EAST MCT Proposal

Study Title: PRECISE- AAPT: PRagmatic Evaluation of CT In StablE Anterior Abdominal Penetrating Trauma

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Specific Aims

Despite multiple published algorithms, anterior abdominal penetrating trauma (AAPT) continues to presents a diagnostic and management challenge. Hemodynamically stable patients without peritonitis, evisceration, or evidence of hemorrhage are eligible for a variety of management pathways: observation with serial examinations, computed tomography (CT) imaging, local wound exploration, or diagnostic laparoscopy[1,2]. Most data on CT utility in this population are over a decade old or based on small cohorts at single institutions[2-4]. Given the significant advances in axial imaging capabilities, metanalyses of historical data are insufficient and do not address this persistent knowledge gap A contemporary, prospective, multicenter study is necessary to determine if CT scanners can reliably exclude clinically relevant injuries requiring therapeutic intervention, thereby identifying patients appropriate for discharge in earlier phases of care, reducing unnecessary admissions and procedures.

In this study we aim to:

1. Determine the negative predictive value (NPV) of contemporary CT scans (>48 slice) in excluding clinically significant injuries (CSI) requiring intervention in hemodynamically stable trauma patients without peritonitis presenting with AAPT. We hypothesize that patients without clear evidence of solid organ or hollow viscus injuries identified on CT may be safely discharged from the emergency department without hospital admission.
2. Describe institutional variation in management of patients with AAPT. We hypothesize that practice patterns vary widely between institutions, with very few groups using local wound exploration or diagnostic peritoneal lavage in the evaluation of these patients.
3. Compare hospital length of stay and outcomes for patients with AAPT. We hypothesize that hospital length of stay (LOS) will vary significantly across management strategies and that CT-based discharge will be associated with decreased LOS.

We will conduct a prospective, pragmatic, observational study of adult patients presenting with AAPT and eligible for conservative management (CM). Collecting data on clinical decision-making, imaging results, and intraoperative findings, will generate a high-quality dataset that reflects real-world management and helps identify the imaging findings associated with the greatest likelihood of failing CM.

We anticipate that the results of this study will provide contemporary, multicenter data on how trauma centers manage stable AAPT patients and the diagnostic role of CT in their care. A better understanding of how this tool can be used in selecting appropriate patient disposition will inform future guideline development and improve systems resource allocation.

Research Strategy

Significance: What gap in knowledge does the study address? 1,000 characters.

In hemodynamically stable, patients without peritonitis presenting with AAPT, conservative management (CM) can be pursued through observation with serial examinations, local wound exploration, or diagnostic imaging[1,5-7]. Despite advances in image resolution, reconstruction algorithms, and photon-counting detector CT imaging, existing studies and meta-analyses rely on data that is over a decade old or collected from single centers using a small sample of patients[2-4,8]. Current recommendations support an observation period of 24 hours after AAPT to ensure a clinically significant injury (CSI) does not develop[2]. However, it is unclear if CT scan can be used to identify patients appropriate for early discharge.

Innovation: How does the study challenge or improve current understanding of the topic of interest? 500 characters.

The results of this study will inform practice management guidelines through an improved understanding of risk stratification for stable patients with AAPT. We hypothesize that our study will show CT scan can reliably identify patients who are at low risk of CSI requiring intervention after AAPT and can be discharged from the emergency department without need for prolonged observation. This has the potential to improve resource utilization and morbidity at trauma centers across the country.

Approach: 2,000 words

Aims & Outcomes

This study has one primary aim and two secondary aims. Through this pragmatic, multicenter study, we aim to:

Primary Aim

- Determine the utility of contemporary CT scanners in excluding clinically significant injury (CSI) in hemodynamically stable trauma patients without peritonitis and with anterior abdominal penetrating trauma (AAPT). We define CSI as any injury requiring therapeutic intervention including , but not limited to, patients requiring admission for observation, operative intervention by surgery, or an interventional radiology procedure. The primary outcome will be the negative predictive value (NPV) of CT scan in this patient population. We hypothesize that patients without injuries identified on CT may be safely discharged from the emergency department without hospital admission.

Secondary Aims

- Describe institutional variation in management of hemodynamically stable trauma patients without peritonitis with AAPT. We hypothesize that practice patterns vary widely between institutions.
- Compare hospital length of stay and outcomes for hemodynamically stable trauma patients without peritonitis with AAPT. We hypothesize that hospital length of stay and outcomes will vary significantly across management strategies, with CT-based discharge associated with the lowest burden.

To achieve these aims, we plan to do a prospective study of hemodynamically stable AAPT patients without peritonitis presenting to participating centers. AAPT is inclusive of gunshot and stab wounds. Patient management, including duration of observation and appropriateness of discharge, will be at the discretion of local surgeons, thereby providing a pragmatic view of practice management patterns after AAPT. Patients will first be stratified for analysis based on initial management strategy (Figure 1). The management arms displayed in Figure 1 are reasonable patient care strategies based on published guidelines[1,2,5,7]. While data will be collected on all eligible patients regardless of their initial management strategy, we are particularly interested in the CT scan results for those undergoing diagnostic imaging. Within the subset of patients undergoing CT scan, we will further categorize patients based upon their imaging findings (Figure 1). This will allow us to determine which imaging findings are the most important predictors of failing nonoperative management. Calculating NPVs for each of these imaging finding subgroups will help us identify which patients are eligible for earlier discharge due to low associated risk of decompensation.

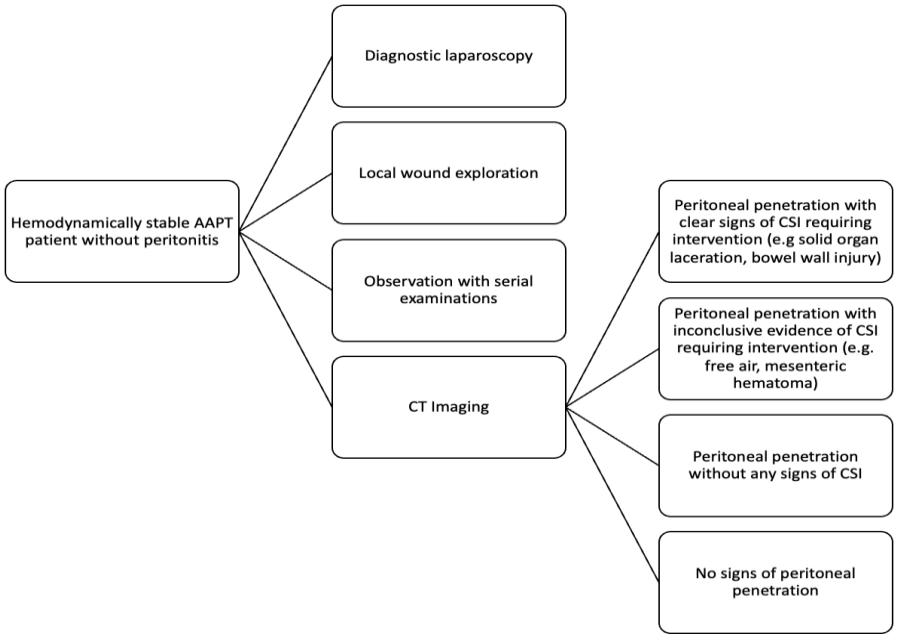

Figure 1. Stratification plan for initial management strategy and imaging findings in patients with penetrating trauma (gunshot or stab) to the anterior abdominal wall eligible for conservative management.

Inclusion Criteria: The study population includes all patients ≥ 18 years of age presenting to a level I or II trauma center with a penetrating wound to the anterior abdomen without an indication for immediate operative exploration. Patients with injuries from gunshot wounds and stab wounds will be eligible for inclusion. We will perform post hoc analysis to evaluate outcomes by injury mechanism. We define the anterior abdomen as inferior to the costal margins, superior to the inguinal ligaments and pubis, and medial to the anterior axillary lines. GCS ≥14. Patients with superficial, non-limb threatening injuries will be included.

Trauma centers will be eligible to participate in this study if they have a 64-detector or greater CT scan available for their trauma patients, a minimum slice thickness of 2mm for source images and reformats, and 24-hour radiology coverage for image interpretation[9,10].

Exclusion Criteria: Exclusion criteria include patients < 18 years of age, penetrating wounds to the back and or flank, limb-threatening injuries, traumatic brain injury, severe intoxication, pregnancy, current incarceration, hemodynamic instability upon presentation, peritonitis or evisceration on secondary exam, and thoracoabdominal penetrating injuries outside of the defined borders of the anterior abdomen. Patients transferred from an outside hospital to a participating center and those with imaging completed at an outside facility will be excluded.

Variables to be Collected: Table format with definitions if not obvious

Check Boxes: Gender, presenting institution, mechanism of injury, medical history, non-operative management strategy, ED imaging studies, operative management, rationale for operative management, ED disposition, complications, discharge location, mortality, readmission within 30 days (yes/no)

Text Variables: Age, weight, height, BMI, initial heart rate, initial systolic blood pressure, initial GCS, ED imaging findings, intraoperative findings, total time spent in ED, ICU length of stay, hospital length of stay. For length of stay, each partial or full day will count as one calendar day. For time spent in the ED, each partial or full hour will count as one hour. Time spent in ED will begin at time of presentation and end when the patient has a disposition assigned (e.g. admission, discharge, or surgical/IR intervention)

Institution Information: Baseline institution data collected at the beginning of the study will include: trauma center verification level, CT detector count, CT slice thickness,

contrast phases obtained in trauma imaging protocols, and average experience level of trauma radiologists

Statistical Analysis Plan: Statistical tests to evaluate the hypothesis, sample size justification, power analysis, effect size, Type I error, Power, handling of missing data, confounding and bias control, planned subgroup & sensitivity analyses, software to be used.

To calculate the negative predictive value (NPV) of CT scan for excluding CSI after penetrating abdominal trauma in patients without immediate indication for operative intervention, we will need to determine the number of true and false negatives. True negatives will be defined as patients without significant injury identified on CT scan who do not require therapeutic intervention. False negatives will be defined as patients without significant injury identified on CT scan who do require intervention for intra-abdominal injuries by surgery or interventional radiology at the time of index admission or within 30 days of injury. NPV with 95% confidence will be calculated using exact binomial methods. We will also report sensitivity, specificity, and positive predictive value of CT scan in this population. To describe institutional variation in management strategies, chi-square or Fisher's exact tests will be used. Multilevel logistic regression will be used to adjust for patient factors. Nonparametric tests will be used to compare median hospital length of stay across management strategies. Descriptive statistics will be used to summarize patient demographics; patient characteristics across management strategies will be compared using chi-square and non-parametric tests as appropriate.

We plan to analyze the data as a single cohort of all patients with AAPT and perform sub-analyses dichotomizing patients by mechanism of injury (e.g. GSW versus stabbing). The sub-analyses will allow us to account for differences in management strategies and patient physiology between these mechanisms of injury. To account for institutional variation, we will use hierarchical logistic regression, with institution as a random effect, to evaluate likelihood of CT use, operative management, and CSI. Institution-level factors will be compared using descriptive statistics for imaging protocols (e.g. detector count), variation in discharge rates for patients with negative CT scans, and variation in intervention rates for similar CT scan results.

For this study, statistical significance will be set at $p < 0.05$. Sensitivity analyses will be performed using complete cases and multiple imputation will be used to handle missing data. All data will be analyzed in R. Based on pooled meta-analysis data[6] showing a false-negative rate of 8.7% for CT scans in stable patients with anterior abdominal stab wounds, we calculated an NPV of 91.3%. To calculate the NPV of modern-day CT scanners with 95% confidence, we need a sample size of 950 patients. We expect to enroll 30 centers in this study; therefore, each will need to contribute

approximately 32 patients over the 18-month study period to achieve the necessary sample size.

Logistics

Number of Sites & Number of Patients per Site:

We anticipate a total of 30 trauma centers participating. Based on the number of patients meeting the above inclusion criteria at our trauma center annually, we expect to enroll approximately 1,350 patients over the course of 18 months.

Data Collection Tool:

All de-identified patient data will be entered into a data collection instrument built in REDCap. Each patient will be given a study-specific unique ID number to reduce the risk of confidentiality breach. Only necessary research team members will have access to the password-protected REDCap database. Upon conclusion of the study, the PI and Co-PI at the primary site will download the data onto institutional, password-protected computers. Data sharing will adhere to the protocol outlined in the primary institutions Data Use Agreement. All communications related to the study will be sent via HIPAA compliant emails. A data dictionary will be created and a kickoff meeting with comprehensive training will be used to ensure consistency in data collection between centers. Regular check-in meetings to discuss issues with data collection and questions will be scheduled. Data audits will be performed periodically to assess missingness and evaluate for discrepancies between sites. Within our REDCap instrument, we will utilize mandatory fields, data validation, and include relevant definitions to support complete and accurate data entry.

Identify individuals that will be primarily responsible for data collection:

The PI and co-PI will primarily be responsible for the data collection process. Surgical fellows, residents, and medical students will assist with data collection at our site.

Human Subjects, Resources, & Environment

Has IRB approval been obtained at the Primary Site?

Yes – pending approval

Is a DUA required for participation in the study?

Yes

If applicable, list the primary contact (email/name) to contact for DUA.

Emma Burke, emma.burke@bcm.edu

Does the study require informed consent?

Given that this would be a pragmatic study, and the minimal associated risks, a waiver of consent will be requested. No specific interventions are required and patients will be managed at the surgeon's discretion.

Consent Procedure:

Not applicable

Does the study require funding?

No

If so, what is the source of funding? Will funding be available at the time of MCT initiation?

Not applicable

Outline what resources are available to you to ensure the study will be completed.

Baylor College of Medicine (BCM), the primary institution for this study, has a robust clinical research infrastructure to support the execution of this multicenter study. The Dan L. Duncan Institute for Clinical and Translational Research has dedicated coordinators and biostatisticians available to ensure efficient data collection and analysis. Secure access to REDCap is provided through our institution and support is available through a dedicated research information technology team. BCM's history of successful initiatives reflects a commitment and capacity to manage large-scale research projects.

Is this study being actively reviewed or in review by any additional surgical societies?

No

Statistical plan/Data analysis developed with the assistance of a statistician.

Yes

Statistical support available to the PI to perform the analysis at the completion of the study:

Yes

If “yes”, who will be analyzing the data?

The co-PIs on this study will analyze the data in conjunction with a biostatistician from the Dan L. Duncan Institute for Clinical and Translational Research Biostatistics Core.

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