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Comparison of static podobarography between diabetic and non-diabetic neuropathy patients

Comparação da podobarografia estática entre pacientes com neuropatia diabética e não diabéticos

Comparación de podobarografía estática entre pacientes diabéticos y no diabéticos con neuropatía

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Letícia Carollyne Galvão
ORCID: https://orcid.org/0000-0001-5928-0973
State University of Ponta Grossa, Brazil
E-mail: leticiacg.galvao@gmail.com
Rodolfo Martins Kravutschke
ORCID: https://orcid.org/0000-0001-8737-8564
State University of Ponta Grossa, Brazil
E-mail: rodolfo_mk@hotmail.com
Ricardo Zanetti Gomes
ORCID: https://orcid.org/0000-0002-9651-8298
State University of Ponta Grossa, Brazil
E-mail: zanetticons@uol.com.br
Gabriel Farhat
ORCID: https://orcid.org/0000-0002-1790-2540
State University of Ponta Grossa, Brazil
E-mail: gabrielfarhat@yahoo.com.br
André Amaro Mamédio dos Santos
ORCID: https://orcid.org/0000-0003-1077-0095
State University of Ponta Grossa, Brazil
E-mail: andre.amaro.mamedio@gmail.com

Abstract
Objective: To compare the pedobarographic findings of plantar pressure distribution in individuals with typical diabetic neuropathy with non-diabetic individuals. *Methods*: 25 patients with typical diabetic neuropathy were randomly selected and another 25 non-diabetic patients were selected electively. After undergoing clinical examination according to the report and recommendations of the San Antonio Conference on Diabetic Neuropathy, glycated hemoglobin (HbA1c) and static podobarography tests were performed to identify pressure points in the feet and distribution of plantar pressure. *Results*: The mean age of 62.24 (± 9.01) years, mean body mass index (BMI) of 29.69 (± 5.9) Kg / m² and mean HbA1c of 8.9 (± 3.29% of non-diabetic patients, mean age was 61.04 (± 9.69). The mean hallucin pressure in the diabetic group was 111.16 (± 64.25) kPa, in the non-diabetic group was 78.91 (± 4.43) Kg / m² and HbA1c was 5.3 (± 0.24) ± 38.48) kPa and the comparison showed ap = 0.015. *Conclusion*: An increase in pressure was found in the hallux region of diabetic patients when compared to non-diabetic patients.
Keywords: Diabetic neuropathies; Diabetes complications; Case-control studies; Biomechanical phenomena.

Resumo
Objetivo: Comparar os achados podobarográficos de distribuição da pressão plantar em indivíduos portadores de neuropatia diabética típica com indivíduos não diabéticos. *Metodologia*: Foram selecionados randomicamente 25 pacientes com neuropatia diabética típica e eletivamente 25 pacientes não diabéticos, após passar por exame clínico conforme os Report and Recommendations of the San Antonio Conference on Diabetic Neuropathy foram realizados exames de hemoglobina glicada (HbA1c) e podobarografia estática, para identificar os pontos de pressão nos pés e a distribuição da pressão plantar. *Resultados*: A amostra dos pacientes diabéticos teve média de idade de 62,24(±9,01) anos, média de índice de massa corporal (IMC) de 29,69(±5,9)Kg/m² e média de HbA1c de 8,9(±3,29)%, dos não diabéticos a média de idade foi de 61,04(±9,69) anos, média de IMC de 28,73(±4,43)Kg/m² e de HbA1c 5,3(±0,24)%. A média da pressão no hálux no grupo diabético foi de 111,16(±64,25)kPa, no grupo não diabético foi de 78,91(±38,48)kPa e a comparação demonstrou um p=0,015. *Conclusão*: Encontrou-se aumento da pressão na região do hálux dos pacientes diabéticos quando comparados com os não diabéticos.
Palavras-chave: Neuropatias diabéticas; Complicações do diabetes; Estudos de casos e controles; Biomecânica.

Resumen

Objetivo: Comparar los hallazgos podobarográficos de la distribución de la presión plantar en individuos con neuropatía diabética típica con individuos no diabéticos. *Método*: Se seleccionaron aleatoriamente 25 pacientes con neuropatía diabética típica y electivamente 25 pacientes no diabéticos. Luego de someterse a un examen clínico de acuerdo con el Informe y Recomendaciones de la Conferencia de San Antonio sobre Neuropatía Diabética, se realizó hemoglobina glucosilada (HbA1c) y podobarografía estática para identificar los puntos de presión en los pies y la distribución de la presión plantar. *Resultados*: La muestra de pacientes diabéticos tuvo una edad media de 62,24 (±9,01) años, índice de masa corporal (IMC) medio de 29,69 (±5,9)Kg/m² y HbA1c media de 8,9(±3,29)%, la edad media de los no diabéticos fue 61,04(±9,69) años, IMC medio de 28,73(±4,43)Kg/m² y HbA1c 5,3(±0,24)%. La presión media en el hallux en el grupo de diabéticos fue de 111,16(±64,25)kPa, en el grupo de no diabéticos fue de 78,91(±38,48)kPa y la comparación mostró una p=0,015. *Conclusión*: Fue encontrado un aumento de la presión en la región del dedo gordo de los pacientes diabéticos en comparación con los pacientes no diabéticos.

Palabras clave: Neuropatías diabéticas; Complicaciones de la diabetes; Estudios de casos y controles; Biomecánica.

1. Introduction

Diabetes Mellitus (DM) is one of the main chronic diseases affecting about 422 million people in the world, being a current ongoing epidemic responsible for 1.6 million annual deaths (Malta et al., 2022; SBD, 2016; Santos et al., 2015). The Brazil is the fifth country in the world in number of adults with DM (Leitao et al., 2021). The increase in the prevalence of DM has put pressure on the costs of health systems and the need for preventive strategies aimed at controlling the disease (Andrade et al., 2019). Long-term hyperglycemic status has an important role in the pathogenesis of disease complications. In addition, chronic complications result in several degrees of disability: diabetic retinopathy, diabetic arteriopathy, diabetic nephropathy and diabetic neuropathy (ADA, 2014; Tschiedel, 2014; Muzy et al., 2021).

Diabetic neuropathy is the most common neuropathy in the Western world (Banchellini et al., 2008) and the main cause of non-traumatic lower limb amputation, to more than 70% of the total, therefore early diagnosis and prevention of ulceration and amputation remains a challenge (Santos et al, 2015). In this scenario, we have the podobarography, a computerized examination technique that allows to evaluate the plantar pressure, considered an useful tool because the neuropathic patients have structural abnormalities, which associated with loss of sensibility, compromise the entire biomechanics of the feet, causing changes in gait and plantar pressure, increasing the risk of callosities and diabetic foot ulceration (McLellan et al., 2007; Rodrigues et al., 2011; Hills et al., 2001; Lott et al., 2008; Vela et al., 1998).

The aim of the present study is to compare the podobarographic studies of distribution of plantar pressure in individuals with diabetic neuropathy with non-diabetc individuals.

2. Methodology

Study type

The Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) iniciative guideline was used to relate this study.

The Certificate of Presentation for Ethical Appreciation (CAAE) number is 26814314.9.0000.0105. This essay is a cross-sectional case-control study. Diabetic patients were selected from eight Basic Health Units (BHUs) participants in the health work education (HWE) program of the State University of Ponta Grossa (UEPG), from a previous total of 1916 diabetics, from a previous randomized epidemiological study, 25 patients with diabetic neuropathy.

Sample

The sample had a total of 50 patients, of whom 25 were diabetic and 25 were non-diabetics. Patients had been considered diabetic those who are enrolled in the BHUs and accompanied by family health teams as having DM2 in treatment

with oral or injectable hypoglycemic agents, or patients not treated with glycated hemoglobin (HbA1c) above 6.5% (SBD, 2016).

Regarding the 25 non-diabetic individuals were invited to participate in the study, being considered those with HbA1c below 5.7% (SBD, 2016) and respecting the characteristics of diabetic patients in order to comparable. All of the patients signed the informed consent form. The research was approved by the Research Ethics Committee of UEPG (REC-UEPG).

Inclusion and exclusion criteria

Patients with motion disorders, history stroke, previous orthopedic surgeries or ulceration and amputation of lower limbs, pregnant women, patients in whom it was not possible to complete and adequate physical examination, patients with equilibrium, where its stabilometry had a variation greater than 4 centimeters in the podobarometric examination or patients who could not adequate to the podobarographic examination of the feet, were excluded. Also excluded patients who had another cause of neuropathy, patients who did not attend for laboratory or non-laboratory examinations and who have opted for give up the research, regardless of the group to which they belonged.

Clinical methods

The clinical records of the patients who entered the sample with the objective description of each patient's data regarding sex, age, occupation, marital status and schooling.

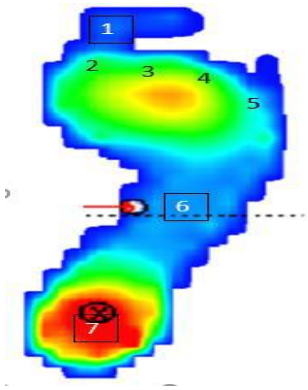
It was performed the Michigan Neuropathy Screening Instrument (MNSI) (Alex et al., 2010). The exam has had performed according to the Report and Recommendations of the San Antonio Conference on Diabetic Neuropathy (Sarnow et al., 1994). The data was collected and recorded on the clinic Data collection and physical examination were carried out by themselves. In addition, after the clinical evaluation, complementary tests were performed: hemogram, HbA1c, fasting glycemia, and podobarography.

Podobarography

Incidentally, podobarography was performed with positioning, orientation and individually data collection, in comfortable clothing, barefoot parallel and arms along the body, keeping the eye horizontal in the condition of eyes open, non-contact support. Each individual was instructed to position themselves on the pressure platform, placed one meter away from the wall while the computerized evaluation ran for 30 seconds. Data processing of static foot pressure analysis was obtained by means of the podobarometry composed of a platform of force of quartz with piezoelectric properties, with a size of 575 X 450 X 25mm, with 2704 and a sampling frequency of 150 HZ, which podobarometric analysis of the pressure discharge and the oscillations of posture. The values were collected and recorded by the FootWork program.

The podobarometric data collected were maximum pressure at one point maximum of each foot (in kPa), plantar contact surface (in cm^2), the dominance of between the two feet (in %), the difference in pressure exerted on the rear foot and the forefoot (in%) - anteroposterior pressure distribution (APPD), the shape of the arch plantar (normal, flat or cavus) and the maximum pressure exerted in each region of the foot, being divided into seven parts according to Figure 1.

Figure 1 - Representation of plantar pressure distribution regions.



Legend: 1 – hallux; 2 – 1st metatarsal head; 3 – 2nd metatarsal head; 4 – 3rd and 4th metatarsal heads; 5 – 5th metatarsal head; 6 – midfoot; 7 – heel (hindfoot). Source: Authors.

Statistics

After the results, the patients were divided into two groups, one of diabetics and one of non-diabetics for data comparison. The groups were considered comparable according to gender, age and body mass index (BMI).

For analysis of Anteroposterior Pressure Distribution, it was considered normal the distribution of 38 to 42% in the forefoot and 58 to 62% in the hindfoot, as found described for the normal population (Merolli & Uccioli, 2005).

The information was stored and analyzed through the MedCalc program Statistical Software version 16.4.3 (MedCalc Software bvba, Ostend, Belgium; https://www.medcalc.org; 2016), with the T-Student test for comparison of the means of the groups, Fisher's Exact Test for comparison of proportions between the groups and Pearson's Linear Correlation for parametric, considering p significant less than or equal to 0.05.

3. Results

The sample of 50 patients, in which the female majority, had on average of the age of the diabetic of 62.24 ± 9.01 years and the non-diabetic was of 61.04 ± 9.69, showing that the groups are similar in this variable (p = 0.727). Most people in the sample, in both groups, is sedentary and non-smoker. Diabetic patients, have a positive family history for diabetes and some deformity in the feet, such as areas of pre-ulceration, bone prominence abnormality, callosity and alterations of the plantar arches (claw foot or midfoot arthropathy) at the time of examination. The mean time of diagnosis of diabetes was 9 ± 8.65 years. Clinical and sociodemographic data can be observed in the chart 1. Regarding the anthropometric data, the mean BMI was 29.69 ± 5.9kg / m² for non-diabetics and 28.73 ± 4.43 kg / m² for diabetics (p = 0.155). The distribution in BMI groups can be seen in Figure 2.

Chart 1. Clinical and sociodemographic data of analyzed samples.

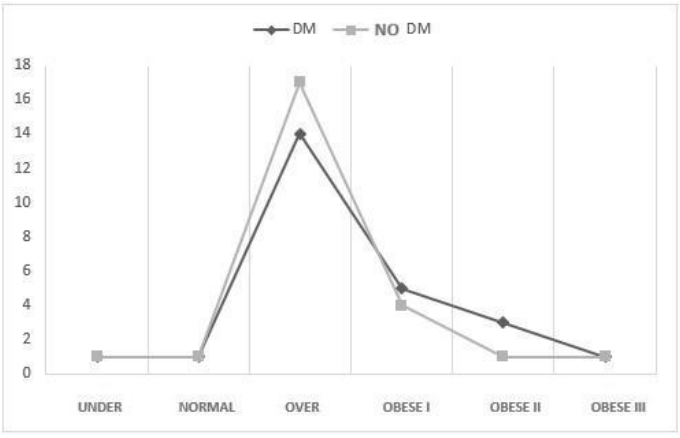
Variables	Total			Type 2 Diabetes				
				Yes (n=25)		No (n=25)		
	n	%		n	%	n	%	*p*
Gender								1,0*
Female	27	54		14	56	13	52	
Male	23	46		11	44	12	48	
Scholarity								<0,005*
Not Literate	2	4		2	8	0	0	
Elementary School	29	58		20	80	9	36	
High School	9	18		1	4	8	32	
College	10	20		2	8	8	32	
SAH								<0,001*
Yes	29	58		21	84	8	32	
No	21	42		4	16	17	68	
Smoking								1,0*
Yes	2	4		1	4	1	4	
No	32	64		16	64	16	64	
Former smoker	16	32		8	32	8	32	
Dyslipidemia								0,02*
Yes	29	58		19	76	10	40	
No	21	42		6	24	15	60	
Sedentary Lifestyle								1,0*
Yes	33	66		17	68	16	64	
No	17	44		8	32	9	36	
Type 2 Diabetes in family history								<0,005*
Yes	30	60		20	80	10	40	
No	20	40		5	20	15	60	
Deformities								<0,001*
Yes	14	28		14	56	0	0	
No	36	72		11	44	25	100	

Legend: SAH - Systemic Arterial Hypertension.
**Fisher's exact test*

Source: Authors.

According to chart 1, a higher prevalence of SAH, dyslipidemia, deformities and type 2 diabetes in family history was observed in patients with DM, as well as a lower level of scholarity in this group.

Figure 2. Group distribution according to BMI categories.



Legend: DM – diabetes mellitus. Source: Authors.

The Figure 2 shows the predominance of overweight in the two groups studied.

The treatment measures for Diabetes Mellitus adopted by the patients diabetics varied in monotherapy with oral antidiabetics, association of hypoglycemic agents and insulin therapy with the majority of patients - 84% (n = 21) use of Metformin alone or in combination with another medicine. Data from laboratory tests and podobarographic data are described in chart 2 and chart 3.

Chart 2. Laboratory tests of studied samples.

Parameter		**Type 2 Diabetes**		***p***
		Yes (n=25)	***No (n=25)***	
Hemoglobin	Average ± SD	13,8±1,39	14,428±1,46	0,825*
Fasting Glucose	Average ± SD	162,8±73,08	96,56±8,73	<0,001*
HbA1c	Average ± SD	8,9±3,29	5,3±0,24	<0,001*

Legend: HbA1c – glycated hemoglobin; SD - standard deviation.
**Student's t-test*

Source: Authors.

The chart 2 shows a significant increase in fasting glucose and HbA1c values in patients with DM.

Chart 3. Podobarometric data of studied pacients.

Variables		**Type 2 Diabetes**		***p***
		Yes (n=25)	**No (n=25)**	
Pmax (kPa)[1]	Right Left	241,68±51,57 224,57±40,62	273,61±62,52 233,9±41,84	0,352* 0,886*
Surface[1] (cm²)	Right Left	127,13±16,52 120,547±16,2	124,81±14,73 126,12±16,78	0,580* 0,866*
Dominance[2]	Normal Right Left	5 (20%) 18 (72%) 2 (8%)	10 (40%) 12 (48%) 3 (12%)	0,240**
Forefoot and Hindfoot[2]	Normal Altered	5(20%) 20(80%)	6(20%) 19(80%)	1,0**
Plantar arch[2]	Normal Planar Hollow	7(28%) 16(64%) 2(8%)	12(48%) 13(52%) 0(0%)	0,163**

Legend: Pmax – maximum pressure; [1]Average±SD (standard deviation), [2]n(%).
**Student's t-test*
***Fisher's exact test*

Source: Authors.

As for the podobarometric data presented in chart 3, there was no statistically significant difference for the analyzed parameters.

The group of diabetic patients had a mean BMI of 28.7 ± 5.9 kg / m² and a mean maximum plantar pressure of 256.9996 ± 41.6kPa. The coefficient of Pearson's correlation was r = 0.265 and was not statistically significant (p = 0.119). The non-diabetic group had a mean BMI of 29.69 ± 5.9 kg / m² and a mean maximum plantar pressure of 263.6936 ±

40.51kPa. The correlation coefficient of Pearson was r = 0.52 and the correlation was statistically significant (p = 0.0074).

The mean maximum pressure per region can be observed in chart 4.

Chart 4. Comparison between maximum pressure exerted in each region of the feet.

Variables		**Type 2 Diabetes**		***p***
		Yes (n=25)	**No (n=25)**	
Pmax by Regions	1	111,16±64,25	78,91±38,48	0,015*
	2	118,4±39,05	110,17±33.79	0,484*
	3	133,148±40,6	122,13±39,06	0,851*
	4	117,76±41,59	120,08±32,86	0,256*
	5	76,68±33,7	80,95±40,92	0,348*
	6	136,64±31,47	116,75±26,06	0,362*
	7	244,1±54,52	241,72±46,91	0,467*
Legend: Pmax - maximum pressure. **Student's t-test*				

Source: Authors.

In chart 4, there was statistical significance in the hallux region (region 1) with p of 0.015.

4. Discussion

Diabetic neuropathy usually causes irreversible neural lesions, so the best approach to this disease, as well as non-diabetic patients neuropathy, is the secondary prevention, performing a glycemic control adequate to the during the course of the disease, in order to avoid the onset of neuropathy as well as any complications of diabetes (Yu et al., 2011).

Considering the relevance of this pathology and the risks of ulceration and amputation associated with diabetic neuropathy and the relationship with the increase in plantar pressure, podobarography becomes important to evaluate the pressure distribution in diabetic patients and to compare with non-diabetic individuals diabetics to correlate the findings with the neuropathic condition, thus obtaining a preventive clinical alternative in the development of these conditions (Herman et al., 2012; Cavanagh et al., 1987).

This study made use static podobarography opting for this concept due to greater ease of examination, availability, ease of applied method and without large statistical differences in the results of dynamic podobarography, although most of the studies had used the dynamic way to assess the footprint of diabetic patients (Mclellan et al., 2007).

The sample of diabetic patients in this research was demonstrated according to the population sample found in other studies with patients with diabetic neuropathy, as well as mean BMI, diabetes and mean levels of HbA1c (Santos et al., 2015; Herman et al., 2012; Rodrigues et al., 2011). The sample of non-diabetic patients was similar in the variables of age, sex and BMI, keeping the groups homogeneous, with statistically significant difference in HbA1c values and fasting glycemia, the absence of disease, according to the current diagnostic criteria of the Brazilian Diabetes Society (SBD, 2016).

The highest proportion of diabetic individuals with arterial hypertension systemic and dyslipidemia when compared with non-diabetic patients observed in this study reinforces the association of DM with Metabolic Syndrome described in the literature. A positive family history of DM2 presented a similar prevalence studies to assess risk factors for disease (Hills et al., 2001; Lott et al, 2008).

Diabetic patients in our sample had an average maximum pressure higher than non-pathological patients found in the literature (Mclellan et al., 2007; Vela et al., 1998), with studies demonstrating increased pressure in diabetic patients (Sacco et

al., 2009). However, when compared to nondiabetic patients in our sample, there was no significant difference between mean maximum pressure. A hypothesis for it is that the pressure changes in the feet of the individuals increase along the plantar surface as BMI, resulting in a maximum maximum pressure (Tuna et al., 2004; Abbott et al., 2002).

With regard to the plantar arch, the two groups of our study presented similar frequencies of normal, flat or caval arch. Studies show that in diabetic subjects, the higher frequency is of flat in more advanced cases and with a longer time of disease (Alex et al., 2010).

When comparing the increase of the BMI with the increase of the maximum pressure in the group of diabetics in our sample, there was no statistical significance. However, in the non-diabetic group, the correlation between BMI and increased plantar was moderate and statistically significant. These data are in agreement with findings from the literature showing that the increase in body mass is not a predictor of increase of plantar pressure in diabetic individuals, with peripheral neuropathy remaining as a factor of changes in plantar pressure peaks (Tuna et al., 2004; Abbott et al., 2002).

A previous study, done only with diabetic patients, considered that an anteriorization occurs in the distribution of the pressure of the feet of diabetic patients. However, in our study, when compared it to the non-diabetic group, there was no difference with statistical significance, it does not demonstrate compliance with findings in the literature (Herman et al., 2012; Rodrigues et al., 2011; Alex et al., 2010), this is due in part to the difficulty of comparing the data between the studies by the different anatomical divisions adopted for the regional analysis of the variables, finding different values depending on the established division.

For comparison of pressure peaks in foot regions, our study opted for division into seven parts, according to a recent study (Rodrigues et al., 2011) in the hallux region, one of the most common sites of ulceration and amputation of diabetic patients (Merolli & Uccioli et al., 2005; Deschamps et al., 2013), confirming the plantar alteration in specific regions of the neuropathic patients' feet and corroborating findings from the literature increase the pressure in this region (Rodrigues et al., 2011; Merolli & Uccioli et al., 2005; Deschamps et al., 2013; Cavanagh & Ulbrecht, 1994).

The studies also show an important change in the pressure peak in the other regions of the forefoot, especially in the head of the 1st and 2nd metatarsals (Rodrigues et al., 2011).

Studies in diabetic patients with ulceration or had undergone amputation showed a significant increase of the pressure in the hallux and metatarsal regions (Rodrigues et al., 2011; Cavanagh & Ulbrecht, 1994). In our study, these alterations were found in patients without ulceration, showing that it is possible to evaluate blood pressure changes and the risk of complications, so that the outcome can be prevented.

5. Conclusion

In the final analysis, it was possible to notice that there is an increase in pressure in the hallux of diabetic patients when compared with non-diabetic patients.

Thus, the need for further studies to elucidate the relationship between increased pressure in the hallux region and the emergence of ulceration in diabetic patients is reinforced, in order to establish effective prevention measures.

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