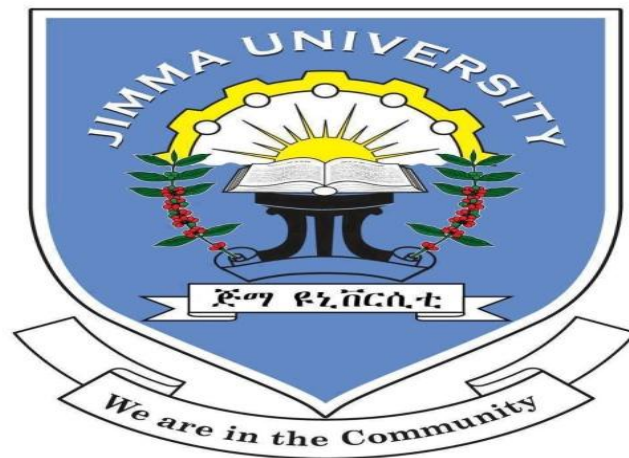**BURDEN, RISK FACTORS AND OUTCOMES OF DIABETIC FOOT ULCER IN DIABETES MELLITES PATIENTS ADMITTED TO NEKEMTE REFERAL HOSPITAL, EAST WOLLEGA ZONE,WEST ETHIOPIA.**

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A THESIS SUBMITTED TO SCHOOL OF GRADUATE STUDIES, JIMMA UNIVERSITY INSTITUTE OF HEALTH SCIENCES, SCHOOL OF PHARMACY, FOR PARTIAL FULFILLMENT OF THE REQUIREMENTS FOR THE DEGREE OF MASTERS OF SCIENCE [MSC] IN CLINICAL PHARMACY.

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JIMMA, ETHIOPIA

JIMMA UNIVERSITY
COLLEGE OF HEALTH SCIENCES,
SCHOOL OF PHARMACY

BURDEN, RISK FACTOR AND OUTCOMES OF DIABETIC FOOT ULCER IN DIABETES MELLITES PATIENTS ADMITTED TO NEKEMTE REFERAL HOSPITAL, EAST WOLLEGA ZONE,WEST ETHIOPIA.

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ABSTRACT

BACKGROUND: Diabetic foot ulcer are very common in people with diabetes throughout the world, affecting up to 15% of diabetic patients during their lifetime. Foot ulcers significantly contribute to morbidity and mortality of patients with diabetes mellitus. The diabetic patients with foot ulcers require long-term hospitalization and carry the risk of limb amputation. The presence of peripheral neuropathy ,peripheral vascular disease, and poor glycemic control in conjunction with minor foot trauma increases the likelihood that patients with diabetes will develop foot ulcers.

OBJECTIVE: To identify burden, risk factor and outcomes of diabetic foot ulcer in diabetes patients of Nekemte referral hospital (NRH) from March 15 to June 15, 2018.

METHODS AND PARTICIPANTS: A general prospective cohort study of diabetes mellitus patients who had diabetic foot ulcer was conducted in Nekemte referral hospital from March 15 to june 15, 2018. Study participants were selected by using convenience or haphazard sampling technique. The Wagner classification of diabetic foot ulcer was used to assess the severity of foot ulcers. Size of ulcer was determined by multiplying the largest by the second largest diameter perpendicular to the first and the etiology of diabetic foot ulcer was identified by using gram stains. Multivariate logistic regression was used to analyze the associations between dependent variable and independent variables.

RESULTS: From 644 diabetes mellitus, 115 diabetes foot ulcer patients were admitted to the Nekemte referral hospital; of these patients, 64(55.65%) were male. About 26(22.61%) of them were in the age range of 58-67, while mean age of participants was 44.44 ±14.69. Regarding their area of residence, Fifty-eight (50.43%) participants came from urban area. Among the total study participants, 61 (53.04%) of them had type 2 diabetes mellitus. The mean fasting blood glucose level among diabetic patients with foot ulcer was 147.93mg/dl ±45.03. Gram-positive bacteria were the most causative micro organism for the diabetic foot infections which accounted for 42(54.55%). Ulcer size was greater than 5cm^2 in 23 (20.00%) of the patients.

From diabetes patients evaluated during the study period, 17.86% had foot ulcers. Of these patients, 35(30.43%) were undergone amputations. Grade of diabetic foot ulcer[AOR=1.7; 95% CI: 1.604,

4.789],inappropriate antibiotics[AOR = 2.526; 95% CI: 1.767, 8.314], Overweight [AOR = 2.767; 95% CI: 1.827, 9.252], obesity [AOR = 3.020; 95% CI: 2.556, 16.397],blood glucose control[AOR = 2.592; 95% CI: 1.937, 7.168], and neuropathy [AOR = 1.565; 95% CI: 1.508, 4.822] were found to be a predictor of amputation in multivariable logistic regression analysis. Cloxacillin was the most commonly prescribed antibiotics for treating diabetic foot ulcer accounting 56(34.15%) followed by metronidazole 43(26.22%) and ceftriaxone33 (20.12%).

CONCLUSION AND RECOMMENDATION: The incidence and rate of amputation of diabetic foot ulcer among diabetic patients in Nekemte referral hospital was high. Blood glucose level, Higher BMI, inappropriate antibiotics given, neuropathy, and advanced grade of diabetic foot ulcer were factors that predict outcomes of diabetic foot ulcer. The most commonly prescribed antibiotics for treating diabetic foot ulcer was cloxacillin. Gram positive bacteria were the most isolate organism. Provision of special emphasis for patients having neuropathy and advanced grade of diabetic foot ulcer, decreasing excessive weight gain, managing hyperglycemia, and appropriate antibiotics prescription practice would decrease outcomes of diabetic foot ulcer.

KEY WORDS: Diabetic foot ulcer, incidence, risk factors, outcomes, Nekemte referral hospital

ACKNOWLEDGMENT

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LIST OF ABBREVIATIONS/ACRONYMS

AOR…………………………….Adjusted Odds Ratio

BP………………………….. Blood Pressure

CI……………………………Confidence Interval

COR………………………….Crude Odds Ratio

DFU…………………………. Diabetic Foot Ulcer

DM……………………………Diabetes Mellitus

EUDIP………………………..European Union Diabetes Indicators Project

FBS…………………………. .Fasting Blood Sugar

HbA1c………………………. Glycosylated Hemoglobin

HDL…………………………..High Density Lipoprotein

IDSA………………………….Infectious Diseases Society of America

IWGDF……………………… International Working Group on the Diabetic Foot

JUMC……………………… Jimma University Medical Center

LDL…………………………. Low Density Lipoprotein

LEA…………………………. Lower Extremity Amputation

MRSA…………………….. Methicillin Resistant Staphylococcus Aereus

NIDDM……………………….Non insulin Dependent Diabetes Mellitus

NRH…………………………..Nekemte Referal Hospital

NUH…………………………..National University Hospital

PAD…………………………. .Peripheral Arterial Disease

PVD…………………………. .Peripheral Vascular Disease

QOL…………………………...Quality of life

SD……………………………..Standard Deviation

SPSS…………………………..Statistical Package for Social Sciences

SSTI…………………………...Skin and Soft Tissue Infections

UK……………………………..United Kingdom

WHO…………………………..World Health Organization

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1. INTRODUCTION

1.1. Background

Diabetes mellitus is a non-communicable disease and one of the most common chronic diseases (1).World health organization defined diabetes mellitus (DM) as a metabolic disorder of multiple etiology characterized by chronic hyperglycemia with disturbances of carbohydrate, fat and protein metabolism resulting from defects in insulin secretion, insulin action, or both(2).

According to the International Diabetes Federation (IDF), 425 million people were estimated to live with diabetes in 2017, out of which about an estimated 15.5 million adults aged 20-79 years were living with diabetes in Africa Region, representing a regional prevalence of 3.3%. Africa's most populous countries, including Ethiopia, have the highest numbers of people with diabetes. Ethiopia, which is one of the developing nations, is at a risk of increased diabetes incidence. About 2.57 million of the population is estimated to live with diabetes in 2017(3).

Complications of DM have become a major public health problem in all countries. It causes significant physical and psychological morbidity, disability and premature mortality among those affected patients and imposes a heavy financial burden on health service(4). It is characterized by multiple long-term complications affecting almost every system in the body. It often leads to blindness, heart and blood vessel disease, stroke, kidney failure, amputations, and nerve damage(5)

Diabetic foot is defined as the foot of the diabetic patients with ulceration, infection, and/ or distraction of the deep tissues associated with neurological abnormalities and varying degrees of peripheral vascular disease of the lower limb(6). Diabetic foot ulcers are a common and much feared complication of diabetes, with recent studies suggesting that the lifetime risk of developing a foot ulcer in diabetic patients may be as high as 15%(7). The development of a foot ulcer usually involves several mechanisms, such as neuropathy, increased biomechanical stress, external trauma and peripheral arterial disease (PAD) (8). Foot infection was defined according to the International Working Group on the Diabetic Foot classification system as at least two clinical signs or symptoms of infection in or around the DFU including purulence, erythematic, pain, tenderness, warmth and/or indurations(9).

Diabetic patients who present with foot ulceration is associated with many risk factors. PAD is present in approximately one-half of all patients with foot ulcers and is considered an important predictor of outcome. Therefore, marked differences in patient, foot and ulcer characteristics can exist between patients with and without PAD(10).

Foot ulcers significantly contribute to morbidity and mortality of patients with diabetes mellitus. The diabetic patients with foot ulcers require long-term hospitalization and carry the risk of limb amputation(11).

Along with increased morbidity, foot ulcers can lead to lifelong disability and may substantially diminish the quality of life (QOL) for these patients. Specifically, patients with DFU have restrictions on mobility, poor psychosocial adjustment, and lower self-perceptions of health than patients who do not have ulcers. Survival from the time of diagnosis was significantly reduced for the foot ulcer group compared with the control group (12, 13).

Foot ulceration is a preventable condition, where simple interventions can reduce amputations by up to 70%through programs that could reduce its risk factors. Identifying the role of risk factors contributing to this condition will enable health providers to set up better prevention programs that could result in improving patients' quality of life and henceforth, reducing the economic burden for both the patient and the health care system(14). Many practical guidelines have been published, with most recent one the evidence-based global consensus for the prevention and management of diabetic foot by the International Working Group on the Diabetic Foot (IWGDF) Editorial Board(15).

Diabetes mellitus (DM) has been established as one of the most common and important disease states associated with an increased risk of postoperative infections and poor outcomes after lumbar spinal surgery(16). Only recently have studies reported that patients with DM patients undergoing degenerative cervical spine surgery also have an increased risk for several preoperative complications, including increase in length of hospital stay, inpatient mortality, and postoperative infection(17).

For patients with DM undergoing any surgical intervention, it is generally thought that maintaining tight glycemic control in the preoperative period might reduce the risk of these complications. For instance, tightly controlled preoperative various glycemic markers, such as the glycated hemoglobin A1c (HbA1c) level, have been associated with decreased infectious complications following total joint arthroplasty(18).

1.2. Statements of the problem

Diabetes mellitus is one of the commonest medical conditions prevalent all over the globe. This associated to many complication due to its progressive involvement of various organ. The basic examples includes gradual onset of neuropathies', vasculophathies, retinopathies', reduced immune system and thus increased incidence of infection. Diabetes is a serious chronic disease that requires special attention and is also described as Global Epidemic(6, 7).

Diabetic foot complications are common amongst people living with diabetes. Foot ulcerations are one of the most feared complications for both people with diabetes and health care providers due to their negative impact on lives resulting in overall poor prognosis of the disease leading to long period of hospitalization and substantial health care costs(19). It has been reported that approximately 33% of diabetes-related costs have been linked to the treatment of foot ulcers, the majority of which are related to inpatient hospital admissions. Hospital inpatient care accounts for at least 50% of the national diabetes cost burden overall and hospital charges and costs related to diabetic foot ulcers specifically have increased significantly over the past 5years(20).

Foot problems remain very common in people with diabetes throughout the world, affecting up to 15% of diabetic patients during their lifetime. Diabetic foot ulcers increases morbidity, high expenditure for therapeutic management and precede amputations in about 85% of patients. Frequency of lower limb amputations can be lowered by 49-87% by preventing the development of diabetic foot ulcers(7).

In the UK, 50% of the hospital bed occupancy of diabetic patients is caused by foot problems. DFU have a profound effect on patients' quality of life and result in a great burden on the health service resources. Diabetes-related foot ulcers represent challenges for the individual and for the health care system, as they increase the demand for specialized health care. Even though preventive strategies have been shown to be cost-effective, meeting this demand in the health care system remains an enormous challenge from the financial and workforce perspectives(5).
Foot complications, especially foot ulcers, constitute a major public health problem for diabetes patients in sub-Saharan Africa and are important causes of prolonged hospital admission and death in patients from this part of the continent(21).

Foot ulceration and supervening infection are a major cause of morbidity in diabetes patients. Diabetes foot lesions necessitate more hospital admissions than any other specific complications of diabetes(22). The prevalence of these infections in DFU has been reported to range between 25±60%. Although the critical nature and prevalence of infected DFUs are well appreciated, the development of these infections in the first place has received less attention(9).

In many less-developed countries, foot infections are especially common where there are no available chiropody services, or lesions are ignored or detected relatively late in the course of the infection after unsuccessful home therapy, such as soaking in hot water or application of unproven home remedies or after seeking medical assistance from traditional healers. In those patients diabetes have an infectious etiology. Patients often present to hospital only after gangrene and infection have developed, or after localized infection has progressed to systemic sepsis that might not be amenable to conventional supportive therapy with antimicrobials(23).

Skin and soft tissue infections (SSTIs) are leading causes of morbidity and occasionally mortality in persons with diabetes mellitus. SSTIs are more common and more severe in diabetic than in non-diabetic patients and constitute a leading cause of hospitalization. The risk of SSTI-related hospitalization is more than twice as high in diabetic than in non-diabetic patients. Diabetes is independently associated with increased emergency department visits for SSTI, longer hospital stays and infection-attributable death. The rising prevalence of diabetes is likely to cause increasing numbers of diabetes-related SSTIs in hospitalized patients (24).

Foot wounds are now the most common diabetes-related cause of hospitalization and are a frequent precursor to amputation. Individuals with diabetes have a 30-fold higher lifetime risk of undergoing a lower-extremity amputation compared with those without diabetes. An infected foot wound precedes about two-thirds of lower extremity amputations, and infection is surpassed only by gangrene as an indication for diabetic lower-extremity amputation. Individuals with diabetes have at least a 10-fold greater risk of being hospitalized for soft tissue and bone infections of the foot than individuals without diabetes (25). In addition, 28% to 51% of amputated diabetics will have a second amputation of the lower limb within five years of the first amputation. This was thought to be due to neuropathy, peripheral vascular disease, poor diabetes control and longer duration of diabetes(26).

Diabetic foot ulcerations can take weeks or months to heal and can sometimes not heal at all. Owing to poor healing results, many patients will need to be admitted to hospital for inpatient treatment. Non-healing ulcerations can result in diabetes foot complication such as local infection and gangrene(19).

Primary and secondary prevention of diabetic foot ulcers can be achieved by daily foot examinations for painless ulcers or injuries, regular podiatrist visits, use of appropriate foot wear, and maintenance of optimal diabetes self-care. Despite this, adverse outcomes following the onset of foot ulcers are poor, and they are the most common reason for amputation (27).

Generally, diabetic foot complications remain the major medical, social, and economic problem for all types of diabetes. Without early and optimal interventions, wounds can rapidly deteriorate and lead to unnecessary amputations. Following amputations, patients not only suffer the clinical and psychological consequences of limb loss, but amputation itself is predictive of a five-year mortality that is higher than those of breast cancer in females and prostate cancer in males(28).

Diabetic foot ulcer is the most fatal complication of diabetes mellitus(7). Despite this, no study has been done on incidence, risk factor and outcomes of diabetic foot ulcer in NRH. This study will identify the magnitude and risk factors associated with the outcomes of diabetic foot ulcer patients in this area.

1.3. Significance of the study

As the study was concerned no study has been done on incidence, risk factors and outcomes of diabetic foot ulcer in NRH. The finding of this study will help to decrease the occurrence of diabetic foot ulcer and its complication in the area by suggesting effective strategies for prevention or delay of the most common component risk factor of foot ulceration.

Although in recent years in Ethiopia much effort has been put into the development of guidelines in order to stimulate the delivery of uniform and structured care, prospective data on outcomes and predictors of outcome in patients with diabetic foot ulcers are limited.

The findings of this study will assist health care professionals to understand factors related to diabetic problem and it also will help policy makers, program planning bodies and service providers to evaluate quality of existing policies, treatment strategies, programs and treatment guidelines and to improve or change them to attain optimum level of functioning and also helps as a baseline for future studies. Finally since there is a limited research at country and lower level, this study can be used as resource for other studies related to complications in diabetes.

2. LETERATURE REVIEW

2.1. Burden of diabetes foot ulcer

The global prevalence of diabetes mellitus has been projected to increase and affecting over 425 million individuals in 2017(3). As the incidence of DM is rising dramatically, so are the risks of developing diabetic foot disease. The lifetime risk persons with diabetes developing diabetes foot ulcers was reported to be as high as 25%(29). The study conducted in USA by J. Bradford Rice, in 2014 shows that of the diabetic patients included in the analysis, approximately 12.8% ages 65+ years and 4.8% ages 18–64 years had recent episodes of foot ulcers during the study period(30). A cross-sectional survey of diabetic patients conducted in Taiwan in 2003 showed that from a nationally representative sample diabetic foot problems were present in 2.9% of the diabetes patients(31).

Nagaraj C etal conducted a community-based study among urban poor in Bangalore, India in 2014 and it was found that the mean age of the study subjects was 55.97 years old with a standard deviation (SD) of ±11.6 years, and of whom 48 (74%) were female. Illiteracy was present in 20 (30.77%) of the subjects, and 18 (27.69%) of the subjects had completed high school. Among the 65 subjects, 41 (63.08%) were unemployed. Foot ulceration and hypoesthesia were the most common findings. Ulcers were present in 5 (8%) of the study subjects(1).

The prevalence of diabetes in Singapore is 8.2% in 2004. Diabetic foot problems (DFP) are very common in Singapore, accounting for approximately one fifth of all emergency admissions in National University Hospital (NUH). Every year, almost 700 lower limb amputations resulting from diabetic foot complications were performed (32).

According to the study done by Danmusa UM et al(2016) in Nigeria on Medical records of all patients who visited the diabetic clinic and those admitted at the medical wards of Ahmadu Bello University, Zaria diagnosed with DFU over the period of six (6) months were reviewed and it was found that the prevalence of DFU in patients with diabetic mellitus (DM) was 6.0% with more cases in men (67.2%) than women (32.8%). The prevalence of DFU in relation to type of DM was 6.5% and 0% for DM type-II and DM type-I respectively. The distribution of DFU in relation to clinical stages was 40%, 25.7%, 17.1% and 11.4% for stages-IV, III, II and I.

Patients in the age group 51-60 years had the highest frequency of DFU (28.6%), but there was no DFU in those 10-20 years and > 80 years(29).

The descriptive, cross sectional, hospital-based study conducted in Khartoum, Sudan showed that the prevalence of diabetic foot ulcer is 18.1%(26). However, study done by Nyamu PN etal in kenya shows that The prevalence of diabetic foot ulcers was 4.6% in tertiary clinic(11).

A cross sectional study was conducted on 216 diabetic clients attending Arbaminch hospital by Deribe et al in 2013 Showed that about 32(14.8%) has diabetic foot ulcer, 129(59.7%) were male, 61(28.2%) from rural, 132(61.11%) were overweight, 97(44.5%) have poor diabetic foot self care practice and 80(37%) of them have secondary education(33). Similarly A cross sectional study carried out by Dawit Worku et al in 2008 In Jimma university medical center(JUMC)on pattern of diabetes complication showed that the prevalence of diabetic foot ulcer accounts 4.5%among diabetes patients, The mean (±SD) age of the patients was 44.4 (±15.6) years, and 192 (62.9 %) were males.(34). Another study conducted Among 279 study participants in the diabetic clinic of Gondar University Referral Hospital by Tesfamichael G. Mariam et al in 2017,of which thirty-eight (13.6%) patients had developed foot ulcer(35). The study conducted in Ayder referral hospital,Mekele showed that 12% of the diabetic patients have foot ulcer currently with 38% of them are with Wagner's grade 0(5).

2.2. Risk factor of diabetes foot ulcer

The population of diabetic patients who present with foot ulceration is heterogeneous: although most patients have peripheral poly neuropathy, there are several other characteristics that may vary among patients, such as the presence of peripheral arterial disease (PAD), infection and co-morbidities(10).The presence of peripheral neuropathy, peripheral vascular disease, and poor glycemic control in conjunction with minor foot trauma increases the likelihood that patients with diabetes will develop foot ulcers. Ulcers, in turn, often progress to infections of the surrounding tissue, osteomyelitis, and amputation(13).

A study done by Cancienne JM et al(2017) at USA implies that The rate of infection ranged from a low of 0.5% up to 3.5% for patients with an HbA1c level >11.0 mg/dL (p=.012) and patients with an HbA1c level of 7.5 mg/dL or above had a significantly higher risk for deep infection compared with patients below this threshold(18). But another study done in USA by Margolis DJ

etal 2002 shows that wound size, wound duration, and wound grade are all significantly associated with the likelihood of a wound healing(36).

A prospective study done by boyko at Veterans Affairs Medical Center in Washington with diabetes showed that significant predictors of foot ulcer includes A1C, impaired vision , prior foot ulcer, prior amputation, monofilament insensitivity, tinea pedis , and onychomycosis(37).

Healthy Lifestyle, Dietary restrictions and alcohol consumption are very crucial for optimal management of DM. Exercising according to standard recommendations is very important not only for better glycemic control, but also for reduction of cardiovascular complications. The Jordanian study conducted by Khattab et al (2010) found that poor glycemic control was more common among patients who did not practice any physical activity and did not follow dietary regimens(38). Ahmed et al (2008) also conducted a study to evaluate the association between alcohol consumption and glycemic control among adult diabetic patients in Northern California, USA. Alcohol consumption was found to have an inverse association with glycemic control(39).

Another a prospective cohort study of diabetic foot ulcer patients across 14 centers in Europe done by L. Promper etal in 2008 showed that, independent baseline predictors of non-healing in the whole study population were older age, male sex, heart failure, the inability to stand or walk without help, end-stage renal disease, larger ulcer size, peripheral neuropathy and PAD. Infection emerged as a specific predictor of non healing in PAD patients only(10).

Similarly, the a longitudinal data study done by Stephan Pscherer in 2012 from general practices in Germany found that the presence of peripheral arterial disease to be the biggest risk factor for amputation , followed by advanced age ≥70 years , poly neuropathy, male gender, diabetes duration and an HbA1c value >7.5%(40).

The study conducted by Tseng etal in Tiwan in2006 showed that the prevalence of amputation did not differ significantly between men and women with type 1 diabetes but was significantly higher among men than among women with type 2 diabetes (0.9% v. 0.7%). Height (every 10-cm increment) was remained an independent predictor of lower-extremity amputation (41).

Increasing age, wound depth, the presence of ischemia, a low albumin level, and the lack of simultaneous ulceration were the most significant independent predictors of an unfavorable outcome(42). But A prospective study was conducted by salaam etal at Pakistan in 2017 on patients with diabetic foot ulceration attending the Madinah Teaching Hospital indicates that Patient age of 50 and older, long duration of diabetes (>10 years), rural origin, and heel ulcers were significantly associated with poor outcome(43).

A retrospective study done in Indonesia with foot problems in 2017 showed that foot problems accounted for 16.2% of total diabetic admission. All patients had type 2 diabetes with no gender predominance. The mean age was 54.3 ± 8.6 years and diabetes control was very poor. Before admission, the ulcers had already developed for 4.7 ± 2.9 weeks; however, the majority of patients were unaware of the preceding causes. Ulcers were neuropathic in 42.2% of cases, neuro ischemic in 29.9% and pure ischemic at lesser percentage. More than 70% of ulcers were in Wagner grade≥3 with infection event in nearly all patients. The most common isolates from culture were Gram negative bacteria(44).

According to the study done by Lipsky etal(2010) in Singapore, the only culture isolate with a significantly increased prevalence was methicillin-resistant Staphylococcus aureus (MRSA); but Significant independent risk factors associated with higher mortality rates included having a polymicrobial culture with Pseudomonas aeruginosa , a mono microbial culture with other gram-negatives, greater illness severity and being transferred from another hospital(24). Another study done in singapore by Nather A et al (2008) showed that pathogens such as methicillin-resistant Staphylococcus aureus (MRSA) and Staphylococcus aereus are significant predictor factors for limb loss(32). On contrary, the study done in Thialand in 2014 showed that Gram-negative bacilli were more prevalent (58.8%) than were gram-positive cocci (41.2%). The most commonly isolated organism was Escherichia coli (18.7%), followed by Pseudomonas spp. (12.6%) and Staphylococcus aureus(11.8%). Mixed organisms were found in 33.6% of the DFUs and were most prevalently a combination of gram-negative organisms(28).

A prospective 12-Yr Follow-Up Study conducted in Pima Indians in Lower Extremity Amputations in NIDDM among diabetic subjects found that the incidence rate of first lower-extremity amputations was higher in men than in women. Rates increased significantly with increasing duration of diabetes. Presence of media arterial calcification, retinopathy, or

nephropathy; absence of patellar tendon reflexes; impaired great toe vibration-perception threshold; and degree of fasting and 2-h post load hyperglycemia were significant risk factors for amputations. Serum cholesterol concentration, blood pressure, age, and absence of Achilles tendon reflexes were not predictive of amputations(45).

According to the study conducted by Hennis in a Caribbean Population of Black African descent, women had higher amputation rates than those reported in the Global Lower Extremity Amputation Study, apart from the U.S. Navajo population. Independent risk factors for all diabetes-related LEAs were poor footwear, elevated HbA1c , peripheral neuropathy, and peripheral vascular disease(46).But the study conducted in Switzerland found that wagner grade>=4,presence of fever, increased creatinine level and prior hospitalization were associated outcomes of diabetic foot ulcer(22)

A descriptive, cross sectional, hospital-based study done by Almobarak et al(2017) in Khartoum, Sudan Among different metabolic variants like hypertension, albuminuria, retinopathy, neuropathy, HbA1c, cholesterol, high density lipoprotein (HDL), low density lipoprotein (LDL) and triglyceride, only duration of diabetes was significantly associated with DFU. Living with diabetes for more than 10 years is associated with an increase in the diabetic foot probability by 3.16 folds. The adjusted effect for living with diabetes for more than 20 years on the diabetic foot complication probability is an increase by 1.73 folds. However, living with diabetes for more than 5 years had a non-significant adjusted effect on diabetic foot probability(26).

The study conducted in Gondar reported that rural residence, type 2 diabetes mellitus, overweight, obesity, poor foot self-care practice, and neuropathy were factors associated with diabetic foot ulcer(35). Additionally a cross sectional study was conducted on 216 diabetic clients attending Arbaminch hospital and showed that rural residence, absence of co-morbidity, mean arterial blood pressure greater than 90, duration of diabetes for more than 10years, are independent factor associated with DFU(33).

2.3. Outcomes of diabetes foot ulcer

Diabetic foot ulcer and amputation continue to cause considerable morbidity among persons with diabetes foot ulcer has been recognized as an important antecedent of lower extremity amputation in multiple studies(5). Amputation for non-traumatic causes is a frequent outcome in the diabetic foot. The life-time risk for American diabetics was estimated at 5% to 15%, 15 times that of the non-diabetic population(42).

According to the study done by Lipsky BA etal in UK, Outcomes of diabetic foot infections like mortality and amputations have greatly improved with appropriate antibiotic therapy. Compared to outcomes Each reported that the amputation rate dropped from about 70% to about 30% and the mortality rates from about 9% to about 4%(47). Another study done byWong ML and Coppini DV in UK showed that the antibiotics commonly used were cefradine,clindamycin,and combinations of clindamycin + ciprofloxacin or amoxicillin + flucloxacillin. In the remaining 30 uninfected wounds (35%), no antibiotics were prescribed(48). But the study done in Sweden showed that metronidazole (56%) and ciprofloxacin (54%) were the most commonly used, followed by flucloxacillin(40%) and cefadroxil (31%). Clindamycin was used who had a deep soft tissue infection only or a combined in 42 patients (19%)(49).

A prospective observational study was conducted by Formosa C in 2016 in university of malta showed 77% of ulcers had healed/resolved completely and 23% results in lower limb amputations over maximum period of one year. In the healed ulcer group 72.4% were neuropathic, 23.7% were neuroischaemic and 3.9% were ischemic. Amongst the amputated group 65.2% were neuropathic, 30.4% were neuroischaemic and 4.3% were ischaemic. The mean duration between estimated ulcer onset and first assessment was 12.68 ± 2.84 for the resolved group and 18.26 ± 6.87 for the amputated group(19).

A prospective study done by Lavery L A etal(2006) showed that, 151 (9.1%) patients developed 199 foot infections, all but one involving a wound or penetrating injury. Most patients had infections involving only the soft tissue, but 19.9% had bone culture–proven osteomyelitis. For those who developed a foot infection, compared with those who did not, the risk of hospitalization was 55.7 times greater and the risk of amputation was 154.5 times greater. Foot wounds preceded all but one infection. Independent risk factors for foot infection from a multivariate analysis included wounds that penetrated to bone , wounds with a duration 30 days (4.7), recurrent wounds

(2.4), wounds with a traumatic etiology (2.4), and presence of peripheral vascular disease (1.9)(25).

Another study done by Limin Jia etal(2017) in Australia reported that foot infection developed in 342 patients for an overall incidence of 40.1%; 32.4% incidence in DFUs healed <3 months, 55.9% in DFUs healed between 3±12 months. Independent risk factors for developing infection were: DFUs healed between 3±12 months, deep DFUs, peripheral neuropathy, previous DFU history, foot deformity, female gender and years of age (9).

Additionally cohort study in14 centers in Europe showed that the cumulative incidence of diabetes-associated lower limb amputations was 18.2% (19.8% men; 15.5% women) for type 2 diabetes patients over the study period of 5 years. Twice as many amputations were performed on patients above the age of 70 years than on those younger than 50 years, reflecting the distinct age dependence(40). Similarly the study conducted by Cawich etal(2014) reported that, approximately 0.75% annual risk for patients with diabetes to develop foot infections. The mean duration of hospitalization was 22.5 days. Sixteen patients (3.6%) were treated conservatively without an operative procedure and 430 (96.4%) required some form of operative intervention. There were 885 debridement, 193 minor amputations and 60 major amputations (50).

According to The study conducted by oyibo etal(2001) on both diabetic foot clinics (Manchester and San Antonio),The majority of ulcers were neuropathic (67.0%) and present on the forefoot (77.8%) with a median area of 1.5 cm^2. Amputations were performed for 15% of ulcers; 65% healed; 16% remained unhealed and 4% of patients died. The median time to healing was 10 weeks. Ulcer area at presentation was greater in the amputation group compared to healed ulcers (3.9 vs. 1.2 cm^2) and predicted healing. Patient's age, sex, duration/type of diabetes, and ulcer site had no effect on outcome. Foot ulcers were located on the forefoot, mid-foot and hind-foot of 77.8, 11.9 and 10.3% of patients, respectively. There was no difference in median time taken for ulcers to heal or amputation amongst the different sites of ulceration(51).

On the other hand the study undertaken in a Mediterranean country (Central Greece) by Spanos et al(2017), from a total of 103diabetic patients with ulcer (mean age 69.7+9.6 years, 77% male) were treated and followed up for 12 months. Ulcer healing, minor amputation, and major amputation rates were 41%, 41%, and 18%, respectively, while the mortality rate was 18%(12).

Another study conducted in Thialand by Thewjitcharoen Y etal showed that,Major amputations, Complete healing, and mortality were 4.2%,82.1% and1.1%respectively of the patients and peripheral vascular diseanse (PVD)and DFU of the heel was a predictive factor. The distribution of the ulcers according to the Wagner classification was as follows: Wagner 1 (22.5%); Wagner 2 (32.8%); Wagner 3 (32.1%); Wagner 4 (11.8%); and Wagner 5 (0.8%) (28).

A prospective study was conducted by salaam etal at Pakistan in 2017 on patients with diabetic foot ulceration attending the Madinah Teaching Hospital indicates that Regarding the outcome, 68% healed completely, 27.7% underwent amputation, and 4.5% died during this period(43).
But according to the study done in National University Hospital (NUH) in Singapore (2007), Surgery was performed in 74.8% of patients and major amputation in 27.2% of patients (below-knee in 20.3% and above-knee in 6.9% (32).

According to the study done in jamaica by Ferguson etal(2013),from Participants included 143 women and 45 men (mean age 56 years; mean diabetes duration 16 years). The prevalence of amputations was 8.5% and was higher among men (22.2%) compared to women. Prevalence of current ulcers and current foot infections was 4.3% and 3.7%, respectively. Overall, 12% of patients had at least one of these foot complications. Foot complications were more prevalent among men, patients with high blood pressure (BP ≥ 130/80mmHg) or peripheral neuropathy. And factors associated with foot complications were: neuropathy, high BP and diabetes duration(52).

A prospective cohort study of newly hospitalized, adult diabetes done by Gulam-Abbas Z et al.(2002) in Tanzania showed that from patients who had foot ulcers, 30 (33%) were selected for surgery (minor and major amputations); the rest were managed conservatively. Patients who underwent surgery were more likely than those who did not to have gangrene or neuropathy. On stratification by severity of ulcers, patients with Wagner score ≥4 were significantly more likely than those < 4 to have neuro ischaemic foot lesions or delayed presentation to hospital. The overall mortality rates for amputees and non-amputees were similar (29%); the highest in-patient mortality rate (54%) was observed among patients with severe (Wagner grade ≥4) ulcers who did not undergo surgery(21). Another study was obtained in Kenya in that, Wagner stage 2 ulcers were the commonest (49.4%) but stage 4 ulcers had their highest neuropathic score (7.8/10) and longest duration (23.6weeks). Aerobic infective pathogens were isolated from 73.2% of the ulcers. The risk factors of diabetic foot ulcers in the study were poor glycaemic control, diastolic

hypertension, dyslipidaemia, infection and poor self-care but higher body mass index was not predictors(11).

According to A hospital based cross-sectional study conducted by Mamo T etal in 2015 at Tikur Anbessa Specialized Hospital ,Among the participants, only 9 (4.5%) had foot examination in the last 5 years. Thirty one (15.5%) participants had history of previous ulcer, 1 (0.5%) had history of amputation, 11 (5.5%) had deformity of shape and structure of the foot(53).

2.4. Conceptual frame works

Patient related factors

- o Sex
- o Age
- o Residence
- o Income
- o Occupation
- o Educational status
- o BMI
- o Alcohol
- o Cigarette

Disease related factors

- o Retinopathy
- o Nephropathy
- o Neuropathy
- o Peripheral vascular disease
- o Coronary Heart disease
- o FBS
- o Causative microorganism
- o Duration of DM
- o Site and Size of ulcer
- o Grade of ulcer
- o co-morbidity
- o previous ulceration

Amputation

Drug related factors
- o Dose
- o Frequency
- o Duration
- o Selection

Figure1: Conceptual framework showing causal pathway associated with outcomes of diabetic foot ulcer in NRH,west Ethiopia from March 15- June 15, 2018.

3. OBJECTIVES

3.1. General objective

✓ To assess the incidence, risk factor and outcomes of diabetic foot ulcer in diabetes mellitus patients admitted to NRH

3.2. Specific objectives

✓ To determine the incidence of diabetic foot ulcer
✓ To assess the outcomes of diabetic foot ulcer
✓ To identify factors affecting outcome of diabetic foot ulcer
✓ To identify the causative microorganism for diabetic foot ulcer
✓ To assess the appropriateness of antibiotics prescribed

4. METHODS AND MATERIALS

4.1. Study area and period

A study was conducted at NRH from March 15 to June 15, 2018. The hospital is located in Nekemte town, which is located 330 km to the west of Addis Ababa, the capital city of Ethiopia. The hospital is a referral hospital and gives health service for more than 10, 000,000 people living in west Ethiopia. There were about 2420 diabetic patients who have been following diabetic clinic annually. This hospital serves as a referral hospital, a teaching hospital, and research center, and the hospital has one diabetic follow-up clinic.

4.2. Study Design
A general prospective cohort study was conducted.

4.3. Population
4.3.1. Source Population

All diabetes mellitus patients who were admitted to Nekemte referral hospital

4.3.2 Study Population.

All diabetes mellitus patients who had diabetic foot ulcer admitted to NRH during the study period and fulfilling the inclusion criteria:

4.4. Eligibility Criteria
4.4.1. Inclusion criteria

✓ Patients ≥18 years who were be diagnosed as diabetes and admitted to the NRH.
✓ Diabetic patients who had diabetic foot ulcer and admitted to the ward.
✓ Patients who were willing to participate in the study.
✓ Diabetes mellitus patients who had any visible foot lesions.

4.4.2. Exclusion criteria

✓ Diabetic patients who had traumatic ulcer due to other than normal cause like car accident, burn and any injury to sharpened materials.
✓ Diabetic patients who were severely ill and unable to communicate throughout the study period.

4.5. Study Variables

4.5.1. Dependent Variables

- Amputation

4.5.2. Independent variable

- Socio demographic variables: age, sex, marital status, educational status, area of residence, body mass index and average monthly income
- Behavioral factors: smoking cigarette, alcohol consumption
- Clinical factors: FBS, co morbidity, history of ulceration, category of diabetes, diabetic complication, duration of diabetes mellitus, ulcer size, grade of foot ulcer, site of foot ulcer and appropriateness of antibiotics.
- Drug related factors: Dose, frequency, duration and selection.

4.6. Sample Size and Sampling Technique

4.6.1. Sample Size

Single population proportion formula was used to calculate the required sample size considering the following assumptions: n is required sample size, p is Incidence of of Amputation which was 29%, the rate found at Muhimbili National Hospital, Dar es Salaam, Tanzania(21). Z is standardized normal distribution value at the 95% CI: 1.96 and d is the margin of error of 5%.

$$n = \frac{(Z\alpha/2)^2 \, p \, (1-p)}{d^2}$$

z= 1.96
P= 29% (0.29)
d= 0.05

$$n = \frac{(1.96)^2 \, (0.29) \, (0.71)}{(0.05)^2} = 316$$

The expected number of population in the study period (N), based on the average number of patients coming to the hospital was 156. The corrected sample size, using the following correction formula was 104. A 10% contingency yielded a final sample size of 115

$$\text{Corrected sample size} = \frac{n \times N}{n + N}$$

$= \dfrac{(316)\,(156)}{(316 + 156)}\quad = 104$

4.6.2. Sampling Technique

Study participants were selected by using convenience or haphazard sampling technique.

4.7. Outcome endpoints

4.7.1. Primary outcomes

+ Incidence of amputation

4.7.2. Secondary outcomes

+ Pattern of infection with micro-organisms

Outcome measures

The Wagner classification of diabetic foot ulcer was used to assess the severity of foot ulcers.

Extent (i.e. size) was determined by multiplying the largest by the second largest diameter perpendicular to the first.

The etiology of diabetic foot ulcer was identified by using gram stains. Amputation and healing status were measured during the study using a checklist and assessed by close follow up of the patient through telephone interview of the patient/ caregiver/ proxy on weekly basis.

4.8. Data collection procedures

4.8.1. Data collection instrument

Data was collected using questionnaire which was developed after reviewing different literature

4.8.2. Data collection process and management

One medical doctor, one nurses and one pharmacist were recruited as data collector; one medical doctor was assigned to supervise the data collection process. The supervisor and principal investigator were closely followed the data collection process at the spot. Data was collected by using a questionnaire. Data collectors collect all relevant information on presence/absence of co-morbidity and diabetic complications from the case records and interview. They record as presence of co-morbidity and diabetic complications when the patient was previously diagnosed with co-morbidity and any diabetic complication and receiving medication for treating those diseases. Appropriateness of antibiotics was identified based on standard guidelines of IDSA for diagnosis and treatment of diabetic foot infection which is based on the most likely coverage of antibiotics for treatments of diabetic foot infection for identified gram stain results and their correct dosage regimens. For assessing the appropriateness of antibiotics prescribed two clinical pharmacists were involved. A pus swab was obained from the ulcers prior to any ulcer cleaning and avoiding other contamination. The samples were delivered to the laboratory immediately and a thin smear was prepared on Grease or oil free slides.

4.9. Operational definitions

Diabetic Foot ulcer: The foot of a diabetic patient that has the potential risk of pathologic consequences, including infection, ulceration, and/or destruction of deep tissues

Healing: The complete closure of the ulcer with skin intact (complete epithelialization) and without, drainage or sinus formation

Amputation: The complete or partial removal of a limb or body appendage by surgical or traumatic means.

Minor amputation: Amputation involving below ankle

Major amputation: Amputation of legs which involves above the ankle

Grades of diabetics foot ulcer: For purpose of this study we used Wagner system for classification of diabetic foot ulcer which uses 6 wound grades (scored 0 to 5) to assess ulcer depth(54).

- ✓ **Grade 0 diabetic foot ulcer:** No ulcer, but the foot is at risk for ulceration
- ✓ **Grade 1 diabetic foot ulcer:** Superficial ulceration
- ✓ **Grade 2 diabetic foot ulcer:** Ulcer with deep infection, but without involvement of the bone

✓ **Grade 3 diabetic foot ulcer:** Ulcer with osteomyelitis.

✓ **Grade 4 diabetic foot ulcer:** Presence of localized gangrene on the foot.

✓ **Grade 5 diabetic foot ulcer:** Presence of gangrene of the whole foot.

Neuropathy: It was diagnosed if the patient had at least one manifestation from the following list of manifestations: burning pain, vibration from the skin, gradual numbness, freezing, extreme sensitive to touch, muscle weakness, and lack of coordination.

Peripheral Vascular Disease: It is an arterial and vein disease at the peripheral region, which often occurs in diabetic patient.

Glycemic control: for purpose of this study we categorized patients based on American Diabetic Association (ADA) recommendation in to two groups:

☐ **Good glycemic control:** Fasting blood glucose of 70-130 mg/dl.

☐ **Poor glycemic control:** Fasting blood glucose of <70 mg/dl and >130mg/dl

Appropriate drug: Antibiotics prescribed in accordance with infectious diseases society of America (IDSA) guideline for treatment of diabetic foot infection recommendation based on gram stains and dosage regimens.

In appropriate drug: Antibiotics prescribed inconsistent with infectious diseases society of America (IDSA) guideline for treatment of diabetic foot infection recommendation based on gram stains and dosage regimens.

4.10. Data processing and analysis

The data was entered in to computer using EPI-manager 4.0.2 software. Data checking and cleaning was done by principal investigator on daily basis during collection before actual analysis. Analysis was done using statistical software for social sciences (SPSS) 24. Descriptive data was generated and placed in terms of frequency and percentage. Results were expressed as proportions and as means ± Standard Deviations (SD). Multivariate logistic regression was used to analyze the associations between dependent variable and independent variables by using crude odds ratio (COR) and adjusted odds ratio (AOR) at 95% confidence level. Each variable was evaluated independently in a bivariate analysis and association was determined using cross tabulation and COR with 95% CI. All variables associated with the amputation at a probability level of less than or equal to 0.25 on the bivariate analysis were entered into a

multivariate logistic regression analysis to control for confounders. A p-value of less than 0.05 is considered statistically significant.

4.11. Data quality assurance

The completeness of the data to be collected from the patient was checked by the principal investigator in order to maintain consistency. The data collectors as well as the supervisor were given two day training on the overall data collection procedure. Five percent of the sample was pre-tested to check acceptability and consistency of data collection tool two weeks before the actual data collection.

4.12. Ethical consideration

Ethical clearance was obtained from the ethics review board of Jimma University. Permission was obtained from medical director of the NRH to access diabetes patients and conducts the study. The benefit and risks of the study was explained to each participant included in the study and written consent were obtained from each patient involved in the study. To ensure confidentiality, name and other identifiers of patients and health care professionals were not recorded on the data collection tools.

5. RESULT

5.1. Socio-demographic characteristics.

Over the study period, 115 diabetes foot ulcer patients were admitted to the NRH medical service; of these patients, 64(55.65%) were males. About 26(22.61%) of them were in the age range of 58-67, while mean age of participants was 44.44 ±14.69. About 34(29.57%) of the diabetic foot ulcer were overweight and 16(13.91%) were obese while the mean body mass index (BMI) was 24.94 ±3.69kg/m2. Eighty (69.57%) were married. Regarding their educational status, 40(34.78%) was above secondary. Fifty-eight (50.43%) participants came from urban area as shown in table1.

Table 1: Socio-demographic characteristics of respondents in Nekemte referral hospital, west Ethiopia,2018.

Variables		Frequency	Percent
Sex	Male	64	55.65
	Female	51	44.35
Age	18-27	16	13.91
	28-37	14	12.17
	38-47	15	13.04
	48-57	24	20.87
	58-67	26	22.61
	68-77	20	17.39
Marital Status	Married	80	69.57
	Single	21	18.26
	Window	8	6.96
	Divorced	6	5.22
Residence	Urban	58	50.43
	Rural	57	49.57
Occupation	Farmer	31	26.96
	Government employee	19	16.52
	Private employee	17	14.78
	Merchant/trade	17	14.78
	House wife	13	11.30
	Daily labor	8	7.00
	NGO	6	5.22
	Student	4	3.48

Monthly Income(Ethiopian birr)	<685	30	26.09
	685-1370	36	31.30
	1371-2740	25	21.74
	>2740	24	20.87
Educational level	Illiterate	24	20.87
	Primary school	29	25.22
	Secondary school	22	19.13
	Above Secondary school	40	34.78
BMI	<24.5	65	56.52
	24.5-29.5	34	29.57
	>29.5	16	13.91

NGO: Nongovernmental organization

5.2. Behavioral characteristics. Thirty (26.09%) of the study participants were smokers currently and 38 (33.04%) study participants were currently alcohol drinkers. Previously about 39 (33.91%) of the diabetic foot ulcer patients were drink alcohol and about 30 (26.09%) of the diabetic foot ulcer patients were smokers as described in table 2.

Table 2: life style approaches of diabetic foot ulcer patients attending the Nekemte referral hospital,west Ethiopia, 2018.

Variables		Frequency	Percent
Drinking Alcohol previously	No	76	66.09
	Yes	39	33.91
Drinking Alcohol Currently	No	77	66.96
	Yes	38	33.04
Smoking cigarette previously	No	85	73.91
	Yes	30	26.09
Smoking cigarette Currently	No	85	73.91
	Yes	30	26.09

5.3. Clinical characteristics. About Fifty-eight (50.43%) of the participants had chronic health problems or co-morbidity with other diseases, and among these, 56(48.69%) participants were

hypertensive. About 56(48.69%) of the diabetic foot ulcer had diabetic complication, among these, 55 (47.83%) study participants had retinopathy as described in table 3.

Table 3: Presence of co-morbidities and diabetic complications among diabetic foot ulcer patients admitted to the Nekemte referral hospital, west Ethiopia, 2018.

Variables		Frequency	Percent
Retinopathy	Yes	55	47.83
	No	60	52.17
Neuropathy	Yes	52	45.22
	No	63	54.78
Coronary heart disease	Yes	27	23.48
	No	88	76.52
Nephropathy	Yes	46	40.00
	No	69	60.00
Peripheral vascular disease	Yes	42	36.52
	No	73	63.48
Hypertension	Yes	56	48.69
	No	59	51.30
Ischemic heart disease	Yes	41	35.65
	No	74	64.35
Dyslipidemia	Yes	40	34.78
	No	75	65.22

Among the total 115 study participants, 61 (53.04%) of them had type 2 diabetes mellitus. The mean fasting blood glucose level among diabetic patients with foot ulcer was 147.93mg/dl ±45.03.Twenty six participants (22.61%) were diabetic for more than 10 years. Fifty three (46.09%) participants had poorly controlled blood glucose levels. Forty two (54.55%) of microorganism isolated was gram positive. Ulcer size was greater than 5cm^2 in the 23(20.00%) of the patients as shown in table 4.

Table 4: Clinical characteristic of diabetic foot ulcer patients in diabetes mellitus patients admitted to Nekemte Referral Hospital, west Ethiopia, 2018.

Variables		Frequency	Percent
Types of DM	Type 2 DM	61	53.04
	Type 1 DM	54	46.96
Duration of Diabetic Mellitus	<5years	42	36.52
	5-10years	47	40. 87
	>10 years	26	22.61
Ulcer which develop Infection	Yes	77	66.96
	No	38	33.04
Gram stain result	Gram positive	42	54.55
	Gram negative	20	25.97
	Poly microbial	15	19.48
	No bacteria	38	33.04
Glycemic Control	Good control	62	53.91
	Poor control	53	46.09
Size of Ulcer	<1cm2	66	57.39
	1-5cm2	26	22.61
	>5cm2	23	20.00

DM: Diabetes mellitus

5.4. Incidence of diabetic foot ulcer.

Over the study period, 644 diabetes patients were admitted to the NRH medical service; of these, 115(17.86%) had foot ulcers. After the gram stain was performed, about 77(66.96%) of the patients with foot ulcer developed infection and 38(33.04%) of the patients does not developed foot infection as described in figure 2.
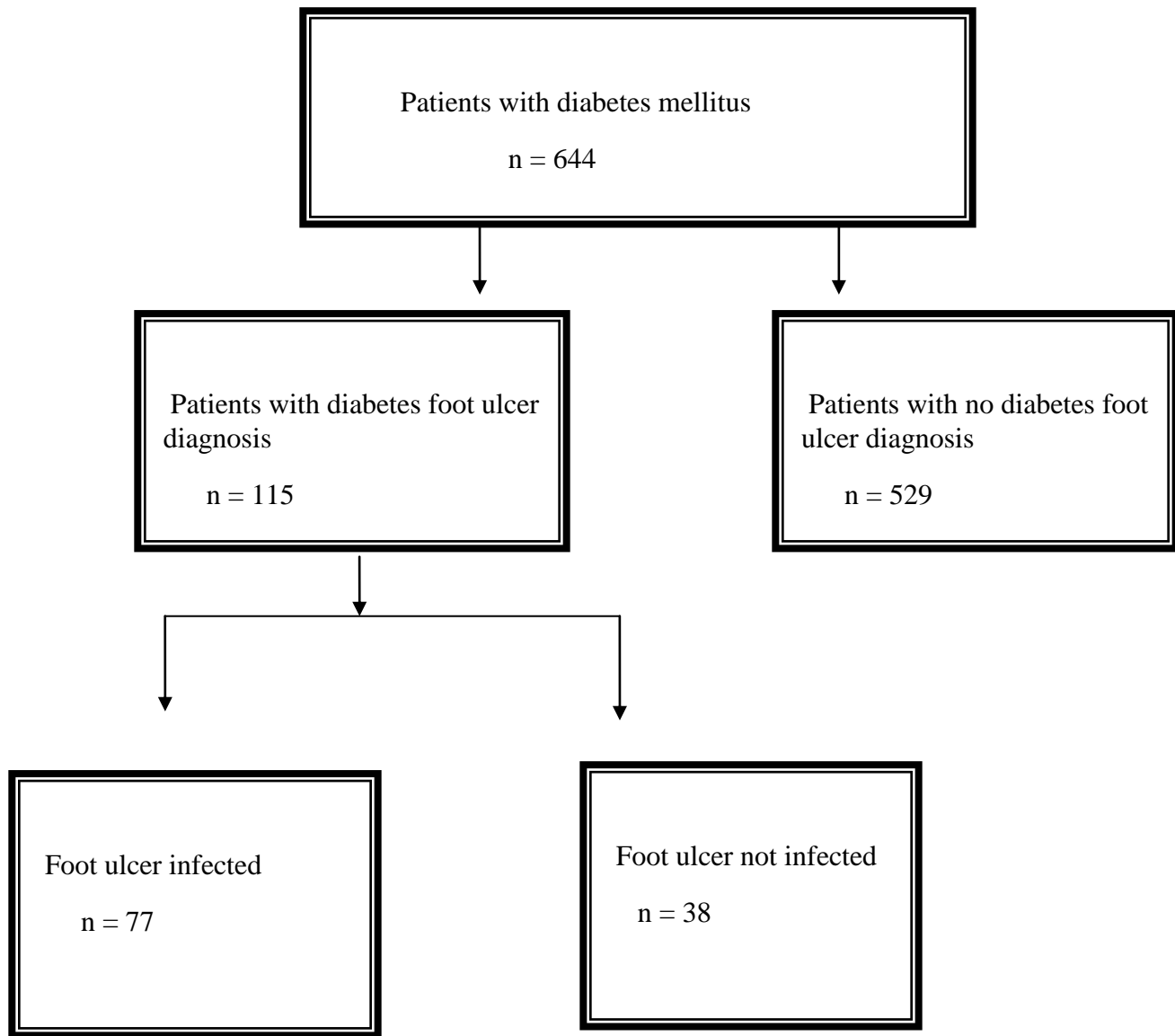
Figure2: Flow chart for patients enrolled in the study in Nekemte referral hospital,west Ethiopia,2018.

Eight (6.96%) of patients was in grade four diabetic foot ulcer. From Wagner grade four diabetic foot ulcer patients about three (37.50%) of them were males and five (62.50%) of them were females as described in figure 3.

Grades of diabetic foot ulcer
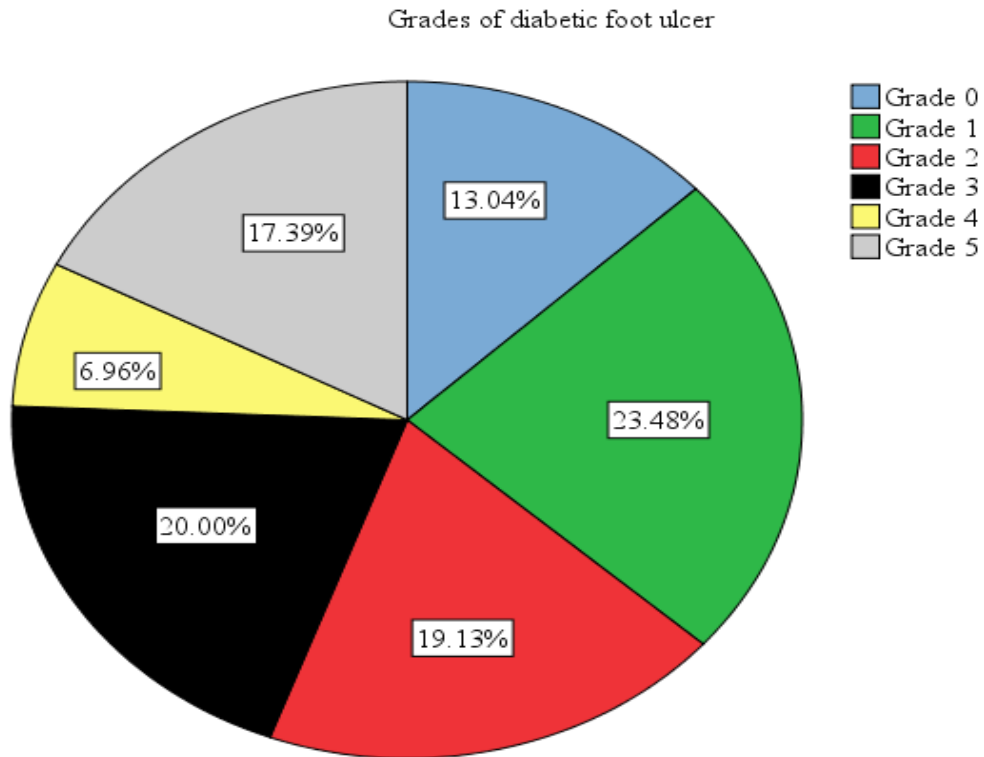
Figure3: Wagner classification of diabetic foot ulcers patients in Nekemte referral hospital, west Ethiopia, 2018.

From the diabetes mellitus who had developed diabetic foot ulcer, about 31(26.96%) of ulcer were located on dorsal/interdigital toes as shown in figure 4. About 49(42.61%) of the diabetic foot ulcer patients had previous history of ulcer of any location, whereas 66(57.39%) of the patients did not have previous history of ulcer.
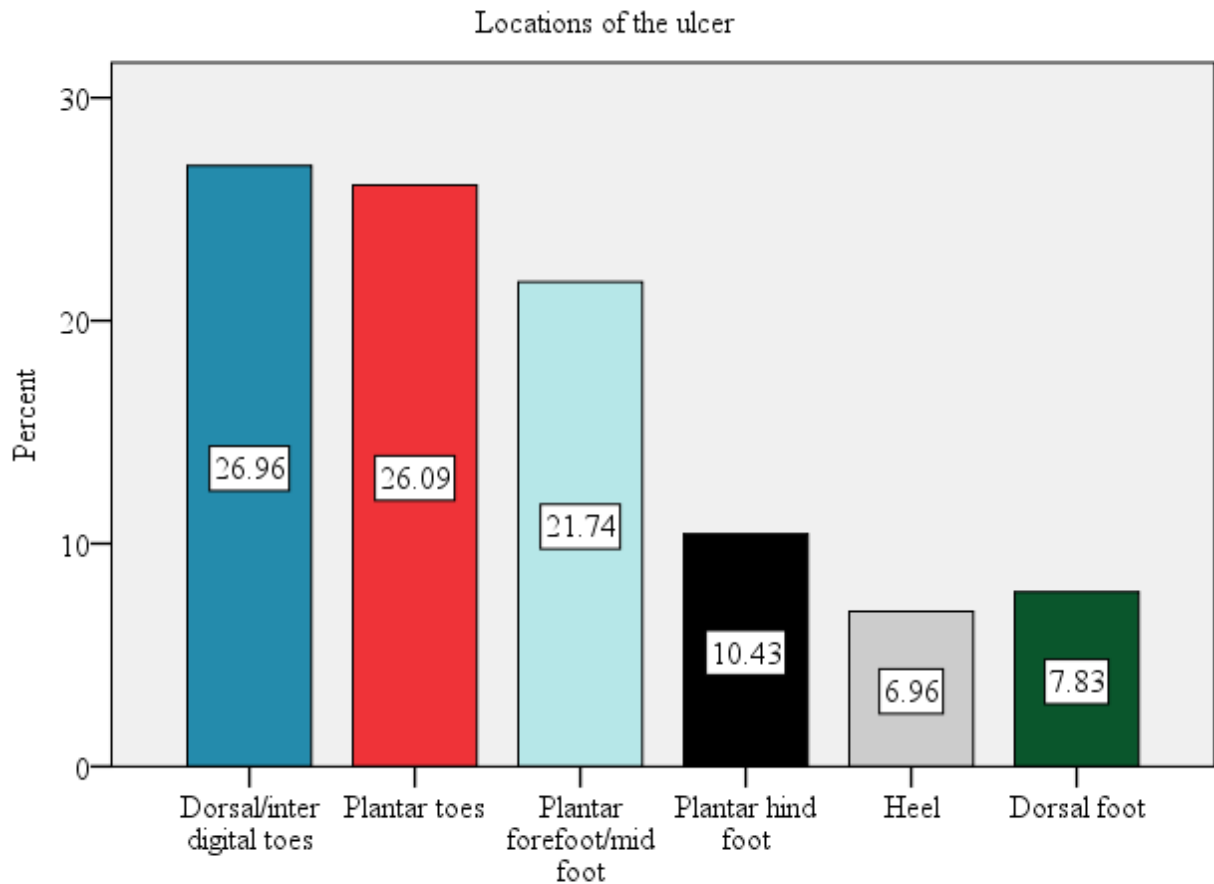
Figure 4: Location of diabetic foot ulcers patients in Nekemte Referral Hospital, west Ethiopia, 2018.

5.5. Risk factors and outcomes of Diabetic Foot Ulcer.

From the patients who developed diabetic foot ulcers ,80(69.57%) were healed and 35(30.43%) of them were amputated. From amputated diabetic foot ulcer patients, 20(57.14%) and 15(42.86%) were undergone minor and major amputation, respectively. From the patients who undergone major amputation, 9(60%) of them were amputated below knee and 6(40%) of them were amputated above knee.

Grade of diabetic foot ulcer[AOR = 1.7; 95% CI: 1.604, 4.789],inappropriate antibiotics[AOR = 2.526; 95% CI: 1.767, 8.314], overweight [AOR = 2.767; 95% CI: 1.827, 9.252], obesity [AOR = 3.020; 95% CI: 2.556, 16.397],blood glucose control[AOR = 2.592; 95% CI: 1.937, 7.168], and

neuropathy [AOR = 1.565; 95% CI: 1.508, 4.822] were found to be a predictors of amputation in multivariable logistic regression analysis.

Those diabetic patients who had Grade ≥4 diabetic foot ulcer were1.7 times more likely to be amputated than those Grade < 4 diabetic foot ulcer [AOR = 1.7; 95% CI: 1.604, 4.789]. Patients with diabetic foot ulcer who had taken inappropriate antibiotics prescription were 2.5 times more likely to be amputated than those taken appropriate antibiotics[AOR = 2.526; 95% CI: 1.767, 8.314]. Overweight diabetic patients were 2.8 times more likely to undergone amputation as compared to diabetic patients with normal weight [AOR = 2.767; 95% CI: 1.827, 9.252]. Obese diabetic patients were 3.02 times more likely to undergone amputation as compared to diabetic patients with normal body mass index [AOR = 3.02; 95% CI: 2.556, 16.397]. Those with diabetic foot ulcer who had poor blood glucose control were 2.6 more likely to undergone amputation as compared to diabetic foot ulcer patients who had good controlled blood glucose level [AOR = 2.592; 95% CI: 1.937, 7.168]. Furthermore, those diabetic foot ulcer patients who had neuropathy were 1.6 times more likely to undergone amputation as compared to those diabetic foot ulcer patients without neuropathy [AOR = 1.565; 95% CI: 1.508, 4.822] as described in table 5.

Table 5: Multivariate logistic regression analysis result of factors associated with amputation among diabetic foot ulcer patients admitted to NRH, west Ethiopia, 2018.

Variables		Amputation		COR(95%CI)	P value	AOR(95%CI)	P value
		Amputated N (%)	Not Amputated N (%)				
Residence	Rural	17(29.82)	40(70.18)	1.720[0.392,7.554]	0.247	1.547[0.364,6.579]	0.416
	Urban	18(31.03)	40(68.97)	1		1	
Sex	Male	19(29.69)	45(70.31)	1.639[0.169,2.410]	0.158	1.660[0.178,2.451]	0.221
	Female	16(31.37)	35(68.63)	1		1	
Drinking Alcohol Currently	Yes	12(31.58)	26(68.42)	1.516[0.107,2.485]	0.240	1.594[0.128,2.761]	0.693
	No	23(29.87)	54(70.13)	1		1	
Smoking cigarette currently	Yes	12(40)	18(60)	1.426[0.362,5.622]	0.188	1.359[0.346,5.345]	0.222
	No	23(27.06)	62(72.94)	1		1	
Previous history of Ulcer	Yes	16(32.65)	33(67.35)	1.656[0.175,2.462]	0.235	1.674[0.182,2.499]	0.317
	No	19(28.79)	47(71.21)	1		1	
Types of DM	Type 2 DM	23(37.70)	38(62.30)	1.483[0.117,2.001]	0.074	1.431[0.108,1.715]	0.057
	Type 1 DM	12(22.22)	42(77.78)	1		1	
Hypertension	Yes	16(28.57)	40(71.43)	2.951[0.216,4.186]	0.167	1.109[0.267,4.604]	0.509
	No	19(32.20)	40(67.80)	1		1	
Ischemic Heart Disease	Yes	14(34.15)	27(65.85)	1.184[0.298,4.708]	0.152	1.133[0.345,5.156]	0.361
	No	21(28.38)	53(71.62)	1		1	
Dylipidemia	Yes	13(32.50)	27(67.50)	2.645[0.141,2.937]	0.157	1.766[0.185,3.170]	0.629
	No	22(29.33)	53(70.67)	1		1	

Retinopathy	Yes	17(30.90)	38(69.10)	1.345[0.092,1.386]	0.113	1.358[0.097,1.319]	0.052
	No	18(30)	42(70)	1		1	
Neuropathy	Yes	20(38.46)	32(61.54)	2.658[1.561,12.602]	0.029	1.565[1.508,4.822]	0.004
	No	15(23.81)	48(76.19)	1		1	
Coronary Heart Disease	Yes	9(33.33)	18(66.67)	1.176[0.035,2.891]	0.078	1.179[0.135,1.915]	0.179
	No	26(29.55)	62(70.45)	1		1	
Nephropathy	Yes	18(39.13)	28(60.87)	1.645[0.148,2.814]	0.100	1.227[0.173,3.013]	0.604
	No	17(24.64)	52(75.36)	1		1	
Peripheral Vascular Disease	Yes	13(30.95)	29(69.05)	1.243[0.283,5.452]	0.177	1.440[0.343,6.048]	0.864
	No	22(30.14)	51(69.86)	1		1	
Body mass index	<24.5	15(23.08)	50(76.92)	1	0.073	1	0.122
	24.5-29.5	12(35.29)	22(64.71)	7.054[1.410,35.296]	0.032	2.767[1.827,9.252]	0.021
	>29.5	8(50)	8(50)	7.729[2.828,72.134]	0.017	3.020[2.556,16.397]	0.019
Glycemic Control	Poor Control	21(39.62)	32(60.38)	2.779[1.755,10.231]	0.048	2.592[1.937,7.168]	0.023
	Good Control	14(22.58)	48(77.42)	1		1	
Duration of Diabetic Mellitus	<5years	14(33.33)	28(66.67)	1	0.184	1	0.174
	5-10years	14(29.79)	33(70.21)	2.273[0.299,5.418]	0.071	1.171[0.279,4.910]	0.061
	>10years	7(26.92)	19(73.08)	1.672[0.112,4.011]	0.157	1.596[0.103,3.439]	0.558
Size of Ulcer	<1cm2	16(24.24)	50(75.76)	1	0.215	1	0.109
	1-5cm2	11(42.31)	15(57.69)	1.515[0.109,2.431]	0.190	1.608[0.139,2.665]	0.253
	>5cm2	8(34.78)	15(65.22)	1.881[0.154,5.027]	0.132	1.894[0.158,5.054]	0.130
Appropriateness of Antibiotics	Inappropriate	21(53.85)	18(46.15)	6.192[1.108,34.614]	0.012	2.526[1.767,8.314]	0.017
	Appropriate	14(36.84)	24(63.16)	1		1	

Grade of Ulcer	Grade < 4	19(21.84)	68(78.16)	1	0.001	1	0.005
	Grade ≥ 4	16(57.14)	12(42.86)	3.209[1.790,13.033]		1.70[1.604,4.789]	

From the total diabetics foot ulcer patients, 77(66.96%) of ulcer progressed to infection and 38(33.04%) of them did not. From the patients who developed infection, gram positive organism is identified in 42(54.55%), gram negative identified in 20(25.97%) and poly microbial were seen in 15(19.48%).

From total number of the patients, about 9(7.83%) of the patients who had diabetic foot ulcer on Dorsal/inter digital toes were amputated and about 4(3.48%) of the patients who had ulcer on heel were amputated as described in table 6.

Table 6: The location of Diabetic foot ulcer patients admitted to Nekemte referral hospital, west Ethiopia, 2018.

Location of ulcer	Amputation		
	Yes (%)	No (%)	Total (%)
Dorsal/inter digital toes	9(7.83)	22(19.13)	31(26.96)
Plantar forefoot/mid foot	8(6.96)	17(14.78)	25(21.74)
Plantar toes	6(5.22)	24(20.87)	30(26.09)
Dorsal foot	5(4.35)	4(3.48)	9(7.83)
Heel	4(3.48)	4(3.48)	8(6.96)
Plantar hind foot	3(2.61)	9(7.83)	12(10.44)

5.6. Antibiotics prescribed to treat Diabetic Foot Ulcer.

Cloxacillin was the most commonly prescribed antibiotics for treating diabetic foot ulcer followed by Metronidazole and ceftriaxone as described in table 7.

In order to assess the appropriateness of antibiotics based on gram stain and dosage regimen of antibiotics it was required to review each antibiotic prescribed for diabetic foot ulcer patients. Then to say appropriate or inappropriate it was compared with standard guidelines of infectious diseases society of America(IDSA) for diagnosis and treatment of diabetic foot infection(55).

From the total patients given antibiotics about 38(49.35%) of them prescribed appropriately and 39(50.65%) were prescribed inappropriately.

Table 7: Most commonly prescribed individual antibiotics for treating diabetic foot ulcer in Nekemte referral hospital,west Ethiopia, 2018.

Antibiotics	Frequency	Percentage
Cloxacillin	56	34.15
Metronidazole	43	26.22
Ceftriaxone	33	20.12
Ampicillin	9	5.49
Chrompenicol	8	4.88
Gentamycin	5	3.05
Ceftazidime	4	2.44
Ciprofloxacillin	3	1.83
Vancomycin	2	1.22
Amoxacillin	1	0.61
Total	164	100

6. DISCUSSION

This study assessed burden, risk factor and outcomes of diabetic foot ulcer at NRH, western Ethiopia. The study found that the incidence of diabetic foot ulcers amongst diabetic patients at the *NRH* was 17.86%. The study in Taiwan, Singapore and Bangalore, India found the incidence of 2.9%,8.2% and 8%, respectively which were lower than our study(1, 31, 32). The differences might be due to variation in racial difference, differences in life style and socio-cultural variation of study participants. A study was comparable with the study done in Arbaminch and Gondar which found prevalence of 14.8% and 13.6%, respectively (33, 35).

The majority of the patients who developed diabetic foot ulcer were male (55.65%). This figure is similar with the study done in Nigeria, Arbaminch and Jimma which was 67.2% and 59.7% and 62.9%, respectively (29, 33, 34). The variation of DFU related to sex, might be reflection of variation in societal role between male and females in western Ethiopia, typically in the study area. Males spent most of their time outside homes doing jobs that need more energy compared to women. The increase in DFUs among diabetic patients, particularly in current study area, is worrying situation for individual families as males are the backbone and the sole earning members of the family, particularly in western Ethiopian population.

The mean age of the diabetic foot ulcer patient was 44.44±14.69 which is comparable with the study done in Jimma which found 44.4 (±15.6) years(34). However, the mean age of the patients were lower than the study done in Bangalore, India (55.97±11.6years), Indonesia (54.3 ± 8.6 years) and Central Greece (69.7+9.6 years)(1, 12, 44). This difference may be due to studies were conducted in different centers offer different qualities of diabetes care.

The majority of the DFU was in grade 1(23.48%). However, the study done at Ayder referral hospital found that 38% of the patients with foot ulcers were Wagner's grade 0(5). In Nigeria most of the DFU were in grade 4 with distribution of DFU in relation to clinical stages was 40%, 25.7%, 17.1% and 11.4% for stages-IV, III, II and I,respectively (29). In our study, the distribution of DFU was 6.96%, 20.00%, 19.13% and 23.48% for stages-IV, III, II and I. In Thailand the majority of the patients had grade2 (32.8%) with distribution of the ulcers according to the Wagner classification was as follows: Wagner 1 (22.5%); Wagner 2 (32.8%); Wagner 3 (32.1%); Wagner 4 (11.8%); and Wagner 5 (0.8%)(28).

This study found that almost half of patients had poor glycemic control and it showed that poor blood glucose control patients were 2.6 times more likely to be amputated as compared with those who had a good blood glucose control. This is consistent with the studies conducted in USA, Germany, India, and Sudan (16, 26, 40, 45).This indicates that importance of good glycaemic control should be implied and emphasized by these findings as a key aspect of primary intervention in diabetic foot ulcer management and also to prevent unnecessary limb wastage.

The finding of this study showed that overweight diabetic patients were 2.8 times more likely to under gone amputation as compared with those who had a normal weight. Furthermore, these obese diabetic patients were 3 times more likely to under gone amputation as compared to those diabetic patients with normal body mass index. This is consistent with the studies conducted in Gondar(35). But the study done in Kenya showed that higher body mass index (BMI) was not associated with diabetic foot ulcer(11). The possible reason could be due to the presence of higher foot pressure in those heavily weighed and with higher body mass index (BMI) diabetic patients as well obesity and overweight might decrease intensively the normal blood circulation pattern at the lower extremities; as a result, this might lead them to develop diabetic foot ulcer.

Advanced Wagner stage ulcers were a significant risk factor for amputation .Diabetes foot ulcer patients who had Wagner Grade≥ 4 were 1.7 times more likely to be amputated as compared to diabetic foot ulcer patients who had Wagner Grade<4. This result is consistent with the studies conducted in USA and Tanzania(21, 36). The possible reason was most of the patients in advanced Wagner stage were developed gangrene.

Peripheral neuropathy was another variable which was predictors of amputation in diabetic foot ulcer patients. Diabetic patients who had neuropathy were 1.6 times more likely to be amputated as compared to diabetic patients without neuropathy. This result is consistent with the studies conducted in Germany and Gondar (35, 40). Diabetic patients with high blood glucose level are exposed to micro-vascular complication and neuropathy, and the occurrence of neuropathy may increase the risk for foot ulceration due to increased pressure load and shearing forces.

The most commonly prescribed individual antibiotics in NRH during study period for patients was cloxacillin 56(34.15%) followed by Metronidazole 43(26.22%) and Ceftriaxone 33(20.12%). Study in UK by Wong ML and Coppini DV showed that the most commonly prescribed

antibiotics was cefradine,clindamycin,and and ciprofloxacin(48). However, the study done in Sweden showed that metronidazole (56%) and ciprofloxacin (54%) were the most commonly used, followed by flucloxacillin(40%) and cefadroxil (31%)(49). The study done in Switzerland by pittet D showed that the antibiotics most commonly used included semi synthetic penicillins(fluxacillin or amoxicillin-clavulanic acid),second and third generation cephalosporins and fluoroquinolones(22). The variety of individual antibiotic use in variety of setting was mostly due to availability and preference of the physicians.

The outcome of diabetic foot ulcer is strongly associated with inappropriate antibiotics given to treat diabetic foot infection. Diabetes foot ulcers who had taken inappropriate antibiotics were 2.5 more times to be amputated than diabetic foot ulcer which had been treated with appropriate antibiotics. This is similar with the study conducted in UK in which the amputation rate dropped from about 70% to about 30% with appropriate antibiotics therapy(47). In our study area, about half of the antibiotics were prescribed inappropriately. Therefore, because of excessive and inappropriate use of antibiotics for treating diabetic foot infections, resistance to the usually employed bacteria will possibly increasing to alarming levels in the study area unless tackled.

The duration of diabetes prior to presentation had no effect on the outcome of diabetic foot ulcers. Previous studies done in Germany, Pakistan, Jamaica, Khartoum and Arbaminch have demonstrated the inhibitory effects of diabetes on wound healing but the duration of diabetes independently may not be as important as overall blood glucose control (which was not looked at in this study)(26, 33, 40, 43, 52).

There were fewer Type 1 diabetic patients in this study, but the type of diabetes had no effect on amputations. This is similar to the study done in both diabetic foot clinics (Manchester and San Antonio)(51). Sixty four (55.65%) of patients in this study were male. However, sex had no effect on the outcome of diabetic foot ulcers. On the contrary, the previous study done in Germany and Jamaica was showed that being male increase the risk of amputation (40, 52). The study done in the Australia found that amputation is more prevalent in females as compared to males(9). This could be a reflection of the male–female ratio of new foot ulcers occurring in the community.

Ulcer site and size had no effect on the likelihood of an ulcer leading to an amputation. A previous study has shown that ulcer area and ulcer site were a risk factor for amputation. The study done in

both diabetic foot clinics (Manchester and San Antonio) showed that Ulcer area at presentation was greater in the amputation group compared to healed ulcers and Ulcer area correlated with healing time and predicted healing(51). The ventral foot (heel to toes) had the most ulcer lesions probably because of weight-bearing pressure. Despite this, ulcer site had no association with outcome in our study. However, the study done in Pakistan found that heel ulcer is associated with the outcome of diabetic foot ulcer patients(43). This due to in our study, most of the patients had early presentation with superficial ulcer, before osteomyelitis and gangrene had developed.

Diabetic patients who live in rural areas of Ethiopia often spent most of their time in farm area or outdoors and may be subjected to rodent bites of their feet. Bites to the feet of patients with diabetes can lead to the development of ulceration due to poor wound healing process and less opportunity for health care service for it. Diabetic patients who lived in the rural area often walk with bare feet. This may expose their feet to harm and lead to the development of foot ulcer. Despite, these most of the patients in our study area were come from urban and the place of the residence had no significant associations with the outcomes of diabetic foot ulcer. Previous studies done in Pakistan, Arbaminch and Gondar have demonstrated that diabetic foot ulcer significantly associated with the rural residence of the patients (33, 35, 43).

The most causative organisms for diabetic foot ulcer in NRH during study period for patients was gram positive 42(54.55%) followed by gram negative 20(25.97%) and poly-microbial 15(19.48%). Study in Thailand showed that most causative organisms for diabetic foot ulcer were gram negative, gram positive and poly microbial respectively(28). The study in Singapore in 2010 showed that gram positive organism is the most prevalent (32). Similarly, the study conducted in the Switzerland found that the most causative organism for diabetic foot ulcer were gram positive followed by gram negative bacteria(22).

According to the gram-stain results about 77(66.96%) of the patients presents with diabetic foot ulcer developed infection and 38(33.04%) of them did not developed any type of infection. This figure is higher than the study done in Austrialia and Jamaica in which the incidence of diabetic foot infection were 40.1% and 3.7% ,respectively(9, 52). This difference in incidence of diabetic foot infection is might be due to the difference in the quality of service, life style of the patients and quality podiatric service.

From the total diabetic foot ulcer patients, 35(30.43%) of them were amputated and from amputated diabetic foot ulcer patients, 20(57.14%) and 15(42.86%) were undergone minor and major amputation, respectively. This figure was higher than the study done in university of Malta and lower than the study done in Singapore and comparable with the study done in Pakistan and Tanzania (19, 21, 32, 43). This is due to the differences in quality of diabetic foot care and may be related to the difficulty of obtaining consent for major or even minor surgery that required amputation of an affected limb. The reason for this reluctance lies in part in cultural factors where loss of limb may be considered worse than loss of life.

As strength, the study was conducted among DFU patients as the foot complication of Diabetes mellitus patient is increasing in developing world and this study was a general prospective cohort and may be used as baseline information for other researchers. As limitations, fasting plasma glucose was used to assess adequacy of glycemic control instead of glycosylated hemoglobin (HbA1c) and culture and sensitivity tests was not done to identify specific strain of the pathogen. Further,the follow-up period was short, thus failing to take into account any non- healing ulcers resulting in amputation after this time and Patients were followed by telephone not by face to face interview.

7. CONCLUSION

The incidence of diabetic foot ulcer among diabetic patients in Nekemte Referral Hospital was found to be high. Blood glucose level, Higher BMI (overweight and obesity), inappropriate antibiotics given, neuropathy, and advanced grade of diabetic foot ulcer were factors that predict outcomes of diabetic foot ulcer.

Majority of the study participants had foot ulcer Wagner's grade 1and most of diabetic foot ulcers were located on dorsal/interdigital toes.

The rate of amputation of the diabetic foot ulcer was found to be high in which most of the patients were amputated below ankle. From the patients amputated above ankle most of them amputated below knee.

The most commonly prescribed antibiotics for treating diabetic foot ulcer was cloxacillin, Metronidazole and ceftriaxone respectively. About half of antibiotics were prescribed inappropriately. The most causative microorganism for diabetic foot ulcer was gram positive. However, some of diabetic foot ulcer patients didn't grew any bacteria.

8. RECOMMENDATIONS

Based on the study finding the following recommendations are drown to reduce the incidence of diabetic foot ulcer and its associated unwelcomed effects.

- ✓ East wollega zone health sector and Nekemte referal hospital diabetic clinic diabetic care providers should strive to reduce its incidence through enhancing the regular diabetic foot evaluation.
- ✓ In addition to the routine care, especial emphasis should be given by treating health care provider for patients having neuropathy and advanced grade of diabetic foot ulcer
- ✓ To minimize the risk of developing diabetic foot ulcer, Health educators should emphasize on the benefit of weight reduction
- ✓ In this study empiric diagnosis and treatment were common which can increase risk of inappropriate antibiotics use. Therefore laboratory services should be strengthened like culture and sensitivity tests to identify specific strain of the pathogen for definitive treatment. Through this prescribers have to minimize empiric antibiotics prescribing to the possible level.
- ✓ Presence of clinical pharmacist plays pivotal role in order to facilitate and promote appropriate use of drugs by intervening different problems in prescribing, dispensing and providing necessary advices for the patients and health professionals regarding the overall issues related to drugs
- ✓ Health facilities should be aware of that nearly half of patients do not achieve adequate level of glycemic control and take appropriate action.
- ✓ The ongoing medical education of health professionals who care for diabetic foot ulcer should include information on the clinical and public health risks of inappropriate antibiotics use.
- ✓ Further researches should be conducted using HbA1c.

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ANNEX I: Data collection tool

PART 1.Socio-demographicand socio-economic status information

Instruction1: This Question is about socio demographic and diabetic foot ulcer related information. Encircle the response of the participants for close ended questions and write the response on the space provided for open ended questions.

No	Back ground information	Response
01	Age	_____ years
02	Sex	1. Male ☐ 2. Female ☐
03	Weight	_____kg
04	Height	_____ m
05	Marital status	1. Married ☐ 2. Single ☐ 3. Divorced ☐ 4. Widowed ☐
06	Where did you live?	1.Rural ☐ 2.Urban ☐
07	How much in average do you think your Monthly Income?	_____Birr
08	What is your educational level?	1. Illiterate ☐ 2. grad1-8 ☐ 3. grade 9-10 ☐ 4.Collage&above ☐
09	What is your occupation	1. Farmer ☐ 2. Merchant/Trade ☐ 3. Private ☐ 4. Government employee ☐ 5. NGO ☐ 6. House wife ☐ 7. Student ☐ 8. Daily labor ☐ 9. other (Specify) _____

Part II: life style Approaches of Diabetic foot ulcer patients

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10. **Alcohol**

10.1. Do you ever drink alcohol regularly? Yes ☐   No ☐

10.2. If yes to q. no 10.1, do you currently drink alcohol on a regular basis? Yes ☐   No ☐

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11. **Cigarette Smoking**

11.1. Do you ever smoke cigarettes? Yes ☐   No ☐

11.2. Are you currently a smoker? Yes ☐   No ☐

Part III: Diabetic foot ulcer characteristics

12	Types of DM	1.type 1DM ☐ 2.type 2 DM ☐
13	Duration of DM (from the date of diagnosis reported by the patient)	_____year(s)
14	Previous history of ulcer	1.Yes ☐ 2.No ☐
15	If the response is yes for question no 16. What is the final outcome during that time?	1.healed ☐ 2.Amputated ☐
16	Size(area) of the ulcer	_____cm2
17	Location of the ulcer	1.Dorsal/inter digital toes ☐ 2.plantar toes ☐ 3. plantar forefoot/mid foot ☐ 4 plantar hind foot ☐ 5.heel ☐ 6.dorsal foot ☐
18	Is ulcer develops infection?	1.yes ☐ 2.No ☐

19	Organism isolated from foot ulcer	19.1.Gram positive ☐ 19.2.Gram negative ☐ 19.3. poly microbial ☐
20	Which antibiotics are given for treating foot ulcer?(including dose, frequency and duration)	1_____ 2_____ 3_____ 4_____
21	What is the current status of your foot ulcer?	1. Healed ☐ 2. Amputated ☐ 3. Dead ☐
22	Present grade of ulcer (Verified and recorded from physician's clinical note)?	1.Grade 0 ☐ 4.Grade 3☐ 1. Grade 1 ☐ 5.Grade 4☐ 2. Grade 2 ☐ 6.Grade 5☐
23	If amputated, specify the location?	1.Below the ankle ☐ 2.Above the ankle ☐
24	If it is major amputation specify the location	1.Below knee ☐ 2.Above knee ☐

Part IV: Blood Glucose Levels

25. Fasting blood sugar value (mg/dl)

25.1. Recent _____

25.2. On immediate previous appointment _____

25.3. On second previous appointment (immediately before the previous appointment) _____

Part V: Co-morbidities and DM Complications

26. Presence of co morbidities 26.1 Present ☐   26.2. Absent ☐

27. If the response for the above question is *present*, which of the following co-morbidity is present? (can tick more than once)

 27.1. Hypertension ☐

27.2. Ischemic Heart Disease ☐

27.3. Dyslipidemia ☐

28.Presence of diabetic complications

28.1. Present ☐   28.2. Absent ☐

29. If the response for the above question is *present*, which of the following diabetic complication is present? (can tick more than once)

29.1. Retinopathy ☐   29.4.Nephrophaty ☐

29.2. Neuropathy ☐   29.5. Peripheral vascular disease ☐

29.3. Coronary Heart disease ☐

Gaaffiilee qorannoo Afaan oromoo dhaan.

KUTAA1ffaa: Gaaffile dhimma enyummaa hawaasummaa fi diinagdee

Ajaja 1ffaa: Gaaffile armaan gaditiif deebii hirmaataan filate irra marsudhaan akkasumas gaaffilee tokko tokkof bakka duwwaa irratti guutuudhaan deebisaa.

Lakk	Enyummaa ,hawaasummaa fi diinagdee	Deebii
01	Umrii(waggaan)	_____
02	Saala	1. Dhiira 2. Dhalaa
03	Dheerina(meetiraan)	_____
04	Ulfaatina(Kiiloogiraamiidhaan)	_____
05	Haala maati/Sadarkaa fuudhaa fi heerumaa	1. Kan Fuudhe/Heerumte 2. Kan Hin Fuune/Herumne 3. Kan Walgadhise/te 4. Kan abbaan ykn haati manaa jalaa du'e/te
06	Bakka jireenyaa	1. Baadiyaa 2. Magaalaa
07	Galiin keessan kan ji'aa giddugaleessaan meeqa ta'a jettanii yaaddduu?(Qarsiin)	_____
08	Sadarkaan barnoota keessanii meeqa?	1. Hin baranne 2. Kutaa 1-8 3. Kutaa 9-10 4. Kolleejjii fi sanaa oli
09	Hojiin keessan maali?	1. Qonnan bulaa 2.Daldalaa 3. Hojii dhuunfaa 4. Hojjetaa mootummaa 5. Hojjetaa miti -mootummaa 6.Haadha manaa 7. Barataa/ttuu 8. Hojii humnaa 9. kan biroo,yoo jiraate _____

KUTAA2^{ffaa}: Gaaffile waa'ee Dhugaaatii alkoolii, Sijaaraa ykn tamboo fayyadamuu namoota madaa/uraa lukaa qabanii

---

10. **Dhugaaatii alkoolii fayyadamuu**

10.1.Alkoolii hin dhugdaa? 1.Eeyyee ☐   2. Lakki ☐

10.2.Yoo hin dhugda ta'e amma guyyaama guyyaatti dhugdaa? 1. Eeyyee ☐   2.Lakki ☐

---

11. **Sijaaraa ykn tamboo fayyadamuu**

11.1.Sijaaraa ykn tamboo hin xuuxxaa? 1.Eeyyee ☐   2.Lakki ☐

11.2. yeroo ammaa kana hin xuuxxaa?   1. Eeyyee ☐   2. Lakki ☐

KUTAA3^{ffaa}: Gaaffile haala dhukkuba madaa/uraa lukaa qabanii

12	Gosa dhukkuba sukkaaraa	1. Gosa 1ffaa ☐ 2. Gosa 2ffaa ☐
13	Erga dhukkuba sukkaaraan qabamuu kee bartee kaasee waggaa meeqa ta'eera?	_____
14	Duraan dhukkuba madaa/uraa lukaa qabdaa?	1.Eeyyee ☐ 2.Lakki ☐
15	Yoo gaaffii 16 f deebiin kee eeyyee ta'e yeroo sanatti firiin isaa maal ture?	1.Fayyeera ☐ 3.Narraa citeera ☐
16	Balinni madaa/uraa lukaa hammami?	_____cm2
17	Bakkeen madaa/uraa lukaa eessa?	1.Quba lamaan gidduu ☐ 2.Quba lukaa jalaan ☐ 3. Gidduu/fuldura jala lukaa ☐ 4 Duuba lukaa jalaan ☐ 5.Koomee lukaa ☐ 6.Irra/gubbaa lukaa ☐
18	Madaa/uraa lukaa infeekshinii uumeeraa?	1..Eeyyee ☐ 2. Lakki ☐
19	Madaa/uraa lukaa irraa organizimiin argame maali?	19.1.Graam positiivii ☐ 19.2.Graam negatiivii ☐ 19.3. orgaanisimii akaakuu garaa garaa ☐

20	madaa/uraa lukaa yaaluudhaaf qoricha(doosii,turtii fi deddeebi'insa isaanii wajjiin) maaltu kenname?	1_____ 2_____ 3_____ 4_____
21	Haalli madaa/uraa lukaa yeroo ammaa maal fakkaata?	1. Fayyeera ☐ 2. Narraa citeera ☐ 3. Du'eera ☐
22	Yoo hin fayyine tae yeroo ammaa sadarkaan madaa/uraa lukaa kee meeqa?	1.sadarkaa 0 ☐ 4. sadarkaa 3☐ 1. sadarkaa 1 ☐ 5. sadarkaa 4☐ 2. sadarkaa 2☐ 6. sadarkaa 5☐
23	Yoo citeera tae bakka kamtu cite?	1.Koronyoo miilaa gadi ☐ 2. Koronyoo miilaa oli ☐
24	Yoo koronyoo miilaa oliitu sirraa cite ta'e bakki isaa eessa?	1. Jilbaa gadi ☐ 2. Jilbaa oli ☐

KUTAA4^{ffa} : Gaaffile hanga gluukoosii dhiiga keesa jiruu ibsu

Hanga gluukoosii dhiiga keesa jiruu

25.Hanga sukkaara dhiiga keesa jiruu osoo hin nyaatiin (mg/dl)

25.1. Kan ammaa _____

25.2. kan beellama yeroo darbee _____

25.3. kan beellama yeroo darbee duraa _____

KUTAA5^{ffaa}: Dhukkuboota biroofi kompliikeeshinii sukkaaraa

26. Dhukkuboota biro qabduu? 26.1 eeyyee ☐   26.2. lakki ☐

27.yoo gaffii 26 ffaaf deebiin kee eeyyee ta'e dhukkuba kam qabda? (tokkoo ol itti maruu dandeessa)

 27.1. dhiibbaa dhiigaa ☐

27.2. dhukkuba onnee ☐

27.3. Dyslippideemiyaa ☐

28.Rakkoon dhukkuba sukkaaraan wal qabatanii dhufan jiruu?

28.1. eeyyee ☐   28.2 . lakki ☐

29. yoo gaffii 28 ffaaf deebiin kee eeyyee ta'e Rakkoon dhukkuba sukkaaraan wal qabatanii maal faa tu jira (tokkoo ol itti maruu dandeessa)

29.1 Rakkoo ijaa ☐   29.4.Rakkoo kalee ☐

29.2. Hadooduu ☐   29.5. Rakkoo ujummoo dhiigaa qarqaraa ☐

31.3. Rakkoo onnee wajjiin wal qabate ☐   31.6.Kanbiroo,yoo jiraate_____

የመጥየቆች ጥያቄዎች

1ኛ ክፍል፡- ጥያቄዎች የማኅንነት ማህበረሰባዊ ጥያቄ ?

1ኛ ትእዛዝ ፡- ከዚህ በታች ላሉት ጥያቄዎች ተሳትፈው የመረጠው መልስ በማንበብ እንዲሁም ለእያንዳዱ ጥያቄዎች በባዶ ቦታ ላይ በመሙላት ይመልሳል፡፡

ቁጥር ማንነት ፤ ማህበራዊ እና ኢኮኖሚያዊ	መልስ
01. እድሜ 9 በዓመት	---------------
02. ጸታ	1. ወንድ 2. ሴት
03. ርዝመት በሜትር	------------
04. ክብደት (በኪ.ግራም)	--------------
05. የቤተሰብ ሁኔታ(የት.ደረጃ)	1. ያገባ/ች/ 2. ያላገባ/ ች/ 3. የተፋታ/ ች/ 4. ባል ወይም ሚስት የሞተበት/ ባት/
06. የኑሮ ቦታ	1. ገጠር 2. ከተማ
07. ገቢዎች በመካከለኛ ወራት ስንት ሆነ ብላችሁ ታስባላችሁን(በገንዘብ)	--------------------
08. የትምህርት ደረጃዎች ስንት ነው ?	1. አልተማርኩም 2. ከ1-8 ክፍል 3. ከ9-10 ኛ ክፍል 4. ኮሌጅ እና ከዚያ በላይ
09. ሥራዎት ምድን ነው ?	1. አርሶ አደር 2. ነጋዴ 3. የግል ስራ 4. የመንግስት ሰራተኛ 5. የመንግስት ሰራተኛ ያልሆነ 6. የቤት እመቤት 7. ተማሪ 8.የጉልበት ስራ 9. ሌላ ካለ -----------

2ኛ ክፍል - ስለ አልኮል መጠጦችን፤ ሲጋራ መጠቀም ቁስል፤ የእግር ቁስል ያለቸው ሰዎች

10. አልኮል መጠጥን መጠቀም
10.1. አልኮል ትጠጣለህ ? አዎን ☐ አይይ ☐
10.2. የምትጠጣ ከሆነ አሁን በየቀኑ ትጠጣለህ ?አዎን ☐ አይይ☐
11. ሲጋራን መጠቀም
11.1 ሲጋራ ትጠቀማለህ (ታጨሳለህ) ? አዎን ☐ አይይ ☐
11.2 ባሁኑ ሰዓት ታጨሳለህ ?አዎን ☐ አይይ ☐

3ኛ ክፍሎች ፡- የቁስል በሸታ ዓይነቶች / የእግር ቁስል ላላቸው

12	የስኳር በሸታ ዓይነቶች	1.አንደኛ ዓይነቶች ☐ 2. 2ኛ ዓይነቶች ☐
13	በስኳር በሸታ መያዝህን ካወክ አንስቶ ስንት ዓመት ሆነዋል፡፡	------------
14	ከዚህ በፊት የእግር ቁስለት በሸታ / አለብህ/ብሸ	1.አዎን ☐ 2.አይይ☐
15	16 ኛው ጥያቄ ያንተ መልስ አዎን ከሆነ በዚያ ግዜ ውጤቱ ምን ነበር ?	1.ድኗል ☐ 2.ተቆርቷል ☐
16	የቁስሉ ስፋት/የእግር ቁስል ስፋት ምን ያህል ነው?	--------- cm2

17	የቁስሉ ቦታ /የእግር ቁስሉ ቦታ የት ነው?	1.ሁለቱጣቶች መሐል☐
		2. የእግርጣቶች ሰረ ☐
		3. የእግር ፌትለፌት/የእግር ሰረ☐
		4. የእግ ሆሀላ☐
		5. የእግር ተረደዘ☐
		6. የእግር ላይ ☐
18	የእግር ቁስሉ /የእግር ቁስሉ ኢንፌክሽን ፈጥሯል?	1.አዎን ☐ 2.አይይ ☐
19	ቁስሉ ከእግር ቁስል ላይ የተገኘው ኦርጋኒዝም ምንድን ነው?	19.1 ግራም ፖስቲቭ.☐
		19.2 ግራም ነጋቲቭ ☐
		19.3 የተለያዩ ዓይነት ኦርጋኒስም ☐
20	የእግር ቁስሉን ለማከም መድሐኒት (ደስ፣ቆይታቸው እና ምልልሳቸው ጋር ምን ተሰጠ?	1. ------------------------
		2. ------------------------
		3.------------------------
		4. ----------------------
21	የቁስሉ ሁኔታ/የእግር ቁስሉ ባሁኑ ሰዓት ምን ይመስላል	1.ድፍል ☐
		2.ተቆርቷል ☐
		3.ምቷል ☐
22	ያልዳነ ከሆነ ባሁኑ ሰዓት የቁስሉ ደረጃ /የእግር ቁስሉ ደረጃ	1.ደረጃ 0 ☐
		2..ደረጃ 1☐
		3.ደረጃ 2☐
		4.ደረጃ 3 ☐
		5.ደረጃ 4 ☐
		6.ደረጃ 5☐

23	የተቆረጠ ከሆነ የት ቦታ ተቆረጠ ?	1. ከቁርጭምጭሚት በታች ☐
		2. 2 ከእግር ቁርጭምጭሚት በላይ ☐
24	ከእግር ቁርጭምጭሚት በላይ የተቆረጠብህ ከሆነ ቦታው	1. ከጉልበት በታች ☐
		2. ከጉልበት በላይ ☐

4ኛ. ክፍል፦ ደም ውስጥ ያለውን የግሉኮስ መጠን የሚገልጽ ጥያቄ ደም ውስጥ ያለ የግሉኮስ መጠን

25. ደም ውስጥ ያለ የስኳር መጠን ሃይበላ (mg/dl)
25.1 ያሁኑ ----------------
25.2 ያለፈው ቀጠሮ --------------
25.3 ያለፈው ቀጠሮ በፊት --------------

5ኛው ክፍል፡- ሌሎች በሽታዎች እና የስኳር ኮምፕሌሽን

26. ሌሎች በሽታዎች አሎት ? 26.1 አዎን □ 26.2 አይይ □

27. ለ26ኛው ጥያቄ መልስህ አዎን ከሆነ ምን ዓይነት በሽታ አለህ ? ከአንድ በላይ ልታክልበት ትችላለህ ?

27.1 የደም ግፊት □

27.2 የልብ በሽታ □

27.3 ዲሲሊቲዲሚያ □

28. ከስኳር በሽታ ጋር መጡ በሽታዎች አሉ?

28.1 አዎን □   28.2 አይይ □

29. ለ28ኛው ጥያቄ መልስህ አዎን ከሆነ ከስኳር በሽታ ጋር ተያይዘው መጡ ችግሮች ምን ምን አሉ (አንድ በላይ ላይ ላክበብ ትችላላችላለህ)

29.1 የዓይን ችግር □

29.2 በደንዘዝ □

29.3 ከልብ ችግር ጋር ተያይዞ □

29.4 የኩላሊት ችግር □

29.5 የደም ቧቦ ችግር □

29.6 ሌላ ካለ ------------------------

ANNEX II: Informed English consent form

Dear/ Sir/Madam,

Greeting:

Hello, my name is Firomsa Bekele I am here today to collect data to asses burden, risk factor and outcomes of diabetic foot ulcer in Nekemt referral hospital. Therefore, for the success of this research your medical chart and your response to interview is a great.

There is no possible risk associated with participating in this study except the time spent to deliver information for us. All information taken from your medical chart or given by you will be kept strictly confidential and the data are stored without your name and only used for the purpose of this study. None of this would affect the care you receive from NRH, but will help in future planning for the hospital and your care. Your participation is voluntary and you are not obligated to participate in the study. If you feel discomfort with the study, it is your right to drop it.

I would be grateful if you could sign the attached form to say you have no objections to our accessing any records and interviewing you. Would you be willing to assist me by having a 15-20 minutes' interview with me? Interview accepted; **Yes_____   No_____**
If the interviewee responds "Yes" please proceed and let him/her to sign or if replies "No" gratitude him/her and quit the interview. If you have any questions concerning the study, please call Firomsa Bekele(PI) (+251) 19536460

_____   _____

Signature of interviewer   Signature of respondent

Date: _____ (Day/month/year)

Principal Investigator: Firomsa Bekele

Jimma University, CHS, School of Pharmacy, Department of Clinical Pharmacy

EMAIL:firomsabekele21@gmail.com

Guca waligaltee

Ani maqaankoo Firoomsaa Baqqalaan jedhama anis kanan asi dhufeefi qorannoo kan mata dureen isaa burden, risk factor and outcomes of diabetic foot ulcer in Nekemte referral hospital jedhamu irratti gaggeessuufidha. Kanaaf deebiiniifi odeeffanoon kaardii keessanii naaf barbaachisoodha.

Qorannoo kana irratti hirmaachuu keessaniif rakkoon isinirra gahu hin jiru yoo yeroo keessan gubuu ta'e malee. Odeeffannoon isinii fi kaardii keessan irraa argamus icciitiidhaadhaan kan qabamuufi akkasumas maqaan keessanis akka hin barreeffamne isinitti himna.odeeffannoon fudhannus tajaajila fayyaa isin hospitaala kanaa argattan hin miidhu garuu gara fuulduraatti isiniifi hospitaala kana hin gargaara. Hirmaannaan keessanis fedhaani malee dirqiidhaan miti. Yoo qorannoon kun isinitti hin tolle rakkoo tokko malee yaada kennuu dhiisuu dandeessu.

Yaadakoo fudhachuu keessan kan ittiin mirkaneeffadhu mallattoo keessan otoo mallatteessitanii natti tola. Daqiiqaa15-20 yaada keessan isinirraa fudhadhuuf na gargaaruu dandeessu?.

Qorannoo kana irratti hirmaachuuf eyyamamo dhaa? 1. Eeyyeen   2.Lakki

Mallatoo Nama raga funaanee..………………Guyyaa…………..

Mallatoo Nama deebii kennee…………………Guyyaa…………

የስምምነት ቅጽ

እኔ ስሜ ፍሮምሳ በቀለ እባላለው እኔ እዚህ መጣሁት ለጥናት (ምርምር) ሲሆን አርእስቱም (burden ,risk factor & outcomes of diabetic foot ulcer in Nekemte referral hospital) ነው፡፡ ስለዚህ መልሶትን የካርዱ ሪፓርት ለእኔ አስፈላጊ ነው፡፡

በዚህ ጥናት (ምርመራ) ላይ ለመሳተፍ የሚደርስቦ ችግር የለም፡፡ ሰዓቶን ከማቃጠል በስተቀር ፡፡የእርሶ ሪፓርት እና በካርዱ የሚገኘው በሚጥር የሚያዝ እና እንዲሁም ስሞትም እንደማይጻፍ እነግሮታለው፡፡የምንወስደው መጠይቅም እርሶ ከዚህ ሆስፒታል የሚገኙትን አገልግሎት አይነዳም ነገር ግን ለወደ ፊት እርሶንና ይህንን ሆስፒታል ይጠቅማል የእርሶ ተሳትፎም በፍላጎት እንጂ በግዴታ አይደለም፡፡ይህ መጠይቅ ሳይመቾት ሲቀር ያለ አንዳች ችግር ሐሳብ መስጠት ማቆም ይችላለ፡፡

ሐሳቤን መቀበሎን የማርጋግጠው ፍርማዎትን ቢፈርሙ ደስ ይለኛል ከ15-20 ደቂቃ ሐሳቦን ከእርሶ ለመውሰድ ሊረዱኝ ይችላለ?

በዚህ መጠይቅ ላይ ለመሳተፍ ፍቃደኛ ኖት ? 1 አዎን ----   2 አይደለም-------

ማስረጃውን የሰበሰበው ፈርማ ---------- ቀን -------

መልስ የሰጠው ሰው ፈርማ -------------- ቀን -----------