

Diagnosing Fibromyalgia in Primary Care

Jonathan H. Aebischer, Amanda W. St. John, Kim D. Jones, & Robert M. Bennett

Oregon Health & Science University

Abstract

Fibromyalgia (FM) is a complex chronic widespread pain syndrome that affects the minority of the population, but can cause great disability. Diagnosis precedes appropriate management; however, many primary care providers demonstrate difficulty in confidently establishing this diagnosis, leading to sub-/specialty referrals, expensive workups, and impaired quality of life for the patient. Replacing the sole tender point examination of prior criteria, newly-proposed 2013 diagnostic criteria for FM offer a user-friendly tool with use of a patient-reported questionnaire on not only pain sites that account for chronic widespread pain in FM, but also numerous contributing somatic and psychogenic symptoms. Not entirely phasing out physical examination, simple and swift bedside tests for allodynia and widespread tenderness have also proven useful in diagnosis of FM. A consecutive volunteer sample of 357 adult patients in primary care clinics was enrolled to test these methods of diagnosis and assess their characteristics using a cross-sectional analysis method. The 2013 diagnostic criteria demonstrated excellent sensitivity to detecting those with FM and a potentially stronger specificity than in other studies, ruling out 2/3 of cases with p-values <0.0001 . Bedside tests for allodynia and widespread tenderness also offered significant results at detecting FM at p-values between <0.0001 to 0.0004 . This study demonstrates that a patient-reported questionnaire of symptoms supplemented by a quick, convenient physical examinations may expedite diagnosis of FM in primary care settings.

INTRODUCTION

Fibromyalgia (FM) is a chronic widespread pain syndrome that conservatively affects 3.4% of women and 0.5% of men in the United States (1, 2). In primary care, up to 1 in 20 patients has symptoms consistent with FM (3). Besides pain, FM is also characterized by numerous other problems including abnormal pain processing, sleep disturbances, fatigue, psychological distress, and coexisting conditions including headaches, irritable bowel syndrome, interstitial cystitis/painful bladder syndrome, chronic pelvic pain, temporomandibular pain disorder, and systemic exertion intolerance disease (4, 5).

The etiology of FM involves a combination of pathophysiologic factors, but, like other chronic illnesses, it is thought to occur in genetically predisposed individuals who experience selected triggers, which include persistent pain, stress, trauma (physical and/or emotional), autoimmune conditions, infections, endocrine disorders, or simply aging (5, 6). These triggers may put into effect an irreversible cascade of altered pain maintenance and modulation through peripheral and central nervous sensitization, which are key pathophysiological processes involved in FM (6). Given the limitations of measuring the central nature of pain outside of a research laboratory, making a definitive diagnosis in these multisymptomatic patients remains a challenge for many providers, particularly those in primary care clinics. Due to these difficulties, the diagnosis of FM often takes 2-3 years with many patients seeing 3-4 medical providers before receiving an accurate diagnosis (7, 8).

Diagnostic criteria endorsed by the ACR in 1990 emphasized tender point examination (at least 11 of 18 positive points) and the presence of chronic (greater than 3 months) widespread pain as essential features of FM (9); however, criticisms persist on this criterion's lack of consideration for other key somatic symptoms of the condition (10). The past 2.5 decades have offered more comprehensive criteria undergoing revisions for better diagnosing FM. In 2013, a 2-part questionnaire was developed that includes a 28-item pain location inventory (PLI) and 10-

item symptom severity impact questionnaire (SIQR) to account for not only chronic widespread pain sites in a patient, but also the multiple somatic and psychogenic symptoms that FM encompasses (11, 12). Compared to the proposed 2011 Modified diagnostic criteria, the 2013 criteria were found to have equal sensitivity, somewhat stronger specificity, and enhanced ease of utility (11). This presents an opportunity for clinicians to efficiently diagnose FM by employing a user-friendly tool.

Diagnosing FM swiftly and accurately may reduce unnecessary tests, sub-/specialty referral, healthcare costs, and affect a patient's quality of life (7, 13). Although general practitioners can easily establish a diagnosis of FM in individuals with chronic widespread pain (10), consultation with a rheumatologist are often helpful in challenging cases or where confirmation is needed (14). Many have argued that primary care, not rheumatology or anesthesiology, should be the medical home for individuals with FM (15, 16).

Toward these ends, we conducted a study in primary care with the following 4 aims: (1) determine the prevalence of FM in primary care clinics using a validated questionnaire, contrasting symptoms profiled in FM subjects versus other subjects; (2) test whether adding office-based measures of skin roll tenderness and pain threshold testing using sphygmomanometry increases the diagnostic accuracy of FM; (3) confirm that subjects previously diagnosed with FM do indeed have FM (true positives); and (4) profile symptoms in subjects who have a history of FM but do not meet validated criteria (false positives).

SUBJECTS AND METHODS

This descriptive cross sectional study was conducted October 2015 to April 2016. The study was conducted as part of a research requirement for completion of a Doctor of Nursing Practice degree. The study was approved by the university's institutional review board prior to enrollment of subjects. Neither investigators nor subjects were compensated for their

participation.

Study Subjects

The overarching principle of enrolling subjects was to obtain a sample that was representative of the diversity of patients routinely encountered in primary care settings. Subjects were recruited from a federally qualified health center/family practice clinic (55%) and a separate internal medicine clinic (45%), both affiliated with an academic healthcare institution in the Pacific Northwest of the United States.

All subjects were at least 21 years of age, able to read and speak English fluently, and demonstrated mental and intellectual capacity for providing written informed consent. A convenience sample of subjects was consented and joined the study prior to or following a scheduled visit with her/his primary care provider. There were no restrictions upon gender, comorbidities, past or current therapies, disease severity, or reason for the visit in enrollment. Exclusion criteria for this study included age below 21 years, lack of proficiency in reading or writing English, and inability to provide written informed consent to participate.

Demographic and Clinical Measures

Individual data collection began with recording of basic subject data from chart lore as well as reliable subject report. Demographic data included 1 of the family medicine or internal medicine clinics at which the subject was enrolled, subject age, subject gender, presence or absence of common comorbidities for fibromyalgia (table 1), and the reason for visit (table 2). Classification of fibromyalgia by diagnosing providers were based on 1990 tenderpoint examination criteria and/or the American College of Rheumatology-endorsed preliminary diagnostic criteria of 2010. All other comorbidities were based upon standardized and/or published guideline.

Table 1

Diagnosis (n = 356)	Quantity	Percent (%)
No diagnoses	66	18.5
Osteoarthritis of knee(s)	48	13.5
Osteoarthritis of hip(s)	44	12.4
Osteoarthritis of hand(s)	34	9.6
Osteoarthritis of spine	48	13.5
Spinal stenosis	15	4.2
Temporomandibular pain disorder	12	3.4
Rheumatoid arthritis	8	2.2
Systemic lupus erythematosus	3	0.8
Psoriatic arthritis	1	0.3
Fibromyalgia	54	15.2
Restless leg syndrome	20	5.6
Irritable bowel syndrome	29	8.1
Interstitial cystitis/painful bladder syndrome	6	1.7
Chronic neck pain	49	13.8
Chronic low back pain	87	24.4
Polymyalgia rheumatic	6	1.7
Migraine headache	43	12.1
Tension headache	33	9.3
Painful neuropathy	19	5.3
Chronic pelvic pain	24	6.7
Major depressive disorder	151	42.4
Generalized anxiety disorder	91	25.6
Post-traumatic stress disorder	27	7.6
Chronic hepatitis C infection	11	3.1
Human immunodeficiency virus infection	0	0
Lipid disorder	78	21.9
Chronic controlled substance prescription	51	14.3
Postoperative pain disorder	9	2.5

Table 2

Reason for visit (n = 356)	Quantity	Percent (%)
Chronic pain condition	49	13.8
Acute pain condition	42	11.8
Infection	42	11.8
Discharge follow-up	13	3.7
Prescription refill	9	2.5
Wellness visit	77	21.6

Obesity	9	2.5
Diabetes mellitus	15	4.2
Hypertension	23	6.5
Skin cancer	0	0
Skin infection	22	6.2
Organ cancer	1	0.3
Fatigue	4	1.1
Headache	6	1.7
Recent injury	10	2.8
Endocrine disorder	12	3.4
Autoimmune disorder	2	0.6
Neurological disorder	8	2.2
Cardiovascular disorder	15	4.2
Otolaryngologic disorder	23	6.5
Orthopedic disorder	12	3.4
Chronic respiratory disorder	8	2.2
Acute respiratory disorder	8	2.2
Acute psychiatric disorder	0	0
Chronic psychiatric disorder	16	4.5
Gastrointestinal disorder	9	2.5
Integumentary disorder	4	1.1
Other	14	3.9

The American College of Rheumatology 1990 diagnostic criteria for fibromyalgia was defined by the presence of persistent widespread pain and tenderness in at least 11 of 18 specific tender point sites (9). Informative and influential literature had notably identified skin roll tenderness points as a defining aspect of a tender point examination to test for widespread pain (17). 4 pairs of skin roll tenderness sites (bilateral upper trapezii, bilateral radii, bilateral anterior thighs, and bilateral Achilles tendon pinch) were assessed by an investigator applying 4 kg of pressure between the thumb and forefinger; interphalangeal tenderness was assessed by applying pressure on the distal, proximal, and metacarpophalangeal joints. The presence or absence of pain, as determined by the subjects, was recorded in a yes/no classification.

Two greatly similar studies have demonstrated lower pain threshold levels among individuals with fibromyalgia through assessing for sphygmomanometry-evoked allodynia (18, 19). Similar to these experiments in literature, in this study, using appropriately-fitting blood

pressure cuffs, investigators manually inflated the cuff on the upper arm of the subject at a rate of 10 mmHg every second. Subjects were advised to verbalize the point “at which the blood pressure cuff would bring forth pain.” The quantity of mmHg was then measured at which pain was induced.

Questionnaires

Electronic data collection was conducted and stored through Survey Monkey, secure access and log-in to which was restricted to only the investigators. Following enrollment, the investigators would complete aforementioned confidential demographic data about a subject by chart lore and/or reliable subject report (collection site, subject gender, subject age, presence or absence of comorbidities, reason for visit). In addition, the presence or absence of skin roll and interphalangeal tenderness and the level in mmHg at which pain was induced by sphygmomanometry would be recorded by the investigator. Subjects would then be asked to complete the remains of the questionnaire on Survey Monkey.

Because chronic widespread pain is a necessary component of making a diagnosis of fibromyalgia, subjects were first questioned by the survey of the presence or absence of pain, and, if present, the duration of the pain (greater than or less than 3 months). If the subject denied pain, the survey was complete; however, if the subject endorsed pain, regardless of duration, s/he would complete a 28-item pain location inventory (PLI), a symptom impact questionnaire (SIQR) 2-item global and 9-item functional assessment, and a 10-item SIQR symptom assessment. All individual and collective results were then stored in the secure Survey Monkey website and the subject was thanked for her/his time and participation.

Statistical Analysis

All data were analyzed using Stata software, version 14. Descriptive statistics were used to profile the sample. T-test analyses were used to compare characteristics of subjects with and without FM.

RESULTS

Of the 357 subjects consented, complete data were available on 356 (1 subject did not complete the questionnaire). 55% of subjects were enrolled from the family practice site, while 45% were from the internal medicine clinic site; however, there were no significant differences between the 2 sites on age, gender, or percentage with a history of FM.

The average subject was 50 (+/- 16.3) years old and 250 (~70%) were female. Electronic medical record review determined that 14.5% of subjects had a history or chart record of a FM diagnosis (47 women, 6 men). The most common comorbidities among subjects with a history of FM were depression (79%), controlled substance refill (53%), and chronic low back pain (49%) for female subjects, and osteoarthritis of the hips (50%), chronic low back pain (50%), and depression (50%) for male subjects. The most common comorbidities among subjects without a history of FM were depression (34%), anxiety (24%), and no diagnoses (20%) for female subjects, and depression (41%), no diagnoses (25%), and chronic low back pain (25%) for male subjects. The most common reasons for clinic visit on the day of enrollment were for a prescription refill (42%), chronic pain condition (38%), and acute pain condition (15%) among subjects with a history of FM, and wellness visit (23%), prescription refill (14%), and infection (12%) among subjects without a history of FM. Among subjects whose visit was for a chronic pain condition (n = 48), 20 subjects (42%) had a history of FM; meanwhile, among subjects whose visit was for an acute pain condition (n = 40), 8 subjects (20%) had a history of FM.

With regards to skin roll tenderness, 53-72% of subjects with a history of FM reported tenderness at any tested sites with no significant difference between sites ($p = 0.4669$). Among subjects without a history of FM, 9-19% reported tenderness at any tested sites, also without significant differences between sites ($p = 0.7658$). All sites were roughly equally effective in distinguishing subjects with a history of FM from subjects without a history of FM (all p values < 0.0001) (table 3).

With regards to assessing for sphygmomanometry-evoked allodynia, subjects with a history of FM reported significantly lower pain thresholds compared to those without a history of FM (mean 131 mmHg vs 185 mmHg [$p < 0.0001$]) (table 3). There was no statistical significance between pain threshold testing between females and males with a history of FM ($p = 0.4160$) (table 4); however, pain threshold testing by sphygmomanometry were significant for comparing females with and without a history of FM ($p < 0.0001$) (table 5) and males with and without a history of FM ($p = 0.0004$) (table 6).

Table 3

	n	Mean age (years) +/- SD	Mean percentage with skin roll tenderness (%) +/- SD	Blood pressure at which allodynia induced +/- SD
History of fibromyalgia	53	52.7 +/- 13	60.9 +/- 5	131 +/- 36
No history of fibromyalgia	303	49.6 +/- 17	14.2 +/- 4	185 +/- 39
P value	-	-	<0.0001	<0.0001

Table 4

	n	Mean age (years) +/- SD	Blood pressure at which allodynia induced
Females with history of fibromyalgia	47	52.5 +/- 14	129 +/- 45
Males with history of fibromyalgia	6	54.3 +/- 12	146 +/- 60
P value	-	-	0.4160

Table 5

	n	Mean age (years) +/- SD	Blood pressure at which allodynia induced
Females with history of fibromyalgia	47	52.5 +/- 14	129 +/- 45
Females without history of fibromyalgia	202	48.5 +/- 17	180 +/- 41
P value	-	-	<0.0001

Table 6

	n	Mean age (years) +/- SD	Blood pressure at which allodynia induced
Males with history of fibromyalgia	6	54.3 +/- 12	146 +/- 60
Males without history of fibromyalgia	100	51.7 +/- 17	197 +/- 31
P value	-	-	0.0004

With regards to the questionnaire, 157 subjects (44%) endorsed pain, 120 of whom lasting longer than 3 months, and 37 of whom lasting less than 3 months. Of the 53 subjects with a history of fibromyalgia, 50 endorsed some kind of pain, thereby having questionnaire results. The average mean SIQR total scores were significantly higher in subjects with a history of FM compared to those without FM ($p < 0.0001$) (table 7), the most severe symptoms, from worst to least, being sleeping difficulties, stiffness, fatigue, tenderness, environmental sensitivity, pain, anxiety, balance difficulties, memory problems, and depression. Meanwhile, the average mean PLI scores for subjects with a history of FM were significantly higher ($p < 0.0001$) than subjects without a history of FM; however, the mean average PLI scores for subjects with a history of FM was not diagnostic for FM (table 7).

Table 7

	n	Mean PLI score +/- SD	Mean SIQR score +/- SD
With history of fibromyalgia	50	13.54 +/- 7.43	62.46 +/- 18.36
Without history of fibromyalgia	107	5.24 +/- 5.03	36.01 +/- 23.06
P value	-	< 0.0001	< 0.0001

Based on 2013 criteria, among subjects with a history of FM who filled out the questionnaire ($n = 50$), 17 subjects (15 females, 2 males) were determined to have FM based on PLI score >17 and SIQR score >21 . The most common reason subjects did not meet diagnostic criteria for FM was due to inadequate quantities of pain locations rather than symptom scores.

Among subjects without a history of FM who filled out the questionnaire, 4 females and no males met diagnostic criteria for FM.

DISCUSSION

Data from this study identified the following novel findings: 4.78% of patients attending a primary care clinic met diagnostic criteria for FM. Among those with a history of FM, 32.07% were true positives, and 67.92% were false positives. Moreover, two clinically accessible measures of pressure-evoked allodynia successfully identified FM subjects from pain and pain-free controls. Sphygmomanometer-induced pain was significantly lower in FM patients compared to controls, while pressure or rolling-induced skin tenderness averaged at 6 sites was also significantly lower in FM patients compared to pain-free controls. Consistent with previous findings, individuals with FM compared to pain and pain free controls had a great number and severity of symptoms and comorbidities (9, 11).

Our study offered a unique insight into a testing of diagnostic criteria that have mostly been tested only in pain specialty and rheumatology settings (11). The 2013 diagnostic criteria boast sensitivity, specificity, and accuracy of 81%, 80%, and 80% (11), a remarkable improvement to detect the absence of FM from a precursor in 2009, which demonstrated the same values as 84%, 67%, and 74%, respectively (12). With decades more years of research in support, the 1990 ACR diagnostic criteria showed comparable sensitivity, specificity, and accuracy rates of 84%, 81%, and 80% to the 2013 proposed criteria (9), though these were meant only for research rather than clinical use, and have been reported to miss up to 20% of cases (14). Studies on the preliminary ACR diagnostic criteria of 2010, which also utilize a questionnaire of patient self-selected pain sites and symptom severity (20), reveal estimated sensitivity, specificity, and accuracy rates of 92-93%, 85-97%, and 88% (14); however, these criteria have been criticized for lack of user-friendliness in clinical practice (11). Nonetheless, newer criteria since 1990 have demonstrated good efficacy in a variety of populations, including youth, and

offered contingently appropriate treatments (21, 22).

Although the enrollment of subjects in this study with a history of FM was comparably high (15.2%) to national averages (3.9%) (1, 2), which may have been influenced by a subject's increased willingness to volunteer for a study relevant to her/his health, the percentage of those who indeed met diagnostic criteria (4.78%) is strikingly closer. This implies either an increased sensitivity of the criteria utilized by the diagnosing provider, or a superior sensitivity and accuracy of the 2013 criteria.

Many subjects with a history of FM in this study did not satisfy the 2013 diagnostic criteria due to below-threshold PLI scores. One confounder is the relatively high prevalence of fibromyalgia among subjects with controlled substance refills. Although evidence is insufficient to support chronic opioid therapy for individuals with chronic pain disorders (23), 54% of individuals with FM received regular controlled substance refills, causing one to wonder if this could affect PLI and/or SIQR self-scoring. One experiment revealed persistently high pain levels and symptom severity in subjects with FM receiving chronic opioid therapy (24), and our results concur with this: the number of respondents with a history of FM receiving controlled substances refills who had persistent PLI and SIQR scores of $>/17$ and $>/21$ were 9 and 25 of 26 respondents. Meanwhile, the number of respondents with a history of FM not receiving controlled substances refills who had the same PLI and SIQR scores were 8 and 24 of 24 respondents.

Not altogether discounting the value of assessing for widespread tenderness and allodynia in FM, two nearly mirror studies have documented on lower pain thresholds using sphygmomanometry among individuals with fibromyalgia as opposed to healthy controls and even other individuals with chronic pain disorders (12, 13). Sensitivities and specificities for sphygmomanometry-evoked allodynia in FM in these studies, particularly at a cut-off <170.9 mmHg, were 69-70% and 80-69% (12, 13). Our study concurs with these studies, boasting p-

values between undetectable (<0.0001) to 0.0004 in identifying lower pain thresholds through sphygmomanometry in subjects with and without FM. Although newer proposed diagnostic criteria have emphasized the role of measuring the somatic symptoms of fibromyalgia, these studies may highlight a need to re-address the presence of tenderness and allodynia, as demonstrated in the 1990 ACR criteria with assessing tender points.

As primary care providers overwhelmingly self-report inadequacy, lack of self-knowledge, and a consistent delay to confirming a diagnosis of FM (25, 26), this study offers a glimpse of swift, convenient, and user-friendly tools and methods for diagnosing FM. As effective management of any disorder is contingent upon securing a diagnosis with confidence, and many providers in a variety of practices, including primary care, agree on many common and relevant signs and symptoms of fibromyalgia (27), a diagnostic tool that is accurate and all-encompassing of the signs and symptoms of FM is required. Acknowledging both the concepts of allodynia and widespread tenderness as well as a patient-rated severity of symptom score, one study supported the use of both practices in primary care settings to aide diagnosis of FM (28). Our study suggests that easily-performed physical examinations, such as abbreviated skin roll tenderness exam or pain threshold testing with sphygmomanometry, alongside a patient-reported questionnaire may strengthen diagnostic confidence of FM in primary care settings.

Limitations of this study include the limited and localized geographic area in which data was collected – an academic and healthcare institution in a metropolitan region – which may not be representative of a statewide or national sample. In addition, there were a limited number of males with a history of FM (6), providing scant data on the minority of individuals this condition affects. In relation to comorbidities, the cross-sectional nature of this study does not allow for inferences about their timing, which would have offered insight into primary vs secondary

etiologies of fibromyalgia. In relation to treatment, although we considered the effect of controlled substances upon the reliability and validity of diagnostic criteria, we did not take into account whether or not subjects were on FDA approved pharmacotherapies, such as pregabalin, duloxetine, or milnacipran (29), and how that may affect responses to questionnaire components. Lastly, subjects who did not report pain were not asked to complete the entire survey, which may have limited our ability to further compare controls on all variables.

Acknowledgements

We are indebted to our mentors, Madeleine Sanford MSN, FNP and Kaitlin Haws DNP, ANP, WHCNP, and their respective Oregon Health and Science University departments, family medicine and internal medicine, for their contributions and allowance in carrying out this study. In addition, we thank our subjects for their participation in this study.

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