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PROPIVERINE / BEHAVIORAL-THERAPY COMBINATION THERAPY IN OVER-ACTIVE-BLADDER PATIENTS, AND TRIAL TO EVALUATE URGENCY

Hypothesis / aims of study

We compared the effect of the low-dose propiverine hydrochloride, an anti-musucarinic agent, and that combined with behavioral therapy in the overactive bladder (OAB) patients except benign prostatic hyperplasia (BPH). We also examined changes of these therapies on frequency and degree of urgency.

Study design, materials and methods

Sixty male patients with OAB (68 to 72 years old), that had no (nocturnal) polyuria were registrated. They did not have BPH (18-28 ml, median; 21ml), and the postvoid residual urines was 20ml or less. They were assigned at random into two groups, 30 patients for propiverine hydrochloride (10mg, morning) alone group (DT), and others for propiverine hydrochloride and behavioral therapy (ex. micturition instruction, water intake management, sleep instruction) combination group (CT). In patients backgrounds, no significant difference between two groups. Bladder diary was recorded for 4 days before and 2 months after treatment. Evaluation parameters were the micturition frequency of daytime and nighttime, average voided volume (AVV), maximum voided volume (MVV), the amount of one day micturitions, the number and degree (0 [nothing] - 9[very much], VAS) of urgency around a day, maximam urinary flow rate (Qmax), QOL index, and the adverse effects. BVI6100 (DIAGNOSTIC ULTRASOUND) was used to measure a bladder volume. Before research, we checked the error rate between real bladder volume and the measured value under 20%.

Results

Changes of the parameters before and after treatments was shown below. (before treatment / after treatment in DT / in CT (mean)]. All except 1) and 9), CT showed better results compared with DT.

Amount of one day micturitions (1650, 2050, 1850 mL)
Amount of nighttime micturitions (240, 260, 190 mL)
MVV (170, 240, 260 mL)
Qmax (10.5, 12.6, 14.1 mL/sec)
Daytime micturition episodes (9.4, 8.2, 7.0)
Nighttime frequency (1.6, 1.2, 0.8)
AVV (151, 220, 240 mL)
QOL index (5.5, 2.6, 2.1)
Urgency frequency (5.8, 3.8, 3.6)
Urgency degree (VAS) (7.5, 4.3, 3.2)

Urinary incontinence disappeared in all the urge incontinence patients of the CT and that effect was superior to DT. Although the very slight dryness in a mouth suited six examples, it was possible to have continued taking medicine. Interpretation of results

CT was more effective than DT in a micturition frequency, uroflowmetry, and urgency, but not in the frequency of the urgency.

Concluding message

Unlike the case of a micturition frequency, it is difficult to quantify the urgency. In order to judge the effects of treatments for urgency, it is essential to evaluate both frequency and degree.

References

trials registry.

FUNDING: none CLINICAL TRIAL REGISTRATION:

This clinical trial has not yet been registered in a public clinical

HUMAN SUBJECTS: This study was approved by the Institutional Review Board of Kobe Medical Center and followed the Declaration of Helsinki Informed consent was obtained from the patients.