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DUTASTERIDE IS EFFECTIVE FOR PATIENTS WITH BENIGN PROSTATIC HYPERPLASIA IN HEMODIALYSIS.

Hypothesis / aims of study

Among dialysis patients urine production is kept, complaining of lower urinary tract symptoms (LUTS) are observed, some were reported underwent surgery for benign prostatic hyperplasia (BPH). However, there are many patients with complications having difficulty in surgery , it is often managed by a placement of catheter. Dutasteride (DUT) reduces prostate volume and improves LUTS by releasing the mechanical obstruction in the prostatic urethra. This drug is metabolized in the liver, is likely to be excreted in feces and has a possibility to use for dialysis patients. However, the reports of this drug used for dialysis patients has not been published as far as our knowledge, and there are many unanswered questions such as therapeutic effect, changes in hormone levels. In this report, we examined effectiveness and changes in hormone levels using DUT to the patients with hemodialysis, complaining of LUTS associated with BPH.

Study design, materials and methods

We included for 12 cases during hemodialysis, diagnosed BPH and the control was insufficient in the previous treatment (I-PSS ≧8, QOL index≧2, prostate volume≧30mL:before DUT add-on). DUT 0.5mg was administered once a day for over six months continuously. After evaluation of the patient's age, background of the complications. Then we evaluated IPSS and QOL index, prostate volume (PV), residual urine volume (RU), and urination diary as a clinical evaluation. After an evaluation of the measured values, we examined changes of the serum PSA, testosterone (T), dihydrotestosterone (DHT) levels. Some factors were compared to the one previously reported and its trends 1-3).

Results

The median age of the patients was 75 years (57-86), PV were 46.9mL (30.8-174.0)mL, RU were 84.0mL (0-550.0); two cases of urinary retention. The previous treatments of LUTS were 10 cases by α blockers and two by CIC. The time period from hemodialysis to the start of DUT were 9 months (0–33). IPSS score was discussed in the amount of change from the baseline, 12Week and 24W measuring -8.0±4.9 (p<0.01) and -8.1±4.3% (p<0.01) in order respectively (v.s. baseline). PV was discussed in the rate of change from the baseline, 12W, 24W, and 52W measuring -8.3±12.4 (p<0.05), -21.3±11.6 (p<0.001), and -31.7±11.5% (p<0.01) in order respectively (v.s. baseline). The rate of change of Serum T and DHT were 19.5±21.8, 24.7±27.5, 18.7±17.9% (n.s.), -64.4±21.2 (p<0.01), -74.1±19.3 (p<0.001), and -72.8±17.0% (p<0.001) at 2W, 12W, and 24W each, respectively (v.s. baseline). The rate of change of serum PSA were -44.5±11.8 (p<0.001) and -50.0±21.7% (p<0.001) at 24W and 52W, respectively (v.s. baseline). Complication was not observed, that made possible an oral administration continuously.

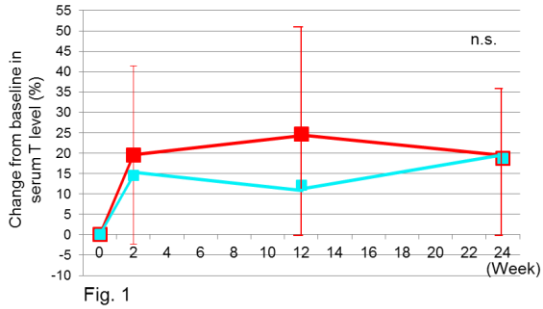

Fig. 1

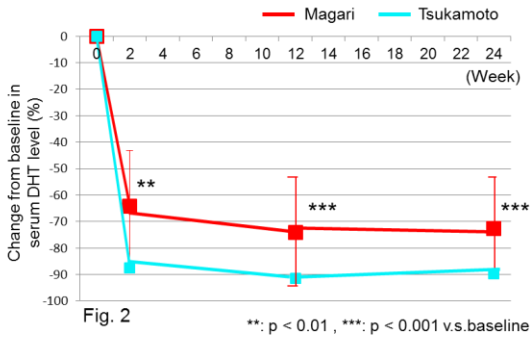

Fig. 2 **: p < 0.01 , ***: p < 0.001 v.s.baseline

Change from baseline in serum T (Fig. 1) and DHT (Fig. 2) level

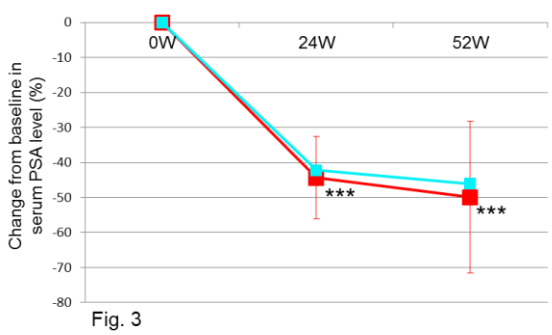

Fig. 3

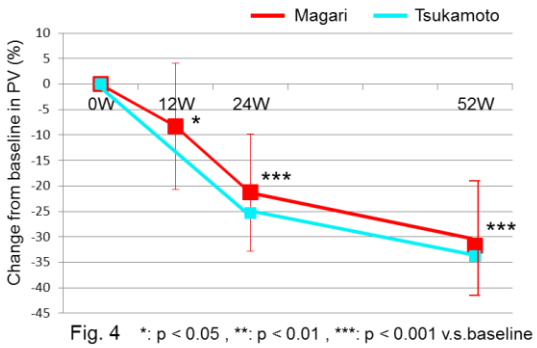

Fig. 4 *: p < 0.05 , **: p < 0.01 , ***: p < 0.001 v.s.baseline

Change from baseline in serum PSA level (Fig. 3) and PV (Fig. 4)

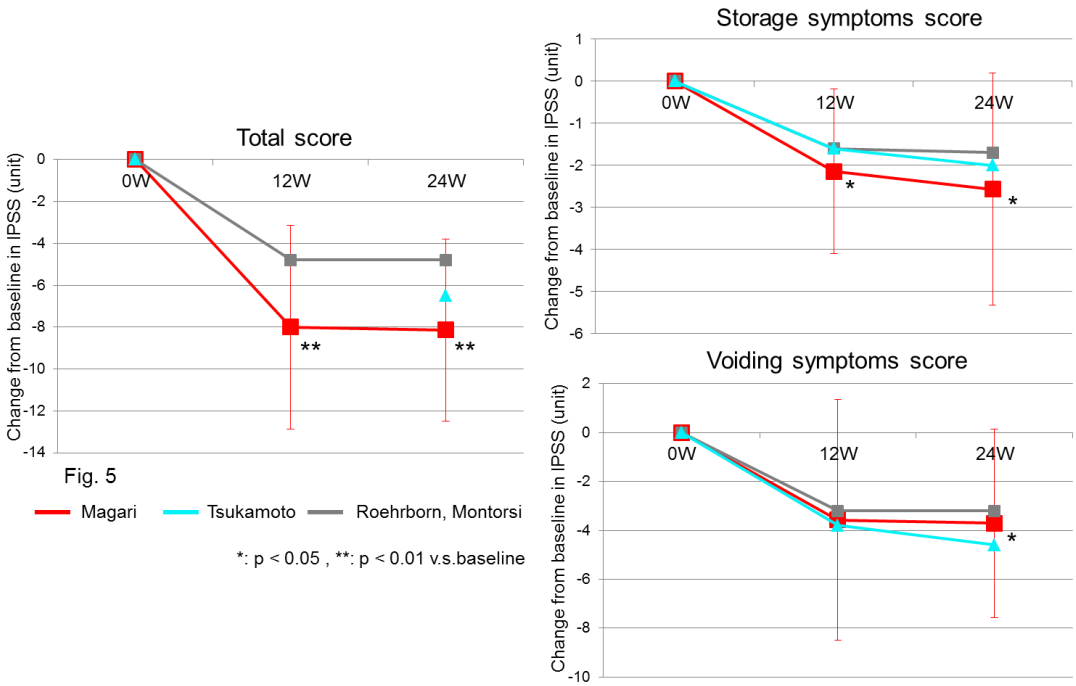

Fig. 5

Change from baseline in IPSS (Fig. 5)

Interpretation of results

We examined a study added on DUT to a severe case which control was insufficient in the previous treatment, we were able to confirm an effect like the report of Tsukamoto, et al (1-3). Changes in the serum T and PV were also similar trends as that of the non- dialysis patients

Concluding message

This study report is the first one that examined the effect of DUT for hemodialysis patients. Moreover, this is the first report to examine the changes not only IPSS score but also serum T, DHT, and PSA values. There are few target cases, and the large scale examination is difficult. However, in the study, it suggests that for BPH patients with urine production even in small amounts, DUT is effective and reasonable to use, as same as for non-dialysis patients.

References

1. Roehrborn CG, Siami P, Barkin J, Damião R, Major-Walker K, Nandy I, Morrill BB, Gagnier RP and Montorsi F: The effects of combination therapy with dutasteride and tamsulosin on clinical outcomes in men with symptomatic benign prostatic hyperplasia: 4-year results from the CombAT study. Eur Urol 57: 123-131, 2010.
2. Montorsi F, Roehrborn C, Garcia-Penit J, Borre M, Roeleveld TA, Alimi JC, Gagnier P and Wilson TH: The effects of dutasteride or tamsulosin alone and in combination on storage and voiding symptoms in men with lower urinary tract symptoms (LUTS) and benign prostatic hyperplasia (BPH): 4-year data from the Combination of Avodart and Tamsulosin (CombAT) study. BJU Int.107:1426-1431, 2011.
3. Tsukamoto T, Endo Y and Narita M: Efficacy and safety of dutasteride in Japanese men with benign prostatic hyperplasia. Int J Urol. 16: 745-750, 2009.

Disclosures

Funding: This study receives permission from the Kurosawa Hospital Ethical Review Board. We explained the contents of this study to a patient and obtained its consent in a document. We conformed to Helsinki Declaration and we considered human rights enough and examined this time. **Clinical Trial:** No **Subjects:** HUMAN **Ethics Committee:** Kurosawa Hospital Ethical Review Board **Helsinki:** Yes **Informed Consent:** Yes