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Understanding Differences in Patient Descriptions of Rheumatoid Arthritis Flares Using OMERACT Core Domains

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ABSTRACT. ***Objective.*** Recently, there has been consensus on domains that constitute flares in rheumatoid arthritis (RA); however, variations in patients' flare descriptions continue to be observed. This study evaluates how demographic and clinical characteristics influence these differences.

Methods. Participants enrolled in a prospective RA registry completed a qualitative survey that included the open-ended question "What does a flare mean to you?" Responses were categorized into Outcome Measures in Rheumatology (OMERACT) core and research domains. Univariate analyses evaluated demographic and clinical characteristics. Regression analyses determined independent variables associated with flare description variations.

Results. Among 645 participants, the median Disease Activity Score in 28 joints (DAS28) with C-reactive protein was 2.1 (IQR 1.6-2.9); 58% of the participants reported at least 1 flare in the past 6 months. Participants reported a median of 3 (IQR 2-5) OMERACT domains when describing flares. Fatigue was more commonly noted among females (odds ratio [OR] 6.12; $P < 0.001$). Older participants were less likely to report emotional distress (OR 0.97; $P = 0.03$), swollen joints (OR 0.99; $P = 0.04$), physical function decrease (OR 0.98; $P = 0.02$), and a general increase in RA symptoms (OR 0.98; $P = 0.005$). Participants with a higher DAS28 score were less likely to report symptoms of stiffness (OR 0.70; $P = 0.009$), and those who experienced a flare within the last 6 months were more likely to describe flares as pain (OR 2.53; $P < 0.001$) and fatigue (OR 2.00; $P = 0.007$).

Conclusion. Variations in patients' flare descriptions can be driven by a patient's disease activity, the experience of a recent flare, as well as different demographic characteristics, such as age and gender. Understanding the interplay of these characteristics can guide a physician's approach to the management of patients' RA flares.

Key Indexing Terms: flare, OMERACT, patient perspective, qualitative, rheumatoid arthritis

Flare is an important, distinct feature of rheumatoid arthritis (RA), often rendering patients immobile and contributing to a poor quality of life.[1] Despite its significant presence in disease activity, a standardized definition for RA flare has yet to be determined. As various studies have previously stated, variability in flare definitions can affect communication between a clinician and patient, as a patient's perspective on a flare can differ from that of a physician.[1-4]

Although several studies in recent years have begun to evaluate the possible measures in which to standardize criteria for a flare, 1 group in particular—the Outcome Measures in Rheumatology (OMERACT) RA Flare Group—has come to a

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consensus on outcome measures to determine the criteria for a flare. OMERACT, an international group composed of patients with RA and healthcare professionals, was able to develop 8 core domains that constitute a flare through combined rounds of Delphi exercises. These core domains represent the domains agreed upon by both healthcare professionals and patients in focus groups, with additional domains still being explored.[3,5-8]

In originally identifying the core domains, several patient and physician characteristics were observed throughout the Delphi process as part of the exploratory analyses; however, it is unclear how these specific factors affect patients' flare descriptions.[7] The importance of understanding which characteristics drive differences in flare description may assist physicians in clearly communicating treatment of flares specifically for each patient. In order to analyze the interplay between different clinical characteristics—specifically, disease activity and patients' experience of a recent flare—we evaluated how these variables affect variations in patients' perspectives.

METHODS

Patient population. Data were collected from patients enrolled in the Brigham and Women's Rheumatoid Arthritis Sequential Study (BRASS) located in Boston, Massachusetts. BRASS, which began enrollment in March 2003, is a prospective, observational cohort of more than 1500 patients. Patients aged 18 years or older with a clinical diagnosis of RA were recruited from practices of attending rheumatologists and fellows. All diagnoses of RA were either verified according to the 1987 American College of Rheumatology criteria or were based on the rheumatologists' clinical opinion.

Study design. Participants completed annual study visits, where patient-reported and clinical data were collected through an interview; physician assessment, including a 28-joint count; a self-administered questionnaire; and a blood draw. Additionally, disease activity was ascertained annually using the Disease Activity Score in 28 joints with C-reactive protein (DAS28-CRP3).[9] Further details regarding the study protocol using the BRASS registry are reported elsewhere.[10,11] The flare questionnaire was added to the annual study visits in 2015, and flare data were analyzed from 2015 to 2019.

Ethics and consent. All the study procedures, informed consent, and materials used under the BRASS registry (ClinicalTrials.gov: NCT01793103) were approved by the Institutional Review Board (IRB) of Brigham and Women's Hospital, Partners Health Care, Boston, Massachusetts (IRB protocol number 2002P001762). Written informed consent to publish the material was obtained from all participants.

Measures. As part of their study visit, patients were asked to answer several questions pertaining to RA flares. Participants were asked to report whether they had experienced a flare in the past 6 months and answer the open-ended question "What does a flare mean to you?" Flare descriptions were then recorded and independently categorized by 2 reviewers. Patient responses were sorted into OMERACT core domain(s) or research domain(s). Research domains were defined as domains that were still being analyzed as potential flare domains per OMERACT.[5] The following flare domains were classified as OMERACT core domains: pain, tender joints, swollen joints, physical function decrease, fatigue, stiffness, patient global assessment (PtGA), and participation.[5,7] Pain included painful/tender joints as a subcategory. Participation was defined as a decrease in activities (ie, work, family, and social). In addition, the physical function decrease domain encompassed 5 subgroups: immobility, hard to do normal tasks, ask for help, cut back on physical activity, and need for medical equipment, such as a cane, a walker, or arthritis gloves. Emotional distress and sleep disturbance were characterized as research domains. Depressive symptoms and irritability were groups categorized under emotional distress. As an example, consider the following patient flare description: "A flare means pain or discomfort (swelling) in the joints. Would do everything but would be in pain while completing errands." In that description, one can see that after the 2 reviewers independently categorized this recorded response, the final classification would have been the painful and swollen joint domains. In the event of discordance, a third reviewer was selected as an arbitrator.

Statistical analyses. Univariate analyses evaluated demographics, such as age, gender, race, and clinical characteristics. Descriptive statistics used nonparametric measures for nonnormally distributed variables. Multivariable logistical regression analyses were then used to determine the primary predictors of variations found in patients' descriptions of RA flares. The primary predictors were age, gender, race, education, experiencing flare or not in the past 6 months, disease duration, the DAS28-CRP3, and obesity. The primary outcomes were the OMERACT core and research domains. Sleep and participation decrease were not outcomes in the model since they had too few responses: 15 and 6, respectively.

RESULTS

Out of the more than 1500 patients enrolled in our BRASS study, 696 patients completed the flare baseline questionnaire. Out of these 696 individuals, 645 participants completed all the necessary components needed for analysis, including answering the question "What does a flare mean to you?"; in addition, they each had a disease activity score. Table 1 describes the baseline clinical and demographic characteristics of these 645 patients. The study cohort had a mean age of 60 (SD 13) years, and they had longstanding disease with a median disease duration of 14 (IQR 6-23) years. Approximately 82% of the participants

Table 1. Clinical and demographic characteristics of the cohort.

	Value, N = 645
Age, yrs, mean (SD)	60 (13)
Gender, female	532 (82)
Race, White	596 (92)
Education	
Did not graduate college	153 (24)
Graduated college	492 (76)
Obesity, BMI[a] ≥ 30	149 (26)
Disease duration, yrs, median (IQR)	14 (6-23)
DAS28-CRP3, median (IQR)	2 (2-3)
Reported flare in the past 6 months	354 (58)
Disease activity	
Remission or low DAS28-CRP3	538 (83)
Moderate or high DAS28-CRP3	107 (17)
RA medication	
Corticosteroid	153 (24)
bDMARD	360 (56)
TNFi	248 (38)
Non-bDMARD	442 (69)
MTX	352 (55)
NSAID	242 (38)

Data are in n (%) unless otherwise indicated. [a]BMI calculated as weight in kilograms divided by height in meters squared. bDMARD: biologic disease-modifying antirheumatic drug; CRP: C-reactive protein; DAS28: Disease Activity Score in 28 joints; MTX: methotrexate; NSAID: nonsteroidal antiinflammatory drug; RA: rheumatoid arthritis; TNFi: tumor necrosis factor inhibitor.

were female; 92% were White; 26% were obese, with a BMI of 30 or greater; and 76% had a college education or greater. Participants who were on corticosteroids comprised 24% of the cohort, whereas 56% of the patients were on a biologic disease-modifying antirheumatic drug. At least half of the participants were on methotrexate, and 38% of the participants were on tumor necrosis factor inhibitors. At the time of the analysis, 38% of the patients were on nonsteroidal antiinflammatory drugs. This cohort had a median DAS28-CRP3 score of 2.1 (IQR 1.6-2.9), indicating low disease activity, with 58% of the participants reporting at least 1 flare in the past 6 months. Supplementary Table S1 (available with the online version of this article) shows a comparison of the demographic characteristics between participants who completed the flare questionnaire and those who did not, using data from their BRASS baseline study visit. Regarding the 2 groups, those who did not complete the flare questionnaire were older when enrolled—at a mean age of 58 (SD 15) years—compared to those who did complete the questionnaire; this finding was statistically significant. There was also a higher percentage of individuals who did not graduate college among the nonparticipant group (41%) compared to those in the participant cohort (24%).

Patients' flare descriptions were recorded and categorized according to the flare domains shown in Table 2. Participants reported a median of 3 (IQR 2-5) OMERACT domains when describing flares. Of the OMERACT core domains mentioned, pain (79.2%) and its subcategory painful joints (35.5%), along with a decrease in physical function (41.2%), were the most commonly reported. Among the participants who voiced a decrease in physical function as part of their flare description, hard to do normal tasks (20.8%) was frequently noted in their descriptions, followed by immobility (18.6%). With regard to the OMERACT research domains, emotional distress was reported more often (9.3%) than sleep disturbance (2.3%). Patients mentioned irritability the most (3.6%) out of the categories that comprise emotional distress when prompted to describe a flare.

Table 2. Domain frequencies.

	Value, N = 645, n (%)
Pain	
Total	511 (79.2)
Painful joints	229 (35.5)
Swollen joints	225 (34.9)
PtGA[a]	131 (20.3)
Stiffness	106 (16.4)
Physical function decrease	
Total	266 (41.2)
Immobility	120 (18.6)
Hard to do normal tasks	134 (20.8)
Ask for help	10 (1.6)
Cut back on physical activity	58 (9)
Need medical equipment	2 (0.3)
Fatigue	130 (20.2)
Emotional distress	
Total	60 (9.3)
Depressive symptoms	18 (2.8)
Irritability	23 (3.6)
Participation decrease[b]	6 (0.9)
Sleep disturbance	15 (2.3)

[a] PtGA is defined as an increase in RA symptoms. [b] Participation is defined as a decrease in activities (ie, work, family, and social). PtGA: patient global assessment; RA: rheumatoid arthritis.

Selected examples of flare descriptions given by patients with RA in our analysis are depicted in Figure 1. As one can see in Figure 1A, flare descriptions from patients with low DAS28-CRP3 scores (ie, DAS28-CRP3 < 3.2) vs moderate or high DAS28-CRP3 scores (ie, DAS28-CRP3 ≥ 3.2) included several of the same domains from both OMERACT core and research domains. However, patients with a low DAS28 were more likely to describe a flare as increased stiffness (Table 3). Figure 1B highlights differences in flare definitions when looking at selected quotes from female vs male patients. Female patients were more likely to include fatigue as part of their flare definition (Table 3).

Table 3 demonstrates the primary covariates associated with variations in patients' flare descriptions through logistical regression analyses. In total, 7 flare domains that were modeled had statistically significant differences between patient characteristics and the descriptions they used for flares. Age became a significant factor in variations to flare definitions when the following flare domains were analyzed as outcomes: swollen joints, physical function decrease, emotional distress, and PtGA (models 2, 4, 5, and 6, respectively). Patients who are older were less likely to include swollen joints (odds ratio [OR] 0.99; $P = 0.04$), physical function decrease (OR 0.98; $P = 0.02$), emotional distress (ie, irritability; OR 0.97; $P = 0.03$), and a general increase in RA symptoms (OR 0.98; $P = 0.005$) as part of their flare description. Females were more likely (OR 6.12; $P < 0.001$) to describe a flare as fatigue (model 3). Patients with a lower DAS28-CRP3 score tended to describe a flare as stiffness (OR 0.70; $P = 0.009$; model 7). According to models 1 and 3, patients who experienced a flare in the past 6 months were more likely to describe a flare as pain (OR 2.53; $P < 0.001$) and fatigue (OR 2.00; $P = 0.007$). Disease duration was another significant factor, as patients with longer disease duration tended to mention pain (OR 1.02; $P = 0.03$) and fatigue (OR 1.03; $P = 0.02$) more often in their flare descriptions. Race, obesity, and education were patient characteristics that had no effect on driving differences in flare descriptions across all 7 flare domains modeled.

DISCUSSION

Our analysis demonstrated that there were variations in how patients defined their flares and that these differences varied by patient clinical and demographic characteristics. The majority of patients described their flares as multidimensional, corresponding to more than 1 OMERACT core domain. We were interested in investigating how the interplay of clinical factors, such as between a patient's disease activity and occurrence of a recent flare, would affect patients' flare descriptions. In doing so, we observed that a patient's disease activity or recent flare status

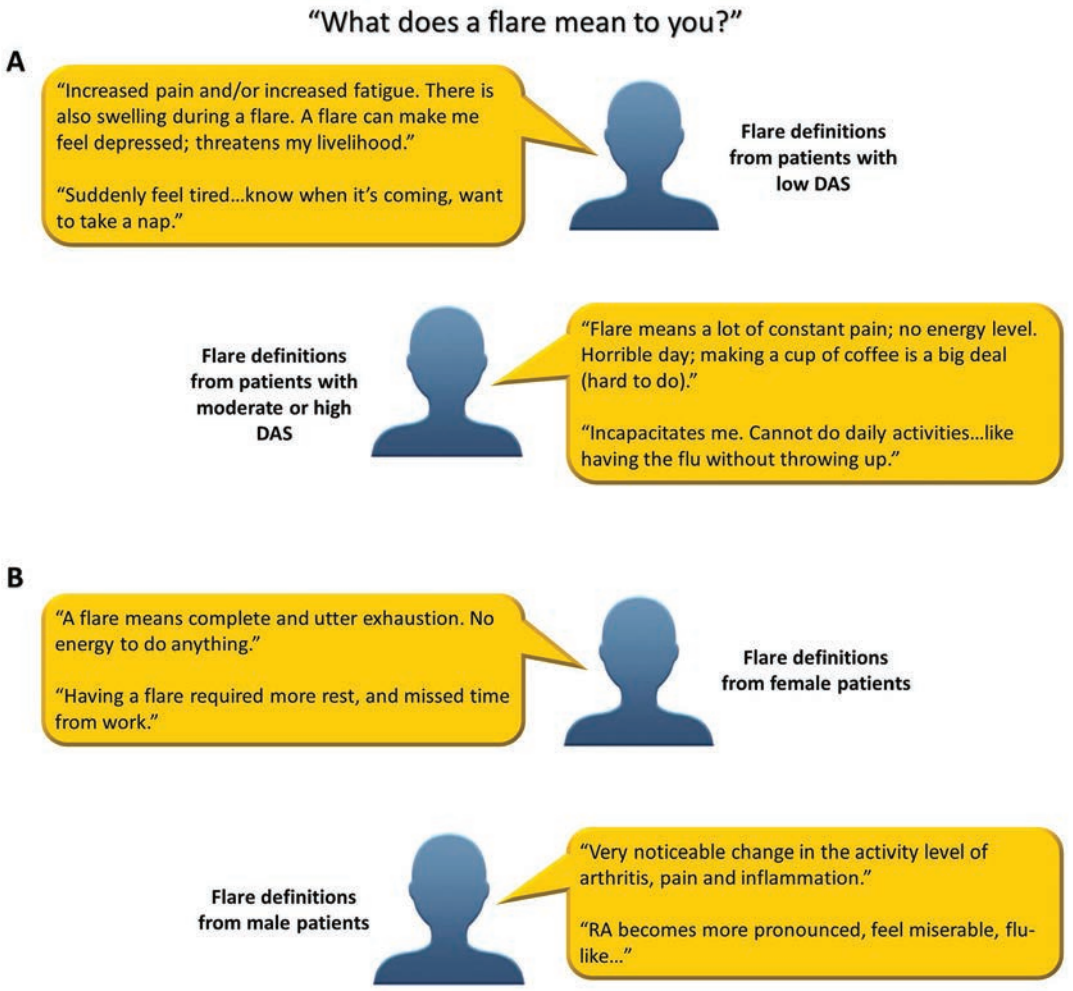

Figure 1. Selected examples of flare descriptions given by patients with RA. (A) Panel A demonstrates flare descriptions from patients with a low DAS and those with a moderate or high DAS. This panel depicts how patients from both DAS groups express similar OMERACT domains when describing a flare. However, patients with a low DAS are more likely to describe a flare as stiffness (not seen in this figure; see Table 3). (B) Panel B demonstrates flare definitions from both female and male patients, highlighting how female patients will describe a flare as increased fatigue more than male patients. DAS: disease activity score: OMERACT: Outcome Measures in Rheumatology; RA: rheumatoid arthritis.

individually can have a significant influence on the variations in patient-reported domains.

Other investigators have explored how patients define their flares, and this has contributed to the work in developing the OMERACT core domains for an RA flare.[2-5,7] Previous work from Bartlett et al[7] demonstrated that age, education, disease duration, and a patient's primary language influenced their descriptions of flares. Bartlett et al's[7] analysis sought to develop domains that would represent flares as a worsening of signs and symptoms with an intensity and duration that would prompt a change in treatment. From that study's patient Delphi panel, older patients were more likely to identify physician global assessment and labs as important when describing a flare. However, in our present analysis, older patients were less likely to include swollen joints, physical function decrease, emotional distress, and a general increase in RA symptoms when describing a flare. Disease duration demonstrated effects on variations seen in patient flare descriptions in our study, with patients in this BRASS cohort reporting a median disease duration of 14 (IQR 6-23) years, which is similar to the average disease duration of 18 years in Bartlett et al's analysis. We were unable to look at language as a covariate, since all participants in our study were English-speaking. Unlike in Bartlett et al's study, gender was a patient characteristic that was significant in driving differences in flare descriptions in our analysis, whereas education had no statistical influence on flare descriptions in our study. The differences between Bartlett et al's analysis and our study may be partially because of our inclusion of each patient's current DAS28-CRP3 score. Although our analysis demonstrated that patients with a higher DAS28-CRP3 score were less likely to describe a flare as increased stiffness, this observation is important in understanding that despite a higher DAS28-CRP3 score, patients may become used to certain symptoms in their disease course, such as stiffness;

Table 3. Adjusted ORs of clinical and demographic characteristics associated with flare description by flare domains.

	Flare Description, N = 645, adjusted OR (95% CI)						
	Model 1: Pain	Model 2: Swollen Joints	Model 3: Fatigue	Model 4: Physical Function Decrease	Model 5: Emotional Distress	Model 6: Global Increase in RA	Model 7: Stiffness
Age	1.00 (0.98-1.01)	**0.99 (0.97-0.99)**	0.98 (0.96-1.00)	**0.98 (0.97-0.99)**	**0.97 (0.95-0.99)**	**0.98 (0.96-0.99)**	0.99 (0.97-1.01)
Female	1.07 (0.61-1.86)	0.92 (0.58-1.47)	**6.12 (2.17-17.20)**	1.35 (0.84-2.17)	2.02 (0.76-5.36)	1.02 (0.58-1.80)	0.89 (0.49-1.62)
White	1.86 (0.87-3.98)	1.07 (0.53-2.17)	1.88 (0.70-5.10)	1.34 (0.67-2.69)	1.43 (0.41-4.97)	1.18 (0.50-2.80)	0.57 (0.25-1.29)
College degree (or higher)	1.27 (0.75-2.13)	0.90 (0.58-1.40)	0.94 (0.54-1.61)	0.75 (0.49-1.15)	0.62 (0.31-1.23)	0.63 (0.38-1.04)	0.84 (0.48-1.48)
DAS28-CRP3	0.81 (0.65-1.02)	0.93 (0.76-1.13)	1.10 (0.87-1.37)	0.92 (0.76-1.12)	0.97 (0.71-1.32)	0.83 (0.65-1.05)	**0.70 (0.52-0.92)**
Had flare in the past 6 months	**2.53 (1.58-4.04)**	1.22 (0.83-1.79)	**2.00 (1.21-3.31)**	1.20 (0.82-1.74)	1.23 (0.64-2.36)	1.01 (0.64-1.58)	1.41 (0.86-2.30)
Disease duration	**1.02 (1.00-1.04)**	1.00 (0.98-1.01)	**1.03 (1.01-1.05)**	1.01 (1.00-1.03)	1.02 (0.99-1.04)	1.01 (0.99-1.03)	1.00 (0.98-1.03)
Obesity	0.95 (0.58-1.57)	1.36 (0.91-2.04)	0.84 (0.5-1.43)	1.26 (0.85-1.88)	1.55 (0.81-2.97)	0.88 (0.53-1.45)	0.67 (0.38-1.19)

Values in bold are statistically significant. CRP: C-reactive protein; DAS28: Disease Activity Score in 28 joints; OR: odds ratio; RA: rheumatoid arthritis.

therefore, they would be more attuned to other symptoms that become more prominent during a flare.

Our study also considered how the presence or absence of a recent flare influenced which domains were reported more often by patients. Among the domains used in our analysis, certain domains describe mostly symptoms of a flare vs others that focus on the effect of these symptoms. For example, we found that it was the experience of having a recent flare in the past 6 months that drove patients to describe their flares more often with domains that depicted symptoms: pain and fatigue. This seems to parallel work done by van Tuyl et al[12] regarding the patient perspective on remission in RA and how patients describe remission. In van Tuyl et al's study, patients characterized remission not only by mentioning the absence or decrease of specific symptoms, but also by drawing on their experiences of the effects of these symptoms. Our analysis demonstrates that there is a complex interplay between a patient's flare experience, their disease activity, and whether they describe flares with specific symptoms or a depiction of the effects of these symptoms.

Our study had several limitations. Most participants had longstanding disease and had lower disease activity, which may limit how representative the participants are of all patients with RA. Although we attempted to gather information on the smoking status of our study participants, we were unable to analyze smoking status as a potential covariate in the association of reported flare domains because of missing data. Differences in flare descriptions could also have resulted from the length of our recall period.[13] Therefore, it is possible that certain core domains were influenced by how recent the flare was for those domains reported more often as a result of a positive flare status. Future studies that collect information about the flare experience in real time can address this concern. On the other hand, our study has several strengths, including the following: the large number of patients included in the cohort, our ability to include patients' disease activity scores, and the design of our flare questionnaire where participants were asked to define a flare in response to an open-ended question. This follows the bottom-up approach in Hewlett et al's[1] study regarding patient perspectives on RA flares.[14]

Similar to other studies analyzing patient perspectives on RA flares, we found that there are clinical and demographic characteristics that differentially affect how a patient describes their flares, and that disease activity also affects the way patients may depict their flares to physicians. This analysis sheds light on how important it is for a clinician to consider that, in general, patients describe the effects of their flares differently, and understanding how these differences arise may help physicians better manage patients' disease. This may be an important component moving forward in operationalizing the standard definition of RA flare using OMERACT core domains, in order to ensure that these domains can serve as an effective communication tool for patients with RA and their physicians.

ONLINE SUPPLEMENT

Supplementary material accompanies the online version of this article.

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