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A MULTICENTER, OBSERVATIONAL, OPEN-LABEL 4 WEEK STUDY OF EFFICACY AND PATIENT'S SATISFACTION OF TAMSULOSIN MONOTHERAPY VS. TAMSULOSIN WITH SOLIFENACIN IN MEN WITH LOWER URINARY TRACT SYMPTOMS (LUTS) RELATED TO BENIGN PROSTATIC HYPERPLASIA (BPH).

Hypothesis / aims of study

To assess the efficacy and patient's satisfaction in the treatment of lower urinary tract symptoms (LUTS) related to benign prostatic hyperplasia (BPH), prospective, randomized, real practice-based application of alpha-blocker monotherapy vs. alpha blocker with antimuscarinic were compared.

Study design, materials and methods

175 male patients with moderate degree of LUTS (both voiding and storage symtoms) from 5 centers were enrolled in randomized pattern. Patients were divided into 2 groups; group 1 included patient treated with tamsulosin 0.2mg monotherapy (15 patients/ center), group 2 was included with tamsulosin 0.2mg combined with solifenacin 5mg (20 patients/center). Inclusion criteria were male patients with no history of LUTS-related medications, aged from 40 to 80 years old, maximal uroflow rate (Qmax)≥10ml/sec, post-void residual urine (PVR)≤100mL, total International prostatic symptom score (IPSS)≥8, OAB symptom score (OABSS)≥3, prostate size on digital rectal exam. was from 20 to 60gm and PSA value≤4ng/mL.. Parameters included 3 days-voiding diary, IPSS/QoL, uroflow/PVR, Patient's perception of bladder condition (PPBC), OABSS and evaluated at 0 and 4 weeks. Statistical analysis was done with Student's t-test.

Results

Baseline measurements showed no difference (except PVR) between two groups (Table 1). After 4 weeks treatment, parametrs such as IPSS/QoL (P<0.001) , PPBC (P<0.05), OABSS (P<0.001) improved significantly in both groups. Nocturia (P<0.05) and No. of urgency (P<0.05) were significantly improved in group 2 (Table 1). No incidence of acute urinary retention was reported and a case of moderate degree dry mouth was reported.

Table 1. Baseline LUTS characteristics and parameters in both groups after 4 weeks of treatment of the two groups of patients

Parameters	Group 1		Group 2	
	Baseline	4 weeks	Baseline	4 weeks
Age(mean)	65.93±7.36		63.8±10.43	
Body weight(kg)	66.79±9.34		68.22±10.04	
PSA (ng/mL)	1,55±1.09		1.36±1.08	
Uroflowmetry Qmax (mL/sec)	14.21±5.8	13.38±5.86	16.89±10.57	17.36±11.22#
Voided volume (mL)	196.15±134.24	196.83±110.21	199.99±129.33	237.24±139.56
PVR (mL)	34.38±30.62	57.62±59.60#	22.68±21.81	26.38±21.52#
IPSS (total)	18.84±5.93	14.51±6.62**	20.37±6.51	13.04±7.23**
QoL	4.32±0.92	3.50±1.23*	4.11±1.0	3.44±1.18*
OABSS	7.11±2.37	4.48±2.46**	6.78±2.03	4.05±2.89**
PPBC	4.12±0.83	3.58±1.12*	3.95±0.89	3.35±1.05*
Voiding diary Day-time frequency(times/day)	7.18±2.17	6.14±2.44	7.75±2.3	6.73±2.11*
Nocturia	1.91±1.02	1.90±1.02	1.87±1.17	1.45±0.92
No. of Urgency/day	2.97±2.55	2.23±2.86	3.44±3.03	1.76±2.31*
No of urgency incontinence	0.07±0.28	0.01±0.05	0.09±0.26	0.16±0.87
Voided volume (mL)	1621±672.66	1606.12±515.02	1613.3±543.29	1498.05±480.90

PSA-prostatic specific antigen; PVR-postvoided residual; IPSS-International prostatic symptom score; QoL-Quality of life; OABSS-OAB symptom score; PPBC-Patient's perception of bladder condition. * p<0.05, ** p<0.001, baseline vs 4 weeks; # p<0.05, group 1 vs group 2

Interpretation of results

Both groups of tamsulosin and tamsulosin with solifenacin treatment showed significant improvement in voiding and storage parameters after 4 weeks therapy. Although short duration of medications, patient's satisfaction was also acceptable.

Concluding message

After 4 weeks treatment of tamsulosin monotherapy and combination of tamsulosin with solifenacin showed improvement of important LUTS parameters, satisfaction and combination groups showed better results in number of urgency and nocturia compared with monotherapy group. No urinary retention case was reported.

References
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