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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Keywords: cultural adaptation, rheumatoid arthritis, questionnaire

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 umiar-kowany 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 effectiveness, 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 α > 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 | Maximum | 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|
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 equaled 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).

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

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

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
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 translation procedure to ensure its validity.
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

![Image](image1.jpg)

Index funkcjonowania stopy
(Foot Function Index-Polish version)

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 / jesień
Najgorszy wyobrażany ból

Jak silny jest ból Pani/Pana stopy?
1. Kiedy jest najgorszy?
    Brak bólu / jesień
    Najgorszy wyobrażany

2. Rano?
    Brak bólu / jesień
    Najgorszy wyobrażany

3. Kiedy Pani/Pan chodzi bośo?
    Brak bólu / jesień
    Najgorszy wyobrażany

4. Kiedy Pani/Pan stoi bośo?
    Brak bólu / jesień
    Najgorszy wyobrażany

5. Kiedy Pani/Pan chodzi w butach?
    Brak bólu / jesień
    Najgorszy wyobrażany

6. Kiedy Pani/Pan stoi w butach?
    Brak bólu / jesień
    Najgorszy wyobrażany

7. Kiedy Pani/Pan chodzi w obuwiu z wkładkami ortopedycznymi?
    Brak bólu / jesień
    Najgorszy wyobrażany

8. Kiedy Pani/Pan stoi w obuwiu z wkładkami ortopedycznymi?
    Brak bólu / jesień
    Najgorszy wyobrażany

9. Pod koniec dnia?
    Brak bólu / jesień
    Najgorszy wyobrażany

Jak wielką trudność sprawia Pani/Panu:
10. Chodzenie po domu?
    Bez trudności / niemożliwe do robienia
    Tak trudne, że

11. Chodzenie na zewnątrz?
    Bez trudności / niemożliwe do robienia
    Tak trudne, że

12. Przejeżście 300 m?
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). 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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