Clinical and Experimental Rheumatology 11: 123-128, 1993

The Italian version of the Functional Disability Index of the Health Assessment Questionnaire. A reliable instrument for multicenter studies on rheumatoid arthritis

R. RANZA[1], A. MARCHESONI[1], G. CALORI[2], G. BIANCHI[3], M. BRAGA[4], S. CANAZZA[5], B. CANESI[6], M. FUMAGALLI[7], C. MASTAGLIO [8], A. MATHIEU[9], F. FANTINI[1]

[1]Cattedra di Reumatologia, Istituto G. Pini, Milano; [2]Divisione di Statistica Medica ed Epidemiologia, Istituto Scientifico San Raffaele, Milano; [3]Cattedra di Reumatologia, Istituto E. Bruzzone, Genova; [4]Cattedra di Immunologia Clinica, Università di Brescia; [5]Divisione di Reumatologia, Ospedale S. Anna, Ferrara; [6]Divisione di Reumatologia, Ospedale Niguarda Ca'Granda, Milano; [7]Reumatologia, Ospedale V. Buzzi, Milano; [8]Reumatologia, Ospedale M. Pelascini Gravedona, Como; [9]II Cattedra di Reumatologia, Università di Cagliari, Italy.

ABSTRACT. *A working group of ten rheumatology institutes (UNIREUM) was formed in Italy to promote multicenter therapeutic studies on rheumatoid arthritis. The Functional Disability Index (FDI) of the Health Assessment Questionnaire (HAQ) was chosen as a measure of disability. This paper reports the results of a multicenter study to validate an Italian translation of the instrument and to assess its reliability and validity. Two questions were modified to achieve cross-cultural equivalence. Back-translation into English showed agreement with the American instrument. Reproducibility was high: the test-retest correlation coefficient was 0.989 and ranged from 0.81 to 0.99 for the centers taken separately. Validity was confirmed by a correlation coefficient of 0.95 between the patient self-attributed and the physician-attributed FDI scores. We conclude that our Italian version of the HAQ FDI is a reliable and valid self-administered instrument.*

Key words: disability, translation, reliability, outcome, self-assessment.

Introduction

Rheumatoid arthritis (RA) has the highest prevalence among the inflammatory arthropathies and rheumatologists are still searching for a treatment regimen to modify its long term outcome. In 1989 a working group of ten rheumatology institutes (UNIREUM) from northern and central Italy was formed to promote multicenter therapeutic trials. First, a uniform database and a common methodology for data collection and quality control were adopted. Because disability is a major outcome dimension in RA (1), it was considered to be of primary importance to have a reliable instrument to evaluate the patient's functional status over time. The traditional American Rheumatism Association (ARA) Functional Class is a measure of function which provides only four possible categories (2). The Stanford Health Assessment Questionnaire (HAQ) Functional Disability Index (FDI) is composed of 20 questions in 8 categories of functional activities. We chose the FDI because: i) its data collection and coding procedures are standardized; ii) its reliability and validity have been demonstrated (3-6); and iii) it is self-administered, relatively brief, and easy for the researcher to code.

The FDI of the HAQ was therefore translated into Italian and validated using methods similar to those used in validation studies for other languages (7-13).To ensure a

Roberto Ranza, MD; Antonio Marchesoni, MD; Gigliola Calori, MD; Gerolamo Bianchi, MD; Marina Braga, MD; Stefano Canazza, MD; Bianca Canesi, MD; Mario Fumagalli, MD; Claudio Mastaglio, MD; Alessandro Mathieu, MD; Flavio Fantini, MD.

Please address reprint requests to: Roberto Ranza, MD, Cattedra di Reumatologia, Istituto G. Pini, via G. Pini 3, 20122 Milano, Italy.

Received June 29, 1992; accepted in revised form on Sept. 28, 1992.

Table I. The Italian version of the HAQ-FDI and its back translation into English.

	Senza alcuna difficoltà Without any difficulty	Con poca difficoltà With little difficulty	Con molta difficoltà With much difficulty	Non riesco I am not able

riuscite a (are you able to):

Cat. 1. Vestirvi e lavarvi (dressing and washing)

C1 (**) Vestirvi compreso allacciarvi le stringhe delle scarpe e abbottonarvi e sbottonarvi ?
Dress yourself including lacing shoes and doing buttons ?

C2 Lavarvi i capelli (Wash your hair) ?

Cat. 2. Alzarvi (arising)

C3 (**) Alzarvi da una sedia senza braccioli ?
Stand up from an armless chair ?

C4 Entrare e uscire dal letto (Get in and out of bed) ?

Cat. 3. Mangiare (eating)

C5 Tagliare la carne (Cut your meat) ?

C6 (**) Portare alla bocca una tazza o un bicchiere pieni ?
Lift a full cup or glass to your mouth ?

C7 (*)(**) Spezzare il pane con le mani ?
Break bread with your hands ?

Cat. 4. Camminare (walking)

C8 (**) Camminare su un terreno piano (Walk on flat ground) ?

C9 Salire 5 gradini (Climb up 5 steps) ?

Cat. 5. Igiene personale (personal hygiene)

C10 (**) Lavare ed asciugare ogni parte del vostro corpo ?
Wash and dry every part of your body ?

C11 Fare il bagno nella vasca (Take a tub bath) ?

C12 (**) Sedervi ed alzarvi dal water ?
Sit down and get up off the toilet ?

Cat. 6 - Prendere (reach)

C13 (**) Prendere e tirare giù un oggetto di un chilo (come una scatola di zucchero)
da un ripiano posto appena sopra la vostra testa ?
Reach and pull down a one kilo object (like a bag of sugar) from a flat area just above your head ?

C14 (**) Piegarvi a raccogliere un indumento dal pavimento ?
Bend down to pick up clothing from the floor ?

Cat. 7. Aprire (opening)

C15 Aprire la portiera della macchina (Open the car door) ?

C16 (**) Svitare il coperchio di un barattolo (gia' aperto in precedenza) ?
Unscrew the lid of a jar (which had been previously opened) ?

C17 (**) Aprire e chiudere i rubinetti (Turn faucets on and off) ?

Cat. 8 - Attivita' varie (various activities)

C18 Andare a fare la spesa (Do the shopping) ?

C19 Entrare ed uscire dalla macchina (Get in and out the car) ?

C20 (*)(**) Sbrigare faccende come passare la lucidatrice o l'aspirapolvere oppure fare lavoretti domestici ?
Do domestic tasks like dusting and polishing or household jobs ?

(*) questions modified compared with the original FDI of the HAQ.
(**) tasks that the subject performed, using pre-determined tools, in the presence of the physician after the retest.

reliable instrument in view of the cultural differences among the various regions of our country, the study included all ten of the Italian centers participating in the clinical trials on RA. This paper reports the results of this multicenter validation study.

Materials and methods

Translation. Two translators aware of the field of application and of the target population of the questionnaire, translated the requisite components of the FDI into Italian. Subsequently a panel which included one rheumatologist per center plus the two translators met to discuss the appropriateness of the translation in cultural terms. Two questions were modified: the substituted sentences are marked with a single asterisk in Table I, which presents the Italian translation for the 20 items included in the FDI. In a further step two American translators, blind to the original questionnaire, back-translated the entire text into English (Table I). The panel of rheumatologists then met with the four translators and reviewed the discrepancies; no further major modifications were required.

Reliability. A test-retest study was used to assess the reliability of the instrument. The questionnaire was administered to clinic outpatients; no help from health professionals or physicians was allowed. In addition to the Italian FDI, a joint examination was performed and a Ritchie index (14) recorded. Patients returned in 7 to 12 days for a further clinical evaluation and were not informed of the retest.

Validity. After the retest a physician, blind to both the test and the retest and using predefined tools, asked the patient to perform at least one activity from each of the 8 categories of the FDI (the activities are marked in Table I with a double asterisk). On a third questionnaire, the physician reported his judgment on the difficulty the subject had in performing the tasks. Finally the physician completed a Lee index (15).

Study population. The study included patients from 8 of the 10 centers. Every center was asked to enroll 15 outpatients as follows: 5 patients with functional class I or II RA according to the 1987 ARA criteria (16) (functional capacity complete or adequate to conduct their activities) (group 1), 5 with class III or IV RA (varying degrees of limitation or incapacity to perform habitual tasks) (group 2), and 5 non-RA subjects who did not meet the 1987 ARA criteria for RA, exhibiting no tenderness, swelling or limitation of motion in any joint and with no incapacitating clinical musculoskeletal involvement.

Statistical analysis. The Spearman correlation coefficient for test-retest reliability and patient-physician validity was used. The correlations among the 8 categories of the FDI were also evaluated by the Spearman correlation coefficient. The Kruskal-Wallis test was performed to analyze differences between the test-retest delta scores.

Results

The demographic and clinical data for the 80 RA patients and the 40 non-arthritic subjects are summarized in Table II. A wide range of RA patients, in terms of ARA functional class, are represented; the class IV patients were fewer in number and older. The distribution of the Lee and Ritchie indices and the duration of morning stiffness are

Table II. Demographic and clinical characteristics of the study population based on ARA functional class.

Functional class	I	II	III	IV	Non-arthritic	All
Number of patients (%)	16 (13.3)	24 (20)	34 (28.3)	6 (5.1)	40 (33.3)	120 (100)
Female/male (%)	11/5	21/3	29/5	5/1	33/7	99/21 (82.5/17.5)
Age: mean ± SD (range)	53.9 ± 13.8 (27 - 70)	50 ± 13.3 (20 - 71)	57.7 ± 11.9 (35 - 79)	65.8 ± 4.6 (58 - 71)	44 ± 10.4 (23 - 65)	51.5 ± 13 (20 - 79)
Disease duration (mean ± SD) (range)	3.8 ± 3.3 (0.4 - 9)	8.7 ± 7.7 (2 - 22.1)	11 ± 6.6 (3.1 - 21)	19.9 ± 6.9 (15.3 - 24.8)	—	
Morning stiffness mean ± SD (minutes)	80.7 ± 57.4	129 ± 88.2	117.3 ± 97.1	200 ± 146.5	19.6 ± 51.1	
Ritchie index (mean ± SD)	12.2 ± 9.4	13.9 ± 8.8	16.3 ± 7.4	14 ± 10.7	—	
Lee index (mean ± SD)	2.9 ± 2.6	8 ± 6.3	12.7 ± 4.7	13 ± 8.3	0.48 ± 0.9	
Functional Disability Index Score (mean ± SD)	0.76 ± 0.55	1.07 ± 0.72	1.79 ± 0.72	1.98 ± 0.49	0.1 ± 0.16	

Table III. Distribution of study population based on ARA functional class and FDI score of the test questionnaire.

FDI score	Functional class I	II	III	IV	Non-arthritic
0 - 1	12 (75%)*	11 (45.8%)	6 (17.7%)	0	40 (100%)
1.1 - 2	4 (25%)	10 (41.7%)	15 (44.1%)	3 (50%)	0
2.1 - 3	0	3 (12.5%)	13 (38.2%)	3 (50%)	0

*Percentages refer to the column values.

consistent with the attributed functional class. In the last row of the table the average FDI scores are reported: the mean value increased with the ARA functional class. The average FDI score was lowest in non-arthritic patients, but was greater than 0; similarly the average Lee index and the average duration of morning stiffness among non-arthritic patients showed positive but very low values.

Table III shows the distribution of the study subjects based on ARA functional class (recruiting criteria) and the FDI scores for the test phase.

In Table IV the differences in the mean FDI score between test and retest, and the test-retest Spearman correlation coefficients for each component and for the entire instrument are reported for the 80 patients with RA. The test-retest correlation coefficients for the different centers are also given.

In Table V the differences in the mean value, and the correlation coefficients between the patient retest FDI score and the physician attributed FDI score, based on the items with double asterisk in Table I, are outlined. The Spearman correlation coefficients among the components of the FDI as assessed on the basis of the test questionnaire results are reported in Table VI.

Discussion

The aim of the first phase of the study was to obtain a translation of the Functional Disability Index of the Stanford Health Assessment Questionnaire appropriate to Italian social and cultural conditions, without modifying the structure of the instrument. It was necessary to change two questions: "open a new milk carton?" was modified because in Italy milk cartons are different from those in the U.S. and are equally difficult to open for non-arthritic people. Therefore, "break bread with your hands?" was substituted. Secondly "do chores such as vacuuming or yardwork?" was changed since the vacuum cleaner is not a widespread appliance in Italy and very few people do yardwork: the substitute was "do domestic tasks like dusting and polishing or household jobs?" In addition, some linguistic modifications were incorporated to render the Italian more idiomatic:

Table IV. FDI test-retest delta scores and correlation coefficients in 80 patients with rheumatoid arthritis.

Global FDI	Delta-score (test-retest)	Correl. coefficient (Spearman)	p value
Cat. 1	0.08 ± 0.37	0.91	0.03
Cat. 2	0.01 ± 0.40	0.87	0.04
Cat. 3	0.0 ± 0.37	0.92	0.02
Cat. 4	-0.02 ± 0.34	0.90	0.03
Cat. 5	-0.02 ± 0.34	0.92	0.02
Cat. 6	-0.05 ± 0.36	0.92	0.02
Cat. 7	-0.02 ± 0.52	0.82	0.06
Cat. 8	-0.01 ± 0.3	0.94	0.02

Spearman coefficients for the whole instrument in the test-retest

All centers together: 80 RA pts. = 0.97 (0.01); all 120 pts. = 0.989 (*)

Each center for 80 RA patients:

Center 1 = 0.93 (*) Center 4 = 0.96 (*) Center 7 = 0.96 (*)
Center 2 = 0.94 (*) Center 5 = 0.97 (*) Center 8 = 0.81 (**)
Center 3 = 0.99 (*) Center 6 = 0.98 (*)

*p value < 0.001; ** p = 0.005

Table V. FDI retest-physician delta scores and correlation coefficients in 80 patients with rheumatoid arthritis.

Selected FDI items	Physician delta score	Correl. coeff. (Spearman)	p value
C1	0.02 ± 0.34	0.91	0.03
C3	0.02 ± 0.34	0.88	0.05
C6 - C7	0.03 ± 0.35	0.89	0.04
C8	-0.06 ± 0.3	0.89	0.03
C10 - C12	-0.14 ± 0.42	0.90	0.03
C13 - C14	-0.01 ± 0.3	0.92	0.03
C16 - C17	-0.11 ± 0.45	0.88	0.03
C20	-0.16 ± 0.48	0.85	0.04

Spearman coefficients for all selected items of the instrument in the retest-physician.

All centers together: 80 RA pts. = 0.95 (0.02); all 120 pts. = 0.95 (*).

Each center for 80 RA patients:

Center 1 = 0.95 (*) Center 4 = 0.81 (0.004) Center 7 = 0.98 (*)
Center 2 = 0.93 (*) Center 5 = 0.997 (*) Center 8 = 0.99 (*)
Center 3 = 0.91 (*) Center 6 = 0.98 (*)

*p value < 0.001

Table VI. Correlation coefficients among the components of the FDI as assessed on the basis of the test questionnaire.

	Cat. 1	Cat. 2	Cat. 3	Cat. 4	Cat. 5	Cat. 6	Cat. 7	Cat. 8
Cat. 1	1	0.73	0.78	0.72	0.77	0.76	0.67	0.76
Cat. 2		1	0.62	0.62	0.57	0.61	0.57	0.68
Cat. 3			1	0.73	0.67	0.75	0.73	0.70
Cat. 4				1	0.71	0.71	0.65	0.73
Cat. 5					1	0.71	0.68	0.75
Cat. 6						1	0.70	0.75
Cat. 7							1	0.71
Cat. 8								1

a comparison of the back-translated text (Table I) with the original text (3) showed insignificant differences.

The study population was representative of the entire spectrum of disease-related functional impairment as assessed by ARA functional class. The demographic and clinical characteristics and mean FDI scores were consistent with the functional class of the patients (Table II). In the non-arthritic group, 25 out of the 40 subjects had both test and retest FDI scores equal to 0, while 15 (37.5%) had a positive FDI score both in the test and in the retest. The mean value was 0.275 ± 0.13 (range 0.125 - 0.5); 73.3% were female and the mean age was 46.8 ± 9.7 years (range 31 - 59). There was no significant difference between these 15 and the other non-arthritic patients ($p = 0.2$). The test-retest Spearman correlation coefficient was 0.921.

As shown in Tables I and III we found a close correspondence between the ARA functional class (physician-attributed functional status) and the FDI score (patient's self-attributed functional status). Taking the physician's judgment as the "gold standard", the data suggest that the Italian FDI is valid. Reproducibility for the 80 RA patients was high.

Table IV shows the differences in the mean FDI scores for the test and retest for each of the 8 categories: the Spearman coefficients ranged from 0.82 to 0.94. The means of the delta scores were close to 0, and were not statistically different as assessed by the Kruskal-Wallis test ($p = 0.3$). For the 80 RA patients the global instrument test-retest Spearman correlation coefficient was 0.97; for the 8 centers they ranged from 0.81 to 0.99 (Table IV).

Table V lists the Spearman correlation coefficients between the 80 RA patients' self-attributed retest FDI scores and the physician-attributed FDI scores; they ranged from 0.85 to 0.92. For the entire instrument the Spearman correlation coefficient was 0.95; the centers' values ranged from 0.81 to 0.99. These correlations are a little lower than the test-retest correlations, but confirm the face validity of the instrument.

Finally, the Spearman correlation coefficients among the various categories of the FDI are reported in Table VI: they ranged from 0.57 to 0.78. As the coefficients are similar, we can conclude that all of the items contribute about equally to the computation of the total score. The correlation coefficients are far enough from 0 and 1 to conclude that, due to the lack of redundancy among the components of the instrument, all of the items were pertinent to the measurement of our patients' functional ability. We conclude from this study that our Italian version of the HAQ FDI is a valid and reliable self-administered instrument to assess disability in patients with RA.

A prospective multicenter study has been in progress since 1990 to evaluate the efficacy and toxicity of disease-modifying drugs in RA. The study will also evaluate this Italian version of the self-administered FDI as a long term outcome measure (construct validity) and to determine if it can be used to assess the clinical efficacy of treatment over a 6 to- 12 month period (discriminant validity).

Acknowledgements

We would like to thank Karen Joyce for overseeing the translation of the questionnaire, and Catherine Williams and Daniel Bloch for reviewing the manuscript.

References

1. FRIES JF: Toward an understanding of patient outcome measurement. *Arthritis Rheum* 1983; 26: 697-703.
2. STEINBROCKER O, TRAEGER CH, BATTERMAN RC: Therapeutic criteria in rheumatoid arthritis. *JAMA* 1949; 140: 659-62.
3. FRIES JF, SPITZ PW, KRAINES RG, HOLMAN HR: Measurement of patient outcome in arthritis. *Arthritis Rheum* 1980; 23: 137-45.
4. FRIES JF, SPITZ PW, YOUNG DY: The dimension of health outcomes: the health assessment questionnaire, disability

and pain scales. *J Rheumatol* 1982; 9: 789-93.

5. WOLFE F, KLEINHEKSEL SM, CATHEY MA, HAWLEY DJ, SPITZ PW, FRIES JF: The clinical value of the Stanford Health Assessment Questionnaire Functional Disability Index in patients with rheumatoid arthritis. *J Rheumatol* 1988; 15: 1480-8.
6. PINCUS T, CALLAHAN LF, BROOKS RH, FUCHS HA, OLSEN NJ, KAYE JJ: Self-report questionnaire scores in rheumatoid arthritis compared with traditional physical, radiographic and laboratory measures. *Ann Intern Med* 1989; 110: 259-266.
7. EKDAHL C, EBERHARDT K, ANDERSSON SI, SVENSSON B: Assessing disability in patients with rheumatoid arthritis - Use of a Swedish version of the Stanford Health Assessment Questionnaire. *Scand J Rheumatol* 1988; 17: 263-71.
8. BOSI FERRAZ M, MAGALHAES OLIVEIRA L, ARAUJO PMP, ATRA E, TUGWELL P: Cross-cultural reliability of the physical ability dimension of the Health Assessment Questionnaire. *J Rheumatol* 1990; 17: 813-17.
9. SINGER F, KOLARZ G, MAYRHOTER F, SCHERAK O, THUMB N: The use of questionnaires in the evaluation of the functional capacity in rheumatoid arthritis. *Clin Rheumatol* 1982; 1: 251-61.
10. SIEGERT CE, VLEMING LJ, VANDENBROUCKE JP, CATS A: Measurement of disability in Dutch rheumatoid arthritis patients. *Clin Rheumatol* 1984; 3: 305-9.
11. KIRWAN JR, REEBACK JS: Stanford Health Assessment Questionnaire modified to assess disability in British patients with rheumatoid arthritis. *Br J Rheumatol* 1986; 25: 206-9.
12. PEREZ ER, MACKENZIE CR, RYAN C: Development of a Spanish version of the modified Health Assessment Questionnaire. *Arthritis Rheum* 1989; 32: S 100 (abstract).
13. GUILLEMIN F, BRIANCON S, POUREL J: Mésure de la capacité functionelle dans le polyarthrite rhumatoide: Adaption Francaise du Health Assessment Questionnaire (HAQ). *Rev Rhum Mal Osteartic* 1991; 58: 459-65.
14. RITCHIE DM, BOYLE JA, MCINNES JM, JASANI MK, DALAKOS TG, GRIEVESON P, BUCHANAN WW: Clinical studies with an articular index for the assessment of joint tenderness in patients with rheumatoid arthritis. *Q J Med* 1968; 37: 393-406.
15. LEE P, MUKUNDRAI KJ, ARSON DW, BUCHANAN WW: Evaluation of a functional index in rheumatoid arthritis. *Scand J Rheumatol* 1973; 2: 71-77.
16. ARNETT FC, EDWORTHY SM, BLOCH DA *et al.*: The American Rheumatism Association 1987 revised criteria for the classification of rheumatoid arthritis. *Arthritis Rheum* 1988; 31: 315-24.