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SIGNIFICANCE OF RESIDUAL URINE IN DRUG THERAPY FOR PATIENTS WITH BENIGN PROSTATIC HYPERPLASIA ACCOMPANIED BY OVERACTIVE BLADDER (BPH/OAB)

Hypothesis / aims of study
To compare the effects of the α_1-adrenoceptor antagonist (α_1-blocker) naftopidil on BPH/OAB patients in a 50-mg maintenance group and a 75-mg increased dose group, and to examine patient background factors that necessitate a dose increase.

Study design, materials and methods
Patients with an International Prostate Symptom Score (IPSS) of 8 or above, a quality of life (QOL) index of 2 or above, urgency score component of the Overactive Bladder Symptom Score (OABSS) of 2 or above, total OABSS of 3 or above, and prostate volume of 20 mL or greater were selected for the study. Patients with organic diseases other than benign prostatic hyperplasia and patients who had undergone surgery or other treatment not involving internal medicine of the urinary tract or genital tract within six months of the start of the study were excluded. Patients were given an initial treatment of 50 mg/day naftopidil, and OABSS urgency scores were evaluated at Week 8. If the urgency score in Week 8 was 1 or below, treatment was assessed as having been effective, and the dose was maintained at 50 mg/day (“E Group”). If the urgency score in Week 8 was 2 or above, treatment was assessed as having been insufficiently effective, and the dose was increased to 75 mg/day (“I Group”). In both groups, treatment was continued for another eight weeks (i.e., a total of 16 weeks from the start of treatment). The primary endpoints were change in IPSS, OABSS and QOL index at Weeks 8 and 16. Statistical analysis involved performing a Bonferroni test after a Friedman test at the start of treatment and at Weeks 8 and 16. In addition, logistic regression analysis was performed on background factors in patients who were given an increased dose of naftopidil and in patients given a maintenance dose from Week 8. Analyses were conducted using SPSS software.

Results
Of the 106 patients enrolled in the study, 31 were excluded for protocol violations, including failure to visit hospital and failure to take an increased dose. Furthermore, one patient in the I Group dropped out due to an adverse reaction (dizziness). Ultimately, 26 patients in the E Group and 48 patients in the I Group were analyzed. Total IPSS, total OABSS and QOL index at Week 8 decreased significantly in both the E Group and the I Group. In the I Group, the urgency score component of the OABSS improved significantly after the dose was increased (from Week 8 to Week 16). The results of multivariate logistic regression analysis revealed that a postvoid residual urine volume (PVR) of 40 mL or greater at the start of treatment was a significant background factor for a dose increase.(Table)

Interpretation of results
Naftopidil is an α1-blocker, and an increase in dose was expected to have an enhanced effect on the prostate. Consequently, in patients in whom the initial treatment was insufficiently effective (i.e., urgency score component of OABSS was 2 or above), increasing the dose of naftopidil after initial treatment was expected to depend on the size of the prostate. However, in contrast to expectations, PVR was the major factor related to increasing the naftopidil dose.

Concluding message
This study suggests that with BPH/OAB patients, it may be possible to determine whether urinary urgency can be treated with α1-blocker monotherapy as an initial treatment or whether it requires secondary treatment involving an increased dose of α1-blocker or a 5α-reductase inhibitor, etc., based on pretreatment PVR. Pretreatment PVR is thus an important factor when managing BPH/OAB patients with drug therapy.

Table: the results of multivariate logistic regression analysis on patient background factors that necessitate a dose increase

	SE	p	Exp(B)	EXP(B) 95% CI	
Age	**0.045**	**0.413**	**0.964**	**0.883**	**1.053**
Prostate volume	**0.659**	**0.525**	**1.52**	**0.418**	**5.535**
IPSS total score	**0.064**	**0.982**	**1.001**	**0.884**	**1.134**
IPSS-QOL	**0.454**	**0.169**	**0.535**	**0.22**	**1.303**
PVR	**0.66**	**0.026**	**4.354**	**1.195**	**15.873**

OABSS	**0.175**	**0.063**	**1.386**	**0.983**	**1.954**

References
1. none

Disclosures
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