TRANSDUCER SELECTION IN THE SPEED AND QUALITY OF IMAGE ACQUISITION IN FAST EXAMS

Statistical Analysis Plan

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Background

The Focused Assessment of Sonography for Trauma (FAST) is a rapid point-of-care ultrasound exam performed on blunt and penetrating trauma patients who are too critically injured to be transported to a CT scanner. In performing this exam, time to acquisition of adequate images is crucial to clinical decision-making as patients undergoing this exam have a high probability of deteriorating if not intervened on appropriately.

Low-frequency ultrasound is used to image the abdominal cavity in these patients, using either a curvilinear transducer or a phased-array transducer. Both of these transducers are capable of acquiring the images necessary to interpret a FAST exam, but it has not been studied whether using one transducer instead of the other improves time to image acquisition or image quality.

In this study, we will recruit ultrasound operators (trained emergency medicine residents, faculty, or advanced practice providers) and healthy participants on which the ultrasound exam will be performed. We will ask the ultrasound operators to perform the FAST exam using different types of ultrasound transducers on the healthy test patients.

Study Outcomes

In this study, the following data will be collected:

- Baseline characteristics of each participant (demographic information, training level, prior experience with performing FAST ultrasounds if known)
- Time to completion for each FAST exam performed with a phased-array transducer and for a curvilinear transducer, from start to completion of the exam
- Technical quality of each of the four required views of the FAST exam (subxiphoid, right upper quadrant, left upper quadrant, and suprapubic view)

The primary outcome of this study is time to FAST exam completion. The secondary outcome is technical quality of the ultrasound images.

Arms of the Study

This study has two arms being compared. The first arm is the phased-array transducer arm, which collects the above mentioned outcomes for. The second arm is the curvilinear transducer arm. Each ultrasound operator will be randomized to one of the two arms to begin with. There will be no blinding of the participants or of the study investigators. After each participants completes their FAST ultrasound, they will cross-over to the other arm of the study. Thus, each participant will perform two FAST exams, one with each type of transducer.

Statistical Analysis

For the primary outcome of time to completion of the ultrasound exam, we will report descriptive statistics for each arm. We will report any differences between these descriptive statistics for each type of transducer. If there are enough participants in each subgroup to make meaningful comparisons, we may also report subgroup descriptive statistics based on the training level of the participants.

We will perform a t-test to analyze the two arms for differences in mean time to completion of each ultrasound. Additional subgroup comparisons based on the level of training of participants may be performed.

For the secondary analysis, Fisher's exact test will be used to determine if there is a statistically significant difference between the numbers of technically adequate for interpretation ultrasound exams performed for each arm. A numeric scale for quality of the images may also be used, and if so, a t-test to analyze differences in numeric scale rating of image quality between the two arms will be used.

Summary

Each participant will be randomized to one of two arms, where they will perform a FAST exam on a healthy volunteer for the purposes of determining if there is a difference in the time to completion or the imaging quality of a phased-array transducer or curvilinear transducer for this application.