Delay in fibromyalgia diagnosis and its impact on the severity and outcome: a large cohort study

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Abstract

Objective

To evaluate the impact of the diagnostic delay on fibromyalgia (FM) severity.

Methods

Data were retrospectively extracted from a large database of patients with FM belonging to the Italian Fibromyalgia Registry (IFR) residents on the Marche Region. The diagnosis of FM was formulated according to the 2016 American College of Rheumatology (ACR) criteria. The following information was obtained: time to diagnosis [categorised in early diagnosis (ED) if FM diagnosed within one year, late diagnosis (LD) if FM diagnosed more than 1 year but less than 5 years, and very late diagnosis (VLD) if FM diagnosed over 5 years from symptoms onset], revised Fibromyalgia Impact Questionnaire (FIQR), modified Fibromyalgia Assessment Status (FASmod), and Polysymptomatic Distress Scale (PDS) [consisting of the sum of Widespread Pain Index (WPI) and Symptom Severity Scale (SSS)].

Results

The study included 616 FM patients (92.2% female), with a mean disease duration of 6.46 (SD 4.14) years and a mean (SD) time to diagnosis of 3.45 (2.39) years. The ED group included 169 patients, the LD 320 patients, and the VLD 127 patients. Comparing the differences among groups, a significant difference in disease severity was observed in all the clinimetric indices in increasing the time to reach the diagnosis (p=0.000001): the median PDS scores were 13.36 (interquartile range [IQR] 7.00–20.00), 16.09 (IQR 9.00–22.00), and 23.00 (IQR 18.25–26.00) for ED, LD, and VLD, respectively.

Conclusion

Delayed diagnosis is associated with poorer patient outcomes, including worsening severity.

Key words

fibromyalgia, early diagnosis, diagnostic delay, disease severity, patient-reported outcomes

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Introduction

Fibromyalgia (FM) is a chronic and multifaceted condition, hallmarked by chronic widespread musculoskeletal pain alongside a spectrum of additional symptoms including fatigue, disrupted sleep patterns, depressive states, and anxiety (1-3). Within Italy, the prevalence of FM is approximated at 2.2% among the general population (4). It ranks as the second most prevalent rheumatic disease, trailing only behind osteoarthritis (5). Despite advances in comprehending its pathological underpinnings, as many as 75% of FM patients remain incorrectly diagnosed (6). These persistent characteristics not only impose significant economic burdens on individuals and society but also detrimentally impact the patient's life quality and their interpersonal connections with friends, family, and employers (7-10).

For medical professionals, especially general practitioners who manage the majority of FM cases, diagnosing FM poses significant challenges (11, 12). Diagnostic delays (DD) in FM are associated with increased healthcare expenditures, diminished therapeutic outcomes, and heightened financial strain (13-15). However, the influence of DD on the disease's severity and the patient's symptom profile remains underappreciated.

This study aimed to investigate the impact on disease severity of the duration between the initial presentation of symptoms and complaints and the establishment of a definitive FM diagnosis.

Methods

Setting and patients

The study, which was retrospective and cross-sectional in design, assessed data obtained from the records of residents of the Marche Region who were diagnosed with FM and registered with the Italian Fibromyalgia Registry (IFR) (16). Enrolment involved patients from a tertiary-level rheumatology centre (Rheumatology Unit, "Carlo Urbani" Hospital, Università Politecnica delle Marche), designated as the regional hub for FM diagnosis and treatment. The cross-sectional analysis included patients whose FM diagnosis was established by FS, a rheumatologist with over three decades of experience in FM management. Diagnosis was based on the American College of Rheumatology (ACR) 2016 criteria (17). Despite the introduction of newer criteria, the ACR 2016 standards remain highly valuable for clinical and epidemiological studies aimed at identifying FM patients (18).

The IFR includes adult patients across all disease severity levels. Exclusion criteria encompassed individuals with conditions that could hinder clinical and clinimetric assessment (such as coexisting inflammatory arthritis or severe symptomatic osteoarthritis) and those with major neurological disorders affecting the peripheral nervous system or central nervous system (for example, those with polyneuropathies, Parkinson's disease, Alzheimer's disease, or other forms of dementia). The inclusion in IFR is anonymous and voluntary, with each patient providing informed consent. The local Ethics Committee (Comitato Unico Regionale - ASUR Marche, n. 1970/AV2) granted approval for all research methods employed in the study.

Demographic variables

The objective behind selecting variables for the IFR was to compile a coherent, needs-oriented, and streamlined dataset. Key sociodemographic information collected included age, sex, body mass index (BMI), marital status (categorised as single, married, divorced/separated), levels of formal education (spanning from primary school to university), and onset of symptoms.

Clinimetric assessment

The clinimetric evaluation of IFR was based on the traditional questionnaires employed for FM, namely the revised Fibromyalgia Impact Questionnaire (FIQR) (19), the modified self-administered Fibromyalgia Assessment Status (FASmod) (20, 21), the Polysymptomatic Distress Scale (PDS) scale (22).

The FIQR is an updated version of the original Fibromyalgia Impact Questionnaire (FIQ), realised to address the limitations of the initial tool. The FIQR comprises twenty-one 0–10 numerical

rating scales (NRS, with 10 indicating the "worst" condition), exploring three primary health domains: function, overall impact, and symptoms. All queries are reflective of the past seven days. The final FIQR score, which ranges from 0 to 100 (with higher scores denoting increased disease severity), is computed by dividing the sum of the nine-item function domain (0–90 range) by three, maintaining the sum of the two-item overall impact domain (0–20 range) as is, and halving the sum of the ten-item symptom domain (0–100 range). These sub-scores are subsequently aggregated (23). The established thresholds for disease severity are: 0–23 for remission, 24–40 for mild, 41–63 for moderate, 64–82 for severe, and 83–100 for very severe conditions (24).

The FASmod consists of two parts. The initial section includes two questions regarding fatigue and unrefreshing sleep over the last week, each rated on a 0-10 NRS, with a maximum subscore of 20. The second section features a mannequin diagram highlighting 19 body areas, where patients identify their painful regions, each scored as 1. The overall FASmod score ranges from 0 to 39, with severity cut-offs set at 0–12 for remission, 13–20 for mild, 21–28 for moderate, 29–33 for severe, and 34–39 for very severe conditions (24).

The PDS is based on variables from the 2016 ACR criteria, adapted for surveys and clinical studies, incorporating the Widespread Pain Index (WPI) and the Symptom Severity Scale (SSS) for calculation. The WPI evaluates pain in 19 specific body areas over the preceding week, with each area contributing a score of 1, and higher totals indicating more extensive pain. The SSS, comprising six items, explores the presence of clinical symptoms (such as lower abdominal pain, headaches, and depression) over the past six months and the severity of cognitive symptoms (fatigue, cognitive difficulties, waking up tired) over the last week, with a 4-point scale for cognitive symptoms (0=no issue, 3=severe issue). These components are summed for a total score, where higher values (up to a maximum of 12) signify greater symptom severity. The WPI and SSS scores combine to form a PDS total score (range 0–31), with higher scores reflecting more pronounced features of disease severity (25). PDS severity thresholds are: 0–5 for remission, 6–15 for mild, 16–20 for moderate, 21–25 for severe, and 26–31 for very severe conditions (24).

Table I. Demographic and clinical features of the patients.

Variable	Mean	Median	SD	IQR
Age (years)	52.36	53.00	9.34	45.50 - 59.00
BMI	26.20	26.46	2.69	24.40 - 27.70
Disease duration (years)	6.46	5.00	4.14	3.00 - 9.00
Diagnostic delay (years)	3.45	3.00	2.39	1.00 - 5.00
FIQR_overall impact	8.62	9.00	5.56	3.00 - 13.00
FIQR_physical function	12.43	12.00	6.96	6.00 - 17.66
FIQR symptoms	25.46	26.25	11.30	16.50 - 34.50
FIQR total score	46.71	48.08	21.78	27.58 - 63.91
FASmod	23.01	24.00	9.28	15.00 - 31.00
PDS total score	16.36	17.00	8.90	8.00 - 23.00
WPI	10.29	10.00	4.95	6.00 - 15.00

SD: standard deviation; IQR: interquartile range; BMI: body mass index; FIQR: revised Fibromyalgia Impact Questionnaire; PDS: Polysymptomatic Distress Scale; SSS: Symptom Severity Scale; WPI: Widespread Pain Index; FASmod: modified Fibromyalgia Assessment Status.

Statistical analysis

Patients were classified into three categories according to the duration between symptom onset and diagnosis: those receiving an early diagnosis (ED) had symptoms for less than 1 year before being diagnosed; a late diagnosis (LD) was assigned to individuals whose symptoms began more than 1 year but less than 5 years prior to their diagnosis; and a very late diagnosis (VLD) referred to patients whose symptoms had been present for more than 5 years before they were diagnosed.

The variables investigated in this study are presented as median values and, where appropriate, interquartile ranges (IQR), alongside mean values and standard deviations (SD). The Shapiro-Wilk test was utilised to assess the normality of the distribution. For nominal variables, when appropriate, univariate comparisons were conducted using the Chi-square (χ^2) test or Fisher's exact test. The Kruskal-Wallis test was applied to evaluate differences in disease severity across categories of diagnostic delay, due to the non-normal distribution of the total scores and subscales for the FIQR and FASmod, as well as for the PDS and WPI. Results were reported as two-tailed *p*-values, with significance established at *p*-values less than 0.05. The analyses were performed using MedCalc version 22.0 for Windows (MedCalc Software, Mariakerke, Belgium).

Results

The study sample included 616 FM patients (92.2 % female), with a mean age of 52.36 (SD 9.34) years and a mean disease duration of 6.46 (SD 4.14) years. The 75.3% of patients were married and the majority held college degrees (high school education or above). The patients were moderately overweight, with a mean BMI of 26.20 (SD 2.69) kg/m^2. For the demographic variables studied (age, marital status, education) and for the BMI, no significant differences emerged among the three distinct groups categorised according to DD.

Regarding disease severity, the median value of FIQR was 48.08 (IQR 27.58–63.91), FASmod was 24.00 (IQR 15.00–31.00), PDS was 17.00 (IQR 8.00–23.00), and WPI was 10.00 (IQR 6.00–15.00). According to FIQR disease severity cut-off points, 28 patients (4.5%) had very severe FM, 136 patients (22.1%) had severe FM, 197 patients (32.0%) had moderate FM, 138 patients (22.4%) had mild disease and 117 patients (19.0%) were in remission. The demographic and clinical features are summarised in Table I.

The mean time for reaching the FM diagnosis was 3.45 (SD 2.39) years. Men and women did not differ in diagnostic delay (F-ratio = 0.201, *p*=0.654). Ac-

Table II. Demographic and clinical features of the patients, according to categories of diagnostic delay (early diagnosis, late diagnosis and very late diagnosis).

	Delay categorisation											
	Early diagnosis				Late diagnosis				Very late diagnosis			
	Mean	Median	SD	IQR	Mean	Median	SD	IQR	Mean	Median	SD	IQR
Age (years)	51.69	52.00	9.64	45.00 - 58.25	52.49	53.00	9.45	46.00 - 59.00	52.93	54.00	8.65	46.00 - 59.00
BMI	26.16	26.50	2.60	24.40 - 27.70	26.11	26.41	2.47	24.51 - 27.70	26.47	26.60	3.26	24.50 - 28.27
Disease duration (years)	3.53	3.00	1.69	2.75 - 4.00	5.84	5.00	3.01	4.00 - 7.00	11.93	11.00	3.80	10.00 - 14.00
Diagnostic delay (years)	1.10	1.00	0.82	1.00 - 1.00	3.27	3.00	1.22	2.00 - 4.00	7.06	7.00	1.65	6.00 - 7.00
FIQR overall impact	6.79	5.00	5.62	2.00 - 10.00	8.68	8.50	5.37	4.00 - 13.00	10.88	11.00	5.09	7.25 - 15.00
FIQR physical function	10.00	8.66	6.82	4.66 - 13.66	12.39	12.00	6.70	6.33 - 17.66	15.76	17.00	6.48	10.75 - 20.25
FIQR symptoms	21.36	21.00	11.35	11.50 - 29.62	25.16	26.00	10.91	16.50 - 34.50	31.67	32.50	9.43	26.62 - 38.87
FIQR	38.61	35.00	21.80	18.62 - 55.83	46.35	47.33	20.81	27.58 - 63.50	58.38	61.16	18.96	48.58 - 71.04
FASmod	19.76	19.00	9.43	12.00 - 28.00	22.55	23.00	8.73	16.00 - 29.00	28.48	31.00	8.02	26.00 - 34.00
PDS	13.36	10.00	8.01	7.00 - 20.00	16.09	16.00	9.10	9.00 - 22.00	21.03	23.00	7.58	18.25 - 26.00
WPI	8.65	7.00	4.99	5.00 - 13.00	9.98	9.00	4.52	6.00 - 14.00	13.26	14.00	4.67	10.00 - 17.00

SD: standard deviation; IQR: interquartile range; BMI: body mass index; FIQR: revised Fibromyalgia Impact Questionnaire; FASmod: modified Fibromyalgia Assessment Status; WPI: Widespread Pain Index; PDS: Polysymptomatic Distress Scale; SSS: Symptom Severity Scale.

cording to the DD categorisation, 169 (27.43%) patients received an ED, 320 (51.95%) patients a LD, and 127 (20.62%) patients a VLD.

Examining the three groups, a reduced DD was significantly associated with a lower disease severity: the median FIQR scores were 35.00 for ED, 47.33 for LD, and 61.16 for VLD (Kruskal-Wallis test, p=0.000001). Similarly, the median FASmod scores were 19.76 for ED, 23.00 for LD, and 31.00 for VLD (p=0.000001), while the median PDS scores were 13.36 for ED, 16.09 for LD, and 23.00 for VLD (p=0.000001) (Table II, Fig. 1).

Exploring more in detail the FIQR, a delayed diagnosis showed a direct impact also in its subdomains (physical activity, overall impact and symptoms). The three items that showed a greater severity according to a delayed diagnosis include item 15, related to sleep quality (mean 7.15); item 13, related to fatigue (mean 6.82); item 12, related to pain (mean 6.79) (Fig. 2).

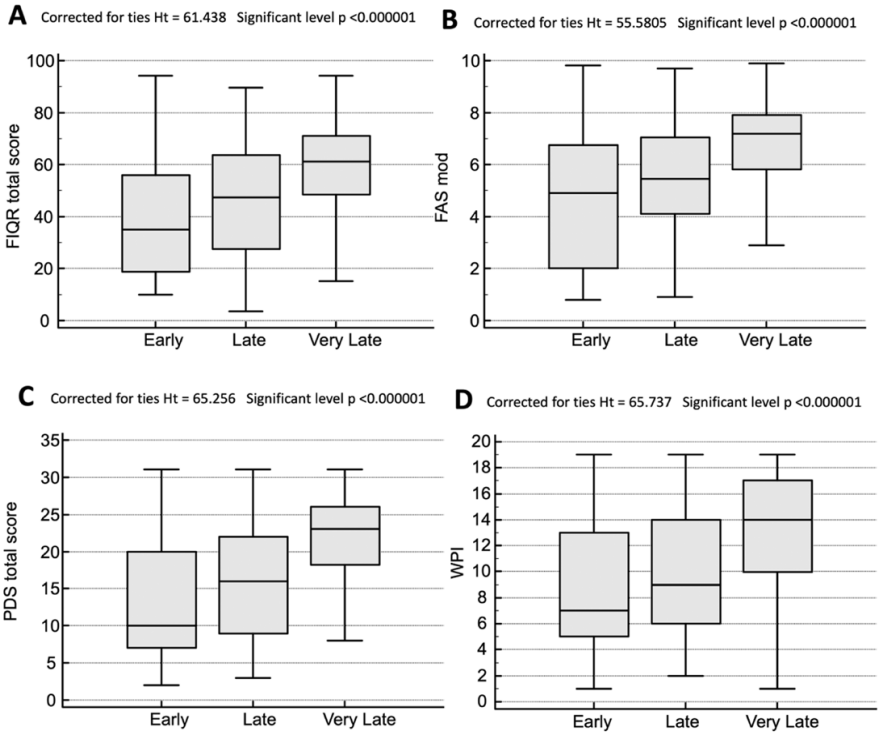

Fig. 1. Box and whisker plots of fibromyalgia quantitative measures of severity and categories of diagnostic delay (early diagnosis, late diagnosis and very late diagnosis).
The boxes represent the interquartile range. The middle lines inside boxes are the medians. The highest and lowest values are the maximum and the minimum data recorded. Kruskal-Wallis test for the three categories: (**A**) FIQR, Ht = 61.438, p=0.000001. (**B**) FASmod, Ht = 55.580, p=0.000001. (**C**) PDS, Ht = 65.256, p<0.000001. (**D**) WPI, Ht = 65.737, p=0.000001.
FIQR: revised Fibromyalgia Impact Questionnaire; FASmod: modified Fibromyalgia Assessment Status; PDS: Polysymptomatic Distress Scale; WPI: Widespread Pain Index.

Discussion

This study demonstrated that the severity of FM is correlated with the duration taken to diagnose it. A diagnosis made within a period shorter than one year is associated with reduced disease severity. Despite advancements in diagnostic techniques, the availability of screening tools, and the enhanced awareness among physicians in recent years, the interval between the onset of symptoms and the diagnosis of FM remains significantly extended (14). Various forms of oversight can contribute to DD, including the misinterpretation of test outcomes, an oversight in acknowledging or addressing specific symptomatology, or a failure to refer the patient to a specialist or hospital for further evaluation or treatment.

Experts familiar with the diagnosis of FM assert that this condition can be identified beyond the use of specific criteria (26). The debate over the diagnostic criteria for FM has been signifi-

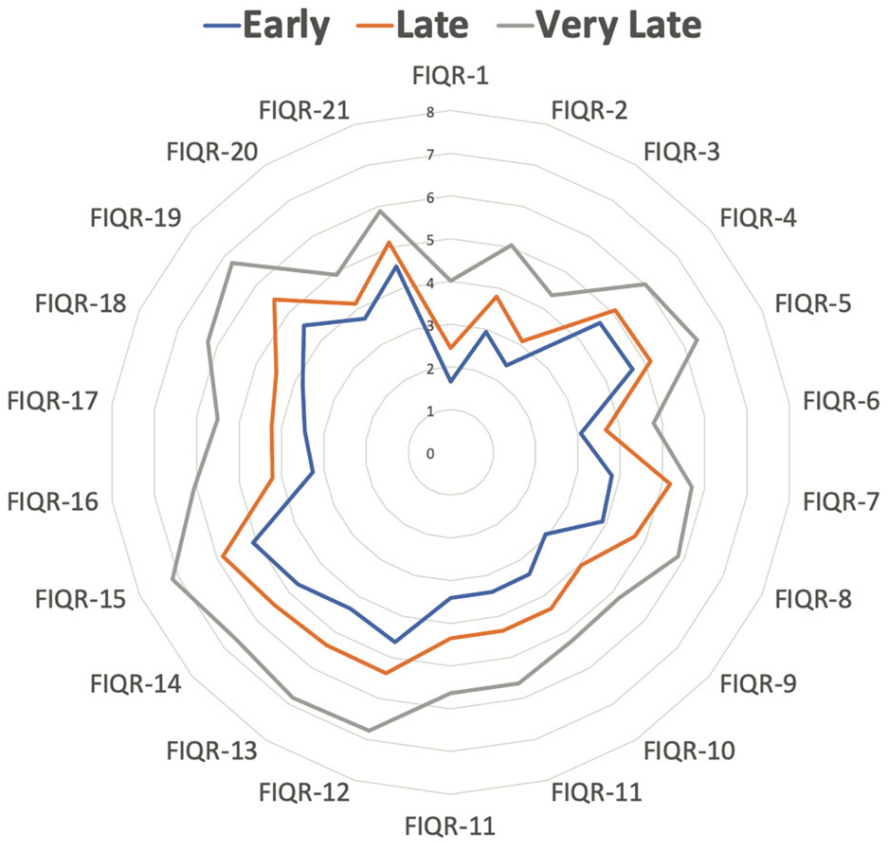

Fig. 2. Spydergrams of the FIQR domains according to the categories of diagnostic delay (early diagnosis, late diagnosis and very late diagnosis).
The domain scores are plotted from 0 (best, at the centre) to 10 (worst, outside). FIQR function from items 1 to 9; FIQR overall impact items 10 and 11; FIQR symptoms from items 12 to 21.
FIQR: revised Fibromyalgia Impact Questionnaire; FIQR1: brush or comb hair; FIQR2: walk continuously for 20 minutes; FIQR3: prepare a homemade meal; FIQR4: vacuum, scrub or sweep floors; FIQR5: lift and carry a bag full of groceries; FIQR6: climb one flight of stairs; FIQR7: change bed sheets; FIQR8: sit in a chair for 45 minutes; FIQR9: go shopping for groceries; FIQR10: cannot achieve goals; FIQR11: feel overwhelmed; FIQR12: pain rating; FIQR13: fatigue rating; FIQR14: stiffness rating; FIQR15: sleep quality; FIQR16: depression level; FIQR17: memory problems; FIQR18: anxiety level; FIQR19: tenderness level; FIQR20: balance problems; FIQR21: environmental sensitivity.

cant over the years and much work has been done in the last few decades to enhance the FM screening and diagnosis criteria (18). In 1990, the ACR established a set of standards to differentiate FM from other chronic pain conditions (27). Based on tender point examinations, which showed tenderness in at least 11 out of 18 pain locations in patients with chronic pain for an FM diagnosis, the 1990 ACR criteria were established. The 1990 ACR criteria, however, had several drawbacks. Primary care physicians found it challenging to perform the tender point examination, and it overlooked significant concomitant symptoms like fatigue, cognitive dysfunction, and sleep disturbance (28, 29). Therefore, in 2010/2011, the ACR proposed new FM criteria (25).

The notion of "widespread pain" was added to the 2010/2011 ACR criteria for FM, which eliminated the tender point examination. A systemic symptom-based assessment of fatigue, sleep issues, and somatic and cognitive disturbances was also included in these criteria. The WPI, which is used to determine the number of pain locations, does not take the spatial distribution of those locations into account, therefore applying these criteria may result in misclassification. Moreover, there is no accepted definition of generalised pain, making it challenging to distinguish between myofascial pain syndrome and other localised functional pain syndromes. The shortcomings of the 2010/2011 ACR criteria were briefly summarised as follows (30): dilution, inconsistency, loss of specificity, and the inability to detect comorbid FM in patients with other illnesses. The ACR released updated criteria in 2016 to address these issues (17). The 2016 ACR criteria are still the most accurate, despite ongoing efforts to increase the accuracy of FM diagnosis; for this reason, clinical practice and epidemiological research should employ these criteria (31).

However, the complexity of correctly categorising symptoms and the plethora of diagnostic and classification criteria – notably, the American Pain Society's proposal of entirely different diagnostic criteria in 2019 compared to the ACR 2016 (32) – remain significant challenges, especially in the context of general medicine. In this regard, the Royal College of Physicians of the United Kingdom has recently highlighted the need to provide "digestible" guidelines for the recognition and diagnosis of FM in both primary and secondary care settings (33).

DD inevitably lead to delays in treatment, but the implications extend beyond that. DD are associated with an increased number of treatments that may be compounded by significant side effects. In addition to increasing the number of medical consultations, the DD is linked to an increased number of surgical procedures these patients undergo, with diminished benefits derived from the surgical intervention itself (15).

DD is challenging to measure and has often been attributed to individual shortcomings rather than systemic or organisational flaws. Notably, there is a paucity of data regarding the duration required to diagnose FM. To our knowledge, no prior research has explored or pinpointed the factors influencing the time to FM diagnosis with the use of a relatively objective data source, as has been done in our study. Our research endeavoured to establish a timeline for the onset of initial complaints as a starting point for calculating the duration until an FM diagnosis is confirmed, marking both the novelty and challenge of this investigation. In a preceding study by Choy and colleagues, which encompassed 800 FM patients across six European countries, Mexico, and

South Korea, the average duration to obtain a definitive FM diagnosis was reported as 2.3 years, with most countries reporting times ranging from 2.1 to 2.7 years. Furthermore, patients who sought advice from three or more physicians before receiving an FM diagnosis had consultations with an average of 3.7 physicians (14).

The substantial nature of DD is corroborated by studies emanating from diverse geographical regions. In a survey conducted by Clark *et al*. it was reported that patients in Latin America and Europe faced delays of 3.5 and 2.5 years, respectively, prior to obtaining an accurate diagnosis of FM (34). Furthermore, significant DD have been documented in the United States and Egypt, with findings indicating that patients often undergo a waiting period of up to five years to secure a definitive diagnosis of FM (6, 35). The data from our study identify a delay of 3.4 years, positioning it within the, albeit wide, range reported by these cited studies.

Nonetheless, obtaining a diagnostic clarification that elucidates an individual's medical condition is critically important for patients. White *et al*. have provided evidence that a diagnosis of FM significantly increases patient satisfaction (36). Prolonged DD, extending over several years, can significantly intensify the frustration and dissatisfaction among patients who are already grappling with the debilitating effects of chronic pain.

To the best of our knowledge, this represents the first Italian study aimed at assessing the impact of DD on the severity of FM. The cornerstone of our study is the utilisation of an extensive, meticulously curated database. This database encompasses records of outpatient clinical encounters, offering a "real-world" perspective. A strength of this study is also the large sample.

Nonetheless, this study is not without its limitations. The foremost constraints pertain to the validity and generalisability of our findings, since this is a monocentric study. Thus, the extrapolation of the outcomes of our study to different healthcare settings or frameworks beyond Italy's boundaries may be limited. Multicentric studies are imperative to bolster our observations. Moreover, the assessment was cross-sectional. A ubiquitous challenge in opinion-based research is the potential for participants' inability to fully recollect their experiences and sentiments, a limitation that our study also shares. Respondents' feelings, attitudes, and perceptions are subject to temporal fluctuations. Our survey captures a snapshot of participants' experiences without delving into their temporal evolution.

In conclusion, this study reveals a significant delay in the diagnosis of FM, and the delay is associated to worse disease severity. Future clinical guidelines should focus on this issue, devising diagnostic protocols for both specialists and primary care providers to facilitate timely and accurate patient evaluations. Pursuing an expedited diagnosis for FM might also yield significant economic benefits and lower healthcare consumption.

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