

CLINICAL SCIENCE

BRAZILIAN VERSION OF THE FOOT HEALTH STATUS QUESTIONNAIRE (FHSQ-BR): CROSS-CULTURAL ADAPTATION AND EVALUATION OF MEASUREMENT PROPERTIES

Ana F. B. Ferreira,^I Ieda M. M. Laurindo,^I Priscilla T. Rodrigues,^I Marcos Bosi Ferraz,^{II} Sérgio C. Kowalski,^{III} Clarice Tanaka^{IV}

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OBJECTIVE: To conduct a cross-cultural adaptation of the Foot Health Status Questionnaire into Brazilian-Portuguese and to assess its measurement properties.

INTRODUCTION: This instrument is an outcome measure with 10 domains with scores ranging from 0-100, worst to best, respectively. The translated instrument will improve the examinations and foot care of rheumatoid arthritis patients.

METHODS: The questions were translated, back-translated, evaluated by a multidisciplinary committee and pre-tested (n = 40 rheumatoid arthritis subjects). The new version was submitted to a field test (n = 65) to evaluate measurement properties such as test-retest reliability, internal consistency and construct validity. The Health Assessment Questionnaire, Numeric Rating Scale for foot pain and Sharp/van der Heijde scores for foot X-rays were used to test the construct validity.

RESULTS: The cross-cultural adaptation was completed with minor wording adaptations from the original instrument. The evaluation of measurement properties showed high reliability with low variation coefficients between interviews. The α -Cronbach coefficients varied from 0.468 to 0.855, while correlation to the Health Assessment Questionnaire and Numeric Rating Scale was statistically significant for five out of eight domains.

DISCUSSION: Intra- and inter-observer correlations showed high reliability. Internal consistency coefficients were high for all domains, revealing higher values for less subjective domains. As for construct validity, each domain revealed correlations with a specific group of parameters according to what the domains intended to measure.

CONCLUSION: The FHSQ was cross-culturally adapted, generating a reliable, consistent, and valid instrument that is useful for evaluating foot health in patients with rheumatoid arthritis.

KEYWORDS: Foot; Health Status; Rheumatoid Arthritis; Translation.

INTRODUCTION

Foot problems, particularly foot pain and foot deformity,

are the cause of numerous visits to physicians.¹ A patient with a painful foot or foot deformity is more susceptible to falls due to impaired balance and may have marked functional deterioration, reducing his or her health-related quality of life and independence; thus, foot problems are a public health issue.²⁻⁵

The prevalence of foot problems in patients with rheumatoid arthritis (RA) is more than 50%, with one study reporting the proportion to be as high as 93 out of 99 patients.⁶ Clinical studies suggest that foot pain may be problematic in about one-third of patients in early disease with more frequent involvement of the metatarsophalangeal joints (34%) than the midtarsal (4%) and ankle (20%) regions.⁷

^IRheumatology Service, Hospital das Clínicas, Faculdade de Medicina da Universidade de São Paulo/SP, Brazil.

^{II}Department of Medicine and the São Paulo Center for Health Economics, Federal University of São Paulo – São Paulo/SP, Brazil.

^{III}Rheumatology Department, Federal University of Rio Grande do Norte – Rio Grande do Norte, Brazil.

^{IV}Department of Physiotherapy, Communication Science & Disorders, Occupational Therapy, Faculdade de Medicina da Universidade de São Paulo/SP, Brazil.

Phone: 11 8196.6494

Email: anafferreira@usp.br

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A severe negative impact on mobility and functional capacity is observed when the patient's feet begin to be affected,⁸ and studies have shown that feet are affected earlier than hands in the course of the disease.⁹⁻¹¹ Furthermore, Priolo et al. (1997) stated that foot involvement is indicative of a more aggressive disease.¹¹

The development of clinics specialized in treating feet of patients with RA has provided health professionals with an opportunity to gain a greater understanding of the impact of RA on feet and ankles. Treatment of foot-related conditions often requires more than systemic drug therapy, such as podiatry, physiotherapy and orthopedic services.^{8,10} The RA burden and the efficacy of multidisciplinary foot-health care in RA are measurable using several generic^{3,12,13} instruments and a single RA-specific⁴ foot-health instrument, which are used for both routine clinical purposes and research.

The Foot Health Status Questionnaire (FHSQ) was developed and validated in Australia as a patient outcome measure of foot health, and has now been used in nearly ten countries.¹⁴ It was primarily intended to assess the outcome of surgical treatment, but it was validated across pathologies such as skin, nail, neurological, orthopedic and musculoskeletal disorders, among other conditions.¹⁵⁻¹⁹ The FHSQ has also been used to evaluate the effectiveness of foot orthoses.²⁰ This instrument is divided into three sections. Section I evaluates foot health in four domains: Foot Pain, Foot Function, Footwear, and General Foot Health. Section II evaluates general health in four domains: General Health, Physical Activity, Social Capacity and Vigor. Sections I and II are composed of questions with response options presented in phrases and corresponding numbers. Section III collects general demographic data of the patients. This structure makes the FHSQ a complete instrument, which has been shown to have good responsiveness and reliability.^{14,15} The scores for the FHSQ may be easily obtained using software (The Foot Health Status Questionnaire, Version 1.03). The answers to the questions are entered, and the software provides a score for each domain ranging from 0 to 100 (worst and best conditions, respectively).^{14,15}

The cross-cultural adaptation of this instrument will be of great use because until now, Brazil has lacked instruments for researchers focusing on foot health status. As Beaton et al. (2000) point out, translated versions of questionnaires may be useful and may provide researchers with an instrument that allows international comparisons of scores.²¹

The purpose of this study was to conduct a cross-cultural adaptation of the FHSQ into Brazilian-Portuguese and evaluate measurement properties of the Brazilian version of the FHSQ (FHSQ-Br).

MATERIALS AND METHODS

The author of the original instrument was contacted, and he provided the FHSQ software and his consent to the translation and evaluation of the instrument's measurement properties.

The cross-cultural adaptation was divided into four phases, according to Guillemin et al. (1993): (i) translation of the FHSQ into Brazilian-Portuguese, (ii) back-translation to evaluate the initial translation, (iii) committee analysis to identify cultural differences and language errors in the new instrument and (iv) a pre-test to assess cultural equivalence, considering the patients' impressions about the instrument. A written report including every suggestion and decision was made for each phase.²¹ To assess the measurement properties of the FHSQ-Br, we conducted three phases: (i) test-retest reliability (inter and intra-observers), (ii) internal consistency and (iii) construct validity. Construct validity was evaluated by comparing patient answers to the FHSQ-Br to clinical parameters commonly used in RA follow-up. The study was approved by the Ethics Committee of the São Paulo University Medical School, and all patients signed an informed consent document.

Cross-cultural adaptation

i) Translation. The FHSQ was translated into Brazilian-Portuguese by two bilingual Brazilian translators with different profiles, creating versions T1 and T2. Only one of the translators was aware of the concepts explored in the questionnaire. The different profiles of the translators ensured the use of unexpected words in the translation.²¹⁻²⁵ Versions T1 and T2 were discussed with both translators and with a team coordinator to synthesize the translations and to create Version 1.

ii) Back-translation. Version 1 was back-translated into English by two bilingual native English-speaking teachers, neither of whom was aware of the concepts explored and neither had any medical background.²¹⁻²⁵ The two back-translations (BT1 and BT2) were discussed with both back-translators and with the team coordinator to check if the translated version truly reflected the original instrument and to explore unexpected meanings of the translated items.²¹⁻²⁵ Based on these adaptations, Version 2 was created and was ready to be subjected to committee analysis.

iii) Committee Analysis. The committee consisted of two rheumatologists, two physiotherapists, two translators, two back-translators and the team coordinator. The purpose of this phase was to achieve semantic, idiomatic, experiential and conceptual equivalence of the translated version. Semantic equivalence refers to the actual meaning

of the words; idiomatic equivalence refers to attention to colloquialisms; experiential or cultural equivalence questions if the activities explored are common in that culture; and conceptual equivalence questions the cultural importance given to the situation being explored.^{21-23,26} Version 3 was created only after every item of the FHSQ had been thoroughly discussed and agreed upon by the committee.

iv) Pre-test. The pre-test group was composed of 40 RA patients from the Rheumatology Outpatient Division/ University of São Paulo. They were asked to answer the items on Version 3, commenting on the instructions, questions, answers and what they found confusing about the questionnaire. An answer option stating “not applicable” was added to every question, to be marked if the respondent did not understand the question. Any item of the instrument marked “non-applicable” by more than 10% of the patients was re-written and re-tested until all items were accepted by more than 90% of the patients. Version 4 was then created and named FHSQ-Br.

Evaluation of the measurement properties

i) Test-retest Reliability. The study group was composed of sixty-five RA patients. None of them had participated in the pre-test phase. The patients were diagnosed according to the American College of Rheumatology revised criteria (1987).²⁷ Patients who had undergone foot surgery or therapeutic alterations or who were designated as functional class IV were excluded.²⁸

Each patient was asked to answer the FHSQ-Br three times in face-to-face interviews, always in the afternoon. Although the original version is a self-administered instrument, due to the educational level of the patients in this study, the authors chose to administer the instrument using an interview format. Interviewers were instructed to simply read the questions to the patients and tick their answers, providing no explanations to the questions to avoid interference. Patients who did not have a clear understanding of the questions were excluded at that moment.

The first interview was conducted by interviewer A, the second interview was conducted 45 minutes after the first by interviewer B and the third and final interview was conducted 15 days later, again by interviewer A. During these 15 days, the patients did not have any modifications to their treatment and were asked to maintain their regular activities. Such instructions were intended to ensure the stability of the clinical status to test the instrument reliability.²⁴

ii) Internal Consistency. The scores obtained from the interviews were used to determine correlations between different questions on the same domain.

iii) Construct Validity. The Health Assessment

Questionnaire (HAQ), Numeric Rating Scale (NRS) and foot X-rays were correlated to the FHSQ-Br scores, which ranged from 0 to 100 (worst and best conditions, respectively), to assess the construct validity.²⁴ The HAQ is a disease-specific instrument used worldwide for the evaluation of RA.²⁵ The scores of the HAQ range from 0 to 3, from the best to worst condition, respectively.²⁵ The NRS for foot pain was used to score patient “foot pain in the last few days.” These scores range from 0 to 10, in which 0 is equivalent to no pain at all and 10 is the worst pain imaginable. Foot X-rays were scored using the Sharp/van der Heijde method, which assesses joint surface erosion (0 to 120) and joint space narrowing (0 to 48) of 6 joints, resulting in a score that ranges from 0 to 168 for both feet.²⁹

Statistical Analysis. The variation coefficients of the scores from the three interviews were used to test the inter- and intra-observer reliability. The α -Cronbach coefficient was applied to test the internal consistency of the domains. Spearman Correlation was used to determine the construct validity.

RESULTS

Cross-cultural adaptation. Over the translation, back-translation, and committee analysis phases, minor adaptations to wording and sentence structure were required in sections I and II for better understanding. One of the two items that needed to be adjusted was Question 12, which stated “I am limited in the number of shoes I can wear.” In Portuguese the word “number” could be misleading and suggest shoe size, so it was changed to “tipos,” meaning “kinds.” The other item was Question 15b, which gives examples of moderate activities, one of which is “playing golf.” Golf is not a common sport in Brazil, especially in our study group, so considering there were other suitable examples in the question, it was decided that the elimination of the words “playing golf” would cause no interference.

During the pre-test phase, three items of the instrument were adapted. The first one was in Question 15d; the words “steep hill,” when translated into Portuguese, were inadequate for an urban scenario and were replaced by “ladeira.” The second item, on Question 25, asked if the patient was “a pensioner or health care cardholder.” It was replaced with “Do you have public health insurance?” (“Você paga INSS ou previdência social?”), which is more comprehensible to the Brazilian population. Finally, in Question 29, “...completed a trade certificate or any other educational qualification since leaving school” was replaced with “have you attended any continuing education program after leaving school?” (“Você fez algum aperfeiçoamento ou especialização desde que saiu da escola?”). All questions were considered applicable after these corrections.

Evaluation of Measurement Properties. A field test was conducted on a study group of 65 RA patients selected as described earlier. The FHSQ-Br, which includes demographic and clinical data, was collected in addition to the HAQ, NRS and foot X-rays. This information is presented in Tables 1 through 3.

Test-retest reliability. Out of the 65 patients from the study group who participated in the first interview, 61 participated in the second interview to test inter-observer

Table 1 - Demographic data characterizing the study group

Age in years (n=65), mean (range)	55.1 (21-77)
Female sex (n=65), n (%)	63 (96.9)
Level of education (n = 40)	
Illiterate, n (%)	2 (5)
Pre-school, n (%)	24 (60)
High-school, n (%)	12 (30)
College, n (%)	2 (5)
Have any continued education (n=65), n (%)	15 (23.1)
Economic status (n = 40)	
Economically active, n (%)	5 (12.5)
Economically not active, n (%)	24 (60)
Retired, n (%)	11 (27.5)
Marital status (n = 40)	
Single, n (%)	4 (10)
Married, n (%)	25 (62.5)
Divorced, n (%)	2 (5)
Widowed, n (%)	9 (22.5)
Have private health insurance (n=65), n (%)	8 (12.3)

Table 2 - Clinical data characterizing the disease and associated diseases of the study group (n = 65)

RA duration in years, mean (range)	16.4 (1-38)
Functional Class:	
Class I, n (%)	11 (16.92)
Class II or III, n (%)	54 (83.08)
Patients with associated diseases:	
Number of associated diseases; mean (range)	2.8 (1-7)
Diabetes, n (%)	8 (12.3)
Osteoarthritis, n (%)	22 (33.8)
Blood Pressure, n (%)	37 (56.9)
Back Pain, n (%)	11 (16.9)
Depression, n (%)	11 (16.9)
Other diseases, n (%)	28 (43.1)
Smoke cigarettes, n (%)	5 (7.7)
Exercise regularly, n (%)	13 (20)

Table 3 - FHSQ-Br mean scores across the domains, HAQ, NRS and Sharp/van der Heijde mean scores of the study group

FHSQ-Br Domain (n=65)	mean (range)
Foot Pain	39.8 (0-87.5)
Foot Function	48.15 (12.5-100)
Shoes	5.9 (0-75)
General Foot Health	24.5 (0-60)
General Health	42.2 (0-100)
Physical Activity	33.9 (0-83.3)
Social Capacity	61.1 (0-100)
Vigour	42.9 (0-81.2)
HAQ (n=40)	1.2 (0-2.88)
NRS (n=65)	7.3 (2-10)
Sharp/van der Heijde (n=50)	49.8 (8-113)

HAQ - Health Assessment Questionnaire; NRS - Numbered Rating Scale.

reliability and 55 in the third interview to test intra-observer reliability. The scores obtained from the three interviews were analyzed and showed low variation coefficients, representing the homogeneity of the scores from all interviews. The mean FHSQ-Br score of the three interviews and inferior and superior limits of the confidence interval are detailed in Figure 1.

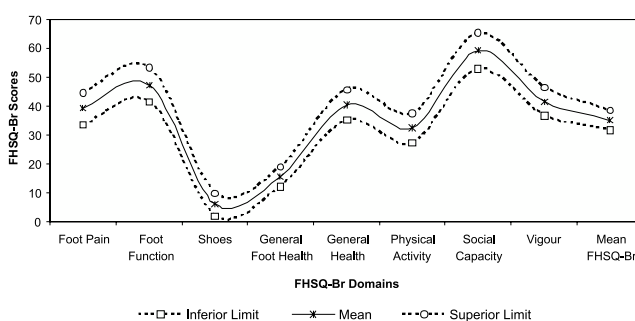


Figure 1 - Mean FHSQ-Br score of the three interviews and inferior and superior limits of the confidence interval

Internal consistency. The α -Cronbach coefficients varied from 0.468 (general health) to 0.855 (physical activity), showing statistically significant correlations for all domains. The correlation coefficients are presented in Table 4.

Construct validity. The HAQ was answered by 40 patients and the NRS was answered by all 65 patients; foot X-rays were obtained from 50 patients in the study group.

The mean FHSQ-Br scores showed a significant correlation to the HAQ scores (-55.6%; $p < 0.001$). Individually, five out of eight domains showed significant correlations, with p-values ranging from 0.001 to 0.046. The mean FHSQ-Br

Table 4 - The α -Cronbach coefficients for the analysis of the internal consistency of the domains of the FHSQ-Br

Domains	α -Cronbach coefficient	
	Value	CI 95%
Foot Pain	0.680	(0.525 ; 0.794)
Foot Function	0.813	(0.722 ; 0.879)
Footwear	0.824	(0.731 ; 0.889)
General Foot Health	0.758	(0.597 ; 0.859)
General Health	0.468	(0.223 ; 0.653)
Physical Activity	0.855	(0.794 ; 0.904)
Social Capacity	0.698	(0.497 ; 0.819)
Vigour	0.679	(0.524 ; 0.793)

showed significant correlation with the NRS scores (-58.6%; $p < 0.001$). Individually, five out of eight domains also showed significant correlations, with p -values ranging from 0.001 to 0.034. Significant correlations were found for only two out of the eight domains between the FHSQ-Br scores and the Sharp/van der Heijde scores for foot X-rays. Correlation coefficients and p -values are detailed in Table 5.

DISCUSSION

Although patients with RA complain of foot pain and of foot problems affecting their performance of activities of daily life, physicians sometimes overlook or neglect the feet in routine examinations.^{30,31}

Disease-related foot-health instruments may help health professionals in measuring the impact on feet related to RA. The Foot Health Status Questionnaire, one of these instruments, was developed and validated in Australia as a patient-outcome measure of foot health. The cross-

cultural adaptation of the FHSQ into Brazilian-Portuguese enables clinicians to compare results and outcomes of their treatments among different populations with different profiles and lifestyles.

The FHSQ was translated into Brazilian-Portuguese with no difficulty, and it is fully adapted to the culture; very few items needed to be analyzed in detail through all of the development phases. Furthermore, during the pre-test phase, only three questions had to be reformulated, and after the necessary changes, every item of the questionnaire was approved by more than 90% of the patients, concluding the instrument's cultural adaptation.

The FHSQ-Br is a self-administered instrument;¹⁴ however, in Brazil, we chose to administer it with an interviewer, considering the social-economic and educational level of the studied population.

Our study group reflects the RA segment of the Brazilian population because the demographic and clinical data collected are similar to what has been previously reported for the Brazilian population regarding age, sex distribution, disease duration, HAQ scores and percentage of illiterate or pre-school level patients.³²

The scores obtained from this study group reflect the difficulty that patients have in completing their daily activities as a consequence of their foot disease. Attributes like foot pain and foot function reflect their disabilities.

The inter- and intra-observer reliability values were in line with those found by the authors of the original instrument, which varied from 0.740 to 0.915.¹⁴ The FHSQ-Br internal consistency analysis showed fair results. General health (0.468) and Physical Activity (0.855) showed the lowest and highest results, respectively. The internal consistency of the original instrument varied from 0.851 to

Table 5 - Correlation coefficients and p -values for the analyses between the domains of the FHSQ-Br and the clinical parameters of the study group

Correlations			Foot Domains				General Health Domains				Mean FHSQ-Br Score
			Foot Pain	Foot Function	Shoes	General Foot Health	General Health	Physical Activity	Social Capacity	Vigour	
Demographic Data	N° of Associated Diseases	CC	0.2%	-1.3%	8.0%	8.4%	-8.5%	-17.6%	-4.0%	-5.5%	-6.3%
		p	0.985	0.918	0.526	0.504	0.141	0.162	0.753	0.663	0.618
	Age	CC	7.1%	19.1%	-1.9%	0.5%	40.6%	-6.8%	-9.8%	11.7%	12.2%
		p	0.572	0.128	0.878	0.969	0.001*	0.592	0.439	0.355	0.332
	RA Duration	CC	-12.8%	3.9%	-1.6%	-7.3%	-1.5%	6.7%	-3.7%	-3.0%	-10.1%
		p	0.433	0.811	0.475	0.654	0.182	0.680	0.398	0.856	0.537
Clinical Parameters	NRS	CC	-84.9%	-59.9%	-6.9%	-46.4%	-6.3%	-29.0%	-4.5%	-5.8%	-58.6%
		p	<0.001*	<0.001*	0.583	<0.001*	0.034*	0.019*	0.251	0.210	<0.001*
	HAQ	CC	-43.1%	-63.9%	21.3%	-39.8%	4.3%	-69.5%	-1.8%	-6.7%	-55.6%
		p	0.005*	<0.001*	0.187	0.011*	0.794	<0.001*	0.046*	0.096	<0.001*
	Sharp/van der Heijde Score	CC	0.3%	0.8%	-8.4%	-19.3%	30.7%	-17.3%	-5.0%	19.5%	-2.4%
		p	0.986	0.956	0.006*	0.178	0.030*	0.230	0.298	0.176	0.867

CC - Correlation Coefficients; RA - Rheumatoid Arthritis; HAQ - Health Assessment Questionnaire; NRS - Numbered Rating Scale.

0.884, depending on the domain being analyzed.¹⁴ When compared to other parameters intended to measure disease impact,^{25,29,33} the FHSQ-Br showed significant correlations, indicating that the instrument is actually measuring what it is intended to measure.²⁴ For instance, the HAQ and the NRS scores were significantly correlated with five out of the eight domains of the instrument.

The FHSQ-Br is a complete and valid instrument, easy to understand, acceptable to patients, and able to be administered in 10 to 15 minutes.

Even though RA is a chronic disease, it presents clinical variations with acute periods. This clinical characteristic associated with patient physical limitations constituted the main limitation of our study. Further studies should

be conducted in Brazil with other foot conditions for comparison with our results and proceed with eventual adaptations of the FHSQ for these other conditions.

This study shows that the FHSQ-Br will be of great value in assessments of RA patients in clinical settings and in research.

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