



Classification of functioning and assessment of fracture risk of a large Italian osteoporotic population. The Physiatric Approach To Osteoporosis project

F. GIMIGLIANO¹, A. MORETTI², I. RICCIO², G. LETIZIA MAURO³, R. GIMIGLIANO², G. IOLASCON²

Background. Osteoporosis is a skeletal disorder characterized by compromised bone strength predisposing to an increased risk of fracture. Osteoporotic fractures cause significant morbidity, disability, and decrease in quality of life.

Aim. The aims of the Physiatric Approach To Osteoporosis (PATO) project were to classify osteoporotic patients with or without fragility fractures, using the Brief ICF (International Classification of Functioning, Disability and Health) Core Set for Osteoporosis and to calculate the fracture risk with the WHO FRAX[®] (World Health Organization Fracture Risk Assessment Tool) algorithm.

Design. Cross-sectional survey.

Setting. Seventy-nine Italian Rehabilitation Services distributed throughout Italy.

Population. Osteoporotic patients.

Methods. Each physiatrist involved in the survey was asked systematically to record demographic data, presence of fragility fractures, anamnestic risk factors included in the FRAX[®] Assessment Tool, ICF categories as they are listed in the Brief ICF Core Set for Osteoporosis, and treatment data of 100 osteoporotic patients (50 with at least a clinical fragility fracture and 50 without).

Results. In accordance with the FRAX[®] algorithm, the 35.22% of the interviewed osteoporotic patients had a FRAX[®] MAJ \geq 20.00 and the 70.32% had a FRAX[®] HIP \geq 3.00. The most commonly impaired ICF categories were the sensation of pain for the body functions, the structure of the trunk for body structures, lifting and carrying objects for the domain of activities and participation, and products or substances for personal consumption for the environmental factors.

Conclusion. The FRAX[®] Assessment tool has been recognized as useful to identify people at high risk of

¹Department of Physical and Mental Health and Preventive Medicine Second University of Naples, Naples, Italy

²Department of Medical and Surgical Specialties and Dentistry Second University of Naples, Naples, Italy

³Department of Surgical, Oncologic and Stomatologic Disciplines University of Palermo, Palermo, Italy

fracture and the Brief ICF Core Set seems to be an important framework to be followed when dealing with osteoporotic patients in an outpatient setting or for clinical studies.

Clinical Rehabilitation Impact. Osteoporosis is well recognized as a disabling disease, posing a significant challenge for the society, therefore physiatrists should always be involved, from prevention to treatment.

KEY WORDS: Osteoporosis - Fractures, bone - Disability evaluation - Rehabilitation.

The Italian population has one of the highest life expectancies in the world, increasing at a rate of 4 months per year from 1950 to 2005, thus reaching 78.4 years for men and 87.4 years for women.^{1,2} Increased life expectancy is associated with a greater frailty of elderly people and a higher prevalence of chronic and degenerative diseases, such as osteoporosis.³ Osteoporosis is a skeletal disorder characterized by compromised bone strength predisposing to an increased risk of fracture.⁴ The World Health Organization (WHO) considers osteoporosis to be second only to cardiovascular diseases as a critical health problem,⁵ and previous analyses have shown that the incidence and costs of hip fractures in Italy are already comparable to those of acute myocardial

Corresponding author: F. Gimigliano, Via de Crecchio 4, 80134, Naples, Italy. E-mail: francescagimigliano@gmail.com

infarction.⁶ A 3-year multicenter survey, recently, estimated that in Italy there is an annual incidence of about 410,000 fragility fractures in the population over 65 years (87,000 hip fractures, 48,000 humeral fractures, 85,000 wrist fractures, 36,000 ankle fractures, and 155,000 vertebral fractures).⁷

In order to evaluate the fracture risk of patients, WHO has recently developed the FRAX[®] (Fracture Risk Assessment Tool) algorithm, that calculates the 10-year probability of hip fracture and the 10-year probability of a major osteoporotic fracture (clinical spine, forearm, hip or shoulder fracture).⁸ Osteoporotic fractures cause significant morbidity, disability, mortality, and decrease in quality of life. Based on the International Classification of Functioning, Disability and Health (ICF, <http://www.who.int/classification/icf>),⁹ it is now possible to define the typical spectrum of problems in functioning in patients with osteoporosis. The most relevant ICF categories related to osteoporotic patients were identified to develop the Comprehensive ICF Core Set and the Brief ICF Core Set.¹⁰ The Comprehensive ICF Core Set reflects the important and complex impairments, limitations in activity and restrictions in participation involved, as well as the numerous interactions with environmental factors. Compared to the Comprehensive ICF Core Set, the Brief ICF Core Set results in a reduction in the number of chapters represented, as well as in a reduction regarding the ICF categories contained in each chapter. The result of this reduction represents a first proposal for a more practical ICF-based tool to be used in clinical studies.¹¹

On behalf of the Italian Society of Physical Medicine and Rehabilitation (SIMFER) we conducted a National Survey named Physiatrist Approach To Osteoporosis - PATO project. The specific aims were:

1. to classify the Italian osteoporotic population with or without clinical fragility fractures, using the Brief ICF Core Set for Osteoporosis;
2. and to calculate the fracture risk of our population with the WHO FRAX[®] algorithm.

Materials and methods

Patients and data collection

We carried out a cross-sectional national survey, on behalf of SIMFER, including a proportional strati-


fied sample of osteoporotic patients, referring to 79 Italian Rehabilitation Services distributed throughout Italy. Each Rehabilitative Unit was asked to enroll, in a six months period (February-July 2010), 100 osteoporotic patients (50 with at least a clinical fragility fracture and 50 without).

The inclusion criteria were aged over 50 year-old and the diagnosis of osteoporosis (T-score ≤ -2.5 SD at dual energy X-ray absorptiometry - DXA [spine or hip scans] or Quantitative Ultrasound - QUS [heel scan], and/or presence of a fragility fracture, and/or secondary osteoporosis). We decided to exclude any patient who presented cognitive or significant motor impairment not related to the osteoporotic disease.

The physiatrists involved in the survey were systematically asked to record demographic data (area of residence, age, sex, weight and height), presence of a fragility fracture, anamnestic risk factors related to the FRAX[®] Assessment Tool, ICF categories as they are listed in the Brief ICF Core Set for Osteoporosis, and treatment data (previous therapies) (see Figure 1 for the original form and Appendix 1 for the English translation of the form).

The FRAX[®] Assessment Tool is based on individual patient models that integrate the clinical risk factors and bone mineral density (BMD) at the femoral neck. For each clinical risk factors a yes or no response was asked. The risk factors used were: age, sex, weight and height, presence of a previous fracture (a fracture in adult life occurring spontaneously, or a fracture arising from a trauma which, in a healthy individual, would not have resulted in a fracture), a history of hip fracture in the patient's mother or father, glucocorticoids use, current smoking, use of 3 or more units/day of alcohol, a diagnosis of Rheumatoid Arthritis or of secondary osteoporosis, and optionally the femoral neck BMD.¹² According to the National Osteoporosis Foundation recommendations, treatment of osteoporosis should be considered when the patient with low bone mass has a 10-year hip fracture risk (FRAX[®] HIP) of $\geq 3\%$ or a 10-year risk of a major osteoporosis-related fracture (FRAX[®] MAJ) of $\geq 20\%$ as assessed with the FRAX[®] tool.¹³

The Brief ICF core set for osteoporosis includes a total of 12 categories: 4 for body functions (emotional functions b152, sensation of pain b280, mobility of the joints b710, and muscle power functions b730); 2 for body structures (lower extremity s750



SIMFER

Società Italiana di Medicina Fisica e Riabilitativa

Questionario progetto PATO

Paziente (iniziali): _____ Località: _____ Data Visita: _____
 Et : _____ Sesso: F M Peso: _____ Altezza: _____ Tscore _____ Metodo _____

Motivo della visita:

frattura femorale altra frattura non-vertebrale frattura vertebrale ipercalcemici
 rachialgia osteoporosi artrosi altro _____

Terapie pregresse: Sedativi Antidepressivi Ca VitD Altri farmaci per l'osteoporosi

Anamnesi

Anamnesi	SI	NO
Attualmente fuma?		
Assume 3 o pi� unit� di alcool al giorno? *		
I suoi genitori hanno subito una frattura di femore?		
� in terapia con glucocorticoidi? **		
Ha avuto una diagnosi di artrite reumatoide?		
Ha avuto una diagnosi di osteoporosi secondaria?		
Ha subito una frattura?		

* (1 unit  alcool= 285ml birra/120 ml vino/60 ml aperitivo/30ml alcool)
 ** (> 3 mesi   5 mg di prednisolone o eq.)

CATEGORIE ICF	QUALIFICATORE ICF								
	PROBLEMA								
	0	1	2	3	4	8	9		
<i>Funzioni corporee</i>									
b152	Funzioni emozionali								
b280	Sensazione di dolore								
b710	Funzioni della mobilit� dell'articolazione								
b730	Funzioni della forza muscolare								
<i>Strutture corporee</i>									
s750	Struttura dell'arto inferiore								
s760	Struttura del tronco								
<i>Attivit� e partecipazione</i>									
d430	Sollevare e trasportare oggetti								
d450	Camminare								
d920	Ricreazione e tempo libero								
FACILITATORE									
BARRIERA									
4+ 3+ 2+ 1+ 0 1 2 3 4 8 9									
<i>Fattori ambientali</i>									
e110	Prodotti o sostanze per il consumo personale								
e355	Operatori sanitari								
e 580	Servizi, sistemi e politiche sanitarie								

Terapia consigliata:

Antiosteoporosi: Antirassorbitivi Anabolici Ca VitD Altro _____

 Numero Centro
 Timbro

Figure 1.—PATO questionnaire.

This document is protected by international copyright laws. No additional reproduction is authorized. It is permitted for personal use to download and save only one file and print only one copy of this Article. It is not permitted to make additional copies (either sporadically or systematically, either printed or electronic) of the Article for any purpose. It is not permitted to distribute the electronic copy of the article through online internet and/or intranet file sharing systems, electronic mailing or any other means which may allow access to the Article. The use of all or any part of the Article for any Commercial Use is not permitted. The production of reprints for personal or commercial use is not permitted. It is not permitted to remove, cover, overlay, obscure, block, or change any copyright notices or terms of use which the Publisher may post on the Article. It is not permitted to frame or use framing techniques to enclose any trademark, logo, or other proprietary information of the Publisher.

and trunk s760); 3 for activities and participation (lifting and carrying objects d430, walking d450, and recreation and leisure d920); and 3 for environmental factors (products or substances for personal consumption e110, health professionals and health services e580, system and policies e355).¹⁰ The severity of a problem for each functioning category (body functions, body structures, and activities and participations) was quantified using a qualifier scale with the following response options: 0 (no problem), 1 (mild problem), 2 (moderate problem), 3 (severe problem), 4 (complete problem). For the environmental categories a comparable 0-4 response scale was used to assess the extent to which each category was reported as a barrier, while a positive sign was added to each 0-4 response to indicate when the category was perceived as a facilitator. Moreover a response option of 8 was applied when the information were not sufficient to specify the problem severity and a response option of 9 was used when the category was not applicable for the patient.⁹

The role of the investigator had to be limited to the data collection.

The survey was approved by local ethical committees.

Statistical analysis

A descriptive analysis was performed using STATA 11.0. Continuous variables are reported as means and standard deviations, categorical variables as absolute values and proportions.

Results

Of the 79 Italian Rehabilitation Services that were asked to participate in the Survey, only 72 collected some data and only the 39% reached at least the 90% of the target of 100 osteoporotic patients. Their distribution and the number of patients interviewed are reported in Table I. At the end of the data collection period, of the 7900 expected forms, we received a total of 5238 forms, but we had to exclude from the analysis 529 forms which were related to patients who did not meet the inclusion and exclusion criteria or whose data were incomplete for gender and age. Therefore the final analysis was made on 4709 patients, of which, 1976 (41.96%) did not have any fragility fracture and 2733 (58.04%) had already had at least one fragility fracture (Figure 2).

TABLE I.—Geographical distribution of the Rehabilitation Services and the number of patients interviewed.

		Number of centers involved	Number of centers that participated	Number of total patients interviewed			Number of valid patients			Number of non valid patients		
				Frequency	Percent	Cumulative percent	Frequency	Percent	Cumulative percent	Frequency	Percent	Cumulative percent
North Italy	E.R.	8	7	441	8.42	8.42	407	8.64	8.64	34	6.43	6.43
	F.V.G.	1	1	25	0.48	8.90	15	0.32	8.96	10	1.89	8.32
	Liguria	3	3	280	5.35	14.24	275	5.84	14.80	5	0.95	9.26
	Lombardia	11	10	980	18.71	32.95	862	18.31	33.11	118	22.31	31.57
	Piemonte	2	2	175	3.34	36.29	161	3.42	36.53	14	2.65	34.22
	T.A.A.	1	1	96	1.83	38.13	95	2.02	38.54	1	0.19	34.40
	Veneto	5	4	181	3.46	41.58	129	2.74	41.28	52	9.83	44.23
Center Italy	Lazio	10	8	577	11.02	11.02	503	10.68	10.68	74	13.99	13.99
	Marche	3	3	155	2.96	13.97	136	2.89	13.57	19	3.59	17.58
	Toscana	5	5	209	3.99	17.96	194	4.12	17.69	15	2.84	20.42
	Umbria	2	1	17	0.32	18.29	17	0.36	18.05	0	0.00	20.42
	Abruzzo	1	1	88	1.68	1.68	83	1.76	1.76	5	0.95	0.95
South Italy	Basilicata	1	1	46	0.88	2.56	45	0.96	2.72	1	0.19	1.13
	Calabria	5	5	333	6.36	8.92	287	6.09	8.81	46	8.70	9.83
	Campania	7	7	678	12.94	21.86	647	13.74	22.55	31	5.86	15.69
	Molise	1	1	28	0.53	22.39	27	0.57	23.13	1	0.19	15.88
	Puglia	6	5	343	6.55	28.94	314	6.67	29.79	29	5.48	21.36
	Sicilia	7	7	586	11.19	40.13	512	10.87	40.67	74	13.99	35.35
Totals	79	72	5,238			4,709			529			

Values are expressed as absolute numbers or percentages. The following abbreviations have been used: E.R.=Emilia Romagna; F.V.G.=Friuli Venezia Giulia; T.A.A. Trentino Alto Adige.

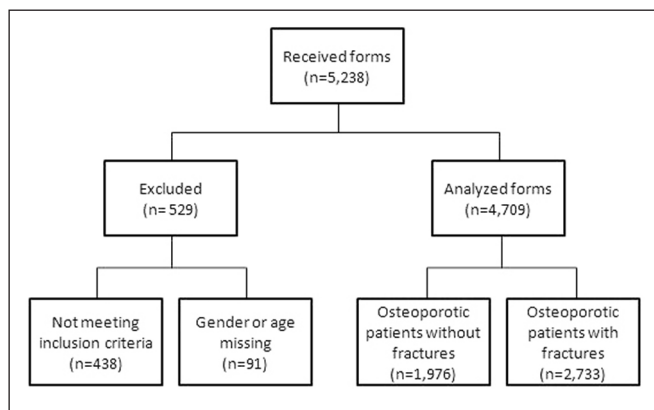


Figure 2.—Flow chart of patients interviewed in the survey.

The general characteristics of the population are detailed in Table II. Over 90% of the subjects interviewed were women; the mean age of the population was about 70 year old, those subjects who had already experienced a fragility fracture were older; the mean BMI was about 25; only the 30.69% of the overall population was receiving an antiosteoporotic treatment at the moment of the interview. Considering the patients who had already had a fragility fracture, the most frequent site reported was the spine (see Table III for further details).

The 10-year probability of any major osteoporotic fracture or of a hip fracture was assessed with the FRAX® tool (Table IV). BMD values at the femoral

TABLE II.—General characteristics of the population.

	All subjects (N.=4709)	Fractured subjects (N.=2,733)	Non-fractured subjects (N.=1,976)
Sex	M (N.=398; 8.45%) W (N.=4311; 91.55%) (N.=4709)	M (N.=295; 10.79%) W (N.=2438; 89.21%) (N.=2733)	M (N.=103; 5.21%) W (N.=1873; 94.79%) (N.=1976)
Age (mean±SD)	70.37±9.25 (N.=4709)	72.64 ± 9.09 (N.=2733)	67.23±8.51 (N.=1976)
BMI (mean±SD)	25.49±4.04 (N.=4,506)	25.71±4.07 (N.=2584)	25.21±3.97 (N.=1922)
Current smoking	986 (20.94%) (N.=4709)	505 (18.48%) (N.=2733)	481 (24.34%) (N.=1976)
Alcohol (≥3 units/day)	375 (7.97%) (N.=4707)	218 (7.98%) (N.=2732)	157 (7.95%) (N.=1975)
Parent hip fracture	1,019 (21.64%) (N.=4709)	639 (23.38%) (N.=2733)	380 (19.23%) (N.=1976)
Glucocorticoids use	387 (8.22%) (N.=4709)	230 (8.42%) (N.=2733)	157 (7.95%) (N.=1976)
Diagnosis of rheumatoid arthritis	194 (4.12%) (N.=4709)	116 (4.24%) (N.=2733)	78 (3.95%) (N.=1976)
Secondary osteoporosis	354 (7.52%) (N.=4706)	223 (8.17%) (N.=2730)	131 (6.63%) (N.=1976)
Previous antiosteoporotic treatment	1,445 (30.69%) (N.=4709)	945 (34.58%) (N.=2733)	500 (25.30%) (N.=1976)

Continuous data are expressed as means and standard deviations (SD), categorical data are expressed as absolute values and percentages. M: men; W: women; BMI: Body Mass Index.

TABLE III.—Description of fragility fractures.

	Frequency	Percentage	Cumulative percentage	Age (mean±SD)	Sex nM(%)	BMI (mean±SD)
No fracture	1,976	41.96	41.96	67.24 (±8.52)	102 (5.16%)	25.21 (±3.98)
Hip	621	13.19	55.15	76.82 (±8.77)	96 (15.46%)	25.52 (±3.84)
Spine	824	17.50	72.65	71.52 (±8.25)	103 (12.50%)	26.02 (±3.98)
Any other site	506	10.75	83.39	68.81 (±9.51)	43 (8.50%)	25.48 (±4.32)
Unspecified	545	11.57	94.97	71.50 (±8.49)	37 (6.79%)	25.56 (±4.27)
Multiple site	237	5.03	100.00	76.30 (±7.74)	17 (7.17%)	25.87 (±3.82)
Total	4,709	100.00				

Continuous data are expressed as means and standard deviations (SD), categorical data are expressed as absolute values and percentages. SD: standard deviation; nM: number of men; BMI: Body Mass Index.

This document is protected by international copyright laws. No additional reproduction is authorized. It is permitted for personal use to download and save only one file and print only one copy of this Article. It is not permitted to make additional copies (either sporadically or systematically, either printed or electronic) of the Article for any purpose. It is not permitted to distribute the electronic copy of the article through online internet and/or intranet file sharing systems, electronic mailing or any other means which may allow access to the Article. The use of all or any part of the Article for any Commercial Use is not permitted. The production of derivative works from the Article is not permitted. The production of reprints for personal or commercial use is not permitted. It is not permitted to remove, cover, overlay, obscure, block, or change any copyright notices or terms of use which the Publisher may post on the Article. It is not permitted to frame or use framing techniques to enclose any trademark, logo, or other proprietary information of the Publisher.

TABLE IV.—Fracture risk of the population according to FRAX algorithm.

	All subjects (N.=4495)	Fractured subjects (N.=2582)	Non-fractured subjects (N.=1913)
FRAX-MAJ*	17.78±11.98	23.11±12.03	10.58±7.20
FRAX-MAJ ≥ 20.00**	1583 (35.22)	1401 (54.26)	182 (9.51)
FRAX-HIP*	8.88±9.98	12.13±11.13	4.51±5.79
FRAX-HIP ≥ 3.00**	3161 (70.32)	2267 (87.80)	894 (46.73)

*continuous data are expressed as means and standard deviations; **categorical data are expressed as absolute values and percentages.
FRAX-MAJ: 10-year probability risk of a major osteoporotic fracture; FRAX-HIP: 10-year probability risk of a hip fragility fracture.

TABLE V.—Brief ICF Core Set for osteoporosis and frequencies and percentages of subjects who referred an alteration of each of these ICF categories.

	All subjects (N.=4709)	Fractured subjects (N.=2733)	Non-fractured subjects (N.=1976)
b152	2718/4683 (58.04%)	1721/2711 (63.48%)	997/1972 (50.56%)
b280	3965/4682 (84.69%)	2382/2710 (87.90%)	1583/1972 (80.27%)
b710	3728/4681 (79.64%)	2338/2709 (86.30%)	1390/1972 (70.49%)
b730	3411/4667 (73.09%)	2167/2696 (80.38%)	1244/1971 (63.12%)
s750	3026/4673 (64.75%)	1921/2702 (71.10%)	1105/1971 (56.06%)
s760	3514/4674 (75.18%)	2128/2704 (78.70%)	1386/1970 (70.36%)
d430	3819/4672 (81.74%)	2347/2703 (86.83%)	1472/1969 (74.76%)
d450	3273/4675 (70.01%)	2067/2706 (76.39%)	1206/1969 (61.25%)
d920	2948/4664 (63.21%)	1877/2695 (69.65%)	1071/1969 (54.39%)
e110	B: 1006/4620 (21.77%) F: 1137/4620 (24.61%)	B: 652/2657 (24.50%) F: 762/2657 (28.68%)	B: 354/1963 (18.03%) F: 375/1963 (19.10%)
e355	B: 1083/4618 (23.45%) F: 891/4618 (19.29%)	B: 682/2656 (25.68%) F: 624/2656 (23.49%)	B: 401/1962 (20.44%) F: 267/1962 (13.61%)
e580	B: 1220/4616 (26.43%) F: 609/4616 (13.19%)	B: 767/2654 (28.90%) F: 442/2654 (16.65%)	B: 453/1962 (23.09%) F: 167/1962 (8.51%)

Values are reported as absolute numbers and percentages in round brackets.
B: barrier; F: facilitator.

neck were not considered in the calculation because the data were missing for most of the subjects. In accordance with the FRAX[®] algorithm, the 54.26% of fractured subjects had a FRAX[®] MAJ≥20.00 and the 87.80% had a FRAX[®] HIP≥3.00, while among those who had not experienced a fragility fracture yet, the 9.51% had a FRAX[®] MAJ≥20.00 and the 46.73% had a FRAX[®] HIP≥3.00.

In Table V there is a description of how the ICF categories included in the Brief ICF core set were represented in the overall population and in the 2 sub-populations of patients with and without a fragility fracture. In the table the frequencies and percentages of subjects who referred that the category was impacting their lives (ICF qualifier responses 1-4) are reported. The percentage of those who

referred that the items were not specified (value 8 of the ICF qualifiers) or not applicable (value 9 of the ICF qualifiers) was irrelevant (<1.00%) in most of the cases, except for d920 (3.68%) and e580 (8.01%). As for the body functions, the sensation of pain seemed to be the most commonly impaired function followed by the mobility of the joints and muscle power functions, while emotional functions resulted to be the least compromised. Of the body structures, the structure of the trunk seemed to be the most commonly impaired in our population. The most commonly limited activity resulted to be lifting and carrying objects, followed by walking, and recreation and leisure. For the environmental factors, e110 was considered in the majority of the cases as a facilitator, while both e355 and e580 were mostly perceived as barriers.

Discussion

The main goals of the PATO survey were to gain a better understanding of functioning and health of persons with osteoporosis, using the Brief ICF Core Set for Osteoporosis; and to calculate the fracture risk with the WHO FRAX[®] algorithm of our population. Osteoporosis is a widespread disease in Italy. In 2001, the ESPO study assessed a random sample of 11,011 women and 4981 men, all over Italy rating a prevalence of osteoporosis in women aged 40-79 year-old of approximately 18.5% and in men aged 60-79 year-old of 10%. Higher rates of osteopenia were reported (44.7% and 36% in women and men respectively). The authors claimed that osteoporosis and osteopenia were strongly associated with fragility fractures, independently of all traditional risk factors, including age.¹⁴ More recently, Tarantino *et al.* reported an annual incidence of new fragility fractures at any site of 410,000, thus confirming that osteoporosis is a leading cause of morbidity in the Italian population.⁷ The majority of these fractures require a rehabilitative approach both in case of a surgical or conservative treatment.^{15, 16} This is why in our survey we decided to involve physiatrists usually dealing with the management of osteoporotic patients. The number and the geographic distribution (north, center and south of Italy) of the physiatrists, initially involved in the Survey, were in line with the geographic distribution of the general Italian population. Moreover the physiatrists involved

in the study work in different rehabilitative settings such as outpatient clinic, inpatient clinic, community based rehabilitation and so on.

Several international guidelines suggest the use of the FRAX[®] algorithm to assess the 10-year fracture risk for osteoporotic patients.^{17, 18} The FRAX[®] tool is used in 173 countries worldwide.¹⁷ In Italy, Pedrazzoni *et al.* published a retrospective study in which they estimated the absolute risk of fracture in a large cohort of postmenopausal women with the Italian version of FRAX[®].¹⁹ A recent study reported that of the 45% of patients who, according to FRAX[®] thresholds, would have required an anti-osteoporotic pharmacological treatment, only the 27% actually received the treatment.²⁰ Recent data showed that Italy is one of the European countries with the highest osteoporosis treatment uptake, being the 57% of osteoporotic patients who had already sustained a hip or spine fracture under treatment.²¹ However of the osteoporotic population that we interviewed only the 30.69% was already receiving a pharmacologic treatment for osteoporosis despite the fact that over the 70% of the population had a FRAX[®] HIP \geq 3.00.

When dealing with chronic health conditions such as osteoporosis it is important not only to assess body functions and structures, but also activities and participation and environmental factors.²² The biopsychosocial model of ICF allows us for a detailed assessment of body functions and structures, activities and participation as well as environmental factors, and directs us for the appropriate rehabilitative approaches for optimizing functioning.²³ Üstun underlined that, in daily practice, clinicians would only need a small fraction of the 1454 ICF categories.²⁴ Therefore the ICF Research Branch of the German WHO FIC (Family of International Classifications) collaborating centre at the University of Munich and the CAS (Classification, Assessment, Surveys and Terminology Team) at the WHO, together with partner organizations worldwide, realized the ICF Core Sets project, in order to select sets of categories out of the whole classification which might be used for the assessment and reporting of functioning in specific health conditions.²⁵ In particular the Comprehensive ICF Core Sets would include the typical spectrum of problems in functioning in patients with a condition and serve as a multidisciplinary guide for their assessment, while the Brief ICF Core Sets would include the minimum categories to be rated in all

patients included in a clinical study.¹¹ This is the reason why in our survey we decided to use the Brief ICF Core Set for osteoporosis and not the Comprehensive one. Moreover the brief version contains only 12 categories, and this allowed us to keep the whole questionnaire in just one page.

Pain and in particular back pain is referred as one of the most common symptoms in osteoporotic patients with or without a vertebral fracture. Whether or not the back pain is due to osteoporosis is still controversial.²⁶⁻³⁰ In our survey, the sensation of pain resulted to be the most commonly impaired body function, and the trunk the most commonly impaired body structure. In fact over the 80% of the overall population interviewed, including the subgroup of osteoporotic patients who had not yet experienced any fragility fracture, referred an impairment in b280 (sensation of pain) category, and over the 75% of the whole population presented a certain degree of impairment at the trunk. The mean age of patients interviewed was about 70 year-old and this might justify the high percentage of people who presented impairment in the categories b710 (mobility of joint functions) and b730 (muscle power functions), percentages that were significantly higher in the subgroup of those who had already experienced a fragility fracture. Emotional functions resulted to be the least impaired body function category. The order of both body functions and structures that our population considered as a problem matches perfectly with the percentage of experts at the Consensus Conference willing to include the categories in the Brief ICF Core Set.¹⁰ The ability of carrying on independently the various activities of day living (ADL) is the basis of what is the perception of the individual quality of life. Limitations and restrictions in activities and participation are, in fact, of great importance to define the functioning level of osteoporotic patients. In our population the most commonly limited activity was referred to be the one of lifting and carrying objects, followed by walking, and recreation and leisure. As for the environmental factors the most interesting data regards the ICF code e110, which is products or substances for personal consumption, including drugs. We agree with Cieza *et al.* that anti-osteoporotic drugs might influence osteoporotic patients' functioning as a barrier due to their side effects and/or as a facilitator by preventing fractures.¹⁰ These results might also reflect the Italian Directives for anti-osteoporotic drugs

prescription. Most of these drugs are, in fact, for free for those people who sustained a hip fracture or who had a vertebral fracture (with a minimum reduction of the 20% of one of the three heights of the vertebral body) but not in case of a fracture in any other site³¹. Therefore, in the presence of a vertebral or a hip fracture, drugs may be seen as a facilitator, while in case of any other fracture, or for those osteoporotic patients who haven't had a fragility fracture, but according to the FRAX[®] algorithm are at high risk of experiencing one, they are seen as a barrier, being at the same time necessary and expensive. Bell *et al.* reported that a dedicated osteoporosis health professional-directed intervention to low trauma non-hip fracture patients in an outpatient setting is effective in improving investigations, initiating treatment, reducing future fractures, and improving referral to specialist bone clinic.³² It is interesting to see how in our study the code e355 (health professionals) was seen as a barrier in about 25% of fractured subjects and in 20% of the non-fractured subjects. According to Kanis *et al.*, Italy is one of the European countries where osteoporosis is officially documented as a national health priority but there is not yet an action plan for its management.³³ In our study the code e580, health services, systems and policies, was seen as a barrier by about the 26% of the population interviewed. It is also relevant to notice that, in our survey, environmental factors were the ICF codes with the highest rate of missing data. Moreover most of the queries that we received from the psychiatrists involved in the Survey were on how to qualify them.

One of the limitations of our survey is related to generalizability. To be sure that our population would have been representative of the osteoporotic patients in Italy we should have involved physicians with all the different specializations dealing with osteoporotic patients (physical and rehabilitation medicine, orthopaedics and traumatology, internal medicine, endocrinology, rheumatology, gynecology, and so on). Instead we decided to involve only psychiatrists who were members of SIMFER and who were experts in osteoporosis. On the other side, the psychiatrists involved were working in different rehabilitative setting (inpatients, outpatients, community-based rehabilitation patients) and this, together with the decision to leave the inclusion and exclusion criteria as simpler as possible, was done to guarantee the highest level of external generalizability

as possible. Another limitation of the study is that, in order to keep the survey as simpler as possible and no longer than one page, we did not add any validated comorbidity assessment tool and therefore we cannot assess the burden of the comorbidities that might have had an impact on patients functional status. Another limitation was that we were able to assess only the clinical fragility fractures and not all the fragility fractures.

Conclusions

In line with the mission of the International Society of Physical and Rehabilitation Medicine, the aim of rehabilitation is to optimize functioning and health-related quality of life and minimize disability.³⁴ ICF represents the universal language of functioning and should be used to describe the whole rehabilitation cycle.³⁵ This is the first study applying the Brief ICF Core Set for Osteoporosis in such a large cohort of patients. Osteoporosis is well recognized as a disabling disease, posing a significant challenge for the society, therefore physiatrists should always be involved, from prevention to treatment. In accordance with the FRAX[®] algorithm, the 70.32% had a FRAX[®]-HIP \geq 3.00. The most commonly impaired ICF categories were the sensation of pain for the body functions, the structure of the trunk for body structures, lifting and carrying objects for the domain of activities and participation, and products or substances for personal consumption for the environmental factors. Therefore in our opinion the FRAX[®] Assessment tool has been recognized as useful to identify people at high risk of fracture and the Brief ICF Core Set for osteoporosis seems to be an important framework to be followed when dealing with osteoporotic patients in an outpatient setting or for clinical studies. The bio-psycho-social model of ICF in fact enlarges both the health professionals and patients point of view on the concept of health in its widest meaning.

References

- National Institute for Statistics: Italian Statistics 2005 Rome: National Institute for Statistics; 2005.
- World Health Organization. WHO statistical information system (WHOSIS) [Internet]. Available from: <http://apps.who.int/ghodata/?vid=720> [cited 2015, Jul 28].
- Piscitelli P, Iolascon G, Gimigliano F, Gimigliano A, Marinelli A, Di Nuzzo R *et al.* Osteoporosis and cardiovascular diseases' cosgregation: epidemiological features. *Clin Cases Miner Bone Metab* 2008;5:14-8.
- Osteoporosis Prevention, Diagnosis, and Therapy. NIH Consensus Statement 2000 March 27-29;17:1-36.
- Kanis JA, Burlet N, Cooper C, Delmas PD, Reginster JY, Borgstrom F *et al.* European Society for clinical and economic (aspects of osteoporosis and osteoarthritis ESCEO): European guidance for the diagnosis and management of osteoporosis in postmenopausal women. *Osteoporos Int* 2008;19:399-428.
- Piscitelli P, Iolascon G, Gimigliano F, Muratore M, Camboa P, Borgia O *et al.* Incidence and costs of hip fractures compared to acute myocardial infarction in the Italian population: a 4-year survey. *Osteoporos Int* 2007;18:211-9.
- Tarantino U, Capone A, Planta M, D'Arienzo M, Letizia Mauro G, Impagliazzo A *et al.* The incidence of hip, forearm, humeral, ankle, and vertebral fragility fractures in Italy: results from a 3-year multicenter study. *Arthritis Res Ther* 2010;12:R226.
- Kanis JA, Oden A, Johansson H, Borgström F, Ström O, McCloskey E. FRAX and its applications to clinical practice. *Bone* 2009;44:734-43.
- World Health Organization. International Classification of Functioning, Disability and Health: ICF. Geneva: WHO; 2001.
- Cieza A, Schwarzkopf SR, Sigl T, Stucki G, Melvin J, Stoll T *et al.* ICF Core Sets for Osteoporosis. *J Rehabil Med* 2004;(Suppl 44):81-6.
- Cieza A, Ewert T, Ustün TB, Chatterji S, Kostanjsek N, Stucki G. Development of ICF Core Sets for patients with chronic conditions. *J Rehabil Med* 2004;(44 Suppl):9-11.
- Kanis JA, Johnell O, Oden A, Johansson H, McCloskey EV. FRAX[™] and the assessment of fracture probability in men and women from the UK. *Osteoporos Int* 2008;19:385-97.
- National Osteoporosis Foundation. Clinician's Guide to Prevention and Treatment of Osteoporosis. Washington, DC: National Osteoporosis Foundation; 2010.
- Maggi S, Noale M, Giannini S, Adami S, Defeo D, Isaia G *et al.* Quantitative heel ultrasound in a population-based study in Italy and its relationship with fracture history: the ESOP study. *Osteoporos Int* 2006;17:237-44.
- Gimigliano F, Iolascon G, Riccio I, Frizzi L, Gimigliano R. Post-surgical rehabilitative approach to fragility fractures. *Aging Clin Exp Res* 2013;25(Suppl 1):S23-5.
- Riccio I, Tirelli A, Gimigliano F, Iolascon G, Gimigliano R. Rehabilitative approach in patients with vertebral fragility fracture. *Aging Clin Exp Res* 2013;25(Suppl 1):S109-11.
- Kanis JA, Johansson H, Oden A, Cooper C, McCloskey EV. Epidemiology and Quality of Life Working Group of IOF. Worldwide uptake of FRAX. *Arch Osteoporos* 2014;9:166.
- Kanis JA, McCloskey EV, Johansson H, Cooper C, Rizzoli R, Reginster J-Y, on behalf of the Scientific Advisory Board of the European Society for Clinical and Economic Aspects of Osteoporosis and Osteoarthritis (ESCEO) and the Committee of Scientific Advisors of the International Osteoporosis Foundation (IOF). European guidance for the diagnosis and management of osteoporosis in postmenopausal women. *Osteoporos Int* 2013;24:23-57.
- Pedrazzoni M, Girasole G, Giusti A, Barone A, Pioli G, Passeri G *et al.* Assessment of the 10-year risk of fracture in Italian postmenopausal women using FRAX[®]: a north Italian multicenter study. *J Endocrinol Invest* 2011;34:e386-91.
- Elvey MH, Pugh H, Schaller G, Dhotar G, Patel B, Oddy MJ. Failure in the application of fragility fracture prevention guidelines. *Ann R Coll Surg Engl* 2014;96:381-5.
- Díez-Pérez A, Hooven FH, Adachi JD, Adami S, Anderson FA, Boonen S *et al.* Regional differences in treatment for oste-

- oporosis. The Global Longitudinal Study of Osteoporosis in Women (GLOW). *Bone* 2011;49:493-8.
22. Oral A, Küçükdeveci AA, Varela E, Ilieva EM, Valero R, Berteau M *et al.* Osteoporosis. The role of physical and rehabilitation medicine physicians. The European perspective based on the best evidence. A paper by the UEMS-PRM Section Professional Practice Committee. *Eur J Phys Rehabil Med* 2013;49:565-77.
 23. Stucki G, Melvin J. The International Classification of Functioning, Disability and Health: a unifying model for the conceptual description of physical and rehabilitation medicine. *J Rehabil Med* 2007;39:286-92.
 24. Üstün B, Chatterji S, Kostanjsek N. Comments from WHO for the Journal of Rehabilitation Medicine Special Supplement on ICF Core Sets. *J Rehabil Med* 2004;(44 Suppl):7-8.
 25. Stucki G, Cieza A, Ewert T, Kostanjsek N, Chatterji S, Üstün B. Application of the International Classification of Functioning, Disability and Health (ICF) in clinical practice. *Disabil Rehabil* 2002;24:281-2.
 26. Folman YI, Shabat S, Gepstein R. Relationship between low back pain in post-menopausal women and mineral content of lumbar vertebrae. *Arch Gerontol Geriatr*;39:157-61.
 27. Francis R, Spray TO, Hide G, Sutcliffe AM, Wilkinson P. Back pain in osteoporotic vertebral fractures. *Osteoporos Int* 2008;19:895-903.
 28. Ahn S, Song R. Bone mineral density and perceived menopausal symptoms: factors influencing low back pain in postmenopausal women. *J Adv Nurs* 2009;65:1228-36.
 29. Li S, He H, Ding M, He C. The correlation of osteoporosis to clinical features: a study of 4382 female cases of a hospital cohort with musculoskeletal symptoms in southwest China. *BMC Musculoskelet Disord* 2010;11:183.
 30. Zhao Y, Liu Y, Zheng Y. Osteoporosis and related factors in older females with skeletal pain or numbness: a retrospective study in East China. *J Int Med Res* 2013;41:859-66.
 31. AIFA 2006-2007: Notes for the appropriate use of medicinal products. *Official Gazette* 2007;(Suppl 7):61.
 32. Bell K, Strand H, Inder WJ. Effect of a dedicated osteoporosis health professional on screening and treatment in outpatients presenting with acute low trauma non-hip fracture: a systematic review. *Arch Osteoporos* 2014;9:167.
 33. Kanis JA, Borgström F, Compston J, Dreinhöfer K, Nolte E, Jonsson L *et al.* SCOPE: a scorecard for osteoporosis in Europe. *Arch Osteoporos* 2013;8:144.
 34. Imamura M, Gutenbrunner C, Stucki G, Li J, Lains J, Frontera W *et al.* The International Society of Physical and Rehabilitation Medicine: the way forward - II. *J Rehabil Med* 2014;46:97-107.
 35. Rauch A, Cieza A, Stucki G. How to apply the International Classification of Functioning, Disability and Health (ICF) for rehabilitation management in clinical practice. *Eur J Phys Rehabil Med* 2008;44:329-42.

Presented at the 8th Mediterranean Congress of Physical and Rehabilitation Medicine in Cyprus.

Funding.—The Survey was sponsored by Warner Chilcott. All the data that might have been influenced by the sponsor have not been taken in account for the following publication.

Acknowledgments.—We would like to acknowledge all the PRM physicians that contributed to the data collection. Their names are listed in alphabetical order. Addevico Marco, Agostini Lorenzo, Albergati Michele, Ammirati Caterina, Arioli Giovanni, Ballotta Massimo, Bertolini Carlo, Bloccari Laura, Boiani Loretta, Cagnana Annalisa, Campagnoli Giovanni, Capezza Maria, Caraffa Giorgio, Carnesalini Giancarlo, Cattaneo Maria Grazia, Cattozzo Margherita, Celestini Marcello, Ceppatelli Simone, Cisari Carlo, Colarossi Roberto, Consolandi Alberto, Contrino Luciano, Coppadoro Franca, D'amico Maria, Dalla Toffola Elena, De Buono Donatella, De Chiara Raffaele, De Giglio Vito, De Marchi Massimo, De Martino Eduardo, De Simone Giovanni, Delli Bergoli Michelina, Di Girolamo Livia, Di Pietro Gioconda, Dombace Vincenzo, Farina Stefano, Fasani Marcella, Fenoglio Claudia, Ferlini Gregorio, Finizio Carmine, Fiorani Claudio, Fiore Piero, Fletzer David, Giorgio Chiara, Groppelli Caterina, Hartmann Emma, Lavacca Maria, Lavarra Francesco, Lecce Aldo, Listrani Alessandro, Lobbia Luciana, Lorenzini Michela, Magagni Gianandrea, Maggiolini Francesca, Magnani Giovanni, Magnani Maurizio, Manfredini Monica, Mangone Giuseppe, Marchese Angela, Marchesi Gianfranco, Mauri Angelo, Mazzei Rosa, Megna Gianfranco, Menconi Agnese, Mercante Oriano, Milano Edoardo, Mileto Antonio, Moretti Michele, Olivieri Maurizio, Pagani Rita, Parolo Elena, Pasquetti Pietro, Pellegrini Simonetta, Pellizzon Massimo, Pepe Antonio, Peron Paola, Pestelli Germano, Piazzini Diana, Pironcini Simonetta, Posteraro Giuseppe, Puglisi Claudio, Ralfaetà Gloria, Rizzo Daniele, Romaniello Vitina, Romeo Alfredo, Roncato Andrea, Ronconi Gianpaolo, Rossi Renata, Saraceni Vincenzo, Scaglione Giuseppe, Schieroni Maria Pia, Sciacca Rosario, Seminara Carmelo, Sguazzini Giovanni, Silvestrin Roberto, Smiderle Crisina, Specchia Alessandro, Sterzi Silvia, Tabarrini Laura, Tontodonati Chiara, Tumiatto Claudia, Tuvo Stefano, Uliano Domenico, Vena Salvatore, Zambuto Alfredo, Zampolini Mauro, Zannato Rosangela, Zucchi Francesca, Zucchini Elisabetta.

Conflicts of interest.—The authors certify that there is no conflict of interest with any financial organization regarding the material discussed in the manuscript.

Received on September 16, 2014.

Accepted for publication on May 19, 2015.

Epub ahead of print on May 21, 2015.