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Evaluating Statin Use for Outpatients Based on to ACC/AHA Indication

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A graduation research project submitted as partial fulfillment for the requirements of the bachelor's degree in Pharm-D

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Dedication

With gratitude to the Almighty for His guidance and support in completing this research. To the one who gave generously and with grace, who illuminated our minds with his experience and broadened our hearts with his wisdom, to the sweat that graces your brow with purity and fragrance, from you we have learned so much, and now we hope to give back in some small way... Our beloved fathers.

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List of abbreviation

ACEI	Angiotensin Converting Enzyme inhibitor
ACS	Acute coronary Syndrome
AEs	Adverse effects
ACC	American College of Cardiology
AHA	American Heart Association
ARBs	Angiotensin receptor blocker
ASCVD	Atherosclerotic cardiovascular
BB	Beta blocker
BMI	Body Mass Index
CCB	Calcium channel blocker
CKD	Chronic kidney disease
CVD	Cardiovascular disease
CAD	Coronary artery disease
CHD	Coronary heart disease
DM	Diabetes mellitus
HF	Heart failure
HDL-C	High-density lipoprotein cholesterol
HR	High risk
HMG-CoA	Hydroxy-methylglutaryl coenzyme A
HTN	Hypertension
IHD	Ischemic heart disease
LDL-C	low-density lipoprotein cholesterol
LR	Low risk
MR	Medium risk
MI	Myocardial infarction
NDHP	Non dihydropyridine
N	Number
PAD	Peripheral artery disease
PCE	pooled cohort equations
P	P value
TC	Total cholesterol
TG	Triglycerides
T2DM	Type 2 diabetes mellitus
U.S	United states

Abstract

Background: According to AHA/ACC guidelines for the use of statin for treatment of blood lipid. There are four groups of patients need statin as a primary or secondary prevention.

Objective: To evaluate Statin Use for Outpatient Based on ACC/AHA Indications .

Methods: This is a prospective cross-sectional study was conducted in a private cardiology clinic at Sanaa city from January 2024 to June 2024. Data collection was from the electronic medical records by using a structured questionnaire (covering demographic data, diagnostic data and medications data). All data were analyzed using SPSS Statistics version 21.0 for Windows®.

Results: The sample of the study was 100. The Male frequency 53 with ASCVD risk was more compared to female 47 . Most patients 75 were not smoking, whereas 25 of the patients were smokers. The results showed that most of the patients 26 were suffering of Hypertension-DM-Dyslipidemia. No patients in the low risk category out of 14 is in need to drug, only 3% patients out of 8 in the moderate category is in need to Statin or BB+CCB or BB. There were 44 patients with ASCVD had drug based on guidelines, while 56 of the patients didn't had drug based on guidelines, The results reveal significant correlations between ASCVD risk factors and several variables. The most influential factors on risk are age, gender, smoking, diagnosis, serum creatinine (SrCr), and CKD stage. Age, gender, diagnosis, SrCr, and CKD stage showed positive correlations with ASCVD risk, while smoking had a negative correlation. No significant correlations were found with qat chewing, weight, or body mass index (BMI).

Conclusion: This study shows that 44 patients with ASCVD had drug based on guidelines, while 56 of the patients didn't had drug based on guideline. Statin used for Primary prevention in 48 patients with ASCVD and in 38 patients for Secondary prevention, on the other hand, statin use for 14 patients with ASCVD for no reason.

Chapter One: Introduction

1. Introduction

1.1 Background:

According to statistics provided by American heart association In which data collected from According to statistics provided by American heart association In which data collected from 2015 to 2018 indicates that 38.1% of adults in the United States, equivalent to 93.9 million individuals, had total cholesterol levels equal to or exceeding 200 mg/dL[1]. Furthermore, elevated levels of low-density lipoprotein cholesterol were responsible for 4.51 million deaths worldwide in 2020, indicating a 19% Increase compared with 2010[2].

Dyslipidemia is the abnormal lipid status in the blood that Is defined as an elevated level of triglycerides (TG), or elevated total cholesterol (TC), or elevated low-density lipoprotein cholesterol (LDL-C), or low levels of high-density lipoprotein cholesterol (HDL-C) or a combination of these features. The global burden of dyslipidemia has increased over the past three decades and is considered an important public health issue both in low-middle-income and high-income countries[3].

Dyslipidemia is a well-known risk factor for cardiovascular disease (CVD) and related mortality in both developed and developing nations[4]. According to the World Health Organization (WHO), the global prevalence of elevated plasma levels of TC in adults aged ≥25 years was ~39% in 2008 and more than one-third of mortality caused by CVD was attributable to raised plasma LDL-C levels[3].

Atherosclerotic Cardiovascular Disease (ASCVD) is a significant health concern characterized by the buildup of fatty deposits (plaque) in the arteries, leading to reduced blood flow and increased risk of events such as heart attacks and strokes. There are Several factors contribute to the development of ASCVD, including:

- Age: Risk increases with age, particularly in men over 45 and women over 55.
- Gender: Men have a higher risk at younger ages; women's risk increases post-menopause.
- Family History: A family history of heart disease raises individual risk.
- Hypertension: High blood pressure damages arteries and increases risk.
- High Cholesterol: Elevated low-density lipoprotein (LDL) cholesterol is a key risk factor.
- Diabetes: Significantly raises the likelihood of cardiovascular events.

- Smoking: A major contributor to ASCVD.
- Obesity: Excess body weight, especially around the abdomen, heightens risk.
- Physical Inactivity: Sedentary lifestyle is linked to other risk factors.
- Unhealthy Diet: Diets high in saturated fats, trans fats, and sodium can lead to ASCVD.
- Chronic Kidney Disease: Associated with a higher risk of cardiovascular disease.
- Inflammation: Chronic inflammatory states can contribute to atherosclerosis[5].

Among lipid-lowering drugs, statins are the cornerstone of therapy, in addition to healthy lifestyle interventions[6]. The intensity of statin therapy is divided into 3 categories: high-intensity, moderate-intensity, and low-intensity[7]. High-intensity statin therapy typically lowers LDL-C levels by ≥50%, moderate-intensity statin therapy by 30% to 49%, and low-intensity statin therapy by <30%. Of course, the magnitude of LDL-C lowering will vary in clinical practice[8].

The American Heart Association (AHA) and the American College of Cardiology (ACC) released a new guideline in 2018. The aim of the treatment recommended in these guidelines focuses on the intensity of statins instead of the target low-density lipoprotein cholesterol (LDL-C). The guideline identified four primary patient groups labelled as "high-risk patients" for ASCVD, and for whom statin therapy is indicated[9]. The four patient groups that would benefit from statin therapy include the following:

1) Patients with clinical ASCVD.
2) Patients with LDL-C >190 mg/dL.
3) Patients aged 40–75 years with diabetes and LDL-C from 70–189 mg/dL.
4) Patients with high 10-year risk of ASCVD (≥7.5%) aged 40-75 years with LDL-C between 70-189 mg/dL

CTT meta-analysis[10] showed that LDL-C lowering with statins reduces major ASCVD events. In a meta-analysis of 5 RCTs,[11] high-intensity statins compared with moderate-intensity statin therapy, significantly reduced major vascular events by 15% with no significant reduction in coronary deaths. Moderate-intensity statin therapy also reduces major vascular events and coronary heart disease (CHD) deaths in patients with ASCVD[12-13-14]. In RCTs, most of which included moderate-intensity statin therapy, there was a significant reduction in major vascular events among those >75 years of age[15].

Patients with primary severe hypercholesterolemia (LDL-C levels ≥190 mg/dL [≥4.9 mmol/L]) have a high-risk of ASCVD[15] and premature and recurrent coronary events[16].

Patients with severe hypercholesterolemia who are adherent to statins, achieve <50% reduction in LDL-C levels with maximally tolerated statin therapy[17].

Most adults 40 to 75 years of age with diabetes mellitus are at intermediate or high-risk (PCE ≥7.5% 10-year risk) of ASCVD events[18-19]. Three of 4 double-blinded primary-prevention RCTs of moderate statin therapy in large cohorts with diabetes mellitus in this age range showed significant reductions in ASCVD events[20]. A meta-analysis of these trials found that moderate-intensity statin therapy is associated with a risk reduction of 25%[21], resulting in a risk level similar to that of people without diabetes mellitus and with no apparent difference in benefit between type 1 and type 2 diabetes mellitus. Therefore, on the basis of a high level of evidence, moderate-intensity statin therapy is indicated in patients 40 to 75 years of age with diabetes mellitus for primary prevention.

Primary prevention of ASCVD over the life span requires attention to prevention or management of ASCVD risk factors beginning early in life. One major ASCVD risk factor is elevated serum cholesterol, usually identified clinically as measured LDL-C. Screening can be performed with fasting or nonfasting measurement of lipids. In children, adolescents (10 to 19 years of age), and young adults (20 to 39 years of age), priority should be given to estimation of lifetime risk and promotion of lifestyle risk reduction. Drug therapy is needed only in selected patients with moderately high LDL-C levels (≥160 mg/dL [≥4.1 mmol/L]) or patients with very high LDL-C levels (190 mg/dL [4.9 mmol/L]). Three major higher-risk categories are patients with severe hypercholesterolemia (LDL-C levels ≥190 mg/dL [≥4.9 mmol/L]), adults with diabetes mellitus, and adults 40 to 75 years of age. Patients with severe hypercholesterolemia and adults 40 to 75 years of age with diabetes mellitus are candidates for immediate statin therapy without further risk assessment[22].

Statins have served as the primary treatment for preventing CVDs for many years, starting with the introduction of lovastatin in 1987, which was the first statin available for commercial use[23]. These medications work by competitively inhibiting HMG-CoA reductase, a crucial enzyme that controls the rate of cholesterol production in the liver. This inhibition leads to a

decrease in cholesterol synthesis within the liver. In response to the lowered cholesterol, hepatocytes increase the production of LDL. Receptors, enhancing the uptake and recycling of LDL cholesterol. Consequently, this process results in reduced levels of LDL cholesterol in the bloodstream. This reduction in serum LDL levels is the primary mechanism through which statin therapy decreases the risk of cardiovascular problems and improves overall outcomes[24]-[25]. One early study observed a dose-dependent decrease in LDL. Cholesterol levels, ranging from 25% to 60%, with atorvastatin therapy[12]. A number of research studies have investigated the role of statin therapy in lowering the occurrence of significant vascular events[26]-[27].

In general, statins are considered safe and well -tolerated medications, and they are the most commonly prescribed drugs worldwide. Clinical trials have shown that statins effectively lower LDL cholesterol levels and improve patient prognosis without increasing complications[28]. These drugs also have additional benefits, such as reducing inflamma- tion markers such as C-reactive protein and pro-inflammatory cytokines. Statins improve endothelial function in patients with cardiovascular risk factors and are associated with protective effects in coronary artery disease (CAD)[29]-[30].

They also play a role in preventing stroke, improving outcomes in acute coronary syndrome, reducing the risk of atrial fibrillation after heart surgery, and benefiting patients with heart failure. Statin treatment has demonstrated cardiovascular risk reduction, even in healthy individuals with elevated inflammation markers[31]-[32]. Additionally, the regulation of hepatic LDL-receptor-related protein 1 expression is considered a mechanism underlying the protective effects of statins On the cardiovascular system[33]-[34].

While statins have many beneficial effects, they also have some detrimental ones, adverse effects (AEs) are reported and include muscle pain and damage, increased blood glucose levels, which may contribute to type 2 diabetes mellitus (T2DM), hepatotoxicity, digestive problems, cognitive effects, and the development of rashes or flushing. But the most relevant adverse effects are the effects that impact muscles, blood glucose, and liver function. Adverse effects that affect muscles are the most common adverse effects of statins. It was said that about one-third of people taking statins experience muscle symptoms such as muscle pain, itching, stiffness… etc. Rhabdomyolysis, severe myonecrosis with myoglobinuria or acute renal failure, is a rare but

serious adverse effect of using statins. Life-threatening rhabdomyolysis occurs in only 0.001%-0.005% of patients[35].

1.2 Problem statement:

Recently, it has been noted that there has been an increase in the prescription of statins by doctors, and a lack of knowledge among doctors about the recent guidelines, including AHA/ACC guideline for treatment of high blood lipids. This made us consider this issue and decide to conduct this study to know the evaluation of statin use in Outpatient Based on AHA/ACC indication

1.3 General Objectives:

• To evaluate Statin use for Outpatient patients according to ACC/AHA indications.

1.4 Specific Objectives:

• To identify barriers faced by healthcare providers in adhering to ACC/AHA guidelines for statin therapy during patient Outpatient .
• To analyze the impact of appropriate statin use on patient outcomes, including readmission rates and cardiovascular events, within a specified follow-up period.
• To assess the effectiveness of patient education regarding statin therapy and its influence on adherence to prescribed medication.

1.5 Research questions

• To what extent are Outpatients prescribed statins in accordance with ACC/AHA guidelines?
• What demographic and clinical characteristics are associated with the appropriate prescription of statins at Outpatient ?
• What barriers do healthcare providers encounter when prescribing statins Based on ACC/AHA guidelines during patient discharge?

Chapter Two: Literature review

2. Literature review

2.1 In the study conducted Muntner P, et al., 2022, the Objective was to evaluate a simple approach to identify adults meeting the 2018 AHA/ACC cholesterol guideline definition of very high risk for atherosclerotic cardiovascular disease. Among 16,344 patients with a history of a major ASCVD event, 94.0% met the 2018 AHA/ACC cholesterol guideline definition for very high risk including 92.9%, 96.5%, 93.1%, and 96.2% **,** with a recent ACS, history of MI, history of stroke and symptomatic PAD, respectively. The incidence of ASCVD events per 1,000 person-years was 50.4 (95% CI: 47.6-53.3) among all patients with a history of a major ASCVD event versus 53.1 (95% CI: 50.1-56.1) among patients who met the 2018 AHA/ACC cholesterol guideline definition of very high risk. The study Concluded that the vast majority of patients with a recent ACS, history of MI, ischemic stroke or symptomatic PAD meet the 2018 AHA/ACC cholesterol guideline definition of very high risk[40].

2.2 According to study reported Tan NC, et al 2018, the objective was to determine the proportions and factors influencing patients with dyslipidemia on LLT who achieved their recommended LDL-C treatment goals. Amongst the 917 patients treated with LLT, 60·9% were females and 56·2% aged >60 years. The commonest statins prescribed were simvastatin (77·7%), atorvastatin (15·3%), rosuvastatin (4·3%) and lovastatin (3·4%). Those who attained LDL-C treatment goals included 89·4%, 77·4% and 70% of the LR, MR and HR groups. Overall, 72·4% of the patients achieved LDL-C treatment goals. Despite 98·4% of them self-reported LLT adherence, only 85·5%, 69·5% and 50% of the LI, MI and HI subgroups attained the desired outcomes, respectively. As conclusion overall, 27·6% of patients with dyslipidemia, including 30% of the HR group, did not achieve LDL-C treatment goals, despite on LLT. Addressing their concerns and adjusting medication doses of their LLT are needed for better outcomes. The effect of the intensity of lipid-lowering medications on the LDL cholesterol treatment goals of Asian patients with dyslipidemia in primary care[41].

2.3 According to study reported by Alburikan KA et al., 2017, the aim was to evaluate the adherence to the 2013 American College of Cardiology/American Heart Association (ACC/AHA) guideline recommendations for statin therapy in the treatment of elevated blood cholesterol in high-risk patients. The result of the study showed that, between 1 June and 31 December 2015, 1094 consecutive adult patients with a prescription for any statin medications

were identified. Of these 1094 patients, 753 (68.8%) patients met the inclusion. The mean age (standard deviation) of the patients was 58.5 (8.9) years, and 436 (57.9%) were men. About half had ASCVD (n=402, 53.5%) and almost one-third had diabetes (n=225, 29.9%). Seven (0.9%) had an LDL-C level of >190 mg/dL, 81 (10.8%) had a 10-year risk of >7.5%, and 37 (4.9%) had no risks. The mean estimated 10-year ASCVD risk rate was 4.9 (4.4 %, and the mean (SD) LDL-C level was 83.6 (44.2) mg/dL or 2.2 (1.1) mmol/L. Most had received atorvastatin (n=648, 86.1%). The majority were hypertensive (n=549, 72%) with a mean (SD) systolic blood pressure (SBP) of 131.1 (21.6) mm Hg. Many were taking beta-blocker treatment (473 patients; 62.8%), followed by antidiabetic medication (451 patients; 59.9%) and aspirin (439 patients; 58.3%). Most patients had received high-intensity statin therapy (n=422), which included most patients with ASCVD (n=335, 83.3%) while 26.2% (n=59) of patients with diabetes received high-intensity statin therapy. Most patients with an LDL-C level >190 mg/dL (n=6, 85.7%) and with an estimated 10-year ASCVD risk of >7.5% (n=73, 90.1%) received moderate-intensity statin therapy. In conclusion, approximately one-third of patients received statin therapy at an inappropriate intensity according to the guideline recommendation. Wide application of the 2013 ACC/AHA cholesterol guidelines in our practice would optimize the utilization of statin therapy at the ideal intensity in high-risk patients[36].

2.4 In the systemic review conducted by Hope HF, et al., 2017, the Objective was to identify predictors of statin adherence for the primary prevention of CVD. A total 19 studies met the inclusion criteria and nine were evaluated as high quality using the QA tool. The proportion of patients classed as “adherent” ranged from 17.8% to 79.2%. Potential predictors of statin adherence included traditional risk factors for CVD such as age, being male, diabetes and hypertension. Income associated with adherence more strongly in men than women, and highly educated men were more likely and highly educated women less likely to be adherent. Alcohol misuse and high BMI associated with non-adherence. There was no association between polypharmacy and statin adherence. The evidence base for the effect of other lifestyle factors and health beliefs on statin adherence was limited. The review conclude that patients with more traditional risk factors for CVD are more likely to be adherent to statins. The implications for future research are discussed[39].

2.5 In the study conducted Olufade T, Zhou S, et al., 2017, the objective was to characterize changes in statin utilization patterns in patients newly initiated on therapy in the 2 years following the release of the 2013 American College of Cardiology/American Heart Association (ACC/AHA) cholesterol management guideline in a large US health plan population .The study reveals that SBG1 (with atherosclerotic cardiovascular disease [ASCVD]; N=1046/quarter), SBG2 (without ASCVD, with low-density lipoprotein cholesterol ≥190 mg/dL; N=454/quarter), SBG3 (without ASCVD, aged 40–75 years, with diabetes mellitus, low-density lipoprotein cholesterol 70–189 mg/dL; N=1391/quarter), SBG4 (no ASCVD or diabetes mellitus, age 40–75 years, low-density lipoprotein cholesterol 70–189 mg/dL, estimated 10-year ASCVD risk of ≥7.5%; N=705/quarter). Demographic variables, statin utilization patterns, lipid levels, and comorbidities were analyzed for pre- and post guideline periods. Post guideline, gradually increased high-intensity statin initiation occurred in SBG1, SBG2, and in SBG3 patients with 10-year ASCVD risk ≥7.5%. Moderate- to high-intensity statin initiation gradually increased among SBG4 patients. Recommended-intensity statin choice changed to a greater degree among patients treated by specialty care physicians. Regarding sex, target-intensity statin initiation was lower in women in all groups before and after guideline release. Conclusively, prescriber implementation of the guideline recommendations has gradually increased, with the most marked change in the increased initiation of high-intensity statins in patients with ASCVD and in those treated by a specialist. Initiation Patterns of Statins in the 2 Years After Release of the 2013 American College of Cardiology/American Heart Association (ACC/AHA) Cholesterol Management Guideline in a Large US Health Plan[42].

2.6 In the study conducted by Zupec JF, et al., 2016, the objective was to describe the prescribing habits of statin therapy in primary care patients with ASCVD before and after the ACC/AHA guidelines were published. A total, 220 patients were included in the analysis with 110 in the before and 110 in the after cohort. For the primary outcome analysis, the rate of high-intensity statin utilization in the before versus after groups was significantly greater (25.5% vs 41.8%, P = 0.01). For ages 76 to 89 years, 36 of 37 and 29 of 30 patients in the before and after groups were receiving moderate- to high-intensity statin therapy (97.3% vs 96.7%, P = 0.99). Subgroup analysis in the after cohort for all ages showed no change in statin therapy for 77% of patients. The Conclusions drawn from the study suggest that high-intensity statin prescribing increased in patients with ASCVD after release of the ACC/AHA cholesterol guidelines. Our

data indicate that national evidence-based guidelines may influence clinical practice in very high risk patients[37].

2.7 According to study reported by Maddox TM, et al., 2014, the Objectives was to examine the impact of the 2013 ACC/AHA cholesterol guidelines on current U.S. cardiovascular practice. Among a cohort of 1,174,545 patients, 1,129,205 (96.1%) were statin-eligible (91.2% ASCVD, 6.6% diabetes, 0.3% off-treatment LDL-C ≥190 mg/dl, 1.9% estimated 10-year ASCVD risk ≥7.5%). There were 377,311 patients (32.4%) not receiving statin therapy and 259,143 (22.6%) receiving nonstatin therapies. During the study period, 20.8% of patients had 2 or more LDL-C assessments, and 7.0% had more than 4. The study Concluded that in U.S. cardiovascular practices, 32.4% of statin-eligible patients, as defined by the 2013 ACC/AHA cholesterol guidelines, were not currently receiving statins. In addition, 22.6% were receiving nonstatin lipid-lowering therapies and 20.8% had repeated LDL-C testing. Achieving concordance with the new cholesterol guidelines in patients treated in U.S. cardiovascular practices would result in significant increases in statin use, as well as significant reductions in nonstatin therapies and laboratory testing[38].

Chapter Three: Methodology

3. Methodology

3.1 Study Design

This is a prospective cross-sectional study of all patients who attended the clinic. Data were collected through a retrospective medical records review of all of the patients who were managed at the cardiology clinic between January 2024 to June 2024.

3.2 Study setting and duration

This study was carried out from January 2024 to June 2024 for a period of 6 months, the samples of this study were collected from discharged patients in a private cardiology clinic at Sana'a city

3.3 Ethical approval and consent to participate

Full ethical clearance was obtained from the qualified authorities who approved the study design.

3.4 Sample size and sampling method

All patients coming from different Yemeni cities with CVD were interviewed by trained 6th year clinical pharmacy students. From 120 patients who visited the clinic for cardiology services, during the study period using convenience sampling method, a total of 100 patients were selected.

3.5 Inclusion and exclusion criteria

All patients with CVD who attended to the private cardiology clinic were included. Patients who refused to participate were excluded from the study.

3.6 Study tools

Patients' questionnaire including patient's demographic data, diagnostic data and medications data was prepared; some questions were inserted as yes or no questions, others as multiple choices and the others opened questions.

3.7 Data collection

Thirteen clinical pharmacy students in the final year (6^{th} year of pharmacy) were chosen and trained by a supervisor. Then the investigators were divided into groups distributed over the clinic's working days to interview the patients who visited the private cardiology clinic for cardiology services. The data were collected by interviewing the right patient after having a prescription from the physician

3.8 Statistical analysis

Categorical variables were represented as frequency and percentage. The p-value was > 0.05, showing normal distribution of the data. All data were analyzed using SPSS Statistics version 21.0 for Windows® (IBM Corp., Armonk, NY, USA). Statistical differences among groups were evaluated using Pearson's chi-squared test. A p-value <0.05 was considered statistically significant.

Chapter Four: Results

4.Results

4.1 Sociodemographic characteristics of atherosclerotic cardiovascular disease (ASCVD) risk scores in Sana'a city, Yemen

Figure 1. shows a pie chart on the gender of the patients, there were 53 male patients and 47 female patients. The Male frequency with ASCVD risk was more compared to female.

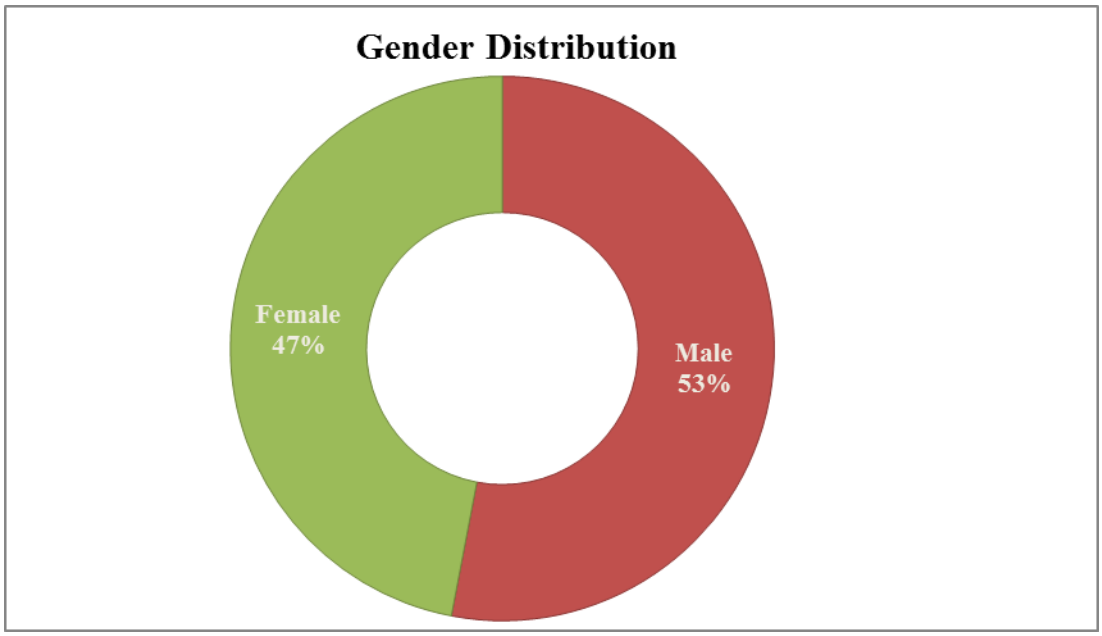

Figure 1. Gender distribution of respondents. of atherosclerotic cardiovascular disease (ASCVD) risk scores in Sana'a city, Yemen

The study showed that most patients 27 were at age 40-49 years, 26 at age 50-59 years and 26 at age 60-69 years. Most of patients 19 in very high-risk category were at age 60-69 years and none of the patients was at age 30-39 years.

Regarding education level, the highest number of the patients 45 were Illiterate followed by University or Higher 24. While the lowest number of patients 10 were Secondary.

Most patients 66 had history of Qat Chewing, whereas 34 had no Qat Chewing. Most patients 75 were not smoking, whereas 25 of the patients were smokers.

The result in Table 1. showed that, 47 of the patients had history of hospital admission.

Table 1. Sociodemographic characteristics of atherosclerotic cardiovascular disease (ASCVD) risk scores in Sana'a city, Yemen.

Characteristics	ASCVD Category				Total
	Very High	High	Moderate	Low	
Age					
30-39 years	0	0	0	3	3
40-49 years	5	7	7	8	27
50-59 years	13	9	1	3	26
60-69 years	19	6	0	1	26
70-79 years	14	1	0	0	15
80-89 years	3	0	0	0	3
Total	54	23	8	15	100
Education Level					
Illiterate	27	10	1	7	45
Primary	15	3	0	3	21
Secondary	2	4	3	1	10
University /Higher	10	6	4	4	24
Total	54	23	8	15	100
Qat Chewing					
Yes	37	17	6	6	66

No	17	6	2	9	34
Total	54	23	8	15	100
Smoking					
Yes	17	7	1	0	25
No	37	16	7	15	75
Total	54	23	8	15	100
History of Hospital Admission					
Yes	25	15	3	4	47
No	29	8	5	11	53
Total	54	23	8	15	100

4.2 Diagnosis classification

Table 2. shows that the patients diagnosis profile includes hypertension with and without other risk factors. The result showed that, most of the patients 26 were suffering of Hypertension-DM-Dyslipidemia, while 22 of the patients had Hypertension-IHD-Dyslipidemia. And less of patients 1 had HTN-DM-Dyslipidemia, HTN-HF and HTN-HF-Dyslipidemia.

Most of patients 18 with very high ASCVD had HTN-DM-Dyslipidemia, most of patients 8 with high ASCVD had HTN-IHD-DM-Dyslipidemia. Only patients who diagnosed with HTN only were those with low ASCVD.

Table 2. Diagnosis profile

Diagnosis	ASCVD Category				Total
	Very High	High	Moderate	Low	
HTN	0	0	0	12	12
HTN, IHD, Dyslipidemia	14	5	2	1	22
HTN, IHD, DM, Dyslipidemia	9	8	0	0	17
HTN, DM, Dyslipidemia	18	5	3	0	26
HTN, Stroke, Dyslipidemia	1	0	0	0	1
HTN, Dyslipidemia	8	5	3	0	16
HTN, HF	0	0	0	1	1
HTN, HF, DM, Dyslipidemia	4	0	0	0	4
HTN, HF, Dyslipidemia	1	0	0	0	1
Total	**55**	**23**	**8**	**14**	**100**

4.3 CKD Stages profile

Table 3. shows that the patients CKD Stages profile includes ASCVD Category **from Stage 1** to **Stage 4**. The result showed that, most of the patients 43 were in Stage1, while 27 of the patients were in Stage2, 26 patients were in Stage3, and only 4 patients 43 were in Stage 4.

Table 3. CKD Stage Profile

CKD Stage	ASCVD Category				Total
	Very High	High	Moderate	Low	
Stage 1	15	11	6	11	43
Stage 2	18	5	2	2	27
Stage 3	18	7	0	1	26
Stage 4	3	0	0	1	4
Total	54	23	8	15	100

4.4 Characteristics of the patients

Regarding patient risk group, we noted that most of patients 48,4% were with 10-year ASCVD risk ≥7.5%, while less of them 3.3% were with LDL-C ≥ 190mh/dL.

Dyslipidemia was a common comorbidity, affecting nearly half of the patients (49.7%). Although only a small percentage (22.2%) had atherosclerosis, diabetes (26.1%) and hypertension (6.8%) were also prevalent risk factors.

Most patients (59.6%) were taking Atorvastatin, while 40.4% were taking Rosuvastatin, suggesting a focus on cholesterol management. Notably, only 3.3% had elevated LDL levels, indicating that many patients either had lower levels or were effectively managing them with medication."

Table 4. Characteristics of the patients

Categories variables		Number of patients	%
Patient risk groups	Atherosclerotic cardiovascular disease	40	22.2
	Diabetes mellitus	47	26.1
	LDL-C ≥ 190mg/dL	6	3.3
	10-y ASCVD rusk ≥ 7.5%	87	48.4
Comorbidities	HTN	12	6.8
	Coronary artery disease	39	22.3
	Dyslipidemia	87	7.49
	Stroke	1	0.6
	Heart failure	6	3.4
	Chronic kidney disease	30	17.2
Type of statin therapy	Atorvastatin	34	59.6
	Rosuvastatin	23	40.4

4.5 Body Mass Index Distribution and Blood Pressure of patients with ASCVD

Table 5. shows that body mass index distribution varies by patients with ASCVD. Most of the patients 54 with ASCVD have a higher prevalence Normal weight and 12 have obesity. In contrast, 32 have overweight body mass and only 2 patients were underweight. Regarding to the Blood pressure of patients with ASCVD the result in table 3. Showed that most of the patients 75% had normal pressure and only 25 who had high pressure.

Table 5 Body Mass Index Distribution and Blood Pressure of patients with ASCVD

Characteristics	ASCVD Category				Total
	Very High	High	Moderate	Low	
Body Mass Index					
Underweight	2	0	0	0	2
Normal	28	16	3	7	54
Overweight	18	4	5	5	32
Obese	6	3	0	3	12
Total	54	23	8	15	100
Blood Pressure					
Normal	33	23	7	12	75
High	21	0	1	3	25
Total	**54**	**23**	**8**	**15**	**100**

4.6 Drug need based on guidelines * ASCVD Category

Table 3. illustrate the required medications according to each risk category based on guidelines. 44 patients do not require any medications with the majority (16) in the very high risk category.

No patients in the low risk category out of 14 is in need to drug. Only 3 patients out of 8 in the moderate category is in need to Statin or BB +CCB or BB.

A combination of drugs such as (Antiplatelet + Statin), (Antiplatelet + ACEI), (Antiplatelet + CCB), (BB + Statin), (BB+ NDHP), (Antiplatelet + BB + Statin) are prescribed to 18 patients in

the very high category with just one patient in the moderate category and 3 patients in the high category.

Statin and Antiplatelet are drugs that commonly used in the very high risk category, however one patient uses statin only in the moderate category and 7 patients in the high category use statin only or antiplatelet only or combination of both.

Table 6. Drug need based on guidelines for patients with ASCVD

Drug need based on guidelines	ASCVD Category				Total
	Very High	High	Moderate	Low	
Statin	6	3	1	0	10
ACEI/ARBs	2	4	0	0	6
CCB [NDHP]	2	0	0	0	2
BB	4	4	1	0	9
Antiplatelet	6	0	0	1	7
Antiplatelet + Statin	8	3	0	0	11
Antiplatelet + ACEI	3	0	0	0	3
Antiplatelet + CCB	1	0	0	0	1
BB + Statin	3	0	0	0	3
BB + CCB	1	0	1	0	2
Antiplatelet + BB + Statin	2	0	0	0	2
No need drug	16	9	5	14	44
Total	**54**	**23**	**8**	**15**	**100**

4.7 Current Drugs Used Based on guidelines * ASCVD Category

The result in Figure 2. showed that, most of the patients 44 with ASCVD had drug based on guidelines, while 56 of the patients didn't had drug based on guidelines.

Table 7. Drugs used based on guidelines for patients with ASCVD

Current Drugs Used Based on Guideline	ASCVD Category				Total
	Very High	High	Moderate	Low	
Yes	16	9	5	14	44
No	38	14	3	1	56
Total	54	23	8	15	100

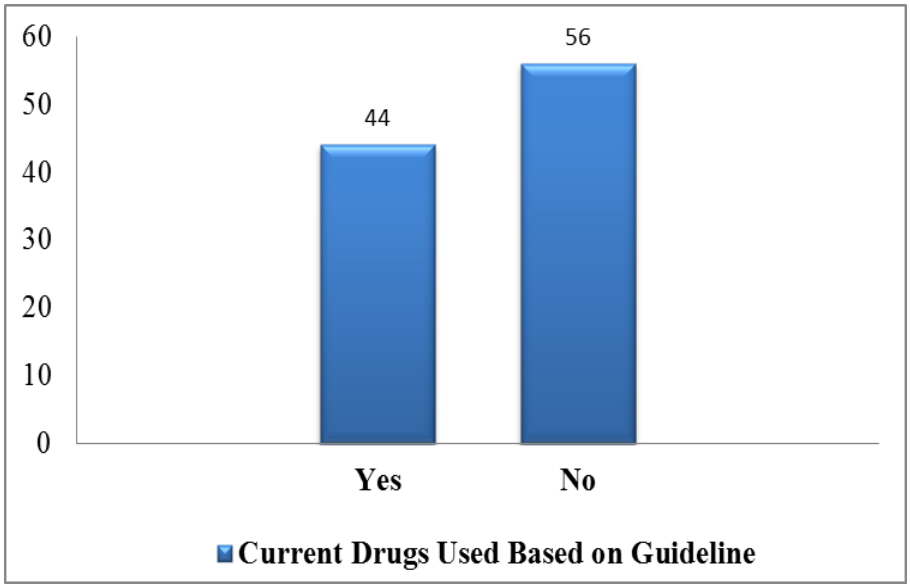

Figure 2. Drugs used based on guidelines for patients with ASCVD in Sana'a city, Yemen

4.8 The reason of statin use for patients with ASCVD

Statins are a well-studied drug class that have proven to be a cost-effective solution to reducing ASCVD risk for primary prevention of ASCVD events. Statin used for Primary prevention in 48 **patients with ASCVD** and in 38 **patients** for Secondary prevention, on the other hand, statin use for 14 patients with ASCVD for no reason.

Table 8. The reason of statin use for patients with ASCVD

Reason of statin used	ASCVD Category				Total
	Very High	High	Moderate	Low	
Primary prevention	31	12	5	0	48
Secondary prevention	23	11	2	2	38
No indicator, No reason	0	0	1	13	14
Total	54	23	8	15	100

4.9 Correlation Analysis Between ASCVD Risk Factors and Demographic and Clinical Variables

Pearson correlation coefficient was used to find out whether there is a statistically significant correlation or not between the demographic variables (AGE, Gender, Educational Level, Diagnosis, smoke, Chew Qat, History Hospital Admission, SrCr, CKD Stage, Hight, Wight, Body Mass Index), and ASCVD Risk Factors? What is the type of this relationship, is it a positive or negative correlation? This is as follows:

Table 9. Correlation Analysis Between ASCVD Risk Factors and Demographic and Clinical Variables

Demographic and Clinical Variables	Pearson Correlation	p.value	Verbal indication
AGE	.646**	.000	Function
Gender	-.388-**	.000	Function
Educational Level	-.206-*	.040	Function
Diagnosis	.296**	.003	Function
Smoke	-.279-**	.005	Function
Chew Qat	-.072-	.475	non function
History of Hospital Admission	-.088-	.385	non function
SrCr	.322**	.001	Function
CKD Stage	.321**	.001	Function
Hight	.029	.776	non function
Wight	-.071-	.483	non function
Body Mass Index	-.076-	.451	non function

The table shows the correlations between ASCVD Risk Factor and several other variables using Pearson's correlation coefficient. Here are the key results:

- **Age**: There is a strong positive correlation between age and ASCVD risk factor, with a correlation coefficient of **0.646**, significant at the ($p < 0.01$) level.

- **Gender**: There is a negative correlation with ASCVD risk factor, with a coefficient of **-0.388**, significant at the ($p < 0.01$) level, indicating that gender influences risk levels.
- **Education Level**: A weak negative correlation exists with ASCVD risk factor (**-0.206**), significant at ($p < 0.05$).
- **Diagnosis**: There is a positive correlation of **0.296**, significant at ($p < 0.01$).
- **Smoking**: A negative correlation of **-0.279** is seen with ASCVD risk factor, significant at ($p < 0.01$).
- **Qat Chewing**: There is no statistically significant correlation with ASCVD risk factor (correlation **-0.072**).
- **History of Hospital Admission**: The correlation is weak and not significant (**-0.088**).
- **Serum Creatinine (SrCr)**: A positive correlation of **0.322** is significant at ($p < 0.01$).
- **CKD Stage**: A similar positive correlation (**0.321**) is significant at ($p < 0.01$).
- **Height**: There is no significant correlation (**0.029**).
- **Weight**: No significant correlation is found, with a value of **-0.071**.
- **Body Mass Index (BMI)**: No significant correlation is found, with a value of **-0.076**.

In summary, the most significant factors affecting ASCVD risk in this study are age, gender, smoking, diagnosis, SrCr, and CKD stage.

4.10 Correlation Between ASCVD Risk Factors and Clinical & Pharmacological Variables

Pearson correlation coefficient was used to find out whether there is a statistically significant correlation or not between the Pharmacological Variables (Statin Used Based on AHA, The reason of statin use, LDL-C, Blood Pressure, Current Drugs Used Based on Guideline), and ASCVD Risk Factors? What is the type of this relationship, is it a positive or negative correlation? This is as follows:

Table 10. Correlation Between ASCVD Risk Factors and Clinical & Pharmacological Variables

Clinical & Pharmacological Variables	Pearson Correlation	p.value	Verbal indication
Statin Used Based on AHA	-.178-	.077	non function
The reason of statin use	-.469-**	.000	Function
LDL-C	.226*	.024	Function
Blood Pressure	.282**	.004	Function
Current Drugs Used Based on Guideline	.388**	.000	Function
Drug need based guideline	-.266-**	.007	Function

The table shows the correlations between ASCVD Risk Factor and several other variables using Pearson's correlation coefficient. Here are the key results:

- **Statin Used Based on AHA**: The correlation coefficient is -0.178 with a p-value of 0.077. This indicates a weak and statistically insignificant negative correlation between ASCVD risk factors and statin use based on AHA guidelines.
- **The reason for statin use**: The correlation coefficient is -0.469** with a p-value of 0.000, indicating a significant negative correlation. This suggests that the reason for statin use has a strong inverse relationship with ASCVD risk factors.

- **LDL-C**: The correlation coefficient is 0.226* with a p-value of 0.024, showing a significant positive correlation. Higher LDL-C levels are associated with higher ASCVD risk factors.
- **Blood Pressure**: The correlation coefficient is 0.282** with a p-value of 0.004, indicating a statistically significant positive correlation. Higher blood pressure is associated with increased ASCVD risk.
- **Current Drugs Used Based on Guidelines**: The correlation coefficient is 0.388** with a p-value of 0.000, showing a strong positive correlation, meaning that adherence to current drug guidelines is associated with ASCVD risk management.
- **Drug need based guideline**: The correlation coefficient is -0.266** with a p-value of 0.007, showing a significant negative correlation, suggesting that fewer drugs needed based on guidelines may reduce ASCVD risk factors.

Chapter Five: Discussion

5. Discussion

5.1 Main finding and significance

In this observational study, we evaluated adherence to the 2018 ACC/AHA guideline recommendations for statin therapy in the treatment of blood cholesterol in high-risk patients. We found that more than half of the patients with ASCVD didn't receive statin therapy according to the guideline recommendations. This results contradict the results of Zupec and colleagues who reported that only one third of statin-eligible patients, as defined by the 2013 ACC/AHA cholesterol guidelines, were not currently receiving statins[38].

We found that one-half of the patients were with 10-year ASCVD risk ≥7.5%, one quarter of the patients had DM and least of them 3.3% were with LDL-C ≥ 190mm/dL. The study in Saudi Arabia showed that bout half had ASCVD and almost one-third had diabetes[36].

It was found that most of the patients 75 had normal pressure and only 25 who had high pressure. This findings were not supporting the idea that most of the patient who took statin therapy have high blood pressure.

We have identified the required medications according to each risk category based on guidelines. 44 patients do not require any medications with the majority (16) in the very high risk category, this indicate that many patients don't require any medications. Statin only were required for about 10 patients , Antiplatelet+Statin for 11 patients.

It was found that most patients 66 had history of Qat Chewing, whereas only 25 of the patients were smokers. A study in Austria reported that 60% of the patients with ASCVD risk were smokers and 40% of the patients[43].

Statins are a well-studied drug class that have proven to be a cost-effective solution to reducing ASCVD risk for primary prevention of ASCVD events. We evaluated statin use based on primary and secondary prevention and the results showed that statin used for primary prevention

in 48 patients with ASCVD and in 38 patients for secondary prevention, on the other hand, statin use for 14 patients with ASCVD for no reason. A study in Austria reported that 142 of the patients used statin for primary prevention and 151 for secondary prevention[43].

5.2 Limitation of the study

The study has some limitations. Including: Some patients were not cooperative with us by giving us some of the information in the questionnaire, so they were excluded. We found some difficulties in knowing the patient's heights to measure BMI. Also, One of the difficulties we faced was that we could not collect many samples due to the difficulty of communicating with the patients, so the samples were few.

Chapter Six: Conclusion and Recommendation

6. Conclusion and Recommendation

6.1 Conclusion

This study shows that 44 patients with ASCVD had drug based on guidelines, while 56 of the patients didn't had drug based on guideline. Statin used for Primary prevention in 48 patients with ASCVD and in 38 patients for Secondary prevention, on the other hand, statin use for 14 patients with ASCVD for no reason., The results reveal significant correlations between ASCVD risk factors and several variables. The most influential factors on risk are age, gender, smoking, diagnosis, serum creatinine (SrCr), and CKD stage. Age, gender, diagnosis, SrCr, and CKD stage showed positive correlations with ASCVD risk, while smoking had a negative correlation. No significant correlations were found with qat chewing, weight, or body mass index (BMI).

6.2 Recommendation

- Health care professionals should rely on Guidelines when prescribing medications to patients. such as AHA/ACC guideline for treatment of high cholesterol level
- The ministry of Health should provide and develop programs for Health care professionals about any recent published guidelines.
- Clinical pharmacists should be present in all branches of the hospital to correct any errors.
- Patients with DM, at risk of ASCVD, older than 40 and with dyslipidemia should have regular check-ups such as: Lipid profile and blood pressure.
- Closer monitoring for adverse effect of statins such as muscle-related toxicity
- Adhering to best practices in clinical care and clinical pharmacology, such as avoiding complicated treatment regimens, utilizing a single pharmacy for all prescriptions, and recognizing patient risk factors.
- Further researches must be done on all departments of Yemen's hospitals

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Appendices

Appendix A : Data collection sheet

Questionnaire

Evaluating Statins Use for Discharged Patients according to ACC/AHA Indications

No. of case ( ) Place the collection of sample……

Name of pt. /……

Age: ……. Sex: M / F Hight/…….. wight/…….

Educational level:

( ) Illiterate

( ) Primary

( ) Secondary

( ) University / Higher

Diagnosis:

……

……

Diabetic: ( ) Type I ( ) Type II

Smoking: ( ) YES ( ) NO

Qat : ( ) YES ( ) NO

History of Hospital admission :

( ) YES ( ) NO

Scr: ……..

ASCVD risk factor : ……

Statin use based on AHA :

……

……

LIPID PROFILE:

Date	HDL	LDL	T. Cholesterol

BP:

Date	

Current Drugs:

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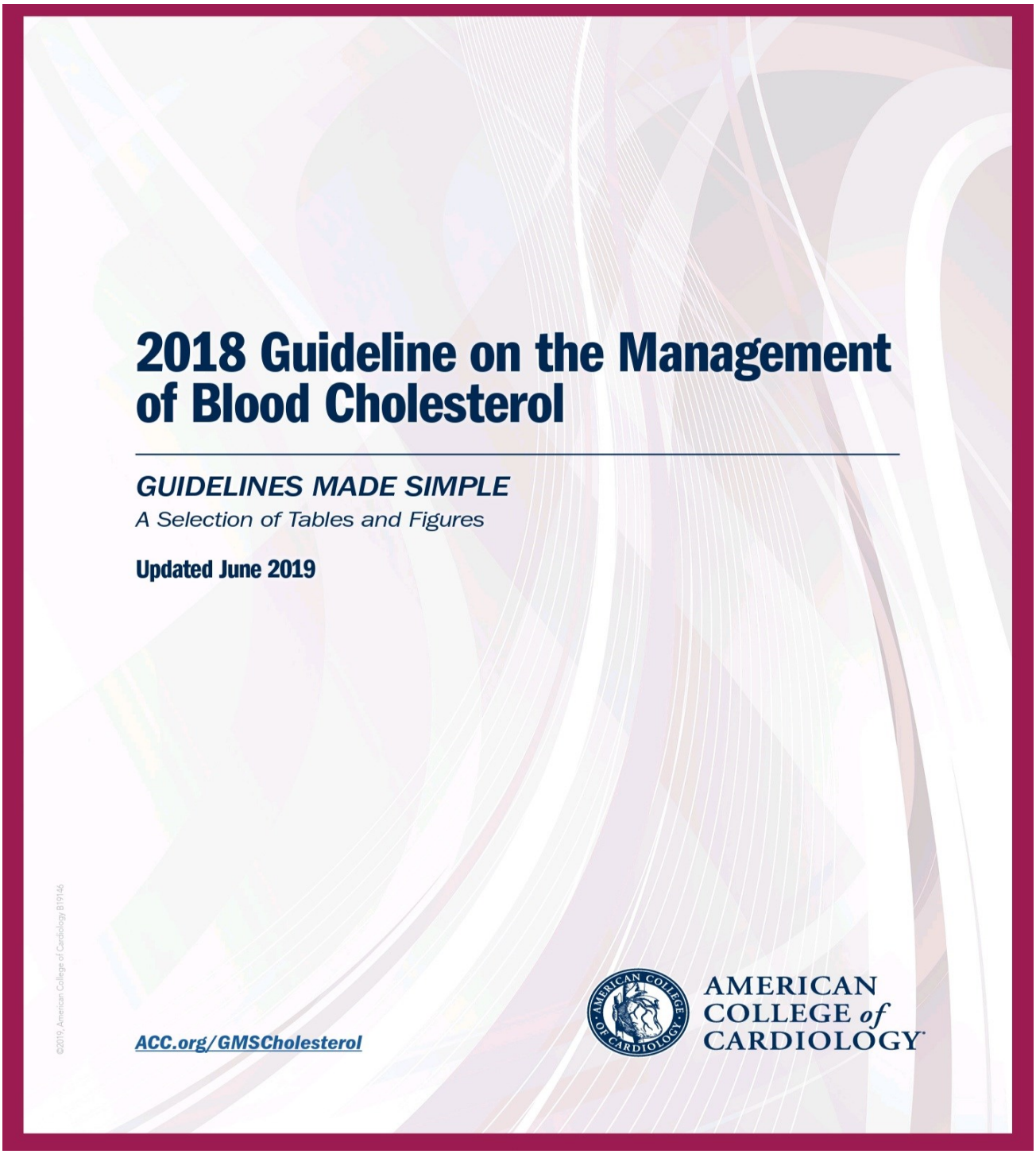
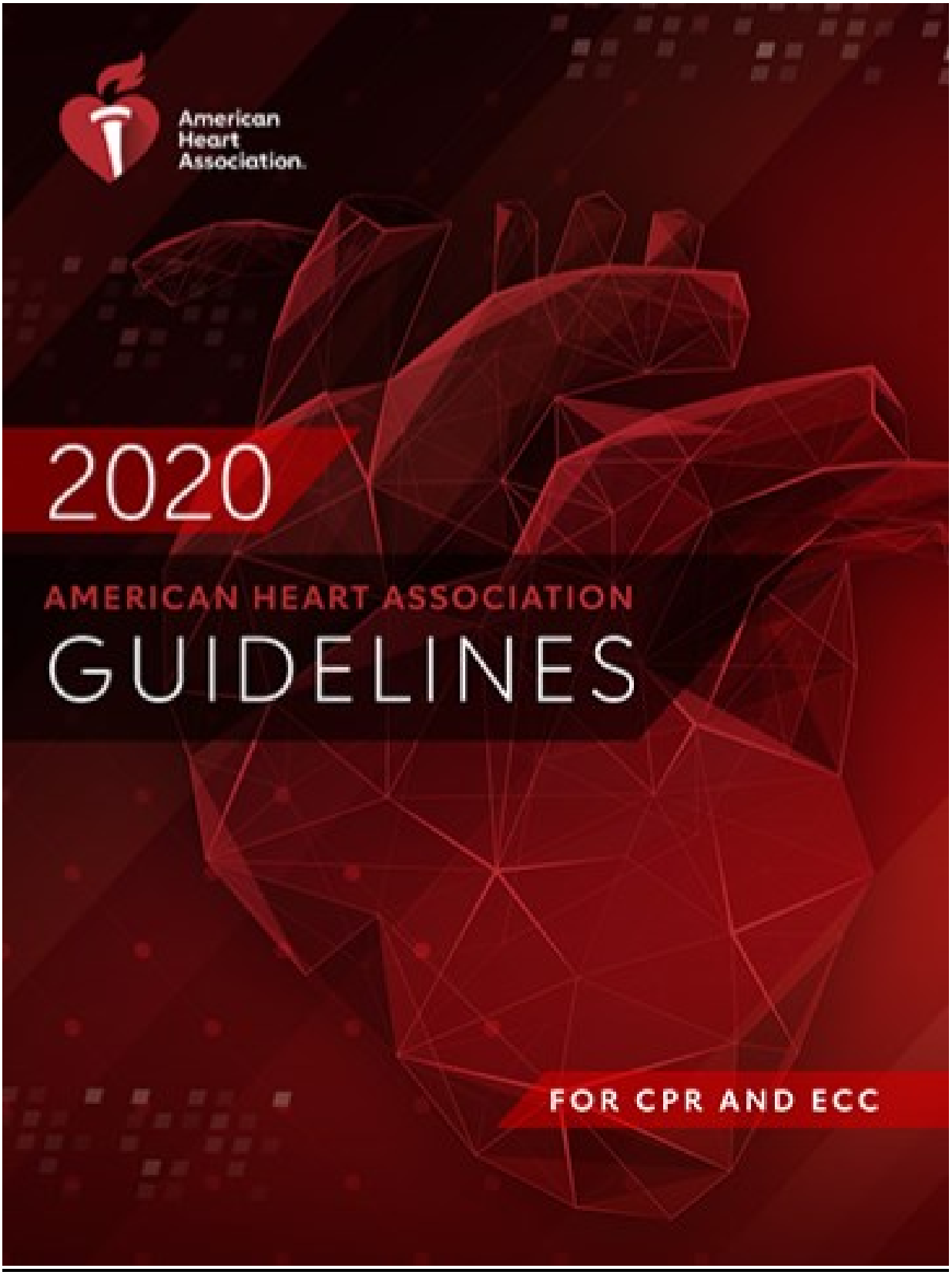
Appendix B : Guideline on the Management of Blood Cholesterol




American
Heart
Association.
2020
AMERICAN HEART ASSOCIATION
GUIDELINES
FOR CPR AND ECC

Arabic Summary

المقدمة

وفقًا لإرشادات الجمعية الأمريكية للقلب والكلية الأمريكية لأمراض القلب بشأن استخدام الستاتين لعلاج الدهون في الدم، هناك أربع مجموعات من المرضى يحتاجون إلى الستاتين كوقاية أولية أو ثانوية.

هدف البحث

تقييم استخدام الستاتين للمرضى الخارجيين وفقًا لمؤشرات الكلية الأمريكية لأمراض القلب والجمعية الأمريكية لأمراض القلب

أسلوب الدراسة

هذه دراسة مقطعية مستقبلية أجريت في عيادة خاصة لأمراض القلب في مدينة صنعاء من يناير 2024 إلى يونيو 2024. تم جمع البيانات من السجلات الطبية الإلكترونية باستخدام استبيان منظم (يغطي البيانات الديموغرافية وبيانات التشخيص وبيانات الأدوية). تم تحليل جميع البيانات باستخدام برنامج SPSS Statistics الإصدار 21.0 لنظام ويندوز®.

النتائج

كانت عدد عينات الدراسة 100. كان معدل الذكور المعرضين لخطر الإصابة بـ ASCVD أعلى بنسبة 53% مقارنة بالإناث بنسبة 47. وكان معظم المرضى75 غير مدخنين، في حين كان 25 من المرضى مدخنين. وأظهرت النتائج أن معظم المرضى 26 كانوا يعانون من ارتفاع ضغط الدم والسكري وخلل شحميات الدم. لا يوجد مرضى في فئة المخاطر المنخفضة من أصل يحتاجون إلى دواء، فقط 3 مرضى من أصل 8 في الفئة المتوسطة يحتاجون إلى ستاتين أو قافلات البيتا+قافلات قنوات الكالسيوم أو قافلات البيتا. . تلقى معظم المرضى 44 المصابين بـ ASCVD الدواء بناءً على الإرشادات، في حين لم يتلق 56 من المرضى الدواء بناءً على الإرشادات، كما أظهرت النتائج وجود ارتباطات مهمة بين عوامل خطر تصلب الشرايين (ASCVD)وعدة متغيرات. العوامل الأكثر تأثيرًا على الخطر هي العمر، الجنس، التدخين، التشخيص، مستوى الكرياتينين (SrCr)، ومرحلة مرض الكلى المزمن .(CKD Stage) العمر والجنس والتشخيص ومستوى الكرياتينين ومرحلة مرض الكلى أظهرت ارتباطًا إيجابيًا مع عامل الخطرASCVD ، بينما التدخين أظهر ارتباطًا سلبيًا. من ناحية أخرى، لم يكن هناك ارتباط كبير مع مضغ القات أو الوزن أو مؤشر كتلة الجسم.(BMI) .

الاستنتاج

تظهر هذه الدراسة ان 56 مريضاً مصابين بمرض القلب والأوعية الدموية التصلبي تناولوا الدواء بناءً على الإرشادات، في حين أن 56 من المرضى لم يتناولوا الدواء بناءً على الإرشادات. تم استخدام الستاتين للوقاية الأولية لدى 48 مريضًا مصابًا بمرض القلب والأوعية الدموية التصلبي وفي 38 مريضًا للوقاية الثانوية، من ناحية أخرى، تم استخدام الستاتين لدى 14 مريضًا مصابًا بمرض القلب والأوعية الدموية التصلبي بدون سبب.

الجمهورية اليمنية

وزارة التربية والتعليم العالي والبحث العلمي

الجامعة الإماراتية الدولية

كلية الطب و العلوم الصحية

قسم صيدلة سريرية (فارما دي)

تقييم استخدام أدوية خافضة الدهون -ستاتين- للمرضى الخارجيين وفقا لمؤشرات الكلية الأمريكية لأمراض القلب / وجمعية القلب الأمريكية (ACC/AHA)

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