Specific Aims

Living with a urethral foley catheter can be a painful and traumatic experience for male patients, hindering their ability to work, participate in daily activities, and causing embarrassment due to the external urine bag.[1-4] It also increases the risk of urinary tract infections. Patients who undergo urethroplasty for urethral stricture disease, a condition that most commonly affects middle-aged men[5] who are active contributors to the workforce, require a urethral catheter for surgical healing. However, there is currently no evidence-based consensus on the optimal duration of foley catheter placement following urethroplasty, with published literature reporting durations ranging from 3-21 days.[1] We suspect that in the absence of evidence, providers may be requiring patients to keep their catheters in place for longer than it is needed for healing to occur, subjecting patients to unnecessary morbidity and risk catheter-associated infections. This randomized non-inferiority study aims to evaluate the impact of foley duration (7-10 days versus 18-21 days) on perioperative complication risk and stricture recurrence, with the goal of defining the optimal duration of urethral foley placement following urethroplasty.

Aim #1: Determine if there is a difference in the risk of early stricture recurrence between patients with a catheter for 7-10 days compared to 18-21 days following urethroplasty. *Several previous studies have suggested that early catheter removal is not associated with an increased risk of stricture recurrence. Islam et al. demonstrated similar rates of extravasation and no significant difference in perioperative complications or stricture recurrence between patients with foley removal at 7 days and 21 days.[6] Smaller cohorts by Al-Qudah et al. and Bansal et al. also showed no significant difference in stricture recurrence between early and late foley removal groups.[7,8] However, these studies have not been enough to change clinical practice.*

Aim #2: Determine if there is a difference in the risk of perioperative complications (within 90 days) between patients with a catheter for 7-10 days compared to 18-21 days following urethroplasty. *Several small studies have suggested that there is no difference in perioperative complications between early and later foley removal following urethroplasty. Bansal et al. demonstrated a slightly higher risk of urinary extravasation among patients with foleys < 7 days compared to > 7 days.[8] Poelaert et al. reported a lower risk among patients with foleys < 10 days compared to > 10 days, following buccal graft urethroplasty.[9] Islam et al. also showed no significant difference in perioperative complications between early and later foley removal groups.[6] However, these studies have not been sufficient to change clinical practice, and only one specifically addressed the risk of perioperative complications between groups.*

Aim #3: Determine if catheter duration impacts perceived health-related quality of life and workforce productivity loss following surgery. *Previous literature has demonstrated that chronic urethral catheterization negatively impacts patients' perceived quality of life.[10] However, no prior research has assessed the burden of short-term urethral catheterization on perceived health-related quality of life or its impact on workforce productivity loss in either short- or long-term catheterization.*

Aim #4: Demonstrate that there is no need to routinely perform a retrograde urethrogram at the time of foley catheter removal, regardless of the duration (7-10 days or 18-21 days). *Urology providers often perform imaging (voiding cystourethrogram/retrograde urethrogram) to evaluate for urinary extravasation at the time of postoperative foley removal. This practice is laborious, costly, cumbersome, uncomfortable for patients, and may increase the risk of urinary tract infections. Recent data from the largest network of reconstructive urologists (TURNS) suggests that although urinary extravasation on initial postoperative imaging has a high specificity for short-term recurrence, it has a low specificity.[11] Additionally, recent research comparing outcomes in patients with and without imaging at the time of foley removal demonstrated no difference in clinical outcomes or complications. No study, however, has assessed the need to perform imaging with early catheter removal.[12] By demonstrating that there is no need to do this imaging regardless of timing of foley removal patients may avoid undergoing an uncomfortable and cumbersome procedure.*

No prior study has directly assessed the optimal duration of urethral foley after urethroplasty using a randomized prospective trial. This study anticipates that early foley removal at 7-10 days is non-inferior to removal at 18-21 days in regard to stricture recurrence risk and/or perioperative complication risk. Furthermore, it is expected that early foley removal (7-10 days) will be associated with improved patient perceived quality of life and decreased workforce productivity loss in the early postoperative period following urethroplasty.

References

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