

SOLIFENACIN INFLUENCES NOT ONLY STORAGE SYMPTOMS BUT ALSO SLEEP QUALITY OF PATIENTS WITH NOCTURIA AND SLEEP DISTURBANCE.Hypothesis / aims of study

Nocturia is one of the most bothersome symptoms in the elderly. Multiple factors may result in nocturia, including pathologic conditions, such as cardiovascular disease, diabetes mellitus, lower urinary tract obstruction, anxiety or primary sleep disorders, and sleep apnea. Nocturia is caused by nocturnal polyuria (nocturnal urine overproduction), a diminished nocturnal bladder capacity or a combination of the two conditions¹. Nocturia is also more prevalent in association with a reduced bladder capacity. Antimuscarinic drugs are often used to treat patients with storage symptoms, depress involuntary bladder contractions and improving bladder capacity. As a result, improving nocturia by use of antimuscarinic drugs might affect the patients' sleep. The aim of this study is to determine whether antimuscarinic drugs affect the quality of sleep in the patients with sleep disorders and nocturia.

Study design, materials and methods

A total of 10 patients (mean age 73.7 years: 9 male, 1 female), with nocturia (mean of 3.9 episodes per night), were enrolled in this study. All patients administered 5mg solifenacin o.d. for more than 8weeks. We evaluated the change of overactive bladder symptom score (OABSS), and nocturia before and 8 weeks after the administration of solifenacin. To assess the sleep disturbance, we used Athens Insomnia Scale (AIS) as self questionnaire, and Actiwatch for assessing the objective sleep quality. The AIS is a self-administered questionnaire consisting of 8 items; 5 items assess difficulty with sleep induction, awakening during the night, early morning awakening, total sleep time, and overall quality of sleep and the remaining 3 items pertaining to the next-day consequences of insomnia (problems with sense of well-being, overall functioning, and sleepiness during the day). Each item of the AIS can be rated from 0 (no problem at all) to 3 (very serious problem)². We evaluated the patients by AIS score before and 8 weeks after the administration of solifenacin. Sleep quality was identified by continuous actiwatch monitoring. Actiwatch-16 (Minimitter-Respironics Inc., Bend, Oregon) is a wrist-worn activity monitor to collect activity and score data for sleep parameters. Actigraphic data were scored as sleep or wake by Actiware[®] version 5.0 analysis software (Minimitter-Respironics Inc., Bend, Oregon). Patients wore the Actiwatch-16 for 7 days before and 8 weeks after the administration of solifenacin. Total sleep time and sleep efficiency (the total sleep time as a percentage of time in bed) were evaluated. All values are expressed as the mean \pm SD. Statistical comparisons before and after the administration were made using the Wilcoxon signed rank test. A value of $P < 0.05$ was considered statistically significant.

Results

Total OABSS significantly improved from 6.5 ± 2.4 at baseline to 4.3 ± 1.6 at 8 weeks. Nocturia also significantly improved from 3.9 ± 1.2 at baseline to 2.7 ± 1.3 . Total AIS significantly improved from 9.2 ± 2.8 at baseline to 6.8 ± 3.8 at 8 weeks. Among the total 10 patients, 7 patients improved AIS score, 2 patients experienced no change, and one patient was worsened. Total sleep time recorded by Actiwatch was significantly increased from $358.52 (\pm 47.19)$ minutes at baseline to 381.45 ± 41.55 minutes at 8 weeks. Sleep efficiency recorded by Actiwatch was significantly increased from 72.4 ± 7.67 % at baseline to 74.88 ± 7.11 % at 8 weeks.

Interpretation of results

This is the first report to evaluate the quality of sleep after the administration of the antimuscarinic drug, solifenacin. Solifenacin improved the OAB symptoms as the other solifenacin clinical studies. Although polysomnography is believed to be the most reliable device to study sleep quality, it is difficult to use at home or for long period of time. Actiwatch can conveniently record continuously for days and weeks. Our data suggested that solifenacin has a possibility not only of improving the OAB symptom but also the sleep disturbance for a patient suffering from sleep disturbance and nocturia.

Concluding message

This study demonstrated that solifenacin is an effective treatment for OAB. Solifenacin may not only improve storage symptoms but also sleep quality in reducing nocturia.

References

1. Curr Urol Rep (2008) 9(5):362-367
2. SLEEP (2005) 28(6):728-735

Specify source of funding or grant	None
Is this a clinical trial?	Yes
Is this study registered in a public clinical trials registry?	No
What were the subjects in the study?	HUMAN
Was this study approved by an ethics committee?	Yes
Specify Name of Ethics Committee	local ethics committee
Was the Declaration of Helsinki followed?	Yes
Was informed consent obtained from the patients?	Yes