Reliability and validity of the national institute of health chronic prostatitis symptom index questionnaire in Turkish Population

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Abstract

**Background/aim:** To develop the first Turkish version of the National Institute of Health Chronic Prostatitis Symptom Index Questionnaire’(NIH-CPSI) and to investigate its validity and reliability in men with chronic prostatitis/chronic pelvic pain syndrome (CP/CPPS) and healthy controls.

**Material and methods:** A total of 204 patients, 116 CP/CPPS and control group, which 88 healthy individuals join, were included in this prospective study. The NIH-CPSI form was first translated into Turkish and later on back to English. By using the Turkish version of the NIH CPSI, 40 patients completed the same questionnaires twice at 2-weeks intervals for test-retest concordance. To evaluate internal consistency and test-retest reliability, cronbach alpha value, the Spearman correlation test were utilized respectively.

**Results:** Our findings demonstrated statistically significant differences in NIH-CPSI scores between the patients and control groups cases (p<0.001). Cronbach’s alpha coefficient value of NIH-CPSI was 0.864. Reliability of test-retest was 0.909 (p<0.001). Additionally, Spearman correlation test has shown that the results obtained by Turkish NIH-CPSI were significantly correlated.

**Conclusion:** The first Turkish version of the NIH-CPSI was found to be a reliable and valid instrument for Turkish patients with chronic prostatitis in the clinical and research settings.
Keywords: National institute of health chronic prostatitis symptom index (NIH-CPSI); chronic prostatitis/chronic pelvic pain syndrome (CP/ CPPS); Turkish validation.

1. Introduction

Despite the higher prevalence of benign prostatic hyperplasia (BPH) and prostate cancer in men older than 50 years; prostatitis is the most frequently diagnosed urological problem in men younger than 50 years and the third most common urologic diagnosis again in cases with an age value of >50 years [1] Chronic prostatitis / chronic pelvic pain syndrome (CP / CPPS) is a common urological disease characterized by the limited response to conventional management approaches and has a complicated healing process. [2] Men suffering from chronic CP/CPPS are the largest population being evaluated in the outpatients clinics. The incidence of the pathology ranges from 5% to 14.2%.[3,4] and relevant research studies have shown that approximately 16% of men may present with a prostatitis attack at least once in their lifetime. [5]

The National Institutes of Health (NIH) classification describes four patterns of prostatitis. Type 1 acute bacterial prostatitis, type 2 chronic bacterial prostatitis, type 3 chronic prostatitis/chronic pelvic pain syndrome (CP/CPPS) and lastly type 4 asymptomatic prostatitis.[6] Chronic prostatitis/ chronic pelvic pain syndrome (CP/CPPS) has been defined with pelvic pain noted in at least three of the previous six months with no other underlying causes detected. Additionally,
National Institutes of Health (NIH) subclassifies category III as inflammatory chronic pelvic pain syndrome (IIIa) and non-inflammatory chronic pelvic pain syndrome (IIIb). [5]

CP/CPPS is associated with certain symptoms including pain (during urination and in the abdomen, lower back, rectum, and genital area), dysuria, urinary urgency, perineal discomfort, obstructive or irritative voiding difficulties, and hematospermia. Pain is the predominant characteristic symptom of CP/CPPS and it is not only associated with disturbed quality of life but also significant sexual dysfunction.[7,8,9] Diagnosis of the pathology is usually made based on the symptoms stated where the duration and persistence of these symptoms constitute the first step in the evaluation of CP/CPPS. The National Institutes of Health-Chronic Prostatitis Symptom Index (NIH-CPSI) is a commonly used tool to diagnose CP/CPPS, evaluate the severity of symptoms and to provide available rational treatment options.

The form consists of three subscales with a total score ranging from 0 to 43: pain or discomfort (with a total score ranging from 0 to 21), urinary symptoms (with a total score ranging from 0 to 10), and impact on the quality of life (QOL) (with a total score ranging from 0 to 12 points. [1] Pain scores of perineal or ejaculatory discomfort ≥ 8 are the good predictors of patients with moderate to severe CP/CPPS.[10] It has been shown that, as the symptoms get more severe form, the scores will also be higher. (Figure 1).

The translation and linguistic validation of the NIH-CPSI into various languages were made in a successful manner previously.[1,4,11,12] In this present study, we mainly aimed to form and validate the Turkish version of the NIH-
CPSI. In addition, we also investigated whether the patients' responses to urinary symptoms were compatible with the International Prostate Symptom Score (IPSS) and Visual Analogue Scale (VAS) evaluations.[13,14]

2. Material and methods

2.1. Study design

116 CP/CPPS patients referring to Dr. Lutfi Kirdar Kartal Training and Research Hospital Urology Department with recurrent symptoms and no response to conventional management approaches for at least 6 months and 88 healthy controls were included into the program of this prospective study. Patients with psychiatric disorders, cancer history, benign prostatic hyperplasia, and other severe comorbidities were all excluded from the study program. All of participants completed the Turkish NIH-CPSI by themselves. Additionally, they were also asked to complete the International Prostate Symptom Score (IPSS) and visual analog scale (VAS) regarding the urinary symptoms. To evaluate the test-retest reliability, 40 patients were asked to re-complete the NIH-CPSI once again two weeks later. The study protocol was approved by the ethics committee of our hospital, and all the participants were asked to sign a detailed informed consent stating all procedures in line with the Helsinki Declaration (193/2013).

2.2. Translation process

To perform the translation process, the multi-step validation method defined by Hutchinson et al. was used as a guide.[15] These steps are outlined below:
1. The questionnaire was translated from English to Turkish by two independent translators with proper skill and fluency in speaking both English and Turkish.

2. To compare and evaluate the translated Turkish forms, a meeting was held between the research group and the two translators.

3. The final form of the questionnaire on which a consensus has been reached was translated back into Turkish language by the two translators simultaneously, regardless of the source of the original questionnaire.

4. Minor inconsistencies were resolved, and the final form was given during the second meeting between the translators and the researchers.

5. Finally, in an attempt to determine whether the final version of the questionnaire was appropriate and easily understandable a pilot study was carried out with the inclusion of 15 symptomatic patients demonstrating the highest NIH-CPSI symptom scores. This study demonstrated the final questionnaire to be understandable and the final updated form was approved without any changes (Figure 2). 15 patients were selected from the patients

2.3. Statistical analysis

The general characteristics of the participants were evaluated by using descriptive statistics, and the data were presented as mean ± standard error of mean (SEM). To assess the psychometric analysis of NIH-CPSI, reliability, internal consistency, and test-retest reliability were taken into consideration. Internal consistency was evaluated using the Cronbach alpha value, while test-retest reliability was evaluated using the Spearman correlation test. Discriminant
validity was evaluated based on the information obtained by comparing the results of the patients with those of the control group. Mann-Whitney U test was used to investigate potential differences and similarities between the groups. All statistical analyses were performed using SPSS 22.0 (IBM® SPSS® Statistics V22.0, 2013, USA), and p<0.05 was considered statistically significant.

3. Results

A total of 116 CP/CPPS patients and 88 healthy controls were included into the study program and the demographic characteristics of the patients are shown in Table 1. The mean age of the CP/CPPS and control groups were 38 and 39.4 years, respectively (p = 0.519). The mean duration of the symptomatic status in CP/CPPS group was 12 months. There was a significant difference regarding the NIH-CPSI (both the overall scale and subscales) scores of both groups (p<0.001) (Table 1). Spearman correlation test supported the significant correlation of our Turkish NIH-CPSI results. Cross tabulation with correlations between the VAS, I-PSS, QOL, total NIH-CPSI and its subscales are being demonstrated in Table 2.

The NIH–CPSI pain scores and VAS in the subgroup patients were found to be highly correlated (0.66). Also, the correlation between voiding scores and IPPS was found to be highly significant by reaching the value of 0.01. (r = 0.54) (Table 2). In test-retest evaluation again, the total NIH-CPSI score (0.909) was
found to be correlated well with the scores of the subgroups (p<0.001). Last but not least, the psychometric analysis has shown a great internal consistency with high Cronbach's alfa coefficient values for the overall NIH-CPSI index (0.864) (Table 3).

4. Discussion

Clinical studies by using questionnaire forms are preferred method in the objective evaluation of subjective complaints. The National Institutes of Health-Chronic Prostatitis Symptom Index (NIH-CPSI) has been commonly used to evaluate symptom severity in patients with chronic prostatitis/chronic pelvic pain syndrome (CP/CPPS). With the help of this well-prepared questionnaire, urologists have the chance to understand the past history of the disease and also evaluate the response obtained as a results of the treatment applied.

Like all other questionnaires, NIH-CPSI has also been translated into many languages, and its validation studies have been performed. To obtain an appropriate, convenient, and easily understandable form, each translation should be conducted by qualified, experienced translators. In our current study we worked with two independent translators during the four main steps of the process to prepare the Turkish version of NIH-CPSI from the original English form following the steps defined by Hutchinson et al. In the final stage, we conducted a pilot study with 15 patients.[15]

Statistical evaluation of our findings demonstrated well that the Turkish version of the NIH-CPSI had excellent test-retest reliability (r = 0.909) and high
internal consistency (Cronbach's alpha = 0.864). Internal consistency was assessed in line with the original studies of Litwin et al.[1] In the original questionnaire, nine items had high test-retest reliability (r: 0.83 to 0.93) and internal consistency (Cronbach's alpha: 0.86 to 0.91).

Other validation studies concerning the application of NIH-CPSI namely the Italian version (Cronbach's alpha = 0.84-0.96), the Korean version (Cronbach's alpha= 0.86 to 0.97), the Japanese version (Cronbach's alpha = 0.83 to 0.87), Brazilian version (Cronbach's alpha = 0.85-0.93), Persian version (Cronbach's alpha = 0.865)[11,12,16,17,18] showed the similar results with high level confirmation of the internal consistency.

Our study is not the first study regarding the use of NIH-CPSI or treatment of CP/CPPS in Turkey but our study is the first study on Turkish validation of NIH-CPSI. For example in their original study although Arda E et al., used the UPOINT classification according to NIH-CPSI scores in the treatment of CP/CPPS patients but no validation of NIH-CPSI in Turkish has been mentioned in this study.[19] Again in the study performed by Sönmez et al. in 2011, the sexual dysfunction of CP/CPPS patients have been included and the NIH-CPSI form was used. However, Turkish validation of NIH-CPSI has also not been used in this trial.[20]

On the other hand again, despite numerous validation studies conducted on NIH-CPSI; none of them focused on the correlation with VAS and IPSS questionnaires so far.[11, 13] In the light of this fact again, apart from being the first Turkish NIH-CPSI validation study, our study has a distinct position from
other studies considering the excellent correlation between the results of NIH-CPSI subgroups and also IPSS and VAS questionnaires (Pain-VAS correlation: 0.66, urinary symptom-IPSS correlation: 0.54).

Our study had some potential limitations. First, the socio-cultural characteristics of the patients were variable and the number of participants in the control group was not as high as in the CP/CPPS group. The socio-cultural differences, such as educational levels and dialects, of patients have also been shown to affect the understandability of the form.[1,3,11] Secondly, our study was not a multicenter one which might give further reliable data.

5.Conclusion

In the light of our current findings, we believe that the Turkish version of NIH-CPSI is a simple, feasible and reliable form to be used in CP/CPPS patients. However we believe that further clinical studies concerning the use of the Turkish version among Turkish patients need to be conducted in an attempt to increase well the sensitivity of this test. Such studies will be provide valuable relevant data to establish the profile of Turkish patients with CP/CPPS and also to determine the prevalence of cases with these symptoms in our country.

References


18. Allameh F, Tehrani MMM, Tasharofi MA, Jamshouran MAG. Validation of the Persian Version of the National Institute of Health
Chronic Prostatitis Symptom Index. Urology Journal 2020. doi: 10.22037/uj.v0i0.5444


Table1. Baseline characteristics: Age, duration of symptoms, NIH-CPSI scores, VAS, I-PSS and QOL in the study groups

<table>
<thead>
<tr>
<th></th>
<th>CP/CPPS</th>
<th>Controls</th>
<th>p*</th>
</tr>
</thead>
<tbody>
<tr>
<td>No. of patients</td>
<td>116</td>
<td>88</td>
<td></td>
</tr>
<tr>
<td>Mean age (SEM)</td>
<td>38 (9.3)</td>
<td>39.4 (10.7)</td>
<td>0.519</td>
</tr>
<tr>
<td>Duration of symptoms, month (Range)</td>
<td>12 (16-240)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mean Score of NIH-CPSI (SEM)</td>
<td>22.8 (7.7)</td>
<td>2.5 (1.7)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td></td>
<td>NIH-CPSI Total</td>
<td>NIH-CPSI Pain</td>
<td>NIH-CPSI Void</td>
</tr>
<tr>
<td>------------------</td>
<td>----------------</td>
<td>---------------</td>
<td>---------------</td>
</tr>
<tr>
<td>NIH-CPSI Total</td>
<td>r=0.77**</td>
<td></td>
<td></td>
</tr>
<tr>
<td>NIH-CPSI Pain</td>
<td>r=0.77**</td>
<td>r=0.66**</td>
<td>r=0.25*</td>
</tr>
<tr>
<td>NIH-CPSI Void</td>
<td>r=0.72**</td>
<td>r=0.33**</td>
<td>r=0.29**</td>
</tr>
<tr>
<td>NIH-CPSI Qol</td>
<td>r=0.66**</td>
<td>r=0.25*</td>
<td>r=0.54**</td>
</tr>
<tr>
<td>VAS</td>
<td>r=0.66**</td>
<td>r=0.22*</td>
<td>r=0.48**</td>
</tr>
<tr>
<td>IPSS</td>
<td>V</td>
<td>r=0.24*</td>
<td>r=0.54**</td>
</tr>
</tbody>
</table>

*Correlation is significant at the 0.01 level

Table 2. Correlation matrix (Spearman) of VAS, I-PSS, QOL, and NIH-CPSI and its subscales among 116 patients with CPPS.
* Correlation is significant at the 0.05 level VAS: Visual Analog Scale, NIH-CPSI: National Institute of Health Chronic Prostatitis Symptom Index, IPSS: International Prostate Symptom Score, Qol: Quality of life.

Table 3. Reliability of the test-retest analysis (Spearman) and Internal consistency (Cronbach’s alpha coefficient) of the present study

<table>
<thead>
<tr>
<th>Domain</th>
<th>Cronbach’s alpha</th>
<th>Test</th>
<th>Re-Test</th>
<th>Correlation</th>
</tr>
</thead>
<tbody>
<tr>
<td>NIH-CPSI total</td>
<td>0.864</td>
<td>22.8 (7.7)</td>
<td>22.5 (7.1)</td>
<td>0.909**</td>
</tr>
<tr>
<td>Pain</td>
<td>0.862</td>
<td>9.5 (4.8)</td>
<td>9.4 (5.5)</td>
<td>0.886**</td>
</tr>
<tr>
<td>Urinary symptoms</td>
<td>0.819</td>
<td>6 (3.2)</td>
<td>5.7 (2.9)</td>
<td>0.925**</td>
</tr>
<tr>
<td>Life quality impact</td>
<td>0.762</td>
<td>7.3 (2.3)</td>
<td>7.4 (2.5)</td>
<td>0.874**</td>
</tr>
</tbody>
</table>

** Correlation is significant at the 0.01 level. NIH-CPSI: National Institute of Health Chronic Prostatitis Symptom Index.
Figure 1: NIH-chronic prostatitis symptom index (NIH-CPSI)

<table>
<thead>
<tr>
<th>Pain or Discomfort</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>1. In the last week, have you experienced any pain or discomfort in the following areas?</td>
<td>Yes</td>
</tr>
<tr>
<td>a. Area between rectum and testicles (perineum)</td>
<td>1</td>
</tr>
<tr>
<td>b. Testicles</td>
<td>1</td>
</tr>
<tr>
<td>c. Tip of the penis (not related to urination)</td>
<td>1</td>
</tr>
<tr>
<td>d. Below your waist, in your pubic or bladder area</td>
<td>1</td>
</tr>
<tr>
<td>2. In the last week, have you experienced:</td>
<td>Yes</td>
</tr>
<tr>
<td>a. Pain or burning during urination?</td>
<td>1</td>
</tr>
<tr>
<td>b. Pain or discomfort during or after sexual climax (ejaculation)?</td>
<td>1</td>
</tr>
<tr>
<td>3. How often have you had pain or discomfort in any of these areas over the last week?</td>
<td>Never</td>
</tr>
<tr>
<td>4. Which number best describes your AVERAGE pain or discomfort on the days that you had it, over the last week?</td>
<td>0</td>
</tr>
<tr>
<td>NO PAIN</td>
<td>PAIN AS BAD AS YOU CAN IMAGINE</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Urination</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>5. How often have you had a sensation of not emptying your bladder completely after you finished urinating, over the last week?</td>
<td>Not at all</td>
</tr>
<tr>
<td>6. How often have you had to urinate again less than two hours after you finished urinating, over the last week?</td>
<td>Not at all</td>
</tr>
<tr>
<td>7. How much have your symptoms kept you from doing the kinds of things you would usually do, over the last week?</td>
<td>None</td>
</tr>
<tr>
<td>8. How much did you think about your symptoms, over the last week?</td>
<td>None</td>
</tr>
</tbody>
</table>

Quality of Life

9. If you were to spend the rest of your life with your symptoms just the way they have been during the last week, how would you feel about that? | Delighted | Pleased | Mostly satisfied | Mostly dissatisfied | Unhappy | Terrible |  |

Scoring the NIH-Chronic Prostatitis Symptom Index Domains

Pain: Total of items 1a, 1b, 1c, 1d, 2a, 2b, 3, 4 = _____

Urinary Symptoms: Total of items 5 and 6 = _____

Quality of Life Impact: Total of items 7, 8 and 9 = _____
NIH-Kronik Prostatit Sektör İndeksi (NIH-CPSI)

Ağrı ya da RAHATSIZLIK

1. Son 1 hafta içerisinde aşağıda belirtilen wüct bölgelerinde ağrı ya da rahatsızlık hissettiğiniz mi?

<table>
<thead>
<tr>
<th></th>
<th>Evet</th>
<th>Hayır</th>
</tr>
</thead>
<tbody>
<tr>
<td>a) Makot ve hayalar(testister) arasında</td>
<td>1</td>
<td>0</td>
</tr>
<tr>
<td>b) Hayalarda(Testierde)</td>
<td>1</td>
<td>0</td>
</tr>
<tr>
<td>c) Penis ucuna</td>
<td>1</td>
<td>0</td>
</tr>
<tr>
<td>d) Kaslar ya da mesane üzerinde</td>
<td>1</td>
<td>0</td>
</tr>
</tbody>
</table>

2. Son 1 hafta içerisinde aşağıdaki faaliyetler arasında ağrı veya rahatsızlık hissettiğiniz mi?

<table>
<thead>
<tr>
<th></th>
<th>Evet</th>
<th>Hayır</th>
</tr>
</thead>
<tbody>
<tr>
<td>a) İşyerken</td>
<td>1</td>
<td>0</td>
</tr>
<tr>
<td>b) Meni başlaması sonrasında</td>
<td>1</td>
<td>0</td>
</tr>
</tbody>
</table>

3. Yukarıda belirtilen ağrı yada rahatsızlık hissini ne sıklıkla hissettiğiniz?

- 0. Hiç
- 1. Nadiren
- 2. Bazen
- 3. Sıklıkla
- 4. Genellikle
- 5. Hep

4. Son 1 hafta içerisinde ağrı ya da rahatsızlık hissettiğiniz günler en iyi şekilde tanımlayan seçeneğinde hangisidir?

<table>
<thead>
<tr>
<th></th>
<th>0</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
<th>6</th>
<th>7</th>
<th>8</th>
<th>9</th>
<th>10</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ağrı yok</td>
<td>Hayal edebileceğim</td>
<td>en şiddetli ağrı</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

İŞME

5. Son 1 hafta süresince işemenizi tamamladıktan sonra idrar keseniz tam olarak boşlamadığını hissini ne sıklıkla duyдумuz?

<table>
<thead>
<tr>
<th></th>
<th>0 Hiç</th>
<th>1 Beşte birinden daha az</th>
<th>2 Yardan daha az</th>
<th>3 Yaklaşık olarak yarım yaraya</th>
<th>4 Yardan daha fazla</th>
<th>5 Hemen hemen her zaman</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ağırlık</td>
<td>0 Mutlu</td>
<td>1 Memnun</td>
<td>2 Tatminkar</td>
<td>3 Bazen tatminkar bazen tatminizsiz</td>
<td>4 Çoğunlukla tatminizsiz</td>
<td>5 Mutlu</td>
</tr>
</tbody>
</table>

BELIRİTLERİN ETKİSİ

6. Son 1 hafta süresince işemenizi tamamladıktan sonra iki saat içerisinde ne sıklıkla tekrar yaptınız?

- 0 Hiç
- 1. Beşte birinden daha az
- 2 Yardan daha az
- 3 Yaklaşık olarak yarım yaraya
- 4 Yardan daha fazla
- 5. Hemen hemen her zaman

YAŞAM KALİTESİ

7. Son 1 hafta süresince genellikle yaptığınız işlere hastalıkımız belirtileri nedeniyle hangi sıklıkta yapmanız durumunda kaldıınız?

- 0 Hiç
- 1. Çok az
- 2. Biraz
- 3. Çok fazla

8. Son 1 hafta içerisinde hastalıkınızla ilgili belirtileri ne sıklıkta düştündürüz?

- 0 Hiç
- 1. Çok az
- 2. Biraz
- 3. Çok fazla

NIH-Kronik Prostatit Sektör İndeksi Skor bölümü

Ağırlık (1-4):
- Ağrı (1-4):
- İşe (5-6):
- Eski Kalite (7-9):

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