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Konstantinidis C[1], Andreadakis S[2], Skriapas K[3], Kartaklis P[4], Thomas C[4], Serafetinidis E[5], Gekas A[4], Delakas D[5]
1. *National Institute of Rehabilitation, Athens, Greece,* ***2.*** *Foundation of Social Insurance, Kilkis, Greece,* ***3.*** *Urology Department , General Hospital of Larissa, Larissa, Greece,* ***4.*** *Urology Department, General Hospital "Agios Andreas", Patra, Greece,* ***5.*** *Urology Department, General Hospital "Asclepio", Voula, Athens, Greece*

COMBINATION TREATMENT WITH A-BLOCKERS AND ANTICHOLINERGICS FOR LUTS IN MEN WITH BPH

Hypothesis / aims of study

Lower urinary tract symptoms (LUTS) are commonly associated with benign prostatic hyperplasia (BPH). The LUTS – BPH entity includes both voiding and storage symptoms. On the other hand, (OAB) describes a condition characterized by an urgent need to pass urine, with or without urge incontinence, usually with frequency and nocturia. Storage symptoms seem to be the most bothersome for the patients with BPH and with the most important impact in their quality of life. Nevertheless these symptoms may overlap with overactive bladder (OAB) symptoms [1]. Anticholinergic agents are effective in relieving overactive bladder symptoms [2]. However, anticholinergic therapy has historically been contraindicated in patients with LUTS associated with BPH because of concerns for developing acute urinary retention. Our aim was to assess the safety and efficacy of the latest form of an anticholinergic agent (tolterodine, prolonged release tabs, 4 mg) combined with the standard treatment (a-blocker, tamsulosin), in the management of LUTS associated with BPH.

Study design, materials and methods

We evaluated 103 men who presented with LUTS suspected of being resulted from BPH, by IPSS-questionnaire, U/S and uroflowmetry. These patients were selected to have similar baseline characteristics regarding IPSS score, prostatic volume, Qmax and RU. Exclusive criteria were: Qmax less than 10 ml/s, residual urine over 50 ml, prostate volume over 50 ml, and suspicious PSA value. All patients were treated initially with tamsulosin 0.4 once daily. After 10 days of treatment, 37 patients were still experiencing bothersome lower urinary tract symptoms including urinary frequency, urgency +/- incontinence, and they were included in the main study. They were randomly divided in two groups. Group (A), n=18 who continued the tamsulosin monotherapy and group (B), n=19, who received additionally 4mg of tolterodine prolonged release once daily. Reassessment was done with the same tools after 8 weeks.

Results

	Group (A), n=18 Tamsulosin		group (B), n=19 Tamsulosin + tolterodine	
	Pre-treatment	Post-treatment	Pre-treatment	Post-treatment
IPSS	17.5±2.2	16.3±3.1	18.0±2.0	13±3,2
Storage IPSS	11.6±2.1	10.7±2.0	12.2±2.2	8.2±1.9
Voiding IPSS	6.1±2.3	5.9±2.9	6.2±2.2	5.3±2.0
Qmax	13.8±3.7	15.1±4.5	13.6±3.1	14.4±2.6
RU	24.0±13	19.3±12.2	27.1±14.6	23.2±15.9
QoL	5.1±0.4	4.3±0.3	5.2±0.2	3.1±0.3

Storage IPSS: questions 1, 2, 4, 7 Voiding IPSS: questions 3, 5, 6

Interpretation of results

The evaluation in the therapeutic effect after 8 weeks showed greater decrease in total (5) and storage (4) IPSS-score in the combination group, compared to 1.2 and 0.9 respectively in the Tamsulosin monotherapy group. The improvement in Quality of life was also greater in the combination group. Concerning safety, there were 4 pts(21%) who experienced dry mouth in the combination group, one (5,26%) who reported constipation and another one with eye-dryness in the same group, when there was only one patient who experienced dizziness in the tamsulosin group (5.55%). There was one patient in the group B who complained for severe difficulty to start voiding, but there was no urinary retention.

Concluding message

Patients with OAB symptoms and confirmed BPH, who are not sufficiently relieved with a-blockers, may benefit from the addition of an anticholinergic agent. The patients' selection based on prostate volume, Qmax and urine residual keeps the risk for urinary retention low. The combination therapy seems to provide greater relief from the symptoms associated with LUTS/BPH than monotherapy with a-blockers. The incidence of adverse effects in the combination therapy is higher than a-blockers monotherapy, but the therapy is generally well tolerated.

References

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Is this a clinical trial?	**Yes**
Is this study registered in a public clinical trials registry?	**No**
Is this a Randomised Controlled Trial (RCT)?	**No**
What were the subjects in the study?	**HUMAN**

Was this study approved by an ethics committee?	**No**
This study did not require ethics committee approval because	**The drugs which are used in this study are indicated for the symptoms of the patients**
Was the Declaration of Helsinki followed?	**Yes**
Was informed consent obtained from the patients?	**Yes**