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PATIENT-REPORTED OUTCOME OF SOLIFENACIN TREATMENT IN WOMEN WITH OVERACTIVE BLADDER - MULTICENTER, OPEN-LABEL STUDY

Hypothesis / aims of study

Urgency and urgency incontinence represent two most bothersome symptoms of overactive bladder (OAB) both causing a significant decrease in quality of life (QoL) of affected women. The mainstay of OAB treatment are antimuscarinics and with solifenacin being one among them. The aim of this patient-reported outcome study was to estimate the real efficacy and tolerability of solifenacin in treatment of OAB patients with focus on urgency and Qol.

Study design, materials and methods

100 consecutive OAB women who experienced at least one urgency episode (UE) daily were included in this independent, prospective, multicentric, open-label study. All patients received solifenacin 5 mg once daily for 3 months and filled out the 3-day voiding diary, symptoms/adverse events screening tool and validated questionnaires (UDI – Urogenital Distress Inventory, IIQ – Incontinence Impact Questionnaire). Urgency was assessed by a simple 4-step Urgency Perception Score (UPS) where steps 3 and 4 represented urgency and urgency incontinence, respectively. Frequency of urgency episodes (UE) was expressed by 7 categories, where 0 meant no UEs, category 1: 1-2 UEs a month, category 2 – one UE per week, category 3 – 2-3 UEs per week, category 4 – one UE daily, category 5 – 2 UEs daily, category 6 – 3-4 UEs daily and category 7 meant 5 or more UEs a day. The UE botherness was assessed on a VAS (Visual Analog Scale) score where number 0 meant no bother and number 100 represented unbearable bother. After 1 month and 3 months of treatment all patients filled out all above listed questionnaires, additionally, patients assessed also the success and tolerability of solifenacin treatment.

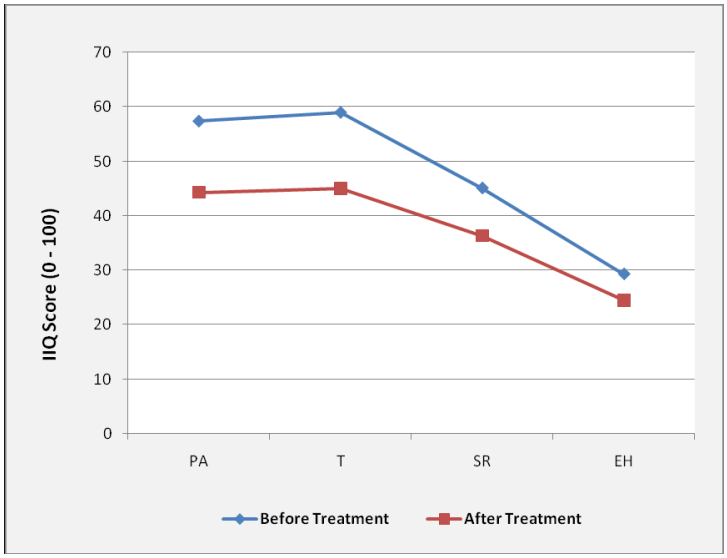
Results

Between June 2010 and December 2010 we recruited 100 women with OAB. The average age of patients was 54.4 years (from 25 to 78 years) and their average BMI amounted to 27.7 kg/m^2. They experienced OAB problems for 84 months on the average. The estimated average bother of urgency on a VAS scale was 72.9. The 3-month treatment was completed by 91 women. The frequency, intensity and botherness of urgency episodes significantly decreased at 4 weeks and after 3 months ($p< 0.000$, Table 1). All OAB symptoms asessed at 3 months have significantly improved ($p< 0.05$) when compared to the first month of treatment, bedwetting being the only exception ($p= 0.86$). At the start of the study 66 out of 91 patients (72.5 %) complained on UUI, this number decreased after 1 month to 60 (65.9 %) and to 62.6 % after 3 months (57 patients). Decrease in urgency led to a significant improvement in QoL ($r = 0.45$, $p= 0.000$). The improvement in QoL after 3 months of treatment is presented in Figure 1. The most common adverse event was dry mouth which occurred in 35.2 % women at 4 weeks, this prevalence decreased to 27.7% at 3 months. The overall success rate of treatment based on VAS scale was 74.2%.

Table 1: Improvement in OAB symptoms after solifenacin tratment with focus on urgency

URGENCY	**START** mean (min-max; S.D.)	**1 MONTH** mean (min-max; S.D.)	**3 MONTHS** mean (min-max; S.D.)
INTENSITY (from 1 to 4) mean (min-max; S.D.)	3.2 (2-4; 0.8)	2.7 (1-4; 0.9)	2.4 (1-4; 0.9)
3 and 4= urgency and urgency incontinence (%)	79.8%	51.0%	41.8%
FREQUENCY (from 1 to 7) mean (min-max; S.D.)	5.9 (2-7; 1.2)	5.2 (0-7; 1.6)	4.6 (0-7; 2.0)
urgency at least once a day	100.0%	87.9%	75.8%
BOTHERNESS (from 0 to 100) mean (min-max; S.D.)	72.9 (6-100; 17.4)	57.4 (0-95; 23.3)	47.3 (0-95; 24.6)
Urinary Frequency mean (min-max; S.D.)	7.7 (3-24; 4.1)	6.1 (3-15; 2.6)	5.6 (2.7-11.7; 2.3)
Nocturia mean (min-max; S.D.)	2.6 (0-10.3;1.5)	1.9 (0-10, 1.4)	1.8 (0-8; 1.4)
Urgency Incontinence (No. of episodes)	2.6 (0-24; 3.7)	1.6 (0-12; 1.6)	1.4 (0-4,7; 1.4)
Incontinence at Night (bedwetting) (No of episodes)	0.8 (0-4; 1.0)	0.5 (0-4; 0.9)	0.4 (0-2.7; 0.8)
Pad Use (No.)	2.1 (0-12.7; 2.5)	1.5 (0-6; 1.5)	1.5 (0-6; 1.6)

Figure 1: Improvement in QoL after solifenacin treatment of OAB shown as lower IIQ scores of all four IIQ domains (PA – Physical Activity, T – Travel, SR – Social Relations, EH – Emotional Health).



Interpretation of results

We observed that after introduction of solifenacin the urgency intensity, frequency and botherness significantly improved. The UEs after three months were significantly improved not only when compared to the start of treatment but also when compared to the end of first month of treatment. The improvement in OAB symptoms had led to a better QoL, and the greatest improvement in QoL was observed in physical activity and travel domain, followed by the improvement in social activity and emotional health domain. Patients estimated the treatment success at 73.8% what was really high and this seemed to be in a direct correlation with the improvement of OAB symptoms (UDI Irritative Score). The prevalence of dry mouth increased during the first month of treatment when roughly one third of patients (35.2%) complained about this problem. This prevalence then decreased at the end of the 3-month treatment interval when only every forth patient (27.7%) reported dry mouth. Despite of high prevalence of dry mouth this AE was the main reason for discontinuation of treatment
in one patient only.

Concluding message

Solifenacin treatment of women with OAB was effective and well tolerated in our study. All OAB symptoms significantly improved after 3 months what led to a better QoL. Both, objective and objective improvement of symptoms were observed. The only significant adverse event was dry mouth.

Disclosures

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