IMPAIRED TACTICAL SENSORY PERCEPTION IN PEOPLE WITH DIABETES MELLITUS: ASSESSING THE INTEREVALUATORS AGREEMENT

PERCEPÇÃO SENSORIAL TÁTIL ALTERADA EM PESSOAS COM DIABETES MELLITUS: TESTANDO A CONCORDÂNCIA INTERAVALIADORES

PERCEPCIÓN SENSORIAL TÁCTIL ALTERADA EN PERSONAS CON DIABETES MELLITUS: EVALUANDO LA CONCORDANCIA INTEREVALUADORES

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ABSTRACT

Obcjetive: impaired tactile sensory perception is a complication of diabetes mellitus which predates the neuropathy and can be identified by the nurse. It should involve neurological examination of the feet, evaluation of the sensitivity (tactile, pain-thermal and vibratory) and tendinous reflexes. Evaluators should be able to implement the evaluations. For this, training is necessary. Purpose: to establish the degree of interevaluator agreement in the assessment of altered tactile sensory perception in patients with diabetes *mellitus*. Methods: a cross-sectional study was carried out with three evaluators to obtain agreement on the assessment of the feet of patients with diabetes at a referral outpatient clinic in Campina Grande, Paraíba, Brazil. A total of 60 lower limbs (feet) of 30 patients were evaluated from the protective, thermal, vibration, pain and Achilles reflex. For the evaluation of inter-rater agreement, the Kappa coefficient was used and the level of significance was adopted with p <0.05. Results: most patients were female, with a mean age of 59.3 years old, diagnosis time of 12.6 years. Overall agreement was observed, with a variation in Kappa coefficient between 0.814 and 0.902 among the gold-standard evaluators. The index obtained indicate near perfect agreement. Conclusion: the evaluators were considered fit to perform the neurological evaluation of the feet of patients with diabetes *mellitus* after a training period. Inter-rater agreement is critical for clinical research, as it favors the fit between assessments in different techniques for collecting clinical information.

Keywords: Diabetic Neuropathies; Touch Perception; Reproducibility of Results; Nursing Assessment; Nursing.

RESUMO

Introdução: a percepção sensorial tátil alterada é uma complicação do diabetes mellitus que antecede a neuropatia e que pode ser identificada pelo enfermeiro. Deve envolver exame neurológico dos pés, avaliação da sensibilidade (tátil, dolorosa-térmica e vibratória) e de reflexos tendíneos. Os avaliadores devem estar aptos a implementar as avaliações. Para isso, treinamento é necessário. Objetivo: estabelecer o grau de concordância interavaliadores na avaliação da percepção sensorial tátil alterada em pacientes com diabetes mellitus. Métodos: estudo transversal realizado com três avaliadores para obter a concordância na avaliação dos pés de pacientes com diabetes atendidos em um ambulatório de referência de Campina Grande, Paraíba, Brasil. Foram avaliados 60 membros inferiores (pés) de 30 pacientes, a partir dos testes de sensibilidade protetora, térmica, vibratória, dolorosa e o reflexo aquileu. Para a avaliação da concordância interavaliadores, foi utilizado o coeficiente de Kappa e adotado o nível de significância com o valor p < 0,05. **Resultados:** a maioria dos pacientes era do sexo feminino, com idade média de 59,3 anos, tempo de diagnóstico de 12,6 anos. Observou--se concordância geral, havendo variação no coeficiente de Kappa entre 0,814 e 0,902 entre os avaliadores com o padrão-ouro. Os índices obtidos indicam concordâncias quase perfeitas. Conclusão: os avaliadores foram julgados aptos a realizar a avaliação

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neurológica dos pés de pacientes com diabetes mellitus após período de capacitação. A concordância interavaliadores é fundamental para pesquisas clínicas, uma vez que favorece o ajuste entre as avaliações em diferentes técnicas para a coleta de informações clínicas.

Palavras-chave: Neuropatias Diabéticas; Percepção do Tato; Reprodutibilidade dos Testes; Avaliação em Enfermagem; Enfermagem.

RESUMEN

Introducción: la percepción táctil alterada es una complicación de la diabetes mellitus aue antecede a la neuropatía v puede ser identificada por el enfermero. Debe incluir la prueba neurológica de los pies, evaluación de sensibilidad (táctil, dolorosa térmica y vibratoria) y de reflejos de los tendones. Los evaluadores deben estar aptos para implementar las evaluaciones y, para ello, deben capacitarse. Objetivo: establecer el grado de interevaluadores en la prueba de percepción sensorial táctil alterada en pacientes con diabetes mellitus. Método: estudio transversal con tres evaluadores para obtener la concordancia en la evaluación de los pies de pacientes con diabetes en atención ambulatoria de referencia de Campina Grande, Paraiba, Brasil. Se evaluaron 60 miembros inferiores (pies) de 30 pacientes con las pruebas de sensibilidad protectora, térmica, vibratoria, dolorosa y el reflejo del tendón de Aquiles. Se utilizó el coeficiente de Kappa y se adoptó un nivel de significancia con valor p < 0,05 para evaluar la concordancia interevaluadores. **Resultados:** la mayoría de los pacientes era de sexo femenino, edad promedio 59,9 años, tiempo de diagnóstico 12, 6 años. Se observó concordancia general, con variación en el coeficiente Kappa entre 0,814 y 0,902 entre los evaluadores con estándar de oro. Los índices obtenidos indican concordancias casi perfectas. Conclusión: después de su capacitación, los evaluadores fueron considerados aptos para realizar la evaluación neurológica de los pies de pacientes con diabetes mellitus. La concordancia interevaluadores es fundamental para la investigación clínica pues permite ajustar evaluaciones en distintas técnicas para la recogida de información clínica.

Palabras clave: Neuropatías Diabéticas; Percepción del Tacto; Reproducibilidad de los Resultados; Evaluación en Enfermería; Enfermería.

INTRODUCTION

Diabetes *mellitus* (DM) is characterized by metabolic disorders with hyperglycemia, due to some defect in the action and/ or secretion of insulin.¹ The chronicity of the disease is associated with long term damage, dysfunction and failure in different organs, especially the eyes, kidneys, nerves, heart and blood vessels. Currently, the disease affects 425 million people worldwide.²

In Brazil, data from the Surveillance of Risk Factors and Protection for Chronic Diseases by Telephone Inquiry (Vigitel) show that the number of people with DM increased 61.8% in the 20-year period, from 5.5% in To 8.9% in 2016. The confirmed cases of the disease surpass 12 million people.³

Among the DM microvascular complications, peripheral neuropathy is the most prevalent, affecting approximately 50% of people with the disease.⁴ When more sensitive diagnostic methods are used, the prevalence of this complication may increase and reach values close to 100%.⁵ The impaired tactile sensory perception (ITSP) is an event that precedes the neuropathy and, when diagnosed early, one can plan and implement actions for the prevention of the onset of lesions and, consequently, lower limb amputations due to diabetes.

The identification of ITSP can be performed by the nurse and necessarily involves the evaluation of the sensitivity (tactile, painful, thermal and vibratory) and tendinous reflexes of the feet.^{2,6,7} Despite the importance of performing these tests in clinical practice, health professionals, for the most part, neglect this care, either due to lack of time, lack of equipment and materials or lack of knowledge. These tests should be performed in primary or secondary care and in specialized clinics, however, the practitioner should be trained to examine the feet of people with diabetes and thus identify the ITSP.

After the training it is necessary to carry out inter-rater reliability tests. This is a strategy that evaluates the objectivity and agreement in the clinical evaluation from the agreement between two or more evaluators (judges) in relation to an evaluator considered gold standard in the application of the tests.⁸

Agreement between judges can be defined as the degree to which two or more evaluators, using the same rating scale, provide the same rating for the same observable situation.⁹ Obtaining interevaluator agreement in studies that include clinical evaluations is essential since it allows biases and errors to be avoided, acquisition of reliable and comparable data measurements, and greater assurance of methodological accuracy in obtaining information in clinical studies.

In view of the above, the present study is justified due to the importance of the training of professionals, among them nurses, to perform the sensitivity tests to evaluate the ITSP, since they are part of the multiprofessional health team that assists individuals with DM in public and private institutions. In spite of the understanding of the importance of diabetic foot prevention, it is observed that the adopted strategies have not been focused on the neuropathy screening, there are no specific protocols, resulting in the weaknesses of such follow-up regarding the evaluation and performance of the scrutiny of patients' feet by health professionals.

The objective of this study was to establish the degree of interevaluator agreement in the assessment of the ITSP in patients with DM.

METHOD

This is a cross-sectional study carried out in an endocrinology outpatient clinic of a public hospital in the city of Campina Grande, Paraíba, Brazil. The evaluation of the ITSP was compared among three evaluators, a specialist nurse considered gold standard in the assessment of the feet of people with DM, a researcher nurse and a nursing student. Before the data collection, training was done in the form of training of the evaluators by the specialist nurse in the tests to assess the sensitivity of the feet of people with diabetes. The training was divided in three moments: explanation with theoretical classes on the ITSP and diabetic neuropathy; laboratory tests with the evaluators and in a clinical setting with the patients.

The study included patients with medical diagnosis of DM who were in clinical treatment at the outpatient clinic, had the capacity to express themselves orally, and expressed their agreement to participate autonomously. Those who had some lesion/amputation in lower limbs and cognitive deficiency were excluded.

It is recommended that when the standard deviation or the population frequencies of the variable to be studied are not known, a pre-test should be performed with 30-40 individuals and the behavior of this subgroup should be considered as the population estimate.¹⁰ Therefore, a sample of 30 patients was chosen. All patients treated at the outpatient clinic were able to participate in the study, and there were no sample losses.

Data collection occurred in April 2017. The study was conducted in a single moment, when the evaluation was performed between the nurse (gold standard), the research nurse and the nursing student.

In the data collection procedure, an instrument was used with information about the patient's identification, number of records, name, age, sex, schooling, diagnosis time, DM complications, foot care and whether they had already been examined by some professional previously.

A total of 60 lower limbs (feet) of 30 patients were evaluated, with four tests in each foot (right and left), corresponding to the total of 180 tests: protective, thermal, vibration, pain and aquileu reflex tests. In all tests it was considered adequate (normal) if the patient hit two out of three attempts; and inadequate (abnormal) with two responses that demonstrated lack of sensitivity at a given point.¹¹

The abnormal response to the 10g monofilament test in any area of plantar testing added to one or more tests with change in responses was considered to be a diagnosis of ITSP.¹²

To evaluate the plantar protective sensitivity, the esthiometer, also called 10g monofilament of Semmes Weinstein, from SORRI^{*} was used. The esthiometer was applied perpendicular to the surface of the skin, slightly bending it and not applying over the region with callus or scar. The studied regions were: hallux (plantar surface of the distal phalanx) and the first, third and fifth heads of the metatarsals of each foot. At the time of the test, the patient was asked whether or not he or she felt the application of the monofilament.¹²

In the evaluation of pain sensitivity the sharp tip of the reflex hammer was applied to the region of the back of the hallux, taking care not to pierce the skin.¹² As for the thermal sensitivity test, the 128 Hz tuning fork was used. The points explored were the dorsum of the foot (deep fibular nerve, superficial fibular nerve and sural nerve), and the patient was asked about the identification of sensitivity to cold and heat.¹²

Vibration sensitivity was assessed by applying the 128 Hz tuning fork device to the distal hallux phalangeal on both feet and the patient was instructed to inform the evaluator when the tuning fork stopped vibrating.¹³

The aquileu reflex test was performed with the patient sitting, with the foot relaxed and suspended in discrete dorsiflexion. A soft blow was applied with the reflex hammer over the Achilles tendon, considering the normal response with the reflex plantar flexion of the foot, consequent to the percussion of the tendon. The result was considered abnormal when foot reflex flexion of the foot was absent or decreased.¹³

The evaluation was performed in a closed room, without noise, with the patient lying down, respecting a 10 minute interval between evaluations. The evaluators collected information about each patient's tests sequentially independently. Information were blinded. The evaluators were instructed not to consult the results of the other professionals and not to discuss the evaluation during the collections, in order to avoid influences on the answers.

Data were double typed in the Epi Info program, version 3.5.1, and after consistency check they were exported to the Statistical Package for Social Science (SPSS), version 21. The Kappa coefficients¹⁴ to establish the degree of agreement among the evaluators for the ITSP variable, which was categorized as yes or no, were calculated. Descriptive analysis (simple and percentage frequencies) was also performed.

Patients who had a change in the monofilament test plus a change in one more test had the diagnosis of ITSP for analysis of the results of the assessments of agreement among the professionals. In this way, attempts were made to ensure the uniformity of the evaluation or classification process in order to control or minimize biases in the subsequent analyzes.

The tests were performed on each foot (right and left), with this, it was necessary to apply the Kappa coefficient separately, since there is difference in sensory perception from foot to foot in the same patient.

It is pointed out that the test for analysis of concordances between evaluators employed in several studies has been the Kappa coefficient.¹⁴⁻¹⁶ The degree of agreement of the measures established by the Kappa coefficient is represented as follows: values less than 0.00, insignificant; between 0.00 and 0.19, weak agreement; between 0.2 and 0.39, small agreement; between 0.40 and 0.59, moderate agreement; between 0.61 and 0.79, substantial agreement; between 0.81 and 1.00, almost perfect agreement.¹⁴ In this study, interevaluator agreement values between 0.81 and 1.00 were considered acceptable, that is, almost perfect agreement to perfect agreement.

The study is in accordance with Resolution 466/12, which deals with research with humans. The project was sent to the *Comitê de Ética e Pesquisa* da *Universidade Federal de Campina Grande* and obtained a favorable opinion, under Protocol 2.065.147. The subjects who agreed to participate in the study signed the informed consent form.

RESULTS

The majority of the evaluated patients were female, with a mean age of 59.4 years (\pm 13.86), with elementary education level (83.3%). The DM time of diagnosis was 12.63 years (\pm 9.36). Most had no diabetes complications and reported having foot care. But when asked about the examination of the feet, most stated that they never had their feet examined by a health professional (Table 1).

Table 1 - Profile of patients with diabetes mellitus at the reference pu-
blic outpatient clinic. Campina Grande/PB, Brazil, 2017

Variable				
Gender				
Male	7	23.3		
Female	23	76.7		
Age				
Mean ± standard deviation	59.4 ±13.86			
Median (minimum - maximum)	59.5 (26 – 91)			
Schooling				
Illiterate	2	6.7		
Elementary School	25	83.3		
High School	2	6.7		
Higher Education	1	3.3		
Diagnostic time				
Mean ± standard deviation	12.63 ±9.36			
Median (minimum - maximum)	12 (0 – 37)			
Complications of DM				
Yes	12	40		
No	18	60		
Foot Care				
Yes	18	60		
No	12	40		
Foot exam				
Yes	9	30		
No	21	70		

Source: study data, 2017.

The 30 patients were evaluated to establish the degree of agreement in the evaluation by the three evaluators. Four tests were performed on each foot (right and left), corresponding to the total of 180 tests. The Kappa coefficient values found ranged from 0.814 to 0.902, rates considered almost perfect. Kappa values ranged from 0.431 to 1 (Table 2).

Table 2 - Degree of agreement between the evaluators and the gold standard in the assessment of impaired tactile sensory perception in patients with diabetes *mellitus*. *Campina Grande*/PB, Brazil, 2017

	Kappa coefficient		
Evaluator	Right foot		
Researcher nurse	0.870 (0.515-1.0)	0.902 (0.546-1.0)	< 0.001
Nursing Academic Student	0.814 (0.431-1.0)	0.869 (0.492-1.0)	< 0.001
6 1 1 0017			

Source: study data, 2017.

DISCUSSION

DM has been considered one of the main chronic diseases of the present time. The increase in the number of people with the disease may be related to population aging, as well as to a higher life expectancy of patients with DM.⁵ The mean age of the population with the disturb, close to the elderly age, implies the need for more attention to comorbidities associated with the problem, such as systemic arterial hypertension and other cardiovascular diseases, and that may impact the quality of life of these people. The mean age of the patients in this study was for adults (59.4 years) similar to that found in other studies.^{17,18}

The sample predominantly consisted of female patients with DM, as well as in most of the studies on the disease.^{19,20} This may be justified by the fact that male patients are less likely to seek health services, and in turn are more careless about foot care.

Most patients reported incomplete primary education, corroborating another study.¹⁷ It is observed in clinical practice that the low school level has been an aggravating factor for the occurrence of chronic complications. And the lack of reading, writing and text comprehension skills may interfere with self-care in diabetic patients.

A study has found that patients with some microvascular complications (retinopathy or diabetic nephropathy) are at greater risk of developing foot complications.¹³ In this investigation, it was verified that 40% of the patients declared some clinical compromise that represented complications of DM. In this sense, it is necessary that the person with diabetes be investigated for acute and/or chronic complications and their relation to the time of diagnosis of the disease. It is understood that the complications increase proportionally with the time of disease onset and to identify this association can be a strategy to minimize the appearance of these complications early.¹⁷ Although most reported being careful with their feet, a large part of the sample (40%) reported not having this practice. Research has evaluated the self-care of the feet of patients with diabetes and concluded that there is a need to make people with DM aware of this type of examination and prevent injuries that can lead to ulcers.²¹ Thus, the health professional should provide guidelines for the patient to be able to perform self-care based on diabetes knowledge and for the purpose of creating self-knowledge for the identification of abnormalities.

In this study, 70.0% of the patients reported never having had their feet examined by a health professional. A study carried out in *Pernambuco* with patients with diabetic foot found that among the patients submitted to amputation, 81.2% did not have their feet examined in the previous consultations, showing that an individual who does not have his feet examined for prevention or control of the foot diabetic patient is 3.39 times more likely to undergo amputation.⁴ Failure to assess feet may imply the absence of guidance and teaching of foot care, increase risk of ulcerations in a late diagnosis about the problem.

Dealing with patients with DM is a challenge, both in terms of their capacity for self-care and in the diagnosis of ITSP Nursing. The challenge for nurses is their assertiveness to perform monitoring tests for complications of the problem.

ITSP is a common complication in individuals with DM, especially those with a longer diagnosis time and who have low adherence to the treatment, being usually indifferent to the disease, belittling it. In this sense, the nurse must be sensitive enough to identify those with high risk in their development. In addition, it must have knowledge and ability to perform the screening of this complication, in order to institute preventive measures that minimize the risk of complications in the feet, especially ulcerations, which are the main causes of lower limb amputation in this population.

During the follow-up visit to the person with DM, the patient should be advised on foot care to prevent complications and, if necessary, refer him to the medical evaluation to collaboratively perform glycemic control, as his or her lack of control is one of the main factors that triggers the ITSP.

The clinical examination of the feet associated with anamnesis can confirm the presence and severity of peripheral neuropathy and peripheral arterial disease, the two most important risk factors for foot ulceration.¹³

ITSP can be diagnosed by an abnormal response to the protective sensitivity test or monofilament test in any area of plantar testing, and a second altered test such as vibration sensitivity, pain sensitivity, or aquileu reflex.^{2,12} In this sense, it is important to highlight the relevance of conducting the various tests for the diagnosis of ITSP in patients with DM to be routinely employed in the services, as well as the investigation of signs and symptoms reported by patients with DM.

The monofilament test is an important tool to predict the prognosis of patients with diabetic foot, thus allowing a better selection of patients for intervention and early management.^{5,12,13} The monofilament or esthiometer is an economical, noninvasive, accurate, reliable and practical test modality for nurses to identify patients at increased risk of developing ulcers or those candidates for future amputations.

The trained nurse can perform the tests to assess the sensitivity in the feet of patients with DM and to identify the early ITSP. And, being agile and efficient in the execution of the different tests, it can initiate early care for the prevention of injuries from the identification of the areas with altered sensitivity. For this, professional training is essential. For this reason, in this study, a previous training of the team of evaluators was carried out on the possible sensitivity tests to be used in the evaluation of the ITSP. It was verified that the degree of agreement between the gold-standard specialist and the nurse and between the gold-standard and academic specialist was higher than 80%, a rate considered almost perfect.¹⁴ Thus, the nurse and nursing student were considered fit to perform the tests at the end of the training.

Agreement between evaluators provides a limit on accuracy in subsequent evaluations. Researchers have used interevaluator reliability in their studies as an important step in clinical research. It is also a valuable strategy for the calibration of professionals for the application of clinical evaluation instruments.^{15,16,22,23} For this reason, in this study, a previous training of the team of evaluators was carried out on the possible sensitivity tests to be used in the evaluation of ITSP.

The degree of agreement between the gold-standard specialist nurse and the nurse and the nursing student ranged from 0.814 to 0.902 in the evaluation of the right and left feet, and almost perfect agreement was found.¹⁴ A study of 35 patients from an intensive care unit (ICU) to evaluate corneal lesions found that, after training and qualification of an intensive care nurse by an ophthalmologist, considered a gold standard for corneal evaluation, the nurse was considered suitable for corneal examination. An interevaluator agreement degree of 0.88 was established.¹⁶

In another study conducted with 85 patients from an adult ICU, interevaluator agreement was conducted by two nurses and two nursing students in the corneal evaluation of adult patients admitted to the ICU of a public hospital. The result according to the Kappa index ranged from 0.84 to 0.93, obtaining a near perfect degree of agreement.¹⁵

After assessing the feet of patients with DM and through the alterations detected in the sensitivity tests and the diagnosis of ITSP Nursing, a plan of care should be drawn to intervene in the problem and to prevent future complications such as diabetic foot and amputations. Despite the absence of studies that use the Kappa coefficient for the evaluation of ITSP, this investigation demonstrated that procedures for the training, training and evaluation of the ability to perform clinical tests, from the agreement among evaluators, are efficient strategies for the acquisition of competence of researchers and standardization of this evaluation for the collection of data in clinical research.

A limitation of the present study is considered in the fact that the evaluation of the ITSP considered only people with DM. However, it is known that this phenomenon can happen in other populations with other types of problems, such as cancer patients in chemotherapy.²⁴ Thus, new studies are carried out to evaluate ITSP in other groups that have predisposing conditions to the development of this complication.

CONCLUSION

The objective of establishing the degree of inter-rater agreement in the evaluation of the ITSP, through the sensitivity tests in patients with DM, was reached. Kappa coefficient was obtained with agreement index considered almost perfect. It should be borne in mind that it is necessary to establish trustworthiness between researchers to start collecting data from a clinical study. This procedure is important for reducing collection biases and minimizing errors that may occur due to the non-standardization of techniques for data collection. These strategies are essential so that the clinical information obtained is reliable and the results are reproducible.

The training of nurses in performing the neurological assessment of the feet of patients with DM is fundamental for the identification of ITSP and prevention of complications, through the implementation of an adequate care plan favoring a better quality of nursing care aimed at minimizing the risk of lower limb amputations as a result of the disease.

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