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The Validity and Reliability of the Turkish Version of the Toronto Clinical Scoring System

Toronto Klinik Skorlama Sisteminin Türkçe Versiyonunun Güvenirliliği ve Geçerliliği

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ABSTRACT Objective: The Toronto Clinical Scoring System has been preferred in clinical trials owing to its ease of use and its ability to classify the severity of neuropathic pain. The aim of this study to apply the Turkish version of Toronto Clinical Scoring System to Turkish patients and to determine its validity and reliability. **Material and Methods:** This study enrolled a total of 103 patients including 39 with diabetic polyneuropathy (diabetic polyneuropathy, group 1), 32 with diabetes mellitus but without diabetic polyneuropathy (group 2), and 32 healthy individuals (group 3). The gender, body mass index, hemoglobin A 1c and duration of diabetes were recorded respectively. The Toronto Clinical Scoring System was translated into Turkish language to determine the validity. The Leeds Assessment of Neuropathic Symptoms and Signs, Pain Detect Questionnaire, Michigan Neuropathy Screening Instrument were performed. Correlations between Toronto Clinical Scoring System and the other 3 neuropathy diagnosis scales and their relationships with the data of nerve conduction velocity were evaluated. **Results:** There was a strong positive correlation and a statistically significant relationship between the Toronto Clinical Scoring System and the other neuropathy diagnosis scales. When the item about "upper extremity symptoms" was removed from the first part of the Turkish version of the Toronto Clinical Scoring System, Cronbach's Alpha coefficient increased from 0.132 to 0.943. There was a significant relationship between the Toronto Clinical Scoring System and the nerve conduction velocity data. The sensitivity and specificity of Toronto Clinical Scoring System score ≥5 were 100% and 96.88%, respectively. **Conclusion:** Turkish version of the Toronto Clinical Scoring System is a reliable and valid instrument for the measurement of neuropathic pain in Turkish speaking patients with polyneuropathy.

Key Words: Toronto clinical scoring system; diabetic polyneuropathy; nerve conduction velocity; the Leeds assessment of neuropathic symptoms and signs; pain detect questionnaire; michigan neuropathy screening instrument

ÖZET Amaç: Toronto klinik skorlama sistemi klinik çalışmalarda kullanım kolaylığı ve nöropatik ağrının şiddetini klasifiye edebilme becerisinden dolayı tercih edilmiştir. Bu çalışmanın amacı Toronto klinik skorlama sisteminin Türkçe versiyonunu Türk hastalara uygulamak ve skalanın güvenirlilik ile geçerliliğini belirlemektir. **Gereç ve Yöntemler:** Bu çalışmaya diyabetik polinöropati tanılı 39 hasta (diyabetik polinöropati, grup 1), Diabetes mellitus tanılı ancak diyabetik polinöropati tanısı olmayan 32 hasta (grup 2) ve 32 sağlıklı birey (grup 3) olmak üzere toplam 103 hasta dahil edildi. Cinsiyet, beden kitle indeksi, HgbA1c ve diyabet süresi sırayla kayıt edildi. Güvenirliliğini belirlemek amacıyla TCSS sistemi Türkçe diline çevrildi. Leeds nöropatik belirti ve bulgu değerlendirmesi, ağrı anketi ve Michigan nöropati tarama testi yapıldı. Toronto klinik skorlama sistemi ve diğer üç nöropati tanı skalası arasındaki korelasyonlar ve bunların sinir ileti değeri verileri ile ilişkisi değerlendirildi. **Bulgular:** Toronto klinik skorlama sistemi ile diğer nöropati tanı skalaları arasında istatistiksel açıdan anlamlı bir ilişki ve güçlü bir pozitif korelasyon saptandı. Toronto klinik skorlama sisteminin Türkçe versiyonunun ilk bölümünden "Üst ekstremite semptomları" hakkındaki madde çıkarıldığında Cronbach alfa katsayısı 0,132'den 0,934'e yükseldi. Sinir ileti değerleri verileri ile Toronto klinik skorlama sistemi sistemi arasında anlamlı bir ilişki vardı. Toronto klinik skorlama sistemi ≥5 skorunun sensitivitesi ile spesifitesi sırasıyla %100 ve %96,88 olarak bulundu. **Sonuç:** Toronto klinik skorlama sisteminin Türkçe versiyonu, Türkçe konuşan polinöropatili hastalarda nöropatik ağrının ölçülmesinde güvenilir ve geçerli bir araçtır.

Anahtar Kelimeler: Toronto klinik ve skorlama sistemi; diyabetik polinöropati; sinir ileti değeri; Leeds nöropatik belirti ve bulgu değerlendirmesi; ağrı anketi; Michigan nöropati tarama testi

Diabetes mellitus (DM) is an endocrinological disorder characterized by persistent hyperglycemia that can appear due to absolute or relative insulin deficiency.[1] DM leads to several microvascular and macrovascular complications that disrupt the quality of daily life, and bring economic burden to the patient. The most common complication is diabetic polyneuropathy (DPN), which starts from the feet and affects the upper extremities over time.[1] DPN mainly affects the peripheral nerves of feet, legs, hands, arms and manifests itself with symptoms such as numbness, tingling, burning, and throbbing.[1] Motor deficits have been observed to occur at the late stages of the disease. Hypertension, obesity, female gender, being over 60 years of age, alcohol consumption, smoking, and duration of diabetes are known risk factors of DPN.[2,3] It is estimated that 110 million people worldwide are affected by DPN. The global prevalence of DPN varies between 5% and 60% in diabetic patients.[4-7] Typically, loss of foot sensation develops insidiously and silently. For this reason, an increase in shoe-size, calluses on feet, deterioration of foot skin, and crack formation occur without the patient being aware of them. DPN is an important risk factor for foot ulceration, nerve injury, and non-traumatic foot amputations.[8] Early diagnosis of DPN has a very important place in preventing serious complications caused by this disease and in following foot care.

According to the American Diabetes Association, DPN is diagnosed based on at least one of five tests. These tests are clinical symptoms, clinical examination, quantitative sensory testing, nerve conduction velocity (NCV), and autonomic markers. The NCV is the gold standard for the diagnosis of DPN since it is objective, sensitive, valid, and includes both nerve conduction velocity and needle electromyography.[9]

The Toronto Clinical Scoring System (TCSS) has been preferred in some clinical trials owing to its ease of use, acceptability by patients, its ability to classify the severity of neuropathıc pain due to DPN and its representation of the clinical changes associated with the progression of DPN.[10]

The purpose of this study was to examine whether the Turkish version of the TCSS is a valid and reliable tool to assess pain and to be used as a clinical and research instrument.

MATERIAL AND METHODS

INSTRUMENT

TCSS scale which has not been used in Turkey was translated into Turkish language. It consists of three parts.[10] The first part involves scoring the symptoms at lower and upper extremity complaints (numbness, burning, weakness, pain, ataxia). “0” indicates the absence of symptoms, and “1” indicates the presence of symptoms. The second part involves scoring the examination of the ankle and patellar reflexes. “0” indicates normal reflexes, “1” indicates reduced reflexes, and “2” indicates the absence of reflexes. The third part involves scoring the sensation of the big toe. Vibration, position, touch, pinprick, and thermal sensation are evaluated. “0” indicates normal sensory examination, and “1” indicates abnormal sensory examination. Total score ranges from a minimum of 0 (no neuropathy) to a maximum of 19 points. Six points are obtained from the symptoms, 8 points are obtained from the reflexes, and 5 points are obtained from the sensory examination of the big toe. Scoring is interpreted as: 0-5: No neuropathy, 6-8: Mild neuropathy, 9-11: Moderate neuropathy, 12+: Severe neuropathy.

TRANSLATION AND FACE VALIDITY

An allowance to guide Turkish version and reliability-validity study was obtained from Dr. R. Vera Bril. For the translation procedure, guidelines for cross-cultural modifying with five phases were applied.[11] The questionnaire was translated into Turkish by a professional medical translator. The Turkish form was translated back to English by a native speaker doctor who was ignorant of the English form. The translated questionnaire form in English was compared with the original English TCSS and checked for the differences. After last round of translation, the preliminary version of the Turkish TCSS was tested in 10 patients in a pilot study to check understandability.

PARTICIPANTS AND METHOD OF VALIDATION

Informed consent was obtained from all patients. The study was approved by local ethic committee (approval number: 26379996). This study enrolled a total of 103 patients including 39 with DPN (group 1), 32 with DM but without DPN (group 2), and 32 healthy individuals (group 3). All patients with DM underwent NCV. Polyneuropathy was diagnosed according to NCV results. The values that Ovayolu et al. referred to were taken into account when diagnosing DPN.[12] Study of NCV was performed by the Keypoint DANTEC device (Skovlunde, Denmark). Stimulation duration was 0.2 ms for motor, and 0.1 ms for sensory stimuli. All stimulations were performed supramaximally. Bipolar stimulus electrodes were used for all stimuli. NCV under limit for the lower extremity was 42 m⁄s motor conduction velocity and sensory conduction velocity. Under limit the amplitude of motor unit potential was taken as 3 mV for peroneal nerve and 4 mV for tibial nerve. The amplitude of the sensory nerve action potential was accepted 6 pV for sural nerve. Decrease of motor and sensorial amplitude more than 40% of normal value were evaluated as polyneuropathy.

Patients with dialysis therapy, liver disease, HIV, alcohol/drug addiction, peripheral vasculitis/autoimmune disorder, radicular neuropathy, cancer, cerebrovascular disease, chemotherapy/radiotherapy, and medications such as antipsychotics that might worsen clinical symptoms were excluded from the study. The clinical and demographic characteristics of the patients [gender, age, body mass index (BMI), HgbA1c, and duration of diabetes] were recorded. The TCSS was translated into Turkish language to determine the validity in reflecting the presence and severity of DPN in a Turkish patient cohort. Leeds assessment of neuropathic symptoms and signs (LANSS), Pain detect questionnaire (PD-Q) and Michigan neuropathy screening instrument (MNSI) were also used for determining neuropathıc pain. The validity and reliability of these scales were previously proven.

LANSS: It consists of 7 items in total. Five items are related to pain and its character, and two items are related to sensory examination. Yucel et al proved the validity and reliability of this scale in Turkish patients.[13]

PD-Q: Validity and reliability of the scale was proved by Alkan et al.[14] It consists of four sections in total. The scoring result is between 1 and 38.

MNSI: The self assessment of this scale was divided into two main parts: self-evaluation of the patient (section A) and physical examination (section B). “A” section has a total of 15 items and the patient is asked to mark the “yes” or “no” box in each item. The “B” section is based on clinical examination.[15]

STATISTICAL ANALYSIS

The SPSS 20.0 was used for statistical analysis. Descriptive statistics (frequency, mean and standard deviation) were used for analysis of sociodemographic and clinical features. Categoric parameters were assessed with Chi-square. The normality of the parameters was assessed with the Kolmogorov-Smirnov test. For two independent groups, Mann Whitney U test was used. For more than two dependent groups, One way anova was used. To examine the relation of quantitative data to each other Spearman test was used. The results were analyzed in a 95% confidence interval and a significance level of $p<0.05$. Receiver Operator Characteristic (ROC) curves were utilised to detect cut-off scores, sensitivity and specificity.

RELIABILITY ANALYSIS

A Cronbach’s Alpha coefficient was used to assess the internal consistency of the questionnaire. A Cronbach’s Alpha coefficient >0.6 was considered acceptable. The test-retest reliability was determined by Spearman-Brown coefficient, which is obtained by dividing the test into two halves. If the test was reliable at a perfect level, the coefficient value will be close to 1.

VALIDITY ANALYSIS

The correlation coefficient between two different tests that measure the same trait was calculated. The r value was required to be >0.70. If there was no other test that measures the same trait, it could also benefit from tests that measure similar traits.

The r value between 0.50 and 0.70 was considered sufficient evidence for validity. It was the examination of structural validity with the help of differences between groups. The independent-samples t-test or the Mann-Whitney U-test could be used. The difference between those with and without polyneuropathy in the Table 1 was tested with the Mann-Whitney U-test.

RESULTS

There were 18 (46.1%) male patients and 21 (53.9%) female patients in group 1; 14 (43.7%) male patients and 18 (56.3%) female patients in group 2, and 21 (65.6%) male patients and 11 (34.4%) female patients in group 3, respectively (p>0.05). The demographic characteristics and BMI of patients are shown in Table 1.

RELIABILITY

The internal consistency analysis of TCSS was evaluated using Cronbach's Alpha coefficient and a total score of 0.935 was obtained. The TCSS was examined in two tables, including "symptom" and "examination". Cronbach's Alpha value >0.6 in the subscales indicates the presence of item internal consistency (Table 2). If Cronbach's Alpha coefficient increases when an item is removed from the scale, it is claimed that this item is an item that "reduces the reliability". We only see it in the item about "upper extremity symptoms" on the TCSS.

VALIDITY

The test-retest reliability coefficient which was tested by using split-half (Spearman-Brown coefficient) was 0.934 and also considered highly reliable.

The correlation of the TCSS with the LANSS, MNSI, and PD-Q was evaluated (Table 3). A statistically significant **(p<0.001)** and strong positive correlation was found between the TCSS and the other three scales **(r:0.8-1.00).**

The NCV test was performed in all diabetic patients. Correlation and relationship of the data obtained from this test with the results of the LANSS, MNSI, TCSS, and PD-Q were evaluated (Table 4). Accordingly, there was a significant relationship between the TCSS and all the NCV data **(p<0.05).** There was also a moderate negative correlation between the TCSS and the conduction velocities of the peroneal, sural and tibial nerves **(r:0.40-0.60).** However, there was a weak negative correlation between the TCSS and the amplitudes of the peroneal, sural and tibial nerves (r:0.20-0.39).

SENSITIVITY AND SPECIFICITY

The sensitivity and specificity of the TCSS were determined providing that the cut-off value of the scale was accepted as 5. As a result of the study, the sensitivity and specificity of the TCSS was 100% and 96.88%, respectively (Table 5).

DISCUSSION

Several scoring systems such as LANSS, PD-Q, and MNSI can be used to diagnose neuropathic pain due to DPN.[13-15] Nerve and skin biopsies have a very important place in the evaluation of peripheral neuropathy. However, such invasive proce-

TABLE 1: Comparison of gender, BMI, diabetes duration, HgbA1c and age between the groups.

	Group 1 (n=39)	Group 2 (n=32)	Group 3 (n=32)	p-value
Gender				
Male (n[%])	18 (46.1%)	14 (43.7%)	21 (65.6%)	0.167
Female (n[%])	21 (53.9%)	18 (56.3%)	11 (34.4%)	
BMI (mean ± SD)	30.55±5.23	28.63±5.23	26.24±5.18	0.003
Diabetes duration (mean ± SD)	13.31±9.09	13.5±8.9	----	----
HgbA1c (mean ±SD)	9.05±1.8	7.74±2.02	---	----
Age (years) (mean ± SD)	59.21±9.91	55.44±11.49	37.25±14.39	<0.001

* p<0.05; Chi-square; one-way anova; student's t-test; BMI: body mass ındex; HgbA1c: hemoglobin A1c.

TABLE 2: Comparison of gender, BMI, diabetes duration, HgbA1c and age between the groups.

	Cronbach's Alpha values for all items	Cronbach's Alpha values (When the item is removed)
Upper extremity symptoms	0.182(**)	0.943(*)
Foot symptoms		
Pain	0.660	0.932
Numbness	0.867	0.926
Tingling	0.886	0.925
Ataxıa	0.677	0.931
Weakness	0.834	0.926
Examination of the big toe		
Pinprick	0.840	0.926
Heat	0.888	0.925
Rough touch	0.904	0.924
Vibration	0.609	0.933
Position	0.587	0.933
Reflex examination		
Patella reflex	0.722	0.934
Ankle reflex	0.810	0.931

*An İncrease in Cronbach's Alpha value reduces the reliability, **Cronbach's Alpha value<0.25 reduces the reliability.

dures are used for research purposes rather than the evaluation of medical condition. Compared to other methods, the NCV test is more objective and reliable, and also is considered as the gold standard for the diagnosis of DPN.[9] Although sensitivity, specificity, and reproducibility of the NCV test are high, it is not accepted widely in the clinical practice because nerve electrophysiological examination is expensive and time-consuming.[16]

DPN has a clinical course that is usually characterized by silent and unusual symptoms. Therefore, most patients do not have any diagnosis and do not receive any treatment during this process. However, since DPN is a risk factor for foot ulceration and amputation, choosing a fast, cheap, and reliable method to identify high-risk patients is very important in making a clinical decision.

In a study of Bril et al. investigating the reliability and validity of the TCSS for DPN in 81 diabetic patients, there was a strong correlation between the TCSS and NCV datas (amplitudes and velocities of peroneal and sural nerves).[10] In our study, there was a moderate correlation and significant association between the TCSS score and the NCV datas in patients with DM (amplitudes, velocities and latencies of peroneal, sural and tibial nerves). The TCSS was lower in those with better glycemic control in both studies. But we did not apply NCV to control group. Because it was composed of healthy patients with no symptoms of polyneuropathy. However, using NCV in control group might increased the quality of our study. So this was one of the limitations of our study.

TABLE 3: Correlation of the TCSS with the LANSS, MNSI and PD-Q.

		LANSS	MNSI	PD-Q
TCSS	p	*<0.001*	*<0.001*	*<0.001*
	r	0.862	0.882	0.899

The Spearman's correlation coefficient. LANSS: The Leeds Assessment of Neuropathic Symptoms Signs, PD-Q: Pain Detect Questionnaire, MNSI: Michigan Neuropathy Screening Instrument, TCSS: Toronto Clinical Scoring System.

Another study which was designed by Taksandae et al. evaluating the sensitivity and specificity of physical markers in the diagnosis of DPN, they determined that the absence of the ankle reflex had the highest sensitivity.[17] Similarly, ankle reflex examination has the highest internal consistency and sensitivity value in our study.

Liu et al. investigated the correlation of TCSS with severity of diabetic neuropathy. Also, sensitivity, and specificity of TCSS score >or=6 were

TABLE 4: Correlation and relationship between the NCV data and the LANSS, MNSI, TCSS, and PD-Q.

		PD-Q	LANSS	TCSS	MNSI
Tibial nerve					
Speed	p	0.330	**0.027***	**<0.001***	0.134
	r	-0.117	-0.263*	-0.439	-0.179
Amplitude	p	**0.032***	**0.021***	**0.001***	0.338
	r	-0.255*	-0.273*	-0.394	-0.115
Latency	p	0.258	0.068	**0.002***	0.166
	r	0.136	0.218	0.357	0.166
Peroneal nerve					
Speed	p	0.099	**0.002***	**<0.001***	0.143
	r	-0.197	-0.369	-0.502	-0.176
Amplitude	p	0.072	**0.006***	**0.002***	0.340
	r	-0.215	-0.323	-0.370	-0.115
Latency	p	**0.024***	**0.006***	**0.002***	0.055
	r	0.268*	0.324	0.356	0.229
Sural nerve					
Speed	p	0.066	0.107	**<0.001***	0.087
	r	-0.219	-0.193	-0.454	-0.205
Amplitude	p	0.067	0.209	**0.001***	0.259
	r	-0.219	-0.151	-0.377	-0.136
Latency	p	0.289	0.682	0.006	0.358
	r	0.128	0.049	0.326	0.111

*p<0.05, The Spearman's correlation coefficient was used.

LANSS: The Leeds Assessment of Neuropathic Symptoms Signs; PD-Q: Pain Detect Questionnaire; MNSI: Michigan Neuropathy Screening Instrument; TCSS:Toronto Clinical Scoring System; NCV: Nerve conduction velocity.

76.6% and 75.6%, respectively.[18] Similarly there was a significant relationship between TCSS and NCV datas in our study. But the sensitivity and specificity of TCSS score >or=5 were 100% and 96.88%, respectively. The values found in our study were remarkably higher than the results of Liu et al. The most important limitation of our study is that sensitivity and specificity are not determined for different cut off values for TCSS.

Hu et al. compared the clinical efficacies of the MNSI and TCSS in Diabetic patients with DPN. As a result of the study, it was observed that the MNSI and TCSS were highly correlated with the NCV.[19] Similarly, in our study it was found that the TCSS and MNSI were correlated with the NCV data. Also there were a strong positive correlation and a statistically significant relationship between the TCSS and MNSI, PD-Q, LANSS.

We concluded that the Turkish version of the TCSS is highly reliable and valid in detecting neuropathic pain in DPN patients. Cronbach's Alpha coefficient, which indicates item internal consistency in both parts of the TCSS, was found to be greater than 0.6 in reliability analysis. Moreover, when the item about "upper extremity symptoms" was removed from the first part of the Turkish version of the TCSS, Cronbach's Alpha coefficient increased to 0.943. The possible explanation for this situation may be the fact that 'upper extremity symptoms' is a non-specific symptom related question which may include neuropathic and non-neuropathic symptoms together. Also it does not

TABLE 5: The sensitivity and specificity of the TCSS.

			Gold Standard Test (NCV)	
			Polyneuropathy (+)	Polyneuropathy (-)
TCSS	>5	n (%)	39 (55.7%)	1 (100%)
	<5	n (%)	0	31 (44.3%)

TCSS: Toronto Clinical Scoring System.

Specificity: (31/1 + 31)x100= 96.88%, Sensitivity: (39 /39+0)x100= 100%.

contain a specific word such as pain, numbness, tingling, weakness or ataxia therefore the patient does not understand it. Due to not having discrete symptom question, it may change the results of TCSS scores. Also TCSS is used primarily for evaluating the feet but not for upper extremity.[10]

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