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Cho S[1], Kwon S[2], Lee K W[3], Yoo T K[4], Shin D G[5], Kim S W[6], Bae J H[7], Choi H[7], Kim Y H[3]

1. *Department of urology, Inje University, Ilsanpaik Hospital, Goyang, Korea,* ***2.*** *The Department of Mathematics, College of Natural Sciences, Ajou University,* ***3.*** *The Department of Urology, Soonchunhyang University Bucheon Hospital, Soonchunhyang University College of Medicine,* ***4.*** *The Department of Urology, Ulji University Nowon Hospital, Ulji University College of Medicine,* ***5.*** *The Department of Urology, Busan University Hospital, Busan University College of Medicine,* ***6.*** *The Department of Urology, Seoul University Hospital, Seoul University College of Medicine,* ***7.*** *The Department of Urology, Korea University Ansan Hospital, Korea University College of Medicine*

A MULTICENTER REAL-LIFE STUDY OF THE EFFICACY OF AN ALPHA-BLOCKER WITH OR WITHOUT ANTICHOLINERGIC AGENT (IMIDAFENACIN) TREATMENT IN PATIENTS WITH LOWER URINARY TRACT SYMPTOMS/BENIGN PROSTATIC HYPERPLASIA AND STORAGE SYMPTOMS

Hypothesis / aims of study

To evaluate the efficacy and safety of combination therapy comprising a short-acting anticholinergic, imidafenacin and an alpha-blocker compared with monotherapy with an alpha-blocker only in men with lower urinary tract symptoms (LUTS) and storage symptoms.

Study design, materials and methods

The 12-week, prospective, double-blind, randomized trial enrolled men with LUTS and storage symptom. The inclusion criteria were a total International Prostate Symptom Score (IPSS) ≥12, an IPSS question 4 score ≥2, ≥8 micturitions in 24 h, and a prostate volume >20ml. The primary outcome was a change in the micturition number from baseline. Bladder diary variables, Patient Perception of Intensity of Urgency Scale (PPIUS) scores, IPSS and safety were assessed.

Results

Of 260 patients screened, 221 completed the study. Patients were randomly assigned to receive an alpha-blocker only (n = 111, group 1) or combination therapy comprising an alpha-blocker and an anticholinergic (n = 110, group 2) for 12 weeks. Group 1 and 2 showed significant improvement in their 24-h micturition numbers (-1.87 and -2.08, respectively), nocturia episodes (-0.48 and -0.53, respectively), total IPSS (-9.9 and -8.8, respectively), and PPIUS scores (-0.19 and -0.24, respectively). Micturition number per 24 h, daytime frequency, urgency, the PPIUS score, the IPSS question 4 score and IPSS QoL score improved significantly in the combination therapy group, but changes in total IPSS, nocturia episodes, and safety outcomes did not differ significantly between the groups.

Interpretation of results

Compared with treatment with an alpha-blocker alone, combination therapy comprising an anticholinergic and an alpha-blocker showed superior efficacy and its safety was similar in patients with LUTS and storage symptoms.

Concluding message

Based on the results from the present study, short-acting anticholinergic agents could be considered as the first-line starter medications that do not cause serious side effects in male LUTS patients with storage symptoms.

Table 1. Outcome measurements based on the voiding diary and International Prostate Symptom Score data, Full Analysis set

Variables	**Group 1 (*n* = 111)**					**Group 2 (*n* = 110)**					***p* value†**
	Baseline	4 wk	**12 wk**	**def**	***p* value‡**	Baseline	4 wk	**12 wk**	**def**	***p* value‡**	
Voiding diary											
	10.05	8.75	**8.18**	**1.87**	**<0.0001**	9.95	8.39	**7.87**	**2.08**	**<0.0001**	**0.0416**
Micturition/24h											
	8.06	7.10	**6.69**	**1.39**	**<0.0001**	7.82	6.62	**6.26**	**1.55**	**<0.0001**	**0.0142**
Frequency/24h											
Nocturia/24h	1.99	1.64	**1.51**	**0.48**	**0.0014**	2.13	1.77	**1.61**	**0.53**	**0.0006**	0.1634
Urgency/24h	4.15	3.08	**2.30**	**1.85**	**<0.0001**	3.59	2.04	**1.76**	**1.83**	**<0.0001**	**0.0031**
PPIUS	2.29	2.14	**2.10**	**0.19**	**0.0231**	2.17	2.00	**1.93**	**0.24**	**0.0054**	**0.0026**
IPSS											
Total score	22.18	14.78	**12.28**	**9.9**	**<0.0001**	21.94	14.60	**13.14**	**8.8**	**<0.0001**	0.7738
Storage	9.14	6.13	**5.14**	**4.00**	**<0.0001**	9.18	5.71	**4.96**	**4.22**	**<0.0001**	0.3906
Voiding	13.04	8.65	**7.14**	**5.90**	**<0.0001**	12.76	8.88	**8.19**	**4.57**	**<0.0001**	0.3667
QoL	4.75	3.31	**2.84**	**1.91**	**<0.0001**	4.82	3.28	**2.90**	**1.92**	**<0.0001**	**0.0452**
Question 4	3.44	2.16	**1.60**	**1.84**	**<0.0001**	3.26	1.78	**1.52**	**1.74**	**<0.0001**	**0.0251**
Safety											
Qmax	10.84	13.42	**13.98**	**3.14**	**0.002**	10.46	11.95	**12.88**	**2.42**	**<0.0001**	0.510
PVR, mL	34.91	33.1	30.33	4.58	0.277	30.48	32.73	33.14	2.64	0.582	0.953

Group 1 = Placebo + Alfuzocin hydrochloride; Group 2 = Imidafenacin + Alfuzosin hydrochloride; def = defferences from baseline; PPIUS = Patient Perception of Intensity of Urgency Scale; QoL = quality of life; Qmax = Maximum flow rate; PVR = post-voided residual volume; **† =** Analysis for differences between two groups using generalized linear model, **‡ =** analysis for differences of times in same group using T test.

Disclosures

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