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Reliability and Validity of the Turkish Version of Pain Modulation Index

Ağrı Modülasyon İndeksi'nin Türkçe Versiyonunun Geçerlilik ve Güvenilirliği

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Abstract

Objective: Chronic pain has significant impact on individuals and society. It is not just a symptom but is considered to be a separate disease in its own right. The aim of this study is to translate into Turkish and assess the validity and reliability of the "Pain Modulation index", which was developed to be used as an indicator of the changing central pain processing process in individuals presenting with chronic pain.
Materials and Methods: Study included 125 patients who had chronic pain. The Turkish translation was carried out using the "forward-backward translation" method. After adjustments were made according to the feedback of 10 volunteers, the study was started on the patient population. To evaluate the reliability of the scale, the test-retest was conducted with a 15-day interval. To evaluate its validity, Pain Detect and the Central Sensitization Inventory were applied on the first visit, along with the Pain Modulation index.
Results: Since the scale has 2 factors, the Cronbach's alpha coefficient was calculated separately for the factors, and it was found to be 0.89 for factor 1 and 0.82 for factor 2. intraclass correlation coefficient values were determined as 0.95 for factor 1 and 0.92 for factor 2. the results of the Turkish version of the pain modulation scale were found to correlate significantly with pain detect and central sensitization inventory ($p<0.05$).
Conclusion: The Turkish version of the pain modulation scale is a fast and easily applicable scale with high validity and reliability for clinical and epidemiological studies in patients presenting with chronic pain.
Keywords: Central sensitization, pain, nociplastic pain, pain modulation scale, surveys and questionnaires

Öz

Amaç: Kronik ağrı, hem birey hem de toplum üzerinde önemli etkiye sahiptir. Sadece bir semptom olmayıp, kimi zaman kendi başına bir hastalık süreci haline gelebilmektedir. Bu çaışmanın amacı, kronik ağrı ile başvuran hastalarda santral ağrı işlenim süreçlerini değerlendirmek amacıyla geliştirilmiş olan Ağrı Modülasyon indeksinin Türkçe'ye çevrilmesi ve geçerlilik ve güvenilirliğinin değerlendirilmesidir.
Gereç ve Yöntem: Çalışmaya kronik ağrısı mevcut olan 125 hasta dahil edilmiştir. Türkçe'ye çeviride ileri ve geri çeviri yöntemi kullanılmıştır. 10 sağlıklı gönüllü üzerinde denendikten ve geri bildirimlerine göre düzeltmeleri gerçekleştirildikten sonra, hasta popülasyon üzerinde uygulanmıştır. Güvenilirliği değerlendirebilmek için, 15 gün ara ile gönüllülere anket tekrar uygulamıştır. Geçerliliğinin değerlendirilmesi amacı ile ise pain detect ve santral sensitizasyon envanterleri de ilk vizitte hastalara uygulanmıştır.
Bulgular: Ölçek 2 alt başlıktan oluşmakta olup, her iki alt başlık için Cronbach alfa katsayısı ayrı ayrı hesaplanmıştır. Birinci alt grup için 0,89, ikinci alt grup için ise 0,82 olarak hesaplanmıştır. Sınıf içi korelasyonlar birinci alt başlık için 0,95 ve ikinci alt başlık için 0,92 olarak hesaplanmıştır. Ayrıca ağrı modülasyon indeksi skorları, pain detect ve santral sensitizasyon envanteri skorları ile korele saptanmıştır ($p<0,05$).
Sonuç: Ağrı modülasyon indeksinin Türkçe versiyonu, kronik ağrılı durumlarda, hem klinikte hem de araştırma amaçlı çalışmalarda hızlı ve kolayca uygulanabilen, geçerli ve güvenilir bir ölçektir.
Anahtar kelimeler: Merkezi sensitizasyon, ağrı, nosiplastik ağrı, ağrı modülasyon ölçeği, anketler ve soru formları

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Introduction

Chronic pain is reported to affect more than 30% of the World population. It results in wide ranging negative consequences such as high healthcare costs, loss of work-force and increased disability (1). Pain is a highly subjective sensation that can be influenced and caused by psychological parameters. The International Association for the Study of Pain (IASP) and the latest International Classification of Diseases has categorized pain into nociceptive, neuropathic and nociplastic pain (2). This latest classification aims to better describe painful conditions resulting from the hypersensitivity of the central nervous system in the absence of nociceptive or neuropathic input as nociplastic pain, of whose etiology and mechanism is still not fully understood (3). Central sensitization is the proposed mechanism that results from disordered pain modulation pathways in the central and peripheral nervous system. Although nociplastic pain seems to have many overlapping qualities with neuropathic pain and central as well as peripheral sensitization most probably plays a similar role in its development, the two are separate entities.

Objective quantification and classification of pain using standardized tests facilitates diagnostic and treatment approaches in the management of chronic pain. Different scales have been developed such as Pain Detect, The Leeds assessment of neuropathic symptoms and signs (LANSS) pain scale, Douleur Neuropathique 4 Questions which assess the quality and severity of neuropathic pain and have been widely used in clinical studies. Nociplastic pain which results from the disordered modulation of pain in the absence of nerve injury is a new concept that is hard to measure and categorize. Current neuropathic pain assessment questionnaires are unable to differentiate neuropathic from nociplastic pain.

Austin et al. (4) first developed an 18-item index to better recognize disorders of pain modulation in 2019, which they named Pain Modulation index (PMI) This measure does not classify the painful condition as neuropathic or nociplastic, but instead tries to diagnose the underlying central sensitization process. In this study, we aimed to translate the PMI into Turkish and asses it's validity and reliability in the Turkish population.

Materials and Methods

An application was made to the Ege University Hospital Ethics Committee and approval was obtained with file number E.227599 (decision no: 21-7T/44, date: 08.07.2021). The original developers of PMI were asked for their approval via e-mail for the translation of the index into Turkish. The study was registered at clinicaltrials.gov with the registration number 21-7T/44.

Translation

Translation of the original index into Turkish was carried out separately by two physicians who are efficient in both languages. It was then back translated into English by two professional translators. This version of the index was first asked to 10 volunteers to assess its comprehensibility and clarity. After this first pilot application and according to volunteers' feedback, the final version was approved.

Sample Size

Sample size calculation was carried out similar to the original article, using the ratio of sample size to item number which in our case was found to be a minimum of 90 volunteers for a ratio of 5:1 (4,5).

Patient Selection

Volunteers were recruited from the physical and rehabilitation medicine outpatient clinic of our university hospital. Patients who had ongoing non-cancer pain of more than 3 months of duration were invited to take part in the study. All patients meeting the eligibility criteria were informed about the study and those who accepted to participate were asked to sign the written informed consent form before any further data collection and examination.

Patient Visits

Patient demographics and clinical diagnosis were recorded. All patients were asked to fill out the Turkish version of the PMI in addition to pain detect and central sensitization inventory on the first visit. Visual analog scale (VAS) pain levels were recorded. Patients were reached by phone and invited to the hospital between day 14-21 to fill out PMI for a second time, in order to assess reliability of the questionnaire.

Study Parameters

a. PMI: This index is composed of 2 factors, first one containing 11 and second one containing 7 items. Factor 1 mainly assesses pain qualities such as allodynia and hyperalgesia and responsiveness to medication. Factor 2 includes questions relating to mood, cognitive and behavioral symptoms. Each item is scored from 0 to 3. Higher scores denote more dysfunctional pain modulation. Original English version was developed by Austin et al. (4).

b. Pain Detect: Pain detect questionnaire was developed in Germany and is widely used in clinical and research settings (6). Its Turkish validation was reported in a study by Alkan et al. (7). The questionnaire is scored between 0 and 38. Lower scores denote lack of neuropathic pain while higher scores suggest possibility of neuropathic pain.

c. Central Sensitization Inventory: This inventory was developed by Mayer et al. (8) to assess the hyperactivity and hypersensitivity of pain pathways. It consists of 25 items, each one scored from 0 to 4. Scores higher than 40 denote the presence of central sensitization. Düzce Keleş et al. (9) carried out its Turkish validity and reliability study.

Statistical Analysis

Demographic and clinical parameters were presented using descriptive statistics namely mean±standard deviation for numeric data and number (percent) for categorical data. Reliability of PMI was assessed using the test-retest method. For

internal consistency of PMI, test and re-test scores for factor 1 were used to calculate a Cronbach alpha coefficient for each factor. Factor internal consistency and homogeneity was assessed by calculation an intraclass correlation coefficient for each item and for each factor. Reliability of PMI was assessed by carrying out correlation analyses between PMI factor 1, PMI factor 2, Pain Detect, Central Sensitization Inventory and VAS pain scores.

Results

One-hundred and twenty-five patients were enrolled in the study between August 2021 and July 2022. All participants had non-cancer painful conditions for more than 3 months of duration.

Demographics and Disease Characteristics

Patient characteristics are presented in Table 1. Of the 125 volunteers, 42 had neck pain and 42 had lower back pain. The remainder consisted of patients with shoulder, knee and Fibromyalgia related widespread pain.

Pain levels measured using VAS and pain detect, central sensitization inventory and PMI scores are presented in Table 2.

Reliability and Validity of PMI

Internal consistency was found to be high for both factor 1 and factor 2 of the PMI. Cronbach alfa coefficient was found to be 0.89 and 0.82 for factor 1 and factor 2 respectively.

Reliability assessment using correlation analysis between test and re-test scores revealed that both factor 1 and factor 2 of PMI were reliable. Item by item and total factor correlation analysis results between first and second applications of PMI are presented in table 3. total item intraclass correlation coefficient for factor 1 and factor 2 were found to be 0.95 and 0.92 respectively.

It was found that for most items of the PMI, female patients had significantly higher scores than male patients ($p<0.05$) except for items 1, 8, 9 and 13 of factor 1 (Table 4). We detected a significant correlation between factor 1 and factor 2 scores, and between each pairing of factor 1, factor 2, pain detect, central sensitization inventory and VAS scores ($p<0.05$). Correlation analysis results between different pain assessment questionnaires are given in Table 5.

Discussion

Pain is described as a disturbing sensation that is produced as a reaction to noxious and potentially dangerous stimuli from our environment, that acts as a defense mechanism (10). But apart from this primitive mechanism, psychological mechanisms and learning from previous experience also affects how and when an organism perceives pain (11). Until very recently, pain was broadly categorized as nociceptive and neuropathic pain. This dual classification failed to describe some patients with chronic pain without overt noxious stimuli and who could not be categorized into either category (12). Nociplastic pain was proposed in 2016 as a third classification option for those patients who had findings of disordered central pain processing (2). Nociplastic pain is defined by IASP as" pain of at least 3 months duration, that arises from altered nociception despite no clear evidence of actual or threatened tissue damage causing the activation of peripheral nociceptors or evidence for disease or lesion of the somatosensory system causing the pain". Central sensitization is not part of the definition of nociplastic pain, yet the two concepts have many overlapping qualities that are at least present in the region of pain (2,13). Diagnostic criteria of nociplastic pain contains items relating to central sensitization namely static or dynamic mechanical allodynia, heat or cold allodynia, and/or painful after-sensations

Table 1. Demographic and disease characteristics

Age, years, mean±SD	49.5512.40±
Sex, n (%)	
Female	97 (77.6%)
Male	28 (22.4%)
Marital status, n (%)	
Married, co-habitation	90 (72%)
Single	35 (28%)
Education, n (%)	
Literate	1 (0.8%)
Primary education	19 (15.2%)
Secondary education	40 (32%)
College or higher	65 (52%)
Occupation, n (%)	
Blue collar	2 (1.6%)
White collar	79 (63.2%)
Homemaker	30 (24%)
Retired	13 (10.4%)
Student	1 (0.8%)
Pain duration, n (%)	
3-6 months	27 (21.6%)
6-12 months	9 (7.2%)
12 months<	89 (71.2%)
Pain localization, n (%)	
Neck	42 (33.6%)
Lower back	42 (33.6%)
Shoulder	7 (5.6%)
Knee	12 (9.6%)
FMS, widespread	22 (17.6%)
Pain detect classification, n (%)	
Non-neuropathic pain	70 (56.0%)
Possible neuropathic pain	33 (26.4%)
Neuropathic pain	22 (17.6%)

SD: Stanard deviation

Table 2. Scores of clinical parameteres, mean±SD	
Central sensitization inventory	41.29±17.83
Pain detect	11.56±7.81
Pain modulation index	
Test factor 1	17.27±9.19
Test factor 2	12.35±5.16
Re-test factor 1	17.96±8.91
Re-test factor 2	12.55±5.10
VAS current pain level	6.30±2.70
VAS worst pain level	8.02±2.39
VAS average pain level	7.10±2.34
VAS: Visual analog scale, SD: Standard devitaion	

Table 3. Test-retest scores and intraclass correlation coefficient (ICC) of items from PMI			
	Mean score±SD	**Re-test mean score±SD**	**ICC**
Items (factor1)	17.2±9.1	17.9±8.9	0.95
Item 1	1.34±1.10	1.34±1.05	0.89
Item 2	1.62±1.18	1.70±1.10	0.87
Item 3	1.24±1.28	1.36±1.26	0.89
Item 4	1.33±1.24	1.36±1.19	0.93
Item 5	1.59±1.25	1.68±1.22	0.91
Item 6	1.49±1.19	1.57±1.18	0.90
Item 7	1.69±1.17	1.80±1.10	0.87
Item 8	1.71±1.21	1.78±1.15	0.91
Item 9	1.89±1.17	1.89±1.14	0.90
Item 10	1.74±1.28	1.86±1.23	0.90
Item 11	1.63±0.98	1.63±0.94	0.84
Items (factor 2)	12.3± 5.1	12.5±5.1	0.92
Item 1	1.65±1.00	1.74±0.94	0.85
Item 2	1.62±1.07	1.70±1.01	0.90
Item 3	1.82±1.06	1.87±1.00	0.87
Item 4	2.10±1.00	2.06±0.98	0.90
Item 5	1.96±1.05	1.92±1.00	0.89
Item 6	1.86±1.08	1.88±1.05	0.88
Item 7	1.33±1.07	1.37±1.02	0.90
SD: Standard deviation, ICC: Interclass correlation coefficient			

after any of the evoked pain hypersensitivity assessments (13). Central sensitization may be present in all types of chronic painful conditions such as osteoarthritis, intervertebral disc herniation, rheumatological conditions and fibromyalgia. Nociplastic pain may be accompanied by migraine headaches, temporomandibular dysfunction, irritable bowel syndrome and mood disorders which are also commonly present in patients with central sensitization. Differentiation of pain subtypes is needed to effectively manage and treat these painful conditions (14). The definition of painful concepts is an everchanging field, recognition of central sensitization and disordered pain processing mechanisms may aid the clinician in diagnosing nociplastic pain more easily. PMI is the first inventory developed to assess the disordered pain processing that results in central sensitization.

In the Turkish translation of PMI, similar to the original index, we have found a high correlation between factor 1 and factor 2 sub scores (4). In our study, most of the patients had mechanical lower back and neck pain. A smaller number of patients had fibromyalgia and rheumatological conditions that presented with widespread pain. Our index scores correlated strongly with central sensitization inventory scores, which was previously

Table 4. Comparison of item scores between male and female patients			
Items	**Sex**	**mean±SD**	**p-value**
Factor 1			
Item 1	F	1.41±1.143	0.161
	M	1.11±0.956	
Item 2	F	1.78±1.157	0.003*
	M	1.04±1.105	
Item 3	F	1.32±1.303	0.199
	M	0.96±1.201	
Item 4	F	1.47±1.226	0.014*
	M	0.82±1.188	
Item 5	F	1.73±1.238	0.020*
	M	1.11±1.227	
Item 6	F	1.67±1.179	0.001*
	M	0.86±1.044	
Item 7	F	1.80±1.160	0.039*
	M	1.29±1.150	
Item 8	F	1.81±1.202	0.078
	M	1.36±1.193	
Item 9	F	1.93±1.295	0.482
	M	1.75±1.295	
Item 10	F	1.98±1.225	0.000*
	M	0.93±1.184	
Item 11	F	1.76±0.933	0.005*
	M	1.18±1.056	
Factor 2			
Item 1	F	1.76±0.977	0.016*
	M	1.25±1.005	
Item 2	F	1.69±1.074	0.198
	M	1.39±1.066	
Item 3	F	1.98±1.010	0.002*
	M	1.29±1.084	
Item 4	F	2.27±0.919	0.001*
	M	1.54±1.105	
Item 5	F	2.07±0.961	0.000*
	M	1.39 ±1.084	
Item 6	F	2.03±1.033	0.000*
	M	1.36±0.970	
Item 7	F	1.54±1.100	0.000*
	M	0.79±0.787	
*p<0.05, F: Female, M: Male, SD: Standard deviation			

Table 5. Correlation analysis results for pain assessment questionnaires					
r	**VAS pain**	**CSE**	**PD**	**PMI factor 1**	**PMI factor 2**
VAS pain	1				
CSE	0.487**	1			
PD	0.487**	0.533**	1		
PMI factor 1	0.544**	0.736**	0.612**	1	
PMI factor 2	0.466**	0.824**	0.440**	0.699**	1
**p>0.01, r: Correlation coefficient, VAS: Visual analog scale, CSE: Central sensitization inventory, PD: Pain detect, PMI: Pain modulation inventory					

found to be a valid and reliable questionnaire to assess pain in knee osteoarthritis in patients who had symptoms of central sensitization (15). Similar to our study, the authors found central sensitization and pain detect scores correlated well with each other. Úbeda-DıOcasar et al. (16) also reported that central sensitization inventory and pain detect scores correlated well. In our study we found that women had higher scores in 14 of the 18 items of PMI. This finding is compatible with previous reports that utilized pain detect, central sensitization inventory and LANSS (6,17). This further supports our claim that PMI is a valid measure of chronic disordered pain processing, which is more commonly reported in female patients (18). Central sensitization plays a part in almost all chronic painful conditions. Pain Detect, LANSS and other neuropathic pain assessment indexes classify neuropathic pain using characteristics of central sensitization. The new classification system proposed by IASP that separates neuropathic pain from nociceptive pain, which lacks a clear neuropathic origin may predispose these indexes categorize nociplastic pain together with neuropathic pain. The use of a new index such as PMI that does not classify pain as neuropathic or nociceptive but diagnose a disordered pain processing pathway that leads to central sensitization may help avoid miscategorization of patients, especially for research purposes.

Most of the volunteers in our study were high school or college educated. Patients with lower education levels and who are illiterate may have a harder time expressing different symptoms related to central sensitization and also have difficulties in answering these types of questionnaires. In our study, questions were answered by the patients themselves, but in real life situations, patients who have difficulty understanding some questions or who are illiterate may need help from healthcare providers in order to better diagnose and classify chronic painful conditions. PMI being a brief and easy to understand tool, may be helpful in these kinds of situations where time and staff are limited.

We have enrolled enough volunteers to assess the Index's validity and reliability. But this cross-sectional study needs to be supported by prospective and long-term interventional studies to assess the sensitivity of PMI to changes of pain severity with treatment. Our patient group consisted mainly of mechanical lower back and neck pain sufferers. A larger study with more patients with fibromyalgia and other regional and generalized pain syndromes would help PMI become a commonly used tool for assessing central sensitization and central pain processing disorders.

Conclusion

Turkish version of PMI is a reliable and valid tool for the assessment of chronic pain that can be used both in the clinical setting and for research purposes.

There still remains the need for further studies evaluating its validity in different painful conditions and its sensitivity to change with treatment of nociplastic pain.

Ethics

Ethics Committee Approval: An application was made to the Ege University Hospital Ethics Committee and approval was obtained with file number E.227599 (decision no: 21-7T/44, date: 08.07.2021).

Informed Consent: Patient consent was obtained for this study.

Foonotes

Authorship Contributions

Concept: E.C.S., S.H., E.Ç., Design: E.C.S., S.H., E.Ç., Data Collection or Processing: E.C.S., E.Ç., Analysis or Interpretation: E.C.S., S.H., Literature Search: E.C.S., Writing: E.C.S., E.Ç.

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