

A PILOT STUDY TO INVESTIGATE THE USE OF TAMSULOSIN IN WOMEN WITH LOWER URINARY TRACT SYMPTOMS

Hypothesis / aims of study:

Lower urinary tract symptoms (LUTS) are common in women. Although many women have primarily storage symptoms, others have a combination of storage and voiding symptoms without having a defined mechanical obstruction. Anti-muscarinic drugs are commonly used to treat women with LUTS whether they have primarily storage or storage and voiding symptoms. It is doubtful that anti-muscarinics improve voiding symptoms, and may actually worsen such symptoms. It has been postulated that alpha-blockers may help in women with LUTS if the predominant symptoms are voiding related. This may be due to bladder neck relaxation as has been shown in children or due to other yet not well defined mechanisms. Previous small scale studies have been equivocal and larger randomized controlled trials have not been performed. Tamsulosin, an alpha 1 a,d subtype selective alpha blocker with minimal side-effects and an excellent safety profile, has anecdotally been noted to improve such symptoms in women. At the time of this study, no validated female LUTS questionnaires were available, and thus the the American Urological Association symptom index was used as it best divided symptoms between storage and voiding. This randomized, double-blinded, placebo-controlled study compared the symptomatic improvement afforded by tamsulosin vs. placebo in female LUTS with a significant component of voiding symptoms.

Study design, materials and methods:

Women with an AUA total symptom score ≥ 13 , AUA Obstructive score ≥ 5 , were randomized into a multi-center, double blind, placebo- controlled trial of eight weeks duration. Patients were randomized to tamsulosin 0.4 mg or placebo once daily. The AUA symptom index was the primary measure of efficacy. The Incontinence Impact Questionnaire and Urinary Distress Inventory Questionnaire were secondary endpoints.

Results

No patients had a symptom score of less than 8.

Total AUA Symptom Score and Change From Baseline

AUA symptom score	Placebo	Tamsulosin 0.4 mg	AUA symptom score	Placebo	Tamsulosin 0.4 mg
All Patients	N=33	N=37	Moderate (8-19)	N=18	N=16
Baseline	19.9	20.4	Baseline	16.4	14.8
Change From Baseline	-4.0	-5.2	Change From Baseline	-4.4	-1.3

AUA symptom score	Placebo	Tamsulosin 0.4 mg
Severe (20-35)	N=15	N=21
Baseline	24.0	24.6
Change From Baseline	-2.8	-8.7*

*P=0.017 (tamsulosin 0.4mg versus placebo)

Tamsulosin was well tolerated.

Interpretation of results

Evaluating all patients, the change from baseline in AUA score was in favor of tamsulosin but did not reach statistical significance compared to placebo. However, the subset of patients with a total AUA symptom score ≥ 20 showed a statistically significant improvement from tamsulosin treatment. Considering the relatively small number of patients, the improvement

appears clinically significant. However, these results must be confirmed in a trial designed to specifically look at this patient population as the primary prespecified analysis.

Concluding message

Tamsulosin treatment resulted in statistically significant improvement in women with severe LUTS with an obstructive component as measured with AUA symptom score. These results need to be validated using newly developed LUTS specific instruments for women and specific QOL instruments.

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