

The Magnitude and Associated Factors of Diabetic Foot Ulcer Among Patients with Chronic Diabetic Mellitus in Northeast Ethiopia, 2021

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Introduction: Diabetic disease and its complications are major public health problems that result in long-term hospitalization, amputation, and poor quality of life for patients. This study aimed to determine the magnitude and associated factors of diabetic foot ulcers among patients with chronic diabetic mellitus in northeast Ethiopia.

Methods: An institutional-based cross-sectional study was conducted. The sample was selected using a systematic random sampling technique based on inclusion criteria. Data were collected using a self-administered pre-tested structured questionnaire. The collected data were entered into EpiData 3.1 and exported to SPSS 25 for statistical analysis. A binary logistic regression model was used to analyze the association between dependent and independent variables. All variables with P -value <0.25 were included in multivariable logistic regression. Adjusted odds ratio at 95% confidence intervals and considered significant with P -value <0.05 in final statistical significance was used to determine the level of association.

Results: The overall 283 samples of diabetic cases in the follow-up were included. The magnitude of diabetic foot ulcer was 7.1% (95% CI=3.92, 47.2%). Duration greater than 5 years (AOR=2.28, 95% CI=3.04, 17.69), history of ulceration (AOR=7.24, 95% CI=1.25, 11.78), peripheral neuropathy (AOR=5.77, 95% CI=1.33, 12.155), oral hypoglycemic (AOR=3.2, 95% CI=4.02, 4.36) and insulin (AOR=2.6, 95% CI=1.75, 4.36) were found to be the significant factors of diabetic foot ulcer.

Conclusion: The magnitude of diabetic foot ulcer patients was 7.2% and associated with duration of diabetes mellitus, history of ulceration, peripheral neuropathy, and oral hypoglycemic medication. Therefore, attention is needed for prevention, early detection, and caring for foot ulcers.

Keywords: diabetes, magnitude, Ethiopia, foot ulcer, factors

Introduction

Diabetes mellitus is one of the top causes of micro-vascular and macro-vascular complications around the world. In 2019, around 463 million adults had diabetes, with this number anticipated to rise to 700 million adults by 2045.¹ A diabetic foot ulcer is a long-term macro-vascular diabetic complication of diabetes mellitus. World Health Organization (WHO) reported in 2016, around 1.6 million diabetes mellitus complications due to diabetic foot ulcers with a lifetime incidence of foot ulcers occurring in one-fourth of diabetic people.² According to the International Diabetic Federation, 9.1–26.1 million patients get DFU each year.³ The global and African prevalence of diabetic foot ulcer was 6.3% and 7.2% which was higher in males and type 2 diabetes mellitus respectively.⁴ Diabetes complications are more common in sub-Saharan Africa as a result of delayed diagnosis and inadequate case management.^{5,6}

Diabetic foot ulceration has a significant cause of physical, psychological, and financial burden for both patients and healthcare sectors in patients with diabetes. It showed that a total of 15% of diabetic individuals face a lifetime risk and also

around 20% of diabetic patients hospital admissions due to diabetic foot ulcers.^{4,7} Diabetic foot ulceration acts as an antecedent to the development of gangrene and lower limb amputation is carried out more than 20 times as frequently in people with diabetes than in those without diabetes if necessary care is not given. Although, once DFU has developed, there is greater chance of ulcer advancement which could lead to amputation. Furthermore, it is reported that every 30 seconds one leg is amputated due to DFU worldwide with more than 50% mortality rate after diagnosis. An increase in the number of individuals who have diabetic-related amputation makes the mortality rate worse than other several common cancers.^{8,9}

Several studies reported that factors that contribute to development of diabetic foot ulceration were old age, duration of diabetes mellitus, poor self-care practice, and delay in medical attention typically in the setting of peripheral arterial disease, peripheral neuropathy, and trauma. In addition, the presence of comorbidities like ischemia from peripheral vascular disease, obesity, and hypertension act as fuel to develop.^{10,11}

DFU is associated with significant mortality included from peripheral neuropathy, and early effective prevention, detection and caring through health education, controlling of blood sugar, and preventing trauma may improve severe complications and quality life of the patients.⁷ In developing countries like Ethiopia most complications of diabetic mellitus develop due to delayed diagnosis, high cost of treatment, and other related socio-economic problems. For example, the cost of DFU is estimated as one-third of the total cost of diabetic-related treatment.^{9,12} In Ethiopia, the magnitude and associated factor varies depending on sitting and time. Since there is no study in this area even if the fact that the disease is on the rise, this study is aimed to investigate the magnitude of diabetic foot ulcers and associated factors in the northeast part of Ethiopia.

Materials and Methods

Study Design, Study Area, and Study Period

An institutional-based cross-sectional study design was conducted to assess diabetic foot ulcers among patients with chronic diabetes at DBCSH from January–February. The study was conducted in Debre Berhan Comprehensive Specialized Hospital. It is located in North Shoa Zone, Amhara regional state, northeast part of Ethiopia. It is 130 km far from the capital city Addis Ababa, and 695 km far from the regional city Bahir Dar. The town has nine kebeles. According to data obtained from 2007 Central Statistics Agency of Ethiopia, Debre Berhan town has a total population of 108,825. There is one governmental referral hospital in the town.

Population

Source population was all patients with diabetes who have a diabetic follow-up in the diabetic clinic of DBCSH. The study populations were all patients with diabetes who were under follow-up at the DBCSH during the study period.

Sample Size Determination, Sampling Procedure, and Study Variables

The sample size was calculated using a single population proportion formula by considering the prevalence from a study done on diabetic foot ulcers in Felege Hiwot Referral Hospital Ethiopia at 21.2%²³ at a 95% confidence level and a 5% margin of error. It gives an initial sample size of 257 by taking into consideration a 10% nonresponse rate; the final sample size was 283.

A systematic random sampling technique was employed to select study participants. The diabetes clinic runs twice weekly and there were about 565 patients with diabetes on follow-up taken from the diabetes mellitus outpatient clinic register. First, the total number of patients with diabetes patients was determined. Then, we got a total of 565 patients with diabetes mellitus. To get the final sample size, the interval was taken by dividing 565 by the final sample size (283). Then, we got Kth interval of two. Then, the first patient was selected randomly from the one or two by a lottery method, and the next patient was interviewed and examined in every second interval.

Dependent variable: Diabetic foot ulcer

Independent variables: Socio-demographic factors, Clinical characteristics, and Behavioral characteristics

Operational Definitions

Diabetic foot ulcers: These are non-traumatic lesions of the skin on the foot distal to malleoli of a person who has diabetes mellitus.

Gangrene: is a death of body tissue due to a lack of blood supply.

Fitting footwear: is footwear which is properly fitted to the patient who wears it with the absence of too tight, or too wide, high heel, poor quality, or hard leather.

Diabetic foot self-care practice: this means assessing the diabetic foot self-care practice of the patients. Based on the question and response of the study participants' responses, mean will be used as a cutoff point to determine the level of self-care practice. Patients with DM who score less than the mean score are considered as poor foot self-care practice. Above the mean designated as "Good foot self-care practice".

Peripheral vascular disease: palpate the posterior tibial artery and dorsalis pedis artery in both feet and record pulsations as absent or present.

Neuropathy (painful neuropathy): it was diagnosed if the patient had at least one manifestation from the following list of manifestations: describe sharp, stabbing, burning, shooting, or electric shock type pain, which may be worse at night and can disrupt sleep.

Inappropriate footwear: the shoes that are not appropriate with the shape and size of the shoe with the foot.

Data Collection Tools and Methods

The data were collected by using a data extraction tool adapted from different studies which consisted of socio-demographic, clinical, and behavioral characteristics factors. Interview and self-administered structured questionnaire were conducted. The questionnaires were first prepared in English language and translated to the local Amharic language to facilitate the data collection process. Finally, the questionnaires were re-translated to English by language experts for analysis purposes. Two BSC nurses and one MSC supervisor were involved in the data collection in a specific period.

Data Quality Assurance

To ensure the quality of the data the questionnaires were adapted from different published articles with some modification and checked by senior researcher and academician. Pretest on 5% was done before the actual data collection. The finding of the pretest was discussed among data collectors and supervisors to ensure a better understanding of tools and procedures so that it was modified for final data collection accordingly. The principal investigators and supervisors made day-to-day on-site supervision during the whole period of data collection and checked the collected data for completeness, clarity, and consistency on a daily basis. Both data collectors and supervisors were trained for two days on the data collection tool.

Data Processing and Analysis Plan

The collected data were cleaned, edited coded, entered into EpiData 3.1 software, and exported into SPSS version 25 for final analysis. Descriptive statistical analysis was computed to calculate means, standard deviations, frequencies, and percentages. Logistic regression analysis was performed separately to estimate the effects of each factor. Crude odds ratios (COR) and corresponding 95% confidence intervals were used to quantify an unadjusted strength of association between the independent and the outcome variables. Independent variables which result in a *p*-value less than 0.25 in bivariate analysis were candidates to be considered for the final multivariable model. During multivariable analysis, variables having a *p*-value <0.05 were taken as significant determinants of diabetic foot ulcers. Finally, the findings were presented by tables, figures, and narrations.

Results

Socio-Demographic Characteristics

A total of 283 diabetes mellitus follow-up clients participated in this study with a response rate of 100%. Of whom greater than half of the participants (55.8%) were females and their mean age was 55.32±29.27 years. Slightly more than

Table 1 Socio-Demographic Characteristics to Determine the Magnitude of Diabetic Foot Ulcer Among Chronic Diabetic Mellitus Patients at DBCSH Northeast Ethiopia, 2021 (n=283)

Characteristics	Category	Frequency	Percent (%)
Age	20–28	28	9.9
	29–37	31	11.0
	38–46	83	29.3
	47–55	22	7.8
	56–64	19	6.7
	65–73	22	7.8
	74–82	31	11.0
	≥83	47	16.6
Sex	Female	158	55.8
	Male	125	44.2
Marital status	Single	54	19.1
	Married	168	59.4
	Divorced	31	11.0
	Widowed	30	10.6
Residence	Rural	157	55.5
	Urban	126	44.5
Education	Cannot read and write	18	6.4
	Reading and writing	84	29.7
	Primary education	50	17.7
	Secondary education	18	6.4
	Diploma	95	33.6
	Degree and above	18	6.4
Occupation	Employed	156	55.1
	Farmer	30	10.6
	Unemployed	97	34.3

half (55.5%) were living in rural areas and 59.4% were married. From total respondents, those who cannot read and write were 6.4% (Table 1).

Behavioral and Clinical Characteristics of the Respondents

More than two-thirds of participants, 230 (81.3%), were not made physical exercise and 261 (92.2%) were followed for the treatment of type II diabetes mellitus. Two hundred and forty-two (85.5%) of the respondents had good foot self-care practice. Around 26% of the respondents developed peripheral neuropathy. Regarding the treatment of medication, about 237 (83.7%) patients took oral hypoglycemia. Whereas, 24 (8.5%) patients took both insulin and oral hypoglycemia. Two-thirds of participants had more than 5-year duration with diabetes mellitus after diagnosis (Table 2).

The Magnitude of Diabetic Foot Ulcer Among Study Participants

The magnitude of diabetic foot ulcers was 7.1% (95% CI=3.92, 47.2%). This study is based on Wagner's classification of severity of the ulcer; the vast majority of the patients with diabetic foot ulcer were classified as grade 0. The magnitude of patients with diabetic foot ulcer in this study is shown in Figure 1.

Factors Associated with the Development of Diabetic Foot Ulcer

In bivariate analysis, sex, occupation, alcohol intake, duration of DM treatment, history of ulceration, peripheral neuropathy, and current medications were fitted at a *p*-value less than or equal to 0.25. These variables fitted at bivariate logistic regression analysis were entered into multivariate analysis. In multivariate analysis, duration on DM treatment,

Table 2 Clinical and Diabetic Information of the Study Participants in DBCSH Northeast Ethiopia, 2021 (n=283)

Characteristics	Frequency	Percent (%)
Alcohol intake		
Yes	125	44.2
No	158	55.8
Foot self-care practice		
Poor foot self-care practice	41	14.5
Good foot self-care practice	242	85.5
Skin texture		
Dry and crack	30	10.6
Smooth and moist	253	89.4
Physical exercise		
Active	53	18.7
Inactive	230	81.3
Comorbid hypertension		
Yes	57	20.1
No	226	79.9
Type of DM		
Type I	22	7.8
Type II	261	92.2
Duration on DM		
<5 years	60	21.2
>5 years	223	78.8
Current anti-diabetic medication		
Oral hypoglycemic drug	237	83.7
Insulin	22	7.8
Both	24	8.5
Follow-up regularly		
Yes	229	80.9
No	54	19.1
Peripheral neuropathy		
Yes	74	26.1
No	209	73.9
Foot pulses		
Absent	45	15.9
Present	238	84.1
Appropriate footwear		
Yes	10	3.5
No	273	96.5

history of ulceration, peripheral neuropathy, and current medications were found to be significant factors for diabetic foot ulcer with a *p*-value less than 0.05 level of significance. Those who had the symptom of peripheral neuropathy disease were 6.23 times more likely to develop diabetic foot ulcers than those who had not peripheral neuropathy disorder (AOR=6.23, 95% CI=1.49, 26.003) (Table 3).

Discussion

This cross-sectional study showed the magnitude and associated factors in the diabetic foot which gives clues to the magnitude and contributed factors in the study area. The overall magnitude of foot ulcers in diabetic patients was 7.1%. This is comparable with a similar study in Indian (8%),¹³ Pakistan (7.02%),¹⁴ and Norway (7.4%).¹⁵ Whereas, this finding is lower than the previous study done in the Harari region in Ethiopia (21.1%),² Addis Ababa (20.7%),¹⁶

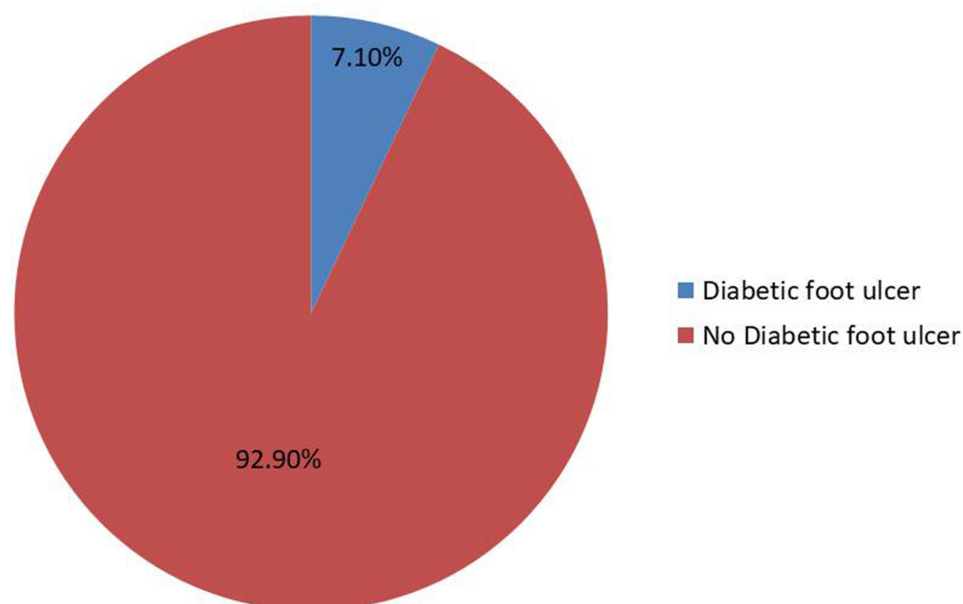


Figure 1 The magnitude of diabetic foot ulcer patients in DBCSH northeast Ethiopia, 2021 (n=283).

and Tanzania (15%),¹⁷ and higher than that of a study conducted in Dessie, Ethiopia (4.4%).¹⁸ The variation may be in different sample sizes and study design used, some were retrospective follow-up studies for a long time.

This study revealed that those diabetic patients who had peripheral neuropathy disease were 6.23 times more likely to develop diabetic foot ulcers as compared to those who had no peripheral neuropathy disorder (AOR=6.23, 95% CI=1.49, 26.003). This finding was supported by a study conducted in Gondar university hospital diabetes patients with peripheral neuropathy who were 21.76 times more likely to develop diabetic foot ulcer compared to those without.¹⁹ The other study in southern Ethiopia revealed that a presence of peripheral neuropathy was 4.48 times more likely to develop diabetic foot ulcer than those patients who had no peripheral neuropathy.²⁰ In another case-control study done in Tikur Anbessa Hospital, Ethiopia patients with peripheral neuropathy were 7.56 times more likely to develop foot ulcers.²¹ A possible explanation is that in patients with peripheral neuropathy, the sensitivity and loss of vibration sensation significantly increases the risk of trauma, and the patient is unaware of the onset of sores/ulcers.

This study showed that patients with diabetes who take only oral hypoglycemic medication were 3.2 times more likely to develop diabetic foot ulcers than those patients who take a combination of oral hypoglycemic medication and insulin. Patients who took insulin only were 2.6 times more likely to develop diabetic foot ulcer than those patients who took a combination of oral hypoglycemic medication and insulin. This is supported by a case-control study done in Tikur Anbessa Specialized Hospital in Ethiopia patients who take a combination of oral hypoglycemic medication and insulin were 89% less likely to develop diabetic foot ulcers than patients who took insulin only.²¹

This study showed that patients who lived with DM for more than 5 years were 2.28 times more likely develop diabetic foot ulcer than patients who lived with DM for less than 5 years (AOR=2.28, 95% CI=3.04, 17.69). This is supported by a study done in Felege Hiwot referral hospital at Bahir Dar, Ethiopia that revealed that patients who follow for 6–10 years were 2.44 times more likely to develop DM complications than those who are living with DM for <5 years respectively.¹⁰ Another study conducted in the southern part of Ethiopia showed patients living with diabetes mellitus greater than 10 years were 1.91 times more likely to develop diabetic foot ulcer than patients living with diabetes mellitus for less than 5 years.²⁰ A study in Sudan bared that diabetic patients who had follow-up for 5 years or more were 1.09 times more likely to develop DFU than those patients with DM for less than 5 years (AOR=1.09; 95% CI=1.05, 1.14).²² This is perhaps due to a diabetic person may have been exposed to hyperglycemic conditions for a lifetime, and cumulative glycemic load can have toxic consequences and affect any part of the body including skin and feet. Long-

Table 3 Bivariate and Multivariate Regression Analysis of Factors Associated with Diabetic Foot Ulcer Among DM Patients in DBCSH Northeast Ethiopia, 2021 (n=283)

Variables	Foot Ulcer		Bivariate COR (95% CI)	Multivariate AOR (95% CI)
	Yes	No		
Sex				
Male	4 (3.2%)	121 (96.8%)	1	
Female	16 (10.1%)	142 (89.9%)	3.408 (1.110, 10.469)*	0.5 (0.076, 2947)
Occupation				
Employer	17 (10.9%)	139 (89.1%)	5.809 (1.312, 25.731)*	9.1 (0.772, 106.799)
Farmer	1 (3.3%)	29 (96.7%)	3.547 (0.454, 27.719)	0.86 (0.134, 5.637)
Other	2 (2.1%)	95 (97.9%)	1	
Alcohol intake				
Yes	14 (11.2)	111 (88.8%)	3.195 (1.191, 8.575)*	3.1 (0.708, 13.217)
No	6 (3.8%)	152 (96.2%)	1	
Duration of DM				
>5 years	11 (18.3%)	62 (81.7%)	5.338 (1.098, 13.583)**	2.28 (3.040, 17.69)**
≤5 years	9 (4.0%)	201 (96%)	1	1
History of ulceration				
Yes	14 (8.7%)	147 (91.3%)	1.841 (0.686, 4.940)**	7.24 (1.257, 11.781)**
No	6 (4.9%)	116 (95.1%)	1	
Peripheral neuropathy				
Yes	13 (17.6%)	61 (82.4%)	6.150 (2.349, 16.101)**	5.77 (1.325, 12.155)**
No	7 (3.3%)	202 (96.7%)	1	
Current medication				
Oral hypoglycemia	10 (21.7%)	36 (78.3%)	4.981 (2.338, 9.497)**	3.2 (4.021, 9.644)**
Insulin	7 (5.1%)	130 (94.9%)	5.159 (1.834, 14.508)**	2.6 (1.780, 4.362)**
Mixed	3 (3%)	97 (97%)	1	1

Note: *Signifies those p-values were ≤0.25 and **p-value <0.05.

term hyperglycemia triggers a reaction between glucose and collagen, leading to the formation of advanced glycation end products.²³

As a limitation, the nature of the cross-sectional study does not show the relation of causes and effects. There might be recall bias or reporting bias regarding the contributing factors, such as alcohol use or exercise frequency.

Conclusion and Recommendation

The study showed that the magnitude of diabetic foot ulcers among people with diabetes attending diabetic follow-up clinics at DBCSH was 7.1%. The major associated factor for DFU, history of ulceration, peripheral neuropathy, and current medication were has a high contribution for DFU in this study. The study recommended that health education for patients and attendants should be provided regularly and further community-based and prospective follow-up studies will be beneficial to identify the clear incidence and prevalence of diabetic foot ulcers and to determine the potential risk factor of diabetic foot ulcers.

Abbreviations

AOR, adjusted odds ratio; CI, confidence interval; COR, crude odds ratio; DBCSH, Debre Berhan Comprehensive Specialized Hospital; DM, diabetes mellitus; DUF, diabetes foot ulcer; WHO, World Health Organization.

Data Sharing Statement

Data will be available upon request from the corresponding author.

Ethical Approval and Consent

Ethical clearance for the proposed study was obtained from School of Nursing and Midwifery, Asrat Woldeyes Health Science Campus, Debre Berhan University research ethical committee (DBU 070/21). A letter of cooperation was sent to the director of Debre Berhan Comprehensive Specialized Hospital, then to the department coordinators. The letters of informed consent granted by the School of Nursing, and Midwifery, and the purpose of the study were explained to the study participants. Then, the signed written informed consent was obtained from study participants. Confidentiality of the information was kept throughout the study by excluding the names of study participants as identification in the data collection form, and the data were used only for the proposed study. To maintain confidentiality, all collected data were coded and locked in a separate room before entering the computer. After entering the computer, the data were locked by password, and the data were not disclosed to any person other than the principal investigator. The study follows the declaration of Helsinki ethical principles.

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Author Contributions

All authors made a significant contribution to the work reported, whether that is in the conception, study design, execution, acquisition of data, analysis, and interpretation, or in all these areas; took part in drafting, revising, or critically reviewing the article; gave final approval of the version to be published; have agreed on the journal.

Disclosure

The authors report no conflicts of interest in this work.

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