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Abnormalities of plantar pressure distribution in early, intermediate, and late stages of diabetic neuropathy

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ABSTRACT

Inconsistent findings with regard to plantar pressure while walking in the diabetic population may be due to the heterogeneity of the studied groups resulting from the classification/grouping criteria adopted. The clinical diagnosis and classification of diabetes have inherent uncertainties that compromise the definition of its onset and the differentiation of its severity stages. A fuzzy system could improve the precision of the diagnosis and classification of diabetic neuropathy because it takes those uncertainties into account and combines different assessment methods. Here, we investigated how plantar pressure abnormalities evolve throughout different severity stages of diabetic polyneuropathy (absent, $n = 38$; mild, $n = 20$; moderate, $n = 47$; severe, $n = 24$). Pressure distribution was analysed over five areas while patients walked barefoot. Patients with mild neuropathy displayed an increase in pressure–time integral at the forefoot and a lower peak pressure at the heel. The peak and pressure–time integral under the forefoot and heel were aggravated in later stages of the disease (moderate and severe) compared with early stages of the disease (absent and mild). In the severe group, lower pressures at the lateral forefoot and hallux were observed, which could be related to symptoms that develop with the aggravation of neuropathy: atrophy of the intrinsic foot muscles, reduction of distal muscle activity, and joint stiffness. Although there were clear alterations over the forefoot and in a number of plantar areas with higher pressures within each severity stage, they did not follow the aggravation evolution of neuropathy classified by the fuzzy model. Based on these results, therapeutic interventions should begin in the early stages of this disease to prevent further consequences of the disease.

1. Introduction

Plantar pressure distribution has been widely investigated in patients with diabetic polyneuropathy (DN) for decades because of its relationship to tissue breakdown risk and plantar ulcer formation [1–4]. Although this relationship is well accepted by clinicians and researchers, there are still inconsistencies regarding the number of compromised foot areas, which areas are the most compromised, and when the alterations in peak pressure and pressure–time integral begin during diabetes progression. Some studies showed an increase in pressure only over the forefoot [5,6]. Some studies showed an increase in pressure over the entire plantar area without highlighting any one area [7–9], and other studies did not indicate which plantar areas experienced higher pressures [10,11]. Another factor that contributes to the inconsistent findings in this area is the classification criteria for the patients included in these previous studies. Patients without DN may or may not have been considered neuropathic, and different degrees of DN might have been included in the same group.

Inconsistent findings with regard to plantar pressure distribution while walking in the diabetic population may be due to the heterogeneity of the studied groups resulting from the classification/grouping criteria adopted. Patients without neuropathy may or may not have been considered neuropathic, and different degrees of neuropathy may have been included in the same group.

Regarding the grouping criteria, there are rarely two patients with exactly the same symptoms due to the continuous evolution of DN. Currently, the clinical classification of these patients is based

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on a clear logic—i.e., either they have DN or not—and this distinction is not easy to make. There are many clinical instruments for classifying DN and each one evaluates different aspects of the disease, such as symptoms; pain, tactile, and thermal sensitivity; vibratory perception; and tendon reflex. In addition to the clinical assessment, a nerve conduction study is an objective and reliable tool for diagnosing nerve damage, but it does not always correlate well with symptoms and signs [12].

DN has an insidious onset, manifesting itself in different ways and at different stages of the disease. Even if clinical examinations combine different types of assessments, there are no objective criteria for interpreting the association of those results. This leaves the diagnosis to either a subjective or semi-objective decision by a health professional or a grading system that uses a simple sum of the output scores. In clinical practice, the fuzziness nature of the decision-making process for diagnosis and treatment, which is based on the expertise of the health professional and the interpretation of many aspects of a patient, led us to evaluate patient gait using a different grouping logic.

For plantar pressure studies, participant groups are usually divided into DN groups with or without ulceration. However, patients with DN have wide ranging clinical statuses; thus, a DN group will include patients who present with only a few neuropathy symptoms combined with incipient somatosensorial losses and patients with a complete absence of plantar sensitivity and a very advanced foot impairment with muscle atrophy [8,13–15]. Thus, a DN group is highly heterogeneous, especially when joint and muscle functions are not described or used to classify the foot areas that are expected to be impaired and influence plantar pressure behaviour in severe cases.

From the beginning of plantar pressure distribution description in this population [16], diverse groups have been studied. Several studies have observed differences in peak pressure between groups [5,17,18]; however, these studies differ in the way they grouped and compared the individuals. Pataky et al. [5] and Bennetts et al. [19] studied diabetic individuals who were supposedly without DN. Conversely, Sawacha et al. [8], Guiotto et al. [13], Owings et al. [17] and Sacco et al. [14] studied only patients with DN but did not distinguish their severity status. Bacarin et al. [9] and Giacomozzi et al. [15] compared two subsets of DN patients divided into groups based on their history of previous ulceration. The studies by Caselli et al. [18] and Pham et al. [11] were the only ones that divided the diabetic subjects into four severity degrees in a clear manner using a classification procedure based on a simple sum of questionnaire output scores [11,20].

In the context presented, a linguistic fuzzy model is an option for classification, because it addresses issues of uncertainty in the allocation of elements in determined sets [21]. This type of model allows us to simulate the cognitive aspect of the decision-making process performed by healthcare specialists and to translate subjective opinions into objective criteria [21], and it is capable of objectively measuring a subjective judgement. Fuzzy logic has already been applied to other diseases, such as breast cancer [22], that have uncertain boundaries for the different stages of disease severity.

Because determining DN stage can indicate plantar pressure patterns, the identification of which is crucial for implementing early preventive strategies, we investigated the plantar pressure distributions of patients with DN of differing severity stages while they walked. DN severity was classified using a fuzzy model (artificial intelligence) developed previously [23]. We hypothesised that patients with later stages of DN would have a greater magnitude of pressure related-variables over the anterior parts of the foot compared with patients with early and intermediate stages of DN.

2. Methods

For this study, 129 subjects were recruited from three different settings: (i) the database of the Physical Therapy, Speech and Occupational Therapy Department, (ii) a primary care centre (from the Medical School), and (iii) from a National Diabetes Association. Patients were continuously recruited, assessed and allocated into four groups during a period of 6 months. The final groups were diabetic subjects with the absence of neuropathy (D, $n = 38$), mild neuropathy (MiN, $n = 20$), moderate neuropathy (MoN, $n = 47$), and severe neuropathy (SN, $n = 24$) (Table 1). All subjects were informed of the research procedures and signed an informed consent approved by the local ethics committee (Comitê de Ética em Pesquisa da Faculdade de Medicina USP, protocol number 320/10).

The classification into four groups was performed using a fuzzy expert system proposed by Watari et al. [23]. It uses three modalities of DN assessments validated by the International Diabetes Federation as inputs: symptoms (based on the MNSI questionnaire), tactile sensitivity (10 g Semmes–Weinstein monofilament), and vibratory perception (128 Hz tuning fork). This fuzzy model was built based on the knowledge of experts in evaluating DN signs and symptoms. The combination of each assessment resulted in a DN degree that was represented by a number between 0 and 10 and was calculated by the centre of area defuzzification method. This value was used to sort the participants into the disease classes, as follows: (i) 0–2.5: absent neuropathy; (ii) 2.6–4.5: mild neuropathy; (iii) 4.6–7.5: moderate neuropathy; and (iv) 7.6–10: severe neuropathy. Patients with a history of previous plantar ulceration were included in the severe neuropathy group. These classifications using this fuzzy model were strongly correlated with the classifications made by a group of specialists (Pearson's coefficient $r = 0.943$) and the accuracy level of the fuzzy model was considered excellent (ROC curve area = 0.985). More details of the model can be found in a publication by Watari et al. [23].

The eligibility criteria were as follows: presence of diabetes mellitus (types 1 or 2); under 65 years of age; ability to walk freely without any assistive device; absence of active ulcers at the time of

Table 1
Mean (standard deviation) or median (interquartile interval) of socio-demographic and clinical data of the studied groups: diabetic subjects without neuropathy (D), with mild neuropathy (MiN), moderate neuropathy (MoN) and severe neuropathy (SN).

	D ($n = 38$)	MiN ($n = 20$)	MoN ($n = 47$)	SN ($n = 24$)
Sex (% male)	52	17	53	67
Age (years)	56.5 ± 7.0	56.4 ± 6.2	58.8 ± 4.9	58.5 ± 5.1
Body mass index (m/kg^2)	28.7 ± 4.4	29.5 ± 4.3	29.4 ± 4.9	28.2 ± 3.5
Fast glycaemia (mg/dL)	147.2 ± 59.9^{a}	172.2 ± 77.9^{b}	$186.2 \pm 91.6^{a,b}$	189.8 ± 91.6
Diabetes duration (years)	$7.2 \pm 6.2^{c,d,e}$	9.0 ± 7.7^{c}	13.7 ± 7.7^{d}	13.0 ± 7.1^{e}
Gait speed (m/s)	1.86 (0.35)	1.80 (0.25)	1.91 (0.36)	1.83 (0.34)

ANOVA test, followed by Newman Keuls post hoc tests ($p < 0.05$).
Symbols represent statistically significant difference between groups. Legend of symbols: (a) $p = 0.007$; (b) $p = 0.03$; (c) $p = 0.0004$; (d) $pp < 0.001$; (e) $p = 0.0005$.