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THE EFFECTS OF WITHDRAWING THE ALPHA-1 BLOCKER FROM ALPHA-1 BLOCKER PLUS 5-ALPHA-REDUCTASE INHIBITOR COMBINATION THERAPY ON PATIENTS WITH BENIGN PROSTATIC HYPERPLASIA FROM THE PERSPECTIVE OF URODYNAMICS STUDY

Aims of study
Recently, the number of drugs used for treating benign prostatic hyperplasia (BPH) has increased. At present, the combination therapy using an alpha-1 blocker and 5-alpha-reductase inhibitor (5ARI) is recommended for patients with a large prostate. However, many questions remain. They include how long combination therapy should be continued and whether therapeutic effects decrease if combination therapy is changed to single-drug therapy. In this instance, we withdrew the alpha-1 blocker from the combination therapy based on the drug profile, and examined the effects of the withdrawal on patients with BPH by performing an urodynamic study (UDS).

Study design
We administered an alpha-1 blocker (silodosin 8mg/day) and 5ARI (dutasteride 0.5mg/day) combination therapy to untreated patients with lower urinary tract syndrome (LUTS) caused by BPH. After one year's combination therapy, we randomly divided the patients into the following two groups: a group that continued with the combination therapy (CT group) and a group where the alpha-1 blocker was withdrawn from the combination therapy (single administration therapy of 5ARI; ST group). The changes in subjective symptoms were examined using the International Prostate Symptom Score (IPSS) and the Overactive Bladder Symptom Score (OABSS) before and one year after the division of the patients into two groups. The changes in the storage and voiding function were also examined using UDS. (Figure.1)

Results
In the CT group, 57 patients were analyzed (the average age was 71.1 years and the prostate volume was 43.0 mL at the time of the division). In the ST group, 60 patients were analyzed (70.2 years and 41.6 mL). The average IPSS and the average OABSS changed from 11.1 to 10.4 and from 3.7 to 3.4, respectively, for the CT group, and from 10.8 to 10.2 and from 3.6 to 3.3, respectively, for the ST group. Thus, no significant differences in the change of IPSS and OABSS were observed between these two groups. The bladder outlet obstruction index (BOOI) obtained from the UDS changed from 46.1 to 41.8 and from 42.9 to 39.9 for the CT group and ST group, respectively. There was no significant difference in the improvement of these two groups. The frequency of detrusor overactivity (DO), which is the parameter of the storage function, decreased (from 30% to 26%) in the CT group, and increased (from 27% to 32%) in the ST group.
After the changing from combination therapy to 5ARI single-drug therapy, the IPSS worsened in 21 patients (35%), and the average IPSS increased by 3.3. UDS revealed that bladder outlet obstruction (BOO) worsened (BOOI changed from 41.0 to 42.2) and the storage function also worsened (maximum cystometric capacity changed from 326 mL to 298 mL) in these patients. Therefore, the deleterious change of subjective symptoms in these patients was suggested to be related to the reduction of storage and voiding functions.

Concluding message
Although the alpha-1 blocker was withdrawn from the alpha-1 blocker and 5ARI combination therapy for BPH after one year, no adverse effects of the withdrawal were observed on subjective symptoms and bladder outlet obstruction (BOO). No significant differences were observed in the improvements of subjective symptoms and BOO between the combination therapy and single administration groups. When side effects and medication costs were taken into account, the withdrawal of alpha-1 blocker from the combination therapy was considered reasonable. However, the storage function tended to worsen after changing to single-drug therapy. Therefore, the withdrawal must be carefully performed for patients with storage dysfunction.

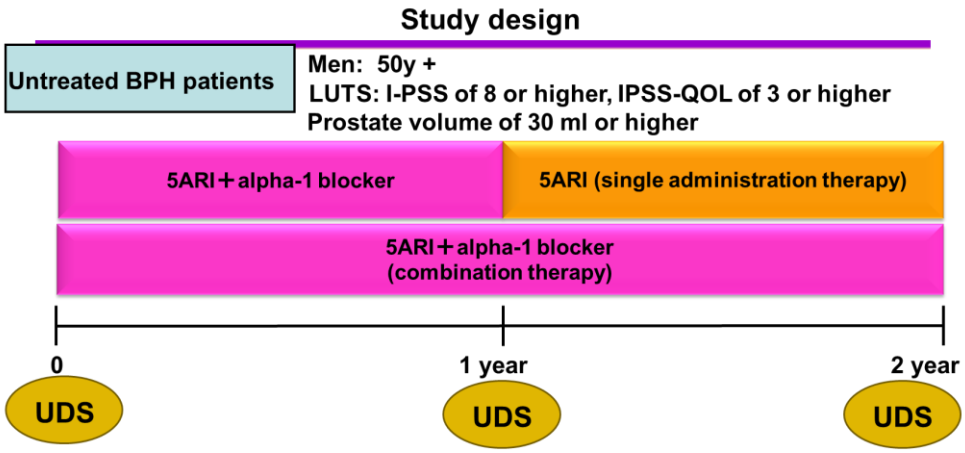

Figure.1

Disclosures
Funding: None **Clinical Trial:** Yes **Public Registry:** No **RCT:** Yes **Subjects:** HUMAN **Ethics Committee:** The Ethics Committee at Nagoya University Graduate School of Medicine. **Helsinki:** Yes **Informed Consent:** Yes