## PD23-07

### SERENOA REPENS, LYCOPENE AND SELENIUM VS. TAMSULOSIN IN THE TREATMENT OF LUTS / BPH: AN ITALIAN MULTICENTER RANDOMIZED COMPARATIVE STUDY BETWEEN SINGLE OR COMBINATION THERAPIES. (PROCOMB STUDY)

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INTRODUCTION AND OBJECTIVES: The following multicenter randomized protocol aimed to evaluate the efficacy and tolerability of the combination therapy between SeR, Ly and Se (Profluss ®) + tamsulosin versus monotherapies with Ser, Ly and Se (Profluss ®) or tamsulosin in patients with LUTS / BPH.

METHODS: From March 2011 to March 2012, 225 patients from 11 Italian centers were enrolled in this randomized, double-blind study.

The inclusion criteria were: age between 55 and 80 years old, absence prostate cancer, PSA $<4$ ng/ml, IPSS $\geq 12$, prostate volume $\leq 60$ cc, peak flow $\leq 15$ ml/s, post -void residual (PVR) $<150$ ml. The participants were randomized with a 1:1:1 ratio into 3 treatment arms each consisting of 75 patients: group A (Profluss ® 1 tablet per day for 1 year), group B (tamsulosin 0.4 mg 1 tablet a day for 1 year) and group C ( Profluss ® 1 tablet per day for 1 year + tamsulosin 0.4 mg 1 tablet per day for 1 year).

RESULTS: Of all patients, 219 patients completed 12 months of treatment. The treatment groups were statistically balanced. At the intergroup analysis, significant differences were found between group C and group A in terms of IPSS (median change: -2, $p<0.01$), IPSS% (median change: -9.3, $p<0.01$), peak-flow (median change: 1, $p = 0.04$), peak-flow% (median change: 10.5, $p = 0.02$) and PVR (median change: -20.0, $p=0.001$). We demonstrated a significant increase of at least 3 points in the IPSS in 71.6 % of subjects in group C when compared to group A ( 53.7 %, $p = 0.01$) and group B (51.3 %, $p = 0.04$), a significant decrease of 25% of the IPSS in 44.6 % of patients in group C compared to group A ( 23.9 %, $p = 0.004$) and group B (23.1 %, $p = 0.002$) and a significant increase of 30 % of peak-flow in 47.30 % of patients of Group C compared to group A (29.85%, $p=0.03$) and group B (30.77%, $p=0.03$). Significant differences were found in terms of IPSS (median change: -2.0, $p = 0.002$), IPSS% (median change: -9.0, $p=0.008$), peak-flow (median change: 0.8, $p=0.04$) and peak-flow% (median change: 6.4, $p=0.02$) between group C and group B.

No difference between the two groups in terms of PVR ($p=0.23$).

CONCLUSIONS: In this multicenter, randomized, double-blind study the combination therapy with Ser-Se-Ly + tamsulosin 0.4 mg for 1 year was demonstrated to be more effective than the individual monotherapies in terms of reduction of the symptom score (IPSS) and in terms of increasing the Qmax in patients suffering from LUTS / BPH of moderate to severe

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## PD23-08

### COMBINATION OF TAMSULIN (0.4 MG) AND DUTASTERIDE (5 MG) FOR BENIGN PROSTATIC HYPERPLASIA. OBJECTIVE ANALYSIS OF STROMAL COMPONENTS OF THE TRANSITION ZONE

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INTRODUCTION AND OBJECTIVES: We conducted an objective (stereological) histological analysis of the stromal components of the transition zone of benign prostatic hyperplasia (BPH) patients using or not using a combination of tamsulin (0.4-mg) and dutasteride (5-mg).

METHODS: BPH samples were analyzed in the transition zone of 5 patients submitted to open surgery without previous treatment (control group) and 5 patients with BPH, submitted to open surgery, which underwent treatment with tamsulosin + dutasteride for 3 months prior to surgery.

The samples were removed after open surgery, and fixed in 4% buffered formalin for a maximum period of 24 hours. Fragments from the 2 groups were subjected to the following histochemical techniques; hematoxylin-eosin, Masson's trichrome and Picrosirius red for analysis of connective tissue, and immunohistochemical staining by using the anti-alpha-actin for the analysis of smooth muscle fibers and anti-elastin for analysis elastic system. Quantitative analysis was performed using Image J software with the differentiation method of color segmentation.

RESULTS: The analysis of sections stained by Picrosirius observed under polarized light showed no difference in collagen arrangement and distribution between treated and untreated patients. Both groups presented reddish homogeneous fibers in all analyzed fields, characterizing the presence of thicker fibers, possibly collagen type I. In the sections stained by Masson's trichrome, the quantitative analysis showed a significant decrease of approximately 34% of the collagen in individuals that used combo dart, when compared to controls. The immunohistochemical analysis showed an increase of 42% in the elastic system fibers in patients using combodart, when compared to controls. Regarding smooth muscle fibers, the patients in combodart group presented an increase of 81%.

CONCLUSIONS: Although these results are preliminary, with a small number of patients, to our knowledge, this is the first report of a comparative objective of BPH stromal components of controls and patients using combodart. The study would continue increasing the number of patients and an analysis of other components of the stroma and parenchyma.

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## PD23-09

### ALFUZOSIN AND FLUBRIPROFEN COMBINATION THERAPY FOR THE MANAGEMENT OF LOWER URINARY TRACT SYMPTOMS

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INTRODUCTION AND OBJECTIVES: To compare the efficacy and safety of alfuzosin alone, flurbiprofen alone, and alfuzosin plus flurbiprofen combination for lower urinary tract symptoms (LUTS) caused by benign prostatic obstruction (BPO).

METHODS: Seventy-eight patients complaining of LUTS secondary to BPO were enrolled in this clinical trial. Patients without any cardiac or hepatorenal insuffenciency and without peptic ulcus history were randomly assigned to receive alfuzosin XL 10 mg, flurbiprofen SR 200mg or combination treatment. Trans-rectal ultrasound was performed for measurement of prostatic volume firstly, then patients were evaluated by using International Prostate Symptom Score (IPSS) (irritative, obstructive and total separately), uroflowmetry (maximal and average urinary flow rate (Qmax and Qave)) and both at baseline and following a 4-week treatment course.

RESULTS: There was not any difference among the groups regarding age and baseline values of prostate volume, irritative, obstructive and total IPSS, Qmax, Qave and residue ($P > .05$). The total, irritative and obstructive IPSS and residue decreased significantly in all 3 groups after treatment ($P < .01$). Qmax and Qave significantly improved only in combination therapy group ($P < .01$) without any additional significant side effect.

CONCLUSIONS: A combination of an alpha blocker alfuzosin with flurbiprofen which is a member of the phenylalkanoic acid