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Factors related to wound risk in patients with Type 2 *Diabetes mellitus*

Fatores relacionados ao risco de feridas em pacientes com Diabetes mellitus Tipo 2

Rebeca Barbosa da Rocha[1,2], Cristiano Sales da Silva[1,2,3], Cristiana Maria dos Santos[1,2], Pedro Renan de Souza Lima da Silveira[1,2], Geice Pereira de Sousa[1,3], Maria Karliane Arruda Fontenele[1,3], and Vinícius Saura Cardoso[1,2,3]*

[1] Center of Medical Specialties, Parnaíba, Piauí, Brazil
[2] Biosignal Laboratory. Postgraduate program in Biomedical Sciences. Federal University of Piauí, Parnaíba, Piauí, Brazil
[3] Biosignal Laboratory. School of Physical Therapy. Federal University of Piauí, Parnaíba, Piauí, Brazil

***Corresponding author**: Vinicius Saura Cardoso – E-mail: vscfisio@ufpi.edu.br

ABSTRACT
Few studies have addressed the sociodemographic characteristics and risk of wound development in northeastern Brazil. The objective of the study was to determine the prevalence of wound risk and the related factors in people with diabetes in the municipality of Parnaíba, Piauí State, Brazil. A cross-sectional study was conducted with 300 people with diabetes. The volunteers were assessed using a sociodemographic questionnaire, a 10 g monofilament, a 128 Hz tuning fork, a reflex hammer, and a wound risk rating scale. Male sex (OR 2.33, 95% CI 1.22-4.42), age (OR 1.03, 95% CI 1.01-1.05), physical inactivity (OR 2.35, 95% CI 1.26-4.38), and a longer duration of diabetes (OR 3.28, 95% CI 1.56-6.91) were associated with wound risk. This study demonstrated a high wound risk related to age, male sex, duration of diabetes, and physical inactivity and a high prevalence of complications such as diabetic peripheral neuropathy and amputations.

Keywords: Diabetic foot. Diabetes mellitus. Epidemiology. Foot ulcer. Secondary prevention.

RESUMO
Poucos estudos abordam as características sociodemográficas e o risco de feridas no nordeste brasileiro. O objetivo do estudo foi determinar a prevalência de risco de feridas e os fatores relacionados em pessoas com diabetes no município de Parnaíba, estado do Piauí, Brasil. Estudo transversal realizado com 300 pessoas com diabetes. Os voluntários foram avaliados por meio de questionário sociodemográfico, monofilamento de 10 g, diapasão de 128 Hz, martelo de reflexo e escala de classificação de risco de feridas. Sexo masculino (OR 2,33; IC 95% 1,22-4,42), idade (OR 1,03; IC 95% 1,01-1,05), inatividade física (OR 2,35; IC 95% 1,26-4,38) e duração maior de diabetes (OR 3,28; IC 95% 1,56-6,91) foram associados ao risco de feridas. Este estudo demonstrou um alto risco de feridas relacionado a idade, sexo feminino, duração da diabetes e inatividade física e alta prevalência de complicações como a neuropatia periférica diabética e amputações.

Palavras-chave: Diabetes mellitus. Epidemiologia. Pé diabético. Prevenção secundária. Úlcera do pé.

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INTRODUCTION

Diabetes mellitus (DM) is a major global health problem[1]. In 2015, there were approximately 415 million people with DM worldwide and an estimated 642 million will have the disease by 2040[1]. This incidence has increased primarily in low- and middle-income countries[2]. The National Health Survey, conducted in 2015, showed that approximately 9.4% of the population has DM in Brazil[3]. Morbidity and mortality in DM are associated with the emergence of several complications, such as diabetic peripheral neuropathy (DPN), peripheral arterial disease (PAD), and wounds on the diabetic foot[2].

Early microvascular complications can occur in people with glucose intolerance, even before type 2 DM (DM-2) [4]. However, the progression of DM and its complications are linked to several factors, such as the time that the person remains with an out of control glycemic index[4,5]. The maintenance of glycemic control following diagnosis is an important factor in delaying the progression of DM-2; this result may be related to metabolic memory[6,7]. However, the mechanisms by which it is reflected in the control of DM are still unclear; the time required after diagnosis, and the level of control must be known for this effect to be achieved[6,7].

The progression of DM-2 is also influenced by the sociodemographic characteristics of each region and country, including age, ethnicity, income, and the presence of comorbidities[4]. The study by Bezerra et al.[8] compared the sociodemographic characteristics of Brazil and France, and demonstrated lower mean age, duration of DM-2, body mass index, waist circumference, and greater use of oral hypoglycemic agents in the Brazilian population. The proportion of people with NPD, foot injuries, and amputation were higher among these patients[8].

Studies conducted in Brazil have shown that the prevalence of wound risk is 34%, 35.9%, and 61.1% in São Paulo, Alagoas, and Goiás, respectively[9-11]. These numbers are divergent between the different regions of the country, because Brazil has continental dimensions and distinct epidemiological and sociodemographic characteristics between regions[12]. However, the Ministry of Health's recommendations for people with DM-2 do not consider these differences[13].

It is necessary to understand the inter-regional sociodemographic and clinical profiles of people with diabetes so that health care can be implemented according to the specific needs of the population. Few studies have addressed the sociodemographic characteristics and risk of wound development in northeastern Brazil, which makes it difficult to understand the reality of these patients and to apply treatment that is specific to the particularities of the region. The question that guided this study was: What is the prevalence of wound risk and related factors in people with DM-2 in the municipality of

Parnaíba, Piauí State, Brazil? Our hypothesis is that wound risk is highly prevalent among people with DM-2 in the municipality of Parnaíba. Thus, the objective of the present study was to determine the prevalence of wound risk and the related factors in people with DM-2 in the municipality of Parnaíba.

METHODOLOGY

This observational, cross-sectional, analytical study was conducted between July 2018 and August 2019. The study sample consisted of 300 participants who were diagnosed with DM-2 over the age of 18 years who utilized the health services of Parnaíba, Piauí State, Brazil. The exclusion criterion for the study were as follows: patients who have not included a medical diagnosis of DM-2 or a diagnosis of DM-2 in the medical record or patients who had gestational diabetes or type 1 DM.

The required sample size was calculated using an online calculator (RaoSoft®)[14], taking into account the population with DM in the city (according to the most recent data [2015] from the Basic Attention Information System), with a margin of error of 5%, a confidence level of 90%, and a level of heterogeneity of 50%, resulting in 266 samples.

All patients with DM were approached in the waiting rooms of the health services and were invited to participate in the study. The city has two specialty centers and 42 family health strategies. The study was performed in two specialty medical centers and six basic health units (BHUs) in Parnaiba city. The BHUs were selected randomly with the criterion that they belong to different regions of the city and that the health team was available to receive the researchers. The completion and evaluation of questionnaires were performed in the BHU space and in the households during home visits, with the help of community health agents.

The volunteers were interviewed for sociodemographic characteristics and clinical information. They subsequently underwent neurological foot evaluation to classify the risk of wounds. Sociodemographic and clinical data regarding DM were collected using a questionnaire created by the researchers, including sex, education, smoking history, duration of DM, medications, comorbidities, adherence to physical activity (≥ 5 days a week) and BMI verification.

Neurological assessment was performed as recommended by the International Consensus on Diabetic Foot[15] through the verification of vibratory perception in the hallux using a 128 Hz tuning fork, superficial sensitivity using a 10 g Semmes–Weinstein monofilament, and response to the Achilles reflex test. The absence or reduction of sensitivity determined using a tuning fork and a 10 g monofilament was considered indicative of DPN. The feet were inspected for deformities and wounds. Data collection

was performed in a single visit to the health service.

After the evaluation, the participants were grouped into four categories according to the International Working Group on Diabetic Foot's classification scale of wound risk: risk 0 (absent DPN), risk 1 (DPN), risk 2 (DPN or deformities), and risk 3 (DPN with a history of ulcer and/or amputation) [15].

Statistical analyses were performed using the Statistical Package for the Social Sciences software, Version 21.0 (IBM Corp., Armonk, NY). Patient medical records were accessed when missing data were identified and the imputation through the mean was also used. Continuous and categorical data of the sociodemographic characteristics were summarized using the mean and standard deviation/percentage, respectively. The independence between the variables of each risk group for injuries was verified using the chi-squared test for categorical data and t-test for continuous data. A value of $p < 0.05$ was considered statistically significant. Wound risk factors were determined using simple and multiple logistic regression analyses.

The study was conducted in accordance with the principles of the Declaration of Helsinki, with the approval of the local ethics committee (approval code 2.689.629) and authorization from the city hall in which it was developed. All participants provided written informed consent.

RESULTS

A total of 300 participants were recruited for the study, of whom 71.7% presented some risk for wounds. The majority of the subjects were women (62,6%), which 63,2% were at risk for wounds. The average age of the participants was 62.1 ± 12.4 years, and they had a low education level (up to elementary school). Most people had DM for less than 10 years, and the average time since DM diagnosis was 8.94 ± 7.3 years.

Drug treatment for the volunteers consisted mainly of oral hypoglycemic agents, and there was a high prevalence of smokers, ex-smokers, and hypertensive patients. The risk 3 category was the most prevalent, with 52.3% of smokers and 51.3% of hypertensive patients in this category. Table 1 shows the characteristics of the participants according to the wound risk classification. A significant difference was found between the groups regarding age (p= 0.000), sex (p= 0.000; 0.001), education (p= 0.000), smoking history (p= 0.000), BMI (p= 0.000; 0.003), time with DM (p= 0.000; 0.002), medication (p= 0.000; 0.002; 0.007), presence of hypertension (p= 0.032), and physical activity (p= 0.000).

Table 1. Sociodemographic characteristics and clinical profile of volunteers according to wound risk

Variable	R0 (n = 85) N (%)	R1 (n = 50) N (%)	R2 (n = 56) N (%)	R3 (n = 109) N (%)	P
Age (years)**	57.78±12.1	65.18±13.08	67.35±11.8	61.44±11.4	0.000*
Sex	-	-	-	-	-
Female	69 (81.2)	37 (74)	33 (58.9)	49 (44.9)	0.001*
Male	16 (12.8)	13 (26)	23 (41.1)	60 (55.1)	0.000*
Literacy					
Illiterate	8 (9.4)	10 (20)	16 (28.6)	24 (22.1)	0.014*
Incomplete elementary school	49 (57.6)	30 (30)	32 (57.2)	55 (50.5)	0.011*
Complete elementary school	6 (7)	2 (4)	2 (3.5)	8 (7.3)	0.513
High school	18 (21.2)	8 (16)	5 (8.9)	17 (15.5)	0.015*
Higher education	4 (4.8)	0 (0)	1 (1.8)	5 (4.6)	0.273
Ex-smoker	35 (41.1)	20 (50)	24 (42.8)	57 (52.3)	0.000*
Smoker	3 (3.5)	3 (6)	2 (3.5)	9 (8.2)	0.113
BMI (kg/m^2)	-	-	-	-	-
<24.9	20 (23.5)	24 (48)	19 (33.9)	49 (44.9)	0.000*
25-29.9	35 (41.2)	11(22)	22 (39.3)	31 (28.5)	0.003*
≥30	30 (35.3)	15 (30)	15 (26.8)	29 (26.6)	0.989
Duration of DM	-	-	-	-	-
0-5 years	53 (62.3)	27 (54)	24 (42.9)	34 (31.2)	0.002*
6-10 years	20 (23.5)	13 (26)	17 (30.4)	25 (22.9)	0.252
>10 years	12 (14.2)	10 (20)	15 (26.7)	50 (45.9)	0.000*
Medication	-	-	-	-	
OHA	70 (82.3)	41 (82)	39 (69.7)	56 (51.3)	0.007*
Insulin	4 (4.8)	1 (2)	4 (7.1)	23 (21.1)	0.000*
Combined (OHA + Insulin)	9 (10.5)	4 (8)	9 (16.1)	23 (21.1)	0.002*
No medication	2 (2.4)	4 (8)	4 (7.1)	7 (6.5)	0.161
Hypertension	42 (49.4)	31 (62)	35 (62.5)	56 (51.3)	0.032*
Cardiopathy	9 (10.5)	5 (10)	7 (125)	10 (9.1)	0.593
Nephropathy	8 (9.4)	6 (12)	5 (8.9)	9 (8.2)	0.699
Regular physical activity	28 (32.9)	10 (20)	6 (10.7)	18 (16.5)	0.000*
Amputation	0 (0)	0 (0)	0 (0)	32 (29.3)	-
Active wounds	0 (0)	0 (0)	0 (0)	52 (47.7)	-

R, risk; BMI, body mass index; OHA, oral hypoglycemic agent
*significant p-values; **mean ± standard deviation

Table 2 describes the findings from the univariate analysis for the association between sociodemographic characteristics and clinical profile with the presence of wound risk. This model demonstrated an association between the presence of wound risk and age (OR 1.04, 95% CI 1.01-1.06), male sex (OR 2.76, 95% CI 1.50-5.08), BMI 25-29.9 kg /m^2 (OR 0.41, 95% CI 0.22-0.78), BMI ≥30 kg /m^2 (OR 0.44, 95% CI 0.23-0.84), DM duration greater than 10 years (OR 4.06, 95% CI 1.98-8.33), use of insulin (OR 3.34, 95% CI 1.12-9.96), and physical inactivity.

Table 2. Univariate analysis for the association of sociodemographic factors and clinical profile with wound risk

Variable	B**	Odds Ratio (95% CI)	P
Age	0.41	1.04 (1.01-1.06)	0.000*
Sex	-	-	-
Female	-	1	-
Male	1.07	2.76 (1.50-5.08)	0.001*
Literacy	-	-	-
Illiterate	0.91	2.50 (0.63-9.92)	0.193
Incomplete elementary school	-0.46	0.95 (0.28-3.19)	0.941
Complete elementary school	-0.22	0.80 (0.17-3.65)	0.773
High school	-0.54	0.57 (0.15-2.13)	0.410
Higher education	-	1	-
Ex-smoker	0.23	1.26 (0.76-2.10)	0.364
Smoker	0.64	1.90(0.55-6.80)	0.322
BMI (kg/m^2)	-	-	-
<24.9		1	
25-29.9	-0.87	0.41 (0.22-0.78)	0.007*
≥30	-0.81	0.44 (0.23-0.84)	0.014*
Duration of DM			
0-5 years	-	1	-
6-10 years	0.31	1.37 (0.74-2.53)	0.310
>10 years	1.40	4.06 (1.98-8.33)	0.000*
Medication			
OHA	-	1	-
Insulin	1.20	3.34 (1.12-9.96)	0.030*
Combined (OHA + Insulin)	0.72	2.05 (0.93-4.51)	0.071
No medication	1.47	4.37 (0.98-19.47)	0.053
Hypertension	0.29	1.34 (0.81- 2.22)	0.251
Cardiopathy	-0.38	0.96 (0.42-2.18)	0.967
Nephropathy	-0.13	0.98 (0.41-2.33)	0.977
physical inactivity	0.96	2.61 (1.46-4.68)	0.001*

BMI, body mass index; OHA, oral hypoglycemic agents
*Significant p-values; **Equation coefficient

Multivariate analysis was performed and adjusted with variables that were significant in the univariate analysis to investigate for factors related to wound risk. Age (OR 1.035, 95% CI 1.012-1.058), sex (OR 2.332, 95% CI 1.229-4.422), duration of DM >10 years (OR 3.287, 95% CI 1.563-6.916), and physical inactivity (OR 2.351, 95% CI 1.262-4.381) were the independent factors that best explained the risk of injuries. Table 3 shows the values related to this analysis.

Table 3. Multivariate analysis for factors associated with wound risk

Variable	Intercept	SE	Wald	Odds Ratio (95% CI)
Male	0.847	0.327	6.720	2.332 (1.229-4.422)
Age	0.034	0.011	8.750	1.035 (1.012-1.058)
Physical inactivity	0.855	0.318	7.248	2.351 (1.262-4.381)
Duration of DM				
0-5 years	-	-	9.854	1
6-10 years	0.239	0.331	0.520	1.270 (0.664- 2.428)
>10 years	1.190	0.379	9.835	3.287 (1.563- 6.916)

SE, standard error

DISCUSSION

In this study, we investigated the prevalence of wound risk in people with type 2 DM and the related factors. Our results showed the prevalence of wound risk in 71.7% of the participants, thus confirming our hypothesis. The factors that best explained this finding were age, male sex, duration of DM, and physical inactivity.

The prevalence of people at wound risk in this population was higher than that found in other study conducted in India (52%), France (27.2%), and other Brazilian cities (61.1%)[9,16,17]. The number of people with DPN and amputations was also greater than that found in other studies[8,9,18]. The prevalence of DPN in this study was 52.7%, which is higher than that reported in India (39.2%) and other studies conducted in Brazil (Ceará, 37.9%; and Minas Gerais, 36.89%)[8,18,19]. These data highlight the differences between profiles of people with DM in different regions and demonstrate a greater impact of DM on the population of the present study.

The analysis of inequalities related to DM between people from different regions of Brazil must consider the different cultural, economic, and health service offer characteristics between the regions. Health is a duty of the state in Brazil, where it provides subsidies for some medicines and supplies for self-monitoring of DM[20]. However, the purchase of these depends on the local government, resulting in an unequal supply in the population and supply is considered insufficient in some regions[20]. Thus, the patient must pay for his treatment, which increases inequalities in the country, considering that the Northeast presents monthly revenue of approximately 56.7% of the collected by people in other regions[20].

When comparing our results with data found in populations from other countries and in Brazil, it was possible to notice a higher average age, shorter time since the diagnosis of DM, and a smaller number of people who use insulin. The participants' time since diagnosis (8.9 ± 7.3 years) in this study also differed from that reported in studies from other Brazilian regions, having mean times of 14.5 ± 9 years (Midwest region) and 10.6 ± 9 years (Southeast region), and the 17.8 ± 10.8 years reported in France[8,9,18]. This discrepancy may be related to the late diagnosis of DM in the studied population,

indicating maintenance of hyperglycemia for longer periods before diagnosis.

Late diagnosis of DM is a Brazilian reality[3]. A study performed with samples from all regions of Brazil showed an increase in the prevalence of DM when testing participants' glycated hemoglobin (HbA1c) test in volunteers, in which 7.5% of people reported having a diagnosis of DM, while 9.4% of volunteers were diagnosed by association of self-reference and laboratory examination[3]. This shows a lack of diagnosis and high blood glucose levels in parts of the population. Undiagnosed DM is also a problem in other countries such as Bangladesh[21]. According to the International Diabetes Federation, most people with undiagnosed DM live in low- and middle-income countries[22].

Late diagnosis of DM leads to complications[23], which justifies the greater number of people with high wound risk in this study. The high risk can also indicate a difficulty in maintaining glycemic control in those diagnosed. The study by Viana et al.[24] investigated the factors related to low glycemic control in the five regions of Brazil, which demonstrated that most patients did not reach the goal of 7% in HbA1c levels; however, living in the Northeast was one of the factors related to the worst values of HbA1c. The results of this study demonstrated a smaller number of people who use insulin in this region[24].

These data corroborate those of the present study that contained a lower proportion of people using insulin (25.6%). Insulin, in general, is the therapy used when oral medications do not control a patient's glycemia, without considering other reasons that it is prescribed[25].

The study by Salci et al.[26] in the city of Teresina, located in the same state in which our study was conducted, demonstrated that health actions aimed at the population with DM were not in accordance with the public policies recommended for people with DM. In contrast, the city of Pelotas, located in the southern region, showed an expansion of health services, with an above average number of medical consultations and greater access for people with chronic diseases like DM[27]. This figure reflects the reduction in the hospitalization rate for conditions sensitive to primary care in this city, including DM[28].

The differences in the prevalence of complications related to DM can also be associated with the higher educational level in countries such as France, Canada, and the southern and southeastern regions of Brazil compared to that in the population examined in this study. This factor is considered protective against DM and its complications[29]. People with greater access to education are more likely to take advantage of the health and information services for their own care[30]. A study conducted in Canada, in which 85.8% of the population had at least high school level education, showed that the prevalences of DPN and wounds were 18.2% and 5.8%, respectively, which was lower than those reported in this study[30].

This study has some limitations: 1- It presents the limitations inherent in observational studies such as the impossibility of interpreting the causal relationship between the variables; 2- Failure to carry out an analysis of health policies implemented in the region and verification of the relationship between the type of service that the volunteer was receiving and the study variables. It is hoped that this study will be a stimulus to carry out more research that analyzes the health policies implemented in different regions of Brazil and the impact on the prevention of complications related to DM-2.

CONCLUSION

This study demonstrated a high wound risk related to age, male sex, duration of DM, and physical inactivity and a high prevalence of complications such as DPN and amputations.

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