THE EFFECT OF SURGICAL STABILIZATION OF RIB FRACTURES ON CLINICAL AND PATIENT-CENTERED OUTCOMES: A RANDOMIZED CLINICAL TRIAL

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Population:	Adult trauma patients admitted to MHH TMC with severe blunt chest trauma
Number of Sites:	One site: MHH TMC
Study Duration:	Prospective; 18 months
Subject Duration:	Duration of admission to MHH TMC + 6-month follow-up

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GENERAL INFORMATION

Randomized clinical trial with a parallel observational arm comparing the effectiveness of surgical stabilization of rib fractures to usual care in trauma patients with severe thoracic trauma. Study will evaluate for differences in clinical metrics as well as patient-centered outcomes. Prospective enrollment over 18 months with a 6-month follow-up period is intended.

ABSTRACT

BACKGROUND: Rib fractures are the most common injury in blunt thoracic trauma and are a major source of morbidity and mortality. In severe cases, usual care with pain medications is often insufficient to prevent respiratory failure, pneumonia, and tracheostomy. Additionally, patients may go on to have pain that far exceeds their hospitalization and limits their ability to return to work. Surgical stabilization of rib fractures (SSRF) is a promising intervention that may decrease morbidity and time to return to work.

PROBLEM: Few high-quality studies have been performed that compare SSRF to usual care. Of these, even fewer have considered patient-centered outcomes following discharge. Furthermore, SSRF is often performed late as salvage therapy rather than early as a preventative intervention.

STRATEGY: To address this gap in knowledge, we propose to perform a randomized trial with a parallel observational arm of blunt trauma patients with multiple rib fractures comparing the effectiveness of early SSRF to usual care on clinical and patient-centered outcomes. The primary endpoint is hospital length of stay. Secondary endpoints will include clinical outcomes (incidence of respiratory failure, pneumonia, tracheostomy, mortality) and patient-centered outcomes (health status and time to return to work).

BACKGROUND INFORMATION

Approximately 350,000 people suffer rib fractures in the United States each year, with more than one-third requiring hospitalization.[1,2] Severe chest trauma may result in prolonged mechanical ventilation, post-traumatic pneumonia, long-term disability, and death. Morbidity and mortality increase with each fractured rib, and an inflection point seen at six or more rib fractures.[3] Usual care typically consists of breathing exercises and pain control, often including opioids. However, despite usual care, rib fracture patients are more physically disabled at 30 days post-injury than a reference group of chronically ill patients and lose 70 days of work or usual physical activity.[4]

An alternative to usual care is surgical stabilization of rib fractures (SSRF). Surgical stabilization of fractures is a well-established tenet of orthopedic surgery that is proven to facilitate bone healing, decrease the mobility of fractures, decrease pain, and improve mechanical function. Decreasing the mobility of fractured ribs has been shown to improve pain in small studies, and it may decrease the consumption of opioid pain medications.[5] However, because the SSRF literature is plagued by industry bias and low-quality studies, the indications for the procedure remain unclear and it is rarely performed.

Evidence for SSRF in Flail Segments: In three small, randomized trials of patients with flail segments (radiographic findings of ≥3 consecutive ribs with ≥2 fractures), SSRF has been shown to decrease the duration of mechanical ventilation, the incidence of pneumonia, the duration of intensive care, and overall medical costs.[6,7,8] Similarly, recent systematic reviews and meta-analyses of these studies have supported the reduction in duration of mechanical ventilation, pneumonia, and tracheostomy.[9,10] However, these trials and meta-analyses are limited by study heterogeneity, narrow inclusion criteria, and small sample sizes ($n < 50$). For these reasons, SSRF has not been widely adopted in the flail segment population.

Evidence for SSRF in Non-Flail Chest Wall Injury: Most patients with severe chest trauma do not have a flail segment. Rather, patients may have multiple consecutive fractures or fractures with displaced fragments. Although the use of SSRF for non-flail chest indications is an attractive option, only low-quality evidence exists to support its use.[11,12] This paucity of evidence is further highlighted by a recent systematic review in which only three studies of SSRF in non-flail chest (all retrospective reviews) could be identified.[13]

In addition to a paucity of evidence for traditional outcome metrics, no high-quality trials have evaluated the effect of SSRF on patient-centered outcomes, such as health status and quality of life.[14] To address these gaps in knowledge, this proposal aims to determine the comparative effectiveness of early SSRF to usual care on traditional outcome metrics and patient-centered outcomes, such as long-term health status and quality of life in blunt trauma patients suffering multiple rib fractures.

GOAL AND SPECIFIC AIMS

Aim 1: Compare the effectiveness of SSRF to usual care alone on traditional clinical metrics and patient-centered outcomes.

Aim 2: Evaluate for heterogeneity of treatment effect in high-risk subgroups.

Aim 3: Determine the impact of multiple rib fractures on post-discharge health status and time to return to work or usual physical activity.

HYPOTHESIS

Patients with severe chest trauma who undergo SSRF will have decreased rates of opioid consumption as measured in morphine milligram equivalents per day. Patients with severe chest trauma who undergo SSRF will also have improved health status (as measured by the EuroQOL-5D-5L) at 30 days and 3 months, earlier return to work or normal physical activity, and decreased time from injury to resolution of chest wall pain.

STUDY DESIGN

Single center, pragmatic, prospective, randomized clinical trial with a parallel observational arm to compare usual care alone to usual care plus early surgical stabilization of rib fractures. Screening will occur at admission. Randomization will occur after informed consent has been obtained. A 1:1 allocation ratio using a permuted block design of 4 or 6 will be used to ensure equal number of patients in each group. Randomization will be performed using the randomization module in REDCap and stratified by unit of admission. If randomized to SSRF, the procedure should occur as early as possible after admission (given competing/concomitant injuries), ideally within 72 hours. Study enrollment will occur over 18 months. Total study duration including follow-up = 24 months.

Primary Outcome:

- Hospital length of stay (days)

Secondary Outcomes (Clinical Metrics):

- Mortality
- Incidence of respiratory failure requiring mechanical ventilation > 24 hours
- Incidence of tracheostomy
- Inpatient incidence of pneumonia
    - >10,000 cfu/mL on bronchioalveolar lavage -or-
    - Clinical diagnosis of pneumonia with subsequent antibiotic treatment
- Utilization of regional anesthesia (binary outcome)
- Opioid usage (continuous and binary)
- Lengths of stay
    - Hospital-free days (= 30 minus number of hospital days; in-hospital death = 0)
    - Ventilator-free days (= 30 minus number of ventilator days; in-hospital death = 0)

  - ICU-free days (= 30 minus number of intensive care unit days; in-hospital death = 0)
- Re-intervention rates for surgical complications, including bleeding, seroma, and surgical site infection

Secondary Outcomes (Patient-Centered Outcomes):

- Health status at 30 days, 3 months, and 6 months as measured by the EuroQol-5D-5L
- Time from injury to return to work or usual activity (days)
- Time from injury to resolution of pain (days)

STUDY POPULATION

All adult trauma patients admitted with a blunt chest injury to Memorial Hermann – TMC Emergency Department (ED) will be screened for this trial. Patient meeting the eligibility criteria listed below will be approached for participation in this trial.

Inclusion Criteria:

- Age ≥16 years**
- Blunt trauma mechanism
- Severe chest wall injury:
  - Radiographic flail segment (defined as ≥2 fractures in ≥3 consecutive ribs) -or-
  - ≥5 consecutive rib fractures -or-
  - ≥1 rib fractures with bicortical displacement
- At least one true rib (1-7) fractured and accessible for stabilization

**Subjects sixteen years of age and older are considered as adult trauma subjects in a large percent of the trauma centers. Sixteen and seventeen year olds are able to drive in most states and are at high risk for motor vehicle accidents resulting in blunt or penetrating injuries. Excluding this age group would significantly decrease the external validity of the proposed project. Additionally, it is difficult to differentiate a 16 or 17 year old from one who is 21 or older at the time care is initiated in the ED until positive identification can be obtained. Children 15 years of age or younger or less than 50 kg body weight will be excluded from this trial. Children's intravascular volume is different than the adult's, requiring adjustments to the standard adult treatment protocols.

Exclusion Criteria:

- Age < 16 years
- Severe traumatic brain injury (best resuscitated GCS ≤ 8 as measured at 24h)
- Spinal cord injury
- Pre-existing congestive heart failure or oxygen-dependent pulmonary disease
- Any reason for which SSRF could not occur within 72 hours of admission

STUDY PROCEDURES

Screening:

Clinical research staff are available 24/7 to conduct screening upon ED admission. The research staff will continue to monitor those patients who have experienced blunt chest trauma with possible rib fractures. Patients and/or their legally authorized representative (LAR)/family member that are eligible for the study will be approached for participation in the trial. An informed consent will be obtained prior to randomization.

Randomization:

Eligible subjects who have consented to participate will be randomized into one of two groups: 1) Control arm or 2) Intervention arm. The two arms are described in detail below. A 1:1 allocation ratio using a permuted block design of 4 or 6 will be used to ensure equal number of patients in each group. Randomization will be performed using the randomization module in REDCap and stratified by unit of admission.

Control Arm: Control patients will receive usual care per our established institutional guidelines, consisting of pulmonary toilet, lung volume expansion exercises, and a multimodal approach to oral pain medication management. For severe pain not responding to oral therapy, intravenous narcotics, lidocaine, or ketamine may be added. Regional analgesia techniques such as epidural analgesia, paravertebral analgesia, and intercostal nerve blockade may also be considered. The pain medication regimen is deescalated as pulmonary status and pain control allow. (https://med.uth.edu/surgery/files/2017/06/Chest-Management-of-Multiple-Rib-Fractures-2013.pdf)

For patients who fail all of these therapies and desire to proceed with SSRF, the procedure may be offered late, as salvage therapy.

Intervention Arm: The intervention will consist of early surgical stabilization of the fractured ribs plus usual care. If randomized to SSRF, the procedure should occur as early as possible (given the patient clinical status and need for more emergent procedures), ideally within the first 72 hours of hospital admission. Since stabilization of all fractures may not be possible due to anatomic exposure (*e.g.*, the first, second, and third ribs may be difficult to access due their location), the surgery must stabilize at least one true rib (ribs 1-7). Stabilization of the true ribs is considered more critical due to their greater contribution to chest wall volume and mechanical respiratory function.

Observation Arm: Patients refusing consent to randomization will be invited to participate in the observational arm. Patients selecting this option will be asked to complete the same assessments as the randomized groups.

Equipment: In order to maintain a pragmatic approach, surgical stabilization will be performed using any commercially available internal rib fixation system, at the discretion of the operating surgeon.

Data Collection

The clinical research staff will follow the subjects throughout their hospitalization (or up to 30 days, whichever comes first) for complications such as surgical site infections, pneumonia, need for reoperative procedures and other complications commonly associated with rib fractures.

The data will be reviewed and entered into the UT Redcap database. Each subject will be assigned a study specific number. The subject's medical record and the MHH-TMC trauma registry will be utilized for data collection purposes. Data will be collected until discharge or 30 days (whichever occurs first) and questionnaires will be conducted up to 6 months post ED admission.

Follow Up

Subjects will be asked to complete a health status questionnaire at 30 days, 3 and 6 months post ED admission. The EuroQol-5D-5L form will be utilized to complete the questionnaire. This questionnaire will be completed in person (if subject is scheduled for a routine clinic visit at those timepoints) or via telephone conversation. The purpose of this questionnaire is to collect information pertaining to the patient-centered outcomes. A member of the research team will conduct the follow up questionnaires for the outcomes.

DATA AND SAFETY MONITORING

An internal data and safety monitoring board (DSMB) will review the study at 50% enrollment to evaluate for substantial benefit or harm to one of the treatment groups. The DSMB committee will consist of an independent surgeon, statistician, and clinician to be named that is not affiliated with the clinical care of the patient population. The DSMB will review the information collected to address the primary and secondary outcomes. The DSMB will provide a report following their review after 75 subjects have been enrolled which will include a decision on how trial enrollment shall proceed.

STATISTICS

The primary and secondary outcomes will be analyzed on an intention to treat basis, though a per protocol analysis will also be performed. Demographics, injury characteristics, and eligible rib fracture patterns will be reported. Subgroup analyses will be stratified *a priori* by unit of admission. All statistical analyses will be performed using STATA® (version 15.1; StataCorp; College Station, TX) and R© (The R Foundation) commercially available software.

Sample Size Calculation

We expect to enroll 150-250 total patients. We calculated the effect size we will be able to detect in hospital LOS, assuming a median LOS of 10 days (IQR 6-15) in the control group and two-sided alpha of 0.05. A sample size of 150 patients (75 per group) will provide 85% power to detect a difference of 3 days (*i.e.*, median LOS of 7 days in intervention group). With a sample size of 250 patients, we will have 89% power to detect a difference of 2.5 days in hospital LOS.

Frequentist Analysis

Generalized linear models (GLMs) will be used to analyze all outcomes and will include treatment group and unit of admission (stratifying variable) as covariates. For LOS outcomes, negative binomial or zero-inflated negative binomial (for outcomes with large number of zeros; *e.g.*, ventilator days, ICU days) regression models will be used. Binary outcomes will be analyzed with log binomial regression models to estimate relative risks (RRs). For longitudinal outcomes, we will use mixed models including treatment group, time, and center as covariates and a random intercept (and slope if needed) for subject. We will report RRs or group differences and 95% confidence intervals for all outcomes.

Bayesian Analysis

Bayesian statistics will be used to detect differences in treatment effects overall and in different patient subgroups. Models will be the same as in frequentist analyses (*i.e.*, GLMs with same covariates). For LOS outcomes, neutral priors centered at RR of 1.0 with 95% prior interval of 0.33-3.0 (0.5-2 for binary outcomes) will be used for the treatment effect (in the log RR scale, a Normal distribution with mean of 0 and variance of 0.57). A Normal (0, 10) prior will be used for the intercept term. Normal (0, 1) will be used for all other variables in the model. For sensitivity analyses, we will specify enthusiastic and skeptical priors based on the best published evidence (*i.e.*, Cochrane review). For all Bayesian analyses, we will report posterior medians and 95% credible intervals for group comparisons and probabilities of benefit or harm from the intervention.

Feasibility: From unpublished historical data from the Red Duke Trauma Institute from the calendar year 2017, approximately 300 patients matched these enrollment criteria. Accordingly, enrollment of 150-250 patients is expected over the course of the study.

Limitations:

- Low sample size – If recruitment is lower than expected, data will be used to obtain the least biased estimate of the treatment effect for use in a larger trial. Bayesian analysis will be performed regardless to assess for the probability of benefit.
- Inability to blind – It is not possible to blind either the clinicians, the research coordinator, or the research associates administering the EuroQOL to the randomization allocation. However, the statistician will be blinded.
- High dropout rate – Not all trauma patients reliably return to clinic post-discharge. In order to minimize the dropout rate, we would proactively obtain a variety of contact points (multiple contact phone numbers for patient/family, mailing address, email address). Health status and quality of life metrics can be completed by telephone or electronically if necessary. Historically, this strategy has been effective in minimizing loss to follow-up, as evidenced by the 95% 6-month follow-up rate of patients in the Damage Control Laparotomy trial that was recently completed at the Red Duke Trauma Institute [Harvin, *et al*; unpublished data]. If large loss to follow-up is experienced, dropouts will be evaluated for non-random causes.

ETHICS

Written informed consent will be obtained from each patient prior to enrollment. In the event, the patient is unable to provide informed consent, the LAR or family member will be approached to provide consent for the patient. An assent form will be provided to those subjects 16 and 17 years of age. A member of the study team will discuss the trial details to the patient and/or LAR/family member and will allow them time to make a decision regarding participation.

DATA HANDLING AND RECORD KEEPING

All data will be reviewed and entered into a RedCap database managed by UTHealth. Each subject will be assigned a study specific number once they have signed consent and been enrolled into one of the three study arms. Data utilized for this trial will be obtained from the subject's medical records and the MHH-TMC trauma registry.

All hard copy data will be kept in a secure, locked office and all electronic documents will be kept on password-protected computers accessible to only personnel directly involved with this trial.

QUALITY CONTROL AND ASSURANCE

Each item on the web forms will have validity checks performed to ensure that the data entered are accurate and that items are not skipped during entry by mistake. Checks will be developed by both clinical investigators and research assistants. Depending on the question, any item found that does not meet the respective edit criteria will have an appropriate error message displayed when the user tries to save the data. Errors will be classified as either "hard" errors meaning that a valid response is required before the data can be saved or as "soft" errors in which the entry operator can either correct the errors or override them to indicate that the data are correct although it does not meet the edit criteria. Examples of hard errors would be items such as identifiers and event dates. An example of a soft error would be values that are outside a pre-defined range.

When the data record is saved, a form status field will be updated to indicate the status of the form. There are currently four status states that the form can have. These statuses are: the form is incomplete, the form is complete, the form was saved with errors, and the form is complete with errors. For the first status, the entry user will have the option to save a record as —incomplete for situations where they have partially entered a form and must stop because of an interruption. This will allow the user or the study coordinator to pull up the form at a later time and finish completing it. If the form was entered without any errors, then the record will be saved as complete. If the user overrides any soft errors found, the record will be saved as —saved with errors.

PUBLICATION PLAN

The final clinical trial protocol will be formulated into a manuscript for pretrial publication. The results of the study will be published at internal meetings and used to inform the management of patients with rib fractures at the Red Duke Trauma Institute. Publication of the results of the trial will be sought in a peer-reviewed journal (intended: *JACS*, *J Trauma Acute Care Surg*). Presentation at a national meeting (AAST, EAST, WTA, or ACS) is also intended.

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ATTACHMENTS

Appendix A. EuroQOL-5D-5L tool.

EuroQOL-5D-5L at 1, 3 and 6 months

Mobility
- I have no problems walking
- I have slight problems walking
- I have moderate problems walking
- I have severe problems walking
- I am unable to walk

Self-Care
- I have no problems washing or dressing myself
- I have slight problems washing or dressing myself
- I have moderate problems washing or dressing myself
- I have severe problems washing or dressing myself
- I am unable to wash or dress myself

Usual Activities
- I have no problems doing my usual activities
- I have slight problems doing my usual activities
- I have moderate problems doing my usual activities
- I have severe problems doing my usual activities
- I am unable to do my usual activities

Pain
- I have no pain or discomfort
- I have slight pain or discomfort
- I have moderate pain or discomfort
- I have severe pain or discomfort
- I have extreme pain or discomfort

Anxiety)
- I am not anxious or depressed
- I am slightly anxious or depressed
- I am moderately anxious or depressed
- I am severely anxious or depressed
- I am extremely anxious or depressed

“Your Health Today” (0-100)

Are you back to work or usual physical activity? (yes/no)
- If yes, when?

Has your rib pain completely or almost completely resolved? (yes/no)

If yes, when?

Appendix B. List of Data Elements to be Collected

Study number
Gender (male/female)
Age
Race (white, black, Hispanic, Asian, other, unknown)
Trauma type (blunt/penetrating)
Mechanism (MVC, MCC, fall, auto pedestrian, ATV, assault, crush, GSW, stab, other)
Date/time of injury
PH vital signs
Transfer? (yes/no)

ED arrival date/time
ED vitals
ED CBC
ED BMP
ED rTEG
ED lactate
ED base excess

Unit of admission
Randomization group (SSRF/usual care)

R 1st rib fx?
- Segmental?
- Displaced?

R 2nd rib fx?
- Segmental?
- Displaced?

R 3rd rib fx?
- Segmental?
- Displaced?

R 4th rib fx?
- Segmental?
- Displaced?

R 5th rib fx?
- Segmental?
- Displaced?

R 6th rib fx?
- Segmental?

Displaced?
R 7th rib fx?
Segmental?
Displaced?

L 1st rib fx?
Segmental?
Displaced?
L 2nd rib fx?
Segmental?
Displaced?
L 3rd rib fx?
Segmental?
Displaced?
L 4th rib fx?
Segmental?
Displaced?
L 5th rib fx?
Segmental?
Displaced?
L 6th rib fx?
Segmental?
Displaced?
L 7th rib fx?
Segmental?
Displaced?

Radiographic flail segment? (yes/no)
Flail chest? (yes/no)
Right clavicle fx? (yes/no)
Left clavicle fx? (yes/no)
Right scapula fx? (yes/no)
Left scapula fx? (yes/no)

Mechanical ventilation immediately prior to SSRF? (yes/no)
Tracheostomy prior to SSRF? (yes/no)
Clinical suspicion of PNA prior to SSRF? (yes/no)
Chest tube prior to SSRF? (yes/no)

Date/time of SSRF
Time from admission to SSRF (hours)
Procedure time (min)
Hardware system (Synthes/KLS Martin)
Right ribs stabilized by SSRF
1 (yes/no)
2 (yes/no)

3 (yes/no)
…
Left ribs stabilized by SSRF
1 (yes/no)
2 (yes/no)
3 (yes/no)
…
VATS? (yes/no)
Thoracotomy? (yes/no)

w-RTS
ISS
AIS head/neck
AIS face
AIS chest
AIS abdomen
AIS extremity
AIS external

Regional analgesia for rib fxs? (yes/no)
If yes, what kind? (epidural, paravertebral, intercostal, serratus plane, other)

Post-SSRF PNA? (yes/no)
Post-SSRF hardware infection? (yes/no)
Post-SSRF seroma requiring intervention? (yes/no)
Post-SSRF hematoma requiring intervention? (yes/no)
Post-SSRF hardware failure? (yes/no)
Post-SSRF need for hardware removal for any reason? (yes/no)

Post-SSRF SSI? (yes/no)
Superficial? (yes/no)
Deep? (yes/no)
Organ space? (yes/no)
DVT? (yes/no)
PE? (yes/no)

Discharge date/time
Discharge disposition (home, rehab, SNF, LTAC, transfer to other hospital, level 1 psych, morgue, other)
Total opioid use (MME)
MME/day
Opioid prescription at discharge? (yes/no)
Tramadol prescription at discharge? (yes/no)

Ventilator days
ICU days
Hospital days

Did the patient survive to 1 month? (yes/no)
Was the patient able to answer questions at 1 month? (yes/no)
Did the patient consent to be asked questions at 1 month? (yes/no)

Did the patient survive to 3 months? (yes/no)
Was the patient able to answer questions at 3 months? (yes/no)
Did the patient consent to be asked questions at 3 months? (yes/no)

Did the patient survive to 6 months? (yes/no)
Was the patient able to answer questions at 6 months? (yes/no)
Did the patient consent to be asked questions at 6 months? (yes/no)