

CASE REPORT

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Evaluation of the Cardiovascular Risk of Patients Using Statins in a University Medical Clinic Outpatient in Belo Horizonte

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HIGHLIGHTS

What is already known?

- LDL levels are a important modifiable risk factor for cardiovascular diseases.
- In Brazil, almost 19% of the population has high LDL levels.

What was shown?

- 66% of the analyzed patients were classified as high cardiovascular risk.
- Under 10% of the patients combined different types of lipid-lowering drugs.
- Almost 70% of the analyzed patients didn't achieve the therapeutic goals.

How can the study aggregate to the literature?

- This study illustrates why therapeutic inertia must be challenged.
- Dual therapy should be encouraged.

ABSTRACT

Introduction: The primary prevention of cardiovascular diseases is a challenge in the current scenario since, despite the existence of modifiable risk factors, including low-density serum lipoprotein levels, it is estimated that in Brazil, only 58.3% of users of hypolipidemic drugs reach the recommended therapeutic targets. **Objective:** To report the current state of statin prescription in a secondary-level public clinic and the degree of control according to the cardiovascular risk of patients. **Method:** This is a cross-sectional retrospective study carried out based on data from the medical records of 170 patients using statins, where cardiovascular risk was assessed using the risk calculator of the Brazilian Society of Cardiology. **Results:** Of the 170 participants, 66% (113) were classified as “high cardiovascular risk,” of which only 65% (73) were using statins. Patients classified as “very high cardiovascular risk” accounted for 16% (28) of the participants, among whom only 69% (18) were statin users. Furthermore, 69% (117) of the total participants did not reach the intended therapeutic target. Regarding cardiovascular risk classification, there was a significant predominance of patients classified as high-risk. Additionally, it was noted that simvastatin was the most widely used statin in all categories of cardiovascular risk. **Conclusion:** The results showed that most patients using statins did not reach their therapeutic target based on their cardiovascular risk. Therefore, it is necessary to implement measures such as promoting the continued training of prescribers, motivating the use of cardiovascular risk calculation tools, reassessing patients as needed, and adjusting medications to achieve therapeutic targets.

Keywords: Cardiovascular risk; Statins; Dyslipidemias.

INTRODUCTION

The primary and secondary prevention of cardiovascular diseases (CVD) remains a significant challenge, especially in communities with low access to medical care. This is due to the influence of various factors: financial, local, infrastructure, and human resources.¹ Dyslipidemias are an important modifiable risk factor for CVD, especially regarding low-density lipoprotein cholesterol (LDL-C) levels.² In Brazil, it is estimated that 18.6% of citizens have high LDL-C levels, with only 58.3% of users of hypolipidemic drugs achieving the recommended therapeutic targets.³

Several epidemiological studies, Mendelian randomization studies, and randomized clinical trials have consistently shown a relationship between absolute changes in plasma LDL-C and the risk of developing atherosclerotic cardiovascular disease (ASCVD).⁴ The strong consistency among these studies, combined with biological and experimental evidence, provides a compelling basis for the causal association between LDL-C and ASCVD risk, indicating that reducing LDL-C decreases ASCVD risk in proportion to the absolute reduction achieved in LDL-C.⁵

Therapeutic targets are established according to the patient's risk stratification. The use of risk scores or algorithms is proposed to stratify the risk for CVD while setting therapeutic goals for the patient. The Atherosclerosis Department of the Brazilian Society of Cardiology (SBC-DA) adopts the Framingham global risk score as a reference, which estimates the 10-year risk of CVD. The SBC-DA, therefore, proposes the stratification of patients into very high risk, high risk, intermediate risk, and low risk.²

It is emphasized that the use of hypolipidemic agents, more specifically statins, constitutes a group of medications responsible for reducing LDL-C levels and, thus, decreasing the risk of atherosclerosis and CVD.

It is worth noting that statins also have other effects, called pleiotropic effects, which may lead to the stabilization of atherosclerotic plaques, support of endothelial function, and containment of vascular inflammation, factors that consequently reduce the incidence of CVD.⁶

The objective of this study is to evaluate the current state of statin prescription in a secondary-level public outpatient clinic and the degree of clinical control according to the therapeutic target based on the cardiovascular risk classification of the patients. In addition, it aims to compare the data obtained in the research with data present and dated in the bibliography, identifying and analyzing similarities and divergences between already documented statistics and those acquired.

METHODS

Study Design

This is a cross-sectional retrospective study conducted based on data from the medical records of patients using statins and monitored by the Internal Medicine specialty at a University Clinic during the year 2022. The study was evaluated and approved by the Research Ethics Committee on September 5, 2023. This study did not receive any funding from third parties.

Participants

A total of 247 medical records were collected and analyzed, with 170 individuals included after applying the inclusion and exclusion criteria, having signed the Free and Informed Consent Form (TCLE). The inclusion criteria embraced patients over 18 years of age who were prescribed statins and whose medical records contained sufficient data to calculate their cardiovascular risk. Patients under 18 years of age, those with unallocated or incomplete medical records, and individuals who refused to sign the informed consent form were excluded from the study.

Instruments

The data was obtained using a collection form developed by the researchers, which contained clinical and sociodemographic information. The form was used to organize and tabulate data, including demographic characteristics, relevant medical history, cardiovascular risk factors, and lipid profiles. Information regarding continuous medications, particularly hypolipidemic agents and dosages, was also recorded.

Procedures

Data from the medical records were reviewed and cardiovascular risk was assessed using the Brazilian Society of Cardiology (SBC) risk stratification calculator. Researchers evaluated whether each patient was within the recommended therapeutic target based on their most recent lipid profile and other relevant clinical data.

Statistical analysis

Qualitative variables were described using simple frequencies and percentages. Quantitative variables were associated with the median and interquartile range. Data were organized and analyzed using Microsoft® Office Excel.

RESULTS

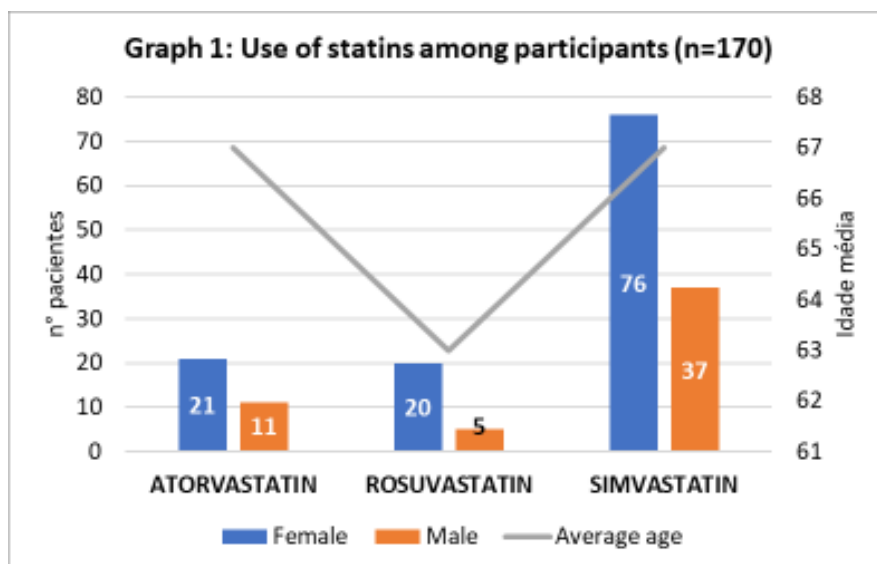
Patient Profile

During the study collection period, 247 participants using statins attended the University Outpatient Clinic, with 170 (69%) being Medical Clinic patients with an average age of 65 years (58 to 72 years). There was a significant predominance of the female gender with 117 (69%) patients compared to the male gender.

Statins Used

In the sample, outpatient prescriptions for Simvastatin, Atorvastatin, and Rosuvastatin were identified in different doses, with Simvastatin being the most used

statin, covering 113 (66%) patients, with 76 (67%) being female (Graph 1). In the second place, Atorvastatin was present in the prescription of 32 (19%) users.



Regarding other hypolipidemic agents, it was found that only 13 Medical Clinic patients were using them, with 8 (4.7%) using Fibrate, while 7 (4.1%) were using Ezetimibe in association with statin. The predominance of each statin's doses is shown in Table 1, as well as the distribution of patients using combined therapy with another hypolipidemic agent.

Table 1 – Statins and doses utilized

Medicamento	ATORVASTATIN	ROSUVASTATIN	SINVASTATIN
5mg	0 (0%)	1 (4.2%)	0 (0%)
10mg	2 (6.3%)	3 (13%)	2 (1.8%)
20mg	8 (25%)	17 (71%)	49 (43%)
40mg	18 (56%)	3 (13%)	62 (55%)
80mg	4 (13%)	0 (0%)	0 (0%)
Other hypolipidemic drug	4 (13%)	4 (16%)	5 (4.4%)
Fibrate	2 (6.3%)	3 (12%)	3 (2.7%)
Ezetimibe	2 (6.3%)	3 (12%)	2 (1.8%)

Comorbidity Profile

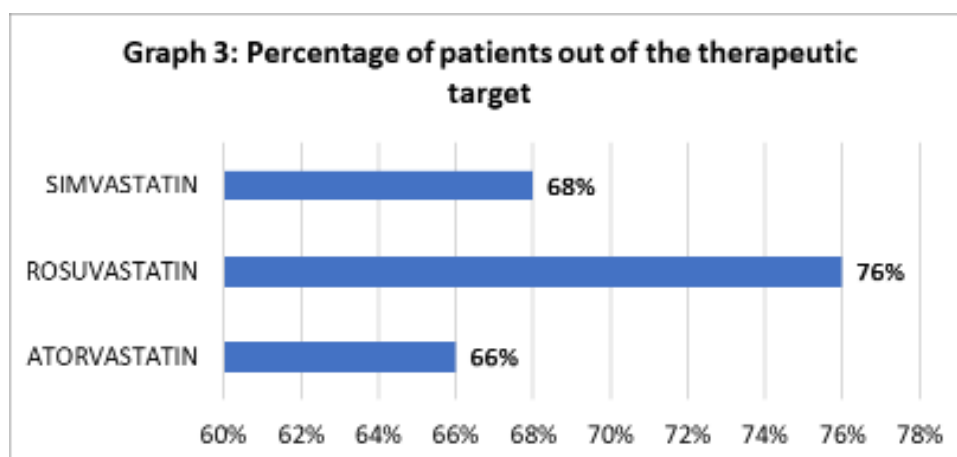
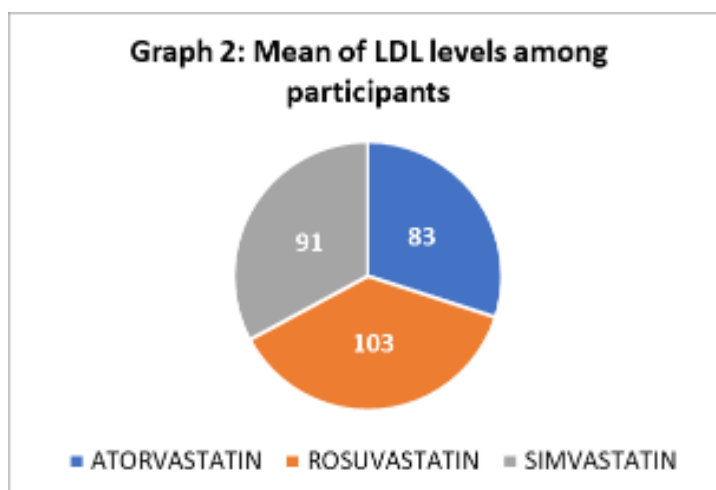
In addition to dyslipidemia, it was possible to identify the presence of other risk factors for cardiovascular diseases (CVD) in our sample, such as hypertension, diabetes mellitus, current smoking, physical inactivity, and obesity. Among the Medical Clinic patients, 159 (94%) were hypertensive, 85 (50%) had diabetes mellitus, and 21 (14%) reported being active smokers. Regarding body weight, 59 (81%) patients were overweight or obese when evaluated during the outpatient consultation. Concerning previous history, 19 (11%) reported having had a previous acute myocardial infarction (AMI), while only 10 (5.9%) reported a history of stroke. Finally, 17 (10%) participants stated they had a diagnosis of heart failure (HF), while 20 (12%) already had some de-

gree of chronic kidney disease (CKD) based on the TFG calculation by the Brazilian Society of Nephrology (SBN) calculator. The prevalence of a family history of AMI or stroke was 43%, reported by 57 patients, respectively.

Cardiovascular Risk and Therapeutic Target

Regarding the cardiovascular risk (CVR) stratification of the interviewees, there was a significant predominance of patients classified as high cardiovascular risk based on the SBC calculator, equivalent to 113 (66%) users of the Medical Clinic sample, with 73 (65%) using Simvastatin. In second place were patients stratified as very high cardiovascular risk, comprising a group of 28 (16%) participants, with 18 (69%) using Simvastatin. Patients identified as intermediate and low risk accounted for 14% and 2.9% of the respondents, respectively.

It is extremely important to establish therapeutic targets for patients according to their cardiovascular risk as a way to reduce the incidence of cardiovascular events and increase survival. In this regard, it was possible to analyze that 117 (69%) users did not reach the expected therapeutic target, with 77 (65%) of them using Simvastatin. The proportion of patients outside the therapeutic target, considering the LDL levels found and the statin used, is detailed in Graphs 2 and 3, respectively.



Regarding the cardiovascular risk classification among users of each type of statin, it can be observed that there was a prevalence of Simvastatin in all CVR categories compared to Atorvastatin and Rosuvastatin, as shown in Graph 4.

DISCUSSION

The predominant profile of patients using statins in this study is composed of hypertensive women in the age range of 65 years, with a significant number of patients also having diabetes, being sedentary, alcohol consumers, and smokers, which translates into a predominance of high (66%) or very high (16%) cardiovascular risk classification. Most of these patients (69%) are outside the therapeutic target for LDL levels according to their cardiovascular risk, with the majority of the total sample using Simvastatin (66.4%).

The large number of patients using Simvastatin may be related to its availability in the Brazilian public health system and the higher tendency of initial prescriptions by attending physicians. However, recent studies on cardiovascular event prevention show that in higher-risk individuals, the use of high-potency statins should be prioritized over starting treatment with lower doses or less potent drugs.⁷

The therapeutic approach changes that could be analyzed in the medical records occurred exclusively in the group of patients using low-potency statins, but they were discrete, highlighting the need for greater intensification of treatment in these patients.

On the other hand, most patients with inadequate LDL levels found in the study are in the group of patients using rosuvastatin, a high-potency statin, which may be related to factors such as its unavailability in the public system, the high cost leading to low adherence to treatment, and inadequate dose adjustments in treatment, as only 13% of patients use the medication at its maximum dosage. Additionally, several

studies unanimously recommend the use of drugs such as Ezetimibe and PCSK9 inhibitors to achieve the therapeutic target in high or very high-risk patients.⁹⁻¹⁰ However, these drugs still have a high cost and are not yet accessible in the public health system, which explains the underutilization among the analyzed patients, in addition to greater discontinuation and low adherence to treatment.

Overall, 31% of the patients analyzed in the study were within the therapeutic target for dyslipidemia. In comparison with the reality of Brazilian healthcare, the EPICO study, conducted in 32 cities in the state of São Paulo, showed that only 14% of patients with dyslipidemia using statins achieved the therapeutic target for LDL levels in their treatments. However, it is worth noting that this study was conducted based on primary care data, with a lower proportion of high cardiovascular-risk patients in its analysis. In another cross-sectional study conducted in Brazil with patients with a history of acute myocardial infarction, it was found that 31% of patients were within the therapeutic target for LDL cholesterol, a number similar to our research, with significant underutilization of other available therapies in this patient profile.¹¹ In comparison with other countries, a study conducted by the European Society of Cardiology found that 43.9% of European patients with dyslipidemia are within the therapeutic target, which demonstrates a significant potential for improvement in the approach to dyslipidemia in the Brazilian population.¹²

The number of patients outside the therapeutic target may also indicate a difficulty in adherence to treatment. Factors such as recent initiation of medication use, a higher number of comorbidities, low education level, and low socioeconomic status are more commonly related to poor therapeutic adherence.¹³ On the other hand, some authors attribute poor adherence to a failure in risk perception by the

patients themselves in the Brazilian population, with even those with a higher level of education demonstrating a lack of knowledge about the importance of controlling cholesterol levels and their therapeutic targets.¹⁴

According to the DA VINCI study, there is a global underutilization of the combination of available therapeutic resources. Although the use of statins is the first line of treatment for dyslipidemias, it is noted in the present study that less than 10% of patients use other hypolipidemic agents concomitantly with statins, demonstrating a problem in the treatment of these patients.¹⁵

This issue could be explained by the economic limitation demonstrated by the patients in this study, all of whom come from the Unified Health System (SUS), as they historically belong to a less affluent class, and few hypolipidemic medications are offered free of charge by SUS. However, an Irish study showed similar numbers, with only 8.5% of patients using combined ezetimibe, for example, raising suspicion that non-economic factors have a determining impact on the ineffective prescription for LDL control.¹⁶

Another possible explanation for the inadequacy of patients' LDL levels concerning their targets would be therapeutic inertia on the part of prescribers. Therapeutic inertia is characterized by the failure of the attending physician to initiate or intensify treatment when the therapeutic target has not been achieved.¹⁷ It was observed that in 83% of cases, there were no changes in statin prescriptions when the therapeutic target was not reached; however, it was not possible to analyze the subsequent conduct adopted in all medical records, constituting a limitation of the study.

In an observational study conducted in Spain, it was shown that in the management of dyslipidemia, phy-

sicians generally do not pay attention to the existence of fundamental cardiovascular risk factors for establishing the therapeutic target. Thus, it was found that in many situations, the isolated analysis of total cholesterol or HDL levels is used as a form of evaluation for dyslipidemia treatment. This may translate, in clinical practice, into hypolipidemic prescriptions without the correct calculation of the patient's cardiovascular risk and their cholesterol level targets. Thus, therapeutic inertia becomes a common problem in various patient profiles, regardless of their cardiovascular risk classifications, with a significant difference in the physician's subjective perception of dyslipidemia treatment compared to its real effectiveness.¹⁸

It is noteworthy that in another study conducted in the Netherlands to demonstrate the effects of rapid and progressive intensification of dyslipidemia treatment in very high-risk patients, the results indicated the achievement of ideal targets in more than 80% of cases with a more active approach.¹⁹⁻²⁰

Limitations

It is important to state that this study is based on data from a single secondary care facility in Brazil, and its population may not represent broader populations, such as patients from other regions, hospitals, or healthcare settings with different standards of care, and its results may not be generalizable. Furthermore, potential selection bias may arise from the exclusion of incomplete or missing medical records, which could limit the representativeness of the study population.

Additionally, the study type and design present intrinsic limitations, not being able to objectively evaluate factors such as medication adherence, lifestyle, and socioeconomic status, since its results rely on pre-existing data from medical records, which are not always complete. Moreover, as a cross-sectional study, it does not allow for the assessment of changes in cardiovas-

cular risk or treatment effectiveness over time. For this reason, more studies should be conducted in other centers with different designs, to evaluate lipid-lowering treatment prescribing patterns concerning the population's cardiovascular risk.

CONCLUSION

In the University Medical Clinic Outpatient, it was observed that 69% of patients were outside the therapeutic targets proposed by the SBC through cardiovascular risk stratification. However, the statistical analysis of this research revealed that this is a problem not only in Brazil.

With this study, the need to implement cardiovascular risk calculation tools more significantly, as well as to promote the continued training of prescribers, is highlighted, aiming to reduce the subjective perception of therapeutic targets. In this sense, the objective is to avoid the maintenance of prescribed therapy without being effective in reducing cardiovascular outcomes.

Simultaneously, efforts to reduce therapeutic inertia should be undertaken, as this has proven to be a pertinent problem in the study. In only 17% of cases, there was a change in conduct, even with the low number of patients within the stipulated target, a value that suggests a significant potential for improvement in reducing cardiovascular events through the reduction of LDL levels.

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