

EFFICACY ASSESSMENT IN OVERACTIVE BLADDER - BLADDER DIARY OR OVERACTIVE BLADDER SYMPTOM SCORE (OABSS)

Hypothesis / aims of study

The efficacy of treatment for overactive bladder (OAB) is usually assessed by a bladder diary. However, such diary keeping is a burden for patients, and the analysis is not simple for physicians. The *Overactive Bladder Symptom Score (OABSS)*¹⁾ is a symptom assessment tool with four questions on OAB symptoms. We compared the bladder diary with the OABSS as a tool for assessment of the efficacy of OAB treatment.

Study design, materials and methods

Consecutive treatment-naïve OAB patients visiting the authors' hospitals were enrolled in the study. Patients with obvious bladder pathologies and abnormal metabolic conditions, including polyuria, were excluded.

The patients maintained a bladder diary for 3 days and responded to the OABSS questionnaire. The OABSS is designed to quantify OAB symptoms into a single score ranging from 0 to 15 (Table 1). It consists of four questions on OAB symptoms: daytime frequency (scored from 0 to 2), night-time frequency (0 to 3), urgency (0 to 5), and urgency incontinence (0 to 5). The scoring for the questions was designed so as to place more weight on urgency and urgency incontinence than on the frequencies. The reliability and validity of the questionnaire have been confirmed previously¹⁾. The patients received an anti-muscarinic agent, solifenacin at the dose of 5mg or 10mg per day. At week 12, they visited again with a bladder diary maintained for the previous 3 days and filled the OABSS again at the clinic.

The therapeutic effects were evaluated by the changes in the bladder diary variables and the OABSS. The diary variables analyzed included number of voidings, urgency and urgency incontinence, and the mean and maximum voided volumes during the daytime. Wilcoxon's signed-rank test was used for analysis to compare the pre- and post-values. The sensitivity of the symptomatic improvement was evaluated by the effect size of the change ((mean of change)/(standard deviation of change)). $P < 0.05$ was considered to denote significance

Results

A total of 51 patients were included in the analysis (mean age: 70.6 years). Table 2 summarizes the pre-and post-treatment values of the diary variables and the OABSS, as well as the differences. Significant improvement was noted for all the diary variables and the OABSS. A statistically more significant change was found for episodes of urgency and urgency incontinence than for the voiding frequency. The effect size was the largest for the OABSS (total score for the 4 items: 2.04), followed by the OABSS urgency score (1.92), and urgency incontinence episodes according to the bladder diary or the OABSS urgency incontinence score (1.15). The mean voided volume increased by 35 ml post-treatment. The total amount of urine voided during the daytime and the 24-hour urine volume remained almost unchanged (945 to 956 ml and 1491 to 1426 ml, respectively)

Interpretation of results

Symptomatic improvement with solifenacin treatment was consistently reflected both by the changes in the bladder diary variables and the individual and total OABSS scores. Among the efficacy indices, the total OABSS score was most the most sensitive.

The higher sensitivity of OABSS could be explained by 2 reasons. First, OABSS combines all OAB symptoms into a single score. Since OAB is a symptom complex, evaluation of all the symptoms rather than a single or a limited number of symptom(s) would show a better performance in the assessment of symptoms and their change. Small and unrecognizable improvements in individual symptoms may be converted into a larger and more recognizable change when they are collectively evaluated. Second, OABSS places more weight on the scores for urgency and urgency incontinence (maximum score: 5) than on voiding frequency (maximum score: 2 or 3). For OAB patients, the most bothersome symptom is urgency, or perhaps urgency incontinence when that symptom is present. In addition, OABSS has the advantage of its simplicity and wider applicability. However, the bladder diary provides prospective and more accurate assessment of symptoms along with a precise estimation of the voided volume. More detailed analysis, including the intensity of the urgency at each void, amount of leakage or the urine output, is only feasible with the maintenance of a diary record. Only a bladder diary can confirm that the reduction in voiding frequency is due to an increase in single voided volume and not a lowering of the one-day urinary output.

Concluding message

OABSS is a sensitive instrument to monitor the efficacy of therapy for OAB. Owing to its sensitivity and simplicity, OABSS would be a more convenient tool to use in daily practice, although a bladder diary would be indispensable for detailed analysis of the treatment efficacy.

Table1. 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 desire 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. Assessment of the efficacy based on the bladder diary variables and OABSS

Assessment item	Pre	Post	P	Change	Effect size
Bladder diary (episode per day)					
Daytime frequency	9.0*	7.5	<0.05	1.5 (2.9)**	0.78
Night-time frequency	2.3	1.3	<0.01	1.0 (1.2)	0.52
Urgency	2.6	1.3	<0.01	2.3 (2.0)	0.83
Urgency incontinence	1.3	0.1	<0.01	1.3 (2.0)	1.15
Max voided volume (ml)	212	254	ns	42 (104)	0.40
Average voided volume (ml)	126	161	<0.01	35 (45)	0.78
OABSS (points)					
Daytime frequency	1.2	0.7	<0.05	0.5 (0.8)	0.63
Night-time frequency	2.1	1.6	<0.05	0.5 (0.8)	0.63
Urgency	3.4	1.1	<0.01	2.3 (1.2)	1.92
Urgency incontinence	2.3	0.7	<0.01	1.6 (1.4)	1.15
Total score	9.1	4.1	<0.01	4.9 (2.4)	2.04

*mean, **mean (standard deviation)

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
What were the subjects in the study?	HUMAN
Was this study approved by an ethics committee?	Yes
Specify Name of Ethics Committee	Japan Red Cross Medical Center Ethics Committee
Was the Declaration of Helsinki followed?	Yes
Was informed consent obtained from the patients?	Yes