Original Article

Efficacy and Safety of Long-Acting Beta Agonist/Long-Acting Muscarinic Antagonist/Inhaled Corticosteroid Along with Rosuvastatin in Moderate to Severe COPD Patients

Vanitha G[1], Sivagami R[2], Preethi A[3]

[1]Assistant Professor, Department of Pharmacology, Government Medical College, Namakkal, Tamil Nadu, India. [2]Associate Professor, Department of Pharmacology, Government Stanley Medical College, Chennai, Tamil Nadu, India. [3]Assistant Professor, Department of Pharmacology, Government Medical College Krishnagiri, Tamil Nadu, India

Abstract

Background: COPD is a heavy burden in India, made worse by smoking and rural biomass fuel use. Inhaler combinations with LABA, LAMA, and steroids are standard, yet many patients continue to flare. Rosuvastatin, though designed for cholesterol control, also exerts anti-inflammatory effects. That raised the question, could it help COPD patients too? The aim is to test whether rosuvastatin, added to routine triple inhaler therapy, improves outcomes in moderate-to-severe COPD. **Material and Methods:** A prospective study ran from June 2024 to May 2025. One hundred and twenty patients were enrolled. Half used only triple inhalers, half took an added 10 mg of rosuvastatin daily. The participants were assessed during one year with lung performance (FEV1) status, frequency of exacerbations, and the St. George Respiratory Questionnaires. The chi-square and t-tests were used and p was set to be below 0.05. **Results:** Patients on rosuvastatin were less likely to exacerbate (1.3 vs 2.1/year), had better increase in FEV1 (110 mL vs 40 mL) and had more significant quality score improvement (–12.5 vs -6.3). In three instances there was mild muscular pain and there were no significant side effects. **Conclusion:** The combination of rosuvastatin to standard therapy had obvious clinical positive results and no significant safety problems. This requires bigger trials before it becomes a standard practice.

Keywords: COPD, rosuvastatin, India, and lung health, inhaler therapy.

Received: 03 February 2026 **Revised: 20 February 2026** **Accepted: 05 March 2026** **Published: 13 March 2026**

Introduction

Chronic Obstructive Pulmonary Disease (COPD) is now among the leading killers in the world with millions of people contracting it on a yearly basis.[1] Other than survival, it is another major cause of long-term disability.[10] The issue in India appears different compared to the west. Men even get tobacco smoke exposed and many of the women spend years getting used to indoor smoke caused by firewood or cooking with dung.[2,3] All these exposures make the burden high than in most other regions.

According to the recommendations of the Global Initiative of Chronic Obstructive Lung Disease (GOLD 2024), inhaled long-acting 2 adenergic agonists (LABA), muscarinic antagonists (LAMA) and corticosteroids (ICS) are still the most crucial elements of medication.[4] Even with these medications, however, flare-ups, inflammatory response and progressive loss of lung functionality persist. Cost, poor inhaler technique and follow-up are also issues to aggravate the situation in India.[5]

Some other statins that are used in cholesterol and cardiovascular disease also have an effect on inflammation. Specifically, rosuvastatin reduces the C-reactive protein and stabilizes the blood vessels.[6] COPD is characterized by chronic inflammation and these effects can be handy.[7] Although some studies such as STATCOPE have not shown any significant effect,[8] other articles and meta-analysis are pointing to improvement in patients, especially those with frequent attacks.

The generic statins are inexpensive and available in government stock in India in large numbers. Nevertheless, their role in COPD has rarely been investigated in local research. This research was to be done to test the hypothesis that the concomitant use of rosuvastatin with regular triple inhaler therapy would result in decreased flare-ups and improved health outcomes in patients of moderate and severe COPD who presented before a tertiary care hospital in Tamil Nadu.

Materials and Methods

Design and setting: It was an arrangement made as a prospective

Address for correspondence: Dr. Vanitha G, Assistant Professor, Department of Pharmacology, Government Medical College, Namakkal, Tamil Nadu, India.
E-mail: ?@gmail.com

DOI:
10.21276/amit.2026.v13.i1.415

How to cite this article: Vanitha G, Sivagami R, Preethi A. Efficacy and Safety of Long-Acting Beta Agonist/Long-Acting Muscarinic Antagonist/Inhaled Corticosteroid Along with Rosuvastatin in Moderate to Severe COPD Patients. Acta Med Int. 2026;13(1):667-670.

study in the Pharmacology Department of [Institution], Tamil Nadu. The patients attracted to the hospital are not solely community members of the city limits, but also attractive to those living in villages that use solid fuel cooking in large quantities and this provides the cohort with a broad exposure background.

Study duration: The enrolment and follow-up were between June 2024 and May 2025.

Eligibility: Adults aged 40 to 75 years of age and diagnosed with COPD on the post-bronchodilator results of spirometries were invited. It included only people with moderate or severe disease, based on GOLD 2024. Active liver disease, severe kidney dysfunction, recent cardiac events, uncontrolled diabetes and history of statin intolerance were not taken into consideration. Informed consent was given by all the participants.

Sample size and grouping: A total of 120 patients were recruited. Sixty were given regular triple inhalers. The remaining sixty were treated with the same inhaler dose with 10 mg rosuvastatin one daily.

Data collected: Data on demographic information, smoking habits, exposure to household biomass and co-morbidity were taken as baseline records. Spirometry (FEV1), symptom diary and the St. George, Respiratory Questionnaire were used to support clinical assessment. Reviewing of patients took place after every three months. Exacerbations, hospitalization and drug related complaints were observed. Liver enzymes and creatine kinase would be added to blood tests as required.

Study outcomes: Three outcomes were in the focus: annual number of exacerbations, difference in FEV 1 and difference in SGRQ scores. Additional outcomes were hospitalizations and side effects.

Analysis: All of the values were placed into Excel and analysed using SPSS v21. The comparison of continuous data was conducted with the t-tests, the proportions were analyzed with the chi-square. Significant results were considered when level of probability was below 0.05.

Results

Baseline profile: A total of 120 patients were entered in the group of 60 patients. The mean age was a bit above 61 years with majority of the population being men. Men tended to have a smoking history and women to have been exposed to smoke of cooking fuels more frequently. Basal values of FEV1, SGRQ, and other clinical variables were almost similar in the two groups [Table 1].

Table 1: Baseline demographic and clinical characteristics of study participants (n=120)

Characteristic	Group A (Triple inhaler, n=60)	Group B (Triple inhaler + Rosuvastatin, n=60)
Mean age (years)	60.9 ± 7.2	61.5 ± 7.7
Male sex (%)	71.7	71.7
Smoking history (%)	66.7	65.0
Biomass exposure (%)	28.3	30.0
Mean FEV1 (L)	1.14 ± 0.36	1.12 ± 0.39
Mean SGRQ score (points)	58.6 ± 9.4	59.3 ± 10.1

Data are mean ± SD or %. Baseline comparisons used t-test for continuous variables and chi-square for categorical variables. No significant differences were found between groups.

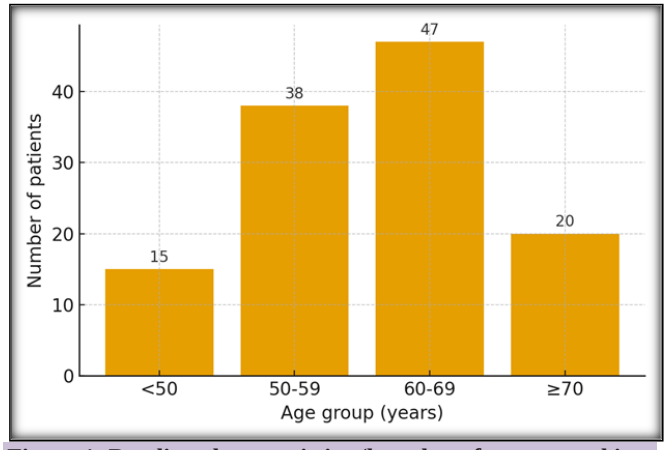

Figure 1. Baseline characteristics (bar chart for age, smoking, biomass exposure)

Groups started with similar profiles across age and exposure histories.

Exacerbations: When tracked for one year, patients taking rosuvastatin had fewer flare-ups. They averaged just over one exacerbation per year, while the control group had about two. This gap was unlikely due to chance ($p < 0.01$). Hospital stays for severe episodes were also fewer in the rosuvastatin group [Table 2].

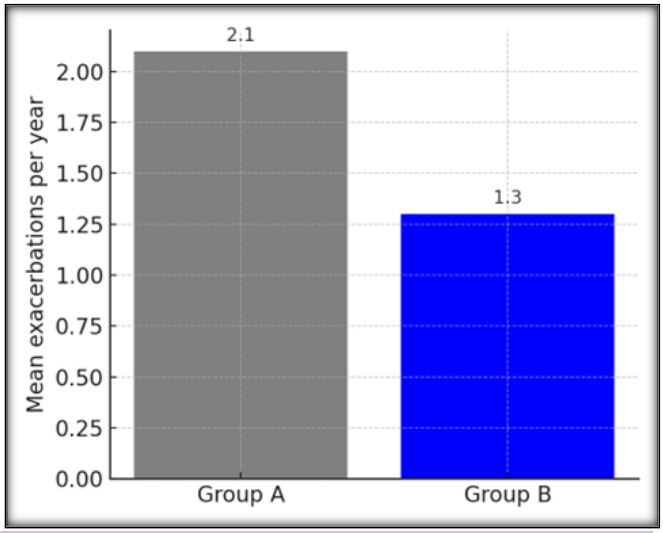

Figure 2: Exacerbation pattern across groups (stacked bar chart)

Rosuvastatin group had fewer total events and admissions compared with controls.

Lung function and quality of life: By the end of one year, the intervention arm showed a larger rise in FEV1 values. The mean gain was about 110 mL, compared with 40 mL in the control arm. Quality-of-life scores also improved more in the rosuvastatin group, with SGRQ dropping by around 12 points, compared with 6 points in controls [Table 3].

Table 2: Exacerbation and hospitalization outcomes over 12 months

Outcome	Group A (n=60)	Group B (n=60)	p-value
Mean annual exacerbations	2.1 ± 0.7	1.3 ± 0.5	<0.01
≥1 hospital admission (%)	36.7	18.3	0.04
Outpatient-managed events (%)	63.3	46.7	0.05

Exacerbation values are mean ± SD; hospital outcomes expressed as %. t-test applied for mean exacerbations; chi-square used for categorical comparisons.

Table 3: Change in spirometry and quality-of-life scores at 12 months

Parameter	Group A (Triple inhaler)	Group B (Triple inhaler + Rosuvastatin)	p-value
FEV1 change (mL)	+40 ± 20	+110 ± 35	0.03
SGRQ change (points)	–6.3 ± 3.1	–12.5 ± 4.0	<0.05

FEV1 = forced expiratory volume in one second; expressed as mean change from baseline in milliliters. SGRQ = St. George's Respiratory Questionnaire (points). Comparisons done with independent t-tests.

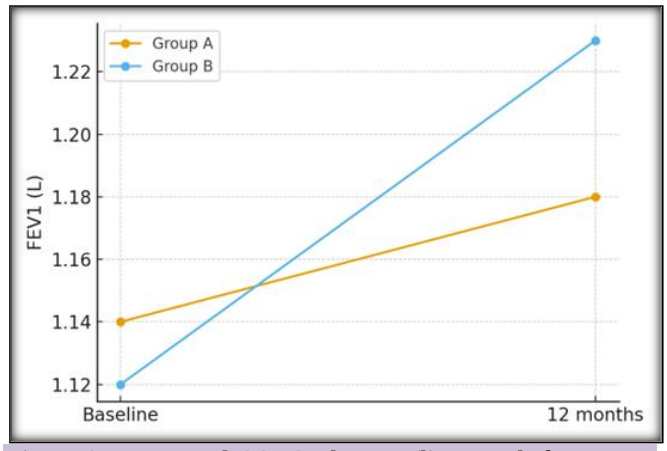

Figure 3: FEV1 and SGRQ changes (line graph for FEV1; donut chart for SGRQ)

Both lung function and quality-of-life improved more in the rosuvastatin group.

Safety: The treatment was mostly well accepted. Three rosuvastatin patients reported muscle pains, which resolved after themselves. No severe kidney or liver complications were developed in the course of monitoring.

Discussion

This paper proposes that the use of rosuvastatin with inhaler regular therapy dose cut the rate of exacerbation, enhanced breathing examination and simplified the life of patients with moderate-chronic COPD. It was not a dramatic effect but was consistent in most measurements. That change is important to the patients who find it difficult already despite regular therapy.

There was less exacerbations in the group of rosuvastatin. This has been reminiscent of smaller studies that had indicated anti-inflammatory effects of statins in COPD.[9,11] The results of the STATCOPE trial were different and no benefit was provided.[12] That trial ruled out patients that were highly inflamed at baseline, and our population experienced frequent flare-ups and multiples of exposures. This could be the cause of the distinction.

Gains on lung functions were minor, yet actual. Mean changes of patients in intervention group were approximately 110 mL to FEV1 as opposed to 40 ml to FEV1 in controls. Even a 70 mL difference is not insignificant in a chronic illness where the majority of patients lose lung capacity every single year. Other cohorts in East Asia have also demonstrated similar pattern when long-term statin use appeared to delay the lung decline.[14]

Rosuvastatin increased the quality of life. The SGRQ score decreased by more than 12 points which is more than twice what can be regarded as meaningful to the patients.[16] This is an indication that people were not merely breathing a little better, but they were also feeling that it was being the case since it was in their everyday lives.

Side effects were few. Three of the participants stated that they experienced muscle pain, and none of them needed to discontinue the drug. There were no significant liver or kidney issues. This coincides with the World rosuvastatin safety background of Indian and Asian environments.[17]

In the general perspective, in India COPD treatment remains largely centered within smoking cessation, oxygen delivery, and inhalers which are provided under government initiatives.[18] A large proportion of patients particularly women who cook on wood or dung still face high exposure and repeated attacks. This might be as an add-on with a cheap oral drug such as rosuvastatin as benefit is established with larger trials.

Limitations: Only one centre and a small sample were used in our work. Part of the exacerbations was patient-reporting, which is prone to error. An example of biomarkers (CRP) that could have made the action of rosuvastatin clear was not measured. Lastly, follow-up was after one year only.

Future work: After that, multicentre experiments involving more people, longer follow-up and biomarker assessment should be carried out. Subgroup analysis based on the smoking, biomass exposure, and cardiovascular comorbidity would assist in defining the greatest beneficiaries.

Conclusion

The supplementation of rosuvastatin to the normal triple inhaler

therapy in moderate-to-severe COPD was also associated with a reduction of flare-ups, lung functioning, and quality of daily living. The medication was highly tolerated containing minimal side effects. Although the findings are couples of hope, they were done in one-centre research of few numbers. Bigger and more prolonged studies are required before rosuvastatin can be suggested as a standard supplement in COPD treatment.

Financial support and sponsorship
Nil.

Conflicts of interest
There are no conflicts of interest.

References
1. World Health Organization. Global Health Estimates 2020: Deaths by Cause, Age, Sex, by Country and by Region. Geneva: WHO; 2021.
2. Salvi S, Barnes PJ. Chronic obstructive pulmonary disease in non-smokers. Lancet. 2009;374(9691):733-43.
3. India State-Level Disease Burden Initiative CRD Collaborators. The burden of chronic respiratory diseases across Indian states, 1990–2016: findings from the Global Burden of Disease Study. Lancet Glob Health. 2018;6(12):e1363-74.
4. Global Initiative for Chronic Obstructive Lung Disease (GOLD). 2024 Global Strategy for the Diagnosis, Management, and Prevention of COPD. Report.
5. Jindal SK, Aggarwal AN, Chaudhry K, et al. A multicentric study on epidemiology of chronic obstructive pulmonary disease and its relationship with tobacco smoking and environmental tobacco smoke exposure. Indian J Chest Dis Allied Sci. 2006;48(1):23-9.
6. Ridker PM, Danielson E, Fonseca FA, et al. Rosuvastatin to prevent vascular events in men and women with elevated C-reactive protein. N Engl J Med. 2008;359(21):2195-207.
7. Agustí A, Celli BR, Criner GJ, et al. Global initiative for chronic obstructive lung disease 2023 report: GOLD executive summary. Eur Respir J. 2023;61(4):2300239.
8. Young RP, Hopkins RJ, Agusti A. Statins as adjunct therapy in COPD: how do we cope after STATCOPE? Thorax. 2014;69(10):891-4.
9. Salvi S, Agarwal A. India needs a national COPD prevention and control programme. J Assoc Physicians India. 2012;60 Suppl:5-7.
10. Lopez-Campos JL, Tan W, Soriano JB. Global burden of COPD. Respirology. 2016;21(1):14-23.
11. Ingebrigtsen TS, Marott JL, Nordestgaard BG, et al. Statin use and exacerbations in individuals with COPD. Thorax. 2015;70(1):33-40.
12. Criner GJ, Connett JE, Aaron SD, et al. Simvastatin for the prevention of exacerbations in moderate-to-severe COPD. N Engl J Med. 2014;370(23):2201-10.
13. Janda S, Park K, FitzGerald JM, Etminan M, Swiston J. Statins in COPD: a systematic review. Chest. 2009;136(3):734-43.
14. Huang CC, Chan WL, Chen YC, et al. Statin use and the risk of COPD exacerbations. Eur Respir J. 2011;37(3):530-7.
15. Mancini GB, Etminan M, Zhang B, et al. Reduction of morbidity and mortality by statins in patients with chronic obstructive pulmonary disease: a systematic review. Chest. 2011;140(3):634-43.
16. Jones PW. St George's Respiratory Questionnaire: MCID. COPD. 2005;2(1):75-9.
17. Government of India. National Programme for Prevention and Control of Cancer, Diabetes, Cardiovascular Diseases and Stroke (NPCDCS): Operational Guidelines. New Delhi: Ministry of Health and Family Welfare; 2013.