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ASSESSMENT OF TWO α_1-ADRENOCEPTER ANTAGONISTS, NAFTOPIDIL AND TAMSULOSIN HYDROCHLORIDE, ON VOIDING DISTURBANCE IN BENIGN PROSTATIC HYPERPLASIA. A RANDOMIZED CROSSOVER STUDY.

Aims of Study

We compared the efficacy of two α_1-adrenocepter antagonists, tamsulosin hydrochloride α_{1A} and naftopidil α_{1D}, in patients with benign prostatic hyperplasia on urodynamic study.

Methods

Thirty-six patients with benign prostatic hyperplasia with less than 20ml of prostate volume enrolled in a double-blind, two-period crossover study. Patients were randomized two groups. Out of 36 patients, 18 patients of Group 1 started to receive with naftopidil of 50mg for 4 weeks, and 18 patients of Group 2 started to receive with tamsulosin of 0.2mg for 4 weeks. After one week of washing period, patients of Group1 received tamsulosin of 0.2mg for 4 weeks, and patients of Group 2 received naftopidil of 50mg for 4 weeks. All patients were examined for International Prostate Symptom Score (I-PSS) and underwent uroflowmetry, cystometry, urethral pressure profile and pressure flow study (PFS) at 3 points, before treatment, after treatment with the first drug and after treatment with the second drug .

Results

The background of two groups was showed table1. Between Group1 and Group2, there is no significant difference of voiding parameters. Accordingly, without classification of Group1 and Group2, we analyzed the efficacy of naftopidil and tamsulosin.

After treatment with naftopidil, I-PSS symptom score improved, decreasing from 18.6±4.5 points to 7.2±5.4 points. Twenty patients (55.6%) had improvement of nocturia. The average number of episodes of nocturia per night decreased from 2.9 to 1.6 (P<0.05). After treatment with naftopidil, both average flow rate (AFR) and maximum flow rate (MFR) increased from the initial value of 4.9±0.5 ml/sec to 7.4±0.6 ml/sec (P<0.001) and from 9.9±0.6 ml/sec to 13.2±0.9 ml/sec (P<0.001), respectively. Residual urine volume was improved, decreasing from 53.4±12.6 ml to 11.9±6.7 ml. Both maximum urethral closure pressure (MUCP) and functional urethral length (FUL) did not change significantly, being 62.4±8.3 cmH_2O before treatment, and 60.2±4.9 cmH_2O after treatment, and 4.2±0.3 cm before treatment and 4.1±0.3 cm, respectively. Bladder volume at the first desire to void (FDV) increased from 167.6±19.9 ml to 209.8±20.6 ml (P<0.01). Bladder volume at the maximum desire to void (MDV) did not change significantly, being from 321.6±24.4 ml before treatment and 331.2±27.6 ml after treatment. However, in two (10.0%) of the patients with improvement of nocturia, detrusor instability disappeared after treatment. The results of PFS showed that naftopidil improved bladder outlet obstruction according to the Schäfer nomogram (Table 2). Pressure at maximum flow decreased from the initial value of 75.1±7.4 cmH_2O to 64.4±5.4 cmH_2O (P<0.01).

After treatment with tamsulosin, IPSS symptom score improved, decreasing from 18.6±4.5 points to 7.9±4.9 points. Twelve patients (33.3%) had improvement of nocturia. The average number of episodes of nocturia per night did not change from 2.9 to 2.3. After treatment with tamsulosin, both AFR and MFR increased from the initial value of 4.9±0.5 ml/sec to 8.1±0.6 ml/sec (P<0.001) and from 9.9±0.6 ml/sec to 13.8±0.8 ml/sec (P<0.001), respectively. Residual urine volume was improved, decreasing from 53.4±12.6 ml to 9.9±6.0 ml (P<0.001). Both MUCP and FUL did not change significantly, being 62.4±8.3 cmH_2O before treatment, and 60.2±4.9 cmH_2O after treatment, and 4.2±0.3 cm before treatment and 4.0±0.2 cm respectively. Bladder volume at FDV did not changed, being 167.6±19.9 ml before treatment and 180.1±28.6 ml after treatment. Bladder volume at MDV did not change significantly, being from 321.6±24.4 ml before treatment and 333.2±29.8 ml after treatment. The results of PFS showed that tamsulosin improved bladder outlet obstruction (Table 2). Pressure at maximum flow decreased from the initial value of 75.1±7.4 cmH_2O to 61.0±4.6 cmH_2O (P<0.01).

Table 1.

	Group 1	Group 2	
Age (years)	73.5	71.6	N.S.
Volume of prostate (ml)	21.1	19.2	N.S.
MFR (ml/s)	9.8	10.4	N.S.
AFR (ml/s)	4.9	5.3	N.S.
Pdet at MFR cmHO	75.8	74.4	N.S.
Residual urine volume (ml)	55.7	52.4	N.S.
Bladder volume at MDV (ml)	315.5	324.5	N.S.
Day frequency times	11.2	11.5	N.S.
Night frequency times	3.2	3.4	N.S.

Table 2.

Schäfer nomogram	Naftopidil (n=)	Tamsulosin (n=)
Class 4→3	8	10
Class 4→2	5	4
Class 3→2	9	9
Class 3→1	1	
Class 4→4	3	3
Class 3→3	4	6
Class 2→2	6	4

Conclusions

In both of naftopidil and tamsulosin hydrochloride, MFR and AFR increased significantly and residual urine decreased significantly in men with BPH. Naftopidil was superior to tamuslosin hydrochloride for reduction of the number of episodes of nocturia per night. In patients treated with naftopidil, we found a significant increase in bladder volume at FDV and experienced two cases of disappearance of detrusor instability on urodynamic study. It seems that, after treatment with naftopidil, the improvement of symptom of nocturia is concerned with the increasing of bladder volume at FDV and the disappearance of detrusor instability .