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Introduction and Objective: Silodosin is a highly selective alpha-1A antagonist that is widely used in the treatment of benign prostatic hyperplasia (BPH). We investigated the factors that influence the efficacy of silodosin.

Materials and Methods: One hundred and thirty-two Japanese patients with clinical BPH were entered into this study from October 2008 to July 2010. The dose of silodosin was 8 mg/day. Serum prostate specific antigen (PSA), international prostate symptom score (IPSS), overactive bladder symptom score (OABSS), and maximum flow rate (Qmax) were recorded before and after 12 weeks on silodosin

**Results:** IPSS decreased from  $16.6 \pm 6.2$ (mean  $\pm$  SD) to 10.9  $\pm$  6.2 (P<0.001), Qmax increased from 10.73± 5.46 to  $12.29 \pm 6.09$  mL/sec (P=0.051) and overactive bladder rate decreased from 59.2% to 29.4%. Next, the background factors in patients who showed improvement in Qmax (group A:  $8.69 \pm 4.07$  to  $13.89 \pm$ 5.97 [mL/sec]) and those who did not (group B:  $12.85 \pm 6.26$  to  $9.85 \pm 4.53$ [mL/sec]) were studied. Before treatment, age, period of illness, IPSS and prostate volume (PV) did not differ between the two groups; however, PSA was lower in group A (2.35  $\pm$  1.72 versus 4.98  $\pm$  6.04 )(P=0.0133). There was a positive correlation between PSA and PV (r=0.239, P=0.0217) in all the patients; however, PV did not differ between groups A and B. Moreover, PSA density (PSAd: PSA / PV [ng/mL/cc]) in group A (0.071 ± 0.050) was significantly lower than that in group B  $(0.145 \pm 0.189)$  (P=0.0222). PSAd and PV did not show correlation (r=0.138. P=0.189). The reasons PSA and PSAd were significantly lower in group A were not clarified. Nevertheless, the results showed that PSA production may be negatively correlated with the sensitivity to silodosin and may suggest that higher PSA and PSAd indicate a larger volume of glandular tissue and less capacity of smooth muscle to relax under treatment with silodosin

Conclusions: BPH patients with lower PSA and PSAd showed a better response to silodosin treatment, suggesting that these factors may predict the effectiveness of alpha-1 antagonists and contribute to the selection of treatment.

MP-09.09, Table 1. Baseline characteristics of study patients.

Characteristics	Alfuzosin group	Udenafil group	Combination group
	(n=20)	(n=21)	(n=21)
Mean age (years)	62.0±7.3	61.0±5.9	59.8±6.3
Mean prostate volume (ml)	$32.3 \pm 7.9$	$30.4 \pm 7.0$	$30.4 \pm 7.0$
Mean IPSS*	$18.3 \pm 4.2$	16.2±6.1	$18.0 \pm 6.4$
Mean IPSS-Q0L**	$3.9 \pm 0.5$	$3.3 \pm 1.5$	$3.3 \pm 0.8$
Mean IIEF***	$14.9 \pm 4.7$	12.8±3.5	61.0±5.9
Mean Qmax (ml/sec)	9.5±1.9	$9.7 \pm 5.4$	$9.9 \pm 4.0$
Mean post-void residual urine volume (ml)	35.3±21.0	38.0±23.0	32.5±21

<sup>\*</sup>International prostate symptom score, \*\* International prostate symptom score-quality of life,
\*\*\* International index of erectile function

## MP-09.09

Korea

Efficacy and Safety of Combination of Alfuzosin and Low Dose Udenafil Once Daily versus Monotherapy in Patients with Comorbid Lower Urinary Tract Symptoms and Erectile Dysfunction: Randomized Prospective Open-label Study

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Introduction and Objective: The purpose of this study was to assess the efficacy and safety of the alfuzosin 10mg once daily (OD), the PDE-5 inhibitor udenafil 50mg OD, and the combination of both on lower urinary tract symptoms (LUTS) suggestive of benign prostatic hyperplasia (BPH) with erectile dysfunction (ED).

Materials and Methods: A randomized, open-label, three-arm study was conducted from September 2009 to February 2010. Patients aged 50-76 year were randomized to receive alfuzosin (n=20), udenafil (n=21), or the combination of both (n=21) for 12 weeks. International prostate symptoms score (IPSS), IPSS quality of life (IPSS-QOL), maximum flow rate (Qmax), post-void residual volume (PVR), transrectal ultrasonography (TRUS) and erectile function domain of the international index of erectile function (IIEF) were evaluated at baseline, 6 and 12 weeks. Complications were also evaluated.

Results: Baseline characteristics of patients were shown at table 1. There was no statistical difference of baseline parameters in three groups. After 12 weeks, changes in IPSS from baseline was significantly improved in Alfuzosin and combination groups ( Alfuzosin: -17.4%, combination: -26.7%, p<0.05, udenafil: -1.8%, p>0.05). Qmax and PVR were significant

improved in Alfuzosin (Qmax and PVR with percentage changes of 13.6%, -27.9%, respectively, p<0.05) and combination groups (Qmax and PVR: 22.3%, -26.4%, p<0.05). Improvement of IIEF was significant with udenafil and combination treatments (combination: 52.1%, udenafil: 34.9%, p<0.05, alfuzosin: 8.0%, p>0.05). Especially, IPSS, Qmax and IIEF were significant improved in combination treatment compared with alfuzosin or udenafil only (p<0.05). All three treatments were well tolerated.

Conclusions: The combination treatment of alfuzosin and low dose udanafil once daily is more effective than monotherapy in patients with comorbid ED and LUTS suggestive of BPH, And combination treatment is also safe.

## MP-09.10

Rapid Increases in Healthcare Utilization and Cost Due to Benign Prostatic Hyperplasia in South Korean Males: Retrospective Population-Based Analysis

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