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RESEARCH

The effect of solifenacin treatment for urge urinary incontinence on sexual function in premenopausal and postmenopausal women: a prospective observational study

Premenopozal ve postmenopozal kadınlarda urge üriner inkontinans için kullanılan solifenasinin cinsel fonksiyon üzerine etkisi: prospektif gözlemsel bir çalışma

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Abstract

Purpose: The aim of this study is to determine whether solifenacin used for urge urinary incontinence improves sexual function and if so this improvement differs between premenopausal and postmenopausal women.

Materials and Methods: 120 women, 48 premenopausal and 72 postmenopausal were enrolled in the study. They filled out the Female Sexual Function Index (FSFI) before, three months, and six months after the solifenacin 5mg daily treatment for urge urinary incontinence. The results were interpreted in two groups, premenopausal and postmenopausal. The FSFI scores for baseline and for post-treatment were compared for both groups and with each other.

Results: All domains of FSFI except orgasm were improved with the use of Solifenacin. The mean FSFI scores following three months (n=110) and six months (n=65) of solifenacin treatment are significantly improved compared to the baseline in both premenopausal and postmenopausal patients. This improvement in FSFI scores does not significantly differ between premenopausal and postmenopausal groups.

Conclusion: Solifenacin treatment for lower urinary tract symptoms has been shown to have a positive impact on the sexual functions of both premenopausal and postmenopausal women. Although treatment with solifenacin improved sexual dysfunction in women, this improvement did not vary between premenopausal and postmenopausal women.

Keywords:. Urinary incontinence, urge; cholinergic antagonists; sexual dysfunction,physiological

Öz

Amaç: Bu çalışmanın amacı urge üriner inkontinans tedavisinde kullanılan solifenasinin cinsel fonksiyonlarda iyileşme sağlayıp sağlamadığını değerlendirmek ve eğer düzelme var ise bunun premenopozal ve postmenopozal kadınlar arasında farklılık gösterip göstermediğini belirlemektir.

Gereç ve Yöntem: 48 premenopozal ve 72 postmenopozal olmak üzere 120 kadın hasta çalışmaya dahil edilmiştir. Hastalar urge üriner inkontinans nedenli başlanan 5 mg/gün solifenasin tedavisinden önce ve tedaviden üç ay ve altı ay sonra Kadın Cinsel İşlev İndeksini (FSFI) doldurdular. Sonuçlar premenopozal ve postmenopozal olmak üzere iki grupta yorumlandı. Başlangıç ve tedavi sonrası FSFI skorları önce toplam hasta grubunda ve sonrasında gruplar arası karşılaştırıldı.

Bulgular: Solifenasin kullanımı ile orgazm hariç tüm FSFI alt gruplarında belirgin iyileşme gözlenmiştir. Üç aylık (n=110) ve altı aylık (n=65) solifenasin tedavisini takiben ortalama FSFI skorları hem premenopozal hem de postmenopozal hastalarda başlangıca kıyasla önemli ölçüde iyileşmiştir. FSFI skorlarındaki bu iyileşme premenopozal ve postmenopozal gruplar arasında anlamlı farklılık göstermemiştir.

Sonuç: Alt üriner sistem semptomları için başlanan solifenasin tedavisinin hem premenopozal hem de postmenopozal kadınların cinsel fonksiyonları üzerinde olumlu bir etkisi olduğu gösterilmiştir. Solifenasin tedavisi kadınlarda cinsel fonksiyonları iyileştirmesine rağmen, bu iyileşme premenopozal ve postmenopozal kadınlar arasında farklılık göstermemiştir.

Anahtar kelimeler: Üriner inkontinans, urge; kolinerjik antagonistler; cinsel işlev bozukluğu, fizyolojik

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INTRODUCTION

Urinary incontinence (UI) is a highly significant healthcare problem, characterized by an involuntary loss of urine, negatively affecting psychological and social life, sexual function, emotional well-being, productivity, and, therefore, the overall quality of life. Women are more likely to experience urinary incontinence than men due to a number of factors, including pregnancy, childbirth, and menopause. UI prevalence increases with advancing age and becomes even more prominent in women aged >40 years[1]. Despite its prevalence, urinary incontinence is still a stigmatized condition that many people are reluctant to discuss. Still, with proper treatment and management, it can often be effectively managed and even cured.

The first line of treatment for urge urinary incontinence is conservative. Lifestyle modifications such as bladder training, weight loss, fluid intake management, urinary irritants restriction, and pelvic floor muscle training are recommended[2]. Pharmacologic treatment consists of anticholinergic agents and beta-3 adrenergic agonists or a combination. Alternative management options include intravesical botulinum toxin-A in refractory cases. Electrical stimulation and posterior tibial nerve stimulation are also effective modalities[3]. Solifenacin is a commonly used anticholinergic agent developed to treat urge urinary incontinence (UUI) and overactive bladder (OAB) symptoms. It has in vitro selectivity for bladder tissue and positively impacts the quality of life in women with UUI and OAB complaints.

Coital incontinence is a type of urinary incontinence that occurs during sexual activity. It may occur at penetration due to stress urinary incontinence or during orgasm due to detrusor overactivity[4]. There fore it can significantly impact sexual function and intimacy, leading to a decline in sexual satisfaction. It is a commonly overseen problem since the patients usually do not complain due to embarrassment or social restrictions, especially in conservative populations such as ours. The fear of leakage during sexual activity can lead to feelings of anxiety and insecurity, which can affect sexual function and intimacy. It can make it difficult to relax and enjoy sexual activity, leading to a decline in sexual satisfaction. This condition can lead to a reduction in the frequency and quality of sexual activity, leading to a decrease in the overall health and satisfaction of the relationship.

Several data in the literature show that solifenacin can improve sexual function through its effect on urinary incontinence. However, no research analyzes its impact according to the menopausal state of the patients[5]. The present study aimed to determine whether solifenacin used for UUI prospectively improves female sexual function and if it improves whether it differs in premenopausal and postmenopausal women. We believe that our study will contribute to the national literature with the information that solifenacin used for UUI may contribute to a decrease in sexual dysfunction and that there is no study demonstrating the sexual dysfunction improvement comparison between premenopausal and postmenopausal women.

MATERIAL AND METHODS

This study was conducted on women presented in Arnavutkoy State Hospital Gynecology Clinic with lower urinary tract symptoms that planned to start treatment with solifenacin 5 mg/d. It is conducted according to the Good Clinical Practices Guideline of Helsinki. And the Institutional Medical Ethics Committee of Haseki Training and Research Hospital (Protocol number:2021/121) approved the study procedures. All participants provided written informed consent.

Sample

Between January- September 2022, 48 premenopausal and 72 postmenopausal, sexually active women presented with lower urinary tract symptoms (LUTS) and were planned to initiate Solifenacin 5mg treatment were enrolled in the study prospectively. After obtaining written informed consent, 120 patients aged 19-80 were included in the study. Subjects were excluded from participation if they had urinary tract infections, stress urinary incontinence, urinary retention, grade 2 or above pelvic organ prolapse according to the Pelvic Organ Prolapse Quantification (POP-Q) scale, and drug contraindications such as narrow-angle glaucoma. All participants agreed to involve and provided written informed consent for inclusion in the study. The inclusion criteria integrated women over the age of 18 and sexually active.

Procedure

Patients underwent a thorough evaluation that included a detailed anamnesis, physical and gynecological examination, pelvic ultrasound, and uroflow test. All women were examined employing the Pelvic Organ Prolapse Quantification (POP-Q) system. Women with stage 2 or higher pelvic organ prolapse were excluded, as well as those with a history of pelvic muscle training since it is known that pelvic floor muscle exercises improve sexual function. To identify their symptoms, patients filled out bladder diaries and questionnaires, as is standard practice in Urogynecology.

The decision to initiate solifenacin treatment was achieved following the initial evaluation and discussed with the patient. The patients were informed about the possible side effects including dry mouth, constipation, blurry eyes, urinary retention, and emesis. All patients were asked to complete the Turkish version of the Female Sexual Function Index (FSFI) to assess sexual function before and at three and six months after treatment to compare the pre and post-treatment differences. Female Sexual Function Index (FSFI) was used to assess sexual function in both premenopausal and postmenopausal groups at pre-treatment and three and six months post-treatment.

Measure

Female Sexual Function Index (FSFI)

The Female Sexual Function Index (FSFI) is a self-report questionnaire that assesses various aspects of female sexual function. The questionnaire consists of 19 items and measures six domains of sexual function: desire, arousal, lubrication, orgasm, satisfaction, and pain. It uses a scoring system to determine scores in each domain, with higher scores indicating better sexual function.

Desire refers to a woman's level of sexual interest and desire. Arousal refers to physiological and psychological responses to sexual stimuli, including lubrication and vaginal swelling. Lubrication refers to the production of natural lubrication in response to sexual stimulation. Orgasm refers to the peak of sexual pleasure and the release of sexual tension. Satisfaction refers to a woman's overall level of satisfaction with her sexual experiences. Pain refers to any pain experienced during sexual activity. Each item in the FSFI is scored on a scale of 0 to 6 and the scores from each of the six domains are combined to form a total score, with higher total scores indicating better sexual function. Wiegel et al. conducted a study and found an FSFI total score of 26.55 to be the optimal cut score for distinguishing between women with and without sexual function[6]. The FSFI has been validated for use in different cultures and populations and has been shown to have high reliability and validity. A Turkish version of the FSFI, consisting of 19 questions, was created as a concise and comprehensive self-assessment tool to evaluate key aspects of female sexual function. Oksuz et al. conducted a study on the reliability and validity of the FSFI Turkish version[7]. The FSFI Turkish version is shown to be psychometrically robust, simple to administer, and capable of distinguishing between clinical and non-clinical groups. Results have indicated that the FSFI Turkish version is reliable and valid for use in the Turkish population.

Statistical analysis

Data were analyzed using NCSS (Number Cruncher Statistical System) 2007 (Kaysville, Utah, USA). Power analysis was used, and a total of 120 patients eligible for the study protocol were selected to obtain clinically and statistically significant differences at a 5% significance level, 85% power, an effect size of 0.25, and a correlation between measurements of 0.5. The statistical analysis was done using the paired sample t-test and independent samples t-test. Data were presented as mean ± standard deviation. A p-value of less than 0.05 was considered statistically significant.

RESULTS

There were 48 premenopausal and 72 postmenopausal patients enrolled in the study. At three months follow-ups, three patients from the premenopausal group and seven from the postmenopausal group were withdrawn from the study. Four of them were lost at follow-up, and six complained of the adverse effects (constipation=4, dry mouth=2) and discontinued the drug. 45 premenopausal and 65 postmenopausal patients were left. At six months follow-up, 22 patients were in the premenopausal, and 43 patients were in the postmenopausal group. 33 patients were lost in the follow-up, and 12 complained of the adverse effects and discontinued the drug (constipation=8, dry mouth=2, emesis=2) (Figure 1). The average age in the premenopausal group was 46.88 (±3.36), and 55.20 (±7.75) in the postmenopausal group.

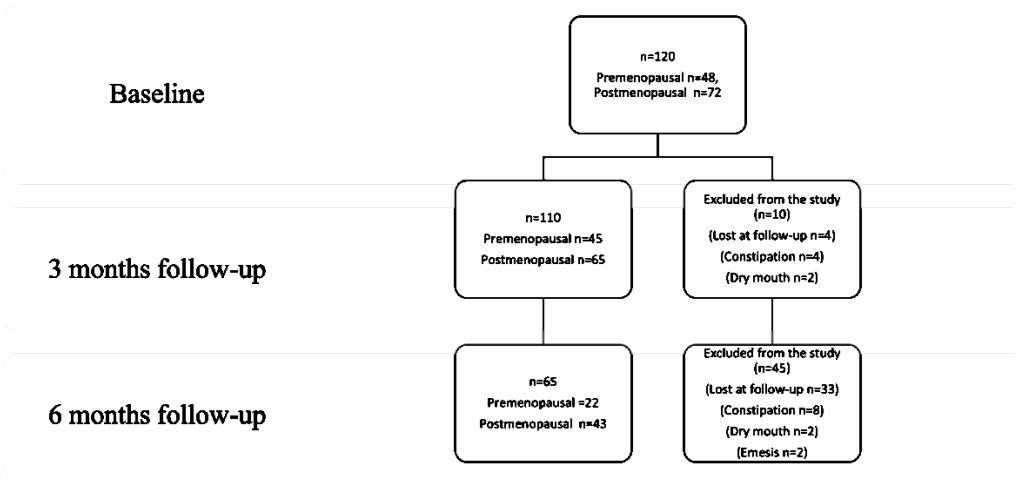

Figure 1. Follow chart of the study patients

The total FSFI scores, median values ± standard deviation, at baseline were 17.14±5.40 and 19.11±5.01 at three months follow-ups. (p<0.01) Pre and post-treatment were for desire 2.51±0.89 and 2.96±0.86 respectively (p<0.01), for arousal 2.86±1.08 and 3.17±1.10 respectively (p<0.01), for lubrication 3.07±1.43 and 3.41±1.35 respectively (p<0.01), for orgasm 2.16±1.81 and 2.11±1.10 respectively (p=0.75), for satisfaction 2.49±1.02 and 2.78±0.95 respectively (p<0.01), for pain 4.32±1.07 and 4.68±0.82 respectively (p<0.01). Solifenacin treatment improved all aspects of female sexual function except for orgasm. The orgasm rate was decreased with solifenacin treatment, but this decrease was not found to be statistically significant. (Table 1)

Table 1. Solifenacin effect on FSFI scores at baseline and 3 months follow-up

	Pre-treatment Mean ± SD (n=110)	**3 Months Follow-up Mean ± SD (n=110)**	**p**
Desire	2.51 ±0.89	2.96 ±0.86	<0.01
Arousal	2.86 ±1.08	3.17 ±1.10	<0.01
Lubrication	3.07 ±1.43	3.41 ±1.35	<0.01
Orgasm	2.16 ±1.81	2.11 ±1.10	0.75
Satisfaction	2.49 ±1.02	2.78 ±0.95	<0.01
Pain	4.32 ±1.07	4.68 ±0.82	<0.01
Total FSFI score	17.14 ±5.40	19.11 ±5.01	<0.01

SD: standard deviation

The total FSFI scores, median values ± standard deviation, at baseline were 17.69±4.81 and 20.12 ±4.40 at six months follow-up.(p<0.01) Pre and post-treatment scores were for desire 2.58 ±0.80 and 3.10 ±0.76 respectively (p<0.01), for arousal 3.01 ±0.98 and 3.44 ±0.97 respectively (p<0.01), for lubrication 3.25 ±1.32 and 3.67±1.20 respectively (p<0.01), for orgasm 2.22 ±1.88 and 2.17 ±1.06 respectively (p=0.83), for satisfaction 2.53 ±0.95 and 2.90 ±0.82 respectively (p<0.01), for pain 4.41 ±0.93 and 4.84 ±0.67 respectively (p<0.01). Solifenacin treatment improved all aspects of female sexual function except for orgasm. The decrease in orgasm rate due to solifenacin treatment was observed but not deemed statistically significant. (Table 2)

Table 2. Solifenacin effect on FSFI scores at baseline and 6 months follow-up

	Pre-treatment Mean ± SD (n=65)	6 Months Follow-up Mean ± SD (n=65)	p
Desire	2.58 ±0.80	3.10 ±0.76	<0.01
Arousal	3.01 ±0.98	3.44 ±0.97	<0.01
Lubrication	3.25 ±1.32	3.67±1.20	<0.01
Orgasm	2.22 ±1.88	2.17 ±1.06	0.83
Satisfaction	2.53 ±0.95	2.90 ±0.82	<0.01
Pain	4.41 ±0.93	4.84 ±0.67	<0.01
Total FSFI score	17.69 ±4.81	20.12 ±4.40	<0.01

SD:standard deviation

Tables 3 and 4 demonstrate the effect of solifenacin on sexual function according to premenopausal/menopausal state at pre-treatment and after three and six months of treatment. Solifenacin treatment improved all domains of FSFI except orgasm in both groups.

Table 3. Improvement in FSFI scores at pre-treatment and three months post-treatment follow-up in premenopausal and postmenopausal women

	Premenopausal (n=45)		Postmenopausal (n=65)		
FSFI	Mean	Sd.	Mean	Sd.	p
Desire	.4759	.9183	.4435	.4345	.802
Arousal	.3931	.5597	.2576	.5216	.141
Lubrication	.4655	.7830	.2576	.3574	.061
Orgasm	.0275	2.0311	.0913	1.5108	.702
Satisfaction	.3655	.7688	.2478	.3239	.273
Pain	.3793	.8941	.3391	.9050	.790
Total score	2.4517	3.2803	1.6739	1.6542	.098

Table 4. Improvement in FSFI scores at pre-treatment and six months post-treatment follow-up in premenopausal and postmenopausal women.

	Premenopausal (n=22)		Postmenopausal (n=43)		
FSFI	Mean	Sd.	Mean	Sd.	p
Desire	.5181	.8133	.5302	.4383	.703
Arousal	.5590	.8846	.3558	.5165	.070
Lubrication	.6681	1.1107	.2860	.3461	.052
Orgasm	.0909	2.3484	.0279	1.6009	.836
Satisfaction	.4363	.6637	.3348	.4932	.671
Pain	.3818	.5586	.4558	.9424	.443
Total score	2.9272	3.7779	2.1674	2.0999	.098

The improvement in FSFI scores with solifenacin treatment does not significantly differ between premenopausal and postmenopausal groups neither in three months follow-up nor in six months follow-up.

DISCUSSION

Urge incontinence is a common and significant health problem affecting men and women. The prevalence usually increases depending on aging, has a peak around menopausal time, and continues to increase between the ages of 60 to 80[8]. The main risk factors for female urinary incontinence are age, parity, obesity, mode of delivery, and menopause[9]. In a study by Sensoy et al., aging and menopause were the most important risk factors for urinary incontinence[10].

World Health Organization (WHO) Constitution describes health as complete physical, mental, and social well-being. Urinary incontinence can impair the social life, quality of life, psychological health, and sexual functions of women. Urge urinary incontinence (UUI) is defined as loss of urine with a sudden urge to urinate due to involuntary detrusor contractions. Urge urinary incontinence (UUI) had a prevalence of 13.59%, according to a population-based study in the United States (US) [11]. UUI is a significant healthcare problem that needs to be addressed, negatively affecting sexual function, emotional well-being, productivity, and overall quality of life[12].

Sexual dysfunction is a commonly overseen problem since the patients usually do not complain about it due to embarrassment or social restrictions with an estimated prevalence of almost 50%. While it can be a source of embarrassment, it is a treatable condition with a variety of treatment options available. Female sexual function is multifactorial and can be negatively affected by urgency, frequency symptoms, and urinary incontinence during intercourse. Coital incontinence is defined as the involuntary leakage of urine during sexual intercourse. It may occur due to detrusor overactivity[4]. Sexual functions may improve due to the improvement of urgency and urge incontinence complaints. The Female Sexual Function Index (FSFI) is a self-report measurement questionnaire that evaluates sexual disorders and provides scores on six domains of sexual function: desire, arousal, lubrication, orgasm satisfaction, and pain. According to the latest report of the International Consultation on Sexual Medicine, FSFI remains the gold standard evaluation tool with a recommendation grade of A for evaluating female sexual dysfunction[13].

Urinary problems are common in menopause, and overactive bladder (OAB) symptoms increase with age. Especially women in menopause suffer from it since it is not an easy topic to discuss. Hakimi et al. reported that OAB and UUI significantly and negatively affected sexual function in menopausal women. Sacco et al. conducted a study on women in menopause and showed that UUI was one of the most important factors concerning sexual function[14,15].

A study conducted by Su et al., including 833 women, conveys that both urge urinary incontinence and stress urinary incontinence causes sexual dysfunction. Pure urge urinary incontinence has a negative effect on lubrication and sexual pain domains of FSFI explicitly[16]. Therefore it is logical to assume that improvement in UUI would improve sexual dysfunction incidence. There are several studies in the literature showing the relationship between sexual function and treatment options. A comprehensive review of the effect of overactive bladder (OAB) treatment options on female sexual function reveals that all treatment options, including pelvic floor physiotherapy, anticholinergics, beta3 adrenergic agonist, intravesical injection of Botulinum Toxin A, sacral neuromodulation and percutaneous tibial nerve stimulation improved sexual function in female patients[17].

Solifenacin is an oral anti-muscarinic agent, selective for bladder tissue, and efficient in treating UUI and OAB symptoms[5]. With solifenacin treatment and a decrease in urgency and urge incontinence amounts, women may become more confident and willing to have sexual relations with their partners. That may explain the improvement in sexual functions in patients with a different point of view. There are several types of research on the effect of anticholinergics and beta-3 adrenergic agonists on sexual function. Young et al. conducted a prospective study including 5 Korean urology centers and 148 sexually active women with overactive bladder symptoms. All patients filled out King's Health Questionnaire and FSFI at baseline and after 12 weeks of the solifenacin 5 mg daily treatment. It was reported that solifenacin positively impacts sexual functions since the score of desire and satisfactory domains of FSFI showed significant improvement with the solifenacin treatment[18].

Del Rosso et al. conducted a study on 33 women diagnosed with OAB, who had an FSFI score< 26.55 that were initiated solifenacin 5 mg daily treatment[19]. Overall total FSFI scores significantly improved after three months of solifenacin treatment, and sexual desire, satisfaction, orgasm, arousal, lubrication, and pain domains showed a significant improvement. Therefore it was reported that anticholinergic treatment for OAB symptoms improves sexual functions and quality of life of the patients. A prospective study by Zachariou et al. evaluated 85 women suffering from OAB[20]. Patients were divided into two groups: a group treated with beta-3 adrenergic agonists for three months and a group with no treatment. Compared to the baseline scores, all FSFI domains showed significant improvement after three months of beta-3 adrenergic agonist

therapy. Also, Cakir et al. investigated the effect of anticholinergics on sexual function in OAB patients[21]. They found that all FSFI domains except lubrication are improved with treatment though they showed no difference between different anticholinergic drugs. These previous studies are consistent with our findings, proving that urgency and urge urinary incontinence symptoms treated with solifenacin 5 mg daily positively impact sexual functions.

Despite much proof of UUI treatment improving sexual function, there are no available data investigating any difference between premenopausal and postmenopausal patients. This information is essential since the aging population increases over time. Clinicians should be more focused on older patients` needs and somewhat unmentioned problems. This presented study showed that the mean FSFI scores following three months and six months of solifenacin treatment are significantly improved compared to the baseline in both premenopausal and postmenopausal patients. All domains of FSFI significantly improved except orgasm, which was not statistically significant. All studies in the literature have only three months follow-up period, which makes our study stand out with its six months follow-up outcomes since UUI is a chronic healthcare problem. Only one study in the literature conducted by Sand et al. showed a significant sexual function improvement in OAB patients that were treated with transdermal oxybutynin for up to 6 months[22].

The limitations of the present study include the absence of a control group. However, a control group without urinary incontinence would not be appropriate since it would not show the effect of urinary incontinence on sexual dysfunction. On the other hand, a control group of a different drug for urinary incontinence would not be suitable either since different treatments would affect the results differently. Neither a control group with conservative treatment would work since pelvic floor muscle training would directly affect sexual function as well. Therefore the study was designed without a control group. Secondly, the sample size was relatively small; therefore, further ongoing studies are being performed to overcome this obstacle and increase the power of the study.

This study inquired into the effect of solifenacin on sexual function and improvement in sexual functions over a longer observational period of time. Also showed that although solifenacin treatment for lower urinary tract symptoms improves sexual function, this improvement does not vary between premenopausal and postmenopausal women. In conclusion, the management of UUI/OAB with solifenacin treatment is found to have a positive impact on the sexual functions of both premenopausal and postmenopausal women. Women with UUI/OAB should also be evaluated in terms of sexual function and should be explained that by treatment of UUI/OAB, their sexual functions will most likely improve.

Yazar Katkıları: Çalışma konsepti/Tasarımı: IST; Veri toplama: IME; Veri analizi ve yorumlama: IME; Yazı taslağı: IME; İçeriğin eleştirel incelenmesi: IME; Son onay ve sorumluluk: IME, IST; Teknik ve malzeme desteği: IST; Süpervizyon: IST; Fon sağlama (mevcut ise): yok.
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