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ORIGINAL ARTICLE

Early diagnosis of diabetic neuropathy and prophylaxis of diabetic foot

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Abstract

Introduction: the diabetic foot is one of the most serious complications of diabetes mellitus. About 50% of non-traumatic amputations occur in these patients. In addition, it is an important public health problem and constitutes a chronic and complex metabolic disorder that is characterized by impaired metabolism of glucose and other complications in essential organs for the maintenance of life.

Objective: to evaluate the sensitivity and specificity of diabetic neuropathy using the Michigan self-assessment and physical examination in type 1 and type 2 diabetics.

Methods: this is a cross-sectional study. The "Michigan Neuropathy Screening Instruments" classification was used to assess the degree of peripheral neuropathy, in which participants answered the questionnaire and were evaluated for the presence of foot lesions. All participants were stratified by the risk of developing foot ulcers according to the IWGDF protocol.

Results: the sample had 200 participants. Regarding the IWGDF classification, 23 patients were classified as moderate risk (11.50%) and 61 as high risk for developing foot ulcers (30.50%). Using a cutoff of 2.5 on the physical examination score to diagnose neuropathy, a sensitivity of 97.62% and a specificity of 47.41% were obtained. Using a score greater than or equal to 6 in the self-assessment for the diagnosis of neuropathy, a sensitivity of 50.00% and a specificity of 94.83% were found.

Conclusion: the association of the Michigan physical examination (high sensitivity) with self-assessment (high specificity) increases the accuracy for the diagnosis of diabetic neuropathy.

Keywords: diabetes mellitus, diabetic neuropathy, diabetic angiopathy, diabetic vascular diseases, diabetic feet, neuropathy.

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Authors summary

Why was this study done?
This study was done to evaluate the sensitivity and specificity of diabetic neuropathy using the Michigan self-assessment and physical examination in diabetics and, consequently, prevent the formation of foot lesions.

What did the researchers do and find?
In our cross-sectional study, the "Michigan Neuropathy Screening Instruments" classification was used to evaluate the degree of peripheral neuropathy, in which the participants answered the questionnaire and were evaluated by the presence or not of lesions on the feet, the protective sensitivity was evaluate with the 10 g monofilament, the vibratory sensitivity with the 128 Hz tuning fork and the presence or not of the Achilles reflex with the neurological hammer. All participants were stratified for the risk of developing foot ulcers according to the IWGDF protocol.

What do these findings mean?
When we combine the Michigan physical examination (high sensitivity) with self-assessment (high specificity), the accuracy is high, making these tests important predictors of diabetic neuropathy.

Highlights
Physical examination in Michigan, using a cutoff point greater than or equal to 2.5, we obtained a test with high sensitivity (97.62%)
Michigan self-assessment, using a cutoff point for the diagnosis of neuropathy greater than or equal to 6, we obtained a test with high specificity (94.83%).
We conclude that the association of self-assessment with the Michigan physical examination increases the accuracy of the diagnosis of neuropathy.

INTRODUCTION

The description of the nature of diabetic neuropathy and its relationship with diabetes mellitus was made in 1864 by Marchal de Calvi, in 1905 Williamson described the physiological measures for the evaluation of diabetic neuropathy and, in the same century, important studies related to the subject appeared[1].

Diabetic neuropathy can be defined as the presence of signs and/or symptoms of peripheral nerve dysfunction in diabetic patients after excluding other causes[2]. It is one of the most frequent microvascular complications of diabetes[3], with an estimated prevalence of 50% of diabetics, and 20% can be already present on the time of diagnosis of diabetes[2]. Its early diagnosis allows the prevention of foot ulcer formation and, consequently, decreases the rate of amputation in diabetics[4].

The gold standard for the diagnosis of neuropathy is the test that evaluates nerve conduction velocity (NCV)[2]. In addition, questionnaires were created that serve as a screening tool for its diagnosis.

The Michigan Neuropathy Screening Instrument (MNSI) is the most commonly used screening instrument. It consists of a 15-item questionnaire about sensory changes with "yes" or "no" answers. The second part of the questionnaire consists of 5 items regarding the inspection of the feet (presence of calluses, infection, ulceration, deformities or fissures) and the neurological examination: evaluation of the vibratory sensitivity with the 128Hz tuning fork, of the Achilles reflex and tactile sensitivity with the 10g monofilament[3].

The "American Diabetes Association" recommends screening for diabetic neuropathy at the time of diagnosis and annually in type 2 diabetics or in type 1 diabetics for more than 5 years[3].

A recent guideline, "IWGDF (International Working Group on Diabetic Foot) guidelines on the prevention and management of diabetic foot disease" was published in 2019 and aims to prevent and manage diabetic foot, and, consequently, improve foot care on diabetics[5].

To reduce costs for both the patient and his family and the health system, in addition to the integration of the multidisciplinary team, we chose to study diabetic neuropathy based on the classification of the "Michigan Neuropathy Screening Instruments", performing the tests with the tuning fork, with the 10g monofilament fiber and evaluating the Achilles reflex with the hammer, in order to diagnose the degree of diabetic neuropathy and, consequently, prevent the appearance of foot ulcers[5].

The aim of this study is to evaluate the sensitivity and specificity for diabetic neuropathy of the Michigan self-assessment and physical examination in type 1 and 2 diabetics, as well as prevent the formation of foot lesions.

METHODS

Study design

Cross-sectional study.

Study location and period

This study was carried out in the outpatient clinics of the "Centro Universitário FMABC", from May 2021 to June 2022, with the recruitment of diabetic patients.

Study population and eligibility criteria

200 patients answered the Michigan questionnaire (Michigan Neuropathy Screening Instrument) and underwent physical examination according to this protocol. As eligibility criteria, patients diagnosed with type 1 or type 2 diabetes mellitus were included; they authorized participation in the study signing the TCLE; over the age of 18, both sexes. Patients with cognitive deficits or psychiatric disorders; who refused to sign the TCLE and with age below 18 years were excluded.

Data collection

The participants answered the Michigan questionnaire (Michigan Neuropathy Screening Instrument: it is already validated in Brazil[6]) and were analyzed for the presence of neuropathy by assessing the presence of deformities in the feet, the presence of ulcers,

an evaluation of sensitivity protection through the 10g monofilament, as for the vibratory sensitivity with the 128Hz tuning fork and the Achilles reflex.

The 10g monofilament test was performed with patients with their eyes closed in dorsal decubitus, and it was positioned on the distal phalanx of the hallux, at the base of the fifth metatarsal and at the base of the first metatarsal.

The vibratory sensitivity was evaluated with the patient sitting down with the feet supported and the 128Hz tuning fork was positioned in the dorsal region of the distal phalanx of the hallux.

The Achilles reflex was assessed with the neurological hammer with the patient standing and the leg resting on a chair. The reflex was assessed with the patient at rest and, if it was absent, the Jendrassik maneuver was performed in which the patient crossed the fingers of the hands (assessment of the reflex with effort).

The patients were classified, according to the IWGDF, in the risk stratification for the development of ulcer in: very low (0), low (1), moderate (2) and high risk (3).

Data analysis

As a procedure for data analysis, a descriptive analysis was initially performed. Qualitative variables were described as mean and standard deviation (mean + SD) and presented as absolute frequencies and percentages. To evaluate the normality pattern of the quantitative variables, the Shapiro Wilk Test was performed: when the p found is greater than 0.05, the variable adheres to the normality pattern; if the p value found is less than 0.05, it indicates that the variable does not present normal distribution. For the correlation of variables, Pearson's correlation coefficient was used. In the variables that did not adhere to the normality pattern, the Mann Whitney test was used. The collected data were analyzed using the statistical program Stata 11.0.

Ethical and legal aspects of the research

This study was approved by the Research Ethics Committee Faculdade de Medicina do ABC (CAAE: 44890321.9.0000.0082 and number 4.713.250) and the participants signed the Informed Consent Form).

RESULTS

A total of 200 patients who met the inclusion and exclusion criteria were evaluated, 102 males, corresponding to 51%, and 98 females, corresponding to 49%. As for race, 149 were white (74.5%), 49 were black (24.5%) and 2 were brown (1.0%). The mean age of the patients was 60.45 years (SD = 14.28), with a range of 18 to 92 years. The mean time since the diagnosis of diabetes was 15.14 years (SD = 10.12) with a range of 1-43 years.

As for the continuous use of medication, most participants use some medication daily: 163 of them use oral antidiabetics, 104 use insulin, 144 use antihypertensives and 133 use some oral hypolipidemic.

As for associated comorbidities, patients were evaluated for smoking, previous stroke, previous acute myocardial infarction, heart disease, chronic kidney disease, retinopathy, arterial hypertension, dyslipidemia, and also for amputation. and previous ulcer. 24 (12%) of the participants were smokers, 16 (8%) reported a previous stroke, 38 (19%) had a previous AMI, 90 (45%) had retinopathy, 28 (14%) had chronic kidney disease, 70 (35%) had heart disease, 135 (67.5%) had dyslipidemia, 144 (72%) were hypertensive, 56 (28%) had a previous ulcer, 30 (15%) had a previous amputation.

In self-assessment in the Michigan questionnaire the average score obtained was 3.79 points with a range of 0-10. In the physical examination of the Michigan protocol, an average of 3.74 points with a range of 0-9. The most frequent score was 4 points, present in 25 participants (12.50%).

The Shapiro Wilk test was performed to assess whether the quantitative variables showed a normality pattern (table 1). It was observed that both the self-assessment and the physical examination did not adhere to the normal range, and both were submitted to the Mann Whitney test.

Regarding the IWGDF classification, 52 patients were classified as very low risk (26.0%) - Category 0 IWGDF, 64 as low risk (32.0%) - Category 1 IWGDF, 23 as moderate risk (11.5%) - Category 2 IWGDF and 61 as high risk for developing foot ulcers (30.50%) - Category 3 IWGDF.

To facilitate the data analysis, the IWGDF classification was divided into two categories characterizing the new category, as shown below: group 0 includes very low risk (IWGDF 0) and low risk (IWGDF 1) patients represented by 116 participants (58%); group 1 includes moderate (IWGDF 2) and high risk (IWGDF 3) patients represented by 84 participants (42%).

Correlating the new category of the IWGDF with both the self-assessment and the physical examination of Michigan, there was a correlation between the evaluated variables, with statistical significance. Therefore, the higher the IWGDF rating, the higher the Michigan self-assessment and physical examination values. Two ROC (Receiver Operating Characteristic) curves were then generated for each of the correlations with the new IWGDF category, as well as two tables detailing specificity and sensitivity (Appendices D and E).

Table 1: Verification of the normality distribution of the quantitative variables using the Shapiro Wilk test

Variable	Sample	W	V	Z	Prob>z
MichiganPhysicalEx x 10	200	0.98255	2.603	2.201	0.01387
MichiganSelfAss x 13	200	0.95404	6.857	4.430	<0.0001

Correlating the new category of the IWGDF with Michigan's self-assessment, the area under the curve found was 0.81, demonstrating a good diagnostic ability, with a confidence interval ranging from 0.75 to 0.87. Using a score greater than or equal to 6 in the self-assessment for the diagnosis of neuropathy, a sensitivity of 50% and a specificity of 94.83% were obtained (table 2).

Correlating the new category of the IWGDF with the physical examination of the Michigan assessment, the area under the curve found was 0.85, also demonstrating a test with good diagnostic ability, with a confidence interval ranging from 0.80 to 0.90. Using a score greater than or equal to 2.5 in the physical examination for the diagnosis of neuropathy, a sensitivity of 97.62% and a specificity of 47.41% were obtained.

Table 2- Specificity and sensitivity table correlating the new IWGDF classification with the Michigan Self-Assessment

Cut-off point	Sensitivity	Specificity
≥ 0	100,00%	0,00%
≥ 1	98,81%	8,62%
≥ 2	92,86%	34,48%
≥ 3	83,33%	56,90%
≥ 4	75,00%	65,62%
≥ 5	65,48%	86,21%
≥ 6	50,00%	94,83%
≥ 7	38,10%	97,41%
≥ 8	27,38%	99,14%
≥ 9	15,48%	100,00%
≥ 10	2,38%	100,00%

Table 3 - Specificity and sensitivity table correlating the new IWGDF classification with the Michigan Physical Examination

Cut-off point	Sensitivity	Specificity
≥ 0	100,00%	0,00%
≥ 0,5	98,81%	14,66%
≥ 1	98,81%	18,10%
≥1,5	97,62%	29,31%
≥ 2	97,62%	33,62%
≥ 2,5	97,62%	47,41%
≥ 3	96,43%	55,17%
≥ 3,5	89,29%	64,66%
≥ 4	77,38%	69,83%
≥ 4,5	67,86%	84,48%
≥ 5	61,90%	85,34%
≥ 5,5	47,62%	92,24%
≥ 6	40,48%	94,83%
≥ 6,5	33,33%	98,28%
≥ 7	23,81%	99,14%
≥ 7,5	19,05%	100,00%
≥ 8	15,48 %	100,00%
≥ 8,5	8,33%	100,00%
≥ 9	1,19%	100,00%
> 9	0,00%	100,00%

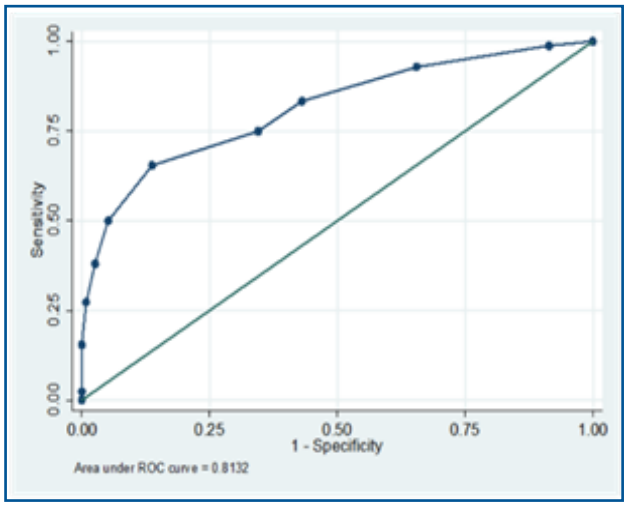

Figure 1: ROC curve correlating the new IWGDF classification with the Michigan Self-Assessment

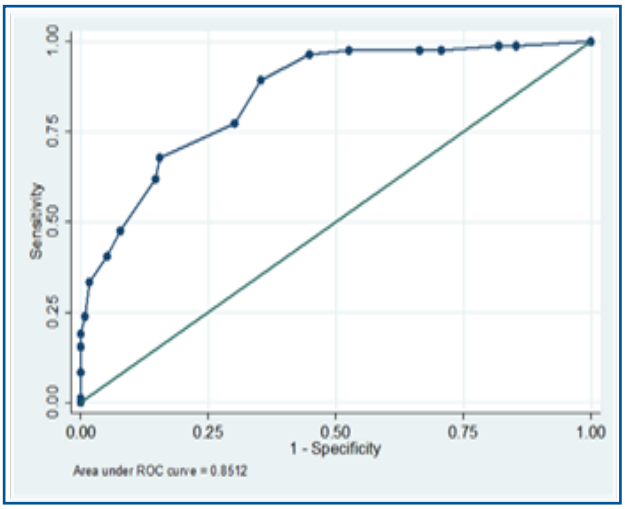

Figure 2: ROC curve correlating the new IWGDF classification with the Michigan Physical Examination

DISCUSSION

Several pathophysiological mechanisms have been proposed as a theory for the development of neuropathy, including the formation of advanced glycosylation products, in which their accumulation in the cell wall would lead to vascular dysfunction, with consequent nerve ischemia[7]. Other factors such as obesity, hypertriglyceridemia, hypercholesterolemia and low HDL-cholesterol are an important role in its development[2].

Chronic intracellular hyperglycemia associated with genetic predisposition can affect the microvasculature, generating several complications in the kidneys, eyes and nervous system[8].

The duration of diabetes and glycemic control are the main predictors of the development of neuropathy and its severity[7]. Cohort studies have shown that approximately 66% of patients with type 1 diabetes and 59% of patients with type 2 diabetes develop some type of neuropathy[7]. Peripheral nerves, both sensory and motor, are the most affected, leading to diabetic peripheral polyneuropathy, with decreased sensitivity or hyperalgesia and a decrease in muscle strength may also occur[9]. Diabetic polyneuropathy is the most common clinical form, followed by autonomic, acute sensory, focal and multifocal neuropathies[2].

Distal sensorimotor polyneuropathy usually manifests after 5-10 years of the diagnosis of diabetes, starting in the distal portions of the legs, with progressive rise. Patients refer tingling, complain of pins and needles, numbness and a feeling of heaviness[3]. Autonomic neuropathy presents as its first manifestation a tachycardia at rest, and dyspnea or chest pain may also occur during physical activity, silent myocardial ischemia and orthostatic hypotension[3]. The presence of peripheral arterial disease and/or neuropathy in diabetics significantly increases the risk of amputation. The presence of nephropathy and retinopathy are also important risk factors for amputation[10].

Most diabetics with ulcers have neuropathy and 15-20% of them have peripheral arterial disease also. Ulcers can be classified as either neuropathic or vascular (ischemic). Neuropathic lesions are characteristically painless, circular, with calluses and located under areas of bony prominence, mainly in the plantar region. Ischemic ulcers are usually painful, irregular, without calluses, clear and located in a different topography than the plantar surface of the foot[11].

The "American Diabetes Association" recommends regular inspection of the feet of diabetic patients, with pulse palpation, reflex assessment, and assessment of protective sensitivity and proprioception using monofilament in addition to vibratory perception[10].

The use of inappropriate footwear is an important triggering factor for injuries, and patients should be aware about the importance of the use of appropriate shoes[10].

Another important factor is the association of the diabetic foot with ischemic feet affected by chronic peripheral arterial disease, which can aggravate the situation and increase the risk of developing ulcers. Therefore, the diagnosis is important to help in the treatment of diabetic neuropathy and prevent its complications.

Peripheral neuropathy associated with deformities and reduced joint mobility are factors that can lead to the development of ulcers. In this sense, strategies aimed at prevention, in addition to patient and health professional education associated with multidisciplinary treatment, are able to reduce its complications[7].

Ulcers arise in diabetic patients in the presence of two or more risk factors, with peripheral neuropathy and peripheral arterial disease representing the main factors. Neuropathy generates a decrease in sensitivity and, in association with the deformity, there is a greater likelihood of foot injuries. Peripheral arterial disease is present in more than 50% of diabetics with ulcerated lesions on the feet[7]. Most ulcers occur due to neuropathy or the association of ischemic lesions with neuropathy.

Distal polyneuropathy is the most common type found in diabetics, manifesting after 5 to 10 years of diabetes diagnosis. The loss of fine fibers generates excruciating pain and a burning sensation, in association with various autonomic symptoms. In these cases, the nerve conduction study is usually normal[3]. When thick fibers are involved, the main complaints are numbness and decreased protective sensitivity[8].

A high degree of suspicion associated with the early diagnosis of microvascular complications is essential, it was estimate that 25% of those newly diagnosed with type 2 diabetes have already developed one or more complications[8].

The "American Diabetes Association" recommends screening for distal polyneuropathy at the time of diagnosis in those patients with type 2 diabetes, 5 years after diagnosis in those with type 1, and then annual follow-up[12].

According to the 2019 IWGDF consensus, there are 5 pillars to prevent the formation of foot ulcers: identifying the foot at risk of a injury; the regular inspection of the foot; education of the patient, family members and health professionals; guidance on the use of suitable footwear; the treatment of risk factors for the formation of foot ulcers[7].

The IWGDF consensus established a risk classification for the formation of foot ulcers and, according to the category, a recommendation was made for the period in which this patient should be reassessed. IWGDF category 0 patients are at very low risk and annual evaluation is recommended. Those classified as IWGDF 1 are at low risk, and evaluation is recommended once every 6 or 12 months. Patients with grade 2 IWGDF are at moderate risk and the recommendation is that it be evaluated every 3-6 months. Those classified as category 3 are at high risk for foot ulcers, and evaluation is recommended once every 1 to 3 months[7].

Patient, family and health care professional education plays an important role in preventing foot ulcers. Diabetics, especially those with IWGDF 1 or higher, should learn to recognize foot ulcers and the initial signs of formation of lesions, and should be advised about what steps they need to follow when these signs appear[7].

In patients with peripheral arterial disease, the use of the WIFI classification (wound/ischemia/infection) is recommended to stratify the risk of amputation and the benefit of limb revascularization[7].

The aim of this study was to assess diabetic patients for the risk of developing ulcers, using the IWGDF classification, as mentioned in the text above, in addition to diagnose early patients with peripheral neuropathy using the Michigan questionnaire.

The Michigan self-assessment consists of a questionnaire regarding neuropathy symptoms, which must be completed by the patient. The Michigan physical exam consists of inspecting the feet for foot deformities, calluses, or ulcers; by evaluating the protective sensitivity through the 10 g monofilament; by evaluating the vibratory perception through the 128Hz tuning fork; and by assessing the Achilles reflex with the neurological hammer[3].

Two hundred diabetics were evaluated, both type 1 and type 2, with an average time of diabetes diagnosis of 15 years. According to the literature, the longer the duration of diabetes, the greater the risk of developing neuropathy, increasing the risk of formation of lesions on the feet[9]. We could see it on this study, that 30.50% of the patients were classified as IWGDF 3, therefore, high risk for the development of foot ulcers.

Statistical analysis was performed correlating the IWGDF classification with the Michigan physical examination and the IWGDF classification with the Michigan self-assessment, demonstrating that there is a correlation between the variables with statistical significance.

We found in the physical examination of Michigan that using a cutoff point greater than or equal to 2.5, we obtained a test with high sensitivity (97.62%), which may help in the screening of diabetic neuropathy. Furthermore, analyzing the ROC curve, we observed that it is a test with a high diagnostic capacity.

Regarding the Michigan self-assessment, using a cutoff point for the diagnosis of neuropathy greater than or equal to 6, we obtained a test with high specificity (94.83%) and with a high diagnostic capacity according to the area under the ROC curve. The literature usually uses a score greater than 7 for the diagnosis of neuropathy, we chose to decrease the value in order to increase the sensitivity of the self-assessment, which can be used in basic health units as a screening tool.

A limitation of this study is the fact that the questionnaire was answered by the research participant. Often, the patient did not understand very well the question that had been asked, thus generating some invalid answers. Therefore, associating the self-assessment with the physical examination of Michigan, we present a high accuracy for the diagnosis, which can be used in the screening for neuropathy.

All evaluated patients received a pamphlet at the end of the evaluation containing some guidelines of how they can take care of the feet and prevent the formation of lesions: examine the feet daily in search of cracks, calluses and wounds; keep your feet always clean and dry; wash with warm water and dry with a towel between the fingers; avoid walking barefoot; wear comfortable shoes and seamless socks; have a healthy eating; perform physical exercises daily; strictly control blood glucose and stop smoking.

This study produced a better understanding of diabetes mellitus and how to prevent the appearance of ulcers with minimal risk to the patient, considering that there is no change in the treatment of the participants and the proposed intervention brings minimal chances of physical, psychological or social harm.

CONCLUSION

We conclude that the association of self-assessment with the Michigan physical examination increases the accuracy of the diagnosis of neuropathy. Therefore, we recommend the serial assessment of diabetics, associating self-assessment with the Michigan physical examination, for the early diagnosis of neuropathy and guidance regarding foot care. Finally, patient guidance is the main factor to prevent the formation of foot ulcers and, consequently, diabetic foot.

Author Contributions

All authors contributed to the manuscript. Bárbara Peres Lapetina Gonçalves Saraiva: Participated in data collection, data analysis, statistical analysis and writing of the text. Juliana Daud Ribeiro: Participated in the study design, statistical analysis, discussion of results and final version of the text. Bárbara de Araújo Casa: Participated in data collection phase and revision of the text. Renato Hideki Osugi: Participated in data collection phase and writing of the text. Gustavo Sawazaki Nakagome: Participated in data collection phase. Orlando Vitorino de Castro Neto: Participated in data collection phase. Fernando Adami: Participated in statistical analysis and writing of the text. Manuela de Almeida Roediger: Participated in statistical analysis and writing of the text. João Antonio Correa: Participated in the general orientation of the research, definition of the study design and final revision of the text.

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Conflicts of Interest

The authors report no conflict of interest.

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Resumo

Introdução: o pé diabético é uma das complicações mais sérias do diabetes mellitus. Cerca de 50% das amputações não traumáticas ocorrem nesses pacientes. Além disso, é um importante problema de saúde pública por ser um distúrbio metabólico crônico e complexo que se caracteriza pelo comprometimento do metabolismo da glicose associada a outras complicações em órgãos essenciais para manutenção vital.

Objetivo: avaliar a sensibilidade e especificidade para neuropatia diabética da autoavaliação e do exame físico de Michigan nos diabéticos tipo 1 e tipo 2.

Método: trata-se de um estudo transversal. Foi utilizada a classificação “Michigan Neuropathy Screening Instruments” para avaliação do grau de neuropatia periférica, em que os participantes responderam ao questionário e foram avaliados quanto a presença de lesões nos pés. Todos os participantes foram estratificados quanto ao risco de desenvolver úlcera nos pés de acordo com o protocolo do IWGDF.

Resultados: a amostra contou com 200 participantes. Quanto à classificação do IWGDF, 23 pacientes foram classificados como risco moderado (11,50%) e 61 como alto risco para o desenvolvimento de úlceras nos pés (30,50%). Utilizando-se um corte de 2,5 na pontuação do exame físico para diagnosticar a neuropatia, foi obtida uma sensibilidade de 97,62% e uma especificidade de 47,41%. Utilizando-se uma pontuação maior ou igual a 6 na autoavaliação para o diagnóstico de neuropatia, foi obtida uma sensibilidade de 50,00% e uma especificidade de 94,83%.

Conclusão: a associação do exame físico de Michigan (alta sensibilidade) com a autoavaliação (alta especificidade) tem melhor acurácia para o diagnóstico de neuropatia diabética.

Palavras-chave: diabetes mellitus, neuropatia diabética, angiopatia diabética, doença vascular diabética, pé diabético, neuropatia.