



Original Article

Fibromyalgia Health Assessment Questionnaire: Sensitivity to Change[☆]

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ABSTRACT

Objective: To analyze the responsiveness of the Fibromyalgia Health Assessment Questionnaire (FHAQ) in a group of patients with fibromyalgia (FM).

Methods: Observational, prospective and longitudinal study related to the project ICAF was taken part in 15 Spanish centers. 232 patients were included and diagnosed of FM: 98.3% were women, the mean age was 47 years old, they were analyzed at a basal visit and 3 months visit, afterwards an appropriated treatment was prescribed. The statistical analysis was performed including: mean comparison, mean standardized response (RME), basal standard media (DE), intraclass correlation coefficient (R), standard error of the mean (EEM), minimal detectable difference (DMD) and percentage change in real.

Results: The difference in mean comparison of the FHAQ in the baseline visit and the 3 months visit was of 0.098 (95% CI: 0.034–0.16), with a $P < .003$. Nevertheless the RME was 0.21, a slightly change, the DE=0.57, $R=0.81$, EEM=0.25, and the DMD=0.69. The percentage change in real was 17% (39 patients). But the sense of the change was positive in 28 cases (less punctuation in the 3 months visit) and negative in other 11 cases (higher punctuation in the 3 months visit).

Conclusions: The punctuation in the 3 months visit was significant better than the basal, but the results of this study do not let it to consider that the FHAQ have enough change susceptibility to recommend it in longitudinal studies. The well knowing fact, some patients can become worse with the treatment prescribed would be to the detriment of the FHAQ psychometric value.

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Fibromyalgia Health Assessment Questionnaire: evaluación de la sensibilidad al cambio

RESUMEN

Objetivo: Analizar la sensibilidad al cambio del cuestionario Fibromyalgia Health Assessment Questionnaire (FHAQ) en un grupo de pacientes con fibromialgia (FM).

Métodos: Estudio observacional, prospectivo longitudinal, incluido en el Índice combinado de afectación en pacientes con fibromialgia, Proyecto ICAF (Índice combinado de afectación en pacientes con fibromialgia), realizado en 15 centros españoles. Se incluyeron de forma consecutiva 232 pacientes con FM con una edad media de 47 años, 98,3% mujeres, que se evaluaron en una visita basal y tres meses después de que se les instaurara un tratamiento según práctica médica habitual. El análisis estadístico incluyó: Comparación de medias, Respuesta Media Estandarizada (RME), medida basal estándar (DE), coeficiente de correlación intraclase (R), error estándar de medida (EEM), diferencia mínima detectable (DMD) y proporción de cambio real.

Palabras clave:

Fibromialgia

Evaluación

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[◇] Annex 1 includes members of the group.

Resultados: La diferencia de puntuación media del FHAQ en la visita basal y a los tres meses fue de 0,098 (IC 95%: 0,034-0,16) con una $p < 0,003$. Sin embargo la RME fue de 0,21 (cambio pequeño); DE=0,57, R=0,81, EEM=0,25, DMD=0,69. La proporción de cambio real fue del 17% (39 pacientes). No obstante, el sentido del cambio fue positivo en 28 casos (menor puntuación a los 3 meses) y negativo en los otros 11 (mayor puntuación a los 3 meses).

Conclusiones: La puntuación a los 3 meses fue significativamente mejor que la basal, pero con los resultados de este estudio no se puede considerar que el FHAQ sea suficientemente sensible al cambio como para recomendar su uso en estudios longitudinales. El hecho, conocido, de que muchos pacientes pueden empeorar con el tratamiento empleado, ha ido en detrimento de la valoración psicométrica del FHAQ.

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Introduction

The assessment of functional capacity in fibromyalgia (FM), as in other chronic conditions in which mobility is limited by pain and other symptoms, is the key to estimating the severity of the disease and its prognosis. It is also very important for patients because it affects them personally, socially and in their work.¹ It is also important to society because it has implications in the indirect costs of illness, constituting a frequent cause of sick leave or poor performance at work in these patients.²

However, despite their undeniable importance in the management of fibromyalgia, there is little questionnaires can do to specifically measure functional capacity in FM. The physical function scale of the Fibromyalgia Impact Questionnaire (FIQ-FF)³ has often been used for this purpose, although its validity to measure disability is poor. Other questionnaires have generally also been used, such as the 36-question Short Form Health Survey (SF-36), also not without limitations.⁴ On other occasions we have used the Health Assessment Questionnaire (HAQ),⁵ but it specifically measures functional ability, and was designed for patients with rheumatoid arthritis, so that its items are not always applicable to patients with FM.

Based on the above, in 2000 the use of the Fibromyalgia Health Assessment Questionnaire (FHAQ) 4 was proposed in an attempt to more adequately measure functional ability in FM. The FHAQ is an 8-item questionnaire derived from the HAQ, and a Spanish version has demonstrated a higher construct validity than FF-FIQ and similar to the HAQ, with the advantage of being shorter, simpler and easier to respond quantifiably.⁶

In addition to showing its validity to measure a construct (in this case functional capacity), a questionnaire of these characteristics must prove its ability to detect changes in a situation over time, something required if intended for routine use routinely in the clinical practice. That is, the questionnaire should be sensitive to predictable changes in disability over time, varying the score consistently with the state of the patient.⁷ There is nevertheless no studies in the literature that examine the sensitivity to change of FHAQ. Therefore, the aim of this study is to analyze the sensitivity to change of the FHAQ questionnaire to see if it can be a useful tool to detect changes in the activity of FM over time depending on the patient's condition.

The ICAF study (combined index of involvement in patients with fibromyalgia),⁸ although not designed specifically to study the sensitivity to change of FHAQ, allows for analysis in this regard. Thus, one can explore the behavior of the scale regarding changes in the health of patients to complete its validation and advise or discourage its general use.

Methods

Design

We performed an observational, prospective and longitudinal study, in which consecutive patients were recruited

from rheumatology outpatient clinics of 15 hospitals in Spain (ICAF project, phase II); the data collection took place between October 2008 and June 2009. All patients signed informed consent and the clinical research ethics committees of the hospitals of the main investigators approved the study protocol.

Patients and Acquisition of Variables

We included, consecutively, patients over 18 and under 65 years of age, diagnosed with FM according to the 1990 ACR criteria, which according to routine clinical practice had been treated with one of the following drugs: tricyclic antidepressants, other antidepressants or pregabalin, alone or in combination. Any of these drugs could be introduced according to routine clinical practice, i.e., the rheumatologist, based on symptoms and patient characteristics, prescribed treatment as appropriate in his opinion, without further prejudice in order to maintain patient treatment with painkillers, tranquilizers, exercise, or other psychological therapy. Once the treatment was established, any of the ones indicated by the protocol, patients were selected for study. It is estimated that treatment with antidepressants and/or pregabalin will lead to a perceptible change in the patient's symptoms, as they constitute drugs that reduce the severity of symptoms and, therefore, have a predictable impact on the ability to function. Exclusion criteria were the presence of concomitant pathology that could produce functional disability (inflammatory rheumatic diseases, cardiovascular problems and obesity) or severe psychiatric problems that were not previously controlled by medical treatment. We also excluded patients who were involved in legal proceedings (litigation, disability, disabilities).

Sociodemographic and clinical data that include sex, age and date of onset of illness or employment status were gathered through a standardized questionnaire. The study participants also completed a series of self-administered questionnaires, among which we included the FHAQ, scored by calculating the average of 8 items. The questionnaire was completed on 3 occasions: the first time at patient inclusion in the study (visit 1), a week later, at the time when the treatment was instituted to assess the test-retest reliability (visit 2) and, finally, at 3 months after the start of the prescribed treatment (visit 3).

Health was defined as any change in the patient's clinical condition, including either the prescription of a new drugs, modification of the previous prescription or the performance of new diagnostic procedures, the development of comorbidities, or the need for referral to another specialist to manage their disease.

Statistical Analysis

First, we performed a descriptive analysis of demographic data of the sample, whose results are shown as means with corresponding standard deviations (SD) and percentages.

We calculated the average score of FHAQ at baseline and 3 months to estimate the statistical change between the two scores.

To assess sensitivity to change we evaluated 3 different analysis possibilities, depending on the design of study.⁹ As there is no external standard against which to measure functional capacity we employed an analysis for homogeneous samples with homogeneous expected change. The statistical coefficients used were based on group-level effect sizes, including the mean response (SMR: mean change/standard deviation for change). According to literature, the SMR values of 0.20, 0.50 and 0.80 represent small, moderate and severe, change sensitivity, respectively.¹⁰

According to some authors,⁹ significant changes at the group level are not useful for assessing individual change and thus emphasize the importance of studying the sensitivity measured at the individual patient level. For this purpose, various indices have been proposed such as the minimum detectable difference ($MDD = 1.96 \times \sqrt{2} \times SEM$), it was also considered. The MDD is the minimum change score, which probably reflects a real change greater than measurement error. To calculate the standard deviation (SD) we used intraclass correlation coefficient (R) and standard error of measurement ($SEM = SD \times [(1 - R) / 2]$) at baseline.

A complementary approach appears when the rate of change exceeds reliable or MDD. This index represents the percentage of patients who show a higher change than expected by mistake.

Results

Descriptive

The study included a total of 232 patients, of which 98.3% were women. The mean age \pm SD at first visit was 47 ± 8 years. The time since onset of pain at the time the study was 9 ± 8 years and the time since diagnosis of FM 4 ± 4 years. Regarding employment status, most patients were active workers (56%) and housewives (22%), 14% were retired, primarily due to the disease, and 6.5% of patients were unemployed. Sociodemographic variables and baseline characteristics of the sample are shown in Table 1.

Sensitivity to Change

The difference in mean score between baseline FHAQ and at 3 months was 0.098 (95% CI, 0.034–0.16) with $P < .003$. The SMR was $0.098/0.47 = 0.21$ (small change).

The baseline standard deviation was $SD = 0.57$ and the intraclass correlation coefficient $R = 0.81$. This gave a $SEM = 0.25$. All this implies that the minimum detectable difference (MDD) is 0.69.

With these data, the real rate of change is 17% (39 of the 232 patients in the sample). However, the direction of change was positive in 28 cases (lowest score at 3 months) and negative in the other 11 (rated at 3 months).

Discussion

In this study we analyzed the sensitivity to change of the FHAQ, i.e., we have analyzed the behavior of the scale on expected health changes in FM patients after standard medical treatment.

FHAQ scores significantly improved at 3 months when using a comparison of means, but the low value obtained in relation

to the SMR in this study indicates that the FHAQ exhibits minimal sensitivity to change in the sample, i.e., there is a possibility that the instrument may not be able to detect with high reliability a statistically significant change at the group level.

As for the real exchange rate (clinical and not just statistical), less than a fifth of the sample showed a difference higher than the expected error, and also the response was not homogeneous, as some had improved and others worsened.

All these results should be interpreted with caution because the analysis used for the study is based on the assumption that patients are homogeneous, and predicted change is too. Our results are reasonably homogeneous on some patients of the same demographic baseline characteristics, but have a very important variability in the response to standard medical treatment, as only a certain percentage of patients responded to treatment. This percentage was estimated at 25% of those treated with antidepressants.¹⁹ This variability is detrimental for the indices used, and for that reason they may have been abnormally diminished.

The selection criteria of the ICAF study only ensures that all patients in the intervention were homogeneous in the sense that in all of the cases where it had been introduced for the first time, some of the pharmacological treatments were considered effective. However, when the intervention is framed in routine clinical practice, it also allows the use of other non-pharmacological therapies. Several studies have shown the usefulness of these therapies in improving functional capacity, especially cognitive therapy conductual¹¹, físico¹² exercise programs, or a combination of both.¹³ Although there were no patients in psychological treatment, some exercised and this may also affect the expectation of change not being homogeneous, since patients who perform regular and adequate exercise would have expected a change in functional capacity greater than those who received drug treatment only.¹⁴ It is therefore not likely to meet the assumption needed to calculate statistical power. In addition, this would explain the observed difference in direction of change, being sometimes positive and other times negative, and that the improvement observed in some patients could be due to the positive effects of other therapies (e.g., exercise), while negative change could also be motivated by the opposite (stop exercise or personal conflicts appearing or worsening during that period).

Moreover, one might think that the interval of the intervention (only 3 months) was insufficient to observe significant changes and that the results would be different if this range was extended. However, this reasoning does not apply in this case, since the drugs tested have shown efficacy in the short term, usually 3–6 months, not long term.^{15,16}

Our explanatory hypothesis is that the questionnaire indeed detected a significant change from the point of view of comparison of means, but not from the point of view of the minimum detectable difference, the deviation from the standard baseline measurement and intraclass correlation coefficient, probably not for a lack of sensitivity of the instrument, but because the drugs used to treat fibromyalgia produce inconsistent improvement of symptoms, and not just translate into a significant improvement in functional capacity, as has already been published in a study that applied the HAQ in FM patients and scored stable over time with a slow downward trend over the years.¹⁷ The two classic meta-analysis studies of antidepressants in FM^{18,19} do not mention improvement in functional capacity measures, but symptomatic improvement in pain, fatigue and sleep quality. However, more recent studies with new drugs such as duloxetine²⁰, milnacipram^{21,22} or pregabalin²³, do detect functional improvement, but it is evaluated, in almost all

Table 1
Sociodemographic and Clinical Characteristics of Patients.

Variable	N			%
Male	4			1.7
Female	228			98.3
Active worker	130			56.3
Illness associated pension	31			13.4
Retired and preretired	2			0.9
Homemaker	51			22.1
Unemployed	15			6.5
Other employment situation	2			0.9
Other	n	Mean, years	SD	
Age at first visit	232	47	8	
Age at the onset of generalized pain	224	37	10	
Age at diagnosis of FM	227	43	8	
Time since onset of pain	224	9	8	
Time since onset of FM	227	4	4	

SD, standard deviation; FM, fibromyalgia; n, total number; %, percentage.

cases, with the physical function SF36 scale. In conclusion, there is enough evidence to show that the FHAQ is sensitive to change, but not to rule out this hypothesis, so it is recommended to reevaluate the questionnaire in a study made specifically for this purpose, which ensures, on the one hand, the homogeneity of the sample in all baseline parameters, and in which the improvement in functional capacity is measured with a separate standard to rule out the patients who have not improved or have worsened despite further treatment. The FHAQ remains an effective instrument to measure functional capacity of patients in cross-sectional studies, but data from this study cannot confirm its usefulness as an outcome measure in longitudinal interventions.

Conflict of Interests

The ICAF study was financed by Pfizer and the Fondo de Investigación Sanitaria (FIS) PI 07/0202.

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Appendix 1.

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