

Quality of life related to foot health status in women with fibromyalgia: a case-control study

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Abstract

Introduction: To date, the Foot Health Status Questionnaire (FHSQ) has not been applied to women who suffer from fibromyalgia. The main purpose of this study was to compare both foot and general health-related quality of life between women with fibromyalgia and healthy matched women. We hypothesized that women with fibromyalgia may present an impaired quality of life related to foot and general health.

Material and methods: A sample of 208 women, mean age of 55.00 ± 8.25 years, was recruited from an outpatient clinic and divided into 2 groups, 104 women with fibromyalgia (for the case group) and 104 healthy matched women (for the control group). Demographic data and the domains of the FHSQ scores were registered.

Results: Statistically significant differences ($p < 0.001$) between case and control groups were found for both all specific foot domains (pain, foot function, foot health and footwear) and all general wellbeing domains (general health, physical activity, social capacity and vigor), showing a worse foot and general health-related quality of life (with lower scores for all FHSQ domains) in the women with fibromyalgia compared to healthy matched women.

Conclusions: Impaired foot and general health-related quality of life was observed in women who suffered from fibromyalgia compared to healthy matched women.

Key words: fibromyalgia, foot, foot injuries, musculoskeletal pain, quality of life.

Introduction

Fibromyalgia may be considered as the most frequent central sensitization syndrome, with a higher prevalence in women who suffer from chronic widespread pain and other symptoms that lead to considerable functional impairment [1]. Its prevalence may reach up to 2.10% of the worldwide population, 2.31% of the European population, and 2.40% of

the Spanish population. This painful syndrome may cause quality of life impairment in women who suffer it. In Spain, enormous economic costs were reported and reached up to 12,993 million euros per year [2].

Women were more likely to suffer from fibromyalgia, showing a younger age than patients diagnosed with other pain conditions and higher presence of several psychiatric comorbidities combined with other types of pain, such as headaches and connective tissue diseases. Consequently, women with fibromyalgia seemed to show a higher demand of medical outpatient services use [3].

Regarding health-related quality of life questionnaires applied to women who suffered from fibromyalgia, general quality of life tools, such as the EuroQoL 5-Dimensions 5-Levels (EQ-5D-5L) [4], 15-Dimensions (15D) [5], Assessment of Quality of Life 8-Dimensions (AQoL-8D) [6], Short Form Health Survey 12-item (SF-12) [7] and 36-item (SF-36) [8], and specific condition tools, such as the Fibromyalgia Impact Questionnaire (FIQR) [9], were used with adequate correlations between these questionnaires in this kind of population [10].

Although women with fibromyalgia did not seem to show a higher prevalence of stiffness or mobility abnormalities as well as hyperkeratosis or other foot problems, these patients may experience significantly more pain in the foot than healthy subjects and, consequently, demand more pain-killing drugs [11]. Based on these antecedents, foot health-related quality of life measurements may be necessary in order to determine the impact of fibromyalgia in women who suffer from this syndrome. For this purpose, the Foot Health Status Questionnaire (FHSQ) may be considered a foot and general health-related quality of life tool with specific foot domains (pain, foot function, foot health and footwear) and general well-being domains (general health, physical activity, social capacity and vigor) [12, 13].

To date, the FHSQ has not been applied to women who suffer from fibromyalgia [12, 13]. Thus, the main purpose of this study was to compare both foot and general health-related quality of life between women with fibromyalgia and healthy matched women. We hypothesized that women with fibromyalgia may present an impaired quality of life related to foot and general health.

Material and methods

Study design

An observational case-control study was performed following the Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) criteria [14]. From March to May 2018, a sample of 208 women was recruited by a con-

secutive sampling method from a university podiatric medicine and surgery unit which provided interventions for foot problems at the University of Extremadura (Plasencia, Spain).

Sample size calculation

The sample size was calculated by means of the difference between two independent groups using the G*Power 3.1.9.2 software [15] and the foot pain domain score (mean \pm SD) from the FHSQ [12, 13] of a prior pilot study ($n = 30$) with two groups. A case group of 15 patients with fibromyalgia (FHSQ score for foot pain domain of 38.58 ± 24.35) and a healthy matched control group of 15 subjects (FHSQ scores for foot pain domain score = 56.26 ± 29.23) were used for the data analysis. Furthermore, a 2-tailed hypothesis, an effect size of 0.65, an α error probability of 0.01, a power ($1 - \beta$ error probability) of 0.95, and an allocation ratio (N_2/N_1) of 1 were used in order to carry out the sample size calculation. Therefore, a total sample size of 170 participants, with 85 subjects per each group, was determined. Considering 20% of possible subjects lost to follow-up, 204 subjects would be necessary. Finally, 208 participants, 104 cases with fibromyalgia and 104 healthy matched controls, were included in the study.

Patients

A sample of 208 women, mean age of 55.00 ± 8.25 years, was recruited from an outpatient clinic and divided into 2 groups, 104 women with fibromyalgia (for the case group) and 104 healthy matched women (for the control group).

For the control group, women older than 18 years old were included in the healthy-matched control group if they reported no spontaneous or chronic pain (at least during the prior 3 months) and no pain-related conditions and were not taking antidepressant or analgesic medications [16].

For the case group, women older than 18 years old diagnosed with fibromyalgia according to a validated experienced rheumatologist diagnosis, based on a combination of both 1990 and modified 2010 criteria, were included [16–20]. Tender points were positively screened if patients experienced pain under a 4 kg pressure by means of digital palpation located at the 18 points proposed by the American College of Rheumatology [17]. In addition, the presence of fatigue, sleep disorders and other self-reported symptoms by the patient was considered [18].

Exclusion criteria considered for both groups were women older than 18 years old, prior existence of other types of rheumatic diseases different from fibromyalgia, neurological alterations, other systemic, neoplastic or inflammatory condi-

tions, diagnosis of psychiatric illnesses (e.g. schizophrenia), non-controlled endocrine conditions (e.g. hyperthyroidism, hypothyroidism or diabetes), pregnancy, non- or semi-independence in daily life activities, and difficulties understanding the instructions for completing the research course [16].

Outcome measurements

Demographic data such as age, height, weight, and body mass index (BMI) were collected before self-reporting the questionnaire. The Spanish validated self-FHSQ (1.03 Version) was composed of 3 sections. Section one was composed of 13 questions and divided into 4 specific domains regarding foot health-related quality of life: foot function (four questions), foot pain (four questions), footwear (three questions), and general foot health (two questions). Adequate content, criterion, and construct validity (Cronbach α from 0.89 to 0.95) and test-retest intraclass correlation coefficient reliability (ICC from 0.74 to 0.92) were reported for section one. Section two was composed of 4 overall health-related quality of life domains (physical activity, general health, social capacity and vigor), whose questions were largely adapted from the SF-36 [21]. Finally, section three included descriptive data such as socioeconomic status, comorbidities, satisfaction or medical record data. Each question showed several responses by means of a Likert ordinal scale, including only 1 response as the most correct. This tool generated different scores for each domain obtained by means of computer software, whose scores varied from 0 to 100. Considering the health-related quality of life, a score of 0 indicated the worst health status while 100 indicated the best health status [12, 13, 22, 23].

Ethics considerations

The Bioethics and Biosafety Committee of the Extremadura University (Spain) approved this study (approval code: 24/2018). All voluntary women signed the informed consent forms before beginning this study. Ethical standards concerning research on human beings according to the Helsinki Declaration (World Medical Association) and the Council of Europe Convention about human rights and biomedicine, and those standards of the UNESCO Universal Declaration about the Human Genome and Human Rights, as well as other national or institutional rules, were respected [24].

Statistical analysis

The FHSQ (v1.03) was used to obtain the foot and general health related quality of life scores. In all analyses, statistically significant differences with a P -value $< .01$ and a confidence interval (CI) of 99% were considered. Furthermore, all analyses

were performed by means of the SPSS 22.0 software (Chicago, IL, USA).

First, the Kolmogorov-Smirnov test was used to assess normality, and a normal distribution was considered with p -value > 0.01 . Demographic data and FHSQ domains were non-parametric data. Thus, median and interquartile range (IR) as well as maximum and minimum (range) values were used to describe the total sample, women with fibromyalgia (case group), and healthy matched women (control group). The Mann-Whitney U test was applied to assess differences between case and control groups.

Results

Demographic data

A total sample of 208 women between 26 and 83 years old with a median \pm IR of 55.00 \pm 8.25 years completed the study. The sample was divided into 2 groups, 104 women with fibromyalgia (for the case group) and 104 healthy matched women (for the control group). Regarding Table I, demographic characteristics did not show any statistically significant difference ($p > 0.01$) between the groups.

FHSQ domains

As shown in Table II, statistically significant differences ($p < 0.001$) between case and control groups were found for all specific foot domains (foot pain, foot function, foot health and footwear) and general wellbeing domains (general health, physical activity, social capacity and vigor), showing a worse foot and general quality of life (with lower scores of all FHSQ domains) in the women with fibromyalgia compared to healthy matched women.

Discussion

To the authors' knowledge, the present study may be considered as the first research applying the FHSQ [12, 13, 22, 23] which demonstrates specific impairment of the foot health-related quality of life. According to the health-related quality of life questionnaires applied to women who suffered from fibromyalgia – both general quality of life questionnaires, such as the EQ-5D-5L [4], 15D [5], AQoL-8D [6], SF-12 [7] and SF-36 [8], and specific disease questionnaires, such as the FIQR [9] – our findings showed similar results with an impaired general-health related quality of life in women with fibromyalgia [10].

Although women who suffer fibromyalgia show similar foot characteristics of stiffness or mobility and hyperkeratosis or other conditions [11], our study showed a worse foot health related quality of life compared to healthy women. This may be due to the fact that these patients present a central sensitization process [1] as well as more

Table I. Comparison of demographic characteristics of the total sample, women with fibromyalgia and healthy matched women with normalized reference values

Parameter	Total group Median \pm IR n = 208	Fibromyalgia Median \pm IR n = 104	Healthy controls Median \pm IR n = 104	Mann-Whitney U P-value
Age [years]	55.00 \pm 8.25 (26–83)	56.00 \pm 9.00 (26–83)	55.00 \pm 5.00 (45–82)	0.016
Weight [kg]	70.00 \pm 15.00 (43–120)	70.50 \pm 14.00 (50–90)	70.00 \pm 17.50 (43–120)	0.300
Height [m]	1.60 \pm 0.07 (1.45–1.79)	1.60 \pm 0.06 (1.45–1.75)	1.61 \pm 0.09 (1.50–1.79)	0.166
BMI [kg/m ²]	27.26 \pm 5.07 (18.59–43.51)	27.47 \pm 3.90 (18.59–37.46)	26.48 \pm 6.74 (18.75–43.51)	0.627

BMI – body mass index, IR – interquartile range. In all the analyses, $p < 0.01$ (with a 99% confidence interval) was considered statistically significant.

Table II. Comparison of FHSQ scores of the total sample, women with fibromyalgia and healthy matched women with normalized reference values

Variable	Total group Median \pm IR n = 208	Fibromyalgia Median \pm IR n = 104	Healthy controls Median \pm IR n = 104	Mann-Whitney U P-value
Foot pain	48.12 \pm 49.38 (0–100)	35.62 \pm 25.00 (0–90)	76.50 \pm 34.00 (0–100)	< 0.001
Foot function	59.37 \pm 57.00 (0–100)	37.50 \pm 37.50 (0–100)	88.00 \pm 31.00 (0–100)	< 0.001
Footwear	25.00 \pm 50.00 (0–100)	00.00 \pm 41.67 (0–100)	42.00 \pm 43.67 (0–100)	< 0.001
General foot health	25.00 \pm 47.50 (0–100)	25.00 \pm 25.50 (0–85)	43.00 \pm 35.00 (0–100)	< 0.001
General health	40.00 \pm 40.00 (0–100)	20.00 \pm 30.00 (0–90)	60.00 \pm 30.00 (0–100)	< 0.001
Physical activity	56.00 \pm 49.67 (0–100)	38.88 \pm 33.33 (0–100)	78.00 \pm 38.00 (11–100)	< 0.001
Social capacity	50.00 \pm 53.13 (0–100)	37.50 \pm 37.50 (0–100)	75.00 \pm 38.00 (0–100)	< 0.001
Vigor	37.50 \pm 31.25 (0–100)	25.00 \pm 31.25 (0–100)	44.00 \pm 32.00 (0–100)	< 0.001

FHSQ – Foot Health Status Questionnaire, IR – interquartile range. In all the analyses, $p < 0.01$ (with a 99% confidence interval) was considered statistically significant.

foot pain and analgesic medication use than the general population [11]. Prior FHSQ studies have shown an impaired quality of life in some domains of the specific foot and general health for specific foot problems such as hallux valgus [25], calcaneal apophysitis [26], foot arch height [27], lesser toe deformities [28], plantar heel pain [29, 30], onychomycosis [31] or hyperkeratosis [32], as well as general conditions such as Alzheimer disease [33] and breast cancer [34]. Nevertheless, our findings showed the most significant results of health-related quality of life impairment for all foot specific and general domains of the FHSQ compared to these prior studies.

Implications for clinical practice

Although other studies have previously shown general health-related quality of life differences between women with fibromyalgia and healthy controls [8–10], our study added specific foot

health-related quality of life domains such as foot pain, foot function, foot health and footwear. For the medical research field, the present study provides the quality of life differences related to overall health (general health = -29.04 ; physical activity = -28.37 ; social capacity = -24.30 ; vigor = -22.96 points) and specific foot health (foot pain = -31.69 ; foot function = -36.46 ; foot health = -20.95 ; footwear = -19.53 points) in women with fibromyalgia compared to healthy matched women. Future interventional studies, i.e. generic treatments such as pregabalin [35] or specific interventions such as foot trigger points dry needling [36, 37] and custom-made foot orthotics [38] in women with fibromyalgia, could use these clinical differences as key references in order to normalize the specific foot and general health-related quality of life. In line with prior research [8], we highlight that health authorities should pay more attention to improving the general and foot specific health-related quality of life in women with fibromyalgia.

Some limitations should be considered regarding the present study. First, the consecutive sampling method may be the main limitation of this research. Second, although adequate validity and reliability have been shown for the FHSQ [12, 13, 22, 23], its reliability has not yet been established specifically for women who suffer from fibromyalgia and should be considered for future studies. Finally, quality of life could be modified according to socio-demographic factors such as the origin of women with fibromyalgia from rural or urban areas [39] as well as physical factors such as reduced bone mineral density [40].

In conclusion, an impaired foot and general health-related quality of life was observed in women who suffered from fibromyalgia compared to healthy matched women.

Conflict of interest

The authors declare no conflict of interest.

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