Original Article

Assessment of Satisfaction and Quality of Life using Patient-reported Outcome Measures after Perineal Urethrostomy: A Prospective Analysis

Prabhat Kumar[1], Rohit Upadhyay[2], H Singh Kamalkant[1], Amit Kumar[1], Vijoy Kumar[3]

[1]MCh Urology Resident, Department of Urology, Indira Gandhi Institute of Medical Sciences, Patna, India, [2]Associate Professor, Department of Urology, Indira Gandhi Institute of Medical Sciences, Patna, India, [3]Professor and Head, Department of Urology, Indira Gandhi Institute of Medical Sciences, Patna, India

Abstract

Introduction: Conventionally, success after urethroplasty has focused on objective measures such as urinary flow rates, post-void residual (PVR) volumes, and appearance of the urethra on cystoscopy and/or retrograde urethrogram. The objective of this study was to prospectively analyze the pre- and post-operative patient-reported outcome measures describing patients' satisfaction and quality of life (QoL) after perineal urethrostomy and to compare these results with objective data.

Materials and Methods: We prospectively collected data from 30 consecutive patients who underwent perineal urethrostomy for complex anterior urethral stricture from April 2017 to January 2019. Patient demographics, International Prostate Symptom Score (IPSS), QoL score, urethral stricture surgery patient-reported outcome measure (USS-PROM), maximum flow rate, and PVR urine were collected before, and 2 and 8 months after surgery. General estimation equation was used to compare the results and linear regression analysis to correlate both questionnaires with objective data.

Results: Mean age was 63 years. All patients had undergone previous urethral surgery in the form of multiple DVIU, urethral dilatation, substitution, or augmentation urethroplasties. The mean USS-PROM score improved from 13.4 preoperatively to 3.10 after surgery ($P < 0.001$) and 85.6% of patients were satisfied or very satisfied with surgical results. Strong negative correlation was found, respectively, between flow rate and USS-PROM and with IPSS.

Conclusion: Significant improvements in urinary symptoms and in QoL are expected after perineal urethrostomy for complex anterior urethral stricture and they are correlated with objective measures.

Key words: Patient-reported outcome measures, Perineal urethrostomy, Stage urethroplasty, Urethral stricture

INTRODUCTION

Urethral stricture disease is one of the most challenging problems in urology which has great impact on quality of life (QoL) of the patients. The detrimental impact of this condition on the lives of affected men is due to worsening symptoms of lower urinary tract obstruction; recurrent urinary tract infection and urinary sepsis, acute urinary retention, and injury to the upper tract. There is a high rate of recurrence after treatment even in the best of centers and often requires repeated surgical intervention. The aim of any intervention in urethral stricture is to restore patient's normal pattern of voiding and to maintain a good QoL.[1] Urethroplasty with single-stage reconstruction is considered the gold standard for the management of urethral stricture disease which offers the best chance of the long-term cure.[2,3]

However, in the era of the single-stage repair, there are still some indications for staged urethroplasty. Strictures associated with local adverse conditions such as fistula, false passage, abscess, cancer, or a prior unsuccessful complex urethroplasty are best treated with staged procedures. Another group of patients difficult to treat is those with lichen sclerosus urethral disease or those who have undergone complicated failed hypospadias repair. Perineal

Corresponding Author: Dr. Prabhat Kumar, Quarter No. 22, New MDH, IGIMS Campus, Patna, India.

urethrostomy should be a temporary or definitive solution to a complex penile or bulbar urethral stricture. The definition of what constitutes a urethroplasty success varies widely in literature. The outcome measures used to assess success of urethroplasty are predominantly clinician-driven indicators of technical success (e.g., maximum flow rate, urethrography)[4,5] that is not always the true indicator of fundamental aims of the operation, which are to minimize symptoms, reduce disability, and improve health-related QoL (HRQoL) in men with the urethral stricture disease by restoring normal voiding pattern. Only patients can assess these outcomes.

PROMs are validated questionnaires completed by patients to measure their perceptions of their own functional status and well-being.[6] Little has been published using patient-perceived symptoms and QoL outcomes after perineal urethrostomy, although the recent development of a urethral stricture surgery-patient-reported outcome measure (USS-PROM) is gaining considerable importance in the evaluation of patients' perception of surgical success.[7-9] Purpose of this study was to prospectively analyze the pre- and post-operative patient-reported outcome measures describing patients' satisfaction and QoL after perineal urethrostomy and to compare these results with objective data.

PATIENTS AND METHODS

We prospectively collected data from 30 consecutive male patients older than 18 years who underwent perineal urethrostomy for complex anterior urethral stricture from April 2017 to January 2019. Patients lost to follow-up were excluded from analysis. Patient demographics, International Prostate Symptom Score (IPSS), QoL score, USS-PROM, maximum flow rate, and post-void residual (PVR) urine were collected before and 8 months after surgery. Pre-operative evaluation included history taking for demographic characteristics. Stricture etiology, location and extension of the stenosis, and previous treatments were collected. Retrograde and voiding cystourethrography were done preoperatively in all subjects to assess stricture length and site. The USS-PROM was developed in 2011 as the first questionnaire specifically designed for patients with urethral stricture disease. The USS-PROM incorporates lower urinary tract symptom (LUTS) and HRQoL domains, and a treatment satisfaction question. The LUTS domain is composed by a 6-item LUTS bother questions that generate a total score that varies from 0 (asymptomatic) to 24 (most symptomatic); by a separated LUTS-specific QoL question; and by the Peeling's voiding picture, an illustration of a man voiding scored between 1 (best) and 4 (worst). Peeling voiding score was not considered in this study as

patients could not void in standing position due to perineal urethrostomy. Satisfaction following perineal urethrostomy was assessed by asking men two questions, including: (1) "Were you satisfied with your surgical procedure?" With answers on a 5-point Likert scale (very satisfied, satisfied, neither satisfied or unsatisfied, and very unsatisfied) and (2) "If you could go back in time, would you still have agreed to undergo perineal urethrostomy surgery?" With answers of yes/no/maybe. Perineal urethrostomy was done as a part of staged urethroplasty repair for complex anterior urethral stricture. The perineostomy was made using standard flap urethroplasty [Figures 1 and 2]. The surgery was considered a failure when any post-operative instrumentation was needed. The follow-up scores of IPSS, QoL, USS-PROM, Q_{max}, and PVR were compared with pre-operative scores and among them. The results of the IPSS and USS-PROM were also correlated with Q_{max} using linear regression analysis. All statistical analyses were done using the SPSS 18.0 with two-sided significance considered at $P < 0.05$.

Figure 1: Stage urethroplasty with perineal urethrostomy

Figure 2: Perineal urethrostomy in case of extensive balanitis xerotica obliterans

RESULTS

A total of 30 consecutive patients were included in the study, of whom four were lost to follow-up and excluded from analysis. Baseline characteristics of the analyzed population are given in Table 1. Mean age was 63 years. Mean stricture length was 4.8 cm. Stricture was panurethral in 10 (38.46%) patients while penile and bulbar in eight and six patients, respectively. Most common etiology was balanitis xerotica obliterans in 11 (42.3%) patients followed by idiopathic in eight patients. 12 (46.1%) patients had SPC at the time of surgery. All patients had undergone previous urethral surgery in the form of multiple DVIU, urethral dilatation, and substitution or augmentation urethroplasties. Overall success rate was 84.61%. Two patients developed stenosis of their perineostomy and had to undergo revision surgery. Two patients developed recurrence of stricture, of which one was managed by DVIU and another one was managed by intermittent self-calibration. Baseline to 8 months post-operative differences of various parameters are explained in Table 2. The mean 6-item LUTS score of the USS-PROM questionnaire was 13.40 at baseline and 3.1 at 8 months after perineal urethrostomy ($P < 0.001$). Mean pre-operative IPSS score was 24 and significantly decreased to 4.5 at 8 months visit, respectively ($P < 0.001$). The mean LUTS-specific QoL score was 4.7 at the pre-operative evaluation and dropped to 1.17 at the 8-month follow-up ($P < 0.001$). The mean Q_{max} increased from 4.64 ml/s to 12.5 ml/s after the procedure ($P < 0.001$). The mean PVR decreased from 79.25 ml to 20.4 ml at 8 months of follow-

up as compared with pre-operative values ($P < 0.001$). There was a strong negative correlation between USS-PROM and Q_{max} between pre-operative and post-operative values when subjected to linear regression analysis ($r = -0.581$, $P < 0.001$). Overall, 22 of 26 men (84.61%) of the patients were either "satisfied" or "very satisfied" with the results of their perineal urethrostomy at 8 months of follow-up. 2 patients (7.6%) who were dissatisfied had developed stenosis of perineal urethrostomy and had to undergo revision surgery. The other unsatisfied patient was a young man due to his perineal ejaculation and constant pelvic discomfort. On the question "If you could go back in time, would you still have agreed to undergo perineal urethrostomy surgery?," 21 of 26 (80.76%) patients answered in affirmative. On the question "Would you like to undergo second-stage urethroplasty to restore normal anatomy?," 20 of 26 (76.92%) patients chose to continue with perineal urethrostomy.

DISCUSSION

This study presents clinical and patient-reported outcome measures after perineal urethrostomy as a part of staged urethroplasty procedure for complex anterior urethral stricture using USS-PROM and satisfaction analysis questionnaire. Overall success rate was 84.61% which is very high as compared to that reported by Barbagli *et al.* (70%)[10] but inferior to that reported by Fuchs JS (94.8%).[11] In this study, there was continuous improvement in IPSS, QoL, and USS-PROM scores 8 months after perineostomy. In this study, 84.61% of patients were satisfied or very satisfied with surgical results which are somewhat inferior to that reported by Barbagli *et al.* (97%).[10] This study demonstrated a high percent of post-operative satisfaction with a large majority of men (80.76%) reporting that they would have undergone the operation again. We also observed a strong association of patient satisfaction with surgical success as determined

Table 1: Baseline characteristics of analyzed population

Parameters	n (%)
Mean age (years)	63 (21–82)
Mean stricture length (cm)	4.8 (2–14)
Site of stricture	
Panurethral	10 (38.46)
Penile	8 (30.76)
Bulbar	6 (23.07)
Penobulbar	2 (7.69)
Etiology	
BXO	11 (42.3)
Idiopathic	8 (30.76)
Trauma	2 (7.69)
Infection	2 (7.69)
Catheter induced	2 (7.69)
Previous hypospadias surgery	1 (3.84)
Previous interventions	
Multiple DVIU	12 (46.15)
BMGU	2 (7.69)
Multiple procedures	7 (26.92)
Anastomotic urethroplasty	2 (7.69)
Failed hypospadias repair	1 (3.84)
Preputial skin flap urethroplasty	2 (7.69)
SPC *in situ*	12 (46.1)

Table 2: Baseline to 8-month post-operative differences

Parameters	Baseline mean	8-month mean	Mean difference	P value
USS-PROM	13.4 (10.4–16.4)	3.1 (4.1–2.1)	−10.3	<0.001
IPSS	24 (33.5–13.5)	4.5 (3.5–5.5)	−19.5	<0.001
QoL	4.7 (4.05–5.37)	1.17 (0.71–1.85)	−3.53	<0.001
Q_{max} (ml/sec)	4.64 (3.59–5.7)	12.5 (16.75–8.25)	7.86	<0.001
PVR (ml)	79.25 (39.25–119.25)	20.4 (10.2–30.6)	−58.85	<0.001

QoL: Quality of life, USS-PROM: Urethral stricture surgery-patient-reported outcome measure

by traditional measures such as improvement in uroflow (Q_{max}), IPSS, and urethrogram. We also found that men with post-operative sexual complaints, new or persistent urinary pain/dysuria, discomfort due to perineal ejaculation and pelvic pain, men reporting poor urinary QoL reported dissatisfaction for their surgical procedure. There is also a concern of negative body image in patients undergoing perineal urethrostomy and inability to void in standing position, leading to dissatisfaction for the procedure, but in this study, we found that majority of men (76.92%) chose not to go for formal reconstruction of their urethra as the second-stage surgery. This is similar to that reported by Peterson *et al.* (73% of the patients refused to undergo second-stage surgery) and Peterson *et al.* (69% of the patients chose to continue with their perineostomy).[12] This shows that patients with complex anterior urethral strictures have already undergone various interventions and unobstructed voiding is their primary concern while consenting for perineal urethrostomy rather than body image or problems of perineal ejaculation.

In addition to symptoms questionnaires, we used uroflowmetry and PVR to evaluate surgical outcomes and also demonstrated significant improvements after perineal urethrostomy. Many investigators have used uroflowmetry to determine the success of urethroplasty but usually do not correlate it with subjective findings.[13,14] In this study, the mean Q_{max} improved from 4.64 mL/s preoperatively to 12.5 mL/s 8 months after surgery. These improvements in Q_{max} were more modest when compared with those reported in other series.[13,15] Maybe this occurred due to older patients (mean age of 63 years); men may have a component of benign prostatic hyperplasia or have a long-standing urethral obstruction due to complex urethral stricture, leading to detrusor dysfunction. Similarly, in his series, DeLong *et al.* found a median improvement in Q_{max} of 12 mL/s after surgery, but when splitting the cohort by age, patients with <45 years experienced an improvement of 16 mL/s versus 8 mL/s achieved in those older than 45 years.[16] Both studies highlight that setting a Q_{max} cutoff at which all men should be evaluated for stricture recurrence is fallacious rather we should use patient's individual pre-operative and post-operative data to arrive at any conclusion.

Monitoring patient symptoms should be an important part in any surveillance protocol for stricture recurrence. IPSS is the most frequently used questionnaire in the evaluation of urethroplasty outcomes.[17] It was first used by Morey *et al.* who demonstrated significant improvements in IPSS after successful reconstruction and a strong negative relationship between the IPSS and Q_{max}.[18] Jackson *et al.*, in 2011, developed and validated a USS-PROM as an attempt to standardize patient-centered evaluations of interventions

for urethral strictures.[19] The USS-PROM was also recently validated to Italian and German.[20,21]

Our study is perhaps the first one to report prospectively the results of USS-PROM for patients undergoing perineal urethrostomy for complex anterior urethral stricture, and hence, no direct comparison is possible. In our study, the mean 6-item LUTS score of the USS-PROM questionnaire was 13.40 at baseline and 3.1 at 8 months after perineal urethrostomy ($P < 0.001$). Moreover, there was a strong negative correlation between USS-PROM and Q_{max} between pre-operative and post-operative values when subjected to linear regression analysis ($r = -0.581$, $P < 0.001$). Our study confirms that traditional measures of success correlate strongly with patient satisfaction. Uroflowmetry findings were also significantly worse in men who were dissatisfied with lower maximum flow rates and importantly, less improvement in flow rates from pre-operative values.

To date, the best strategy to evaluate stricture recurrence is not clear. Instead, there are many different protocols varying from invasive testing such as urethral calibration, cystoscopy, and retrograde and voiding cystourethrography to non-invasive such as symptoms questionnaire and uroflowmetry employed in surveillance after urethroplasty. Due to inhomogeneity in surveillance protocols, comparison across different study is not possible. One important limitation of this study is use of USS-PROM for perineal urethrostomy which is actually designed for formal urethral reconstruction. Moreover, small sample size and short-term follow-up period are other limitations.

CONCLUSION

Perineal urethrostomy is a good and sometimes necessary option when dealing with complex anterior urethral stricture, particularly in patients with multiple comorbidities. QoL after this procedure is not negatively affected and patients are usually satisfied with their treatment.

REFERENCES

1. Voelzke BB. Critical review of existing patient reported outcome measures after male anterior urethroplasty. J Urol 2013;189:182-8.
2. Barbagli G, Kulkarni SB, Fossati N, Larcher A, Sansalone S, Guazzoni G, *et al.* Long-term followup and deterioration rate of anterior substitution urethroplasty. J Urol 2014;192:808-13.
3. Andrich DE, Dunglison N, Greenwell TJ, Mundy AR. The long-term results of urethroplasty. J Urol 2003;170:90-2.
4. Wong SS, Aboumarzouk OM, Narahari R, O'Riordan A, Pickard R. Simple urethral dilatation, endoscopic urethrotomy, and urethroplasty for urethral structure disease in adult men. Cochrane Database Syst Rev 2012;12:CD006934.
5. Black N. Patient reported outcome measures could help transform healthcare. BMJ 2013;346:167.
6. Dawson J, Doll H, Fitzpatrick R, Jenkinson C, Carr AJ. The routine

use of patient reported outcome measures in healthcare settings. BMJ 2010;340:186.

7. Jackson MJ, Chaudhury I, Mangera A, Brett A, Watkin N, Chapple CR, *et al*. A prospective patient-centred evaluation of urethroplasty for anterior urethral stricture using a validated patient-reported outcome measure. Eur Urol 2013;64:777-82.

8. Erickson BA, Breyer BN, McAninch JW. The use of uroflowmetry to diagnose recurrent stricture after urethral reconstructive surgery. J Urol 2010;184:1386-90.

9. Kessler TM, Fisch M, Heitz M, Olianas R, Schreiter F. Patient satisfaction with the outcome of surgery for urethral stricture. J Urol 2002;167:2507-11.

10. Barbagli G, De Angelis M, Romano G, Lazzeri M. Clinical outcome and quality of life assessment in patients treated with perineal urethrostomy for anterior urethral stricture disease. J Urol 2009;182:548-7.

11. Fuchs JS, Shakir N, McKibben MJ, Scott JM, Viers B, Pagliara T, *et al*. Changing trends in reconstruction of complex anterior urethral strictures: From skin flap to perineal urethrostomy. Urology 2018;122:169-73.

12. Peterson AC, Palminteri E, Lazzeri M, Guanzoni G, Barbagli G, Webster GD, *et al*. Heroic measures may not always be justified in extensive urethral stricture due to lichen sclerosus (balanitis xerotica obliterans). Urology 2004;64:565-8.

13. Erickson BA, Breyer BN, McAninch JW. Changes in uroflowmetry maximum flow rates after urethral reconstructive surgery as a means to predict for stricture recurrence. J Urol 2011;186:1934-7.

14. Heyns CF, Marais DC. Prospective evaluation of the American urological association symptom index and peak urinary flow rate for the followup of men with known urethral stricture disease. J Urol 2002;168:2051-4.

15. Lumen N, Spiers S, De Backer S, Pieters R, Oosterlinck W. Assessment of the short-term functional outcome after urethroplasty: A prospective analysis. Int Braz J Urol 2011;37:712-8.

16. DeLong J, Buckley J. Patient-reported outcomes combined with objective data to evaluate outcomes after urethral reconstruction. Urology 2013;81:432-6.

17. Yeung LL, Brandes SB. Urethroplasty practice and surveillance patterns: A survey of reconstructive urologists. Urology 2013;82:471-5.

18. Morey AF, McAninch JW, Duckett CP, Rogers RS. American urological association symptom index in the assessment of urethroplasty outcomes. J Urol 1998;159:1192-4.

19. Jackson MJ, Sciberras J, Mangera A, Brett A, Watkin N, N'dow JM, *et al*. Defining a patient-reported outcome measure for urethral stricture surgery. Eur Urol 2011;60:60-8.

20. Barbagli G, Romano G, Sansalone S, Lazzeri M. Italian validation of the English PROM-USS-Q questionnaire in patients undergoing anterior urethroplasty. Urologia 2011;78:98-107.

21. Kluth LA, Dahlem R, Becker A, Schmid M, Soave A, Rosenbaum C, *et al*. Psychometric validation of a German language version of a PROM for urethral stricture surgery and preliminary testing of supplementary ED and UI constructs. World J Urol 2016;34:369-75.