

THE EFFECT OF TOLTERODINE EXTENDED RELEASE (ER) WITH OR WITHOUT TAMSULOSIN HCL (0.2MG) ON THE FEMALE LOWER URINARY TRACT SYMPTOMS WITH MAXIMAL URINARY FLOW RATE LESS THAN 12ML/SEC

Hypothesis / aims of study

We assessed the effect of tamsulosin HCl (0.2 mg) with or without tolterodine extended release (2 mg) on female patients who had a maximal flow rate less than 12 ml/s who are suspected of suffering functional BOO.

Study design, materials and methods

From January 2007 to December 2008, 250 patients with a maximal flow rate less than 12 ml/sec were selected for this study. The patients were treated with tamsulosin alone (0.2 mg/day) (group I) or tamsulosin combined with tolterodine (2 mg/day)(group II). The effectiveness of these medications was assessed at baseline and after 12 weeks of treatment on the basis of the International Prostate Symptom Score (IPSS) and other measures, including the maximal urinary flow rate (Qmax) and the postvoid residual urine volume.

Results

For the group I (n=106), the total IPSS, the voiding symptom score, the Qmax and the residual urine volume were significantly improved from baseline after 12 weeks of treatment ($p<0.05$), whereas the storage symptom score was not. For the group II (n=75), the storage symptom score also significantly improved from baseline after treatment as well ($p<0.05$). After 12 weeks of treatment, there were no significant differences in subjective symptom score and objective uroflow parameters between two groups, except for storage symptoms (group I; 4.3 ± 1.6 vs group II; 3.8 ± 0.9) and postvoid residual urine (group I; 31.8 ± 22.4 vs group II; 56.1 ± 29.7) which were not considered meaningful value to induce harmful effect in clinical setting.

Interpretation of results

Combination therapy with tamsulosin and tolterodine significantly improved the subjective symptoms and uroflowmetric measures of female patients with a maximal flow rate of less than 12 ml/s.

Concluding message

Combination therapy may be an effective, safe treatment approach for female patients with a low maximal urinary flow rate and who are suspected of suffering from functional BOO.

References

1. Athanasopoulos A, Gyftopoulos K, Giannitsas K, Perimenis P: Effect of alfuzosin on female primary bladder neck obstruction. *Int Urogynecol J Pelvic Floor Dysfunct* 2009;20(2):217-22 .
2. . Goldman HB, Zimmern PE. The treatment of female bladder outlet obstruction. *BJU Int* 2006;98:359-366.
3. Groutz A, Blaivas JG, Chaikin DC. Bladder outlet obstruction in women: Definition and characteristics. *Neurourol Urodynam* 2000;19:213-20.

Specify source of funding or grant	N/A
Is this a clinical trial?	Yes
Is this study registered in a public clinical trials registry?	Yes
Specify Name of Public Registry, Registration Number	Chonnam National University Hospital Research Institute of Clinical Medicine
Is this a Randomised Controlled Trial (RCT)?	No
What were the subjects in the study?	HUMAN
Was this study approved by an ethics committee?	Yes
Specify Name of Ethics Committee	Ethic Committee of Chonnam National University Hospital Research Institute of Clinical Medicine
Was the Declaration of Helsinki followed?	Yes
Was informed consent obtained from the patients?	Yes