

Translation, cross-cultural adaptation and validation of the Pain Catastrophizing Scale (PCS) into Bengali in patients with chronic non-malignant musculoskeletal pain

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Running head: Pain Catastrophizing Scale (PCS) valid in Bengali.

Abstract.

Aim: To develop a culturally adapted and validated Bengali Pain Catastrophizing Scale (BePCS).

Methods: The English PCS was translated, adapted and back translated into and from Bengali, pre-tested by 30 adult patients with chronic non-malignant musculoskeletal pain. The BePCS was administered twice with 14 days interval to 90 patients. Convergent validity was measured by comparing the BePCS score with scores of the domains physical functioning and mental health of the Bengali SF-36, through Spearman's correlation coefficient. Test-retest reliability was assessed by intra-class correlation coefficient (ICC) and Spearman's rank correlation coefficient and internal consistency by Cronbach's alpha. Content validity was assessed by index for content validity (ICV) and floor and ceiling effects.

Results: The BePCS was well accepted by the patients in the pre-test. The content validity was excellent, both I-CVI and S-CVI were 1. Construct validity: the convergent validity was -0.424 for physical functioning and -0.413 for mental health, indicating a moderate negative correlation. Total BePCS score showed excellent internal consistency a mean Cronbach's α 0.92. Internal consistency for subscales rumination, magnification and helplessness, were Cronbach's α 0.903, 0.72 and 0.872 respectively. The test-retest reliability of total BePCS was 0.78($p < 0.001$) and for the subscales

ruminantion 0.872 ($p < 0.001$), magnification 797 ($p < 0.001$) and helplessness 0.927 ($p < 0.001$), showing excellent test-retest reliability.

Conclusions: The interviewer-administered BePCS appears to be an acceptable, reliable and valid instrument for measuring health-related quality of life in Bengali speaking patients with chronic non-malignant musculoskeletal pain. Further evaluation in the general population and in different medical conditions should be done .

Word count 250

Key words: Pain Catastrophizing Scale, Bengali, chronic non-malignant musculoskeletal pain, cross-cultural adaptation

What is new? The PCS was translated and validated for use in Bengali patients with chronic non-malignant musculoskeletal pain.

The Bengali PCS administered by interviewers demonstrated psychometric properties similar to the original English version and translations in other languages.

The questionnaire should be evaluated and used in people from the general population and in patients with different medical conditions to assess and compare the health status and impact of different disorders in Bangladeshi patients.

With about 164 million in Bangladesh and about 265 million total speakers worldwide, Bengali is the seventh most spoken language in the world, so it is important that this questionnaire is now available for studies in this part of the world.

Introduction

Pain as a symptom is now considered the fifth vital sign (1); it accounts for approximately 80% of physician visits and for an estimated US\$ 100 billion annually regarding cost of healthcare and loss of productivity (2). Chronic non-specific musculoskeletal pain is a burden for patients. It is associated with high socio-economic costs (3,4,5) and significantly affects the psychosocial status of affected people as well as their families and carers (6).

Chronic pain has complex underlying pathophysiology, and is determined by multiple psychological, social and biological factors. One of these factors is pain catastrophizing, characterized by patients magnifying their feelings about painful situations and continually thinking about these situations (7). Catastrophizing also involves feelings of helplessness and rumination about pain. Pain catastrophizing is related to multiple health outcomes like pain intensity, interference of pain with patients' life, physical disability and mental well-being (8). Pain catastrophizing causes a negative mental setting to bear actual or anticipated pain (9). Pain feeling has been found to increase from 7% to 33% in pain ratings, depending on the extent of catastrophizing (10). Catastrophizing plays an important role in pain chronicity and has a positive correlation with pain intensity and disability (11). It not only causes an increased perception of pain and emotional stress, but also prolongs pain episodes and catastrophizing is a significant predictor of the severity of pain, and of the ways how people cope with pain (12,13). Catastrophizing thus influences various substantial pain-related outcomes including: greater pain intensity and chronicity, depression, anxiety, pain-related disability and analgesic use (14). Pain catastrophizing has been associated with poor pain treatment response in patients with chronic pain (9). Previous studies reveal that if pain catastrophizing diminishes, pain intensity, disability and chronic condition would decrease (15). It appeared possible to modify pain catastrophizing in patients undergoing surgery (16). In psychological research it is postulated that pain catastrophizers may enact pain behaviors in order to receive support or empathy from their social environment (17). It has been shown that higher levels of catastrophizing pain behavior were associated with a more intense inference of pain by the observers, which may lead to over-cautious treatment decisions of those who take care of these patients (17,18).

The Pain Catastrophizing Scale (PCS) was developed in 1995 by Sullivan et al. to measure the individual degree of pain catastrophizing. The PCS is a multidimensional questionnaire, consisting of three subscales: helplessness, magnification, and rumination. The English version of the PCS has been investigated extensively, and its psychometric properties are good (19,20). The psychometric properties of the questionnaire have been confirmed at least for ten other languages, including German, Brazilian, Chinese, Portuguese, and Arabic (21,22,23, 24). There are more than 164 million people in Bangladesh (25) and about 265 million Bengali speaking people worldwide and it is the seventh language according to population (26).

A culturally adapted and validated Bengali version of the PCS for the people of Bangladesh is not yet available. The purpose of this study is the translation of the PCS into Bengali, cultural adaptation of the Bengali version and to test its validity and reliability in adult patients with chronic non-malignant musculoskeletal pain.

2. Materials and methods

2.1. Patients

The study has been conducted in the department of Rheumatology (inpatient and outpatient), of the Bangabandhu Sheikh Mujib Medical University.

Consecutive adult female/male patients between 18 and 70 years of age, who visited the rheumatology outpatient and inpatient department between September 2015 to August 2016, who suffered from chronic non-malignant musculoskeletal pain (pain persisting \geq six weeks) (10) at the spine or any part of the body and who consented to participate were enrolled in this study. Excluded were severely ill patients, patients with communication problems, patients who had a history of malignant disorders, those who suffered from alcohol or substance abuse and those who had acute pain or needed urgent surgery or other interventions. Substance/alcohol abuse was identified by taking history and defined as: alcohol / substance used in amounts which are harmful to the individual or others

The sample size of the study was 95 patients, as calculated by Study Size 3.0, a validated statistical software developed by Creostat HB35 HB in Sweden (27). Our expected intraclass correlation coefficient (ICC) for the assessment of test-retest reliability was 0.9 and the minimal acceptable ICC was 0.7. So using a two-sided test with $\beta = 0.2$ (80% power) and $\alpha = 0.05$, the sample size required was 22.873. Thus for the assessment of the test-retest reliability of the questionnaire and considering drop-out of some patients during retesting, a sample size of 32 was considered to be sufficient. These 32 patients were collected by simple random sampling from the 95 patients who were enrolled for the test.

2.2. The Pain Catastrophizing Scale

The PCS was developed in 1995 at the University Centre for Research on Pain and Disability of the McGill University of Canada by Michael JL Sullivan, in order to facilitate research on the mechanisms by which catastrophizing develops and its impact on pain experience (28). The PCS is a 13-item

instrument with 5-point scales with the endpoints (0) not at all and (4) all the time. The PCS yields a total score and three subscale scores assessing: rumination, magnification and helplessness. It can be scored by summing all of the ratings for each subscale (range, 6-item helplessness 0–24; 3-item magnification 0–12; 4-item rumination 0–16 points) or by the total score of its 13 items (range 0–52 points) with higher scores representing greater pain catastrophizing. Patients having a PCS score of more than 30 represent a clinically relevant level of catastrophizing and are considered at high risk for the development of chronic pain/disability, and a score of >30 is an indication for considering psychological intervention

2.3. Translation procedure

For translation and validation of the Bengali version of PCS, we obtained permission from the original author (Sullivan MJ). For translation and cultural adaptation of the English PCS into Bengali, we followed the recommendations by Beaton et al. (29). Forward translation which was carried out by two translators whose mother tongue is Bengali. One of the translators was the first author (MSMM), and the other was a Bengali teacher working in Dhaka University who was not apprised of the translation background. Comprising both translations, a synthesized form of the Bengali version was formed. Two English linguistic professionals – one from the department of English, Dhaka University another from a local college of Dhaka– translated the synthesized Bengali version of PCS into English (back-translation). An Expert Committee composed of five persons– a language professional, three rheumatologists and one statistician committee– reviewed and compared all the translations and the original English PCS. They verified the semantic, idiomatic, experiential and conceptual equivalence between the English and Bengali versions; a consensus was reached to form two sets of the prefinal Bengali version of the questionnaire. The two questionnaires differed in the wording of some of the items.

2.4. Testing of prefinal version

The two prefinal Bengali versions of the PCS were tested in a sample of 30 adult patients with chronic non-malignant musculoskeletal pain. Each subject completing the questionnaires was interviewed to find out what he or she thought was meant by each questionnaire item, and about the response they gave, and whether they had any further suggestions. If a participant was able to understand both of the translations of the same item, he or she was asked which translation (in the prefinal version-1/2) he or she would prefer. Based on the response of these participants, the adapted version was prepared.

The adapted version was administered twice with 14 days interval to 90 Bangladeshi patients who were suffering from chronic nonmalignant musculoskeletal pain.

For measuring the physical functioning and mental health these domains of the Bengali version of the SF-36 were applied. (30)

2.5. Questionnaire administration

The questionnaire was used as a self-administered one for literate participants and interviewer-administered one in case of illiterate participants. The literate participants were allowed to read the questionnaire themselves and give the replies as per their own understanding. In case of illiterate participants, the interviewer read the questionnaire in a clearly audible voice, without giving explanation. The responses were recorded by the interviewer.

2.6. Statistical analysis

All data were assessed using SPSS 22.0 (SPSS inc. Chicago, IL., USA). All tests were two-tailed and conducted at a 5% level of significance. There were no missing data for any items. Both the content validity and construct validity were assessed. Reliability was assessed through three ways: internal consistency, test-retest reliability and item to scale correlation. The internal consistency was measured using Cronbach's alpha. The internal consistency was considered acceptable when Cronbach's alpha was equal to or exceeded 0.70 (31). The item to scale correlation was assessed using Spearman's rank correlation (ρ) between scale and their constituent items, taking a value of $\rho \geq 0.40$ as acceptable (32). Test-retest reliability was assessed using intraclass correlation coefficient (ICC). An ICC between 0.60 and 0.74 was considered good, between 0.75 and 1.00 was excellent and considered acceptable for test-retest reliability (33). Content validity was assessed by the item-level content validity index (I-CVI) and the scale-level content validity index (S-CVI). Content validity indices were assessed by three rheumatologists as experts. Each expert rated each item either 1 (not relevant), 2 (somewhat relevant), 3 (quite relevant) or 4 (highly relevant). Then, for each item, the I-CVI was computed as the number of experts giving a rating of either 3 or 4 (thus dichotomizing the ordinal scale into relevant and not relevant), divided by the total number of experts. The S-CVI was measured by averaging calculation method (S-CVI/Ave), i.e. by the average of the I-CVIs for all items on the scale. The scale was judged to have excellent content validity if the I-CVI = 1 for each item and the S-CVI/Ave ≥ 0.9 , as recommended by Polit & Beck (2006) (34).

The **Mann-Whitney U test** (also called the **Mann-Whitney-Wilcoxon (MWW)**, **Wilcoxon rank-sum test**, or **Wilcoxon-Mann-Whitney test**) was used to compare between two groups with respect to a variable that does not follow a normal distribution.

The **Kruskal-Wallis test** (sometimes also called the "one-way ANOVA on ranks") is a rank-based nonparametric test. It was used to determine whether there are statistically significant differences between two or more groups of an independent variable on a continuous or ordinal dependent variable.

The intraclass correlation coefficient (ICC) or the intraclass correlation, is a descriptive statistic . It was used when quantitative measurements are made on units that are organized into groups. It describes how strongly units in the same group resemble each other.

2.7. Ethical clearance

The Institutional Review Board (IRB) of Bangabandhu Sheikh Mujib Medical University provided clearance to conduct the study (No. BSMMU IRB 11606). All the participants were informed in details about the nature of the study. Only the individuals willing to participate in the study were included. Informed written consent was taken from the participants. Every participant enjoyed his/her right to participate or refuse to participate and to withdraw participation at any time. The principal investigator maintained the confidentiality of the information obtained from the participants. Data were intended to be used solely for this study.

3. Results

3.1. Socio-demographic data

A total of 95 patients could be included in the study. Their mean age was 37 years (SD 13.01), 43 male (45.3%) and female 52 (54.7%). The rheumatological diagnoses are summarized in table 1. There were 27 patients (24.8%) who were below the secondary education level and 68 patients (71.6%) were at secondary level and above (Table 1). Thirty-eight patients (40%) came from a rural area and 57 (60%) patients were from the urban area. We found no significant difference between patients BePCS score and their age ($p=0.971$), sex (table 2) or educational level ($P=0.145$). Though BePCS scores were lower in people with higher educational level, the differences were insignificant as per the Kruskal-Wallis test (Table 3). The BePCS total and subscale scores were higher in female but this difference was not statistically significant (table 2).

3.2. Content validity

The item-level content validity index (I-CVI) and the scale-level content validity index (S-CVI) were the assessment tools of content validity. All items of the scale showed excellent content validity, both I-CVI and S-CVI were 1.

3.3. Construct validity

Convergent validity was measured by comparing the BePCS score with the scores of the physical functioning and mental health domain of the Bengali version of the SF-36 (30) through Spearman's correlation coefficient (r_s). The convergent validity was found to be -0.424 for physical functioning and -0.413 for mental health, indicating a moderate negative correlation.

3.4. Internal consistency and test-retest reliability

The total BePCS score showed an excellent total internal consistency with Cronbach's alpha 0.92. Internal consistency for subscales rumination, magnification and helplessness, were Cronbach's α 0.903, 0.72 and 0.872, respectively (Table 4).

The test-retest reliability of the BePCS scale was measured by the intraclass correlation coefficient. The test-retest reliability of the total BePCS was 0.781 ($p < 0.001$) and for the subscales rumination 0.872 ($p < 0.001$), magnification 0.797 ($p < 0.001$) and helplessness 0.927 ($p < 0.001$), indicative of a strong correlation between test and retest scores and hence showing excellent test-retest reliability (table 5).

4. Discussion

The pivotal components of cultural adaptation of a standard scale or instrument are translation and standardization of questionnaires. Occasionally assembling appropriate words pose a great challenge for translators. The PCS is the most commonly used tool to assess catastrophizing patients suffering from chronic pain. This study intended to validate the culturally adapted Bengali version of the PCS in adult Bangladeshi patients suffering from chronic non-malignant musculoskeletal pain. The process of translating and back-translating the English PCS to BePCS was carried out in accordance with the established guideline of Beaton et al. (29). After the validation of the original scale, all three subscales of the Bengali version (rumination, magnification, and helplessness), as well as the total of the scale, showed good internal consistency and similar correlation coefficients with the original scale except magnification subscale. The Cronbach's α of our study were 0.90, 0.72, 0.87 and 0.92 for the subscales rumination, magnification and helplessness and the total PCS scale respectively comparable with those reported in the original study of Sullivan MJ (19) where the values were 0.87, 0.66, 0.78 and 0.87 respectively. The internal consistency for 'helplessness,' 'magnification,' 'rumination,' and total scale of the Korean PCS was Cronbach's $\alpha = 0.90, 0.71, 0.86, \text{ and } 0.93$ respectively (14) which is consistent with our study. Another study conducted by Suren et al. 2014 (10) also found a low Cronbach's α of magnification subscale was 0.55. A possible explanation of the low Cronbach's α of the magnification subscale may be that it has only few items (Osburn 2000) (35). Moreover, some of our patients got afraid listening to the statement of magnification subscale 'I wonder whether something serious may happen.'

We observed that PCS scores were non significantly higher in female compared to male patients. The possible explanation may be as our female population were more occupied with household activities individually and manually. Women experienced pain more intensely due to lower threshold to pressure

pain than men (Suren et al. 10). Fibromyalgia and attention seeking behavior from the family members or spouse may be a contributory factor besides the physical factors. Moreover in our study the highest number of patients were suffering from rheumatoid arthritis which is a female predominant disease. Studies conducted by Suren et al. 2014 (10) and Turner & Clancy 1986 (36) showed higher PCS scores in females. But Granot and Ferber 2005 (37) and Ruscheweyh et al. 2011 (38) reported that male and female patients did not significantly differ regarding the extent of pain catastrophizing.

The convergent validity was examined by investigating the relationship between BePCS scores and physical functioning and mental health domain of the SF 36. The correlation coefficients for these relationships were -0.424 and -0.413, which means there were moderately negative correlations between the BePCS and physical and psychological functioning respectively. These results, in general, were consistent with other studies (14). Our finding that the PCS scores correlated negatively more with physical than with psychological functioning may be explained by the fact that in the other studies the participants were collected from pain clinics where headache and other types of functional pain are seen more often (23,24), whereas, in our study were predominantly included patients with rheumatoid arthritis, spondyloarthritis and ankylosing spondylitis (table 1).

The test-retest reliability of the BePCS showed excellent Intraclass Correlation Coefficient 0.78 which was consistent with the study conducted by Cho, Kim, and Lee, 2012 (14) (ICC= 0.79) and with the original English version of PCS (ICC=0.75) by Sullivan MJ (19).

Age is another factor evaluated in studies associated with PCS scores (37, 38). They did not find any correlation between age and the PCS score. In the present study also no significant correlation was found between age and the total PCS or PCS subscale scores. In our study, we looked for a possible relation between educational level and catastrophizing; the PCS scores of the lower literacy group were higher than those of the higher literacy group, but this was not statistically significant. Other studies described by Yap et al. (22) in China and Granot and Ferber (36) in a group of 38 Israeli patients also found no impact of educational level with PCS scores. Suren et al. 2014 (9) on the other hand found that PCS scores of high school graduates in Turkey were higher than those of primary school graduates. Further studies in other countries are needed regarding the relationship between PCS scores and educational status.

Pain catastrophizing has a social function and could affect family or significant others. It has been found in some previous studies that patients having higher PCS scores consumed higher amounts of analgesics and suffered from chronic and severe pain (39, 40). That is why, the Pain Catastrophizing Scale (PCS) has been developed in several other versions (41).

Limitations: Our study showed some limitations. We could not study a possible correlation between various psychological scores, pain and disability (e.g. Beck Depression Inventory, Pain Anxiety

Symptom Scale-20 etc.) as it was done in some other studies (e.g. Korean PCS) (13) as these scales have not yet been validated in Bengali. As our study was carried out in a tertiary level hospital, it may not be fully representative for the whole Bengali speaking population. Sensitivity to change could not be evaluated due to temporal constraint.

A strength of the study is that it is the first study in the Bengal language and it will create opportunities to study this important fields of catastrophizing and chronic pain in 265 million Bengali speaking people. Our study showed acceptable validity and excellent internal consistency, construct and content validity and reliability of the Bengali version of the PCS.

In conclusion, the Bengali version of the PCS (BePCS), being a valid and reliable tool, may be used to screen the probability of catastrophizing suffering from chronic pain. The BePCS can be a valuable tool for patient education, treatment planning and assess the need for psychological intervention.

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