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ORIGINAL ARTICLE

FOOT FUNCTION ASSESSMENT AND CROSS-CULTURAL ADAPTATION OF THE FOOT FUNCTION INDEX TO POLISH IN RHEUMATOID ARTHRITIS PATIENTS

OCENA FUNKCJONOWANIA STOPY ORAZ ADAPTACJA KULTUROWA I WALIDACJA POLSKOJĘZYCZNEJ WERSJI KWESTIONARIUSZA FOOT FUNCTION INDEX U CHORYCH Z REUMATOIDALNYM ZAPALENIEM STAWÓW

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ABSTRACT

Aim

To assess rheumatoid arthritis (RA) patients' functional status and to perform a cross-cultural adaptation of the original Foot Function Index (FFI) questionnaire to develop the Polish version.

Methods

Thirty-one female patients with RA participated in this observational study. The patient's health statuses were evaluated with the culturally adopted FFI (FFI-PL), the Polish version of SF-36 (SF-36-PL), the Polish version of the Beck Depression Inventory (BDI-PL) and a Visual Analogue Scale of foot pain (VAS-pain). Construct validity, internal consistency and criterion validity were calculated for the FFI Polish version after the translation and cross-cultural adaptation process.

Results

Subsequent analyses showed numerous significant correlations. The FFI-PL total results were moderately correlated with VAS-pain, BDI-PL and SF-36-PL. The FFI-pain results were highly correlated with the FFI total results. The FFI-disability results were correlated with the BDI-PL and SF-36-PL. Surprisingly, no correlations were found in the study group between FFI-PL results and age, working time, or years since diagnosis.

Internal consistency of the Polish FFI ranges from 0.996 to 0.998. Test-retest analysis ranged from 0.985 to 0.994.

Conclusions

The FFI-PL is an effective tool for assessing RA patients' functional status. The Polish adaptation of the FFI presents good to excellent psychometric properties. Polish researchers and clinicians may use this tool for foot and ankle assessment and monitoring.

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STRESZCZENIE

Cel

Ocena funkcjonowania chorych w przebiegu reumatoidalnego zapalenia stawów oraz adaptacja kulturowa i walidacja polskojęzycznej wersji kwestionariusza Foot Function Index (FFI).

Materiał i metody

Do badań zakwalifikowano trzydziestu jeden pacjentów płci żeńskiej z reumatoidalnym zapaleniem stawów. Ocena chorych została przeprowadzona za pomocą zaadoptowanego kwestionariusza FFI (FFI-PL), polskiej wersji kwestionariusza Short Form Health Survey (SF-36-PL), polskiej wersji skali depresji Becka (BDI-PL) oraz wizualnej skali analogowej (VAS-pain). Obliczono trafność konstrukcji, spójność wewnętrzną oraz trafność kryterialną dla polskiej wersji kwestionariusza FFI po przeprowadzonej adaptacji kulturowej.

Wyniki

Przeprowadzona analiza statystyczna wykazała, że wynik ogólny FFI-PL był w sposób umiarkowany skorelowany ze skalą VAS-pain, BDI-PL oraz SF-36-PL. Wartość podskali FFI-pain była silnie skorelowana z wynikiem ogólnym FFI-PL. Wyniki w podskali FFI-disability były skorelowane ze skalą BDI-PL oraz SF-36-PL. Nie wykazano korelacji pomiędzy wartościami FFI-PL a wiekiem, zatrudnieniem oraz czasem trwania choroby.Współczynnik spójności wewnętrznej polskiej wersji FFI wynosił od 0,996 do 0,998. Rzetelność powtarzalności testu wynosiła od 0,985 do 0,994.

Wnioski

Polska wersja kwestionariusza FFI jest efektywnym narzędziem do oceny funkcjonalnej chorych z reumatoidalnym zapaleniem stawów. Polska adaptacja kwestionariusza FFI posiada wysokie właściwości psychometryczne i nadaje się do stosowania w badaniach klinicznych.

Słowa kluczowe: adaptacja kulturowa, reumatoidalne zapalenie stawów, kwestionariusz

Introduction

Foot dysfunctions are prevalent and may significantly affect the quality of life of people of any age (Fujii. 2019). The prevalence of foot dysfunctions ranges from 10% to 24%. However, most cases concern the elderly, obese individuals, people with RA and those with neuropathy in the course of diabetes (Budiman-Mak *et al.,* 2013). RA is an autoimmune systemic inflammatory disorder of connective tissue. Progressive inflammation leads to the destruction and deformation of the joints, resulting in pain, functional limitations, and disability. Researches reported that serious foot problems affect up to 90% of patients with RA and are the first symptom of the disease in 15% of cases (Walmsley *et al.,* 2010). Foot dysfunctions most commonly occur in the subtalar and mid-tarsal joints in RA.

Nonetheless, the onset of RA starts with synovitis of the metatarsophalangeal joints (Coughlin. 2000). Wickman *et al.* and Grondal *et al.* state that the great impact of foot pathology results in atrophy of lower limbs muscle, disturbance in postural stability and as a result higher risk of falling (Wickman *et al.,* 2004; Grondal *et al.,* 2008) In turn, these changes significantly reduce patient's psychological functioning, physical independence, economic status, and quality of life (Rojas-Villarraga *et al.,* 2009).

Specific measure instruments play an essential role in assessing the patient's health condition, and disease progression, defining treatment effectivity, including psychosocial and functional aspects resulting from the advancement of the disease. Many measures evaluating foot dysfunctions and their outcomes on quality of life and everyday functioning in RA patients have been successfully validated and practically used (Otter *et al.* 2012; Budiman-Mak *et al.,* 2013). The Foot Function Index is used at a high rate, relative to other clinically used tools (Hunt *et al.,* 2013). This scale has been repeatedly translated and culturally adapted to the language spoken in the country where they are used according to the standards established earlier in the literature (Nadal *et al.,* 2008; Paez-Moguer *et al.,* 2014;Martinelli *et al.,* 2014).

The cross-cultural adaptation of the FFI has been conducted in Spanish, Italian, Chinese, Danish and German languages (Nadal *et al.,* 2008; Paez-Moguer *et al.,* 2014; Martinelli *et al.,* 2014; Jorgensen *et al.,* 2015; Gonzalez-Sanchez *et al.,* 2018). Data obtained from the cross-culturally adapted versions pointed out excellent test-retest reliability, good internal consistency (Cronbach's $\alpha > 0.90$) and good correlation of the inter and intra-observer reproducibility and it is a valid and reliable tool for use in both clinic and research assessment (Nadal *et al.,* 2008; Paez-Moguer *et al.,* 2014; Martinelli *et al.,* 2014; Jorgensen *et al.,* 2015; Gonzalez-Sanchez *et al.,* 2018). According to our knowledge validated Polish versions of the original Foot Function Index are unavailable.

The present study aimed to assess RA patients' functional status and to culturally adapt the original FFI to the Polish version and verify its reliability and validity in a group of 31 Polish-speaking female patients with RA.

Material and methods

Methods

Patient sample

A total of 31 Polish-speaking consecutive patients were enrolled in the study. We have defined the following data in the basic characteristics such as age, disease duration and sociodemographic background. Participant inclusion criteria were as follows: female adults with RA diagnosed according to ACR/EULAR (American College of Rheumatology/European League Against Rheumatism) criteria from 2010, arthritis-related pain and/or swelling of the joints within the feet, agreement to participate voluntarily in the study and giving prior informed consent (Aletaha *et al.,* 2010). Participant exclusion criteria were: cognitive, proprioceptive, sensory impairment or foot fracture and surgery during the last three months. All participants were recruited as a convenient sample from the Department of Rheumatology, Dega's Clinical Hospital in Poznan, representing different sociodemographic characteristics.

Description of the questionnaire

FFI is a widely recognized subjective tool for pain assessment, disability, and activity limitation produced by foot morbidity in patients with RA (Budiman-Mak *et al.,* 1991). FFI consists of 23 items grouped in three subscales: pain (9 items), disability (9 items), and activity limitation (5 items). Each item is rated on a horizontal 10-cm visual analog scale (VAS) without subdivisions. The subscales are tabbed "no pain" and "intense pain" (pain subscale), "no difficulty" and "impossible" (disability subscale), and "never" and "always" (limitations subscale). A subscale score is calculated by summing and dividing by the maximum total possible for the subscale items that the patient indicated are applicable. The total FFI score is obtained by averaging the three subscale scores. A higher score is indicative of greater levels of foot limitation/pain/disability. The reliability of this system has been described in detail previously (SooHoo *et al.,* 2006; Bal *et al.,* 2006).

Translation and adaptation procedure

As there is no Polish language version of the original version of the Foot Function Index, we conducted a preliminary validation

process of questionnaires to produce assessment tools equivalent to the original English versions. The cross-cultural adaptations of the questionnaires were compliant according to guidelines set up by the International Quality of Life Assessment (Beaton *et al.,* 2000).

In the first stage, two native Polish-speaking professional translators working independently converted the original FFI into a Polish version (FFI-PL). Stage two comprised the comparison and synchronization of originals and two translated versions by the two translators and authors of the project. In the third stage, two native English speakers, who were bilingual and without previous contact with the originals, translated the Polish version of the questionnaires into the language of the original documents. In the final stage, a committee of translators, orthopedists, a statisticians reviewed all the translations to draft a pre-final version of the questionnaires.

Ethical considerations

This study was approved by the Research Ethics Committee at Poznan University of Medical Sciences No. 323/13, all the participants were informed and signed the free consent statement.

Study methods

The 31 female subjects completed the FFI-PL, the SF-36-PL, the BDI-PL and the VAS-pain. The FFI-PL was completed twice at a 24-hour interval. SF-36-PL is a self-administered questionnaire of 36 questions aimed at overall physical and mental health assessment. The SF-36 was chosen since in a previous study, it has been shown to have good psychometrics in the context of foot-ankle diseases (Sohoo *et al.,* 2006). VAS pain consists of a 10-cm long line divided into 10 sections ranging from 0 to 10. The patient scores from 0, representing no pain, to 10, the worst pain imaginable (Landorf *et al.,* 2008). BDI is a 21-question multiple-choice self-report inventory psychometric test for measuring the severity of depression in a variety of settings and populations (Wang *et al.,* 2013).

Statistical analysis

A descriptive analysis was performed to calculate the means and standard deviations (SDs) of the demographic variables, and a summary of the other variables. For details (see Table 1,2). The reliability of the FFI questionnaire was assessed by analyzing its internal consistency using Cronbach's alpha coefficient and the test-retest reliability method. Test-retest reliability was assessed using the Intraclass Correlation Coefficients (ICCs), type 2.1. Values of ICCs above 0.80 were considered evidence of excellent reliability (Nunnally *et al.,* 2005). Criterion validity was examined by calculating Spearman's rank correlation coefficient (rS) between the FFI-PL, SF-36-PL, BDI-PL and VAS foot pain. The correlation was weak if rS was < 0.4, moderate if it was between 0.4 and 0.7, and strong if it was greater than 0.7. We also examined our research participants for the presence or absence of floor and ceiling effects. These effects show the proportion of patients who gain the lowest or highest possible scores and are considered to be present when more than 15% of the examined individuals achieve these scores. The statistical analyses were done using Statistica Software. The significance level was set as $p < 0.05$.

Table 1. Clinical and sociodemographic parameters of the analyzed group.

	N	Mean	Median	Minimum	Maksimum	Lower Quartile	Upper Quartile	SD
Age	31	50.29	47.00	39.00	61.00	45.00	55.00	7.14
Years since diagnosis	31	11.32	10.00	1.00	35.00	7.00	15.00	7.47
Working time	31	25.18	25.00	6.00	40.00	20.00	35.00	8.75

Table 2. Descriptive statistics of FFI-PL, VAS, SF-36-PL, BDI-PL.

	N	Mean	Median	Minimum	Maksimum	Lower Quartile	Upper Quartile	SD
VAS	31	36.68	31.00	2.00	88.00	17.00	49.00	25.71
FFI total	31	40.00	37.68	0.00	86.47	27.05	56.52	20.69
FFI pain	31	38.51	32.10	0.00	88.89	20.99	59.26	23.72
FFI disability	31	46.75	44.44	0.00	100.00	28.39	62.96	26.07
FFI Activity	31	30.54	31.11	0.00	82.22	8.89	46.67	24.80
BDI total	31	12.71	10.00	0.00	30.00	5.00	21.00	8.56
SF-36 total	31	101.68	104.00	29.00	144.00	78.00	129.00	29.87

Descriptive statistics of analyzed group and questionnaires

Cross-cultural adaptation

The translation and back-translation of the questionnaire presented no difficulty either in language or in comprehension of the items. The translated version of the FFI-PL is shown in Figure 1.

Internal consistency

The FFI-PL demonstrated excellent internal consistency. Cronbach's alpha values on the three subscales equaled: disability 0.96; activity limitation 0.95 and pain 0.94-the subscale that scored lowest. The internal consistency for the overall scale FFI-PL was 0.94.

Concurrent validity

Spearman's rank correlation coefficient was used to assess the association between FFI and SF-36-PL, VAS-pain and BDI-PL. To demonstrate convergent validity, we assumed moderate to high correlations between the FFI-PL subscales and the SF-36-PL, VAS-pain, BDI-PL. The correlation between the FFI-PL and the other questionnaires was high to moderate in all cases. For details (see Table 3).

Test re-test reliability

The test-retest reliability was confirmed by excellent ICC value for FFI subscales and equalled 0.95 (95% CI from 0.90 to 0.97) and 0.91 (95% CI from 0.82 to 0.95) for consistency and conformity respectively.

Floor and ceiling effect

We have analyzed floor and ceiling effects for the general results of the FFI-PL. In the case of FFI-PL, in both the test and retest, and 3.22% of patients received the minimum score (1 participant), and 3.22% of patients received the maximum score (1 participant). Floor or ceiling effects were not detected as less than 15% achieved the minimum or maximum possible scores.

The correlation between patients' clinical characteristics and the results of the FFI-PL

We have assessed the correlation between selected patients' clinical, sociodemographic parameters and the results of the adapted assessment tools. Statistically significant correlations were identified between level of education and disability, whereas higher education level was correlated with lower disability score in the subscale. We also found significant correlations between professional activity, seniority and physical limitations, whereas those who were more active and had longer seniority declared less disability and activity limitations. Surprisingly, neither age nor years since diagnosis were correlated with the FFI-PL scores. Moreover, reported working time was also not related to FFI-PL scores. For details (see Table 4, 5, 6).

Discussion

Foot problems are strongly associated with the presence of RA. At the time of diagnosis, up to half of RA patients already have foot dysfunctions and in many cases, foot

Table 3. Correlations between FFI-PL and other outcome measures.

	VAS-pain	FFI-PL total	FFI-PL pain	FFI-PL Disability	FFI Activity Limitation	BDI-PL	SF-36-PL total
VAS-pain		mod	—	mod	—	—	mod
FFI-PL total	rS = 0.43*		high	high	high	mod	mod
FFI-PL pain	rS = 0.24	rS = 0.78**		mod	mod	—	—
FFI-PL Disability	rS = 0.56**	rS = 0.83**	rS = 0.45*		mod	mod	high
FFI Activity Limitation	rS = 0.297	rS = 0.80**	rS = 0.43*	rS = 0.64**		mod	mod
BDI-PL	rS = 0.35	rS = 0.47**	rS = 0.16	rS = 0.59**	rS = 0.48**		high
SF-36-PL total	rS = 0.51**	rS = 0.53**	rS = 0.22	rS = 0.70**	rS = 0.54**	rS = 0.71**	

Spearman's correlation (Rs): low < |0.4| moderate (mod) = |0.4 – 0.7| high > |0.7|
*p < 0.05, **p < 0.01

Table 4. Correlations between the level of education and FFI.

Level of education	p-value	Secondary to University Education	Occupational Education
FFI total	0.21	25	6
FFI pain	0.84	25	6
FFI Disability	0.03*	25	6
FFI Activity	0.17	25	6

*p < 0.05

Table 5. Correlations between professional activity and FFI.

Professional activity	p-value	Active	Non-Active
FFI total	0.05	12	19
FFI pain	0.76	12	19
FFI Disability	0.01*	12	19
FFI Activity	0.003*	12	19

*p < 0.05

Table 6. Correlations between seniority in years and FFI

Variables	N	R Spearman	p
Seniority in years & FFI total	31	rS = 0.33	0.09
Seniority in years & FFI pain	31	rS = 0.01	0.97
Seniority in years & FFI Disability	31	rS = 0.52	0.01*
Seniority in years & FFI Activity	31	rS = 0.33	0.08

Spearman's correlation (Rs): low < |0.4| moderate (mod) = |0.4 – 0.7| high > |0.7|
*p < 0.05

pain is the reason for medical consultation. One of the most popular questionnaires to analyze functional status in patients with RA is the HAQ-DI (Bruce *et al.*, 2005). However, it does not evaluate the functional status of a patient's foot. In this study, we demonstrated that the results of the FFI-PL subscales were correlated with the results of other questionnaires used. We found convergent criterion validity with all scales that has been addressed in the study. Surprisingly no correlations were found between such important clinical parameters as age or years since diagnosis.

Nonetheless, an internationally recommended translation procedure was used to provide a Polish version of the FFI. The translation was performed using an established

methodology to ensure the questionnaire was translated and adapted to a Polish context. The adapted version of the Foot Function Index questionnaire has shown to be a valid and reliable instrument among patients with foot disorders. The results of the present FFI-PL adaptation of the 23-item FFI questionnaire are comparable with former studies that used the original English version (Saag *et al.*, 1996; Bal *et al.*, 2006; Goldstein *et al.*, 2010; Treventhan *et al.*, 2010). The analysis showed the FFI-PL to be equivalent to the original scale and the other cross-cultural adaptations made (Naal *et al.*, 2008; Paez-Moguer *et al.*, 2014; Martinelli *et al.*, 2014; Jorgensen *et al.*, 2015; Gonzalez-Sanchez *et al.*, 2018). Cronbach's

Index funkcjonowania stopy
(Foot Function Index-Polish version)

Numer .....

Chora strona PRAWA/LEWA
Proszę postawić znak na liniach, które najlepiej ilustrują Pani/Pana doznania w ubiegłym tygodniu.

Przykład
Kiedy ból jest najgorszy?
Brak bólu_____/_____ Najgorszy wyobrażalny ból

Jak silny jest ból Pani/Pana stopy?
1. Kiedy jest najgorszy?
Brak bólu _____Najgorszy wyobrażalny ból
2. Rano?
Brak bólu _____Najgorszy wyobrażalny ból
3. Kiedy Pani/Pan chodzi boso?
Brak bólu _____Najgorszy wyobrażalny ból
4. Kiedy Pani/Pan stoi boso?
Brak bólu _____Najgorszy wyobrażalny ból
5. Kiedy Pani/Pan chodzi w butach?
Brak bólu _____Najgorszy wyobrażalny ból
6. Kiedy Pani/Pan stoi w butach?
Brak bólu _____Najgorszy wyobrażalny ból
7. Kiedy Pani/Pan chodzi w obuwiu z wkładkami ortopedycznymi?
Brak bólu _____Najgorszy wyobrażalny ból
8. Kiedy Pani/Pan stoi w obuwiu z wkładkami ortopedycznymi?
Brak bólu _____Najgorszy wyobrażalny ból
9. Pod koniec dnia?
Brak bólu _____Najgorszy wyobrażalny ból

Jak wielką trudność sprawia Pani/Panu:
10. Chodzenie po domu?
Bez trudności _____Tak trudne, że niemożliwe do zrobienia
11. Chodzenie na zewnątrz?
Bez trudności _____Tak trudne, że niemożliwe do zrobienia
12. Przejście 300 m?

Bez trudności _____ Tak trudne, że niemożliwe do zrobienia

13. Wchodzenie po schodach?
Bez trudności _____ Tak trudne, że niemożliwe do zrobienia

14. Schodzenie ze schodów?
Bez trudności _____ Tak trudne, że niemożliwe do zrobienia

15. Stanie na czubkach palców?
Bez trudności _____ Tak trudne, że niemożliwe do zrobienia

16. Wstawanie z krzesła?
Bez trudności _____ Tak trudne, że niemożliwe do zrobienia

17. Wchodzenie na krawężniki?
Bez trudności _____ Tak trudne, że niemożliwe do zrobienia

18. Szybkie chodzenie?
Bez trudności _____ Tak trudne, że niemożliwe do zrobienia

Jak często:

19. Używa Pani/Pan przyrządu (-ów) ortopedycznych (wkładek ortopedycznych) w domu z powodu problemów ze stopami?
Nigdy _____ Cały czas

20. Używa Pani/Pan przyrządu(-ów) ortopedycznych (wkładek ortopedycznych) na zewnątrz z powodu problemów ze stopami?
Nigdy _____ Cały czas

21. Zostaje Pani/Pan w domu przez większą część dnia z powodu problemów ze stopą?
Nigdy _____ Cały czas

22. Pozostaje Pani/Pan w łóżku przez większą część dnia z powodu problemów ze stopą?
Nigdy _____ Cały czas

23. Ogranicza Pani/Pan swoją codzienną aktywność z powodu problemów ze stopą?
Nigdy _____ Cały czas

Figure 1. Foot Function Index Polish Version (FFI-PL)

a was 0.94 for the overall scale, very similar to the original version, which showed alpha values of 0.95, 0.94, 0.73 and 0.92 for the "FFI total", "pain", "activity limitation" and "disability" respectively (Budiman-Mak *et al.,* 1991). The FFI-PL demonstrated excellent internal consistency, with the total of the items giving a Cronbach's a similar value to those reported in other cross-cultural adaptations, such as the Chinese version: Cronbach's a 0.99 and ICC 0.98, German: Cronbach's a 0.98 and ICC 0.97, Spanish: Cronbach's a 0.69–0.96 and Italian: Cronbach's a: 0.98 and ICC: 97, Danish: Cronbach's a: 0.97 and ICC: 91 (Naal *et al.,* 2008; Paez-Moguer *et al.,* 2014; Martinelli *et al.,* 2014; Jorgensen *et al.,* 2015; Gonzalez-Sanchez *et al.,* 2018).

However, previous studies have shown that the two original items of the activity limitation subscale concerning assistive devices were not always relevant to the study population, and both items were leading to ceiling effects (Goldstein *et al.,* 2010). The German and Dutch validation of the FFI completely deleted this scale from their questionnaires (Naal *et al.,* 2008; Jorgensen *et al.,* 2015; Gonzalez-Sanchez *et al.,* 2018). The revised form of the FFI has shown reliable subscales that assess health-related quality of life in patients with foot compliances. The Spanish version of the FFI (FFI-Sp) showed moderate-to-high correlations between the change in FFI-Sp and the change in Foot Health Status Questionnaire, VAS-Pain and SF-12 (Paez-Moguer *et al.,* 2014). The original English, Italian, and German versions have shown a high correlation between the SF-36 and the VAS-Pain (Naal *et al.,* 2008; Martinelli *et al.,* 2014;

SooHoo *et al.,* 2006). This suggests that the responsiveness of the FFI is well established in both the English versions as well as in the cultural-adapted versions. The minimal clinical difference in the FFI is 12 for pain, seven for disability, and seven for total FFI (Landorf *et al.,* 2008). Still, we decided to use the original version of the FFI as the basis for the adaptation into Polish, since the revised form FFI has not yet been widely used in clinical outcome research. The pain subscale the one which gave the lowest Cronbach's value was in contrast with the Chinese version in which activity limitation had the lowest Cronbach's a 0.79 (Gonzalez-Sanchez *et al.,* 2018). Items 20, 22, had a corrected item/total correlation coefficient of less than 0.6. Similar to the results of the Spanish version of FFI. Our research confirms the effectiveness of using the FFI-PL.

Study limitations

The study is based on small sample size. Our population was restricted to female patients with RA, which may limit the generalizability of the findings to other populations. At the same time, we did not analyze associations between FFI-PL and other, culturally adapted to Polish conditions, disease-specific measure for RA patients.

Conclusions

The FFI-PL is an effective tool to assess RA patients' feet' functional status, which affects the general condition of RA patients. The Polish version of the FFI is a reliable and valid tool with good internal consistency and test re-test reliability. It can be recommended for use both in the clinical environment and in studies and trials in which one wants to measure the pain, function, and activity limitation related to foot problems.

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Conflict of interest

The authors declare that they have no competing interests.

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