

Outpatient evaluation of the loss of protective plantar sensitivity in patients with type 2 Diabetes Mellitus in a tertiary health care service

Avaliação ambulatorial da perda de sensibilidade protetora plantar em pacientes com Diabetes Mellitus tipo 2 num Serviço Terciário de Atenção à Saúde

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ABSTRACT: Introduction: Diabetic peripheral neuropathy (DPN) is a frequent but under-recognized complication of diabetes mellitus (DM). Loss of protective sensitivity (LPS) is an important feature of DPN, potentially leading to ulcers and amputations if not detected early. Objective: To determine the prevalence of LPS in individuals with type 2 diabetes (T2DM) in a tertiary healthcare service, correlating it with alterations in nerve fibers, comorbidities, and other risk factors. Methodology: A cross-sectional, exploratory, and descriptive study with a quantitative approach carried out on T2DM patients. Data was collected through anamnesis, clinical examination of the feet, medical record analysis, and by testing various sensitivities. Results: 76 people took part, with an average age of 65.4 years (60.5% women). The average time since DM diagnosis was 17.6 years, and the average glycated hemoglobin was 9.4%. LPS was detected in 15.8% (n=12) of the participants, with 58.3% of whom were men, 58.3% obese, 91.7% hypertensive, 75.0% with diabetic kidney disease (DKD), 33.3% with

retinopathy, 50.0% ex-smokers, and 83.4% using insulin. Conclusion: Although few people were affected by PSPP, the data from this study corroborated the literature regarding the association of obesity, arterial disease, DKD, retinopathy, smoking and insulin use with LPS. This reinforces the importance of periodic foot examinations in T2DM patients.

KEY WORDS: Diabetes mellitus; Diabetic neuropathy; Diabetic foot.

RESUMO: Introdução: A Neuropatia periférica diabética (NPD) é uma complicação frequente do diabetes mellitus (DM), porém pouco reconhecida. A perda da sensibilidade protetora plantar (PSPP) é uma característica importante da NPD, podendo ocasionar úlceras e amputações se não detectada precocemente. Objetivo: Determinar a prevalência da PSPP em pessoas com DM tipo 2 num serviço terciário de saúde, correlacionando com alterações nas fibras nervosas,

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comorbidades e outros fatores de risco. Metodologia: Estudo transversal, exploratório e descritivo com abordagem quantitativa, realizado em pacientes com DM2. Os dados foram coletados por anamnese, exame clínico dos pés e análise do prontuário, e testando diferentes sensibilidades. Resultados: Participaram 76 pessoas, com idade média de 65,4 anos (60,5% mulheres). O tempo médio de diagnóstico do DM2 foi 17,6 anos e a média de hemoglobina glicada 9,4%. Detectou-se PSPP em 15,8% (n=12) dos participantes, sendo 58,3% homens, 58,3% obesos, 91,7% hipertensos, 75,0% com doença renal do diabetes (DRD),

33,3% com retinopatia diabética, 50,0% ex-fumantes e 83,4% em uso de insulina. Conclusão: Apesar de poucos acometidos com PSPP, os dados desse estudo corroboram com a literatura, quanto à associação de obesidade, doença arterial, DRD, retinopatia, tabagismo e uso de insulina com a PSPP. Isso reforça a importância do exame periódico dos pés em pacientes com DM2.

PALAVRAS-CHAVE: Diabetes mellitus; Neuropatia diabética; Pé diabético.

INTRODUCTION

Diabetes mellitus (DM) is a metabolic disorder characterized by chronic hyperglycemia resulting from impaired insulin secretion, insulin action, or both. Although it is not curable, DM can be managed through lifestyle modifications and pharmacological treatment¹.

Data from the World Health Organization (WHO) indicate a significant global increase in the incidence of the disease². According to the International Diabetes Federation (IDF), the prevalence of diabetes among Brazilian adults was 10.5% in 2021³. Globally, the estimated prevalence was 6.1%, affecting approximately 529 million individuals, with type 2 diabetes mellitus (T2DM) accounting for 96% of cases⁴. Several factors contribute to this increase in developing countries, including obesity, sedentary behavior, and unhealthy diets².

DM, when poorly controlled, may lead to various macrovascular and microvascular complications. The former includes coronary artery disease, cerebrovascular disease, and peripheral vascular disease, while the latter encompasses diabetic retinopathy, diabetic kidney disease (DKD), and diabetic neuropathy².

Diabetic neuropathy can be classified as peripheral or autonomic and is a subject of ongoing research due to its high prevalence. It is estimated that one-third of patients already present a reduction in myelinated nerve fibers at the time of DM diagnosis. If untreated, this reduction tends to progress, leading to the loss of protective sensitivity (LPS), which, in conjunction with increased pressure points, becomes a major risk factor for ulcerations, infections, and even limb amputation. This condition is referred to as diabetic foot². In Brazil, the estimated risk of LPS ranges from 85% to 89%, with a prevalence of distal symmetrical polyneuropathy of 14.3%⁵.

It is estimated that up to 25% of diabetic patients will develop foot ulcers during their lifetime, which contribute to more than 85% of amputations. Diabetic foot remains the leading cause of non-traumatic amputations in many countries⁶. Notably, not all patients exhibit symptoms, making early diagnosis difficult and reinforcing the importance of routine foot examinations⁷.

Thus, diabetic neuropathy has significant social and economic implications. Early diagnosis is essential for preserving and improving the individual and collective health of diabetic patients. The aim of this study was to determine the prevalence of loss of protective sensitivity (LPS) in patients with type 2 diabetes mellitus (T2DM) treated in a tertiary healthcare setting. It also sought to correlate LPS with alterations in small

and large nerve fibers, and with DM-related comorbidities and other risk factors for chronic complications.

MATERIALS AND METHODS

Individuals over the age of 18, of both sexes, who attended the diabetes outpatient clinic of a tertiary health care service were invited to participate in the study. The study was approved by the local Research Ethics Committee under opinion number 4.206.918 and CAAE number 31063620.6.0000.5373. All participants signed an informed consent form. Data collection was carried out between August 2020 and September 2021.

Initially, all participants completed a questionnaire consisting of a diabetic foot assessment form, divided into three parts:

(1) The first part involved a medical history focused on neurological symptoms using the Neuropathy Symptom Score (NSS), which included questions describing pain and scoring each answer as 0 (normal), 1 (altered but atypical), or 2 (typical alteration). This scale allowed for differentiation of symptoms as positive (pain) or negative (numbness), and classification as mild (NSS 3–4), moderate (NSS 5–6), or severe (NSS 7–9). Absence of pain or discomfort in the legs exempted the patient from the remaining questions on the scale, but not from the comorbidity evaluation or physical examination. Pain intensity was quantified using the Visual Analog Scale (VAS), ranging from 0 to 10 and classifying pain as mild (0–2), moderate (3–7), or severe (8–10). Additional questions addressed comorbidities and risk factors such as smoking, alcohol use, hypertension, and cardiovascular diseases, among others^{8,9}.

(2) The second part consisted of a general physical examination including anthropometric measurements and body fat distribution assessment by measuring weight (kg), height (cm), and abdominal circumference (cm). Blood pressure and heart rate were also recorded while the participant was seated.

(3) The third part involved a specific physical examination. Patients removed shoes and socks and were examined in the supine position on an examination table. The materials used included a 10g Semmes-Weinstein monofilament, a 128 Hz tuning fork, a wooden stick (with blunt and pointed ends), Two test tubes (one filled with heated tap water, the other with refrigerated water), and a reflex hammer. All procedures were first demonstrated

on the patient's forearm to ensure understanding using an area without sensory impairment. If the patient failed to understand, the response was recorded as "questionable due to possible lack of understanding"⁹.

The monofilament test, used to assess ulceration risk, was performed bilaterally at three plantar sites: the hallux, and the heads of the first and fifth metatarsals. Sufficient pressure was applied to bend the filament, and the patient was asked whether they could feel the touch and identify its location^{8,10}.

For thermal sensitivity testing, the test tubes were applied to the dorsum of the feet near the hallux to assess the patient's ability to differentiate between hot and cold. This procedure evaluated small unmyelinated C fibers (warm sensitivity) and small myelinated A-delta fibers (cold sensitivity)^{8,10}.

Pain sensitivity (pin-prick test) was assessed using the wooden stick. The blunt and pointed ends were alternately applied to the dorsum of the hallux on both feet, and the patient was asked whether the stimulus elicited pain. In cases of hallux amputation, testing was conducted near the amputation site. Then, to assess A-delta fibers, the pointed end was pressed with equal pressure along the anterior leg toward the dorsum of the foot. Patients were asked whether the pressure sensation remained the same, decreased (hypoesthesia), or increased (causing pain or hyperalgesia)^{8,10}.

To evaluate large A-alpha and A-beta fibers, vibratory sensitivity was tested using a 128 Hz tuning fork. After striking the fork to induce vibration, its base was placed on the dorsum of the hallux bilaterally. In cases of hallux amputation, the fork was placed on the head of the first metatarsal. Patients were asked whether the tuning fork was vibrating. If confirmed, the examiner stopped the vibration, and the patient was asked to indicate when it ceased. Absence of vibration perception or delayed recognition of vibration cessation were considered abnormal^{8,10}.

Motor evaluation included bilateral assessment of the Achilles reflex using a reflex hammer. Absence of response indicated neurological alteration of large A-alpha and A-beta fibers^{8,10}.

Neurological assessment allowed classification of neuropathy according to involvement of small and/or large fibers, and severity using the Neuropathy Impairment Score (NIS). A score of zero was given for a normal neurological exam, and one point for each abnormal test (with the Achilles reflex scoring zero if normal and two if altered). Final scores classified NIS as mild (3–5), moderate (6–8), or severe (9–10). LPS was defined as an abnormal result in the 10g Semmes-

Weinstein monofilament test plus at least one abnormal result in the vibratory, thermal, or pain sensitivity tests^{8,10}.

Additionally, dorsalis pedis and posterior tibial pulses were bilaterally assessed via palpation. Pulses were categorized as normal, diminished, or absent. The latter two were suggestive of **peripheral arterial disease (PAD)**⁹.

The combination of neurological and vascular assessments allowed classification of ulceration risk according to guidelines from the American Diabetes Association (ADA), the American Association of Clinical Endocrinologists (AACE), and the Brazilian Diabetes Society (SBD). Risk levels were defined as:

- Level 0: no LPS or PAD
- Level 1: LPS present (with or without foot deformity)
- Level 2: PAD present (with or without deformity)
- Level 3: history of ulcer or amputation^{9,11,12}.

The questionnaire and physical exams were conducted during routine outpatient visits and did not interfere with regular care procedures.

Laboratory test results, including glycated hemoglobin (HbA1c) and cholesterol levels, were obtained from medical records, using the most recent values at the time of examination. The presence of diabetic kidney disease (DKD) or retinopathy was also recorded. Patients who were cognitively unable to answer the questionnaire or complete the physical examination were excluded from the study.

RESULTS

A total of 76 patients participated in the study, including 46 women (60.5%) and 30 men. The mean age was 65.4 ± 14.1 years. The average duration since diabetes diagnosis was 17.6 ± 9.3 years, and the mean body mass index (BMI) was 29.9 ± 5.0 kg/m². Mean systolic and diastolic blood pressures were 132 ± 19 mmHg and 80 ± 12 mmHg, respectively. Loss of protective sensitivity (LPS) was detected in 15.8% (n = 12) of the participants.

The mean HbA1c was $9.4 \pm 1.9\%$, ranging from 6.1% to 13.9%, with only 14.5% of patients presenting values below 7.0%, which is considered good glycemic control by ADA and SBD standards. Seventy participants showed elevated cholesterol levels. Clinical data for patients with (n = 12) and without LPS (n = 64) are presented in Table 1.

TABLE 1 - Clinical data of 76 individuals with type 2 diabetes, with (n = 12) or without (n = 64) Loss of protective sensitivity (LPS)

Variable	With LPS (n = 12)	Without LPS (n = 64)	p-value
Age (years)	63.0 ± 10.3	65.9 ± 14.8	0.292
Sex (M/F)	7 M (58.3%) / 5 F (41.7%)	23 M (35.9%) / 41 F (64.1%)	0.362
Duration of diabetes (years)	20.5 ± 10.1	17.0 ± 9.2	0.121
BMI (kg/m ²)	30.5 ± 6.3	29.7 ± 6.8	0.365
Systolic BP (mmHg)	141.75 ± 23.9	130.3 ± 18.4	0.037
Diastolic BP (mmHg)	81.9 ± 13.11	79.9 ± 12.2	0.304
HbA1c (%)	10.4 ± 2.07	9.2 ± 1.87	0.024

It was observed that 83.3% (n = 10) of patients with LPS and 60.9% (n = 39) of those without LPS used insulin in combination with other antidiabetic agents for glycemic control.

Regarding the type of nerve fibers affected among patients with LPS, small fiber involvement was found in 25% (n

= 3), large fiber involvement in 8.4% (n = 1), and both types in 66.6% (n = 8). Findings from the Neuropathy Symptom Score (NSS) and Neuropathy Impairment Score (NIS) for patients with and without LPS are shown in Table 2.

TABLE 2 - Distribution of 76 patients with type 2 diabetes according to Neuropathy Symptom Score (NSS) and Neuropathy Impairment Score (NIS)

Classification	With LPS (n = 12)	Without LPS (n = 64)
NSS		
Mild	3 (25%)	12 (18.8%)
Moderate	2 (16.6%)	14 (21.9%)
Severe	6 (50%)	15 (23.4%)
Not evaluated*	1 (8.4%)	23 (35.9%)
NIS		
Mild	2 (16.6%)	6 (9.3%)
Moderate	8 (66.8%)	3 (4.7%)
Not classified**	2 (16.6%)	55 (86.0%)

* NSS not evaluated due to absence of symptoms during anamnesis.

** NIS not classified due to scores below minimum (0–2) or normal neurological exam.

As for the dorsalis pedis and posterior tibial pulses, 41.7% (n = 5) of patients with LPS had normal pulses, while 58.3% (n = 7) presented diminished pulses on physical examination. Among patients without LPS, 73.4% (n = 47) had normal pulses and 26.6% (n = 17) had diminished pulses.

Systemic arterial hypertension and dyslipidemia were present in 91.6% (n = 11) of patients with LPS and in 90.6% (n = 58) and 92.2% (n = 59), respectively, of patients without LPS.

Diabetic kidney disease (DKD) and diabetic retinopathy were observed in 75.0% (n = 9) and 33.3% (n = 4) of patients with LPS, and in 53.1% (n = 34) and 21.9% (n = 14) of patients without LPS, respectively.

Smoking and alcohol consumption were observed in 58.4% (n = 7) and 8.4% (n = 1) of patients with LPS, and in 50% (n = 32) and 17.2% (n = 11) of those without LPS, respectively.

Previous cardiovascular disease was reported by 50.0% (n = 6) of patients with LPS and 37.5% (n = 24) of those without LPS. Among those with LPS, three (50%) had a history of acute myocardial infarction (AMI), four (75%) had heart failure (HF), and three (50%) had arrhythmias. Among patients without LPS, 10 (41.6%) had HF, 13 (54.1%) had coronary insufficiency (of whom 8 had prior AMI), and 8 (33.3%) had arrhythmias.

Ulceration of the lower limb, history of amputation, and intermittent claudication were detected in 8.4% (n = 1), 16.7% (n = 2), and 25% (n = 3) of patients with LPS, and in 9.3% (n = 6), 1.5% (n = 1), and 21.8% (n = 14) of those without LPS, respectively.

DISCUSSION

This study investigated the presence of Loss of protective sensitivity (LPS) in 76 patients with type 2 diabetes mellitus

(T2DM) undergoing outpatient follow-up at the endocrinology department of a tertiary health care service in the interior of São Paulo, Brazil. It also analyzed correlations between LPS and the type of affected nerve fibers (small or large), as well as with comorbidities and other risk factors for chronic complications related to diabetes.

The study population was predominantly composed of women over 60 years of age with a diabetes duration greater than 15 years. The average time since diagnosis among this group was similar to that reported in other tertiary services in Brazil¹³. The predominance of women may reflect the greater tendency of females to seek medical care. A high prevalence of poor glycemic control was also observed, as only 14.5% of the patients had HbA1c levels below 7%, in line with findings from the international literature^{14,15}. In Brazil, studies indicate that only around 20% of T2DM patients maintain HbA1c levels below this threshold^{15,16}.

Despite the poor glycemic control and long disease duration, the prevalence of LPS found in this sample was relatively low (15.8%), lower than expected based on the literature, especially considering the tertiary care setting. Toscano et al.¹⁷ reported an LPS prevalence of 53.3% in a service in northeastern Brazil. A possible explanation for the lower prevalence observed in the present study is the fact that data collection occurred during the COVID-19 pandemic—a period during which elective consultations significantly decreased, particularly among patients with more severe conditions and multiple diabetes-related comorbidities.

One relevant clinical aspect of T2DM and poor glycemic control is the frequent presence of excess body weight. In this sample, the mean BMI was on the borderline between overweight and obesity, which aligns with existing literature, given that

excess weight is a known factor in the pathophysiology of T2DM¹⁰. In fact, approximately 90% of patients with T2DM are overweight¹¹.

Another important observation was the higher proportion of LPS patients requiring insulin therapy to achieve glycemic control compared to those without LPS. Additionally, LPS patients tended to have a longer duration of diabetes. A statistically significant difference in HbA1c levels was found between the groups, with higher values in the LPS group, indicating worse glycemic control. This is noteworthy, as chronic hyperglycemia and longer disease duration are key indicators for initiating insulin therapy in T2DM. According to the literature, insulin is typically required 10 to 15 years after diagnosis. Furthermore, patients with longer disease duration and poor glycemic control are more prone not only to insulin dependence but also to chronic complications of hyperglycemia, such as peripheral neuropathy¹⁸.

In the current study, most patients with LPS exhibited involvement of both small and large nerve fibers, indicating more advanced neuropathic damage due to prolonged poor glycemic control. This finding is consistent with Neuropathy Impairment Score (NIS) results, which showed that approximately two-thirds of LPS patients had scores consistent with moderate to severe neuropathy. These patients are, therefore, at nearly six times greater risk of developing lower limb ulcers¹⁹.

As previously mentioned, chronic hyperglycemia is associated with the onset and progression of diabetes-related complications, both microvascular and macrovascular. Moreover, patients with long-standing poor glycemic control often present multiple complications simultaneously^{20,21}. In this study, at least two chronic complications were identified in 40.8% of the sample. A higher proportion of patients with LPS had diminished peripheral pulses (dorsalis pedis and posterior tibial) compared to those without LPS. This suggests the concurrent presence of peripheral neuropathy (a microvascular complication) and peripheral arterial disease (a macrovascular complication), both of which contribute to the pathophysiology of diabetic foot²².

In addition to peripheral arterial disease, other macrovascular complications such as coronary artery disease and ischemic cerebrovascular disease were also evaluated. The prevalence of prior cardiovascular disease was higher among patients with LPS than those without, in agreement with the literature, which reports an association between diabetic peripheral neuropathy and cardiovascular disease²³.

There are also reports of associations between diabetic peripheral neuropathy and diabetic retinopathy and nephropathy. Tesfaye et al.²⁴ found a significant correlation between diabetic retinopathy and the presence of LPS. Similarly, Deery et al.²⁵ found an association between diabetic kidney disease and LPS and showed that patients with end-stage kidney disease had a tenfold higher risk of amputation compared to those without this complication²⁶.

Smoking may contribute to peripheral neuropathy through multiple mechanisms of neuronal injury, including the local generation of advanced glycation end products, oxidative stress, reduced insulin signaling, endoplasmic reticulum stress, mitochondrial dysfunction, and DNA damage leading to neuronal

apoptosis²⁷. In the present study, the percentage of smokers was higher among patients with LPS compared to those without, consistent with findings by Ramos et al.²¹, who also observed an association between smoking and LPS.

In this study, a history of amputation was reported in two of the 12 patients with LPS (16.7%), while only one (1.6%) of the 64 patients without LPS had a prior amputation. Considering that amputation is one of the most serious outcomes associated with both peripheral neuropathy and peripheral arterial disease, this finding is significant. Moreover, literature suggests that patients with LPS have a higher frequency of amputations compared to those without sensory loss. In an observational study of diabetic patients by Canata et al.²⁹, the reported amputation rates were 17.5% in those with LPS and 7.9% in those without.

Regarding cholesterol levels, the proportion of patients with dyslipidemia was similar between the groups with and without LPS. Canata et al.²⁹ also found no significant association between dyslipidemia and LPS in diabetic patients, although contrasting results have been reported by Wiggin et al.³⁰, highlighting this as an ongoing topic of discussion in the literature.

Similarly, the prevalence of arterial hypertension was comparable between groups. This result was somewhat surprising, as hypertension is generally considered a major risk factor for diabetic peripheral neuropathy, as shown by Ramos et al.²¹. Once again, the authors believe that the absence of more severe and frail patients from consultations during the COVID-19 pandemic may have influenced these findings.

CONCLUSION

Although the COVID-19 pandemic may have directly impacted the lower prevalence of LPS observed in this sample—considering that patients with more severe conditions and a greater number of diabetes-related comorbidities were less likely to attend routine outpatient consultations during this period—several noteworthy findings emerged.

It is particularly relevant that this tertiary care service dealt with a predominantly elderly population, with long-standing diabetes, overweight, and poor metabolic control.

Among patients with LPS, there was a tendency toward simultaneous involvement of both small and large nerve fibers, indicating a more severe degree of peripheral neuropathy. This finding requires heightened attention from the clinical team responsible for their care. Furthermore, the data showed a trend toward an association between LPS and other complications of T2DM, such as peripheral arterial disease, diabetic retinopathy, and diabetic kidney disease (DKD), as well as other risk factors for LPS and diabetic peripheral neuropathy, including smoking and a history of amputation.

Ultimately, these findings reinforce the need to improve care for patients with T2DM at the primary and secondary health care levels, aiming to prevent the development and/or progression of chronic diabetes-related complications. Moreover, screening for LPS would be extremely important in these settings to optimize referrals to tertiary services, particularly for patients with microvascular and macrovascular complications, and especially those with a history of amputation.

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