Original Research

Diabetic Foot Ulcer Among Adults Attending Follow-Up Diabetes Clinics in Wolaita Zone, Southern Ethiopia: An Unmatched, Case-Control Study

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ABSTRACT

Background: Diabetic foot ulcer is a major public health problem, and among the leading causes of this complication in Ethiopian patients with diabetes. Despite the magnitude of this problem, data regarding the determinants of diabetic foot ulcers are limited.

Objective: This study aimed to assess the determinants of diabetic foot ulcers among adults attending follow-up visits in diabetes clinics in the Wolaita Zone, southern Ethiopia.

Methods: An institution-based case-control study was done from September 10 to December 28, 2020, in southern Ethiopia. We recruited 137 patients with diabetic foot ulcers and 408 patients without any diabetic foot ulcers using a consecutive sampling method. EpiData version 3.1 (EpiData Association, Odense, Denmark) and SPSS version 25 (IBM-SPSS Inc, Armonk, New York) were used for data entry and analysis. Descriptive statistics were calculated followed by a multivariate logistic regression analysis. Results: Having a low wealth index (adjusted odds ratio [AOR] = 2.6; 95% CI, 1.177–5.662); being obese (AOR = 3.6; 95% CI, 1.380–9.547; P = 0.003), being overweight (AOR = 3.1; 95% CI, 1.480–6.436; P = 0.009), having peripheral neuropathy (AOR = 3.9; 95% CI, 1.641–9.430; P = 0.002), living with diabetes for > 10 years (AOR = 2.3; 95% CI, 1.191–4.475; P = 0.013), and practicing poor diabetic foot self-care (AOR = 6.0; 95% CI, 3.156–11.312; P = 0.000) were significantly associated with having a diabetic foot ulcer.

Conclusions: This study suggests there is a need for education and counseling of patients on decreasing weight and improving foot-care practice, especially in those who are economically disadvantaged, have peripheral neuropathy, and have lived with diabetes for more than 10 years. (Curr Ther Res Clin Exp. 2022; 83:XXX–XXX)

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Introduction

Diabetes mellitus (DM) is a common global public health problem that can result in serious illness and premature death.1,2 The prevalence of the disease is increasing. By 2040, it is estimated that approximately 642 million people will have DM worldwide, with a large proportion in low- and middle-income countries.3 According to a 2017 International Diabetes Federation report, nearly 15.5 million adults were living with diabetes in Africa,3 and more than 2.5 million cases of DM were reported in Ethiopia alone.4 An increase in the prevalence of diabetes is expected to be accompanied by an increase in its complications. Of all the complications of diabetes, diabetic foot ulcer (DFU) is the major cause of morbidity and mortality and is associated with many other devastating complications.3,5,6

Globally, DFU accounts for 50% of hospitalizations of patients with DM and is responsible for 50% to 70% of nontraumatic lower-limb amputations.3,5,6 The International Diabetes Federation estimates that for every 30 patients with DM worldwide a minimum
of 1 limb is amputated because of DFU. The estimated 5-year relative mortality after DFU is 48.3%. According to a World Health Organization report in 2016, DM was the direct cause of approximately 1.6 million deaths, and 25% of individuals with DM will have an ulcer at some stage of their life.

Although DFU is a significant global problem, its lifetime burden is highest in low- to middle-income countries due to late diagnosis, poor awareness, and lack of quality health services. DFU is a growing major public health problem for patients with DM in sub-Saharan Africa and is responsible for many prolonged hospitalization and deaths in patients from this part of the continent. In sub-Saharan Africa, the prevalence of DFU is estimated to be between 7.2% and 13.0%. Moreover, the pooled prevalence of amputation and hospital mortality caused by DFU in these nations has been estimated to be 15.5% (95% CI, 12.5%–18.6%) and 14.2% (95% CI, 9.9%–19.0%), respectively.

DFU is the leading cause of these complications in patients with DM and the prevalence of DFU among patients with DM in Ethiopia is 12% to 32%. DFU has been associated with various risk factors, such as type 2 DM, obesity, rural residence, poor foot self-care practice, duration of DM, peripheral neuropathy, peripheral vascular disease, and older age. Although some studies have been conducted in different parts of Ethiopia, the current study differs in that it is a case-control study, and to the best of the knowledge of the authors, it is the first study regarding risk factors for DFU conducted in the Wolaita Zone.

The association of khat chewing and physical exercise with DFU has not been well addressed in previous studies in Ethiopia, although these 2 factors may contribute to the development of this complication of DM. A clear understanding of risk factors associated with DM is crucial for effective programs designed and implemented to reduce the incidence and mortality associated with this disease. Thus, this study aimed to assess the associations between a number of factors and the presence of DFU in patients with DM living in the Wolaita Zone, southern Ethiopia. The findings of this study could be useful as a guide for evidence-based design of interventions initiated to decrease the incidence of this disease in Ethiopia.

Methods

Study design and setting

A facility-based unmatched case-control study was conducted at Wolaita Sodo University Teaching and Referral Hospital (WSUTRH), Sodo Christian hospital, and Dubo S Mary hospital from September 10 to December 28, 2020. All hospitals are located in Wolaita Zone, situated 329 km southwest of the capital Addis Ababa, and 167 km south of the regional capital city of Hawassa. Two hospitals (Sodo Christian hospital, and Dubo St Mary hospital) are private hospitals. WSUTRH is the only public teaching and referral hospital in Wolaita Zone, and provides a broad range of medical services to both inpatients and outpatients of all age groups in its catchment area of about 2 million people. Pretest was done at Bele hospital, a public primary hospital in Wolaita Zone, some 13 km from the nearest data collection site (Dubo St Mary hospital).

Population

The potential study population was composed of all patients with DM who were being treated at these 3 hospitals for a diagnosis of DFU. The study control population included all patients with DM treated at these same 3 hospitals without a diagnosis of DFU.

Inclusion criteria

Cases (patients with DM diagnosed with DFU) aged 18 years and older, and controls (patients with DM without DFU) aged 18 years and older who underwent follow-up at 1 of the 3 study hospitals during the study period and who gave their consent were eligible to be included in the study.

Exclusion criteria

Patients with DM (with DFU and without DFU) who had traumatic ulcers, were critically ill, or mentally impaired during data collection were excluded. Patients who were diagnosed with DM at the time of the study data collection and known patients with DM with a follow-up history <1 year were also excluded because the records of complications were to be reviewed.

Study variables and measurement

The outcome variable for this study was DFU diagnosed by a physician as being at least grade 1 (superficial ulceration) according to Wagner’s classification of DFU severity that was identified by a review of the patient’s card (ie, medical record). The ulcer must have been present for more than 1 week and fewer than 6 months at the time of the study data collection. The associated (ie, predictor) variables were selected based on previous similar studies and were grouped into 3 sets of factors: sociodemographic characteristics, behavioral factors, and clinical factors. Participants’ knowledge of DM was assessed using a 10-point score and direct questioning (risk factors of DM, signs and symptoms of DM, complications of DM, and control and management of DM). Those who scored 10 and above using a knowledge related to DM 20-question assessment questionnaires were labeled as having “good knowledge”; otherwise, they were assumed to have “poor knowledge.”

The wealth index is produced from the variables that could be assessed by direct questioning (selected household assets ownership, such as the house where household members reside, transportation materials, television, radio, electricity, telephone, refrigerator, Internet, personal computer, bed, separate sleeping room, and kitchen), materials used for housing construction, and access to utilities (such as type of water access and sanitation facilities). The data collected were subjected to a factor analysis using principal component analysis in SPSS (IBM-SPSS Inc, Armonk, New York) and used to assign patients to low, middle, and high wealth index groups. Foot self-care practices were assessed using a 7-point score. Those who scored 7 and above using a 14-question foot self-care practice assessment questionnaire were labeled as having “good self-care practice”; otherwise, they were assumed to have “poor self-care practice.”

Physical exercise was considered regular if participants reported to be doing at least 150 to 300 minutes of moderate-intensity aerobic activity, or at least 75 to 150 minutes of vigorous-intensity aerobic physical activity, or an equivalent combination of moderate- and vigorous-intensity activity throughout the week.

Body mass index (BMI) was calculated as the measured body weight of the individual patient (in kilograms) divided by the square of their measured height (in meters). Participants were assigned to 1 of the 3 groups: BMI 18.5 to 24.59 (normal range), BMI 25 to 29.9 (overweight), and BMI >29.9 (obese).

Blood glucose levels were measured using a glucometer after patients were informed to fast overnight, or at least 8 hours before the sample blood was obtained. A drop of blood from a patient’s finger—after cleansing the tip of the finger with a dry wipe and slightly pricking with a lancet—was applied to a chemically treated, disposable test strip and inserted into an electronic blood glucometer. Patients with a fasting blood glucose level ≤130 mg/dL...
were labeled as having “Well control”; otherwise labeled as having “Poor control.” Blood pressure was measured 3 times using a mercury sphygmomanometer with a 4-hour interval between each reading. Before their blood pressure was measured, the patient had rested for at least 30 minutes. Patients were considered hypertensive if their average systolic blood pressure was $\geq 140$ mm Hg or diastolic blood pressure was $\geq 90$ mm Hg, or if they were on hypertension-lowering medication(s); otherwise they were labeled as normotensive. Patients were considered to have neuropathy if their medical records indicated they reported any form of neuropathy consisting of numbness or pain, or had neuropathy diagnosed by a clinical examination using a monofilament, vibration, position, and temperature sensation testing as well as a current or past history of foot ulcer, gangrene, or amputation. Peripheral vascular disease was diagnosed based on either a clinical history or physical examination documented in the patient’s file. Findings considered diagnostic included absent or diminished pulses, abnormal skin color, poor hair growth, and cool skin, or ankle brachial index measurements, where an ankle brachial index value of 0.70 to 0.90 was considered as mild occlusion and ankle brachial index value $<0.70$ as a severe occlusion.

Ethical approval and consent to participate

Ethical approval was obtained from the Wolaita Sodo University College of Health Science School of Nursing Institutional Review Board of Research Committee (approval No. CHSM/ERC/67) and an official letter of request for cooperation was written by the community and research directorate of the university to the respective health facility heads. Letters of permission and cooperation were obtained from the heads of all 3 hospitals. Written informed consent was obtained from all study patients before they were interviewed. No personal details were recorded or produced on any documentation related to the study participants and confidentiality was assured. Patients were informed they were not obliged to participate.

Sample size and sampling procedure

To determine the sample size, a double proportion population formula for a case-control study using Epi Info version 7 (Centers for Disease Control and Prevention, Atlanta, Georgia) was employed with the following assumptions: 95% confidence level, 80% power, a case to control ratio of 1:3, odds ratio (OR) of 0.54, which is the ratio of the odds of patients with hypertension among cases to the odds of patients with hypertension among controls, and 67.8% probability of exposure to hypertension among control patients. After adding a nonresponse rate of 10% the final sample size was 545 (137 cases and 408 controls). The samples were proportionally allocated to size. A consecutive sampling method was then used to recruit study participants for the cases and controls.

Source of data and data collection methods

Data were collected using a structured interviewer-administered questionnaire, adapted with some modifications from previous, related studies. Data were collected via interviews, medical record reviews, measurements, and direct observation of these patients with DM. Blood samples were obtained by finger pricks for testing in the respective hospital clinical chemistry laboratory. Anthropometric measurements and foot examinations were performed by 3 trained medical interns (ie, physicians in training who have completed medical school but do not yet have a license to practice medicine unsupervised) working in study hospitals (1 in each study hospital). The final questionnaire had 3 subparts: sociodemographic characteristics, behavioral factors, and clinical factors. Item questions were checked for reliability and internal consistency using Cronbach alpha coefficients. Knowledge of DM was assessed using a 20-item questionnaire with a Cronbach alpha of 0.89, and diabetes foot self-care practice was assessed using a 14-item questionnaire with a Cronbach alpha of 0.91. The tool was translated into the local language and subsequently translated back to English by different language experts to check for internal consistency. Data were collected by 3 nurses with bachelor’s degrees and 3 medical interns who had experience in data collection and were supervised by the authors.

Data quality control

The tool was pretested on 5% of the sample size in the nearby Bele primary hospital. All required revisions were made to the study tool based on the pretest. Experienced enumerators, 3 nurses, and 3 medical interns were recruited for data collection. Before the actual data collection, 2-day intensive training on the aim of the study and sampling procedures was provided to the enumerators. Selected patients were oriented about the study and their random selection; data from participants were obtained in private settings after an in-depth discussion designed to remove their doubts and clarify any potential confusion. All the requirements used to minimize anthropometric measurement errors were met, including routine calibration of equipment, measurement resampling, and other standardized techniques. The supervisors (ie, the principal investigator and coauthor) routinely checked the completed questionnaires to ensure that all data had been obtained appropriately. Before beginning the data analysis, the item variables were converted correctly.

Data processing and analysis

The data were entered into EpiData version 3.1.1 (EpiData Association, Odense, Denmark) and then transferred to SPSS version 25 for analysis. Descriptive statistics were calculated. Bivariable and multivariable logistic regression analyses were also performed. Factors that were significant in the bivariable analysis with a P value $<0.25$ were retained for further consideration in a multivariable logistic regression. ORs with 95% CIs were computed and a P value $<0.05$ was used to determine the cutoff points for statistical significance. The necessary assumption of model fitness during logistic regression was checked using Hosmer-Lemeshow goodness-of-fit test statistics. Multicollinearity was checked by the use of a variable inflation factor, and all showed no multicollinearity with a variable inflation factor $<5$.

Results

Sociodemographic characteristics of participants

This study included a total of 545 patients with DM, 137 patients with DFU, and 408 patients with DM without DFU with a response rate of 100%. Patients with DFU were older than patients without DFU with the mean (SD) age of 51.67 (11.11) years and 40.51 (0.59) years ($P=0.003$), respectively. Slightly more than half of the cases and controls were men 71 (51.8%) and 213 (52.2%), respectively. The proportion of cases and controls who completed at least a secondary education was 63 (46.0%) and 233 (57.1%), respectively. A large proportion of the cases and controls lived in urban areas, 95 (69.3%) and 271 (66.4%), respectively. There were significantly more patients with DFU who belonged to the lower wealth index group than among the controls with DM 83 (60.6%) versus 99 (24.3%), respectively, with a P value of 0.000 (Table 1).
Table 1
Sociodemographic characteristics of adult patients with diabetes mellitus.

| Variable          | Category       | Cases* (n = 137) | Controls† (n = 408) | P value |
|-------------------|----------------|------------------|---------------------|---------|
| Age, y            | 18–27          | 7 (5.1)          | 51 (12.5)           | 0.007   |
|                   | 28–37          | 28 (20.4)        | 113 (27.7)          |         |
|                   | 38–47          | 33 (24.1)        | 97 (23.8)           |         |
|                   | >47            | 69 (50.4)        | 147 (36.0)          |         |
| Sex               | Male           | 71 (51.8)        | 213 (52.2)          | 0.451   |
|                   | Female         | 66 (48.2)        | 195 (47.8)          |         |
| Marital status    | Married        | 82 (61.3)        | 237 (58.1)          | 0.269   |
|                   | Single         | 53 (38.7)        | 171 (41.9)          |         |
| Educational status| No education   | 25 (18.2)        | 58 (14.2)           | 0.162   |
|                   | Primary education | 49 (37.8)    | 117 (28.7)          |         |
|                   | Secondary education | 33 (24.1) | 120 (29.4)          |         |
|                   | Tertiary and above | 30 (21.9)  | 113 (27.7)          |         |
| Occupational status| Unemployed     | 53 (38.7)        | 163 (40)            | 0.266   |
|                   | Employed       | 84 (61.3)        | 245 (60)            |         |
| Residence         | Urban          | 95 (69.3)        | 271 (66.4)          | 0.301   |
|                   | Rural          | 42 (30.7)        | 137 (33.6)          |         |
| Wealth index      | High           | 28 (20.4)        | 225 (55.1)          | 0.000   |
|                   | Medium         | 26 (19.0)        | 84 (20.6)           |         |
|                   | Low            | 83 (60.6)        | 99 (24.3)           |         |

* Values are presented as n (%).

Clinical and behavioral characteristics of participants

There were significantly more patients diagnosed with DM for more than 10 years among the cases compared with the controls 101 (73.7%) versus 160 (39.2%) (*P = 0.000*). The number of people who had poor glycemic control was higher among the case patients compared with the control patients 83 (60.6%) versus 142 (4.8%). The number of patients with type 2 DM among the cases was higher than that of controls 94 (68.6%) versus 167 (40.9%). Hypertension affected 64 (46.7%) of the cases compared with 83 (20.3%) of the controls. Peripheral neuropathy was significantly more prevalent among the cases than among the controls 64 (46.7%) versus 28 (6.9%) (*P = 0.000*). The prevalence of foot deformity was higher among the cases than the controls: 24 (17.5%) versus 60 (14.7%), respectively. The difference in the proportion of obese patients between the 2 groups was significant: 77 (56.2%) cases versus 63 (15.4%) controls (*P = 0.000*) (Table 2).

A significantly higher proportion of patients with DM among the controls compared with the cases claimed that they had a current history of khat chewing 42 (10.3%) versus 6 (4.4%). Slightly more than half of the patients among the cases and the controls had poor knowledge about DM: 71 (51.8%) and 211 (51.7%), respectively. The proportion of patients with good diabetes self-care practices among the cases and controls was significantly different: 22 (16.1%) and 253 (62.0%), respectively (Table 3).

Determinants for developing a DFU

During the bivariate logistic regression, age, educational status, wealth index, blood glucose level control, hypertension, BMI, peripheral neuropathy, current history of khat chewing, type of DM, duration of DM, and diabetes foot self-care practices were all associated with a higher likelihood of development of DFU. Results of multivariable regression indicated that wealth index, BMI, peripheral neuropathy, duration of DM, and diabetes foot self-care practice were significantly associated with the development of DFU.

Patients with DM who were assigned to the low wealth index group were 2.6 times more likely to have DFU than those in the high wealth index group (adjusted OR [AOR] = 2.58; 95% CI, 1.177–5.662; *P = 0.018*). Participants who were obese and overweight were 3.6 and 3.1 times more likely to experience DFU than patients with normal weight (AOR = 3.6; 95% CI, 1.380–9.547; *P = 0.003* and AOR = 3.1; 95% CI, 1.480–6.436; *P = 0.009*), respectively.

Moreover, patients with DM who had peripheral neuropathy were 3.9 times more likely to develop DFU than those without peripheral neuropathy (AOR = 3.9; 95% CI, 1.641–9.430; *P = 0.002*). Patients with a long history of DM (>10 years) were 2.3 times more likely to experience DFU than those who lived with DM <10 years (AOR = 2.3; 95% CI, 1.191–4.475; *P = 0.013*). Patients who reported poor foot self-care practice was 6 times more likely to have DFU than those who reported good foot self-care practice (AOR = 6.0; 95% CI, 3.156–11.312; *P = 0.000*) (Table 4).

Discussion

This study attempted to identify the determinants of DFU among patients with DM who underwent follow-up in the diabetes clinics of WSUTRH, Sodo Christian hospital, or the Dubo St Mary hospital. A comparison of the patients’ sociodemographic, behavioral, and clinical characteristics was performed to identify independent risk factors for a diagnosis of DFU.

In this study, patients assessed as being in the low wealth index group were 2.6 times more likely to be diagnosed with DFU than those in the high wealth index group. This has also been reported in previous studies conducted in Palestine,25 Singapore,26 and India,27 which all reported that a lower socioeconomic status was associated with increases in the prevalence of DFU, perhaps because patients with lower socioeconomic status cannot afford the medications and service charges that can improve their health. In addition to high morbidity and mortality, the economic burden, in terms of direct and indirect costs, is higher in patients with DM with DFU.28 Moreover, people with a lower wealth index are less likely to have therapeutic footwear.

BMI has a significant positive association with the development of DFU.14–16,18 Consistent with prior studies, the current study revealed that obese and overweight patients with DM were 3.6 and 3.1 times more likely to have DFU than those with normal weight. This might be explained by the fact that obesity, an important part of metabolic syndrome, is associated with worse hypertension and dyslipidemia, as well as worse glycemic control and is an independent risk factor for peripheral vascular disease, all of which are considered to be risk factors for developing DFU. A higher BMI also hampers patients with DM from performing healthy foot self-care practices. This emphasizes the need for obese patients with DM to understand the need for good dietary practices and regular physical exercise.
Patients with DM with DFU usually have a long past history of DM.\cite{25,29-31} Consistent with prior studies, the current study found that the duration of DM was strongly associated with the presence of DFU. Patients who had been diagnosed with DM for more than 10 years were 2.3 times more likely to develop DFU than patients who have been diagnosed with DM for 10 years or less. Previous studies in Ethiopia\cite{15,36,32} reported similar findings. This is likely the result of the cumulative glycemic burden associated with longer duration of DM that increases the chances of developing complications, including peripheral vascular disease, neuropathy, nephropathy, and retinopathy as well as DFU.

Peripheral neuropathy is reported to be responsible for about 50% of the cases of DFU.\cite{31} The current study revealed that those with peripheral neuropathy were 3.9 times more likely to develop DFU than did patients with DM without neuropathy. Another case-control study conducted in Addis Ababa, Ethiopia, also reported that patients with DM with peripheral neuropathy were more likely to experience DFU.\cite{18} Previous cross-sectional studies...
conducted in other parts of Ethiopia, Gondar,14 and Jimma15 similarly reported this association as have other studies conducted outside Ethiopia (eg, in Egypt,20 Sri-lanka,21 and Jordan22). These results are likely explained by the fact that neuropathic tissues are more vulnerable to infections and injuries resulting from increasing focal foot pressure and shearing forces. In addition, loss of protective pain sensations may result in serious ulcerations being unreported or unrecognized by the patient as well as by his or her doctors. Loss of sensation can lead to repeated microtrauma, breakdown of overlying tissue, and eventually ulceration.

Furthermore, patients who reported poor diabetes foot self-care practices were 6 times more likely to have a DFU than those reporting good diabetes foot self-care practices. This finding is consistent with previous studies conducted in Gondar,14 Arbamich,15 Addis Ababa,16 Palestine,23 and Egypt.20 Poor self-care practices like not washing the feet daily, drying inappropriately after washing, walking barefoot, not inspecting the feet daily, or wearing ill-fitting shoes might all increase the risk of ulceration and infection. This finding suggests that patients with DM may need more self-management support to optimize the care of their feet.

These results suggest that public health programs aimed at decreasing the prevalence of DFU are more likely to be effective if they focus on high-risk patients with DM, such as those who are overweight, have peripheral neuropathy, are economically disadvantaged, practice poor foot self-care, and those who have had DM for more than 10 years. Interventions that concentrate on improving DM patients’ knowledge of how being overweight and physically inactive, as well as practicing poor foot self-care, can adversely influence their health should be studied, especially in patients with DM who are economically disadvantaged and those who do not have access to effective diabetes education programs.

**Limitations of the study**

Due to the case-control nature of the study, the study results may have been influenced by recall bias. Although training was given to the data collectors to avoid introducing bias, the study patients were likely exposed to social desirability bias, especially with respect to the reporting of behavioral characteristics. Fasting blood sugar level was used to assess the status of glycemic control instead of glycosylated hemoglobin due to availability and cost problems. Glycosylated hemoglobin is a much better measure of long-term glucose control than are blood glucose measurements. The case–control study design—as opposed to a prospective, longitudinal design—and the use of only 3 hospitals also adversely influenced the reliability of study conclusions. Larger, prospective, longitudinal studies with directly observed or measured behaviors and better laboratory measures of long-term glucose control are needed to evaluate these findings.

**Conclusions**

Many of the factors identified in this study as being significantly associated with the development of DFU are modifiable, or at least controllable. This suggests there is an opportunity to reduce the number of patients with DFU. Unfortunately, large prospective trials are lacking that demonstrate which, if any, interventions designed to modify or control these factors will be effective.

**Declaration of Competing Interest**

The authors have indicated that they have no conflicts of interest regarding the content of this article.

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L. G. Gebrekirstos developed the project and took part in data curation, formal analysis, funding acquisition, investigation, methodology, resources, software, supervision, validation, visualization, writing-original draft, writing-review, and editing; M. T. Abadi, M. H. Gebremedhin, T. B. Wube, and E. A. Lake contributed to data curation, formal analysis, methodology, resources, software, supervision, validation, writing the original draft, and review and editing.

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