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COMPARISON OF THE EFFECTS OF SILODOSIN AND TAMSULOSIN FOR THE TREATMENT OF BENIGN PROSTATIC HYPERPLASIA

Hypothesis / aims of study
Tamsulosin has been widely used for the treatment of benign prostatic hyperplasia (BPH). Recently, silodosin, a new alpha1A-adrenoceptor selective antagonist, has been reported to be effective for storage and voiding symptoms in BPH patients [1,2]. The aim of the present study is to compare the effects of silodosin and tamsulosin for the treatment of BPH for one year.
Study design, materials and methods
A total of 149 male patients with BPH, with a mean±SD age of 71.7±7.9 years old were randomly assigned either to the silodosin treatment group or the tamsulosin treatment group. The inclusion criteria was IPSS total score of 8 or more, maximum flow rate (Qmax) less than 15ml/sec, total prostate volume measured by ultrasonography more than 20ml. Exclusion criteria included patients with prostate cancer, urethral stricture, apparent neurogenic bladder and those on medication that might affect voiding function such as alpha-blockers, anticholinergics and/or antiandrogen drugs. Silodosin with a daily dose of 8mg (4mg twice daily) and tamsulosin (0.2-0.4mg daily) were administered and the effects of the drug were assessed before, and at 1,3,6 and 12months after the therapy
Results
The baseline characteristics of the two groups were well matched in terms of age, PSA level, total prostatic volume, IPSS, average and maximum flow rates (Qave and Qmax, respectively), and postvoid residual urine volume (PVR) (Table1). 0, 5, 5 and 13 patients dropped out at 1,3,6, and 12 months after the therapy in the silodosin group, respectively, and1, 15, 26 and 36 patients in the tamsulosin group, respectively. Dropout rates at 12 months were significantly greater in the tamsulosin group than the silodosin group（P<0.0001）.IPSS, Qmax and PVR decreased significantly at 1,3,6, and 12 months after the therapy in the both groups. However, the changes in these parameters were not significantly different between the two groups. (Table2). PSA level and total prostatic volume did not change after one year in the two groups.
Interpretation of results
Both silodosin and tamsulosin improved lower urinary tract symptoms and urinary flow rate significantly in patients with BPH. Although efficacies of these drugs were not significantly different, silodosin appeared to be more tolerable than tamsulosin after 12 months.
Concluding message
Both silodosin and tamsulosin were effective for the treatment of BPH.

TABLE 1: Baseline characteristics of the two groups

	Silodosin (n=75)	Tamsulosin (n=74)	P-Value
Age	71.3±8.2	72.2±7.6	P=0.469
PSA(ng/mL)	3.2±3.6	3.7±3.7	P=0.471
Total prostatic volume (mL)	42.0±23.7	41.2±23.0	P=0.828
Total IPSS	18.8±7.3	17.8±6.4	P=0.357
QOL score	4.7±1.0	4.6±1.2	P=0.867
Qave (ml/sec)	4.5±6.9	4.9±4.9	P=0.728
Qmax (ml/sec)	7.7±2.8	8.4±3.3	P=0.156
Postvoid residual			

TABLE 2：Changes in total IPSS, Qmax, and postvoid residual urine volume

		Silodosin		Tamsulosin		P-Value
Total IPSS	1M	n=69	-6.1±7.0	n=67	-5.6±6.2	P=0.629
	3M	n=64	-7.8±6.9	n=53	-7.0±5.8	P=0.543
	6M	n=57	-7.6±7.8	n=42	-6.6±7.3	P=0.510
	12M	n=56	-6.1±9.0	n=34	-6.8±7.6	P=0.714
Total storage subscore	1M	n=69	-2.0±3.4	n=67	-2.2±2.9	P=0.697
	3M	n=64	-2.5±3.7	n=53	-2.8±2.4	P=0.610
	6M	n=57	-2.5±3.8	n=42	-2.6±3.1	P=0.795
	12M	n=56	-2.0±4.2	n=34	-2.7±2.9	P=0.373
Total voiding subscore	1M	n=69	-2.6±4.1	n=67	-2.5±3.9	P=0.865
	3M	n=64	-3.6±4.2	n=53	-3.1±3.7	P=0.432
	6M	n=57	-3.5±4.6	n=42	-2.5±4.3	P=0.258
	12M	n=56	-2.8±4.7	n=34	-3.0±4.2	P=0.866

QOL score	1M 3M 6M 12M	n=67 n=64 n=57 n=56	-1.4±1.6 -1.7±1.7 -1.7±1.6 -1.8±1.8	n=66 n=52 n=42 n=34	-1.4±1.9 -1.4±1.7 -1.3±2.0 -1.8±1.9	P=0.906 P=0.422 P=0.214 P=0.851
Qave (ml/sec)	1M 3M 6M 12M	n=68 n=69 n=66 n=59	0.2±7.2 0.6±7.3 1.0±7.4 2.5±6.4	n=65 n=57 n=47 n=38	0.1±5.7 0.6±5.6 0.6±6.1 0.3±6.4	P=0.932 P=0.957 P=0.805 P=0.097
Qmax (ml/sec)	1M 3M 6M 12M	n=68 n=69 n=66 n=59	2.5±4.8 3.4±6.5 3.9±4.9 3.4±4.2	n=65 n=57 n=47 n=38	1.8±5.1 2.6±5.6 2.6±5.9 3.2±4.6	P=0.411 P=0.484 P=0.194 P=0.794
Postvoid residual (ml)	1M 3M 6M 12M	n=69 n=70 n=68 n=61	-23.3±73.3 -36.2±91.4 -35.5±98.8 -35.6±90.9	n=66 n=57 n=47 n=38	-23.7±102.8 -35.4±133.2 -36.2±150.5 -49.6±167.4	P=0.980 P=0.969 P=0.978 P=0.591

References

1. BJU Int 2006; 98: 1019–1024
2. J Urol 2009; 181: 2634–2640

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Is this a clinical trial?	**Yes**
Is this study registered in a public clinical trials registry?	**No**
Is this a Randomised Controlled Trial (RCT)?	**Yes**
What were the subjects in the study?	**HUMAN**
Was this study approved by an ethics committee?	**Yes**
Specify Name of Ethics Committee	**Institutional Review Board of Dokkyo Medical University**
Was the Declaration of Helsinki followed?	**Yes**
Was informed consent obtained from the patients?	**Yes**