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Patient-reported outcome measures in patients with systemic lupus erythematosus with or without concurrent fibromyalgia

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Abstract

Objective. Patients with systemic lupus erythematosus (SLE) often have concomitant fibromyalgia (FM) or similar symptoms including chronic pain, fatigue, or depression. This study explored whether Patient-Reported Outcomes Measurement Information System (PROMIS) measures provide richer information than 2016 American College of Rheumatology (ACR) FM criteria survey.

Methods. Patients with SLE in our convenience cohort were categorized into groups: 1) concurrent FM chronic pain, 2) concurrent non-FM chronic pain, and 3) no chronic pain using 2016 ACR FM Survey. Based on PROs in the FM Survey, we captured comparable PROMIS measures (e.g., depression, fatigue). Associations by pain group were tested using Kruskal-Wallis rank sum test, Shapiro-Wilk normality test, chi-squared test, or Fisher's exact test. Violin plots explored differences across groups.

Results. The cohort (n=181) included 31 patients with FM pain, 23 with non-FM chronic pain, and 127 with no chronic pain. Median PROMIS symptom scores (fatigue, sleep disturbance, pain intensity and interference, depression) were highest and cognitive function lowest in the FM group, despite 13% being in remission. There were significant differences on 4 PROMIS measures (cognitive function, fatigue, pain intensity, pain interference) between FM pain and non-FM pain

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Author contributions

All authors earned authorship according to ICMJE guidance:

- Substantial contributions to the conception or design of the work; or the acquisition, analysis, or interpretation of data for the work; AND
- Drafting the work or reviewing it critically for important intellectual content; AND
- Final approval of the version to be published; AND
- Agreement to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

Ethical considerations

The NYU Grossman School of Medicine Institutional Review Board approved this study. Consent to participate was obtained in writing from all participants.

groups ($p < 0.02$), the former being worse. There were no significant differences in SLE Disease Activity Index (SLEDAI) score.

Conclusion. SLE patients with non-FM chronic pain have similar symptoms to FM compared with SLE patients without chronic pain; however, symptoms are not as severe as those meeting FM criteria. PROMIS measures may be used to classify severity more precisely for disease categorization and management.

Keywords

patient-reported outcome measures; pain; fibromyalgia; lupus

Background.

Patients with systemic lupus erythematosus (SLE) often have concomitant fibromyalgia (FM) or symptoms similar to FM, including chronic pain, fatigue, sleep disturbance, and/or depression, which are potentially distinct from immune-mediated disease activity and comprise Type 2 SLE symptoms,(1) “a prototypical nociplastic pain syndrome consisting of widespread pain in four of five specific body regions, with concurrent symptoms, including fatigue, sleep disturbance, memory problems, lack of concentration, and depression.”(2) Recent work showed that about one in six patients with SLE fulfill the 2016 classification criteria for FM(2, 3) (i.e., concurrent fibromyalgia), while nearly the same proportion reported chronic pain that does not qualify as a FM diagnosis such as osteoarthritis, and 65% had no pain.(4)

Changes in pain, co-occurring symptoms, and functional status are associated with rheumatologic conditions, making measurement of validated patient-reported outcome measures (PROs) critical for tailoring care and understanding trends in quality of life and associated clinical factors.(5) However, studies of SLE and FM vary by PRO measures, making comparability challenging.(6–10) Capturing and analyzing PROs can help identify potential interventions to improve quality of life, disease management, and survival in patients with rheumatologic conditions. In particular, manifestations of lupus affect physical function, fatigue, pain, and other PROs,(11, 12) potentially affecting survival.(13, 14)

This study explored patterns of symptoms using Patient-Reported Outcomes Measurement Information System (PROMIS)(15) measures to more deeply phenotype symptomatology, function, and quality of life in patients with SLE who may or may not have FM, particularly to expand on assessments with the 2016 American College of Rheumatology (ACR) FM criteria. This approach builds on previously published studies that sought to discern typologies of SLE that extend beyond classical clinical findings.(1, 16, 17) The goal was to understand how PROMIS measures might vary by pain group and whether there might be additional value of wider score ranges and more granular scores for disease identification, characterization, and management, including whether PROMIS measures might serve as potential alternatives to classify symptom clusters in a population with SLE who may or may not have laboratory results or physician assessment indicative of SLE activity. This was approached by comparing patient-reported responses to the FM criteria survey around the

same time as the NIH PROMIS PROs in a cohort of SLE patients seen in an outpatient setting.

Methods.

Population.

The convenience sample is a subset of NYU Lupus Cohort participants previously described who completed the 2016 FM Criteria Survey (n=316 of 524 total approached) (4). In a separate study and consenting process, a different group of 270 completed at least one PROMIS measure, which were only available in English during the study period. All participants were 18 years or older recruited between September 2022 and March 2023 during an in-person, routine rheumatology visit; they all fulfilled at least one SLE classification criteria according to the attending rheumatologist: ACR revised classification, (18) European Alliance of Association for Rheumatology/ACR classification,(19) or SLICC classification.(20)

Data.

The Fibromyalgia Criteria Survey included questions on depression, fatigue, pain, sleep, and cognition. Participants also responded to at least one NIH PROMIS measure that overlap in concept with the FM survey (i.e., Emotional Distress – Depression, Fatigue, Pain Intensity, Pain Interference, Sleep Disturbance, and Cognitive Function – Abilities) within 90 days of the FM Criteria Survey and in-person visit. (See Table 1.) The FM Criteria Survey screens out respondents who do not have chronic pain and then distinguishes between a diagnosis of FM or non-FM chronic pain with yes/no and categorical response options.(2) Patients can report any chronic pain in at least 4 of 5 regions for 3 or more months on the Widespread Pain Index (WPI) and had FM symptoms present at a “similar level for at least 3 months” on the Symptom Severity Scale (SSS).(2) If patients reported $WPI \geq 7$ for pain and $SSS \geq 5$ for symptoms, they were classified with FM, as were patients with WPI of 4–6 and $SSS \geq 9$. PROMIS scores were captured through Computer Adaptive Testing (CAT) items and are considered “normal” at the median of 50, standard deviation of 10, and range of 20–80, with “worse” symptoms yielding scores over 50 and “worse” function yielding scores lower than 50.(15, 21) A clinically important difference is approximately two points for patients with SLE. (22) The recall for the FM questions is 3 months, whereas it is 7 days for PROMIS measures; we allowed up to 90 days between FM survey and PROMIS responses. Ultimately, the FM Criteria Survey delineated three groups of patients with SLE who had 1) FM, 2) non-FM chronic pain, or 3) no chronic pain. By rules of the survey, for those in the third group, the Widespread Pain Index (WPI) and the Symptom Severity Score (SSS) were not completed. The results of the FM survey have been previously published.(4)

For this subsetting sample, patients who answered at least one PROMIS measure were slightly younger (median 39 years vs 44 years, $p=0.007$) than those who did not. STROBE cohort reporting guidelines were used.(23) The PROMIS measures were only available in English for the study, excluding anyone who could not complete in English. In addition to patient-reported measures, we obtained demographic information on age, sex, self-reported race allowing for multiple choices including “other”, and ethnicity

(Hispanic or not). We also calculated the number of days between PROMIS and FM survey administration. SLEDAI score (categorized as <4, 4–7, 8–12, >12), Systemic Lupus International Collaborating Clinics (SLICC) damage index, DORIS (“Definition of Remission in SLE”) remission status (with prednisone≤5mg) and FM Criteria Survey responses were obtained during an in-person, standard-of-care visit with the rheumatologist. At the same time, the SLEDAI clinical score was recorded and the full SLEDAI score calculated when laboratory results were returned. These data were then used to define the status of DORIS remission. SLICC damage was completed yearly.” The study was approved by the New York University Grossman School of Medicine Institutional Review Board.

Analytic Methods.

The Kruskal-Wallis rank sum test was performed for continuous variables across the three pain groups, because none of the continuous variables were distributed normally, based on the Shapiro-Wilk normality test. Chi-squared tests were applied for categorical variables for overall differences across pain groups. Violin plots explored differences across the three defined pain groups. Where comparisons were made only between two groups, FM pain and non-FM chronic pain groups, the Fisher’s exact tests for categorical variables was applied; due to small cell sizes within FM survey response options, associations were explored between FM and PROMIS measure values nonparametrically using Kruskal-Wallis rank sum tests with a Bonferroni correction. Complete cases were analyzed. All statistical tests were two-sided and conducted in R statistical software (R Foundation for Statistical Computing, Vienna, Austria).

Results.

The final sample of 181 patients came from the 316 patients who completed the FM questionnaire who also completed at least one PROMIS measure (57%). The sample was 89% female, 34% Black/African American, 19% Asian, 29% white, and 23% Hispanic, and with a median age of 39 years. Of the total 181 patients, 30% (n=54) had chronic pain “more days than not during the last 3 months” and continued to complete the FM questionnaire (Supplementary figure 1). The cohort included 31 (17%) with FM, 23 (13%) with non-FM chronic pain, and 127 (70%) with no chronic pain.

There were no significant differences by pain group in demographic characteristics, days between PROMIS and FM survey administration, SLEDAI score, or SLICC damage index score. However, of those in DORIS remission, there were proportionately more persons in the no pain group ($p=0.017$); DORIS remission was achieved in 32% ($n=40/127$) of those without chronic pain versus 13% ($n=4/31$) and 17% ($n=4/23$) in those with FM and non-FM chronic pain, respectively.(Table 2) The absolute number of days between FM survey and PROMIS responses showed no significant differences in PROMIS scores by days between surveys (mean 1.4 days, median 0 days; $p>0.13$, data not shown).

Overall, FM Criteria Survey questions on fatigue and memory issues were significantly different between the two chronic pain groups (i.e., categorized by the FM Criteria Survey as those with chronic pain, with or without fibromyalgia, $n=54$)($p<0.02$). PROMIS scores for cognitive function were similar for the two chronic pain groups (41.2 for FM pain group

and 41.4 for non-FM pain), while there appears to be a trend toward more severe “memory issues” in the FM pain group (74% of FM group ranking a 2 or 3 on memory issues and 39% of non-FM chronic pain group).(Table 2)

When comparing all three groups (n=181; FM, non-FM chronic pain, and no chronic pain) by PROMIS scores for fatigue, sleep disturbance, cognitive function, and depression, these measures were significantly different across the three groups ($p<0.001$), with the FM group consistently having higher symptom and lower function scores, the non-FM chronic pain group in the middle, and the no chronic pain group having the lowest symptoms and highest function scores. (See Table 2; Figure 1; Supplementary figure 2.) The pattern also held for PROMIS pain intensity and pain interference scores ($p<0.001$). Exploratory pairwise tests suggested that both FM and non-FM pain groups were significantly different from the no-pain group on all PROMIS measures. The FM and non-FM pain groups were not significantly different by PROMIS measures, except for PROMIS fatigue and pain interference scores.

The FM survey and PROMIS score response trends were concordant. Exploratory analyses suggested that among participants completing the FM survey, the PROMIS depression score median was higher at 60.5 for those reporting depression (i.e., moderate depression for PROMIS) versus 53 for those not reporting depression ($p<0.001$). Unlike the dichotomized FM response categories for depression, fatigue, sleep, and memory, measures on the FM survey ranged 0–3. As FM survey responses for fatigue worsened from 0–3, the PROMIS fatigue score also worsened (median=59 to median=68, $p<0.001$); those rating a 2 or 3 on the FM survey reported moderate fatigue according to PROMIS scores. As FM survey responses for “waking unrefreshed” worsened from 0–3, the PROMIS sleep disturbance score also worsened (median=54 to median=64, $p<0.001$); PROMIS scores indicated moderate sleep disturbance for FM survey responses of 2–3. Finally, as the FM survey response for “memory issues/lack of concentration” worsened from 0–3, PROMIS cognitive function scores worsened (median=48 to median=36, $p<0.001$) from normal to moderate symptoms according to PROMIS.

Discussion

As demonstrated here, the overlapping PROMIS patient-reported measures for pain, depression, fatigue, sleep disturbance, and cognitive function are strongly associated with the 2016 FM criteria survey questions and show statistically significant differences among patients by pain group and directional trends as might be expected. Using a disease-independent PRO measurement tool, such as PROMIS, would allow for exploration and definition of patient subtypes across a wider array of measures than the FM Criteria Survey, potential development of a screening tool, advancement of FM research, and further study of the impact of medications and other interventions for patients with rheumatic conditions and secondary FM, a highly prevalent condition in patients with rheumatic diseases.(2, 3)

In SLE, there has been a recognition of two classes of symptoms: Type 1 or typical inflammatory symptoms, and Type 2 or symptoms more closely related to FM.(1, 16, 17) In most studies of Type 2 SLE, there is differentiation between a patient who meets concurrent

FM criteria or has isolated and infrequent Type 2 symptoms. As there may be two or more separate, underlying processes occurring, it would be helpful to define these patient groups as also meeting FM criteria or having Type 2 symptoms without FM. This cross-sectional study revealed Type 2 lupus symptoms exist in patients with SLE who report chronic pain, regardless of whether they meet criteria for concurrent FM. These symptoms are not associated with SLEDAI activity or SLICC damage score and may represent a distinct entity, as others have suggested.(5) While SLE patients with FM have more prominent Type 2 symptoms, the presence of similar symptoms in the non-FM chronic pain group raises important questions regarding pathophysiology. It may be beneficial to study these groups separately as it is not clear if the Type 2 symptoms in lupus patients with non-FM chronic pain and lupus patients with FM represent two or more separate underlying processes. Other work has shown PROMIS scores can be used to identify distinct patterns of Type 2 symptoms in patients with SLE (5); our study expands on that to explore trends in scores for other PROMIS measures in a SLE cohort that includes diagnosed FM patients; adding measures may help identify other classes of symptoms/function typologies in future work.

Our study shows that SLE patients with non-FM chronic pain also have symptoms common to FM, such as fatigue, sleep disturbance, and cognitive issues, more often than SLE patients without chronic pain, but they do not have these symptoms as severely as those meeting FM criteria. Studies have been addressing the optimal tool to measure Type 2 symptoms for research purposes.(5, 16) We propose PROMIS measures as an appropriate instrument to gauge and address Type 2 SLE, because PROMIS measures show more variation and nuance between SLE patients in pain with and without FM; further, computer-adaptive testing tools make survey completion quicker and tailored to each patient.(24) It has been postulated that FM can develop in patients with inflammatory disease that is not well controlled.(4) That our patients in DORIS remission were more likely to be in the no-pain group supports this hypothesis. However, the most interesting group to be explored longitudinally are those in DORIS remission who have FM. Patients may have different underlying pathophysiology, and it will be important to distinguish between these when studying treatment options and symptom changes.

This study has limitations, including recall period differences, definitional differences, and small cell sizes for some responses. Both the FM survey and PROMIS measures are point-in-time surveys that have different recall periods (i.e., in the last week vs. the last 3 months). The FM survey asks questions with yes/no or 0–3 response ranges, while PROMIS yields scores ranging from 20–80. In particular, a yes/no response on the FM survey gives no information about severity (e.g., mild, moderate, severe); in some cases, a “no” or “0” response may be due to the absence of a formal diagnosis (e.g., depression). The PROMIS pain measures are conceptually different from those in FM, with the latter primarily focused on the number of body parts and locations that hurt persistently over 3 months while the former asks about pain interference and intensity. Of note, small numbers may contribute in part to observed differences identified between groups and make robust conclusions regarding associations between FM survey response and PROMIS scores challenging. The study environment yielded a broadly representative cohort of patients who have SLE in an urban setting.

To further understand differences in disease manifestation and patient experiences of their health condition that may be reflective of differential pain and disease processes and treatment effects, study results suggest integrating externally-validated PROs that are sensitive to changes in health status, such as PROMIS measures. Future work should incorporate PROMIS measures into studies to understand nuanced trends and symptom severity over time, because such measures can highlight meaningful and quantifiable changes in outcomes(21) and potentially identify new, more complete symptom classification that goes beyond laboratory results or physician classification.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

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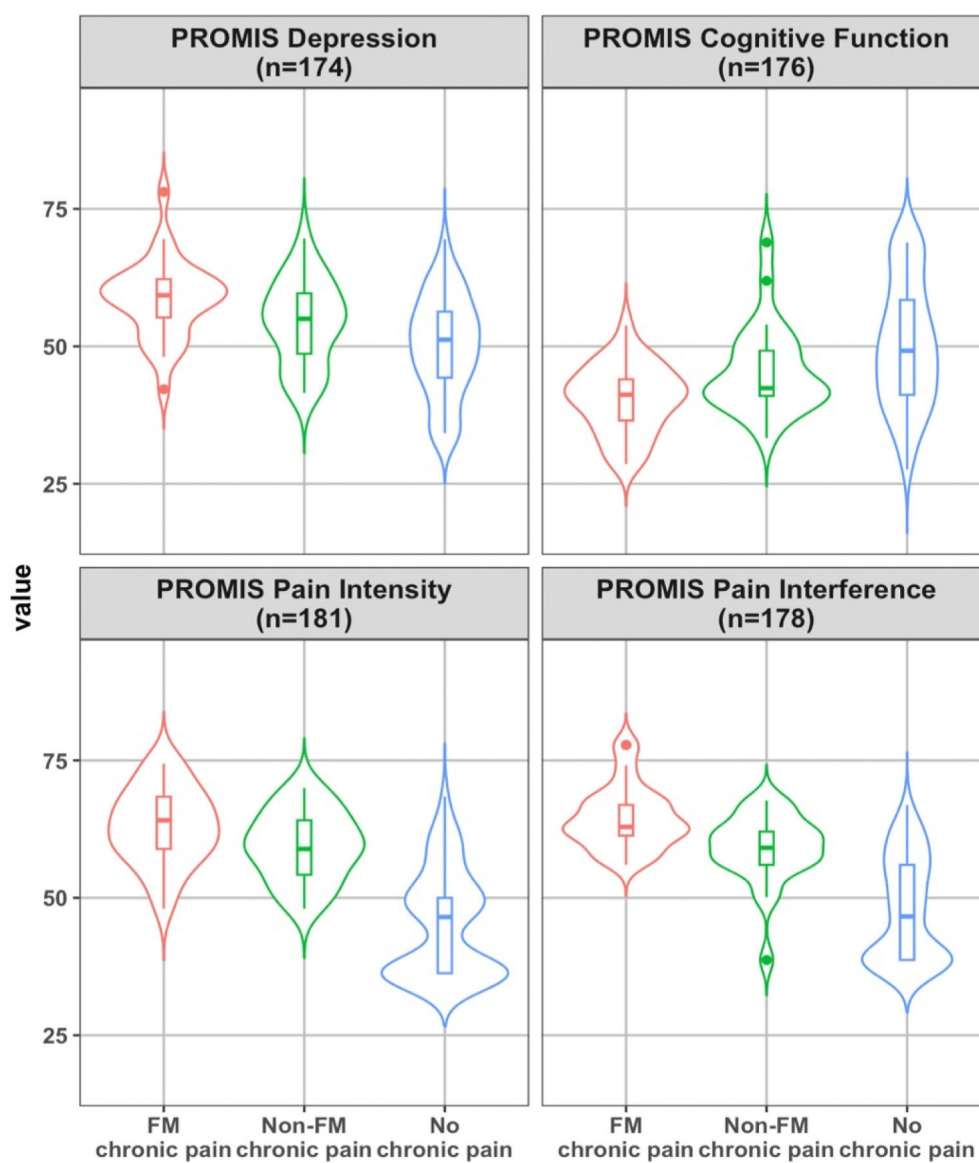


Figure 1. Comparison of selected PROMIS patient-reported outcome scores by chronic pain group: fibromyalgia (FM) pain, non-FM chronic pain, and no chronic pain

Table 1.

Comparable patient-reported measures across surveys

PROMIS measures (median=50, score range 20–80)	Fibromyalgia (FM) criteria survey questions
PROMIS Emotional distress – Depression	Depression (yes/no)
PROMIS Cognitive Function – Abilities	Memory issues/concentration (0–3)
PROMIS Fatigue	Fatigue (0–3 scale)
PROMIS Pain Intensity	Pain (location, more than 50% of time, headaches, pain/cramps in lower abdomen)
PROMIS Pain Interference	
PROMIS Sleep Disturbance	Waking unrefreshed (0–3)

Note: FM survey questions answered only by participants with chronic pain.

Table 2.

Characteristics of patient cohort with lupus among three groups: concurrent fibromyalgia (FM), non-FM chronic pain, and no chronic pain, n=181

	Overall	FM	Non-FM chronic pain	No chronic pain	P value
n (%)	181	31 (17)	23 (13)	127 (70)	
Age (median [IQR])	39 [30.0, 48.0]	37 [29.0, 47.8]	42 [35.0, 52.5]	38 [29.3, 47.0]	0.140
Female sex	161 (88.8)	35 (97.4)	21 (84.6)	105 (87.3)	0.151
Race (%), n=181 *					0.328
Asian	35 (19.3)				
Black	61 (33.7)				
Other/Not reported	33 (18.2)				
White	52 (28.7)				
Ethnicity (%), n=170 *					0.365
Hispanic	39 (22.9)				
Not Hispanic	131 (77.1)				
PROMIS Depression (median [IQR]), n=174	53.0 [45.9, 58.9]	59.3 [55.3, 62.2]	55.0 [48.7, 59.7]	51.2 [44.3, 56.3]	<0.001
PROMIS Cognitive function (median [IQR]), n=176	46.9 [40.6, 54.5]	41.2 [36.5, 44.0]	42.4 [41.0, 49.2]	49.2 [41.2, 58.5]	<0.001
PROMIS Fatigue (median [IQR]), n=181	57.1 [50.7, 64.1]	67.9 [60.8, 73.9]	59.1 [58.1, 65.9]	53.5 [48.5, 61.2]	<0.001
PROMIS Sleep disturbance (median [IQR]), n=181	50.0 [36.3, 58.9]	64.1 [58.9, 68.4]	58.9 [54.2, 64.1]	46.5 [36.3, 50.0]	<0.001
PROMIS Pain intensity (median [IQR]), n=181	54.5 [38.7, 61.5]	62.9 [61.3, 66.9]	59.1 [56.0, 62.1]	46.6 [38.7, 56.0]	<0.001
PROMIS Pain interference (median [IQR]), n=178	54.5 [49.5, 60.0]	60.0 [57.8, 65.8]	58.5 [52.9, 61.3]	52.3 [46.8, 56.7]	<0.001
SLEDAI (median [IQR]), n=181	2.0 [2.0, 4.0]	2.0 [0.0, 4.5]	2.5 [1.8, 4.3]	3.0 [2.0, 4.0]	0.742
SLICC damage index score (median [IQR]), n=181	1.0 [0.0, 2.0]	1.0 [0.0, 2.0]	1.0 [0.0, 1.5]	1.0 [0.0, 2.0]	0.834
DORIS remission (prednisone ≤ 5mg), n=48/181	48 (48/181=0.27)	4 (4/48=0.08 4/31=0.13)	4 (4/48=0.08 4/23=0.17)	40 (40/48=0.83 40/127=0.31)	0.017
Completed FM survey (n)	54	31	23		
WPI (median [IQR])	7.0 [4.0, 11.0]	10.0 [8.5, 16.0]	4.0 [2.0, 5.0]		<0.001
SSS (median [IQR])	8.0 [5.0, 10.0]	9.0 [8.0, 10.0]	5.0 [4.0, 8.0]		<0.001
Fatigue (%)					0.014
0	0 (0.0)	0 (0.0)	0 (0.0)		
1	11 (20.4)	2 (6.5)	9 (39.1)		
2	18 (33.3)	12 (38.7)	6 (26.1)		
3	25 (46.3)	17 (54.8)	8 (34.8)		
Waking unrefreshed (%)					0.147
0	7 (13.0)	2 (6.5)	5 (21.7)		
1	9 (16.7)	5 (16.1)	4 (17.4)		

	Overall	FM	Non-FM chronic pain	No chronic pain	P value
2	18 (33.3)	9 (29.0)	9 (39.1)		
3	20 (37.0)	15 (48.4)	5 (21.7)		
Memory issues/lack of concentration (%)					0.001
0	8 (14.8)	0 (0.0)	8 (34.8)		
1	14 (25.9)	8 (25.8)	6 (26.1)		
2	23 (42.6)	15 (48.4)	8 (34.8)		
3	9 (16.7)	8 (25.8)	1 (4.3)		
Headaches (%)	43 (79.6)	28 (90.3)	15 (65.2)		0.054
Abdominal pain/cramps (%)	26 (48.1)	20 (64.5)	6 (26.1)		0.012
Depression (%)	26 (48.1)	19 (61.3)	7 (30.4)		0.049

Note: IQR=interquartile range; PROMIS=Patient Reported Outcome MeasurementInformation System; SLEDAI=Systemic Lupus Erythematosus (SLE) Disease Activity Index; SLICC= Systemic Lupus International Collaborating Clinics; DORIS=Definition of Remission in SLE; WPI=Widespread Pain Index; SSS=Symptom Severity Scale

* cell values suppressed if any demographic category n<11

Note: Blank cell indicates answer not available for patients without chronic pain