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THE EFFECT OF TAMSULOSIN IN FEMALE PATIENTS WITH LOWER URINARY TRACT SYMPTOMS AND PREDICTIVE FACTORS FOR THERAPEUTIC OUTCOME: MULTICENTER, PROSPECTIVE STUDY

Hypothesis / aims of study

Recently, Tamsulosin, α1-adrenoreceptor antagonist have been used in female patients with lower urinary tract symptoms (LUTS). However, there is a few clinical evidence that tamsulosin are effective in female patients with LUTS and that is limited to the patients with low maximal flow rate (Q_{max}) who were suspected of having bladder outlet obstruction. Furthermore, there is no report concering the predictive factors for the effect of tamsulosin. Therefore, we performed a multicenter, prospective study to evaluate the effect and outcome predictors of tamsulosin in female patients with LUTS.

Study design, materials and methods

The total 82 female patients with LUTS, irrespective of Q_{max}, from 4 medical centers were included. Initial evaluations included International Prostate Symptom Score (IPSS) for subjective assessment of LUTS, measurements of Q_{max}, postvoid residual urine volume (PVR), micturition frequency in daytime and night, mean voided volume from uroflowmetry (UFR) and voiding diary for objective assessment and IPSS-quailty of life (QOL), Urogenital Distress Inventory (UDI-6) for QOL assessment and measurements of blood pressure, pulse rate for assessment of adverse events. All patients were treated with tamsulosin at a dose 0.2mg/day and after 2 and 4 weeks of treatment, we reevaluated the patients and analyzed the differences of these parameters.

Results

The mean age of the patients was 53.4±9.8 years old and among the 82 patients, 50 (61%) had moderate LUTS, 32 (39%) had severe LUTS and 60 (73.2%) had Q_{max} of <15ml/sec, 22 (26.8%) had Q_{max} of ≥15ml/sec.

Total IPSS, voiding and storage symptom scores were significantly decreased after 2,4 weeks of treatment and voiding symptom score was more decreased than storage symptom score (35.5% vs 25.3%, $p<0.05$). There were significant improvements in Q_{max}, PVR, frequency in daytime and night, mean voided volume, IPSS-QOL and UDI-6 scores (Table 1).

When the improvement of LUTS after treatment was defined as decrease in IPSS more than 20% after 4 weeks of treatment, 58 (70.7%) were improved and in multivariate analysis to determine the predictive factors influencing the improvement, voiding symptom score of IPSS before treatment was significantly associated with the improvement of LUTS, wherease age, Q_{max}, PVR and storage symptom score were not (Table 2). There was significant decrease in systolic blood pressure after 4 weeks of treatment, however did not cause associated adverse events.

Interpretation of results

Tamsulosin was effective for the treatement of female LUTS in terms of IPSS, parameters of voiding diary, IPSS-QOL, UDI-6 scores and the effect of tamsulosin could be predicted by voiding symptom score of IPSS and was not affected by Q_{max} before treatment.

Concluding message

In female patients with LUTS, tamsulosin was effective and well tolerated for improving subjective, objective voiding symptoms and QOL, irrespective of Q_{max}. Therefore, tamsulosin may be an initial treatment option in female patients with LUTS, especially in patients with severe voiding symptom of LUTS.

References

Table 1. The effect of tamsulosin in female patients with lower urinary tract symptoms (mean±SD)

	Baseline	4 weeks	Difference	p-value
IPSS	18.3±5.0	11.1±4.3	7.2±6.0	<0.0001*
Storage symptom score	7.3±1.9	5.2±1.9	2.0±2.3	<0.0001*
Voiding symptom score	11.1±4.2	6.4±2.6	4.7±4.2	<0.0001*
IPSS-QOL score	4.1±0.7	2.7±0.8	1.4±0.9	<0.0001†
UDI-6	6.2±2.4	4.3±2.1	1.9±2.1	<0.0001*
Irritative symptom score	2.6±1.1	1.8±0.9	0.8±1.0	<0.0001†
Stress symptom score	1.1±1.1	0.9±0.9	0.2±0.9	0.12†
Obstructive symptom score	2.6±1.2	1.6±1.2	1.0±1.2	<0.0001†
Maximal flow rate (ml/sec)	11.5±4.9	15.7±6.0	4.2±2.9	<0.0001*
Postvoiding residual (ml)	66.3±41.6	49.6±30.9	16.8±39.4	<0.0001*
No. of daytime frequency	8.7±2.3	6.8±2.0	1.9±1.8	<0.0001†
No. of nocturia	2.3±1.0	1.6±0.9	0.8±1.0	<0.0001†
Mean voided volume	138.7±49.6	209.0±55.6	70.3±49.3	<0.0001*
Systolic blood pressure (mmHg)	121.3±10.3	117.8±11.3	3.5±8.3	<0.0001*
Diastolic blood pressure (mmHg)	74.8±10.7	73.9±7.5	0.9±10.3	0.436*
Pulse rate	74.5±7.9	73.9±7.8	0.6±7.7	0.464*

*Paired t-test; †Wilcoxon signed rank test.

Table 2. Multivariate logistic regression analysis of pretreatment parameters with respect to the improvement of lower urinary tract symptoms

Parameters	Improvement of LUTS (decrease in IPSS>20%)

		Relative risk (95% CI)	p-value
Age		0.99 (0.94-1.05)	0.774
Maximal flow rate	<15ml/sec	1.00 (reference)	
	≥15ml/sec	2.36 (0.54-10.45)	0.256
Postvoiding residual		1.01 (0.99-1.03)	0.497
Storage symptom score of IPSS		1.04 (0.75-1.46)	0.813
Voiding symptom score of IPSS		1.34 (1.13-1.59)	0.001

Specify source of funding or grant	**none**
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 was part of normal clinical practice and common in clincal situation and rare risk to the patients.**
Was the Declaration of Helsinki followed?	**Yes**
Was informed consent obtained from the patients?	**Yes**