

Form "EAST Multicenter Study Proposal"**Details #38** (submitted 10/12/2017)**Study Title**

Optimal Management of Traumatic Esophageal Perforation

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Are you a current**member of EAST?**

No

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

Patrick Bosarge

My Multicenter Study**proposal is...**

Retrospective

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

Traumatic esophageal perforation is rare, yet it is associated with significant morbidity and mortality. There is substantial variability in the way that these injuries are managed, ranging from a complete non-operative approach to endoscopic stenting to operative primary repair, esophagectomy with primary anastomosis, or esophageal diversion. Previous studies have evaluated the efficacy of these different treatment options in relatively small groups of patients; however, in order to obtain an adequate sample size, most studies have included a very heterogeneous patient population with different primary etiologies (Boerhaves, iatrogenic perforation, traumatic injury, etc) and underlying pathologies (malignancy, esophageal motility disorder, etc). Additionally, these studies have been performed over a relatively long time period, sometimes up to twelve years, during which time the clinical management has changed dramatically. Increasingly, these injuries/perforations are managed endoscopically with stent placement alone. Recent prospective studies have demonstrated good outcomes in heterogeneous patient populations with stent placement with operative intervention reserved for cases of stent failure. Thus, I would like to evaluate the trauma population in particular to determine outcomes for different treatment modalities in traumatic esophageal perforation, specifically focusing on esophageal stenting. In order to accrue enough patients I would need multi-institutional collaboration.

Primary aim

To evaluate traumatic esophageal injury from both blunt and penetrating trauma and compare the different management strategies that are being used for this population.

Secondary aims

To evaluate safety and efficacy of esophageal stenting for traumatic esophageal perforation.

Inclusion Criteria

All trauma patients who present to a Level 1 ACS accredited trauma center with traumatic esophageal perforation.

Exclusion Criteria

Patients under the age of 18, pregnant females, prisoners.

**Therapeutic
Interventions**

None. This will be an analysis of retrospectively collected observational data collected over the previous 5 years.

Primary Outcome

Patient mortality

Secondary Outcomes

Initial treatment, esophageal leak, mediastinitis, empyema, pneumonia, sepsis, additional drainage procedures (type and number), hospital length of stay, ICU length of stay, need for endoscopic re-intervention or surgery after initial endoscopic management

List specific variables to be collected & analyzed

Age, sex, ASA score, ISS score, pre-existing medical comorbidities (smoking, alcohol use, CV disease, pulmonary disease), diagnostic imaging, location of injury (cervical, upper 1/2 thoracic, lower 1/2 thoracic), injury mechanism, time to first intervention, initial lactic acid, initial base deficit, initial albumin, vitals on presentation and before intervention, concomitant injuries, specialty performing management (initial and subsequent – ENT, CV surgery, Thoracic surgery, Trauma/General Surgery, GI medicine), patient disposition, mortality rates, complications related to injury and/or esophageal leak after intervention

Outline the data collection plan and statistical analysis plan succinctly

Data will be collected at each collaborating institution and sent to the PI/Co-PI. The data will undergo analysis at the University of Alabama at Birmingham (Co-PI home institution) by the departmental statistician.

Outline consent procedures here, if applicable

Waived. This is a retrospective study.

Succinctly outline a risk/benefit analysis

Risks include potential loss of HIPPA data, though patients will be de-identified. Benefits include a better understanding of an appropriate treatment algorithm to manage a rare yet life threatening condition.

Dasari BV et al. The Role of Esophageal Stents in the Management of Esophageal Anastomotic Leaks and Benign Esophageal Perforations. Ann Surg. 2014 May; 259 (5): 852-60.

Kaman L, et al. Management of Esophageal Perforation in Adults. Gastroenterology Res. 2010 Dec; 3 (6): 235-244.

Onat S, et al. Factors Affecting the Outcome of Surgically Treated Non-iatrogenic Traumatic Cervical Esophageal Perforation: 28 Years Experience at a Single Center. J Cardiothorac Surg. 2010 May 31; 5: 46.

Include a brief listing of key references

Schweigert M, et al. Spotlight on Esophageal Perforation: A Multinational Study Using the Pittsburgh Esophageal Perforation Severity Scoring System. Journal Of Thoracic and Cardiovascular Surgery. 2016 Apr; 151 (4): 1002-9.

Sudarshan M, et al. Management of Esophageal Perforation in the Endoscopic Era: Is Operative Repair Still Relevant? Surgery. 2016 Oct; 160 (4): 1104-10.