EAST MULTICENTER STUDY PROPOSAL

(Proposal forms must be completed in its entirety, incomplete forms will not be considered)

GENERAL INFORMATION

Study Title: Outcomes of emergency surgery and trauma cases done at night.

Primary investigator / Senior researcher: Kevin M. Schuster

Co-primary investigator:

BACKGROUND AND SIGNIFICANCE

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

The specialty of acute care surgery by its nature will require surgeons to perform procedures in the overnight hours. The optimal approach to managing coverage schedules for acute care surgeons has not been determined. Studies that have focused on performance of elective procedures after overnight call have been inconsistent in that some studies of complex and simple routine operations have not demonstrated a difference in outcome [1,2]. A commonly referenced study by Rothschild evaluated broad types of operative procedures and did demonstrate differences in complication rates when less than 6 hours of sleep opportunity was recorded [3]. This has been examined by non-surgical procedure based specialists as well with evidence of poorer performance after night call [4]. Transplant surgeons, like acute care surgeons also often operate in the overnight hours and results of studies of transplant surgeon outcomes at night have been mixed also [5,6].

These studies unfortunately have multiple limitations and limited applicability to acute care surgery. Acute care surgeons are often influenced by sleep deprivation in that they are often starting operative cases after having worked sixteen or more hours with little to no rest. Much of their work is also non-operative and they may have responsibilities outside the operating room even in the overnight hours that may influence outcomes. Cases performed by acute care surgeons are also variable with respect to complexity with the majority of cases being less complex. Therefore identifying differences in outcomes will likely will require examining a greater fraction of complex cases matched with similar day cases as more simple operations will likely not have differences in
outcomes [2]. Other issues that have not been controlled for in previous studies are the volume of work outside of the operating room that may be influencing outcome, surgical volume, and experience of the surgeon. It has been suggested the younger surgeons in addition to the lack of clinical experience are less likely to be able to cope with sleep deprivation in the setting of current training paradigms [7]. If there are increased complications or mortality changing to a “night-float” type of schedule may mitigate these findings. Acute care surgeons may in some cases already be working these schedules and this will provide another potential line of investigation.


The specific aims of this multicenter study are:

Primary aim:
Primary aim should be succinctly stated here – single sentence ideal:

1. Identify any increase in mortality or complications that occurs when comparing day and night cases performed by acute care surgeons.

Secondary aims:
Any secondary aims should be stated here:

2. Examine the impact of non-surgical volume whether trauma or acute care surgical consultation on the outcomes of acute care surgical cases performed at night.
3. Examine the influence of surgical experience and years of training on outcomes of acute care surgical cases.

EXPERIMENTAL DESIGN/METHODS
Inclusion Criteria:

Any case that meets criteria for moderate or greater complexity performed in the preceding five years and has a case of matching complexity done during day time hours at that center will be eligible for inclusion.

Exclusion Criteria:

Cases of low complexity (laparoscopic cholecystectomy, appendectomy, incision of drainage of cutaneous abscess) will be excluded.

Therapeutic Interventions:

None, retrospective study only.

If no specific interventions are required and this is only a retrospective or prospective observational study, include that language here. Such as: “Prospective observational study only. Patients will be managed according to surgeon’s discretion.”

Outcomes Measures:

Primary Outcome:
(List here)

Primary outcome is 30 day mortality.

Secondary Outcomes:
(List here)

Secondary outcomes include complications, hospital and ICU length of stay, hospital re-admission and unplanned return to the operating room.

Variables:

List the specific variables to be collected and analyzed here. For organization, it is useful to divide these into categories for consideration. Examples of categories might include: Demographics, Admission physiology, Management variables, Surgical variables, Outcomes

Demographics:

Admission date
Discharge date
Age
Gender
Race
Payor (Commercial, Managed care, Medicare, Medicaid, self-pay)
Discharge Disposition (Home, Home with services, Rehabilitation, Nursing Home)

Comorbidities:

DM
Smoking (prior, active, never)
Dyspnea
Functional status
Vent dependent
COPD
Ascites within 30 days
CHF within 30 days
Hypertension
ARF
On dialysis
Disseminated cancer
Open wound
Immunosuppression
Bleeding disorder
Active Sepsis

Admission physiology:

Systolic blood pressure
Heart rate
Respiratory rate
Temperature

White blood cell count
Hemoglobin
Platelets
Creatinine
Albumin
Bilirubin

PaO2
FiO2

Operative Variables:
Start time
End time
Operation
Fascia closed (abdominal surgeries)
Colostomy created
Skin closed
Estimated Blood Loss
Complications:

Surgical site infection (superficial, deep, organ space)
Wound disruption
Pneumonia
Pulmonary embolism
Mechanical ventilation over 48 hours
Acute renal failure
Urinary tract infection
CVA
Cardiac arrest
Acute myocardial infarction
Need for transfusion
Deep venous thrombosis
Sepsis
Septic shock
Survival

Others:

Type of call system in place (standard call, night float)
Surgeon years of experience
Number of trauma admissions/alerts over same night
Number of emergency surgery consults over the night
Number of other operations performed over the same night.

Data Collection and Statistical Analysis:
Outline the data collection plan and statistical analysis plan succinctly here

An example might include:

• Standardized data will be collected for each patient (see data sheet, Appendix A). Risk factors for failure to achieve primary closure of the open abdomen will be assessed using univariate and multivariate analysis.

• Continuous variables will be compared using Student’s t-test and the Mann Whitney U test. The Chi-squared tests or Fisher’s exact test will be used to compare categorical variables. All variables with a p value <0.2 on univariate analysis will be entered into a multivariable logistic regression analysis to identify independent risk factors for failure to achieve primary fascial closure and development of complications. Data will be reported as adjusted odds ratios with 95% confidence intervals. Statistical significance will be set at a p<0.05.

Initial data will be collected simply as the entire list of moderately or significantly complex cases completed at an institution and the start time of the case by the acute care surgery service. Cases will be matched on a 1:1 basis by the performing institution and submitted to the lead institution for review by two other surgeons. Once the list is finalized complete data collection will be initiated. No patient identifiers will be transferred as a coding system will be used to identify the cases.

The potential confounders for mortality and complications as outlined above in the introduction and variables collected sections will be captured. The variables include basic demographics, comorbidities and pre-operative physiology. The main variable of interest time of operation start as well as surrogate operative outcomes
including blood loss, operative time, creation of an enterostomy and abdominal closure will be captured. Traditional outcome variables of mortality and routine surgical complications as listed above will be captured. All variables with a statistically significant or an expected clinically important impact on mortality or complications will be entered into multivariable logistic regression models with the primary indicator variable of case time. Model outcomes will include mortality, complications, operative time (linear regression) and blood loss (linear regression). Adjusted odds ratios and 95% confidence intervals will be reported with p<0.05 significant.

Based on a crude power analysis for a univariable impact of night time cases on mortality it is estimated that mortality will be 10% and increased to 15% with a night time start. Given these estimates 724 patients per group will be necessary to identify a mortality difference. Because the null hypothesis is there is no difference between groups we will only be able to prove that there is at most a small difference between groups. If baseline mortality is lower than expected the number of patients necessary to provide evidence for at most a small difference in mortality would be smaller.

Consent Procedures:
Outline consent procedures here, if applicable. As an example for a prospective study where waiver of consent will be sought, verbiage might include:

“This is a prospective observational study, designed to prospectively record data on patients who are managed according to institutional patient management protocols. Thus, waiver of informed consent is requested. Data will be recorded on a data sheet and transferred to a secured database that is devoid of patient identifiers.”

This is a retrospective study with minimal risk and waiver of consent will be requested. The only risk is release of patient information. Data will be initially collect at each institution with patient identifiers however these will all be deleted once data collection on each patient is complete.

Risk/ Benefit Analysis:
Succinctly outline a risk / benefit analysis. An example of this might include:

“The incidence and natural history DISEASE PROCCESS TO BE STUDIED is unknown. If the optimal timing for and type of intervention can be identified to optimize outcomes in these patients, then significant benefit will result.”

This is a minimal risk study. All data from submitting institutions will be de-identified. The only risk is the release of protected health information at the institutional level.

Instructions for submitting data collection tools:
All data submissions should be entered through the EAST Multicenter Trial Taskforce website portal. Instructions can be found on the EAST website. The data collection sheet located under the Multicenter Trial Taskforce
heading for this study can be utilized to record the data, and then the information transferred to the portal entry system. For any questions regarding this study, please contact the PI.

References:
*Include a brief listing of key references here:*


