

COMPARISON OF DISCONTINUATION AND CONTINUATION OF TAMSULOSIN IN BENIGN PROSTATIC HYPERPLASIA PATIENTS WITH COMBINATION THERAPY OF TAMSULOSIN AND DUTASTERIDE

Hypothesis / aims of study

This study was conducted to compare symptoms of patients with discontinuation and continuation of tamsulosin who had been diagnosed of benign prostatic hyperplasia (BPH) and undergone combination therapy of tamsulosin and dutasteride.

Study design, materials and methods

This study included 108 men with BPH who visited our clinic from April, 2008 and October, 2010. All patients had not been given tamsulosin or dutasteride to treat BPH before the study commenced. All subjects were assessed by using International Prostate Symptom Score (IPSS). Those patients with an IPSS of 8-19 and prostate volume ≥ 25 ml by transrectal ultrasonography (TRUS) were selected for the study. The efficacy of this regimen was assessed every 12 week after commencing two drugs administration. After 48 weeks, randomization was performed and patients were given same combination drugs (group 1) or only dutasteride 0.5 mg (group 2).

Results

Among 108 patients, a total of 69 patients completed the study; 36 patients (52%) in group 1 and 33 (48%) in group 2. The mean age of all patients was 67.96 ± 7.88 year and mean prostatic volume was 40.45 ± 12.81 ml. The mean prostate-specific antigen was 3.31 (0.4-9.9) ng/ml before the study. At 60 weeks, IPSS was obtained and 61 patients mentioned that their symptoms were improved (Fig. 1). IPSS between two groups at first visit, 48 weeks and 72 weeks was 14.7 vs. 15.8 ($p=0.322$), 12.1 vs. 12.8 ($p=0.582$) and 10.9 vs. 11.9 ($p=0.897$) (Fig. 2). In both groups, there were statistically significant differences in the baseline and 72 weeks IPSS (group 1: $p<0.001$, group 2: $p<0.001$).

Concluding message

In patients with moderate IPSS before the treatment, there were not statistically significant differences on IPSS between tamsulosin discontinuation group and combination therapy group after 72 weeks combination therapy period.

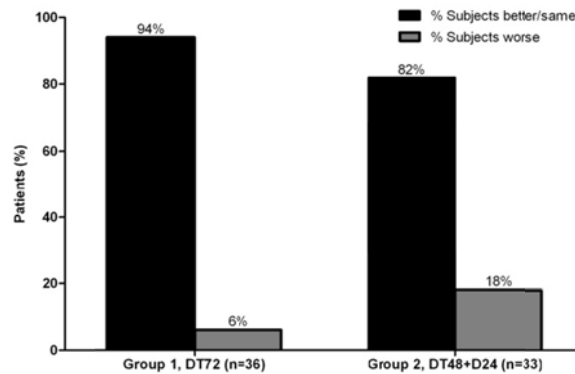


Fig. 1. Patients satisfaction question on the treatment at week 60. The results of each group was not statistically significant by chi-square test ($p=0.208$).

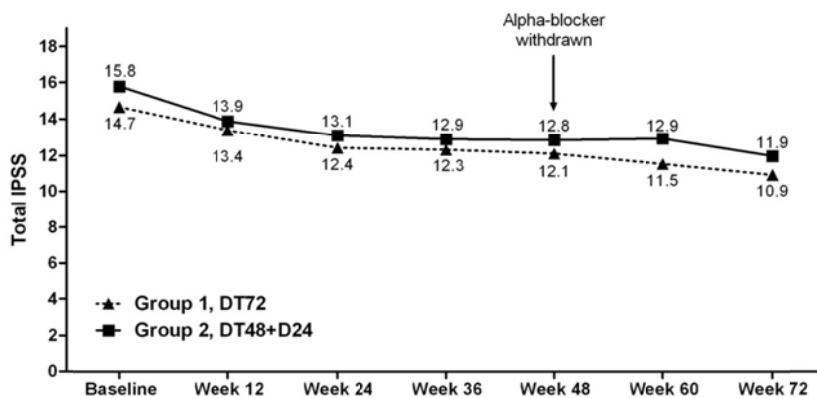


Fig. 2. Mean IPSS for group 1 and 2.

References

1. Alpha-blocker therapy can be withdrawn in the majority of men following initial combination therapy with the dual 5alpha reductase inhibitor dutasteride. Barkin J, et al. Eur Urol 2003;44:461-66
2. Finasteride monotherapy maintains stable lower urinary tract symptoms in men with benign prostatic hyperplasia following cessation of alpha blockers. Nickel JC et al. CUAJ 2008;2:16-21.
3. Discontinuation of alpha-blockade after initial treatment with finasteride and doxazosin for bladder outlet obstruction. Baldwin KC, et al. Urol Int 2001;66:84-8.

<i>Specify source of funding or grant</i>	No.
<i>Is this a clinical trial?</i>	Yes
<i>Is this study registered in a public clinical trials registry?</i>	No
<i>Is this a Randomised Controlled Trial (RCT)?</i>	Yes
<i>What were the subjects in the study?</i>	HUMAN
<i>Was this study approved by an ethics committee?</i>	Yes
<i>Specify Name of Ethics Committee</i>	Hanyang university guri hospital IRB
<i>Was the Declaration of Helsinki followed?</i>	Yes
<i>Was informed consent obtained from the patients?</i>	Yes