Content Validity and Test-Retest Reliability of the Gujarati Version of the Central Sensitization Inventory

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Abstract: Background: Central sensitization (CS) is a state of heightened sensitivity of the central nervous system to both noxious and non-noxious stimuli. The Central Sensitization Inventory (CSI) is a sound screening tool to help clinicians to detect patients with CS. To date, no Gujarati version exists. Objectives: The aim of this study was to translate and cross-culturally adapt the CSI into Gujarati, and to check content validity, face validity, internal consistency, test-retest reliability, agreement and minimum detectable change (MDC) of CSI-G in chronic low back pain (CLBP) patients. Methods: Translation and cross-cultural adaptation of the original English version of the CSI-G was performed according to published guidelines. The content validity was ascertained by 23 healthcare professionals. The internal consistency, test-retest reliability, agreement and MDC was determined on CLBP patients (n=31) with a time interval of 7-days. Results: The content validity and Face validity was found to be excellent. The internal consistency was excellent (Cronbach's α=0.914) and MDC was found to be 5.092 points. The test-retest reliability showed very high correlation in CLBP patients (ICC = 0.971). Conclusion: The original CSI was translated into Gujarati and did not pose any problems during data acquisition. The CSI-G seems to be reliable instruments to measure CS in Gujarati patients with CLBP. [Bid D NJIRM 2016; 7(5):18-24]

Keywords: Central Sensitization Inventory- Gujarati (CSI-G), Central Sensitization, Chronic Low back Pain, Reliability, Validity

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Introduction: Central sensitization (CS) is a state of heightened sensitivity of the central nervous system to both noxious and non-noxious stimuli. The accurate data regarding prevalence of CS in various chronic pain conditions are not known. Abnormal pain processing in the central nervous system (CNS) rather than from actual damage and/or injury to anatomic structures of body may lead to increased neuronal response and central sensitization (CS) [1-3] and this may be responsible for mechanical hyperalgesia, allodynia, and/or referred pain which are frequently seen in chronic pain syndromes [3-7]. CS is described by the International Association for the Study of Pain (IASP) as: "Increased responsiveness of nociceptive neurons in the central nervous system to their normal or subthreshold afferent input"[8]. The outcome of the processes involved in CS is an increased responsiveness to a variety of peripheral stimuli including mechanical pressure, chemical substances, light, sound, heat, cold, and electrical stimuli. The increased sensitivity to various stimuli results in a large decreased load tolerance of the neuromusculoskeletal system. Although the precise mechanism of CS is not fully understood; several contributing mechanisms have been put forward: It may be an altered sensory processing in the brain [9], malfunctioning of descending anti-nociceptive mechanisms [10], increased activity of pain facilitatory pathways, temporal summation of second pain or wind-up [9, 11], and long-term potentiation of neuronal synapses in the anterior cingulate cortex [12]. Besides the above top-down mechanisms included in the pathophysiology of CS, it is important to understand that there are bottom-up mechanisms as well [13-16].

In clinical practice CS is often diagnosed by Quantitative sensory testing [17]. A high cost prohibits its applicability in clinical practice. As such there is no gold standard in diagnosis of CS. In clinical practice diagnosis of CS requires confirmation by some standard clinical measurements for appropriate treatment. To address this problem Mayer et al have developed CSI, an alternate method to assess the signs and symptoms of CS [18]. CSI measures the overlapping clinical features present in CS patients. It has been designed to identify the symptoms of CS and to alert clinicians about the presenting symptoms besides pain, which is very often the patient's primary complaint. Neblett et al [19] introduced CSI normative scores in a heterogeneous group of patients with pain syndromes, including chronic fatigue syndrome, fibromyalgia, and irritable bowel syndrome. The development of CSI has significantly improved the assessment of CS in clinical practice. This has been supported by the validation studies of psychometric properties of CSI [18-20]. Translating a questionnaire instead of creating a questionnaire allows comparisons of different populations, permits

researchers to examine functional status across a broad spectrum of people, and permits the exchange of information across cultural and linguistic barriers. It is now widely recognized that questionnaires intended for use across cultures must not only be translated well linguistically but also adapted culturally in order to maintain the content validity of the instrument [21]. So, CSI should be translated into multiple languages to allow clinicians in countries where English is not native language to use CSI.

The items of the original version of CSI were developed by an interdisciplinary team, including physicians, rehabilitation specialists, physiotherapists, health psychologists, clinical psychologists, and psychophysiological specialists, working exclusively with chronic pain patients. They formulated items related to somatic and emotional indices of sixteen central sensitization and central sensitivity syndromes [18], in which no further exploration or qualitative analysis was done. A reliability study was only performed in healthy, non-painful participants (students), including 2 time-points with approximately 5 days in between [18]. The reliability study showed high inter-item correlations, but the variability of the items was rather low because only healthy individuals took part in that study (8 items scored below 1, all items scored below 2) [18]. Hence the results cannot be generalized to pain patients.

We believe that there is a need to translate and validate the CSI for clinical use in patients with CLBP. Furthermore clinicians may be able to provide more accurate treatments when patient groups can be identified through the CSI. To fulfill this need and to allow the use of the CSI in Gujarati population, a Gujarati translation of the CSI part A and B was developed. Only CSI-G part-A was subject of further analyses. The following research questions were formulated: 1) What is the Content validity and Face validity of CSI-G? 2) What are the internal consistency, test-retest reliability and agreement of CSI-G in a CLBP patient sample?

Methods: Participants: Native Gujarati patients with CLBP were recruited for the study from four physiotherapy departments in Surat City. Patients were excluded if they had back pain related to vertebral fracture, myelopathy, back surgery, cognitive impairment, infectious disease, cardiovascular or respiratory problems, neurological deficits, cancer, or any other systemic diseases with possible effect on the musculoskeletal system. Ethical approval for the study was obtained from the CTRI approved Institutional Ethical Committee of Nirmal Hospital, Surat and all procedures were conducted in accordance with the declaration of Helsinki. Written consent was taken from health care professionals those who participated in content validity study of CSI-G. Also, written informed consent was obtained from each patient before participation. The CSI-G was applied at 2 time points with approximately 7-days gap to allow wash out the memory of response given.

Questionnaires: The CSI-G contains a Part-A of 25 statements related to current health symptoms. Each of these items is measured on a 5-point temporal Likert scale, with the following numeric rating scale: never (0), rarely (1), sometimes (2), often (3), and always (4). A cumulative score ranges from 0 to 100. Additionally, information is collected in Part-B on previously diagnosed CS and related conditions.

Translation: The translation procedure was based on previously published guidelines [22, 23]. Forward translation of the original English version of the CSI into Gujarati was produced by two independent bilingual translators whose first language was Gujarati. One of the translators was aware of the concepts being examined in the questionnaires whereas the other translator was not. The two forward translations were compared and single consensus Gujarati version of the CSI-G was then constructed.

A backward translation (Gujarati to English) was undertaken by two independent native English speakers at Surat. Neither back-translator was aware or informed of the concepts explored or had ever seen the original versions of the questionnaires. The review committee considered all the versions of the questionnaires. The committee consisted of one researcher with experience in questionnaire development and evaluation, one researcher with experience in the questionnaires being translated, an experienced physiotherapist and two well-educated bilingual persons. The committee's considerations were around four areas: semantic equivalence (the meaning of words), idiomatic equivalence (equivalent expression for idioms and colloquialisms), experiential equivalence (the target cultural context), and conceptual equivalence (the validity of the concept).

Penultimate version of the CSI-G questionnaire was applied on 20 patients with CLBP to determine whether all questions were clear and comprehensible. No modification to the questionnaire was required at this phase and the final CSI-G was then developed and subjected to further psychometric testing.

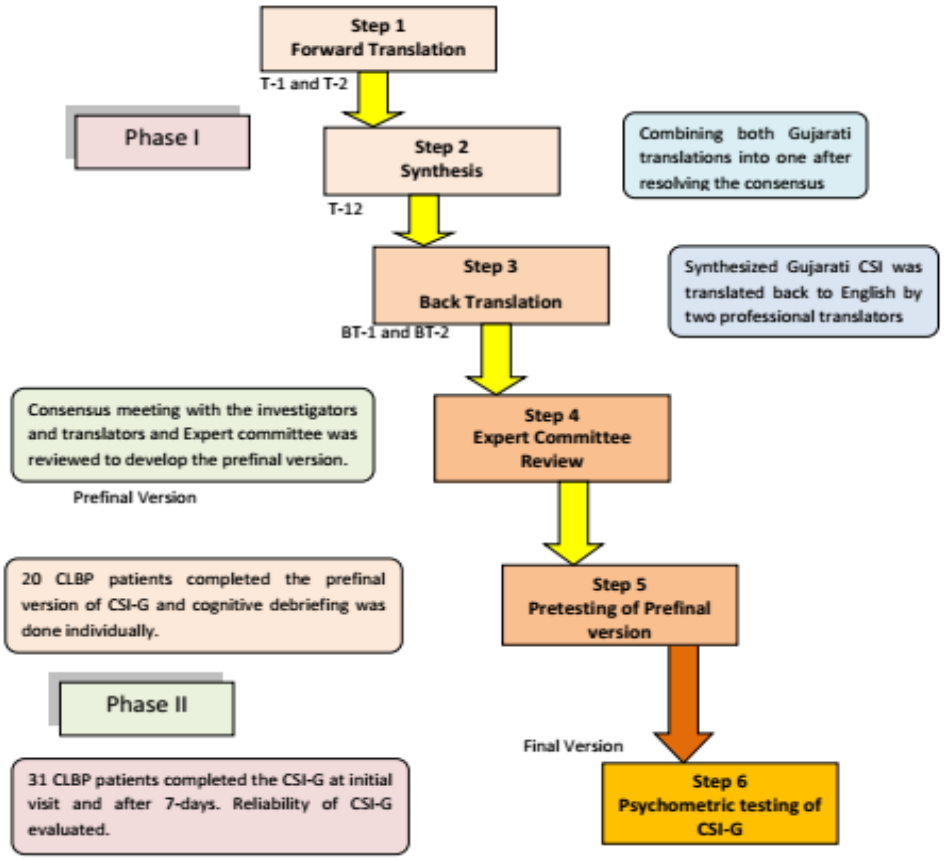
Psychometric Testing Face Validit: Face validity is a subjective assessment of whether the measure appears relevant to the ones to be measured. Face validity was assessed by asking one question to each of the patients, 'Do you think this scale is relevant to your condition.' The answer was noted as 'yes' or 'no'. Face validity of the CSI-G was established when all the 31 patients questioned about the relevance of the scale to their condition, all answered 'yes'.

Content Validity: Content equivalence was assessed under two headings:

1. Are the words in the translated Guajarati version presented fluently and correctly as in the original version? For this answers from 23 expert panel members fall between 'mostly agree' to 'strongly agree' (average=6.85) on a 7-point Likert scale.
2. Do the words and phrase in the translated Gujarati version have the same semantic meaning compared with the original version? For this answers from 23 expert panel members fall between 'mostly agree' to 'strongly agree' (average=6.86) on a 7-point Likert scale.

Content relevance: is assessed by asking: How the Gujarati statement is relevant to assessing CS in CLBP patients? For this answers from 23 expert panel members fall between 'mostly agree' to 'strongly agree' (average=6.9).

Figure-1: Flow chart of study design of CSI-G



Content representativeness: was assessed by asking "How well is the content (Part-A: Item no. 1 to 25 and Part-B: Item no. 1 to 10) of CSI-G scale is representing the entire domain of assessing the CS of patients with CLBP?" For this answers from 23 expert panel members falls between 'mostly agree' to 'strongly agree' (average=6.22) on a 7-point Likert scale. Additionally, the total scores were normally

distributed and the percentage of missing items were <5%, also proves content validity of this questionnaire. For content validity 23 health/allied health professionals, were included[23]. For test-retest reliability the convenient sample size was 31 patients having CLBP.

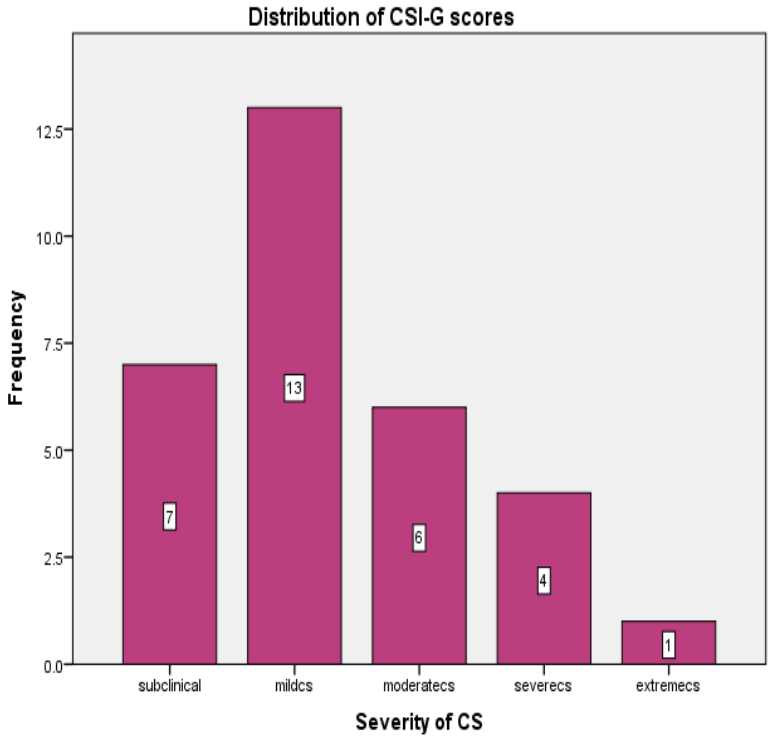
Statistical Analyses: Internal consistency of the CSI-G was examined with Cronbach's α coefficient. Cronbach's α values range from 0 to 1, where values above 0.7 indicate adequate internal consistency for a scale [24]. Intra-class correlation coefficients (ICC, model two-way random, type absolute agreement) were calculated for examining the test-retest reliability.

The ICC values ranges from 0 to 1; 1= perfect reliability, 0.90 to 0.99 = very high correlation; 0.70 to 0.89 = high correlation; 0.50 to 0.69 = moderate correlation; 0.26 to 0.49 = low correlation and 0.00 to 0.25 =little, if any, reliability [25]. Agreement was determined by the Bland-Altman method in which the individual differences were plotted against the individual mean scores. Significance level was set at 5%[26]. The standard error of measurement (SEM=Average SD x √1-ICC) was used to determine the measurement error. The SEM was then converted into the Minimal Detectable Change (MDC), which expresses the minimal magnitude of change that likely reflects true change rather than measurement error. The $MDC_{95\%}$ was estimated from the SEM and calculated as $1.96 \sqrt{2} \times SEM$[27].

Results:

The present study used 31 CLBP patients. From this sample, 23 subjects were females (74.2%) and 8 subjects were males(25.8%). The mean age was 52.77(± 13.20) years. The severity level of CS in those patients as described by Neblett Randy et al[28] is shown in this bar graph (Figure-2) which describes five categories of CSI severity ranging from Subclinical (0-29), Mild (30-39), Moderate (40-49), Severe (50-59) and Extreme (60-100) and the CSI-G item wise score distribution for all the 25 items with range, SD and mean is shown in figure-3.

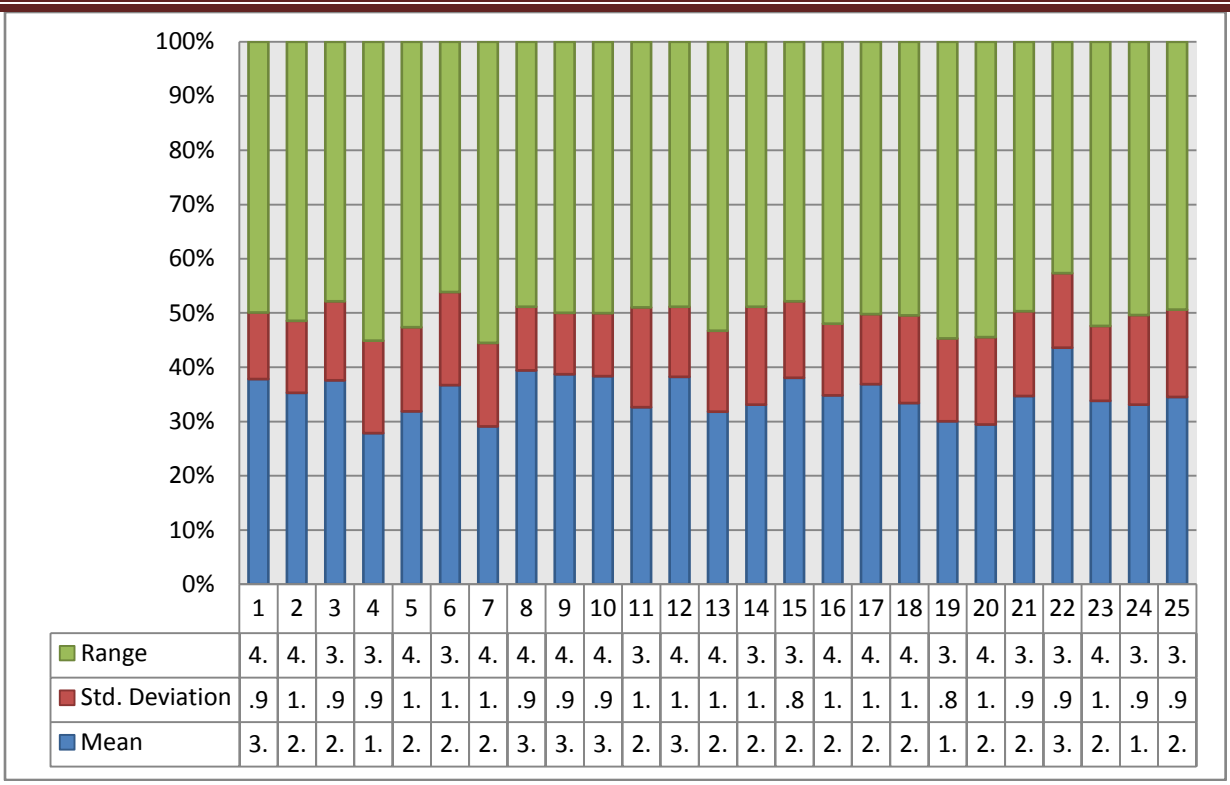
Figure-2: Distribution of CSI-G scores in the sample depicting severity of CS



Internal Consistency: CSI-G exhibited excellent internal consistency shown by a Cronbach's α value of 0.914.

Reliability: The CSI-G was filled out twice by 31 CLBP patients. The CSI-G mean total scores of the first and second assessment were, respectively, 44.16(± 13.8) and 43.96 (± 13.2).

Figure-3: CSI-G Score Distribution item-wise



The ICC in the CLBP patients, based on the total scores of the first and second assessment, was 0.971 (ICC 2,1; 95% CI = 0.941–0.986; p<0.001).An analysis of individual item scores revealed that 24 out of 25 items showed an ICC >0.85 (range 0.852–0.993) except item number 10 (ICC 2,1; 0.662; p<0.001).

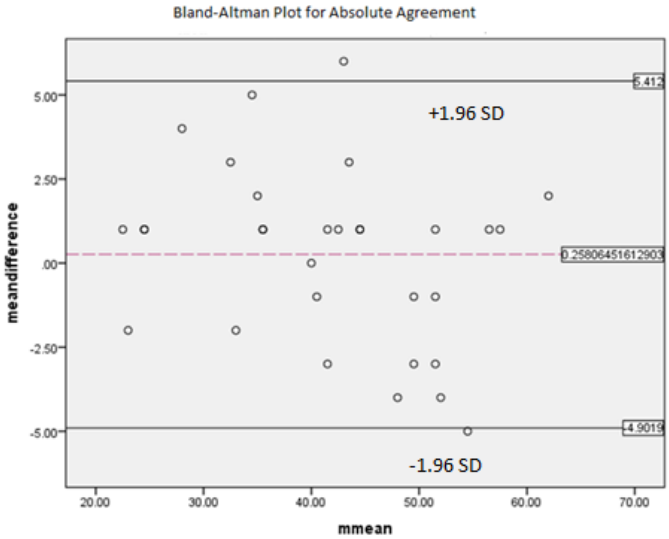
Table-1: Test-Retest Item-wise Correlation 'r'

Item No.	'r'- value	Item No.	'r'- value
1	.991	14	.962
2	.985	15	.915
3	.981	16	.986
4	.981	17	.962
5	.992	18	.960
6	.947	19	.696
7	.988	20	.852
8	.993	21	.982
9	.871	22	.983
10	.662	23	.986
11	.988	24	.965
12	.985	25	.926
13	.868	------	------

Agreement: The Bland-Altman Plot (Figure-4) shows the difference in total scores against the mean total scores for both the CLBP patients. The The SEM for the CSI-G was 1.837. Calculations revealed a MDC of 5.092 points for CSI-G (scale range = 0–100).

mean difference approached zero, indicating that no bias had occurred. In CLBP patients, one outlier was seen outside the 95% CI band. The Bland-Altman analysis showed that the mean difference was 0.258±2.632 for the CSI-G.

Figure-4: Bland-Altman Plot for measuring with-in subject variation and the limits of agreement of CSI-G scores



Discussion: The aim of this study was to translate and cross-culturally adapt the CSI into Gujarati, and to check content validity, face validity, internal consistency, test-retest reliability, agreement and

minimum detectable change (MDC) of CSI-G in CLBP patients. As a first step in analyzing the psychometric validation of the CSI-G, the questionnaire was translated from English into Gujarati and finalized in a consensus meeting including Gujarati-speaking researchers from Surat. In our opinion, the translation into Gujarati was appropriate, since the data collection did not reveal any confusion or problems mentioned by the participants.

The test-retest reliability showed excellent Cronbach's α value (0.914) and ICC value (ICC = 0.971) for CLBP patients, which confirms that the CSI-G is a psychometrically robust questionnaire. This study indicates that the CSI-G is reliable and useable instrument in Gujarati culture. This is in accordance with coefficients described earlier in other studies [28-30]. This is also in conformity with the findings of Mayer et al [18], in which Pearson's correlation (r =0.82) was used. Pearson's correlation is a commonly used measure in test-retest reliability assessment, however, it is more correct to use the ICC due to its sensitivity to any bias between or among measurement times[31].

Mayer et al [18] used only healthy controls and 5-days of time interval for test-retest analyses in their study, so it is possible that the consistency of filling out the CSI twice was more compared to CLBP patients. In the present study a 7-days interval was chosen, thereby reducing the likelihood of remembering the responses given during the first assessment considering the high number of the items and also answers from the first assessment were held back.

The SEM and MDC provide researchers and clinicians with some direction for true changes in the measurement, which is not due to random measurement error. The result showed a MDC of 5.092 points for CSI-G (Scale range 0-100). Scores at or above this MDC value are likely to be due to patient improvement instead of measurement error. Estimated minimal meaningful changes should be greater than the MDC value.

No relevant information could be made out of Part-B of CSI-G as most of the patients found it difficult to understand the labels of diagnosed diseases mentioned in this section. Whoever scored high on Part-A of CSI-G were able to say "yes" to one or more diagnoses of Part-B suggesting this could be an extra sign of CS.

Conclusion: Our results suggest that the CSI-G has been successfully translated and cross-culturally adapted from English to Gujarati. The preliminary evidence generated by the psychometric testing showed that the CSI-G demonstrates psychometric properties similar to the English version. This study provides us with the evidence that the CSI-G is a reliable and valid measure to assess CS in Gujarati-speaking CLBP patients. Construct validity and Responsiveness of the CSI-G should be evaluated in further studies.

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