


Translation, validation, and diagnostic accuracy of the Arabic version of the Michigan neuropathy screening instrument

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Abstract

The Michigan Neuropathy Screening Instrument (MNSI) is used to screen patients for diabetic neuropathy (DNP). We aimed to translate the MNSI questionnaire into Arabic (MNSIq-Ar) and to assess the validity and diagnostic performance of the MNSI Arabic version (MNSI-Ar).

Cronbach alpha α and the interclass correlation coefficient were used to measure the reliability and reproducibility of the MNSIq-Ar. The instrument's validity was assessed by Spearman correlation with the Utah Early Neuropathy Scale (UENS), the Modified Toronto Neuropathy Score (mTCNS), diabetic neuropathy symptoms (DNS), and sural nerve amplitude (SNA). The construct validity of the MNSI-Ar was assessed by its ability to differentiate the severity of DNP (using the Kruskal–Wallis test). The diagnostic performance was assessed through the receiver operator curve area.

We recruited 89 participants (mean [SD] age, 50.8 [12.3] years; 48% men). The MNSIq-Ar showed an α of 0.81 and intraclass correlation coefficient = 0.94, and the correlation coefficients with UENS, mTCNS, DNS, and sural nerve amplitude were 0.67, 0.83, 0.73, and -0.49 , respectively (all $P < .0001$). The MNSI-Ar was able to differentiate the different severities of DNP. The receiver operator curve area was 0.93 with a high sensitivity of 95.9% and 100% for probable and confirmed DNP, respectively.

MNSI-Ar is a reliable and valid tool to screen for diabetic neuropathy in the Arabic language with a good diagnostic performance and high sensitivity.

Abbreviations: DM = diabetes mellitus, DNP = diabetic neuropathy, DNS = diabetic neuropathy symptoms, MNSI = Michigan Neuropathy Screening Instrument, Arabic version, MNSIq = Michigan Neuropathy Screening Instrument questionnaire, MNSIq = Michigan Neuropathy screening instrument questionnaire, Arabic version, MP = nerve motor potential, mTCNS = Modified Toronto Neuropathy Score, SNA = sural nerve amplitude, SP = sensory potential, UENS = Utah Early Neuropathy Scale.

Keywords: diabetes, diagnosis, neuropathy, screening, sensitivity

1. Introduction

Peripheral polyneuropathy is a common neurological disease, with a prevalence of 2% to 8%.^[1] Diabetes mellitus (DM) is the most common cause of peripheral neuropathy.^[2,3] The preva-

lence of diabetes in the general population is 12% to 14%.^[4] Diabetes is more prevalent in Arab countries and in the Middle East. For example, in Saudi Arabia, diabetes affects 20% to 30% of the adult population.^[5,6] The prevalence of diabetes is

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increasing worldwide, particularly in Arab countries.^[7] Neuropathy affects 8% of patients with diabetes at the baseline, 42% at 10 years, and 50% at 20 years.^[4,8,9] The cost of diabetic neuropathy care exceeds \$10 billion annually in the United States, and the difference between the health care costs of mild and severe cases may reach 80%.^[3] Early recognition may delay the progression of diabetic neuropathy and reduce the complications of neuropathy.^[10] Hence, several guidelines have recommended annual screening for neuropathy among patients with diabetes.^[11–13] Additionally, therapeutic clinical trials are targeting early neuropathy cases, which make the availability of a valid and reliable screening tool important.^[14] Another important reason for validating a neuropathy screening instrument is that early lifestyle intervention could modify the disease course.^[15]

There are several screening tools for early diabetic neuropathy, and these include the Michigan Neuropathy Screening Instrument (MNSI),^[16] the Utah Early Neuropathy Scale (UENS),^[17] the Toronto Clinical Neuropathy Score (TCNS) and its modified version (mTCNS),^[18] the lower extremity portion of the Neuropathy Impairment Score (NIS-LL), and the Diabetic Neuropathy Symptoms (DNS) Score.^[19] The UENS showed a better profile in diagnosing neuropathy than the NIS-LL and the Michigan Diabetic Neuropathy Scale (MDNS).^[17] The UENS was also found to be a sensitive measure for changes that occurred during a one-year follow up period.^[17] The mTCNS showed the best screening profile among seven other screening/diagnostic tools.^[14] Clinical trials have used these tools as part of outcome assessments.^[20] Monofilament testing is another tool that can be used to screen for diabetic neuropathy; however, a recent meta-analysis found it to be an insensitive screening tool.^[21] The Neuropathic Pain Diagnostic Questionnaire (DN4) is used to diagnose neuropathic pain and has been translated and validated in the Arabic language. However, it is not specific for painful neuropathy and includes various pain localizations, such as radiculopathy, entrapment neuropathy, and cranial neuropathy. In addition, as many patients with neuropathy do not complain of pain, DN4 may miss this group of patients.^[22] Our aim was to translate the MNSI questionnaire into Arabic and to assess the validity and diagnostic performance of the MNSI Arabic version (MNSI-Ar) and describe its sensitivity and specificities as well as its positive and negative predictive values.

2. Methods

2.1. Study design and participants

We conducted a prospective cross-sectional study between June 2018 and February 2020 at King Abdulaziz University Hospital. The institutional review board at the King Abdulaziz University Hospital approved the protocol. All participants provided informed consent. Our inclusion criteria were Arabic language as their first language, the absence of any other neurological diagnosis affecting the sensory and motor system, such as stroke or multiple sclerosis, age ranges between 18 and 75 years, and a history of DM diagnosed by a physician and confirmed by either hemoglobin A1c $\geq 6.5\%$ or the use of hypoglycemic agents. As diabetic neuropathy is associated with longer disease duration and an older age group, we included a small subset of participants without DM who fulfilled criteria 1 and 2 above and who were aged 50 to 75 years. The purpose in including participants in the older age group without diabetes was to ensure that the Arabic version of the MNSI questionnaire was not measuring symptoms

related to age that can be found in persons with no neuropathy. This subset of patients was excluded in a sensitivity analysis (supplementary appendix D, <http://links.lww.com/MD/G464>).

2.2. Translation and cultural adaptation

The author obtained permission from the MNSI owner to translate the MNSI questionnaire (MNSIq). The translation process followed cross-cultural adaptation guidelines.^[23,24] Two neurologists and 1 translator, all fluent in Arabic, independently translated the MNSIq into Arabic (MNSIq-Ar). Consensus was established between the 3 versions, and then the Arabic version was back translated into English independently by 2 persons who speak English as their first language; both of these translations were equivalent to the original MNSIq. The MNSIq-Ar draft was piloted on 10 DM patients, and then the final MNSIq-Ar was produced (supplementary Appendix A, <http://links.lww.com/MD/G461>).

2.3. Data collection

A training session was held for the neurologists and senior neurology residents (physicians who have finished two years of the neurology residency program) to standardize the data collection procedure and examination techniques. Consecutive patients visiting the neurology and endocrinology clinic who fulfilled our criteria were recruited as participants in the study. They were asked to complete the Arabic version of the MNSI questionnaire (MNSIq-Ar). A trained physician blinded to the MNSIq-Ar administered the following: the MNSI examination (MNSIe), the Utah Early Neuropathy Scale (UENS), the modified Toronto Clinical Neuropathy Score (mTCNS), the DNS Score, and 10-g monofilament examinations.^[16,17,19] A blinded, trained electrophysiology technician performed the nerve conduction study (NCS) of bilateral sural and tibial nerves. To check for reproducibility, 49 participants were asked to complete the MNSIq-Ar again 2 weeks after the initial visit.

The patients were classified into diabetic neuropathy versus no neuropathy based on the probable diabetic neuropathy criteria developed by the Toronto diabetic neuropathy expert group for primary analysis; however, the diagnostic performance was evaluated based on the confirmed criteria, in addition to evaluation based on probable criteria.^[25] We used 2 methods to grade the severity of the neuropathy among the diabetic neuropathy patients. The first method was NCS, where grade 1 indicated normal bilateral sural nerve sensory potentials (SP) and tibial nerve motor potentials (MP), grade 2 indicated that the SP amplitude was abnormal (SP < 6 microVolt), and grade 3 indicated that both the SP and MP amplitudes were abnormal (MP < 4 milliVolt). The second method used monofilament testing, where grade 1 indicated normal monofilament sensation (8 correct responses of 8 trials), grade 2 indicated reduced monofilament sensation (1–7 correct responses of 8 trials), and grade 3 indicated absent monofilament sensation.

2.4. Outcomes

We assessed the test reliability and reproducibility of MNSIq-Ar. We looked at the concurrent validity by assessing the correlation between MNSIq-Ar and MNSIe, UENS, mTCNS, DNS, and sural nerve amplitude (SNA). We assessed construct validity by assessing the ability of the MNSI-Ar (MNSIq-Ar + MNSIe) score

to differentiate different grades of severity of diabetic neuropathy according to NCS and monofilament testing. We chose to use MNSI-Ar instead of MNSq-Ar when investigating the ability of the test to differentiate grades of diabetic neuropathy severity as this tool was developed and validated as a single tool (MNSI) rather than MNSIq alone. Additionally, the construct validity was assessed through the diagnostic performance of the MNSIq-Ar and MNSI-Ar, which include the receiver operator characteristic (ROC) area under the curve (AUC) for diagnosing diabetic neuropathy as well as the sensitivity, specificity, and positive and negative predictive values.

2.5. Statistical analysis

The demographic features were described using the mean, standard deviation (SD), and frequencies. The reliability of the MNSIq-Ar was assessed using Cronbach α (>0.8 is sufficient), inter-item correlations, and corrected item-total correlations. Reproducibility was assessed using the intraclass correlation coefficients between the baseline MNSIq-Ar and retests. A Bland-Altman plot was used to assess the absolute agreement between the baseline test and retest. The agreement between each item (test-retest) was assessed with Cohen weighted κ coefficients (>0.7 is sufficient). For concurrent validity correlations, we used Spearman correlation coefficients. For construct validity, we used the Kruskal-Wallis test to compare the different MNSI-Ar scores across different grades of severity with Bonferroni-corrected Mann-Whitney U tests for post hoc pairwise comparison. The diagnostic properties of MNSI-Ar were evaluated through the ROC AUC for diagnosing diabetic neuropathy (ROC area >0.8 is a good performance, whereas >0.9 is an excellent performance). The diagnostic properties of MNSIq-Ar and MNSI-Ar included the sensitivity, specificity, and positive and negative predictive values. Statistical analyses were performed using STATA version 13 (Stata-Corp, College Station, TX).

3. Results

Between June 2018 and February 2020, 89 patients (43 men) participated in the study; 76 were patients with diabetes, and 12 were participants without diabetes. There were 49 patients in the neuropathy group and 40 participants in the non-neuropathy group, with the mean \pm standard deviation ages at 52.9 ± 11.1 and 48.1 ± 13.3 , respectively ($P=.06$); men represented 42.9% and 55% of these 2 groups, respectively ($P=.3$). The mean MNSIq-Ar score was 5.7 ± 1.9 among the neuropathy group and 2.4 ± 2.6 among the non-neuropathy group. Forty-nine patients underwent retesting (30 with neuropathy and 19 with no neuropathy), and 65 patients underwent the nerve conduction study (35 with neuropathy and 30 with no neuropathy).

3.1. Reliability and reproducibility

The internal consistency of the MNSIq-Ar was satisfactory, with a Cronbach α of 0.81, a mean inter-item correlation of 0.19, and an item-total correlation of 0.4 to 0.73 in 10 items; the other 5 items (7, 8, 13, 14, and 15), which describe symptoms typically associated with severe neuropathy, ranged from 0.07 to 0.25 (Table 1). The intraclass correlation coefficient was 0.94 with a 95% confidence interval (CI) (range: 0.9–.97), which suggests excellent reproducibility. The Bland-Altman blot showed satisfactory agreement, with a mean difference of 0.27 and 95% limits (-2.12 to 2.66). (supplementary Appendix B, Figure A-B, <http://links.lww.com/MD/G462>).

3.2. Concurrent and construct validity

The mean scores of the MNSIq-Ar, MNSIe, UENS, mTCNS, and DNS were 4.2 ± 2.8 , 2.7 ± 2.4 , 8 ± 7.96 , 11.4 ± 8.6 , and 1.96 ± 1.48 , respectively. The mean SNA was $9.7 \pm 8.6 \mu\text{V}$. The Spearman correlation coefficients between the MNSIq-Ar and the MNSIe, UENS, mTCNS, DNS, and SNA were 0.58, 0.67,

Table 1
The reliability and stability of the Michigan Neuropathy Screening Instrument (MNSI) questionnaire, Arabic version.

Questions	Reported positive symptom in no neuropathy (n = 40)	Reported positive symptom in neuropathy (n = 49)	P	Corrected item-total correlation	Cronbach α if item deleted	Test-retest weighted κ
1. Are your legs and/or feet numb?	27.5%	89.8%	.00	0.725	0.771	0.91
2. Do you ever have any burning pain in your legs and/or feet?	37.5%	71.4%	.00	0.474	0.793	0.70
3. Are your feet too sensitive to touch?	15%	28.6%	.13	0.422	0.797	0.51
4. Do you get muscle cramps in your legs and/or feet?	45.0%	75.5%	.00	0.466	0.794	0.78
5. Do you ever have any prickling feelings in your legs or feet?	35%	79.6%	.00	0.705	0.773	0.91
6. Does it hurt when the bed covers touch your skin?	12.5%	34.7%	.02	0.498	0.792	0.70
7. When you get into the tub or shower, are you able to tell the hot water from the cold water?	5%	18.4%	.06	0.251	0.807	0.9
8. Have you ever had an open sore on your foot?	5%	8.2%	.55	0.121	0.812	0.65
9. Has your doctor ever told you that you have diabetic neuropathy?	7.5%	42.9%	.00	0.4	0.799	0.60
10. Do you feel weak all over most of the time?	35%	77.6%	.00	0.553	0.786	0.69
11. Are your symptoms worse at night?	25%	69.4%	.00	0.471	0.793	0.80
12. Do your legs hurt when you walk?	35%	79.6%	.00	0.603	0.782	0.78
13. Are you able to sense your feet when you walk?	5%	12.2%	.24	0.076	0.815	-0.03
14. Is the skin on your feet so dry that it cracks open?	27.5%	32.7%	.6	0.135	0.819	0.66
15. Have you ever had an amputation?	0.0%	4.1%	.20	0.096	0.812	1.00

0.83, 0.73, and -0.49 , respectively (all $P < .0001$) (supplementary Appendix B, Figure C-G, <http://links.lww.com/MD/G462>). Among the diabetic neuropathy group, the MNSI-Ar score differentiated between grades of severities stratified by NCS ($P = .005$) and monofilaments ($P < .0001$), Table 2. For pairwise comparison, the MNSI-Ar score differentiated between Grades 1 and 3 stratified by both NCS and monofilament ($P < .01$, $P < .01$, Bonferroni corrected). The MNSI-Ar differentiated between Grades 1 and 2 stratified by monofilament ($P = .006$, Bonferroni corrected). The MNSI-Ar did not differentiate between grades 2 and 3 stratified by NCS or monofilament.

3.3. Diagnostic performance

The diagnostic performance of the MNSI-Ar supported its construct validity (outlined in detail in the supplementary Appendix C, <http://links.lww.com/MD/G463>). Based on the probable neuropathy criteria, the ROC AUC was excellent at 0.93 (95% CI 0.86–0.97) (supplementary Appendix C, Figure H, <http://links.lww.com/MD/G463>). However, as MNSI-Ar is primarily a screening tool, a cut-off with higher sensitivity would likely be more appropriate, such as ≥ 4 , which had a 95.9% sensitivity and 62.5% specificity as shown in Table 3. Based on the confirmed neuropathy criteria, the ROC AUC was excellent at 0.91 (95% confidence interval 0.81–0.97).

4. Discussion

Clinical practice and clinical trials use standard tools for screening, diagnosis, and outcome measurement which, in many instances, are patient-reported measures. As diabetic neuropathy is highly prevalent and annual screening is recommended, it is important to make a screening tool available in many languages, including Arabic. The usefulness of these tools is inherited from its validity. Several previous reports showed appropriate validity of the original MNSI.^[26,27] Hence, some clinical trials have incorporated MNSI in the case definition of diabetic neuropathy.^[28,29] In the original MNSI study, many patients with no diabetic neuropathy answered positively to questions in the MNSIq.^[16] This highlights the importance of validating the MNSIq. In this study, we found that the MNSI-Ar had a

satisfactory reliability and validity for use as a screening tool for diabetic neuropathy.

The MNSIq-Ar demonstrated satisfactory reliability overall; however, certain questions did not contribute to its reliability. Five questions (7, 8, 13, 14, and 15) showed low item–total correlation. These items describe symptoms that are more prevalent in advanced neuropathy. The item–total correlation was also low (< 0.4) for these 5 questions in a previous validation study in another language.^[30] Question 13 “Are you able to sense your feet when you walk?”—showed low item–total correlation and low reproducibility. A previous study that derived data from a randomized trial showed that the prevalence of positive answers to this item was 10% among patients with diabetes without neuropathy and 12% among diabetic neuropathy patients, which is similar to the prevalence in our study as shown in Table 1.^[27] Omitting this question did not alter the diagnostic performance of the test, which is likely due to the low prevalence of this symptom among neuropathic patients. Each item’s reproducibility was not examined in all previous validation and translation studies.^[26,30–32] However, in our study, all the items had satisfactory reproducibility except for Q13. The measures of the test’s overall reliability and reproducibility in our study were comparable to the test’s previous validation in other languages.^[30–32]

The MNSIq-Ar showed good concurrent validity with a strong correlation with other neuropathy screening tools. Of the tools we used, 2 (UENS and mTCNS) have been shown to have the highest AUC compared to other scales at 0.88 to 0.94 for UENS and 0.99 for mTCNS.^[14,17] The AUC reported for UENS and mTCNS were examined against criteria that used NCSs, epidermal nerve fiber densities, and the quantitative sudomotor axon reflex.^[14,17] The MNSI-Ar correlation with UENS and mTCNS along with the correlation with NCSs and the ability to differentiate different grades of NCSs neuropathy severity adds to the collective evidence suggestive of MNSI-Ar validity.

There is no criterion standard method to diagnose distal neuropathy, including diabetic neuropathy. Therefore, validity in our study was measured using three different methods with two or more different approaches for each method. We assessed the diagnostic performance and, specifically, the ROC AUC as one of the methods of evaluating validity. To classify the patients into

Table 2
The MNSI Arabic scores categorized according to the nerve conduction study and monofilament tests (only patients with neuropathy included).

Test to Classify the Neuropathy Severity Grades	Neuropathy Severity Grades	n (%)	MNSI-Ar	
			Mean (SD)	Median (IQR)
Nerve conduction study	Normal	13 (37.1)	7.9 (4.2)	8 (5–11)
	Sensory abnormalities only	13 (37.1)	10.8 (2.6)	10 (9.5–13)
	Sensory and motor abnormalities	9 (25.7)	13.2 (1.9)	14 (12–14)
Monofilaments	Normal	16 (32.7)	7.2 (3.3)	7.5 (5.5–9.5)
	Reduced	22 (44.9)	10.9 (2.5)	11 (9–13)
	Absent	11 (22.5)	12.5 (2.6)	14 (10–14)

IQR = interquartile range, MNSI-Ar = Michigan neuropathy screening instrument-Arabic version, SD = standard deviation.

* $P \leq .001$ for comparisons between MNSI-Ar scores between normal NCS versus sensory and motor abnormalities. (Bonferroni corrected). There was no difference in MNSI-Ar scores between sensory abnormalities and sensory and motor abnormalities or normal versus sensory abnormalities. (Bonferroni corrected).

** $P \leq .006$ for comparisons between MNSI-Ar scores between normal versus reduced and versus absent. (Bonferroni corrected). There was no difference in the MNSI-Ar scores between reduced versus absent.

Table 3**The sensitivity, specificity and predictive values of the MNSI-Ar and MNSIq-Ar.**

Cut-off	PCC	Sensitivity (95% CI)	Specificity (95% CI)	PPV (95% CI)	NPV (95% CI)
MNSI-Ar					
Probable diabetic neuropathy criteria ≥4	80.9%	95.9% (86%–99.5%)	62.5% (45.8%–77.3%)	75.8% (63.3%–85.8%)	92.6% (75.7%–99.1%)
Confirmed diabetic neuropathy criteria ≥6	75.4%	100% (83.9%–100%)	63.6% (47.8%–77.6%)	56.8% (39.5%–72.9%)	100% (87.7%–100%)
MNSIq-Ar					
Probable diabetic neuropathy criteria ≥3	80.9%	93.9% (83.1%–98.7%)	65% (48.3%–79.4%)	76.7% (64%–86.6%)	89.7% (72.6%–97.8%)
Confirmed diabetic neuropathy criteria ≥4	70.8%	95.2% (76.2%–99.9%)	59.1% (43.2%–73.7%)	52.6% (35.8%–69%)	96.3% (81%–99.9%)

CI=confidence interval, MNSI-Ar=Michigan neuropathy screening instrument-Arabic version, MNSIq-Ar=Michigan neuropathy screening instrument questionnaire-Arabic version, NPV=negative predictive value, PCC=percentage correctly classified, PPV=positive predictive value.

the neuropathy and no neuropathy groups, we used two different diabetic neuropathy diagnosis criteria: probable criteria and definite criteria.^{12,51} We chose to include probable criteria in the analysis as many patients with diabetic neuropathy have normal NCS.¹³¹ The AUCs were stable using these 2 different criteria and were consistent with the previously reported AUC.^{126,321}

Our study has several limitations. We did not include other objective measures for neuropathy, such as epidermal nerve fiber densities and quantitative sudomotor axon reflex; however, the MNSIq-Ar showed a good correlation with NCS parameters. The absence of a gold standard test to diagnose diabetic neuropathy is a major limitation in all similar studies. Also, we did not correlate the MNSI-Ar with other outcomes, such as falls, foot ulcers, and amputation. The sensitivity of the MNSI-Ar to change was not explored because the pain may take a long time to improve, and the main use of the instrument is as a screening rather than an outcome assessment tool. In conclusion, the MNSI-Ar was shown to be a reliable and valid screening tool for diabetic neuropathy in Arabic-speaking patients. The diagnostic performance suggests that it is appropriate to use it as a screening tool.

Author contributions

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