JOURNAL OF NUTRITION COLLEGE
Volume 15, Nomor 1, Tahun 2026, Halaman 41-49
Received: 13 Maret 2025, Revised: 24 Juli 2025
Accepted: 23 September 2025, Published:30 Januari 2026
Online di: http://ejournal3.undip.ac.id/index.php/jnc/ , DOI:10.14710/jnc.v15i1.49366

IMPACT OF STATIN THERAPY ON LDL REDUCTION AND ITS NUTRITIONAL IMPLICATIONS: A SYSTEMATIC REVIEW

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ABSTRACT

***Background*:** *Elevated low-density lipoprotein (LDL) cholesterol is a major contributor to cardiovascular disease risk. Statins are widely prescribed as a first-line treatment to lower LDL levels, although treatment outcomes can vary based on drug combinations and the patient's nutritional status.*

Objective: *This review aims to systematically assess the effectiveness of statin therapy in lowering LDL cholesterol and to explore the potential benefits of combination treatments and the role of nutrition in enhancing therapeutic outcomes.*

Methods*: A systematic review was conducted using the PRISMA guidelines. Literature searches were performed on PubMed for the period between 2019 and 2024, focusing on clinical trials, randomized controlled trials, and meta-analyses involving human subjects. After screening and eligibility assessments, seven studies were included in the final analysis.*

Results: *Statins were consistently found to reduce LDL cholesterol and lower the risk of cardiovascular events. Combination therapies, including statins with ezetimibe, omega-3 fatty acids, or fenofibrate, yielded superior outcomes compared to monotherapy. Rosuvastatin demonstrated greater LDL-lowering potential than atorvastatin, though with a slightly increased risk of diabetes. Moreover, nutritional factors—such as adequate fiber intake, healthy fats, and micronutrients like vitamin D and magnesium—were shown to support and potentially enhance the effectiveness of statin treatment.*

Conclusion: *Statin therapy, whether used alone or in combination with other agents, is effective in managing LDL cholesterol and preventing cardiovascular disease. Integrating pharmacological treatment with personalized nutritional strategies may further improve therapeutic success and long-term health outcomes in patients with dyslipidemia.*

Keywords: *LDL cholesterol; statins therapy; nutrition impact*

INTRODUCTION

Low-Density Lipoprotein (LDL) plays a central role in transporting cholesterol throughout the body's tissues and blood vessels.(1) Often labeled as "bad cholesterol," LDL has a tendency to adhere to arterial walls, which can result in fat buildup and narrowed arteries—commonly referred to as atherosclerosis.(1) Elevated LDL levels are associated with plaque formation, obstructing blood flow and heightening the risk of cardiovascular events. Ideally, LDL cholesterol should be maintained below 100 mg/dL.(2) On the other hand, High-Density Lipoprotein (HDL), or "good cholesterol," assists in the removal of cholesterol from the bloodstream. Estrogen is a hormone that helps sustain high HDL and lower LDL levels.(3)

Statins are widely prescribed to manage dyslipidemia. These drugs act by blocking the enzyme HMG-CoA reductase (3-Hydroxy-3-Methylglutaryl-Coenzyme A), a key component in the synthesis of cholesterol and other essential non-sterol isoprenoids within the endoplasmic reticulum.(4,5) Common examples of statins include simvastatin, atorvastatin, and pravastatin. As first-line agents, statins are used to decrease LDL cholesterol and to prevent both the initial and recurring onset of cardiovascular diseases by limiting atherosclerotic plaque development.(4)

Based on the latest guidelines from the ACC/AHA, around 156 million Americans between the ages of 40 and 75 are eligible for statin treatment, reflecting its prevalent use.(6) However, despite their proven benefits, many statin users in clinical studies continue to face considerable residual cardiovascular risk. In some cases, excessive dosing may also lead to side effects. Furthermore, statins do not effectively target all atherogenic lipoproteins, such as lipoprotein(a) and other harmful variants.(7) While statins are vital in dyslipidemia management, their therapeutic benefits may be enhanced by

incorporating nutritional strategies. Nutrients such as dietary fiber, healthy fats, and certain micronutrients have demonstrated positive effects on lipid profiles and cardiovascular health.[7]

Accordingly, this review seeks to examine how effective statins are in lowering LDL cholesterol and to investigate how specific dietary components may improve their therapeutic outcomes. By bridging insights from pharmacology and nutrition, this study aims to support a more integrative approach to dyslipidemia treatment and cardiovascular risk reduction.

METHODS

We followed the Preferred Reporting Items for Systematic Review and Meta-Analysis (PRISMA) guidelines outlined by Liberati et al. in 2009 to ensure these systematic reviews' rigor and methodological soundness. These guidelines offered a structured approach crucial for maintaining high reporting and transparency standards throughout the review process. Utilizing the PRISMA framework, we crafted a comprehensive search strategy to identify all relevant studies within our scope. This carefully designed strategy enhanced the reliability and replicability of our findings.

An extensive literature search was conducted across leading academic databases via the PubMed search engine, covering studies published between 2019 and 2024. To capture a wide range of relevant research, search terms such as "LDL levels" and "statin drug therapy" were employed. After selecting studies that met the inclusion criteria, data were extracted using a standardized data collection form. Key information gathered from each study included the author(s), year of publication, characteristics of the study population, details of the intervention, measured outcomes, and study design. This organized and methodical process ensured the inclusion of a representative set of studies and supported a comprehensive synthesis of the current body of evidence.

CRITERIA

Only studies that met the following criteria were included in this review: they involved human participants, applied recognized research methodologies (including clinical trials, meta-analyses, or randomized controlled trials), and were published in English. The inclusion was limited to English-language publications to maintain consistency in analysis and because English is the dominant language used in international scientific literature. Thus, we shall assess the correlation between LDL levels and statin medication. After removing duplicates, the authors independently assessed the publication titles, abstracts, and methodologies. Studies that satisfied the necessary criteria were included in the final analysis after the researchers evaluated the remaining publications' complete texts in the second step. Information about the author, the research nation, the technique used to measure LDL levels, statin medication therapy, and the therapeutic mechanism of statin medication.

"A Systematic Review of Statin Therapy Effectiveness in Reducing LDL Levels"
Key word: *ldl levels, statin drug therapy*

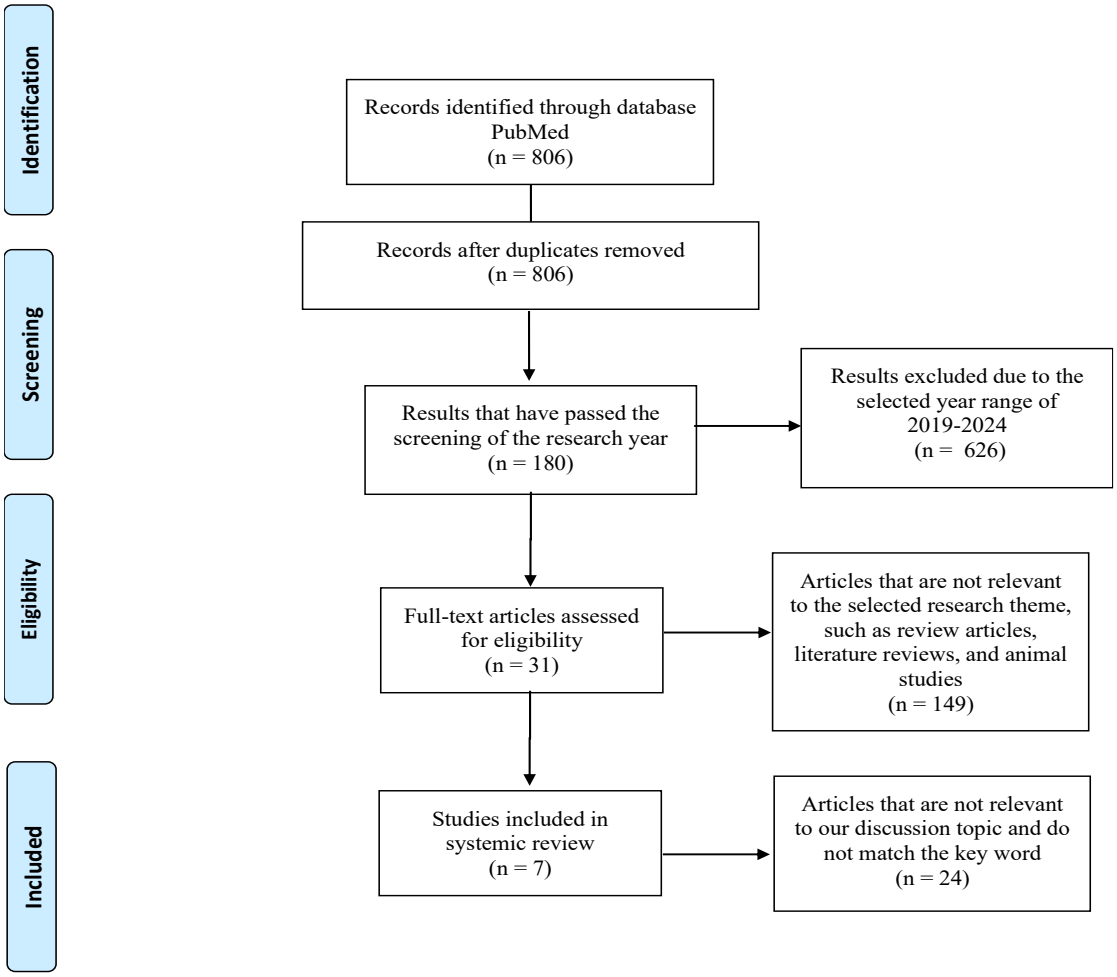

Figure 1. Preferred Reporting Items for Systematic Reviews (PRISMA) chart for systematic review

RESULTS

The initial search process was comprehensive, producing many studies entered into the search engine for further review. To refine this substantial collection, we applied a strict filter to exclude articles outside our predefined year range of 2019 to 2024. This filtering step was essential in narrowing the dataset to a more manageable 180 articles for the initial screening phase. Each article underwent a preliminary assessment during this phase to determine its relevance to our research objectives. This assessment involved a quick review of the abstracts and titles to ensure the studies met the primary inclusion criteria established at the start of our research process. As a result of this initial screening, we identified 31 studies that warranted a more thorough evaluation of their full texts to determine their eligibility.

In the subsequent, more detailed review, we closely examined the full texts of these 31 studies. This thorough evaluation revealed that many of these studies, totaling 149, needed to align with the specific research theme we were investigating. These excluded studies encompassed a variety of article types, including review articles, literature reviews, and research focused on animal models, which were outside the scope of our study. Additionally, as we delved deeper into the content of these studies, we found that 24 of them did not match the specific keywords used in our search strategy. Upon further analysis, they needed to be more relevant to our discussion focus. This meticulous process of elimination and selection was essential to ensure the integrity and relevance of our systematic review. Ultimately, after these rigorous screening and evaluation processes, we successfully identified seven studies that met all the criteria and were deemed suitable for inclusion in our systematic review, thus providing a solid foundation for our subsequent analysis and discussions

Table 1. The Relevant Studies Of Statin Therapy Effectiveness In Reducing LDL Levels

NO	AUTHOR'S NAME	RESEARCH METHODS AND POPULATION	RESEARCH RESULT
1	Junya Ako, Koutaro Yotoke, Kenichi Tsujita, Ryohei Tanigawa, Ryo Kamei, Hideki Suganami, et. al (2024)	Phase III, multicenter, open-label Trial (n = 109)	Pitavastatin monotherapy was substituted, and K-924 showed good and bearable results for 52 weeks. K-924 may improve LDL-C lowering therapy without requiring an increase in medication dosage. A significant decrease in LDL-C of -30.3±14.3%, with p<0,001, was seen in research involving 109 patients.
2	Masashi Sakuma, Satoshi Limuro, Tomohiro Shinozaki, et al (2022)	REAL-CAD Trial (n = 11,105)	Based on log-likelihood, the optimal model for the primary outcome, which includes cardiovascular death, nonfatal myocardial infarction, nonfatal ischemic stroke, and unstable angina necessitating emergency care, was identified at the LDL-C threshold of 70 mg/dl. For every 10 mg/dL rise in LDL/C, the hazard ratio in models with an LDL-C threshold of > 70 mg/dl is 1,07 (95% CI: 1,01-1,13). A progressive reduction in the risk of cardiovascular events occurs until the LDL-C level reaches 70 mg/dl. Lowering LDL-C to less than 70 mg/dl eliminates the association between higher LDL-C levels and the risk of cardiovascular disease.
3	Yasuhiro Nakano, Mitsutaka Yamamoto, Tetsuya Matoba, at.al (2022)	The CuVIC trial (n = 79)	Following the treatment period, the S+E group's low-density lipoprotein cholesterol (LDL-C) levels were considerably lower than those of the S group (80.9 ± 3.7 vs. 67.7 ±3.8 mg/dl, p = 0.0143). Both oxysterol (β-epoxy cholesterol, 4β-hydroxycholesterol, and 27-hydroxy cholesterol) and cholesterol, a measure of cholesterol absorption, decreased in the S+E group. According to IVUS analysis, plaque regression in the S+E group was higher than in the S group (-6.14% vs. -1.18% in each group, p = 0.042). A substantial positive link exists between a reduction in LDL-C, a drop in campesterol and 27-hydroxy cholesterol, and plaque regression.
4	Ji Eun Jun, In-Kyungg Jeuang, Jae Myung Yu, et.al (2020)	randomized, double-masked, placebo-controlled, parallel-group, and phase III multicenter (n=103)	Compared to ATOMEFA, the initial TG decreases in this group were more significant (-29.8% vs. 3.6%, P<0,001), and the ATOMEGA group achieved TG <200 mg/dL more successfully than the atorvastatin group (62.9% vs. 22.3%, P <0,001). This group experienced a higher initial TG change (-29.8% vs. 3.6%, P<0,001), and ATOMEGA achieved TG <200 mg/dL more successfully than atorvastatin (62.9% vs. 22.3%, P <0,001). When compared to atorvastatin, this group demonstrated better TG accomplishments <200 mg/dL (62.9% vs. 22.3%, P <0,001) and larger initial TG changes (-29.8% vs. 3.6%, P <0,001). In comparison to atorvastatin, the ATOMEGA group was more successful in obtaining TG <200 mg/dL (62.9% vs. 22.3%, P <0,001), and the early decreases in TG were higher in this group (-29.8% vs. 3.6%, P <0,001).
5	Yong-Joon Lee, Sung-Jin Hong, Woong Chol Kang, et.al (2023)	LODESTAR trial (n=4400)	Adults with random coronary artery disease, n=2204, received rosuvastatin, n=2196 atorvastatin. p<0,001 for the decrease in LDL, significant. Rosuvastatin showed a more significant decrease in LDL but with a higher risk of new diabetes than atorvastatin.

Table 1. 1 The Relevant Studies Of Statin Therapy Effectiveness In Reducing LDL Levels (Continue…)

NO	AUTHOR'S NAME	RESEARCH METHODS AND POPULATION	RESEARCH RESULT
6	Sang-Hyun Ihm, Woo-Baek Chung, Jong-Min Lee (2020)	multicenter, randomized, double-masked, parallel-group, therapeutic-confirmatory clinical Trial (n = 347)	The total number of subjects for combination therapy is 174, and monotherapy is 173. The P value shows statistical significance on various parameters. Average changes in LDL-C from the beginning to week 8 were significant, with P <0,001 for combination therapy and P <0,01 for monotherapy in week 4 (p <0,01) and week 8 (p<0,01).
7	Dirk J. Blom, Wael Almahmeed, Khalid Al-Rasadi, Joseph Azuri, Veronique Daclin, Meral Kayikcioglu, Florence Mercier, Alvaro J. Ruiz, Raul D. Santos (2019)	Cross-sectional observational study (n=334)	The LDL-C target is met by 32% of patients. 36.6% of people with coronary artery disease achieved the LDL-C target. 27% of patients without coronary artery disease achieved the LDL-C target. 27.9% of patients who received statins and CAIs achieved their LDL-C targets. 28% of patients who received the highest dose of statins (without CAI) achieved the LDL-C target. The LDL-C target was achieved by 37.5% of patients treated with low-dose statins (without CAI).

The first journal article reports significant findings about the safety and effectiveness of the drug pravastatin K-924.[8] As per the study results, the administration of pravastatin K-924 causes a substantial decrease in the level of cholesterol lipoprotein LDL-C in the blood.[8] This decrease is maintained throughout the treatment period, indicating the effectiveness of pravastatin in lowering LDL-C levels.[8] In addition, pravastatin K-924 raises high-density lipoprotein (HDL-C) levels in a few patients.[8] However, the range of increases varies across individuals.[8] Regarding safety, the sampling effect reported by pitavastatin K-924 is often mild to moderate, with a severe sampling effect that is slow and does not exhibit any side effects that can be directly linked to medication use.[8]

According to observations, long-term pitavastatin K-924 medication did not significantly impair liver function.[8] According to the study, pitavastatin K-924 has a tolerable safety profile for long-term usage and is very effective at raising HDL-C levels and decreasing LDL-C levels.[8]

Sakuma et al. conducted a second trial to investigate the impact of statin medications on controlling low-density lipoprotein levels and cardiovascular events.[9] The research is a follow-up examination of the REAL-CAD experiment's 11,105 coronary artery disease participants.[9] The results show that in Japanese patients with stable CAD, high dosages of pitavastatin (4 mg/day) significantly lower the risk of cardiovascular events when compared to low doses (1 mg/day).[9] According to another research, lowering LDL-C levels to roughly 70 mg/dL regularly reduces the risk of cardiovascular disease; however, lowering levels below this threshold has no appreciable extra advantages.[9]

In the third study, Nakano and colleagues examined the effect of intensive lipid-lowering therapy using statins, both as monotherapy and in combination with ezetimibe, on reducing coronary plaque volume.[10] This study was part of a CuVIC trial subgroup, a prospective, open, blinded endpoint study involving 260 patients with coronary artery disease undergoing coronary stenting procedures.[10] Of this population, 79 patients (39 in the statin group and 40 in the statin and ezetimibe combination group) received serial intravascular ultrasound (IVUS) images of non-culprit lesions at the beginning and after a 6-8 month follow-up period.[10] The results showed that the group that received the combination of statin and ezetimibe had significantly lower levels of low-density lipoprotein (LDL-C) cholesterol compared to the group that received statins alone (67.7 ± 3.8 mg/dL versus 80.9 ± 3.7 mg/dL, p = 0.0143).[10] In addition, cholesterol absorption markers such as campesterol and oxysterol (β-epoxycholesterol, 4β-hydroxycholesterol, and 27-hydroxycholesterol) were also lower in the combination group.[10] IVUS analysis showed a more significant plaque volume reduction occurred in the combination group compared with the statin monotherapy group (−6.14% vs. −1.18%, p=0.042).[10] Decreased levels of campesterol and 27-hydroxycholesterol had a significant positive correlation with reduced plaque volume, while decreased LDL-C did not show a significant correlation.[10]

The fourth study demonstrated that statin medications can significantly lower LDL levels in patients at risk for cardiovascular disease.[11] In this study, patients with mixed hyperlipidemia were given a combination of statins and omega-3 fatty acids (OM3-FAs) [11]. Using a randomized, double-masked, placebo-controlled design, the Trial included adults whose LDL levels were less than 110 mg/dl, and whose fasting triglyceride levels were between 200 and 500 mg/dL.[11] The findings demonstrated that, compared to atorvastatin alone, combining OM3-FAs with atorvastatin considerably decreased triglyceride and non-HDL-C levels.[11] Even in cases where LDL levels are under control, the results emphasize the significance of considering additional cardiovascular risk factors, such as elevated triglyceride levels.[11]

In the fifth study enrolling 4,400 adult patients with coronary artery disease was an open-label, randomized experiment conducted across many centers.[12] The participants were split into two groups: 2,444 received rosuvastatin, while the remaining received atorvastatin.[12] According to the findings, the rosuvastatin group's average LDL cholesterol levels during therapy were lower than those of the atorvastatin group (1,8 mmol/L vs. 1,9 mmol/L).[12] In terms of all-cause death, myocardial infarction, stroke, or coronary revascularization, both medications had the same level of efficacy during three years. Nevertheless, atorvastatin is more likely than rosuvastatin to.[12]

In the sixth study, Pitavastatin's effectiveness and tolerance were compared to the combination of pitivastatin and phenofibrate.[13] The trial involved patients who had received pitavastatin alone as a pre-treatment and was carried out at many centers using random, double-masked, and parallel designs.[13] Apolipoprotein, fibrinogen, and highly sensitive C-reactive protein were among the other lipid profile abnormalities that were more pronounced in the combination group.[13] Furthermore, the safety profile of this combination medication was comparable to that of pitavastatin monotherapy and it demonstrated good tolerance.[13]

The seventh study showed that was still low even though they had received intensive lipid

modification therapy (LMT).[14,15] Of the 334 patients who participated, only 32% achieved their LDL cholesterol targets.[14,15] Patients taking high-dose statins or a combination of statins with cholesterol absorption inhibitors (CAIs) showed slightly higher target achievement rates than those taking lower-dose statins without CAI.[14,15] High basal LDL-C levels, insufficient statin doses, and low use of CAIs are some causes of low LDL-C target achievement.[14,15] Proprotein convertase subtilisin/kexin type 9 (PCSK9) inhibitor therapy may be appropriate for most patients.[14,15]

DISCUSSION

This systematic review examines the effectiveness of statin therapy in lowering LDL cholesterol levels and the benefits of combination treatments. Findings suggest that using statins with ezetimibe or Omega-3 fatty acids reduces LDL more effectively than statin monotherapy. Rosuvastatin appears to be more effective than atorvastatin in lowering LDL levels. However, some studies have limitations, such as small sample sizes and variations in research methods, which may affect consistency. Despite these factors, the results provide valuable insights for optimizing cholesterol-lowering strategies.

Statins work by inhibiting HMG-CoA reductase, reducing cholesterol production, and increasing LDL receptor activity in the liver. Ezetimibe complements this by blocking cholesterol absorption in the intestine, leading to a greater LDL reduction. Omega-3 fatty acids also enhance lipid regulation by lowering triglycerides and improving LDL receptor function. Studies show that combining these therapies leads to better outcomes in managing cholesterol and reducing plaque buildup compared to monotherapy.

A combination of pitavastatin and fenofibrate is particularly effective for managing mixed dyslipidemia in high-risk cardiovascular patients. Pitavastatin lowers LDL cholesterol, while fenofibrate activates PPARα, improving fatty acid oxidation and lipid metabolism. This combination reduces non-HDL cholesterol, triglycerides, and inflammation while increasing HDL levels, providing a more comprehensive approach to cardiovascular risk reduction.

For patients with familial hypercholesterolemia or inadequate LDL control with statins alone, combining statins with cholesterol absorption inhibitors like ezetimibe offers greater LDL reduction. Large studies, such as REAL-CAD, highlight the importance of achieving lower LDL targets to reduce cardiovascular risks. Overall, this review reinforces the role of statins as essential in lipid management and highlights the benefits of combination therapy in optimizing cardiovascular health outcomes.

Recent evidence highlights that although statins are effective in reducing LDL cholesterol, dietary factors significantly contribute to enhancing their therapeutic outcomes. Statins act by blocking the enzyme HMG-CoA reductase, which plays a central role in the liver's cholesterol production pathway, thereby lowering endogenous cholesterol levels.[16] Simultaneously, consuming a diet high in dietary fiber and low in saturated fat has been shown to amplify the cholesterol-lowering effects of statins.[16] Fiber aids in reducing LDL cholesterol by binding to bile acids in the gastrointestinal tract, promoting their excretion, and stimulating the liver to utilize more cholesterol to produce new bile acids.[11,16] Moreover, the inclusion of omega-3 fatty acids (OM3-FAs) in the diet has demonstrated additional benefits by lowering triglyceride levels and improving lipid metabolism.[10] Taken together, these findings underscore the potential benefits of integrating statin therapy with strategic dietary adjustments to improve cardiovascular health outcomes.

While statins are essential for lowering LDL cholesterol, nutrition also plays a vital role in enhancing their effectiveness. A balanced diet with healthy fats and proper supplementation can further improve patient outcomes.[9] Studies suggest that increasing fiber intake and reducing saturated fats not only support statin therapy but also help minimize potential side effects.[12]

Furthermore, some studies highlight that patients with adequate nutritional intake, particularly antioxidants and essential micronutrients like vitamin D and magnesium, tend to respond better to statin treatment.[13] Nutrient deficiencies may negatively impact lipid metabolism and the body's ability to benefit from statins. Vitamin D helps regulate cholesterol synthesis and may enhance the expression of LDL receptors in the liver, improving LDL clearance.[17] Magnesium acts as a cofactor for enzymes involved in lipid regulation and supports proper muscle and nerve function, potentially reducing statin-related side effects like myopathy.[18] Antioxidants such as vitamin E and selenium help reduce oxidative stress, which contributes to atherosclerosis and may interfere with lipid-lowering pathways.[19,20] Therefore, considering nutritional factors as part of a comprehensive approach to managing dyslipidemia is crucial for optimizing treatment outcomes.

Building on this evidence, a growing body of literature emphasizes the broader physiological mechanism through which nutrition interacts with statis therapy, reinforcing the need for combined approach. Nutritional status plays a crucial role in

the effectiveness of statin therapy, as adequate intake of antioxidants and essential micronutrients like vitamin D and magnesium supports lipid metabolism, reduces inflammation, and enhances overall cardiovascular health. Antioxidants help combat oxidative stress and improve endothelial function, while vitamin D and magnesium serve as cofactors in key metabolic pathways and may reduce statin-related side effects such as muscle pain. Conversely, nutrient deficiencies can impair the body's ability to respond optimally to statins, diminishing their lipid-lowering effects and increasing the risk of adverse reactions. Therefore, addressing nutritional factors is essential for optimizing treatment outcomes in dyslipidemia management.

CONCLUSION

The reviewed studies confirm that statins, whether used alone or with other medications, effectively lower LDL cholesterol and reduce cardiovascular risk. Research highlights that pitavastatin and rosuvastatin significantly decrease LDL levels while maintaining a strong safety profile. Additionally, combining statins with ezetimibe enhances cholesterol reduction and improves heart health. Large studies like REAL-CAD show that achieving lower LDL targets is linked to reduced mortality in coronary artery disease patients, emphasizing the importance of statins and combination therapy in preventing heart disease.

To optimize treatment, personalized nutritional planning should be integrated into statin therapy. A combination of medication and dietary modifications can enhance long-term health outcomes, making it a key strategy in managing dyslipidemia and reducing cardiovascular disease risk.

SUGGESTIONS FOR FURTHER RESEARCH

1. Evaluating the Synergy Between Statins and Dietary Patterns:
   Further investigation is required to determine how specific dietary approaches, such as the Mediterranean or DASH diet, can optimize the LDL-lowering effects of statin therapy.
2. Micronutrient Influence on Statin Effectiveness:
   Future research should examine how micronutrients like vitamin D, magnesium, and antioxidants contribute to improving statin efficacy while minimizing potential adverse effects.
3. Effects of Omega-3 Supplementation in Statin Users:
   Additional studies are needed to validate the impact of omega-3 supplementation on lipid metabolism in individuals undergoing statin therapy, particularly those with elevated triglyceride levels.[11]
4. Nutritional Status as a Determinant of Statin Therapy Outcomes:
   Observational studies or clinical trials should assess the impact of a patient's initial nutritional status on the success of statin therapy, particularly in populations at higher risk.

ACKNOWLEDGEMENTS

The author sincerely thanks Universitas Santo Borromeus for the facilities and opportunities that greatly supported the writing of this journal. Deep appreciation is also conveyed to all lecturers of the Faculty of Health Sciences, Bachelor's Program in Nutrition Science, for their guidance, support, and valuable insights. The author is also truly grateful to fellow colleagues whose constant encouragement, support, and help played a vital role in the successful completion of this journal.

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