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ORIGINAL ARTICLE

Quality of Life and Psychological Status in Patients With Primary Sjögren's Syndrome and Sicca Symptoms Without Autoimmune Features

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Objective. **To compare pain, fatigue, and sicca symptoms; quality of life; and psychological status between patients with primary Sjögren's syndrome (SS) and those with sicca symptoms but no autoimmune features (sicca asthenia polyalgia syndrome [SAPS]), and to determine whether a psychological pattern can be detected in patients with SAPS, which could suggest psychological distress as the cause.**

Methods. **This cross-sectional, prospective study included 111 patients with primary SS according to the American-European Consensus Group criteria and 65 SAPS patients with no focus on lip biopsy and no anti-SSA/SSB antibodies. Pain, fatigue, and sicca symptoms were assessed using visual analog scales; quality of life was assessed using the Short Form 36 (SF-36); and psychological distress by the Symptom Checklist-90-Revised (SCL-90-R) questionnaire.**

Results. **No difference was observed between primary SS and SAPS patients for pain, fatigue, sicca symptoms, quality of life, and psychological status. Fatigue and pain, but not dryness, were correlated with both quality of life and psychological distress in both groups. For primary SS patients, physical and mental composite scores on the SF-36 correlated well with global severity index (GSI) scores of the SCL-90-R ($r = -0.29$, $P = 0.006$ and $r = -0.61$, $P < 0.0001$, respectively).**

Conclusion. **Patients with primary SS and SAPS do not differ in quality of life or psychological status. Although both diseases probably have a different origin, they may require the same psychological support or psychiatric care. The strong correlation between the composite physical and mental scores of the SF-36 and the GSI scores of the SCL-90-R in primary SS patients emphasizes the importance of the psychological dimension in results of the SF-36.**

KEY WORDS. Sjögren's syndrome; Quality of life; Depression; Anxiety.

INTRODUCTION

Ocular and oral dryness are frequent and disabling symptoms. Medical investigations proposed for patients reporting ocular and oral dryness not due to drug side effects usually involve clinical examination; blood tests, including the assessment of anti-SSA/SSB autoantibodies; and a labial salivary gland biopsy to diagnose autoimmune diseases such as primary Sjögren's syndrome (SS) and secondary SS, sarcoidosis, amyloidosis, or lymphoma. For patients with ocular and oral dryness with no apparent cause and no features of autoimmunity (no evidence of autoantibodies and focus score <1 on lip biopsy), dry eyes and mouth syndrome (DEMS) (1) or sicca asthenia polyalgia syndrome (SAPS) (2) are proposed. Patients with DEMS/SAPS could have heterogeneous etiology such as salivary gland atrophy with aging, incomplete subclinical primary SS, or fibromyalgia (3). Indeed, as the name indicates, patients with SAPS often report polyalgia and chronic fatigue. Patients with definite autoimmune primary SS also frequently report polyalgia and fatigue. Therefore, it can be difficult in clinical practice to differentiate between the 2 conditions.

The consequences of primary SS and SAPS symptoms

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Table 1. Demographic and clinical data of patients with primary Sjögren's syndrome (SS) and sicca asthenia polyalgia syndrome (SAPS)*

Characteristic	Primary SS (n = 111)	SAPS (n = 65)	*P*
Sex, no. female/male	102/9	56/9	0.21
Age, years	55.4 ± 13.9	55.5 ± 13.7	0.96
Duration of symptoms, years	10.6 ± 7.2	10.7 ± 8.5	0.94
Employed, %	47.7	44.4	0.87
Pain score (VAS), mm	44.7 ± 33.3	49.8 ± 30.3	0.38
Asthenia score (VAS), mm	62.6 ± 29.8	61.0 ± 31.6	0.78
Ocular dryness (VAS), mm	57.2 ± 31.9	62.5 ± 29.6	0.38
Oral dryness (VAS), mm	57.5 ± 33	53.1 ± 32.7	0.48
Skin dryness (VAS), mm	53.6 ± 27	52.1 ± 34.8	0.82
Vaginal dryness (VAS), mm	43.2 ± 36.3	44.0 ± 35.8	0.91
Tracheal dryness (VAS), mm	42.5 ± 35	29.9 ± 29.5	0.10
Schirmer score, mm/5 minutes	5.4 ± 7.4	10.4 ± 10.1	0.0003
Lissamine green score (0–9)	6.1 ± 2.7	2.9 ± 2.2	< 0.0001
Salivary flow, ml/minute	0.23 ± 0.25	0.28 ± 0.17	0.42
ESR, mm/hour	26.6 ± 26.6	12.4 ± 11.1	0.0001
IgG, gm/liter	14.49 ± 6.88	10.1 ± 2.87	< 0.0001
RF, IU/ml	179.8 ± 477.4	6.01 ± 19.9	0.003
ANA titer	836.4 ± 756.5	77.5 ± 228.5	0.0038
β_2-microglobulin, mg/liter	1.88 ± 0.94	1.49 ± 0.68	0.0057

* Values are the mean ± SD unless otherwise indicated. Statistical analysis was performed using *t*-test, except for sex and employed (chi-square test). VAS = visual analog scale; ESR = erythrocyte sedimentation rate; RF = rheumatoid factor; ANA = antinuclear antibody.

regarding quality of life and psychological state have been seldom studied. Functional scales of quality of life, such as the Medical Outcomes Study 36-Item Short Form Health Survey (SF-36), have now been validated in numerous chronic diseases and have demonstrated decreased health-related quality of life in rheumatic disorders such as systemic lupus erythematosus, rheumatoid arthritis (RA), fibromyalgia, and primary SS (4–6). Data on quality of life in patients with SAPS are scarce; only 2 small studies have assessed quality of life in patients with sicca symptoms without autoimmune features (7,8). The Symptom Checklist-90-Revised (SCL-90-R) is a validated functional scale evaluating psychological disorders (9) that has been used for various chronic diseases such as RA (10) and fibromyalgia (11) and can be used to detect a psychological profile in patients with primary SS or SAPS.

Actually, decreased quality of life and psychological distress could be causes or consequences of SAPS. If psychological distress was the cause of SAPS, a psychological pattern might be detected in these patients. Therefore, we investigated quality of life and psychological symptoms using the SF-36 and SCL-90-R questionnaires in patients with primary SS and SAPS in a cross-sectional prospective study.

PATIENTS AND METHODS

Patients. This prospective study included 187 consecutive patients participating in a multidisciplinary consultation for ocular and/or oral dryness in the Department of Rheumatology of Bicêtre Hospital (Le Kremlin Bicêtre, France) between January 2000 and September 2002. All patients underwent the same investigations: clinical examination, including unstimulated salivary flow obtained during 5 minutes; biologic tests, including detection of anti-SSA/SSB antibodies using commercial enzyme-linked immunosorbent assay (Varelisa, Pharmacia-Upjohn, Germany) confirmed by counterimmunoelectrophoresis; and labial salivary gland biopsy. Patients completed the SF-36 and SCL-90-R questionnaires (see below) at home prior to hospitalization. Most patients rated pain (joint or muscle); fatigue; and ocular, oral, cutaneous, vaginal, and tracheal dryness using a 100-mm visual analog scale (VAS). For each item, the time reference was within the past 7 days.

The patients were divided into 2 subgroups on the basis of clinical and immunologic assessment. The first subgroup comprised patients with primary SS (n = 111) who fulfilled the American-European Consensus Group (AECG) criteria (12), and the second subgroup comprised patients with SAPS (n = 65) who met the following criteria: ocular and/or oral dryness, and asthenia or pain in limbs; absence of nodular infiltrate on labial salivary gland biopsy (Chisholm score <3); absence of anti-SSA/Ro or anti-SSB/La antibodies; and absence of any well-defined connective tissue disease. The mean ± SD age of patients with primary SS and SAPS was 55.4 ± 13.9 and 55.5 ± 13.7 years, respectively (Table 1). A total of 92% of patients with primary SS and 84% of patients with SAPS were women. Eleven patients did not fulfill the primary SS or SAPS criteria for the following reasons: 7 patients had anti-SSA antibodies and 4 had positive salivary gland biopsy results, but none of them met the 4 required criteria for

Table 2. Proportion of patients with primary SS fulfilling the criteria of the American-European Consensus Group (AECG) for SS (12), patients with SAPS, and patients without primary SS according to the AECG but with 1 objective immunologic abnormality*

	Primary SS (n = 111)	SAPS (n = 65)	No primary SS or SAPS (n = 11)	*P*†
Subjective ocular dryness	97.3	95.4	81.8	0.49
Subjective oral dryness	94.6	92.3	90.9	0.56
Schirmer test ≤5 mm/5 minutes	78.5	43.6	18.2	< 0.0001
Lissamine staining ≥4	77.6	37.0	63.6	< 0.0001
Chisholm score 3–4	93.3	0	36.4	–
Decreased salivary flow‡	39.1	20.8	0	0.18
Anti-SSA or anti-SSB antibodies	58.6	0	63.6	–

* Values are the percentage unless otherwise indicated. SS = Sjögren's syndrome; SAPS = sicca asthenia polyalgia syndrome.
† Statistical analysis was performed using chi-square test between primary SS patients and SAPS patients.
‡ Decreased saliva flow ≤0.1 ml/minute studied in only 23 primary SS patients, 24 SAPS patients, and 3 patients with no primary SS and no SAPS.

primary SS or the 3 objective criteria for primary SS (Table 2). These 11 patients were excluded from the main study.

Short Form 36. The SF-36 questionnaire is designed to evaluate health-related quality of life within the previous 4 weeks. It is composed of 36 questions, with 8 scales assessing 2 dimensions. The first dimension is physical health function involving the following 4 scores: physical functioning (the extent to which health interferes with various activities), role-functioning physical (the extent to which health interferes with usual daily activities such as work, housework, and school), bodily pain, and general health. These physical scores are summarized by the physical composite score (PCS). The second dimension is mental health function, which involves the following 4 scores: vitality, social functioning, role-functioning emotional (limitations due to emotional problems), and mental health. These mental scores are summarized by the mental composite score (MCS). Each scale gives a standardized raw score that ranges from 0 to 100, with 0 implying the worst possible health status and 100 the best possible health status. A validated French version of the SF-36 questionnaire was used (13–15). The values of our 2 groups are presented in terms of the SF-36 French general population values for women 45–64 years old (n = 443) (Table 3) (14).

SCL-90-R. The SCL-90-R (9) is a 90-item self-reporting symptom inventory measuring current psychological symptom status during "the past 7 days including today." Each item is rated on a 5-point scale of distress, ranging from 0 (not at all) to 4 (extremely). The scale encompasses the following dimensions: somatization, obsessive compulsive, interpersonal sensitivity, depression, anxiety, hostility, phobic anxiety, paranoid ideation, psychoticism, and various symptoms. Scores for each of the first 9 dimensions are the average rating given to the symptoms for that factor. Three global scores are also obtained: the global severity index (GSI), the positive symptom distress index (PSDI), and the positive symptom total (PST). The GSI is the average rating given to all 90 items and could correspond to the best indicator for the distress level (range 0–4). The PST is the number of symptoms reported, which corresponds to the number of items rated >0. The PSDI is the average rating (range 1–4) given to the symptoms rated >0. A validated French version of the SCL-90-R questionnaire was used (16,17). The values of our 2 groups are presented in terms of the results of 702 consecutive women (mean ± SD age 45 ± 8.8 years) who agreed to complete the SCL-90-R questionnaire during a screening medical consultation proposed by the French social security in the region of Loire, France, during a 2-month period (Table 3) (data extracted from reference 18).

Statistical analysis. Continuous data were expressed as the mean ± SD, and categorical variables were expressed as the percentage. Distribution of continuous values (VAS, SF-36, and SCL-90-R scores), which were evaluated by frequency histograms and normal plots and formally tested by the Shapiro-Wilk W test, was normal. Comparison of mean scores between patients with primary SS and those with SAPS was made using the parametric Student's 2-sided *t*-test for continuous variables. Chi-square test (with Yates' correction, when appropriate) was used to compare qualitative data, expressed as the percentage, between the primary SS and SAPS groups. *P* values less than 0.05 were considered significant. Correlations between the SF-36 and SCL-90-R were analyzed using Spearman's test. Statistical analysis was performed using Microsoft Excel (Microsoft, Redmond, WA) and Analyse-it 1.71 software (Leeds, England).

RESULTS

Demographic and clinical data for patients with primary SS and SAPS. The study included 111 patients with primary SS and 65 with SAPS. Demographic data between

Table 3. Quality of life scores for SF-36 dimensions and psychological symptom status for SCL-90-R dimensions in patients with primary SS and SAPS*

Dimensions	Primary SS	SAPS	*P*†	Normal women‡
SF-36, no.	109	63		443
Physical function	56 ± 27.6	61.6 ± 23.5	0.17	82.1 ± 20.3
Role-functioning physical	30.1 ± 39	39.8 ± 40	0.12	81.8 ± 31.2
Bodily pain	41.8 ± 23.9	42.4 ± 20.9	0.86	69.1 ± 24
General health	33.2 ± 19.2	39.4 ± 19.2	0.04	67.1 ± 18.7
Vitality	38.0 ± 19	38.6 ± 19.2	0.83	58.5 ± 18
Social functioning	50.7 ± 25.3	51.6 ± 24.5	0.82	79.0 ± 22.6
Role-functioning emotional	44.7 ± 40.7	50.5 ± 43.8	0.38	80.5 ± 33.1
Mental health	51.1 ± 20	51.0 ± 18.5	0.97	65.5 ± 17.3
PCS	31.7 ± 12.4	33.8 ± 11.7	0.29	NA
MCS	39.6 ± 11.1	39.0 ± 12.2	0.75	NA
SCL-90-R, no.	101	64		702
Somatization	1.15 ± 0.7	1.23 ± 0.7	0.52	NA
Obsessive compulsive	1.07 ± 0.7	0.96 ± 0.8	0.38	NA
Interpersonal sensitivity	0.59 ± 0.6	0.65 ± 0.6	0.55	NA
Depression	1.02 ± 0.7	0.99 ± 0.8	0.84	NA
Anxiety	0.74 ± 0.6	0.70 ± 0.6	0.72	NA
Hostility	0.58 ± 0.5	0.54 ± 0.6	0.66	NA
Phobic anxiety	0.38 ± 0.5	0.53 ± 0.8	0.16	NA
Paranoid ideation	0.47 ± 0.6	0.50 ± 0.6	0.72	NA
Psychoticism	0.29 ± 0.3	0.31 ± 0.3	0.76	NA
GSI	0.77 ± 0.5	0.78 ± 0.5	0.89	0.76 ± 0.6
PSDI	1.83 ± 0.8	1.86 ± 0.6	0.79	2.41 ± 0.5
PST	40.3 ± 18.4	40.8 ± 18.7	0.86	27.6 ± 17.4

* Values are the mean ± SD unless otherwise indicated. SF-36 = Short Form 36; SCL-90-R = Symptom Checklist-90-Revised; SS = Sjögren's syndrome; SAPS = sicca asthenia polyalgia syndrome; PCS = physical composite score; NA = not available; MCS = mental composite score; GSI = global severity index; PSDI = positive symptom distress index; PST = positive symptom total.
† *P* indicates the statistical significance of the differences between primary SS and SAPS patients, assessed by Student's *t*-test.
‡ French general population values for women 45–64 years old for the SF-36 (n = 443) (14) and women ages 45 ± 8.8 years for the SCL-90-R (n = 702) (data extracted from reference 18).

the 2 groups were similar (Table 1). The mean ± SD age of the patients with primary SS and SAPS was 55.4 ± 13.9 and 55.5 ± 13.7 years, respectively. Likewise, scores for pain, asthenia, or multiple types of dryness did not differ significantly (Table 1). Among the 6 items of the AECG criteria for primary SS, the subjective dryness criteria were fulfilled at the same frequency in both groups (Table 2). An objective measure of oral dryness, studied in only a minority of patients, showed an equally diminished salivary flow: 9 (39.1%) of 23 patients with primary SS and 5 (20.8%) of 24 patients with SAPS ($P = 0.18$). Scores on the Schirmer and/or lissamine green tests (available for 107 of 111 patients with primary SS and 62 of 65 patients with SAPS) were more frequently abnormal for patients with primary SS than for those with SAPS: 84 (78.5%) of 107 and 27 (43.6%) of 62, respectively, for Schirmer's test ($P < 0.0001$) (Tables 1 and 2). Subjective ocular dryness and Schirmer's test were significantly correlated in patients with primary SS ($r = -0.3$, $P = 0.01$ between left or right eye Schirmer's test and ocular dryness VAS) but not in patients with SAPS ($r = -0.17$, $P = 0.2$ and $r = -0.15$, $P = 0.3$ for right and left eye, respectively). Extraglandular involvement, defined as the presence or confirmed records of skin, lung, or neurologic involvement; synovitis; lymphadenopathy; spleen enlargement; or previous lymphoma, was observed in 39 (35.8%) patients with primary SS. Two of these patients (1.8%) had records of central nervous system involvement that corresponded to a history of retrobulbar optic neuritis in the context of primary SS in a 68-year-old woman and lymphocytic meningitis in a 69-year-old man.

Quality of life in patients with primary SS and SAPS. Scores for all dimensions of the SF-36 were available for 100 patients with primary SS and 62 patients with SAPS. For both groups, each of the 8 scales evaluating quality of life was lower compared with the control group (Table 3). The mean ± SD PCS results were 31.7 ± 12.4 and 33.8 ± 11.7 for patients with primary SS and SAPS, respectively ($P = 0.29$), and the mean ± SD MCS results were 39.6 ± 11.1 and 39.0 ± 12.2, respectively ($P = 0.75$). The groups were not significantly different on any dimension of the SF-36 scale, except for general health scores, which were significantly lower for patients with primary SS than those with SAPS (33.2 ± 19.2 versus 39.4 ± 19.2, $P = 0.04$) (Table 3). Among patients with primary SS, no difference in quality of life was observed between patients having (n = 35) versus not having (n = 65) present or previous extraglandular involvement ($P = 0.11$ for PCS, $P = 0.33$ for MCS) or between patients having versus not having anti-SSA/SSB antibodies (anti-SSA antibodies: $P = 0.15$ for PCS, $P = 0.14$ for MCS; anti-SSB antibodies: $P = 0.86$ for

Table 4. Correlation between visual analog scale (VAS) scores for pain, asthenia, and ocular and oral dryness and SF-36 and SCL-90-R global scores in patients with primary SS and SAPS*

	Primary SS			SAPS		
VAS	n	*P*	r	n	*P*	r
Pain						
PCS	59	< 0.0001	−0.49	49	0.006	−0.38
MCS	59	NS	NS	49	NS	NS
GSI	63	0.008	0.33	52	0.005	0.38
Asthenia						
PCS	59	0.0002	−0.46	49	0.04	−0.29
MCS	59	NS	NS	49	0.01	−0.36
GSI	63	0.0006	0.42	52	0.006	0.37
Ocular dryness						
PCS	59	NS	NS	49	NS	NS
MCS	59	NS	NS	49	< 0.0001	−0.56
GSI	63	0.04	0.25	52	NS	NS
Oral dryness						
PCS	59	NS	NS	49	NS	NS
MCS	59	NS	NS	49	NS	NS
GSI	63	NS	NS	52	NS	NS

* Correlation analysis was performed using Spearman's rank correlations. NS = not significant; see Table 3 for additional definitions.

PCS, $P = 0.22$ for MCS). The 11 patients without primary SS according to AECG criteria but with 1 objective immunologic abnormality had mean ± SD PCS and MCS (29.0 ± 16.1 and 36.9 ± 15.6, respectively) comparable with patients with primary SS and SAPS.

Psychological status in patients with primary SS and SAPS. Scores for all dimensions of the SCL-90-R were available for 100 patients with primary SS and 64 patients with SAPS. The mean ± SD GSI results were 0.77 ± 0.49 and 0.78 ± 0.52 for patients with primary SS and SAPS, respectively ($P = 0.89$). The groups did not differ significantly on any dimension (Table 3). The 3 most affected dimensions for both groups were somatization, depression, and obsessive compulsiveness. Patients with SAPS and primary SS, compared with women from the French general population, seemed to have quantitatively more symptoms (using PST results) but equivalent psychological distress (using GSI results) (Table 3). Among patients with primary SS, no difference in psychological status was observed between patients with (n = 35) versus those without (n = 65) previous extraglandular involvement ($P = 0.94$ for GSI) or between patients with versus those without anti-SSA/SSB antibodies (anti-SSA antibodies: $P = 0.84$ for GSI; anti-SSB antibodies: $P = 0.51$ for GSI). The 11 patients without primary SS according to AECG criteria but with 1 objective immunologic abnormality had mean ± SD GSI, PSDI, and PST scores (0.71 ± 0.53, 1.86 ± 0.5, and 35.0 ± 17.2, respectively) comparable with patients with primary SS and SAPS.

Correlations between VAS, SF-36, and SCL-90-R scores in patients with primary SS and SAPS. The MCS of the SF-36 was highly correlated with the GSI of the SCL-90-R results in patients with primary SS (n = 91; $P < 0.0001$, r = −0.61) and those with SAPS (n = 61; $P = 0.0001$, r = −0.47). The PCS of the SF-36 was correlated with GSI results in patients with primary SS (n = 91; $P = 0.006$, r = −0.29) but not in patients with SAPS (n = 61; $P = 0.33$, r = −0.12). For both groups, pain was correlated with PCS and GSI results (Table 4). Fatigue was correlated with PCS and GSI results for patients with primary SS and with PCS, MCS, and GSI score for patients with SAPS (Table 4). Ocular dryness was correlated with GSI results for patients with primary SS and with MCS for patients with SAPS (Table 4). Oral dryness was not correlated with any score in both groups (Table 4).

DISCUSSION

This study assessed quality of life and psychological status by use of validated scales in 2 populations with the same symptoms, which were of autoimmune origin in the primary SS group and of unknown origin in the SAPS group. The extent to which these symptoms were associated with quality of life impairment and psychological status was not significantly different between the 2 groups.

The validity of our results was supported by strong correlations between the MCS of the SF-36 and SCL-90-R in each group, which means that the responses to the questionnaires were consistent. The absence of difference in scores on the 2 questionnaires between patients with primary SS and SAPS could be due to the fact that some patients with SAPS may have an incomplete form of primary SS or may develop primary SS; however, the equal duration of symptoms in both groups does not support this hypothesis. It is unlikely that the lack of difference was due to an insufficient number of patients in each group. Indeed, the current study exploring quality of life and

psychological status in patients with SAPS is the largest published to date.

Decreased quality of life has already been demonstrated in patients with primary SS using the SF-20 questionnaire (6), the SF-36 questionnaire (5,19,20), and the World Health Organization's multicultural quality of life instrument (20). Our patients with primary SS had a relatively poorer quality of life than the patients in the study published by Bowman et al, the largest series in the literature to date (20). Interestingly, in our study, cornerstone symptoms in this population, ocular and oral dryness, did not correlate with SF-36 results. As mentioned, the quality of life in patients with sicca symptoms but no autoimmune features has rarely been studied; a significantly lower quality of life, using the SF-36, has been found in such patients (n = 15) compared with controls (n = 126) and patients with primary SS (n = 90) (7). Likewise, in another study, the same level of alteration in quality of life was found between the so-called "patients with sicca symptoms but without SS" (n = 9) and patients with primary SS (n = 26) (8). Our study, the only one dealing simultaneously with a high number of patients with well-defined SS according to the recent European-American consensus group and a high number of sicca patients without SS, clearly demonstrates that impairment of quality of life assessed by SF-36 is the same in both groups.

Only 1 study involving the SCL-90-R in patients with primary SS demonstrated that such patients (n = 33) were significantly more affected than healthy patients (n = 33) regarding somatization, anxiety, and obsessive compulsiveness, 3 of the most affected dimensions in our primary SS group (21). Depression, one of the highest rated dimensions among patients with primary SS in our study, is a frequently reported condition in this population. Depression was reported more frequently by patients with primary SS (n = 51) than controls (n = 51) in a study involving the Hospital Anxiety and Depression scale (22) and more frequently by patients with primary SS (n = 34) than those with RA (n = 32) in a study involving use of the Psychological Well-Being Index (23). However, anxiety, significantly more frequent in patients with primary SS compared with controls (22) or patients with RA (23), was not among the most affected dimensions in our study of primary SS. To our knowledge, no previous study has assessed psychological status in patients with sicca symptoms and no autoimmune features. The present study is the first to suggest that psychological symptoms are the same between patients with primary SS and SAPS, and not very different from women in the general population. However, these women who were recruited during a screening medical consultation proposed by the French social security were not necessarily free of psychiatric symptoms, because prevalence of depression in France could be up to 20% in women (24,25).

We were not able to identify a psychological profile for patients with SAPS, which could have argued in favor of a psychosomatic origin of this disorder. Indeed, the scores of the somatization dimension were the same in both groups. However, the moderately impaired SCL-90-R scores in both groups, compared with the possible range of results, probably indicate that the psychological distress in both groups was mild and might suggest that the SCL-90-R questionnaire is not be the best tool for this purpose.

VAS scores for fatigue and pain were correlated with both quality of life and psychological distress in both groups. Fatigue in primary SS could be related to other immune markers not examined in this study, and, in general, origin of fatigue in many chronic debilitating diseases is not understood. Regardless, use of the VAS to assess fatigue and pain, which are much easier to realize in a practical way than using the SF-36 or SCL-90-R scales, can be an interesting method to roughly assess quality of life in patients with primary SS. Interestingly, VAS scores for oral dryness and quality of life were not correlated; therefore, oral dryness may not be the most disturbing symptom in these patients. However, the mean ± SD salivary flow (0.23 ± 0.25 ml/minute) was not as low as that reported in the literature. The fact that the unstimulated salivary flow examination was performed in 5 minutes rather than 15 minutes in only 23 patients with primary SS and 24 patients with SAPS could explain this discrepancy. Although the proportion of abnormal Schirmer scores in patients with primary SS was high (78.5%), ocular dryness and quality of life were not correlated. Conversely, in patients with SAPS, even though Schirmer test scores were close to the normal range, ocular dryness and the MCS of the SF-36 were highly correlated ($r = -0.56$, $P < 0.0001$). This observation could reflect a relation between subjective ocular dryness and the mental dimensions of quality of life, which could be specific to patients with SAPS.

Finally, the strong correlations between the MCS and PCS of the SF-36 with the GSI of the SCL-90-R in patients with primary SS emphasize the importance of the psychological dimension of the SF-36. Because this questionnaire is used frequently for various chronic somatic medical conditions, and is included among endpoints of numerous clinical trials, it is important to be aware that it measures principally psychological rather than general well-being. Therefore, it appears to be important to have a specific questionnaire to assess the symptoms of patients with primary SS, such as the Health Assessment Questionnaire for RA (26) or the Bath Ankylosing Spondylitis Disease Activity Index for ankylosing spondylitis (27). Two specific questionnaires, termed Sicca Symptoms Inventory and Profile of Fatigue and Discomfort, were recently developed in the United Kingdom and validated in English, and must be translated and validated in different languages (20,28).

In conclusion, quality of life and psychological status are equally affected and closely related to pain and fatigue symptoms in patients with primary SS and SAPS. Although both diseases probably have a different origin, they may require the same psychological support or psychiatric care.

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