

Form "EAST Multicenter Study Proposal"

Study Title Use of Surgical Fixation for Chest Wall Stabilization in Severe Traumatic Rib Fractures

Primary investigator / Senior researcher Amanda Celi, MD and Bryan Mores, MD

Email of Primary investigator / Senior researcher aceli@emory.edu

Co-primary investigator Rondi Gelbard, MD and Christopher Dente, MD

Use this area to briefly (1-2 paragraphs only) outline the burden of the problem to be examined

Surgical fixation of chest wall injuries is a historically underutilized procedure. Surveys of Trauma/Ortho/Cardiothoracic surgeons from 2009 showed only 22% of these physicians were aware of any literature on the topic. The majority of previous studies are small, include only flail segments and therefore do not include severe/debilitating rib fracture patterns. Flail chest is defined as 3 adjacent ribs that are fractured in at least 2 places resulting in paradoxical motion of the free segment of the chest wall. "Severe rib fractures" usually refers to >3 fractured ribs, ribs angulated into the chest, severely displaced fractures, and those associated with a large hemothorax, persistent pneumothorax, prolonged ventilation, and severe pain from non union or malunion. There is a significant morbidity associated with both flail chest and severe rib fractures. Severe rib fractures may in fact warrant rib fixation but the use of operative rib fixation is understudied in the trauma population. Unfortunately there are no absolute indications for surgical treatment of rib fractures.

Primary aim

Determine the absolute indications for surgical stabilization of rib fractures and to determine if surgical stabilization of rib fractures improves patient outcomes compared to medical management alone.

Secondary aims

1. Surgical treatment of thoracic injury in the setting of multiple rib fractures
2. Flail chest
3. Greater than or equal to 3 rib fractures with displacement

Inclusion Criteria

4. Greater than or equal to 30% hemothorax volume loss AND severe pain OR respiratory failure
5. Persistent air leak AND severe pain OR respiratory failure
6. Nonunion or Malunion AND severe pain OR respiratory failure

Exclusion Criteria

1. Age less than 15
2. Severe Head Injury mandating Intracranial Monitoring Devices
3. Hemodynamic instability due to concomitant injuries
4. Patients that expire within 24 hours of injury

Therapeutic Interventions

Standard care for patients with rib fractures including analgesia (i.e. PO/IV pain medication or PCA), pulmonary toilet (i.e. suctioning, incentive spirometry), chest physiotherapy, operative technique protocols.

1. Respiratory failure (need for mechanical ventilation)
2. Pneumonia
3. Tracheostomy

Primary Outcome

4. Duration of chest tube
5. Total ventilator days
6. Intensive care unit and hospital length of stay
7. Mortality

1. Narcotic Requirements

Secondary Outcomes

2. Oxygen Requirements
3. Daily Maximum Incentive Spirometer Volume

- Demographics
- BMI
- Pre-existing pulmonary disease
- Mechanism of Injury
- Injury Pattern
- Injury Severity Score
- Time to surgery
- Pre and Post op Analgesia
- Pulmonary toilet
- Operative Times
- Number of ribs fixed
- Outcomes
- Respiratory failure (mechanical ventilation)
- Pneumonia
- Tracheostomy
- Chest Tube Days
- Ventilator Days
- Length of Stay
- Mortality
- Narcotic Requirements
- Oxygen Requirements
- Daily Maximum Incentive Spirometer Volume

List specific variables to be collected & analyzed

Outline the data collection plan and statistical analysis plan succinctly

This will be a prospective study. Standardized data will be collected for each patient (see variable list above). Data will then be analyzed using comparative statistics (uni variate and multi variable analyses) to identify differences between the operative and non-operative groups. Data will be reported as adjusted odds ratios with 95 % confidence intervals. Statistical significance will be set at a $p < 0.05$.

Outline consent procedures here, if applicable

The patient will be consented for inclusion in the study when they agree and consent to undergo operative fixation of their rib fractures. This study involves minimal risk to the patients as there is no additional intervention outside of the standard of care for the management of flail chest or severe rib fractures. The rights and welfare of the patients will not be adversely affected. Furthermore, the data is already collected and documented as a part of the patients' medical records.

Succinctly outline a risk/benefit analysis

The risks to the patient are minimal and are the risks associated with standard open fixation of the ribs, including, but not limited to bleeding, infection, injury to surrounding organs and death. However, when compared to medical management alone, this operation can improve patient outcomes in regards to respiratory failure (mechanical ventilation), pneumonia rates, tracheostomy rates, chest tube days, ventilator days, length of stay, and mortality. This study may identify the optimal timing and type of intervention to optimize outcomes in patients with these types of injuries. This may result in significant benefit to patients in the future.

Yihan Lin MD, Maridi Rodil BS, Benoit Herbert MD, Rober Stovall MD, Jeffrey Johnson MD, Walter Biffi MD, Ernest Moore MD, Carlton Barnett MD, Clay Cothren Burlew MD, Charles Fox MD, Gregory J. Jurkovich MD, Fredric Pieracci MD, Denver Medical Center. A Prospective Controlled Trial of Surgical Stabilization of Severe Rib Fractures. Session XA: Pages18-26. Paper 18: 2-220

Fitzpatrick DC, Denard PJ, Phelan D, Long WB, Madey SM, Bottlang M. Operative stabilization of flail chest injuries: review of literature and fixation options. *Eur J Trauma Emerg Surg.* 2010 Oct;36(5):427-433.

Bottlang M1, Helzel I, Long WB, Madey S. Anatomically contoured plates for fixation of rib fractures. *J Trauma.* 2010 Mar;68(3):611-5.

Voggenreiter G1, Neudeck F, Aufmkolk M, Obertacke U, Schmit-Neuerburg KP. Operative chest wall stabilization in flail chest--outcomes of patients with or without pulmonary contusion. *J Am Coll Surg.* 1998 Aug;187(2):130-8.

Include a brief listing of key references

Marasco SF1, Sutalo ID, Bui AV. Mode of failure of rib fixation with absorbable plates: a clinical and numerical modeling study. *J Trauma.* 2010 May;68(5):1225-33.

Khandelwal G1, Mathur RK, Shukla S, Maheshwari A. A prospective single center study to assess the impact of surgical stabilization in patients with rib fracture. *Int J Surg.* 2011;9(6):478-81.

Althausen PL1, Shannon S, Watts C, Thomas K, Bain MA, Coll D, O'mara TJ, Bray TJ. Early surgical stabilization of flail chest with locked plate fixation. *J Orthop Trauma.* 2011 Nov;25(11):641-7.

Messing JA1, Gall V, Sarani B. Successful management of severe flail chest via early operative intervention. *J Trauma Nurs.* 2014 Mar-Apr;21(2):83-5.

Gauger EM1, Hill BW, Lafferty PM, Cole PA. Outcomes after operative management of symptomatic rib nonunion. *J Orthop Trauma.* 2015 Jun;29(6):283-9.

Fitzpatrick DC, Denard PJ, Phelan D, Long WB, Madey SM, Bottlang M. Operative stabilization of flail chest injuries: review of literature and fixation options. *Eur J Trauma Emerg Surg*. 2010 Oct;36(5):427-433. Epub 2010 Jun 3.

Cacchione RN, Richardson JD, Seligson D. Painful nonunion of multiple rib fractures managed by operative stabilization. *J Trauma*. 2000 Feb;48(2):319-21.

Fowler, Taylor, Bellino, Althausen Surgical Treatment of Flail Chest and Rib Fractures. *J Am Acad Orthop Surg*. 2014 Dec;22(12):751-760. Review

Marasco SF, Davies AR, Cooper J, Varma D, Bennett V, Nevill R, Lee G, Bailey M, Fitzgerald M. Prospective randomized controlled trial of operative rib fixation in traumatic flail chest.

J Am Coll Surg. 2013 May;216(5):924-32

Mayberry JC, Ham LB, Schipper PH, Ellis TJ, Mullins RJ. Surveyed opinion of American trauma, orthopedic, and thoracic surgeons on rib and sternal fracture repair. *J Trauma*. 2009 Mar;66(3):875-9

Tanaka H, Yukioka T, Yamaguti Y, Shimizu S, Goto H, Matsuda H, Shimazaki S. Surgical stabilization of internal pneumatic stabilization? A prospective randomized study of management of severe flail chest patients. *J Trauma*. 2002 Apr;52(4):727-32

Fabricant L, Ham B, Mullins R, Mayberry J. "Prolonged pain and disability are common after rib fractures" *Am J Surg*. 2013 May;205(5):511-5