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TAMSULOSIN ADMINISTRATION IMPROVES LOWER URINARY TRACT SYMPTOMS(LUTS) REGARDLESS OF THE PROSTATE VOLUMES IN MEN

Hypothesis / aims of study

In medical therapy of LUTS suggestive of BPE, alpha-blockers and 5 alpha-reductase inhibitors are used in single or combination therapy. As a single therapeutic agent, clinical benefit of 5 alpha-reductase inhibitor is known to be closely related with baseline prostate volumes: finasteride is effective in patients with prostate volumes over 40ml[1]. In case of alpha-blockers though, it is not yet known whether the efficacy of alpha-blockers are associated with prostate volumes or not. In this study, we evaluated whether the clinical efficacy of tamsulosin is correlated with baseline prostate volumes.

Study design, materials and methods

Patients were enrolled from May to July 2004. Inclusion criteria were patients with IPSS over 6, age over 40. Patients with previous history of recent BPH medication within 3 months, BPH related surgery, urinary tract infection and urethral stricture were excluded. Patients were evaluated initially by demographic factors, IPSS/QOL questionnaire, digital rectal examination, transrectal ultrasonography, urinalysis, serum PSA, uroflowmetry and residual urine(RU) measured with bladder scan. Patients were grouped by baseline prostate volume(PV): PV < 20ml (group A), 20ml ≤ PV<30ml (group B), 30ml ≤ PV<40ml (group C), PV≥40ml(group D). After the initial evaluation, all the patients enrolled were given tamsulosin 0.2 mg per day. After 8 weeks of tamsulosin treatment, clinical efficacy was determined by changes of IPSS/QOL scores, Qmax and RU volumes. Statistical analysis was done with mixed model analysis using SPSS 12.0 software.

Results

Overall 672 patients were enrolled initially and 580 patients finished the protocol. Most of violating the protocol was follow up loss of patients (n= 65, 71%). All the analysis was done with intention-to-treatment based. Baseline characteristics of patients grouped by baseline PV is summarized in table 1.

Table 1. Baseline characteristics of patients

group	A		B		C		D	
Prostate volume	PV < 20ml		20ml ≤ PV<30ml		30ml ≤ PV<40ml		PV≥40ml	
n	95		241		191		145	
	mean	SD	mean	SD	mean	SD	mean	SD
Age*	62.5	8.19	62.4	8.19	63.6	7.87	65.9	7.56
PSA**	1.10	1.02	1.40	1.33	1.83	1.49	2.81	1.73
IPSS	20.07	6.76	18.68	7.28	18.71	6.28	19.67	7.15
QOL	4.23	1.04	4.03	0.95	3.92	1.01	3.98	1.07
Qmax	11.76	5.94	12.76	6.48	12.28	5.69	11.26	5.25
RU volume***	41.43	62.45	26.07	30.61	39.80	69.98	69.70	47.25

* statistically significant difference between group A&D, B&D ($p<0.05$)
** statistically significant difference between group A&D, B&D, A&C, B&D ($p<0.05$)
***statistically significant difference between group B&D, C&D, A&B ($p<0.05$)

After 8 weeks of treatment with tamsulosin 0.2 mg, total IPSS score was decreased by 6.2 point(31.7%) and Qmax was increased by 1.8ml/sec(29.7%). 62.4% of patients showed symptomatic improvement defined by 25% decrease of total IPSS score. When clinical outcomes were compared according to the different PV groups, there were no statistically significant differences among groups except significant Qmax changes between group B and D (table 2).

Table 2. Clinical outcomes classified by prostate volumes

group	A		B		C		D	
	mean	SD	mean	SD	mean	SD	mean	SD
IPSS at 8 weeks	13.46	7.48	12.61	7.29	12.85	6.72	13.09	6.66
IPSS change(%)	32.89	32.33	30.87	33.06	31.31	30.04	33.01	26.98
QOL at 8 weeks	3.00	1.32	2.84	1.25	2.87	1.09	2.73	1.05
QOL change(%)	28.77	28.87	28.82	30.95	25.67	25.76	27.47	33.77
Qmax at 8 weeks	13.50	6.87	13.92	6.48	14.33	5.61	13.93	5.73
Qmax change(%)*	25.06	64.91	18.27	44.49	26.48	57.12	55.99	212.97

* statistically significant difference between group B&D ($p<0.05$)

Interpretation of results

After 8 weeks of tamsulosin administration, there were no significant differences in the improvement of clinical parameters among the different prostate volume groups.

Concluding message

Clinical efficacy of short term tamsulosin medication is not affected by the prostate volume. It may be necessary that the results of this study should be confirmed in further long term follow-ups.

References:

1. Prostate volume predicts outcome of treatment of benign prostatic hyperplasia with finasteride: meta-analysis of randomized clinical trials**.** Urology 1996; 48: 398-405