Validation of Qualisex questionnaire to evaluate sexual dysfunction in women affected by fibromyalgia

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Abstract

Objective

Fibromyalgia (FM) may have consequences on sexual life. The objective was to validate the Qualisex questionnaire in the assessment of sexual dysfunction in women affected by FM.

Methods

We consecutively enrolled FM women (American College of Rheumatology-ACR 2016) referring to our Fibromyalgia Clinic, from 2020 to 2022. Demographic, clinical data and evaluation of FM symptoms severity (Revised Fibromyalgia Impact Questionnaire (R-FIQ), Symptoms Severity Scale-SSS, Widespread Pain Index-WPI) were assessed. Hospital Anxiety and Depression Scale (HADS) and Qualisex questionnaire were anonymously administered. Qualisex includes 10 questions on different items of sexual life with higher scores suggestive of greater negative impact of the disease on sexuality.

Results

The cohort was composed by 373 FM women. Cronbach's alpha test was used to validate Qualisex questionnaire (0.878). Moreover, we observed higher values of Qualisex in married women ($p<0.001$), in women with lower grade of education ($p=0.002$) and with lower sexual feeling with partner ($p<0.001$). Higher values of Qualisex Total score showed a positive correlation with HADS-A/D ($p<0.001$ $r=0.312$; $p<0.001$ $r=0.542$ respectively), VAS pain, VAS fatigue, VAS dryness ($p<0.001$ $r=0,438$; $p<0.001$ $r=0.375$; $p<0.001$ $r=0.370$ respectively) and relationship duration ($p<0.001$ $r=0.202$). Multivariate analysis revealed a significant influence of relationship duration, VAS pain, fatigue, dryness, HADS-A/D, R-FIQ and all Qualisex items, on Qualisex Total score corrected for patients' age ($p<0.001$).

Conclusion

This study validated Qualisex questionnaire as a good test for the sexual disorders' evaluation in FM women. Its use allows the assessment of different factors associated with sexual dysfunction, showing an impact of FM on sexuality. Moreover, due to demotivation feelings, sexual dysfunction contributes to worsen patients' quality of life.

Key words

fibromyalgia, sexuality, Qualisex questionnaire

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Introduction

Fibromyalgia (FM) is one of the principal causes of chronic widespread pain. It is the third most common musculoskeletal condition, after lumbar pain and osteoarthritis, with a 2–3% worldwide prevalence, which is proportional to population age, peaking at 50–60 years old, and a female to male ratio about 3:1 (1, 2). Over pain, FM is characterised by a complex symptomatology comprising, above all, fatigue, sleep and functional disturbances. Patients with FM often complain about a wide spectrum of clinical symptoms involving almost all organs and systems, with a severity varying from patient to patient and within each patient during the syndrome course (3): cognitive dysfunction (especially 'fibro-fog'), memory deficits (4), headache, with or without a history of migraine (5), dyspepsia, abdominal pain and alternating constipation and diarrhoea, part of a full-blown irritable bowel syndrome (6), genitourinary disorders (such as urinary urgency in the absence of urinary tract infections (7)), dysmenorrhoea or vulvar vestibulitis, which leads to difficulties in sexual intercourses (8). Psychologically, patients with FM present a preponderant negative affectivity, identified by the presence of negative emotions and a generalised distress state (9). The lifetime prevalence of anxiety disorders in patients with FM is 60%, while depression is observed in 14–36% of patients, compared with 3.7% and 6.6% of healthy individuals respectively (10).

FM-related emotional symptoms, including pain, depression, and anxiety, may have a negative impact on sexual function and overall quality of life (11, 12). Symptoms of female sexual dysfunction include lack of sexual desire, sexual aversion, arousal, orgasm disorder, vaginismus, and dyspareunia (13). As known, sexual function is a central component of people's well-being, and FM seems to profoundly affect all its dimensions (14). More than 85% of women diagnosed with FM suffers from sexual dysfunction (15). FM interferes with women's sexual functioning through fatigue, widespread pain, including increased genital pain, decreased lubrication, and affectation of pelvic floor muscles (16-19). In addition to bodily well-being, FM also distresses self-image and relationships emphasising depression, stress, and hypoactive sexual desire (20-23). These features may lead to avoidance behaviours, lack of receptiveness, absence of sexual relations and/or an increased risk of relationships' breakdown (24-26). Furthermore, drugs generally used to treat FM are known to negatively affect sexual function (17, 27).

Therefore, the evaluation of sexuality with its several features becomes essential in FM. So far, different questionnaires and their subscales have been used in FM patients to assess sexual function in general, or sexual desire, such as the Questionnaire for Screening Sexual Dysfunctions-Short Form (28), the Female Sexual Function Index (23, 29, 30), the Changes in Sexual Functioning Questionnaire (12, 15), the Index of Sexual Satisfaction (21) or the Arizona Sexual Experiences Scale (31). However, they are rather complex and neither of them have been specifically developed for subjects with rheumatic and musculoskeletal diseases (RMDs).

The main purpose of this study was to validate the Qualisex questionnaire in FM. The Qualisex is a brief questionnaire originally created for French patients with rheumatoid arthritis (32), and recently adapted to Italian language for Sjögren's syndrome (SS) and FM patients (33). The secondary aim of this study was, using this new tool, to evaluate correlations, if any, between sexual dysfunction and FM patient reported outcomes.

Materials and methods

We consecutively enrolled sexually active women, aged between 18 and 60 years, affected by FM according to the 2016 American College of Rheumatology (ACR) diagnostic criteria (34), referring to our out-patient Fibromyalgia Clinic, from 2020 to 2022. As in previous reports (33, 35), women were classified as sexually active/inactive based on the question: "During the past 4 weeks, have you engaged in sexual activities with your partner?". Once obtained informed consensus, demographic and

clinical examination as well as the evaluation of FM symptoms severity (Revised Fibromyalgia Impact Questionnaire (FIQ-R), Symptoms Severity Scale (SSS) and Widespread Pain Index (WPI)) were assessed for each patient. Medical and pharmacological histories were also collected. All patients were asked to evaluate the quality (excellent, good, poor, very poor) of their relationship with their partner. Patients scored on a visual analogue scale (VAS) from 0 to 10 the fatigue, the dryness and the pain perceived along the previous two weeks. They were also asked about the possible presence of partner's erectile dysfunction.

WPI and SSS were used to diagnose and assess FM disease activity. In addition, the FIQ-R was administered to all patients (36). Hospital Anxiety and Depression Scale (HADS) and Qualisex questionnaire for sexual dysfunction were anonymously administered.

The HADS is a frequently used, self-administered questionnaire, specifically developed to detect states of anxiety and depression in out-patient clinical settings. It is composed of two 7-item scales, one for anxiety and one for depression, which should be used as two separate measures of emotional disturbances (37).

The Qualisex questionnaire includes 10 questions, with answers scored from 0 to 10. The total Qualisex score is the mean of the results for the 10 questions (Question n. 10 is scored on an opposite scale). The final Qualisex score is on a 0–10 scale where higher scores indicate worse sexual function. About missing data, if only 1 of the 10 questions is unanswered (or answered as not applicable), the Qualisex score is the mean of the other 9 questions: proceed as above but ignoring the missing result and divide the sum by 9. If 2 or more questions are unanswered, the score cannot be calculated.

The French original version of the Qualisex questionnaire had previously been translated to Italian (Fig. 1) (33) according to available guidelines (38).

Ethics

The study was approved by the local institutional ethics committee and conducted in accordance with the Declaration of Helsinki.

Statistical analyses

For Qualisex Questionnaire validation, a measure of reliability and internal consistency was assessed through Cronbach's alpha coefficient: Cronbach's value >0.7 is generally regarded as satisfactory (39). The variables studied are presented as mean values and standard deviations (SD). Categorical variables are reported as numbers with frequencies (%). Missing data were not replaced. Percentages were calculated based on data available. The normal distribution was tested with the Shapiro-Wilk test. Comparisons of continuous variables between two groups were performed using an independent samples T test. Chi-squared analysis tested the differences between categorical variables. The significance of the correlations was evaluated with Pearson's coefficient. A two-sided p-value <0.05 was considered statistically significant. Variables found to be significantly associated with Qualisex total score, with a p<0.05 were then analysed in multivariate analyses. A backward selection method was used to select the variables. Variables with significance levels below 5% were maintained in the model. The multivariate models were adjusted for age. All statistical analyses were carried out with IBM SPSS Statistics for Macintosh, v. 22.0 (IBM Corp., Armonk, NY, USA).

Results

The cohort enrolled was composed by 373 FM women, with a mean age of 49.1 years. Data are summarised in Table I. Half of them was in menopause status but only 18.3% was in replacement therapy. Regarding demographic/cultural data, we observed high education levels in the cohort, as 28.7% of them obtained graduation and 56.5% concluded high school. Employed women were 61% and, according to the aging range of our patients, 5% were pensioners and 3.4% students. About affective/sexual relationship, 70% of FM women were married, with a mean relationship duration of 18.2 years. We observed an excellent and good feeling with partner in more than half of our patients. We also investigate a possible partner erectile dysfunction, that was present in 10% of cases. Drugs for FM treatment as duloxetine, amitriptyline, muscle relaxants, benzodiazepines and painkillers were taken by 86.2% of our patients. Cardiovascular, and metabolic disorders were the most relevant con-

Table I. Demographic data.

	FM (n=373)
Age (yrs), media ± SD	49.1 ± 10.4
Menopause, n (%)	185 (49.6)
Age menopause (yrs), media ± SD	48.7 ± 7.3
Replacement therapy, n (%)	69 (18.3)
Education level, n (%):	
- Primary school	1 (0.2)
- Secondary school	54 (14.6)
- High school	211 (56.5)
University/graduation	107 (28.7)
Employment, n (%):	
- employed	227 (61)
- housewife	78 (20.6)
- pensioner	18 (5)
- awaiting employment	37 (10)
- student	13 (3.4)
Marital status, n (%):	
- married/cohabitant	259 (69.4)
- widow	6 (1.6)
- unmarried	53 (14.4)
- divorced/separate	55 (14.6)
Sexual relationship duration (yrs), media ± SD	18.2 ± 11.7
Sexual feeling, n (%)	
- excellent	100 (26.6)
- good	137 (36.7)
- sufficient	94 (25.3)
- poor	42 (11.4)

Table II. Disease activity and anxiety/depression evaluation.

	FM (n=373)
FIQR (0-100), media ± SD	68.8 ± 18.2
WPI (0-19), media ± SD	11.3 ± 4.8
SSS (0-12), media ± SD	8.8 ± 2.4
VAS dryness (0-10), media ± SD	5.6 ± 3.4
VAS pain (0-10), media ± SD	6.8 ± 2.7
VAS fatigue (0-10), media ± SD	7.9 ± 1.9
HADS A, media ± SD	11.9 ± 4.3
- healthy (0-7), n (%)	56 (15)
- borderline (8-10), n (%)	89 (23.9)
- unhealthy (11-21), n (%)	228 (61.1)
HADS D, media ± SD	9.5 ± 4.1
- healthy (0-7), n (%)	117 (31.4)
- borderline (8-10), n (%)	108 (28.9)
- unhealthy (11-21), n (%)	148 (39.7)

FIQ: Fibromyalgia Impact Questionnaire; WPI: Widespread Pain Index; SSS: Symptom Severity scale; VAS: Visual Analogue Scale; HADS: Hospital Anxiety and Depression Scale.

Table III. Qualisex questionnaire results.

QUALISEX: influence on sex of media ± SD	FM (n=373)
1 Healthy condition	6.5 ± 3.1
2 Drugs/treatment	3.6 ± 3.4
3 Healthy condition and libido	6.5 ± 3.3
4 Healthy condition and sexual performance	6.7 ± 3.1
5 Healthy condition and partner feeling	5.7 ± 3.6
6 Loss of self-esteem	3.4 ± 3.6
7 Sexual attraction	6.1 ± 3.4
8 Pain	6.6 ± 3.1
9 Fatigue	6.9 ± 3.1
10 Satisfactory sex life	3.6 ± 3.1
Total	5.3 ± 2.7

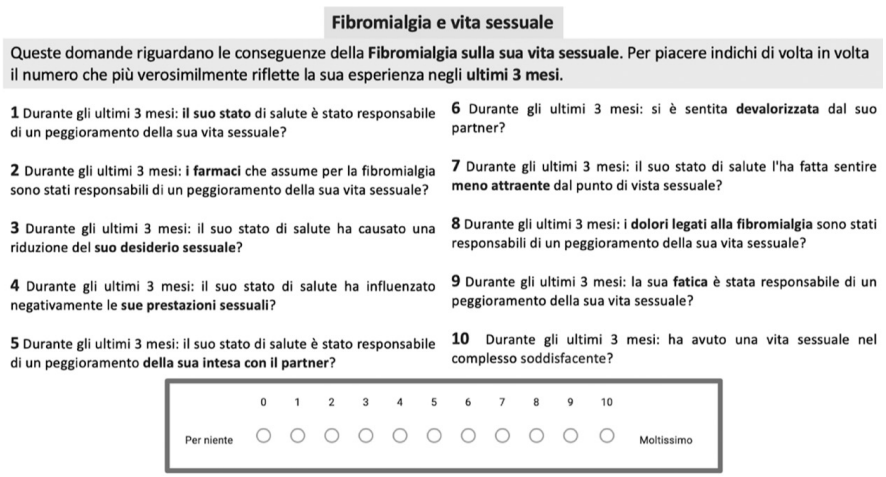

Fig. 1. Italian version of Qualisex questionnaire.
The Qualisex score is calculated as follows:
- Sum = result question 1 + result question 2 + result question 3 + result question 4 + result question 5 + result question 6 + result question 7 + result question 8 + result question 9 + (10 - result question 10).
- Qualisex = Sum / 10.
Qualisex is the mean of the results for the 10 questions (but question 10 is scored on an opposite scale). The final Qualisex is on a 0-10 scale where higher scores indicate more impact of fibromyalgia on sexuality.

ditions concomitant with FM in this cohort.

Table II reports the assessment of FM disease activity expressed by FIQR, WPI and SSS, highlighting a high disease activity. We observed high values of VAS pain and VAS fatigue. Regarding anxiety and depression prevalence, evaluated through HADS-A/D questionnaire, we detected a high percentage of anxiety disorder, and a more homogeneous distribution of depressive alteration, despite unhealthy status remained dominant.

The validation of the Qualisex Questionnaire, the main purpose of the study, was obtained on a female population of 373 FM patients. Cronbach's alpha test presented a value of 0.878, considered satisfactory and with an adequate internal consistency.

The Qualisex total score was 5.3±2.7; total score and the score of each component are showed in Table III.

Evaluating the impact of FM and its several physical and psychological characteristics on sexual life, we observed many significative and interesting correlations. Higher values of VAS dryness, VAS fatigue and VAS pain were related to higher Qualisex total scores, indicative of worse sexual quality (p<0.001 r=0.370; p<0.001 r=0,375; p<0.001 r=0,438 respectively). Also, a longer duration of sexual relationship presented a positive correlation with Qualisex total score (p<0.001 r 0.202), while patients' age did not show any correlation with sexual quality. Both anxiety and depression, reported in a large proportion of patients, showed a positive correlation with Qualisex Total, however a stronger relation with depression disorders was observed (p<0.001 r=0.312; p<0.001 r=0.542 respectively) (Fig. 2).

Interestingly, we noticed that patients married and with a lower grade of education presented worse sexual life. Also, as expected, a poor partner feeling reported by patients, contributed to higher Qualisex scores. Menopause status, BMI, pharmacological treatment, and the presence of comorbidities did not influence patients' sexual function (Fig. 3). We did not find any correlation between sexual quality, assessed by Qualisex total score, and FM disease activity, evaluated by FIQ-R, WPI and SSS (p>0.05).

Finally, we conducted a multivariate analysis revealing a significant influence of relationship duration, VAS pain, fatigue and dryness, HADS-A, HADS-D, and all specific items of Qualisex, on Qualisex Total corrected for patients' age (p<0.001).

Discussion

This study focused on the assessment of sexuality and its dysfunctions, significant aspects of FM women quality of life. Over the past few years, sexual side of patients' life and healthy/welfare has been increasingly studied in different disorders and RMDs. FM is a complex condition that involves physical and psychological domains where sexuality plays a very important role. Fatigue, general and genital pain, decreased lubrication, depression, anxiety, and stress get worse sexual quality directly but also impacting on sexual desire, self-image, and relationships; drugs used to treat FM could also provide to a poor sexual life. For example, selective serotonin reuptake inhibitors (SSRI), often used to treat depression in women with FM, have been found to negatively affect female sexual responses. Women taking these drugs often complain about decreased sexual desire (12, 40). Female sexual interest/arousal disorder and lack of desire are indeed the most frequent sexual dysfunctions in FM women (29).

All whole sexual features must be considered in FM patients and can be analysed by different Questionnaires. Rosen *et al*. used the Female Sexual Function Index (FSFI) survey, a 19-item, multidimensional, self-assessment interview form to evaluate the basic features of female sexuality (desire, arousal, lubrication, satisfaction, orgasm, and pain during sexual intercourse) (41). A specific questionnaire, the validated Spanish translation of the Sexual Desire Inventory (SDI), particularly focuses on sexual

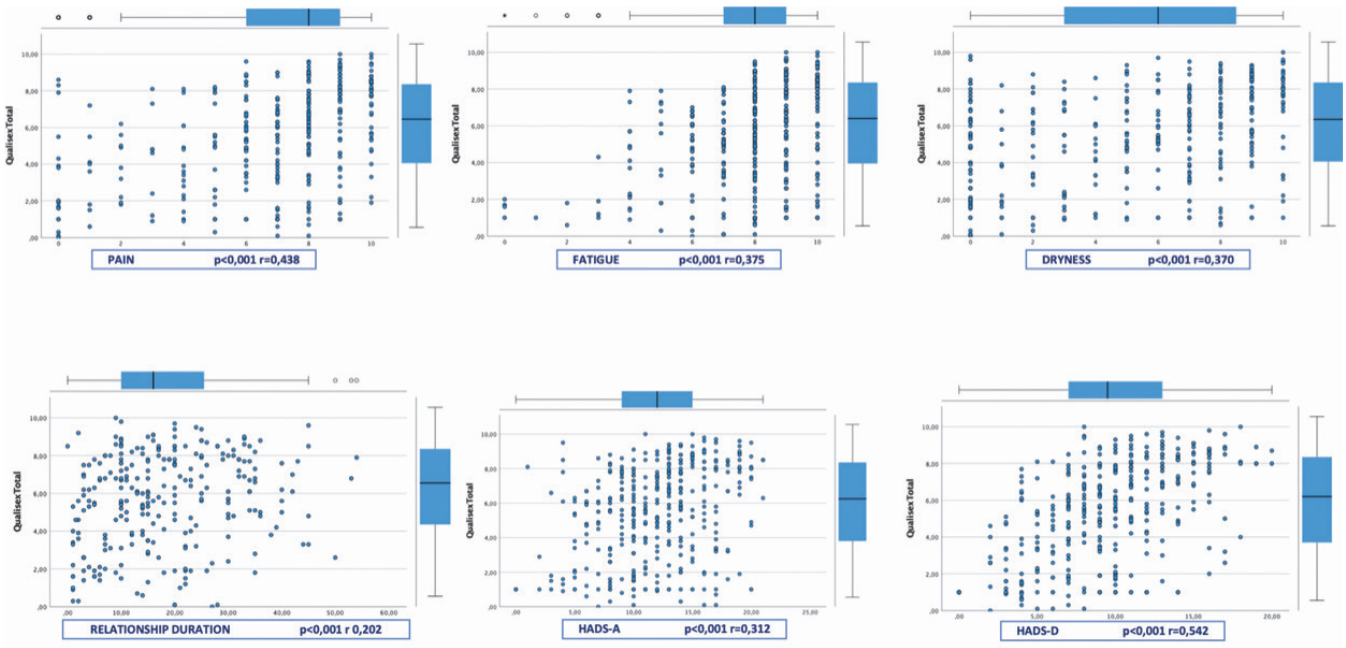

Fig. 2. Qualisex questionnaire total score correlations.
Higher values of Qualisex total score showed a positive correlation with VAS pain, VAS fatigue, VAS dryness, relationship duration and HADS anxiety and depression.
HADS: Hospital Anxiety and Depression Scale.

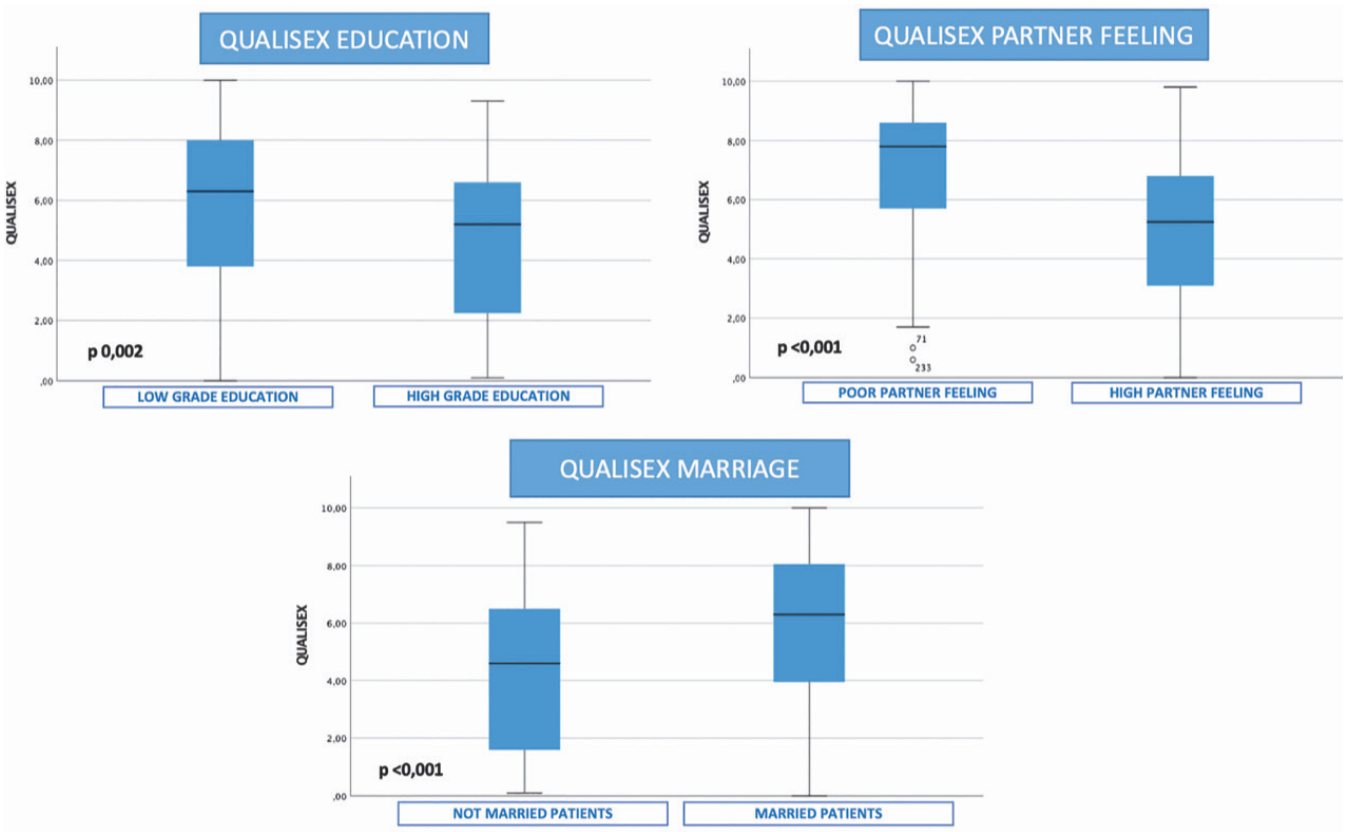

Fig. 3. Impact of education, marriage and partner feeling on Qualisex total score.
Higher values of Qualisex were reported in married women, in women with lower grade of education and with lower sexual feeling with partner.

desire (42). This questionnaire includes 13 items to evaluate individuals' level of sexual desire or desire for sexual activity in the previous month, consisting of 2 subscales: Dyadic Sexual Desire and Solitary Sexual Desire (43).

The Qualisex questionnaire is the most recent and specific tool developed to evaluate sexual life in patients with

RMDs. Patients with RMDs have difficulties in sexual life in relation with pain, stiffness, and fatigue. Gossec *et al*. elaborated and validated Qualisex to assess sexuality in Rheumatoid Arthritis, emphasising the poor satisfaction during sexual intercourse possibly linked to joint involvement and hip pain (33, 44-46). In 2018, Sommerfleck *et al*. demonstrated that Qualisex is a valid questionnaire to assess sexuality in axial spondyloarthritis (axSpA) observing that, among female axSpA patients, those with longer disease duration and higher disease activity presented a worse sexual life (47). In a previous study we were the first to adapt and preliminarily validate the Qualisex in a small cohort of Italian women with SS and FM demonstrating sexual dysfunction in both groups (33).

The originality of Qualisex resides both in its elaboration and scoring. It was developed with the collaboration of patients (32); therefore it reflects patient preferences in terms of aspects of sexuality assessed and wording, and that is an important aspect in a delicate area such as sexuality.

The present study defined Qualisex as a valid and reliable instrument for sexual analysis in FM female patients, inclusive of the different features highlighted above. Qualisex items explored the most salient domains of patient's sexual life. Unlike other questionnaires where yes/no responses can lead to loss of information, the quantitative scoring of Qualisex, from 0 (no impact of FM on sexuality) to 10 (maximal impact of FM on sexuality) will allow a quantitative evaluation of the impact of FM and its therapies on patients' sexual life.

Appling this new and efficacy tool, our work confirmed some of the results described by previous studies (23, 30): physical symptoms of pain, fatigue, and dryness as well as anxiety and depression, are associated with a low quality of sexual life.

To the best of our knowledge, this is one of few studies including such many all-ages FM female patients. In line with the results of previous studies, conducted using different questionnaires, no significant differences in Qualisex scores among different age groups were found; in opposite, the duration of the relationship was a crucial factor for a worse sexual quality. Education level also contributed to a different perception of sexual quality, probably due to a different consideration of this issue in the sociocultural contest.

Pain and fatigue are cardinal symptoms in FM syndrome, also the main determinants of sexual dysfunction in our patients, as demonstrated by the direct correlation of VAS fatigue and VAS pain with high Qualisex scores and by the higher scores obtained in questions n. 8 and n. 9. In FM, pain could affect the whole body from head to toe, differently described by patients (48). The type, location and severity of pain depends on several modulating factors, such as working activities, comorbidities (such as obesity) (49) and variations in temperature (50,51). Physical or mental stress is also a known factor associated with worsening pain. Women agreed that generalised and genital pain was present in the sexual relationship before, during and/or after coitus, lasting hours, or days. Despite that, we did not observe any correlation with disease activity. On the contrary, Yilmaz *et al*. observed that disease severity, measured by the FIQ, was negatively associated with sexual function, determined with the FSFI (23). Probably this discrepancy is derived by the broader analysis obtained by Qualisex, where other factors gained importance.

Among psychological traits, similarly to SS (33), mood disorders negatively influence sexual life; there is controversy, however, whether sexual dysfunction in patients with FM is intrinsic to the disease itself or independently associated with depression.

Previous studies indicated that selective serotonin reuptake inhibitors can affect various phases of sexual function such as excitement, desire, decreased orgasm experience, and increased pain. In this study, we did not find any relation between FM treatment, including antidepressant, and poor sexual quality. These results are in line with the one of Bazzichi *et al*. (17) who reported no differences in sexual satisfaction between FM women regardless of whether they took antidepressants. Nevertheless, sexual dysfunction among FM women taking antidepressants remains a common phenomenon, and this should be taken into consideration when choosing the type of treatment to offer to FM women, particularly because suppression of sexual desire and arousal may be related to delay or absence of orgasm (17, 52-53).

Pain, fatigue, stiffness, dryness, lack of libido, altered body image in FM women are accompanied by lack of understanding from the partner. Partners also senses that the woman agrees to sexual relations just to please them. As such, moral dilemmas and feelings of fear, guilt and frustration emerge, putting the relationship in danger. The intricate and multifaceted nature of FM has implications for family, social and work relationships, causing coping and adaptation processes (23, 54). Although they feel desired, women often suffer of self-image disorders leading to the fear and worry of 'not meeting expectations'. The body is vital to female and sexual identity, but FM provides invisibility to female. For women, feeling understood and visible can improve their adaptation, dispelling the fear of their relationship breaking down (55).

The disease as well as an unsatisfactory sex life concur to stress feeling of guilt, discouragement, and fear. Although less dominant than in the past, we must not forget the difficulty in speaking about an intimate/private topic also for their Catholic extraction, as reported by patients themselves.

Moreover, in clinical practice, sexual problems are not being addressed by physicians for several reasons, comprising visiting time issues. Sexuality remains an area that many feel unable to discuss, and rheumatologists may be unsure whether such problems are or not within their domain of care and expertise.

One limit of the present study is that it did not investigate sexuality in FM male patients, still little studied; it will be interesting to analyse sexual sphere in male physicality and psychology, considering the well-known gender differences in FM (56).

Conclusions

The present study validated the Qualisex questionnaire in FM patients as

a successful tool in the assessment of sexuality, an important feature of quality of life and self-identity. Qualisex questionnaire is an optimal instrument to detect the impaired sexuality in FM female patients, to establish a more correct intervention, pharmacological, psychotherapeutic (single or couple) and supportive, reducing the destructive circle that FM and poor sexual quality determine. FM impacts on it causing a worsening of sexual quality, of relational and family life. Besides a demotivation feeling, inability to live a "normal everyday life" and the reduced sexual function contribute to an unsatisfactory quality of life.

Being such an important component of patient's health, it is desirable that in the next future sexuality would be properly assessed by all the rheumatologists. In this perspective, the validation of a new, simple, complete and reliable tool such as Qualisex for women with FM represents an important step.

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