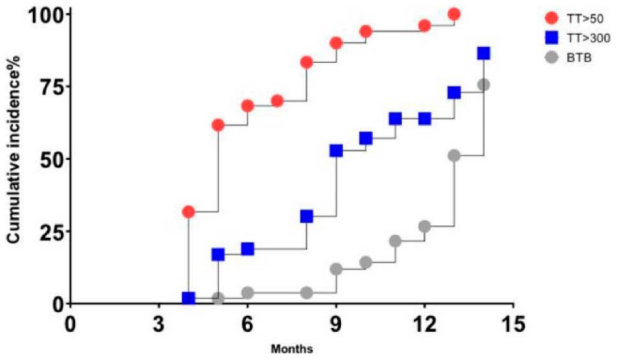
periodically (3, 6 and 12 m) after ADT cessation. 3 outcomes of recovery were evaluated: return to non-castrate level (TT > 50 ng/dL), to normal (TT ≥ 300 ng/dL) and back to baseline level (BTB −TT≥ baseline level). We performed a time-to-event analysis and reported the cumulative incidence of each outcome. Multivariable analysis was conducted to investigate predictors of recovery.

RESULTS: In this preliminary report, from 64 initially enrolled patients, 1 year follow-up T data from 50 pts were available. Mean age was 64,6y (± 5,89), 28% had type 2 diabetes (DM) and 61% hypertension (HTN). Mean baseline TT was 450ng/dl (± 170) ng/dL, 112,7 at 3m (± 96,9), 208,5 (±197) at 6m, 337,7 (± 170) at 9m and 378,2 (± 166) at 12 m. Figure 1 represents the cumulative incidence of each outcome according to time. Median time to achieve T>50 was 5 m, to achieve T>300 was 9,1 m and BTB 13,13 m. At 1 year, 98% had return back from castrate-level, 76% had TT normalized and only 42% had return BTB. In multivariable analysis including DM, HTN, age and baseline T, only baseline T was significantly associated with a greater chance of recovery, with 88,5% and 46,9% achieving normal T at 1y for patients with baseline T greater and lower than 450 ng/dl (HR: 3,56, p=0,0008)

CONCLUSIONS: In this prospective analysis of a population exposed to neoadjuvant short-term ADT, T recovery rates were relatively high at1 year, with 98% having TT>50 ng/dl, about 2/3 third having TT back to TT>300 ng/dl, but with less than half with BTB level. An effort should be made to measure TT before starting ADT.



Source of Funding: Janssen-Cilag Farmacêutica Ltda

PD11-08

THE EFFECT OF VAGINAL TESTOSTERONE ON SEXUAL FUNCTION AND VAGINAL HEALTH: INTERIM ANALYSIS FOR PIVOT (PREVENTION OF RECURRENT URINARY TRACT INFECTION USING VAGINAL TESTOSTERONE)

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INTRODUCTION AND OBJECTIVE: During menopause, declining estrogen levels can lead to vaginal atrophy and changes in vaginal flora. Vaginal estrogen treats atrophy thereby restoring flora, which prevents UTIs and improves sexual function in post-menopausal women. While estrogen is effective, some patients have contraindications or are unwilling to use it. Vaginal testosterone cream (VT) has been shown to improve vaginal atrophy, however, its effects on overall vaginal health, urinary tract infections and sexual function have not been fully described.

METHODS: This is a randomized, double-blind study that enrolled postmenopausal women with rUTIs. Patients were randomized to VT or placebo. Vaginal health index (VHI), Female Sexual Function Index (FSFI), and vaginal swab to assess flora via DNA sequencing were collected at baseline and at one, four and nine month follow up.

RESULTS: A total of 52 women have been enrolled to date (25 placebo arm, 27 VT arm). Average VHI at enrollment was 14.52 +/- 0.67. The baseline VHI for the VT group was 15 +/- 4.39 while the VHI for the placebo arm was 14.03 +/- 4.30. There was no significant difference in mean VHI scores for either group at one month. The VT group experienced a steady increase in VHI starting at the four month time point. By 9 months, women in the VT arm had experienced statistically significant increase in VHI (15.00+/-4.39 to 17.50 +/- 4.43, p = 0.04) (Table 1). Both groups experienced improvement in FSFI scores compared to baseline (Table 2). With respect to microbiome, there were significant differences between groups at baseline; with treatment although statistically significant trends were seen, the clinical significance of these trends remains unknown. Data on urinary tract infections is still being collected in this ongoing study.

CONCLUSIONS: Interim analysis showed greater long term improvement in VHI scores with VT as compared to placebo, while FSFI improved in both groups. Longer treatment follow up and increased patient enrollment will be valuable in determining the effects of VT on vaginal microbiome and recurrent UTI.

Vaginal Health Index Parameters	Pre - Treatment (Mean +/- Standard Deviation)	One Month Post-Treatment (Mean +/- Standard Deviation)	Four Months Post-Treatment (Mean +/- Standard Deviation)	Nine Months Post-Treatment (Mean +/- Standard Deviation)
Elasticity	2.92 +/- 0.86	3.07 +/- 0.59	3.43 +/- 0.79	3.25 +/- 0.5
Fluid volume (pooling of secretions)	2.72 +/- 1.0	2.53 +/- 0.64	2.71 +/- 0.76	3.25 +/- 1.26
pH	2.32 +/- 1.34	2.87 +/- 1.51	3.43 +/- 1.40	3.5 +/- 1.73
Epithelial Integrity	3.52 +/- 1.0	3.53 +/- 0.99	3.86 +/- 0.69	4 +/- 0.82
Moisture	2.84 +/- 1.17	3.00 +/- 0.53	3.28 +/- 1.11	3.5 +/- 1.00
Vaginal Health Index Score	14.32 +/- 4.39	15.00 +/- 2.56	16.71 +/- 3.59	**17.5 +/- 4.43**

Table 1. Vaginal Health Index Scores pre- and post- treatment on patients using VT. **p <0.05

	Placebo		Vaginal Testosterone	
	Baseline	Nine Months Post-Treatment	Baseline	Nine Months Post-Treatment
Desire	2.27+/- 1.19	2.55 +/- 0.75	1.73 +/- 0.75	2.6+/- 1.24
Arousal	1.47 +/- 1.78	2.25 +/- 1.98	1.25 +/- 1.36	1.2 +/- 1.58
Lubrication	1.83 +/- 2.06	2.93 +/- 2.45	1.13 +/- 1.36	1.45 +/- 1.92
Orgasm	1.82 +/- 2.42	2.30 +/- 1.96	1.06 +/- 0.88	1.67 +/- 2.27
Satisfaction	2.67 +/- 1.70	3.30 +/- 1.54	2.35 +/- 1.16	2.73 +/- 1.61
Pain	1.98 +/- 2.19	3.0 0+/- 2.85	0.80 +/- 0.40	1.27 +/- 2.04
Total	11.94 +/- 9.90	16.33 +/- 10.90	8.32 +/- 5.01	10.92 +/- 9.98

Table 2. Female Sexual Function Index scores for women in the placebo (n=25) and VT (n=27) arms at baseline and at nine months post treatment.

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PD11-09

PROSPECTIVE RANDOMIZED TREATMENT OF ERECTILE DYSFUNCTION AFTER RADICAL PROSTATECTOMY WITH AUTOLOGOUS ADIPOSE-DERIVED REGENERATIVE CELLS

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INTRODUCTION AND OBJECTIVE: We have previously reported safety and preliminary efficacy outcomes from a phase 1 clinical trial using autologous adipose-derived regenerative cells (ADRCs) to treat erectile dysfunction (ED) in 21 men after radical prostatectomy (RP). To further evaluate the effectiveness of the stem cell intervention, we here performed a randomized double-blind placebo-controlled phase 2 trial.

METHODS: The trial was approved by The Danish National Committee on Health Research Ethics (60915) and included 70 men (58-67 years) with normal erectile function (EF) before robotic-assisted RP, and undetectable PSA levels at inclusion. Patients were randomized (35:35) to placebo or ADRC treatment using REDCap. The trial's primary endpoint was changes in EF using the International Index of Erectile Function 5 (IIEF-5) and Erection Hardness Score (EHS) questionnaires as an online survey at baseline, 1, 3, 6, and 12 months after treatment. The secondary endpoint was an objective measure of nocturnal erection at baseline and 6 months after