasm for point-of-care echocardiography[3]. While the standard transthoracic echocardiogram (TTE) remains the ideal platform for evaluating detailed cardiac structure and function [4, 5] the portability and relative cost-effectiveness of handheld echocardiogram (HHE) machines [6–8] make them suitable for resource-limited settings and underserved areas [2, 9–11]. Some of the 3rd generation HHE machines are equipped to provide adequate 2-D imaging, M-mode, color flow Doppler, and basic measurement. These machines can export images to a digital imaging and communication in medicine (DICOM) platform for possible quantitative analysis[2], although they lack the full capabilities of a standard machine, such as spectral Doppler imaging, ECG synchronization, tissue Doppler imaging and 3-D imaging [3, 12]. One such HHE machine is the Lumify® probe (Lumify, Philips, the Netherlands) a handheld, mobile application-based echocardiogram device that connects to an android device (Fig 1).

Previous studies have demonstrated the accuracy of HHE machines for focused cardiac imaging when compared to the standard echocardiogram, even when performed by non-cardiologists with adequate training [13–18]. Focused questions have included the presence of pericardial effusion, basic assessment of ventricular structure and function, and in some cases volume and hemodynamic assessment [13–15, 19–26]. Some adult studies have also demonstrated accuracy when used for focused quantitative measurements, either by visual estimation or by indirect methods of quantifying ejection fraction (EF) [21, 22, 24, 27]. Wholesale extrapolation of the adult experience to children is problematic.

Within the field of pediatrics, HHE machines are used for qualitative evaluation of structure and function, screening of valvar pathologies and for structural congenital heart disease [11, 19, 28, 29]. The smaller body size and faster heart rate of children presents unique resolution

challenges, making HHE machines less desirable for comprehensive imaging in children [3, 4]. Pediatric studies assessing the accuracy of HHE machines for quantitative assessment are therefore needed. There are currently no studies comparing quantitative ventricular function such as left ventricular ejection fraction (LVEF) and fractional shortening (FS) which are the commonly reported and validated indicators of ventricular systolic function using the newer generation of HHE machines in pediatric patients.

The goal of this study was to compare standard quantitative measures of left ventricular function, specifically LVEF and FS, obtained by the newer Lumify HHE machine with standard TTE in a cohort of pediatric patients with and without congenital heart disease. Ultimately, we anticipate using the Lumify in underserved areas for focused cardiac imaging where capacity for simple quantitative measurements are not available. We hypothesized that there would be good agreement between HHE and TTE and that a short and focused echocardiogram performed with the Lumify HHE would serve as a reliable screening tool for cardiac assessment in children in underserved areas.

METHODS

Patient population and selection

We prospectively enrolled 60 pediatric outpatients from March to May 2018 at the Vanderbilt Pediatric Heart Institute. The study was approved by the Vanderbilt Institutional Review Board. Patients with biventricular heart structure with and without congenital heart disease from birth to 18 years undergoing comprehensive TTE were included in the study. Patients with single ventricle anatomy were excluded due to their complex ventricular anatomy. Pediatric patients and their families were approached after their standard TTE appointment. Those agreeing to participate signed the appropriate consent and/or assent. All patients who consented for the study were included and no patient was excluded from HHE imaging after consent.

TTE imaging and interpretation

Patients were first imaged by a qualified sonographer at the Vanderbilt University Medical Center pediatric echocardiography laboratory utilizing the hospital standard TTE machines – Philips EPIQ7 equipped with harmonic imaging, pulsed and continuous wave Doppler and multi-frequency transducers. The standard VUMC pediatric echocardiogram protocol was used. The clinical TTE studies were interpreted by attending cardiologists or by the patient's primary cardiologists, in accordance with the American Society of Echocardiography's recommendations for a complete transthoracic echocardiographic examination[5]. Reports included quantitative and qualitative assessments of all cardiac structures as well as color and spectral Doppler evaluation.

HHE sonographic equipment, imaging and interpretation

For this study we used the Lumify handheld ultrasound device. The device is a 4–1 MHz phased array transducer for transthoracic cardiac imaging. It has M-mode and color Doppler capabilities but lacks spectral Doppler and ECG synchronization. The transducer performs most of the beamforming, image acquisition, and reconstruction processing, and the

smartphone/tablet serves as the display screen connected to a cloud-based application. Control settings include the ability to adjust the 2D gain and the depth of images on the Android tablet via the Lumify software[2]. The device is also equipped with two sets of distance calipers and elliptical measure and the images can be exported to a DICOM platform or via email for offline analysis.

Following completion of the standard TTE, patients and families were approached and recruited after informed consent/assent was obtained. Focused handheld imaging was performed by a pediatric cardiology fellow blinded to the TTE study using the following simplified protocol: 1) parasternal long axis 2D cine images of the LV including the mitral and aortic valves; 2) parasternal long axis M-mode still frame through the LV at the level of the papillary muscles; 3) parasternal short axis 2D cine imaging at the level of the papillary muscles; 4) parasternal short axis M-mode still frame through the LV at the level of the papillary muscles; 5) apical-4 chamber 2D cine imaging. The protocol also permitted qualitative assessment of ventricular structure and function and pericardial effusion.

The time taken to perform the HHE protocol was recorded using the internal clock of the machine. HHE images were exported in a DICOM format wirelessly and stored on the hospital server. Measurements were made using a dedicated imaging viewing software in our echocardiography laboratory (Xcelera R4.1L1-SP2 version) by the same pediatric cardiology fellow on the same day. FS measurements were obtained from the M-mode, and LVEF was obtained by the 5/6 area length technique according to the recommendations of the American Society of Echocardiography [5]. The right ventricular (RV) function was assessed subjectively by visual estimation. No RV quantification was done. The HHE measurements FS, LVEF, and qualitative evaluations were entered into a secured database on separate days from the TTE measurement of FS and LVEF performed by cardiologists in the department. The measurements were then reviewed for agreement in a blinded fashion. Images were also compared for agreement of qualitative left and right ventricular function and structure using an ordinal scale of normal, mild, moderate or severe. Pericardial effusion was graded as trivial, small, moderate or large when present.

STATISTICAL METHODS

Baseline characteristics for continuous variables were presented as means $\pm$ standard deviation (SD) for normally distributed variables and median with (range) for skewed data. Categorical variables were reported as number (%) of the total group. Agreement was defined by a Kappa statistic for categorical variables. K statistics of 0.41 to 0.60 were considered as moderate agreement, 0.61 to 0.80 as good agreement and greater than 0.81 as excellent agreement. Kappa values were reported with their p-values. Lin's concordance correlation coefficient (CCC) estimated by variance components and Bland-Altman limit of agreement (loa) [30] were used to compare agreement between TTE and HHE for continuous variables. CCCs of 0.51 to 0.70 were considered moderate positive correlation, 0.71 to 0.90 as good positive correlation and 0.91 or greater as excellent positive correlation. All coefficients were reported with their 95% CI. The mean differences in FS and LVEF were evaluated using the t-test and the Wilcoxon rank sum test. Data were analyzed using

STATA version 15.1, 2017. (Stata Statistical Software: Release 15. College Station, TX: StataCorp LLC)

RESULTS

We enrolled 60 patients for the study. Fifty-five children were included in the quantitative analysis, while all 60 patients were included in the qualitative analysis. Four patients were excluded from quantitative analysis due to inadequate image quality by HHE and one patient was excluded due to poor image quality on both the TTE and HHE. The median age (range) for all participants was 94 (1-225) months, and 40 participants (67%) were males. The median duration of HHE was 2.3 (1–5) minutes for all 60 participants (Table I). There was no difference in HHE FS or LVEF between male and female patients ($p=0.62$ and $p=0.37$). There was also no gender difference in TTE FS or LVEF ($p=0.56$ and $p=0.25$). There was no difference in FS or LVEF by age group for either HHE ($p=0.86$ and $p=0.95$) or TTE ($p=0.87$ and $p=0.75$) respectively.

Echocardiographic assessment of qualitative ventricular function with HHE

Table II displays the Kappa coefficient for the qualitative analysis of ventricular function and structure and pericardial effusion between HHE and TTE. The assessment demonstrates a strong agreement between HHE and TTE in the qualitative assessment of ventricular structure and function. There was only moderate agreement for pericardial effusion at 0.66 ($p\text{-value} < 0.05$).

Echocardiographic assessment of fractional shortening and left ventricular ejection fraction

Echocardiographic assessment demonstrated a strong CCC between HHE and TTE for FS (CCC=0.82) and LVEF (CCC=0.81) (Table III, Fig 2a and 2b). Bland–Altman analysis demonstrated a small mean bias between HHE and TTE for assessment of FS (0.32% with loa of -6.4% to 7.1%) and LVEF (0.89% with loa of -5.2 to 6.9%) (Fig 3a and 3b). The means and standard deviations of FS and LVEF and the CCC and confidence intervals for children 5 years and under as assessed by HHE and TTE are also shown in Table III. The CCC for fractional shortening in children in this age group demonstrated a moderate agreement at 0.59. CCC and Bland – Altman loa graphs for children under five years are also shown in Fig 4a, 4b and 5a, 5b respectively.

DISCUSSION

The role of HHE in children continues to evolve. HHE is finding wider applicability in focused cardiac assessment and screening for cardiac pathologies and may especially be useful in resource-limited settings [11, 19]. Further, despite concerns by certain experts [3], HHE could be an option for both inpatient and outpatient focused cardiac assessment by non-cardiologists with adequate training in resource-limited settings [22, 31].

The different resolution requirements and imaging depths in children [4, 23] require more studies with HHE to characterize its place in focused cardiac assessment. This study compared quantitative assessment of FS and LVEF using a newer HHE machine compared

to standard TTE. Our study demonstrates that the Lumify probe has good agreement with the standard TTE, even in children under 5 years of age. The Lumify probe may therefore provide reliable screening for focused cardiac assessment in resource-limited settings, where the capacity for standard quantitative ventricular functional assessment may not be feasible and trained personnel are not readily available.

This study evaluated a design that may be applicable in resource-limited settings. The study was performed by a pediatric cardiology fellow with more experience than medical residents, but less experience than an attending cardiologist. The fellow was able to obtain interpretable images that showed moderate to strong agreement with images obtained and interpreted by experienced sonographers and attending cardiologists using a standard machine. Our findings are consistent with prior studies performed with handheld echo machines by personnel with varying levels of echocardiographic training[32, 33].

As in prior studies our series had an acceptable concordance and limit of agreement with left ventricular size, left ventricular function and right ventricular size and function [14, 16, 18, 31, 34]. Prior studies demonstrated variable ability to characterize right ventricular structure[14, 31, 34]. However, in our study the qualitative characterization of right ventricular structure and function showed good agreement between HHE and TTE.

The time taken to perform the studies was a critical aspect of this study. The physician-patient ratio is low in resource-limited settings and long scanning times may preclude efficient patient care and discourage its use. The scan time using our protocol averaged 2.3 minutes (range 1-5 minutes) which is comparable and, in some cases, better than protocols that have been reported in prior studies [14, 20, 28, 31, 34]. Our findings demonstrate that as proficiency with HHE is achieved, imaging could be obtained more quickly to answer focused and emergent questions that may improve triage, as well as change patient flow in various clinical settings.

Our assessment focused on both quantitative and qualitative measurements of ventricular function and structure, as we envisioned the supplemental role this ultraportable machine could play at point-of-care service areas and in resource limited settings when quantitative evaluation may not be available. In this context, the instrument will not have to render precise quantitative measurements but could be used to identify abnormalities and categorize them into levels of severity with confidence, given the moderate to strong correlation and agreement with TTE in this study.

In the realm of pediatric echocardiography, HHE has significant barriers due to its lack of higher frequency transducers. The Lumify is limited to a 4-1 MHz phased array probe. A higher frequency probe would be optimal for pediatric patients [4]. However, when used for simple quantitative measurement, our study demonstrates that the Lumify probe performs sufficiently well in children, even in those under five years and in heterogeneous populations with and without repaired or unrepaired congenital heart disease.

In the evolving application of HHE, training is essential. Previous studies have demonstrated that more experienced operators have improved sensitivity and specificity in the identification of pathology [28]. HHE should be performed by professionals with experience

in echocardiography, or non-cardiologists with adequate and appropriate training. Skills in acquiring and interpreting HHE images should be taught to novices, to include didactic and proctored training before its use in resource-limited settings. In this regard, the guidelines of the American Society of Echocardiography should be used for image acquisition, analysis, and interpretation. [3] Non-cardiologists using HHE must understand its limitations. Maintenance of competency is also essential for non-cardiologists trained in focused cardiac imaging. We recommend it only be used for focused examinations in resource-limited situations.

Our study showed moderate agreement for identification of pericardial effusion. This finding was due to two missed trivial pericardial effusions reported on the TTE but not on the initial interpretation of the HHE images. These discordant findings defined on the severity of clinical implications and relevance, are not a significant limitation, as trivial pericardial effusions do not portend adverse outcomes for the patients. The concordance for FS for children under 5 years in our study is low, likely due to our small sample size. Further HHE quantitative studies with larger sample sizes are needed to assess the performance of HHE in children under 5 years.

LIMITATIONS

This was a single-center study that enrolled a small number of patients that focused on a very specific question of quantitative left ventricular function and structure in children using a newer handheld machine. The generalizability of our findings may be limited, and more studies are needed to ascertain the ability to accurately use the HHE for quantitative ventricular assessment.

One of the disadvantages of the HHE machine is lack of comprehensive measurement software. Images need to be exported to an offline DICOM platform for analysis, which may not be available in point-of-care and resource-limited settings. Our results however, demonstrate that subjective ventricular function can be accurately assessed using HHE when quantitative measurement is unavailable.

The study was performed by a second-year pediatric cardiology fellow, so applicability to novice personnel for training may be limited. The HHE studies were performed under non-optimal conditions after the children were done with their standard echocardiograms. Therefore, winning their cooperation in most instances was challenging, which may have limited HHE image quality and worsened agreement.

CONCLUSION

The Lumify HHE machine demonstrates good correlation and agreement with standard TTE, even in children under 5 years of age. Given the known limitations of HHE, it may best be adapted for screening for focused cardiac assessment in resource-limited settings and should not be a substitute for a standard TTE.

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Fig 1.
Lumify ultrasound probe and phone interface

Fig 2.

a, b Comparison of concordance correlation coefficient (CCC) between standard transthoracic echocardiography (TTE) and handheld echocardiography (HHE) for left ventricular fractional shortening and ejection fraction in entire cohort.

Fig 3.
a, b Comparison of Bland – Altman plot of standard transthoracic echocardiography (TTE) and handheld echocardiography (HHE) for left ventricular fractional shortening and ejection fraction in entire cohort

Fig 4.

a, b Comparison of concordance correlation coefficient between standard transthoracic echocardiography (TTE) and handheld echocardiography (HHE) for left ventricular fractional shortening and ejection fraction in children under 5 years.

Fig 5.

a, b Comparison of Bland – Altman plot of standard transthoracic echocardiography (TTE) and handheld echocardiography (HHE) for left ventricular fractional shortening and ejection fraction in children under 5 years.

Table I

Basic demographics and standard transthoracic echocardiography (TTE) study indications

Demographics	N=60 (%, median, range)
Age (months)	94 (1-225)
Weight (kg)	23.1 (2.8 – 149)
Height (cm)	123 (49 – 188)
BSA ^a (m2)	0.89 (0.19 – 2.5)
Gender	
Male	40 (67%)
TTE^b indication	
Murmur	5 (8.3%)
Left-sided congenital heart disease	15 (21.6%)
Right-sided congenital heart disease	6 (10%)
Septal defects	12 (20%)
Muscular dystrophy	2 (3.3%)
Dilated cardiomyopathy	2 (3.3%)
Heart Transplant	6 (10%)
Others ^c	14 (23.3%)

^aBSA, body surface area^bTTE transthoracic echocardiography^cChest pain, abnormal ECG, family history of cardiac disease, Kawasaki disease, pulmonary hypertension

Table II

Agreement between standard transthoracic echocardiography (TTE^a) and handheld echocardiography (HHE^b) for left and right ventricular structure and function

Variable	Agreement (^c k) N=60	p-value
Left ventricular function	1.00	<0.001
Left ventricular structure	0.75	<0.001
Right ventricular function	1.00	<0.001
Right ventricular structure	1.00	<0.001
Pericardial effusion	0.66	<0.001

^aTTE transthoracic echocardiography

^bHHE handheld echocardiography

^ck Kappa statistic

Table III

Agreement between standard transthoracic echocardiography (TTE) and handheld echocardiography (HHE) for fractional shortening and left ventricular ejection fraction measurement for all participants and the subset of children ≤ 5 years of age

Variable	No of patients	TTE, mean (^c SD)	HHE, mean (SD)	Agreement (95% ^d CI)
All participants				
Ejection Fraction	55	61 $\pm$ 5.7	60.1 $\pm$ 4.6	0.81 (0.72 – 0.90)
Fractional shortening	55	37.1 $\pm$ 6.0	36.8 $\pm$ 5.4	0.82 (0.73 – 0.90)
Children ≤ 5 years				
Ejection Fraction	21	60 $\pm$ 5.1	59.9 $\pm$ 4.2	0.79 (0.63 – 0.96)
Fractional shortening	20	37.1 $\pm$ 5.4	36.6 $\pm$ 4.6	0.59 (0.31 – 0.88)

^aSD standard deviation

^bCI confidence interval