Original article

Validation and psychometric properties of the EULAR Sjögren’s Syndrome Patient Reported Index (ESSPRI) into Brazilian Portuguese

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\textbf{A B S T R A C T}

Objective: To carry out the cross-cultural adaptation of EULAR Sjögren’s Syndrome Patient Reported Index (ESSPRI) for Portuguese language and evaluate its psychometric properties.

Method: Cross-sectional study of patients with primary Sjögren’s syndrome (SS). The psychometric properties (intraobserver reproducibility and construct validity) were studied. In construct validity, ESSPRI was compared with the Patient’s Global Assessment (PGA), Profile of Fatigue and Discomfort (Profad), Sicca Symptoms Inventory (SSI) and Functional Assessment of Chronic Illness Therapy (Facit-F). Statistical tests used were: Cronbach’s alpha, intraclass correlation coefficient (ICC), Bland–Altman method and Spearman coefficient. A value of $p \leq 0.05$ was considered significant.

Results: There was no difference between versions in both languages; thus, a Brazilian consensus version was obtained. All subjects were women aged 49.4 ± 11.6 years, with onset of symptoms of 7.2 ± 5.4 years, and time of diagnosis of 3.0 ± 3.3 years. The mean ESSPRI was 6.87 ± 1.97. The intraobserver reproducibility was high and significant (0.911) and, with Bland–Altman method, there was no systematic bias in the agreement of measures among evaluations. A moderate correlation of ESSPRI with all tested instruments was observed.

\textsuperscript{*} Study conducted at Department of Internal Medicine and Service of Rheumatology, Hospital Universitário Cassiano Antonio Moraes (HUCAM), Universidade Federal do Espírito Santo (UFES), Vitória, ES, Brazil.

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Conclusion: The Brazilian Portuguese version of ESSPRI is a valid and reproducible version.
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Validação e propriedades psicométricas do Eular Sjögren’s Syndrome Patient Reported Index (ESSPRI) para a língua portuguesa

RESUMO

Objetivo: Fazer a adaptação transcultural do Eular Sjögren’s Syndrome Patient Reported Index (ESSPRI) para a língua portuguesa e avaliar as suas propriedades psicométricas.

Método: Estudo transversal de pacientes com síndrome de Sjögren primária (SS). Foram estudadas as propriedades psicométricas (reprodutibilidade intraobservador e a validade de construto). Na validade de construto, o ESSPRI foi comparado com o Patient’s Global Assessment (PaGA), Profile of Fatigue and Discomfort (Profad), Sicca Symptoms Inventory (SSI) e Functional Assessment of Chronic Illness Therapy (Facit-fatigue). Os testes estatísticos usados foram o α-Cronbach, coeficiente de correlação intraclass (CCI), método de Bland-Altman e coeficiente de Spearman. Foi considerado significativo o p ≤ 0,05.

Resultados: Não houve diferença entre as versões nas duas línguas e obteve-se, assim, a versão consensual brasileira. Todos os indivíduos foram mulheres de 49,4 ± 11,6 anos, com início dos sintomas de 7,2 ± 5,4 anos e tempo de diagnóstico de 3 ± 3,3 anos. A média do Esspri foi de 6,87 ± 1,97. A reprodutibilidade intraobservador foi alta e significativa (0,911) e, no método de Bland-Altman, não houve viés sistemático na concordância das medidas entre as avaliações. Houve correlação moderada do Esspri com todos os instrumentos testados.

Conclusão: A versão do Esspri em português é válida e reprodutível.
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Introduction

Sjögren’s syndrome (SS) is an autoimmune, chronic syndrome with slow and progressive evolution. SS is considered as the second most common autoimmune rheumatic disease, affecting 0.17% of Brazilian population, similar to other European studies using the American-European criterion (2002) for diagnostic classification. SS is morphologically characterized by a lymphocytic infiltrate in salivary and lacrimal glands, but 20–40% of patients present extraglandular manifestations in musculoskeletal, pulmonary, gastrointestinal, hepatic, hematologic, vascular, dermatological, renal, and neurological systems.

Quality of life is impaired in different aspects: physical, psychological and social, as a result of dryness and extraglandular manifestations. Although SS is a prevalent disease with great impact, there is little evidence for its treatment. In the last decade, many new drugs, especially those pertaining to the class of biological agents, have been developed and it is expected that these drugs can be tested in this disease. In this context, the European League Against Rheumatism (EULAR) developed the EULAR Sjögren’s Syndrome Patient Reported Index (ESSPRI), a measuring instrument that has been used as an endpoint in clinical trials to evaluate the subjective perception of the patient with respect to the most important and frequent symptoms, such as fatigue, pain and dryness, and their impact on the disease. Previous instruments such as the Profile of Fatigue and Discomfort (PROFAD), the Sicca Symptoms Inventory (SSI) and the short version of the Profile of Fatigue and Discomfort – Sicca Symptoms Inventory (PROFAD-SSI) have the limitation of assessing only an aspect of this disease (only fatigue/pain, or only dryness), whereas ESSPRI gathered in a single composite index these three symptoms.

ESSPRI is completed by the patient and it contains just three items to be given an activity level score between 0–10: pain, fatigue and dryness, the final ESSPRI score is the mean of all three scores and therefore also between 0–10. ESSPRI was preliminary validated by a multicenter study in 2011 and 2014. This instrument has reproducibility = 0.94, and its sensitivity to change is low (−0.37), but significantly higher when compared to SSI (p = 0.006) and PROFAD (p = 0.049). After 16, 24, 36 and 60 weeks of treatment with rituximab, ESSPRI showed significant improvement (decrease of the patient’s symptoms) compared to the initial evaluation.

Currently, ESSPRI is being extensively used and has shown a correlation with quality of life and functional status measures, and can be considered a useful predictor of health status of patients with pSS.

The aim of this study was to carry out a cross-cultural adaptation of ESSPRI into Portuguese language and to evaluate its psychometric properties (Annex 1).

Patients and methods

This was a cross-sectional study approved by the Research Ethics Committee of the Health Sciences Center, Universidade Federal do Espírito Santo, under Opinion number 008/10 on February 24, 2010. All patients were informed about the objectives of this study and signed the an Informed Consent Form.
Patients

The study sample consisted of subjects with SS coming from the Sjögren’s Syndrome Outpatient Clinic, Rheumatology Department, Hospital Universitário Cassiano Antônio Moraes (HUCAM), in Vitória-ES.

Methods

Inclusion and exclusion criteria

Patients included fulfilled the following criteria: diagnosed with SS according to European-American Criteria (2002) for the classification of this disease; aged over 18 years old; and agreed to participate. Subjects with other autoimmune diseases, cirrhosis, sarcoidosis, known hepatitis C infection, acquired immunodeficiency syndrome, preexisting lymphoma, graft versus host disease; head and neck radiation in the past; and previous use of anticholinergic drugs, were excluded.

Domains and calculation of ESSPRI

The ESSPRI questionnaire consists of three items to be given an activity level score between 0–10: pain (joint and/or muscle pain), fatigue and dryness (0 = no symptom at all and 10 = worst symptom imaginable). The patient must check the alternative that best describes the severity of his/her symptoms in the worst stages in the last two weeks. Each domain represents the severity of the symptom independently; however, it is also possible to obtain a final score by averaging the scores of the three domains.

Although the instrument is self-administered, it was decided in this study to use only a face-to-face interview, in view of the low education level of participants.

Transcultural adaptation

To test the equivalence (conceptual, of the item, semantic and operational) of ESSPRI, an international methodology was followed to generate the consensus version into Portuguese, a method also used by other Brazilian authors.

Psychometric properties. The psychometric properties verified were: internal consistency, intraobserver reproducibility, and construct validity. To test reproducibility, ESSPRI was applied twice by the same observer (intraobserver evaluation), with an interval of 2 days between the first and the second evaluation, taking into account that this is an instrument based only on the subjective perception of the patient’s symptoms. To access construct validity, we studied the correlation power between ESSPRI and PROFAD, SSI, Functional Assessment of Chronic Illness Therapy (FACIT-F) and subjective perception of disease activity by the patient through the use of a visual scale (Patient’s Global Assessment – PGA).

Statistical analysis

To study the semantic equivalence, a sample of 20 patients was used. There is no mathematical formula for a sample calculation at this stage, and small samples are considered sufficient for this qualitative analysis. As for the study of psychometric measurement properties (validation and reproducibility), the sample was calculated based on the use of at least five patients per domain of the instrument. The minimum calculated sample was 15 patients.

To evaluate psychometric properties, the following analyzes were performed: (1) Cronbach’s alpha for internal consistency; (2) intraclass correlation coefficient (ICC) and the graphic method of Bland–Altman statistics for intraobserver reproducibility; (3) Spearman correlation coefficient of ESSPRI versus PGA, PROFAD, SSI and FACIT-F for construct validity.

In statistical analysis, the software SPSS 19.0 was used, and a p value ≤0.05 was considered significant.

Results

In the evaluation stage of semantic equivalence, a pre-test with the consensual version of ESSPRI (Table 1) was carried out. The test was applied to 20 patients and there were no “not

### Table 1 - Clinical and demographic characteristics of 62 patients with primary Sjögren syndrome.

<table>
<thead>
<tr>
<th>Variable</th>
<th>n (%)</th>
<th>Mean ± SD</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (years)</td>
<td>49.4 ± 11.6</td>
<td></td>
</tr>
<tr>
<td>&lt;50</td>
<td>25 (40.3)</td>
<td></td>
</tr>
<tr>
<td>≥50</td>
<td>37 (59.7)</td>
<td></td>
</tr>
<tr>
<td>Female gender</td>
<td>62 (100)</td>
<td></td>
</tr>
<tr>
<td>Elapsed time from early symptoms (years)</td>
<td>7.2 ± 5.4</td>
<td></td>
</tr>
<tr>
<td>&lt;1</td>
<td>4 (6.5)</td>
<td></td>
</tr>
<tr>
<td>1–5</td>
<td>25 (40.3)</td>
<td></td>
</tr>
<tr>
<td>&gt;5</td>
<td>33 (53.2)</td>
<td></td>
</tr>
<tr>
<td>Diagnostic time (years)</td>
<td>3.0 ± 3.3</td>
<td></td>
</tr>
<tr>
<td>&lt;1</td>
<td>16 (25.8)</td>
<td></td>
</tr>
<tr>
<td>1–5</td>
<td>40 (64.5)</td>
<td></td>
</tr>
<tr>
<td>&gt;5</td>
<td>6 (9.7)</td>
<td></td>
</tr>
<tr>
<td>Interval between symptoms and diagnosis (years)</td>
<td>4.3 ± 4.9</td>
<td></td>
</tr>
<tr>
<td>&lt;1</td>
<td>18 (29)</td>
<td></td>
</tr>
<tr>
<td>1–5</td>
<td>27 (43.6)</td>
<td></td>
</tr>
<tr>
<td>&gt;5</td>
<td>17 (27.4)</td>
<td></td>
</tr>
<tr>
<td>Systemic manifestations in last visit</td>
<td>29 (46.8)</td>
<td></td>
</tr>
<tr>
<td>Systemic manifestations in previous visits</td>
<td>38 (61.3)</td>
<td></td>
</tr>
<tr>
<td>Inactive disease</td>
<td>29 (46.8)</td>
<td></td>
</tr>
<tr>
<td>Active disease</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Low activity</td>
<td>24 (38.7)</td>
<td></td>
</tr>
<tr>
<td>Moderate activity</td>
<td>9 (14.5)</td>
<td></td>
</tr>
<tr>
<td>Clinical features:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Objective xerophthalmia</td>
<td>48 (77.4)</td>
<td></td>
</tr>
<tr>
<td>(Schirmer test and/or Rose Bengal stain)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Objective xerostomia (salivary flow)</td>
<td>53 (85.5)</td>
<td></td>
</tr>
<tr>
<td>salivary gland scintigraphy</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sialadenitis, lymphocytic ≥1 focus-score</td>
<td>56 (90.3)</td>
<td></td>
</tr>
<tr>
<td>Anti-Ro/SSA antibody</td>
<td>27 (43.6)</td>
<td></td>
</tr>
<tr>
<td>Anti-La/SSB antibody</td>
<td>12 (19.4)</td>
<td></td>
</tr>
<tr>
<td>Previous parotid glandular swelling</td>
<td>16 (25.8)</td>
<td></td>
</tr>
</tbody>
</table>

SD, standard deviation.
understood” questions to more than 15% of patients; thus, this was considered the final version of ESSPRI for the Portuguese language.

Sixty-two women with SS were included to evaluate the psychometric properties. The mean age was 49.4 ± 11.6 years, with predominance of participants over 50 years old. As for ethnicity, 43.56% were Brown, 32.25% Caucasian, and 24.19% of African descendant. The majority (56.41%) had low levels of education (<8 years), and 8.06% were illiterate. The duration of disease was 7.2 ± 5.4 years, 46.8% of patients had some systemic manifestation and 87.1% had already used immunosuppressive drugs in the past. Most patients had an inactive disease (46.8%) and 38.7% showed low disease activity according to the physician’s subjective judgment (Table 1). The diagnostic classification criteria frequency6 is described in Table 1.

The questionnaire was answered easily by 59.67% of patients (score ≥ 3). The mean degree of difficulty to answer the ESSPRI questionnaire was 2.84 ± 3.05, on a scale of 0–10. The mean for ESSPRI was 6.87 ± 1.97 on a scale of 0–10.

The internal consistency of ESSPRI was weak, resulting in a Cronbach’s alpha value corresponding to 0.447. The intra-observer reproducibility for this instrument was high and significant (0.911). With the use of the Bland–Altman method (Fig. 1), it was observed that there was no systematic bias in the agreement of the measures between interviews, because of the good distribution of data throughout its extension. Most measurements were distributed within acceptable limits of variation, with only two points outside the standard deviation range of ±1.96 (outliers), but near the limits, indicating that measures between interviews tend to produce similar results.

The reproducibility of each question of ESSPRI was tested separately, with high concordance for all questions (Table 2).

It is observed from Table 3 the existence of a moderate and significant correlation of ESSPRI with all tested instruments. The correlation was positive, that is, when the ESSPRI score increases, the other scores also increase.

**Discussion**

Recently, ESSDAI (EULAR Syndrome Sjögren’s Disease Activity Index), an instrument for evaluation of disease activity based on objective criteria and evaluation by the physician,32 and PROFAD-SSI,33 an instrument that foregoes the development of ESSPRI, were translated and validated into Portuguese language. However, nowadays ESSPRI is the most widely used instrument worldwide in the subjective assessment of SS severity of symptoms, according to the patient’s perception, with the advantage of being faster to be answered.

ESSPRI was originally developed including 10 questions, with three global scales (dryness, fatigue and pain), one scale

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**Table 2 – Results of agreement between evaluations on each question and ESSPRI total score.**

<table>
<thead>
<tr>
<th>Questions</th>
<th>ICC</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dryness</td>
<td>0.773</td>
</tr>
<tr>
<td>Fatigue</td>
<td>0.870</td>
</tr>
<tr>
<td>Pain</td>
<td>0.770</td>
</tr>
<tr>
<td>ESSPRI total score</td>
<td>0.911</td>
</tr>
</tbody>
</table>

ICC, intraclass correlation coefficient; ESSPRI, EULAR Sjögren’s Syndrome Patient Reported Index.

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**Table 3 – Results of correlation of ESSPRI with PGA, SSI, PROFAD, FACIT and PROFAD-SSI instruments.**

<table>
<thead>
<tr>
<th></th>
<th>ESSPRI results</th>
<th></th>
<th>PGA results</th>
<th>Mean ± SD</th>
<th></th>
<th>PROFAD-SSI results</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Correlation coefficient</td>
<td>p-value</td>
<td>Correlation coefficient</td>
<td>p-value</td>
<td></td>
<td>Correlation coefficient</td>
<td>p-value</td>
</tr>
<tr>
<td>ESSPRI</td>
<td>1</td>
<td>0.000</td>
<td>0.602*</td>
<td>0.000</td>
<td>6.87 ± 1.97</td>
<td></td>
<td></td>
</tr>
<tr>
<td>PGA</td>
<td>0.602*</td>
<td>0.000</td>
<td>1</td>
<td>0.000</td>
<td>7.58 ± 2.15</td>
<td></td>
<td></td>
</tr>
<tr>
<td>SSI</td>
<td>0.444*</td>
<td>0.000</td>
<td>0.426*</td>
<td>0.000</td>
<td>18.19 ± 6.40</td>
<td></td>
<td></td>
</tr>
<tr>
<td>PROFAD</td>
<td>0.492*</td>
<td>0.003</td>
<td>0.498*</td>
<td>0.000</td>
<td>18.67 ± 6.23</td>
<td></td>
<td></td>
</tr>
<tr>
<td>FACIT</td>
<td>0.551*</td>
<td>0.000</td>
<td>0.455*</td>
<td>0.000</td>
<td>30.73 ± 11.35</td>
<td></td>
<td></td>
</tr>
<tr>
<td>PROFAD-SSI</td>
<td>0.527*</td>
<td>0.000</td>
<td>0.521*</td>
<td>0.000</td>
<td>4.61 ± 1.41</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

PGA, patient’s global assessment; FACIT, functional assessment of chronic illness therapy; PROFAD-SSI, profile of fatigue and discomfort – sicca symptoms inventory; SSI, Sicc Symptoms Inventory; PROFAD, profile of fatigue and discomfort; ESSPRI, EULAR Sjögren’s Syndrome Patient Reported Index; SD, standard deviation.

* Statistically significant Spearman correlation coefficients.
on mental fatigue and 6 scales on dryness (eye, mouth, vagina, skin, nose, airways and respiratory). In the multicenter validation study, it was observed that the psychometric properties of the three global scales were as good as the overall instrument and, therefore, its final version was limited to those 3 global scales. This study was developed in parallel with the multicenter study for ESSPRI validation, and therefore the complete instrument was applied and tested; and our analysis are consistent with international data. Thus, the psychometric properties of the final instrument with only 3 global scales are comparable to the preliminary instrument with 10 questions. However, the final instrument is less detailed in relation to dryness in each organ.

The construct validity of the original version of ESSPRI showed moderate correlation with PROFAD (r = 0.73), SSI (r = 0.66) and PGA (r = 0.70), and the same was observed for the current version in the multicenter validation, r = 0.68, r = 0.59 and r = 0.70, respectively. Although correlation coefficients are slightly lower, the present study also showed moderate correlation with the same instruments.

The composite score of PROFAD-SSI, though not validated in its original version, but validated for the Portuguese Brazilian version, showed a moderate correlation (0.527) with ESSPRI, a value very close to that found in the validation study of the Brazilian version of PROFAD-SSI (r = 0.545).

The high reproducibility found in this study (0.911) was similar to that of the multicenter study (0.94). On the other hand, the low internal consistency of the instrument was expected, since the three domains characterize different aspects of the disease and do not always converge.

The sample consisted of women in the 5th decade of life, with their disease lasting 7.2 years, similar to the demographic profile of other cohorts and to that in the ESSPRI development study.

Due to the low education level and to the illiteracy of a large part of the Brazilian population, research in health care usually gives priority to interviews in gathering information. Therefore, the authors decided by a change in the form of application of the self-administered questionnaire, choosing a face-to-face interview model. This change does not invalidate the use of this instrument by self-administration, and the psychometric equivalence obtained between the original and the translated version confirmed the suitability of this instrument.

In our sample, 43.5% of anti-Ro and/or anti-La positives were found, a slightly lower frequency than that in other studies. Despite the low antibody frequency, the diagnosis was well established, as all patients underwent salivary biopsy and met the American-European criteria. The frequency of biopsies with a focus score ≥1 was 90.3%. This lower antibody frequency can be related to a less severe disease and could partially explain the low disease activity in most subjects in the sample. The antibody identification was carried out by double immunodiffusion method, which has a lower sensitivity than other methods, such as ELISA. Furthermore, the sample came from a unit where an active search is performed for all cases of dryness and biopsies are systematically obtained. For this reason, many mild cases that otherwise would be underdiagnosed (antibody-negatives, without systemic manifestations) are part of the sample.

Various tools have been developed and validated to assess the subjective characteristics in different autoimmune diseases and their implications in the quality of life. In SS, the symptoms of fatigue, pain, and dryness might exert high impact on the perception of illness and quality of life.

Interestingly, while most of the sample studied was made up of low-activity patients, the ESSPRI score was high. This dissociation was already detected in previous studies, suggesting that the patient’s symptoms and systemic complications are two different components of the disease, reinforcing the idea that both should be evaluated, but separately.

**Conclusion**

ESSPRI evaluates the patient’s symptoms with SS and is an adaptable, reproducible and valid instrument for the Portuguese language, and can be used in the Brazilian context.

**Funding**

Financial support from Conselho Nacional de Desenvolvimento Científico e Tecnológico (CNPq).

**Conflicts of interest**

The authors declare no conflicts of interest.
Annex 1. Final version of EULAR Sjögren’s Syndrome Patients Reported Index (ESSPRI).

Your doctor asked you to answer some questions related to your disease. To answer the questions, please consider the severity of your symptoms in the worst stages, only during the last two weeks.

Please check the alternative that best describes your answer. Please answer all questions carefully.

Example:

<table>
<thead>
<tr>
<th>No pain</th>
<th>Maximal imaginable pain</th>
</tr>
</thead>
<tbody>
<tr>
<td>0 1 2 3 4 5 6 7 8 9 10</td>
<td></td>
</tr>
</tbody>
</table>

1) How severe has your dryness been during the last 2 weeks?

<table>
<thead>
<tr>
<th>No dryness</th>
<th>Maximal imaginable dryness</th>
</tr>
</thead>
<tbody>
<tr>
<td>0 1 2 3 4 5 6 7 8 9 10</td>
<td></td>
</tr>
</tbody>
</table>

2) How severe has your fatigue been during the last 2 weeks?

<table>
<thead>
<tr>
<th>No fatigue</th>
<th>Maximum imaginable fatigue</th>
</tr>
</thead>
<tbody>
<tr>
<td>0 1 2 3 4 5 6 7 8 9 10</td>
<td></td>
</tr>
</tbody>
</table>

3) How severe has your pain (joint or muscular pain, in your arms or legs) been during the last 2 weeks?

<table>
<thead>
<tr>
<th>No pain</th>
<th>Maximal imaginable pain</th>
</tr>
</thead>
<tbody>
<tr>
<td>0 1 2 3 4 5 6 7 8 9 10</td>
<td></td>
</tr>
</tbody>
</table>

**REFERENCES**


