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PROPIVERINE TREATMENT IMPROVES QUALITY OF LIFE IN FEMALE PATIENTS WITH WET OVERACTIVE BLADDER

Hypothesis / aims of study

Propiverine is a drug with a dual action as antimuscarinic and calcium antagist. Although propiverine is not available worldwide for use, it has been commonly used for ten years in Japan. Propiverine has been approved for urinary frequency or urgency incontinence caused by neurogenic bladder or unstable bladder by Japanese Ministry of Health, Laver and Welfare. Since the 2001 standardization of terminology by the ICS, the term of unstable bladder defined by idiopathic detrusor overactivity has been abandoned and overactive bladder (OAB) defined by symptoms has been widely used. A variety of anticholinergics have been launched for treatment of OAB and a lot of studies to show the efficacy and impacts of those drugs on symptoms and QOL have been published. However, there is a lack of study to access the efficacy of propiverine on symptoms, especially urgency, and its impact on QOL in patients with OAB. The present study was conducted to study the efficacy of propiverine treatment in symptom and QOL improvement in OAB patients.

Study design, materials and methods

This was a multicenter, 8-week, open, prospective study. Female adult patients with wet OAB (urgency and once or more urgency incontinence episodes/week) were enrolled, and propiverine (20mg/day) was administered for 8 weeks. Patients completed one-day frequency-volume chart, two validated symptoms and QOL questionnaires, King's Health Questionnaire and ICIQ-SF (International Consultation on Incontinence Questionnaire-Short Form), preceding the baseline, week 4 and week 8 visits. Patients were asked to enter the episodes of incontinence and urgency with or without incontinence on the diary, in addition to the frequency-volume. Statistical analysis was made by a stratified Wilcoxon test.

<u>Results</u>

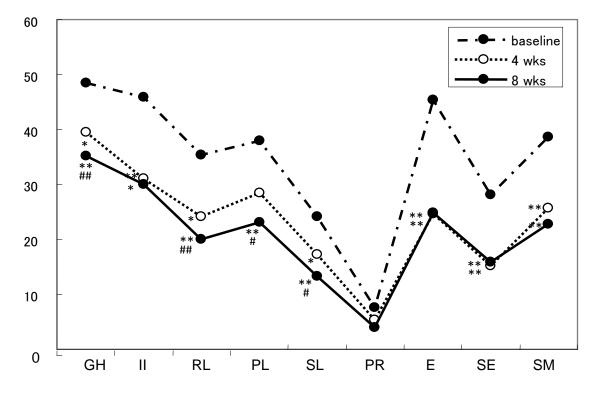
Of enrolled 58 patients, 49 who completed the diary and all the questionnaires were analyzed. Mean age of the patients were 68 years, ranging from 44 to 88. On the assessment according to the diary, mean number of micturition per day significantly decreased (11.7 at baseline, 9.7 at 4 wks, 9.6 at 8 wks, p<0.001), mean episodes of urge incontinence per day significantly decreased (2.5 at baseline, 0.6 at 4 wks, 0.7 at 8 wks, p<0.001) and mean episodes of urgency per day significantly decreased (5.9 at baseline, 3.1 at 4 wks and 2.3 at 8 wks, p<0.001). Mean total score of the ICIQ-SF (ranging 0 to 21 points) was significantly declined; 8.4 at baseline, 4.6 at 4 wks and 3.6 at 8 wks (p<0.01). In the ICIQ-SF, mean individual score for frequency of incontinence, volume of incontinence and QOL significantly improved after treatment; 2.9 at baseline, 1.6 at 4 wks and 1.5 at 8 wks for frequency of incontinence (p<0.001); 3.0 at baseline, 1.8 at 4 wks and 1.7 at 8 wks for volume of incontinence (p<0.001); 4.0 at baseline, 2.4 at 4 wks and 1.9 at 8 wks for QOL (p<0.001). In the assessment of QOL by the King's Health Questionnaire, QOL was significantly improved in all 8 domains except the domain of personal relationships, both at 4 and 8 weeks (Figure).

Interpretation of results

Although propiverine was proved to be effective in improving urinary frequency and urgency incontinence related with detrusor overactivity, there has been a lack of study to reveal efficacy of propiverine treatment on urgency that is a key symptom of OAB and on QOL in patients with OAB. The present study demonstrated that propiverine improves not only urinary frequency and urgency incontinence but also urgency. In addition, propiverin treatment was revealed to improve QOL in female patients suffering from severe OAB with urgency incontinence.

Concluding message

Propiverine improves symptoms and QOL in female patients with wet OAB, as well as a variety of newly developed anticholinergics.



GH: General Health, II: Incontinence Impact, RL: Role Limitations, PL:Physical Limitations, SL: Social Limitations, PR: Personal Relationships, E: Emotion, SE: Sleep/Energy, SM: Severity Measure

Mean \pm SD, * p<0.05 vs baseline, ** p<0.01 vs baseline, # p<0.05 vs 4 wks, ## p<0.01 vs 4wk (Wilcoxon tset)

Figure: Changes of QOL scores of the King's Health Questionnaire following propiverine treatment

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HUMAN SUBJECTS: This study was approved by the Nagoya University ethics committee and followed the Declaration of Helsinki Informed consent was obtained from the patients.