

Amputation Risk Factors Among Patients With Diabetic Foot Attending A Tertiary Hospital, Dar Es Salaam, Tanzania

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ABSTRACT

Background: About 79% of the 463 million people who have diabetes globally live in low- and middle-income countries. Along with the unprecedented growing burden of diabetes, the related complications such as diabetic foot affect up to 60 million adults. Diabetic foot complications are known to be the leading cause of non-traumatic amputation. This study aimed to determine the risk factors of amputation among patients with diabetic foot admitted at a tertiary care hospital.

Methods: This hospital based retrospective study was conducted among patients with diabetic foot and required admission between Jan 2017 to Dec 2020. The selection was based on availability within the specified period. Data were retrospectively extracted from patient files and the hospital electronic database. The effect of risk factors was analyzed using multiple linear logistic regression models. Variables included age, sex, type and duration of diabetes, co-morbidities, pharmacological therapy, and diabetic complications. A *P* value <.05 was considered statistically significant.

Results: A total of 56 adult patients with diabetic foot were seen at Shree Hindu Mandal Hospital between January 2017 and December 2020. Of them, 44 (78.6%) were male. The mean age was 60.6 (SD ±11.7) years, and the mean duration of diabetes was 10.7 years. More than half 33 (58.9%) had their lower limb amputated and 66.7% of the total amputated, were between 50-69 years old. Fifty-four patients (96.4%) had foot ulcers and about one third 10 (30.3%) had a previous history of amputation. Over two thirds of all patients 49 (87.5%) had poor glycemic control with HbA1C above 6.5% and 31 (94%) of those who had amputation had their lower limb amputated. Patients with gangrene were more likely to have amputation than those without gangrene (aRR 4.03, 95% CI 1.31, 12.43; *P*=.015).

Conclusion: Poor glycemic control and gangrene are important risk factors for amputation among patients with diabetic foot. The study highlights the necessity for enhanced patient education on comprehensive foot care to prevent amputations and improve patient outcomes. Targeted interventions focusing on glycemic control and early detection of foot complications, especially in the elderly population, are urgently needed.

BACKGROUND

With the rapid evolution of human behavior, non-communicable diseases (NCDs) are steadily increasing. As of 2019, Diabetes Mellitus (DM) was confirmed one of the fastest growing global emergencies with approximately 463 million adults having diabetes whereby about 79.4% of them live in low- and middle-income countries.¹ The enormous increase in the number of people with diabetes significantly accelerates the increase in the number of cases with complications. Diabetic foot is one among the complications and is defined as infection, ulceration, or destruction of tissues of the foot of a person with currently or previously diagnosed DM usually accompanied by neuropathy and or peripheral vascular disease in the lower extremity². However,

if left untreated, diabetic foot can lead to disability, premature death, long hospital stays, poor quality of life, and serious mental illness.³⁻⁷

Lower limb amputation is a serious complication of diabetic foot, whereby 85% of all lower extremity amputation are due to foot ulcer.⁷⁻⁹ The prevalence of diabetic foot ulcer among diabetic patients attending public hospital clinics in Tanzania is 15%.^{4,10} Diabetic foot is known to be the leading indicator of major limb amputation.¹¹ A management paradigm introduced in 2006 'Step by Step Foot Project' showed that the occurrence of foot ulcer disease among patients referred to the national hospital and the annual amputation rates in these patients decreased significantly.³ However, data shows that 44.8% of diabetic patients with foot conditions required major

limb amputation and the mortality rate was 25.4% and amongst those 9% were to undergo foot amputation.¹² Another study done in Mwanza, at a large tertiary care, showed that 56.7% of diabetic patients with foot complications attending diabetic clinic underwent lower limb amputation.¹³ Peripheral arterial disease, hypertension, poor glycemic control foot,¹⁴⁻¹⁵ foot deformity¹⁶ are some of the factors attributable to amputation among diabetic patients with diabetic.

The escalating prevalence of diabetes globally, particularly in low and middle income countries, has given rise to a heightened burden of associated complications, among which diabetic foot complications stand out as significant contributors to both morbidity and mortality. In the context of this overarching concern, our study embarked on a focused exploration of specific research inquiries aimed at unraveling the intricacies of risk factors associated with amputation among diabetic patients presenting with diabetic foot complications.

Our primary objectives encompassed the identification of key risk factors contributing to amputations in this population. We delved into demographic characteristics, including age and gender, seeking to discern any specific patterns or susceptibilities linked to a heightened likelihood of amputation. Additionally, we scrutinized the role of glycemic control in amputation risk, considering factors such as HbA1C levels and blood glucose measurements. The evaluation extended to previous medical history, specifically assessing the impact of prior amputations on the likelihood of subsequent amputations in diabetic patients with foot complications. Furthermore, we examined the influence of distinct foot conditions, such as gangrene, foot infection, and osteomyelitis, on the predisposition to amputation.

Through the exploration of these research questions, our aim was to furnish a comprehensive understanding of the multifaceted factors contributing to amputations in diabetic patients contending with foot complications. Such insights hold paramount significance for the formulation of targeted preventive strategies, the refinement of clinical management practices, and the ultimate reduction of amputation incidence in this vulnerable population.

This study was dedicated to identify the risk factors associated with amputation among diabetic patients admitted to a tertiary care hospital with diabetic foot complications. The findings from this investigation are anticipated to not only illuminate the current landscape but also lay the groundwork for a prospective study that will delve deeper into the factors identified. Beyond its immediate implications, the gathered information is poised to play a pivotal role in informing and facilitating the implementation of targeted national strategies and programs focused on diabetes and NCD management. This comprehensive approach aims to contribute to the ongoing efforts to enhance the care and outcomes of diabetic patients, particularly those grappling with diabetic foot complications.

METHODS

Study Design and Settings

This was a hospital based retrospective study, conducted between March 2021 and June 2021 at Shree Hindu

Mandal Hospital (SHMH) a tertiary care hospital; located in Ilala City center, receiving over 300 patients with Diabetes per month seen by endocrinologists as well as general practitioners.

Study Population

All patients diagnosed with diabetes and presented with diabetic foot that required hospitalization between Jan 2017 and Dec 2020 were eligible for the study. All diabetic patients with foot ulcers treated as outpatient were excluded from the study. The sample size depended on data availability between the specified times.

Data Collection

Data was obtained from patient files and hospital electronic database. The primary outcome was amputation with the following predictors: age, sex, type of diabetes, duration of diabetes, co-morbidities such as hypertension and stroke, pharmacological therapy prescribed for diabetes, diabetic complications such as retinopathy, nephropathy, and diabetic foot signs (gangrene, ulcer, bacterial foot infection). The exposure was poor glycemic control defined by Glycemic control as having HbA1C less than 6.5% or FBG less than 7.0 mmol/L or RBG less than 11.1 mmol/L.¹ Smoking and alcohol consumption were considered potential confounders for amputation.

Data Analysis

Descriptive statistics for patient demographics was obtained using frequencies for categorical variables and means for continuous variables. To identify independent predictors with strong association with lower extremity amputation, we performed multiple linear logistic regression for all variables with amputation as the dependent outcome variable and calculated relative risks (RR) and 95% confident intervals. Model reliability was determined by the Hosmer and Lemeshow test of goodness of fit. Analysis was done with the Statistical Package for Social Sciences (IBM version 23.0; SPSS Inc., Chicago, IL, USA) and SAS. A *P* value <.05 was considered statistically significant. To address potential confounding factors, smoking and alcohol consumption were identified during the data collection process as variables of interest. The decision to consider smoking and alcohol as potential confounders was based on established literature linking these factors to diabetic foot complications. Specifically, previous studies have indicated that smoking and alcohol consumption may influence the progression of diabetic foot ulcers and contribute to adverse outcomes.

In the multiple linear logistic regression models, we explicitly adjusted for smoking and alcohol consumption as confounding variables to discern their independent effects on the risk of amputation among diabetic patients with foot complications. This adjustment aimed to isolate the specific impact of factors such as poor glycemic control and the presence of conditions like gangrene from the potential influence of smoking and alcohol. The inclusion of these variables in the analysis enhances the robustness of our findings and ensures a more accurate assessment of the identified risk factors.

Ethical approval

In this retrospective study, conducted with ethical approval obtained on 8th November 2021 (Ref No:

NIMR/HQ/R.8a/Vol.III/95) from the National Institute of Medical Research, informed consent was not sought as all data were anonymized. The names of participants were completely removed during the de-identification process, ensuring that none of the individuals could be identified. Confidentiality measures were rigorously upheld to safeguard the privacy of the participants. The absence of participant names in the study data and analyses, coupled with strict confidentiality protocols, preserved the anonymity of individuals and upheld ethical standards throughout the research process.

RESULTS

Socio-demographic Characteristics

A total of 56 adult patients were enrolled in the study. The mean age was 60.6 (SD ±11.7) years, range (36-89). The majority of the patients were between 50-69 years 36 (64.3%). Male were 44 (78.6%). Thirty-three patients (58.9%) had amputation, and of these 19 (57.6%) underwent major amputation. Additionally, of those who had amputation on admission, 10 (30.3%) had previous history of amputation whereby 9 (90%) had major amputation.

Clinical Characteristics

All patients had Type II DM, with a mean duration of DM of 10.7±6.7. All patients except one were on pharmacological therapy, 23 (41.1%) being on insulin regimen only, and 13 (23.2%) were on oral hypoglycemics. Poor glycemic control was notable for a number of patients (n=46) at the time of admission at the hospital as indicated by their plasma glucose level and among those 31 (55.4%) had amputation. Forty-five (80.4%) of the patients were hypertensive and 27 (81.8%) were amputated (Table 1). Gangrene, foot infection, osteomyelitis, Fasting Blood glucose and random blood glucose were significant predictors of amputation in the univariate analysis. Multivariate logistic regression analysis showed that independent risk factors of amputation were age between 50 and 69, gangrene and foot infection (Table 2). Patient with gangrene had four times the risk of amputation as compared to those without gangrene.

TABLE 1: Continued

Variable	All n (%)	Amputated n (%)
Smoking		
No	10 (17.9)	7 (21.2)
Yes	5 (8.9)	5 (15.2)
Not recorded	41 (73.2)	21 (63.6)
Alcohol		
No	5 (8.9)	5 (15.2)
Yes	9 (16.1)	6 (18.2)
Not recorded	42 (75)	22 (66.6)
Comorbidities		
Hypertensive	45 (65.2)	27 (65.9)
Nephropathy	11 (15.9)	5 (12.2)
Retinopathy	5 (7.3)	3 (7.3)
Stroke	8 (11.6)	6 (14.6)
Foot complications*	N=56	N=33
Ischemic foot	30 (53.6)	19 (57.6)
Neuropathic foot	26 (46.4)	15 (45.5)
Ischemic and neuropathic	22 (39.3)	14 (42.4)
Foot ulcer	54 (96.4)	32 (97)
Gangrene	35 (62.5)	29 (87.9)
Foot infection	39 (69.6)	28 (84.8)
Osteomyelitis	9 (16.1)	8 (24.2)
Mortality	2 (3.6)	2 (6.1)

*The percentages are calculated based on total number of patients and patients who underwent amputation

TABLE 1: Clinical Characteristics for Categorical Variables

Variable	All n (%)	Amputated n (%)
Age groups in years		
30-49	8 (14.3)	4 (12.1)
50-69	36 (64.3)	22 (66.7)
70-89	12 (21.4)	7 (21.2)
Sex		
Female	12 (21.4)	6 (18.2)
Male	44 (78.6)	27 (81.8)
Type of therapy for DM		
Oral medications only	13 (23.2)	9 (27.3)
Insulin regime only	23 (41.1)	11 (33.3)
Insulin + Oral medications	19 (33.9)	13 (39.4)
Not on medication	1 (1.8)	0 (0)

Continue

TABLE 2: Risk Factors for Amputation

Variable	cRR [95% CI]	P-value	aRR [95% CI]	P value
Age Groups				
30-49	1		1	
50-69	1.22[0.58,2.56]	.595	1.87[0.93,3.75]	.044
70-89	1.17[0.50,2.71]	.720	1.46[0.70,2.71]	.224
Gender				
Female	1		1	
Male	1.23[0.67,2.26]	.512	0.88[0.56,1.37]	.567
Gangrene				
No	1		1	
Yes	4.35[1.76,10.73]	.001	4.03[1.31,12.43]	.015
Foot infection				
No	1		1	
Yes	2.44[1.13,5.27]	.023	2.28[1.97,4.79]	.029
Osteomyelitis				
No	1		1	
Yes	1.67[1.17,2.39]	.005	1.07[0.74,1.57]	.713
Ischaemia				
No	1		1	
Yes	1.48[0.51,4.32]	.472	1.02[0.71,1.46]	.922
Neuropathy				
No	1		1	
Yes	0.91[0.31,2.64]	.861	0.92[0.57,1.47]	.996
Ischemia and neuropathy				
No	1		1	
Yes	1.14[0.73,1.77]	.562	0.77[0.50,1.17]	.213
Insulin plus Oral regimen				
No	1		1	
Yes	1.27[0.82,1.95]	.283	1.25[0.37,4.17]	.719
Oral regimen only				
No	1		1	
Yes	1.12[0.70,1.81]	.627	1.34[0.39,4.6]	.638
Insulin regimen only				
No	1		1	
Yes	0.72[0.44,1.18]	.184	1.36[0.41,4.52]	.621
Duration				
Not known	1			
<10	1.24[0.74,2.09]	.410	1.04[0.72,1.50]	.835
>10	1.24[0.72,2.14]	.448	1.49[0.94,2.36]	.091
FBG	1.06[1.01,1.11]	.015	1.03[0.98,1.08]	.201
HbA1C	1.06[0.96,1.18]	.269	1.02[0.95,1.10]	.597
RBG	1.03[1.01,1.06]	.014	1.02[0.99,1.05]	.155

cRR, crude risk ratio; aRR, adjusted risk ratio

DISCUSSION

The current study aimed to determine important risk factors of amputation among diabetic patients with diabetic foot admitted at SHMH a tertiary care hospital in Tanzania. Results from this study showed that gangrene, foot infection, osteomyelitis, Fasting Blood glucose and random blood glucose (both low and high) were important risk factors for amputation.

This study confirmed that patients with gangrene, foot infection and osteomyelitis were more likely to undergo limb amputation. These foot conditions require vigorous

and aggressive surgical treatment and thus the majority will end up with loss of the affected limb. Similar findings were observed in other studies where the reasons were due to patient's reluctance in seeking medical attention⁴ in belief that the symptoms will eventually fade away. However, with the advanced technology and intergraded healthcare services it is expected that the numbers would significantly reduce if physicians reminded their patients on taking care of their health in relation to their illness, which is treating patients as a whole and not for the reasons that brought them to the hospital.

In light of the multivariate analysis, which adjusted for potential confounders, our study underscores the crucial role of age, gangrene, and foot infection as the primary and independent risk factors for amputation among diabetic patients presenting with foot complications. While our initial univariate analysis indicated associations with additional factors such as osteomyelitis, FBG, and RBG, the multivariate model clarified that age, gangrene, and foot infection remained the significant predictors. The emphasis on age aligns with existing evidence that advancing age is a well-established risk factor for diabetic foot complications and subsequent amputation. Older individuals may face challenges related to decreased tissue healing capacity and increased susceptibility to infections, contributing to the elevated risk observed in this study. The prominence of gangrene and foot infection in the multivariate analysis highlights the critical impact of these complications on the likelihood of amputation. These findings underscore the urgency of preventive measures, early detection, and aggressive management of gangrene and foot infections in diabetic patients. Comprehensive foot care strategies, including patient education and regular monitoring, are imperative to mitigate these risk factors and reduce the incidence of amputations. While our initial univariate analysis identified associations with osteomyelitis, FBG, and RBG, the refined multivariate analysis emphasizes the specific factors independently contributing to amputation risk. This nuanced interpretation aligns with our commitment to providing a thorough and accurate representation of the study findings, aiding clinicians and healthcare practitioners in targeted interventions and patient care.

Despite the majority of patients being on either insulin or combination of insulin and oral hypoglycemics, the majority still had poor glycemic control. Our findings differ from a study done in Mwanza where more than half were on oral hypoglycemics.¹⁷ This difference can be explained by the presence of an endocrinologist specialized in diabetic care who frequently reminds the junior doctors on appropriate management of patients with diabetes. The current recommendations for management of patients with DM type 2 encourage use of combination therapy to maintain A1C at target,¹⁸ since type 2 DM is a progressive disease. However, affordability of medications to treat the disease is a huge barrier to attaining good glycemic control. As depicted from our study population, majority fall in the retirement age, it is possible that they cannot afford the medications due to high cost and hence difficult to achieve the desirable glycemic levels.

In this study, the most affected population was the elderly and a few middle-aged patients. A prospective study done in the northeastern part of Tanzania describing the surgical management of Diabetic foot ulcers showed similar results in the age group pattern.¹¹ Increasing age increases the risk of foot ulcer as well as amputation. Comprehensive management and care in this stratum are essential in order to prevent and minimize the risk of complications.

In further dissecting the study findings, it is imperative to explore the potential mechanisms that underlie the identified associations, incorporating both biological and sociocultural perspectives. The recognized risk factors,

such as poor glycemic control, gangrene, and foot infection, may be intricately linked to a range of biological and sociocultural factors.

From a biological standpoint, the association between inadequate glycemic control and increased amputation risk can be elucidated by examining microvascular complications. These complications, impacting blood flow to the lower extremities, form a critical pathway to understanding the biological foundations leading to amputation. Additionally, conditions like foot infection and gangrene often involve complex inflammatory responses, warranting a deeper exploration into the inflammatory cascades and their implications for tissue damage and subsequent amputation.

On the sociocultural front, factors such as healthcare accessibility and awareness play pivotal roles. Limited access to healthcare services or delayed seeking of medical attention can contribute significantly to the progression of foot complications, influencing the likelihood of amputation. Furthermore, health literacy levels among diabetic patients, particularly in understanding proper foot care practices, can shape preventive measures. Initiatives aimed at improving health literacy may help mitigate some of the identified risk factors associated with diabetic foot complications. Additionally, cultural beliefs influencing patient attitudes towards seeking medical help can impact the trajectory of foot complications. Addressing cultural perceptions surrounding illness and treatment-seeking behavior becomes crucial in the prevention and management of diabetic foot complications.

This comprehensive exploration of both biological and sociocultural factors enhances the interpretation of study findings, offering a nuanced understanding of the mechanisms driving amputation risk. It underscores the importance of holistic approaches to diabetic foot care and prevention, integrating both medical and sociocultural dimensions for more effective outcomes.

Limitations

This study, focused on understanding the risk factors associated with amputation in diabetic patients presenting with diabetic foot at Shree Hindu Mandal Hospital, carries certain limitations that warrant consideration. One notable limitation stems from the retrospective design, where reliance on available patient records resulted in some missing information. Crucial variables, including the duration of diabetes, history of smoking or alcohol consumption, and detailed foot examination records, were not consistently documented. These gaps in data introduce potential biases and constrain the thorough analysis of certain associations.

In addition, the study's sample size was inherently limited, consisting of 56 participants, dictated by the availability of data within the specified period. While efforts were made to derive meaningful conclusions, the relatively small sample size raises concerns about the statistical robustness and generalizability of the findings to broader populations. Moreover, the study's confinement to Shree Hindu Mandal Hospital, a single tertiary care facility in Dar Es Salaam, Tanzania, poses a limitation to the external validity of the results. Caution is advised when extrapolating these findings to other healthcare settings

or diverse populations.

Furthermore, certain clinical parameters essential for a comprehensive assessment of diabetic patients, such as weight, height, and lipid profiles, were not available for analysis. The absence of these data restricts the exploration of their potential impact on the risk of amputation. Additionally, the study introduced selection bias by exclusively including hospitalized diabetic patients with foot complications, excluding outpatient cases with foot ulcers treated outside the hospital setting. This selection bias may influence the overall representation of diabetic foot cases in the population.

In light of these limitations, this study contributes valuable insights to the existing literature on diabetic foot complications and amputation risk factors. However, future research endeavors with larger sample sizes, more diverse populations, and comprehensive data collection are essential to further elucidate these complex associations.

CONCLUSION AND RECOMMENDATION

In conclusion, this study not only identifies key risk factors for amputation among diabetic patients with foot complications but also highlights actionable insights for clinical practitioners and sets the stage for future research endeavors. By integrating these findings into clinical practice and fostering ongoing research initiatives, we can strive towards more effective preventive measures and improved outcomes for individuals with diabetic foot complications.

Gangrene, foot infection, glycemic control, and osteomyelitis were identified as important risk factors for amputation in our study population. These findings underscore the critical importance of proper foot care, thorough foot examination, adherence to medications, and glycemic control in minimizing diabetic foot cases. It is imperative that clinical practitioners prioritize intensive glycemic management strategies and remain vigilant for specific foot conditions such as gangrene, implementing timely and aggressive interventions to address these complications.

Additionally, to translate our findings into actionable measures, implementation strategies should focus on integrating comprehensive foot care education into routine diabetes management protocols. Targeted interventions to improve health literacy, particularly regarding proper foot care practices, can be instrumental in reducing the risk of amputation among diabetic patients. Furthermore, collaborative efforts between healthcare providers, community organizations, and policymakers are essential for implementing strategies that enhance access to quality healthcare and address socioeconomic determinants influencing amputation risk.

As recommended by the American Diabetes Association, regular foot examinations are paramount for identifying risk factors for ulcers and amputation. Therefore, adherence to guidelines recommending at least an annual foot examination, and more frequent assessments for patients with a high-risk foot, is crucial in preventing diabetic foot complications and reducing the burden of amputations.

By adopting a multifaceted approach that incorporates these recommendations into clinical practice and research initiatives, we can strive towards improved outcomes and better quality of life for individuals with diabetic foot complications.

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