

Characteristics of Patients with Familial Hypercholesterolemia and Acute Coronary Syndrome Prescribed PCSK9 Inhibitors

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ABSTRACT

Background: Patients with Familial Hypercholesterolemia (FH) or statin intolerance are significantly increasing. Therefore, a novel class of lipid-lowering drugs called Proprotein Convertase Subtilisin Kexin type 9 (PCSK9) inhibitors are prescribed for FH patients and statin intolerant. PCSK9 inhibitors are human monoclonal antibodies that slow down the LDL Receptor's (LDLR) degradation by binding to PCSK9 adjacent to its binding site with LDL receptors, increasing LDL-C uptake and decreasing LDL-C blood level. **Objectives:** To evaluate the proper prescribing of PCSK9 inhibitors by measuring adherence to ACC/AHA and ESC/EAS guidelines at two tertiary care hospitals; King Fahad Medical City (KFMC), and Security Forces Hospital (SFH) - Riyadh - Saudi Arabia. **Materials and Methods:** An observational retrospective cohort study was carried out. Researchers included all patients started on PCSK9 inhibitors, specifically evolocumab for the last three years (from 2020 until the end of 2022) at SFH and KFMC. A data collection sheet (Excel sheet) with 51 questions (variables) is considered the primary research tool; the data were collected from the patient's medical files as another tool. Statistical analysis of categorical variables and continuous variables have been done using SPSS version 20 program. p -values less than 0.05 are deemed statistically significant. **Results:** Of the 201 patients, 142 (70.6%) were eligible for PCSK9 inhibitors treatment in accordance with ACC/AHA and ESC/EAS guidelines criteria. (66.7%) of patients were male, the mean age was (53.67 ± 12.25) and (42.3%) were obese. Clinically, most of the patients had a history of a previous MI (70.1%), and (32.3%) had two major ASCVD. High-risk conditions were (69.2%) with hypertension and (63.2%) with diabetes. LDL-C level after 4-6 weeks of PCSK9 inhibitors initiation, was observed among the 161 (80.1%) cases of the study sample, while the attrition was in 40 (19.9%) cases. Statistical analysis measured a significant 37.1% reduction rate (p -value<0.001) from baseline to 6 weeks' follow-up LDL-C laboratory confirmed post-treatment effect of PCSK9 inhibitors. The physicians' adherence to the ESC/EAS and ACC/AHA recommendations criteria in prescribing PCSK9 inhibitors was (70.6%). **Conclusion:** Most physicians adhered to the ESC/EAS and ACC/AHA recommendations criteria in prescribing PCSK9 inhibitors to FH patients and ACS patients. The results show that up to (70.6%) of physicians at King Fahad Medical City (KFMC) and Security Forces Hospital (SFH) adhere to ACC/AHA and ESC/EAS guidelines for prescribing PCSK9 inhibitors to FH patients and ACS patients this adherence was manifested by the number of patients (38%) who attained the LDL-C level ≤ 1.8 mmol/L (≤ 70 mg/dL).

Keywords: PCSK9 Inhibitors, Familial Hypercholesterolemia, Acute Coronary Syndrome, ACC/AHA and ESC/EAS Guidelines Eligibility Criteria, LDL-C.

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INTRODUCTION

Acute Coronary Syndrome (ACS) is a syndrome caused by fatty plaque in blood vessels, while Familial Hypercholesterolemia (FH) is a hereditary lipid disorder that is autosomal dominant genetic mutations in one or more of three genes cause this condition: These genes are for Proprotein Convertase Subtilisin/Kexin



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Type 9 (PCSK9), Apolipoprotein B (APOB), and Low-Density Lipoprotein (LDL).^{1,2} These disorders will increase the LDL level in most cases, increasing lipid accumulation and elevate the risk of acute coronary syndrome and early Atherosclerotic Cardiovascular Disease (ASCVD).^{3,4} LDL levels in Familial Hypercholesterolemia (FH) and Acute Coronary Syndrome (ACS) for untreated LDL can range from approximately 200 to 400 mg/dL (5-10 mmol/L), with the majority of instances being >160 mg/dL (4.14 mmol/L), regardless of treatment with available Lipid-Lowering Therapies (LLTs).^{5,6} Lipid-lowering agents can vary, including statins and ezetimibe, which are considered the standard primary of care for LDL elevation. Other LLTs can be used as adjunctive therapy, like Fibrates and bile acid sequestrants.⁷ On the other hand, achieving the targeting LDL level in some patients with hypercholesterolemia had been a challenge with standard care.⁸

Focusing on familiar hypercholesterolemia, as well as a coronary syndrome really highlights the new very high risk ASCVD definition, which includes one major event and two or more multiple high-risk conditions or two major events. The new targeted LDL goal is less than 70 mg/dL. The currently available data is illustrating that approximately 85% of patients who are already on a maximum tolerated high intensity statin plus or minus is that they will need a PCSK9 inhibitor to achieve LDL goals of under 70 mg/dL. By adding PCSK9 inhibitor providers will be able to almost double the fibrous, cap thickness of vulnerable plaque, as well as reduce the degree of lipid arc by over 50% thereby improving plaque stabilization and minimizing plaque rupture and subsequently future cardiac events. There is a huge need and intensification of the therapies, especially in the new very high risk ASVD definition. Recent studies have shown a significant effect of early adding PCSK9 inhibitors to statin therapy on lowering LDL levels in Familial Hypercholesterolemia and Acute Coronary Syndrome (ASC) patients hence, a reduction in ASCVD risk and mortality.⁹⁻¹¹

Saudi Arabia is one of countries with the highest cardiovascular death rates (46%) among Gulf Council Countries (GCC).^{12,13} However, despite the high rate of deaths, there is a lack of local standardized lipid management guidelines that apply to the population's specific characteristics, which results in poor diagnosis and treatment of FH.¹⁴ Usually, healthcare practitioners in Saudi Arabia mainly refer to the American College of Cardiology (ACC) and American Heart Association (AHA) and European Society of Cardiology (ESC), and European Atherosclerosis Society (EAS) guidelines.^{15,16}

Our primary objective in this study was to assess the adherence of prescribing physicians to ACC/AHA and ESC/EAS guidelines while prescribing PCSK9 inhibitors to patients who were diagnosed with FH by Dutch Lipid Clinic Network score (where is definite FH>8, Probable FH 6-8, Possible FH 3-5, Unlikely FH<3), at two tertiary care hospitals; in KFMC and SFH - Riyadh

- Saudi Arabia. The secondary objective was to determine the percent of reduction in LDL after starting the PCSK9 inhibitor as an indicator to the guideline adherence.

MATERIALS AND METHODS

At Saudi Arabia's KFMC and SFH in Riyadh, an observational retrospective cohort study was carried out. We included all Saudi patients (age 20 years and older) who started on PCSK9 inhibitors specifically, evolocumab for the last three years (since introduction of evolocumab to the hospitals from 2020 until the end of 2022) at KFMC and SFH in Riyadh - Saudi Arabia. All patients have been started on evolocumab as documented in the hospital's electronic system during those three years. We found that during the defined study period, we had 201 patients (Figure 1) started on evolocumab, 26 of them at Security Forces Hospital.

A data collection sheet (Excel sheet) with 51 questions (variables) is considered the primary research tool; the data were collected from the patient's medical files by Princess Nourah Bint Abdulrahman University pharmacy interns at KFMC and SFH.

The External Research Review Committee (ERRC) at KFMC and SFH achieved research approval for the study protocol under the following numbers (H-01-R-012) and (H-01-R-069), and a pilot sample validated and tested the research tool.

The inclusion criteria were (Figure 2): Clinical diagnosis of FH (by Dutch Lipid Clinic Network score (where is definite FH>8, Probable FH 6-8, Possible FH 3-5, Unlikely FH<3), or ACS with index diagnosis of ST-segment elevation myocardial infarction (STEMI), non ST-segment elevation myocardial infarction (NSTEMI) or unstable angina. Individuals with FH who, either with or without additional LLTs, have not reached the LDL-C objective in FH patients without a clinical diagnosis of ASCVD and in ASC patients for at least four weeks prior to the screening visit (LDL cholesterol 1.8 mmol/L or greater (70 mg/dL)) with a daily maxim tolerated statin and ezetimibe treatment.

The patients who met the following exclusion criteria were not eligible: those who had different LDL thresholds based on their cardiovascular risk status; had LDL level below 70 mg/dL (<1.81 mmol/L) and had a history of documented CVD, LDL <100 mg/dL (<2.59 mmol/L) in patients without a history of documented CVD; those who have an LDL level of <160 mg/dL (<4.14 mmol/L) at the screening visit; those who use fibrates other than fenofibrate within six weeks of the screening visit; those whose fasting serum triglycerides were above 400 mg/dL (>4.52 mmol/L) at the screening visit,⁸ and those with severe physical disability or dementia, and estimated life expectancy of patients with FH or ACS < 1 year for non-cardiac reasons.^{17,18}

Statistical Analysis

SPSS version 28.0 (IBM, Armonk, NY, USA) software was used for statistical data analysis. Categorical variables

include Acute Coronary Syndrome (ACS) patients, Familial Hypercholesterolemia (FH) patients, and Familial Hypercholesterolemia (FH) patients with Atherosclerotic Cardiovascular Disease (ASCVD). Continuous variables will be reported as mean and Standard Deviation (SD). Demographic and clinical characteristics were described using frequencies and proportions. Symmetry of the data was inspected by histogram plots. The data was summarized using median and Interquartile Range (IQR) as well as Mean $\pm$ SD. Both the baseline Low-Density Lipoprotein (LDL) cholesterol and the repeated measure LDL-C matched sample, had non-symmetric distributions as observed by Shapiro-Wilk test. Therefore, the Related-Samples Wilcoxon Signed Rank Test was used for measuring the difference at the 95% confidence interval. *p*-values less than 0.05 are deemed statistically significant.

RESULTS

Patients

According to our study, there have been a total of 201 patients analyzed with an LDL-C baseline of (4.05 $\pm$ 2.27) even after the maximally tolerated statin and ezetimibe with an adherence to the guidelines 70% of total patients. Therefore, most patients were eligible for the treatment with evolocumab, which is about (70.6%) and (29.4%) of the patients were not eligible to be treated with evolocumab according to the criteria. The baseline characteristics of the patients are demonstrated in (Figure 3). (66.7%) of patients were male, the mean age was (53.67 $\pm$ 12.25) and (42.3%) were obese. Clinically, the majority of patients (Table 1) reported a prior history of Myocardial Infarction (MI) 70.1%, and 32.3% had two major ASCVD. High-risk conditions were (69.2%) diagnosed with hypertension and (63.2%) with diabetes (Figure 4).

Statins and other lipid-lowering agents

Most patients (90%) received high-intensity statin, Rosuvastatin was the most frequently used agent with 55%, and 40 mg was the most reported dose of statin (45%). Alongside statins, 74.1% of patients were on 10 mg ezetimibe. Other LLTs were prescribed for only 10% of patients, mainly Fenofibrate 200 mg.

PCSK9i Eligibility and adherence

According to ACC/AHA and ESC/EAS recommendations, 70.6% of all patients (*n*=142) were eligible for PCSK9i treatment as they had an LDL-C level of 1.8 mmol/l or above when taking ezetimibe plus a high-intensity statin. In contrast, (29.4%) of all patients (*n*=59) did not meet the eligibility criteria, which is suggestive of low percentage of the physicians were not adhering to guidelines while prescribing the PCSK9 inhibitors, and thus their prescriptions got rejected by health care providers.

The most important note observed that is individuals with ASCVD who were deemed to be at extremely high risk, which includes those who have a history of several significant ASCVD events or just one significant ASCVD event together with numerous high-risk factors,^{19,20} these individuals make up 73% of our population.

LDL-C analysis

Researchers collected baseline LDL-C levels from all participants, then a comparison to post-treatment LDL-C levels was made. The baseline LDL-C level ranged between (0.20-15.14) with a mean of 4.00 $\pm$ 2.14 (mmol/L) for all the intention to treat 201 study sample. On the other hand, the LDL-C level after 4-6 weeks of PCSK9 inhibitors initiation, was observed among the 161 (80.1%) cases of the study sample, while the attrition was in 40 (19.9%) cases. Post treatment minimum LDL-C (mmol/L) was 0.12 and the maximum was 19.27 with a mean of 2.95 $\pm$ 2.81 mmol/L. Both the pre-treatment and post-treatment LDL-C

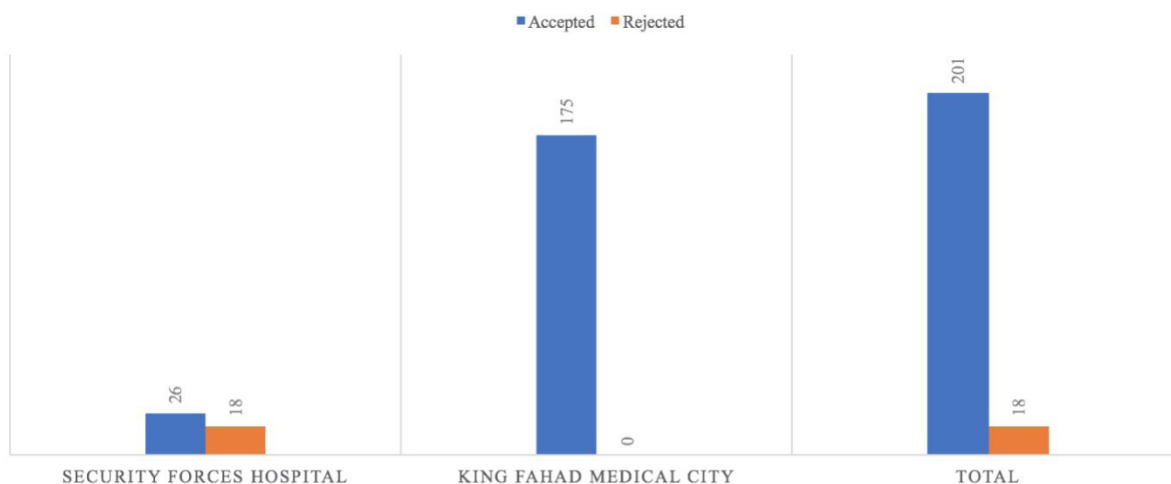


Figure 1: Number of accepted and rejected participants at KFMC and SFH.

levels had non-normal distributions. Therefore, the LDL-C data was dichotomized with respect to the normal threshold value of ≤ 1.8 . The pre-treatment LDL-C of >1.8 among the matched pair study sample had thereby exceeded in 151 (93.8%) cases, of which 56 (37.1%) attained the threshold level of ≤ 1.8 in the post-test period. Related-Samples Wilcoxon Signed Rank Test measured a significant 37.1% reduction rate (p -value <0.001) from baseline to 6 weeks' follow-up LDL-C laboratory confirmed post-treatment effect of PCSK9 inhibitors (Tables 2 and 3).

DISCUSSION

This study evaluates the physician's adherence to the ESC/EAS and ACC/AHA guidelines while prescribing PCSK9 Inhibitors for patients with Familial Hypercholesterolemia and Acute Coronary Syndrome. However, statins and ezetimibe have traditionally been the drugs of choice for Familial Hypercholesterolemia as mentioned by Versmissen *et al.*, 2008;²² some patients still find statins and ezetimibe intolerable, unaffordable, or insufficient to drop LDL-C levels to therapeutic levels. Moreover, PCSK9I might have some limitations as well, thus new researches on gene therapy

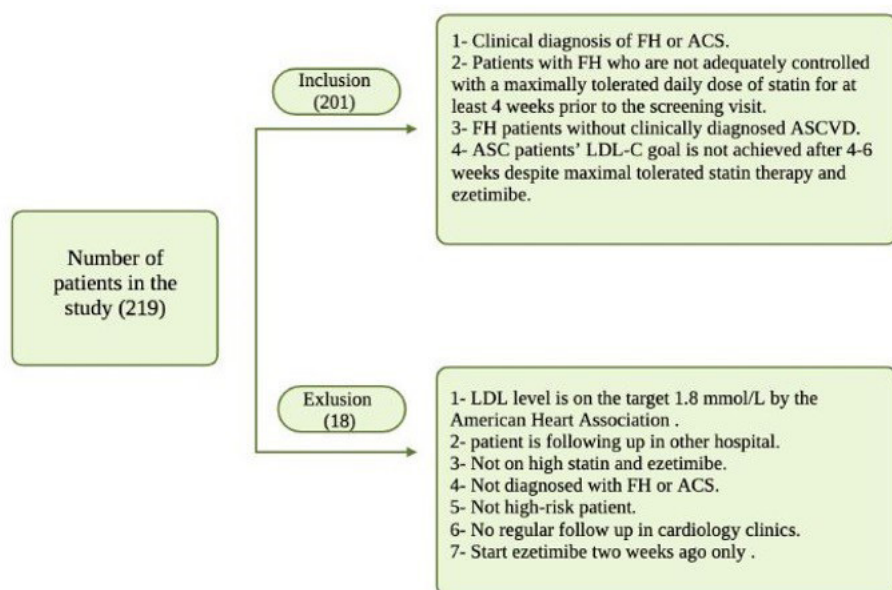


Figure 2: Inclusion and exclusion criteria of participants.

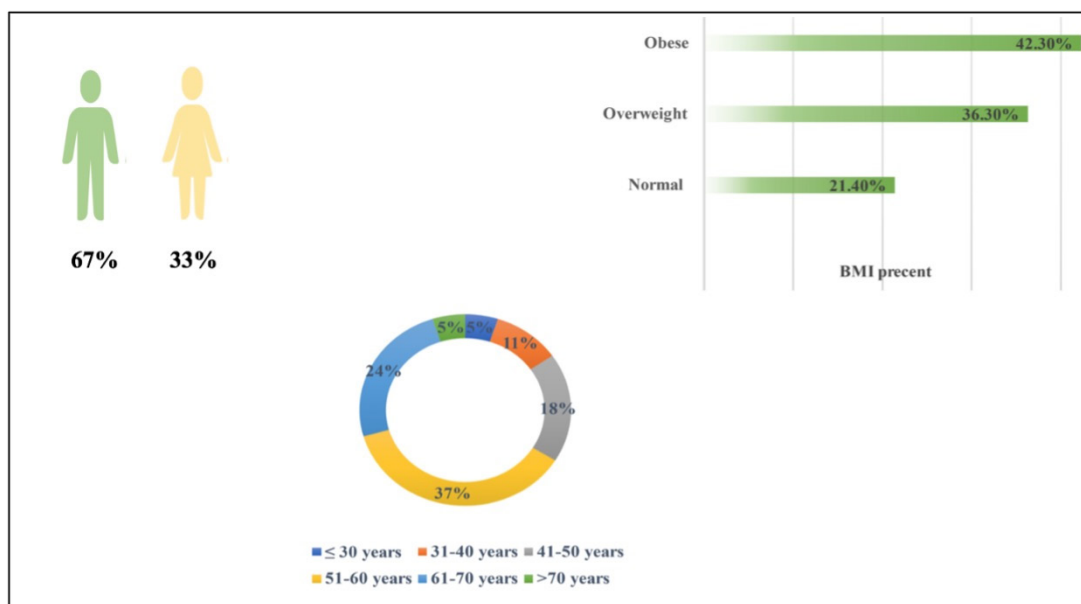


Figure 3: Demographics of the participants.

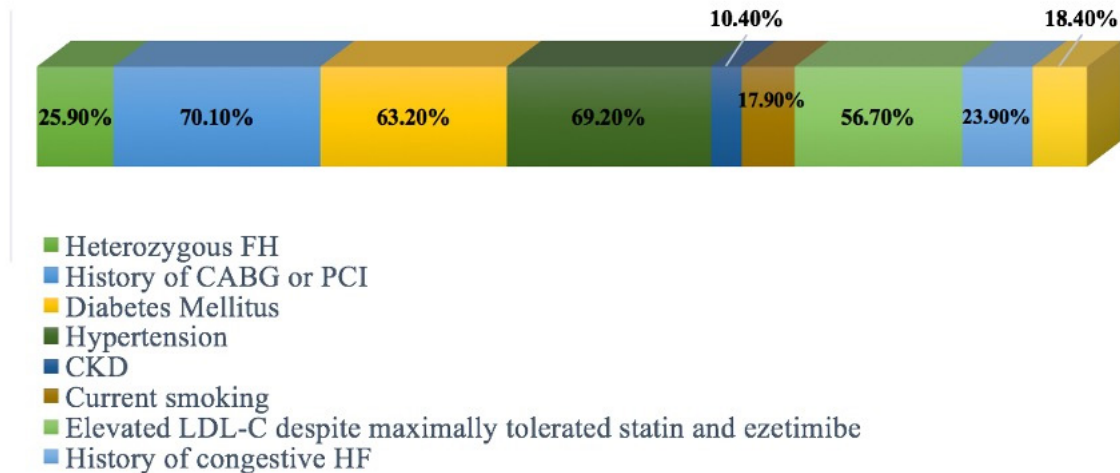


Figure 4: High risk conditions of patients.

Table 1: Patients clinical characteristics.

Characteristics	Percentages
Recent Acute Coronary Syndrome	8%
Segment Elevation Myocardial Infarction (STEMI)	22.9%
Non-Segment Elevation Myocardial Infarction (NSTEMI)	12.9%
Unstable angina	7%
History of Myocardial Infarction (other than recent ACS)	70.1%
History of Ischemic Stroke	8%
Symptomatic peripheral arterial disease (history of claudication with ABI < 0.85, or previous revascularization or amputation)	0.5%
Number of Major ASCVD	Percentages
0	25.4%
1	31.3%
2	32.3%
3	10%
4	1%

is targeting those population as discussed in Jiang *et al.*, 2018.²¹⁻²³ Beyond the effects of statins and ezetimibe, PCSK9 inhibitors can offer the tendency to optimize LDL-C in most of those with Familial Hypercholesterolemia, Acute Coronary Syndrome, and insufficient statin response as mentioned clearly by Sabatine *et al.*, 2017. Who founded that inhibition of PCSK9 with evolocumab on a background of statin therapy lowered LDL cholesterol levels to a median of 30 mg per deciliter (0.78 mmol/L) and reduced the risk of cardiovascular events.²⁴ With Evolocumab's minimal interval dosing (either 140 mg every 2 weeks OR 420

mg once monthly) and high success rate in comparison to other medications, the issue of healthcare systems either supporting or impeding the best delivery of hyperlipidemia therapy should be improved with adhering to the guidelines same as the adherence to eligibility criteria that was set in the study conducted by Charles, 2016, where they set the eligibility of patients to PCSK9 I, is to meet FDA-insurance criteria for PCSK9 inhibitor therapy as an adjunct to diet-maximally tolerated cholesterol lowering therapy in HeFH or CVD.^{25,26}

ESC/EAS and ACC/AHA guidelines included the use of Evolocumab, and thus the criteria was set for the physicians and clinical pharmacists to follow and to check each patient's eligibility. The percentage of each criterion in this study was as follow: 7.5% for patients aged 40-75 years who had an initial level of LDL-C of at least 5.7 mmol/L, and for individuals who, despite being on maximum tolerated statin and ezetimibe dose, they attained an on-treatment LDL-C level of 3.4 mmol/L or above. Followed by 11.9% in heterozygous FH patients 30-75 years LDL-C $\geq$ 2.6 mmol/L taking statin and ezetimibe and a reduction of LDL-C levels less than 50% from baseline. Patients with very high-risk heterozygous FH who do not meet the treatment target when they were on the highest tolerated dose of ezetimibe and statins (15.9%). Patients with ACS who did not reach the LDL-C target after 4-6 weeks when and were on the highest tolerable dose of statin and ezetimibe were 24.9%. 64.2% for the patients who used the maximal statin dose plus ezetimibe dose, and were with clinical ASCVD and LDL-C of 1.8 mmol/L or higher or non-HDL-C of 2.6 mmol/L or higher are at extremely high risk. Individuals with numerous major ASCVD events in the past or one major ASCVD event plus multiple high-risk conditions make up the group of patients with clinical ASCVD who are considered to be very high risk (73.6%), as mentioned by the study of Gencer *et al.*, 2017.²⁶

Table 2: Related-Samples Wilcoxon Signed Rank Test for 161 matched sample Low-Density Lipoprotein (LDL) cholesterol.

LDL-C				
Baseline	Mean±SD	Median (IQR)	Correlation	p-value
After 4-6 weeks of PCSK9 inhibitors	4.05±2.27	3.54 (2.22)	0.726	< 0.001

Table 3: Intention to treat (n=201) with respect to Completed treatment (n=161).

LDL-C after 4-6 weeks of PCSK9 inhibitors			
LDL-C after 4-6 weeks of PCSK9 inhibitors ≤ 1.8	Baseline_Low-density lipoprotein cholesterol		
	≤ 1.8	> 1.8	Total
> 1.8	5 (50.0%)	56 (37.1%)	61 (37.9%)
Total	5 (50.0%)	95 (62.9%)	100 (62.1%)
The reduction rate among 151 (93.8%) cases of the total matched sample with > 1.8 LDL-C at baseline, had reduced to ≤ 1.8 as observed in 56 (37.1%) cases after 4-6 weeks of PCSK9 inhibitors in the total matched sample.	10 (6.2%)	151 (93.8%)	161 (80.1%)

We found in our study that the patients with clinical ASCVD who were deemed to be with very high risk, as defined by our study and Koskinas *et al.*, 2021 study¹⁸ accounted for the largest percentage of patients who met the criteria. These patients were the ones who had a history of several major ASCVD events and multiple high-risk conditions with (73.6% and 54.8%). Furthermore, in this analysis, the most prevalent risk factors were hypertension (69.2%), Percutaneous Coronary Intervention (PCI), and coronary artery bypass grafting procedures (70.1%). In the Koskinas *et al.*, 2021 study, hypertension and current smoking were the highest risk factors (50.6%) (40%). Moreover, the statistics show that ACS patients account for more than 50% of all patients in both studies. The eligibility criteria for ACC/AHA and ESC/EAS was (70.6%) compared to (14%) in the Koskinas study. Percentage of subjects who adhered to the criteria of statin and ezetimibe therapy was (74.1%). In comparison, the percentage in Koskinas study was only (60.5%).¹⁸

To our knowledge, this is the first study to evaluate the physicians' adherence to the guidelines ESC/EAS and ACC/AHA in prescribing PCSK9 inhibitors in Saudi Arabia. According to the data, collected from the two tertiary care facilities (KFMC and SFH - Riyadh - Saudi Arabia), 70.6% of doctors follow the ACC/AHA and ESC/EAS standards.

LIMITATIONS

This study had some limitations, such as small size sample, lack of follow-ups with some patients, including regular blood tests for LDL-C readings after prescribing evolocumab, unknown medication adherence status for all patients, and an old computerized system that led to missing needed data.

CONCLUSION

This cohort study evaluated the characteristics of Saudi patients with Familial hypercholesterolemia or Acute coronary syndrome who have been prescribed PCSK9 inhibitors and the physicians'

adherence to the criteria of the ESC/EAS and ACC/AHA guidelines in Saudi Arabia. The results show that up to 70.6% of physicians at King Fahad Medical City and Security Forces Hospital adhered to ACC/AHA and ESC/EAS while prescribing PCSK9 inhibitors to FH patients and ACS patients. Furthermore, a noteworthy 50% decrease in LDL-C was noted in patients who fulfilled ACC/AHA and ESC/EAS guidelines criteria. However, whether our patients were adhering to their medication is a separate question; further studies are needed.

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ABBREVIATIONS

FH: Familial Hypercholesterolemia; **ACS:** Acute Coronary Syndrome; **ASCVD:** Atherosclerotic cardiovascular disease; **PCSK9:** Proprotein Convertase Subtilisin Kexin type 9; **LDLR:** Low Density Lipoprotein Receptor; **LDL-C:** Low Density Lipoprotein Cholesterol; **KFMC:** King Fahad Medical City; **SFH:** Security Forces Hospital; **ACC/AHA:** American College of Cardiology and American Heart Association; **ESC/EAS:** European Society of Cardiology and European Atherosclerosis Society; **APOB:** Apolipoprotein B; **LLT:** Lipid-Lowering Therapies; **GCC:** Gulf Council Countries; **SD:** Standard Deviation; **IQR:** Interquartile Range; **STEMI:** Segment Elevation Myocardial Infarction; **NSTEMI:** Non-Segment Elevation Myocardial Infarction; **PCI:** Percutaneous coronary intervention. **SPSS:** Statistical Package for the Social Sciences.

CONFLICT OF INTEREST

The authors declare that there is no conflict of interest.

FUNDING

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AUTHORS CONTRIBUTIONS

Samar Zuhair Alshawwa: Project administration, Methodology, Investigation, Formal analysis, Data curation, Writing - review and editing, Funding acquisition. **Lama AlRebdi, Nouf AlMasri and Mayada AlSuwaid:** Writing - review and editing, Methodology, Investigation, Formal analysis, Data curation. **Amal Alnajjar and Reem Bahmaid:** Writing - review and editing, Supervision, Conceptualization, Project administration, Methodology, Formal analysis. **Faisal AlQarni, Khaled AlMatrafi and Sadaf Jamal Glani:** Writing - review and editing, Supervision, Methodology, Formal analysis.

ETHICAL APPROVAL

The External Research Review Committee (ERRC) at KFMC and SFH achieved research approval for the study protocol under the following numbers (H-01-R-012) and (H-01-R-069), and a pilot sample validated and tested the research tool.

SUMMARY

- The study aimed to evaluate the proper prescribing of PCSK9 inhibitors by measuring adherence to ACC/AHA and ESC/EAS guidelines at two tertiary care hospitals at Riyadh - Saudi Arabia.
- Statistical analysis measured a significant 37.1% reduction rate (p -value < 0.001) from baseline to 6 weeks' follow-up LDL-C laboratory confirmed post-treatment effect of PCSK9 inhibitors. Most physicians adhered to the ESC/EAS and ACC/AHA recommendations criteria in prescribing PCSK9 inhibitors to Familial hypercholesterolemia patients and Acute coronary syndrome patients.

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