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WHAT OUTCOME IS EXPECTED FOR BPH PATIENTS AFTER WITHDRAWAL OF DUTASTERIDE?

Hypothesis / aims of study

The CombAT study proved that the significant improvement of lower urinary tract symptoms (LUTS) associated with benign prostatic hyperplasia(BPH) has continued for about 18 months after administration of either dutasteride or combination therapy. After this period, the patients' symptoms remained stable but further significant improvements have not been seen. Dutasteride is a type of drug which reduces prostate volume (PV) and relieves symptoms. If treated with dutasteride for a mid to long term period, the PV reduction rate was gradually reduced. For this reason, we assume that dutasteride withdrawal might be possible if temporary. However, there have been few studies on the change of PV and symptoms after withdrawal of dutasteride. So we conducted this study to determine whether withdrawal of dutasteride worsens the symptoms of BPH patients.

Study design, materials and methods

A total of 18 BPH patients treated with dutasteride for over two years were entered into the study. Seventeen patients of which had been treated with combination therapy of dutasteride and α-blocker, one patient had been treated with monotherapy of dutasteride. We examined the total International Prostate Symptom Score (IPSS-T), voiding sub-score (IPSS-V), storage sub-score (IPSS-S), quality of life (IPSS-QOL), PV, serum prostate specific antigen (PSA) and total testosterone (TT), maximal flow rate (Qmax) each three months for half a year after stopping prescription of dutasteride. Primary endpoints were the change of PV from baseline. Secondary endpoints were the change of IPSS-T, IPSS-V, IPSS-S, IPSS-QOL, serum PSA and TT, Qmax. We divided the patients into two groups according to the changes of IPSS-T : group A, under 3 point change of IPSS-T ; group B, 3 points or greater worsening of IPSS-T.

Results

After withdrawal of dutasteride, IPSS-T, IPSS-V, IPSS-S, IPSS-QOL were not significantly deteriorated in all 18 BPH patients. The PV and serum PSA level increased, and serum TT decreased significantly from baseline at six month. The Qmax did not change significantly. Patients were divided into groups A and B, eleven (65%) and six (35%) patients, respectively. Curiously, IPSS-T and IPSS-V of group B were significantly better than those of group A (Table1). In group B, IPSS-S became worse (Fig. 1) and testosterone decreased (Fig. 2), and PV did not change significantly from baseline at six months.

Interpretation of results

Withdrawal of dutasteride could be executed with no significant symptom deterioration in all 18 BPH patients during the six months study period. Baseline IPSS-T and IPSS-V of group B were significantly better than those of group A (Table1). This finding suggested that even if baseline symptoms were stable, it did not mean their clinical course after withdrawal of dutasteride was secured. In group B, IPSS-S deteriorated (Fig. 1) and TT declined (Fig. 2), PV did not changed significantly from baseline at six month. These changes of variables meant that storage symptoms deterioration might be correlated with decrease of TT rather than increase of PV. If the increase rate of TT was higher after administration of dutasteride, the storage symptoms tend to be improved significantly[1)] . To date there are few studies of about the deterioration of storage symptoms accompanied by decrease of TT after withdrawal of dutasteride. The present study has the following limitations. It was open label, not controlled, and the number of patients was limited. This clinical trials is ongoing, therefore, extensive studies will be required.

Concluding message

We proved that withdrawal of dutasteride could be conducted with almost no significant deterioration of symptoms during the six-month study period. If deterioration of symptoms were detected, the decline of TT after the withdrawal of dutasteride might be related worsening of storage symptoms.

Table1

	Group A (n=11)	Group B (n=6)	P-value※
age (year)	77.3±6.73	77.1±7.05	0.47
PV (g)	29.5±12.7	32.6±14.2	0.34
PSA (ng/ml)	2.28±2.38	2.18±1.05	0.25
TT (ng/ml)	6.03±1.16	5.86±0.73	0.37
IPSS-T	11.5±7.95	5.67±3.35	0.03
IPSS-V	6.91±5.04	1.83±1.34	0.005
IPSS-S	4.55±3.17	3.83±2.67	0.32
IPSS-QOL	3±1.41	2.33±0.47	0.09
Qmax (ml/s)	10±1.26	10.84±4.17	0.36

Data indicated as Mean ± SD

※Analysis between two groups using Student's t test

P<0.05 was considered as statistical significance

Figure 1
Mean changes from baseline of IPSS-S was analysed using student's t-test. *P<0.05 was considered as statistical significance.

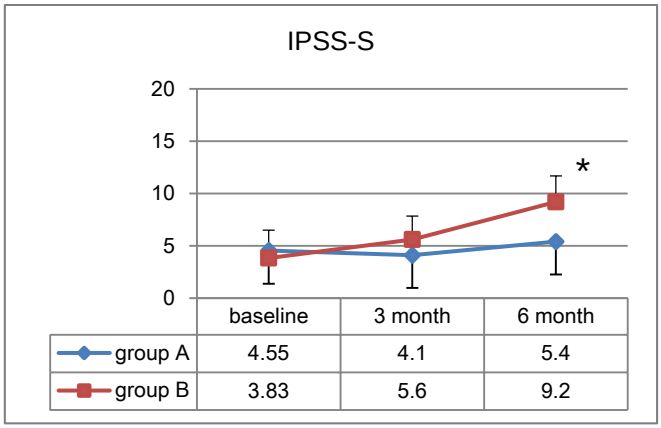
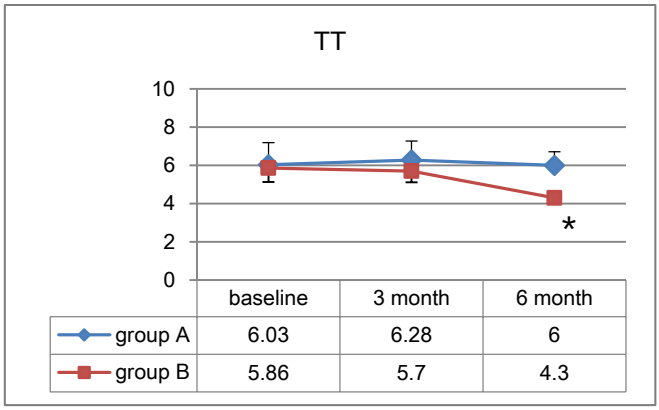


Figure 2
Mean changes from baseline of TT was analysed using student's t-test. *P<0.05 was considered as statistical significance.



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1. The aging male, 2014;17(1): 51-56

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