Predictive model to identify the risk of losing protective sensibility of the foot in patients with diabetes mellitus

Esther Chicharro-Luna 1; Francisco José Pomares-Gómez 2; Ana Belen Ortega-Avila 3; Ana Marchena-Rodriguez 3; José Francisco Javier Blanquer-Gregori 4; Enmanuel Navarro-Flores 5.

1Department of Behavioral Sciences and Health, Nursing Area, Faculty of Medicine, University Miguel Hernández, San Juan de Alicante, Spain
2Endocrinology and Nutrition, University Hospital San juan de Alicante, Spain
3Department of Nursing and Podiatry, Faculty of Health Sciences, University of Malaga, Malaga, Spain
4San Blas Health Center, Departament of Physiology, Faculty of Medicine, University Miguel Hernández, San Juan de Alicante, Spain
5Department of Nursing, Faculty of Nursing and Podiatry, Frailty Research Organized Group, Universidad de Valencia, Valencia, Spain

Correspondence
Emmanuel Navarro-Flores, PhD, Department of Nursing, Faculty of Nursing and Podiatry, Frailty Research Organized Group, Universidad de Valencia, Valencia 46010, Spain.
Email: emmanuel.navarro@uv.es

Abstract

Diabetic neuropathy is defined as the presence of symptoms and signs of peripheral nerve dysfunction in diabetics. The aim of this study is to develop a predictive logistic model to identify the risk of losing protective sensitivity in the foot. This descriptive cross-sectional study included 111 patients diagnosed with diabetes mellitus. Participants completed a questionnaire designed to evaluate neuropathic symptoms, and multivariate analysis was subsequently performed to identify an optimal predictive model. The explanatory capacity was evaluated by calculating the R^2 coefficient of Nagelkerke. Predictive capac- ity was evaluated by calculating sensitivity, specificity, and estimation of the area under the receiver operational curve. Protective sensitivity loss was detected in 19.1% of participants. Variables associated by multivariate analysis were: educational level (OR: 31.4, 95% CI: 2.5-383.3, P = .007) and two items from the questionnaire: one related to bleeding and wet socks (OR: 28.3, 95% CI: 3.7-215.9, P = .001) and the other related to electrical sensations (OR: 52.9, 95% CI: 4.3-643.9, P = .002), which were both statistically significant. The pre- dictive model included the variables of age, sex, duration of diabetes, and edu- cational level, and it had a sensitivity of 81.3% and a specificity of 95.5%. This model has a high predictive capacity to identify patients at risk of developing sensory neuropathy.

KEYWOR DS

Diabetic foot, Diabetic neuropathy, Mellitus Diabetes, Predictive models.

1 | INTRODUCTION

Diabetic neuropathy is defined as the presence of signs and symptoms of peripheral nerve dysfunction in dia- betics.[1] It is directly related to the length of the disease, poor metabolic control,[2-5] size, dyslipidemia, blood pres- sure (BP), weight, and glucose intolerance.[6] It affects 60% to 65% of patients with diabetes, with over half of casesbeing asymptomatic; therefore, the International Diabetes Federation[7] and the American Diabetes Association (ADA)[8] recommend screening for polyneuropathy (PN) using clinical tests, either at the time of diagnosis of type 2 diabetes mellitus (DM2), or 5 years after diagnosis of type 1 diabetes mellitus (DM1); subsequent screening should be performed at least annually. The 20% of patients with neuropathy will develop an ulcer in the foot, progressing in many cases to an amputation due the pres- ence of peripheral vascular disease. These complications affect the mobility of the individual and therefore their quality of life.

Sensory neuropathy is associated with hypoesthesia or anaesthesia in 50% to 70% of patients, which often remain unnoticed because only 10% to 20% of patients find neuropathic pain,[9] defaulting the diagnostic. For this reason, ADA recommends exploring the pressure sensi- tivity with a 10 g monofilament, the vibratory sensitivity with a 128-Hz tuning fork, and the pain sensitivity with a pinprick.[8,10] Monofilament is considered by many authors[11] as the gold standard for screening,[11,12] although other authors use a tuning fork to garner greater predic- tive value and sensitivity.[10,11,13] The most recommended combination is the assessment of pressure sensitivity (monofilament) and vibration (biotensiometer)[14-16] as it improves the reliability of the results and better predicts the appearance of ulcers. The objective of this study was to develop a predictive model with clinical variables to identify patients with a high risk of developing sensory neuropathy. The hypothesis in this research was: it is possible to design a predictive model of loss of protective sensitivity in diabetic foot.

2 | METHODS

A cross-sectional observational study of 111 patients was performed.

Inclusion criteria comprised diagnosis of DM1 or DM2 (without cognitive or visual impairment).

Exclusion criteria comprised patients who were preg- nant or who had an alcohol dependency, a vitamin B12 deficiency, hypothyroidism, or both feet amputated.

The study was approved by the Clinical Research Ethics Committee (CEIC 13/305) with date of 2 May 2013 at University Miguel Hernández of Elche. The informed consent of all subjects was obtained before starting the study and also adhered to the ethical stan- dards of the Declaration of Helsinki.[17] Strobe guidelines declaration were completed.[18]

Sociodemographic variables, type of diabetes, disease duration, and lifestyles (smoking, diet, and physical activ- ity) were collected through their history.

Blood glucose, glycosylated haemoglobin, triglycerides, total cholesterol, high-density lipoprotein cholesterol, low- density lipoprotein cholesterol, creatinine, and glomerular filtration rate were assessed. Weight, height, body mass index (BMI), and BP were recorded in adherence to the rec- ommendations of the American Heart Association,[18] as well as comorbidities and complications derived from diabetes. For peripheral vascular evaluation, the presence of pallor,

coldness, and the existence of pain in the back of the calf was investigated during ambulation to assess for possible intermittent claudication. Subsequently, the presence of posterior tibial pulse and pedium was recorded on both feet, and the ankle-arm index was determined using a Hadeco bidirectional Smartdop 45 Doppler probe; these were accomplished following the recommendations of various studies on vascular pathology.[19-22]

As a limitation, patients were selected by consecutive sampling in endocrinology service, and may be a non- representative sample.

A questionnaire was designed to assess positive and negative neuropathic signs and symptoms. Using existing neuropathic screening questionnaires,[23-33] a panel of experts (comprising an endocrinology specialist, a family and community medicine specialist, and three podia- trists, all of whom have over 10 years of experience in the treatment of diabetic patients) proposed a total of 64 items related to different types of neuropathy (i.e., sensory, motor, and autonomic); of these, 57 items were included in the final questionnaire.

3 | RESULTS

3.1 | Prevalence of sensory neuropathy

Table 1 describes patient demographics and characteris- tics. Regarding the exploration with Semmes-Weinstein monofilament, reduced sensitivity in

both feet was found in 18.8% of participants (15.3% in the right foot; 14.4% in the left foot). The foot areas most affected were the first toe (18% altered in the right and 18.9% in the left), the third toe (19.8% in right foot; 18.9% in left foot), and the fifth toe (15.3% in right foot; 17.1% in left foot; Table 2).

TABLE 1 Characteristics of the patients

Variable	Subjects (n = 111)
Male/female (n [%])	73 (65.8)/38 (34.2)
Mean age ± *dt* (years) (95%)	57.92 ± 13.24 (95% CI 55.45 to 60.38)
DM duration mean ± *dt* (years) (95% CI)	17.59 ± 10.70 (95% CI 15.59 to 19.59)
DM Type 1/Type 2 (no [%])	34 (30.6)/77 (69.4)
Education (no education/primary/vocational studies degree-training/university) (no [%])	1 (0.9)/33 (29.7)/45 (40.5)/32 (28.8)
Marital status (single/married/separated-single/widowed/other) (No [%])	9 (8.1)/82 (73.9)/14 (12.6)/5 (4.5)/1 (0.9)
Obesity (mean ± SD) (BMI > 30 kg/m^2)	53 (47.7)
TAS mean ± SD (mm Hg) (95%)	139.18 ± 16.87 (95% CI 136.04 to 142.31)
TAD mean ± SD (mm Hg) (95%)	73.63 ± 10.49 (95% CI 71.67 to 75.58)
Index altered ankle arm (<1 or >1.3)	39 (35.5)
Sedentarism (No [%])	19 (17.1)
Smoker (n [%])	17 (15.3)
Fasting glucose > 126 mg/dl (n [%])	78 (70.3)
HbA1c > 7% (n [%])	67 (60.9)
Triglycerides > 150 mg/dl (n [%])	26 (24.1)
HDL (women < 50 mg/dl; men < 40 mg/dl) (n [%])	31 (28.7)
LDL cholesterol > 100 mg/dl (n [%])	37 (34.3)
Total cholesterol > 250 mg/dl (n [%])	17 (15.7)
Creatinine (women > 1.1 mg/dL men and >1.3 mg/dl) (n [%])	22 (20)
Index microalbumin/creatinine > 30 mg/dl (n [%])	13 (14.9)
Glomerular filtration rate < 60 mL/min (n [%])	13 (12.3)
Ischemic heart disease (n [%])	20 (18)
Nephropathy (no [%])	15 (13.6)
Retinopathy (no [%])	45 (41.3)

Note: No. (%) for qualitative variables; mean ± SD for quantitative variables.
Abbreviations: BMI, body mass index; DM, diabetes mellitus; HbA1c, glycosylated haemoglobin; HDL, high-density lipoprotein; LDL, low-density lipoprotein; TAD, diastolic blood pressure; TAS, systolic blood pressure.

TABLE 2 Clinical examination of sensory neuropathy with Semmes-

Weinstein monofilament and pinprick

Place explored	Semmes-Weinstein monofilaments (pressure)		Pinprick (pain)	
	Right foot n (%) patients affected area	Left foot n (%) patients affected area	Right foot n (%) patients affected area	Left foot n (%) patients affected area
First plantar toe	20 (18)	21 (18.9)	14 (12.8)	14 (12.8)
Third toe plantar	22 (19.8)	21 (18.9)	18 (16.5)	18 (16.5)
Fifth toe plantar	17 (15.3)	19 (17.1)	15 (13.8)	12 (11)
First metatarsal head	14 (12.6)	11 (9.9)	10 (9.1)	8 (7.3)
Third metatarsal head	13 (11.7)	10 (9)	10 (9.1)	7 (6.4)
Fifth metatarsal head	16 (14.4)	15 (13.5)	15 (13.6)	12 (10.9)
Arc	6 (5.4)	6 (5.4)	3 (2.7)	3 (2.7)
Zonal latero-plantar midfoot	11 (9.9)	8 (7.2)	9 (7.7)	6 (5.5)
Plantar heel	14 (12.6)	13 (11.7)	12 (10.9)	8 (7.3)
Interdigital space (dorsal)	7 (6.4)	8 (7.3)	8 (7.3)	8 (7.3)

With respect to vibrational sensitivity, the average value of the Rydel-Seiffer graduated tuning fork on the first toe was 4.16 ± 2.33 (95% CI: 3.73-4.60) on the right foot and 4.27 ± 2.09 (95% CI: 3.87-4.66) on the left foot. By averaging all the joints examined, the results in 65.8% of participants were indicative of pathology. When assessing sensitivity to pain with a pinprick over 11 areas, there was evidence of neuropathy alteration in 15.5% of cases. On the dorsum of the first toe at the level of the nail fold, pain sensitivity was pathological in both feet in 10.9% of participants (Table 2). Finally, at least two cases of altered points of sensitivities (19.1% of participants) presented sensory involvement.

3.2 | Identification of associated variables

The questionnaire revealed, via bivariate analysis, 18 vari- ables that were significantly associated with the presence of sensory neuropathy (Table 3). In the simple adjust- ment of the variables included in the history, none of them were significant. Table 4 describes the main results obtained in the multivariate logistic model for the identifica- tion of variables associated with the risk of loss of protective sensation in the foot. This logistic model comprises item 15 (Have you had a wound on your foot and noticed when your socks were stained with blood?) and item 6 (During the last 3 months, have you experienced a pins-and-needles feeling in your feet or legs?), and—as

explanatory variables—age, sex, duration of diabetes, and level of education. Of these variables, lower educational level was found to increase the risk of presenting sensory neuropathy (OR: 31.4, 95% CI: 2.5-383.3, *P* = .007). The model explains the presence of neuropathy alteration in 67.8% of patients with sensory neuropathy, with a sensitivity of 81.3% and a them were significant. Table 4 describes the main results obtained in the multivariate logistic model for the identifica- tion of variables associated with the risk of loss of protective sensation in the foot. This logistic model comprises item 15 (Have you had a wound on your foot and noticed when your socks were stained with blood?) and item 6 (During the last 3 months, have you experienced a pins-and-needles feeling in your feet or legs?), and—as explanatory variables—age, sex, duration of diabetes, and level of education. Of these variables, lower educational level was found to increase the risk of presenting sensory neuropathy (OR: 31.4, 95% CI: 2.5-383.3, *P* = .007). The model explains the presence of neuropathy alteration in 67.8% of patients with sensory neuropathy, with a sensitivity of 81.3% and a specificity of 95.5%. Figure 1 describes the receiver opera- tional curve (ROC), with a predictive capacity with an area under the ROC curve of 0.957 (0.911-0.999).

TABLE 3 Survey questions associated in the bivariate loss of protective sensation foot, ordered by significance analysis

Question	OR	IC95%	*P*-value*
Question 15 Have you had a wound in the foot and has realised when he saw blood-stained socks?	9.2	(3.0 to 28.3)	<.001
Question 6 Do you ever feel in your feet or legs like you have needles?	6.7	(2.3 to 19.5)	<.001
Question 24 Does any of the 2 feet flatter than before?	11.2	(2.5 to 49.7)	.001
Question 11 Do you have pain or unpleasant sensations when your feet touch?	5.8	(2.0 to 16.7)	.001
Question 2 Do you ever feel in your feet or legs pain rubbing the sheets?	5.5	(2.0 to 15.1)	.001
Question 4 Do you ever feel in your feet or legs are numb, quilts or sleeping?	7.3	(2.0 to 26.7)	.002
Question 27 You have made him one of the two red, hot or swollen feet without pain and without prior stroke?	5.0	(1.8 to 13.8)	.002
Question 16 Do you feel that you lose your balance and fall because you can feel that you fail your feet?	4.8	(1.7 to 13.4)	.002
Question 9 Do you ever feel in your feet or legs as if he does not wear socks when?	4.3	(1.5 to 12.3)	.006
Question 13 You have burned feet for not having noticed the temperature?	20.7	(2.2 to 196.8)	.008
Question 5 Do you ever feel in your feet or legs as if he were power?	3.6	(1.3 to 9.6)	.010
Question 14 Do you notice when shoe pinches or rubs somewhere in the foot?	3.7	(1.3 to 10.3)	.013
Question 19 Do you notice red hot or feet?	3.6	(1.3 to 9.7)	.011
Question 12 Are you able to tell if the water is hot or cold when your feet wet?	3.9	(1.3 to 12.1)	.016
Question 26 Have you done any of the two shorter and wider than before feet?	5.2	(1.3 to 20.0)	.017
Question 3 Do you ever feel in your feet or legs itching or tingling?	4.5	(1.2 to 16.3)	.023
Question 18 Do you have fissures or cracks on your feet?	3.0	(1.1 to 8.0)	.027
Question 37 Enough Suda in the head or chest after meals?	2.9	(1.1 to 8.0)	.037

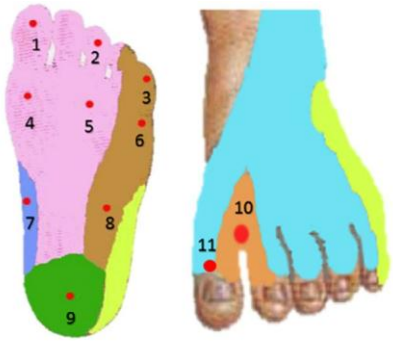
Note: Statistical significance $P < .05$.

Abbreviations: CI, confidence interval; OR: odds ratio.

TABLE 4 Predictive model of risk of loss of protective sensation of the foot (multivariate analysis)

Sensory impairment		Multivariate model				
		B	error	OR	CI 95%	***P*-value**
Question 15	Never	0		one		
	If, once or frequently	3344	1.0	28.3	(3.7 to 15.9)	.001
Question 6	Never	0		one		
	If, once or frequently	3969	1.3	52.9	(4.3 to 43.9)	.002
Age	<50 years	0		one		
	50-65 years	1367	1.4	3.9	(0.3 to 59.8)	.326
	>65 years	1186	1.6	3.2	(0.2 to 69.3)	.446
Sex	Woman	0		one		
	Man	2085	1.4	8.0	(0.5 to 124.8)	.136
Years evolution diabetes	0-10 years	0		one		
	From 11 to 20 years	0.114	1.2	1.1	(0.1 to 12.8)	.927
	From 21 to 30 years	0.833	1.2	2.3	(0.2 to 23.1)	.479
	≥31 years	2322	1.4	10.2	(0.7 to 51.1)	.091
level studies	Media-university	0		one		
	Uneducated-primary	3448	1.3	31.4	(2.5 to 83.3)	.007
Cte		−10.217	3.0			.001

Note: Bold values are statistical significance $P < .05$. Question 15: Have you had a wound in the foot and has realised when he saw bloodstained socks? Question 6: Do you ever feel in your feet or legs like you have needles?
Abbreviations: CI, confidence interval; OR: odds ratio.



Pinprick sensation reduced/ absent n (%)											
	1	2	3	4	5	6	7	8	9	10	11
Right	14 (12.8)	18 (16.5)	15 (13.8)	10 (9.1)	10 (9.1)	15 (13.6)	3 (2.7)	9 (7.7)	12 (10.9)	8 (7.3)	9 (8.3)
Left	14 (12.8)	18 (16.5)	12 (11)	8 (7.3)	7 (6.4)	12 (10.9)	3 (2.7)	6 (5.5)	8 (7.3)	8 (7.3)	9 (8.3)

Figure 1. Assessment of pinprick sensation

4 | DISCUSSION

The early detection of this form of neuropathy by simple screening could prevent significant complications. The study of nerve conduction uses an accurate, objective, and sensitive test to assess peripheral neuropathy and its progression,[34] but it remains rarely used in clinical practice because of its low availability in primary care centres and high implementation costs. Screening per- formed in primary care centres is currently unsatisfac- tory in frequency; therefore, the risk of each patient remains unstratified. Only 39.5% of patients with DM2 have ever been screened in consultation with monofila- ment, and one-third of patients with diabetes and severe peripheral neuropathy have not been diagnosed by their primary care physician.[35] In this sense, the use of pre- dictive logistic models can be an adequate, simple, and rapid tool to predict the risk of developing neuropathy and determine which patients require a more in-depth diagnostic procedure with additional, non-traditional diagnostic tests.

These models, which are increasingly popular in clinical research, can be defined as mathematical tools that assess the risk of experiencing an adverse outcome based on the patient's clinical profile.[36] In most cases, they are suitable for use in both the incidence of events and the identification of risk factors associated with a particular event or compli- cation. Olaye's diagnostic statistical model of peripheral neuropathy[16] is based on exploration with monofilament and pinprick, including risk factors such as the severity of neuropathy, family history of diabetes, disease duration, age, height, sex, and HbA1c. Weinberg[36] et al established a predictive model of symptomatic neuropathy, only includ- ing as variables frequency heart rate, disease duration, and measurement of respiratory sinus arrhythmia.[37]

Our model is based on the clinical presentation of the patient, which was determined using two questions, and on explanatory variables or risk factors collected in their history (age, sex, duration of disease, and level of education), allowing a more nuanced approach to neuropathy screening using a simple questionnaire. It does not require obtaining variables on the day of clinical presentation; therefore, it is a simple, fast, and accessible tool for all healthcare professionals. Of all the variables included in the model, we observed that “low educational level” increases the risk of losing protective sensitivity (OR: 31.4, 95% CI: 2.5-383.3, P = .007); however, the confidence interval is quite high, so the risk—although present—may be overestimated by the sample size. Those with a lower level of education typically have poorer health habits, causing increased obesity, physical inactivity, and

suscepti- bility to psychosocial risks, which increases the risk of suf- fering from neuropathy.[38-42] Therefore, it is important to establish preventative programs aimed at less educated populations to reduce the prevalence of PN.

5 | CONCLUSION

The model obtained has a high explanatory and predictive capacity to identify patients at risk of presenting dis- tal sensory PN. The prediction is obtained through two simple and variable questions collected in the history, so it can be very useful for clinical practice among different professionals. Its implementation would help to stratify the risk of developing this type of neuropathy and thereby reduce the incidence of foot complications.

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Key Messages

- Prevalence of sensory peripheral neuropathy is 19.1%
- Using a simple model, the risk of losing of protective foot sensibility can be

predicted with a sensitivity of 81.3% and a specificity of 95.5%

- Sociodemographic data can predict the risk of losing of protective foot sensation