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Multi-institutional 1-Year Bulbar Urethroplasty Outcomes Using a Standardized Prospective Cystoscopic Follow-up Protocol

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Abstract

OBJECTIVE—To evaluate multi-institutional outcomes of bulbar urethroplasty utilizing a standardized cystoscopic follow-up protocol.

METHODS—Eight reconstructive surgeons prospectively enrolled urethral stricture patients in a multi-institutional study and performed postoperative cystoscopy at 3 and 12 months. Anatomic failure was defined as the inability to pass a flexible cystoscope without force. Functional failure was defined as the need for a secondary procedure. Men not compliant with the 12-month cystoscopy were called and asked if any interval secondary procedures had been performed. Patients with bothersome voiding complaints at cystoscopy were considered symptomatic.

RESULTS—Of 213 men in study, 136 underwent excisional urethroplasty (excision and primary anastomosis [EPA]) and 77 underwent repair with buccal grafts. Cystoscopy compliance was 79.8% at 3 months and 54.4% at 12 months. Anatomic success rates were higher at 3 vs 12 months for EPA repairs (97.2% [106 of 109] vs 85.5% [65 of 76; $P = .003$] but not buccal repairs (85.5% [53 of 62] vs 77.5% [31 of 40]; $P = .30$). Functional success rates at a year were higher but statistically similar to anatomical success rates (EPA—90.3% [93 of 103]; $P = .33$; buccal—87% [47 of 54]; $P = .22$). Of the 20 anatomic recurrences, only 13 (65%) were symptomatic at the time of cystoscopic diagnosis.

CONCLUSION—Rates of success are lower when using the anatomic vs traditional definition. Of recurrences found by cystoscopy, only 65% were symptomatic. One-year patient cystoscopy

compliance was poor and its ability to be used as the gold standard screening methodology for recurrence is questionable.

Surgical reconstruction is the gold standard treatment for urethral stricture disease. Reported success rates after urethral reconstruction vary widely depending on the location and length of the stricture and the type of procedure required but in general range between 50% and 100%.¹ Because definitions of success vary widely in the literature, all success rates must be evaluated on a report-by-report basis, making comparisons between studies difficult.²

Most urethroplasty outcomes studies use a functional definition of success—the concept being that freedom from repeated surgery represents a satisfied patient. Less stringent definitions of success in other studies allow for a single endoscopic salvage procedure before classifying a patient's urethroplasty as a failure. A more strict anatomic definition of success is less often used but requires a normal urethral lumen during retrograde urethrogram or cystoscopy regardless of patient symptoms.³ Although follow-up regimens have been shown to differ widely among existing literature, what is generally agreed on is that without standardization of a definition of success, progress in the field will be slowed as individual techniques and clinical indications cannot be critically analyzed in meta-analyses.²

The primary aim of this study was to evaluate surgical outcomes from a multi-institutional, prospective, urethral reconstructive study that used a strict cystoscopic definition of urethroplasty failure. We hypothesized that using a stricter anatomic definition of urethroplasty success may result in higher failure rates as compared with traditional functional success rates.

MATERIALS AND METHODS

The Trauma and Urologic Reconstructive Network of Surgeons (TURNS) is a multi-institutional outcomes research group that collects prospective outcomes data on urologic diseases that are traumatic and reconstructive in nature. All members are fellowship-trained reconstructive surgeons practicing in academic institutions. All data are collected prospectively by the respective surgeons and stored in a single, web-based, institutional review board-approved data repository.

Study Eligibility and TURNS Follow-up Protocol

All men undergoing urethral reconstruction at 1 of the 8 institutions in the TURNS network who were aged ≥ 18 years at the time of surgery were eligible for participation in the prospective study. Participating patients sign institution-specific consent forms and are made aware that their respective physicians will be performing cystoscopy or urethroscopy at 3 and 12 months after urethroplasty to screen for recurrence, with yearly clinic follow-up thereafter. Cystoscopy after a year is left to surgeon and patient discretion if the 12-month cystoscopy is normal. For the purposes of the study, the 12-month cystoscopy was considered to be any cystoscopy performed between 11 to 15 months after surgery. At each postoperative visit, validated questionnaires about urinary and sexual function were collected along with uroflowmetry and postvoid residual data, but these data were not

included in this analysis as the focus was on anatomic recurrences as determined by cystoscopy alone. To assess the correlation between the anatomic appearance of the urethra by cystoscopy and patient-reported symptoms after urethroplasty, we included information about the presence of bothersome voiding symptoms at the time of postoperative clinic visits (ie, patient complaining of slow flow, painful urination or urinary tract infection at the time of either routine or patient-initiated postoperative follow-up).

Study Population

We analyzed all enrolled men who underwent single-stage bulbar urethral reconstruction from June 2010 to August 2011. Surgical techniques were not necessarily standardized and were left to each surgeon's discretion. However, all men in the study ultimately underwent 1 of 3 types of urethroplasty, which have been described in detail elsewhere: excision and primary anastomosis (EPA),⁴ dorsal and/or ventral buccal onlay,^{5,6} and augmented (dorsal and/or ventral) anastomotic repairs.⁷ Men were excluded if the stricture involved the posterior or penile urethra.

Outcomes

The primary outcome in this study was an anatomic success on the 3- and 12-month cystoscopy (16F–17F flexible cystoscope). Anatomic success was strictly defined as the ability to pass the cystoscope beyond the area of reconstruction with ease. A secondary outcome was functional success, which we defined as freedom from secondary procedures (ie, no urethral dilations or repeat urethroplasties during the follow-up period) and lack of concerning patient-reported voiding symptoms. For this outcome, we included patients who were noncompliant with the cystoscopic study protocol but were interviewed in the office or by telephone. During the phone conversation, if the routine visit could not be rescheduled or was refused, we asked the patients if they had required any secondary procedures since we had seen them last or if they were having any new postoperative voiding concerns. If the answers to both questions were “no,” they were considered a functional success. In other words, a functional success was determined from the patient's perspective, whereas anatomic recurrence was determined from the surgeon's perspective. Patients who were lost to follow up at 1-year (ie, no cystoscopy or office or phone contact) were not included in the final analysis.

Statistical Analysis

First, we determined anatomic and functional success rates using simple statistics and compared them using 2-way chi square analysis. Second, we compared cystoscopy compliance rates and surgical success rates between surgeons using chi square analysis. Third, we compared the relationship between study compliance and reported outcomes using Pearson correlation coefficients. Statistical significance for all tests was set at a *P* value of .05. Statistical analysis was performed using SAS 9.3 (Cary, NC).

RESULTS

There were a total of 213 bulbar urethroplasties included in the analysis, of which 136 (63.8%) were EPA and 77 (36.2%) were substitution or augmented anastomotic repairs

using buccal mucosa. The mean number of single-stage bulbar urethroplasties per surgeon enrolled in the study was 27.3 ± 12.4 .

Follow-up

Overall patient adherence to the 3- and 12-month cystoscopy was 79.8% (range, 60%–90%) and 54.4% (range, 26.7%–78.3%), respectively. Patient follow-up compliance differed by surgeon ($P = .025$ at 3 months and $P = .003$ at 12 months) but not by surgery type (12 month; anastomotic 55.9% vs buccal 51.9%; $P = .58$).

Of the 97 men who did not return for their 1-year follow-up cystoscopy, 41 (19.8% of the total cohort) were contacted by phone, resulting in a total 1-year overall follow-up of 73.7% and a mean follow-up time of 13.1 ± 1.2 months. Importantly, of these 41 men, 28 (68.3%) had returned for their 3-month follow-up cystoscopy and none had evidence of cystoscopic recurrence at that time. There were 56 (26.3%) men who we considered to be lost to follow-up at 1 year (no cystoscopy or office or phone visit). Importantly, 26 (46.4%) of these men underwent their 3-month cystoscopy and none were found to have recurrence at that time.

Anatomic vs Functional Success Rates

Anatomic success rates were statistically higher at 3 vs 12 months for EPA repairs (97.2% [106 of 109] vs 85.5% [65 of 76]; $P = .003$) but not buccal repairs (85.5% [53 of 62] vs 77.5% [31 of 40]; $P = .30$).

The functional success rates included 41 men who were assessed at 1 y by phone call alone, none of whom required secondary repairs. For the functional success cohort, we also included the 3 men who were anatomic failures but were functional successes, as these men declined surgery for their anatomic narrowing (2 buccal repairs and 1 EPA—in each case, despite evidence of narrowing, the men reported “much improved voiding” and refused further intervention). This resulted in a 1-year functional success rate of 90% for EPA (93 of 103; $P = .33$) and 87% for buccal repairs (47 of 54; $P = .22$), which were improved, but statistically similar compared with the anatomic success rate.

Of the 20 total recurrences found by cystoscopy, 17 underwent dilation or urethrotomy during the follow-up period, and 7 men ultimately required revision urethroplasty. There were no significant differences in success rates between surgeons. Individual success rates were positively correlated with follow-up protocol adherence for EPA ($r = 0.71$; $P = .05$) but not buccal repairs ($r = -0.03$; $P = .87$).

Symptoms at the Time of Cystoscopic Recurrences

Of the 20 men found to have recurrence by cystoscopy, only 65% were symptomatic at the time of recurrence (ie, complaining of bothersome urinary difficulty at the time of clinic visit or returning to clinic because of symptoms). Men with recurrence after EPA were more likely to report symptoms at time of cystoscopy (8 of 11, 72%) than those with recurrence after buccal grafting (5 of 9, 55%), although the difference was not statistically significant ($P = .42$). Men with buccal grafts had anatomic failures much earlier than those undergoing EPA (mean days to failure, 84 ± 71 days vs 298 ± 54 days, respectively; $P = .01$).

COMMENT

This study analyzed the multi-institutional 1-year outcomes after single-stage bulbar urethroplasty using a standardized cystoscopic follow-up protocol to assess anatomic failures. Consistent with our initial hypothesis, we found that anatomic success rates were lower than prior series that use a functional success definition of freedom from repeat surgery. One-year anatomic success rates were 86% for EPA and 78% for urethroplasties using buccal mucosa. Importantly, our second main finding is that our functional success rates were similar to those in the existing literature (90% for EPA and 87% for buccal graft urethroplasty), suggesting that lower anatomic success rates are due to the more stringent definition rather than to poorer outcomes at the contributing centers.³ The fact that anatomic and functional success rates did not vary between the 8 surgeons further supports the generalizability of our findings.

Anatomic Success After Urethroplasty

The primary outcome of the study used a strict, cystoscopic definition of anatomic failure. As a group, we believed that establishing the anatomic success rates were important in the complete evaluation of our reconstructive procedures, allowing for accurate comparison between subsequent research studies and various institutions. From a clinical and practical standpoint, there are factors that must be considered when interpreting anatomic successes, however. First, only patients returning for their 1-year follow-up cystoscopy were included in the 1-year anatomic success calculation, resulting in nearly 50% of the initial cohort being excluded from the analysis. These strict exclusion criteria likely introduced selection bias, as it is often assumed that men with postoperative voiding symptoms suggestive of recurrence will be more likely to return for follow-up visits, potentially negatively skewing the results.

Importantly, this study offers moderate support that the previously mentioned assumption is correct by showing that surgeons reporting higher follow-up adherence were also found to have higher overall success rates. Although this may seem counterintuitive, as one might expect more asymptomatic recurrences to be found, we believe that if we assume similar overall success rates between surgeons, those with better compliance rates must have been performing more cystoscopies on asymptomatic normal urethras. Likewise, none of the patients who did not return for their 1-year follow-up visit had narrowing at their 3-month cystoscopy and none had undergone any salvage procedures in the intervening 9 months. Thus, asymptomatic patients appear less likely to follow up.

A second factor to consider when analyzing these anatomic recurrence rates is that an anatomic recurrence does not necessarily equate to a functional recurrence. This statement is supported by the fact that many patients in the study with anatomic recurrences were asymptomatic, and a few even elected to not perform a secondary procedure when the anatomic narrowing was encountered.

Functional Success After Urethroplasty

Traditional urethroplasty definitions have largely analyzed only the need for secondary procedures after reconstruction, which themselves are generally reserved for men with

recurrence, or persistence, of obstructive voiding symptoms (ie, a functional recurrence). Although we as a group felt that the use of the functional definition of failure falls short of what will be required to improve urethral reconstructive research efforts, these reported success rates may be consistent with what is important to our patients, which is improved urination relative to their preoperative voiding. Indeed, prior research has shown that bothersome obstructive symptoms may not be experienced until the urethra is <10F,⁸ meaning many with anatomic recurrence may not experience symptoms. Importantly, analysis of functional success rates in this population revealed success rates (91% for EPA and 87% for buccal) much more in line with prior studies.^{1,3,5,9}

Analysis of Cystoscopy as the Gold Standard for Determining Recurrence

We believe that the high rate of anatomic failures in asymptomatic patients found in this study highlights the importance of performing at least 1 anatomic analysis of the reconstructed urethra in the postoperative period. However, there are problems with the anatomic definition of failure that must be addressed. First, the 1-year compliance rate for cystoscopy was only 50%. Exact reasons for noncompliance could not be determined in all patients, but anecdotally, many of the men simply didn't see the utility of making a trip (often long trips to tertiary care centers) to be told what they already know—their surgery was a success. Second, cystoscopy is an invasive and costly test and despite the high test sensitivity, nearly 90% of the men ultimately underwent cystoscopy to evaluate a normal urethra.¹⁰ Finally, cystoscopy may actually be too sensitive of a test for assessment of stricture recurrence. Although cystoscopy is excellent at diagnosing anatomical recurrences that we as surgeons believe are important, functional recurrences are what concern patients the most. Similarly, the medical utility of determining an early failure is unknown and has not been well studied. As patient-reported outcome measures become increasingly prevalent in surgery as a way to measure surgical outcomes and determine reimbursement, both our methods to diagnose and to define failure after urethral reconstruction will likely need to become more fluid—although agreeing on a definition will certainly remain a significant challenge as we continue to advance and refine the reconstructive field.¹¹ We believe that with continued refinement, our use of 2 separate definitions of failure, one that is determined by the patient (functional) and one that is determined by the surgeon (anatomic), can become a useful means to report future urethral reconstructive outcomes.

Limitations

There are limitations to the study that should be addressed. First, our success rates at 1 year may not be durable over the long term. However, the study design was meant only to analyze the utility of the short-term cystoscopic protocol, and long-term data on this cohort will follow. Second, although we purposely limited our analysis to assessing anatomic and functional success (freedom from repeat surgery and symptoms), it is likely that had we included their questionnaire and uroflowmetry data, our ability to diagnose recurrence without cystoscopy may have improved. Finally, the compliance rates for follow-up were poor, perhaps biasing our anatomic success rates. However, this limitation only further emphasizes the need for an alternative, noninvasive, and sensitive way to screen for recurrence, as compliance rates will likely always be lower than expected in most postsurgical populations.

CONCLUSIONS

Using a strict anatomic definition of failure, this multi-institutional study found that success rates for both excisional and buccal urethroplasty in the bulbar urethra were lower than those that had been previously reported. This may be related to lower than expected follow-up compliance. When a functional definition of failure was used in the same cohort, overall outcomes improved, more closely resembling published literature. Importantly, a large percentage of anatomic failures were asymptomatic, although the long-term significance of this finding is unknown. Despite the clinical utility of routine cystoscopic screening, the uniformly poor follow-up compliance in the study questions the ability of cystoscopy, or any other invasive testing, to become the gold standard methodology for diagnosing postoperative stricture recurrences.

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