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Masumori N[1], Horita H[2], Yanase M[3], Aoki M[4], Miyao N[5], Sakai S[6], Kunishima Y[7], Tsukamoto T[1]
1. *Sapporo Medical University,* ***2.*** *Saiseikai Otaru Hospital,* ***3.*** *Sunagawa City Hospital,* ***4.*** *Kushiro Red Cross Hospital,* ***5.*** *Muroran City Hospital,* ***6.*** *NTT East Japan Sapporo Hospital,* ***7.*** *Obihiro Kyokai Hospital*

THE ADD-ON EFFECT OF SOLIFENACIN FOR PATIENTS WITH REMAINING STORAGE SYMPTOMS AFTER TREATMENT WITH ALPHA 1-BLOCKERS

Hypothesis / aims of study
Storage symptoms such as urgency and frequency are commonly observed in men with lower urinary tract symptoms suggestive of benign prostatic obstruction. Although alpha 1-blocker monotherapy is efficacious in improving voiding symptoms and to a certain extent storage symptoms, additional administration of anti-cholinergic agents are sometimes necessary to control the remaining storage symptoms. Several recent studies have indicated the efficacy and safety of combining alpha 1-blockers and anti-cholinergic agents, such as tolterodine and propiverine. However, clinical data derived from solifenacin is still insufficient. Therefore this study investigated the add-on effect of solifenacin for men with remaining storage symptoms after treatment with alpha 1-blockers in real-life clinical practice.

Study design, materials and methods
Since this study was conducted in a real-life clinical practice setting, no strict inclusion criteria were applied. Patients who reported that they were bothered by the remaining storage symptoms even after at least 4 weeks treatment by an alpha 1-blocker were candidates for the study. Indication of additional administration of solifenacin was clinically decided based on experience of each urologist. Solifenacin, 2.5 or 5.0mg/day (the dosage selected by the physician based on the patient's age and comorbidity), was given for 12 weeks. During the study period, a change in type and dosage of alpha 1-blocker was not allowed. The International Prostate Symptom Score (IPSS), QOL index, overactive bladder symptom score (OABSS), maximum flow rate (Qmax) and postvoid residual urine volume (PVR) were determined before and after treatment.

Results
Thirty-two men were enrolled. Average age was 73.0 years-old. Tamsulosin (0.2mg/day), silodosin (8mg/day) and naftopidil (25mg/day in 1, 50mg/day in 1, 75mg/day in 1) was used in 26, 3 and 3 patients, respectively. The average dosage of solifenacin given was 4.3mg/day (20 patients: 5mg/day, 12 patients: 2.5mg/day). The IPSS, QOL index and OABSS were significantly improved by the additional administration of solifenacin (Table 1). Although the storage symptom score was significantly improved, there were no changes observed in voiding symptom score, Qmax and PVR. One patient (3.1%) showed significant increase of PVR from 62 to 246ml. Although 2 men (6.3%) reported difficulty of voiding, this side effect disappeared following termination of solifenacin.

Interpretation of results
Additional administration of solifenacin for patients with lower urinary tract symptoms suggestive of benign prostatic obstruction treated with alpha 1-blockers revealed significant improvement of the remaining storage symptoms without deterioration of voiding symptoms, Qmax and PVR in real-life clinical practice.

Concluding message
Under the supervision of an experienced urologist, the additional administration of solifenacin to patients with lower urinary tract symptoms suggestive of benign prostatic obstruction, treated with alpha 1-blockers, is effective in controlling the remaining storage symptoms and in improving QOL.

Table 1
Change in parameter before and after solifenacin treatment

Parameter	Before	12 weeks	p-value
IPSS total score	15.1 ± 7.2[1)]	11.8 ± 6.4	p < 0.01[2)]
IPSS storage symptoms	8.3 ± 3.6	6.0 ± 3.2	p < 0.01[2)]
IPSS voiding symptoms	4.9 ± 4.5	4.5 ± 3.6	not significant[2)]
QOL index	4.2 ± 1.3	3.1 ± 1.2	p < 0.01[2)]
OABSS	8.1 ± 3.5	5.3 ± 3.3	p < 0.01[2)]
Qmax (ml/sec)	11.0 ± 6.1	12.1 ± 9.7	not significant[3)]
PVR (ml)	16 ± 25	25 ± 52	not significant[3)]

1) mean ± standard deviation, 2) Wilcoxon signed rank test, 3) Paired t-test.

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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?	**No**
This study did not require eithics committee approval because	**it is a real-life clinical practice based on experience of each urologists**
Was the Declaration of Helsinki followed?	**Yes**
Was informed consent obtained from the patients?	**No**