Editorial

Old and new criteria for the classification and diagnosis of fibromyalgia: comparison and evaluation

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Fibromyalgia (FM) is a complex chronic pain condition that affects at least 2% of the adult population in Italy (1) and is fraught with diagnostic ambiguity, uncertainty concerning the pathophysiology underlying its symptoms, and difficulties in managing it competently (2, 3). Abnormal central nociceptive processing may contribute to FM by heightening responses to various noxious stimuli that lead to mechanical hyperalgesia.

In 1992, a consensus document was produced at the Second World Congress on Myofascial Pain and Fibromyalgia in Copenhagen, and later published in The Lancet (4), which added that FM is part of a multidimensional disease characterised by fatigue, sleep disorders, headache, cognitive effects, mood disturbances, irritable bladder, dysmenorrhea, extreme sensitivity to cold, restless legs, odd patterns of numbness and tingling, intolerance to exercise, and other symptoms. As the number and severity of symptoms varies from patient to patient, it is difficult to develop unified diagnostic criteria.

The variability of the symptoms associated with FM can lead physicians to consider rheumatic or autoimmune diseases (5). There is abundant clinical experience that patients with rheumatic disorders including systemic lupus erythematosus, Sjögren's syndrome, and rheumatoid arthritis (RA) have simultaneous FM more often than a control population (6, 7). Patients with other autoimmune inflammatory diseases and concurrent FM may be misdiagnosed and, more importantly, their treatments may be mistargeted (5). Furthermore, comorbid FM in patients with rheumatic disorders diminishes the quality of life measured by the Short Form-36 (8-10).

This editorial reviews the previous criteria and definitions of FM and discusses its implications.

How the definiton of fibromyalgia has evolved

In order to recognise FM, it is necessary to have an accurate definition. The British neurologist, Sir William Gowers, was the first to describe diffuse pain (as "fibrositis") and its accompanying symptoms of pain, fatigue and disturbed sleep (11). He believed that the pain was due to the proliferation or inflammation (or both) of subcutaneous and fibrous tissue, a histopathology that has still not been satisfactorily demonstrated. After the end of World War II, a high prevalence of fibrositis was noted, with up to 70% of returning British soldiers being affected at one hospital. A 1949 rheumatology textbook called *Arthritis and Allied Conditions* had a chapter on fibrositis in which the author stated that "there can no longer be any doubt concerning the existence of such a condition," and attributed the cause to stress, infections and psychological factors. An important contribution was made by Dr Hench, who proposed the first clinical definition in 1976, but it probably did more harm than good. His only two criteria were pain and no physiological explanation (12), and so the diagnosis was made by ruling out rather than ruling in. Consequently, diagnosing physicians had to investigate the symptoms by ordering potentially limitless tests, which all had to be normal before the diagnosis could be postulated. We continue to see this today as new patients with classic FM arrive carrying reports of normal magnetic imaging of the entire body and serological tests: a "connective tissue disease work-up."

Smythe was the first to define and classify FM as a rule-in diagnosis in 1979 (13). His criteria included tender points in at least 12 out of 14 anatomic locations using 4 kg of pressure (although,

in practice, this pressure is approximate as its is based on the fact that the nail bed blanches under a force of 4 kg in a normotensive examiner), and four necessary signs and symptoms: widespread pain of at least three months' duration, disturbed sleep, skin-roll tenderness at the upper border of the trapezius, and normal laboratory test results. He and his colleague Moldofsky also found a relationship between disordered slow-wave sleep and the symptoms of FM.

Yunus *et al*. (14) proposed a formal set of criteria for the diagnosis of FM based on the findings of the first controlled clinical study designed to validate symptoms and tender points in FM patients. These criteria require aching, pain and stiffness for a minimum of three months; a minimum of five out of 40 possible tender points; three out the ten symptoms of decreased physical activity due to symptoms, weather-related and stress/anxiety-related symptom aggravation, sleep disturbances, fatigue/tiredness, anxiety, headaches, irritable bowel syndrome, swelling and/or numbness (14).

The American College of Rheumatology (ACR) attempted to establish criteria to differentiate FM patients from other subjects with widespread pain in the light of statistics showing that 15% of the general population experience widespread pain at any given time (15). The committee compared signs and symptoms in 293 patients deemed by experts to have FM, and 265 control patients matched for age, gender, and concomitant rheumatic disorders (16). The symptom of widespread pain of at least three months' duration and tenderness in at least 11 out of 18 points became the ACR's diagnostic criteria, which had a sensitivity of 88% and a specificity of 81% in comparison with expert opinion as the gold standard test (Table I). However, the requirement of a tender point examination proved to be something of a barrier: most patients with symptoms suggesting FM are first seen by their primary care doctors, and one study found that, although 96% of the surveyed primary care physicians claimed to be familiar with FM, only 25% understood its tender point count criterion (17).

Table I. 1990 ACR 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 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 he 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.

The concept of using tender points as the defining feature of FM has been criticised because the number of tender points cannot be an objective assessment of whole body pain, tender points can be mistaken for the trigger points of myofascial pain syndrome or pain due to other diseases such as osteoarthritis, and females are generally more sensitive to pain and therefore have a tendency to report more tender points (18, 19).

When the number of tender points is used as the main diagnostic criterion for FM, there is therefore a chance of mistaking another disease for FM. Furthermore, as tender points provide the main diagnostic information, the main mechanism of FM can be mistakenly considered a muscle disorder rather than a neurological disorder. A tender point examination is subjective, open to individual interpretation, and reflects an overall reduction in the pain threshold rather than a pathological process at the soft tissue site. In addition, population-based studies have shown that tender points are more common in distressed individuals (19). Thirdly, the number of 11 or more tender points may not be accurate in confirming the diagnosis. Many patients with a clinical diagnosis of FM have been found to have fewer than 11 tender points, and some specialists diagnose FM using a "fibromyalgia inclination diagnosis" that does not rely on the number of tender points (20). Fourthly, there is no agreement as to whether the examination should be made using digital palpation, myalgic scoring or dolorimetry. Although digital examination is the most widely used, it is difficult for examiners to assess each of the 18 tender points by applying an equal pressure of 4 kg using the index finger, and so it is often not used by physicians caring for FM patients. Some clinics use a pressure gauge instead of a finger, but this is difficult to put into practice at busy centres. Fifthly, if FM is diagnosed only on the basis of the duration of whole body pain and the number of tender points, no consideration is given to the extra-pain symptoms that are characteristic of the disease. Finally, FM-related pain may fluctuate, which can affect the number of tender points, and it has been found that a tender point test does not adequately measure

Table II. 2010 ACR preliminary diagnostic criteria.

1.WPI (widespread pain index): note the number of areas in which the patient has had pain over the last week. In how many areas has the patient had pain?

Put a check to indicate a painful region. Score will be between 0 and 19

Shoulder girdle, left	Hip (buttock, trochanter), left	Jaw, left	Upper back
Shoulder girdle, right	Hip (buttock, trochanter), right	Jaw, right	Lower back
Upper arm, left	Upper leg, left	Chest	Neck
Upper arm, right	Upper leg, right		Abdomen
Lower arm, left	Lower leg, left		
Lower arm, right	Lower leg, right		

2. SS (symptom severity) scale score:
- o Fatigue
- o Walking unrefreshed
- o Cognitive symptoms

For each of the 3 symptoms above, indicate the level of severity over the past week using the following scale:
0. no problem
1. slight or mild problems, generally mild or intermittent
2. moderate, considerable problems, often present and/or at a moderate level
3. severe: pervasive, continuous, life-disturbing problems

Considering somatic symptoms in general, indicate whether the patient has:*
0. no symptoms
1. few symptoms
2. a moderate number of symptoms
3. a great deal of symptoms

The SS scale score is the sum of the severity of the 3 symptoms (fatigue, walking unrefreshed, cognitive symptoms) plus the extent (severity) of somatic symptoms in general. The final score is between 0 and 12.

**Somatic symptoms that might be considered:* muscle pain, irritable bowel syndrome, fatigue/tiredness, thinking or remembering problems, muscle weakness, headache, pain/crambe in the abdomen, numbness/tingling, insomnia, depression, constipation, pain in the upper abdomen, nausea, nervousness, chest pain, blurred vision, fever, dry eyes, ringing in the ears, heartburn, oral ulcers, loss of/change in taste, seizures, shortness of breath, loss of appetite, rash, easy bruising, hair loss, frequent urination, painful urination, and bladder spasms.

A patient satisfies the diagnostic criteria for fibromyalgia if the following 3 conditions are met:
1. WPI ≥7 and SS scale score ≥5 or WPI 3–6 and SS scale score ≥9
2. Symptoms have been present at a similar level for at least 3 months
3. The patient does not have a disorder that would otherwise explain the pain

symptom severity or the effectiveness of new treatments.

Taking into account the presence of symptoms other than pain and the questions raised by a reliance on tender points, new diagnostic criteria have recently been published that can be viewed as being complementary to the 1990 criteria (21). These recommend that the tender point examination be replaced by a combination of a quantitative widespread pain index (WPI), determined by counting the number of areas on the body where the patient has felt pain in the previous week (the checklist includes 19 specified areas), and a symptom severity scale (SS) determined by rating the severity of the three common symptoms of fatigue, walking unrefreshed and cognitive disturbances on a 0–3 scale (3 being the most pervasive). An additional three points can be added to account for the extent of additional symptoms such as numbness, dizziness, nausea, irritable bowel syndrome or depression, to give a final score of 0–12. To meet the criteria for a diagnosis of FM, a patient would have WPI ≥7 and SS scale score ≥5 or WPI 3–6 and SS scale score ≥9 (Table II).

The aims of these criteria were to simplify the diagnosis of FM and provide guidelines that are suitable for use in primary care practice without requiring a tender point examination; to acknowledge the importance of the numerous non-pain symptoms of FM, such as perceived cognitive impairment ("*fibrofog*"), fatigue and sleep disturbance; to assess disease severity, and to develop a method of longitudinally monitoring patients. None of these objectives could be achieved using the older classification criteria.

In order to develop the new criteria, Wolfe *et al*. carried out a 2-phase, multicentre, case-control study that involved more than 600 in phase 1 and 300 in phase 2 (21). The cases were defined as patients with a previous diagnosis of FM made on clinical grounds by a physician, or using the 1990 classification criteria, or both. The controls were age- and gender-matched patients with non-inflammatory painful disorders such as degenerative back pain and other regional pain syndromes, and without a previous diagnosis of FM. The results showed that approximately 25% of the FM patients did not meet the ACR 1990 criteria, and that the new, simplified clinical case definition correctly classified 88.1% of the patients who had met them without a physical or tender point examination. One interesting discovery was that the 19 locations identified as probable areas of pain did not include any joints, and the list of somatic symptoms made no mention of joint pain or problems relating to joints.

Conceptual differences from the old classification criteria

The evolution of the clinical understanding of FM over the last twenty years has highlighted the importance of symptoms other than pain, which form an integral part of the condition and contribute to global suffering. The new diagnostic criteria changed the definition of FM from that of a "peripheral pain-defined disease" to a "systemic symptoms-based disease". The somatic symptoms of FM are given appropriate importance by the inclusion of the SS scale, which also provides a measurement of disease severity in patients with current or previous FM, and allows the disease to be monitored over time. The criteria may therefore be satisfied by a high symptoms score even if the WPI is not high.

Advantages over the old classification criteria

The 1990 ACR criteria required a tender point examination, which was found to be difficult to apply in primary care, whereas the new diagnostic criteria simplify clinical diagnosis by doing away with the need for such an examination. Confusion concerning the examination meant that most primary care physicians did not check tender points (or did so incorrectly), and so the diagnosis was often based on symptoms in any case. The new criteria are aimed at standardising symptom-based diagnoses so that all physicians use the same process. However, they have not been widely embraced. When the 1990 ACR classification criteria are used as the gold standard, it has been found that the new criteria make a correct diagnosis in 83% of the cases; furthermore, the number of controls satisfying the new criteria has risen to 9% from the 2% satisfying the old criteria, and the overall rate of FM among all study patients has increased from 38% to 45%. The previous classification criteria did not have any provision for assessing disease severity or monitoring patients with a previous diagnosis of FM.

Limitations of the new diagnostic criteria.

The new criteria have been provisionally accepted by the ACR, but the results of validation studies are awaited before they receive final acceptance. The finding that as many as 25% of patients with physician-diagnosed FM did not satisfy the 1990 ACR classification criteria was important, but the new criteria do not solve this problem because inflammatory and other painful disorders are excluded and so they cannot be applied to patients with RA, systemic lupus erythematosus, or other conditions. Furthermore, they do not distinguish primary and secondary FM, and their performance in the primary care setting has not yet been validated by prospective studies. A diagnosis based on the new criteria depends on physicians' subjective assessments of the extent and severity of the patient's somatic symptoms, and it can be argued that making a diagnosis made without a physical examination will probably miss important physical findings and other potential causes of the symptoms. Finally, although no objective parameters are currently accepted for routine use in clinical practice, the criteria still rely on clinical grounds and do not incorporate any objective laboratory or imaging data.

For all of these reasons, a diagnosis made using the new criteria is likely to differ from one physician to another, which is why they cannot be recommended until the validation studies have been completed.

2011 modification of the ACR 2010 diagnostic criteria.

The 2010 criteria altered the case definition of FM by recognising that symptoms were a central part of the syndrome and, by doing so, imposed the requirement of interviewing each patient in sufficient detail to be able to evaluate their extent and severity. Although they provided rules for categorising symptom severity and making a diagnosis, they did not permit self-diagnosis, and so any diagnosis based *primarily* on self-reporting is not considered valid. This means that patients cannot be presented with a checklist of symptoms that can be scored, although it is possible for physicians to use forms to gather information that can be used as part of the diagnostic process. When developing a model of FM for use in surveys and epidemiological studies, Wolfe *et al*. proposed a modification of the 2010 ACR criteria, which we shall call the 2011 criteria (22). The modified criteria are not ACR criteria, but based on the official criteria. In essence, they eliminated physician assessments of the extent of somatic symptoms by replacing them with a 4-point item (0–3) representing the sum of the presence/absence of headaches, lower abdominal pain or crambe, and depressive symptoms during the previous six months. They also asked patients to report areas of "pain or tenderness" for the WPI whereas, in our ACR 2010 study, this assessment was restricted to physicians. The modified criteria are almost the same as the ACR 2010 criteria, with the exception that the 4-item SS scale was changed as shown in Table III: the scores for a diagnosis of FM are a WPI of ≥7 and an SS score of ≥5, or a WPI of 3-6 and an SS score of ≥9, provided that the symptoms have been present at a similar level for at least three months and

Table III. 2011 modification of the 2010 ACR diagnostic criteria.

1. WPI (widespread pain index): note the number of areas in which the patient has had pain over the last week. In how many areas has the patient had pain?

Put a check to indicate a painful region. Score will be between 0 and 19

Shoulder girdle, left	Hip (buttock, trochanter), left	Jaw, left	Upper back
Shoulder girdle, right	Hip (buttock, trochanter), right	Jaw, right	Lower back
Upper arm, left	Upper leg, left	Chest	Neck
Upper arm, right	Upper leg, right		Abdomen
Lower arm, left	Lower leg, left		
Lower arm, right	Lower leg, right		

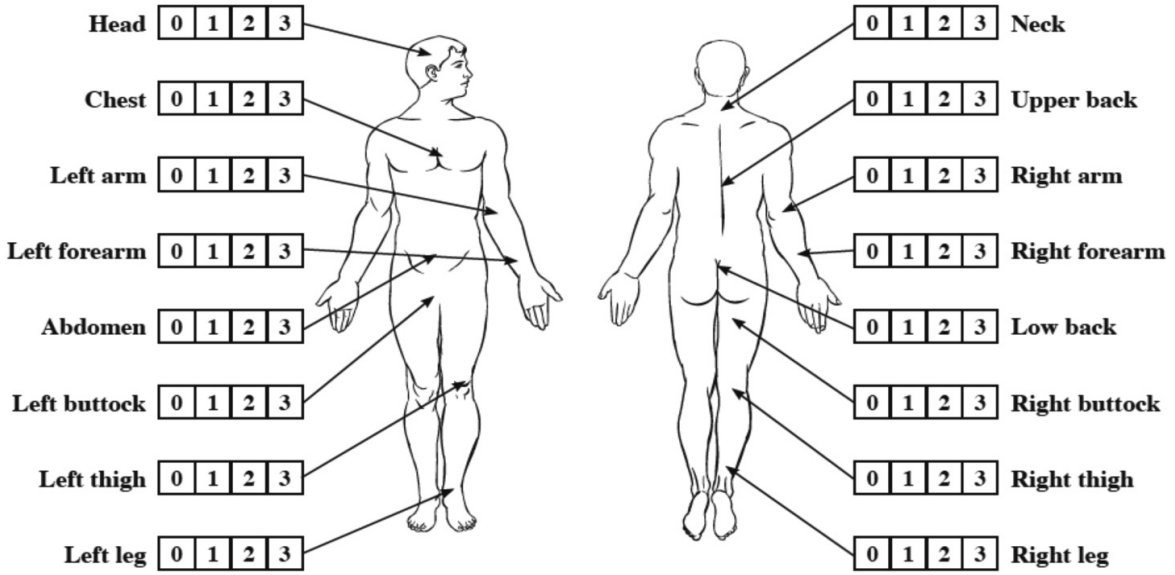
2. SS (symptom severity) scale score: fatigue; waking unrefreshed; cognitive symptoms.

For the each of these 3 symptoms, indicate the level of severity over the past week using the following scale: 0 = No problem; 1 = Slight or mild problems; generally mild or intermittent; 2 = Moderate; considerable problems; often present and/or at a moderate level; 3 = Severe: pervasive, continuous, life-disturbing problems.

The SS score is the sum of the severity of the 3 symptoms (fatigue, walking unrefreshed, and cognitive symptoms) plus the sum of the number of the following symptoms occurring during the previous 6 months: headaches, pain or crambe in lower abdomen, and depression (0–3). The final score is between 0 and 12.

A patient satisfies the diagnostic criteria for fibromyalgia if the following 3 conditions are met:
1. WPI ≥7 and SS scale score ≥5, or WPI 3-6 and SS scale score ≥9;
2. Symptoms have been present at a similar level for at least 3 months;
3. The patient does not have a disorder that would otherwise sufficiently explain the pain.

1. Please indicate below the amount of **pain** and/or **tenderness** you have experienced in the past week in each of the body areas listed below by putting an X in the boxes. Please be sure to mark both right and left sides separately.



Nomogram 1=0.2 4=0.8 7=1.5 10=2.1 13=2.7 16=3.3 19=4.0 22=4.6 25=5.2 28=5.8 31.6.5 34=7.1 37=7.7 40=8.3 43=9.0 46=9.6
2=0.4 5=1.0 8=1.7 11=2.3 14=2.9 17=3.5 20=4.2 23=4.8 26=5.4 29=6.0 32=6.7 35=7.3 38=7.9 41=8.5 44=9.2 47=9.8
3=0.6 6=1.3 9=1.9 12=2.5 15=3.1 18=3.8 21=4.4 24=5.0 27=5.6 30=6.3 33=6.9 36=7.5 39=8.1 42=8.8 45=9.4 48=10

SAPS= self administered pain scale

Total SAPS ☐

2. What number between 0 and 10 best describes the average level of **fatigue** you have experienced in the past week?

No fatigue 0 1 2 3 4 5 6 7 8 9 10 *Fatigue as bad as it can be*

3. How much of a problem has **sleep** been in the past week?

No problem 0 1 2 3 4 5 6 7 8 9 10 *Severe problem*

Fig. 1. The self-administered Fibromyalgia Assessment Status (FAS).

the patient does not have a disorder that would otherwise explain the pain. The same authors also developed a "fibromyalgianess scale" (FS) ranging from 0–31 and representing the sum of the WPI (0–19) and the modified 4-item SS (0–12) (23, 24).

Survey diagnostic criteria

The creation of the modified 4-item SS scale is only one of several other possible modifications, and alternative means of clinically diagnosing FM have been suggested.

Wolfe had previously shown that a score of at least 8 points on the Regional Pain Scale (RPS), which assesses the presence of pain in 19 articular and non-articular body regions, combined with a score of at least 6 cm on the fatigue visual analogue scale provided the best diagnostic precision consistent with a diagnosis of FM (25). The combination of these two measures became known as the *Survey Criteria*. Katz, Wolfe and Michaud next compared the diagnostic precision of the *Survey Criteria*, the ACR criteria, and a physician's clinical diagnosis (26). The *Survey Criteria* (≥8 points on the RPS plus ≥6 cm on the fatigue visual analogue scale) showed approximately 75% concordance among all these definition criteria in 206 patients with FM and, in a cohort with clinically diagnosed FM syndrome, an RPS score of ≥8 had a sensitivity of 83.2%, a specificity of 87.6%, and accuracy of 85.4%. The authors reported that a score of ≥6 cm on the fatigue visual analogue scale "was also at the optimum level" for diagnosing FM, but did not provide any

more information. Using these data, Wolfe and Rasker devised the Symptom Intensity Scale (SIS), the score of which is calculated by adding the fatigue visual analogue scale score and half the RPS score, and dividing the result by 2 (27). The scale is therefore a continuous rather than a categorical variable, and the scores can range from 0 to 9.75. The authors gave the questionnaire to 25,417 patients with various rheumatic diseases and found that a optimal cut off point of ≥5.75 differentiated FM and identified 95% of the patients who would satisfy the *Survey Criteria*. They also found a linear relationship between the SIS score and the key symptoms of FM. Even more importantly, the association between the SIS score and general health was closer than that of the scores of the Health Assessment Questionnaire (a 27-question patient activity scale), the Arthritis Impact Measurement Scale, or the Short Form-36 (SF-36). The SIS score also correlated with mood, the probability of having diabetes, the need for hospitalisation, the number of comorbidities, the rate of disability, and the risk of early death. The SIS is therefore a diagnostic tool as well as a simple measure of general health in all patients with rheumatic diseases.

We have recently developed a new composite disease-specific index called Fibromyalgia Assessment Status (FAS), that combines a patient's assessment of fatigue, sleep disturbances and pain in the 16 non-articular sites in the Self-Assessment Pain Scale (SAPS) in a single measure (28). The SAPS considers pain in the 16 non-articular sites by asking respondents to "indicate below the amount of pain and/or tenderness you have experienced in the last seven days in each of the body areas listed below by putting an X in the boxes (see Fig. 1). Please be sure to mark both right and left sides separately". Below these instructions, a series of site descriptions are followed by four boxes labelled 0=none, 1=mild, 2=moderate, and 3=severe. The scale scores range from 0 to 48 but, in order to integrate them into one scale, they are transformed into a scale of 0 to 10 and used to calculate FAS, a short and easy to complete self-administered index combining a set of questions relating to non-articular pain (SAPS range 0–10), fatigue (range 0–10), and the quality of sleep (range 0–10) that provides a single composite measure of disease activity (range 0–10). The final score is calculated by adding the three sub-scores and dividing the result by three. All three measures are printed on one side of one page for rapid review, and scored by a health professional without the need for a ruler, calculator, computer or website (Fig. 1).

The FAS index was constructed using a traditional development strategy. Its psychometric properties were tested in 226 FM patients, and it fulfilled the established criteria for validity, reliability and responsiveness. Factor analysis showed that SAPS and fatigue contributed most, and respectively explained 47.4% and 31.2% of the variance; sleep explained 21.3%. Testing for internal consistency showed that Cronbach's alpha was 0.781, thus indicating a high level of reliability. As expected, closer significant correlations were found when FAS was compared with the total FIQ (Fibromialgia Impact Questionnire) score and the scores of the FIQ subscales, particularly job ability, tiredness, fatigue and pain, but the correlation between FAS and the mental component summary scale score (MCS) of the SF-36 was particularly interesting. Test/re-test reliability was satisfactory. The FAS index also showed a high effect size. When receiver operating characteristic (ROC) curve analysis was used to distinguish FM and RA patients, the discriminating power of the FAS index was good, with an area under the curve (AUC) of 0.872 (95% CI: 0.838 to 0.902). At an optimal FAS cut-off value of 5.7, sensitivity and specificity in differentiating FM and RA were 78.8% and 74.5%, respectively. Higher cut-off values led to greater sensitivity but lower specificity, whereas a cut-off value of 4.6 gave a sensitivity of 58.7% with a specificity of 91.9%.

We use the FAS index as part of our office routine. Most patients can complete it with no instruction in two minutes or less, and we believe it should be used to confirm a diagnosis of FM in patients with chronic diffuse pain at rest, and to identify comorbid distress in patients with other diseases such as RA. Furthermore, a comparison of the paper and on-line versions (http://www.fibromialgiamonitor.net/ita) completed by a focus group showed no significant differences between the two. The FAS index complements a careful patient history and physical examination, and its symptom and general health correlations facilitates the characterisation of our patients' illnesses in line with the biopsychosocial model. It can also be used as a research tool to measure the prevalence of FM in patients with other diseases such as RA. Although the FAS index is not yet recognised by the ACR as part (or all) of the classification criteria for FM, it has already been shown to be a valid research instrument, and will very likely form the cornerstone of the new criteria (28, 29).

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