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Original Article

Translation and Psychometric Evaluation of the Profile of Fatigue and Discomfort—Sicca Symptoms Inventory (Short Form) for Patients with Primary Sjögren's Syndrome: Validity and Reliability Analysis of the Turkish Version

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Abstract

Background: The study aimed to translate the Profile of Fatigue and Discomfort—Sicca Symptoms Inventory Short Form questionnaire into the Turkish language (PROFAD-SSI-SF-T) and to investigate its psychometric properties.

Methods: The study was completed by 104 patients with primary Sjögren's syndrome (pSS), and 83 patients filled out the scale a second time after 7 days for the retest measurement. The PROFAD-SSI-SF-T, Functional Assessment Chronic Illness Therapy (Fatigue) (FACIT-F), EULAR Sjögren's Syndrome Patient Reported Index (ESSPRI), European Quality of Life 5 Dimensions (EQ-5D), and Patient Global Assessment (PaGA) were applied to 104 patients with pSS for convergent validity.

Results: PROFAD-SSI-SF-T found excellent internal consistency (Cronbach's $\alpha = 0.935$) and high test–retest reliability (ICC: 0.83; 95% CI: 0.75-0.88). The standard error of measurement ranged from 1.01 to 3.52, and the minimum detectable difference ranged from 0.92 to 1.17. There was a range from low to high correlation between the PROFAD-SSI-SF-T with ESSPRI, FACIT-F, and EQ-5D. There were no floor and ceiling effects in the PROFAD-SSI-SF-T scale.

Conclusion: The PROFAD-SSI-SF-T is a valid and reliable scale to evaluate fatigue, discomfort, and sicca symptoms in Turkish patients with primary Sjögren's syndrome.

Keywords: Sjogren's syndrome, fatigue, validity and reliability, questionnaire, Turkish

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Introduction

Primary Sjögren's syndrome (pSS) is an autoimmune disease that features lymphocytic infiltration and progressive deterioration of exocrine glands. The prevalence ranges from 0.03% to 2.7% of the population.[1] The disease can present with systemic involvement, such as neuropathy and vasculitis, as well as the involvement of the skin, lungs, and kidneys. Clinical symptoms can be divided into 2 categories: primary symptoms, which are common and affect most patients, such as dryness (mouth, eyes, etc.), pain, and fatigue. Secondary symptoms affecting approximately 20%-40% of patients can be severe systemic findings.[1,2]

Fatigue is described as a feeling of overwhelming tiredness, energy deficiency, and exhaustion, and it is the leading cause of functional impairment in patients with pSS. Patients acknowledge fatigue as a significant symptom that needs to be managed. Fatigue in pSS leads to reduced physical activity, mental health, and sleep problems, depression, and loss of workability, culminating in poor quality of life.[3,4] According to population-based studies, around 20% of healthy individuals document fatigue, and this percentage increases to 60%-70% in individuals with autoimmune disorders. Fatigue is a common non-exocrine symptom among pSS patients, with a reported prevalence of 70%.[5]

The Fatigue Assessment Scale (Fatigue) (FACIT-F), used to evaluate fatigue in pSS patients, is also in many other diseases.[6] Other questionnaires include the Short Form-36, the EULAR Sjögren Syndrome Patient Report Index (ESSPRI), and Fatigue Severity Scale.[2,7,8] However, despite the importance of fatigue in pSS

being emphasized in studies, most of the fatigue evaluation tools used are not specific to pSS. Bowman et al therefore developed the Profile of Fatigue and Discomfort—Sicca Symptoms Inventory (PROFAD-SSI) to evaluate multidimensional fatigue in pSS patients while capturing other dimensions of the disease. The PROFAD-SSI is scored on an 8-item Likert scale, between 0 and 7, and consists of 64 questions that evaluate the patient in 8 different subgroups, including somatic fatigue, vascular dysfunction, cognitive fatigue, arthralgia, oral, ocular, vaginal, and cutaneous dryness.[9,10] However, the PROFAD-SSI was found to be difficult and lengthy for patients, particularly when utilized as an outcome evaluation instrument in clinical studies. Therefore, the same colleagues developed a shorter version of the PROFAD-SSI (PROFAD-SSI-SF) with 19 items. However, these 19 items are still grouped into the same 8 subgroups.[11]

Patient-reported outcome measures (PROMs) are mostly utilized in daily practice and sine qua non in clinical trials. These tools are universally accepted as having an important role in perceiving patients' own health and disability status. Moreover, PROMs are particularly useful in clinical studies, as they take less time and are easy to evaluate.[12] A valid instrument is undoubtedly needed to assess the effects of fatigue and sicca symptoms of Turkish pSS patients. Therefore, the objective of the study was to analyze its psychometric properties, including internal consistency, intraclass correlation coefficient, and convergent validity, using a comprehensive statistical analysis.

Materials and Methods

The study was approved by the Gazi University Ethics Commission (Approval No: E-77082166-604.01.02-27470 Date: January 26, 2021). An informed consent form was obtained from every patient, and the present study adhered to the Declaration of Helsinki. The study was also registered on ClinicalTrials.gov (NCT number: NCT04975087).

Main Points

- There are no structured specific instruments for evaluating fatigue and sicca symptoms involvement in patients with pSS.
- There is a necessity for Turkish versions of scales and scoring that assess patients with pSS.
- PROFAD-SSI-SF-T is a reliable and valid instrument to evaluate fatigue and sicca symptoms in patients with pSS.

Translation and Cross-cultural Adaptation

For the translation and psychometric properties of the Turkish version of the PROFAD-SSI-SF (PROFAD-SSI-SF-T) scale, permission was obtained from the scale developer.[11] The cultural adaptation and translation process of the PROFAD-SSI-SF scale was carried out in 5 stages suggested by Beaton et al.[13]

Stage 1: Initial Translation

The PROFAD-SSI-SF was translated from English to Turkish by 2native Turkish speakers. One of them was an English linguistic scientist unfamiliar with the study, and the other translator was a physiotherapist familiar with the study.

Stage 2: Synthesis of the Translations

The Turkish translations were synthesized and converted into a single translation.

Stage 3: Back Translation

The synthesized Turkish translation was translated back to English by 2 independent bilingual translators unfamiliar with the study.

Stage 4: Expert Committee

The two Turkish-to-English translations were synthesized and integrated into a single translation.

Stage 5: A Test of the Prefinal Version

A pilot study was tested with 40 participants (20 healthy subjects and 20 pSS patients) to assess comprehensibility. The final version of the PROFAD-SSI-SF scale was obtained (Supplementary Material).

Patients

One hundred four patients with pSS (96 females and 8 males), who were diagnosed according to the 2016 ACR/EULAR classification criteria for pSS criteria,[14] were included in the present study. Inclusion criteria for patients in the present study were: (1) having a diagnosis of pSS; (2) being over the age of 18; (3) having Turkish as a first language; and (4) volunteering. Exclusion criteria for patients were: (1) having other rheumatic diseases; (2) being illiterate; and (3) having cognitive impairment. The demographic characteristics of participants were recorded. Each participant was requested to fill out the PROFAD-SSI-SF-T, FACIT-F, ESSPRI, The EuroQol 5 Dimension (EQ-5D), and Patient Global Assessment (PaGA). In addition, for the assessment of test–retest reliability, 83 patients with a stable health conditions were asked to fill in the scale for the second time 7 days after the first evaluation.

Outcome Measures

Profile of Fatigue and Discomfort—Sicca Symptoms Inventory (Short Form)

The PROFAD-SSI-SF has 19 items with 8 domains. The PROFAD has 9 items divided into 4 subgroups: somatic fatigue, mental fatigue, arthralgia, and vascular dysfunction, and the SSI has 10 items divided into 4 subgroups: oral, ocular, cutaneous, and vaginal dryness. The items are graded from no problem at all (0 scores) to as bad as imaginable (7 scores) on an 8-score. The PROFAD-SSI-SF scale has been demonstrated to have a significant correlation across all subgroups. In addition, there is a similar high reliability to the PROFAD-SSI long form (PROFAD-SSI-LF).[9] The PROFAD-SSI-SF has the advantage that it is shorter and more useful to clinicians for the evaluation of patients; hence, the scale decreases the document burden on patients. A lower score shows much better symptoms. The scale evaluates the last 2 weeks.[11]

Functional Assessment Chronic Illness Therapy (Fatigue)

The FACIT-F, which is used for the assessment of rheumatologic diseases such as pSS, osteoarthritis, and rheumatoid arthritis, is a self-reported scale with 13 items. The questionnaire assesses fatigue in activities of daily living: physical, functional, emotional, and social consequences of fatigue. Each item is scored on 5 responses between "Not at all" and "Very much," with 2 positive items reverse scored. The scale measures the past 7 days. An increasing score indicates worse global fatigue. The questionnaire is easy to use in clinic assessment.[15]

EULAR Sjögren's Syndrome Patient Reported Index

The ESSPRI, a self-reported scale, assesses symptom severity, including complaints of pain, fatigue, and global dryness (ocular, skin, oral, nasal, vaginal, etc.) in patients with SS. Each item independently presents the severity of the different symptoms. The scale is scored 0-10 numerical scale for each item. A zero score shows no symptoms; however, a score of 10 shows the highest symptoms. In this regard, a higher score shows a higher level of symptoms, and the measure assesses the past 2 weeks. If the ESSPRI score is lower than 5, it is considered an acceptable disease status; however, if its score is higher than 5, it indicates worsened disease activity.[16]

The European Quality of Life 5 Dimensions

The EQ-5D is a 5-item questionnaire that examines individuals' quality of life. These 5 items consist of mobility, personal care, pain/

discomfort, usual activities, anxiety, and depression. Each item is evaluated separately and has 3 standard responses: "I do not experience difficulty," "I experience moderate difficulty," and "I experience extreme difficulty." In addition, a final item scored between 0 and 100 numerical scale assesses individual's current health status in the questionnaire. The closer the scores to 100, the better the health status is.[17]

Patient Global Assessment

The PaGA assessment was evaluated using a 0-10 cm numerical scale, where higher PaGA values indicate more severe disease activity.[18]

Statistical Analysis

Statistical analyses were conducted utilizing the Statistical Package for the Social Sciences (SPSS®) version 22.0 (IBM SPSS Corp., Armonk, NY, USA). Post hoc power analysis for the sample size of the current study was analyzed using G*Power 3.1.9.2 software. The correlation coefficient between the PROFAD-SSI-SF-T total score and FACIT-F score was chosen for post hoc analysis. The power of the study (1-β) was found to be 84.2% (correlation ρ H1= 0.5, α = 0.05; total sample size = 104; lower and upper critical r = −0.16 and 0.16).

To assess the normality of the data, the Kolmogorov–Smirnov test was employed. Data were shown as mean and standard deviation (SD) as being normally distributed. The psychometric properties of the PROFAD-SSI-SF-T (internal consistency, intraclass correlation coefficient, and test–retest reliability) were investigated. All values were regarded as statistically significant at $P < .05$.[19]

Reliability

Internal consistency and test–retest reliability analysis were reported to investigate the reliability of PROFAD-SSI-SF. Intraclass correlation coefficient (ICC) (95% CI) was examined for the test–retest value. Intraclass correlation coefficient values were determined as very high between 0.90 and 1.00, high between 0.70 and 0.89, moderate between 0.50 and 0.69, low between 0.26 and 0.49, and very low between 0 and 0.25.[20] Internal consistency was examined with Cronbach's α. Cronbach's α of 0.80 or higher is stated as excellent.[21]

Reproducibility

Reproducibility (absolute reliability) was investigated using standard error of measurement (SEM) and minimal detectable difference (MDD) values. The SEM was evaluated with the formula of SD × $\sqrt{1-ICC}$.[21] The MDD was assessed with the formula of 1.96 × SEM × $\sqrt{2}$.[22]

Validity

Construct validity was evaluated through convergent validity. To demonstrate the correlation between PROFAD-SSI-SF and other inventories (FACIT-F, ESSPRI, EQ-5D, and PaGA), a Pearson correlation analysis was utilized and considered as very high between 0.90 and 1.00, high between 0.70 and 0.89, moderate between 0.50 and 0.69, low between 0.30 and 0.49, and negligible between 0 and 0.29.[23]

Floor and Ceiling Effects

In order to identify potential floor and ceiling effects, the proportion of patients attaining the lowest and highest scores was computed. If the percentages were greater than 15%, floor and ceiling effects were assumed to be acceptable.[24]

Results

Ninety-six (92.3%) of the participants were female, and 8 (7.7%) were male in the study. The average age of the patients was 53.83 ± 12.21, while the mean duration of the disease was 8.33 ± 7.62 years. Detailed demographic and clinical characteristics of pSS patients were provided in Table 1.

Table 1. Patient Characteristics in the Study

Characteristics	n (%) or Mean ± SD
Gender	
Female	96 (92.3)
Male	8 (7.7)
Age (years)	53.83 ± 12.21
BMI (kg/m²)	28.98 ± 6.26
Working status	
Employed	23 (22.1)
Not employed	81 (77.9)
Time since the diagnosis (years)	8.33 ± 7.62
Time since the symptom onset (years)	11.02 ± 11.18
Regular medication use	
Yes	86 (82.7)
Patient-reported outcomes	
FACIT-F	1.6 ± 0.9
PaGA	5.1 ± 2.5
EQ-5D	
Mobility	1.6 ± 0.4
Personal care	1.3 ± 0.4
Usual activities	1.7 ± 0.5
Pain	2.0 ± 0.6
Anxiety/depression	1.8 ± 0.6
ESSPRI	
Pain	5.3 ± 3.2
Fatigue	5.1 ± 3.0
Dryness	5.2 ± 2.9
Total score	5.2 ± 2.6

All correlations are statistically significant with $P < .001$.
BMI, body mass index; EQ-5D, The European Quality of Life 5 Dimensions; ESSPRI, EULAR Sjögren's Syndrome Patient Reported Index; FACIT-F, Functional Assessment Chronic Illness Therapy (Fatigue); PaGA, Patient Global Assessment.

Reliability

The internal consistency of 19-item PROFAD-SSI-SF-T was found excellent (Cronbach's α = 0.935). When each item of the scale was deleted, the Cronbach's α value of the scale was between 0.929 and 0.933. Indeed, all items were determined as contributing to the total Cronbach's α score (Table 2). Hence, the final form of the PROFAD-SSI-SF-T had 19 items, similar to the original version (Supplementary Material).

Test–re-test Reliability

Of all patients, 83 (79.8%) randomly selected patients completed PROFAD-SSI-SF-T 7 days after the first evaluation. Test–retest reliability (baseline: 12.9 ± 7.1 vs. retest: 12.7 ± 7.2) of PROFAD-SSI-SF-T was high (ICC: 0.83; 95% CI: 0.75-0.88). Moreover, test–retest reliability was reported to be 0.70 (95% CI: 0.58-0.80) for somatic fatigue, 0.82 (95% CI: 0.74-0.88) for the mental fatigue subgroup, 0.71 (95% CI: 0.59-0.80) for arthralgia subgroup, 0.66 (95% CI: 0.52-0.77) for vascular dysfunction subgroup, 0.73 (95% CI: 0.61-0.81) for the cutaneous dryness subgroup, 0.65 (95% CI: 0.49-0.79) for the vaginal dryness subgroup, 0.72 (95% CI: 0.60-0.81) for the ocular sicca subgroup, and 0.69 (95% CI: 0.56-0.79) for the oral sicca subgroup. According to the ICC values, PROFAD-SSI-SF-T subgroups have also high test–retest reliability (except for vascular dysfunction, vaginal dryness, and oral sicca subgroup because of moderate reliability) (Table 3).

Reproducibility

As a result of the reproducibility analysis, SEM was reported to range from 1.01 to 3.52, and MDD was reported to range from 0.92 to 1.17 (Table 3).

Convergent Validity

The correlation of the PROFAD-SSI-SF-T with FACIT-F (r = 0.71, $P < .001$) was high. The correlation of the PROFAD-SSI-SF-T with: EQ-5D pain (r = 0.57, $P < .001$); ESSPRI pain (r = 0.54, $P < .001$); ESSPRI fatigue (r = 0.61, $P < 0.001$); ESSPRI dryness (r = 0.60, $P < .001$); and ESSPRI total (r = 0.67, $P < .001$) were moderate. The correlation of the PROFAD-SSI-SF-T with EQ-5D

Table 2. Internal Consistency Analysis of the 19-item PROFAD-SSI-SF-T

Items	Mean	SD	Scale Variance if Item Deleted	Corrected Item–Total Score Correlation	Cronbach's α if Item Deleted
Item 1	3.77	2.34	990.570	0.595	0.932
Item 2	3.39	2.44	987.252	0.597	0.932
Item 3	3.63	2.28	979.799	0.695	0.931
Item 4	4.02	2.35	976.061	0.695	0.930
Item 5	2.97	2.56	972.398	0.657	0.931
Item 6	3.07	2.55	976.157	0.638	0.931
Item 7	4.42	2.24	988.323	0.654	0.931
Item 8	3.39	2.77	977.375	0.585	0.933
Item 9	3.06	2.77	965.238	0.643	0.931
Item 10	3.69	2.66	976.793	0.611	0.932
Item 11	2.56	2.74	976.951	0.587	0.933
Item 12	4.01	2.40	972.157	0.713	0.930
Item 13	2.85	2.58	977.543	0.627	0.932
Item 14	3.09	2.47	986.087	0.591	0.932
Item 15	2.41	2.66	975.875	0.614	0.932
Item 16	3.58	2.59	958.403	0.743	0.929
Item 17	2.12	2.43	995.091	0.545	0.933
Item 18	3.49	2.74	969.201	0.631	0.932
Item 19	2.70	2.66	968.720	0.655	0.931

Total Cronbach's α: 0.935.
PROFAD-SSI-SF-T, Profile of Fatigue and Discomfort—Sicca Symptoms Inventory (short form) Turkish.

mobility ($r=0.42$, $P < .001$); EQ-5D personal care ($r=0.31$, $P=.001$); EQ-5D usual activities ($r=0.37$, $P < .001$); and EQ-5D anxiety/depression ($r=0.39$, $P < .001$) were low. The correlation of the PROFAD-SSI-SF-T with PaGA ($r=0.22$, $P < .05$) was negligible. For investigating the validity of the correlation of its subgroups with other outcomes was analyzed and given in detail (Table 4).

Floor and Ceiling Effects

The vascular dysfunction, cutaneous dryness, and vaginal dryness subgroups showed a floor and ceiling effect. In addition, only the ceiling effect was found in the arthralgia subgroup (Table 3).

Discussion

The PROFAD-SSI-SF was translated into Turkish for the first time in the present study, and its psychometric properties were examined. Results of the present study adaptation and psychometric properties demonstrated that the PROFAD-SSI-SF-T indicated excellent reliability (internal consistency and ICC (95% CI), and there was no floor and ceiling effect (except vascular dysfunction, cutaneous, and vaginal dryness subgroups). The results showed that the PROFAD-SSI-SF-T had high validity for FACIT-F and, in addition, moderate validity for EQ-5D pain, ESSPRI pain, ESSPRI fatigue, ESSPRI dryness, and ESSPRI total score. However, the PROFAD-SSI-SF-T with EQ-5D mobility, personal care, usual activities, and anxiety/depression were low in validity.

The PROFAD-SSI-SF result (0.93) also supports the excellent internal consistency of the Turkish version, with the found Cronbach's α coefficient being similar to the original version (0.99) and the Brazilian version (0.80).[11,25] As the number of questions in the scale increases, Cronbach's α value increases. Indeed, if these items were deleted, Cronbach's α value decreases. Briefly, it is clearly shown that each item contributes to the scale. Therefore, we think that the scale assesses the symptoms of fatigue and sicca appropriately, thanks to its excellent internal consistency. Obtaining excellent internal consistency in a scale is significant for reliability in examining a specific disease.

Table 3. PROFAD-SSI-SF-T Descriptive Statistics. Internal Consistency and Test–Retest Reliability

Scores	Number of Items	Score Mean ± SD	Minimum	Maximum	Floor Effect (%)	Ceiling Effect (%)	Test–Retest Reliability ICC (95% CI (Lower–Upper Bound))	SEM	MDD
Somatic fatigue	4	3.7 ± 2.04	0	7	4.80	4.80	0.70 (0.58-0.80)	1.12	0.99
Mental fatigue	2	3.02 ± 2.3	0	7	14.42	7.69	0.82 (0.74-0.88)	1.01	1.16
Arthralgia	2	3.9 ± 2.2	0	7	6.73	14.42	0.71 (0.59-0.80)	1.23	1.00
Vascular dysfunction	1	3.05 ± 2.7	0	7	35.57	18.26	0.66 (0.52-0.77)	1.61	0.93
Cutaneous dryness	1	3.6 ± 2.6	0	7	22.11	22.11	0.73 (0.61-0.81)	1.39	1.03
Vaginal dryness	1	2.5 ± 2.7	0	7	42.30	11.53	0.65 (0.49-0.79)	1.62	0.92
Ocular sicca	3	3.3 ± 2.1	0	7	6.73	7.69	0.72 (0.60-0.81)	1.13	1.02
Oral sicca	5	2.8 ± 2.1	0	7	9.61	2.88	0.69 (0.56-0.79)	1.16	0.98
PROFAD	9	13.7 ± 7.8	0	28	1.92	0.96	0.80 (0.70-0.86)	3.52	1.13
SSI	10	12.3 ± 7.7	0	28	4.80	0.96	0.80 (0.70-0.86)	3.47	1.13
PROFAD-SSI-SF-T	19	12.9 ± 7.1	0	27.78	0.96	0.96	0.83 (0.75-0.88)	2.95	1.17

CI, confidence interval; ICC, intraclass correlation coefficient; MDD, minimal detectable difference; PROFAD-SSI-SF-T, Profile of Fatigue and Discomfort—Sicca Symptoms Inventory (short form) Turkish; SEM, standard error of measurement.

Table 4. Association of PROFAD-SSI-SF-T with Its Subgroups and Other Outcome Measures

		FACIT-F	PaGA	EQ-5D Mobility	EQ-5D Personal care	EQ-5D Usual Activities	EQ-5D Pain	EQ-5D Anxiety/depression	ESSPRI Pain	ESSPRI Fatigue	ESSPRI Dryness	ESSPRI Total score
Somatic fatigue (first)	*r*	0.78[a]	0.37[a]	0.41[a]	0.43[a]	0.37[a]	0.56[a]	0.49[a]	0.57[a]	0.65[a]	0.49[a]	0.66[a]
	P	<.001	<.001	<.001	<.001	<.001	<.001	<.001	<.001	<.001	<.001	<.001
Mental fatigue (first)	*r*	0.60[a]	0.13	0.38[a]	0.14	0.28[b]	0.41[a]	0.40[a]	0.32[b]	0.47[a]	0.41[a]	0.46[a]
	P	<.001	.181	<.001	.158	.004	<.001	<.001	.001	<.001	<.001	<.001
Arthralgia (first)	*r*	0.54[a]	0.22[b]	0.32[a]	0.32[b]	0.32[b]	0.61[a]	0.30[b]	0.61[a]	0.46[a]	0.32[b]	0.54[a]
	P	<.001	.028	.001	.001	.001	<.001	.002	<.001	<.001	.001	<.001
Vascular dysfunction(first)	*r*	0.56[a]	0.20[b]	0.37[a]	0.41[a]	0.36[a]	0.52[a]	0.37[a]	0.46[a]	0.52[a]	0.37[a]	0.53[a]
	P	<.001	.039	<.001	<.001	<.001	<.001	<.001	<.001	<.001	<.001	<.001
Cutaneous dryness (first)	*r*	0.49[a]	0.22[b]	0.41[a]	0.27[b]	0.28[b]	0.36[a]	0.29[b]	0.39[a]	0.44[a]	0.51[a]	0.51[a]
	P	<.001	.027	<.001	.005	.004	<.001	.003	<.001	<.001	<.001	<.001
Vaginal dryness (first)	*r*	0.35[a]	0.01	0.23[b]	0.08	0.17	0.30[b]	0.09	0.27[b]	0.27[b]	0.51[a]	0.41[a]
	P	<.001	.891	.021	.429	.100	.003	.401	.007	.008	<.001	<.001
Ocular sicca (first)	*r*	0.52[a]	0.08	0.21[b]	0.07	0.28[b]	0.37[a]	0.21[b]	0.32[b]	0.40[a]	0.43[a]	0.44[a]
	P	<.001	.411	.035	.463	.005	<.001	.033	.001	<.001	<.001	<.001
Oral sicca (first)	*r*	0.53[a]	0.12	0.16	0.14	0.20[b]	0.37[a]	0.23[b]	0.37[a]	0.49[a]	0.57[a]	0.55[a]
	P	<.001	.226	.099	.145	.039	<.001	.019	<.001	<.001	<.001	<.001
PROFAD (first)	*r*	0.74[a]	0.27[b]	0.45[a]	0.39[a]	0.40[a]	0.63[a]	0.47[a]	0.59[b]	0.63[a]	0.48[a]	0.66[a]
	P	<.001	.005	<.001	<.001	<.001	<.001	<.001	<.001	<.001	<.001	<.001
SSI (first)	*r*	0.57[a]	0.13	0.33[b]	0.17	0.27[b]	0.42[a]	0.25[b]	0.41[a]	0.48[a]	0.62[a]	0.58[a]
	P	<.001	.190	.001	.081	.005	<.001	.011	<.001	<.001	<.001	<.001
Total score (first)	*r*	0.71[a]	0.22[b]	0.42[a]	0.31[b]	0.37[a]	0.57[a]	0.39[a]	0.54[a]	0.61[a]	0.60[a]	0.67[a]
	P	<.001	.026	<.001	.001	<.001	<.001	<.001	<.001	<.001	<.001	<.001

EQ-5D, The European Quality of Life 5 Dimensions; ESSPRI, EULAR Sjögren's Syndrome Patient Reported Index; FACIT-F, Functional Assessment Chronic Illness Therapy (Fatigue); PROFAD-SSI-SF-T, Profile of Fatigue and Discomfort—Sicca Symptoms Inventory (short form) Turkish;PaGA, Patient Global Assessment.

[a] $P < .001$.

[b] $P < .05$.

Marx et al[26] emphasized that there was no statistical difference between 2 days and 2 weeks for health status tools. The PROFAD-SSI-SF-T was filled out by pSS patients again 7 days following the first assessment. There was a time interval of 2 days for the test–retest analysis of the Brazilian version. In the Brazilian version, Miyamoto et al[25] stated that the test–retest ICC value was high ($r=0.69$-0.85). The original PROFAD-SSI-LF version demonstrated ICC values ($r=0.67$-0.79), tested a day after the first evaluation.[9] Similarly, it was presented that the test–retest score of PROFAD-SSI-SF-T was high in the current study (ICC: 0.83; 95% CI: 0.75-0.88). Moreover, the test–retest scores of the subgroups were also found to be high.

Reproducibility provides information on the accuracy of repeated PROFAD-SSI-SF-T scores. The SEM and MDD are demonstrated in the same units as the original assessment instruments, hence they have clinical benefits. The SEM, which presents a range around the analyzing value, shows the size of the calculation error contained at a scale. The MDD gives a value for the minimum detectable difference. This value indicates whether the observed change is real and potentially an evaluation error. The original and Brazilian versions did not investigate the SEM and MDD values.[11,25] The current study was also the first one to investigate SEM and MDD. The low SEM and MDD reported in the current study showed that the PROFAD-SSI-SF-T was a sensitive measurement instrument to assess pSS patients.

Convergent validity was emphasized with significant correlations between PROFAD-SSI-SF-T and its mostly subscales with all the other scales. A high positive correlation between PROFAD-SSI-SF-T and FACIT-F; a moderate positive correlation between PROFAD-SSI-SF-T with EQ-5D mobility, EQ-5D pain, ESSPRI pain, ESSPRI fatigue, ESSPRI dryness, and ESSPRI total score; and a low positive correlation between PROFAD-SSI-SF-T with EQ-5D personal care, EQ-5D usual activities, and EQ-5D anxiety/depression were stated. The correlations of Brazilian PROFAD-SSI-SF-T with FACIT-F, EQ-5D mobility, EQ-5D pain, EQ-5D personal care, EQ-5D usual activities, EQ-5D anxiety/depression, ESSPRI pain, ESSPRI fatigue, ESSPRI dryness, and ESSPRI total score were assessed and significant correlations between low and moderate were reported.[25] A moderate correlation of PROFAD-SSI-LF-somatic fatigue with the SF-36 vitality subgroup and WHOQOL-BREF physical health subgroup was found. In addition, there was a low correlation between PROFAD-SSI-LF and all subgroups of EQ-5D.[9] Between the PROFAD-SSI-SF total score and all subgroups with the visual analog scale strong correlations.[11] The PaGA and EQ-5D personal care subgroups indicated a negligible correlation with the mostly subgroups of PROFAD-SSI-SF-T (mental fatigue, vaginal dryness, ocular sicca, oral sicca, and SSI). The PaGA and EQ-5D personal care subgroups indicated a negligible correlation with the most subgroups of PROFAD-SSI-SF-T (vaginal dryness, mental fatigue, ocular sicca, oral sicca, and SSI). However, these subgroups were found to have a low correlation in PROFAD-SSI-LF and the Brazilian version.[9,25] These scales do not have items evaluating similar activities or symptoms. The reason for these negligible correlations with both the PaGA and EQ-5D personal care subgroups and subgroups of PROFAD-SSI-SF-T (vaginal dryness, mental fatigue, ocular sicca, oral sicca, and SSI) scales can be explained in this way. Similar scales from other version studies were utilized in the study, and the convergent validity of PROFAD-SSI-SF-T was shown.

Floor and ceiling effects were shown for the first time in the scale in the present study because floor and ceiling effects were not investigated in the original and Brazilian versions.[11,25] The PROFAD-SSI-SF-T, whose floor and ceiling effects were calculated as 0.96% each, indicated there were no floor and ceiling effects. However, floor and ceiling effects were observed in the subgroups of vascular dysfunction, vaginal dryness, and cutaneous dryness. The fact that the present study did not find any floor or ceiling effect among the pSS patients, which is significant for the responsiveness and discriminative power of the PROFAD-SSI-SF-T for any evaluation.

The current study did not evaluate all assessment parameters of reliability and validity. Hence, additional studies are needed to assess other significant assessment parameters, such as responsiveness, which is examined by presenting minimal clinical differences. Another limitation is the absence of Rasch analysis in the current study.

The study indicated that the PROFAD-SSI-SF-T is a reliable tool for evaluating fatigue, discomfort, and sicca symptoms among Turkish patients with pSS. Moreover, it has also proven to be a proper research and clinical instrument tool.

Ethics Committee Approval: This study was approved by the Ethics Committee of Gazi University (Approval Nnumber: 2021-147; Date: January 26, 2021).

Informed Consent: Informed consent was obtained from the patients who agreed to take part in the study.

Peer-review: Externally peer-reviewed.

Author Contributions: Concept – F.S., A.T.; Design – F.S., S.B.; Supervision – F.S., D.O.; Resources – F.S., S.B., G.G.P.; Materials – F.S., G.G.P.; Data Collection and/or Processing – F.S., S.B., G.G.P.; Analysis and/or Interpretation – F.S.; Literature Search – F.S., A.T.; Writing – F.S.; Critical Review – D.O., A.T.

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Supplementary. Yorgunluk ve Rahatsızlık Profili – Sikka Semptomları Ölçeği (19 soru maddesi)

Lütfen, son iki hafta içerisinde her semptomun ne kadar kötü olduğunu 0'dan 7'ye kadar olan sayılardan birini seçerek değerlendirin.

1. Son iki hafta içinde; halsizlik, yorgunluk veya uyku problemi yaşadığım en kötü sorundur.
   sorun değil 0 1 2 3 4 5 6 7 hayal edemeyeceğiniz kadar kötü
2. Son iki hafta içinde; bir işi başlatmak devam ettirmek veya tamamlamak için çok çaba sarf ediyorum, kendimi "bir savaştaymış" gibi hissetmek yaşadığım en kötü sorundur.
   sorun değil 0 1 2 3 4 5 6 7 hayal edemeyeceğiniz kadar kötü
3. Son iki hafta içinde; bitkin ve enerjisiz hissetmek yaşadığım en kötü sorundur.
   sorun değil 0 1 2 3 4 5 6 7 hayal edemeyeceğiniz kadar kötü
4. Son iki hafta içinde; kaslarımı güçsüz veya kendimi halsiz hissetmek yaşadığım en kötü sorundur.
   sorun değil 0 1 2 3 4 5 6 7 hayal edemeyeceğiniz kadar kötü
5. Son iki hafta içinde; sağlıklı düşünememek veya konsantre olmakta zorlanmak yaşadığım en kötü sorundur.
   sorun değil 0 1 2 3 4 5 6 7 hayal edemeyeceğiniz kadar kötü
6. Son iki hafta içinde; unutkanlık veya hata yapmak yaşadığım en kötü sorundur.
   sorun değil 0 1 2 3 4 5 6 7 hayal edemeyeceğiniz kadar kötü
7. Son iki hafta içinde; kollarımdaki ve bacaklarımdaki rahatsızlık hissi yaşadığım en kötü sorundur. (örneğin: Büyük eklemlerinizdeki veya kaslarınızdaki (kalça, diz, omuz) rahatsızlık, ağrı, sızı veya yaygın vücut ağrısı vs.)
   sorun değil 0 1 2 3 4 5 6 7 hayal edemeyeceğiniz kadar kötü
8. Son iki hafta içinde; parmaklarımdaki ve el bileğimdeki ağrı ve şişlik yaşadığım en kötü sorundur.
   sorun değil 0 1 2 3 4 5 6 7 hayal edemeyeceğiniz kadar kötü
9. Son iki hafta içinde; ellerimdeki rahatsızlık ve soğukluk hissi yaşadığım en kötü sorundur.
   sorun değil 0 1 2 3 4 5 6 7 hayal edemeyeceğiniz kadar kötü
10. Son iki hafta içinde; kuru cilt veya ciltte kaşıntı yaşadığım en kötü sorundur.
    sorun değil 0 1 2 3 4 5 6 7 hayal edemeyeceğiniz kadar kötü
11. Son iki hafta içinde; vajinal kuruluk yaşadığım en kötü sorundur. (örneğin: vajinal kuruluk nedeniyle cinsel ilişki sırasında rahatsızlık)
    sorun değil 0 1 2 3 4 5 6 7 hayal edemeyeceğiniz kadar kötü
12. Son iki hafta içinde; göz ile ilgili problemler (kum kaçma/batma hissi, ağrı, yanma, kaşıntı veya tahriş) yaşadığım en kötü sorundur.
    sorun değil 0 1 2 3 4 5 6 7 hayal edemeyeceğiniz kadar kötü
13. Son iki hafta içinde; gözde tahriş (dumanlı ortamlarda gözlerin tahrişi, rüzgarlı, klimalı veya düşük nemli ortamlarda gözde rahatsızlık yaşanması) yaşadığım en kötü sorundur.
    sorun değil 0 1 2 3 4 5 6 7 hayal edemeyeceğiniz kadar kötü
14. Son iki hafta içinde; görme problemleri (bulanık ve zayıf görme, okuma, TV seyretme, gece araba kullanma, bilgisayar ekranına bakma veya banka ATM ekranına bakmada zorlanma veya kısıtlanma) yaşadığım en kötü sorundur. (gözlük kullanıyor olsa bile)
    sorun değil 0 1 2 3 4 5 6 7 hayal edemeyeceğiniz kadar kötü
15. Son iki hafta içinde; yemek yemede güçlük (yemek yerken ağız kuruluğu, yiyeceklerin zor yutulması, yiyecekleri yutmak için sıvı ihtiyacı, yiyecek kalıntılarını çalkalamaya ihtiyaç duymak, yiyeceklerden daha az tat almak) yaşadığım en kötü sorundur.
    sorun değil 0 1 2 3 4 5 6 7 hayal edemeyeceğiniz kadar kötü
16. Son iki hafta içinde; boğaz veya burun kuruluğu yaşadığım en kötü sorundur. (örneğin: nefes alırken ağız kuruluğu, ağız kuruluğu ile konuşmada güçlük çekilmesi, kolay konuşmak için bir içeceğe ihtiyaç duyulması, burun kuruluğu, boğaz kuruluğu, ağız kuruluğu).
    sorun değil 0 1 2 3 4 5 6 7 hayal edemeyeceğiniz kadar kötü
17. Son iki hafta içinde; ağız kokusu yaşadığım en kötü sorundur. (örneğin: nefesimin kötü kokması, yapışkan tükürük)
    sorun değil 0 1 2 3 4 5 6 7 hayal edemeyeceğiniz kadar kötü
18. Son iki hafta içinde; ağız kuruluğu nedeniyle sıvı ihtiyacımın artmış olması yaşadığım en kötü sorundur. (örneğin: yatak başına su götürmek, gece su içmek için uyanmak, gece tuvalete gitmek için uyanmak)
    sorun değil 0 1 2 3 4 5 6 7 hayal edemeyeceğiniz kadar kötü
19. Son iki hafta içinde; ağız-diş problemleri yaşadığım en kötü sorundur. (örneğin: ağız ülserleri, tükürük bezlerinde şişlik, ağız kuruluğundan dolayı boğuluyor hissi, tat alma sorunları, diş hekimine gitmek)
    sorun değil 0 1 2 3 4 5 6 7 hayal edemeyeceğiniz kadar kötü