College of Health Sciences

Department of Internal Medicine

Title: Assessment of statin utilization pattern for primary prevention in patients with type 2 DM who have follow up at diabetic clinic in Tikur Anbessa Specialized Hospital; A Hospital-Based Cross Sectional Study, 2021

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A thesis to be submitted to the Department of Internal Medicine, College of Health Sciences, Addis Ababa University, in partial fulfillment of the specialty certificate in Internal Medicine.

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Declaration

This is to certify that the thesis entitled Assessment of statin utilization pattern for primary prevention in patients with type 2 DM who have follow up at diabetic clinic in Tikur Anbessa Specialized Hospital. A Hospital-based cross sectional study was carried out by myself and has not been submitted in part or in full for any other degree or any other university.

The thesis comprises only my original work for specialty certificate in internal medicine. Due acknowledgement has been made in the text to all other materials used.

This thesis is submitted for the qualification of "Specialty in Internal Medicine" complies with the regulations of the University and meets the accepted standards with respect to originality and quality.

Name: Ayanaw Guadie Signature _____ Date _____

Assessment of statin utilization pattern for primary prevention in patients with type 2 DM who have follow up at diabetic clinic in Tikur Anbessa Specialized Hospital. A Hospital-based cross sectional study, 2021

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Contents

ACRONYMS AND ABBREVATIONS

Abbreviation	Definition
TASH	Tikur Anbessa Specialized Hospital
ADA	American diabetic association
WHO	World health organization
DM	Diabetes mellitus
AACE	American association of clinical endocrinology
CVD	Cardiovascular disease
ASCVD	Atherosclerotic cardiovascular disease
NCD	Non- communicable disease
LDL	Low density lipoprotein
HDL	High density lipoprotein
ACS	Acute coronary syndrome
MI	Myocardial infarction
PAD	Peripheral arterial disease
BMI	Body mass index
HTN	Hypertension
TG	Triglyceride
SBP	systolic blood pressure

Abstract

Background: cardiovascular disease is the leading cause of morbidity and mortality among type 2 diabetic (T2DM) patients. Statin therapy is effective in reducing cardiovascular events for both primary and secondary prevention of ASCVD.

Objective: to assess statin utilization extent for primary prevention of CVD in patients with type 2 DM who are above 40yrs having follow up at diabetic clinic TASH.

Methods and materials: a hospital based cross-sectional study was conducted based on data collected using structured questionnaire by face-to-face interview and the digital record system from june 10, 2021, to September 20,2021.Data entry was made using Epi info version 3.1 and was analyzed using SPSS software version 25.

RESULT: A total of 376 of patients with the age above of 40 with T2DM were participated in this study. statin prescription rate was 87.4%. almost all of patients (99.1%) who are taking statin were on moderate intensity and above with 59.3%% and 39.8%% received moderate and high -intensity statin respectively. From the study conducted, the most commonly prescribed statin was Atorvastatin (85.6%). Predictors of statin prescription were age, use of Both insulin and metformin, occupational status and monthly income as independent determinants of statin use. Use of both insulin and metformin increased the odds of statin use by 2.29 times as compared to the counterparts [AOR= 2.29; 95% CI: 1.07, 4.95]. Having other occupation led to 79% less odds for statin use as compared to government employees [AOR=0.21; 95% CI: 0.09, 0.51]. For each 1-year increase in the age of the patients, the odds of using statin increases by 5% [AOR= 1.05; 95% CI: 1.02, 1.10].

CONCLUSION: In conclusion this study done at showed the highest rate of statin prescription of 87% for primary prevention of ASCVD in type 2 DM patients who are above 40 compared to other studies done recently.Which is consistent with contemporary guidelines recommendation for dyslipidemia and primary prevention of ASCVD.

KEY WORDS- TYPE 2 DM, STATINS, UTILIZATION PATTERN, ADDIS ABABA

1. INTRODUCTION

1.1. Background

Globally, an estimated 422 million adults were living with diabetes in 2014, compared to 108 million in 1980. The global prevalence (age-standardized) of diabetes has nearly doubled since 1980, rising from 4.7% to 8.5% in the adult population [1].

Diabetes prevalence in the WHO African region increased by 129·0% (from 3·1% in 1980 to 7·1% in 2014; This increase is second only to the WHO eastern Mediterranean region, in which the prevalence of diabetes increased by 132·2% (from 5·9% in 1980 to 13·7% in 2014 9. As in other parts of the world, more than 90% of people living with diabetes in sub-Saharan Africa have type 2 diabetes[2].

The presence of T2DM is considered an ASCVD risk equivalent; therefore, individuals with diabetes are considered to be at high, very high, or extreme risk. Approximately 65% of diabetes-related mortality is due to heart disease and CVA[3].

Atherosclerotic cardiovascular disease (ASCVD) defined as coronary heart disease, cerebrovascular disease, or peripheral arterial disease presumed to be of atherosclerotic

origin -the leading cause of morbidity and mortality for individuals with diabetes and results in an estimated $37.3 billion in cardiovascular-related spending per year associated with diabetes[4].

Epidemiologic data from Finland similarly suggest that individuals with Diabetes without prior myocardial infarction and prior myocardial infarction without diabetes indicate similar risk for CHD death in men and women [5]

Mortality rates in diabetes appears to relate to the synergism of hyperglycemia with other cardiovascular risk factors such as dyslipidemia (elevated triglycerides, low HDL-cholesterol and small-dense LDL), hypertension, obesity, reduced physical activity, and cigarette smoking

[6].Therefore, the control of cardiovascular risk factors, including dyslipidemia, is essential. According to American Diabetes Association (ADA)standards of care recommend moderate-

intensity statins for all Diabetic patients between the age of 40 and 75 years as a primary prevention. Primary prevention refers to those patients without documented atherosclerotic cardiovascular disease (ASCVD) whilst secondary prevention refers to those with documented ASCVD[4].

AACE-2017 guideline recommend statins for all diabetics b/n 40-75 age with target LDL-<100 and NON- HDL cholesterol < 130 and for those with 1 or more cardiovascular risk factor or ASCVD 10yr risk > 20 with target LDL <70 and NON-HDL cholesterol < 100[3].

The objective of this study is to determine the extent of statin therapy use for primary prevention of CVD in TYPE 2 DM patients who are above 40yrs having follow up at TASH diabetic clinic.

1.2 Statement of the Problem

According to WHO 2016 report of diabetes in Ethiopia is rising with prevalence of 3.8% Rapid demographic, sociocultural, and economic transitions are driving increases in the risk and prevalence of diabetes and other non-communicable diseases (NCDs) in sub-Saharan Africa [1][2]

Diabetes confers an increased risk of cardiovascular disease (CVD) and CVD is the leading cause of morbidity and mortality in patients with diabetes. Statin therapy is considered one of the cornerstone of both primary and secondary cardiovascular disease prevention in patients with diabetes[7] [8]

Even though statins are recommended to all type 2 DM above 40yrs to reduce all cause mortality, Underutilization is reported in many forms such as inappropriate dosing, issues with adherence, and discontinuation of medication therapy [9].

There are very few studies on statin utilization pattern for primary prevention of CVD for patients with diabetes done in Axum at which around 55 % them were on statins . one study in Jimma which showed only 36% type -2 DM patients were on statins for both secondary and primary prevention [10] [11].

So, this study will address the statin utilization pattern for primary prevention among type 2 DM who have follow up at TASH diabetic clinic.

1.3 Significance of the study

This study may inform us the gap in reducing cardiovascular risks and guide us to improve our patient care. It also may be helpful to different stakeholders like health care facilities, and clinician working in the scope and possibly for researcher and police makers. So, it is really important to known our statin utilization pattern and factors which affect its prescription**.**

2.LITERATURE REVIEW

2.1 Epidemiology of diabetes

Diabetes is increasing with an estimated 422 million adults were living with diabetes in 2014, compared to 108 million in 1980. The global prevalence (age-standardized) of diabetes has nearly doubled since 1980, rising from 4.7% to 8.5% in the adult population [1]. According to WHO 2016 report of diabetes in Ethiopia is rising with prevalence of 3.8% Rapid demographic, sociocultural, and economic transitions are driving increases in the risk and prevalence of diabetes and other non-communicable diseases (NCDs) in sub-Saharan Africa [1][2]

2.2 Diagnosis of DM

Diagnosis of diabetes is made by fasting plasma glucose>= 126mg/dl or 2hr-plasma glucose>= 200mg/dl during OGTT or A1C>= 6.5% or in patients with classic symptoms of hyperglycemia with random plasma glucose >= 200mg/dl[4].

2.3 Use of statins in ASCVD

Use of statins for both primary and secondary prevention is supported by many RCTs and meta-analytic studies. Statins reduce the risk of CVD-associated morbidity and mortality through their effects on lipids and are also thought to have anti-inflammatory and other plaque-stabilization effects[12]

The beneficial cardiovascular effects of statins are associated with their pleiotropic properties (Wassmann, S. *et al.,* 2001). These pleiotropic properties include: improvement of endothelial dysfunction, increased nitric oxide availability, antioxidant properties, inhibition of inflammatory responses, stabilization of plaques, reduction of vascular cell adhesion molecules, stimulation of endothelial progenitor cell recruitment and immunomodulation (Takemoto, M. *et al.,* 2001[13]

The Cholesterol Treatment Trialists (CTT) Collaboration showed that statins are beneficial in reducing the risk of CVD events in people without prior evidence of CVD (CTT Collaboration 2010)**s**[14]

Multiple clinical trials have demonstrated the Reduction of LDL cholesterol with a statin reduced the risk of major vascular events, vascular and all-cause mortality**.** A 2012 CTT Collaboration report further showed 20% relative risk reduction in major vascular events with statins per 1mmol/L reduction in LDL cholesterol, regardless of baseline risk [15]**.**

In CARDS study, multicenter randomized placebo-controlled trial done in UK and Ireland, which used atorvastatin 10mg for primary prevention in type 2 dm patients without high LDL value they found that acute coronary heart disease events were reduced by 36% (–55 to –9), coronary revascularizations by 31% (–59 to 16), and rate of stroke by 48% (–69 to –11). Atorvastatin reduced the death rate by 27% (–48 to 1, p=0·059)[16].

In JUPITER trial, in which people with no prior cardiovascular disease or diabetes were randomly allocated to rosuvastatin 20 mg or placebo and followed for up to 5 years, they found out that statin use was associated with a 39 percent reduction of ACS, Stroke and cardiovascular death (P=0.0001), a 36 percent reduction in VTE (P=0.08), a 17 percent reduction in total mortality (P=0.15) and with a 28 percent increase in diabetes among those who had one or more major risk factor for diabetes (P=0.01)[17].

In HOPE-3 (Heart Outcomes Prevention Evaluation) trial which assess whether the effects of lipid-lowering or antihypertensive medications are influenced by adherence to healthy lifestyle factors showed Rosuvastatin reduced CVD events in participants with both healthy lifestyle factors (HR: 0.74; 95% CI, 0.62–0.90) and in participants with no adherence to healthy life style factors. (HR: 0.79; 95% CI, 0.61–1.01)[18].

2.4 New onset DM in statin users.

Use of statin is associated with increased risk of new onset diabetes particularly in those with baseline high risk groups and with high dose as supported by safety studies.

Comprehensive network meta-analysis of randomized controlled trials (RCTs) investigating the impact of different types and doses of statins on new-onset DM which includes Seventeen RCTs reporting the incidence of new-onset DM during statin treatment from 1994 to 2012 showed difference in risk among statins and dosage with rosuvastatin 20 mg/day found to be the highest with 25% increased risk for DM compared with placebo (odds ratio 1.25, 95% credible interval

0.82 to 1.90) followed by atorvastatin 80 mg/day compared with placebo (odds ratio 1.15, 95% credible interval 0.90 to 1.50). , pravastatin 40 mg/day was associated with the lowest risk for new-onset DM compared with placebo (odds ratio 1.07, 95% credible interval 0.86 to 1.30)[19].

Another meta-analysis which includes 20 studies, 18 cohort and 2 case-control Studies, Showed New onset diabetes risk were higher in statin users than nonusers (RR 1.44; 95% CI 1.31-1.58). and statins showed a class effect, from rosuvastatin (RR 1.61; 1.30-1.98) to simvastatin (RR 1.38; 1.19-1.61)[20].

2.5 Pattern and predictors of statin use

Studies show the trends of statin use among high-risk populations for primary prevention is increasing in the past 02 decades. Retrospective longitudinal cohort study conducted from January 2002 to December 2013 in US Overall, statin use among US adults 40 years of age and older in the general population increased by 79.8% from 17.9% in 2002-2003 to 27.8% in 2012-2013. Among those with established ASCVD, statin use was 49.8%and 58.1%in 2002-2003 and 2012-2013, respectively. simvastatin (41.4%) and atorvastatin (28.3%) were the most commonly used statins, followed by pravastatin (16.2%), rosuvastatin (11.2%), and lovastatin (7.0%)[21].

Another retrospective observational study focusing on the utilization of statins in Taiwan in all hospitals and clinics 6.3% of adult population were on statins being Atorvastatin was the most commonly used agent (28.4%–36.7%) followed by simvastatin with 21.7% and rosuvastatin with prescription rate of 19.5%[22].

Prior experiences on statin utilizations pattern among diabetic patients shows statin prescription and utilization varies from country to country and among hospitals. In a retrospective, cross-sectional, observational study done in USA about patterns and predictors of prescriptions for lipid-lowering therapy (LLT) in subgroups of patients with atherosclerotic cardiovascular disease (ASCVD) and/or diabetes mellitus a large medical-care reported in 2014 showed 40% with diabetes and 49% of patients with ASCVD were on statins. Predictors of higher rates of any statin regimen included age 50 to 69 years, male sex, absence of comorbidities and Those with indications of ischemic stroke, PAD, and DM were less likely to receive statins than those with coronary conditions[23] .

A cross-sectional study conducted in 2016 in Malaysia which involved hospitalized T2DM patients aged between 40 to 75 years 65% had a statin therapy prescription for primary prevention in T2D [24] .

A cross-sectional study done in Germany regarding statin utilization in type 2 DM statin use were significantly higher in the secondary compared to the primary prevention group (38.1% [95% CI 37.4–38.9%] vs. 18.5% [95% CI 18.0–19.0%], respectively). Positive predictors for statin prescription were secondary prevention, hypertension, former smoking, baseline LDL-cholesterol, and microalbuminuria. [25].

In Saudi Arabia cross sectional study about statin use in type 2 DM for primary and secondary prevention of cardiovascular disease 70.6% and 97.7% of diabetes were on primary and secondary statin prevention respectively[26].

In Indian study in evaluation of statin use in type 2 DM prescription rate were 55.2%. Statin prescription was significantly greater among diabetologists (64.4%) compared with internists (53.3%) and endocrinologists (46.8%; $p<0.001$) Atorvastatin being the most commonly prescribed Statins.[27].

In Ghanaians study, statin therapy prescribing pattern for primary prevention of cardiovascular disease in patients with type 2 DM. A retrospective review of prescription records conducted in 2019 patients who attended the Diabetes Clinic only 49% patients were found to be received a statin. A total of 76% of statin therapies were of moderate- intensity dose 23%were of low-intensity dose and only 1% was of high-intensity dose and atorvastatin was the most common statin prescribed [13].

From secondary analysis of data from a previous study among type 2 diabetics at specialized diabetes clinic in Gaborone, Botswana. statins prescription rate was 45.5%. The probability of statin prescription was high in participants with high baseline low-density lipoprotein cholesterol (risk ratio RR: 1.49; 95%CI: 1.17 -1.89), increasing duration of diabetes (RR: 1.01; 95%CI 1.00 - 1.03) and the presence of chronic kidney disease (RR: 1.35; 95%CI: 1.06 - 1.74) [28].

Little is known about statin utilization in case of Ethiopia for primary prevention of CVD. In one study aimed to evaluate prescribing pattern of statins for primary prevention of CVD in T2D

patients, a retrospective study conducted in T2D patients with the age group of 40–75 years 55.7% study subjects were found to be received statin for their primary prevention of CVD. Low, moderate and high intensive dose of statins were prescribed in 27.8%, 46.1%,and 26.1%, respectively Commonly prescribed type of statins was simvastatin (37.2%), atorvastatin (32.8%) and rosuvastatin (15.6%)[10].

Another hospital-based cross-sectional study conducted to evaluate statin initiation and determinants in Gebr Tsadik Shewa General Hospital, Bonga, they found 42.5%patients were statins, among those 60.78% started for secondary prevention. The majority of patients had atorvastatin with moderate dosage .Physician reluctance and unavailability of drugs were the most common reasons not to initiate statins[29].

3.OBJECTIVE

3.1. General Objective

- To assess statin utilization pattern for primary prevention of CVD in patients with diabetes with age above 40yrs who have follow up at diabetic clinic, TASH.

3.2. Specific Objectives

- To determine proportion of diabetic patients with age above 40yrs who are on statins

- To identify Predictors of Statin Prescription in Diabetic Patients with age above 40yrs .

4.METHODS AND MATERIALS

4.1. Study setting

Study area: The study was conducted in the diabetic clinic of Tikur Anbessa Specialized Hospital, Addis Ababa, Ethiopia. Tikur Anbessa Specialized Hospital is the largest tertiary referral hospital in Ethiopia. It is also the main teaching hospital for the College of Health Sciences, Addis Ababa University. The college has 873 Academicians and 1107 health professionals. The hospital launched digital record system since 2018 where in the clinical data and other pertinent profiles of the patients be stored and retrieved when needed. It has 36 clinics which provides service for around 420,000 patients visit annually. The diabetic clinic is one of the clinics which provides care and follow-up for patients with diabetes mellitus in the endocrine unit which has 7 endocrinologists. It provides service for these patients in all working days of the week with daily average of 70 to 80 cases attending the clinic. The study was conducted in DM clinic of the hospital.

4.2 Study period:

- The data collection was conducted from June 10, 2021, to september 20, 2021.

4..3 Study design:

- Hospital based cross sectional study was conducted at TASH in diabetic clinic.

4.4 Source and study Population

4.4.1 Source population

- The source populations were all those patients who had follow up in diabetic clinic.

4.4.2 Study population

- All type 2 DM patients aged above 40 years and who had follow up at the diabetic clinic for at least 06 months.

4.4.3 Study participants

- All type- 2 DM patients aged 40 years and older who had follow up at diabetic clinic during the study period.

4.5. Sample size calculation and sampling technique

- Sample size for the patients was calculated with the following formula: assuming 95% CI

$$n = \frac{Z^2 x\ (p)(1-p)}{d^2} = \frac{1.96^2 x 0.5(1-0.5)}{0.05^2} = 384$$

Z α/2 = is standard normal variant (at 5% type 1 Error (P <0.05) it is 1.96

d = margin of error was taken as 0.05.

q =1-p: the probability of non-occurrence of the event of interest.

p = expected proportion of the population with the event outcome.

A sample size of 384 patients was calculated assuming a population proportion of 50% or 0.5(because there is no previous study, at TASH), confidence interval of 95%, margin of error of 0.05, and given total population less than 10,000.

By using sample size correction nf=no/ (1+ no/N),

where no is the estimated sample size which means 384, N-the average total number of type 2 DM having follow at diabetic clinic is around 3200. By adding 10% for possible missing or incomplete data, the corrected final sample size was 376.This study included type 2 DM above 40yrs who had follow up at the study period.

4.6 Inclusion and exclusion criteria for patients

4.6.1 Inclusion criteria

- All type- 2 DM patients who were above 40yrs on follow up at TASH.

4.6.2 Exclusion criteria:

- Patients with angina
- History of ACS/MI
- History of stroke.
- Patients with PAD.

4.7 Study variables

4.7.1 Dependent variables:

- Statin prescription

4.7.2 Independent variables:

- Age
- HTN
- Lipid level
- Sex
- BMI
- Educational status
- Placement
- Occupation
- Complications
- Socioeconomic status
- Multidrug user
- Comorbidities

4.8 Data collection

Data was collected by using structured questionnaire by face-to-face interview and digital record. A structured questionnaire prepared in English and translated to Amharic. Finally, it was translated back to English to check its consistency. Data was collected by 6 trained BSc nurses. Appropriate explanation was given on definition of some terms, purpose and importance of the research to participants.

4.9 Data analysis and presentation

Data was abstracted from the patients and the digital medical record for patients with type 2 DM in the follow up clinic using standard questionnaire tool. Data entry were made using Epi info version and was analyzed using SPSS software. Descriptive statistics such as mean, median and Standard Deviations (SD) were used to summarize the result. Each variable was evaluated independently in a bivariate analysis and association determined using cross tabulation and COR (crude odds ratio) at 95% CI (confidence interval). All variables associated with statin prescription at a p-value < 0.05 on the bivariate analysis were entered into a multivariate logistic regression analysis to control for confounders.

4.10 – Data quality control

Training was given to the data collectors and pre-test was done in 15 patients before the data collection period. The collected data was checked for completeness and consistency on each day of data collection.

4.11 OPERATIONAL DEFINITIONS

1) type 2 DM- physician dx of type 2 DM will be considered as type 2 DM
2) CKD – estimated glomerular filtration rate less than 60ml/min/1.73m2 will be considered as CKD based on CKD-EPI 2021.
3) Intensity of statin will be taken as moderate and high accordingly

   - Moderate-intensity statin therapy (30 to 50 percent LDL-C reduction) includes daily treatment with:

- Lovastatin 40 mg

- Pravastatin 40 to 80 mg
- Simvastatin 20-40 mg
- Atorvastatin 10 to 20 mg
- Rosuvastatin 5 to 10 mg.

High-intensity statin therapy (≥50 percent LDL-C reduction) includes daily treatment with:

- Atorvastatin 40 to 80 mg
- Rosuvastatin 20 to 40 mg

NEUROPATHY – physician dx of any form of neuropathy or current complaints of burning sensation or numbness of extremities.

Retinopathy- physician dx of any form degree of retinopathy.

5 Ethical considerations

The study was done in conformity with the ethical guidelines. Ethical clearance for the study was obtained from AAUMF Institutional Review Board.

Informed verbal and written consent were obtained from participants. The safety and privacy of subjects was protected by using their identification numbers in data collection and analysis process.

6 Dissemination of the results

The results of the study will be presented to Addis Ababa University, college of public health and medical science, Internal Medicine department.

7. Results

7.1 Sociodemographic characteristics of the respondents

n this study a total of 376 were participated with the mean (±SD) reported age of the respondents was found to be 57.86±9.44. Nearly half of the respondents were male (44.9) and almost all respondents were urban residents (99.5) and 93.3 % are from Addis Ababa .Nearly two third of the respondents were married(68.9) and one fourth of the respondents have monthly income above 5000(27.5) and 20.7% are government employees.

Variables	**Frequency**	**Percent**
Age		
40-50	89	23.7
50-60	152	40.3
60-70	95	25.3
70-80	40	10.7
Sex		
Male	169	44.9
Female	207	55.1
Occupation		
Government employee	78	20.7
Business man	67	17.8
Housewife	111	29.5
Farmer	4	1.1
Other a) Retired b) Driver c) Unemployed d) Servant	115 77 19 6 13	30.6 20.5 5 1.6 3.5
Marital status		
Married	253	68.9
Single	13	3.5
Divorced	28	7.6
Widowed	73	19.9
Monthly income		
<1000	54	15
1000-2000	72	20
2000-3000	85	23.6
3000-4000	50	13.9
>5000	99	27.5
Educational status		
No formal education	47	12.6

Primary school	80	21.4
High school	103	27.6
Diploma	89	23.9
Degree & above	54	14.5
Resident		
Urban	373	99.5
Rural	2	0.5
Region		
Addis Ababa	350	93.3
Oromia	21	5.6
Amhara	3	0.8
SNNPR	1	0.3

7.2 Clinical parameters

In this study nearly one third of the respondents were diagnosed at the age of 26-40(27.7) where the mean duration of DM was found to be 12.14±10.82. Almost all of the respondents had comorbidity (91.9) where nearly three forth had hypertension comorbidity (72.1) and 37.2% had dyslipidemia and 13.7% were obese. Most of the respondents have microvascular complications (72.1%) Neuropathy was the most frequent (71.3%).11.4% had CKD and 13% retinopathy.

Variables		Frequency	Percent
Age at diagnosis			
	11-25	3	0.8
	26-40	104	27.7
	41-55	220	58.5
	56-70	43	11.4
	>70	6	1.6
Mean duration of DM		12.14±10.82	
Smoking status			
Never smoker		344	91.1
Former smoker		32	8.9
HTN			
Mean SBP		131.69±15.19	
Mean DBP		78.17±12.37	
BMI			
Underweight		10	2.7
Normal		159	42.9
Overweight		151	40.7
Obese		51	13.7
Presence of comorbidity			
Yes		343	91.0

No		33	9
Type of comorbidity			
HTN	Yes	271	72.1
	No	105	27.9
Dyslipidemia	Yes	140	37.2
	No	236	62.8
OA		25	6.6
RVI		11	2.9
B. asthma		10	2.7
BPH		9	2.4
others		72	19.1
Presence of microvascular complications	Yes	271	72.1
	No	105	27.9
Types of microvascular complications			
Neuropathy	Yes	268	71.3
	No	108	28.7
CKD	Yes	43	11.4
	No	333	88.6
Retinopathy	Yes	49	13
	No	327	87

7.3 Lab Parameters

The Mean LDL value was 100.5±39.5 and 44% had LDL level above 100 whereas mean HDL was found to be 42.89±11.65 where among females nearly three forth had HDL level less than or equal to 50(72.3). Most of the respondent's cholesterol level lies below or equal to 200 (84.8) and the mean A1c was 11.14 +- 3.909, with 81.5% of them having A1c above 7.

Variables		Frequency	Percent
LDL			
	Mean LDL	100.5±39.5	
	≤70	90	26.8
	70-100	97	28.9
	100-130	81	24.1
	>130	68	20.2
HDL			
	Mean HDL	42.89±11.65	
Male	>40	72	44.4
	≤40	90	55.6

Female	>50	51	27.7
	≤50	133	72.3
TG			
	Mean TG	156.09±86.97	
	>150	142	41
	≤ 150	204	59
Total cholesterol			
	Mean cholesterol	156±47.42	
	>200	52	15.2
	≤200	290	84.8
Mean FBS		164.59±58.79	
Glycated hemoglobin			
	Mean glycated hemoglobin	11.14±3.9.09	
	≤7	57	18.5
	>7	251	81.5
Mean GFR		92.48±23.19	
Mean Creatinine		0.85±0.45	

7.4 Statin and other medication use

Most patients were taking metformin 83.2%, Nearly one fourth of the respondents take the anti-diabetic agents Sulfonylureas plus metformin whereas 34.3 take both insulin and metformin. One fourth of patients were taking ASA. Statin was prescribed for 87.4% patients and three forth (76.3%) of the respondents have current statin use 11.1 % of statin prescribed patient were not taking statin mainly due to cost (84.2%). Almost 60% of statin therapy were of moderate intensity statin and 39.8% patients were on high intensity statin. The most used type of statin was Atorvastatin (85.6%) followed by simvastatin 11.9% most have health insurance as source of medication 65.2%.

Anti-diabetic agents			
Metformin	Yes	76	20.2
	No	300	79.8
Sulfonylureas	Yes	11	2.9
	No	365	97.1
Sulfonylureas plus metformin	Yes	96	25.5
	No	280	74.5
Insulin	Yes	75	19.9
	No	301	80.1
Metformin plus DPP-4 inhibitors	Yes	12	3.2
	No	364	96.8

Both insulin and metformin	Yes	129	34.3
	No	247	65.7
Anti HTN agent	**total**	239	63.6
ACE-inhibitors	Yes	169	44.9
	No	207	55.1
Beta blockers	Yes	31	8.2
	No	345	91.8
Calcium channel blockers	Yes	112	29.8
	No	264	70.2
Diuretics	Yes	58	15.4
	No	318	84.6
More than one antihypertensives	Two Three Four	59 27 6	15.7 7.2 1.6
Anti-platelets			
Aspirin	Yes	94	25
	No	282	75
Clopidogrel	Yes	0	0
	No	376	100
Statin use			
Yes		327	87.4
No		47	12.6
Current statin use			
Yes		287	76.3
No		89	23.7
Reason not to use statin	GI intolerance	3	7.9
	Cost	32	84.2
	Other	3	7.9
Type of statin			
Atorvastatin	Yes	280	85.6
	No	47	14.4
Rosuvastatin	Yes	3	0.9
	No	324	99.1
Lovastatin	Yes	5	1.5
	No	322	98.5
Simvastatin	Yes	39	11.9
	No	288	88.1
Mean doses of			
Atorvastatin		29.64±11.75	
Rosuvastatin		16.67±5.77	
Lovastatin		28±10.95	
Simvastatin		31.28±10.05	
Dose intensity of statin			
Low		3	0.9

Moderate	194	59.3
High	130	39.8
Source of medications		
Free	36	9.9
Payment	91	24.9
Health insurance	238	65.2

7.5 Predictors of statin use

In this study, based on the p-value of the bivariable analysis and/or the potential to confound the association of factors with statin use, 14 variables were identified as candidate variables for multivariable analysis. These are Age, HDL, TG, Total Cholesterol, sex, educational status, occupational status, Neuropathy, CKD, Monthly income, Use of Metformin alone, use of Sulfonylureas plus metformin, use of Both insulin and metformin. Multivariable analysis however identified 3 variables namely age, use of Both insulin and metformin and occupational status as independent determinants of statin use.

For each 1 year increase in the age of the patients, the odds of using statin increases by 5% [AOR= 1.05; 95% CI: 1.02, 1.10].

Having other occupation led to 79% less odds for statin use as compared to government employees [AOR=0.21; 95% CI: 0.09, 0.51]. Use of both insulin and metformin increased the odds of statin use by 2.29 times as compared to the counterparts [AOR= 2.29; 95% CI: 1.07, 4.95]. Those patients with monthly income of 3000-4000 ETB had 78% less odds of using statin as compared to those with monthly income of >5000 ETB.

We also checked whether there is effect of statin use in the level of LDL using linear regression, and we found that for each one shift of patients from not using to using of statin, the level of LDL decreases by 20.44 mg/dl [β= -20.44; 95% CI: -30.34, -10.53].

Explanatory variables			Current statin use		**COR 95% CI**	**AOR 95% CI**
			Yes	No		
Age			57.86±9.44		1.05(1.02,1.08) *	1.05(1.02,1.1)*
Sex	Male		134(79.3)	35(20.7)	1.35(0.83,2.19)	0.73(0.37,1.46)
	Female		153(73.9)	54(26.1)	1	1
Educational status	No formal education		33(70.2)	14(29.8)	0.41(0.16,1.09)	0.74(0.21,2.68)
	Primary school		61(76.3)	19(23.8)	0.56(0.23,1.39)	1.16(0.41,3.25)
	High school		78(75.7)	25(24.3)	0.54(0.23,1.3)	1.28(0.52,3.18)
	Diploma		68(76.4)	21(23.6)	0.56(0.23,1.38)	2.58(0.7,9.47)
	Degree & above		46(85.2)	8(14.8)	1	1
Occupation	Government employee		58(74.4)	20(25.6)	1	1
	Business man		49(73.1)	18(26.9)	1.41(0.51,3.86)	2.75(0.74,10.22)
	Housewife		79(71.2)	32(28.8)	0.75(0.34,1.66)	0.95(0.36,2.5)
	Farmer		4(100)	0(0)	0.06(0.01,0.56) *	0.31(0.01,10.82)
	Other		97(84.3)	18(15.7)	0.23(0.11,0.48)*	0.21(0.09,0.51) *
Complications	Neuropathy	Yes	212(79.1)	56(20.9)	1.67(1.01,2.76)	0.81(0.37,1.76)
		No	75(69.4)	33(30.6)	1	1
	CKD	Yes	36(83.7)	7(16.3)	1.7(0.72,3.92)	1.56(0.44,5.49)
		No	251(75.4)	82(24.6)	1	1
Socio economic Monthly income	<1000		42(77.8)	12(22.2)	0.94(0.42,2.1)	0.48(0.16,1.44)
	1000-2000		57(79.2)	15(20.8)	1.02(0.49,2.16)	0.43(0.16,1.17)

	2000-3000		23(27.1)	62(72.9)	0.73(0.37,1.43)	0.71(0.29,1.75)
	3000-4000		35(70)	15(30)	0.63(0.29,1.36)	0.22(0.07,0.65)*
	>5000		78(78.8)	21(21.2)	1	1
Multidrug user	Metformin	Yes	51(67.1)	25(32.9)	0.55(0.32,0.96)	0.77(0.26,2.28)
		No	236(78.7)	64(21.3)	1	1
	Sulfonylureas plus metformin	Yes	68(70.8)	28(29.2)	0.68(0.4,1.14)	0.64(0.29,1.39)
		No	219(78.2)	61(21.8)	1	1
	Both insulin and metformin	Yes	107(82.9)	22(17.1)	1.81(1.06,3.1) *	2.29(1.07,4.95) *
		No	180(72.9)	67(27.1)	1	1

***** Significant at p-value less $\leq$ 0.05

7.6 DISCUSSION

A total of three hundred and seventy- six of patients with the age above of 40 with T2DM were participated in this study with 55.1% being male and 44.9% being female (Table 1). 99.5% were from urban area and 93.3% of patients were from Addis Ababa (table1) About 40.3% of the study population was between 50-60 years while 10.7% were between 70 to 80 years (Table 1). 72.1% were hypertension, 37.2% of patients had dyslipidemia and 13.7% were obese .71.3% patients having neuropathy and 13. % having retinopathy and 11.4% having CKD (Table 2).

Nearly two third of patients were on one or more anti-hypertensive and 88% of hypertensives were taking antihypertensive medication during the study period. the most commonly used anti-hypertensive were ACE inhibitors and around 15.7% patients were on two antihypertensives.

About 82% of the study population had high recorded glycated hemoglobin (above 7%). Approximately 44% of the study population had LDL level above 100mg/dl and around 20.2% having LDL above 130mg/dl.

Only 55.7% participants had LDL level less than 100 which is the target LDL according to the current ASCVD prevention guidelines. 26.8% participants had LDL level less than 70 md/dl.

statin was prescribed for 87.4% patients and 76.3% participants were taking statin at time of the study period.11% statin of prescribed patients was not taking statin mainly due to cost issue (84.2%) (table 4). statin prescription rate for primary prevention in this study is higher than other studies reported in India, Malaysia, Ghana, Saudi Arabia and Botswana with rate of 55.2%,65%,49%,70.6% and 45.5% respectively.

02 other local studies recently reported in Ethiopia, in Axum and Bonga general hospitals showed 55.7% and 42.5% rate of statin use for primary prevention. Which is lower than our study. almost all of patients (99.1%) who are taking statin were on moderate intensity and above with 59.3%% and 39.8%% received moderate and high -intensity statin respectively; which is consistent with the recommended statin dosage for T2DM patients aged 40 yrs. in contemporary guidelines.

From the study conducted, the most commonly prescribed statin was Atorvastatin (85.6%%) followed by simvastatin (11.9%%), lovastatin (1.5%) and rosuvastatin (0.9%). This is comparable to studies reported in India and Ghana where the most commonly prescribed statin for primary prevention in T2DM was Atorvastatin.

predictors of statin prescription were age, use of Both insulin and metformin, occupational status and monthly income as independent determinants of statin use.

Having other occupation led to 79% less odds for statin use as compared to government employees [AOR=0.21; 95% CI: 0.09, 0.51].

Use of both insulin and metformin increased the odds of statin use by 2.29 times as compared to the counterparts [AOR= 2.29; 95% CI: 1.07, 4.95]. Those patients with monthly income of 3000-4000 ETB had 78% less odds of using statin as compared to those with monthly income of >5000 For each 1-year increase in the age of the patients, the odds of using statin increases by 5% [AOR= 1.05; 95% CI: 1.02, 1.10].

We also checked whether there is effect of statin use in the level of LDL using linear regression, and we found that for each one shift of patients from not using to using of statin, the level of LDL decreases by 20.44 mg/dl [β= -20.44; 95% CI: -30.34, -10.53].

From a study done among type 2 diabetics at specialized diabetes clinic in Gaborone, Botswana, The probability of statin prescription was high in participants with high baseline low-density lipoprotein cholesterol (risk ratio RR: 1.49; 95%CI: 1.17 -1.89), increasing duration of diabetes (RR: 1.01; 95%CI 1.00 - 1.03) and the presence of chronic kidney disease (RR: 1.35; 95%CI: 1.06 - 1.74) [28] .

in our study this additional traditional risk factors didn't show association with statin prescription, which might be because high rate of physician prescription of statin according to the contemporary guideline recommendation irrespective of additional cardiovascular risk factors

7.7 Limitations of the study

This study was conducted at a single center that may have limitation in generalizability. It also didn't assess efficacy, adherence, success of statin use. the other intrinsic limitation of the study is the design was not good enough to give the opportunity to determine the impact of Statin therapy for primary prevention of CVD in T2DM on the overall cardiovascular morbidity and mortality of these patients.

7.8 Conclusion and recommendation

In conclusion this study done at showed the highest rate of statin prescription of 87% for primary prevention of ASCVD in type 2 DM patients who are above 40 compared to other studies done recently. And almost all participants were on moderate and high intensity statin. Which is consistent with contemporary guidelines recommendation for dyslipidemia and primary prevention of ASCVD. Which might be the site where of the study conducted, the largest specialized referral hospital in the country with its own diabetic clinic which is run by Diabetologists and endocrinologists. factors affecting statin use were age, occupation, monthly income and combined insulin and metformin use. This study showed the statin prescription rate is high but not all statin prescribed patients were taking due to drug unavailability in the hospital

and unable to afford in the private pharmacy. So we recommend Improvement is needed with regard to consistent statin availability in the hospital knowing the proven benefit of statins in reducing the mortality and morbidity of diabetic patients. We also recommend future researches to be a multi-centered and include large number of participants.

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9 ANNEXES

Annex-I: Checklists

Eligibility criteria

Inclusion Criteria	
Is the patient above 40yrs	Yes□ No□
Is the patient type 2 DM	Yes□ No□
Exclusion Criteria	
Is the patient had MI Is the patient had PAD Is the patient had stroke Is the patient has angina pain	Yes□ No□

Part I: patient's sociodemographic data

No	Variables	Response
101	Card number	
102	Age	
103	Sex	Male□ Female□
104	Occupation	Student□ Government employee□ Businessman□ Housewife□ Farmer□ Other: _____
105	Marital status	Married□ Single□ Divorced□ Widowed □
106	Monthly income	<1000□ 1000-2000□ 2000-3000□ 3000-4000□ >5000
107	Educational status	No formal education□ Primary school□ High school□ Diploma□ Degree and above□
108	Living area	Urban□ Rural□ Semi urban□
109	Region	Addis Ababa□ Oromia□ Amhara□ SNNRP□ Others: ____

number	variable		response
201	Age at dx of DM		
202	Duration of DM		
203	BMI		
204	Smoking status	Never –smoker	
		Former smoker	
		Current smoker	
205	HTN	SBP	
		DBP	
206	Presence of comorbidity		
207	Type of comorbidity	HTN	
		Dyslipidemia	
		others	
208	Presence of microvascular complications		
209	Types of microvascular complications	Neuropathy	
		CKD	
		Retinopathy	
210	Number of additional ASCVD RISK factors		

Part- III

Lab parameters

number	variable	response
301	LDL	
302	HDL	
303	TG	
304	Total cholesterol	
305	FBS	
306	Glycated hemoglobin	
307	eGFR	

Part IV

Statin and other medications use

number	variable	response
401	Anti-diabetic agents	- Metformin - Sulfonylureas - Sulfonylureas plus metformin - Insulin - Metformin plus DPP-4 inhibitors - Both insulin and metformin
402	Anti HTN	ACE-inhibitors Beta blockers Calcium channel blockers Diuretics
403	Anti-platelets	Aspirin clopidogrel
404	Statin prescribed	Yes/no
405	Current statin use	Yes/no If –no- reason a) cost b) GI intolerance c) other
406	Type of statin	Atorvastatin Rosuvastatin Lovastatin simvastatin
407	Dose intensity of statin	Low Moderate high
408	Source of medications	Free Payment Health insurance