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ORIGINAL RESEARCH ARTICLE

Feasibility of patient-performed lung ultrasound self-exams (Patient-PLUS) as a potential approach to telemedicine in heart failure

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Abstract

Aims Patient-performed lung ultrasound (LUS) in a heart failure (HF) telemedicine model may be used to monitor worsening pulmonary oedema and to titrate therapy, potentially reducing HF admission. The aim of the study was to assess the feasibility of training HF patients to perform a LUS self-exam in a telemedicine model.

Methods and results A pilot study was conducted at a public hospital involving subjects with a history of HF. After a 15 min training session involving a tutorial video, subjects performed a four-zone LUS using a handheld ultrasound. Exams were saved on a remote server and independently reviewed by two LUS experts. Studies were determined interpretable according to a strict definition: the presence of an intercostal space, and the presence of A-lines, B-lines, or both. Subjects also answered a questionnaire to gather feedback and assess self-efficacy. The median age of 44 subjects was 53 years (range, 36–64). Thirty (68%) were male. Last educational level attained was high school or below for 31 subjects (70%), and one-third used Spanish as their preferred language. One hundred fifty of 175 lung zones (85%) were interpretable, with expert agreement of 87% and a kappa of 0.49. 98% of subjects reported that they could perform this LUS self-exam at home.

Conclusions This pilot study reports that training HF patients to perform a LUS self-exam is feasible, with reported high self-efficacy. This supports further investigation into a telemedicine model using LUS to reduce emergency department visits and hospitalizations associated with HF.

Keywords Heart failure; Lung ultrasound; Telemedicine; Patient education

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Introduction

Heart failure (HF) affects over 5 million Americans with 550 000 new patients diagnosed every year. Annually, HF costs over $33 billion, with an estimated $20 billion spent on over 1 million annual hospitalizations. Acute HF (AHF) is also the number one Medicare discharge diagnosis that leads to readmission within 30 days.[1,2] Studies have identified risk factors for increased mortality, the presence of AHF phenotypes, and the efficacy of acute treatment and secondary prevention.[3,4] Hospital readmission is associated with increased costs and mortality. While guideline-directed medication therapy has been shown to be effective in reducing mortality, this has not translated into a reduction in hospitalizations.[5]

Home telemonitoring models have had mixed success in reducing hospitalizations in HF patients. These models evaluate self-reported symptoms, weight change, as well as blood pressure and heart rate changes, to trigger further escalation of care.[6,7] Changes in these variables are often insensitive and non-specific, which may be a major limitation in the detection of early signs of AHF.[8–10]

Several studies have shown that elevations of intracardiac pressures are specific, early events in the transition from chronic HF to AHF. Elevations in left atrial pressure may be the earliest sign of AHF, leading to pulmonary congestion and rising pulmonary artery pressures. The HOMEOSTASIS study pioneered a management approach guided by left atrial pressure assessment via an implantable device. This study showed that medication titration to lower left atrial pressures were feasible, sustainable through the median study period of 25 months, and associated with improvements in patient symptoms.[11] Studies using implantable pulmonary artery pressure monitors in a telemedicine model, show similar promise in the ability to titrate medications to meet pressure goals, leading to reductions in hospitalizations. For example, the CHAMPION study, using an implantable pulmonary artery pressure device in subjects to guide medication titration, showed a reduction in admissions by 43% and mortality by 57%, even accounting for patients on appropriate GDMT.[12–14]

Similarly, the development of pulmonary oedema is initially subclinical and directly correlated with these intracardiac pressure elevations. Lung ultrasonography (LUS) has demonstrated high accuracy in the detection of pulmonary oedema, with overall sensitivities and specificities above 90% reported in several studies.[15] Importantly, there is a dose–response relationship to the number of B-lines and affected lung regions and the amount of pulmonary congestion. Several studies show a reduction in the number of B-lines in AHF patients from initiation of treatment to improvement, admission to discharge, as well as in patients pre- and post-haemodialysis.[16,17]

Specific aims

With the ability of LUS to indirectly and non-invasively assess for elevated left atrial and pulmonary artery pressures, the study authors sought to assess the feasibility of training patients to perform a LUS self-exam that may be integrated with a home-based telemedicine model for HF management.

Methods

Study design

The patient PLUS study was a single site, prospective, pilot study conducted between August 2019 and February 2020, to determine if HF patients could be trained to perform a four-zone LUS self-exam. The study was approved by the Olive View-University of California, Los Angeles (UCLA) Medical Center Institutional Review Board. Informed consent were obtained from each patient prior to study enrolment.

Study setting

The emergency department of a public safety net hospital, which serves a culturally and economically diverse population, was the recruitment site.

Selection of participants

Patients with a history of HF were screened for eligibility by the research team on weekdays from 8 am to 12 am. The treating physician assisted with determining study eligibility. Patients were excluded from the study if they were younger than 18 years, older than 65 years, non-English or non-Spanish speakers, pregnant, incarcerated, had acute distress or altered mental status, declined to participate, or had a physical limitation to performing a LUS self-exam (e.g., visual disturbance).

Study intervention

All enrolled patients were first interviewed by a research assistant for demographic information, such as age, gender, preferred language, familiarity with tablet or smartphone technology, personal use of ultrasound, and last educational level attained. Relevant clinical information related to their HF was also extracted from their medical records. They then underwent a fifteen-minute training session featuring a video in their choice of Spanish or English (Supporting information, *Video S1*). All training materials, including the video and questionnaires, were reviewed for appropriate cultural sensitivity and basic health literacy by the research team, which consisted of native speakers of both English and Spanish.

Training content covered the rationale for patient-performed LUS as part of an integrated home-based telemonitoring system, and its potential use to guide HF treatment. Subjects were trained to use a low-frequency transducer on lung exam preset, with the indicator pointed cephalad, on four lung zones (right lateral, right anterior, left anterior, and left lateral). They were instructed to record 6 s video clips of each zone. In addition, participants were instructed to recognize and troubleshoot common pitfalls, such as rib shadowing artefacts (*Figure 1*). While the instructional video served as the primary method of training, the research assistant and a member of the clinical team were available if needed to answer any other questions during the training.

The ultrasound system consisted of a Butterfly iQ ultrasound transducer (Guilford, CT, USA) attached to an Apple iPad tablet (Cupertino, CA, USA), and featuring the Butterfly Cloud server-based image archival system. The tablet was

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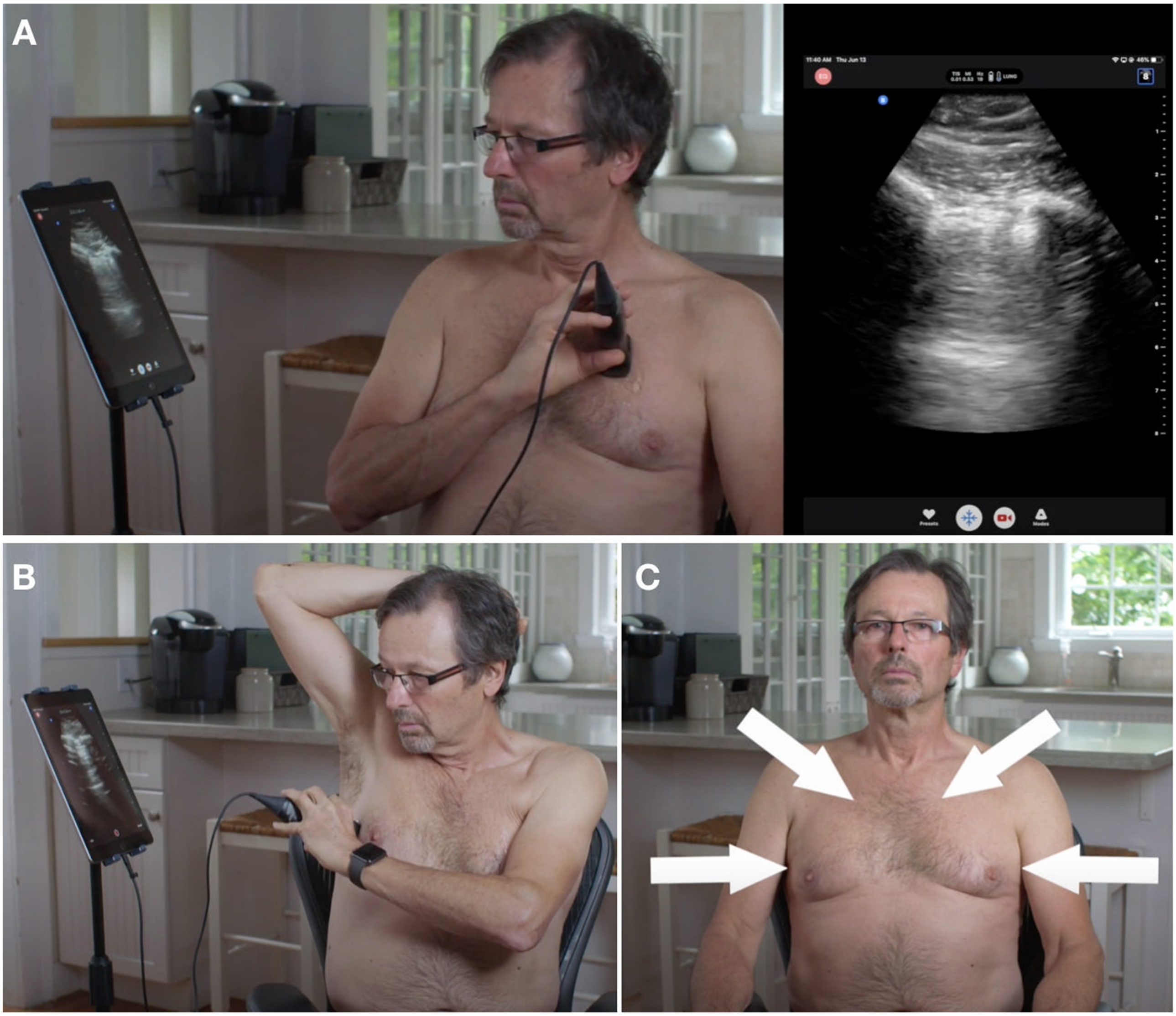
Figure 1 Lung zones in study protocol. These screenshots of an actor from our educational video show a left anterior (LA) zone being obtained with an image from the handheld ultrasound machine (A). A right lateral (RL) zone is being obtained (B), and the approximate location of all four zones in the lung ultrasound self-exam (C).



mounted to a stand to allow participants to use both hands during the exam.

After completion of training, the participant was asked to perform the same four-point LUS self-exam. To simulate a home environment in which participants will have access to a training video, participants were allowed to replay any portion of the training video at any time during the exam. However, the clinician and the research assistant were not available to assist.

After exam completion, each participant was asked to complete a survey that included questions regarding the training and exam, as well as their self-efficacy in performing the exam at home.

Exam review

Each LUS self-exam was stored in the above-described cloud server. A call schedule of randomized pairs of experts was assigned to each day of enrolment. A pool of six experts was available, all board-certified emergency physicians with an additional 1 year of post-residency fellowship training in point-of-care ultrasound, including experience with image acquisition and interpretation of at least 100 LUS exams. Immediately after each exam, two experts were notified via text messaging to log into the cloud-based PACS and to assess whether each of the video clips of the four lung zones met the criteria for interpretation. Studies were considered interpretable if they met all three of the following criteria: presence of at least one intercostal space, a visceral-parietal pleural interface, and the presence of A-lines, B-lines, or both. Investigators' assessments were blinded from each other. If there was disagreement between the two experts, a third expert blinded to their assessments was asked to assess the disputed exam for interpretability.

Outcomes

Descriptive statistics were calculated, including the proportion of subjects with one, two, three, and four lung zones deemed interpretable. In addition, the proportion of individual lung zones that were deemed interpretable was calculated.

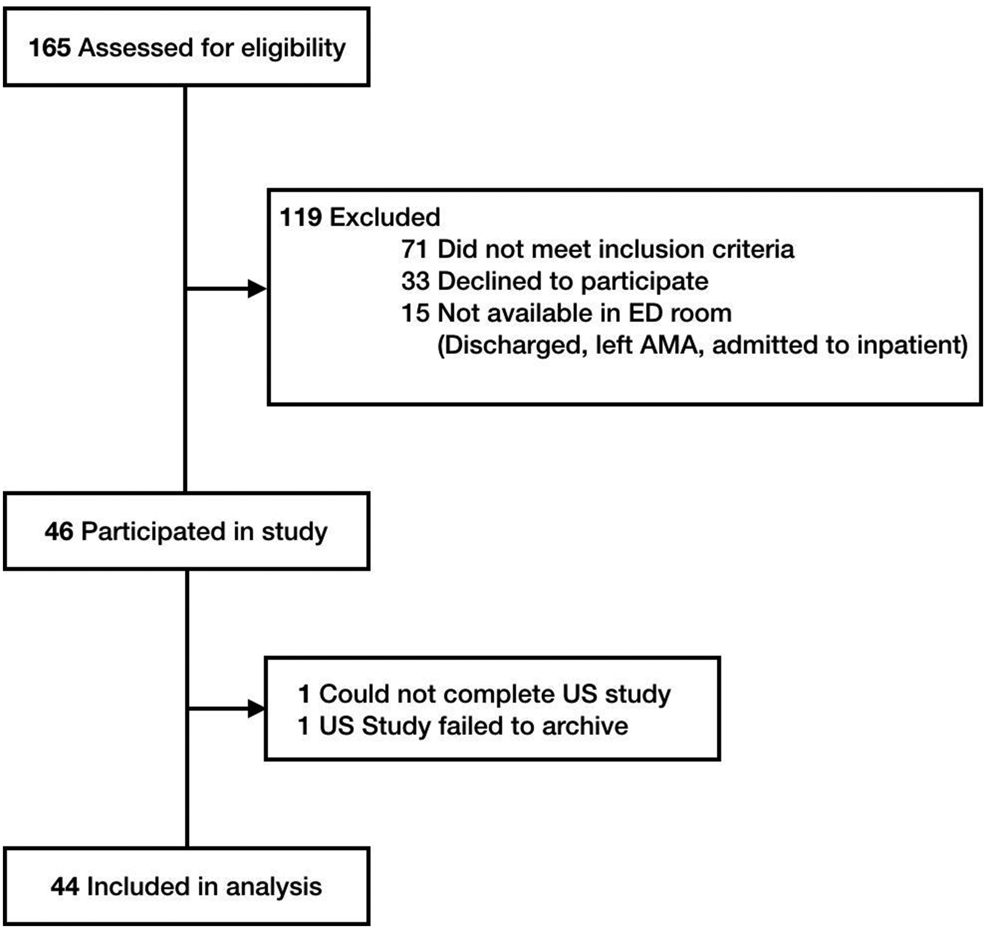
Agreement between experts was calculated for all studies as well as by lung zone. Interrater reliability was calculated using Cohen's kappa statistic.

Questionnaire data consisting of various measures of self-efficacy and their relative proportions were presented using a diverging stacked bar chart.[18]

Results

Of 165 potential subjects screened, 79 subjects met inclusion criteria and were available to participate. Of these eligible subjects, 46 subjects gave written informed consent and were enrolled in this study. One subject refused to complete the study, while video clips failed to archive for another subject. Therefore, data from 44 subjects were included in the analysis (*Figure 2*). There were twice as many male subjects (68%), and the median age was 53 years. In terms of HF characteristics, the median ejection fraction was 30%, 59% had a New York Heart Association (NYHA) classification III or IV, and 30% had an ischaemic aetiology of HF. Sixty-eight per cent of subjects presented with symptoms and/or signs

Figure 2 Patient PLUS CONSORT flow diagram. Patient PLUS indicates patient-performed lung ultrasound; CONSORT, Consolidated Standards of Reporting Trials.



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of worsening HF. Fifty-nine per cent of subjects had at least two of the following comorbidities: diabetes mellitus, hypertension, chronic kidney disease, or cerebrovascular accident. Thirty per cent reported Spanish as their preferred language, and 70% had a high school level education or below (*Table 1*).

A total of 176 ultrasound video clips were obtained from 44 subjects. Eighty-six per cent of subjects performed self-exams in which at least 3 of 4 lung zones were interpretable, with 61% able to obtain all four zones that were interpretable. Overall, 150 of 176 video clips (85%) were interpretable, with right anterior zones having the highest proportion of interpretability (98%), while right lateral zones had the lowest proportion (75%) of interpretability (*Figure 3*).

The two experts agreed in assessment of interpretability in 153 of 176 studies, for an overall agreement of 87%. Of the 23 studies that required a third expert to assess for interpretability, 11 studies were deemed interpretable and 12 deemed not interpretable. Agreement was highest in the right anterior zone (91%), followed by left lateral (89%), right lateral (86%), and left anterior (81%) zones. The calculated Cohen's kappa statistic was 0.49.

Subjects reported high self-efficacy in their ability, indicated as 'probably or definitely yes', to perform the ultrasound exam (98%) and their or a family member's ability to perform the exam at home (98%). All subjects reported that they definitely were willing to perform this ultrasound exam, or have a family member perform the exam on them, at home (*Figure 4*). In terms of difficulty associated with the self-exam, 20% reported some difficulty obtaining a good window, especially lateral windows (7%), and a minority had difficulty with recording the clips on the tablet device (7%) (*Table 2*).

Table 1 Demographic characteristics (n = 44)

Subject characteristics	Number (%)
Male	30 (65%)
Age (median, range)	53 (36–64)
Ejection fraction (median, range)	30% (10–65%)
NYHA Class III or IV	26 (59%)
Ischaemic aetiology of HF	13 (30%)
Presenting with symptoms of worsening heart failure	30 (68%)
History of diabetes mellitus	22 (50%)
History of hypertension	29 (66%)
History of chronic kidney disease	20 (45%)
History of cerebrovascular accident	4 (9%)
With ≥2 comorbidities	26 (59%)
Spanish as preferred language	13 (30%)
Last educational level attained	
Elementary or less	10 (23%)
Junior high	6 (14%)
High school	15 (34%)
Some college	8 (18%)
Bachelor's degree or higher	5 (11%)
Current use of smartphone or tablet?	38 (86%)
Every used an ultrasound before?	1 (2%)
If yes, how many times have you used?	6–10

HF, heart failure; NYHA, New York Heart Association.

Discussion

This is the first study to report the feasibility of training HF patients to perform a LUS self-exam. Our results suggest that select patients with HF are able to perform their own LUS studies after a brief training session. Many factors support further development of this approach. First, this past decade has seen a rapid adoption in telehealth visits, which has been accelerated by the COVID-19 pandemic. The use of patient LUS self-exams in a virtual visit allows providers to glean valuable patient information beyond the physical exam.[19] Second, advances in technology have significantly reduced the cost, and improved the portability and compatibility of handheld ultrasound units. The per unit cost of many handheld ultrasound machines is less than US $5000, which is a fraction of implantable cardiac monitoring devices.[20] Lastly, artificial intelligence has helped to enhance diagnostic accuracy by increasing objectivity and reliability in semi-quantitative measures such as left ventricular systolic function and the number of B-lines.[21]

While our study results are promising, there are important issues related to patient-performed LUS self-exams that warrant further investigation, including patient selection, appropriateness of training protocols, optimization of LUS protocols, and integration into an appropriate disease management programme.

Study population

Our study participants were largely self-selected, with 31 of 79 (42%) of eligible study participants declining to participate. In this pilot study, we also recruited study subjects younger than 65 years old, to increase the likelihood of smartphone and tablet literacy, as evidenced by the 86% of subjects who reported current smartphone or tablet use. However, our study demographics reflect a lower socio-economic status than the national population, with greater than 70% reporting a high school level of education or lower, and one-third reporting Spanish as their primary language, compared with less than 40% reporting high school education or less and 14% reporting Spanish as their primary language in the US Census.[22] Our study population had clinical characteristics similar to other HF studies, including a median ejection fraction of 30%, NYHA Class II, and the presence of similar comorbidities.

Despite these factors, our study participants performed well in their LUS self-exam. In addition, nearly all subjects rated their training experience and self-efficacy in performing serial self-exams highly and expressed interest in performing these ultrasound self-exams in the home.

While this study did not incorporate validated instruments for self-care, such as the European Heart Failure Self-care Behavior Scale or Self-care Heart Failure Index,

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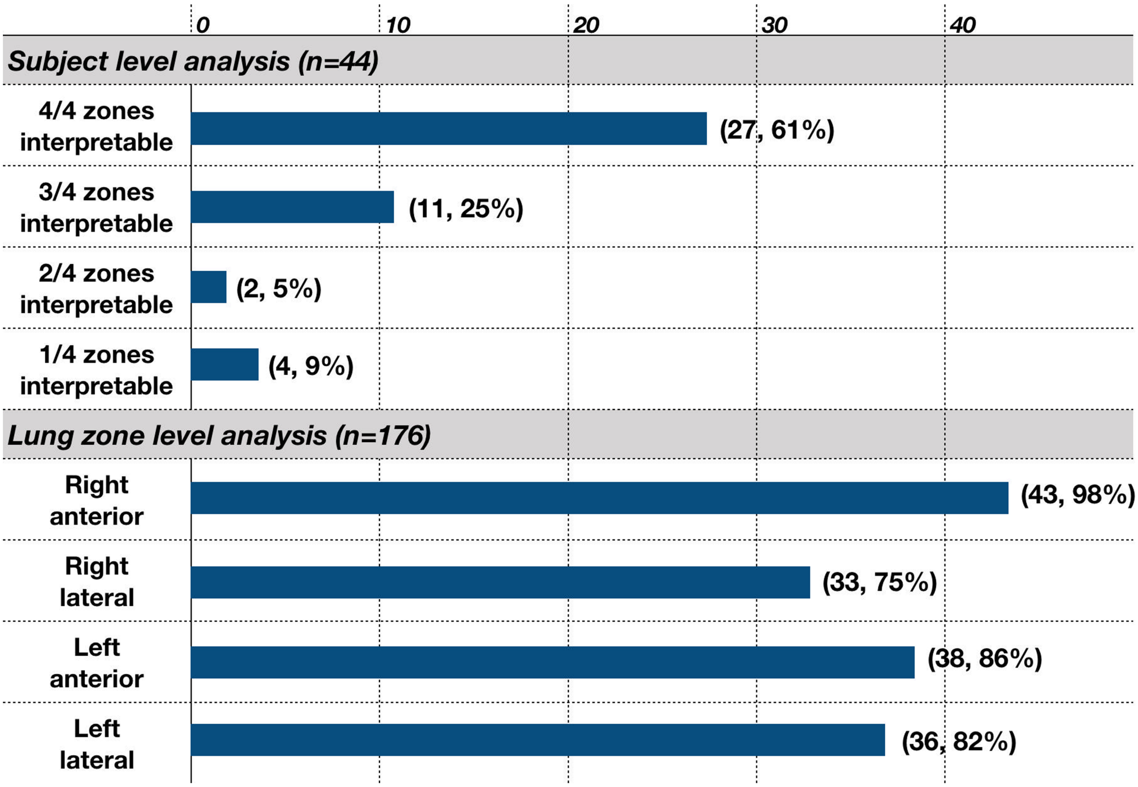
Figure 3 Interpretability of lung exams by subject (top) and by lung zone (bottom). Subject level analysis describes the number and percentage of subjects that have 'X' number of four total lung zones that were interpretable. Lung zone-level analysis grouped by the number and percentage of studies involving the specified lung zone that was deemed interpretable.



recognizing these psychometric properties, along with familiarity with technology, are likely determinants of their ability to successfully perform LUS.[23] Future work incorporating patient ultrasound self-exams will benefit from selecting patients (or their caregivers) that are motivated in self-care and with mental acuity appropriate for ultrasound training.

Image acquisition

LUS has been successfully taught to novice physician sonographers, nurses, and paramedics, as well as respiratory therapists.[24] Each group has demonstrated that after a brief educational intervention, they can perform similarly to experts in image acquisition and interpretation. These results suggest that LUS requires minimal feedback and direction in optimizing image quality. Based on our and prior study results, teaching learners to quickly recognize rib shadowing as well as the visceral-parietal pleural interface is feasible, regardless of their educational level or whether they have medical training.

In our study, the lateral lung zones had the lowest proportions for interpretability, with 75% of right lateral and 82% of left lateral zones deemed interpretable, compared with 98% for right anterior and 86% for left anterior zones. A post-hoc review of the lateral zone studies that were not interpretable showed a high proportion of liver and cardiac structure images. This was also seen in many of the non-interpretable left anterior studies. This reflects a limitation in our training video, which did not cover the sonographic appearance of either structures or techniques to avoid imaging these structures. Due to concerns of training a lay population in performing a LUS self-exam, our study group excluded this content to streamline training and to improve skills retention. However, this content may be included in future studies that incorporate a stepwise training method that features multiple videos and/or sessions.

In contrast to prior LUS studies performed by non-physicians, our study only assessed our subjects' ability to acquire interpretable LUS. We did not assess subjects' ability to interpret their LUS. There may be a role for training patients to self-interpret, as recognition of worsening findings may prompt patients to improve their self-care. However, we envision this approach to be similar to other telemedicine models that incorporate remote biosensor devices, which incorporate robust communication and clinician-directed titration of therapy to achieve optimal measurements.

Figure 4 Participant perceptions regarding ability to perform LUS. In this diverging stacked bar chart, negative responses are reflected as negative percentages to the left of 0%, and positive responses are reflected as positive percentages to the right of 0%.

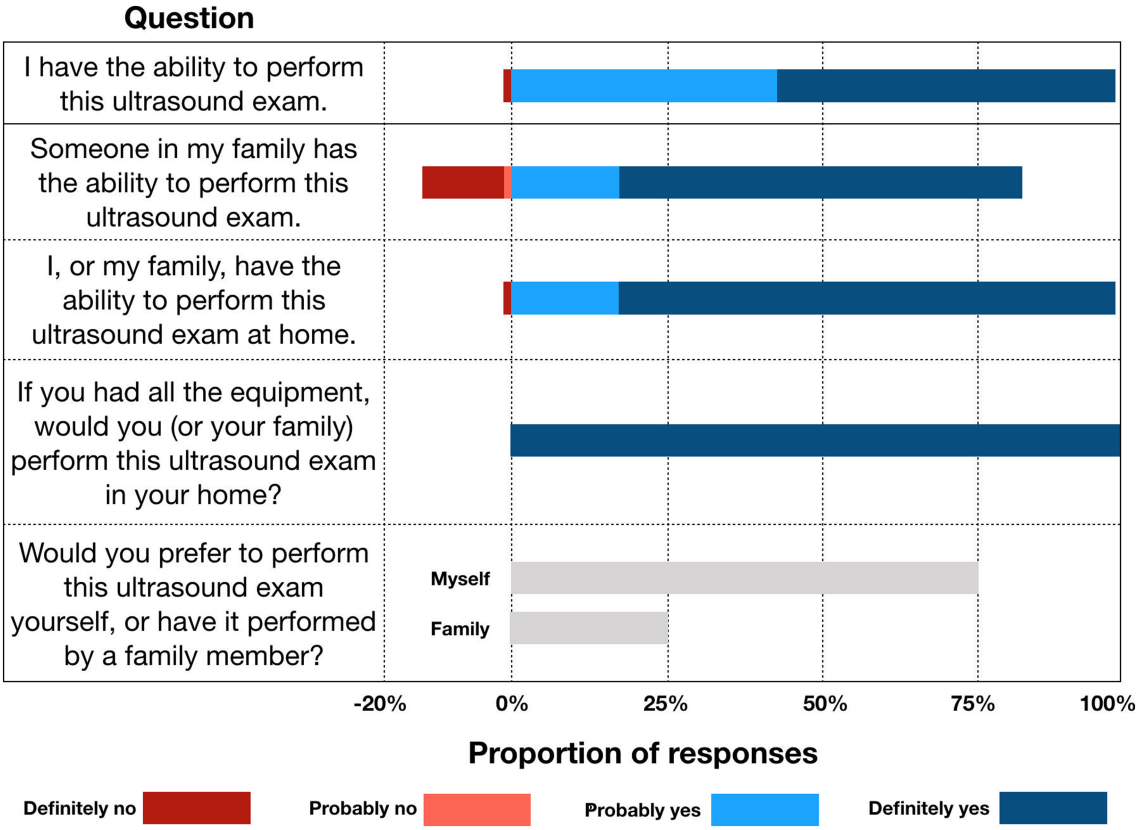


Table 2 Subject feedback on difficulties encountered in lung ultrasonography (n = 44)

	Number (%)
No comment	16 (36%)
'Nothing' or 'It was easy.'	11 (25%)
Difficult to identify a good window	9 (20%)
Recording the clips/use of tablet	3 (7%)
Imaging lateral windows	3 (7%)
EKG leads in the way	2 (5%)

EKG, electrocardiography.

Study protocol

Our study used a four-lung zone protocol that balances high diagnostic accuracy for pulmonary oedema with technical ease, with the latter consideration important for serial exams performed by non-medically trained individuals. This technique is based on a four-lung zone method, which has been shown to have similar discriminatory power in demonstrating changes in the number of B-lines on patients undergoing stress echocardiography as Volpicelli's eight-lung-zone method as well as Jambrik's 28-lung-zone method. In fact, Scali *et al*. conclude that 'the time-consuming 28-S scan can be conveniently replaced with the 4-S scan… with no significant loss of information'.[25] The HF Association of the European Society of Cardiology recommends a 28-point LUS protocol in which <15 B-lines as the goal for medication titration in AHF. However, this likely is unrealistic for home telemedicine-based HF management programmes.[26] Studies of clinic patients with HF suggest that ≤3 B-lines in 5 or 8 lung zones is associated with up to three-fold to four-fold reduction in readmissions. In a randomized clinical trial, Rivas-Lasarte *et al*. demonstrated that medication titration using serial eight-lung-zone ultrasounds in an outpatient setting was associated with an almost 50% reduction (with a hazard ratio of 0.52) in the primary composite endpoint of urgent visit, hospitalizations, or death, during a 180 day follow-up period, as compared with usual care.[27]

However, more studies need to evaluate the threshold change in B-lines associated with an increase in left atrial pressures in patients with early AHF, as well as the optimal balance between reliability of patient self-exams over an extended period and the ability to detect early increases in B-line associated with AHF.

Limitations

This was a small, single-centre study, which limits the study's generalizability. As discussed previously, our younger study population and high study refusal rate indicate a very selective study population. However, our study population's clinical characteristics, and specifically HF severity, were similar to other studies involving HF patients. In addition, our study population had lower educational attainment than the national average, and their ability to perform LUS suggests that training is feasible for many HF patients with higher educational attainment and facility with technology. Additionally, subjects enrolled in this study were assessed once in their LUS self-exam. While they reported high confidence in their ability to perform the same LUS at home, we did not assess their ability to reliably perform the exam over a follow-up period. Prior studies have shown that patients are able to consistently perform tasks like assessing their blood pressure or blood glucose at home reliably, but further work needs to assess whether this applies to LUS self-exams. Similar to prior interventions involving serial biometric measurements, patient PLUS study investigators stress that patients likely to benefit from this approach involving serial LUS, should meet criteria involving cognitive and social factors. Future studies should explore the ability of a wider set of HF patients, including those who are older, to perform a similar LUS protocol at home. Such studies should also be conducted in a longitudinal manner, to ensure that the skills from such training can be maintained.

Another potential source of bias in this study may be that experts were not blinded to the purpose of the study. Although they were blinded to interpretations by each other, the desire for a successful outcome may have biased their interpretations. However, in the 23 studies when the two experts disagreed, the third expert reported an equal proportion as interpretable and uninterpretable, which supports the use of this protocol to mitigate this bias.

Also, while there was high agreement (97%) between experts, there was only moderate interrater reliability according to Cohen's kappa statistic. The kappa statistic can underestimate true agreement in studies when the experts are well-trained, and the evaluation rubric or definition is clear. McHugh writes, 'if raters are well trained and little guessing is likely to exist, the researcher may safely rely on per cent agreement to determine interrater reliability'.[28]

Lastly, home ultrasound devices are currently not available for consumer use. Therefore, despite feasibility, this study currently has limited relevance. However, as telehealth continues to advance, innovative technologies that help clinicians to obtain important data from patients to guide treatment remotely will be paramount. Many ultrasound and health technology companies are already beginning to explore consumer-accessible products.[29]

Conclusions

With the development of disease management programmes to prevent hospital readmission for AHF, there has been mixed success in demonstrated clinical outcomes.[30]

While serial measurements of blood pressure, weight, and symptoms prove insensitive, recent studies involving home medication titration using implantable cardiac monitoring devices show promise in reducing ED visits and hospitalizations, as well as mortality. This study supports further investigation of patient-performed LUS, which is a non-invasive alternative to implantable cardiac monitoring devices. Interval worsening of LUS exams, as interpreted by clinicians, could prompt patients to titrate home medications. Clinician-directed repeat LUS exams via remote teleguidance, along with assessment of patient symptoms, may indicate clinical improvement.

This model, similar to outcomes described by studies involving serial haemodynamic measurement using implantable devices, could lead to reductions in emergency department visits and hospital admission for AHF. In addition, this model's relatively low cost and non-invasive approach may increase access to more patients with HF. However, further investigation should focus on patient selection, training of LUS to promote reliability, and validated home-based LUS protocols that are integrated into HF disease management programmes.

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Conflict of interest

All study authors certify that they have no affiliations with or involvement in any organization or entity with any financial interest in the subject matter or materials discussed in this manuscript.

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Supporting information

Additional supporting information may be found online in the Supporting Information section at the end of the article.

Video S1. Supporting Information.
Training video in English.
Training video in Spanish.

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