Podium Session 2: Stones, BPH & Voiding Dysfunction June 23, 2013, 1350-1450

POD-02.01

Evaluating the Change of Overactive Bladder Symptoms in Women Post-pubovaginal Sling Procedure for Stress Incontinence

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Introduction and Objectives: It has long been suggested that pubovaginal sling (PVS) procedures are incapable of relieving urge/mixed urinary incontinence (UUI/MUI) and may induce de novo overactive bladder (OAB). Based on evidence in our clinic, we investigated the ability of PVS to alleviate UUI/MUI and improve OAB.

Methods: 132 female PVS patients from October 2010 through March 2012 were prospectively analyzed. Patients were evaluated using the V8 questionnaire on five occasions (preoperative, postoperative, 10-12 weeks, 15-20 weeks, 20-28 weeks). Ordinal questionnaire results were tested for significance using the Wilcoxon Signed Rank Test in SPSS. Preoperative results were considered baseline. The frequencies of patients suffering from severe OAB symptoms (individual scores ≥3 on questionnaire) were analyzed using a two-tailed Z test. Any score of 8 or more on the V8 questionnaire was considered a state of OAB.

Results: Mean patient age at time of PVS was 51.7 years. 120 (90.91%) patients presented with at least mild OAB prior to PVS for stress urinary incontinence. 64 (48.5%) of these patients suffering from MUI experienced a drop in OAB symptoms below the threshold score of 8, marking a clinically important improvement. Only 3 (2.27%) patients developed pure de novo OAB (no OAB preoperative). 6 (4.54%) patients were lost to follow up. Statistically significant improvements were seen across patients at each postoperative visit in all eight dimensions of the V8 questionnaire ($p<0.001$). The frequency of patients suffering from severe OAB symptoms (≥3) also dropped significantly in each dimension of the questionnaire (alpha = 0.05, Z<-1.96).

Conclusions: Contrary to prior beliefs, PVS procedures for stress incontinence have shown to be clinically and statistically significant in the treatment of urinary incontinence and OAB symptoms. Relative to their baseline preoperative OAB, most patients in our community setting improved or remained stable following PVS.

POD-02.02

Bone Density Abnormalities in Vitamin-D Inadequate Patients Presenting with Urolithiasis to a Tertiary Stone Centre

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Background and Objectives: Vitamin D plays a vital role in bone health and stone-formers are at risk of premature bone loss that may be exaggerated by VDI. Therefore, the aim of the present study was to assess abnormalities in bone density studies for patients with VDI presenting with urolithiasis to a tertiary stone clinic.

Methods: A retrospective review of prospectively collected data was performed for patients presenting to stone clinic from November, 2009 to August, 2012. Demographic and clinical data were collected together with metabolic stone work-up and bone density studies. VDI was defined as VD levels <30 ng/ml. A Dual-energy X-ray Absorptiometry (DXA) scan was used to evaluate the Bone Mineral Density (BMD) at the femoral neck and lumbar spine. The World Health Organization (WHO) criteria were used to define patients with abnormal BMD; normal (within ±1 SD), osteopenia (−1 to −2.5 SD), and osteoporosis (<−2.5 SD). Patients with primary hyperparathyroidism or hypercalcemia were excluded.

Results: A total of 49 patients with VDI with DXA studies were included; 26 (53.1%) were males. Mean age was 51.5 years, mean BMI was 27.9 kg/m2 and mean serum VD was 18.4 ng/ml. Twenty-nine patients (59.2%) had abnormal DXA studies where 23 (46.9%) had osteopenia and 6(12.3%) had osteoporosis in the femoral neck and/or lumbar spine. When using age-matched Z-score, there were 21 patients (42.9%) had abnormal T-score DXA studies where 17 (34.7%) had osteopenia and 4 (8.2%) had osteoporosis. Median serum VD was not significantly different between patients with normal and abnormal DXA scans [19.2 vs. 17.2 ng/ml, $p=0.10$). Similarly, median serum VD did not significantly differ between osteopenics and osteoporotics [17.6 vs. 15.6 ng/ml, $p=0.64$].

Conclusion: A high prevalence of abnormal DXA scans was found in patients presenting with urolithiasis and VDI. These findings need to be considered during evaluation and replacement of VD in this population.

POD-02.03

Validation of a Clinical Nomogram to Predict the Successful Shockwave Lithotripsy of Renal and Ureteral Calculi

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Introduction and Objectives: Shock wave lithotripsy (SWL) outcomes are dependent on patient and stone-related factors; there are few reliable algorithms predictive of treatment success. We previously created a nomogram using pre-treatment patient and stone variables to predict successful SWL using the Phillips Lithotron. This study aims to validate that nomogram in a different, more current set of patients treated on a different lithotripter to determine if the nomogram is valid and generalizable.

Methods: Patients treated at our lithotripsy unit from June 2010 to September 2012 were reviewed. Analysis was restricted to those with a solitary renal or ureteral calculus <20 mm in maximum dimension, with a pre-treatment CT scan within 4 weeks of SWL, and follow-up at our institution. Demographics, stone, patient, treatment and follow-up data were collected from a prospective database. Patients were treated on the Storz Modulith SLX-F2 lithotripter.

Results: 270 patients (67.5% male) were analyzed. Mean stone size was 52±37 mm^2 for ureteral stones and 66±54mm^2 for renal stones; 50.3% of renal stones were in the lower pole. Single treatment success rates for ureteral and renal stones were 62% and 75%, respectively. On univariate analysis, predictors of SWL success, regardless of stone location, were age ($p=0.04$), body mass index ($p=0.048$), stone size ($p<0.01$), mean stone density (MSD; $p<0.01$), gender ($p=0.029$), stone location ($p<0.01$) and skin-to-stone distance (SSD; $p<0.01$). By multivariate logistic regression, stone area, stone location, MSD and SSD remained significant predictors (area-under-curve [AUC]=0.79).

Conclusions: Patient and stone parameters have been identified to create a nomogram that predicts SWL outcomes. These parameters have been validated in two independent cohorts of patients treated on entirely different lithotripters. Use of a nomogram can facilitate optimal treatment decisions and provide more accurate single-treatment success rates for SWL.

POD-02.04

OnabotulinumtoxinA (onabotA) in Patients with Overactive Bladder (OAB) and Urinary Incontinence (UI): Consistent Effect over Repeat Treatment

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Introduction and Objectives: OnabotA 100U was effective in 2 placebo-controlled pivotal studies for the treatment of patients with idiopathic OAB and UI who were inadequately managed with anticholinergic (ACH) therapy. Here we report a pre-specified interim efficacy/safety analysis of the extension trial.

Methods: Patients could enter a 3-year extension study to receive multiple treatment of intradetrusor onabotA. Data were integrated across studies; patients were analyzed by onabotA treatment cycle (up to 5). Change from baseline (BL; before any treatment at week 12 in OAB symptoms, proportion with a positive treatment response on the treatment benefit scale (TBS), duration of effect (time to pateints' request for re- treatment), health-related quality of life (HRQOL), adverse events (AEs), and use of clean intermittent catheterization (CIC) due to elevated postvoid residual urine (PVR) were assessed.

Results: A total of 825, 558, 253, 113, and 47 patients received 1, 2, 3, 4, and 5 onabotA 100U treatment, respectively, in this interim cut. Reductions vs. BL were seen in OAB symptoms; UI reductions at week 12 were -3.25, -3.70, -3.49, -2.79, and -2.55 in cycles 1-5. High proportions of patients had a positive response on TBS (73.9, 78.9, 77.3, 72.9, and 77.1% at week 12 in cycles 1-5). A consistent duration of effect was observed; median time to request for re-treatment was 24.0, 25.7, and 24.1 weeks for cycles 1, 2, and 3 (too few had yet requested re-treatment in cycles 4 and 5). Large improvements from BL in HRQOL were seen after each onabotA treatment. The most common AE in each treatment cycle was uncomplicated urinary tract infection (26.9, 24.2, 24.5, 20.4, and 14.9%). The proportion of patients requiring CIC due to elevated PVR was 4.6, 4.1, 4.7, 5.3, and 2.1% in cycles 1-5. No change in the AE profile was observed.

Conclusions: Repeated onabotA treatment in OAB patients with UI inadequately managed with ACHs showed sustained improvements in OAB symptoms, patient perception of improvement, and HRQOL. A consistent safety profile was seen, with no new safety signals.

POD-02.05

Autologous Muscle Cell Mediated Therapy for Stress Urinary Incontinence in Women: Combined Safety & Efficacy Results From Two Studies

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Introduction and Objectives: Two multicentre studies assessed 12-month safety and potential efficacy of Cook MyoSite Incorporated Autologous Muscle Derived Cells (AMDC) for treatment of stress urinary incontinence (SUI) in women.

Methods: Enrolled patients had SUI refractory to prior treatment and had no symptom improvement over the past 6 months. AMDC products were derived from biopsies of the quadriceps femoris. In Study I, patients received intrasphincteric injection of 10 (n=16), 50 (n=16), 100 (n=24), or 200 x 10^6 (n=8) AMDC. In Study II, patients (n=16) received 200 x 10^6 AMDC. The primary outcome measure was safety determined by the incidence and severity of adverse events (AEs). Secondary outcomes of efficacy were based on 3-day diaries and 24-hour pad tests at baseline and 12 months.

Results: Eighty patients received AMDC treatment; 72 patients completed diaries and pad tests at 12-month follow-up. No serious procedure- or treatment-related AEs occurred. No AEs related to AMDC product were reported. All biopsy and injection-related AEs were expected complications of the procedures, and either self-resolved or were easily treated. Compared to lower dose groups, the 100 and 200 x 10^6 dose groups had higher percentages of patients with ≥50% reduction in stress leaks and pad weight at 12-month follow-up (Table 1). Additionally, the lowest dose group had the lowest percentages of patients with no stress leaks and negative pad tests.

Table 1. POD-02.05. Percentage of patients meeting endpoint at 12 months*

12-month outcomes	10 x 10^6	50 x 10^6	100 x 10^6	200 x 10^6
≥50% reduction in stress leaks	53% (8/15)	69% (9/13)	85% (17/20)	77% (17/22)
No stress leaks over 3 days	20% (3/15)	39% (5/13)	30% (6/20)	32% (7/22)
0-1 stress leaks over 3 days	40% (6/15)	54% (7/13)	50% (10/20)	55% (12/22)
≥50% reduction in pad weight	20% (3/15)	43% (6/14)	52% (11/21)	64% (14/22)
Negative pad test (<1.3 g)	7% (1/15)	29% (4/14)	24% (5/21)	32% (7/22)

*Two patients who met inclusion criteria, but who reported no stress leaks over 3 days at baseline, were excluded from the 12-month stress leak analysis since it was impossible for them to show improvement.

Conclusions: Doses of 10, 50, 100, and 200 x 10^6 AMDC appear safe with no serious treatment-related AEs reported. Additionally, more patients may be responsive to doses of ≥100 x 10^6 AMDC, providing key information for a future placebo-controlled trial.

POD-02.06

Content Analysis and Predictive Factors in 3288 Patients' Online Ratings of Urologists

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Introduction and Objectives: Online physician rating sites have emerged as putative aids in the vetting of physician quality by patients. We sought to assess how urologists are rated, and what factors might influence these ratings.

Methods: We compiled an anonymized database of urologists from Ontario using the online rating site RateMDs.com. Comments were searched for explicit mention of diagnosis, surgery, bedside manner, and some non-linguistic devices. Where appropriate, Students' T-tests and analysis of variance (ANOVA) were used.

Results: 3288 ratings were identified for 224 urologists (median 15, range 1-35), 75.4% of practicing urologists listed by the Ontario College of Physicians and Surgeons. The mean rating was 3.96 out of 5 (SD 1.33; median 4.75; range 1-5). 2215 urologists (67.4%) were rated 4 or higher. A higher word count was associated with lower rating (word count 1-50, mean 4.24; 51-100, 3.88; >100, 3.29, $p<0.001$). A specific diagnosis was mentioned in 1056 cases (32.1%). Among the most common five diagnoses, mean rating was highest for kidney cancer (4.67) and lowest for vasectomy (3.77; $p<0.001$). Patients explicitly mentioning surgery rated their urologists higher than those who did not (4.28 vs. 3.85, $p<0.001$). Comment on good bedside manner was associated with higher ratings (mean 4.74 vs. 3.91, $p<0.001$); comment on poor bedside manner resulted in lower ratings (mean 2.45 vs. 4.01, $p<0.001$). Comments with at least one word in full capital letters were accompanied by lower ratings than those that did not employ all-caps (mean 3.11 vs. 4.03, $p<0.001$).

Conclusions: Many urologists are represented in online ratings by patients, and most reviews are favourable. Those who note surgery, a cancer diagnosis or good bedside manner rated urologists highly, while longer comments, the use of all-caps or mention of a poor bedside manner were associated with lower ratings. Urologists should be aware of these patient forums and guarded in their interpretation of them.