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Defining Success after Anterior Urethroplasty: An Argument for a Universal Definition and Surveillance Protocol

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Study Need and Importance: A successful urethroplasty has been variably defined as absence of retreatment, functional success measured by lack of voiding symptoms or strong force of stream, or anatomical success on cystoscopy or urethrography. Until we have universal agreement regarding which outcomes should define urethroplasty success, we will struggle to progress the field of urethral stricture treatment because we cannot compare techniques across studies or in meta-analyses. We sought to evaluate how success rates differ after anterior urethroplasty simply by changing the definition of success.

What We Found: The estimated probability of success after first-time, anterior urethroplasty is highly dependent on the way success is defined. The 1- and 5-year estimated probabilities of success after urethroplasty, from highest to lowest, are 94% and 75% for freedom from retreatment, 88% and 71% for anatomical success (lumen >17Fr on cystoscopy), 84% and 58% for maximum uroflowmetry rate >15 ml/second, 67% and 37% for absence of weak stream on questionnaires, and 57% and 23% for absence of failure by any of the preceding definitions ($p < 0.001$; see Figure).

Limitations: Limitations include our retrospective design, lack of controlling for different surgeons or institutions, use of 1 question from our patient-reported questionnaires dedicated to weak stream and lack of comparing postoperative outcomes to preoperative values.

Interpretation for Patient Care: The variability in definitions for a successful urethroplasty has resulted in an inability to compare urethroplasty outcomes across studies. While a universally agreed upon definition of success is important to advance the field of academic medicine, we must take care to balance our need for an objective/reproducible definition of success with a patient-centered definition that does not utilize unnecessary invasive testing. Until then, this side-by-side description of success rates should help compare studies that use different outcomes.

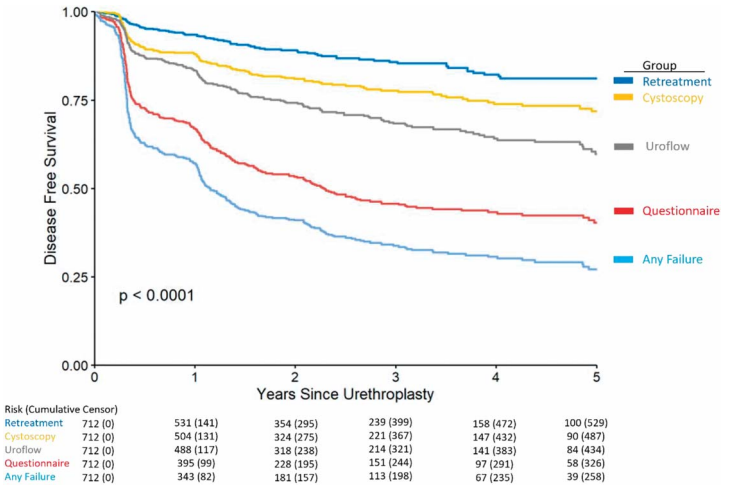

Figure. Kaplan-Meier survival curve demonstrates the 5-year estimated probability of success of anterior urethroplasty according to different definitions of success.

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Defining Success after Anterior Urethroplasty: An Argument for a Universal Definition and Surveillance Protocol

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Abbreviations and Acronyms

AUA-SI = American Urological Association Symptom Index
E = stricture etiology
L = stricture length
LS = lichen sclerosis
PROM = Patient-Reported Outcome Measure
Qmax = maximum flow rate on uroflowmetry
S = stricture location
TURNS = Trauma and Urologic Reconstructive Network of Surgeons
uroflow = uroflowmetry

Purpose: A successful urethroplasty has been defined in different ways across studies. This variety in the literature makes it difficult to compare success rates and techniques across studies. We aim to evaluate the success of anterior urethroplasty based on different definitions of success in a single cohort.

Materials and Methods: Data were collected from a multi-institutional, prospectively maintained database. We included men undergoing first-time, single-stage, anterior urethroplasty between 2006 and 2020. Exclusion criteria included lack of followup, hypospadias, extended meatotomy, perineal urethrostomy, posterior urethroplasty and staged repairs. We compared 5 different ways to define a "failed" urethroplasty: 1) stricture retreatment, 2) anatomical recurrence on cystoscopy, 3) peak flow rate <15 ml/second, 4) weak stream on questionnaire and 5) failure by any of these measures. Kaplan-Meier survival curves were generated for each of the definitions. We also compared outcomes by stricture length, location and etiology.

Results: A total of 712 men met inclusion criteria, including completion of all types of followup. The 1- and 5-year estimated probabilities of success were "retreatment," 94% and 75%; "cystoscopy," 88% and 71%; "uroflow," 84% and 58%; "questionnaire," 67% and 37%; and "any failure," 57% and 23%. This pattern was inconsistent across stricture length, location and etiology.

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Ethics Statement: Study received Institutional Review Board approval (IRB No. 00005058).
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Conclusions: The estimated probability of success after first-time, anterior urethroplasty is highly dependent on the way success is defined. The variability in definitions in the literature has limited our ability to compare urethroplasty outcomes across studies.

Key Words: urethral stricture, follow-up studies, recurrence, retreatment

A successful urethroplasty was defined as "lack of retreatment" during the 1990s to early 2000s, with success rates near 90%.[1] However, the decision about when to reoperate varies by surgeon. To make the definition of success more objective and/or more patient centered, there has been a move toward using alternative definitions of success in the last 10−20 years. These include lack of voiding symptoms, strong force of stream, or lack of recurrence on cystoscopy or urethrography.[2] Unfortunately, this variety of outcomes reported in the literature makes it difficult to compare success rates across studies.

The surveillance protocols used to monitor for failure after urethroplasty are just as variable as the actual definitions of success.[1,3] In fact, the American Urological Association urethral stricture guidelines endorse the importance of urethroplasty followup but admit there is not consensus on what should be included in a surveillance protocol.[4] The European Association of Urology guidelines suggest a risk-based approach for followup: doing 1 postoperative anatomical test (eg cystoscopy) and then repeating it later only for high-risk strictures or if uroflowmetry (uroflow) or symptoms warrant.[4] This approach spares the patient unnecessary invasive testing, but it also detects fewer failures compared to cystoscopy at each followup.

Until we have universal agreement regarding which outcomes to use to define urethroplasty success, we will struggle to progress the field of urethral stricture treatment because we cannot compare techniques across studies or in meta-analyses. In support of defining a universally adopted definition of success, we sought to evaluate the success of anterior urethroplasty based on different definitions of success in a single large cohort. We hypothesized that defining a successful urethroplasty by cystoscopic criteria, uroflow data or patient-reported questionnaire data would result in lower success rates when compared to the historical standard (ie freedom from retreatment).

METHODS

STROBE (Strengthening the Reporting of Observational studies in Epidemiology) guidelines for reporting observational studies were followed. The study received Institutional Review Board approval (IRB No. 00005058).

Source of Data

Data were collected from the Trauma and Urologic Reconstructive Network of Surgeons (TURNS) multi-institutional database, which is prospectively maintained by the respective surgeons and stored in a single, web-based, Institutional Review Board-approved data repository of men undergoing reconstructive procedures. Seven institutions contributed patients for this study, with 5 of the institutions contributing over 50 patients each.

TURNS Followup Protocol

All TURNS surgeons follow a similar surveillance protocol after urethroplasty. Patients undergo uroflow, post-void residual volume measurement, and complete urinary and sexual function questionnaires at 3 and 12 months postoperatively, and annually thereafter. Cystoscopy is performed at 3 and 12 months and then only as indicated by symptoms or flow rate.

Study Population

We included cis-gender men who underwent a first-time, single-stage, anterior urethroplasty for urethral stricture from 2006 to 2020. Included repair types were anastomotic (including nontransecting anastomotic), graft substitution urethroplasty (including augmented-anastomotic) and genital flap substitution urethroplasty, or any combination of these. Men were excluded if they had no followup data, had a history of hypospadias or underwent an extended meatotomy, perineal urethrostomy, posterior urethroplasty or staged repair. Finally, we limited the cohort to those with at least 1 postoperative data point for each of the definitions of success (Fig. 1).

Definitions of Success

We evaluated success after urethroplasty based on 5 different definitions of urethroplasty failure: 1) receipt of stricture retreatment (dilation, direct vision internal urethrotomy, redo urethroplasty or self-dilation), 2) anatomical recurrence on flexible cystoscopy (lumen <17Fr), 3) uroflow maximum flow rate (Qmax) <15 ml/second (voided volume >120 ml), 4) symptomatic failure-based validated questionnaires (see below) and 5) failure by any of the 4 definitions above. For the any failure definition, men failed at the time of their first failure by any of the definitions. For the remainder of the manuscript, these definitions will be referred to as "retreatment," "cystoscopy," "uroflow," "questionnaire" and "any failure."

The questionnaires used by the TURNS group evolved over time to reflect the current literature. We used the American Urological Association Symptom Index (AUA-SI),[5] Urethral Stricture Surgery Patient-Reported Outcome

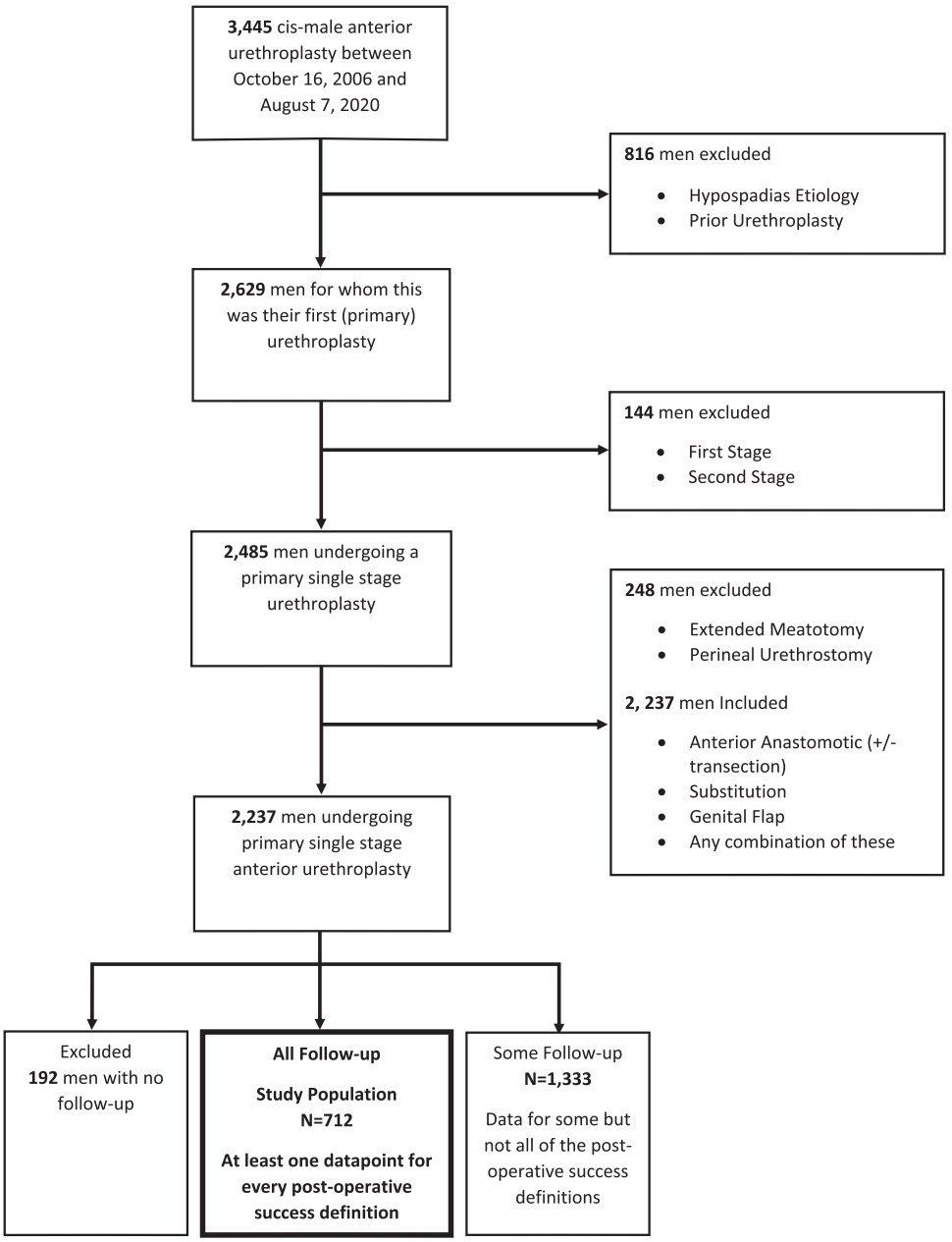

Figure 1. Flow diagram demonstrates patient cohort after applying exclusion criteria.

Measure (PROM),[6] and Urethral Stricture Symptoms and Impact Measure.[7] Prior work has shown that a report of weak urinary stream is more sensitive and specific for cystoscopic recurrence than total AUA-SI score.[8] Therefore, we used the question dedicated to weak urinary stream from all 3 questionnaires. Specifically, the AUA-SI asks, "During the last month, how often have you had a weak urinary stream?" and only the response "Not at all" was deemed success. The Urethral Stricture Surgery PROM asks, "In the past 4 weeks, would you say the strength of your stream is…" and only "Normal" was deemed success. Lastly, the Urethral Stricture Symptoms and Impact Measure prompts, "In the past 14 days, I had a weak stream" and only "Never" was deemed success. Thus, any degree of weak stream was considered failure across all questionnaires.

Statistical Analysis

Demographic and clinical characteristics were compared between the study cohort and men in the database who met all the other criteria for inclusion except did not have adequate followup. Comparisons were made using Student's t-test and chi-square test, as appropriate.

Kaplan-Meier survival curves were generated for each of the different definitions of success. Followup started at the time of urethroplasty and patients were censored if they experienced a failure according to the specific definition, at the date of last followup for that outcome or at 5 years. Statistical comparisons were performed with log-rank test.

Lastly, we evaluated the estimated probabilities of success according to a new validated anterior urethral stricture classification system.[9] Specifically, success estimates were

Table 1. *Clinical and demographic information based on completeness of followup*

	Some Followup	All Followup	p Value*
No. pts	1,333	712	
Median kg/m^2 body mass index (IQR)	28.6 (24.9, 33.2)	29.0 (25.5, 33.7)	0.2
Median yrs age (IQR)	48.5 (33.3, 61.9)	45.3 (32.9, 56.7)	0.012
Median cm stricture length (IQR)	3.0 (1.5, 5.0)	3.0 (1.7, 5.0)	0.8
No. L stage (%):			<0.001
L1 (≤2.0 cm)	571 (43)	282 (40)	
L2 (2.1–7.0 cm)	636 (48)	381 (54)	
L3 (≥7.0 cm)	100 (8)	49 (7)	
Missing	26 (2)	0 (0)	
Median mos followup (IQR)	8.3 (3.6, 21.7)	26.1 (12.6, 51.8)	<0.001
No. prior direct vision internal urethrotomies (%):			0.022
0	601 (51)	344 (49)	
1	351 (30)	191 (27)	
2	121 (10)	85 (12)	
3	53 (5)	49 (7)	
4	22 (2)	22 (3)	
5–10	28 (2)	12 (2)	
>10	4 (0)	7 (1)	
No. prior dilations (%):			0.6
0	574 (47)	335 (47)	
1	310 (26)	170 (24)	
2	138 (11)	88 (12)	
3	65 (5)	36 (5)	
4	32 (3)	19 (3)	
5–10	56 (5)	46 (7)	
>10	32 (3)	17 (3)	
No. diabetes cases (%)	174 (13)	70 (10)	0.032
No. E stage (%):			<0.001
E1 (external trauma)	186 (14)	127 (18)	
E2 (idiopathic)	737 (55)	430 (60)	
E3a (iatrogenic—trauma, ie transurethral resection of the prostate)	224 (17)	111 (16)	
E3c (iatrogenic—radiation)	87 (7)	15 (2)	
E4/6 (infectious/ inflammation/LS)	68 (5)	23 (3)	
Missing	31 (2)	6 (1)	
No. S stage (%):			<0.001
S1 (bulbar)	953 (72)	579 (81)	
S2 (penile)	297 (22)	100 (14)	
S3 (panurethral)	27 (2)	14 (2)	
Missing	56 (4)	19 (3)	
No. repair type (%):			0.9
Substitution graft	747 (56)	397 (56)	
Substitution flap	22 (2)	13 (2)	
Anastomotic	564 (42)	302 (42)	

* Student t-test and chi-square test for significance.

compared according to stricture length (L; ≤2 cm, 2–7 cm, ≥7 cm), location (S; penile urethra, bulbar urethra and panurethral stricture involvement) and etiology (E; external trauma, idiopathic, iatrogenic—internal trauma [ie transurethral resection of the prostate], iatrogenic—radiation induced and infectious/inflammatory/lichen sclerosis [LS]). The goal was to determine whether success estimates by each definition decreased with higher LSE stages.

RESULTS

A total of 2,045 men met demographic and surgical inclusion criteria. There were 1,333 men who did not complete all of the recommended followup and were thus not included in our primary analysis. Thus, our final cohort consisted of 712 men, each of whom had at least 1 data point for every definition of success. Compared to the 1,333 men excluded for poor followup, men in the study cohort were slightly younger, slightly less likely to have diabetes, more likely to have proximal bulbar strictures and more likely to have traumatic stricture etiology; otherwise, the cohorts were not meaningfully different (Table 1).

The Kaplan-Meier estimates for success after urethroplasty by each definition are shown in Figure 2. The median followup times and interquartile ranges by definition were 24 months (11.9, 44.7) for retreatment, 19.1 months (9.7, 42.6) for cystoscopy, 18.4 months (7.9, 41.5) for uroflow, 12.8 months (3.9, 28.1) for questionnaire and 11.4 months (3.7, 24.4) for any failure. The 1- and 5-year estimated probabilities of success (95% CI), from highest to lowest are 94% (0.92, 0.96) and 75% (0.69, 0.81) for retreatment, 88% (0.86, 0.91) and 71% (0.66, 0.76) for cystoscopy, 84% (0.81, 0.86) and 58% (0.53, 0.64) for uroflow, 67% (0.64, 0.71) and 37% (0.32, 0.43) for questionnaire, and 57% (0.53, 0.61) and 23% (0.19, 0.29) for any failure ($p < 0.001$).

When comparing 1-year outcomes by L, S and E,[9] higher LSE stages generally had lower estimated probabilities of success, but this was not consistent across the different definitions (Table 2). We did not compare 5-year outcomes by LSE stage due to the small sample size.

DISCUSSION

Overview

We show that the estimated probability of success after urethroplasty changes dramatically simply by changing the way success is defined. At 5 years, success varies from 75% free of retreatment to 37% free from symptoms of a slow stream on questionnaires. This is the first time that all these definitions of success have been compared in 1 cohort. These differences in success estimates are not due to different types of men completing the different types of followup, but rather simply by the way success is defined.

There were statistically significant differences between the cohort of men who completed all types of followup and those who did not complete all the recommended types of followup. None of these differences appeared clinically significant. Many believe that patients who are highly compliant with followup are different than those who never follow up; however, our data are unable to support that notion in a clinically meaningful fashion.

Role for Research-Based Definition of Success

The concept of a "research-based" definition in urology is not novel and can be likened to biochemical recurrence following radiotherapy for prostate cancer. The

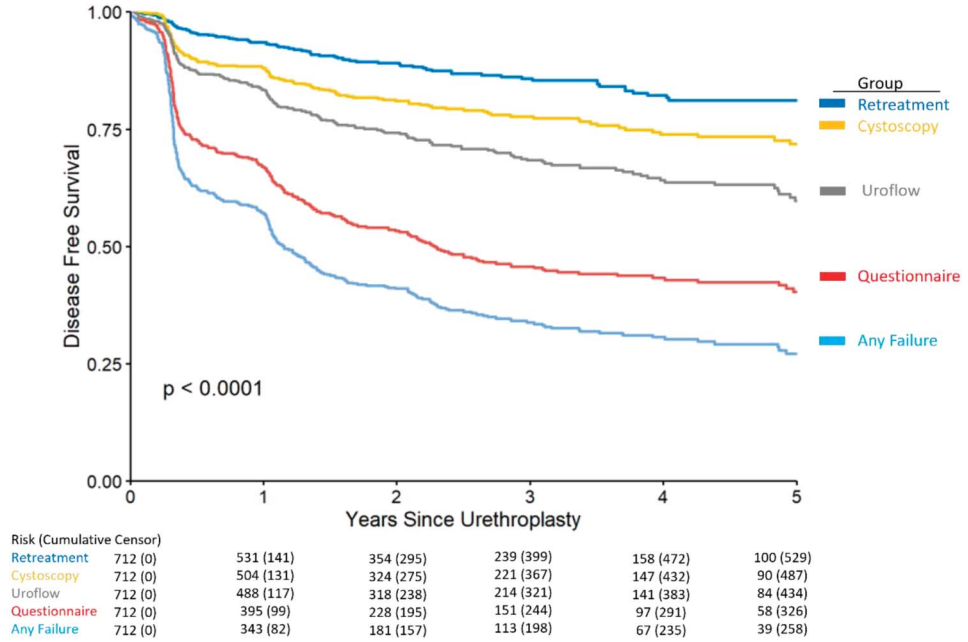

Figure 2. Kaplan-Meier survival curve demonstrates the 5-year estimated probability of success of anterior urethroplasty according to different definitions of success.

ASTRO (American Society for Radiation Oncology) definition of biochemical recurrence is not intended to represent a threshold value at which to initiate treatment.[10] Instead, it is meant as a research definition to standardize clinical trials. Similarly, a research-based definition of urethroplasty success may differ from clinical success but is essential for multi-institutional comparisons and randomized trials.

Success by Retreatment

When we defined success after urethroplasty by lack of retreatment, we had an estimated probability of success of 94% at 1 year and 75% at 5 years. These estimates are comparable to other studies that use a similar definition. A retrospective review of 169 men undergoing bulbar urethroplasty showed a success rate of 91% for anastomotic and 75% for graft/flap repairs approximately 5 years postoperatively.[11] Another group reported 98% success with anastomotic urethroplasty after 4 years of followup.[12] Similarly, others report 84%–95% success with a mean followup between 53 and 70 months.[13,14]

It is important to acknowledge that the "retreatment" definition of success may be biased for at least 3 reasons: 1) the threshold for repeat intervention differs by surgeon, 2) patient insurance and poor access may prevent retreatment even when needed, and 3) raw success rates without censoring do not readily account for patients who are lost to followup and may seek retreatment elsewhere. Thus, we were concerned that historical studies using this definition might overestimate success. However, we show that

Table 2. *Differences in 1-year estimated probability of success after urethroplasty according to different definitions of success and stricture characteristics*

	Estimated Probability of Success at 1-Yr Followup (95% CI)*							
Stricture Characteristic	Retreatment	p Value	Cystoscopy	p Value	Uroflow	p Value	Questionnaire	Overall p Value
L1 (length ≤2 cm)	0.96 (0.93, 0.98)	0.002	0.94 (0.91, 0.97)	<0.001	0.84 (0.80, 0.89)	0.7	0.67 (0.61, 0.73)	0.3
L2 (length 2–7 cm)	0.92 (0.89, 0.95)		0.85 (0.81, 0.89)		0.84 (0.81, 0.88)		0.68 (0.64, 0.73)	
L3 (length ≥7 cm)	0.93 (0.86, 1.00)		0.81 (0.70, 0.93)		0.76 (0.64, 0.89)		0.57 (0.45, 0.74)	
S1 (bulbar)	0.95 (0.93, 0.97)	0.023	0.90 (0.87, 0.92)	0.1	0.87 (0.84, 0.90)	<0.001	0.72 (0.69, 0.76)	<0.001
S2 (penile)	0.88 (0.82, 0.95)		0.85 (0.78, 0.93)		0.71 (0.63, 0.81)		0.47 (0.38, 0.58)	
S3 (panurethral)	NA (<10 at risk)		NA (<10 at risk)		NA (<10 at risk)		NA (<10 at risk)	
E1 (trauma)	0.95 (0.91, 0.99)	0.037	0.90 (0.85, 0.96)	0.019	0.86 (0.79, 0.92)	<0.001	0.72 (0.64, 0.80)	0.045
E2 (idiopathic)	0.93 (0.91, 0.96)		0.89 (0.86, 0.92)		0.86 (0.83, 0.90)		0.70 (0.66, 0.75)	
E3a (iatrogenic—internal trauma)	0.95 (0.91, 0.99)		0.87 (0.80, 0.93)		0.79 (0.71, 0.87)		0.59 (0.50, 0.69)	
E3c (iatrogenic—radiation injury)	1 (1.00, 1.00)		0.86 (0.70, 1.00)		NA (<10 at risk)		NA (<10 at risk)	
E4/E6 (infectious/inflammatory/LS)	0.78 (0.63, 0.97)		0.70 (0.53, 0.91)		0.69 (0.52, 0.91)		NA (<10 at risk)	

NA, not available.
* ANOVA test for significance.

the impact of censoring appears minimal—our success estimates with censoring are very similar to retrospective reports that did not censor.

Success by Cystoscopy

Our cystoscopic success of 88% at 1 year and 71% at 5 years is similar to other studies, though this is the first to publish 5-year cystoscopic success estimates. In 2014, the TURNS group reported their 1-year success rate of 1-stage bulbar urethroplasty using this cystoscopic definition of success. Of the 213 men, surgery was successful in 86% for anastomotic and 77% for substitution repairs.[15] Others reported a 90% cystoscopic success rate in 69 men with a mean followup of 34 months after bulbar urethroplasty.[16]

Cystoscopy is an excellent option for an objective, reproducible, research-based definition of success. Further, cystoscopy is not confounded by factors such as urine volume or enlarged prostate. However, cystoscopy may not be a good tool for measuring clinical (rather than research) success because it is costly and invasive. In addition, approximately 35%–42% of men with an anatomical recurrence on cystoscopy are asymptomatic; this potential to overestimate failures further limits its utility to measure clinical success.[15–17] Lastly, poor compliance hinders use for both clinical- and research-based definitions of success as only 50%–65% of men comply with cystoscopy in followup.[15,18]

Success by Uroflow Qmax > 15 ml/second

Our success estimates by uroflow were 84% at 1 year and 58% at 5 years. Uroflow is the most common test used to evaluate for stricture recurrence.[1] Uroflow can, however, be confounded by bladder dysfunction, urethral inflammation and bladder volume.[19,20] The threshold of 15 ml/second for Qmax was chosen because we have shown it to have an excellent balance between sensitivity (76%) and specificity (84%).[21]

Success by Questionnaire

Defining success based on any degree of weak stream resulted in the lowest success of 67% at 1 year and 37% at 5 years. Focusing on a patient-centered method to define success has been a prior topic of interest after urethroplasty. Kessler et al noted that even when the surgeon deemed the urethroplasty a failure, 80% of men were subjectively "satisfied" or "very satisfied."[22] On the other hand, some men can report weak stream not attributable to a recurrence on cystoscopy, as is suggested here by the finding that our 5-year success by questionnaire is lower than by cystoscopy.

LSE Stage

LSE stage has previously been correlated with outcomes.[9] So, the finding that "retreatment" correlates best with LSE stage is not a validation of "retreatment" as the optimum definition. Since the decision to proceed with retreatment is a subjective one, it is likely that this finding merely reflects the surgeon's preoperative assessment that the stricture in question is high risk (long and/or high-risk S) and has a high likelihood of needing retreatment.

Arriving at Research-Based Definition

This paper is not meant to dictate what the "research-based" definition of successful urethroplasty should be. Our goal is to provide a fair comparison of success in a single group of men using currently available definitions. As a group, urologists could choose one of these outcomes to be the universal, research-based definition going forward. Conversely, we could develop algorithms for a tiered followup approach (eg questionnaires, followed by cystoscopy for concerns).

Limitations

This study is limited by its retrospective design. Further, we do not control for surgeons or institution. However, we believe this increases the external validity of our findings since we included multiple surgeons utilizing multiple urethroplasty techniques. In addition, we used 3 different questionnaires over the course of the study, which could lead to imprecision in our outcome. Yet, we used 1 question assessing weak stream from each questionnaire, which limits influence on the results over time; still, we did not do any test to validate that these weak stream questions are comparable across PROMs. Our focus on weak stream means that we did not assess many other PROMs that patients may value. These can include pain and erectile or ejaculatory function.[23] However, since we were already testing multiple outcome measures, it was beyond the scope of this paper to also include alternative patient-reported outcomes. Further, the success estimates in this study are dependent on the cutoffs we used within each definition. While each of these cutoffs was evidence based, a change in the cutoff will impact the success estimate. Lastly, we did not include preoperative data for comparison. Therefore, we do not know if a low peak flow or weak stream is actually an improvement from the preoperative state. This may have overestimated the failures.

CONCLUSIONS

We found that the estimated probability of success after first-time, anterior urethroplasty is highly dependent on the way success is defined. The variability in definitions used across studies, as well as the lack of universal agreement on the important aspects of surveillance, has resulted in an inability to compare urethroplasty outcomes across studies. While a universally agreed upon definition of success is important, we must also consider the need for a research-based definition, ie one that is objective and reproducible to allow critical analysis of outcomes following urethroplasty.

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EDITORIAL COMMENT

The goal of curative open (urethroplasty) or endoscopic (dilation, urethrotomy) urethral stricture treatment is for the narrow area of the urethra to be widened indefinitely to the extent that bothersome symptoms are relieved and future organ damage is prevented.

The hypothesis is that defining success as "freedom from retreatment" will be associated with a higher success rate than when outcomes are reported using cystoscopic criteria, uroflow data or symptom assessment. Those who develop recurrences that are not treated are considered a success, an overestimation of the success rate. Conversely, if one defines success as absence of symptoms, one would expect success to be underestimated because the development of obstructive symptoms can be associated with etiologies other than stricture recurrence.

Although this paper suggests that the historical definition of urethroplasty success prior to the early 2000s has been "freedom from retreatment," papers that included patients undergoing urethroplasty dating back to the 1980s have used cystoscopy or urethrography between 3 and 12 months after surgery to define early and technical success.[1,2] I would not consider this a "research"-based definition, but rather a clinical definition, as it assesses the anatomical result once wound healing has occurred. With urethroscopy, which takes less than 20 seconds, narrow caliber recurrences can be detected long before the patient presents to the emergency room in retention. I think urethroscopy should be included as a standard for early outcome assessment.

The more difficult issue is how to assess long-term results. Late failures can happen with substitution urethroplasty in particular, and indefinite annual cystoscopy is not practical, as the authors point out. This manuscript nicely documents that

how one defines success can determine the success rate, and the importance of further research to develop criteria to best define long-term success. For that, the authors are to be congratulated.

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