A multicenter prospective cohort study of endoscopic urethral realignment versus suprapubic cystostomy after complete pelvic fracture urethral injury

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BACKGROUND: Pelvic fracture urethral injury (PFUI) occurs in up to 10% of pelvic fractures. There is mixed evidence supporting early endoscopic urethral realignment (EUR) over suprapubic tube (SPT) placement and delayed urethroplasty. Some studies show decreased urethral obstruction with EUR, while others show few differences. We hypothesized that EUR would reduce the rate of urethral obstruction after PFUI.

METHODS: Twenty-six US medical centers contributed patients following either an EUR or SPT protocol from 2015 to 2020. If retrograde cystoscopic catheter placement failed, patients were included and underwent either EUR or SPT placement based on their institution's assigned treatment arm. Endoscopic urethral realignment involved simultaneous antegrade/retrograde cystoscopy to place a catheter across the urethral injury. The primary endpoint was development of urethral obstruction. Fisher's exact test was used to analyze the relationship between PFUI management and development of urethral obstruction.

RESULTS: There were 106 patients with PFUI; 69 (65%) had complete urethral disruption and failure of catheter placement with retrograde cystoscopy. Of the 69 patients, there were 37 (54%) and 32 (46%) in the EUR and SPT arms, respectively. Mean age was 37.0 years (SD, 16.3 years) years, and mean follow-up was 463 days (SD, 280 days) from injury. In the EUR arm, 36 patients (97%) developed urethral obstruction compared with 30 patients (94%) in the SPT arm ($p = 0.471$). Urethroplasty was performed in 31 (87%) and 29 patients (91%) in the EUR and SPT arms, respectively ($p = 0.784$).

CONCLUSION: In this prospective multi-institutional study of PFUI, EUR was not associated with a lower rate of urethral obstruction or need for urethroplasty when compared with SPT placement. Given the potential risk of EUR worsening injuries, clinicians should consider SPT placement as initial treatment for PFUI when simple retrograde cystoscopy is not successful in placement of a urethral catheter. (*J Trauma Acute Care Surg.* 2023;94: 344–349. Copyright © 2022 Wolters Kluwer Health, Inc. All rights reserved.)

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Traumatic genitourinary injuries are uncommon, occurring in 0.5% of trauma patients. Urethral injuries are particularly rare, occurring less frequently than kidney, bladder, penile, testicle, or scrotal injuries.[1] In patients with pelvic fractures, however, urethral injuries are present in 2% to 10% of cases.[2,3] When the pelvic ring fractures, urethral injuries result from the forceful disassociation of the prostatic and membranous urethra from the anterior urethra at the level of bulbar-membranous urethral junction.[4] These specific injuries, known as pelvic fracture urethral injuries (PFUIs), add significant complexity, complications, and cost to these patients' overall management.[5]

Pelvic fracture urethral injury can cause urinary obstruction, extravasation of urine, and sepsis related to infected hematoma or urinoma. As such, when a PFUI is diagnosed, the urologist's primary concern is obtaining prompt urinary drainage. With partial urethral injuries, it is often possible to pass a catheter retrograde into the bladder without difficulty. With complete urethral injuries, however, finding the proximal urethra, either blindly with a catheter or even with retrograde cystoscopy, is often not possible. Therefore, placement of a suprapubic tube (SPT) is almost universally performed immediately upon diagnosis of a complete PFUI.

There is long-standing controversy surrounding the subsequent management of PFUI.[6] For complete urethral injuries, some urologists advocate for SPT placement with planned delayed urethroplasty, and others support early endoscopic urethral realignment (EUR). The primary theory supporting EUR is that, if a catheter can be placed spanning the gap between the avulsed ends of the urethra, healing will occur around the catheter as the pelvic hematoma resorbs and distraction of the two ends of the urethra lessens. Subsequently, advocates of EUR theorize that there will be less fibrosis, decreasing the need for urethroplasty in the future. However, proponents of SPT placement with planned delayed urethroplasty point out that EUR may increase complications associated with the urethral injury and delay time to definitive treatment without any change in the need for future surgery.[7] Furthermore, EUR is often undertaken in the first days after significant pelvic trauma, exposing patients to additional procedures, risk of infection of the pelvic hematoma, and additional blood loss.

Lastly, there is ongoing debate surrounding urethroplasty after EUR. Some studies suggest that prior urethral manipulation (such as attempted EUR) may make urethroplasty for PFUI more difficult,[7,8] while others propose that urethroplasty will be less challenging if the ends of the urethra are brought into closer alignment with EUR.[9] In addition, some previous studies have suggested that erectile dysfunction and incontinence may be higher in men undergoing EUR, while more recent evidence suggests that these complications are related to the underlying traumatic injury rather than the choice of management.[8] The American Urological Association guidelines do not recommend one treatment over the other because of lack of high-quality evidence.[9]

The debate about early management of PFUI continues to vex urologists interested in trauma and is unresolved in large part because of a lack of well-powered prospective studies comparing the two treatment options. The scarcity of urethral injuries makes them difficult to study, as even tertiary referral centers do not see many primary cases. In this multi-institutional prospective cohort study, we aimed to compare the outcomes of two routinely practiced management approaches for PFUI: SPT with planned delayed urethroplasty versus EUR. We hypothesized that EUR for PFUI lowers the incidence of urethral strictures and subsequent need for urethroplasty.

PATIENTS AND METHODS

Data Source

The methodology for this study has been previously published.[10] The study is a prospective observational cohort study and was conducted in conjunction with the American Association for Surgery of Trauma Multi-institutional Trials Committee. Forty-two US centers were enrolled in the study from 2015 to 2020. Upon study initiation, centers were placed into either the EUR or SPT arms based on their usual management of PFUI. Twenty-six centers contributed complete PFUI patients to the study, of which 13 centers had been assigned to the EUR arm, and 13 had been assigned to the SPT arm. Institutional review board approval was obtained by each participating site. The methods used for this study are in accordance with Equator Network guidelines for observational cohort studies (Supplemental Digital Content, Supplementary Data 1, http://links.lww.com/TA/C680).

Study data were collected and managed using Research Electronic Data Capture electronic data capture tools hosted at University of Utah.[11] Research Electronic Data Capture is a secure, web-based software platform designed to support data capture for research studies, providing (1) an intuitive interface for validated data capture, (2) audit trails for tracking data manipulation and export procedures, (3) automated export procedures for seamless data downloads to common statistical packages, and (4) procedures for data integration and interoperability with external sources.

Study Population and Measurement

Adult patients presenting with blunt trauma and evidence of PFUI (clinical suspicion or diagnosed via retrograde urethrogram) underwent retrograde cystoscopy to confirm complete urethral disruption. If retrograde cystoscopic catheter placement failed, patients were eligible for study inclusion and underwent either EUR or SPT placement based on their institution's study arm. Endoscopic urethral realignment was performed within 7 days of injury and involved the simultaneous passage of cystoscopes antegrade (via the SPT tract or open cystotomy) and retrograde (via the urethral meatus) to place a catheter across the urethral injury. The technique for EUR has been discussed previously.[12] An intention-to-treat strategy was used, such that patients were included in the EUR arm even if realignment was unsuccessful (Fig. 1). Patients were excluded if they were younger than 18 years, female, sustained a penetrating injury, or did not have a pelvic fracture. Patients were also excluded if they had partial or minor distraction injuries of the urethra, such that retrograde cystoscopy was successful in the placement of a catheter (attempted in all patients). Patients were also excluded if they were lost to follow-up sooner than 1 year after their injury unless the primary outcome of urethral obstruction was identified before 1 year.

The primary endpoint was development of urethral obstruction. Obstruction was identified via cystoscopy, urethrography, or failed passage of a catheter. The secondary endpoint was receipt of bulbomembranous anastomotic urethroplasty to address urethral obstruction. Each institution followed their own follow-up and surveillance protocols.

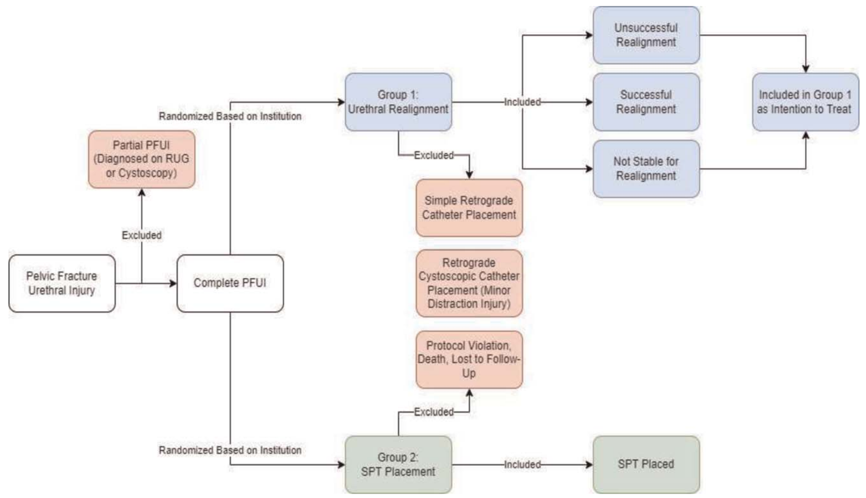

Figure 1. Treatment protocol.

Statistical Analysis

A power calculation was performed a priori, taking into account the likely number of participating centers and the yearly incidence of PFUI. It was calculated that a total of 96 patients would need to be enrolled (48 in each arm) to detect a 15% treatment effect with 80% power, 0.05 significance level for a two-sided *z* test of proportions, and an intracluster correlation coefficient of 0.03. This power calculation accounted for 20% loss to follow-up or death, with a final expected cohort of approximately 77 men or 38 per arm.

Fisher's exact test was used to analyze the relationship between PFUI management and development of urethral stenosis and need for urethroplasty. Multivariable analysis was not used given the lack of any significant differences in the simple bivariate comparisons of variables.

RESULTS

A total of 133 patients presented with PFUI. Thirty-eight patients were excluded from the study because of partial urethral injuries or minor distraction injuries, determined by imaging, cystoscopy, or the ability to place a catheter with the aid of retrograde cystoscopy alone without combined antegrade/retrograde approach. Another 29 patients were excluded for either protocol violation (e.g., no cystoscopy performed to confirm injury), penetrating mechanism, death during initial admission, or lack of follow-up after initial admission (Fig. 2).

Sixty-nine patients from 26 institutions (13 institutions in each arm) met the criteria for inclusion, with 37 patients (53.6%) in the EUR arm, and 32 (46.4%) patients in the SPT arm. There were no significant differences in demographics between the two groups (Table 1). The mean age was 35.5 years (SD, 15.1 years)

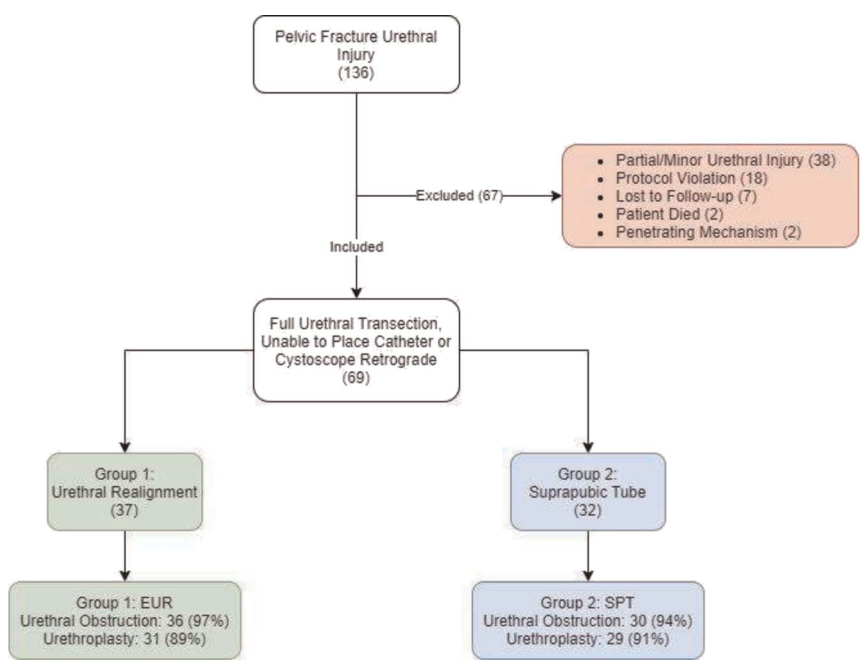

Figure 2. Study flowchart.

TABLE 1. Demographics, Injury Characteristics, and Outcomes of Early EUR Versus SPT Placement for Patients With PFUIs

Variable	All Patients	EUR	SPT	*p*
No. patients, n (%)	69 (100)	37 (53.62)	32 (46.38)	
Demographics				
Age (95% CI)	37.0 (33.07–40.93)	35.45 (30.43–40.49)	38.80 (32.38–45.18)	0.404
BMI (95% CI)	27.09 (25.79–28.38)	26.77 (25.07–28.46)	27.48 (25.39–29.58)	0.586
Medical comorbidities ≥1 (%)	17 (24.64%)	9 (24.32%)	8 (25.0%)	0.948
Injury characteristics				
ISS (95% CI)	29.72 (26.58–32.86)	31.06 (26.89–35.22)	28.2 (23.24–33.16)	0.368
Mechanism of injury — MVC, MCC, n (%)	50 (72.46)	29 (78.38)	21 (65.62)	0.237
Solid organ injury, n (%)	25 (36.23)	15 (40.54)	10 (31.25)	0.423
GI injury, n (%)	8 (11.59)	2 (5.41)	6 (18.75)	0.084
Spinal cord injury, n (%)	6 (8.70)	4 (10.81)	2 (6.25)	0.503
Major vascular injury, n (%)	17 (24.64)	12 (32.43)	5 (15.62)	0.106
Bladder injury, n (%)	18 (26.09)	10 (27.01)	8 (25.0)	0.059
Trauma management				
Pelvic angioembolization, n (%)	16 (23.19)	7 (18.92)	9 (28.12)	0.366
Outcomes				
Urethral obstruction, n (%)	66 (95.65)	36 (97.30)	30 (93.75)	0.471
Urethroplasty, n (%)	60 (89.55)	31 (88.57)	29 (90.62)	0.784
Mean follow-up (95% CI), d	463.9 (396.5–531.3)	452.1 (354.9–549.2)	477.6 (379.7–575.4)	0.709

BMI, body mass index; CI, confidence interval; GI, gastrointestinal; ISS, Injury Severity Score; MCC, motorcycle collision; MVC, motor vehicle collision.

in the EUR arm and 38.0 years (SD, 17.8 years) in the SPT arm ($p = 0.4$). The most common sign of PFUI was blood at the meatus (75.4%). The mechanism of injury was motor vehicle related in 78.4% of patients in the EUR arm and 65.6% in the SPT arm. Of those in the EUR arm, 1 patient (2.7%) was unable to be realigned, and the SPT was left until urethroplasty was performed (this patient was included in the EUR arm in an intention-to-treat strategy).

Concomitant injuries were common (Table 1). Not counting the pelvic fractures that every patient in the cohort sustained, 34 patients (49.3%) suffered at least one other major injury (i.e., gastrointestinal, solid organ, spinal cord, bladder, or major vascular). Fourteen patients (20.3%) suffered two or more other injuries. Sixteen patients (23.2%) underwent pelvic arterial angioembolization, of which 9 patients underwent complete bilateral internal iliac artery embolization, 3 underwent unilateral internal iliac artery embolization, and 4 underwent unilateral embolization of smaller branches of the internal iliac artery.

In the EUR arm, 36 patients (97.3%) developed urethral obstruction compared with 30 patients (93.8%) in the SPT arm ($p = 0.471$). Urethroplasty was performed in 31 (88.6%) and 29 patients (90.6%) in the EUR and SPT arms, respectively ($p = 0.784$). Two patients in the EUR arm underwent urethral dilation, and one of those patients was able to avoid urethroplasty with a follow-up of 12.7 months.

Among patients who developed urethral obstruction, time to urethroplasty was not significantly different between the two groups. In the EUR arm, mean time to urethroplasty was 168 days, compared with 162 days in the SPT arm ($p = 0.818$). Mean follow-up of the entire cohort was 463 days from initial injury (interquartile range [IQR], 249–656 days). For the EUR patients, mean follow-up was 452 days (IQR, 266–633 days); for SPT patients, mean follow-up was 477 days (IQR, 230–701 days).

DISCUSSION

In this prospective multi-institutional observational cohort study, we found no difference in the rate of obstruction or urethroplasty in patients with complete PFUI undergoing EUR or SPT placement with planned delayed urethroplasty. These findings contradicted our hypothesis but are supported with more recent single-center case series and a recent meta-analysis.[13–15] We found that the rates of urethral obstruction and urethroplasty were high in both groups. Furthermore, 97.3% of patients in the EUR arm developed obstruction, as well 93.8% in the SPT arm.

Our results show that 88% of patients who underwent EUR after PFUI underwent urethroplasty. In contrast, early studies of PFUI suggested that urethral realignment, usually performed via an open approach with urethral sounds and/or catheters passed into the pelvic hematoma, decreased the need for urethroplasty by 50%.[16,17] These findings were corroborated by a meta-analysis at the time, which also showed a decreased stricture rate among those undergoing urethral realignment compared with SPT placement alone.[18]

It is important to consider the significant limitations of prior studies, however. The studies were not prospective and often did not define how urethral realignment was performed. Given that most of the early studies were performed more than 20 years ago, realignment was usually performed via an open approach in contrast to today where almost all are performed endoscopically. Furthermore, many of the studies in the meta-analysis likely involved referred patients, rather than those treated primarily at reporting institutions, reducing the likelihood of a consistent approach to realignment. Lastly, it is probable that patients in prior studies included those who underwent retrograde catheter placement with or without cystoscopy. In this scenario, a major methodologic problem is inclusion bias within the urethral realignment group. Those patients with partial urethral injuries or minor distraction defects where "urethral realignment" was accomplished with simple retrograde catheter placement or retrograde cystoscopy alone would naturally improve the outcomes associated with this group because of the fact that their injury was by definition less severe. We chose to group partial and minor injuries together and exclude them in the analysis since few would argue against a retrograde catheter placement with or without retrograde cystoscopy if possible. In partial urethral injuries, a catheter may be passed successfully or, during a retrograde cystoscopy, the intact urethra can be followed into the bladder. A wire can be placed, and a catheter can be placed over the wire into the bladder using a council tip catheter and the Seldinger technique. Likewise, in "minor distraction" defects, the urologist can find the proximal end of the urethra, even though it has been completely disrupted, presumably because of the close proximity of the proximal urethra, and similarly pass the cystoscope into the bladder and place the catheter. By only including patients who had failed retrograde cystoscopic catheter placement, we attempted to minimize or eliminate inclusion biases between each arm. Similarly, by including patients who had failed realignment in an intention to treat strategy, we would not bias the realignment arm to less severe injuries given that, in the SPT arm, these patients would have been treated with an SPT alone, and there would have been no assessment of whether they could not have been realigned successfully.

Contemporary studies have been more in line with our findings. From Harborview, Chung et al.[15] reported that, despite their universal treatment with EUR, 91% of patients developed urethral obstruction.

Some believe that patients undergoing EUR may have an easier urethroplasty compared with SPT placement alone, although the evidence for this is largely limited to expert opinion.[19] While our study provides evidence that EUR does not lower the rate of urethral obstruction and the need for posterior urethroplasty, we were not able to ascertain differences in difficulty of urethroplasty because of the variability of the technique and lack of consistent intraoperative reporting among 26 different centers. However; the long-term success of immediate SPT placement with delayed urethroplasty is well established, with success rates of 85% to 97%.[20,21]

The study has several limitations. First, we were unable to achieve several secondary endpoints originally proposed in the study design, including postoperative erectile function, urethroplasty difficulty, and success rates of urethroplasty. In each of these areas, we were limited by missing data, variability in postoperative follow-up, and patients being lost to follow-up. Second, this was not a randomized study, and centers were permitted to choose their treatment arm if they had a preference, which could introduce bias into the study results and limit generalizability. Furthermore, there is likely some variability in the success rates of retrograde cystoscopic catheter placement for PFUI of any degree. Consequently, some centers may have had greater success with retrograde cystoscopic catheter placement, excluding patients from the study, which other centers may have included given possible failure at retrograde catheter placement. Lastly, the a priori power calculation required a final cohort of 77 patients, but only 69 patients were included in the study. This allows for the possibility that outcomes may have been different with a larger sample size.

CONCLUSION

Early endoscopic realignment for complete PFUI does not decrease the rate of postinjury obstruction or the need for subsequent urethroplasty. Given the potential complications and increased complexity of managing patients via EUR, urologists should consider SPT placement with delayed urethroplasty as a preferred management strategy.

AUTHORSHIP

B.J.M. contributed in the data acquisition, and analysis and interpretation of data. S.K. contributed in the study design, data acquisition, and analysis and interpretation of data. J.H. contributed in the data acquisition, critical revision, and study design. J.P.S. contributed in the data acquisition and critical revision. B.D.F. contributed in the data acquisition and critical revision. N.V.J. contributed in the data acquisition and critical revision. R.D.d.S. contributed in the data acquisition and critical revision. J.A.B. contributed in the data acquisition and critical revision. S.G. contributed in the data acquisition and critical revision. B.M. contributed in the data acquisition and critical revision. F.N.B. contributed in the data acquisition and critical revision. J.E. contributed in the data acquisition and critical revision. E.C.O. contributed in the data acquisition and critical revision. K.J.C. contributed in the data acquisition and critical revision. B.A.E. contributed in the data acquisition, critical revision, and study design. M.B.G. contributed in the data acquisition and critical revision. P.H.C. contributed in the data acquisition and critical revision. C.R.H. contributed in the data acquisition and critical revision. G.P.M. contributed in the data acquisition and critical revision. P.R. contributed in the data acquisition and critical revision. A.S. contributed in the data acquisition and critical revision. C.B. contributed in the data acquisition and critical revision. A.A. contributed in the data acquisition and critical revision. S.D.B. contributed in the data acquisition and critical revision. B.N.B. contributed in the data acquisition, critical revision, and study design. G.M.A. contributed in the data acquisition and critical revision. M.M. contributed in the data acquisition and critical revision. S.P.E. contributed in the data acquisition, critical revision, and study design. I.W.S. contributed in the data acquisition and critical revision. J.S. contributed in the data acquisition and critical revision. A.J.V. contributed in the data acquisition and critical revision. R.A.M. contributed in the data acquisition and critical revision. J.B.M. contributed in the study design, data acquisition, analysis and interpretation of data, and critical revision.

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DISCLOSURE

The authors declare no conflicts of interest.

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