428

Park D S[1], Lee S R[1], Jeon H G[1], Hong J Y[1], Kim D[2]
1. *CHA Bundang Medical Center, CHA University,* ***2.*** *Myongji Hospital, Kwandong University College of Medicine*

A PROSPECTIVE OPEN-LABEL CLINICAL OBSERVATIONAL STUDY TO EVALUATE THE EFFECTIVENESS OF ADDING TAMSULOSIN TO SOLIFENACIN ON INCREASED DAYTIME FREQUENCY OR NOCTURIA IN THE MALE PATIENTS WITHOUT BLADDER OUTLET OBSTRUCTION.

Hypothesis / aims of study
Some patients complain of increased daytime frequency or nocturia without any underlying diseases such as benign prostate hyperplasia or overactive bladder. In these cases increased bladder afferent sensory is assumed to be one of the possible causes. Anti-cholinergic drugs have been used to control detrusor contraction for frequent voiding but cannot be good enough in all cases. Recently alpha-blocker, tamsulosin, is reported to have an inhibitory effect on the C-fiber afferent nerves, thereby improving bladder storage function. Therefore combination therapy with anti-cholinergic drug and tamsulosin is expected to be more effective in treatment of increased daytime frequency or nocturia.

Study design, materials and methods
Men aged ≥45 years with 8 or more micturitions per 24 hours and 1 or more nocturia per 24 hours, a post-void residual urine of 50 ml or less and a peak flow rate of 10 ml per second or greater were randomized to 12 weeks of solifenacin monotherapy (group 1) or solifenacin plus tamsulosin (group 2). The patients completed the International Prostate Symptom Score (IPSS), 3-days voiding diary, and uroflowmetry before the treatment, 3 weeks and 12 weeks after the treatment. Voiding symptom score was defined as the sum of scores for questions 1, 3, 5, and 6 of the IPSS. Bladder storage symptom score was defined as the sum of scores for questions 2, 4, and 7 of the IPSS. Score sum of IPSS, voiding symptom, and bladder storage symptom were evaluated between two groups. Total number of voids, daytime voids, and nocturia in 3-days voiding diary were also evaluated. Adverse events were monitored throughout the study.

Results
A total of 60 men were enrolled (Study was designed to have a power of 80% for detecting when the mean number of daytime voids at baseline decreased by 2.0 compared with the mean number of daytime voids at 12 weeks at the 5% significance level. The standard deviation and withdrawal rate was assumed to be 2.5 and 20%, respectively. Then 30 persons in each group were determined). All patients completed the 12 weeks of the treatment. Score sum of IPSS, voiding symptom, and bladder storage symptom improved after the treatment (Table. 1). Total number of voids, daytime voids, and nocturia also improved after the treatment in both groups. However, compared with group 1, total number of daytime voids was significantly decreased in group 2 (p=0.046). There was no difference in residual urine volume and adverse events between two groups (p=0.315 and p=0.731, respectively).

Interpretation of results
Both solifenacin monotherapy and combination therapy with solifenacin and tamsulosin were effective in treatment of increased daytime frequency and nocturia. But compared with two groups combination therapy with solifenacin and tamsulosin was significantly effective for the treatment on increased daytime frequency.

Concluding message
Treatment modality involving solifenacin combined with tamsulosin could be a viable option, particularly in patients with increased daytime frequency.

	Solifenacin			Solifenacin + Tamsulosin			p-value
	Baseline	3 weeks	12 weeks	Baseline	3 weeks	12 weeks	
Score sum of IPSS	16.8±3.3	14.6±3.5	11.9±3.3	16.9±4.1	13.2±2.3	9.9±2.3	0.128
Score sum of voiding symptoms	4.7±2.2	4.0±2.3	3.1±2.0	4.5±2.2	3.4±1.4	2.4±1.2	0.265
Score sum of storage symptoms	7.4±1.9	6.8±1.8	5.8±1.6	7.6±2.2	5.9±1.5	4.6±1.1	0.123
Total number of voids in 3 days	30.5±6.6	28.1±4.8	27.3±4.3	31.9±4.6	25.2±3.6	23.0±2.8	0.084
Total number of daytime voids in 3 days	21.8±5.6	20.2±4.0	19.9±3.5	22.7±3.3	17.4±2.6	15.7±2.5	**0.024**
Total number of nocturia in 3 days	8.7±1.9	7.9±1.7	7.4±1.6	9.2±2.6	7.8±1.8	7.3±1.9	0.834

Specify source of funding or grant	**None**
Is this a clinical trial?	**Yes**
Is this study registered in a public clinical trials registry?	**No**
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	**Institutional Review Board of Bundang CHA Medical Center**
Was the Declaration of Helsinki followed?	**Yes**
Was informed consent obtained from the patients?	**Yes**