

Moderated Posters 4: Voiding Dysfunction June 26, 2012, 1240-1440

MP-04.01

The Role of Dutasteride in Preventing BPH Clinical Progression in Asymptomatic Men with an Enlarged Prostate

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Introduction and Objectives: Prostatic enlargement is a risk factor for acute urinary retention (AUR), need for surgery, as well as developing lower urinary tract symptoms (LUTS). Treatment with 5-alpha reductase inhibitors has been studied in men with moderate-severe LUTS¹⁻³. Our study aims to assess the role of dutasteride in preventing clinical progression in asymptomatic men with larger prostates.

Methods: Using data obtained from the REDUCE study, we assessed the outcomes of men with a prostate size >40 mL and baseline International Prostate Symptom Score (IPSS) <8. Men treated with any medications for benign prostatic hyperplasia (BPH) at time of study entry or who did not complete the end-of-study IPSS questionnaire were excluded. We compared the risk of BPH clinical progression at four years between those randomized to dutasteride versus placebo. BPH clinical progression was defined as a >4 point worsening on IPSS, AUR related to BPH, urinary tract infection, or BPH related surgery. A multivariable logistic regression analysis (MVA) assessed the effect of dutasteride on BPH clinical progression adjusting for age, IPSS, prostate volume, post-void residual, and peak urinary flow rate.

Results: Our study cohort consisted of 1617 men; 825 on placebo, 792 on dutasteride. A total of 464 patients (29%) experienced BPH clinical progression; 297 (36%) on placebo, 167 (21%) on dutasteride ($p<0.001$). The relative risk reduction (RRR) was 44% and the absolute risk reduction was 15%. Among the 76 patients (4.7%) who had AUR and the 46 patients (2.8%) who had BPH-related surgery, the RRR for dutasteride was 79% and 81%, respectively. On MVA, dutasteride significantly reduced BPH clinical progression with an odds ratio of 0.47 (95%CI 0.37-0.59, $p<0.001$).

Conclusions: This study is the first to explore the benefit of treating asymptomatic or mildly symptomatic men with enlarged prostates. In this cohort, dutasteride significantly decreased the incidence of BPH clinical progression.

MP-04.02

Comparison of Ultrasound and Fluoroscopic Imaging for Urodynamic Assessment of Non-neurogenic Voiding Dysfunction in Males

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Introduction and Objectives: Ultrasonography is becoming an attractive modality in the assessment of voiding dysfunction. The goal of this study was to compare imaging findings of ultrasound and fluoroscopy in the urodynamic assessment of non-neurogenic male voiding dysfunction.

Methods: Males requiring urodynamic investigation for non-neurogenic voiding dysfunction were prospectively recruited. All patients underwent urodynamics using both fluoroscopy and ultrasound imaging. Fluoroscopy was performed during filling and voiding phases. Ultrasound study was performed on a SonoSite Titan ultrasound machine using a 5-2 MHz convex transducer. Transabdominal ultrasound was performed to image the bladder and kidneys during the filling phase. Intravesical protrusion of the prostate (IPP) and anterior bladder wall thickness measurements were carried out at a bladder volume of 200 ml. Imaging findings were compared with urodynamic results.

Results: 160 male patients (age 27 to 92, mean 66.3 yrs) were studied. Of the 160 patients, 13 were unable to void and 10 had poor visualization of the prostatic urethra on fluoroscopy. 84 patients were urodynamically diagnosed with bladder outlet obstruction (BOO). Receiver Operating Characteristic plot (ROC) analysis demonstrated that IPP was predictive of BOO (AUC=0.90, $p<0.0001$) whereas bladder wall thickness measurement was not predictive of BOO (AUC=0.61, $p=0.05$). IPP cutoff of 8.5 mm had a sensitivity of 83% and specificity of 91% for BOO in men. All patients with IPP of >12.5 mm were obstructed. 2 patients with sphincter active voiding were diagnosed fluoroscopically.

Conclusions: Ultrasonography is a feasible alternative imaging modality in urodynamic assessment of non-neurogenic male voiding dysfunction. Ultrasonographic IPP was predictive of BOO in our study. The role of IPP warrants further investigation.

MP-04.03

Does Independently-interpreted Retrograde Urethrography Accurately Diagnose and Stage Anterior Urethral Stricture Disease?

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Introduction and Objectives: The retrograde urethrogram (RUG) is an essential tool in the preoperative evaluation of anterior urethral strictures. This study aims to assess the accuracy and adequacy of RUG interpretation between the primary physician performing the procedure and the independent physician interpreting the films.

Methods: A retrospective review was performed on a cohort of 397 patients undergoing anterior urethroplasty over a seven-year period. Preoperative RUG findings (stricture presence, location, and length) as reported by both the primary physician performing the urethrogram and the independent interpreter were abstracted from the medical records. This data was compared to the gold standard of intra-operative stricture location and length. RUG adequacy was defined as comment on the presence, location, and length of urethral stricture.

Results: Only 49% (196/397) of independently-reported RUG studies were deemed adequate and 87% of independently-reported studies correctly diagnosed the presence of a stricture. When assessing stricture location, 49% of independently-reported studies correctly identified the location of the stricture compared to 96% of primary physician-reported cases ($p<0.001$). The mean stricture length reported by the independent observer was 3.23 cm compared to 4.18 cm by the primary physician and 4.56cm intra-operatively. The differences between independently-reported, primary physician-reported, and intra-operative lengths were all statistically significant ($p<0.001$). Upon linear regression analysis, the independently-reported length showed a 0.47 R²-coefficient of correlation to the intra-operative length ($p<0.001$) compared to a 0.93 R²-coefficient of correlation between the primary physician-reported length and the intra-operative length ($p<0.001$).

Conclusions: Our study suggests that independently-reported RUGs are neither adequate nor accurate for use in preoperative staging of anterior urethral stricture.

MP-04.04**Do Cuff Size/Reservoir Size Impact Erosion, Revision, Infection and Outcome Rates in Patients Who Underwent AUS Placement for Stress Urinary Incontinence after Primary Treatment for Prostate Cancer**

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Introduction and Objectives: Urinary incontinence is a common complication after radical prostatectomy and radiation therapy (RT). The AUS (artificial urinary sphincter) is considered the gold standard for patients who develop urinary incontinence post prostatectomy or after RT for prostate cancer (PC). We compared AUS done at our institution for urinary incontinence status post PC treatment and their complication rate. We looked at, if cuff size and reservoir size made a difference in terms of erosion, infection, revision and dryness at follow-up.

Methods: A retrospective database review was conducted of 54 patients who underwent AUS placement for stress urinary incontinence after primary treatment for PC between June 2002 to April 2011. Patients were divided based on cuff size and size of reservoir. This data were then compared with respect to erosion, infection, revision and dryness at follow-up.

Results: Total no. of erosions, infections, revisions were 13%, 13% and 33.3%. When these results were stratified based on cuff size small (4 cm) vs. normal, then: infection 23.5% vs. 7.4%, $p=0.186$, erosion 18.8% vs. 11.1%, $p=0.655$, revision rates 41.2% vs. 28.6%, $p=0.348$ and dry at follow-up 66.7% vs. 73.7%, $p=0.704$. When these results were stratified based on pressure of reservoir 51-60 vs. 61-70, then: erosion 23.1% vs. 9.5% $p=0.348$, infection 30.8% vs. 4.5%, $p=0.052$, revision 38.5% vs. 30.4%, $p=0.624$, dry at follow-up 25% vs. 13.3%, $p=0.589$. Subanalysis evaluated the effect of prior RT on: erosion 18.2% vs. 15.4% $p=1.000$, infection 41.7% vs. 8% $p=0.025$, revision 33.3% vs. 40.7% $p=0.734$, dry at follow-up 73.7% vs. 28.6% $p=0.069$.

Conclusions: We found that cuff size did not make a difference on any parameters studied. If a smaller pressure reservoir was used, the rates of infection were lower, which was statistically significant (SS). Prior RT was a factor in increased infection rates which was SS and being dry at follow-up which approached SS. Patients who underwent RT, had smaller cuff size or a smaller pressure reservoir tended to have worse outcomes.

MP-04.05**The Sphincter Sum: a Practical and Effective Tool for Evaluating Patients with Post-prostatectomy Incontinence**

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Introduction and Objectives: The AdVance Male Sling (American Medical Systems, Minnetonka MN) has become an established treatment option for post-prostatectomy incontinence. To our knowledge the optimal preoperative selection criteria for this procedure have yet to be defined. We describe the sphincter sum as a cornerstone of our current selection process for this procedure and correlate with subjective surgical outcomes.

Methods: A retrospective chart review of 80 consecutive male sling patients was performed. The external urinary sphincter in all patients was evaluated preoperatively with flexible cystoscopy. Based on level of coaptation, presence of scars and degree of fixation, we assigned a score from 1 (completely fixed open) to 5 (appears normal) at rest and with active contraction. The two scores were totaled to give the sphincter sum which ranges from 2 – 10. Patients were categorized into 2 groups for comparison, those with "optimal" features (sphincter sum >8) and those with "adverse" features (sphincter sum ≤7). A telephone survey was performed with questions about degree of improvement, pad use, quality of life (QOL) pre and postoperatively.

Results: 65 of 80 subjects responded to the telephone survey and were included in the study. 44 patients had "optimal" sphincter features while 21 had "adverse" features. The subjective success rate was significantly higher in the "optimal" group, 89% vs. 62% ($p=0.024$). The subjective dry rate was also significantly higher in this group, 64% vs. 33% ($p=0.03$). Patients with sphincter sum >8 reported significantly lower levels of ongoing pad use and significantly lower levels of QOL impairment

from residual incontinence.

Conclusions: The best results with the AdVance male sling are realized in patients with sphincter sum >8 indicating a high degree of residual external urinary sphincter function. We find the sphincter sum to be an effective tool for evaluating prospective patients for this procedure.

MP-04.06**Revision Urethroplasty for Recurrent Urethral Stricture: a Comparative Analysis of Efficacy and Outcomes**

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Introduction and Objectives: Urethroplasty is a cost effective treatment of urethral stricture with 5-year stricture-free rates over 80%. What to offer patients with failures after urethroplasty remains a question. The purpose of this study is to compare clinical factors, type of urethroplasty, and patency rates in revision compared to urethroplasty naïve patients.

Methods: Retrospective analysis of 541 urethral reconstructions performed by a single surgeon from Aug '03 to Mar '11 was done. Age, stricture length, location, etiology, comorbidities, previous intervention and type of surgery performed were examined. The primary outcome was cystoscopic urethral patency with secondary measures of bothersome LUTS, UTI or chordee. Statistical analysis was Fischer's, Chi-squared, and unpaired t-test when appropriate.

Results: 466 (86.1%) patients met our criteria and had complete follow-up. 96 (20.6%) patients had a previous urethroplasty. Revision patients had longer strictures (6.0 vs. 4.6 cm, $p<0.0001$), occurred with increased frequency in the penile urethra (57.3 vs. 7.8%, $p<0.0001$) and were more often associated with Lichen sclerosis (23.5 vs. 8.6%, $p<0.01$). Revision patients were significantly more likely to undergo a staged procedure or urethrostomy-based procedure (47.9 vs. 4.3%, $p<0.0001$). Patency did not significantly differ between repeat and naïve urethroplasties (92.8 vs. 93.5%, $p=0.9$). Patients with revision experienced more chordee (13.4 vs. 1.9, $p<0.0001$), but did not differ significantly in occurrence of UTI (4.1 vs. 2.7%, $p=0.32$) or bothersome LUTS (8.2 vs. 10.8%, $p=0.6$).

Conclusions: Revision urethroplasty is an effective treatment option for recurrent stricture after urethroplasty. Patency rates are gratifying (92.8%) and comparable to urethroplasty naïve patients. Patients presenting for revision are more likely to have longer strictures, strictures in the penile urethra or lichen sclerosis. Patients undergoing revision urethroplasty experience higher rates of chordee.

MP-04.07**Primary Realignment versus Suprapubic Cystostomy for the Management of Posterior Urethral Distraction Defects: a Systematic Review and Meta-analysis**

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Introduction and Objectives: The early management of posterior urethral distraction defects associated with blunt trauma is controversial. Options include primary realignment (PR) and suprapubic cystostomy (SPC). Early realignment may reduce stricture incidence, but some authors have raised concerns regarding increased rates of impotence and incontinence. A systematic review was conducted to compare PR with SPC for the management of posterior urethral distraction defects with regards to rates of stricture, impotence, and incontinence.

Methods: Two electronic databases (MEDLINE and EMBASE) were searched with the assistance of a librarian. Title, abstract, and full text screening was carried out by 2 independent reviewers, with discrepancies resolved by consensus. Narrative reviews, surveys, and historical articles were excluded. Only studies reporting a direct comparison of PR versus SPC for management of posterior urethral distraction injuries associated with blunt trauma in adults were included. Quality assessment of the included articles was performed in duplicate. Stricture incidence was evaluated for all included studies, as were impotence and incontinence rates when reported. All outcomes were treated as dichotomous data with calculation of odds ratio, and were pooled using a random effects model with Review Manager 5.1.

Results: Our comprehensive search yielded 161 unique articles. Nine papers were included in the meta-analysis. Stricture rate was significantly lower in the PR group (OR = 0.15, 95%CI 0.04 to 0.55, $p < 0.01$). There was no significant difference between the two interventions with regards to impotence (OR = 1.19, 95%CI 0.73 to 1.92, $p = 0.49$) or incontinence (OR = 0.75, 95%CI 0.38 to 1.48, $p = 0.41$).

Conclusions: PR appears to reduce the incidence of stricture formation following posterior urethral distraction defect associated with blunt trauma, as compared to SPC, without increasing rates of impotence or incontinence.

MP-04.08

The Mesh Wallstent (UroLume) in the Treatment of Detrusor External Sphincter Dyssynergia in Men with Spinal Cord Injury

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Introduction and Objectives: To evaluate the long-term efficacy and safety of the UroLume stent for the treatment of detrusor sphincter dyssynergia (DSD) in spinal cord injured (SCI) patients.

Methods: Twenty-four spinal cord injured patients with neurogenic bladder and DSD associated with high detrusor pressures and incomplete emptying on preoperative video-cystometrograms (VCMG) were retrospectively reviewed. 11 patients were on clean intermittent catheterization (CIC) and 13 with indwelling Foley's catheter. All patients underwent UroLume stent insertion according to standardized protocol. Postoperative patient and physician satisfaction, complications and re-obstruction rates were also analyzed. Paired t-test is used and p value < 0.05 was taken as significant.

Results: The mean follow-up was 4.1 (2.5-11) years. The mean age was 46 (33-58) years. 87.5% had a cervical level injury. The mean duration of neurological disability prior to intervention was 9.2 (2-25) years. None of the patients had previous sphincterotomy. The mean postoperative stay was 3.7 (1.8-5.6) days. Mean time for removal of suprapubic tube was 28.7 (11.3-26.1) days. Mean residual volume was 502 (281-923) ml before treatment, 260 (14-530) ml ($p < 0.02$) at 3 months, 260 (47-473) ml ($p < 0.03$) at 1 year, and 270 (92-448) ml ($p < 0.03$) at 10 years. There was a 55% decrease in incidence of autonomic dysreflexia at 1 year, and among 11 patients with autonomic dysreflexia preoperatively, 4 (36%) patients continued to complain of mild, and 1 (9%) of severe dysreflexia at one year postoperatively. None of the patients required an indwelling catheter or CIC at 1 year, however 20.8% required either an indwelling catheter (4 patients) or CIC (one patient) at 5 years due to poor bladder emptying. The overall complication rate was 54%.

Conclusions: The treatment of DSD in SCI patients with UroLume stent is safe and effective. However, common complications were observed including the need for re-stenting.

MP-04.09

Surgical Treatment of Male Incontinence Using the Argus Male Sling: Our First Five-Case Experience

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Introduction and Objectives: Male incontinence, often as a result of prior prostate therapies such as radical prostatectomy, TURP, radiotherapy, or cryotherapy, affects quality of life. Pad costs, social isolation and negative body image are just some of the detrimental effects of incontinence. Recently, the Argus Male Sling has come to Canada and we report our first 5 cases performed in Calgary.

Methods: All five patients received urodynamics, cystoscopy and preoperative assessment with 24 hr pad testing, questionnaires (IPSS, ICIQ-UI, UDI-6), and a nursing visit. On a single day, all 5 patients underwent implantation of the Argus sling. Operative times, postoperative course including hospital stay, clinic visits and nursing calls were all recorded.

At this time, the preoperative data and postoperative data up to 1 month was available.

Results: All 5 had prior radical prostatectomy. 1 man had a prior male sling procedure. The average age was 69.6 yrs. No significant change in PVR was recorded at 1-month (preop: 35.6 and 1 month: 69.6 cc). No change in voided volume was noted but the peak flow did drop from 21.2 cc/sec to 9.6 cc/sec. Degree of bother as scored on the IPSS moved from 4 preop to 0.8 postoperative ICIQ-UI dropped from 13 to 3.6. UDI-6 dropped from 10 to 3.4. Preoperative 24 hr pad weight was 5.6 oz and postoperative 0 oz (no pads used). 3 patient required in and out catheter postoperative and perineal pain was the most common complaint.

Conclusions: The Argus male sling is a new device to Canada. At the time of preparation, our 1 month data supported its role in the treatment of male incontinence. Improvements in incontinence, degree of bother, and pad usage were excellent. We report our experience with this device to review our own outcomes and provide data and guidance to other urologists considering the Argus male sling in the management of male stress incontinence.

MP-04.10

A Potential Gold Standard for Reconstruction of Long Segment Bulbar Urethral Strictures - Intermediate Outcomes of the Dorsal Onlay Augmented Anastomosis with Buccal Mucosa Graft

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Introduction and Objectives: Long segment bulbar urethral strictures remain somewhat of a reconstructive dilemma. Endoscopic procedures alone have poor outcomes and generally, these strictures are not amenable to anastomotic repair; thus tissue transfer is typically required. The objective of this study is to assess the intermediate-term results of a dorsal onlay "augmented anastomosis" using buccal mucosa to reconstruct long segment bulbar urethral strictures.

Methods: 164 patients prospectively underwent open reconstruction for long segment bulbar urethral strictures from Nov. 2003 to Jan. 2011. Buccal mucosa graft and dorsal onlay "augmented anastomosis" was utilized in all cases. Preoperatively, all patients underwent urethrography and flexible cystoscopy. Mean stricture length was 4.9 cm (range 3-12 cm). All patients were followed up with flexible cystoscopy and subjective symptom assessment at 6 and 12 months, with annual symptom assessments thereafter. Mean length of follow-up was 3.0 years. Stricture recurrence was defined as a segment < 16 Fr caliber on cystoscopy, or intractable obstructive voiding symptoms.

Results: Postoperative complications included post-void dribbling (41.5%), urinary tract infection (3.7%), ejaculatory dysfunction (3.1%), transient orchalgia (10.4%), and donor site morbidity (4.3%). 96.3% (158/164) of patients had no evidence of cystoscopic stricture recurrence on follow-up. Six patients underwent direct vision internal urethrotomy for recurrence postoperatively and 5 are stricture free, ranging from 16 months-8 years post urethrotomy.

Conclusions: To date, this series represents the largest cohort of patients reconstructed with this technique. This 96.3% stricture free rate on cystoscopy will continue to be analyzed in the long-term. Using a buccal mucosa graft with a dorsal onlay "augmented anastomotic" repair yields excellent mid-term results and shows promise as a potential gold standard for reconstruction of long segment bulbous urethral strictures.

MP-04.11**Effect of Baseline Characteristics of Subjects with Overactive Bladder on Changes in Daytime and Nighttime Urgency Urinary Incontinence Episodes Following Antimuscarinic Treatment**Herschorn, Sender¹; Wang, Joseph²; Ntanos, Fady²¹University of Toronto, Toronto, ON, Canada; ²Pfizer Inc., New York, NY, United States**Introduction and Objectives:** We assessed whether clinical and demographic characteristics are predictive of antimuscarinic efficacy for daytime and nighttime urgency urinary incontinence (UUI) episodes.**Methods:** Subjects ≥ 18 y with overactive bladder (OAB; ≥ 1 UUI episode, ≥ 8 micturitions per 24 h) were randomized to receive the maximum approved doses of fesoterodine (FESO; 8 mg), tolterodine extended release (TER; 4 mg) or placebo (PBO) in a 2:2:1 ratio in two 12-week, double-blind, head-to-head trials. Subjects in the FESO group received 4 mg/d during the first wk and 8 mg/d thereafter. All subjects completed 3-day bladder diaries at baseline and wk 12. In a post hoc analysis of data pooled from these trials, changes from baseline to wk 12 in daytime and nighttime UUI episodes/24 h were analyzed using ANCOVA models including significant baseline values as covariates; treatment, study, country, gender, age, BMI, and prior antimuscarinic treatment (yes/no) as factors; and two-way interaction terms with treatment. Only subjects with daytime or nighttime baseline UUI >0 were included in the respective analyses.**Results:** Greater baseline UUI severity was predictive of increased antimuscarinic efficacy for both daytime and nighttime UUI episodes. Age, prior antimuscarinic treatment and symptom bother also significantly predicted efficacy on both daytime and nighttime UUI. FESO 8 mg (n=1498) was more efficacious than TER 4 mg (n=1515) in reducing daytime UUI episodes in the overall population and in subjects with higher baseline UUI severity; there were similar trends for nighttime UUI episodes (FESO n=897; TER n=909).**Conclusions:** Baseline UUI severity, age, prior antimuscarinic treatment, and symptom bother were predictive of antimuscarinic efficacy for both daytime and nighttime UUI episodes.**MP-04.12****The Selective β_3 -Adrenoreceptor Agonist Mirabegron Is Effective and Well Tolerated in Patients with Overactive Bladder Syndrome**Herschorn, Sender¹; Nitti, Victor²; Auerbach, Stephen³; Lee, Misun⁴; Martin, Nancy⁴¹University of Toronto, Toronto, ON, Canada; ²New York University School of Medicine, New York, NY, United States; ³Hoag Memorial Presbyterian Hospital, Newport Beach, CA, United States; ⁴Astellas, Deerfield, IL, United States**Introduction and Objectives:** The efficacy and tolerability of mirabegron in a Phase III trial of patients with OAB in Canada and the United States are presented.**Methods:** This 12wk, multicentre, randomized, double blind, parallel-group, placebo-controlled trial enrolled patients >18 yrs with symptoms of OAB for >3 mos. Patients who completed a 2wk, single-blind, placebo run-in, and experienced >8 micturitions/24h and >3 urgency episodes (with or without incontinence) over a 3 day micturition diary period during screening, were randomized to receive placebo or mirabegron 50 or 100mg once daily for 12wks. Co-primary endpoints were the changes from baseline to final visit in the mean number of incontinence episodes and micturitions/24h. Efficacy was assessed according to patient micturition diaries and safety assessments included adverse event (AE) reporting.**Results:** 1328 patients were randomized and received study drug (placebo n=453; mirabegron 50 mg n=442; mirabegron 100mg n=433). Both mirabegron groups demonstrated statistically significant improvements compared with placebo in the coprimary and secondary efficacy endpoints at 4 and 12 wks. The incidence of treatment-emergent AEs was similar across the placebo and mirabegron 50 and 100 mg groups (50.1, 51.6 and 46.9%, respectively). The most commonly reported ($>3\%$) AEs in any treatment group were hypertension (6.6, 6.1 and 4.9%, respectively), urinary tract infection (1.8, 2.7 and 3.7%), headache (2.0, 3.2 and 3.0%) and nasopharyngitis (2.9, 3.4 and 2.5%). The incidence of serious AEs was 2.0, 2.5 and 3.2%, and discontinuation rates due to AEs were 3.8, 4.1 and 4.4%, respectively.**Conclusions:** In this study, mirabegron demonstrated statistically significant improvements in key OAB symptoms and was well tolerated in patients with OAB.**MP-04.13****Open-label, Ascending Dose Cohort Study of LiRIS (lidocaine-releasing intravesical system) in Women with Moderate to Severe Interstitial Cystitis**Steele, Stephen S.¹; Nickel, J. Curtis¹; Steinhoff, Gary²; Egerdie, Blair³; Gajewski, Jerzy⁴; Bailly, Greg⁴; Himes, Julie⁵¹Queen's University, Kingston, ON, Canada; ²University of British Columbia, Victoria, BC, Canada; ³The University of Western Ontario, Kitchener, ON, Canada; ⁴Dalhousie University, Halifax, NS, Canada; ⁵Taris Biomedical, Lexington, MA, United States**Introduction and Objectives:** LiRIS is a novel intravesical drug-delivery system which releases therapeutic amounts of lidocaine into the bladder over 2 weeks. This phase 1b open-label, ascending dose cohort study evaluated the tolerability, safety, efficacy and limited pharmacokinetics of LiRIS in women with moderate to severe IC.**Table 1. MP-04-12. Efficacy results: adjusted mean* (standard error) change from baseline**

	Placebo	Mirabegron 50 mg	Mirabegron 100 mg
Co-primary endpoints			
Number of incontinence episodes/24h at final visit	-1.13 (0.112)	-1.47 [†] (0.114)	-1.63 [†] (0.117)
Number of micturitions/24h at final visit	-1.05 (0.132)	-1.66 [†] (0.133)	-1.75 [†] (0.135)
Key secondary endpoints			
Volume voided/micturition at final visit	7.0 (2.41)	18.2 [†] (2.44)	18.0 [†] (2.47)
Number of incontinence episodes/24h at Wk 4	-0.72 (0.116)	-1.20 [†] (0.119)	-1.18 [†] (0.122)
Number of micturitions/24h at Wk4	-0.77 (0.127)	-1.19 [†] (0.129)	-1.37 [†] (0.131)

*Least squares mean adjusted for baseline, gender and geographical region ; $p < 0.05$ versus placebo † with and ‡ without multiplicity adjustment.

Methods: 18 women with IC, meeting NIDDK criteria, having baseline bladder pain of at least 4 (0-10) were enrolled at 4 Canadian centres. Patients received either LiRIS 200 mg (cohort 1) or LiRIS 650 mg (cohort 2) for 2 weeks. LiRIS safety, efficacy, cystoscopic appearance of bladder pre-and post- LiRIS, and limited PK were collected.

Results: Both LiRIS 200 mg and LiRIS 650 mg were well tolerated. Clinically meaningful reductions were seen in pain (VAS 0-10 scale -4.9 for 200 mg; -3.6 for 600 mg), urgency (VAS 0-10 scale -6.5 for 200 mg; -3.5 for 600 mg), voiding frequency (-7 episodes per day) and disease questionnaires (ICSI 0-20 scale -5.4 for 200 mg; -4.5 for 600 mg). Cystoscopic exam showed improvement on Day 14 (LiRIS removal) compared with Day 1 (LiRIS insertion) including resolution of Hunner's lesions in 6 of 7 patients with baseline lesions. Global Response Assessment (7-item scale) showed an overall responder rate of 69% at Day 14 which was maintained with an overall responder rate of 69% two weeks later (Day 28). Extended follow-up suggests the pain response was maintained to Day 60. The adverse events were typical of those seen in patients with IC and consistent with a cystoscopic procedure. The majority of adverse events reported were mild to moderate in intensity with no LiRIS related serious adverse events. The systemic levels of lidocaine were very low; no adverse events were attributable to lidocaine exposure.

Conclusions: LiRIS 200 mg and LiRIS 650 mg was safe, well tolerated and showed preliminary efficacy including mucosal healing and extended duration of effect in patients with moderate to severe IC.

MP-04.14

Noninvasive Diagnosis of Painful Bladder Syndrome / Interstitial Cystitis Using Near Infrared Spectroscopy

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Introduction and Objectives: Painful bladder syndrome/interstitial cystitis (PBS/IC) is defined as a syndrome of urgency, frequency, and suprapubic pain in the absence of positive urine culture or obvious bladder pathology. Diagnosis of PBS/IC is currently based on clinical judgment of treating urologist after ruling out other urinary pathologies, using invasive cystoscopic and urodynamic (UDS) studies. One potential etiology of PBS/IC is bladder mucosa inflammation associated with abnormal angiogenesis and ulcerative lesions in bladder mucosa. Near infrared spectroscopy (NIRS) is a noninvasive optical technique to monitor tissue oxygenation and hemodynamics. The purpose of this study was to examine ability of NIRS to differentiate subjects identified as PBS/IC from other marked bladder conditions.

Methods: Twenty-four patients with lower urinary tract dysfunction were divided into 2 groups, PBS/IC (4 male aged: 27.5±8 yrs) and non-PBS/IC (8 male and 12 female aged: 47.7±4.8 yrs) after standard diagnostic investigations. Detrusor oxygen saturation percentage (TSI%), a direct index of tissue metabolism, were studied in all subjects using a NIRS instrument, simultaneous to UDS study. After one minute baseline measurement in supine rest position with empty bladder, the detrusor TSI% was recorded by the NIRS that was placed and fixed over the bladder. Statistical difference of the detrusor TSI% values between two groups were studied.

Results: Mean resting values of detrusor TSI% were significantly different ($p<0.0005$) between 2 groups (74.2%±4.9 in PBS/IC vs. 63.6%±5.5 in non-PBS/IC).

Conclusions: Noninvasive NIRS interrogation of the bladder demonstrated significant increase in detrusor oxygen saturation in patients diagnosed as PBS/IC. This observation may support previous reports that indicated bladder mucosa inflammation associated with abnormal angiogenesis and ulcerative lesions in bladder mucosa as the main etiology of the PBS/IC. This study presents potential application of SR-NIRS for noninvasive diagnosis of PBS/IC.

MP-04.15

Monitoring of Lower Urinary Tract Function in Patients with Spinal Cord Injury Using Near Infrared Spectroscopy

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Introduction and Objectives: One of the most important conditions where there is loss of normal bladder function is spinal cord injury (SCI). Currently, evaluation of bladder function is limited to periodic invasive urodynamic testing (UDS). The purpose of this study was to assess the feasibility and usefulness of near-infrared spectroscopy (NIRS) in monitoring bladder function in patients with SCI during bladder filling and emptying and to investigate the correlations of NIRS measures with simultaneous UDS parameters. NIRS is a non-invasive optical method to study tissue oxygenation, hemodynamics and function by monitoring changes in the chromophore concentrations of oxygenated (O_2Hb), deoxygenated (HHb) and total hemoglobin (tHb).

Methods: 10 adult paraplegic patients with neurogenic bladder dysfunction who were referred for regular urodynamic evaluation were recruited. Changes in O_2Hb , HHb and tHb, and tissue saturation index (TSI%) in the detrusor were monitored and recorded by a wireless NIRS system during the urodynamic evaluation. Time points of urgency and urinary leakage were marked and patterns of change in NIRS parameters were compared to standard urodynamic pressure tracings.

Results: Strong consistency between changes in NIRS-derived tHb and changes in intravesical pressure were observed during filling across the subjects. During bladder filling a gradual increase in O_2Hb and tHb with minimal changes in HHb was observed. Interestingly, a drop in TSI% was detected seconds before strong urgency and urinary leakage.

Conclusions: Our preliminary data suggest a relationship between non-invasive NIRS measures and UDS parameters during bladder filling in SCI patients.

MP-04.16

The Signal Transduction of Skin Electrode Can Launch on the Bladder of Diabetic Rabbits and Ameliorate Its Hypomotility

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Introduction and Objectives: Vesica and urethra dysfunction caused by the damage of vesical peripheral nerve below spinal neuron is known as peripheral neurogenic bladder (PNB). The patients of PNB mainly present hypocontraction and over dilatation of bladder and even uroschisis. So we investigate if the signal of skin electrode can be conducted to bladders of diabetic rabbits and improve their vesical hypomotility.

Methods: 30 of male New Zealand rabbits were randomly divided into Group DM (diabetes mellitus, induced by alloxan) and Group C (control). Four weeks after modeling, saved rabbits (9 in Group DM and 10 in Group C) were stimulated by skin electrode on the projection area of bladder with three levels of exporting voltage (5.84V, 8.00V, 11.00V) to observe changes of vesical signals and pressure.

Results: The total attenuation percentage of signals was 99.88% (SD=0.00%) in Group C, and 99.93% (SD=0.00%) in Group DM. Although attenuation percentage (AP) within each group did not depend on the strength of exporting voltage (EV), AP in Group DM was larger than that in Group C ($p<0.01$). Received vesical signals increased with the strength of EV ($p<0.01$), and were all weaker in Group DM than in Group C ($p<0.01$) when EV were the same in both groups. Meanwhile, vesical pressure of rabbits in both groups increased with vesical signals ($p<0.05$), and were all smaller in Group DM than in Group C ($p<0.01$). Linear correlation existed between vesical pressure and signals with a coefficient of 0.869 ($p<0.01$) in Group C and 0.750 ($p<0.01$) in Group DM.

Conclusions: Signals from skin electrode could be conducted to bladder to increase vesical pressure after significant attenuation in both Control group and DM group, so this could be used as the therapy of hypodynamic PNB such as diabetic cystopathy due to its non-invasion and effectiveness.

MP-04.17

Cost-effectiveness of Sacral Neuromodulation in Refractory Overactive Bladder: A Canadian Perspective

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Introduction and Objectives: A significant number of patients with refractory overactive bladder (OAB) and urgency incontinence will fail conservative treatment with optimized medical therapy (OMT) and may benefit from minimally invasive procedures including sacral neuromodulation (SNM) or botulinum toxin (Bont-A) injection. The goal of this study was to estimate the cost-effectiveness of SNM vs. OMT and Bont-A.

Methods: An economic Markov model with Monte Carlo simulation was used to assess the incremental cost-effectiveness ratio (ICER) of SNM vs. Bont-A and OMT. The model calculated the ICER in deterministic (base-case) and probabilistic (sensitivity) analysis from a provincial payer's perspective over a 10-year time horizon with 9-month Markov cycles. Other utilization data were acquired from recent publications and from an expert panel of 7 Canadian surgeons. Cost data were derived from provincial health insurance policy, drug benefit formulary, and hospital data.

Results: The annual (year 1-10) incremental Quality-Adjusted Life Years (QALY) for SNM vs. Bont-A was 0.05-0.51 and SNM vs. OMT was 0.19-1.76. The annual incremental cost of SNM vs. Bont-A was \$7,237 in year-1 and -\$9,402 in year-10 and was between \$8,878 to -\$11,447 vs. OMT. In the base-case deterministic analysis, the ICER for SNM vs. Bont-A and OMT were within the acceptable range (\$44,837 and \$15,130 respectively) at the second year of treatment, with SNM being dominant in the consequent years. In the base-case analysis the probability of ICER being below the acceptability curve (Willingness-To-Pay = \$50,000) in Canada was >99% for SNM vs. Bont-A at year 3 and >95% for OMT at year 2.

Conclusions: SNM is a cost-effective treatment option for the management of patients with refractory OAB when compared to Bont-A and OMT. From a Canadian payers' perspective, sacral neuromodulation should be considered as first line treatment option in patients with refractory overactive bladder.

MP-04.18

Sacral Neuromodulation Failures

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Introduction and Objectives: Sacral neuromodulation (SNM) is a validated treatment option for refractory voiding dysfunction. It does not work for all patients, and/or there can be complications that require its removal. There are no studies examining the status of patients who have had a sacral neuromodulator removed. The goal of this study is to examine the current treatment(s) and quality of life of patients who have had a sacral neuromodulator removed. Reasons for device removal and attitudes towards SNM will also be described.

Methods: Patients treated by SNM in Halifax between the years of 1995-2008 by a single urologist were identified. 96 patients had a sacral neuromodulator placed for refractory voiding dysfunction and of these, 22 patients subsequently had the device removed. There were no exclusion

criteria. Reasons for device removal, current treatments, and attitudes toward SNM were assessed by chart review and questionnaire answers. Current quality of life was assessed by the ICIQ-LUTSqol questionnaire.¹

Results: A 45% participation rate (10/22) was achieved. Reasons for device removal were device pain (7), and lack or loss of effect (3). Subsequent treatments are ileocystoplasty (2), urinary diversion with cystectomy (3), oral anticholinergics (4), opioid analgesics (3) or observation (2). Average score on the ICIQ-LUTSqol questionnaire was 53 out of 76 (range 22-65), with an average bother score of 6.7 out of 10 (range 0-10). When asked if they would consider SNM again, responses were "yes" (5), "maybe" (2), and "no" (3).

Conclusions: Sacral neuromodulation offers a less invasive option for patients with refractory voiding dysfunction. However, patients should be counseled about the possibility for device complications necessitating removal. Many of these patients are subsequently treated by more invasive surgical interventions, yet continue to have a poor quality of life. Many patients would consider trying SNM again.

MP-04.19

A Cost-effectiveness Analysis of Tension-free Vaginal Tape vs. Burch Colposuspension for Female Stress Incontinence

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Introduction and Objectives: Stress urinary incontinence (SUI) represents a common and debilitating problem among adult women. Multiple methods to treat SUI exist, including the commonly performed tension-free vaginal tape (TVT) and Burch colposuspension (BC). In this study, we sought compare the cost-effectiveness (CE) of TVT to BC for treating SUI.

Methods: A Markov decision model was created to simulate treatment of SUI with TVT vs. BC. Of note, primary failure with TVT or BC was treated with a second TVT. Costing data were obtained from the Medicare Resource Based Relative Value Scale (RBRVS). Data regarding the success of TVT vs. BC were obtained from the peer-reviewed literature, as were corresponding utilities for different continence states. Sensitivity analyses (SA) were performed. The model was evaluated using Treeage Pro 2011 software (Treeage Software Inc., Williamstown, MA).

Results: At 10 year follow-up, TVT was more cost-effective (CE=85.27) than and dominated BC (CE=117.96, Table 1). Sensitivity analysis demonstrated that TVT was more cost-effective than BC irrespective of cost of procedure but that if the probability of success after TVT fell below 67%, then BC would become the more cost-effective strategy (CE=118.02 vs. 120.72).

Conclusions: Our study demonstrated that TVT was more cost-effective than BC as a treatment for female SUI. The clinical effectiveness of the two treatments impacts their CE more than their respective procedural costs. These results should be validated and confirmed in large, prospective trials.

Table 1. MP-04.19

Category	Effectiveness (QALY)	Incremental effectiveness (QALY)	Cost (\$)	Incremental cost (\$)	Incremental cost/incremental effectiveness (\$/QALY)	Avg CE (\$/QALY)
TVT	5.79	0.00	\$493.45	0	0	85.27
Burch colposuspension	5.78	-0.01	\$681.93	\$188.48	-32957.53	117.96

QALY: quality adjusted life-years; TVT: tension-free vaginal tape.

MP-04.20

Urinary Tract Mesh Erosion Following Female Pelvic Surgery

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Introduction and Objectives: Synthetic mesh is commonly used in the treatment of stress urinary incontinence (SUI) and pelvic organ prolapse (POP). Mesh erosion into the urinary tract is a rare but serious complication. The purpose of this study was to describe the management of mesh erosion into the urinary tract and to report the outcomes of a large cohort at our tertiary centre.

Methods: A retrospective review of women presenting to our centre between 2003-2011 with mesh erosion into the urinary tract was completed. Data was recorded and analyzed using SPSS version 15.0™.

Results: Forty patients (mean age = 57) presented with erosion into the bladder (n=16, 40%) and/or urethra (n=24, 60%). Mesh erosion was a result of SUI surgery in 85% of patients and POP surgery in 15%. Mean time from mesh insertion to diagnosis of erosion was 72.4 mos (3-360mos). Twenty percent had undergone a previous attempt at mesh removal. Mesh erosion was treated with cystoscopy +/- laser (n=12), transvaginal excision (n=17), and open retropubic surgery (n=7). One patient refused treatment and 3 were pending surgery at the time of this review. Ten patients (25%) required more than one surgery to remove mesh. Twenty-three patients (57.5%) had recurrent SUI and 12 (30%) required surgery to correct recurrent SUI (pubovaginal sling with rectus abdominis fascia). Of these, one was repeated and 66.7% were successful (i.e. no SUI). Patients with urethral erosion were more likely to develop recurrent SUI than those with bladder erosion, (p=0.012). Overall, 52.5% had voiding dysfunction at last follow-up. Mean follow-up was 16.1 mos from diagnosis of erosion and 12.2 mos from mesh removal.

Conclusions: This is the first report of a large cohort of patients with mesh erosion into the urinary tract. Mesh erosion results in increased morbidity requiring surgery to remove mesh and often surgery to correct recurrent SUI. Voiding dysfunction is common following treatment of mesh erosion.

MP-04.21

Long-term Outcomes of Pessary Use in Women with Pelvic Organ Prolapse

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Introduction and Objectives: The main objective of this retrospective study is to evaluate whether long-term use of vaginal pessaries is an appropriate conservative treatment for women with pelvic organ prolapse (POP).

Methods: From 1998 to 2010, 429 women with POP had a pessary trial. A pessary maintenance regime was chosen at one-month follow-up, and additional visits were then scheduled yearly. Data collected included information concerning pessary use, incidence of vaginal erosions or other associated morbidities, and subjective satisfaction rate.

Results: Average age at presentation was 71.1 ± 9.7 years old. 62% (n=258) of women had a successful pessary trial, defined as a one-month use of the pessary with subjective improvement of symptoms and no significant complication. Median duration of pessary use was 35 months (1-136). The satisfaction rate was 96%. Pessary self-maintenance regime, compared to maintenance by nurses, was associated with a prolonged pessary use (p=0.021). The overall erosion rate was 16%. Multivariate analysis demonstrated that erosions are associated with older age (p=0.011), constipation (p=0.018), and use of topical estrogen (p=0.001). The severity of vaginal atrophy increased with older age (p<0.001) and older patients were therefore more likely to use topical estrogen cream p<0.001. Both the severity of vaginal atrophy and intensive estrogen treatment before pessary trial were associated with a higher rate of erosions (p<0.001 and p=0.04). 66% (n=170) of women who underwent a successful pessary trial are still using a pessary.

Conclusions: Vaginal pessaries appear to be an appropriate treatment option for troublesome POP. These results show that patient's satisfaction is excellent. Regular maintenance and follow-up are essential, especially

as the occurrence of vaginal erosions is difficult to predict. Erosions do not seem totally preventable by the use of topical estrogen.

MP-04.22

Management and Outcomes of Complex versus Simple Female Urethral Diverticula

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Introduction and Objectives: Urethral diverticula (UD) are an uncommon presentation in urology, and their diagnosis and management can be challenging. Misdiagnosis and/or ineffective treatment can lead to significant complications. While appearing as small benign cystic masses, many UD can be larger and more complex, completely encircling the urethra. Complete excision of these may require mobilization of the urethra from under the pubis, and more challenging closure of the urethra. This study evaluates the management and outcomes of these complex cases.

Methods: A retrospective review of all patients presenting with UD between 2002 and 2011 was carried out. Complex cases were defined as those requiring circumferential dissection around the urethra, and those recurring after prior excision attempts.

Results: 21 cases were available for review, and of these 12 (57%) were considered complex. Mean follow-up was 17.5 weeks. 11 cases were complex based on being circumferential, and 2 were recurrences. Presentation, management and outcomes are detailed in Table 1. In the complex group, 6 (50%) had preoperative stress incontinence (SUI), and 2 of these had fascial slings placed at the time of surgery. Of the remaining 4 patients, 2 had persistent SUI postoperatively. No recurrences, voiding dysfunction, or fistulae have been observed.

Conclusions: Many patients presenting with urethral diverticula are found to have complex masses completely encircling the urethra. These cases require more extensive dissection to achieve complete excision, and tissue interposition is often required. The risk of de novo SUI is low, and for patients with pre-existing SUI the decision to perform concomitant sling placement must be individualized as it is not always necessary.

Table 1. MP-04.22. Presentation, Management and Outcomes of Simple Versus Complex Urethral Diverticula

	Simple (9)	Complex (12)
Age (mean)	41.7	42.8
BMI (mean)	28.1	30.2
Preoperative SUI	0	6 (50%)
Operative time (median; min)	83 (40-120)	180 (120-480)
Martius flap	0	12 (100%)
Catheter duration (mean; days)	3	6.3
Concomitant sling	0	2 (16.7%)
Postoperative de-novo SUI	1 (11.1%)	0
Postoperative persistent SUI	n/a	2 (33.3%)
Complications	0	Hematoma and wound dehiscence (1), transfusion 2 units PRBCs (1), labial skin blister (1)

BMI: body mass index; SUI: stress urinary incontinence; PRBCs: packed red blood cells.

MP-04.23**Developing a Multi-disciplinary Lower Urinary Tract Centre: the vesia [Alberta Bladder Centre] Experience**

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Introduction and Objectives: To deal with waitlists for lower urinary tract care, we have created vesia [Alberta Bladder Centre], a multi-disciplinary team composed of urology, uro-gynecology, pelvic floor physiotherapy, specialized family practitioners and nursing. Patients are triaged within the centre to see the earliest available appropriate care provider.

Methods: A review of the first year (2011) of practice at vesia [Alberta Bladder Centre] was conducted using all available sources of data. All practitioners share a common electronic medical record (EMR). Every patient encounter including phone calls is captured and available for review. The patient visits include: office visits, uroflow studies, ambulatory urodynamics, nursing assessments, pelvic floor physiotherapy. Visits to our website (vesia.ca) will also be captured since its launch.

Results: In 2011, 9434 patient visits were logged at vesia. 3498 patients were seen by a provider other than a urologist. Wait-list time for an office appointment with an urologist dropped from 9 months on average for most benign conditions to 2 months. Two specialty-trained primary care physicians working completed 910 patient encounters, while 359 assessments were performed by our "in house" pelvic health physiotherapist. Our full-time RN recorded 1830 patient encounters in 2011, including uroflow studies, urodynamics, teaching sessions and postoperative assessments. As a result, our in-hospital urodynamics wait-list fell from 10 months to 1 – 2 months within the first 6 months of opening.

Conclusions: vesia [Alberta Bladder Centre] is a new model to treat lower urinary tract disorders. In our first year of operation we were able to provide an additional 3498 patient assessments beyond our usual capacity as solo urology practitioners. The focus on patient education through websites, patient handouts, and on-site nursing care, and the ability to triage patients to the most appropriate practitioner makes this an attractive model.