Form "EAST Multicenter Study Proposal"
Details #48 (submitted 10/31/2017)

Study Title
The Emergency Surgery Score (ESS): A Prospective Multicenter Validation of ESS as a Tool to Predict Postoperative Mortality and Complications after Emergency General Surgery

Primary investigator / Senior researcher
Haytham Kaafarani, MD MPH

Email of Primary investigator / Senior researcher
hkaafarani@mgh.harvard.edu

Co-primary investigator
N/A

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My Multicenter Study proposal is...
Prospective
Within the field of surgery, emergency general surgery (EGS) disproportionately contributes to hospitalization costs, surgical mortality and patient volume. EGS patients constitute 7.1% of all hospitalizations. Economic analysis shows that the average adjusted cost per EGS hospitalization is $10,744, accounting for approximately $28.37 billion annually on a national level. Studies have demonstrated that, when outcomes from EGS are compared to that of non-EGS, excess mortality and post-operative complications are observed. Tools such as the ACS risk calculator are not accurate in EGS because they do not account for the acuity of disease at presentation and erroneously assume that different risk factors affect EGS and non-EGS in a similar fashion. Therefore, acute care surgeons often rely on their intuition and gestalt to inform patients and their family of the risk of postoperative adverse outcomes.

The Emergency Surgery Score (ESS) has been suggested as the equivalent of the trauma Injury Severity Score (ISS) for EGS. ESS is a user-friendly but comprehensive calculator composed from 22 variables including demographics, co-morbidities, markers of acuity of disease and laboratory variables, and ranges from 0 to 29. In the retrospective validation study, ESS predicted postoperative death with a c-statistic of 0.86; the probability of death at 30 days gradually increased from 0% to 36% then 100% at scores of 0, 11, and 22, respectively. A subsequent study suggested that ESS is also effective in predicting the risk of occurrence of postoperative complications, which increased from 7% to 53% to 91% at scores of 0, 7, and 15, respectively (c-statistic= 0.78). At present, ESS is the only risk calculator created from and for EGS, and the only one that accounts for the acuity of disease at presentation to the hospital. However, ESS has not yet been prospectively validated, and its effectiveness as well as shortcomings have not yet been evaluated in a real clinical multicenter setting. At the time of a clear need for establishment of a national EGS database, where ESS can serve for risk adjustment and quality benchmarking, we propose a prospective multicenter study to evaluate the ability of ESS to predict the risk of 30-day mortality and the risk of occurrence of postoperative complications in the high risk EGS population undergoing emergent laparotomy.

**Primary aim**

Specific Aim 1: To prospectively evaluate the ability of ESS to predict the risk of 30-day any-cause mortality in EGS patients undergoing emergency laparotomies.

**Secondary aims**

Specific Aim 2: To prospectively evaluate the ability of ESS to predict the risk of occurrence of any 30-day postoperative complication in EGS patients undergoing emergency laparotomies

**Inclusion Criteria**

All patients older than 18 years old undergoing any urgent or emergent laparotomy surgery from 2018-2020 at the participating institutions. These will include but are not limited to laparotomies for small bowel obstruction, mesenteric ischemia, bleeding, and hollow viscus perforation.

**Exclusion Criteria**

Urgent/emergent Trauma, vascular and laparoscopic procedures (e.g. appendectomy, cholecystectomy), inguinal hernia repairs and soft tissue procedures (e.g. necrotizing soft tissue infection) will be excluded.

**Therapeutic Interventions**

Therapeutic Interventions: None.

**Primary Outcome**

Primary Outcome: Any-cause 30-day postoperative mortality

**Secondary Outcomes**

Secondary Outcome: 30-day postoperative complications (see below)
1) The following variables will be collected and analyzed to determine a patient’s ESS. The definitions will be as per the ACS-NSQIP Database:

- **Demographics**: Age, Race/ethnicity, Transfer from outside emergency department, transfer from an acute care hospital inpatient facility.

- **Comorbidities**: Ascites, BMI, dyspnea at baseline, functional dependence, history of COPD, hypertension, steroid use, ventilator requirement within 48 hours preoperatively, weight loss in the preceding 6 months, history of disseminated cancer

- **Laboratory values**: Albumin, Alkaline phosphatase, BUN, creatinine, INR, platelets, SGOT, sodium, WBC

2) The following variables will be collected as they are our outcomes of interest:

- **30-day mortality**

- **Post-operative complications**: superficial surgical site infection, deep incisional surgical site infection, wound dehiscence, pneumonia, unplanned intubation, pulmonary embolism, ventilator requirement >48 hours, renal insufficiency, acute renal failure, urinary tract infection, stroke/cerebrovascular accident, cardiac arrest requiring cardiopulmonary resuscitation, myocardial infarction, bleeding requiring transfusion, graft/prosthesis/flap failure, deep vein thrombosis/thrombophlebitis, sepsis, and septic shock

- **Length of hospital stay**

- **Destination of discharge**: (home, home with nursing services, rehabilitation, LTAC, nursing home, hospice)

**Outline the data collection plan and statistical analysis plan succinctly**

Standardized data, as detailed above, will be collected for each patient undergoing urgent/emergent surgery at these institutions from 2018-2020 within the first 72 hours from admission. Based on the data, each patient’s ESS will be calculated. For patients with a calculated ESS, outcomes (as detailed above) will be collected up until discharge from the hospital or 30 days, whichever comes later. The observed versus calculated rates of mortality and complications will be compared.

**Outline consent procedures here, if applicable**

An institutional review board application will be submitted with likely waiver of patient informed consent, as this is an observational data collection study. Data will be collected in a secure database (e.g. RedCap).
The risk involved in this prospective observational study is minimal, as we are not aiming to change surgical management or examine any specific “therapeutic intervention”. Harnessing the power of ESS both as a bedside tool to help clinical decision-making, as well as a tool for quality benchmarking of emergency surgical care could prove to be of paramount importance.


