

Editorial

Criteria for fibromyalgia? What is fibromyalgia? Limitations to current concepts of fibromyalgia and fibromyalgia criteria

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Fibromyalgia is an arbitrarily and broadly defined disorder of widespread pain and multiple symptoms that is strongly influenced by culture, context and social forces. The boundaries of fibromyalgia are not always easy to discern. How many and which symptoms are required? How many painful sites are needed? How many tender points? Criteria for fibromyalgia have served many purposes, the most important of which is to characterise and define the disorder. The definition of fibromyalgia has been malleable, however, because fibromyalgia “has no binding definition ... and no way of objectively testing for it” (1).

Readers may be surprised to know that well-regarded, major criteria sets for fibromyalgia have identified different groups of patients. Yunus’s 1981 criteria were cited >1000 times through 1990 (2), but their minimal requirement of 3 tender points and aching or stiffness in 3 anatomic sites meant that many patients identified by these criteria would not have satisfied the 1990 American College of Rheumatology (ACR) criteria for fibromyalgia that required of least 11 tender points and widespread pain (3). Although agreement between the ACR 1990 criteria and the ACR 2010 or modified 2011 criteria is good (4, 5), the ACR 2010 criteria let some patients into the diagnosis who had pain in only 3 anatomic areas. The most recent 2016 criteria revisions imposed a strict definition of generalised pain, so as to avoid identifying patients with severe regional pain syndromes as having fibromyalgia (6). But the result of this change was to exclude 13.8% of 2010/2011 positive cases. (J Albin & F Wolfe, accepted for publication) Thus, each set of criteria modifications effectively changes the fibromyalgia case definition.

In the seminal 1990 ACR criteria study, 16 physicians enrolled 135 cases of primary fibromyalgia and 135 control cases. The characteristics of these patients would form the basis of the de facto case definition of fibromyalgia (3). These study physicians were deeply influenced by the 1977 Smythe-Moldofsky paper that first proposed the use of tender points in diagnosis (7). It should be no surprise that tender points were effective in diagnosing fibromyalgia, as the physicians referring cases to the study relied on tender points for their clinical diagnoses. Who is to say that the prior Yunus criteria, which had a lower tender point requirement, did not identify fibromyalgia patients? If patients contributed to the 1990 criteria study had been referred using the Yunus criteria, it is certain that the 1990 criteria would have been very different. Fibromyalgia criteria also substantially changed the understood definition of fibrositis in effect through 1980 by adding to it. Moldofsky, a psychiatrist interested in sleep problems, added “unrefreshed sleep” to the Smythe and Moldofsky criteria of 1977 (7). The ACR 1990 criteria added “widespread pain” as a criterion—something never required previously. Fibro fog, a hot term in the first decade of the 21st century, produced 104 Google hits in the 1990s and 13,800 hits in the following 10 years. It was added to the 2010 criteria as “cognitive difficulties.”

In addition to simple definitional problems, the 1990 criteria always had problems with validity and reliability (6). Most primary care physicians didn’t know how to or were unwilling to perform the tender point examination. In addition, tender points did not just measure pain threshold, they measured pain threshold and dis-

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stress. Gracely called the tender point count “some unspecified combination of tenderness and distress” (8). It has also been called “a sedimentation rate for distress” (9). Physicians who used tender points invariably tested patients after interviewing them and eliciting their symptoms. Tender points probably worked in expert hands because physicians adjusted their examinations based on the information they obtained in the interview. The 2010/2011/2016 (2010+) symptom based criteria also have problems with reliability in the same way that all questionnaires that measure feelings do (10).

Walitt *et al.* used the US National Health Interview Survey (NHIS) and surrogate (a limitation) fibromyalgia criteria to investigate fibromyalgia in the US population in 2016 (11, 12). They found that 3/4 of patients reporting a physician diagnosis of fibromyalgia did not meet fibromyalgia criteria. What? Could it be that the tricky and difficult to use tender points were not applied, or the questionnaire of the 2010+ criteria was not used by primary care physicians? Fibromyalgia, like beauty, may be in the eye of the beholder (the clinician) who sees fibromyalgia straight on as pain and distress. It seems possible that the default clinical criteria now being used in primary care medicine is just the presence “pain and distress.” It is important to remember that physician determined fibromyalgia criteria, including the 1990 criteria, were constructed by physicians, not discovered by them. In that respect, fibromyalgia and fibromyalgia criteria have important intellectual and social links to neurasthenia of a previous century (13).

Evidence exists that pharmaceutical companies have influenced and increased the diagnosis of fibromyalgia by advertising and physicians educational activities (14, 15). Extensive advertising including direct to patient advertising in the US identify those who might satisfy fibromyalgia criteria but are undiagnosed, but also those who are undiagnosed and would never satisfy fibromyalgia criteria—those identified in the Walitt study (11, 12).

Even with “good” criteria, there are other problems with fibromyalgia and

fibromyalgia criteria. When does fibromyalgia begin or end? Fibromyalgia diagnostic criteria are based on reaching a sufficient level of symptom severity. However, persons with fibromyalgia may have many symptoms and multiple interactions with physicians for years before fibromyalgia is diagnosed (16-18). Fibromyalgia often cannot be distinguished from other similar disorders (19-21). Fibromyalgia may not be diagnosed even if criteria are met, as physicians may choose not to diagnose fibromyalgia, and use other terms to characterise fibromyalgia symptoms (12, 22).

In 2017, 40 years after Smythe and Moldofsky’s startling paper, it seems possible to summarise some aspects of fibromyalgia that came to be learned through applications of criteria to patients and trials.

1. Fibromyalgia “has no binding definition ... and no way of objectively testing for it” (1).
2. Fibromyalgia is a constructed disorder, just as neurasthenia was. Its prevalence and acceptance depend on factors largely external to the patient.
3. Fibromyalgia is a dimensional disorder (a continuum disorder) and makes perfect sense as such. Considering it as a categorical disorder runs into misclassification problems described above. The polysymptomatic distress (PSD) scale of the 2010+ criteria to access the continuum.
4. Comparing one end of the continuum with the other end (“normals” vs. fibromyalgia) in a research study tells one very little about the disorder and its mechanisms. It is possible to make rules for this type of almost always statistically significant comparison: every feeling, symptom, physical finding, neuroscience measure, cost and outcome will be worse when you compare fibromyalgia to “normal subjects.”
5. Fibromyalgia may not truly be a syndrome, and it is important that future mechanistic studies examine the range and content of symptoms.
6. Given the arbitrary and variable nature

of the fibromyalgia definition, we should consider whether the “pain and distress” type of fibromyalgia subject identified by Walitt in the general population should be considered de facto as part of the fibromyalgia definition.

7. As fibromyalgia is a socially constructed dimensional disorder, and arbitrarily and inconsistently named and diagnosed, we should be wary of accepting as sufficient current reductionist neurobiologic causal explanations.

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