FİZİKSEL TIP VE REHABİLİTASYON BİLİMLERİ DERGİSİ
Journal of Physical Medicine and Rehabilitation Sciences J PMR Sci. 2021;24(3):231-7

ORİJİNAL ARAŞTIRMA ORIGINAL RESEARCH

DOI: 10.31609/jpmrs.2020-80845

Frequency of Fibromyalgia in Patients with Sjögren's Syndrome and its Effect on Disease Severity

Sjögren Sendromu Olan Hastalarda Fibromiyalji Sıklığı ve Hastalık Şiddetine Etkisi

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ABSTRACT Objective: This study aims to determine the frequency of fibromyalgia syndrome (FMS) among patients with primary Sjögren's syndrome (pSS), and the relationship between FMS and the parameters indicating disease activity. **Material and Methods:** Fifty patients with a diagnosis of Sjögren's syndrome, aged 18-75, were included in this prospective, cross-sectional study. The demographic characteristics of the patients, regular medications and the routine erythrocyte sedimentation rate (ESR) values measured when they came for examination were recorded. The 2013 American College of Rheumatology (ACR) fibromyalgia criteria were applied to all patients and the EULAR Sjögren's Syndrome Patient Reported Index (ESSPRI) was applied to evaluate Sjögren's syndrome disease activity. The frequency of patients diagnosed with FMS according to the 2013 ACR criteria was calculated. The patients were divided into 2 groups according to whether they had FMS or not. The ESSPRI scores and ESR were statistically analyzed between the groups. **Results:** FMS was detected in 42% of 50 patients with pSS. The mean ESSPRI score and scores for the fatigue and pain parameters were significantly higher in patients with FMS ($p<0.05$), while no significant difference was found in the dryness parameter ($p>0.05$). The mean ESR was significantly higher in patients with FMS ($p<0.05$). **Conclusion:** The results of this study show that FMS is seen at a high rate in patients with pSS and this may negatively affect the disease activity. We think that clinicians should be aware of the possible relationship between FMS and pSS and the need to treat both conditions simultaneously.

Keywords: Primary Sjögren's syndrome; fibromyalgia; EULAR Sjögren's Syndrome Patient Reported Index; disease activity; erythrocyte sedimentation rate

ÖZET Amaç: Bu çalışma, primer Sjögren sendromu (pSS) olan hastalarda fibromiyalji sendromu (FMS) sıklığını ve FMS ile hastalık aktivitesini gösteren parametreler arasındaki ilişkiyi belirlemeyi amaçlamaktadır. **Gereç ve Yöntemler:** Bu prospektif, kesitsel çalışmaya, 18-75 yaşları arasında Sjögren sendromu tanısı almış 50 hasta dâhil edildi. Hastaların demografik özellikleri, düzenli kullandıkları ilaçlar ve muayeneye geldikleri zaman ölçülen rutin eritrosit sedimantasyon hızı (ESH) değerleri kaydedildi. Tüm hastalara 2013 Amerikan Romatoloji Koleji [American College of Rheumatology (ACR)] fibromiyalji kriterleri uygulandı ve Sjögren sendromu hastalığı aktivitesini değerlendirmek için EULAR Sjögren's Sendromu Hasta Bildirim İndeksi [EULAR Sjögren's Syndrome Patient Reported Index (ESSPRI)] uygulandı. 2013 ACR kriterlerine göre FMS tanısı konan hastaların sıklığı hesaplandı. Hastalar FMS olup olmamasına göre 2 gruba ayrıldı. Gruplar arasında ESSPRI skorları ve ESH istatistiksel olarak analiz edildi. **Bulgular:** pSS'li 50 hastanın %42'sinde FMS tespit edildi. Yorgunluk ve ağrı parametreleri skorları ve ortalama ESSPRI skoru FMS'li hastalarda anlamlı olarak yüksekti ($p<0,05$), kuruluk parametresinde anlamlı bir fark bulunmadı ($p>0,05$). Ortalama ESH, FMS'li hastalarda anlamlı olarak daha yüksekti ($p<0,05$). **Sonuç:** Bu çalışmanın sonuçları, pSS'li hastalarda FMS'nin yüksek oranda görüldüğünü ve bunun hastalık aktivitesini olumsuz etkileyebileceğini göstermektedir. Klinisyenlerin FMS ile pSS arasındaki olası ilişkinin ve 2 durumu aynı anda tedavi etme ihtiyacının farkında olmaları gerektiğini düşünmekteyiz.

Anahtar Kelimeler: Primer Sjögren sendromu; fibromiyalji; EULAR Sjögren's Sendromu Hasta Bildirim İndeksi; hastalık aktivitesi; eritrosit sedimentasyon hızı

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Peer review under responsibility of Journal of Physical Medicine and Rehabilitation Science.

Received: 27 Dec 2020 ***Received in revised form:*** 31 Mar 2021 ***Accepted:*** 06Apr 2021 ***Available online:*** 12 Apr 2021

Primary Sjögren's syndrome (pSS) is an autoimmune rheumatic disease that affects primarily the exocrine glands.[1] pSS is characterized by lymphocytic infiltration of the lacrymal and salivary glands, and can cause a wide spectrum of conditions, from dry eye, dry mouth and widespread bodily pain to mild neurological disorders and peripheral neuropathies.[2,3] Sjögren's syndrome, caused by immune-mediated glandular involvement, predominates the clinical picture, accompanied by fatigue, musculoskeletal pain and other systemic manifestations in a significant percentage of patients.[4]

Fibromyalgia syndrome (FMS) is a common cause of chronic, widespread musculoskeletal pain, with a prevalence of 2-7% reported in the general population.[5-7] Patients often present with fatigue and sometimes with ocular dryness and dry mouth.[5-10] In some patients, FMS may accompany rheumatic diseases.[8,9,11,12] There have been studies in literature evaluating the prevalence of FMS in patients with pSS, although they have yielded variable results, with prevalence rates as high as 55%. Recent studies, however, have reported a prevalence rate of FMS in the 12-31% range among patients with pSS.[13-16]

While there is a wealth of studies reporting on the association between FMS and pSS, there have been fewer studies evaluating the effect of FMS on disease activity in patients with pSS. These studies have mostly focused on determining disease activation through the use of patient-based questionnaires; and only one study aimed to evaluate disease activity based on erythrocyte sedimentation rate (ESR).[14]

The present study seeks to determine the frequency of FMS among patients with pSS, and to evaluate the relationship between FMS and clinical parameters, laboratory parameters and the parameters indicating disease activity. The present study hypothesizes that FMS may increase disease activity in patients with Sjögren's disease.

MATERIAL AND METHODS

PATIENTS

This cross-sectional study was approved by the University of Health Sciences Bursa Yüksek İhtisas Training and Research Hospital Clinical Research Ethics Committee (date: 04.07.2018, no: 2011-KAEK-25 2018/07-41) and conducted in the physical therapy and rehabilitation and rheumatology clinics. This study was performed in compliance with the principles of the 2008 Declaration of Helsinki. Seventy patients diagnosed with pSS according to the American-European Consensus Group criteria were evaluated for eligibility for the study.[17]

INCLUSİON CRİTERİA

1) Age 18-75 years, 2) Diagnosed with pSS by salivary gland biopsy and by the American-European Consensus Group criteria.

Exclusion Criteria

1) Presence of a mental disorder, 2) Presence of a chronic condition, such as diabetes mellitus, hypertension, hypothyroidism or kidney insufficiency, 3) Pregnancy, 4) Patients undergoing therapy with duloxetine, anti-depressants, anti-psychotic medications or pregabalin, 5) Presence of another rheumatic disease, 6) Patients diagnosed with FMS and using medication for FMS, 7) Patients with myofascial pain syndrome, polyneuropathy, chronic fatigue syndrome, metabolic and inflammatory myopathies.

Of the 70 initial patients, 20 failed to meet the exclusion criteria, and were excluded, and the remaining 50 patients were included in the study (Figure 1). All participants were informed of the study procedure and all signed a written informed consent form. The patients underwent a physical examination for inflamed and painful joints, muscle weakness, dry skin, rashes, and swollen lymph nodes, and the demographic characteristics of the patients such as age, gender, and duration of illness, regular medications they used for pSS and ESR that measured at final visit were recorded. All patients were administered the Pain Location Score (PLS) and the Symptom Impact Questionnaire (SIQ) for evaluation according to the 2013 American College of Rheumatology (ACR) Fibromyalgia criteria, and the EULAR Sjögren's Syndrome Patient Reported Index (ESSPRI) was adminsitered to evaluate Sjögren's syndrome disease activity.

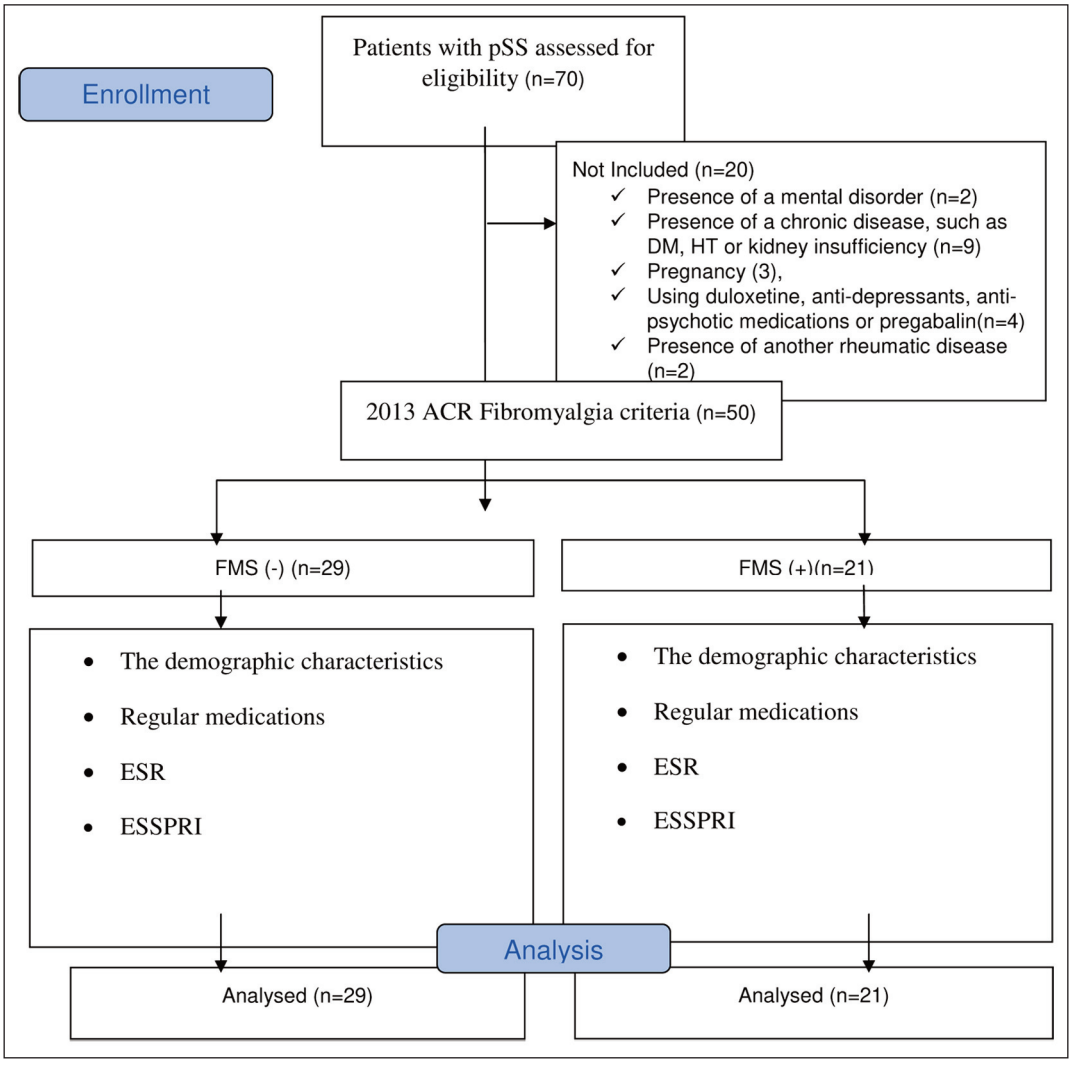

FIGURE 1: Flow chart of the study.

pSS: Primary Sjögren's syndrome; DM: Diabetes mellitus; HT: Hypertension; ACR: American College of Rheumatology; FMS: Fibromyalgia syndrome; ESR: Erythrocyte sedimentation rate; ESSPRI: The EULAR Sjögren's Syndrome Patient Reported Index.

EVALUATION PARAMETERS

2013 ACR Fibromyalgia Diagnostic Criteria: Due to the low sensitivity and specificity of the 1990 fibromyalgia diagnostic criteria, the ACR Alternative Diagnostic Criteria, which evaluates a higher number of areas for pain and grades patient symptoms on a larger scale, was adopted for the study. The scale, published by Benett et al. in 2013, comprises a PLS and a SIQ. Patients with symptoms and pain duration of at least three months, a PLS of ≥17 and a SIQ score of ≥21 are considered to have FMS. The PLS is based on an evaluation of pain in 28 areas over the preceding 7 days, with a total possible score range of 0-28 points. The SIQ score is calculated based on the score in a total of 10 items, including pain, energy, stiffness, sleep, depression, memory problems, anxiety, tenderness to touch, balance problems, sensitivity to loud noises, bright light, odors and cold over the preceding 7 days. Each item is scored 0-10 points, with a total possible score range of 0-100 points The final SIQ score is the total score divided by 2.[18]

The ESSPRI: The ESSPRI is a patient-reported index addressing the domains of dryness (ESSPRI-1), fatigue (ESSPRI-2) and pain (ESSPRI-3), and was designed to evaluate symptom severity in patients with pSS. The global description of fatigue was ob-

tained by asking the patient to rate symptom severity on a 0-10 numerical scale.[19] This instrument was validated by Seror et al. in 2015.[20]

ESR: The ESR is measured by the Westergren method using ALS 100 device (2016 Turkey).

Fifty patients included in the study were divided into two groups, as those with and those without FMS, according to the 2013 ACR criteria. Statistical analysis was performed to evaluate the differences in demographic characteristics, laboratory findings, drugs used for Sjögren's syndrome, ESSPRI scores and sedimentation rates between the two groups.

STATISTICAL ANALYSIS

For the analysis of the study data, demographic characteristics were evaluated using descriptive statistics. A Shapiro-Wilk test was used to evaluate whether or not the data were normally distributed. An independent samples t test was used to compare normally distributed data between the groups and mean±standard deviation (SD) values were analyzed. A Mann-Whitney U test was used to compare data without normal distribution and median (minimum-maximum) values were calculated. Fisher's exact test was used to compared categorical data between the groups. Pearson correlation test was used for correlation analysis. Then multiple regression analysis was applied. A p value of less than 0.05 was considered statistically significant. The data was analyzed using IBM SPSS 22.0 statistical software.

RESULTS

While PLS ≥17 was detected in 22 patients, SIQ ≥21 was detected in 42 patients. However, according to the 2013 ACR criteria, because the patients who were both together were diagnosed with FMS, 21 of the patients had met the criteria. Therefore, 21 patients (42%) were diagnosed with FMS (Table 1). The demographic characteristics linked to the presence or absence of FMS are presented in Table 2. There was a statistically significiant difference in age between the patients with and without FMS (age was greater in patients with FMS) ($p<0.05$), whereas there was no significant difference in terms of gender, disease duration or the medications received ($p>0.05$) (Table 2).

TABLE 1: The frequency of fibromyalgia syndrome and PLS and SIQ scores in patients with pSS.

	Patients with pSS (n=50)
PLS	14.36±7.28
SIQ score	47.90±22.87
PLS ≥17, n (%)	22 (44%)
SIQ score ≥21, n (%)	42 (84%)
Frequency of fibromyalgia syndrome, n (%)	21 (42%)

mean±SD; pSS: Primary Sjögren Syndrome; PLS: Pain Location Score; SIQ: Symptom Impact Questionnaire.

TABLE 2: Comparison of the demographic characteristics and the medications used by primary Sjögren syndrome patients with and without FMS.

	FMS (-) (n=29)	FMS (+) (n=21)	p value
Age (year)	49.03±13.56	56.33±7.98	0.032*
Gender (F/M) (%)	28/1 (96.6%/3.4%)	20/1 (95.2%/4.8%)	0.817
Disease duration (month)	16 (0-181)	17 (0-192)	0.694
ANA (+) (1/320) (n/%)	23 (79.3%)	17 (81%)	0.887
SSA +	17 (58.6%)	12 (57.1%)	0.918
SSB +	6 (20.7%)	9 (42.9%)	0.095
RF + (>20)	7 (24.1%)	8 (38.1%)	0.293
Drugs			
HQ	23 (79.3%)	16 (576.2)	0.795
Corticosteroids	12 (41.4%)	12 (57.1%)	0.276
Azathioprine	3 (10.3%)	2 (9.5%)	0.925

*p value of less than 0.05 was considered statistically significant; Mean±SD and Median (min-max).
The Independent Samples t-test and Fisher's exact test were used; FMS: Fibromyalgia syndrome; F: Female; M: Male; ANA: Anti-nuclear antibodies; RF: Rheumatoid factor; HQ: Hydroxychloroquine.

The mean ESSPRI score and scores for the fatigue and pain parameters were significantly higher in patients with FMS ($p<0.05$), while no significant difference was found in the dryness parameter ($p>0.05$) (Table 3). The mean ESR was significantly higher in patients with FMS ($p<0.05$) (Table 3).

A correlation analysis of the FMS and ESSPRI scores, sedimentation values of all participants revealed a statistically significant correlation between all parameters ($p<0.05$) (Table 4). In the regression analysis, a statistically significant effect was found in the sedimentation, ESSPRI 3 and ESSPRI mean values of FMS (Table 5).

TABLE 3: Comparison of the ESSPRI scores and sedimentation rates of primary Sjögren syndrome patients with and without FMS.

	FMS (-) (n=29)	FMS (+) (n=21)	p value
ESSPRI-1 (Dryness)	5 (0-10)	7 (0-10)	0.059
ESSPRI-2 (Fatigue)	6 (0-10)	9 (4-10)	***0.045****
ESSPRI-3 (Pain)	6 (0-10)	9 (4-10)	***<0.001****
ESSPRI (Mean)	6.33 (1-10)	8.67 (4.67-10)	***0.003****
Sedimentation	28 (11-84)	45 (9-94)	***0.011****

*p value of less than 0.05 was considered statistically significant; Median (min-max). The Mann-Whitney U test was used; FMS: Fibromyalgia syndrome; ESSPRI: The EULAR Sjögren's Syndrome Patients Reported Index.

DISCUSSION

The frequency of FMS was found high in patients with pSS. Furthermore, a significant association was detected between FMS and disease activity. To the best of our knowledge, there has to date been few studies evaluating FMS in patients with pSS and its association with disease activity.

pSS and FMS are two conditions with common symptoms, such as dry mouth and eye, fatigue and pain. There have to date been few studies evaluating the association between FMS and pSS. The rate of co-occurrence ranged between 6.9% and 57% in the initial studies, whereas recent studies have reported lower rates of co-occurrence. In a study investigating the prevalence of FMS in multiple rheumatic diseases, FMS was diagnosed in 12% of 25 patients with pSS.[14] In a Spanish population, Torrente-Segarra et al. reported that FMS was present in 14.6% of the patients with pSS.[16] The two studies mentioned above, however, used 1990 ACR Fibromyalgia Diagnostic criteria, which has been the subject of controversy due to the absence of 18 tender points described in 25% of patients, the absence of a marker indicating disease severity, and the absence of symptoms such as fatigue, sleep disorder and cognitive impairment. Consequently, new diagnostic criteria were published in 2010 that were revised in 2013.[21] In a study using the 2010 ACR diagnostic criteria, FMS was found to be present in 28% of 69 patients with pSS.22 Using alternative diagnostic criteria published in 2013, the present study reports the presence of FMS in 42% of pateints with pSS. The authors consider that the differences between the studies may be attributed to the use of different diagnostic criteria.

There have been very few studies evaluating the effect of FMS on the symptoms and activity of pSS. Fatigue has been the most commonly studied symp-

TABLE 4: Correlation of FMS and ESSPRI scores, sedimentation in all participants.

	ESSPRI 1 (Dryness)	ESSPRI 2 (Fatigue)	ESSPRI 3 (Pain)	ESSPRI (Mean)	Sedimentation
FMS r value	0.274	0.309	0.522	0.435	0.347
p value	***0.027****	***0.015****	***<0.001****	***0.001****	***0.007****

*p value of less than 0.05 was considered statistically significant; Pearson correlation test was used; FMS: Fibromyalgia syndrome; ESSPRI: The EULAR Sjögren's Syndrome Patients Reported Index.

TABLE 5: Examining the variables affecting with FMS by multiple regression analysis.

		Unstandardized coefficients		Standardized coefficients		
Model		**Beta**	**Standard error**	**Beta**	**t value**	**p value**
1	(Constant)	-0.436	0.206		-2.114	0.040
	ESSPRI-1	0.013	0.021	0.086	0.607	0.547
	ESSPRI-2	-0.012	0.030	-0.066	-0.405	0.688
	ESSPRI-3	0.088	0.029	0.491	0.021	***0.004****
	ESSPRI mean	0.088	0.026	0.435	3.350	***0.002****
	Sedimentation	0.007	0.003	0.298	2.471	***0.017****

*p value of less than 0.05 was considered statistically significant; Multiple regression analysis was used; FMS: Fibromyalgia syndrome, ESSPRI: The EULAR Sjögren's Syndrome Patients Reported Index.

tom. In a study involving 106 patients diagnosed with PSS, fatigue was reported in 30.2% of patients, and it was stated that depression, neurotism and FMS play a major role in fatigue related to pSS.[23] In another study, fatigue was found to be significantly more common in cases with both pSS and FMS.[14] In a study of 437 patients with pSS, fatigue was reported in 87% of patients with concurrent FMS, in comparison to 58% of patients with pSS but without concurrent FMS. The same study reported a higher rate of fatigue in the presence of FMS among patients with pSS.16 The present study used the second domain of the ESSPRI to evalute fatigue, the level of which was found to be higher in the presence of FMS in patients with PSS, and these findings are consistent with those of other studies.

It has been stated that the fatigue in patients with PSS is related to psychological factors.[24,25] Pain, helplessness and depression can cause fatigue, and pain is a common symptom for both pSS and FMS.[24] Koh et al. found a significant correlation between fatigue and pain in patients with pSS.[26] In a study by Torrente-Segarra et al., the level of pain was found to be significantly higher in patients with pSS and concurrent FMS.[16] The present study also reports higher pain levels among patients with pSS and concurrent FMS.

In a study in literature evaluating the presence of dry skin and mucosa in the co-existence of FMS and pSS, no significant difference was reported in favor of dry mouth, whereas dry skin was significantly more common in the presence of FMS and pSS.[16] The present study found no significant difference between patients with and without FMS. The lack of a separate evaluation of dryness for the mucosa and skin can be regarded as a limitation of the present study. There have been few studies addressing this subject, and so there is a need for more comprehensive research.

Our review of literature revealed only one study evaluating disease activity in FMS-pSS using ESR. In that study, ESR was found to have no significant effect on the co-existence of FMS and pSS in 25 patients with pSS.[16] The authors consider, however, that such a result may be attributable to the small number of patients in their study, and the detection of FMS in only 12% (3 patients) of patients. The present study identified significantly higher ESR values in patients with pSS and concurrent FMS, which may be due to the larger sample size and the detection of FMS in 42% of patients with pSS. Furthermore, the pathogenesis of FMS is unknown, and consequently, no specific therapy is advised. Primary treatment is currently limited to symptom management. There are studies suggesting that the underlying undetermined autoimmune process may be the cause of the pathogenesis, although this has yet to be elucidated. According to these studies, the high levels of such autoimmune markers as anti-nuclear antibodies detected in these patients support this theory.[27] The authors suggest that these autoimmune processes may be the cause of the significantly higher ESRs in patients with PSS and concurrent FMS. However, in a comparison of patients with and without FMS, the higher ESRs found in those with FMS may have been linked to the significantly higher age in this group of patients. However, the statistically significant correlation between ESSPRI scores, sedimentation rates and FMS supports the authors' opinion that autoimmune processes could be effective.

LIMITATIONS

The small number of patients in the present study, and the lack of discrimination between mucosal and skin dryness, may be regarded as limitations of the present study. The study may also be limited by the lack of balance of the age factor between patients with and without FMS. The main focus of our study, however, was to determine the frequency of FMS among patients with pSS, and so adjusting for the age factor would have disrupted the content of the study.

CONCLUSION

The present study reports a frequency rate of 42% for FMS among patients with pSS, according to the 2013 FMS alternative diagnostic criteria. Fatigue and pain scores and ESR values were higher in patients with pSS and concurrent FMS. The authors therefore consider that FMS may negatively affect disease activity in patients with pSS. The authors sug-

gest that clinicians should be aware of the possible association between FMS and pSS, and the need to treat the two conditions simultaneously. There is a need for more comprehensive studies involving a larger number of patients in order to evaluate disease activity in the presence of co-existing FMS and pSS.

Source of Finance

During this study, no financial or spiritual support was received neither from any pharmaceutical company that has a direct connection with the research subject, nor from a company that provides or produces medical instruments and materials which may negatively affect the evaluation process of this study.

Conflict of Interest

No conflicts of interest between the authors and / or family members of the scientific and medical committee members or members of the potential conflicts of interest, counseling, expertise, working conditions, share holding and similar situations in any firm.

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