

## TOLTERODINE IMMEDIATE RELEASE IMPROVES SEXUAL FUNCTION IN WOMEN WITH OVERACTIVE BLADDER

### Hypothesis / aims of study

Quality of life studies indicate that OAB has a greater negative impact on everyday life than other serious conditions such as diabetes. The detrimental effect of OAB on female sexual health is more prominent than urinary incontinence. We know that tolterodine Immediate Release (IR) has a beneficial effect of urinary symptoms in OAB. The goal of this study was to evaluate impact of tolterodine IR on sexual function in patients with OAB.

### Study design, materials and methods

This was a before after, 3 months, longitudinally designed study. A total of 30 sexually active women with OAB from 20 to 52 years were included. All outpatients had self reported OAB. Initial screening included a comprehensive history and lower urinary tract assessment via International Consultation on Incontinence Questionnaire- Short Form (ICS-SF), a physical and urogynecological examination. Diagnosis of OAB was based on history according to ICS definition and confirmed when necessary with an extensive urodynamic study. Women without sexual activity, with apparent neurologic disease, those with contraindications of tolterodine use or previous tolterodine consumption were not included in this study. All patients filled out International Consultation on Incontinence Questionnaire-Short Form (ICIQ-SF) and Arizona Sexual Experience Scale (ASEX) before treatment with 2 mg tolterodine IR bid and monthly thereafter to completion of 3 months follow up. Due to multiple correlated measurement of the main study outcome, longitudinal data analysis methods were considered suitable for analysis and SAS 9.1 statistical software was used to conduct it. Expected outcomes were: decrease in ICIQ-SF score and decrease in ASEX total score. All ASEX items score were expected to decrease individually.

### Results

A total of 30 sexually active participants aged 20 to 52 years participated in this study. Twenty eight women were followed up monthly for 3 months. Two patients did not come back for any follow up. Mean age of participants was 36.3  $\pm$  7 years (mean  $\pm$  SD).

In the beginning of study, mean score of ICIQ-SF was 14.07  $\pm$  5.25 (mean  $\pm$  SD). Mean of this score decreased to 8.57  $\pm$  4.52 (mean  $\pm$  SD), 7.21  $\pm$  4.20 (mean  $\pm$  SD) and 6.64  $\pm$  4.03 (mean  $\pm$  SD) in the first, second and third follow up, respectively. As is shown in table 1 mean of scores for sexual desire, arousal, vaginal lubrication, orgasm and orgasm satisfaction decreased significantly ( $p < 0.01$ ) with each follow up. Degree of ASEX score improvement was not dependent of baseline ICIQ score (Figure 1). Twenty one (79%) women had sexual dysfunction before intervention. After 1 month treatment with tolterodine IR 12 (40%) patients and after 2 and 3 months 7 (23.3%) and 4 (13.3%) patients were suffering from sexual dysfunction, respectively. When compare with baseline significantly more patients were free from sexual dysfunction, according to ASEX, after 3 month treatment with tolterodine.

	Baseline		First follow up		Second follow up		Third follow up	
	Estimate	Standard error	Estimate	Standard error	Estimate	Standard error	Estimate	Standard error
Desire	4.1000	0.1685	-0.6071	0.2203	-1.1779	0.1911	-1.4479	0.2155
Arousal	4.0000	0.2712	-0.9503	0.2736	-1.5276	0.2746	-1.7789	0.2933
Vaginal lubrication	3.4333	0.2333	-0.6228	0.2305	-1.1342	0.2496	-1.2103	0.2768
Orgasm	3.7667	0.2612	-0.8833	0.2410	-1.0983	0.2419	-1.5040	0.2612
Orgasm satisfaction	3.9333	0.2667	-0.7706	0.2793	-1.1949	0.2996	-1.7559	0.3253

Table 1- Individual

ual ASEX items score at baseline and its changes with triple follow up sessions. All the changes are statistically significant.

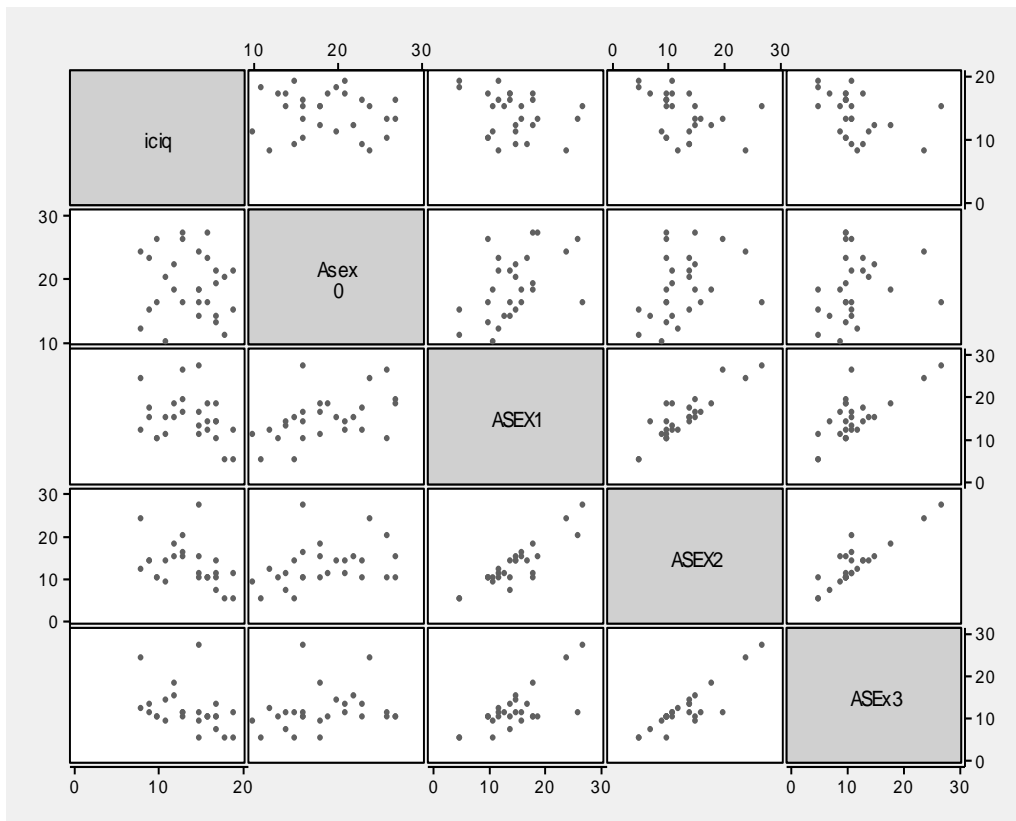


Figure 1-ASEX score in follow up sessions in relation to baseline ICIQ score.  
(ASEX 0, 1, 2 and 3 means ASEX total score at baseline, first, second and third follow up sessions respectively.)

#### Interpretation of results

As was expected, tolterodine IR significantly improves symptoms of OAB. In our study ICIQ-SF mean score was significantly at the end of each month of study. This result is in concordance with previous study. The goal of this study was to evaluate effects of tolterodine IR on female sexual dysfunction (FSD) in women with OAB and we found significant improvements in total score and each item score of ASEX

#### Concluding message

Tolterodine IR significantly improves sexual function of women with OAB. Sexual function improvement is independent of baseline urinary problem severity.

<b><i>Specify source of funding or grant</i></b>	<b>no grant</b>
<b><i>Is this a clinical trial?</i></b>	<b>Yes</b>
<b><i>Is this study registered in a public clinical trials registry?</i></b>	<b>Yes</b>
<b><i>Specify Name of Public Registry, Registration Number</i></b>	<b>tabriz university of medical sciences 85106</b>
<b><i>What were the subjects in the study?</i></b>	<b>HUMAN</b>
<b><i>Was this study approved by an ethics committee?</i></b>	<b>Yes</b>
<b><i>Specify Name of Ethics Committee</i></b>	<b>ethics committee of tabriz university of medical sciences /code 858</b>
<b><i>Was the Declaration of Helsinki followed?</i></b>	<b>Yes</b>
<b><i>Was informed consent obtained from the patients?</i></b>	<b>Yes</b>