

Quantifying the Amount of Training Needed for Novice Ultrasonographers to Become Proficient in Measuring Left Ventricular Mass Index

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Abstract

Introduction: Undiagnosed, or masked, hypertension may occur in up to a third of patients with normal clinical blood pressures. Masked hypertension could be detected by measuring left ventricular mass index (LVMI) using point-of-care ultrasound as it directly correlates with ambulatory blood pressures. This study was designed to determine how much training is needed for a novice to develop proficiency measuring LVMI.

Methods: This is a pilot prospective cohort study comparing an instructed novice learner group to an expert control assessing improvement in LVMI using limited echocardiography. The scans took place at the University of South Carolina School of Medicine Ultrasound Institute. The novices were two PGY-3 family medicine residents and two medical students. Three attending physicians and one cardiology ultrasound technician served as expert ultrasonographers. Each novice completed a minimum of 30 scans on volunteers.

Training utilized self-directed online modules and a group training lab involving real-time feedback from an expert while scanning volunteers. Then the novices completed individual blinded volunteer scanning with an expert proctor. The average of the three expert ultrasonographer measurements were used as the control during this study.

Results: LVMI Deviation was plotted as a function of the number of scans attempted and fit to a linear regression model. According to the model, novices would need to attempt greater than 35 scans to approximate the expert's measurements.

Conclusion: Our data suggest that it is possible for novices to accurately perform point-of-care ultrasound to measure LVMI after 35 supervised examinations. This is well within the reach of most practicing primary care physicians. Confirmatory studies will be required.

Keywords: Left Ventricular Mass Index; Ultrasound

Introduction

About 1 of 3 U.S. adults (70 million) have high blood pressure. Only about half have their high blood pressure under control [1]. 34% of patients with normal clinic blood pressures may actually have masked hypertension detected on ambulatory blood pressure monitoring [2]. Masked hypertension is defined as a patient that has normotensive or pre-hypertensive blood pressures in clinic/ambulatory setting, but would have an abnormal ambulatory blood pressure. It is important to make the diagnosis of masked hypertension early, because when discovered these patients are more likely to have already suffered end organ damage such as vasculopathy, retinopathy or left ventricular hypertrophy. Currently, ambulatory blood pressure monitoring is the recognized gold standard for detecting masked hypertension.

Ultrasound can be used to measure left ventricular mass index (LVMI) which is linearly correlated with average blood pressure on ambulatory blood pressure monitoring. Bedside LVMI measurement could potentially serve as a surrogate for ambulatory blood pressure monitoring [3,4].

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Ultrasound used at the point-of-care has become an increasingly useful tool. However, ultrasound is only effective with an operator who has gained the necessary skills to use it as well as interpret the data obtained. Point-of-care ultrasound studies suggest novices can be trained toward proficiency in certain techniques [5].

The minimal number of supervised exams to become proficient at LVMI assessment is currently unknown. We attempted to elucidate this in our study by tracking a group of novice learners' improvement in accuracy of LVMI measurement. By comparing their measurements to that of an expert sonographer our plan was extrapolate the number of exams that would be needed to approach the accuracy of an expert.

Methods

This study was used as a pilot prospective cohort study that the Palmetto Health Institutional Review Board reviewed and granted exempt status. Funding was provided by a grant from the Richland Memorial Hospital Foundation for the total project cost which was \$5,750.

21 volunteers were randomly selected from the educational ultrasound model program at the University of South Carolina Ultrasound Institute. Volunteers in this program range from college students to retirees, and information on volunteers' health or medical condition was not available. It is worth noting they are not excluded from the program based on being known to have pathology or for being difficult to scan. For the purposes of this study, only the name, weight and height of the volunteers involved were recorded. No other personal or demographic information was obtained.

Insufficient data existed to determine the sample size that would be needed to document achievement of proficiency by novice sonographers. The American College of Emergency Physicians' guidelines recommend 25 - 50 prior to independent performance based on consensus opinion. Thus, we decided on an arbitrary number, (thirty scans), in this range as the goal number of scans to be performed [6].

A group of medical students and residents who had minimal prior exposure to ultrasound were selected to be the group of novice sonographers. The novice group consisted of two third year family medicine residents and two third year medical students. One of the third-year residents had never used an ultrasound. The second third year resident completed a 3-week ultrasound elective 1 year prior to the study, where there were multiple scans obtained, but only 10 scans consisted of cardiovascular scans. The two medical students attend the University of South Carolina School of Medicine where the Ultrasound Institute has been integrated in their curriculum. As first and second year medical students there are multiple lab days designated for practicing obtaining scans, however neither medical student had acquired > 20 cardiovascular scans. All of the scans obtained by the two medical students were completed one year prior to the study. They collected data across six ultrasound sessions spanning November 2015 - February 2016. The novice group had minimal exposure to ultrasound technology between these scheduled sessions. Parasternal Long Axis (PLAX) Scans were collected from a pool of 21 models (7 males and 14 females) in a double blinded manner and scanned in different sequences to minimize procedural bias.

Expert physician sonographers were recruited from the teaching faculty at the University of South Carolina School of Medicine. Two of these experts were physicians who completed a point-of-care ultrasound fellowship. The third completed several courses in ultrasound, had performed over 500 cardiac ultrasounds and was credentialed by the facility to independently perform them.

A skilled sonographer was recruited to obtain the "gold standard" measurements. The skilled sonographer was a Registered Diagnostic Cardiac Sonographer with over seven years of experience.

Left Ventricular Mass Index (LVMI) was calculated and subtracted from the corresponding Gold Standard LVMI per model to yield a Left Ventricular Mass Index Deviation (LVMI Deviation) according to the methods laid out in this study. Average LVMI Deviation was calculated by averaging each novice ultrasonographer's obtained LVMI Deviation at the corresponding scan number. Statistical analysis of the collected data included generating multiple linear regression models. Our linear regression model building process found that a linear relationship between our outcomes and scan number was reasonable.

Experimental Protocol/Study Design

The study was performed at The Ultrasound Institute at the University of South Carolina School of Medicine. The study began in October 2015 with the novice group first completing a set of self-directed online modules from the Society of Ultrasound in Medical Education, <http://www.susme.org/learning-modules/learning-modules>. The content validity of the set of self-directed online modules was assessed by expert ultrasonographers. The SUSME has several tools that are used in training medical personal in the use of ultrasound. The online modules that applied to the study were labeled under Physics and Cardiac. The Physics section had three lectures that applied to our research that took a little over 30 minutes to complete. The Cardiac section also had three lectures that took approximately 30 minutes to complete. The novices were given one week to complete the online modules. They were not restricted in how many times they could watch the videos.

After completion of the online modules, the novice group met with one of the expert ultrasonographers for limited hands-on ultrasound training at the Ultrasound Institute. During that time, there was a brief lecture on cardiac echocardiography as well as hands-on instructional training with a GE logiq i3S-RS Transducer (GE Healthcare, Little Chalfont, Buckinghamshire, United Kingdom) and two randomly selected volunteers. In order to not possess any bias at the start of the study all the novices were given the same instructions on modules to complete as well as attend the same cardiac lecture and practice on the same number of models supervised by the expert ultrasonographer. During the initial lecture by the expert ultrasonographer specific topics included obtaining the parasternal long axis view (PLAX), pitfalls in obtaining accurate measurements and the risk associated with left ventricular hypertrophy. There were two initial volunteers. At no point in the study was there any discussion on specific pathologies versus normal individuals when measuring the left ventricular mass index on the volunteers.

Prior to the data collection, each volunteer was assigned one study ID number to be used throughout the study that correlated with their collected measurements obtained by the skilled ultrasonographer. The first scanning session for data collection was performed November 2015. At this session, the volunteers were assigned unique experiment ID numbers. The heights, weights, and genders of each model were also recorded. This information was stored in a securely locked cabinet behind several locked doors. This information was never conveyed to the novice group. The novice group reported to the Ultrasound Institute one hour prior to each data acquisition session to set up each of the two rooms.

Each experimental room at the Ultrasound Institute was prepared to have three volunteers at a time. Room setup consisted of securing a disposable large blue drape on the walls above each of the volunteers' beds to blind their identities. A gown and disposable white drape on each bed were utilized to blind the volunteers from trainees and only allow visualization of the areas to be scanned. The models were not present in the room during the set-up period or the break down period. The only interaction between the novices and the volunteers occurred during the skilled session, when the volunteers were draped. A GE logic-E portable laptop ultrasound unit was turned on, the GE logiq i3S-RS Transducer was selected and inserted, and the default "Cardiac" settings were selected on the machine. Blank forms to record the names and collected measurements were distributed at the front desk on the first day.

Once set-up was completed, the novice group vacated from the examination area to a separate secured room behind closed doors to blind the identity of the volunteers as they entered the examination area. The expert ultrasonographers assisted the volunteers in the examination room if the need arose. Prior to beginning the experimental scans, the expert ultrasonographers ensured that each model signed in at the front desk with their study ID numbers.

After the patients were blinded and ready, the experts then retrieved the novice group from their secured room to begin data collection. The novice groups were divided into two groups of two. While one group was scanning the volunteers, the other group kept track of timing. The two groups alternated between keeping time first and scanning patients across each scan session.

Two large rooms were used as opposed to individual exam rooms in an effort to respect the agreed upon 2 hours per skilled lab day of the standardized models and ultrasonographers. Data collection timing was strictly enforced as follows: scan time, personalized feedback

and switch time (switching from one patient to the next) were allotted 5 minutes, 4 minutes, and 1 minute respectively. Adding the additional time and space of switching from one exam room per patient was deemed unnecessary for our particular study.

During the study, each of the two rooms had three volunteers. Data acquisition per room totaled 30 minutes with two rooms scanned for a total of one hour per novice group. Scan sessions therefore lasted for a total of two hours. It was the responsibility of the novice group to find the cardiac window, collect LVMI measurements, and record their measurements. Collected LVMI measurements were in accordance with the ASE standard and included Left Ventricular End Diastolic Diameter (LVEDD), Posterior Wall Diameter (PWD), Interventricular Septal Diameter (IVSD). Devereux's equation was applied to these collected values to calculate Left Ventricular Mass [7]. The left ventricular masses were indexed against the patient's Body Surface Area (BSA) to generate LVMI [6]. After finding the cardiac window and obtaining the LVMI measurements during the "scan time" window, the expert ultrasonographer would provide personalized feedback to the novice during the "feedback" time period. The feedback included suggestions for improvement, identified areas of strengths, and provided technique analysis.

Once the scan sessions were completed, the novice group returned to their secured locations and waited until all of the volunteers left the building. When all of the volunteers departed, the expert ultrasonographers provided a final 5 - 10 minute lecture of feedback to the novice group. After the feedback, the novice group would go to the examination rooms and clean all of the equipment change the drapes/sheets/gowns and prepare the rooms for the next scan session. The first rounds of scans were completed November 2015 and the second round of data acquisition was completed February 2016. The "gold standard" patient values for the study were collected by the skilled cardiac ultrasonographer in November 2015. The skilled ultrasonographer recorded three sets of LVMI measurements per patient which were then averaged as the gold standard. These measurements were recorded and withheld from all of the participants, including the expert ultrasonographers, until the completion of the skilled lab days. This information was securely stored within a locked cabinet behind several locked doors. The skilled sonographer was blinded to the results of the novice sonographers as well.

Data Analyses

Data analysis was conducted through the utilization of R (Foundation for Statistical Computing, Vienna, Austria). We were interested in determining predictors for absolute percent deviation between the trainee's estimate of LVMI and that of the cardiology ultrasound technician. The predictor of interest was scan number. Although the two subsets of trainees (Medical Students and Residents) have different levels of clinical training, their pre-experimental exposure to ultrasound technology and Parasternal Long Axis Cardiac Scans were essentially equivocal. For this reason and recognizing that this is a pilot study with a limited number of trainees, we did not include level of clinical training into the regression model. In future studies, we will include trainee predictors such as level of medical training, gender, age, and other identified variables. We did not consider scan-fixed effects, such as time of scan random effects, for this pilot study but will also include these effects in future studies. Predictors for both trainee and patient (both of whom contributed multiple observations) also were taken into consideration in our regression models but were not of primary interest. In developing a regression model, we used linear mixed effect modeling to test whether a patient random effect was needed. Because the random intercept for "patient" was zero, we constructed standard multiple linear regression models that treated trainees and patients as fixed effects. We also included a quadratic term for scan number in the model building process to test whether a linear relationship between our outcome and scan number was tenable.

Results

Our volunteer population had an average LVMI of approximately 70.00g/m² as determined by our skilled ultrasonographer which is within the gender-specific population ranges that are conventionally accepted as normal [7]. The four novices attempted a total of 142 scans for a cumulative average of 35.5 attempted scans per novice ultrasonographer. Administrative errors during the first scanning session limited the availability of the volunteers. This resulted in one novice ultrasonographer group completing three more scans than the other group.

The novice group failed to acquire an adequate cardiac window within the experimental timeframe 21 times during the 142 collected scans; these failures resulted from performance and/or technique errors and were not the result of technical errors or equipment mal-

function. For these 21 scans, the collected LVMI data were not included in the results analysis of this study but failure rate was recorded as the novices acquired more scans (Figure 4).

The final model was adjusted for trainee and had an intercept of 30.4 and a coefficient for scan number of -0.603 (-0.9595, -0.2465); the adjusted R² value for the final model is 0.1283 with p value of 0.001. These variables suggest an initial LVMI Deviation from Standard of 30.4% and a deviation regression by approximately 0.6% per attempted scan (Table 1). Patient-specific and Ultrasonographer-specific LVMI Deviation data were collected in an effort to track individualized novice ultrasonographer improvement. Each of the four novice groups noticed downward trends in their ultrasonographer-specific LVMI Deviation regressions as the number of attempted scans increased (Figure 1). Obtained LVMI Deviations varied more greatly between the individual novice group at lower scan numbers and was reduced at higher scan numbers (Figure 2). This apparent downward trend in LVMI Deviation from standard as scan number increased continued on a per-patient basis when combining the obtained values from each novice ultrasonographer. However, the per-patient regressions were not statistically analyzed as there was not enough data to form a statistically significant conclusion.

| Predictor | Estimate | Std Error | P value |
|---|----------|-----------|---------|
| Intercept | 30.397 | 5.220 | < 0.001 |
| Scan Num. | -0.603 | 0.182 | 0.001 |
| Med Student 1 | 0.000 | 0.000 | < 0.001 |
| Med Student 2 | 2.420 | 5.295 | 0.646 |
| Resident 3 | 8.504 | 5.364 | 0.116 |
| Resident 4 | 15.190 | 5.405 | 0.006 |
| 95% Conf. Interval for Scan Num: (-0.9595, -0.2465) | | | |
| Adjusted R-squared value for Final Model: 0.1283 | | | |

Table 1: Final Multiple Regression Analysis Model Variables. Data analysis was completed through utilization of R [10].

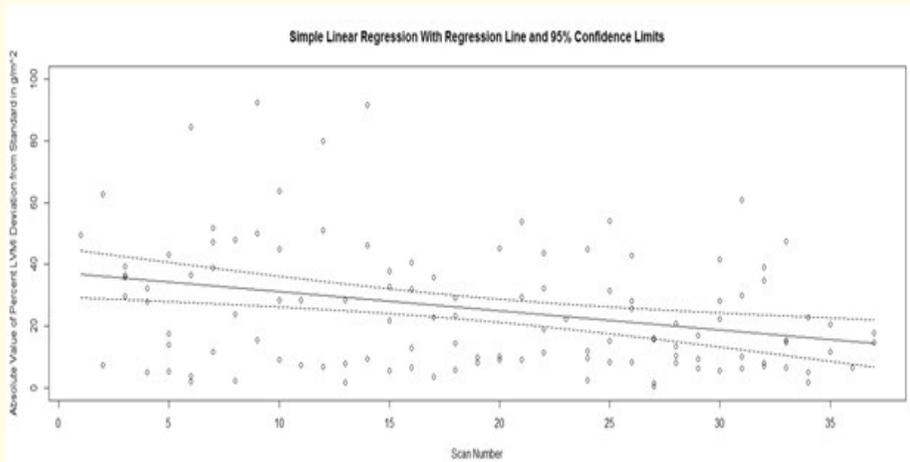


Figure 1: Linear regression model depicting downward trend in novice ultrasonographer’s experimentally obtained LVMI Deviation from Standard. The dotted lines above and below the regression line represent the 95% CI.

The overall ability of the novice group to obtain a suitable PLAX view cardiac window was also analyzed (Figure 3). Through the 142 attempted scans, there were 21 scans which failed to produce usable measurements. As the number of scan sessions increased, the average frequency of identifying an appropriate PLAX cardiac window to obtain LVMI measurements increased; consequently, the average

frequency of the novice group failing to obtain LVMI measurements for data analysis decreased (Figure 4). It is unclear if this subjective pattern is statistically significant as analysis was not performed due to limited data.

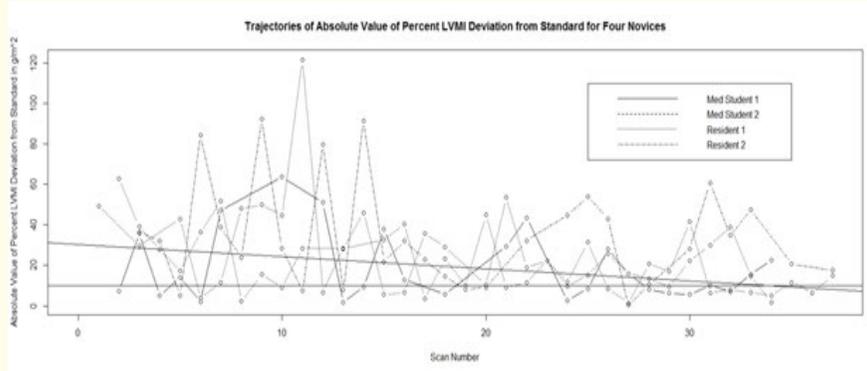


Figure 2: Differences between the four trainees in their ability to be within a 10% margin of error (the solid horizontal line). A higher degree of variability existed between the novices earlier in the study. The decreased amount of variability becomes most evident by comparing the data spread after scan number 20 and before.



Figure 3: Representative PLAX view with LVMI measurements as obtained by an expert ultrasonographer (A) and a novice ultrasonographer (B) during the study.

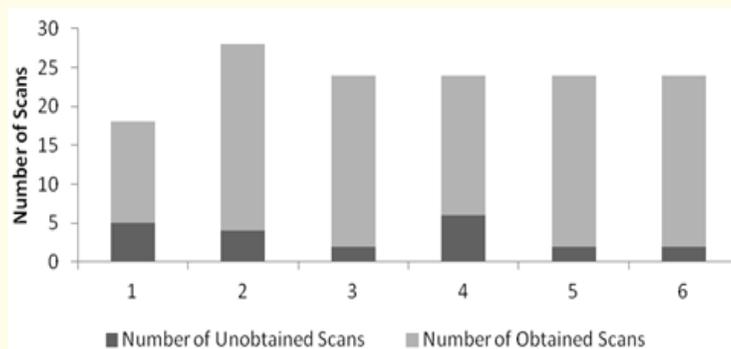


Figure 4: Stacked bar graph demonstrating the decrease in number of failed scans and increase in successful scan acquisitions per scanning session.

Discussion

The results of this pilot study indicate that beginner ultrasonographers can reasonably be expected to vary from a skilled sonographer by 30 - 40% above or below the standard after undergoing the training protocol identified above. This deviation from standard can be expected to diminish by approximately 0.6% per each additional scan. As a pilot study, we found that a robust self-study training protocol coupled with expert feedback enabled the novice group to approach skilled ultrasonographer measurements of LVMI; Moderate variation exists among the LVMI Deviation for each trainee but the variation decreased as attempted scan number increased. Because our novice ultrasonographers only completed an average of 35.5 scans, we were not able to show that they were able to reliably obtain an accepted variability of 10% from standard. This variability is evidenced by the increase in number of unobtained scans during session number 4 depicted in Figure 4. The increase in unobtained scans can be an indication that before 35 scans, the trainees cannot reliably obtain an adequate image that approximates the LVMI gold standard. It can be dangerous to extrapolate data from such a limited exposure pilot study, but statistically significant improvement was noted among the trainees. If novices note continual improvement beyond 35 scans, it is reasonable to expect trainees to start approximating LVMI gold standard after 51 successfully obtained scans.

There were several limitations that were identified by the completion of this pilot study; any future studies and/or any training protocols should take these limitations into consideration. Firstly, the model population used in this study was not an appropriate randomized subset of the general population. The model population was disproportionately female as many male patients were lost to follow up. There was no selection or exclusion process based on the presence of existing cardiac disease. In an effort to improve study logistics, this study was completed in a nonclinical environment concerning patient position and prepping. Volunteers blinding and draping may have hindered adequate window acquisition by the novice group, particularly at lower attempted scan numbers as the novices were still uncomfortable with the technology. For instance, female volunteers were not asked to completely disrobe and clothing undergarments were left on. This hindered appropriate cardiac window identification as their undergarments frequently required adjustment during the timed acquisition stage. Additionally, in the interest of completing the desired number of scans, the interactions were timed, which satisfied a secondary goal of the study which was to begin to develop a protocol that would fit the time restraints of a primary care physician already in practice to utilize this invaluable training.

Future studies would be to develop a large randomized control trial using point of care ultrasound to measure left ventricular mass index for screening left ventricular hypertrophy to improve patient outcomes compared to standard of care (24-hour ambulatory blood pressure monitoring).

While previous studies [8-10] have outlined the utility and feasibility of using handheld ultrasonography as part of a limited echocardiogram, none have looked at the ideal training and experience necessary to ensure competency with the technology and adequacy of the obtained measurements. This pilot study intended to help delineate the necessary components of a successful training program for novice ultrasonographers and answer specifically how many scans are needed to attain measurement accuracy.

Acknowledgements

Contributions

Richland Hospital Research and Education Foundation Grant-In Aid Award.

Poster/Podium Presentations

- **Poster Presentation**
 - Palmetto Health Medical Scholarship Day of Focus – April 22, 2016 – Third Place Recipients
- **Poster Presentation**
 - 2016 South Carolina South Carolina Medical Association Annual Meeting – April 30, 2016 – First Place Recipients

- **Podium Presentation**

- 2016 South Carolina AHEC Resident Scholarship Symposium – June 12, 2016 – Third Place Recipients

Disclosures

None.

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