Title

PD14-07 PHASE I DEVELOPMENT OF A PATIENT REPORTED OUTCOME MEASURE FOR MALE URETHRAL STRICTURE DISEASE

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IPSS/UF assessment per study protocol. ROC curves were generated to identify IPSS questions and UF parameters that most strongly correlated with cystoscopic recurrence. Preliminary analysis led us to create a single hybrid PROM value that combined the patient's quality of life (QOL) score and their score on question #5 (weak stream) of the IPSS (Q5_QOL). This single value (range 0 to 10), was analyzed along with the two UF parameters that most accurately predicted recurrence – max flow rate (Qm) and the value obtained by subtracting the average flow rate (Qa) from the Qm (Qm-Qa). Contingency tables were then created (a positive test for cystoscopic recurrence was defined as having a UF parameter <= to a set value or a Q5_QOL score >= to a set value) and the specific protocol found to have the highest sensitivity/specificity was validated using this cohort's pre-operative IPSS and UF data.

RESULTS: The IPSS/UF parameters with the highest sensitivity (92%) and specificity (63%) were an Qm-Qa of 7 mL/sec or less combined with a Q5_QOL score of 4 or greater. Had this protocol been utilized in our study population, only 8% of all recurrences would have been missed and 57% of the men could have avoided unnecessary cystoscopy. Importantly, only 1% of men with Qm-Qa values > 7 and a Q5_QOL of < 4 were later found to have a recurrence (negative predictive value). This protocol was validated in the same cohort with 84 men who had pre-operative data available and demonstrated a 97.62% sensitivity in detecting a stricture.

CONCLUSIONS: The combined use of UF and select PROM questions showed acceptable sensitivity and specificity as compared to cystoscopy when being utilized to screen for stricture recurrence. Validation in a unique dataset revealed a test sensitivity well above 90%. Further refinement of PROM and UF parameters that can better account for patient specific factors such as age, bladder function and the degree of obstruction from the prostate will continue to improve our ability to diagnose recurrence without the need for routine cystoscopy.

Source of Funding: none

PD14-07

PHASE I DEVELOPMENT OF A PATIENT REPORTED OUTCOME MEASURE FOR MALE URETHRAL STRICTURE DISEASE

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INTRODUCTION AND OBJECTIVES: Patient reported outcome measures (PROMs) are important for assessing aspects of urethral stricture disease that are known only to the patient. PROM-based results are tied increasingly to health care funding and management. The availability of comprehensive, valid and reliable PROMs for urethral stricture is important. Our objective is to develop a urethral stricture-specific PROM to be used for assessing treatments for urethral stricture. Here we describe a Phase I study to elicit vital content related to men with a urethral stricture.

METHODS: We performed concept elicitation interviews with men with urethral strictures in the pre- and post-op setting. Qualitative interviews were stopped after concept saturation was reliably noted (n=16). Interviewees included 12 men with bulbar and 4 men with penile strictures. Median age was 51 (range 29-70). The cohort included Caucasian (13), Hispanic (1), African-American (1), and Asian (1) men. The interviews were audio-recorded and transcribed. Specific content regarding impaired urinary/sexual function and quality of life were excerpted and coded by investigators using a qualitative analysis program. We organized the content into domains by consensus. Existing PROMs with content relevant for urinary and sexual function were reviewed to incorporate legacy items.

RESULTS: We identified 35 potential items (13 legacy and 22 new) for possible PROM inclusion. Most content pertained to urinary impact (n=15), function (n=7) and symptoms (n=6). Seven items were related to sexual impact (n=4), symptoms (n=2) and function (n=1). Urinary content included emotional impact of urethral stricture including worry (n=4), embarrassment (n=2), and depression (n=1), as well as those related to changing daily activities to manage stricture symptoms (n=4) including "I quit doing things I like to do" and "I had to plan everything ahead." Urinary function content included obstruction (n=4) and trouble aiming the stream (n=1). Urinary symptom content related to pain (n=3), nocturia (n=1) and urgency (n=1). Of the items related to sexual activity (n=7), most related to ejaculation (n=5), both weak (n=2) and unsatisfying (n=1), while pain was also elicited (n=2).

CONCLUSIONS: Using qualitative inductive methodology, we have obtained patient-centered data suitable for a comprehensive urethral stricture-specific PROM. Future studies will include cognitive interviews of the draft instrument and multi-center field testing to assess the instrument's measurement properties, including its sensitivity to detect change following treatment.

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PD14-08

SEXUAL FUNCTIONAL OUTCOMES WITH DORSAL VS. VENTRAL SUBSTITUTION BULBAR URETHROPLASTY

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INTRODUCTION AND OBJECTIVES: Sexual dysfunction after substitution bulbar urethroplasty may include erectile dysfunction (ED) and ejaculatory dysfunction (EjD). Proposed mechanisms include neural injury and bulbospongiosus myopathy. We sought to describe the incidence of ED and EjD with substitution bulbar urethroplasty and compare incidence between the ventral vs. dorsal approach. We hypothesize that the SD incidence will be lower with ventral substitution as it requires less dissection.

METHODS: Data on all patients who underwent a dorsal or ventral buccal onlay urethroplasty for a bulbar urethral stricture from 2009-2014 were retrospectively reviewed from six centers in the Trauma and Urologic Reconstruction Network of Surgeons (TURNS). The pre-operative scores were compared to the post-operative scores for the Sexual Health Inventory for Men (SHIM, for ED) and Male Sexual Health Questionnaire (MSHQ, for EjD).

RESULTS: A total of 194 men underwent buccal graft onlay urethroplasty: 120 (61.9%) ventral and 74 (39.1%) dorsal. Of the 194 men patients, 112 patients had pre-op questionnaires, 137 patients had 6-month post-op questionnaires and 99 had questionnaires at 12 months post-op. Clinical characteristics were similar between both groups when comparing stricture etiology, stricture location within the bulb, smoking, diabetes, coronary artery disease and previous urethroplasty (all $p>0.05$). The dorsal group had longer strictures than the ventral group: 4.5 cm vs. 4.0 cm, respectively ($p=0.02$). Pre-op MSHQ was 14.0 in both the dorsal and ventral groups ($p>0.05$). Pre-op SHIM was 22.5 in the ventral group vs. 24.0 in the dorsal group ($p>0.05$). There was no significant change in SHIM or MSHQ scores in either group post-operatively ($p>0.05$). Furthermore, the difference in differences was not significant. Individual items in each questionnaire were also examined and showed no change after surgery when examined at the group level.

CONCLUSIONS: Validated patient reported outcome measures do not detect an effect on either erectile or ejaculatory function with substitution bulbar urethroplasty. Further, there is no difference between ventral vs. dorsal approach. Individual patient experiences will vary with some having improved function and others impaired function; but, on average, there is no effect.

Comparison of Median pre-op and post-op MSHQ and SHIM Scores for Dorsal vs. Ventral Substitution Urethroplasty

	Dorsal	Ventral
SHIM pre-op	24	23
SHIM 3 mo post-op	23	22
SHIM 12 mo post-op	23	23
MSHQ pre-op	14	14
MSHQ 3 mo post-op	18	17
MSHQ 12 mo post-op	17	16

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