Podium Session 5: Functional Urology (Incontinence/Neurology/ LUTS/Men's Health) July 1, 2014, 1015-1145

POD-05.01

2014 PRIZE ESSAY WINNER

Stemming the Tide of Mild to Moderate Post-prostatectomy Incontinence: A Retrospective Comparison of Transobturator Male Slings and the Artificial Urinary Sphincter

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Introduction: The AUS remains the gold standard of treatment for post-prostatectomy incontinence (PPI), although most patients with mild-moderate PPI prefer a sling without strong evidence of procedural equivalence. This study compares outcomes of two procedures for the treatment of mild-moderate PPI.

Methods: A retrospective review of 124 patients (76 transobturator sling, 48 AUS) with mild-moderate PPI requiring intervention over an 8-year period. Primary outcomes included continence and change in number of incontinence pads. Secondary outcomes included global patient satisfaction, improvement, and complication rates. Mild to moderate incontinence was defined as requiring ≤5 incontinence pads/day.

Results: There was no significant difference in age (66.2 vs. 68.1 years; p=0.17) or prostate cancer characteristics for slings and AUS respectively. Patients receiving an AUS had higher Charlson comorbidity scores (3.1 versus 3.9; p=0.0007) and were more likely to have previous radiotherapy (3.9 vs. 14.6%; p=0.045). Median length of follow-up was 7 months for the slings and 11 months for the AUS group. There was no difference in overall continence rates, 88.2% versus 87.5% (p=0.79), rate of improvement, 94.7% vs. 95.8% (p=1.00), or patient satisfaction, 93.4% versus 91.7% (p=0.73), for slings and AUS, respectively. Complication rates were equivalent (19.7% vs. 16.7%; p=1.00), though there was a significantly higher proportion of Clavien Grade 3 complications with AUS (0% versus 75%; p=0.006), including device infection, or erosion. Transient urinary retention postoperatively was significantly higher with slings at 18.7% versus 5.7% (p=0.011).

Conclusions: For mild to moderate PPI there is no difference with respect to continence, satisfaction, or improvement rates, between AUS and slings. Complications arising with AUS tend to be more severe and require operative intervention more frequently. Our study supports the use of male slings as first line treatment for mild-moderate PPI.

POD-05.02

The Validity and Reliability of the Neurogenic Bladder Symptom Score (NBSS)

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Objectives: The neurogenic bladder symptom score (NBSS) is a tool to measure urinary symptoms and consequences among patients with acquired or congenital neurogenic bladder. This paper describes the validity and reliability of the NBSS.

Methods: Exploratory factor analysis was used to assess item variability and subscale structure. Reliability was assessed with Cronbach's alpha, and correlation with retest data. Validity was assessed with a priori hypotheses specifying relationships with the AUA-SS, ICIQ-UI, and urinary-specific QOL (SF-Qualiveen) and a self-assessed global bladder problem score. Known groups analysis was used to further assess construct validity.

Results: A cohort of 230 patients with spinal cord injury, (35%), multiple sclerosis (59%), and congenital neurogenic bladder (6%) were included in this study. Factor analysis suggested 3 domains within the NBSS (incontinence, storage and voiding symptoms, and consequences). Overall internal consistency was high, with a Cronbach's alpha of 0.89. Test-rest reliability was also excellent, with an intraclass correlation coefficient of 0.91. Validity was demonstrated with the confirmation of hypothesized correlations with the AUA-SS, ICIQ-UI, and SF-Qualiveen, and significant differences in NBSS scores among known groups (those with a history of seeing a urologist had a significantly higher mean score (22.1 vs. 17.1, p<0.001), as did those who had a higher global bladder problem score (22.1 vs. 12.6, p<0.001).

Conclusions: The NBSS, developed specifically to assess the symptoms and consequences associated with neurogenic bladder dysfunction, has appropriate psychometric properties. Depending on the measurement need, individual domains may be selected, or it can be used as a comprehensive score.

POD-05.03

Urological Issues in an Adult Spina Bifida (SB) Population: What Is the Ideal Follow-up Interval?

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Introduction and Objectives: The International Children's Continence Society (ICCS) recommends follow-up every 3 years for adult SB patients, however little data exist on the topic. Our goal was to investigate the ideal follow-up interval for these patients based on the development of urological issues (UI) over time.

Methods: Retrospective review of records from a multidisciplinary adult SB clinic in a tertiary centre. Patient age, sex, voiding pattern (CIC or not), number of clinic visits and length of follow-up were recorded. For each unique visit, presence of symptoms, type of UI (if any) requiring intervention, and time lapsed since last appointment were obtained. The interval between the development of UI was assessed using a time-to-event analysis.

Results: Data on 123 patients (46%M, 54%F) and 586 unique clinic visits were collected. Median age, length of follow-up and number of clinic visits were 26.8 years (range 18-67), 48 months (0-321) and 4 visits (1-20), respectively. UI were identified in 267 visits (46%) and of those 21% were asymptomatic (p<0.0001). The most common UI were incontinence (29%), urinary tract infection (25%), and stones (19%). In symptomatic patients, the median time to present with a urological issue was 12 months and 83% had become symptomatic by 2 years of f/u. Among the asymptomatic cases, 12, 23 and 40% had developed UI at 12, 24 and 36 months of f/u, respectively. The only variable significantly associated with the development of UI on Cox proportional hazards analysis was the presence of symptoms (hazard ratio 6.8; p<0.0001; age, sex and voiding pattern not significant).

Conclusions: Most adult SB patients (>80%) with UI are symptomatic by 2 years of follow-up, however over time the proportion of asymptomatic patients with UI rises steadily reaching a worrisome 40% at 3 years. Hence, the 3-year follow-up interval suggested by ICCS seems long and may pose risks. Based on our data, it may be prudent to recommend shortening the follow-up interval to every 12 to 18 months.

POD-05.04

A Search for Microorganisms in Patients with Urologic Chronic Pelvic Pain Syndromes (UCPPS): A Culture Independent Analysis of Cases and Controls in the NIH MAPP EP Study

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Introduction: We used novel state-of-the-art culture-independent methodology to compare the microbiota of the lower urinary tract in subjects with UCPPS and controls enrolled in the NIH MAPP study.

Methods: VB1, VB2 and VB3 (in males only) urine specimens were collected from UCPPS subjects and asymptomatic controls. Specimens were analyzed with Ibis T-5000 Universal Biosensor system technology which employs a polymerase chain reaction-electron spray ionization-time-of-flight-mass spectoscopic-based technology to provide comprehensive identification of all bacterial species.

Results: Up to 97 species and 42 genera were identified from 417 male (191 cases; 226 controls) and 363 female subjects (181 cases; 182 controls). In males, overall species and genus composition significantly differed between patients and controls in VB1 only (p=0.008 species level, p=0.011 genus level), while no significant differences were observed at any level in VB2 or VB3. In female subjects, overall species composition did not significantly differ between patients and controls at any level (p=0.571, 0.726 species level, p=0.865, 0.222 genus level in VB1 and VB2, respectively), however several species (E. coli, Lactobacillus gasseri) and genus (Corynebacterium) were over/underrepresented in VB1 samples comparing cases vs. controls Overall species composition did not significantly differ between flare (n=83) and non-flare (n=127) patients at any level (p=0.14, 0.69 species level, p=0.94, 0.83 genus level, in VB1 and VB2, respectively) However, when adjusted for antibiotic use and menstrual phase, women who reported a flare remained more likely to have fungi present in VB2 specimens than women who did not report a flare (OR= 8.3, CI=[1.7-39.4]).

Conclusions: While we were not able to implicate the lower urinary tract microbiota in etiology or maintenance of urologic CPPS symptoms, changes in microbiome may be involved in symptom patterns of some patients with IC/BPS and CP/CPPS.

POD-05.05

Lessons Learned from the Prospective Evaluation of Penile Traction Physiotherapy Device Utilization in 100 Consecutive Men with Peyronie's Disease

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Introduction and Objectives: Despite limitations to evidence, traction therapy (TT) for Peyronie's disease (PD) is expanding. Publications suggest TT in conjunction with intralesional (IL) and oral therapies or post-PD surgery. TT remains heterogenous, given the myriad of devices available and absence of defining trials for type, frequency, duration, traction force, etc. Mulhall's group TT data shows 20% use in the first month with poor use afterwards. We report a large prospective series and the practice changing lessons learned.

Methods: From January 2013 to March 2013, 100 men initiated TT. All underwent standardized TT teaching by a single urosurgeon; follow-up at 1-month with the TT device applied by the patient as at-home. 42 patients qualified for and completed the IL program (hospital-based/sponsored, 168 pts per year, 12 IL injections over 12 weeks) through mid-10/13 with in-clinic evaluation q2 weeks. 55/58 non-IL patients were seen in follow-up with TT device at about 6 months.

Results: All patients were seen at 4 weeks, with 28/100 men using TT optimally. The most common deficit was lack of sufficient traction; seeing the penis stretched with their own device reinforced technique. Self-scoring utilized (1-4 strap holder, spacers showing 1-6, based on www.mens-progress.com device, but modifiable to most TT). Email updates encouraged if not in IL program (used by 34/58). IL patients had q2 week TT review. Adequate traction was maintained in 42/42 at end of IL, and 37/58 at non-IL 6 month follow-up. Three academic institutions utilizing same TT device reviewed this data set, instituting general and site-specific optimizations.

Conclusions: Findings are applicable to all TT patients, regardless of device type. Given cost and time considerations, in-person device optimization may be considered standard operating procedure. Self-scored measurements provide objective patient feedback between urosurgeon assessments while electronic updates may serve as a secondary motivator.

POD-05.06

Does Patient Age at Presentation of Peyronie's Disease Influence Treatment Satisfaction?

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Introduction: Peyronie's disease (PD) occurs in men younger than 40, with up to 10% of men with PD presenting in this age range, including teenagers; outcomes data are limited in this group. We present the impact of age at PD presentation upon patient satisfaction for PD management.

Methods: From 09/11 through 09/12, an academic single-institution 312 patient consecutive cohort with PD was followed through 09/13 at minimum. Patients were stratified according to decade of age at presentation, and baseline characteristics, imaging, treatments, IIEF-5 and PD specific outcomes, and IPSS data were retrospectively reviewed.

Results: 289 of 312 patients comprise the study group, having been treated medically, surgically, or both, and completing a minimum of 1-year follow-up. 23/24 patients who were 29 years of age or younger (acquired disease without history of congenital penile curvature) completed follow-up. Psychosocial burden was increased, and PD treatment satisfaction and outcome measures decreased in men less than 29 years of age compared to all other groups.

Conclusions: Patient reported treatment satisfaction for PD is multifactorial in nature and includes disease severity, treatments available and/or utilized, and patient perceptions and expectations. In our series, treatment satisfaction in a large group of younger men was markedly decreased. These data serves to reinforce that younger men may comprise a unique subset of PD patients biologically, as previously published, but also psychosocially, with expectations often of a return to 'complete normalcy' regardless of urosurgeon counseling.

POD-05.07

Observations, Outcomes and Complications of Urethroplasty for Bublomembranous Stenosis after Radiation Treatment for Prostate Cancer

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Introduction and Objectives: Urethral stenosis is an under-reported complication of radiotherapy for prostate cancer. The objective of this study is to report outcomes of urethral reconstruction for radiation induced bulbomembranous urethral stenosis.

Methods: A retrospective review of 735 urethroplasties performed by a single surgeon identified 35 patients requiring reconstruction for radiation induced bulbomembranous stenosis. Primary outcome was urethral patency (cystoscopy) and secondary outcomes were 90-day complications, de-novo incontinence, erectile dysfunction and LUTS. Outcomes were compared using Fisher's exact test.

Results: Of the 35 patients, 20 and 15 had stenosis related to external beam radiation therapy (EBRT) or brachytherapy (BT) respectively. Mean stricture length was 3.5 cm with 40.7 months of follow-up. Many (42.9%) patients presented with "permanent" suprapubic catheters and 45.7% reported preoperative erectile dysfunction. Reconstruction was performed by excision and primary anastomosis (epa) in 23 patients (65.7%) while 12 required tissue transfers with either buccal mucosa graft (20.0%) or penile island flap (14.3%). Thirty patients (85.7%) achieved cystoscopic patency with no difference between techniques (p=0.317). A 90-day complication rate of 28.2% was observed (Clavien 1-2) with no difference

between techniques (p=1.000). Adverse change in continence occurred in 25.7% of patients but was 13.3% when excluding those who had previous TURP. Postoperatively 40% of patients described persisting storage LUTS and 23.3% described adverse change in erectile function (exclusively with epa).

Conclusions: Reconstruction of radiation induced bulbomembranous strictures yields satisfying patency rates. However radiation induced urethral stenosis is not an isolated problem as many patients may have detrusor dysfunction, erectile dysfunction or incontinence as a consequence of treatment either before or after urethroplasty.

POD-05.08

Cardiovascular Safety of Combination Therapy with Mirabegron and Solifenacin in Patients with Overactive Bladder in a Randomised, Double-blind, Dose-ranging, Phase II Study (Symphony)

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Table 1. POD-05.08. Patient demographics (Full Analysis Set [FAS]) and change from Baseline to End of Treatment in blood pressure, pulse rate, and QTcF interval (Safety Analysis Set [SAS])

	PBO	MIRA 25 mg	MIRA 50 mg	SOLI 2.5 mg	SOLI 5 mg	SOLI 10 mg	SOLI 2.5 mg + MIRA 25 mg	SOLI 2.5 mg + MIRA 50 mg	SOLI 5 mg + MIRA 25 mg	SOLI 5 mg + MIRA 50 mg	SOLI 10 mg + MIRA 25 mg	SOLI 10 mg + MIRA 50 g
FAS population	***N=80***	***N=76***	***N=77***	***N=77***	***N=150***	***N=76***	***N=146***	***N=147***	***N=141***	***N=150***	***N=78***	***N=80***
Mean age, years (SD)	54.7 (13.4)	55.0 (14.5)	53.6 (14.0)	56.3 (11.6)	54.1 (15.5)	55.0 (12.8)	56.0 (14.0)	53.8 (14.6)	55.2 (14.5)	54.0 (14.2)	56.6 (12.5)	55.3 (13.8)
Female, n (%)	53 (66.3)	50 (65.8)	51 (66.2)	51 (66.2)	100 (66.7)	52 (68.4)	100 (68.5)	98 (66.7)	92 (65.2)	100 (66.7)	51 (65.4)	53 (66.6)
SAS population	***N=81***	***N=78***	***N=78***	***N=79***	***N=156***	***N=78***	***N=149***	***N=149***	***N=144***	***N=152***	***N=81***	***N=81***
Baseline hypertension†, n (%)	0	0	1 (1.3)	0	0	1 (1.3)	0	1 (0.7)	0	2 (1.3)	1 (1.2)	0
Patients using antihypertensives‡, n (%)	2 (2.5)	3 (3.8)	4 (5.1)	3 (3.8)	5 (3.2)	2 (2.6)	6 (4.0)	3 (2.0)	7 (4.9)	3 (2.0)	1 (1.2)	5 (6.2)
Pulse rate (bpm)*												
Mean change from baseline (SE) [95% CI]	0.1 (0.9) [-1.6, 1.8]	-0.2 (0.9) [-1.9, 1.5]	1.0 (0.9) [-0.7, 2.7]	0.1 (0.9) [-1.6, 1.8]	0.1 (0.6) [-1.1, 1.3]	0.9 (0.9) [-0.9, 2.6]	0.7 (0.6) [-0.5, 1.9]	1.1 (0.6) [-0.1, 2.3]	1.5 (0.6) [0.3, 2.8]	0.6 (0.6) [-0.7, 1.8]	0.6 (0.9) [-1.1, 2.2]	1.3 (0.9) [-0.3, 3.0]
Systolic BP (mmHg)*												
Mean change from baseline (SE) [95% CI]	-2.6 (1.1) [-4.8, -0.5]	-0.2 (1.1) [-2.4, 2.0]	0.7 (1.1) [-1.5, 2.8]	-2.0 (1.1) [-4.2, 0.2]	-1.7 (0.8) [-3.3, -0.1]	-2.7 (1.1) [-4.9, -0.5]	-1.3 (0.8) [-2.9, 0.2]	-0.6 (0.8) [-2.2, 1.0]	-0.7 (0.8) [-2.4, 0.9]	-2.1 (0.8) [-3.7, -0.6]	-2.6 (1.1) [-4.7, -0.4]	-0.4 (1.1) [-2.6, 1.7]
Diastolic BP (mmHg)*												
Mean change from baseline (SE) [95% CI]	-1.2 (0.7) [-2.7, 0.2]	-0.3 (0.8) [-1.8, 1.2]	0.3 (0.8) [-1.2, 1.8]	-1.2 (0.8) [-2.6, 0.3]	-0.6 (0.5) [-1.7, 0.4]	0.0 (0.8) [-1.5, 1.5]	-0.3 (0.6) [-1.4, 0.7]	0.2 (0.6) [-0.9, 1.3]	-0.0 (0.6) (-1.1, 1.1)	-0.8 (0.6) [-1.9, 0.2]	-1.0 (0.8) [-2.4, 0.5]	-0.2 (0.7) [-1.6, 1.3]
QTcF interval (msec)												
Mean change from baseline (SD)	2.7 (11.9)	1.8 (13.2)	1.2 (13.4)	2.0 (14.7)	3.4 (11.4)	4.9 (13.4)	3.3 (14.1)	2.2 (12.7)	2.3 (11.7)	3.0 (11.6)	5.3 (12.7)	3.5 (15.8)

†SBP was ≥ 140 mm Hg and/or DBP was ≥ 90 mm Hg at Baseline

‡At Baseline and during treatment phase; *Vital signs assessed by investigator using standard office device

FAS = all randomized patients who received ≥ 1 dose of double-blind study medication with primary efficacy data at Baseline and ≥1 post-Baseline visit; SAS = all randomized patients who received ≥1 dose of double-blind study medication, analyzed as treated

QTcF = QT interval corrected using Fridericia's correction formula (QTc=QT * RR1/3 where RR=1000*(60/heart rate)

Mean Baseline pulse rate (SD) ranged from 71.5 (9.3) to 73.2 (11.1) bpm; mean Baseline SBP (SD) ranged from 128.0 (16.0) to 130.9 (13.4) mmHg; mean Baseline DBP (SD) ranged from 75.7 (8.8) to 78.3 (8.5) mmHg; and mean Baseline QTcF (SD) ranged from 406.9 (18.4) to 411.5 (15.6) msec

Introduction and Objectives: In the Symphony study, the β3-adrenoceptor agonist, mirabegron (MIRA), combined with the antimuscarinic agent, solifenacin (SOLI), was effective in the treatment of overactive bladder (OAB). Here we report on cardiovascular (CV) safety parameters, comparing MIRA and SOLI combination therapy with monotherapy and placebo.
Methods: In this Phase II, multicentre, randomised, double-blind, parallel-group, placebo- and monotherapy-controlled trial, males and females aged ≥18 years with symptoms of OAB for ≥3 months, were randomised to one of 12 treatment groups for 12 weeks in a 2:1 ratio for primary (SOLI 5 mg; SOLI 2.5 mg+MIRA 25 mg; SOLI 2.5 mg+MIRA 50 mg; SOLI 5 mg+MIRA 25 mg; SOLI 5 mg+MIRA 50 mg) vs. secondary (placebo; SOLI 2.5 mg; SOLI 10 mg; MIRA 25 mg; MIRA 50 mg; SOLI 10 mg+MIRA 25 mg; SOLI 10 mg+MIRA 50 mg) groups. Vital signs (blood pressure [BP] and pulse rate) and ECG parameters were assessed at Baseline (BL) and each study visit; vital signs were assessed by investigator and patient (AM and PM recording over 5 consecutive days [data not shown]). Mean change from BL to End of Treatment (EoT) in vital signs was analysed using an ANCOVA model with MIRA and SOLI dose as the main factors; their interaction, sex, age group, and geographic region as fixed factors, and BL value as a covariate. LS means and 95% confidence intervals are presented for parameters of interest.
Results: 1306 patients received ≥1 dose of study drug. No dose-related differences were observed between combination therapy and monotherapy (either SOLI or MIRA) in mean change from BL to EoT in BP, pulse rate, or QTcF interval (Table 1). MIRA's effect on vital signs, and the small prolongation in QTcF seen with SOLI, were observed in similar magnitude in the combination groups.
Conclusions: The combination of MIRA and SOLI may provide an attractive therapeutic approach that maximises efficacy in OAB patients with no additional CV safety concerns.

POD-05.09

Urinary Incontinence in Women: What is the Trigger to Finally Seek Treatment?

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Objectives: Urinary incontinence has consistently been shown to be highly prevalent and have a tremendous impact on the quality of life (QoL) of Canadian women. Currently there is a paucity of information in the published literature exploring why women wait or what finally drives them to seek treatment. Through a short questionnaire, this study attempts to uncover the reasons for delaying treatment and reveal what finally motivates women to seek help in treating their urinary incontinence.
Methods: A convenience sample of all women presenting with urinary incontinence at a single centre were invited to complete an anonymous, cross-sectional, self-report questionnaire. The survey included both open and closed-ended questions. Descriptive and qualitative statistics were used to assess the incontinence, reasons why they delayed seeking treatment advice, and what motivated them to approach a health care professional. QoL was evaluated with a 10 cm visual analogue scale (VAS).
Results: The sample size of this cross-sectional study was 150 women with an average age of 57.8 (SD +/- 12.1). Type of incontinence was: 33% urgency, 16.6% stress and 50.4% mixed. The average duration of symptoms prior to presenting to a health care provider was 36.8 months (SD +/- 27.8) and average VAS was 5.65 (SD +/- 2.66). Thinking it was a normal part of aging was the most common reason for waiting (53.3%) followed by thinking it would go away on its own (36.6%). The primary reasons for seeking medical attention were increasing urinary leakage (70%), decreased QoL (66.6%), and embarrassment (43.3%).
Conclusions: As far as the authors are aware this is the first study to explore the variables surrounding why incontinent women delay seeking treatment and what finally motivates them to approach a healthcare provider. It is obvious that education about the plethora of treatment options available is warranted rather than waiting until their embarrassment brings them to our doorstep.