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The impact of changes in fibromyalgia diagnosis criteria: using NAMCS data (2010–2019) to identify trends

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Abstract

Background Fibromyalgia is currently diagnosed under the 2016 research criteria, a combination of the 2010 and 2011 criteria revisions. The current guidelines have led to ongoing misdiagnosis issues dating back to the criteria initially established by the 1990 American College of Rheumatology (ACR). Given the extensive revisions to the diagnostic criteria in 2016, instances of over-and under-diagnosing as well as measurement errors corresponding to the different diagnostic criteria utilized, the current study sought to investigate changes in the incidence of fibromyalgia diagnoses and the associations between fibromyalgia diagnosis and relevant comorbidities and somatic symptoms of interest.

Methods This retrospective, observational, cross-sectional study of adults (18 + years of age) used the most recently available National Ambulatory Medical Care Survey (NAMCS) datasets from 2010 to 2019. A plot of annual point estimates of the proportion of visits where fibromyalgia was diagnosed (and associated 95% confidence intervals) was generated. In addition, a multivariable logistic regression model was constructed to assess the relationship of covariates available in the NAMCS on the outcome of fibromyalgia diagnosis (yes/no).

Results Since the implementation of the 2010 ACR criteria, the percentage of visits resulting in a fibromyalgia diagnosis increased prior to the release of the 2016 criteria, after which a general downward trend was observed. Both rheumatoid arthritis (OR 5.51, 95% CI 2.87–10.58) and depression (OR 2.61, 95% CI 1.90–3.58) were found to be strongly associated with a fibromyalgia diagnosis. Other comorbid conditions showed minimal associations.

Conclusions Based on the fluctuation in the proportion of NAMCS visits resulting in a fibromyalgia diagnosis post-implementation of the 2016 criteria, the current criteria may not accurately represent the sensitivity to comorbid conditions seen in the 2010 criteria through symptom severity scales. The analysis of comorbidities and somatic symptoms revealed that rheumatoid arthritis and depression continue to be two defining comorbidities in the diagnosis of fibromyalgia; however, diagnostic challenges remain.

Clinical trial number Not applicable.

Keywords Fibromyalgia, Comorbidities, Diagnostic criteria, Somatic symptoms

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Background

Fibromyalgia is estimated to have a prevalence of up to 6.4% in the United States, with most of the afflicted population being middle-aged women [1]. However, over the last three decades, fibromyalgia diagnoses and the diagnostic criteria have been reviewed and updated to ensure accuracy and specificity as physicians attempt to make valid diagnosis. The American College of Rheumatology (ACR) established the initial diagnostic benchmarks in 1990 [2]. These preliminary criteria included a history of widespread pain present for at least three months and pain in 11 of 18 tender point sites found throughout the body at high-mobility locations as the primary method of diagnosis [2]. In 2010 the preliminary criteria were updated, and the tender points were eliminated from the definition of fibromyalgia [3]. The Symptom Severity Scale (SS) or (SSS) was developed, and the Widespread Pain Index (WPI) was used to create a new criteria that included (WPI ≥ 7 and SS ≥ 5) or (WPI 3–6 and SS ≥ 9) [3]. Using this definition provided by Wolfe et al., physicians were able to accurately classify 82.6% of patients.

Fibromyalgia diagnostic misclassifications due to measurement errors were evident as the 2010 criteria required a patient self-report and a detailed assessment, and therefore, in 2011, the diagnostic criteria were updated [4]. The Fibromyalgia Symptom (FS) score, a scale that combines the WPI and the SSS, was introduced to measure the severity of the symptoms reported by patients and the physical and psychological distress experienced [4]. The FS score is also known as the Polysymptomatic Distress Scale (PDS) or "fibromyalgia-ness" scale, and it is used to determine the distress experienced by patients as a continuum with FM symptoms ranging from mild to severe rather than FM positive or negative cases of FM [4–6]. Hence, the greater the PDS score the more physical and mental impact and the lower quality of life patients with FM can have [6]. In 2016, the somatic symptoms were highlighted, and the 2010/2011 ACR fibromyalgia criteria definition was updated to a syndrome of moderate to severe symptoms that exist in a continuum rather than as a category (having or not having FM) [7]. Finally, the 2016 ACR research diagnostic criteria were established. The updated criteria include (a) WPI ≥ 7 and SSS score ≥ 5 or WPI of 4–6 and SSS score ≥ 9; (b) presence of pain in 4 of 5 regions; (c) presence of symptoms for at least three months; and (d) a diagnosis of fibromyalgia which does not exclude the presence of other conditions [7]. The 2016 update combines the 2010 and 2011 revisions, which can be used as a diagnostic and classification criterion. However, Wolfe et al. (2019) raised concerns about clinicians failing to identify 50% of positive cases as the International Classification of Diagnoses (ICD) codes used to identify cases may not accurately capture the diagnosis of fibromyalgia [8]. These authors found a misclassification rate of 15.3% among physicians in a university rheumatology-focused clinic which led to additional misdiagnosis concerns. Furthermore, the average time to receive a fibromyalgia diagnosis between 2008 and 2011 was 6.42 years from the inception of symptoms [9]. Worse, in 2019 the weighted average of the median lag time from consulting a physician with rheumatoid arthritis symptoms to rheumatoid arthritis specialist referral was 2.13 months. The weighted average median lag time from onset of rheumatoid arthritis symptoms to therapy after diagnosis was 11.79 months [10].

The significant delay in acquiring a fibromyalgia diagnosis, and therefore, access to effective treatment to manage symptoms severely impact patients who suffer from a rapid onset of primary fibromyalgia symptoms and those with a wide array of comorbidities. By 2023, it was increasingly apparent that fibromyalgia is a multidimensional disorder given the overlap and variation of symptoms presentation [6]. Consequently, the diagnostic criteria remains uncertain and potentially biased due to the varying spectrum of symptoms experienced by individuals.

Given the extensive revisions to the diagnostic criteria, the over- and under-diagnosis, and the potential measurement errors, the current study aimed to estimate the annual proportion of US adults diagnosed with fibromyalgia by evaluating the nationally representative National Ambulatory Medical Care Survey (NAMCS) data for the years 2010–2019 to provide insight into changes in the frequency of fibromyalgia diagnosis corresponding to the different diagnostic criteria utilized over this period. Additionally, the authors investigated associations between fibromyalgia diagnosis and relevant comorbidities and somatic symptoms of interests (rheumatoid arthritis, lupus, depression, anxiety, diabetes, sleep disturbances, repetitive injuries (tendonitis), cognitive symptoms, fatigue, irritable bowel syndrome) described in the ACR 2010 diagnostic criteria [3] to understand better the potential impact of self-reported symptoms evident in the diagnosis of the disease.

Methods

This study was a retrospective, cross-sectional, observational study which utilized the most recently available NAMCS datasets from the years 2010–2016 and 2018–2019 (no NAMCS data was available for the year 2017). The NAMCS is an annual survey conducted by the Centers of Disease Control and Prevention (CDC). The annual NAMCS data is comprised of a national probability sample of visits made to the offices of non-federally employed physicians classified by the American Medical Association or the American Osteopathic Association as providing primarily office-based patient care [11, 12].

This database includes data going back to 1993 and hundreds of publications are based on these annual datasets.

The complexity of the methodology involved in the NAMCS surveys, as well as the National Hospital Ambulatory Medical Care Survey, led to two National Center for Health Statistics (NCHS, the organization that oversees the conduct of these surveys) statisticians to publish an article explaining the methodology utilized and which included sample text, designed to be included as the methods sections of publications which utilize this data [13]. It is this McCaig and Burt (2012) paper, as well as a previous publication utilizing NAMCS data by some of the authors of the current paper, on which the below brief summary of the NAMCS survey methods is based. For interested readers, further details can be found in the McCaig and Burt (2012) paper [14] and/or on the NAMCS website [13].

NAMCS data is collected from a group consisting of physicians and non-physician clinicians, including nurse practitioners and physician assistants from the United States (anesthesiologists, pathologists, and radiologists are excluded). The total physician sample is divided into fifty-two random subsamples approximately equal in size, with each subsample randomly assigned to one of the fifty-two weeks in a year. Each physician systematically selects a random sample of visits during an assigned reporting week and then each physician, physician support staff, or the US Census Bureau's field representatives perform data collection. A random sample of these logged visits from the reporting week is then selected for inclusion in the database. The data collected includes patient symptoms, diagnoses, medications, procedures, planned treatment, demographic, socioeconomic, dietary, and other health-related information. The NAMCS is approved by the Ethics Review Board of the NCHS, with waivers of the requirements to obtain informed consent from patients and patients' authorization of the release of medical-record data by health care providers. Data processing, including all medical and drug coding, are performed by Society of Research Administrators International, Inc. (Durham, North Carolina) and subjected to quality-control procedures [12, 13]. NAMCS datasets from the years 2010–2016 and 2018–2019 were included in the study. Data from patients ≥ 18 years of age were included. For eligible visits, information was included on patient age, gender, race, ethnicity, metropolitan status area (MSA), body mass index (BMI) category, physician specialty, all relevant comorbidities diagnosed at each visit (as established by the appropriate DIAG variable codes) as well as all relevant coded reasons for each visit (as established by the appropriate RFV variable codes) that were available in the database. The database contains five diagnosis code variables and five reason for visit code variables. Thus, for each patient visit as many as five diagnoses and five reasons for visit may be available. The endpoint of all analyses was the diagnosis of fibromyalgia (yes/no).

The diagnosis of fibromyalgia endpoint was constructed by assessing each participant visit for relevant ICD-9/ICD-10 codes for a diagnosis of fibromyalgia (ICD-9: 7291-; ICD-10: M797). Otherwise, the participant visit was deemed to have not been one where fibromyalgia was diagnosed. The collected NAMCS data were analyzed using the sampled visit weight, which represented the product of the corresponding sampling fractions at each stage in the sample design. The sampling weights were adjusted by the NCHS for survey nonresponse as appropriate within the database, yielding a nonbiased national estimate of visit occurrences, percentages, and characteristics. Consistent with the multi-stage, cluster-sampling methods used in NAMCS, all analyses were weighted and clustered to extrapolate results to generate average annual US national estimates. That is, the analysis of the survey, as designed, allows for the generation of national average annual ambulatory care visit totals for the years 2010–2016 and 2018–2019 by extrapolation of the survey sample ($n = 248{,}164$) [13–15].

Demographic and patient visit characteristics information was summarized using appropriate summary statistics. In addition, a plot of the proportion of visits at which fibromyalgia was diagnosed (by year) was constructed to assess any trends over the study timeframe.

A multivariable logistic regression model was constructed to evaluate the predictive value of each independent variable of interest, adjusting for covariates available in the datasets, on diagnosis of fibromyalgia. Odds ratios (ORs) with corresponding 95% confidence intervals (CIs) for each level of each discrete variable included in the model, in comparison to each variable's reference group, were generated and reported. NAMCS survey year was included in the model as a continuous variable. The variables included in the model were grouped for analysis as shown in Table 1. The NCHS recommends that any variable with a survey estimate based on < 30 records, with a > 30% missing data or a relative standard error (RSE) of > 30%, be excluded from analyses due to potential unreliability.

The full model including all predictors converged, however suffered from quasi-complete separation of data points (i.e. one or more of the predictor variables was nearly perfectly associated with the outcome of fibromyalgia, thus resulting in a near perfect separation of the "Yes" and "No" levels of fibromyalgia based on one or more of the predictors and calling the model fit into question). This is typically due to variables with small cell counts and/or which are strongly associated with the outcome. Following recommended practices, removing the variables ethnicity and soft tissue disorder/myalgia from

Table 1 Demographic and participant visit characteristics

Characteristic	Weighted frequency[a] (%) of visits *N* = 248,164[b]
BMI (mean ± SE)	29.2 ± 0.09
Gender	
Female	472,014,489 (60.2)
Male	311,513,220 (39.8)
Race	
Non-White	95,835,452 (16.6)
White	481,506,931 (83.4)
Ethnicity	
Hispanic or Latino	72,693,777 (12.3)
Not Hispanic or Latino	516,320,589 (87.7)
Urbanicity	
Urban (MSA)	712,139,567 (90.9)
Rural (non-MSA)	71,388,142 (9.1)
Specialty	
Medical Care	231,355,616 (29.5)
Surgical Care	176,986,577 (22.6)
Primary Care	375,185,516 (47.9)
Diabetes	
Yes	119,626,482 (15.3)
No	663,901,227 (84.7)
Depressive Disorder	
Yes	90,164,943 (11.5)
No	693,362,766 (88.5)
Generalized Anxiety Disorder	
Yes	25,758,024 (3.3)
No	757,769,685 (96.7)
Malaise / Fatigue	
Yes	8,997,102 (1.1)
No	774,530,607 (98.9)
Rheumatoid Arthritis	
Yes	4,795,425 (0.6)
No	778,732,284 (99.4)
Lupus[c]	
Yes	1,742,762 (0.2)
No	781,784,947 (99.8)
Irritable Bowel Syndrome[c]	
Yes	2,216,384 (0.3)
No	781,311,325 (99.7)
Cognitive Function Symptoms[c]	
Yes	552,357 (0.1)
No	782,975,353 (99.9)
Sleep Disorder[c]	
Yes	4,023,448 (0.5)
No	779,504,261 (99.5)
Soft Tissue Disorder	
Yes	4,435,393 (0.6)
No	779,092,316 (99.4)
Cramps / Spasms[c]	
Yes	696,976 (0.1)
No	782,830,733 (99.9)
Weight Gain[c]	
Yes	7,227,339 (0.9)
No	776,300,370 (99.1)
Stomach Pain[c]	

Table 1 (continued)

Characteristic	Weighted frequency[a] (%) of visits *N* = 248,164[b]
Yes	3,905,686 (0.5)
No	779,622,023 (99.5)
Nausea[c]	
Yes	5,736,626 (0.7)
No	777,791,083 (99.3)
Diarrhea[c]	
Yes	5,763,434 (0.7)
No	777,764,275 (99.3)
Itching[c]	
Yes	88,488 (<0.1)
No	783,439,221 (> 99.9)
Fibromyalgia	
Yes	5,206,059 (0.7)
No	778,321,650 (99.3)

[a] Survey weighting, stratification, and clustering accounted for reflecting unbiased, national annual estimates of visit occurrences for the portion of the population meeting the study inclusion and exclusion criteria

[b] Out of the 1,659 survey visits as which fibromyalgia was diagnosed, IBS ($n = 17$; Relative Standard Error [RSE] = 32%) and lupus ($n = 25$; RSE = 35%) and general anxiety disorder (RSE = 35%) were either reported at less than 30 visits and/or had a RSE > 30%. Per the NCHS, the estimate for these variables in this table are potentially unreliable due to the small count (and/or elevated RSE value). Caution is urged in interpreting this estimate

[c] Out of the 1,659 survey visits as which fibromyalgia was diagnosed, sleep disorder, cognitive function symptoms, cramps/spasms, weight gain, stomach pain, nausea, diarrhea and itching was reported at less than 15 visits. Per the NCHS, these estimates are entirely unreliable and thus not reported in this table even though the variables were included in the model

the model remedied the model fit issues. In order to be able to assess the full impact of all possible comorbidities in the model while following the above stated NCHS guidelines, estimates for comorbidities with gross violations will not be reported. For any variables for which violations were only marginal across any respective threshold, the authors made the decision to retain the variables in the model and incorporate a footnote in the model table urging caution in the interpretation of the affected results. Subsequent checking of all multivariable logistic regression model assumptions for this final model yielded no further concerns.

As this was a retrospective, hypothesis generating type of study, no adjustments for multiple comparisons were made. In addition, aligning with current thinking regarding best practices against significance testing from thought leaders in statistics, statistical significance was not reported for any results [16]. Further, a focus on the provided confidence intervals is urged to ensure the readers' awareness of both interval width (narrower being more informative) and location (further from zero indicating increasing importance). All analyses were generated using SAS version 9.4 [17].

Sampling errors were determined using appropriate SAS SURVEY procedures, which account for the clustered nature of the sample. Further, the appropriate SAS procedure options (NOMCAR and DOMAIN) to address missing data and use of domains to determine accurate variance estimates were implemented in the analyses as recommended by the NCHS [13–15]. The data for analyses was de-identified and cleaned by the CDC prior to release. Due to the data sources used being publicly available and de-identified, an exemption from the Campbell University Institutional Review Board was received.

Results

Across the 9 years included, a total of 248,164 visit records from the NAMCS database met the inclusion criteria. Table 1 presents the demographic and participant visit characteristics based on weighted frequency (%) of survey visits. The survey sample size extrapolates to an average annual estimated total of 783,527,709 ambulatory care visits amongst those meeting the study inclusion/exclusion criteria. The survey design allows us to estimate that the majority of all annual visits were made by females (60.2%), those who identified as in the White race group (83.4%) and those visiting urban ambulatory care centers (90.9%). Amongst the comorbidities and somatic symptoms of interest, diabetes (15.3%) and depression (11.5%) were by far the most common. Almost all others were recorded at less than 1% of visits. A diagnosis of fibromyalgia was reported in 0.7% of visits. A summary of all other available variables of interest can be found in Table 1.

Figure 1 shows annual point estimates of the proportion of visits at which fibromyalgia was diagnosed (and associated 95% confidence intervals). An increase in the proportion of visits with a fibromyalgia diagnosis after the implementation of the 2010 ACR criteria is evident in the graph. The percentage of visits resulting in fibromyalgia diagnosis nearly doubled from 0.58% in 2010 to 0.99% in 2011. In the years following 2011, the proportion of

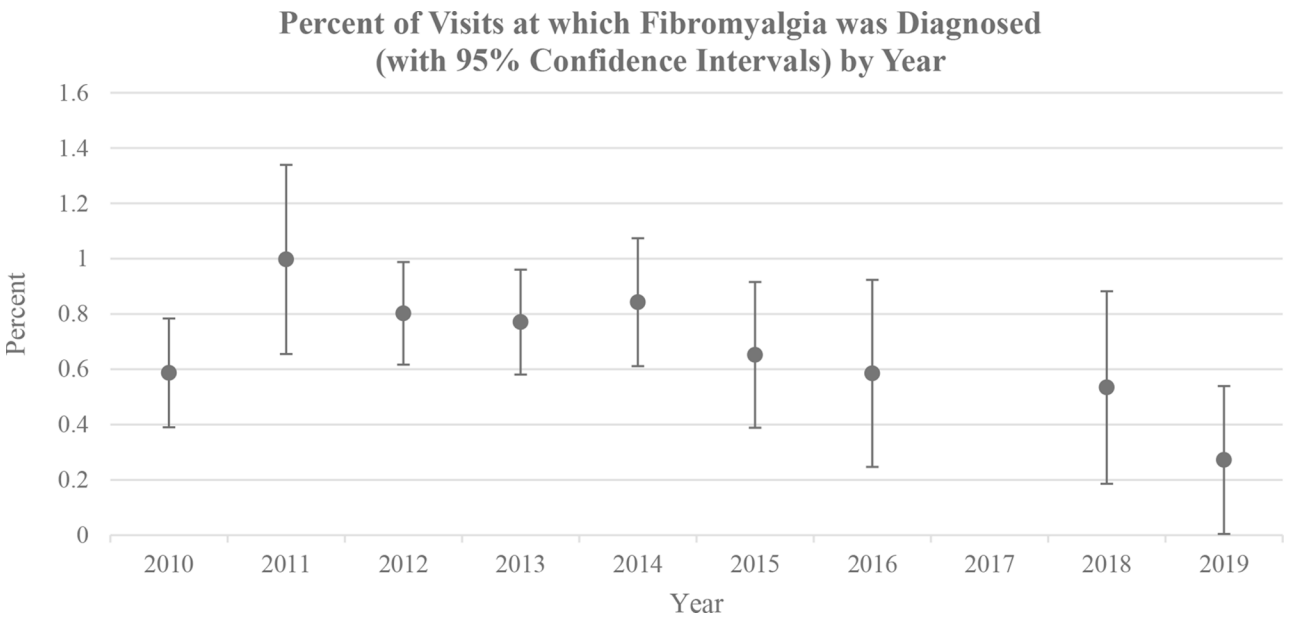

Fig. 1 Percent of visits at which fibromyalgia was diagnosed by year. *Footnote: No data collection for the National Ambulatory Medical Care Survey (NAMCS) was conducted in 2017

visits with a fibromyalgia diagnosis remained roughly steady at around 0.80% of visits through 2014. However, beginning with the (current) 2016 ACR research criteria, the proportion of visits with a fibromyalgia diagnosis steadily decreased, reaching a decade-low 0.27% in 2019, the most recently available data, half of the 2010 diagnosis rate.

The multivariable logistic regression model was constructed for the outcome of fibromyalgia diagnosis and included comorbid conditions diagnosed at a given visit, comorbid conditions that were recorded as the reason for the visit as well as available demographic-type covariates (Table 2). After adjusting for these included covariates, evidence of associations between fibromyalgia diagnosis and certain comorbidity diagnoses as well as demographic-type variables was noted. Visits involving a rheumatoid arthritis diagnosis showed 451% higher odds (OR: 5.51, 95%CI 2.87, 10.58) of a fibromyalgia diagnosis compared to visits without. A second strong association was found in visits where depression was diagnosed, which demonstrated 161% higher odds (OR: 2.61, 95%CI 1.90, 3.58) of fibromyalgia diagnosis. Several conditions commonly associated with fibromyalgia in literature - diabetes, generalized anxiety disorder, malaise/fatigue, lupus or IBS - showed no association with fibromyalgia, which may at least in part be due to the small number of visits at which these conditions were diagnosed. The very small counts for cramps/spasms, weight gain, stomach pain, nausea, diarrhea, itching at visits were indicated as the reason for the visit didn't allow any valid estimates to be generated.

Certain other disparities in odds of fibromyalgia diagnosis were evident: visits by female patients had 183% higher odds (OR: 2.83, 95%CI 1.95, 4.11) of having fibromyalgia diagnosed compared to visits by male patients. Visits by individuals who identified as non-White had 44% lower odds of having fibromyalgia diagnosed (OR: 0.56, 95%CI 0.37, 0.84) than visits by individuals who identified as White. The medical specialty of the physician providing the diagnosis also played a role in influencing the odds; visits at which the patients saw a medical care specialist, as opposed to a primary care provider, had 50% increased odds of diagnosis (OR:1.50, 95%CI 1.04, 2.18). Alternatively, visits at which patients saw a surgical care specialist, as opposed to a primary care provider, had 71% lower odds (OR: 0.29, 95%CI 0.14, 0.58) of being diagnosed with fibromyalgia.

Discussion

This study sought to assess fibromyalgia diagnosis trends over the 2010–2019 decade. The diagnostic criteria and the definition of fibromyalgia have evolved over the study time period (2010–2019), therefore, determining any impact on the relationship between the prevalence of fibromyalgia and the changing criteria and disease definition is important. Researchers further investigated associations between fibromyalgia diagnosis and the somatic symptoms experienced by patients given the implementation of the PSD scale or the FS score implemented in 2011, which popularized the idea of fibromyalgia as a multi-dimensional disorder that exists on a continuum of physical and psychosocial distress rather than a positive or negative case of FM [4–6].

Table 2 Multivariable logistic regression model for fibromyalgiaa, B

Variable	Odds ratio (95% CI)
Diabetes	
Yes vs. No	0.85 (0.44, 1.67)
Depressive Disorder	
Yes vs. No	2.61 (1.90, 3.58)
Generalized Anxiety Disorder[b]	
Yes vs. No	1.24 (0.46, 3.37)
Malaise / Fatigue	
Yes vs. No	1.26 (0.69, 2.28)
Rheumatoid Arthritis	
Yes vs. No	5.51 (2.87, 10.58)
Irritable Bowel Syndrome[b]	
Yes vs. No	2.34 (0.85, 6.43)
Lupus[b]	
Yes vs. No	2.19 (0.77, 6.21)
Year	0.93 (0.86, 1.01)
BMI	1.01 (1.00, 1.01)
Sex	
Female vs. Male	2.83 (1.95, 4.11)
Race	
Non-white vs. White	0.56 (0.37, 0.84)
MSA	
MSA vs. Non-MSA	0.93 (0.56, 1.56)
Specialty	
Medical care vs. Primary care	1.50 (1.04, 2.18)
Surgical care vs. Primary care	0.29 (0.14, 0.58)

CI: Confidence Interval; BMI: Body Mass Index; MSA: Metropolitan Statistical Area

[a] Survey weighting, stratification, and clustering accounted for reflecting unbiased, national annual estimates of visit occurrences for the portion of the population meeting the study inclusion and exclusion criteria

[b] Out of the 1,659 survey visits as which fibromyalgia was diagnosed, IBS ($n=17$; Relative Standard Error [RSE] = 32%) and lupus ($n=25$; RSE = 35%) and general anxiety disorder (RSE = 35%) were either reported at less than 30 visits and/or had a RSE > 30%. Per the NCHS, the estimate for these variables in this table are potentially unreliable due to the small count (and/or elevated RSE value). Caution is urged in interpreting this estimate

[c] Out of the 1,659 survey visits as which fibromyalgia was diagnosed, sleep disorder, cognitive function symptoms, cramps/spasms, weight gain, stomach pain, nausea, diarrhea and itching was reported at less than 15 visits. Per the NCHS, these estimates are entirely unreliable and thus not reported in this table even though the variables were included in the model

The study found that the implementation of the modified 2010 criteria, which had a sensitivity of 84% and a specificity of 87%, was immediately followed by a spike in fibromyalgia diagnoses from 0.58% in 2010 to 0.99% in 2011 [7]. This increase in prevalence contrasts with the sharp decline in individuals diagnosed with fibromyalgia shortly after the introduction and adoption of the modern criteria in 2016, with diagnosis rates dropping from around 0.8% throughout the early 2010s to 0.27% by 2019. This corroborates a study conducted by Wolfe et al. in 2023, which found the 2016 criteria to be associated with a significantly large percentage of fibromyalgia patients who do not satisfy the criteria despite being FM+ (39.7%), supporting the idea that the specificity of the 2016 criteria could limit the number of FM + diagnosis [6]. A direct comparison of the 1990, 2010, and modified 2010/2011 ACR fibromyalgia criteria conducted by Jones et al. found that the modified 2010/2011 criteria resulted in a significantly higher fibromyalgia prevalence than those of 1990 and 2010, with an increase from 1.7% in 1990 to 5.4% under the modified 2010/2011 criteria [18]. Our findings mirror this dramatic shift with the sharp increase in fibromyalgia prevalence in NAMCS visits after the implementation of the 2010 criteria - rising from 0.58 to 0.99%.

Based on the findings of this study, we hypothesize that perhaps the specificity of the 2016 criteria for fibromyalgia diagnosis, which aimed to minimize the misclassification of regional pain disorders and combine patient reports of the severity of the symptoms (FS score) with a physician assessment moved too far in the categorical direction for a disorder as complex and multi-dimensional as fibromyalgia [7]. This conjecture is supported by Ablin et al., who, in their comparative analysis of the two criteria, found that all misclassified individuals failed to meet generalized pain requirements, and no other variables contributed [19]. Furthermore, the minimum WPI score requirement for a fibromyalgia diagnosis only increased from three in the 2011 criteria to four in the 2016 criteria. This one point adjustment resulted in 13.8% of cases that were positive under the 2011 criteria failing to meet the new generalized pain requirement [19]. Fluctuations in prevalence based on narrowing the 2010 criteria raise important questions about the current 2016 diagnostic methods and their applicability in a clinical setting.

Historically, the viability of the diagnostic criteria in a clinical setting was a common complaint of those utilizing the 1990 ACR criteria, despite its relative succinctness as it mainly relied on the physical examination of "tender points" [4]. It seems that in return to the relative concision of the diagnostic criteria, the 2016 criteria may have also reintroduced problems with underrepresenting the apparent broad spectrum of fibromyalgia despite the attempt to use the FS scale to include the self-report of the patient and the existence of the symptoms on a continuum [7]. Therefore, patients suffering from a manifestation of fibromyalgia centered on the various associated symptoms such as fatigue, sleep disturbances, cognitive changes, or somatic complaints may be documented as FM- due to not meeting the specific WPI scores requirement of the 2016 criteria (≥ 7 and SSS ≥ 5 or WPI 4 to 6 and SSS ≥ 9) despite the intent to use generalized pain criteria to ensure that other local pain syndromes were not captured. For instance, a patient with severe fatigue and emerging cognition issues who only experiences minor pain might be misdiagnosed. This pain-centric approach to diagnosis has been documented to disproportionately

cause misdiagnosis across multiple disorders among women, who comprise the main fibromyalgia demographic and 60.2% of our study population [20, 21].

The multivariable logistic regression model was used to explore possible associations between fibromyalgia and various comorbidities and somatic symptoms available in the NAMCS, to determine their predictive capabilities of a fibromyalgia diagnosis. This model examined conditions relevant to fibromyalgia available in the NAMCS dataset while adjusting for demographic/visit characteristics and common symptoms. These conditions include rheumatoid arthritis, lupus, depression, anxiety, diabetes, sleep disturbances, repetitive injuries (tendonitis), cognitive symptoms, fatigue, and irritable bowel syndrome. Evidence of an association between fibromyalgia diagnosis and some comorbidities and somatic symptoms was found, adding to the preponderance of evidence around the complex web of disorders associated with fibromyalgia in a clinical setting. Visits at which rheumatoid arthritis was diagnosed showed 5.51 times greater odds of a fibromyalgia diagnosis (95% CI 2.87, 10.58) compared to visits without rheumatoid arthritis. This reinforces the idea that the overlap between rheumatoid arthritis and fibromyalgia that was documented in the 2016 revisions persists [7]. However, in the current study, visits with other rheumatic diseases such as lupus showed only 2.19 times greater odds of a FM diagnosis (95% CI 0.77, 6.21) compared to visit without lupus. This finding is not consistent with previous research as noted by Haliloglu, et al. whom observed the prevalence of fibromyalgia in patients with other rheumatological diseases such as lupus, Sjögren's disease, and osteoarthritis (amongst others related diseases) to be a clinical common problem in FM [22]. Similarly to Haliloglu, et al. but contrary to our study, in a study completed by Denvir, et al. that attempted to determine the prevalence of rheumatic diseases, FM was diagnosed in 120 patients (8.9%, 95% CI 7.3–10.5%) who met lupus criteria [23].

In the current study there was a low prevalence of visits with both a diagnosis of fibromyalgia and depression. Nearly 12% of visits included in our study (11.6%) had a diagnosis of depression. Amongst those with FM, only 23% had depression, a low percentage despite the evidence of the prevalence of depression in fibromyalgia [24]. This potential underreporting adds to the diagnostic challenges as individuals with FM may be reluctant to acknowledge depression symptoms given the stigma associated with mental health issues [25]. The overlap of symptoms that depression and FM can have (such as fatigue, pain, and cognitive issues), the limited screening for depression, and patients' inability to describe and communicate depressive symptoms also complicate the diagnosis of FM [26]. However, according to our analysis, visits at which depression was diagnosed were shown to have 2.61 times greater odds of a fibromyalgia diagnosis (95% CI 1.90, 3.58) compared to visits without. Similar findings on the prevalence of rheumatoid arthritis and depression in the fibromyalgia population have been reported in other studies [27, 28]. Therefore, individuals diagnosed with depression first may be more likely to be diagnosed with fibromyalgia; but not all individuals with fibromyalgia may report depressive symptoms or receive a proper diagnosis of depression.

Other comorbidities and somatic symptoms commonly associated with fibromyalgia in the literature, such as anxiety, sleep disturbances, and IBS did not demonstrate significant relationships to fibromyalgia diagnosis in the current analysis. For example, a 2021 study reported that 55% of fibromyalgia patients self-reported insomnia [29]. However, in our study, we estimated that while individuals with sleep disorders had an odds ratio of a fibromyalgia diagnosis of 1.95, the small number of visits at which a sleep disorder was diagnosed yielded a broad associated confidence interval (95% CI 0.63–6.01).

Recent literature has suggested that metabolic syndromes may increase the risk of an individual being diagnosed with fibromyalgia, resulting in up to 5.6 times higher risk [30, 31]. Our results indicate only a minimal association between fibromyalgia diagnosis and metabolic dysfunction. Diarrhea specifically is estimated to exhibit an odds ratio of 0.27 (95% CI 0.11, 0.62), decreasing the odds of fibromyalgia diagnosis by 73%. However, the small number of visits identified as involving metabolic dysfunction in the data may at least partly explain this lack of relationship. These discrepancies further serve to highlight the complexity of diagnosis and, therefore, the challenge of effectively treating fibromyalgia in clinical settings. While the relationship between fibromyalgia and various comorbidities and somatic symptoms remains unclear, the association of fibromyalgia and factors like depression or rheumatoid arthritis reinforces the impact of fibromyalgia on a patient's experienced quality of life as documented in previous studies [6, 32–34].

Despite discrepancies in comorbid conditions, most of the patient characteristics included in the model had the expected impact on the odds of fibromyalgia diagnosis. Female individuals exhibited 2.83 times increased odds of fibromyalgia diagnosis compared to male individuals (95% CI 1.95, 4.11). This has been historically documented as the main fibromyalgia patient demographic, and was further confirmed here [1, 18]. Race also played a part in the odds of diagnosis, with non-White individuals having 44% lower odds of a fibromyalgia diagnosis than White individuals (OR: 0.56, 95% CI 0.37, 0.84). Opposite findings were reported among the active components of the U.S. armed forces in 2020, where non-Hispanic Black individuals had twice the odds of a fibromyalgia diagnosis compared to non-Hispanic White

individuals [34]. Reasons for potential race and sex disparities are unknown. They could be caused by some sort of external diagnostic bias, as documented in other disorders [21, 35]. These findings highlight the importance of physicians being made aware of these disparities to minimize unintentional bias in diagnosis and to recognize the individualized and patient-centered presentation of symptoms.

Conclusions

The results obtained in this study confirm the complexity of fibromyalgia and the careful consideration of balancing patient characteristics and the sensitivity and specificity in fibromyalgia diagnostic criteria. The proportion of NAMCS visits resulting in a diagnosis of fibromyalgia was consistently higher under the 2010 fibromyalgia criteria but has decreased significantly since the implementation of the 2016 criteria. Before the 2016 criteria, the proportion hovered steadily around 0.8% of visits; in the years since the numbers have been decreasing. It is believed this discrepancy is due to the 2016 fibromyalgia criteria's move toward a more pain-focused approach to diagnosis as opposed to the symptoms-based diagnosis of the 2010 and 2011 criteria. The current study also suggests an increase in the odds of a fibromyalgia diagnosis in populations with specific comorbidities such as rheumatoid arthritis (5.51 times the odds) and depression (2.61 times the odds). However, not all individuals with fibromyalgia may report depressive symptoms or receive an accurate diagnosis of depression. Individuals with fibromyalgia may hesitate to acknowledge depression due to mental health stigma. The authors note the higher odds involving only a rheumatoid arthritis diagnosis rather than other rheumatic diseases such as lupus, included in the current study, despite the known prevalence of lupus in patients with FM.

Further, the results of this study suggest that the 2016 ACR-established research diagnostic criteria may need to be revised again, given the steady decrease in fibromyalgia diagnoses over most of the last decade. The fibromyalgia-related evidence in this study suggests potential shortfalls of the 2016 criteria, which might have reintroduced issues with underrepresenting the broad spectrum of fibromyalgia, leading to patient frustration, patients being misdiagnosed or undiagnosed, and healthcare providers not getting a complete picture of the patient's condition. Moreover, future studies should be designed to identify other possible factors responsible for the decrease in FM diagnosis and the relationship between FM, mental health issues, and rheumatologic diseases, given the overlap of pain, physical limitations, and fatigue. Finally, the authors highlight the importance and relevance of the robust, national data reported and hope it helps readers form current, accurate inferences about the prevalence of fibromyalgia in the United States. We further hope the results foster clinician awareness of the relationship between specific comorbidities and somatic symptoms, individual patient characteristics, clinical manifestations, and a final diagnosis of fibromyalgia.

Strengths and limitations

This study has several considerable strengths. A well respected and nationally representative database was utilized. Further, a sample size of nearly a quarter of a million patient visits over a nearly decade-long timeframe met the study inclusions/exclusion criteria and was utilized in all analyses. Nearly 40% of the visits included in the study were by male patients. This high male visit percentage in a disease that is more common in women allows for a thorough investigation into any differences by sex. This study also offers insight into the nature of fibromyalgia diagnosis trends and associations with somatic symptoms, some rheumatic diseases, and relevant comorbidities of interest, such as depression. Finally, it is important to note that the NAMCS survey uses physician-based reporting to collect data, helping to reduce/prevent bias found in self-reported patient surveys. However, there were database limitations.

The most recently available decade worth of NAMCS data was utilized, but the survey was not conducted in 2017, resulting in nine years' worth of data being included in this study. Information bias may be present in the inclusion criteria as variables of interest included in the analyses were restricted by the data available in the NAMCS survey. The authors used information on somatic symptoms defined by the ACR 2010 diagnostic criteria and other rheumatoid diseases of interest, such as lupus. There could also be an underrepresentation of comorbidities due to relevant diagnosis codes or reasons for visits used by the provider. Although the NAMCS survey uses a multi-stage probability sample design that covers all 50 states and Washington, DC, it could exclude certain types of healthcare settings and providers. Further, its focus is on visits rather than individuals, which means it may not fully reflect the overall US population demographics regarding healthcare utilization and access. 90% of visits in the study occurred in areas classified as urban, which is not commensurate with the urban/rural distribution of the US population. However, the survey uses the Office of Management and Budget definitions for urban and rural classifications, aligning with US Census Bureau data. This ensures consistency in categorizing urban and rural areas across the survey and population estimates.

Abbreviations

ACR	American College of Rheumatology
SS / SSS	Symptom Severity Scale
WPI	Widespread Pain Index

FS	Fibromyalgia Score
PDS	Polysymptomatic Distress Scale
ICD	International Classification of Diagnoses
PHQ	Patient Health Questionnaire
NAMCS	National Ambulatory Medical Care Survey
CDC	Centers for Disease Control and Prevention
NCHS	National Center for Health Statistics
MSA	Metropolitan Statistical Area
BMI	Body Mass Index
RFV	Reason For Visit
OR	Odds Ratio
CI	Confidence Interval
RSE	Relative Standard Error
FM	Fibromyalgia

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Author contributions
All authors contributed to the study's conception and design. MJ performed data management and analysis. AR and SAM wrote the first draft of the manuscript. All authors reviewed, commented on and edited all previous versions of the manuscript and all authors read and approved the final manuscript.

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Data availability
The datasets analyzed during the current study are available in the Centers for Disease Control and Prevention (CDC) repository. https://www.cdc.gov/nchs/namcs/documentation/index.html.

Declarations

Ethics approval and consent to participate
This is an observational study using de-identified, publicly available datasets and was therefore considered not human subject research by the Campbell University IRB.

Consent for publication
Not applicable.

Competing interests
The authors declare no competing interests.

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