Remotely Guided Ultrasound Among Non-Medical Personnel To Assess Normal Lung Parenchyma

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A. SPECIFIC AIMS

The aim of this study is to determine whether non-medical personnel, with no experience in ultrasound (US) use can effectively utilize the technology with remote guidance by expert assistance to assess for normal lung parenchyma among healthy volunteers.

B. BACKGROUND AND SIGNIFICANCE

US has become an increasingly utilized modality in the healthcare setting. Advances in US technology and a burgeoning field of research showing its efficacy has rendered US a crucial tool in such fields as emergency and critical care medicine. The portability and ease of use of US has led to its use in the fields of wilderness, polar and aerospace medicine as well. Portable US machines have been taken on mountaineering expeditions and launched to the International Space Station, at which times it has been used to diagnose high altitude pulmonary edema and monitor intracranial pressure among astronauts, respectively (Wimalasena et al 2013, Lerner et al 2016). Emergencies in remote environments such as space may necessitate the use of US by non-medical personnel, at which time the data gathered would be transmitted to medical professionals to be analyzed and upon which clinical decisions would be made. Small studies have shown the effectiveness of utilizing non-medically trained personnel in obtaining adequate US images for such evaluations as optic nerve sheath diameter and carotid artery dynamics (Martin et al 2012).

Extreme environments such as space, expose those in it to such risks as depressurization, which can lead to multiple lung pathologies such as pulmonary edema and/or pneumothorax (Galdamez et al 2017). In such circumstances, remotely guided ultrasound may prove crucial to quickly identifying such medical complications of extreme environments. This initial pilot study will determine the feasibility of using remotely guided ultrasound among non-medical personnel on healthy volunteers to identify normal lung parenchyma by identifying commonly used indicators of such (e.g. lung-sliding, a-lines). If the results of the study indicate that such operations are feasible, further investigations into whether non-medical personnel are able to identify lung pathologies among confirmed cases of such conditions as pulmonary edema or pneumothorax may be pursued.

C. RESEARCH DESIGN AND METHODS

1. Rationale/overview

This study will assess the feasibility of remotely guided US use by individuals without ultrasound training to assess for normal lung parenchyma in healthy volunteers (patients) and amongst themselves. The untrained operators (operators) will perform US examinations of the lung under the guidance of a medical professional (expert) with experience in ultrasound technique. During the first portion of the study, the professional will guide the operator step by step on how to conduct an US exam of the ‘patient’s’ lung. This simulation will be analogous to an untrained US operator assessing a potentially ill patient with the assistance of a remotely located physician.

The second portion of the study, during which time the participant will carry out an US exam on themselves, would be analogous to a lone patient in possession of US technology carrying out a self-examination under similar guidance of an expert. During both parts of the studye images will be saved and reviewed at a later time by an ultrasound expert to determine quality and clinical functionality in recognizing normal lung parenchyma. Images obtained by 'operators' will be compared against those obtained by US-trained clinicians (clinicians) captured from the same 'patient'. Real world examples of these scenarios would include an astronaut with respiratory distress after experiencing a rapid decompression event being evaluated by another healthy astronaut (or by themselves as in the second scenario) by US under the guidance of the flight surgeon at Mission Control.

2. Research Site

The study will be conducted at the Clinical Skills Center (CSC) at Stony Brook University School of Medicine (SBU)

3. Study sample

A convenience sample of 20 healthy volunteers will be recruited from the Stony Brook undergraduate campus to participate as 'operators' in the study. 'Patients' will be recruited from a pool of standardized patient models who regularly participate in activities in the CSC. 10 US-trained clinicians will be recruited from SBU.

4. Screening

Healthy volunteers will be recruited from the Stony Brook undergraduate campus. They will be screened for prior medical training, particularly regarding US technique. Those with any amount of US training and more than minimal medical/nursing training will be ineligible for participation.

5. Procedures

Volunteers will meet with study personnel in the CSC at SBU. Informed consent will be obtained from all groups ('operators', 'patients', 'clinicians'). A survey will be conducted to evaluate the subjects' prior experience in ultrasound. Subjects who qualify will continue to participate in the study.

The 'patient' will initially be evaluated by US by an expert and 'ideal' images will be captured and stored for later comparison against those obtained by 'operators'.

The 'operator' will be given an smart phone/table with video communication function and will be connected with the US 'expert', who will be located in a different room, physically and audibly out of range. For the first portion of the study, the 'expert' will instruct the 'operator' on how to conduct an US exam limited to the lung. Using the two-way video and audio communication through the video communication application, the expert will guide to the operator on how to utilize the US machine, where to place the probe, and how to capture and save images. The 'patient' will be instructed not to assist the 'operator' in any way. For the second portion of the study, the 'operator' will utilize the US machine to conduct a similarly limited lung exam on themselves, again with the assistance of the 'expert' but no other study personnel.

Finally, the ‘clinicians’ will carry out similarly limited lung exams on the ‘patient’, first without instruction from the ‘expert’ and then again under similar guidance as the previous portions of the study.
During all portions of the study, time to image capture will be measured by observing personnel. All captured images will be sent to expert reviewers at which time a quality score will be generated. Ultrasound experts will blindly evaluate images obtained from both untrained and trained groups. Using the 'Ultrasound Quality Scorecard', evaluators will assess the quality of the image obtained and the technique carried out to obtain the image. These quality and technique criteria include 'Discernable Lung Parenchyma', 'Presence of A-lines', 'Lack of Obstruction from Rib Shadowing', 'Correct Probe Selection', Correct Depth Setting', 'Correct Gain Selection'. For each criterion (both quality and technique), a binary 'Yes/No' score will be given. Total 'Yes' scores will be summed for each ultrasound exam (minimum 0, maximum 6), with the higher number of 'Yes' responses signifying a higher quality ultrasound exam. Each ultrasound exam will be scored by three separate experts, with the average of the three scores being reported as the 'Final Score'. Reviewers will be comprised of three experts in the field of US, all MDs who have received formal training in US and have at least 5 years of clinical US practice experience. Each captured image will be reviewed and scored by all three reviewers.

D. STATISTICAL ANALYSIS PLAN
‘Final Scores’ determined from the score sheets will be compared between the ‘operators’ and ‘clinicians’.
Mean scores of the two groups will be reported, with their respective standard deviations.
Student’s T-Test will be carried out to assess difference between the two groups.
All hypothesis testing will be carried out using two-sided 5% significance level.

E. FUNDING STATUS, DETAILS
This project will not receive any funding.

F. HUMAN SUBJECTS RESEARCH PROTECTION FROM RISK

Risk to Subjects/Adequacy of Protection Against Risks-
US is a safe and non-invasive diagnostic modality and poses no physical risk to participants in the study. Psychological risk is minimal but not absent, as a participant may discover abnormal lung physiology or pathology that may cause psychological harm.
Risk is minimal in this project, no additional protection against risk is necessary.

Potential Benefits of Proposed Research to the Subjects and Others/Importance of the Knowledge to be Gained-
There will be no benefits to participants involved in the study. We anticipate that this study will provide important information regarding the feasibility and utility of remotely guidance ultrasound use on patients in remote settings in the absence of trained medical personnel. The results of this study will contribute to a growing body of ultrasound research.

G. DATA SAFETY MONITORING PLAN (for more than minimal risk studies)

Unnecessary for this study

G. LITERATURE CITED

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