

Moderated Poster Session 1: BPH/LUTS/Inflammation

June 29, 2009, 1630–1730

MP-1.01

Are patients on 5- α reductase inhibitors appropriately referred to urology in the province of Quebec?

Yafi F, Aprikian A, Tanguay S, Kassouf W

McGill University Health Centre, Division of Urology, Montréal, QC

Introduction and Objective: Benign prostatic hyperplasia (BPH) is one of the most common urological complaints encountered by general practitioners (GPs). 5- α -reductase inhibitors (5-ARI) are new synthetic agents currently used in its management. We sought to investigate practice patterns, indications for urological consultations and level of awareness by GPs who treat patients with 5-ARIs.

Materials and Methods: We conducted a survey which was mailed in both French and English to over 8000 registered GPs in Quebec. The questions covered each physician's BPH patient load, their preferred management plans for BPH, their knowledge of and comfort with 5-ARI, the type of 5-ARI they most often prescribed and clinical scenarios related to their use, when to refer to a urologist, and their role in prostate cancer chemoprevention.

Results: Of the surveys mailed, 520 (6.5% response rate) were returned. Mean years from graduation was 24.8 (median 25, range 3–58) years with more than 90% of responders indicating they see less than 20 patients per week with BPH and 1–5 new consults for lower urinary tract symptoms. Overall, 34.1% of GPs initiated 5-ARI therapy themselves while the rest were renewals initiated by the urologist. Among GPs, 20% and 12% use 5-ARI alone and in combination as first-line therapy for BPH. Once on therapy, 73% do not refer to urology if PSA does not decline after 6–12 months of 5-ARI treatment. Only 7% correlated 5-ARI with more aggressive prostate cancer. Interestingly, 39.1% would not advocate its use in chemoprevention for prostate cancer in asymptomatic patients regardless of the percent risk reduction.

Conclusion: There still is a preference among GPs to use α -blockers over 5-ARI in the management of BPH as well as a hesitancy to use them as preventative measures for prostate cancer. Importantly, there is a lack of awareness of the effect of 5-ARIs on PSA kinetics and reluctance to refer to a urologist in the face of stable borderline PSA despite 5-ARI therapy. Further education among GPs needs to be instilled about these drugs in order to safely optimize their usage at the primary care level and to avoid delays in cancer detection.

MP-1.02

Does the learning curve affect the safety and efficacy of GreenLight HPS laser photoselective vapourization prostatectomy?

Wong C¹, Spaliviero M¹, Araki M²

¹University of Oklahoma Health Sciences Center, Oklahoma City, OK, USA; ²Okayama University Graduate School of Medicine, Okayama, Japan

Introduction and Objective: We evaluate the impact of the learning curve on the safety and efficacy of GreenLight HPS laser photoselective vapourization prostatectomy (PVP) for treatment of lower urinary tract symptoms (LUTS) secondary to benign prostatic hyperplasia (BPH).

Materials and Methods: We prospectively evaluated our initial laser PVP experience on patients with LUTS secondary to BPH. Only patients without prostate adenocarcinoma, urethral strictures, bladder tumours, prior prostate surgery, urinary retention, diabetes mellitus and neurogenic bladder were included for study. Patients were stratified into initial (I) and latter (II) halves of the cohort. Transurethral PVP was systematically performed using a GreenLight HPS side-firing laser system. Voiding trials were performed 2 hours postsurgery; if unable to void, a urethral catheter was

replaced. American Urological Association Symptom Score (AUASS), maximum flow rate (Qmax) and postvoid residual (PVR) were measured preoperatively and at 1, 4, 12, 24 and 52 weeks postsurgery.

Results: Eighty-two consecutive patients were identified (41 [I] and 41 [II]), all of whom had outpatient procedures. The patient age (67, standard deviation [SD] 10, v. 64, SD 9, yr, $p = 0.124$), American Society of Anesthesiologists risk score (2.1, SD 0.6, v. 2.2, SD 0.7, $p = 0.689$) and prostate volume (74, SD 45, v. 66, SD 36, mL, $p = 0.354$) were comparable between the groups. Mean laser time (13, SD 8, v. 12, SD 7, min, $p = 0.634$), operating time (31, SD 21, v. 30, SD 21, min, $p = 0.902$) and energy usage (86, SD 56, v. 85, SD 56, kJ, $p = 0.930$) were similar between the groups. AUASS, Qmax and PVR values showed significant improvement within each group ($p < 0.05$) (Table 1). The majority of

Table 1. MP-1.02

AUSS	Preoperation	1 wk	4 wk	12 wk	24 wk	52 wk
Group I, mean (SD) [n]	20 (6) [41]	9 (4)* [40]	7 (4)* [39]	5 (3)* [29]	4 (2)* [25]	3 (2)* [20]
Group II, mean (SD) [n]	24 (6) [41]	6 (3)* [32]	5 (2)* [34]	4 (2)* [26]	4 (2)* [16]	4 (2)* [9]
<i>p</i> value	0.019	0.002	0.002	0.489	0.935	0.560
Qmax, mL/s						
Group I, mean (SD) [n]	10 (3) [41]	21 (7)* [40]	23 (8) [39]	24 (8)* [29]	23 (7)* [25]	24 (9)* [20]
Group II, mean (SD) [n]	9 (5) [41]	23 (6)* [32]	23 (7)* [34]	23 (6)* [26]	21 (5)* [16]	22 (4)* [9]
<i>p</i> value	0.283	0.207	0.988	0.444	0.254	0.460

patients were catheter-free at discharge (66% v. 66%, $p = NS$). No urethral strictures or urinary incontinence were noted. The incidence of urinary retention, hematuria, urinary tract infection and bladder neck contracture were low and did not differ between the groups.

Conclusion: Our experience suggests that the learning curve has little effect on the safety and efficacy of GreenLight HPS laser PVP if a systematic approach is routinely employed.

MP-1.04

GreenLight laser TURP versus electrocautery TURP: a retrospective, multisurgeon cohort study from a community hospital in Canada

Schultz T¹, Mador D¹, Hobart M¹

¹Division of Urology, University of Alberta, Edmonton, AB

Introduction and Objective: To compare outcomes and complications of GreenLight laser TURP to electrocautery TURP with the primary outcome being blood transfusion rate and the secondary outcomes being operating time and length of stay.

Materials and Methods: Consecutive GreenLight laser TURPs were retrospectively reviewed and compared with electrocautery TURPs by

complete chart review and electronic health record. All operations occurred at the Misericordia Hospital in Edmonton, Alta. Baseline characteristics of consecutive patients included age, ASA score, preoperative PSA, TRUS prostatic volume, preoperative HgB and preoperative Cr. Primary outcome was the transfusion rate and secondary outcomes were operating time and length of hospital stay. The Student *t* test and Fisher exact tests were used to compare the results between the 2 groups.

Results: Electrocautery TURPs (*n* = 584) from January 2005 to October 2006 were compared with GreenLight laser TURPs (*n* = 152) from September 2007 to December 2008. Median follow-up time was 7 months. Baseline characteristics in the electrocautery TURP cohort were mean age of 71 years, and ASA score of 2.3, which was not significantly different (*p* = NS) than the GreenLight laser TURP cohort with a mean age of 71 and mean ASA score of 2.4. There was a significant difference with preoperative PSA (8.9 v. 5.5), preoperative HgB (143 v. 140) and preoperative Cr (109 v. 105) with all values being lower in the GreenLight TURP cohort (*p* < 0.01). The primary outcome of transfusion rate was significantly higher with electrocautery TURPs being 9.3% compared with 0% in GreenLight TURPs (*p* < 0.01). Secondary outcomes were also significantly different with operating time of GreenLight TURPs being longer (50.5 v. 37.7 min, *p* < 0.01) and length of stay being shorter (1.1 v. 1.6 d, *p* < 0.01). Thirty-five percent of GreenLight laser TURPs were performed as outpatient surgery versus 0.7% of electrocautery TURP (*p* < 0.01).

Conclusion: This retrospective cohort study shows that patients undergoing GreenLight laser TURP have a significantly lower transfusion rate, a longer operating time, and a shorter hospital stay compared with electrocautery TURP.

MP-1.05

Rapid improvement of symptoms of benign prostatic hyperplasia with treatment with silodosin, an α -blocker highly selective for α -1A-adrenoceptors: results of a phase 3 clinical study

Hill L¹, Marks L², Gittelmann M³, Volinn W¹, Hoel G¹

¹Watson Laboratories, Inc., Salt Lake City, UT, USA; ²University of California at Los Angeles, Urological Sciences Research Foundation, Los Angeles, CA, USA; ³South Florida Medical Research, Aventura, FL, USA
Introduction and Objective: Efficacy and safety of silodosin were evaluated in men with symptoms of benign prostatic hyperplasia (BPH).

Materials and Methods: In this randomized, double-blind, parallel-group study, men aged 50 years or older with International Prostate Symptom Scores (IPSS) of 13 or greater and peak urinary flow rates (Qmax) of 4 to 15 mL/s received 8 mg silodosin or placebo once daily for 12 weeks. Primary end point was change in IPSS from baseline to week 12, with last observation carried forward (LOCF). Changes in Qmax were also evaluated. Efficacy was assessed by analysis of covariance, and safety by adverse events (AEs), electrocardiography, vital signs and clinical laboratory tests.

Results: Of 461 study participants, 416 (90.2%) completed the study. Six of 228 patients (2.6%) receiving placebo and 20 of 233 (8.6%) receiving silodosin discontinued treatment because of adverse events (AEs). Most patients were white (*n* = 404; 87.6%). Median age was 64 years in both groups. Total IPSS baseline scores were similar for silodosin and placebo groups. A significantly greater decrease from baseline in total IPSS was observed with silodosin compared with placebo at week 12 and within 3–4 days (week 0.5) of first dose (Table 1). At week 12, significant improvement with silodosin versus placebo was also observed for IPSS irritative and obstructive subscores. Improvement in Qmax was greater with silodosin than placebo at week 12 and at 2–6 hours postdose. Serious AEs occurred in 3 (1.3%) patients in each treatment group; none were considered treatment related. The most common AEs in patients receiving silodosin were (generally mild) retrograde ejaculation (29.2% v. placebo 0.9%), headache (3.4% v. 1.3%), diarrhea (3.0% v. 0.4%), dizziness (2.6% v. 1.8%), nasal congestion (2.6% v. 0%) and orthostatic hypotension (2.6% v. 2.2%). No treatment-related cardiac events occurred.

Conclusion: Silodosin provided rapid, significant relief of BPH-associated symptoms, was generally well tolerated, and had a placebo-like cardiovascular safety profile.

Table 1. MP-1.05. Summary of efficacy

Efficacy variable	Baseline score, mean (SD)		Change from baseline, mean (SD)		Difference between treatments, <i>p</i> value
	Silodosin	Placebo	Silodosin	Placebo	
IPSS	21.5 (5.4)	21.4 (4.9)			
Week 0.5 (OC)*			-3.9 (5.4)	-2.0 (4.3)	< 0.0001
Week 12 (LOCF)			-6.5 (6.7)	-3.6 (5.8)	< 0.0001
IPSS irritative	9.5 (2.6)	9.4 (2.4)			
Week 12 (LOCF)			-2.3 (3.0)	-1.4 (2.7)	0.0004
IPSS obstructive	12.0 (3.8)	12.0 (3.6)			
Week 12 (LOCF)			-4.2 (4.3)	-2.2 (3.8)	< 0.0001
Qmax, mL/s	9.0 (2.6)	9.0 (2.8)			
2 to 6 h, (OC)†			2.7 (3.5)	0.8 (3.0)	< 0.0001
Week 12 (LOCF)			2.2 (4.3)	1.2 (3.8)	0.0060

CI = confidence interval; LOCF = last observation carried forward; OC = observed cases.
 *3 to 4 days after first dose.
 †2 to 6 hours after first dose.

MP-1.06

PRX302, a PSA-activated protoxin, is well tolerated and induces symptomatic relief and prostate volume reduction when administered transperineally to men with BPH

Pommerville P¹, Steinhoff G², Denmeade S³, Merchant R⁴, Buckley T⁵, Abi-Habib R⁴

¹Can-Med Clinical Research, Inc., Victoria, BC ²Dr. Steinhoff Clinical Research, Victoria, BC; ³Johns Hopkins School of Medicine, Baltimore, MD, USA; ⁴Prottox Therapeutics, Inc., Vancouver, BC; ⁵University of Victoria, Victoria, BC

Introduction and Objective: PRX302 is a protoxin modified for activation by PSA. In a Phase I study, transperineal administration of PRX302 to men with BPH was well-tolerated and provided sustained symptomatic relief. Here we report results of a Phase II study of transperineal administration of increasing volumes of PRX302 in patients with BPH.

Materials and Methods: A total of 18 patients (3 cohorts of 6 patients each) with mean age of 66.1 years and mean prostate volume of 49.2 mL received transperineal injections of PRX302 under TRUS guidance. PRX302 was administered through a single injection into the transition zone of each lobe of the prostate at a fixed concentration of 3 µg/mL and volumes equivalent to 10%, 20% and 30% of prostate volume. Three deposits of equal volume were made along the needle track in each lobe.

Results: PRX302 was well tolerated. No serious adverse events or grade 3 or higher adverse events were seen to date. Most adverse events were mild to moderate and transient. In addition, no effect on erectile function was observed with similar IIEF scores pre- and posttreatment. Mean IPSS decreased from 20.2 (standard deviation [SD] 4.7) at screening to 13.1 (SD 5.1) at 1 month and 10.6 (SD 6.4) at 3 months posttreatment (*p* < 0.01). Quality of life scores decreased from a mean of 4.5 (SD 1.1) at screening to 2.7 (SD 1.5) at 1 month and 2.4 (SD 1.5) at 3 months posttreatment (*p* < 0.01). These decreases were maintained at 6 months, indicating a sustained symptomatic relief following treatment. In addition, a dose response was observed with cohorts 2 and 3 showing a more marked

decrease in IPSS (10.9 and 10.3 points) compared with cohort 1 (2.8 points) at day 90 posttreatment. Mean prostate volume decreased by 21.6% and 23.2%, at 1 and 3 months posttreatment, respectively. In addition, mean Q_{max} increased from 10.8 (SD 3.2) mL/s at screening to 12.0 (SD 5.0) and 12.0 (SD 4.8) mL/s, at 1 and 3 months following treatment.

Conclusion: Transperineal administration of increasing volumes of PRX302 was well tolerated. Sustained symptomatic improvements in the form of decreased IPSS and QOL scores were observed along with reduction in prostate volume and increase in Q_{max} . PRX302 appears to provide symptomatic relief and constitutes a promising treatment for patients with BPH.

MP-1.07

A multicentre randomized trial comparing bipolar versus monopolar transurethral resection of the prostate

Mendez Probst C, Nott L, Razvi H

Saint Joseph's Health Care, London, ON

Introduction and Objective: Monopolar transurethral resection of the prostate (TURP) is the gold standard therapy for men with lower urinary tract symptoms (LUTS) due to benign prostatic hyperplasia (BPH). Inherent with the use of monopolar transurethral electrosurgery however, are the risks of bleeding, tissue burns, dilutional hyponatremia and irrigant toxicity. Although generally considered safer, the experience with bipolar electrosurgery for TURP application is limited. The objective of this trial was to evaluate both monopolar and bipolar (Gyrus-VISTA platform) TURP outcomes in a multicentre, single-blinded trial

Materials and Methods: Forty-four patients from 4 Canadian sites were randomized to undergo TURP with either the bipolar or monopolar devices. All patients underwent baseline determinations of AUA symptom score, peak urinary flow rate, postvoid residual bladder volume and transrectal ultrasound prostate volume. The primary outcome measure was improvement in AUA symptom score (AUA SS), quality of life assessment (AUA QOL) and bother assessment (AUA B) questionnaires and secondary measures included procedural times, duration of urethral catheterization, length of hospitalization, complications and the degree of thermal artifact in the tissue specimens. Patients were followed for 6 months after surgery.

Results: Twenty-two patients were randomized to each treatment arm, pre-operative demographic data were not statistically different between the groups. AUA SS, AUA QOL, AUA B and sexual function assessments at all data collections times were no different for either group. The only differences observed were in the procedure time (60.7 for bipolar v. 47.4 min for monopolar, $p = 0.042$) and the duration of urethral catheterization (1.5 for bipolar v. 1.1 d for monopolar, $p = 0.03$). There was no statistically significant difference in the pathological degree of thermal artifact or the rate of complications between groups. There was no difference in the change of postoperative hemoglobin among groups, and no patient required blood transfusion

Conclusion: This trial suggests equivalent short-term outcomes for men undergoing monopolar or bipolar TURP. Although admittedly monopolar TURP is associated with a relatively low risk of complications, eliminating the need for a return electrode pad and the risk of dilutional hyponatremia would appear to be added safety features favouring the bipolar technology.

MP-1.08

Sacral nerve root neuromodulation for the treatment of intractable interstitial cystitis: 14 years experience of one centre

Gajewski J, Al-zahrani A

Urology Department, Dalhousie University, Halifax, NS

Introduction and Objective: The primary objective of this study is to evaluate the clinical efficacy and the long-term tolerability of the sacral nerve root neuromodulation in the treatment of intractable cases of interstitial cystitis.

Materials and Methods: This is a single institution, nonrandomized, retrospective study to evaluate the clinical efficacy of sacral nerve

root neuromodulation as treatment for the intractable cases of interstitial cystitis that failed the behavioural and the pharmacological mode of management for the period of 1994 to 2008. The primary end point of this study is the overall improvement on the global response scale.

Results: Fifty-two patients underwent sacral nerve root neuromodulation for the treatment of intractable interstitial cystitis. Four (8%) were male while 48 (92%) were female. The mean age was 42 (20–65) years. The average follow-up was 39 (1–169) months. Thirty-seven patients (71%) showed long-term success rate with an average improvement in their symptoms on the global response scale of (67%). We had to remove the sacral neuromodulator in 15 patients with explantation rate of (29%). The average symptoms improvement on the global response scale in the explantation group was (38%). The reason for removal was back pain in 4 patients (8%), leg electrical stimulation in 2 patients (4%) and poor outcome result from the stimulator in 10 patients (19%).

Conclusion: The sacral nerve root neuromodulation is an effective mode of management for the cases of intractable interstitial cystitis with a very good long-term efficacy and tolerability. It should be considered before any major surgical intervention for the management of intractable interstitial cystitis cases.

MP-1.09

Does intravesical therapeutic solution efficacy persist with second round of instillations?

Teichman J, Mayson B

Department of Urologic Sciences, University of British Columbia, Vancouver, BC

Introduction and Objective: In prior studies of interstitial cystitis/painful bladder syndrome (IC/PBS) patients treated with alkalized lidocaine without heparin or with heparin (therapeutic solution) have shown improvements in voiding frequency, nocturia, pain and dyspareunia. The studies have reported various therapeutic solution "cocktails" and dosing regimens over 2 or 3 weeks. There is no data on durability of response, or efficacy of a second round of therapeutic solution instillations. We report our experience of IC/PBS subjects who opted for a second round of intravesical therapeutic solution.

Materials and Methods: Consecutive IC/PBS subjects who opted for a second round of intravesical therapeutic solution were studied. All subjects were on stable dose of oral medications. Therapeutic solution (8 mL 2% lidocaine, 4 mL HCO_3^- , 2 mL heparin 10 000 U/mL) was administered 3 times per week for 3 weeks. We characterized nocturia, duration between daytime voids, voided volumes, Pain Urgency Frequency (PUF) scores, Interstitial Cystitis Symptom Index (ICSI) and Interstitial Cystitis Problem Index (ICPI) scores at baseline and after 4 weeks or longer after therapy. We recorded Patient Overall Rating of Improvement in Symptoms (PORIS) and patient report of durability of response. Success was defined as PORIS of 50% greater. After a second round of intravesical therapeutic solutions, PORIS scores were obtained.

Results: There were 36 evaluable subjects over 9 months. Mean age was 49 years, and mean duration of symptoms before therapy was 7 years. At follow-up, after the first round of intravesical therapeutic solution, 29 subjects (81%) reported success. Mean durability was 5 weeks. Of 29 subjects reporting success after the first round, 25 subjects (86%) maintained success after the second round of instillations; whereas of 7 subjects not considered successful responders after the first round, 2 subjects (29%) had successful outcomes after the second round, ($p < 0.001$). PORIS outcomes after first and second rounds of therapy correlated with an $r^2 = 0.50$, ($p < 0.0001$). Subjects showed statistical improvements before and after therapy for nocturia, frequency, voided volumes, PUF, ICSI and ICPI scores ($p < 0.001$).

Conclusion: A second round of intravesical therapeutic solutions yields successful outcomes in more than 80% of IC/PBS subjects in this highly selected cohort. Subjects who derive initial benefit are likely to derive benefit from a second round of therapy. The optimal duration and regimen of intravesical therapy are yet to be determined.

MP-1.10

“URO-trainer”: virtual transurethral resection (TUR) of the bladder training for novice urologists

Kruck S, Amend B, Gakis G, Bedke J, Huber S, Renninger M, Hennenlotter J, Horstmann M, Seibold J, Schilling D, Nagele U, Stenzl A, Sievert K
University of Tuebingen, Tuebingen, Germany

Introduction and Objective: New virtual-reality based simulation opens new fields in medical training and education. “Flight simulators for surgeons” potentially shorten the learning curve for surgical skills, particularly for inexperienced trainees. The new generation “URO-Trainer” from STORZ allows realistic transurethral resections of the bladder associated with satisfying visual simulations and haptic sensations. The aim of this study was to validate the use of the virtual reality trainer for transurethral bladder resections.

Materials and Methods: Five residents in their first postgraduate year and 5 medical students were assessed on their ability to perform virtual cystoscopy and bladder tumour resection. All subjects completed 5 standardized 5-minute resection scenarios. Additionally, 5 TUR-experienced residents performed 5 standardized 5-minute transurethral resections with fluorescence and white light cystoscopy. Skills were evaluated by computer-generated parameters including inspected bladder area, resected tumour mass and blood loss using statistical software.

Results: Among TUR beginners ($n = 10$), the mean inspected bladder area increased during virtual training from 46.5% (standard deviation [SD] 22.9%) to 62.9% (SD 13.4%, $p = 0.13$). Significant improvements were also noted for mean tumour resection rates from 30.2% (SD 17.7%) to 58.4% (SD 11.2%, $p = 0.0028$). Blood loss was reduced from 92.0 (SD 45.6) mL to 58.2 mL (SD 29.1 mL, $p = 0.097$). The computer-recorded scores demonstrated a positive training effect for the residents experienced with cystoscopy and unskilled students within a few training sessions. Experienced urologists ($n = 5$) showed superior inspection (51% v. 49.8%; SD 16.9% v. 9%, $p = 0.08$) and resection rates (55.6% v. 37.8%; SD 20.5% v. 10.3%, $p = 0.08$) with fluorescence guidance.

Conclusion: This study supports the need for simulator-based education programs for urological residents. Endourological training is changing rapidly and the increasing availability of new generation virtual TUR-simulators with visual perception and haptic force feedback have to demonstrate a “real life” benefit. Virtual reality and photodynamic diagnostic based simulation help to increase recognition of tumour areas and improve resection quantity and quality. Further investigations will potentially assist in determining when a resident should begin to perform the initial patient surgery in order to ensure complete resection and reduce morbidity. Finally, even new techniques such as the photodynamic diagnostic can be educational and reduce learning curves.