

COMPARISON OF ALFUZOSIN 10MG WITH OR WITHOUT PROPIVERINE 10MG, 20MG IN MEN WITH LUTS AND OAB: RANDOMIZED, SINGLE-BLIND, PROSPECTIVE STUDYHypothesis / aims of study

To evaluate the efficacy and safety of alfuzosin 10mg and/or propiverine 10mg, 20mg in male with lower urinary tract symptom and overactive bladder after 8weeks treatment

Study design, materials and methods

A total of 137 men were enrolled from October 2010 to December 2011. Estimated sample size was 132 which was calculated with minimum difference of OABSS (3.9), power (80%) and drop-out rate (20%). Inclusion criteria were men aged ≥ 40 , IPSS ≥ 8 , QOL item score ≥ 3 , Overactive Bladder Symptom Score (OABSS) ≥ 3 and OABSS urgency item score ≥ 2 . TRUS, PSA, peak urinary flow rate (Qmax), postvoid residual volume(PVR), IPSS and OABSS were assessed initially. Patients were randomly assigned to receive alfuzosin 10mg (group I), alfuzosin 10mg plus propiverine 10mg (group II) or alfuzosin 10mg plus propiverine 20mg (group III). Visits were occurred at 4 and 8 weeks and OABSS, IPSS, Qmax and PVR were compared with baseline.

Results

A total of 88 men completed this study. Means of age, prostate volume, PSA and Qmax of three groups at baseline were not statistically different (Table 1). In all groups, OABSS, storage and voiding symptom score of IPSS were reduced significantly compared to baseline after 8 weeks of treatment. Improvements of OABSS in group II and III were greater than group I statistically ($p=0.03$) but no significant difference was found between group II and III. Improvements of IPSS and QOL in three groups were not different significantly compared to each other (Table 2). Qmax and PVR at 8 weeks in three groups were not different compared to baseline.

Interpretation of results

In men with LUTS and OAB, addition of propiverine 10mg and 20mg will improve OAB symptoms without negative effect to urinary flow and residual urine volume. In addition low dose propiverine also has beneficial effects to men with LUTS and OAB.

Concluding message

Alfuzosin 10mg combined with propiverine 10 or 20mg is more effective than only alfuzosin monotherapy in men with LUTS and OAB.

Table 1. Patients baseline Characteristics

	Group 1 (n=32)	Group 2 (n=34)	Group 3 (n=22)	p
Age(years)	59.8 \pm 9.9	59.8 \pm 9.9	64.3 \pm 11.1	0.215
Prostate size(ml)	25.7 \pm 8.3	29.7 \pm 11.6	27.4 \pm 11.0	0.333
PSA(ng/ml)	2.0 \pm 2.3	1.7 \pm 1.7	1.6 \pm 1.5	0.715
Qmax(ml/sec)	14.9 \pm 8.0	12.7 \pm 5.6	15.8 \pm 6.2	0.240
Voided Vol.(ml)	229.3 \pm 158.2	217.7 \pm 136.0	209.6 \pm 123.1	0.881
PVR(ml)	21.1 \pm 41.6	14.9 \pm 21.6	39.8 \pm 39.5	0.074

Table2. Comparison of OABSS, IPSS (Baseline Vs after 8 weeks of treatme

		Group 1	p	Group 2	p	Group 3	p
Baseline	IPSS	16.2 \pm 6.7		19.1 \pm 7.0		15.7 \pm 6.8	
	Storage Sx	7.6 \pm 3.4		8.5 \pm 3.0		7.4 \pm 2.7	
	Voiding Sx	9.4 \pm 4.8		10.6 \pm 5.0		9.3 \pm 5.2	
	QOL	4.3 \pm 2.2		4.3 \pm 1.0		4.8 \pm 5.3	
	OABSS	6.1 \pm 2.9		7.5 \pm 2.5		7.3 \pm 3.0	
Score At 8Wks	IPSS	10.9 \pm 7.2	<0.001	12.4 \pm 7.0	<0.001	12.4 \pm 7.3	0.09
	Storage Sx	4.2 \pm 3.0	<0.001	5.8 \pm 3.2	<0.001	5.4 \pm 3.4	0.013
	Voiding Sx	6.6 \pm 5.0	0.001	6.6 \pm 4.6	<0.001	6.9 \pm 5.3	0.027
	QOL	2.9 \pm 1.3	0.001	3.2 \pm 1.3	0.004	3.2 \pm 1.6	0.174
	OABSS	4.8 \pm 3.2	<0.001	4.8 \pm 3.1	<0.001	4.7 \pm 2.8	<0.001

p- value :
Score at 8
weeks
compared
to baseline

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