

Radiation-induced complex anterior urinary fistulation for prostate cancer: a retrospective multicenter study from the Trauma and Urologic Reconstruction Network of Surgeons (TURNS)

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Abstract

Purpose To characterize anterior urinary fistulae following radiotherapy for prostate cancer.

Methods Over 10 years, 31 men were identified to have an anterior urinary fistula. A retrospective database was created to evaluate patient demographics, presentation, diagnostic procedures, operative interventions, outcomes, and complications. Comparisons between men who underwent cystectomy versus bladder-sparing surgeries were performed.

Results At a median age of 73 (interquartile range (IQR) 68.5, 79) years, presenting symptoms included as follows: pubic pain (19/31, 61%), urine drainage via fistula (10/31, 32%), or a superficial wound infection (6/31, 19%). Recent instrumentation prior to diagnosis of anterior urinary fistula

was reported by 18/31 (58%) at a median of 14.9 months (IQR 7.9, 103.8) after manipulation. Anterior fistula formation was either isolated to the pubic symphysis (19/31, 61%) or the thigh (12/31, 38%). Nineteen men underwent a cystectomy, whereas 12 men underwent a fistula repair. Excluding grades 1 and 2, 30- and 90-day postoperative complications were limited to four and two men, respectively, all of whom had a grade 3 complication. At 6-month follow-up, 26/31 (84%) men reported their pain had resolved. There was one fistula recurrence managed with subsequent cystectomy.

Conclusions Complex anterior urinary fistulae to the pubic symphysis and thigh are devastating yet treatable conditions. Universally, these men have a history of radiotherapy and repeated endoscopic interventions. Surgical intervention with either cystectomy or primary repair was highly successful.

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Abbreviations

EBRT External beam radiotherapy

BT Brachytherapy

RP Radical prostatectomy

Introduction

Prostate cancer remains one of the most commonly treated cancers [1]. Severe urinary adverse events after prostate cancer treatments are rare but can be devastating [2, 3]. One such adverse event is urinary fistulae following surgery, radiotherapy, and/or ablative therapy [4]. Fistulae may develop anteriorly (e.g., pubic symphysis) or posteriorly

(e.g., rectum) and may originate from the bladder, prostate, or urethra. In particular, anterior urinary fistulae to the thigh result from initial fistulation to the pubic symphysis or around it and down the obturator foramina to tract along fascial planes of the adductor muscle into the anterior or posterior thigh [5].

It is estimated that up to 3% of men will develop a rectourethral fistula after prostate radiotherapy [i.e., external beam radiotherapy (EBRT) and/or brachytherapy (BT)] [6]. The exact incidence of anterior fistulae is unknown. A constellation of symptoms are associated with anterior urinary fistulae including osteitis pubis, osteomyelitis, recurrent urinary tract infections, pelvic pain, urine leakage, and/or sepsis [7]. As such, the patients' quality of life is severely impacted [8].

To date, there are limited data on anterior urinary fistulae following treatment for prostate cancer [4, 6, 9]. By describing the largest series of this adverse event, our objective is to characterize differences in patient presentation and surgical management for urinary fistulae to the pubic symphysis and/or the thigh following treatment for prostate cancer. We will summarize key strategies and clinical recommendations for the treatment of this rare and complex complication.

Materials and methods

From April 2005 to September 2015, a multi-institutional, retrospective review of men who developed anterior urinary fistulae following radiation for prostate cancer was performed. Utilizing de-identified patient data pooled from members of the Trauma and Urologic Reconstruction Network of Surgeons (TURNSresearch.org), we collected demographic data, outpatient and inpatient records, and details regarding the exact nature of each patient's clinical condition. All men underwent prostate cancer treatment (primary radiotherapy or radical prostatectomy plus radiotherapy) with curative intent. Anterior urinary fistula was defined as a direct fistulous connection from the urinary tract (i.e., bladder, prostate, or urethra) to the pubic symphysis and/or the thigh. The diagnosis of an anterior urinary fistula was confirmed by the presence of urine within or through the pubic symphysis or thigh demonstrated via any imaging modality such as cystogram, retrograde urethrogram, computed tomography (CT), and/or magnetic resonance imaging (MRI) scans. Men with fistula to the rectum or posterior soft tissue were excluded from analysis.

Baseline demographic variables

Baseline demographics including patient age, height, weight, body mass index were all collected. Past medical

history of hypertension, hyperlipidemia, diabetes, coronary artery disease, human immunodeficiency syndrome, benign prostatic hyperplasia, chronic obstructive pulmonary disease, bladder cancer, gastroesophageal reflux disease, prior hernia surgery, prior bowel surgery, and heart surgery was recorded. A sum of all medical problems was calculated to be the total number of comorbidities. Smoking history and alcohol usage were tabulated. Treatment for prostate cancer was divided into surgery, radiation, or both. Specific subtypes of radiation including primary EBRT, BT, adjuvant EBRT, salvage EBRT, combined EBRT plus BT, and/or proton beam therapy were verified. For BT, both high dose rate and lower dose conventional therapies were grouped together. Inciting events prior to the development and diagnosis of the urinary fistula were recorded. Such inciting events included prior urethral instrumentation with either a transurethral resection of the prostate (if in situ), internal urethrotomy, cystolitholapaxy, urethral dilation, and/or bladder neck resection. Presenting symptoms of each case were categorized into any combination of pubic pain, urine drainage from the fistula site, and/or wound infection. Resolution of symptoms was independently and subjectively assessed at each participating site. The location of each fistula was determined by either radiography or physical examination. This was described as either an anterior thigh, posterior thigh, or pubic symphysis fistula.

Operative variables and outcomes

The exact surgical management of each patient was captured. We distinguished patients by whether they underwent primary repair or cystectomy and urinary diversion. We defined primary repair as surgical correction of the fistula with either excision of the fistulous tract or urethroplasty whereby diseased urethra/prostate was removed and a posterior urethroplasty was performed. The type of flap (gracilis, rectus, or omental) utilized and type of urinary diversion (ileal conduit versus continent diversion) were collected. We recorded the operative estimated blood loss (EBL), transfusion requirements, and the presence of adjunct surgeons (plastics, orthopedics, or colorectal). Operative failure was defined by recurrence of fistulae or development of another urinary fistula. Postoperative complications were graded according to the Clavien–Dindo classification system [10].

Statistical analysis

Descriptive statistical analysis was performed with STATA v11 (College Station, TX). Comparative analysis utilized Wilcoxon rank-sum test for continuous variables and Fisher's exact test due to small sample sizes. Statistical significance was defined as p value <0.05 .

Results

Presenting characteristics of men with anterior urinary fistulae

Over a 10-year period, 31 men were evaluated and treated for an anterior urinary fistula. The median age of men at the time of their initial evaluation was 73 years (interquartile range (IQR) 68.5, 79). The median body mass index (BMI) of patients at the time of their surgical intervention was 28 kg/m² (IQR 24, 31).

The median number of comorbidities among the cohort was 4 (IQR 3, 5). The most common comorbidities included the following: hypertension (20/31, 65%), hyperlipidemia (16/31, 52%), coronary artery disease (8/31, 26%), diabetes (6/31, 19%), and gastroesophageal reflux (6/31, 19%). The majority of men (24/31, 77%) reported a smoking history.

All men had treatment for prostate cancer with radiation; radiation was used as primary therapy (23/30, 77%), or adjuvant (5/30, 17%) or salvage therapy (2/30, 7%) after radical prostatectomy. Frequencies of primary radiotherapy implicated in fistula formation included primary EBRT (13/23, 57%), BT (5/23, 22%), BT + EBRT (5/23, 22%). One patient had received proton beam radiotherapy.

The median time from the development of symptoms to fistula diagnosis was 0.8 months (IQR 0.1, 3.9). The most common symptoms were as follows: pubic pain (19/31, 61%), urine drainage via the fistula tract (10/31, 32%), and/or a superficial wound infection (6/31, 19%). A total of 10/31, 32% men were using a wheelchair due to the crippling pain associated with walking.

A total of 18/31 (58%) men reported undergoing treatment for either a bladder neck contracture or a membranous urethral stricture prior to fistula development. Among these 18 men, the median number of months from the last endoscopic intervention to diagnosis of an anterior fistula was 14.9 (IQR 7.9, 103.8) months. The most common types of endoscopic treatment included the following: transurethral resection of the prostate (9/18, 50%), direct internal urethrotomy (4/18, 22%), transurethral resection of the bladder neck (3/18, 17%), cystolitholapaxy (2/18, 11%). Multiple endoscopic interventions were performed in 11/18 men (61%). The most common types of radiation therapy in men who received treatment for bladder neck contracture or a membranous urethral stricture prior to fistula development included EBRT (12/18, 67%), EBRT + BT (5/18, 28%), and BT (1/18, 5%).

Diagnostic workup and surgical interventions

Multiple imaging modalities were used to diagnose the fistula in six men, whereas a single-imaging modality was

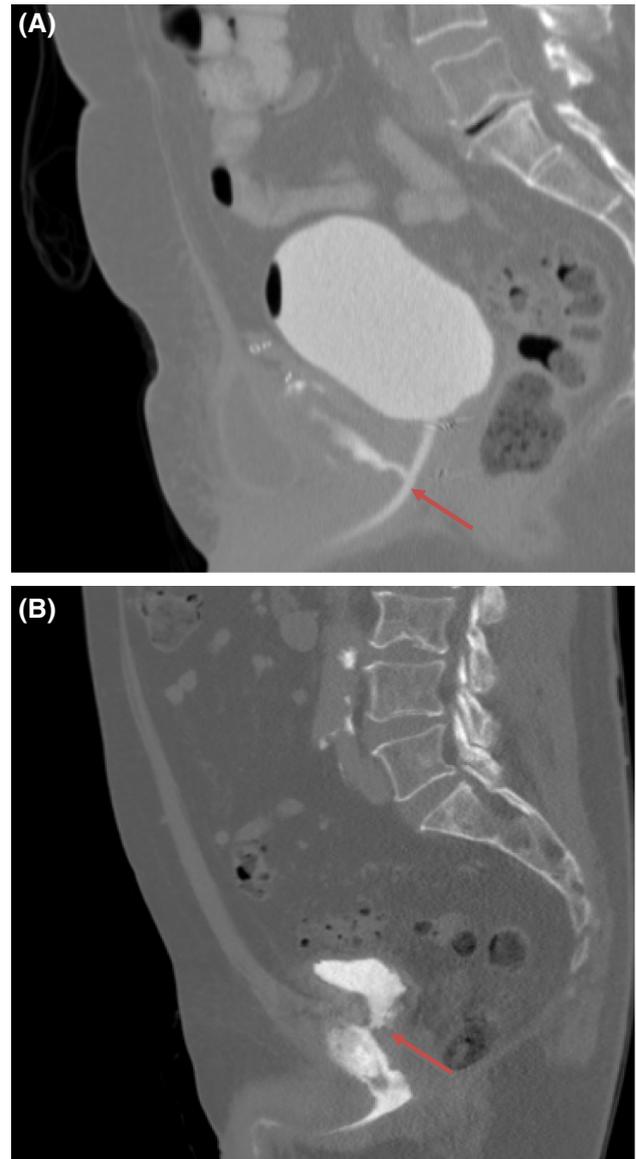


Fig. 1 Sagittal views of a pelvic computed tomography scan demonstrating contrast extravasation (*arrow*) from prostatic urethra toward pubic bone (a) and involving the pubic symphysis (b) (*arrow*)

used in 25 men. The most common single-imaging modality used was an MRI (14/25, 56%), followed by retrograde urethrogram/voiding cystourethrogram (7/25, 28%) or a CT scan (7/25, 28%). A pelvic CT performed with a cystogram may better delineate contrast extravasation (Fig. 1a, b). Isolated imaging with an MRI appropriately identified the anterior fistula in the 14 men in which it was performed (Fig. 1a, b). Anterior fistula formation occurred either isolated to the pubic symphysis (19/31, 61%) or progressed into the thigh (12/31, 38%) (Fig. 2). The anterior thigh was involved in the majority of cases (11/12, 92%).

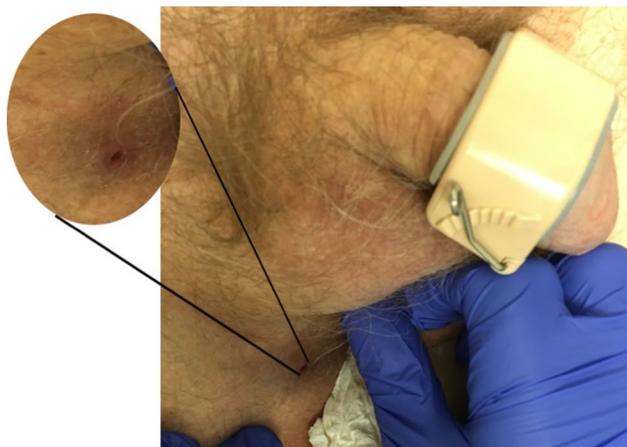


Fig. 2 Medial thigh urinary fistula in a patient who had brachytherapy for prostate cancer and osteitis pubis

The median time from evaluation to operation was 2.1 months (IQR 0.7, 7.3). A total of 19/31 men underwent a simple cystectomy or cystoprostatectomy, and 12/31 men underwent primary repair. Adjunct surgeons were present in nine cases with plastic surgeons (4/9, 44%), orthopedic surgeons (3/9, 33%), or both (2/9, 22%) assisting the primary urologist.

Urinary diversion

For men who underwent a simple cystectomy, an ileal conduit was created in 18/19 (95%) men and one patient had an Indiana pouch. Pubectomy was performed in 6/19 (46%), and a flap was performed in 9/19 (47%). The types of flaps performed were omental (7/9, 78%) or rectus (2/9, 22%) flaps. The median operative time for the 19 cystectomy and diversions was 7 h (IQR 6, 8) with an EBL of 275 cc (IQR 150, 400 cc). Two men required a blood transfusion (2 units and 1 unit). The median length of stay was 8 days (IQR 7, 11).

Primary repair

For the men who underwent primary repair, a fistulotomy and primary closure or excision and posterior urethroplasty was performed. A primary closure and excision of the fistula tract was performed in cases with healthy tissue where minimal debridement was required, a tension-free closure was possible, and there was no distal stricture present. In cases whereby tissues were non-viable, the fistula tract was capacious, and/or there was a distal stricture present, prostate tissue and/or the urethral stricture was removed, and a posterior urethroplasty was performed. Pubectomy was

performed in 7/12 (64%), and a flap was performed in 8/12 (67%). The types of flaps performed with a primary repair included as follows: rectus (5/8, 63%) gracilis (2/8, 25%), and omental (1/8, 13%) flaps. When rectus or omental flaps were used, a combined abdominoperineal approach was performed. The median operative time for primary repair procedures was 8 h (IQR 5, 9) with an EBL of 350 cc (IQR 175, 550 cc). Two men required a blood transfusion (2 units and 3 units). The median length of stay of this cohort was 8 days (IQR 4, 16).

There were no statistically significant differences in the number of men who underwent a simple cystectomy and urinary diversion versus bladder-sparing procedures by radiation subtypes, previous number of endoscopic procedures, types of endoscopic procedures, flap usage, pubectomy usage, length of stay, EBL, or total operative time (Table 1). When institutions were sub-stratified by surgeon, there were no statistical differences in surgical preferences toward urinary diversions nor primary repair.

Postoperative complications and outcomes

Complications at 30 days occurred in 18/31 men. The majority of low-grade complications (grade ≤ 2) were attributable to postoperative ileus. Of the 18 men, there were two men that had greater than a Clavien–Dindo grade ≥ 3 complication (one grade 3a and one grade 3b). Both men had an infectious complication within 30 days. These same men presented to their urologist with a wound infection. Complications at 90 days occurred in 10/31 men. Of these, there were two different men that had a Clavien–Dindo grade ≥ 3 complication (both grade 3a). Both grade 3a complications were attributable to a postoperative infection. These men did not initially present with a wound infection upon initial evaluation. There were no statistical differences in major (i.e., \geq grade 3) 30- or 90-day postoperative infectious complications when stratified by whether men underwent a cystectomy versus primary repair or if a pubectomy was performed. There were no postoperative mortalities.

At 3-month follow-up, 26/31 (84%) men reported their pain had resolved. Operative failure occurred in one patient approximately 17 months after primary repair with urethroplasty and gracilis flap for an anterior fistula to the pubic symphysis. The patient presented with a recurrent urinary fistula, pubic osteomyelitis, and pain. This patient was managed with simple cystoprostatectomy, pubectomy, and ileal conduit urinary diversion. His pubic pain subsequently resolved thereafter. An artificial urinary sphincter was placed in two men approximately 6 months after primary fistula repair/urethroplasty and both were continent thereafter.

Table 1 Comparison of preoperative, intraoperative, and postoperative details between men who underwent cystectomy versus primary repair fistula repair

	Cystectomy or diversion <i>n</i> = 19 (IQR ^a or %)	Primary repair <i>n</i> = 12 (IQR ^a or %)	<i>p</i> value ^b
Age	71 (67, 79)	75.5 (69, 81)	0.22
Body mass index	28 (26, 32)	27 (23, 31)	0.5
<i>Type of radiation</i>			
EBRT alone	12 (63)	4 (50)	0.22
Brachy alone	2 (11)	3 (38)	
EBRT + BT	5 (26)	1 (13)	
# of endoscopic procedures	1 (1, 2)	2 (1, 4)	0.36
<i>Types of endoscopic procedure(s)</i>			
Internal urethrotomy	3(20)	0	0.26
Transurethral resection of prostate	7 (47)	2 (22)	
Bladder neck resection	3 (20)	3 (33)	
Dilation	1 (7)	2 (22)	
Cystolitholapaxy	1 (7)	2 (22)	
Pubectomy (yes)	3 (16)	4 (40)	0.44
Flap used (yes)	8 (42)	6 (60)	0.46
<i>Operative details</i>			
Length of stay (days)	8 (7, 14)	7.5 (2, 10)	0.62
Estimated blood loss (mL)	300 (150, 400)	300 (150, 500)	0.46
Operating time (h)	6 (5.7, 7.5)	9 (5, 9)	0.36
<i>Complications</i>			
# \geq Grade 3 at 30 days	2 (11)	0 (0)	0.8
# \geq Grade 3 at 90 days	1 (10)	1 (10)	

^a Interquartile range

^b Wilcoxon rank-sum test used for continuous variables and Fisher's exact or chi-squared tests for categorical variables

Discussion

Complex urinary fistula following treatment for prostate cancer is an uncommon yet devastating condition if not treated. In particular, anterior urinary fistula involving the pubic symphysis or the adductor canal and thigh is a rare complication that poses unique challenges for both patient and surgeon. Due to the rarity of anterior urinary fistulae, practice algorithms to guide clinical intervention are lacking. It is estimated from prior series that due to debilitating symptoms and/or development of pubic osteomyelitis, 75–94% of patients will undergo some surgical intervention [4, 11]. Yet, characterization of the types of surgical interventions has not been well reported.

In effort to address current shortcomings in the medical literature on this topic, we pooled data from the TURNS group to better delineate evaluation and management strategies utilized by reconstructive urologists. We demonstrate that men with anterior urinary fistulae present most often with pubic pain that in many cases is crippling; in fact, 32% of men were wheelchair bound due to pain with walking. Clinical suspicion of an anterior urinary fistula should be raised in men who have undergone radiation for treatment

of prostate cancer and had been recently instrumented, especially for a stricture or bladder neck contracture. Interestingly, a majority of men (over 75%) reported a smoking history.

Often, the time from presentation to diagnosis of an anterior urinary fistula is short and MRI was the single-imaging modality that correctly identified the anterior fistula. As a result, we recommend an MRI as part of any workup where an anterior fistula is suspected (Fig. 3).

When considering whether to perform a simple cystectomy versus primary repair, urologists should weigh patient preferences and several key factors. (1) A patent distal urethra is necessary to perform a primary fistula closure or urethroplasty. Restricted flow and back-pressure of urine will cause re-fistulation following a primary repair if a distal stricture is present. (2) Preoperative continence may dictate a patient's preference postoperatively. The risks of incontinence, repeat surgery with an artificial urinary sphincter, and a decline in quality of life may shift preferences toward urinary diversion. In our cohort, only two men went on to have a subsequent artificial sphincter but were certainly not the only ones with urinary incontinence. (3) Bladder capacity must be of adequate volume prior to performing a

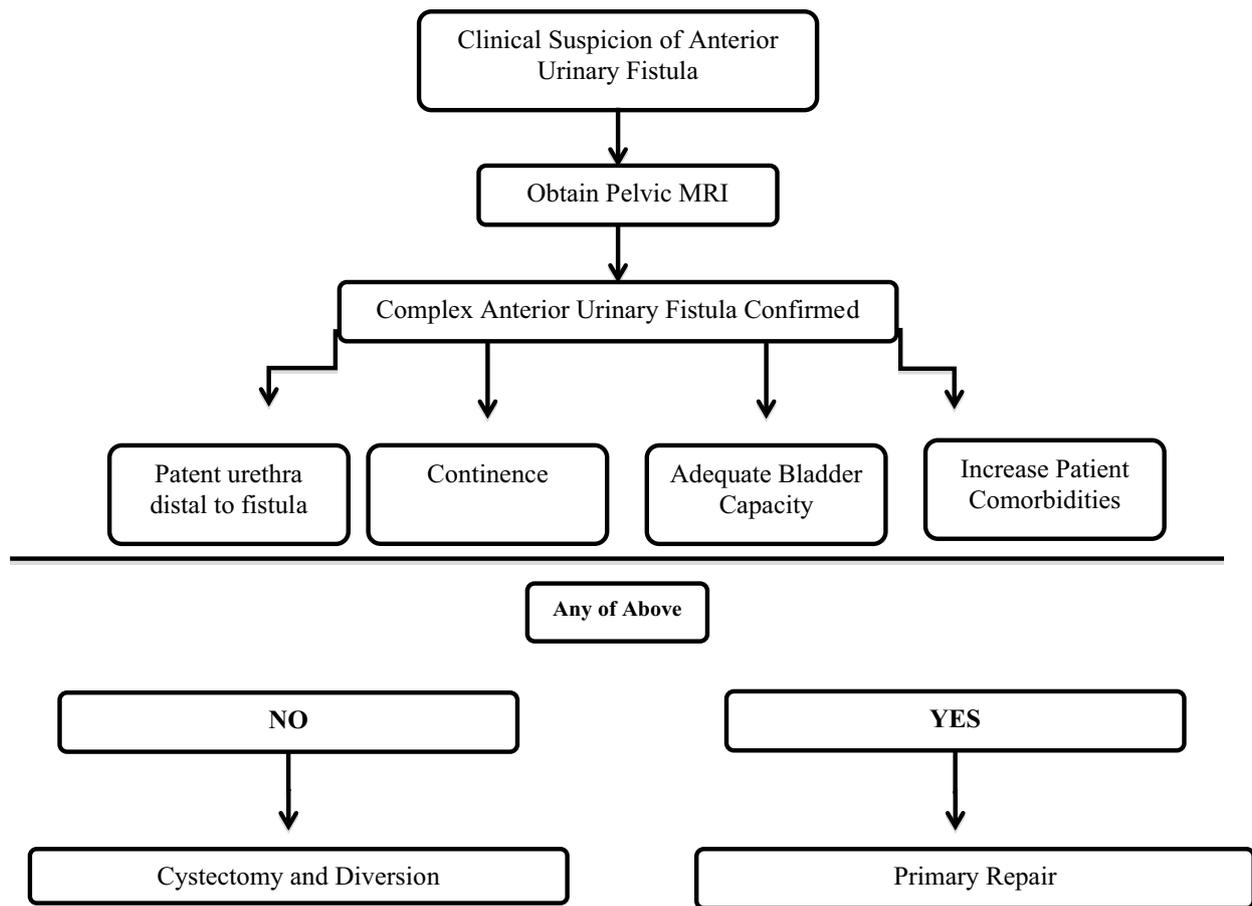


Fig. 3 Proposed algorithm for management of complex anterior urinary fistulae

primary repair to prevent postoperative lower urinary tract symptoms. Lastly, patients with numerous comorbidities may be unfit for simple cystectomy and urinary diversion, although the complication rates were similar (Fig. 3).

To date, only three groups have reported series of anterior urinary fistulae. Previously Bugeja et al. [4] described a series of 16 patients who developed urosymphyseal fistulae after radiotherapy with or without radical prostatectomy. All patients had some form of radiotherapy as either primary or salvage treatment and presented with symptoms roughly 8 years after their initial cancer treatment. Interestingly, 80% of men had a bladder neck contracture that had previously undergone an intervention (e.g., bladder neck incision or resection). Of the 16 men, eight had urinary fistulae tracking to the adductor canal. Similar to our cohort, roughly half of men underwent a cystectomy and urinary diversion, which was dictated by bladder size, compliance, and location of the fistula. In this series, a pubectomy was performed in all cases and was debrided to healthy bone. Patients remained on bone-culture-specific antibiotics for a mean of 7 days. In our series, pubectomy was performed

in less than 50% of men overall; however, this increased to over 60% if a primary repair was performed. Whether a pubectomy was performed did not decrease postoperative infectious complications, pain resolution, nor fistula recurrence. Complete debridement of devitalized tissue and adequate coverage with a flap may improve success in primary repair; however, its role in urinary diversion is more a surgical principal rather than supported by data.

Matsushita et al. [11] published a series of 12 patients with pubovesical fistulae following surgery and/or EBRT. The authors from two major medical centers found that all men had a bladder neck contracture, and subsequent surgical intervention was a common occurrence in all cases leading to fistulation. The median time from treatment to fistula development was 35.9 months. All but two patients were treated with cystectomy and urinary diversion. Unlike this study, the current series had a shorter time (15 months versus 36 months) from the date of last endoscopic intervention to the diagnosis of an anterior fistula. This reinforces the temporal relationship between endoscopic intervention and development of anterior urinary fistula as recent

instrumentation may be a contributing risk factor, especially treatment of a bladder neck contracture. Extravasation of urine postoperatively combined with radiation-induced fibrosis, poor wound healing, epithelization, and micro-infections may all may explain this causal relationship.

A small series presented by Kaufman et al. [9] describes a surgical technique for rectus flap interposition for four men with anterior prostatico-symphyseal fistulas. In their series, the authors describe a prostate-sparing-fistula closure technique for four men who received radiation for prostate cancer and developed an anterior fistula. Postoperative complications were low and no fistula recurred. We found that the type of procedure performed would dictate the type of flap used. Gracilis flaps were used in the current series for a primary repair, while omental flaps were most commonly used in cystectomies. We advise routine use of a pedicle flap (rectus, omental, or gracilis) for coverage to eliminate dead space and separate the pubic symphysis from the bladder (if spared).

Taken together, regardless of the type of surgical intervention, success is high with the majority of patients reporting resolution of pain. Although these are major interventions, postoperative morbidity in our cohort was low and limited to infectious complications.

This study has several limitations. Our cohort represents a heterogeneous group of patients that had varying doses of radiation that were not available for analysis. Similarly, details of patients' cancer staging were not available. Nevertheless, this multi-institutional retrospective series represents the largest report on complex anterior urinary fistula managed by expert reconstructive urologists. Furthermore, it represents a contemporary series of radiation dosing which is most reflective of the current toxicity.

Conclusion

Complex anterior urinary fistulae to the pubic symphysis and thigh are devastating and challenging clinical conditions that may arise following treatment for prostate cancer. A history of radiation and repeated endoscopic interventions are common antecedents to the development of complex anterior urinary fistulae. Urologists should be aware of the potential sequelae of urinary fistula formation following repeated endoscopic interventions. Despite this debilitating condition, surgical interventions are highly successful with pain resolution in the majority of men and minimal postoperative complications. Weighing a patient's urethral patency, continence, bladder capacity, and comorbidities dictates the type of surgical repair performed.

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Author contributions EC Osterberg and BN Breyer involved in protocol/project development, data collection, data analysis, and manuscript writing/editing; AJ Vanni involved in data collection and data analysis; T Gaither involved in data collection, data analysis, and manuscript writing/editing; MA Awad involved in data collection, data analysis, and manuscript writing/editing; J Broghammer, SC Pate, HW Wyre, JB Myers, SP Elliott, S Krishna, LC Zhao, C McClung, and BA Erickson involved in data collection and manuscript writing/editing.

Compliance with ethical standards

Conflict of interest All of the authors declare they have no conflict of interest.

Ethical approval All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards. This article does not contain any studies with animals performed by any of the authors.

Informed consent Informed consent was obtained from all individual participants included in the study.

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