Construction of a US Fibromyalgia Registry Using the Fibromyalgia Research Survey Criteria

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Abstract

Utilizing billing records, we identified patients seen at Mayo Clinic with a diagnosis or history of fibromyalgia who were then contacted for enrollment in a fibromyalgia research registry. Fibromyalgia was confirmed through medical record review. Eligible patients were mailed an invitation that included a demographic questionnaire and the Fibromyalgia Research Survey. The Fibromyalgia Research Survey yields a widespread pain score (scale range 0–19) and a symptom severity score (scale range 0–12). A total of 4,034 patients returned the completed survey; 92.8% were female, their mean age was 57.4 (±13.4), and 83.7% were from the Midwest region of the United States. The mean widespread pain score for all participants was 11.3 (±4.5) and the mean symptom severity score was 8.2 (±2.4), indicating moderate-to-severe fibromyalgia symptoms, which is not unusual for patients presenting to a tertiary care center. Using a systematic process, we describe the creation of a fibromyalgia registry for future research. Clin Trans Sci 2013; Volume 6: 398–399

Keywords: pain, epidemiology, rheumatology

Introduction

Registries and data banks serve several purposes in healthcare including advancing the study of less known illnesses by providing an evidence-based resource for surveys and clinical trials and serving as an epidemiological resource to assess trends in health and identify risk factors. For example, the National Data Bank of Rheumatic Diseases, the largest patient-based multidisease, multipurpose rheumatic disease registry has developed and validated diagnostic criteria for rheumatoid arthritis, systemic lupus erythematosus, fibromyalgia (FM), and osteoarthritis.[1] Additionally, it has advanced the study of risk factors, disease outcomes, and served to assess the effectiveness of pharmacological and nonpharmacological treatment modalities for rheumatic diseases. Other examples of registries include the Emergency General Surgery Registry[2] that facilitated data collection to identify and define emergency general surgery patients, and the Pediatric Clinical Outcomes Registry[3] that facilitates outcome research for an array of patient diagnoses.

Given the advancement of knowledge that has resulted from the previous examples, it seems logical that a poorly understood symptom complex such as FM could be advanced from establishment of a registry. The Mayo Fibromyalgia Clinic is a unique national resource established in 1999 to provide consultative care for patients with FM.[4,5] The Fibromyalgia Clinic sees approximately 1,800 patients a year and is uniquely positioned to establish and populate a registry.

Our objective was to create an FM registry to facilitate prospective data collection for epidemiologic and survey research.

Methods

In order to identify patients who might be eligible for inclusion in the registry, we used billing records to select patients who visited Mayo Clinic between January 1, 2000 and June 30, 2011 and had a diagnosis or history of FM (N = 20,731). Patients who required an interpreter, lived outside of the United States, did not provide research authorization, or were deceased were excluded (n = 2,506). Presence of an FM diagnosis was established through medical record review. Patients who did not have a diagnosis of FM (n = 967) in the medical record were excluded.

Eligible patients (n = 17,267) were sent a demographic questionnaire and the FM research survey. The FM research survey has been validated for use in epidemiologic research without the requirement of an examiner and assesses pain and other symptoms associated with FM.[6] Responses were entered into a Research Electronic Data Capture Database.[7] All data were double-entered to ensure quality. Participants were classified as meeting FM research survey criteria if their widespread pain index (WPI) score was ≥7 and their symptom severity (SS) score was ≥5, or if their WPI was between 3 and 6 and their SS score was ≥9. WPI scores range from 0 to 19 and SS scores range from 0 to 12.

The study was approved by the Mayo Clinic Institutional Review Board.

Results

A total of 4,034 patients returned completed surveys, 714 declined participation, and 1,937 were returned due to undeliverable address. Descriptive statistics of participants by FM research survey criteria are summarized in *Table 1*. The majority of participants were female (92.8%) with a mean age of 57.4 (±13.4). Despite the majority of participants being residents of the Midwest region of the United States (83.7%), survey participants were from all but one of the 50 states (Vermont) and Puerto Rico. The mean WPI score for all participants was 11.3 (±4.5) and the mean SS score was 8.2 (±2.4). As expected, participants who met FM research survey criteria had worse WPI and SS scores than those who did not meet criteria.

Discussion

We describe a systematic process by which we created a registry of well-phenotyped patients with FM. The registry provides a resourceful sampling frame for future clinical studies. This registry is unique in that it has the ability to be linked to a patient's electronic medical record. This allows for examination

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Variable	Meet criteria (n = 3,360)	Do not meet criteria (n = 674)	Total (n = 4,034)	p-value
Age	56.6 ± 13.3	61.2 ± 13.3	57.4 ±13.4	<0.0001
Caucasian	2,978 (88.6)	612 (90.8)	3,590 (90.0)	0.10
Sex				0.13
Male	234 (7.0)	58 (8.6)	292 (7.2)	
Female	3,126 (93.0)	616 (91.4)	37,42 (92.8)	
BMI	29.8 ± 7.3	28.2 ± 6.6		<0.0001
WPI	12.4 ± 3.8	5.8 ± 3.6		<0.0001
SS	8.8 ± 1.9	4.9 ± 2.2		<0.0001
Fatigue	2.4 ± 0.6	1.4 ± 0.8		<0.0001
Cognition	1.8 ± 0.8	0.9 ± 0.7		<0.0001
Unrefreshing sleep	2.4 ± 0.7	1.4 ± 0.8		<0.0001

Mean ±SD or *N* (%).
BMI, body mass index; SD, standard deviation; SS, symptom severity; WPI, widespread pain index.

Table 1. Demographic characteristics of responders by fibromyalgia research survey criteria.

We are planning to update this registry annually with patients seen in the previous year, which may improve our response rate.

Conclusion

The Mayo Clinic Fibromyalgia Registry, which is linked to the electronic medical record, offers an excellent sampling frame for future retrospective and prospective studies that could advance the science of FM.

Acknowledgment

of comorbidities, laboratory values, and radiographic reports seen in this patient population. For example, two ongoing studies evaluating fatigue and its predictors in patients with FM are currently utilizing this registry.[8,9]

Although our initial sampling frame started with patients with a diagnosis or history of FM identified through medical record review (no tender point exam could be conducted as patients were not present), all participants completed the FM research survey, and 83.2% fulfilled FM research survey criteria. This in part could be explained by evidence that patients with FM can switch between criteria-positive and criteria-negative states.[10]

Since this registry was created through a comprehensive search of patients seen at Mayo Clinic, a tertiary care center, it may be more representative of patients who present to tertiary clinics and have more severe symptoms. Therefore, outcomes of surveys or clinical studies utilizing this registry may not be generalizable to patients with less severe symptoms.

Despite the low response rate to the initial invitation for enrollment, we believe this could be attributed to the length of time (up to 10 years) between patient visit and contact for participation.

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