Specific Aims

Traumatic bladder injuries are uncommon but carry significant morbidity if not properly managed. Current national trauma and urology guidelines provide broad recommendations regarding surgical management, yet practice patterns vary considerably with respect to follow-up imaging and urinary catheter duration. Intraperitoneal injuries are universally managed with surgical repair followed by urinary catheterization for an ill-defined period. Extraperitoneal injuries, depending on associated injuries and specific injury characteristics, may be managed surgically or nonoperatively, with the latter often requiring prolonged catheterization. In both injury types, follow-up imaging is frequently obtained before catheter removal to confirm healing.

High-quality evidence-based guidance regarding the optimal duration of catheterization and the necessity or timing of follow-up imaging is lacking. This variability contributes to potentially unnecessary imaging and prolonged catheter use, both of which have been associated with higher rates of catheter-associated urinary tract infections (CAUTIs).

The long-term goal of this research is to establish evidence-based guidelines for the management of traumatic bladder injuries that optimize healing while minimizing complications and healthcare resource use. The objective of this proposal is to define the role of follow-up imaging in both surgically and nonoperatively managed bladder injuries and to determine the ideal urinary catheter duration. Our central hypothesis is that early (≤7 days) follow-up imaging after surgical repair will not increase radiologic finding of postoperative leak and allow for shorter catheterization, thereby reducing CAUTIs. This hypothesis is supported by preliminary institutional observations where early imaging patients had similar rates of urinary leak on initial follow-up imaging (3.5% (1/29) vs 8.6% (6/70), p=0.67) and significantly shorter duration of urinary catheterization (7.0 ± 4.0 days vs 14.0 ± 7.0 days, p=0.0001) and lower rates of CAUTI (6.9% (2/29) vs 30% (21/70), p=0.017).

We will pursue the following specific aims:

1. Evaluate differences in postoperative urinary leak incidence (primary outcome), catheter duration, and CAUTI between patients undergoing early (≤7 days) and late (>7 days) postoperative imaging following bladder repairs.
2. Evaluate differences in postoperative urinary leak incidence (primary outcome), catheter duration, and CAUTI between patients undergoing early (≤7 days) and late (>7 days) postoperative imaging by bladder injury location (intraperitoneal versus extraperitoneal versus combined).
3. Evaluate differences in urinary leak incidence (primary outcome), catheter duration, and CAUTI between operative and nonoperative management of isolated extraperitoneal bladder injuries.

This study will provide the first high-quality, comparative evidence to standardize the use and timing of follow-up imaging and to define optimal catheterization duration in traumatic bladder injuries. Results will directly inform trauma and urology guidelines, lower CAUTI rates, reduce urinary catheter duration, and improve patient outcomes while optimizing healthcare resource utilization through selective follow-up imaging.

Research Strategy

Significance

Traumatic bladder injuries, although relatively uncommon, represent a complex urologic and trauma challenge with the potential for significant patient morbidity. Current national trauma and urology guidelines provide general recommendations for identifying candidates for surgical repair. However, there remains substantial variation in follow-up imaging practices and the duration of urinary catheterization. This variability stems from a lack of high-quality evidence, resulting in management strategies that may increase the risk of CAUTIs and lead to unnecessary imaging.

Critical Barrier to Progress

The primary barrier to optimizing care for traumatic bladder injuries is the absence of evidence-based protocols defining the ideal duration of catheterization and the necessity or timing of follow-up imaging. Without standardized, data-driven guidance, clinicians rely on institutional habits and anecdotal experience, leading to inconsistent care and preventable complications.

Importance of Topic

Prolonged urinary catheterization is strongly associated with higher CAUTI rates and increased healthcare costs. Similarly, follow-up imaging may be overutilized without a clear understanding of its impact on patient outcomes. Establishing evidence-based standards for these practices will directly reduce healthcare-associated infections and optimize resource utilization.

Advancement of Scientific Knowledge and Clinical Practice

If the aims of this project are achieved, the study will provide definitive, comparative evidence on how early follow-up imaging affects CAUTI rates and urinary catheter duration in both surgical and nonoperative management of traumatic bladder injuries. It will establish evidence-based, injury-specific catheterization durations to replace current broad, non-specific time frames. In addition, it will clarify the optimal role and timing of imaging, with the potential to eliminate unnecessary cystography studies.

Impact on the Field

Successful completion of this project will fundamentally shift both the concepts and methods guiding bladder injury management. The work will move practice away from prolonged, one-size-fits-all catheterization toward individualized, evidence-based protocols tailored to injury characteristics. It will reduce reliance on routine follow-up imaging by introducing criteria-driven strategies that optimize diagnostic yield. Findings will inform revisions to national trauma and urology guidelines, promoting standardized, high-quality care across institutions. Ultimately, these changes are expected to decrease CAUTI incidence, improve patient-reported outcomes, and reduce healthcare costs. By addressing this critical evidence gap, the proposed research will deliver immediate and actionable findings that will directly improve clinical practice, enhance patient safety, and promote efficient healthcare resource utilization.

Innovation

This project challenges the current clinical paradigm for the management of traumatic bladder injuries, which relies on broad, non-specific guidelines and institutional preference rather than evidence-based, individualized protocols. While current recommendations endorse urinary catheterization and follow-up imaging, they do not define the optimal duration of catheterization or the most effective timing or necessity of imaging. This study introduces a data-driven, outcome-based approach to determine whether early follow-up imaging facilitates earlier safe urinary catheter removal and reduces CAUTIs.

Novelty in Concept and Approach

This will be the first multicenter study to directly compare early (≤7 days) versus delayed (>7 days) follow-up imaging after both surgical and nonoperative management of traumatic bladder injuries. The project employs a comparative effectiveness approach across multiple injury types and management strategies, an analytic framework not previously applied to this patient population. By explicitly linking imaging timing to downstream patient-centered outcomes, rather than focusing solely on healing rates, the study reframes the role of follow-up imaging in bladder injury care.

Novelty in Application

The study applies established epidemiologic and statistical methods to a clinical area where they have not been systematically employed, using multivariable modeling to account for injury severity and treatment heterogeneity.

Refinement and Improvement of Practice

The findings from this study are intended to directly inform national guideline revisions, replacing one-size-fits-all urinary catheterization protocols with tailored, evidence-based recommendations. By identifying patients who can safely undergo earlier urinary catheter removal, the research has the potential to significantly reduce CAUTI rates and lower healthcare costs, while also enhancing patient comfort and satisfaction.

In summary, this work is innovative both in its design and in its clinical implications. It transforms postoperative and nonoperative bladder injury management from an experience-driven to an evidence-driven process and establishes a framework that can be adapted to other areas of trauma and urology practice.

Approach

Study Design

This prospective, multicenter, observational cohort study will enroll adult and pediatric patients (≥14 years of age) with traumatic bladder injuries (grade ≥2) presenting to participating Level I and II trauma centers. The primary objective is to compare clinical outcomes based on the timing of follow-up cystography, defined as early (≤7 days) versus delayed (>7 days), following surgical repair of bladder ruptures. Secondary objectives include comparison of outcomes by injury location (extraperitoneal versus intraperitoneal) and between operative and nonoperative management of isolated extraperitoneal bladder injuries.

Statistical Analysis

Descriptive statistics will characterize baseline demographics and injury patterns. The primary analysis will compare postoperative urinary leaks rates between early and delayed imaging groups using chi-square or Fisher's exact tests. Continuous outcomes (e.g., catheter duration) will be compared using t-tests or Wilcoxon rank-sum tests. Multivariate logistic regression will adjust for potential confounders including patient demographics, injury type and severity, concomitant injuries, and management team.

Participating Sites

We anticipate collaboration with 20-30 Level I and II trauma centers. Based our institutional trauma registries, each site is expected to enroll 5-15 eligible patients annually over a 3-year recruitment period, yielding a target sample size of 750 patients. Sample size calculations were based on preliminary institutional data comparing early (≤7 days) versus late (>7 days) follow-up imaging after traumatic bladder injury. In our pilot cohort (n=99), early imaging was associated with lower CAUTI rates (6.9% [2/29] vs 30.0% [21/70], p=0.017; absolute difference 23.1%), shorter urinary catheter duration (7.0 ± 4.0 vs 14.0 ± 7.0 days, p=0.0001; absolute difference 7.0 days), and no increase in urinary leak rates (3.5% [1/29] vs 8.6% [6/70], p=0.67; absolute difference 5.1%). Using a two-sided $\alpha = 0.05$ and 80% power, detecting the observed CAUTI difference requires 49 patients per group (total n=98) under equal allocation. For catheter duration, 17 patients per group (total n=34) are needed under equal allocation. Urinary leak requires a substantially larger sample size of 368 patients per group (total n=736) to detect the observed difference. Early imaging following surgical repaired occurred in approximately 25% of our institutional case with traumatic bladder injuries grade ≥2. Assuming a 1:3 weight, we would need to enroll 136 patients and 44 patients to detect the observed differences for CAUTI and catheter duration. Taken to extreme where only 10% of patients would undergo early imaging, we would need to enroll 290 patients and 90 patients to detect the observed differences for CAUTI and catheter duration. To ensure adequate power for the outcomes (CAUTI and catheter) while accommodating potential attrition and variability in practice across sites, we plan to enroll a minimum of 400 patients across participating trauma centers.

Eligibility Criteria

- **Inclusion:**
  - Confirmed full-thickness bladder injury (grade ≥2) by cystography or intraoperative findings from a traumatic mechanism
  - Initial evaluation and/or definitive surgical management at study institution
- **Exclusion:**
  - Age <14 years
  - Death during admission or any body region AIS score 6
  - Concomitant urethral, ureteral injury, or suprapubic catheterization
  - Lost to follow-up prior to urinary catheter removal or postoperative/interval imaging
  - Neurogenic bladder
  - Iatrogenic bladder injuries
  - End-stage renal disease

Data Collection and Management

Data will be prospectively recorded in a centralized, secure REDCap database using standardized

electronic case report forms with predefined fields and drop-down menus to ensure consistency. Collected variables will include:

- Demographics (age, sex, comorbidities, etc.)
- Injury mechanism (blunt vs penetrating) and severity (GCS, AIS scores for each body region [head, face, neck, thorax, abdomen, spine, extremities, skin], ISS, AAST bladder injury grade, and bladder injury size)
- Diagnostic modalities (urinalysis, imaging, intraoperative findings)
- Bladder injury classification (intraperitoneal vs. extraperitoneal, AAST grade, size of largest defect, number of bladder defects)
- Concurrent injuries (pelvic fracture, pelvic hematoma, rectal injury, vaginal injury, etc.) and intervention (pelvic fixation, pelvic packing, bowel resection, etc.)
- Management strategy (operative vs. nonoperative, leak test at time of surgery, pelvic drain, antibiotic prophylaxis)
- Bladder repair team (trauma, urology, orthopedic surgery) and bladder postoperative management team (trauma, urology, orthopedic surgery)
- Follow-up imaging (timing, modality, number of studies)
- Catheter duration
- Complications (CAUTIs, bacteremia, superficial surgical site infection, and deep surgical site infection)

Communication and Coordination

The University of Maryland, Baltimore will serve as the coordinating center for protocol implementation, study governance, and day-to-day communications. Each participating site will designate a site principal investigator and a research coordinator who will be the primary points of contact. Routine communications will include hosting quarterly videoconferences to review enrollment, address data queries, and ensure adherence to study protocols. Quarterly emails will summarize progress in recruitment and data collection.

Anticipated Multi-Institutional Challenges and Solutions

Using a traditional IRB model for this multicenter study could cause substantial delays, as each site would independently review the protocol, often resulting in inconsistent stipulations that require reconciliation before enrollment. To promote efficiency and consistency across sites, each participating center will be provided with our institution's IRB-approved protocol and supporting documents to facilitate the preparation and timely submission of their local IRB applications.

Negotiating separate Data Use Agreements at each site may be prolonged by varying institutional policies, legal language, and data security requirements. Centralized templates and early engagement with institutional legal teams will be used to expedite execution.

A waiver of consent will be requested, as both treatment approaches reflect current standard of care and pose minimal additional risk, reducing barriers to enrollment and minimizing delays.

Variations in data definitions, documentation standards, and electronic medical record systems across centers can impede pooled analyses. Standardized case report forms, uniform coding, and training for site coordinators will ensure consistency.

All data will be transmitted via encrypted, institution-approved channels and stored on HIPAA-compliant servers, with access restricted to authorized personnel.

Anticipated Results and Impact

We hypothesize that early postoperative cystography will not increase rates of urinary leak and will reduce CAUTI rates and shorten catheter duration after surgical repair of traumatic bladder injuries. We further anticipate that, compared with nonoperative management, operative repair of isolated extraperitoneal bladder injuries will yield similar benefits without added complications. This study will generate the first prospective, multicenter data to inform the necessity and optimal timing of follow-up imaging after surgical repair and to optimize management strategies for isolated extraperitoneal bladder injuries. Findings will directly support future EAST guideline updates and advance the standardization of care across trauma centers.

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