Methods & Protocols

Efficacy of customized insoles in the improvement of plantar pressure in patients with diabetic neuropathy: Protocol of a randomized and controlled clinical trial

Eficácia das palmilhas customizadas na melhora da distribuição da pressão plantar em pacientes com neuropatia diabética: Protocolo de um ensaio clínico randomizado e controlado

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ABSTRACT | OBJECTIVE: To evaluate the influence of customized insoles in the plantar pressure of diabetes patients with neuropathy in comparison to the sham group. **METHODS:** The work method, duly registered at the Registro Brasileiro de Ensaios Clínicos – REBEC (Clinical Trial Brazilian Register) (http://www.ensaiosclinicos.gov.br/) RBR-5NQK4K, includes a randomized, controlled, prospective, double-blinded clinical trial, with a sample of 46 volunteers that will be randomly randomized in a 1: 1 ratio to be referred to intervention and control groups. The intervention group will receive customized insoles, with a retrocapital bar and an ethyl vinyl acetate plaque (EVA) in the same shape as the retrocapital bar, in order to reduce the pressure on the forefoot. In the control group, flat insoles will be prepared without any therapeutic objective. This project was developed according to the standard protocol for randomized clinical trials (SPIRIT). Along with the clinical evaluation, demographic data of the sample will be collected to identify and confirm the presence of peripheral neuropathy, next, the pedobarographic will be evaluated, and finally, the patients will answer the FAAM questionnaire to assess foot functionality. The primary outcome will be analyzing pressure points in KiloPascal (kPa) in the patients' feet through pedobarographic of the patients in the intervention and control groups. The secondary outcome will be the foot functionality in activities of daily living through the FAAM (Foot and Ankle Ability Measure), considering the volunteers in the initial evaluation, third and sixth months. FINAL **CONSIDERATIONS:** Mainly, results of this study will show whether there is a structural alteration in the analysis of the plantar pressure due to the continuous use of insoles and present the evaluation of whether the use of therapeutic insoles improves the foot functionality of the same users when compared to sham insoles.

KEYWORDS: Diabetic neuropathies. Dynamic orthoses. Plantar callosity.

RESUMO | OBJETIVO: Avaliar a influência das palmilhas customizadas na pressão plantar de diabéticos com neuropatia em comparação ao grupo sham. **MÉTODOS:** O método do estudo, devidamente registrado no Registro Brasileiro de Ensaios Clínicos – REBEC (Clinical Trial Brazilian Register) (http://www.ensaiosclinicos.gov.br/) RBR-5NQK4K, incluiu um ensaio clínico randomizado, controlado, prospectivo, duplo-cego, com uma amostra de 46 voluntários que serão randomizados aleatoriamente numa razão de 1: 1 para serem direcionados aos grupos intervenção e controle. O grupo intervenção receberá palmilhas customizadas, com barra retrocapital e placa de etil vinil acetato (EVA) no mesmo formato da barra retrocapital, com a finalidade de reduzir a pressão no antepé. No grupo controle, as palmilhas planas serão confeccionadas sem nenhum objetivo terapêutico. Este projeto foi conduzido de acordo com o padrão de protocolo para ensaios clínicos randomizados (SPIRIT). Junto com a avaliação clínica, serão coletados dados demográficos da amostra para identificar e confirmar a presença de neuropatia periférica, em seguida, será avaliada a podobarografia e, por fim, os pacientes responderão ao questionário FAAM para avaliação da funcionalidade do pé. O desfecho primário será a análise dos pontos de pressão em KiloPascal (kPa) no pé dos pacientes com neuropatia diabética por meio da podobarografia nos pacientes do grupo intervenção e controle. O desfecho secundário será a funcionalidade do pé nas atividades de vida diária através do questionário FAAM (*Foot and Ankle Ability Measure*), considerando os voluntários na avaliação inicial, 3º e 6º meses. **CONSIDERAÇÕES FINAIS:** os futuros resultados deste estudo nos mostrarão principalmente se há ou não uma alteração estrutural na análise da pressão plantar decorrente do uso contínuo da palmilha, além de avaliar se o uso da palmilha terapêutica é eficaz na funcionalidade do pé nos mesmos portadores quando comparado à palmilha sham.

PALAVRAS-CHAVE: Neuropatias Diabéticas; Órteses Dinâmicas; Calosidade Plantar.

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Introduction

According to epidemiological data reported in a study in 2017, there are 425 million people aged between 20 and 79 years affected by diabetes mellitus (DM) worldwide.[1] In Brazil, in 2016, 8.9% of the population were diagnosed with this disease.[2] Therefore, this is considered a public health issue that affects the general population and creates high costs for the health systems worldwide. In the United States of America alone, in 2012, 245 billion dollars were spent on diabetes management. Among all the causes, hospitalization (43%), medications (18%), diabetes supplies (12%), visits to the doctor's office (9%), and stays in residential/nursing institutions (8%) stand out.[3]

Characterized by sustained hyperglycemia, type 2 DM occurs due to chronic and progressive insulin deficiency, associating peripheral resistance mechanisms to insulin.[4] The complex and multifactorial etiology of this subtype of DM involves several physiopathological mechanisms, mainly genetic and environmental. Aging, hyperglycemic, and hyperlipidemic diets, and sedentary habits contribute to the progress of this endocrine disorder.[4,5] Another relevant factor in the increased glycemia is obesity; researchers[6,7] reported a significant association between obesity and insulin resistance.

Considering its several clinical repercussions, diabetic neuropathy (DN) is a condition that can have an early diagnosis in individuals affected by type 2 DM, even during the diagnosis of the relevant endocrine disorder. DN appears as a distal and autonomic sensorimotor symmetric polyneuropathy, with sensorial, motor, vascular, sudomotor, respiratory, cardiovascular, gastrointestinal, and genitourinary signals and symptoms.[8] Over 40% of diabetes mellitus patients develop some level of DN, even if they keep proper glycemic control. This leads to the conclusion that other factors are associated with the genesis of the neurological disorder, not only hyperglycemia. Currently, several studies have related comorbidities to a lifestyle unfavorable to the evolution of the involvement of peripheral nerves. Such factors include obesity, hypertriglyceridemia and hypercholesterolemia, systemic arterial hypertension, and smoking habits, which accelerate nerve lesions. Therefore, just like type 2 DM, DN also presents a complex character, affected by metabolic and vascular factors.[9]

In 2003, a group of experts developed a diabetic foot ulcer classification system called PEDIS, which evaluates important lesion criteria such as perfusion, extension, depth, infection, and sensitivity.[10] One of the main methods used to identify and quantify determined sensory, painful, and vibratory alterations is the Quantitative, sensitive Test (QST). This is a fast, practical method that presents good tolerability among patients.[11]

Pedobarographic is a technique in which the foot plant pressure is measured on a sensitive surface based on specific points of higher or lower pressure. In this context, the evaluation of the diabetic foot, susceptible to the formation of ulcers due to sensitive and structural alterations, is a useful tool in analyzing these patients' prognoses, identifying areas of higher mechanical stress.[12,13]

Aiming at preventing the formation of ulcers in diabetic feet, mainly those presenting hammer and claw toes, the use of pedobarography is a suitable approach for the characterization of plantar regions susceptible to lesions. Diabetic patients with sensory neuropathy and increased risk of lesions at the extremities are included.[12,13]

Some studies have pointed out that wearing proper shoes, with individual adjustments, tends to be an effective measure for protection against the maintenance of pressure concentrated on some plantar areas. In this sense, long-standing diabetic patients presenting sensorimotor neuropathy and peripheral arterial disease associated with the diabetic foot might be favoured.[14]

The strategy aiming to attenuate the pressure overload, with a better distribution on the plantar area, tends to be protective, preventing ulcer relapse. Therefore, customized insoles are believed to be allied in compensating the disorder by redistributing the pressure so that mechanical stress is reduced in specific areas.[15]

Previous studies already identified the benefits of the customized insoles to diabetic feet at risk of ulceration.[16] A systematic review reported evidence that supports the use of interventions to prevent the appearance of the first ulcer on foot.[17] However, there is no scientific evidence that proves the regression or stagnation of plantar pressure measured by

the pedobarographic of patients using customized insoles. Therefore, more studies are needed to test this hypothesis.[18]

Aiming at creating an instrument to evaluate daily and sports functionalities of the ankle and foot musculoskeletal disorders, the FAAM questionnaire was devised in 2005.[19] Some years later, researchers brought this questionnaire to Brazil and verified that the FAAM Brazilian version was valid and reliable when applied to the local population.[20]

The original version of the instrument, written in English, is divided into two domains, with twenty-one questions about Activities of Daily Living and another eight questions that assess Sport. In the end, three scores are generated, one for each scale and the instrument's total score. For each question, there is a five-point Likert scale. The option "Not Applicable" (N/A) is not scored, and the results are transformed into a percentage, at which 100% would be the highest level of functionality.[19] These same authors performed the validation of the FAAM for patients with foot problems resulting from Diabetes Mellitus.[20]

For this reason, the objective of this study is to evaluate the influence of customized insoles in the plantar pressure and functionality of patients with diabetic neuropathy compared to the sham group at the moment of the evaluation and after 3 and 6 months.

Methods

Study design

The work method, duly registered at the Registro Brasileiro de Ensaios Clínicos – REBEC (Clinical Trial Brazilian Register) (http://www.ensaiosclinicos.gov.br/) RBR-5NQK4K, includes a randomized, controlled, prospective, parallel and double-blinded clinical trial, through the characterization of the sample of patients registered in the Laboratório de Pacientes Diabéticos de Difícil Controle da Universidade Estadual de Ponta Grossa (Diabetic Patients of Difficult Control of the State University of Ponta Grossa), who will be admitted in the study after having signed the informed consent form and (13) confirmed the diabetic neuropathy through a complete clinical diagnosis, being the patients with fasting blood glucose above 100 milligrams per decilitre mg/dl and (glycated hemoglobin) HbA1c above 6.5% in the absence of treatment.

This protocol has already been approved by the Ethics and Research Committee of the State University of Ponta Grossa (CEP/UEPG), with the technical opinion nº 3.103.384 / 2018, approved on 27th December 2018. This project was conducted pursuant to the standard protocol for randomized clinical trials (SPIRIT). The results will be reported following the consolidated standards of reporting trials (CONSORT).

Participants

A total of 46 volunteers will be recruited in the city of Ponta Grossa, PR, being selected from the eight Basic Health Units (UBS) of the PET Health program at the State University of Ponta Grossa, namely: UBS Antero Machado de Mello Neto, UBS Antônio Horácio Carneiro de Miranda , UBS Eugênio José Bocchi, UBS Félix Vianna, UBS Horácio Droppa, UBS Nilton Luiz de Castro, UBS Otoniel dos Santos Pimentel and UBS Silas Sallen, in addition to social networks and on the recommendation of specialist doctors in the city.

Recruitment will begin in December 2018 and end in December 2019. The study will include patients over 18, from both genders, affected by type 2 Diabetes Mellitus that are part of the reported population, affected by typical diabetic neuropathy, as described in the variables analyzed, with increased plantar pressure in the forefoot region of either of the feet. Patients excluded will be those with fasting glycemia under 100 mg/dl and HbA1c below 5.7% in the absence of treatment, patients with movement disorders, previous history of the encephalic vascular accident, previous orthopedic surgery or ulceration and amputation of lower limbs, pregnant women, patients that for some reason cannot be completely and properly examined or patients that cannot move independently due to their unsuitability for the foot pedobarographic examination. Patients presenting other causes for neuropathy, patients that missed the appointment for laboratory examination or other, and those opting for dropping the research, regardless of the group to which they belonged, will also be excluded.

Outcomes

The primary outcome is analyzing pressure points in the feet of patients with diabetic neuropathy through pedobarography, including patients of the intervention and control groups.

The secondary outcome is assessing foot functionality in activities of daily living through the FAAM questionnaire (Foot and Ankle Ability Measure). The evaluations will be carried out at baseline and in the third and sixth months.

Randomization

After analyzing eligibility criteria, the randomization sequence will be carried out using Microsoft Excel (Microsoft Corporation, Redmond, WA) followed by a concealed allocation through sealed and opaque envelopes that will refer the volunteers to groups 1 or 2: intervention or control respectively.

The composition of groups with their respective volunteers will be revealed after the final analyses, considering the volunteers in the initial evaluation, third and sixth months.

Interventions

The intervention group will receive customized insoles with a retrocapital bar and an ethyl vinyl acetate plaque (EVA) in the same shape as the retrocapital bar. Both will be placed proximally to the metatarsal head region and bilaterally as suggested and analyzed in a previous study.[15]

In the control group, flat insoles will be prepared without any therapeutic objective.

Adverse reactions will be evaluated in the third and sixth months.

Blinding

As the purpose of this study is a double-blind project, a large research team is needed. Therefore, the blind participants in this study are the therapist and the evaluator.

An external researcher will perform both the randomization and the blind allocation of the insoles, who will not participate in the other phases of the research. The same external researcher will be responsible for replacing the participant's name with the allocation number in the analysis software. The insoles will receive a different number than the one registered in the software. In addition to the number, the destination group will also be registered for the proper preparation of the insole. The insoles will be sealed to prevent any participant other than the patient from having access to them.

The therapist will deliver the insoles to the patients. He will have access to the sealed insoles and, therefore, will not have access to the insole model. This procedure will guarantee the first blinding.

Patients will receive the insoles on different days and times so that they are not on this occasion and are not informed of the group to which they belong. However, as the insoles are visibly different, we cannot guarantee the blinding of the subjects.

The evaluator, the main researcher, will evaluate pedobarography, clinical examinations, and the FAAM questionnaire. This researcher will access patient data using the randomization number without having access to the type of insole that each patient is using. Therefore, the second blinding is guaranteed.

Data analysis

Two doctors and four medical students were on the team, all previously trained to perform the clinical evaluation. The evaluation of pedobarography was carried out by the main researcher, who has 10 years of experience in the area.

Along with the clinical evaluation, demographic data of the sample will be collected to identify and confirm the presence of peripheral neuropathy. Next, the pedobarography will be evaluated, and finally, the patients will answer the FAAM questionnaire to assess foot functionality.

The data collected will include gender, age, profession, marital status, schooling, time of diabetes diagnosis reported by the patient, time of diabetic neuropathy

reported by the patient, whether there is hypertension or dyslipidemia based on their report, whether they drink alcohol and how much alcohol they consume per day, whether the patient smokes and how many cigarettes are consumed per day, height, weight, and BMI based on the general physical examination. The patients will be asked whether they exercise based on the frequency within a week and what kind of exercise, whether there are reports of surgeries, allergies, and what kind of medication they use. Regarding medication, they will be asked specifically which medicines are used to control diabetes and which other complications from diabetes they have. If the patient is not able to report, medical reports will be surveyed. Questions will be asked about diabetes, hypertension, glycemia, and obesity occurrence in the family background.

The pedobarometric data that will be collected is the Maximum Peak Pressure (PPM) in each foot in KiloPascal (kPa), forefoot/hindfoot pressure relation, footstep predominance between the two feet (in %), and maximum pressure put on each foot region. These authors divided the foot into zone 1, hallux; zone 2, first metatarsal head; zone 3, second metatarsal head; zone 4, third and fourth metatarsal heads; zone 5, fifth metatarsal head; zone 6 midfoot; and zone 7, heel. In this study, zones 1 to 5 belonged to the forefoot, while zones 6 and 7 were located in the hindfoot.

All the five items previously mentioned and that are part of the PEDIS will be analyzed. However, greater emphasis will be given to the sensitivity evaluation, which will classify the plantar region investigated in a dichotomous way showing the presence or absence of sensitivity.

The pedobarometric data that will be included are the peak pressure maximum pressure peak (MPP) on each foot in KiloPascal (kPa), forefoot/hindfoot pressure relation, footstep predominance between the two feet (in %), and maximum pressure put on each foot region. The authors divided the foot into zone 1, hallux; zone 2, first metatarsal head; zone 3, second metatarsal head; zone 4, third and fourth metatarsal heads; zone 5, fifth metatarsal head; zone 6 midfoot; and zone 7, heel. In this study, zones 1 to 5 belong to the forefoot, while zones 6 and 7 will be located in the hindfoot.

The Quantitative Sensory Test (QST) will be applied to investigate the 1st, third and fifth metatarsus and toes in the patients' bilateral plantar face using the 10g monofilament. The vibration sensation in the dorsal face of the bilateral hallux will be carried out using the 128 Hz tuning fork.[21] A thorough physical examination will follow, taking into consideration the search for motor, autonomic or sensitive alterations in extremities and lower limbs of the patients looking for deformations or alterations. Next, complementary exams will be used, such as hemogram and pedobarography as described in the research instrument. Foot functionality in activities of daily living will also be evaluated using the FAAM questionnaire (Foot and Ankle Ability Measure).

An analysis of subgroups will be carried out by stratifying two groups classified as light or moderate neuropathy, according to the score obtained in the sensitive-motor analysis as described below.

The patients will be asked to contract the muscles that work in the plantar flexion, dorsal flexion, and bilateral hallux extension to verify motor strength. The score ranges from 0 to 5, in which 0 - 2 represents low contraction (moderate neuropathy) and 3 – 5 means moderate contraction (light neuropathy).

Tactile sensitivity will be carried out in 6 points of each foot plantar face, in which a score ranging from 0 – 3 reveals moderate sensitivity (light neuropathy) and 4-6 shows low sensitivity (moderate neuropathy). Regarding the vibration sensation, the score ranges from 0 – 1, in which 0 represents good vibration sensation (light neuropathy), while 1 shows low vibration sensation (moderate neuropathy).

Equipment and instruments

The processing of the data of the static pressure analysis of the feet was obtained using pedobarometric equipment composed of a quartz force platform with piezoelectric properties, with a dimension of 575 X 450 X 25mm, with 2704 capacitive pickups and a sampling frequency of 150 Hertz (HZ), which allowed a pedobarometric analysis of pressure discharge and posture oscillations. The values were collected and recorded by the FootWork program.

The insoles used in both groups were the STANDARD EVAPOD model (Podaly Pedoposturologia, Brusque, SC, Brazil), with EVA coverage of 3 mm of density 21, ta base resin of 1.6 mm, and lining of 0.6 mm.

In the intervention group, a retrocapital bar with a medial and lateral soft hemicupula composed of Latex called Podasoft was used, with a hardness of density 10, in addition to a soft plate of 5mm and density 21, located below the retrocapital bar and in the same format.

Size Sample Calculation

The sample calculation was carried out only for the primary outcome, a quantitative variable (plantar pressure), and repeated measurements. Therefore, the expected effect size was set at 0.30, according to results obtained in a previous study.[15]

A 0.05 significance level and 80% statistical power were established, which led to a number of 46 people, already accounting for the 15% probable sample loss throughout the six months. The volunteers will be randomly randomized in a 1:1 ratio and referred to intervention and control groups with 23 participants each.

Statistical Analysis

The intention-to-treat statistical analysis model will be previously applied. In this model, patients should always be evaluated according to their initial randomization, thus preserving the balance of the prognosis derived from the allocation.[21]

Initially, descriptive data analysis will be performed with simple frequency estimates of qualitative variables, mean, median, standard deviation, minimum and maximum of all quantitative variables per group at the beginning of the study, in the 3rd and sixth months. In the intra-group analysis, Student's t-test or Mann-Withney's U test was used. The differences between the intervention and control groups will be evaluated using statistical tests for independent samples, Student's t-test for variables with normal distribution, or Mann-Whitney U test for those without normal distribution. Differences between follow-up periods will be investigated with repeated measures tests, or ANOVA or Friedman with Tukey or Dunn test as post hoc, respectively.

Tests will be considered significant when $p < 0.05$, and the analysis will be supported by SPSS 21.[22] Dispersion measures such as confidence interval and standard deviation will be calculated later.

The pressure of both feet will be calculated over the follow-up period to analyze differences between groups and between baseline and third and sixth months.

Final considerations

To date, there is no scientific evidence proving the regression or interruption of the patients' pedobarographic anatomic change with the use of insoles, even if some improvement has been observed empirically. Therefore, a study aiming at confirming their benefits is still needed to promote a better quality of life to those patients.18 The follow-up was chosen in this project to analyze neuropathy patients who wear insoles is using pedobarography to evaluate accurately how much pressure is applied to each foot plantar region. The pedobarography examination enables the demonstration of frequent alterations in the indices of pressure concentration in the foot regions. This modern technique allows the evaluation of plantar pressure, soil contact surface, maximum pressure on the feet, dominance – right or left, and plantar arch shape – normal, flat, or high.[22,23]

Some studies have reported the high reliability of static analysis test-retest when compared to the dynamic analysis.[23,24,26] Due to that evidence and the practicality of the procedure, the static analysis was chosen for this study.

A cohort study published in 2016 identified that around 42.2% of the people who present plantar ulcers die within five years due to DM complications.[25]

Clinical Relevance

The future results of this study will show mainly whether there is a structural alteration in the analysis of the plantar pressure due to the continuous use of insoles and present the evaluation of whether the use of therapeutic insoles improves the foot functionality of the same users when compared to sham insoles.

Authors' contributions

Farhat G, Alves FBT, Martins CM, and Zanetti RG contributed to the manuscript conception and design, data analysis and interpretation, and critical review of the manuscript content. Galvão LC and Kravutschke RM contributed to the data analysis and interpretation and critical review of the manuscript. All authors approved the manuscript final version and are responsible for all aspects of this work, including guaranteeing its accuracy and integrity.

Competing interests

No financial, legal or political competing interests with third parties (government, commercial, private foundation, etc.) were disclosed for any aspect of the submitted work (including but not limited to grants, data monitoring board, study design, manuscript preparation, statistical analysis, etc.).

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