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# Expert Opinion on the Prescription Practice of Statins in Lipid Management with a Specific Focus on Rosuvastatin Use in Indian Settings

## Research Article

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### Abstract

**Objective:** The present survey-based study aims to gather the clinicians' perspective regarding the prescription patterns of statins with a specific focus on the rosuvastatin for effective lipid management in comorbid conditions in Indian settings.

**Methodology:** The cross-sectional survey gathered expert opinions using a 24-item, multiple-response questionnaire related to current feedback, clinical observations, and specialists' clinical experiences on lipid management, statins use, and prescription patterns of rosuvastatin.

**Results:** Fifty-three percent of clinicians noted that 20-30% of patients with dyslipidemia require combination therapy with statins. Moreover, 71% of clinicians recommended initiating statin therapy in patients with comorbidities such as diabetes or hypertension. Nearly 58% of clinicians agreed to the ACC/AHA 2019 lipid guidelines recommending the administration of the maximum tolerated dose of statins in individuals with LDL-C levels >190 mg/dl. Most clinicians recommended prescribing rosuvastatin for hyperlipidemia patients with hypertension or diabetes, and it was also the preferred statin for dyslipidemia patients. The 10 mg dosage was favored among those with diabetes, while the 20 mg dosage was recommended for patients with cardiovascular disease. Combinations of rosuvastatin and fenofibrate effectively reduced LDL/TG/hs-CRP, increased HDL, and decreased the risk of CVD. Clopidogrel was preferred to combine with rosuvastatin, and 20-30% of patients may have required this combination. The recommended duration of therapy for rosuvastatin + clopidogrel + aspirin in high CV-risk patients was 6-12 months.

**Conclusion:** The survey highlighted clinicians' preferences for combination statin therapy in dyslipidemia, emphasizing early initiation in patients with diabetes or hypertension. Rosuvastatin emerged as the preferred choice, with dosages tailored to patient conditions. Additionally, respondents favored combination therapies with fenofibrate and clopidogrel, citing their additional benefits in reducing cardiovascular risk markers.

**Keywords:** Cardiovascular Diseases; Dyslipidemia; Hyperlipidemia; Statins; Rosuvastatin

## Introduction

According to the latest special report on the Global Burden of Disease published in the Journal of the American College of Cardiology, the global death tolls attributable to cardiovascular disease (CVD) surged from 12.4 million in 1990 to 19.8 million in 2022 [1].In India, CVD stands as the foremost cause of both death and disability [2].This stark reality highlights the urgent need for comprehensive strategies aimed at preventing and managing CVD. CVD represents a significant contributor to both mortality and morbidity across the Asia-Pacific region. The escalating prevalence of CVD risk factors, including plasma lipid disorders, observed in numerous Asian nations, is a major concern [3].

According to the World Health Organization, high cholesterol levels contribute to approximately 4.5% of global mortality rates and account for 2% of disability-adjusted life years (DALYs) in individuals aged 18 and older, underscoring the profound impact of dyslipidemia on public health [4]. Elevated serum triglyceride (TG) levels exceeding 1000 mg/dL significantly elevate the risk of acute pancreatitis. Globally, in 2019, the total numbers of deaths and DALYs attributed to high low-density lipoprotein cholesterol (LDL-C) were 1.47 and 1.41 times higher than that in 1990 [5].A study involving 18,288 participants across four US cohorts reported that elevated LDL-C has persisted as a leading modifiable risk factor and is closely linked to atherosclerotic CVD. In 2021, it was reported that 3.81 million CV deaths and 3.81 million deaths overall were attributed to elevated LDL-C levels, with the all-cause DALYs due to high LDL-C reaching 1,090 per 100,000. Exposure to lower cumulative LDL-C levels in young and middle-aged adults has been associated with reduced long-term CV risk [6].

Statins serve as the cornerstone of lipid management strategies. These medications belong to a class of lipid-lowering drugs that operate by inhibiting the enzyme 3-hydroxy-3-methyl-glutaryl coenzyme A reductase, a crucial player in the key step of cholesterol production. By targeting this enzyme, statins effectively lower levels of total cholesterol and LDL-C, with modest effects on triglycerides. Additionally, emerging evidence suggests that statins may exert anti-inflammatory properties and contribute to stabilizing arterial plaque [7].Rosuvastatin is widely prescribed and recognized as one of the most potent statins available. With rapid absorption, it achieves peak plasma concentration within three hours of administration. The lipid-lowering efficacy of rosuvastatin remains consistent regardless of the time of administration and this could be attributed to its relatively long half-life, which spans approximately 20 hours. Rosuvastatin demonstrated efficacy in reducing major vascular events across various clinical studies [8,9].

Lipid management remains a persistent challenge, particularly in patients with comorbid conditions, where tailored treatment approaches are crucial. Understanding the prescription patterns of statins is essential for optimizing patient care and improving treatment outcomes The present survey-based study aims to gather clinicians' perspectives on the effectiveness of statins, with a particular emphasis on the prescription pattern of rosuvastatin, for managing lipids in Indian settings.

## Methods

A cross sectional, questionnaire based survey was carried out among clinicians with expertise in treating dyslipidemia in the major Indian cities from June 2023 to December 2023.

### Questionnaire

The questionnaire booklet titled START (To Study The clinical usAge of Rosuvastatin in dyslipidemia coexist with Diabetes, HyperTeNsion or Cardiovascular disease in Indian Patients) study was sent to the physicians who were interested to participate in the study. The START study questionnaire comprised 24 questions addressing current feedback, clinical observations, and specialists' experiences regarding lipid management, as well as the use and prescription patterns of statins, particularly rosuvastatin. The study was conducted after receiving approval from Bangalore Ethics, an Independent Ethics Committee which was recognized by the Indian Regulatory Authority, Drug Controller General of India.

### Participants

An invitation was sent to leading clinicians in managing dyslipidemia in the month of March 2023 for participation in this Indian survey. About 502 doctors from major cities of all Indian states representing the geographical distribution shared their willingness to participate and provide necessary data. Clinicians were provided the option to skip any questions they did not wish to answer and were instructed to complete the questionnaire independently, refraining from consulting colleagues. Prior to the initiation of the study, written informed consent was obtained from all study participants.

### Statistical analysis

The data were analyzed using descriptive statistics. Categorical variables were presented as percentages to provide a clear understanding of their distribution. The frequency of occurrence and the corresponding percentage were used to represent the distribution of each variable. To visualize the distribution of the categorical variables, pie, and bar charts were created using Microsoft Excel 2013 (version 16.0.13901.20400).

## Results

According to the survey data, 45% and 40% of clinicians observed that 21-30% and 11-20% of young patients (<40 years) have dyslipidemia, respectively. Additionally, 49% and 34% of clinicians reported that 21-30% and 10-20% of the patients presenting to routine practice have comorbid hyperlipidemia and hypertension, respectively. Similarly, 48% of the clinicians noted that 21-30% of the patients have comorbid hyperlipidemia and diabetes. Moreover, 48% of clinicians indicated that 20-30% of patients with hypertension were prescribed statins as an additional therapy for primary prevention. Sedentary lifestyle, obesity (particularly visceral obesity), and cigarette smoking were identified as the major reversible traditional risk factors to be addressed to reduce the risk of cardiovascular disease by 29%, 27%, and 26% of clinicians, respectively.

As per 47% of the clinicians, nearly 20-30% of patients with dyslipidemia have a risk attributable to ACS. The majority of clinicians (62%) identified the increased prevalence of dyslipidemia


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and ACS in the age group 45-60 years. Nearly 56% of the clinicians recommended measuring the 'lipid profile' once in 3 months among patients with ACS, whereas 40% recommended it once in 6 months. According to 42% and 41% of the clinicians, 10-20% and 20-30% of patients requiring dual antiplatelet therapy + statins. As per 30% of the clinicians, statins are believed to reduce CV risk by less than 21-30% in patients with diabetes.

The majority (57%) of clinicians strongly agreed that high doses of potent statins reduce CV events to a greater extent than low-dose statin therapy. More than half (57%) of the clinicians noted that a combination of statins and fibrates results in a greater reduction in CV events than statins alone. According to 53% of the clinicians, 20-30% of patients with dyslipidemia required combination therapy with statins. Nearly 71% of clinicians recommended initiating statin therapy in all comorbid patients with diabetes or hypertension. A significant proportion (58%) of clinicians supported the American College of Cardiology and American Heart Association (ACC/AHA) 2019 lipid guidelines, which advocated administering the maximum tolerated dose of statins in individuals with LDL-C levels >190 mg/dl.

Majority (90%) of the clinicians advocated prescribing rosuvastatin as a lipid-lowering agent for patients with hyperlipidemia who also have hypertension or diabetes (Table 1). Additionally, rosuvastatin was preferred by a significant proportion of clinicians (95%) as the recommended statin for patients with dyslipidemia (Figure 1). A significant portion (64%) of clinicians favored the 10 mg dosage of rosuvastatin among those with diabetes, regardless of their lipid levels (Table 2). When considering patients with CVD, regardless of their lipid levels, 51% of clinicians preferred the 20 mg dosage, while 40% favored the 10 mg dosage (Figure 2).

Around 58% of clinicians observed that the combination of rosuvastatin and fenofibrate helps in reducing LDL/TG/high-sensitivity C-reactive protein (hs-CRP), offering a comprehensive approach to managing the lipid triad (Table 3). Majority (71%) of the clinicians preferred clopidogrel as the antiplatelet agent to be combined with rosuvastatin (Figure 3). According to 45% and 44% of clinicians, 20-30% and 10-20% of patients would require the combination of rosuvastatin and clopidogrel (Table 4). Moreover, 44% of clinicians suggested a therapy duration of 6-12 months with rosuvastatin + clopidogrel + aspirin for secondary prevention in high CV-risk patients. Majority (87%) of the clinicians favored adding fenofibrate to rosuvastatin for patients with elevated triglyceride levels (Figure 4).

## Discussion

The present study adds to the growing body of evidence supporting the use of statins for lipid management across various comorbid conditions, including diabetes or hypertension, as well as among individuals with LDL-C levels exceeding 190 mg/dl. Additionally, it suggests that 20-30% of patients with dyslipidemia may require combination therapy involving statins. Furthermore, clinicians noted that combining statins with fibrates leads to a greater reduction in CV events compared to statins alone. According to the 2019 ACC/AHA guideline on the primary prevention of CVD, statin therapy is recommended as the initial treatment for primary

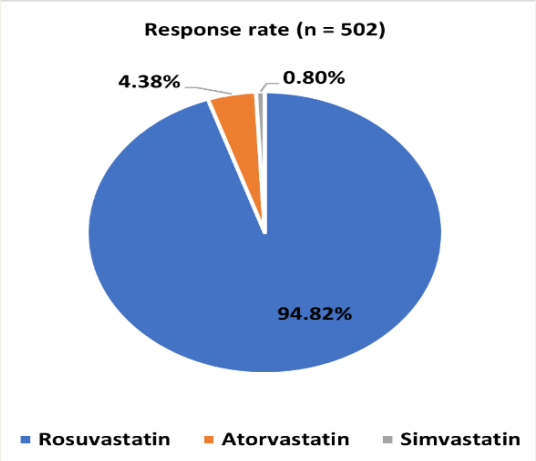


**Figure 1:** Distribution of response to preferred statin for patients with dyslipidemia

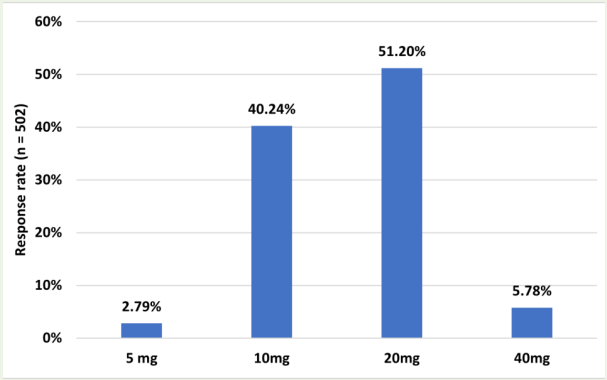


**Figure 2:** Distribution of response to preferred strength of rosuvastatin in patients with cardiovascular disease (irrespective of lipid levels)

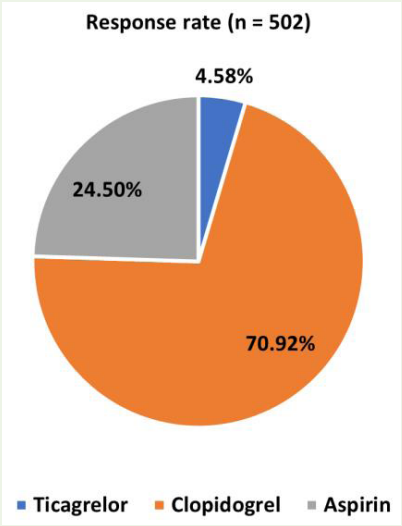


**Figure 3:** Distribution of response to the preferred antiplatelet agent to be combined with rosuvastatin



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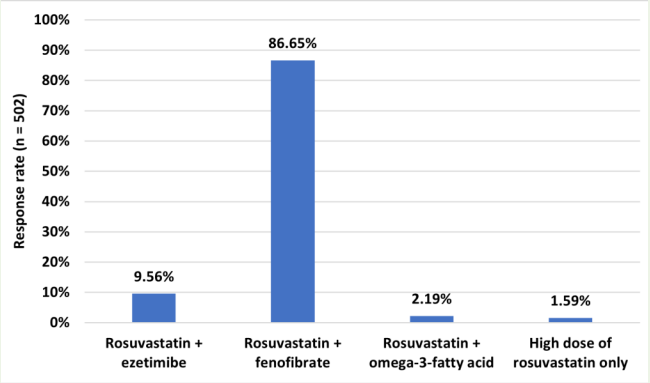


**Figure 4:** Distribution of response to the preferred drug as an add-on to rosuvastatin in patients with high triglycerides

Table 1: Distribution of response to preferred lipid-lowering agents in hyper-lipidemia with hypertension or diabetes

| Lipid lowering agent | Response rate (n = 502) |
|---|---|
| Rosuvastatin | 450 (89.64%) |
| Atorvastatin | 29 (5.78%) |
| Fibrates | 10 (1.99%) |
| Niacin | 3 (0.6%) |
| Ezetimibe | 6 (1.2%) |
| Omega-3-fatty acid | 4 (0.8%) |

Table 2: Distribution of response to preferred strength of rosuvastatin in diabetes patients (irrespective of lipid levels)

| Strength | Response rate (n = 502) |
|---|---|
| 5 mg | 19 (3.78%) |
| 10 mg | 323 (64.34%) |
| 20 mg | 145 (28.88%) |
| 40 mg | 15 (2.99%) |

Table 3: Distribution of responses to opinions on rosuvastatin and fenofibrate combination therapy for managing the lipid triad

| Opinions | Response rate (n = 502) |
|---|---|
| Reduces LDL/TG/hs-CRP | 291 (57.97%) |
| Increases HDL | 31 (6.18%) |
| Decreases CVD risk | 37 (7.37%) |
| All of the above | 143 (28.49%) |

hs-CRP: High-sensitivity C-reactive protein, LDL: low-density lipoprotein, HDL: High density lipoprotein, CVD: cardiovascular diseases

Table 4: Distribution of response to the percentage of patients requiring the combination of rosuvastatin and clopidogrel in clinical practice

| Percentage | Response rate (n = 502) |
|---|---|
| <10 | 23 (4.58%) |
| 10-20% | 203 (40.44%) |
| 20-30% | 224 (44.62%) |
| 30-40% | 52 (10.36%) |

prevention of atherosclerotic cardiovascular disease (ASCVD) in several patient groups, including individuals with elevated LDL-C levels (≥190 mg/dL), those aged 40 to 75 years with type 2 diabetes mellitus (T2DM), and those assessed to be at increased ASCVD risk following a clinician-patient risk discussion [10].

A review by Catapano et al. emphasized that for individuals who fail to achieve sufficient reduction in LDL-C, especially those at elevated risk or those unable to tolerate maximum statin therapy, combination therapy involving a low-dose statin and other lipid-modifying agents may be an effective option [11].Agouridis et al. found that, according to current evidence, combination therapy involving statins and fibrates positively modifies the lipid profile of patients with T2DM. This treatment approach is particularly effective in addressing the high TG and low HDL-C profile, a pattern associated with increased CVD risk [12].

In the present study, a significant proportion of clinicians recommended rosuvastatin as a lipid-lowering agent and recommended statin in patients with hyperlipidemia who also have hypertension or diabetes. Furthermore, the majority of the clinicians recommended a 10 mg dosage of rosuvastatin among those with diabetes and a 20 mg dosage in CVD patients. Barakat et al. found that rosuvastatin effectively reduced LDL-C levels in diabetic patients with dyslipidemia [13]. A pooled analysis of data from five trials demonstrated that rosuvastatin had consistent efficacy across various patient subgroups, including those aged 65 years and older, female individuals, postmenopausal individuals, hypertensive patients, those with atherosclerosis, individuals with T2DM, and obese individuals [14].A comparative study conducted by Berne et al. found that rosuvastatin demonstrated superior efficacy over atorvastatin in reducing LDL-C levels and attaining European LDL-C targets in patients diagnosed with T2DM [15].In a comprehensive systematic review and network meta-analysis comprising 50 randomized controlled trials involving 51,956 participants with dyslipidemia, CVD, or T2DM, researchers investigated the lipid-lowering or increasing efficacy of seven statins. The study concluded that rosuvastatin demonstrated superior performance, ranking first in lowering LDL-C and Apo lipoprotein B, as well as increasing Apolipoprotein A-1levels compared to simvastatin, fluvastatin, atorvastatin, lovastatin, pravastatin, and pitavastatin [16].A comparative study conducted by Berne et al. found that rosuvastatin demonstrated superior efficacy over atorvastatin in reducing LDL-C levels and attaining European LDL-C targets in patients diagnosed with T2DM [15].

Among dyslipidemia diabetic patients, rosuvastatin at a dosage of 10 mg was found to be the most effective in reducing LDL-C levels [13].The URANUS study found that a significantly higher proportion of patients achieved the 1998 LDL-C goal when treated with rosuvastatin 10 mg compared to those treated with atorvastatin 10 mg in individuals with T2DM [15].Aleem et al. compared the efficacy of rosuvastatin at doses of 5 mg and 10 mg in patients with T2DM and dyslipidemia and found that 10 mg of rosuvastatin demonstrated greater reductions in lipid levels [17].In high-risk patients with hypercholesterolemia, rosuvastatin 10 mg demonstrated superior efficacy compared to atorvastatin 20 mg in reducing LDL-C, thereby


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facilitating the achievement of LDL-C goals and enhancing other lipid parameters [18].In a post-marketing study conducted by Shah et al., which assessed the lipid-modifying efficacy and safety of approved dose ranges of rosuvastatin among Indian hyperlipidemia patients in routine clinical settings, it was revealed that rosuvastatin at doses of 5 mg, 10 mg, and 20 mg effectively improved lipid parameters and enabled the attainment of lipid goals in a diverse cohort of Indian hyperlipidemic patients. Additionally, for individuals with a higher CV risk profile, starting doses of rosuvastatin at 10 mg and 20 mg were found to be more effective [19].

Most of the current survey respondents recommended combining rosuvastatin with fenofibrate to lower LDL/TG/hs-CRP, elevate HDL, and reduce CVD risk. Clopidogrel was the preferred choice for combination therapy with rosuvastatin. Clinicians also favored supplementing rosuvastatin with fenofibrate for patients with elevated TG levels. Furthermore, clinicians advocated for a treatment duration of 6-12 months for rosuvastatin + clopidogrel + aspirin therapy for the secondary prevention of high CV risk.

Machado-Duque et al. found that the combination of rosuvastatin and fenofibric acid is an effective treatment option for patients diagnosed with mixed dyslipidemia and at high risk for CV events with reduced LDL-C and TG level [20]. In a comprehensive review comprising 46 articles, conducted by Biswas et al., it was observed that combination therapy involving rosuvastatin and fenofibric acid was advantageous and well-tolerated, exhibiting a safety profile similar to that of statin monotherapy. Moreover, the combination of moderate dose rosuvastatin with fenofibric acid resulted in a reduction of CV risk factors [21].

Gao et al. reported that the combination of rosuvastatin and clopidogrel bisulfate has proven to be effective in treating elderly patients with coronary heart disease (CHD). This regimen demonstrates the ability to enhance cardiac function, as well as to lower blood lipid levels and reduce inflammatory factors [22].Deng et al. found that intensive rosuvastatin therapy combined with 7-day dual antiplatelet therapy using aspirin and clopidogrel significantly reduced the risk of recurrent ischemic stroke within 90 days for patients with mild to moderate acute ischemic stroke, compared to rosuvastatin plus single antiplatelet therapy. This treatment approach did not lead to an increase in bleeding events, statin-induced liver injury, or systemic anticoagulant medication-associated myopathy. These benefits were more pronounced in subgroups with high-risk factors, such as elderly patients (>68 years old), those with hypertension, diabetes, hyperlipidemia, prior stroke history, or those not receiving antiplatelet therapy before the study [23]. Pillai et al. examined the prescription practices of fixed-dose drug combinations (FDCs) containing rosuvastatin, clopidogrel, and aspirin in Indian patients diagnosed with ACS. The findings revealed that a significant portion of patients were prescribed the FDC of rosuvastatin, clopidogrel, and aspirin primarily for the treatment of unstable angina/ACS [24].

The current survey provides more insights into prescription practices tailored to Indian contexts, aiding both clinicians and researchers in making informed decisions. This research seeks to enhance patient care strategies and contribute to the development of evidence-based guidelines and recommendations for optimizing treatment outcomes. The findings of the current study underscore the importance of statins, particularly rosuvastatin, in managing lipid levels in patients with comorbid conditions. One notable strength of the study lies in the utilization of a meticulously designed and validated questionnaire for collecting expert data. However, it is important to acknowledge that personal viewpoints and preferences may have influenced the conclusions drawn from the study, introducing the possibility of bias. Therefore, interpreting the results while considering these limitations is crucial. Further research efforts should be directed towards confirming and expanding upon the findings presented in this study.

## Conclusion

The present survey further corroborated the significance of statin combination therapy, with notable benefits observed when combined with fibrates for reducing cardiovascular events. Rosuvastatin emerged as a favored lipid-lowering agent, especially in patients with hyperlipidemia, hypertension, or diabetes. Combination therapy, particularly with fenofibrate, is favored to address multiple lipid parameters and reduce cardiovascular risk. Clopidogrel is the preferred choice for combination therapy with rosuvastatin, and a treatment duration of 6-12 months is recommended for secondary prevention in high cardiovascular risk patients.

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