Validation of the revised Symptom Impact Questionnaire with a proposed fibromyalgia phenotype using experimentally-induced pain and patient self-reports

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[†]*In recognition of his distinguished scientific contribution and his compassionate care of rheumatology patients, we dedicate this article to the memory of our co-author, Dr Robert M. Bennett who conceived this study and passed away on May 22, 2020.*

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ABSTRACT

Objective. *The Symptom Impact Questionnaire (SIQR), now used for over a decade, has strong psychometric properties based on patients' subjective questionnaire data and correlations with other general measures of severity. However, the construct validity of the SIQR in assessing the central features of fibromyalgia (FM) has not been tested specifically with more objective measures. This study examined the construct validity of the SIQR using clinical examination of prominent features of FM, as well as patient questionnaire data.*

Methods. *We determined if SIQR severity groups (low, moderate, high severity) in 158 chronic pain patients (50 FM, 108 Pain/No FM) predicted four central features of FM tenderness and pain: digital palpation tenderness, blood pressure cuff evoked pain, widespread pain locations, and a persistent deep ache question.*

Results. *Low, moderate, and high SIQR severity groups showed concomitant increases in tenderness in response to digital evoked palpation ($F=23.5$; $p<0.0000$; $\eta_p^2=0.23$; MR=.54), blood pressure cuff evoked pain ($F=17.0$; $p<0.0000$; $\eta_p^2=0.18$; MR=0.48) and number of pain location ($F=38.8$; $p<0.0000$; $\eta_p^2=0.33$; MR.59). Strongest differences in SIQR severity were found in response to the question, "I have a persistent deep aching over most of my body" ($F=87.5$; $p<0.0000$; $\eta_p^2=0.53$; MR=0.74).*

Conclusion. *The SIQR strongly predicts the central features of FM tenderness and pain including its widespreadness and its multifaceted character. We propose that tenderness, both locally and over most of the body, attendant to the SIQR is the hallmark of the FM phenotype: tenderness is focal, diffuse, deep, and superficial.*

Introduction

The Revised Fibromyalgia Impact Questionnaire (SIQR) (1) and its non-FM version the Symptom Impact Questionnaire (2) are updates of the original FM Impact Questionnaire (FIQ) first published in 1991. The SIQR has identical questions with the exception that the word "fibromyalgia" is replaced by "medical problems." The FIQR/SIQR can be used to assess severity in multiple pain and rheumatic disorders (2, 3). They have demonstrated excellent reliability and validity(1, 4) and they correlate strongly with other measures of severity such as the SF-36 (4). Furthermore, newly added symptoms like "tenderness to touch" and "environmental sensitivity" in the SIQR distinguish between patients with rheumatoid arthritis, systemic lupus erythematous, and major depressive disorder (2). When combined with widespread pain, the SIQR predicts FM diagnosis among patients in rheumatology and migraine pain clinics with a sensitivity of .80 and specificity of .80 (3).

Despite these strong psychometric properties and diagnostic predictions, they are based mostly on patients' subjective questionnaire responses but lack validation with experimentally induced pain. The purpose of the study was to examine the construct validity of the SIQR using clinical examination of prominent features of FM. This goal was accomplished by testing chronic pain patients with and without FM to determine if FM severity predicted several central features of FM tenderness and pain: digital palpation tenderness, blood pressure cuff evoked pain, and widespread pain locations. A further objective was to test the construct validity of a single encapsulating phenotypical question, "I have a persistent deep aching over most of my body," as an iconic representation of the tender-

ness and pain experienced by people with FM (5, 6).

Methods

Setting

Patients were recruited from a federally qualified health centre/family practice clinic and a separate internal medicine clinic, both affiliated with an academic healthcare centre (IRB# 00015219 including patients' written consent). The main aim in enrolling subjects was to obtain a sample that was representative of the diversity of patients normally seen in a primary care setting. The unpublished SIQR data for this study was taken from a previously published study (5). In the study, a total of 352 patients, mean age 50±16.3 years, 70% female, were studied. Of these, 158 patients presented with pain that included 50 patients (14.2%) who carried a chart diagnosis of FM and 108 (30.7%) with chronic pain but not FM. The third group of 192 (54.5%) who had neither pain nor FM acted as a pain-free control group to assess the baseline validity of experimentally provoked pain (5). They were not assessed for the SIQR nor for pain locations (PLI), and therefore excluded from further consideration.

Symptom Impact Questionnaire (SIQR) and pain diagnoses

A patient was determined to have a chart diagnosis of FM if a senior clinician had documented that diagnosis in the patient's records (ICD M79.1) (5). All patients completed a questionnaire that included the SIQR and the PLI (7) which assesses pain at 28 locations (axial, near axial, and peripheral). The SIQR is a 100-point scale that measures physical function, quality of life and symptom impact over the past 7 days (4). The SIQR is the FM neutral version of the FIQR questionnaire. It can be used with a broad array of chronic pain diagnoses. Scores over 45 generally identify people with FM, with a SIQR mean of 62.1 in FM patients and 41.5 in rheumatology/migraine clinics patients without FM (3). Both questionnaires are available online at www.FIQR.info (8). We divided the 158 patients into 3 equal groups which correspond to the 2009 FIQR validation study findings of low, moderate, high severity. The Pain/no FM group had one or more of the following pain or FM-related related disorders in decreasing order of prevalence: tension headaches, generalised anxiety disorder, osteoarthritis of the hip(s), migraine headache, major depressive disorder, restless leg syndrome, osteoarthritis of hand(s), osteoarthritis of the knee(s), chronic low back pain, irritable bowel syndrome, osteoarthritis of the spine, and chronic neck pain. The four measures of tenderness and pain consisted of two experimentally provoked examination tests that elicited patient responses and two patient self-reported assessments.

Experimentally provoked pain measures.

Skinfold roll/digital palpation (SRDP)

Pressure evoked allodynia or tender points have become standard in understanding FM. To shorten the screening protocol, we avoided use of the 1990 ACR defined tender points and instead assessed 5 paired pain locations and a body pain diagram (5). Skinfold roll tenderness was assessed by smooth horizontal rolling of skin between thumb and 2 fingers. Pain intensity induced by the 3 of skinfold rolls locations was recorded as yes/no. The bilateral locations were upper trapezii, brachio-radialis, anterior thighs. For digital palpation, pain was evoked by the investigator applying 4 kg/pressure over 4 seconds with the presence or absence of pain, being determined by the subject's verbal response recorded in a yes/no classification. Areas digitally palpated were the Achilles tendon and 2 joints (1st and 2nd proximal interphalangeal joints). Previously, the SRDP was shown to differentiate between the Pain/No FM and a No Pain control group, as well as the FM group (5). A Cronbach alpha of 0.87 and item-total correlations ranging from 0.52-0.63 showed good internal consistency that justified summing the scores to produce a 0-10 scale to measure the extent of sensitivity to pressure. In the current study, the correlation of SRDP with other pain measures were moderately strong: -0.53 with BP cuff-evoked pain, 0.64 with the PLI, and 0.61 with the persistent deep aching question. The SRDP experimentally induced pain is utilised here to test the construct validity of the SIQR. Examiners were trained by RB and blind to SIQR, PLI scores and chart diagnosis as these were assessed and collected after the examiner tests were completed.

Blood pressure cuff evoked pain

We sought to extend novel findings by 2 earlier investigators which have demonstrated lower pain thresholds in FM patients using BP cuff-evoked pain (9, 10). Participants were evaluated seated and using appropriately fitting BP cuffs on the arm selected by the patient. Investigators manually inflated the cuff on the upper arm of the subject a single time at a rate of ~10 mmHg per second to a maximum of 220 mmHg. Patients were asked to state the point at which the cuff pressure caused pain. The level of mmHg was then recorded at which pain was induced. If no pain was induced, an upper level of 220 mmHg was recorded. Correlation of BP cuff-evoked pain with other pain measures were -0.53 with SRDP, -0.46 with the PLI, and -0.43 with the persistent deep aching question. Previously, blood pressure cuff evoked pain was shown to differentiate between No Pain controls, Pain/No FM and FM patient groups (5).

Pain location inventory (PLI)

PLI sites included 28 anatomical: right jaw, left jaw, neck, mid-upper back, front of chest, mid-lower back, right upper back, left upper back, right lower back, left lower back, right shoulder, left shoulder, right arm, left arm, right wrist, left wrist, right hand, left hand, right hip, left hip, right thigh, left thigh, right knee, left knee, right ankle, left ankle, right foot, left foot (7). They included approximately equal number of axial, near axial and peripheral sites. Cronbach alpha of 0.92 and item-total correlations ranging from 0.33–69 showed good internal consistency. Correlations of the PLI with other pain measures were; BP cuff-evoked pain (r= -0.46), SRDP (r=0.64), and persistent deep aching question (r=0.71).

Deep aching question

"I have a persistent deep aching over most of my body" (0-10). This symptom was developed by the OHSU Fibromyalgia Research Group to reflect the pain/tenderness phenotype in FM (11). Correlations of persistent deep aching with other pain measures were moderately strong with -0.43 with BP cuff-evoked pain, 0.61 with SRDP, and 0.71 with the PLI.

In sum, the four pain measures were moderately inter-correlated but not duplicative.

Statistical methods

Multivariate analysis of covariance (MANCOVA) was conducted with 3 levels of SIQR severity (low, moderate, high) on four outcome variables (digital palpation tenderness BP pressure cuff-evoked pain, PLI, 'persistent deep aching' question), with gender as a covariate. This was followed by univariate analysis of covariance separately for each measure. Standard multiple regression was used to explore the construct validity of "persistent deep aching" as it relates to the tenderness and pain measures, and SIQR severity. Partial eta square and whole MR were used to indicate effect sizes. All significant tests and CI are .05, two-tailed. Statistica 13.3 was employed.

Results

The distribution for the SIQR for the total sample of 158 pain patients (50 FM and 108 chronic pain/no FM) was symmetrical and approximately normal, with a mean and median of 44.5 (24.6) and 47.2. The mean SIQR for FM and Pain/No FM patients were 62.4 (18.4) and 36.1 (22.7). Cronbach alpha was 0.95. One hundred and fifteen (73%) of patients were female, while 43 (27%) were male. SIQR distribution for the sample was divided without regard to diagnosis into approximate thirds consisting of low severity (n=54; range 0-29; X^{-}=16.1 (8.0), moderate severity (n=54; range 30–59; X^{-}=46.5 (8.1) and high severity (n=50; range 60-100; X^{-}=72.9 (9.2). These means approximate those reported previously (3, 8). The creation of three SIQR severity groups allows for the observation of distinct levels of pain/tenderness along the SIQR spectrum.

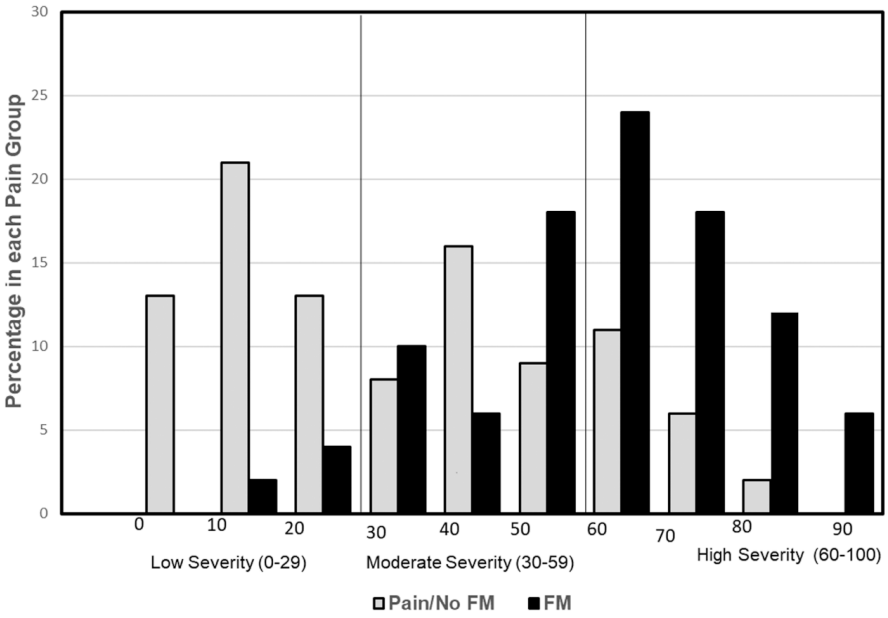

Fig. 1. SIQR (0-100) by severity category and pain group.
Distribution of FM and pain no FM subjects in low, moderate, and high severity categories. FM predominates in the high severity category and no FM pain in the low severity category.

SIQR severity categories and pain groups

Figure 1 shows the severity distribution from low to high severity for the FM group (6%; 34%, 60%) and Pain/No FM group (47%, 34%, 19%; χ^2=35.6; p<0.0000). Percentages *within* severity categories for FM and Pain No FM are for low severity (94% *vs*. 6%); moderate severity (69% *vs*. 31%) and high severity (40% *vs*. 60%). Thus, both FM and Pain No FM patients are found across the SIQR spectrum with FM patients predominating in the high severity category and the Pain/no Fm in the low severity category.

Age was unrelated to SIQR (r=0.12; p>0.13). But there was a marginally significantly (χ^2= 5.8; p=0.055) greater representation of female patients in the more severe categories (63%; 72%; 84%) and male patients in the lower severity categories (37%; 28%; 16%); gender was thus covaried in all subsequent analyses. A MANCOVA (3 levels of severity and gender covariate) on the 4 tenderness/pain outcome measures revealed strong differences between SIQR severity categories (F=18.7, p<0.0000) and a weaker one for gender (F=2.7; p<0.032). Univariate ANCOVAs were then conducted separately for each of the four pain/tenderness measures controlling for gender.

Experimentally provoked pain-tenderness measures

Figures 1a and 1b present the group means for digital palpation tenderness and BP cuff-evoked pressure pain (adjusted for gender). As shown, there were wide differences between the three severity groups. Of a possible 10 digital palpation tenderness points (0-10), the low, moderate, and high SIQR severity groups showed on average 1.8, 3.8 and 5.3 mean tender points (F=23.5; p<0.0000; η_p^2=0.23; MR=0.54). A similar, but somewhat weaker, difference was found for severity groups with blood pressure cuff-evoked pain, with the mild SIQR severity group withstanding higher blood pressure: mmHg of 182.0 for mild severity, 158. mmHg for moderate severity, and 130.1 mmHg for high severity (F=17.0; p<0.0000; η_p^2=0.18; MR=.48). On both examination tests, male pain patients reported slightly less tenderness and pain respectively (F=6.8; p<0.00; η_p^2=.04 for tenderness palpation; F=5.6; p<0.019; η_p^2 =.04 for blood pressure cuff evoked pain), but the effect sizes were small relative to those found with severity categories.

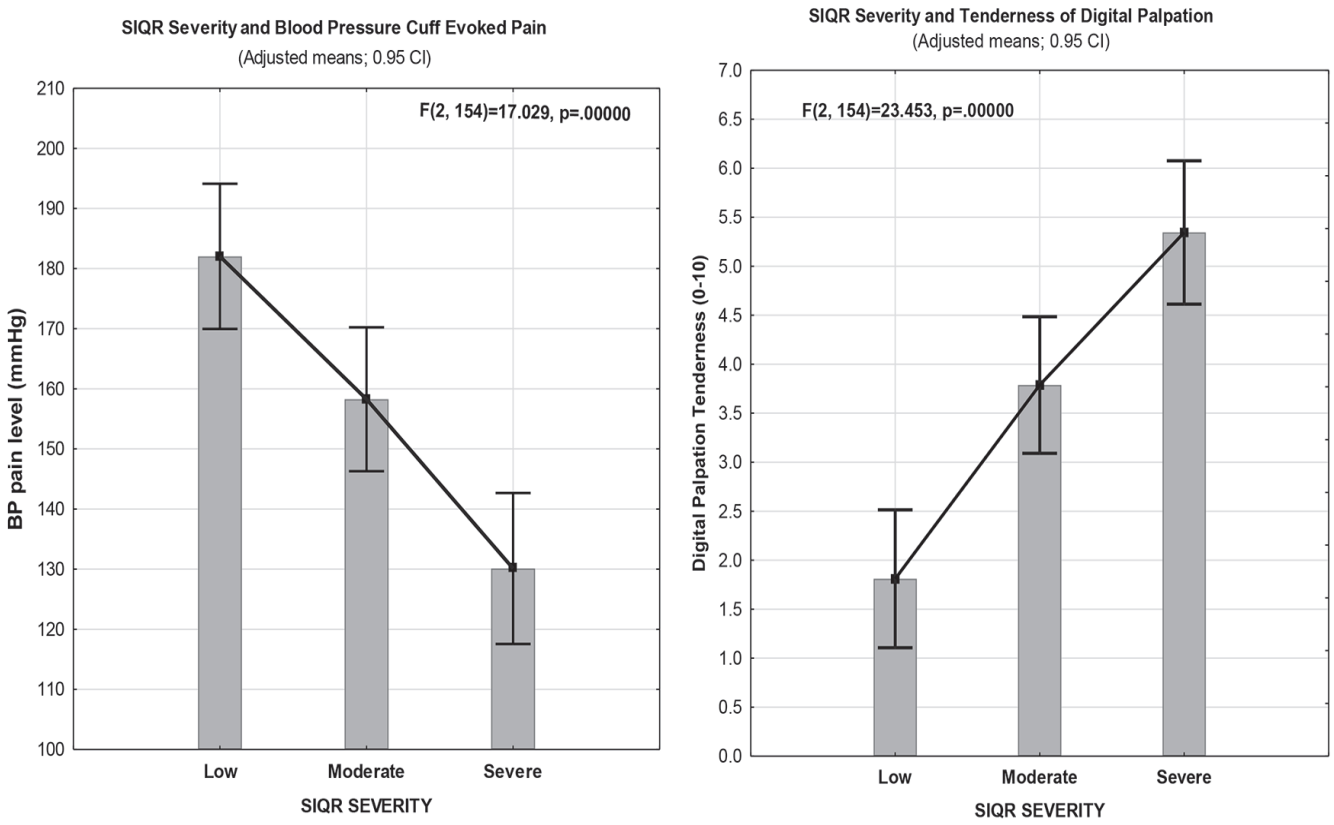

Fig. 2. Experimentally induced pain/tenderness.
Mean tenderness of digital palpation and blood pressure cuff evoked pain according to 3 SIQR severity categories.

Patient self-reported (questionnaire) data

Figures 2a and 2b present the number of pain locations, a count of 0-28 pain locations reported by patients and their response to the question "I have a persistent deep aching over most of my body". Adjusting for gender, on average the patients in each of the severity group reported 3.1, 8.1 and 12.7 pain locations respectively (F=38.8.; p<0.0000; η_p^2=.33; MR.59). Gender was marginally significant (F=3.3; p<0.07). On the persistent deep aching question (0-10), the means separating the 3 severity groups were substantial, consisting of 1.1, 4.6 and 8.0 across the 10-point scale (F=87.5; p<0.0000; η_p^2=0.53; MR=0.74). Interestingly, female and male patients did not differ in regard to persistent deep aching (F=0.04; p<0.83). The persistent deep aching question was also correlated with the SIQR "tenderness to touch" symptom (r=0.67).

Construct validity of "persistent deep aching" as a simple marker for FM and SIQR severity

We have previously reported that this question, combined with tenderness in the right Achilles, is a useful, practical screen for suspicion for FM (ROC=.85) (5). In the current study, this single "persistent deep aching" item correlated with the total SIQR, r=0.75, and SIQR Symptom subscale, r=0.78, suggesting that this one item maybe a useful question for practitioners to ask patients to estimate SIQR severity.

To further pursue the construct validity of this question we used standard multiple regression analyses to ascertain which of the current tenderness and pain measures, combined or singly, contributed to variance in "persistent deep aching". Overall, the three measures combined generated a MR=0.74 (Adj. R^2=54), with unique variance contributed by digital palpation tenderness (β=0.24; p<0.001) and pain locations (β=0.53, p<0.0001), but BP cuff-evoked pain pressure no longer was significant (β=-0.06, p=0352). The PLI subscales, axial (β=0.38, p<0.000), near axial (β=0.21, p<0.007) and peripheral (β=0.22, p<0.01) locations were all significant and unique contributors to the deep ache question providing further construct validity. Adding "tenderness to touch," (SIQR) to digital palpation and the PLI, raised the MR to 0.79, explaining 61% of the variance (tenderness to touch, β=0.35, <0001; pain location; β=0.42, <0.0001; digital palpation tenderness, β=0.15, p<0.038). Thus, all three of these pain parameters contributed *unique* variance to "persistent deep aching".

Discussion

In this study we have assessed the central features of the pain/tenderness phenotype found in FM by using four widely differing metrics measured by two different means. We experimentally provoked digital palpation tenderness and BP cuff-evoked pressure pain and assessed patient self-reported pain with a 28-pain location count and a one item "deep persistent aching" question using a VAS intensity scale. Collectively, these methodologically diverse measures assessed several features of FM pain/tenderness that were moderately intercorrelated but not du-

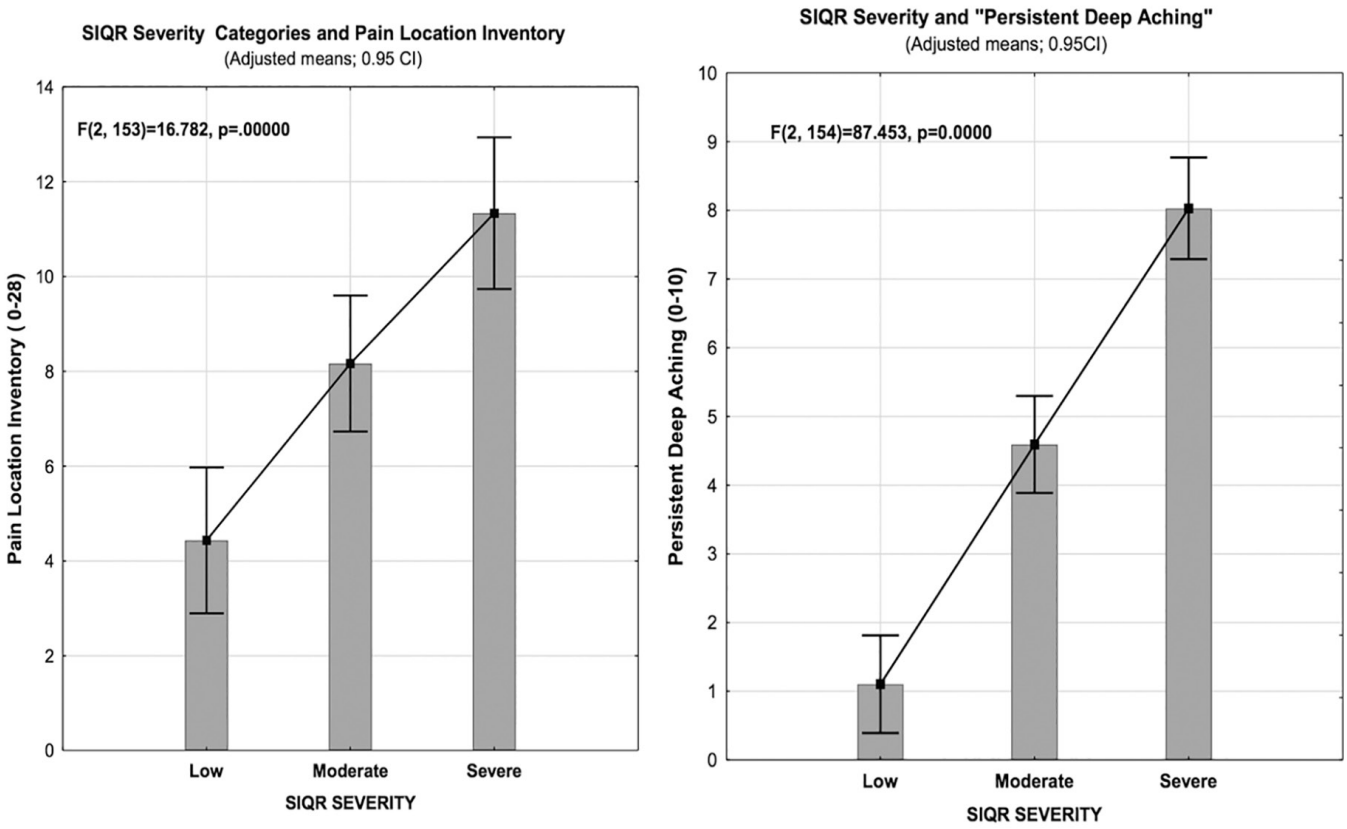

Fig. 3. Patient self-reported pain/tenderness.
Mean pain locations and "persistent deep aching" according to 3 SIQR severity categories.

plicative, providing convergent validity. On all four pain-metrics, the SIQR severity categories showed substantial linear increases in pain/tenderness, and with Pain/No FM and FM patients predominating in the low and high severity categories respectively, provided strong construct validity for the SIQR scale. These differences indicate that the pain experienced in high SIQR severity/FM patients differs from that of low SIQR severity/chronic pain patients without FM.

The increased awareness of pain in each of the two pain-provoked assessments were correlated with self-report of tenderness (0.49 and 0.57) as well as widespread pain (0.46 and 0.64) and the original 10 worded question (0.43 and .61). Taken as a whole, people with FM experience hyperalgesia at all anatomical sites. Unlike focal tenderness of myofascial pain syndrome, we suggest that people with FM have widespread tenderness whether provoked by an examiner or described in self report. We propose that tenderness, both locally and over most of the body, is the hallmark of FM: it is focal, diffuse, deep, and superficial. These data are bolstered by recent arguments that tenderness expression has been ignored in FM (12) or even suppressed in the 2010 criteria in favour of the WPI: there the single binary item "muscle tenderness" (Y/N) was found to be the strongest predictor of FM, and in fact, slightly stronger than the 19-point WPI count.

As FM pain and tenderness are associated with a variety of anatomical structures, we intentionally assessed both focal and diffuse pain in bone, tendon, muscle and skin tissue. Pain over bony prominences was evoked by gradually increasing pressure over the firsts interphalangeal joint. Similarly, Achilles tendon tenderness was assessed with a gradually increasing pinch over a tendon. Achilles tendon tenderness at the junction near the gastrocnemius represents yet another anatomical type of pain and is perhaps most similar to tender points from the 1990 ACR criteria (*e.g.* discrete areas of soft tissue that are painful to less than four kg of palpatory pressure). The blood pressure cuff-evoked pain between two fingers stimulated superficial structures of skin, fat and muscle over the radial area and upper trapezius and upper anterior thigh. Allodynia, in which non painful stimuli are perceived as painful, is ubiquitous on FM and is likely due to central sensitisation as described over the past two decades (13). Importantly, previous authors have demonstrated sphygmomanometer- evoked allodynia (9, 10) as well as skin roll tenderness (14).

The three SIQR severity groups were found to report more pain in all three PLI regions (axial, proximal and peripheral). Notably these areas included both bone and soft tissue. The PLI is more specific and comprehensive than the 19-point Widespread Pain Inventory (WPI), which explicitly excluded peripheral pain locations (15). While these multi-focal pain location counts assess the "widespreadness" of pain, they do not explicitly address whether the pain is superficial or deep, or diffused. The question, "I have a deep persistent aching over most of the body" was developed in part to correct

for this shortcoming. It captures four features of the overarching FM pain in one question: aching pain, deep pain, widespreadness of pain, and its persistence. Regarding superficial pain, it correlates with 0.67 to the SIQR item "tenderness to touch". Multiple regression found that palpation evoked tenderness (pressure sensitivity), widespread pain locations (multi-focal) and tenderness to touch (superficial pain) *all* contributed *uniquely* to the persistent deep aching question.

We suggest that this one item embodies the unique pain phenotype experienced by FM patients. Salaffi *et al*. found this same question in a Yes/No response format to be the best predictor among 54 ranked items in their screen for FM (6). Equally significant, the question was rated the most "relevant and important" by 139 expert physicians familiar with FM and experienced in the differential diagnosis of chronic multisite pain conditions. Considering the problems that physicians have in diagnosing FM, we propose that it may be the single most efficient and clear question for clinicians to ask patients when assessing for suspicion of FM (yes/no) and estimating its severity (0-10) (5, 6).

A major strength of this study is that it was conducted in 2 separate primary care practices in 2 location by 2 different clinicians of opposite genders (AS and JA). Subjects were recruited at the time of being seen for a routine follow-up evaluation; thus, they were representative of pain patients seen in primary care. It was not possible to evaluate inter-rater agreement on the examination pain probes. As noted, however, neither examiners were aware of the patient's SIQR score or PLI (nor FM diagnosis) at time of examination since the questionnaire was administered after the experimentally induced pain was completed. Methodologically, the study design also combined data generated from three different sources that included the electronic medical record, clinician examination, and patient self-reports that produced converging validity. There are a few issues in the interpretation of these results. There were only 43 males (27%) in the sample with most falling in the mild and moderate severity category. Of the FM sample only 6% were male. This is the first clinical study to examine the SIQR in relation to experimentally induced pain and tenderness and patients' self-reports. Future studies may want to employ standard laboratory-based measures of pain (*e.g*. heat, cold, electrical, pressure algometry) (21), including with patients with concurrent visceral pain disorders (22).

This study was relatively small, but the results were statistically robust. The importance of rapid recognition of FM cannot be overstated. An early and accurate diagnosis reduces subsequent medical and surgical consultations. Subspecialty consultations by their very nature are organ specific (*e.g*. urologic, gynaecologic, gastrointestinal) rather than holistic. Not surprisingly they often lead to futile diagnostic procedures that may further delay diagnosis and treatment of FM. With the absence of clinically-assessable unequivocal biological markers for the diagnosis of FM and the reservations that many practitioners still hold about FM (15-19), it is imperative to arrive at a clearly defined FM pain/tenderness phenotype that clinicians can use to distinguish the FM pain/tenderness experience from those of other chronic pain disorders. A clearly defined pain/tenderness phenotype will not only help to dispel uncertainties that physicians may have about FM, but also aid in the diagnosis and monitoring of a patients' clinical progress, as well as enhance research studies designed to improve FM outcome. In conclusion the SIQR scale, the non-FM version of the FIQR, is strongly associated with the pain/tenderness phenotype observed in FM patients.

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