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EFFICACY OF TAMSULOSIN OCAS 0.4 MG IN FEMALE WITH LOWER URINARY TRACT SYMPTOMS: A RANDOMIZED, DOUBLE-BLIND, PLACEBO CONTROLLED STUDY

Hypothesis / aims of study
We evaluated the clinical efficacy and safety of tamsulosin OCAS 0.4 mg in the treatment of patients with female lower urinary tract symptoms.

Study design, materials and methods
A total of 120 female 25 to 65 years old with lower urinary tract symptoms (LUTS) and an International Prostate Symptom Score (IPSS) >/=8, frequency (8 or more voids per 24 hours) and urgency (3 or more episodes per 24 hours) with or without urgency urinary incontinence were entered into the study. Subjects were randomized to receive tamsulosin OCAS 0.4 mg or placebo during 12 weeks. Successful treatment outcomes use primary end point of International Prostate Symptom Score quality of life 2 or less and secondary end point of total International Prostate Symptom Score 7 or less. Other outcome measures included International Prostate Symptom Score individual item scores, King's Health Questionnaire quality of life domains, objective assessment parameters of 24-hour frequency volume chart, maximum flow rate and post-void residual urine.

Results
Using a primary end point, 39 of 50 (78%) evaluable tamsulosin OCAS 0.4 mg subjects responded in contrast to 21 of 50 (42%) evaluable placebo subjects ($p < 0.02$). The secondary end point revealed a successful outcome in 82% of tamsulosin OCAS 0.4 mg subjects vs 47% in placebo ($p < 0.01$). Of the 7 International Prostate Symptom Score individual item scores, only item scores of frequency and straining showed statistically significant reductions with tamsulosin OCAS 0.4 mg ($p < 0.01$). All King's Health Questionnaire quality of life domains except domain of severity measures showed statistically significant improvement with tamsulosin OCAS 0.4 mg ($p < 0.05$). There were no differences between treatment groups in all objective assessment parameters. Of all evaluable subjects 26 of 50 (52%) on placebo experienced adverse events vs 18 of 50 (36%) on terazosin ($p > 0.05$).

Concluding message
Tamsulosin OCAS 0.4 mg therapy significantly improved IPSS quality-of-life scores and King's Health Questionnaire scores. These findings might seem surprising, because previous studies have shown that alpha-adrenoreceptor antagonists are not effective in women with lower urinary tract symptoms.

Disclosures
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