
The Italian Fibromyalgia Registry: a new way of using routine real-world data concerning patient-reported disease status in healthcare research and clinical practice

F. Salaffi¹, S. Farah¹, M. Di Carlo¹, L. Sinigaglia², M. Galeazzi³, R. Gerli⁴, M. Sonnatì⁵, V. Giorgi⁶, P. Sarzi-Puttini⁶ on behalf of the Italian Society of Rheumatology (SIR), M. Masullo⁷ on behalf of the Ministero della Salute - Direzione Generale della Programmazione Sanitaria, Roma, Italy

¹Rheumatology Clinic, Dipartimento di Scienze Cliniche e Molecolari, Università Politecnica delle Marche, Jesi, Ancona;

²Divisione di Reumatologia, ASST Gaetano Pini-CTO, Milano; ³Unità Operativa di Reumatologia, Dipartimento di Scienze Mediche, Chirurgiche Neuroscienze, Siena;

⁴UO di Reumatologia, Dipartimento di Medicina, Università di Perugia;

⁵Hippocrates Sintech S.r.l., Genova;

⁶Rheumatology Unit, Internal Medicine Department, ASST Fatebenefratelli-Sacco, Milano Statale University School of Medicine, Milan; ⁷Ministero della Salute, Direzione Generale della Programmazione Sanitaria, Roma, Italy.

Fausto Salaffi, MD, PhD

Sonia Farah, EngD

Marco Di Carlo, MD

Luigi Sinigaglia, MD

Mauro Galeazzi, MD

Roberto Gerli, MD

Massimo Sonnatì

Valeria Giorgi, MD

Piercarlo Sarzi-Puttini, MD

Maurizio Masullo, MD

Please address correspondence to:

Marco Di Carlo,

Clinica di Reumatologia,

Università Politecnica delle Marche,

Ospedale Carlo Urbani,

Via Aldo Moro 25,

60035 Jesi (AN), Italy.

E-mail: dica.marco@yahoo.it

Received on December 22, 2019; accepted in revised form on February 3, 2020.

Clin Exp Rheumatol 2020; 38 (Suppl. 123): S65-S71.

© Copyright CLINICAL AND EXPERIMENTAL RHEUMATOLOGY 2020.

Key words: fibromyalgia, epidemiology, patient-reported outcome measures, registry

Funding: funding for the development of IFR was provided by the Italian Society of Rheumatology (SIR).

Competing interests: none declared.

ABSTRACT

Objective. Fibromyalgia (FM), the most frequently encountered cause of widespread musculoskeletal pain, affects an estimated 2% of the general Italian population. However, it is not a homogeneous clinical entity, and a number of interacting factors can influence patient prognosis and the outcomes of standardised treatment programmes. Registries are a source of high-quality data for clinical research, but relating this information to individual patients is technically challenging. The aim of this article is to describe the structure and objectives of the first Italian Fibromyalgia Registry (IFR), a new web-based registry of patients with FM. **Methods.** The IFR was developed to collect, store, and share information electronically entered by physicians throughout Italy who are members of the Italian Society of Rheumatology and have a particular interest in FM. It has a web-based architecture that uses two separate servers and an encryption algorithm to ensure the confidentiality and integrity of the exchanged data. The questionnaires included on the platform are the Revised Fibromyalgia Impact Questionnaire (FIQR), the modified Fibromyalgia Assessment Status (ModFAS), and the Polysymptomatic Distress Scale (PDS).

Results. The registry includes data relating to 2,339 patients (93.2% female) who satisfied the 1990 or 2010/2011 American College of Rheumatology Classification Criteria for Fibromyalgia at the time of diagnosis. At the time of this analysis, the patients had a mean age of 51.9 years (SD 11.5) and a mean disease duration of 7.3 years (SD 6.9). The majority were married (71.3%),

and generally well educated. The overall median FIQR, ModFAS and PDS scores and 25th-75th percentiles were respectively 61.16 (41.16-77.00), 8.91 (41.16-77.00), and 19.0 (13.00-24.00). The six highest scoring items indicating the greatest impact of the disease on the patients related to fatigue/energy (7.18), sleep quality (6.87), tenderness (6.69), pain (6.68), stiffness (6.66), and environmental sensitivity (6.35). A high proportion of the responding patients reported experiencing pain in the neck (80.46%), upper back (68.36%), and lower back (75.05%).

Conclusion. The IFR is the most comprehensive FM registry in Italy, and provides healthcare professionals with a secure, reliable, and easy-to-use means of monitoring the patients' clinical progression, treatment history and treatment responses. This can help clinicians to plan patient management, facilitates research study patient recruitment, and provides the participating pain clinics with statistics based on real-world data. It also helps address the Italian Ministry of Health long-term goal of using precision medicine for chronic pain prevention and treatment. It is hoped that the IFR will enhance both scientific research and clinical practice.

Introduction

Fibromyalgia (FM) is a complex chronic pain condition that affects at least 2% of the adult population in Italy (1), and is fraught with diagnostic ambiguity, pathophysiological uncertainties, and management difficulties (2-4). Diagnosing FM can be challenging, and a multinational survey has found that it takes an average of 2.3 years to make a

diagnosis after the first presenting event (5). In order to meet these challenges, it is crucial to improve our knowledge of the full spectrum of disease characteristics and treatment approaches, which requires the collection of a wide range of patient data from multiple clinical sites. The clinical practice of precision medicine, which involves appropriately treating groups of patients with matching clinical or genetic characteristics, is often facilitated by consulting a patient registry: *i.e.* “an organised system that uses observational study methods to collect uniform data (clinical and other) to evaluate specified outcomes for a population defined by a particular disease, condition or exposure, and that serves a predetermined scientific, clinical or policy purpose” (6). Considerable research into the essential properties and implementation of disease registries has shown that condition-specific registries are an efficient means of collecting and analysing the personal, clinical and health data of large cohorts of patients with the same disease (7, 8). They contain real-world data

generated during the course of patient care that can complement the findings of randomised controlled trials (RCTs) insofar as they provide valuable information for determining the efficacy and safety of therapeutic interventions in different sub-groups of patients (*e.g.* those of different ages or with various co-morbidities) and different clinical settings (9, 10). Although they have some limitations, they also provide interesting alternative research avenues, and are being increasingly used to study patients with inflammatory arthritides (11-14).

To the best of our knowledge, no previous web-based registry in Europe has grouped a population of FM patients and provided registered physicians direct access to all their data with the aim of helping them to find eligible patients during the process of initial clinical trial recruitment (10, 15). With the support of the Italian Institute of Health, the Italian Fibromyalgia Registry (IFR) was founded by the Italian Society of Rheumatology in 2019 with the aims of: i) establishing a prospective web-based

registry of ambulatory FM patients referred for multidisciplinary treatment in Italy; ii) assessing and monitoring their condition over time by means of demographic data, clinical descriptors, and uniform outcome measures estimated using standardised and validated instruments at each participating site; iii) establishing disease severity cut-off points to support healthcare decision making; iv) providing researchers with reliable real-world data in order to answer important research questions, test hypotheses concerning various aspects of widespread chronic pain and its management, assess study feasibility, and facilitate clinical research patient recruitment; and v) supporting collaborative research projects by promoting cooperation among centres and assisting with the implementation of research projects.

With the aim of facilitating the creation of other registries of patients experiencing pain, this paper describes how the IFR was developed and implemented, its structure and content, the characteristics of the enrolled patients,

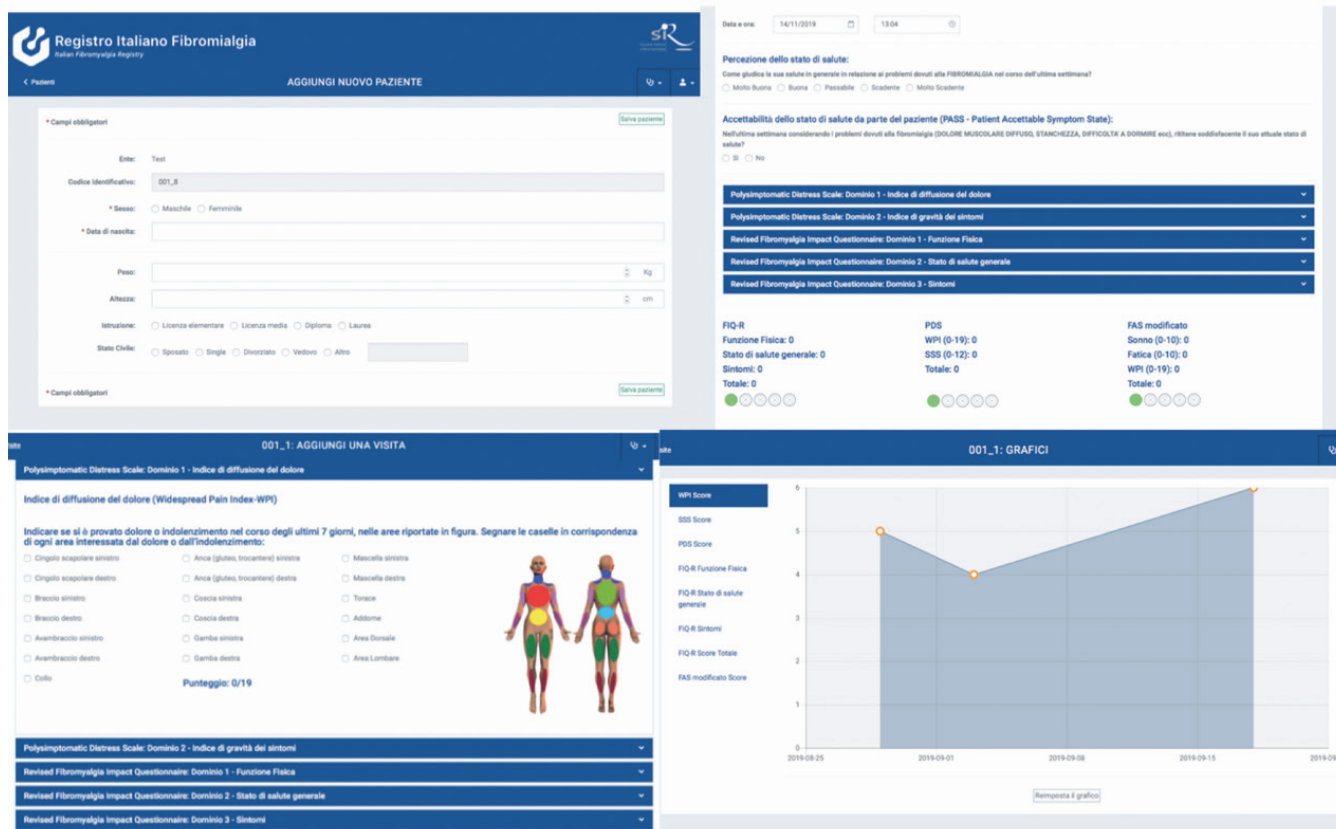


Fig. 1. Screenshots of the Italian Fibromyalgia Registry (IFR) website.

the policy and procedures for accessing IFR data sets for research purposes, the type of access requests required, and its strengths and shortcomings.

Materials and methods

Registry design

The IFR has a web-based architecture that uses two separate servers and an encryption algorithm to ensure the confidentiality and integrity of the exchanged data. All the patient data are anonymised when entered into the database by irreversibly removing the link between individual patients and their data, and making it virtually impossible to re-establish the link in order to preserve patient confidentiality. The server provides daily data backup and resides in the territory of the EU as prescribed by EU Regulation 2016/679. The platform is only available to registered and authorised users (www.registrofibromyalgia.it) (Fig. 1), each of whom is given a unique identifier and password. Users are required to accept the registry's privacy policies at the time of the first login (once again in compliance with the EU Regulation 2016/679), in the absence of which access is denied. Furthermore, each user has a specific level of privilege and data access: researchers can view the anonymised data they have been granted permission to use; physicians can add, view, edit, or delete data relating to their own patients; and study owners can view all the data of the patients enrolled in the studies overseen by them.

The quality of the IFR database is monitored under the responsibility of a Registry Coordinator and her assistant. A series of quality controls incorporated in the IFR allow instant, automated data validation (*e.g.* out-of-range values, logical inconsistencies), and regular manual data cleaning is programmed in order to identify discrepancies and missing data for the variables targeted as important, and generate queries to be sent to the participating centres.

Participating centres and target population

The study population consists of consecutively recruited adult patients who fulfil the 1990 (16) or 2010/2011 (17)



Fig. 2. Geographical distribution of the rheumatology centres participating in the Italian Fibromyalgia Registry (IFR).

American College of Rheumatology (ACR) classification criteria for FM and have been examined by rheumatologists at 19 centres in northern, central and southern Italy (Fig. 2). The exclusion criteria are: a) known cardiovascular disease; b) moderate/severe chronic lung disease; c) uncontrolled hypertension; d) uncontrolled thyroid disorders; e) orthopaedic or musculoskeletal conditions that prohibit moderately intense exercise; f) active suicidal ideation; g) planned elective surgery during the study period; h) inflammatory rheumatic conditions (*i.e.* rheumatoid arthritis, systemic lupus erythematosus, and other connective tissue diseases); and i) schizophrenia or other psychoses. The study protocol, and patient information sheet and consent form have been approved by our local Ethics Committee (Comitato Unico Regionale - ASUR Marche, no. 1970/AV2).

Business model

The registry is an no-profit academic project whose business model is based on fees to cover the administrative costs of handling data access requests on the basis of their complexity (*e.g.* the preparation of an extraction/analysis plan, data extraction, statistical analyses, and report preparation), and financial contributions to cover the costs of maintaining the data repository and ensuring its long-term sustainability.

Measurements and instruments

The patients were asked to complete

a package of questionnaires covering their sociodemographic data, disease duration, quality of life, and disease-related variables. The variables included in the IFR were chosen with the aim of creating a uniform minimal needs-based data set. The essential sociodemographic variables are age, sex, body mass index (BMI), marital status (single, married, divorced/separated), the level of formal education (primary school, middle school, and high school/university), and the type(s) of pharmacological and non-pharmacological treatments currently received.

Clinimetric assessment

The questionnaires considered for clinical evaluation were the revised Fibromyalgia Impact Questionnaire (FIQR) (18), the modified Fibromyalgia Assessment Status (ModFAS) questionnaire (19), and the Polysymptomatic Distress Scale (PDS) (17).

The FIQR is the updated version of the Fibromyalgia Impact Questionnaire (FIQ) (20) and was constructed to overcome the limitations of the original instrument (21). It consists of twenty-one 0-10 numerical rating scales (NRS, with 10 being the "worst") that explore the three main domains of function, overall impact, and symptoms. The revised version extended the original scale by adding new questions related to memory, tenderness, balance, and environmental sensitivity. All the questions refer to the previous seven days. The final score (range 0-100, with

greater values indicating greater disease severity) is calculated as follows: the algebraic sum of the 9-item function domain (range 0–90) is divided by three; the algebraic sum of the 2-item overall impact domain (range 0–20) remains as it is; and the algebraic sum of the 10-item symptom domain (range 0–100) is divided by two. These three sub-scores are then added together. For FIQR the cut-offs that distinguish the severity of the disease have also been published (22).

The self-administered ModFAS questionnaire is the updated version of the Fibromyalgia Assessment Status (FAS) questionnaire (19), and is divided into two sections. The first section consists of two questions concerning the symptoms of fatigue and unrefreshing sleep during the previous week, each of which is scored by means of an NRS ranging from 0 (no problem) to 10 (severe problem) to give a maximum total score of 20. The second section is a widespread pain index (WPI): patients are asked to indicate which of 19 areas of the body was painful during the previous week (score 0–19). The final ModFAS score ranges from zero to 39. The PDS is derived from the variables used in the 2010/2011 ACR criteria as modified for surveys and clinical research (17), and the score is obtained by summing the scores of the WPI and the symptom severity scale (SSS) (range 0–31): the WPI is a 0–19 count of painful non-articular body regions and the SSS is a 0–12 measure of the severity of three symptoms (fatigue, sleep, and cognitive problems). It has been found that a score of ≥ 13 has a specificity of 91.8% and a sensitivity of 96.6% for a diagnosis of FM (17), and disease severity categories of none (0–3), mild (4–7), moderate (8–11), severe (12–19), and very severe (20–31) have also been established (23).

All the questionnaires were distributed to IFR team members (clinicians and researchers) for a final round of comments.

Case report forms were used to test the feasibility of implementing/running the IFR, and further information was collected, including the time taken to complete each questionnaire/interview,

Table I. Demographic data expressed as mean values with standard deviation (SD), and median values with 25th–75th percentiles.

	Mean	Median	SD	25 th –75 th percentiles
Clinical and demographic data:				
Age (years)	51.91	11.52	53.01	45.0 – 59.0
Disease duration (years)	7.34	6.93	5.00	2.00 – 10.00
BMI (kg/m ²)	25.65	25.77	4.20	22.86 – 27.70

BMI: body mass index.

Table II. Demographic data expressed in absolute numbers and percentages.

	Number	Percentage
Marital status:		
Single	413	17.7
Married	1,667	71.3
Divorced/separated	200	8.6
Widowed	59	2.5
Educational level:		
Primary school	155	6.6
Middle school	660	28.2
High school/university	1,524	65.2

Table III Mean (SD) and median (25th–75th percentiles) FIQR, ModFAS and PDS total and subscale scores.

	Mean	Median	SD	25 th –75 th percentiles
FIQR				
FIQR total score (0–100)	57.86	61.16	23.37	41.16 – 77.00
FIQR physical function (0–30)	16.06	16.16	7.73	10.00 – 22.33
FIQR overall impact (0–20)	11.06	12.00	6.04	6.00 – 16.00
FIQR symptoms (0–50)	30.74	33.00	11.45	23.00 – 40.00
ModFAS				
ModFAS total score (0–39)	25.13	27.00	8.92	19.00 – 32.00
ModFAS fatigue (0–10)	7.18	8.00	2.80	4.00 – 8.00
ModFAS sleep (0–10)	6.87	8.00	2.93	4.00 – 9.00
ModFAS WPI (0–19)	11.08	11.00	4.89	8.00 – 15.00
PDS				
PDS total score (0–31)	18.59	19.00	7.36	13.00 – 24.00
PDS WPI (0–19)	11.08	11.00	4.89	8.00 – 15.00
PDS SSS (0–12)	7.51	8.00	3.48	5.00 – 10.00

FIQR: Revised Fibromyalgia Impact Questionnaire; ModFAS: modified Fibromyalgia Assessment Status; PDS: Polysymptomatic Distress Scale.

the patients' perceived degree of difficulty in completing the questionnaires, and the clinical usefulness of the collected material.

Statistical analysis

Descriptive statistics were used to document the characteristics of the patients enrolled in the IFR, including measures of central tendency (mean and/or median values) and dispersion (standard deviation [SD] or interquartile range [IQR]). Parametric techniques can be used to analyse certain ordinal level data but, as our data were generally not

normally distributed (as shown by the Kolmogorov-Smirnov test for normal distribution), the use of non-parametric techniques provided a more conservative estimate of statistical significance. The differences between the completed questionnaires were examined using the independent Man-Whitney U-test, and chi-squared tests were used to assess sex-related differences in the other demographic data. The data were processed using MedCalc 18.6 statistical software packages for Windows XP, and the level of significance for all the tests was 5%.

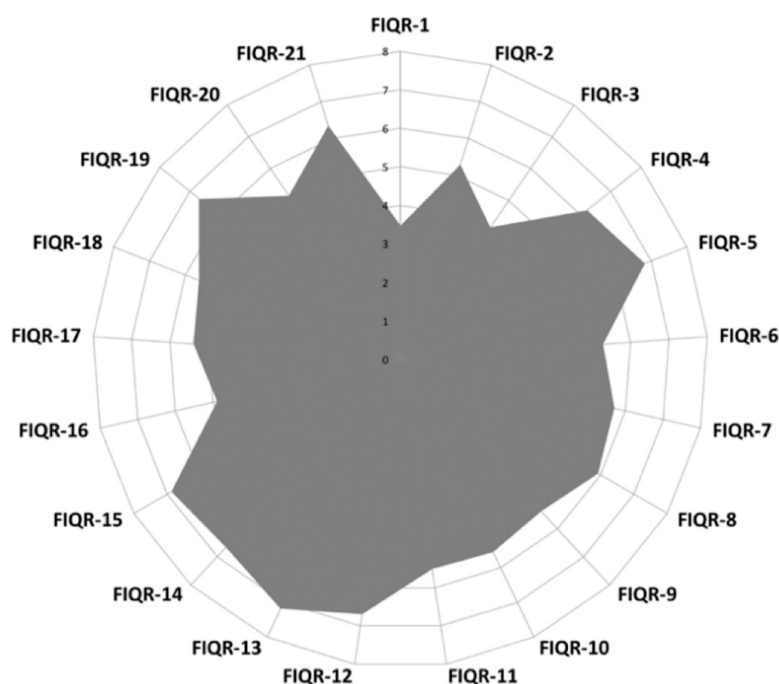


Fig. 3. Spidergrams of the individual FIQR items. The scores are plotted from 0 (best, at the centre) to 10 (worst, on the outside). FIQR: Revised Fibromyalgia Impact Questionnaire.

Table IV. Mean scores of each item in the FIQR.

Item	Item description	Score	SD
FIQR-1	Brush or comb hair	3.47	3.23
FIQR-2	Walk continuously for 20 minutes	5.29	3.34
FIQR-3	Prepare a homemade meal	4.14	3.09
FIQR-4	Vacuum, scrape, or sweep floors	6.20	3.03
FIQR-5	Lift and carry a bag full of groceries	6.82	3.55
FIQR-6	Climb one flight of stairs	5.28	3.18
FIQR-7	Change bed sheets	5.69	3.42
FIQR-8	Sit in a chair for 45 min	5.92	3.19
FIQR-9	Go shopping for groceries	5.38	3.23
FIQR-10	Cannot achieve goals	5.55	3.11
FIQR-11	Feel overwhelmed	5.50	3.23
FIQR-12	Pain rating	6.68	2.68
FIQR-13	Fatigue rating	7.18	2.80
FIQR-14	Stiffness rating	6.66	2.78
FIQR-15	Sleep quality	6.87	2.93
FIQR-16	Depression level	4.88	3.24
FIQR-17	Memory problems	5.39	3.08
FIQR-18	Anxiety level	5.62	3.08
FIQR-19	Tenderness level	6.68	2.75
FIQR-20	Balance problems	5.15	3.19
FIQR-21	Environmental sensitivity	6.35	3.02

FIQR: Revised Fibromyalgia Impact Questionnaire; SD: standard deviation.

Results

Demographic characteristics and descriptive statistics

A total of 2,339 patients (2,181 women and 158 men) were entered in the IFR between November 2018 and December 2019: the female:male ratio reflects that frequently observed in FM popula-

tions. At the time of enrolment, the patients were aged 18–80 years (mean age 51.91 years, SD 11.5), and had a mean disease duration of 7.34 years (SD 6.9). Pain has been present for ≥ 5 years in about half of the patients (49.38%) and for < 1 year in 12.35%. The majority of patients were married (71.3%), gener-

ally well educated, and moderately overweight (mean BMI was 25.65 kg/m², SD 4.20; 982 patients [42%] were normal weight [BMI < 25.0 kg/m²], 1,053 [45%] overweight [BMI 25.0–29.9 kg/m²], 217 [9.3%] moderately obese [BMI 30.0–34.9 kg/m²], and 87 [3.7%] severely obese [BMI > 35.0 kg/m²]). Tables I and II summarise the demographic data.

Table III shows the FIQR, ModFAS and PDS sub-scale and total scores. The median total score (25th–75th percentiles) was 61.16 (41.16–77.00) for the FIQR, 8.91 (41.16–77.00) for the ModFAS, and 19.0 (13.00–24.00) for the PDS.

Figure 3 and Table IV show the mean scores of the individual FIQR items. The six highest scoring items (those that have a greater impact on patients) were related to symptoms such as pain (FIQR-12: mean score 6.68), fatigue/energy (FIQR-13: mean score 7.18), stiffness (FIQR-14: mean score 6.66), sleep quality (FIQR-15: mean score 6.87), tenderness level (FIQR-19: mean score 6.69), environmental sensitivity (FIQR-21: mean score 6.35), and the functional activities of vacuuming or sweeping floors (FIQR-4: mean score 6.20), and lifting and carrying a bag full of groceries (FIQR-5: mean score 6.82). The lowest scoring items included depression level (FIQR-16: mean score 4.88), and the functional activities of brushing/combining hair (FIQR-1: mean score 3.47), and preparing a home-made meal (FIQR-3: mean score 4.14).

The WPI was used to assess the presence of pain at 19 body sites. A high proportion of patients reported experiencing pain in the neck (80.46%), upper back (68.36%), and lower back (75.05%) (Fig. 4). There was no sex-related difference in relation to any of the sites.

Discussion

Modern communication technology is a powerful means of improving clinical data collection and patient management, and the advent of precision medicine is increasing the importance of the use of patient registries in healthcare. The IFR is a secure, reliable, easy-to-

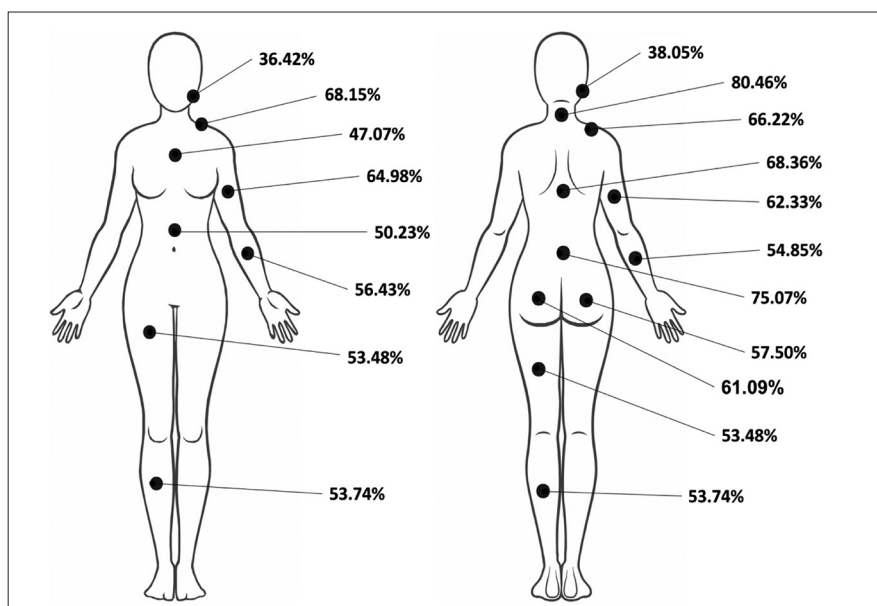


Fig. 4. Percentage of painful locations revealed by the WPI.
WPI: Widespread Pain Index.

use means of allowing healthcare professionals to record and monitor their patients' clinical progression, treatment history and treatment responses using well-known clinical descriptors and outcome measures. There are currently only two other longitudinal FM registries, the US registry (15) and the Brazilian registry (10). However, their data collection procedures are different from those of the IFR, which is also richer in terms of clinical/medical data and outcome measures.

The need for a large, multi-site FM registry has increased over the last few years. In 2017, the Italian Ministry of Health expressed its wish to be able monitor the clinical outcomes of FM patients and obtain national administrative statistics. Its main aims were to develop approaches that could incorporate the principles of precision medicine into the prevention and treatment of chronic pain, and track clinical and patient-reported outcomes. At the same time, one of the strategies of the Italian Society of Rheumatology was to develop a nationwide FM research infrastructure in order to facilitate the carrying out of large-scale observational and interventional studies. The IFR was therefore designed to be used for clinical, administrative and research purposes.

Research into FM is also important internationally because the condi-

tion is still not recognised as a disease throughout Europe. There is therefore a need to help raise awareness among patients and healthcare professionals alike, and improve access to early diagnosis and treatment in the Member States of the European Union, as was underlined in a recent (2017) European Parliamentary Question (24). In order to be able to achieve these goals, it is fundamental to facilitate research into FM by developing data collection programmes.

Many patient registries focus on cancer or rare conditions that require multicentric data in order to reach the critical mass required for meaningful research. FM is not a rare disease but, as there is no gold standard treatment, a large registry is needed in order to be able to analyse the efficacy and safety of different approaches and interventions in various patient sub-populations and clinical settings.

We have shown that it is feasible to collect uniform and reliable data from a large number of tertiary rheumatology care centres that can help clinicians to plan effective patient management strategies and provide the participating pain clinics with useful statistics concerning the characteristics of their patients and practices. Furthermore, our findings show that the IFR makes it possible to conduct observational

studies and satellite research projects using real-world data relating to various aspects of chronic pain. "Satellite" research is based on studies that link the data contained in the IFR database (e.g. age, sex, educational level, BMI) to other sets of data (e.g. governmental administrative databases or new clinical variables). Finally, IFR data can be accessed in order to facilitate the recruitment of the patients needed for research projects or clinical trials.

Nineteen centres have so far joined the IFR, and we expect this number to increase in the near future. Additional features will also be implemented, including tools to facilitate communication (forums or real-time chat) and the telemonitored follow-up of patients (Web-Chat), which will be particularly useful in the case of patients who are unable to attend frequent visits to major hospitals.

Developing and implementing a multi-site patient registry is complex and, although the IFR has a number of strong points, some of them have also proved to be an Achilles heel in terms of the associated costs of human resources, and have affected its long-term sustainability and expansion to other sites because, in addition to a Registry Coordinator, IFR data collection and cleaning require at least one full-time administrative assistant working at the coordinating centre.

Conclusions

The IFR is a large database of FM patients referred to one of 19 Italian tertiary care centres who can be monitored in a real-world context on the basis of their demographic and clinical characteristics using identical clinical descriptors and uniform validated outcomes with the aim of improving our knowledge of the condition itself and prioritising research into its most relevant aspects. IFR-based research will enable us to correlate patterns of disease severity with treatments and treatment outcomes at the various centres.

This paper describes the development, implementation, and research potential of the IFR, which has so far enrolled 2,339 patients and made available a large amount of data. We believe that

the IFR will not only facilitate research and improve everyday clinical practice, but will also contribute to informing national and international evidence-based healthcare policies, thus benefiting individual FM patients and society as a whole.

Appendix

Working Group – affiliations

Northern Area: Piercarlo Sarzi Puttini, Sara Bongiovanni (Milano - Ospedale FBF-Sacco); Lorenzo Dagna, Giulio Cavalli (Milano - Ospedale San Raffaele); Alberto Batticiotto (Varese); Fabio Fischetti (Trieste); Flavio Mozzani, Daniele Santilli (Parma); Marcello Govoni, Sara Bonazza (Ferrara); Carlo Salvarani, Gianluigi Bajocchi, Marco Ghini (Reggio Emilia, Modena).

Central Area: Fausto Salaffi, Sonia Farah, Marco Di Carlo (Jesi, coordinating centre); Serena Guiducci, Francesca Nacci (Firenze); Laura Bazzichi, Camillo Giacomelli (Pisa); Giovanni Biasi, Stefano Barbagli (Siena); Roberto Gerli, Ilenia Ricucci (Perugia); Manuela Di Franco, Chiara Gioia (Roma, Ospedale Umberto I, La Sapienza); Elisa Gremese, Annunziata Capacci (Roma, Ospedale Gemelli); Roberto Giacomelli, Francesco Carubbi (L'Aquila).

Southern Area: Florenzo Iannone (Bari); Fabiola Atzeni, Mariateresa Cirillo (Messina); Giuliana Guggino (Palermo); Mario Bentivegna (Ragusa).

References

1. SALAFFI F, DE ANGELIS R, GRASSI W *et al.*: Prevalence of musculoskeletal conditions in an Italian population sample: Results of a regional community-based study. I. The MAP-PING study. *Clin Exp Rheumatol* 2005; 23: 819-28.
2. SARZI-PUTTINI P, ATZENI F, SALAFFI F, CAZZOLA M, BENUCCI M, MEASE PJ: Multi-disciplinary approach to fibromyalgia: What is the teaching? *Best Pract Res Clin Rheumatol* 2011; 25: 311-9.
3. ATZENI F, TALOTTAR, MASALA IF *et al.*: One year in review 2019: fibromyalgia. *Clin Exp Rheumatol* 2019; 37 (Suppl. 116): S3-S10.
4. HÄUSER W, SARZI-PUTTINI P, FITZCHARLES MA: Fibromyalgia syndrome: under-, over- and misdiagnosis. *Clin Exp Rheumatol* 2019; 37 (Suppl. 116): S90-7.
5. CHOY E, PERROT S, LEON T *et al.*: A patient survey of the impact of fibromyalgia and the journey to diagnosis. *BMC Health Serv Res* 2010; 10: 102.
6. OUTCOME DECIDE CENTER (DEVELOPING EVIDENCE TO INFORM DECISIONS, EFFECTIVENESS): Registries for Evaluating Patient Outcomes: A User's Guide. 3rd ed. Rockville, MD 20850: Agency for Healthcare Research and Quality, U.S. Department of Health and Human Services 2014.
7. DROLET BC, JOHNSON KB: Categorizing the world of registries. *J Biomed Inform* 2008; 41: 1009-20.
8. MOLINA-ORTIZ EI, VEGA AC, CALMAN NS: Patient registries in primary care: Essential element for quality improvement. *Mt Sinai J Med* 2012; 79: 475-80.
9. PROVAN SA, AUSTAD C, HALSAA V, HAMMER HB, KVIEN TK, UHLIG T: Fibromyalgia in patients with rheumatoid arthritis. A 10-year follow-up study, results from the Oslo Rheumatoid Arthritis Register. *Clin Exp Rheumatol* 2019; 37 (Suppl. 116): S58-62.
10. MARTINEZ JE, PAIVA ES, REZENDE MC *et al.*: EpiFibro (Brazilian Fibromyalgia Registry): data on the ACR classification and diagnostic preliminary criteria fulfillment and the follow-up evaluation. *Rev Bras Reumatol Engl Ed* 2017; 57: 129-33.
11. SCIRÈ CA, CAPORALI R, SARZI-PUTTINI P *et al.*: Drug survival of the first course of anti-TNF agents in patients with rheumatoid arthritis and seronegative spondyloarthritis: analysis from the MonitorNet database. *Clin Exp Rheumatol* 2013; 31: 857-63.
12. MARCHESONI A, GOVONI M, VALENTINI G *et al.*: The Italian registry of aggressive rheumatoid arthritis - The GIARA project. *J Rheumatol* 2007; 34: 2374-81.
13. IANNONE F, SALAFFI F, MARCHESONI A *et al.*: Five-year survival on infliximab in rheumatoid arthritis patients: analysis from an Italian registry (GISEA) by different calendar years. *Clin Exp Rheumatol* 2015; 33: 524-30.
14. CODULLO V, IANNONE F, SINIGAGLIA L *et al.*: Comparison of efficacy of first- versus second-line adalimumab in patients with rheumatoid arthritis: experience of the Italian biologics registries. *Clin Exp Rheumatol* 2017; 35: 660-5.
15. WHIPPLE MO, MCALLISTER SJ, OH TH, LUEDTKE CA, TOUSSAINT LL, VINCENT A: Construction of a US fibromyalgia registry using the Fibromyalgia Research Survey criteria. *Clin Transl Sci* 2013; 6: 398-9.
16. WOLFE F, SMYTHE HA, YUNUS MB *et al.*: The American College of Rheumatology 1990 Criteria for the Classification of Fibromyalgia. Report of the Multicenter Criteria Committee. *Arthritis Rheum* 1990; 33: 160-72.
17. WOLFE F, CLAUW DJ, FITZCHARLES MA *et al.*: Fibromyalgia criteria and severity scales for clinical and epidemiological studies: A modification of the ACR preliminary diagnostic criteria for fibromyalgia. *J Rheumatol* 2011; 38: 1113-22.
18. SALAFFI F, FRANCHIGNONI F, GIORDANO A, CIAPETTI A, SARZI-PUTTINI P, OTTONELLO M: Psychometric characteristics of the Italian version of the revised Fibromyalgia Impact Questionnaire using classical test theory and Rasch analysis. *Clin Exp Rheumatol* 2013; 31 (Suppl. 79): S41-9.
19. SALAFFI F, SARZI-PUTTINI P, GIROLIMETTI R, GASPARINI S, ATZENI F, GRASSI W: Development and validation of the self-administered Fibromyalgia Assessment Status: a disease-specific composite measure for evaluating treatment effect. *Arthritis Res Ther* 2009; 11: R125.
20. BURCKHARDT CS, CLARK SR, BENNETT RM: The fibromyalgia impact questionnaire: development and validation. *J Rheumatol* 1991; 18: 728-33.
21. BENNETT R: The Fibromyalgia Impact Questionnaire (FIQ): A review of its development, current version, operating characteristics and uses. *Clin Exp Rheumatol* 2005; 23 (Suppl. 39): S154-62.
22. SALAFFI F, DI CARLO M, ARCÀ S, GALEAZZI M: Categorisation of disease severity states in fibromyalgia: a first step to support decision-making in health care policy. *Clin Exp Rheumatol* 2018; 36: 1074-81.
23. WOLFE F, BRÄHLER E, HINZ A, HÄUSER W: Fibromyalgia prevalence, somatic symptom reporting, and the dimensionality of polysymptomatic distress: results from a survey of the general population. *Arthritis Care Res (Hoboken)* 2013; 65: 777-85.
24. EUROPEAN PARLIAMENT: Question for written answer E-005826/2017 to the Commission [homepage on the Internet]. 2017. Available from: (https://www.europarl.europa.eu/doceo/document/E-8-2017-005826_EN.html?redirect).