Severe Rheumatoid Arthritis (RA), Worse Outcomes, Comorbid Illness, and Sociodemographic Disadvantage Characterize RA Patients with Fibromyalgia

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ABSTRACT. ***Objective.*** Fibromyalgia (FM) is a controversial construct. Recently suggested survey criteria identify persons with FM characteristics without physical examination or clinical diagnosis, thereby obviating many of the objections to FM. Little is known about FM among patients with rheumatoid arthritis (RAF). We used the survey definition to characterize persons with RAF and to obtain insight into possible pathogenic mechanisms.

Methods. A total of 11,866 patients with RA completed the Regional Pain Scale (RPS) and a 0–10 visual analog scale (VAS) for fatigue. FM was diagnosed in patients with an RPS score ≥ 8 and a VAS fatigue score ≥ 6.

Results. Altogether 1731 (17.1%) patients with RA fulfilled the criteria. Fewer RAF patients were married (64.9% vs 69.8%) and more were divorced (14.8% vs 10.4%); fewer were college graduates (19.7% vs 28.1%) and more did not finish high school (15.0% vs 8.9%). We found 35.8% of patients with FM but only 21.5% of those without FM had incomes less than 185% of the US poverty guidelines. Patients with RAF had higher validated hospitalization rates for major comorbid conditions and received treatment for comorbid conditions more often (expressed as odds ratios and 95% confidence interval): hypertension (1.5, 1.4–1.7), cardiovascular (1.8, 1.6–2.0), diabetes (1.9, 1.6–2.3), and depression (2.7, 1.8–4.2). RAF were 3.3 (3.0–3.7) times more likely to have been work-disabled (54.5% vs 26.4%) or to have total joint replacement (14.0% vs 11.2%; OR 1.3, 1.1–1.5), and incurred greater direct 6-month medical costs (US $6477 vs $4687). RAF patients had more severe symptoms across all scales, including the Health Assessment Questionnaire (1.8 vs 1.0), pain (6.7 vs 3.4), Medical Outcomes Study Short Form-36 (SF-36) physical component score (23.5 vs 33.5), SF-36 mental component score (29.5 vs 46.1), and quality of life assessed by EuroQol mapped utilities (0.33 vs 0.65).

Conclusion. FM exists in a substantial number of patients with RA (17.1%), who have more severe RA by subjective and objective measures, greater medical costs, worse outcomes, more comorbidities, sociodemographic disadvantage, and substantially worse quality of life. We hypothesize that illness severity and sociodemographic disadvantage both play a role in producing the clinical picture of FM. (J Rheumatol 2004;31:695–700)

Key Indexing Terms:
RHEUMATOID ARTHRITIS FIBROMYALGIA OUTCOME
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Fibromyalgia (FM) is a controversial construct that has stimulated vigorous opposition, in part because of psychosocial and societal issues. It also has many supporters, including national arthritis organizations, biomedical researchers, pain specialists, rheumatologists, and other practitioners. Those who are against FM dismiss it as a non-disease that creates illness and disablement and is harmful to patients and society. Such objections inhibit research when it is felt that clinical diagnosis itself may be harmful.

However, there is much to learn about the symptom complex called FM. Just what kind of a disorder is it? Does it have its underpinnings in society, psychosocial issues, psychological issues, the disablement system, or in some intrinsic disease severity mechanism? Just who are the people with FM? Is there any way to study them now that the concept is the seat of polarized debate and politicization? The ideal way to study such a condition is in epidemiological studies, for they avoid biased referral and underlying clinician assumptions. But epidemiological studies yield few patients, given the FM rate of 2–4%[1-9]. In

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addition, it is sometimes difficult to draw clinically meaningful conclusions from epidemiological studies.

The 1990 American College of Rheumatology (ACR) FM criteria[10] study established that FM did not differ in its signs and symptoms in patients with other rheumatic diseases from those who had (primary) FM, and recommended that the distinction between primary and secondary/concomitant FM be abolished. This recommendation can provide a way to study FM by allowing the use of patients who are seeing rheumatologists for other disorders and who are not expected to have been given a formal diagnosis of FM. In this study we use patients with diagnosed rheumatoid arthritis (RA) who were referred to rheumatologists because of RA. This method avoids biased selection and allows one to examine FM in the context of a well defined rheumatic illness. In addition, we used proposed survey criteria for FM. By doing this we remove the rheumatologist from the equation, as he or she does not know if the patient does or does not satisfy the new criteria, and we remove societal issues as well.

We examine FM in patients who also have RA. We address questions such as whether one can effectively identify FM in RA. Are patients somatizing, exaggerating? Do they have more severe RA? What are their psychosocial and psychological characteristics? What are the outcomes? As the term FM may, in itself, be inflammatory to some, we use the term here to mean a "fibromyalgia symptom complex."

MATERIALS AND METHODS

Patient population. This study was performed using the National Data Bank for Rheumatic Diseases (NDB). The NDB is a rheumatic disease research data bank in which patients complete detailed self-report questionnaires at 6-month intervals[11-14]. Eligible patients in this study were those with RA who had completed at least one biannual survey. We selected the most recent survey for each patient for the primary analysis of this study. The resultant data set contained data for 11,866 patients with RA. Patients were diagnosed and referred to the NDB by 843 rheumatologists across the US. More than 90% of rheumatologists were in private practice, and were not fulltime university physicians.

Demographic and disease status variables. NDB participants were asked to complete semiannual detailed 28-page questionnaires about all aspects of their illness. At each assessment, demographic variables were recorded including sex, age, ethnic origin, education level, current marital status, medical history, work status, and total family income. Disease status and activity variables collected included the Stanford Health Assessment Questionnaire functional disability index (HAQ disability)[15,16], visual analog scale (VAS) for pain, global disease severity and fatigue scales[17], the Arthritis Impact Measurement Scales (AIMS) anxiety and depression scales[18,19], and the Rheumatoid Arthritis Disease Activity Index (RADAI)[20–22]. Patients also completed the Medical Outcomes Study Short Form-36 (SF-36), from which the physical component score (PCS) and the mental component score (MCS) were calculated[23,24]. Utilities were mapped from HAQ and anxiety and depression values based on a regression model derived from the simultaneous administration of the EuroQol[25-27], HAQ, and anxiety and depression scales to 2299 patients with RA[28].

Direct medical costs represented expenditures for physician and health care worker visits, medications, diagnostic tests and procedures, and hospitalizations. In the study surveys, patients reported all drug use, hospitalizations, medical visits, procedures, and laboratory testing. Medical costs reflected both RA and non-RA direct costs. The cost methodology of the NDB has been described previously[11].

Validated comorbid conditions. In addition to self-reports described above, comorbid conditions were studied by identifying comorbid diagnoses through medical and hospital records. We also compared patient groups for use of medications associated with comorbid conditions as, for example, in the use of antidiabetics and antihypertensive drugs.

Poverty level. To determine poverty levels, we used the US Health and Human Services (HHS) poverty guidelines for 48 contiguous states for the years 1998–2003[29]. A level of 185% of the HHS poverty guideline selected for this study is a commonly used measure of poverty, and is used to determine eligibility for the school breakfast and lunch programs.

Fibromyalgia diagnosis. The survey diagnosis of FM was made by use of the Regional Pain Scale (RPS)[30] and VAS fatigue scale. Patients reported if they had pain in each of 19 nonarticular areas identified by the RPS. The RPS is the most effective self-report variable available to distinguish FM patients from those with other diagnoses[30]. According to the suggestion of Wolfe[30], we operationally diagnosed FM in RA patients who had fatigue scores ≥ 6 and RPS ≥ 8. For additional validation of the study survey criteria for FM, we identified 1629 FM clinic patients seen by the first author in the Wichita Arthritis Center outpatient clinic, and compared their characteristics with characteristics of 2078 RA patients who satisfied the survey FM criteria. Results from these 2 groups are given in the Appendix. These data show that, except for HAQ score, which was greater in the RA patients with FM, other variables were remarkably similar between the groups, despite different diagnostic methods.

Statistical methods. Because of the very large sample size, essentially all group comparisons are significant at the 0.05 level. Therefore we have omitted p values from the tables. Adjusted income was calculated following censored interval regression. Other adjustments were performed using either logistic or ordinary least-squares regression. Statistical computations were performed using Stata, version 8.0[31].

RESULTS

Of the 11,866 RA patients in this study, 2078 (17.5%) satisfied survey criteria for FM.

Sociodemographic characteristics. Table 1 presents the sociodemographic characteristics of study participants. Because the sample size is very large, statistically significant changes are almost always found in this Table as well as in subsequent analyses. Readers are, therefore, urged to examine differences for clinical significance. The largest and most clinically significant difference is in total household income, with FM patients having an annual household income that is US$11,191 (95% CI 9827–12,554) less than in non-FM patients. To adjust for demographic differences, income was also studied using censored interval regression adjusted for age, sex, education level, and ethnic origin. The adjusted difference between the groups was $12,678 (95% CI 11,173–14,184). The income difference was also related to the percentage of patients at 185% of the US poverty guidelines: 35.8% of patients with FM but only 21.5% of those without FM were at this poverty level.

Patients with FM were 1.9 years younger and had RA for 0.7 years longer than non-FM patients. Slightly fewer FM patients were non-Hispanic whites (2.8%), with the major differences coming from slight increases in African-Americans and Hispanic groups. Fewer patients with FM were married (4.9%), and the major contribution to nonmar-

Table 1. Sociodemographic characteristics of RA patients with and without fibromyalgia (FM).

Variable	FM (–), n = 9788 Mean (SD) or %	FM (+), n = 2078 Mean (SD) or %
Age, yrs	60.4 (13.2)	58.5 (13.1)
Sex, % male	24.0	15.5
Ethnicity, %		
Non-Hispanic White	91.9	88.7
African-American	3.5	5.1
Asian-American	1.2	0.9
Native American	0.9	1.3
Hispanic	1.9	3.2
Puerto Rican	0.2	0.4
Other	0.4	0.5
Education category, yrs, %		
0–8	2.1	3.5
8–11	6.8	11.5
12	37.1	38.6
13–15	26.0	26.7
≥ 16	28.1	19.7
Marital status, %		
Married (total)	69.9	64.9
Never married	5.9	5.8
Married (1st marriage)	63.3	58.1
Separated	1.0	1.4
Divorced	10.4	14.8
Widowed	12.8	13.2
Widowed/remarried	1.5	1.1
Divorced/remarried	5.1	5.6
Disease duration, yrs	14.3 (10.6)	15.0 (11.2)
Economic factors		
Total income (US $)	47,862 (28,846)	36,671 (26,846)
Poverty level (185% US guidelines), %	21.5	35.8

ried status was from divorce. More FM patients did not have a high school education and fewer were college graduates.

Overall, analysis of sociodemographic characteristics shows socioeconomic disadvantage for FM patients compared to those without FM, with the major disadvantages being in total household income and education categories.

Comorbidity. Table 2 displays the odds ratios (OR) of self-reported current and lifetime comorbidity for RA patients with FM compared to RA patients without FM. The strongest association for FM was depression and psychiatric illness (OR 3.4), but for almost every current medical condition (with the exception of stroke, alcoholism, and cancer), and for every lifetime medical condition, the OR was significantly increased in persons with FM.

Because it was possible that patients might have been reporting perceived rather than actual comorbidity[32], we validated the self-reports in Table 2 by examining medication use and hospitalization records for conditions in which medication and *International Classification of Disease-9* codes would be unlikely to represent perceptions. Table 3 shows that patients with FM were more often being treated for depression, diabetes, pulmonary disease, and cardiovascular disease than those without FM. In addition, according to hospital records, patients with FM were more often hospitalized for congestive heart failure, diabetes, and pulmonary disease. If 95% CI are relaxed to 90% CI, differences exist for myocardial infarction and hypertension as well.

Direct medical costs. As shown in Table 4, patients with RA and FM had greater direct medical costs, with an overall difference of $1790 per 6-month observation period. The costs were distributed equally across the domains of drug costs, hospitalization costs, and outpatient medical visit costs.

Table 2. Association of current and lifetime comorbid illnesses with fibromyalgia among RA patients.

Comorbid Condition	Current Comorbidity			Lifetime Comorbidity		
	OR	z Score	95% CI	OR	z Score	95% CI
Depression	3.4	21.0	3.1–3.9	3.0	20.9	2.7–3.3
All psychiatric illnesses	3.4	21.0	3.1–3.8	2.9	20.5	2.6–3.2
All GI problems (GI, ulcer, stomach problems, gall bladder)	2.8	17.6	2.5–3.1	2.4	18.1	2.2–2.7
Allergies	2.9	13.7	2.5–3.4	2.6	14.5	2.3–2.9
Asthma	2.6	11.5	2.2–3.0	2.2	11.9	1.9–2.5
Pulmonary problems	2.3	10.2	2.0–2.7	2.3	12.0	2.0–2.6
GI ulcers	2.8	8.9	2.2–3.5	2.1	11.9	1.9–2.4
Fractures	3.0	8.2	2.3–3.9	2.0	9.2	1.7–2.3
Diabetes	1.9	8.0	1.6–2.2	1.9	8.5	1.6–2.2
Hypertension	1.5	7.8	1.4–1.7	1.6	9.3	1.4–1.8
Renal disease	2.4	6.9	1.9–3.1	2.2	9.1	1.8–2.5
Cataracts	1.7	6.5	1.4–2.0	1.6	7.5	1.4–1.9
GU problems	1.9	5.8	1.5–2.4	1.9	10.9	1.7–2.1
Liver problems	2.5	5.7	1.8–3.4	2.3	7.9	1.9–2.8
Neurologic problems	2.4	5.6	1.8–3.4	2.2	6.5	1.8–2.9
Gall bladder disease	2.3	4.7	1.6–3.2	1.9	10.0	1.6–2.1
Myocardial infarction	2.0	3.2	1.3–3.0	1.8	6.1	1.5–2.2
Stroke	1.6	1.7	0.9–2.7	1.8	5.2	1.5–2.3
Alcoholism	1.9	1.5	0.8–4.6	1.7	3.5	1.3–2.4
Cancer	1.2	1.0	0.8–1.6	1.1	1.7	1.0–1.3

GI: gastrointestinal, GU: genitourinary.

Table 3. Medical and hospital treatment* for comorbid conditions among RA patients with and without fibromyalgia (FM). Data are percentages.

Treatment for	FM (–)	FM (+)	OR (95% CI)
Drug treatment			
Depression	9.6	22.5	2.7 (1.8–4.2)
Diabetes	5.9	10.7	1.9 (1.6–2.3)
Pulmonary disease	16.2	24.8	1.7 (1.5–1.9)
Cardiovascular disease	18.8	29.5	1.8 (1.6–2.0)
Cancer	1.0	0.6	0.5 (0.4–1.1)
Hospitalization			
Myocardial infarction (MI)	0.06	0.13	2.5 (0.8–7.1)
Congestive heart failure (CHF)	0.2	0.6	4.6 (2.4–8.7)
MI or CHF	0.2	0.7	3.7 (2.1–6.4)
Diabetes	0.1	0.5	4.5 (2.1–11.6)
Pulmonary disease	0.2	0.6	2.6 (1.2–5.5)
Hypertension	0.4	0.7	1.7 (0.9–3.0)

* Adjusted for age and sex.

Table 4. Semiannual direct medical costs* for RA patients with and without fibromyalgia (FM). Data are US dollars.

	FM (–)	FM (+)	Cost Difference
Total costs	4687	6477	1790 (1557–2022)
Drug costs	3181	3776	596 (441–751)
Hospitalization costs	732	1324	591 (443–739)
Outpatient costs	775	1377	602 (554–650)

* Adjusted for age and sex.

Longterm outcomes: work disability and total joint arthroplasty. As shown in Table 5, 60.8% of RA patients under the age of 65 years reported work disability, as did 55.4% of FM patients of all ages; 54.4% of those under age 65 were currently receiving disability payments and 42.7% were receiving social security disability payments. For the work measures in Table 4, OR were increased from 3.3 to 4.3 for FM compared to non-FM patients. The Table also shows that FM patients had an increased rate of total joint arthroplasty compared to those without FM.

Table 5. Work disability and total joint arthroplasty in RA patients with and without fibromyalgia (FM). Data are percentages.

	FM (–)	FM (+)	OR (95% CI)
Work disability			
Work disability — ever (all ages)	26.4	55.4	3.3 (3.0–3.7)
Work disability — ever (age < 65)	27.5	60.8	4.0 (3.5–4.6)
Any current disability payment (< age 65)	23.1	54.4	4.0 (3.5–4.6)
Social Security disability (current) < age 65	14.9	42.7	4.3 (3.7–5.1)
Joint replacement			
Total joint arthroplasty	11.2	14.0	1.3 (1.1–1.5)

* Adjusted for age, sex, and duration of RA.

Clinical measures. Table 6 compares clinical severity measures for the 2 groups. For every variable in the Table, FM patients had substantially more abnormal scores. For example, scores for pain, global severity, and HAQ were 6.7, 5.0, and 1.8, respectively, for RA FM patients compared to 3.4, 3.1, and 1.0 for patients without FM. Quality of life was very abnormal in FM patients, as measured by the SF-36 and utility scores.

As shown in Table 7, corticosteroid use was increased by more than 25% in those with FM (46.1% vs 36.4%). There was slightly greater use of biologics and COX-2 nonsteroidal antiinflammatory drugs by this group, and opioid use was doubled (37.7% vs 16.5%). Although methotrexate (MTX) usage is reduced, this percentage reflects current MTX use and does not consider those patients who had used and then discontinued MTX. When lifetime MTX use is considered, however, 65.3% of those with FM and 63.8% without FM had used MTX.

A small number of erythrocyte sedimentation rate (ESR) determinations were available for patients enrolling as part of the infliximab safety registry. Of 1636 tests, 1336 were in patients without FM and 300 were in patients with FM. ESR values were 29.0 mm/h and 33.2 mm/h for the non-FM and FM groups, respectively. To put these values in perspective, we used 1968 RA patients' ESR values from the Wichita data bank and determined percentile ranks for ESR values. A value of 29.0 mm/h is at the 49th percentile and a value of

Table 6. Current disease severity and status variables in RA patients with and without fibromyalgia (FM).

Variable	FM (–) Mean (SD) or %	FM (+) Mean (SD) or %
Clinical variables		
Pain (0–10)	3.4 (2.5)	6.7 (2.1)
Global severity (0–10)	3.1 (2.3)	6.0 (2.1)
Sleep disturbance (0–10)	3.3 (2.9)	6.3 (2.8)
HAQ (0–3)	1.0 (0.7)	1.8 (0.5)
Anxiety (0–10)	3.2 (1.8)	5.1 (1.9)
Depression (0–10)	2.2 (1.6)	3.9 (2.0)
GI severity (0–10)	1.6 (2.1)	3.9 (3.0)
Fatigue (0–10)	3.8 (2.6)	8.1 (1.1)
Thinking or memory problems, (%)	27.7	57.5
SF-36		
Physical component score	33.5 (10.2)	23.5 (6.6)
Mental component score	46.1 (12.7)	29.5 (12.8)
RADAI variables		
Arthritis activity — 6 mo (0–10)	4.0 (2.6)	7.0 (2.1)
Arthritis activity — now (0–10)	3.3 (2.6)	6.8 (2.3)
RADAI joint score (0–48)	10.4 (7.7)	23.5 (8.6)
AM stiffness (category)	1.7 (1.3)	3.1 (1.5)
RADAI score (0–10)	3.1 (1.9)	6.1 (1.6)
Utility (quality of life)		
EuroQol (mapped)	0.7 (0.2)	0.3 (0.2)

HAQ: Health Assessment Questionnaire, GI: gastrointestinal, SF-36: Medical Outcomes Study Short Form-36, RADAI: RA Disease Activity Index.

Table 7. Current treatments among RA patients with and without fibromyalgia (FM).

Treatment, %	FM (–)	FM (+)
Prednisone	36.4	46.1
Biologic agents	34.1	36.5
MTX	52.2	47.5
NSAID (all)	69.2	69.2
COX-2 drugs	29.2	34.7
No analgesics	76.1	50.8
Non-opioid analgesics	7.4	12.2
Opioid analgesics	16.5	37.1

MTX: methotrexate, NSAID: nonsteroidal antiinflammatory drugs, COX-2: cyclooxygenase-2.

33.2 mm/h is at the 57th percentile. By contrast, values for the pain scores in Table 6 are at the 35th and 74th percentiles for the non-FM and FM patients, respectively.

DISCUSSION

We tried to approach FM issues in a way that is neutral to the ongoing FM controversy by studying the set of all patients in the National Data Bank who were diagnosed by their rheumatologists as having RA, not FM. In effect, the observations we are making occur in a setting where we ask, "What are the characteristics of FM if you have not been diagnosed with the condition?" This approach sidesteps the controversies regarding selection and diagnostic bias, spectrum bias, disability, creating illness, and "invented" diagnosis. Although we cannot avoid using the word fibromyalgia, we are using it only in the sense of "fibromyalgia-like symptom complex." It is also important that the operational survey criteria we use here are not suitable for clinical diagnosis and should not be used for that purpose. Later in the discussion we add additional thoughts regarding diagnosis and diagnostic criteria in this syndrome.

Our results demonstrate that patients with RA and FM have sociodemographic handicaps that include less education, proportionately increased minority status, higher divorce rates, lower household income, and greater rates of poverty. They also have more serious comorbid illnesses, such as diabetes and cardiovascular diseases, which were validated by review of hospital and medication records. Patients with FM also received disability pensions at rates that were more than 4 times greater than in those without FM, and had rates of total joint replacement that were 25% greater. In addition, they had annual direct medical costs that were $3580 greater than in RA patients without FM. Steroid usage was 21% greater in FM patients and opioid use was more than doubled. Quality of life was very low, 0.3 on the 0–1 utility scale. For every self-reported RA severity and status measure, FM patients were substantially more severe (Table 6). Difference in self-report measures (such as pain) spanned 39 percentiles, but differences in ESR (in a limited sample) spanned only 8 percentiles.

From the data of this study it seems possible to come to a number of conclusions. Social disadvantage plays some role in the genesis of FM. Comorbid illness also contributes, either as a psychological stressor or through some other (unknown) mechanism. Whether axial skeletal pain, which is more common in FM, is a manifestation of axial skeletal disease or is a manifestation of FM, or both, cannot be easily distinguished. However, back surgery during the 6-month analysis period of this study was significantly more common in those with FM (OR 6.3, 95% CI 1.4–28.1). As a minimum, this suggests the possibility that there is more non-RA musculoskeletal disease in those with FM, and that this might be causally linked to FM genesis. There is also evidence that RA is more severe in patients with FM. The limited data from ESR determinations also suggest this is the case, as does the increased rate of total joint surgery and work disability. However, total joint replacement and work disability, and all of the clinical measures of Table 6, can reflect pain and suffering rather than inflammatory disease or RA damage. Even so, we believe that a conservative interpretation of the data, taken as a whole, suggests that RA is more severe in those with FM.

The data of this study, then, confirm the sociodemographic disadvantage of patients with FM and document increased rates of depression, but add evidence that physical illness (comorbidity) and RA severity also contribute to the expression of FM symptoms. Regardless of possible causal relationships, descriptive data on the 17.5% of patients with FM show they have far worse symptoms of pain and distress (Table 6), and more concomitant illnesses, utilize increased medical services, and have high rates of work disability and joint replacement. These data suggest that it is important for physicians to think of FM and FM symptoms in patients with RA.

The FM survey criteria used here are essentially cross-sectional symptom criteria, as are the ACR FM criteria. By contrast, criteria for RA are independent of time: once you have RA you are always considered to have RA, even when you are in remission. It is well known that patients diagnosed with the ACR FM criteria may meet the criteria at one time, but not meet the criteria at a subsequent point[33]. If that is the case, how can any FM criteria be useful? It is perhaps that in the clinic we sense that a diagnosis of FM, whether made *in pectore* or to the patient, represents a prediction that over time the patient will continue to display characteristics of FM. Stated somewhat differently, a diagnosis of FM implies that the probability of subsequently meeting FM criteria is high — that FM represents a kind of trait characteristic. And it is perhaps for that reason that the characterization of FM is useful to the clinician. But is this supposition true? We used the National Data Bank to identify patients with RA in this study who had at least 2 assessments for FM using the survey criteria. Over a mean of 2.1 (SD 1.1) years, 54% of patients who met the criteria at first assessment also met the criteria at the followup. By contrast,

Appendix. Comparison of Wichita clinic fibromyalgia (FM) patients and National Data Bank (NDB) FM patients with RA.

Clinical Variables	FM (Wichita data set) n = 1629 Mean (SD)	RA FM (+) (NDB) n = 2078 Mean (SD)
Pain (0–10)	6.6 (2.3)	6.7 (2.1)
Global severity (0–10)	5.9 (2.4)	6.0 (2.1)
Sleep disturbance (0–10)	6.9 (2.6)	6.3 (2.8)
HAQ (0–3)	1.2 (0.7)	1.8 (0.5)
Anxiety (0–10)	5.5 (2.0)	5.1 (1.9)
Depression (0–10)	3.7 (2.0)	3.9 (2.0)
GI severity (0–10)	4.5 (3.0)	3.9 (3.0)
Fatigue (0–10)	6.9 (2.6) (8.4, 1.2)*	8.1 (1.1)

* If fatigue < 6 is excluded.

only 10% of those who did not meet the criteria at first met them subsequently. These data support the idea of a trait-like state for FM and the usefulness of criteria that are based on cross-sectional assessments.

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