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RESEARCH REPORT

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Assessing diabetic polyneuropathy in Spanish-speaking patients: Translation and validation of the Toronto Clinical Neuropathy Score

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Abstract

Background and Aims: Diabetic sensorimotor polyneuropathy (DSP) is a common complication of diabetes. The Toronto Clinical Neuropathy Score (TCNS) is a useful tool for detecting DSP. However, it is not available in Spanish. The study aimed to translate and culturally adapt the TCNS and modified (mTCNS) scales into Spanish and evaluate their measurement properties.

Methods: A multistep forward-backward method was used for translation and cultural adaptation. A panel of physicians subjected the final Spanish versions of TCNS and mTCNS (TCÑS, mTCÑS) to cognitive debriefing. Consecutive patients with diabetes mellitus and DSP were recruited from an outpatient clinic, and the TCÑS and mTCÑS were tested for construct validity, along with other measures.

Results: The internal consistency of both TCÑS and mTCÑS was excellent, as evidenced by Cronbach's Alpha coefficients of 0.83 and 0.85, respectively. Furthermore, there was a robust positive correlation between TCÑS and mTCÑS. In addition, TCÑS was found to exhibit a strong negative correlation with sural sensory nerve action potential amplitude ($r = -0.9206$) and peroneal compound motor action potential amplitude ($r = -0.729$), while demonstrating a positive and strong correlation with the Michigan Neuropathy Screening Instrument ($r = 0.713$).

Interpretation: The TCÑS and mTCÑS are reliable and valid translations of the original TCNS. The TCÑS and mTCÑS can be used to diagnose and measure the severity of neuropathy in Spanish-speaking patients with diabetes.

KEYWORDS
diabetic neuropathy, reliability, validity

Abbreviations: NC, nerve conduction study; TCNS, Toronto Clinical Neuropathy Score.

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1 | INTRODUCTION

Diabetes mellitus is the most common cause of polyneuropathy worldwide and is becoming an increasing burden in countries in which the prevalence of obesity is rising.[1] The gold standard for the diagnosis of polyneuropathy has been nerve conduction studies (NCS).[2] Several scoring systems exist for the diagnosis and classification of diabetic sensorimotor polyneuropathy (DSP). They include the Toronto Clinical Neuropathy Scoring (TCNS)[3] and its modified score (mTCNS),[4] the Michigan Neuropathy Screening Instrument (MNSI),[5] and the Neuropathy Disability Score among others.[6]

The TCNS consists of a brief, easily administered semi-structured clinical interview and examination. The TCNS (Table 1) is weighted to emphasize sensory symptoms and deficits, the first features typically observed in DSP. TCNS has been shown to be a valid and reliable for the diagnosis and staging of DSP.[3] The TCNS have been validated against morphometry, with a significant negative correlation with sural nerve fibre density.[3]

The TCNS has 11 items that assess symptoms and signs of DSP, taking into account sensory, motor, and lower-limb reflex findings that are typically evaluated in patients with neuropathy. Symptoms such as numbness, tingling, pain, weakness, ataxia, and upper-limb symptoms are assessed and classified as present or absent. Signs such as light touch, pinprick, temperature, position, and vibration are graded as normal or abnormal at the toes, and knee and ankle reflexes are also evaluated and graded as normal, reduced, or absent on both sides. The maximum TCNS is 19 points, where higher scores indicate worse neuropathy.[3] TCNS has been validated in a broad spectrum of polyneuropathies.[7]

TABLE 1 The components of the modified Toronto Clinical Neuropathy Score (mTCNS).

Symptom scores	Sensory test scores
Foot pain	Pinprick
Numbness	Temperature
Tingling	Light touch
Weakness	Vibration
Ataxia	Position sense
Upper limb symptoms	
Symptom scores are graded as	Sensory test scores are graded as
0 = absent	0 = normal
1 = present but no interference with sense of well-being or activities of daily living	1 = reduced at the toes only
2 = present, interferes with sense of well-being but not with activities of daily living	2 = reduced to a level above the toes, but only up to the ankles
3 = present and interferes with both sense of well-being and activities of daily living (both)	3 = reduced to a level above the ankles and/or absent at the toes

Note: Maximum mTCNS is 33. Symptoms and signs (sensory tests) are considered present as a result of polyneuropathy in the opinion of the investigator.

The modified TCNS (mTCNS).[4] eliminated reflex testing since it represents late-stage DSP, and is highly variable between raters. In addition, sensory and symptom scoring options were expanded. For symptom items, these were transformed into a Likert scale based on interference in the patient's well-being or activities of daily living as described in Table 1. Similarly, each examination item is rated from 0 to 3. The mTCNS score graduated from 0 to 33.

Early detection and treatment of DSP is essential for preventing further damage and improving quality of life.[8] However, the availability of validated DPN assessment tools in Spanish is limited, which can hinder the quality of care and communication. Standardized Spanish assessments would allow for better management of DSP, ultimately leading to improved health outcomes for Spanish-speaking patients with DSP or other polyneuropathies.

The aim of the current study was to translate, adapt, and cross-culturally validate the TCNS and mTCNS into Spanish. Secondly, we aimed to evaluate its measurement properties for use in research and clinical practice for the Spanish-speaking population.

2 | METHODS

2.1 | Translation and cultural adaptation of the Spanish version of TCNS and mTCNS

We use the principles of the ISPOR Task Force[9] for translation and cultural adaptation. The TCNS, mTCNS were translated into Spanish following a multistep forward-backward method, whereby the measure is first translated into the new language and after the translation is approved, it is translated back to the original language by a different person. We obtained permission from Dr. Bril, the primary developer of both scales, to conduct these studies.[3] Three independent translators: one neurologist, one family doctor, and one nonmedical certified professional translator completed the first translation; all were bilingual with Spanish as the first language. Subsequently, the three translators and the principal investigator (J.I.) achieved a consensus to reconcile all three Spanish versions. Differences in individual translations of the questions were compared, discussed, and resolved using a consensus method to create one preliminary Spanish TCNS and mTCNS version. Those versions were back-translated independently by one neurologist and one certified professional translator (both were bilingual with English as the first language), who were not familiar with the original English versions. Any inconsistencies were discussed and resolved after each step. Finally, the committee met with the author of TCNS to review the new retranslated English version and finally produced the TCÑS and mTCÑS. Because the TCNS is administered by a physician, we conducted cognitive debriefing, with five physicians (three neurologists and two family physicians) who reviewed the TCÑS, mTCÑS, and reported any ambiguities with the items.

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3 | VALIDATION

We performed a cross-sectional study in patients with diabetes mellitus with symmetrical distal DSP as defined by England and Toronto consensus criteria.[2,10] All patients were recruited from the outpatient clinic of the Diabetic and Neurology Unit of Hospital Padre Hurtado, Santiago de Chile, between August 2017 and March 2018. The Research Ethics Board of the Servicio Salud Metropolitano Sur Oriente approved the study protocol, and all patients provided written informed consent.

To avoid potential selection bias, we enrolled consecutive patients. We excluded patients if they had known nondiabetic causes of neuropathy (e.g., vitamin deficiencies, uremia, thyroid disease, lumbar or cervical radiculopathy, inflammatory neuropathy, or the presence of alcoholism). We tested the TCÑS, mTCÑS in each patient. To assess construct validity, we also used the Michigan Neuropathy Screening Instrument (MMSI), the EuroQol five-dimensional (EQ-5D-5L) questionnaire, and NCS.

3.1 | The Michigan Neuropathy Screening Instrument

The Michigan Neuropathy Screening Instrument (MMSI) is composed divided in two domains: (1) a patent-reported questionnaire (15 questions) regarding neuropathic symptoms and (2) a physical examination (five items) completed by a clinician. Each patient completed the MNSI questionnaire in the researcher's presence; if the patient could not read, the researcher read the questions. The examination component included foot skin inspection for deformities, ankle reflex, monofilament test, and vibration sensation tested by a 128-Hz tuning fork placed over a great toe. An expert physician completed the medical examination.[5] We used a validated Spanish version.[11]

3.2 | EQ-5D-5L questionnaire

EQ-5D-5L is a generic measure of overall health status, consisting of 5-items, each addressing one attribute or domain.[12] The EQ-5D-5L dimensions are: mobility, usual activities, self-care, pain, and depression/anxiety, each with five response options. EQ-5D-5L is scored as health utilities, where a score of 1 indicates perfect health and 0 means death; negative scores are possible, indicating states valued as worse than death. Spanish scoring algorithm was used.[13]

3.3 | Neurophysiological assessment

All patients were evaluated with nerve conduction studies (NCS) of the nondominant median nerve, both peroneal and sural nerves. Recordings were performed using Nicolet® VikingQuest® EMG/NCS/EP System, with temperature control (32–34°), careful distance measures, and well-defined recording without artifacts response. We used a silver disk electrode with a standardized size of 10 mm and a silver ground electrode with 30 mm. All neurophysiological tests were performed by a clinical neurophysiologist (I.A. and F.P.) in one visit. Clinical neurophysiologists were blinded to the clinical measures. The mean values of repeat nerve conduction velocities (CVs) and amplitudes were calculated. Sensory responses were averaged. Latencies and amplitudes were determined automatically, distance values were entered into the Counterpoint, and conduction velocities were calculated automatically. A severity qualitative assessment was performed using sensitive and motor conduction amplitudes.

3.4 | Statistical analysis

We used Cronbach's alpha coefficient was used to assess the internal consistency of the questionnaire. A Cronbach's alpha coefficient >.7 was considered acceptable.[14] Statistical analysis was performed using Stata/SE 12.0 software, and a $p < .05$ was considered statistically significant.

3.4.1 | Construct validity

Concurrent validity was tested by assessing the correlations between the TCÑS, and mTCÑS scores with (MMSI and EQ-5D-5L scores and with NCS) using Pearson correlation coefficients. The *r*-value was required to be >0.70 (strong correlation). 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 (moderate correlation) was considered sufficient evidence for validity. For a minimum correlation of 0.5, alpha 0.5 and 80% power, 29 individuals are required.

4 | RESULTS

4.1 | Translation

In developing the translation of TCÑS, mTCÑS, we paid attention to retaining the original construction of the English version. During the translation process, translators did not find a relevant language or meaning discrepancy. Cognitive debriefing did not identify any significant problems in the concept, wording, or cultural relevance of the items. The translated forms were accepted by the user satisfactorily and had any problem completing the questionnaire. The final version of both scales is available (Table S1).

4.2 | Construct validity

33 patients were enrolled (25 women and 8 men) with a mean age of 63.8 ± 15 years. All patients had type 2 DM. Demographic details are described in Table 2. Cronbach's alpha coefficient for the TCÑS was

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TABLE 2 Patient background and correlations of clinical factors with TCÑS, mTCÑS (Pearson's correlation).

	Characteristic in the patient sample ($n = 34$)	TCÑS		mTCÑS	
		Correlation (95% CI)	*p* value	Correlation (95% CI)	*p* value
Age (year)	63.8 ± 15	0.214	.23	0.148	.4
Female	25 (68%)				
Time since DSP onset (year)	5 ± 4	0.144	.42	0.08	.66
Age at DSP onset (year)	59.5 ± 13.5	−0.096	.1	−0.017	.1
Diabetes duration (year)	12.7 ± 9.08	−0.095	.1	−0.1	.2
BMI (mean ± *SD*)	32.9 ± 7	−0.35	.29	−0.21	.33
HgbA1c (mean ± *SD*)	8.63 ± 2	−0.1	.1	−0.1	.1
Insulin therapy	22 (66.7%)				

Abbreviations: BMI, body mass index; HgbA1c, glycated hemoglobin.

TABLE 3 Univariate correlation for the relationship between TCÑS mTCÑS and MMSI.

	MMSI symptoms score		MMSI exams score		MMSI total score	
	Coefficient Correlation Pearson (95% CI)	*p* value	Coefficient Correlation Pearson (95% CI)	*p* value	Coefficient Correlation Pearson (95% CI)	*p* value
TCÑS						
Symptoms score	0.518	.002	0.4	.000	0.51467	.001
Sensory test score	0.44	.01	0.478	.005	0.5	.000
Reflex scores	0.35	.01	0.3	.3	0.41	.02
Total TCÑS score	0.99	.000	0.5	.000	0.713	.000
mTCÑS						
Symptoms score	0.746	.000	0.6	.000	0.781	.000
Sensory test score	0.75	.000	0.5655	.001	0.665	.000
Total mTCÑS score	0.99	.000	0.6	.000	0.6	.000

0.83, and for mTCÑS was 0.85, indicating good internal consistency. The median overall score of TCÑS was 8.9 ± 5.1, and mTCÑS was 12.1 ± 8.2.

A high correlation was observed between the TCÑS and sural SNAP amplitude ($r = -0.9206$, $p < .001$) and peroneal CMAP amplitude ($r = -0.729$, $p < .006$). The mTCÑS showed a moderate correlation with sural SNAP amplitude ($r = -0.681$, $p = .002$) and peroneal CMAP amplitude ($r = -0.681$, $p = .002$). The correlation between EQ-5D-5L and TCNS was moderate ($r = -0.568$, $p = .001$), the same as mTCÑS ($r = -0.662$, $p = .001$). The correlation coefficients between the TCÑS, mTCÑS and MMSI, are described in Table 3.

5 | DISCUSSION

The purpose of the present study was to translate the TCNS and mTCNS for use with the Spanish-speaking population. Overall, this study replicated the main findings obtained in the original research with regard to the properties of the scales,[4] our results confirm a correlation with the NCS studies similar to the original version and excellent internal consistency.

The TCNS is a widely used clinical tool for assessing DSP, which has been translated and adapted into various languages such as Turkish and Japanese.[15,16] As type 2 diabetes continues to be a prevalent epidemic, it is crucial to enhance multicenter clinical research on DSP, the most common complication associated with diabetes. The TCÑS and mTCÑS allow Spanish speakers, the second most-spoken first language worldwide, to use this clinical and research tool.

The original TCNS validation study demonstrated a strong correlation between TCNS and NCS.[3] In our study, we found a strong and significant association between the TCNS score and the NCS. Furthermore, mTCNS showed a moderate and significant correlation with these variables. These results highlight the utility of the TCNS and mTCNS in assessing DSP in Spanish speakers and support their use in multicenter clinical research.

It is essential to highlight that the reliability and validity of a scale may vary depending on the population and context in which it is used. Nevertheless, the findings of this study align with previous research that has assessed the reliability and validity of the original English versions of TCNS and mTCNS in patients with DSP. However, further clinical investigations are necessary to assess the TCÑS and mTCÑS in patients with a broader range of polyneuropathies, as the original

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version of TCNS has been validated in a variety of neuropathies.[7] Additionally, test–retest reliability will need to be assessed in future work.

This study has certain limitations: as it was conducted in a hospital setting, the results may not be generalized to a different population, for example, patients followed in the community. Additionally, all our patients had type 2 DM, so we could not compare to people with type 1 DM.

In conclusion, TCÑS and mTCÑS are reliable and valid instruments for the measurement of diabetic neuropathy in Spanish speakers with polyneuropathy to be used as clinical and research instruments.

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CONFLICT OF INTEREST STATEMENT

Dr. Idiáquez Rios, Dr. Acosta, Dr. Prat, Dr. Gattini, Dr. Pinono do not report conflicts of interest. Dr. Barnett-Tapia has served as member of advisory board for Alexion, argenx, Sanofi, and has been a consultant for Janssen and Takeda. She has research received grants from Grifols, Octapharma, US Department of Defence, MGNet and Muscular Dystrophy Canada. None of these are related to this work.

DATA AVAILABILITY STATEMENT

The data that support the findings of this study are available on request from the corresponding author. The data are not publicly available due to privacy or ethical restrictions.

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REFERENCES

1. Feldman EL, Callaghan BC, Pop-Busui R, et al. Diabetic neuropathy. *Nat Rev Dis Primers*. 2019;5(1):41. doi:10.1038/s41572-019-0092-1
2. England JD, Gronseth GS, Franklin G, et al. Distal symmetric polyneuropathy: a definition for clinical research: report of the American Academy of Neurology, the American Association of Electrodiagnostic Medicine, and the American Academy of Physical Medicine and Rehabilitation. *Neurology*. 2005;64(2):199-207. doi:10.1212/01.WNL.0000149522.32823.EA
3. Bril V, Perkins BA. Validation of the Toronto clinical scoring system for diabetic polyneuropathy. *Diabetes Care*. 2002;25(11):2048-2052. doi:10.2337/diacare.25.11.2048
4. Bril V, Tomioka S, Buchanan RA, Perkins BA, the mTCNS Study Group. Reliability and validity of the modified Toronto Clinical Neuropathy Score in diabetic sensorimotor polyneuropathy. *Diabet Med*. 2009;26(3):240-246. doi:10.1111/j.1464-5491.2009.02667.x
5. Moghtaderi A, Bakhshipour A, Rashidi H. Validation of Michigan neuropathy screening instrument for diabetic peripheral neuropathy. *Clin Neurol Neurosurg*. 2006;108(5):477-481. doi:10.1016/j.clineuro.2005.08.003
6. Yang Z, Chen R, Zhang Y, et al. Scoring systems to screen for diabetic peripheral neuropathy. *Cochrane Database Syst Rev*. 2018;2018(7):CD010974. doi:10.1002/14651858.CD010974.pub2
7. Abraham A, Barnett C, Katzberg HD, Lovblom LE, Perkins BA, Bril V. Toronto Clinical Neuropathy Score is valid for a wide spectrum of polyneuropathies. *Eur J Neurol*. 2018;25(3):484-490. doi:10.1111/ene.13533
8. Davies M, Brophy S, Williams R, Taylor A. The prevalence, severity, and impact of painful diabetic peripheral neuropathy in type 2 diabetes. *Diabetes Care*. 2006;29(7):1518-1522. doi:10.2337/dc05-2228
9. Wild D, Grove A, Martin M, et al. Principles of good practice for the translation and cultural adaptation process for patient-reported outcomes (PRO) measures: report of the ISPOR task force for translation and cultural adaptation. *Value Health*. 2005;8(2):94-104. doi:10.1111/j.1524-4733.2005.04054.x
10. Dyck PJ, Albers JW, Andersen H, et al. Diabetic polyneuropathies: update on research definition, diagnostic criteria and estimation of severity. *Diabetes Metab Res Rev*. 2011;27(7):620-628. doi:10.1002/dmrr.1226
11. Ticse R, Pimentel R, Mazzeti P, Villena J. Elevada frecuencia de neuropatía periférica en pacientes con Diabetes mellitus tipo 2 de un hospital general de Lima-Perú. *Rev Med Hered*. 2013;24(2):114-121. http://www.scielo.org.pe/scielo.php?pid=S1018-130X2013000200004&script=sci_arttext
12. Brooks R. EuroQol: the current state of play. *Health Policy*. 1996;37(1):53-72. doi:10.1016/0168-8510(96)00822-6
13. Garcia-Gordillo MA, Adsuar JC, Olivares PR. Normative values of EQ-5D-5L: in a Spanish representative population sample from Spanish Health Survey, 2011. *Qual Life Res*. 2016;25(5):1313-1321. doi:10.1007/s11136-015-1164-7
14. de Vet HCW, Terwee CB, Mokkink LB, Knol DL. *Measurement in Medicine: A Practical Guide*. Cambridge University Press; 2011 https://play.google.com/store/books/details?id=_OcdeTg9i28C
15. Kaymaz S, Koylu S, Kaymaz TI, Aykan AA. The validity and reliability of the Turkish version of the Toronto clinical scoring system (TCSS). *J PMR Sci*. 2019;22(2):41-47. doi:10.31609/jpmrs.2019-65511
16. Yuzuru J, Nobuo S, Yukihara K. Reliability study of the revised Japanese version of the Toronto Clinical Neuropathy Score for patients with diabetic peripheral neuropathy. *Diabetes*. 2013;56(12):932-937. doi:10.11213/tonyobyo.56.932

SUPPORTING INFORMATION

Additional supporting information can be found online in the Supporting Information section at the end of this article.

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