Project Summary:

A Multi-Center Study of Renal and Bladder Trauma

Principal Investigator:
Jeremy B. Myers, MD, FACS
University of Utah Department of Surgery
Slag Lake City, UT

Co-investigator:
Raminder Nirula, MD
University of Utah Department of Surgery
Slag Lake City, UT

Study Purpose and Objectives: We aim to evaluate the diagnosis, management, and outcomes of genitourinary tract trauma

What is Your Research Hypothesis?

We have several hypotheses that we hope to investigate with this multi-center study of genitourinary (GU) trauma.

Lower urinary tract trauma:

1 – Is operative repair of extraperitoneal bladder injury associated with a lower post-injury leak rate and better outcomes?

2 - Extraperitoneal injuries can be stratified based upon location, radiologic, and clinical characteristics into high risk and low risk for post injury leak and complication. High-risk injuries benefit from upfront repair of the injury in the acute injury setting.

Renal trauma:

1 – A model based upon clinical and radiologic characteristics can help predict patients at high risk for post injury hemorrhage and help guide management of renal injury.

2 - Aggressive intervention for blunt and penetrating renal injuries is associated with decreased incidence of delayed renal hemorrhage and improved outcomes as compared to conservative management.

3 – Renal urinary extravasation is best managed with aggressive urinary drainage in the acute injury setting.

GENERAL BACKGROUND:

Genitourinary (GU) trauma is relatively rare with kidney injury occurring in less than 1% of trauma admissions[1, 2] and bladder injury occurring in 0.2 % of trauma admissions.[3] Because GU injuries are relatively rare, there is a lot of disparity in the literature regarding recommendations for their management. Study of GU trauma is important because the injuries are associated with higher mortality[4] and can lead to severe morbidity if they are not managed well.

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BLADDER TRAUMA BACKGROUND:

Lower urinary tract injury from trauma involves the bladder and the proximal urethra. These injuries most often are caused by blunt trauma and are accompanied by a pelvic fracture. Bladder injuries occur in about 4% of pelvic fractures. In Utah, at level 1 trauma centers, as well as in other large studies, the overall incidence of bladder trauma was 0.2% of all trauma admissions.[1, 2] The rarity of these injuries make it very challenging to study management and outcomes. Large published series have no more than 100-150 injuries and were mostly published 1-2 decades ago when many aspects of the management of pelvic trauma were substantially different than today.[3, 4]

Questions in Bladder Injury:

Bladder injury results from a tear in the bladder and may be one of two major types: intraperitoneal (communicating with the peritoneal cavity), or extraperitoneal (confined in the retroperitoneal space surrounding the bladder). The management of intraperitoneal injury is

straightforward and involves surgical repair of the bladder injury and eliminating the communication with the peritoneal cavity. Extraperitoneal injuries, however, are managed with a spectrum of aggressiveness depending upon the experience and comfort level of the surgeon. These injuries can heal in many cases with urinary catheter drainage for a period of time; however, the complication rate with catheter drainage alone is higher. [5, 6] Defining which injuries need surgical management versus those that can be managed conservatively is difficult since there is such a variation in practice patterns. Urinary leak after bladder injury can be a devastating complication and can lead to chronic infection, the need for removal of pelvic hardware and even urinary diversion. A multi-center study could better define the characteristics of bladder injuries more likely to fail conservative management and create evidence-based guidelines for which types of injuries that would do better with surgical management.

Additional questions in the management of bladder injury include how to manage these injuries when there is the need for concomitant pelvic fracture fixation. Many urologists feel that these injuries should be repaired at the time of anterior pelvic fixation to avoid contamination of the orthopedic hardware, but whether there is actually a higher risk of morbidity is not known. In addition, when the bladder injury is approached surgically the retroperitoneal space of Retzius is developed and the tamponade effect on urinary leak is destroyed, which may make urinary leak longer, more protracted and harder to manage.

Summary:

Study of genitourinary (GU) trauma outcomes with multiple participating trauma centers will allow rapid definition of best management practice. This type of study could lead to trauma guidelines in GU trauma that will influence care throughout the United States and the world.

Power calculation for lower urinary tract trauma:

Is there a decreased rate of prolonged urinary leak associated with surgical repair of extraperitoneal bladder injury versus conservative management with catheter drainage alone?

Bladder trauma occurs in 0.2 % of trauma admissions. The database should survey approximately 40,000 trauma admissions per year. Thus the number of bladder injuries entered

into the database should be about 80 per year. Extraperitoneal bladder injury is more common than intraperitoneal bladder injury and accounts for about 66% of cases or about 53 cases per year.

The urinary leak rate in these injuries varies based upon management strategies of individual trauma institutions. In our recent review we found a 19% rate of persistent leakage in injuries that were mostly managed conservatively without surgical repair (69% of injuries).

We hypothesize that there would be as high as a 75% decrease in persistent urinary leak associated with operative repair versus conservative management of these injuries.

For the purpose of our power calculation we could assume an approximate 20% rate of urinary leak associated with extraperitoneal injury or about 11 patients per year in the database and that operative repair would decrease this rate by 75%. The number of patients needed to detect this difference would be 152 and the database would have to run for 2-3 years to detect this difference.

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RENAL TRAUMA BACKGROUND:

Renal injuries are relatively uncommon, occurring in about 1% of patients hospitalized after traumatic injury.[1, 2] Of all genitourinary (GU) trauma, however, the kidney is by far the most commonly injured organ.[3, 4] Extrapolations based upon large renal trauma series estimate there to be an annual incidence of 245,000 traumatic renal injuries worldwide.[4] In large population based studies, blunt injury is the leading mechanism of injury and accounts for between 81-95% of cases. With the advent of advanced trauma critical care, as well as precise methods of assessing renal trauma with computed tomography (CT scan), the vast majority of patients, even those with high-grade injuries, can be managed conservatively.[5]

Ideal management strategies have yet to be defined for many aspects of high-grade renal injury. A large multi-institutional study could investigate several questions about its management. These questions include: the sequelae associated with poor compliance with imaging recommendations, optimal management of ongoing or delayed renal hemorrhage, conservative versus aggressive management of urinary leak, and comparative outcomes of patients undergoing nephrectomy versus non-surgical management. The significant variation in practice patterns between trauma institutions would allow definition of optimal management of renal trauma.

Specific Aims:

Imaging:

We have found that compliance with recommended imaging in renal trauma is not ideal. Current recommendations are to evaluate renal trauma with computed tomography (CT scan) with IV contrast and then obtain delayed images when there is a high-grade injury identified or there is

peri-nephric fluid.[4] We found that compliance with these imaging recommendations was low among level 1 trauma hospitals in Utah (75%), as well as from tertiary referring hospitals (61%).[6] We hypothesize that improper staging of renal injuries due to lack of excretory images on CT scan may lead to adverse sequelae including higher readmission rate, prolonged morbidity, and even delayed nephrectomy due to unrecognized and poorly managed urinary leak. With a larger series from multiple institutions we could determine if poor compliance with recommended imaging leads to actual measurable increased morbidity.

Renal Hemorrhage:

A multi-institutional study could answer two interesting questions about hemorrhage risk and management in renal trauma. The first issue is defining a prognostic model to predict the need for intervention for renal hemorrhage. Potential interventions include nephrectomy, partial nephrectomy, and angioembolization. There have been several studies that have attempted to correlate findings on initial CT scan with hemorrhage risk.[7-10] Several characteristics were defined in these studies including the size of perinephric hematoma, active vascular extravasation, location and complexity of laceration, and interruption of Gerota's fascia surrounding the kidney. These studies, however, are limited as they are single institution studies or from closely linked regional facilities and there is significant variation in the intervention rate between the studies. A multi-institutional study would be able to define the intervention rate associated with presenting CT scan characteristics across the United States.

The second issue that can be investigated with this study is the timing of intervention for renal hemorrhage. Since there is significant variation between institutions regarding the threshold for intervention when patients are hemorrhaging from a renal laceration, the study could define the best time to intervene based upon outcome measures.[7] It may be that it is best to intervene early and aggressively, thereby preventing growth of a large hematoma, minimizing ongoing bleeding and the adverse physiologic consequences that go with it, and finally, thrwarting complications like ileus or abdominal compartment syndrome. Conversely, our proposed study could demonstrate that aggressive intervention is not warranted until a certain threshold is reached in order to avoid complications of angiography and/or surgery.

Urinary extravasation:

Similar to renal hemorrhage the management of urinary extravasation in grade 4 AAST injuries is very variable between trauma centers.[11-13] Some urologists will aggressively place ureteral stents at identification of urinary extravasation, while others will not intervene until there is development of a symptomatic urinoma identified by fever or elevated serum creatinine. This practice variation again would serve well to evaluate if aggressive control of urinary leak into the retroperitoneum benefits patients compared to conservative management. Simple measures of outcomes within 30-90 days would allow definition of morbidity with either approach.

Implications of nephrectomy:

Patients have worse renal function after trauma nephrectomy. This is obvious and has been demonstrated in previous studies.[14, 15] Do patients also have longer ICU stay, as well as other increased measurable morbidity and mortality? Patients in a large renal trauma registry can be matched with other patients based upon injury severity score, interventions, blood transfusion, as well as other factors. This type of matching may allow a more sophisticated quantification of morbidity than simple measurement of post trauma renal function. A greater understanding of the impact of nephrectomy on immediate peri-trauma outcomes would encourage systems to embrace strategies that minimize nephrectomy.

Summary:

Study of GU trauma outcomes with multiple participating trauma centers will allow rapid definition of best management practice. This type of study could lead to trauma guidelines in GU trauma that will influence care throughout the United States.

Power calculations renal trauma:

Is there an improved outcome associated with aggressive treatment of active bleeding from the kidney in high-grade renal injury?

The incidence of high-grade renal injury per year is 0.5% among patients admitted for trauma at level 1 trauma hospitals. In our trauma system 5,000 trauma cases are admitted per year. This translates to 25 high-grade renal injuries per year.

We are hoping to enroll 8-10 level 1 trauma facilities in our study through the AAST. Thus our conservative estimate is to survey approximately 40,000 trauma admission per year and capture 200 high-grade renal injuries per year.

Some measures of risk for ongoing renal bleeding include a medial laceration in the kidney, active vascular extravasation, and a perinephric hematoma greater than 3.5 cm. In our recent study, we found 75% of patients evaluated had at least one of these characteristics in high-grade renal injury. Thus we could estimate enrollment of 150 injuries per year that had at least one risk factors for ongoing hemorrhage in our database.

The intervention rate varies significantly between institutions from close to 20% to about 10% for active hemorrhage in high-grade renal trauma. Averaged between the institutions we could expect about a 15% intervention rate. We would hypothesize between a 50% improvement in measurable outcomes with aggressive intervention compared to conservative management. These measureable outcomes would be factors like blood transfusion, ICU stay, development of abdominal compartment syndrome etc…

Assuming a 15% intervention rate and a 50% improvement in outcomes a statistical power calculation reveals that we would need 556 number of patients enrolled in the study. This would be achievable in 2-3 years of the study.

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Location of the Study: AAST Multicenter Trials

WAIVER OF CONSENT:

Consent should be waived for this study. There are several reasons that this is essential to carrying out the study. The first reason involves the retrospective data entry and the data's minimal risk to patients. The data will be entered typically at 1-3 months after discharge from the hospital and is based upon patients that are identified in the trauma registry, not during their acute trauma. Because of the retrospective nature of the data, it would be difficult to obtain consent from patients prior to entering their data. There is no easy method for the active clinical trauma service to identify patients with GU trauma and have them consented for future study entry. In addition, contacting the patients would be difficult as many of the patients suffering

trauma have variable psychosocial circumstances and may not have fixed addresses and feasible methods for contact. Another important consideration is that the data has minimal risk to patients. It is de-identified when it is entered to the AAST and patients are assigned a unique subject number. This is likewise true of radiology that is uploaded to the AAST site by study centers. In attempting to contact patients that have suffered recent severe abdominal trauma, patients may experience psychological stress by reliving some or all of the traumatic events. Additionally, families would have to be contacted after having lost their loved ones who have died because of the trauma, which would obviously be very stressful for the families. The risk of repeated psychological trauma, for a de-identified retrospective database that has minimal risk to patients, outweighs the ideal goal of obtaining consent for participation in this study.

The last consideration is the data-integrity. Unfortunately patients suffering GU trauma have very high injury severity scores, are often critically ill and have a high death rate. These types of patients cannot sign a consent or understand what the consent means. Many times there is no family available for these patients and consent for procedures is assumed. Lack of consent in many of these patients and subsequent exclusion from the study would enrich the study for low-grade injuries. As such, the study goals and conclusions would be corrupted because the patient population included in the study would not represent a true population of GU injury patients.

PARTICIPANT INCLUSION CRITERIA: Patients suffering GU trauma identified in the level 1 trauma database, will retrospectively be reviewed and details of their injuries will be entered into the AAST data site.

PARTICIPANT EXCLUSION CRITERIA:
No luminal bladder injury
No renal injury AAST grade 3 or greater
< 18 years of age

DESIGN:
This study is a retrospective case review of patients entered into a centralized database after their bladder or renal trauma. Typically patients will be entered 4-8 weeks after their trauma admission and any subsequent complications have passed. The study is projected to last 2-3 years.