

Factors Associated with Amputation and Lower Limb Ulcer in People with Diabetes Mellitus

Fatores Associados a Amputação e Úlcera de Membro Inferior em Pessoas com Diabetes Mellitus

Factores Asociados a la Amputación y Úlcera de Miembros Inferiores en Personas con Diabetes Mellitus

RESUMO

Objetivo: Este estudo tem como objetivo identificar os fatores associados a amputação e úlcera de membro inferior em pessoas com diabetes mellitus atendidas por ação de campanha. **Método:** Os participantes do estudo foram selecionados por amostragem aleatória simples, a partir das pessoas que compareceram ao mutirão e estavam dentro dos critérios estabelecidos. A amostra foi composta por 1.543 voluntários diagnosticados com diabetes mellitus. A idade média foi de $62,09 \pm 11,86$ anos, com mediana de 63 anos. **Resultados:** A análise univariada revelou que sexo masculino, maior tempo de diabetes e uso de insulina estiveram significativamente associados à presença de amputação. Para úlcera, um maior tempo de diabetes foi um fator de risco significativo. **Conclusão:** Espera-se que os resultados deste estudo possam propiciar uma melhora e requalificação da assistência de modo a promover mudanças nas práticas gerenciais de pessoas com diabetes mellitus.

DESCRIPTORES: Diabetes Mellitus; Pé Diabético; Amputação Cirúrgica.

ABSTRACT

Objective: The objective of this study was to ascertain the factors associated with amputation and lower limb ulcers in individuals with diabetes mellitus who attended a campaign. **Method:** Participants were selected through a randomisation process, whereby individuals attending the campaign and fulfilling the predetermined criteria were selected at random. The final sample comprised 1,543 volunteers who had been diagnosed with diabetes mellitus. The mean age of the sample was 62.09 years (± 11.86 years), with a median age of 63 years. **Result:** Univariate analysis revealed that male gender, longer duration of diabetes and insulin use were significantly associated with the presence of amputation. Furthermore, a prolonged duration of diabetes was identified as a significant risk factor for the development of ulcers. **Conclusion:** It is hoped that the results of this study will lead to improvements and requalification of care, with a view to promoting changes in the management practices of people with diabetes mellitus.

DESCRIPTORS: Diabetes Mellitus; Diabetic Foot; Surgical Amputation.

RESUMEN

Objetivo: El objetivo de este estudio era identificar los factores asociados a la amputación y las úlceras de las extremidades inferiores en personas con diabetes mellitus asistidas por una campaña. **Método:** Los participantes en el estudio fueron seleccionados por muestreo aleatorio simple entre los que asistieron a la campaña y cumplían los criterios establecidos. La muestra estaba formada por 1.543 voluntarios diagnosticados de diabetes mellitus. La edad media era de $62,09 \pm 11,86$ años, con una mediana de 63 años. **Resultado:** El análisis univariante reveló que el sexo masculino, una mayor duración de la diabetes y el uso de insulina se asociaban significativamente con la presencia de amputación. En el caso de las úlceras, una mayor duración de la diabetes fue un factor de riesgo significativo. **Conclusión:** Se espera que los resultados de este estudio puedan conducir a una mejora y recalificación de los cuidados con el fin de promover cambios en las prácticas de gestión de las personas con diabetes mellitus.

DESCRIPTORES: Diabetes Mellitus; Pie diabético; Amputación quirúrgica.

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INTRODUCTION

DM has a high prevalence in people over 50 years of age, but it can often manifest as a silent disease. Concomitant with the progression of the disease over the years and poor adherence to glycemic control, one of the chronic complications that may arise is the diabetic foot, representing a late-stage lesion of previous Peripheral Vascular Disease (PVD), which is sometimes asymptomatic. In this context, campaign initiatives serve as strategies for screening and preventing complications in people with DM ⁽¹⁾.

The diabetic foot is defined as any condition affecting the lower limbs in people with diabetes, ranging from ulcers, infections, tissue destruction, gangrene, or any lesion that may compromise foot health. Approximately 85% of individuals over 60 years of age who develop foot ulcers eventually require lower limb amputation ⁽²⁾.

According to the Brazilian Society of Angiology and Vascular Surgery (SBACV), the incidence of lower limb amputations varies worldwide; however, in Brazil, this number has been steadily increasing, as the av-

erage was 75 procedures per day in 2020, 79 amputations in 2021, and rose to 82 amputations per day in 2022 ⁽³⁾.

This study is justified because limb amputation has a social impact on the amputee. Therefore, knowledge about the clinical and sociodemographic characteristics of people with DM, especially patients who have undergone amputation, is essential so that healthcare professionals can implement more effective intervention measures, focusing on comprehensive care, and so that management can implement support strategies according to the specific needs of this population.

Considering the magnitude of the disease and the reduced life expectancy resulting from amputations, it is believed that knowledge regarding the factors associated with lower limb amputation in individuals with diabetic foot ulcers (DFUs) in the Itabuna region can facilitate the planning of educational strategies that promote self-care and better disease management. Therefore, the present study aims to identify the factors associated with amputation and lower limb ulcers in people with diabetes mellitus

who were treated through a campaign in a municipality in the interior of Bahia.

METHOD

A cross-sectional study was conducted with individuals with DM in a municipality located in the interior of Bahia. Study participants were selected by simple random sampling from among those who attended the campaign and met the established criteria. They completed a standardized questionnaire with clinical and epidemiological questions, followed by a fundus examination to assess diabetic retinopathy and a diabetic foot assessment.

The inclusion criteria adopted were: having a diagnosis of diabetes mellitus, regardless of gender or age, and undergoing the available examinations in the care pathway according to medical indications and the presence of chronic complications. The exclusion criterion adopted was being prediabetic. To assess factors associated with the risk of amputation, standard care records were evaluated; these were completed according to the specific care provided to each

patient in question, with proper authorization and signature of the Informed Consent Form (ICF), and data generated from the care—such as laboratory variables and imaging studies—were analyzed.

The sociodemographic variables were age, sex (male and female), and educational level (illiterate/low education/high education). For clinical variables, the following were assessed: time since diagnosis ($\leq$ or $>$ 10 years), current treatment (not using insulin and using insulin or oral medication for DM), presence of associated diseases (hypertension; cardiovascular diseases; acute myocardial infarction; obesity; and nephropathy) or complications; smoking; and alcohol abuse.

Statistical analysis was conducted in three main stages. Initially, the characteristics of the population were described using means and standard deviations for continuous variables and absolute and relative frequencies for categorical variables. Student's t-tests were used for normally distributed variables, while the Mann-Whitney test was applied for non-parametrically distributed variables. Next, univariate analysis was conducted using chi-square tests for categorical variables and Student's t-tests or Mann-Whitney tests for continuous variables. In the multivariate analysis, variables with a p-value less than 0.20 in the univariate analysis were included in the binary logistic regression model, with adjustment for potential confounders based on clinical and statistical relevance. Additionally, model validation was performed using the Hosmer-Lemeshow test to assess the fit of the logistic regression. The analyses were conducted using the R statistical software, employing the 'glm' package for logistic regression and the 'car' package for assessing multicollinearity among variables. All procedures were performed using the Stata statistical software version 12.0 (Stata Corp®).

This study is part of a project titled "Assessment of the Main Complications Observed in Diabetic Patients Treated at the Diabetes Clinic," which was approved by the Research Ethics Committee (CEP) of the "Instituto De Ensino Superior Presidente Tancredo De Almeida Neves - UNIPTAN," under opinion number 5,779,758, followed by the Certificate of Submission for Ethical Review (CAAE) protocol 64219922.3.0000.9667. The subjects participated in the study through an agreement formalized by signing the

Informed Consent Form (ICF), and the purpose of the study was clearly explained to them.

RESULTS

A total of 1,542 volunteers diagnosed with DM participated in the study, with a mean age of 62 years $\pm$ 11.8. The sample was predominantly female (64.7%), with incomplete elementary school education (41.2%) and without health insurance (92.2%) (Table 1).

Table 1. Sociodemographic characteristics of the sample evaluated in the campaign in the municipality of Itabuna, Bahia, 2023

	n	%
Gender (n = 1,542)		
Female	997	64,7
Male	545	35,3
Education (n = 1,518)		
Illiterate	224	14,8
Elementary school (completed/incomplete)	780	51,4
Incomplete/complete secondary education	426	28,0
Incomplete/complete higher education	88	5,8
Health insurance (n = 1,520)		
No	1.402	92,2
Yes	118	7,8

Source: Survey data.

The assessment of foot health-related aspects revealed that 81.5% of those evaluated reported wearing inappropriate footwear; the prevalence of lower limb amputation (at least one limb) was 1.9%, of ulcers in at least one foot was 2.9%, of fungal infec-

tions was 30.5%, and of deformities was 86.2%. Regarding the assessment of peripheral arterial disease, the posterior tibial and/or pedal pulses were palpable bilaterally in 83.1% and 89.6%, respectively, and there was no loss of sensation in 75.1% (Table 2).

Table 2. Clinical characteristics of the diabetic foot in the sample evaluated during the campaign in the municipality of Itabuna, Bahia, 2023

	n	%
Inappropriate Footwear (n = 1,459)		
No	270	18,5
Yes	1.189	81,5
Fungal infection (n = 1,491)		
No	1.036	69,5
Yes	455	30,5
Deformity		
No	206	13,8
Yes	1.290	86,2
Amputation (n = 1,542)		
No	1.512	98,1
Yes	30	1,9
Ulcer (n = 1,501)		
No	1.457	97,1
Yes	44	2,9
Posterior Tibial Pulse (n = 1,477)		
Palpable bilaterally	1.227	83,1
Palpable Unilaterally	90	6,1
Absent	160	10,8
Pedious pulse (n = 1,480)		
Palpable bilaterally	1.326	89,6
Palpable Unilaterally	58	3,9
Absent	96	6,5

Source: Survey data.

Univariate analysis revealed that male gender (OR = 3.23; 95% CI: 1.53–6.84; $p = 0.002$), longer duration of diabetes (OR = 1.05; 95% CI: 1.02–1.09; $p = 0.002$), and insulin use (OR = 4.95; 95% CI: 2.38–10.31; $p < 0.001$) were significantly associated with the presence of amputation. For ulcers, a longer duration of diabetes (OR = 1.03; 95% CI: 1.00–1.06; $p = 0.045$) was a significant risk factor.

High blood pressure and obesity did not show a statistically significant association with amputation or ulcers. Table 2 presents the complete results of the univariate analysis.

Table 3. Univariate analysis of factors associated with amputation and ulcers among individuals treated during the campaign in the municipality of Itabuna, BA, 2023.

Variable	Amputation			Ulcer		
	OR	95% CI	p-value	OR	95% CI	p-value
Age (years)		0,99-1,04	0,124	1,03	1,00-1,06	0,045
Male	3,23	1,53-6,84	0,002	1,5	0,98-2,30	0,061
Duration of Diabetes (years)	1,05	1,02-1,09	0,002	1,03	1,00-1,06	0,045
Insulin Use	4,95	2,38-10,31	<0,001	1,78	1,08-2,95	0,022
Hypertension	1,12	0,75-1,67	0,586	0,92	0,65-1,29	0,617
Obesity	1,08	0,62-1,88	0,789	1,14	0,71-1,84	0,589
Smoking	2,1	1,02-4,32	0,043	1,22	0,76-1,95	0,414
Alcoholism	0,78	0,42-1,47	0,445	1,02	0,61-1,71	0,936

Source: Survey data.

In the multivariate logistic regression, male gender (adjusted OR = 3.35; 95% CI: 1.56–7.18; $p = 0.002$) and insulin use (adjusted OR = 3.68; 95% CI: 1.65–8.22; $p = 0.001$) remained

independently associated with amputation. No variable remained significantly associated with ulcers after adjustment. Details of the adjusted models are presented in Table 3.

Table 4. Multivariate analysis of factors associated with amputation and ulcers among individuals treated during the campaign in the municipality of Itabuna, BA, 2023.

Variable	Amputation (Adjusted OR; 95% CI; p)			Ulcer (Adjusted OR; 95% CI; p)		
Male	3,35	1,56-7,18	0,002	1,32	0,87-2,01	0,183
Duration of Diabetes (years)	1,03	0,99-1,08	0,073	1,04	1,00-1,07	0,056
Insulin Use	3,68	1,65-8,22	0,001	1,5	0,92-2,43	0,104

Source: Survey data.

DISCUSSION

In the present study, regarding gender, there was a predominance of females among those who participated in the campaign (64.7%). This finding reflects what the scientific literature demonstrates regarding women being more concerned with health and seeking services more frequently. Consequently, there is evidence of a higher prevalence of women diagnosed with the disease compared to men⁽⁴⁾.

Regarding age group, although the average age was 62 years, it should be noted that DM is increasing at an alarming rate among young people and adults. By the year 2022, it was estimated that in Brazil, approximately 9% of the adult population had diabetes. Considering that in most cases the diagnosis is made late, this percentage may be even higher due to underreporting⁽⁵⁾.

Among the complications caused by diabetes, diabetic foot stands out. The diabetic foot is also considered a public health problem due to high amputation rates. It is defined as any condition related to vascular impairment, ulcers, nerve complications,

and/or deformities affecting the lower limbs of people with DM, resulting from metabolic imbalance⁽⁵⁾.

A recent study highlights the need for a change in social behavior among men. Socially, men tend to neglect their health, fail to practice self-care, and often, out of fear, end up seeking healthcare services only when clinical signs and symptoms manifest. Consequently, the focus is not routinely on disease prevention but rather on treatment and/or rehabilitation. The literature also indicates that, although men are more likely to undergo amputations, women are more susceptible to death during the procedure, as well as in the postoperative period⁽⁶⁾.

The term “amputation” refers to the removal of a limb or part of a limb. This procedure becomes necessary after the extremities (limbs) suffer some type of trauma, or as a result of chronic complications from a medical condition. Thus, it serves as an alternative to improve the individual’s health, although it is highly associated with high mortality rates⁽⁷⁾.

Consequently, there has been a significant increase not only in the percentage of people over the years but also in the emergence of chronic complications resulting from poor

glycemic control, and, most notably, in the prevalence of amputations, representing a breakdown in comprehensive care and highlighting the importance of identifying risks for the effective prevention of peripheral neuropathy and/or foot injuries in people with DM, especially when associated with other complications such as cardiovascular disease, retinopathy, or diabetic nephropathy⁽⁸⁾.

There are many risk factors that can lead individuals with DM to amputation; among them, consistent with the results of this study, are the use of insulin as drug therapy and a duration of diabetes exceeding 10 years. The longer the duration of diagnosis, the greater the chances of developing complications if patients are not monitored by professionals, do not follow the prescribed therapy, and do not undergo routine follow-up examinations. The scientific literature addresses amputation as a fully preventable procedure, but this requires monitoring, health education initiatives that promote patient empowerment, and effective assessments to identify changes that may contribute to the development of lesions as early as possible, thereby reducing and controlling complications⁽⁶⁾.

The etiology of ulcers is multifactorial and can be classified as ischemic or arterial. Regarding their pathophysiology, persistent hyperglycemia causes damage to peripheral nerves, leading to a loss of tactile sensation or pain perception in the individual, a condition further exacerbated by the presence of calluses, fungal infections, deformities, areas of repetitive stress, or ill-fitting footwear; these factors are therefore important to identify when examining patients’ foot health⁽⁸⁻⁹⁾.

When an ulcer develops as a result of lesions on the extremities of these patients, healing is often difficult due to impaired blood flow. Ulcers on the limbs of individuals with diabetes, in

addition to representing a high cost to public health due to high hospitalization rates, also have a social impact, as they affect their lives, routines, experiences, and body image. Furthermore, they account for 85% of limb removals that are preceded by foot ulcers and progress to amputation ⁽¹⁰⁾.

Furthermore, it is important to emphasize the importance of clinical foot examinations to screen for biomarkers that are precursors to lesions characteristic of the diabetic foot. It is a low-cost, practical, simple, and effective method for screening for neuropathy and peripheral vascular disease ⁽¹¹⁾.

Patients who undergo any type of amputation due to diabetic foot will require an additional amputation within 3 years of the first procedure,

and 50% of patients will die within 5 years of the first major amputation. Furthermore, it leads to changes in daily biopsychosocial life, as it impairs quality of life, reduces autonomy, and the ability to perform activities of daily living, and consequently, alters family dynamics. Given this, it is clear how essential public policies, services, and health management are in this process of addressing the disease ⁽¹²⁾.

CONCLUSION

The findings of this study show that people with diabetes are more vulnerable to amputation. It was observed that several factors may be associated with an increased prevalence of lower limb amputations, namely:

being male, insulin use, and duration of diabetes mellitus.

Such analyses provide a holistic and comprehensive perspective for healthcare professionals to promote effective interventions for their patients. Identifying these risk factors allows healthcare professionals to develop more effective prevention and intervention strategies tailored to the specific needs of each patient. A holistic approach, taking these multiple aspects into account, is crucial for reducing the incidence of amputations and significantly improving the quality of life for people with diabetes. Future research may further deepen our understanding of these factors, contributing to the development of even more personalized and effective care protocols.

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