

Current trends in disability claims due to fibromyalgia syndrome

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ABSTRACT

Fibromyalgia syndrome (FMS) affects 0.4–8% of the general population predominantly in the female population with a F:M ratio of 3–9:1. It is characterised by persistent widespread pain and other associated clinical conditions such as chronic fatigue, irritable bowel syndrome (IBS), temporomandibular joint dysfunction (TMJD), sleep disorders and cognitive impairment. FMS diagnosis at present is purely clinical because no medical or laboratory examinations are able to identify it with certainty. FMS is not fully recognised worldwide, and patients often do not receive the treatment and disability benefits planned for other chronic diseases even though it gives rise to a very significant social burden due to direct and indirect healthcare costs and the loss of productivity and work. This article describes the medico-legal situation of FMS patients around the world, particularly issues related to the recognition of the disease by health institutions and the provision of disability benefits. We also discuss the current means of assessing disabilities in the medico-legal context, and their possible future improvements.

Introduction

Fibromyalgia syndrome (FMS) affects 0.4–8% of the general population mainly between the third and sixth decade of life; the male/female ratio varies from 3:1 to 9:1, depending on the diagnostic criteria used (1). The disease is characterised by persistent widespread pain (WP), muscle stiffness and associated clinical conditions such as chronic fatigue, irritable bowel syndrome (IBS), temporomandibular joint dysfunction (TMJD), sleep disorders and cognitive impairment. There is also the frequent occurrence of behavioural disorders,

anxiety, depression, eating disorders and drug abuse (2). No specific aetiology has yet been identified, and FMS is considered a multifactorial disrupted nociceptive disease caused and maintained by different pathogenetic mechanisms (3-4). As it cannot be detected by means of laboratory or instrumental tests, the diagnosis is purely clinical and based on the presence of WP, the severity of the associated symptoms, and the exclusion of other medical conditions (5). FMS is included as M79 (other soft tissue disorders, not elsewhere classified) or M79.0 (rheumatism, unspecified) in the tenth revision of the International Statistical Classification of Diseases and Related Health Problems (ICD-10), first published by the World Health Organisation (WHO) in 1992. However, it is not fully recognised worldwide, and patients often do not receive the treatment and disability benefits planned for other chronic diseases even though it gives rise to a very significant social burden due to direct and indirect healthcare costs and the loss of productivity and work. One-third of North Americans with FMS claim disability benefits, and such claims are an emerging problem throughout the world (6-7). This article describes the medico-legal situation of FMS patients around the world, particularly issues related to the recognition of the disease by health institutions and the provision of disability benefits. We also discuss the current means of assessing disabilities in the medico-legal context, and their possible future improvements.

United States

FMS was first legitimised in the US in 1990 after the publication of the ACR classification criteria. In 2007 the Food and Drug Administration (FDA) approved pregabalin as the first-line drug

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Table

| | United States | Canada | Australia | UK | Germany | France | Scandinavian Countries | Italy | Spain |
|---|---------------|--------|-----------|----------|---------|----------|------------------------|-------|-------|
| Estimated prevalence of FMS in general population | 2% | 1.5-3% | NA | 2.9-4.7% | 2.1% | 1.6-1.8% | 1.3% | 3% | 2.7% |
| Official recognition by health services | + | + | - | + | NA | - | - | + | NA |
| FMS specific ICD code | + | - | + | - | - | + | - | - | - |
| FMS disability evaluation protocol | + | - | - | - | - | - | - | - | - |
| Inclusion of FMS in the list of disabilities | + | - | - | + | - | - | - | - | - |
| FMS patients receiving disability payment | 26,5% | 35% | NA | NA | NA | NA | 8.2% (Finland) | NA | NA |

NA: not available +: yes -: no

for its treatment. In 2012, the Social Security Administration (SSA) published a federal ruling that laid down the protocol for FMS patients claiming recognition of a Medically Determinable Impairment (MDI) (8). The core element of the ruling is that FMS can only be classified as an MDI by a licensed physician (a medical or osteopathic doctor). The specific criteria for diagnosing FMS are based on the 1990 American College of Rheumatology (ACR) Criteria for the Classification of Fibromyalgia or the 2010 ACR Preliminary Diagnostic Criteria. Nevertheless, a diagnosis of FMS alone is not sufficient but must be accompanied by other evidence such as the patient's medical history, a physical examination, pharmacological and non-pharmacological treatments consistent with the diagnosis, the outcomes of such treatments in terms of improving, worsening or stabilising symptoms, and the physician's assessment of the patient's physical strength and functional abilities over time. The ruling also requires evidence for the 12-month period before the date of application, unless evidence from an earlier period is required to confirm the existence, severity or duration of the disorder, or establish the onset of disability. Other evidence can be obtained from medical sources (*i.e.* psychologists) or non-medical sources such as neighbours, friends, relatives, clergy, past employers, rehabilitation counselors, teachers and SSA personnel who have interviewed the patient. Once an MDI has been established, an evaluation is to be made of the intensity and persistence of pain and any other dis-

ability symptoms related to the patient's working capacity. If a patient is engaged in substantial and gainful work at the time of the evaluation, he/she is considered "not disabled". In the case that pain or other symptoms cause a limitation or restriction that has more than a minimal effect on working activities, the patient is considered "severely impaired" and it is necessary to consider whether the impairment meets or medically equals the criteria of any of the disabling diseases listed in the Listing of Impairments (for example, 14.09D – inflammatory arthritis), and disability is defined on the basis of this equivalence (9). If the patient's condition does not fall into any of the listed categories or their equivalents, residual functional capacity (RFC) must be assessed in order to determine whether he/she is still capable of doing any previously relevant work or any other work that exists in significant numbers in the national economy; this has to be done longitudinally because the symptoms of FMS are often fluctuating. A patient who is capable of doing any previously past relevant work is considered "not disabled"; in the case that he/she is not capable of doing any previously relevant work or does not have any work experience, it must be determined whether he/she can do any other work, bearing in mind that WP and other symptoms such as fatigue may lead to exertional limitations that prevent him/her from doing the full range of unskilled work. According to US patient association reports, the majority of FMS patients are considered not to qualify for disability benefits, particularly when they first

apply, and they have to appeal with the help of a lawyer, which increases the cost but also the chance of success (10). Regarding private insurance, long-term disability (LTD) insurance companies routinely deny or limit claims for disability due to FMS. In some cases, insurers exclude the coverage of FMS because of the lack of instrumental or laboratory diagnostic tests and the subjectivity of the symptoms reported by the patient. However, since October 2015, FM has had its own official diagnostic code in the US ICD-10-CM (M79.7, Fibromyalgia) (11), and recent data indicate a continuous increase in disability benefits being granted to US citizens. According to these data, approximately three million people in the US receive some benefit for disability related to the musculoskeletal system and connective tissue disorders, which account for 27% of all disability benefits (12). At this time, some authors have reported that 26.5% of American FMS patients receive some form of disability payment, and 14.4% some form of social security disability insurance (SSDI) benefits (13).

Canada

In a recent position paper, the Canadian Rheumatology Association (CRA) recognised FMS as a valid syndrome affecting up to 3% of Canadians, but also specified that, although FM symptoms may be truly disabling in a very select number of patients, the current social culture of disablement surrounding FMS should be dispelled and a mere diagnosis does not equate with disability (14). There are currently two types of

disability benefit for Canadian FMS patients: the Canada Pension Plan (CPP) (15) and private insurance companies. The CPP provides disability benefits to people who are aged <65 years and meet the CPP contribution requirements (four of the previous six years, or three of the previous six years in the case of people who have contributed for at least 25 years) but, in order to qualify for a benefit, the disability must be both “severe” and “prolonged”, and it must prevent working at any job on a regular basis. Both the “severe” and “prolonged” criteria must be met at the time of application, and must be supported by adequately documented medical evidence. Monthly benefits are paid up to the age of 65 years, after which they are converted into a normal pension. There are no specific references to FMS in the CPP disability evaluation protocol, and the final decision is made on the basis of the medical condition and documentation of the claimant. Canadian private insurance companies usually reject disability claims by FMS patients because of a lack of the objective medical documentation often specified in the insurance contract, sometimes even naming the specific clinical conditions requiring it. However, there are cases in which court decisions have awarded disability insurance benefits to FMS patients (16), and denying an FMS claim on the grounds of a lack of objective medical evidence is against existing case law. Even if a disability insurance policy requires objective medical evidence to approve a disability claim, the Supreme Court of Canada has indicated that it will not allow discrimination against a disability on the basis that there is no objective medical evidence for it (17). Such evidence is only required if the insurance company can provide objective proof (such as a private investigators report) that the claimant is only feigning disability, and so, in the case of an FMS disability claim, a judge assesses disability only on the basis of the claimant’s credibility. In 2013, the CRA and Canadian Pain Society (CPS) issued new recommendations for the rational care of patients with FMS. In addition to diagnostic and therapeutic recommendations, and although considering

that patients with a diagnosis of FMS are entitled to disability benefits, the CRA-CPS Committee expressed concern about the number of patients who receive disability benefits in Canada and that some of these use an FMS diagnosis inappropriately (18). In order to avoid this, it is recommended that doctors make an accurate assessment not only of pain, but also of the other symptoms associated with the disease. FMS currently has no specific diagnostic code in the Canadian ICD-10-CA (19). It is currently estimated that about 35% of patients with a diagnosis of FMS are receiving disability payments in Canada (13).

Australia

No data are available concerning the prevalence of FMS in Australia or the number of Australians that receive disability benefits because of FMS. However, it is known that at least 800,000 people were receiving an Australian Disability Support Pension in 2011, a number that had increased by almost 100,000 over the previous two years and exceeded the absolute number of people receiving unemployment benefits (20). For this reason, the Australian Government introduced New Impairment Tables in order to assess people’s ability to work and greatly reduce the number of people receiving disability benefits (21). On the basis of the new guidelines, in order to be eligible for disability support, the medical condition must be “fully diagnosed, stabilised and treated” as determined by means of an examination by a qualified medical practitioner and proved by supporting evidence such as compensation reports, details of any current or planned treatment, hospital or outpatient records, and reports concerning medical and surgical history and imaging, physical examination, rehabilitation and specialist evaluations. A Job Capacity Assessment determines the impact of the medical condition on the ability to work and whether the patient would benefit from employment assistance (22). This approach can be particularly difficult in the case of FMS because of medical evidence is not specific, there are no detectable lesions to

explain the often fluctuating symptoms, and treatments are only slightly effective or entirely ineffective. Chronic pain conditions (and FMS in particular) are not included in the List of Recognised Disabilities based on determinations approved by the Secretary of the Australian Government Department of Social Services in 2014 (23). However, in a Statement of Principles, the Repatriation Medical Military Authority recognised that FMS (and death due to FMS) can be related to relevant services rendered by veterans or members of the Australian Military Forces under the Veterans Entitlements Act, or the Military Rehabilitation and Compensation Act. The factors connected with the circumstances of a person’s relevant service, which must have existed before FMS started, are being the victim of severe childhood abuse before the clinical onset of FMS or an inability to obtain appropriate clinical management. Moreover, FMS has to be contracted before or during the person’s relevant military service, but not afterwards (24). Finally, the Australian ICD-10-AM code for FMS is M79.7 (25).

Europe

United Kingdom

The British National Health Service (NHS) recognises the existence of FMS as a specific disease, but a certain degree of criticism is reported in the medical community because many practitioners maintain it is a psychiatric condition. Nevertheless, a patient diagnosed as having FMS by a Pain Clinic or Rheumatology Department can apply for an Employment and Support Allowance (ESA), an Incapacity Benefit-Severe Disablement Allowance (IB/SDA) and a Disability Living Allowance (DLA), but only a minority receive a disability benefit, especially in the first instance. The law states that FM sufferers are entitled to state benefits in the UK also on the basis of the 2010 Equality Act, which defined a disability as a physical or mental impairment that has a substantial and long-term adverse effect on the ability to carry out normal day-to-day activities (26). British patients with FMS must demonstrate specific disability requirements. To qualify for an

IB, claimants have to undertake a medical assessment of incapacity for work called a Personal Capability Assessment, as do new claimants for an ESA; IB recipients have also had to undergo this assessment since April 2011. Notably, the medical condition entered in the claim form does not itself entitle a patient to an IB/SDA or ESA. A diagnosed medical condition also does not mean that someone is automatically entitled to a DLA, which depends on how much he/she needs help with personal care and/or mobility because of the disability. An applicant would not be granted a DLA simply on the basis of a diagnosis of chronic pain syndrome or FMS; the decision is based on the need for care/supervision and the difficulties in getting around caused by the condition and any associated physical or psychological complications (27). In 2012, about 20,000 FMS patients were receiving an IB/SDA and/or ESA, and about 40,000 a DLA. However, these data are controversial because there is no specific classification of the disease (FMS is included in the categories “chronic pain syndromes” and “other soft tissue disorders”) (28).

France

It is estimated that almost two million French people suffer from FMS, but it is still not recognised by the French health authorities. In 2007, the National Academy of Medicine published a report stating that there was broad consensus concerning the fact that FMS is a clinical reality that must be recognised as autonomous once other conditions that can be the source of chronic pain are ruled out (29). In 2010, the French National Health Authority issued a report concluding that, although controversy remains within the medical world concerning the existence or organic or functional causes of FMS, patients should have access to treatment (30). However, in response to a parliamentary question in 2015, the French Minister of Social Affairs, Women’s Rights and Health stated that FM could not be included in the List of Long-Term Impairments, although some patients may be granted the full support of National Health Insurance (for an off-list dis-

ease) on the basis of a physician’s assessment of the severe and debilitating nature of FMS in an individual subject (31). In October 2016, the first Report of the Parliamentary Investigation Commission on Fibromyalgia in France was published highlighting that patients with FMS should have the same social treatment that is delivered to patients with other chronic diseases that access to benefits related to disability through the production of specific recommendations (32). However, French medical practitioners are still sceptical about the nature of FMS and consider it a psychological disease, which has some negative implications in terms of the quality and effectiveness of the prescribed treatments. FMS is coded as ICM-10-M79.7, but is not present in the database of the CPAM (Caisse Primaire d’Assurance Maladie). No information is available concerning the number of French FMS patients receiving disability benefits.

Italy

The status of FMS is rapidly changing in Italy. After its autonomous recognition by some Italian regional governments, the Italian Superior Health Council recognised it as “a chronic but not necessarily permanent disease that is disabling only in some patients” in 2016. This does not allow its inclusion in the list of Chronic Disabling Diseases, because there is a lack of scientific studies that would allow the identification and differentiation of the most severe forms, and there are few therapies that could be dispensed by the National Health System (33). An ongoing epidemiological assessment has the aim of estimating the size of the FMS population and the percentage of patients with debilitating forms who need protection and disability benefits in order to estimate the impact of including FMS in the list of disabling diseases. However, although FMS has not yet been codified, some FMS patients have obtained a form of disability benefit on the basis of the severity of their clinical picture. The only regional government that exempts FMS patients from paying for specific drugs and treatments is that of Trentino-Alto Adige (34).

Spain

The data regarding the prevalence of FMS in Spain are controversial. According to some authors, the diagnosis is becoming so common that its prevalence increased from 2.4% in 2000 to 13% in 2005; however, in this way, truly disabled patients are confused among the enormous number of diagnoses (5,980,000), which is unmatched by any other country in the world. Obviously, the Spanish healthcare and welfare system cannot cope with such numbers, particularly as some studies have shown that 25–50% of the patients are disabled or unable to work (35). An epidemiological study of FMS patients in Spain found that only 34% of patients were engaged in productive work, while 13% were unemployed, 11% on sick leave, 23% worked from home, and 23% received a disability pension (36). A temporary inability to work is recognised in Spain for a maximum of 12 months, which is extended for a further six months in the case of treatment. If a patient cannot return to work, the Spanish Institute for National Social Security (INSS) may initiate a procedure for the recognition of permanent disability. If this is rejected, it is possible to appeal at the Social Work Court or the Superior Court of Justice. The total number of INSS procedures due to FMS is not known, but an analysis of the appeals filed with the Supreme Court of Justice in the period 1978–2008 showed 75% were rejected; the only statistically significant factor related to rejection was the absence of tender points upon clinical examination (35).

Germany

At the end of 2013, 7.5 million people living in Germany (9.4% of the country’s total population) were registered as being severely disabled (*i.e.* more than 50% disabled as determined by a *Versorgungsamt* or Pension Office) (37), an increase of about 260,000 (3.6%) in comparison with 2011. In the case of illness, German workers are entitled to six weeks of full salary, and then a sickness benefit (within three years) for a total of 78 weeks at 70% of their entire salary, which may not exceed 90% of their net salary. This ap-

plies to all types of disease, including FMS. There is also a right to a permanent disability benefit but, on the basis of the available information, the majority of claims are rejected in the case of FMS. Applicants must demonstrate that they have tried different treatments (orthopaedic treatment, psychological therapies, pain treatment, hospital admission) and medical evaluations without significant success, and have some degree of inability to work. The degree of FMS-related disability is difficult to assess, and claims are generally problematic and inconclusive. Recent data suggest that the prevalence of FM in the general population is about 2.1% (1,700,000 subjects) (38).

Scandinavian countries

Prolonged pain in muscles and joints is the main cause of temporary disability or sickness allowances in Sweden (39). Disability benefits are approved when a disease impairs a person's ability to work by at least 25%. A disability allowance can be obtained if the patient is a Swedish citizen, needs assistance for at least two hours a day, is unable to study or work, or if the additional costs for drugs or treatments exceed \$1,480 a year, provided that a physician makes a statement describing the disability and how it affects the patient's activity and work (40). Approximately 8% of employed Swedish women received full-time disability benefits in 2005, but the exact amount of disability due to FMS is not known. Swedish working women with FMS report better health than non-working women with FMS in terms of pain, fatigue, stiffness, depression, disease-specific health status and the physical aspects of the quality of life and overall health status; however, physical capacity tests show that they are equally impaired. Moderate pain levels are considered compatible with work, while severe pain appear to compromise work; fatigue is better tolerated if women with severe symptoms continue to work (41). Information regarding the situation in Denmark is limited, but there is general scepticism about the real existence of FMS in the Danish medical community, and it is not officially recognised. In relation

to disability claims, the Danish Social Security System requires the completion of a "resources profile" describing the patient's challenges in the field of work, social competence, learning ability, work-related wishes, social network, and a health and disease description. Clearly, as an FMS diagnosis is crucial, the absence of FMS specialists and uncertainties about its real existence means that decisions are often inconclusive, and claimants are mainly directed towards psychological and behavioural rehabilitation strategies. The estimated number of Danish patients with FMS is about 50,000 (a prevalence of 1%), although it is possible that there are a number of undiagnosed cases (42). There is also little information regarding disability due to FM in Finland. The Finnish Social Insurance Institution has reported that the total prevalence of disability benefits due to musculoskeletal diseases is 8.2%, but no data are available concerning FMS diagnoses. Some studies have shown that about 40% of FMS patients report disability retirement, and most report difficulties at work or that there are receiving partial sickness benefits or pensions. The cumulative incidence of early disability retirement is 9.5% among Finnish FMS patients, and the cumulative risk of retirement is higher in the patients with more significant intensity of symptoms (43).

Discussion

On the basis of the most recent information, claims for disability due to FMS is a widespread problem, and medico-legal approaches vary widely in different countries. In most cases, FMS is not fully recognised or not included in the list of disabling impairments, which is why only a small proportion of patients are acknowledged to be disabled and receive the related financial benefits, particularly when they first apply. A specific protocol for evaluating the disability of FMS patients exists only in the United States, where the number of patients with benefits has rapidly increased over the last few years (44). The problem of FMS-related disability is not new as it was raised just a few years after the publication of the first diagnostic crite-

ria in 1990 (45-46). There are various reasons for the difficulty in quantifying the disability of FMS patients or the impact of FMS on their working capacity and quality of life. First of all, the diagnosis remains purely clinical and is based on systems used to score the widespread pain and the associated symptoms reported by the patients, and excluding other diseases by means of laboratory and instrumental screening. Evaluating the presence and number of tender points is now considered subjective and limitative, and is no longer used for diagnostic purposes; furthermore, none of the proposed laboratory tests has proved to be capable of diagnosing the disease with certainty, and their use has not been scientifically validated (47). Secondly, there is no accepted method of quantifying disability, and so impairment is based on the patients' reports of symptom severity and limited daily activities. Using specific questionnaires such as the Fibromyalgia Impact Questionnaire (FIQ) or Short Form Health Survey (SF-36) to assess the degree of disability is also controversial because they may be subject to accentuated symptoms when used for purely medico-legal purposes, as may happen when financial compensation is requested for other conditions, and there have been reports of FMS claimants exaggerating their symptoms (48). Psychological factors such as personality traits, depression, catastrophising, a poor internal locus of control, persecution mania, social isolation and financial difficulties can also accentuate FMS symptoms, making it more difficult to assess disability and raising doubts about an applicant's credibility (49-50). Unfortunately, there is no clinical method of assessing the validity and credibility of self-reporting, and subjective symptoms are often more severe than thought by healthcare professionals and adjudicators. Physical effort measurement systems may be considered, but fear of muscle or tendon injury, pain, fatigue or psychological factors may interfere with the tests and make the results unreliable. A patient's disability may be due to the fear of experiencing more pain or fatigue (kinesiophobia), and may not correspond to the usual

perception of disability but be interpreted as the patient's unwillingness to improve his/her condition and lead to a negative decision by adjudicators. Thirdly, assessing working capacity can be particularly difficult because it depends on the loss of physical capacity and fatigue, impaired concentration and memory, difficulties in taking action because of non-restorative sleep, difficulties in reaching workplace, and conflicts with employers and colleagues. It is generally desirable that patients with FMS keep their jobs for as long as possible in order to avoid further physical disability and social isolation; on the other hand, only patients whose symptoms are not particularly debilitating can continue working with acceptable productivity. Furthermore, an inability to adapt work to a patient's physical and cognitive difficulties frequently leads to a lost job and economic problems that induce a disability claim, particularly at a time of serious economic crisis. One controversial question is the possibility of malingering as it has been estimated that this accounts for 7.5-33% of all disability claims. There are no specific data concerning patients with FMS, but it is reasonable to believe that, as in the case of many other diseases subject to disability evaluation, some claimants simulate the disease for economic reasons. Malingering can be suspected in the presence of determinants other than illness, atypical or exaggerated symptoms, inconsistencies in the presentation of claimants in interviews, and activity and behaviour that is incongruent with the claims. On the other hand, it can probably be excluded in patients who receive aggressive treatment or in the presence of objective collateral corroboration, obvious and significant losses, and self-defeating behaviour. An analysis of patient behaviour or investigations of lifestyles or working behaviours outside of the medico-legal context (testimony, photographs or videos) can be helpful, although this approach may be misleading because of the known fluctuations in FMS symptoms. In addition, the enormous amount of information about the diseases available on line, including dedicated patient and association sites and forums,

can provide sufficient hints for reporting symptoms that are not objectively detectable at the time of a medical examination. FMS patients suspected of malingering seem to have particular demographic and clinical profiles that can be taken into account (51) but, although psychological tests have been proposed, they cannot identify fraudulent behaviour with absolute certainty. Another much-debated question concerns the role of trauma in the onset of FMS and the related disability. Most FMS patients report traumatic physical and/or psychological events in their medical history, which may act as a trigger for alterations in nociceptive system functions. The exact mechanism underlying this is still unknown, but it is thought that stressors may stimulate the release of nociceptive neuromodulators such as substance P (52). The role of stressors in inducing FMS-related non-painful symptoms is also unclear. Some authors believe that FMS may be a part of a post-traumatic stress disorder (PTSD), and almost 45% of FMS patients have PTSD symptoms (53). According to the same authors, stressful events may precede the onset of pain by many years as only 4% of their patients identified a traumatic event in the same year as that in which FMS appeared, although it must be remembered that this information is based on self-reports which are subject to recall or response biases (54). In any case, clinical experience has taught us that a certain number of patients diagnosed as having FMS on the basis of the ACR criteria have no medical history of any kind of trauma, and so a causal link between trauma and FMS cannot be considered proven as many other genetic, epigenetic, psychological and environmental factors may be involved (1). This should therefore be considered when the onset of the FMS and the related disability is attributed to road or work accidents, stalking, mobbing, sexual and/or domestic violence and abuse, divorce, iatrogenic diseases, or any traumatic event caused by third parties, although some adjudicators accept that these may be precipitating factors in the genesis of FMS (54). Deterioration and disability due to subsequent traumatic events are considered

medically implausible because of the fluctuations and inherent lack of regression of FMS symptoms over time (1). It is interesting to note that US Gulf War Veterans who develop FMS do not have to prove a connection between war-related traumatic events and disease onset in order to be eligible for at least 10% disability compensation (55).

Future perspectives

Assessing disability due to FMS is still controversial and any improvements will require major scientific advances (56). In terms of diagnosis, new biomarker models under investigation include the metabolomic profiling of patients with chronic pain (57); the results obtained in FMS patients look encouraging although further validation is still needed (58). Other promising areas of diagnostic research seem to be the identification of genomic profiles or micro-RNA signatures in blood cells and cerebrospinal fluid (59-61), and abnormalities in small nerve fibres as it has been found that skin samples taken from FMS patients have fewer unmyelinated dermal nerve fibres than those taken from patients with depression and healthy control subjects, whereas myelinated nerve fibres were spared (62). The interpretation of this finding is still unclear because this pattern was found in only 50% of FMS patients, but it may help in differential diagnosis (63). Important information with diagnostic potential may come from functional magnetic resonance imaging (fMRI) as some authors have reported altered resting-state connectivity between the insular cortex and other brain regions known to participate in pain perception/modulation, and this may play a pathogenic role insofar as this altered connectivity is associated with the experience of chronic pain in FMS patients (64). From the medico-legal point of view, quantifying disability remains a major issue because there are still no validated instruments for doing so. A diagnosis of FMS alone is not sufficient to prove disability state and, even if FMS leads to a disability, this does not automatically justify a benefit. Moreover, the possibility of obtaining a benefit also depends on factors such as

social policy, economic resources, national culture, whether the health system is public or private, and so on. It has to be accepted, as things stand, that there is no FMS severity score suitable for a medico-legal evaluation because of the type of symptoms and the lack of any objective laboratory and/or instrumental tests. The assessment of a FMS patient who needs benefits can therefore only be based on medical sources and scientific evidence such as physical tests (even though these can be influenced by temporary conditions, the fear of pain and activity, and psychological factors related to the desire to obtain compensation) combined with non-medical data (the number of working or school days lost, job or academic performance, the loss of a job or income, the loss of relationships, etc.) over a period of at least several months. The lack of an appropriate system of scoring severity on the basis of a medical evaluation makes it necessary to provide appropriate medical staff training in clinically evaluating patients as a whole, defining the intensity, persistence and recurrence of symptoms on the basis of non-medical evidence, and evaluating the impact of symptoms on a patient's quality of life and earning capacity. All of these factors could help the competent authorities to assess the severity of FMS disability. In our opinion, this determination should be made on a medical basis by expert physicians using a multi-level bio-psychosocial model that integrates clinical, psychological and social evaluations of individual patients (past traumatic experiences, pain intensity over time, self-reported disability, working difficulties, distress and psychiatric conditions, litigation, specific severity scores, and the risk of malingering).

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