FACTORS ASSOCIATED WITH STATIN PRESCRIPTION PATTERNS AMONG TYPE 2 DIABETES MELLITUS ATTENDING DIABETIC CLINIC AT MUHIMBILI NATIONAL HOSPITAL, DAR ES SALAAM, TANZANIA

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A Dissertation submitted in Partial Fulfillment of Requirement for the Degree of Master of Medicine in Internal Medicine at

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CERTIFICATION

The undersigned certifies that, he has read and hereby recommends for examination by Muhimbili University of Health and Allied Sciences a dissertation entitled: **"*statin prescription patterns and associated factors among patients with type 2 diabetes mellitus attending diabetic clinic at Muhimbili National Hospital Dar es salaam, Tanzania***" in partial fulfilment of the requirements for the degree of Master of Medicine in Internal Medicine Muhimbili University of Health and Allied Sciences.

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Dr Reuben Mutagaywa

(Supervisor)

DECLARATION AND COPYRIGHT

I, **Dr Aneth T Bideberi**, declare that this **dissertation** is my own original work and that it has not been presented and will not be presented to any other University for a similar or any other degree award.

Signature: …… Date: ……..

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DEDICATION

This thesis is dedicated to my family, especially my husband, Mujuni Rutasera Njunwa, Mr Telesphore Bideberi (my late father),Mrs Agnes Gabriel Bgoya (my mother), my sisters (Grace Bideberi, Veronica Bideberi) and Kennedy Bideberi (my brother). I am thankful for the love, encouragement, support and prayers throughout this journey. You are so dear to me in unspeakable ways.

ABSTRACT

Background: It is undeniable that statins are under-prescribed despite being essential drugs for prevention of cardiovascular diseases among diabetes patients. Currently in Tanzania there is scarcity of data on this subject.

Objectives: To describe statin prescription patterns and associated factors among type 2 diabetic patients attending the diabetic clinic at Muhimbili National Hospital in Dar es Salaam, Tanzania.

Methodology: A Hospital based cross-sectional study was conducted at Muhimbili National Hospital diabetic clinic from September to November 2020. Data obtained from type 2 diabetes patients attending diabetes outpatient monthly clinic until the target of 395 patients was reached. A structured questionnaire was used to collect socio-demographic characteristics such as age, sex, level of education, occupation, health insurance status ,clinical characteristics including laboratory parameters, risks factors such as diabetes duration, history of cigarette smoking, hypertension, chronic kidney disease and presence of comorbidities. Statin prescription history (both type and dosage) was obtained from patients as well as from the electronic medical records for determination of patterns. Data analysis was done using IBM SPSS version 23. Descriptive statistics were presented in proportions and means ± sd. Inter-group comparisons were performed using chi square test. Logistic regression was used to examine for associations and control confounders and effect modifiers whereby p value of < 0.05 was considered statistically significant.

Results: The mean (SD) age of the study participants was 58.1±10.3 years, out of which 371(93.9%) were aged ≥40 years. Two-thirds, 241(61.0%) of the patients were females. Half of the patients, 208(52.7%) had elementary to primary education. About two-third 257(69.4%) of patients had health insurance coverage. Among 400 patients who were approached for the study 395(98.8%) were eligible for statin prescriptions. Proportion of statin prescription was 47.3%. Moderate intensity statin was the only pattern found. Statin prescription was significantly greater among patients attended by endocrinologists (66.1%) compared with

general practitioner (n=33.9%). Atorvastatin was prescribed in 95% and rosuvastatin in 5%. On univariate analysis: age>40years, diabetes duration, insurance coverage, hypertension, high LDL levels and proteinuria were found to be associated with moderate intensity statin pattern. In the adjusted model, insurance coverage (OR: 9.34; 95%CI: 4.63–18.85), hypertension (OR: 2.00; 95%CI: 1.04–3.86), and proteinuria (OR: 3.91; 95%CI: 1.30–11.74) were associated with an increased likelihood of moderate intensity pattern.

Conclusion: A significant number of patients at MNH diabetic clinic were not on statins despite qualifying for the prescription. Moderate intensity statins was the only pattern found. Worryingly, over half of high risk group of patients were not receiving statins at all. The findings call for further studies on reasons for low statin prescription practices in this tertiary facility. Future studies should also explore on awareness of clinicians to recommended evidence based treatment patterns and other factors driving their prescription practice to this group of patients

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LIST OF ABBREVIATIONS

ACC: American college of cardiology
ADA: American Diabetes Association
AHA: American Heart Association
ASCVD: Atherosclerotic cardiovascular disease
BMI: Body mass index
CAD: Coronary artery disease
CI: Confidence interval
CKD: Chronic kidney disease
CKD EPI Chronic Kidney Disease Epidemiology Collaboration
CVD: Cardiovascular disease
CVE: Cerebral vascular event
DM Diabetes Mellitus
HDL-C: High density lipoprotein cholesterol
HMG-COA: 3-hydroxy-3-methyl-glutaryl-CoA
LDL-C: Low density lipoprotein cholesterol
MNH: Muhimbili National Hospital
MUHAS: Muhimbili University of Health and Allied Sciences
OR: Odds ratio
PAD: ` Peripheral arterial disease
SPSS: Statistical package for social sciences
T2 DM: Type 2 Diabetes mellitus
WHO: World Health Organization

DEFINITION OF TERMS

1. **Hypertension** is defined as self-reported history of hypertension, the use of blood pressure lowering medications or sustained blood pressure ≥140/90 mmHg in more than one visit.(1)
2. **Cardiovascular disease (CVD)** is defined as the history of coronary artery disease, cerebrovascular diseases (ischemic stroke, transient ischemic attacks), or peripheral arterial diseases (PAD).
3. **Coronary artery disease (CAD)** is defined as any documented definite or probable myocardial infarction, CAD-related revascularisation (surgery, angioplasty, stenting, or any combination of these), or stable angina in patients' medical records.(2)
4. **Statin patterns** is defined as moderate or high intensity dose in patients with type 2 diabetes.

    i. **Moderate intensity dose** include: atorvastatin 10-20 mg, rosuvastatin 5-10 mg, simvastatin 20-40 mg, pravastatin 40-80 mg, lovastatin 40 mg, fluvastatin 40 mg twice a day/80mg once a day and pitavastatin 2-4 mg whereas

    ii. **High intensity dose** include: atorvastatin 40-80 mg and rosuvastatin 20-40mg.(3)

1. 0 INTRODUCTION

1.1 Background

Cardiovascular disease(CVD), which includes coronary artery disease (CAD), cerebrovascular accident, and peripheral arterial disease(PAD), is the leading cause of morbidity and mortality in patients with type 2 DM (4).

Patients with type 2 diabetes have an increased prevalence of lipid abnormalities, contributing to their high risk of CVD. Multiple clinical trials have demonstrated the beneficial effects of statin therapy on CVD outcomes in subjects with and without coronary heart disease(CHD) (5,6). Subgroup analyses of patients with diabetes in larger trials (7–10) and trials in patients with diabetes (11,12) showed significant primary and secondary prevention of CVD events and CAD death in patients with diabetes.

Meta-analyses, including data from over 18,000 patients with diabetes from14 randomized trials of statin therapy (mean follow-up 4.3 years),demonstrated a 9% proportional reduction in all-cause mortality and 13% reduction in vascular mortality for each mmol/L (39mg/dL) reduction in LDL cholesterol (5).

Accordingly, statins are the drugs of choice for LDL cholesterol lowering and cardio-protection. High intensity statin therapy achieve approximately a 50% reduction in LDL cholesterol and moderate intensity statin regimens achieve 30–50% reductions in LDL cholesterol. Low-dose intensity statin therapy is generally not recommended in patients with diabetes but is sometimes the only dose of statin that a patient can tolerate(13). For patients who do not tolerate the intended intensity of statin, the maximally tolerated statin dose should be used. As in those without diabetes, absolute reductions in atherosclerotic cardiovascular disease(ASCVD) outcomes (coronary arterial disease death and nonfatal myocardial infarction) are greatest in people with high baseline ASCVD risk(known ASCVD and/or very high LDL cholesterol levels), but the overall benefits of statin therapy in people with diabetes at moderate or even low risk for ASCVD are convincing (14,15).

The relative benefit of lipid-lowering therapy has been uniform across most subgroups tested (6,14), including subgroups that varied with respect to age and other risk factors.

1.1.1 Primary Prevention (Patients without ASCVD)

For primary prevention, moderate-dose statin therapy is recommended for those 40 years and older though high-intensity therapy may be considered on an individual basis in the context of additional ASCVD risk factors (8). The evidence is strong for patients with diabetes aged 40–75 years, an age-group well represented in statin trials showing benefit (12,16,17). Since risk is enhanced in patients with diabetes, as noted above, patients who also have multiple other coronary risk factors have increased risk, equivalent to that of those with ASCVD. As such, recent guidelines recommend that in patients with diabetes who have multiple ASCVD risk factors, it is reasonable to prescribe high-intensity statin therapy (9,18). Furthermore, for patients with diabetes whose ASCVD risk is.20%, i.e., an ASCVD risk equivalent, the same high intensity statin therapy is recommended as for those with documented ASCVD(12). However, heterogeneity by age has not been seen in the relative benefit of lipid lowering therapy in trials that included older participants (6,12,14) and because older age confers higher risk, the absolute benefits are actually greater (14,15). Moderate-intensity statin therapy is recommended in patients with diabetes that are 75 years or older (3).However, the risk-benefit profile should be routinely evaluated in this population, with downward titration of dose performed as needed.

1.1.2 Secondary Prevention (Patients with ASCVD)

Due to the fact that that ASCVD portends a high risk, high-intensity statin therapy is indicated and has been shown to be of benefit in multiple large randomized cardiovascular outcomes trials that are mentioned below.

This recommendation is based on the Cholesterol Treatment Trialists' Collaboration involving 26 statin trials, of which 5 of them compared high-intensity versus moderate-intensity statins. Together, they found reductions in non-fatal cardiovascular events with more intensive therapy, in patients with and without diabetes (9,14,19).Over the past few years, there have been multiple large randomized trials investigating the benefits of adding non-statin agents to statin therapy, including those that evaluated further lowering of LDL cholesterol with ezetimibe and protein convertase subtilisin/ kexin type 9 (PCSK9) inhibitors (19,20).

Each trial found a significant benefit in the reduction of ASCVD events that was directly related to the degree of further LDL cholesterol lowering. These large trials included a significant number of participants with diabetes. For patients with ASCVD who are on high-intensity (and maximally tolerated) statin therapy and have an LDL cholesterol below 70 mg/dl(1.8mmo/l), the addition of non-statin LDL-lowering therapy is recommended following a clinician-patient discussion about the net benefit, safety, and cost.

The American Diabetes Association (ADA) standards of medical care in diabetes of 2019 (3) recommends that:

- For patients of all ages with diabetes and ASCVD high-intensity statin therapy should be added to lifestyle therapy. (Grade A recommendation).
- For patients with diabetes aged <40 years with additional ASCVD risk factors, the patient and provider should consider using moderate-intensity statin in addition to lifestyle therapy. (Grade C recommendation).
- For patients with diabetes aged 40–75 years (grade A recommendation) and >75 years (grade B recommendation) without ASCVD, use moderate-intensity statin in addition to lifestyle therapy. In clinical practice, providers may need to adjust the intensity of statin therapy based on individual patient response to medication (e.g side effects, tolerability, low-density lipoprotein [LDL] cholesterol levels, or percent LDL reduction on statin therapy).For patients who do not tolerate the intended intensity of statin, the maximally tolerated statin dose should be used. (Grade E recommendation).

- For patients with diabetes aged 40 years and above with multiple traditional cardiovascular risk factors without obvious ASCVD high intensity statins to be considered.(Grade C recommendation)

Lipid-Lowering drugs (LLDs) including statins are paramount in the primary and secondary prevention of CVD among diabetes patients. Given the importance of statins in the prevention of CVD, initiation and proper dosage prescription of statins among diabetes patients should be highly emphasized. Proper adherence to the guidelines and awareness of the factors associated with statin therapy initiation will minimize CVD complications hence ensure proper management and well-being of diabetic patients.

1.2 Literature Review

Statins are considered to be powerful cholesterol lowering drugs and the most lipid-lowering therapy of choice in diabetes type 2 patients. Statin treatment has been proved to markedly reduce the risk of cardiovascular disease and improve survival. Despite the fact that statins do not fully correct abnormalities in diabetic dyslipidemia (low HDL cholesterol and high triglycerides) their safety and efficacy have been proven (21).Given the key role that statins play in prevention of cardiovascular diseases in diabetes type 2 patients, it is important to know patterns and factors associated with prescription in diabetes type 2 patients so as to provide the tailored treatment according to cardiovascular risk profile of a patient. Studies in the world have reported suboptimal utilization of statin therapy due to various reasons (22,23) and they are going to be discussed here.

A study done in Malaysia among diabetes patients has shown, 81.1% of patients were statin users and 18.9% were statin non-users. Statin medications included simvastatin 79.2%, atorvastatin 11.6%, lovastatin 5.8%, rosuvastatin 2.1%, and pravastatin 1.3%. Overall nearly one-fifth of type 2 diabetes patients were not on statins despite the therapeutic necessities (11).

The study done in Ethiopia on prescribing patterns of statins, Low, moderate and high intensive doses of statins were prescribed in 27.8%, 46.1%, and 26.1%, respectively. Overall, a significant percentage of the participants did not receive their recommended statin for primary prevention of CVD which is below the guidelines' recommendation (25).

A recent study in Botswana revealed that 477(95.4%) participants were eligible for a statin prescription. Clinicians prescribed statins in 217(45.5%) of eligible participants, and only one (4.4%) ineligible participants. The probability of statin prescription was high in participants with high baseline low-density lipoprotein cholesterol, increased duration of diabetes and the presence of chronic kidney disease (26).

In most clinical guidelines, the presence of CVD, CKD, patient's age, diabetes duration and presence of CVD risk factors such as hypertension and cigarette smoking are indicators of prescribing statins among patients with type 2 diabetes (27). The recommendations are based mainly on the rationale that the presence of any of the above factors is associated with an increased risk of CVD.

Various studies done worldwide suggest that some socio-demographic and other diagnostic related factors are associated with statins prescription patterns among type 2 DM patients and these are discussed hereunder.

1.2.1 Age

Advanced age has been shown to be an important determinant of statin prescription among diabetes population, cross-sectional study in Ireland reported that patients aged 65–74 years were more likely to be prescribed a statin than those aged 50–64 years , as were those in the oldest age 75 and over (28).

Other studies also examined the association between statin use and age and found that statins were mostly prescribed to people with advanced age (29–31).None of these studies has evaluated the relation between factors other than demographics and the prescribing of LLDs (32).

1.2.2 Body mass index

A high body mass index (BMI) is associated with increased cardiovascular risk. The Dyslipidaemia International Study (DYSIS) found that statin intensity increased with increasing BMI , an association that was retained even after adjusting comorbidities (33). Increasing statin use with increasing BMI is also seen in the study by Neutel *et al* (29).Also study by Maria Garcia *et al* (34) showed that intensity of statins increased with BMI increase.

1.2.3 Diabetes duration

Statin prescription pattern has been shown to increase with diabetes duration. Due the fact that the longer diabetes duration poses an increased risk for cardiovascular diseases, ADA guideline recommends moderate intensity statins for patients with diabetes for more than ten years (27). This practice has also been found in the study by Mwita *et al* where the statin-prescribed group had a significant longer duration of diabetes compared to non-statin group (26).

1.2.4 Smoking

Few studies have mentioned smoking as among the positive predictors for statin prescription pattern although reasons for this association have been not well been known. In the study done by Berthold *et al*, former smokers had higher odds of receiving statins when compared with current smokers and never smokers in secondary prevention. In primary prevention, prescription rates were comparable among never smokers, former smokers and current smokers (35).Another evidence from Chaure *et al* (36) ,statins were intensified more in patients with history of smoking.

1.2.5 High baseline low-density lipoprotein cholesterol

Findings from previous studies show that clinicians tend to frequently prescribe statins to patients with high baseline cholesterol levels (high LDL) rather than looking at other atherosclerotic cardiovascular risks(35,37). Studies by Garcia *et al*(34) and Chaure *et al*(36) have shown similar results. Dutch guideline, however, also provides two simplified recommendations for the primary prevention: men aged 50–70 years and women aged 50–75 years should receive lipid-lowering therapy when their TC/HDL ratio is higher than 6 for non-smoking patients and when their TC/HDL ratio is higher than 5 for smoking patients (38).

1.2.6 Chronic kidney diseases

Chronic kidney disease (CKD) has been shown to increase the likelihood of prescribing statins in diabetes, as statins reduce mortality by up to 36% in patients with kidney failure (27,39,40).

KDIGO recommends statin dosing based on regimens that have been studied and shown to be beneficial in randomized trials done specifically in patients with eGFR <60 mL/min/1.73 m^2. This includes moderate-intensity statins such as daily atorvastatin 20 mg, rosuvastatin 10 mg, simvastatin 40 mg, pravastatin 40 mg, fluvastatin 80 mg, or pitavastatin 2 mg (41).

1.2.7 Hypertension

In most clinical guidelines presence of hypertension has stood as an indicator for statin prescription (27,42).As one of the atherosclerotic cardiovascular risk factors, hypertension poses risk to development of cardiovascular diseases like stroke and coronary heart diseases. Evidence from various observational studies has also shown an increased odds of statins prescription among patients with hypertension (43,44).

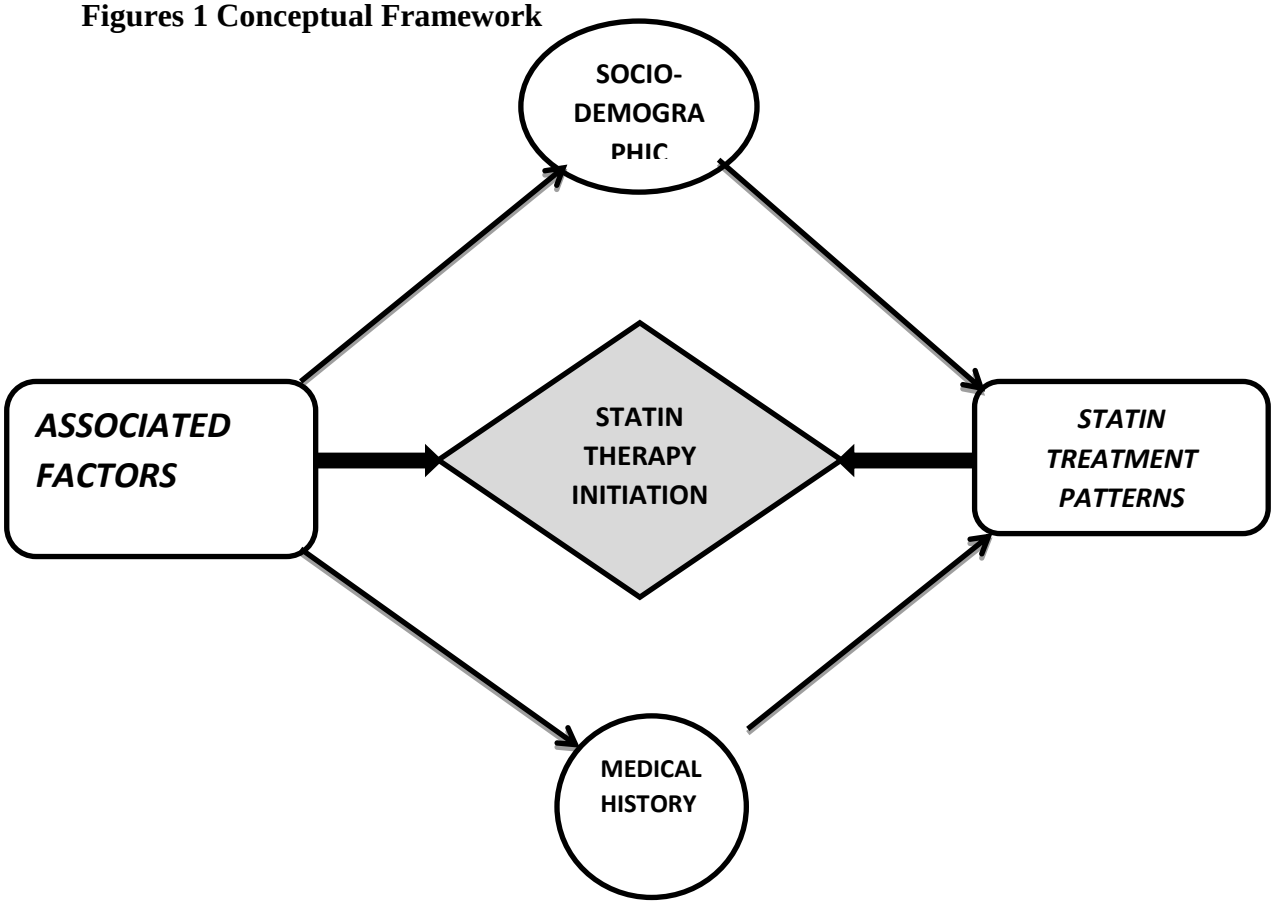
1.2.8 Proteinuria

In the previous studies statin therapy improved renal function and reduced proteinuria (45,46), possibly due to their anti-inflammatory activity and improvement of endothelial function, which reduces abnormal permeability to plasma proteins.This benefit has prompted clinicians to frequently prescribe statins to patients with diabetes so as to prevent progression of kidney disease especially to those presenting with early kidney disease (26,46).

1.2.9 Prevention of Primary/secondary Atherosclerotic cardiovascular diseases

Atherosclerotic cardiovascular diseases including coronary arterial disease, cerebral vascular events and peripheral arterial disease have been the major cause of morbidity and mortality in these patients. Therefore clinicians tend to prescribe statins frequently in diabetes type 2 patients to prevent such complications, evidence from previous studies have demonstrated this practice (25,47–49).

Figures 1 Conceptual Framework



The figure above illustrates factors associated with initiation of statin therapy. They are divided into socio-demographic and medical history factors. Socio-demographic factors associated with statin treatment patterns include age, income level and insurance status. Medical history factors linked with statin treatment patterns include the duration of diabetes, having past medical history of stroke, smoking, hypertension, chronic kidney disease, high levels of LDL, high body mass index, peripheral arterial diseases and coronary artery diseases.

Initiation of statin therapy in diabetic individuals is now not based on the calculation of 10yrs atherosclerotic cardiovascular disease risk as for non-diabetes patients as it was done previously. Only the presence of identified risk factors determine the treatment pattern either moderate or high intensity in this group.

2.0 PROBLEM STATEMENT AND OBJECTIVES

2.1. Problem Statement

There is evidence of statin benefit among patients with diabetes regardless of their cholesterol levels or prior cardiovascular disease history. Despite the evidence, there is under-prescription of statins in clinical practice. However, an increase in statin prescribing may be linked to changing clinical guidelines, which have been identified as drivers of a process of medicalization as they generally widen the definition of disease. So far no studies in Tanzania have been done to ascertain statin treatment patterns and associated factors among diabetes type 2 patients. Hence there was a need to investigate.

2..2 Rationale

Tanzania, like other developing countries, is facing a higher burden of cardiovascular diseases (CVDs). The country is experiencing rapid growth of modifiable and intermediate-risk factors that accelerate CVD mortality and morbidity rates. In rural and urban settings, diabetes is among the cardiovascular risk factors which contribute to mortality and morbidity. High cholesterol is one of the most important and modifiable risk factors for the development of the disease. Appropriate prescription of cholesterol-lowering medications, therefore, represents one of the most important and accessible interventions for combating the burden. Obtaining baseline data on patterns of statin prescriptions, prevalence, and adherence to dosages of statins by benefit groups, socio-demographic and clinical determinants of statins prescription is critical for future intervention and prospective studies.

2..3 Research Question

What are the statin prescription patterns and associated factors among type 2 DM patients at MNH diabetic clinic?

2.4 Objectives

2.4.1 Broad Objective

To determine statin prescription patterns and associated factors among type 2 DM patients attending diabetes clinic at Muhimbili National Hospital Dar es salaam, Tanzania.

2.4.2 Specific Objectives

1. To describe statin prescription patterns among type 2 DM patients at MNH Diabetes clinic according to American Diabetes guideline (ADA)

2. To determine the factors associated with statin prescription patterns among type 2 DM patients at MNH-Diabetes clinic

3.0 METHODOLOGY

3.1 Study Design

A hospital-based cross sectional study

3.2 Study Area and Setting

The study was conducted at Muhimbili National Hospital in Dar es salaam, Tanzania. The diabetic clinic is a public facility within Muhimbili Hospital that operates 3 days a week. The diabetic clinic receives about 50-70 patients in a day. The clinic receives both insured and none insured diabetic patients from within and outside of Dar es Salaam. The hospital has routine diabetic clinics every Tuesday, Wednesday, and Thursday. Overall, 5 Endocrinologists, 1 General practitioner, 9 nurses and 1 medical record officer run the clinic. The clinic provides routine diabetic services such as glucose monitoring, vitals, weight and height assessment, medications prescriptions and diet advice sessions.

3.3 Study Population

Adult type 2 DM patients, seen by clinicians at Diabetic clinic of MNH

3.4 Inclusion Criteria

1. A cohort of type 2 DM patients attending Diabetes clinic at MNH at least for >3months
2. Provision of informed consent from patient or caretaker

3.5 Exclusion Criteria

Pregnant women, low risk group (less than 40 years with no ASCVD risk)

3.6 Sample Size

$$n = \frac{z^2 p(1-p)}{e^2}$$

Z = level of confidence (1.96 for 95% confidence level)

p = expected proportion (previous or pilot study)

ε = margin of error

p=55.7% (Prescribing pattern of statins for primary prevention of cardiovascular diseases in patients with type 2 diabetes: insights from Ethiopia Gebre Teklemariam et al)(25)

Ɛ = boundary of error (5%), Sample size calculation in prevalence studies (50).

$$n = \frac{1.96^2 * 55.7(100-55.7)}{5^2}$$

N=379

The minimal sample size obtained was 379 people.

3.7 Sampling Technique And Study Procedures

Consecutive sampling technique with consecutive enrollment of study participants was used whereby all consenting adult DM patients attending the Muhimbili diabetic clinic were recruited into the study. The recruitment process was conducted on every clinic visit until the required sample size was met.

3.8 Study Variables

3.8.1 Dependent Variables

- **Statin prescription patterns**

Statin benefit group VS statin intensity

- For patients with diabetes aged <40 years without additional ASCVD risk factors- NONE
- For patients with diabetes aged ≥40 years without ASCVD – moderate intensity statins
- All ages with diabetes and ASCVD - high intensity statins
- Age ≥40 years with multiple(≥2 traditional cardiovascular risk factors)-high intensity statins

3.8.2 Independent Variables

Demographic characteristics: Age, gender, and education level, insurance status etc.

Clinical parameters:

- Traditional cardiovascular risk factors: smoking history, duration of diabetes mellitus, obesity and hypertension.
- Atherosclerotic cardiovascular diseases: Acute coronary syndrome, Peripheral arterial disease and cerebral vascular events
- Chronic diabetic complications: neuropathy, retinopathy and nephropathy
- Cardiovascular risk stratification including moderate and high risk strata (where moderate risk <2, while high risk ≥2 traditional risk factors)

Laboratory records: low-density lipoproteins, protein in urine, creatinine, HbAIC

Estimation of kidney function (eGFR) – from Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) formula

3.9 Data Collection

The investigator interviewed the patients and recorded laboratory results from the electronic system for all the recruited participants. Statin prescription was also confirmed from the electronic system.

3.9.1 Patient interview:

An interviewer based structured case report form (questionnaire) was administered to consented patients or caretakers for those who are unable to communicate. Information collected included socio-demographic characteristics such as age, gender, marital status, education level, and insurance status. Medical Information collected included current status of risk factors such as the history of hypertension, smoking, diabetes duration, acute coronary syndromes (ACS), arterial revascularization, stroke, peripheral artery disease. Use and dosage of statins, diabetic and other medications were also obtained.

3.9.2 Clinical measurements

Weight was measured on a SECCA weighing scale without shoes and recorded to the nearest 0.5Kg. Height was measured using a height measuring rod and recorded to the nearest 0.5cm. Body Mass Index (BMI) was calculated as weight in kilograms (kg) divided by height in meters (m) squared expressed in Kg/m ². The value obtained was classified as underweight (<18.5Kg/m²), normal (18.5-24.9Kg/m ²), overweight (25-29.5Kg/m²) or obese (>30Kg/m²) (57). Blood pressure was measured by placing a cuff 2cm above the elbow crease on the bare arm with the midline of the bladder on the brachial artery. Then obliteration pressure was obtained and cuff was inflated 20-30mmHg beyond the obliteration pressure. Cuff was deflated and the first and fifth Korotkoff sounds was recorded as systolic and diastolic blood pressures in mmHg respectively(51). Hypertension was defined as SBP of at least 140mmHg and DBP of at least 90mmHg(1). Alternatively, hypertension was defined as a documented history of hypertension with the current use of antihypertensive medications regardless of blood pressure level at the time of recruitment. Results were recorded on the clinical characteristics case report form (refer appendix 2).

3.9.3 Laboratory investigations:

The patient's serum cholesterol levels, proteinuria, creatinine and HbAIC levels were documented provided that these investigations were obtained in the previous visits.

3.10 Data Processing and Analysis

Data was entered and analyzed using SPSS version 23.0. The magnitude of statin prescriptions was obtained by calculating proportions. The differences in clinical characteristics and laboratory parameters for every outcome were summarized as proportions, mean ± SD, as appropriate depending on normality. Groups were compared for differences using the Chi-square test. All variables with a p-value <0.2 in the bivariate analysis were entered into the multivariate analysis model, where a p-value <0.05 was considered statistically significant.

3.11 Ethical Approval

Ethical clearance was obtained from the MUHAS research and publication committee. Permission to conduct the research was sought from MNH administration. Eligible patients were recruited only after verbal or written consent form, or their next of kin, for patients who could not provide verbal or written consent. All the principles of the Declaration of Helsinki were adhered during data collection process.

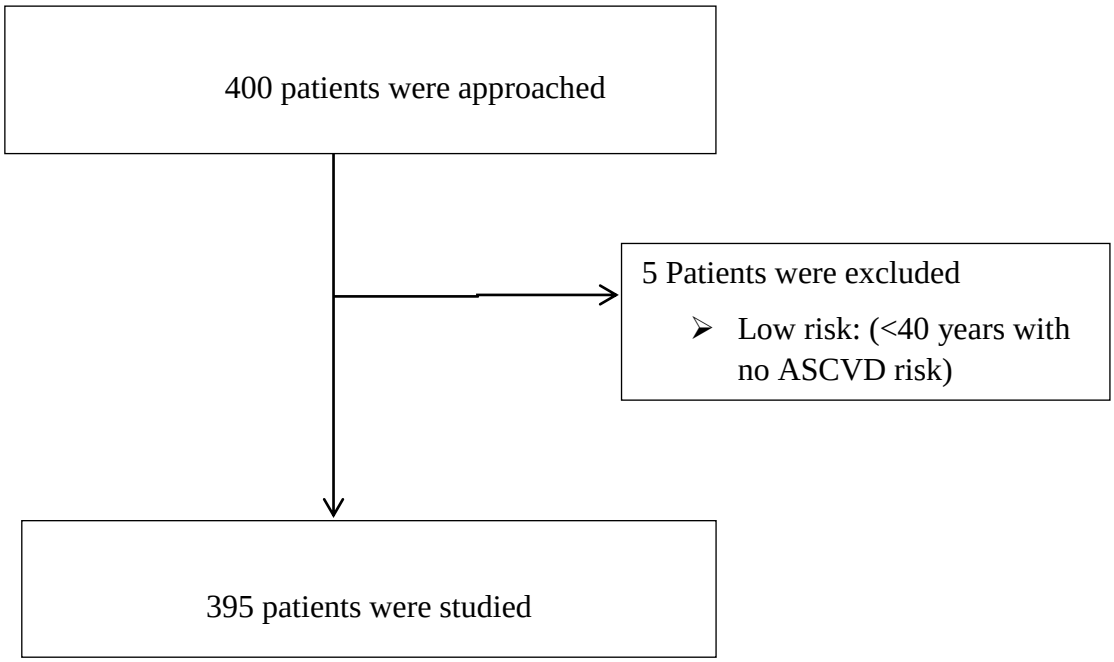
3.12 Data Dissemination

The results of this study will be presented to the Department of Internal Medicine. The final report will be available at the MUHAS library. Findings will be presented in a scientific conference and thereafter published in a peer-reviewed journal.

4.0 RESULTS

In a period of 3 months of the study, from September to November 2020, out of 1500 patients who attended clinic consecutive sampling was done, where 400 participants were approached, 5 participants had low risk for cardiovascular disease (not requiring statin therapy), hence were excluded, the remaining 395 were studied and analyzed as shown in figure 2.

Figures 2 Consort diagram to show the recruitment process of participants



The mean (SD) age of the study participants was 58.1±10.3 years, out of which 371(93.9%) aged ≥40 years. Two-third, 241(61.0%) of the patients were females. Half of the participants, 208(52.7%) had elementary to primary education. About two-third 257(69.4%) of patients had health insurance coverage. As per BMI, 77(44.8%) were overweight. About half the patients, 192(48.6%) had blood pressure of ≥140/90mmhg.The mean (SD) duration of diabetes was 10.2 (7.6) years with half of them having ≥ 10 years of the disease. Hypertension, coronary arterial disease, peripheral arterial disease and cerebral vascular events were found in 307(77.7%), 8(2%), 12(3%) 27(6.8%) respectively. Neuropathy, retinopathy and nephropathy were seen in 309(78.3%), 234(59.2%), 121(30.6%) respectively. For patients who had their LDL recorded, 59 (42.7%) had normal LDL while 82 (20.8%) had high values. Also for patients whose HbAIC were recorded, 44(27.3) reached the control target. Proteinuria was found in 104(26.3) and decline in kidney function as expressed by estimated glomerular filtration rate was found in 81(32.5).As per atherosclerotic risk stratification, majority of patients 348 (88.1%) had high risk followed by moderate risk 47(11.9%). The socio-demographic and clinical characteristics of the patients are described in **Table 1.**

Table 1 Socio-demographic and clinical characteristics of T2DM patients attending diabetic clinic at MNH September to November 2020 (n=395)

Characteristics	Frequency n (%),
Age, mean ± SD, years	58.1±10.3
Age<40	24(6.1)
Age≥40	371(93.9)
Sex	
Male	154(39.0)
Female	241(61.0)
Education level	
≤Primary	208(52.7)
≥Secondary	187(47.3)
Insurance	
Non insured	120(30.4)
Insured	275(69.6)
Evaluated/Attended by	
General Practitioner	134(33.9)
Endocrinologist	261(66.1)
BMI	
Normal	84(21.3)
Overweight	177(44.8)
Obese	134(33.9)
BP	
<140/90	203(51.4)
≥140/90	192(48.6)
Diabetes duration	
Diabetes duration, means±sd	10.2±7.6
<10years	194(49.1)
≥10years	201(50.9)
Hypertension	
No	88(22.3)
Yes	307(77.7)

CAD	
No	387(98.0)
Yes	8(2.0)
PAD	
No	383(97.0)
Yes	12(3.0)
CVE	
No	368(93.2)
Yes	27(6.8)
Chronic complications	
Neuropathy	309(78.3)
Retinopathy	234(59.2)
Nephropathy	121(30.6)
LDL	
Normal	59(42.7)
High	82(20.8)
No records	254(64.3)
HbAIC	
<6.5(on target)	44(27.3)
≥6.5(not on target)	117(72.7)
No records	234(59.2)
eGFR	
<60mls/min/1.73m^2	81(32.5)
≥60mls/min/1.73m^2	168(67.5)
No records	
Protein in urine	
Negative	152(38.5)
Positive	104(26.3)
Risk strata	
Moderate	47(11.9)
High	348(88.1)

The most frequently prescribed type of statin was atorvastatin n=178(95%) at the dosage of 20mg, followed by rosuvastatin n=9(5%) at the dosage of 10mg.

Figures 3 Prescribed statins among T2DM patients attending clinic at MNH Diabetic clinic

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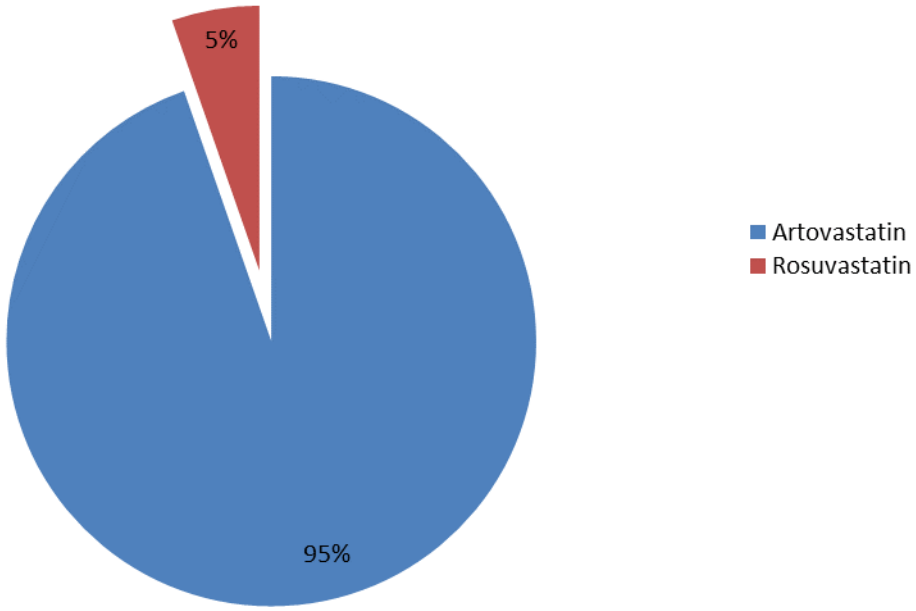
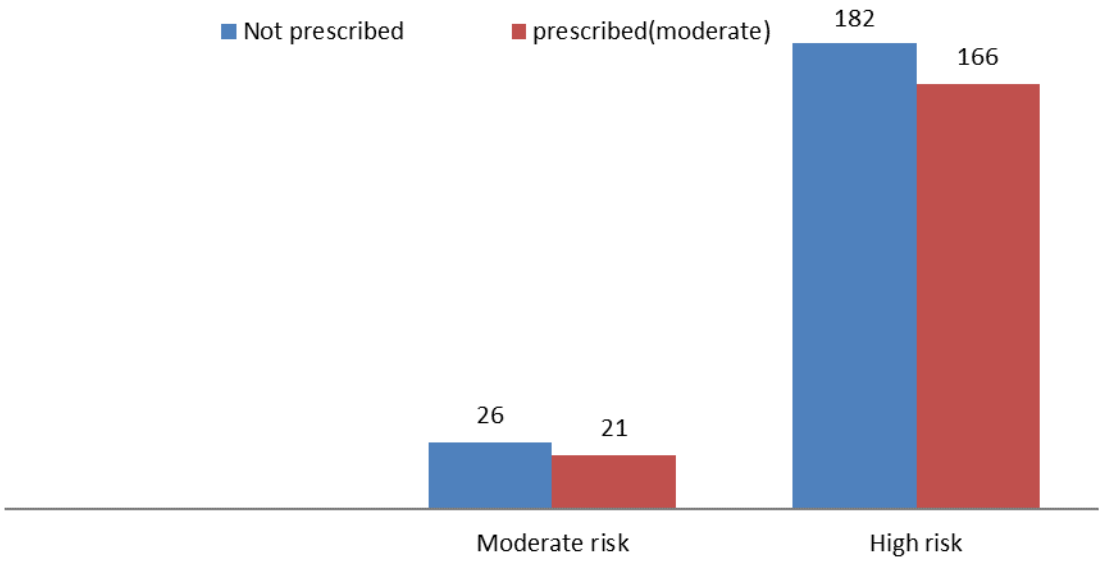


4.1 Statin prescription patterns in relation to CVD risk stratification among type 2 DM patients at DM Clinic- MNH2

In this study, 395 patients were eligible for statins prescription of which 187(47.3%) were prescribed with statins. About 47(11.9%) had moderate risk, and among them 21(44.7%) received moderate intensity statin. Majority of the study participants had high risk 348(88.1%) among which 166(47.7%) received moderate intensity statins and the remaining 182(52.3%) did not receive statins. Moderate intensity statin was the only pattern found. **(Figure 4)**

Figures 4 Prescription of statins in relation to risk stratification among T2DM patients at Diabetic clinic MNH



4.2 Factors associated with statin prescription patterns among type 2 DM patients at MNH Diabetes clinic

There was a significant association between statin prescription pattern by age whereby individuals with ≥ 40 years were more likely to be prescribed with moderate intensity statin than those of < 40 years {n=185(49.9%) versus n=2(8.3%) p=0.001}. Moderate intensity statin pattern was seen more in individuals with health insurance than those without {n=175(63.6%) versus n=12(10.0%) p=0.001}. Patients with diabetes duration of ≥ 10 years were likely to be prescribed moderate intensity statin than those with less than <10 years {n=110(54.7%) versus n=77(39.7%) p=value 0.003}.

Individuals with history of hypertension were more likely to receive moderate intensity statins than non-hypertensive individuals {n=160(52.1%) versus n=27(30.7%) p=0.023}. Patients who had coronary arterial disease were more likely to be on moderate intensity statin therapy compared to those without coronary artery disease {n=7(87.5%) versus n=1(12.5%)p=0.022} Those with high levels of LDL were also more likely to be prescribed moderate intensity statins compared to those with normal LDL levels {n=56(68.3%) versus n=38(64.4%) p=0.001}. Those with negative protein in urine were more likely to receive moderate intensity statins than their comparator (n=91(59.9%) versus n=60(57.7%) p=0.001}

Moreover, diabetic complications such as neuropathy, retinopathy and nephropathy were seen in 78.3%, 59.2%, and 30.6%, respectively, and moderate intensity statins were prescribed more in nephropathy n=75(62%) followed by retinopathy n=119(50.9%) and neuropathy n=150(48.5%) Among the cardiovascular diseases, cerebral vascular event was leading by n=27(6.8%) followed by peripheral arterial disease n=12(3.0%) and coronary arterial disease n=8(2.0%) and participants received moderate intensity statins from 50% and above in each condition.

However, gender, education level, prescriber's title, history of cigarette smoking, reduced eGFR <60ml/min/1.73m^2 and HbAIC ≥ 6.5 were not associated with moderate intensity statin prescription **(Table 2).**

Table 2 Shows factors associated with statin prescription patterns among type 2 DM patients at MNH Diabetes clinic

Factors	Total(N)	Statin Pattern Received*	Not received	P value
Age				
<40	24(6.1)	2(8.3)	22(91.7)	
≥40	371(93.9)	185(49.9)	186(50.1)	**0.001**
Sex				
Male	154(39.0)	77(50.0)	77(50.0)	
Female	241(61.0)	110(45.6)	131(54.4)	0.398
Education level				
≤Primary	208(52.7)	90(43.3)	118(56.7)	
≥Secondary	187(47.3)	97(51.9)	90(48.1)	0.087
Insurance				
Non Insured	120(30.4)	12(10.0)	108(90.0)	
Insured	275(69.6)	175(63.6)	100(36.4)	**0.001**
Evaluated/attended by				
General Practitioner				
Endocrinologist	134(33.9)	61(45.5)	73(54.5)	
	261(66.1)	126(48.3)	135(51.7)	0.604
BMI				
Normal	84(21.3)	34(40.5)	50(59.5)	
Overweight	177(44.8)	81(45.8)	96(54.2)	0.138
Obese	134(33.9)	72(53.7)	62(46.3)	
BP				
<140/90	203(51.4)	91(44.8)	112(55.2)	
>140/90	192(48.6)	96(50.0)	96(50.0)	
				0.303
Diabetes duration				
<10yrs	194(49.1)	77(39.7)	117(60.3)	
≥10yrs	201(50.9)	110(54.7)	91(45.3)	**0.003**
Cigarette Smoking				
No Hx of smoking	354(89.6)	169(47.7)	190(52.3)	
Smoking hx	41(10.4)	18(43.9)	23(56.1)	0.641
Hypertension				
No	88(22.3)	27(30.7)	61(69.3)	
Yes	307(77.7)	160(52.1)	147(47.9)	**0.023**
eGFR				
<60ml/min/1.73m^2	81(32.5)	50(61.7)	31(38.3)	
≥60ml/min/1.73m^2	168(67.5)	103(61.3)	65(38.7)	0.949

Protein in urine				
Negative	152(38.5)	91(59.9)	61(40.1)	
Positive	104(26.3)	60(57.7)	44(42.3)	**0.001**
HbAIC				
<6.5(on target)	44(27.3)	31(70.5)	13(29.5)	
≥6.5(not on target)	117(72.7)	71(60.7)	46(39.3)	0.252
LDL				
Normal	59(42.7)	38(64.4)	21(35.6)	
High	82(20.8)	56(68.3)	26(31.7)	**0.001**
CAD				
No	387(98.0)	180(46.5)	207(53.5)	
Yes	8(2.0)	7(87.5)	1(12.5)	**0.022**
PAD				
No	383(97.0)	181(47.3)	202(52.7)	0.851
Yes	12(3.0)	6(50.0)	6(50.0)	
CVE				
No	368(93.2)	170(46.2)	198(53.8)	
Yes	27(6.8)	17(63.0)	10(37.0)	0.092
Presence of Complication				
Neuropathy	309(78.3)	150(48.5)	159(51.5)	0.364
Retinopathy	234(59.2)	119(50.9)	115(49.1)	0.092
Nephropathy	121(30.6)	75(62.0)	46(38.0)	**0.001**
Risk stratification				
Moderate	47(11.9)	21(44.7)	26(55.3)	
High	348(88.1)	166(47.7)	182(52.3)	0.697

BP blood pressure, *BMI* body mass index, *eGFR* estimated glomerular filtration rate, *LDL* low density lipoprotein, *HbAIC* glycated haemoglobin, *CAD* coronary arterial disease, *PAD* peripheral arterial disease, *CVE* cerebral vascular event, *Hx* history.

***moderate intensity statins was the only pattern observed**

The multivariate logistic regression examined associations between statin prescription patterns and various factors. Insurance coverage (OR: 9.34; 95%CI: 4.63–18.85), hypertension (OR: 2.00; 95%CI: 1.04–3.86), and proteinuria (OR: 3.91; 95%CI: 1.30–11.74) were associated with an increased likelihood of a moderate intensity statin prescription. Age, diabetes duration, BMI, and education level were not associated with moderate intensity statin prescription after adjustment for the other variables in the model **(Table3)**

Table 3 Multivariate logistic regression on factors associated with statin prescription patterns

Variables	Odds ratio	95% CI	P-Value
Age ≥ 40	0.14	0.03-0.72	0.018
Education ≥secondary	0.92	0.55-1.52	0.734
BMI ≥overweight	0.72	0.35-1.47	0.365
High LDL			
No	Ref		
Yes	1.04	0.51-2.12	0.921
Insurance			
No	Ref		
Yes	9.34	4.63-18.85	**0.001**
Hypertension			
No	Ref		
Yes	2.00	1.04-3.86	**0.038**
Protein in urine			
No	Ref		
Yes	3.91	1.30-11.74	**0.015**

5.0 DISCUSSION

The current study sought to provide data on statin prescription patterns for the prevention of CVD among participants with type 2 diabetes mellitus. Prescription pattern were evaluated in relation to risk stratification in patients with T2DM.It was found that statins were prescribed in about half of the participants with T2DM who were eligible for prescription. Findings of this study were similar to those found by Mwita *et al* (45), Dermoz *et al* (44) and Gupta et al(52) and in which statin prescription were 45.5% and 55.7% respectively. The explanation for such a low prescription rate could be due to the following reasons; firstly lack of local guidelines, secondly inadequate adherence to already recommended international guidelines, thirdly limited access to medications and lipid tests due to poor social economic status.

Of those patients received statins (n = 187), moderate intensity statins was the only pattern found in 47.3%, similarly to 46.1% in the study done by Dermoz *èt al*. (25).Likewise, almost half of patients166 (47.7%) in a high risk group (n=348) were prescribed with moderate-dose statins, contrary to the recommendations (3,53) while more than half in this group did not receive statins despite being at high risk.

In this study, atorvastatin was found to be the most commonly prescribed type of statin, followed by rosuvastatin. Similarly, in a study done by Gupta *et al* (52)atorvastatin was the most commonly prescribed type of statin (74.1%), followed by rosuvastatin (29.2%)In contrast to this, Dermoz *èt al*(25) demonstrated that simvastatin (37.2%) was the mostly prescribed statin followed by, atorvastatin (32.8%) and rosuvastatin (15.6%). Reasons could be availability, cost, and physician preference

With regards to cholesterol levels it was found that having high levels of low density lipoprotein increased the odds of being prescribed with statins. Those with high LDL had one more chance of being prescribed with moderate statins than the comparator. This also confirms the observation from previous studies that clinicians tend to prescribe statins based on the baseline LDL-C levels than to the patients' overall CVD risk profile as described in clinical guidelines. (45,59).Although there is a lack of local guidelines, MNH diabetes clinic

has adopted ADA guidelines which recommend statins along with lifestyle changes regardless of cholesterol levels for all patients with diabetes aged > 40 with or without CVD(3). These findings may suggest a need for deliberate efforts for improving the understanding and implementation of the adopted guidelines.

Concerning insurance coverage, those who had medical insurance had nine times chances of being prescribed with statins. This finding has been observed in other studies (48,54,55)

This can be explained by the easy access of these drugs in insurance packages, hence forth facilitate prescription. On the other hand, even among those who are medically insured and eligible, some were not on statin prescription. This might as well have been caused by absent guidelines in the hospital to guide statin prescription.

Likewise patients who had history of hypertension as a comorbidity had two times chance of being prescribed with statins as compared to those without hypertension. This association has also been reported by various other studies (43,56). Therefore having comorbidity like hypertension along with diabetes should be regarded as a high risk for developing cardiovascular diseases hence this should trigger intervention by the clinicians in order to provide the best care to these patients before they succumb to cardiovascular complications.

Patients with proteinuria had four times chances of being prescribed with statins as compared to their counterparts. This finding was similar to that of Berthold Hk *et al*, in which their study reported that patients with proteinuria had increased odds of statin prescription in Germany (35).

Since proteinuria is a marker of renal disease, it’s encouraging to see patients with proteinuria in this study received statin prescriptions. We can commend clinicians for recognizing proteinuria as a predictor of CVD and an indication for statins in patients with diabetes.

Interestingly, the present study found that of those participants who received statin therapy, only 40.4% were found to have normal range cholesterol level. Certainly, only one third (35.7%) of patients in this study had detailed lipid profile. This indicates noncompliance with the standard guidelines about monitoring of lipid profile that all patients with T2DM should be tested at least annually (53). This might also be the reason for low percentage of patients to have normal range cholesterol levels. Therefore there is a need to emphasize periodic monitoring of their lipid levels in optimizing the utilization of statins in response to the CVD risks factors. Such an initiative will ensure that statin prescription decisions are, at least in part, based on the risk assessment and lipid profile.

There was no significant association found between longer diabetes duration and statin prescription. In contrast some studies and clinical guidelines have reported association of longer diabetes duration and tendency to statin prescription (38, 45). The difference here may be because almost half of the patients (49%) had less than 10 years diabetes duration from the time of diagnosis.

Smoking was also not found to be associated with statin prescription in this study. This lack of association was also found in other studies as well (45). However this finding is inconsistent with other studies which showed that patients with history of smoking had increased odds of being prescribed with statins (29) The overall low smoking and alcohol consumption habits in the Tanzania population could attribute to this effect(57).Also, one of the lifestyle modifications in diabetes mellitus is to limit cigarette smoking.

Increase in Age and BMI were also not associated with statin prescription in this study, this was contrary to other studies (29,58) where the odds of being prescribed were seen in more elderly and in overweight/obese patients. This could be attributed to differences in population representation or the fact that prescribes fear to increase the burden of pills to these high risk group to avoid adverse effects as majority have also been prescribed with other medications.

6.1 STRENGTHS OF THE STUDY AND LIMITATIONS

6.1 Strengths of the Study

Our study was a large hospital based cross sectional study of the first kind in a tertiary hospital that assessed statin prescription patterns and its associated factors. The study has helped to identify the gaps in statin prescribing practice among clinicians and raise awareness for development of local guidelines in-order to guide treatment.

6.2 Limitations

Our study had several limitations which include: lack of standard risk stratification tool, lack of systematic collection data on microvascular complications (especially renal disease). There is also a possibility of recall bias in participants to some of the disease presentations that could have resulted in inaccurate estimation of their co-morbidities. Also absence of baseline cholesterol levels of these patients to justify dosages and lack of data on the side effect profile of statins. Moreover, a qualitative analysis to determine causes of low statin prescriptions by clinicians was not performed

7.0 CONCLUSION AND RECOMMENDATIONS

7.1 Conclusion

This study showed suboptimal statin prescription among type 2 diabetes patients attending diabetic clinic at Muhimbili National Hospital. Moderate intensity statins was the only pattern found among diabetes patients.

7.2 Recommendations

Strategies to optimize prescriptions at the clinic should focus on; exploring reasons for low statin prescription, clinicians' awareness of recommended guidelines, continuing medical education as well as time to time prescription audits and dissemination of results to improve quality of preventive care among patients with type 2 diabetes mellitus.

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APPENDICES

Appendix 1: Questionnaire on Demographic Information

PATIENT'S IDENTIFICATION

- ✓ Questionnaire No. .....
- ✓ Registration No. .....
- ✓ Patient's initials.....
- ✓ Date of initial study enrollment.....
- ✓ Date of Birth.....
- ✓ Gender Male ☐ Female ☐

- ✓ Physical address.....
- ✓ Level of education…….(tick)
    - ➢ elementary to primary……..
    - ➢ secondary to College/university…..
- ✓ Occupation……..(tick)
    - ➢ Jobless…….
    - ➢ Employed in the state sector……..
    - ➢ Employed in the private sector …….
    - ➢ Independent job……
    - ➢ Retired……
- ✓ Insurance…….yes/no

Appendix 2: Case Report Form on Clinical Characteristics

VITALS

- ✓ Blood pressure ……mmHg
- ✓ Height ..... meters Weight..... Kgs
- ✓ Body mass Index (BMI)..... Kg/m^2
- ✓ FBG/RBG……mmol/l

MEDICAL HISTORY

Atherosclerotic risk factors

- ✓ Duration of diabetes……
- ✓ Smoking status…….(tick)
  - ➢ No history of smoking……
  - ➢ History of smoking ……
- ✓ Hypertension(informed diagnosis/on medications) …….yes/no
- ✓ Chronic kidney Disease(informed diagnosis)……yes/no

Atherosclerotic cardiovascular diseases-(ASCVD)

- o Cerebral vascular event(stroke)……..yes/no
- o Coronary arterial disease(history of admission due to cardiac chest pain/coronary intervention)…….yes/no
- o Peripheral arterial disease (history of claudication, Skin color changes on the extremities ,vascular intervention)….. yes/no

- ✓ Presence of complications
  - ➢ Neuropathy(eg. numbness, erectile …….yes/no
  - ➢ Nephropathy(evidence of decline in eGFR)……yes/no
  - ➢ retinopathy(Vision abnormalities/eye interventionpost Diabetes)…….yes/no

RISK STRATIFICATION IN RELATION TO STATIN USE (TICK BELOW)

- o LOW RISK- <40 years without ASCVD risks (NONE)
- o MODERATE RISK- >40years without ASCVD risks(MODERATE INTENSITY STATINS)……yes/no
- o HIGH RISK-<40 and >40years with ASCVD/ ≥40years with ≥2 traditional risk factors for CVD (HIGH INTENSITY STATINS)……..yes/no

Appendix 3: Case Report Form on Laboratory Investigations

Lab workup

- ✓ Baseline Lipid Profile

  Total Cholesterol .....mg/dl

  LDL .....mg/dl

  HDL ..... mg/dl

  TGA .....mg/dl

- ✓ Urine protein……..
- ✓ Creatinine……..
- ✓ eGFR……..
- ✓ HbAIC……

Appendix 4: Case Report Form on Medications

Statin prescription……yes/no

If yes…

- Type……..
- Dosage…….

Hypertension medications……yes/no

Diabetic medications……yes/no

Prophylaxis medications eg aspirin/Clopidogrel……..yes/no

Attending clinician……(TICK)

- ✓ General Practitioner…….
- ✓ Endocrinologist……

Appendix 5: Informed Consent Form - English Version

CONSENT TO PARTICIPATE IN THE STUDY TITLED "STATINS TREATMENT PATTERNS AND ASSOCIATED FACTORS AMONG TYPE 2 DIABETES PATIENTS AT MUHIMBILI DIABETIC CLINIC''

My Name is Dr Aneth T Bideberi, a resident doctor in the department of Internal Medicine at Muhimbili University of Health and Allied Sciences (MUHAS). I am conducting a research study on statin treatment patterns and associated factors among type 2 diabetes patients at Muhimbili diabetic clinic.

I hereby request your participation.

Purpose of the study: This study aims to determine statins treatment patterns and associated factors among type 2 diabetes patients at Muhimbili diabetic clinic. Information obtained from this study will be of key importance for creating awareness on the current recommended clinical guidelines to guard treatment in the prevention of cardiovascular diseases among diabetes patients.

How to participate: Participants who are willing to participate in this study will have to sign a consent form or to be assisted by the next of kin or caretakers for those who are unable to communicate well.

A short interview will be done for all patients to ascertain associated factors for being on statins such as duration of diabetes, hypertension, stroke, peripheral diseases and other social-economic factors.

Confidentiality: Information obtained from this study will be kept confidential. None of the data will link directly to you and the information will be used solely for research purposes.

Costs: You will not be required to pay any extra amount for your participation in this study.

Voluntary participation and the right to withdraw from the study: Your participation is voluntary and you have the right to withdraw from participating in this study at any time. Whatever your decision may be, it will not affect in any way to your rights to care and treatment.

Risk: No risk is expected to arise from participating in this study

Benefits: Your participation will help to determine statins treatment patterns and associated factors among type 2 diabetes patients at Muhimbili diabetic clinic and associated factors that will form a basis on recommendations that will guard treatment in this group of patients.

If you have any questions or concerns during the study, you may contact the following:

Dr. Aneth T. Bideberi
Principal Investigator
Muhimbili University of Health and Allied Sciences (MUHAS)
Department of Internal Medicine
P.O. Box 65001 Dar es Salaam.
Mobile phone: 0759334883

OR

Dr Reuben Mutagaywa the supervisor for this study. Mobile phone +255 717-921-555.

In case you need any information concerning your rights as a participant please contact

Dr Bruno Sunguya,
Director of Research and Publication (DRP) of MUHAS
P. O. Box 65001, Dar es Salaam, Tanzania. Tel: +255-022-2152489, Fax: +255-022-2152489,
Email: drp.muhas.ac.tz.

INVESTIGATOR'S STATEMENT

The investigator has educated the research participant on the purpose and applications of this study.

Signed…… Date…….

PARTICIPANT'S STATEMENT

I…… willingly agree to take part in this study. I do this with a full understanding of the purposes of the study and the procedures involved which include answering questions from a study questionnaire which have been explained to me by Dr Aneth T Bideberi

Signature of patient----------

Signature of witness----------

Date----------

I have read the consent form and my questions have been answered and I agree to participate in this study.

Signature: Participant/Relatives……...

Date of signed consent…….

I …… have read the consent form and my questions have been answered and I agree to participate in this study.

Signature: Participant/Relatives……

Date of signed consent……

Appendix 6: Informed Consent Form Swahili Version

RIDHAA YA KUSHIRIKI KATIKA UTAFITI KUHUSU MUUNDO WA MATIBABU YA TULI KWA WAGONJWA WENYE KISUKARI KATIKA KLINIKI YA MUHIMBILI

Jina langu ni Dr.Aneth T Bideberi anayesoma shahada ya uzamili katika Idara ya Tiba ya Magonjwa ya Ndani katika Chuo Kikuu cha Muhimbili cha Afya na Sayansi Shirikishi (MUHAS). Ninafanya utafiti juu ya utolewaji wa dawa za kupunguza mafuta yenye lehemu na viashiria vya kuwekwa kwenye matibabu kwa wagonjwa wenye kisukari aina ya pili. Ninaomba ushiriki wako.

Lengo la utafiti: Lengo la utafiti huu ni kuhimiza umuhimu wa matumizi ya kanuni za matibabu katika kuzuia magonjwa ya moyo kwa wagonjwa wenye kisukari.

Jinsi ya kushiriki: Washiriki ambao wako tayari kushiriki katika utafiti huu watalazimika kusaini fomu ya idhini au ndugu wa karibu kutoa idhini kwa niaba ya mgonjwa ambaye hataweza kujieleza. Mahojiano mafupi yatafanyika kwa wgonjwa wote.

Usiri: Taarifa zilizopatikana kutoka kwenye utafiti huu zitahifadhiwa kwa usiri. Hakuna taarifa ambayo itaunganishwa kwako moja kwa moja na taarifa itatumika tu kwa kusudi la utafiti.

Gharama: Hutatakiwa kulipa kiasi chochote cha ziada kwa kushiriki kwako katika utafiti huu.

Ushiriki wa hiari na haki ya kujiondoa kwenye utafiti: Ushiriki wako ni hiari na una haki ya kujiondoa kushiriki katika utafiti huu wakati wowote. Vyovyote uamuzi wako unaweza kuwa, hauwezi kuwa na athari kwa njia yoyote ya haki zako za utunzaji na matibabu.

Hatari: Hakuna hatari inatarajiwa kutokana na kushiriki katika utafiti huu

Faida: Ni matumaini yetu kuwa matokeo ya utafiti huu yatasaidia kuboresha huduma zetu kwa wagonjwa wenye kisukari ilikuwakinga na magonjwa ya moyo.

Ikiwa una maswali yoyote au wasiwasi wakati wa utafiti, unaweza kuwasiliana na wafuatao:

Dr Aneth Telesphore Bideberi,
Mtafiti husika katika utafiti huu,
Chuo Kikuu cha Afya na Sayansi Shirikishi (MUHAS)
Idara ya magonjwa ya ndani
P.O. Box 65001 Dar es Salaam.
Nambari ya simu: 0759334883
AU
Dr Reuben Mutagaywa, msimamizi wa utafiti. Nambari ya simu: +255717-921-555
Ikiwa unahitaji maelezo yoyote kuhusu haki zako kama mshiriki tafadhali wasiliana na:
Dr Bruno Sunguya,
Mkurugenzi wa utafiti na machapisho, MUHAS,
P. O. Box 65001, Dar Es Salaam, Tanzania. Simu: +255-022-2152489, Fax: +255-022-2152489, Barua pepe: drp.muhas.ac.tz.

KAULI YA MTAFITI

Mimi mpelelezi nimemuelimisha mshiriki wa utafiti juu ya madhumuni na matumizi ya huu utafiti.

Saini..... Tarehe.....

KAULI YA MSHIRIKI

Mimi..... kwa hiari nakubali kushiriki katika utafiti huu.Ninafanya hivyo kwa ufahamu kamili wa madhumuni ya utafiti huu na taratibu zilizohusika ambazo ni pamoja na kujibu maswali ya utafiti na kuwa na vipimo vya maabara, ambayo yote yameelezwa na Dr Aneth. T. Bideberi

Saini ya mshiriki..... Saini ya Shahidi.....

Tarehe.....

Mimi ..... nimesoma fomu ya ridhaa na maswali yangu yamejibiwa na ninakubali kushiriki katika utafiti huu.

Saini: Mshiriki / jamaa .....

Tarehe ya idhini iliyosainiwa .....

Mimi ..... nimesoma fomu ya ridhaa na maswali yangu yamejibiwa na ninakubali kushiriki katika utafiti huu.

Saini: Mshiriki / jamaa .....

Tarehe ya idhini iliyosainiwa .....