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MP-07.01

Urinary Retention in Patients with Overactive Bladder Treated with Mirabegron Alone and in Combination with Solifenacin: The Results of Two Randomised, Double-blind, Phase II Studies

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Introduction and Objectives: Urinary retention (UR) and increased post voiding residual (PVR) volume, are reported in two Phase II studies: mirabegron (MIRA)+solifenacin (SOLI) combination therapy in patients with overactive bladder (OAB; NCT01340027; Study 1) and MIRA monotherapy in male patients with lower urinary tract symptoms (LUTS) and bladder outlet obstruction (BOO; NCT00410514; Study 2).
Methods: Study 1: 439 male and 867 female patients aged ≥18 years with symptoms of OAB for ≥3 months and PVR volume <150 mL were randomised to 1 of 12 treatment groups for 12 weeks: SOLI 2.5, 5 or 10 mg + MIRA 25 mg or 50 mg in combination; SOLI 2.5, 5 or 10 mg or MIRA 25 or 50 mg monotherapy; or placebo. Study 2: 200 male patients with LUTS and BOO (International Prostate Symptom Score ≥8, BOO Index ≥20), aged ≥45 years were randomised 1:1:1 to MIRA 50 or 100 mg or placebo for 12 weeks. In both studies the incidence of UR was assessed using a predefined MedDRA query, and change from Baseline (BL) to End of Treatment (EoT) in PVR volume was calculated.
Results: Study 1: UR (preferred term) was reported for 0.2% of patients (2/1306). Of which 1 case, receiving the 2.5+25 mg combination, was considered to be acute UR. Another 0.5% patients (6/1306) had increased residual urine volume (preferred term). Mean change from BL to EoT in PVR volume was similar across treatment groups although a dose response effect could not be excluded in the combination groups (Table 1). Study 2: UR was absent in all treatment groups except placebo (1/200) and MIRA 100 mg (1/200; Table 1). The increase in PVR volume at EoT was not statistically significant in the MIRA 50 mg group.
Conclusions: The β3-adrenoceptor agonist MIRA as monotherapy in male patients with LUTS and BOO, and in combination with the antimuscarinic SOLI in OAB patients, did not appear to increase the risk of UR.

Table 1. MP-07.01. Incidence of urinary retention and change from Baseline to End of Treatment in PVR volume

STUDY 1	PBO (n=81)	MIRA 25 mg (n=77)	MIRA 50 mg (n=78)	SOLI 2.5 mg (n=79)	SOLI 5 mg (n=156)	SOLI 10 mg (n=78)	SOLI 2.5 mg + MIRA 25 mg (n=149)	SOLI 2.5 mg + MIRA 50 mg (n=149)	SOLI 5 mg + MIRA 25 mg (n=144)	SOLI 5mg + MIRA 50 mg (n=153)	SOLI 10 mg + MIRA 25 mg (n=81)	SOLI 10 mg + MIRA 50 mg (n=81)
Incidence of urinary retention, n (%)	0	0	0	0	0	0	1 (0.7)	1 (0.7)	0	0	0	0
Incidence of acute urinary retention, n (%)	0	0	0	0	0	0	1 (0.7)†	0	0	0	0	0
Residual urine volume increased, n (%)	0	0	0	1 (1.3)	0	0	1 (0.7)	0	1 (0.7)	1 (0.7)	0	2 (2.5)
Mean baseline PVR volume (SD)	13.1 (19.6)	16.1 (22.0)	12.8 (20.0)	14.6 (22.2)	13.7 (23.2)	18.2 (27.9)	16.3 (24.0)	13.2 (24.4)	14.7 (23.5)	13.4 (21.5)	17.1 (29.3)	11.6 (15.1)
Mean change in PVR from baseline to EoT (SD)	–1.4 (21.3)	1.8 (23.5)	0.2 (21.7)	10.7 (49.5)	7.5 (34.8)	6.6 (31.0)	2.0 (28.9)	3.5 (25.2)	6.0 (32.4)	10.7 (32.8)	6.3 (31.8)	13.9 (32.9)

STUDY 2	Placebo (n=65)	Mirabegron 50 mg (n=70)	Mirabegron 100 mg (n=65)
Incidence of urinary retention, n (%)‡	1 (1.5)	0 (0)	1 (1.5)
Mean baseline PVR volume (SD)	60.7 (68.6)	54.1 (58.9)	52.6 (63.8)
Mean PVR volume at EoT (SD)	62.1 (65.3)	72.7 (99.0)	84.4 (121.3)
Mean adjusted change from baseline (SE)	0.55 (10.7)	17.9 (10.2)	30.8 (10.6)
P value*	—	0.2402	0.0459

*P values for comparison of each mirabegron group to the placebo group; adjusted for pooled centres and Baseline values
†60-year-old male patient who was also receiving tamsulosin required catheterization after 4 days of treatment, concomitant urinary tract infection occurred after day 5, and on day 9 treatment was discontinued; acute urinary retention was reported as resolved on day 5
‡Both episodes of urinary retention lasted approximately 1 day, and resolved without invasive intervention in the patient who received mirabegron 100 mg, but required catheterization in the patient who received placebo

MP-07.02

Rates of Urinary Retention in Mirabegron-treated Patients

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Introduction and Objectives: Mirabegron (MIRA) is the first β3-adrenoceptor agonist approved for treatment of overactive bladder (OAB). Rates of urinary retention (UR) were evaluated in several clinical trials of MIRA and a post-marketing (PM) case series analysis on all UR cases up to 06/30/2013.

Methods: Clinical trials were: 3 randomized placebo (Pbo)-controlled, 12-week, Phase III studies (046, 047, 074) and a 1-year, randomised, active-controlled, Phase III study (049) of MIRA 25 mg (074 only), 50 and 100 mg qd, with tolterodine extended release 4 mg (TOLT), as active control (046, 049); a Pbo-controlled study (060) of MIRA 50 or 100 mg qd in men with lower urinary tract symptoms and bladder outlet obstruction (BOO).

Results: In a pooled analysis of the 12-week trials, incidence of UR was low, and less in MIRA- (1/2736; <0.1%) than in Pbo- (7/1380; 0.5%) or TOLT- (3/495; 0.6%) treated patients. Rates of acute UR (AUR) were: 1/2736 (<0.1%) for MIRA 50 mg; 3/1380 (0.2%) for Pbo; and 3/495 (0.6%) for TOLT. There was no difference between treatment groups in change from baseline to final visit in postvoid residual volume. In Study 049, 1 patient in each of the MIRA 50 and 100 mg groups, and 3 in the TOLT group reported UR (none serious). AUR requiring catheterisation was reported by no patients on MIRA 50 mg and 1 each on MIRA 100 mg and TOLT. In Study 060, 2 patients (1 Pbo, 1 MIRA 100 mg) reported UR lasting 1 day; the case in the Pbo group, but not the MIRA 100 mg group, required catheterisation. In the PM analysis, UR events were reported for 189 of 253430 patients (0.075%). However, almost all presented with at least 1 confounding factor (e.g. age >70 yrs or concomitant BOO).

Conclusions: The incidence of UR was lower with MIRA than Pbo or TOLT in clinical trials. No association between MIRA and UR was found following a review of the global safety database, published literature and epidemiological data.

MP-07.03

Cystoscopic Patency and IPSS Improvement Are Independently Associated with Improved Urinary Quality of Life after Urethroplasty

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Objectives: Urethroplasty is a reliable and cost-effective treatment for urethral stricture. Typically, the treatment goal is a patent urethra with improvement in voiding function and patient quality of life (QoL). This study aims to prospectively assess the interrelation between IPSS change, urinary QoL and cystoscopic patency after urethroplasty.

Methods: Patients undergoing urethral reconstruction over a 2-year period were offered enrolment in a prospective study examining voiding function and urinary QoL after urethroplasty. Patients completed the IPSS questionnaire at preoperative baseline and at 6 months. IPSS scores were analyzed with a change of ≥4 points considered significant. Cystoscopy to assess urethral patency was performed at 6 and 18 months. Differences and associations were compared with Fisher's exact test and Pearson correlation.

Results: A total of 49 patients with completed follow-up. Urethroplasty significantly improved voiding function with a mean improvement in IPSS scores of 9.46 (16.3 to 6.8; p<0.001). Likewise urinary QoL was significantly improved with a mean decrease in bother of 3.14 (4.59 to 1.44; p<0.0001). Urethral patency (>16Fr) as assessed by cystoscopy at 6 and 18 months was 93.9%. Cystoscopic patency (surgeon success) correlated with an improvement in urinary quality of life (r=0.29, p=0.0467). Improvement in IPSS also correlated with an improvement in urinary QoL (r= 0.45, p = 0.001). Cystoscopic patency (surgeon success) however was not significantly associated with change in IPSS by Fisher's exact test (p=0.245) nor was there any significant correlation (p=0.330). Patients who did not experience significant improvement in IPSS scores tended to be younger (43.8 years) and have diverse stricture etiology.

Conclusions: In addition to establishing urethral patency, urethoplasty improves voiding function and urinary QoL. Both cystoscopic patency and improvement correlate with improved urinary QoL but do not correlate with each other. Cystoscopy and IPSS should not be used in isolation to define urethroplasty success.

MP-07.04

Repeat OnabotulinumtoxinA Treatment for Overactive Bladder and Urinary Incontinence: Interim Analysis of Long-term Efficacy and Safety Data With 2.4 Years' Follow-up

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Introduction: A pre-specified third interim analysis of a long-term extension study assessed the efficacy and safety of repeated onabotulinumtoxinA treatments for patients with overactive bladder (OAB) symptoms, including urinary incontinence (UI), who were inadequately managed by anticholinergic medications.

Methods: Patients who completed either of the two pivotal phase 3 studies could enter a 3-year extension study in which they received multiple onabotulinumtoxinA 100U treatments. Data were analyzed by treatment cycle. Change from baseline (BL) in OAB symptoms, proportions of patients with a positive response on the Treatment Benefit Scale (TBS; co-primary endpoint), health-related quality of life (HRQOL), duration of effect, adverse events (AEs), and clean intermittent catheterization (CIC) initiation were assessed.

Results: 829 patients entered this extension study; median follow-up was 126 weeks (2.4 years). Discontinuation rates due to AEs/lack of efficacy were low (4.5%/4.9%). Mean UI episodes/day (co-primary endpoint; BL=5.55) were reduced from BL at week 12 following repeat onabotulinumtoxinA treatment by -3.26, -3.70, -3.87, -3.20, and -3.22 (cycles 1-5, respectively). Improvements in other OAB symptoms and HRQOL (exceeding minimally important differences; ≥2.5X) were consistently observed with repeat onabotulinumtoxinA. Positive TBS responses were reported (74.0, 80.9, 80.4, 79.4, 86.1%). Median duration was 24.0, 31.6, 27.9, 24.3, and 23.9 weeks. Urinary tract infection was the most common AE, with no changes in the overall AE profile. CIC rates were 4.6, 4.0, 4.3, 4.6, and 2.9%.

Conclusions: Sustained improvements in OAB symptoms, patients' perception of their condition, and HRQOL were observed following repeated onabotulinumtoxinA treatment in patients with OAB and UI who were inadequately managed with anticholinergic medications. This third interim analysis revealed no new safety concerns with repeated onabotulinumtoxinA treatment.

MP-07.05

Determining the Best Incision for Bulbar Urethroplasty: A Comparison of Complications and Outcomes of Lambda and Midline Perineal Incisions

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Introduction and Objectives: Urethroplasty has evolved to become a highly effective treatment for urethral stricture. There is currently a paucity of literature comparing the types of incisions used for bulbar urethroplasty. The objective of this study is to compare the morbidity and outcomes of the lambda perineal incision (LPI) to the midline perineal incision (MPI).

Methods: A retrospective review was performed of 532 patients undergoing urethroplasty with an isolated perineal incision from August 2004

to June 2013. Exclusion criteria included involvement of the penile urethra, including penile, panurethral, or penobulbar strictures. Ninety-day wound complications were reported using the Clavien-Dindo classification. Patient demographics, surgical outcomes, and complication data were additionally collected.
Results: 489 patients had complete datasets available for analysis. A lambda incision was used in 389 patients, and a midline in 100. Mean patient age (44.5 years) and comorbidities were not different between the two groups. In the 90-day perioperative period, there were significantly more wound specific complications for the LPI compared to the MPI. Wound complications (any Clavien grade) occurred in 18.5% (72 patients) of LPIs compared to 9.0% (9 patients) of MPIs ($p<0.05$). The majority of wound complications were Clavien 1 complications (15.7% of LPIs (61 patients) vs. 8% of MPIs (8 patients), $p<0.05$). The primary complication driving this difference was wound edge separation, which occurred in 10.5% of LPIs (41 patients) compared to 0% of MPIs ($p<0.001$). There were no significant differences in Clavien 2 or higher wound complications between the two groups (3.1% of LPIs (12 patients) vs. 1% of MPIs (1 patient), $p=0.5$). Additionally, there were otherwise no significant differences in incisional pain, wound abscesses, wound infection, or wound complications requiring reoperation between the LPI and MPI groups ($p=0.7$). Urethroplasty success as measured by cystoscopic patency was not different between the two groups (95.4% of LPIs vs. 100% MPIs, $p=0.09$).
Conclusions: The midline perineal incision when used for urethroplasty has less wound specific complications than a lambda incision with no identifiable impact on urethroplasty outcomes.

MP-07.06

Long-term Rates of Urinary Incontinence Following Treatment of Localized Prostate Cancer: A Systematic Review and Meta-analysis

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Introduction and Objectives: Following surgery for localized prostate cancer, the rates of urological side effects, including urinary incontinence (UI), vary widely. This may be a result of the varying definitions used to describe UI. Considering the long life expectancy following treatment of localized prostate cancer, it is important to understand the long-term side effects of treatment. The primary objective of this study was to determine the rate of UI 3 years following surgery for localized prostate cancer. The secondary objective was to assess for differences in the incidence of this side effect based on subjective and objective definitions of UI.
Methods: MEDLINE, EMBASE and the Cochrane Central Register of Controlled Trials were searched for eligible contemporary studies (2009 to 2013). Randomized controlled trials and observational studies were included. The primary outcome was UI three or more years after surgery for localized prostate cancer. Meta-analysis was conducted using a random effects model to pool the proportion of patients with UI and 95% CIs were calculated. The rate of UI based on a subjective versus objective definition was assessed in a subgroup analysis.
Results: Fourteen studies met the inclusion criteria. The pooled rate of UI post-prostatectomy was 9.2% (95% CI 4.3 to 18.6). The pooled rate of UI did not change when 2 studies of laparoscopic and/or robotic prostatectomy were excluded (9.4% [95% CI 4.1 to 20.0]). When UI was defined subjectively, the pooled rate of UI was 15.2% (95% CI 4.7 to 39.5) compared to 7.0% (95% CI 2.6 to 17.2) when UI was defined objectively.
Conclusions: Overall, 1 in every 11 patients report UI following surgery for localized prostate cancer. The rate varies from 1 in 7 with subjective definition to 1 in 14 with objective definition.

MP-07.07

Urethral Transection Does Not Influence Erectile Function after Anterior Urethroplasty: A Prospective Analysis

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Objectives: Urethral Reconstruction is an effective therapy for urethral stricture of diverse etiologies. Urethral transection during urethroplasty poses a theoretical risk of erectile dysfunction. The purpose of this study is to prospectively evaluate erectile function post urethral reconstruction and to examine the effect urethral transection on erectile function.
Methods: Patients undergoing anterior urethroplasty completed International Index of Erectile Function (IIEF) questionnaires at baseline and postoperatively at 6 months. The Erectile Function (EF) domain of the IIEF was utilized to assess erectile function. A significant decline was defined as a 5-point decrease in EF domain score. Overall mean change in EF domain scores were compared using the paired t-test and Fishers exact test.
Results: A total of 46 anterior urethral reconstructions with complete baseline and 6 month postoperative IIEF scores. The average age was 47 years with a mean stricture length of 3.4 cm. Twenty-two urethroplasties involved complete transection of the urethra while the other 24 had various non-transecting techniques. Mean baseline and postoperative EF domain scores were 16.85 and 17.17 respectively ($p=0.82$). Overall, at a minimum of 6 month follow-up the incidence of adverse change in EF (5 point decrease in EF domain score) was 15.2% (7). Urethral transection did not significantly affect the occurrence of erectile dysfunction ($p=0.69$). Stricture location (bulbar versus penile) were not found to have a significant impact on EF postoperatively ($p=0.29$).
Conclusions: Urethroplasty can result in a decline in erectile function in some patients but overall is associated with minimal adverse change in erectile function. Urethral transection does not affect the occurrence of erectile dysfunction 6 months after urethroplasty.

MP-07.08

A Single Centre Contemporary Analysis of the Utility of Retrograde Urethrogram in the Management of Pelvic Fracture Urethral Injuries

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Objectives: Initial management of Pelvic Fracture Urethral Injury (PFUI) calls for assessment with retrograde urethrogram (RUG) then either urethral realignment or placement of a suprapubic catheter with delayed reconstruction. We aim to assess the utility of RUG for the management of these injuries and examine management strategies employed at our Level 1 Trauma Center.
Methods: The Alberta Trauma Registry is a comprehensive database of all major traumas at the University of Alberta Hospital. The database from 2001-2013 was queried for all traumas with an Injury Severity Score (ISS) > 12, injury code for pelvic fracture, and text containing "bladder" or "urethra". Follow-up was cystoscopy and retrograde urethrogram. Failure was defined as patients developing stenosis requiring surgical intervention.
Results: 26 patients were identified with pelvic fracture urethral injuries. Mean age was 36±13 years and mean ISS score was 26.7±7.6. 77% (20/26) of patients had RUG performed at initial assessment. 21 patients had complete disruption, and 5 had partial disruption. 12 patients were managed with suprapubic catheter, and 14 with placement of an aligning catheter with no significant difference in ISS between the two groups. Only 2 patients had successful unassisted catheter insertion. Of the 6 patients who did not receive RUG, 5 (83%) had complete disruption and required operative insertion suprapubic catheter insertion. Urethral stenosis occurred in 6 realignment cases (43%), and 11 (92%) with suprapubic catheter ($p<0.05$).
Conclusions: Patients sustaining PFUI have a significant severity score, but this does not typically influence urologic management. Nearly all patients without RUG had high-stage injuries, were very unlikely to have blind aligning catheter placement and typically require suprapubic catheter

insertion. RUG does not significantly alter management, and definitive diagnosis and management of PFUI occurs at time of endoscopy.

MP-07.09

The Oral Mucosa Graft Harvest Preferences of Reconstructive Urologists

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Objectives: The oral mucosa graft (OMG) has become the most commonly used tissue source for urethroplasty. Despite being widely accepted as a tissue source there is no consensus on graft harvest technique. This study aims to better describe the global practice of oral mucosal graft harvest.

Methods: An online survey examining oral mucosal harvest preference techniques of members of the Society of Genitourinary Reconstructive surgeons was conducted via email from September to November 2013. Respondents were surveyed with a total of twelve questions examining their urethroplasty practice as well as preferences for intubation, graft site/size, exposure, donor site closure and graft shape.

Results: There was a response rate of 32.2% (n=84). The majority of respondents (91.7%) perform urethroplasty using OMGs and 46.1% perform over 40 urethroplasties per year. Of those performing urethroplasty 81.9% harvest their own grafts. Urologists not harvesting their own OMGs tend (66.6%) to use maxillofacial or ENT surgeons for graft harvest. 21.5% of surgeons use nasotracheal intubation for unilateral graft harvest while 37.7% routinely use nasotracheal intubation for bilateral graft harvest. Most urologists (84.6%) prefer the cheek as the donor site over lip (14.1%) or lingual (1.2%) locations. Over half (51.3%) of respondents use a dedicated retractor for graft harvest and 59.0% of respondents routinely leave the donor site open. Graft shape preferences were 60.8% for a rectangular shape and 30.8% for ovoid. Most urologists (79.7%) tailor the graft dimensions based on the stricture length.

Conclusions: Although there is no definite consensus on oral mucosal graft harvest technique most reconstructive urologists harvest their own grafts, prefer the cheek as a donor site, leave the donor site open, prefer a rectangular graft shape and tailor graft dimensions according to stricture length.

MP-07.10

Artificial Urinary Sphincter Erosion after Radical Prostatectomy in Patients Treated with and without Salvage Radiation

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Introduction: Over the last 10 years, there has been an increase in the number of patients undergoing radiation after radical prostatectomy (RP). Significant stress incontinence after RP is common and the artificial urinary sphincter (AUS) is the gold standard of treatment. Our objective was to assess if radiation after RP has increased the rate of erosion and infection in men who have had an AUS in the last 10 years.

Methods: We retrospectively examined 118 patients from December 2001-January 2012 who underwent a RP with or without postoperative radiation and subsequently had an AUS implanted. We divided the patients into two cohorts, those with AUS implantation between December 2001-December 2006 (n=36) (Group 1) and between January 2007-January 2012 (n=82) (Group 2). We reviewed all patient records for age, cuff size, history of postoperative radiation, previous incontinence surgery, revisions and complications (erosion/infection).

Results: The mean age was similar between groups, 67 years in Group 1 (range: 52-82) and Group 2 (range: 50-82) (p=0.980). The number of patients treated with postoperative radiation was similar between Groups (36% vs. 32%, p=0.640, respectively). There was no difference in the incidence of erosion between Groups 1 and 2 in those treated with and without radiation (p=1.0 and p=0.87, respectively). The incidence of infection was similar between Groups 1 and 2 in patients treated with and without radiation (p=0.305 and p=0.359, respectively). However, the overall relative risk of erosion was significantly higher in those who had radiation compared to those who did not (RR 4.05, 95%CI 1.1-15.3).

Conclusions: Over the last 10 years, there has not been an increase in the number of patients undergoing AUS after RP and radiation at our centre. During this time, the incidence of erosion and infection has not increased. However, as documented in past reports, the relative risk of erosion remains higher in patients who have had radiation.

MP-07.11

Building an Innovative Delivery Model for Overactive Bladder (OAB): A Multidisciplinary Approach

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Introduction and Objectives: Successful treatment of OAB is dependent on accurate diagnosis, patient education, behavioural modifications, physical therapies, and the ability to offer appropriate medical and surgical interventions when appropriate. This can be difficult to provide in a conventional urological setting. In 2011, vesia [Alberta Bladder Centre] was developed as a multidisciplinary clinic for lower urinary tract disorders, including OAB. The new delivery system aims to ensure: 1) timely access, 2) reduce the cost on the healthcare system, and 3) reduce unnecessary diagnostics. The purpose of this study is to describe and report on a new model for delivering OAB care.

Methods: To assess the effect of the vesia clinic on OAB care, a retrospective analysis of the electronic record was undertaken. A comparison of one full year of OAB visits before and after the implementation of the vesia OAB model was performed.

Results: The year prior to the vesia delivery model being implemented, the clinic saw 150 unique patients for 173 OAB-related visits (average frequency of visits per patient = 1.15). On average, these patients cost the healthcare system $142.25 (all costs in 2012 dollars). Ninety-one of (60%) these patients underwent a cystoscopy. The year after the vesia delivery model was implemented, the clinic saw 1,035 unique patients for 1,776 OAB-related visits (average frequency of visits per patient = 1.72). On average, these patients cost the healthcare system $112.67. Three hundred thirteen (30%) of these patients underwent cystoscopy. Overall, the vesia model increased OAB consults by nearly 900 unique patients, increased the frequency of visits by 49% while decreasing the average patient cost by 21%.

Conclusions: The growing demand for OAB care necessitated the development of an innovative delivery model. Based on our analysis, the vesia OAB model represents an approach capable of increasing access for OAB care, while reducing overall costs to the healthcare system.

MP-07.12

The Devastated Urethra: Our Experience in the Management of Refractory Post-prostate Therapy Urethral Strictures

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Introduction and Objectives: Urethral strictures may develop from the treatment of both benign and malignant prostate etiologies and can be challenging to manage. We reviewed our local experience in managing refractory post-prostate therapy urethral strictures (PPUS) via a novel treatment pathway.

Methods: We performed a retrospective analysis of all patients at our Centre diagnosed with a urethral stricture following various prostate therapies between May 2008 and October 2013. Multiple variables were assessed, including: initial diagnosis, method of stricture treatment and number of treatments. All patients underwent initial endoscopic management followed by a standardized self-catheterization program developed at our Centre.

Results: Forty-six patients were identified with initial diagnoses of prostate cancer in 28 (61%) and benign prostatic hyperplasia (BPH) in 18 (39%). All patients underwent initial endoscopic management [direct visual internal urethrotomy (DVIU) or transurethral incision of bladder neck (TUIBN)] by us (38) and/or the referring urologist (8). In total, a mean of 1.50 (95%CI 1.22-1.78) endoscopic procedures were performed per patient. 41 (89%)

patients were stabilized following endoscopic resection combined with a standardized self-dilation program. Five (11%) patients were refractory to the above measures and required more invasive treatment: 2 (4.3%) cystectomy with ileal conduit, 2 (4.3%) open vesicourethral anastamotic revision, 1 (2.2%) YV-plasty. All three patients who underwent open bladder neck reconstructive procedures remain with stable outlets at cystoscopic follow-up (6-48 months).
Conclusions: In our large cohort of refractory PPUS, we have demonstrated a successful outcome in the majority of cases with minimal operative intervention. In select cases, a variety of reconstructive surgical procedures may be required. These observations support our novel simplified approach to these refractory patients.

MP-07.13
Intravesical OnabotulinumtoxinA (BTA) for Bladder Dysfunction in "Real World" Clinical Practice
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Introduction and Objectives: BTA was approved for use in North America for refractory neurogenic detrusor overactivity (NDO) in 2012, and for idiopathic detrusor overactivity (IDO) in Canada in October 2013. BTA remains off-label for refractory bladder pain syndrome (BPS). Few studies have been published evaluating the long-term use of BTA. We report our long-term clinical experience with BTA for refractory bladder storage dysfunction (NDO, IDO, BPS) at our institution, with attention to baseline data, growth in uptake, and persistence with therapy. This represents the largest report of single centre patients.
Methods: A retrospective chart review of all patients injected between July 20, 2009 (when charts became available via electronic record) and October 30, 2013 was performed.
Results: Overall a total of 1256 injections were performed on 433 unique patients with mean age of 57 years (19 -- 91). The majority of patients (79%) were injected under local anesthesia only. The number of BTA treatments ranged from 1 to 14. Sixty-four percent of patients have received more than 1 injection while 41% have received 3 or more, and 14% 6 or more. Overall, 36% discontinued BTA at any time due to attrition, lack of effect, or change in bladder management. In 2010, 210 injections (18/month) were performed, while 262 were done in 2011 (22/month), and 330 in 2012 (28/month). In the first 10 months of 2013, 370 injections have been performed (31/month). Indications included NDO in 51%, IDO in 40% and BPS in 6%. For the NDO group, 60% were female, compared to 80% of the IDO and 96% of the BPS groups. In the NDO group, 28% had spinal cord injury (SCI), 34% multiple sclerosis (MS), and 38% had other causes. Ten percent of the entire cohort initiated clean intermittent catheter (CIC), 26% already performed CIC, and 17% had indwelling catheters or suprapubic tubes. There were no serious adverse events.
Conclusions: Intravesical BTA is a well-tolerated and safe. Popularity of BTA for patients with bladder dysfunction is growing. A significant number of patients initiated CIC in our blended cohort. Persistence with treatment is high, at 57%, despite the challenging nature of the patient population.

MP-07.14
Monotherapy versus Combination Therapy with Antimuscarinics in Patients with Persistent LUTS Storage Symptoms Refractory to Alpha-adrenergic Treatment: Patterns of Adherence and Persistence
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Introduction and Objectives: Benign prostatic hyperplasia (BPH), with lower urinary tract symptoms (LUTS), is one of the most a common age-related disorders affecting men and is often accompanied by storage symptoms. The objective of this study was to assess persistence and adherence of LUTS/BPH patients on alpha blocker (AB) monotherapy compared to those using combination alpha blocker plus antimuscarinic (AM) therapy.
Methods: This was a retrospective analysis of anonymous patient longitudinal claims data. All patients who had claims for any of 5 AB medications and 6 AM agents during an index period from April 1, 2011 to March 31, 2012 were included. Persistence to LUTS/BPH AB medication was assessed using a standard definition of 3x 30 day supply. Exposure was calculated as the proportion of days patients took the prescribed AM medication while on AB therapy during the observation period.
Results: Patients on LUTS/BPH AB monotherapy remained on their medication for an average of 225 days compared with 263 days for those on AB/AM combination therapy ($P<0.0001$). At 1 year, 49.4% of patients taking AB monotherapy and 57.5% of those taking AB/AM combination therapy were still taking their prescribed medication ($P<0.0001$). The majority of patients on AB monotherapy stopped treatment in the first 30 days of the study period whereas those on AB/AM combination therapy tended to discontinue later. Surprisingly, patients with the highest exposure to their AM medication had the lowest persistence to their LUTS/BPH AB medication, suggesting they might have had more significant storage symptoms and greater response to the AM medication.
Conclusions: This is the first study to report that patients taking an AM medication in combination with their LUTS/BPH AB medication had greater persistence to LUTS/BPH treatment over a 1-year period. The addition of specific AM medications may offer LUTS/BPH patients benefits that translate into better persistence with AB therapy.

MP-07.15
Urodynamic and Cystoscopy Findings in Men Less Than 50 Years of Age with Lower Urinary Tract Symptoms
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Introduction and Objectives: In men over 50 years of age, lower urinary tract symptoms (LUTS) are often consistent with presumed BPH. However, in men < 50 years LUTS may have different underlying etiologies, but misdiagnosed as chronic prostatitis or prostadynia without objective evidence. These men may receive prolonged periods of empiric therapy without improvement. Through correlation of presenting urinary symptoms with urodynamic and cystoscopy findings we aimed to examine if such investigations are helpful in identifying the underlying etiology of LUTS.
Methods: Retrospective analysis was performed on 49 men who underwent urodynamic studies and cystoscopy for bothersome LUTS. Patients with neurological disease, urethral stricture, urogenital malignancies, acute urinary tract infection, and acute prostatitis were excluded. Seventeen patients unable to void or with incomplete data were also excluded. Chi-Square and Fisher's Exact Test were applied.
Results: Median patient age was 43 (range, 19-49 years). Storage symptoms were identified as 84% frequency, 61% urgency, 55% nocturia, and 10% urge urinary incontinence. Voiding symptoms were identified as 49% hesitancy, 55% impaired flow, 20% incomplete emptying, and 47% post void dribble. Cystoscopy revealed 47% elevated bladder neck, and 33% glomerulations. Urodynamic studies identified 29% detrusor overactivity, 41% functional outlet obstruction. Anatomical bladder outlet obstruction

was identified in 22%. Overall, 59% of patients were diagnosed with overactive bladder, 76% voiding dysfunction, 4% bladder outlet obstruction, and 22% painful bladder syndrome. In 11 (22%) men, underlying LUTS were multifactorial.
Conclusions: Urodynamic studies and cystoscopy both appear helpful in identifying the underlying cause of bothersome LUTS in young men.

MP-07.16

Transcorporal Artificial Urinary Sphincter for Post-prostatectomy Incontinence: Intermediate Term Outcomes from the Alberta Experience

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Introduction and Objectives: The artificial urinary sphincter (AUS) is still the existing standard for surgical treatment of post-prostatectomy incontinence (PPI). However, implanting an AUS in the setting of previous failed AUS, urethroplasty, or radiation may be challenging. Transcorporal AUS (TCAUS) is a salvage technique that can be used in this population. The aim of our study is review the intermediate term outcomes of TCAUS at our institution.
Methods: We performed a retrospective review of patients undergoing TCAUS for PPI over a 5-year period by a single surgeon. The primary outcome was continence (defined by requiring ≤1 pad post-operation). Secondary outcomes included patient satisfaction, improvement, and complication rates.
Results: Twelve patients with a mean age of 71.2 years were identified. All patients had high-risk features including previous eroded AUS (5), previous urethroplasty (6), radiation therapy (3), or urethral atrophy (1). Mean duration of postoperative catheterization was 2.6 days, with a mean hospitalization of 2.8 days. Mean length of follow-up was 19.1 months. Continence was achieved in 10/12 (83.3%) and the mean change in continence pads from pre to post operation was 6.5. Urethral erosion, requiring explantation, occurred in 2/12 (16.7%). Mean length of follow-up was 19.1 months. Symptom improvement was demonstrated in 100% (12/12) with an overall satisfaction of 83.3% (10/12).
Conclusions: TCAUS is a successful salvage procedure for patients with PPI complicated by pelvic radiation, previous failed AUS, and/or prior urethroplasty. Based on intermediate term outcomes, successful continence is achieved in 83% with an acceptable rate of complications.

MP-07.17

Effect of the β3-adrenoceptor agonist, mirabegron, on Quality of Life in Older Patients with Overactive Bladder: A Post-hoc Analysis of Pooled Data from 3 Randomised Phase 3 Trials

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Objectives: Post-hoc analyses of data from 3 randomised, double-blind, placebo-controlled, 12-week Phase III trials (Studies 046, 047, 074) in patients with symptoms of overactive bladder (OAB) were conducted to evaluated the effect of the β3-adrenoceptor agonist, mirabegron (MIRA; 25 mg) [Study 074] and 50 mg [pooled data] once-daily), on measures of health-related quality of life (HRQoL) in the subset of patients aged ≥65 years.
Methods: Change from Baseline (BL) to Final Visit (FV) in outcome measures (Table 1) for the Full Analysis Set-Incontinence (FAS-I) population are presented for MIRA 25 mg and 50 mg.
Results: There were 97 and 99 patients aged ≥65 years in the placebo and MIRA 25 mg FAS-I groups of Study 074, and 345 and 355 patients aged ≥65 years in the pooled placebo and MIRA 50 mg FAS-I groups. Patient demographic and baseline characteristics were similar across groups. MIRA 25 mg and 50 mg produced improvements from BL to FV, that were numerically larger than seen with placebo, in symptom bother score; total HRQoL, and its subscales of coping, concern, social and sleep; and patient perception of bladder condition (PPBC). Numerically greater improvements vs. placebo were seen with MIRA 50 mg than MIRA 25 mg on all outcomes except PPBC. The Minimally Important Difference (a 10-point change in total HRQoL, its subscales and symptom bother, and a 1-point change in PPBC) was reached on all outcomes except the social subscale of HRQoL (MIRA 25 mg and PPBC (both MIRA doses). MIRA 25 and 50 mg were well-tolerated: adverse events (AEs) such as dry mouth and constipation were few. There were no AE reports of confusion in any group.
Conclusions: Treatment with MIRA 25 mg and 50 mg leads to an improvement in measures of HRQoL in patients aged ≥65 years with symptoms of OAB, consistent with its favourable efficacy and tolerability profile in this patient population.

Table 1. MP-07.17. Effects of mirabegron 25 mg (Study 074) and mirabegron 50 mg (pooled data) vs placebo on measures of quality of life in patients aged ≥65 years (FAS-I).

	Pooled analysisa		Study 074a	
	Placebo	Mirabegron 50 mg	Placebo	Mirabegron 25 mg
Symptom bother	*n=320*	*n=322*	*n=95*	*n=99*
Adjusted Mean Change from Baseline to Final Visit (SE), 95% CI	-13.22 (1.088) (-15.35,-11.09)	-21.60 (1.089) (-23.73, -19.46)	-14.56 (2.027) (-18.54, -10.59)	-19.34 (1.972) (-23.21, -15.47)
Adjusted difference vs placebo, mean (SE), 95% CI	na	-8.38 (1.533) (-11.38, -5.37)	na	-4.78 (2.824) (-10.32, 0.77)
Total HRQoL	*n=319*	*n=321*	*n=96*	*n=99*
Adjusted Mean Change from Baseline to Final Visit (SE), 95% CI	12.01 (0.977) (10.10, 13.93)	17.67 (0.978) (15.76, 19.59)	11.74 (1.782) (8.24, 15.24)	15.18 (1.737) (11.77, 18.59)
Adjusted difference vs placebo, mean (SE), 95% CI	na	5.66 (1.375) (2.97, 8.36)		3.43 (2.476) (-1.43, 8.29)
Coping	*n=320*	*n=321*	*n=96*	*n=99*
Adjusted Mean Change from Baseline to Final Visit (SE), 95% CI	14.01 (1.164) (11.73, 16.29)	20.30 (1.168) (18.01, 22.59)	13.72 (2.134) (9.53, 17.91)	18.65 (2.081) (14.56, 22.73)
Adjusted difference vs placebo, mean (SE), 95% CI	na	6.29 (1.641) (3.07, 9.51)	na	4.93 (2.972) (-0.91, 10.76)
Concern	*n=320*	*n=323*	*n=96*	*n=99*
Adjusted Mean Change from Baseline to Final Visit (SE), 95% CI	14.16 (1.128) (11.95, 16.37)	21.50 (1.128) (19.29, 23.71)	13.82 (2.080) (9.74, 17.91)	18.19 (2.037) (14.20, 22.19)
Adjusted difference vs placebo, mean (SE), 95% CI	na	7.34 (1.585) (4.23, 10.45)	na	4.37 (2.894) (-1.31, 10.05)
Social	*n=321*	*n=321*	*n=96*	*n=99*
Adjusted Mean Change from Baseline to Final Visit (SE), 95% CI	8.28 (0.868) (6.58, 9.98)	10.13 (0.873) (8.41, 11.84)	7.86 (1.550) (4.82, 10.90)	8.81 (1.510) (5.85, 11.78)
Adjusted difference vs placebo, mean (SE), 95% CI	na	1.84 (1.224) (-0.56, 4.24)	na	0.95 (2.154) (-3.28, 5.18)
Sleep	*n=321*	*n=323*	*n=96*	*n=99*
Adjusted Mean Change from Baseline to Final Visit (SE), 95% CI	10.33 (1.107) (8.16, 12.50)	15.93 (1.109) (13.76, 18.11)	10.18 (2.083) (6.09, 14.27)	12.37 (2.030) (8.39, 16.36)
Adjusted difference vs placebo, mean (SE), 95% CI	na	5.61 (1.562) (2.55, 8.67)	na	2.19 (2.907) (-3.52, 7.90)
PPBC	*n=318*	*n=318*	*n=88*	*n=95*
Adjusted Mean Change from Baseline to Final Visit (SE), 95% CI	-0.55 (0.062) (-0.67, -0.43)	-0.88 (0.062) (-1.00, -0.76)	-0.44 (0.120) (-0.67, -0.20)	-0.86 (0.115) (-1.08, -0.63)
Adjusted difference vs placebo, mean (SE), 95% CI	na	-0.33 (0.087) (-0.51, -0.16)	na	-0.42 (0.166) (-0.75, -0.09)

CI, confidence interval; FAS-I, Full Analysis Set-Incontinence (all randomised patients who received ≥1 dose of study drug, and had micturition measurements and ≥1 incontinence episode in the 3-day micturition diary at Baseline and micturition measurements in ≥1 post-Baseline diary); HRQoL, Health-related Quality of Life; na, not applicable; PPBC, Patient Perception of Bladder Condition; SE, standard error

Symptom bother assessed using the 8 items that comprise the symptom bother scale of the 33-item Overactive Bladder Questionnaire (OAB-q); total HRQoL assessed using the remained 25 items of the OAB-q. Scores for the Total HRQoL scale and subscales are transformed onto a 0 to 100 scale with a score of 0 indicating worst severity; scores for symptom bother are transformed onto a 0 to 100 scale with a score of 100 indicating worst severity; PPBC is assessed on a 6-point scale, ranging from 1 ["My bladder does not cause me any problems at all"] to 6 [My bladder condition causes me many severe problems"].

Adjusted mean change from baseline and corresponding 95% CI are generated from the ANCOVA model with treatment group, gender, age group (<65 or≥ 65 years), study and treatment by age group interaction as fixed factors and baseline as a covariate for the pooled analysis and an ANCOVA model with treatment group, gender, age group, geographical region and treatment by age group interaction as fixed factors and baseline as a covariate for Study 074. Difference of the adjusted mean is calculated by subtracting the adjusted mean of placebo from that of active treatment.

aStudies 046, 047 and 074; clinicaltrials.gov identifiers NCT00689104; NCT00662909 and NCT00912964 respectively