KARDIOLOGIA POLSKA
Polish Heart Journal
The Official Peer-reviewed Journal of the Polish Cardiac Society since 1957
Online first
This is a provisional PDF only. Copyedited and fully formatted version will be made available soon
ISSN 0022–9032 e-ISSN 1897–4279

# Dyslipidemia treatment and attainment of LDL-cholesterol treatment goals in patients participating in the Managed Care for Acute Myocardial Infarction Survivors program

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**Article type:** Original article
**Received:** November 6, 2022
**Accepted:** November 28, 2022
**Early publication date:** February 19, 2023

**Dyslipidemia treatment and attainment of LDL-cholesterol treatment goals in patients participating in the Managed Care for Acute Myocardial Infarction Survivors program**

**Short title:** Dyslipidemia treatment and attainment of LDL goals – MACAMIS program

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**WHAT'S NEW?**

The improved prognosis in patients participating in the 12-month, nationwide Managed Care for Acute Myocardial Infarction Survivors (MACAMIS; "KOS-Zawał") program has been previously demonstrated. In this study, we aimed to assess the management of dyslipidemia and the achievement of *low*-density lipoprotein cholesterol (LDL-C) therapeutic goals in patients participating in the MACAMIS program at one of three large tertiary cardiovascular centers. In this cohort, high-intensity statin therapy was prescribed to 85.5% of patients at hospital discharge, but only 20.4% of patients achieved the LDL-C target of <55 mg/dl (<1.4 mmol/l) at 12 months. There is a continuing need to optimize lipid-lowering therapy to achieve therapeutic goals and to reduce cardiovascular risk.

**ABSTRACT**

**Background:** Patients after acute myocardial infarction (AMI) are at very high cardiovascular (CV) risk. Therefore, appropriate management of dyslipidemia with adequate lipid-lowering therapy is crucial for preventing subsequent CV events in these patients.

**Aims:** Our analysis aimed to assess the treatment of dyslipidemia and the attainment of *low*-density lipoprotein cholesterol (LDL-C) treatment goals in patients after AMI who participated in the Managed Care for Acute Myocardial Infarction Survivors (MACAMIS) program.

**Methods:** This study is a retrospective analysis of consecutive patients with AMI who agreed to participate and completed the 12-month MACAMIS program at one of three tertiary referral cardiovascular centers in Poland between October 2017 and January 2021.

**Results:** 1499 patients after AMI were enrolled in the study. High-intensity statin therapy was prescribed to 85.5% of analyzed patients at hospital discharge. Combined therapy with high-intensity statin and ezetimibe increased from 2.1% at hospital discharge to 18.2% after 12 months. In the whole study cohort, 20.4% of patients achieved the LDL-C target of <55 mg/dl (<1.4 mmol/l), and 26.9% of patients achieved at least 50% reduction in LDL-C level one year after AMI.

**Conclusions:** Our analysis suggests that participation in the managed care program might be associated with improved quality of dyslipidemia management in AMI patients. Nonetheless, only one-fifth of patients who completed the program achieved the treatment goal for LDL-C. This highlights the constant need for optimizing lipid-lowering therapy to meet treatment targets and to reduce CV risk in patients after AMI.

**Key words:** cardiovascular risk; low-density lipoprotein cholesterol; lipid-lowering therapy; myocardial infarction; secondary prevention

## INTRODUCTION

The decrease in low-density lipoprotein cholesterol (LDL-C) level by one mmol/L with statin therapy reduces the 5-year incidence of major coronary events, coronary revascularization, and stroke by about one-fifth [1]. Adding ezetimibe to statin therapy lowers LDL-C level and may further reduce the rate of cardiovascular events [2]. The reduction in atherosclerotic cardiovascular disease (ASCVD) risk is directly and positively correlated with the achieved absolute LDL-C reduction, irrespectively of baseline cholesterol concentration [3]. Clinical trials on the anti-proprotein convertase subtilisin/kexin type 9 (PCSK9) monoclonal antibodies added to statin therapy showed that the lower the LDL-C values achieved, the lower the risk of future cardiovascular events, with no lower limit for LDL-C values [4]. Additionally, recent data suggest that the current approach to LDL-C reduction in high-risk patients should not only focus on maintaining low LDL-C level but also on the early achievement of LDL-C treatment goals [5, 6]. The reduction in major vascular events by lowering the LDL-C level is the most significant in patients in the highest cardiovascular disease risk categories [7]. Patients after myocardial infarction are at very high risk for recurrent ASCVD events. Due to the large heterogeneity of this population, it is suggested that some of them should be identified as individuals at extremely high cardiovascular risk who could benefit from lowering the LDL-C level most significantly [8, 9]. Therefore, appropriate management of dyslipidemias with the use of adequate lipid-lowering therapy is crucial to efficiently reduce cardiovascular risk after acute coronary syndrome (ACS). At the same time, the real-world data clearly show that only 18% of the very high-risk patients achieve the LDL-C treatment target, and even less in the population of high-risk patients in Central and Eastern European Countries [10,11].

The Managed Care for Acute Myocardial Infarction Survivors (MACAMIS; “KOS-Zawał”) program was implemented to improve the quality of medical care during the first 12 months after myocardial infarction, which is considered the most vulnerable time after ACS with an

exceptionally high risk of recurrent cardiovascular (CV) event. In brief, the program includes treatment of acute myocardial infarction (AMI), cardiac rehabilitation, prevention of sudden cardiac death, and prescheduled cardiology outpatient visits for one year following AMI [12, 13]. The comparison of outcomes of patients after AMI participating and not participating in the MACAMIS program showed that the managed care after myocardial infarction was associated with improved prognosis. However, the reasons for the potential advantage of this program, especially in terms of secondary prevention, including lipid-lowering therapy, have not been not sufficiently explored [14].

The aim of our analysis was to assess the treatment of dyslipidemia and the attainment of LDL-cholesterol treatment goals in patients participating in the MACAMIS program.

## METHODS

All consecutive adult patients who had been admitted to one of three tertiary referral centers in Southern Poland (Silesian Center for Heart Diseases in Zabrze, Leszek Giec Upper-Silesian Medical Centre in Katowice, and Jagiellonian University Medical College, Institute of Cardiology, Department of Interventional Cardiology in Krakow) for AMI between October 2017 and January 2021, who agreed to participate in the MACAMIS program and completed the program (attended all outpatient cardiology visits) were included in the study. The MACAMIS program consists of four treatment modules: the treatment of the acute phase of myocardial infarction (including coronary angiography, percutaneous coronary intervention, coronary artery bypass grafting or conservative treatment, and a follow-up visit within 14 days after discharge), cardiac rehabilitation, electrotherapy (i.e., implantation of cardiac implantable electronic devices, including implantable cardioverter-defibrillator), and specialized ambulatory cardiac care during the 12 months (at least 3 visits) following AMI, including the laboratory tests [12, 13].

The data on the baseline characteristics, the baseline lipid profile (measured during index hospitalization), and at 12 months, cholesterol-lowering treatment at hospital discharge, and all ambulatory cardiology visits during the 12-month program were extracted from the hospital and ambulatory medical records. The approval of a bioethics committee was not required for this study, considering that it was a retrospective analysis of an anonymized dataset.

The cholesterol-lowering treatment during the MACAMIS program and after 12 months were defined as medications prescribed at the second last and the last ambulatory cardiology visit, respectively. High-intensity statin therapy included a prescription fill for atorvastatin 40–80

mg daily or rosuvastatin 20–40 mg daily. Maximal statin therapy was considered as atorvastatin 80 mg daily and rosuvastatin 40 mg daily.

### Statistical analysis

Categorical variables are shown as absolute and relative frequencies (percentages). The normality of continuous variables distribution was assessed by the Shapiro-Wilk test. Quantitative variables were not normally distributed and are therefore presented as median (interquartile range [IQR]). The ordinal or continuous variables, measured repeatedly over time, were compared using Friedman and Wilcoxon signed-rank tests. *P*-value <0.05 was considered significant. All reported *P*-values are two-sided. The statistical analyses were performed using Statistica version 13.3 (TIBCO Software, Palo Alto, CA, US).

## RESULTS

A total of 1499 patients who completed the 12-month MACAMIS program were enrolled in the study (median age of 65 [57–71] years, 71.5% males). The presentation of AMI was ST-segment elevation myocardial infarction (STEMI) in 43% and non-ST-segment elevation myocardial infarction (NSTEMI) in 57% of patients. More details on the baseline clinical characteristics of patients are presented in Table 1.

The data on the lipid profile were available for 1421 (94.8%) patients at baseline (median LDL-C level of 115.0 (82.0–150.0) mg/dl) and 1354 (90.3%) patients at 12 months (median LDL-C level of 75.0 (58.2–98.0) mg/dl). The lipid profile at baseline and the end of the MACAMIS program are presented in Table 2. The median change of LDL-C level between the index hospitalization and the last ambulatory visit in the subgroups of patients stratified by cholesterol-lowering therapy was the most remarkable in patients on the combination therapy with high-intensity statin and ezetimibe (n = 65, a median absolute difference of LDL-C level –53 mg/dl (–1.4 mmol/l); median relative change of LDL-C level –41.7%), as presented in Table 3.

The comparison of cholesterol-lowering therapy prescribed at hospital discharge, during the 12-month managed care program (at the second last ambulatory visit), and at the last ambulatory visit (at 12 months) is presented in Figure 1. High-intensity statin therapy (atorvastatin 40–80 mg daily or rosuvastatin 20–40 mg daily) was prescribed at hospital discharge to 85.5% of analyzed patients (including 2.1% on high-intensity statin with ezetimibe combination therapy). At the last ambulatory visit, high-intensity statin therapy was prescribed to 80% of patients (including 18.2% on high-intensity statins combined with ezetimibe).

In the whole study cohort, 20.4% of patients achieved the LDL-C target of <55 mg/dl (<1.4 mmol/l), and 26.9% of patients attained at least 50% reduction from the baseline LDL-C level. In the analysis of subgroups of patients stratified by cholesterol-lowering therapy, the LDL-C target of <55 mg/dl (<1.4 mmol/l) was achieved by 20.9% of patients on high-intensity statin therapy and 28.4% of patients on combination therapy with high-intensity statin and ezetimibe. In addition, the 50% LDL-C reduction was attained by 28.7% of patients on high-intensity statin therapy and 41.5% of patients on high-intensity statin and ezetimibe combination therapy (Figure 2).

The analysis of changes in the statin therapy during a 12-month managed care program showed that in 69.4% of patients the lipid-lowering therapy was maintained, in 10.1% was deescalated, and in 20.5% intensified as referred to treatment at hospital discharge (Figure 3). Among patients in whom statin treatment was withdrawn during the 12-month program, the most common reason for discontinuation were patients' reluctance to continue therapy (70.3%), followed by muscle pain (18.9%) and elevated liver enzymes (5.4%).

## DISCUSSION

Patients after ACS are at very high risk of recurrent CV events. This fact was recognized by the recent 2019 European Society of Cardiology (ESC) and European Atherosclerosis Society (EAS) Guidelines for the management of dyslipidemias which included this group of patients in the very-high CV risk category, requiring more stringent LDL-C goals than other patients [15].

Our study encompassed 1499 patients with AMI who completed the 12-month, nationwide MACAMIS program. In this cohort, only 20.4% of patients achieved the LDL-C target of <55 mg/dl (<1.4 mmol/l), which is the recommended goal in the very-high CV risk group of patients according to the 2019 ESC/EAS dyslipidemia guidelines [15]. In the subgroups of patients stratified by the type of cholesterol-lowering therapy, the LDL-C target of <55 mg/dl (<1.4 mmol/l) was achieved by 20.9% of patients on high-intensity statin therapy and 28.4% of patients on a high-intensity statin with ezetimibe combination therapy.

In contrast, in the international DA VINCI study conducted in 18 European countries, 18% of the secondary prevention patients achieved the LDL-C goal of <55 mg/dl (<1.4 mmol/l); 22% of patients on high-intensity statin therapy, and 21% of patients using ezetimibe in combination with statins attained the LDL-C goal of <55 mg/dl (<1.4 mmol/l), respectively [10]. Moreover, in the DA VINCI study, among patients on PCSK9 inhibitor treatment in combination with any lipid-lowering treatment, the LDL-C goal of <55 mg/dl (<1.4 mmol/l) attainment was 58%

[10]. It is worth emphasizing that, since the nationwide drug program for PCSK9 inhibitors was approved in Poland in November 2020 and started in 2021, none of the patients from the MACAMIS program were treated with PCSK9 inhibitors, neither at baseline nor during the 12-month MACAMIS program.

In recent years, the results of several studies presenting the "real-world" lipid-lowering therapy in the Polish setting have been published. For example, in the analysis of consecutive patients admitted to the Department of Internal Diseases in 2019 and 2020, only 1 in 5 patients with dyslipidemia achieved the 2019 ESC/EAS guideline-recommended level of LDL-C (according to the patient's risk category) [16].

The results from the multicenter POLASPIRE survey, which included patients with acute coronary syndrome and/or undergoing myocardial revascularization in Poland, showed that only 2.3% of the study population had controlled all of the five main risk factors well (non-smoking, blood pressure <140/90 mm Hg, LDL-C <1.8 mmol/l and glucose <7.0 mmol/l, body mass index <25 kg/m$^2$) [17]. Contrary to our analysis, patients who participated in the POLASPIRE survey were admitted not only to the teaching centers but also to municipal hospitals (which may differ in terms of the quality of secondary prevention and ambulatory care). In this study, 68.1% of patients hospitalized for ACS were prescribed a high-dose statin, which was a much lower rate than in our analysis (85.5%) [18]. However, within 12 months following discharge, statin therapy was more often up-titrated in the POLASPIRE cohort, and after one year the rate of patients on high-statin therapy was almost the same as in the MACAMIS cohort (approximately 80%). On the other hand, ezetimibe was prescribed only in 2.6% of cases in POLASPIRE (as compared to our cohort, where 21.7% of patients were treated with ezetimibe at one year). Finally, one-fourth fewer patients achieved the LDL-C goal of <55 mg/dL (<1.4 mmol/l) in the POLASPIRE cohort than in patients participating in the MACAMIS program.

The Hyperlipidaemia Therapy in tERtiary Cardiological cEnTer (TERCET) Registry included Polish ACS secondary-prevention patients [19]. In this analysis, 29.9% of patients with NSTEMI and 32.4% of patients with STEMI achieved the therapeutic target of LDL-C <70 mg/dl at 1-year, which was the recommended goal of LDL-C according to the 2016 ESC/EAS Guidelines and Polish Forum for Prevention Guidelines on Dyslipidaemia published in the same year [20, 21]. Compared to the TERCET population, the LDL-C target of <70 mg/dl was achieved by a numerically higher percentage of patients (42.4%) who completed the 12-month MACAMIS program. Thus, the differences in the rates of patients on high-intensity lipid-lowering therapy and patients achieving treatment goals between the current study considering

patients participating in the MACAMIS program and previous studies, including TERCET and POLASPIRE, might reflect improved quality of dyslipidemia management in AMI patients participating in this managed care program.

Considering the high heterogeneity of the very-high CV risk group and data from PCSK9 inhibitors trials, the extremely high CV risk category of ACS patients has been recently proposed. The extremely high CV risk category includes patients who might benefit from even more significant LDL-C reduction than the very-high risk group. Individuals considered at extremely high CV risk are patients who experience a second vascular event within 2 years and patients with acute coronary syndrome and multivessel disease, polyvascular disease, familial hypercholesterolemia, or diabetes mellitus (with at least one additional risk factor) [5]. Our study shows that even less strict LDL-C treatment goals are hardly met in real-world patients after AMI on the combination therapy with high-intensity statin and ezetimibe. It underscores the need for broader availability and applicability of PCSK9 inhibitors in secondary prevention.

There are some study limitations that should be acknowledged. The main limitation of our study is its observational character and lack of a control group consisting of patients who did not participate in the MACAMIS, which might allow for a direct comparison of secondary prevention efficacy in this program. Furthermore, data on the use of cholesterol-lowering treatment are based on medical recommendations and patients' declarations. Therefore, the influence of patients' noncompliance with medical recommendations on the results is a substantial study limitation. However, this aspect reflects the real-world conditions of the analysis.

## CONCLUSIONS

Our study suggests that participation in the MACAMIS program might be associated with improved quality of dyslipidemia management in real-world AMI patients. Nonetheless, still, only one-fifth of patients who completed the program achieved the treatment goal for LDL-C. This highlights the constant need for optimizing lipid-lowering therapy to meet treatment targets and to reduce cardiovascular risk in very-high risk patients after AMI.

Furthermore, it shows that LDL-C treatment goals are hardly met in real-world patients after AMI, even on a high-intensity statin with ezetimibe combination therapy, which underscores the need for broader availability and applicability of PCSK9 inhibitors in secondary prevention.

**Article information**

**Conflict of interest:** None declared.

**Funding:** None.



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**Table 1.** Baseline clinical characteristics of patients after AMI who completed a 12-month managed care program

| **Characteristics** | **All patients (n = 1499)** |
|---|---|
| Sex, male, n (%) | 1072 (71.5) |
| Age, years, median (IQR) | 65 (57–71) |
| Hypertension, n (%) | 1015 (67.7) |
| Diabetes mellitus, n (%) | 397 (26.5) |
| Smoking status | |

| | |
|---|---|
| Current smoker, n (%) | 377 (25.2) |
| Former smoker, n (%) | 192 (12.8) |
| Previous MI, n (%) | 335 (22.3) |
| Previous PCI, n (%) | 349 (23.3) |
| Previous CABG, n (%) | 97 (6.5) |
| Previous stroke, n (%) | 57 (3.8) |
| PAD, n (%) | 113 (7.5) |
| AMI presentation | |
| STEMI, n (%) | 645 (43.0) |
| NSTEMI, n (%) | 854 (57.0) |
| PCI, n (%) | 1377 (91.9) |
| CABG, n (%) | 64 (4.3) |
| Time from admission for AMI to last ambulatory visit, days | 338 (333–350) |

Abbreviations: AMI, acute myocardial infarction; CABG, coronary artery bypass grafting; NSTEMI, non-ST-segment elevation myocardial infarction; PCI, percutaneous coronary intervention; STEMI, ST-segment elevation myocardial infarction; PAD, peripheral artery disease

**Table 2.** Lipid profile at baseline and at 12 months

| **Lipid profile** | **At baseline** | **At 12-months** | ***P*-value** |
|---|---|---|---|
| TC, mg/dl, median IQR) | 190.0 (155.0–228.0) | 141.0 (121.0–165.0) | <0.01 |
| LDL-C, mg/dl, median IQR) | 115.0 (82.0–150.0) | 75.0 (58.2–98.0) | <0.01 |
| Non-HDL-C, mg/dl, median IQR) | 133.0 (101.0–196.0) | 91 (73.0–115.0) | <0.01 |
| HDL-C, mg/dl, median IQR) | 45.0 (37.5–56.0) | 47.0 (41.0–57.0) | <0.01 |
| Triglycerides, mg/dl, median IQR) | 116.0 (82.0–173.3) | 113.0 (86.0–159.0) | 0.37 |

Abbreviations: HDL-C, high-density lipoprotein cholesterol; LDL-C, low-density lipoprotein cholesterol; TC, total cholesterol

**Table 3.** LDL-C levels at baseline and after 12 months in the whole study cohort and subgroups of patients stratified by cholesterol-lowering therapy

| **Cholesterol-lowering treatment during managed care program** | **LDL-C level (mg/dl) at baseline, median (IQR)** | **LDL-C level (mg/dl) at 12 months, median (IQR)** | **Median absolute difference of LDL-C level, mg/dl** | **Median relative change of LDL-C level, %** |
|---|---|---|---|---|
| All patients (n = 1290) | 115.0 (82.0–150.0) | 75.0 (58.2–98.0) | –34.0 | –32.0 |
| No treatment (n = 20) | 92.3 (64.5–122.3) | 102.1 (65.5–138.0) | 14.0 | 13.3 |
| Ezetimibe (n = 8) | 104.3 (97.1–125.8) | 120.4 (87.5–137.1) | –5.4 | –5.2 |
| Low- to moderate-dose statins (n = 207) | 90.0 (66.0–130.0) | 76.0 (59.4–97.0) | –10.0 | –12.0 |
| Low- to moderate-dose statins + ezetimibe (n = 12) | 123.0 (65.4–187.0) | 92.7 (66.5–141.2) | –12.5 | –6.4 |
| High-intensity statins (n = 972) | 118.4 (87.0–151.3) | 75.0 (58.0–97.0) | –40.0 | –35.4 |
| Atorvastatin 40/60 mg (n = 409) | 116.0 (83.1–148.0) | 78 (63.4–100.0) | –31.0 | –31.0 |
| Atorvastatin 80 mg (n = 297) | 123.7 (93.2–159.7) | 75.4 (59.2–99.0) | –46.0 | –37.8 |
| Rosuvastatin 20/30 mg (n = 152) | 108.5 (81.5–143.3) | 67.9 (51.0–87.0) | –36.1 | –37.3 |
| Rosuvastatin 40mg (n = 114) | 127.4 (88.0–158.0) | 67.3 (52.0–92.0) | –49.5 | –40.6 |
| High-intensity statins + ezetimibe (n = 65) | 136.0 (104.4–167.8) | 67.7 (51.0–100.0) | –53.0 | –41.7 |
| Atorvastatin 40/60 mg + ezetimibe (n = 16) | 128.0 (104.0–189.7) | 66.2 (47.0–111.3) | –67.7 | –49.8 |

| | | | | |
|---|---|---|---|---|
| Atorvastatin 80 mg + ezetimibe (n = 21) | 141.5 (105.6–166.3) | 74.6 (55.7– 104.0) | –50.2 | –38.7 |
| Rosuvastatin 20/30 mg + ezetimibe (n = 20) | 132.7 (102.7–159.5) | 71.1 (46.3–89.9) | –52.4 | –40.0 |
| Rosuvastatin 40 mg + ezetimibe (n = 8) | 136.7 (97.9–182.9) | 66.5 (36.4–92.9) | –69.8 | –49.0 |

Abbreviations: IQR, interquartile range; other — see Table 2

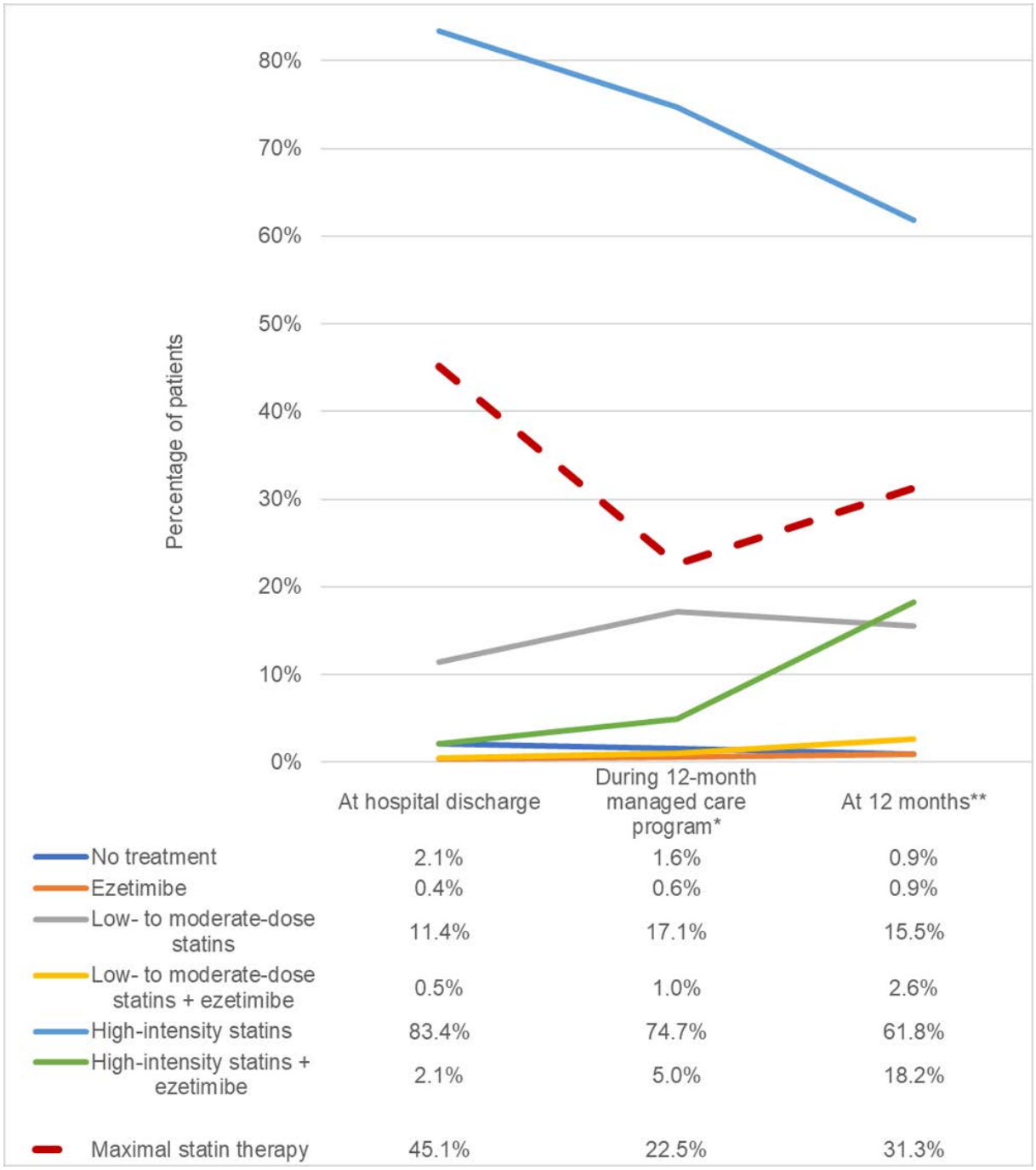
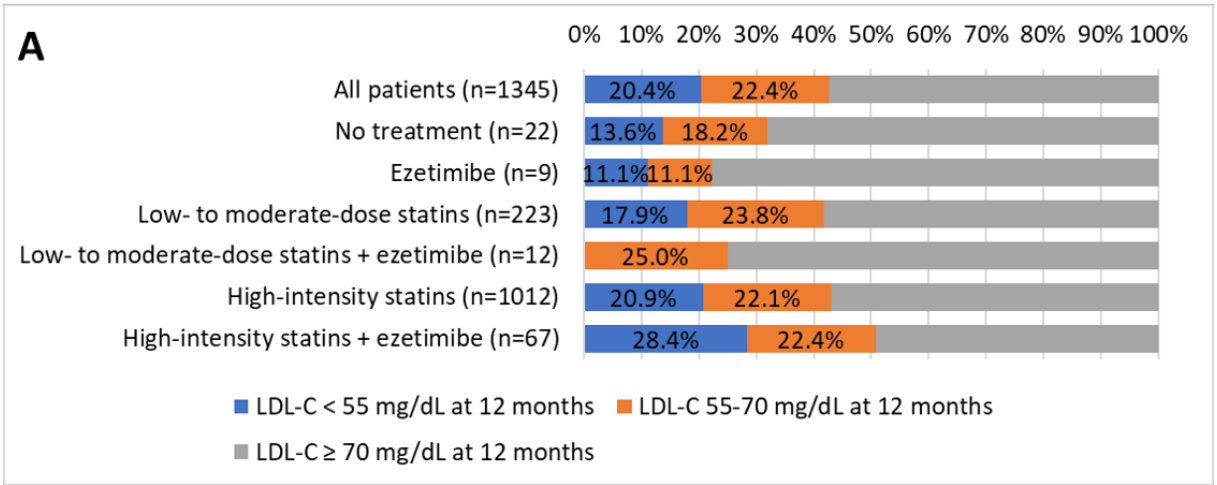



**Figure 1.** The comparison of cholesterol-lowering therapy prescribed at hospital discharge, during a 12-month managed care program, and at the last ambulatory visit (at 12 months).

*$P$-value for comparison of treatment at discharge vs. during managed care program <0.001

**$P$-value for comparison of treatment during managed care program vs. after 12 months <0.001



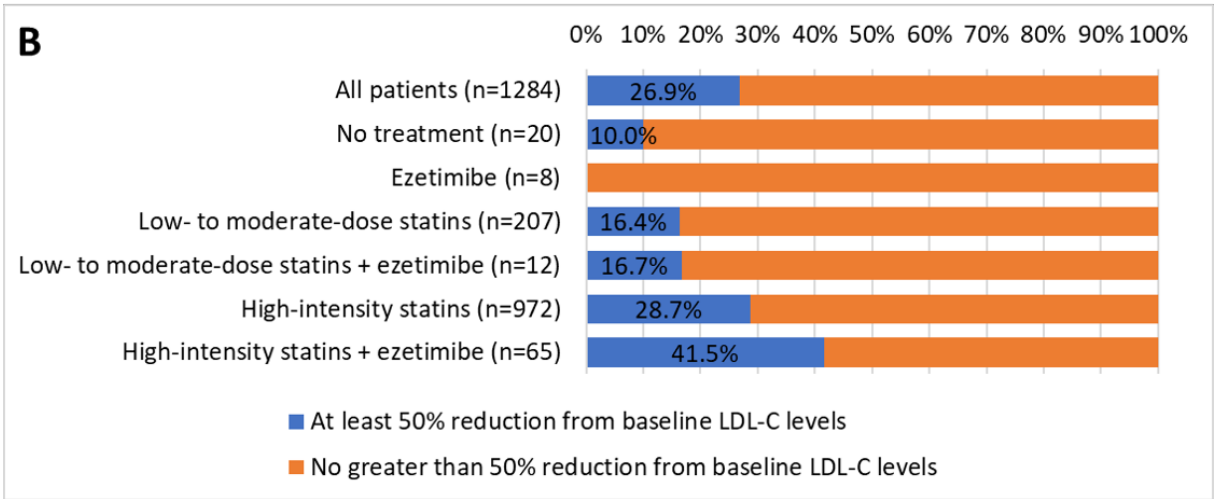




**Figure 2.** Percentage of patients achieving low-density lipoprotein cholesterol (LDL-C) targets at 12 months in the whole study cohort and subgroups of patients stratified by cholesterol-lowering therapy. **A.** LDL-C targets defined as LDL-C <55 mg/dl and between 55 and 70 mg/dl. **B.** At least 50% reduction from the baseline LDL-C level

Abbreviations: see Table 2

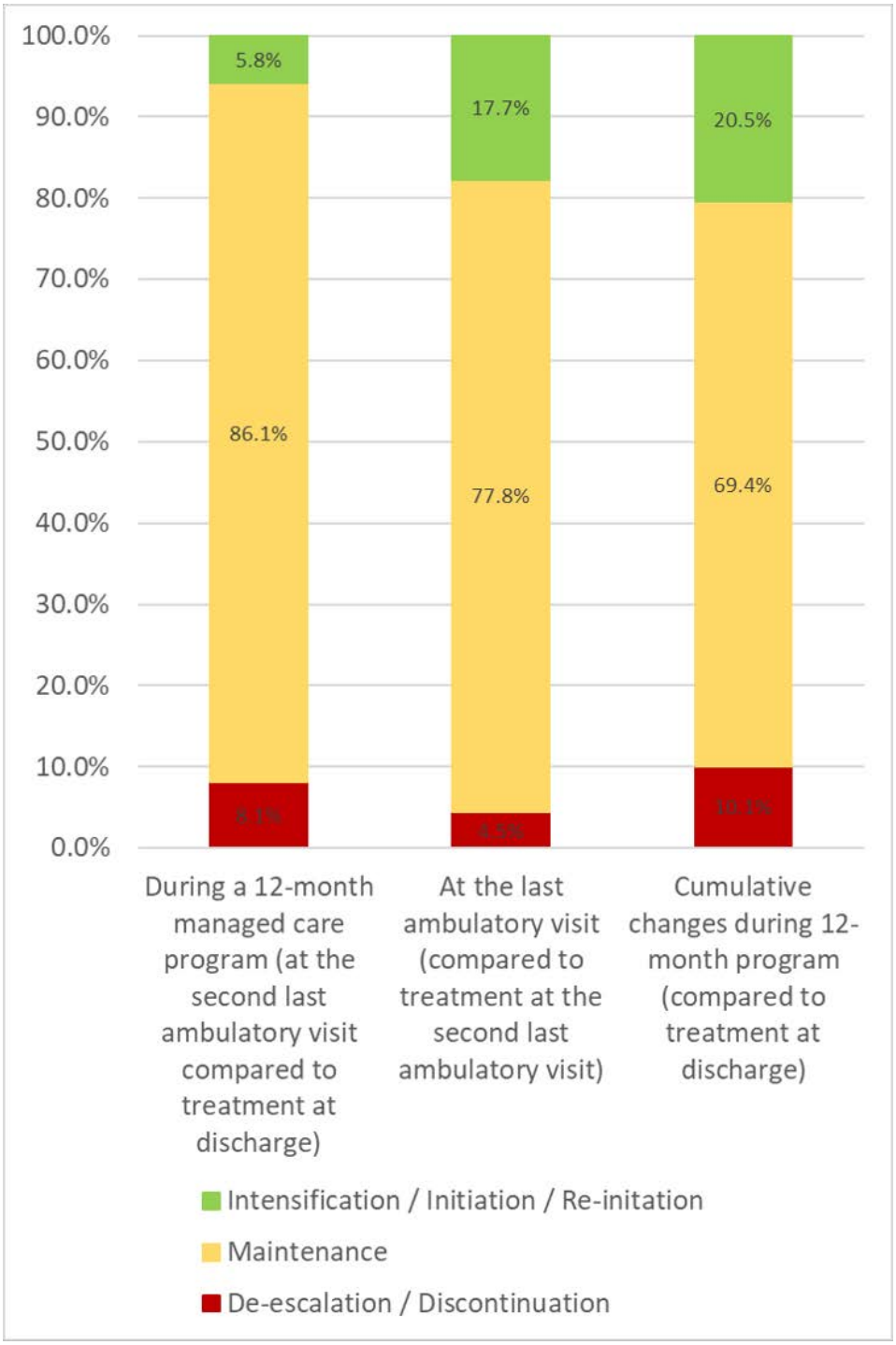



**Figure 3.** Changes in the lipid-lowering therapy during the 12-month managed care program