THE SPANISH NATIONAL INSTITUTES OF HEALTH-CHRONIC PROSTATITIS SYMPTOM INDEX: TRANSLATION AND LINGUISTIC VALIDATION

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ABSTRACT

Purpose: The prominence of health related quality of life end points in international clinical research underscores the importance of well validated and translated measures to enable cross-cultural comparison. The National Institutes of Health (NIH)-Chronic Prostatitis Symptom Index (CPSI) assesses symptoms and health related quality of life in men with chronic nonbacterial, NIH type III prostatitis. To expand its use to Spanish speaking patients we performed a translation and linguistic validation.

Materials and Methods: The 9-item NIH-CPSI was translated into Spanish according to a standard methodology of 2 forward translations, 1 reconciled version, back translation of the reconciled version and 3 independent reviews by bilingual experts. The purpose of this methodology was to create a single universal Spanish version that would be acceptable to native Spanish speakers inside and outside of the United States. After the translation process the Spanish version was pre-tested in Argentina, Mexico, Spain and the United States. Patient responses were analyzed to identify necessary modifications. The internal consistency of the CPSI was evaluated using Cronbach’s α. Pearson’s product moment correlations were used to evaluate construct validity.

Results: Data were collected from chronic prostatitis patients, including 15 in Argentina, 15 in Mexico, 4 in the United States and 3 in Spain. The translation had high reliability overall and in all subscales (Cronbach’s coefficient α = 0.81 to 0.94), and the subscales correlated well with each other (r = 0.76 to 0.97). However, patients expressed difficulty in distinguishing the response categories “a menudo” (“often”) from “normalmente” (“usually”) in question 3. We revised “a menudo” to “muchas veces” (“much of the time”) and “normalmente” to “casi siempre” (“almost always”) to improve the distinctiveness of response categories.

Conclusions: The Spanish NIH-CPSI has high reliability as well as face and construct validity in Spanish speaking men from various countries. The Spanish NIH-CPSI permits cross-cultural comparisons of men with chronic nonbacterial prostatitis.

KEY WORDS: prostate, questionnaires, prostatitis, quality of life, translations

Despite the commitment of the National Institutes of Health (NIH) to include minority patients in clinical research1 the lack of validated foreign language outcomes instruments is a serious impediment to recruiting and retaining non-English speaking minorities. Particularly urgent are efforts to develop valid and reliable Spanish versions of quality of life questions in order to assess health outcomes for non-English speaking minorities.2

Moreover, due to the increasing prominence of health related quality of life in international clinical research, valid and reliable measures are necessary to enable cross-cultural comparison nationally and internationally.

The NIH-Chronic Prostatitis Symptom Index (CPSI) is a 9-item reliable and valid tool that assesses pain, urinary symptoms and quality of life impact in men with chronic nonbacterial, NIH type III prostatitis but research and the clinical uses of the instrument are limited to English speaking men. The exclusion of non-English speaking men from research studies jeopardizes results by introducing selection bias, impairing patient recruitment and compromising the power to test ethnic and cultural hypotheses. Reliable Spanish translated health related quality of life instruments exist for other urological conditions, such as prostate cancer5 and benign prostatic hyperplasia.6 To expand the use of the NIH-CPSI to Spanish speaking patients with chronic prostatitis we performed a translation and linguistic validation. We created a single universal Spanish version that would be acceptable to native Spanish speakers inside and outside of the United States.
MATERIALS AND METHODS

Translation method. The linguistic translation methodology chosen was a rigorous forward-backward-forward technique using native and/or fully bilingual speakers in every stage. This methodology has been used successfully to translate the Functional Assessment of Cancer Therapy quality of life instrument into 40 languages, including Spanish.5,7

The translation procedure involved 7 steps (see appendix).5,7 In steps 1 and 2 professional translators who were bilingual native Spanish speakers from different countries of origin performed independent forward translations of the NIH-CPSI into Spanish. The translators were instructed to use simple language rather than phrases that may be more precise but difficult for patients with a lower reading level to comprehend. In addition, they were asked to capture the meaning of a question in the translations rather than perform literal translations. Step 2 consisted of a third independent translator who resolved discrepancies in the 2 forward translations, resulting in a reconciled version. In step 3 the reconciled version then underwent back translation by a fourth professional translator who was a bilingual native English speaker. After this initial translation process was complete step 4 involved contacting bilingual health professionals from Spain and Argentina as well as a linguist originally from Cuba to review the forward, reconciled and back translations. Reviewers were instructed to work independently and consider simple language that would be easily understood by patients with diverse educational levels. Reviewers selected the most appropriate translation for each item from the reconciled and independent forward translations, and were asked to provide alternative translations to improve items with inadequate existing translations. In step 5 all recommendations made by reviewers were discussed in detail by the coordinating team, individual reviewers and the professional translation team until at least 2 of 3 reviewers agreed on a single translation for each item. As a result, a new forward translation document was created and resubmitted to bilingual reviewers for step 6, which involved grammar and spelling verification. In the last step a final version was formatted and sent for pre-testing.

Pre-testing. To examine the comprehensibility, acceptability and psychometric properties of the translated instrument the Spanish NIH-CPSI was pre-tested in a convenience sample of 37 Spanish speaking patients with a mean age plus or minus standard deviation of 52.4 ± 16.6 years from various countries who had been clinically diagnosed with chronic prostatitis by an attending physician, including 15 in Argentina, 15 in Mexico, 3 in Spain and 4 in the United States. Mean time since diagnosis was 28.0 ± 38.5 months. All men were asked to self-complete the NIH-CPSI. They were then interviewed by a nurse or study coordinator to determine whether any questions were difficult to comprehend, or irrelevant to their symptoms or health related quality of life. Information obtained during patient interviews was later considered when determining the final language version. Specifically qualitative patient comments on item comprehension were recorded and combined with reviewer comments.

Analysis. The NIH-CPSI consists of 3 subscales, including 8 pain, 2 urinary symptoms and 3 quality of life impact items. Internal consistency of the overall Spanish NIH-CPSI and its 3 subscales was evaluated using Cronbach’s coefficient α.5,6 To evaluate construct validity 2 symptom scores were correlated with quality of life impact scores and item correlations were calculated using the Pearson product moment correlation.10 Few missing item responses (1 to 3 persons) on questionnaire items 1a to 1d, 2a and 2b were substituted with the mean value of its respective section (1a to 1d, 2a and 2b) to derive the pain subscale score. The psychometric properties of the Spanish NIH-CPSI were also compared with those of the original validated English version.3

RESULTS

Modifications to the NIH-CPSI based on reviewer input. Of the 29 parts, including headings and responses, that underwent translation 19 were re-translated as a result of the disagreement of the bilingual reviewers with the reconciled version. This re-translation was done to maintain consistency throughout the questionnaire and improve clarity of the wording and responses. Two examples of the process of resolution were a change in terminology, and a change in translation and sentence structure.

As an example of a change in terminology, the English version contains the phrase “pain or discomfort” 6 times. The reconciled translation was “dolor o incomodidad,” which when back translated is “pain or discomfort.” However, a reviewer noted that “incomodidad” was not generally used in the medical sense and “molestia,” which is also “pain or discomfort” when back translated, conveyed the proper meaning in the medical sense. The other reviewers agreed. The final version was revised to “dolor o molestia,” which seems the simplest and most appropriate translation for the medical context.

As an example of a change in translation and sentence structure, the English version contains the sentence, “In the last week, have you experienced any pain or discomfort in the following areas?” The reconciled translation was, “Ha tenido usted dolor o incomodidad en las partes siguientes durante la ultima semana?” The back translation is, “Have you felt pain or discomfort in the following areas during the last week?” Three reviewers agreed that “la semana pasada” was more accurate than “la ultima semana” as the translation for “in the last week.” Two of the 3 reviewers preferred to place this phrase denoting the recall period at the beginning rather than at the end of the sentence. All agreed to change the terminology for pain or discomfort from “dolor o incomodidad” to “dolor o molestia” for consistency throughout the questionnaire. Furthermore, a reviewer noted that the word “areas” would be hard to understand and considered highbrow, instead suggesting “en las partes del cuerpo siguientes.” The other reviewers agreed. Thus, the final version is, “Durante la semana pasada, ha tenido usted dolor o molestia en las partes del cuerpo siguientes?” This same sentence structure is repeated 6 times throughout the questionnaire.

Psychometric analyses. Reliability: The 9-item Spanish NIH-CPSI showed high internal consistency (table 1). The α coefficient for the overall index and its subscales was 0.81 to 0.94, which is similar to the reliability of the English version.

<table>
<thead>
<tr>
<th>Domain</th>
<th>Version α</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Spanish</td>
</tr>
<tr>
<td>Pain</td>
<td>0.87</td>
</tr>
<tr>
<td>Urinary symptoms</td>
<td>0.81</td>
</tr>
<tr>
<td>Life quality impact</td>
<td>0.86</td>
</tr>
<tr>
<td>Overall NIH-CPSI</td>
<td>0.94</td>
</tr>
</tbody>
</table>

Correlation matrix of the overall Spanish NIH-CPSI index and subscales

<table>
<thead>
<tr>
<th>Domain</th>
<th>Pain</th>
<th>Urinary Symptoms</th>
<th>Quality of Life Impact</th>
<th>NIH-CPSI</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pain</td>
<td>1.00</td>
<td>1.00</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Urinary symptoms</td>
<td>0.80</td>
<td>0.76</td>
<td>1.00</td>
<td></td>
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<tr>
<td>Life quality impact</td>
<td>0.88</td>
<td>0.76</td>
<td>1.00</td>
<td></td>
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<tr>
<td>Spanish NIH-CPSI</td>
<td>0.97</td>
<td>0.89</td>
<td>0.94</td>
<td>1.00</td>
</tr>
</tbody>
</table>
**SPANISH PROSTATITIS SYMPTOM INDEX (NIH-CPSI)**

1. **Dolor o molestia**
   Durante la semana pasada, ¿ha tenido usted dolor o molestia en las partes del cuerpo siguientes?
   - En el área entre el recto y los testículos (perineo)  
     - Sí: ☐  
     - No: ☐
   - En los testículos  
     - Sí: ☐  
     - No: ☐
   - En la punta del pene (dolor o molestia no relacionados con orinar)  
     - Sí: ☐  
     - No: ☐
   - Debajo de la cintura, en el área del pubis o de la vejiga  
     - Sí: ☐  
     - No: ☐

2. **Durante la semana pasada, ¿ha tenido usted...**
   - Dolor o ardor al orinar?  
     - Sí: ☐  
     - No: ☐
   - Dolor o molestia durante o después del orgasmo (eyaculación)?  
     - Sí: ☐  
     - No: ☐

3. **Durante la semana pasada, ¿con qué frecuencia ha tenido usted dolor o molestia en alguna de las partes de su cuerpo indicadas arriba en la primera pregunta?**
   - Nunca  
     - ☐
   - Pocas veces  
     - ☐
   - Algunas veces  
     - ☐
   - Muchas veces  
     - ☐
   - Casi siempre  
     - ☐
   - Siempre  
     - ☐

4. **¿Qué número describe mejor el nivel PROMEDIO de dolor o molestia, en los días que lo tuvo, durante la semana pasada?**
   (Los números de menor a mayor que aparecen abajo sirven para indicar que el dolor va de débil a fuerte.)
   - Sin dolor  
     - ☐
   - 1  
     - ☐
   - 2  
     - ☐
   - 3  
     - ☐
   - 4  
     - ☐
   - 5  
     - ☐
   - 6  
     - ☐
   - 7  
     - ☐
   - 8  
     - ☐
   - 9  
     - ☐
   - 10  
     - ☐
   - Dolor tan fuerte como usted se pueda imaginar  
     - ☐

5. **Orinar**
   Durante la semana pasada, ¿con qué frecuencia ha tenido usted la sensación de que no se le vació completamente la vejiga al terminar de orinar?
   - Ni una vez  
     - ☐
   - Menos de 1 de cada 5 veces  
     - ☐
   - Menos de la mitad de las veces  
     - ☐
   - Más o menos la mitad de las veces  
     - ☐
   - Más de la mitad de las veces  
     - ☐
   - Casi siempre  
     - ☐

6. **Durante la semana pasada, ¿con qué frecuencia tuvo usted que volver a orinar menos de dos horas después de haber orinado?**
   - Ni una vez  
     - ☐
   - Menos de 1 de cada 5 veces  
     - ☐
   - Menos de la mitad de las veces  
     - ☐
   - Más o menos la mitad de las veces  
     - ☐
   - Más de la mitad de las veces  
     - ☐
   - Casi siempre  
     - ☐

7. **Efecto de los síntomas**
   Durante la semana pasada, ¿cuánto han impedido sus síntomas que usted hiciera las cosas que habitualmente hace?
   - Nada  
     - ☐
   - Sólo un poco  
     - ☐
   - Algo  
     - ☐
   - Mucho  
     - ☐

8. **¿Cuánto pensó en sus síntomas durante la semana pasada?**
   - Nada  
     - ☐
   - Sólo un poco  
     - ☐
   - Algo  
     - ☐
   - Mucho  
     - ☐

9. **Calidad de vida**
   ¿Cómo se sentiría si tuviera que pasar el resto de su vida con síntomas iguales a los que ha tenido durante la semana pasada?
   - Encantado  
     - ☐
   - Complacido  
     - ☐
   - En general, satisfecho  
     - ☐
   - Con sentimientos contrarios, confundido (igualmente satisfecho e insatisfecho)  
     - ☐
   - En general, insatisfecho  
     - ☐
   - Descontento  
     - ☐
   - Muy mal  
     - ☐

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**Puntuación del NIH-Índice de Síntomas de Prostatitis Crónica**

Dolor: Total de las preguntas 1a, 1b, 1c, 1d, 2a, 2b, 3 y 4 =

Síntomas urinarios: Total de las preguntas 5 y 6 =

Efecto sobre la calidad de vida: Total de las preguntas 7, 8 y 9 =

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Spanish NIH-CPSI.
Validity: The domains of the Spanish NIH-CPSI correlated well with each other (table 2). The high correlation of 0.76 to 0.88 in the symptom and quality of life impact subscales help to support the construct validity of the instrument. In addition, the correlations are somewhat higher than those of the original English version (0.35 to 0.77).

Modifications made after pre-testing. The purpose of pre-testing was to obtain data from patients with chronic prostatitis on the acceptability, appropriateness and comprehensibility of the translated version. Two response categories were re-translated as a result of comments made by patients during pre-testing. The only difficulty that patients had was in distinguishing the response categories “a menudo” (“often”) from “normalmente” (“usually”) because these terms have equivalent meanings in Spanish rather than indicating increasing frequency, as in the original English version. We revised “a menudo” to “muchas veces” (“much of the time”) and “normalmente” to “casi siempre” (“almost always”) to improve the distinctiveness of these response categories.

DISCUSSION

We describe the method used to translate the NIH-CPSI from its original English language into Spanish. The adaptation of a rigorous double back translation technique combined with pre-testing in the United States and in native Spanish speaking countries enabled the achievement of a high quality Spanish translation that can be used worldwide (see figure). There were several limitations to our study. Sample size was relatively small, especially in the United States, where many versions of Spanish are spoken. Because the index is used in various settings, data should be forthcoming to determine whether the instrument performs as well in the United States as in Latin America and Mexico, where sample size was larger. Also, demonstration of the validity of the Spanish index requires further testing in the field. In addition, chronic prostatitis remains a clinical diagnosis and we relied on the clinical judgment of urologists and primary care physicians to select study participants. In conclusion, the similarity of the psychometric properties of the English and Spanish versions of the NIH-CPSI supports their measurement equivalence.

APPENDIX: TRANSLATION PROCESS*

Start: Source document (English version of the NIH CPSI®)

Step 1: Forward translation (bilingual native Spanish speaker residing in Mexico): English to Spanish

Forward translation (bilingual native Spanish speaker residing in the United States, originally from Panama): English to Spanish

Result: Two independent forward translations

Step 2: Reconciliation of forward translations (bilingual native Spanish speaker (residing in the United States, originally from Mexico) not involved in forward translation process)

Result: Reconciled version that includes input from both forward translations

Step 3: Back translation of reconciled version (bilingual native English speaker): Spanish to English

Result: Back translation into English to compare to source document

Step 4: Review by bilingual health professionals residing in Spain and Argentina, and a linguist residing in the United States, originally from Cuba

Result: Revised language version based on reconciliation of discrepancies among source document, step 2 forward translation and step 3 back translation

Step 5: Review by Center on Outcomes, Research and Education coordinating team and language coordinator

Result: One translated version based on resolution of discrepancies among reviewers

Step 6: Spelling and grammar verification

Result: Revised language document ready for pre-testing in native countries

Step 7: Pre-testing of translated questionnaire with 37 patients

Result: Final translated instrument ready for use in clinical research and practice

* Adapted from Bonomi et al.7

REFERENCES


