Development of the Fibromyalgia Burden Assessment: measuring the multifaceted burden of fibromyalgia

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ABSTRACT

Objective. *To develop a questionnaire assessing the burden of fibromyalgia's impacts on patients' lives.*

Materials and methods. *A literature review was conducted to identify impacts of fibromyalgia and their consequences on patients' lives. Exploratory interviews were performed with 15 fibromyalgia patients in France, Germany and Spain. Using patients' wording, items were generated simultaneously in French, German, Spanish, and UK English. Relevance and comprehension of the resulting questionnaire versions were tested with 21 additional fibromyalgia patients; questionnaires were revised accordingly.*

Results. *Three domains, Burden associated with the impacts of fibromyalgia, Symptoms and Influencing factors, were identified from the literature review. Following patient interviews, the burden domain was further divided based on the nature of the impact: Pain, Physical impact (including tiredness, sleep problems and other symptoms), Activities of Daily Living impact (including autonomy and coping), Social and Family Life impact, Work, Studies and Personal Finances impact, Psychological impact (including cognitive impact), and Relationship to Medicine and Disease. The resulting test versions of the questionnaire contained 79 items. Comprehension tests identified problematic items and cultural differences and suggested deletions or rewording. After revision and linguistic harmonization, the pilot version of the questionnaire contained 62 items divided into 7 sections, and was named Fibromyalgia Burden Assessment (FMBA©).*

Conclusion. *The FMBA is a self-reported questionnaire allowing the assessment and a better understanding of the impacts of fibromyalgia and the burden associated with these on patients' daily lives. It is available in UK English, French, German and Spanish. Its scoring and validation remain to be undertaken.*

Introduction

Fibromyalgia is a chronic condition whose etiology remains unknown. It affects 0.5% to 5% of the adult general population worldwide (1). A recent study estimates the prevalence of fibromyalgia in Europe from 1.4% (France) to 3.7% (Italy) (2). It is more common in women than in men, and is more likely to increase as people age (2, 3).

Fibromyalgia is characterised by chronic widespread pain associated with tenderness and fatigue. Other common symptoms include sleep disturbance, depression, anxiety, headaches, bowel dysfunction, and cognitive dysfunctions. It is a major public health issue and a growing economic concern (4).

The multiplicity of symptoms makes fibromyalgia a debilitating condition for some patients, whose quality of life may be considerably affected. Numerous studies describe the negative consequences of fibromyalgia on physical capacities, daily life activities, cognitive function, emotional and psychological state, and patients' personal and social relationships (1, 5-7). Fibromyalgia may also result in work disability, leading to productivity losses (1, 8, 9).

There are very few disease-specific questionnaires that measure the multiple aspects and impacts of fibromyalgia on patients' lives, and their perception of the disease (10). The Fibromyalgia Impact Questionnaire (FIQ) is the instrument most commonly used to evaluate fibromyalgia patients. It was initially designed to assess the health status of women with fibromyalgia by measuring the impact of fibromyalgia on daily life activities and work status, and the intensity of fibromyalgia symptoms (including depression, anxiety, sleep, pain, stiffness, fatigue and well-being) (11, 12). A revised FIQ (RFIQ) was recently developed; this version resolves deficiencies with the FIQ's content and scoring algorithm that were identified after its initial development (13). Despite these amendments, neither the RFIQ nor any other current instrument completely captures the distress, difficulty and burden of coping with fibromyalgia (10), a little-recognised and multifaceted illness for which there is no consensus on diagnosis and treatment and no cure.

We developed the Fibromyalgia Burden Assessment (FMBA) to thoroughly assess these aspects and consequences of the disease, and to contribute to a better evaluation of fibromyalgia patients. The questionnaire was developed simultaneously in UK English, French, German and Spanish following an acknowledged methodology, essential for its acceptance by health authorities, regulators and researchers (14). This article describes how the content of the FMBA questionnaire was established and the methodology used for its development.

Materials and methods

European clinical expert group

A European multidisciplinary group of experts familiar with fibromyalgia in their everyday practice was set up to provide clinical input and expertise throughout the development phase: two rheumatologists and a psychiatrist specializing in pain, three specialists in patient self-reported questionnaires and three linguists (UK English, Spanish and German). The expert group ensured the clinical and scientific relevance of the content of the questionnaire at each stage of its development.

Ethics

The project was performed in accordance with Good Clinical Practices and in compliance with local regulatory requirements. Whenever required, the appropriate national authorities and institutional review boards approved the project before study commencement. Each patient gave informed consent to participate.

Development of the conceptual model – Literature review

A literature search was performed to identify the domains of patients' lives that are impacted by fibromyalgia, how patients live with the disease and how it is currently assessed with existing questionnaires. This included concepts measured or described in published articles, and the domains of patient-reported outcomes (PROs) questionnaires used to measure the functional impact and disability of the disease.

The literature search was carried out in biomedical databases, including MEDLINE and Excerpta Medica since 1996, the collection of Mapi Research Trust, and Patient-Reported Outcome and Quality of life instrument databases (ProQolid). Keywords for the search were "fibromyalgia AND disability OR cost-of-illness OR activities-of-daily-living OR social impact OR social limitations OR functional impact OR functional limitation". Relevant information extracted from the final set of articles selected was classified into domains, which were recorded in extraction tables. Domains of interests were identified and were subsequently completed with the experience shared by the members of the clinical expert group. These domains provided the structure for designing the patient interview guide.

– Patient exploratory interviews

The objectives of the patient interviews were: a) to capture concepts about patients' experience with fibromyalgia and the way it affects their lives, b) to explore their experience of the impacts caused by fibromyalgia and how they live and cope with these impacts, and c) to document their assessment, perception and feelings about the disease with their own wording.

Interviews were performed with 15 patients in France, Germany and Spain (n=5 in each country), enrolled by the members of the clinical expert group. Eligible patients were male or female adults (at least one male per country), with or without employment, with a range of levels of education. Patients had been diagnosed with fibromyalgia for at least 6 months, with a history of widespread pain for at least 6 months, and pain in at least 11 of the 18 tender point sites on digital palpation, as defined by the American College of Rheumatology (ACR) criteria (15). Patients were willing and able to participate in a one-hour interview and spoke the local language fluently. Patients with a major physical handicap, significant psychiatric disorder or receiving anti-psychotic medication were excluded.

A psychologist from each country conducted the face-to-face exploratory interviews at the patients' homes or at the clinic, following a specific patient interview guide. A semi-directive approach was used; this enabled patients to speak freely in response to open questions, allowing them to express their feelings and perceptions about their condition.

Interviews were audio recorded and fully transcribed word-for-word. A trained researcher from each country analysed the transcripts following the themes of the interview guide using a common grid for all countries. The analysis grid included: a) main domains, general concepts, detailed concepts in English and local language, b) detailed concept description and explanation in English, c) patient's own words in local language. The results from each country were combined to create an initial conceptual model.

Item generation and development of questionnaire test version

Information relevant to our research question that was identified from patient interviews was analysed and organized into general concepts, then further grouped into detailed concepts with their corresponding quotes. These concepts were discussed with the expert clinician group. Based on the clinicians' expertise and experience of fibromyalgia as well as importance to patients, concepts were selected for inclusion in the questionnaire. Using patients' quotes, items were generated simultaneously in French, German, and Spanish for each of the concepts identified during a two-day item generation meeting. Questionnaire specialists, native speakers of each target language, and a linguist participated in the meeting. The items in UK English were developed by the native English speaker, using the framework of the definition given to each of the concepts. Each item generated was consolidated and compared across the four languages to ensure conceptual equivalence and relevance. The first version of the UK English, French, German and Spanish questionnaires was drafted and provided to the expert clinician group for review and approval.

Comprehension tests and questionnaire revision

The purpose of the comprehension test interviews was to have the target population assess 1) the relevance of the concepts covered by the questionnaire and 2) the ease of comprehension, cross-cultural validity, clarity, appropriateness of wording and acceptability of the questionnaire to patients (instructions, questionnaire items and response scales).

A set of 20 patient interviews was planned in France, Germany, Spain and the UK (n=5 each). The eligibility criteria and the clinicians who recruited the patients were the same as for the exploratory interviews, but the patients who participated in the comprehension testing were not the same patients. A psychologist conducted face-to-face interviews at patients' homes or at the clinic, using a structured patient interview guide.

The expert clinician group then met to discuss the patients' feedback, issues, difficulties and rewording suggestions; decisions were made on which items should be deleted, added, reformulated, or kept as they were. An international harmonization meeting with the questionnaire specialists, native speakers of each target language and linguists was conducted to ensure the conceptual equivalence of the items across the four languages. The first version of the questionnaire was amended accordingly in the four languages and the resulting pilot version was approved by the group of clinical experts.

Table I. Description of the patient population participating in exploratory interviews (n=15) and comprehension testing interviews (n=21).

Patient characteristics	Exploratory interviews	Comprehension testing interviews
Sex		
Male	3	4
Female	12	17
Age (years)		
Mean	47.6	50.0
Range	29-62	20-68
Time since FMS* diagnosis (years)		
Mean	3.3	3
Range	0.5-13	<1-15
Professional situation:		
Employed	10	8
Homemaker	3	0
Unemployed	0	3
Retired	1	2
Unemployed due to health	1	8
Living situation:		
Living with partner/family	13	17
Living alone	1	3
Living in a community	1	0
Living with parents	0	1
Highest level of education:		
No education	1	0
Primary school	2	4
Secondary school	1	5
Professional qualification/College	8	8
Undergraduate degree/Graduate degree	3	4
Medication		
Drug	13	19
Non-drug	2	2

*FMS: fibromyalgia syndrome.

Results

Development of the conceptual model – Literature review

The literature search retrieved 303 abstracts and 67 articles. Twenty-six questionnaires that had been used or developed in patients with fibromyalgia were identified from the articles. These questionnaires and articles contained concepts that could be grouped into the following domains: "Burden associated with the impact of fibromyalgia" on physical functioning, work, health, activities of daily living, quality of life, satisfaction, cognition, well-being, social, coping, psychological, pain, sleep, or disease; "Symptoms", comprising disease, tenderness, pain, fatigue, weakness, agility/mobility and other symptoms; "Influencing Factors", comprising personal history, psychological aspects, personality/character, health, trauma, socio-demographic characteristics, lifestyle/environment, medication/treatment, and other aspects *(e.g.*, sensory factors, social desirability).

– Patient exploratory interviews

The characteristics of the interviewed patients are presented in Table I. Fifteen patients, 3 male and 12 female, participated in the exploratory interviews (1 male per country). Mean age was 47.6 years. Most patients lived in a couple or family, and were treated (drug or non-drug treatment) for their fibromyalgia.

The analysis of interviews suggested that fibromyalgia negatively affects different aspects of patients' lives that could be classified into the 13 following global concepts: Autonomy, Coping, Pain, Tiredness, Activities of Daily Living, Physical Impact, Social Impact, Psychological Impact, Cognitive Impact, Work, Sleep, Relationship to Medicine and Disease and Other Symptoms. Global concepts were organised into a conceptual model illustrated in Figure 1. Concepts were grouped together based on the nature of the impact, resulting in seven domains: Pain; Physical impact (including tiredness, sleep problems and other symptoms); Activities of Daily Living impact (including autonomy and coping); Social and Family Life impact; Work,

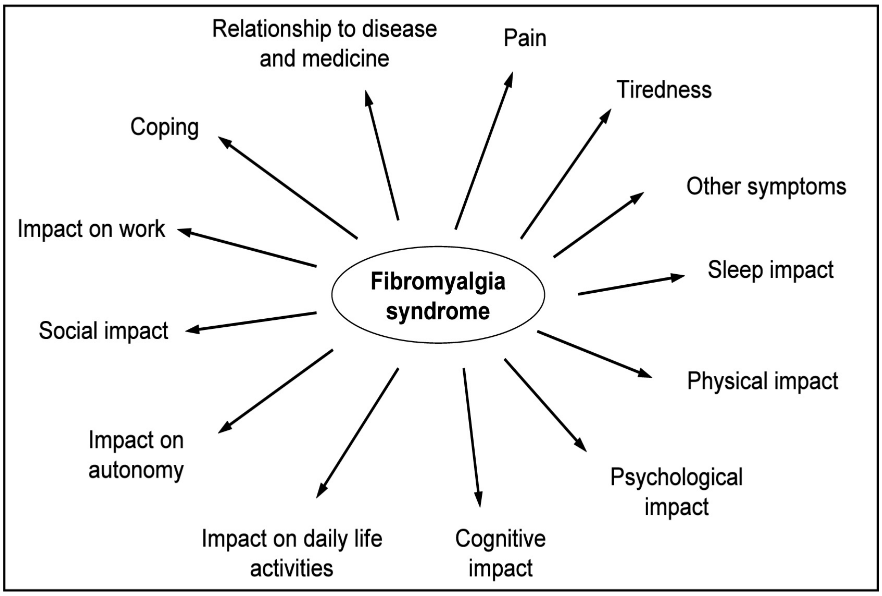

Fig. 1. Conceptual model of fibromyalgia burden based on patient exploratory interviews (n=15), literature review and clinical experts' experience

Studies and Personal Finances impact; Psychological impact (including cognitive impact); and Relationship to Medicine and Disease.

Item generation and development of the questionnaire test version

With the help of patients' quotes, items were generated for each of the global concepts of the conceptual model. The resulting test questionnaire was developed simultaneously in French, German, Spanish and UK English language versions, and contained 79 items grouped into 7 sections measuring the burden associated with "Pain due to fibromyalgia" (10 items), "The physical impact of fibromyalgia" (12 items), "The impact of fibromyalgia on your daily activities" (11 items), "The impact of fibromyalgia on your social and family life" (10 items), "The impact of fibromyalgia on your work/studies and personal finances" (5 items), "The psychological impact of fibromyalgia" (24 items), "Fibromyalgia, doctors and treatments" (7 items). One general item asked patients about how difficult it is for them to live with fibromyalgia. In order to best capture how hard it is for the patients to cope and live with each of the impacts being assessed, answer choices were on a 3-point response scale: "No, this does not apply to me", "Yes, this applies to me, but it is not hard to live with", "Yes, this applies to me and it is hard to live with".

Comprehension tests
– Description of patients

The content validity of the French, German, Spanish and UK English versions of the questionnaire was tested with patients from the target population, *i.e.* fibromyalgia patients. For each of the items and the response scales, they were asked their opinion about the relevance and the ease of comprehension; they were also asked to reformulate each of the items to evaluate their understanding. Twenty-one patients – 17 female and 4 male – were recruited in France (n=6), Germany (n=5), Spain (n=5) and the UK (n=5). Patients' socio-demographic and clinical characteristics are presented in Table I. Mean age was 50.0 years. Eight patients were unemployed due to their health status, and 13 lived with their partner or family. Nineteen were treated (drug or non-drug treatment) for their fibromyalgia.

– Patients' comments

In all four countries, patients found the questionnaire clear and easy to understand in general. They found the length appropriate and the layout was well accepted. For some of the items, patients raised issues which differed across countries. These included the lack of conceptual clarity or of relevance because they did not experience the feeling, symptom or situation being assessed; a too strong similarity between items or concepts; and the inappropriateness of some words used in items. Overall, patients also agreed on the response options chosen, although some German and Spanish patients found them too extreme for some items.

Following these comprehension tests, 17 items were deleted; as requested by most patients, one item was added about experiencing headaches. Upon patients' request, a response option was also added to better reflect how patients perceive the burden: "Yes, this applies to me and it is quite hard to live with".

Pilot questionnaire

After clinical expert review and final harmonisation across the four languages, the resulting French, German, Spanish and UK English pilot questionnaires contained 62 items divided into 7 main sections plus 1 general item (Table II). Each of the items had to be answered on a 4-point response scale: "No, this does not apply to me", "Yes, this applies to me, but it is not hard to live with", "Yes, this applies to me and it is quite hard to live with", "Yes, this applies to me and it is hard to live with".

Discussion

The qualitative work conducted during the development phase of this study highlighted the negative effect of fibromyalgia on patients' everyday lives, and enabled them to share their own experiences, perceptions and feelings. Patient reports were homogeneous across France, Germany, and Spain, and were corroborated with counselors' interviews (data not shown), suggesting great consistency of patients' experiences with fibromyalgia across countries.

Fibromyalgia has profound consequences on the way patients live their lives, as well as behaviour and attitudes they develop to cope with the disease. Patients commonly establish strategies to cope with their condition on a daily basis. Some rely on a caregiver's help and support; many report avoiding,

Table II. Conceptual content of the FMBA*.

Domain (#items)	Item content	Number of items
Pain due to fibromyalgia (9 items)	Burden due to causes of pain	3
	Burden due to pain occurrence and location	3
	Burden due to limitations because of pain	1
	Burden due to pain level	2
Burden associated with the physical impact of fibromyalgia (10 items)	Burden due to stiffness	1
	Burden due to headache problems	1
	Burden due to bladder problems	1
	Burden due to stomach problems	1
	Burden due to having to do things slowly	1
	Burden due to tiredness	2
	Burden due to sleep problems	2
	Burden due to physical suffering	1
Burden associated with the impact of fibromyalgia on your daily life activities (11 items)	Burden due to difficulties in daily tasks	9
	Burden due to needing help	1
	Burden due to difficulty planning activities	1
Burden associated with the impact of fibromyalgia on your social and family life (8 items)	Burden due to impact on social life	2
	Burden due to lack of social understanding	1
	Burden due to impact on friendships	1
	Burden due to impact on family relationship and partnership	4
Burden associated with the impact of fibromyalgia on your work / studies and personal finances (4 items)	Burden due to lower efficacy	1
	Burden due to lack of social and societal understanding	2
	Burden due to financial impact	1
Burden associated with the psychological impact of fibromyalgia (15 items)	Burden due to emotions	7
	Burden due to relationship to body	1
	Burden due to lack of fibromyalgia recognition	1
	Burden due to change	2
	Burden due to limits and difficulties	1
	Burden due to cognitive difficulties	2
	Burden due to psychological suffering	1
Burden associated with the fibromyalgia, doctors and treatments (4 items)	Burden due to wait for diagnosis	1
	Burden due to treatment inefficacy	1
	Burden due to relationship with doctors	2
Overall impression (1 item)	Burden due to having to deal with fibromyalgia	1

*FMBA, Fibromyalgia Burden Assessment.

limiting or slowing down activities or physical effort; others have to stop activities completely. The lack of knowledge about and recognition of fibromyalgia by both the medical world and patients' friends and family contribute to additional emotional and psychological troubles. Most, if not all, patients find fibromyalgia extremely hard to live with and perceive it as a real burden. While some patients compare their condition to a handicap, others describe it as "heavy" and "a burdensome weight on their shoulders". In agreement with previous research, patients reported that this burden is eased over time and with the establishment of a diagnosis (16, 17).

Fibromyalgia's impacts can result directly from the symptoms associated with the condition: pain in particular has significant consequences for patients' lives. Fatigue and sleep problems are also major issues for fibromyalgia patients; they get tired easily, are tired when waking up and feel constantly tired; they are unable to get refreshing or restorative sleep. Most patients complain of a total lack of energy. Their daily activities, such as driving, using a computer, or doing housework, and everyday movements like holding objects, are often impaired. The impact extends to their relationships with their family, partners and friends. Professional activities are also affected.

Our findings are consistent with previous qualitative studies, and underline the need for a patient-centered approach and a comprehensive assessment of multidimensional aspects to capture the full picture of fibromyalgia burden (5, 18-22). The FMBA moves beyond the scope of the existing fibromyalgia-specific questionnaires by documenting how distressing these multiple detrimental effects are to patients and by assessing how they cope and live with the disease on a daily basis.

According to current regulatory authorities' recommendations, establishing content validity is essential to scientifically sound instrument development process (14, 23). Authorities also emphasize that patient-reported outcome questionnaires should be based on a clear and well-founded conceptual model. The use of a structured and standardised methodology for the FMBA's development addresses this point; the development of the conceptual model from 36 patients in total, and the further validation with literature review and clinical experts ensures the measure's robustness and content validity. Male fibromyalgia patients were included, and care was taken at the item generation stage to create items adapted to both men and women. Interviewed patients had to have been diagnosed with fibromyalgia, and were recruited by rheumatologists and a psychiatrist and pain specialist. The comprehension tests confirmed the relevance of content and of the response option format of the FMBA to patients, as well as its good acceptability despite its length. The cognitive skills needed to answer are kept low by the simplicity of the questionnaire and by using the same response options throughout the questionnaire. Altogether, this should ensure the clinical relevance of the FMBA and its appropriateness to the general adult fibromyalgia population.

The simultaneous development of a UK English, French, German, and Spanish version maximized the cultural and conceptual equivalence and anticipated possible future translation issues in other languages from the same linguistic groups. The UK version will be used to support communication and as a master version for other future translations. The availability of these different versions will highly facilitate its use in European studies. The next steps will be the determination of the questionnaire's scoring and psychometric properties and its validation in a quantification study.

Impacts of fibromyalgia on patients' lives are multidimensional and are experienced as real burden by patients for whom it is extremely difficult to live and deal with. It is likely that the use of several questionnaires is necessary in order to comprehensively measure all these different aspects of fibromyalgia (10). To our knowledge, there are no fibromyalgia-specific questionnaires that enable the capture of the distress and burden associated with these. Currently, the FIQ (and more recently the RFIQ) is the questionnaire most commonly used to assess health status in fibromyalgia patients by capturing fibromyalgia-related symptoms and physical functioning impact (11-13). Both versions evaluate the intensity of the main symptoms associated with fibromyalgia (*e.g.* pain, stiffness, fatigue, anxiety, depression) patients experience and patients' ability to perform daily tasks. The generic SF-36 contains domains similar to those of the FMBA and has been used recently to assess health-related quality of life of fibromyalgia patients (24); however, it does not allow the burden associated with the impacts to be assessed. The FMBA is a fibromyalgia-specific questionnaire that was specifically designed to capture how distressing the multiple detrimental effects of fibromyalgia are to patients and by assessing how they cope and live with the disease on a daily basis. The FMBA includes dimensions on pain, impacts of fibromyalgia on patients' physical activities, daily activities, social and family lives, psychological aspects, work and finances. The items and response option modalities should enable a comprehensive and accurate measure of how hard it is for patients to live and cope with the impacts fibromyalgia has on their daily lives.

We believe the FMBA is an interesting innovation for use in clinical trials for the assessment of the overall benefit of a drug therapy or treatment approach. Anecdotal reports suggest that use of the FMBA encourages patients to talk about their distress and thus facilitates patient-doctor communications (data not shown). Finally, by assessing the burden associated with fibromyalgia and its impact on patients' lives, the FMBA should also be of great value in supporting decision-making in healthcare policy.

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