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A RANDOMIZED CONTROL TRIAL COMPARING SILODOSIN AND URAPIDIL IN FEMALE PATIENTS WITH LOWER URINARY TRACT SYMPTOM –INTERIM REPORT-

Hypothesis / aims of study

Few reports are available on the effects of α1-AR antagonists in female patients with lower urinary tract symptom (LUTS) [1] [2]. We investigated the effectiveness of silodosin (α1A-adrenoceptor antagonist) and urapidil (non selective α1-adrenoceptor antagonist) at reducing urinary symptoms in female patients with LUTS.

Study design, materials and methods

A single-institution, randomized trial for patients compared silodosin versus urapidil in female patients with LUTS. Eligibility criteria included females patients aged 20 or older not already taking silodosin and having International Prostate Symptom Score (IPSS) of ≧8 point and post void residual urinary volume (PVR) of ≧50ml.

Patients were randomly assigned to either silodosin (8 mg silodosin daily) or Urapidil (60mg daily) group. Objective changes in urination status in terms of bladder function were assessed using uroflowmetry (UFM), subjective symptoms and Quality of life (QOL), according to the IPSS criteria. Both groups underwent UFM and their subjective symptoms were assessed pre-treatment and 1, 2, and 3months.

Results

A total of 49 patients were enrolled in this study (24 with silodosin group and 25 with urapidil group). 39 of 49 were completed the study between September 2013 and February 2016.

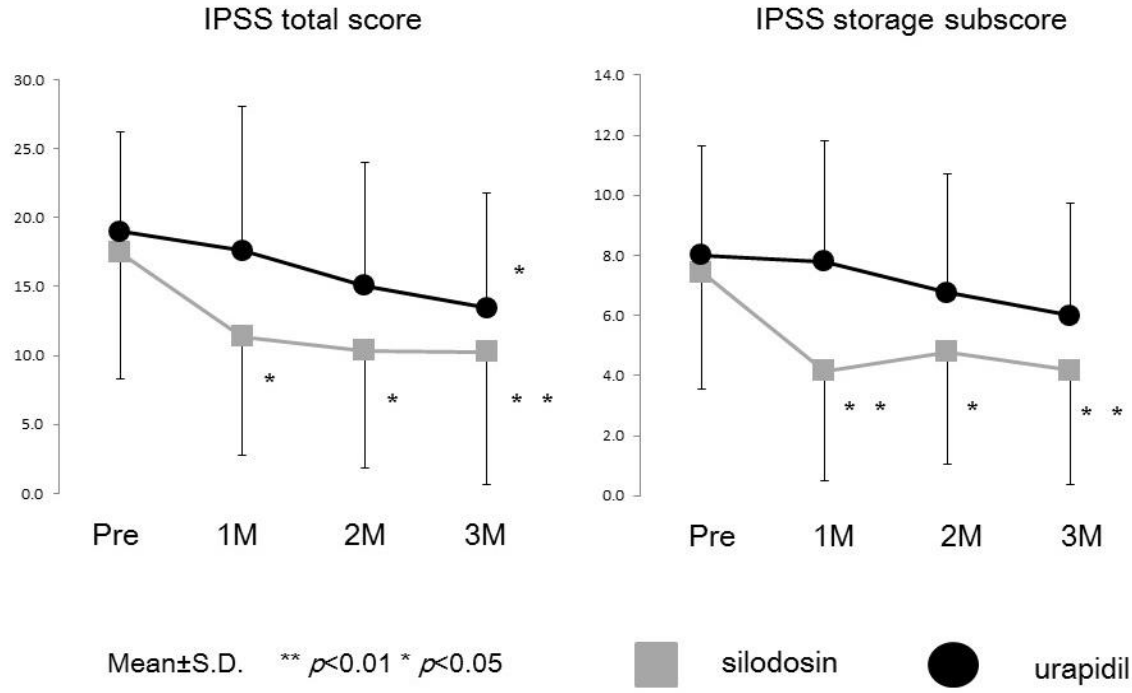
In the silodosin group, there was a continuous and significant improvement of IPSS total from 1M to 3M. In the urapidil group, there was a significant improvement of IPSS total at 3M.

In the silodosin group, there was a continuous and significant improvement of IPSS storage subscore from 1M to 3M. In the urapidil group, there was no significant improvement. A significant difference between the two groups was observed only at 1M.

Objective changes (UFM and PVR) were no significant improvement in both groups. (Figure 1)

Adverse events was reported more frequency in the urapidil group. Five patients occurred low blood pressure upon standing and one patient occurred gastric distress.

Figure 1



Interpretation of results

In the silodosin group, there was a continuous and significant improvement of IPSS storage subscore from 1M to 3M. Studies involving spontaneously hypertensive rats have revealed that they have a decreased bladder blood flow and more frequent urination compared with controls. However, when administered silodosin, the spontaneously hypertensive rats experienced an increase in bladder blood flow, accompanied by an improvement in urinary frequency. In addition, alpha 1A receptor expression has been reported to be greater than alpha-1D receptor expression in bladder blood flow, and in ischemic conditions, silodosin

improves bladder function by restoring bladder blood flow. Hence, it is possible that drugs selective for alpha-1A improve storage functions by improving bladder blood flow [3].
Limitations of this study include the non-blinding and lack of a placebo control. Furthermore, the study size may have influenced the discrepancies seen between the objective measures and subjective symptoms.

Concluding message

To our knowledge, this is the first prospective, randomized control study investigating female LUTS using silodosin and urapidil. This study is on-going and future studies including more patients are needed to confirm our findings.

References

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Disclosures

Funding: non **Clinical Trial:** Yes **Registration Number:** Clinical Trial: UMIN000011755 **RCT:** Yes **Subjects:** HUMAN **Ethics Committee:** Kinki University Faculty of Medicine
No.25-087 **Helsinki:** Yes **Informed Consent:** Yes