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# EFFICACY OF TAMSULOSIN 0.2MG AND TAMSULOSIN 0.2MG PLUS TOLTERODINE 2MG FOR TREATMENT OF WOMEN WITH LOWER URINARY TRACT SYMPTOMS

#### Hypothesis / aims of study

Women with overactive bladder and other lower urinary tract symptoms (LUTS) may not be improved by monotherapy with antimuscarinic agents or alpha-blockers. To evaluate the efficacy and safety of tamsulosin and tamsulosin plus tolterodine in women with lower urinary tract symptoms, herein we assessed changes of international prostate symptom score (IPSS), bladder diary variables, and safety and tolerability following two different treatments.

### Study design, materials and methods

Randomized, multicenter trial at 4 urology centers involving women over 18 years or older who had a total IPSS of 8 or higher and a bladder diary documenting micturition frequency ( $\geq$  8 times per 24 hours), urgency (> 1 episode per 24 hours), and nocturia (( $\geq$  2 episodes). Additional inclusion criteria were maximal urinary flow rate (Qmax,  $\leq$  15 ml per second) with a postvoid residual urine (PVR, <50 ml). Patients were randomly assigned to receive tamsulosin (0.2 mg, n=40) or both tamsulosin (0.2 mg) plus tolterodine (2 mg, n=40) for 12 weeks.

#### **Results**

IPSS decreased significantly in both groups. IPSS at baseline, at week 4, at week 8, and at week 12 was 23.33, 17.00, 16.50, 12.17 in tamsulosin group and 23.20, 18.20, 17.60, 15.00 in tamsulosin plus tolterodine group, respectively. Qmax at baseline and at week 12 was 11.90 ml/sec and 19.38 ml/sec in tamsulosin group and 10.44 ml/sec and 20.72 ml/sec in tamsulosin plus tolterodine group. At week 12, PVR was increased from 7.67 ml to 17.67 ml in tamsulosin group and from 10.60 ml to 13.20 ml in tamsulosin plus tolterodine group. Fig 1, 2, and 3 showed these results in graphs. Likewise other diary variables such as urgency, frequency, nocturia, quality of life (QoL), PPBC, and OAB-q were also markedly improved in both groups by week 12. However, there were no significant differences in the changes of these variables between two groups.

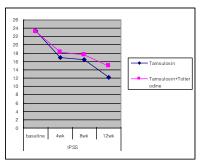


Fig 1. Changes of IPSS.

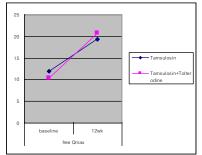


Fig 2. Changes of Qmax.

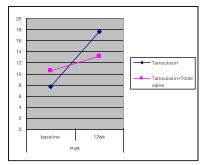


Fig 3. Changes of PVR.

#### Interpretation of results

Alpha-blocker tamsulosin 0.2mg was effective in women with LUTS as men with LUTS. Tamsulosin 0.2mg plus tolterodine 2mg combination therapy for 12 weeks also provided benefit for women with LUTS.

<u>Concluding message</u> Although there were no significant differences between two groups, both tamsulosin monotherapy and treatment with tamsulosin plus tolterodine improved IPSS, QoL, Qmax, and PVR in women with LUTS.

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Is this a clinical trial?	No
What were the subjects in the study?	HUMAN
Was this study approved by an ethics committee?	Yes
Specify Name of Ethics Committee	IRB, Daegu Catholic University Medical Center
Was the Declaration of Helsinki followed?	Yes
Was informed consent obtained from the patients?	Yes