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A STUDY ON THE EFFICACY AND SAFETY OF COMBINATION THERAPY WITH ALPHA-BLOCKERS AND ANTICHOLINERGICS IN THE BENIGN PROSTATIC HYPERPLASIA PATIENTS ACCOMPANIED WITH OVERACTIVE BLADDER SYMPTOMS.

Abstract Text:

Hypothesis / aims of study

Benign prostatic hyperplasia patients usually accompanies overactive bladder symptoms. Adding anticholinergics in these patients evokes us fear about deteriorating of obstructive symptoms. We evaluated the relative benefit and harm of anticholinergics compared with alpha-blocker only group in terms of emptying efficiency and storing symptoms.

Study design, materials and methods

From October 2000 to February 2006, 152 male patients who had emptying symptoms as well as storing symptoms were selected in this study. All patients scored more than 8 IPSS (international prostate symptom score) and more than 3 score in storing symptom domain (IPSS question 2, 4, 7). All patients received IPSS, TRUS (transrectal ultrasonography), uroflowmetry with RU (residual urine) measurement. In 98 patients alpha-blocker plus anti-cholinergic were used (group I) and in 54 patients alpha-blocker only (group II). Used anti-cholinergics were tolterodine and propiverine. After mean 15.0 months later follow up evaluation was done. IPSS score was divided as emptying domain (question 1,3,5,6) and storing domain (question 2,4,7). Between the 2 groups the amount of change in each domain of IPSS, total IPSS, QoL, uroflowmetry and RU were compared. Statistical program was SPSS 11.0. and statistical method was Independent T-test and p value less than 0.05 was regarded as significant.

Results

The age of group I and group II was 64.7 ± 10.9 , 62.2 ± 12.0 years. Prostate volume was 32.3 ± 13.6 , 32.3 ± 9.6 cc. Total IPSS was 17.5 ± 6.3 , 17.7 ± 5.9 . Emptying symptom domain score was 9.7 ± 5.1 , 10.5 ± 4.5 and storing symptom domain score was 7.8 ± 2.6 , 7.2 ± 2.6 . QoL was 3.3 ± 0.8 , 3.0 ± 1.0 . Peak flow rate was 14.1 ± 7.1 , 12.8 ± 5.9 ml/s and RU was 35.4 ± 41.7 , 36.7 ± 41.6 ml. All the values was not different between 2 groups ($p > 0.05$). After mean 15.0 months later, the changes of storing symptom domain score was -2.5 ± 2.3 , -1.6 ± 2.5 for group I and group II respectively and the difference was significant ($p = 0.028$). But the changes of all the other parameters was not different between 2 groups (Table 1).

Interpretation of results

Emptying symptom domain score, peak flow rate, residual urine had the trend of more improvement in alpha-blocker only group. But, it was not significant. Storing symptom domain score, QoL, total IPSS had the trend of more improvement in combination therapy group. But, statistical significance was only seen in the changes of storing symptom domain score.

Concluding message

Combination of anticholinergics with alpha-blockers in benign prostatic hyperplasia with overactive bladder patients seems not to lower emptying efficiency significantly but improve storing symptom significantly.

Table 1. Amount of changes of each parameters in combination group and alpha-blocker only group after 15 months later.

Changes of	Combination group (N=98)	Alpha-blocker only group (N=54)	P value
Emptying symptom domain	-2.2 ± 4.5	-2.8 ± 3.9	0.479
Storing symptom domain	-2.5 ± 2.3	-1.6 ± 2.5	0.028
Quality of life	-0.5 ± 0.9	-0.3 ± 0.9	0.177
Total IPSS	-4.7 ± 5.7	-4.4 ± 5.8	0.702
Peak flow rate	-0.8 ± 5.3	1.1 ± 5.0	0.123
Residual urine	5.5 ± 52.2	-6.3 ± 43.0	0.297

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CLINICAL TRIAL REGISTRATION: This clinical trial has not yet been registered in a public clinical trials registry.

HUMAN SUBJECTS: This study did not need ethical approval because It was retrospective study and is not different from everyday prescribing. but followed the Declaration of Helsinki Informed consent was not obtained from the patients.