Title: EASiUR Trial: Efficient Anterior Shoulder Ultrasound Reduction Multicenter Prospective Randomized Trial

NCT #: NCT04820491

Document date: July 17, 2020

Document Type: Protocol and Statistical Analysis Plan

EASiUR Trial: Efficient Anterior Shoulder Ultrasound Reduction Multicenter Prospective Randomized Trial

Principal Investigator:
Jordan Tozer

Other Investigators:
David Evans, MD: Key Study Personnel
Jacob Wayman: Key Study Personnel

Institutional affiliations:
VCU Health
Cleveland Clinic Akron General

I. BACKGROUND AND SIGNIFICANCE

The shoulder joint is the most common joint requiring reduction by emergency physicians, accounting for almost 50% of all major joint dislocations.[1] This presentation amounts to roughly 200,000 emergency department visits each year. [2] The estimated incidence of shoulder dislocations in the United States is 23.9 per 100,000 person/year with male gender and young age being the two largest risk factors. [2] The current standard of care for this presentation is to identify the dislocation on both physical exam and X-ray and then confirm the success of reduction by physical exam and X-ray following reduction. X-ray imaging does expose the patient to radiation, although minimally when as compared to other radiation-based imaging. However it is now being recommended by one study that pre and post-reduction X-rays can be omitted to help decrease the length of stay, radiation exposure and overall cost. The recommendation is that X-ray can be replaced with the application of ultrasonography. [3] The aim of this study is to further assess the efficacy of point of care ultrasonography to diagnose and gauge the reduction success of shoulder dislocations in an emergency department setting.

With increasing availability and utilization of ultrasound, multiple studies suggest that this imaging modality can play an integral role in the diagnosis of and reduction confirmation for shoulder dislocations. [4-8] Studies assessing accuracy of diagnosis deemed ultrasound to be 100% specific and 100% sensitive. [9-10] A recent meta-analysis concluded that ultrasound is highly sensitive and specific for shoulder reductions, dislocations, and associated fractures. [9] Another study identified that diagnostic radiographs increased patient length of stay by 30 minutes. [11] The ease, efficacy, and timeliness of ultrasound has the potential to decrease the length of stay for emergency department patients. A WJEM systematic review recommended that "while the data is supportive of the use of ultrasound for the diagnosis of shoulder dislocation, further studies are needed prior to routine implementation. Future studies should compare the different techniques to determine which is most

accurate, record performance time for the ultrasound, include more data on posterior dislocations, include more data on fracture identification, and validate one of the above techniques with increased sample sizes". [8]

Overall, the utilization of point of care ultrasonography has been well studied and has recurrently shown to be useful and efficacious. The goal of this study is to expand on this literature as it pertains to utilization in the emergency department setting. The study will evaluate the impact of POCUS on length of stay, x-ray reduction, and satisfaction of patients presenting with suspected shoulder dislocation.

II. STUDY OBJECTIVE(S); INCLUDING SPECIFIC AIMS AND/OR HYPOTHESES

The primary objective of this study is to determine if there is any difference in the length of stay between patients with shoulder dislocation who are treated with traditional x-ray imaging for diagnosis and reduction confirmation and those that are treated with POCUS for diagnosis and reduction confirmation.

Hypothesis: The use of POCUS for shoulder dislocation and reduction confirmation will reduce the length of stay for ED patients.

The secondary objectives of this study include evaluating patient satisfaction, providing a cost analysis, time to diagnosis, confirmation of reduction, and volume of x-ray reduction.

III. METHODS

This study is a prospective, randomized, non-blinded evaluation of the use of ultrasound to diagnosis shoulder dislocation in emergency departments. The study population will consist of patients aged 18-65 that present to the VCU Emergency Department between August 1, 2020 and December 31, 2022 with suspicion of an uncomplicated shoulder dislocation.

Procedural Overview/Design:

1. Assess patient for enrollment. Apply inclusion and exclusion criteria (below).
2. Discuss Informed consent with patient. If patient consents, proceed to step 3.
3. Randomize patient with premade numbered envelopes stating standard of care or ultrasound protocol (description below).

A. Diagnosis of dislocation

1. Standard of Care (control): Order shoulder x-rays as felt necessary for standard of care of diagnosis of shoulder dislocation and reduction (portable XR versus done in radiology)

2. Ultrasound (experiment): No x-rays ordered. Initial evaluation with ultrasound; may also evaluate nearby areas for concern of fracture. Order x-rays after ultrasound as seen fit for other injuries of diagnostic uncertainty.

B. Shoulder reduction: Per standard of care
C. Confirmation of Reduction
   a. **Standard of Care (control):** Order shoulder x-rays as felt necessary for standard of care of reduction confirmation.
   b. **Ultrasound (experiment)**: Use ultrasound for reduction confirmation. No x-rays ordered unless ultrasound did not adequately confirm
D. Post-reduction care (sling, follow-up, etc.): Per standard of care

	Control Group	Experimental Group
Diagnosis of Dislocation	Standard of Care (x-ray)	Ultrasound
Shoulder Reduction	Per Standard of Care	Per Standard of Care
Confirmation of Reduction	Standard of Care (x-ray)	Ultrasound

B. Study Population:

Inclusion Criteria:

1. Patients who are 18 years of age or older; *and*
2. Present to the VCU Emergency Department between August 1, 2020 and December 31, 2022; *and*
3. Have clinical signs of uncomplicated shoulder dislocation; *and*
4. Agree to participation in the study; *and*
5. Provides a written consent to be included in the study.

Exclusion criteria:

1. Patients who have a level 1 or 2 trauma activation, and/or;
2. Patients who are pregnant, incarcerated, or unable to consent, and/or;
3. Patients who have a past medical history of shoulder replacement in dislocated shoulder; and/or
4. Provider Discretion

E. Assessment of Resources

1. Has sufficient access to the study population:
Emergency Medicine attending and resident physicians will perform the study. They will already be in the Emergency Department and therefore will be notified of a patient meeting inclusion criteria and immediately be able to complete study following consenting process.

2. Has sufficient time to conduct and complete the study:

This will be a long-term project in the emergency department. Not all ED physicians will be participating in this study. The resident physicians and a select group of attending physicians will receive a curriculum and conduct the study.

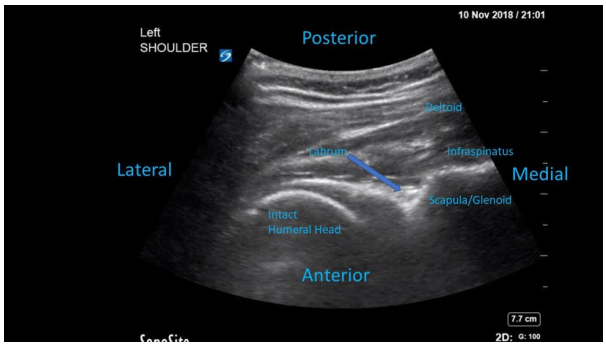
3. Has adequate qualified staff members to conduct the study:
All members of the protocol are CITI trained, and will be trained in the data abstraction process once they have been approved by the IRB to work on the protocol. The resident, as a physician, is qualified to read and interpret medical records, and to accurately abstract data and guide students to abstract data from those charts relevant to the study. Any residents or medical students interacting with patients will be trained by the PI in the appropriate procedures for consenting a patient.

4. Facility is adequate to conduct the study:
The facility is adequate to conduct both the prospective data collection component as well as the retrospective chart review. The requirements are technological, including the point-of-care ultrasound machine, probes, and CCAG owned computers for data abstraction and analysis.

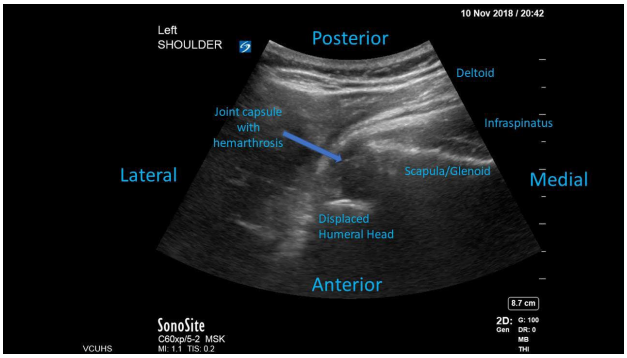
5. Staff has been adequately trained on the protocol and their specific research related duties:
The co-investigators will be trained on the objectives of the protocol, as well as where in the chart to locate the variables to be abstracted for the study prior to formally collecting data for the study.

D. Study Procedures
- Image acquisition: Shoulder Dislocation
  - Usually curvilinear probe (footprint and depth)
  - Posterior view: Set probe just inferior to scapular spine
  - Follow the scapula LATERALLY; Look for the humeral head
    - If NOT Dislocated, the humeral head should be at same depth as scapula/glenoid
    - ANTERIOR dislocation will appear with head displaced away from probe relative to glenoid on the screen (in the anterior direction)
    - POSTERIOR dislocation with appear with head towards probe relative to glenoid on the screen (in the posterior direction)

Anterior Shoulder Dislocation



Same shoulder status-post reduction. Note head now aligned with scapula/glenoid



IV. DATA COLLECTION

Patient list and partial data will be sourced from the electronic medical record. Data abstraction will be completed in EPIC and billing.

Demographics
Age
Gender
Weight
Race
Insurance Status

Past Medical History
Prior shoulder dislocations

Study Procedure Data
Group assignment (control or experimental)
Experience of person performing ultrasound if in experiment group
- Minimal: Minimal prior experience, sufficient training completed
- Moderate: Prior shoulder ultrasound experience
- Expert: Fellowship trained, or significant prior exposure

Type of sedation/block/analgesic given
- Intra-articular? Nerve block? Procedural sedation?

Technique of shoulder reduction performed
Number of x-rays ordered
If ultrasound group, what x-ray was ordered and why
- Portable?

Findings
Type of dislocation (anterior versus posterior)

Fractures identified
Missed diagnoses

Timeline in ED
ED LOS
LOS after being roomed
Time to discharge
Time the resident physician spent in room
Time to perform ultrasound
Diagnosis of dislocation/initial evaluation
Confirmation of reduction

Patient satisfaction survey

	1 (Extremely Dissatisfied)	2 (Dissatisfied)	3 (indifferent)	4 (Satisfied)	5 (Extremely Satisfied)
Were you satisfied with the overall care you received today?					
Did you comfortable with your wait time while in the Emergency Department?					
Do you feel you got imaging of your shoulder in a timely fashion?					
Do you feel your physician discussed your diagnosis appropriately?					
Do you feel your physician updated you often enough?					
Do you feel that your physician explain all procedures in a way that was clear and you could understand?					

Cost Analysis
Not necessary as patient's ultrasound exam will not be billed.

Issues/misdiagnosis
Any concerns by patients or participants will be addressed by PI as soon as possible. We do not anticipate any issues or missed diagnoses.

V. DATA ANALYSIS

A. Sample Size Considerations
   1. This study will be a multicenter study. Due to the infrequent nature of this injury, the data collection phase will take place over several years.

B. Statistical Methodology

Descriptive statistics will be used to evaluate demographic variables. Categorical variables will be reported as n (%) and will be analyzed by chi-square or Fisher's exact test as appropriate. Normally distributed continuous variables will be reported as mean and standard deviation and will be analyzed by student's t-test. Non-normally distributed continuous variables will be reported as medians and interquartile range and analyzed using Mann-Whitney U test. The primary outcome of difference in average length of stay in the ED will be analyzed by paired students T-test. Secondary outcomes will be evaluated by paired student t-tests as well. Statistical analysis will be performed using SPSS® Software (version 24; 2016) and the level of significance set at p value less than 0.05.

VI. DATA AND SAFETY MONITORING PLAN (if applicable)

This data will be stored behind the VCU firewall and on Redcap and if any transfer of data is necessary this will be done on RedCap. Once the data is collected the data will be de-identified for analysis.

VII. STUDY LIMITATIONS

Potential selection bias based on the inclusion/exclusion criteria may reduce external validation. Theoretical user error could cause misinterpretation in ultrasound findings; this is a low risk, and has built in protection. It may be a challenge to get IRB approval across all institutions Missing data or incomplete data for specific fields may also present error.

VIII. ETHICAL CONSIDERATIONS

A. *Informed Consent (Applies to studies using human subjects)*

Only patients who are able to provide written consent will be included. Those patients who are able to provide consent will be provided a brief explanation of the study and given the opportunity to ask questions, and ultimately provide or decline written consent. Ultrasound is a common modality used to evaluate minor musculo-skeletal issues in routine patient care in the emergency department and poses no harm to patient as it uses no ionizing radiation. The conduct of this research will present no more than minimal risk to the patient.

B. *Risks and Side Effects (Applies to studies using human subjects)*

Ultrasound evaluation poses minimal risks and side effects to patients. If the ultrasound evaluation is insufficient it could interfere with patient care activities increasing the risk for morbidity and mortality as a result of delayed treatment as above.

C. *Benefits to Subjects (Applies to studies using human subjects)*

Potential benefits to patients in the experimental arm of this study include decreased length of stay and decreased exposure to ionizing radiation.

D. *Costs to Subject*

The patient will be responsible for the cost of their care, whether it is an ultrasound or an x-ray.

E. *Compensation to Subject*

There will be no compensation for subjects.

F. *Provisions for vulnerable subjects*

There will be no vulnerable subjects in this study as per inclusion criteria.

G. *Subject Privacy and Data Confidentiality*

C. Privacy of Participants:

Privacy of participants will be protected by the following: Patient information will be stored in secure software and on VCU computers and mobile devices.

D. Confidentiality of Data

As described above, all data will remain on-site at VCU, maintained in a secure environment and password protected. Data will be summarized and presented in aggregate form for reporting purposes. Dissemination will include a report to VCU. A manuscript will be drafted for peer-review publication.

3. Plan for Record Retention and disposal

Records will be stored for 3 years following completion of the study and then destroyed.

4. Limits to Confidentiality

There is no anticipated limit to confidentiality.

IX. PLANS FOR DISSEMINATION OF FINDINGS

Findings will be disseminated via a peer-reviewed publication and through presentations. Finding will be presented in aggregate form, without comparison or specific identification of institutions within the VCU Hospital Network. Specifically, the results will be presented to the local stakeholders and at least one national conference. Staff members working on this project have a strong track record of publishing manuscripts in peer-reviewed journals and presenting at statewide and national conferences. In addition, a comprehensive report of the study findings will be created and made available to VCU stakeholders.

X. REFERENCES

Janitzky AA, Akyol C, Kesapli M, Gungor F, Imak A, Hakbilir O. Anterior Shoulder Dislocations in Busy Emergency Departments: The External Rotation Without Sedation and Analgesia (ERWOSA) Method May Be the First Choice for Reduction. *Medicine (Baltimore)*. 2015;94(47):e1852. doi:10.1097/MD.0000000000001852

[2] Zacchilli MA, Owens BD. Epidemiology of shoulder dislocations presenting to emergency departments in the United States. *J Bone Joint Surg Am* 2010; 92:542.

[3] Kendall JL, Hoffenberg SR, Smith RS. History of emergency and critical care ultrasound: the evolution of a new imaging paradigm. Crit Care Med. 2007;35(5):S126eS130.

[4] Blakeley CJ, Spencer O, Newman-Saunders T, et al. A novel use of portable ultrasound in the management of shoulder dislocation. *Emerg Med J*. 2009;26(9):662-3.

[5] Halberg MJ, Sweeney TW, Owens WB. Bedside ultrasound for verification of shoulder reduction. *Am J Emerg Med*. 2009;27(1):134.e5-6.

[6] Mackenzie DC, Liebmann O. Point-of-care ultrasound facilitates diagnosing a posterior shoulder dislocation. *J Emerg Med*. 2013;44(5):976-8.

[7] Beck S, Chilstrom M. Point-of-care ultrasound diagnosis and treatment of posterior shoulder dislocation. *Am J Emerg Med*. 2013;31(2):449.e3-5.

[8] Gottlieb M, Russell F. Diagnostic Accuracy of Ultrasound for Identifying Shoulder Dislocations and Reductions: A Systematic Review of the Literature. *West J Emerg Med*. 2017;18(5):937–942. doi:10.5811/westjem.2017.5.34432

[9] Abbasi S, Molaie H, Hafezimoghadam P, et al. Diagnostic accuracy of ultrasonographic examination in the management of shoulder dislocation in the emergency department. *Ann Emerg Med*. 2013;62(2):170-5.

[10] Lahham S, Becker B, Chiem A, et al. Pilot study to determine accuracy of posterior approach ultrasound for shoulder dislocation by novice sonographers. *West J Emerg Med*. 2016;17(3):377-82.

[11] Shuster M, Abu-Laban RB, Boyd J. Prereduction radiographs in clinically evident anterior shoulder dislocation. *Am J Emerg Med*. 1999;17(7):653-8.

XI. APPENDICES

A. Instruments, rating scales, consent forms, etc.