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# THE AMERICAN COLLEGE OF RHEUMATOLOGY 1990 CRITERIA FOR THE CLASSIFICATION OF FIBROMYALGIA

## Report of the Multicenter Criteria Committee

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**To develop criteria for the classification of fibromyalgia, we studied 558 consecutive patients: 293 patients with fibromyalgia and 265 control patients. Interviews and examinations were performed by trained, blinded assessors. Control patients for the group with primary fibromyalgia were matched for age and sex, and limited to patients with disorders that could be confused with primary fibromyalgia. Control patients for the group with secondary-concomitant fibromyalgia were matched for age, sex, and concomitant rheumatic disorders. Widespread pain (axial plus upper and lower segment plus left- and right-sided pain) was found in 97.6% of all patients with fibromyalgia and in 69.1% of all control patients. The combination of widespread pain and mild or greater tenderness in ≥11 of 18 tender point sites yielded a sensitivity of 88.4% and a specificity of 81.1%. Primary fibromyalgia patients and secondary-concomitant fibromyalgia patients did not differ statistically in any major study variable, and the criteria performed equally well in patients with and those without concomitant rheumatic conditions. The newly proposed criteria for the classification of fibromyalgia are 1) widespread pain *in combination with* 2) tenderness at 11 or more of the 18 specific tender point sites. No exclusions are made for the presence of concomitant radiographic or laboratory abnormalities. At the diagnostic or classification level, the distinction between primary fibromyalgia and secondary-concomitant fibromyalgia (as defined in the text) is abandoned.**

The seminal 1977 paper by Smythe and Moldofsky, "Two contributions to understanding of the 'fibrositis' syndrome" (1), revived interest in the long known but generally neglected syndrome of fibromyalgia (fibrositis). By proposing diagnostic criteria, the authors stimulated other investigators and began a cascade of interest that would lead to the publication of more than 60 research papers and to increasing clinical acceptance of the syndrome. In 1986, a consortium of centers interested in the fibromyalgia syndrome began a study of criteria for the diagnosis of primary and secondary-concomitant fibromyalgia. Prior to this committee's effort, a number of criteria sets, all generally similar in that they were based on some combination of tender point examination and symptoms, were proposed either formally as "crite-

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ria" or informally as de facto criteria used during a clinical report (1–7). These sets were useful and advanced the concept of fibromyalgia considerably.

Even so, there were serious methodologic problems with these criteria sets. Most had not been tested clinically, and none had been tested beyond the centers in which they were designed. No studies had used blinding. Most often, the definitions for the historical features, and even the physical examination features, were imprecise. The most important concern about the criteria, however, was that they tended to be circular; that is, the criteria confirmed the definition of fibromyalgia that was held by the investigators who developed them, a confirmation that might have been assisted by the unblinded status. It was with these objections in mind that the committee undertook the current study.

The committee's 4 specific objectives were 1) to provide a consensus definition of fibromyalgia; 2) to establish new criteria for the classification of fibromyalgia; 3) to study the relationship of "primary" fibromyalgia to "secondary" or "concomitant" fibromyalgia in terms of classification criteria; and 4) to ascertain how well previous criteria sets worked in a multicenter data set and to establish their relationship to the new criteria.

The concept of fibromyalgia (fibrositis) has evolved and, in the minds of many, differs significantly from the view of the disorder held 30–50 years ago (8–10). In part, these changes are the result of diagnostic criteria that tended to define the syndrome. Thus, the emphasis on irritable bowel syndrome and modulating factors advanced by Yunus and coworkers (2) added a dimension to the syndrome defined by the criteria of Smythe and Moldofsky (1). Among some investigators, however, fibromyalgia may be thought of as a psychological disorder (11,12) or, perhaps, a local myofascial pain syndrome (13). This disarray in construct has led to a blurring of the margins of the disorder and to the consequent idea that fibromyalgia means something different to every observer (14).

An important purpose of this report, then, is to define the fibromyalgia syndrome by the de facto recognition of its characteristics by interested investigators in multiple centers. In doing this, we have studied the syndrome in 16 centers in the United States and Canada, in academic and clinical settings, and among proponents and doubters. The consensus of the committee was to adopt the term *fibromyalgia*, which was first suggested by Hench in 1976 (15), rather than the older term *fibrositis*.

In the presence of other medical disorders that might "cause" or at least influence the symptoms of fibromyalgia, the term *secondary* or *concomitant fibromyalgia* has been applied (16,17). This terminology (secondary or concomitant) has had widespread usage but not universal acceptance. Previous criteria sets have generally not addressed this secondary or concomitant fibromyalgia, since the common symptoms and signs of fibromyalgia (sleep disturbance, fatigue, and morning stiffness; modulations of symptoms by external factors; and local tenderness "tender points") might be influenced by the secondary or concomitant conditions and render invalid the criteria used for "primary" fibromyalgia. To evaluate differences between the signs and symptoms of primary and secondary or concomitant fibromyalgia as they affect classification criteria, we studied both types of patients, together with appropriate control subjects. In this report, we propose criteria for fibromyalgia that may apply equally well to both primary and secondary syndromes.

There *appear* to have been 2 major directions in criteria sets. Wolfe and coworkers (4,5) have suggested that high counts of tender points are sufficient to diagnose the syndrome, without considering symptoms beyond widespread or generalized pain. From a differing perspective, Yunus et al (2,6) have emphasized the combined importance of symptoms and tender points, but have required as few as 2 tender points (defined as *severe* tenderness to palpation) in the presence of characteristic symptoms. Beyond the questions of whether either approach is effective and which approach is better, there is another important question of whether the different criteria sets imply a different definition of the syndrome. Other investigators have taken a middle ground, requiring symptoms and higher counts of tender points (3). In this report, we investigate how well previous criteria worked in our study sample.

## PATIENTS AND METHODS

In the fall of 1986, 25 investigators with a known interest in fibromyalgia were invited to participate in a criteria study of the syndrome. Twenty-two investigators participated in the planning and design stages of the trial. Because of other commitments, only 16 centers were able to enter patients into the trial. Centers entering evaluable patients into the trial included Fargo, ND (J. Fiechtner), Hamilton, Ontario, Canada (P. Tugwell and P. Clark), Wheeling, WV (T. J. Romano), Grand Forks, ND (J. Lessard), Portland, OR (R. Bennett and S. Campbell),

London, Ontario, Canada (G. McCain), Toronto, Ontario, Canada (Toronto Western Hospital; W. J. Reynolds), Tulsa, OK (D. Hamaty and B. Howard), Farmington, CT (M. Abeles), Willow Grove, PA (R. Gatter and C. M. Franklin), Toronto, Ontario, Canada (Sunnybrook Hospital; A. Fam), Peoria, IL (M. B. Yunus and A. T. Masi), Boston, MA (D. L. Goldenberg and R. Sims), Toledo, OH (R. Sheon and S. J. Farber), San Antonio, TX (I. J. Russell), and Wichita, KS (F. Wolfe).

**Protocol development.** A draft of the protocol and study questionnaire was prepared by 1 of the authors (FW) and mailed to potential investigators. The changes proposed by the investigators were incorporated, and 2 additional cycles of review and incorporation occurred. Helpful suggestions were received from the American College of Rheumatology Diagnostic and Therapeutic Criteria Committee. The protocol was further revised by 3 of the authors (CB, HAS, and PT).

In November 1986, physical examination training sessions for potential investigators and study coordinators were held in Boston and Chicago. Patients and controls for these sessions were provided by Drs. R. Katz (Chicago) and D. Goldenberg (Boston). Study center participants performed examinations according to a Latin square blinded design. Results of the examinations were immediately entered into a computer, and the analysis of the data was reported to the group. Based on these results, specific areas of disagreement and problems with the physical examination were identified and corrected. The protocol was reviewed by each investigator, and the final changes, based on review of the questionnaire and the physical examination, were made. Slides and a video tape of the examination technique were made at these sessions and distributed to each investigator.

**Study protocol.** Each center was asked to provide 40 patients: 10 with primary fibromyalgia plus 10 age- and sex-matched control patients, and 10 with secondary or concomitant fibromyalgia plus 10 age- and sex-matched control patients. Half of the patients and controls were new patients (seen for the first time in the clinic), and half were returning patients. Controls for primary fibromyalgia patients were the next age- and sex-matched patient with neck pain syndromes, low back pain syndromes, local (regional) tendinitis, trauma-related pain syndromes, and possible (not satisfying diagnostic criteria) systemic lupus erythematosus, rheumatoid arthritis, or similar disorders. Secondary or concomitant fibromyalgia included fibromyalgia in patients with "classical or definite rheumatoid arthritis, osteoarthritis of the knee or hand, low back pain syndromes, cervical pain syndromes (or combinations)." Controls for secondary or concomitant fibromyalgia patients were the next age- and sex-matched patient with the same diagnosis, but without fibromyalgia.

**Diagnosis.** The diagnostic classification of study subjects as fibromyalgia patients or control patients was made by the investigator using his or her *usual method of diagnosis*. Similarly, the investigator determined whether the patients had primary or secondary-concomitant fibromyalgia using his or her *usual method of classification*. As a general definition, primary fibromyalgia syndrome was fibromyalgia occurring in the absence of another significant condition. Secondary-concomitant fibromyalgia syndrome was fibromyalgia occurring in the presence of another significant rheumatic disorder. To avoid argument over the existence or nonexistence of "secondary fibromyalgia," which is believed by some investigators to be fibromyalgia caused by another condition, we adopted the term *secondary-concomitant fibromyalgia* to indicate fibromyalgia occurring in the presence of another significant rheumatic disorder which may have been caused by or was merely associated with the patient's fibromyalgia, according to the individual view of each study investigator. The investigator also performed and recorded the results of a joint examination. All subsequent interviews and all tender point and dolorimetry assessments were performed by a trained assessor. Assessors were other medical staff who, following the investigator's initial examination and with no knowledge of the findings or diagnosis, interviewed and examined the study subjects and completed the study forms.

To be sure that investigators and blinded assessors performed similarly, they performed (pre-study) practice examinations together until the results of their examinations were in agreement. Examinations of "test patients" were completed independently, using standard protocol forms, and were compared.

The blinded assessors directly entered the interview data onto the study questionnaire. At the time of examination, patients were given visual analog scales relating to pain, global severity, and duration of morning stiffness.

**Dolorimetry.** Dolorimeters (Chatillon Instruments, Kew Gardens, NY) were provided to each center. These pressure algometers are spring-loaded gauges capped with a 1.54-$cm^2$ stopper. Five centers had their own Chatillon instrument. These instruments allowed slightly higher readings than the ones provided. To control for the different instruments, all scores >6.5 kg/1.54 $cm^2$ were recorded as 6.5 kg/1.54 $cm^2$. Investigators were told to advance the instrument at a rate of approximately 1 kg per second, and to instruct the patient to "tell me when this becomes painful."

Dolorimetry was performed at 6 "active" sites: the right occiput at the suboccipital muscle insertion region, the right trapezius at the midpoint of the upper border, the right paraspinous 3 cm lateral to the midline at the level of the mid-scapula, the right second costochondral junction (just lateral to the junction on upper surface), the right lateral epicondyle 2 cm distal to the epicondyle, and the right knee at the medial fat pad just proximal to the joint line. Three "control" sites were also assessed: the right forearm at the dorsal distal third of the forearm, the right thumbnail with thumb placed on the table, and the midpoint of the dorsal right third metatarsal.

**Tender point examination.** Tender points were evaluated by palpation with the pulp of the thumb or the first 2 or 3 fingers, at a pressure of ~4 kg. This level of pressure was determined by having examiners palpate the cork end of the dolorimeter and observing the effort required to reach the 4-kg mark. Twenty-four "active" sites (12 pairs) were examined: occiput at the suboccipital muscle insertions, low cervical at the anterior aspects of the intertransverse spaces at C5–C7, trapezius at the midpoint of the upper border, supraspinatus at origins, above the scapula spine near the medial border, paraspinous 3 cm lateral to the midline at the level of the mid-scapula, second rib at the second costochon-

dral junctions, just lateral to the junctions on the upper surfaces, lateral pectoral at the level of the fourth rib at the anterior axillary line, lateral epicondyle 2 cm distal to the epicondyles, medial epicondyle at the epicondyles, gluteal at the upper outer quadrants of buttocks in anterior fold of muscle, greater trochanter just posterior to the trochanteric prominence, and knees at the medial fat pad proximal to the joint line. Six "control" sites (3 pairs) were examined: forearm at the distal dorsal third of the forearm, thumbnail, and midfoot at the midpoint of the dorsal third metatarsal.

The following scoring system for grading the severity of tender points (18) was used: 0 = no pain; 1 (mild) = complaint of pain without grimace, flinch, or withdrawal; 2 (moderate) = pain plus grimace or flinch; 3 (severe) = pain plus marked flinch or withdrawal; 4 (unbearable) = patient "untouchable," withdraws without palpation. A grimace was a "facial expression." A flinch was defined as "a slight body movement." A marked flinch was defined as an "exaggerated body movement." Withdrawal was defined as "moving the body part away from the examiner." "Tender" was not interpreted as pain. Only a statement of "pain" was accepted for scores greater than 0. In this report, "mild or greater" tenderness refers to any palpation score of 1 or greater; "moderate or greater" refers to palpation tenderness of 2 or greater.

**Skinfold tenderness.** Skinfold tenderness was assessed by rolling the upper border of the trapezius between the thumb and second and third fingers, using moderate pressure. Skinfold tenderness was recorded as present if either the left side or the right side was painful on examination.

**Study variables.** In this study, we employed variables that had already been shown to differ among primary fibromyalgia patients and controls in previous studies. The 11 symptom variables included sleep disturbance, fatigue, morning stiffness, anxiety, irritable bowel syndrome, frequent headaches, Raynaud's phenomenon, sicca symptoms, prior depression, paresthesias, and "pain all over." The 10 modulating factor variables included noise, fatigue, stress, activity, anxiety, humidity, warmth, cold, poor sleep, and weather change. The pain variables included 30 sites assessed for the number and location of painful sites. The physical examination variables included 30 tender point sites and 9 dolorimetry sites assessed for the location and score of tender point sites, and score of active and control dolorimetry sites.

We also included variables that were suspected to differ between fibromyalgia patients and controls but had not been effectively studied previously. The 2 symptom variables were urinary urgency and dysmenorrhea; the 3 modulating factor variables were vacation, rest, and working various numbers of hours; and the 3 physical examination variables were skinfold tenderness, reactive hyperemia, and reticular skin disturbance.

The quality of sleep ("sleep disturbance") was assessed by asking the patient if he awakened tired or nonrefreshed "never," "seldom," "often or usually," or "always." "Often or usually" or "always" was scored as positive, and other replies as negative. Similar questioning was used to assess fatigue (e.g., "If you are fatigued, are you 'seldom,' 'often or usually,' or 'always' fatigued?"), as well as for most of the other questions (e.g., anxiety [or nervousness], frequent headaches, etc.). Irritable bowel syndrome was determined by asking the patients about symptoms; it was defined as "periodically altered bowel habits with lower abdominal pain or distension, usually relieved or aggravated by bowel movements; no blood." The duration of morning stiffness was rounded to the nearest 15 minutes and recorded. To obtain information regarding the regions in which patients were having pain, interviewers were free to use various techniques for eliciting information, but were required to fill out a questionnaire in which 30 locations were described, endorsing each location as "yes" or "no." Symptoms of fatigue referred to the previous week; all other symptoms referred to the previous month.

Reticular skin discoloration was defined as "a fish-net-like red, blue, or purple mottled appearance to the skin, most readily seen along the inner aspects of the arms, thighs, and low back." Raynaud's phenomenon was based on patient report and was diagnosed according to the American Rheumatism Association Glossary Committee definition, requiring the description of "dead white" pallor (19). Sicca syndrome was identified if patients reported symptoms of oral and/or ocular dryness. Dysmenorrhea was identified if patients reported a history of painful menstruation. Reactive hyperemia was assessed over the midpoint of the trapezius after tender point examination at this site. The appearance of erythema 2 minutes after palpation was considered a positive test result.

Widespread pain was identified when all of the following were present: pain on the left side of the body, pain on the right side of the body, pain above the waist, and pain below the waist. In addition, axial skeletal pain (cervical spine or anterior chest or thoracic spine or low back) had to be present. In this definition, left or right shoulder and buttock pain was considered as pain for each involved side. Low back (lumbar) pain was considered lower segment pain. Thus, pain in 3 sites (e.g., right shoulder, left buttock, and thoracic spine) qualifies as widespread pain.

**Statistical analysis.** Data were analyzed by computer using SAS version 6.03 (20). Chi-square tests with correction for continuity were used for $2 \times 2$ tables. To facilitate comparisons of variables within and between groups, the cross-product ratio (odds ratio) and the phi statistic were calculated. Continuous variables were compared with *t*-tests. Analysis of variance was used to test for differences among centers for the dolorimetry and tender point analyses. For the purposes of statistical analyses, ordinal data were dichotomized at a critical level for frequency estimation and other analyses. To control for multiple comparisons, statistical significance was declared at the 0.001 level. All tests were 2-tailed.

Potential criteria items were initially examined for their discriminatory power in univariate and multivariate analyses. These data were used by the committee to reduce the number of tender points required in the examination, and to identify candidate symptom variables and groups of variables. In subsequent analyses, various combinations of symptoms were tested in combination with different levels of tender point positivity to identify which items or groups of items performed best.

Three centers lost their independent assessor after the study was under way. The center investigator performed

**Table 1.** Demographic and severity variables for patients with primary fibromyalgia syndrome (PFS), secondary-concomitant fibromyalgia syndrome (SCFS), and all FS patients, as well as their age- and sex-matched control patients*

| Variable | Patients | | | Controls | | |
|---|---|---|---|---|---|---|
| | PFS (n = 158) | SCFS (n = 135) | All FS (n = 293) | PFS (n = 135) | SCFS (n = 130) | All FS (n = 265) |
| Age (years) | 44.7 (10.41)† | 51.9 (12.53) | 49.1 (12.83) | 45.9 (11.14)† | 52.5 (13.61) | 48.0 (11.98) |
| Sex (% female) | 92.4 | 84.4 | 88.7 | 91.1 | 84.6 | 87.9 |
| Ethnic group | | | | | | |
| Caucasian (%) | 91.1 | 94.8 | 92.8 | 90.3 | 89.9 | 90.1 |
| Hispanic (%) | 5.7 | 4.4 | 5.1 | 5.2 | 6.9 | 6.1 |
| Black (%) | 1.3 | 0.7 | 1.0 | 1.5 | 0.8 | 1.1 |
| Physician-rated severity of | | | | | | |
| Fibromyalgia (0–100 scale) | 69.9 (7.51) | 70.1 (16.61) | 69.9 (18.43) | | | |
| SC disorder (0–100 scale) | | 52.8 (21.89) | | 44.7 (22.10)‡ | 52.00 (20.73) | 48.2 (21.72) |
| Patient-rated severity | | | | | | |
| Pain (0–100 scale) | 62.3 (25.00)§ | 65.9 (21.31)§ | 64.0 (23.38)§ | 46.3 (28.89) | 43.9 (26.11) | 45.2 (27.53) |
| Global severity (0–100 scale) | 57.5 (28.83)§ | 59.3 (27.41)§ | 58.3 (28.15)§ | 39.9 (30.90) | 34.6 (29.88) | 37.3 (30.46) |

* Values are the mean (SD). See Patients and Methods for definitions of patient groups.
† Statistically significantly different from SCFS patients and PFS and SCFS controls, as indicated, at the 0.0001 level.
‡ Statistically significantly different from SCFS controls at the 0.006 level.
§ Statistically significantly different from respective controls at the 0.0001 level.

the examinations for 10 patients in Tulsa (OK), 7 patients in Portland (OR), and 3 patients in Farmington (CT). A total of 92.8% of the examinations were conducted by the independent, blinded assessors. Because the total number of patients examined by the center investigator was small, we chose to analyze rather than to exclude these data. Only 2 fibromyalgia control patients were seen in Boston during the course of the study, but the center continued to enter fibromyalgia patients beyond the requested 10. In all, they entered 21 patients. These patients were also included in the analysis.

To determine if it was appropriate to pool the data from patients seen in the clinic for the first time (new patients) with the data from returning patients, we analyzed 4 scores by multivariate analysis of variance (MANOVA): 1) the number of painful areas, 2) the symptom score (sum of positive items: sleep disturbance, fatigue, paresthesias, headache, anxiety, irritable bowel syndrome), 3) the total active tender point score, and 4) the total active dolorimetry score. No differences were noted between patient groups ($P > 0.5$). Therefore we pooled "new" and "returning" data in the subsequent analyses.

## RESULTS

**Characteristics and diagnoses of patient and control groups.** *Demographics and baseline severity.* Table 1 presents the demographic and disease severity data for the primary fibromyalgia group, the secondary-concomitant fibromyalgia group, the 2 groups combined, and the respective control groups. Patients with secondary-concomitant fibromyalgia were significantly older (by 7.2 years) than those with primary fibromyalgia, reflecting the expected age distribution of the concomitant conditions. No differences in distribution by sex or ethnic group were noted. Both the patients and the controls had at least moderate pain and severity scores by physician rating and self rating, but the various fibromyalgia groups had clinically and statistically more abnormal ratings.

**Table 2.** Rheumatic disease diagnoses in primary fibromyalgia syndrome (PFS) control patients and patients with secondary-concomitant fibromyalgia syndrome (SCFS)*

| Diagnosis | PFS controls (n = 135) | SCFS patients (n = 135) |
|---|---|---|
| Inflammatory arthritis | 42.0 | 34.6 |
| Rheumatoid arthritis | 25.8 | 26.6 |
| Polyarthritis and systemic disorders† | 8.9 | 4.0 |
| Systemic lupus erythematosus | 7.3 | 4.0 |
| Axial skeletal syndromes | 30.7 | 28.2 |
| Low back pain syndromes | 20.2 | 19.3 |
| Neck pain syndromes | 10.5 | 8.9 |
| Osteoarthritis | 0.0 | 37.0 |
| Osteoarthritis of knee or hand | – | 37.0 |
| Nonarticular disorders | 21.7 | 0.0 |
| Tendinitis | 10.5 | – |
| Regional syndromes | 11.2 | – |
| Arthralgia syndromes | 4.0 | 0.0 |

* Values are the percentage of patients with the diagnosis. For PFS control patients, the diagnostic categories included suspected cases or cases that did not meet diagnostic criteria; SCFS patients had established cases that met diagnostic criteria. Two PFS patients were not classified.
† Includes psoriatic arthritis, scleroderma, mixed connective tissue disease, erythema nodosum, carpal tunnel syndrome, and sarcoidosis.

**Table 3.** Pain complaints and symptoms for primary and secondary-concomitant fibromyalgia patients and their control patients*

| Variable | Test n | Patients | Controls | $\chi^2$ | $P$ | Odds ratio | $\phi$ statistic |
|---|---|---|---|---|---|---|---|
| Primary fibromyalgia | | | | | | | |
| No. of patients | – | 158 | 135 | – | – | – | – |
| Pain complaints | | | | | | | |
| 15+ painful regions | 293 | 59.5 | 13.3 | 63.7 | <0.001 | 9.5 | 0.473 |
| Widespread pain | 293 | 97.5 | 71.1 | 38.3 | <0.001 | 15.6 | 0.371 |
| Symptoms | | | | | | | |
| General symptoms | | | | | | | |
| Sleep disturbance | 288 | 75.6 | 31.1 | 55.7 | <0.001 | 6.9 | 0.447 |
| Fatigue | 290 | 78.2 | 38.1 | 46.6 | <0.001 | 5.8 | 0.408 |
| Morning stiffness | 265 | 76.2 | 59.3 | 7.9 | <0.001 | 2.2 | 0.181 |
| Other symptoms | | | | | | | |
| Paresthesias | 291 | 67.1 | 32.3 | 33.5 | <0.001 | 4.3 | 0.346 |
| Anxiety | 290 | 44.9 | 21.6 | 18.4 | <0.001 | 3.3 | 0.244 |
| Headache | 282 | 54.3 | 30.5 | 15.1 | <0.001 | 2.7 | 0.269 |
| Irritable bowel | 292 | 35.7 | 13.3 | 18.0 | <0.001 | 3.6 | 0.256 |
| Interpretive symptoms | | | | | | | |
| "Pain all over" | 283 | 68.8 | 21.7 | 60.7 | <0.001 | 7.8 | 0.470 |
| Secondary-concomitant fibromyalgia | | | | | | | |
| No. of patients | – | 135 | 130 | – | – | – | – |
| Pain complaints | | | | | | | |
| 15+ painful regions | 265 | 51.1 | 12.3 | 44.0 | <0.001 | 7.4 | 0.416 |
| Widespread pain | 265 | 97.8 | 66.9 | 41.8 | <0.001 | 21.7 | 0.407 |
| Symptoms | | | | | | | |
| General symptoms | | | | | | | |
| Sleep disturbance | 263 | 73.3 | 22.7 | 65.5 | <0.001 | 9.4 | 0.452 |
| Fatigue | 264 | 85.2 | 40.3 | 55.2 | <0.001 | 8.5 | 0.465 |
| Morning stiffness | 230 | 78.0 | 55.1 | 12.6 | <0.001 | 2.9 | 0.181 |
| Other symptoms | | | | | | | |
| Paresthesias | 263 | 57.9 | 38.5 | 9.1 | <0.001 | 2.2 | 0.194 |
| Anxiety | 265 | 51.1 | 21.5 | 23.7 | <0.001 | 3.8 | 0.307 |
| Headache | 259 | 51.1 | 24.2 | 18.8 | <0.001 | 3.3 | 0.278 |
| Irritable bowel | 263 | 22.4 | 11.6 | 4.6 | <0.001 | 2.2 | 0.143 |
| Interpretive symptoms | | | | | | | |
| "Pain all over" | 248 | 64.8 | 16.3 | 58.5 | <0.001 | 9.57 | 0.494 |

* Values are the percentage of patients with the pain complaint or symptom. See Patients and Methods for definitions of patient groups. Morning stiffness represents >15 minutes duration.

*Secondary-concomitant and control disorders.* Patients with secondary-concomitant fibromyalgia had *established disease* that could be classified into 3 major categories: inflammatory arthritis (34.6%), axial skeletal syndromes (28.2%), and osteoarthritis of the knee or hip (37.0%) (Table 2). Primary fibromyalgia control patients were classified into 3 categories. *Possible* inflammatory arthritis (42.0%) comprised a category of inflammatory disorders, and axial skeletal syndromes constituted 30.7% of the controls. The remaining disorders (33.7%) generally constituted regional nonarticular syndromes or nonspecific arthralgias.

**Symptoms and physical findings in primary and secondary-concomitant fibromyalgia patients.** *Pain complaints.* There were significant differences in the location and extent of pain complaints in fibromyalgia patients and in control patients (Table 3). Patient groups characteristically had multiple painful regions (15+ painful regions in fibromyalgia patients 51–60% versus 12–13.3% in controls). Widespread pain was found in more than 97% of the patients and in approximately 70% of the controls. Pain in the thoracic, lumbar, and cervical regions in fibromyalgia patients was present at rates of 72.3%, 78.8%, and 85.3%, compared with 24.2%, 45.5%, and 50.6% rates, respectively, in controls. Patients and controls differed for all variables at the 0.001 level.

*Symptoms.* The most characteristic symptoms of the fibromyalgia groups were fatigue, sleep disturbance, and morning stiffness. These symptoms were found in 73–85% of the patients. "Pain all over," paresthesias, headache, and anxiety were moderately

**Table 4.** Comparison of key study variables in patients with primary fibromyalgia syndrome (PFS) and patients with secondary-concomitant fibromyalgia syndrome (SCFS)*

| Variable | PFS patients (n = 158) | SCFS patients (n = 135) | $\chi^2$ | $t$ | $P$ |
|---|---|---|---|---|---|
| Historical data | | | | | |
| Pain complaints | | | | | |
| 15+ painful regions | 59.5 | 51.1 | 1.747 | | 0.186 |
| Widespread pain | 97.5 | 97.8 | 0.000 | | 1.000 |
| Symptoms | | | | | |
| General symptoms | | | | | |
| Sleep disturbance | 75.6 | 73.3 | 0.100 | | 0.752 |
| Fatigue | 78.2 | 85.2 | 1.894 | | 0.169 |
| Morning stiffness >15 minutes | 76.2 | 78.0 | 0.130 | | 0.718 |
| Other symptoms | | | | | |
| Paresthesias | 67.1 | 57.9 | 2.236 | | 0.135 |
| Anxiety | 44.9 | 51.1 | 0.893 | | 0.345 |
| Irritable bowel | 35.7 | 22.4 | 5.503 | | 0.019 |
| Headache | 54.3 | 51.1 | 0.169 | | 0.681 |
| Interpretative symptoms | | | | | |
| "Pain all over" | 68.8 | 64.8 | 0.341 | | 0.559 |
| Physical examination data | | | | | |
| Dolorimetry scores | | | | | |
| Active sites (0–6.5 scale) | 3.5 (1.28) | 3.4 (1.30) | 0.740 | | 0.459 |
| Control sites (0–6.5 scale) | 5.1 (1.37) | 5.0 (1.34) | 0.493 | | 0.622 |
| Tender point palpation scores and counts | | | | | |
| Average tenderness (0–4 scale) | 1.6 (0.64) | 1.5 (0.66) | | 1.107 | 0.269 |
| Mild or greater (0–24 sites) | 20.0 (4.25) | 19.3 (4.39) | | 1.474 | 0.141 |
| Moderate or greater (0–24 sites) | 13.0 (6.81) | 12.0 (7.10) | | 1.191 | 0.235 |
| Severe (0–24 sites) | 5.2 (5.91) | 4.7 (5.25) | | 0.742 | 0.459 |
| Skinfold tenderness | 65.1 | 54.8 | 3.167 | | 0.075 |

* Values are the percentage of patients with the pain complaint, symptom, or skinfold tenderness, and the mean (SEM) dolorimetry scores (kg/1.54 $cm^2$) and tender point scores and counts. Tender point palpation scores and counts refer to the 24 active sites. Average tenderness is the total tender point score for the 24 sites divided by 24, or the mean score for tenderness per site. Other tender point variables are the number of sites that were tender, according to degree of tenderness (see Patients and Methods for further details).

common symptoms, occurring in approximately 45–69%. Less common (<35%) were irritable bowel syndrome, sicca symptoms, and Raynaud's phenomenon. Patients and controls differed for these symptoms at the 0.001 level.

*Modulating factors.* Modulation of musculoskeletal symptom by factors such as cold, poor sleep, anxiety, humidity, stress, fatigue, weather change, and warmth were found in 60–79% of fibromyalgia patients, but were found only somewhat less frequently in controls.

Pain and other symptoms in primary and secondary fibromyalgia patients were compared as shown in Table 4. Except for irritable bowel syndrome, which was identified in more patients with primary than secondary-concomitant fibromyalgia ($P = 0.019$), no differences between the 2 groups were noted.

Table 5 gives the physical examination data for the various patient and control groups. As with pain and symptoms, patients and controls differed at the 0.001 level for variables in this section. Fibromyalgia patients had a mean tender point count of 19.7 sites (of 24 tender point sites examined) at a response level of mild tenderness or greater. Mean dolorimetry scores <4 kg/1.54 $cm^2$ were found in 68.6% of all fibromyalgia patients. The most discriminating and least variable measure of tenderness between patients and controls was "mild or greater" tenderness as determined by palpation. Skinfold tenderness was another characteristic finding, but reticular skin abnormality (14.6%) and reactive hyperemia (49.8%) had little discriminatory power (Table 6). In the tender point examination, no patient had a score of 4 for any tender point site examined.

As with pain and other symptoms, physical findings in primary fibromyalgia patients did not differ from those in secondary-concomitant fibromyalgia patients (Table 4).

**Criteria for fibromyalgia.** Tender points were the most powerful discriminator between fibromyalgia patients and controls (Tables 5 and 6). As suggested by the data in Table 5 and Figure 1, tenderness scores, using patients' responses of "mild or greater" tenderness, provided the most discriminating power. Figure

**Table 5.** Dolorimetry and tender point scores for patients with primary fibromyalgia syndrome, secondary-concomitant fibromyalgia syndrome, and all fibromyalgia syndrome patients, as well as their age- and sex-matched control patients*

| | | | | | Patients | |
|---|---|---|---|---|---|---|
| | Patients | Controls | *t* | *P* | F† | *P* |
| Primary fibromyalgia | | | | | | |
| No. of patients | 158 | 135 | | | | |
| Dolorimetry scores | | | | | | |
| Active sites (0–6.5 scale) | 3.5 (0.10) | 4.9 (0.12) | 9.1 | <0.001 | 7.6 | <0.001 |
| Control sites (0–6.5 scale) | 5.1 (0.11) | 5.7 (0.11) | 3.6 | <0.001 | 5.2 | <0.001 |
| Tender point palpation scores and counts | | | | | | |
| Average tenderness (0–4 scale) | 1.6 (0.05) | 0.6 (0.06) | −13.5 | <0.001 | 6.4 | <0.001 |
| Mild or greater (0–24 sites) | 20.0 (0.34) | 8.3 (0.64) | −16.8 | <0.001 | 2.0 | <0.016 |
| Moderate or greater (0–24 sites) | 13.0 (0.54) | 4.0 (0.54) | −11.7 | <0.001 | 6.0 | <0.001 |
| Severe (0–24 sites) | 5.2 (0.47) | 1.4 (0.27) | −7.0 | <0.001 | 7.3 | <0.001 |
| Skinfold tenderness | 65.1 | 17.6 | 63.0‡ | <0.001 | 8.8§ | 0.479¶ |
| Secondary-concomitant fibromyalgia | | | | | | |
| No. of patients | 135 | 130 | | | | |
| Dolorimetry scores | | | | | | |
| Active sites (0–6.5 scale) | 3.4 (0.11) | 4.9 (0.12) | 9.5 | <0.001 | 7.8 | <0.001 |
| Control sites (0–6.5 scale) | 5.0 (0.12) | 5.8 (0.96) | 5.1 | <0.001 | 6.2 | <0.001 |
| Tender point palpation scores and counts | | | | | | |
| Average tenderness (0–4 scale) | 1.5 (0.06) | 0.5 (0.05) | −13.4 | <0.001 | 7.7 | <0.006 |
| Mild or greater (0–24 sites) | 19.3 (0.38) | 7.7 (0.61) | −16.2 | <0.001 | 1.7 | <0.065 |
| Moderate or greater (0–24 sites) | 12.0 (0.61) | 3.1 (0.45) | −11.7 | <0.001 | 6.6 | <0.001 |
| Severe (0–24 sites) | 4.7 (0.45) | 1.1 (0.22) | −7.0 | <0.001 | 7.7 | <0.001 |
| Skinfold tenderness | 54.8 | 15.7 | 41.7‡ | <0.001 | 6.5§ | 0.407¶ |
| All fibromyalgia syndrome | | | | | | |
| No. of patients | 293 | 265 | | | | |
| Dolorimetry scores | | | | | | |
| Active sites (0–6.5 scale) | 3.4 (0.07) | 4.9 (0.08) | 13.2 | <0.001 | 13.5 | <0.001 |
| Control sites (0–6.5 scale) | 5.1 (0.79) | 5.7 (0.74) | 6.1 | <0.001 | 9.6 | <0.001 |
| Tender point palpation scores and counts | | | | | | |
| Average tenderness (0–4 scale) | 1.5 (0.04) | 0.5 (0.04) | −19.1 | <0.001 | 11.1 | <0.001 |
| Mild or greater (0–24 sites) | 19.7 (0.25) | 8.0 (0.44) | −23.0 | <0.001 | 3.1 | <0.05 |
| Moderate or greater (0–24 sites) | 12.5 (0.41) | 3.6 (0.36) | −16.6 | <0.001 | 11.6 | <0.001 |
| Severe (0–24 sites) | 5.0 (0.33) | 1.3 (0.17) | −9.8 | <0.001 | 14.1 | <0.001 |
| Skinfold tenderness | 60.3 | 16.7 | 106.2‡ | <0.001 | 7.5§ | 0.445¶ |

* Values are the mean (SEM) except for skinfold tenderness, which is the percentage positive. See Table 4 and Patients and Methods for definitions and explanations of scoring systems.
† F statistic for difference among centers.
‡ Chi-square statistic.
§ Odds ratio.
¶ Phi statistic.

2 displays the receiver operating curve for the 24 tender points examined. The best separation between patients and controls occurred at about the thirteenth tender point for *mild* tenderness and at about the sixth tender point for *moderate or greater* tenderness.

Although some individual symptoms (sleep disturbance, "pain all over," and fatigue) had good discriminating power (as estimated by the accuracy score), variables that were slightly more discriminating could be made by combining individual variables

**Table 6.** Comparison of the sensitivity, specificity, and accuracy of criteria items in the 1990 study of criteria for the classification of fibromyalgia*

| Criterion (ref.) | Sensitivity (%) | Specificity (%) | Accuracy |
|---|---|---|---|
| Pain symptoms | | | |
| Posterior thorax pain | 72.3 | 75.5 | 73.9 |
| 15+ painful sites | 55.6 | 87.2 | 70.6 |
| Neck pain | 85.3 | 49.6 | 67.5 |
| Low back pain | 78.8 | 54.4 | 66.6 |
| Widespread pain | 97.6 | 30.9 | 65.9 |
| Symptoms | | | |
| Sleep disturbance | 74.6 | 73.1 | 73.8 |
| "Pain all over" | 67.0 | 80.9 | 73.6 |
| Fatigue | 81.4 | 60.8 | 71.7 |
| Morning stiffness >15 minutes | 77.0 | 57.3 | 67.2 |
| Paresthesias | 62.8 | 64.4 | 63.6 |
| Anxiety | 47.8 | 78.4 | 62.9 |
| Headache | 52.8 | 72.6 | 62.3 |
| Prior depression | 31.5 | 87.4 | 58.0 |
| Irritable bowel syndrome | 29.6 | 87.5 | 57.1 |
| Sicca symptoms | 35.8 | 77.0 | 55.4 |
| Urinary urgency | 26.3 | 84.5 | 54.2 |
| Dysmenorrhea history | 40.6 | 68.3 | 53.4 |
| Raynaud's phenomenon | 16.7 | 90.4 | 51.6 |
| Modulating factors | | | |
| Noise | 24.0 | 91.3 | 68.5 |
| Cold | 79.3 | 52.5 | 66.6 |
| Poor sleep | 76.0 | 53.4 | 65.2 |
| Anxiety | 69.0 | 57.8 | 63.7 |
| Humidity | 59.6 | 67.8 | 63.6 |
| Stress | 63.0 | 57.6 | 60.4 |
| Fatigue | 76.7 | 42.3 | 60.3 |
| Weather change | 66.1 | 53.8 | 60.3 |
| Warmth | 78.0 | 23.5 | 50.8 |
| Tenderness | | | |
| 11 of 18 tender points (present report) | 90.1 | 77.7 | 84.2 |
| 12 of 14 tender points (1) | 64.7 | 89.0 | 76.3 |
| Dolorimetry, 6 sites | 68.6 | 76.2 | 72.2 |
| Other physical findings | | | |
| Skinfold tenderness, trapezius | 60.3 | 83.3 | 71.2 |
| Reticular skin disturbance | 14.6 | 94.5 | 52.4 |
| Reactive hyperemia, trapezius | 49.8 | 30.9 | 40.4 |
| Combinations | | | |
| Widespread pain and 11 of 18 tender points (present report) | 88.4 | 81.1 | 84.9 |
| 5 minor criteria (Yunus et al [2]) | 76.8 | 76.2 | 76.5 |
| 2 of sleep disturbance, fatigue, morning stiffness | 81.3 | 61.1 | 72.2 |
| 2 minor criteria (Yunus et al [6,7]) | 94.5 | 50.4 | 72.1 |
| Screening questionnaire (Campbell [21]) | 51.9 | 89.1 | 68.9 |
| 3 minor criteria (Yunus et al [2]) | 94.2 | 39.3 | 68.1 |
| 3 of sleep disturbance, fatigue, morning stiffness | 56.0 | 82.4 | 67.9 |
| 3 minor criteria (Yunus et al [6,7]) | 85.7 | 49.6 | 67.7 |
| 1 of sleep disturbance, fatigue, morning stiffness | 95.5 | 29.4 | 65.6 |

* Sensitivity, or the true positive rate, is the proportion of fibromyalgia patients positive for the criterion. Specificity, or the true negative rate, is the proportion of controls negative for the criterion. Accuracy is the mean of sensitivity and specificity values. The false positive rate is the percentage of controls positive for the criterion and can be calculated by subtracting the specificity value from 100. See Patients and Methods for details of criteria assessments. A total of 558 patients and controls are represented.

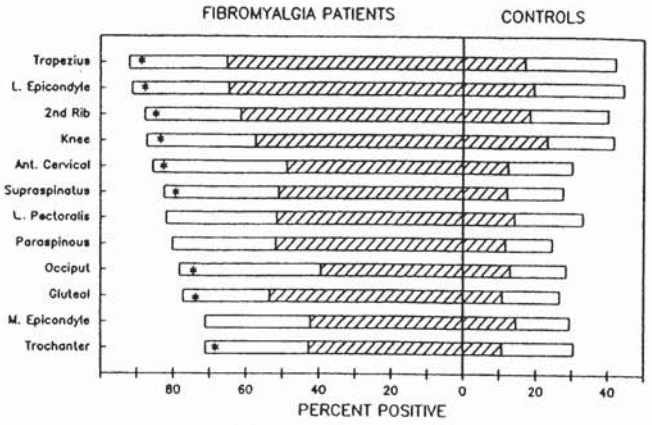


**Figure 1.** Percentage of fibromyalgia patients and control patients with "mild or greater" or "moderate or greater" tenderness at the 24 tender point sites examined. Values are means of the paired (left and right) tender point sites. Open bars show mild or greater tenderness; hatched bars show moderate or greater tenderness. * = tender point site retained in the 1990 criteria for fibromyalgia. L = left; Ant. = anterior; M. = medial.

(Table 6). We examined various variables and combinations of variables, including those noted in Table 6 and those suggested by previous criteria sets (1,2,6, 7,21). Combinations suggested by Yunus (minor criteria) had good accuracy scores. Of particular interest was the finding that the simultaneous occurrence of sleep disturbance, fatigue, and morning stiffness, required in certain previous criteria sets, was found in only 56% of patients.

The committee reduced the number of tender

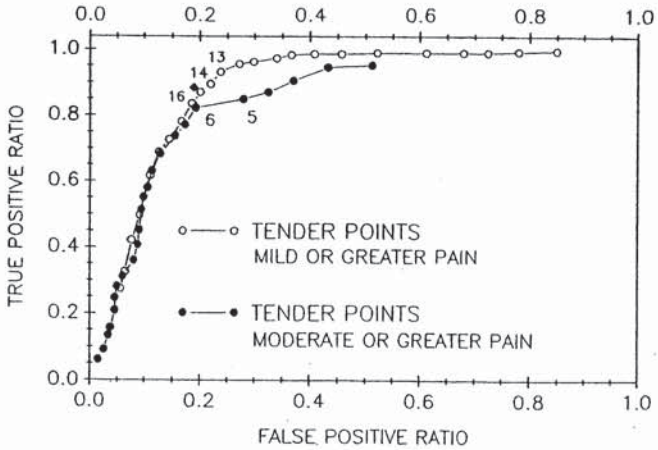


**Figure 2.** Empiric receiver operating characteristic curves for cumulative number of tender point sites scored either as mild or greater tenderness or as moderate or greater tenderness. Twenty-four "active" sites were examined. True positive ratio = the proportion of patients with fibromyalgia at each tender point score; false positive ratio = the proportion of controls at each tender point score. ◆ = sensitivity and specificity of 1990 criteria (11 of 18 tender points and widespread pain).

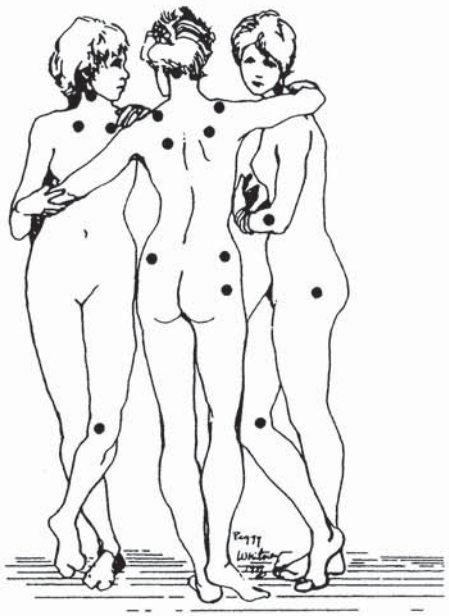

**Figure 3.** Tender point locations for the 1990 classification criteria for fibromyalgia (The Three Graces, after Baron Jean-Baptiste Regnault, 1793, Louvre Museum, Paris). See Table 8 for details of the tender point site locations.

points required for examination from 24 to 18 (Figure 1) (see Discussion). The presence of 11 of 18 tender points (defined as mild or greater tenderness) in the presence of widespread pain provided the most sensitive, specific, and accurate criteria for the diagnosis of primary, secondary-concomitant, and the combined fibromyalgia syndrome. The exact locations of the 18 tender points are shown in Figure 3. No combination or set of combinations of tender points and symptoms could be found that performed better than the tender point and widespread pain criteria.

## DISCUSSION

The results of this study show that fibromyalgia can be identified, with good sensitivity (88.4%) and specificity (81.1%), from among the other rheumatic conditions by the use of simple criteria. In the design of this study, the committee wished to make the criteria test as rigorous as possible by selecting as controls for primary fibromyalgia patients those patients with other rheumatic conditions that might reasonably be confused with fibromyalgia. In selecting controls for secondary-concomitant fibromyalgia patients, controls were the "next" patient with the same disorder but without fibromyalgia (see Patients and Methods). Some controls were particularly "difficult" patients who were attending chronic pain clinics and who had had symptoms for long durations. It is worth emphasizing that both the patients and the controls had moderate levels of pain and self-rated and physician-rated global severity (Table 1). Studies of rheumatoid arthritis, osteoarthritis, and similar disorders that have used these pain and severity scales have reported levels similar to those noted in our control patients (22).

The committee was aware that the way the investigators perceived the syndrome might affect the diagnosis and the sensitivity and specificity of the diagnostic criteria. To reduce diagnosis–criteria circularity, a "consensus" diagnosis of fibromyalgia was obtained by inviting the participation of all centers in Canada and the United States who had a known interest in fibromyalgia. In fact, this consensus strategy reduced the sensitivity and specificity of the criteria. For example, if a center conceived of fibromyalgia in terms of the criteria of Smythe and Moldofsky (1), patients who lacked morning stiffness but who otherwise met criteria would have been classified as control patients by the center, but as fibromyalgia patients by the new criteria. Using the construct of fibromyalgia proposed below, these 1990 criteria should be expected to perform with greater sensitivity and specificity in practice.

Among the objections to the fibromyalgia construct has been the lack of "objective" abnormalities. Local tenderness is subject to both the investigator's strength of palpation as well as his or her interpretation of the degree of tenderness or pain complaint. Poor sleep, fatigue, and other symptoms are similarly subject to the investigator's interpretation. To deal with this concern, we used blinded, trained examiners, unaware of the diagnosis or physical findings of the examination by the investigator. The use of standardized questionnaires to obtain historical information provided a uniform database free from interviewer-introduced bias. The evaluation of tender points with a dolorimeter has been validated as providing objective data (21).

In developing criteria for fibromyalgia, the committee believed a priori that pain location and distribution, morning stiffness, fatigue, sleep disturbance, the number, location, and scores of tender points, dolorimetry scores, and combinations of these elements might effectively differentiate patients and controls. In fact, widespread pain turned out to have very high sensitivity (97.6%). When the criterion of widespread pain was combined with that of 11 of 18 tender points (defined as mild or greater tenderness), which was the variable that had the best overall sensitivity, specificity, and accuracy, the best diagnostic criteria

were identified. Combinations of symptoms (Table 6) provided effective differentiation of patients and controls at various levels of sensitivity, specificity, and accuracy. Various combinations of tender point levels and groups of symptoms were tested (as in the criteria described by Yunus et al [2]), but none proved to be as sensitive, specific, and accurate as the combination of widespread pain and 11 of 18 tender points. Nevertheless, this combination should be tested in an independent sample or compared with other criteria in an independent data pool since it is possible that it might not perform as well as we have noted here.

The tender point sites selected by the committee for use with the 1990 criteria are among those used in other criteria sets. Three lower-segment sites (buttocks, trochanters, knees) were retained to emphasize the widespread nature of the tenderness and because of the concern that insufficient lower-segment sites could lead to false-positive diagnoses in patients with shoulder girdle pain and similar syndromes. The medial epicondyle and the lateral pectoral sites, which had low discriminatory power (Figure 1), were eliminated, as were the paraspinous sites; thus, the total number of tender point sites was reduced to 18, a level the committee considered to be manageable.

A critical issue in the fibromyalgia examination and in diagnostic criteria is how a positive tender point should be identified. The committee found that any indication of pain ("mild or greater") was a better discriminator than pain determinations that called for grimace, flinch, or other manifestations of pain ("moderate or greater") (Figures 1 and 2 and Table 5). In addition, there was less variability between centers when "mild or greater" pain was used as the end point. The number of tender points required for the 1990 criteria are based on "mild or greater tenderness"; the use of other tenderness end points with these criteria will significantly influence the sensitivity and specificity.

The symptoms of fibromyalgia are potentially "soft," and may be subject to examiner interpretation. Although "pain all over" was a powerful discriminatory symptom in this study, caution should be used in utilizing symptoms that may be interpretative on the part of the patient and/or the examiner. We found the scoring system for symptoms that was suggested by Campbell et al (21) to be useful, and we suggest its use clinically and in research. In this system, symptoms are scored as "never," "seldom," "often or usually," and "always." "Often or usually" and "always" are scored as positive. Sleep disturbance was best identified in our study by "waking unrefreshed," and we confirm the suggestion of most authors that sleep disturbance be phrased in those terms.

The "consensus" construct of fibromyalgia identifies the syndrome as associated with generalized pain and multiple painful regions, particularly in the axial skeleton. Multiple tender points are essential when using "mild or greater" tenderness as the end point. Sleep disturbance, fatigue, and stiffness are the central symptoms of fibromyalgia, and each is present in more than 75% of fibromyalgia patients. The simultaneous presence of these 3 symptoms, however, is not required. Indeed, only 56% of patients had all 3

**Table 7.** Comparison of the sensitivity, specificity, and accuracy of the American College of Rheumatology 1990 criteria for the classification of fibromyalgia with previous criteria sets in our study population*

| Criteria set, author (ref.), year | Fibromyalgia syndrome (n = 558) | | | Primary fibromyalgia (n = 293) | | | Secondary-concomitant fibromyalgia (n = 265) | | |
|---|---|---|---|---|---|---|---|---|---|
| | Sensitivity (%) | Specificity (%) | Accuracy | Sensitivity (%) | Specificity (%) | Accuracy | Sensitivity (%) | Specificity (%) | Accuracy |
| Criteria committee (present report), 1990 | 88.4 | 81.1 | 84.9 | 88.6 | 80.7 | 85.0 | 88.1 | 81.5 | 84.9 |
| Wolfe et al (24), 1985 | 95.8 | 73.8 | 85.6 | 96.7 | 73.0 | 86.1 | 94.7 | 75.0 | 85.1 |
| Yunus et al (6,7), 1988 | 86.3 | 80.7 | 83.7 | 88.6 | 77.0 | 83.3 | 83.7 | 84.6 | 84.1 |
| Goldenberg et al (25), 1986 | 78.8 | 82.3 | 80.4 | 78.3 | 80.7 | 79.4 | 79.3 | 84.1 | 81.6 |
| Yunus et al (2), 1981 | 83.6 | 76.6 | 80.3 | 85.4 | 76.3 | 81.2 | 81.5 | 76.9 | 79.2 |
| Campbell et al (21), 1983 | 45.8 | 95.0 | 68.2 | 42.0 | 94.7 | 73.7 | 50.4 | 95.3 | 71.5 |
| Smythe and Moldofsky (1), 1977 | 39.2 | 95.5 | 64.6 | 35.2 | 94.8 | 61.5 | 43.9 | 84.6 | 68.1 |

* Tender point sites and historical data items may differ slightly in the current study compared with previous criteria sets; therefore, sensitivity, specificity, and accuracy data for previous criteria sets should be considered close approximations. All categories represent patients plus their age- and sex-matched controls.

**Table 8.** The American College of Rheumatology 1990 criteria for the classification of fibromyalgia*

1. History of widespread pain.

   *Definition.* Pain is considered widespread when all of the following are present: pain in the left side of the body, pain in the right side of the body, pain above the waist, and pain below the waist. In addition, axial skeletal pain (cervical spine or anterior chest or thoracic spine or low back) must be present. In this definition, shoulder and buttock pain is considered as pain for each involved side. "Low back" pain is considered lower segment pain.

2. Pain in 11 of 18 tender point sites on digital palpation.

   *Definition.* Pain, on digital palpation, must be present in at least 11 of the following 18 tender point sites:
   *Occiput*: bilateral, at the suboccipital muscle insertions.
   *Low cervical*: bilateral, at the anterior aspects of the intertransverse spaces at C5–C7.
   *Trapezius*: bilateral, at the midpoint of the upper border.
   *Supraspinatus*: bilateral, at origins, above the scapula spine near the medial border.
   *Second rib*: bilateral, at the second costochondral junctions, just lateral to the junctions on upper surfaces.
   *Lateral epicondyle*: bilateral, 2 cm distal to the epicondyles.
   *Gluteal*: bilateral, in upper outer quadrants of buttocks in anterior fold of muscle.
   *Greater trochanter*: bilateral, posterior to the trochanteric prominence.
   *Knee*: bilateral, at the medial fat pad proximal to the joint line.

   Digital palpation should be performed with an approximate force of 4 kg.
   For a tender point to be considered "positive" the subject must state that the palpation was painful. "Tender" is not to be considered "painful."

* For classification purposes, patients will be said to have fibromyalgia if both criteria are satisfied. Widespread pain must have been present for at least 3 months. The presence of a second clinical disorder does not exclude the diagnosis of fibromyalgia.

symptoms, and 81% had 2 of the 3. Other symptoms, such as anxiety, irritable bowel syndrome, modulating factors, etc., are less common but are seen more commonly in patients than in controls. This "consensus" definition differs from some previous definitions in that it recognizes that symptoms of sleep disturbance, fatigue, and stiffness may not all be present in patients with fibromyalgia.

Primary and secondary-concomitant fibromyalgia were essentially indistinguishable with the study variables, and the criteria proposed worked equally well in both groups. The committee suggests abolishing the distinction between primary and secondary-concomitant fibromyalgia at the level of diagnosis. The 1990 criteria, therefore, do not distinguish between these putative groupings. In other words, a diagnosis of fibromyalgia remains a valid construct irrespective of other diagnoses; "exclusionary tests" such as radiographs, antinuclear antibody titers, T4 levels, etc. are not a requisite for diagnosis. However, it is evident that fibromyalgia often occurs in association with other rheumatic disorders, and it is incumbent upon the physician to seek out such problems, since the effective treatment of these conditions may influence the management of fibromyalgia.

Table 7 presents the sensitivity, specificity, and accuracy of previous criteria sets that have been used in the diagnosis and classification of fibromyalgia, as applied to the current study sample. The original criteria of Smythe and Moldofsky (1), as well as the criteria from the Oregon group (21,23), are highly specific but lack sensitivity. They have been used mainly as "classification criteria" in treatment protocols, in which such specificity is desirable, but they fail to identify more than half of the patients classified as having fibromyalgia by center investigators. These criteria sets therefore have limited value as "clinical criteria." Previous criteria sets described by Wolfe et al (24), Yunus et al (2,6,7), and the Boston group (25) performed well in the study sample. The criteria from the Peoria and Boston groups are based on tenderness levels of "moderate or greater"; when "mild or greater" tenderness is used in these same criteria, the specificity is reduced to <40%. This discrepancy was not appreciated prior to the current multicenter study. Palpation of tender points with the thumb was more discriminatory than was dolorimetry. The use of dolorimetry is not recommended in routine clinical practice; it may still be of use in assessing relative severity in research studies and in the medicolegal setting.

The 1990 criteria (Table 8) can be appropriate 2-stage criteria for clinical and epidemiologic investigations of the fibromyalgia syndrome. The sensitivity of the criteria suggests that they may be useful for diagnosis as well as classification. Only 1.7% of patients with fibromyalgia who meet the tender point criteria will be misclassified by the widespread pain criterion. This suggests that determining the location of pain can be an excellent screening question. The new criteria are relatively simple to apply and have

acceptable levels of sensitivity and specificity. With the less restrictive definition of fibromyalgia inherent in the study sample, the sensitivity and specificity of the criteria will be improved.

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