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Translation and Cross-Cultural Adaptation of the Measuring Instrument Michigan Neuropathy Screening Instrument for the Portuguese Population

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ABSTRACT

Aim: The cross-cultural adaptation of the Michigan Neuropathy Screening Instrument (MNSI) for the Portuguese population and the determination of reliability and internal consistency of this instrument.

Methods: 30 patients (12 female and 18 male), aged 55-83 years were selected from a podiatry consultation, selection criteria were to havediabetes type 2 and knowing how read and write. In this methodological study the translation and back translation of the MNSI and subsequent approval of pre-final version by expert committee was performed. Intra Class Correlation (ICC) and kappa (k) statistics and the analysis of internal consistency by Cronbach's Alpha (α) were conducted to determine the metric characteristics of intra- and interobserver reliability.

Results: For the Clinical examination of MNSI intra and interobserver agreement ICC = 0.96 and ICC=0.94 respectively were found, a k coefficient ranged 0.42 - 1; and α = 0.97, 0.98. The MNSI questionnaire results showed a k coefficient ranged 0.35 - 1 and α = 0.762, 0.714.

Conclusions: The Portuguese version of MNSI provided to be a good screening instrument for Diabetic Peripheral Neuropathy (DPN). It is ready to be used in primary health care settings as an early screening tool to improve more elective electrophysiological examination referral.

Keywords: Diabetes mellitus, Diabetic neuropathy, Diabetic foot, Screening, Primary health care

Introduction

Diabetes is currently one of the largest global health emergencies of the 21st century [1,2]. Recent estimations from International Diabetes Federation (IDF) [2] indicate that in 2017, 424.9 million people around the world had diabetes. Numbers in Portugal are also worrying, 13.3% of the population (more than 1 million people) had diabetes in 2015 [3].

Chronic hyperglycemia is associated with tissue and the nerve damage, which is often associated with a high morbidity index [2,4]. Diabetic Peripheral Neuropathy (DPN) affects the sensory nerves of the distal extremities, namely the feet, which is particularly meaningful because it can allow injuries to go unnoticed, leading to ulceration, serious infections and in some cases lower limb amputations [2]. The most common symptoms of DPN are induced by the involvement of small fibers and include pain and dysesthesia (unpleasant sensations

of burning and tingling) and by the involvement of large fibers, which may cause numbness and loss of protective sensation, this last one is a risk factor for diabetic foot ulceration [4]. It is estimated that approximately 25% of individuals with diabetes have favourable conditions for the appearance of lesions on the feet [5].

The International Guidelines define DPN as the presence of symptoms and/or signs of peripheral nerve dysfunction in people with diabetes, after the exclusion of other causes. The current recommendations for the screening of peripheral nerve dysfunction have not recommended electrophysiological examination as a screening tool, but the presence of clinical signs and symptoms using medical history and simple clinical tests (ankle reflexes, vibration perception, temperature and protective sensation) at least annually [4].

In clinical practice a simple, sensitive and inexpensive screening instrument for DPN is essential, because early diagnosis is required for a proper treatment [6,7]. The early identification of the neuropathic process offers a crucial opportunity for the patient to actively guide the glycemic control and to implement the improvement of foot care prior to significant morbidity [4,7]. According to "Standards of Medical Care in Diabetes"in addition to periodic evaluations of diabetes and foot care, it's essential that all patients with microvascular complications and particularly those with high-risk foot conditions (history of ulcer or amputation, deformity, loss of protective sensation, or peripheral arterial disease) and their families, should be provided general education about risk factors and appropriate management to prevention of foot complications [4].

Previous studies show that Semmes Weinstein Monofilament Test (SWMT) can possibly be useful for diagnosing the DPN in daily clinical practice [8-10], but the recommendations by American Diabetes Association (ADA) suggest the use of more than one clinical test [4].

Recently, different clinical scoring systems have been developed to synthesize a large amount of information from the clinical evaluation of neurological function and provide a quantitative value to document the presence and severity of the DPN. Most of these screening instruments are non-invasive, inexpensive, with good relationship specificity/sensitivity and are highly predictive of clinical diagnosis [6,7]. One of these instruments, the MNSI created by Feldman and colleagues of Department of Neurology at the University of Michigan in 1994 [11], this is currently one of the most widely used instruments in different international researches [12-15].

Doe to the increase in the number of individuals with DPN in Portugal, the lack of a Portuguese screening tool that allows primary health care professionals to screen diabetic patients and prevent many diabetic foot complications, the main objective of this study was to conduct the cross-cultural adaptation and contribute to the validation of the MNSI for Portuguese of Portugal.

Materials and Methods

Subjects

Patients with diabetes type 2 that knew how read and write were selected by convenience from the podiatry consultation of the Associação para o Estudo da Diabetes Mellitus e de Apoio ao Diabético do Algarve (AEDMADA). Subjects were excluded if they had cognitive changes or who any additional associated problem that impeded the assessment of any MNSI component. A total of 30 individuals accepted to participate and signed informed consent, accordingly to the most recent version of the Declaration of Helsinki. The protocol was approved by the Ethics Committee of the Regional Health Administration of Algarve.

Study design

This is a methodological study to translate and adapt the MNSI original version to the Portuguese of Portugal language and evaluate its reliability in a sample of diabetic patients.The MNSI instrument was developed to adapt and simplify the criteria assessment of DPN proposed by the San Antonio Consensus and the Mayo Clinic. The creation of the MNSI fulfilled a gap on screening tools for DPN because it's a fast and objective screening tool with a quantitative evaluation system. The MNSI is divided into two parts: questionnaire and clinical examination [11].

The questionnaire component consists of 15 "yes or no" questions about foot sensation (pain, numbness, and sensitivity to temperature), including one relevant to general asthenia (Q10) and one relevant to peripheral vascular disease (Q4), which are not counted in the final score. These questions reflect common symptoms reported in DPN together with two questions to register non-neuropathic and primarily vascular symptoms. The answers are registered as 0 "no" and 1 "yes" with the exception of the question 7 and 13 which are inverted. A score of ≥ 7.0 is considered abnormal [11].

The questionnaire is followed by a clinical examination involving 1) foot inspection (deformities, dry skin, callus, infection, or ulceration), 2) semiquantitative assessment of vibration perception (present – 0; decreased – 0.5; absent – 1), 3) semiquantitative assessment of protective sensation (normal – 0; reduced – 0.5; absent – 1), and 4) grading of ankle reflexes (present – 0; reinforcement – 0.5; absent – 1). A score ≥ 2.5 is considered abnormal. In components of MNSI, the higher the score, the greater the neuropathy [11]. More recently a cut-off point of ≥ 4 has been used to improving the performance of the instrument [15].

Translation Process: The guidelines used for the translation process and cross-cultural adaptation were the American Association of Orthopaedic Surgeons (AAOS) reviewed by Beaton, et al. [16]. This process involved the adaptation of: a) individual items, b) instructions and c) response options. Authorization of the original author of this instrument was obtained previous to this process.

The translation was composed of the following stages: Initial Translation: Two independent translations (T1 and T2) were done from the original language (English), into the target one (Portuguese of Portugal). The two independent translations were performed by two bilingual translators (whose mother language is the Portuguese), with different profiles and backgrounds: translator T1 was a healthcare professional and knowledgeable about the MNSI concepts; translator T2 was a non health professional unaware of the MNSI concepts.

Synthesis of the Translations: In this phase a mediator (impartial person) worked with both translators (T1 and T2) in the synthetization of their translations, according to the original instrument producing one common translation (T12).

Back Translation: Working with the T12 version and blind to the original version, two independent bilingual translators, whose mother

language was English and were unaware of the MNSI concepts, made a back translation (BT1 and BT2) into the original english language.

Expert Committee: The Committee was composed of health professionals, languages professionals and all translators involved in the previous stages. Once the two back translations were crossed, a third Consensus English version was produced and compared to the Original English Version to verify if there were differences of meaning between them. Finally,a pre-final Portuguese version was elaborated.

Psychometric analysis

Once the translation process was completed, we started the application of MNSI. Apart from the Portuguese Version of MNSI, we conducted a demographic questionnaire to characterize the sample. Each participant filled the MNSI questionnaire twice with a time interval of 20 days. Two observers (1 and 2) performed the MNSI clinical examination during the first visit in order to determine interobserver agreement. Examinations were repeated with a 20 days interval by observer 1 to determine intraobserver agreement. Both observers were nurses with different levels of experience in clinical treatment and management of diabetic foot; observer 1 expert nurse with more than 10 years of experience and observer 2 general nurse with less than 2 years of experience.

Psychometric characteristics are fundamental to formulate a valid conclusion [17,18] over the objective of the MNSI tool. For this purpose, particular attention was given to reliability.

Statistical analysis

All analyses were conducted with IBM SPSS Statistics version 22. The MNSI performance was evaluated by determining the reliability and descriptive statistical methods.

Reliability was evaluated through internal consistency (homogeneity) through the use ofCronbach's α in two applications of MNSI; temporal stability (test-retest reproducibility) was assessed by the intraclass correlation coefficient (ICC) with 95% of confidence interval (CI) and intra- and interobserver agreement was assessed by *k* statistic in each item of MNSI clinical examination [17,18].

On MNSI clinical examination, the variables were dichotomized in "Present" or "Absent". Those who were "Present/Reinforcement", "Decreased" and "Reduced" were considered "Absent" to simplify the statistical analysis.

Results

Demographic and clinical data

A total of 30 patients participated in the study, 60% male (n=18) and 40% female (n=12); age ranged 55-83 years (mean 69.5 ± 7.65) and 70% of our sample was aged ≥ 65 years. Mean duration of diabetes was 13.5 ± 9.29 years, however 50% (n=15) had diabetes<10 years. Mean of percentage of HbA1c 7.2 ± 1.3 (55 mmol/mol). Hypertension was the most present comorbidity in 83.3% of the patients; the remaining demographic results can be consulted in Table 1.

Mean MNSI questionnaire score was 2.9 ± 2.54 and MNSI clinical examination score was 2.6 ± 1.71. Three subjects (10%) had a positive score in questionnaire for a cut-off point of ≥7 and 11 (36.66%) for a cut-off point of ≥ 4. Twenty-two (73.33%) had a positive score in clinical examination for a cut-off point of ≥ 2.5.

Table 1: Demographic characteristics of sample (n=30).

Variable	*Number (%)*
Gender	
Male	18 (60.0)
Female	12 (40.0)
Age in years (mean 69.50 ± 7.65)	
< 65 years	9 (30.0)
≥ 65 years	21 (70.0)
Marital Status	
Single	1 (3.3)
Married	23 (76.7)
Widow	3 (10.0)
Divorced	3 (10.0)
Job Situation	
Employee	7 (23.3)
Unemployed	2 (6.7)
Housewife	3 (10.0)
Retired	18 (60.0)
Level of Education	
≤ 12º year	26 (86.7)
> 12º year	4 (13.3)
Duration of DM (mean 13.50 ±9.29)	
< 10 years	15 (50.0)
≤ 10 years	15 (50.0)
BMI	
Under weight	0 (0.0)
Normal weight	7 (23.3)
Over weight	11 (36.7)
Obese	12 (40.0)
HbA1c (mean 7.2 % ± 1.3)	
≤ 7%	12 (40.0)
>7%	12 (40.0)
Not observed	6 (20.0)
Associated disease	
Hypertension	25 (83.3)
Coronary heart disease	8 (26.7)
Renal disease	5 (16.7)
Retinopathy	9 (30.0)
Smoking	
Smoker	0 (0.0)
Non-Smoker	30 (100)
Alcohol	
Yes	7 (23.3)
No	23 (76.7)
Medication	
Oral Antidiabetic	26 (86.7)
Insulin	5 (16.7)
Oral Antihypertensive	23 (76.7)

Translation process

No significant differences between the versions were found in the process of translation and back translation. Therefore, the final consensus version was mainly to clarify the semantics and sentence construction throughout the instrument, in order to use a clear and simple language for patients.

Psychometric analysis

MNSI Questionnaire: Reproducibility analysis showed an excellent agreement, ICC = 0.96 IC (0.91 – 0.98), proving that the Portuguese version of MNSI behaves similarly over time. Table 2 shows that most of the items offers an acceptable value of agreement on the test-retest (k ranged between 0.35 - 1.00). The questions that showed lower concordance were Q5 (k = 0.35) and Q3 (k = 0.37). The questions with a greater concordance were Q13 and Q 15 (k = 1.00). Regarding the internal consistency, Cronbach's α was calculated for the test (α = 0.76) and retest (α = 0.71) showing a good internal consistency (α > 0.7).

MNSI Clinical Examination: The values of intra and interobserver reliability were ICC = 0.98 IC (0.94 – 0.99) and ICC = 0.97 IC (0.94 – 0.99), respectively. Clinical examination of MNSI is therefore reliable in-between observations over time and between different observers.

The k values for the inter and intraobserver agreement for each item of the clinical examination can be found in Table 3. The ankle reflex of the sensory tests showed the lowest values of agreement (kLF = 0.43 e kRF = 0.42), and the vibration perception shows higher values (kLF = 0.71 e kRF = 0.71) among different observers. Regarding observations made over time by the same observer the monofilament test, showed the lowest values (kLF = 0.64 e kRF = 0.64) and the ankle reflex showed the highest values (kLF= 0.87 e kRF = 0.87).

The Cronbach's α was calculated twice, when the clinical examination was performed by the two observers. The results were the αobserver1 = 0.97 and αobserver2 = 0.98. Demonstrating that the clinical examination had a very good internal consistency.

Table 2: Kappa Coefficients MNSI Questionnaire.

Item	Kappa
Q1	0.80
Q2	0.89
Q3	0.37
Q4	0.67
Q5	0.35
Q6	0.63
Q7	96.6*
Q8	0.79
Q9	0.89
Q10	0.43
Q11	0.73
Q12	0.60
Q13	1.00
Q14	0.43
Q15	1.00

*Percent Agreement

Table 3: Kappa Coefficients MNSI Clinical Examination.

Items	Interobserver	Intraobserver
Appearance RF†	0.91	1.00
Appearance LF†	0.84	0.86
Ulceration RF	1.00	100*
Ulceration LF	1.00	100*
Ankle Reflex RF	0.42	0.87
Ankle Reflex LF	0.43	0.87
Vibration perception RF	0.71	0.64
Vibration perception LF	0.71	0.82
Monofilament RF	0.43	0.64
Monofilament LF	0.52	0.64
Final Score	0.80	0.75

*Percent Agreement † RF (Right Feet); LF (Left Feet)

Discussion

MNSI has been translated and culturally adapted in different countries like Italy, Nigeria, France, USA, Brazil, Iran, Turkey, and others [12-15,21-23], and is a widely used screening instrument for DPN.

During this study a 73.3% prevalence of DPN was screened during clinical examination of MNSI, and a 10% prevalence during the MNSI questionnaire.Previous studies have similar results with a prevalence ranging from 11 to 55% in clinical examination and from 5 to 46% in the questionnaire [12,14,15,21,23-25]. Most of these investigators who did not use the questionnaire component for the evaluation of DPN argued that, when used alone, it is relatively poor in predicting the presence of DPN when compared to the clinical examination.

Clinical examination screened 5 times more subjects with risk of DPN than the questionnaire alone, similar results have reported [15,25]. This can be explained by the fact that nearly 50% of patients with DPN despite having pathological changes in peripheral nerves, remain asymptomatic, allowing the degeneration of nerve cells, fiber demyelination and axonal degeneration continues to be tested [26].

In this study, the mean MNSI questionnaire score was 2.9 ± 2.54 and the mean MNSI clinical examination score was 2.6 ± 1.71. Other authors presented values ranging between 1.83 – 6.7 to questionnaire and between 1.55 – 1.84 to clinical examination [15,23,27].

When analyzed individually the various questions/items of the MNSI questionnaire, the questions which showed lower concordance were the Q3"Are your feet too sensitive to touch?" (k = 0.37), Q5 "Do you ever have any prickling feelings in your legs or feet?" (k = 0.35) and Q14 "Is the skin on your feet so dry that it cracks open?" (k = 0.43). The use of expressions such as "too sensitive" or "do you ever have", can be a bit subjective because it does not specify the quantity. Q14 is asking for two different situations "dry skin" and "cracks open" that can mislead the patient because he can have dry skin without cracks and answer 'no', because he/she only has dry skin. All the other questions have good values of agreement. The Hermann study [15] indicates that the questions that have more sensitivity are the Q9 and Q4 and more specificity are Q15 and Q6.

Nevertheless, the diagnosis of DPN does not only depend on the

symptoms [22]. Researchers have been paying special attention to the validation of MNSI clinical examination [22,23,29], therefore it is important to especially analyze k values and inter- and intraobserver agreement for different quantitative sensory tests.

We found that the MNSI clinical examination demonstrated good results of inter- and intraobserver reliability (ICC = 0.97; 0.98 respectively) and furthermore excellent internal consistency (αobserver1 = 0.97; αobserver2 = 0.98). Although Lunetta, et al. [24] did not use the same statistical approach their results are similar to ours, once they report a 88.75% of interobserver reproducibility of and a 95 and 94% of within-observer reproducibility, with a good correlation (r = 0.71 and r = 0.76)between the two measurements (P < 0.001). Also, Bax, et al. [27] in previous years, have shown an acceptable k test coefficient for intraobserver (k = 0.65; 0.63) and interobserver (k = 0.61) agreement. MNSI Clinical examination reveals to be a reliable test for the DPN screening.

When separately observing the performance of the different quantitative sensory tests of MNSI clinical examination (ankle reflexes, vibration perception protective sensation), it appears that the one with the best interobserver agreement is the 128 Hz tuning fork (k = 0.71) followed by monofilament (k = 0.52) and the best intraobserver agreement is the ankle reflexes (k = 0.87). Other authors describe similar values in the application of these tests [8, 27-29]. Taksande, et al. [29] revealed that among all the physical signs, absent ankle reflex was highly sensitive for detecting neuropathy, anticipating that the evaluation of this signal is very important.

Zhao, et al. [30] concludes very recently that the evaluation of DPN through ankle reflexes, temperature and vibration perception (128Hz tuning fork) together, yields similar results to conventional NCT (gold standard) and therefore may provide a valuable tool for screening diabetic patients for DPN. Although temperature is not an item in the MNSI clinical examination, it may be important to consider this aspect in future studies.

Despite these recent findings, among various quantitative sensory testing, the SWMT still remains the most commonly used by clinicians, for its accuracy, inexpensive and convenience. On the other hand, the monofilament, as shown in this study and others [8,10,28,29] does not provide very high reliability values, which can be explained by the lack of consensus on the agreed protocol on the use of this tool (location and number of sites tested; number of insensitive sites being classified as presence of neuropathy). For this reason, the sensitivity and specificity of the SWMT as a tool for neuropathy detection can be compromised [9].

The lack of agreement between the methodology to be used in applying SWMT and that rely on subjective patient responses [7] leads to the necessary training and experience of evaluators. Some studies claim that evaluators experience in the use of monofilament is low [28,31] the same may have been revealed in this study which might explain the lower interobserver agreement values of the SWMT (k = 0.43; 0.52).

Miranda-Palma, et al. [32] concludes that the use of the 128Hz tuning fork tested in only two sites is, as sensitive as, the monofilament applied in eight, which additionally to the good inter- and intraobserver agreement presented in this study, reinforces the value of the tuning fork in the evaluation of DPN. Al-Geffari [25] suggests that the application of the 128Hz tuning fork in addition to the 10g monofilament identify patients at risk of neuropathy.

Most of the studies consulted compare the validity of quantitative sensory tests to the NCT, once this one offers more objective electrophysiological measures of the nerve function in diabetic patients. Nonetheless they say that the NCT, is not sustainable for a quick and practical diagnosis, because this technique requires a laboratory and an experienced neurologist which is not universally available in primary care settings, additionally it is also uncomfortable for the patient [15,22,29]. Contrary MNSI can be easily performed by a healthcare professional in primary care settings and various studies have confirmed it can be a simple and reproducible method for clinical screening, although it still requires a skilled evaluator [15,22,24,27].

Conclusion

The translated and culturally adapted version of MNSI developed in this study showed a good intra- and interobserver agreement and internal consistency; is reproducible and can therefore be used in clinical practice as screening tool for DPN, to allowing a more effectively electrophysiological examination referral, in order to avoiding diabetic foot complications like ulceration and lower limb amputations.

We do believe however that MNSI questionnaire performance may be improved in future studies, namely eliminating or correcting some subjective terms used by more accurate terms and by introducing temperature in the clinical examination.

In future studies in the Portuguese population it may be interesting to testing the MNSI validity against the gold standard (nerve conduction test), in order to additionally validate this instrument as a diagnose tool has it has been done for outer countries [11,12,15,22,23].

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Conflict of Interest

The authors declare that they have no conflict of interest, including financial and non-financial interests, affiliations or any personal, racial and intellectual properties.

References

1. American Diabetes Association (2018) Classification and Diagnosis of Diabetes: Standards of Medical Care in Diabetes. Diabetes Care, 41 (Suppl 1), S13-27.

2. International Diabetes Federation (2017) IDF Diabetes Atlas, Eighth Edition.

3. Sociedade Portuguesa de Diabetologia (2016). Diabetes: Factos e Números – O Ano de 2015 – Relatório Anual do Observatório Nacional da Diabetes. Lisboa: Sociedade Portuguesa de Diabetologia.

4. American Diabetes Association (2019) Microvascular Complications and Foot Care:Standards of Medical Care in Diabetes. Diabetes Care, 42 (Suppl 1), S124-138.

5. Boulton, AJ., Armstrong, DG., Albert, SF., Frykberg, RG., Hellman, R., Kirkman, MS., et al. (2008) Comprehensive Foot Examination and Risk Assessment. A report of the Task Force of the Foot Care Interest Group of the American Diabetes Association, with endorsement by the American Association of Clinical Endocrinologists. Diabetes Care, 31(8): 1679-1685.

6. Lavery, LA., Armstrong, DG., Boulton, A. (2004) Screening for Diabetic Peripheral Neuropathy. Diabetic Microvascular Complications Today, October: 17-19.

7. Perkins, BA., Bril, V. (2003) Diabetic neuropathy: a review emphasizing diagnostic methods. Clin Neurophysiol, 114(7): 1167-1175.

8. Valk, GD., Sonnaville, JJ., Houton, WH., Heine, RJ., Eijk, JT., Bouter, LM., et al. (1997) The assessment of diabetic polyneuropathy in daily clinical practice: reproducibility and validity of semmesweinstein monofilaments examination and clinical neurological examination. Muscle Nerve, 20(1): 116-118.

9. Tan, LS. (2010) The clinical use of the 10g monofilament and its limitations: A review. Diabetes Res Clin Pract., 90(1): 1-7.

10. Birke, JA., Rolfsen, RJ. (1998) Evaluation of a Self-Administered Sensory Testing Tool to Identify Patients at Risk of Diabetes-Related Foot Problems. Diabetes Care, 21(1): 23-25.

11. Feldman, EL., Brown, MB., Stevens, MJ., Canal, N., Thomas, PK., Greene, DA. (1994) A Practical Two-Step Quantitative Clinical and Electrophysiological Assessment for the Diagnosis and Staging of Diabetic Neuropathy. Diabetes Care, 17(11): 1281-1299.

12. Fedele, D., Comi, G., Coscelli, C., Cucinotta, D., Feldman, EL., Ghirlanda, G., et al. (1997) A Multicenter Study on the Prevalence of Diabetic Neuropathy in Italy. Diabetes Care, 20(5): 836-843.

13. Ugoya, SO., Echejoh, GO., Ugoya, TA., Agaba, EI., Puepet, FH., Ogunniyi, A. (2006) Clinically Diagnosed Diabetic Neuropathy: Frequency, Types and Severity. J Natl Med Assoc, 98(11): 1763-1766.

14. Wu, EQ., Borton, J., Said, G., Le, TK., Monz, B., Rosilio, M., et al. (2007) Estimated prevalence of peripheral neuropathy and associated pain in adults with diabetes in France. Curr Med Res Opin, 23(9): 2035-2042.

15. Herman, WH., Pop-Busui, R., Braffett, BH., Martin, CL., Cleary, PA., Albers, JW., et al. (2012) Use of the Michigan Neuropathy Screening Instrument as a measure of distal symmetrical peripheral neuropathy in Type 1 diabetes: results from the Diabetes Control and Complications Trial/Epidemiology of Diabetes Interventions and Complications. Diabet Med, 29(7): 937-944.

16. Beaton, DE., Bombardier, C., Guillemin, F., Ferraz, MB. (2000) Guidelines for the Process of Cross-Cultural Adaptation of Self-Report Measures. Spine (Phila Pa 1976), 25(24): 3186-3191.

17. Martín Arribas, MC. (2004) Diseño y validación de cuestionarios. MatronasProfesión, 5(17): 23-29.

18. Ferreira, PL., Marques, FB. (1998) AvaliaçãoPsicométrica e Adaptação Cultural e Linguística de Instrumentos de MediçãoemSaúde: PrincípiosMetodológicos Gerais. Universidade de Coimbra.

19. Fortin, MF., José Côté. (2009) Fundamentos e etapas do processo de investigação. Loures: Lusodidacta.

20. Wynd, CA., Schmidt, B., Schaefer, MA. (2003) Two Quantitative Approaches for Estimating Content Validity. Western JNurs Res, 25(5): 508-518.

21. Tres, GS., Lisbôa, HR., Syllos, R., Canani, LH., Gross, JL. (2007) Prevalence and Characteristics of Diabetic Polyneuropathy in Passo Fundo, South of Brazil. Arq Bras de Endocrinol Metab, 51(6): 987-992.

22. Moghtaderi, A., Bakhsipour, A., Rashidi, H. (2006) Validation of Michigan neuropathy screening instrument for diabetic peripheral neuropathy. ClinNeurolNeurosurg, 108(5): 477-481.

23. Mete, T., Aydin, Y., Saka, M., Yavuz, HC., Bilen, S., Yalcin, Y., et al. (2013) Comparison of Efficiencies of Michigan Neuropathy Screening Instrument, Neurothensiometer, and Electromyography for Diagnosis of Diabetic Neuropathy. Int J Endocrinol, doi: 10.1155/2013/821745.

24. Lunetta, M., Moli, RL., Grasso, G., Sangiorgio, L. (1998) A simplified diagnostic test for ambulatory screening of peripheral diabetic neuropathy. Diabetes Res Clin Pract, 39(3): 165-172.

25. Al-Gelferri, M. (2012) Comparison of different screening tests for diagnosis of diabetic peripheral neuropathy in Primary Health Care setting. Int J Health Sci (Qassim), 6(2): 127-134.

26. Boulton, AJM. (2005) Management of Diabetic Peripheral Neuropathy. Clin Diabetes, 23(1): 9-15.

27. Bax, G., Fagherazzi, C., Piarulli, F., Nicolucci, A., Fedele, D. (1996) Reproducibility of Michigan Neuropathy Screening Instrument (MNSI). A comparison with tests using the vibratory and thermal perception thresholds. Diabetes Care, 19(8): 904-905.

28. Smieja, M., Hunt, DL., Edelman, D., Etchells, E., Cornuz, J., Simel, DL. (1999) Clinical Examination for the Detection of Protective Sensation in the Feet of Diabetic Patients. JGen Intern Med, 14(7): 418-424.

29. Taksande, B., Ansari, S., Jaikishan, A., Karwasara, V. (2011) The Diagnostic Sensitivity, Specificity and Reproducibility of the Clinical Physical Examination Signs in Patients of Diabetes Mellitus for Making Diagnosis of Peripheral Neuropathy. J EndocrinolMetab, 1(1): 21-26.

30. Zhao, Z., Ji, L., Zheng, L., Yang, L., Yuan, H., Chen, L., et al. (2016) Effectiveness of clinical alternatives to nerve conduction studies for screening for diabetic distal symmetrical polyneuropathy: A multi-center study. Diabetes Res Clin Pract. 115: 150-156.

31. Edelman, D., Sanders, LJ., Pogach, L. (1998) Reproducibility and Accuracy among Primary Care Providers of Screening Examination for Foot Ulcer Risk among Diabetic Patients. Prev Med, 27(2): 274-278.

32. Miranda-Palma, B., Sosenko, JM., Bowker, JH., Mizel, MS., Boulton, AJ. (2005) A comparison of the monofilament with other testing modalities for foot ulcer susceptibility. Diabetes Res Clin Pract, 70(1): 8-12.