COLLEGE OF HEALTH SCIENCE

SCHOOL OF NURSING AND MIDWIFERY

PREVALENCE OF AMPUTATION AND ASSOCIATED FACTORS AMONG DIABETIC FOOT ULCER PATIENTS ADMITTED AT SELECTED PUBLIC HOSPITALS IN ADDIS ABABA, ETHIOPIA: A RETROSPECTIVE STUDY

BY: SARON DERSO, BSC

PRIMARY ADVISOR: DR, FEKADU AGA, PHD, ASSOCIATE PROFESSOR

CO- ADVISOR :SR. NETE TEWFIK, MSC, LECTURER

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APPROVAL SHEET

COLLEGE HEALTH SCIENCE SCHOOL OF ALLIED SCIENCES
DEPARTMENT OF NURSING AND MIDWIFERY

I, the undersigned MSc student, declare that I have submitted my original work on a title of prevalence of amputation and associated factors among Diabetic foot ulcer patients admitted at selected hospital in Addis Ababa Ethiopia for the examination.

Submitted by:

Saron Derso (BSC)

Signature _____ Date _____

This research thesis by Saron Derso is accepted in its present form by the board of examiners as satisfying partial fulfillment of the requirements for the degree of master of science in adult health nursing.

Approved by

Name

_____ Date _____

Advisors:

Name of Primary advisor

Dr. Fekadu Aga (PhD, Associate professor)

Signature _____ Date : _____

Name of co -Advisor

Sr. Nete Tofik (MSc, lecturer)

Signature _____ Date _____

DEPARTMENT HEAD

Name _____ Signature _____ Date _____

STATEMENT OF DECLARATION

By my signature below, I declare and affirm that this thesis is my own work. I have followed all ethical principles of scholarship in the preparation, data collection, data analysis and completion of this thesis. All scholarly matter that is included in the thesis has been given recognition through citation. I affirm that I have cited and referenced all sources used in this document. Every effort has been made to avoid plagiarism in the preparation of this thesis.

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STUDENT

Name: _____ Signature: _____ Date: _____

RESEARCH ADVISORS:

_____	_____	_____	_____
NAME	RANK	SIGNITURE	DATE
_____	_____	_____	_____
NAME	RANK	SIGNITURE	DATE

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ABBREVIATIONS AND ACRONYMS

DFU	Diabetic foot ulcer
DM	Diabetic mellitus
DM OPD	Diabetic mellitus outpatient department
ETB	Ethiopian birr
FBS	Fasting blood sugar
HbA1c	HemoglobinA1c
Hb	Hemoglobin
IJSAR	International Journal of Sciences & Applied Research
LEA	lower extremity amputation
MIIH	Minilik II hospital
PAD	Peripheral arterial disease
RBS	Random blood sugar
SPHMMC	St, Paul's hospital millennium medical college
STATA	stastical data analysis
TASH	Tikur Anbessa Specialized hospital
WBC	White blood cell
Y12MC	Yekatit 12 medical college
NT	Number of sample taken in TASH
NS	Number of sample taken in SPHMMC
NMH	Number of sample taken in Y12MH
NM	Number of sample taken in MIIH

TABLE OF CONTENTS

LIST OF TABLES

LIST OF FIGURES

ABSTRACT

Background: Diabetes is one of the most common metabolic disorders, with numerous long-term complications affecting nearly every system in the body. One of the most common complications associated with the disease is foot ulcer, which frequently results in lower extremity amputations.

Objective: to determine the prevalence of amputation and associated factors among diabetic foot ulcer patients admitted at selected public hospitals in Addis Ababa, Ethiopia

Methods: Institution based retrospective (from 2021 to 2023) study design that employed systematic random sampling technique was done. The data was collected by structured data extraction checklist from HMIS and electronic eye care systems. The data was coded and entered into Epi-Data version 4.6 and analyzed using STATA 14 statistical software. Bivariate and multivariate logistic regression analyses were employed to identify the prevalence of amputation and its associated factors among diabetic foot ulcer patients. The statistical significance of association between variables was decided using 95% confidence interval and p-value <0.05.

Result. The overall prevalence of amputation among DFU were 30.2% (94/311), Multivariate logistics regression analysis showed that for a 1% increase in HbA1c there is 34% more likely to get amputation (AOR, 1.34, 95% CI: 1.00-2.03, *P* value, 0.044). The odds of having amputation among DFU male patients were 3.25 times more likely than in female (AOR 3.25, 95% CI: 1.41-7.49, *P* value, 0.005). The risk of having amputation was 10.58 times more likely among smoker than nonsmokers (AOR 10.58, 95% CI: 4.91-22.81, *P* value, 0.000), 3.83 times among type 2 DFU patients than type 1 DFU (AOR, 3.83, 95% CI: 1.50- 9.75, *P* value, 0.005) 2.92 times among those who have PAD those who don't have PAD (AOR, 2.92, 95% CI: 1.32-6.46, *P* value, 0.008).

Conclusion and Recommendation: The prevalence of amputation among DFU patients observed in this study is high. The study identified HbA1C, sex, history of smoking, type of DM and PAD are important risk factors for amputation among DFU patients. Therefore, DFU patients should regularly monitor their HbA1C value and educational initiatives and efforts to provide better treatment for diabetic patients are required.

Key words: Amputation, Diabetic foot ulcer, Diabetes Mellitus, Retrospective study

1. INTRODUCTION

1.1 Background

Diabetes mellitus is a chronic metabolic condition that is becoming more common. It is characterized by sustained hyperglycemia, which can have long-term health effects(1). Elevated blood glucose levels (BGLs) resulting from reduced insulin sensitivity, production, or both are a hallmark of diabetes mellitus (DM). It is now one of the world's leading cause of morbidity and mortality due to its accelerated rising prevalence(2) The International Diabetes Federation estimated that 537 million persons globally, or one in ten adults, had diabetes in 2021, and that an additional 541 million adults were at high risk of developing the disease.(3). Diabetic foot ulcer (DFU) is one of microvascular complications of diabetes mellitus caused by uncontrolled blood glucose which can leads to amputation.

Diabetic foot is a complication of diabetes with a wide range of symptoms, including ulceration, osteomyelitis, osteoarticular destruction, and gangrene, as a consequence of advanced disease(4). In Europe and Australia, there are between 7 and 41 major amputations per 100,000 people per year as a result of vascular disorders or diabetes.(5) DFU is typically brought on by peripheral artery lesions, peripheral neuropathy, and in extreme circumstances, amputations. diabetic foot ulcers are the cause of 80% of non-traumatic amputations.(6) In high-income nations, the number of people living with peripheral arterial disease(PAD) increased by 13.1% between 2000 and 2010, but in low- and middle-income countries, it increased by 28.7%.(7, 8).

DFUs are commonly seen in lower extremity amputations. LEAs were responsible for approximately 6.8 million amputations (61% to 69%).(9) Amputation is a transformative experience that alters quality of life, physical capacity, body image, and stress resilience—all of which are linked to depression (10). It is a common and mutilating orthopedic surgery that affects the physical appearance and produces significant functional disadvantages(11) The history of amputations in DFU patients reflected their progression. Miller's study found that patients with minor amputations were more likely to suffer below-the-knee amputations.(12)

In Ethiopia, amputation is the only effective treatment for chronic conditions such as injuries, diabetes, tumors, and infections. Ethiopians suffered from a lack of competent rehabilitation programs for these destitute patients, who ended up on the streets as glorified beggars. However, there is no conclusive information regarding the primary causes of these handicapping conditions(11) Diabetic foot ulcer occurs in 28 (12%) of the study participants, with 10 (38%) of the patients with foot ulcers are Wagner's grade 0(13). This was less prevalent as compared to the study conducted in Tikur Ambesa Hospital Ethiopia which is 31.1% in which 34.6% of them were in Wagner's grade 3or 4. On the other hand this was slightly lower than a study conducted in Arbaminch in which diabetic foot ulcer was observed among 14.8% diabetic patients(13).

After amputation, patients can experience a distorted body image, decreased self-esteem, social isolation, and increased dependency on others(14). Diabetes mellitus is linked to markedly higher incidence of a number of crippling microvascular complications, including Renal damage, neuropathy, retinopathy, and macro vascular problems like atherosclerosis and stroke(15). The ultimate healing rates for diabetics with active ulcers are 65–75% for those who visit a hospital, but 15-20% of every person who has an ulcer gets their leg amputated; the length of the follow-up (16).

1.2 Statement of problem

Diabetes causes high blood glucose levels, with other complications; these can damage blood vessels and nerves and may result in peripheral neuropathy and vascular disease. These two conditions are associated with the development of diabetic foot ulcers(17). DFU refers to a group of symptoms resulting from either past or present diabetes, such as dryness, soreness, infection, or degeneration of the foot's tissue(18).Diabetes is the largest risk factor for lower extremity amputation in US adults, with an estimated 150000 diabetes-related major or minor amputations each year(19).

The World Health Organization (WHO) estimates that diabetes directly contributed to 1.6 million deaths in 2016, with one-fourth of diabetic people developing foot ulcers at some point in their lifetime (20). According to the International Diabetes Federation (IDF), 5–22% of the world's diabetes cases occur in low- and middle-income nations, where 4 out of 5 adults aged 20–79 have the disease (10). Diabetes complications are more common in Sub-Saharan Africa as a result of delayed diagnosis and inadequate case management (21).

Up to 25% of diabetes patients are estimated to develop diabetic foot ulcers (22). People with diabetes are 25 times more likely to require an amputation than those without this metabolic condition, and it is the primary cause of infection (16). Diabetic foot ulcer patients are at increased risk of lower-extremity amputation (LEA). The incidence of LEA is eight times higher in people with diabetes than those without it and approximately 80% of diabetes-related LEA are preceded by a diabetic foot ulcer (23).

Patients with DFUs have a high risk of amputation, which was found to result in mortality for 50% of patients over a 5-year period (24). Regular check-up helps to prevent lower-limb amputations and even foot ulceration, but this increases the burden on the healthcare system (16). Diabetes-related foot ulcers (DFUs) are now more than just a sign of potential complications; they also influence the risk of mortality and lower-extremity amputation on their own (14). The problem can lead to a burden on the economy, society, and public health particularly in low-income communities because it typically affects the 30- to 45-year-old age group that is considered economically productive (23).

About 3 million adults in Ethiopia have diabetes and the prevalence of both microvascular and macrovascular complications have been rising among these patients (21) . Roughly half of them develop infections that may lead to amputations, disabling conditions, prolonged hospital stay, and even death and many individuals will require hospitalization for therapy as a result of their lengthy recovery time (25).

The healing rates for diabetics with active ulcers are 65–75% for those who visit a hospital, and depending on the length of follow-up, 15-20% of all ulcer patients require amputation (16). So amputation has a great effect on economic crisis, also affects quality of life of individuals who live with DM may develop depression and stress because of its new body image. However, we have limited published studies in the area of diabetes related amputation in Ethiopia. So the aim of this study is to determine the prevalence of amputation and associated factors among diabetic foot ulcer patients in selected hospitals in Ethiopia.

1.3 Significance of the study

The prevalence of amputation and its associated risk factors was determined, and this study would have a significant contribution to the community and improve health science by providing new findings and expanding previous studies. It would also help the health sectors to by offering baseline data for the development of guideline to facilitate diabetic clinical practice. It would also benefit the policymakers in designing effective control strategies in Ethiopia to reduce the incidence of amputation. It would help the health professionals to become aware of the severity of the problem and give attention and care for diabetic patients thereby avoiding complications, prolonged hospital stays and minimize mortality and morbidity related to the problem. We have limited research in the field of this inquiry. So, it would be a baseline for another research. Therefore, this study aims to assess the prevalence of amputation and associated factors among diabetic foot ulcer patients in selected hospitals in Ethiopia.

2. LITERATURE REVIEW

This literature review addressed various studies on the prevalence of diabetic foot ulcers conducted in various countries including Ethiopia. This includes prevalence of amputation, as well as associated factors and a conceptual framework. I used different journals most literatures are from different electronic databases.

2.1 Overview of diabetic foot ulcer amputation

The most frequent consequence of diabetic foot ulcers is amputation of the lower extremities. Infections that could cause amputations, disabilities, extended hospital stays, and even death progressed in about half of the cases. Many patients will require hospitalization or treatment Because of the extended healing period (25). Different studies in different countries show the Prevalence of amputation among diabetic foot ulcer patients (15, 25-33).

A retrospective cohort study done in England revealed that the prevalence of amputation among diabetic foot ulcer patient was 26.3%(34).in contrast a study conducted in Spain the prevalence of amputation was 11.2%(30). A study conducted in Poland indicated that between 2010 and 2019 the annual number of amputations in patients with diabetes increased significantly from 5,049 to 7,759, the mean percentage of amputations in patients with diabetes was 68.6% of all amputations (35). According to a study conducted in Australia revealed that the prevalence of lower extremity amputation among diabetic foot ulcer patient was 34.1% (33).

A retrospective study conducted in China revealed that the prevalence of amputation was 8.9%(36). In contrast, another retrospective study conducted in China shows 56.9% amputation rate (37). A systematic review and meta-analysis study conducted in India showed that the prevalence of amputation among DM patients were 19%(38). On the other hand a prospective study conducted in India showed that the prevalence of amputation among diabetic foot ulcer patients was 28.4%(28). A cross-sectional study conducted at King Abdul-Aziz University Hospital in Saudi Arabia has also reported the 29.7% prevalence of lower extremity amputation (29).

An observational study conducted in Nigeria shows that the prevalence of lower extremities amputation was 35.4 %(39). According to a study conducted in Ghana showed that the prevalence of amputation among diabetic foot ulcer patient was 3%(32). A cross-sectional study was conducted at Sudan revealed that the prevalence of lower limb amputation among diabetic patient was 17.1%(31). According to Institution based cross sectional study conducted in Adama shows that the prevalence of amputation among diabetic foot ulcer patient was 35.5%(15). Similarly prospective observational stud done in Nekemte, Ethiopia revealed that the prevalence of amputation among diabetic foot ulcer patients was 30.43%(25).

2.2 Associated factors of amputation

A retrospective cohort study conducted in California shows that peripheral arterial diseases and diabetic type 2 were significantly associated with amputation(26). A study conducted in Romania revealed that being age >70, male sex and type2 DM were statically significant risk factor for lower limb extremity amputation(40). Similarly, a study done in Netherland revealed that amputation rate among men were 2.3 higher than women, and age above 63years associated risk with lower extremity amputation (41). According to prospective cohort study conducted in Iran shows that cigarette smoking, nephropathy, neuropathy, and ischemic heart diseases are strongly associated with amputation (42).

A systematic review and meta-analysis study conducted in India showed that there was a significant association between advanced age and amputation due to foot ulcer(38). Another systematic review and meta-analysis study conducted in Korea showed that hypertension, ischemic heart disease; cerebrovascular disease and peripheral vascular disease were identified as predictor of higher major amputation rate(43). According to hospital-based case–control study done in Indonesia HbA1c presence of PAD, hypertriglyceridemia , and hypertension are the independent risk factors associated with subsequent amputation in DFU(44).

According to a cross section study done in Malaysia shows that being type 2DM, duration of time with diabetics > 10 years, diabetic nephropathy, diabetic neuropathy, diabetic foot conditions of Wagner grade greater than 3 and necrotizing fasciitis there are strongly

associated with amputation(45). A retrospective study conducted in China shows that male sex, larger

ulcer size, higher grade of Wagner classification, peripheral arterial disease and higher fibrinogen level has a higher association risk factor for lower limb amputation(37). An observational study conducted in Nigeria shows that ulcer duration more than 1 month and presence of osteomyelitis were significant independent predictors of LEA(39).

According to institution based cross-sectional study done in Ethiopian being age of 61 to 69 years, being rural resident, having grade 3 DFU, having Peripheral Arterial Disease (PAD), and Random Blood Sugar (RBS) 400 to 599 mg/dl were significantly associated with amputation(15). Another prospective observational study done in Nekemte, Ethiopia showed that in inappropriate antibiotics and Wagner grade $\geq$ 4 were significant risk factors for amputation among DM foot ulcer patients (16).

2.3 Conceptual framework

A conceptual framework used to determine prevalence and associated factors of amputation among diabetic foot ulcer patient was developed based reviewing the literature sources most of them are from pub med. (1, 15, 21, 25, 37). This conceptual framework shows hypothesized associations between diabetic foot ulcer amputation and different risk factors such as sociodemographic variables, and clinical biomarkers, Medical condition and behavioral characteristics complication and comorbidity those have directly Association to diabetic foot ulcer amputation. Medical condition and behavioral characteristics has directly association to complication and Comorbidities and amputation they have triangle like association.

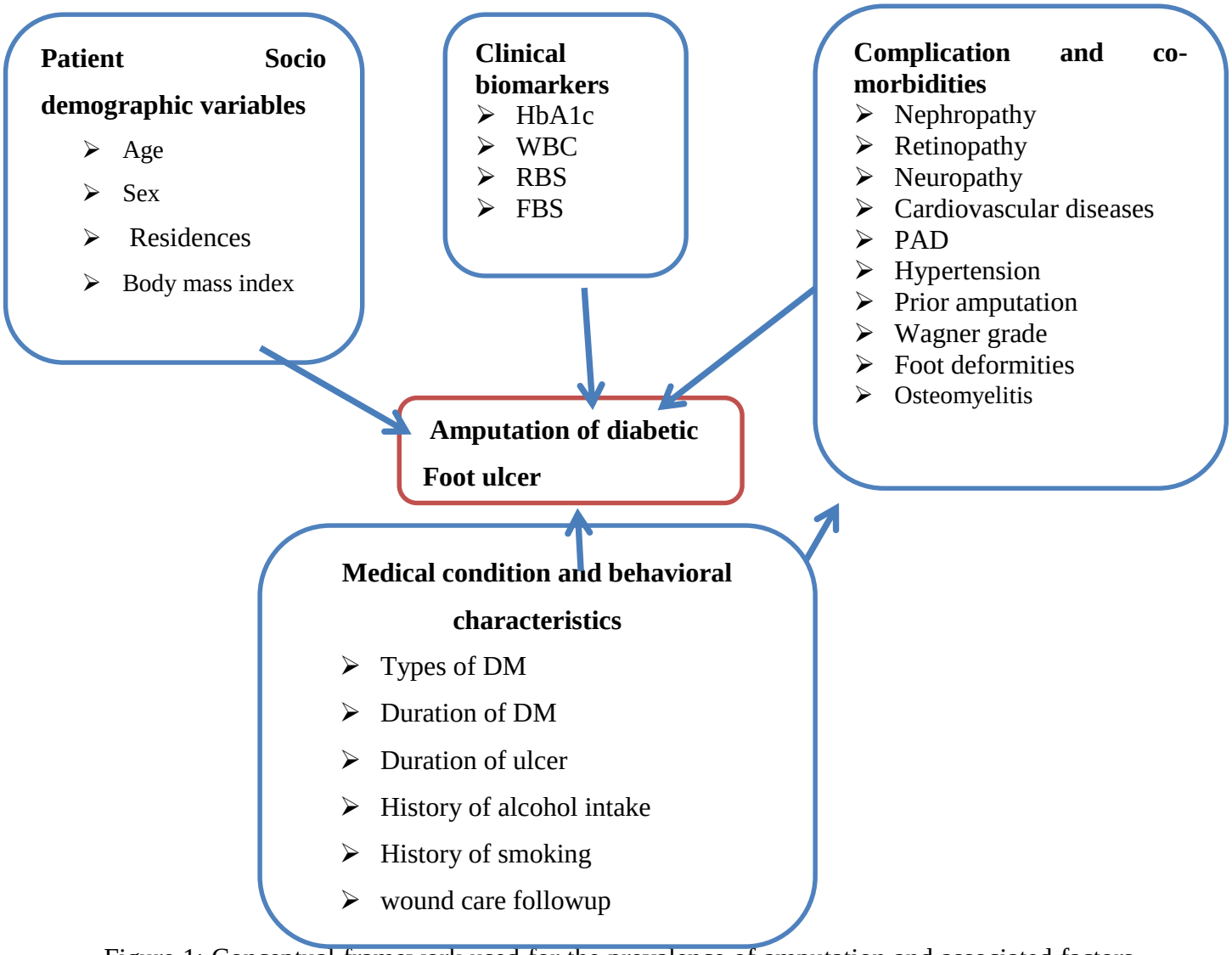


Figure 1: Conceptual framework used for the prevalence of amputation and associated factors among diabetic foot ulcer patients admitted at selected hospitals (1, 15, 21, 25, 37).

3. OBJECTIVES

3.1 General objective

- To determine the prevalence of amputation and associated factors among diabetic foot ulcer patients admitted at selected governmental hospitals in Addis Ababa, Ethiopia, 2024

3.2 Specific objectives

- To determine the prevalence of amputation among diabetic foot ulcer patients admitted at governmental hospital in Addis Ababa Ethiopia, 2024
- To identify factors associated with amputation among diabetic foot ulcer patients admitted at governmental hospital in Addis Ababa Ethiopia, 2024

4. METHODS

4.1 Study Area

This study was conducted at selected public hospitals in Addis Ababa, Ethiopia's capital city. Addis Ababa, also serves as the home of the African Union and the UN World Economic Commission for Africa. It has an area of 527 square kilometers and situated between 2320 and 3000 meters above sea level, and has an annual average temperature range of 10 and 32 degrees Celsius with annual rainfall around 1200mm. There are 11 sub cities in Addis Ababa. The city's expected population in 2021 was estimated 5.46 million;(46) according to population prediction values of world health organization. In Addis Ababa, there are 13 governmental public hospitals, one university hospital, six federal hospitals, and six regional hospitals. 4 hospitals are selected by using simple random sampling (lottery) method.this study was carried out at St. Paul's Hospital Millennium Medical College, Minilik II Hospital, Yekatit 12 medical Hospital, and Tikur Anbessa Specialized Hospital.

Tikur Anbessa Specialized Hospital (TASH) is one of the tertiary referral hospitals in the country and is affiliated with Addis Ababa University. It has 50 DM patients on average monthly admission and the Hospital has 600 annual admissions of patients with DM from these 20 patients where DFU on average per month and 240 per year. St. Paul Millennium Medical College Hospital (SPMMC) is under the Ministry of Health, the Hospital has 1080 annual admissions of DM patients and it has 90 average monthly admissions of patients with DM from these 15 patients where DFU on average per month and 180 per year. Minilik II hospital is one of the public Hospitals under the Addis Ababa City Administration Health Bureau the average annual admission rate is 456 and the average monthly admission is 380 patients with DM from these 13 patients where DFU on average per month and 156 per year. Yekatit 12 Hospital Medical College(Y-12HMC) is also under Addis Ababa Health Bureau and has 45 average monthly admissions of DM in the Diabetic clinic and 540 annual admissions from these 18 patients where DFU on average per month and 216 per year.This Data is collected From each hospital log book.

4.2 Study design and period

An institution based retrospective (January 1, 2021 to December 31, 2023) study design was used to determine the prevalence of amputation and associated factors of among diabetic foot ulcer patients admitted at selected governmental hospitals from February 19 to March 19 2024.

4.3 Source of population

The source of population was medical cards of all adult patients that were admitted and treated in the selected public hospital in Addis Ababa.

4.4 Study population

The study population was all cards of adult patients who were admitted and treated for DFU of selected public hospital from January 1, 2021 to December 31, 2023.

4.5 Inclusion and exclusion criteria

4.5.1 Inclusion criteria

All medical cards of adults treated for diabetic foot ulcer, age 18 years and above.

4.5.2 Exclusion criteria

All medical cards of patients who amputated because of trauma and non-eligible was excluded

4.6 Sample size determination

The sample size of study participants is calculated used the single population proportion formula. The prevalence of amputation was 30.43% from the study conducted at Nekemte referral hospital(25). By using the following formula, the sample size calculated for P=0.30 is 322.

$$ni = \frac{\left(\frac{z\alpha}{2}\right) 2\, p(1-p)}{d2}$$

Where, ni = required sample size

Z α/2 = critical value for normal distribution at 95% confidence level (1.9

P= the prevalence of amputation among diabetic foot ulcer patients

d= 0.05 is margin of error.

Then after adding 32 (10%) nonresponse rates, the optimal sample size was 354.

Since, the study population is less than 10,000 so, correction formula is necessary

$$nr = \frac{n}{1 + n/N}$$ **= 354/1+354/2519= 311**

nr = the calculated sample size

N = total population

4.7 Sampling procedure and technique

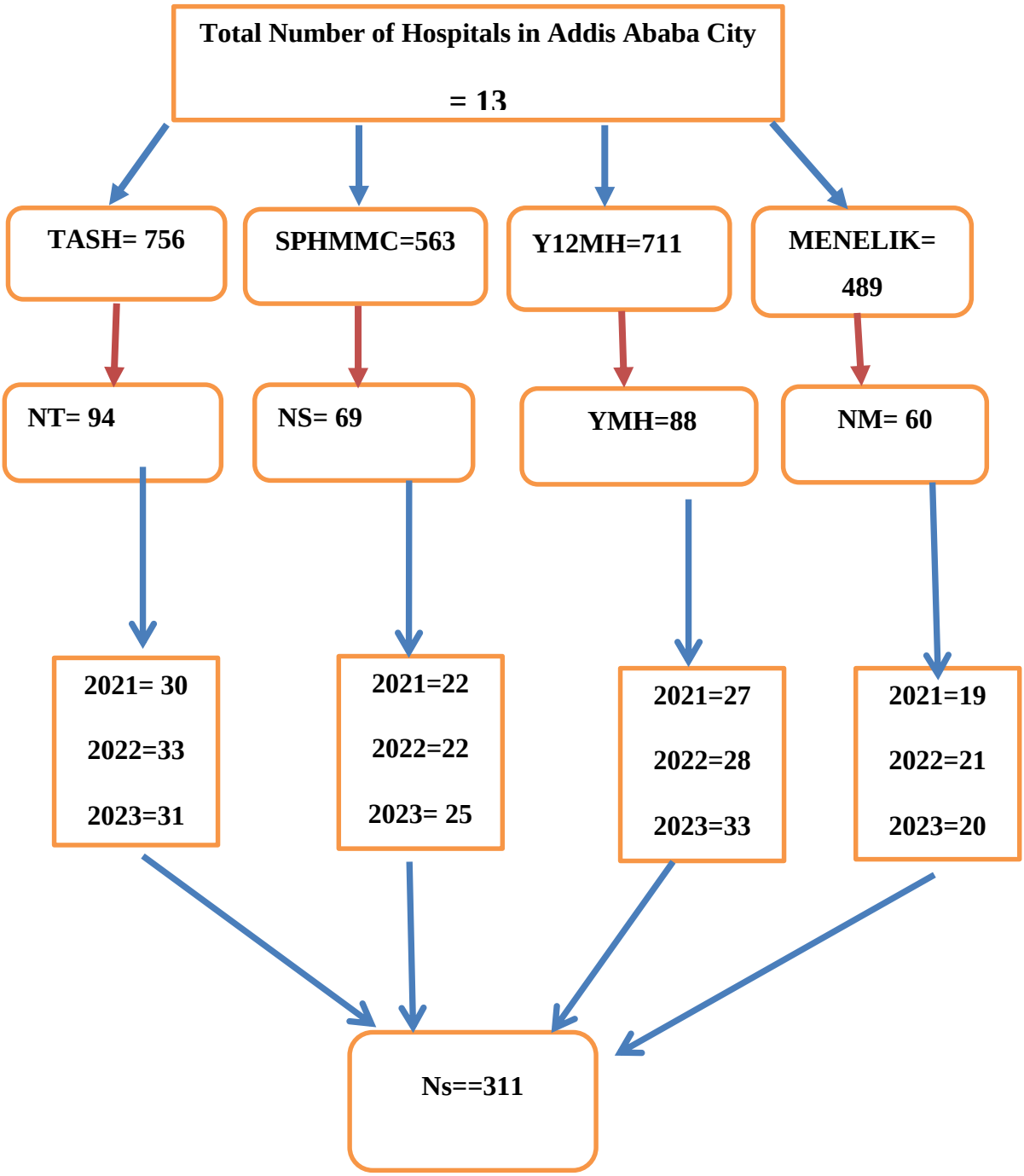
There are a total of 13 public hospitals in Addis Ababa city among this 11 of them deliver amputation service, and from these 4 hospitals were selected by using simple random sampling (lottery) method and the calculated sample size is distributed to each hospital by proportionally depending on the number of admitted patients with in the last three years, then from each hospital by using systemic random sampling patients with diabetic foot ulcer would selected from the sample size proportionally distributed to each hospitals. The total admitted patients over the past three years to TASH, SPHMMC, Yekatit 12 medical hospital collage and Menelik II hospital are 10498 from this 2519 patients met the inclusion criteria

Table 1: Diabetic foot ulcer patients admitted at selected hospitals, in Addis Ababa Ethiopia.

Name of selected hospital	Previous 3 year's admission and proportional allocation							
	2021		2022		2023		TA	Total
	NA	AL	NA	AL	NA	AL	TA	
TASH	240	30	262	33	254	31	94	756
SPHMMC	182	22	178	22	203	25	69	563
Y12MH	216	27	225	28	270	33	88	711
MIIH	156	19	172	21	161	20	60	489
							311	2519

NB.NA Number of admission, AL –Allocation, TA –Total admission

Figure 2: Sampling procedure and technique that used to identify the prevalence of amputation and associated factors among diabetic foot ulcer patients admitted at selected hospitals, in Addis Ababa Ethiopia, 2024



The total sample frame of the study is 2519

4.8 Study variables

4.8.1 Dependent variable

- Amputation due to diabetic foot ulcer

4.8.2 Independent variables

- Socio-demographic characteristics and clinical biomarker (age,sex,BMI,Residence HbA1c, WBC count, RBS, FBS,)
- Medical condition and behavioral characteristics (duration of DM, type of DM, duration of ulcer, wound care follow up, history of alcohol intake, history of smoking)
- Complication and co-morbidities (retinopathy, neuropathy, PAD, hypertension, Nephropathy, prior history of amputation, osteomyelitis, , foot deformity, Wagner grades)

4.9 Operational definition

Amputation is the loss or removal of a body part such as a finger, toe, hand, foot, arm or leg

Diabetic foot ulcer is occurrence of ulcer or lesion starts from foot or toe due to uncontrolled blood glucose.

Wagner grade

Grade 0 -Skin lesions absent, hyperkeratosis below or above bony prominences

Grade 1 -Skin and immediate subcutaneous tissue are ulcerated

Grade 2 -Lesions are deeper and may penetrate to tendon, bone or joint capsule

Grade 3 -Deep tissues are always involved, osteomyelitis may be present

Grade 4- Gangrene of some portion of the toes or forefoot

Grade 5- the entire foot is gangrenous

4.10 Data collection instrument and procedure

4.10.1 Data collection instrument

The data was gathered from medical records using pre-tested structured data extraction checklists that have been adapted from published literature sources (15, 25, 27, 36, 44). The checklists are made up of questions on the prevalence of amputation and associated factors among diabetic foot ulcer patients. The questions were addressed three sections socio-demographic characteristics and clinical biomarkers, medical condition and behavioral characteristics, complication and comorbidities.

4.10.2 Data collection procedure

Patients who were /meet the inclusion criteria was selected by systematic random sampling from the sample size proportionally distributed to each hospital, and the relevant information on the patient was gathered and reviewed from their registration and medical records. Four nurses with a BSc in nursing and one senior supervisor with a BSc in nursing who have experience in collecting data was selected and trained to collect the data. The data collectors and supervisors was trained for one day on the relevance of the study, the confidentiality of client information, eligibility criteria, and how to collect the data.

4.11 Data quality control

The data collection tool was prepared in English language. The data collectors received training on data collection methods prior to the actual data collection day. During the training, mechanisms for ensuring the confidentiality of the information of the patients throughout the whole data collecting and study process was discussed and established. To assure the quality of the data, the supervisors was examined the consistency and completeness of the questionnaires filled out by the data collectors. The supervisor was also paid a visit to the data collectors during the data collection period. Before the actual data collection pre-test was conducted on 5% of the study population at St. Peter hospital two weeks before the actual data collection to evaluate the clarity of questions and validity of the instrument that was used.

4.12 Data analysis and processing

The collected data was entered into Microsoft excel worksheet 2010. The data was thoroughly screened for errors and properly coded before subjecting to statistical analysis. The data was imported from Microsoft Excel and analyzed using STATA software version 14. Descriptive statistics were used for continuous data. The associations of the amputation due to diabetic foot ulcer with the different risk factors such as socio-demographic characteristics and clinical biomarkers (age, sex, residence,BMI, HbA1c, FBS), medical condition and behavioral characteristics (duration of DM, type of DM, duration of ulcer, history of alcohol intake, history of smoking) and Complication and comorbidities (retinopathy, neuropathy, PAD, hypertension, duration of hypertension prior history of amputation, osteomyelitis, , foot deformity, Wagner grade) were assessed by using logistic regression. Univariate; and multivariable logistic regression models were fitted containing the appropriate independent variables with 95% confidence interval and less than 0.05 level of precision. Multicollinearity tests among the independent variables were done by the variance inflation factors (VIF) and a result of <10 were included. The Hosmer-lemeshow goodness test was used to test model fitness. After bivariate logistic regression analysis, P-value <0.25 was taken to multiple logistic regression analysis. Finally, P-value <0.05 and 95% level of confidence interval were considered as statistically significant

4.13 Ethical approval

Ethical clearance for the start of the study was obtained from Addis Ababa University, College of Health Sciences, School of Nursing and Midwifery research commite with protocol number of SNM/04/2024. Following the approval, an official letter of cooperation was written to TASH, Yekatit 12 Hospital Medical College, Menelik II Hospital and St. Paul's Hospital Millennium Medical College, and permission were secured at all levels. Information related to those patients were kept strictly confidential and were not disclosed to any person.

5. RESULT

Table 2 shows that the majority of the participants were male (76.8%), urban (92.9%), non-alcohol drinker (56.2 %), non-smoker (77.4%) and had fast blood sugar ≥126 (44.69%), type 2 DM (80.7%), regular wound care follow-up (93.89%), non-prior history of amputation (81.67%), and Wagner grade 1(41.8%). Out of 311 DFU patients, 94(30.23%) were amputated and the rest 217(69.77%) were not, of 94(30.23%) amputated DFU patients, 42.5%, 37.2%, 15.9%, and 4.2% were digit, one side below Knee, bilateral below knee and above knee amputation.

Table 2: Characteristics of the study participants

Variables	**Category**	**Frequency**	**Percent**
Sex	Female	72	23.2
	Male	239	76.8
Residence	Rural	22	7.0
	Urban	289	92.9
History of Alcohol drinking	No	175	56.2
	Yes	136	43.7
History of Smoking	No	241	77.4
	Yes	70	22.5
	≤95	79	25.40
Fast blood sugar(mg/dL)	96-125	93	29.90
	≥126	139	44.69
Type of diabetes mellitus	Type 1	60	19.3
	Type 2	251	80.7
Wound care follow-up	Regular	292	93.89
	Irregular	19	6.11
Prior history of amputation	No	254	81.67
	Yes	57	18.33
Neuropathy	No	197	63.3
	Yes	114	36.5
Retinopathy	No	250	80.3

	Yes	61	19.6
PAD	No	106	34
	Yes	205	66
Hypertension	No	143	46
	Yes	168	54
Heart disease	No	254	81.6
	Yes	57	18.3
Nephropathy	No	245	78.7
	Yes	66	21.2
Osteomyelitis	No	270	87
	Yes	41	13.1
Foot deformity	No	275	88.4
	Yes	36	11.5
Amputation status	Yes	94	30.23
	No	217	69.77

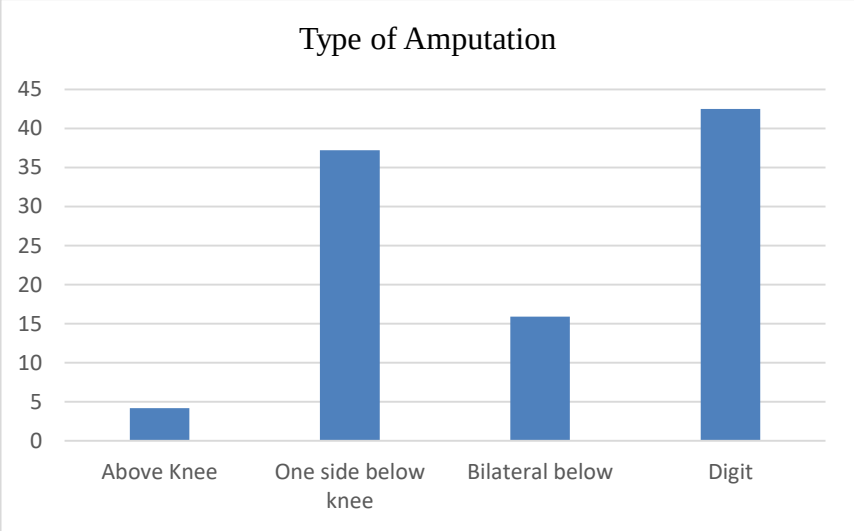


Figure 3. Different type of amputation among DFU patients in the study area

Table 3 shows that the highest prevalence of amputation was observed in alcohol drinker (37.5%), those DFU patients that develop neuropathy (38.6%), retinopathy (49.2%), PAD (38.0%), hypertension (38.1%), nephropathy (47.0%). Though highest prevalence were

recorded in fast blood sugar ≥126 (67.6%), rural (40.9%), those DFU patients that has no osteomyelitis and has foot deformity, there was no statistically significant association between fast blood sugar, osteomyelitis, foot deformity in relation to amputation among DFU patients (P-value> 0.005).

The risk of having amputation among DFU patients who develop neuropathy was 1.84 times more than who doesn't develop neuropathy (COR: 1.84, 95% CI: 1.12- 3.03, *P* value 0.015). The amputation among DFU patients developing retinopathy has higher prevalence (49.2%) as compared to those that doesn't develop retinopathy (25.6%) and the risk of developing amputation among DFU patients who have retinopathy were 2.81times more likely than who do not have retinopathy (COR, 2.81,95%CI: 1.57- 5.00, *P* value 0.000). The highest prevalence of amputation was observed among DFU patients who develop PAD (38.0%) than and who doesn't develop PAD (15.1%) and the odds of acquiring amputation among DFU patients who develop PAD was 3.45 times more likely than who do not develop PAD (COR, 3.45,95%CI: 1.89-6.30, *P* value 0.000) (Table 3).

Univariate logistic regression analysis showed that BMI, HbA1C, sex, history of alcohol drinking and smoking, type of diabetes mellitus, neuropathy, retinopathy, PAD, nephropathy, hypertension, and duration of DM were independently associated with amputation among DFU patients with statistically significant result (*P* value < 0.05) (Table 3). Whereas age, residence, wound care follow up, duration of ulcer, prior history of amputation, heart disease, osteomyelitis and foot deformity were not statistically significant for having amputation among DFU patients (*P* value > 0.05) (Table 3).

Table 3: Univariate logistic regression analysis of amputation among DFU patients

Variables	Category	Amputation		COR (95%CI)	P-value
		Yes	No		
Age (mean±SD) in year	58.89 ± 10.84	-	-	1.01 (0.99- 1.04)	0.104
BMI(mean±SD) kg/m^2	24.20 ± 2.20	-	-	1.21(1.05- 1.39)	0.007
HgA1C(mean±SD) in %	6.64 ± 1.70	-	-	1.53(1.31-1.80)	0.000
Duration of DM(month)	14.77 ± 7.10	-	-	1.05(1.02 - 1.09)	0.001
Duration of ulcer(year)	2.58 ± 1.83	-	-	1.11(0.97- 1.26)	0.105
Fast blood sugar (mg/dL)	≤95	21 (26.6%)	58(73.4%)	1	
	96-125	28 (30.1%)	65 (69.9%)	1.18(0.61-2.31)	**0.610**
	≥126	45(67.6%)	94(32.4%)	1.32(0.71-2.43)	0.372
Sex	Female	11(15.3%)	61(84.7%)	1	
	Male	83(34.7%)	156(65.3%)	4.97(2.17-11.33)	0.000
Residence	Rural	9 (40.9%)	13(59.1%)	1	
	Urban	85(29.4%)	204(70.6%)	0.60 (0.24-1.46)	0.262
History of Alcohol drinking	No	43(24.6%)	132(75.4%)	1	
	Yes	51(37.5%)	85(62.5%)	1.84 (1.12 - 3.00)	0.014
History of Smoking	No	51(21.2%)	190(78.8%)	1	
	Yes	43(61.4%)	27(38.6%)	5.93 (3.34-10.51)	0.000
Type of diabetes mellitus	Type 1	10(16.7%)	50(83.3%)	1	
	Type 2	84(33.5%)	167(66.5%)	2.51(1.21-5.20)	0.013
Wound care follow up	Regular	91(31.2%)	201(68.8%)		
	Irregular	3(15.8%)	16(84.2%)	0.414 (0.11-1.45)	0.170
Prior history of amputation	No	21(36.8%)	36(63.2%)		
	Yes	73(28.7%)	18183.4%	1.44(0.79-2.64)	0.230
Neuropathy	No	50(25.4%)	147(74.6%)	1	
	Yes	44(38.6%)	70(61.4%)	1.84(1.12-3.03)	0.015
Retinopathy	No	64(25.6%)	186(74.4%)	1	
	Yes	30(49.2%)	31(50.8%)	2.8125(1.57-5.00)	0.000
PAD	No	16(15.1%)	90(84.9%)	1	
	Yes	78(38.0%)	127(62.0%)	3.45(1.89- 6.30)	0.000
Hypertension	No	30(21.0%)	113(79.0%)	1	
	Yes	64(38.1%)	104(61.9%)	2.31(1.39- 3.85)	0.001
Heart disease	No	71(28.0%)	183(72.0%)	1	
	Yes	23(40.4%)	34(59.6%)	1.74(0.96-3.16)	0.067
Nephropathy	No	63(25.7%)	182(74.3%)	1	
	Yes	31(47.0%)	35(53.0%)	2.55(1.45- 4.48)	0.001
Osteomyelitis	No	82(30.4%)	188(69.6%)	1	
	Yes	12(29.3%)	29(70.7%)	0.94(0.46- 1.95)	**0.886**
Foot deformity	No	82(29.8%)	193(70.2%)	1	
	Yes	12(33.3%)	24(66.7%)	1.17(0.56-2.46)	**0.666**

*COR= Crude odds ratio

As shown in Table 4, a unit increase in HbA1C will increase the amputation prevalence by 34 % (AOR, 1.34, 95% CI: 1.12 -1.61, *P* value, 0.001) among DFU patients. The odds of having amputation among DFU male patients were 3.25 times more likely than in female (AOR 3.25, 95% CI: 1.41- 7.49, *P* value, 0.005). The risk of having amputation among smoker DFU patients was 10.58 times more likely than nonsmokers (AOR 10.58, 95% CI: 4.91-22.81, *P* value, 0.000). The risk of having amputation among type 2 DFU patients was 3.83 times higher than type 1 diabetic (AOR, 3.83, 95% CI: 1.50- 9.75, *P* value, 0.005). The risk of acquiring amputation in DFU patients who have PAD has 2.92 times more likely in those that doesn't have PAD (AOR, 2.92, 95% CI: 1.32-6.46, *P* value, 0.008). Multivariate logistic regression analysis showed that age, BMI, neuropathy, retinopathy, nephropathy and hypertension were not statistically significant associated with amputation among DFU patients (*P* value > 0.05) (Table 4).

Table 4: Multivariate analysis of amputation among DFU patients

Variables	Category	Amputation		AOR (95%CI)	P-value
		Yes	No		
Age (mean ± SD)	58.89 ± 10.84	-	-	0.96 (0.93 - 1.00)	0.064
BMI(mean ± SD)	24.22 ± 2.16	-	-	1.08(0.90- 1.29)	0.404
HbA1C(mean ± SD)	6.64 ± 1.70	-	-	1.34(1.12 -1.61)	0.001
Duration of DM(month)	14.77 ± 7.10	-	-	1.03(0 .98- 1.08)	0.186
Duration of ulcer(month)	2.58 ± 1.83	-	-	1.10 (0.93- 1.30)	0.243
Sex	Female	11(15.3%)	61(84.7%)	1	
	Male	83(34.7%)	156(65.3%)	3.25(1.41- 7.49)	0.005
History of Alcohol drinking	No	43(24.6%)	132(75.4%)	1	
	Yes	51(37.5%)	85(62.5%)	1.18(0.62- 2.27)	0.605
History of Smoking	No	51(21.2%)	190(78.8%)	1	
	Yes	43(61.4%)	27(38.6%)	10.58(4.91-22.81)	0.000
Type of diabetes mellitus	Type 1	10(16.7%)	50(83.3%)	1	
	Type 2	84(33.5%)	167(66.5%)	3.83(1.50- 9.75)	0.005
Wound care follow up	Regular	9(31.2%)	201(68.8%)	1	
	Irregular	3(15.8%)	16(84.2%)	0.50(0.12 - 2.05)	0.338
Prior history of amputation	No	21(36.8%)	36(63.2%)	1	
	Yes	73(28.7%)	18183.4%	1.01(0.42- 2.45)	0.969
Neuropathy	No	50(25.4%)	147(74.6%)	1	
	Yes	44(38.6%)	70(61.4%)	1.45(0.69 - 3.05)	0.317
Retinopathy	No	64(25.6%)	186(74.4%)	1	
	Yes	30(49.2%)	31(50.8%)	1.53(0.63 - 3.73)	0.343
PAD	No	16(15.1%)	90(84.9%)	1	
	Yes	78(38.0%)	127(62.0%)	2.92(1.32-6.46)	0.008
Hypertension	No	30(21.0%)	113(79.0%)	1	
	Yes	64(38.1%)	104(61.9%)	1.45(0.72- 2.90)	0.293
Heart disease	No	71(28.0%)	183(72.0%)	1	
	Yes	23(40.4%)	34(59.6%)	1.09(0.49- 2.42)	0.827
Nephropathy	No	63(25.7%)	182(74.3%)	1	
	Yes	31(47.0%)	35(53.0%)	1.04(0.463- 2.35)	0.918

*AOR= Adjusted odds ratio

6. DISCUSSION

The present study made an effort to determine the prevalence of amputation and associated factors among DFU patients admitted at selected public hospitals in Addis Ababa, Ethiopia. The overall prevalence of amputation among DFU in this study (30.23%) was in close agreement with the prevalence reported in Nekemt hospital Ethiopia (30.43%), in Saudi Arabia (29.7%) (29). Morbach (47). reported an amputation prevalence of 15.4%, whereas Lipsky (48) reported a prevalence of 21.4%. This study found an amputation prevalence of 30.23%, which differed from the earlier investigations by Morbach and Lipsky. This could be due to the differences in the early treatment and good monitoring of DFU patients. Out of 94(30.23%) amputated DFU patients, 42.5%, 37.2%, 15.9%, and 4.2% were digit, one side below knee, bilateral below knee and above knee amputation**.**

The varies independent variables such as age, sex, BMI, HbA1C, FBS, residence, history of alcohol intake, history of smoking, neuropathy, retinopathy, nephropathy, PAD, type of DM, duration of DM, wound care follow up, prior amputation, duration of ulcer, hypertension, heart disease, nephropathy, osteomyelitis, and foot deformity has been assessed to see the its impact on amputation among DFU patients and their association were evaluated using univariate and multivariate logistics regression. According to Univariate logistics regression analysis, sex, BMI, HbA1C, history of alcohol intake, history of smoking, neuropathy, retinopathy, nephropathy, PAD, type of DM, duration of DM, hypertension, and nephropathy were found statistically significant result with p value < 0.25 for the occurrence of amputation among DFU patients; However, multivariate logistics regression analysis showed HbA1C, sex, type DM, history of smoking and PAD has been identified as having statistically significant association for having amputation among DFU patients.

In our study HbA1c was found to be statically significant predictor of amputation among DFU patients. This finding is in line with the study conducted in south west Iran(20) and Saudi Arabia(29). Another Meta-analysis study done by Selvin 4(49) had shown that an increase in HbA1c increases the risk of major limb loss**.** As high glycated hemoglobin inhibits endothelium-mediated vasoactive responses. A high glucose level alters the structure of erythrocytes, making blood more viscous, restricting blood flow and accelerating thrombus formation, increasing the risk of amputation. Thus, blood glucose control is crucial in the

healing of diabetic ulcers.(50) Adler. showed that Individuals with diabetes have a much higher risk of lower limb amputation due to hyperglycemia. Glycemic control may help minimize the frequency of lower limb amputations by slowing the advancement of DFU, wounds, and neuropathy (51).

In this study, the highest prevalence of amputation was observed in male (34.7%)than female (15.3%) the risk of acquiring amputation among male DFU patients was3.25 higher than Female DFU patients. This finding is close to the study conducted in Romania which shows men had a 2.75 times higher risk of amputation compared with women (52).this could be due to life style of male .they are more exposed to different substances like smoking, alcohol drinking habits this may delay the healing process of DFU. This higher the risk of having amputation. Women have a lower risk of foot ulceration than men. which appears to be the result of less severe neuropathy, increased joint mobility, and lower foot pressures.(53)

In the current study, higher prevalence of amputation was observed in smoker (61.4%) than non-smoker (21.2%).This finding is in line with Yesil,(54) who found a statically significant association of amputation with their smoking history. Another study done , also reported the odds of amputation for smokers was 3.44 times higher than for non-smokers with statistical significant result (20).

In this study Type of DM also have significant association to amputation among DFU patients being type 2 diabetics have highest prevalence (33.5%) than type 1 diabetics patients (16.7%) The risk having amputation among type 2 diabetes patients was 3.83 higher than type 1 diabetes patients. Amputations in T1DM and T2DM patients may have evolved differently due to several circumstances. Those with T1DM are frequently younger and have less comorbidity than those with T2DM; because symptom onset is faster in T1DM, these patients also tend to seek medical care earlier than those with T2DM.(52)but.T2DM are more old age they may develop diabetics complications and may have comorbidity this slow the healing of DFU and this leads to having higher amputation than T1DM.

The other independent variable is PAD is a condition where there is poor vascular health due to smoking, atherosclerosis, calcification, hypertension, inflammation, or damage insufficient blood flow to the distant limbs, particularly in the lower body. The clinical appearance of these patients may include pallor, discomfort, paresthesia, poikilothermia,paralysis,and

pulselessness. Critical ischemia can cause tissue hypoxia and gangrene change in extreme cases, which may necessitate surgical amputation.

PAD have significant association to amputation among DFU patients. The risk of acquiring amputation who develop PAD was 2.92 higher than who doesn't have PAD. This finding is in line with Taipei Veteran General Hospital, conducted in china(55)

8.CONCLUSION

The prevalence of amputation among DFU patients observed in this study is high. The study identified sex, history of smoking, type of DM, PAD and hemoglobin A1C as important risk factors for amputation among DFU patients. Patients with type 2 DM and having PAD, and being smoker and increase HbA1C value present a high risk of needing amputation among DFU patients.

8.1. RECOMMENDATIONS

Based on the findings of this study the following recommendations were forwarded:

Ministry of health

✓ Ministry of health should incorporate educational initiatives and efforts to provide better treatment for diabetic patients are required. Since a unit increase HbA1C value increase the amputation. Prepare training to create awareness on the prevalence of amputation and what factors are associated with it.

Hospital administrators and policy makers

✓ Rigorous measures during follow up are the key to the prevention, early detection, and management of amputation.

✓ The multidisciplinary team must be able to implement an excellent surveillance system that improves allowing identification of risk factors and contributes towards implementing strategies to reduce the DFU.

For the researchers

✓ Finally, researchers should conduct prospective study designs to get better information including variables not included in this study. I also recommended large sample size.

9. STRENGTH AND LIMITATION OF THE STUDY

9.1 Strength of the study

The study contained data from 30% of Addis Ababa public hospitals, which is scientifically representative of the study area. The study used publicly available data from records, which may make the study easier and less expensive to conduct than prospective studies.

It addresses the most of the independent variables related with amputation due to diabetic foot ulcer furthermore, this study includes the two types of diabetes.and it locates which part is amputated.

9.2 Limitation of the study

Wagner classification was also had significant association to amputation in this study. However, the confidence interval is very wide so it was removed from the multivariate logistic regression, and wide 95CI shows low precision I recommend large sample size for next study. The nature of design is retrospective used secondary data which may miss some essential variables

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10. ANNEXES

Annex I: Data extraction checklist

This is a data collection format Data Extraction Checklist to identify prevalence and associated factors of amputation among diabetic foot ulcer patients admitted at Tikur Anbessa Specialized Hospital, St, Paul's Hospital Millennium Medical College, Yekatit 12 Hospital Medical College and Menelik II hospital from February 19 to March 19 2024.

Name of Datacollector_____Date_____Qualification_____

Data Collector agreement: "I certify that I have filled the questionnaire in accordance with the training that is given to me and instructions stated in it.

Signature _____Date_____

Checked by supervisor for completeness: - Supervisors Name_____ signature _____

S.no	SocioDemographic and biomarkers	Possible choice
1.	Age	----------
2.	Sex	1.Male 2. Female
3.	BMI	--------
4.	Residence	1. urban 2. Rural
5	. HbAlc	
6	Fasting blood sugar(FBS)	……

S.no	Part II Medical conditions and behavioral characteristics	Possible answer
7.	Types of DM	1. Type 1 2 Type 2
8	Duration of DM	
9	Duration of ulcer	----------
10	Wound care follow up	Regular Irregular
11	History of alcohol intake	1. Yes 2. No
12	History of smoking	1. yes 2 .No

S.no	**Part III: complication and comorbidities'**	**Possible answer**
13	Neuropathy	1. Yes 2. No
14	Retinopathy	1.yes 2.No
15	PAD	1. Yes 2. No
16	Hypertension	1. Yes 2. No

17	Osteomyelitis	1.Yes 2.No
18	Nephropathy	1.Yes 2.No
19	Foot deformity	1.yes 2.No
20	wound care	1.Regular follow up 2.Not regular follow up
21	Prior amputation	1.Yes 2.No
22	Wagner's grade	1. Grade 0 2. Grade 1 3. Grade 2 4. Grade 3 5. Grade 4
23	Patient amputated?	1. Yes 2. No
24	If the above question is Yes	1.unilateral 2.bilateral 3.digit 4. above knee

THANK YOU!