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The effect of overactive bladder treatment with anticholinergics on female sexual function in women: a prospective observational study

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Abstract

Purpose The aim of the study was to determine the effect of anticholinergics used for overactive bladder treatment on the sexual function of women.

Methods Between January 2016 and August 2018, over 18 years old, 216 sexual active women with OAB and 165 healthy women as control group were prospectively enrolled in the study. Five different anticholinergics were used for the treatment. Female Sexual Function Index (FSFI), eight-item overactive bladder awareness tool (OAB-V8), and Beck Depression Inventory form were completed before and after 3 months. Baseline and post-treatment scores were compared with a control group of age-matched healthy women.

Results Patients with OAB reported at baseline significantly worse sexual function in all FSFI domains compared to healthy control group (21.47 ± 3.22 vs. 26.79 ± 5.56, $p < 0.01$). Three months after treatment, over 85% of participants reported clinically relevant improvements in sexual function, with statistically significant changes in mean FSFI scores.

Conclusions Treatment of OAB with anticholinergics can improve sexual function of sexual active women with OAB. Patients may be informed about this potential benefit of anticholinergic treatment, to improve their sexual function.

Keywords Anticholinergic · Female sexual functions · Overactive bladder

Introduction

Overactive bladder (OAB) is a condition defined by the International Continence Society as the presence of "Urinary urgency, usually accompanied by frequency and nocturia, with or without urgency urinary incontinence (UUI), in the absence of urinary tract infection (UTI) or other obvious pathology [1]." Worldwide prevalence is expected to increase from 10.7% in 2008 to 10.9% by 2018. The prevalence of OAB worldwide is estimated to be greater in women than in men in 2008 (11.6% vs. 9.7%, respectively), 2013 (11.7% vs. 9.8%), and 2018 (11.9% vs. 10.0%) [2]. This condition can impair health-related quality of life such as work productivity, sexuality, and emotional well-being in men and women [3, 4].

Sexual wellbeing is an important aspect of women's health. Female sexual function is multifactorial and can be impaired by internal and external somatic or psychological factors. Also, female sexual dysfunction (FSD) is a common problem among the general population [5] and prevalence of FSD is estimated to be as high as 50% [6]. But it is under-reported, especially in Middle Eastern countries. Many studies have shown that OAB has a negative effect on female sexual function [7–9]. In the EpiLUTS study, women with OAB reported worse sexual function [10]. Similarly, individual with OAB reported lower rates of sexual activity in the multinational EPIC study [3].

The first-line pharmacological treatment is anticholinergics (AC) and beta-3 adrenergic agonists for newly diagnosed OAB [11, 12]. The effectiveness and safety of AC and beta-3 adrenergic agonists have been confirmed in many clinical studies and meta-analyses [13, 14]. There are few

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studies showing that these medical treatments also improve female sexual function [15, 16].

In the light of this information, we aimed to prospectively investigate the effect of AC agents on sexual function in women before and after treatment for OAB, using the Female Sexual Function Index (FSFI) questionnaire.

Methods

The study protocol has been approved by our local institutional Ethics Committee and all individuals gave written informed consent. Between January 2016 and August 2018, over 18 years old, 216 sexual active women diagnosed with OAB in a stable partner relationship were prospectively enrolled in this controlled observational study. Detailed medical histories were obtained from all individuals such as age, body mass index (BMI), frequency of intercourse, and associated comorbidities by face-to-face interview. General and neurological complete physical examinations were performed to assess the patients. OAB was defined as the presence of urinary frequency ($\geq$8/day), nocturia ($\geq$2/night), urgency with or without urge incontinence (UI) for $\geq$3 months [17]. Additionally, 165 age-matched women, without low urinary tract symptoms (LUTS) or OAB, were enrolled into the control group to enable baseline comparisons. This control group was collected from outpatient clinics during routine cervical smear screening.

Subjects were excluded from participation if they had active UTI, bladder or pelvic tumors, stress urinary incontinence, bladder or kidney stones, neurologic disorders affecting bladder function, postvoid residual volume over 100 mL, and contraindications to anticholinergic drug use. Gynecological examinations were performed in all participants to exclude pelvic organ prolapse. The Beck Depression Inventory (BDI) form was used for psychological evaluation [18], and the participant whose BDI score $\geq$14 was also excluded from the study.

Sexual function was evaluated with a detailed 19-item questionnaire, FSFI, including sexual desire, arousal, lubrication, orgasm, satisfaction, and pain during sexual intercourse [19]. A Turkish language version of the FSFI, validated by the Turkish Society of Andrology, was used. Scores range from 2 to 36, and women with a total score $\leq$26.55 were considered as FSD [20]. All women were asked to answer the question: "Do you have sexual distress associated with sexual dysfunction?" and only women who gave a negative answer were finally available for analysis, since sexual distress needs special questionnaires to be evaluated.

Patients diagnosed with OAB admitted to the urology outpatient clinic were evaluated by their physicians. All physicians recorded the demographic data of patients and completed FSFI, eight-item OAB awareness tool (OAB-V8), and BDI forms before treatment began. The OAB-V8 is an eight-item questionnaire that evaluates the severity of symptoms such as urinary frequency, nocturia, urgency, and urgency incontinence. Responses are graded on a six-point Likert scale ranging from 0 to 5. If overall score is eight or greater, it is considered as OAB [21]. The AC agents available for the treatment of OAB in Turkey are oxybutynin [immediate release (IR)], tolterodine [IR, extended release (ER)], darifenacin, trospium (IR), solifenacin, propiverine (ER) and (IR), and fesoterodine. Side effects profile was also evaluated during the study. Dry mouth and constipation were evaluated with adverse event score as "Absent" (0 points), "Slight" (1 point), "Mild" (2 points), "Moderate" (3 points) or "Severe" (4 points). Finally, 216 patients of study group received AC agents, once daily, for 3 months. Three months after the treatment, the questionnaires were completed again.

The primary endpoints were changes in the domains of FSFI in OAB patients before and after treatment. Secondary endpoints included differences in sexual function OAB patients before and after treatment in comparison to healthy controls. The validated Turkish version of the OAB-v8 was also completed two times by the all patients (before and 3 months after treatment) to report benefits of the treatment in OAB.

The demographic profile of the participants was analyzed using the χ^2-test. Differences in OAB-V8, FSFI, adverse event scores were initially analyzed by ANOVA and p-values were calculated using the t test for intergroup analysis. Statistical significance was accepted $p < 0.05$. Data are presented as the mean $\pm$ standard deviation (SD). Our data were evaluated with the use of SPSS software, USA, release 13.0.

Results

The characteristics of the participants, including age, BMI, comorbidities, OAB-V8, and BDI scores and parity are presented in Table 1. The mean ages of the OAB patients and healthy controls were 46.1 $\pm$ 6.4 (18–49) and 45.6 $\pm$ 8.4 (18–51) years, respectively. Baseline demographic characteristics were similar between OAB patients and the control group except mean OAB-V8 scores.

All of the women scored < 14 in the BDI. AC agents used by total of 216 patients were tolterodine ER (n = 43), solifenacin 5 mg (n = 56), darifenacin 7, 5 mg (n = 34), propiverine ER (n = 45) and fesoterodine 4 mg (n = 38). Treatment with AC agents revealed statistically significant improvement in five FSFI domains but there was no significant change in subscales of lubrication. Over the 85% of patients reported increases in total FSFI score compared to baseline value (Table 2).

Patients with OAB reported at baseline significantly worse sexual function in all FSFI domains compared

Table 1 Demographic characteristics of groups

Parameter	OAB patients ($n=216$)	Control group ($n=165$)	p
Age (years)	46.1 ± 6.4 (18–49)	45.6 ± 8.4 (18–51)	> 0.05
Body mass index (kg/m^2)	27.6 ± 5.1	26.3 ± 4.6	> 0.05
Parity	2.1 ± 1.1	2.0 ± 1.2	> 0.05
Postmenopausal	43 (19.9%)	31 (19.3%)	> 0.05
BDI score	3.49 ± 3.11 (1–9)	3.68 ± 3.01 (1–11)	> 0.05
Comorbidities			
DM	12 (5.55%)	8 (4.84%)	> 0.05
Hypertension	16 (7.40%)	15 (9.09%)	> 0.05
CVD	4 (1.85%)	3 (1.81%)	> 0.05
Dyslipidemia	10 (4.62)	8 (4.84%)	> 0.05
OAB-V8 scores	20.3 ± 8.9	6.9 ± 5.6	0.001

Continuous variables are presented as the mean ± SD, categorical variables are presented as number and %

BDI Beck Depression Inventory, *DM* diabetes mellitus, *CVD*, cardio vascular diseases, *OAB-V8* eight-item overactive bladder awareness tool

to healthy control group (21.47 ± 3.22 vs. 26.79 ± 5.56, $p < 0.01$). AC agents significantly improved sexual function and the posttreatment results were similar to scores from to control group in two subscales after treatment: orgasm and pain (Table 2). In addition, there was also a marked decrease in the OAB-V8 scores in women suffering from OAB (Table 3).

There was no significant difference in efficacy among the five AC agents used in the study. The data obtained using the FSFI and OAB-V8 questionnaires showed that the improvement in sexual function and OAB symptoms were similar in all drug groups. Detailed comparison is shown in Table 3. There were no differences in frequency of dry mouth and constipation among the different drug users (p value: 0.73 and 0.52, respectively) and no patient left treatment because of side effects (Table 3).

Discussion

In the present study, sexual functions of women with OAB were evaluated before and after AC treatment and compared to healthy women. The mean values of total FSFI are 21.47 and 26.79 in study group before treatment and control group, respectively. The results suggest that women with OAB have FSD according to cut-off value accepted for diagnosis (≤ 26.55). Although the results in the control group were above the cut-off value, they were below the expectation. This condition may be related to the reluctance of the Turkish people to discuss specific issues such as sexuality with their physicians.

Several studies have been reported on the effects of OAB on female sexual function and quality of life [7, 9, 22]. The first-line pharmacological treatment of OAB should include the use of oral AC agents or oral beta-3 adrenoceptor agonist [11, 12]. Therefore, it seems logical to expect improvement in sexual functions after medical treatment of women suffering from OAB. However, there are few studies showing the relationship between AC agent use and sexual functions in the literature.

Table 2 Change in Female Sexual Function Index (FSFI) before and 3 months after treatment with the anticholinergic (AC) agents in study group and in comparison to control group

	Pre-treatment scores in study group	Post-treatment scores in study group	Post-treatment Improvement in study group	Pre-treatment scores versus post-treatment scores in study group (two sample paired t test)	Control group scores	Pre-treatment scores in study group versus control group (Student t test)	Post-treatment scores in study group versus control group (Student t test)
	Mean ± SD	Mean ± SD	(n %)	p Values	Mean ± SD	p Values	p Values
Desire (1.2–6)	2.94 ± 0.69	3.19 ± 0.61	84 (38.8%)	< 0.01	3.72 ± 1.61	< 0.01	= 0.005
Arousal (0–6)	3.43 ± 0.89	3.85 ± 0.74	95 (43.9%)	< 0.01	4.37 ± 1.56	< 0.01	< 0.01
Lubrication (0–6)	4.19 ± 0.62	4.09 ± 0.56	13(6, 01%)	= .063	4.73 ± 1.16	< 0.01	< 0.01
Orgasm (0–6)	3.51 ± 0.71	4.10 ± 0.42	162 (75%)	< 0.01	4.21 ± 0.99	< 0.01	0.071
Satisfaction (0.8–6)	3.26 ± 1.01	3.68 ± 0.89	79 (36.5%)	< 0.01	4.99 ± 1.06	< 0.01	< 0.01
Pain (0–6)	4.14 ± 0.88	4.53 ± 0.78	129 (59.7%)	< 0.01	4.57 ± 1.28	< 0.0014	0.552
Total FSFI (2–36)	21.47 ± 3.22	23.72 ± 2.61	194 (89.8%)	< 0.01	26.79 ± 5.56	< 0.01	< 0.01

Table 3 OAB-V8, FSFI score, and adverse event score for each anticholinergic agent

Drug	Tolterodine (Tol)	Darifenacin (Dar)	Solifenacin (Sol)	Propiverine (Pro)	Fesoterodine (Fes)	Total	*p Value
n	43	34	56	45	38	216	
Pre-treatment							
OAB-V8 score	20.4 ± 7.8	19.8 ± 8.1	20.5 ± 6.9	20.7 ± 7.1	19.7 ± 6.7	20.3 ± 8.9	0.23
FSFI (total)	21.59 ± 3.69	21.33 ± 3.51	20.98 ± 3.83	21.65 ± 2.99	20.08 ± 3.01	21.47 ± 3.22	0.15
Post-treatment							
OAB-V8 score	11.1 ± 4.8	10.7 ± 5.7	10.6 ± 6.1	11.3 ± 5.2	10.7 ± 4.9	10.9 ± 5.9	0.48
FSFI (total)	24.13 ± 3.75	23.97 ± 3.69	23.36 ± 3.73	23.82 ± 3.01	22.53 ± 2.98	23.72 ± 2.61	0.76
Δ-Value	+ 2.54	+ 2.64	+ 2.38	+ 2.17	+ 2.45	+ 2.25	0.83
Adverse event scores							
Dry mouth	1.31 ± 1.25	1.29 ± 1.12	1.32 ± 1.21	1.34 ± 1.18	1.31 ± 1.20	1.38 ± 1.17	0.73
Constipation	1.14 ± 1.08	1.09 ± 1.02	1.13 ± 1.01	1.12 ± 1.19	1.16 ± 1.10	1.11 ± 1.18	0.52

ER extended released, *OAB-V8* eight-item overactive bladder awareness tool, *FSFI* Female Sexual Function Index

*p-Values were calculated using ANOVA

In the study reported by Zachariou et al. [16], sexual active women with OAB were divided into two groups. Group A, 110 patients with OAB were treated with tolterodine 4 mg ER for 3 months and group B, 90 patients did not wish to receive any therapy. Their results revealed that tolterodine ER applied for OAB treatment improved all domains of FSFI including pain, orgasm, arousal, sexual enjoyment, sexual desire, and even vaginal wetness. They also showed the decrease in urinary parameters after treatment using a 3-day micturition diary. In another study involving 30 patients, it was reported that the use of tolterodine IR improved sexual functions [23]. They used the Arizona Sexual Experience Scale (ASEX) to assess sexual functions. But some parameters, like painful intercourse and urinary leakage during intercourse, are missed in this questionnaire. Rogers et al. [24] revealed that long-term tolterodine ER treatment for OAB resulted in a relief of symptoms in sexual active women. Their study also validated improved sexual health. Sand et al. [25] showed that transdermal oxybutynin treatment for OAB improved sexual function. However, another study reported that treatment of OAB symptoms with AC agents, in female patients evaluated with the Pelvic Organ Prolapse/Urinary Incontinence Sexual Function Questionnaire (PISQ), did not guarantee improvement in sexual health [26]. According to our study, most of women treated with AC agents have achieved significant increases in all but one of the FSFI domains. There were no improvements in the lubrication scores; however, there were no significant increases in vaginal dryness or dyspareunia as well. When the results of AC treatment were compared with the control group, orgasm and pain scores were found similar between two groups. But total FSFI scores did not approach those of control group. As was expected, AC agents significantly improve symptoms of OAB. Moreover, in our study, the OAB-V8 mean scores were significantly improved in the all drug groups. This is compatible with previous studies [27].

The studies on sexual function and OAB treatment in the literature have been performed with a single AC agent. We conducted an observational study; therefore, we were able to evaluate the effect of five different AC agents on total FSFI scores separately. As a result, we found that the effect of different AC agents on sexual functions was similar. Although a study comparing the effects of all anticholinergic drugs is not available in the literature, some noteworthy articles have been published in which fewer drugs are compared. In one of these studies, it was reported that four different AC agents had significant improvement compared to placebo. But there were no significant differences between the different interventions of drugs [28]. In another analysis, it was reported that the ER forms were superior to the IR forms [29]. According to another study, similar forms of AC drugs (like ER) do not have superiority in terms of effect or side effects to each other except Imidafenacin [30]. The AC drugs prescribed by our clinicians were compatible with the literature In terms of preferring ER form. So, it seems logical that improvement in sexual functions is similar among drug groups in presented study.

In OAB patients, many factors can negatively effect sexual functions. Fear of urinary incontinence during sexual intercourse and dyspareunia caused by dermatitis in the vulvovestibular region due to UI can cause FSD. However, in a recent study, the continent women also experienced pain with intercourse [22]. Women with OAB not only suffer from UI, but also suffer from suprapubic pain, discomfort, dysuria and vulvodynia [31]. These symptoms may be aggravated during or after intercourse, and therefore they may negatively affect sexual life. In addition, patients with UI

may also be embarrassed by their incontinence and may lose their self-confidence.

In conclusion, treatment of OAB with AC agents can improve sexual function of sexual active women with OAB. Our study demonstrated that all domains of FSFI improved except lubrication, but only orgasm and pain domains have reached the level of healthy women. The limitation of this study is lack of placebo group. Thus, the effect of placebo on sexual function was not evaluated. Certainly, more studies with a placebo controlled design and a larger sample size are required to respond to all questions precisely. Despite this limitation, we believe that we have achieved significant results. So, patients may be informed about this potential benefit of AC treatment, to improve their sexual function.

Compliance with ethical standards

Conflict of interest The authors declare that they have no conflict of interest.

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