EFFECT OF BASELINE COMPLICATIONS OR CO-MORBIDITIES ON INCIDENCE OF DIABETIC FOOT ULCER AMONG ADULT DIABETIC PATIENTS ATTENDING PUBLIC HOSPITALS, HADIYA ZONE, SOUTHERN ETHIOPIA

MPH THESIS

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Effect of Baseline Complications or Co-Morbidities on Incidence of Diabetic Foot Ulcer among Adult Diabetic Patients Attending Public Hospitals, Hadiya Zone, Southern Ethiopia: Retrospective Cohort study

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BIOGRAPHIC SKETCH

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ACRONYMS AND ABREVIATIONS

AHR: Adjusted Hazards Ratio

BMI: Body Mass Index

CI: Confidence Interval

DFU: Diabetic Foot Ulcer

DM: Diabetes Mellitus

DMFU: Diabetes Mellitus Foot Ulcer

EGFR: Estimated Glomerular Filtration Rate

ESR: Erythrocyte Sedimentation Rate

GC: Gregorian Calendar

HbA1C: Glycated Hemoglobin

HR: Hazards Ratio

IDF: International Diabetes Federation

IR: Incidence Rate

NDS: Neuropathic Disability Score

NEMMWUTH: Negist Eleni Mohammed Memorial Wachamo University Teaching Hospital

OPD: Out Patient Department

OR: Odds Ratio

PAD: Peripheral Arterial Diseases

RR: Relative Risk

SNNPR: Southern Nations Nationalities and Peoples Region

WHO: World Health Organizations

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ABSTRACT

Background: Diabetic foot disease is a major medical, social, and economic problem that is, seen in every continent and constitutes a major burden to the patient and the health care system. The lifetime risk of a person with diabetes developing diabetic foot ulcers is as high as 25%. As the best knowledge of investigator, there was limited evidence on effect of baseline complications and co-morbidities on incidence of diabetic foot ulcer among adult patients on diabetic care follow up in the study areas.

Objective: to determine the effect of baseline complications and co-morbidities on incidence of diabetic foot ulcer among adult diabetic patients attending public hospitals of Hadiya zone, southern Ethiopia, from 1 January 2015 to 31 December 2019.

Methods: An institution based retrospective cohort study was conducted in Hadiya Zone Public Hospitals, from March 01-15, 2020. The data were collected from individual folder and database by using data extraction format for 200 exposed and 201 unexposed populations. Kaplan-Meier failure curves were used to estimate the probability of developing diabetic foot ulcer. The Cox proportional hazard model was used to determine the effect of baseline complications or co-morbidities on diabetic foot ulcer occurrence. Adjusted hazard ratio was estimated and interpreted with 95% CI at p-value < 0.05.

Results: The incidence rate of diabetic foot ulcer was 4.7/1000 person-months with 95% CI of (3.1/1000, 7.1/1000) in the group with at least one baseline complications (co-morbidities) and 0.93/1000 person-months with 95% CI of (0.35/1000, 2.5/1000) in the cohort without at least one baseline complications (co-morbidities), respectively. Baseline complications or co-morbidities that were found to have significant effect on diabetic foot ulcer were retinopathy (AHR=3.43, 95% CI; 1.11 10.59), nephropathy (AHR=2.86, 95% CI; 1.19 6.89), peripheral neuropathy (AHR =6.19, 95% CI; 1.98 19.38), peripheral vascular diseases (AHR= 3.04, 95 % CI; 1.19 7.76) and obesity (AHR=5.99, 95% CI; 1.71 21.05).

Conclusions: The overall incidence of diabetic foot ulcer was high in the study population. Health professionals should give tailored advice on major complications and co-morbidities of DM for all adult patients at initiation of DM treatment.

Key words: Adults, diabetes mellitus, incidence, effect, complications, co-morbidities, diabetic foot ulcer.

1. INTRODUCTION

1.1. Background

Diabetes mellitus (DM) is one of the most frequent metabolic disorders; with an estimate of 415 million people living with this condition worldwide and the number is projected to 642 million by 2040 (IDF, 2015). Incidence and prevalence are rising, carrying high costs (more than 471 billion US dollars in 2012) and rates of morbid-mortality, with premature deaths (Daniela Martins-Mendeset al., 2014). Around 4.8 million people died in 2012 due to diabetes, half of them were under 60 years (Daniela Martins-Mendes et al., 2014; WHO, 2013). The incidence of diabetic foot has increased due to the worldwide prevalence of diabetes mellitus and the prolonged life expectancy of diabetic patients (IDF, 2012).

The diabetic foot is one of the major complications of this disease, with an estimated 10% to 25% of diabetic patients developing a diabetic foot ulcer (DFU) in their lifetimes (Frykberg et al., 2006), causing a considerable burden in health care and patient well-being (IDF, 2012; Monteiro-Soares et al., 2011; Singh N et al., 2005). The occurrence of a DFU bodes poorly for the clinical course of patients with diabetes, with higher rates of re-ulceration, lower extremities amputation, contra lateral lower extremities amputation and death compared to persons with diabetes who have not experienced a DFU (Frykberg et al., 2006). Diabetic foot is the most frequent cause of hospitalization for the patients with diabetes, representing up to 25% of all diabetic hospital admissions (Al-Maskari F and El-Sadig M., 2007). Also, it is the most common cause of non-traumatic lower limb amputation and precedes 85% of the case (M. Monteiro-Soares et al., 2011).

Even though the cascade of diabetic foot complications–DFU has been linked to higher mortality risk (Fortington et al., 2013), an increasing number of DM complications are also associated with higher mortality (Brownrigg et al., 2012). Review on risk factors for foot ulceration showed that neuropathy, retinopathy, nephropathy and peripheral vascular diseases were contributing factors for DFU (Merza Z and S.Tesfaye, 2003). DFU is usually considered

a marker of diabetes complication status, i.e., a marker for neuropathy and associated vascular disease in the foot. Nevertheless, adjustment for baseline complication rarely conduct ed when assessing the effect of baseline complications and co-morbidities on incidence of DFU (Merza Z and S. Tesfaye, 2003). In addition, simple models for their prediction (specially using the same core variables) were seldom proposed.

In developed countries, one in every six people with diabetes will have an ulcer during their lifetime. The risk is even higher in developing countries (Tesfamichael G. Mariam et al., 2017). Foot wounds are now the most common diabetes related cause of hospitalization and are frequent precursors to amputation (Lawrence A. Lavery et al., 2006). 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 (Lawrence A. Laveryet al., 2006)

1.2. Statement of the Problem

Diabetic foot disease is a major medical, social, and economic problem that is, seen in every continent and constitutes a major burden to the patient and the health care system (Boulton A. J. M., 2001). 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 (Boulton AJ et al., 2005). The lifetime risk of a person with diabetes developing diabetic foot ulcers (DFU) is reported to be as high as 25% (Singh N et al., 2005). Studies suggest that 2.5% of diabetic patients develop DFU each year, and 15% of them develop DFU during their life time (Shojaiefard A et al., 2008). As the incidence of DM is rising dramatically worldwide, so is the incidence of diabetic foot disease (Boulton A. J. M., 2001).

On the basis of 2015 prevalence data from the International Diabetes Federation, it is estimated that annually, foot ulcers develop in 9.1 million to 26.1 million people with diabetes worldwide (IDF, 2015). The proportion of persons with diabetes and a history of foot ulceration is understandably higher than the proportion with an active ulcer; 3.1 to 11.8% of persons with diabetes, or 12.9 million to 49.0 million persons worldwide and 1.0 million to 3.5 million in the United States alone, have a history of foot ulceration (Shojaiefard A et al., 2008; IDF, 2015; SDSMG, 2014).

In developing countries, foot ulcers are one of the most feared and common complications of DM. The IDF estimated that there were 14.2 million people living with diabetes in Africa in 2010 with a projected rise to 34.2 million by 2040 (IDF, 2015). In Nigeria, around 10% of people with diabetes suffer lower limb complications and the incidence is rising (Ogbera A. O et al., 2005). IDF estimates the number of cases of diabetics in Ethiopia to be about 1.3 million in 2015 and projected that it would increase to about 3.5 million by the year 2040 (IDF, 2015). Recent study done in northwest Ethiopia suggested that the incidence of diabetic foot ulcer among the diabetic patients was 17.86% (Firomsa Bekele et al., 2019).

Complications and co-morbidities with their related factors predicting foot ulcers include obesity, peripheral neuropathy, retinopathy, nephropathy, PAD, peripheral arterial occlusive

disease, hypertension, male sex, diabetes for >10 years, abnormal structure of foot (bony abnormalities, callus, thickened nails), smoking, trauma, history of previous ulcer or amputation, visual impairment and poor glycemic control (Yesil et al., 2009; Alvin C. Powers *et al.*, 2015).

Although, different studies were tried to determine the effect of baseline complications and co-morbidities on incidence of diabetic foot ulcer, they had been incompletely characterized across different socioeconomic and demographic settings (M. Monteiro-Soares et al., 2011). There was limited evidence on incidence of diabetic foot ulcer in Ethiopia particularly in the study settings because of no prior study done on problem under study. Thus, this study was aimed to determine the effect of baseline complications and co-morbidities on incidence of diabetic foot ulcer in adult diabetic patients which is very crucial to prevent the devastating effect of foot ulcer among diabetic patients and thereby improve their life expectance.

1.3. Significance of the Study

The Findings from the effect of baseline complications and co-morbidities on incidence of diabetic foot ulcer among adult diabetic patients will be used as input for local health program planners, health bureaus, and health departments to improve or strengthen strategies for reduction of complications associated with diabetic foot ulcer in diabetic cohort. In addition, the findings of the study will be availed as baseline information for researchers interested to do further research on effect of baseline complications and co-morbidities on incidence of diabetic foot ulcer among adult diabetic patients. This study will provide insight to the association between baseline complications and co-morbidities and diabetic foot ulcer among adult patients with diabetes that will be used by study hospitals to reduce complications associated with DFU. Moreover, the information obtained from this study will add to the existing knowledge of health care providers to give due attention during follow up time on complications and co-morbidities that contribute to diabetic foot ulcer. This study will also benefit individuals by improving awareness on baseline complications of DM and co-morbidities associated with it which in turn decrease life threatening complication accompanied with diabetic foot ulcer.

1.4. Hypothesis

The hypothesis to be tested was that there was no difference on incidence of diabetic foot ulcer among adult diabetic patients with and without baseline complications and co-morbidities.

1.5. Objectives

1.5.1. General Objective

To determine the effect of baseline complications and co-morbidities on incidence of diabetic foot ulcer among adult diabetic patients attending public hospitals in Hadiya zone, southern Ethiopia, from 1 January 2015 to 31 December 2019.

1.5.2. Specific Objectives

1. To determine the incidence of diabetic foot ulcer among adult diabetic patients with and without baseline complications or co-morbidities those are on follow-up care at public hospitals.
2. To assess the effect of baseline complications or co-morbidities on diabetic foot ulcer among adult diabetic patients attending public hospitals.

2. LITERATURE REVIEW

2.1. Overview of Diabetic Foot Ulcer

Diabetic foot ulcer is one of the life threatening complications of diabetes mellitus diseases occurring in 25% of patients suffering from the diseases. Diabetic foot ulcer (DFU) can also be explained as a full-thickness penetration of the dermis of the foot in a person with diabetes. The global incidence of diabetic foot ulcer is increasing due to worldwide prevalence of diabetes mellitus diseases. There are some reasons for the occurrence of DFU even if their magnitude is not the same across the continent, country, region or district.

2.2. Incidence of Diabetic Foot Ulcer

Studies showed that the incidence of diabetic foot ulcer was 6.3% in the global population (Pinidiyapathirage M. J et al., 2012; Ekpenyong C. E et al., 2012; Al-Maskari F and El-Sadig M., 2007). Prospective study done in Washington, USA showed that the incidence of DFU in study cohort was 5.0/100 person-years (Edward J. Boyko et al., 2006). Moreover, the study conducted in Maryland showed that the incidence of DFU in study cohort, one- and 3-year rates of ulcer recurrences were 30% and 64%, respectively and had a lower wagner's stage on presentation (stage 4: 7.7% versus 22.4%; $P < 0.001$) (Caitlin W. Hicks et al., 2019). Furthermore, longitudinal study done in Australia showed that the overall incidence of DFU in the study cohort was 5.21 per 1,000 patient-years and the proportion was 6.2% and regarding sex differences; In men, the incidence was 6.01 (4.33-8.12) per 1,000 patient-years compared with 4.53 (3.19-6.25) per 1,000 patient years in women (Mendel Baba Bpod (Hons) et al., 2010).

Another study conducted in northwestern United Kingdom revealed that the proportion of diabetic foot ulcer in population with diabetes was 2.2% (Shojaiefard A., 2008). Similar study done in United Kingdom suggested that 2.5% of diabetic patients develop DFU each year and 15% of them develop DFU during their life (Shojaiefard A et al., 2008). Furthermore, recent prospective study conducted in United Kingdom showed that the cumulative incidence of DFU in a study cohort was 6.1 per 1000 persons- years and the proportion was 7.7% (Paisey R. B et al., 2019).

One study conducted in Norway indicated that the incidence of DFU in the study population was 64.9%, but in the general population its incidence was estimated to be 1 to 4% (Fredrik A. Nilsen et al., 2018). Likewise, the study done in Portugal on independent contribution of DFU for lower extremity amputation showed that the incidence of DFU in study cohort was 26.6% (Daniela Martins-Mendes et al., 2014). Furthermore, study done in Netherlands revealed that the proportion of recurrent DFU in the study cohort was 57.5% (Michal Dubsky et al., 2012).

The prospective study conducted in Ahvaz, Iran on incidence and predictors of diabetic foot ulcer showed that the cumulative and annual incidence of DFU in the study cohort was 5.62% and 2.8% respectively (Leila Yazdanpanah et al., 2018). Moreover, the study conducted in United Arab Emirates showed that the incidence of DFU in study population was 42.5% (Venkatramana Manda et al., 2012). Likewise, retrospective study conducted in Japan showed that the 5-year and 10-year cumulative diabetic foot ulcer incidence rates in patients with type 2 diabetes were 1.9% and 3.7%, respectively (Masuomi Tomita et al., 2016).

Once more, the prospective study done in Korea showed that the overall incidence of diabetic foot ulcer in diabetic patients was 0.5% (Dong-Il Chun et al., 2019). Retrospective study conducted in Ghana showed that the overall incidence in the study population was 12.57% (Osei Sarfo-Kantanka et al., 2018). Furthermore, prospective study conducted in Nekemet Referral Hospital, northwest Ethiopia showed that the incidence of diabetic foot ulcer among the study cohort was 17.86% (Firomsa Bekele et al., 2019).

2.3. Effect of Baseline Complications and Co-Morbidities with Related Factors on Diabetic Foot Ulcer

As it was observed from review of relevant literatures; the complications and co-morbidities with their related factors that had effect on predicting foot ulcers include obesity, peripheral neuropathy, retinopathy, nephropathy, PAD, peripheral arterial occlusive disease, hypertension, male sex, diabetes for >10 years, abnormal structure of foot (bony abnormalities, callus, thickened nails), smoking, trauma, history of previous ulcer or amputation, visual impairment and poor glycemic control (Yesil et al., 2009; Alvin C. Powers *et al.*, 2015). Therefore, it would be paramount important to assess the effect of baseline complications and co-morbidities on

DFU by controlling other factors for setting effective preventive, control and treatment strategies of this devastating complication of diabetes mellitus diseases.

2.3.1. Effect of Baseline Complications and Co-Morbidities on Diabetic Foot Ulcer

Study done by Lawrence A. Lavery et al showed that the presence of peripheral vascular disease (aOR 1.9; 1.0–3.6) was risk factor for DFU (Lawrence A. Lavery et al., 2006). One study done by Caitlin W. Hicks et al showed that neuropathy (motor, sensory and autonomic) was found to be major complication of diabetes mellitus predicting DFU in diabetic patients (Caitlin W. Hicks et al., 2019). Similarly, the study done by Mendel Baba Bpod(Hons) et al showed that peripheral sensory neuropathy (HR 95% CI, 2.24;1.35-3.71), retinopathy (HR 95% CI, 3.86; 2.26-6.59), cerebrovascular disease (HR 95% CI, 3.76; 1.97-7.19), PAD (HR 95% CI, 1.85; 1.10-3.13) and pulse pressure (HR 95% CI,1.07; 1.00-1.14) were found to be complications of DM predicting diabetic foot ulcer (Mendel Baba Bpod (Hons) et al., 2010).

Study results on incidence and predictors of DFU showed that presence of Peripheral neuropathy (aOR 95% CI, 13.86; 3.43-56.03), peripheral vascular diseases (aOR 95% CI, 7.94; 2.63-25.19), nephropathy (95% 2.79; 1.02-7.78), ischemic heart diseases (aOR 95% CI, 4.83; 1.67-14.45), overweight/obesity (OR 95% CI, 1.66; 0.65-4.2) and hypertension (aOR 95% CI, 7.43; 2.72-20.88) were found to be complications and co-morbidities associated with diabetic foot ulcer (Leila Yazdanpanah et al., 2018; Mostafa A. Abolfotouh et al., 2011). DFU was 3.51 times more likely in patients who had neuropathy than in patients without (Leila Yazdanpanah et al., 2018). Another prospective study done by Leila Yazdanpanah and his colleagues on DFU ulcer free – survival revealed that dyslipidemia (RR 95% CI, 5.853; 1.775-19.292), diabetic neuropathy (RR 95% CI, 5.224; 2.393-11.407), retinopathy (RR 95% CI, 2.806; 1.351-5.825), nephropathy (RR 95%, 3.286; 1.410-7.658) and hypertension were found to be complications and co-morbidities associated with diabetic foot ulcer (Leila Yazdanpanah et al., 2018).

One study done by Masuomi Tomita et al had shown that microangiopathy was independent predictor of diabetic foot ulcer in diabetic patients (Masuomi Tomita et al., 2016). Once more, case-control study done in India stated that peripheral neuropathy (aOR 95% CI, 3.8; 1.70- 8.53)

and obesity (aOR 95% CI, 0.43; 0.23-0.82) were found to be complications of DM predicting development of diabetic foot ulcer (Revathi.V, 2016). Moreover, study done in United Arab Emirates stated that neuropathy, arterial disease, and peripheral neuropathy were found to be risk factors for developing foot ulceration in DM patients (Venkatramana Manda et al., 2012).

Retrospective study in Cross River State, Nigeria showed that peripheral sensory neuropathy (p_ 0.016∗) and peripheral vascular disease were found to be complications of DM predicting diabetic mellitus foot ulcer (DMFU) (Akaninyene Asuquo Otu et al., 2013). Another retrospective study done by Wondwossen and his colleagues on diabetes diseases in Ethiopian patients revealed that neuro-ischaemia and neuropathy were found to be complications of DM associated with diabetic foot ulcer (Wondwossen Amogne et al., 2011).

2.3.2. Effect of Socio-Demographic Factors

Prospective study done in Maryland revealed that younger age on onset of DM (HR 1.02 per year 95% CI; 1.01-1.04) was found to be independent predictor for foot ulcer recurrence and mean age of patients was 59.2 ± 3.8 years (Caitlin W. Hicks et al., 2019). Case-control study done by Dr.Revathi.V had shown that male sex (aOR 95% CI, 2.02; 1.16-3.51) was significant predictor of DFU in diabetic patients (Revathi.V, 2016). Another Case-control study conducted in Saudi Arabia showed that male gender (95% CI, 2.25; 1.01-5.02) and age of 40 years or more (OR 95% CI, 1.07 ;1.03-1.10) were socio-demographic factors predicting DFU (Mostafa A. Abolfotouh et al., 2011).

The prospective study conducted in Ahvaz, Iran on incidence and predictors of diabetic foot ulcer showed that male gender was found to be predictor of DFU incidence in patients with diabetes and the odds of DFU were 3.23 times more in men than in women (Leila Yazdanpanah et al., 2018). Another prospective study done by Leila Yazdanpanah and his colleagues on DFU ulcer free – survival revealed that male gender (HR 95% CI,3.278; 1.501-7.157) was found to be significant factor associated with DFU incidence in patients with diabetes (Leila Yazdanpanah et al., 2018). Furthermore, Prospective study done in Nekemte, northwest Ethiopia showed that sex was significant predictor of diabetic foot ulcer in DM patients and majority of them (55.65%) were males (Firomsa Bekele et al., 2019).

2.3.3. Effect of Clinical Features of the Diabetes Mellitus

Longitudinal study conducted in Washington revealed that wounds penetrated to bone (aOR 6.7; 2.3–19.9), wound duration of_30 days (aOR 4.7;1.6–13.4), a history of recurrent wounds (aOR 2.4;1.3–4.5) and wounds with a traumatic etiology (2.4;1.1–5.0) were found to be independent risk factors associated with DFU (Lawrence A. Lavery et al., 2006). Another lon-gitudinal study done in Australia showed that intermittent claudication (HR 95% CI, 2.77;1.52-5.04), eGFR (HR 95% CI, 2.12; 1.30-3.51), HbA1c (HR 95% CI, 1.22; 1.07-1.40), diabetes duration and antihypertensive therapy were found to be the strongest independent predictors of an active DFU in DM patients (Mendel Baba Bpod (Hons) et al., 2010).

Prospective study conducted in Manchester, UK showed that history of foot ulcers at baseline, ab normal NDS (≥ 6/10), reduced number of pedal pulses and increasing abnormal ankle reflex score were found to be clinical features associated with incidence of DFU in diabetic patients (Abbott C. A et al., 2002). Likewise, another prospective study conducted in Netherlands revealed that plantar location of the ulcer (OR 95% CI, 8.62; 2.2–33.2), presence of osteomyelitis (OR 95% CI, 5.17; 1.4-18.7), HbA1c >7.5% (OR 95% CI, 4.07; 1.1-15.6) and CRP >5 mg/l (OR 95% CI, 4.27; 1.2-15.7) were found to be independent predictors for DFU recurrence (Michal Dubsky et al., 2012).

Retrospective study done in Aarhus N., Denmark showed that Reduced muscle strength for ankle dorsal flexion, ankle plantar flexion, knee extension, and knee flexion were all related to DFU occurrence in patients with diabetes mellitus (Anne Sofie Bruno Pedersen et al., 2019). Moreover, case-control study done in India stated that presence of a previous history of foot ulcer (aOR 95% CI,18.10; 8.84- 37.06) and medication taken (aOR 95% CI, 2.63; 1.52-4.55) were significantly associated clinical factors with the development of diabetic foot ulcer in DM patients (Revathi.V, 2016). Another case-control study conducted in Saudi Arabia showed that DM diseases duration of 20 years or more (OR 95% CI, 1.09; 1.02-1.16), earlier age onset of diabetes and higher ESR (aOR 95% CI, 1.03; 1.01-1.05) were associated factors with diabetic foot ulcer (Mostafa A. Abolfotouh et al., 2011).

The prospective study conducted in Ahvaz, Iran on incidence and predictors of diabetic foot ulcer showed that previous histories of DFU (RR 95% CI, 15.13; 10.97, 20.86), foot deformity (Patients with foot deformity were 3.02 times more likely to develop DFU than were patients without) (RR 95% CI, 2.56; 2.04, 3.22), decreased distal pulses and insulin utilization were found to be significant factors for DFU incidence in patients with diabetes (Leila Yazdanpanah et al., 2018). Another prospective study done by Leila Yazdanpanah and his colleagues on DFU ulcer free – survival revealed that history of DFU (RR 95% CI, 17.521; 7.132-43.045), nephropathy callus formation in the feet (RR 95% 3.853; 1.856-7.999), vibration sensation (RR 95% CI, 15.037; 4.562- 49.570), foot deformity (RR 95% CI, 2.56; 2.04, 3.22) and diabetes duration (RR 95% CI, 1.007; 1.003-1.010) were found to be clinical factors associated with DFU in patients with diabetes mellitus (Leila Yazdanpanah et al., 2018).

Retrospective study done by Akaninyene Asuquo Otu et al showed that intermittent claudication was clinical feature predicting DFU in patients with diabetes mellitus (Akaninyene Asuquo Otu et al., 2013). Once more, study done by Kumarasinghe A. Sriyani et al showed that impaired vibration sense, abnormal monofilament test on first, third, and fifth toes were found to be clinical factors associated with DFU in diabetes mellitus patients (Kumarasinghe A. Sriyani et al., 2013).

The retrospective study done by Wondwossen and his colleagues on diabetes diseases in Ethiopian patients revealed that vision impairment and inadequate metabolic control of glucose were found to be major risk factors for diabetic foot disease (Wondwossen Amogne et al., 2011). Furthermore, prospective study done in Nekemte, northwest Ethiopia showed that bacterial infections were identified as significant predictors of diabetic foot ulcer in DM patients (Firomsa Bekele et al., 2019).

2.3.4. Effect of Patient Self Foot-Care Practices

Retrospective study done by Akaninyene Asuquo Otu et al showed that walking barefoot was patient self foot-care practices predicting DFU in patients with diabetes mellitus (Akaninyene Asuquo Otu et al., 2013). Likewise, study done by Kumarasinghe A. Sriyani et al showed that type of foot wear patients' use (wearing slippers) was found to be significant risk factor for DFU

in diabetic patients (Kumarasinghe A. Sriyani et al., 2013). The retrospective study done by Wondwossen and his colleagues on diabetes diseases in Ethiopian patients revealed that wearing ill-fitting shoes was found to be risk factor for DFU related with patient self-care practices (Wondwossen Amogne et al., 2011).

2.3.5. Effect of Patient Behavioral Factors

Prospective study done by Leila Yazdanpanah and his colleagues on DFU ulcer free – survival revealed that prior cigarette smoking (RR 95% CI, 3.303; 1.333-8.183) was found to be significant behavioral factor associated with diabetic foot ulcer in patients with diabetes mellitus (Leila Yazdanpanah et al., 2018). Another study done by Mendel Baba Bpod (Hons) et al showed that alcohol consumption (HR 95% CI, 1.16; 1.05-1.27) was found to be behavioral factor predicting diabetic foot ulcer in adult diabetic patients (Mendel Baba Bpod (Hons) et al., 2010). Once more, the retrospective study done by Wondwossen and his colleagues on diabetes diseases in Ethiopian patients revealed that lack of follow up (poor health seeking behavior) was found to be major risk factors for diabetic foot disease (Wondwossen Amogne et al., 2011).

2.3.6. Effect of Awareness Related Factors on DM and Foot Ulcer

Prospective study conducted in Manchester, UK showed that any previous podiatry or foot care advice (RR 95% CI,3.23; 2.27, 4.60) was significant knowledge about DM and DFU related predictor of diabetic foot ulcer (Abbott C. A et al., 2002). Another prospective study done by Leila Yazdanpanah and his colleagues on DFU ulcer free – survival revealed that patients' advice on self-care of their feet was found to be knowledge related predictive factors for DFU in patients with diabetes mellitus (Leila Yazdanpanah et al., 2018).

2.4. Conceptual Framework

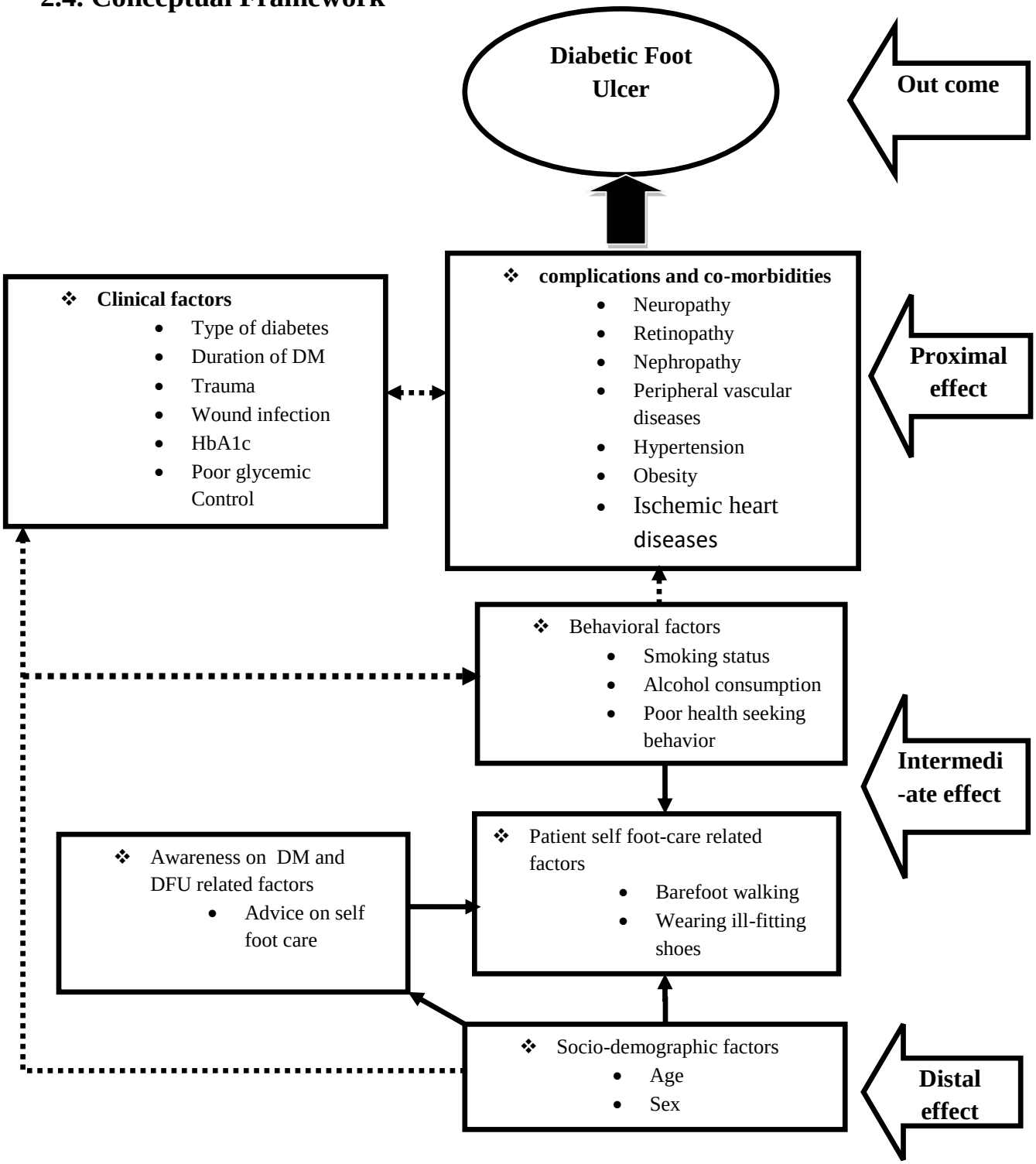

Figure 1.Conceptual framework describing the effect of complications and co-morbidities on diabetic foot ulcer among adult diabetic patients attending public hospitals, Hadiya Zone, Southern Ethiopia, 1 January 2015 to 31 December 2019

3. METHODS AND MATERIALS

3.1. Study Area and Period

The study was carried out in Hadiya zone public hospitals. Hadiya Zone, one of the major Zones in Southern Nations, Nationalities and Peoples Regional State (SNNPRS).Hadiya Zone is located in the northern part of the Southern region of Ethiopia. Its capital, Hosanna, is 232 kilo-meters south of Addis Ababa and situated 196 Km from Hawassa which is the capital city of SNNPRS. Hadiya Zone has a population of 1.5 million and it is divided in to 14 districts, including Hosanna town. Hadiya zone has four public hospitals namely: Wachemo University Nigist Elleni Mohammed Memorial Teaching hospital, Shone, Gimbichu and Homacho primary hospitals which are located in Hosanna town the capital city of Hadiya Zone, Shone town the capital of Shone town administration, Gimbichu town capital of Gimbichu Town Administration and Homacho town the capital of Gibe district. From the total 1.5 million population of Hadiya zone 750,320 (50.74%) females and 728,560 (49.26%) males, 1,324,185 (89.54%) rural population and 154,695 (10.46%) urban population according to 2017 population projection (FDRE CSA, 2017). Wachemo University Nigist Elleni Mohammed Memorial Teaching hospital was built in 1984 GC and it was serving people from Hosanna town and its perspective Woredas. The public hospitals provide services in various outpatient and inpatient departments. Hospitals have been providing chronic diabetes care and support to both new and follow up patients since the emergence of the diseases and their establishment. The study period was from March 01 to 15, 2020.

3.2. Study Design

An institution based retrospective cohort study design was undertaken.

3.3. Source Population

All adult patients with diabetes mellitus who had been on chronic follow up in public hospitals of Hadiya zone were source populations for this study.

3.4. Study population

All adult diabetic patients who had been on chronic follow up between 1 January 2015 and December 2019 were study population and adults with chronic complications and co-morbidities at entry were exposed and those with no chronic complications and co-morbidities were non-exposed.

3.5. Inclusion and exclusion criteria

3.5.1. Inclusion criteria

Diabetic patients who were ages 18 years and older with no diabetic foot ulcer at the time of start of diabetes care during the retrospective study period were included in the study. Adults' records of at least one follow up visit including the initiation of the care fulfilling eligibility were included in the study.

3.5.2. Exclusion criteria

Adult diabetic patients who were on follow up between 1 Jan 2015 and 31 December 2019 had minimum and maximum follow up period of 0.3 and 58 months, respectively. Participants' registration that had unknown initiation date, outcome of interest at the beginning, undefined outcome, and transferred in with incomplete baseline data minimizing important factors were excluded. Adults who are transferred out to other health facilities were also excluded.

3.4. Sample Size Determination

Objective one: The required sample size for objective one was determined using formula for event and sample size calculation with the following assumptions: The significance level of 5%, 95% confidence level, 80% power, and $\pi 1$ and $\pi 2$ are the proportions to be allocated to groups 1 and 2 and for equal allocation $\pi 1 = \pi 2 = ½$ (Equal allocation ($\pi 1 * \pi 2 = ¼$). p =17.86%, taken from the proportion of diabetic foot ulcer and incidence rate(IR) = 59.52 per 1000 person year that converted to five years gives 0.297 person-year in study conducted in northwest Ethiopia (Firomsa Bekele, 2019) and Based on the above assumption HR = - log(s/t) = 0.748 ; s/t was proportion of DFU.

Event = $(Z_{\alpha/2}+Z_{\beta})\ ^{2}4/\ ((\ln HR)\ ^{2}))$ = 373 (Collet, 2013)

Where $Z_{\alpha/2}$ and Z_{β} are standard normal percentiles which give 1.96 (95% CI) and 0.84(80%)

N = Events / Pr (event), where Pr is the probability of an event and it is calculated by

Pr{event} = 1 - (π1S1 (T)+ π 2 S 2 (T)) = 1 – 1/2 (S1 (T)+ S 2 (T) where S(T)= exp (-λt), IR = λt and $S1(t_5)$ = exp (-0.297) = 0.743 and $S2(t_5)$ = Exp (- 0.297 * HR) =0.801

Pr {event} = 1 – 1/2 (S1 (T) + S 2 (T) = 1- 1/2 (0.743+0.801) = 0.228

N= N_{ev}/Pr (event) = 373/0.227 =1,636

Objective two: Sample size for objective two was performed by using Stata command of power log rank, Schoenfeld method by considering the following parameters: significance level (α) of 5%, Power (1-β) of 80%, the hazard ratio of 0.645 for age of patient with DFU Vs no DFU (Firomsa Bekele et al., 2019), withdrawal of 10% for incomplete data during follow up period and in adjusting for censoring 0.5 of the probability of event taken and allocation ration 1:1. By having all the above parameters; the Stata command for estimated sample sizes for two-sample comparison of survivor functions calculated for specific objective two was 422.

From both objectives sample size calculations; the objective one sample size 1,636, the largest even greater than total study populations in public hospitals was not feasible for the study, but the objective two sample size which was calculated for factor age of patients with DFU Vs without gave the optimum sample size that was 422. Therefore, the final sample size was 422; 210 exposed and 212 unexposed, respectively. The total adult population of the study hospitals was 675 and used for this study as a source population.

3.5. Sampling Procedure and Technique

First the two public hospitals were stratified in to primary and secondary hospitals based on level of service they provide. Then, the study subjects from each stratum were taken by proportional allocation in accordance with population size they had. The study participants were identified from each hospital's diabetic follow up cohort database by listing medical record number according to the start date of the follow-up.

Then after, study participants' record was selected by simple random sampling method using age and eligibility criteria and included for data review. Profiles of all adult patients receiving diabetic care between 1 January 2015 and 31 December 2019 were reviewed for event diabetic foot ulcer. The calculated minimum total sample size was 422 and the total study population at public hospitals of the Hadiya Zone was 675. 401 study population fulfilling eligibility criteria were included for this study. Patients in the exclusion list were excluded. Data about DFU were collected from patients' folder by tracing their medical records from database/patient folder.

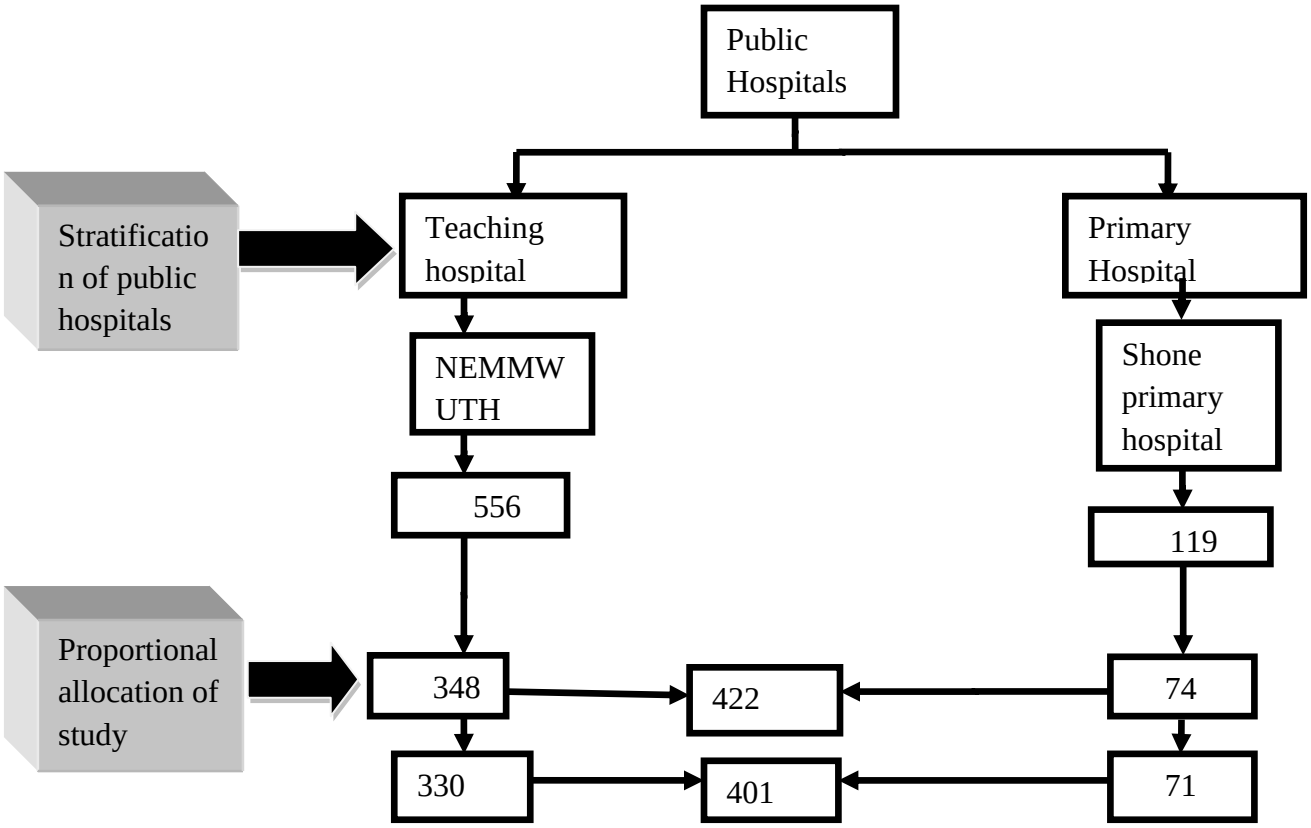

Figure 2.Showing the sampling procedures of study populations for the study that was conducted in Hadiya zone public hospitals, March 01 to 15, 2020

3. 6. Data Collection Methods

The data were extracted using data extraction format, which adapted from review of relevant literatures and was used as a tool for this study. The extraction format included information about Socio-demographic characteristics like age and sex and behavioral factors like smoking status and alcohol consumption. Data on clinical, complications and co-morbidities, patient self foot-care and awareness on DM and DFU related factors like history of DFU, duration of DM,

type of diabetes mellitus, HbA1c level, neuropathy, retinopathy, nephropathy, peripheral vascular diseases, hypertension and advice on patient foot self-care, Walking barefoot and Wearing ill-fitting shoes were extracted from patient folder/database. Two diploma Nurses from outpatient department (OPD) and one data clerk were recruited as data collectors to extract information from the individual folders or database after they had given two days intensive training on how to review records of the patients. Along with the two supervisors (BSc.) nurses from OPD were also involved during data collection time to supervise the overall data collection process.

3.6.1. Data Collection Procedure

The data for this study were collected by using secondary data collected routinely in Hadiya zone public hospitals for clinical monitoring and evaluation purposes. The data entered in a patient folder or electronic database and updated during the follow-up time were used. Structured data extraction format was used for extracting information from individual folder or electronic database. Patients who developed foot complication during follow up period their clinical status were recorded on their individual folder and outcome status labeled as diabetic foot ulcer. This diabetic foot ulcer was an event during data collection period.

3.7. Measurement of Variables

Time to development of diabetic foot ulcer was dependent variable for this study. Diabetic foot ulcer defined as a non-traumatic lesion of the skin (partial or full thickness) on the foot of a person who has diabetes mellitus (Alvin C. Powers *et al.*, 2015). Patients who experienced diabetic foot ulcer starting from the first registration date and on wards by tracing their medical records were identified as event and those who did not develop diabetic foot ulcer as censored.

Independent variables were socio-demographic characteristics like sex, age. complications and co-morbidities, clinical, behavioral, patient self foot-care and awareness on DM and DFU related factors were like neuropathy, retinopathy, nephropathy, peripheral vascular diseases, hypertension, obesity, history of DFU, duration of DM, type of diabetes mellitus, HbA1c, glycemic control, wound infection, smoking status, alcohol consumption, advice on patient foot self-care, walking barefoot and wearing ill-fitting shoes.

3.8. Operational Definitions

Diabetic foot ulcer: is a non-traumatic lesion of the skin (partial or full thickness) on the foot of a person who has diabetes mellitus (Alvin C. Powers *et al.*, 2015).

Time to event (diabetic foot ulcer): The time from the start of diabetes mellitus care to the development of DFU that can be expressed in persons- months observations.

Baseline complications of DM: The micro-vascular (neuropathy, retinopathy and nephropathy) and macrovascular (peripheral arterial diseases, cerebrovascular diseases, myocardial infarction and ischemic heart attack) diseases present in diabetic patients at diagnosis due to poor glycemic control (Alvin C. Powers *et al.*, 2015).

Baseline co-morbidities with DM: The co-occurrence of diseases such as hypertension, obesity, ischemic heart diseases and dyslipidemia together with diabetes mellitus in the same patient as a result of diabetes mellitus itself or due to other factors at diagnosis (Alvin C. Powers *et al.*, 2015).

Incidence rate: Number of patients with DFU among adult patients on diabetic follow- up care per person at risk person - time observations. Numerator = number of patients with DFU during the entire follow up period. Denominator = Time each person observed totaled for all persons (total person-month observations).

Severity of Diabetic Foot Ulcer: It can be described using Wagner's Classification as;

***Grade 0*:** no ulcer, but the foot is at risk for ulceration.

***Grade1*:** superficial ulceration.

Grade2: ulcer with deep infection without involvement of bone.

Grade3: ulcer with deep infection with involvement of bone (osteomyelitis).

***Grade4*:** localized gangrene.

Grade5: gangrene of the whole foot.

Body Mass Index (BMI): It is the ratio of the individual patient's body weight to his/her height squared and its' ranges can be described as; BMI < 18.5 kg/m2 = underweight, BMI ranges 18.5–24.5 kg/m2 = normal, BMI ranges from 24.5 to 30 kg/m2 = overweight and BMI > 30 kg/m2 = obese.

Diabetic Neuropathy: It will be diagnosed if the patient has at least one manifestation from the following list; burning pain, vibration loss from the skin, gradual numbness, dizziness, extreme insensitive to touch, muscle weakness, and lack of coordination (Alvin C. Powers *et al.*, 2015).

Diabetic Retinopathy: Non-inflammatory vision impairment problem resulted from damage to small blood vessels and neurons of the retina in known diabetic patients (Yesil et al., 2009).

Diabetic nephropathy: It will be diagnosed if the following manifestations like high blood sugar, advanced glycation end product formation and damaged glomerular filtration barrier are observed in patients with diabetes (Alvin C. Powers *et al.*, 2015).

Glycemic control: We will consider that the blood glucose is in control if the fasting blood glucose level is between 70 to 130mg/dl and post meal glucose of less than 180mg/dl (Alvin C. Powers *et al.*, 2015).

Peripheral Vascular Disease: It is an arterial and venous disease at the peripheral region characterized by leg pain, skin ulcers, cold skin, poor nail and hair growth which often occurs in diabetic patient (Alvin C. Powers *et al.*, 2015).

Censored: Patients who have not experienced the event of interest (DFU) during the specified study follow up period.

3.9. Data Quality Control

The data extraction format was developed in English from the review of relevant literatures and patient registration book as well. Before actual data collection, the data retrieval form was pre-tested in 5 % of total sample on the same source of record review in the hospital. Based on the findings of pre-test some modification was done for the tools. Then, data collection was conducted using a data retrieval form. Two days intensive training to data collectors and supervisors, about the purpose, study tool and an overall data collection procedure to be eminently maintained by them during data collection time, was given. The supervisors checked the completeness and consistency of the filled data retrieval form immediately before

submission. In addition, double data entry was done by two data clerk and checked for validation by the principal investigator of the research. Data was cleaned for outliers, missing values, incompleteness, and inconsistency. The principal investigator supervised the overall quality of the data collection.

3.10. Methods of Data Analysis

Following the data collection activities, the data was entered to Epi Data version 3.1, and exported to statistical packages Stata version 14.2 for data processing and analysis. Descriptive statistics was done to summarize findings and the result was reported using mean (SDs) and median (IQR) for continuous variables and percentage to investigate the characteristics of the categorical data. Person-months of follow up were calculated by assessing the date of start of diabetic care or censoring. Kaplan-Meier survival curves were used to examine the cumulative probability of time to development of diabetic foot ulcer among categorized variables. The time to event was calculated in months using the time interval between the date of diabetic care initiation and date of event or censoring. The log-rank test was used to test the significance of observed differences between categories and considered statistically significant at a p-value less than 0.05. Then bivariate analysis was carried out to identify candidate variables associated with event (outcome) variable for multivariate Cox regression analysis model. Variables significant and not significant with $P < 0.25$ in bivariate analysis were entered into multivariate Cox proportional hazards regression model to determine their effect on DFU. Life table was used to estimate the probability of developing diabetic foot ulcer (event) every twelve months. Moreover, Schoenfeld residual test greater than 0.05 was used to check the proportionality hazard assumption and proportionality hazard assumption graphically checked. Finally, the decision was made using the adjusted hazard ratio (AHR) and confidence interval (CI) at 95% confidence level and with $P < 0.05$ to declare variables significance. Multicollinearity was checked by using variance inflation factor greater than 10 and variables that have multicollinearity sign were dropped out. Data was censored for development of DFU based on record if it occurred at the end of study period. Data was censored on 15, March 2020 GC.

3.11. Ethical Considerations

Ethical clearance was obtained from Haramaya University, college of health and medical science institutional health research ethics review committee (IHRERC). A permission letter obtained from the school of graduate studies was submitted to Hadiya zone public hospitals to grant official permission. After discussion and explanation about the purpose, method and anticipated benefit of the study by principal investigator; informed, voluntary, written and signed consents was obtained from hospitals heads to ensure confidentiality, prior to the actual data collection. The heads were given the right to ask any question and refuse the study at any time during data collection. Privacy and confidentiality of the information provided by each record review was kept properly. For this purpose, names and medical record number and other specific addresses were not reviewed.

3.12. Information Dissemination

The findings of this study would be primarily submitted to Haramaya University College of health and medical science, school of graduate studies. In addition, it would also be disseminated to Hadiya zone public hospitals. Besides, the study findings would be considered to be published and present on local or international conferences and peer-reviewed journals.

4. RESULTS

4.1. Socio-demographic Characteristics

A total of 422 adult diabetic patients' were included in the study. Of these, 401 of the patients' medical records were included in the study which makes data availability of 47.4% and 47.63% for both exposed and unexposed groups, respectively and overall of 90.72%.

Most of the respondents were males; 138 (47.26%) and 154 (52.74%) exposed and unexposed to at least one of the baseline complications (co-morbidities), respectively and the difference between the cohorts was not significant (p =0.086). The mean ages for both exposed and unexposed were 49.49 (±10.22) and 43.65 (±8.69), respectively and the difference was statistically significant (p = 0.010).

Table1.Baseline socio-demographic characteristic of the study participants in public hospitals of Hadiya zone, south central Ethiopia, from 1 January 2015 to December 31, 2019

Variables	Baseline complications				
	At least one baseline complication present (n = 200)		No baseline complication (n = 201)		Chi2 P-value
Sex (n = 401)					0.086
Male	138	47.26%	154	52.74%	
Female	62	56.88%	47	43.12%	

4.2. Behavioral and Awareness on DM and DFU related characteristics

When the advice status of the study cohorts compared, most of the respondents took advice about DM and DFU after the start of DM treatment;139 (50.73%) and 135 (49.27) among exposed and unexposed to at least one of the baseline complications, respectively. The observed difference between the two cohorts in relation to advice status was not statistically significant (p = 0.615). Regarding the barefoot walking, 23 (79.31%) and 6 (20.69%) of the respondents had history of barefoot walking among exposed and unexposed groups, respectively and the difference was significant (p = 0.001).

About 19 (70.37%) and 8 (29.63%) of the respondents had history of wearing ill-fitting shoes among exposed and unexposed, respectively (p = 0.027). Similarly, about 39 participants; 33 (84.62%) and 6 (15.38%) had history of cigarette smoking among exposed and unexposed, respectively. Moreover, when alcohol drinking status of respondents compared, about 31 (81.58%) and 7 (18.42%) of the respondents had history of alcohol drinking; among exposed and unexposed, respectively (p = 0.000). Most of the respondents had regular follow up; 140 (45.44%) and 175 (54.56%) exposed and unexposed to at least one baseline complications (co-morbidities), respectively (p = 000).

Table 2.Behavioral and awareness related characteristics of the respondents in public Hospitals of Hadiya Zone, Southern Ethiopia, from 1 January 2015 to December 31, 2019

Variables	Baseline complications (co-morbidities)				
	At least one baseline complication present (n = 200)		No baseline complication (n = 201)		Chi2 P-value
Patient took training about DM and DFU (n = 401)					0.615
Before the start of the treatment	61	48.03%	66	51.97%	
After the start of the treatment	139	50.73%	135	49.27%	
History of barefoot walking (n = 401)					0.001
Yes	23	79.31%	6	20.69%	
No	177	47.58%	195	52.42%	
Patient history of wearing ill-fitting shoes (n = 401)					0.027
yes	19	70.37%	8	29.63%	
No	181	48.40%	193	51.60%	
Patient history of cigarette smoking (n = 401)					0.000
Yes	33	84.62%	6	15.38%	
No	167	46.13%	195	53.87%	
Patient history of alcohol drinking (n =401)					0.000
Yes	31	81.58%	7	18.42%	
No	169	46.56%	194	53.44%	
Patient come appointment regularly (n =401)					0.000

Yes	140	44.44%	175	55.56%	
No	60	69.77%	26	30.23%	
Number of appointments patient missed (n= 401)					0.001
No	140	44.44%	175	55.56%	
One	23	63.89%	13	36.11%	
Two and above	37	74.00%	13	26.00%	
Patient contacted health professionals (n =401)					
Yes	192	49.23%	198	50.77%	0.124
No	8	72.73%	3	27.27%	

Note; percentages are row percentages and chi2 = Chi-square p-value

4.3. Baseline complications and co-morbidities related with diabetes mellitus

Among the exposed 200 respondents at baseline; 38 (19%) and 162 (81%) were exposed and unexposed to retinopathy, respectively. Similarly, among the exposed 200 respondents at baseline; 54(27%) and 146 (73%) were exposed and unexposed to nephropathy, respectively. Moreover, of the 200 exposed respondents; 42 (21%) and 158 (79%) were exposed to peripheral neuropathy at baseline, respectively.

Of the 200 study participants exposed at baseline; 31 (15.50%) and 169 (84.50%) were exposed and unexposed to peripheral vascular diseases, respectively. Similarly, out of the 200 exposed study participants at baseline; 167 (83.50%) and 33 (16.50%) were experienced and not experienced hypertension, respectively. Likewise, of 200 respondents exposed to at least one of the baseline complications; 16 (8%) and 184 (92%) were exposed and unexposed to obesity, respectively. Furthermore, among 200 study participants exposed at baseline; 31 (15.50%) and 170 (84.50%) were developed and not developed ischemic heart diseases at baseline, respectively.

Table **3.**Baseline complications and co-morbidities of DM among adult diabetic patients in public hospitals of Hadiya Zone, Southern Ethiopia, from 1 January 2015 to December 31, 2019

Variables	Baseline complications or co-morbidities		
	At least one baseline complication present (n = 200)	No baseline complication absent (n = 201)	Chi2 P - value

Retinopathy	38	19%	0	0.000
Nephropathy	54	27%	0	0.000
Peripheral neuropathy	42	21%	0	0.000
Peripheral vascular diseases	31	15.5%	0	0.000
Hypertension	167	83.5%	0	0.000
Obesity	16	8%	0	0.000
Ischemic heart diseases	31	15.5%	0	0.000

Note; percentages are column total percentages and chi2= chi-square p-value

4.4. Clinical features of DM while patients were on follow up

When comparing respondents according to type of DM they suffered; about 192 (50.66%) and 187 (49.34%) were sufferers of type II DM among patients with and without baseline complications or co-morbidities, respectively. The observed difference between the groups was not statistically significant (P = 0.192). Similarly, there was significant difference in the fasting level of glycemic control between the cohorts; nearly two third (65.70%) and more than one third (34.30%) of the respondents' fasting glycemic level was persistently more than 130mg/dl for groups with and without baseline complications or co-morbidities, respectively (p = 0.000).

Regarding the BMI of the respondents; Most of their BMIs were in the range of 18-24.5kg/m^2; 141 (44.76%) and 174 (55.24%) among exposed and unexposed to at least one of the baseline complications (co-morbidities), respectively (p = 0.000). Similarly, when the two study cohorts were compared according to recent blood pressure; 171 (69.51%) and 75 (30.49%) of the respondents' BP was more or equals 140/90mmhg for those with and without baseline complications (co-morbidities), respectively. The observed difference for BP was statistically significant (p = 0.000). Likewise, among the respondents in both cohorts with BP of more than 140/90mmhg; 158 (74.18%) and 55 (25.82%) of them started anti-hypertensive treatment from exposed and unexposed to baseline complications (co-morbidities), respectively.

Most of the respondents pulse pressure was persistently more than 40mmhg; 170 (69.39%) and 75 (30.61%) among exposed and unexposed to baseline complications (co-morbidities), respectively (p = 0.000). Similarly, higher proportion of respondents' HbA1c measured in recent three months was more than 5.2%; 124 (68.51%) and 57 (31.49%) for groups with and without

baseline complications (co-morbidities), respectively and the observed difference between the groups was significant (p = 0.000). Likewise, regarding ESR status of the study participants; about 70 (75.27%) and 23 (24.77%) had ESR of more than 7mm/hr for groups exposed and unexposed to baseline complications (co-morbidities), respectively (p = 0.000). Moreover, when respondents compared according to trauma status, about 39 (67.24%) and 19 (32.76%) of them had history of trauma among groups with and without baseline complications (co-morbidities), respectively and the difference seen between the two groups was significant (p = 0.004).

Of the 401 respondents; about 30 (69.77%) and 13 (30.23%) had history of wound infection among the respondents with and without baseline complications, respectively (0.006). Once more, among the 36 respondents who had wound infection history; 13 (65.00%) and 7 (35.00%) of them had recurrent wound infection in both exposed and unexposed to at least one of the baseline complications (co-morbidities), respectively (p = 0.019). Moreover, from those study participants who had wound infection; 7(58.33%) and 5 (41.67%) had wound infection involved bone for groups with and without baseline complications (co-morbidities), respectively (p = 0.022).

Most of the respondents' C-reactive protein level was in the range of 5-10gm/l; 81 (39.13%) and 126 (60.87%) for those respondents with and without baseline complications (co-morbidities), respectively (p = 0.000). Similarly, of the 401 study participants; 9 (81.82%) and 2(18.18%) of them had foot deformity among patients with and without baseline complications (co-morbidities), respectively (p = 0.032). Moreover, during the five year study period; 22 (84.62%) and 4 (15.38%) respondents developed diabetic foot ulcer among exposed and unexposed to baseline complications (co-morbidities), respectively. The observed difference between the two groups was statistically significant (p = 0.000). Among the 26 respondents who developed diabetic foot ulcer in the exposed to at least one of the baseline complications (co-morbidities); 4, 7,6 and 5 had grade I, II, III, and IV ulcer, respectively. The observed difference between the two cohorts was statistically significant (p = 0.007).

Table 4.Clinical features of DM in adult diabetic patients on follow up in Hadiya Zone public Hospitals, Southern Ethiopia, from 1 January 2015 to December 31, 2019

Variables	Baseline complications (co-morbidities)				
	At least one baseline complication present (n = 201)		No baseline complication (n = 200)		Chi2 P-value
Type of DM (n =401)					0.192
Type I	8	36.36%	14	63.64%	
Type II	192	50.66%	187	49.34%	
Fasting level of glycemic control (n =401)					0.000
Persistently 70-130mg/dl	64	32.99%	130	67.01%	
Persistently > 130mg/dl	136	65.70%	71	34.30%	
Post meal level of glycemic control (n =401)					0.000
< 180mg/dl	39	26.71%	107	73.29%	
>180mg/dl	161	63.14%	94	36.86%	
BMI of the patient measured at every visit (n =401)					
Persistently 18-24.5kg/m^2	141	44.76%	174	55.24%	0.000
Persistently 24.5-30kg/m^2	40	70.18%	17	29.82%	
Persistently >30kg/m^2	19	65.52%	9	34.48%	
BP of the patient measured at every visit (n =200)					0.000
Persistently 110/80-130/80mmhg	29	18.71%	126	81.29%	
Persistently =>140/90mmhg	171	69.51%	75	30.49%	
Took anti-hypertensive treatment (n =243)					0.000
Yes	158	74.18%	55	25.88%	
No	12	40%	18	60%	
Pulse pressure recorded at every visit (n =401)					0.000
Persistently 30-40mmhg	30	19.23%	126	80.77%	
Persistently >40mmhg	170	69.39%	75	30.61%	
HbA1c of the patient measured at every three months (n = 401)					0.000
4.9-5.2%	76	34.55%	144	65.45%	
> 5.2%	124	68.51%	57	31.49%	
Erythrocyte Sedimentation Rate (n =401)					0.000
3-7mm/hr	130	42.21%	178	57.79%	
>7mm/hr	70	75 .27%	23	24.73%	
History of trauma (n =401)					0.004

Yes	39	67.24%	19	32.76%	
No	161	46.94%	182	53.06%	
History of wound infection (n =401)					0.006
Yes	30	69.77%	13	30.23%	
No	170	47.49%	188	52.51%	
Recurrent wound infection (n= 43)					0.019
Yes	13	65.00%	7	35.00%	
No	17	73.91%	6	26.09%	
Wound infection involved bone (n=43)					0.022
Yes	7	58.33%	5	41.67%	
No	23	73.33%	8	26.67%	
C-reactive protein recorded at each visit					0.000
5-10gm/l	119	61.34%	75	38.66%	
>10gm/l	81	39.13%	126	60.87%	
Foot deformity					0.032
Present	9	81.82%	2	18.18%	
Absent	191	48.97%	199	51.03%	
Developed diabetic foot ulcer during the follow up period					0.000
Yes	22	84.62%	4	15.38%	
No	178	47.47%	197	52.53%	
Grade of foot ulcer					0.007
Grade I	4	100%	0		
Grade II	7	87.50%	1	12.50%	
Grade III	6	85.00%	2	25.00%	
Grade IV	5	83.33%	1	16.67%	

Note; percentages = row total percentages

4.5. Incidence rate of diabetic foot ulcer

All the study participants (401) contributed a total of 8941.6 person-months of observations; 4675.8 person- months in the cohort with baseline complication and 4265.8 person-months in the cohort without baseline complications or co-morbidities, respectively. 22 patients (subjects) developed diabetic foot ulcer in the cohort with at least one baseline complications (co-morbidities) and 4 patients developed diabetic foot ulcer in the cohort without baseline complications (co-morbidities).

The incident rate of diabetic foot ulcer was 4.7/1000 person-months with 95% CI of (3.1/1000, 7.1/1000) in the group with at least one baseline complications (co-morbidities) and 0.93/1000 person-months with 95% CI of (0.35/1000, 2.5/1000) in the cohort without at least one baseline complications (co-morbidities), respectively. The overall incidence rate in both cohorts was 2.9/1000 person-months with 95% CI of (1.97/1000, 4.3/1000). There was variation in proportion of diabetic foot ulcer among cohorts with and without at least one baseline complications: 22 [11%, 95% CI (7.02%, 16.2%)] and 4 [1.9%, 95% CI (0.54, 5.02)], respectively. The overall proportion of diabetic foot ulcer was 6.48% with 95% CI of (4.28, 9.35).

The median time to develop diabetic foot ulcer showed variation for both cohorts; 22.85 months and 21.5 months for those with and without at least one baseline complications (co-morbidities), respectively. There was variation in occurrence of diabetic foot ulcer in both cohorts; at 3 months and 14 months for the cohort with and without at least one baseline complications (co-morbidities), respectively. Nearly three fourth and all of diabetic foot ulcer cases occurred after 12 months of follow up for cohorts with and without baseline complications (co-morbidities), respectively. The life table analysis showed that the probability of developing diabetic foot ulcer at 12 and 24 months in the cohort with at least one baseline complication (co-morbidity) was 3.34% and 7.12%, respectively. The corresponding values in the cohort without baseline complication (co-morbidity) were 0 and 2.49%, respectively.

Table 5. Life table analysis of diabetic foot ulcer among adult diabetic patients on follow up in Public Hospitals, Hadiya Zone, Southern Ethiopia, from 1 January 2015 to December 31, 2019

Baseline complications	Months of follow up	beginning total	cumulative failure	95% CI	
Present	0 -12	200	0.0334	0.0152	0.0729
	13-24	153	0.0712	0.0397	0.1258
	25-36	98	0.1214	0.0725	0.1996
	37-48	46	0.3230	0.2055	0.4839
	49-60	8	0.3230	0.2055	0.4839
Baseline complications					
Absent	0-12	201	0		
	13-24	150	0.0249	0.0081	0.0752
	25-36	88	0.0249	0.0081	0.0752
	37-48	21	0.0249	0.0081	0.0752
	49-50	4	0.4149	0.0779	0.9711

Log-rank test for equality of survivor functions

Cohort had Baseline complication	Events observed	Events expected
Yes	22	14.96
No	4	11.04
Total	26	26.00

chi2 (1) = 8.05 Pr>chi2 = 0.0045

Figure 3.Log-rank test showing difference of survival for diabetic patients with and without baseline complications (co-morbidities) in Public hospitals, Hadiya Zone, Southern Ethiopia, from 1 January 2015 to 31 December 2019

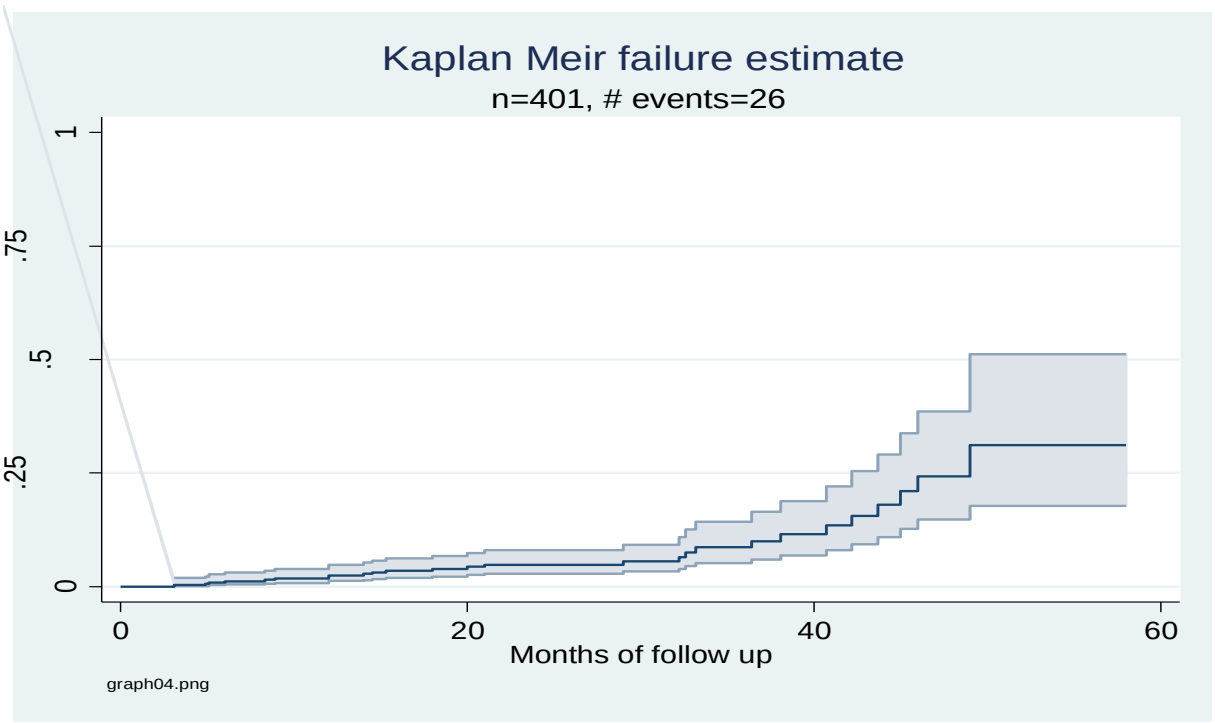

Figure **4.**Showing overall probability of diabetic foot ulcer for retrospective cohort study conducted in public Hospitals, Hadiya Zone, Southern Ethiopia, from 1 January 2015 to 31 December 2019

Single Kaplan- Meir curve showed that there was increase in diabetic foot ulcer incidence over the study period indicating that there was corresponding decrease in diabetic foot ulcer free survival (fig 4). Likewise, double Kaplan- Meir curve showed that there was variation in foot ulcer incidence for both cohorts over the study period; there was continuous increasing in the cohort with baseline complications, but constant from month 20 to month 50 for cohort without baseline complications (co-morbidities), respectively. Then after 50th month it tends to increase in the cohort without baseline complications (co-morbidities) (fig 5).

The Kaplan-Meier failure analysis and log-rank test were used to compare the failure probabilities of the two groups. The overall probability of developing diabetic foot ulcer in the cohort with baseline complications was significantly different from that of the cohort without baseline complications (co-morbidities), i.e., the risk of developing DFU was higher in the cohort with baseline complications (co-morbidities) (log rank, p = 0.0045) (Fig.3).

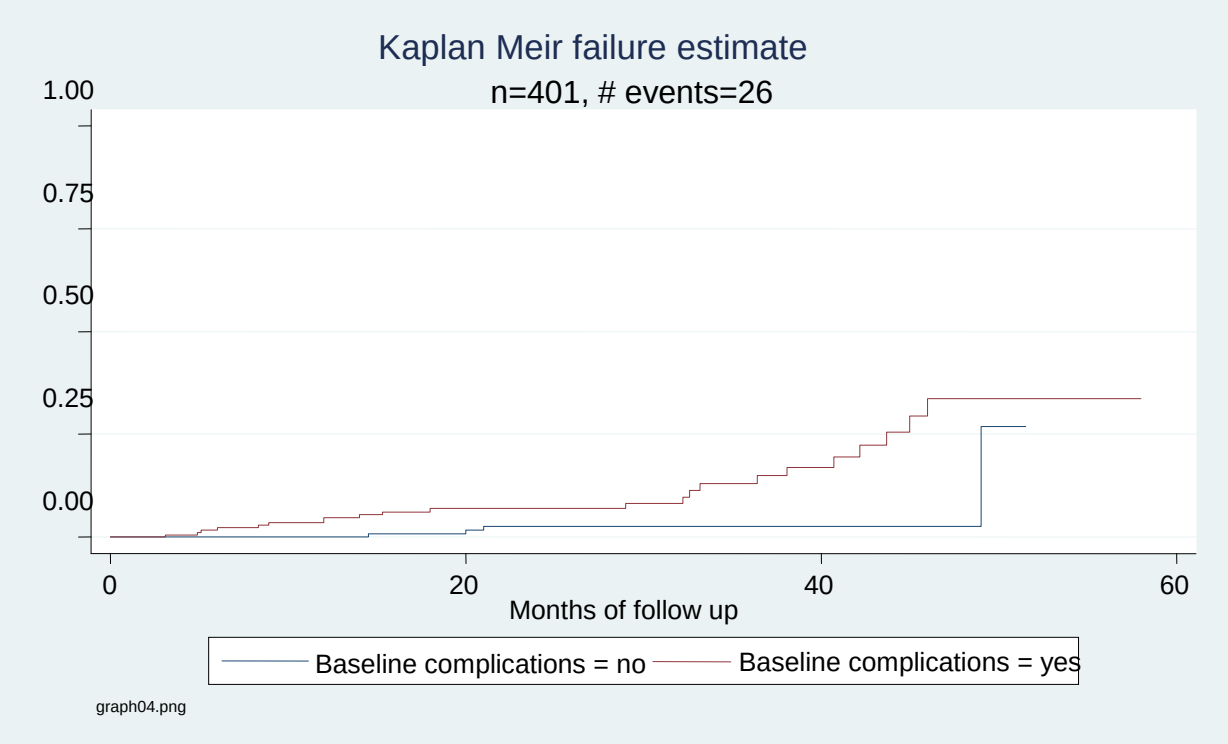

Figure **5.**Kaplan-Meir failure estimate of diabetic foot ulcer among adult diabetic patients with and without baseline complications (co-morbidities) in Public Hospitals, Hadiya Zone, Southern Ethiopia, from 1 January 2015 to 31 December 2019

4.6. Effect of socio-demographic, behavioral, awareness, baseline complications or co-morbidities and clinical features related characteristics on incidence of diabetic foot ulcer

In bivariate analysis; age, barefoot walking, wearing ill-fitting shoes, cigarette smoking, alcohol drinking, follow up status, patients' health professionals contact status (health seeking behavior), retinopathy, nephropathy, peripheral neuropathy, peripheral vascular diseases, hypertension, obesity and ischemic heart diseases, fasting glucose level, BMI, history of trauma, history of wound infection, C- reactive protein and foot deformity were identified as having effect on incidence of diabetic foot ulcer.

The risk of DFU was higher among patients who had retinopathy at baseline than those without retinopathy (CHR = 6.64, 95% CI; 2.97 14.81)*. Similarly, the hazard of DFU was higher in patients who had nephropathy at baseline compared with patients who had no nephropathy (CHR

= 6.47, 95% CI; 2.94 14.22) **. Likewise, the risk of developing DFU was higher in patients with peripheral neuropathy at baseline compared to those without it baseline (CHR = 11.37, 95% CI; 5.02 25.77) **. Furthermore, the risk of DFU was higher in patients who had peripheral vascular diseases at baseline than those who had no peripheral vascular diseases at baseline (CHR = 5.19, 95% CI; 2.31 11.66) **.

The hazard of developing diabetic foot ulcer was higher in patients who had hypertension at baseline than those who had no hypertension (CHR = 3.64 95% CI; 1.44 9.15)*. Similarly, the risk of DFU was higher in diabetic patients who had obesity at baseline compared with those who had no obesity at baseline (CHR = 5.81, 95% CI; 2.15 15.70) **. Moreover, the hazard of developing DFU was 4.57 times higher in patients with baseline ischemic heart diseases than patient without baseline ischemic heart diseases (CHR = 4.57, 95% CI; 1.89 11.00) **.

When there was one unit increase in age of respondents, the risk of DFU increased by 10% (CHR = 1.09, 95% CI; 1.06 1.14). Similarly, the hazard of DFU was higher in patients who smoked cigarettes compared with those who did not smoke (CHR = 3.80 95% CI; 1.65 8.77) **. Likewise, the risk of developing diabetic foot ulcer was higher in patients who drank alcohol than those who did not drink (CHR = 7.76, 95% CI; 3.53 17.06) **. Furthermore, the hazard of DFU was higher in diabetic patients who had no regular follow up than those who had regular follow up (CHR = 3.65, 95% CI; 1.65 8.05) *.

The risk of diabetic foot ulcer (DFU) was higher in patients with fasting glycemic control of more than 130mg/dl compared with patients whose fasting glycemic control was in the range of 70- 130mg/dl (CHR = 2.72, 95% CI; 1.73 19.45). Similarly, the risk of developing DFU in patients with history of wound infection was 10.37 times higher than those who did not have wound infection history (CHR = 10.37, 95% CI; 4.59 23.44). Furthermore, the risk of developing DFU was 10.20 times higher in patients with foot deformity than patients with normal foot (CHR =8.60, 95% CI; 3.19 23.18) **.

Table 6. Bivariate analysis of predictors of diabetic foot ulcer among adult diabetic patients in Public Hospitals, Hadiya Zone, Southern Ethiopia, from 1 January 2015- December 31, 2019

Predictors	Diabetic foot status		CHR 95% CI	P- Value
	Developed	censored		
Retinopathy at baseline				
Present	10	28	6.64 (2.97 14.81)*	0.000
Absent	16	247	ref	
Nephropathy at baseline				
Present	15	39	6.47 (2.94 14.22)*	0.000
Absent	11	336	ref	
Peripheral Neuropathy at baseline				
Present	17	25	11.37 (5.02 25.77)*	0.000
Absent	9	350	ref	
Peripheral vascular diseases at baseline				
Present	9	22	5.19 (2.31 11.66)*	0.000
Absent	17	353	ref	
Hypertension at baseline				
Present	21	147	3.64 (1.45 9.15)***	0.006
Absent	5	228	ref	
Obesity at baseline				
Present	5	11	5.81 (2.15 15.70)**	0.001
Absent	21	364	ref	
Ischemic heart disease at baseline				
Present	7	24	4.57 (1.89 11.00)**	0.001
Absent	19	351	ref	
Age	26	375	1.1(1.06 1.14)*	0.000
Sex				

Male	19	273	1.18 (.49 2.83)	0.716
female	7	102	ref	
Time patient took advice about DM &DFU				
At the start of DM treatment	7	120	ref	
After start of DM treatment	19	255	1.07 (0.44 2.57)	0.876
History of barefoot walking				
Yes	10	27	6.00(2.67 13.49) *	0.000
No	16	358	ref	
History of wearing ill-fitting shoes				
Yes	6	21	2.94 (1.14 7.56) ***	0.025
No	20	354	ref	
History of cigarette smoking				
Yes	8	20	3.80 (1.65 8.77) **	0.002
No	18	355	ref	
History of alcohol drinking				
Yes	11	27	7.76 (3.53 17.06) **	0.000
No	15	348	ref	
Patient had regular follow up				
Yes	11	304	ref	
No	15	71	3.65 (1.65 8.05) **	0.001
Type of DM				
Type I	0	22	ref	
Type II	26	253	$1.79e^{+15}$ (0)	1.00
Fasting level of glycemic control				
70-130mg/dl	6	188	ref	
>130mg/dl	20	187	2.72 (1.73 19.45)	0.004

Post meal level of glycemic control				
< 180mg/dl	5	141	ref	
>180mg/dl	21	234	1.81 (0.67 4.88)	0.241
BMI				
18-24.5kg/m^2	8	336	ref	
24.5-30kg/m^2	13	29	8.44(3.34 21.31)*	0.000
> 30kg/m^2	5	10	11.66(3.86 35.18)*	0.000
Blood Pressure				
110/80-130/80mmhg	5	150	ref	
>=140/90mmhg	21	225	2.19(0.82 5.86)	0.115
Patient started anti-hypertensive treatment				
Yes	16	197	0.29(0.11 0.82)	0.020
No	5	25	ref	
Not recorded	5	153	0.16(0.05 0.56)	0.004
Pulse pressure				
30-40mmhg	5	151	ref	
>40mmhg	21	224	2.22(0.83 5.93)	0.111
HA1c level				
4.9-5.2%	10	210	ref	
> 5.2%	16	165	1.65 (0.74 3.68)	0.218
Erythrocyte Sedimentation Rate				
3-7mm	10	298	ref	
>7mm	16	77	5.74 (2.53 13.00)	0.035
History of trauma				
Yes	15	41	5.97 (2.73 13.06)*	0.000
No	11	334	ref	
History of wound infection				
Yes	13	18	10.37 (4.59 23.44)*	0.000
No	13	357	ref	

Recurrent wound infection				
Yes	11	8	2.15 (0.67 3.35)	0.302
No	14	368	ref	
Wound infection involved bone				
Yes	5	7	4.47(1.75 8.64)	0.032
No	21	358	ref	
C-reactive protein				
5-10mg/l	10	286	ref	
>10mg/l	16	89	4.20(1.90 9.29)	0.026
Foot deformity				
Yes	5	6	8.60 (3.19 23.18)*	0.000
No	21	369	ref	

In multivariate analysis; baseline complications and co-morbidities that were found to have effect on incidence of diabetic foot ulcer were retinopathy, nephropathy, peripheral neuropathy, peripheral vascular diseases and obesity (table 8).

When the effects of peripheral neuropathy, patient health seeking behavior, age, BMI and trauma were controlled, the risk of diabetic foot ulcer was higher among adult diabetic patients who had retinopathy at baseline compared with those who had no retinopathy (AHR =3.43, 95% CI; (1.11 10.59). Similarly, when the effects of age, history of wound infection, BMI, peripheral neuropathy and foot deformity were controlled, the risk of developing DFU was higher among adult diabetic patients who had nephropathy at baseline compared with those who had no nephropathy (AHR = 2.86, 95% CI; 1.19 6.89). Moreover, when the effects of BMI, history of wound infection, obesity, ischemic heart diseases and peripheral vascular diseases were controlled, the hazard of diabetic foot ulcer was higher in adult diabetic patients who had peripheral neuropathy at baseline than those who had no peripheral neuropathy (AHR =6.19, 95% CI; 1.98 19.38).

When the effects of controlling for BMI, history of wound infection, peripheral neuropathy, foot deformity and age were controlled, the risk of diabetic foot ulcer was higher among adult

diabetic patients who had peripheral vascular disease compared with those who had no peripheral diseases (AHR = 3.04, 95% CI; 1.19 7.76). When the effects of history of wound infection, peripheral neuropathy, BMI, nephropathy and foot deformity were controlled, the risk of DFU was higher in patients who had obesity at baseline compared to patients who had no obesity at baseline (AHR= 5.99, 95% CI; 1.71 21.05).

In addition to baseline complications; other variables that were found to have significant effect on diabetic foot ulcer were age, BMI, history of trauma, history of wound infection and presence of foot deformity.

When there was one unit increase in age of respondents, the risk of DFU increased by 7% (AHR =1.06, 95% CI; 1.02 1.13). The risk of DFU was higher in patients whose BMI were 24.5-30kg/m^2 and > 30kg/m^2 compared to those whose BMI was in the normal range (18-24.5kg/m^2) (AHR = 4.36, 95% CI; 1.51 12.63) and (AHR = 4.52, 95% CI; 1.27 16.07). Similarly, the hazard of developing DFU was more likely in patients who had trauma history compared with patients who had no it (AHR = 3.39, 95% CI; 1.29 8.88). Likewise, the hazard of DFU was higher in adult diabetic patients who had history of wound infection compared with those who had no wound infection (AHR = 6.87, 95% CI; 2.61 18.07). Moreover, the risk of DFU was higher in patients who had foot deformity than those who had no foot deformity (AHR = 6.02, 95% CI; 1.68 21.50) (table 7).

Table 7.Multivariate analysis of predictors of diabetic foot ulcer among adult diabetic patients in Public Hospitals, Hadiya Zone, Southern Ethiopia, from 1 January 2015- December 31, 2019

Predictors	Diabetic foot status		CHR 95% CI	AHR 95% CI
	Developed	censored		
Retinopathy at baseline				
Present	10	28	6.64 (2.97 14.81)	**3.43(1.11 10.59)**
Absent	16	247	ref	ref
Nephropathy at baseline				
Present	15	39	6.47 (2.94 14.22)	**2.86(1.19 6.89)**
Absent	11	336	ref	ref
Peripheral Neuropathy at baseline				
Present	17	25	11.37 (5.02 25.77)	**6.19(1.98 19.38)**
Absent	9	350	ref	ref
Peripheral vascular diseases at baseline				
Present	9	22	5.19 (2.31 11.66)	**3.04(1.19 7.76)**
Absent	17	353	ref	ref
Obesity at baseline				
Present	5	11	5.81 (2.15 15.70)	**5.99(1.71 21.05)**
Absent	21	364	ref	ref
Ischemic heart disease at baseline				
Present	7	24	4.57 (1.89 11.00)	0.64(0.16 2.44)
Absent	19	351	ref	ref
Age	26	375	1.10(1.06 1.14)	**1.07(1.02 1.13)**
History of barefoot walking				
Yes	10	27	7.65(3.12 18.72)	2.1(0.49 8.89)
No	16	358	ref	
History of cigarette smoking				
Yes	8	20	4.28 (1.77 10.36) **	0.58(0.15 2.16)

No	18	355	ref	
History of alcohol drinking				
Yes	11	27	10.36 (4.37 24.56)	1.97(0.64 6.05)
No	15	348	ref	ref
Patient come appointment regularly				
Yes	11	304		ref
No	15	71	3.65 (1.65 8.05) **	1.18(0.43 3.27)
BMI				
18-24.5kg/m^2	8	336	ref	ref
24.5-30kg/m^2	13	29	10.31(4.22 25.16)	**4.36(1.51 12.63)**
> 30kg/m^2	5	10	21.29 (6.70 67.59)	**4.52(1.27 16.07)**
History of trauma				
Yes	15	41	6.07 (2.77 13.29)	**3.39(1.29 8.88)**
No	11	334	ref	ref
History of wound infection				
Yes	13	18	16.02 (4.11 20.7)	**6.87(2.61 18.07)**
No	11	357	ref	
Foot deformity				
Yes	5	6	10.20 (3.68 28.27)	**6.02(1.68 21.50)**
No	21	369	ref	ref

5. DISCUSSIONS

The study showed that baseline complications; nephropathy, peripheral neuropathy and obesity were found to have significant effect on diabetic foot ulcer. The study also showed that the incidence rate of diabetic foot ulcer was 2.9 per 1000 person- months among 8941.6 months of adult observation among adult diabetic patients. Thus, diabetic patients who had baseline complications or co-morbidities were more risky to develop diabetic foot ulcer than those who did not.

Adult diabetic patients who had retinopathy at baseline were 3.43 times more likely to develop diabetic foot ulcer compared with those who had no retinopathy at baseline. This finding is supported by study findings done in Australia (Mendel Baba Bpod (Hons) et al., 2010) and Iran (Leila Yazdanpanah et al., 2018) which stated that retinopathy was major complication of DM predicting diabetic foot ulcer among adult diabetic patients. This is due to vision problem that adult diabetic patients' with retinopathy encounter which increases risk of feet trauma thereby put their feet at high risk of ulceration.

Adult diabetic patients who had nephropathy at baseline were 2.86 times more risky to develop DFU than patients who had no nephropathy at baseline. This finding agrees with study findings done in Iran (Leila Yazdanpanah et al., 2018 a, b) and Saudi Arabia (Mostafa A. Abolfotouh et al., 2011) which stated that nephropathy was micro-vascular complication of DM predicting DFU. This is due to failure of glomerular filtration of blood sugar which results in high accumulation of sugar in the blood thereby resulting in decreased supply of sugar to peripheral cells for their normal functioning.

Adult diabetic patients who had peripheral neuropathy at baseline were 6.19 times more likely to develop diabetic foot ulcer compared with patients who had no peripheral neuropathy at baseline. This finding agrees with study results conducted in Maryland (Caitlin W. Hicks et al., 2019), Australia (Mendel Baba Bpod (Hons) et al., 2010), Iran (Leila Yazdanpanah et al., 2018), Saudi Arabia (Mostafa A. Abolfotouh et al., 2011), India (Revathi.V, 2016), United Arab Emirates (Venkatramana Manda et al., 2012), Nigeria (Akaninyene Asuquo Otu et al., 2013) and Ethiopia, Addis Ababa (Wondwossen Amogne et al., 2011) which revealed that peripheral neuropathy was

predictor of diabetic foot ulcer. This is due to lose of pain perception at lower extremity in diabetic patients with neuropathy which put them at high risk for foot ulceration.

Adult diabetic patients with peripheral vascular diseases at baseline were 3.04 times more likely to develop diabetic foot ulcer compared with those who had no peripheral vascular diseases at baseline. This finding is consistent with other study findings done in USA, New York (Lawrence A. Lavery et al., 2006), Australia (Mendel Baba Bpod (Hons) et al., 2010), Saudi Arabia (Mostafa A. Abolfotouh et al., 2011), Iran (Leila Yazdanpanah et al., 2018) which stated that presence of peripheral vascular diseases was predictor of DFU. This is due to occlusion of peripheral blood vessels by diseases involving vessels which in turn impair blood supply to peripheral tissue thereby put the foot at risk of ulceration.

Moreover, adult diabetic patients with obesity at baseline were 5.99 times more likely to develop diabetic foot ulcer compared with those who had no obesity at baseline. This finding is in line with study findings done in Iran(Leila Yazdanpanah et al., 2018), Saudi Arabia (Mostafa A. Abolfotouh et al., 2011) and India (Revathi.V, 2016) which stated that obesity was one of the DM complications contributing to diabetic foot ulcer in adult diabetic patients. This might be due to the fact that obese patients are unable to do aerobic exercises which facilitate peripheral cells to use blood sugar thereby exposing tissue cells fail to perform their normal functioning.

In addition to baseline complications and co-morbidities; age, history of alcohol drinking, BMI, trauma, history of wound infection, foot deformity and abnormal vibration senses were found to have effect on diabetic foot ulcer occurrence.

The risk of developing diabetic foot ulcer increased by 7% when there was one unit increase in age of adult diabetic patients. This finding is in agreement with other study findings done in Maryland (Caitlin W. Hicks et al., 2019 and Saudi Arabia (Mostafa A. Abolfotouh et al., 2011) which stated that DM onset on early age and age of 40 or more were contributors for diabetic foot ulcer. This is due to increased risk of developing other diabetic complications or co-morbidities as the age increases which result in corresponding risk of DFU.

Adult diabetic patients with recent BMI of 24.5-30kg/m^2 and > 30kg/m^2 were 4.36 times and 4.52 times more likely to develop DFU than patients with BMI of 18-24.5 kg/m^2, respectively. This finding is consistent with other study findings conducted in Iran (Leila Yazdanpanah et al.,

2018) and Saudi Arabia (Mostafa A. Abolfotouh et al., 2011) which stated that overweight/obesit y was an important predictor of diabetic foot ulcer in adult diabetic patients. This might be due to the fact that obese patients are unable to do aerobic exercises which facilitate peripheral cells to use blood sugar thereby exposing tissue cells fail to perform their normal functioning.

Adult diabetic patients who had history of trauma were 3.39 times more likely to develop diabetic foot ulcer compared with patients who had no history of trauma. This finding agrees with other study findings done in Australia (Mendel Baba Bpod (Hons) et al., 2010) and Nigeria (Akaninyene Asuquo Otu et al., 2013) which revealed that intermittent claudication (trauma involving the feet) was predictor of diabetic foot ulcer in adult diabetic patients. This is due to poor traumatic foot regeneration of died tissue in diabetic patients which predispose their foot to ulceration.

Adult diabetic patients with history of wound infections were 6.87 times more likely to experience DFU than patients without history of wound infection. This study finding is consistent with previous study result done in Washington which stated that wound infection of traumatic etiology was independent predictor of DFU (Lawrence A. Lavery et al., 2006). This is due to delayed healing of wounds in diabetic patients that put them at high risk of developing foot ulcer. Similarly, diabetic patients with foot deformity were 6.02 times more likely to develop DFU than patients with normal foot. This finding is in agreement with two study findings done in Iran on diabetic foot ulcer incidence and ulcer free survival which showed that foot deformity was predictor of DFU in adult DM patients (Leila Yazdanpanah et al., 2018 a, b). This is due to the fact that deformed foot is at high risk of ulceration.

In Current study; sex, barefoot walking, wearing ill-fitting shoes, history of cigarette smoking, history of alcohol drinking, hypertension, ischemic heart diseases, blood pressure, type of DM, HA1c level, C-reactive protein level, recurrent wound infection and wound infection involving bone were identified as not have significant effect on incidence of diabetic foot ulcer. The difference might be due to variation in study setting and population as well.

The estimated incidence of DFU in this study was 2.9 per 1000 person-months. This finding is lower than incidence rates found in other countries; Washington, USA (5.0/100 person-years), Australia (5.21 per 1,000 patient-years) and United Kingdom (6.1 per 1000 person- years);

(Edward J. Boyko et al., 2006), (Mendel Baba Bpod (Hons) et al., 2010) and (Paisey R. B et al., 2019), respectively. The possible explanation might be due to difference in life style, socio-economic status of the patients and duration of study as well.

The finding from this study showed that the proportion of diabetic foot ulcer among adult diabetic patients was 6.48%. This finding is in line with study results done in different areas of the world; 6.3% in global population (Pinidiyapathirage M. J et al., 2012), 6.2% in Australia (Mendel Baba Bpod (Hons) et al., 2010) and 5.62% in Ahvaz, Iran (Leila Yazdanpanah et al., 2018). The possible explanation might be patients receiving treatments that have similar effects. Moreover, this study finding is higher than the study findings done in North Western United Kingdom (2.2%) (Shojaiefard A., 2008), Japan (cumulative five year's incidence of 1.9%) (Masuomi Tomita et al., 2016) and Korea (0.5%) (Dong-Il Chun et al., 2019). This variation might be due to difference in sample size, health seeking behavior of the patients, study settings and educational status of the patients. Furthermore, the finding from this study is lower than the study findings done in Norway (Fredrik A. Nilsen et al., 2018), Portugal (Daniela Martins-Mendes et al., 2014) and North West Ethiopia, Wellaga (Firomsa Bekele et al., 2019); 64.9%, 26.6% and 17.86%, respectively. The observed variation might be due to variation in sample size and study duration.

Strength and Limitations of the study

The study included both NEMMWUTH and Shone primary hospital of the Hadiya Zone public hospitals which are centers to provide chronic diabetic follow up service for all DM patients in the Zone. The study conducted was retrospective cohort which was strong in generating evidence. The study period was short and the result may not be applicable for studies with long duration. Variables with incomplete records were not included. Finally, diabetic foot ulcer due to baseline complications or co-morbidities in the hospitals was not ruled out. Thus, this study finding should be interpreted with these limitations under consideration.

6. CONCLUSIONS AND RECOMMENDATIONS

This study indicated that the overall incidence of diabetic foot ulcer was 2.9 per 1000 person-months which was found to be high diabetic foot ulcer occurrence. The proportion of diabetic foot ulcer among adult diabetic patients in this study setting was found to be 6.48%. Retinopathy, nephropathy, peripheral neuropathy and obesity were baseline complications or co-morbidities that were identified as having significant effect on diabetic foot ulcer among adult diabetic patients.

To Hadiya Zone public hospitals:

- Diabetic mellitus patients with baseline complications or co-morbidities; especially with retinopathy, nephropathy, peripheral neuropathy, peripheral vascular diseases and obesity should be identified as early as possible and especial attention should be given to them during the entire follow up period.
- Due attention should be given in giving advice on major complications and co-morbidities of DM for patients at initiation of DM treatment.
- In addition to baseline complications or co-morbidities; diabetic patients with increased age, history of trauma, history of wound infection and foot deformity should got tailored advice and especial attention during entire follow up period.

To Hadiya Zone Health department

- Capacity of health care providers should be built to manage complications and co-morbidities which were found to have significant effect on diabetic foot ulcer that threaten the life of the patients.
- Strategies should be identified to trace patients and decrease diabetic foot ulcer incidence rate.
- Further study should be conducted using prospective cohort studies to determine other factors that have effect on incidence of diabetic foot ulcer by using larger sample size.

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Annex I: Data Extraction Format

This patient data extraction format is intended to determine the effect of baseline complications and co-morbidities on incidence of diabetic foot ulcer among adult diabetic patients at Hadiya Zone public hospitals, Southern Ethiopia. The study will be conducted through reviewing secondary data. This study is aimed to fill the information gap and provide empirical evidence for program managers, decision makers and diabetic mellitus care program implementers at the different level by enabling them to access a base line data on effect of complications and co-morbidities on diabetic foot ulcer. Moreover it assists in improving the outcome of diabetic care program.

Data extraction format ID. No _____

Name of the reviewer _____ Signature _____ date_____

Name of supervisor._____ Signature _____date _____

Available data: 1. Complete___ ☐ 2. Incomplete _☐ 3. Excluded _____☐

Instructions: If 80% or more questions are answered, the available data will be ticked on complete box.

If less than 80% of questions answered, the available data will be ticked on incomplete box.

If less than 50% of questions are answered, the available data will be ticked on excluded box.

When filling the questionnaire, encircle the number (alternative) of choice from the list.

Part I. Socio-demographic characteristics			
No.	Variable	Coding categories	Skip
101	Age of patient at diagnosis	_____	
102	sex	1. Male 2. Female	
103	Residence	Urban Rural	

Part II: Awareness on DM and DFU and Patient self foot-care related factors

201	Patient took advice on DM and DFU	At the start of DM treatment While on follow up	
202	History of barefoot walking?	Yes No	
203	Ever observed for ill-fitting shoes wear?	Yes No	
Part III: Patient behavior related factors			
301	History of cigarette smoking?	Yes No	
302	History of alcohol drinking?	Yes No	
304	Patient came on appointment regularly?	Yes No	If no;
305	Number of appointments missed	One Two and above	
306	Patient contacted health professionals whenever he/she face problem other than an appointment time	Yes No	
Pat IV: Baseline complications and co-morbidities information			
401	Retinopathy	Present Absent	
402	Nephropathy	Present Absent	
403	Peripheral neuropathy	Present Absent	
404	Peripheral Vascular diseases	Present Absent	
405	Hypertension	Present Absent	

406	Obesity	present Absent	
407	Ischemic heart diseases	Present Absent	
Part VI: Clinical features of patients while on diabetic care follow up			
501	Date at start of treatment	------/-----/------	
502	Type of DM?	Type I Type II	
503	Duration in months from initiation of DM Rx to end of study period?	_____	
504	Fasting level of glycemic control?	70-130mg/dl > 130mg/dl	
505	Post meal level of glycemic control?	< 180mg/dl >180mg/dl	
506	BMI of the patient measured at every visit?	18-24.5kg/ m^2 24.5-30kg/ m^2 >30kg/m^2	
507	BP of the patient measured at every visit?	110/80-130/80mmHG >= 140/90mmHG	
508	Patient started anti-hypertensive Rx immediately?	Yes No	
509	Pulse pressure measured and recorded	30-40mmHG > 40mmHG	
510	The HbA1c of the patient measured in recent every three months?	4.9 - 5.2% > 5.2%	
511	The ESR of the patients' blood checked whenever necessary?	3-7mm/hr > 7mm/hr	

512	History of trauma?	Yes No	
513	History of wound infections?	Present Absent	
514	Was it recurrent?	Yes No	
515	It involved joint/bone?	Yes No	
516	C - reactive protein measured at each visit recorded?	5-10mg/l > 10mg/l	
517	Foot deformity?	Present Absent	
518	Vibration senses?	Normal Abnormal	
519	Developed visual impairment?	Yes No	
520	History of DFU?	Yes No	
521	Developed Diabetic foot ulcer during follow up?	Yes No	
522	Date diagnosed with DFU	------/------/------	
523	Last date of visit	------/-----/-------	
524	Last date of appointment	-----/-----/--------	