Quality of Sexual Life in Women with Primary Sjögren Syndrome

Roberta Priori, Antonina Minniti, Martina Derme, Barbara Antonazzo, Filippo Brancatisano, Silvia Ghirini, Guido Valesini, and Marialuisa Framarino-dei-Malatesta

ABSTRACT. ***Objective.*** To assess the quality of sexual life of women with primary Sjögren syndrome (pSS) and to identify its correlations with disease activity and damage, quality of life, and mood disorders.

Methods. The quality of sexual life of 24 women with pSS was assessed with the Female Sexual Function Index (FSFI). Twenty-four healthy women, matched by age and hormonal status, were enrolled as controls. Mood disorders and quality of life were investigated using the Hospital Anxiety and Depression Scale (HADS) and the Medical Outcomes Study Short Form-36. Patients underwent a gynecological visit with vaginal pH measurement, cervicovaginal swabs, and Pap smears. Disease activity and damage were assessed by the European League Against Rheumatism Sjögren syndrome disease activity and damage indexes.

Results. Patients with pSS showed a pathological mean FSFI score (19.1 ± 7.33) significantly different from controls ($p = 0.004$), both in menstruating women ($p = 0.006$) and in menopausal women ($p = 0.03$). Major differences between the 2 groups were detected in dyspareunia ($p < 0.005$), lubrication ($p = 0.006$), desire ($p = 0.004$), and arousal ($p = 0.018$). The FSFI score was inversely correlated with age ($p = 0.008$) and anxiety HADS ($p = 0.031$). No early anatomical changes, swabs, and Pap smear alterations were revealed in patients with pSS; however, vaginal pH was higher than normal in premenopausal patients (6.0 ± 0.77).

Conclusion. Both premenopausal and postmenopausal women with pSS have a worse sexual quality of life. We reported a greater prevalence of dyspareunia that is statistically significant when compared with controls. The FSFI could be a useful tool to assess this topic, but has been neglected in the care of patients with pSS heretofore. (J Rheumatol First Release July 1 2015; doi:10.3899/jrheum.141475)

Key Indexing Terms:
SJÖGREN SYNDROME FEMALE SEXUAL FUNCTION INDEX FSFI SEXUAL LIFE

Primary Sjögren syndrome (pSS) is a systemic autoimmune disease characterized by chronic inflammation of the exocrine glands, primarily the lacrimal and salivary glands, that leads to signs and symptoms of their dysfunction. Indeed, typical symptoms of pSS are dry eyes and mouth, but other mucosa can also be involved, resulting in a disturbing sicca syndrome that can impair quality of life. In general, patients with pSS experience significant functional disability and have less ability to carry out a wide range of daily activities[1].

As in other autoimmune diseases, pSS predominantly affects women compared to men with a ratio of 9:1, and a higher incidence is observed in peri- and postmenopausal female patients[2].

Even if pSS is considered a "female disease" and a good sexual life is an important factor of global health status, there are few data concerning gynecological and sexual aspects of pSS in the literature.

The first aim of our study was to assess the quality of sexual life of a group of patients with pSS compared with a healthy control group matched for age and hormonal status through a self-administered questionnaire.

A secondary endpoint was to evaluate whether there existed a correlation between disease activity, associated disease damage, and sexual life. The effect of mood disorders on sexual attitude was also evaluated.

Finally, a physical, bacteriological, and cytological examination of genitalia was performed to consider the possible influence of anatomical and/or infectious factors on sexual activity.

From the Department of Internal Medicine and Medical Specialties, Rheumatology Clinic, and Department of Gynecological and Obstetrical Sciences and Urological Sciences, Gynecology Clinic, Sapienza University of Rome; Population Health and Health Determinant Unit, National Centre for Surveillance, Prevention and Health Promotion, National Institute of Health, Rome, Italy.

R. Priori, MD, PhD; A. Minniti, MD; B. Antonazzo, MD; F. Brancatisano, MD; G. Valesini, Professor of Rheumatology, Rheumatology Clinic, Department of Internal Medicine and Medical Specialties, Sapienza University of Rome; M. Derme, MD; M. Framarino-dei-Malatesta, MD, PhD, Gynecology Clinic, Department of Gynecological and Obstetrical Sciences and Urological Sciences, Sapienza University of Rome; S. Ghirini, MSc, Population Health and Health Determinant Unit, National Centre for Surveillance, Prevention and Health Promotion, National Institute of Health.

Address correspondence to Professor G. Valesini, Policlinico Umberto I, Viale del Policlinico 155 - 00161 Rome, Italy. E-mail: guido.valesini@uniroma1.it

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MATERIALS AND METHODS

Study design. This single-center study had a cross-sectional design. Approval was obtained from the Ethical Committee of the university hospital (Policlinico Umberto I, "Sapienza" University of Rome). All participants gave written informed consent. No compensation was paid to the participants.

Twenty-four female outpatients, ages 23–69 years (mean age 50.4 ± 12.0) were consecutively enrolled at the university hospital's Sjögren Syndrome Clinic. Of these patients, 13 were menopausal and 11 were premenopausal. Menopausal and premenopausal state was defined on the basis of medical history. Menopause is defined as the absence of menstrual periods for almost 12 consecutive months.

All had an established diagnosis of pSS according to the American-European Consensus group criteria[3] and all were sexually active (women were classified as sexually active/inactive based on the question: "During the past 4 weeks, have you engaged in sexual activities with your partner?")[4].

At time of enrollment, demographic, clinical, and laboratory data were collected, and disease activity and damage were scored using validated scales [European League Against Rheumatism (EULAR) Sjögren Syndrome Disease Activity Index (ESSDAI)[5], Sjögren Syndrome Disease Damage Index (SSDDI)[6]].

Each patient underwent a gynecological examination assessing vaginal pH by means of specific test strips at the Department of Gynecology-Obstetrics and Urological Sciences of the same university hospital. In menopausal women, vaginal pH is considered to be normal when > 4.5, while a normal pH in premenopausal patients is ≤ 4.5[7]. Vulvovaginal atrophy is diagnosed when 1 or more of the following physical signs are present: pale, smooth, shiny vaginal lining; loss of elasticity; sparse pubic hair; smooth, thin external genitalia; stretching of uterine supportive tissue; and/or pelvic organ prolapse (bulges in the vaginal walls). Because anatomical and/or infectious factors might have an influence on sexual activity, bacteriological and cytological examinations of the genitalia were performed by a Pap test and cervicovaginal swabs to test for common germs, including *Trichomonas vaginalis*, *Chlamydia*, *Neisseria gonorrhoeae*, and *Mycoplasma*.

During the gynecological examination, patients were administered 3 questionnaires, all validated in the Italian language after proper explanation [Female Sexual Function Index (FSFI)[8], Medical Outcomes Study Short Form-36 (SF-36)[9], Hospital Anxiety and Depression Scale (HADS)[10]]. The FSFI is a brief questionnaire that gives a measure of sexual functioning in women; it includes 19 questions divided into 6 domains (desire, arousal, lubrication, orgasm, satisfaction, and pain)[11]. A result is considered pathological when the total score is < 26.554[12]. Higher total or subscale scores indicate better sexual function.

The SF-36 is a multipurpose, short-form health survey with 36 questions divided into 3 principal domains: physical health, general health, and psychological-emotional health. Each question has a score ranging from 0 to 100[13].

The HADS is commonly used to determine the levels of anxiety and depression that a patient is experiencing[14]. It consists of 14 questions, 7 about anxiety and 7 about depression, with a total score ranging from 0 to 21 for either mood disorder. Higher scores represent higher levels of anxiety and/or depression symptoms; the total score is divided into 3 grades: 0–7 (non-case), 8–10 (borderline case), ≥ 11 (case)[15].

We included as controls healthy women who have been admitted to the hospital for routine gynecological examination. Twenty-four healthy women ages 20–65 (mean age 47.0 ± 13.28) were consecutively selected at the Department of Gynecology-Obstetrics and Urological Sciences. Of these, 13 were postmenopausal and 11 were premenopausal. All were sexually active, not using contraceptives or hormone replacement therapy, and not experiencing any rheumatologic disease.

Statistical analysis. Data analysis was performed using IBM SPSS 21.0 release. Statistical tests including Student t test and chi-square test were performed. To identify whether associations existed among FSFI results and disease activity/damage indexes, FSFI results and HADS scores, FSFI results and SF-36 scores, a Pearson correlation was also performed. The threshold significance level was set to 0.05.

RESULTS

Demographic characteristics and hormonal status of cases and controls. Clinical and laboratory data of patients with pSS, including ESSDAI and SSDDI scores, are summarized in Table 1. No significant differences between cases and controls regarding age (p = 0.361), hormonal status (11 menstruating patients and 13 menopausal patients for each group), civil state, parity, or sociocultural status were found. Neither patients nor controls were using contraceptives or hormone replacement therapy. Neither group reported erectile dysfunction in partners.

Gynecological examination. Vaginal dryness and dyspareunia were reported, respectively, in 21 (87.5%) and 19 (79.2%) patients with pSS. Dyspareunia was reported in 8 healthy women (33.3%, p = 0.0009). The complete gynecological examination was normal in menstruating patients with pSS; all menopausal patients showed hypotrophy/atrophy of the external genitalia and the vagina, typical of their hormonal status. Vaginal pH was higher than normal in menstruating patients with pSS (6.0 ± 0.77, normal value ≤ 4.5), while it was normal in the menopausal women (6.5 ± 0.97, normal value > 4.5). Pap testing did not show any significant abnormalities in patients with pSS. Cervicovaginal swabs were positive for low microbial load (less than 1000 colony-forming units of total bacteria) in 11 of 24 cases (45.8%).

Table 1. Rheumatological characteristics of patients with pSS (n = 24). Values are mean ± SD or n (%).

Characteristics	Patients with pSS		
	Premenopausal Patients	Menopausal Patients	Total Patients
n	11	13	24
Mean age, yrs	39.4 ± 7.35	59.8 ± 4.93	50.4 ± 12.00
Positive sialometry*	3 (27.3)	6 (46.2)	9 (37.5)
Swollen salivary glands**	3 (27.3)	1 (7.7)	4 (16.6)
ANA	11 (100)	13 (100)	24 (100)
Anti-SSA and/or anti-SSB	10 (90.9)	7 (53.8)	17 (70.8)
Positive minor salivary glands biopsy***	7 (100)	4 (100)	11 (100)
ESSDAI	2.1 ± 1.47	1.9 ± 2.06	2.0 ± 1.77
SSDDI	1.4 ± 1.21	1.1 ± 1.19	1.21 ± 1.18

* Unstimulated sialometry-positive if less than 1.5 ml/15 min in 3 different determinations. ** Ever experienced swelling of any salivary gland. *** Only 11 patients with pSS underwent a biopsy of minor salivary glands (7 menstruating patients and 4 menopausal patients). The biopsy was considered positive when the number of focus (50 cells/4 mm^2) was ≥ 1. pSS: primary Sjögren syndrome; ANA: antinuclear antibodies; ESSDAI: EULAR Sjögren Syndrome Disease Activity Index; SSDDI: Sjögren Syndrome Disease Damage Index; EULAR: European League Against Rheumatism.

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Questionnaires and disease activity/damage scales. Using the cutoff score of 26.55, 20/24 patients (83.3%) and 9/24 controls (37.5%) were considered to have an impaired sexual function. The mean global FSFI score in patients with pSS was 19.1 ± 7.33; this value, related to a poor quality of sexual life, was significantly lower than in controls (26.1 ± 8.79, p = 0.004). The difference between cases and controls remained highly significant in menstruating women (p = 0.006) and to a lesser extent, in menopausal women (p = 0.032). Taking into account the hormonal status in each group, the mean global FSFI score was lower in menopausal women in both groups with a more significant difference in patients with pSS (menopausal vs premenopausal patients with pSS, p = 0.001) in comparison with controls (menopausal vs premenopausal control women, p = 0.029).

The FSFI domains with a statistically significant difference between cases and controls were pain during sexual intercourse (p < 0.005), lubrication (p = 0.006), desire (p = 0.004), and arousal (p = 0.018). No difference was detected between the 2 groups for orgasm (p = 0.352) or satisfaction (p = 0.069; Table 2).

Mood disorders evaluated by the HADS subscales revealed a pathological level of anxiety in patients with pSS (12.0 ± 4.89) that was statistically significant when compared with healthy controls (6.5 ± 3.09, p < 0.001). Fifteen out of 24 patients with pSS and 4/24 healthy controls scored > 11 for the HADS anxiety, respectively. The OR for the presence of an impaired sexual function in patients with pSS and healthy controls with anxiety was 42 (95% CI 2.0–877.5), while it was 8.33 (95% CI 2.1–32.3) in all women with pSS and healthy women enrolled, with and without anxiety. The mean score on the depression subscale was considered borderline (8.8 ± 3.89), but with a statistically significant difference with the controls mean score (5.3 ± 2.48, p = 0.001).

Patients with pSS had lower scores compared with controls according to the SF-36 physical (43.6 ± 24.59 vs 75.4 ± 15.69, p < 0.001) and mental (41.2 ± 20.8 vs 72.4 ± 15.70, p < 0.001) subscales. The data are summarized in Table 3.

The FSFI global score was inversely correlated to age at enrollment time in cases (p = 0.008) and to the severity of anxiety as recorded by HADS anxiety subscale (p = 0.031), while no correlations were found with SF-36, disease duration, and activity and damage indexes (ESSDAI and SSDDI). In particular, no correlations were detected between FSFI and the constitutional domain and the articular domain of the ESSDAI (r = 0.19, p = 0.35 and r = –0.028, p = 0.89, respectively). No correlations were found between FSFI global score and vaginal pH.

Table 2. FSFI total and domain scores comparison between study group and controls. Values are mean ± SD.

FSFI Total Scores and Domain Scores	Patients with pSS	Healthy Controls	p
FSFI total score	19.1 ± 7.33	26.1 ± 8.79	0.004
FSFI total score in menstruating women	23.8 ± 4.81	30.18 ± 4.92	0.006
FSFI total score in menopausal women	15.0 ± 6.71	22.7 ± 10.00	0.032
Desire	2.7 ± 1.03	3.6 ± 1.13	0.004
Arousal	3.0 ± 1.40	4.1 ± 1.63	0.018
Lubrication	3.1 ± 1.66	4.6 ± 1.84	0.006
Orgasm	3.8 ± 1.65	4.2 ± 1.78	0.352
Satisfaction	4.0 ± 1.63	4.9 ± 1.66	0.069
Pain	2.5 ± 1.89	4.8 ± 1.67	< 0.005

FSFI: Female Sexual Function Index; pSS: primary Sjögren syndrome.

DISCUSSION

In the present article, the prevalence of sexual dysfunction among sexually active women with pSS with partners is investigated and correlated with disease activity and associated clinical features. Sexuality is rarely addressed in quality of life questionnaires or during physician–patient interviews[16], and the topic has been generally overlooked, so far, in the care of rheumatology patients and particularly of women with pSS. Sicca dominates the clinical picture of pSS, and even if this symptom is generally reported only after proper investigation, women with pSS frequently experience vaginal dryness that may lead to dyspareunia. Our study revealed a higher prevalence of vaginal dryness and dyspareunia (87.5% vs 55%, 79.2% vs 61%, respectively) than a previous Italian study[17], where the age of the patients was lower. A significantly impaired sexual function in women with pSS compared with healthy women was demonstrated in our study, where in the majority of cases, the FSFI full-scale score fell under the validated cutoff and under the median full score (27.6) previously reported in an Italian sample recruited in routine gynecological practice[18].

Interestingly, the domains most affected were pain, lubrication, desire, and arousal while the questions about satisfaction and orgasm did not reveal any difference from controls. Lubrication and pain are key problems in pSS even if patients with pSS may have overreported vaginal dryness and pain with intercourse because they were expecting to have these features. However, this finding is consistent with literature suggesting that vaginal dryness and dyspareunia are common among women with pSS, as well as in patients with other connective tissue diseases with an associated SS. Sexual disability is common in many different rheumatic diseases. Tristano[19] found that most of the sexual difficulties experienced by patients with rheumatoid arthritis (RA) are related to disease activity, pain, loss of joint motion, functional disability or fatigue, and sexual dysfunction seemed particularly frequent in patients with RA with an associated SS[16]. The effect of systemic lupus erythematosus (SLE) on sexuality has been studied as well, and a mild sexual dysfunction was described with decreased lubrication

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Table 3. SF-36 physical and mental results and HADS results for anxiety and depression. Values are mean ± SD.

Questionnaires	Patients with pSS	Healthy Controls	p
SF-36			
Physical functioning	59.2 ± 28.16	80.2 ± 23.84	0.008
Physical role functioning	32.3 ± 38.64	89.6 ± 19.39	< 0.001
Bodily pain	46.2 ± 26.66	66.3 ± 25.63	0.011
General health perceptions	36.6 ± 22.06	65.7 ± 17.22	< 0.001
Vitality	32.5 ± 20.16	56.9 ± 18.11	< 0.001
Social role functioning	51.9 ± 26.55	78.9 ± 16.39	< 0.001
Emotional role functioning	32.6 ± 37.60	83.2 ± 27.94	< 0.001
Mental health	47.7 ± 19.31	70.8 ± 13.11	< 0.001
Physical health total score	43.6 ± 24.59	75.4 ± 15.69	< 0.001
Mental health total score	41.2 ± 20.8	72.4 ± 15.70	< 0.001
HADS			
Anxiety	12.0 ± 4.89	6.5 ± 3.09	< 0.001
Depression	8.8 ± 3.89	5.3 ± 2.48	0.001

SF-36: Medical Outcomes Study Short Form-36; pSS: primary Sjögren syndrome; HADS: Hospital Anxiety and Depression Scale.

and dyspareunia[20]. Women with SLE have lower frequency of sexual activity, probably because of vaginal discomfort or pain during intercourse[21]. Bhadauria, *et al*[22] demonstrated that vaginal dryness, ulcerations, and dyspareunia were more common in patients with systemic sclerosis (SSc) than in controls, leading to an impaired sexual function. Schouffoer, *et al*[23], using the FSFI questionnaire in women with SSc, obtained significantly lower values for the global and subscales scores (lubrication, orgasm, arousal, and pain) compared with healthy controls. Considering worse lubrication and increased pain during sexual intercourse, it is reasonable to suppose that such alterations may have a negative effect on desire. Moreover, it is well known that chronic disorders and pain may exert adverse effects on sexual desire and activity[24]. However, according to our results, pain during intercourse does not seem to impair the ability to feel satisfaction and reach orgasm. In a previous study, it was also reported that the frequency of intercourse was not affected by dyspareunia[25]. In the same report, half of the patients had an obvious etiology for dyspareunia (trauma or inflammation) not related to pSS. On the contrary, no peculiar anatomic abnormalities, infections, or relevant cytological abnormalities could explain dyspareunia in our group of patients. In a study by Maddali Bongi, *et al*[26], more than 80% of 62 patients with pSS self-reported a reduced frequency of sexual intercourse because of gynecological symptoms (dryness and dyspareunia), with impaired pleasure and satisfaction. However, in that study, women were older than our patients, with more than 87% in menopause. Further, the patients did not undergo a gynecological examination, and a healthy control group was not given the same questionnaire about quality of sexual life.

In our present study, as expected, age and menopause seem to affect the quality of sexual life; FSFI global score is worse in menopausal women compared to premenopausal women in both the patient and control groups. All menopausal patients with pSS showed hypotrophy or atrophy of the external genitalia and the vagina, features typical of their hormonal status, which might be in part responsible for an impairment of sexual quality of life. In fact, the association between vulvovaginal atrophy and avoiding intimacy, loss of libido, and dyspareunia has been reported before[27,28]. However, sexual dysfunction seems somewhat more relevant in premenopausal patients with pSS because the difference in FSFI global score between cases and controls was more striking in premenopausal women in comparison with menopausal women. Regarding the psychological aspects, mood and sexual life show a bidirectional relationship. An unsatisfactory sexual life could lead to mood disorders and vice versa; depression and anxiety have been found to significantly affect sexual functioning in women. In our study, the patients showing a higher level of anxiety also had a worse quality of sexual life as assessed by FSFI global score, and anxiety is associated to a higher OR for sexual dysfunction; however, it is hard to ascertain which comes first. No associations were found between disease activity, damage, or disease duration, and the quality of sexual life. Nevertheless, it has to be stressed that in this cohort of patients, disease activity (as scored by ESSDAI) was relatively low. A future objective of research in this field will be the correlation between the quality of sexual life and the EULAR Sjögren Syndrome Patient Reported Index, which is a validated index designed to measure patients' symptoms in pSS[29,30].

One limitation of our study is that the selection only of sexually active patients did not allow us to address the question of whether women with pSS are less sexually active than healthy ones because of their disease. Therefore, the extent of sexual dysfunction might actually be underestimated. A control group with a different rheumatologic or chronic disorder was not considered in our study; this drawback might make it difficult to sort out the effect of chronic disease on sexual function and to ascertain whether it is the disease itself or the chronicity that plays a role. However, patients' sexual health is generally neglected[23], and to our knowledge, our study is the first to compare sexual function in patients with pSS with that of healthy controls using validated tools. The results of our present investigation may contribute to a better understanding of the effect of the disease on a patient's well-being and promote the discussion of sexuality in autoimmune diseases. Specific efforts are needed to develop beneficial approaches for targeting pain and lubrication problems, and to improve overall sexual functioning among women with pSS. FSFI could be a useful tool for assessing responses to potential treatments for dry vagina and its consequences. Among such drugs, oral pilocarpine and cevimeline, which have shown the same efficacy in relieving oral dryness[31,32], might be considered.

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