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Are the ACR 2010 diagnostic criteria for fibromyalgia better than the 1990 criteria?

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ABSTRACT

Fibromyalgia (FM) is difficult to diagnose and manage chronic pain condition whose symptoms have no clear pathophysiological cause, although it is thought that patient hypersensitivity to a range of stimuli may give rise to mechanical hyperalgesia as a result of altered central nociceptive processing. The 1990 American College of Rheumatology (ACR) classification criteria, which have been widely used in clinical practice, require the existence of chronic widespread pain (CWP) for > 3 months, and the presence of at least 11 out of 18 specified tender points upon digital palpation, although this latter criterion has long been criticised. The newer 2010 ACR diagnostic criteria state that FM can be defined as CWP associated with somatic symptoms, and recommend the use of a widespread pain index and a scale to rate symptom severity. A modified version of the 2010 criteria removed the physician assessment of the extent of somatic symptoms and replaced it by a summary score of three self-reported symptoms, thus making it easier to use while maintaining its sensitivity. This review discusses the advantages and limitations of all of these criteria

INTRODUCTION

Fibromyalgia (FM) is characterised by chronic widespread pain (CWP) and a range of other symptoms ^[1]. It is difficult to diagnose because FM has no specific diagnostic marker and, although CWP predominates, its symptoms are non-specific and may be due to various causes; furthermore, it can frequently overlap with central sensitivity syndrome ^{[1], [2]}. It has now become clear that

psychological factors are less important than was originally thought: some patients may have concomitant psychiatric disorders but many do not, and the simultaneous presence of other pain and somatic syndromes is more frequently found in twin and epidemiological studies ^[2].

The 1990 American College of Rheumatology (ACR) classification criteria have been extensively used in clinical practice ^[3]. These require a 3-month history of CWP on both sides of the body, above and below the waist, that also involves the upper and/or lower spine; they also require the presence of > 11 out of 18 specified sites that are tender upon digital palpation. The newer 2010 ACR criteria state that FM is characterised by CWP associated with fatigue, sleep and cognitive disturbances, and a range of somatic symptoms^[4], and use a widespread pain index and a scale for rating the severity of fatigue, sleep disorders, dyscognition, and 41 possible somatic symptoms. A modified version of the 2010 criteria removed the physician estimate of the extent of somatic symptoms and replaced it with a summary score of three self-reported symptoms, thus making it easier to use while maintaining its sensitivity ^[5]. In comparison with their predecessors, these modified criteria indicate a greater prevalence of FM with a higher proportion of male patients ^{[6], [7]}.

This review discusses the advantages and limitations of the three sets of criteria with the aim of identifying the criteria that are more likely to lead the correct diagnosis of FM.

ARE THE 2010 ACR CRITERIA BETTER THAN THE 1990 ACR CRITERIA? YES OF COURSE

The 1990 ACR criteria ^[4] have contributed greatly to harmonising study populations in order to facilitate research and, although initially developed as “classification” criteria, have been widely used to diagnose FM in clinical practice. However, there were criticisms of their inclusion of tender

points because there is no specific pathology at the given sites, reduced pressure pain thresholds are not limited to these points and, in any case, are lower in females than males, the tenderness reflects distress rather than the pressure pain threshold itself, and the cut-off value of 11 tender points is diagnostically insensitive.

Granges et al. used an algometer to measure pressure pain thresholds in patients with FM or regional pain syndrome, and healthy pain-free subjects ^[8]. Although the FM patients had lower thresholds at the tender point sites than the patients with regional pain syndrome or pain-free subjects, the mean thresholds at control points were also lower, thus showing that reduced pressure pain thresholds are not restricted to specific sites.

Maquet et al. ^[9] used an algometer to investigate gender differences in pressure pain thresholds, and found that healthy normal females had significantly lower pressure pain thresholds than their male counterparts at all of the FM tender point sites, thus indicating that females are generally more likely to meet the tender point criterion.

In 1997, Wolfe et al. ^[10] showed that the number of tender point in FM patients significantly correlated with the rheumatology distress index (0.55, $p < 0.05$) whereas correlation with algometer-measured pressure pain pressure was lower (0.52, < 0.05) ^[11]. This suggested that tender point counts measure distress more than pressure pain thresholds.

Katz et al. compared the 1990 ACR criteria with epidemiology-based criteria and clinical diagnoses made by a rheumatologist experienced in FM ^[11] in > 200 consecutive patients with a diagnosis of FM recruited in a setting of routine clinical practice, and found only a moderate degree of agreement. The diagnoses based on the three sets of criteria were unanimous in only 33% of cases. Using the diagnosis of the rheumatologist as the gold standard, they found that the cut-off value of

11/18 tender points was highly specific but had a diagnostic sensitivity of no > 50%; Furthermore, reducing the number to eight tender points improved sensitivity to 70% without significantly affecting specificity.

In addition to the controversy associated with tender point counts, it needs to be remembered that pain and tenderness are not the only symptoms in FM. Fatigue, sleep disturbances, stiffness and cognitive impairment are all frequent ^[12], together with other co-morbidities, depression, irritable bowel syndrome, restless leg syndrome and migraine ^[1]. An international survey has shown that > 90% of FM patients suffer from fatigue and > 80% from sleep disturbances ^[12] and, as these symptoms are so frequent, it is difficult to understand why they did not form part of the diagnostic criteria.

From the time of symptom onset to a diagnosis of FM can take more than two years ^[12], with the patients having to consult an average of three physicians. A study based on a general practice research database in the UK has shown that the pre-diagnosis use of healthcare resources (including diagnostic tests and specialist referrals) is significantly higher in patients with FM than controls ^[13] and that, given the reduction in such use decreases after FM has been diagnosed, delayed diagnosis is associated with increased healthcare costs. Studies in the USA ^[14] and Europe ^[15] have also shown that healthcare use is 2–3 times greater in the case of FM patients than in the case of controls and, as the prevalence of FM is 2–5% ^{[16], [17], [18]}, it can be considered a major healthcare burden.

Given the sheer number of FM patients, the 2012 Canadian Pain Society/Canadian Rheumatology Association guidelines for the diagnosis and management of FM recognise that rheumatologists cannot manage all FM patients ^[19]. These guidelines recommended using the ACR 2010 criteria ^[4] and, more specifically, state that “an examination of soft tissues for generalised tenderness should be performed by manual palpation with the understanding that the specific tender

point examination according to the 1990 ACR diagnostic criteria is not required to confirm a diagnosis of FM. FM should depend on the clinical evaluation of individual patients that may suggest some other medical condition. The primary care physician should establish a diagnosis of FM as early as possible without the need for confirmation by a specialist, and communicate this diagnosis to the patient. Repeated investigations after diagnosis should be avoided unless driven by the onset of new symptoms and signs on physical examination.”

In brief, FM is common and an enormous healthcare burden. A delayed diagnosis is costly, and primary care physicians should be trained to recognise the condition. ACR 2010 criteria^[6] facilitate this by removing the need to examine specific tender points as these reflect distress rather than pressure pain thresholds and lead to under-diagnosis in men.

ARE THE 2010 ACR CRITERIA BETTER THAN THE 1990 ACR CRITERIA? NO OF COURSE NOT

The 2010 criteria^[4] replaced the tender point physical examination with a widespread pain index (WPI, a 0–19 count of the number of reportedly painful body regions), and introduced a 0–3 severity scale for the characteristic symptoms of fatigue, unrefreshing sleep and cognitive problems, and the extent of somatic symptom reporting, which were combined to give a 0–12 symptom severity (SS) score, and led to a new definition of FM as a WPI of > 7 and an SS > 5, or a WPI of 3–6 and an SS of > 9. The underlying purpose of these criteria were to simplify diagnosis; offer guidelines suitable for use in primary care practice; acknowledge the importance of the many non-painful symptoms of FM, such as fatigue, sleep disorders and perceived cognitive impairment (“fibrofog”); and provide a means of assessing disease severity and developing a method of longitudinal patient monitoring. They also changed the definition of FM from a “peripheral pain-defined disease” to a “systemic symptom-based disease”.

Wolfe et al. proposed modifying the 2010 ACR criteria by introducing what we call the 2011 criteria ^[5], which replaced the physician assessment of the extent of somatic symptoms with an item (scored 0–3) representing the sum of the presence/absence of headache, lower abdominal pain or cramps, and depressive symptoms during the previous six months. They also introduced the use of patient-reported areas of “pain or tenderness” for the WPI, whereas this assessment was restricted to physicians in the ACR 2010 criteria. These changes were suggested because it had been shown that a quarter of all FM patients failed to satisfy the 1990 ACR classification criteria ^[6]; however, the new criteria did not overcome this limitation as their exclusion of inflammatory and other painful disorders means that they cannot be applied in the case of patients with rheumatoid arthritis (RA), systemic lupus erythematosus (SLE), or other similar conditions ^{[20], [21], [22]}, and do not distinguish primary and secondary FM. Furthermore, a 2010 criteria-based diagnosis requires a physician's evaluation of the extent and severity of a patient's somatic symptoms, and it is likely that the absence of the need for a physical examination will lead to possibly important physical findings and other potential causes of symptoms being overlooked ^{[6], [7]}. Finally, even though no objective parameters are currently used in routine clinical practice, the 2011 criteria and do not include the results of any laboratory or imaging examination ^{[6], [7]}.

Consequently, both the 2010 and 2011 criteria can be faulted on the grounds that they are poorly defined and are totally reliant on the assessment of symptoms as they do not include any evaluation of mechanistic factors ^[7]. FM needs to be diagnosed on a clinical evaluation of individual patients, whereas these criteria may also apply to other medical conditions. Furthermore, the co-existence of ACR classification criteria, a WPI of 7 and an SS score of 5, a WPI of 3–6 and an SS score of 9, and personal opinion is not only confusing in itself, but there is also a risk that the polysymptomatic distress scale may not reflect the severity of FM symptoms, which may be better defined on the basis of mechanical hyperalgesia (i.e. tender point counts)..

Jones et al. ^[23] have shown that estimates of the prevalence of FM vary depending on the criteria used: 1.7% (95% confidence interval [CI] 0.7–2.8) on the basis of the 1990 criteria; 1.2% (95% CI 0.3–2.1) on the basis of the 2010 criteria; and 5.4% (95% CI 4.7–6.1) on the basis of the 2011 criteria, which also identify a higher proportion of men.

CONCLUSIONS

FM is frequently encountered and represents a considerable burden on healthcare resources. Although experts are still seeking the best diagnostic criteria, particularly for early-onset disease, the costs of a delayed diagnosis mean that primary care physicians should be trained to recognise and manage it promptly. The new 2010, modified 2011 or, even better the 2016 diagnostic criteria ^[24] which are further step forward, include a symptom severity scale and CWP index that more appropriately reflect the multifaceted aspects of the syndrome. However, the question as to whether CWP is the sine qua non or may be combined with other symptoms reflecting different stages of a central sensitisation syndrome remains, and may only be answered by the discovery of a clinical or biological marker that can identify the population affected by, or at risk of developing FM.

TAKE-HOME MESSAGES

- ❖ The 1990 ACR classification criteria define FM as chronic widespread pain with pressure pain allodynia or hyperalgesia.
- ❖ The new 2010 and modified 2011 ACR diagnostic criteria also include a symptom severity scale that better reflects the multifaceted nature of the syndrome.
- ❖ The 1990, 2010 and 2011 ACR criteria have advantages and limitations
- ❖ There is still a lack of a specific biomarker in the direction of identifying this multi-symptom syndrome.

REFERENCES

1. D.J. Clauw **Fibromyalgia: a clinical review** *JAMA*, 311 (15) (2014), pp. 1547-1555
2. P. Sarzi-Puttini, F. Atzeni, S. Perrot **Fibromyalgia syndrome: still a medical dilemma** *Reumatismo*, 64 (4) (2012), pp. 183-185
3. F. Wolfe, H.A. Smythe, M.B. Yunus, R.M. Bennett, C. Bombardier, D.L. Goldenberg, *et al.* **The American College of Rheumatology 1990 criteria for the classification of fibromyalgia. Report of the multicenter criteria committee** *Arthritis Rheum*, 33 (2) (1990), pp. 160-172
4. F. Wolfe, D.J. Clauw, M.A. Fitzcharles, D.L. Goldenberg, R.S. Katz, P. Mease, *et al.* **The American College of Rheumatology preliminary diagnostic criteria for fibromyalgia and measurement of symptom severity** *Arthritis Care Res*, 62 (5) (2010), pp. 600-610
5. F. Wolfe, D.J. Clauw, M.A. Fitzcharles, D.L. Goldenberg, W. Häuser, R.S. Katz, *et al.* **Fibromyalgia criteria and severity scales for clinical and epidemiological studies: a modification of the ACR preliminary diagnostic criteria for fibromyalgia** *J Rheumatol*, 38 (6) (2011), pp. 1113-1122
6. F. Salaffi, P. Sarzi-Puttini **Old and new criteria for the classification and diagnosis of fibromyalgia: comparison and evaluation** *Clin Exp Rheumatol*, 30 (6 Suppl 74) (2012), pp. 3-9
7. F. Wolfe **Criteria for fibromyalgia? What is fibromyalgia? Limitations to current concepts of fibromyalgia and fibromyalgia criteria** *Clin Exp Rheumatol*, 35 (Suppl 105(3)) (2017), pp. 3-5
8. G. Granges, G. Littlejohn **Pressure pain threshold in pain-free subjects, in patients with chronic regional pain syndromes, and in patients with fibromyalgia syndrome** *Arthritis Rheum*, 36 (5) (1993), pp. 642-646
9. D. Maquet, J.L. Croisier, C. Demoulin, J.M. Crielaard **Pressure pain thresholds of tender point sites in patients with fibromyalgia and in healthy controls** *Eur J Pain*, 8 (2) (2004), pp. 111-117
10. F. Wolfe **The relation between tender points and fibromyalgia symptom variables: evidence that fibromyalgia is not a discrete disorder in the clinic** *Ann Rheum Dis*, 56 (4) (1997), pp. 268-271
11. R.S. Katz, F. Wolfe, K. Michaud **Fibromyalgia diagnosis: a comparison of clinical, survey, and American College of Rheumatology criteria** *Arthritis Rheum*, 54 (1) (2006), pp. 169-176
12. E. Choy, S. Perrot, T. Leon, J. Kaplan, D. Petersel, A. Ginovker, *et al.* **A patient survey of the impact of fibromyalgia and the journey to diagnosis** *BMC Health Serv Res*, 10 (2010), p. 102
13. G. Hughes, C. Martinez, E. Myon, C. Taieb, S. Wessely **The impact of a diagnosis of fibromyalgia on health care resource use by primary care patients in the UK: an observational study based on clinical practice** *Arthritis Rheum*, 54 (1) (2006), pp. 177-183
14. A. Berger, E. Dukes, S. Martin, J. Edelsberg, G. Oster **Characteristics and healthcare costs of patients with fibromyalgia syndrome** *Int J Clin Pract*, 61 (9) (2007), pp. 1498-1508
15. S. Perrot, C. Schaefer, T. Knight, M. Hufstader, A.B. Chandran, G. Zlateva **Societal and individual burden of illness among fibromyalgia patients in France: association between disease severity and OMERACT core domains** *BMC Musculoskelet Disord*, 13 (2012), p. 22

16. J.C. Branco, B. Bannwarth, I. Failde, J. Abello Carbonell, F. Blotman, M. Spaeth, *et al.* **Prevalence of fibromyalgia: a survey in five European countries** *Semin Arthritis Rheum*, 39 (6) (2010), pp. 448-453
17. F. Heidari, M. Afshari, M. Moosazadeh **Prevalence of fibromyalgia in general population and patients, a systematic review and meta-analysis** *Rheumatol Int* (2017).
18. A. Vincent, B.D. Lahr, F. Wolfe, D.J. Clauw, M.O. Whipple, Oh. TH, *et al.* **Prevalence of fibromyalgia: a population-based study in Olmsted County, Minnesota, utilizing the Rochester epidemiology project** *Arthritis Care Res*, 65 (5) (2013), pp. 786-792
19. M.A. Fitzcharles, P.A. Ste-Marie, D.L. Goldenberg, J.X. Pereira, S. Abbey, M. Choiniere, *et al.* **Canadian guidelines for the diagnosis and management of fibromyalgia syndrome: executive summary** *Pain Res Manag*, 18 (3) (2012), pp. 119-126 (2013)
20. G.J. Macfarlane, M.S. Barnish, E. Pathan, K.R. Martin, K.L. Haywood, S. Siebert, *et al.* **The co-occurrence and characteristics of patients with axial spondyloarthritis who meet criteria for fibromyalgia: results from a UK national register (BSRBR-AS)** *Arthritis Rheumatol*, 69 (11) (2017 Nov), pp. 2144-2150
21. F. Atzeni, I.F. Masala, F. Salaffi, M. Di Franco, R. Casale, P. Sarzi-Puttini **Pain in systemic inflammatory rheumatic diseases** *Best Pract Res Clin Rheumatol*, 29 (1) (2015), pp. 42-52
22. F. Salaffi, M.C. Gerardi, F. Atzeni, A. Batticciotto, R. Talotta, A. Draghessi, *et al.* **The influence of fibromyalgia on achieving remission in patients with long-standing rheumatoid arthritis** *Rheumatol Int* (2017 Sep 5),
23. Jones GTL, F. Atzeni, M. Beasley, E. Flüß, P. Sarzi-Puttini, G.J. Macfarlane **The prevalence of fibromyalgia in the general population: a comparison of the American College of Rheumatology 1990, 2010, and modified 2010 classification criteria** *Arthritis Rheumatol*, 67 (2) (2015), pp. 568-575
24. F. Wolfe, D.J. Clauw, M.A. Fitzcharles, D.L. Goldenberg, W. Häuser, R.L. Katz, *et al.* **2016 Revisions to the 2010/2011 fibromyalgia diagnostic criteria** *Semin Arthritis Rheum*, 46 (3) (2016), pp. 319-329