Usefulness of tenderness to characterise fibromyalgia severity in women

V.A. Aparicio[1,2,3], A. Carbonell-Baeza[1,4], F.B. Ortega[2,5], F. Estévez[1], J.R. Ruiz[1,2]
M. Delgado-Fernández[1]

[1]Department of Physical Education and Sport, School of Sports Sciences, School of Medicine, University of Granada, Spain;
[2]Department of Biosciences and Nutrition, Unit for Preventive Nutrition, NOVUM, Karolinska Institutet, Sweden;
[3]Department of Physiology and Institute of Nutrition and Food Technology, and
[4]Department of Physical Education and Sport, School of Education, University of Seville, Spain;
[5]Department of Physiology, School of Medicine, University of Granada, Spain.

Virginia A. Aparicio, BSc
Ana Carbonell-Baeza, PhD
Francisco B. Ortega, PhD
Fernando Estévez, BSc
Jonatan R. Ruiz, PhD
Manuel Delgado-Fernández, PhD

Please address correspondence and reprint requests to:
Dr Virginia A. Aparicio,
University of Granada,
Department of Physical Education and Sport, School of Sport Sciences,
Carretera de Alfacar s/n,
18011 Granada, Spain.
E-mail: virginiaparicio@ugr.es

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ABSTRACT

Objective. *To investigate the usefulness of tenderness (tender points count (TPC) and algometer score) to characterise fibromyalgia (FM) severity and symptomatology in women.*

Methods. *The study sample comprised 174 women aged 51±7 years. We assessed tenderness using pressure algometry; quality of life by means of the Short-Form 36 Health Survey (SF-36) and the Hospital Anxiety and Depression Scale (HADS). We used the FM impact questionnaire (FIQ) to assess FM severity and symptomatology. Patients were categorised according to three FIQ-derived categories: FIQ <70 vs. ≥70; FIQ <59 vs. ≥59; and FM-type I and II.*

Results. *TPC was significantly higher in the group of patients with FIQ≥59 (16.9±2 vs. 15.6±4, p=0.02), whereas no differences between groups were observed according to FIQ≥70 (17.0±2 vs. 16.2±3, p=0.12) or FM type (16.8±3 for type II vs. 15.9±4 for type I, p=0.13). We observed a significant association between TPC and FIQ-job difficulty, pain, morning tiredness and stiffness dimensions (all p<0.05), yet it was not correlated with total score of FIQ, FIQ-anxiety, fatigue and depression dimensions (all p>0.05). Algometer score was lower in the FIQ≥70 (45.7±12 vs. 51.1±14, p=0.05) and FIQ≥59 (46.7±13 vs. 52.7±14, p=0.05) groups, and there were no difference between FM types (48.7±13 vs. 49.5±14 for type II and I respectively, p=0.81). Algometer score was not associated with total score of FIQ or FIQ dimensions (all p≥0.1).*

Conclusion. *Widespread pain and pain hypersensitivity, as measured by TPC and algometer score, do not seem to be useful to characterise FM severity and symptomatology (measured by FIQ) in women.*

Introduction

Fibromyalgia (FM) is considered a disorder of pain regulation (1), characterised by an increased sensitivity to painful stimuli (hyperalgesia) and lowered pain threshold (allodynia) (2). Additional to the pain, FM patient's symptoms typically include fatigue, stiffness, insomnia-related symptoms or memory and cognitive difficulties (3-6). The prevalence of comorbidities among patients diagnosed with FM is very high (7), which increases patients' needs for appropriate medical management and results in higher healthcare resource utilisation compared with people without FM (8). A recent review suggest that FM pharmacotherapy is more prevalent in clinical practice and that cellular, molecular and pathophysiologic mechanisms contributing to widespread musculoskeletal and neuropathic pain has emerged (9).

Fibromyalgia has an enormous impact on the health-related quality of life of patients (10-11). Furthermore, patients with FM see the disease as having a worse health than arthritis rheumatoid patients and the general population, especially in terms of mental health (10). Several tools have been used for the diagnosis of FM. The tender points count (TPC) has traditionally been such a tool (5) and has been criticised for placing diagnosis at the far end of the severity spectrum, thereby neglecting the appreciation of the spectrum itself (12). In fact, nowadays FM is considered to be more than just a pain syndrome (4-7). Due to the complex nature of the disease, the diagnosis of FM appears to be a dynamic process. Indeed, due to the apparent difficulty and controversy around the assessment of TPC, the American College of Rheumatology (ACR) has recently presented an alternative preliminary diagnostic criteria mainly based on symptoms sever-

ity (13). To note is that this diagnosis criteria statement has newly opened the debate (14-15).

Several health-related questionnaires are often used as complementary information in the diagnosis and monitoring of FM. However, despite the burgeoning theoretical literature and the proliferation of instruments for measuring various health status domains, no unified approach has been developed and there is little agreement concerning the meaning of the results (16). One of the most used and specific questionnaires in FM is the *Fibromyalgia Impact Questionnaire* (FIQ) (17-18). The FIQ was designed in the early 90s, yet, it is still considered as one of the main tools to assess FM symptomatology (17, 19). From a clinical point of view, it is important to discriminate between patients with mild or severe impairment of the disorder. Several studies suggested FIQ cut-off points to establish different degrees of the FM severity (17, 20-21). Bennet *et al*. (17), in a review performed in 2005 about the FIQ development, operating characteristics and uses, reported that a FIQ score ≥70 was useful to establish severe impairment of the disease. More recently, Bennet *et al*. (20) proposed a FIQ cut-off ≥59 and affirmed that this new one was quite in agreement with that suggested originally. In 2008, de Souza *et al*. (21) suggested that both pain and stiffness were universal FM symptoms, but that psychological distress was a feature present only in some patients. Accordingly, they established a new FIQ-based classification of FM type I, characterised by lower levels of anxiety, depressive and morning tiredness symptoms, and FM type II, characterised by elevated levels of pain, fatigue, morning tiredness, stiffness, anxiety and depressive symptoms. The same study was replicated by Calandre *et al*. (22) with a larger sample of patients of both genders, and the authors concluded that the proposed FM classification was reliable and easy to perform.

To further understand whether TPC is a useful tool to characterise FM severity and symptomatology in women is of clinical interest. The present study investigated the usefulness of tender points count (TPC) to characterise FM severity and symptomatology in women. We compared TPC and algometer score, as well as quality of life and FM symptomatology across several published FIQ cut-offs of severity (FIQ <59 *vs*. ≥59 and FIQ <70 *vs*. ≥70) (17, 20), as well as between the FIQ-based classification of FM type I *vs*. type II (21).

Material and methods

Study sample and design

The study sample comprised 174 women aged 51.3±7.3 years old from a local association of FM patients from Granada (Spain). Patients were diagnosed as having FM by a rheumatologist following the ACR criteria (5). Patients were informed about the study aims and methodology and signed a written informed consent to participate. Inclusion criteria were not to have other rheumatic diseases and other chronic pain diseases (*i.e*. neoplasic diseases, etc.).

All the measurements were performed in a single day and by the same trained researchers to reduce inter-examiners error. The study was reviewed and approved by the Ethics Committee of the "*Hospital Virgen de las Nieves*" (Granada, Spain).

Material and procedures

Anthropometrics measurements

Height (cm) was measured using a stadiometer (Seca 22, Hamburg, Germany) and weight (kg) with a scale (InBody 720, Biospace, Seoul, Korea). Body mass index (BMI) was calculated as weight (in kilogrammes) divided by height squared (in metres).

Tenderness

We assessed 18 tender points with standard pressure algometer (EFFEGI, FPK 20, Italy) and following the ACR criteria for classification of FM (5). The pain threshold at each tender point was determined by applying increasing pressure with the algometer perpendicular to the tissue, at a rate of ~1 kg/s. Patients were asked to say 'stop' at the moment pressure became painful. The mean of two successive measurements at each tender point was used for the analysis. Tender point scored as positive when the patient noted pain at pressure of 4 kg/cm^2 or less. For each patient, the number of positive tender points was summed and recorded as the individual's TPC. We also computed the algometer score by summing up the pain-pressure values obtained at each tender point. The examinations were conducted by a trained physiotherapist.

Fibromyalgia Impact Questionnaire

We used the Spanish version (23) of the FIQ (18) to assess FM-related symptoms. FIQ assesses the components of health status that are believed to be most affected by FM. The FIQ total score ranges from 0 to 100 and a higher value indicates a greater impact of the disorder (17).

As mentioned above, patients were categorised as having moderate or severe FM according to the FIQ cut-offs proposed by Bennet (17) and Bennet *et al*. (20): FIQ <70 *vs*. ≥70, for moderate and severe FM, respectively; or FIQ <59 *vs*. ≥59 for moderate and severe FM, respectively. Patients were further categorised following the FIQ-based classification of FM-type I and FM-type II described by Souza *et al*. (21).

Quality of life

The Spanish version of the *Short-Form 36 Health Survey* (SF-36) (24) was used to assess health-related quality of life. The SF-36 is composed of 36 items, grouped into eight subscales. Each subscale score is standardised and ranges from 0–100, where 0 indicates the worst possible health status and 100 the best possible.

We also assessed depression and anxiety by means of the Spanish version of the *Hospital Anxiety and Depression Scale* (HADS) (26). The HADS contains 14 statements, ranging from 0 to 3, in which a higher score indicates a higher degree of distress. The scores build 2 subscales: anxiety (0–21) and depression (0–21) (27).

Statistical analysis

The distribution of the residuals was examined and parametric and non-parametric statistical tests were used as appropriated. We conducted analysis of variance to examine age and BMI dif-

ferences across FIQ groups, whereas Mann-Whitney test was used to examine total score of FIQ as well as FIQ dimensions, and HADS and SF-36 variables across FIQ groups. Spearman correlation coefficients were used to examine the association of TPC and algometer score with FIQ total score and FIQ-dimensions.

All analyses were conducted using SPSS version 16.0 for Windows (SPSS, Chicago, IL) and the level of significance was set at $p<0.05$.

Results

A total 127 patients had valid data on HADS and tenderness. The characteristics of the study sample by FM severity (FIQ <70 *vs*. ≥70 and FIQ <59 *vs*. ≥59 cut-offs) and by FM typology (type I vs. type II) are shown in Table I. BMI was lower in the moderate FM group regardless of the FIQ cut-off point used (both $p\leq0.05$). BMI was similar in type I and type II groups ($p=0.862$). Quality of life and FM symptomatology, as measured by HADS and SF-36 questionnaires, were significantly worse (all $p<0.01$) in the group with FIQ≥70 (severe FM) compared to the group with FIQ<70 (moderate FM), except the SF-36 physical role subscale ($p=0.088$). Likewise, quality of life was worse (all $p<0.05$) in the group with FIQ≥59 (severe FM) compared to the FIQ<59 (moderate FM) group. Patients categorised in the FM type II group had significantly (all $p<0.001$) worse values of quality of life, except the SF-36 physical role subscale ($p=0.089$).

Figure 1 shows the TPC and algometer score mean values across FIQ categories. TPC was significantly higher in the group of patients with FIQ≥59 (16.9±2 *vs*. 15.6±4, $p=0.02$), whereas no differences between groups were observed according to FIQ≥70 (17.0±2 *vs*. 16.2±3, $p=0.12$) or FM type (16.8±3 for type II *vs*. 15.9±4 for type I, $p=0.13$). Algometer score was lower in the group of patients with FIQ≥70 (45.7±12 *vs*. 51.1±14, $p=0.05$) and FIQ≥59 (46.7±13 *vs*. 52.7±14, $p=0.05$), and there were no difference between FM types (48.7±13 *vs*. 49.5±14 for type II and I respectively, $p=0.81$).

There was a significant association between TPC and FIQ-job difficulty, pain, morning tiredness and stiffness dimensions (all $p<0.05$), yet TPC was not associated with total score of FIQ, and FIQ-anxiety, fatigue and depression dimensions (all $p>0.05$)
(Table II). Algometer score was not associated with total score of FIQ or FIQ dimensions (all $p\geq0.1$).

Discussion

The findings of the present study suggest that the usefulness of widespread pain and pain hypersensitivity, as measured by tenderness, to characterise FM severity and symptomatology (measured by FIQ) in women is of concern. These results provide further support on that FM is not just a pain syndrome and confirm the need of diagnosing and monitoring the FM severity and symptomatology with subjective tools.

Our results concur with those reported by de Souza *et al*. (21). They observed no differences in pressure pain threshold (algometer score) between type I and type II FM. Both Souza *et al*. (21) and Calandre *et al*. (22) observed differences between FM groups (I vs. II) in the mental component but not in the physical components of the quality of life. These results are logical due to the fact that this type of FM classifica-

Table I. Characteristics of the female fibromyalgia (FM) sample by severity (FIQ≥70 or FIQ≥59 cut-offs) and by FM typology (type 1 or type 2).

	FM severity by different cut-offs (n=174)					FM typology (n=167)			
	Moderate (FIQ<70) (n=90)	Severe (FIQ≥70) (n=84)	p [a]	Moderate (FIQ<59) (n=48)	Severe (FIQ≥59) (n=126)	p [a]	Type I (n=43)	Type II (n=124)	p [a]
Age (years)*	51.6 (7.8)	50.9 (6.9)	0.512	51.3 (8.4)	51.4 (6.9)	0.962	50.4 (7.3)	51.3 (7.3)	0.481
Body mass index (kg/m²)*	27.3 (5.5)	29.0 (5.46)	0.050	26.8 (5.0)	28.7 (5.6)	0.048	28.0 (6.1)	27.9 (5.3)	0.862
SF-36			p [b]			p [b]			p [b]
Physical functioning	44.4 (30.0-60.0)	30.0 (15.0-40.0)	<0.001	45.0 (35.0-60.0)	30.0 (20.0-45.0)	<0.001	45.0 (33.3-60.0)	30.0 (20.0-45.0)	<0.001
Emotional role	33.3 (0-100)	0 (0-33.3)	0.003	66.8 (0-100)	0 (0-66.7)	<0.001	100 (33.3-100)	0 (0-58.3)	<0.001
Physical role	0 (0-0)	0 (0-0)	0.088	0 (0-0)	0 (0-0)	0.034	0 (0-0)	0 (0-0)	0.089
Vitality	25.0 (18.8-40.0)	10.0 (0-23.8)	<0.001	30.0 (21.3-40.0)	15.0 (5.0-25.0)	<0.001	30.0 (20.0-40.0)	20.0 (5.0-25.0)	<0.001
Mental health	56.0 (44.0-68.0)	36.0 (24.0-48.0)	<0.001	60.0 (52.0-72.0)	40.0 (28.0-56.0)	<0.001	64.0 (60.0-80.0)	40.0 (28.0-52.0)	<0.001
Social functioning	56.0 (44.0-68.0)	32.5 (20.0-47.5)	<0.001	58.8 (43.1-67.5)	32.5 (22.5-55.0)	<0.001	65.0 (45.0-67.5)	32.5 (22.5-51.9)	<0.001
Bodily pain	22.5 (22.5-45.0)	12.5 (0-22.5)	<0.001	35.0 (22.5-47.5)	22.5 (0-22.5)	<0.001	32.5 (22.5-47.5)	22.5 (10.0-22.5)	<0.001
General health	35.0 (25.0-45.0)	25.0 (15.0-35.0)	<0.001	35.1 (30.0-50.0)	25.0 (15.0-35.0)	<0.001	40.0 (30.0-50.0)	25.0 (15.0-35.0)	<0.001
FIQ total score	58.2 (51.5-66.8)	76.8 (73.2-83.3)	<0.001	52.0 (45.9-56.2)	73.2 (68.1-79.7)	<0.001	55.5 (46.4-66.9)	71.9 (66.3-79.4)	<0.001
FIQ-pain subscale	6.6 (5.0-8.0)	8.0 (7.2-9.5)	<0.001	5.5 (4.4-7.0)	8.0 (7.0-9.0)	<0.001	7.0 (4.6-7.5)	8.0 (6.3-9.0)	<0.001
HADS anxiety	10.0 (6.5-12.0)	12.0 (9.0-16.0)	<0.001	8.0 (4.0-10.5)	12.0 (9.0-15.3)	<0.001	7.0 (4.5-9.5)	12.0 (10.0-14.0)	<0.001
HADS depression	7.0 (4.0-9.5)	10.0 (6.5-13.0)	<0.001	5.0 (3.0-8.0)	9.0 (6.0-12.0)	<0.001	4.0 (3.0-6.0)	10.0 (12.0)	<0.001

*Values are means (standard deviation), otherwise median (25th, 75th percentiles); FIQ: Fibromyalgia Impact Questionnaire; SF-36: Short-Form 36 Health Survey; HADS: Hospital Anxiety and Depression Scale; p [a] from analysis of variance, p [b] from Mann-Whitney test.
Patients were categorised into moderate or severe FM group according to the FIQ cut-offs proposed by Bennet (17) and Bennet *et al*. (20): FIQ <70 *vs*. ≥70, for moderate and severe, respectively; and FIQ <59 *vs*. ≥59 for moderate and severe, respectively; as well as the FIQ-based classification of FM-type I and II described by Souza *et al*. (21).

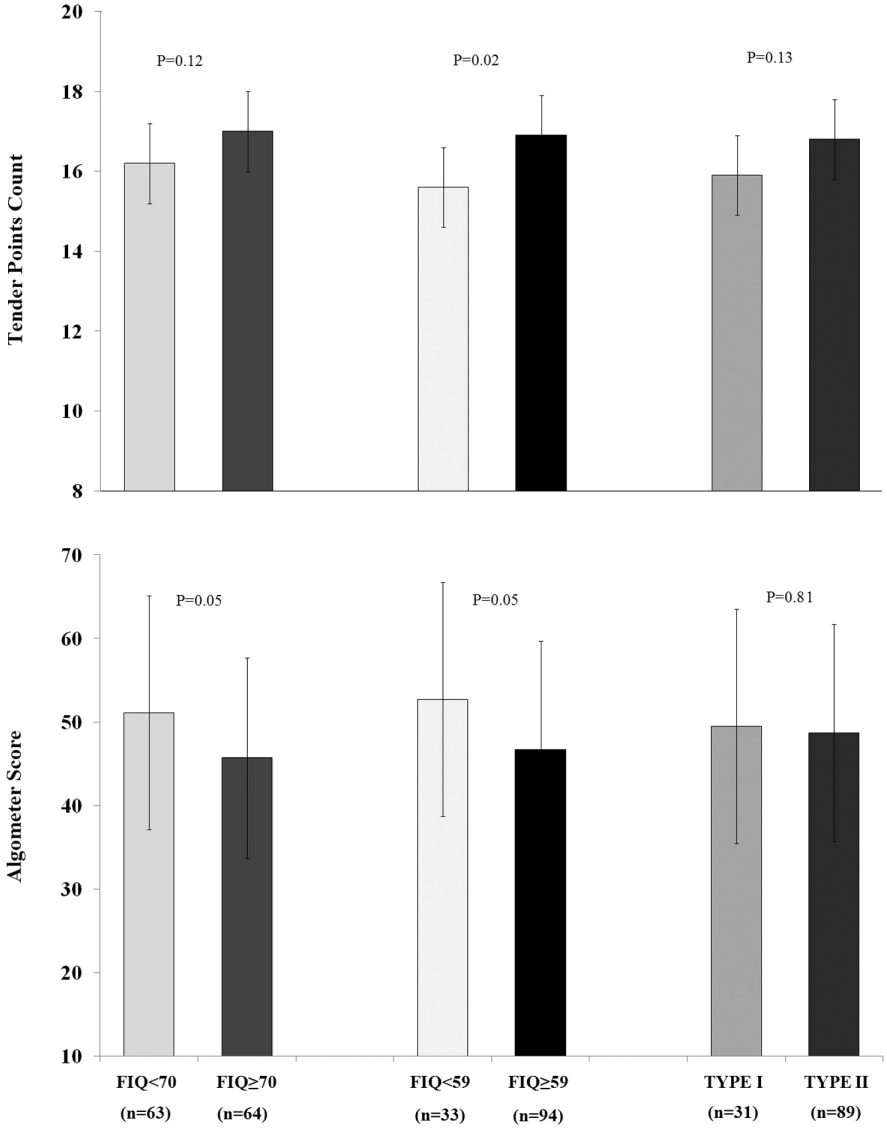

Fig. 1. Differences in tender points count and algometer score attending to the severity and type of fibromyalgia (FM). Values are means and 95% confidence interval.
Patients were categorised into moderate or severe FM group according to the FIQ cut-offs proposed by Bennet (17) and Bennet *et al*. (20): FIQ <70 *vs*. ≥70, for moderate and severe, respectively; and FIQ <59 *vs*. ≥59 for moderate and severe, respectively; as well as the FIQ-based classification of FM-type I and II described by Souza *et al*. (21).

tion is based on distinguishing patients attending to anxiety and depressive symptoms.

Salli *et al*. (28) investigated the relationship between TPC and the severity of the FM in 107 women and observed a positive association between TPC and FIQ total score (r=0.43), which is not in agreement with our results (rho=0.17). They also observed a significant associations of TPC with pain (r=0.51) and with depression (r=0.24), as measured by the Beck Depression Index. The authors concluded that TPC was a simple and noninvasive examination that could supply information about the disease severity and the depression in FM. We observed weaker associations of TPC with FIQ-pain (rho=0.20, p=0.04) and FIQ-depression (rho=0.18, p=0.05). Other studies did not observe significant associations between FIQ total score and TPC as measured by digital palpation of tender point sites (29-30) or algometer (31), which is in agreement with our results.

There are important associations between widespread pain and multiple TPC (19, 32) and it has been shown that significant tenderness can be achieved on specific points also in healthy individuals (33-34). There seem to be a considerable overlap between patients with FM and those with other unexplained syndromes (35). In this regard, patients may be artificially diagnosed as having FM if they have higher TPC with few symptoms and some patients with classical symptoms may be excluded because they exhibit fewer than 11 tender points or pain threshold of more than 4 kg/cm^2 at some specific points (33, 35-38). To note is that TPC as well as the perception of pain are influenced by other factors such as the menstrual cycle (39), cultural features (31, 40) or even ethnicity (41).

Tastekin *et al*. (38) analysed the discriminative value of all tender points, alone and in combination, by investigating the appropriate pressure magnitude that should be applied during tenderness examination. They observed that the pressure pain threshold was different across the tender points, which suggested that the magnitude pressure should be point-specific. In a previous study, Tasketin *et al*. (30) also observed no association between algometer score (the sum of the pain-pressure values obtained for each tender point) and FIQ, which may indicate that this is still not the best solution.

According to the ACR, FM is a chronic widespread pain with widespread allodynia to pressure pain (5). Coster *et al*. (19) observed, in a randomly selected sample from the general population, that only about 50% of individuals reporting chronic widespread pain related to the musculoskeletal system meet the ACR tender point criteria and there was no clear clinical diagnosis for the remaining 50%. Amris *et al*. (42) suggested that musculoskeletal pain in patients with FM and chronic widespread pain has neuropathic features. They suggest that the pain detect questionnaire might be an additional useful and easily applied screening tool assisting in the identification of central sensitisation in patients reporting chronic widespread musculoskeletal pain, and that the Pain Detect Questionnaire (PDQ) has a potential in the future diagnostic assessment of patients with FM. TPC is not replaceable tool for FM diagnosis,

Table II. Spearman correlations of tender points count and algometer score with fibromyalgia (FM) Impact Questionnaire (FIQ) dimensions and FIQ total score in female FM patients (n=127).

	Tender points count		Algometer score	
	rho	*p*	rho	*p*
Total score FIQ	0.168	0.06	-0.156	0.14
Job difficulty	0.266	0.03	-0.264	0.06
Pain	0.195	0.04	-0.103	0.35
Fatigue	0.164	0.07	0.005	0.96
Morning tiredness	0.241	0.01	-0.160	0.15
Stiffness	0.205	0.03	-0.093	0.40
Anxiety	0.033	0.72	0.181	0.10
Depression	0.179	0.05	0.048	0.66

but these results support the need of more than TPC and the importance of the inclusion of subjective scales when diagnosing FM.

We do not know whether these results could be applied to men, and future studies should investigate the usefulness of tenderness to characterise FM severity and symptomatology in men. It would be of clinical interest to replicate this study in other diseases related to pain such as arthritis rheumatoid, lupus, or chronic fatigue syndrome, as well as in the general population.

In conclusion, the findings of this study suggest that widespread pain and pain hypersensitivity, as measured by TPC and algometer score, do not seem to be useful to characterise FM severity and symptomatology (measured by FIQ) in women.

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