reported breast tenderness and/or enlargement were significantly greater in the dutasteride (3.5%) versus the finasteride (1.2%) group ($p<0.01$).

CONCLUSIONS: In properly selected patients, both FIN and DUT are effective therapies for the management of lower urinary tract symptoms secondary to BPH. However, DUT resulted in significantly more sexual side effects and breast complications than FIN. These long-term results suggest that FIN may be a more optimal choice as primary therapy than DUT.

	Baseline FIN (n = 197)	5 year FIN (n = 113)	Baseline DUT (n = 181)	5 year DUT (n = 77)
IPSS	15.9	9.6	16.3	9.9
Qmax (ml/sec)	10.4	9.5	10.3	9.5
PVR (ml)	68	32	59	34
PV (ml)	58.7	47.2 (-19.6%)	57.6	46.4 (-19.4%)
PSA (ng/ml)	4.5	2.3 (-48.9%)	4.8	2.4 (-50%)
IIEF	18.7	16.3	18.9	15.4

Source of Funding: None

1787
EVALUATION OF TRANSPERINEAL PROSTATIC ADMINISTRATION OF A PSA-ACTIVATED PROTOXIN (PRX302) IN MEN WITH LUTS SECONDARY TO BPH

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INTRODUCTION AND OBJECTIVES: Evaluate the potential use of PSA-targeted therapy for the treatment of LUTS 2ry to BPH, through assessment of the safety and tolerability of PRX302, a proaerolysin toxin genetically modified to be activated by PSA. We report long term results from 2 clinical trials of transperineal administration of PRX302 to men with moderate to severe BPH.

METHODS: In the Phase I study, 15 patients were enrolled into 5 cohorts and received PRX302 transperineally under TRUS guidance. PRX302 was administered through a single injection into the transition zone of each lobe with 3 or 4 deposits made along the needle track. The concentration of PRX302 increased from 0.75 to 10.5mg/ml at a volume of 0.25-1.3 ml/deposit. In the Phase II study, 18 patients were enrolled in 3 cohorts and treated transperineally with a 3 mg/mL fixed concentration of PRX302 and at volumes equivalent to 10%, 20% and 30% of prostate volume.

RESULTS: No drug-related SAEs or Grade 3 or higher AEs were observed in either study. Most AEs were mild to moderate and transient with no effect on erectile function. In the Phase I study, mean IPSS showed a decrease of 6.5 points (34%), mean QoL a decrease of 2 points (44%) and mean prostate volume a decrease of 5.5 cc (13%) at 12-months compared to screening. The IPSS still showed a decrease of 4.3 points at 2 years post-treatment. However, no clear dose response was observed and Qmax did not increase in this study. In the Phase II study, irrespective of cohort assignment, the IPSS decreased from 20.1 ± 5.1 at screening to 10.5 ± 7.1 (47.8%) at 12 months post-treatment ($p<0.01$). QOL scores decreased from a mean of 4.6 ± 1.0 at screening to 1.9 ± 1.3 at 12 months post-treatment ($p<0.01$), while mean prostate volume decreased by 27.9%. The mean Qmax increased from 10.6 ± 3.3 mL/sec at screening to 13.6 ± 6.7 mL/sec at 12-months following treatment. A dose response was observed with patients having received volumes equivalent to 20 and 30% of prostate volume showing a more marked and sustained response. A phase II randomised double blinded placebo controlled trial of PRX302 in patients with LUTS secondary to BPH completed enrollment of 91 patients in September 2009. The data will be unblinded, analyzed and presented.

CONCLUSIONS: These studies indicate that transperineal administration of PRX302 to patients with BPH is well tolerated and results in sustained symptomatic relief as evidenced by decreased IPSS and QOL scores along with a reduction in prostate volume and an increase in maximal flow rates (Phase II). PRX302 could offer an interesting therapeutic option for patients with LUTS 2ry to BPH.

Source of Funding: Protox Therapeutic Inc.

1788
NANOPARTICLE-ENHANCED MICROWAVE THERMOTHERAPY

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INTRODUCTION AND OBJECTIVES: Standard treatments for benign prostatic hyperplasia are effective but can carry significant morbidity. New efforts have concentrated on focal ablative therapy. Biocompatible nanoparticles can be injected and excited via application of microwave energy to focus heat on specific sites. We examine the ability of nanoparticles to focally heat and ablate prostate tissue when subjected to transurethral microwave thermotherapy (TUMT) in a canine model.

METHODS: 5 male beagles aged $>=3$ years underwent laparotomy and intraprostatic injection in the left prostatic lobe with 0.5ml of phospholipid-polyethylene glycol-coated 2mg/ml 4nm Fe3O4 nanoparticles. Fiberoptic thermisters were placed on both sides of the prostate and an Urologix Targis® microwave catheter in the urethra. TUMT was applied up to 40W for 18 minutes. Temperatures were recorded. 3 additional beagles underwent a similar procedure. One was euthanized after 24 hours, the others at 72 hours. Histopathologic analysis was performed via hematoxylin and eosin (H&E) and Perl's Prussian blue staining as well as transmission electron microscopy (TEM).

RESULTS: Areas injected with nanoparticles showed a 7.5C increase in temperature compared to contralateral counterparts, with a mean temperature of 47.5C (Figure 1). This difference was maintained for approximately 8 minutes during the TUMT cycle. H&E staining demonstrated focal necrosis and hemorrhage near sites of nanoparticle injection. This was confirmed by colocalized iron staining and TEM (Figures 2-3).

CONCLUSIONS: Superparamagnetic nanoparticles are able to focally heat prostatic tissue with TUMT. Histopathology confirms successful tissue ablation in areas of nanoparticle injection. Future improvements should include nanoparticle targeting as well as refinements in response to microwave energy.