ORIGINAL ARTICLE

Eastern Journal of Medicine
East J Med 29(2): 231-237, 2024
DOI: 10.5505/ejm.2024.09476

Evaluation of Sexual Function of Women with Primary Sjogren's Syndrome and Investigation of the Effects of Lubricants on Sexual Drive

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ABSTRACT

Primary Sjogren's syndrome (pSS) is a chronic autoimmune disease that causes vaginal dryness and dyspareunia secondary to lymphocytic infiltration of exocrine glands. This study aimed to evaluate the sexual functions of premenopausal and postmenopausal women with pSS and to investigate the effects of using polycarbophil-containing vaginal moisturizing gel on sexual function.

The study included 24 female patients (mean age 45.1 ± 6.1, range 33 to 54 years) with pSS, who had an active sex life and reported vaginal dryness. The patients were asked to use 1 g of polycarbophil-containing vaginal gel twice per week for 12 weeks. Patients were assessed using the Female Sexual Function Index (FSFI) and Beck Depression Inventory (BDI) before and after vaginal lubricant use. All patients underwent full gynecologic examinations.

After treatment with vaginal lubricants, significant improvements were observed in the lubrication scores, satisfaction, and pain during intercourse (p=0.032, p=0.002, and p=0.006, respectively). The total post-treatment FSFI score was detected to be higher than the values of pre-treatment [median 22.5 (range, 15.1-32.4) vs. 20 (range, 12.3-28.5), respectively; p=0.004]. Considering the sum and sub-parameters of FSFI in postmenopausal women before and after lubricant treatment, there were significant differences in premenopausal satisfaction, pain reviews, and total FSFI scores (p=0.014, p=0.014, and p=0.032, respectively).

The use of polycarbophil-containing vaginal moisturizing gel improved sexual symptoms in women with Sjogren's syndrome, especially in the premenopausal period, without serious adverse effects; therefore, we concluded that non-hormonal polycarbophil-based gel could be used in the treatment of patients with this condition.

Keywords: Primary Sjogren's syndrome, dyspareunia, vaginal dryness, vaginal lubricant gel, polycarbophil, local non-hormonal therapy, female sexual function index

Introduction

Primary Sjogren's syndrome (pSS) is a chronic autoimmune disease that presents with dryness in mucosal surfaces secondary to lymphocytic infiltration of exocrine glands (1). Unlike pSS, secondary Sjogren's may be associated with autoimmune rheumatic diseases. The incidence rate of disease was found as 7 per 100,000 person-years at risk according to a meta-analysis that was conducted in 2014 (2). In Turkey, the incidence rate is between 0.21% to 0.72% (3). It is more frequently seen between the ages of 50-60 years and it is 10-20 times more frequent in women than men (4-5).

The typical clinical symptoms of pSS are dry eyes and mouth. It may cause sicca syndrome with the involvement of the other mucosal surfaces. Sexual dysfunction secondary to vaginal dryness, which can be the first symptom of Sjogren's disease, can affect quality of life negatively (6). In a study including 105 women, the most disturbing sicca feature was found to be dyspareunia secondary to dryness in the vaginal mucosa (7). The pathogenesis of vaginal dryness has yet to be understood completely; however, local

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Received: 30.10.2022, **Accepted:** 21.07.2023

inflammation is thought to be the cause (8). The use of some topical agents such as vaginal moisturizers and lubricants may alleviate the symptoms and disturbance related to vaginal dryness by changing the fluid distribution of epithelial cells and decreasing the vaginal pH (9).

Menopause is one of the most common causes of vaginal dryness. It is estimated that 15% of premenopausal and 57% of postmenopausal women report vaginal dryness (10). The hypoestrogenic state of menopause decreases the fat composition of vaginal mucosa and vulvar skin, which gradually results in a chronic inflammatory situation that causes atrophy. Many postmenopausal women use lubricants to eliminate dryness during penile-vaginal intercourse and to reach orgasm (11,12).

Women with pSS are more prone to having the abovementioned problems, especially after menopause. There is little data regarding the management of vaginal dryness and related sexual problems in this patient group. In this study, we aimed to evaluate the effects of lubricants on the sexual function of middle-aged women with pSS.

Materials and Methods

This is a prospective study that was conducted between March 2020 and March 2021 after obtaining ethical approval (2020/125 protocol number, 16.03.2020). Written informed consent was obtained from all participants in accordance with the Helsinki Declaration before any procedures were performed. Forty-three patients who were diagnosed as having pSS and followed up in the rheumatology clinic of our hospital were invited for the study. All patients met the criteria of the 2016 American College of Rheumatology/European League Against Rheumatism classification for pSS (13). Twenty-four patients who had active sex lives and reported vaginal dryness were recruited for the study. None of the patients had used vaginal lubricants before the study. All patients had a partner without any sexual dysfunction and they did not report the use of any contraceptive methods or hormone replacement therapy. Patients with chronic renal and hepatic failure, cancer, rheumatologic or autoimmune disorders except for pSS; depression; patients who had undergone gynecologic surgery; and patients who used medicines that might cause vaginal dryness or affect sexual function were excluded. To exclude any anatomic and infectious factors, we performed gynecologic examinations on all patients and took cervical swabs for cytology, and performed HPV DNA screening. Patients with vaginitis were treated before any medication was used.

Patients were asked to use a commercially available polycarbophil-containing vaginal gel (Ainara vaginal gel; Italofarmaco, ITFpharma, Madrid, Spain). The main components of the gel are glycerol (E422), Sodium methyl parahydroxybenzoate (E219), sodium propyl parahydroxybenzoate (E217), polycarbophil, carbopol, sodium hydroxide, hydrochloric acid, and purified water. The participants were asked to insert 1 gr of gel into the vagina twice per week for 12 consecutive weeks. The vaginal gel was self-administered via an applicator. Patients underwent a detailed gynecologic examination during registration and after completing treatment. Vaginal moisturizers contain water and plant-based or synthetic polymers that ease the adhesion of water molecules to the mucosal surface.

The age, social and demographic characteristics, gravidity, parity, menopausal status, comorbid diseases, medications that were used regularly, and previous gynecologic surgery were questioned at the first visit. All patients were asked to complete the Female Sexual Function Index (FSFI) and Beck Depression Inventory (BDI) after their examinations. They were then taught to use vaginal lubricant and instructed to use it twice per week for 12 weeks. Twelve weeks later, they were called for follow-up and were asked to complete the FSFI and BDI again.

The 19-item FSFI was created by Rosen et al. and validated for the Turkish population by Öksüz et al. [14,15]. In the original FSFI, there were six subdivisions: desire, arousal, lubrication, orgasm, satisfaction, and pain, which score between 2-36 in total. The cut-off value of the Turkish version of the test is 26 and higher scores indicate better sexual function (16).

The patients were also evaluated using the BDI, which was developed by Beck et al. in 1961 to detect the level and severity of depression (17). The Turkish version of the test was formed by Hisli et al. in 1988 (18). The questionnaire consists of 21 items scored 0 to 3 according to how patients felt at the time of the procedure. Using it with the BDI, he defined the severity of depression and divided it into four categories; A score of 0-9 is not depressed, 10-15 is mildly depressed, 16-24 is moderately depressed, and 25 or above is severely depressed (19).

The primary aim of our study was the evaluation of sexual function in patients with pSS. The second aim

was to investigate the effects of the use of vaginal lubricant gel on sexual function.

Statistical Analysis: All analyses were performed using the SPSS vers. 23 software package (IBM SPSS Statistics for Windows, Version 23.0. Armonk, NY: IBM Corp). The mean, standard deviation, median, minimum, and maximum values of continuous variables and percentages of categorical variables are outlined. The normal distribution of continuous variables was evaluated using the Kolmogorov-Smirnov test. Wilcoxon's signed-rank test and the dependent t-test were used in the analysis of pre/post-treatment values. $P<0.05$ was defined as statistical significance.

Results

The sociodemographic characteristics, and clinical and laboratory data of the patients are summarized in Table 1. The mean age of the patients was 45.1 ± 6.1 years (range, 33 to 54 years). The mean duration of pSS was 7 years (range 2 to 16 years). The most commonly used agent for the treatment of pSS was hydroxychloroquine, either alone or in combination with eye drops (n=15, 62.5%).

Using 26 as the cut-off point of FSFI, 13/17 (81.25%) premenopausal patients and 6/7 (75%) postmenopausal patients were defined as having sexual dysfunction. Psychiatric and mood symptoms have been widely reported in patients with pSS. Depressive symptoms were found relatively high in women through BDI scores (8.46±7.04, 43.4%).

We found that there were significant differences in terms of lubrication, satisfaction, and pain before and after the use of lubricants. After treatment with vaginal lubricants, the total FSFI scores were detected to be significantly higher than the pre-treatment values (Table 2). The use of vaginal lubricants correlated with better FSFI scores in patients with pSS.

There was no significant difference in all domains of FSFI in post-menopausal women before and after lubricant treatment. However, the level of satisfaction was found higher and the sexual pain was lower in the patients after treatment compared with pre-treatment status. Therefore, the total FSFI score was found to be higher in this group after lubricant treatment (Table 3).

Discussion

In this study, we evaluated sexual quality of life before and after treatment with vaginal lubricants in patients with pSS. We found that women with pSS had more satisfaction and less pain during sexual intercourse after regular application of lubricants compared with no usage ($p=0.002$ and $p=0.006$, respectively). In addition, depression scores were significantly lower than pre-treatment scores ($p=0.007$). A few studies with medium sample sizes suggested that the use of vaginal lubricants to decrease these disturbances might be an option for patients with pSS (20,21). Isık et al. detected that use of vaginal lubricants was correlated with better FSFI scores in premenopausal women (22). However, none of these studies investigated the difference in the sexual lives of women with pSS before and after the use of vaginal lubricants.

Women with pSS have a high risk of developing vaginal dryness and urogenital problems. By using the accredited questionnaires and measures, Priori et al. and Nimwegen et al. showed that women with pSS had impaired sexual function and dyspareunia (20,23). Menopause is also a condition that should be taken into account when it comes to vaginal atrophy. The International Menopause Society and the North American Menopause Society recommended the use of vaginal lubricants to alleviate vaginal dryness in postmenopausal women (24,25). Furthermore, postmenopausal women may favor of vaginal lubricants because they think lubricants help to have wetter, more pleasurable and more comfortable sex (26,27). One might assume, therefore, that postmenopausal women with pSS may benefit from vaginal lubricants more than premenopausal women with pSS. Priori et al. showed no difference in FSFI scores of women with pSS regarding their menopausal status (23). Işık et al. suggested the use of lubricants in pre/peri-menopausal patients with pSS but could not comment on postmenopausal patients because they excluded this population (22). In our study, we compared premenopausal and postmenopausal women with pSS and found that postmenopausal women did not have better scores in any domains of FSFI, whereas premenopausal women had more satisfaction and less pain during sex after treatment with lubricants. Therefore, our study is the first to conclude that lubricants are useful in patients with pSS before menopause. However, there should be more evidence for the role of lubricants in postmenopausal patients with pSS.

When the literature is examined, vaginal lubricants are very helpful in relieving vaginal dryness and dyspareunia symptoms in terms of daily use and sexual intercourse. They are especially beneficial in women who cannot use topical or systemic estrogen.

Table 1. Demographic Characteristics of The Study Population

pSS (n=24)	Mean+SD or n (%)
Age, mean ± SD (years)	45.1±6.1 (33-54)
BMI (kg/m2), mean ± SD (years)	26.7±4.5 (18.7-37.2)
Gravidity, mean ± SD (years)	3.8±2.2 (1-11)
Parity, mean ± SD (years)	3.2±2.1 (1-11)
Med.-(Max-Min)	
Duration of illness, median (min-max)	7.0±3.6
Beck Depression Inventory score, median (min-max)	8.5±7.0 (43.4%)
Smear status, n (%)	
Smear negative	23 (95.8%)
Smear positive	1 (4.2%)
HPV-DNA status, n (%)	
Cervico-vaginal swab status, n (%)	
Cervico-vaginal swab negative	19 (79.2%)
Cervico-vaginal swab positive	5 (20.8%)
HPV-DNA status, n (%)	
HPV-DNA negative	23 (95.9%)
HPV-DNA positive	1 (4.2%)
Menopausal status, n (%)	
Pre-menopausal women	17 (70.8%)
Post-menopausal women	7 (29.2%)
Education status, n (%)	
Education status-Low (primary, 0-8 years)	19 (79.2%)
Education status-Medium (secondary, 9-16 years)	3 (12.5%)
Education status-High (high school/college, ≥17 years)	2 (8.3%)
Medical Treatment, n (%)	
Medication-HCQ	3 (12.5%)
Medication-HCQ+Eye drops	12 (50%)
Medication-HCQ+Corticosteroids	2 (8.3%)
Medication-HCQ+Eye drop+Corticosteroids	1 (4.2%)

Origoni et al. demonstrated significant improvements in the symptoms of patients with GSM, both objectively (using the vaginal health index) and subjectively (using the visual analog scale) after treatment with a hyaluronic acid-based vaginal lubricant applied three times a week for a total of 8 weeks (22). It was also reported that these patients had a high level of satisfaction at the end of the treatment (28). Yodplob et al. found significant improvements in the lower urinary tract and sexual quality of life measures after 4 weeks of treatment with a non-hormonal vaginal polycarbophil-based moisturizing cream for the treatment of genitourinary symptoms of menopause, and these improvements were observed to persist after 12 weeks of treatment (29). In postmenopausal patients, it has been shown that a polycarbophil-containing vaginal gel applied vaginally three times per week is a complete cure for all symptoms of vaginal atrophy in addition to local estrogen (30). In our study, we showed that the use of a polycarbophil-containing vaginal lubricant applied twice per week was associated with better sexual function results and could be used in the treatment of patients with Sjogren's disease who reported vaginal dryness and dyspareunia. It was found to be more effective in premenopausal women than in the postmenopausal group. No serious adverse effects have been associated with the use of vaginal lubricants.

Yıldız et al. showed that female sexual function decreased as the duration of Sjogren's disease increased (31). Moreover, Cetin et al. showed that as the duration of the disease increased, distress and dyspareunia occurred in 94 patients with pSS (21). The mean disease duration in our patients was 7±3.6 years.

Table 2: Comparison of The Pre-Treatment and Post-Treatment FSFI Scores and Beck Depression Scores

The assessment of domains before and after treatment	Pre-treatment Mean+S.D Med. (Min.-Max.)	Post-treatment Mean+S.D Med. (Min.-Max.)	p-value
Desire* (range 1.2-6)	3 (1.2-4.2)	3 (1.2-5.4)	0.2
Arousal (range 0-6)	2.9±1.3	3.5±1.3	0.06
Lubrication (range 0-6)	3.7±0.7	3.9±0.9	0.03**
Orgasm (range 0-6)	3.4±1.32	3.78±1.19	0.06
Satisfaction* (range 0.8-6)	3.6 (1.2-5.2)	4.4 (1.2-6)	0.002**
Pain* (range 0-6)	3.4 (1.2-6)	4.2 (1.2-6)	0.006**
FSFI total score (range 2-36)	20±4.7	22.5±4.6	0.004**
Beck depression score	8.1±7.2	7.1±6.4	0.007**

*Wilcoxon signed-rank test
** p<0.05 defined as statistical significance

Table 3: The Assessment of Domains Pre and Post-Treatment In Menopausal and Postmenopausal Women

	Premenopausal Women	Premenopausal Women		Postmenopausal Women	Postmenopausal Women	
	pre-treatment	post-treatment		pre-treatment	post-treatment	
	(n) mean+SD med. (min.-max.)	(n) mean+SD med. (min.-max.)	p-value	(n) mean+SD med. (min.-max.)	(n) mean+SD med. (min.-max.)	p-value
Desire *	(n=17) 3 (1.2-4.2)	(n=17) 3.6 (1.2-5.4)	0.253	(n=7) 2.4 (1.2-4.2)	(n=7) 2.4 (1.2-4.2)	0.32
Arousal	(n=17) 3.2±1.4	(n=17) 3.7±1.3	0.212	(n=7) 2.4±0.9	(n=7) 3.0±1.1	0.13
Lubrication	(n=17) 3.7±0.7	(n=17) 3.9±0.9	0.11	(n=7) 3.5±0.6	(n=7) 3.9±0.9	0.18
Orgasm	(n=17) 3.7±1.3	(n=17) 3.9±1.2	0.21	(n=7) 2.7±1.3	(n=7) 3.3±1.1	0.16
Satisfaction *	(n=17) 3.6 (2.4-5.2)	(n=17) 4.4 (3.2-5.2)	0.014**	(n=7) 3.6 (1.2-48)	(n=7) 4.4 (1.2-6)	0.06
Pain*	(n=17) 2.8 (1.2-6)	(n=17) 3.6 (1.2-6)	0.014**	(n=7) 3.6 (1.2-6)	(n=7) 6 (2.4-6)	0.10
Total	(n=17) 20.7±4.5	(n=17) 22.7±4.9	0.032**	(n=7) 18.4±5.1	(n=7) 22.0±4.3	0.08

*Wilcoxon signed-rank test ** p<0.05 is defined as statistically significant

Chui et al., in their study comparing Sjogren's patients and healthy controls, found that depression was more common in pSS than healthy controls, emphasizing the importance of early diagnosis and appropriate intervention to reduce the negative impact on the patient's quality of life and disease outcome (32). In our study, depressive symptoms were found to be high in women with Sjogren's syndrome, which is consistent with the literature.

The main limitation of our study is the relatively small size of our sample. Our findings may need to be confirmed by larger populations of women with pSS.

PSS causes both premenopausal and postmenopausal sexual dysfunction in women.

Vaginal dryness and dyspareunia due to Sjogren's syndrome are not recognized and treated adequately. The use of polycarbophil-containing vaginal moisturizing gel improved sexual symptoms in women with Sjogren's syndrome, especially in the premenopausal period, without serious adverse effects; therefore, we concluded that non-hormonal polycarbophil-based gel could be used in the treatment of patients with this condition.

Funding: The authors declare that no funds, grants, or other support were received during the preparation of this manuscript

Availability of data and material: The dataset is available from the corresponding author on reasonable request.

Statements and Declarations

Consent to participate: The authors affirm that human research participants provided informed consent for publication

Competing Interests: The authors have no relevant financial or non-financial interests to disclose.

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

Ethical approval: The study was conducted in accordance with the Declaration of Helsinki (version 2008). Since data acquisition was an anonymous and completely voluntary prospective questionnaire, no further approval by the ethics committee was required.

Consent to participate: Participation in the study was entirely voluntary. Non-participation had no consequences for a student's further course of study. All data were completely anonymized.

Consent for publication: All authors consent to the publication of the manuscript.

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