

## COMPARISON OF EFFICACY AND SAFETY ACCORDING TO ANTICHOLINERGIC MEDICATION TIME IN BENIGN PROSTATIC HYPERPLASIA WITH OVERACTIVE BLADDER.

### Hypothesis / aims of study

In benign prostatic hyperplasia with overactive bladder (BPH/OAB) patients, anticholinergics frequently used to improve storage symptoms after 2-4 weeks medication of  $\alpha$ 1-receptor antagonists or 5 $\alpha$  reductase inhibitors. However, adding anticholinergics to patients with BPH/OAB is not initially applied in clinical practice, because it could aggravate voiding symptoms, increase the risk of acute urinary retention, or increase postvoid residual (PVR) and adverse effects. The aim of this study was to evaluate the effect and safety of initial anticholinergics combined therapy with  $\alpha$ 1-receptor antagonists in BPH/OAB patients.

### Study design, materials and methods

Included in the present study were 50 male patients diagnosed with both moderate or severe BPH (indicated by a total score of  $\geq 8$  on the International Prostate Symptom Score [IPSS] and a score of  $\geq 2$  on the Quality of Life [QoL] index) and OAB (indicated by the Overactive Bladder Symptom Score [OABSS] criteria of a total score of  $\geq 3$  and a question 3 (Q3) (urgency) score of  $\geq 2$  ( $\geq 1$  week)). They were randomly assigned in a prospective and single-blind fashion to either the control group (solifenacin 5 mg/day, 4 weeks after tamsulosin 0.2 mg/day) or the initial combined group (solifenacin 5 mg and tamsulosin 0.2 mg, once daily as initial therapy) for 2 months. IPSS, OABSS, maximal urinary flow rate (Qmax), and PVR were used to grade symptoms, side effects, and the impact on QoL at the start of the study, 1 and 2 months after solifenacin medication.

### Results

There were no significant differences in patient background, including age, prostate volume, Qmax, PVR, mean score of IPSS and OABSS, between the control and initial combined therapy group. In initial combined therapy group, the IPSS storage symptom score and OABSS score were significantly improved compared with the control group after 1 month. The IPSS voiding, storage symptom score and OABSS score were improved compared to baseline scores in both group, but there were no significant differences between the two groups after 2 months. The Qmax did not differ significantly but PVR was higher in the initial combined therapy group after 1 month. However, there were no differences in Qmax and PVR between the two groups after 2 months. There were no serious side effects such as acute urinary retention, urinary tract infection in either group (Table).

### Interpretation of results

Initial combined therapy using  $\alpha$ 1-receptor antagonist and anticholinergics rapidly improved the storage symptom score of the IPSS and OABSS score compared with delayed anticholinergics medication without causing serious side effects.

### Concluding message

This initial combination medication can be considered as an effective and safe treatment method for BPH/OAB patients.

Table. Comparison of variables between the two groups.

	Control Group (n=25)			Initial Combined Therapy (n=25)		
	Baseline	4 weeks	8 weeks	Baseline	4 weeks	8 weeks
Age (years)	62.3 $\pm$ 7.6			61.7 $\pm$ 6.2 <sup>a</sup>		
PV (ml)	32.3 $\pm$ 7.4			31.9 $\pm$ 8.8 <sup>a</sup>		
IPSS (Voiding)	8.8 $\pm$ 1.8	6.9 $\pm$ 1.7	5.7 $\pm$ 1.7	8.7 $\pm$ 1.5	6.8 $\pm$ 1.6	5.6 $\pm$ 1.9
IPSS (Storage)	13.2 $\pm$ 3.1	10.8 $\pm$ 2.6	7.6 $\pm$ 1.8	12.9 $\pm$ 3.0	9.6 $\pm$ 2.4 <sup>b</sup>	7.4 $\pm$ 2.4
OABSS	6.4 $\pm$ 1.5	5.4 $\pm$ 1.4	3.7 $\pm$ 1.4	6.5 $\pm$ 1.7	4.4 $\pm$ 1.5 <sup>b</sup>	3.7 $\pm$ 1.6
Qmax (ml/s)	10.3 $\pm$ 3.9	12.4 $\pm$ 4.1	15.0 $\pm$ 5.0	10.2 $\pm$ 2.6	12.5 $\pm$ 3.1	14.4 $\pm$ 3.8
PVR (ml)	48.2 $\pm$ 21.8	33.9 $\pm$ 12.1	38.4 $\pm$ 11.4	47.5 $\pm$ 20.6	43.6 $\pm$ 15.3 <sup>b</sup>	39.2 $\pm$ 9.1

Values are presented as mean  $\pm$  SD.

Control group, mono-therapy with tamsulosin (0.2 mg/day) for 4 weeks followed by combination therapy with tamsulosin and solifenacin (5 mg/day) for 8 weeks; Initial combined therapy, combination therapy with tamsulosin and solifenacin for 8 weeks. PV, prostate volume; IPSS, International Prostate Symptom Score; OABSS, Overactive Bladder Symptom Score; Qmax, maximal urinary flow rate; PVR, post-void residual urine volume.

<sup>a</sup> P>0.05 when compared to control group.

<sup>b</sup> P<0.05 when compared to control group.

### Disclosures

**Funding:** None **Clinical Trial:** Yes **Public Registry:** No **RCT:** Yes **Subjects:** HUMAN **Ethics Committee:** Kangbuk Samsung Hospital Institutional Review Board **Helsinki:** Yes **Informed Consent:** Yes