

OBSERVATION OF IMIDAFENACIN'S EFFECTS ON NOCTURIA OF PATIENTS WITH OVERACTIVE BLADDER SYNDROME WHO RECORDED THE LEVEL OF THEIR URINARY SENSATION AND FREQUENCY ON BLADDER DIARIES : A STUDY WITH SENSATION-RELATED BLADDER DIARY(SR-BD)

Hypothesis / aims of study

The basic effects of antimuscarinic drugs are inhibiting bladder muscarinic receptors to restrain smooth muscle contractions caused by acetylcholine and reducing detrusor overactivity. In addition to these effects, it is reported recently of antimuscarinic drugs that C-fiber neuronal activity electrical potential is also reduced so that urinary sensation is lessened¹. Antimuscarinic drugs are mainly used for medical treatment of overactive bladder syndrome, but we can't realize the effect for nocturia². Our study examines the effect of Imidafenacin on nocturia and the urinary sensation triggering urination of OAB patients.

Study design, materials and methods

Patients in consultation for urgency were interviewed and asked to complete an Overactive Bladder symptom score(OABSS). The OABSS was examined and urine analysis was performed, residual urine examined by ultrasonography. When asymptomatic macrohematuria was suggested, a cystoscope examination was done. OAB with nocturia was diagnosed when urgency episodes >1 time per week and OABSS total score ≥ 3 and night time frequency ≥ 1 . Exclusion criteria were polyuria(24hr amount of urine/body weight >40ml/kg), residual urine >50ml, bladder cancer, bladder stones, and active urinary tract infection. All participants recorded a Sensation-Related Bladder Diary (24hr SR-BD) that included voided volumes with graded bladder sensation at each micturition De Wachter et al³. defined. The urinary sensation scale used was graded on a 5 degree scale: from 0 to 4, Grade 0: no bladder sensation, 1: first sensation of bladder filling(voiding can be delayed 60 min), 2: first desire to void(voiding can be delayed for 30 min), 3: strong desire to void(voiding cannot be delayed >15 min), 4: "urgent" desire to void(voiding cannot be delayed for >5 min). The patients with OAB and nocturia were treated with imidafenacin 0.2 mg/day for 4 weeks and the modulation of urinary sensation was evaluated by SR-BD. We divided the patients into two groups, patients with nocturnal polyuria(nocturnal urine volume >0.33x24 hr urine volume) (NP group) and ones without nocturnal polyuria (NNP group).

Results

19 patients were recruited for the NP group and 17 for the NNP group.

The administration of imidafenacin significantly improved OABSS Q2 score in both groups and significantly decreased night time frequency in NP group (3.39 \pm 2.47 vs. 2.00 \pm 1.98) and significantly increased nocturnal urine volume in NP group (763.2 \pm 289.6ml vs. 614.2 \pm 204.0ml). Night time frequency in NNP group was not significantly improved (1.72 vs. 1.5) and nocturnal urine volume was not significantly decreased in NNP group. Night time maximum voided volume was significantly increased in NNP group (200.0 \pm 75.2ml vs. 242.6 \pm 110.7ml) and was not significantly increased in NP group (251.7 \pm 91.9ml vs. 266.11 \pm). Hours of undisturbed sleep (HUS) was significantly prolonged in NP group (141.9 \pm 206.1 \pm 114.7min) and was not significantly prolonged in NNP group (190.3 \pm 85.9 vs. 190.0 \pm 93.6min). Treatment made mean voided volume increase at grade 4 significantly

(179.0 \pm 93.4 vs. 243.6 \pm 102.0 ml). There were statistically significant associations between improvement of nocturia and improvement nocturnal polyuria.

Interpretation of results

Improving nocturnal polyuria leads to improving nocturia significantly, and Imidafenacin prolonged HUS by suppressing the nocturnal urine volume and decreased night time frequency in NP group and decreased urgency at night.

Concluding message

Imidafenacin possibly decreases nocturnal urine volume by suppressing C-fiber afferent.

References

1. De Laet K, De Wachter S, Wyndaele JJ. Systemic oxybutynin decreases afferent activity of the pelvic nerve of the rat: new insights into the working mechanism of antimuscarinics. *Neurourol Urodyn* 2006 ;25:156-8211;61
2. Schneider T, de la Rosette JJ, Michel MC. Nocturia: a non-specific but important symptom of urological disease. *Int J Urol*. 2009; Mar;16(3):249-56.
3. De Wachter S, Wyndaele JJ. Frequency-volume charts: A tool to evaluate bladder sensation. *Neurourol urodyn* 2003;22:638-42

Specify source of funding or grant	None
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?	Yes
Specify Name of Ethics Committee	Nishinara Chuo Ethics Committee
Was the Declaration of Helsinki followed?	Yes

Was informed consent obtained from the patients?

Yes
