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COMPARISON OF TAMSULOSIN WITH OR WITHOUT SOLIFENACIN IN MEN WITH BENIGN PROSTATIC HYPERPLASIA AND OVERACTIVE BLADDER: SHORT-TERM RESULTS ON EFFICACY AND SAFETY

Hypothesis / aims of study

Benign prostatic hyperplasia (BPH) is a common condition among elderly men and is often associated with a constellation of lower urinary tract symptoms (LUTS). α1-adrenoceptor antagonists are the most widely used pharmacological agents for LUTS in men with BPH. However, it is not uncommon that storage symptoms, or OAB symptoms persist after treatment with α1-adrenoceptor antagonist. For those patients with persisting OAB symptoms, combination therapy of α1-adrenoceptor antagonist and anticholinergics is a reasonable choice. There are several reports that showed the efficacy and safety of propiverine and tolterodine as anticholinergics in men with BPH. In the present study, we compared the short-term efficacy and safety of tamsulosin alone and combination of tamsulosin and low dose solifenacin in men with BPH and OAB symptoms.

Study design, materials and methods

Men with BPH and OAB symptoms after treatment with α1-adrenoceptor antagonist for at least 4 weeks were alternately allocated to 4-week treatment with either tamsulosin (0.2 mg/day, regulatory max dose in Japan) alone (26 patients, Group 1) or tamsulosin with solifenacin (2.5 mg/day) (25 patients, Group 2). Primary endpoint was improvement of I-PSS and QOL score after the 4-week treatment. Secondary endpoint included improvement of Overactive Bladder Symptom Score (OABSS[1)]) and changes in maximum flow rate and postvoid residual urine (PVR). Wilcoxon rank sum test and Wilcoxon signed-rank test were used for statistical analysis. $P<0.05$ was considered to be significant.

Results

There was no significant difference in patients backgrounds in Group 1 vs Group 2, including age (73.3±27.8 vs 75.1±16.4), I-PSS total score (11.6±5.7 vs 13.9±6.0), QOL score (3.7±1.1 vs 4.0±0.8), OABSS total score (6.4±2.0 vs 7.3±2.6), maximum flow rate (13.5±7.3 vs 13.0±8.5 mL/s) and PVR (33.5±31.7 vs 41.4±24.9 mL). In Group 2, I-PSS total score (from 13.9±6.0 to 11.2±7.6), I-PSS storage symptom score (from 7.2±2.5 to 5.5±3.2), and QOL score (from 4.0±0.8 to 3.3±1.2) were significantly improved, but not in Group 1. I-PSS voiding symptom score did not change significantly in either group (from 4.2±3.0 to 4.2±3.0 in Group 1 and from 5.3±3.5 to 4.6±4.0 in Group 2). Of 4 items of OABSS, scores for nocturia, urgency, and urgency incontinence were improved in Group 2, while in Group 1 only urgency score was improved. Maximum flow rate or PVR did not change significantly in either group. There was no significant side effect in either group.

Interpretation of results

Treatment with tamsulosin plus low dose solifenacin improved I-PSS total score, I-PSS storage score and QOL score, whereas treatment with tamsulosin alone did not. Improvement of OABSS was also better in treatment group by tamsulosin plus solifenacin. Short-term safety was confirmed in both treatment groups.

Concluding message

In men with BPH and OAB, tamsulosin plus low dose solifenacin is more effective treatment than tamsulosin alone.

References

1) Urology 68: 318-323, 2006

Specify source of funding or grant	**none**
Is this a clinical trial?	**Yes**
Is this study registered in a public clinical trials registry?	**No**
What were the subjects in the study?	**HUMAN**
Was this study approved by an ethics committee?	**Yes**
Specify Name of Ethics Committee	**Asahikawa Medical College Institutional Review Board**
Was the Declaration of Helsinki followed?	**Yes**
Was informed consent obtained from the patients?	**Yes**