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ORIGINAL ARTICLE

The American College of Rheumatology Preliminary Diagnostic Criteria for Fibromyalgia and Measurement of Symptom Severity

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This criteria set has been approved by the American College of Rheumatology (ACR) Board of Directors as Provisional. This signifies that the criteria set has been quantitatively validated using patient data, but it has not undergone validation based on an external data set. All ACR-approved criteria sets are expected to undergo intermittent updates.

As disclosed in the manuscript, these criteria were developed with support from the study sponsor, Lilly Research Laboratories. The study sponsor placed no restrictions, offered no input or guidance on the conduct of the study, did not participate in the design of the study, see the results of the study, or review the manuscript or submitted abstracts prior to the submission of the paper. The recipient of the grant was Arthritis Research Center Foundation, Inc. The authors received no compensation. The ACR found the criteria to be methodologically rigorous and clinically meaningful.

ACR is an independent professional, medical and scientific society which does not guarantee, warrant or endorse any commercial product or service. The ACR received no compensation for its approval of these criteria.

Objective. **To develop simple, practical criteria for clinical diagnosis of fibromyalgia that are suitable for use in primary and specialty care and that do not require a tender point examination, and to provide a severity scale for characteristic fibromyalgia symptoms.**

Methods. **We performed a multicenter study of 829 previously diagnosed fibromyalgia patients and controls using physician physical and interview examinations, including a widespread pain index (WPI), a measure of the number of painful body regions. Random forest and recursive partitioning analyses were used to guide the development of a case definition of fibromyalgia, to develop criteria, and to construct a symptom severity (SS) scale.**

Results. **Approximately 25% of fibromyalgia patients did not satisfy the American College of Rheumatology (ACR) 1990 classification criteria at the time of the study. The most important diagnostic variables were WPI and categorical scales for cognitive symptoms, unrefreshed sleep, fatigue, and number of somatic symptoms. The categorical scales were summed to create an SS scale. We combined the SS scale and the WPI to recommend a new case definition of fibromyalgia: (WPI ≥7 AND SS ≥5) OR (WPI 3–6 AND SS ≥9).**

Conclusion. **This simple clinical case definition of fibromyalgia correctly classifies 88.1% of cases classified by the ACR classification criteria, and does not require a physical or tender point examination. The SS scale enables assessment of fibromyalgia symptom severity in persons with current or previous fibromyalgia, and in those to whom the criteria have not been applied. It will be especially useful in the longitudinal evaluation of patients with marked symptom variability.**

INTRODUCTION

The introduction of the American College of Rheumatology (ACR) fibromyalgia classification criteria 20 years ago began an era of increased recognition of the syndrome (1). The criteria required tenderness on pressure (tender points) in at least 11 of 18 specified sites and the presence of widespread pain for diagnosis. Widespread pain was defined as axial pain, left- and right-sided pain, and upper and lower segment pain.

Over time, a series of objections to the ACR classification criteria developed, some practical and some philosophi-

Table 1. Selected clinical characteristics of patients with current or prior fibromyalgia and controls in phase 1*

Variable	Current fibromyalgia	Prior fibromyalgia	Controls
No. of patients (%)	196 (38.1)	67 (13.0)	251 (48.1)
Widespread pain index (0–19)	11.4 ± 4.4	8.2 ± 5.0	3.8 ± 3.2
Physician widespread pain index (0–19)	11.4 ± 4.1	7.2 ± 3.9	3.3 ± 2.5
Widespread pain, % patients	92.9	56.7	31.1
Widespread pain, % physicians	93.9	59.7	24.3
Tender point count (0–18)	15.9 ± 2.3	7.9 ± 4.1	2.5 ± 3.0
ACR 1990 classification criteria positive, % patients	92.9	0.0	0.0
ACR 1990 classification criteria positive, % physicians	93.9	0.0	0.0
ACR 1990 classification criteria positive, % patients or physicians	100.0	0.0	0.0
Physician global severity, categorical (0–3)	2.1	1.5	1.1
Patient global severity, categorical (0–3)	2.4	1.8	1.4
Patient symptom count (0–48)	22.9 ± 8.8	18.2 ± 8.4	9.7 ± 8.4
Physician somatic symptoms (0–3)	2.3 ± 0.7	1.9 ± 0.7	1.2 ± 0.5
HAQ-II score (0–3)	1.3 ± 0.6	1.0 ± 0.7	0.7 ± 0.6
Patient VAS unrefreshed sleep (0–10)	7.3 ± 2.7	5.2 ± 3.4	3.1 ± 3.0
Patient VAS sleep (0–10)	6.5 ± 2.8	4.4 ± 3.2	3.3 ± 3.0
Patient VAS pain (0–10)	6.5 ± 2.3	4.9 ± 2.7	4.1 ± 2.8
Patient VAS fatigue (0–10)	7.0 ± 2.4	5.0 ± 3.1	3.3 ± 2.9
Symptom severity scale (0–12)†	8.0 ± 2.6	6.0 ± 2.6	3.3 ± 2.2
No. of pain medications	3.3 ± 2.3	2.5 ± 1.4	1.9 ± 1.9

* Values are the mean ± SD unless otherwise indicated. ACR = American College of Rheumatology; HAQ-II = Health Assessment Questionnaire II; VAS = visual analog scale.
† Sum of physician somatic symptoms, physician waking unrefreshed, physician cognition, and physician fatigue.

256 who were control subjects. Fibromyalgia subjects were slightly older than controls (mean ± SD age 54.6 ± 12.9 versus 52.3 ± 12.2 years; $P = 0.035$), but did not differ by the percentage of males (8.2% versus 9.0%; $P = 0.732$), percentage of non-Hispanic whites (86.8% versus 85.9%; $P = 0.770$), or education level (mean ± SD 14.2 ± 2.1 versus 14.3 ± 2.2 years; $P = 0.517$).

Diagnosis and diagnostic methods. ACR classification criteria were used in 63.6% of fibromyalgia diagnoses and clinical diagnosis was used in 36.4% of fibromyalgia diagnoses. At the time of the study examination, 74.5% of patients who had been previously diagnosed with fibromyalgia satisfied the ACR classification criteria and 2.0% of controls satisfied the ACR classification criteria. Based on these data, we categorized patients into 3 groups based on prior diagnosis and ACR classification criteria status: 196 patients (38.1%) with current fibromyalgia (ACR classification criteria positive, physician fibromyalgia diagnosis positive), 67 patients (13.0%) with prior fibromyalgia (ACR classification criteria negative, physician fibromyalgia diagnosis positive), and 251 patients (48.1%) who were neither current nor prior fibromyalgia patients (control subjects) (Table 1). Using a 0–10 physician certainty of prior diagnosis scale, the mean certainties were: fibromyalgia 9.4, prior fibromyalgia 8.7, and control diagnosis 9.1. Patients previously diagnosed by clinical criteria were more likely to be classified as prior fibromyalgia (38.3%) compared with patients previously diagnosed by the ACR classification criteria (18.9%; $P < 0.001$). The proportion of patients who were controls or had prior or current fibromyalgia did not differ between the group of 10 expert physicians and the 20 clinical rheumatologists ($P = 0.640$).

Characteristics of patients by fibromyalgia status. There was a clear difference in clinical findings and symptom severity among the groups, the current fibromyalgia patients having the greatest symptom severity with prior fibromyalgia generally occupying the severity scale midpoint between current fibromyalgia and controls (Table 1). However, for the count of patient-endorsed somatic symptoms, the physician somatic symptom scale, and the SS scale, prior fibromyalgia patients had scores that were somewhat closer to current fibromyalgia patients than to control subjects. Figure 1 shows differences between groups for key variables. The tender point count (Figure 1D) demonstrates the clearest distinction between groups, followed by unrefreshed sleep (Figure 1C). Prior and current fibromyalgia patients had similar distributions of somatic symptom counts (Figure 1B), while prior fibromyalgia had the WPI shifted somewhat to the left (Figure 1A). Taken as a whole, these data show that approximately 25% of patients considered to have fibromyalgia by their physicians do not satisfy ACR classification criteria for fibromyalgia, and that they appear to have an intermediate severity position between fibromyalgia patients and control subjects, except for somatic symptoms.

Misclassification rates and fibromyalgia classifiers. To determine variables that best identify fibromyalgia and to examine the predictive power of study variables without the use of tender points, we divided the subjects into ACR