291

Matsukawa Y[1], Hattori R[1], Mizutani K[1], Sassa N[1], Yamamoto T[1], Gotoh M[1]
1. *Department of Urology, Nagoya University Graduate School of Medicine, Japan*

LONG-TERM EFFICACY OF SILODOSIN ON THE LOWER URINARY TRACT FUNCTION IN PATIENTS WITH BENIGN PROSTATIC HYPERPLASIA ACCORDING TO PROSTATE SIZE ~PROSPECTIVE INVESTIGATION USING PRESSURE-FLOW STUDY~

Aims of study

α_1-adrenoceptor (AR) antagonists are widely used as the drug of first choice for lower urinary tract symptoms (LUTS) with benign prostatic hyperplasia (BPH). On the other hand, the efficacy of single use of α_1- AR antagonist to improve LUTS in patients with large prostate is debatable. We prospectively investigated the long-term effects of silodosin, a new α_1-AR antagonist purely selective for the sympathetic α_{1A}-AR subtype, on the lower urinary tract function in patients with BPH according to prostate size, using pressure-flow study (PFS).

Study design

Silodosin was administered at a dose of 8 mg/day to patients with LUTS associated with BPH. The patients were classified into 2 groups according to prostate size; small prostate (SP) group (prostate volume <35ml) and large prostate (LP) group (>= 35 ml). Changes in parameters from baseline to 4 weeks and 1 year after administration were assessed in international prostate symptom score (IPSS), IPSS-quality of life (QOL), overactive bladder symptom score (OABSS), and voiding and storage function as measured by PFS.

Results

130 patients were enrolled to the study, and available data from 102 were analyzed. At baseline, no significant differences were detected in IPSS or IPSS-QOL between LP group (50 cases, mean prostate volume: 54.3ml) and SP group (52 cases, 30.6ml), but LP group had a significantly higher OABSS (6.8 vs 4.8). Comparison of the baseline data obtained by PFS revealed no significant differences in bladder capacity at first desire to void (FDV), maximum cystometric capacity (MCC), maximum flow rate (Qmax), or postvoid residual urine volume (PRV), while detrusor pressure at maximum flow rate (PdetQmax) and bladder outlet obstruction index (BOOI) were significantly higher in LP group. The frequency of uninhibited detrusor contraction was also significantly higher in LP group at baseline. (Table)

At 4 weeks after treatment, both groups showed significant improvement in IPSS-total, IPSS-QOL, OABSS, and no significant difference was noted in the changes in any of these parameters between the 2 groups. For the long-term (1 year) examination, SP group showed further improvement in both IPSS-total and IPSS-QOL, while LP group reduced the effectiveness of improvement in both parameters. (Fig) The improvement in OABSS at 4week was maintained at 1 year in both groups. In PFS, both groups showed a significant increase in FDV and MCC at 4 weeks and further improvement at 1 year with no significant inter-group difference.

Uninhibited detrusor contraction observed before treatment disappeared in 50.0% (4 weeks), 44.1% (1 year) in LP group and 45.0% (4 weeks), 50.0% (1 year) in SP group. PFS during the voiding phase at 4 weeks after administration demonstrated a significant increase in Qmax and PVR, and a significant decrease in PdetQmax and BOOI, regardless of prostate size. No significant differences were observed in changes in the every PFS parameters between the 2 groups at 4 weeks. However, although the improvement in voiding parameters such as PdetQmax and BOOI at 4 weeks was maintained to 1 year in SP group, these parameters changed for the worse compared with that of 4weeks in LP group. (Fig)

Concluding message

Silodosin quickly improves bladder storage function and relieves bladder outlet obstruction, regardless of prostate size. However, in long-term administration, an improvement of bladder outlet obstruction may be reversed in patients with large prostate, despite preservation of an improvement in storage function.

	LP group	SP group	p
	Mean (S.D.)	Mean (S.D.)	
n	50	52	
Age(years)	70.4±7.5	67.9±9.4	0.08
ProstateVol（ml）	54.3±17.2	30.6±3.7	<0.0001
IPSS	18.2 ± 6.7	17.7±6.5	0.69
IPSS-voiding	10.1±4.7	10.0±4.8	0.96
IPSS-storage	8.1±2.7	7.7±2.8	0.44
OABSS	6.8±2.6	4.8±2.9	0.01
QOL	4.7 ±0.8	4.8 ±1.0	0.70
MCC (mL)	225±84	263±95	0.03
Qmax (mL/s)	6.9±3.4	7.6±4.1	0.36
Rv (mL)	63±63	61 ±56	0.90
Pdet Qmax (cmH20）	82.1±25.3	67.7±17.1	0.001

BOOI	68±27	52±21	0.001
Incidence of DO	34/50 (68.0%)	20/52 (38.5%)	0.002

Table: The characteristics of the patients in the 2 groups before administration

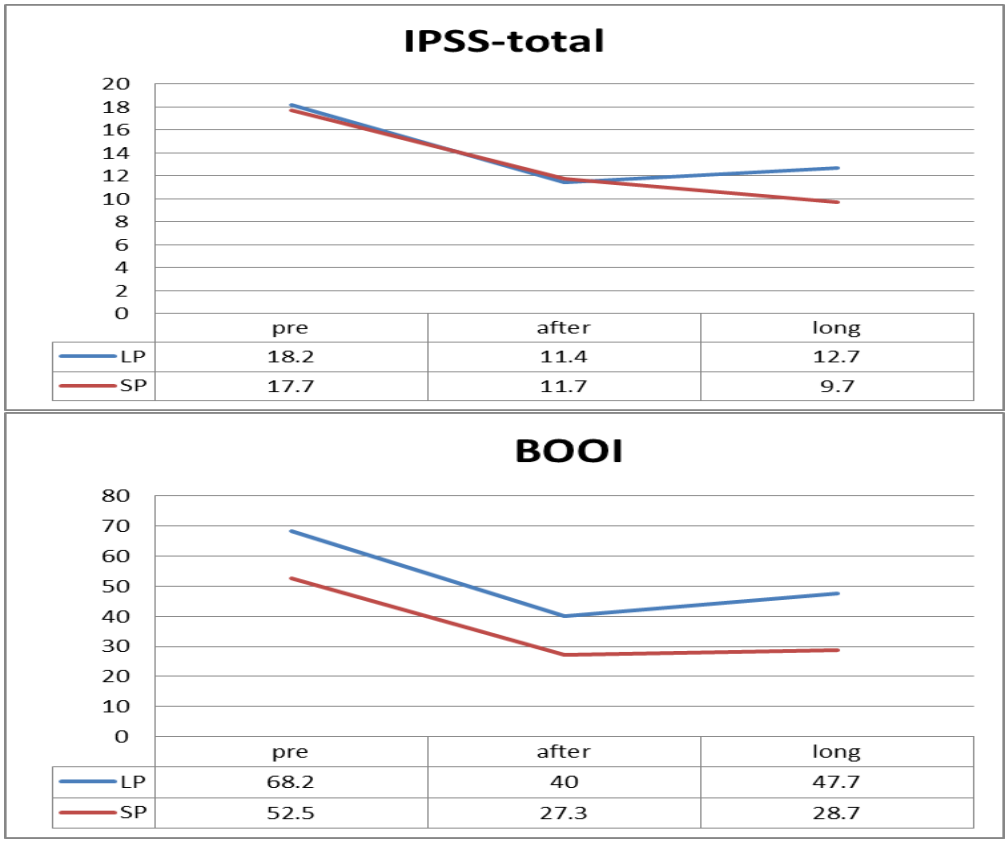

Figure: The change of subjective parameter (IPSS) and objective parameter (BOOI) from baseline to 4 weeks and 1 year after administration

Specify source of funding or grant	**none**
Is this a clinical trial?	**Yes**
Is this study registered in a public clinical trials registry?	**No**
Is this a Randomised Controlled Trial (RCT)?	**No**
What were the subjects in the study?	**HUMAN**
Was this study approved by an ethics committee?	**Yes**
Specify Name of Ethics Committee	**Nagoya University ethical committee**
Was the Declaration of Helsinki followed?	**Yes**
Was informed consent obtained from the patients?	**Yes**