Study Title: Radiographic Evaluation of Delayed Solid Organ Complications (REDSOC) Study

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Background and Significance:

There is no clear evidence as to the necessity of repeat imaging or frequency of intervention in blunt splenic and hepatic injuries. Our group approached this question through a dual institution, retrospective pilot study observing the management of delayed splenic and hepatic complications found on repeat imaging. Delayed complications were defined for each organ as follows. Hepatic injury: pseudoaneurysm, increased hemoperitoneum, injury progression, bile leak/biloma, abscess, vascular thrombosis. Splenic injury: pseudoaneurysm, increased hemoperitoneum, injury progression, abscess, vascular thrombosis, pancreatic fistula, arteriovenous fistula, and delayed contrast extravasation. Blunt splenic and hepatic injuries were defined by the AAST Grading system. This study was performed in the adult population and a current study is ongoing in the pediatric population. Imaging was obtained either via the institution's standard protocol (SP) or physician discretion (PD) defined as change in laboratory values, vital sign abnormalities, clinical change, etc. Of 235 adult spleen and 365 adult liver injuries, only 45% and 33.4%, respectively, underwent repeat imaging. Our data suggested that using a SP in splenic trauma may lead to earlier identification and intervention of delayed complications. Conversely, in hepatic injuries, there was no difference in repeat imaging via SP or PD. In this small pilot study, we were unable to achieve all of our primary and secondary endpoints.

This study did not have power due to a limited number of patients receiving repeat imaging and/or interventions, thus making characterization of types of interventions and final outcomes difficult. Additionally, interventions in low grade injuries are uncommon, and a larger data set would allow for delineation in management between low, moderate and high grade splenic and hepatic injuries. A large multicenter trial would allow for appropriate power for the proposed study and thus allow for us to meet our endpoints. There are multiple variables affecting the management of blunt splenic and hepatic injuries, and currently no clear guidelines exist in regards to repeat imaging. Gaining a better understanding of types of delayed complications, how they present, and current management strategies would assist in creating a standardized algorithm in the treatment of this patient population.

Primary aim:

To define which blunt splenic and hepatic injuries, by AAST Grade, are at risk of delayed complications.

Secondary aims:

Aim 2: To ascertain which patients warrant repeat imaging and when this imaging should be performed.

Aim 3: To identify the incidence of interventions performed for delayed complications found on repeat imaging.

Inclusion Criteria:

All patients (all ages) who present with blunt trauma to the spleen and/ or liver will be included.

Exclusion Criteria:

Patients who suffer a penetrating mechanism will be excluded. Additionally, those who were transferred to another facility prior to admission will be excluded.

Therapeutic Interventions:

This will be a prospective observational study only. Patients will be managed according to the surgeon's discretion.

Primary Outcome:

Delayed complications found on repeat imaging

Secondary Outcomes:

Timing to repeat imaging/ intervention, interventions performed based on complications found, mortality, length of stay, blood transfusion requirements, VTE prophylaxis.

Specific variables to be collected & analyzed:

Age, sex, time from injury, Injury Severity Score (ISS), Abbreviated Injury Scale (AIS), Trauma and Injury Severity Score (TRISS), mechanism of injury initial vital signs, anticoagulant use and reversal agents, initial and repeat imaging, AAST Grade of organs injured, complications found, details regarding initial and any delayed interventions, blood transfusions, details regarding venous thromboembolism prophylaxis, venous thromboembolism complications, hospital length of stay, intensive care unit length of stay, mortality

Data Collection/ Statistical Analysis:

Standardized data will be collected for each patient meeting inclusion criteria (see data collection tool). The de-identified data for each patient will be entered into a secure REDCap database. A total of 3,200 splenic injuries and 1,200 hepatic injuries is recommended to

identify a significant difference between the standard protocol group and the physician discretion group (more detailed sample size and power estimates are available). Complications found on repeat imaging will be assessed using univariate and multivariate analysis. Categorical variables will be compared using Fisher's exact test or Chi-squared test. Continuous variables will be assessed using Student's t-test. For multivariate analysis, a mixed effect multinomial logistic regression will be run with a binary outcome of whether the patient had a delayed complication. Another mixed effect multinomial logistic regression will be run with a binary outcome of whether the patient had an intervention performed. Additional analysis will be completed to determine if there is optimal timing for repeat imaging to identify complications. Data will be reported as adjusted odds ratios with 95% confidence intervals. Statistical significance will be defined by a $p<0.05$.

Consent Procedures:

This is a prospective observational study in which data will be retrospectively recorded on patients according to institutional protocols. Thus, a waiver of consent is requested. Data will be recorded on a data sheet and transferred to REDCap database without any patient identifiers.

Risk/Benefit Analysis:

The data collected and transferred to REDCap for the multicenter trial would be devoid of any patient identifiers and thus a low risk study.

The benefit would be to improve clinical practice as the incidence and characterization of delayed complications in blunt solid organ injury is not well understood. Additionally, understanding types of delayed complications, when they are identified, and if/ how they are treated will allow for a standardized algorithm and improved outcomes for this population of patients.

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