748

Miyamae K[1], Kitani K[1], Hara K[1], Nakakuma K[1], Hamada Y[1], Yamamoto T[2], Maehara A[3], Otsuka Y[4], Otsuka T[4], Kawano T[5], Yoshida M[6]

1. *Department of Urology, Kumamoto Chuo Hospital,* ***2.*** *Yamamoto Urological Clinic,* ***3.*** *Maehara Urological Clinic,* ***4.*** *Otsuka Urological Clinic,* ***5.*** *Kawano Hospital,* ***6.*** *Department of Urology, National Center for Geriatrics and Gerontology*

COMPARISON BETWEEN SILODOSIN AND TAMSULOSIN OF EARLY THERAPEUTIC EFFICACY IN PATIENTS WITH SEVERE BENIGN PROSTATIC HYPERPLASIA

Hypothesis / aims of study

The incidence of benign prostatic hyperplasia (BPH) is high in middle-aged and elderly men and their lower urinary tract symptoms are considered to be more severe with aging. One of the most important treatment goal for the patients with BPH is to early relieve lower urinary tract symptoms and finally to improve quality of life (QOL). At the 40th ICS, we reported the result of STOP-BPH study[1)], which suggested early efficacy and safety of two alpha-1 blockers, Silodosin and Tamsulosin hydrochloride(hereinafter to be referred to as Tamsulosin), widely used in Japan as first line. This time we performed Ad-hoc analysis focused on patients with severe symptoms of the STOP-BPH study.

Study design, materials and methods

Between February and October 2009, we conducted STOP-BPH study ; a randomized comparison of Silodosin and Tamsulosin in previously untreated BPH patients who visited nine medical institutions, which are members of the Kumamoto Research Society for voiding dysfunction. 109 patients were enrolled in the study, and patients were randomly assigned to one of the following two groups: the Silodosin group (treated at 4 mg per dose, twice daily) and the Tamsulosin group (treated at 0.2 mg per dose, once daily).Before and one week after the treatment, evaluation was performed by the I-PSS, Overactive Bladder Symptom Score (OABSS), and QOL score. On their first visit to the medical institutions, the questionnaire(IPSS,OABSS,QOL score) were recorded by patients before the treatment. One week after the treatment, the questionnaire(IPSS,OABSS,QOL score) were recorded by patients again, and the patients reported the term when they felt the effectiveness of the therapy. We performed an ad-hoc analysis of data from 70 patients with severe BPH (IPSS ≥ 20 or QOL score ≥ 5) in the study.

Results

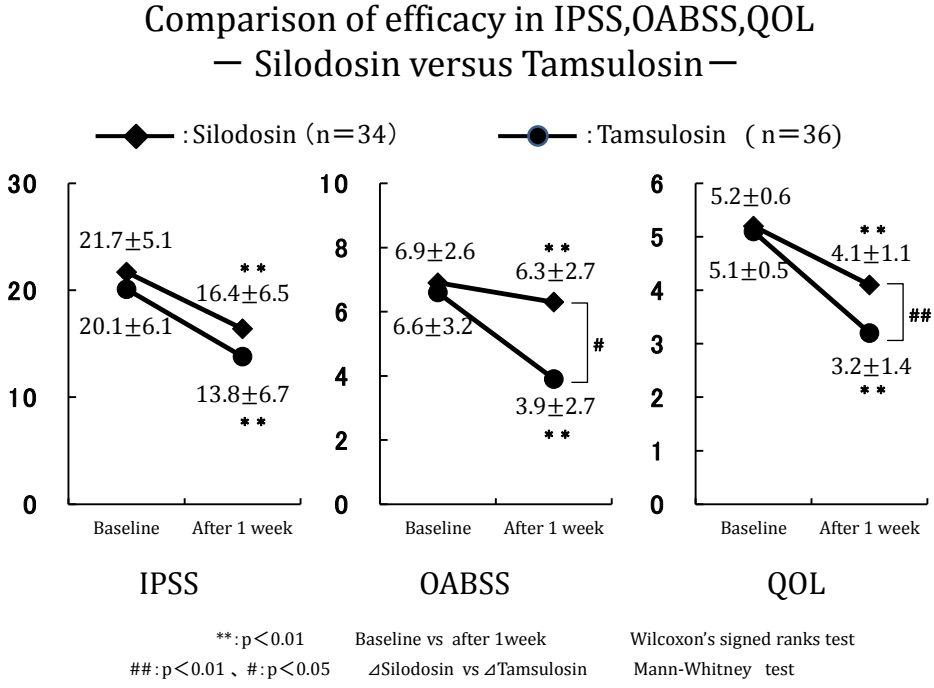
The two groups did not differ in patient demographics. Comparison between before and one week after the treatment demonstrated significant improvement in IPSS total score, QOL score, IPSS voiding symptom score, IPSS storage symptom score, and IPSS post-void symptom score in both groups (Fig). Between-group comparison revealed that for QOL score, OABSS, and IPSS storage symptom score, the change from baseline was significantly greater in the Tamsulosin group than in the Silodosin group (Fig). For the IPSS symptoms, the mean number of post-treatment days until the time when the patients actually felt the effectiveness was 3 days (median) for both groups. One week after the treatment, percentage of patients who desired to continue the therapy were Silodosin group (50.0%) and Tamsulosin group (66.7%). The percentage of patients who wanted to change or discontinue the prescribed therapy were Silodosin group (29.4%) and Tamsulosin group (2.8%). The incidence of adverse drug reactions (ADRs) was as follow. In the Silodosin group, 9 occurrences of ADRs were noted in 13 patients (26.5%) and predominant symptoms included 2 occurrences of diarrhea (5.9%), 2 occurrences of ejaculation disorder (5.9%), and 1 occurrences of dizziness (2.9%). In the Tamsulosin group, 2 occurrences of ADRs were noted in 2 patients (5.6%), consisting of one patient (2.0%) who had gastrointestinal symptoms and one (2.0%) with diarrhea.

Interpretation of results

This ad-hoc analysis confirmed significantly greater improvement of QOL score, OABSS, and IPSS storage symptom score in the Tamsulosin group than in the Silodosin group (Fig). Since it has been reported that storage symptoms (OAB symptoms) occur less frequently than voiding symptoms but result in greater degree of discomfort [2)], the differences noted in improvement of QOL score between the two groups may be explained by the different effects on storage symptoms. The patient survey showed that significantly more patients in the Tamsulosin group desired to continue the prescribed therapy, which may have been related to the greater efficacy and safety of Tamsulosin.

Concluding message

Treatment with both Silodosin and Tam were confirmed the rapid clinical efficacy for severe BPH patients. Tam was superior to Silodosin in the effectiveness in improving storage symptoms (OAB symptoms), safety, the time of onset of effects, and improvement in Tamsulosin QOL. A significantly greater number of patients in the Tamsulosin group than in the Silodosin group expressed their desire to continue the treatment, suggesting that from the viewpoint of patient satisfaction also, Tamsulosin is superior to Silodosin.



References

1. Miyamae K, Kitani K, Miyamoto K, et al. Safety and efficacy of tamsulosin and silodosin on early therapy in patients with BPH: STOP-BPH. Japanese Journal of Urological Surgery 22: 1541-1548, 2009
2. Irwin DE, Milsom I, Hunskaar S, et al. Population-based survey of urinary incontinence, overactive bladder, and other lower urinary tract symptoms in five countries: results of the EPIC study. Eur Urol 50: 1306-1315, 2006

Disclosures

Funding: none of funding **Clinical Trial:** No **Subjects:** HUMAN **Ethics Committee:** Ethics Committee of Kumamoto Research Society for voiding dysfunction **Helsinki:** Yes **Informed Consent:** Yes