EAST Multicenter Study Proposal

Study Title: EAST Multicenter Trial: Damage Control Thoracotomy (DCT) in Thoracic Trauma

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Are you a current member of EAST: Yes

If you selected "No" above please identify a Sponsor that is an active EAST member:

My Multicenter Study proposal is: Retrospective

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

Damage-control surgery is defined by the delay of definitive management of traumatic injuries until normal physiology is restored in the intensive care unit prior to returning to the operating room. The concept of damage-control stems from observations that definitive operations on acutely ill patients in the setting of metabolic exhaustion leads to increased risk of mortality. Damage-control laparotomy is a common practice in the setting of abdominal trauma. The same principles used in damage-control laparotomy have been applied to the thoracic cavity, but literature supporting this practice is scarce.

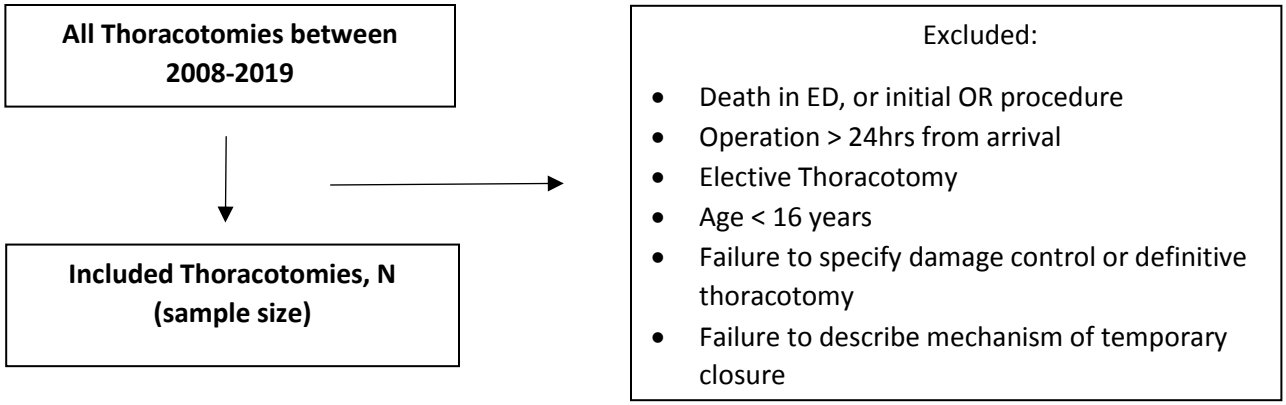
Presently, it is unclear how prevalent damage-control thoracotomy (DCT) operations are in trauma centers across the world. If DCT is used, the optimal strategy for temporary closure is unknown. Whether this operation is safe for severely injured patients is still to be determined. The aim of this multicenter retrospective study is to examine the use of DCT in trauma centers, including types of closure, as well as comparing DCT with definitive thoracotomy rates and complications over the past decade.

Primary Aim: The primary aim of our trial will be to create a taxonomy of chest closure techniques and describe the associated properties of each, including complications.

Secondary Aim: Describe the practice patterns associated with DCT as compared with definitive thoracotomy over the past 10 years, and gain insight on trends in management, survival, and complications.

Inclusion Criteria: Thoracotomies from 2008-2019 for management of Thoracic Trauma, Age > 16, Operation within 24hrs of presentation, Survived to ICU admission

Exclusion Criteria: Death in the ED, OR, or prior to ICU admission, Age < 16, Operation more than 24hrs after presentation, Thoracotomies described as rib fixation or sternotomy, Operations suspended and converted to Damage Control for non-survivable injuries, Thoracotomies that fail to clearly describe the operation as Damage control or Definitive Thoracotomy.



Therapeutic Interventions: Retrospective Study Only

Primary Outcome: Complication and survival rates associated with strategies for temporary closure of the thorax.

Secondary Outcomes: Incidence, ICU Length of Stay, Ventilator Free Days, Pressor Free Days, Post-Operative Complications (Pneumonia, Intra-Thoracic Abscess, Mediastinitis, Empyema, ARDS, Thoracic Compartment Syndrome, Sepsis, Acute Renal Failure, DVT/PE, Unplanned Return to OR)

List specific variables to be collected & analyzed: Standard demographic variables (age, gender, race), mechanism of injury, injury severity data (blunt/penetrating, ISS, head/chest/abdomen AIS, list of injuries), admission physiology (BP, HR, Temp, pH, INR), management variables (location of operation, time to operation, incision type), operative interventions (wound packing, other procedures performed, vascular/organ repair, resections, thoracostomy), mechanisms for temporary closure (skin-only, muscle-only, skin and muscle, adhesion dressing, wound vac), indication for damage control surgery (acidosis, coagulopathy, hypothermia or other), transfusion requirements (pRBCs, platelets, FFP, cryoprecipitate, fibrinogen concentrate, crystalloids, colloid, estimated blood loss, TEG results), post-operative outcomes (time to re-exploration, number of re-explorations, time to definitive closure, discharge status, complications, hospital length of stay, ICU length of stay, ventilator days).

Outline the data collection plan and statistical analysis plan succinctly: Data will be collected using an encrypted database known as REDCap, which can be distributed to institutions using a protected weblink. Descriptive analysis will be completed using means (standard deviations), medians (inter-quartile ranges), and frequencies, as appropriate. Comparisons between damage control and definitive treatment will be completed using independent student t-tests and Mann-Whitney-U tests for continuous variables, and Chi-square tests for frequencies. Multivariate analysis for any complication associated with each closure type will be conducted. Cochran Armitage trend over time analysis will be utilized to provide descriptive epidemiological data on DCT usage and trends in survival.

Outline consent procedures here, if applicable: N/A

Succinctly outline a risk/benefit analysis: This study is an observational study with minimal risk. The major risk to the subjects is a breach of healthcare information. To minimize this risk, patient data will be de-identified once collection is performed. If there is a rare breach in information, this will be reported to institutional review board, the risk management department, and the patient immediately. The study benefits outweigh the risk, this procedure is being performed in trauma centers across the

world. The data describing the procedure and its outcomes is very scarce. Although the procedure is rare, the results of this study could confirm that this procedure is safe, and establish the mechanisms of closures that are associated with the most favorable outcomes.

Include a Brief listing of key references:

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2. Burch, J. M., Ortiz, V. B., Richardson, R. J., Martin, R. R., Mattox, K. L., Jordan, G. L. Abbreviated laparotomy and planned reoperation for critically injured patients. In: Annals of Surgery. 1992.
3. Stone, H. H., Strom, P. R., Mullins, R. J. Management of the major coagulopathy with onset during laparotomy. Ann Surg. 1983;
4. Carmona, R. H., Lim, R. C., Lim, R. C. The role of packing and planned reoperation in severe hepatic trauma. J Trauma - Inj Infect Crit Care. 1984;
5. Ivatury, R. R., Nallathambi, M., Gunduz, Y., Constable, R., Rohman, M., Stahl, W. M. Liver packing for uncontrolled hemorrhage: A reappraisal. J Trauma - Inj Infect Crit Care. 1986;
6. Baracco-Gandolfo, V., Vidarte, O., Baracco-Miller, V., Del Castillo, M. Prolonged closed liver packing in severe hepatic trauma: Experience with 36 patients. J Trauma - Inj Infect Crit Care. 1986;
7. Hirshberg, A., Wall, M. J., Mattox, K. L. Planned reoperation for trauma: A two year experience with 124 consecutive patients. J Trauma - Inj Infect Crit Care. 1994;
8. Lang, J. L., Gonzalez, R. P., Aldy, K. N., Carroll, E. A., Eastman, A. L., White, C. Q., et al. Does temporary chest wall closure with or without chest packing improve survival for trauma patients in shock after emergent thoracotomy? J Trauma Inj Infect Crit Care. 2011;70(3):705.
9. Caceres, M., Buechter, K. J., Tillou, A., Shih, J. A., Liu, D., Steeb, G. Thoracic packing for uncontrolled bleeding in penetrating thoracic injuries. South Med J. 2004.