Title

566 WEIGHT LOSS REDUCES URINARY INCONTINENCE IN MEN WITH TYPE 2 DIABETES: RESULTS FROM THE LOOK AHEAD TRIAL

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2000-December 2011 was performed. A total of 54 combined procedures were performed, compared with 337 IPP and 281 AUS procedures. Comparisons between groups were performed using Chi-square tests for categorical data; the means of continuous data were compared by using the t test and non-parametric alternate if the distribution could not be normalized or the variance was not equal. All statistical tests were two sided and $P < 0.05$ was considered statistically significant.

RESULTS: The surgical approaches consisted of midline penoscrotal incisions for IPP, and transperineal incisions for AUS cuff placement with a secondary lower abdominal incision for AUS reservoir placement. Significant demographic differences between groups included those men undergoing combined implantation having a higher mean age (65.3 years vs. 59.9 years), risk of prostate cancer, prostatectomy and radiation therapy, and a lesser risk of Peyronie's disease, compared to men undergoing IPP alone (all $P < 0.05$). Although the duration of surgery was significantly longer for the combined procedure (mean 218.1 minutes vs. 145.9 minutes for IPP alone and 114.7 minutes for AUS alone, $P < 0.0001$), there was no increased risk of device infection, erosion or malfunction requiring surgical revision in the patients who received combined procedures ($P = 0.37$). Mean hospitalization duration for the combined procedure was 1.2 days (with 45/54 [83.3%] staying <24 hours), and mean follow-up for the combined procedure was 1.62 years, for IPP alone was 1.47 years, and for AUS alone, 2.98 years.

CONCLUSIONS: Combined IPP-AUS insertion is a safe procedure with no increased risk of adverse outcomes compared to individual prosthetic implantation. Patients should be counseled about this surgical option given the clear benefits of this approach, which include a single anesthesia event and faster restoration of erectile function and continence.

Source of Funding: None

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PHASE 3 EFFICACY AND SAFETY OF ONCE-MONTHLY OXYBUTYNIN VAGINAL RING DELIVERING 4 MG/DAY OR 6 MG/DAY VS PLACEBO RING IN WOMEN WITH URGE INCONTINENCE, FREQUENCY, AND URGENCY SYMPTOMS OF OVERACTIVE BLADDER

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INTRODUCTION AND OBJECTIVES: Oxybutynin vaginal ring (OxyVR) is a novel delivery system developed to bypass hepatic metabolism and improve tolerability over oral antimuscarinic agents used to treat overactive bladder (OAB). Our objective was to compare the efficacy and safety of OxyVR delivering 4 or 6 mg/day to placebo vaginal ring (PVR) in women with precisely defined OAB symptoms.

METHODS: In this randomized, double-blind, multicenter, 12-week (W) trial (NCT00685113), women with pure/predominantly urge incontinence were consented and randomized to OxyVR4, OxyVR6 or PVR. A new vaginal ring (VR) was inserted every 4W. Women whose 3-day screening diaries met all 3 OAB-defining criteria comprised the analysis population: ≥5 urge incontinence episodes (IEs)/W; average daily urinary frequency (UFreq) ≥8 voids/24h; average void volume (VV) ≤3L/24h. Women inserting ≥1VR were evaluated for safety. Efficacy was assessed by comparing changes from baseline in total (stress +urge) IEs/W (primary endpoint), UFreq, VV and percent with no IEs in a final 3-day diary.

RESULTS: A total of 1102 women (362 randomized to OxyVR4, 369 to Oxy VR6, 371 to PVR) comprised the safety population; 882 (295, 278, 309, respectively) met all 3 OAB criteria. Groups had similar baseline demographic and OAB characteristics; 94% completed 12W. From baseline to 12W, OxyVR4 and OxyVR6 treatment resulted in statistically significant improvements compared to PVR in weekly IEs and daily UFreq, with no significant differences in VV (**Table 1**). In the final 3-day diary, 36% of OxyVR4 ($P=0.029$), 35% of OxyVR6 ($P=0.074$) vs 28% of PVR-treated women had no IEs. In the safety population, both OxyVR doses were well tolerated, with no serious adverse events (AEs) attributable to treatment. Dry mouth occurred in 6% (OxyVR4) and 8% (OxyVR6) vs 4% (PVR), constipation in 1%, 1% vs 2%, culture-positive urinary tract infections in 8%, 10% vs 8%, respectively. Few withdrew due to AEs (3.6%, 6.8% vs 3.0%, respectively), only 0.2% for dry mouth. Other vaginal complaints reported in 1.9%-5.9% of women overall were distributed equally across groups.

CONCLUSIONS: OxyVR offers women a once-monthly, effective, safe, and well tolerated treatment option for OAB.

Table 1. Changes in Efficacy Variables From Baseline to 12W

	OxyVR4	OxyVR6	PVR
Weekly IEs	(n=295)	(n=278)	(n=309)
Mean Change (±SD)	-20.5 (±18.4)	-21.4 (±17.5)	-16.5 (±24.0)
Median Change	-18.7	-21.0	-14.0
P value*	0.0013	<0.0001	
UFreq	(n=295)	(n=278)	(n=309)
Mean Change (±SD)	-2.9 (±3.9)	-3.2 (±3.2)	-2.0 (±4.0)
Median Change	-2.7	-2.8	-2.0
P value*	0.0005	<0.0001	
VV	(n=292)	(n=276)	(n=302)
Mean Change (±SD)	25.4 (±77.4)	23.6 (±71.6)	18.8 (±64.7)
Median	20.2	15.9	10.6
P value*	0.246	0.414	

IEs=incontinence episodes; UFreq=urinary frequency; VV=void volume.
*Significance between active and placebo groups tested using ANCOVA model.

Source of Funding: Teva Women's Health

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WEIGHT LOSS REDUCES URINARY INCONTINENCE IN MEN WITH TYPE 2 DIABETES: RESULTS FROM THE LOOK AHEAD TRIAL

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INTRODUCTION AND OBJECTIVES: We determined the effect of a lifestyle weight loss intervention on the prevalence, incidence and resolution of weekly or more frequent urinary incontinence in overweight/obese men with type 2 diabetes after 1 year in the Look AHEAD (Action for Health in Diabetes) trial.

METHODS: The Look AHEAD trial is a multicenter randomized clinical trial comparing the effects of an intensive lifestyle intervention (ILI) and diabetes support and education (DSE; the control group) on the incidence of major CVD events in overweight or obese individuals with type 2 diabetes mellitus. All participants self-reported information regarding urinary incontinence (UI, defined as weekly or more frequent leakage episodes) and UI predominant type (urge vs. stress) at entry and 1 year. Multivariate logistic regression models were used to assess the impact of ILI vs. DSE on 1-year prevalence and incidence of UI.

RESULTS: Overall, 1910 men with an average (mean +/−SD) age of 59.9 +/− 6.7 years and BMI of 35.2 +/− 5.5 kg/m2 provided data at both time-points. The baseline prevalence of UI was similar between groups (11.3% vs. 9.7% for ILI and DSE, respectively, $p=0.25$). After one year of intervention, the ILI group lost on average more weight than the DSE group (9.4%+/−7.0% vs. 0.7%+/−4.5%, $p < 0.001$). Compared to the DSE group, the ILI group had a 38% reduced odds of reporting UI at 1 year follow-up (Adjusted Odds Ratio (AOR) 0.62, 95% confidence Interval (95%CI) 0.43-0.88, $p<0.01$). Similarly, compared to the DSE group, the ILI group had reduced odds of reporting urge UI at 1 year follow-up (AOR 0.36 (95% CI 0.22-0.60), $p<0.0001$). In addition, the ILI group had reduced odds, albeit borderline significant, of developing new onset UI over the study period (AOR 0.66 (95%CI 0.42-1.02), $p=0.06$).

CONCLUSIONS: ILI was associated with reduced 1 year prevalent UI. Weight loss interventions should be considered for the prevention and treatment of UI in overweight/obese men with type 2 diabetes.

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PATIENTS WITH COMPLEX STRESS URINARY INCONTINENCE ARE SATISFIED WITH LONG-TERM OUTCOMES FOLLOWING AUTOLOGOUS FASCIAL SLING SURGERY

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INTRODUCTION AND OBJECTIVES: Patients with persistent or recurrent stress urinary incontinence (SUI) after previous anti-incontinence procedures can be a challenging group of patients to treat. A variety of different surgical treatments are employed in these patients, including autologous fascial slings. The objective of this study was to evaluate the long-term patient-reported outcomes of autologous fascial slings in patients with complex SUI, as defined as those with at least one previous anti-incontinence surgery.

METHODS: A cross-sectional analysis was performed on a prospective database of all female pelvic floor patients seen at our institution from 1999 to 2010. All patients that had received an autologous rectus fascial sling and had a history of at least one previous anti-incontinence procedure were selected.

RESULTS: 68 patients met our inclusion criteria. Of these, follow up data was available on 48 patients. Each patient had an average of 2.1 (range 1-6) previous anti-incontinence procedures. Their average VLPP was 32 cm of H2O. At an average follow-up of 6.1 years (range 2-11 years), the dry and success rates in this set of complex patients were 14.6% and 70.8%, respectively. The median satisfaction score was 80% (0 û 100%). There were no predictors of a dry or a successful outcome.

CONCLUSIONS: Despite having a low long-term dry rate, acceptable success and satisfaction scores after autologous fascial slings in patients with complex SUI make it one of the few viable treatment options. The data presented here can be used to counsel complex patients regarding outcomes after autologous fascial slings.

Source of Funding: None

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ARTIFICIAL URINARY SPHINCTER CUFF DOWNSIZING VERSUS PRESSURE REGULATING BALLOON GRADIENT INCREASE AS REVISION TECHNIQUES: A FREEDOM FROM COMPLICATION ANALYSIS

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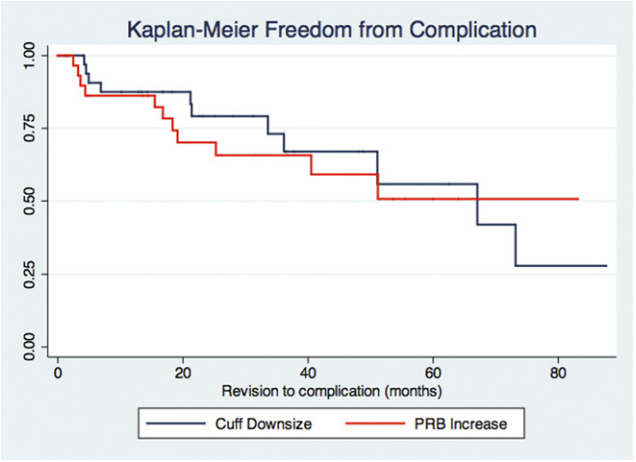
INTRODUCTION AND OBJECTIVES: The longevity of artificial urinary sphincter survival is compromised by mechanical failures, urethral atrophy and erosion. Techniques for improving or restoring incontinence after initial AUS are focused on manipulation of the cuff or the reservoir. Our aim is determine if there is a difference in the rate and timing of subsequent complications between patients who undergo cuff downsizing or a pressure regulating balloon change as a mechanism of AUS revision.

METHODS: The AUS databases from 4 institutions were reviewed for male patients with the following characteristics: 1) First revision of artificial urinary sphincter consisting of either cuff downsizing at the original cuff site or replacement of a higher pressure regulating balloon and 2) Patients who underwent replacement of all components including a downsized cuff and the same reservoir pressure with preservation of the original cuff site. Statistical analysis was performed using STATA/SE v. 12.1 for descriptive statistics and mean difference analysis. Freedom from complications was computed using Kaplan-Maier survival analysis.

RESULTS: 73 patients met the inclusion criteria. Four patients were excluded on the basis of missing critical data. 38 patients underwent cuff down sizing while 29 underwent PRB increase with a mean time from original AUS to revision of 43.9 (SD +/− 38.3) and 28.7 (SD +/− 35.4) months, respectively. A total of 24 patients (12 per group) had complications during the post revision follow-up period at a median of 20 months (range, 2.4 - 127.2). Patients in both groups were equally likely to experience a complication. (p=0.536) The mean time from revision to complication was not statistically different between the groups. (p=0.312) The freedom from complication curves were similar. (p=0.614) (Figure 1).

CONCLUSIONS: Cuff downsizing and PRB increase represent alternative methods to correcting persistent or recurrent urinary incontinence after initial artificial urinary sphincter placement. This data does not demonstrate a difference in number of complications, mean time to complications or freedom from complication. The distribution of complication types in each group appear different, however, the number of events limited analysis.



Source of Funding: None

Pediatrics

Video Session 3

Sunday, May 5, 2013 **1:00 PM-3:00 PM**

V569

ROBOTIC ASSISTED LAPAROSCOPIC IPSILATERAL URETEROURETEROSTOMY TO MANAGE AN ECTOPIC URETER IN A PEDIATIC PATIENT

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INTRODUCTION AND OBJECTIVES: Ipsilateral ureteroureterostomy has been used to treat duplication anomalies of the urinary tract in the pediatric patient. Our objective is to demonstrate the techniques used in robotic surgical management of an ectopic ureter.

METHODS: An 8 year-old female presented to our pediatric urology clinic with complaints of persistent day and night time incontinence. Her exam was notable for perineal excoriation from being persistently damp. Cystoscopy and bilateral retrograde pyelograms demonstrated a complete duplication of her right collecting system. The lower pole empties into her bladder in an orthotopic position. The upper