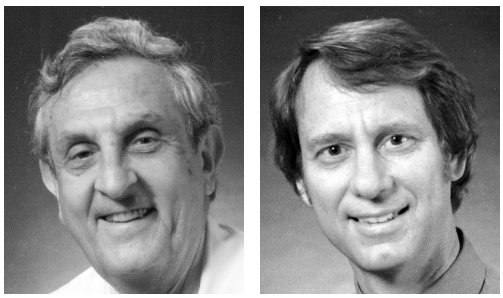
Editorial

The Fibromyalgia Tender Points: Use Them or Lose Them? A Brief Review of the Controversy



Chronic widespread musculoskeletal pain (CWP) has been recognized for centuries[1-3], and may be as old as humanity. Controversy over the etiology and pathogenesis of CWP started in the 19th century[3]. Various terms used to describe somewhat similar clinical conditions included fibrositis, myofascial pain syndrome, muscular rheumatism, psychogenic rheumatism, and fibromyalgia (FM)[3]. Due to a lack of strict definition of these conditions, the same name was sometimes used to describe different clinical presentations, thus adding to the confusion. Smythe and Moldofsky essayed the first modern definition of FM, although still using the term "fibrositis"[4]. They proposed diagnostic criteria that included fatigue, widespread pain, and the presence of at least 12 of 14 tender points (TP) in specific anatomic locations. Other investigators suggested somewhat different criteria, varying the number of TP and their location, but the concept of a TP as an area of allodynia identifiable on physical examination was increasingly accepted[5-9].

In 1990 a committee of the American College of Rheumatology (ACR) published a report that defined classification criteria for FM (chosen in preference to fibrositis)[10] (see Table 1). The criteria included a minimum of 11 out of 18 TP. TP were defined in terms of their surface anatomical locations; the amount of pressure exerted by the examiner's thumb was to be 4 kg/cm^2; it was stipulated that a positive TP could only be so classified if the patient admitted to having pain rather than tenderness. These criteria were accepted by many, but disputed by others. At a 1992 meeting of a committee of the European League Against Rheumatism (EULAR), several objections were raised: the minimum number and location of TP were arbitrary, and the control points mentioned in the ACR committee paper (but not further mentioned in the criteria) could also be painful[11]. Others have pointed out that 11 or more TP could be found in about 5% of healthy population controls, thus questioning their specificity[12,13]. TP were also interpreted as representing psychological distress rather than being a classification criterion for a condition called FM[12]. Wolfe suggested that FM should not be treated as a discrete disorder and TP should be interpreted as indicators of distress rather than part of the classification criteria[14]. Further, whatever one may think of the value of TP, it appears that many rheumatologists did not use them in their physical examination[15,16].

In view of the ongoing debate surrounding TP, it seems appropriate to review the evidence for their validity in assessing patients with CWP, and therefore the validity of both the ACR classification criteria for FM and indeed the concept of FM.

METHODOLOGY FOR ELICITING TENDER POINTS

The ACR committee reviewed data on patients assessed as having FM by its members, and on controls; the latter had various painful conditions such as rheumatoid arthritis (RA), neck or back pain, tendonitis, systemic lupus erythematosus (SLE), and others[10]. Patients deemed to have FM were divided into 2 groups: those with "primary" FM (that is, those with FM in the absence of another painful musculoskeletal condition) and those with "secondary" FM (that is, FM associated with another painful musculoskeletal condition). Controls were divided into those with a painful musculoskeletal condition other than FM, and those with a painful musculoskeletal condition of the same type seen in those with secondary FM but not meeting the diagnostic criteria for FM. Altogether there were 293 patients with FM, and 265 controls. Blinded observers examined TP by both digital palpation and using a dolorimeter. The committee initially chose 12 TP pairs, and eventually eliminated 3 because of their low discriminatory power, leaving 9 pairs. The TP originally selected were those used in "other criteria sets," but no further reference or justification was given for their choice. The sensitivity of ≥ 11/18 TP was reported as 90.1% and the specificity as 77.7% with an accuracy of 84.2%. The sensitivity, specificity, and accuracy of all the classification criteria were 88.4%, 81.1%, and 84.9%, respectively. The TP chosen by the ACR committee had good discriminatory value when patients with FM were

See A pain psychologist's view of tenderness in FM, *page 912*

Table 1. The American College of Rheumatology 1990 Criteria for the Classification of Fibromyalgia[10]. From Wolfe, *et al*, Arthritis Rheum 1990;33:160–72, with permission.

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 quadrant 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 FM 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 FM.

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compared with the controls used in that study. However, a subsequent population study comparing TP in those meeting the ACR classification criteria for FM compared to those with CWP found a significant difference in only 13/18[17]. That is, TP differ in their ability to differentiate FM and CWP, with TP in the lower body showing the greatest differentiation.

The committee also mentioned the use of "control sites" in the examination for TP, but did not mention these again in the Results section, nor did they state that control sites had to be painless in order to accept TP counts as part of the classification criteria. Two studies have shown that pain threshold was decreased in control points in FM subjects, compared to subjects with regional pain and pain-free controls[18,19]. Wolfe also found that positive control points were a common feature in FM, and appeared to be a marker for a generally low pain threshold. He concluded that control points should not be used to disqualify a diagnosis of FM, and that their use should perhaps be abandoned[20]. Importantly, these data also suggest that hyperalgesia in patients with FM is generalized rather than restricted to TP. However, the TP pain threshold is significantly lower than that of control points[19].

Both digital palpation and dolorimetry have been and are used to detect TP. The ACR committee found digital palpation to be more discriminatory in detecting TP. In a study of 15 patients with various rheumatologic conditions Cott, *et al* found no significant difference in inter-rater agreement on the presence/absence of TP between digital palpation and dolorimetry[21]. The 2 blinded raters in that study showed a high degree of agreement in their diagnosis of FM. Similarly high inter- and intra-rater agreement among 3 blinded assessors was reported in detecting TP by dolorimetry and digital palpation[22]. A variety of dolorimeters have been used in detecting TP[6,7,10,18-23].

The ACR committee recommended that TP be assessed as positive or not depending on whether the patient had pain on digital pressure, without trying to quantify the degree of pain perceived[10]. Okifuji, *et al* have suggested a manual TP survey with an 11-point pain scale for each TP, thus allowing the application of parametric statistics in studies[24]. The use of such a scale does not, however, increase accuracy. Nonetheless, pain ratings may be useful in quantifying illness severity and outcome measurement.

Several physiologic variables could conceivably affect the TP count. Thus Hapidou and Rollman showed that there was an increase in TP counts in healthy women without FM in the follicular phase of their menstrual cycle[25]. Bellamy, *et al* have reported diurnal rhythmicity in pain, fatigue, and stiffness in patients with FM[26]. There are no data on the possible diurnal rhythmicity of TP.

EPIDEMIOLOGIC STUDIES OF TENDER POINTS

Croft, *et al* studied a selected sample of 177 subjects registered in 2 general practices in the northwest of England[12]. Subjects were divided into 3 groups: CWP, regional pain, and no pain. They found ≥ 11 TP in 5% of those with no pain, in 19.4% of those with regional pain, and in 40% of those with CWP. There were 18 patients with CWP and ≥ 11 TP (10.2% of the total number examined). The authors also used a number of instruments to assess depression, fatigue, and sleep problems. They concluded that TP were a "measure of general distress" but did not define a distinct disease entity. This was, and remains, an influential study, and its methodology

and results deserve careful consideration. Only 66% of those on the registers replied to the initial questionnaire, and only 71% of the sample selected for further interviewing and examination responded. Two-thirds of the subjects were women. The mean age was 53 years. CWP was present in 41.8% of those who answered the initial questionnaire, and in 25.4% of those who were finally assessed. These figures are much higher than the CWP prevalence of 11.2% previously reported by the same authors, presumably in the same population[27]. The ACR criteria for CWP are misquoted as being pain in at least one area of the axial skeleton and at least 2 "contralateral quadrants" (ACR criteria stipulate pain in the axial skeleton, pain on both sides of the body, and pain that had to be present both above and below the waist). The method of assessing TP pain also differed from that stated in the ACR criteria.

Schochat and Raspe studied prevalence of TP in a local population in Germany, and the relation of TP to pain, mood, health problems, and to cognitive problems[13]. They found significant correlations between TP and age, pain, bodily complaints, and physical mobility. They concluded, like Croft, *et al*[12], that TP were a measure of general distress, and questioned the concept of FM as a distinct entity. They thought that their results indicated the low specificity of TP. This interpretation is contradicted by their own data showing that among the groups of subjects who had no pain, and those who had only one pain location, 11 or more TP were present in only 4.7% and 3%, respectively. The percentage of those with ≥ 11 TP increased to 27.4% in the group that had 2 or more painful sites, but this was also the group in which 30.5% had CWP.

Lindell, *et al* studied a population in southwest Sweden[28]. Questionnaires were mailed out, and a sample of subjects was selected among responders, who were then interviewed and examined. The selected individuals were divided into 5 groups: FM, CWP, chronic regional pain (CRP), no chronic pain, and RA. The FM group had a mean of 14.7 TP; the mean TP counts in CWP, CRP, no pain, and RA were 4.3, 2.7, 1.7, and 3.2, respectively. The number of TP ranged from 0 to 10 in the non-FM groups. There was a large number of nonresponders at both stages of the survey. The findings of this study contrast with those of Croft, *et al*[12], as no subject in the non-FM groups had ≥ 11 TP.

Chronic low back pain is probably the most frequent CRP syndrome. In a population study of low back pain Hüppe, *et al* examined subjects with this condition and found a significant correlation between number of TP and depression, catastrophizing, state of health, and number of symptoms[29]. However, only 2.91% of the subjects had ≥ 11 TP.

Overall, these studies suggest that while TP occur in painful conditions other than FM, as well as in a small percentage of those without pain, a TP count ≥ 11 has high specificity for FM. Because pain and distress are often associated with TP, and some authors conclude that TP count should be viewed as an index of distress, we will examine both TP-pain and TP-distress relationships.

TENDER POINTS, PAIN, AND DISTRESS

It is apparent now that in the clinic[30] and among the general population[12,13], TP are associated both with pain that is anatomically widespread and with psychological distress.

TP and pain sensitivity. Patients with FM show a generalized increase in pain sensitivity to pressure and heat that is not confined to TP[31-35]. Carli, *et al* studied 6 groups of subjects: (1) patients with primary FM; (2) patients with secondary FM (i.e., patients with FM and another rheumatic or systemic disease); (3) patients with CWP and < 11 TP; (4) patients with multiregional pain (MP) but not CWP with < 11 TP; (5) patients with MP with ≥ 11 TP; and (6) healthy subjects[36]. They assessed responses to various psychophysical tests such as von Frey monofilaments, deep pressure algometers, cold, heat, and tourniquet-induced ischemia. The highest values for stiffness and pain were found in the 2 FM groups. There was a moderately high correlation (r = 0.64) between pain threshold at positive control points and TP; there was a more modest correlation (r = –0.45) between TP threshold and number of TP. There were also correlations between number of TP and present pain, pain-area present, and stiffness. Control point thresholds and TP thresholds were good predictors of TP counts. The authors concluded that the diagnosis of FM implies the presence of hyperalgesia to mechanical, thermal, and ischemic stimuli.

Thus inclusion of TP in the ACR criteria has allowed the identification of individuals who are at the upper end of a continuum characterized by increased pain sensitivity and widespread pain. Not surprisingly, such individuals also tend to experience high levels of distress.

TP and distress. Wolfe has called TP a "sedimentation rate for distress"[14]. The existence of a relationship between TP counts and psychological distress is well established. However, among the studies that have investigated this relationship, psychological distress has been defined in different ways. Croft, *et al*[12] defined distress as including fatigue, depressed mood, and sleep problems. Wolfe and Skevington[37] developed a Rheumatology Distress Index (RDI) that is a linear combination of various indices that measure anxiety, depression, sleep disturbance, fatigue, and global illness severity. Petzke, *et al* used the Brief Symptom Inventory, a multiscale measure of psychopathology, as well as a separate measure of depression[38]. Even with these diverse definitions, there appears to be a fairly consistent positive association between number of TP and distress. It should be noted, however, that these relationships are only moderate in magnitude, typically falling between r = 0.30 and 0.40. Wolfe, *et al* found a higher correlation between TP counts and the RDI (r = 0.49), but the global severity component of that index may account for this result[37]. Interestingly, Petzke, *et al* found that pressure pain thresholds determined by random presentation of pressure stimuli were unrelated to distress, whereas manual TP counts, dolorimetry-based counts, and incrementally determined thumb pressure pain threshold were related[38].

McCarberg, *et al* studied 316 patients with FM using both TP counts and the manual tender point survey (MTPS) method of Okifuji, *et al* mentioned above[24]; they found that TP counts and MTPS correlated significantly with psychological distress[39]. However, TP counts accounted for only 3.1% and MTPS for only 8.3% of the variance in distress. Staud, *et al* have demonstrated that the number of painful body areas (using a body diagram of 50 standard areas) accounts for about 9% of the variance in overall clinical pain in FM, and maximal/average pain ratings for 27%; pain-related negative affect accounted for an additional 19% of the variance in their regression analysis[40]. Pamuk, *et al* examined 150 patients with FM and 42 patients with CWP. They assessed anxiety, depression, somatization disorder, and pain, and used the Leeds Assessment of Neuropathic Pain Scale (LANSS), which discriminates between neuropathic and nociceptive pain[41]. They found that the TP count correlated well with pain severity, and with the neuropathic pain score, but not with anxiety/depression and somatization scores.

These studies point to an important characteristic of manual TP counts — they are an amalgam of pain sensitivity and distress: hence, they are at best a partial measure of either. However, the ACR criteria that were developed to define FM included TP as a key component of the classification; TP are clearly linked to distress, and distress is an integral aspect of what we now know as FM. More generally, in comparison to individuals with other chronic pain syndromes (upper extremity pain, cervical pain, thoracic pain, lumbar pain, lower extremity pain, and headache), those with FM have the highest level of psychological distress[42]. FM is part of an "affective spectrum disorder"[43,44], and there is evidence that mood disorders are more common in both those with this disorder and their first-degree relatives[45]. This view has been challenged[46] inasmuch as rates of depression are no higher in patients with FM than in those with RA. Studies that used diagnostic interviews and some form of blinded assessment[47-49] failed to find evidence for increased lifetime risk of major depression in FM. It should be noted that one of these, a study by Raphael, *et al*, evaluated a diverse community sample rather than clinic patients, suggesting these findings have broad generalizability[47]. Moreover, neither comorbid major depression nor degree of depressive symptomatology appears to be associated with either experimental pain sensitivity or functional magnetic resonance (fMRI) indices of activity in relevant areas of the somatosensory cortex[50]. In other words, these fMRI data suggest that sensory-discriminative aspects of pain are at least partly independent of mood in FM. These findings are at odds with the "affective spectrum disorder" hypothesis and lend some support to the notion that affective disorders in FM may be a reaction to illness. Intriguingly, the FM group in another Raphael study showed a higher lifetime risk for anxiety disorders, especially post-traumatic stress disorder (PTSD) and obsessive-compulsive disorder[51]. It has been suggested that chronic pain and PTSD are mutually maintaining[52].

The ACR 1990 classification criteria for FM defined a syndrome that included increased pain sensitivity, widespread pain, and perhaps unintentionally a multifactorial pattern of distress. The inclusion of 11/18 manually determined TP as a diagnostic criterion is at least part of the reason why distressed patients are captured when the ACR criteria are applied. It is worth noting, however, that those who do not meet the TP criteria but do have widespread pain are also more likely to be distressed[53]. Thus widespread pain and distress are related, if only moderately. Application of the ACR criteria results in selection of individuals who tend to have particularly high levels of pain sensitivity and also tend to be distressed. This inadvertent selection for distress via the ACR criteria seems to have resulted in more than a little confusion and considerable debate about whether FM is a discrete or even a legitimate disorder. Although it is important to identify and treat psychological disorders in patients with FM, it does not follow that the association between TP and distress should lead to abandonment of the ACR criteria or FM as a construct. If diagnostic entities are to be abandoned on the basis of their having an association with distress, then the criteria for many other chronic illnesses should also be revised on this basis. For example, the prevalence of major depression in RA is between 13% and 20% and is under-recognized[54].

CRITIQUES AND CHALLENGES TO THE FM CONCEPT AND THE VALIDITY OF TENDER POINTS

The concept of FM, including TP, has been contentious since it was introduced and remains so. Quintner and Cohen argued that the FM construct is tautological: "an illness should not be confused with its own cause"[55]. Clearly, the ACR committee used tautological methodology. This may be necessary when no gold standard exists. The objective of attempting to introduce criteria based on tautological methods is to ensure clarity in scientific communication similar to dictionary word definitions. Similar tautological methods have been used in the definition of criteria for RA and SLE[56,57]. FM, however, is not simply a descriptive term. Despite their discomfort with tautology, Quintner and Cohen recognized that "clinical mechanical allodynia is the fundamental underlying pathophysiological phenomenon." Since these criticisms emerged, there has been growing evidence that FM is associated with considerable changes in the central nervous system (CNS), including high levels of substance P and nerve growth factor in the cerebrospinal fluid[58,59] and various abnormalities identified via functional imaging of the CNS[60-62].

Most other challenges to FM address the issue of TP. TP are central to the concept of FM, but their use has drawn a number of criticisms, examined below.

1. TP are arbitrary and exclusionary

When a cutoff point of 11/18 TP is used, those who fail to meet that criterion cannot, using the ACR definition, have FM. What, then, do those who have CWP but fewer than 11

TP have? Does it make sense to exclude individuals who are so similar to their counterparts with ≥ 11 TP? This concern has been raised repeatedly[11,63]. The opposite issue, having the requisite number of TP but not meeting the definition of FM because pain isn't sufficiently widespread, has also been raised[12,15,52]. These limitations are no different than those for many other disorders whose definition is based on a cutoff point on a continuum[64]. For example, definitions of arterial hypertension use an arbitrary cutoff chosen for clinical and research purposes. It is now accepted that blood pressures below but approaching a certain cutoff (e.g., 140/90 mm Hg) may also be a cause for concern and should be monitored. Thus, the Seventh Report of the Joint National Committee on Prevention, Detection, Evaluation, and Treatment of High Blood Pressure[65] has defined blood pressure 120/80 to 139/89 mm Hg as "prehypertension." Perhaps for clinical purposes a "borderline" range for FM could be defined, taking into account both variation in TP counts and the definition of "widespread pain."

2. Tender points are subject to bias

As noted previously, manual TP counts, and to some extent dolorimetry-based counts, are subject to psychophysical biases. As such, they are an imperfect measure of mechanical pain threshold[34]. Also, as Clauw and Crofford[63] have pointed out, patients can learn where the TP are and become "expectant," such that the number of TP is overestimated. Similar biases may also occur on the part of the examiner. For example, if the first few points are positive the examiner may be biased toward positive findings for remaining points. Nevertheless, the extent to which such biases lead to a misdiagnosis remains undocumented. Interestingly, in one study in which blinded observers were asked to distinguish FM patients from simulators and healthy controls, they did so with 80% accuracy[66]. For research purposes, it seems clear that pain thresholds should be measured using random psychophysical scaling procedures that minimize bias. This would also be true for clinical purposes if the goal were solely to identify those who have abnormal pain thresholds. On the other hand, if the current concept of FM as a constellation of pain sensitivity and distress is maintained, the current ACR criteria including TP counts are appropriate. Psychophysical measurements of pain thresholds should, however, be strongly considered as outcome indices in clinical trials.

3. TP counts do not capture the complexity of FM

Although TP are used to classify patients who have a syndrome that is complex and affects many body systems, they do not capture that complexity[63]. An alternative would be to redefine FM based on a combination of underlying pathophysiological processes (i.e., pain threshold, affective distress, fatigue, etc.). This would be a difficult undertaking, given the range and variation in symptoms in FM, although many other rheumatic diseases are defined in this manner. An advantage of such an approach would be direct evaluation and consideration of symptoms that now seem only incidentally related to TP, such as fatigue, sleep disturbance, and mood disturbance.

4. The relationship of TP to underlying pathology is unclear

In one sense, the significance of TP remains puzzling. It is known that these anatomical locations are more sensitive in healthy controls as well as patients with FM[19,67]. They have proven useful in identifying individuals with hyperalgesia, allodynia, distress, and other symptoms that appear to aggregate in a subset of the population. In a recent and extensive review of the literature, Vierck made a strong case for the role of peripheral tissue abnormalities such as muscle hypoxia and sympathetic nervous activation leading to stimulation of nociceptors that, in turn, leads to CNS sensitization and chronic pain[68]. It is possible that TP represent such areas of increased nociceptor activation.

5. In practice, the TP count is often not done anyway

Katz, *et al*[15] and Hughes, *et al*[16] suggest that in clinical practice the diagnosis of FM is often made without a formal TP count by assessors who have not been trained to apply the ACR criteria uniformly or else do not take the time to do so. However, abandoning the ACR criteria because they are not correctly applied seems nihilistic, especially when achieving proficiency is not difficult[69]. Nonetheless, it seems likely that some physicians make the diagnosis without doing a TP count. This is not surprising, given that it has been suggested[70] that clinicians stop using the ACR criteria. The problem is that clear, generally accepted, substitute criteria have not been identified. If such clinical criteria are developed they should bear some relationship to the criteria that continue to be suggested for research purposes.

ALTERNATIVES TO TENDER POINTS

Chronic widespread pain. CWP has been defined in various ways[53,71,72]. Macfarlane, *et al* developed a schema for classifying respondents who have "widespread pain" in epidemiological studies[53]. They pointed out that the portions of the ACR 1990 criteria pertaining to the distribution of pain describe pain that may not be entirely widespread. Although in the ACR criteria pain must be present on both sides of body, above and below the waist, and in the center to be considered widespread, the extent to which it is present within each of these sites can vary. Thus they developed a coding system they called the "Manchester Definition" of widespread pain[53]. Similar body pain diagrams have also been used by others[40,71,72] and have been coupled with self-reports of pain severity[40]. It is not clear, at present, whether these more precise definitions would, in practice, be an improvement over the portion of the ACR 1990 criteria that define "widespread." Future research could compare classification based on these approaches, with or without TP.

One consequence of extending the definition of FM or abandoning it in favor of CWP would be a dramatic increase in the number of individuals who met those criteria to 10%-15% of the population[63]. Further, we have to keep in mind that there are significant quantitative differences between those

with CWP and ≥ 11 TP (i.e., individuals with FM) and those with CWP but fewer than 11 TP, with regard to social and demographic characteristics, somatic and psychological symptoms, and functional impact[41,73-75].

Survey criteria. Wolfe developed an instrument that he designated a "regional pain scale" (RPS), which assessed various articular and nonarticular body regions for pain[76]. When combined with other assessments such as a fatigue visual analog scale (FVAS) it correctly identified most patients diagnosed as having FM by their rheumatologists. However, it also identified a large number of patients with RA and osteoarthritis (OA) as having FM. When combining a cutoff point of RPS ≥ 8 and a FVAS cutoff point ≥ 6, Wolfe correctly identified 66.3% of FM patients (by the ACR criteria); however, 28.6% of RA patients were also so identified, as were 33.2% of patients with OA. Katz, *et al* used the above criteria (i.e., RPS and FVAS) in a study of 101 patients who had received a "clinical diagnosis" of FM[15]. These patients also were assessed to determine if they met the ACR classification criteria for FM. The results showed a similar concordance of about 72%–75% between the clinician's diagnosis and the RPS + FVAS (termed "survey criteria"), the clinician's diagnosis and the ACR criteria, and the survey criteria and the ACR criteria. The TP count and the RPS were most strongly associated with the clinical diagnosis, but a TP count ≥ 11 had a weaker effect. In this particular study by Katz, *et al*, "clinical diagnosis" rather than ACR criteria served as gold standard for classification, on the grounds that "the criteria often fail to identify patients who have FM"[15].

If clinical diagnosis is to be regarded as equally valid or better than the ACR criteria, one has to ask how the clinician arrives at such a diagnosis. To support their case against the use of ACR criteria, Katz, *et al* quote an article by Fitzcharles and Boulos[77], who found that only 29 out of 76 patients referred to a rheumatology clinic as having FM actually met the ACR criteria, suggesting that clinical diagnoses are highly inaccurate. This finding, coupled with the lack of definition of such criteria, would invalidate their acceptance for scientific purposes. The survey criteria seem to have relatively low sensitivity and low specificity, although Wolfe makes the case that the high percentage of RA and OA patients who had high RPS and fatigue scores may also have had FM[76]. Although unproven, this interpretation may have been true for many with RA, but is unlikely for those with OA, where no such association has been documented.

Katz, *et al*[15] also suggest that "fatigue, cognitive disturbances and other symptoms" may be more important than TP counts. Although non-pain symptoms are important in FM, there is no evidence to suggest that they are of greater importance than hyperalgesia and allodynia, which are key symptoms in FM[78]. Thus, a weakness in the approaches to CWP and survey criteria is that they do not include an evaluation of these features. If other criteria were to be introduced they would require a thorough comparison with the current ACR criteria, which were adopted after painstaking studies.

Alternative assessment methodologies. Pain psychologists interested in FM have pointed to methods of eliciting pain such as random application of pain stimuli or assessment of the wind-up phenomenon, which better measure pain itself and are not influenced by distress[38,79]. These measures are also more sensitive than TP in assessing a therapeutic response. However, they require special training and are more time-consuming than TP count. While there is much to recommend them as measures of improvement, there are no data to assess their specificity and sensitivity in a diagnostic context.

In addition to psychophysical testing, fMRI[61-63] and nociceptive flexion reflex testing[35] have been used to demonstrate abnormal pain processing in FM. Of these, fMRI is more expensive and complex. As Bennett[80] has pointed out, the nociceptive flexion reflex testing may be more easily accessible and convenient because standard electromyographic equipment can be used. The test also appears to eliminate subjective bias and dissimulation.

CONCLUSION

Our review leads us to conclude that TP continue to be useful in the clinical assessment of FM. Suggestions to ignore or abandon them in favor of less well defined clinical diagnoses[15] would return us to the state of confusion that existed prior to introduction of the ACR criteria. In our view this is unacceptable. Measures such as Wolfe's RPS[76] or elaborate body pain diagrams lack the precision and/or the validation required in scientific communication, although they offer the dubious advantage of not requiring physical examination.

Central to the diagnosis of FM is the availability of a reliable, valid measure of pain sensitivity. Measurements of pain thresholds by randomly applying painful stimuli meet this standard and appear to have the added benefit of being independent of "distress." However, formal psychophysical evaluations are time-consuming and do not easily lend themselves to the requirements of clinical practice. One alternative, nociceptive flexion reflex testing, for determining the presence of central allodynia[35] deserves further consideration given its relative simplicity and objective nature. Validated measurements of various aspects of distress, such as fatigue and nonrestorative sleep, should perhaps be reevaluated as adjuncts to the ACR classification criteria, although the experience of the ACR committee suggests this is unlikely to be useful.

Until alternatives are established and receive wide acceptance, TP should remain a component of the criteria for FM. If FM is conceptualized as an amalgam of both abnormal pain sensitivity and distress, the ACR criteria, including the TP examination, remain a straightforward, clinically convenient and valid method of classification. However, manual TP counts are not sensitive measures for following changes in the severity of FM, such as may be required in assessing treat-

ment outcome[81]; dolorimetry may be more useful for this purpose[82]. There are several other validated criteria to follow change such as the Fibromyalgia Impact Questionnaire[83], as well as various pain scales, fatigue scales, quality of life measures, etc[81]. Lower body TP seem to discriminate between FM and CWP better than upper body points, particularly those in the neck and shoulder area[17]. The diagnostic and predictive utility of differentiating these points warrants additional research.

New diagnostic methods should follow from our developing understanding of the underlying pathological processes in FM. It is also possible that with technological advances in imaging, for example, more accurate criteria for the diagnosis of FM will emerge to complement or even replace the current requirement for use of TP. Future advances in diagnosing and understanding FM will likely require better methodologies for separating out the elements of FM, including nociceptive and central pain processes, as well as psychological components of the disorder. Such advances, we believe, will lead to improved clinical diagnostic methods and to more precisely targeted treatments for individuals with this difficult and often misunderstood condition.

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