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SHoC-ED 1

Executive Summary

What you need to know about the
SHoC-ED-1 Study.

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Executive Summary

The Sonography for Hypotension and Cardiac Arrest in the Emergency Department 1 (SHoC-ED 1) study is a multicentre randomized control trial, comparing outcomes in adult patients with hypotension or a raised shock index with and without a Point of Care Ultrasound (PoCUS) examination protocol. The study has been developed by the Atlantic Emergency PoCUS Research Group, to be co-ordinated out of the Saint John Regional Hospital in Saint John, New Brunswick, Canada.

1.0 Introduction

Patients who present to the ER (emergency room) with undifferentiated, non-trauma associated hypotension often have outcomes that are very dependent on quick and accurate diagnosis and intervention [3]. The ACES protocol (Abdominal and Cardiothoracic Evaluation with Sonography in Shock), provides a rapid focused ultrasound protocol for making or refining diagnoses in patients who present to the ER with this type of hypotension [3]. This will be the first study to compare the clinical outcomes of patients who are assessed with this PoCUS protocol as part of their initial workup to those of patients who are assessed without any intervention by ultrasound. The goal of this study is to determine if a PoCUS shock protocol enhances the patient's clinical outcomes, as measured by: 1) Significant change in diagnosis or recommended intervention 2) Frequency of unexpected diagnosis, 3) Patient 7 and 30-day mortality rate, and 4) Total fluid volume given while on ER floor.

Methods

Patient flow will be as follows:

- ER Staff identifies potential candidate, who meets the following criteria
 - ❖ 19 years of age or older
 - ❖ Systolic BP under 100 mmHg or Shock index greater than 1.0
- The staff member will then place a “patient flag” on the candidate's chart. This flag contains the inclusion criteria, exclusion criteria, and consent forms for the patient that must be completed prior to randomization.
- Physician sees patient flag when getting chart, and reviews below exclusion criteria:
 - ❖ Necessity of CPR or other advanced life support interventions before enrollment
 - ❖ History of significant trauma in past 24 hours
 - ❖ A 12 lead ECG diagnostic of STEMI
 - ❖ Mechanism of shock is clear (i.e. not undifferentiated shock)

- ❖ Previously known diagnosis from other hospital
 - ❖ Previously confirmed pregnancy
 - ❖ Vagal episode
 - ❖ Low blood pressure is not actually pathologic hypotension, but instead a normal variant or some other phenomenon.
- Patients meeting inclusion criteria, with no exclusion criteria, and consenting to the study, will be randomized to the control group (normal clinical assessment) or the PoCUS-guided group. In both control and intervention groups, a reassessment will be performed at 60 minutes.

This protocol is depicted in the following flowchart:

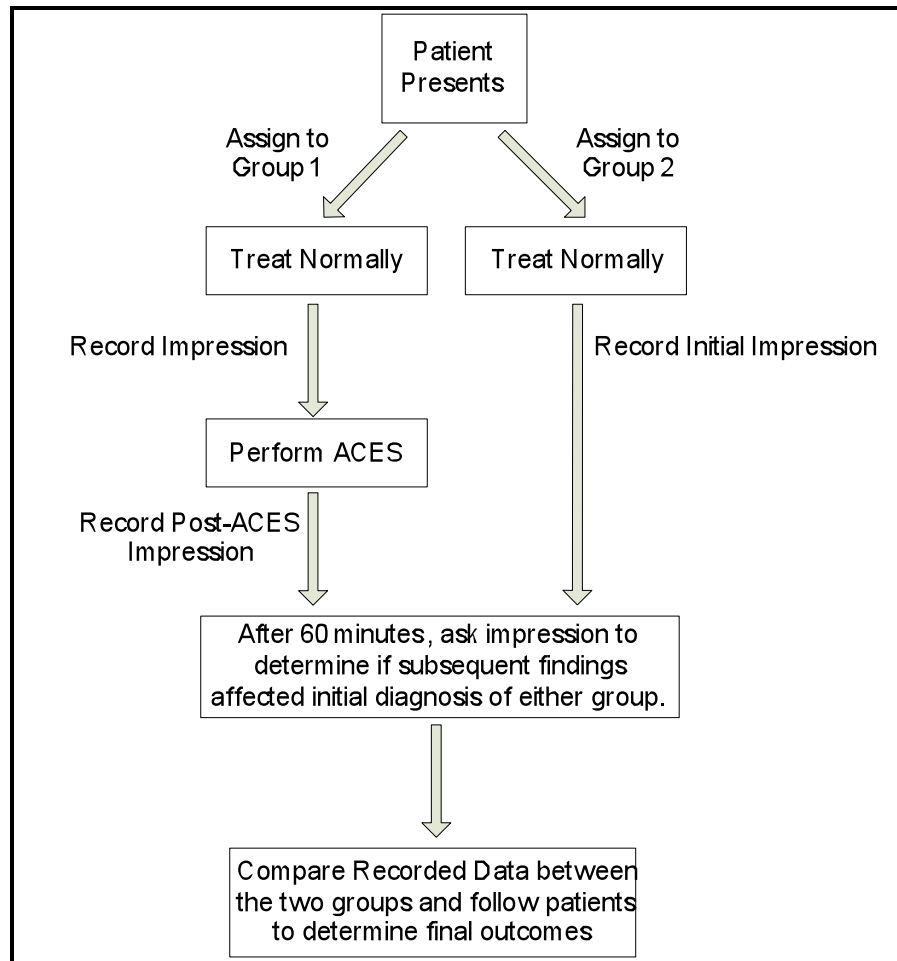


Figure 1: Protocol to be Followed by SHoC-ED 1 Study

Results

Chi-square analyses will be performed for 1) Significant changes in diagnosis/recommendations in intervention change, and 2) Frequency of unexpected diagnosis.

Conclusion

This randomized control trial will determine if a formal PoCUS protocol leads to improved clinical outcomes in patients who present to the ER with undifferentiated, non-trauma associated hypotension. It will also determine the frequency of major diagnosis changes in control and ultrasound groups. It will compare management incorporating the ACES protocol to management with no ultrasound at all.

Study progress and requirements

This section of the satellite package describes how study flow will occur (from study design to submitting a final paper), how a study participant will pass through the ER and how to go about filling out the forms associated with this trial. The forms themselves will accompany the “Satellite Package” that your site will be provided with should you choose to be a part of this study.

Study stages

1. Local ethics approval must be sought before data collection starts. We will assist by providing examples of successful REB/IRB forms.
2. Advertising the study: While the project is being reviewed by REB/IRB, other important study aspects can be completed. One of these aspects is study advertisement. Because patient identification will be done by the nurses (either in triage or when the patient presents in an ambulance), it is important that they are aware this study is going on. While the actual tasks performed by the nurses will be simple – blood pressure recording and review of inclusion criteria – it is important that they are aware the study is going on, so that they know to enroll a patient in the study (process discussed below).
3. Physician education: Another aspect of this study that can be completed while ethics is being sought is physician education. Although the ACES scan (the scan that is to be used in the SHoC-ED study) is only minimally more complicated than content covered the standard EDE-1 or introductory ultrasound course, the additional views can be difficult to master. In light of this, it is appropriate to teach the physicians who are going to be involved in the study how to perform the ACES scan before the study begins. For physicians without further training (EDE-2 / ECCU/ FOCUS) this has been achieved using a modular approach. The Saint John site trained its physicians through use of a powerpoint presentation as part of an ED rounds session, a hands on training session as part of the same presentation using healthy models, and by having study physicians shadow an ACES expert when a hypotensive patient presented to the ER. The powerpoint that was used in Saint John, as well as a copy of the Researcher Education Log that will be used to record how often and by what methods we educate our researchers are in the email that this package was sent with. This log is important in the case that our study is audited.
4. Patient enrollment: After adequate training has occurred, REB/IRB approval received, and ER staff are sufficiently aware of how the study will progress, data collection can begin.

- a. The first stage in data collection is patient identification, which will be done by the ER nursing staff. The nurses will record presentation blood pressure and pulse, as well as review inclusion criteria. To ensure that these are properly recorded and reviewed, a standardized form will be used (Patient Pre-Inclusion form, which can be found below). This form also acts as the consent form, which must be completed before randomization occurs.
 - b. When a patient is identified as being suitable for the SHoC-ED 1 study, the pre-inclusion form will be placed in the chart, which will be recognized by the treating physician. When the doctor begins assessment of the patient, exclusion criteria can be reviewed, and the brief consent form mentioned above can be explained/filled out. After this, the physician can retrieve the randomization envelopes from a convenient location(s) in the ER. At the SJRH, we've placed the pre-inclusion forms in triage rooms, as well as in the Charge Nurse's room.
 - c. The randomization envelopes will include the Case Report Form, which is the document where data will be recorded. CRFs have been constructed specific to both the control and the ultrasound arm of this study, and both are available below. It is important to note that not all of the information required by this study will be recorded on the CRF, but only the information that the physician is required to fill out as part of their ACES scan. The rest of the required information will be collected by a research coordinator through chart reviews, and will be entered into the excel spreadsheet attached to this email.
5. Results from satellite sites will be collected monthly. Although the actual physical documents gathered throughout the course of this study will be kept at your individual site at least until the study's end (and perhaps afterwards, depending on your ethics board's requirements), the updated excel spreadsheet with the month's results should be sent to the main researcher (James Milne), so that they can be entered into the master list. This will be the list that will be sent to a statistician for interpretation at the end of the study.

For further information contact

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