Original article

EpiFibro (Brazilian Fibromyalgia Registry): data on the ACR classification and diagnostic preliminary criteria fulfillment and the follow-up evaluation

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A R T I C L E   I N F O

Article history:
Received 17 March 2016
Accepted 31 July 2016
Available online 23 November 2016

Keywords:
Fibromyalgia
Classification criteria
Diagnostic criteria
Follow-up

A B S T R A C T

Introduction: EpiFibro (Brazilian Epidemiological Study of Fibromyalgia) was created to study Fibromyalgia patients. Patients were included since 2011 according to the 1990 American College of Rheumatology Classification Criteria for Fibromyalgia (ACR1990).

Objectives: To determine how many patients still fulfill the ACR1990 and the ACR2010 criteria in 2014; to determine the correlation between the impact of FM and to describe data on the follow-up evaluation.

Methods: This is a cross sectional study in a multicenter cohort of patients. The data was collected between 2013 and 2015. Physician included patients that fulfilled the ACR1990 criteria on the date of entry. The follow-up data were considered only for patients with at least two evaluations. A minimally significant change was considered to be a 30% variation of parameters scores.

Results: 810 patients’ data were analyzed. Patients presented a mean age of 51.8 ± 11.5 years old. There were 786 female. Most patients met both criteria. There was a greater fulfilling of the ACR2010. There was a moderate correlation between Polysymptomatic Distress...
Introduction

The Fibromyalgia Syndrome (FM) is a clinical condition characterized by chronic widespread pain usually associated to fatigue, sleep disturbances and cognitive symptoms. Its prevalence is high and in Brazil it is estimated at 2.5%.

Significance and innovation

Brazilian Registry on Fibromyalgia. Fulfillment of ACR classification and diagnostic criteria. Follow-up data

Conclusion: InEpiFibro, most patients fulfill simultaneously the ACR1990 and ACR2010. A larger number of patients fulfill the ACR2010 at the time of the evaluation. There was a moderate correlation between the Polysymptomatic Distress Scale and the Fibromyalgia Impact Questionnaire. Most patients remained stable over time.

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Fibromyalgia (ACR1990). The clinical and epidemiological data was already published in 2013.

In 2010, an ACR committee presented the Preliminary Diagnostic Criteria for Fibromyalgia (ACR2010), after two decades of critics on the ACR1990. The new criteria abolished the tender points counting and emphasized the association of fatigue; sleep disorders, cognitive disorders and somatic symptoms to chronic widespread pain. It established 2 scores – an widespread pain index (WPI), composed by 19 potentially painful areas to be identified by the patients, and a symptom severity index (SSI) that results from the sum of fatigue, sleep disturbances, cognitive disorders and somatic symptoms scores (0–3 each). The total score ranges from 0 to 12. In 2011 the somatic symptoms item was modified, which allowed creating a self-report version in order to be used in epidemiological studies.

The sum of these two indices, ranging from 0 to 31, named Polysymptomatic Distress Scale (PDS), can be used for patients’ clinical monitoring. The follow-up measures for the FM patients usually are analogical symptom scales, as for example for pain, and by quality of life or impact questionnaires such as the Fibromyalgia Impact Questionnaire (FIQ) and its revised form, whose versions have been translated and validated to Brazilian Portuguese.

### Objectives

The main objectives of the present study are to determine how many patients still fulfill the ACR1990 and the ACR2010 criteria in 2014, to determine the correlation between the impact of FM measured by the FIQ and by the PDS and to describe data on the follow-up evaluation of the patients enrolled in the registry.

### Patients and methods

This is a cross sectional study in a multicenter cohort of patients with FM. The data was collected between 2013 and 2015, including demographic, clinical information and follow-up parameters. Analogical symptom scales of pain and fatigue, FIQ and the PDS were considered clinical parameters.

Patients were included in Epifibro by their physician, according to a tutorial by the Brazilian Rheumatology Society. It included patients that fulfilled the ACR1990 criteria on the date of the patient’s entry in the registry. Patients with incomplete forms were excluded as that prevented the data analysis for the proposed objectives. The follow-up data were considered only for patients with at least two evaluation forms separated by three months interval as a minimum. A minimally significant clinical change was considered to be a 30% up or down variation of the follow-up parameters scores.

Descriptive statistics and the Pearson correlation coefficient were used.

### Results

A total of 810 patients’ data were analyzed. Patients presented a mean age of 51.8 ± 11.5 years-old. There were 786 female patients (97.0%) and only 24 men (3%). Most patients were attended in public health care (648 patients − 80%) and 162 patients (20%) were treated in private services.

Most patients met both ACR criteria as shown in Table 1. There was a greater fulfilling of the ACR2010 compared to the ACR1990, suggesting that the new criteria are more sensitive and maybe less specific than the older one.

Table 2 shows clinical data in patients’ self-scored reports. There was high intensity of pain and fatigue and a severe disease impact measured by PDS and FIQ.

There was a moderate correlation between PDS and FIQ ($r = 0.576$), as shown in Fig. 1.

Three hundred fourteen patient’s registries with more than one assessment were found, but 88 patients were excluded because an interval between evaluations under 3 months. Thus, 226 patients with one follow-up monitoring parameter registered were considered (FIQ: 222; PDS: 199; both: 195).

### Table 1 – Fulfillment of the 1990 Classification Criteria for Fibromyalgia (ACR1990) and the 2010 Preliminary Diagnostic Criteria for Fibromyalgia (ACR2010).

<table>
<thead>
<tr>
<th></th>
<th>ACR1990</th>
<th></th>
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</thead>
<tbody>
<tr>
<td>Yes</td>
<td>347</td>
<td>39</td>
<td>386</td>
</tr>
<tr>
<td>No</td>
<td>182</td>
<td>44</td>
<td>226</td>
</tr>
<tr>
<td>Total</td>
<td>529</td>
<td>83</td>
<td>612</td>
</tr>
</tbody>
</table>

### Table 2 – Clinical parameters of the Epifibro database patients.

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Values</th>
</tr>
</thead>
<tbody>
<tr>
<td>PNS</td>
<td>8.4 ± 1.4</td>
</tr>
<tr>
<td>FNS</td>
<td>7.9 ± 2.3</td>
</tr>
<tr>
<td>PSD</td>
<td>22.19 ± 5.8</td>
</tr>
<tr>
<td>FIQ</td>
<td>68.0 ± 17.1</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Values</th>
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<tbody>
<tr>
<td>PNS, Pain Numerical Scale (0–10); FNS, Fatigue Numerical Scale (0–10); PSD, Polysymptomatic Distress Scale; FIQ, Fibromyalgia Impact Questionnaire.</td>
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</tr>
</tbody>
</table>
The mean follow-up time was 9.1 ± 7.5 months (1–44). FIQ and PDS measures are shown in Table 3.

### Discussion

In this study, it was observed a female predominance, which is compatible with the literature. Although there is a large majority of patients seen in the Brazilian Public Health System, the private network is also represented in this study.

The intensity of pain and fatigue and the impact clinical parameters shows that the reported cases are severe. Higher severity can be justified by the main data collection centers involved in this study are universities that composes the tertiary care health assistance level. So, this is a limitation of this research that prevents the data to be generalized to all Brazilian fibromyalgia patients. Anyway, it suggests a need for epidemiological studies involving community patients. The same argument may be used for the high male predominance. It is important to emphasize that this is not a prevalence study, but a registry data.

The moderate correlation between the two follow-up parameters (FIQ and PDS) suggests that both can be used in monitoring. The choice of the parameter should be based on the ease of use and the familiarity of the doctors or services. The FIQ has been used in clinical trials and in daily practice since 1993 with reliable results in our population even before being validated formally. In 2006, it was published its formal translation and validation for Portuguese in Brazil. The PDS was recently created and we still have not published data to assess its potential for clinical monitoring.

The observed clinical stability is compatible with evolution studies present in the literature. Kennedy et al. studied 35 patients and showed that 100% continued to have symptoms after 10 years. Other studies have reported improvements in pain over time, but the total resolution of symptoms seems rare. In 2011, Walitt et al. published a 5 year follow-up study with 1555 fibromyalgia patients and found a clinically significant improvement in the overall severity of symptoms, despite the pain improvement be only moderate in 25% of patients.

### Conclusion

In the EpiFibro Cohort, most patients fulfill simultaneously the ACR1990 and ACR2010 criteria for FM. A larger number of patients fulfill the ACR2010 compared to ACR1990 at the time of the evaluation. There was a moderate correlation between the FIQ and the PDS monitoring and most patients remained stable over time.

### Conflicts of interest

The authors declare no conflicts of interest.

### References