Translation, cross-cultural adaptation, and validation of the Bath Ankylosing Spondylitis Functional Index (BASFI), the Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) and the Dougados Functional Index (DFI) in a Spanish speaking population with spondyloarthropathies

M.H. Cardiel[1], J.D. Londoño[1], E. Gutiérrez[1], C. Pacheco-Tena[2], J. Vázquez-Mellado[2], R. Burgos-Vargas[3]

[1]Department of Immunology and Rheumatology. Instituto Nacional de Ciencias Médicas y Nutrición Salvador Zubirán; [2]Department of Rheumatology, Hospital General de México; [3]Research Division. Hospital General de México.

Abstract

Objectives

The Bath Ankylosing Spondylitis Disease Activity Index (BASDAI), the Bath Ankylosing Spondylitis Functional Index (BASFI) and the Dougados Functional Index (DFI) are the most commonly used instruments to measure disease activity and functioning in ankylosing spondylitis (AS). The aim of this study was to translate, adapt and validate these instruments into the Spanish language.

Methods

The BASDAI, BASFI, and DFI questionnaires were translated into Spanish by three independent bilingual physicians who were familiar with the medical aspects of AS and by one professional translator. Two rheumatologists familiar with instrument validation, and who were aware of the purpose of the study, examined semantic, idiomatic and conceptual issues and produced by consensus unified versions of each instrument. English back-translations from the Spanish were done by a professional translator unaware of the original version. Both English versions were compared, and where needed, modifications to the Spanish versions were made. The Spanish versions were administered to 61 ambulatory patients with AS and to 80 patients with undifferentiated spondyloarthropathy for validation purposes. Reliability and responsiveness were measured in 28 patients participating in a physiotherapy program.

Results

Reliability showed an acceptable 24-hour test-retest intraclass correlation coefficient (ICC) – BASFI ICC: 0.68, 95% CI: 0.29-0.85; BASDAI ICC: 0.74, 95% CI: 0.52-0.88 and DFI ICC: 0.87, 95% CI: 0.73-0.94. The construct validity of the instruments was evaluated, and BASDAI was correlated with disease activity measured by the total enthesis count (r_s: 0.34); general well being in the last week (r_s: 0.7); spinal pain (r_s: 0.53) and duration of morning stiffness (r_s: 0.64). BASFI correlated with Schöber's test (r_s: -0.4); occipital-wall distance (r_s: 0.38) and thoracic expansion (r_s: -0.3). DFI correlated with Schöber's test (r_s: - 0.36); occipital-wall distance (r_s: 0.29) and chest expansion (r_s: -0.3). The correlation among DFI and BASFI was r_s: 0.83. All instruments showed clinical responsiveness in the physiotherapy program (baseline and end of program; mean ± SD): BASDAI: 6.25 ± 1.97 and 3.07 ± 2.04 (p=0.0001); BASFI: 5.68 ± 2.29 and 2.88 ± 1.77 (p=0.0001); DFI:16 ± 7.6 and 8.0 ± 5.5 (p=0.001) with effect sizes and standardized effect sizes > 1.

Conclusions

The Mexican Spanish versions of the BASDAI, BASFI, and DFI showed adequate reliability, validity and responsiveness to clinical change. These instruments can be used in the clinical evaluation of Spanish-speaking patients with AS.

Key words

Ankylosing spondylitis, validation studies, functional status.

Mario H. Cardiel, MD, MSc; John D. Londoño, MD; Elizabeth Gutiérrez, PT; César Pacheco Tena, MD, PhD; Janitzia Vázquez-Mellado, MD, PhD; Rubén Burgos-Vargas, MD.

Please address correspondence to: Mario H. Cardiel, MD, Department of Immunology and Rheumatology, Instituto Nacional de Ciencias Médicas y Nutrición Salvador Zubirán, Vasco de Quiroga 15, Sección XVI, Tlalpan CP 14000, México DF, México.
E-mail: mcardiea@sni.conacyt.mx

Introduction

Ankylosing spondylitis (AS) is an HLA-B27 associated chronic inflammatory disease of the peripheral and axial joints and entheses which may lead to various degrees of disability (1). The assessment of AS in different settings for disease control, symptom modification and clinical record keeping is currently done through endpoints emphasizing disease activity and function (2). Currently there are three instruments that are reliable, valid, and sensitive to change that have been recommended by the AS assessment (ASAS) working group to measure such domains. One of these, the Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) (3) measures disease activity while the two others, the Bath Ankylosing Spondylitis Functional Index (BASFI) (4) and the Dougados Functional Index (DFI) (5) measure functioning.

Because of the worldwide distribution of AS, which depends on the prevalence of HLA-B27, and the need for homogenous measures of disease activity and function, instruments have to be cross culturally adapted to different populations. Therefore, we translated, adapted, and validated the original English versions of these three instruments according to accepted guidelines (6) to be used in Spanish-speaking patients with AS.

Material and methods

Instruments

The BASDAI (3) is a six-item self-administered questionnaire that measures symptoms such as fatigue, spinal pain, pain and/or swelling of the peripheral joints, localized tenderness, and morning stiffness during the last week. Questions are presented in the form: "How would you describe the overall level of…". It also measures the severity and duration of stiffness (0 hours to 2 or more hours). The first five items are answered on 0-100 mm visual analogue scales (VAS) with "none" anchored at one extreme and "very severe" at the other. The test-retest reliability provided in the original publication (3) was 0.93 and the mean change – as a measure of responsiveness – reached 16% after a three-week physiotherapy program. Effect size calculated from the original publication was 0.5.

The BASFI is a self-administered questionnaire (4) that measures the ability of the individual to perform 10 items of daily living activities. Each item is answered on 0-100 mm VAS ranging from "easy" at one end to "impossible" at the other. The BASFI test-retest score was 0.89 in the original validation study. The effect size calculated from the original publication was 0.49.

The DFI is also a self-administered questionnaire (5) that measures the capability of the individual to carry out 20 activities of daily living on a 3-grade Likert scale (0 = yes with no difficulty; 1 = yes, but with difficulty; and 2 = no). The score ranges from 0 to 40. The DFI intra-class correlation coefficient is high (ICC: 0.86). Sensitivity to change was originally measured in a nonsteroidal anti-inflammatory drug, placebo controlled double-blind study. Effect size obtained from original data was 0.5 .

Translation procedure

Translation. Original English versions of the questionnaires were provided to three bilingual physicians and one professional translator who were already aware of the purpose of the study and who were also familiar with the treatment and physical limitations of AS. All four were asked to independently produce Spanish versions of these instruments by translating and adapting all questions according to the characteristics of our patients. These four versions were reviewed, and reconciled versions of each instrument were obtained by consensus. These versions were refined by two independent rheumatologists, familiar with the process of instrument validation, who examined semantic, idiomatic and conceptual issues.

Adaptation. Some changes were necessary for cultural adaptation. Based on the results of previous studies using visual analogue scales (VAS) and numerical scales in our clinical settings

(7, 8), the VAS in the BASFI and the BASDAI were transformed to numerical rating scales from 0 to 10 to improve the patient's understanding. Items 1 and 3 in the BASFI required a better description of the type of aids needed as these devices are not commonly used in Mexico. Item 7 also required extra wording to improve understanding. In the BASDAI the term "line" was replaced by "scale" in the instructions section to be consistent with the response options presented. Item 3 required an "or" in pain or swelling instead of pain/swelling to improve understanding. Item 6 was simplified by asking "How long does this stiffness last?" (¿Cuánto le dura esa rigidez?). The response options were presented as a continuous line, going from cero to 2 or more hours, with numbers under the line indicating every half hour instead of every 15 minutes as the original. The DFI questionnaire did not present particular difficulties in terms of adaptation.

Back-translation. The reconciled versions were given to a professional translator who was asked to produce literal translations to English. Both English versions (the original and the back-translated versions) were compared and final Spanish versions were produced (see Appendixes 1-3).

Validation process

The sample. Participants were seen at rheumatology clinics at the Hospital General de México and the Instituto Nacional de Ciencias Médicas y Nutrición Salvador Zubirán, two terciary care centers in Mexico City. All participants were asked to fill out the Spanish-language questionnaires in a self-administered format under the supervision of an interviewer who was able to provide some help, if needed. Reliability was measured by 24-hour test retesting using the intra-class correlation coefficient in 28 patients with AS who participated in a physiotherapy program. Values higher than 0.75 were considered important. Agreement was graphically presented by plotting the difference against the mean according to Bland and Altman (9).

Validation. A total of 144 patients were evaluated, 64 with AS and 80 with undifferentiated spondyloarthropathy. They filled out the questionnaires and underwent a comprehensive clinical evaluation. Constructs used for disease activity to validate the BASDAI were the total enthesis count, general well being in the last week, spinal pain and duration of morning stiffness. The functional instruments (BASFI and DFI) were validated against the Schöber's test, occipital-wall distance and chest expansion. We also used concurrent validation between these two indices. Correlation using Spearman's rank correlation coefficient (r_s) in the expected direction was expected, values of $r_s > 0.4$ were considered clinically relevant. Responsiveness was measured in the subgroup of patients with AS who participated in an intensive physiotherapy program. Effect size was defined as the mean change after treatment compared with baseline, divided by the standard deviation of the baseline scores (10); in this regard, any change ≥ 0.8 was considered a large change (11). The standardized response mean was also calculated by dividing the mean change by the variance of delta (12).

Results

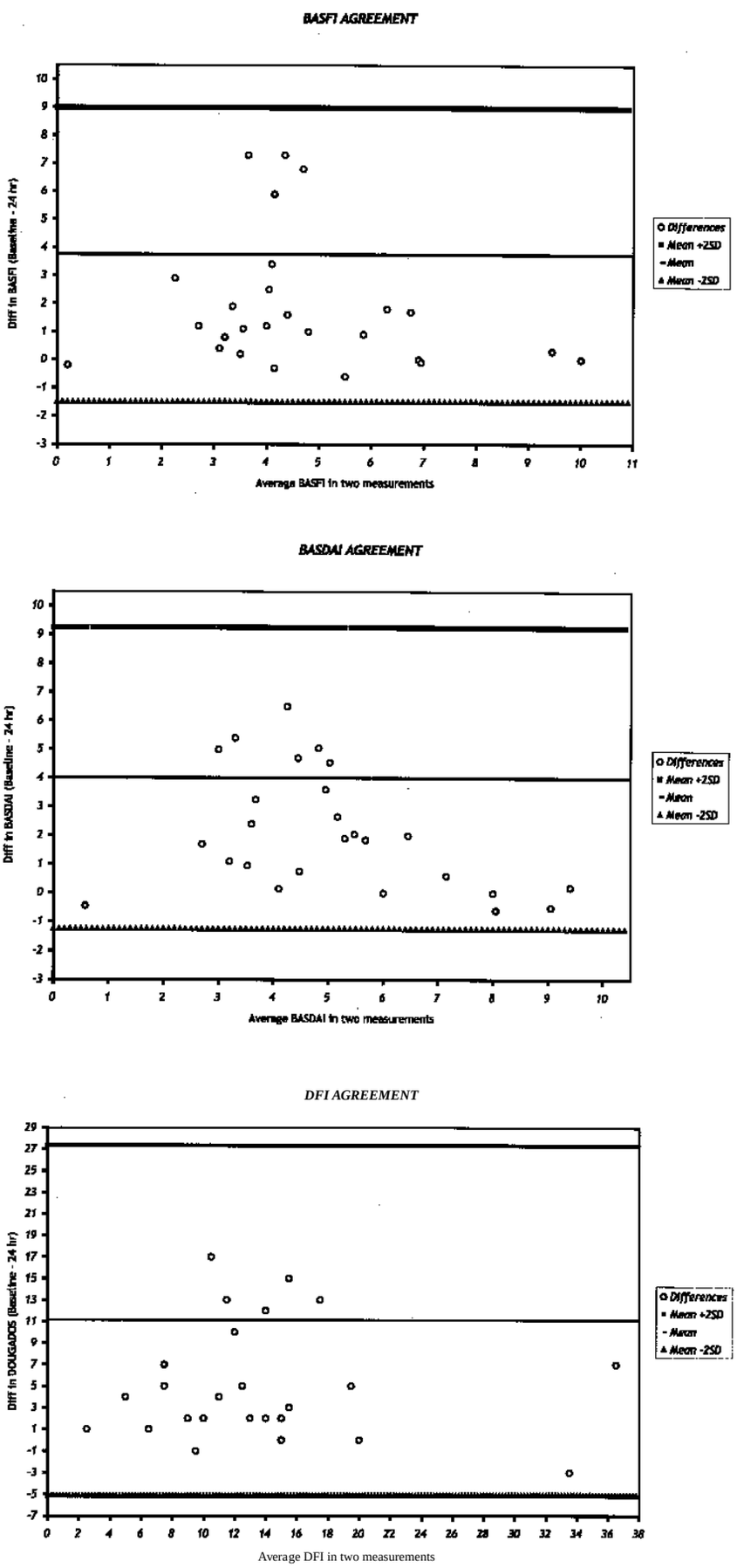
General patient characteristics

Sixty-one patients with AS from two referral centers participated in the validation study. Forty-eight (78%) were males. The age and disease duration (mean ± SD) in the group were 28.6 ± 9 years and 9.6 ± 5.8 years, respectively. Eighty patients with undifferentiated spondyloarhropathy were also included in the validation process, of whom 67.5% were male; age and disease duration were 29 ± 9 and 7 ± 6 years, respectively. Overall, none of the patients had difficulties in answering any of the questionnaires; patients clearly understood and felt comfortable with evaluating them.

Reliability and responsiveness were evaluated in 28 patients with AS participating in a physiotherapy program. Patients were re-tested 24 h after the first administration of the questionnaires. Reliability showed an acceptable 24-hour test-retest using the intra-class correlation coefficient. BASFI ICC: 0.68, 95% CI: 0.29-0.85; BASDAI ICC: 0.74, 95% CI: 0.52-0.88 and DFI ICC:0.87, 95% CI:0.73-0.94. Figure 1 presents the Bland and Altman plots for agreement. None of the observations were located outside the 95% confidence intervals, although important variability was depicted.

Validity. Construct validity: BASDAI was correlated with disease activity measured by the total enthesis count (r_s: 0.34); general well-being in the last week (r_s: 0.7); spinal pain (r_s: 0.53) and the duration of morning stiffness (r_s: 0.64). BASFI correlated with the Schöber's test (r_s: -0.4); occipital-wall distance (r_s: 0.38) and thoracic expansion (r_s: -0.3). DFI correlated with the Schöber's test (r_s: - 0.36); occipital-wall distance (r_s: 0.29) and chest expansion (r_s: -0.3). The correlation between DFI and BASFI was r_s: 0.83.

Responsiveness. Twenty-eight patients participating in a program of intensive physiotherapy were compared with 20 subjects who declined to participate in such a program for different reasons, mainly inability to comply with the schedule due to job or school activities. The program consisted in a flexible, individualized program conducted by a single trained physiotherapist. The program was originally presented with a frequency of three sessions per week over a period of 4 months. Emphasis was placed on pain, muscle strength, elasticity and improving respiratory muscle function. A mean of 28 sessions over 6.5 weeks was obtained. The results measured by all three instruments – BASDAI, BASFI, and DFI – showed a mean change of 50% in comparison to baseline. None of the other outcome measures, including joint swelling or tenderness and entheses counts and mobility measures reached this level of improvement. Effect sizes were 1.6 for BASDAI, 1.2 for BASFI, and 1.05 for DFI. The standardized response means were 1.5 for BASDAI, 1.2 for BASFI and 1.5 for the DFI. These changes were not seen in any other variable in the control group (Table I). Effect sizes in the control group were 0.07 for the BASDAI; 0.05 for the BASFI and -0.16 for the DFI.



Discussion

The cross-culturally adapted versions of the BASDAI, BASFI, and DFI produced in this study maintained all the properties of the original English-language versions of the instruments. All of the procedures used to generate the instruments followed the guidelines of Guillemin *et al.* (6) for the cross-cultural adaptation of health-related quality of life instruments. Thus, disease activity and functioning in Spanish-speaking patients with AS may be adequately evaluated with these versions of the original instruments.

The reliability of these three versions in the 24 h test-retest showed acceptable intraclass correlation coefficients (0.68 – 0.87). The value for the DFI was similar to that reported in the original publication. A 24-hour time frame was selected to minimize any change in the patient's clinical condition that would affect reliability. Although recall bias could be a potential problem, the adminstration of three different instruments made it unlikely that they would remember specific items on all of them. The reported reliability of the BASDAI, BASFI, and DFI were 0.93. 0.89, and 0.86, respectively in the original papers using correlation coefficients (3-5).

In addition, all three instruments were sensitive to changes induced by physiotherapy. These changes were higher than those seen in the original descriptions of the BASDAI and BASFI, a fact which could be explained by the longer duration of the physiotherapy program in our setting. We should also consider that the patients in our study had higher baseline values on the three instruments that could imply a higher probability of significant changes after effective therapy. The mean changes and effect size of the BASDAI, BASFI, and DFI were much better in our study than those seen in other measures of disease activity and functioning assessed in the study (i.e., enthesitis and swollen joint counts, pain scales or the patient's

Fig. 1. Bland-Altman plots for the (**A**) BASFI; (**B**) BASDAI; and (**C**) Dougados Functional Index.

Table I. Responsiveness.

	Physiotherapy			Control		
Variable	Baseline (x ± SD)	Final (x ± SD)	p value	Baseline (x ± SD)	Final (x ± SD)	p value
Patient's global assessment	5.9 ± 2.5	3.3 / 2.1	0.000	4.8 / 3.2	5.9 / 3.3	ns
Physiotherapist's global assessment	5.8 / 2.0	3.1 / 1.8	0.000	4.7 / 2.7	4.8 / 2.6	ns
Pain score	4.9 / 2.8	3.1 / 2.2	0.000	3.0 / 3.2	4.0 / 3.5	ns
BASDAI	6.2 / 1.9	3.0 / 2.0	0.000	2.9 / 2.6	2.7 / 2.6	ns
BASFI	5.7 / 2.3	2.9 / 1.8	0.000	3.8 / 3.6	3.6 / 3.7	ns
DFI	16.0 / 7.6	8.0 / 5.6	0.000	8.0 / 7.1	9.2 / 7.5	ns

BASDAI: Bath Ankylosing Spondylitis Disease Activity Index; BASFI: Bath Ankylosing Spondylitis Functional Index; DFI: Dougados functional index.

global assessment).

Not surprisingly, the ASAS working group has recommended the use of BASDAI and BASFI or DFI to obtain outcome measures in AS patients participating in clinical trials (2). In this context, our study contributes to AS assessment by providing reliable and valid cross-culturally adapted Spanish speaking versions that are sensitive to change for the three most important instruments of disease activity and functioning in use thus far. Worth mentioning is the fact that our study incorporated numerical rather than visual analogue scales for the BASDAI and BASFI to facilitate the answering process. Mexican (7) and Brazilian (13) rheumatoid arthritis studies have previously shown that patients feel more comfortable with numerical rather than visual analogue scales. Regarding the BASDAI and BASFI, van Tubergen *et al.* (8) have recently demonstrated that Dutch, Swiss, and Mexican patients preferred numerical scales to the VAS (38% versus 9% preference), and on the other hand that more patients were unable to answer the VAS (14 versus 2 out of 536 patients). More importantly, van Tubergen's study (8) found no significant differences in reproducibility and responsiveness between the two formats (on the 5-point Likert scales, as well), suggesting that BASDAI and BASFI numerical scales could replace the original VAS.

The Spanish language versions of the BASDAI, BASFI, and DFI produced in this study may be administered to the Mexican population and to populations akin to Mexicans. Regarding other Spanish-speaking populations, the use of these versions may require slight cross-cultural adaptations. Administration of these instruments to illiterate patients will require interviewer assistance and its methodologic properties should be re-evaluated.

References

1. KHAN MA: Update on spondyloarthropathies. *Ann Intern Med* 2002; 136:896-907.
2. VAN DER HEIDJE D, CALIN A, DOUGADOS M, KHAN MA, VAN DER LINDEN S, BELLAMY N: Selection of instruments in the core set for DC-ART, SMARD, physical therapy, and clinical record keeping in ankylosing spondylitis. Progress report of the ASAS working group. *J Rheumatol* 1999; 26: 951-4.
3. GARRETT S, JENKINSON T, KENNEDY LG, WHITELOCK H, GAISFORD P, CALIN A: A new approach to defining disease status in ankylosing spondylitis: The Bath Ankylosing Spondylitis Disease Activity Index. *J Rheumatol* 1994; 21: 2286-91.
4. CALIN A, GARRETT S, WHITELOCK H *et al.*: A new approach to defining functional ability in ankylosing spondylitis: The development of the Bath Ankylosing Spondylitis Functional Index. *J Rheumatol* 1994; 21: 2281-5.
5. DOUGADOS M, GUEGUEN A, NAKACHE JP, NGUYEN M, MERY C, AMOR B: Evaluation of a functional index and an articular index in ankylosing spondylitis. *J Rheumatol* 1988; 15: 302-7.
6. GUILLEMIN F, BOMBARDIER C, BEATON D: Cross-cultural adaptation of health-related quality of life measures:literature review and proposed guidelines. *J Clin Epidemiol* 1993; 46: 1417-32.
7. HERNÁNDEZ-CRUZ B, CARDIEL MH: Intra-observer reliability of commonly used outcome measures in rheumatoid arthritis. *Clin Exp Rheumatol* 1998; 16: 459-62.
8. VAN TUBERGEN A, DEBATS I, RYSER L *et al.*: The use of numerical rating scale as an answer modality in ankylosing spondylitis specific questionnaires. *Arthritis Rheum (Arthritis Care Res)* 2002; 47: 242-8.
9. BLAND JM, ALTMAN DG: Statistical methods for assessing agreement between two methods of clinical measurement. *Lancet* 1986; 1: 307-10.
10. GUYATT G, WALTER S, NORMAN G: Measuring change over time: assessing the usefulness of evaluative instruments. *J Chronic Dis* 1987; 40: 171-8.
11. COHEN J: *Statistical Power Analysis for the Behavioral Sciences*. 2nd ed. Hillsdale, Lawrence Erlbaum Associates; 1988.
12. LIANG MH, FOSSEL AH, LARSON MG: Comparisons of five health status instruments for orthopedic evaluation. *Med Care* 1990; 28: 632-42.
13. FERRAZ MB, QUARESMA MR, AQUINO LR, ATRA E, TUGWELL P, GOLDSMITH CH: Reliability of pain scales in the assessment of literate and illiterate patients with rheumatoid arthritis. *J Rheumatol* 1990; 17: 1022-24.

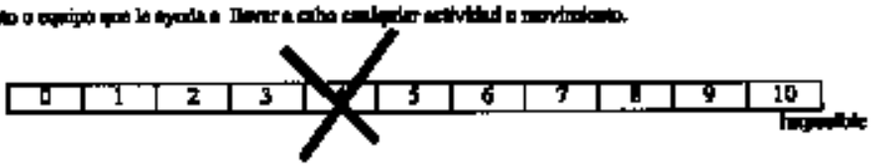
Appendix 1.

Índice funcional de Bath para la espondilitis anquilosante (BASFI).

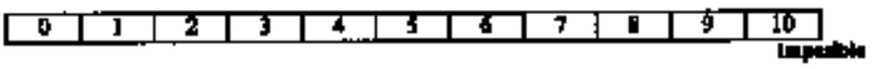
Por favor ponga una cruz en el número que mejor represente el nivel de habilidad que tuvo usted en cada una de las siguientes actividades, durante la semana pasada.

Nota: su apoyo es un aparato o equipo que le ayuda a llevar a cabo cualquier actividad o movimiento.

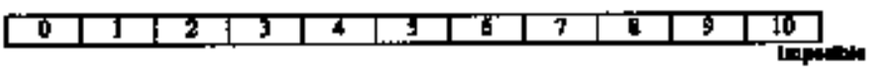
ejemplo:



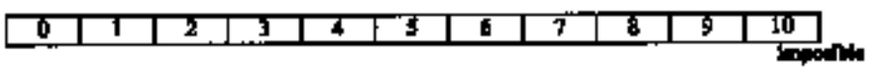
1. Ponerse las medias o los calcetines, sin ayuda ni aparatos (por ejemplo un gancho para ponerse los calcetines)



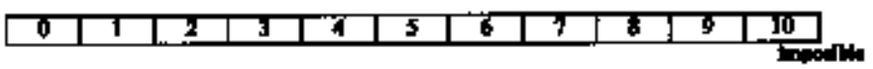
2. Inclinarse hacia adelante, doblando la cintura, para recoger una pluma del piso, sin ayuda de un aparato



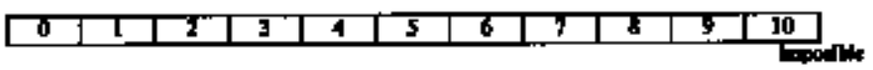
3. Alcanzar algo que se encuentra en una repisa (estante) alta sin ayuda o aparatos (por ejemplo un jalador)



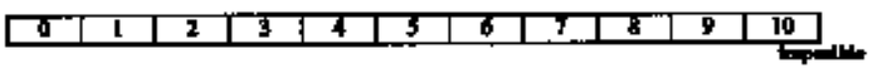
4. Levantarse de una silla que no tenga apoya brazos, sin usar sus manos ni alguna otra ayuda



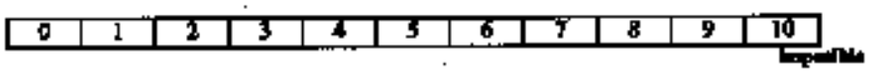
5. Levantarse del piso sin ayuda, estando acostado en el suelo boca arriba



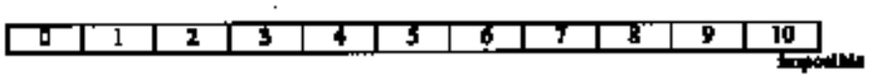
6. Estar parado sin apoyo por 10 minutos, sin molestias



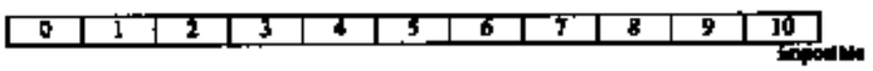
7. Subir de 12 a 15 escalones sin usar el pasamanos ni una muleta. Subiendo los escalones de uno en uno.



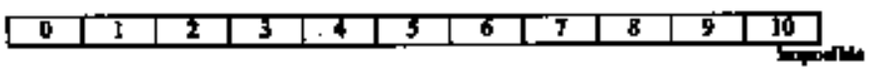
8. Mirar por encima del hombro, sin girar su cuerpo



9. Hacer actividades que necesiten un gran esfuerzo físico (por ejemplo ejercicios de fisioterapia, jardinería, deportes)



10. Hacer las actividades que duran todo el día, ya sea en casa o en el trabajo.



Appendix 2.

Indice de Bath de la actividad de la espondilitis anquilosante (BASDAI).

Por favor marque con una cruz en cada una de las escalas de abajo, para indicar las respuestas relacionadas a cómo se sintió usted la semana pasada.

1. ¿Cómo describiría el grado de cansancio o fatiga que ha tenido?

0	1	2	3	4	5	6	7	8	9	10

nada — muy intenso

2. ¿Qué tanto dolor ha tenido por su enfermedad en el cuello, la espalda o la cadera?

0	1	2	3	4	5	6	7	8	9	10

nada — muy intenso

3. ¿Qué tanto dolor o inflamación ha tenido en otras articulaciones diferentes al cuello, la espalda o la cadera?.

0	1	2	3	4	5	6	7	8	9	10

nada — muy intenso

4. ¿Qué tanto malestar ha tenido en sitios que duelen al tocar o al presionar?

0	1	2	3	4	5	6	7	8	9	10

nada — muy intenso

5. ¿Qué tanta rigidez ha presentado en la mañana desde el momento que se despierta?

0	1	2	3	4	5	6	7	8	9	10

nada — muy intensa

6. ¿Cuánto le dura esa rigidez ?

0 horas — 1/2 — 1 hora — 1 1/2 — 2 o más horas

Appendix 3.

Indice funcional de Deyoudas para espondilitis anquilosante (DFI).

		sí, sin dificultad	sí, con dificultad	no puedo
¿puede usted:				
1	ponerse los zapatos?			
2.	ponerse los pantalones?			
3.	ponerse un sweater?			
4.	meterse a la regadera?			
5.	estar parado durante 10 minutos?			
6.	subir un piso por las escaleras?			
7.	correr?			
8.	sentarse?			
9.	pararse de una silla?			
10.	entrar a un carro?			
11.	inclinarse para recoger un objeto?			
12.	ponerse en cuclillas?			
13.	acostarse?			
14.	voltearse en la cama?			
15.	levantarse de la cama?			
16.	dormir boca arriba?			
17.	dormir boca abajo?			
18.	hacer sus quehaceres domésticos o en su trabajo?			
19.	tener o estornudar?			
20.	respirar profundamente?			
total:				