Validation of the Persian Version of the National Institute of Health Chronic Prostatitis Symptom Index

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Key words: asymptomatic inflammatory prostatitis; asymptomatic inflammatory prostatitides; chronic prostatitis with chronic pelvic pain syndrome; national institute of health chronic prostatitis symptom index; prostatitis; prostatitides

Abstract

Objectives: To compose a comprehensible and fluent Persian translation of the National Institute of Health Chronic Prostatitis Symptom Index (NIH-CPSI), and to determine its linguistic validity in a Persian sample population.

Methods: The standard double-back translation method, provided by the previous studies were utilized by three professional linguists to translate the English version of the NIH-CPSI to Persian, and a group of 10 urologists further reviewed and translated questionnaire. The questionnaire was then presented to the sample study, comprised of 60 men with CP/CPPS and 60 controls with adverse urological history, and the collected data was analyzed through IBM-SPSS software to test its validity, evaluative, and discriminatory power, psychometric qualities and internal consistency.

Results: A total of 80 subjects (42 CP/CPPS patients and 38 healthy controls) were considered eligible for this study. The total Persian NIH-CPSI scores and each subdomain showed significant difference ($P < 0.001$) between the two study groups, indicating a satisfactory discriminant validity for the index. Psychometric analysis established the index to benefit from a high internal consistency. The translation was also considered by both the subjects and the physicians to be easily comprehensible.

Conclusion: The Persian NIH-CPSI is a reliable and valid instrument for evaluating CP/CPPS symptoms in general population, while also benefitting from high discriminatory power, and can be utilized with ease in both clinical practice and laboratory studies.

1. Introduction

Chronic non-bacterial prostatitis (CP) or chronic pelvic pain syndrome (CPPS) is a frequent disorder in general population, with a prevalence ranging from 5% to 14.2%[1,2], and accounting for about 90% of the subject admissions with prostatitis-like symptoms to general physicians

and urologists [3,4]. The National Institute of Health defines CP/CPPS as a primary urological pain in the absence of any secondary etiology, with or without present urethral inflammation [3].

Moreover, CP/CPPS is a poorly-defined clinical entity, and therefore is prone to misdiagnosis, mistreatment, and mismanagement [5]. Furthermore, the lack of a systematized and universally accepted outcome measure has caused inconsistent and vague results in CP/CPPS studies while making patient evaluation a challenge, as well as hindering researches and clinical endeavors in aiding CP/CPPS patients [6,7].

Accordingly, the National Institutes of Health (NIH) Chronic Prostatitis Collaborative Research Network devised the National Institute of Health Chronic Prostatitis Symptom Index (NIH-CPSI) to effectively evaluate both the symptoms of CP/CPPS and the impact they impose on the subject's quality of life. The index consists of nine questions divided into three subsections, each providing measurement for the three most essential fields in CP/CPPS patients' experience; pain, urinary symptoms and the patient's quality of life [6].

The NIH-CPSI has been widely recognized as a standard and authentic outcome measure for CP/CPPS patients, providing a primary endpoint in both clinical practices, in addition to clinical trials[7]. Moreover, it has been acknowledged by the International Prostatitis Collaborative Network as the standard evaluation instrument for males with CP/CPPS symptoms [8]. While primarily published to measure the extent, previous history, and treatment outcomes of CP/CPPS, the NIH-CPSI is shown to benefit from a high discriminatory value, being able to detect chronic prostatitis symptoms in the general population and thus proving to be valuable in epidemiologic studies [9].

Recently, the translation-validation of the NIH-CPSI questionnaire has been performed into German, Italian, Spanish, Finnish, Japanese, Malay, Estonian, and Arabic [10-17]. However, as

of yet, no standardized evaluative tool for CP/CPPS exists in Persian. The current study aims to present a coherent and comprehensive Persian version of the NIH-CPSI and validate it in a Persian sample population.

2. Materials and methods

2.1. Translation procedure

We followed the double translation method, as suggested and utilized by prior studies [10-17]. The original NIH-CPSI questionnaire was translated into Persian by two independent Iranian translators, each unaware of the goals of the study. The translators then compared the versions to each other and the author (F.A.), resolving any inconsistencies and revising several phrases and words to ensure comprehensibility. The revised version was then back-translated into English by a native Australian, fully bilingual (English, Persian) translator. The translated version was then compared to the original NIH-CPSI form by the translators and the authors, finding little to none inconsistencies between the versions, with the idiomatic content being practically identical. We then forwarded the back-translated version to the corresponding author of the original NIH-CPSI, Professor M. S. Litwin, who reviewed the back-translation alongside the original English validation and found it to be a very close approximation. After being assessed on the accounts of proper vocabulary and grammar usage as well as ease of understanding by an Iranian English literature professor, a finalized Persian questionnaire was then harmonized and presented to a committee of ten Iranian urologists. In about two weeks of revision and clinical trial, only one slight adjustment was made, the phrase “How much” in question 8, first translated as “چقدر” being changed to "چه میزان" to further adapt to proper Persian dialect.

2.2. Validation process

The sample population for this study was composed of 60 patients afflicted with CP/CPPS and 60 healthy controls, collected in a span of 3 months, from November 2018 to January 2019. Those patients were included whose diagnosis was under the NIH definition of CP/CPPS type III [(3)], attending Shohada-e-Tajrish Hospital Urology Clinic. All the patients had consecutive referrals across Iran with specific symptoms of CP/CPSS for a time span of at least one year, with the majority of them giving an unsatisfactory history of treatment through conventional methods, including antibiotics, anti-inflammatory drugs, and alpha-blockers. According to the study protocol, those males were excluded, who were designated with chronic bacterial prostatitis (NIH type II)[(3,18)], and reported a previous history of urethritis, malignancies, recurrent urolithiasis, inflammatory bowel disease, benign prostatic hyperplasia, major psychiatric disorders, and neurological diseases; meaning those with a secondary etiology for CP/CPPS were excluded. We selected the control group among healthy personnel of Shohada-e-Tajrish Hospital and Shahid Beheshti University of Medical Sciences, who had no previous urological history, or any other disease capable of presenting with prostatitis-like symptoms. All the participants were fully briefed about their role in a symptom evaluation with a specific questionnaire and signed written consent. Furthermore, any ethical issues concerning the study, subjects, and the authors were discussed and resolved if necessary. At the first visit, all the patients underwent a clinical examination to solidify the clinical diagnosis of CP/CPPS further. Both the patients and controls then completed a short questionnaire regarding their personal information, with the data provided in Table-1.

Afterward, both the CP/CPPS patients and the healthy controls self-completed the Persian version of the NIH-CPSI, and then were asked to fill out the index again in 1 week, to evaluate the test-retest reliability. Two of the authors (F.A. and M.M.M.T.) supervised the process, noted the time of completion for each individual, determined whether any question was deemed

too difficult or irrelevant for the subjects, and considered their subjective opinions in case of any rearrangement in the questionnaire.

2.3. Statistical analysis

The questionnaires were analyzed through the software Statistical Package for Social Sciences (SPSS version 21). Mann-Whitney U test was utilized to compare distributary differences between the two groups. Test-retest reliability, item associations, and data validity were studied through the Intraclass correlation coefficient (ICC) and Pearson product-moment. *P*-values < 0.001 were deemed statistically significant. Finally, the overall internal consistency for the Persian NIH-CPSI and each of its subdomains was assessed by Cronbach's coefficient α[19]. Face validity was utilized in composing the questionnaire, whereas content validity was used in designing the literature.

3. Results

Of the 120 enrolled subjects, a sum of 80 (42 CP/CPPS patients and 38 healthy controls) were considered eligible for our study. Forty (18 of the CP/CPPS patients and 12 of the controls) subjects were excluded on the accounts of only partially filling the questionnaire. As mentioned above, Table 1 depicts the subjects' general information. The mean age for both of the groups was relatively equivalent, with CP/CPPS patients' mean age (SD) being 45.6 (3.4), and the control group's mean age (SD) being 42.7 (3.9). Similarly, both groups completed the questionnaire in a relatively same amount of time. The general compliance of both groups in filling the questionnaire was satisfactory. The mean duration (SD) of CP/CPPS symptoms among the patients was 3.8 (2.3) years.

The Persian NIH-CPSI scores significantly differed between the two groups ($P < 0.001$), with the total mean (SD) score being 22.47 (6.9) for the CP/CPPS patients and 2.1 (2.7) for the control subjects. Mean and IQR for the total NPH-CPSI scores among patients was reported as 20.21 and Q_1-Q_3 (14.23 – 32.68), respectively. Notable differences were seen ($P < 0.001$) between the resulted scores of all the three subdomains. Table 1 presents the performance result for each domain and the total questionnaire, as well as the differences studied with Mann-Whitney U test. Pearson's test was utilized to analyze the association between the sections of the Persian NIH-CPSI, demonstrating that the domains correlated positively with one another. The highest associations were witnessed between the total NIH-CPSI scores, and the pain (0.889) and the QoL (0.846) domains. The urinary symptoms domain also positively correlated with the other subdomains and the total score, albeit not quite as high. Table 2 shows the cross-tabulations of the correlations in-between the three domains and the total NIH-CPSI score. Test-retest reliability, performed on the previous sample of 80 subjects, showed little to no disparity between the score distributions for each of the subdomains and the overall Persian NIH-CPSI. The correlation between the total scores was 0.901 for CP/CPPS patients, 0.912 for the controls, and 0.908 for all 80 subjects. Psychometric analysis dictated a satisfactory internal consistency with α coefficient of 0.865 for the index in general (Table 3).

4. Discussion

Despite the high worldwide prevalence of CP/CPPS among the global population and patient visits to general practitioners and urologists alike, there has not been any effort to establish a standardized outcome measure for the Persian population; absence of such an instrument not only hinders the clinical judgment of Iranian physicians regarding CP/CPPS, but also

contributes to a lack of epidemiologic research regarding CP/CPPS among the Persian population.

What this study provided was the translation-validation process of the NIH-CPSI in an Iranian sample population. The double translation method, as previously accepted and utilized[10-16], was diligently performed in a methodology similar to the German study [10].

The Persian NIH-CPSI scores among CP/CPPS patients were notably similar to the values provided by the previous studies. The mean NIH-CPSI scores across all the subdomains (22.47 total, 10.35 pain, 4.73 voiding symptoms, and 7.38 QoL) were higher when compared to the corresponding values in the English article [6]. Such disparity, however, has also been present in other validation studies, with the scores from the Italian study[11] being similar to our own, and the two years of trial with the German NIH-CPSI resulting in scores higher than our current data[10]. These discrepancies are expected, with the implications behind them ranging from differences in sample qualities to unique characteristics of lingual expressions. Nonetheless, the Persian version of the NIH-CPSI demonstrated content validity and discriminatory viability in distinguishing CP/CPPS patients from the healthy individuals; as the scores in each three of the subdomains in addition to the total score of the two study groups were widely different ($P < 0,001$ U-test).

The association between the pain scores and the total index scores among the prostatitis patients was demonstrated to be significant (0.889), with the score corresponding to those reported in the Italian (0.89) and the Finnish (0.91) studies. The correlation between the total score and the quality of life domain also followed suit (0.846), again comparable to the scores reported by the Italian (0.88) and the Finnish (0.85) studies. The correlation reported between the total NIH-CPSI scores and the urinary symptom subdomain, although statistically significant (0.666), was not as remarkable as the previous domains. However, this trend is also seen in the

previous studies, with the correlation score reported as 0.67 and 0.56 in the Finnish and the Italian studies, respectively. Nonetheless, the correspondence between the correlation scores across the board and the results described by the other studies, including the original English supports the construct validity of the current instrument [6,11,13].

Our results confirmed a high internal consistency of the Persian NIH-CPSI (0.865 with Cronbach). An internal consistency greater than 0.7 for the overall translated index demonstrated acceptable reliability [10]. While in our study, the internal consistency of the pain domain (0.853) and the total index (0.856) were similar to those of the English version, the Cronbach alpha of the voiding symptoms and QoL domains were slightly decreased, compared to the original study. Among other validation studies, internal consistency was presented in the German [10], Italian [11], Spanish [12], Japanese [14], and the Arabic [16] versions, which all demonstrated a Cronbach's alpha comparable to that of the original version; except for the German two-year trial, which presented slightly decreased values compared to the study conducted by Litwin et al. across all the domains. In discussing the attributing factors for this discrepancy, as Schneider et al. describe, differences in patient selection and sample qualities may be crucial since the original North American study sample included subjects with a lower quality of life and pain, but higher urinary symptom scores. Although our study demonstrates a higher internal consistency for the overall questionnaire in comparison to the German study (0.74), the discussion as mentioned above is nonetheless significant in clarifying the slight discrepancy [6,10]. Furthermore, reevaluating the translation procedure may also be noteworthy; albeit as stated before, we performed this method carefully following the previously conducted studies.

As stated, the NIH-CPSI was initially designed with an evaluative goal, rather than a discriminatory one. However, subsequent translation-validations [10-16] and several epidemiologic studies [9,20,21] have all determined the significant discriminatory power of this

questionnaire in differentiating between the CP/CPPS patients and healthy individuals in the general population. NIH-CPSI is to optimally function if adopted widely as a routine tool of evaluating CP/CPPS[6,7] and thus will benefit from the constant translation-validation studies to yield the prime of its use.

The study limitations are concerned mostly with the socioeconomic demographics of its subjects, since a sample population of this proportion may not be a proper presentation of the Persian-speaking population. A better demonstration of the discriminatory power of this index may be available if tested by other physicians in different geographical and socioeconomic settings of Persian speaking populations. Our other limitation concerned the sample-pool of our subjects; Shohada-e-Tajrish hospital is a primary/secondary healthcare center with a broad spectrum of urological patients and therefore provides limited access to CP/CPPS patients when compared with more specialized, tertiary care centers with focus on prostate diseases.

5. Conclusion

To conclude, our study presented and recognized the Persian translated NIH-CPSI as an easily comprehensible and standard instrument in evaluating CP/CPPS symptoms, with significant discriminatory value and construct validity, making it reliable and viable as a primary outcome measure in both clinical practice and sub-clinical studies, in the Iranian population.

6. Acknowledgment

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7. Conflict of Interest

The authors report no conflict of interest.

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Table 1

Basic data of the sample populations, NIH-CPSI and the subdomains scores for each of the subject groups (CP/CPPS patients and healthy controls).

Characteristics[a]	**CP/CPPS**	**Controls**
Number of patients	42	38
Mean age (years)	45.6 ± 3.4	42.7 ± 3.9
Education		
Primary school	18 (30)	14 (23)
High school	26 (43)	25 (42)
University graduate	16 (27)	21 (35)
Mean duration of symptoms (years)	3.8 ± 2.3	
Mean duration of index completion (minutes)	8 ± 2	7 ± 2
Mean NIH-CPSI scores ± (SD)*		
Total (0-43)	22.47 ± (6.9)*	2.1 ± (2.7)*
Pain domain (0-21)	10.35 ± (3.7)*	0.3 ± (0.2)*
Urinary symptoms domain (0-10)	4.73 ± (1.98)*	0.5 ± (0.4)*
Quality of life domain (0-12)	7.38 ± (2.7)*	0.8 ± (0.4)*

Abbreviations: CP/CPPS, Chronic Prostatitis/Chronic Pelvic Pain Syndrome; NIH-CPSI, National Institute of Health Chronic Prostatitis Symptom Index.

[a] Data are presented as mean ± SD or number (percent).

* $P < 0.001$ with Mann-Whitney U-test.

Table 2

Correlation of NIH-CPSI and its subclasses among the CP/CPPS patients through ICC

	Pain	**Urinary symptoms**	**Quality of life**	**NIH-CPSI**
Pain	1.000			
Urinary symptoms	0.389	1.000		
Quality of life	0.612	0.433	1.000	
NIH-CPSI	0.889	0.666	0.846	1.000

Abbreviations: CP/CPPS, Chronic Prostatitis/Chronic Pelvic Pain Syndrome; NIH-CPSI, National Institute of Health Chronic Prostatitis Symptom Index.

$P < 0.001$ with Mann-Whitney U-test.

Table 3

Test-retest reliability analysis (ICC) and internal consistency (Cronbach) of the study.

Characteristics[a]	**alpha**	**CP/CPPS**			**Controls**		
Number of Patients		42			38		
Mean age (years)		45.6 ± 3.4			42.7 ± 3.9		
Domain (range)		Test	Re-test	Correlation	Test	Re-test	Correlation

Overall NIH-CPSI	0.865	22.47	22.21	0.901	2.1	2.2	0.912
Pain	0.853	10.37	10.46	0.894	0.3	0.3	0.900
Urinary symptoms	0.652	4.73	4.62	0.912	0.5	0.4	0.895
Quality of life	0.726	7.38	7.25	0.846	0.8	0.7	0.887

Abbreviations: CP/CPPS, Chronic Prostatitis/Chronic Pelvic Pain Syndrome; NIH-CPSI, National Institute of Health Chronic Prostatitis Symptom Index.

[a] Data are presented as mean ± SD.

پرسشنامه‌ی علائم التهاب مزمن پروستات سازمان ملی بهداشت آمریکا

<u>درد یا ناراحتی</u>

۱. در هفته‌ی گذشته، در نواحی ذیل هر گونه درد یا ناراحتی تجربه کرده‌اید؟

(۱-بله 0-خیر)

الف. ناحیه‌ی بین معقد و بیضه‌ها (پرینه)

ب. بیضه‌ها

ج. نوک آلت تناسلی (در زمان‌های غیر از دفع ادرار)

د. پایین‌تنه، در ناحیه‌ی شرمگاهی یا مثانه

۲. در هفته‌ی گذشته، آیا:

(۱-بله 0-خیر)

الف. هنگام دفع ادرار، درد یا سوزش داشته‌اید؟

ب. هنگام انزال یا بعد از آن، درد یا ناراحتی تجربه کرده‌اید؟

۳. در نواحی ذکر شده در بالا، چند بار در طی هفته‌ی گذشته، درد یا ناراحتی تجربه کرده‌اید؟

0. هرگز

1. به ندرت

2. گاهی

3. به صورت معمول

4. به صورت مکرر

5. به صورت مداوم

۴. کدام عدد میزان درد یا ناراحتی شما را در طول هفته‌ی گذشته *به صورت میانگین* به بهترین نحو توصیف می‌کند؟

0: هیچ دردی

1 2 3 4 5 6 7 8 9

10: بدترین درد قابل تصور برای یک انسان

ادرار

۵. در طول هفته‌ی گذشته چند بار حس کرده‌اید که پس از دفع ادرار، مثانه‌تان به طور کامل خالی نشده است؟

0. چنین حسی نداشته‌ام

1. کمتر از یک مرتبه از هر پنج نوبت

2. کمتر نیمی از دفعات

3. حدود نیمی از دفعات

4. بیش از نیمی از دفعات

5. تقریباً هر بار

۶. در هفته‌ی گذشته چند بار قبل از گذشتن دو ساعت از ادرار کردن، مجبور شده‌اید مجدداً ادرار خود را دفع کنید؟

0. چنین اتفاقی نیفتاده است.

1. کمتر از یک مرتبه از هر پنج نوبت

2. کمتر نیمی از دفعات

3. حدود نیمی از دفعات

4. بیش از نیمی از دفعات

5. تقریباً هر بار

تأثیر علائم

۷. در طول هفته‌ی گذشته، علائمی که تجربه کرده‌اید تا چه اندازه شما را از فعالیت‌های روزمره‌ی خود باز داشته‌اند؟

0. اصلاً

1. اندکی

2. تا حدی

3. خیلی

۸. در طول هفته‌ی گذشته چه میزان به علائم خود فکر کرده‌اید؟

0. اصلاً

1. اندکی

2. تا حدی

3. خیلی

کیفیت زندگی

۹. اگر مجبور باشید باقی زندگی خود را با علائمی مشابه آن‌چه در طول هفته‌ی گذشته تجربه کرده‌اید، سپری کنید، چه حسی خواهید داشت؟

0. خوشحال

1. راضی

2. عمدتاً راضی

3. علی‌السویه (نارضایتی و رضایت در یک حد)

4. عمدتاً ناراضی

5. ناراضی

6. بسیار بد

امتیازدهی حوزه‌های پرسشنامه‌ی علائم التهاب مزمن پروستات سازمان ملی بهداشت آمریکا (NIH-CPSI)

درد: مجموع موارد ۱)الف، ۱)ب، ۱)ج، ۱)د، ۲)الف، ۲)ب، ۳ و ۴ =

علائم ادراری: مجموع موارد ۵ و ۶ =

تأثیر بر کیفیت زندگی: مجموع موارد ۷، ۸ و ۹ =