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Urethrogram: Does Postoperative Contrast Extravasation Portend Stricture Recurrence?

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OBJECTIVE To demonstrate our hypothesis that the presence of extravasation on postoperative urethrogram is inconsequential for disease recurrence in urethroplasty postoperative follow-up.

MATERIALS AND METHODS We utilized the Trauma and Urologic Reconstructive Network of Surgeons database to assess 1691 patients who underwent urethroplasty and post-operative urethrogram. Anatomic and functional recurrence were defined as <17 Fr stricture documented at 12-month cystoscopy and need for a secondary procedure during 1 year of follow-up, respectively. Our primary outcomes were the sensitivity and positive predictive value of post-operative urethrogram for predicting anatomic and functional recurrence of urethral stricture disease.

RESULTS Among 1101 patients with cystoscopy follow-up, 54 (4.9%) had extravasation on initial postoperative urethrogram. Among those 54, 74.1% developed an anatomic recurrence vs 13% without extravasation (P <.001). Similarly, functional recurrence was 9.3% with extravasation vs 3.2 % without extravasation (P = .04). Patients with extravasation more often reported a postoperative urinary tract infection (12.9% vs 2.7%; P <.01) or wound infection (7.4% vs 2.6%; P = .04). Sensitivity of postoperative urethrogram in predicting any recurrence was 27.3%, specificity 98.7%, positive predictive value 77.8%, and negative predictive value 89.3%. Fourty-five of 54 patients with extravasation had a recurrence of some kind, equating to a 22.2% urethroplasty success rate at 1 year.

CONCLUSION Postoperative urethrogram has a high specificity but low sensitivity for anatomic and functional recurrence during short term follow-up. The positive predictive value of urinary extravasation is high: patients with extravasation incur a high risk of anatomic recurrence within 1 year and such patients may warrant increased monitoring. UROLOGY 145: 262−268, 2020.

Urethroplasty remains the gold standard management for urethral stricture disease (USD) given it offers more cost-effective and definitive results than repeated endoscopic management.[1] Despite success rates of urethroplasty, recurrence remains a long-term concern among reconstructive surgeons and their patients. One-year stricture recurrence rates after urethroplasty vary between 6.3% and 18.7% depending on location of the stricture and repair type.[2-5] Multivariate studies have demonstrated stricture length, prior procedures, and type of procedures affect the recurrence risk.[6-8] Early detection of recurrence is a major goal of urethroplasty follow-up.[9]

The classic definition of recurrence is the necessity of a secondary procedure for USD. Defining failure typically requires invasive studies. There are many objective and subjective methods to evaluate stricture recurrence but no standard approach has been established.[9,10] Recent literature suggests early abnormalities such as post-operative contrast extravasation (henceforth, termed extravasation) on post-operative urethrogram may be related to future anatomic stricture recurrence.[11,12] Postoperative urethrogram is used to assess urethral integrity at the time of urethral catheter removal after urethroplasty. Single center series demonstrate low post-operative extravasation rates; further, prolonged catheterization

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leads to extravasation resolution but there is no comment regarding long-term effects.[13,14] Some advocate for omitting such imaging because the rate of extravasation in their hands is low (3%-14%), while others believe extravasation may portend development of fistula, abscess, or stricture recurrence.[14,15]

Long-term urethroplasty success is assessed using uroflowmetry, urethrogram, cystoscopy, and/or patient recorded outcome metrics but their use in the immediate perioperative setting has not been established.[4,16] Furthermore, the frequency and type of long-term follow-up is not standardized, with resistance among patients due to cost and discomfort.[7,9] If extravasation does predict for development of stricture recurrence, surveillance strategies could be tailored by presence of post-operative extravasation. Ultimately, a better understanding of the implications of post-operative urethrogram findings at the post-operative encounter may inform better long-term surveillance strategies. We hypothesize urinary extravasation has no measurable impact on the risk of subsequent urethral stricture recurrence.

METHODS

Study Eligibility and TURNS Follow-up Protocol

Details regarding the prospective collection of data via this multi-institutional outcome research group have been described previously.[4] Briefly, prospective data collection regarding patients undergoing urethroplasty for USD was approved by each site's Institutional Review Board. Ten centers contributed data for this work. Included patients underwent post-operative urethrogram, defined as either pericatheter retrograde urethrogram, voiding cysto-urethrogram or retrograde urethrogram. Patients were followed for 1 year after their urethroplasty. Anatomic success was defined as the ability to atraumatically pass a 17 Fr cystoscope through the area where the urethroplasty took place at 12 months after surgery. Functional recurrence was defined as any patient who underwent surgical treatment during the 1 year follow up period including: urethral dilation, direct vision internal urethrotomy, or repeat urethroplasty. Patients with extravasation were managed at the discretion of each surgeon.

We first performed a descriptive analysis of the cohort for all patients who underwent postoperative urethrogram. Stricture location (distal penile, penile, penile-scrotal junction, bulb), length, repair type (dorsal onlay, ventral only, dorsal inlay, augmented dorsal onlay, lateral onlay, anastomotic, nontransecting, and multistage repairs) and duration of postoperative catheter placement were summarized. Patients with proximal urethral strictures, stenoses or disruptions, such as for pelvic fracture, or radiation were excluded. Complications such as wound infection, fistula occurence, hospital readmission, urinary tract infection (UTI), epididymo-orchitis, positioning complications, or cardiovascular complications were reported for each patient.

Outcomes and Statistics

Fisher's exact test and Chi-squared analysis were applied as appropriate to categorical variables to compare patients with and without stricture recurrence. Similarly, we used Mann−Whitney−Wilcoxon for continous variables. We calculated sensitivity, specificity, positive predictive value (PPV) and negative predictive value (NPV) for extravasation on post-operative urethrogram to predict anatomic and functional recurrence. The gold standard for such comparisons were cystoscopy and need for repeat procedure, respectively. Furthermore we evaluated the relationship between extravasation on post-operative urethrogram and complications. We performed univariate analysis to assess patient factors which predict for extravasation. Due to a low number of events and concern regarding statistical validity multivariate analysis was ommitted. We used STATA version 15 (College Station, TX) for all statistical analysis. P values of $<.05$ were considered statistically significant.

RESULTS

From the 1691 patients with a postoperative urethrogram, 1101 (65.1%) completed the 1-year follow-up protocol with cystoscopy. From this cohort, 54 (4.9%) patients had extravasation on post-operative urethrogram (Fig. 1). There were no differences in rates of extravasation detection by surgeon. Among those 54, 42 (77%) developed a recurrence vs 112 of 1047 (10.7%) recurrence among the patients without extravasation ($P <.01$). Among the 42 with recurrence, 83.3% had a strictly anatomic recurrence. Similarly, for those with a recurrence in the absence of extravasation, 64.9% of cases were anatomic only.

Factors Associated With Extravasation

There was a higher incidence of diabetes among patients who had a documented extravasation ($P = .04$). A personal history of malignancy, cardiovascular disease, radiation, hyperlipidemia, cronic obstructive pulmonary disease and smoking were not statistically related to finding extravasation. The median duration of

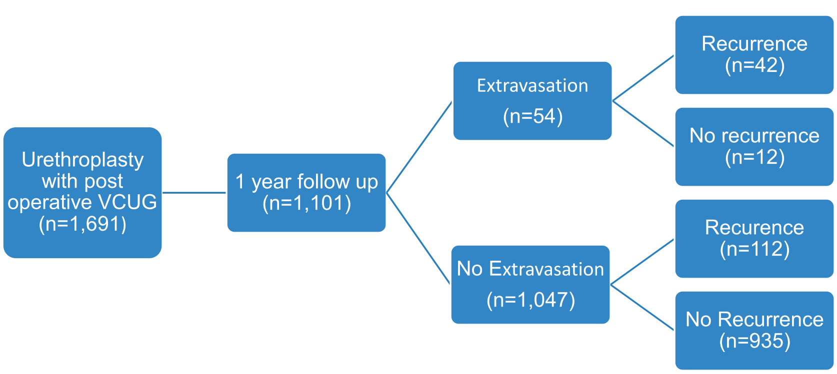

Figure 1. Patient selection flow diagram*. (Color version available online.)

Table 1. Demographics of patients undergoing surgical treatment for USD with postoperative urethrogram

Patient Characteristic	Extravasation (*n* = 54)	No Extravasation (*n* = 1047)	*P* Value
Age median (interquartile range)	50 (33-67)	43 (31-57)	.06
BMI median (interquartile range)	30 (26-35)	29 (25-33)	.16
Medical history *n* (%)			
Diabetes mellitus	11 (20.4)	109 (10.4)	.04
Hyperlipidemia	13 (24.1)	180 (17.2)	.19
Hypertension	19 (35.2)	275 (26.3)	.15
Coronary artery disease	1 (1.8)	27 (2.6)	1.00
Peripheral vascular disease	2 (3.7)	12 (1.15)	.15
Chronic obstructive pulmonary disease	3 (5.6)	14 (1.8)	.09
Cancer	2 (3.7)	68 (6.5)	.60
Pelvic radiation	0 (0)	1 (0.1)	1.00
Smoking history	23 (42.6)	295 (28.2)	.03
Etiology *n* (%)			
Idiopathic	18 (33.3)	544 (52.0)	.01
Iatrogenic	15 (27.8)	170 (16.3)	.04
External trauma	8 (14.8)	185 (17.7)	.70
Failed hypospadias	4 (7.4)	23 (2.2)	.04
Lichen sclerosus	2 (3.7)	32 (3)	.68
Infectious	1 (1.9)	21 (2.0)	1.00
Radiation	1 (1.9)	15 (1.4)	.55
Unknown	7 (13.0)	89 (8.5)	.32

postoperative catheter when no extravasation was detected was 20 days (interquartile range [IQR]: 17-25), compared to 23 days with extravasation (IQR: 18-34; [*P* <.01]) (Table 1). There was no difference in rates of extravastion based on surgeon (*P* = .18).

The highest incidence of extravasation involved repairs of the bulbar urethra (*n* = 22 [40.7%]) (Table 2) but this was also the urethral location most often repaired. When corrected by frequency of repair area itself, extravasation occurred in 15.9% of penile repairs, 13.3% of distal penile repairs, 8.5% of repairs spanning more than 1 location and 3.0% of bulbar repairs. When corrected by frequency of the type of repair, extravasation occured in 7.8% ventral onlay, 7.2% dorsal onlay, and 2.3% excision and primary anastomosis (EPA). Of the extravasation, 61% involved graft use. Among grafts, 47.8% were dorsal onlay repair, 24.0% ventral onlay repair, 15.2% dorsal inlay repair, 6.5% buccal dorsal onlay augmented repair, 4.4% account for complex multistage dorsal onlay and 2.2% for lateral onlay. When length of repairs was analyzed, the average stricture length for the extravasation group was 3.5 cm vs 2.5 cm in the no extravasation group (*P* value <.001). Likewise, multiple simultaneous repairs were associated with a higher incidence of extravasation compared to solitary stricture repairs.

Perioperative Impact of Extravasation

Comparing those with extravasation to those without, complications were more frequently encountered in the extravasation group (Supplementary Table 1). Extravasation patients were more likely to suffer postoperative UTI 12.9% vs 2.7%; *P* <.01. Wound infection was 7.4% vs 2.6% for those with and without contrast extravasation (CE), respectively (*P* = .04). Fistula was similarly presented in patients with extravasation 3.7% vs 0.7% with no extravasation on postoperative urethrogram (*P* = .02).

Predictive Value of Extravasation

For patients with extravasation, we documented a functional recurrence in 5 patients, anatomic recurrence in 37 and no recurrence in 12 (Fig. 1). From the 1047 patients without extravasation,

Table 2. Surgical details of patients undergoing treatment for USD with postoperative urethrogram

Surgical Characteristic	Extravasation (*n* = 54)	No Extravasation (*n* = 1047)	*P* Value
Location *n* (%)			
Distal penile	2 (3.7)	13 (1.2)	<.01
Penile	10 (18.5)	53 (5.1)	
Bulb	22 (40.7)	723 (69.1)	
Spanning more than 1 location	17 (31.5)	182 (17.4)	
Unspecified	3 (5.6)	76 (7.3)	
Length* median (interquartile range) cm	3.5 (2.5-5)	2.5 (1.5-4)	<.01
Days of catheter, median (interquartile range),	23 (18-34)	20 (17-25)	<.01
Repair type *n* (%)			<.01
Graft repair	33 (61)	512 (48.9)	
EPA/NT	10 (18.5)	441 (42.1)	
Flap	2 (3.7)	30 (2.9)	
Other	9 (16.7)	64 (6.1)	
≥ 2 Simultaneous Repairs, *n* (%)	13 (24)	54 (5.2)	<.01

EPA, excision and primary anastomosis; NT, nontransecting urethroplasty.
Other includes perineal urethrostomy, diverticula repair, hypospadias and urethro-cutaneous fistula repair.
* Available in 910 patients.

Table 3. Diagnostic test evaluation of postoperative urethrogram for USD recurrence at 1 year after surgery

	Extravasation, *n* = 54 (%)	No Extravasation *n* = 1047 (%)	*P* Value	VCUG Sensitivity, %	VCUG Specificity, %	VCUG PPV, %	VCUG NPV, %
Overall	42 (77.8)	112 (10.7)	<0.001	27.3	98.7	77.8	89.3
Functional*	5 (9.3)	34 (3.3)	0.04	12.8	95.4	9.3	96.8

NPV, negative predictive value; PPV, positive predictive value.
* Compared to need for repeat surgery for urethral stricture within 1 year.

anatomic recurrence was documented in 78 and functional recurrence in 34. In terms of secondary procedures for patients with functional recurrence in the extravasation group ($n = 5$), treatment was 2 digital video internal urethrotomy (DVIU) and 3 fistula repairs; in the no extravasation group ($n = 34$), 21 underwent DVIU, 11 dilation, 1 DVIU plus mytomicin, and 1 DVIU with nonspecified injection. None of these patients underwent a repeated urethroplasty within 1 year.

Based on these outcomes, sensitivity for post-operative urethrogram to predict an anatomic or functional recurrence was 27.3% (Table 3). In other words, of all the recurences, only 27% had an anormal voiding cysto urethro graphy. However, 45 of 54 with extravasation had a recurrence, equating to a 22.2% urethroplasty success rate in those with extravasation. Functional recurrence sensitivity was 12.8%, specificity 95.4%, PPV 9.3%, and NPV 96.8%. For the subgroup of 545 patients undergoing repairs with graft, the sensitivity to predict anatomic or funcational recurrence was 25.5%, specificity 98.4%, PPV 78.8%, and NPV 85.2%.

DISCUSSION

Within a multi-institutional reconstructive research consortium we found a low, overall rate of extravasation (4.9%) on postoperative urethrogram. In the no extravasation group, 89.3% (935 of 1147) of patients did not require repeat surgery or have anatomic recurrence. Of all the noted recurences, only 27% had an anormal VCUG. The postoperative extravasation relationship with recurrence is striking. 45 of 54 patients with extravasation had a recurrence, equating to a 77.8% urethroplasty failure rate in those with extravasation. The vast majority of these recurrences within the first year after urethroplsty were anatomic. Extravasation only achieved a 9.3% PPV for functional recurrence over the follow-up period. The ultimate clinical significance of an anatomic recurrence remains unclear as some men do not require further intervention.[4,17] However, given these findings our hypothesis must be rejected. The low sensitivity of extravasation for detecting recurrences means that we will need to continue to surveil for recurrences using other methods — the absence of extravasation is not enough to assure us of eventual success of the repair. Likewise, the high PPV of extravasation for predicting recurrence means that those with extravasation must be surveilled with particular vigilance.

Prior reports on postoperative urethrogram extravasation after urethroplasty have varied in incidence from 2.2% to 34%, with potential variation due to length of catheterization, type of repair, surgical technique, or postoperative urethrogram technique.[11,18] Like others, we found a lower rate of post-operative urethrogram extravasation with anastomotic repairs.[16] In our cohort, EPA incurred a 2.3% rate of extravasation vs 7.2% for dorsal onlay repairs. Longer, more complex repairs in the penile urethra were more likely to incur extravasation. However, there was no major differences in calculated sensitivity or specificity among those with graft repairs vs others.

Urinary extravasation has previously been identified as a risk factor for development of strictures in uretero-intestinal and vesicourethral anastomosis.[20,21] Urine extravasation into the corpus spongiosum may potentially result in inflammation, spongiofibrosis, and subsequent stricture recurrence; however, there is a paucity of literature proving a connection between isolated extravasation and functionally poor outcomes.[11,13,15,19,22] It is also possible extravasation is indicative of infection or poor tissue quality, each of which may independently predict for recurrence. Alternatively, it may suggest loss of graft, flap or anastomosis and healing by secondary intention leading to more scarring and potential recurrence. Our finding of increased risk of UTI and wound infections in those with extravasation infers no direction of the association; further work is needed to define any causality of these relationships.

Post-operative urethrogram's predictive power in the postoperative setting has recently been under greater scrutiny. Grossgold et al found 31 of 91 patients had postoperative extravasation after bulbar buccal graft urethroplasties. There was no association between extravasation and anatomic recurrences.[11] In contrast in our series, we demonstrate an association between extravasation and cystoscopic recurrence. Further, we found that the documentation of urine extravasation is relatively low, even in those patients with documented anatomic recurrence. If patients were imaged earlier, it is unknown if extravasation would be a common finding for such patients. Most importantly, we found anatomic recurrence in these patients did not equate to additional surgical procedures, albeit with short-term follow-up. Cystoscopy alone is likely a poor test for stricture recurrence given inconsistenties with patient symptoms, cystostopic findings, and secondary interventions. This calls into question the need for invasive studies such as postoperative urethrogram for all patients.

Based on our data, diabetics, patients with longer strictures, or those undergoing multiple simultaneous repairs were more likely to have extravasation. This could indicate extravasation is simply a marker of high-risk urethroplasty as these factors have been known to be associated with a higher risk of disease recurrence.[8] Type, length, location of repair as well as patient comorbidities could be considered in deciding which patients need closer follow-up and/or post-operative urethrogram. In straight forward cases (such as simple EPA) physical examination and history in the immediate post-operative period may indicate whether closer follow-up is needed.[11]

For those patients requiring closer follow up, the patients' perspective is an important often overlooked consideration.[12] Follow-up after urethroplasty with repeated uroflowmetry and cystoscopy can be burdensome and often objective and subjective measures of success do not match.[12-14,23] Reasons to optimize patient follow-up include cost, burden of patient travel, concerns regarding radiation exposure, and improving patient comfort.[24-26] The development of patient reported outcomes measures may mitigate this issue.[23]

This study has a number of pertinent limitations. This is a retrospective study of prospective data, and was subject to the biases pertinent to such studies.[27] Like any large database, errors of omissions are possible. These errors would be non-differential to our results. The inclusion of multiple surgeons and centers increased statistical power, but we present a heterogeneous collection of patients, imaging techniques, and treatments. Nonetheless there were no differences in extravasation rates by center. Despite large numbers of patients, extravasation was rare. Sufficient numbers of images were not available for centralized review; extravasation was analyzed only as a dichotomous variable. Not all patients with documented recurrence required treatment since many were asymptomatic. By protocol, data was analyzed at 1 year of follow up, so we draw no conclusions about recurrences that may occur later. Additionally if a leak was found on post-operative urethrogram, the catheter may have been left indwelling for a longer period of time; with unmeasured impact on recurrence or time to recurrence. Moreover, clinical suspicion of a complex repair or poor healing may have led to longer catheterization times to begin with which may introduce bias into our results. Indeed, median catheter time was 23 days (IQR:18-34) and 20 (17-25) $P < .001$ for extravasation and nonextravasation groups indicating some possible selection bias by surgeons. We could not control for confounders (such as smoking history, radiation history, diabetes, length of catheter placement, longer or complex repairs) in a valid multi-variate model because the incidence of our primary predictor of interest (extravasation) was low.

CONCLUSIONS

Among experts, the incidence of recurrence after urethroplasty is low. Postoperative urethrogram has a high specificity but low sensitivity for anatomic and functional recurrence at 1 year. Extravasation on postoperative urethrogram is correlated with anatomic recurrence at 1 year. Secondary procedures for these recurrences are rare and not correlated to extravasation. Extravasation is associated with increased peri-operative complications such as wound infection and UTI. Given the high PPV of extravasation for predicting anatomic recurrence, surgeons should consider close surveillance of those with extravasation.

SUPPLEMENTARY MATERIALS

Supplementary material associated with this article can be found in the online version at https://doi.org/10.1016/j.urology.2020.05.109.

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EDITORIAL COMMENT

The meaning of contrast extravasation at the time of post-urethroplasty urethrogram is a matter of debate, in particular its value to predict stricture recurrence. While some studies suggest a positive correlation with future failure, particularly after graft urethroplasty (refs. 11, 15 and 18 in the paper), others like a recent large series from Latin America failed to demonstrate such association.[1]

This is frustrating because, conceptually, the finding of extravasation at 3 weeks suggests that the healing may has not been perfect, and that part of the reconstruction has probably been lost and will heal by second intention, leading to fibrosis. Additionally, exposure of the corpus spongiosum to urine may trigger inflammation increasing also the risk of periurethral scarring.

These contradictory findings are most likely due to insufficient follow up and variable protocols, with diverse definitions of failure. In this scenario, this study has the virtue of presenting a large number of patients from 10 expert centers of excellence, from the Trauma and Reconstructive Network of Surgeons. A retrospective analysis of a prospectively collected database was performed and extravasation was shown to have a strong positive predictive value to portend stricture recurrence at 1 year.

Contrast extravasation is not very frequent and was 4.9% in this series. It has been shown more prevalent after complex and graft reconstructions, and more rarely following bulbar anastomotic procedures. Because of this, some reconstructive urologists - about 30% in a recent survey[2] - do not perform routine imaging studies when removing the catheter.

However, that's in the hands of experts. In my opinion, post-operative urethrography has the value of serving as a quality control tool for the reconstructive urologist, especially those who are initiating their experience. It can also influence management (ie, longer catheterization time) and may evidence those patients with severe extravasation who are at increased risk of complications, like fistula or abscess, who may even need early reoperation. This report adds another significant value to postoperative imaging.

It is important to note that not all extravasations are the same and the degree of extravasation is crucial, as minor or contained extravasations usually are not relevant and may not need a longer catheterization time. However, more extensive or uncontained extravasations may indicate a more severe healing defect and may be at a higher risk of failure and acute complications. It is unfortunate that analysis of the degree of extravasation was not possible to be done in this study, remaining as an important subject for future research.

Although the study is limited by a short follow-up (only 1 year) and some possible biases arising from variations in the data collection, the use of different urethrography techniques and other factors inherent to this type of studies, the series presents solid data indicating that, despite a low sensitivity (so the absence of extravasation does not exclude the risk of stricture recurrence), the presence of extravasation appears as a strong predictor of future stricture failure and, as the authors indicate, those patients should be followed more closely.

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AUTHOR REPLY

The implications of contrast extravasation after urethroplasty certainly deserves more of our attention and study. An unfortunate limitation of our work was the inability to perform centralized imaging review given local-only, non-saving fluoroscopy units at many sites. In prior work, Grossgold et al evaluated extravasation severity and ascribed a 3-tiered grading system. Among 31 observed leaks (resulting from 91 buccal urethroplasties), 11 were "severe," and tended to have worse outcomes at 1 year from surgery.[1] As leaks are attenuated by urethrogram technique, truly comparing across technicians is challenging. In addition, there is no objective method to standardize mild vs severe. The Potter Stewart adage "I know it when I see it" may perfectly describe the current identification of a severe leak.[2]

We agree that extravasations may represent an undesirable pathway for healing. In many ways, extravasation is an end product of an unknown process. The interplay of surgical technique, native tissue quality, and inflammation may all contribute. Urine spillage may trigger spongiofibrosis and stricture recurrence. When we observe a significant leak, dogma dictates longer catheterization times with unclear effect on long-term stricture recurrence rates. The Trauma and Urologic Reconstruction Network of Surgeons is currently studying the role of inflammation in urethral stricture disease (1R21DK115945-01) which hopefully will begin to shed light on these issues.

The use of post-operative imaging as a quality check tool is an important point. These data represent the accumulated experience of experts. Indeed, the same group previously concluded 100 cases are required to reach urethroplasty proficiency.[3] Given challenges with consistent follow up of patients after urethroplasty, a post-operative image may be the sole opportunity to assess the results of surgery. For a reconstructive urologist early in their career, post-operative urethrogram therefore remains essential.

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