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 ½ thoracic, lower ½ 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.
Include a brief listing of key references


