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Gotoh M[1], Yokoyama O[2], Matsukawa Y[1], Nishizawa O[3]
1. *Urology Department, Nagoya University Graduate School of Medicine,* ***2.*** *Urology Department, Fukui University Graduate School of Medicine,* ***3.*** *Urology Department, Sinshu University Graduate School of Medicine*

RESPONSIVENESS OF OVERACTIVE BLADDER SYMPTOM SCORE (OABSS): VERIFICATION BASED ON DATA IN A DOUBLE-BLINDED, RANDOMIZED PLACEBO-CONTROLLED STUDY OF PROPIVERINE HYDROCHLORIDE IN JAPANESE PATIENTS

Hypothesis / aims of study

Overactive bladder (OAB) is a symptom syndrome characterized by urgency with or without urgency incontinence, and usually with frequency and nocturia. These symptoms need to be assessed respectively for treatment evaluation. A bladder diary is a useful tool to assess precise frequency of these symptoms; however, keeping a diary can prove to be a burden for patients. Therefore, a simple questionnaire such as the International Prostate Symptom Score (IPSS) is utilized for comprehensive and objective assessment of symptom severity and treatment efficacy in patients with OAB. The OABSS is a self-administered questionnaire to assess OAB symptoms based on the score of answers to four questions on OAB symptoms: daytime frequency, nighttime frequency, urgency, and urgency incontinence (Table 1). This questionnaire, originally developed by Homma et al, was psychometrically validated with Japanese patients with OAB [1], and is currently used in several regions, including Japan and Taiwan. Nonetheless, responsiveness of the questionnaire has remained an issue to be addressed.

The purpose of this current analysis was to examine responsiveness of the OABSS by using data collected in a double-blinded, randomized placebo-controlled study of propiverine hydrochloride in Japanese patients with overactive bladder.

Study design, materials and methods

OAB patients with eight or more micturitions per 24 hrs and one or more urgency incontinence or urgency episodes per 24 hours were included in the study. After a 2-week placebo administration period, the participants were randomly allocated to propiverine hydrochloride or placebo group, and either drug was administered for 12 weeks. For responsiveness assessment of the OABSS and the bladder diary, effect size (ES: mean of change/standard deviation of pre-administration) and standardized response mean (SRM: mean of change/ standard deviation of change) were calculated. The correlations between treatment related changes in OAB symptoms obtained from the bladder diary and the OABSS items were assessed by Spearman's rank correlation coefficient of 0.1 as low, of 0.3 as moderate and 0.5 as high. An ES was interpreted with 0.2 as small, 0.5 as moderate, and 0.8 as large. Both criteria were applied in the absolute value. The SAS software ver. 9.1 was used for statistical computations.

Results

A total of 554 patients were enrolled. Of these, 284 participants (male:68, female:216) received propiverine hydrochloride (mean age: 56.6 yrs) and 270 participants (male:63, female:207) received placebo (mean age: 58.7 yrs). ESs of the bladder diary variables were -0.858 for urinary frequency, -0.784 for daytime frequency, -0.290 for nighttime frequency, -0.973 for urgency, and -0.642 for urgency incontinence. ESs of the OABSS items were -1.425 for the total score, -0.971 for Q1, -0.369 for Q2, -1.485 for Q3, and -0.936 for Q4. For assessment of the correlations between changes in OABSS items and those in their related variables of the bladder diary, changes in daytime frequency, nighttime frequency, urgency, and urgency incontinence in the bladder diary were moderately to highly correlated with their related OABSS items (0.468 for Q1, 0.422 for Q2, 0.373 for Q3, and 0.507 for Q4, respectively).

Interpretation of results

Compared to the placebo group, the propiverine hydrochloride group showed significantly larger reduction in the number of daytime micturition, urgency episodes, and urgency incontinence episodes in the bladder dairy, as well as in the OABSS. Regarding nighttime frequency, difference in change of the number of nighttime micturition was not statistically significant between the two groups. One of the reasons for this result could come from the complication that nighttime micturition can be affected by multiple factors other than OAB symptoms.

Similar to the bladder diary, the OABSS showed high responsiveness not only in the items of daytime frequency, urgency, and urgency incontinence, but also in the total score. In addition, the changes of the OABSS items were moderately to highly correlated with their related bladder diary variables. The results of this study suggest that the OABSS can be an alternative to the bladder diary for assessment of symptoms severity and treatment efficacy in OAB. On the other hand, the bladder diary would be beneficial to assess other factors affecting nighttime frequency besides OAB.

Concluding message

This study demonstrated that the reliable and validated OABSS was highly responsive to treatment-related changes of OAB symptoms. The OABSS can be a useful tool to assess treatment efficacy in OAB symptoms.

Table 1. Overactive Bladder Symptom Score (OABSS)

Question	Repose	Score
Q1 How many times do you typically urinate from walking in the morning until sleeping at night?	≤7	0
	8-14	1
	≥15	2
Q2 How many times do you typically wake up to urinate from sleeping at night until waking in the morning?	0	0
	1	1
	2	2
	≥3	3
Q3 How often do you have a sudden desire to urinate, which is difficult to defer?	None	0
	＜once/week	1
	≥once/week	2
	About once/week	3
	2-4 times/day	4
	≥5 times/day	5
Q4 How often do you leak urine because you cannot defer the sudden to urinate?	None	0
	＜once/week	1
	≥once/week	2
	About once/week	3
	2-4 times/day	4
	≥5 times/day	5

*Patients were instructed to circle the score that best applied to their urinary condition during the past week; the overall score was the sum of the four scores.

Table 2. Changes from the baseline in efficacy measures and responsiveness of OABSS and Bladder diary

		Treatment	Change from baseline Mean±SD	P-value between treatments (t-test)	ES[a]	SRM[a]	Correlation coefficient[ab]
Bladder diary	Urinary frequency (micturition/24h)	Propiverine	-1.86±1.86	0.001	-0.858	-0.996	–
		Placebo	-1.36±1.67				
	Day time frequency (micturition/day time)	Propiverine	-1.60±1.77	<0.001	-0.784	-0.902	0.468
		Placebo	-1.10±1.53				
	Night time frequency (micturition/night time)	Propiverine	-0.29±0.61	0.471	-0.290	-0.477	0.422
		Placebo	-0.25±0.69				
	Urgency (episode/24h)	Propiverine	-2.84±2.52	<0.001	-0.973	-1.125	0.373
		Placebo	-1.99±2.59				
	Urgency incontinence (episode/24h)	Propiverine	-1.18±1.64	<0.001	-0.642	-0.723	0.507
		Placebo	-0.68±1.04				
	Voided volume (mL/void)	Propiverine	25.48±35.62	<0.001	–	–	–
		Placebo	8.18±36.33				
OABSS	total score	Propiverine	-3.7±2.7	<0.001	-1.425	-1.365	–
		Placebo	-2.4±2.8				
	Q1	Propiverine	-0.3±0.5	0.003	-0.971	-0.555	–
		Placebo	-0.2±0.4				
	Q2	Propiverine	-0.3±0.7	0.122	-0.369	-0.454	–
		Placebo	-0.2±0.7				
	Q3	Propiverine	-1.7±1.5	<0.001	-1.485	-1.091	–
		Placebo	-1.0±1.5				
	Q4	Propiverine	-1.5±1.4	<0.001	-0.936	-1.053	–
		Placebo	-1.0±1.4				

[a] Only the patients who received propiverine were included in the calculation.

[b] Correlation coefficients were calculated to assess the correlation of responsiveness in each item between bladder diary and OABSS.

References

1. Urology 68: 318-323,2006

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)?	**Yes**
What were the subjects in the study?	**HUMAN**
Was this study approved by an ethics committee?	**Yes**
Specify Name of Ethics Committee	**Nagoya University Ethics Committee**
Was the Declaration of Helsinki followed?	**Yes**
Was informed consent obtained from the patients?	**Yes**