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Looking at fibromyalgia differently – An observational study of the meaning and consequences of fibromyalgia as a dimensional disorder

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ABSTRACT

Objective: Despite data showing that fibromyalgia can be represented as a dimensional disorder, almost all assessments treat fibromyalgia as a dichotomous categorial disorder; and research shows that agreement between community diagnosis of fibromyalgia and fibromyalgia criteria is poor. We investigated the validity of FM as a discrete disorder by exploring the relationships of categorical fibromyalgia, the polysymptomatic distress (PSD) scale, and clinical variables.

Methods: In a databank of 33,972 rheumatic disease patients, we studied the categorical diagnosis of fibromyalgia, the PSD scale separately and divided into severity groups, measures of widespread pain, as well as somatic syndrome questionnaires like the Patient Health Questionnaire-15 (PHQ-15), and clinical pain, global, HAQ disability and quality of life scales (EQ-5D).

Results: Clinical and demographic variables became more abnormal with increasing PSD score groups, indicating substantial increase in symptoms and pain. The changes across PSD categories were linear and large. When we compared FM- (PSD 8-11) with FM+ (PSD 12-18) patients we found considerable overlap in scores for pain, HAQ disability, patient global, PHQ-15, psychological status, and other variables. Somatic symptom scores were highly correlated with PSD (r=0.718). There was no evidence of a differential pain effect that was present in FM+ but not FM- subjects.

Conclusion: Fibromyalgia is more accurately considered a dimensional than a dichotomous disorder. There is vast variability among fibromyalgia positive and negative cases that is governed by the strong and linear relationships between the dimensional PSD scale and clinical variables. The PSD scale provides measurements of the fibromyalgia dimension that support and enlighten categorical fibromyalgia and are an effective tool to measure clinical status and changes. Whatever the mechanism of the pain and symptom increase in fibromyalgia, it appears to operate over the entire fibromyalgia symptom dimension, not just in those with categorical fibromyalgia.

Fibromyalgia as it is currently understood arose in the 1950s as a categorical disorder. In practice, it has remained a categorical disorder: patients or research subjects either have or do not have fibromyalgia. Even in recent years, some expert opinion considered fibromyalgia to be a "discrete diagnosis with a clustering of symptoms characterized by central nervous system pain amplification …. [1]" The idea that fibromyalgia could be thought of as dimensional came to the fore following the publication the American College of Rheumatology (ACR) related

Abbreviations: ACR, American College of Rheumatology; EQ-5D, EuroQol-5; FASmod, Modified Fibromyalgia Assessment Scale; FIQ-R, Fibromyalgia Impact Questionnaire; FS, Fibromyalgia severity score; FM2010, fibromyalgia 2010 criteria; FM2011, fibromyalgia 2011 criteria; FM2016, fibromyalgia 2016 criteria; HAQ, Health assessment questionnaire; HRQOL, health-related quality of life; NDB, National Data Bank for Rheumatic Diseases; NIMRD, noninflammatory musculoskeletal and rheumatic disorders; NonpNons, Non-pain and non-fibromyalgia symptoms (scale); PAS-II, Patient activity scale-II; PHQ-4, Patient health questionnaire for depression and anxiety; PHQ-15, Patient health questionnaire-15; PSD, Polysymptomatic distress (scale); SSS, Symptom severity scale; SSS-8, Somatic Symptom Scale 8; WP, widespread or generalized pain; WPI, Widespread pain index.

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2011 fibromyalgia criteria revision (FM2011) in which the fibromyalgia symptom (FS) score —a measure of "fibromyalgianess" or the fibromyalgia dimension, also known as the polysymptomatic distress (PSD) scale, was described [2, 3]. *Dimension* refers to the continuum of fibromyalgia syndrome severity that an individual can experience, in contrast to a dichotomous categorical approach in which an individual is or is not designated as having fibromyalgia. The dimension extends from no symptoms to extensive symptoms in persons who are fibromyalgia positive. But the days of discrete categories could be coming to an end, as the limitations associated with fibromyalgia diagnosis and categorization become better known, and more fibromyalgia experts acknowledge fibromyalgia's dimensionality and make use of the PSD or similar scales [4–6]. Recently, conversion methods were developed to allow the Fibromyalgia Impact Questionnaire (FIQ-R) and the Modified Fibromyalgia Assessment Scale (FASmod) to be rescaled to PSD units [7]. It is now not only possible to measure fibromyalgia severity but also to explore the boundaries between the categories of fibromyalgia and not fibromyalgia.

In this paper, we explore several issues regarding categorical and dimensional fibromyalgia using the PSD scale and the 2016 revisions (FM2016) to the ACR 2010 preliminary fibromyalgia diagnostic criteria (FM2010), in a 33,972-patient dataset, [8,9], updating a previous report on 2,732 patients with rheumatoid arthritis (RA) that utilized FM2011 criteria [10]. We examine whether there is evidence that supports the dichotomization of fibromyalgia into fibromyalgia positive (FM+) and fibromyalgia negative (FM-) cases. Are associations of the PSD with diverging clinical and demographic variables linear throughout its range? Are there differences in FM+ and FM- patients ? How well can one differentiate FM+ from FM- cases? How different is fibromyalgia from functional disorders? We consider the implications of our findings with respect to the meaning and usefulness of fibromyalgia diagnosis and categorization and suggest methods to better describe and categorize fibromyalgia.

Methods

Patients

We studied a 100% sample of 33,972 patients who were referred by community rheumatologists to the National Data Bank for Rheumatic Diseases (NDB), a research data bank with a diagnosis of rheumatoid arthritis (RA), fibromyalgia, or other noninflammatory musculoskeletal and rheumatic disorders (NIMRD [9]. Participants complete a detailed questionnaire on a semiannual basis that assesses status in the previous 6 months. In this report, the confirmed referring physician diagnosis was RA in 25,536 (75.2%), of whom 5,893 (23.1%) satisfied fibromyalgia 2016 criteria; fibromyalgia in 3,510 (10.3%), of whom 2,116 (60.3%) satisfied 2016 fibromyalgia criteria; and NIMRD in 4,926 (14.5%), of whom 935 (18.9%) satisfied fibromyalgia 2016 criteria [8]. The advantages and limitations of using RA subjects has been discussed elsewhere [11]. The first observation in the data bank occurred on 1/1/1999 and the last observation was on 12/10/2014. Where patients had more than 1 observation in the databank, we selected a single observation for study using a random number generator.

Variables

Except for enrollment diagnosis, all variables in the NDB are self-reported. The primary study variables include criteria: FM2016, the 2016 modifications of the 2010 ACR preliminary diagnostic criteria variables for fibromyalgia [8]. FM2011, the 2011 modification is described for comparison only [2]. FM 2016 and FM 2011 are "ACR--related," criteria because they are modifications of the FM2010 criteria but are not ACR endorsed criteria. The ACR made a decision to no longer endorse diagnostic criteria in 2015 [12].

Fibromyalgia related variables include the 4 component variables of the 2016 criteria: the widespread pain index (WPI), the symptom severity scale (ACR SSS or SSS), widespread or generalized pain (0-1), and the polysymptomatic distress (PSD) scale. The WPI (0-19) is a summary count of the number of painful regions from the Regional Pain Scale, a self-reported list of painful regions [13]. The symptom severity scale (0-12) is the sum of the severity scores of 3 (0-3) symptoms (fatigue, waking unrefreshed, and cognitive symptoms) (0–9) plus the sum (0–3) of the number of the following symptoms the patient has been bothered by that occurred during the previous 6 months: (1) headaches (0–1), (2) pain or cramps in lower abdomen (0–1) and (3) depression (0–1). The polysymptomatic distress (PSD) score is the sum of the WPI and SSS of FM 2011 and FM 2016. The PSD scale measures the magnitude and severity of FM symptoms in those satisfying and not satisfying criteria. By definition, FM criteria cannot be satisfied if the PSD is <12. A patient satisfies modified 2016 fibromyalgia criteria if the following 3 conditions are met: (1) WPI ≥ 7 and SSS score ≥ 5 OR WPI of 4–6 and SSS score >9; (2) generalized pain, defined as pain in at least 4 of 5 regions, must be present. Jaw, chest, and abdominal pain are not included in generalized pain definition. (3) Symptoms have been generally present for at least 3 months [8]. PSD severity has also been categorized as none (0-3) none, mild or slight (4-7), moderate (8-11), severe (12-19) and very severe (20-31) [10]. In this study, we categorize the PSD differently, as group and values in Table 1: 1 (0-1), 2 (2-7), 3 (8-11), 4 (12-19), 5 (20-31). We do this to be able to study patients with very low PSD scores (0-1) who might approximate "healthy controls" (0-1). We chose 0-1 because their health-related quality of life score (HRQOL) on the EuroQol-5 (EQ-5D) was 0.91, the mean value found in those with "very good general health [14]." The EQ-5D is also a variable in this study [15].

Study data

This description was modified from a previous report [16]. Fibromyalgia criteria variables in this study that had missing data were FM 2011 and FM 2016 criteria. This occurred because the 2011 criteria utilized the SSS and WPI, and SSS was not defined in criteria until 2011, though available in the NDB in 2009. To calculate FM 2011 and FM 2016 criteria for observations prior to 2009, it was necessary to estimate a predicted SSS from variables similar to SSS variables available in the NDB databank prior to 2009, and then combine that with WPI. We did this using the following non-missing variables in a regression analysis to predict SSS: VAS (visual analog scale) fatigue, VAS sleep disturbance, count of self-reported symptoms, presence or absence of memory problems, age, and sex. From the predicted SSS, we calculated predicted values for FM 2011 and FM 2016 by substituting the predicted value of SSS for the missing value. Analysis of agreement between FM 2016 and predicted FM 2016 resulted in 91.6% agreement and a kappa score of 0.827, indicating almost perfect agreement [17]. Based on these analyses we combined the 9,928 full data for NDB enrollees after 2009 with the 24,044 partially predicted data for enrollees from 1999 through 2009. Missing data in other study non-criteria variables were few, generally less than 2.5%. In instances when participants had more than one observation in the databank, we substituted the first non-missing value for the missing value. As missing data were few, we used simple methods of imputing data, including nearest neighbor matching or mean substitution by sex.

Other variables

We used the generic Patient Health Questionnaire 15 (PHQ-15) to determine somatic symptom severity and to provide a cut-off for a somatization disorder [18]. A level of PHQ-15 ≥ 10 was found to be the optimum level to predict the diagnosis of a "somatoform disorder" in primary care, with a sensitivity of 80.2% and specificity of 58.5% [19]. We used this PHQ-15 level to estimate the probable presence of a somatic syndrome disorder and confirmed this cut-off with the Youden

Table 1
Selected clinical and demographic variables according to PSD grouping (N=33,972).

	PSD 0-1 FM-	PSD 2-7 FM-	PSD 8-11 FM-	PSD 12-19 FM+	PSD 20-31 FM+	PSD 12-31 FM+
Group	1	2	3	4	5	4 & 5
Description of severity	Normal	Slight	Moderate	High	Very high	
Number of subjects	1,900	11,895	6,964	4,113	4,830	8943
Percent in category (%)	5.6	35.0	20.5	12.1	14.2	26.3
VAS Pain (0-10)	0.9 (1.5)	2.6 (2.2)	4.2 (2.4)	5.9 (2.2)	7.0 (2.0)	6.5 (2.2)
Patient global (0-10)	1.0 (1.5)	2.6 (2.1)	3.9 (2.1)	5.2 (2.1)	6.3 (2.1)	5.8 (2.2)
HAQ (0-3)	0.3 (0.5)	0.7 (0.6)	1.1 (0.6)	1.45 (0.6)	1.6 (0.6)	1.6 (0.6)
PAS-II (0-10) [N=21,584]	1.0 (1.1)	2.5 (1.6)	3.8 (1.8)	5.2 (1.6)	6.2 (1.6)	5.7 (1.7)
PHQ-4 (0-12) [N=2,376]	0.3 (9.9)	1.0 (1.8)	2.3 (2.5)	3.6 (3.1)	5.2 (3.7)	4.5 (3.5)
EQ-5D (1-0)	0.91 (0.1)	0.80 (0.1)	0.72 (0.1)	0.62 (0.2)	0.51 (0.2)	0.56 (0.2)
Disabled (%)	1.7	5.9	11.7	24.2	37.8	31.6
WPI (0-19)	0.1 (0.3)	2.0 (1.5)	4.0 (1.8)	9.5 (2.0)	16.1 (2.4)	13.1 (3.9)
SSS (0-12)	0.6 (0.5)	2.6 (1.4)	4.5 (1.7)	6.4 (1.5)	8.0 (1.7)	7.3 (1.8)
Region count (0-5)	0.1	1.5 (1.1)	3.0 (1.5)	4.7 (0.5)	5.0 (0.2)	4.8 (0.4)
NonpNons (0-25)	1.2 (1.4)	2.9 (2.3)	4.8 (3.1)	7.2 (3.6)	10.1 (4.5)	8.8 (4.4)
PHQ-15 (0-28) [N=1,418]	3.1 (1.9)	5.6 (3.1)	8.9 (3.1)	12.2 (3.5)	15.2 (4.7)	13.8 (4.4)
SSS-8 (0-32) [N=1,789]	2.6 (2.3)	6.8 (3.8)	11.2 (4.1)	15.4 (4.6)	18.8 (5.2)	17.2 (5.2)
Opioid use (%)	6.6	16.3	28.2	45.2	52.7	49.2
Psychological (ever) %	13.0	26.5	41.3	57.7	71.6	65.2
BMI	26.4 (5.1)	27.4 (6.1)	28.5 (6.8)	30.1 (7.7)	30.9 (6.9)	30.5 (7.9)
Age (Years)	63.5 (12.9)	62.6 (13.3)	61.0 (13.2)	59.2 (13.0)	55.3 (13.4)	57.1 (13.1)
Sex (% male)	31.7	24.2	17.8	14.1	12.4	13.2
College graduate (%)	38.3	35.7	31.0	27.9	22.5	25.0
RA (%)	84.1	80.5	77.1	70.9	61.6	65.9

Values are mean (SD) unless otherwise noted. PSD=Polysymptomatic distress; VAS=visual analog scale; HAQ=Health assessment questionnaire disability index; PAS-II=Patient activity score-II; WPI=Widespread pain index; SSS=Symptom severity score; PHQ-4=Patient health questionnaire-4 anxiety and depression scale; EQ-5D=EuroQol EQ-5D; NonpNons=Non pain non fibromyalgia symptoms scale; PHQ-15=PHQ-15 Somatic symptom scale; SSS-8=Somatic symptom scale-8; BMI=body mass index; RA=Rheumatoid arthritis. Psychological=Depression, mental illness, alcohol or drug abuse; EQ-5D group 1 represents population estimate of "very good health [14].

index for FM 2016 [20].

The Somatic Symptom Scale 8 (SSS-8) is the short form of the PHQ-15 and comprises 8 items (stomach or bowel problems; back pain; pain in the arms, legs, or joints; headaches; chest pain or shortness of breath; dizziness; feeling tired or having low energy; trouble sleeping), with each symptom scored from 0 ("not bothered at all") to 4 ("bothered very strongly") within the last 7 days [21]. The SSS-8 is considered to be a measure of somatic symptom burden and a high score is ≥12 [21]. We used a cut point of 12 to indicate a positive case.

Other study variables

Functional disability was measured using the Health Assessment Question-Disability Index (HAQ) [22, 23]. Pain severity and patient global was measured by visual analog scores (VAS), and quality of life was measured using the EQ-5D [24]. The PAS-II is a composite disease activity measure of three variables: (pain + global + HAQ) [25].The 4-item Patient Health Questionnaire for Depression and Anxiety (PHQ-4) was used to assess psychological symptom burden. [26]. PHQ-4 scores of ≥6 and ≥9 represent moderate and strong evidence for the presence of a depressive or an anxiety disorder [27]. The non-fibromyalgia symptoms and pain scale (NonpNons) is a 26-item scale consisting of symptoms reported by patients as bothersome in the last six months [28]. It was derived from the NDB semi-annual survey questionnaire. Its component (yes/no) variables include only variables that were not related to musculoskeletal or widespread pain, pain severity or fibromyalgia characteristics: alopecia, anorexia, anxiety, asthma, bruising, constipation, diarrhea, dizziness, dry eyes, dry mouth, dyspnea, fever, hearing problem, nausea, oral ulcers, paresthesias, photo sensitivity, pruritus, rash, Raynaud's phenomena, seizures, taste, tinnitus, urticaria, vision problem and vomiting. The NonpNons scale was designed to investigate the relation of non-pain and non-fibromyalgia symptoms to fibromyalgia diagnosis and to pain extent (WPI).

Bias in referrals

Patients in this dataset were referred by rheumatologists from patients in their practice. RA and NIMRD are unbiased with respect to fibromyalgia as their selection was unrelated to fibromyalgia status or RA or NIMRD status. Unlike RA patients, for whom rheumatology care is required for advanced therapy, patients with NIMRD and fibromyalgia are mostly self-selected or selected on the basis of severity to receive rheumatology care.

Statistical analyses

Data were analyzed by Stata version 15.1[29]. We used logistic and linear regression and simple correlations to compare groups and examine associations between symptoms. The very large sample size resulted in all group differences and associations in Tables 1 and 2 being statistically significant. Therefore, we do not report p-values relating to group comparisons. To further explore and better understand

Table 2
Correlation between polysymptomatic distress scale and clinical variables.

Variable	Correlation with PSD	Correlation with PHQ15	Correlation with SSS-8
PSD component variables			
PSD	1.000	0.718	0.727
WPI	0.958	0.590	0.574
Region count	0.821	0.533	0.553
SSS	0.808	NA	0.780
Non-PSD component variables			
PHQ-15 (n=1,789)	0.718	1.000	NA
PAS-II	0.683	0.712	0.716
SSS-8 (n=1,418)	0.727	NA	1.000
NonpNons	0.656	0.656	0.650
EQ-5D	-0.628	0.628	-0.711
VAS Pain	0.621	0.646	0.657
Patient global	0.587	0.687	0.639
HAQ disability	0.532	0.481	0.593
PHQ-4	0.505	NA	0.560

PSD=Polysymptomatic distress; VAS=visual analog scale; HAQ=Health assessment questionnaire disability index; PAS-II=Patient activity score-II; WPI=Widespread pain index; SSS=Symptom severity score; PHQ-4=Patient health questionnaire-4 anxiety and depression scale; EQ-5D=EuroQol EQ-5D; NonpNons=Non pain non fibromyalgia symptoms scale; PHQ-15=PHQ-15 Somatic symptom scale; SSS-8=Somatic symptomscorer-8. NA=variable pair not available.

associations and differences between FM+ and FM- patients we used visual analyses. Graphs used Lowess regression or linear regression adjusted for age and sex, followed by Stata's margins procedure and marginsplot graph. Descriptions in the text were in accordance with STROBE guidelines for observational studies [30].

Ethics

Ethical approval for this study was obtained from the Via Christi IRB, Wichita, Kansas, USA (FWA00001005). The study was conducted in accordance with the Declaration of the World Medical Association (www.wma.net) and the Helsinki Declaration of 1975, as revised in 1983. Informed consent and permission for publication was obtained from all from study subjects.

Results and discussion

Of 33,972 study subjects, 29.8% satisfied FM 2011 criteria. For those with a diagnosis of fibromyalgia, RA, and NIMRD, the percent positive for FM2016 was 60.2%, 23.1%, and 19.0%, respectively. In Table 1, we studied patients in PSD groups using FM2016 criteria, omitting from this analysis 1,299 of 13,213 (9.8%) patients who were FM2016 negative but who had a PSD score ≥12, to provide a more easily understandable view of FM2016 positive patients and PSD groups. Fig. 1 shows the effects of this subtraction graphically. The light-colored bars represent persons whose PSD scores are ≥12, but who do not satisfy FM2016 criteria. In most instances this occurs when the PSD score is ≥12 but (1) either the WPI is <7 or the SSS is <5, or (2) the widespread pain criterion is not satisfied. Patients referred to the NDB with a diagnosis of fibromyalgia were more likely than those with RA or NIMRD to fail to satisfy FM2016 criteria when PSD ≥12 (17.0% in the fibromyalgia group and 12.1% in the RA or NIMRD group) . This indicates that more persons referred with fibromyalgia have proportionally "criteria-wrong" diagnoses compared with non-fibromyalgia referrals of RA or NIMRD. In addition, the figures indicate that the distribution of PSD scores are shifted to the right in referred FM compared with RA or NIMRD, as would be expected, but also that there is a substantial percent of referred fibromyalgia patients who do not satisfy FM2916 criteria (39.7%).

As might be expected, the PSD 0-1 group in Table 1, which was constructed to approximate healthy or normal controls used in research studies, had very low or normal scores for every clinical variable studied. The PSD 0-1 group was older and proportionately more male than the other groups, with the sex difference between groups increasing with advancing (1-5) PSD group categories.

To demonstrate that sex differences were not a result of diagnosis group interaction, we also studied RA patients separately. The differences in age and sex remained after restricting the analyses to RA only subjects: age in years 62.7 (1) vs 59.0 (4) and 56.0 (5); percent males, 32.7% (1) vs. 15.9% (4) and 15.4% (5). Furthermore, differences in clinical variables remained after adjusting for age and sex in the full dataset. For example, both adjusted and unadjusted pain scores were (1) 0.9, (2) 2.6, (3) 4.2, (4) 5.9, and (5) 7.0. While the differences in age and sex of referred patients may be explained by disease characteristics, we have shown previously that they are the result of expectation bias [31].

All clinical and demographic variable results in Table 1 became more abnormal with increasing PSD groups, indicating substantial increase in symptoms and pain. The changes from the lowest severity group were linear and large. These linear symptom changes with increasing PSD groups can be seen graphically in Figs. 2 and 3. The strength of the variable relationships can be seen in the correlation analyses of continuous PSD scores in Table 2. These correlations were large and clinically meaningful. While the strongest correlations were with fibromyalgia criteria variables, as expected, also strong associations were observed with non-FM specific somatic syndrome variables (PHQ=15 (r

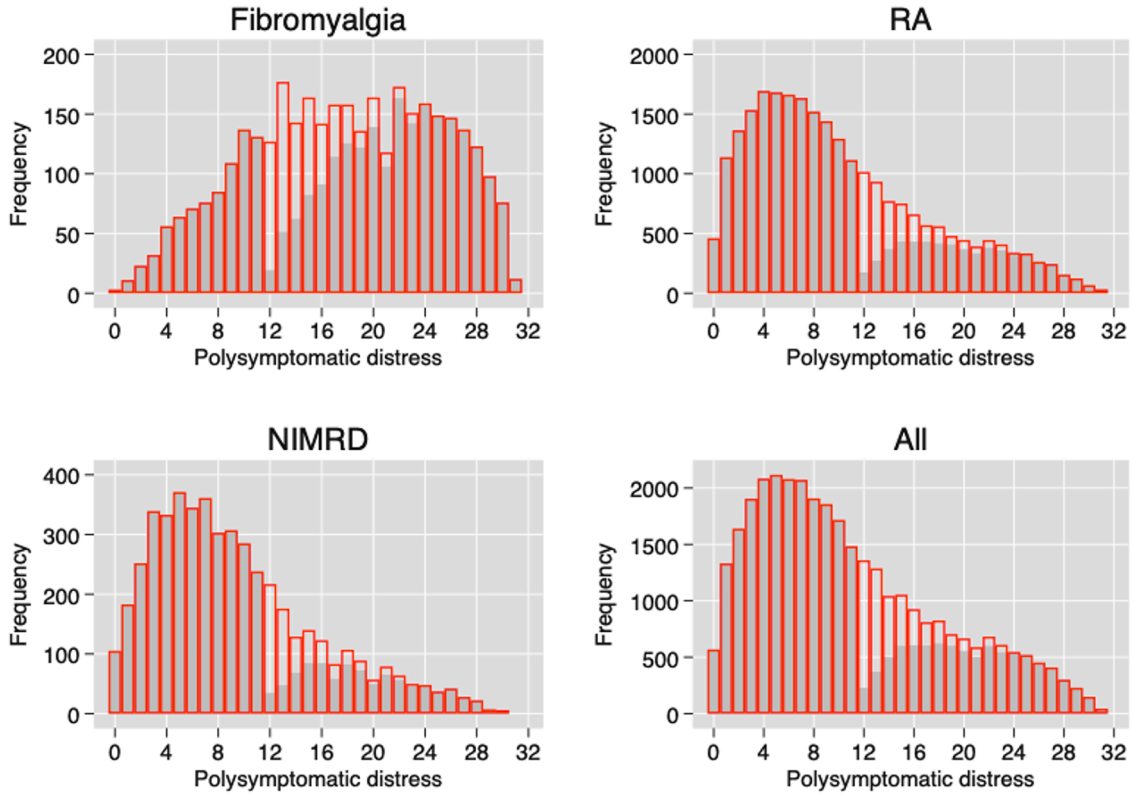

Fig. 1. Histogram of polysymptomatic distress (PSD) scores. Light bars represent patients with PSD scores ≥12 who do not satisfy FM2016 criteria. Dark bars divide patients into FM2016 negative (PSD <12) and FM2016 positive (PSD ≥12) cases. RA: rheumatoid arhritis. NIMRD: other noninflammatory musculoskeletal and rheumatic disorders.

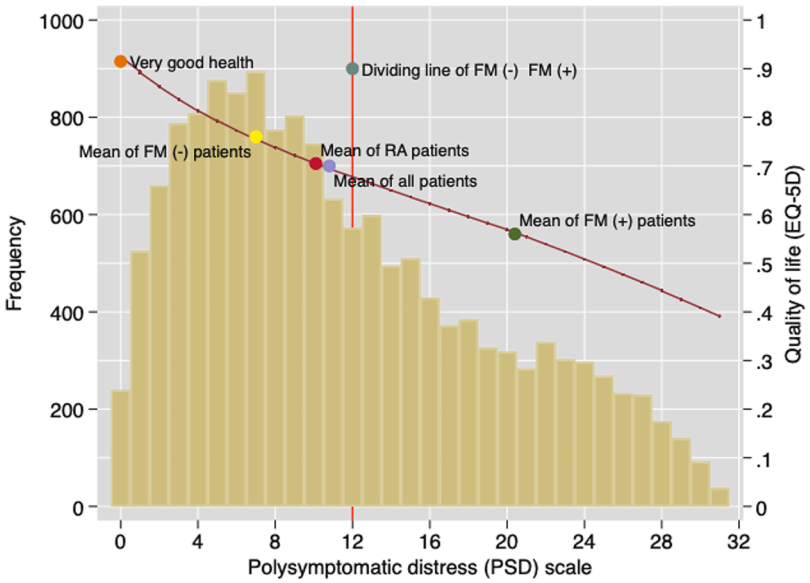

Fig. 2. Lowess regression plot of polysymptomatic distress (PSD) on EuroQol-5D (EQ-5D). "Very good health" represents the mean EQ-5D level from population data of patients indicating very good health [14]. The Red vertical line divides PSD score at 12. Dots in figure indicate locations of mean PSD scores for important clinical groups The mean PSD and EQ-5D for all patients who satisfy FM 2016 criteria is 20.4 and 0.56. The mean PSD and EQ5D for rheumatoid arthritis (RA) patients is 10.1 and 0.72. The histogram shows the distribution of PSD scores in the National Data Bank for Rheumatic Diseases (NDB) databank.

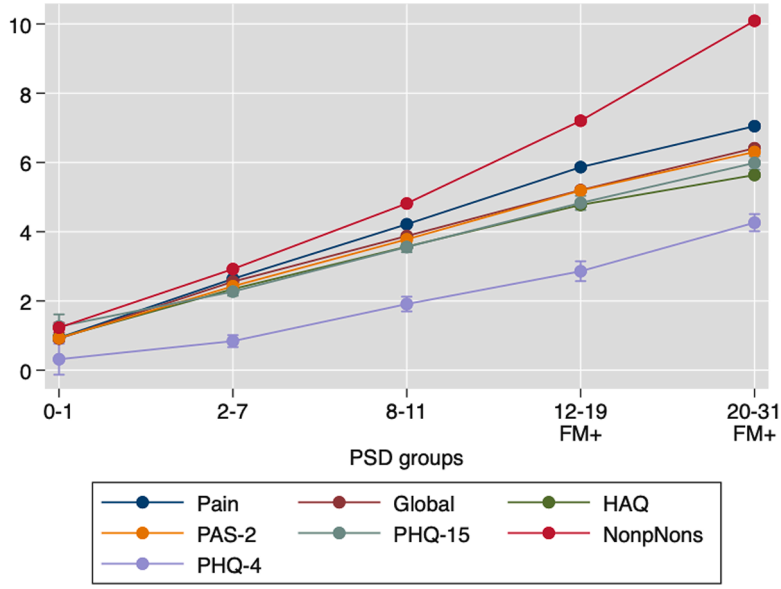

Fig. 3. Regression lines of 0-10 normalized symptom variables on polysymptomatic distress (PSD). PSD=Polysymptomatic distress; HAQ=Health assessment questionnaire disability index; PAS-II=Patient activity score-II; PHQ-4=Patient health questionnaire-4 anxiety and depression scale; EQ-5D=EuroQol EQ-5D; NonpNons=Non pain non fibromyalgia symptoms scale; PHQ-15=PHQ-15 Somatic symptom scale.

= 0.718), SSS-8 (r = 0.727), and NonpNons (r = 0.656).

To determine the effect of FM2016 status in patients with PSD ≥12, (Fig. 1, bottom right), we regressed disabled status and PAS-II on PSD levels and FM2016 status, adjusting for age and sex, restricting observations to PSD values between 12 and 19. As shown in Table 1, for patients with PSD between 12 and 19, the percent disabled was 24.2% and the mean PAS-II score was 5.2. Patients who were FM2016 positive had more severe outcomes. Compared with FM2016 negative subjects, those who were FM2016 positive had a 4.6% greater disability rate (95% CI 2.3% to 6.9%); and PAS-II scores were 0.4 (95% CI 0.3 to 0.5) higher. Thus, FM2016 positive subjects have somewhat worse outcomes compared to FM2016 negative subjects at the same PSD levels.

We next examined the extent to which patients with criteria positive fibromyalgia were different from those who were not criteria positive and had PSD scores <12, using the variables in Table 1. We compared FM- patients in Group 3 (PSD 8-11) with FM+ patients in Group 4 (PSD 12-18). These groups had been previously defined [10]. Given the large sample size, simply obtaining the difference between the groups by subtraction resulted in large, statistically significant differences in means, as expected. For example, pain: 5.9 - 4.2 = 1.7 units. Thus, the mean PSD 8-11 group was different from the PSD 12-19 group in all variables studied.

However, a different and clinically more important question is how different were the individual patients in the groups or, stated conversely, how similar were the patients in the groups. For this question, we turned to graphic analyses. Figs. 4 and 5 display many overlapping histograms bars of the PSD 8-11 non-fibromyalgia patients (Group 3 in Table 1) and the PSD 12-20 fibromyalgia positive group (Group 4 in Table 1). There is considerable overlap in SSS, NonpNons, PHQ-15, VAS pain, HAQ disability, patient global, and PAS-II scores for the two groups. The variability in scores between the two groups are also reflected in the standard deviations of the variables in the 2 groups.

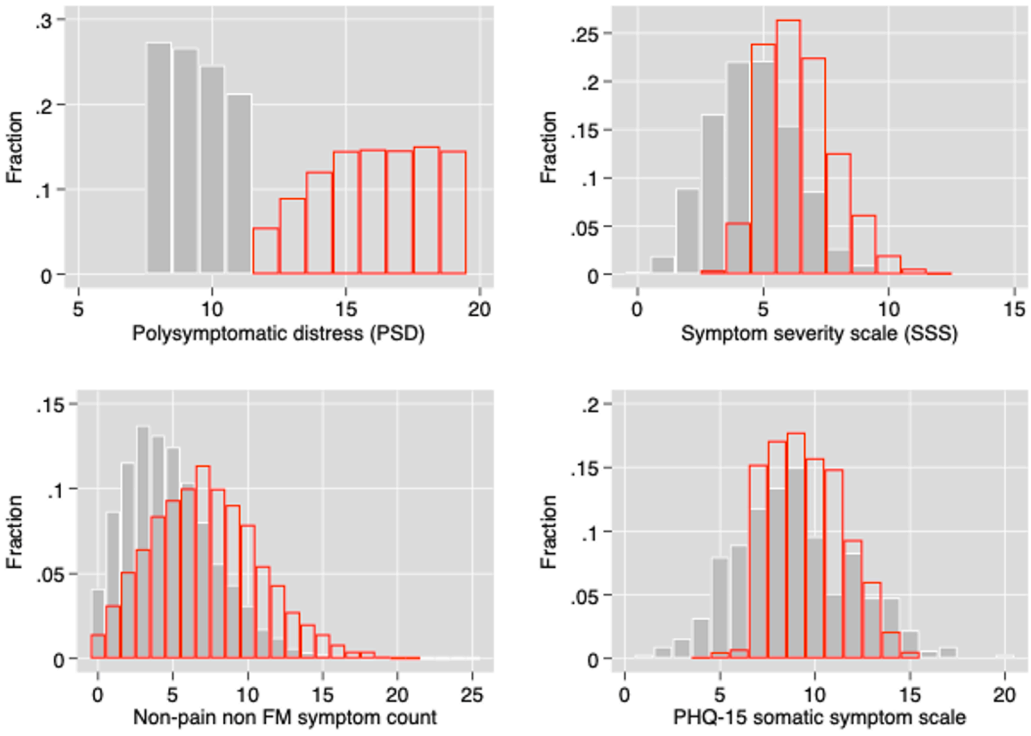

Fig. 4. Overlapping histograms of patients with PSD scores of 12-19 who are fibromyalgia positive (red bars) and those whose PSD scores are between 8-11 and fibromyalgia negative (gray bars). The dark grey represents overlapping bins for the patients in the two groups. The subjects are separated completely by the PSD categorization (upper left) but overlap considerably for symptom severity scale (SSS) (upper right), non-pain-non-fibromyalgia symptom count, and PHQ-15 somatic symptom scale.

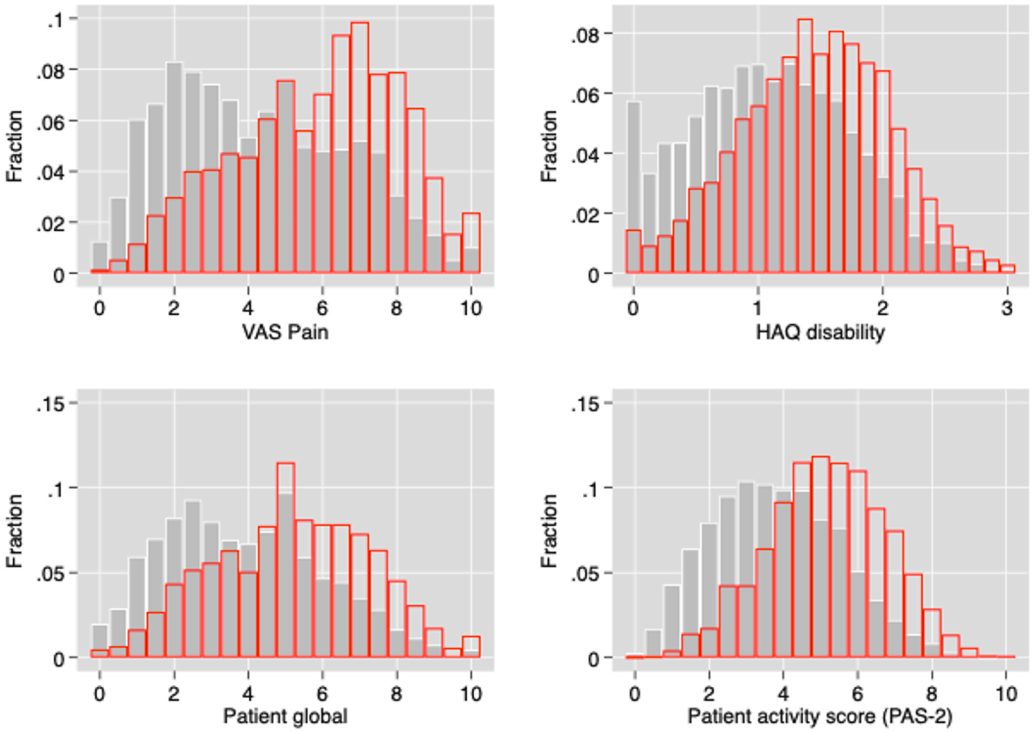

Fig. 5. Overlapping histograms of patients with PSD scores of 12-19 who are fibromyalgia positive (red bars) and those whose PSD scores are between 8-11 and fibromyalgia negative (gray bars). The dark grey represents overlapping bins for the patients in the two groups. There is substantial overlap between the two groups for VAS Pain (upper left), HAQ disability (upper right), patient global (lower left), and patient activity score (PAS-2) (lower right).

To explore if patients with fibromyalgia had clusters of extreme SSS or WPI scores, we graphed SSS against WPI in Fig. 6. Patients with fibromyalgia had linear, gradually increasing scores, and no evidence of extreme values. Rather, the values flowed symmetrically along the Lowess regression line of the total sample of patients.

To understand the extent to which the PSD differed from somatic symptoms as measured by both non-FM specific and FM-specific questionnaires, we plotted the SSS-8, the PHQ-15, and the FM2016 SSS scores against the PSD score in Fig. 7. We found remarkable similarity among each symptom score and PSD, beyond the expected association with SSS (a component of the PSD). This visually documents the correlations with PSD scores in Table 2: PSD-SSS-8 (r = 0.727), PSD-PHQ15

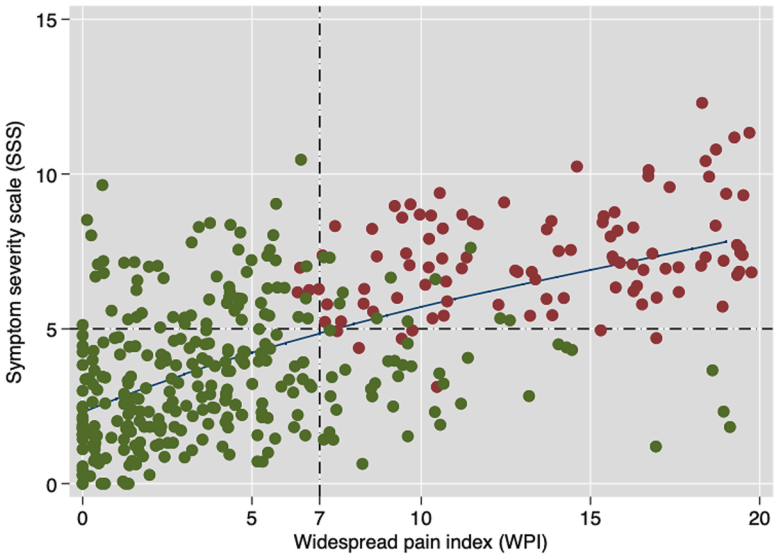

Fig. 6. plots SSS against WPI and shows FM2016 positive patients (red dots) and FM2016 negative patients (green dots). The vertical line at 7 represents the WPI minimum value allowed for FM2016 positive patients and the horizontal line at 5 represents the minimum SSS value for FM2016 diagnosis. There is no evidence of a pattern of extreme values of SSS or WPI. Rather, the dots follow appropriatelty the regression line. The regression line uses the entire 33,972 person dataset. The dots are a 400 person random sample chosen so that visability would be enhanced. A small amount of random noise has been added to increase visablility.

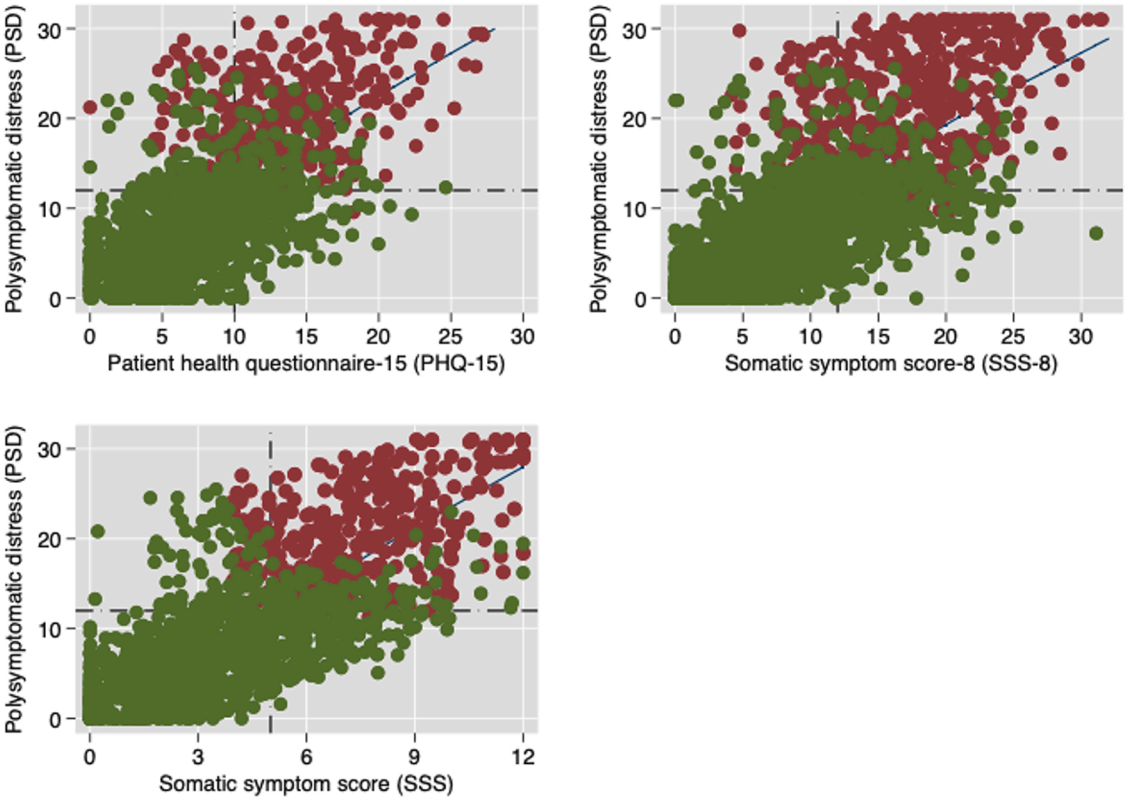

Fig. 7. plots PHQ-15, SSS-8, and SSS somatic symptom indices again PSD. Correlations with PSD are 0.718, 0.727, and 0.808, respectively. Red dots are FM2016 positive cases, green dots are FM2016 negative cases.

(r = 0.718), and PSD-SSS (r = 0.808). Furthermore, the area under the curve (AUC) of the receiver operating curve (ROC) for the diagnosis of FM2016 was similarly high for both SSS and non-FM specific symptoms, 0.861 for the SSS-8, 0.862 for the PHQ-15, and 0.907 for the SSS.

In addition, we examined levels of non-fibromyalgia and non-pain symptoms (NonpNons) in the histograms of Fig. 8. We investigated whether certain levels of symptom scores were strongly associated with fibromyalgia diagnosis by examining the histograms of the NonpNons variable score. As shown in Fig. 8, FM2016 positive patients had much higher mean NonpNons scores (8.8, SD 4.3 vs. 3.9, SD 3.3). Two levels of NonpNons scores, 10 and 15, were studied further. A NonpNons score ≥10 had a sensitivity, specificity and percent correct for the diagnosis of FM2016 of 40.3%, 94.2,%, and 80.0%, respectively. At a level of 15, sensitivity, specificity and percent correct was 10.6%, 99.3%, and 75.9%. 32.0% of FM2016 positive patients had scores >=10 and 7.5% had scores ≥15. These data indicate that very high levels of NonpNons (≥15) are virtually diagnostic of FM2016, with a specificity of 99.3% for ≥15, and that few patients had such scores—only 7.5% of FM2016 positive patients.

Overall, we could find no cut point or mixture of pain and symptoms

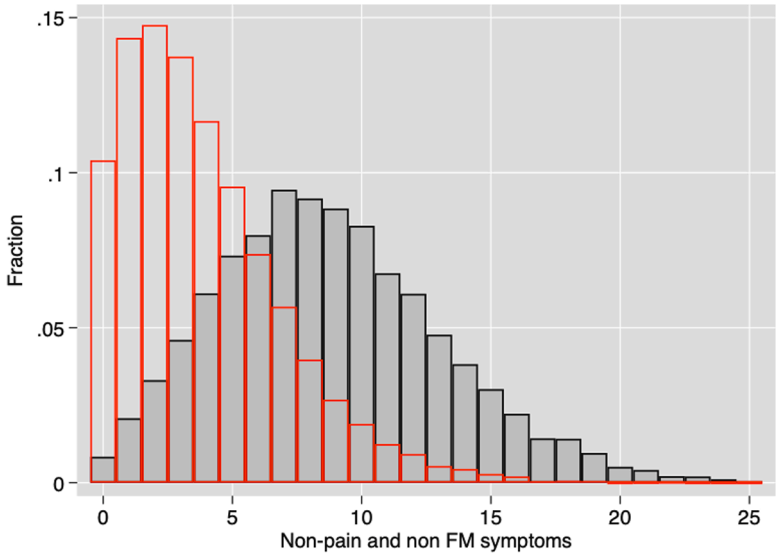

Fig. 8. Histograms of non-pain non-fibromyalgia symptom scale (NonpNons). Red bars represent FM2016 negative subjects; Gray bars represent FM2016 positive subjects.

that would clearly distinguish fibromyalgia from non-fibromyalgia (Table 1 and Figs. 2, 3, and 5), and no "generalized hyperresponsiveness" (Figs. 6 and 7) [4]. Every variable examined had a straight-line relationship with PSD—the measure of fibromyalgia severity, "fibromyalgianess," polysymptomatic distress, or fibromyalgia continuum. The greater the number of painful areas and non-pain symptoms, the greater the PSD score, the more patients are physically and mentally affected, the lower their quality of life, and the more they are disabled.

Fibromyalgia, as we now understand it, arose in mid-20th century North America, although its roots were European and from the 19th century. In the post-2nd world war period, its definition allowed the diagnosis to be applied to those with regional pain, and there was little to no talk of tender points. One thing that has always been present, however, was a sense of inexplicability—that the pain and associated symptoms were unusual and unexpected. Hadler called it "medically inexplicable insufferable physical symptomatology [32]." Brummett and Clauw spoke of "multifocal pain that cannot be fully explained based on damage or inflammation," "diffuse tenderness," a "generalized hyperresponsiveness [that] often challenges clinicians to doubt the veracity of an FM patient's complaints," and "a pan positive review of systems [4]." Others saw the fibromyalgia physical signs, including a "jump sign" [33], to be part of "psychogenic rheumatism [34]. A physician examining a patient with fibromyalgia in that period often observed these recognizable but surprising findings. In our examination of NonpNons scores, we found that very high scores (NonpNons >15) were virtually diagnostic of fibromyalgia, but that very few patients had such scores—only 7.5% of FM2016 positive patients. It seems possible that the inexplicability that various authors spoke of really represents a very small set of patients at the end of the spectrum who had severely abnormal scores.

What followed chronologically were attempts to translate painful symptoms and clinician beliefs into acceptable diagnostic criteria that separated the ordinary patient from the one with fibromyalgia.

Over almost 5 decades, authors and committees put forth sets of criteria that considered various mixtures of tender points, measurements of the extent and number of painful areas, and sets of non-pain symptoms [8,35-39]. The ACR-related 2010 through 2016 criteria defined fibromyalgia in terms of the extent of pain and non-pain symptoms [2,8,38]. The derivation of the PSD scale from criteria elements allowed fibromyalgia severity to be measured and understood using a simple, easy-to-understand measure.

The 2010-2016 criteria and PSD scale, because they did not require a physical examination, resulted in a vast expansion in clinical investigations, including those relating to pathogenesis, prevalence, and diagnosis [40]. However, no set of criteria incorporated a sense of inexplicability [2,36-38,41]. In the decade that followed the introduction of the PSD scale, study after study, however, showed that most patients who reported a physician diagnosis of fibromyalgia did not satisfy fibromyalgia criteria—either because their clinical status had improved, or they were incorrectly diagnosed [42–44]. In primary care practice, fibromyalgia gestalt diagnosis rather than criteria-based diagnosis appeared to be the norm [31,43].

In addition to diagnostic uncertainty relating to severity and varying concepts of the nature of fibromyalgia, all research and clinical criteria foundered when it came to classifying fibromyalgia as to when it began or ended, or when patients went into and out of remission. There are a least two reasons for the apparent misdiagnosis: 1) patients are diagnosed without appropriate reference to criteria—even among experts, and 2) the criteria are inadequate to accurately capture the variable and varying spectrum of clinical symptoms and distress than might be noted in a clinical encounter [45].

We believe the data of this study provide evidence that fibromyalgia is primarily a dimensional disorder, and that categorical fibromyalgia represents a convenient dividing point on a continuum of physical and psychosocial distress that is defined for clinical and heuristic purposes. As Figs. 2 and 3 and Table 1 illustrate, there is no obvious data-based dividing point to separate cases and non-cases. A corollary situation exists with blood pressure, a dimensional disorder, for which experts changed the definitional cut points of hypertension several times, reflecting changing beliefs [46]. But blood pressure classification had several advantages compared to fibromyalgia: measurement was accurate, the assessment variable (blood pressure) was not subjective and not a symptom, and outcome data were available to guide decision making. None of this is available for fibromyalgia diagnosis. The problem of where fibromyalgia begins and ends, and the difficulty of quantifying fibromyalgia symptoms is in part responsible for the high rates of diagnostic disagreement. Kendell in his review of similar disorders concludes that "the boundary between normality and disorder has to be decided arbitrarily on pragmatic grounds [47]." And it appears that fibromyalgia criteria authors and committees made such decisions.

We found evidence that well-validated generic functional status questionnaires SSS-8 and PHQ-15, were strongly correlated with FM-specific PSD and SSS scores. ROC analyses showed AUC values for

FM2016 diagnosis close to 0.90 for all symptom scores: SSS-8 0.861, PHQ15 0.862, and SSS 0.907. It is striking that the SSS AUC value is only slightly higher than for the SSS-8 and PHQ-15. This shows the substantial commonality between fibromyalgia and somatic symptom disorders. It is often written that fibromyalgia shares diagnoses with other functional status disorders. But it could also be interpreted otherwise, that the disorders are approximately the same, but are named differently [48,49]. A key difference between fibromyalgia and PSD and functional status disorders can be found in the questionnaire rather than the disorder, for SSS-8 and PHQ-15, and similar questionnaires, simply do not enquire about the extensiveness of pain.

Proposed fibromyalgia mechanism and causes are numerous. Brummett and Clauw used the term "centralized pain" to characterize observed and proposed mechanisms of fibromyalgia [4]. "Nociplastic pain" has been used to "identify individuals in whom there is pain and hypersensitivity in regions with apparently normal tissues and without any signs of neuropathy [50], and the term has been applied generally to the fibromyalgia concept. Recent research implicates non-inflammatory antibodies [51], and research about generalized sensory sensitivity links fibromyalgia to other pain disorders and to somatic syndromes [52–54].

An important corollary of the pain and symptom continuum of fibromyalgia is that it is not just an important latent variable in fibromyalgia positive patients [4]. Instead, it is present over the full length of the continuum, from those with barely discernable symptoms (PSD=1) to those with the worst possible fibromyalgia symptoms (PSD=31). The increase in both pain and symptoms of the continuum appears to be present in some degree in almost all patients, not just in those with fibromyalgia, but at different levels, and is, perhaps, a common human mechanism. The full nature of pain in fibromyalgia, however, remains unsettled [50,55,56].

With respect to the PSD continuum of fibromyalgianess, our data provides reasons for not comparing categorical fibromyalgia patients to "healthy controls." Persons with categorical fibromyalgia have so many severe distressing symptoms and medical and social problems, that it is virtually certain that they will differ significantly from persons without symptoms for almost every factor studied (Table 1). To better understand the nature of what is called fibromyalgia and the role of the CNS, one needs to look to the entire continuum of fibromyalgia, not just those who are criteria positive. Centralized and/or nociplastic pain are easy appellations to apply, signaling "science" above symptoms. But there is a need for considerable caution. Writing of nociplastic pain, Cohen writes that it "… may turn out to be 'caused' by central sensitisation of nociception (from a 'bottom-up' point of view) but may equally be "caused" by hypervigilance (from a 'top-down' point of view) [55]." At this time, it is more useful to examine the fibromyalgia symptom continuum than categorical fibromyalgia to understand the extent to which such pain mechanisms might explain what is happening.

Without questionnaire assessment, the diagnostic line between FM+ and FM- is unclear in the best of circumstances. Even when using the PSD scale and fibromyalgia criteria, we found substantial overlap of PSD 8-11 and PSD 12+ subjects in very important clinical symptoms, like functional disability (HAQ), pain, non-pain symptom quantity and severity, and psychological status (Figs. 4 and 5). The differences in PSD scores around the diagnostic boundary did not necessarily reflect important clinical differences for many patients, even though the mean differences in grouped PSD scores were easily recognizable. The amount of pain an individual has, for example, is more important than the PSD score and the category one fits in to.

In the end we need to know what to do about fibromyalgia as a diagnosis, for once a diagnostic concept has come into general use, as fibromyalgia has, it tends to become reified [47], and it is often the case that "diagnosis is prognosis [57]." Although it is sometimes acknowledged that fibromyalgia can be understood as either a categorical or a dimensional concept [4], in practice and in almost all research, only the categorical concept is used. Facing patients who are FM2016 negative but symptomatic, a few authors suggest the term "subsyndromal fibromyalgia [4]" to characterize patients with apparent fibromyalgia-like features but PSD scores <12. The subsyndromal concept, however, can lead to circumstances where patients who do not satisfy criteria are designated to have the disorder by implication. Fibromyalgia experts may also explain diagnosis by saying, "The diagnostic gold standard for fibromyalgia will continue to be the rheumatologist's expert opinion … [which is] the only way to capture the variability and severity of interrelated symptoms as they play out over time [45]." But rheumatologists are also uncertain about diagnosis [58–60], most diagnoses are made by primary care physicians, and there is no evidence to support or to contradict the validity of continued, updated diagnoses by specialists.

One solution to the problem of fibromyalgia diagnosis in the community is to simplify by recalling the message of the 2016 criteria revision: "The [criteria] requirement for generalized pain (pain in 4 of 5 regions) provides an efficient screening tool. If fibromyalgia is considered a reasonable possibility, diagnostic criteria may then be applied." In the current analyses, pain in 4 or 5 regions identified 64% of FM2016 cases; and if fatigue or sleep problems are present at a moderate level, the probability of FM2016 increases to 83%. To put these data into perspective, in a study of consecutive primary care patients who reported a diagnosis of fibromyalgia, only 32.2% met FM2016 criteria [43].

Fibromyalgia and the meaning of fibromyalgia diagnosis is a serious problem in medical research and in medicolegal situations where diagnostic accuracy is required. Here we may draw some conclusions from the data of this study and published research, keeping in mind Kendall's comments that "discrete disease entities and dimensions of continuous variation are not mutually exclusive means of conceptualizing [disorders] and "both are compatible with a threshold model of disease [47]." In the hands of experienced or interested physicians, including rheumatology and pain specialists, categorical diagnosis is expected and desirable, but it should be accompanied by a quantitative severity measure such as PSD. Not only does that allow quantitative assessment of the patient's status, but it makes documentary sense when a diagnosed patient's clinical status changes. The fibromyalgia literature is filled with patients who never had fibromyalgia or who may have had it sometime in the past.

In summary, fibromyalgia is more accurately considered a dimensional than a dichotomous disorder. The PSD scale is a measure of the fibromyalgia continuum, varying linearly and directly with clinical variables over its entire range. The greater the number of painful areas and non-pain symptoms, the greater the PSD score, the more patients are physically and mentally affected, the lower their quality of life, and the more they are disabled. While many consider fibromyalgia a primary pain disorder, its symptoms can just as easily be explained by a somatic syndrome designation. If fibromyalgia is driven by centralized pain, as many hypothesize, it is clear that centralization is active on both sides of the diagnostic divide. Clinical diagnosis is biased, variable and inaccurate, but would be dramatically enlightened by the use of a severity measure, such as the PSD scale.

Declaration of Competing Interest

No financial support or conflict of interest

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