CLINICAL OUTCOMES AND ITS PREDICTORS AMONG PATIENTS WITH DIABETES MELLITUS ADMITTED TO JIMMA UNIVERSITY MEDICAL CENTER: A PROSPECTIVE OBSERVATIONAL STUDY

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JIMMA, ETHIOPIA.

JIMMA UNIVERSITY,
INSTITUTE OF HEALTH, FACULTY OF HEALTH SCIENCES,
SCHOOL OF PHARMACY,
DEPARTMENT OF CLINICAL PHARMACY

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MARCH, 2022
JIMMA, ETHIOPIA

Declaration

I undersigned agrees to accept responsibility for the scientific ethical and technical conduct of the research project and provision of required progress reports as per terms and condition of the school of Pharmacy in effect at the time of grant is forwarded as the result of this application.

Name of the student: _____

Date _____ Signature _____

Approval of Advisor

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Date _____ Signature _____

Approval of examiner(s)

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Date _____ Signature _____

Approval of examiner(s)

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Date _____ Signature _____

Approval of school/department head

Name of school/department head: _____

Date _____ Signature _____

ABSTRACT

Background: Diabetes Mellitus (DM) is one of the largest health emergencies of the 21st century and among the top ten causes of death in adults globally in 2017. Although Ethiopia has been challenged by the growing prevalence of DM, important data regarding in-hospital complications and rates of 30-day readmission are lacking. Besides, data on in-hospital mortality rate among admitted diabetic patients in Ethiopia, including Jimma Medical Center (JMC), are also limited.

Objective: To assess clinical outcomes and its predictors among DM patients admitted to JMC.

Methods: A hospital-based prospective observational study involving 120 admitted diabetes patients from October 01, 2020, to June 30, 2021, was conducted in JMC in Ethiopia. Data were collected on variables related to the patient, disease, medication, and clinical outcomes. Data were entered into Epi-data version 4.6.0.4 for cleaning and exported to SPSS version 23.0 for analysis. Kaplan-Mayer and cox-regression were used to compare survival experience and to determine the predictors of clinical outcomes, respectively. Hazard ratios with its two-sided p-value <0.05 was considered to declare statistical significance.

Result: Of 120 DM patients 81 (67.5%) were males. The over all in-hospital mortality was 16(13.34%). Twenty-two patients (18.3%) developed in-hospital complications and 20(19.23%) were readmitted within 30-day of index discharge. Urban residence (AHR: 3.46; 95%CI: [1.12, 9.81]), Age (AHR: 1.03; 95%CI: [1.001, 1.059]), Diabetic Ketoacidosis (DKA) (AHR: 5.01; 95%CI: [1.12, 21.88]), and patients who had: five (5) comorbidities (AHR: 9.65; 95%CI: [1.07, 19.59] and six (6) comorbidities (AHR: 14.02; 95%CI: [1.74, 21.05]) were significant predictors of in-hospital mortality. The use of non-antidiabetic medications such as statins, ASA, antihypertensive medications before admission was remained protective (AHR: 0.135; 95%CI: [0.04, 0.46]). Female gender (AHR: 3.71; 95%CI: [1.36, 10.3]) and renal disease (AHR: 4.48; 95%CI: [1.26, 15.93]) were significant predictors of unplanned 30-day rate of readmission.

Conclusion: This study showed that in-hospital mortality rate was noticeably high. About 1/6th of patients developed in-hospital complications while 1/5th of discharged patients experienced 30-day readmission. Urban residence, age, DKA, and having comorbidities (5 and 6) were predictors of mortality, and non-antidiabetic medications use before admission was protective. Female gender and renal disease were predictors of 30-day readmission. The above-identified predictors need attention to reduce in-hospital mortality, in-hospital complications, and 30-day readmission by JMC.

Keywords: Clinical outcomes, Diabetes Mellitus, Jimma Medical Center.

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Contents

ABBREVIATIONS AND ACRONYM

ACEIs: Angiotensin-Converting Enzyme Inhibitors

ADA: American Diabetes association

AGD: Adverse Glycemic Days

BG: Blood Glucose

COVID-19: Coronavirus disease 2019

DBP: Diastolic Blood Pressure

DFU: Diabetic Foot Ulcer

DKA: Diabetic Ketoacidosis

DM: Diabetes Mellitus

DVT: Deep Vein Thrombosis

FBS: Fasting Blood Sugar

GDP: Gross Domestic Product

HAI: Hospital-Acquired Infection

HAP: Hospital-Acquired pneumonia

HCAP: Health-care Associated Pneumonia

HEs: Hyperglycemic Emergencies

HgA1C: Glycated Hemoglobin

HHS: Hyperosmolar Hyperglycemic State

IDF: International Diabetes Federation

JMC: Jimma University Medical Center

LOS: Length of hospital Stay

RBS: Random Blood Sugar

RVI: Retroviral Infections

SBP: Systolic Blood Pressure

SSA: Sub-Saharan Africa

STTIs: Skin and Soft Tissue Infections

VTE: Venous Thromboembolism

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1. INTRODUCTION

1.1 Background

Diabetes mellitus (DM) is a serious, chronic disease that occurs either because of inadequate insulin production by the pancreas, inability to effectively utilize insulin by the body, or both. It is characterized by its hallmark feature of hyperglycemia (1, 2). There are four types of DM: type 1 diabetes, type 2 diabetes, gestational diabetes, and other specific types (3). Even though Type 1 diabetes occurs most frequently in children and adolescents, the disease can develop at any age (4). It usually accounts for only a minority of the total burden of diabetes in a population. However, type 2 diabetes accounts for about 85 to 95% of all diabetes in high-income countries, with a higher percentage in low-and middle-income countries due to rapid socio-cultural changes, increasing urbanization, aging populations, reduced physical activity, and unhealthy lifestyle and behavioral patterns (3). Associated with this, DM requires continuous medical care with multifactorial risk-reduction strategies beyond glycemic control (5).

According to the IDF report, in 2017, there were 352 million adults with impaired glucose tolerance who are at high risk of developing diabetes in the future. In the same year, it was estimated that 425 million people between 20 to 79 years of age suffered from DM, and the number is expected to rise to 629 million by 2045. Likewise, in 2017, the projected countrywide diabetes (20–79 years) prevalence in Ethiopia estimated by IDF Atlas was 5.2%. According to the estimation poor countries will bear 77% of the worldwide burden of the DM epidemic in the 21st century (6), due to population growth, consumption of unhealthy diets, obesity, and sedentary lifestyles (7).

Diabetes is one of the largest health emergencies of the 21st century (8). It imposes an unacceptably high burden of morbidity, mortality, and healthcare cost to all countries. It is among the top 10 causes of death in adults globally in 2017 (9). The World Health Organization (WHO) estimates that internationally, hyperglycemia is the third-highest ranked risk factor for premature mortality, after high blood pressure and tobacco use. It accounts for 5 million (14.5%) of global all-cause mortality among people aged 20–79 years, which is higher than the combined number of deaths from the three major infectious diseases (1.5 million deaths from HIV/AIDS, 1.5 million from tuberculosis, and 0.6 million from malaria in 2013) (10). About 3.67 million diabetes deaths occurred in low and middle-income countries (11). In 2017, the Global Burden of

Disease Study reported that death associated with diabetes was 1.37 million globally and 158.7 deaths per 100,000population in Sub Saharan-Africa (SSA) (12). In the same year, International Diabetes Federation (IDF) estimated 30,972.2 diabetes-related deaths (20-79 years) in Ethiopia (13). Many governments and public health professionals, and patients, however, remain largely unaware of the current impact of diabetes and its complications (14-18).

The major long-term diabetes complications are macrovascular(peripheral arterial disease, stroke, and coronary artery disease); and microvascular (retinopathy, neuropathy, and nephropathy (5). People with diabetes are two to four times more prone to develop a stroke, require at least 2 to 3 times the healthcare resources compared to people without diabetes, and diabetes care may account for up to 15% of national health care budgets globally (19).

Admission is more common for diabetes patients than without diabetes. Moreover, patients with diabetes are more probable to be admitted for a longer period than those without diabetes (20, 21). In a large study of five states in hospital utilization, 30% of diabetes admitted patients were readmitted within one year of the study period, with diabetes contributing 50% of all hospital stays (22). Re-hospitalizations occurred highly among socioeconomically disadvantaged groups, including those living in lower-income status, and those without private insurance.

In Ethiopia, a previous study in two specialized hospitals in Addis Ababa documented the trend in DM admissions between 2005 and 2009. According to this report, the admissions were increased from 51 per annum to 245 (7% to 34% respectively) over this period (23). A retrospective descriptive study done in the Black Lion Referral Hospital, Addis Ababa indicated that diabetic foot ulcer (DFU) (39%) and cardiovascular disease (21%) as foremost admission diagnoses for type 2 diabetes mellitus (T2DM), and it was diabetic ketoacidosis (DKA) (62%) for type 1 diabetes mellitus (T1DM) (24).

Regardless of the disproportionately high burden of diabetes in low-income countries, there is limited evidence regarding in-hospital mortality in Ethiopia, including JMC. Besides, important data on in-hospital complications and the 30-day unplanned hospital readmissions among admitted diabetic patients in our country, are also lacking. Thus, this prospective observational study was designed to assess clinical outcomes and its predictors among patients with DM admitted to JMC.

1.2 Statement of the problem

Diabetes mellitus is one of the commonest medical conditions prevalent all over the globe. In 2021, it is estimated that 537 million people, representing 10.5% of the global adult population (20–79 years of age) have DM. This number is expected to increase to 643 million (11.3%) in 2030 and 783 million (12.2%) in 2045. Africa Region is anticipated to have the greatest increase in the number of people with diabetes. By 2045, 129% more people with diabetes are likely in this region as compared to 2021 (25). Diabetes prevalence in Ethiopia in the last 17 years (2000-2016) ranges from 0.3% at Debre Berhan Referral Hospital to 7% in Harar town (26, 27).

Currently, DM is the leading cause of global morbidity and mortality. It accounted for 12.2% of all global deaths between the age of 20–79 years (6.7 million) and 32.6% of all deaths occur in people of working age (<60 years). Africa region especially Sub-Saharan Africa (SSA) is largely inflicted (28, 29). International Diabetes Federation reported an estimated 416,163 diabetes-related deaths in Africa, and the majority of those deaths occur in people aged ≤ 60 years (25). In central Ghana, a study showed that inpatient diabetes mortality rates increased from 7.6 per 1000 deaths to 30 per 1000 deaths in 1983 to 2012, respectively. The average 28-day mortality rate was 18.5% (30). In Ethiopia DM-related mortality rate ranges from 2% to 21% (24, 31). It is estimated that 26,448 diabetes-related deaths occur in adults 20–79 years, in 2021 (25).

Diabetes mellitus is now one of the leading causes of blindness, heart attacks, strokes, renal failure, and lower-limb amputations worldwide (32). Diabetic retinopathy caused 1.9% of moderate or severe visual impairment globally and 2.6% of blindness in 2010 (33). The incidence of End-Stage Renal Disease (ESRD) is up to 10 times as high in adults with diabetes as those without (34).

Studies have suggested that patients with diabetes are at higher risk for in-hospital complications like postoperative surgical and systemic complications, including death (35, 36). Mortality and hospital-acquired infection (HAI) were associated with Hyperglycemia among admitted DM patients (37).

Admitted participants with diabetes had a longer length of hospital stay and many admissions than participants without diabetes (38).

In recent studies, the 30-day hospital readmission rate for hospitalized DM patients is estimated to be 14.4–22.7% (22, 39-42). This rate is much higher than all hospitalized patients (8.5–13.5%) (43).

Diabetes Mellitus impacts both quality of life and life expectancy and imposes large economic burdens on individuals and national health care systems directly or indirectly (44). The overall cost of diabetes in SSA was reported as US$19·45 billion, equivalent to 1.2% of cumulative gross domestic product (GDP). About $10·81 billion (55·6%) of this cost arose from direct costs. More than 50% of the total health expenditure in many countries is likely out-of-pocket expenditure. By 2030, the total cost will rise to between $35·33 billion (1·1% of GDP) and $59·32 billion (1·8% of GDP) (45).

The study conducted across the world showed that in-hospital mortality among DM patients was associated with older age, sex difference, Hypertension, hyperlipidemia, comorbidity burden, infection, poor glycemic control, inadequate blood pressure control, lack of foot care, long duration of DM, long hospital stay (46-48).

Common causes of 30-day hospital readmission have been described in different studies from some countries. Their findings confirm that male sex, age, lower socioeconomic and/or educational status, longer duration of prior hospitalization, number of previous hospitalizations, insulin therapy, number and severity of comorbidities, and insurance type were associated with 30-day unplanned hospital readmission (49-51).

Despite different initiatives undertaken by the Ethiopian Diabetes Association and the country having a National Strategic Action Plan (NSAP) for prevention and control of non-communicable disease (NCD) like diabetes, currently, the country has been challenged by the growing magnitude of diabetes. Ethiopia is among the top 4 countries with the highest adult diabetic populations in SSA (8), but important data regarding clinical outcomes were inadequate (52). Therefore, the aim of the current study was to assess Clinical Outcomes and its predictors among patients with DM admitted to JMC.

1.3 Significance of the study

As local data regarding diabetes-related clinical outcomes are limited, it is prudent to provide an insight into the in-hospital mortality, in-hospital complications, and rates of 30-day readmission among patients admitted with DM in JMC. Diabetes-related mortality, in-hospital complications, and Hospital readmissions are important health care quality measures and, drivers of costs. Therefore, this study will help the healthcare professionals to improve the management of these patients by strengthening diabetes care, educating the patients on how to decrease modifiable determinants as the study identified predictors of in-hospital mortality and 30-day readmission. This, in turn, decreases unscheduled readmission, complications, mortality and improves patients' quality of life.

The findings generated by this study could be used as input for the preparation of population-specific local treatment guidelines that can fill the critical gaps in the care of DM.

The study can be also used as an input for future similar studies on related topics and the hospital management can use the findings to expand its diabetes care services.

2. LITERATURE REVIEW

2.1 Clinical outcomes and its predictors

2.1.1 In-hospital mortality and its predictors

A retrospective cohort study conducted in the US from the US Veterans Affairs Healthcare System from 2002 to 2014 on 963,648 adult patients showed that patients with DM had 7.0 and 3.5 deaths/1000-person-years higher all-cause and CVD mortality respectively than nondiabetic individuals. The age, sex, race, and ethnicity-adjusted hazard ratio (HR) for DM–related mortality was 1.29 and declined with adjustment for CVD risk factors (HR, 1.18) and glycemia (HR, 1.03). Cardiovascular disease mortality increased as HbA1c exceeded 7% among DM patients: 1.11, 1.25, and 1.52 for HbA1c 7%–7.9%, 8%–8.9%, and ≥9%, respectively, relative to HbA1c 6%–6.9%). The lowest mortality risk was associated with HbA1c between 6% to 6.9% irrespective of CVD history or age. Diabetes mellitus was associated with a 16% increase in all-cause and an 18% increase in cardiovascular mortality in this cohort (53).

A pooled analysis conducted between January 10, 2018, and August 31, 2018, of 1,002,551 participants individuals from 22 Asian prospective cohort studies (from China, Japan, South Korea, Singapore, Taiwan, India, and Bangladesh between 1963 and 2006) concluded that patients with diabetes had a 1.89-fold risk of all-cause mortality compared with patients without diabetes. The highest relative risk of death was due to diabetes itself 22.8 followed by renal disease 3.08, coronary heart disease 2.57, and ischemic stroke 2.15. Diabetes related-mortality was highly associated among women 2.09 than men 1.74 ($P < .001$) and more evident among adults aged 30 to 49 years 2.43 than ≥ 70 years 1.51 ($P <0.001$) (54).

A retrospective study conducted in Nigeria on 785 type 2 DM patients who were hospitalized to adult medical wards and the accident/emergency unit of the University of Ilorin Teaching Hospital revealed that the overall mortality rate was 32.5%. The mean age at diagnosis and death was 53.43 + 15.07 and 57.07 + 14.29, respectively. Systemic hypertension was diagnosed in 50% of the study participants with a rate of 55% and 43% in males and females, respectively. The highest number of admissions was due to diabetic hyperglycemic emergencies (HEs), septicemia, and diabetic foot syndrome (DFS). Mortality rates were highest in those that presented with hypoglycemia, stroke, and diabetic foot syndrome. There was gender

disproportion in the causes of mortality as more males died from DFS and stroke while the majority of deaths of females were from DKA. Ignorance, poor hygiene, infections, lack of foot care, and inadequate glycemic /blood pressure control were the contributory factors to increased mortality (47).

A retrospective study conducted at Debre tabor General Hospital, North-West Ethiopia from June 1 to 30, 2018 showed of a total of 387 patients the mean length of hospital stay (LOS) was 4.64(±2.802) days. About 79(20.41%) patients had long hospital stays (>7days). Even though 95.60% of patients improved and were discharged, the in-hospital mortality rate was 4.40%. Males were more prone to die earlier than females (log-rank 1.5, P=0.04). Patients diagnosed with DKA precipitated by infection were 4.59 times more prone to have a long LOS compared with DKA precipitated by unknown causes (55).

2.1.2 In-Hospital complications and its predictors

A cluster-randomized trial performed at a tertiary referral hospital of Melbourne, Australia between March and August 2016 on 1002 adult admitted DM patients showed that at cluster level incidence of Adverse Glycemic Days (AGDs) (RBS<72mg/dl or RBS >270mg/dl) decreased by 24% from 243 to 186 per 1,000 patient-days in the intervention arm (P < 0.001) than with no change in the control arm. At the individual level, adjusted number of AGDs per person decreased from a mean 1.4 (standard deviation (SD) 1.6) to 1.0 (0.9) days (228% change [95% CI 245 to 211], P = 0.001) in the intervention arm but did not change in the control arm (1.8 [2.0] to 1.5 [1.8], 29% change [225 to 6], P = 0.23). Early intervention for DM reduced overt hyperglycemia (55% decrease in patient-days with mean glucose >15 mmol/L, P < 0.001) and HAI (P = 0.003). Adverse Glycemic Days were strongly associated with HAI i.e decrease in HAIs paralleled a decrease in AGDs, in spite of some change in mean glucose. The incidence of HAI was observed during severe hyperglycemia, supporting a biological relation between hyperglycemic extremes and HAI (56).

A retrospective study conducted in the USA from 2008–12/31/2013 concluded that of the 26 934 total patients, 779 (2.9%) had T1DM, 2052 (7.6%) had T2DM, and the remaining 89.5% were without diabetes. Venous Thromboembolism (VTE) incidence was 3.6%, 2.4%, and 2.2%, in T1DM, T2DM, and non-diabetes, respectively (p=0.02). Patients ≥65 years developed VTE more

commonly than those <65 years (2.5% vs 2.1%, p=0.04). Among patients <65 years, T1DM was significantly predictive of VTE (p=0.045), but T2DM was not (57).

A systematic literature review of a retrospective study published till December 10, 2020, of 10,801 patients done in Poland showed that in the DM group, the complications were observed usually when compared with the non-DM group, both in acute respiratory distress (31.4 vs. 17.2%; $P < 0.001$), acute cardiac injury (22.0% vs. 12.8%; $P < 0.001$), and acute kidney injury (19.1 vs. 10.2%; $P < 0.001$). Mortality of DM patients was 21.3 vs 6.1% in non-DM patients ($P < 0.001$), while severe disease in the DM group was common 34.8% than 22.8% in the non-DM group. Diabetes is an independent risk factor of the severity of Coronavirus disease 2019 (COVID-19) among admitted patients (58).

A prospective comparative observational study carried out in India reported that, of 97 patients (diabetics ($n = 44$) and nondiabetics ($n = 53$) the mean pneumonia patient outcomes research team (PORT) risk score was higher in diabetics ($124{:}84 \pm 41{:}31$) compared to nondiabetics ($77{:}85 \pm 39{:}77$) ($p < 0{:}001$). The PORT score is a validated way used as a clinical predictor to categorize patients depending on the severity of community-acquired pneumonia. Diabetics commonly presented with extreme temperatures (hypothermia or hyperpyrexia) ($p = 0{:}022$), lower serum sodium levels ($p = 0{:}047$), and lower partial arterial pressure ($p < 0{:}001$) than non-diabetics. Diabetics more frequently displayed bilateral lesions with multilobe or lower lobe involvement, the predominant type of lesion being exudative. Diabetic patients frequently had a severe pulmonary infection and poor prognosis as indicated by a higher mean PORT risk score (59).

2.1.3 Rates of Readmission and its predictors

A study done in the United States in two phases: first a pilot retrospective chart review between October 1, 2013, and December 31, 2013, showed of 7763 admissions, the 30-day readmission rate was 26% for patients with DM, and 22% for patients without DM. The most common cause for readmission was DM-related among patients with DM as primary diagnosis during the index admission. Secondly in the larger study on 37,702 adult inpatient discharges between October 1, 2013, and September 30, 2014, 30-day readmission rates for all encounters (inpatient, ED and Observation care) were 24.3% in DM patients compared to 17.7% in counterparts ($p < 0.001$).

The most common cause for readmission in DM patients as a secondary diagnosis to the index admission was infection-related. The was no significant difference in 30-day readmission among patients who followed hyperglycemic intensive insulin program versus endocrine consults (60).

Another retrospective cohort study conducted by using de-identified administrative claims data in the US in 2009 and 2010 (n = 30,139) revealed that the overall 30-day readmission rate among patients with diabetes was 18.9%. Older patients were significantly more likely to be readmitted. Among admitted patients with diabetes, the majority had hypertension (76.3%), chronic pulmonary disease (23.0%), anemia (23.6%), heart failure (19.8%), fluid and electrolyte disorders (21.9%), peripheral vascular disease (15.5%) and renal failure (16.7%). Patients who received at least one LDL test ($p< 0.025$) and ≥90 day supply of statins ($P<0.01$) were significantly protective to be readmitted to the health facility (61).

A retrospective cohort study of a total, 17,284 adult diabetes patients in New England with 44,203 hospital discharges from an urban academic medical center between January 1, 2004, and December 1, 2012, revealed that the 30-day readmission rate was 20.4%. The study also reported the median time to readmission as 11 days. The study identified 27 factors that were statistically significant as well as independently associated with 30-day readmission ($P<0.05$). The strongest risk factors were lack of outpatient visits within 30 days after discharge, hospital length of stay, recent discharge within 90 days, self-discharge, sociodemographic, comorbidities, and admission laboratory values(62).

A Retrospective cohort and case-control study conducted in an Al Khobar hospital, in the Eastern province of Saudi Arabia during 2000–2008 on 1:1 case (n=62) to control(n=62) ratio, the cases were all the diabetic patients readmitted within 28 days with the same diagnosis for unplanned reasons among 1187 diabetic patients there were 62 patients readmitted within 28 days and 1125 patients not readmitted. The rate of unplanned readmission for diabetic patients was 5.2%. Among 62 cases 84% were readmitted once within 28 days, 11% were readmitted 2 times, 3% 3 times, and 2% 4 times, with a mean $\pm$ SD of readmissions was 1.2 $\pm$ 0.6. Furthermore, 34% of the patients were readmitted one week after discharge, 19% within 2 weeks, 15% within 3 weeks, and 32% within 4 weeks. The mean $\pm$ SD length of time between discharge and readmission was 14.4 $\pm$ 9.5 days. Significant predictors of the 28-day readmission

rate were adherence of health care providers to American Diabetes Association (ADA) guidelines for admission workup ($P< 0.05$) and readiness for discharge criteria ($P< 0.05$) (63).

2.2 Conceptual framework

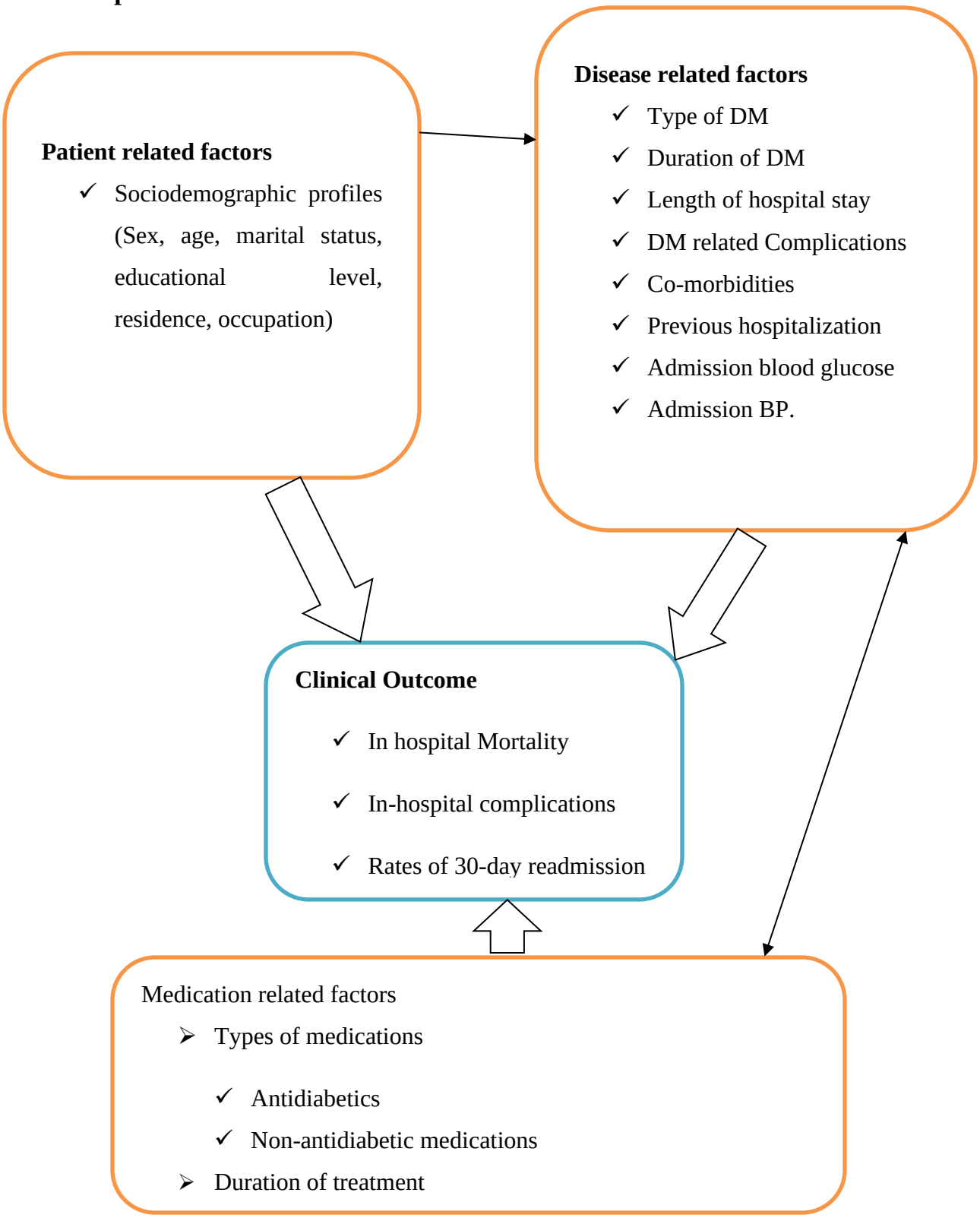

Figure 1: Conceptual framework showing the proposed relationship between the dependent variable and independent variables adapted from different literatures reviewed.

3. OBJECTIVES

3.1 General objective

- To assess Clinical Outcomes and its predictors among patients with DM admitted to JMC.

3.2 Specific objectives

- To assess in-hospital mortality among patients with DM admitted to JMC.
- To identify in-hospital complications among patients with DM admitted to JMC.
- To assess the rate of 30-day readmission among patients with DM admitted to JMC.
- To identify predictors of Clinical Outcomes among patients with DM admitted to JMC.

4. METHODS

4.1 Study area and period

The study was conducted at JMC. The hospital is one of the oldest public hospitals in the country which was established in 1937 during the Italian occupation to serve as a military hospital and rehabilitation. It is located in Jimma town, 352 km Southwest of Addis Ababa, the capital city of Ethiopia. It is the only teaching hospital in southwest Ethiopia, providing services for approximately 15,000 inpatients, 160,000 outpatient attendants, 11,000 emergency cases, and 4500 deliveries annually with a catchment population of over 20 million people. *https://ugapply.com/jimma-medical-center/*. This study was conducted from October 01, 2020, to June 30, 2021 (over nine months), at the Emergency Department, Medical, Surgical, and gynecology / Obstetrics wards of JMC, and every patient was followed for 1-month post-discharge, self-discharge, and / referral.

4.2 Study design

A hospital-based prospective observational study was conducted

4.3 Population

4.3.1 Source population

All patients were admitted to JMC with the diagnosis of DM.

4.3.2 Study population

All patients admitted to the Emergency Department, Medical, Surgical, and gynecology / Obstetrics wards of JMC with the diagnosis of DM during the data collection period and those who fulfill the eligibility criteria.

4.4 Selection criteria

4.4.1 Inclusion criteria

- All patients aged 18 years and above were admitted to Emergency Department, Medical, Surgical, and gynecology / Obstetrics wards with the diagnosis of DM.
- Diabetes mellitus patients stayed ≥24 hours in the hospital after admission.

4.4.2Exclusion criteria

- Patients with gestational DM
- Those who refuse to participate.
- Patients or caregivers who are unable to provide appropriate information (mental or any other health problem sufficient enough to hinder them to provide appropriate information during data collection)

4.5 Sample size Determination and sampling technique

The sample size for the study was determined by using the single population proportion formula by considering the proportion of in-hospital mortality rate (p=11.2%)from the previous study by Kefale et.al at Jimma University Specialized Hospital (64). Z is standardized normal distribution value at the 95% CI: 1.96, d margin of error of 5% and 10% was added for non-response rate.

$$n = \frac{(Z\alpha/2)2pq}{d2}$$

Where n =minimum required sample size from the population

$$n = \frac{(1.96)2*0.112*0.888}{(0.05)2}$$

n= 153

For population size less than 10,000 of compounded as: -

$$Nf = \frac{n}{1+\frac{n}{N}}$$

Where **Nf** = final sample size

n= Original sample size

N= size of the source population

N= number of DM patients admitted to the Emergency room, Medical, Surgical, and gynecology / Obstetrics wards over nine months in 2019. N=382

$$Nf = \frac{153}{1+\frac{153}{382}}$$

=109

Finally, 10% was added for the non-response rate.

Nf= 109 + 11= 120

So based on this, the final sample size was 120.

Sampling technique

All Diabetic patients admitted at the Emergency Department, Medical, Surgical, and gynecology / Obstetrics wards during the data collection period who met the inclusion criteria were recruited in the study using consecutive sampling technique, and every patient was followed till discharge, referral to facilities outside JMC, death. Every patient was followed for 1-month post-discharge, self-discharge, and / referral for any all-cause unplanned 30-day hospital readmission.

4.6 Study variables

4.6.1 Dependent variables

- Clinical outcomes
- ✓ All-cause in-hospital mortality
- ✓ In-hospital complications
- ✓ Rates of 30-day readmission

4.6.2 Independent variables

- **Patient-related factors**

Socio-demographic variables (age, sex, marital status, educational status, residence, and occupation).

- **Disease-related factors**

Type of DM, duration of DM, Length of previous hospital stay, DM-related complications, Co-morbidities, Previous hospitalization, Admission blood glucose level, systolic blood pressure (SBP), diastolic blood pressure (DBP).

- **Medication-related factors:** (types of medications (antidiabetics, non-antidiabetic medications) and Duration of treatment.

4.7 Data collection tools and procedures

The data collection tool was developed by reviewing different related published literature. Initially, the data collection tool was designed in English, then some parts of the tool (the ones that were used directly to collect data from patients or attendants by interviews, patient

information sheet, and informed consent) were translated to Afan Oromo and Amharic and back-translated into English by the independent person to assure its consistency. The semi-structured questionnaire was designed to take information prospectively through face-to-face interviews (socio-demographic data and some part of the clinical characteristics of the patients) and reviewing Patients' medical charts (to collect data on the clinical characteristics of the patients not covered by interviews, clinical outcomes, medication prescribed after admission, and vital signs and laboratory data). The Questionnaire contains five sections: section 1 was used to collect socio-demographic data. Section 2 was used to collect the clinical characteristics of the patients. Section 3 was used to collect data on clinical outcomes. Section 4 was used to collect data on medication prescribed after admission, section 5 was used to collect data on vital signs and laboratory data.

Data were collected by trained two pharmacists (B. Pharm) and one nurse (BSC Nurse); one medical doctor was assigned to supervise the data collection process. The data collectors interviewed eligible participants and reviewed medical charts daily. The principal investigator and supervisor carefully followed the data collection process at the spot.

4.8 Data quality Assurance

To ensure the quality of data, data collectors and a supervisor were trained for one day before starting data collection on how to collect the data, the contents of the questionnaire, ethical concerns, obtaining additional information from the treating physicians, and using patient interviews. The data collectors were also strictly supervised daily and the principal investigator reviewed all filled formats so that any suggestions and corrections were given soon.

The quality of the data was also assured by doing a pretest on 5% (six patients) of the actual sample size before the actual data collection to check the consistency and validity of the data collection tool.

4.9 Data processing and analysis.

Data were entered into Epi-data manager version 4.6.0.4 and then exported to Statistical Package for Social Sciences (SPSS) version 23.0 for cleaning and analysis, respectively. Mean and Standard Deviation (SD) was used to present continuous variables. Categorical variables were

expressed in percentage and frequency. Descriptive analysis was performed, and results were presented by the text, tables, and figures. Kaplan Meier (log-rank test) was used to compare the survival experience of the patients.

The cox-proportional hazard model was used to determine predictors of all-cause in-hospital mortality and 30-day readmission. Bivariate analysis was conducted and variables having a p-value less than 0.25 were considered as candidates for multi-variable regression analysis. The hazard ratio was used as a measure of the strength of association and variables with a p-value of < 0.05 on multi-variable regression analysis were considered statistically significant.

4.10 Ethical consideration

The study was conducted after securing ethical clearance and approval from the Institutional Review Board of Jimma University (*Reference (IRB) No: IRB000236/2012*) and it was submitted to JMC. Then Official permission was obtained from the JMC clinical director before data collection was commenced. After that, a copy of the official permission letter from the medical director was given to each ward head then permission was obtained from each respected ward. Finally, written informed consent was secured from all participants. Lastly, data collection was done by coding data collection formats using anonymous codes.

4.11 Dissemination of Result

The findings of the study will be presented at Jimma University, Institute of Health, School of pharmacy, department of clinical pharmacy for the fulfillment of the requirements for masters of sciences in clinical pharmacy. A report will be communicated to JMC and any other concerned bodies. Presentations at professional, local, national, and international meetings and publications in reputable peer-reviewed, national or international journals will be attempted.

4.12 Operational definitions and definitions of terms

- **Clinical outcome:** - is explained by: mortality- from index admission to discharge from medical records/attending physicians, in-hospital complications, and rate of 30-day re-admissions.
- **Co-morbidity**: the co-occurrence of one or more medical problems with diabetes.
- **Concomitant medications:** one or more drugs used with antidiabetic medications concurrently.
- **Controlled blood glucose:** RBS number between 70 to 250mg/dl among admitted DM patients.
- **Diabetic Ketoacidosis**: refers to blood glucose ≥250 mg/dL, urine ketones level positive and Arterial pH 7.25-7.3(65).
- **Hyperosmolar Hyperglycemic State:** refers to marked elevations in blood glucose (> 600 mg/dL), an admission pH >7.30, serum bicarbonate >18 mEq/L, a small number of ketones may present in serum and urine (66).
- **In-hospital complication** is defined as when a patient develops other additional unwanted medical conditions beyond admission diagnosis during their hospital stay which is confirmed by laboratory investigation or pathology from healthcare records/attending physicians.
- **In-hospital mortality:** defined as the state of being died among DM patients admitted to hospital, confirmed by death summary from healthcare records/attending physicians from index admission to discharge.
- **Length of hospital stay:** refer to the duration of the stay in days in the hospital from the date of admission to the date of death or discharge from the hospital.
- **Poorly controlled blood glucose:** RBS number >250mg/dl among admitted DM patients.
- **Readmissions**: is any unscheduled emergency department (ED) visits or inpatient admission (medical, surgical, and gynecology / Obstetrics wards).
- **Thirty-day readmission timing**: any all-cause unplanned consecutive admission within 30 days (1–30 days) after being discharged alive from the hospital of index admission.

5. RESULT

5.1 Overview of the study participants

Out of 130 consecutive DM patients admitted to JMC over nine months, 120 patients were included in the analysis. Of these patients enrolled, 10 patients were excluded (declined to participate n=10). Therefore, the data of 120 patients were included in the analysis. A majority, 89 (74.17%) of the patients were admitted to the medical ward (figure 2).

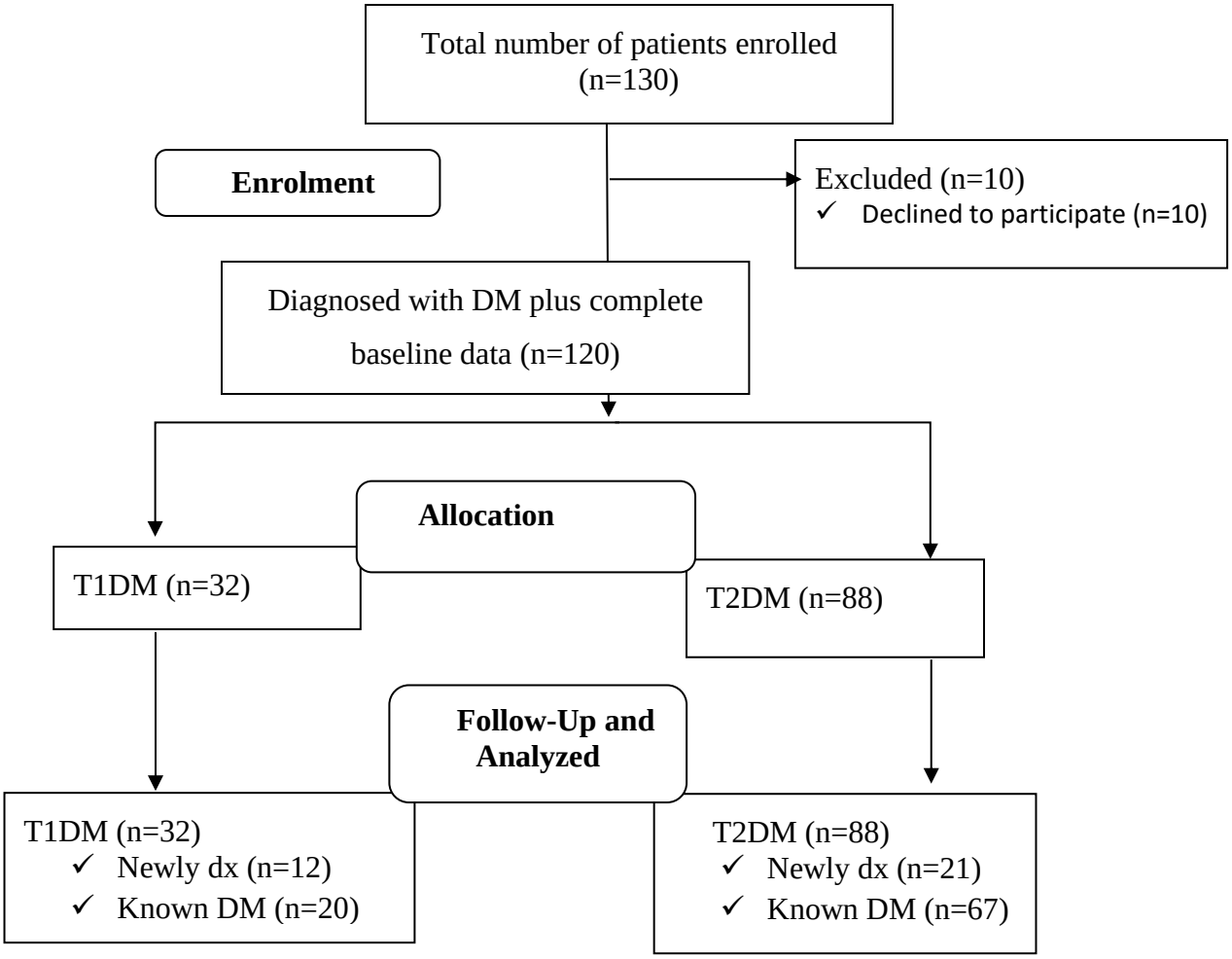

Figure 2: Study flow chart among patients with DM admitted to JMC from October 01, 2020, to June 30, 2021.

(T1DM=Type 1 Diabetes mellitus, T2DM=Type 2Diabetes Mellitus, newly dx= Newly diagnosed Diabetes Mellitus.)

5.2. Sociodemographic characteristics

Eighty-one (67.5%) of study participants were males. The mean age of the participants was 50.21±19.35 years. Around one-third of them (37.5%) were farmers and nearly half 58(48.3%) of them had no formal education (Table 1).

Table 1: Socio-demographic characteristics among patients with DM admitted to JMC from October 01, 2020, to June 30, 2021

Variables	Category	Frequency (n=120)	(%)
Sex	Male	81	67.5
	Female	39	32.5
Age in Years (mean ± SD)	50.21± 19.35		
Residence	Rural	73	60.8
	Urban	47	39.2
Marital status	Married	92	76.7
	Single	27	22.5
	Widowed	1	0.8
Occupation	Government employee	19	15.8
	Merchant	32	26.7
	Farmer	45	37.5
	House wife	24	20
Educational Status	No Formal Education	58	48.3
	Primary	30	25
	Secondary	11	9.2
	College and above	21	17.5

5. 3: Clinical characteristics

5.3.1 Reasons for Hospitalization

Diabetic ketoacidosis (DKA) was the commonest reason for hospitalization where it accounted for 59(49.2%) of admissions. While admissions related to infections were 34(28.33%), and that of diseases of the circulatory system was 16(13.34%). The most common infection responsible

for admission was pneumonia 15(12.5%), whereas the commonest cardiovascular disease attributed for admission was heart failure (HF) 5(4.17%) (Table 2).

Table 2: Reasons for hospitalization among patients with DM admitted to JMC from October 01, 2020, to June 30, 2021

Reason for hospitalization		**Frequency (n=120)**	**%**
Metabolic diseases* (n=66)	Diabetic Ketoacidosis (DKA)	59	49.2
	Hyperosmolar Hyperglycemic State (HHS)	5	4.17
	Hypoglycemia	2	1.67
Infections (n=34)	Pneumonia	15	12.5
	Bacterial meningitis	7	5.81
	Skin and Soft Tissue Infections (SSTI╪) including Diabetic Foot Ulcer (DFU)	6	5
	Tuberculosis (TB)	4	3.33
	Retroviral Infections (RVI)	2	1.66
Diseases of circulatory system (n=16)	Heart Failure (HF)	5	4.17
	Hypertension	4	3.33
	Stroke	4	3.33
	Acute Coronary Syndrome (ACS)	3	2.5
Others¥ (n=4)		4	3.33

*DKA, HHS, and Hypoglycemia

╪Cellulitis, necrotizing fasciitis, septic arthritis, osteoarthritis

¥Renal failure (RF), liver disease, gastrointestinal diseases, anemia.

Baseline Blood Glucose Level during Admission

Of the 120 patients, eighty-seven (72.5%) of them had RBS ≥ 251 mg/dl and only two (1.7%) had RBS ≤ 70mg/dl during hospital admission (figure 3).

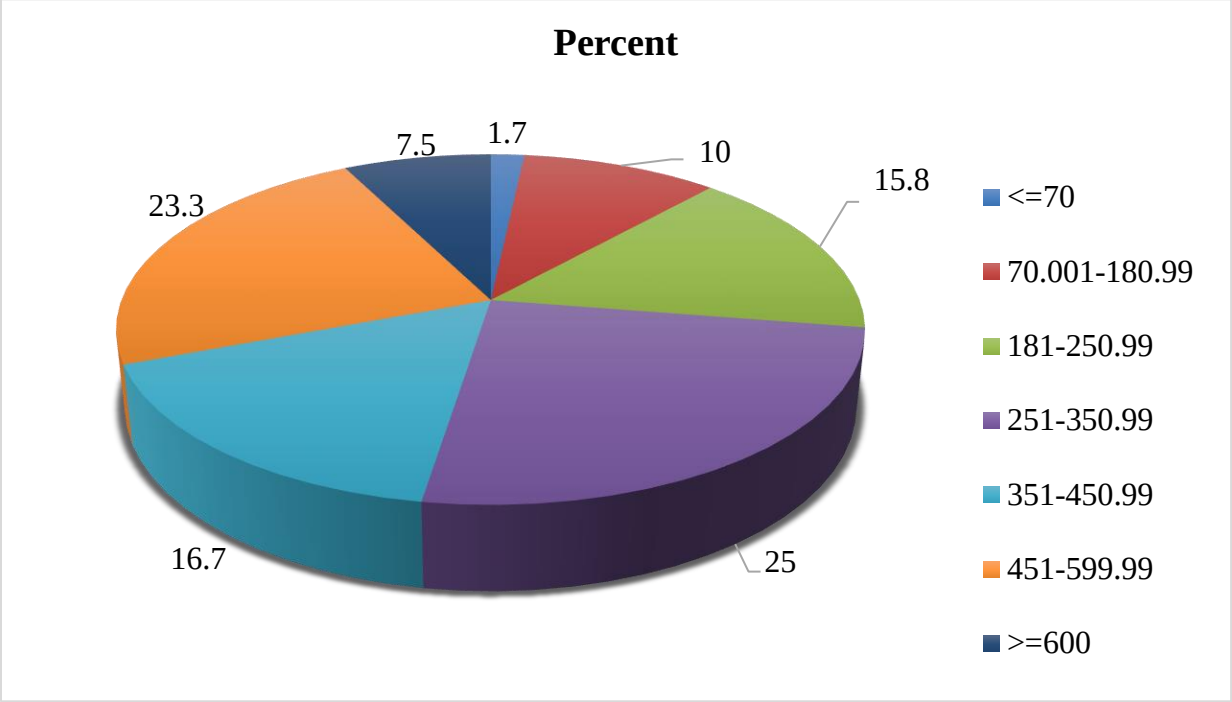

Figure 3: Admission blood glucose (RBS) level among patients with DM admitted to JMC from October 01, 2020, to June 30, 2021

5.3.2 Disease-related factors

Out of 120 patients, 88 (73.3%) were diagnosed with type 2 DM. Eighty-seven patients (72.5%) were known diabetics (Figure 1). The mean duration of diabetes for known diabetics was 3.77 ± 4.67 years and 58(66.67%) of them were diagnosed in the last 5 years (Figure 4). Out of 87 known diabetics, 80(91.95%) patients had a regular follow-up. Fifteen (17.24%) patients had attended their follow-up monthly, 42 (48.27%) patients every 2 months, and 23 (26.44%) patients every 3 months. Forty-three (49.43%) of them had at least one prior history of JMC admission. Among these, 30(69.77%), 12(27.91%), and 1(2.32%) patients had 1, 2, and 3 times a prior history of admission in the last year, respectively.

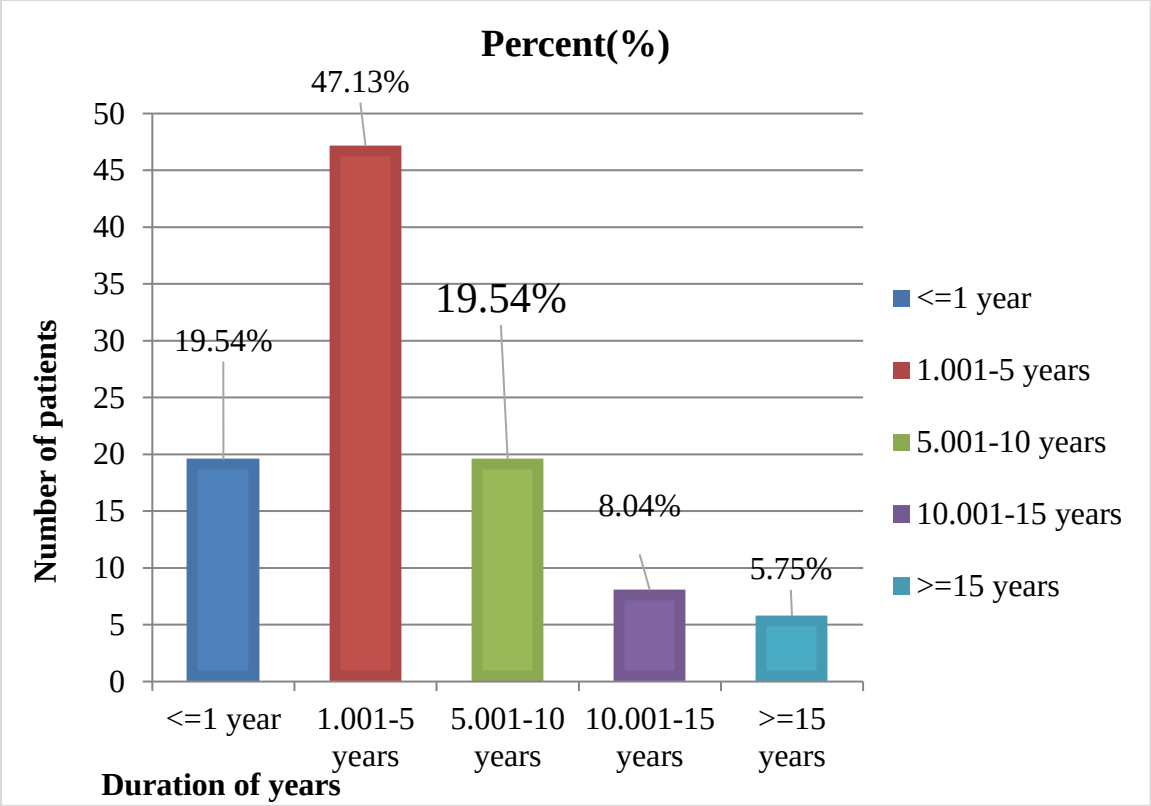

Figure 4: Duration of known diabetes among patients with DM admitted to JMC from October 01, 2020, to June 30, 2021

Overall, 87 (72.5%) patients had at least one acute or chronic comorbidity. Hypertension was the commonest type of comorbidity which was attributed to 51(58.62%), followed by pneumonia 35(40.23%) (Table 3).

Table 3: Prevalence of comorbidities among patients with DM admitted to JMC from October 01, 2020, to June 30, 2021

Variables		**Frequency (n=120)**	**%**
Presence of comorbidities	Yes	87	72.5
	No	33	27.5
Type of comorbidities (n=87)			
Cardiovascular diseases	Hypertension	51	58.62
	Congestive Heart Failure (CHF)	19	21.84
	Acute Coronary Syndrome (ACS)	18	20.69
	Hypertensive Heart Disease (HHD)	15	17.24
	Ischemic Cardiomyopathy (ICMP)	10	11.49
	Stroke	8	9.19
	Deep Vein Thrombosis (DVT)	6	6.89
	Systolic Dysfunction	5	5.75
	Others*	4	4.59
Infections	Pneumonia	35	40.23
	Urinary Tract Infection (UTI)	19	21.84
	Bacterial Meningitis	12	13.79
	Pyelonephritis	10	11.49
	Tuberculosis (TB)	6	6.89
	COVID-19	5	5.75
	Skin and Soft Tissue Infections (SSTI)	5	5.75
	Others ‡	2	2.29
Kidney diseases[†]		20	22.98
Gastrointestinal diseases[ǂ]		10	11.49
Anemia		7	8.04
Other comorbidities[$]		2	2.29

*Atrial Fibrillation, All types of shocks, ischemic heart disease (IHD)

‡ Human Immunodeficiency virus/ acquired immunodeficiency syndrome (HIV AIDS), Sepsis, Malaria

†Acute kidney injury, nephrolithiasis, chronic kidney disease

╫chronic liver disease, Peptic Ulcer Disease

$ cancer (cervical and Acute Myeloid Leukemia (AML)), Electrolyte Abnormalities (Hyperkalemia, hyponatremia)

Ten (11.49%) patients had one comorbidity only, 24(27.59%) patients had two comorbidities, while 53(60.92%) patients had 3 or more comorbidities (figure 5).

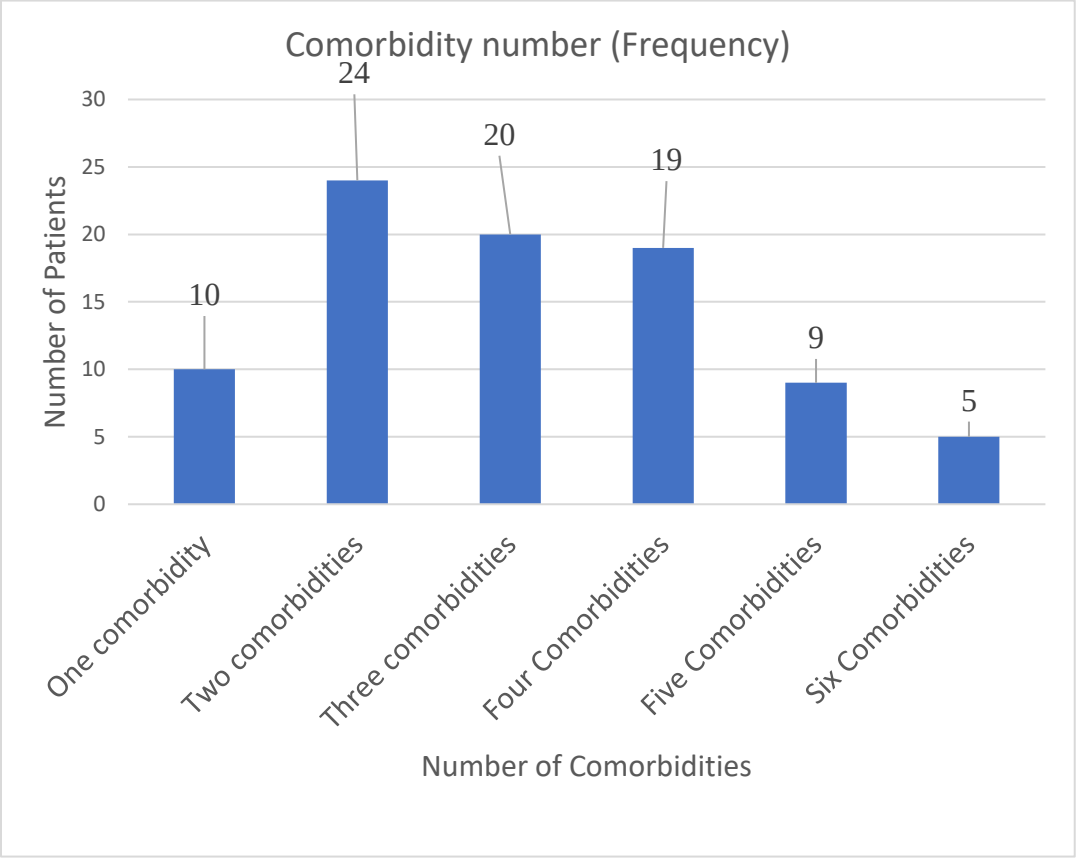

Figure 5: Number of comorbidities among patients with DM admitted to JMC from October 01, 2020, to June 30, 2021.

Among the study participants, 67 (55.8%) of them had at least one long-term diabetic complication, of which neuropathy 42(62.68%) was the most common (Table 4).

Table 4: Prevalence of long-term diabetic complications among patients with DM admitted to JMC from October 01, 2020, to June 30, 2021

Variables	Frequency n=120	%
Presence of long-term diabetes complications		
Yes	67	55.80
No	53	44.20
Specific types of complications (n=67)		
Neuropathy	42	62.68
Nephropathy	17	25.37
Retinopathy	14	20.89
Diabetic foot ulcer	7	10.45

5.4. Medication-related factors

Patients' medication history revealed that, of known diabetic patients, 34(39.08%) patients were taking NPH insulin, followed by metformin 31(35.62%). Similarly, among known DM patients, 50(57.47%) of them were on non-antidiabetic medications. From those medications, the majority 29(58%) of the patients were taking ACEIs (Table 5).

Table 5: Past medication history among patients with DM admitted to JMC from October 01, 2020, to June 30, 2021

Type of medications	**Frequency (n=87)**	**%**
Antidiabetic medications		
Injectable (NPH)	34	39.08
Oral glucose-lowering agents		
Metformin	31	35.62
Metformin + Glibenclamide	17	19.54
Glibenclamide	2	2.29
Injectable (NPH)+ oral glucose-lowering agent (metformin)	3	3.45
Non-antidiabetic medications	**(**n=50)	
Cardiovascular agents		
Angiotensin-converting enzyme inhibitors (ACEIs)	29	58
Antilipidemic agents	21	42
Diuretics	19	38
Beta-blockers (BB)	2	4
Drugs Affecting the Blood		
Antiplatelets	12	24

Besides antidiabetics, there were also non-antidiabetic medications used in the management of admitted diabetic patients. Among those, cephalosporins were the commonest among anti-infectives and were prescribed for 63(52.5%) of the patients. Moreover, antilipidemic 47(39.16%) agents were the most commonly prescribed cardiovascular drugs (Table 6).

Table 6: Patterns of medication use among diabetic patients admitted to JMC from October 01, 2020, to June 30, 2021.

Types of medications*	Frequency n=120	%
Anti-infectives		
Cephalosporins	63	52.50
Vancomycin	23	19.16
Metronidazole	19	15.83
Penicillin's	15	12.50
Tetracyclines	13	10.83
Macrolides	11	9.16
Fluroquinolones	10	8.34
Anti-tuberculosis drugs	8	6.67
Antifungal agents	4	3.34
Antivirals	2	1.67
Other†	4	3.34
Cardiovascular agents		
Antilipidemic agents	47	39.16
(Angiotensin converting enzyme inhibitors (ACEIs)	40	33.34
Diuretics	26	21.67
Calcium channel blockers (CCBs)	17	14.16
Beta blockers (BB)	16	13.34
Drugs Affecting the Blood		
Antiplatelets	41	34.16
Anticoagulants	21	17.50
Ant anemics	9	7.50
Gastrointestinal medicines		

Antiulcer Agents	16	13.34
Cathartics and laxatives	8	6.67
Antiemetics	6	5.00
Vitamins	8	6.67
Analgesics	8	6.67
Antidepressants	6	5.00
Others[$]	4	3.34

*Drug grouped based on Ethiopian Essential medicine lists, 2020

† Clindamycin, Meropenem

$ Adrenaline, Dexamethasone, Dopamine, Prednisolone

5.5. Clinical Outcomes

During the study period out of 120 patients who participated in this study, 16(13.34%) patients died. Four (3.33%) patients were referred to other institutions, while 3(2.5%) of the patients were self-discharged (Figure 6). Of 16 deaths, 8(50%) were admitted due to infections 5(31.25%) due to pneumonia, (2(12.5%) due to TB, 1(6.25%) due to RVI), 2(12.5%) due to DKA, 2(12.5%) CHF, 2(12.5%) due to Renal Failure, and 1(6.25%) each for DFU and cardiogenic shock. Five patients died within 5 days of admission while the remaining 11 were after 5 days of hospitalization.

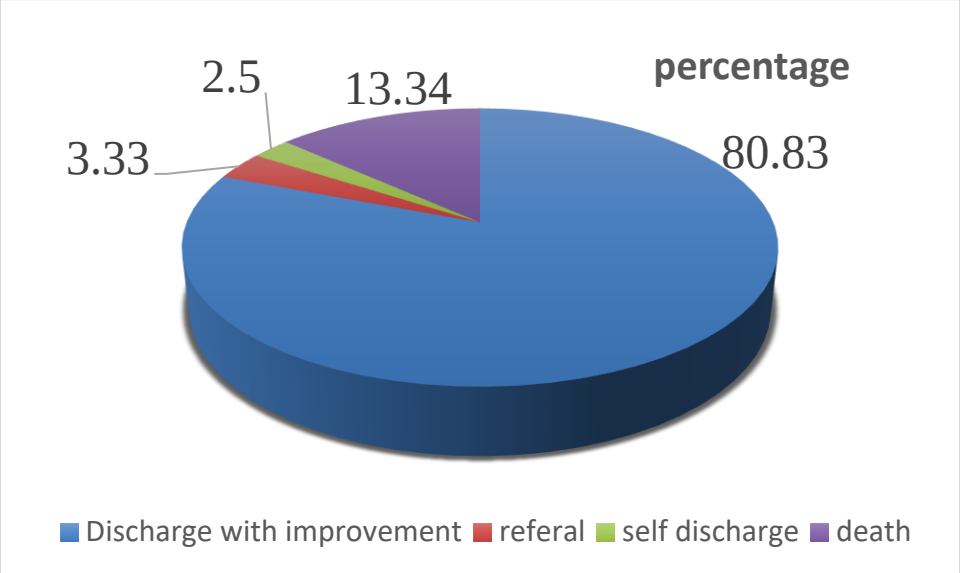

Figure 6: Outcome at discharge among patients with DM admitted to JMC from October 01, 2020, to June 30, 2021.

The mean survival time to in-hospital death was 11.5± 9.49 days. The median length of hospital stay was 8 days (interquartile range of 6-15.75 days). There was no significant difference between T1DM and T2DM for in-hospital mortality among DM patients admitted to JMC (log-rank P=0.503) (Figure 7).

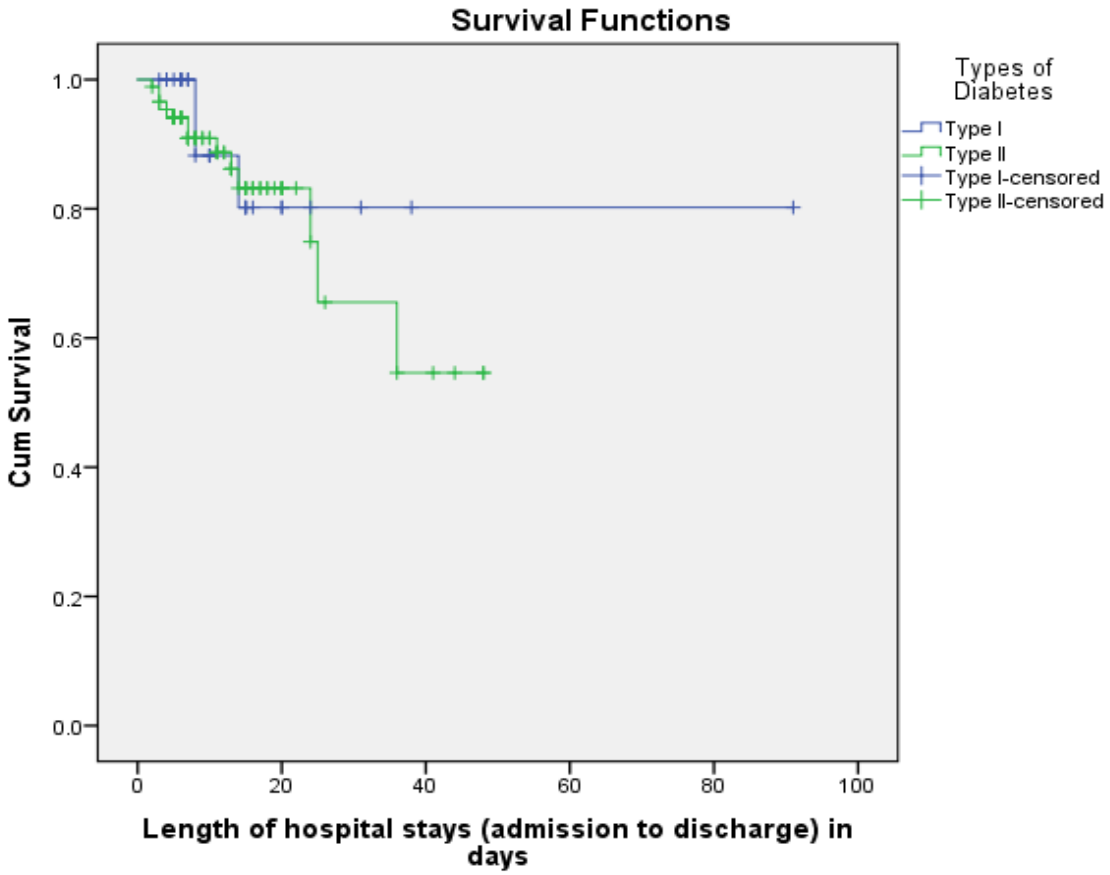

Figure 7: Kaplan-Meir survival curve for T1DM and T2DM patients admitted to JMC from October 01, 2020, to June 30, 2021

Eighty-one (67.5%) of patients had controlled RBS Immediately before discharge or death while 39(32.5%) had poorly controlled RBS (figure 8).

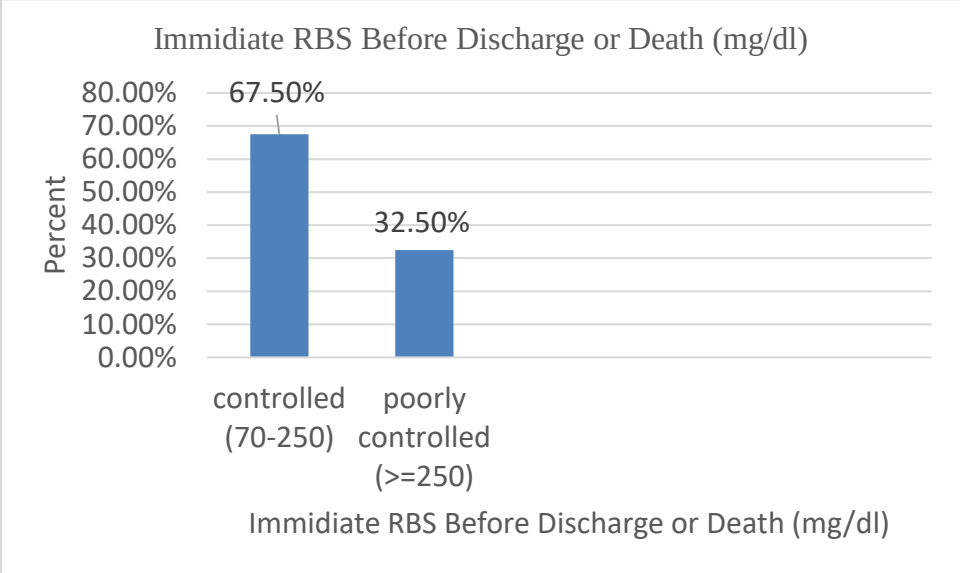

Figure 8: Immediate RBS Before Discharge or Death (mg/dl) among patients with DM admitted to JMC from October 01, 2020, to June 30, 2021.

In-Hospital Complications

Out of 120 patients who participated in this study, 22(18.3%) patients developed in-hospital complications. Among these complications, HAIs 8(36.36%) were commonly seen. More than one complication occurred in 6(27.27%) patients (Table 7).

Table 7: In-Hospital complications among diabetic patients admitted to JMC from October 01, 2020, to June 30, 2021

In-hospital complications	**Frequency (n=22)**	**%**
Hospital-acquired infection*(HAIs)	8	36.36
Deep Vein Thrombosis	6	27.27
Coronavirus disease 2019 (COVID-19)	5	22.73
Septic Shock	4	18.18
Cardiogenic pulmonary edema	3	13.64
Acute kidney injury (AKI)	2	9.09

*Hospital-acquired pneumonia (HAP), pressure bedsore.

5.6 Thirty-day rate of re-admission

Of the 104 patients discharged 20(19.23%) experienced at least one unplanned 30-day hospital readmission. The mean ± SD survival time to the first readmission was 18.50 ± 7.02 days. About 15 (75%) patients were readmitted due to worsening of their preexisting conditions, and 5 (25%) patients were readmitted because of new conditions. The commonest cause of readmission was Hyperglycemic Emergency (DKA and HHS) which contributed 6(30%). Among the readmissions, 8(40%) patients were readmitted in the 3rd week. (Table 8).

Table 8: Thirty-day rate of readmission among diabetic patients admitted to JMC from October 01, 2020, to June 30, 2021.

Readmission characteristics		**Frequency (n=20)**	**%**
Condition on readmission	Worsening of their preexisting conditions	15	75
	New diagnosis	5	25
Reason for 30-day readmission	Hyperglycemic Emergency (DKA and HHS)	6	30
	Health-care associated pneumonia (HCAP)	5	25
	Renal disease	5	25
	Hypertension	2	10
	Congestive Heart failure	2	10
Readmitted within 30-day after how many days back of discharge (in days)	≤ 7 days	1	5
	8-14 days	4	20
	15-21 days	8	40
	22-30 days	7	35

5.7. Predictors of in-hospital Mortality

The result of bivariate analysis of sociodemographic, drug-related, and disease-related factors showed that urban residence (CHR: 3.51; 95%CI [1.25, 9.85]; p = 0.017), elderly age (CHR: 1.04; 95%CI [1.004, 1.062]; p = 0.027), not having formal education (CHR: 0.198; 95%CI [0.059, 0.664]; p = 0.009), primary education (CHR: 0.224; 95%CI [0.054, 0.935]; p = 0.04), DKA (CHR: 4.94; 95%CI [1.11, 21.87]; p = 0.036), having 5 comorbidities (CHR: 10.48; 95%CI [1.08, 101.12]; p = 0.04) and 6 comorbidities (CHR: 19.17; 95%CI [2.11, 173.8]; p = 0.009), and not using of non-antidiabetic medications before admission (CHR: 0.224; 95%CI [0.072, 0.702]; p = 0.01) were significantly associated with in-hospital mortality among admitted DM patients whereas female gender (CHR: 0.31; 95%CI [0.07, 1.37]; p = 0.122), newly diagnosed DM (CHR: 2.81; 95%CI [0.638, 12.38]; p = 0.172), presence of diabetes complications (CHR: 0.022; 95%CI [0.0003, 1.445]; p = 0.074, and diabetes related admission (CHR: 2.45; 95%CI [0.848, 7.09]; p = 0.098) were less likely associated with in-hospital mortality among admitted DM patients. From bivariate analysis variables having a P-value < 0.25 were considered as candidates for multivariable cox proportional hazard regression.

On a multivariate cox proportional hazard regression, the hazard of mortality was 3.46 times higher for patients who live in the urban area (AHR: 3.46; 95%CI [1.12, 9.81]; p = 0.019) as compared with rural living patients. The hazard of mortality was 1.03 times higher as age increased by one year (AHR: 1.03; 95%CI [1.001, 1.059]; p = 0.04). The hazard of mortality was 5.01 times higher in patients who had DKA (AHR: 5.01; 95%CI [1.12, 21.88]; p = 0.038). Also, the hazard of mortality was 9.65 and 14.02 times higher in patients who had five and six comorbidities (AHR: 9.65; 95%CI [1.07, 19.59]; p=0.043 and (AHR: 14.02; 95%CI [1.74, 21.05]; p=0.015, respectively. In contrast, the use of non-antidiabetic medications such as statins, Aspirin (ASA) and other antihypertensive medications before admission) (AHR: 0.135; 95%CI [0.04, 0.46]; p = 0.001) remained protective. Mortality was 86.5% lower among those who used non-antidiabetic medications before admission than non-users of non-antidiabetic medications for their respected medical condition (AHR: 0.135; 95%CI [0.04, 0.457]; p = 0.021) (Table 9).

Table 9: Bivariate and multivariable Cox proportional hazard regression to identify Predictors of in-hospital mortality among DM patients admitted to JMC from October 01, 2020, to June 30, 2021

Variables	Category	Outcome		CHR [95%CI]	P-value	AHR [95%CI]	P-value
		Died	Alive				
Sex	Male	14	67	1		1	
	Female	2	37	0.31 [0.07-1.37]	0.122	0.134[0.07-1.43]	0.134
Residence	Urban	10	36	3.51 [1.25-9.85]	0.017	3.46[1.12-9.81]	0.019*
	Rural	6	68	1		1	
Age (mean ± SD)	50.21± 19.35			1.04[1.004-1.062]	0.027	1.03[1.001-1.059]	0.04*
Educational status	No formal Education	6	52	0.198[0.059-0.664]	0.009	0.27[0.07-1.09]	0.06
	Primary	3	27	0.224[.054-0.935]	0.04	0.31[0.06-1.57]	0.16
	Secondary	1	10	0.419[0.05-3.503]	0.422	0.43[0.05-3.78]	0.45
	College and above	6	15	1		1	
Type of DM	T1DM	3	29	1			
	T2DM	13	75	1.53[0.435-5.37]	0.508		
Previous hx of admission	Yes	8	35	0.707[0.264-1.89	0.49		
to JMC	No	6	38	1			
Newly diagnosed DM	Yes	2	31	2.811[0.638-12.388]	0.172	1.85[0.40-8.50]	0.42
	No	14	73	1		1	
DKA	Yes	2	57	4.94[1.11-21.87]	0.036	5.01[1.12-21.88]	0.038*
	No	14	47	1		1	

Antidiabetic medication before admission	Yes	14	73	1		1	
	No	2	31	0.364[0.08-1.60]	0.182	0.78[0.17-3.67]	0.76
Non-Antidiabetic medication use before admission (CVD drugs)	Yes	12	38	1		1	
	No	4	66	0.224[0.072-0.702]	0.01	0.135[0.04-0.457]	0.021*
Presence of diabetic complications	Yes	16	51	0.022[0.0003-1.445]	0.074	0.71[0.47-5.39]	0.91
	No	0	53	1		1	
RBS immediately before discharge or death	controlled	7	74	1		1	
	Poorly controlled	9	30	3.005[1.12-8.10]	0.03	2.42[0.884-14.89]	0.085
Comorbidity Number	1 comorbidity	0	10	1		1	
	2 comorbidities	0	24	0.07[0-4.07]	0.972	0.004[0.07-9.52]	0.969
	3 comorbidities	3	17	0.297[0.234-28.21]	0.361	2.21[0.198-24.77]	0.519
	4 comorbidities	5	14	4.23[1.05-38.62]	0.201	5.845[0.495-68.99]	0.161
	5 comorbidities	3	6	10.48[1.08-101.12]	0.04	9.65[1.07-19.59]	0.043*
	6 comorbidities	4	1	19.17[2.11-173.81]	0.009	14.02[1.74-21.15]	0.015*
DM Related Admission	Yes	5	65	2.452[0.848-7.09]	0.098	1.324[0.402-4.365]	0.644
	no	11	39	1		1	

AHR: Adjusted hazard ratio, CHR: Crude hazard ratio, CI: Confidence interval, CVD: Cardiovascular disease, DKA: Diabetic ketoacidosis, DM: Diabetes Mellitus, JMC: Jimma medical center, RBS: Random blood sugar (glucose), SD: standard deviation, T1DM: Type one diabetes mellitus, T2DM: Type two diabetes mellitus,*statistically significant at P<0.05

5.8. Predictors of 30-day readmission.

In the bivariate analysis of sociodemographic, drug-related, and disease-related factors showed that female gender (CHR: 3.7; 95%CI [1.34, 10.2]; p = 0.012) and being house wife (CHR: 7.12; 95%CI [1.62, 31.45]; p = 0.009) were significantly associated with 30-day unplanned hospital readmission. On the other hand, known DM (CHR: 4.07; 95%CI [0.84, 19.74]; p = 0.08), history of admission to JMC last year (CHR: 1.89; 95%CI [0.69, 5.17]; p = 0.22), DKA (CHR: 0.44; 95%CI [0.16, 1.19]; p = 0.11), hypertension (CHR: 0.415; 95%CI [0.15, 1.11]; p = 0.08), ICMP (CHR: 2.5; 95%CI [0.81, 7.72]; p = 0.112), renal disease (CHR: 2.10; 95%CI [1.02, 6.01]; p = 0.164), and LOS (CHR: 0.98; 95%CI [0.95, 1.01]; p = 0.196) were less likely associated with 30-day unplanned hospital readmission. From bivariate analysis variables having a P-value < 0.25 were considered as candidates for multivariable cox proportional hazard regression.

On a multivariate cox proportional hazard regression, the hazard of the 30-day rate of readmission was 3.71 times higher for female patients (AHR: 3.71; 95%CI [1.36, 10.3]; p = 0.02). Also, the hazard of the 30-day rate of readmission was 4.48 times higher for patients who had renal disease (AHR: 4.48; 95%CI [1.26, 15.93]; p = 0.021) (Table 10).

Table 10: Bivariate and multivariable Cox proportional hazard regression to identify Predictors of 30-day rate of readmission among diabetic patients admitted to JMC from October 01, 2020, to June 30, 2021.

Variables	Category	30-day Readmission		CHR [95%CI]	p-value	AHR [95%CI]	p-value
		Yes	No				
Sex	Male	11	56	1		1	
	Female	9	28	3.7[1.34-10.2]	0.012	3.71[1.36-10.3]	0.02*
Age (mean ± SD 48.38± 18.96 years)				0.997[0.97-1.02	0.827		
Occupation	Gov't employee	4	10	1		1	
	Merchant	6	22	1.42[0.39-5.02]	0.59	1.9[0.48-7.5]	0.35
	Farmer	4	35	2.4[0.54-10.69]	0.25	4.9[0.79-30.27]	0.087
	House wife	6	17	7.12[1.62-31.45]	0.009	3.06[0.64-14.70]	0.16
Known DM	Yes	18	55	4.07[0.84-19.74]	0.08	5.13[0.93-28.27]	0.06
	No	2	29	1		1	
previous hx of	Yes	9	26	1.89[0.69-5.17]	0.22	0.55[0.13-2.38]	0.42
admission to JMC last year	No	11	58	1		1	
DKA	Yes	7	50	0.44[0.16-1.19]	0.11	0.35[0.12-1.02	
	No	13	34	1		1	0.053
Hypertension	Yes	7	34	0.415 [0.15-1.11]	0.08	0.16[0.04-1.55]	0.08
	No	13	50	1		1	
ICMP	Yes	4	3	2.5[0.81-7.72]	0.11	1.85[0.44-6.33]	0.32

	No	16	81	1		1	
Renal disease	Yes	5	13	2.10[1.02-6.01]	0.164	4.48[1.26-15.93	0.021*
	No	15	71	1		1	
DM Related Admission	Yes	11	54	0.66[0.27-1.64]	0.36		
	No	9	30	1			
LOS (mean ± SD) 12.76 ± 12.06 days				0.98[0.95-1.01]	0.196	0.98[0.95-1.02]	0.49
Presence of diabetic complications	Yes	14	37	0.98[0.37-2.6]	0.97		
	No	6	47	1			
RBS immediately before discharge or death	controlled	11	63	1			
	Poorly controlled	9	21	1.73[0.64-4.72]	0.284		

AHR: Adjusted hazard ratio, CHR: Crude hazard ratio, CI: Confidence interval, DKA: Diabetic ketoacidosis, DM: Diabetes Mellitus, ICMP: ischemic cardiomyopathy, JMC: Jimma medical center, LOS: Length of hospital stay,* SD: standard deviation, statistically significant at P<0.05

6. DISCUSSION

This study assessed the clinical outcomes and its predictors among patients with DM admitted to Jimma Medical Center (JMC). The overall in-hospital mortality for patients with diabetes was 16(13.34%). Urban residence (p=0.019), Age (p=0.04), DKA (p=0.038), and having a number of comorbidity (five (p=0.043) and six (p=0.015)) were independent predictors of in-hospital mortality. Male gender (p=0.02) and renal disease (p=0.021) remained significant predictors of unplanned 30-day rate of readmission.

Of 120 patients admitted to the hospital, 13.34% died. In-hospital mortality is comparable with the report from the USA, (16%) (53), Nigeria, (11%) (67) and Addis Ababa, Ethiopia, (10.6%) (23). However, in a finding from Nigeria, (32.5%), higher overall mortality was reported (47). The discrepancy may be due to differences in the study design and differences in the reason for admission. In this study, among died patients, 37.5% were admitted due to infection. Hence, infection-associated mortality was the leading one in our case. However, a study from Nigeria found that the highest mortality was in those that presented with hypoglycemia, stroke, and DFU (47). Still, the proportion of mortality is higher than the finding of a study done in the Harari region, Ethiopia (4.4%) (68), and WHO report (5.2%) (69). In the current study among died patients, 81.25% were T2DM patients with 56.25% patients above the age of 60 years. The majority of them were known diabetics and consequently, they were presented with multiple comorbidities which might contribute to amplified mortality.

The current study also identified the predictors of mortality among admitted DM patients. Accordingly, rural residence, age, DKA, and having some comorbidities (five and six) were found to be significant and independent predictors of mortality, while the use of non-antidiabetic medications such as statins, ASA, other antihypertensive medications before admission was associated with a lower risk of mortality.

The hazard of mortality was 3.46 times higher for patients who live in urban areas (AHR: 3.46; 95%CI [1.12, 9.81]. This finding was compatible with reports from China (70, 71). But the finding was inconsistent with another study done in China (72) and USA (73, 74). The above studies in China identified a high rate of sedentary life, easy access to energy-rich food, decreased physical activity, and obesity were with a high risk of incident diabetes and in-hospital

mortality(70, 71). Besides, this could be because of comorbidity burden and elderly DM patients among urban residents that may attribute to the higher in-hospital mortality rate in our setup.

The hazard of mortality was 1.03 times higher as age increased by one year (AHR: 1.03; 95%CI [1.001, 1.059]. This was consistent with the study done in the US (53, 75) and Jordan (76). This may be due to an older age may be more likely to have accumulated adverse cardiovascular risk factors, a risk factor for the development of macrovascular complications, the effects of aging and immunosuppression due to increased DM duration may amplify mortality in this group.

The hazard of mortality was 5.01 times higher in patients diagnosed with DKA (AHR: 5.01; 95%CI: [1.12, 21.88]. This was in line with the report from China (72), Nigeria (47, 77), and Addis Ababa, Ethiopia (24). This finding is inconsistent with the study done in Portugal high rates of hospital mortality have been associated with DFUs (78). This increased hazard of mortality due to DKA may be related to cerebral edema, the burden of comorbidities (precipitating factors), some patients presented with septic shock which in turn contributed to DKA-associated mortality in the current study.

The hazard of mortality was 9.65 and 14.02 times higher in patients who had five and six comorbidities as compared with no comorbidity (AHR: 9.65; 95%CI [1.07, 19.59] and (AHR: 14.02; 95%CI: [1.74, 21.15], respectively. This finding was similar to studies done in Italy (79, 80), Israel (81), and Brazil (82) where the most common reported risk factor reported for DM mortality was comorbidity burden. This might be since comorbidity may be associated with increased severity of diseases, it complicates the clinical course of diseases and attenuates the body's natural defense mechanism against diseases by affecting many-body systems simultaneously.

Mortality was 86.5% lower for those who used non-antidiabetic medications such as statins, ASA, and other antihypertensive agents before admission (AHR: 0.135; 95%CI [0.04, 0.457]. This result was supported by a study reported from Iceland where Statin use was associated with 53% lower all-cause mortalities and 50% lower cardiovascular mortality in patients with DM (83). This result was in line with a study from America where Statin therapy in older people (≥ 65 years) without CVD was associated with a lower risk of all-cause mortality by 14%, CVD death by 20%, and stroke by 15% (84). Similarly, it supplements another study conducted in

America, among COVID-19 patients, those with DM receiving statins had a 12% reduction in the adjusted risk of in-hospital mortality (85). It is also supported by the ADA guidelines which recommend low-dose aspirin for diabetic patients with 10-year CVD risk ≥10%. For patients who are at intermediate (5% to 10%) 10-year CVD risk, aspirin can be prescribed based on the clinician's clinical judgment (86). Similarly, ACEIs reduced all-cause mortality, cardiovascular mortality, and cardiovascular events in patients with DM (87, 88).

During the study period, 22(18.3%) patients developed in-hospital complications. The most commonly encountered in-hospital complications were HAIs such as HAP and Pressure ulcers which accounted for 8(36.36%). Deep Vein Thrombosis (DVT), COVID-19, and Septic shock were found to be 6(27.27%), 5(22.73%), and 4(18.18%), respectively. This finding was in line with the study done in the US, where DM was associated with an increased risk of pneumonia among patients undergoing total elbow arthroplasty (89). Similarly, another study from Poland indicated that diabetes has been found to increase complications and mortality rates in hospitalized COVID-19 infected patients (90). This finding is inconsistent with another study done in the USA, where DM is not a risk factor for the development of HAP and mortality associated with this nosocomial infection (91). These differences could be attributed to the double burden of diseases (communicable and non-communicable) and hyperglycemia caused dysfunction of the immune response predisposes the patients to nosocomial infections (92, 93) in developing countries like Ethiopia.

In this study, 20(19.23%) patients have experienced at least one unplanned 30-day hospital readmission. The mean ± SD time to the first readmission was 18.5 ± 7.02 days from index discharge. This finding was comparable with studies conducted in the USA (61, 62). It was slightly lower than the study done in Australia, in which the 30-day readmission rate was 24.6% (94) and another study from the USA (24.5%) (95). This difference might be due to the small sample size associated with it decrease readmission rate reported in the current study. In addition, the study from Australia included older DM patients median age of 87 years (IQR, 77-89 years) which could contribute to a higher readmission rate in their study (94). However, this finding was higher than the study done in Saud Arabia, in which (5.2%) experienced at least one 30-day readmission after index discharge (96). These discrepancies may be due to the difference in the number and severity of comorbidities, self-discharge, and longer duration of DM that may

precipitate 30-day unplanned hospital readmission in our study. Besides, the study from Saud Arabia was a retrospective cohort and case-control study which extracted data from medical records where the majority of diabetic patients were referred to the hospital from specific primary health care centers, and may be better health care provision (completeness to admission workup guidelines and adherence of health team to readiness for discharge criteria) reduced the probability of early readmission at Saud Arabia (96).

The leading reason for 30-day readmission was HEs such as DKA and HHS, (30%), followed by health-care-associated pneumonia, (25%) and renal disease (25%). This finding was supported by the study conducted in the US (95).

This study also identified the predictors of the 30-day rate of hospital readmission among admitted DM patients. Accordingly, female gender and renal disease were found to be significant and independent predictors of unplanned 30-day hospital readmission.

The hazard of the 30-day rate of readmission was 3.71 times higher for female patients (AHR: 3.71; 95%CI [1.36, 10.3]. Similar findings were observed in a study from the USA (97, 98). On the contrary, other studies reported that females have a significantly lower risk of 30-day readmission (99, 100). The observed increase in the risk of readmission in females could be explained by different factors. Eating disorder predisposition in females may be contributing factor to fluctuating blood glucose levels leading to DKA which contributed to 30-day readmission (101). It has also been suggested that women might be readmitted due to pregnancy-associated complications (102).

Also, the hazard of the 30-day rate of readmission was 4.48 times higher for patients who had renal disease (AHR: 4.48; 95%CI: [1.26, 15.93]. This finding was consistent with some studies which reported renal disease was associated with an increased risk of being readmitted to the hospital within 30 days (61, 94). This finding contrasted a study was done in New England which reported that macrovascular complications (CAD, HF, PAD, and stroke), preadmission insulin use, and discharge against medical advice were among significant predictors of the 30-day rate of readmission (103). This increased readmission among renal patients may be attributed to abnormal glucose metabolism. Besides, DM patients with renal problems could also be

readmitted within 30-days of discharge for catheter vascular access and associated infections or pain.

Though a prospective nature and a little bit longer study period (over nine months) provide better data quality and a real picture of the problem, this study suffers from some limitations. Firstly, it was a single-center study. Secondly, RBS was used in the study; rather than HgA1C which better describes the status of glucose control in the last three months. This is because the hospital did not use HgA1C routinely to monitor patients' blood glucose levels so it is too costly for the researcher to pay for all study participants. Thirdly, self-discharged and referred patients were considered to calculate the 30-day hospital readmission rate. Fourthly, it might be difficult to generalize the findings of this study to the entire DM population due to the small sample size, although it is the pre-planned one.

7. CONCLUSION AND RECOMMENDATION

7.1 Conclusion

In this study, the rate of all-cause in-hospital mortality was noticeably high. More than one-eighth of admitted DM patients died in hospital. Infectious diseases were the leading causes of death. About one-sixth of patients were developed in-hospital complications during their hospital stay, and one-fifth of index discharged patients were experienced 30-day readmission. The study showed that urban residence, age, DKA, having many comorbidities (five and six), and use of non-antidiabetic medications such as statins, ASA, and other antihypertensive agents before admission were the statistically significant predictors of in-hospital mortality whereas female gender and renal disease remained significant predictors of unplanned 30-day hospital readmission.

7.2 Recommendation

Based on our research finding we would like to forward the following recommendations: -

For Ministry of Health

- ✓ The Federal Ministry of Health would better participate in urban residents to minimize premature in-hospital mortality due to DM and associated comorbidities.

For Jimma Medical Center Health care professionals

- ✓ Jimma Medical Center has to work on decreasing in-hospital mortality admitted with DKA, elderly age, and comorbid DM patients.
- ✓ It is better if JMC strengthens its health care team to give due attention to admitted DM patients to prevent in-hospital complications.
- ✓ Jimma Medical Center has to devise strategies to reduce in-hospital mortality, in-hospital complications, and 30-day unplanned hospital readmission.
- ✓ Diabetes mellitus follow-up clinic has to work on identifying candidates and initiate timely for non-diabetic medications such as statins, ASA, and other antihypertensive medications to prevent DM mortality and morbidity.
- ✓ Early identification of patients at high risk for unplanned 30-day hospital readmissions like patients who have renal disease and female patients would better get focus at the DM follow-up clinic of JMC.

For researchers

- ✓ Researchers interested in the area should conduct a further nationwide study on a large sample size to identify limitations and gaps in clinical outcomes among admitted diabetes patients.

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ANNEXES

I. Data collection tool

Patient Medical Record Number (MRN): _____

Date of Admission (in Ethiopian Calendar/ GC) _____

Date of Readmission (in Ethiopian Calendar/ GC) _____

Diagnosis_____

Section 1: Socio-demographic characteristics of the patient

1. Age (years) ---------

2. Sex M ☐ F ☐

3. Residence Rural ☐ Urban ☐

4. Marital status A, Married B, Single C, Divorced D, Widowed

5. Occupation A, Government employee B, Merchant C, Farmer D, Students E, Housewife F, Daily Laborer G, NGO's H, Retired I, Others specify_____

6. Educational status A, Unable to read and write B, Able to read and write C, primary D, secondary E, college, and above

7. Type of ward…….

8. Body weight (kg)……, height (m)……, BMI (weight (kg)/height**²(m)……

Section 2: Clinical Characteristics

9. Blood glucose at admission (mg/dl) A, RBS……

B, FBS…….C, HgA1C (%) ……..…

10. Types of Diabetes A, type I B, Type II C, Other

11. Duration of DM since confirmed by a physician (in years): A, newly diagnosed B, known diabetes (write the duration in years) ……

12. Duration of treatment with antidiabetic medications (in years) ……

13. Regular follow-up at the diabetic clinic? A, Yes B, No C, NA

14. If yes for Q 13 how frequently he/she attends the follow-up clinic? A, Monthly B, Every 2 months C, Every 3 months D, Other….

15. Prior history of admission to JMC and/ or Private Health facilities (clinic or Hospital) last year? A, Yes B, No

16. If 'Yes' for Q15 how many times to JMC?

17. If 'Yes' for Q15 how many times to Private health facilities (clinic or hospital)?

18. Length of stay in days for each current event at JMC? .....

19. Length of stay in days for each current event at Private health facilities (clinic or hospital)? ….....

20. Diagnosis/assessment of current admission/ readmission……

21. Is (are) there precipitating risk factors (reason) for current hospital admission/ readmission known?

A) Yes: ____ B) No: _____

22. If 'Yes' for Q21 please tick the type of precipitant (reason) below (more than one option possible)

A, DKA B, HHS C, Hypoglycemia D, Nephropathy E, Neuropathy F, Foot ulcer G, PAD

H, Infection…. H, CVD…….

I, Other…….

23. Antidiabetic medication before admission

A, No medication B, NPH _____ C, RI_____D, Metformin _____

E, Glibenclamide _____F, Metformin + Glibenclamide _____

G, Insulin + Metformin _____H, Others_____

24. non-Antidiabetic medication before admission with started date

A, No medication… B, Simvastatin _____C, Atrovastatin_____

D, Aspirin_____ E, Enalapril_____ F, HCTZ_____

G, Amlodipine_____ H, Others_____

25. Did the patient discontinue antidiabetic medication (s) and or other medication (s) before admission?

A, Yes B, No

26. If yes in question number 25 above, what is the possible cause and since when?

A) Missed dose of the medication: _____ B) patient forgets to take: _____

C) Inappropriately stored (damaged product) injected (if insulin) and /or taken: _____

D) Medication is not available: _____ E) Patient prefers not to take F) other (specify)……

27. Insulin therapy and the response of the patient with HEs at admission/readmission and during the hospital stay

Date	Day 1		Day 2		Day 3		Day 4	
	time	time	time	time	Time	time	time	time
Insulin								
Regular insulin (units) and route								
NPH (units) and route								
Blood glucose (mg/dl)								
Urine ketones								

28. Co-morbidities (more than one option possible)

A, None B, Hypertension C, CKD D, CAD E, Hyperlipidemia F, Stroke E, Obesity G, PAD H, Others_____

29, Presence of diabetic complications

A, None **B**, Retinopathy **C**, Nephropathy **D**, Diabetic Foot Ulcer (DFU) **E**, Neuropathy **F**, Others_____

Section 3: Intervention and Clinical outcomes

30. Treatment interventions (N.B: Put the values in each box)

s.no	Treatment interventions	Values
1	Amount of insulin used till resolution of HE	
2	Amount of insulin used till resolution of ketonuria	
3	Duration of treatment till resolution of ketonuria (hours)	
4	Duration of treatment till resolution of HE (hours)	

31. Episodes of metabolic complications during treatment, if any

s.no.	Metabolic complication	No. of episodes during the hospital stay
1	Episodes of hyperglycemia after resolution of HE	
2	Episodes of hypoglycemia	
3	Episodes of ketonuria after resolution of HE	

32**.** Discharge date (Day/Month/Year) …….

33. Length of hospital stays (admission to discharge) in days…….

34. Treatment outcomes

s.no	Treatment outcome	Time (Day/Month/Year)
A	Discharge with improvement	
B	Referral	
C	Self-discharge	
D	Death	
E	Others	
F	In-hospital complications type ……	After how many days back it developed?
35. Readmitted date within 30 days of discharge		After how many days back of index discharge?
		LOS
36. Number of readmissions: ……		

37. Discharge blood glucose (mg/dl)

A, RBS……B, FBS……C, HgA1C (%) ……

38. If died, date of death (Day/Month/Year) …….

Section 4: Medication prescribed after admission

s.no	37. Medication	Dosage regimen	Start or regimen modification date	Discontinuation date (if any)
1				
2				
3				
4				
5				
6				
7				
8				
9				
10				
11				
12				
13				
14				
15				

Section 5: Laboratory data and vital signs

38. Pertinent laboratory results

		Time				
Blood glucose						
HgA1C						
Vital signs	BP					
	PR					
	RR					
	Temp					
CBC	WBC					

	WBC Differential					
	RBC					
	Hgb					
	Hct					
	MCV					
	MCH					
	MCHC					
	PLT					
RFT	Cr					
	Blood Uria Nitrogen (BUN)					
	Phosphate					
LFT	AST					
	ALT					
	ALP					
	Bilirubin					
U/A						
Lipid panel	TC					
	TG					
	LDL					
	HDL					
Serum Electrolytes	Na					
	K					
	Cl					
	Mg					
	iCa/ TCa					
	PH					
	Albumin					
	ESR					
Other diagnostic procedure						

II. Patient information sheet

Title of the research: Clinical outcomes and its predictors among patients with Diabetes Mellitus admitted to Jimma University Medical Center.

Name of Principal investigator: Dereje Eyob Tediso

Name of Study area: JMC

Research budget covered by: Jimma University

Research objective: To assess Clinical outcomes and its predictors among patients with DM admitted to JMC.

Significance of the study: The finding generated by this study will help the healthcare professionals to improve the management of DM patients by strengthening diabetes care, educating the patients on how to decrease modifiable determinants of in-hospital mortality and 30-day readmission rate. The study can be also used as an input for further future similar studies on related topics and the hospital management can use this result to expand its diabetic care services.

Study procedure: The data collectors were interviewed patients using a semi-structured questionnaire after obtaining consent from the patient and other relevant data were extracted from the patient's chart.

Risks: No risk except the time participants spend during the interview.

Benefits: The study is beneficial for patient's quality service delivery for future encounters and source of data for the hospital and policymakers.

Participant's right: The patient has a full right to stop the interview at any time and not to allow review of his/her chart, or to skip any question that he/she does not want to answer.

Incentives: The patient will not be provided any specific incentive for taking part in the research other than acknowledgment.

Confidentiality: The study result was not included the patient's name, address, and any personal details that may lead to the identification of the patient, and any information communicated was kept confidential.

Agreement: Patients are expected to be fully voluntary to participate in the study.

Contact: if you want any detailed information and encounter inconveniences about the study you can contact with: **Dereje Eyob**. Cell Phone: +251916681542 or email address: derejeyob@gmail.com

III. Patient informed consent

I am informed fully in the language I understand about the aim of the above-mentioned research. I understand the purpose of the study entitled "Clinical outcomes and its predictors among patients with DM admitted to JMC." I have been informed this study which involves collecting 120 samples. I have also read the information sheet or it has been read to me. In addition, I have been told all the information collected throughout the research process will be kept confidential. I understood my current and future medical services will not be affected if I refused to participate or withdrawal from the study. I_____, after being fully informed about the detail of this study, hereby gave my consent to participate in this study and approve my agreement with signature.

Patient Name_____ Signature_____ Date_____

Investigator Name _____ Signature _____Date_____

IV. Data collection Tool Afan Oromo Version

Kutaa 1ffaa.Odeeffannoojireenyahawaassummaa fi eeyyummaaDhukkubsataa

1. Umurii------
2.saala: a) dhiira b) dhalaa
3. Bakka jireenyaa: a) Magaalaab) Baadiyyaa
4. Haala gaa'ela: a) kan fuudhe b) Kanhinfuune c) kanhiike/hiikte d) gursummaa
5.HaalaHojii: a) hojjetaa mootummaa b) daldalaa c) Qote bulaa d) Barataa
e) dafqaan bulaa f) hojjetaamitimootummaa g) soorama kan bahe/kan baate i) kan biraa
6) HaalaBaruumsaa: a) barreessuuf dubbisuu kan hin dandeenye b). dubbisuuf barreesu kan dandahu. c) sadarkaa tokkoffaa kan barate D) sadarkaa lammafffaa kan barate E) diploma fi isaa ol kan barate.
7). kutaa ciisicha dhukkubsataa: ----------
8). Ulfaatina qaamaa:----------dheerina (meetiraan)-------BMI (ulfaatina/dheerina).----------
Kutaa lammaffaa: -Hubannaadhukkubsataarakkoodhukkubasukkaaraawaliinwal-qabateedhufuirratti
9). Dhukkubni sukkaara kun erga si qabaatee waggaa meeqaa?
A. haara B). dhukkubni kun duraanu kan narra jirudha.
10). Turtii wagga meeqaatiif qooricha sukkaara fudhattee?
11.) dhukkuba sukkaara kana tohachuuf hordoffi mana yaalaa qabduu?
a. eyyee b.miti/hin qabu
12). Yoo eyyee jette ji'a meeqa meeqanan hordoffi gootaa?
a. ji'a jiaan. B. jia lama lamaan . C. ji'a sadii sadiin d.kan biro
13.kanaan dura dhukkubsatte beektaa? (dhaabbile fayyaa dhuunfaa ykn dhaabbilee fayyaa mootumaatti) yaalamtea?
a.eyyee b.miti
14.yoo eyyee jettee ,yeroo meqaa garaamana yaalaatti deddeebitee wala'anamuuf.
15 guyyaa meeqaaf ciistee yalamte dhukkuba kana.
16). Erga yaalamte booda qoricha kan addaan kuteetaa.?
a.eyyee b.miti.
17). Yoo eyyee jettee
a. hanga meeqa ituu hin fudhatiin turte?
b. qooricha irranfachudhani
c.qooricha argachuu hin dandeenye.
d.heeyama kootiin qooricha kana fudhachu hin barbaanne, e) others.

V. Patient information sheet Afan Oromo version

Mata duree qoranichaa.: Namoota dhukkuba sukkaara qabaniifi safartuuwwandhukkubaa kana fidaan fi firiwwan Kiliinikaala dhukkubsatoota irratti kan bu'uureefateedha.

Odeeffannoo hirmaataa

Maqaa qorattootaa: Darajjee Iyyoob

Bakkaqorannoo: Giddugala Hospitaala Jimmaa

Baasiiqorannookanhaguugu: Yuniversiitii Jimmaa

Kaayyooqorannoo/barbaachisummaqorrannookanaa:
haalotadhukubsattonidhibeesukkarahospitalaspeshaliziiyuniversittiijimmaaittingalan, wantootasababata'uudanda'anii fi bu'aatajaajilafayyaisaaniikanqorachudha.

Fayyidaaqorannoo: Qorannoonkun haalota, baayyinaa fi murteessitootarakkinaittifayyadamiinsaqoricha,dogoggorafayyadamiinsaqorichaa fi akkasumasta'iiwwanqorichaahinbarbaadamneenwalqabatanii fidhukkubsattootaciisaniiyaalamanirrattimul'atanqorachuunfulduratti faarmaasistoonni rakkinoota eeramankunneenaddabaasuunfurmaataittikennuuni fi ittisuungaheetajaajilakilinikaalfaarmaasiihaarata'eakkadeeggarangargaara.

Tartiibaadeemsaqorannoo: Odeefffannowwan addad adda waahe dhukkuba Kanaan walqabattanfi kan funnanaman gariin gosa murtawaa gaafilleen yommu tahaan innis eyyama dhukkubsatichaanidha.odeeffannowwan hafan immoo chaartii haala dhukkubsataa Sanaa kan ibsu irraa kan fudhatamaniidha.

Rakkoodhukkubsataarragahu: Miidha hin qabu garu gaaffileen gaafatamaan yeroo qisaaseessu qofa male.

Mirgahirmaataa: Mirgihirmaachuuyookindhiisuu fi yeroobarbaadanaddaankutuuhirmaatichaa kan eegamaadha.

Fayyidaa:Qorannichifulduratti: Qoraanichi buhaa kan qabuufi garaa fuula duraattis tajaajila qulqullina qabuu fiduuf.

Kanfaltii: Dhukkubsatichigalataanalahirmaachuudhaafkanfaltiiaddaa kan hin argaatne tahu.

Icciitii: Maqaa fi teessoondhukkubsatichaahincaqafamu.

Waliigaltee: Dhukkubsatichiwaliigalteeguutuugodhajedhameeyaadama.

Wal-qunnamtiiodeeffanno/Gaaffii fi yaadaaf

Kanaan walqabateeyookiin yaadabiraa yoo qabaattan:

Waanisinittihintolleyookingaafattankamiifuunamnidubbisuuqabdan:

DarajjeeIyyoob, Lakk. Mob: 0916681542 yookiinImeelii derejeyob@gmail.com

VI. Informed consent Afan Oromo Version

‘’Giddu gala haandhuura fayyaa jimmaati namoota dhukkuba sukkaara a qabaniFiriiwwanii kiliniikaala fi safartuuwwan dhukkuba kanaa kan qoratuudha.’’ Akkuma beekamu qorannoon godhamukun haala naaf galuun (qooqa/afaan, dhageefadhee) hubadheera.. odeeffannoo ani dhukkubsataan kennu kun haala icitii taheen kan naaf eegamuufi qaaamni sadaffaan ille akka hin dhageenye tahu koo beeksisa..tajaajilaa fayyaa dhukkuba qorannoo gaaffii kanaa irratti illee yoon ani illee hin hirmaanne tajaajilli naf godhamu haala barbaachisuun akka naaf kennnamufi kan walirraa hin ciitne tahu beeksisa. Ani----------, kaayyoo qorannoo kana beeke guuca kana irratti walii galteedhaan ,mallattooo kootiin nan mirkaneessa.

Maqaa dhukkubsataa: ---------- mallato: ---------- guyyaa: -------

Maqaa qorataa: ---------- mallattoo: ---------- guyyaaaa: ----------

VII. Data collection Tool Amharic Version

ክፍል 1. የማህበራዊና የሥነ-ሕዝብ ገፅታዎች

1. ዕድሜ (በዓመት).....
2. ፆታ 1. ወንድ 2. ሴት
3. የሚኖሩበት አካባቢ 1. ገጠር 2. ከተማ
4. የጋባቻ ሁኔታ 1. ያገባ 2. ያላገባ (ላጤ) 3. የፋታ/የፈታች 4. ባሌ/ምስት የሞተበት/ባት
5. የሥራ ሁኔታ 1. የመንግስት ሠረተኛ 2. ነጋዴ 3. አርሶ-አደር 4. ተማሪ 5. የቤት-እመቤት 6. የቀን ሠረተኛ 7. መንግስታዊ ያልሆነ ተቁአም ሠረተኛ 7. ጡረተኛ 8. ሌላ.....
6. የትምህርት ደረጀዎ? 1. ማንበብና መፅሐፍ የማይችል 2. ማንበብና መፅፍ የሚችል 3. 1ኛ ደረጃ የተማረ 4. 2ኛ ደረጃ የተማረ 5. ኮሌጅና ከዚያ በላይ የተማረ
7. የተኙበት የህክምና ክፍል?
8. የሰውነትዎ ክብደት (ኪግ).....ቁመትዎ (ሜትር)..... BMI (ክብደት (ኪግ)/ቁመትዎ*² (ሜትር)

ክፍል 2. ከህመሙ ጋር የተያያዙ ሁኔታዎች

9. የስኳር ህመም ከጀመሮት ስንት ዓመትዎ ነዉ? ሀ. አዲስ ለ. የቆየ .....ዓመት
10. ለስኳር ህመምዎ ህኪምና ከጀመሩ ይኼ ስንተኛ ዓመት ነዉ?
11. ለስኳር ህመምዎ ክትትል ያደርጋሉ? ሀ. አዎ ለ. አይደለም
12. ክትትል የሚያደርጉ ከሆነ በየስንት ግዜ? ሀ. በየወሩ ለ. በየሁለት ወር ሐ. በየሶስት ወር መ. ሌላ
13. በስኳር ህመም ምክንያት ሆስፒታል ተኝተዉ ያዉቃሉ? ሀ. አዎ ለ. አይደለም
14. ተኝተዉ ከሆነ ስንት ግዜ?
15. ተኝተዉ ከሆነ ስንት ቀን?
16. የስኳር ህመም መዲኃንትዎን ሳይወስዱ ቀርተዉ ያዉቃሉ? ሀ. አዎ ለ. አይደለም
17. ሳይወስዱ ቀርተዉ ከሆነ ምክንያቱ ምን ይሁን? ሀ. ሰዓቱን ረስቼ ለ. መዲኃንት መውሰዱን ረስቼ ሐ. መዲኃንቱ ስለሌላ

    መ. መዲኃንትመውሰዱን ስላልፈለኩ

VIII. Patient information sheet Amharic version

ለተሳፊች መረጃ መስጫ ቅን

ተመራማሪ፡ ደረጀ ኢዮብ

የጥናቱ ቦታ፡ ጅማ ዩንቨርሲቲ ሕክሚና *መዕከል*

የጥናቱን ወጪ የሚሸፍነው ድርጅት፡ ጅማ ዩንቨርሲቲ

የጥናቱ አላማ፡ ተኝተው የሚተከሙ የስካር ህሙማን የህክምና ውጤታቸውን እና ተጎደኝ ነገሮችን ለማጥናት

የጥናቱ ሂደት፡ ከታካሚች *ሙ*ለ ፍቃደኝነት ከተገኘ በኋላ መረጽ ሰብሳቢዎች ቃለ-□□ቅ ያደርጉአቸዋል፡፡ እንዲሁም ሌሎች ጠቃሚ መረጃችን ከታካሚወች □መረጽ ቅን □ሰበስባሉ፡፡

□ተሳታፊመብት፡ □ተሳታኝው፡ በጥናቱ ያለመሳተፍና በፈለገው ሰዓት ከጥናቱ የመውጣት መብት የተጠበቀ ነው ::

ዓ ቅማዓ ቅም፡ ተሳታፊው በዚህ ጥናት በመሳተኝ □ሚ□□ኘው ምንም ዓይነትጥቅማጥቅም የለም

የጥናቱ ጥቅም፡ የዚህ ጥናት ውጤት በተመሳሳይ ሁኔታ ሆስ□ታል ለሚገቡ ህሙማን ጥራት ያለው የህክምና አገልግሎት ለመስጠትይጠቅማል

ሚስጥራዊነት፡ □እርሶን ማንነት የሚገልፅ ማንኛውም መረጃ የጥናቱ ውጤት ላይ አይካተትም፡፡

ስምምነት፡ በዚህ ጥናት ላይ የሚሳተፉት ታካሚች ሙሉ አ ቃ□ኛ መሆን አለባቸው በጥናቱ ዙሪያ የበለጠ መረጃ ቢያስፈልግዎ □ሚከተለውን ግለሰብ ማነጋገር ይችላሉ፡፡

ደረጀ ኢዮብ ስል□ ፡- **0916681542** ወይም የኢሜል አድራሻ derejeyob@gmail.com

IX. Patient informed consent Amharic version

የስምምነት ሰነድ

ተኝተው የማታከሙ የስካር ህመማን የህክምና ውጤታቸውን እና ተጎደኝ ነገሮችን ለማጥናት የሚለውን ጥናት አላማውንና ጥቅሙን በሚገበኝ ቋንቋ ተረድቼአለው። ለተሳታፊች የሚሰጠውን የመረጃ ቅጽ አንብበየለው። በጥናቱ ወቅት የሚሰበሰበው መረጃ በምስጢር እንደሚያዝ እና ከጥናቱ ዉስጥ ቢወጣ እንኬን የአሁኑም ይሁን ለወደፊት የሚሰጠኝ አገልገሎት ተፅዕኖ ዉስጥ እንደማይወድቅ ተረድቼአለው።

እኔ..... ፣ የጥናቱን ሙሉ ሀሳብ በመረዳት በጥናቱ ዉስጥ ለመሳተፍ መስማሙቴን በፊርማዬ አረገግጠለሁ።

የታካሚው **ስም**---------- **ኝርማ**----------ቀን_____

መረጃ ሰብሳቢ ስም _____ **ኝርማ** _____ቀን_____