

RESEARCH ARTICLE

Incidence of Diabetic Foot Ulcer and its Predictors among Diabetic Patients Attending in Gedeo Zone Hospitals, Southern Ethiopia, 2020/2021

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Abstract

Background: The incidence of diabetic foot ulcer is growing over earlier decade with an increasing magnitude of diabetes mellitus (DM). The prior work primarily concentrated on the magnitude of DFU but incapable to recognize average time it takes for diabetic patients to develop DFU and difficult for early identification, prevention and treatment of the cause of diabetic foot ulcer.

Objectives: To determine incidence of DFU and its predictors among diabetes mellitus (DM) patients who were attending at Gedeo zone hospitals, 2020/2021 GC.

Materials and Methods: Institution-based Prospective follow up study was conducted in Gedeo zone hospitals From Nov 8/2020 to Sep 25/2021; Simple random sampling (SRS) technique was utilized to select respondents. The data gathering was daily checked for entirety and regularity and it was entered into EPI data version 3.2 data and transferred to Stata version 16 for analysis. The Kaplan-Meier estimation method was used and Cox proportional hazard model was applied.

Results: A total of 208 patients were taken from 4 hospitals 1 referral hospital and 3 Primary hospitals. of the total of study participant diabetic foot ulcer was found to be 10.58% [6.40-14.76]. Age greater than 55 years old [AHR=1.90; 95% CI: 1.56, 3.24], type II diabetes mellitus [AHR=3.02; 95% CI: 1.08, 5.40], Retinopathy [AHR=2.30; 95% CI: 1.43, 5.02], Nephropathy [AHR=3.56; 95% CI: 2.47, 5.70] were significantly associated with diabetic foot ulcer.

Conclusion: This study decided that 10.58% DM patient have foot ulcer. The leading explanations to develop foot ulcer were being older age, retinopathy, and nephropathy were meaningfully connected with DFU.

Keywords: Incidence, Diabetic Foot Ulcer, Predictors, Diabetes Mellitus, Ethiopia

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1 Introduction

Diabetes mellitus (DM) is a cluster of disorders that distress how your body handles glucose. Because glucose is a substantial source of energy for the cells that create up your muscle and tissue, it is crucial to your health. It's also the primary source of energy for your brain [1,2] Diabetic ulcers are the most common foot injuries that lead to amputation of the lower extremity. Diabetic foot complications can be detected by family physicians early on. Diabetic foot management necessitates a thorough understanding of the major amputation risk factors, regular routine evaluation, and meticulous preventative measures [2]. Diabetic foot ulcers are the most common and much feared of complication of diabetes, with recent studies suggesting that the lifetime risk of developing a foot ulcer in diabetic patient may be as high as 14% [3].

Diabetes foot ulcer is a severe long-lasting diabetic consequence characterized by lesions in the deep tissues of the lower extremities, as well as neurological abnormalities and peripheral vascular disease (PVD). The new case of DFU has intensified due to the world frequency of DM and the increased life expectancy of DM patients. A previous study showed that a lower limb is amputated due to diabetes every 30s [2].

Patients whose diabetes was treated with food or oral hypoglycemic agents (OHA) were measured to have type II diabetes. Patients receiving insulin had their diabetes type assessed using a scientifically based methodology that took into account their age at onset, pre-setting weight and symptoms, family history, onset of insulin treatment, and previous ketoacidosis history [5].

Ethiopia is one of the developing country has been sowing change in the life style of people toward urbanization particularly in recent decades. This rapped changes led to the emergency of non-communicable diseases such as DM. According to IDF report in 2015 the estimated adulate population in Ethiopia with Diabetes mellitus is 2,567,900 [3].

2 Methods

2.1 Study area and time frame

The research was carried out in Gedeo Zone South.

March 1, 2020–September 25, 2021, Ethiopia. One of SNNPR's fifteen zones is Gedeo. The zone consists of two administration cities (Dilla and Yirgachefe) and six Woredas (Bule, Dilla Zuriya, Gedeb, Kochore, Wonago, and Yirgachefe Woreda). The administrative hub of the zone is Dilla Town, which is located 90 kilometers from Hawassa and 369 kilometers from Addis Ababa. There are 17 known private health facilities, 35 health centers, 146 health posts, 4 NGO clinics, 3 primary hospitals, and 1 referral hospital in the zone. The region's land size is estimated to be 1347.04 square kilometers based on the existing border delineation.

2.2 Study design

Diabetic patients in Gedeo Zone Hospitals participated in a facility-based prospective cohort follow-up study.

2.3 Population

Source of Population

Every patient with diabetes mellitus who comes to Gedeo Zone Hospitals' diabetic follow-up clinic.

Study population

This study includes DM patients who were follow up From March 1, 2020 to Sep 25, 2021 in Gedeo Zone Hospitals.

Eligibility criteria

Inclusion criteria

- Diagnosed with diabetes mellitus types 2
- Able to complete the consent form

Exclusion criteria

- Severe medical and mental illness
- Current foot ulcer

2.4 Sample size determination

After evaluating a Cox Proportional hazard model assumption, the sample size was estimated using STATA version 16. From population based Prospective cohort study done in south-west of Iran, the incidence of foot ulcer was 5.3% and peripheral neuropathy was the predictor of diabetic foot ulcer show that probability of survival among not having peripheral neuropathy (control) was 0.954, the probability of survival among having peripheral neuropathy (exposure) was 0.856 and the proportion of withdrawals is 0.056 [6]. The calculated sample size by log-rank method was 208.

2.5 Study Variables

Dependent variable: Time to develop of diabetic foot ulcer.

Independent variable:

- **Socio demographic factors:** includes age, sex, place of residence, and educational status.
- **Clinical factors:** HDL, LDL, triglyceride, total cholesterol, baseline proteinuria, BMI, DM duration, fast blood sugar level, type of DM and types of medication).
- **Comorbidities:** Hypertension, Diabetic Neuropathy, peripheral vascular diseases, diabetic nephropathy and diabetic retinopathy.

2.6 Operational definition and Term definition

Diabetic foot ulcer: Non traumatic wounds of the skin (incomplete or full thickness) blew the ankle of the patient who has DM [1].

Event of interest: The incidence of Diabetes Foot Ulcer with-in the follow up period.

Censored: Those who are not experiencing DFU until the end of the study or died before experiencing DFU within the study period, lost to follow up before experiencing the event of interest with in study period by reason not related to the event of interest are considered as censored [6].

Body Mass Index (BMI): is determined by dividing a patient's body weight by the square of their height. BMI ranges <18.5 kg/m^2 are considered underweight, BMI ranges $18.5\text{--}24.5$ kg/m^2 are considered normal, BMI ranges $24.5\text{--}30$ kg/m^2 are considered overweight, and BMI >30 kg/m^2 are considered obese [7].

Fast blood sugar level (FBS): A blood sample was taken after an overnight fast. A FBS level between 70 mg/dL to 126 mg/dL is normal [8].

Lipid profiles: Lipid profiles include total cholesterol, triglycerides, high-density lipoprotein (HDL), and low-density lipoprotein (LDL). The normal value of LDL, less than 100 mg/dL, the normal value of HDL above 40 mg/dL, the normal value of triglycerides less than 150 mg/dL and the normal value of total cholesterol is less than 200 mg/dL [8].

Proteinuria: Proteinuria is a condition characterized by the presence of greater than normal amount of protein in the urine (protein/creatinine ratio greater than 45 mg/mmol) [9].

2.7 Data collection tools and procedure

Diabetic foot ulcer was assessed by using standard scale adapted from different literatures. Questions about other variables including sociodemographic characteristics, clinical factors and comorbidities questioners were adapted from different literatures review. A structured questioner and a face-to-face interviewer process were conducted, with the questioner being adapted from several literature reviews and for data collection 4 BSc nurses was selected and they were supervised by the principal investigator.

2.8 Data Processing and Analysis

Data was entered into Epi-data version 7. Then exported to STATA version 16 statistical data base to check for any incompleteness, coding error and for further analysis. The data was edited, cleaned and coded to make it suitable for analysis. Descriptive statistics were employed to examine data in terms of frequency and percentage, while continuous variables were represented

in terms of mean/median value. The overall incident cases were divided by the total number of person-years (PY) of follow-up to calculate the total incidence rate DFU. Using Kaplan-Meier and log-rank test survival time was estimated and survival curves are compared between different exposure groups. To identify the underline baseline distribution Kaplan-Meier and log-log hazard plot are used. The proportional hazard hypothesis was tested by using Schoenfeld residuals method. Goodness of fit was evaluated by using cox-snell residual procedure. The Variables with $p < 0.2$ in the bi-variable analysis are candidates for multi-variable analysis using backward elimination method. Hazard ratio (HR) with its 95% ($\alpha = 0.05$) confidence level was calculated to display the strength of association.

2.9 Survival Analysis

Censoring is a significant analytical difficulty in most survival analyses. In essence, censorship happens when we have some knowledge about an individual's survival period but not the exact time. When diabetic patients are transferred to another hospital, they discontinue therapy, die, and are not cured by December 2021. (at the end of study). This means that the survival data is right filtered and random.

Non-parametric Survival Methods

Estimations of the survival function and hazard function are useful for summarizing survival data. The survival scattering estimate method produces descriptive numbers such as the median survival time. These approaches are denoted to as non-parametric meanwhile they do not mark any assumptions about the survival time distribution. Preliminary data analysis using non-parametric approaches reveals the shape of each group's survival function and determines whether the groups are proportional, that is, if the estimated survival functions for two groups are nearly parallel (do not cross).

Kaplan-Meier Estimator of Survival Function

The Kaplan-Meier (KM) estimator is the standard non parametric estimator of the survival

function, $S(t)$, proposed by Kaplan and Meier (1958) which is not based on the actual observed event and censoring times, but rather on the ordered in which events occur. It is also called the Product-Limit estimator. KM estimator incorporates information from all of the observations available, both censored and uncensored, by considering any point in time as a series of steps defined by the observed survival and censored times. When there is no censoring, the estimator is simply the sample proportion of observations with event times greater than t . The technique becomes a little more complicated but still manageable when censored times are included.

The Cox proportional Hazards Regression model

Survival models link one or more factors that may alter the proportionate quantity to the time that passes before recovery from severe acute malnutrition. The Cox proportional hazards regression model is one of the most prevalent types of regression models used in survival analysis. Ox (1972) presented a semi-parametric hazard function model that allows for the insertion of covariates while leaving the baseline hazards undefined and only taking positive values.

2.10 Ethical Consideration

Ethical approval was acquired from Institutional Review Board (IRB) of College of Health Sciences and medicine, Dilla University; throughout the data gathering, the aim of the study was elucidated to the study members. After interpretation the agreement form to the respondents, willingness to take part was inquired. The respondents were also informed that they can decline from the interview at any time. They were also informed to ask any question on unclear issues about the study. Participants name were not captured in the questionnaire and after taking consent the interview was conducted in a private setting and confidentiality of the information was maintained. The study won't have any anticipated harm for the study participants.

3 Results

3.1 Socio-demographic Characteristics of respondents

Of the total 214 diabetic patient initially planned for the study 208 (97%) of them participated. The median age of participants was 42(IQR=35-58) years. More than half of 125(60.10%) of

the study subjects were males and Regarding to the residence, 124(59.62%) of participants were urban dwellers, 80(38.46%) of adults were Unable to read and write. 115(55.29 %) were attended Primary school education. Majority 114(54.81%) of respondents were follow christen religion (Table 1).

Table 1 Socio demographic characteristics of participant at Gedeo zone hospital, Ethiopia (N = 208)

Variables		Frequency (208)	Percent (%)
Sex of patient	Male	125	60.10
	Female	83	39.90
Age category	15-24	43	20.67
	25-34	58	27.88
	35-44	20	9.62
	45-54	21	10.10
	55 and above	66	31.73
Residence	Urban	124	59.62
	Rural	84	40.38
Religion	Christian	114	54.81
	Muslim	74	35.58
	Others	20	9.62
Marital status	Single	67	32.21
	Married	108	51.92
	Divorced	13	6.25
	Died	20	9.62
Occupational status	Unemployment	80	38.46
	Gov't employment	66	31.73
	Private job	51	24.52
	Other	11	5.29

3.2 Clinical and Comorbidities Factors

Based on clinical factors and comorbidities 129 of 208 (62.02%) were type I diabetic mellitus patient. Regarding to comorbidities 139(66.83%)

had retinopathy and 126(60.58) had nephropathy, Almost half of study participant using treatment of insulin 102(49.04) and 148(68.75) Trygysride levels are <150 at baseline (Table 2).

Table 2 Baseline Clinical and Comorbidity Information of DM Patients on Follow-up at Gedeo zone hospitals, South Ethiopia, (N= 208)

Variables		Frequency (208)	Percent (%)
Type of DM	Type I	129	62.02
	Type II	79	37.98
Duration of DM	<5 Years	77	28.2
	≤5 Years	196	71.8
HDL level (mg/dl)	≤40	131	62.98
	>40	77	37.02
Triglyceride level (mg/dl)	<150	143	68.75
	≥150	65	31.25
LDL level(mg/dl)	<100	126	60.58
	≥100	82	39.42
Retinopathy	Yes	139	66.83
	No	69	33.17
Nephropathy	Yes	126	60.58
	No	82	39.42
Type of treatment	OHA	98	47.12
	Insulin	102	49.04
	Both OHA & Insulin	8	3.85

3.3 Incidence of diabetic foot ulcer

A total of 22 or 10.58% [6.40-14.76] developed DFU. The follow-up of participants were for a minimum of one month and a maximum of eight months with the median survival time of 4 months. Based on this the total person-time of observation was 816 person-month. The overall new occurrence rate of DFU was found to be 2.6 (95% CI: 6.40–14.76) per 1000 person-month.

3.4 Median time to relapse

The overall follow up period was 8 months and the Study participants were followed for a median of 4 months (inter quartile range (IQR): 2-4 months). Based on life table estimate the cumulative relapse within the first five months of follow up was 64% and in the next 5 months was 17.4% (Table 3).

Table 3 Life table estimate the cumulative relapse within the first four months of follow up was 6% and in the next 5 months

Interval (in months)	Beg. Total at Risk	Average number at Risk in interval	DFU	Censored	Proportion of relapse with in interval	Cumulative probability of relapse	[95%CI]
0 – 2	208	245	2	186	0.064	0.082	[0.912-0.973]
2 – 4	198	132	5	102	0.117	0.60	[0.506-0.640]
4 – 6	120	71	8	96	0.110	0.14	[0.121-0.222]
6 – 8	35	46	7	57	0.168	0.39	[0.300-0.491]

In the Kaplan Meier curve for diabetic foot ulcer patients, the probability of foot ulcer increases as the follow-up time increases. Most patients

terminate throughout 5 months of enrolment as indicated by the curve (Figure 2).

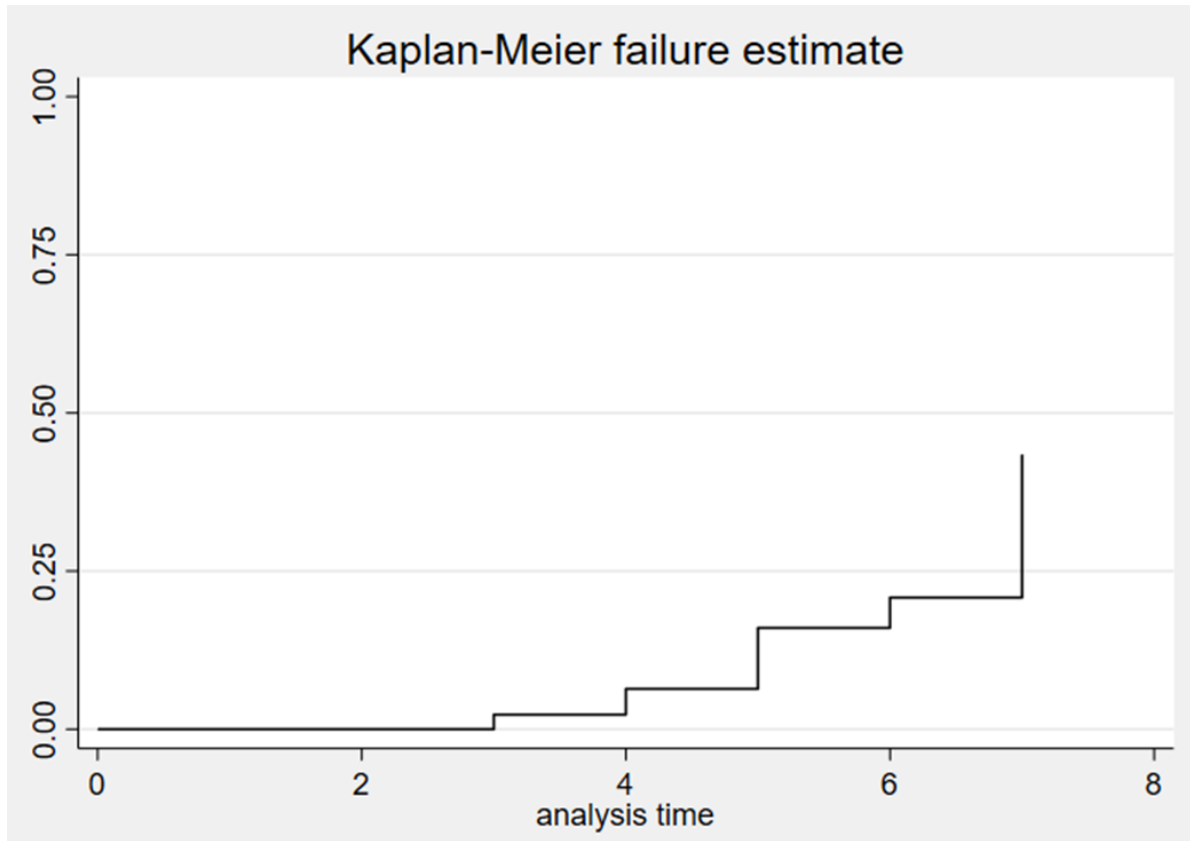


Figure 1 Kaplan meier curve for diabetic foot ulcer patient

3.5 Predictors of time to develop diabetic foot ulcer

In the Univariate analysis the Cox model identified potential predictors of diabetic foot ulcer at p -value ≤ 0.05 level. Consequently, the candidate variables for building a multivariable Cox model were: Sex, Residence, Occupation, Educational status, Religion, Region, Substance, Family history of diabetic mellitus, Comorbidity illness, Age of respondents, Type of treatment, Type of DM, Duration of illness, HDL, Triglyceride, LDL level, retinopathy and Nephropathy.

From the candidate variables considered for building multivariable Cox at 95% CI were Age of respondents, Educational status, Type of DM, retinopathy and nephropathy were statistically significant predictors used in the final Cox model after interaction and model diagnostics was checked. Also we have checked graphically the proportional hazard assumptions using Log-log plots for each predictor then parallel lines indicate proportional hazard assumption was fulfilled.

Therefore, each predictor satisfies the assumptions of proportional hazard regression. The interaction effect were checked among statistical significant variables in the final Cox model. Hence, no significant interactions were detected to consider in the final Cox model. The likelihood ratio test was also done for checking goodness of fit of the model. Hence, no interaction was detected so we can't consider it in the comparison of the models.

Therefore, the likelihood ratio test indicated the main effect model significantly predict diabetic foot ulcer (p -value < 0.001). Also the Cox-Snell residual plot shows the model was good fit. Finally, the interpretation of the AHR at 95% CI was done for the confirmed statistically significant predictors of diabetic foot ulcer in the final Cox model.

Results in this final model showed that, the risks of diabetic foot ulcer in Aged 50 and above patients were 2.9 times more risk as compared to in age 15-24 (AHR=2.9; 95% CI: 1.56-3.24).

Table 4 Cox regression analysis for predictors of diabetic foot ulcer among diabetic patient in Gedeo zone hospitals, Ethiopia 2019(N = 208)

Variables	Survival Status		BI-Variable Model		Multi variable model	
	Event	Censored	HR [95% CI]	p-value	HR [95% CI]	p-value
Sex	Male	12	113	1	1	
	Female	10	73	1.07[0.46-2.51]		0.86[0.78-3.29]
Age of respondents	15-24 years	6	37	2.47[1.46-2.61]		1.08[0.31-2.51]
	25-34 years	8	50	1.89[1.46-2.15]		1.68[0.60-3.55]
	35-44 years	2	18	1.95[1.46-2.28]		6.80[0.59-13.11]
	45-54 years	1	20	1.49[0.46-2.51]		4.00[0.48-4.60]
	55 and above	5	61	1.51[1.47-2.51]		1.90[1.56-3.24]
Residence	Urban	15	109	1		1
	Rural	7	77	0.77 [0.31-1.89]		0.05[0.01-1.31]
Marital status	Single	8	59	1		1
	Married	11	97	0.64[0.25-1.62]		0.81[0.75-1.22]
	Divorced	2	11	2.26[0.46-10.86]		4.35[0.19-12.47]
	Died	1	19	0.51[0.03-1.74]		0.02[0.01-5.02]
Type of DM	Type I	16	113	1		1
	Type II	6	73	0.73[0.28-1.90]		3.02[1.08-5.40]
Duration of DM	<5 Years	14	129	1		1
	≤5 Years	8	57	1.23[0.51-2.93]		0.35[0.13-2.02]
HDL level (mg/dl)	≤40	119	12	1		1
	>40	67	10	1.12[0.48-2.61]		2.21[0.06-3.51]
LDL level(mg/dl)	<100	12	114	1		1
	≤100	10	72	1.28[0.55-2.97]		0.35[0.23-1.02]
Retinopathy	Yes	12	114	1.79[0.73-4.40]		2.30[1.43-5.02]
	No	10	72	1		1
Nephropathy	Yes	13	113	1.19[0.50-2.79]		3.56[2.47-5.70]
	No	9	73	1		1
Type of treatment	OHA	10	88	1.26[0.54-2.93]		3.26[0.45-6.05]
	Insulin	12	90	0.89[0.54- 2.93]		0.77[0.42-3.90]
	Both OHA & Insulin	0	8	1		1
Triglyceride level (mg/dl)	<150	18	125	1		1
	≥150	4	61	0.50[0.04-1.50]		0.35[0.23-1.02]
Educational level	No education	15	100	1		1
	Primary education	3	33	0.74[0.21-2.57]		5.10[0.50-7.13]
	Secondary and Above	4	53	0.52[0.17-1.58]		0.40[0.20-1.09]
Substance use	None	9	83	1		1
	Kchat	0	12	0.64[0.04-0.87]		7.69[0.23-9.86]
	Alcohol	4	43	0.20[0.06-0.88]		0.13[0.03-1.88]
	Tobacco	4	13	0.26[0.07- 0.90]		0.11[0.01-3.02]
	Other	5	35	1		1
Family history of DM	Yes	17	125	0.61[0.22-1.67]		0.67[0.52-1.99]
	No	5	61	1		1
Comorbidity	Hypertension	14	96	1.96[0.78-4.92]		0.43[0.16-2.53]
	HIV	7	72	0.77[0.09-6.27]		0.17[0.15-1.27]
	Asthma	1	12	0.56[0.09-4.37]		0.66[0.16-1.95]
	Other	0	6	1		1

Those participants who had type II DM were 3.03 times more likely to develop DFU than those who had type I DM [AHR=3.02; 95% CI: 1.08-5.40]. The risks of diabetic foot ulcer among

who had Retinopathy were 2.9 times higher than the corresponding reference group (AHR=2.9; 95% CI: 1.43-5.02).

The risks of diabetic foot ulcer among who had Nephropathy were 3.56 times more risk than the corresponding reference group (AHR=3.56; 95% CI: 2.47-5.70) (Table 4)

4 Discussions

This study investigated the incidence and predictors of diabetic foot ulcer among diabetic mellitus patients at Gedeo zone hospitals. In this study of 208 individual diabetic mellitus patients 10.58% of study participants had a diabetic foot ulcer. This finding is in line with studies done in Ethiopia [10]. But it was higher than the studies conducted in Nigeria [11]. This variance might be because of the difference in the inhabitants and the study area because all the matched studies were population based but the current study was institution based hospital-based study. And also, diabetic care in these countries and other developed countries might be well structured than evolving countries like Ethiopia. Besides, in low and middle-income countries many factors such as variation of health care services, limited resource allocation and low health literacy among diabetic mellitus patients contribute to high DFU [12].

Concerning incidence rate (IR) of diabetic foot ulcer, in this study, the incidence rate was 11 per 1000 person-year which means in 1000 Diabetes patients there was 11 Diabetic Foot Ulcer patients per year or if we follow 1000 persons with DM for one year 11 patients will develop the case, diabetic foot ulcer. This result was comparable with the study done in Japan [13] which found the incidence rate of 4 per 100 person-year.

Respondent age was independently associated with an increased hazard of diabetic foot ulcer in this study. Results in this final model showed that, the risks of diabetic foot ulcer in Aged 50 and above patients were 2.9 times higher as compared to in age 15-24 (AHR=2.9; 95% CI: 1.56-3.24). This is consistent with a cross-sectional study in Addis Ababa and Case control study done in Japan [14]. This might be because of hypertension, visual disturbance, and neuropathy increased with increasing age of the patient.

Type of diabetes mellitus was one of the most

predictors of diabetic foot ulcer occurrence. Those diabetic patients who had type II diabetes mellitus were 3.03 times more likely to develop diabetic foot ulcer than those who had type I diabetes mellitus [AOR=3.03; 95% CI: 1.08-5.40]. This finding is similar with the studies conducted in Sudan [11] which indicated type II diabetes mellitus was associated with the development of diabetic foot ulcer. The possible explanation could be in type II diabetic patients; there are related complications of the disease, such as peripheral neuropathy and atherosclerotic peripheral arterial disease; as a result, the patient may have less consumption of oxygen, nutrient transportation and cell detoxification consequence in ulceration in the extremities.

The risks of diabetic foot ulcer among who had retinopathy were 2.9 times higher than the corresponding reference group (AHR=2.9; 95% CI: 1.43-5.02) respectively. The hazard of developing diabetic foot ulcer among DM patients with retinopathy was higher than DM patients who have no diabetic retinopathy. A similar association was found with a cross-sectional study done in Iran [9]. This might be due to retinopathy patients had decreased visual activities, so it is challenging to give foot care activities such as scrutinizing their feet daily and exerting good foot sanitation and these upsurges the risk of DFU.

The risks of diabetic foot ulcer among who had nephropathy were 3.56 times higher than the corresponding reference group (AHR=3.56; 95% CI: 2.47-5.70). Diabetic nephropathy was significantly associated with an increased hazard of DFU in this study. This is consistent with a cross-sectional study in Brazil [15]. This might be due to vascular insufficiency and peripheral neuropathy are more common in patient with diabetic nephropathy, which in turn results in ischemic ulceration or foot ulcer [7]. This presence of vascular insufficiency, which is common in a patient with nephropathy, significantly increases the risk of chronic inflammation, fluid retention, rennin-angiotensin system alterations, and ischemic ulcerations that eventually ends up with foot ulcer.

Since cohort study it has the benefit of showing time-based associations. Because of the secondary nature of the data and in turn the excellence of data, some important variables like self-care practices and main traditional risk factors for DFU such as foot abnormality were not considered.

5 Conclusion

This finding showed that taking Type of DM, nephropathy, retinopathy, and being older age positively associated with DFU. Therefore, proper interventions to DM patient self-care exercise, way of life amendment, and constant follow up to avert DFU. Health service providers have to play their role in undertaking DFU through appropriate health information dissemination and patient's treatment.

Declarations

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Availability of Data and Materials: Data will be made available whenever requested for research purpose.

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Authors' contributions:

All the authors had participated in the title selection, design, proposal preparation, statistical analysis, and interpretation of results, manuscript preparation. They approved this manuscript to be published.

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