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Title:

Monofilament Test or Ipswich Test: Comparative Study in Diabetic Neuropathy at the Bedside.

Teste do Monofilamento ou Ipswich Test: Estudo comparativo em neuropatia diabética à Beira do Leito.

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Introduction: Diabetic neuropathy is a common and underdiagnosed complication of diabetes, associated with high risk of ulcers and amputations. The 10g monofilament is an effective, but less accessible method for screening these complications. The Ipswich Test emerges as a practical and cost-free alternative to detect sensory loss in diabetic feet. **Objectives**: Compare sensitivity, specificity, and effectiveness of the 10g Monofilament Test and the Ipswich Test in screening for peripheral neuropathy in diabetic patients. **Methodology**: A descriptive and interventional study with a qualitative-quantitative approach was conducted between October 2024 and February 2025 at the Hospital Evangélico Mackenzie do Paraná. A total of 92 hospitalized patients diagnosed with diabetes participated. They were assessed using a questionnaire, symptom scoring, and physical examination. The 10g monofilament, tuning fork, wooden stick, and Ipswich Test were applied to standardized points on the feet. **Results**: The average age was 65 years, with a predominance of type 2 diabetes. Only 30.4% had previously had their feet examined, and 47.8% reported neuropathic symptoms. The monofilament showed a sensitivity of 61.36% but lower specificity. The Ipswich Test demonstrated higher specificity (79.15%) and a sensitivity of 43.18%, with a significant association with neuropathic symptoms (p=0.02). **Conclusion:** The low rate of previous foot examinations (30.4%) highlights shortcomings in diabetic neuropathy screening. Although the Ipswich Test has lower sensitivity, its higher specificity and ease of application, requiring minimal training, make it a viable complementary tool—especially in resource-limited settings—to identify advanced casei.

Keywords: Diabetes Mellitus. Diabetic Neuropathy. Diabetic Foot.

Introdução: A neuropatia é uma complicação comum e subdiagnosticada do diabetes, associada à um risco elevado de úlceras e amputações. O monofilamento de 10g é um método eficaz, mas pouco acessível de rastreamento dessas complicações. O Ipswich Test surge como alternativa prática e sem custo para rastrear perda de sensibilidade nos pés diabéticos. **Objetivos:** Comparar a sensibilidade, especificidade e eficácia do Teste do Monofilamento de 10g e do Ipswich Test no rastreio

da neuropatia periférica em pacientes com diabetes. **Metodologia:** Estudo descritivo com abordagem quali-quantitativa, realizado entre outubro de 2024 e fevereiro de 2025 no Hospital Evangélico Mackenzie do Paraná. Participaram 92 pacientes internados com diagnóstico de diabetes, avaliados por escore de sintomas neuropático e exame físico. Foram utilizados monofilamento de 10g, diapasão, palito e Ipswich Test em pontos padronizados dos pés. **Resultados:** A média de idade foi 65 anos, com predominância de diabetes tipo 2. Apenas 30,4% haviam tido seus pés examinados previamente, e 47,8% relataram sintomas de neuropatia. O monofilamento apresentou sensibilidade de 61,36% e menor especificidade. O Ipswich Test teve maior especificidade (79,15%) e sensibilidade de 43,18%, com associação significativa a sintomas neuropáticos (p=0,02). **Conclusão:** A baixa taxa de exames prévios dos pés (30,4%) evidencia falhas no rastreio da neuropatia diabética. Embora o Ipswich Test tenha menor sensibilidade, sua maior especificidade e fácil aplicação, sem exigir amplo treinamento, o tornam uma ferramenta complementar viável, especialmente em locais com recursos limitados para rastrear casos avançados.

Palavras-chave: Diabetes Mellitus. Neuropatia Diabética. Pé Diabético.

Introduction:

Diabetic neuropathy (DNP) is the most prevalent chronic complication of Diabetes Mellitus (DM), affecting 30% of patients with diabetes and more than 50% of individuals over the age of 50 affected by the disease (1). The disease occurs with dysfunction of the nerves of the peripheral and/or autonomic nervous system, and can affect all types of fibers and have varied clinical presentations (2). First, sensory and autonomic symptoms appear due to the involvement of fine fibers, progressing to broad sensory fibers and, finally, motor fibers distally in the lower limbs with progression to the upper limbs (2). The most common symptoms are burning pain, tingling in the limbs, fatigue and cramps (3). Despite the intense pain and reduced quality of life associated with diabetic neuropathy, it is the most underdiagnosed complication and is difficult to measure directly, requiring a physical examination of the foot for diagnosis.

The Brazilian Diabetes Society states that every patient with diabetes should be screened annually for diabetic neuropathy from the moment of diagnosis in type 2 DM, and after 5 years in type 1 DM (4,5). Individuals with diabetes have an imminent 15%-25% risk of foot ulcers

and a 15 times higher risk of lower limb amputation when compared to individuals without diabetes (1).

The 10g Semmes-Weinstein monofilament test evaluates the coarse fibers and identifies advanced cases of neuropathy, which are already at risk of developing ulcers and all the resulting complications, such as foot amputation (6). Abnormal results with this method indicate a 7.7-fold increase in the risk of ulceration (7). However, it is equipment that is not provided by the Unified Health System and is not universally available to examine all patients with diabetes following the recommendations of the guidelines (4). The Ipswich Test (IPTT) was developed as an alternative to detect loss of plantar sensitivity without any specific equipment or cost (8). The method consists of lightly touching 6 or 8 places on the patient's foot with the tip of the examiner's index finger. Usually the tips of the first, third and fifth toes of both feet are touched, and additionally the dorsum of both hallux can be touched (8). Patients are instructed to close their eyes and respond verbally when they feel the examiner's touch. If the patient fails to detect pressure on two or more toes, it means that their foot is at risk of an ulcer (7,9).

This study aimed to comparatively analyze the Monofilament Test and the Ipswich Test, evaluating aspects of the sensitivity, specificity and effectiveness of both tests in screening for peripheral neuropathy.

Material and Methods:

This is a descriptive study with a qualitative and quantitative approach approved by the local Ethics Committee (6.817.931) with informed consent, carried out at the Mackenzie Evangelical University Hospital in Paraná from October 2024 to February 2025. The sample consisted of inpatients with a previous diagnosis of diabetes, aged over 18. Patients with decreased lower limb sensitivity due to another previously established condition were excluded.

Data collection included:

A. Epidemiological data: gender, age, education, health insurance, type of diabetes, time since diagnosis, medication used to control the disease, history of compensated DM, whether they usually carry out self-inspection of the foot, whether any professional had carried out the examination on them previously, whether they had ever had a lower limb ulcer and whether they had had an amputation in the past.

B. Neuropathic Symptom Score (NSS) (10) to assess typical symptoms, location, intensity, period of greatest pain, whether the patient has ever woken up because of these symptoms and whether they have any pain relief positions.

C. Neurological examination to assess loss of protective sensitivity, evaluating vibration sensitivity with a 128Hz tuning fork, pain sensitivity with a Chinese toothpick, cold sensitivity with an icy tuning fork handle, the 10g Semmes-Weinstein monofilament test and the Ipswich Test.

The monofilament and pain sensitivity tests were applied bilaterally to the head and metatarsals of the 1st, 3rd and 5th toes. Vibration sensitivity was assessed on the medial malleolus and thermal sensitivity was tested on the dorsum of the foot. The Ipswich Test was applied at the same points as the Monofilament Test. Loss of protective sensitivity was considered to be the presence of an altered monofilament test associated with an alteration in at least one other test, including decreased or absent vibration sensitivity, decreased or absent pain sensitivity and decreased or absent cold sensitivity.

Statistical analysis:

The data was summarized by calculating descriptive measures for the quantitative variables and constructing frequency (univariate) and contingency tables for the bivariate analysis of categorical variables. The Chi-square test was used to verify the relationship between categorical variables. The Mann-Whitney test was used to check for differences between groups with regard to quantitative variables. The odds-ratio was calculated for some relationships. A logistic regression model was fitted to predict the presence of symptoms among patients.

Results:

Description of the sample

The study sample consisted of 92 hospitalized patients with diabetes mellitus, 96.7% (n=89) without supplementary health insurance. The average age of the group was 65.09± 12.43 years. Table 1 describes the characteristics of the study population.

Table 1. Epidemiological data of the sample studied

VARIABLE	f(n=92)	%
Gender (male)	57	61,95
Education level		
Elementary school	47	51,08
High school	29	31,52
Higher education	11	11,95
Health insurance	3	3,26
Type 2 diabetes	88	95,65
Time since diagnosis		
0-9 years	41	44,56
10-19 years	25	27,17
20-29 years	13	14,13
30-39 years	7	7,60
40-49 years	2	2,17
50-59 years	3	3,26
Did not know	1	1,08
Medications used		
Oral medication	41	44,56
Insulin	20	21,73
Combined therapy	31	33,69
Self-reported compensated diabetes	37	40,21
Foot self-examination	44	47,82
Previous foot exam	28	30,43
Active ulcer	13	14,13
Previous ulcer	18	19,56
Previous amputation	4	4,34

Neuropathic Symptoms Score

Symptoms in the lower limbs were present in almost 47.82% (n=44) of the patients, the most frequent being fatigue, cramps and itching, as shown in Table 2.

Table 2. Most frequent symptoms

VARIABLE	f(n=44)	%
Symptom		
Fatigue	28	63,64
Cramps	28	63,64
Itching	28	63,64
Burning sensation	16	36,36
Numbness or tingling	16	36,36

Neuropathy was classified using the neuropathic symptom score as Mild (3-4 points),Moderate (5-6 points) and Severe (7-9 points), as shown in Table 3.

Table 3. Neuropathy classification by neuropathic symptom score

NEUROPATHIC SYMPTOM SCORE	f(n=44)	%
Mild	19	43,18
Moderate	16	36,36
Severe	9	20,45

Assessment of loss of protective sensitivity (PSP) using monofilament and the IPSWICH test

The statistical analysis comparing the group of symptomatic and asymptomatic patients showed no significant difference in the results of the PSP test (p=1, Odds-ratio=1). However, the test proved to have a sensitivity of 50% and specificity of 50%. The monofilament sensitivity

test showed the highest sensitivity, but the lowest specificity. The Ipswich test showed greater specificity and higher predictive value. There was significant agreement (<0.0001) between the tests, according to the contingency coefficient C(C=0.444),Table 4.

Table 4. Comparison between 10g monofilament and Ipswich test.

TEST	SENSITIVITY	SPECIFICITY	POSITIVE PREDICTIVE VALUE	NEGATIVE PREDICTIVE VALUE
PSP	50%	50%	47,83%	52,17%
Ipswich	43,18%	79,16%	65,51%	60,32%
10g Monofilament	61,36%	39,58%	61,36%	39,58%

Table 5 shows the logistic regression model assessing the factors associated with the presence of symptoms. The coefficients (estimates), standard error, Wald statistics and p-values are presented for each independent variable in the model. In this analysis, Gender and the Ipswitch Test were found to be statistically significant predictors of symptoms. Women with diabetes were 2.69 times more likely to have symptoms than men with diabetes. A Yes result on the Ipswitch test indicates 2.89 times more chance of having symptoms than a No result.

Table 5. Logistic regression model adjustment for presence of symptoms

	ESTIMATE	STANDARD ERROR	WALD	p-value
Intercept	0,207	0,271	0,586	0,586
Gender	0,593	0,251	5,564	0,018
Education level	0,318	0,244	1,708	0,191
IPSWICH test	-0,730	0,260	7,875	0,005

Scale	1000	0,000		

Discussion:

The survey revealed an important deficiency in the prevention, screening, diagnosis and management of diabetic neuropathy in the population treated at the hospital. Only 28 patients (30.4% of the sample) reported having had their diabetic foot examined by a health professional. Previous studies have reinforced the difficulty of routinely implementing this practice in primary care, indicating that up to 83.63% of patients with DM have never undergone a clinical examination of their feet and more than half have never undergone any type of monitoring or visual inspection of their feet during clinical assessment (11).

The main factors associated with inadequate diabetic foot care include low schooling, unsatisfactory glycemic control and the type of drug treatment. Low schooling, observed in 52.16% of the sample, makes it difficult to access and understand self-care guidelines, increasing the risk of complications.

Although lower than rates reported in other regions of Brazil, where this percentage can exceed 84.5% (12), this socio-cultural condition still represents a significant obstacle to adherence to continuous care. The association between social vulnerability, lack of health education programs and inadequate glycemic control contributes to the increased incidence of ulcerations and amputations in DM patients (13).

We found that only 40.22% of the individuals reported maintaining adequate glycemic control in the period prior to hospitalization, which is compatible with other studies in which 79% of patients do not reach the recommended glycemic levels, with discontinuation of medication observed in 25% of them over two years (14). Although most of the participants were using oral hypoglycemic agents (46.6%), only 31.8% were using combined therapy, which may have contributed to inadequate glycemic control. Previous studies have shown that the isolated use of medication alone accounts for up to 86% of cases (15), despite the pathophysiological complexity of DM, which often requires multimodal treatment (16).

Another relevant aspect observed was the low familiarity of professionals with standardized tests for screening NPD, often

compromised by logistical and human resource limitations (9). Tools such as the Ipswich Touch Test (IPTT) and the Neuropathic Symptom Score can complement the traditional physical examination, increasing diagnostic capacity. In the sample studied, 47.82% of patients had neuropathic symptoms. Those with alterations in at least one point on the IPTT were 2.89 times more likely to report symptoms, which reinforces the usefulness of the test as a clinical screening tool.

When comparing the two main methods for assessing protective sensitivity - the 10 g monofilament and the IPTT - different performances were observed. The monofilament showed higher sensitivity (61.36%) but lower specificity (39.58%), while the IPTT showed higher specificity (79%) and lower sensitivity (43.18%). These results are compatible with findings in the literature, which indicate sensitivity and specificity values of up to 81% and 91% for the monofilament, and 77% and 90% for the IPTT, respectively (2). The agreement between the tests in this sample was high ($k=0.88$; $p<0.0001$), which corroborates their complementary use in NPD screening.

Although the sensitivity and specificity values observed were lower than those described in other studies, this divergence can be partially explained by the nature of the sample - made up of hospitalized patients, often in an unstable clinical state, with a higher risk of functional and cognitive impairment, factors which can affect the performance of diagnostic tests. Even so, the simplicity, low cost and applicability of the IPTT reinforce its viability, especially in primary care settings with limited resources.

These findings highlight the urgent need for integrated health education strategies, professional training and increased access to basic tests for the early detection of NPD. Such measures are fundamental to reducing the risk of serious complications and optimizing the clinical management of DM patients, especially in vulnerable populations.

Conclusion:

The deficiency of diabetic neuropathy screening was evidenced by the low proportion of patients who had previously undergone foot examination, representing only 30.4% of the sample analyzed. As far as diagnostic tests are concerned, the Ipswich Test showed lower sensitivity and higher specificity, but it is a method that is easy to apply and does not require extensive staff training, which makes it a viable

complementary tool in places with limited resources for screening advanced cases of diabetic neuropathy.

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