Digestive symptoms associated with α1-adrenoceptor antagonists (α1-blockers) therapy in patients with lower urinary tract symptoms suggestive of benign prostatic hyperplasia (LUTS/BPH)

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**Introduction**

The objective of this study was to evaluate the short-term efficacy and safety, focused digestive symptoms, of two alpha 1-adrenoceptor antagonists (α1-blockers), Silodosin (S) and Tamsulosin (T), in patients with untreated LUTS/BPH.

**Study design, materials and methods**

Drug S or T was administered to patients with untreated BPH, and their efficacy and safety in the early stage of treatment were compared using the questionnaire of International Prostate Symptom Score (IPSS)/quality of life (QOL), the Japanese version of the Gastrointestinal Symptom Rating Scale (GSRS) [1], and the Bristol Stool Form Scale questionnaire [2].

- T group: tamsulosin 0.2mg once daily (Japanese standard dose)
- S group: silodosin 4 mg twice a day

This study was approved by the Asahikawa Medical University Ethical Committee (No. 862) and registered at the Japan Primary Registries Network (JPRN-UMIN000005151).

**Statistical Analysis**

All values were expressed as the mean ± SEM. Statistical analyses were performed using ANOVA. Differences were considered to be significant at a P-value < 0.05.

**Results**

The IPSS and QOL score improved at week 1 in both groups as compared to the baseline (Fig. 2). Although the overall GSRS score showed no significant change in either group. But, the GSRS score for “13. hard stools” was significantly decreased at week 4 in both groups (Fig. 3A). The GSRS subscale score for "constipation" was significantly decreased only in S group at week 4 (Fig. 3B). The Bristol Stool Scale score was significantly increased at week 4 only in the S group (Fig. 4).

**Results-1**

The per protocol set consisted of 20 patients in the S group (mean age, 73.00 ± 6.48 yrs) and 22 patients in the T group (70.15 ± 5.70 yrs) (Fig. 1 and Table 1).

**Results-2**

The GSRS score for “13. hard stools” was significantly decreased at week 4 in both groups. In S group, the GSRS subscale score for “constipation” and the Bristol Stool Scale score were significantly changed at week 4.

**Limitation**

The limitation of this study includes a very small number of the pts.

**Conclusions**

Alpha 1 blockers, which are major therapeutic agents for the treatment of LUTS/BPH, were effective from the early stage of treatment as often reported in the past. Regarding digestive symptoms related to safety, there was “loose stools” trend in both groups, especially “hard stools” in GSRS score showed improvement in S group. This study revealed that the selectivity of alpha-1 adrenergic receptors is associated with digestive symptoms such as diarrhea and loose stools. Therefore, oral drugs for BPH need to be selected by taking into consideration the digestive symptoms, including with the state and type of stool.

**Disclosures Statement**

The authors declare no conflicts of interest associated with this paper.

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**Table 1**

<table>
<thead>
<tr>
<th>Pts characteristics</th>
<th>Pre (pts (n=22))</th>
<th>1 week (pts (n=22))</th>
<th>2 weeks (pts (n=22))</th>
<th>4 weeks (pts (n=22))</th>
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<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>S</td>
<td>3.80 ± 2.04</td>
<td>2.93 ± 1.52</td>
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<tr>
<td>T</td>
<td>3.58 ± 2.04</td>
<td>2.50 ± 1.24</td>
<td>2.12 ± 1.24</td>
<td>1.76 ± 1.12</td>
<td>0.009</td>
</tr>
</tbody>
</table>

**Figure 1.** Patient enrollment.

**Figure 2.** Changes of IPSS total score (A) and QOL score (B).

**Figure 3.** Changes of GSRS score for “13. hard stools” (A) and GSRS subscale score for “constipation” (B).

**Figure 4.** Changes of Bristol Stool Scale score.

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**Hypothesis / aims of study**

Objective of this study was to evaluate the short-term efficacy and safety, focused digestive symptoms, of two alpha 1-adrenoceptor antagonists (α1-blockers), Silodosin (S) and Tamsulosin (T), in patients with untreated LUTS/BPH.