Quality of Life in Women with Fibromyalgia Syndrome: Validation of the QIF, the French Version of the Fibromyalgia Impact Questionnaire

SERGE PERROT, DOMINIQUE DUMONT, FRANCIS GUILLEMIN, JACQUES POUCHOT, JOËL COSTE, and the French Group for Quality of Life Research

ABSTRACT. ***Objective.*** To validate a translated and adapted version of the Fibromyalgia Impact Questionnaire (FIQ) for use in French-speaking populations.

Methods. The FIQ was translated into French by 2 independent translators and then back-translated into English to assess the conceptual equivalence. The translated version was tested and adapted by an expert committee to obtain the Questionnaire de mesure d'Impact de la Fibromyalgie (QIF), the French version of the FIQ. We administered the QIF to 102 women with fibromyalgia (FM): 71 women who consulted once, and 31 women who were follow for 3 visits (D0, M1, and M3). The patients were also asked to answer 4 other questionnaires: the McGill Pain Questionnaire, the Medical Outcome Study Short Form-36 (SF-36), the short form of the Arthritis Impact Measurement Scale 2 (AIMS2), and the General Health Questionnaire (GHQ) (for psychiatric assessment). To ensure test-retest reliability, the patients were asked to complete the QIF 7 days after the first visit and to send it back to the investigators by mail. During each visit, all patients were asked about pain intensity. A tender point count was obtained by thumb palpation and the tenderness threshold of each specific point was assessed by a 4-point scale score to determine the global tender point index.

Results. No major cultural adaptation was needed to obtain the French version of the FIQ. Test-retest reliability coefficients (intraclass correlation coefficient) for each question ranged from 0.04 to 0.84. Two items from the QIF (number of days when the patient felt good and visual analog scale stiffness) did not reach significant levels of test-retest reliability. Internal validity was good. The QIF score correlated well with the SF-36 and AIMS2 scores. The psychological aspects of the QIF were well correlated with those of GHQ-28. None of the items from the McGill Pain Questionnaire was correlated with QIF items. Similarly the clinical data concerning pain assessment were not correlated with QIF items.

Conclusions. QIF is a valid instrument for measuring functional disability and health status in French women with FM. Some of the items were of a limited reliability, perhaps due to the variability of the multiple aspects of this syndrome. (J Rheumatol 2003;30:1054–9)

Key Indexing Terms:
FIBROMYALGIA PAIN ASSESSMENT QUALITY OF LIFE

The assessment of fibromyalgia (FM) is a controversial issue[1,2]. Several authors have tried to identify sensitive and reliable data[3,4]. Total counts of tender points, myalgia score, and the McGill Pain Questionnaire[5] seem to be the most sensitive and reliable ways of measuring pain in FM. Simms, *et al*[3] showed that a visual analog scale (VAS) for sleep and global health perception can be used by the patient and the physician, respectively. Hewett, *et al*[4] demonstrated that scales such as the Arthritis Impact Measurement Scale (AIMS) and symptom checklist-90R can be used to assess a patient's perception of his or her health. It is also important to analyze physical and psychological components and the patients' ability to cope with FM syndrome[6]. In addition to pain, which is one of the most common symptoms, most patients complain of longlasting but changeable symptoms. For example, a patient's main problem may be sleep disturbances at a given time, and then fatigue or functional impairment a few weeks later[7]. Thus global measurements of quality of life or health seem to be well adapted for such patients. Burckhardt, *et al*[8] developed a tool to assess the current health status of women with FM, the Fibromyalgia Impact Questionnaire (FIQ). This questionnaire has been translated into several languages (e.g. Hebrew, German, Swedish, and Turkish[9-12]) and seems to be easy to administer. If research in FM is to progress, we need reliable tools for assessing new therapeutic options (drugs, rehabilitation programs, and education). Such tools are available in a

From the Centre de la Douleur and the Service de Rhumatologie, Hôpital Cochin, Paris, France.

S. Perrot, MD, PhD; D. Dumont, MD; F. Guillemin, MD, PhD; J. Pouchot, MD, PhD; J. Coste, MD, PhD.

Address reprint requests to Dr. S. Perrot, Centre de la Douleur et Service de Rhumatologie A, Hôpital Cochin, 27 Rue du Faubourg Saint Jacques, F 75014 Paris, France. E-mail: serge.perrot@cch.ap-hop-paris.fr

Submitted November 26, 2001; revision accepted September 29, 2002.

number of countries. We developed a translation-adaptation of the FIQ into French: the QIF (Questionnaire de mesure d'Impact de la Fibromyalgie) and evaluated its reliability and validity in French speaking women with FM syndrome.

MATERIALS AND METHODS

Translation and adaptation of the FIQ. The FIQ is a multidimensional self-administered questionnaire designed to assess the current health status of women with FM[8]. This questionnaire consists of 10 questions that measure physical functioning, work status, depression, anxiety, sleep, pain, stiffness, fatigue, and well-being. It includes items from the AIMS and the Health Assessment Questionnaire (HAQ) as well as some unique items. The FIQ was adapted in a crosscultural manner according to published recommendations[13-15] and was translated by 2 independent translators. Both were bilingual and native French speakers. One translator was familiar with the concept of quality of life and health assessment, whereas the other was unaware of the purpose of the translation and had no scientific or medical background. Each translation was then back-translated into English by 2 independent translators who were native English speakers. All of the translators produced a report on the translation process and the difficulties they had encountered during the translation process. A panel of experts including translators, sociologists, linguists, psychologists, methodology experts, and rheumatologists then selected the best translation for each item. The results of tests using this preliminary version in 30 patients with FM were used to perfect the final version of the QUIF.

Patients. The measurement properties of the QIF were studied in a cohort of women who met the American College of Rheumatology (ACR) 1990 Criteria for the classification of FM[16]. The number of the patients that needed to be included in this validation study was estimated at 100 according to previous studies[9,10]. Patients with FM aged between 25 and 70 years who were attending a pain clinic in one of 2 university hospitals in the Paris area (Cochin Hospital in Paris and Avicenne Hospital in Bobigny) were included. Patients with established diagnosis of FM or chronic undiagnosed pain were referred to a tertiary pain clinic by rheumatologists or general practitioners. In some cases, FM was diagnosed in the pain clinic.

We divided the study into 2 parts. The first part consisted of a cross-sectional study: women with FM were asked to answer several different questionnaires and were examined by a physician who assessed several symptoms and pain. The second part consisted of a 3-month followup study to assess how sensitive the QIF was to change. Women enrolled in the second part of the study were asked to attend 3 visits. To make it possible to determine how sensitive the questionnaire is to change, only women who had started taking a new antidepressant or had significantly changed the dosage of their antidepressant treatment were included. Informed consent was obtained from all patients. All data were anonymous. All patients with other rheumatic conditions that could interfere with the assessment of pain and other symptoms were excluded from the study. Demographic data were obtained at study onset.

Data collection. Demographic data and information concerning FM symptoms were recorded, and tenderness was assessed during the inclusion visit.

Assessment of pain and tenderness in FM patients. Spontaneous pain was assessed by the physician using a visual analog scale (VAS) and a Likert scale for pain at rest and in motion. Evoked pain was assessed at 18 specific tender points by manual examination. The tender point score (total number of tender points) and the tender point index (a score between 0 and 3 was assigned for each tender point as follows: 0: no pain, 1: moderate pain, 2: severe pain, and 3: the patient withdrew during examination of the tender point) were determined.

Other questionnaires. Patients were also asked to complete 4 other questionnaires: the short form of the AIMS2 (ASF), the French version of which was developed and validated by our team[17], the Medical Outcome Study Short Form-36 (SF-36)[18], the McGill Pain Questionnaire[4], and the General Health Questionnaire-28 (GHQ-28)[19]. AIMS2 is a validated health-related quality of life (HRQOL) questionnaire, specific for rheumatic diseases[20]. The SF-36 is a well-known HRQOL generic questionnaire, the McGill Pain Questionnaire is especially devoted to the study of pain conditions, and the GHQ-28 questionnaire is one of the most prominent instruments for the screening of minor psychiatric morbidity.

Procedures. The questionnaires were self-administered. In the followup study subgroup, the patients were asked to answer in the QIF 7 days after inclusion and to send it back to the investigator for the test-retest procedure.

Statistical analysis. Test-retest reliability was evaluated by testing and retesting at D0 and D7. Intra-class correlation coefficients were calculated.

Construct validity reflects the relevance of categorization of items into dimensions and can be evaluated by determining whether correlations between items of a given dimension are stronger than correlations between items from other dimensions. Pearson's correlation coefficients were used.

Convergent validity reflects the correlation between the scores for the instrument of interest and the clinical data or scores for other instruments collected at the same time. Pearson's correlation coefficients were used to evaluate these correlations.

Sensitivity to change was studied for each dimension using standardized response means and paired t tests. Given the poor efficacy of many treatments for FM, we were not sure whether we would detect any clinically meaningful changes after 3 months of treatment.

Statistical analysis was performed using the SAS© statistical software.

RESULTS

Translation and adaptation of the FIQ. The translation and adaptation of the FIQ to the French context did not require any major cultural adaptations. The questionnaire was presented so as to avoid any ambiguity. The possible answers to the second question, regarding the numbers of days the patient felt good in the past week, did not include "none", thus we added this option. For the third question, concerning the number of days of work missed in the past week, we added the option of replying 5 days or more. Questions 5 to 10 did not include any reference to time, therefore we specified the last 7 days. The phrase "walk several blocks" was considered inappropriate in the French version and was translated to "walk several hundred meters". The item "do shopping" was translated to *faire les courses* instead of *faire des courses* which could mean do *some* shopping.

The last 5 items were rephrased in a direct way: "did you feel pain" or "did you feel stiff" so the format of all questions was the same.

Patients. One hundred and forty-nine women were invited to join the study. Seventy-one women completed the QIF in the cross sectional study. Of the 78 women included in the followup, 31 completed the 3-month followup.

Patients' baseline characteristics are summarized in Table 1. The average age was 49.4 ± 8.8 yrs (range 23 to 68 yrs). Means and standard deviations of each item of the QIF are summarized in Table 2. Means and standard deviations of FM symptoms and tenderness measures are summarized in Table 3.

It took 3 to 5 minutes for patients to fill in the QIF and none found it difficult to complete. The time required to complete all the questionnaires was about 45 minutes.

Table 1. Demographic characteristics of 102 women with FM.

Variable	
Age, yrs (mean ± SD)	49 ± 8
Marital status (%)	
Married	64.7
Divorced	18.6
Never married	13.7
Widowed	2.9
Job Status (%)	
Working full time	31.4
Housewife	18.6
Unemployed	13.7
Sick listed	10.8
Disability allowance	7.8
Retired	7.8
Long-term disease allowance	6.9
Work accident allowance	2
Litigation	2.9
Disease duration, yrs (with pain)	7.4 ± 6.2
Fibromyalgia duration, yrs (since diagnosis)	1.8 ± 5.4

Test-retest reliability at 7 days. Test-retest reliability coefficients (intraclass correlation coefficient) for each item of the FIQ ranged from 0.04 for number of days felt good to 0.84 for physical functioning (Table 4). Only 4 items from the QIF (physical functioning, number of days of work missed, ability to do job, and VAS for anxiety) reached significant test-retest reliability.

Internal construct validity (Table 5). The first part of the questionnaire demonstrated that physical functioning, number of days felt good, number of days of work missed, and VAS for stiffness were not correlated with any other items and were thus significantly independent. A study of the last 7 items in the questionnaire showed significant correlations in this part of the QIF. Pain was correlated with fatigue and ability to do a job. Fatigue and morning tiredness were well correlated. VAS anxiety and depression were well correlated.

Convergent validity (Table 6). The FIQ physical functioning item was significantly correlated with the ASF physical functioning item (–0.75), the ASF global score (–0.70), the GHQ social impairment score (0.55), and SF-36 bodily pain score (–0.62). The ability to do a job was correlated with the ASF symptom and global scores and with the SF-36 general health score. The QIF VAS for pain was correlated with the ASF symptom and global scores and with the SF-36 bodily pain score. The QIF VAS for fatigue was correlated with the SF-36 vitality score. The QIF VAS for anxiety was correlated with GHQ symptoms, GHQ anxiety, and the ASF mental score. The QIF depression VAS was correlated with the ASF mental health score, the GHQ anxiety, and depression scores. None of the items from the McGill Pain Questionnaire correlated with any of the QIF items. Similarly, neither the tender point score nor the tender point index correlated with any of the QIF items.

Table 2. Means and SD of the QIF dimensions at D0, M1, and M3.

	D0	M1	M3
Physical functioning	13.3 ± 5.6	13.1 ± 5.5**	12 ± 6.3*
Number of days felt good	5.4 ± 1.6	5.6 ± 1.6*	5.4 ± 2.3*
Number of work days missed	1.9 ± 2.3	1.0 ± 1.9	0.66 ± 1.4
Ability to do job	6.5 ± 20	6.2 ± 20*	6.5 ± 22
VAS			
Pain	6.7 ± 18	6.5 ± 17	5.7 ± 25*
Fatigue	6.9 ± 22	6.9 ± 19	6.5 ± 23
Morning tiredness	6.5 ± 22	6.4 ± 23	6.3 ± 20
Stiffness	6.1 ± 22	6.2 ± 23	5.7 ± 23
Anxiety	5.1 ± 27	5.0 ± 25	5.0 ± 30
Depression	4.5 ± 30	4.5 ± 31	4.3 ± 31

* $p < 0.05$ compared to baseline value. ** $p < 0.01$ compared to baseline value.

Table 3. Means and SD of FM symptoms and tenderness measures.

	D0	M1	M3
Tender point count	15 ± 5.3	15.07 = 3.44	15.6 ± 6.19
Tender point index	35 ± 10	34.7 ± 13.4	32.73 ± 11.4
VAS for pain at rest	48.7 ± 24	52.5 ± 24.4	44.9 ± 28.4
Likert-scale for pain at rest	3.1 ± 0.86	3.34 ± 0.76	2.96 ± 0.98
VAS for pain during movement	76.4 ± 19.6	72.5 ± 24.5	67.35 ± 23.24
Likert-scale for pain during movement	4.15 ± 0.67	3.96 ± 0.82	3.77 ± 0.84

Table 4. Test-retest reliability for the QIF items from D0 to D7 (Pearson's correlation coefficients between day 0 and day 7).

	Coefficient
Physical functioning	0.84
Number of days felt good	0.04
Number of work days missed	0.70
Ability to do job	0.80
VAS	
Pain	0.52
Fatigue	0.48
Morning tiredness	0.61
Stiffness	0.26
Anxiety	0.82
Depression	0.73

Sensitivity to change. Sensitivity to change between inclusion in the followup study and the followup visits was assessed. Only 2 items changed significantly between inclusion and M1 (physical functioning and ability to do job). Two items changed significantly between inclusion and M3 (physical functioning and VAS for pain).

DISCUSSION

Due to the multidimensional nature of FM, composite questionnaires are needed for the assessment of this syndrome. Several tools are available in FM. The FIQ (the most popular in clinical trials) was designed to evaluate patients with FM. It explores impairment, disability, emotions, and other symptoms. This questionnaire has been translated into Hebrew, German, Swedish, and Turkish. All of these versions seem to be valid and reliable. We used the international recommendations for the validation of a questionnaire[14,15] to show that the French version of the FIQ is also valid. Test-retest reliability coefficients were high for physical items, ability to do a job, and anxiety (0.84, 0.80, and 0.82 respectively) but low for the items such as days felt good and stiffness. Only 4 items of the QIF (physical functioning, number of work days missed, ability to do job, and VAS for anxiety) reached significant test-retest reliability.

Table 5. QIF internal construct validity: Pearson's correlation coefficient between QIF items (only statistically significant correlations are shown).

	QIF items	Coefficient
Physical functioning	—	
Number of days felt good	—	
Number of work days missed	—	
Ability to do job	VAS for pain	0.71
VAS		
Pain	VAS for fatigue	0.621
Fatigue	VAS for pain	0.621
	VAS for morning tiredness	0.629
Morning tiredness	VAS for fatigue	0.629
Stiffness	—	
Anxiety	VAS for depression	0.639
Depression	VAS for anxiety	0.639

$p < 0.001$ for all coefficients.

Table 6. Validity testing of the QIF (n = 102): Pearson's correlation coefficients between QIF items and clinical assessment of pain (TPS and TPI) and between QIF items and 2 questionnaires (ASF and MPQ).

	TPS	TPI	ASF	MPQ
Physical functioning	0.002	0.068	–0.707*	0.405
Number of days felt good	0.110	0.087	–0.354	0.203
Number of work days missed	0.273	0.018	–0.306	0.254
Ability to do job	0.199	–0.123	–0.601*	0.356
VAS				
Pain	0.254	0.305	–0.513*	0.447
Fatigue	0.153	0.153	–0.468	0.324
Morning tiredness	0.239	0.210	–0.349	0.301
Stiffness	0.311	0.254	–0.387	0.310
Anxiety	0.197	0.102	–0.574*	0.453
Depression	0.195	0.063	–0.511*	0.352

* p = 0.001. TPS: total point score; TPI total point index; ASF: AIMS2 Short Form; MPQ: MacGill Pain Questionnaire.

This is not consistent with other studies in which test-retest reliability was 0.56–0.95[8] or 0.80–0.96[9]. In our study, number of days felt good and stiffness had low Spearman coefficients, unlike in the study by Burckhardt, *et al*[21] on the original FIQ, in the Hebrew validation study, and in the German adaptation. This discrepancy and the difficulties involved in functional assessments were suggested by the study of Wolfe, *et al*[1] who pointed out the lack of good functional assessment of FM by the FIQ. Some centers have found 3 items most likely to be missing from the FIQ: "yard work", "vacuuming", and "walking several blocks". The FIQ underestimated functional impairment by including activities that are not usually performed and thus underestimating the severity of the disease. In our study, one of these items was adapted to the French way of life: "walk several blocks" was translated to "walk several hundred meters". Most of the QIF items were logically well correlated with SF-36 dimensions (Table 7): e.g. the physical functioning dimension of the SF-36 was correlated with physical function (from the QIF); the pain dimension of the SF-36 questionnaire was correlated with pain VAS of the QIF; the ability to do a job (from the QIF) was correlated with pain and general health dimensions of the SF-36; fatigue (from the QIF) was correlated with vitality dimension of the SF-36; morning tiredness (from the QIF) was correlated with vitality dimension of the SF-36; anxiety (from the QIF) was correlated with social function, mental health and vitality dimensions of the SF-36; and depression (from the QIF) was correlated with emotion, social function, mental health, and vitality dimensions of the SF-36.

Because FIQ underestimated functional impairment, and as no other studies have examined the psychometric properties of the questionnaires used in FM, Wolfe, *et al*[1] have developed a new questionnaire (the FHAQ) using Rasch analyses of 5 functional scales and the 20 questions from HAQ as an item bank. FHAQ is an 8-item questionnaire, derived from HAQ. The scoring method used is adapted to patients with FM. This new questionnaire should be tested in different groups of patients with FM and its ability to detect changes should be evaluated. Other quality of life tools have been used in FM including the AIMS2 questionnaire[22] and the CLINHAQ questionnaire[23]. Apart from incomplete functional assessment, we found a good correlation for the QIF with most items from the shortform of the AIMS and from the GHQ-28 questionnaire. We also found a good correlation with the dimensions of the SF-36 questionnaire (Table 7).

We found a poor correlation between pain assessment and self-assessment questionnaires, which is consistent with previous findings[21,24]. Croft, *et al*[25] demonstrated that the tender point score is better correlated with measures of depression, fatigue, and poor sleep, independent of pain status. Callahan and Pincus[26] suggested that this lack of correlation between pain status and other variables, especially daily activities, is a specific feature of FM. It is well known that most treatments used in FM are inefficient whatever the assessment criteria[27].

In most studies on FM, assessment criteria are poorly sensitive to change, and global assessment by the physician is the criterion that is most sensitive to change[28]. Pain assessment does not usually demonstrate significant changes after treatment or during followup[29] but in some studies, more than 50% of patients were lost to followup[30]. Finally, the most important criterion should be the responsiveness of the tool used, i.e. the ability to detect clinically meaningful changes. Dunkl, *et al*[2], recently reported that the FIQ may be the most responsive means of measuring perceived clinical improvement. These authors recommend using the FIQ as a primary endpoint in clinical trials. The lack of change observed during many studies on FM,

Table 7. Validity testing of the QIF (n = 102): Pearson's correlation coefficients between QIF items and SF-36 dimensions. Coefficient correlations for "number of work days missed", "number of days felt good," and "VAS stiffness" did not reach significant values with any of the SF-36 dimensions.

	SF-36 Dimension							
	PHYS	PHYR	EMO	SOC	PAIN	MEN	VIT	PER
Physical functioning	–0.683	–0.443	–0.355	–0.493	–0.624	–0.228	–0.324	–0.420
Number of days felt good	–0.313	–0.218	–0.148	–0.181	–0.367	–0.250	–0.394	–0.340
Number of work days missed	–0.340	–0.166	–0.283	–0.013	–0.219	–0.092	–0.263	–0.349
Ability to do job	–0.472	–0.319	–0.043	–0.285	–0.636	–0.264	–0.325	–0.575
VAS								
Pain	–0.330	–0.251	–0.132	–0.363	–0.730	–0.184	–0.310	–0.364
Fatigue	–0.308	–0.254	–0.233	–0.354	–0.388	–0.295	–0.599	–0.404
Morning tiredness	–0.199	–0.270	–0.101	–0.163	–0.327	–0.223	0.476	–0.301
Stiffness	–0.292	–0.163	–0.150	–0.189	–0.296	–0.236	–0.270	–0.246
Anxiety	–0.217	–0.191	–0.456	–0.387	–0.324	–0.609	–0.437	–0.376
Depression	–0.265	–0.145	–0.559	–0.525	–0.216	–0.784	–0.490	–0.456

Note that higher scores in SF-36 represent healthier subjects contrary to the FIQ, so it is normal that the correlation scores coefficients are negative.

regardless of the treatment or management tested[27,29] should also be a specific feature of FM, as it may be a specific condition rather than a disease.

In conclusion, the French version of FIQ, the QIF, was found to be a valid instrument, and the results correlated with those of other specific tools. We showed that it was unreliable for 2 items out of 10. Despite some bias, because not all patients answered all of the questions, and imperfect functional assessment, the availability of the FIQ in several languages may lead to the initiation of multicenter international studies on the management of this difficult syndrome.

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