Small bowel perforation (SBP) is a rare complication of blunt abdominal trauma, though it has a devastating outcome if left untreated. Estimates of the frequency of small bowel trauma in blunt abdominal trauma range from 5-15% (Mathonnet M 2003) with perforation occurring in 1% or less of blunt abdominal traumas (Fakhry SM 2000, Watts DD 2003). The rarity of this type of injury, combined with the low sensitivity and specificity of many diagnostic tests and procedures, make this a difficult diagnosis, and require a large patient population to examine the problem. Delay in diagnosis of a SBP can result in serious complications and death, making timely diagnosis critical in the treatment of these patients.

The difficulty of diagnosing SBP through CT scan is increasingly well known. Newer data suggests that surgery in <24 hours is necessary in these patients, with surgery in <8 hours preferred (Fang JF 1999, Fakhry SM 2000). Although SBP is an urgent problem, these data suggest that small delays to use the more sensitive diagnostic method of laparoscopy could be beneficial, rather than relying on CT. This study intends to examine whether increased awareness of diagnostic difficulty has improved diagnosis methods and time to surgery.

1. Describe current methods trauma centers are using to diagnose non-duodenal SBP in patients with blunt abdominal trauma.

2. Describe current mortality and morbidity due to blunt near-isolated non-duodenal SBP.

3. Describe the current average time to surgery for patients with blunt near-isolated non-duodenal SBP.

4. Determine the sensitivity and specificity of diagnostic findings for blunt near-isolated non-duodenal SBP.
Inclusion criteria:

All subjects must be ~ 18 who suffered blunt trauma.

First Group (Cases):

1. Had at least one abdominal CT in the ED
2. ICD-9-CM code for small bowel perforation (=863.20)

Second Group (Controls, matched 1:1 for each case on +/- 5 years of age and +/- 30 days from admission)

1. Had at least one abdominal CT in the ED
2. No diagnosis code for perforated small bowel

Third Group (Diagnosed without CT):

1. ICD-9-CM code for small bowel perforation (=863.20)
2. No abdominal CT in the ED

Fourth Group (Non-therapeutic laparotomy or laparoscopy):

1. CPT code for a negative laparotomy (=49000) or an exploratory laparoscopy (=49320)
2. Had at least one abdominal CT in the ED showing no solid organ injury.

Exclusion criteria:

1. Duodenal injuries.
2. Abbreviated Injury Scale (AIS) of >2 for other injuries, including other intra-abdominal injuries.

Therapeutic Interventions

No therapeutic interventions will be implicated in this study, it will be a retrospective data collection study only.
Primary Outcome
Determine the effectiveness of the current diagnostic modalities (mostly abdominal CT scanning) to predict near-isolated non-duodenal small bowel perforation resulting from blunt abdominal trauma, and their effect on time to surgery and related morbidity and mortality.

Secondary Outcomes
Determine the current complication and death rates resulting from near-isolated non-duodenal small bowel perforation, and compare those to older studies' results.

Hospital variables:
- Number of adult yearly trauma admissions
- Adult yearly trauma activations
- Adult yearly blunt mechanism admissions
- Adult yearly trauma patients with an abdominal CT performed in the ED
- Hospital protocol for 2nd CT scan (if any)

Patient variables:
- Demographics
- Date & Time of admission
- Date & Time of surgery
- Date & Time of initial abdominal CTs
- Discharge date
- Abdominal CT findings
- Diagnostic procedures other than CT scan
- Indication of surgery
- Preoperative physical exam findings, vital signs, and lab values
- Operative findings
- Post-op complications
- CT slice level (ie, 32, 64, 128)

List specific variables to be collected & analyzed
No samples or materials will be obtained from patients. Patients’ medical records will be accessed for collection of If data points listed below. Patients included in the study will be maintained in a master patient list, and only study investigators will have access to the list.

All data will already exist in the patient medical record at the time of data collection and no new data, specimens, or samples will be collected from patients. De-identified data for all participating sites will be maintained in a a in an online, secure, HIPAA-compliant database administered by the American Association for the Surgery of Trauma. The website is password protected. Each site PI will have access to subjects enrolled from their site only. No PI will have access to the entire database. The MUSC study PI, however, will have the ability to monitor data input from each participating site. Research records will be entered into this computerized study database and will be assigned a unique ID code. Participating sites will be allowed to submit data to the main database only after MUSC has received a copy of their IRB approval. At MUSC a master key which links MUSC subjects’ names and PATCOMs with the codes for each research record will be maintained until the study has ended and all the information has been collected and verified with the hospital chart. This information will be stored on a password-protected MUSC server accessible only to study team members. Any hard copy information that may have PHI will be stored in a locked drawer or cabinet. Patient names and PATCOM numbers will not be entered into the database. In addition, in lieu of dates, sites will count admission as day zero and all other dates as days from admission to preclude transmission of PHI.

Outline the data collection plan and statistical analysis plan succinctly

Data analyses.

1. Describe current methods trauma centers are using to diagnose non-duodenal SBP in patients with blunt abdominal trauma. Descriptive statistics will be used to evaluate the percentages of patients diagnosed via abdominal CT, Focused Assessment with Sonography in Trauma (FAST), abdominal ultrasound, x-ray, and/or diagnostic peritoneal lavage (DPL). Percentages of positive findings for each diagnostic modality, as well as physical exam, laboratory values, and vital signs (VS), will be calculated for patients with and without SBP.

2. Describe current mortality and morbidity due to blunt near-isolated non-duodenal SBP. Calculate overall mortality rate of patients with SBP, mortality rates by time to surgery, overall morbidity rate as number of complications, and morbidity rate of types of complications.

3. Describe the current average time to surgery for patients with blunt near-isolated non-duodenal SBP. Overall time to surgery will be calculated, as well as percentages of patients with SBP going to surgery in <8 hours, <16 hours, <24 hours, and ~24 hours.

4. Describe the frequency and utility of a second abdominal CT scan, and its association with time to surgery and incidence of post-operative complications in patients with blunt near-isolated non-duodenal SBP who did not go to surgery emergently (=within 4 hours) after an initial CT. Percentage of patients with SBP who had a 2nd abdominal CT scan prior to surgery, percentage with deteriorating physical exam pre-operatively and a 2nd CT scan, average pre-op lab values of patients with 2nd CT scan, and average pre-operative VS of patients with 2nd CT scan. A linear regression will be modeled with outcome of time to surgery and main independent binomial variable of the occurrence of a 2nd CT scan. Other
independent variables may include admission and pre-operative VS, admission and pre-operative lab values, admission and pre-operative physical exam, comorbid conditions, gender, race, payer status, slice level of CT machine, and presence of a hospital protocol regarding a second CT scan. Since there is little in the way of pre-existing data on which to build a sample size calculation, we are using a 'rule of thumb' calculation of 10-20 observations per degree of freedom for a linear regression, and assuming all continuous variables will have a linear relationship with the outcome of time to surgery. We are anticipating a full model with 52 degrees of freedom, which would result in a sample size range of 520 to 1020 patients (260 to 520 with SBP).

5. Determine the sensitivity and specificity of the best combination of diagnostic findings for distinguishing SBP and no SBP in patients with blunt abdominal trauma and no other severe injuries who had at least one abdominal CT. A conditional multivariate logistic regression will be modeled with outcome of SBP or none, and using independent variables of all available diagnostic findings (ie, radiologic, laboratory, physical). Again, since there is little in the way of pre-existing data on which to build a sample size calculation, we are using a 'rule of thumb' calculation of 10-20 observations per degree of freedom multiplied by the inverse percent of expected events for a logistic regression. We anticipate a full model with 24 degrees of freedom, and by design our outcome (or event) will occur in 50% of our patients. Thus we will need a sample size range of 480 to 960 patients (240 to 480 with SBP).

Descriptive statistics will be calculated on hospital level data. Additional descriptive statistics will be calculated on rate of false negative CT scans, rate of negative laparoscopies, and rate of negative laparotomies.

A Minimum of 260 cases and 260 matched controls, plus whatever number of negative laparotomies and laparoscopies, and SBP with no abdominal CT. We anticipate a maximum of 1000 records. We plan to recruit 100 trauma centers to join the study.

Outline consent procedures here, if applicable

No consent will be obtained, this is a retrospective data collection study.

-Risks: There are no physical risks associated with this study because there are no study-related interventions or interaction with the patients. There is, however, the potential risk of loss of confidentiality. Every effort will be made to keep each subject's information confidential.

Succinctly outline a risk/benefit analysis

-Benefits: The subjects whose records are used are not likely to receive any benefit from the proposed research; however, future patients and clinicians may benefit from the knowledge gained.


