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IMPACT OF SYMPTOM IMPROVEMENT ON PATIENTS' BOTHER AND QUALITY OF LIFE IN FEMALE PATIENTS WITH OVERACTIVE BLADDER TREATED BY SOLIFENACIN

Hypothesis / aims of study

To analyze the relationship of symptom improvement with patients' bother and quality of life (QOL), a prospective study was conducted in female patients with overactive bladder (OAB), who were treated by Solifenacin.

Study design, materials and methods

We conducted this study as a prospective, multicenter, open study by a centralized registration between June 2010 and April 2012 in Japan. Eligible patients were treatment naive female patients with OAB, with an urgency episode at least once a week. Symptoms were quantitatively assessed by the OABSS (OAB symptom score), which is a psychometrically validated questionnaire designed to comprehensively quantify symptom severity for four symptoms of daytime frequency, nighttime frequency, urgency and urgency incontinence, based on the total score ranging from 0 to 15 points. Symptom bother and QOL were assessed by the OAB-q (OAB-questionnaire), a validated disease-specific questionnaire. The patients were treated with Solifenacin 5 or 10 mg once daily for 12 weeks, and changes of symptom severity, bother and QOL were assessed before and 12 weeks after the treatment. Since minimal clinically important change in the OAB-q is reported as 10 points for each domain [1], we defined improvement of bother and each QOL domain as a change of more than 10 points. The relationship of improvement of bother and QOL with symptom severity at baseline and a reduction of symptom severity (a decrease ≥ 1 point in each symptom score) after treatment was analyzed by a multivariate analysis.

Results

Data from 523 patients (mean age: 66 years old) were analyzed. 1) Solifenacin significantly improved OABSS total score and also all sub-scores for the four symptoms (Fig.1). 2) Solifenacin also significantly improved the four QOL subscales, total QOL and symptom bother scores in the OAB-q (Fig.2). 3) Severity in nighttime frequency at baseline positively affected the improvement in the QOL subscale of sleep, and severity of daytime frequency at baseline positively affected the improvement of coping and social interaction (Table 1). 4) Improvement of severity in various symptoms positively affected the improvement of bother and the QOL subscales as shown in Table 1

Fig.1 Effect of Solifenacin on OABSS

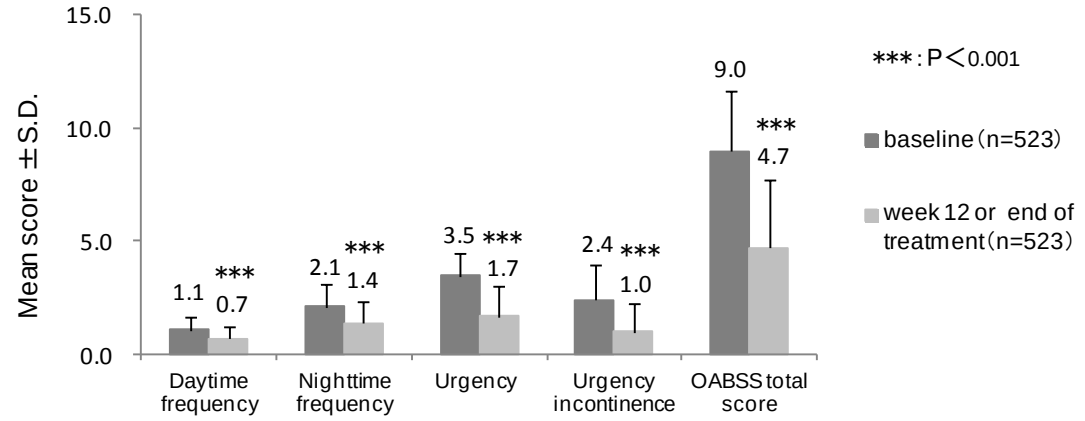

Fig. 2 Effect of Solifenacin on OAB-q subscale score

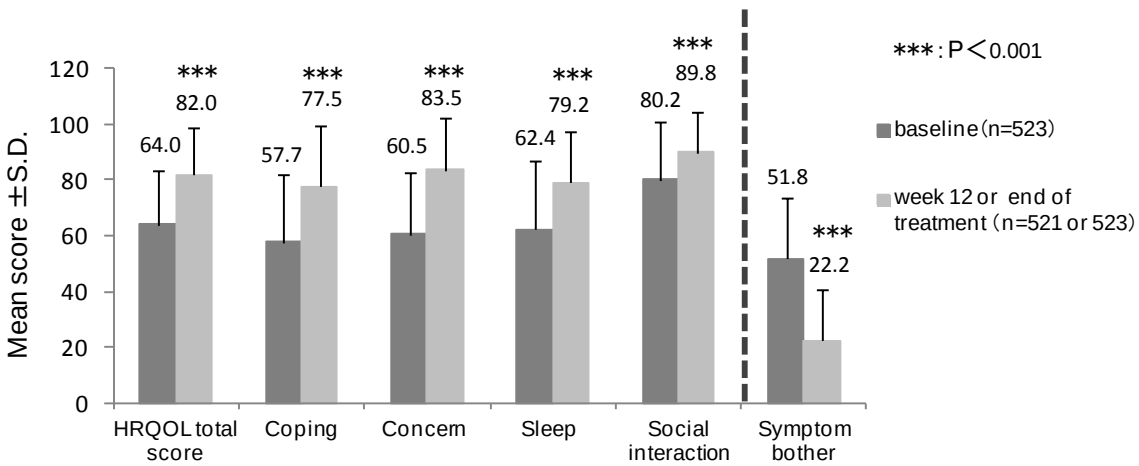

Table 1 Association between importance of change in OAB-q and age, history of OAB, baseline OABSS and change in OABSS after treatment with Solifenacin

Covariate of Interest	OAB-q subscale	Symptom Bother	Coping	Concern	Sleep	Social Interaction	HRQOL total score
		Odds ratio（95% CI）					
Age（years）	50≦ ＜60	0.658 (0.152-2.857)	0.565 (0.218-1.463)	2.158 (0.764-6.096)	0.976 (0.396-2.401)	0.670 (0.287-1.564)	1.099 (0.424-2.849)
（Reference: <50 ）	60≦ ＜70	0.774 (0.206-2.901)	0.737 (0.308-1.765)	1.765 (0.732-4.254)	0.695 (0.308-1.566)	0.830 (0.392-1.760)	1.160 (0.495-2.716)
	70≦ ＜80	0.321 (0.091-1.131)	0.434 (0.184-1.024)	0.805 (0.349-1.855)	0.573 (0.256-1.283)	0.785 (0.373-1.653)	0.574 (0.251-1.312)
	80≦	0.190 (0.046-0.793)*	0.356 (0.131-0.965)*	0.884 (0.324-2.408)	0.825 (0.309-2.199)	1.187 (0.485-2.903)	0.647 (0.241-1.735)
History of OAB	3 months≦ ＜1 year	0.815 (0.363-1.830)	1.235 (0.688-2.216)	1.108 (0.604-2.032)	1.484 (0.838-2.628)	0.893 (0.519-1.539)	0.896 (0.495-1.623)
（Reference:<3 months）	1 year≦ ＜3 years	0.762 (0.341-1.703)	0.744 (0.425-1.301)	1.281 (0.700-2.343)	1.366 (0.774-2.412)	0.867 (0.508-1.480)	0.853 (0.476-1.531)
	3 years≦	0.531 (0.216-1.309)	0.651 (0.330-1.285)	0.699 (0.344-1.423)	1.140 (0.565-2.300)	0.630 (0.317-1.253)	0.591 (0.292-1.194)
OABSS:baseline	Daytime frequency	1.772 (0.926-3.391)	2.166 (1.312-3.574)**	1.265 (0.757-2.116)	1.325 (0.808-2.174)	2.006 (1.228-3.275)**	1.290 (0.782-2.129)
	Nighttime frequency	0.955 (0.641-1.424)	0.916 (0.681-1.234)	0.850 (0.621-1.164)	1.894 (1.395-2.572)**	0.860 (0.647-1.145)	0.887 (0.657-1.198)
	Urgency	1.021 (0.702-1.485)	0.891 (0.666-1.193)	1.039 (0.764-1.412)	1.002 (0.744-1.350)	0.929 (0.697-1.239)	0.981 (0.728-1.322)
	Urgency incontinence	0.987 (0.743-1.312)	0.951 (0.755-1.196)	0.954 (0.752-1.212)	0.888 (0.701-1.126)	0.923 (0.730-1.168)	0.935 (0.740-1.181)
OABSS：changes after treatment	Daytime frequency	1.064 (0.560-2.020)	1.028 (0.649-1.629)	1.337 (0.815-2.193)	1.014 (0.639-1.608)	1.122 (0.728-1.727)	1.337 (0.831-2.146)
	Nighttime frequency	1.704 (1.046-2.770)*	1.295 (0.928-1.808)	1.529 (1.067-2.188)*	1.592 (1.127-2.247)**	1.323 (0.964-1.815)	1.675 (1.182-2.375)**
	Urgency	1.377 (1.013-1.876)*	1.196 (0.958-1.497)	1.267 (1.002-1.605)*	1.120 (0.895-1.401)	1.126 (0.904-1.403)	1.253 (0.998-1.572)
	Urgency incontinence	1.592 (1.166-2.179)**	1.253 (0.988-1.590)	1.135 (0.887-1.453)	1.406 (1.094-1.805)**	1.155 (0.904-1.475)	1.344 (1.052-1.718)*

Change of 10 points or more for each OAB-q subscale after treatment with Solifenacin was defined as important difference.

* : P＜0.05

**: P＜0.01

Interpretation of results

It was suggested that improvement of nighttime frequency, urgency, urgency incontinence by Solifenacin are significant factors for improvement of symptom bother, and improvement of nighttime frequency and urgency incontinence for total QOL.

Concluding message

Solifenacin improved patients' bother and QOL. Symptom severity before treatment and improvement of symptom severity may diversely affect improvement in bother and QOL domains after treatment.

Reference:

References

1. Karin S, et al. Journal of Urology, 2006;176: 627

Disclosures

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