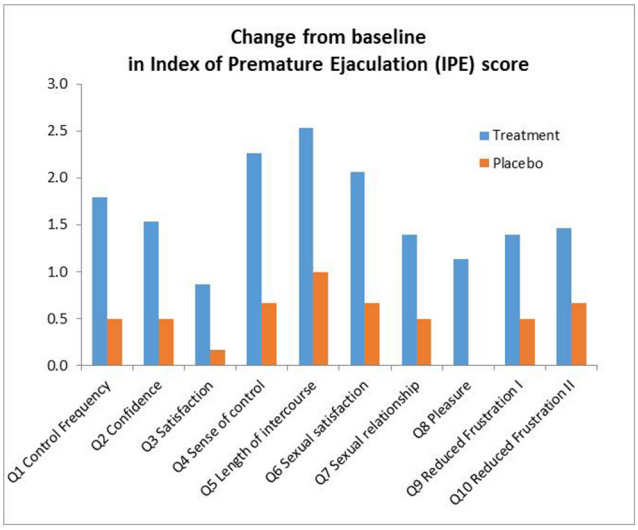
including global rating of distress, medication assessment, and Index of Premature Ejaculation (IPE). Wilcoxon rank-sum test was used for comparison of all outcomes.

RESULTS: An interim analysis was conducted in 21 men who were randomized (15 treatment, 6 placebo) and had complete follow-up data. Baseline mean ± standard deviation IELT was 74.3 ± 31.8 vs 84.9 ± 29.8 seconds among the treatment and placebo groups, respectively (p=0.39). After 2 months, men in the treatment group had significant improvement in IELT with a mean increase of 231.5 ± 166.9 seconds (95% confidence interval of 139-323 seconds) which was significantly greater than men on placebo (94.2 ± 67.1 seconds, p=0.043). A greater proportion of men in the treatment group after one and two months achieved IELT of at least 2 minutes vs placebo (60%, 80.0% vs 33.3% respectively). Compared to placebo, men in the treatment group reported greater improvement in distress relating to intercourse, control of ejaculation, and satisfaction with sexual intercourse over the study period (p<0.01, p=0.01, and p<0.01, respectively). Treatment was well tolerated and no transference was reported.

CONCLUSIONS: Topical 4% benzocaine wipes improved both objective and subjective symptoms of PE compared to placebo.



Source of Funding: PREBOOST ® : Veru Healthcare / The Female Health Company

PD69-03

COMPARISON OF EFFICAY AND SAFETY FOR ERECTILE DYSFUNCTION OF MIRODENALFIL 50MG ONCE DAILY AND 100MG ON-DEMAND IN PATIENTS WITH RADICAL PROSTATECTOMY : MULTICENTER, RANDOMIZED TRIAL.

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INTRODUCTION AND OBJECTIVES: To compare the improvement of erectile dysfunction (ED) as well as safety of mirodenalfil 50mg once daily and 100mg on-demand in patients with radical prostatectomy due to prostate cancer.

METHODS: Prospective study was done with 166 patients who had ED after taken radical prostatectomy due to prostate cancer from June 2013 to October 2014. Out of 184 individuals, 171 met inclusion criteria and 153 finished the research. Patients were divided into two groups. Group 1 had mirodenafil 50mg daily and Group 2 had mirodenafil 100mg on-demand. The ?ve-item version of the International Index of Erectile Function (IIEF-5), SEP Q2, Q3 were assessed immediately before initiation of treatment (V1) and after two (V2), six (V3) and twelve months of treatment (V4). Also, to investigate the safety, blood pressure, pulse, and side effect were evaluated.

RESULTS: Out of 171 individuals, 153 (89.4%) finished the research (group 1: n=74, 48.4%, group 2: n=79, 51.6%). Statistically, there were no difference of IIEF-5 at V1 between two groups. Both groups had meaningful improvement on IIEF-5 in V2,V3, V4 and group 1 had better improvement than group 2 (10.9±4.1 vs. 8.0±5.3, Δ4.0±2.6, p=0.01) (Table1). Group 1 had larger improvements than Group 2 in SEP Q2 and Q3 significantly (V4-Q2: 60.1% vs. 50.7%, p=0.01, Q3: 58.4% vs.48.8%, p=0.01). There was no drop out patients due to cardiovascular problems and other side effects.

CONCLUSIONS: The administration of a 5 mg dose of mirodenafil daily to patients who had erectile dysfunction that had undergone a radical prostatectomy due to prostate cancer had batter effect on the recovery and maintenance of erectile function than 100mg dose of mirodenafil. The side effects were insignificant for both dosing schedules.

Table 1. Comparision of IIEF-5, IPSS, Qmax, and PVR of patients in V1*, V2Δ, and V3ᶲ between two groups

	Group1						Group2							
	V1 (Pre-OP)	V2 (2M)	V3 (6M)	V4 (12M)	Diff. V2 vs. V4	P value	V1 (Pre-OP)	V2 (2M)	V3 (6M)	V4 (12M)	Diff. V2 vs. V4	P value	Diff. Group1 vs. Group2	P value
IIEF-5	23.5±6.2	6.2±8.4	11.7±6.7	16.1±7.3	10.9±4.1+	0.02+	22.8±7.7	5.1±7.4	9.8±6.4	13.1±7.1	8.0±5.3+	0.03+	4.0±2.6+	0.01+
SEP Q2	81.2%	20.4%	43.9%	60.1%	-	0.01*	82.3%	19.4%	37.1%	50.7%	-	0.01*	-	-
SEP Q3	80.4%	19.4%	40.6%	58.4%	-	0.01*	81.6%	17.1%	38.6%	48.8%	-	0.01*	-	-

#IIEF-5 : International Index of Erectile Function (Korean Version), SEP Q (Sexual encounter profile questions)
+Paired T-test, ^Independent T-test, *Chi-square test

Source of Funding: SK chemicals Korea

PD69-04

SAFETY AND EFFICACY OF LOW-INTENSITY EXTRACORPOREAL SHOCKWAVE IN THE TREATMENT OF VASCULOGENIC ERECTILE DYSFUNCTION: A MULTI-CENTER, DOUBLE-BLIND, RANDOMIZED SHAM-CONTROLLED CLINICAL TRIAL

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INTRODUCTION AND OBJECTIVES: To evaluate the safety and efficacy of Low-intensity Extracorporeal Shockwave (LI-ESWT) in the Treatment of Vasculogenic Erectile Dysfunction.

METHODS: A multi-center, double-blind, randomized sham-controlled clinical trial was conducted. 70 patients (46 cases for LI-ESWT treatment group and 24 cases for the placebo group) at age 20-70 years, who had mild or moderate Vasculogenic ED evaluated with the International Index of Erectile Function erectile function domain (IIEF-EF) were recruited for this study. Screening, treatment and results were performed in sequence. 4 weekly sessions for the treatment stage: A total of 5000 shockwaves were applied for each treatment and 4 areas were conducted including: 900 shockwaves in right and left crura, and 1600 shockwaves in each site. Effectiveness was assessed according to the International Index of Erectile Function erectile function domain (IIEF-EF), questions 2 and 3 of the Sexual Encounter Profile (SEP), Global Assessment Question (GAQ) scores, and Erection Hardness Scale (EHS) at baseline and at 1 and 3 months after treatment. The study was approved by Peking University First Hospital ethics committee, and all patients signed an informed consent form.

RESULTS: For Full Analysis Set (FAS) and Per-Protocol Set (PPS), the average IIEF-EF increased significantly from 18.04±3.94 (17.90±3.77) at baseline to 22.02±4.13 (21.95±4.06) at 1 months post treatment, and was 22.54±3.98 (22.49±3.90) at the 3 months follow-up. The success rate by LI-ESWT is 67.39% (73.17%) after 1months post treatment VS 20.83% (23.81%) in the placebo group and is 69.57% (73.17%) after 3 months post treatment VS 20.83% (23.81%) in the placebo group by FAS (PPS). SEP, GAQ, EHS analysis were also significantly improved compared to the placebo controls (p<0.05). No side effects were reported in this study.

CONCLUSIONS: LI-ESWT in patients with mild or moderate Vasculogenic ED is a feasible, noninvasive and effective way for improving male ED.

Source of Funding: None.

PD69-05

EFFICACY AND SAFETY OF FIXED DOSE COMBINATION OF TAMSULOSIN AND TADALAFIL IN PATIENTS WITH BENIGN PROSTATIC HYPERPLASIA AND ERECTILE DYSFUNCTION

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INTRODUCTION AND OBJECTIVES: Lower urinary tract symptoms (LUTS) resulting from benign prostatic hyperplasia (BPH) and erectile dysfunction (ED) are commonly occurred in aged men and known to be mechanistically associated each other. The aim of this study was to evaluate the efficacy and safety of once-daily fixed dose combination (FDC) of tamsulosin and tadalafil in patients with BPH and ED in comparison to tadalafil mono-therapy.

METHODS: In a phase III, multi-center, randomized, double-blinded and placebo-controlled clinical trial, participants were randomly assigned to active treatment groups of either FDCs consisting tamsulosin 0.4 or 0.2mg in combination of tadalafil 5mg or mono-component of tadalafil 5mg for 12-week treatment period, followed by an open-label extension period that continued up to week 24, while being treated with FDC of tamsulosin 0.4 mg and tadalafil 5mg. The primary efficacy variables of the study were assessed after 12 weeks of treatment using the international prostate symptom score (IPSS) and International Index of Erectile Function (IIEF). Other assessments included Sexual Encounter Profile, Global Assessment Question, Qmax, PSA, and PVR at every visit with four- or six-week interval. Eligible patients were men aged over 45 years with BPH confirmed by total IPSS greater than or equal to 13 and ED persistent for longer than 3 months.

RESULTS: Total 510 subjects were enrolled. The mean decrease from baseline in total IPSS at week 12 of the treatment period was significantly greater in the FDC of tamsulosin 0.4 mg group compared to the tadalafil 5mg group ($p=0.0320$). The lower limit of one-sided 97.5% confidence interval of changes from baseline in IIEF-Erectile Function (EF) domain score was greater than the pre-specified non-inferiority margin (-3.22) for both FDCs of tamsulosin 0.4 and 0.2mg. Treatment change from tadalafil 5 mg mono-therapy to FDC of tamsulosin 0.4mg and tadalafil 5mg made significant improvement in total IPSS at week 24 of the extension period after treatment change at week 12 ($p<0.0001$). The most frequent adverse drug reactions included headache, flushing, nasal congestion and ocular hyperaemia, all of which were of mild or moderate intensity and both FDCs of tamsulosin 0.4 and 0.2mg were well tolerated.

CONCLUSIONS: The FDC of tadalafil 5mg and tamsulosin 0.4mg substantiated superiority for BPH/LUTS treatment and non-inferiority for ED treatment over tadalafil 5mg mono-therapy without showing any clinically significant safety issues, supporting favorable benefit-risk balance of the FDC for the treatment of comorbid BPH and ED.

Source of Funding: Hanmi Pharmaceutical Co., Ltd., Seoul, Korea

PD69-06

CLINICAL IMPROVEMENTS IN ERECTILE FUNCTION AND MOOD IN HYPOGONADAL MEN TREATED WITH 4.5% NASAL TESTOSTERONE GEL

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INTRODUCTION AND OBJECTIVES: Male hypogonadism is a clinical syndrome resulting from failure of the testis to produce physiologic levels of testosterone (T) due to disruption of the hypothalamic-pituitary-gonadal axis. Hypogonadism is characterized by many ill-effects including mood disturbances, reduced energy levels, and impaired sexual function. A Phase 3 study investigated the safety and efficacy of a 4.5% testosterone gel administered intranasally (nasal testosterone gel - NTG). Herein we describe the efficacy of NTG administration outcomes on erectile function and mood correlations using validated questionnaires.

METHODS: The study was a 90-day, randomized, open-label, dose-ranging study in hypogonadal men with sequential safety extensions out to 1 year. 4.5% NTG (125 uL/nostril, 11.0mg testosterone/dose) was self-administered using a multiple-dose dispenser either twice daily (BID) or 3 times a day (TID) for a total dose of 22.0mg or 33.0mg, respectively. Titration was performed based on blood levels so as to achieve the eugonadal range (300 -1050 ng/dL). Erectile function and mood were assessed at baseline (day 0), and 30 day intervals through the 90-day treatment period using the International Index of Erectile Function (IIEF) and Positive and Negative Affect Schedule (PANAS), respectively.

RESULTS: Treatment with NTG led to statistically significant improvements in each of the 5 domains of erectile function ($F(3,813) = 83.96$ $p < .001$). Most of the benefit was evident by Day 30 ($t = -9.8714$, $df = 288$, p-value $< .001$) with much smaller increases until study completion (Figure 1). Similar to erectile function, NTG produced clinically and statistically significant improvements in mood (PANAS) by Day 30, with continued (non-significant) improvements seen through study completion (Figure 2).

CONCLUSIONS: NTG achieves large, clinical improvements in erectile function and mood within 30 days of treatment, with the added bonus of improvements in sexual desire. NTG is a safe, effective, and unique form of TTh, and is approved for use in the United States.