

## AT DAILY CLINICAL PRACTICE, IN A CASE ORAL ADMINISTRATION DUTASTERIDE, THERE ARE FEW CASES THAT CAN REDUCE CONCOMITANT DRUG

### Hypothesis / aims of study

Cause disease of lower urinary tract symptoms (LUTS) in older men often benign prostatic hyperplasia (BPH). Thus, α1 blockers are often selected as the first choice. Dutasteride (DUT) is intended that it is reduced to the prostate by inhibiting the production of dihydrotestosterone, to improve the mechanical obstruction of the urethra due to prostatic enlargement. In ComBAT study where a combination therapy with α1 blocker and DUT was observed for over 4 years, it clarified that the combination therapy has reduced a development of urinary retention and surgery by approximately 65% and also suppressed a progression of prostatic enlargement for a long time in comparison to monotherapy with α1 blocker 1). There are many reports for therapeutic outcome of DUT including combination therapy as well as some withdrawals of the drug and concomitant drug 2,3). However, those reports were to follow a strict protocol and examine with properly selected cases; therefore, only a few reports indeed examined the drug withdrawal in actual clinical practice. At this time, we examined at what level we can discontinue such concomitant drugs in reference to combination therapy cases including DUT.

### Study design, materials and methods

We were considered for the 260 cases that can continue for more than a year DUT in Kurosawa hospital. We investigated whether concomitant drugs can be withdrawn prospective, part retrospective. For cases withdrawal of concomitant drugs was impossible, we examined the reason continuation hope, residual urine large amount, prostate enlargement, such as. For it was possible to withdraw the concomitant drugs cases, was investigated in additional.

### Results

The median age of the patients was 76 years (53–93 years), prostate volume were 57.9 mL (12–378), and residual urine volume were 57.9 mL (0–479), respectively. Over one year later, there were 32 cases with DUT withdrawal. The breakdown was 19 cases for lost follow, 6 cases for surgery, and 3 cases for patient's request. When examined 228 cases excluding the above-described cases, we found 44 cases for undone examination, 59 case for a large amount of residual urine, 25 cases for enlarged prostate, 17 cases for symptom instability, and 43 cases for a request to continue, but only 40 cases were for possible dose reduction. Furthermore, 32 out of 40 cases were for possible dose reduction by single-drug of DUT. The prostate volume and residual urine amount after the therapy for the case with a large amount of residual urine were 55.9±34.2ml and 145.6±75.8ml respectively (Fig.1), and for the case with enlarged prostate were 135.8±75.4ml and 17.0±17.3 ml respectively (Fig.2). When we followed a progression for the cases with a possible withdrawal of concomitant drug, the residual urine amount was 15.6±17.8ml, 15.8±16.3ml, 12.8±11.2ml, and 19.8±16.8ml for the point of the drug withdrawal, and 1,3, 6 months after the drug withdrawal respectively (Fig.2). In addition, in 4 cases, subjective symptom has worsened and then internal use of drug was started again a few days after the concomitant drug withdrawal (Fig.4).

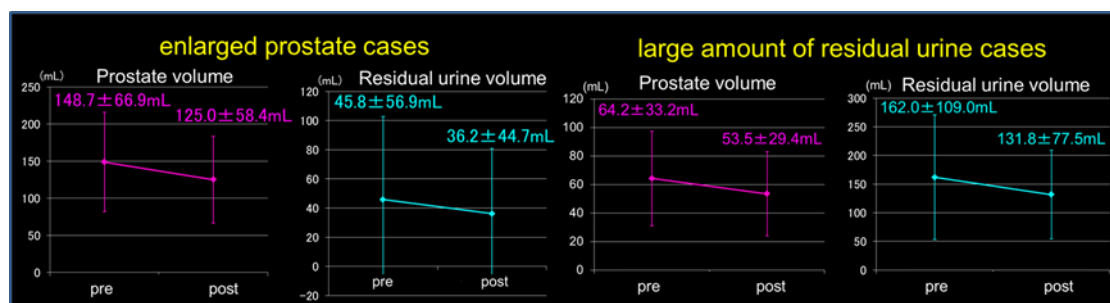


Figure 1

Figure 2

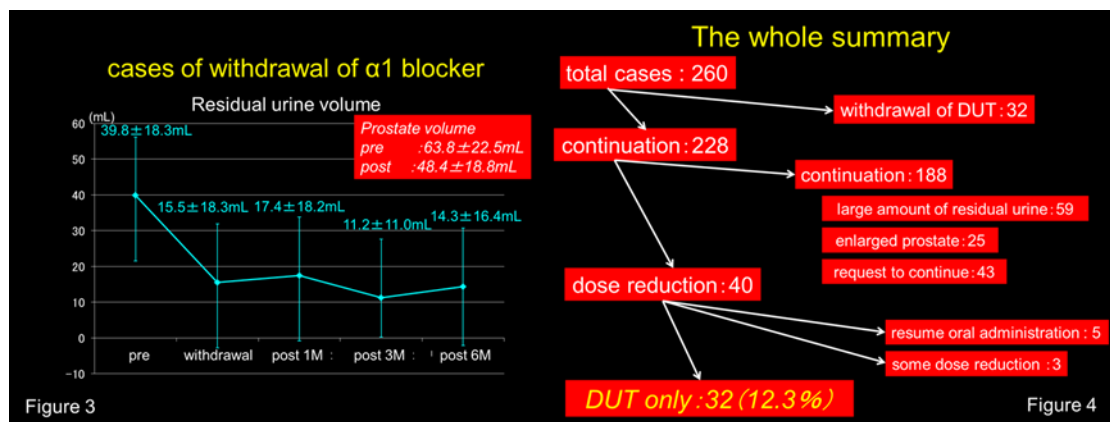


Figure 3

Figure 4

### Interpretation of results

At daily clinical practice, even if continuing the DUT over a year, we were able to confirm that the advanced prostate enlargement of cases or residual urine large amount of cases are found not a few. And, it was actually, possible cases withdrawal of concomitant drug I was also confirmed that not many. In addition, there many cases wish to continue, it was significantly different results from the previous reports.

### Concluding message

It could be the first report for examining a concomitant drug withdrawal in daily medical practice, not an examination based on a strictly-selected case. It was suggested that a case with approximately 50ml of post-therapeutic prostate volume and approximately 50ml of post-therapeutic residual urine amount, or a case with non-sensitiveness/anxious mind could be the case with possible dose reduction. On the other hand, particularly in the elderly and poor general condition cases, it may also seemed without withdraw forcibly.

### References

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### Disclosures

**Funding:** In this examination, we do not receive the subsidy at all. **Clinical Trial:** No **Subjects:** HUMAN **Ethics not Req'd:** This report is the examination that is prospective, part retrospective, and the permission of the ethical committee does not obtain it. However, we explain contents of this examination for the case that can be followed as much as possible and oral obtain its consent. We conformed to Helsinki Declaration and we considered human rights enough and examined this time. **Helsinki:** Yes **Informed Consent:** Yes