Original Article

Impact of Adherence to Lipid-Lowering Guidelines on the Achievement of Lipid Profile Goals in Patients With Acute Coronary Syndrome: A Prospective Cohort Study

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ABSTRACT

Background: Acute coronary syndrome (ACS) is one of the main causes of mortality worldwide, and dyslipidemia is one of its important risk factors. Studies have shown that treatment with high-intensity statins protects against cardiovascular events; other investigations have noted that despite the potential effects of statins, 80% of patients with ACS fail to lower cholesterol levels. We conducted the present study to determine the association between medical compliance to clinical practice guidelines (CPG) and changes in low-density lipoprotein cholesterol (LDL-C) at follow-up among patients with ACS.

Methods: We performed a prospective cohort study on patients diagnosed with ACS. We enrolled 79 adult patients from August 2019 through March 2020. Data on patient characteristics at presentation, hospitalization, and 8 months of follow-up were collected. Adherence was established as a high-intensity statin prescription at discharge according to Peruvian, European Society of Cardiology (ESC) 2019, and American Heart Association (AHA) 2018 guidelines.

Results: Adherence to AHA and ESC guidelines showed a reduction in mean LDL-C values of 44.2 mg/dL ($P = 0.14$). In patients with dyslipidemia, mean LDL-C values were reduced by 60.6 mg/dL ($P < 0.001$). Only 27.8% of the patients did not achieve any goal in their LDL-C levels following the AHA or ESC guideline recommendations.

Conclusions: Due to the high prevalence of dyslipidemia, adequate primary prevention before an acute event occurs is essential. Compliance with CPG by healthcare personnel is related to a reduction in LDL-C levels at follow-up, and patient adherence is essential to achieve LDL-C targets. ***(Iranian Heart Journal 2023; 24(4): 54-62)***

KEYWORDS: Statins, Acute coronary syndrome, Guideline adherence, Cholesterol

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Acute coronary syndrome (ACS) comprises ST-elevation myocardial infarction (STEMI), non-ST elevation myocardial infarction (NSTEMI), and unstable angina (UA) and is a leading cause of mortality in the world. [1, 2] The spectrum of ACS risk factors is broad, and one of the most important ones is dyslipidemia, which manifests itself as elevated plasma low-density lipoprotein cholesterol (LDL-C) and reduced high-density lipoprotein cholesterol (HDL-C) levels. [3, 4] ACS is initiated by the accumulation of LDL-C in the subendothelial space and the activation of the endothelium with the subsequent formation of foam cells. All this increases inflammation, which leads to plaque rupture and the formation of a thrombus that obstructs the coronary artery depriving the blood supply to the heart.

Statins reduce endogenous cholesterol by inhibiting 3-hydroxy-3-methyl-glutaryl-CoA reductase; therefore, the risk of atherosclerotic cardiovascular disease (CVD) events has been demonstrated to decrease by 22%, with each 39 mg/dL of LDL-C reduction after 5 years. [5] Clinical practice guidelines (CPG) synthesize and promote the use of the best available evidence for the appropriate management of a disease. The 2018 American Heart Association (AHA) guidelines recommend that in patients < 75 years with symptoms of CVD, high-intensity statins be initiated or continued and in patients with very high risk and LDL-C ≥ 70 mg/dL, maximal doses of statins be given. Further, ezetimibe should be added to reduce the level to less than 70 mg/dL or 50% of the baseline. [6] Similarly, in the 2016 consensus on lipid management after ACS, the European Society of Cardiology (ESC) recommended that patients who had not previously received statins and had LDL-C values of 70 mg/dL at baseline receive high doses on admission. In patients who have previously received statins and have LDL-C values > 55 mg/dL, doses should be increased to maximum doses, or next-line therapy should be applied to reduce LDL-C to less than 55 mg/dL and by 50% from the baseline. [7] A 2017 Peruvian CPG recommended that patients with ACS initiate long-term statin therapy, whereby high-dose atorvastatin (80 mg per day) is used before discharge without establishing an LDL-C goal at follow-up. [8] Strict adherence to guideline-recommended therapies for hyperlipidemia, with at least 40% long-term adherence is associated with a reduction of cardiovascular events and cost savings with a threshold effect exceeding 80%. [9] Hence, the primary objective of the current study was to determine the association between health professionals' compliance with the recommendations of the AHA, ESC, and Peruvian guidelines and the mean difference in LDL-C levels at 8 months of follow-up in patients over 18 years of age diagnosed with ACS at a national cardiovascular institute. In addition, given the limited insight into the presence of dyslipidemia and its sufficient treatment before an acute event in Peruvian institutions, we sought to exhibit the current situation of primary and secondary preventions with statins in this population.

METHODS

Population and Study Design

We conducted a prospective cohort study and analyzed a primary database. The study population consisted of 79 patients with ACS who underwent an 8-month follow-up from August 2019 through March 2020 at the Instituto Nacional Cardiovascular Carlos Alberto Peschiera Carrillo (INCOR), a specialized cardiology center located in Lima, Peru.

Patients aged >18 years, hospitalized within 72 hours after the onset of symptoms, and within the study period were included.

Incomplete medical records, patients lost to follow-up, and complications, such as cardiogenic shock, severe sepsis, heart failure requiring mechanical ventilation, ventricular tachyarrhythmias, and hemodialysis were excluded.[10, 11]

Variables and Measurements

We considered demographic characteristics (age and sex), altitude (living above 2500 m), comorbidities (hypertension, type 2 diabetes mellitus, dyslipidemia, and previous CVD), and smoking status (non-smokers, former smokers, and current smokers). [12] In addition, prior statin treatment (no treatment, moderate intensity, and high-intensity atorvastatin), ACS type (UA, STEMI, and NSTEMI), a history of percutaneous coronary intervention (PCI), and lipid profile (total cholesterol [TC], high-density lipoprotein [HDL], low-density lipoprotein [LDL] cholesterol, very low-density lipoprotein cholesterol [VLDL cholesterol], and triglycerides) were obtained. Laboratory analyses were performed within 24 hours of the acute presentation of symptoms using the most updated version of the COBAS 60000 module C502, which detects a minimum of 3.87 mg/d of LDL-C, and statin doses prescribed at admission were also obtained (no treatment, 20 mg/dL, 40 mg/dL, and 80 mg/dL of atorvastatin).

During the follow-up period, statin doses (20 mg/dL, 40 mg/dL, and 80 mg/dL) at 8 months, lipid profile, patient adherence to medication, cardiovascular symptoms at that time, and adverse drug reactions reported as myalgia after statin administration were obtained. Atorvastatin was the statin prescribed to all the patients because of its availability at the institution. Patient adherence to medication was assessed by the same healthcare professional using the Morisky medication adherence scale, and follow-up assessment was also performed by the same cardiologist in all the patients. [13] The data were collected by the study authors, previously trained by a cardiologist at the same institution.

Performance Measures

Performance measures for medication at hospitalization and discharge were based on Peruvian, American College of Cardiology (ACC)/AHA 2018, and ESC 2019 guidelines. Adherence to CPG was established as a high-intensity statin prescription at discharge (40-80 mg/dL of atorvastatin). However, according to ESC 2019, if the patient was on current LDL-lowering treatment, treatment was to be intensified if LDL-C values were ≥ 55 mg/dL, and according to ACC/AHA 2018, ezetimibe was to be added if LDL-C values were ≥ 70 mg/ dL on admission. Follow-up was assessed according to the ACC/AHA 2018 and ESC 2019 guideline recommendations since the Peruvian guidelines do not establish a follow-up goal. [11, 13, 20] The goal was reached if LDL-C levels decreased by 50% with respect to baseline values or reached values < 70 mg/dL (< 55 mg/dL for ESC 2019). The reduction in LDL-C levels was established as the mean difference between baseline and follow-up values.

Statistical Analysis

We calculated the sample with the OpenEpi v3 program according to the study of Bansilal et al, [9] assuming a 95% confidence interval (CI), an 80% adherence to CPG recommendations in ACS patients, and a prevalence of 43% in patients with cardiovascular disease. The sample size was set as 64 patients needed to conduct the study.

The database was encoded in a Microsoft Excel sheet and then exported to Stata version 15.00 (StataCorp, TX, US) for data processing. Categorical variables were expressed as frequencies and percentages, and numerical variables were expressed as the mean (the standard deviation). To explore

significant differences between adherence to CPG and other covariables including mean LDL-C at follow-up, we used the Student *t* test or ANOVA when categorical variables were classified into 3 groups. Moreover, the Spearman correlation was used to assess the relationship between age and lipid profile variables and the mean LDL-C variation at follow-up. Finally, to determine how changes in medication influenced the mean LDL-C levels at follow-up, we classified patients who had changed medication from discharge to follow-up and those who continued with high-intensity therapy. These 2 groups were analyzed according to the mean variation in LDL-C levels at follow-up using the Student *t* test. All models were presented with their respective 95% confidence intervals (95% CI), and a *P* value < 0.05 was considered significant.

Ethics Statement

The project was approved by the Ethics Committee of the INCOR Educational Department and the Ethics Committee of the Universidad Científica del Sur. Informed consent was not required as only medical records were evaluated. The project was funded by the 2019 research project fund of the medical school of the Universidad Cientifica del Sur.

RESULTS

Patient characteristics at presentation, during hospitalization, and at 8 months of follow-up were obtained. Seventy-nine patients were included, 86.08% of whom were men. The prevalence rates of hypertension, type 2 diabetes mellitus, and dyslipidemia were 44.30%, 32.91%, and 55.70%, respectively. Of the patients, 82.28% had previous CVD, and 86.08% had not received previous statin treatment. On hospital admission, 77.22% of the patients had STEMI. The mean TC and LDL-C levels were 176.37 mg/dL and 106.8 mg/dL, respectively. On admission, 39.24% of the patients received 80 mg of atorvastatin, while 56.96% received 40 mg. At hospital discharge, 36.71% received 80 mg of atorvastatin, and 62.03% received 40 mg. At follow-up, 81% of the patients were receiving 40 mg of atorvastatin and 7.59%, 20 mg. The mean LDL-C at 8 months was 64.17 mg/dL. Adherence to treatment was high in 69.62% of the patients, while 11.39% and 18.99% had medium and low adherence, respectively. Most of the patients had no cardiovascular symptoms or adverse drug reactions. Twenty-two patients (27.8%) did not meet any LDL-C goal, meaning that this group did not reduce their LDL-C levels by ≥ 50% or achieve LDL-C < 70 mg/dL according to the AHA, nor did they achieve the ESC goal, which established a goal of < 55 mg/dL and a reduction of 50% in LDL-C levels (Table 1).

Among patients with dyslipidemia, the mean LDL-C value was reduced to 60.6 mg/dL (*P* < 0.001), whereas in patients without prior statin treatment, LDL-C was reduced by 46.6 mg/dL compared with 15.5 mg/dL in those who had received prior statin treatment (*P* = 0.012). Patients with STEMI showed a reduction in LDL-C of 50.2 mg/dL compared with those with STEMI or UA (*P* = 0.003). TC values at admission had a moderate negative monotonic correlation with a mean change in LDL-C values ($r = -0.59$; *P* = 0.001). Medical adherence to AHA and ESC guidelines showed a reduction in mean LDL-C values of 44.2 mg/dL (*P* = 0.14). Medical adherence to the Peruvian guidelines in 78 patients showed a mean reduction in C-LDL of 42.3 mg/dL, which was not statistically significant. Finally, patients with high medication adherence according to the Morisky scale showed a mean reduction in C-LDL of 48.2 mg/dL (*P* = 0.005), constituting statistical significance (Table 2).

Table 1: Patient characteristics at presentation, hospitalization, and 8 months follow-up (N=79)

Variable		Frequency	Percentage (%)	Mean	SD
Age				65.65 y	11.47 y
Sex	Male	68	86.08		
Altitude	Yes			2	2.53
Hypertension	Yes	35	44.30		
Type 2-diabetes	Yes	26	32.91		
Dyslipidemia	Yes	44	55.70		
Smoker status	No Former Yes	60 2 17	75.95 2.53 21.52		
Previous CVD*	Yes	65	82.28		
Previous statin treatment	None 20 mg/dL 40 mg/dL	68 2 9	86.08 2.53 11.39		
ACS‡	UA§ NSTEMI¦ STEMI¶	1 17 61	1.27 21.52 77.22		
PCI#	Yes	77	97.47		
Total cholesterol, mg/dL				176.37	42.03
HDL-C, mg/dL				36.97	8.65
LDL-C, mg/dL				106.84	37.70
VLDL-C, mg/dL				32.54	21.84
Triglycerides, mg/dL				162.83	109.27
Admission statin doses	None 20 mg 40 mg 80 mg	2 1 45 31	2.53 1.27 56.96 39.24		
Discharge statin doses	20 mg 40 mg 80 mg	1 49 29	1.27 62.03 36.71		
Statin follow-up (mg)	20 mg 40 mg 80 mg	6 67 6	7.59 84.81 7.59		
Total cholesterol at follow-up, mg/dL				135.54 (23.15) ‡‡	45.47
HDL-C at follow-up, mg/dL				41.38 (11.92) ‡‡	12.66
LDL-C at follow-up, mg/dL				64.17 (39.9) ‡‡	32.1
Triglycerides at follow-up, mg/dL				158.45 (2.68) ‡‡	114.77
No goal achievement at follow-up		22	27.8		
Patient adherence to treatment**	High Medium Low	55 9 15	18.99 11.39 69.62		
Cardiovascular symptoms	Yes	20	25.32		
ADR††	Yes	8	10.13		

- cardiovascular disease; ‡ acute coronary syndrome; § unstable angina; ¦ non-ST elevation myocardial infarction; ¶ ST-elevation myocardial infarction; # percutaneous coronary intervention; ** the Morisky medication adherence scale; †† adverse drug reaction; ‡‡ lipid profile variation in percentages

Table 2: Bivariate analysis between covariables and changes in LDL-C levels (N=79)

Variable		Mean	SD	*P* value
Age (correlation coefficient), y		0.0985		0.39
Sex	Male	-43.69	38.78	0.55
Altitude	Yes	-34.73	20.8	0.76
Hypertension	Yes	-43.42	43.25	0.87
Type 2-diabetes mellitus	Yes	-39.13	31.75	0.56
Dyslipidemia	Yes	-60.67	31.64	**< 0.001**
Smoker status	Yes	-34.90	48.18	0.34
Previous CVD*	Yes	-28.58	39.58	0.12
Previous statin treatment	Yes	-15.53	25.27	0.01
Previous statin treatment, mg	None 20 mg/dL*** 40 mg/dL	-47.03 -26.23 -13.4	37.28 12.03 25.82	0.03
ACS†	UA NSTEMI STEMI	-1.08 -18 -50.22	--†† 27.85 36.56	0.003
PCI‡	Yes	-43.16	37.59	0.47
Total cholesterol on admission (correlation coefficient), mg/dL		-0.59		**0.001**
HDL on admission (correlation coefficient), mg/dL		-0.2		0.08
VLDL on admission (correlation coefficient), mg/dL		-0.08		0.5
Triglycerides on admission (correlation coefficient), mg/dL		-0.07		0.5
Admission statin	None	-80.82	50.73 mg/dL	0.07
Admission statin doses, mg	None 20 mg/dL 40 mg/dL 80 mg/dL	-90.06 -94.4 -37.57 -45.34	68.08 --†† 37.72 32.85	0.1
AHA guideline adherence§	Yes (74)	-44.27	36.96911	0.14
ESC guideline adherence¦	Yes (74)	-44.27	36.97	0.14
Peruvian guideline adherence¶	Yes (78)	-42.36	37.38	--††
Discharge statin doses	20 mg/dL 40 mg/dL 80 mg/dL	-66.72 -43.85 -39.85	--†† 39.35 34.31	0.73
Statin Dose at follow-up (mg)	20 mg/dL 40 mg/dL 80 mg/dL	-68.54 -39.68 -50.17	13.312 37.70 41.31	0.17
Total cholesterol at follow-up, mg/dL		0.33		0.002
HDL at follow-up, mg/dL		0.07		0.54
VLDL at follow-up, mg/dL		0.10		0.36
Triglycerides at follow-up, mg/dL		0.09		0.43
ADR#	Yes	-33.56	54.44	0.46
Patient adherence to treatment**	Yes	-48.22	32.84	0.005
Cardiovascular symptoms	Yes	-31.03	47.0	0.10

- cardiovascular disease; ‡ acute coronary syndrome; § unstable angina; ¦ non-ST elevation myocardial infarction; ¶ ST-elevation myocardial infarction; # percutaneous coronary intervention; ** the Morisky medication adherence scale; †† adverse drug reaction; ‡‡ lipid profile variation in percentages
†† SD or *P* value was not calculated due to the small sample size in the correspondent category.
*** moderate-intensity atorvastatin

DISCUSSION

In this study, we assessed the association between changes in LDL-C levels and physicians' medical compliance with CPG recommendations at 8 months of follow-up. We found a mean reduction in LDL-C of 44.27 mg/dL in patients whose physicians followed the AHA and ESC guidelines and

42.36 mg/dL with the Peruvian guidelines. Overall, 22 patients (27.8%) did not meet any LDL-C goal, meaning that this group achieved neither at least a 50% reduction in their LDL-C values nor an LDL-C < 70 mg/dL.

Our study showed that about half of the patients were previously diagnosed with dyslipidemia, and about one-third had type 2 diabetes mellitus. These results are comparable with a Peruvian study [14] about factors associated with ACS, where 52% of the patients were previously diagnosed with dyslipidemia and 37% with type 2 diabetes mellitus. A comparable study in Japan, [15] with STEMI as the most common presentation of an ACS and a mean baseline LDL-C of 138 mg/dL, reported a prevalence rate of hypertension ranging between 60% and 70%. In comparison with the aforementioned, in our study, hypertension accounted for only 44%, which could be explained by hypertension being underdiagnosed in the Peruvian population due to socioeconomic inequality. [16]

The prevalence of statin prescription on admission was 13.4% and 13% in the previously described studies, respectively. [14,15] A comparison between these 2 studies and ours shows that in general, secondary prevention with statins at admission is low, despite having a large percentage of patients with dyslipidemia, denoting the inadequate control of this disease.

Only 27.8% of the patients did not achieve any goal in their LDL-C levels following the AHA or ESC guidelines. This level of LDL-C goal achievement is acceptable compared with a study in Japan, [17] where 32% of the patients did not achieve any LDL-C goal. Our study can be compared with it because of the very high prevalence of dyslipidemia among the population. However, these results differ from those reported by Pearson [18] (2000), who identified that 62% of the patients did not achieve any LDL-C goal probably explained by the short follow-up period of 3 months compared with 8 months from our study and the previously mentioned (3.7 y). Nevertheless, neither study was performed in an acute setting as an ACS, making our results remarkable as we demonstrated a higher rate of LDL-C goal achievement and low persistent cardiovascular symptoms at follow-up (25%), which could be also explained by the anti-inflammatory pleiotropic properties of statins, whose effects are important during an ACS. [19]

The mean reduction in LDL-C levels in the present study was not statistically significant. Adherence to the Peruvian guidelines showed a mean reduction in C-LDL levels of 42.3 mg/dL, whereas when the AHA and ESC guidelines were followed, the mean reduction was 44.2 mg/dL. A study evaluating medication adherence and its impact on LDL-C levels found that 95% of the patients were prescribed 80 mg of atorvastatin at discharge, which was associated with increased adherence to treatment. [20] In comparison with our study, in which only 36% of the patients received 80 mg of atorvastatin, the finding is of concern since high-intensity statins contribute to a reduction in C-LDL by more than 50%, [6] which may explain and correlate with the findings described in our study.

On the other hand, medical compliance with statin prescription was high compared with previous studies. [21] This is important since the prescription rate of statins following discharge in patients with ACS is reported to be associated with all-cause death (odds ratio [OR], 0.52; 95% CI, 0.36 to 0.76). [15] In addition, it was shown that higher levels of TC on admission were related to a lower mean change in LDL-C values at follow-up (P = 0.001). These results are significant since 150 mg/dL of TC corresponds to 100 mg/dL of LDL-C, and having low LDL-C levels at admission is associated with achieving LDL-C goals as demonstrated in a prior study (OR, 4.81; 95% CI, 3.46 to 6.70). [22]

Patient adherence to medication also influences the achievement of LDL-C goals. In this study, we found that among patients with high adherence to medical treatment, 56.25% achieved the LDL-C goal according to the ESC guidelines, while 60% of those without adequate adherence did not achieve any LDL-C goal at follow-up (P = 0.007). A study on factors associated with reaching the LDL-C target after 6 months in patients with ACS reported that statin medication before an acute event had a significant independent association with LDL-C goal achievement (OR, 0.21; 95% CI, 0.08 to 0.79; P = 0.008), reinforcing the notion that patient adherence to statin therapy is also important for therapeutic success after ACS. [23]

The present study has some limitations. Firstly, the small sample size may have allowed for a probable type 2 error. Secondly, the follow-up was affected by the COVID-19 pandemic, and not all the patients were able to attend their medical follow-up and cardiac rehabilitation since March. Thirdly, external validity is limited because the results came from a single specialized cardiovascular institution, affecting the reproducibility of the study. Finally, adherence to CPG could have been negatively affected if patients with dyslipidemia on admission had had the correct baseline statin medication. However, as this did not occur, these patients were considered naïve; therefore, the compliance was high. Nevertheless, in a different scenario, many of these patients would have received ezetimibe, a medication not available at this institution, on admission.

In conclusion, among patients diagnosed with ACS, there is a high prevalence of dyslipidemia, so adequate primary prevention is necessary before an acute event occurs by means of adherence of healthcare personnel and patients to the CPG recommendations to reduce C-LDL levels in a timely manner during follow-up and achieve the established objectives. Further studies on larger study populations and in an ACS setting are needed to establish more concrete results regarding the importance of physician compliance with guideline recommendations.

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