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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 on 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 ± 7 years (mean ± SD).

In the beginning of study, mean score of ICIQ-SF was 14.07 ± 5.25 (mean ± SD). Mean of this score decreased to 8.57 ± 4.52 (mean ± SD), 7.21 ± 4.20 (mean ± SD) and 6.64 ± 4.03 (mean ± 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.

### Table 1- Individ

<table>
<thead>
<tr>
<th></th>
<th>Baseline</th>
<th>First follow up</th>
<th>Second follow up</th>
<th>Third follow up</th>
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<tbody>
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<td>Estimate</td>
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Table 1- Individual 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.

Specify source of funding or grant
no grant

Is this a clinical trial?
Yes

Is this study registered in a public clinical trials registry?
Yes

Specify Name of Public Registry, Registration Number
Tabriz university of medical sciences 85106

What were the subjects in the study?
HUMAN

Was this study approved by an ethics committee?
Yes

Specify Name of Ethics Committee
edetics committee of Tabriz university of medical sciences 858

Was the Declaration of Helsinki followed?
Yes

Was informed consent obtained from the patients?
Yes