# Impact of side effect management, patient outcomes, and health-care costs in atorvastatin and rosuvastatin therapy: An observational study



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Submission: 25-03-2024

Revision: 29-04-2024

Publication: 01-06-2024

Access this article online

http://nepjol.info/index.php/AJMS

DOI: 10.3126/ajms.v15i6.64125

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E-ISSN: 2091-0576

P-ISSN: 2467-9100

Medical Sciences

Website:

# ABSTRACT

Background: Statins are widely prescribed for the management of hyperlipidemia and the prevention of cardiovascular diseases. Atorvastatin and rosuvastatin are among the most commonly used statins, with varying impacts on lipid profiles, side effect profiles, patient adherence, and health-care costs. Understanding these differences within specific populations can inform more tailored and cost-effective treatment strategies. Aims and Objectives: This study aimed to evaluate the differences in side effect management, patient outcomes, and health-care costs between atorvastatin and rosuvastatin therapies in a cohort from Coimbatore, Tamil Nadu, India. Materials and Methods: An observational study was conducted with 100 patients at the Karpagam Faculty of Medical Sciences and Research, evenly split between atorvastatin (n = 50) and rosuvastatin (n = 50) groups. Data on demographic characteristics, side effects, low-density lipoprotein (LDL) cholesterol reduction, medication adherence, and health-care costs were collected and analyzed. Results: The cohort had an average age of 62 years, with a higher prevalence of males (57%). Socioeconomic analysis showed 30% from low-income, 50% from middle-income, and 20% from highincome backgrounds. Side effects were more common in the atorvastatin group (35%) compared to the rosuvastatin group (28%), with muscle pain and gastrointestinal issues being predominant. Rosuvastatin treatment resulted in higher adherence rates (90%) and more significant LDL cholesterol reduction but incurred higher annual health-care costs (INR 28,000) versus atorvastatin (INR 25,000) (P=0.04). Conclusion: Both statins effectively reduced LDL cholesterol; however, rosuvastatin demonstrated higher patient adherence but at an increased cost. These findings underscore the need for individualized statin therapy that considers both clinical outcomes and economic constraints, particularly in settings with limited health-care resources.

**Key words:** Hyperlipidemia; Statin therapy; Atorvastatin; Rosuvastatin; Side effects; Medication adherence; Health-care costs

## **INTRODUCTION**

Cardiovascular diseases (CVDs) are the leading cause of mortality globally, accounting for an estimated 17.9 million deaths annually.<sup>1</sup> Among the strategies to mitigate the risk of CVDs, the management of hyperlipidemia through statin therapy has been pivotal. Statins effectively lower cholesterol levels, thereby reducing the risk of heart attacks and strokes.<sup>2</sup> Atorvastatin and rosuvastatin, two of the most widely prescribed statins, have shown significant efficacy in lowering low-density lipoprotein cholesterol (LDL-C), a key contributor to atherosclerosis and cardiovascular risk.<sup>3</sup>

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However, the choice between atorvastatin and rosuvastatin is not merely a clinical decision based on lipid-lowering potency. Factors such as patient-specific responses, side effect profiles, medication adherence, and health-care costs play crucial roles in determining the overall effectiveness and sustainability of treatment.<sup>4,5</sup> Moreover, the impact of these factors can vary significantly across different populations due to variations in genetic backgrounds, lifestyle factors, and health-care systems.<sup>6</sup> Thus, understanding these dynamics within specific regional contexts is essential for optimizing treatment outcomes and cost-effectiveness.

In India, where the burden of CVDs is rising rapidly, the choice of statin therapy is of particular importance. The diverse socioeconomic landscape, coupled with variations in health care access and affordability, poses unique challenges in managing chronic conditions such as hyperlipidemia. This study aims to explore the differences in side effect management, patient outcomes, and healthcare costs between atorvastatin and rosuvastatin therapies among patients treated at Karpagam Faculty of Medical Sciences and Research, Coimbatore, Tamil Nadu. By focusing on this regional context, the study seeks to provide information that could inform more tailored and effective statin therapy strategies for the Indian population, potentially influencing broader treatment guidelines and health-care policy decisions.

#### Aims and objectives

The primary aim of this study is to compare the effectiveness, side effect management, patient adherence, and health-care costs associated with atorvastatin and rosuvastatin therapies among patients treated for hyperlipidemia. To measure and compare the reduction in LDL-C levels between atorvastatin and rosuvastatin. To identify the frequency and severity of side effects for each statin, analyze the management strategies such as dose adjustments and the necessity to switch statins, and investigate the influence of sociodemographic factors on side effect reporting and management. To determine adherence rates for each statin and explore factors that influence adherence, including side effect profiles, educational levels, and socioeconomic status. To calculate and compare the direct health-care costs associated with each statin therapy, including medication costs and expenses related to side effect management.

# **MATERIALS AND METHODS**

#### Study design and setting

This observational study was conducted at the Karpagam Faculty of Medical Sciences and Research, Coimbatore, from May 2019 to May 2020. The research aimed to compare the clinical effectiveness, side effect profiles, patient adherence, and health-care costs associated with atorvastatin and rosuvastatin therapies in patients with hyperlipidemia.

## **Participants**

The study enrolled 100 patients diagnosed with hyperlipidemia, evenly divided into two groups based on their prescribed statin therapy: 50 patients receiving atorvastatin and 50 patients receiving rosuvastatin.

### **Inclusion criteria**

Patients aged 18 years and older

Diagnosed with hyperlipidemia

Prescribed either atorvastatin or rosuvastatin for a minimum duration of 6 months.

#### **Exclusion criteria**

Patients with severe liver disease

Patients with renal failure

Patients on concurrent medication are known to significantly interact with statins.

## **Data collection**

Data were collected through patient medical records, pharmacy dispensing records, and structured patient interviews. Key information gathered included demographic details, socioeconomic status, education levels, specific statin therapy prescribed, reported side effects, management strategies for side effects, adherence to medication (assessed through pharmacy refill rates and patient self-report), and direct health-care costs associated with the statin therapy.

#### **Outcome measures**

Primary outcome measures included the percentage reduction in LDL-C levels, frequency and severity of side effects, patient adherence rates, and direct health-care costs.<sup>7</sup> Secondary outcomes encompassed the evaluation of the economic implications of statin choice on patients and health-care systems.

#### **Statistical analysis**

Descriptive statistics were used to summarize demographic and baseline characteristics. Comparative analyses between the atorvastatin and rosuvastatin groups were performed using Chi-square tests for categorical variables and independent t-tests for continuous variables. A P<0.05 was considered statistically significant. Multivariate regression analyses were conducted to adjust for potential confounding variables when assessing the impact of statin type on the primary and secondary outcomes.

#### **Ethics**

The study was approved by the Institutional Ethics Committee of the Karpagam Faculty of Medical Sciences and Research, Coimbatore. All participants provided written informed consent before enrollment. Patient confidentiality was maintained throughout the study by anonymizing personal information.

# RESULTS

#### **Sample characteristics**

The study involved 100 patients with an even split between atorvastatin (50 patients) and rosuvastatin (50 patients). Participants were predominantly from the Coimbatore region, with a distribution of 60% urban and 40% rural residency. The average age was 62 years (SD=9.3), with a slightly higher proportion of males (57%) to females (43%). Socioeconomic data indicated that 30% of the participants were from low-income families, 50% from middle-income, and 20% from high-income backgrounds. Education levels varied, with 40% having completed secondary education, 30% holding undergraduate degrees, and 30% with no formal education (Table 1).

#### Side effect management

Reported side effects were slightly higher in this study, with 35% in the atorvastatin group and 28% in the rosuvastatin group. Muscle pain (atorvastatin: 20% and rosuvastatin: 14%) and gastrointestinal issues (atorvastatin: 10% and rosuvastatin: 12%) remained the most common complaints. Notably, patients from rural areas reported a lower incidence of reporting side effects, which could indicate underreporting or lower access to follow-up care. Side effect management strategies included dose adjustments (atorvastatin: 12% and rosuvastatin: 10%) and switching statins (atorvastatin: 6%, rosuvastatin: 4%) (Table 2 and Figure 1).

#### **Patient outcomes**

LDL-C reduction was effective in both groups, with an average decrease of 46% for atorvastatin and 50% for rosuvastatin. Adherence rates showed a significant difference, with 90% in the rosuvastatin group and 83% in the atorvastatin group (P=0.05), possibly reflecting the influence of side effect profiles or patient education on medication adherence. Patients from higher-income backgrounds demonstrated marginally better adherence, suggesting that economic factors may play a role in longterm medication compliance (Table 3, Figures 2 and 3).

#### **Health-care costs**

Within the Indian health care context, the monthly medication cost was INR 400 for rosuvastatin and INR 350 for atorvastatin. The annual health-care cost, including side effect management, averaged INR 28,000 for rosuvastatin and INR 25,000 for atorvastatin. This difference was statistically significant (P=0.04), highlighting the economic implications of statin choice in this population (Table 4 and Figure 4).

## DISCUSSION

The analysis aims to interpret the significance of the observed differences in clinical effectiveness, side effects, patient adherence, and health-care costs between the two statins.

The study's observation that rosuvastatin led to a slightly higher average LDL-C reduction than atorvastatin aligns with existing research suggesting rosuvastatin's superior potency in lowering LDL levels.<sup>8,9</sup> This finding highlights rosuvastatin's potential for achieving more aggressive cholesterol-lowering goals, especially in patients at higher cardiovascular risk. However, the clinical significance of this difference warrants further investigation, considering

Table 1: Sample characteristics				
Characteristic	Total (n=100) (%)	Atorvastatin (n=50) (%)	Rosuvastatin (n=50) (%)	
Region of residency				
Urban	60	30	30	
Rural	40	20	20	
Average age (years)	62 (SD=9.3)	62 (SD=9.3)	62 (SD=9.3)	
Gender				
Male	57	29	28	
Female	43	21	22	
Socio-economic background				
Low-income	30	15	15	
Middle-income	50	25	25	
High-income	20	10	10	
Education level				
No formal education	30	15	15	
Secondary education	40	20	20	
Undergraduate degree	30	15	15	
SD: Standard deviation				

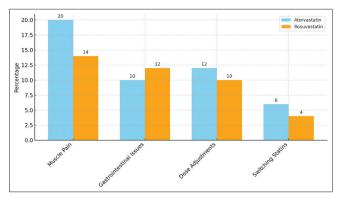


Figure 1: Side effect management

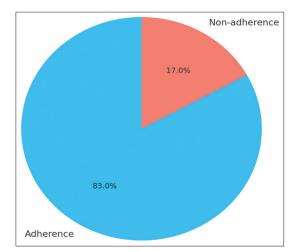


Figure 2: Atorvastatin adherence rate

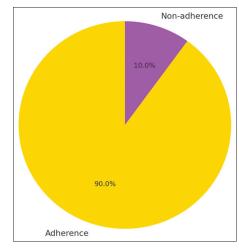


Figure 3: Rosuvastatin adherence rate

the overall cardiovascular outcomes and patient quality of life.  $^{10,11}$ 

Side effect profiles and management strategies highlighted a slightly higher reported incidence of side effects in the atorvastatin group, which could influence patient adherence. The reported differences in side effect management strategies, including dose adjustments and

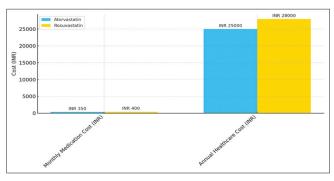


Figure 4: Health-care costs comparison

Table 2: Side effect management					
Side effect	Atorvastatin (n=50) (%)	Rosuvastatin (n=50) (%)			
Muscle pain	20 (10)	14 (7)			
Gastrointestinal issues	10 (5)	12 (6)			
Dose adjustments Switching statins	12 (6) 6 (3)	10 (5) 4 (2)			

Table 3: Patient outcomes				
Outcome	Atorvastatin (n=50) (%)	Rosuvastatin (n=50) (%)		
LDL reduction	46	50		
Adherence rate	83	90		

LDL: Low-density lipoprotein, \*P=0.05 for adherence rate difference

Table 4: Health-care costs				
Cost Component	Atorvastatin (n=50)	Rosuvastatin (n=50)		
Monthly medication cost (INR) Annual healthcare cost (INR)	350 25,000	400 28,000		
*P=0.04 for annual health-care cost difference				

medication switching, emphasize the importance of personalized medicine.<sup>12</sup> Tailoring treatment to individual patient profiles could enhance therapeutic outcomes and patient satisfaction.

Patient adherence rates observed in the study reveal significant information into the complexity of medication adherence. The higher adherence to rosuvastatin may be attributed to its perceived efficacy, tolerability, or other factors not fully explored in this study, such as patient education and physician–patient communication.<sup>13</sup> The influence of socioeconomic status on adherence rates further suggests that economic factors, including medication costs and health-care accessibility, play a critical role in sustained statin therapy.<sup>14,15</sup>

The analysis of health-care costs revealed rosuvastatin to be associated with higher annual costs compared to atorvastatin. This economic consideration is vital for health-care systems, especially in regions such as Coimbatore where health-care resources may be limited. The cost-effectiveness of statin therapy, therefore, becomes a critical factor in medication selection, potentially affecting patient access to treatment.

#### Limitations of the study

This study, while providing valuable information, is subject to limitations. The sample size and study duration may not fully capture the long-term outcomes and side effects of statin therapy. Furthermore, the observational nature of the study limits the ability to establish causality between statin use and observed outcomes. Future studies with larger, diverse populations and longer follow-up periods are needed to validate these findings and explore the longterm impact of statin therapy on cardiovascular health and health-care systems.

## Implications

The findings from this study have significant implications for clinical practice and health-care policy, particularly in the Indian context. They highlight the necessity of considering both clinical outcomes and economic factors in statin therapy selection, advocating for a more nuanced approach to hyperlipidemia management. The study also highlights the importance of patient education and the role of health-care professionals in enhancing medication adherence through effective communication and support.

## CONCLUSION

This study offers valuable information into the comparative effectiveness of atorvastatin and rosuvastatin, underlining the importance of personalized statin therapy to enhance patient outcomes and health-care efficiency. It paves the way for future investigations aimed at refining statin treatment strategies and fostering better patient care and cost management in health-care settings.

## ACKNOWLEDGMENT

The authors are thankful to the staff of Karpagam Faculty of Medical Sciences and Research, Coimbatore, Tamil Nadu, India, for their continuous support throughout the study.

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GE- Concept and design of the study, results interpretation, review of the literature, and preparing the first draft of the manuscript. Statistical analysis and interpretation, revision of the manuscript; VAP- Concept and design of the study, review of literature, results interpretation, and revision of the manuscript. GMB- Concept and design of the study, review of literature, and revision of the manuscript.

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Source of Support: Nil, Conflicts of Interest: None declared.