

PROMIS Provides a Broader Overview of Health-related Quality of Life Than the ESSPRI in Evaluation of Sjögren Syndrome

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ABSTRACT. *Objective.* Sjögren syndrome (SS) has a significant impact on health-related quality of life (HRQOL). We sought to evaluate how the Patient Reported Outcome Measurement Information System (PROMIS) domains in SS may supplement the European League Against Rheumatism (EULAR) Sjögren Syndrome Patient Reported Index (ESSPRI).

Methods. A cross-sectional evaluation was performed on consecutive adult patients during visits to an SS clinic between March 2018 and February 2020. Each patient completed PROMIS short forms related to HRQOL and the ESSPRI, and had a clinical assessment. Patients were either classified as SS by 2016 American College of Rheumatology (ACR)/EULAR criteria, or as “sicca not otherwise specified (NOS)” and used as a comparison group. Univariable and multivariable linear regression models were used to evaluate predictors of PROMIS fatigue (-F), pain interference (-PI), and ability to participate in social roles and activities (-APS).

Results. Two hundred twenty-seven patients with SS and 85 with sicca NOS were included and did not differ in ESSPRI domains; 26% of the SS and 20% of the sicca NOS group had concurrent autoimmune disease. In SS, PROMIS-PI, PROMIS-F, and PROMIS physical function were at least one-half SD worse than US population normative values. PROMIS-PI ($r = 0.73$) and PROMIS-F ($r = 0.80$) were highly correlated with ESSPRI pain and fatigue subdomains. Fatigue and pain interference, but not dryness or mood disturbance, were the strongest predictors of social participation in multivariable analysis.

Conclusion. In our SS cohort, PROMIS instruments identified a high disease burden of pain interference, fatigue, and physical function. PROMIS-F strongly predicted PROMIS-APS. PROMIS-PI and PROMIS-F scores correlated highly with their respective ESSPRI domains. PROMIS instruments should be considered to identify relevant HRQOL patterns in SS.

Key Indexing Terms: ESSPRI, fatigue, health-related quality of life, PROMIS, Sjögren syndrome

Sjögren syndrome (SS) is a chronic, systemic autoimmune disease that may negatively affect health-related quality of life (HRQOL).^{1,2,3} It is characterized by its targeting of the salivary and lacrimal glands, leading to the almost uniform presence of ocular and oral dryness symptoms. Systemic symptoms, including fatigue and joint or muscle pain, are also common. The importance of measuring symptoms and effects has been increasingly recognized in patient care and clinical trials in SS.⁴ The Patient Reported Outcome Measurement Information System (PROMIS) provides universal HRQOL instruments but has not

been previously implemented in SS.⁵ Currently, the European League Against Rheumatism (EULAR) Sjögren's Syndrome Patient Reported Index (ESSPRI) questionnaire comprises single-item responses to pain, fatigue, and dryness domains, and is widely utilized in SS.⁶ Our objectives were (1) to evaluate how selected PROMIS domains in SS would compare to US normative values as well as in those with sicca not related to SS; and (2) to correlate specific PROMIS domains with corresponding ESSPRI domains, hypothesizing that strong positive correlations would be present.

We hypothesized that the common SS patient concerns of dryness and fatigue would significantly contribute to an individual's ability to participate in social roles and activities. Successful social participation is presumed to require low symptomatology and physical dysfunction, and may be a surrogate for overall HRQOL status according to Wilson-Cleary biopsychosocial models.⁷ We also expected anxiety and depression levels to be elevated compared to US normative values, based on prior studies from the Sjögren's International Collaborative Clinical Alliance (SICCA) registry and other SS cohorts.^{8,9}

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METHODS

This was a cross-sectional evaluation of consecutive adult patients with suspected and established SS attending a large tertiary care referral center between March 2018 and February 2020. SS was defined by the American College of Rheumatology (ACR)/EULAR 2016 criteria.¹⁰ Patients who were seen for sicca but did not meet SS criteria were included for comparison (referred to as “sicca not otherwise specified [NOS]”). A subset of participants within each group had concurrent autoimmune disease (systemic lupus erythematosus [SLE], rheumatoid arthritis [RA], systemic sclerosis [SSc], antiphospholipid syndrome [APS], inflammatory bowel disease [IBD], celiac disease, idiopathic inflammatory myopathy [IIM], autoimmune hepatitis, Hashimoto disease). Sociodemographic factors including age, sex, race, ethnicity, disease duration, current smoking status, current use of disease-modifying antirheumatic drugs (DMARDs), and current use of antidepressants and anxiolytics were also recorded. The study received ethical approval from the Johns Hopkins Institutional Review Board (NA_0028677). Patient informed consent was waived as this was a retrospective analysis.

Patient-reported outcomes. Patients completed PROMIS short forms (SF; Depression 4a.v1, Anxiety 4a.v1, Fatigue 8a.v1[F], Physical Function 4a.v2 [PF], Pain Interference 8a.v1 [PI], Sleep Disturbance 4a.v1, Ability to Participate in Social Roles and Activities 8a.v1 [APS]). Raw scores were converted to *t*-score measures. PROMIS *t*-scores are normalized to a score of 50 with an SD of 10 in the US population; higher scores indicate more of the domain being measured. A clinically meaningful difference is generally considered one-half SD, or 5 *t*-score units for some domains.⁵ Within RA, clinically meaningful differences range from 3–7 *t*-score units and 1–3 units for minimal change.¹¹ A broader analysis of PROMIS measures using data pooled from 50 studies cites a minimal important change as 2–6 *t*-score units.¹²

The patients also completed the ESSPRI, an index used to assess the key domains of SS including dryness, pain, and fatigue.⁶ Single-item numerical rating scales (0–10) are used to evaluate each domain. The numerical ratings from each domain may be averaged for a total score.

Statistical analysis. Descriptive statistics, including means and proportions, were calculated for disease-related and sociodemographic variables. Pearson correlation was used to evaluate the relationship between subdomains of the ESSPRI and PROMIS. Low correlation was defined as $r < 0.25$, moderate correlation as $r = 0.25–0.49$, and moderate/high correlation as $r > 0.50$.¹³

Univariable and multivariable linear regression models were used to evaluate predictors of PROMIS-F and PROMIS-APS in patients with SS. The models controlled for age, sex, race (White [null], Asian, Native Hawaiian/Pacific Islander, Black, Native American, other), ethnicity (non-Hispanic [null], Hispanic, other), and symptom duration. Standardized β coefficients were reported for the multivariable model, and statistical significance was defined as a $P < 0.05$.

RESULTS

Two hundred twenty-seven individuals met the 2016 ACR/EULAR criteria for SS and completed PROMIS SF and clinical measures. For comparison, we studied 85 individuals with sicca who did not meet SS criteria. Most individuals with SS had anti-SSA antibodies (91%), abnormal Schirmer test (≤ 5 mm/5 min in at least 1 eye; 69%), and low saliva flow by unstimulated whole sialometry (≤ 0.1 mL/min; 41%; Table 1). Of those who had undergone lip biopsy, focal lymphocytic sialadenitis with a focus score of ≥ 1 was present in 59 out of 84 patients with SS (70%). Some participants within the SS group also had concurrent or multiple autoimmune diseases ($n = 58$) including SLE ($n = 17$), RA ($n = 15$), SSc ($n = 5$), APS ($n = 1$), IBD ($n = 6$), celiac disease ($n = 6$), IIM ($n = 3$), autoimmune

hepatitis ($n = 5$), and Hashimoto disease ($n = 16$). There were 19 participants with concurrent fibromyalgia (8%).

The SS group had a median age (IQR) of 59 (47–68) years and was mostly female (93%) and White (82%; Table 1). Most patients with SS were taking hydroxychloroquine (HCQ; 61%), with a smaller subset of patients taking methotrexate (MTX; 11%), rituximab (RTX; 7%), and azathioprine (3%), leflunomide (2%), mostly prescribed for active manifestations of SS. There was a modest number of patients with SS taking anxiolytics (21%) and antidepressants (24%). Median (IQR) ESSPRI scores were 6 (4–7), indicating moderate patient-reported symptom prevalence. Median (IQR) ESSPRI subdomain scores were 5 (2–7) for pain, 6 (5–8) for dryness, and 6 (4–8) for fatigue. For patients with SS, PROMIS-PI, PROMIS-F, and PROMIS-PF scores were at least one-half SD worse than US population normative values. PROMIS scores for APS, sleep disturbance, anxiety, and depression symptoms were within range for US population normative values. Approximately 25% of individuals with SS had anxiety ($n = 57$) and 19% had depression ($n = 42$). Anxiety and depression were defined as *t*-scores > 1 SD higher than US normative values based on previous correlations from psychiatric assessments, the Generalized Anxiety Disorder-7, and the Patient Health Questionnaire-9.^{14,15}

In comparison, those with sicca NOS were slightly younger with a median age (IQR) of 54 (44–63) years, mostly female (92%), and mostly White (81%). A small proportion of patients had positive Schirmer testing (29%), low saliva flow by unstimulated whole sialometry (21%), and SSA antibodies (2.4%). Median (IQR) ESSPRI scores were similar with a score of 6 (4–7), also indicating moderate patient-reported symptom presence. ESSPRI subdomain scores were 5 (3–7) for pain, 6 (4–8) for dryness, and 6 (3–8) for fatigue. Approximately 33% of individuals with sicca NOS ($n = 28$) had anxiety, 25% ($n = 21$) had depression, and 21% had fibromyalgia ($n = 18$). HCQ was prescribed to 38% of patients with sicca NOS and MTX to 9%; other DMARDs were prescribed infrequently. There were 17 participants (20%) who had autoimmune disease in the non-SS group and were prescribed HCQ for undifferentiated connective tissue disease ($n = 7$), inflammatory joint pain ($n = 8$), and fatigue ($n = 4$). Some of the other participants were already taking HCQ prescribed by their former rheumatologist at the time of their initial assessment. Likewise, there were 2 participants taking RTX at the time of their initial assessment, one of whom had Castleman disease. There was similar use of anxiolytics (28%) and antidepressants (28%) in this comparison group. Patients with sicca NOS experienced a significant amount of pain interference > 1 SD higher than US normative values (mean *t*-score 60.3 [SD 12.0]) and significantly higher than the SS cohort. Social participation (mean *t*-score 43.5 [SD 11.7]) and sleep disturbance (mean *t*-score 55.3 [SD 10.6]) were also worse than the SS cohort.

Generally, PROMIS-PI ($r = 0.73$, $P < 0.001$) and PROMIS-F ($r = 0.80$, $P < 0.001$) showed high positive correlation with ESSPRI pain and fatigue subdomains, respectively (Table 2). PROMIS-F had strong positive correlations with PROMIS-PI ($r = 0.68$) and strong negative correlations with

Table 1. Baseline demographic and clinical characteristics of patients who met 2016 ACR/EULAR classification criteria for Sjögren syndrome (SS) compared to those with sicca not otherwise specified (NOS).

	SS, n = 227	Sicca NOS, n = 85	P
Age, yrs, mean (SD)	57 (14)	54 (12)	0.03
Female sex	211 (92)	78 (92)	0.92
Race, White	187 (82)	69 (81)	0.94
Ethnicity, non-Hispanic	220 (97)	82 (99)	0.28
Symptom duration, months, mean (SD)	13.4 (9.3)	10.5 (7.9)	0.01
Lip biopsy, positive ^a	59/84 (70)	3/80 (3)	< 0.001
Anti-SSA antibody positive	206 (90)	2 (2.4)	< 0.001
Schirmer test (< 5 mm/5 min)	156 (68)	25 (29)	< 0.001
Salivary flow (< 0.1 mL/min)	93 (41)	18 (21)	< 0.001
Current medication use			
Hydroxychloroquine	139 (61)	32 (38)	< 0.001
Methotrexate	25 (11)	8 (9)	0.69
Leflunomide	5 (2)	3 (4)	0.51
Azathioprine	6 (3)	1 (1)	0.44
Rituximab	15 (7)	2 (2)	0.14
Anxiolytic	47 (21)	24 (28)	0.15
Antidepressant	54 (24)	24 (28)	0.41
Concurrent autoimmune disease	58 (26)	17 (20)	0.27
ESSPRI, median (IQR)			
Total (0–10)	6 (4–7)	5 (4–7)	0.89
Pain (0–10)	5 (2–7)	5 (3–7)	0.43
Dryness (0–10)	6 (5–8)	6 (4–8)	0.39
Fatigue (0–10)	6 (4–8)	6 (3–8)	0.56
PROMIS global t-score, mean (SD)			
Pain interference	56.9 (11.0)	60.3 (12.0)	0.02
Physical function	44.2 (9.8)	41.6 (9.0)	0.36
Fatigue	57.2 (10.6)	59.7 (13.2)	0.08
Social participation	46.9 (10.8)	43.5 (11.7)	0.02
Sleep disturbance	52.2 (10.2)	55.3 (10.6)	0.02
Anxiety	52.7 (12.0)	54.7 (12.2)	0.18
Depression	49.1 (11.1)	50.8 (13.3)	0.24

Values are expressed as n (%) unless otherwise specified. Values in bold are statistically significant. ^a Positive lip biopsy defined as focal lymphocytic sialadenitis; of note, 63% of patients with SS and 11% with sicca NOS did not have a completed lip biopsy. ESSPRI: European League Against Rheumatism (EULAR) Primary Sjögren's Syndrome Patient Reported Index; PROMIS: Patient Reported Outcome Measurement Information System.

Table 2. Correlation between ESSPRI domains and PROMIS domains in patients with Sjögren syndrome.

	ESSPRI Total	ESSPRI Pain	ESSPRI Fatigue	ESSPRI Dryness	PROMIS Pain Interference	PROMIS Physical Function	PROMIS Fatigue	PROMIS Social Participation	PROMIS Sleep Disturbance	PROMIS Anxiety	PROMIS Depression
ESSPRI Total	1.00										
ESSPRI Pain	0.83	1.00									
ESSPRI Fatigue	0.85	0.63	1.00								
ESSPRI Dryness	0.70	0.31	0.40	1.00							
PROMIS Pain interference	0.67	0.73	0.58	0.27	1.00						
PROMIS Physical function	-0.45	-0.48	-0.36	-0.23	-0.49	1.00					
PROMIS Fatigue	0.66	0.53	0.80	0.24	0.68	-0.44	1.00				
PROMIS Social participation	-0.66	-0.57	-0.71	-0.29	-0.72	0.52	-0.85	1.00			
PROMIS Sleep disturbance	0.45	0.45	0.42	0.19	0.45	-0.10	0.46	-0.46	1.00		
PROMIS Anxiety	0.32	0.28	0.32	0.17	0.43	0.01	0.36	-0.36	0.45	1.00	
PROMIS Depression	0.35	0.32	0.34	0.16	0.39	-0.04	0.38	-0.40	0.47	0.67	1.00

ESSPRI: European League Against Rheumatism (EULAR) Primary Sjögren's Syndrome Patient Reported Index; PROMIS: Patient Reported Outcome Measurement Information System.

PROMIS-APS ($r = -0.85$). PROMIS-PI had strong negative correlations with PROMIS-APS ($r = -0.72$) and moderate negative correlations with PROMIS-PF ($r = -0.49$; Table 2). PROMIS anxiety and depression had strong positive correlations ($r = 0.67$) with each other but not with other PROMIS domains including pain interference, fatigue, and social participation.

In univariate analysis, age, sex, race, ethnicity, and symptom duration did not significantly predict PROMIS fatigue, pain interference, or social participation (results not shown). In our multivariable linear regression model, pain interference, sleep disturbance, physical function, and social participation were significantly associated with fatigue after controlling for age, sex, race, and symptom duration (Table 3). Fatigue, sleep disturbance, physical function, and social participation were also significantly associated with the pain interference domain. Finally, fatigue was the strongest predictor of the ability to participate in social roles and activities in our multivariable regression model, followed by pain interference and physical function. Dryness, anxiety, and depression symptoms did not significantly predict pain interference, fatigue, or social participation in this cohort of patients. Our results did not differ when excluding those patients with concurrent autoimmune disease. In subset analysis of patients with SS with anxiety ($n = 57$), depression ($n = 42$), and anxiety and/or depression ($n = 68$), anxiety and depression were not significant predictors of fatigue, pain interference, or social participation (Supplementary Table 1, available from the authors on request). Fatigue and physical function remained the strongest predictors for social participation.

DISCUSSION

The primary goal of this study was to provide a better understanding of how patient-reported symptoms from highly reliable and well-validated universal PROMIS questionnaires reflect the SS disease state and correlate with the ESSPRI, the standard SS patient-reported outcome questionnaire. We found strong correlations between questionnaires: a strong positive

correlation was noted between both PROMIS-F and ESSPRI fatigue, and PROMIS-PI and ESSPRI pain. A PROMIS dryness questionnaire does not exist.

Our secondary goal was to investigate predictors of pain, fatigue, and social participation using PROMIS measures in this SS cohort. We found that fatigue has a strong negative correlation with social participation. Pain interference and physical function also significantly contributed to the explained variance in our models. We hypothesized based on prior work in our RA cohort that anxiety and depression symptoms would also positively correlate with fatigue.¹⁶ However, fatigue appeared to be strongly correlated with pain intensity and interference, and less so with mood disturbance. Surprisingly, dryness was not found to be a significant predictor of pain interference, fatigue, or social participation as was hypothesized based on prior literature and anecdotal experience.⁹ We do note that of the participants analyzed, there were a number with comorbid autoimmune disease, including inflammatory arthritis as well as fibromyalgia that may have contributed to the strong influence of pain interference on fatigue and social participation. The proportion of individuals with concurrent autoimmune disease between groups was similar ($P > 0.05$).

Looking at our SS and sicca NOS cohorts in totality, anxiety and depression symptoms were within US population normative values, contrary to previous literature.⁹ However, anxiety and depression, defined as a t -score > 1 SD higher than US normative values, were present in a moderate proportion of our SS cohort—25% and 19%, respectively. Unexpectedly, anxiety and depression symptoms contributed a minor and nonsignificant amount to the explained variance in our fatigue, pain interference, and social participation models. Even in a subset analysis of SS patients with anxiety (PROMIS t -scores > 60), depression (PROMIS t -scores > 60), or both, mood disturbance did not significantly predict these key domains (Supplementary Table 1, available from the authors on request). This reinforces fatigue as perhaps the most pressing SS symptom limiting the ability to

Table 3. Multivariable analysis of predictors for fatigue, pain, and social participation after controlling for age, sex, race, ethnicity, and symptom duration.*

QOL Domain	Fatigue		Pain Interference		Social Participation	
	β	P	β	P	β	P
Age	-0.11	0.004	-0.10	0.05	-0.06	0.10
Sex	-0.005	0.89	-0.03	0.47	0.02	0.64
Race	-0.06	0.09	0.09	0.06	0.008	0.83
Ethnicity	0.01	0.79	-0.04	0.37	-0.01	0.76
Symptom duration	-0.002	0.96	0.004	0.92	-0.02	0.56
Fatigue	–	–	0.41	< 0.001	-0.61	< 0.001
Pain interference	0.43	< 0.001	–	–	-0.19	< 0.001
Sleep disturbance	0.16	0.005	0.15	0.008	-0.05	0.25
Anxiety	0.10	0.10	0.04	0.48	-0.01	0.76
Depression	0.04	0.51	0.10	0.11	-0.06	0.17
Physical function	-0.22	< 0.001	-0.31	< 0.001	0.14	0.001
Social participation	-0.86	< 0.001	-0.34	< 0.001	–	–
Dryness	0.02	0.62	0.05	0.28	-0.04	0.21

* Standardized β reported. QOL: quality of life.

engage with others. This finding represents a large patient care gap necessitating future research and possibly novel pharmacologic and nonpharmacologic adjunctive management strategies.

We also investigated the utility of PROMIS measures to adequately differentiate between cohorts of patients with similar clinical characteristics (ie, SS compared to sicca NOS; Table 1, PROMIS global). Individuals with SS had significantly less pain interference and sleep disturbance compared to those with sicca NOS. Those with SS also reported their social participation significantly higher than those with sicca NOS. Generally, HRQOL domain scores were better in our SS cohort compared to the sicca NOS cohort, consistent with prior studies from the SICCA registry.⁸ ESSPRI domains were not significantly different between SS or sicca NOS groups, highlighting the added benefit of a broader HRQOL assessment for differentiation between similar patient populations. We found that the PROMIS profile provides a more granular overview of patient-reported symptoms and function, allowing for comparisons to population normative values and other diseases. Given these results, development of a PROMIS dryness instrument should be considered in future research if a single questionnaire profile were to be administered. While the Profile of Fatigue and Discomfort–Sicca Symptoms Inventory offers a more detailed assessment of sicca symptoms in both short and long forms, it also lacks domains related to mood and social function.¹⁷

This study has several strengths, including use of a well-characterized SS cohort with many patients from a tertiary referral center. Major limitations of the study include lack of clinical data, specifically the EULAR Sjögren's Syndrome Disease Activity Index, which may affect HRQOL. Detailed clinical data regarding reasons for immunomodulatory/immunosuppressant therapy were unavailable. The majority of patients in our SS cohort were seropositive and received immunosuppressive therapy for active systemic (mostly cutaneous and musculoskeletal) manifestations. Some patients with SS were already on immunosuppressive therapy at the time of their initial assessment at our referral center. Further, this is a cross-sectional analysis, which limits our ability to predict long-term trends in HRQOL throughout the disease course. Additionally, the cohort consisted of mostly White females, limiting generalizability across different sexes, races, and ethnicities.

In conclusion, PROMIS-PI and PROMIS-F scores had strong correlations with respective ESSPRI domains in our SS cohort. Pain interference and fatigue were found to significantly predict the ability to participate in social roles and activities. Contrary to prior literature, anxiety and depression symptoms were not significant predictors of pain interference, fatigue, and social participation, and were within range of US population normative values. Given the ability of PROMIS instruments to identify HRQOL domains of high impact on patients with SS beyond those ascertained through ESSPRI, these questionnaires should be considered as a supplement when evaluating patients with SS in clinical care and trials.

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