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Do the instruments used to assess fibromyalgia symptoms according to American College of Rheumatology criteria generate similar scores in other chronic musculoskeletal pain?

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Abstract

Background As with fibromyalgia, several musculoskeletal disorders are characterized by chronic pain, raising a clinical question – do the instruments used to assess fibromyalgia symptoms according to ACR criteria (ACR criteria) generate similar scores in other chronic musculoskeletal pain?

Objective To compare the symptoms among fibromyalgia and other chronic musculoskeletal pain. Additionally, we also compared the most researched outcomes in fibromyalgia (i.e., present pain at rest and after movement; fatigue; pain severity and impact; function, global impact, and fibromyalgia symptom).

Methods A cross-sectional study. Participants over 18 years old were included if they presented report of chronic musculoskeletal pain (≥ 3 months) and after that, they were divided into two groups (fibromyalgia and chronic pain). They answered the Fibromyalgia Impact Questionnaire-Revised (FIQ-R), Brief Pain Inventory (BPI), Numerical Pain Rating Scale (NPRS) for pain and fatigue, WPI, and SSS.

Results A total of 166 participants were included in this study into two independent groups (chronic pain, n = 83; fibromyalgia, n = 83). We observed significant differences ($p < 0.05$) and large effect sizes (Cohen's d, ≥ 0.7) in clinical outcomes comparisons between groups (i.e., widespread pain; symptom severity; present pain at rest and after movement; fatigue; pain severity and impact; function, global impact, and fibromyalgia symptoms).

Conclusion Fibromyalgia patients (2016 ACR criteria) compared to other chronic musculoskeletal pain patients have higher levels of pain (at rest or after movement) and fatigue, greater impairment in both functionality and global impact, and worse symptoms. Therefore, the WPI and SSS instruments should be used exclusively to assess fibromyalgia symptoms.

Keywords Chronic Pain, Diagnostic Services, Rheumatology, Primary Health Care

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Introduction

Fibromyalgia (or fibromyalgia syndrome) is a chronic condition characterized by widespread pain and complex symptomatology [1], such as fatigue [2], sleep disturbances [3], mood disorders [4], and symptoms not explained by structural changes [5]. Its prevalence varies from 2 to 6% in the world population and is more identified in women aged between 20 and 55 years [2]. The literature recommends that the diagnosis of fibromyalgia should be based on the guidelines of the American College of Rheumatology (ACR) [6]. However, taking into account that it is a disease characterized (in part) by chronic musculoskeletal pain, nothing prevents us from using the same ACR criteria to evaluate other musculoskeletal diseases, as the fibromyalgia assessment/diagnosis (2016 ACR criteria) uses generic instruments such as the Widespread Pain Index (WPI) and the Symptom Severity Scale (SSS) [6].

However, although WPI and SSS instruments perform generic assessments of chronic musculoskeletal pain (on axial region and/or upper and lower limbs) [6], it is necessary to verify whether there is a difference among the clinical outcomes' specificities (e.g., function, global impact, symptoms, pain severity/impact, and fatigue) when comparing patients with fibromyalgia to patients with other chronic musculoskeletal pain. Therefore, the hypothesis of this study was that patients with fibromyalgia have a worse clinical outcome compared to other chronic musculoskeletal pain.

Thus, the objective of this study was to compare (via WPI and the SSS) the symptoms among fibromyalgia and other chronic musculoskeletal pain. Additionally, we also compared the most researched outcomes in fibromyalgia (i.e., present pain at rest and after movement [7, 8]; fatigue [7, 8]; pain severity and impact [9]; function, global impact, and fibromyalgia symptom [10]).

Methods

Study design and ethical considerations

A cross-sectional study performed according to the STROBE Guidelines [11]. The protocol has been approved by the ethics committee of Universidade Federal de São Carlos, in Brazil (report number 4.193.940). This study was disclosed in social media from November 2020 to August 2021.

We disclosed in social media (Instagram® and Facebook®) and through messaging applications (WhatsApp®). All people who manifested interest in taking part in the study were contacted and checked for eligibility criteria. All those who were included in the study received an online form (via GoogleForms®) and agreed to take part in the study by clicking on the "I agree to take part in the present study" after reading the informed online consent form. All participants received an online booklet with information regarding fibromyalgia / chronic pain after the end of their participation (Supplementary material 1).

Participants and study size

Considering the primary outcome of our study (comparisons between groups), we performed the sample calculation *a priori* using the t-test two tails (independent groups) through G*Power (version 3.1.9.7). We used the effect size of 0.44 [12, 13], alpha of 0.05, power of 0.80, and critical f of 1.97. As such, the total sample size was estimated at 166 participants divided into 2 independent groups [14] (fibromyalgia, n = 83; chronic pain, n = 83).

Participants over 18 years old that could read and write in Brazilian Portuguese were included if they presented report of chronic musculoskeletal pain (≥3 months) and after that, they were divided into two groups (fibromyalgia and chronic pain). For the fibromyalgia group, people should have the fibromyalgia diagnosis (participants were considered as with fibromyalgia if they fulfilled the ACR 2016 fibromyalgia diagnostic criteria [6], including the WPI ≥ 7 and the SSS ≥ 5 or WPI = 4–6 and SSS ≥ 9). For the chronic pain group, participants should have a history of chronic pain (≥3 months) but no fibromyalgia (i.e., arthritis, osteoarthritis, low back pain, neck pain, and so on). Namely, participants with chronic pain whose symptoms do not meet the ACR 2016 fibromyalgia diagnostic criteria. Complete database is available at the link < https://docs.google.com/spreadsheets/d/1Yxnof1JH0bUEbD44ZfxBx8ILqcjg58Z/edit?usp=sharing&ouid=104821689851272179944&rtpof=true&sd=true>.

Participants were excluded from the analysis if they had a history of tumors, traumas, acute infections, self-report of severe psychiatric illnesses (including severe depression, bipolarity, and schizophrenia), presence of severe comorbidities in the heart, liver, and/or kidney, presence of neoplasia, systemic autoimmune or inflammatory concomitant diseases, hypothyroidism, pregnancy and/or breastfeeding, and presence of therapeutic intervention in the last six months.

Assessment tools

Participants answered Fibromyalgia Impact Questionnaire-Revised (FIQ-R) [10], Brief Pain Inventory (BPI) [9], and Numerical Pain Rating Scale (NPRS) [7, 8] for pain and fatigue. All participants rated their pain (in two different situations: at rest, and after body movement) and fatigue from 0 (if they did not present pain/fatigue) to 10 (if they presented the worst imaginable pain or fatigue).

FIQ-R assesses the impact of fibromyalgia on life in relation to functional capacity, professional status, psychological disorders, and physical symptoms [15]. Its Brazilian version has excellent test-retest reliability (ICC = 0.75) and comprises 21 items that investigate three

domains: function (9 items, 30 points), global impact (2 items, 20 points), and symptoms (10 items, 50 points) [10, 15]. Scores range from 0 to 100, with the latter being meaningful of a worst condition. The minimal important clinical difference for the FIQ-R is 27 points [16].

We also use BPI, a self-report instrument validated for the Brazilian population [17]. BPI assesses pain severity and impact on a person's life with 15 items that assess presence, severity, location, functional impact, used therapeutic strategies, and treatment efficacy on an 11-point scale ranging from zero (no pain/no interference) to 10 (as bad as it can be). High scores indicate worse pain severity and impact. Its Brazilian version presented a two-dimensional structure (pain severity and interference) and excellent internal consistency (α=0.87–0.91) [9].

We assess pain intensity using the NPRS, a self-report instrument validated for the Brazilian population [7]. NPRS is a single-item instrument that was used for pain and fatigue intensity. We evaluated pain in two different situations: at rest – "Currently and at the moment when you are sitting/lying on the couch watching your favorite TV show, do you feel pain?"; after body movement – "Currently and when you walked from the supermarket parking lot to the grocery store or crossed the street to work, do you feel pain?" [18]. For fatigue, we asked "During the answer to this questionnaire, which number best corresponds to your state of fatigue/body tiredness?". In all questions about pain/fatigue, zero means no pain/fatigue and 10 was the worst pain/fatigue imaginable. In chronic pain conditions, NPRS had a moderate to high test-retest reliability (0.67 to 0.96) [19].

Table 1 Participants' characteristics – values presented in mean (SD).

Variables	Chronic pain group (n=83)	Fibromyalgia group (n=83)	p
Age (years)	43.1 (13.0)	38.7 (10.1)	0.011*
Body mass (kg)	71.7 (13.5)	73.5 (15.5)	0.085
Stature (m)	1.62 (0.0)	1.64 (0.0)	0.766
Body mass index (Kg/m^2)	27.3 (5.2)	27.2 (5.3)	0.795
Widespread Pain Index (score)	4.8 (2.7)	13.3 (3.6)	<0.001*
Symptom Severity Scale (score)	5.9 (2.9)	9.2 (1.9)	<0.001*
Numerical Pain Rating Scale (score)			
Present pain at rest	5.0 (2.5)	6.6 (1.8)	0.007*
Pain after movement	5.4 (2.7)	7.5 (2.2)	0.017*
Present fatigue	5.2 (3.3)	7.9 (1.8)	<0.001*
Brief Pain Inventory (score)			
Pain severity	5.2 (2.2)	6.8 (1.6)	<0.001*
Pain impact	5.5 (2.7)	7.4 (2.0)	0.001*
FIQ-R (score)			
Function (0–30)	11.9 (8.6)	21.5 (5.9)	<0.001*
Global impact (0–20)	9.5 (6.3)	16.3 (3.8)	<0.001*
Symptoms (0–50)	25.8 (12.3)	37.6 (6.9)	<0.001*
Total score (0-100)	47.4 (25.5)	75.5 (14.6)	<0.001*

BPI: Brief Pain Inventory; FIQ-R: Fibromyalgia Impact Questionnaire-Revised. * Significant difference (independent t-test, p<0.05)

Statistical analysis

The distribution of variables was verified using Kolmogorov-Smirnov test. We set the significance level at 5% for all statistical tests, which in turn were processed using the Statistical Package for the Social Sciences software, version 17.0 (Chicago, IL, USA). The comparisons between variables were performed via independent T-test and presented as: mean, standard deviation (SD), mean difference (MD) with confidence interval (95% CI), and effect size [20], calculated using Cohen's d according to classification values: 0.2=small, 0.5=moderate, and ≥0.7 large [21].

Results

Three hundred and ninety-six women volunteered. After the screening, according to the eligibility criteria mentioned in the methods, a total of 166 participants were included in this study into two independent groups (Chronic Pain [CP], n=83; Fibromyalgia [FM], n=83). We observed significant differences (p<0.05) and large effect sizes (Cohen's d, ≥ 0.7) in clinical outcomes comparisons shown in Tables 1 and 2 (i.e., widespread pain [WPI]; symptom severity [SSS]; present pain at rest, after movement, and fatigue [NPRS]; pain severity and impact [BPI]; function, global impact, and fibromyalgia symptoms [FIQ-R]). Prevalence of WPI is similar in both groups. However, the number of regions affected by pain is significantly different between them (Table 1).

Our study shows large effect sizes, indicating the clinical relevance of the comparisons of the present study. Clinical relevance (also known as clinical significance) indicates that the results of a study are meaningful or not for several stakeholders [22]. The clinical relevance facilitates the understanding and interpretation of results for professionals. Currently, the assessment of this approach has become a popular method to assist the transfer of knowledge into clinical practice.

Discussion

Main results synthesis

The objective of this study was to compare (via WPI and the SSS) the symptoms among fibromyalgia and other chronic musculoskeletal pain. Additionally, we also compared the most researched outcomes in fibromyalgia (i.e., present pain at rest and after movement [7, 8]; fatigue [7, 8]; pain severity and impact [9]; function, global impact, and fibromyalgia symptom [10]). Our results showed that patients with fibromyalgia have higher levels of widespread pain and symptom severity than patients with

Table 2 Comparison of Pain and FIQ-R between groups

Variables	Group (n = 166/2)	Mean (SD)	Mean Difference	CI 95%	d
NPRS[a]	Chronic Pain	5.0 (2.5)	-1.62	-2.30, -0.95	0.7[#]
	Fibromyalgia	6.6 (1.8)			
NPRS[b]	Chronic Pain	5.4 (2.7)	-2.12	-2.87, -1.36	0.8[#]
	Fibromyalgia	7.5 (2.2)			
NPRS[c]	Chronic Pain	5.2 (3.3)	-2.66	-3.49, -1.82	1.0[#]
	Fibromyalgia	7.9 (1.8)			
Brief Pain Inventory					
Pain severity	Chronic Pain	5.2 (2.2)	-1.50*	-2.18, -0.99	0.8[#]
	Fibromyalgia	6.8 (1.6)			
Pain impact	Chronic Pain	5.5 (2.7)	-1.95*	-2.68, -1.22	0.8[#]
	Fibromyalgia	7.4 (2.0)			
FIQ-R					
Function	Chronic Pain	11.9 (8.6)	-9.57*	-11.86, 7.29	1.3[#]
	Fibromyalgia	21.5 (5.9)			
Global impact	Chronic Pain	9.5 (6.3)	-6.77*	-8.38, -5.15	1.3[#]
	Fibromyalgia	16.3 (3.8)			
Symptoms	Chronic Pain	25.8 (12.3)	-11.80*	-14.87, -8.73	1.1[#]
	Fibromyalgia	37.6 (6.9)			
Total score	Chronic Pain	47.4 (25.5)	-28.15*	-34.53, 21.77	1.3[#]
	Fibromyalgia	75.5 (14.6)			

CI: Confidence Interval; d: effect size (Cohen's d); FIQ-R: Fibromyalgia Impact Questionnaire-Revised; NPRS: Numerical Pain Rating Scale ([a] present pain at rest, [b] pain after movement, [c] present fatigue); SD: Standard Deviation. * Significant difference (independent t-test, $p<0.05$). [#] Significant effect size (Cohen's d, large effect, ≥ 0.8)

other chronic musculoskeletal pain. Namely, the instruments used to assess fibromyalgia symptoms according to ACR criteria (WPI+SSS) generate significantly different scores in other chronic musculoskeletal pain (the same happens with the other outcomes analyzed). Therefore, reinforcements that these instruments (WPI+SSS) should be used only in patients with fibromyalgia.

Fibromyalgia diagnosis: challenges and perspectives

Since the last century, studies on fibromyalgia have evaluated patients using biomedical models [23, 24]. This evaluation model was strengthened 1990's year when the ACR established classification criteria for fibromyalgia [25]. Then, other updates appeared (2010 and 2011) whose combined review resulted in the 2016 criteria [26]: (A) Widespread pain, defined as pain in at least 4 of 5 body's regions; (B) Symptoms have been present at a similar level for at least three months; (C) Widespread pain index≥7 and symptom severity scale score≥5 (or Widespread pain index of 4–6 and symptom severity scale score≥9); (D) A diagnosis of fibromyalgia is valid irrespective of other diagnoses [6].

Although this initiative is relevant to health sciences, it is possible to note that patients continue to be assessed via the biomedical model [27]. Perhaps, that happening because The prevalence of fibromyalgia appears to differ according to the diagnostic criteria used [28]. The 1990 criteria have been considered stricter than the 2010 criteria, such that only more severely affected patients are identified [29]. Studies recruiting fibromyalgia patients according to the 1990 ACR criteria reported higher mean WPI and SSS scores than studies in which patients were recruited using the 2010 ACR criteria [29, 30]. However, most recent studies as well as international recommendations guide the use of the 2016 ACR criteria [6].

Ours and the literature's results

Chronic musculoskeletal pain is one of the main reasons for referrals to health professionals [31]. It can be caused by a wide variety of inflammatory [32] and noninflammatory conditions [33], including arthritis [34], hypermobility [35], low back pain [32], neck pain [36], growing pains [35], and complex regional pain syndrome [37]. Some patients with fibromyalgia have these symptoms associated with the disease, thus, hindering the diagnostic accuracy of fibromyalgia [28]. As such, some authors have used the WPI in the evaluation of other disorders, e.g., temporomandibular disorders [28], psoriatic arthritis [38], musculoskeletal surgery [39], and headache [39].

Our results indicate that the WPI, as well as the SSS, should be used exclusively on fibromyalgia evaluation. In addition, the scores of the instruments most used in studies on fibromyalgia (FIQ-R, BPI, and NPRS), observed in our study, reinforced that the severity of symptoms is greater in fibromyalgia patients. However, although our results support the use of SSS in patients with fibromyalgia, we highlighted that Elkana et al. [40] found that the SSS has an insignificant relationship between the subjective appraisal of cognitive impairment and the objective cognitive scores on computerized subtests. Therefore, we suggest novel studies in this area.

Strengths and clinical applicability

Although patients with fibromyalgia have chronic musculoskeletal pain in different parts of the body (spine, knee, and so on [1]), it does not mean that patients who have other chronic musculoskeletal pain, but no fibromyalgia, may be evaluated using the same instruments

proposed by the ACR to assess fibromyalgia symptoms (WPI and SSS) [6].

As clinical applicability to evidence-based practice, we suggest to the health professionals, first of all, screen fibromyalgia using specific instruments (e.g., the fibromyalgia rapid screening tool [41]). In the same way, other chronic musculoskeletal pain must be evaluated by specific instruments (respecting the cross-cultural adaptation [42]), because there are questionnaires, scales, and specific tests for low back pain [43], knee pain [44], neck pain [45], temporomandibular disorders [46], and other musculoskeletal diseases. Therefore, the WPI and SSS apply to the individuals which ACR has suggested: fibromyalgia patients [1, 6, 47].

Limitations and prospects for novel studies

Although this was the first study to compare fibromyalgia symptoms, according to ACR criteria (WPI+SSS), to scores in other chronic musculoskeletal pain, our study has limitations that must be addressed. Although participants reported pain and global symptoms lasting>3 months, we do not know the pain duration total values in the groups, the prevalence of headache, cramps in the lower abdomen, and depression during the previous six months. We also do not know if the investigated instruments (WPI+SSS) are sufficient to assess fibromyalgia symptoms or whether they should be associated with computerized tests. Besides, medication use was not controlled in that study, and we did not use a polysymptomatic distress scale— we suggest novel studies to investigate these limitations.

Conclusion

Fibromyalgia patients (2016 ACR criteria) compared to other chronic musculoskeletal pain patients have higher levels of pain (at rest or after movement) and fatigue, greater impairment in functionality and global impact, and worse symptoms. Therefore, WPI and SSS instruments should be used exclusively to assess fibromyalgia symptoms.

List of abbreviations

ACR	American College of Rheumatology
BPI	Brief Pain Inventory
FIQ-R	Fibromyalgia Impact Questionnaire-Revised
MD	Mean Difference
NPRS	Numerical Pain Rating Scale
SD	Standard-Deviation
SSS	Symptom Severity Scale
WPI	Widespread Pain Index

Supplementary Information

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Supplementary Material 1

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Authors' contributions

AP-S designed the study; APDS and MAA collected the data; AP-S, AVDF, APDS, MCS, JMDS, and MAA analyzed and interpreted of the data; All authors wrote the initial draft; All authors read and approved the final manuscript.

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Data availability

The data and materials in this paper are available from the corresponding author on request.

Declarations

Ethics approval and consent to participate

This study was approved by the Research Ethics Committee of the Universidade Federal de São Carlos (report number 4.193.940), whose guidelines have been in accordance with the Declarations of Helsinki. All respondents participated in this study freely and signed an informed consent form.

Consent for publication

Not applicable.

Competing interests

Almir Vieira Dibai-Filho and André Pontes-Silva are BMC Musculoskeletal Disorders' Editors and Reviewers. All other authors do not have any Competing interests.

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