Gender differences in the revised Fibromyalgia Impact Questionnaire: a pilot study

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Abstract

Objective

Fibromyalgia (FM) is a chronic syndrome characterised by widespread musculoskeletal pain associated with symptoms such as fatigue, sleep disturbances and cognitive impairment. Prevalence is higher in females but the application of the 2010/2011 and 2016 revision of the American College of Rheumatology (ACR) criteria reduced prevalence differences and the actual female:male ratio is approximately 3:1. Even if lately some studies have been conducted regarding FM gender differences, disease severity is still assessed using questionnaires, such as the Revised Fibromyalgia Impact Questionnaire (FIQR), designed and validated through a predominantly female sample. The aim of this pilot study was to compare the 21 items of the FIQR among male and female patients in order to evaluate the possible existence of a gender bias.

Methods

In this case-control study, consecutive patients with a diagnosis of FM (2016 ACR criteria) were asked to answer an online survey, including demographic characteristics, disease variables and the Italian version of the FIQR. Among the 544 patients that compiled the questionnaire, 78 patients, 39 males and 39 females, matched for age and disease duration, were consecutively enrolled in order to compare their FIQR scores.

Results

The univariate analysis showed that total FIQR scores and physical function domain scores were significantly higher in females and, among the 21 items of the FIQR, the female group obtained significantly higher scores in 6 of them. Our results showed that female patients obtain significantly higher scores in the FIQR total score and physical function domain score, in particular in 5 out of the 9 sub-items of the FIQR physical function domain.

Conclusion

These preliminary results indicate that the use of the FIQR as a severity index in male patients probably underestimates the disease impact in this group.

Key words

fibromyalgia, revised Fibromyalgia Impact Questionnaire, gender difference

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Introduction

Fibromyalgia (FM) is the second most common rheumatic disorder after osteoarthritis and is clinically characterised by the presence of chronic, musculoskeletal widespread pain (WP) associated with fatigue, sleep disturbances and other cognitive and somatic symptoms. It has been estimated that FM prevalence ranges between 0.7% and 4.4% (1), even if according to the diagnostic and classification criteria considered epidemiological differences exist (2). Higher prevalence of FM syndrome can be observed in Europe compared with other countries, with possible variation between different regions (3, 4). In Italy, the prevalence rate holds at 2.2% (5).

FM sex distribution is more controversial and partially unclear. FM is traditionally considered a female preponderant syndrome, considering that at least 90% (85-95%) of the diagnosis apparently occur in women (6). However, epidemiological studies conducted using the 2010 American College of Rheumatology (ACR) criteria (7) show that 60% or fewer FM subjects are women (8-10) while, using the modified 2011 ACR criteria (11), the female:male ratio appears even lower (2.3:1) (12). As far as we know, epidemiological studies regarding sex distribution according to the 2016 ACR criteria (13) has not been published yet. However, it can be stated that, according to the parameters applied and the criteria considered, sex distribution differs significantly. Different studies revealed that FM women present lower sensibility thresholds to pain than men (14, 15) and higher tender points count (TPC) (14, 16-18). According to the 1990 ACR criteria (19), a patient could be classified as affected by FM in the presence of WP and tenderness in at least 11 out of 18 tender points. Therefore, the use of TPC and 1990 ACR criteria probably presented weaker ability to identify men subjects, and this might be one of the reasons why fewer men were diagnosed as affected by FM. Moreover, the improper previous description of FM as a primarily female syndrome could have resulted in a subsequent selection bias and confirmation bias: because FM is perceived as a ‘female syndrome’, women are more likely than men to consider suffering from it and, for this reason, to refer for evaluation. On the other side, physicians could be more likely to think of and diagnose FM in women than men (10).

As a consequence of this apparent disequilibrium, studies investigating gender differences in FM are little and data available regarding gender differences in clinical features and disease impact among FM patients are limited and generally contradictory. Some studies report that the major clinical characteristics of FM are more present or greater in female subjects (17, 20-22), some studies report more severe symptoms, especially neuropsychiatric symptoms, and worse physical function in male subjects (21-23) and others report no clinical differences (16, 24). However, it must be considered that not only population samples in these studies are extremely different but, in the majority of cases, they also presented a female:male ratio excessively unbalanced towards female subjects. Also validated questionnaires as the Fibromyalgia Impact Questionnaire (FIQ) (25) and the Revised-Fibromyalgia Impact Questionnaires (FIQR) (26) were actually developed from predominantly female population and, for this reason, it can be hypothesised that they may present a gender bias. However, systematic comparison of the FIQR between male and female population have not been made yet. Aim of this pilot study was to compare the total score, the 3 domain scores and the 21 items that compose the FIQR among female and male patients in order to identify the possible presence of a gender bias in this disease impact questionnaire.

Materials and methods

Patients

This case control observational study included patients recruited between May 2020 and December 2022 at the Rheumatologic out-patient ‘Fibromyalgia Clinic’ of Policlinico Umberto I, University Hospital of Rome, Italy. Patients with a diagnosis of FM based on the 2016 ACR criteria (13) were included. Patients with comorbid conditions (*i.e.* inflammatory arthropathies, connective tissue diseases) were excluded. Each patient was asked to answer an online survey including questions about demographic characteristics, disease variables and the specific disease impact questionnaire (FIQR) administered through Google Modules platform. Totally, 544 patients compiled the questionnaire and, among these, 78 patients, 39 men and 39 women, matched for age and disease duration, were consecutively enrolled. Age was matched by 5 years and disease duration was matched by 3 years.

Survey
The survey included questions regarding demographic characteristics (sex, age, height, weight, education level and marital status), disease variables like the Wide-spread Pain Index (WPI) and the Symptoms Severity Scale (SSS) and the validated Italian version of the FIQR (27).

Widespread Pain Index
The WPI is a self-administered questionnaire firstly developed in 2002 (28) and then included in the 2010/2011 and 2016 ACR criteria (7,11,13) for FM. This questionnaire asks patients about pain or tenderness experienced over the previous week in 19 different sites. Each item is scored 0 or 1. The minimum total score is 0 and the maxi-mum is 19.

Symptoms Severity Scale
The SSS is a self-administered questionnaire, included in the 2010/2011 and 2016 ACR criteria (7, 11, 13), that asks patients to indicate the severity of several symptoms over the previous week, using the following scale: 0, no problem; 1, slight or mild problems (generally mild or intermittent); 2, moderate problems (considerable problems, often present and/or at a moderate level); and 3, severe problems (continuous, life-disturbing problems). Symptoms considered are fatigue, trouble thinking or remembering and waking up tired (un-refreshed). Patients are also asked whether they had cramps in the lower abdomen, depression or headache during the previous 6 months. Total score ranges between 0 and 12.

Revised Fibromyalgia Impact Questionnaire
The FIQR (26, 27) is a validated, self-administered questionnaire designed for evaluation of multidimensional aspects of FM. It consists of 21-items, 11-point numerical rating scales (0-10) designed to evaluate three main domains in relation to the previous week: physical function (9 items), overall impact (2 items) and FM symptoms (10 items). The physical function domain score is calculated as the algebraic sum of the 9 specific items divided by three, the overall impact domain score as the algebraic sum of the 2 specific items and the symptoms domain score as the algebraic sum of the 10 specific items divided by two. The total score is calculated as the algebraic sum of the three domains scores and it ranges between 0 and 100 but, even if higher scores indicate more severe disease, defined interpretative cut-offs are not currently established. Recently, an Italian multicentred study (29), proposed new cut-off values for three different FM specific questionnaires, including the FIQR total score. The proposed cut-off values for the FIQR total score were: ≤23 remission, >23 and ≤40 mild disease activity, >40 and ≤63 low disease activity, >63 and ≤82 severe disease activity and >82 very severe disease activity.

Statistical analysis
Continuous variables are shown as mean ± SD and categorical variables are shown as percentages (%). Mann-Whitney U test for independent groups was used to compare means of continuous variables (WPI, SSS, FIQR total score, FIQR physical function, FIQR overall impact, FIQR symptoms and FIQR questions 1-21). All statis-tical analyses were performed using the Statistical Package for Social Science version 27.0 software package for Windows (IBM Corporation, Armonk, NY) and a two-sided *p*-value <0.05 was considered statistically significant.

Table I. Demographic characteristics.

Characteristics	Mean ± DS
Age	46.0 (11.7)
Body Mass Index (BMI)	25.1 (5.6)
Education level	
Middle/High school diploma n (%)	58 (78.4)
Professional degree n (%)	16 (21.6)
Marital status	
Unmarried n (%)	32 (43.2)
Married n (%)	36 (48.6)
Divorced n (%)	6 (8.1)

Table II. Disease variables and FIQR scores.

Score	Mean ± DS
WPI	10.4 (4.9)
SSS	7.9 (2.5)
FIQR *total*	64.5 (20.3)
FIQR *physical function*	17.4 (7.3)
FIQR *overall impact*	13.0 (5.4)
FIQR *symptoms*	34.2 (9.7)

WPI: Widespread Pain Index; SSS: Symptoms Severity Scale; FIQR: Revised Fibromyalgia Impact Questionnaire.

Results

Thirty-nine males affected with FM were compared with thirty-nine females affected with FM, matched for age and disease duration. The demographic characteristics, disease variables and FIQR total, physical function, overall impact and symptoms scores of the total population considered are shown in Table I and II. The mean FIQR total score of our population was 64.5 (±20.3 DS); males obtained a mean FIQR total scores of 58.8 (±23.5 DS) while the mean score was 70.3 (±14.7 DS) in the female population. Therefore, according to the new proposed cut-off values (29), our male population presented a low disease activity state while the female population a severe disease activity state. Results of the univariate analysis of WPI, SSS and FIQR scores are shown in Table III. No significant differences were found between males and females in the mean scores of WPI and SSS questionnaires. On the other hand, significantly higher FIQR total scores (*p*=0.035) and physical function scores (*p*=0.003) were obtained by female group compared to male group (Fig. 1). Moreover, the comparison of the single scores of the 21 questions that compose the FIQR showed that

Table III. WPI, SSS, FIQR total, domains and single question scores based on sex.

Score	M (39)	F (39)	*p*-value
WPI	10.1 (5.0)	10.8 (4.8)	*.578*
SSS	7.6 (2.8)	8.2 (2.1)	*.367*
FIQR total	58.8 23.5)	70.3 (14.7)	***.035***
FIQR physical function	14.8 (8.2)	20.1 (5.1)	***.003***
FIQR overall impact	12.0 (6.2)	13.9 (4.3)	*.290*
FIQR symptoms	32.0 (11.6)	36.6 (6.8)	*.175*
FIQR 1 Brush or comb your hair	2.4 (3.3)	4.3 (2.9)	***.006***
FIQR 2 Walk continuously for 20 minutes	5.6 (3.6)	7.1 (2.7)	*.065*
FIQR 3 Prepare a homemade meal	4.2 (3.4)	5.4 (2.7)	*.127*
FIQR 4 Vacuum, scrub, or sweep floors	5.2 (3.6)	7.5 (2.2)	***.005***
FIQR 5 Lift and carry a bag full of groceries	6.4 (3.0)	8.3 (1.6)	***.002***
FIQR 6 Climb one flight of stairs	5.0 (3.9)	6.8 (2.4)	*.070*
FIQR 7 Change bed sheets	4.7 (3.6)	7.1 (2.7)	***.001***
FIQR 8 Sit in a chair for 45 minutes	6.0 (3.5)	6.9 (2.3)	*.408*
FIQR 9 Go shopping for groceries	4.9 (3.3)	6.7 (2.4)	***.012***
FIQR 10 Daily life impact	6.1 (3.3)	7.1 (2.4)	*.308*
FIQR 11 Symptoms influence	5.9 (3.2)	6.8 (2.5)	*.251*
FIQR 12 Pain level	6.9 (2.6)	7.9 (1.1)	*.412*
FIQR 13 Energy level	7.6 (2.4)	8.5 (1.2)	*.088*
FIQR 14 Stiffness level	7.3 (2.8)	8.2 (1.6)	*.295*
FIQR 15 Sleep quality	6.9 (2.8)	7.4 (2.4)	*.474*
FIQR 16 Depression rate	5.1 (3.0)	5.4 (2.8)	*.767*
FIQR 17 Memory problems	5.2 (3.6)	6.5 (2.7)	*.147*
FIQR 18 Anxiety level	6.3 (2.7)	6.1 (2.9)	*.856*
FIQR 19 Tenderness to touch level	6.5 (3.2)	7.9 (1.6)	*.145*
FIQR 20 Balance problems	5.3 (3.5)	6.1 (3.0)	*.255*
FIQR 21 Sensitivity to loud noises, bright lights, odours, cold	6.2 (2.7)	7.9 (1.6)	***.005***

WPI: Widespread Pain Index; SSS: Symptoms Severity Scale; FIQR: Revised Fibromyalgia Impact Questionnaire.

females obtained significantly higher scores than males answering the following questions: FIQR1 'brush or comb your hair' (*p*=0.006), FIQR4 'vacuum, scrub, or sweep floors' (*p*=0.005), FIQR5 'lift and carry a bag full of groceries' (*p*=0.002), FIQR7 'change bed sheets' (*p*=0.001), FIQR9 'go shopping for groceries' (*p*=0.012) and FIQR21 'sensitivity to loud noises, bright lights, odours, cold' (*p*=0.005) (Fig. 2).

Discussion

FM is a complex clinical syndrome characterised by the development of a broad pattern of symptoms that heavily affect patients' daily lives and activities in addition to patients' wellbeing. Considering this statement, a specific questionnaire, able to capture the total spectrum of FM related symptoms in order to fully evaluate every patient, was necessary. Therefore, in 1991, the first version of the FIQ was published (25) and, since then, it has been extensively used as a measure of therapeutic efficacy. Despite its wide use, either the first version of the FIQ and its subsequent modifications presented some major problems. From our point of view, one of these problems was the probable gender bias caused by the original development of the questionnaire from a predominantly female population. This possible gender bias could be especially supposed in the physical function domain, where four out of the eleven sub-items – 'do laundry with washer and dryer', 'prepare meals', 'wash dishes, cooking utensils by hand', 'make beds' – are actually considered to be more likely to be performed by women (30). One of the aims of the FIQR (26), when it was developed, was to reduce the supposed gender and ethnicity biases of the previous version. Unfortunately, in the paper of Bennet and colleagues, only twelve males completed the questionnaires, thus their FIQR scores cannot be considered representative of a large male population. Moreover, the FIQR underwent a domains weight modification compared to its previous version and the given weight of the physical function domain passed from 10% to 30% of total score. As a matter of fact, it can be supposed that the FIQR still present a plausible gender bias that could significantly influence total scores obtained by female and male patients.

To date, alternative methods for the assessment of FM disease severity, as the Polysymptomatic Distress Scale (PSD) (31), have already been proposed. Since the PDS is derived from the variables used in the 2010 diagnostic criteria for FM, such as WPI and SSS (7), it is considered a useful and simple general severity measure and it is less likely to be influenced by gender differences. However, as compared to the FIQR, the PDS is a less comprehensive measure of FM major domains of illness and overall impact. Considering the evidence that early diagnosis and timely and appropriate treatment are able to positively influence FM history (32-33), a more inclusive instrument to assess FM severity and its evolution during time is definitely more valuable.

In our pilot study we showed that, even if there were no differences in the WPI and SSS scores among the patients enrolled, the female group presented significantly higher FIQR total scores. Interestingly, when we analysed the three domains of the FIQR, significantly higher scores were maintained in female group only in the physical function domain. These preliminary results seem to confirm our first hypothesis of a gender bias in the FIQR and, in particular, it appears that this bias is actually present in the physical function domain. Likewise, the FIQ, also the physical function domain of the FIQR present, at least, four out of nine sub-items – 'vacuum, scrub, or sweep floors', 'lift and carry a bag full of groceries', 'change bed sheets', 'go shopping for groceries' – that could be more likely to be performed by women. Actually, it can be argued that in Western societies of the 21st century it is not unusual for men to perform homework duties (30). However, when we analysed the 21 questions that compose the FIQR, we were able to demonstrate that female patients obtained significantly higher scores answering six questions and five of them corresponded to the

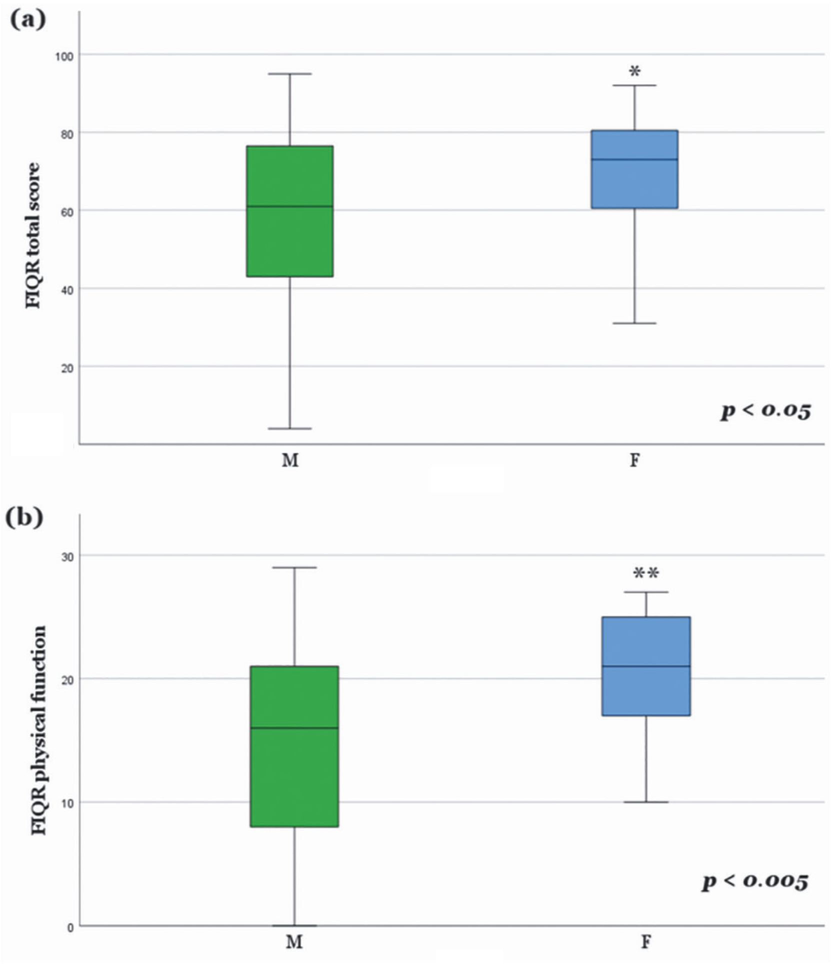

Fig. 1. FIQR total score and FIQR physical function score based on sex. (**a**) Distribution of FIQR total scores among male and female patients. (**b**) Distribution of FIQR physical domain scores among male and female patients.

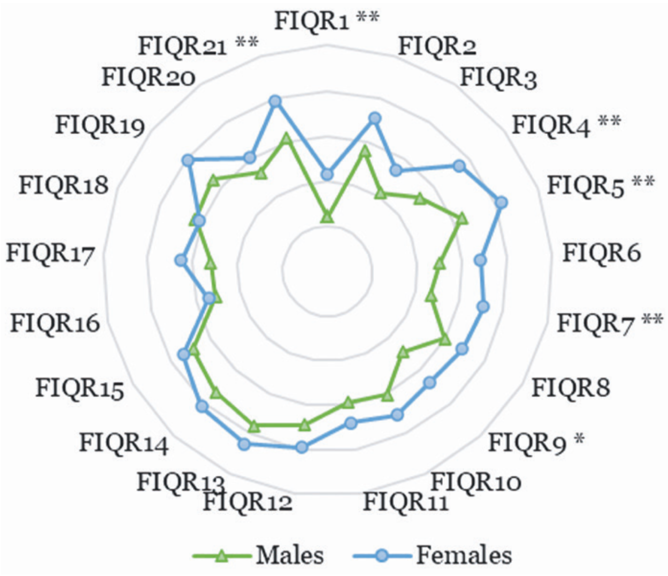

Fig. 2. Comparison of the mean scores of the 21 items that compose the FIQR based on sex. The female group obtained significantly higher mean scores answering the following questions: 'brush or comb your hair' (FIQR1), 'vacuum, scrub, or sweep floors' (FIQR4), 'lift and carry a bag full of groceries' (FIQR5), 'change bed sheets' (FIQR7), 'go shopping for groceries' (FIQR9) and 'sensitivity to loud noises, bright lights, odours, cold' (FIQR21).

sub-items of the physical function domain presumably more performed by women – 'brush or comb your hair', 'vacuum, scrub, or sweep floors', 'lift and carry a bag full of groceries', 'change bed sheets', 'go shopping for groceries'. A possible explanation of these results could be that, as a consequence of different perceived society's expectations, FM experiences between men and women are different. Pain sensitivity and other FM symptoms are differently influenced by biological and psychological factor as well as by coping strategies (34) and it seems reasonable to assume that gender role expectations, masculinity-femininity trait (*e.g.* willingness to report pain) and perceived identification according to typical M/F stereotypes at least partly affect disease impact on patients' daily life. As a matter of fact, when men and women with FM were asked to describe which aspects of daily life were more touched by their syndrome, previously published studies showed that man and women answered differently. A nationwide American survey (35), published in 2018, showed that FM impact on male's quality of life (QoL) involved especially aspects as the decreased ability to do previous hobbies or the negative impact on working careers other than negative effects on their relationships with both family and friends. According to the men that answered this survey, their perceived major role in the society was 'to be strong' and 'to maintain the ability to work' in order to 'support financially their family'. Thus, the more relevant fears of males with FM are mainly related to the perceived loss of their masculinity associated with a limitation of their personal goal achievement capacity (36). On the other hand, when FM women are asked about disease impact on their daily life, they identify three major domains: reduced activities of daily living such as household chores and self-care, avoidance of physical activity and inability to advance in career or education (37). A Spanish qualitative study (38), conducted in 2016, showed that women with FM basically perceive themselves as both caregivers of the home and the family and it has been demonstrated that perceived psychological demands of the family have a significant effect on health status: the greater is the family demand the worse is the health status (39). As far as we know, our is the first study that actually made a systematic comparison of all the items and sub-items of the FIQR between males and females matched for age and disease duration. Previous studies regarding a possible gender difference in disease severity, evaluated by the FIQ or the FIQR, have been published but with discordant results: one reported higher disease severity in males (23), another reported higher disease severity in females (22) and others reported no gender differences in disease severity (21, 40-42). Actually, in all of these studies, with the exception of that by Buskila *et al*. (23), the number of male patients evaluated was much smaller of the one of females, thus limiting a reliable assessment of the actual differences.

A number of limitations can be identified in our study. First of all, our population was small and, in order to confirm our results, it needs to be increased. As a matter of fact, our first population sample included a greater number of patients. Unfortunately, since only 39 men completed our survey, we decided to select a smaller but more balanced and homogenous population sample. It must be highlight that the sex distribution found in our sample is probably a consequence of the previously described selection and confirmation biases (10) and it shows that, to date, men are less likely to have access to third-level centres and, therefore, be diagnosed with FM. Another limitation of this study is that we did not take into account possible confounding clinical factors (*e.g*. obesity, depression, diet, sedentary lifestyle) that could possibly influence FM severity and, therefore, FIQR scores.

Conclusions

In conclusion, our pilot study shows that female patients obtain significantly higher scores in the FIQR total score and physical function domain score, despite similar WPI and SSS scores. The analysis of the 21 items of the FIQR confirmed that this group of patients obtains significantly higher scores in 5 out of the 9 sub-items of the physical function domain. These preliminary results indicate that the use of the FIQR as a severity index in male patients underestimates disease severity in this group. In order to confirm these results, the sample needs to be increased, but it seems reasonable to conclude that a gender-specific instrument for disease severity assessment in FM could be desirable and could better explore the symptomatic differences of affected patients.

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