

Cultural Adaptation of the National Institutes of Health – Chronic Prostatitis Symptom Index (NIH-CPSI) – to Brazilian Spoken Portuguese: NIH-CPSI (Braz)

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ABSTRACT

Objectives: To create a Brazilian version of the National Institutes of Health – Chronic Prostatitis Symptom Index (NIH-CPSI) using a cross-cultural adaptation process. *Materials and Methods:* The nine items of the NIH-CPSI were translated to Portuguese, by two independent translators, of native Portuguese language origin, and it was obtained a single version, that was retranslated to English by two English native spoken translators, in order to correct any discrepancies. Those versions were compared to the original text, the modifications were applied and it was created a final version in Portuguese. That was pre-tested and applied to 30 patients with pain or perineal or ejaculatory disorder. To each item of the pre-final version it was assigned a score according to the grade of understanding and clarity in order to implement the adequate corrections. The final version in Portuguese was submitted to evaluations including face validation and psychometric proprieties of reproducibility and internal consistency, respectively evaluated by the (p) Pearson correlation coefficient and α Cronbach coefficient.

Results: All items applied to 30 patients during pre-test phase had a grade higher than 8 of understanding and clarity, and were considered clearly understandable by the patients. However, at face validation evaluation, there was an inconsistency of item three that was redone. The final produced version, called NIH-CPSI (Braz) showed good reproducibility (p = 0.89-0.99) and internal consistency (α Cronbach coefficient = 0.85-0.93).

Conclusions: NIH-CPSI was adapted to Brazilian spoken Portuguese and its original proprieties were maintained, being a valid instrument for evaluations of symptoms of chronic prostatitis in Brazilian patients.

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INTRODUCTION

Many urological consults refer to symptoms of chronic prostatitis/chronic pelvic pain syndrome (CP/CPPS). Those are very frequent diagnosis in men less than 50 years old with a significant impact of quality of life (1). According to the National Institutes of Health (NIH) (2), there are four categories of prostatitis. CP/CPPS is type III, and includes IIIA (inflammatory) and IIIB (non-

-inflammatory), and represents most cases. This category (III) also presents a challenging diagnosis, has several symptoms and no pathognominic clinical finding (1). It presents chronic pelvic pain, associated to micturition disorders, psychological aspects and impact on quality of life of patients. It has high prevalence with a global rate of 8.2% (3). Laboratorial evaluation using Meares-Stamey diagnostic tests is complex (4), not sensible to non-inflammatory chronic prostatitis (5) and not

easily reproducible in clinical practice (6). Laboratory findings are non-specific and clinical history is important to diagnosis. It is important the use a valid instrument for correct diagnosis, follow-up and evaluation of treatment.

Several symptomatic index for prostatitis were developed, most of them not validated scientifically (7,8). Only the National Institutes of Health (NIH) Chronic Prostatitis Collaborative Research Network produced a valid instrument for evaluation of symptoms of CP/CPPS: the NIH - Chronic Prostatitis Symptom Index (NIH-CPSI) (9). It has nine items, divided in three domains (pain, urinary symptoms and quality of life) and it is used as diagnostic tool for the diagnosis and follow-up of CP/CPPS. Initially it was presented in English, but it was adapted to Spanish (10), Japanese (11), German (12), Italian (13), Estonian (14), Malay (15), Finnish (16), and French (17). However, it was not adapted to Brazilian spoken Portuguese until now. Our goal was to create a Brazilian version of the NIH-CPSI, using a cross-cultural process based on the north-American version.

MATERIALS AND METHODS

NIH-CPSI description

NIH-CPSI (Figure-1) includes the main urinary symptoms related to CP/CPPS with a final score 0-43, divided in three domains: pain or discomfort (4 items, with a total score of 0-21), urinary symptoms (2 items, with a total score of 0-10 points), and impact of quality of life (3 items, with a total score of 0-12 points) (9).

Patients with pain or perineal or ejaculatory discomfort with NIH-CPSA score ≥ 4 are considered with symptoms of CP/CPPS. Those with pain or perineal or ejaculatory discomfort and score ≥ 8 are considered as patients with CP/CPPS moderate to severe (18). The higher the score, more important is the impact of symptoms.

Cross-cultural adaptation

For the process of cross-cultural adaptation, it was followed the "Guidelines of Institute for Work and Health" (19) after authorization of the author. Initially the NIH-CPSI was translated to Portuguese by two independent bilingual native spoken Portu-

guese translators: an urologist physician (T1) and a non-medical translator without knowledge on the subject (T2). A second phase, mediated by a native Portuguese spoken mediator, included comparison and summarization of both translations, producing a single consensual version called T12. From T12, two different back-translations were performed by English, by two independent English native spoken non-medical translators (BT1 and BT2). In a next phase, a panel of specialists, including all translators, Portuguese and English teachers and a moderator evaluated all reported data, solved any discrepancies and created a pre-final version of the questionnaire.

Pre-Test

Pre-final version was submitted to pre--test. At this phase, the version was submitted to 30 consecutive patients that spontaneously attended the Urologic Service of the University Hospital of Universidade Federal de Santa Catarina (UFSC) with pain or perineal or ejaculatory discomfort as the main complains. The exclusion criteria included illiterate patients or those with cognitive deficit that prevented reading and understanding the instrument and those who refused to participate on the project. All patients were informed about the observational characteristic of the study, without any immediate benefit and that the result would be useful for the diagnosis and follow-up of CP/CPPS in the future. At pre-final version, after each of the nine translated items of NIH-CPSI it was included a table in order to the patients score each item, from 1 to 10, according to their grade of understanding and clarity. The translated questions scored 1 to 4 were considered confusing, those 5 to 7 with low understanding and those with 8 to 10 were considered understandable.

Test

The final Portuguese version of NIH-CPSI, that included all modifications suggested during the evaluation of the pre-final version, was applied to other 30 consecutive patients that attended spontaneously the Urological Department of the University Hospital of UFSC with pain or perineal or ejaculatory discomfort. The exclusion criteria again included illiterate patients or those with cognitive deficit that prevented them to understand and read the instrument or that refused to participate on the project.

Figure 1 - National Institutes of Health Chronic Prostatits Symptom Index (NIH-CPSI). Adapted from: (9) Litwin et al., J Urol 1999; 162, p.374, permission of Elsevier.

374	4 CHBONIC PROSTATITIS SYMPTOM INDEX						
	APPENDIX 1. MATIONAL INSTITUTES OF BRALTH CLASSIFICATION SYSTEM FOR PROSTATITIS						
Type	Classification		Definition				
I III:	Acute bacterial prostatitis Chronic bacterial prostatitis Chronic abacterial prostatitis (chronic pelvic pain syndroms)	Ewis No	Evidence of acute bacterial infection Evidence of recurrent bacterial infection No domonstrable infection White blood cells in semen, expressed prestatic secretions or voided bladder 3 (sediment from initial 10 cc urine after prostate massage during Mearce-Stamey 4 glass test ²⁰) No white blood cells in semen, expressed prostatic socrations or voided bladder 3 (sediment from initial 10 cc urine after prostate massage during Mearce-Stamey 4 glass test ²⁰) No symptoms, incidental diagnosis during prostate biopsy or presence of white blood cells in prostatic secretions during evaluation for other disorders				
Λ	Inflammatory	90					
В	Noninflammatory	No :					
IV	Asymptomatic inflammatory prostatitis	No pr					
	APPENDIX 2: NIH CHRONIC PROSTATITIS SYMPTOM INDEX (NIH-CPSE)						
1. In t	or Discomfort the last week, have you experienced any pain of fort in the following areas?		6. How often have you had to urinate again less than two hours after you finished urinating, over the last week? Q. Not at all				
1	Yes Area between rectum and D, seticles (perinsum)	No □ _o	□1 Less than 1 time in 5 □2 Less than half the time □3 About half the time				
c. 1	Posticles U _t (ip of the penis (not related to U _t (arination)	\Box_0	□ More than half the time □ Almost always				
	Below your waist, in your □t public or bladder area.	Ξ.,	Impact of Symptoms 7. How much have your symptoms kept you from doing the kinds of things you would usually do, over the last week?				
	the last week, have you experienced: Yes	No	D. None D. Only a little				
b. 1	Pain or burning during urination? D ₁ Pain or discomfort during or D ₁ after sexual climax (ejaculation)?	D _e	□ ₀ Some □ ₀ A lot				
the	w often have you had pain or discomfort in an	g of	8. How much did you think about your symptoms, over the last week? Do None				
ο. Ο.,	Never Ramly Sometimes		Ui Only a little □i Some □i A let				
\Box_{a}^{c}	Often Urually Always		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				
	hich number best describes your AVERAGE pa comfort on the days that you had it, over the b		week, how would you feel about that? Q. Delighted D. Flemsed D. Mostly satisfied				
0	1 2 3 4 5 6 7 8 9	□ 10	□ Mixed (about equally satisfied and dissatisfied) □ □ Mostly dissatisfied □ Unhappy				
NO P	NO PAIN PAIN AS BAD AS YOU CAN IMAGINE		Q Terrible				
5. He	rination ow often have you had a sensation of not empt	ying					
ev Lij	sur bladder completely after you finished uring ser the last week? , Not at all	ting,	Scaring the MIH-Chronic Prestptitis Symptom Index Domains Pain: Total of items 1a, 1b, 1c, 1d, 2a, 2b, 3, and 4 =				
<u>a</u>	Less than 1 time in 5 Less than half the time About half the time		Urinary Symptoms: Total of items 5 and 6				
	More than half the time Almost always		Quality of Life Impact: Total of items 7, 8 and 9 =				

During this test phase, the instrument was applied twice for each patient. First time was self-administrated and second time, after a time break of one hour, by an oriented medical interview. In this second application, the urologist (C.N.) asked again each question in order to evaluate the understanding of each patient of every item of the instrument and the adequacy of this comprehension to the question intent of the original instrument (NIH-CPSI). This analysis was an evaluation of face validation (15) of final version of the instrument, and determined that the answers of the Brazilian patients really referred to the questions originally proposed by the instrument created by Litwin et al. (9).

The reproducibility of the instrument was evaluated by the coefficient of correlation of Pearson among the answers of the questions of the self-administered questionnaire and those during the interview with the urologist (C.N.) Internal consistency was estimated by the coefficient of α Cronbach, of each domain, D1 (pain and discomfort - items 1-14), D2 (urinary symptoms - items 5-6) and D3 (impact of symptoms on quality of life – items 7-9) in relation to the final score. It was also calculated the coefficient of α Cronbach among all items and final score. SPSS 17-0 software (Statistical Package for Social Sciences) for Windows® was used for statistical analysis.

The research protocol was approved by the Ethical Committee of Research involving Human Beings of the Federal University of Santa Catarina, Brazil (CEPSH-UFSC) # 2388/12.

RESULTS

Cross-cultural adaptation

There were some discrepancies among versions T1, T2, T12, BT1 and BT2 during the process of cross-cultural adaptation. The nine items of the questionnaire (questions and answers) were re-evaluated in order to solve these differences, and some adequacies were introduced to maintain the original meaning of the questionnaire in a colloquial Brazilian manner. Simple common terms and expressions were used always as possible in order to facilitate the understanding of patients and the use in different socioeconomic and cultural groups of Brazilian population. Some examples of adequacy:

"have you experienced any pain or discomfort", is an expression in past participate in English and was translated to simple perfect preterit in Portuguese. Due to these adequacies the back-translations presented some differences but without change of the meaning. Some terms, as "experienced", were translated to common terms in Portuguese, more usual in ordinary language, in order to refer to the original question. Words as "perineum" and "sexual climax" of the original English version were omitted in the Brazilian version, since they are not usual in ordinary Brazilian language, without changing the meaning of the sentences. In the original version, some questions started with an adverbial time adjunct as "in the last week", and others ended with "over the last week", in order to determine the observational time of symptoms throughout one week. The Portuguese version maintained both options but always in the beginning of the sentence in order to facilitate the understanding of the instrument.

Pre-Test

All 30 patients that answered the pre-final version were male with ages from 18 to 65 years old, median 41.4 years. Eight patients (26.7%) attended pre-school, nine (30.0%) high school and 13 (43.3%) universities. During this phase and also in the others no patient refused to participate in the study.

All items showed a median score of understanding and clarity superior to 8 (Table-1). Worse median (8.7) and the highest standard deviation (1.6) referred to item 3 and it was made an adaptation of the translation in order to improve understanding.

Since all other items were adequate in the pre-test phase, it was obtained the Final Version without any further modifications of the pre-final version, and it was called NIH-CPSI (Braz).

Test

The reproducibility of NIH-CPSI (Braz) was evaluated comparing the obtained scores of the self-administered version to those of the assisted by a physician, after an interval of one hour. The coefficients of correlation of Pearson, of each item, and the internal consistency of the NIH-CPSI (Braz) evaluated by the coefficient of α Cronbach are shown in Table-2. Face validation evaluation showed that,

Table 1 - Score of understanding and clarity of items of NIH--CPSI (Braz) during pre-test phase.

Item	Median ± standard deviation
1	9.27 ± 0.87
2	9.50 ± 0.78
3	8.70 ± 1.60
4	9.03 ± 1.12
5	9.27 ± 1.08
6	8.93 ± 1.36
7	9.20 ± 1.03
8	9.30 ± 1.05
9	9.20 ± 0.85

although in pre-test phase all items were considered clear (since they obtained an index of clarity and understanding above 8), during the questionnaire assisted by a doctor patients understood poorly item 3. The main reason was that the question in Portuguese induced to misinterpretation of the local of symptoms instead the symptoms itself. After

clarifying with Litwin the purpose of the question (personal contact) we changed the version to "how often do you present any of the symptoms of questions 1 and 2".

So, the final version of NIH-CPSI (Braz) included a modification after the pre-test phase, in order to reassure the face validation of the instrument. After this last modification (item 3), the questionnaire was again applied to 30 patients that attended the Urologic Departament of UFSC with pain or perineal or ejaculatory discomfort in order to verify the clarity and understanding as was done in the pre-test phase. Median score given by the patients was 9.06 and standard deviation 1.08. The item was clear (with a superior score than obtained in pre--test phase) and the validation of the instrument was adequate. So it was proposed the Brazilian version of NIH-CPSI, called NIH-CPSI (Braz), or Indice de Sintomas da Prostatite Crônica (Figure-2). That version was submitted to the original authors and they considered it adequate.

DISCUSSION

Questionnaires for clinical evaluation of subjective symptoms, that transform them in objective measures, are more frequent and are be-

Table 2 - Reproducibility and internal consistency of NIH-CPSI (Braz).

Domain (score scale)	Item	Median (IC 95%)		Correlation	α
		T1	T2		
Pain localization (0-6)	1.2	1.8 (1.4-2.2)	1.9 (1.5-2.3)	0.91	
Pain frequence (0-5)	3	2.3 (1.8-2.7)	2.4 (2.0-2.8)	0.89	
Pain intensity (0-10)	4	3.8 (2.8-4.8)	4.1 (3.2-5.0)	0.94	
Domain: pain (0-21)	1-4	7.9 (6.3-9.4)	8.4 (7.0-9.8)	0.92	0.90
Domain: Urinary symptoms (0-10)	5.6	3.8 (2.4-5.2)	3.8 (2.4-5.2)	0.99	0.85
Impact (0-6)	7.8	2.6 (1.9-3.2)	2.5 (1.9-3.1)	0.96	
Quality of life (0-6)	9	3.6 (2.9-4.2)	3.5 (2.9-4.2)	0.96	
Domain: impact on quality of life (0-12)	7-9	6.1 (4.9-7.4)	6.0 (4.9-7.1)	0.97	0.93

Results obtained after application and reapplication of NIH-CPSI (Braz) in 30 patients. Correlation evaluated using (p) Pearson coefficient. = α Cronbach coefficient

Figure 2 - Brazilian version of the National Institutes of Health Chronic Prostatits Symptom Index, called NIH-CPSI (Braz).

NIH – CHRONIC PROSTATITIS SYMPTOM INDEX (BRAZ) / (ÍNDICE DE SINTOMAS DA PROSTATITE CRÔNICA)

, , , , , , , , , , , , , , , , , , ,				
Dor ou Desconforto 1. Na última semana, você sentiu alguma dor ou desconforto nas seguintes áreas?	6. Durante a última semana, com que frequência você teve que urinar de novo antes de completar duas horas de ter urinado?			
Sim Não	□, Menos de 1 em 5 vezes			
a. Entre o ânus e os testículos \Box_1 \Box_0	□, Menos de metade das vezes			
1 0				
b. Testículos				
	□ ₅ Quase sempre			
d. Na área abaixo da cintura (re- gião púbica ou área da bexiga) 🖂 , 🖂	Imposto dos Cintomos			
gião púbica ou área da bexiga) \square_1 \square_0	Impacto dos Sintomas			
2. No último comono yeoô continu	7. Na última semana, até que ponto os sintomas o impediram de			
2. Na última semana, você sentiu:	fazer as coisas que você normalmente faz?			
Sim Não	o Nada			
a. Dor ou queimação ao urinar? $\Box_1 \ \Box_0$	□ Apenas um pouco			
b. Dor ou desconforto durante	☐ 2 Algumas vezes			
ou após a ejaculação? \square_1 \square_0	□ ₃ Muito			
3. Com que frequência você apresentou algum dos sintomas	9. Na última semana, quanto você pensou sobre seus sintomas?			
relacionados às questões 1 e 2?	□ Nada			
-				
□ Nunca	Algumes verses			
Raramente	☐ Algumas vezes			
Algumas vezes	□ ₃ Muito			
□₃ Frequentemente	Ovelidada da Wida			
Q Quase sempre	Qualidade de Vida			
□ ₅ Sempre	10. Se você passasse o resto da sua vida com os sintomas que			
4 D	sentiu durante a última semana, como você se sentiria?			
4. Durante a última semana, que número melhor descreve sua	□ Contente			
dor ou desconforto MÉDIO, sendo zero nenhuma dor e 10 a pior	□ 1 Satisfeito			
dor que você possa imaginar.	□ 2 Geralmente satisfeito			
	☐ 3 Igualmente satisfeito e insatisfeito			
NENHUMA A PIOR	☐ 4 Geralmente insatisfeito			
DOR DOR QUE	□ ₅ Infeliz			
VOCÊ POSSA	Péssimo			
IMAGINAR	<u>Indice final =</u> (soma dos escores			
BB1	dos 3 domínios)			
Micção	B. T. I. I. I. A. A. A. A.			
5. Durante a última semana, com que frequência você teve a	Dor: Total dos itens 1a, 1b, 1c, 1d, 2a,			
sensação de não esvaziar completamente a bexiga depois de	2b, 3 e 4 =			
terminar de urinar?	Sintomas Urinários: <i>Total dos</i>			
□ Nenhuma vez	itens 5 e 6 =			
☐ Menos de 1 em 5 vezes	Impacto sobre Qualidade de Vida:			
□ ₂ Menos de metade das vezes	Total dos itens 7, 8, e 9 =			
□ 3 Metade das vezes				
☐ 4 Mais de metade das vezes				
□ ₅ Quase sempre				

coming essential in clinical practice, mainly in scientific researches (19). Such instruments, adequately proposed and validated scientifically, are useful tools for diagnosis and grading of symptoms. Both diagnostic and symptomatic evaluation questionnaires, when validated to different cultures, homogenize scores, allowing comparisons in different places, and different languages and cultures.

In order to use these instruments in different places, cultures and languages than originally proposed, it is necessary to submit them to cross-cultural adaptation. This process involves translation and adaptation to the target culture; only a diligent process maintains equivalent measures and this process must be reliable. This is why we choose to follow the guidelines of Beaton et al. (19) that include translation, synthesis, back-translation, panel of specialists' evaluation, pre-test and evaluation by the original authors.

After the process of adaptation, we proceeded to validate the instrument, evaluating its psychometric proprieties. During validation we evaluated reproducibility, internal consistency and face validation. The reproducibility of the original instrument, described by Litwin et al., was made by comparison of answers of the self-applied questionnaire in two different moments, with an interval or two weeks (9). During validation of the Brazilian version, the reproducibility was made by correlating the answers of self-applied questionnaire to those of the medical assisted questionnaire. We decided not to submit the questionnaire twice (self-application) in order to avoid repeated errors of interpretation. The same error, in both moments, would indicate a good correlation and good reproducibility of the instrument, but without validation. When applying the instrument during a medical interview, it was possible to verify the face validation.

Internal consistency, evaluated by the coefficient of α Cronbach, was made in the same way than in the original work of Litwin et al. (9). The Brazilian version showed a coefficient of α = 0.90; 0.85 and 0.83 of domains D1, D2 and D3 and final score, respectively. In the original questionnaire the coefficient of α Cronbach of the same comparisons was 0.86; 0.79 and 0.87. The coefficient

of α Cronbach among all nine individual items and final score was 0.85 in the Brazilian version and 0.86 in the original version. The reproducibility of 9 items of the Brazilian version, using the correlation coefficient of Person, showed values from 0.89 to 0.90. The original instrument showed coefficients from 0.83 to 0.93 (9). In conclusion, the reproducibility and internal consistency of NIH-CPSI (Braz) were similar to the results of the original questionnaire. Other cross-cultural adaptations of NIH-NCSI showed similar results. For example, the Japanese version showed a reproducibility coefficient from 0.63-0.91 (11). The α Cronbach coefficient varied from 0.83 to 0.87 in the Japanese version and from 0.60 to 0.74 in the German version (12).

The main difference of the Brazilian version from the original NIH-CPSI was related to item 3. If the same translated sentence had been used in the process of cross-cultural adaptation, the answers would be related only to the symptoms of item 1. After talking to the original author, it was clarified that the item 3 should address the symptoms of items 1 and 2 and the question was reformulate in order to be equivalent to the original instrument.

Only patients with prostatitis symptoms were included in the study. The ability of the questionnaire to discriminate symptoms of CP/CPPS from other genitourinary diseases or even asymptomatic patients was well established in several studies (11,16). Items 5 and 6, of the urinary symptoms domains, are very similar to questions 1 and 2 of the IPSS (International Prostate Symptom Score) (20), except in relation of time (during last week in NIH-CPSI instead of last month in I-PSS) and represent bladder symptoms of voiding and storage, respectively.

NIH-CPSI is not intended to be a diagnostic tool of prostatitis, since it is a self-administered questionnaire to patients. Clinical evaluation by an urologist must not be waived for the correct diagnosis. It is recommended the use of NIH-CPSI for grading of symptoms in patients with a clinical diagnosis of prostatitis (18). But it was also used as reference in several population studies of prevalence and incidence of symptoms of prostatitis, by self-application or during medical interviews (21-24).

The final result of the present work, the Brazilian version called NIH-CPSI (Braz) presented in Figure-2 (Indice de Sintomas da Prostatite Crônica) will allow the development in our country of clinical studies of patients with symptoms of CP/CPPS similar to those already performed in different cultures, with comparable results internationally. It will help us establish an epidemiological profile of Brazilian patients and determine the prevalence of these symptoms. It can be used as a complementary tool in clinical practice similar to I-PSS (20), used for the evaluation of benign prostatic hyperplasia.

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CONFLICT OF INTEREST

None declared.

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