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Wada N[1], Hashizume K[1], Kita M[1], Matsumoto S[1], Kakizaki H[1]
1. *The Department of Renal and Urological Surgery, Asahikawa Medical University*

LONG-TERM EFFICACY OF DUTASTERIDE FOR RELIEVING OUTLET OBSTRUCTION AND IMPROVING BLADDER STORAGE FUNCTION IN PATIENTS WITH BENIGN PROSTATIC ENLARGEMENT: A ONE-YEAR PROSPECTIVE URODYNAMIC STUDY

Hypothesis / aims of study
Using urodynamic study (UDS), we previously showed that 24-week treatment of dutasteride can relieve bladder outlet obstruction (BOO) and improve bladder storage function. We performed serial urodynamic studies to evaluate one-year effect of dutasteride on relieving BOO and improving bladder storage function.

Study design, materials and methods
A prospective study was conducted in consecutive 51 patients who had not been satisfied with alpha blocker monotherapy. Inclusion criteria were prostatic volume (PV) ≥30 ml and IPSS ≥8 or QOL index ≥3 under administration of an alpha blocker without anticholinergic agent. Before (baseline), 24 weeks and one year after dutasteride add-on therapy with preceding alpha blocker, we performed filling cystometry and pressure-flow study (PFS). Patients with moderate to severe overactive bladder symptoms at 24th week were given anticholinergic agent together with alpha blocker and dutasteride.

Results
Five patients who underwent prostatectomy during the study period and 6 patients with insufficient data of UDS at one year were excluded from the study. Of the remaining 40 patients, 20 (group A) were taking alpha blocker and dutasteride during one-year study period, while other 20 (group B) were given anticholinergic agent at 24th week and continued it until the end of the study.
Twenty-four weeks after dutasteride add-on, IPSS, voiding and storage symptom subscore of IPSS significantly improved in both groups compared with the baseline (Table). At 24th week, storage symptom subscore of IPSS in group B was higher than that in group A (7.1±3.2 versus 4.4±2.3). Compared with 24th week, there was no further improvement in IPSS, voiding and storage symptom subscore at one year in either group.
PV (ml) at the baseline, 24th week and one year was 57±25, 40±21 and 38±21 in group A, and 69±31, 48±23 and 48±28 in group B, respectively. In both groups, PV significantly decreased at 24th week compared with the baseline. Compared with 24th week, there was no further decrease in PV at one year in either group.
At the baseline, detrusor overactivity (DO) was observed in 13 of 20 patients (65%) in group A and 18 of 20 patients (90%) in Group B. Cumulative DO resolution rate at 24th week and one year was 46% (6/13) and 46% (6/13) in group A, and 6% (1/18) and 33% (6/18) in group B, respectively. Shafer obstruction grade at the baseline, 24th week and one year was 3.1±1.3, 2.2±1.3 and 2.5±1.3 in group A, and 3.7±1.1, 2.9±1.1 and 2.7±1.4 in group B, respectively. BOO index (BOOI) at the baseline, 24th week and one year was 55±27, 33±26 and 41±25 in group A, and 65±29, 48±25 and 46±28 in group B, respectively. In both groups, Shafer obstruction grade and BOOI significantly decreased at 24th week compared with the baseline. Compared with 24th week, there was no further decrease in either Shafer obstruction grade or BOOI at one year in either group.

Interpretation of results
Dutasteride add-on therapy with alpha blocker significantly reduced PV and relieved obstruction after 24 weeks of treatment. This effect of dutasteride was maintained at one year without further improvement after 24 weeks. Compared with 24th week, the prevalence of DO at one year was not changed in group A without anticholinergics, while in group B with anticholinergics prevalence of DO decreased at one year. These results imply that dutasteride can achieve its maximum effect on relieving obstruction and improving bladder storage function within 24 weeks after administration.

Concluding message
Dutasteride add-on therapy can achieve its maximum effect on relieving obstruction and improving bladder storage function within the first 24 weeks after administration.

	Baseline	24th week	One year
Group A (N=20: Combination of alpha blocker and dutasteride during one-year study period)			
IPSS	14.3±4.4	10.4±5.8 †	10.2±5.2 †
Voiding symptom score	7.4±3.8	5.9±4.4 †	5.5±3.2 †
Storage symptom score	6.2±2.5	4.4±2.3 †	4.7±3.2 †
Prostatic volume (ml)	57±25	40±21 †	38±21 †
Schafer grade	3.1±1.3	2.2±1.3 †	2.5±1.3 †
BOOI	55±27	33±26 †	41±25 †
MCC (ml)	234±93	286±92 †	266±96
DO, *n* (%)	13 (65)	7 (35) †	7 (35) †
Group B (N=20: Combination of alpha blocker and dutasteride for 24 weeks, then additional anticholinergics until the end of study)			
IPSS	18.8±9.2	14.4±7.8 †	12.9±7.4 †
Voiding symptom score	9.6±6.3	7.3±5.2 †	6.5±4.7 †
Storage symptom score	9.2±4.1 §	7.1±3.2 † §	6.4±3.7 †
Prostatic volume (ml)	69±31	48±23 †	48±28 †
Schafer grade	3.7±1.1	2.9±1.1 †	2.7±1.4 †
BOOI	65±29	48±25 †	46±28 †
MCC (ml)	197±72	194±77 §	273±119 †‡
DO, *n* (%)	18 (90) §	17 (85) §	12 (60) †

†: p<0.05 versus at baseline, ‡: p<0.05 versus at 24th week, § :p<0.05 intergroup comparison
BOOI: bladder outlet obstruction index MCC: maximum cystometric capacity DO: detrusor overactivity
Using the Wilcoxon matched-pairs signet-ranks test and unpaired t-test except for prevalence of DO using Chi-square test

Disclosures
Funding: non **Clinical Trial:** No **Subjects:** HUMAN **Ethics Committee:** The ethical committee of Asahikawa Medical University **Helsinki:** Yes **Informed Consent:** Yes