The effects of flexible-dose tamsulosin on LUTS and treatment satisfaction in patients with BPH: 12-week, open-label, observational study

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Hypothesis / aims of study

◆ **Alpha-adrenoceptor antagonist**

· Effects of alpha-blockers for LUTS are the proportionate relationship to the dosage

◆ **Tamsulosin**

· Selective alpha 1a-adrenoceptor antagonists

· 0.2mg is more often applied initially in Asia

· Not achieve a satisfactory response of 0.2mg → increase in dose may be considered

◆ **Objective**

· To investigate the effects of flexible-dose tamsulosin on LUTS and treatment satisfaction in patients with BPH.

Study design, materials and methods

◆ **12-weeks, open-label, observational study**

◆ **Subjects**

· Patients aged ≥ 50 yrs who had IPSS of ≥ 8 and Qmax ≤ 15 mL/s

· **Exclusion criteria**: neurogenic bladder, Hx. of AUR or prostate surgery, anatomical lower urinary tract abnormalities beyond BPH and symptomatic UTI

◆ Study design and Protocol

· First 4 weeks: received tamsulosin 0.2mg/d

· Tamsulosin 0.2mg group: maintained starting dose

· Tamsulosin 0.4mg group: increased 0.4mg for remaining 8 wks.

· Patients with reduction of IPSS ≤ 3 or dissatisfaction in TSQ after 0.2mg treatment for 4 wks were decided to receive 0.4mg

· **Primary endpoint**: change of total IPSS and treatment satisfaction by flexible-dose tamsulosin at week 12

· **Secondary endpoint**: proportion of patients with escalation of tamsulosin dose from 0.2 to 0.4mg, changes of IPSS QoL score, storage and voiding subscore by flexible-dose tamsulosin, change of total IPSS in tamsulosin 0.4mg group, comparison of total IPSS at week 12 between tamsulosin 0.2mg group and 0.4mg group, and baseline factors affecting 0.4mg dose escalation.

Results

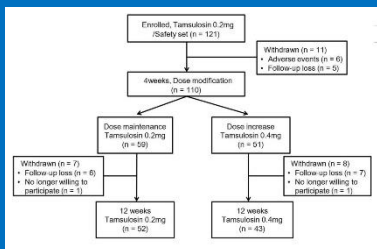

Figure 1. Disposition of participants

Table 1. Patients baseline clinical characteristics

	Total patients (n = 95)
Age (years)	64.6 ± 7.9
Body weight (kg)	67.1 ± 6.5
PSA (ng/mL)	1.5 ± 1.0
Maximum uroflow rate (mL/s)	10.8 ± 2.9
Voided volume (mL)	264.6 ± 128.1
Residual urine volume (mL)	36.0 ± 36.2
IPSS	
Storage subscore	6.8 ± 3.4
Voiding subscore	11.9 ± 4.3
Total score	18.9 ± 6.3
Quality of life score	3.4 ± 0.9
3 days voiding diary	
Frequency	7.5 ± 1.9
Nocturia	1.7 ± 0.8
Urgency	1.1 ± 2.1

PSA: prostate specific antigen, IPSS: International Prostate Symptom Score

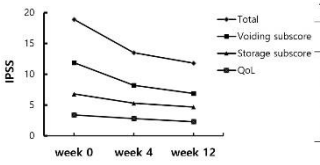

Figure 2. IPSS total and each subscore by flexible-dose tamsulosin treatment in 95 patients

Table 2. Changes in International Prostate Symptom Score in tamsulosin 0.4mg group

	Week 0	Week 4	Week 12	P-value (week 4 vs. week 12)
Total score	20.5 ± 6.7	18.6 ± 7.1	15.2 ± 6.9	0.001
Voiding subscore	13.1 ± 4.4	11.3 ± 4.7	9.2 ± 4.9	0.003
Storage subscore	7.3 ± 3.6	7.0 ± 3.3	5.8 ± 2.9	0.012
Quality of life score	3.5 ± 0.9	3.3 ± 0.9	2.8 ± 1.3	0.001

Table 3. Comparison of mean changes from baseline to week 12 in International Prostate Symptom Score between tamsulosin 0.2mg group and 0.4mg group

	Tamsulosin 0.2mg group (n = 52)	Tamsulosin 0.4mg group (n = 43)	P-value
Total score	-8.6 ± 6.5	-5.3 ± 5.6	0.009
Voiding subscore	-5.9 ± 4.4	-3.8 ± 4.1	0.020
Storage subscore	-2.6 ± 3.1	-1.5 ± 2.8	0.072
Quality of life score	-1.5 ± 1.1	-0.7 ± 1.2	0.003

Table 4. Comparison of baseline clinical characteristics between tamsulosin 0.2mg group and 0.4mg group

	Tamsulosin 0.2mg group (n = 52)	Tamsulosin 0.4mg group (n = 43)	P-value Univariate	P-value Multivariate
Age (years)	64.4 ± 8.5	64.9 ± 7.3	0.760	
Body weight (kg)	66.7 ± 6.8	67.7 ± 6.1	0.655	
PSA (ng/mL)	1.6 ± 1.1	1.3 ± 0.9	0.174	
Maximum uroflow rate (mL/s)	11.4 ± 3.0	10.1 ± 2.8	0.030	0.026
Voided volume (mL)	278.9 ± 136.4	247.3 ± 116.4	0.234	
Residual urine volume (mL)	33.8 ± 34.5	38.7 ± 38.4	0.512	
IPSS				
Storage subscore	6.5 ± 3.2	7.3 ± 3.6	0.231	
Voiding subscore	11.0 ± 4.0	13.1 ±4.4	0.017	
Total score	17.6 ± 5.7	20.5 ±6.7	0.027	
Quality of life score	3.4 ± 0.9	3.5 ± 0.9	0.397	
3 days voiding diary				
Frequency	7.02 ± 1.38	7.97 ± 2.45	0.027	0.073
Nocturia	1.60 ± 0.95	1.88 ± 0.73	0.127	
Urgency	1.12 ± 2.32	1.12 ± 2.04	0.990	

PSA: prostate specific antigen, IPSS: International Prostate Symptom Score

Table 5. Treatment emergent adverse events

Adverse events	No. (%)
Dizziness	5 (4.1))
Erectile dysfunction	4 (3.3)
Insomnia	4 (3.3)
GI discomfort	2 (1.6)
Palpitation	2 (1.6)

Interpretation of results

◆ Flexible-dose tamsulosin treatment, 0.2mg maintenance or 0.4mg dose escalation by treatment satisfaction and LUTS after tamsulosin 0.2mg treatment for 4 weeks in patients with BPH showed significant improvement of LUTS, high satisfaction rate and well tolerated. Maximum uroflow rate was an independent factor affecting tamsuloin 0.4mg dose escalation.

Conclusion message

◆ Flexible-dose tamsulosin treatment in patients with BPH successfully improved LUTS, satisfaction rates and well tolerated.