

Validity and Reliability Study of the Turkish Version of the Hand-Foot Syndrome Quality of Life Scale

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Abstract

Background: Hand-foot syndrome is a symptom of some antineoplastic drugs which affects blood vessels and surrounding tissues, causing redness, swelling, and pain on the palms and soles and affects quality of life.

Aim: The study was carried out methodologically in order to adapt the Hand-Foot Syndrome Scale-14, which was developed for the quality of life of individuals receiving chemotherapy who have hand-foot syndrome, into Turkish and to determine its validity and reliability.

Methods: The research was conducted with 102 patients who received chemotherapy in a University Hospital Chemotherapy Unit. Patient Information Form, National Cancer Institute classification criteria, Hand-Foot Syndrome Scale-14, and Skindex-29 Scale were used to collect data. Translation-back translation technique was used for the language validity of the scale. For the content validity of the scale, 7 experts were consulted. Opinions from experts showed that the correlation between the items of the scale was very strong (Kendall's $W=0.24$, $P=.61$).

Results: As a result of the explanatory factor analysis, a 3-factor structure with a total variance of 60.31% was obtained. When the Cronbach's alpha coefficient values were examined for internal consistency validity, it was determined that the total Cronbach alpha value of the scale was 0.86, and the Cronbach's alpha value of its subscales was 0.84, 0.89, and 0.67, respectively. In addition, it was observed that there was a strong positive correlation between Skindex-29 and Hand-Foot Syndrome Scale-14.

Conclusion: The results of the Turkish version of Hand-Foot Syndrome Scale-14 were found to be consistent with the original scale structure, valid and reliable for the Turkish population.

Keywords: Validity, reliability, HFS-14, chemotherapy, quality of life

Introduction

Hand-foot syndrome (HFS), also known as palmar-plantar erythrodysesthesia syndrome, is a reaction to chemotherapy drugs that affects the hands and feet. It occurs when some antineoplastic drugs leak into the capillaries in the hands and feet. It affects the blood vessels and surrounding tissues, causing redness, swelling, and pain in the palms and soles.¹⁻⁴ The incidence of HFS in patients receiving chemotherapy is between 7.3% and 63%.² The most common drugs causing HFS are Pegylated liposomal doxorubicin (PLD), capecitabine, 5-fluorouracil, cytarabine, docetaxel, cisplatin, sorafenib, sunitinib, lapatinib, and bevacizumab.¹⁻⁶ These drugs have a significant impact on quality of life and lead to dose limitation. Although most patients develop mild HFS (grade 1 or 2 (World Health Organization (WHO) or grade 1 (National Cancer Institute (NCI))), significant functional impairment may occur.⁷ Furthermore, it has been reported in the literature that severe HFS causes morbidity and makes it difficult for the patient to comply with treatment.⁸

While some studies have found that practices aimed at the quality of life of patients with HFS have increased the quality of life, some studies have found no effect on the quality of life.^{9,10} However, general quality of life scales such as the FACT-G questionnaire were used in these studies and general quality of life scales were not specifically designed for this population. In this sense, the quality of life scale developed specifically for HFS (HFS-14) is important in terms of measuring the effect on patients' activities of daily living.⁵ The best way to determine quality of life in individuals with HFS is to use population-specific measurement tools. Although there are few studies in the international

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literature on quality of life scales in individuals with HFS, no study was found on this subject in our country. Therefore, the aim of this study was to adapt the HFS quality of life scale, which was developed to determine the quality of life of individuals with HFS receiving chemotherapy, into Turkish and to determine its validity and reliability.

Materials and Methods

Design of the Research

A methodological design was used in the study.

Sample of the Research

The research was conducted in the Daytime Chemotherapy Unit of a University Hospital between August 01, 2016, and September 30, 2017. In the literature, it is stated that the sample size in scale adaptation studies can be taken as 3-10 times more than the number of items in the scale.^{11,12} In our research, the sample size was calculated by taking 6 times of each item to be measured. Since there were 17 items in the HFS-14 scale, the scale was applied to a total of 102 patients who agreed to participate in the study. Between August 01, 2016, and September 30, 2017, 110 cancer patients who were treated in the Chemotherapy Unit of the Research in a University Hospital and who met the inclusion criteria could be reached and 102 (92.7%) patients agreed to participate in the study. Inclusion criteria were (1) being diagnosed with cancer, (2) receiving outpatient cancer treatment, (3) having developed HFS, (4) being older than 18 years, (5) agreeing to participate in the study. Exclusion criteria were (1) diagnosed with psychiatric illness and (2) participants in another clinical study.

Data Collection Tools

H Patient Information Form

It is an information form prepared by the researcher based on the literature and includes demographic characteristics of the patient and information about the diagnosis and treatment.^{5,6,13-15}

National Cancer Institute Common Terminology Criteria for Adverse Events Version 4.03

Palmar-plantar erythrodysesthesia syndrome classification criteria in version 4.03 of the National Cancer Institute Common Terminology Criteria for Adverse Events toxicity criteria were used to evaluate HFS in the research.

Grade 1: Painless minimal skin changes or dermatitis (e.g., erythema, edema, or hyperkeratosis)

Grade 2: Painful skin changes (e.g., peeling, blistering, bullae, bleeding, edema, or hyperkeratosis) that interfere with ADL

Grade 3: Severe painful skin changes that limit self-care (e.g., peeling, blistering, bullae, bleeding, edema, or hyperkeratosis).

Hand-Foot Syndrome Scale-14

The scale is a 17-item quality of life scale developed by Sibaud et al⁵ in 2011 specific to HFS. The scale is a 3-point Likert-type measurement tool, but 1 item of the scale is related to the area affected by HFS (1, hands; 2, feet; 3, both), another item is related to pain (1, very painful; 2, moderately painful; 3, painless), and the last item is a visual analog scale related to pain (score 0-10). The total score is calculated by summing the scores of each item. The maximum score is 100 and the minimum score is 2 in the scale (14 items are scored between 0 and 6; 2 items are scored between 0 and 3; 1 item is scored between

0 and 10). A high score indicates a low quality of life. The scale has 3 subscales and the Cronbach's alpha values are 0.91, 0.92, and 0.93. The clinical validity of the scale was indicated by Dermatology Life Quality Index and Skindex-16 scale correlations. Moreover, HFS-14 scores were shown to be significantly higher in grade 2 and grade 3 groups than in the grade 1 group.⁵

Skindex-29

It is a scale developed to assess the quality of life of individuals with skin diseases. Skindex-29 includes 3 scales and 29 questions namely symptom (questions 1, 7, 10, 16, 19, 24, and 27), emotion (questions 3, 6, 9, 12, 13, 15, 21, 23, 26, and 28), and function (questions 2, 4, 5, 8, 11, 14, 17, 20, 22, 25, 29, and 30). Each question has options (never = 0, rarely = 25, sometimes = 50, often = 75, always = 100). In this scale, the 3 scales are calculated separately and then the overall total score is calculated. A higher score indicates a worse quality of life. It was adapted into Turkish by Aksu et al (2007)¹⁶ and the Cronbach alpha values are 0.94, 0.76, 0.88, and 0.92, respectively.

Examination of Psycholinguistic Properties (Language Validity)

The English version of the HFS-14 was translated into Turkish by following standard translation methodology. The English version of the scale was translated into Turkish by 2 native English speakers by using the standard "translation-back-translation" technique. The HFS-14 was retranslated from Turkish to English by a translator who was unaware of the English version and knew both languages very well. The English translation was then compared with the original English HFS-14 by 7 bilingual experts (2 oncologists, 2 specialized nurses, and 3 faculty members at a nursing faculty) who were not included in the study. They selected the most appropriate translation for each item or provided alternative translations to improve the items and determine the cultural appropriateness of the scale. Then, as the last step of the adaptation process, the scale was tested with pre-application. The pre-application was carried out with 10 patients, and as a result, the language and content validity of the tool was confirmed. In this pre-application, it was determined that the questions could be understood and no changes were made. Permission to use the scale was obtained from the authors before starting the research.

Ethical Aspects of the Research

This research was conducted in accordance with the principles of Good Clinical Practices and the Declaration of Helsinki. Permission to translate and use the HFS-14 into Turkish was granted by Vincent Sibaud, who developed the scale. In addition to the permission of Akdeniz University Department of Medical Oncology, ethics committee approval was obtained from Akdeniz University Clinical Research Ethics Committee (Decision No: 285 Decision Date: 18.05.2016). Patients who met the inclusion criteria were informed verbally and in writing, and written informed consent was obtained from those who agreed to participate.

Data Analysis

The data obtained from the study were analyzed using Statistical Package for Social Science (SPSS) 22.0 and SPSS Amos 22 package programs. In the analysis of the data, number and percentage were used to evaluate the descriptive information of the patients; "translation-back translation" method was used for language validity; expert opinion was used to evaluate content validity; lower-upper group means (*t*-test) were used to evaluate criterion validity; explanatory

and confirmatory factor analysis was used to evaluate structure validity, and the Cronbach alpha coefficient calculation was used to evaluate internal consistency. In addition, Pearson correlation test was performed and Skindex-29 scale was used for referential validity.

Results

A total of 51.96% of the patients who participated in the research were male and their mean age was 58.52 ± 9.75 years. It was seen that most of them were married (87.25%) and primary school graduates (57.84%), and 39.22% of them were retired and 33.33% of them were housewives when the employment status was considered. All of the patients had general health insurance and 45.10% of them had an income equivalent to their expenses. Almost all of the patients (96.08%) received only chemotherapy treatment and 54.90% of them had grade 1 toxicity (Table 1).

Content Validity

Seven experts were consulted for their opinions to determine the content validity of the scale. The experts were asked to give scores for each of the questions and to indicate their suggestions about the scale, if any. Following the expert opinions, Kendall Coefficient of Concordance (W^a) correlation test was performed to determine the content validity of the HFS-14 scale. According to the table, the Kendall W^a coefficient of concordance correlation test was found to be insignificant at $P > .05$ level (Kendall $W^a = 0.24, P = .61$). This result showed that the expert opinions on the comprehensibility and applicability of the scale were statistically compatible with each other.

Structure Validity

The Kaiser-Meyer-Olkin Measure of Sampling Adequacy (KMO-MSA) measure of sampling adequacy was 0.804, and it was above the recommended value (0.6).¹² Based on this finding, it was concluded that the dataset was suitable for identifying subcomponents through exploratory factor analysis. When the result of Barlett's test of sphericity was analyzed, the P value was found to be .00. This value indicated that the items in the scale were related to each other and that the subscales of the scale effectively measured the purpose to be measured. The 14 items of the HFS-14 were analyzed using varimax rotation and 3-factor delimitation method since the original scale consisted of 3 dimensions. The subgroups with eigenvalues of 5.072, 1.856, and 1.516 were shown in the total variance explained table and in screen plot analysis (Table 2 and Figure 1). The factors explained 60.31% of the total variance. When the subscales were analyzed, it was seen that the first factor explained 36.23% of the total variance, the second factor explained 13.26% of it, and the third factor explained 10.83% of it, respectively. After determining the number of subscales, the factors under which the scale items were grouped were examined. The factor loadings and factor distributions of the scale items as well as the distribution and factor loadings of the scale items according to the subscales are given in Table 2. As a result, when Table 2 is examined, as in the original scale, there are 3 subscales in the Turkish version of the scale, and the first subscale includes items 1, 2, 3, 4, 6, 7, 8; the second subscale includes items 9, 10, 11; and the third subscale includes items 5, 12, 13, 14.

The chi-square/degrees of freedom of the HFS-14 scale was found to be 2.00 (CMIN/DF < 5) and the P value was found to be .00. This value is in accordance with the good fit value. The root mean square error of approximation (RMSEA) value was found to be 0.10. The goodness

Table 1. Sociodemographic and Clinical Characteristics of Patients (n=102)

| Variables | n | % | |
|--|------------------------------|--|-------|
| Gender | Female | 49 | 48.04 |
| | Male | 53 | 51.96 |
| Age* (n=102) | | 58.52 ± 9.75 | |
| Education | Primary school | 59 | 57.84 |
| | Secondary school | 8 | 7.84 |
| | University | 17 | 16.67 |
| | Master's degree and higher | 18 | 17.65 |
| Marital status | Single | 13 | 12.75 |
| | Married | 89 | 87.25 |
| Occupation | Housewife | 34 | 33.33 |
| | Civil servant | 8 | 7.84 |
| | Retired | 40 | 39.22 |
| | Laborer | 10 | 9.80 |
| | Farmer | 5 | 4.90 |
| | Self-employed | 5 | 4.90 |
| | Residence | Province | 59 |
| District | 36 | 35.29 | |
| Village | 7 | 6.86 | |
| Support status | Alone | 3 | 2.94 |
| | Family | 99 | 97.06 |
| Social security | General health insurance | 102 | 100.0 |
| | Private health insurance | 0 | 0.0 |
| Economic status | Income less than expense | 41 | 40.20 |
| | Income equivalent to expense | 46 | 45.10 |
| | Income more than expense | 15 | 14.71 |
| Diagnosis | Colorectal cancer | 20 | 19.61 |
| | Stomach cancer | 3 | 2.94 |
| | Breast cancer | 20 | 19.61 |
| | Ovarian cancer | 15 | 14.71 |
| | Lung cancer | 33 | 32.35 |
| | Pancreatic cancer | 1 | 0.98 |
| | Liver cancer | 2 | 1.96 |
| | Prostate cancer | 5 | 4.90 |
| | Bladder cancer | 2 | 1.96 |
| | Lymph cancer | 1 | 0.98 |
| | Treatment protocol | Chemotherapy (capecitabine, paclitaxel, docetaxel, 5-fluorouracil, cisplatin, and oxaliplatin) | 98 |
| Targeted therapy (bevacizumab) | | 1 | 0.98 |
| Combination of chemotherapy and targeted therapy | | 3 | 2.94 |
| NCI-CTCAE* (n=102) | | Grade 1 | 56 |
| Grade 2 | 35 | 34.31 | |
| Grade 3 | 11 | 10.78 | |

*Data are expressed as mean ± standard deviation. NCI-CTCAE, National Cancer Institute Common Terminology Criteria for Adverse Events.

| Items | Factor (Varimax Rotated) | | | Communalities |
|---|--------------------------|--------|--------|---------------|
| | 1 | 2 | 3 | |
| (2) I find it hard to prepare my meals because of my hand-foot syndrome | 0.734 | | | 0.698 |
| (8) I have difficulty putting on my shoes because of my hand-foot syndrome | 0.696 | | | 0.647 |
| (7) I take longer than usual to get dressed because of my hand-foot syndrome | 0.692 | | | 0.592 |
| (6) I find it hard to put on my stockings/tights (or my socks) because of my hand-foot syndrome | 0.691 | | | 0.632 |
| (1) I find it hard to turn the key in my door because of my hand-foot syndrome | 0.683 | | | 0.494 |
| (4) I have difficulty washing myself, putting on makeup (or shaving) because of my hand-foot syndrome | 0.610 | | | 0.537 |
| (3) I have difficulty performing everyday actions because of my hand-foot syndrome | 0.594 | | | 0.418 |
| (10) I have difficulty walking, even over quite short distances, because of my hand-foot syndrome | | 0.873 | | 0.805 |
| (9) It is hard for me to stand because of my hand-foot syndrome | | 0.853 | | 0.764 |
| (11) I tend to stay seated or lying down because of my hand-foot syndrome | | 0.833 | | 0.807 |
| (13) My work is suffering because of my hand-foot syndrome | | | 0.889 | 0.804 |
| (14) My relationships with others are less amicable because of my hand-foot syndrome | | | 0.692 | 0.523 |
| (12) I find it hard to fall asleep because of my hand-foot syndrome | | | 0.676 | 0.565 |
| (5) I find it hard to drive my car because of my hand-foot syndrome | | | 0.378 | 0.157 |
| Eigenvalues | 5.072 | 1.856 | 1.516 | |
| Variance explained (%) | 36.229 | 13.256 | 10.829 | 60.314 |

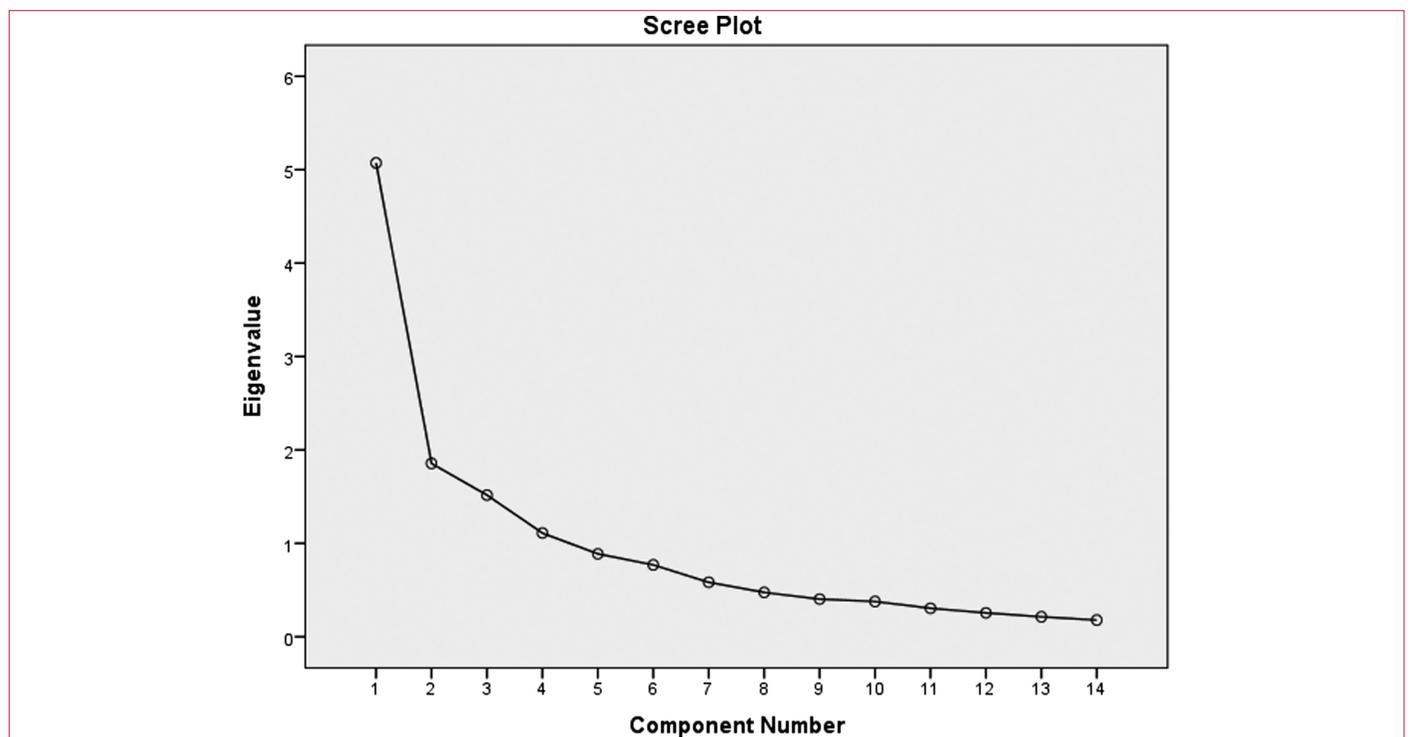


Figure 1. Showing the factor number with Scree plot analysis.

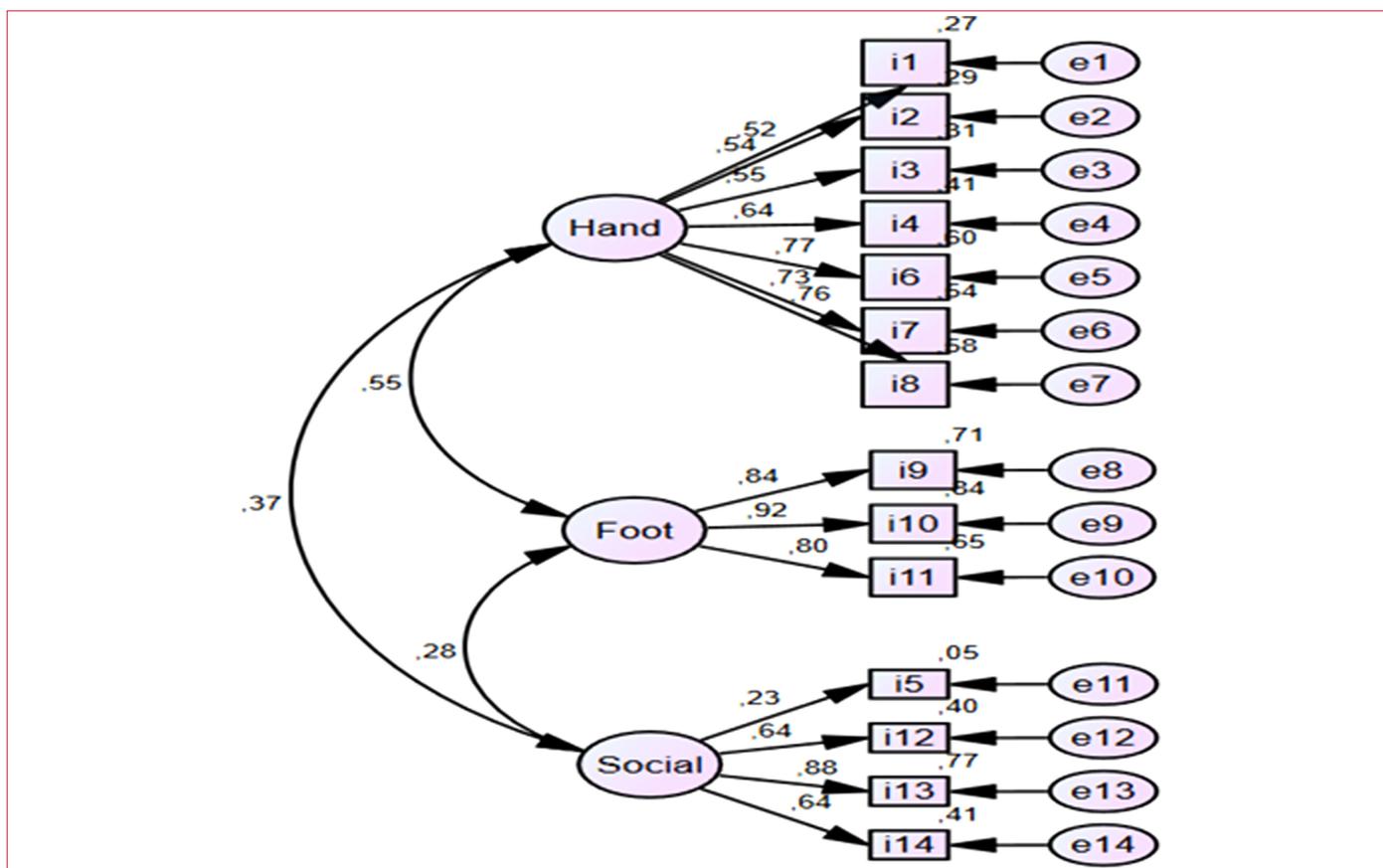


Figure 2. Confirmatory factor analysis identified for hand-foot syndrome scale14.

| Scales | Mean (SD) | Cronbach's Alpha |
|---------------------|----------------------|------------------|
| HFS-14 hand | 13.39 (9.22) | 0.84 |
| HFS-14 foot | 7.47 (5.06) | 0.89 |
| HFS-14 social | 5.67 (3.96) | 0.67 |
| HFS-14 total | 33.60 (17.25) | 0.86 |

SD, standard deviation.
HFS-14, hand-foot syndrome scale-14; SD, standard deviation.

of fit index (GFI) value was found to be 0.83. The comparative fit index (CFI) value was found to be 0.87. The normed fit index (NFI) value was found to be 0.78 (Figure 2).

Internal Consistency Validity

When the Cronbach alpha coefficient values of the HFS-14 Scale were examined, it was observed that the total Cronbach alpha value of the scale was 0.86, and the Cronbach alpha values of the subscales were 0.84, 0.89, and 0.67, respectively. The Turkish version of the scale met acceptable internal reliability standards (Table 3).

For item analysis based on upper-lower group means, 27% of the upper part of the scale score distribution was determined as the

upper group and 27% of the lower part was determined as the lower group. It was seen that the difference between the mean item scores in the upper and lower groups of the Turkish version of the HFS-14 scale was statistically significant ($t = -16.11, P = .00$).

Validity of the Hand-Foot Syndrome Scale-14 According to a Reference

In our research, the validity of the HFS-14 Scale according to a reference was determined by convergent validity. Convergent validity is evaluated by the correlation coefficient obtained by applying a measurement tool with known validity and a new measurement tool to the measurement group.¹⁷ In order to determine the convergent validity, the mutual correlations of the HFS-14 scale and the Scindex-29 scale were examined. There was a strong positive correlation ($r = 0.75$) between the HFS-14 scale and the Skindex-29 scale. The correlation was found to be statistically significant ($P < .01$). In addition, when the total scores of HFS-14 and Skindex-29 scales were compared according to NCI-CTCAE toxicity criteria, a significant difference was found between the 3 groups according to their clinical grades ($F = 54.483, P = .00; F = 36.856, P = .00$) (Table 4).

Discussion

With this study, the psychometric properties of the Turkish version of the HFS-14 scale were determined, and a comparison with the Skindex-29 which is a dermatology-specific quality of life scale was

| | Grade | | | | | | F | P |
|---------------|---------|---------------|---------|---------------|---------|---------------|--------|-------------|
| | Grade 1 | | Grade 2 | | Grade 3 | | | |
| | n | Mean (SD) | n | Mean (SD) | n | Mean (SD) | | |
| HFS-14 total | 56 | 27.02 (10.86) | 35 | 43.77 (12.44) | 11 | 65.27 (16.64) | 54.483 | .000 |
| Skindex total | 56 | 24.26 (8.66) | 35 | 31.33 (10.11) | 11 | 51.10 (12.28) | 36.856 | .000 |

HFS-14, hand-foot syndrome scale-14; SD, standard deviation.

made. The results showed that this scale had acceptable properties for the assessment of quality of life in cancer patients with HFS.

The International Test Commission guidelines were used in the adaptation of the HFS-14 scale into Turkish.¹⁸ It was emphasized that linguistic, psychological, and cultural differences should be taken into account in the translation process, appropriate translation designs and procedures should be used to improve the appropriateness of the scale adaptation, and a pilot study should be conducted with the adapted scale.¹⁸ Accordingly, while developing the Turkish version of the HFS-14 scale, a translation-back translation process was carried out. The translators took into account the inherent differences in the general linguistic structure of English and Turkish, which required an item change beyond translation. Adapting an existing instrument for cross-cultural use requires consideration of cultural and environmental characteristics in addition to language translation. The authors took these approaches into account to strengthen the integrity of the translation process and to achieve the goals of cultural and functional equivalence.

Seven experts were consulted for their opinions to determine the content validity of the scale. It was emphasized that evidence should be provided that the scale items have a similar meaning for all intended populations, and statistical evidence should be provided regarding structure equivalence, method equivalence, and item equivalence.¹⁸ In our research, 7 experts were consulted for their opinions and content validity was confirmed with the obtained results (Kendall $W^a = 0.24, P = .61$).

In our study, Skindex-29, whose validity and reliability were conducted by Aksu et al (2007), was used to determine validity according to a reference. The Turkish version of the HFS-14 scale and Skindex-29 have a strong positive correlation ($r = 0.75$) with each other. In validity and reliability studies of the scale in other languages, Skindex-16 was preferred as a reference scale and a positive correlation was found.^{5,6} Skindex-29 is a dermatology-specific scale whose validity and reliability were conducted in our country and this scale was used as a reference scale to ensure the closest possible similarity. It was also shown that the HFS-14 score may differ between groups with different HFS severity (according to NCI-CTCAE toxicity criteria) ($F = 54.483, P = .00$).

In our study, the KMO-MSA value was found to be 0.80, which was a good value. This value showed that the scale was highly adequate in measuring the intended situation and that the sample size was sufficient for factor analysis. When the results of Barlett's test of sphericity were examined, the P value was found to be .00 and this value showed that the items in the scale were related to each other and that the subscales of the scale effectively measured the intended

purpose. As a result of the factor analysis, it was found that the scale structure consisted of 3 subscales and the rate of explaining the total variance was 60.31%. In the guidelines, it is emphasized that factor analysis should be performed to ensure structure validity and the fact that how it is performed should be reported. In addition, it was stated that it should be performed with an appropriate sample (it was performed with 102 patients) with appropriate characteristics and sufficient number for the analysis.¹⁸ In addition, it is stated in the literature that the sample size in scale adaptation studies can be 3-10 times more than the number of items in the scale.^{11,12} According to the results obtained in the light of all this information, the structural validity of the scale was confirmed.

The chi-square/degrees of freedom of the HFS-14 scale was found to be 2.00 and this value is in accordance with the good fit value. The RMSEA value was found to be 0.10 in our research and this value is required to be $RMSEA \leq 0.08$. Goodness of fit index, CFI, and NFI values were found to be 0.83, 0.87, and 0.78, respectively. These 3 values are required to be ≥ 0.90 . These results show that the scale model created by exploratory factor analysis is close to the original scale model.

The internal consistency of the scale was estimated by Cronbach alpha coefficient. The Cronbach alpha coefficient of the HFS-14 was 0.86 and indicated good internal consistency. Furthermore, it was seen that all subscales had acceptable reliability coefficients ($\alpha = 0.67-0.89$). In other studies, Cronbach alpha coefficient was found to be between 0.91 and 0.95.^{5,6} The results are similar to those of the original study. It was also emphasized that the method for evaluating internal consistency and for calculating Cronbach alpha value can be used.¹⁸ In the light of this information, according to our results, the internal consistency of the measurement tool was confirmed.

The results above show that the Turkish version of the HFS-14 is a valid and reliable tool for the assessment of quality of life in patients with HFS.

Limitation

The limitation of this research is that the generalizability of the results of the study may be limited because the samples were collected from a single center in Turkey.

Conclusion

In conclusion, according to the validity and reliability analyses, this study showed that the Turkish version of the HFS-14 scale had a structure with 3 subscales and that the scale was valid and reliable in this form. It is suggested that this scale adapted to the Turkish

population can be used as a valid and reliable instrument to measure quality of life in cancer patients who receive chemotherapy and targeted therapy and develop HFS. In addition, the scale can be used in descriptive studies to determine the quality of life in cancer patients who develop HFS and can also be used as a pretest and posttest measurement tool to evaluate the effectiveness of interventions to prevent/reduce HFS.

Ethics Committee Approval: Ethics committee approval was received for this study from Akdeniz University Clinical Research Ethics Committee (Decision no: 285, Decision date: 18.05.2016).

Informed Consent: Written informed consent was obtained from all participants who participated in the study.

Peer-review: Externally peer-reviewed.

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