

EFFICACY OF COMBINATION WITH TAMSULOSIN AND ZOLPIDEM TARTRATE ON NOCTURIA IN PATIENTS WITH BPH: A PROSPECTIVE STUDY

Hypothesis / aims of study

Nocturia is a frequent complaint of patients in urologic clinic. Nocturia may be categorized to one of following causes: nocturnal polyuria, low nocturnal bladder capacity or mixed nocturia (a combination of the preceding two categories). Sleep disorder is also associated with nocturia. Tamsulosin, α_1 adrenergic antagonist, is not always effective on nocturia in patients with BPH by increasing nocturnal bladder capacity.

The purpose of this study was to investigate the efficacy and safety of combination with tamsulosin and zolpidem tartrate which was one of the most commonly prescribed hypnotic drugs, in the treatment of nocturia associated with sleep disorder.

Study design, materials and methods

Male patients who had suffered from symptoms of nocturia were included in a 4-week treatment with tamsulosin (0.2mg once daily). Patients who had no improvement in nocturia (nocturia-QOL index ≥ 4) and suspected to have sleep disorder (Athens Insomnia Scale ≥ 6) received additional 2-week treatment with tamsulosin and zolpidem tartrate. The inclusion criteria were age ≥ 50 years, and nocturia-QOL index ≥ 4 . Patients with nocturnal polyuria (with nocturnal polyuria index $>33\%$) were excluded.

Outcomes were evaluated by IPSS, QOL index, Athens Insomnia Scale (AIS), uroflowmetry, and post voided residual urine (PVR). Tolerability was evaluated according to adverse event reports.

Results

A total of 31 patients (mean 70.8 years) were enrolled.

After 4-week treatment with tamsulosin 13 patients decrease nocturia-QOL index ≤ 3 (Group A). 14 of 18 patients who did not decrease nocturia-QOL index ≤ 3 were suspected to have sleep disorder (AIS ≥ 6), and then received additional 2-week treatment with tamsulosin and zolpidem tartrate (Group B).

After 4-week treatment with tamsulosin, in Group A, QOL index were decreased from 4.5 ± 0.8 to 2.6 ± 1.1 ($P \leq 0.01$), nocturia were decreased from 3.4 ± 1.0 to 2.3 ± 1.3 ($P \leq 0.01$), and AIS were decreased from 9.7 ± 6 to 5.1 ± 3.7 ($P \leq 0.01$).

After additional 2-week treatment with tamsulosin and zolpidem tartrate (Group B), QOL index were decreased from 3.9 ± 0.9 to 3.0 ± 0.7 ($P \leq 0.01$), nocturia were decreased from 3.1 ± 0.9 to 2.6 ± 1.0 ($P \leq 0.01$), and AIS were decreased from 10.2 ± 6.9 to 5.6 ± 3.5 ($P \leq 0.01$). There were no adverse effects.

Interpretation of results

Only 4-week treatment with tamsulosin, in 13 of 31 (41.9%) patients, nocturia and QOL index decreased significantly. Interestingly, AIS also decreased (Group A). In the patients who had no satisfaction with the first treatment (nocturia-QOL index ≥ 3), 14 of 18 (77.8%) suspected to have sleep disorder (Group B). In Group B after additional 2-week treatment with tamsulosin and zolpidem tartrate, nocturia, QOL index and AIS decreased significantly. In additional treatment with zolpidem tartrate, there was no newly appearance of voiding disturbance and no increasing of PVR.

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Concluding message

Effectiveness of tamsulosin on nocturia in patients with BPH is limited when etiology of nocturia is associated with sleep disorder. In such patients, zolpidem tartrate, which one of the most commonly prescribed hypnotic drugs, may be effective.

References

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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 was approved by the This study was approved in Gifu University. and followed the Declaration of Helsinki Informed consent was obtained from the patients.