

A Pilot Study on Comparative Evaluation of Pharmaceutical Quality and Plasma Drug Concentration of Branded and Janaushadhi Formulations of Atorvastatin and Losartan Tablets

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ABSTRACT

Background: Affordable access to essential medicines being a major challenge in low- and middle-income countries, India has introduced affordable generics named Janaushadhi. Although branded formulations dominate the market, cost-effective alternatives while improving accessibility, raises concerns of quality and clinical performance among healthcare professionals and patients. **Objectives:** To compare the pharmaceutical quality attributes and exploratory plasma drug levels of branded and Janaushadhi formulations of atorvastatin (10 mg) and losartan (50 mg). **Materials and Methods:** This pilot, observational study evaluated pharmaceutical equivalence using standard pharmacopeial quality control tests and High-Performance Liquid Chromatography (HPLC). Parameters assessed included general appearance, weight variation, hardness, friability, disintegration, dissolution, and content uniformity. Additionally, plasma drug concentrations were measured in patients receiving either branded or Janaushadhi formulations. **Results:** Both branded and Jan Aushadhi tablets complied with pharmacopeial standards for all tested quality parameters. Parameters such as general appearance, weight variation, hardness, friability, disintegration, dissolution, and content uniformity were comparable between the two groups. At 30 min, the dissolution rate of atorvastatin was 76.26% (branded) versus 77.17% (Janaushadhi), while losartan showed 78.41% versus 79%, respectively. Assay values for both formulations were within acceptable limits. Mean plasma concentrations were also comparable, with atorvastatin showing 45.73 µg/mL (branded) versus 43.6 µg/mL (Jan Aushadhi), and losartan showing 32.73 µg/mL versus 36.84 µg/mL. Notably, Jan Aushadhi formulations were substantially more cost effective. **Conclusion:** The findings indicate comparable *in vitro* pharmaceutical quality between branded and Janaushadhi formulations. Observed plasma concentration data suggest similar drug exposure trends; however, these findings are exploratory and require confirmation through well-controlled pharmacokinetic and bioequivalence studies.

Keywords: Atorvastatin, Branded drugs, Janaushadhi, Losartan, Pilot study, Quality control.

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INTRODUCTION

Inexpensive generic medications improve access to essential healthcare, particularly in Low- and Middle-Income Countries (LMICs) (Challenges to the Availability and Affordability of Essential Medicines in African Countries, n.d.). In LMICs, the

availability, affordability, and accessibility of medicines remain critical challenges for healthcare systems. A large proportion of healthcare expenditure in these regions is paid out of pocket, chiefly because of suboptimal medical insurance penetration. In this context, branded drugs often dominate the market, largely due to aggressive marketing strategies, strong brand recognition, and prescriber preference. However, these branded formulations are typically priced higher and are less affordable to economically disadvantaged populations. The higher cost of branded medicines is partly attributed to expenditures on marketing, promotion, and distribution, as well as taxation and supply chains. Affordable alternatives are challenged by the market dominance of more powerful branded medicines (Oldfield *et al.*, 2025).



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To address issues of affordability and accessibility, the Government of India implemented the Pradhan Mantri Bhartiya Janaushadhi Pariyojana (PMBJP), under which quality-assured generic medicines, commonly referred to as Janaushadhi medicines, are made available at significantly lower prices compared with their branded counterparts (Behera *et al.*, 2025). These cost reductions are achieved primarily because Janaushadhi products do not incur heavy marketing expenses, and Active Pharmaceutical Ingredients (APIs) are often sourced from the same manufacturers that supply branded companies, particularly after patent expiry. Many branded drugs available in the market are off-patent formulations, which further underscores that cost differences do not necessarily reflect therapeutic value (Kesselheim *et al.*, 2008).

Janaushadhi medicines are required to comply with stringent quality standards as per the Indian Pharmacopoeia and are regulated by the Central Drugs Standard Control Organization (CDSCO), ensuring their safety, efficacy, and pharmaceutical equivalence to branded products (Kesselheim *et al.*, 2008). These medicines are procured from WHO-GMP-certified manufacturers and undergo rigorous quality testing at NABL-accredited laboratories, ensuring compliance with Indian Pharmacopoeial standards for identity, purity, potency, and dissolution. Despite regulatory assurances, Janaushadhi medicines are not always well received by healthcare professionals and patients. It is widely believed that lower-priced medicines are inferior in quality. Healthcare professionals also express scepticism regarding the quality, bioavailability, and effectiveness of these products, which may negatively influence prescribing practices (Evaluation of Patients' Perceptions Towards Jan Aushadhi Pariyojana in Mumbai and the Suburbs, 2025).

Thus, a combination of social views and perceptions of quality concerns undermines confidence in generic prescription medicines, limiting their role in healthcare. This study addresses a critical need to compare the scientific evidence on the quality and therapeutic effectiveness of branded and Janaushadhi medicines.

There are limited published data comparing branded drugs with Janaushadhi products for the treatment of dyslipidaemia and hypertension, particularly atorvastatin and losartan (Behera *et al.*, 2025; Kesselheim *et al.*, 2008). The present study aims to (i) compare the pharmaceutical quality attributes of branded and Janaushadhi formulations of atorvastatin and losartan using pharmacopeial methods and (ii) explore plasma drug concentration trends in patients receiving these formulations under routine clinical conditions. Evidence generated from this study could contribute to policy-making decisions and prescribing practices, thereby enhancing the quality of patient care and increasing trust in Janaushadhi products.

Despite regulatory assurance of quality and therapeutic equivalence, the acceptance of generic medicines often faces several social barriers. Patient perception plays a crucial role,

as many associate lower prices with inferior quality—the belief that “cheap medicines are bad.” The superior brand image created by pharmaceutical companies further reinforces this perception, persuading both patients and prescribers toward branded formulations. Some healthcare professionals also express doubts about the efficacy and consistency of Janaushadhi medicines, further strengthening the reputation of branded drugs (Alrasheedy *et al.*, 2014; Colgan *et al.*, 2015; Faasse *et al.*, 2016; Humphreys *et al.*, 2025; Patel *et al.*, 2020).

MATERIALS AND METHODS

This study was designed as a pilot, observational, cross-sectional investigation comprising two components:

- *In vitro* pharmaceutical quality evaluation, and
- Exploratory assessment of plasma drug concentrations in patients.

Using branded-generic and generic formulations of atorvastatin (10 mg) and losartan (50 mg). Ethical approval was obtained from the Institutional Ethics Committee prior to commencement of the study (IEC-AIMS-2024-PHARMA-312).

One branded formulation and one Janaushadhi formulation of each of atorvastatin (10 mg) and losartan (50 mg) were selected for evaluation, based on good local availability and prescription frequency in the hospital pharmacy. All samples of both Atorvastatin and Losartan were procured from licensed retail pharmacies to ensure representation of products commonly used by patients.

Tablets from a single manufacturing batch were used for analysis. Tablets were randomly selected from each batch for quality assessment. Twenty tablets from each formulation were used for weight variation, hardness, friability, and assay testing, while six tablets were used for disintegration and dissolution studies in accordance with pharmacopeial recommendations.

All the solvents and chemicals used were of HPLC grade. The Active Pharmaceutical Ingredients (APIs) losartan and atorvastatin were obtained from Yarrow Chemical Products, India. All instruments used for quality testing and HPLC analysis were calibrated and documented.

Quality Control Test

Quality control tests on both branded and Janaushadhi drugs included assessment of general appearance, weight variation, hardness, friability, disintegration, dissolution, and assay of drug content.

Tablet hardness was measured using a Monsanto hardness tester, friability was assessed using a Roche friabilator, and disintegration testing was performed using a USP disintegration apparatus. Dissolution studies were carried out using the

USP Type II (paddle) dissolution apparatus using appropriate dissolution media for each drug. Drug release was analysed spectrophotometrically, and a minimum of 70% drug release within 30 min was within acceptable pharmacopeial limits.

Content uniformity and drug assay were determined using High-Performance Liquid Chromatography (HPLC) under validated chromatographic conditions.

Patient Selection

Patients receiving either branded or generic formulations of atorvastatin or losartan were included in the study. Participants were recruited from both inpatient and outpatient settings.

Inclusion criteria included patients aged 18-80 years, receiving monotherapy with either branded or generic atorvastatin or losartan for at least one month. Patients with severe renal or hepatic impairment, known drug allergies, secondary causes affecting therapy, or those who had switched between branded and generic formulations were excluded (Tables 1, 2).

Written informed consent was obtained from all participants prior to sample collection.

Plasma Drug Concentration Analysis

Approximately 2 mL of venous blood was collected from each patient in EDTA vacutainers, centrifuged to separate plasma, and the plasma samples stored at -80°C until analysis.

Plasma concentrations of atorvastatin and losartan were determined using High-Performance Liquid Chromatography (HPLC) under standardized chromatographic conditions. The chromatograms were analysed to quantify plasma drug concentrations in patients receiving branded and janaushadhi formulations.

RESULTS

Quality control test for tablets

All quantitative results are summarised as Mean $\pm$ SD in Tables 3 and 4.

Hardness

Tablet hardness was evaluated to determine the mechanical strength of the formulations. Both branded-generic and generic tablet formulations of atorvastatin and losartan were within the acceptable IP limits.

Friability Test

All the formulations demonstrated friability values within the acceptable pharmacopeial limit of not more than 1% weight loss, indicating adequate resistance to mechanical stress. No statistically significant difference in friability was observed between branded-generic and generic formulations.

Disintegration test

Disintegration tests were conducted to evaluate how quickly tablets dissolve in a liquid medium. Generic atorvastatin tablets disintegrated within 5 min, while branded tablets took 9 min and 25 sec. For losartan, the generic version disintegrated within 5 min and 20 sec, compared to 6 min and 33 sec for the branded counterpart. Although generic formulations showed faster disintegration, all samples passed the pharmacopeial criteria of disintegration within 30 min, indicating acceptable performance. Generic formulations showed comparatively faster disintegration than branded-generic formulations; however, the differences were not statistically significant and did not impact dissolution behaviour.

Dissolution test

Dissolution testing, essential for predicting bioavailability, showed that branded atorvastatin had an average drug release of 76.26% at 30 min, according to IP standards, while the generic version had a slightly higher release of 77.17%. For losartan, branded tablets released 78.41% of the drug compared to 79% for generics. These results confirm that both generic and branded tablets meet dissolution criteria and provide similar *in vivo* availability. The improved release in generics may be attributed to their faster disintegration times. No statistically significant difference in dissolution profiles was observed between formulation categories.

Content uniformity

Content uniformity tests assessed whether tablets contained the correct amount of Active Pharmaceutical Ingredient (API).

Branded atorvastatin tablets had 102% purity, and generics had 104%, both within the pharmacopeial limit of 94.5-105%. Similarly, branded losartan had 99.09% purity, and generics had 103%, fitting within the 95-105% range. This confirms that both formulations contain the appropriate quantity of drug (Tables 1-7).

Table 1: Cost of Branded vs Janaushadhi versions of Atorvastatin and Losartan.

Formulation	Atorvastatin Brand	Atorvastatin (Jan Aushadhi)	Losartan Brand	Losartan (Jan Aushadhi)
Dosage	10 mg	10 mg	50 mg	50 mg
Price/10 tabs	Rs. 49.40	Rs. 8.80	Rs. 65.2	Rs.12.10

Comparison Between Generic and Branded Atorvastatin

Table 2: Summary of quality control test for Atorvastatin.

-	Brand	Generic	Pharmacopeial Limits	Inference
General Appearance	Round, white	Triangular, white	N/A	No defects
Weight variation	3.806%	5.109%	≤10%	within limit; equivalent
Hardness	Passed	Passed	4-10 kgf	within limit; equivalent
Friability	0.64%	0.72%	Maximum weight loss <1%	Both within the limit; equivalent
Dissolution (30 min)	76.26%	77.17%	>70%	Both within limit; equivalent
Assay (API content)	99%	102%	98-102%	Both within limit; equivalent

Comparison between Generic and Branded Versions of Losartan

Table 3: Summary of quality control test for Losartan.

Parameter	Brand	Generic	Limit (Pharmacopeia)	Inference
General Appearance	Round, Green	Round, Brick red	N/A	No defects observed
Weight variation	3.68%	7.4%	≤10%	Both within limit; equivalent
Hardness	Passed	Passed	4-10 kgf	Both within the limit; equivalent
Friability	0.57%	0.65%	Maximum weight loss <1%	Both within limit; equivalent
Dissolution (30 min)	78.41%	79 %	>75%	Both within limit; equivalent
Assay (API content)	99.09 %	103%	90-110%	Both within limit; equivalent

Comparison of Plasma Concentrations Between Brand and Generic Formulations of Atorvastatin

Atorvastatin

Of a total of 21 patients included, 16 patients received branded atorvastatin and 5 received Jan Aushadhi generic atorvastatin. Participants had multiple comorbidities such as diabetes mellitus, hypertension, coronary artery disease, and hypothyroidism, reflecting typical real-world prescribing conditions.

Plasma concentrations of atorvastatin (branded drugs) showed variability, possibly from differences in patient characteristics, e.g., comorbidities, dosing schedules, etc. After excluding extreme outliers, the plasma drug concentrations ranged from 29.74 to 61.78 µg/mL, with a mean concentration of 45.73 µg/mL.

Among patients receiving generic atorvastatin, plasma drug concentrations ranged from 31.8 to 62.5 µg/mL, with a mean concentration of 43.6 µg/mL. The observed plasma levels were therefore comparable between the two groups.

Comparison of Plasma Concentrations Between Branded and Jan Aushadhi Formulations of Losartan Tablets

Five patients received branded tablets and five received generic tablets of losartan. A total of 10 plasma samples were collected for comparison of plasma concentration.

Among patients receiving branded losartan tablets, plasma concentrations ranged between 22.003 - 41.01 µg/mL, with a mean concentration of 32.73 µg/mL after excluding extreme values. Blood pressure measurements in these patients were generally within controlled ranges, suggesting adequate therapeutic response.

In the generic losartan group, plasma drug concentrations ranged between 28.20 - 51.13 µg/mL, with a mean concentration of 36.84 µg/mL after excluding outliers. Although individual variability was observed, plasma levels were comparable with those observed in the branded group.

Table 4: A comparison of peak concentration of branded Atorvastatin.

Sl. No.	Age/Sex	Social Habits/ Risk-Factors	Comorbidity/ Intervening Factors	Plasma Cholesterol (Mg/dL)	Atorvastatin Plasma Conc. (Mg/mL)	Mean Conc. (Mg/mL)
1.	66Y/F	N/A	DM, HTN, Asthma	155.2	16.40	45.7
2.	62Y/M	N/A	CVA, BPH	149.9	41.23	
3.	51Y/F	N/A	DM, HTN	154.2	13.23	
4.	77Y/M	N/A	DM, HTN	134.5	92.61	
5.	69Y/M	N/A	DM, HTN, CAD	200	29.74	
6.	57Y/M	Alcohol	DM, HTN	277.4	33.10	
7.	60Y/F	N/A	DM, HTN, Hypothyroidism	105.6	95.72	
8.	80Y/F	N/A	DM, HTN, Hypothyroidism	-	59.37	
9.	79Y/M	N/A	DM, HTN, Hypothyroidism, CAD	142.2	43.15	
10.	78Y/M	N/A	MVR	-	18.91	
11.	77Y/M	Alcohol Smoking	DM, CKD, Leriche Syndrome	160	57.09	
12.	62Y/M	N/A	DCLD, HRS	96.8	12.66	
13.	75Y/M	N/A	DM, HTN, AKI	90.5	61.78	
14.	68Y/M	N/A	CLD	-	109.74	
15.	69Y/M	Smoking	DM, HTN	-	40.35	
16.	76/M	N/A	DM, HTN, CAD, Hypovolemia	161.3	98.53	

Table 5: A comparison of peak concentration of generic Atorvastatin.

Sl. No.	Age (yrs) / Sex	Social Habits/ Risk-Factors	Comorbidity/	Cholesterol Level	Plasma Conc. (µg/mL)	Mean Conc. (µg/mL)
1.	58 (F)	N/A	DM, Hypothyroidism	150	40.5	43.6 µg/mL
2.	44 (F)	N/A	MVR	106	45.6	
3.	75Y/M	N/A	DM, HTN, COPD	87.1	31.8	
4.	55Y/F	N/A	HTN, Hypothyroidism	146.3	62.5	
5.	51Y/M	N/A	DM, HTN	-	37.6	

Abbreviations: DM- Diabetes Mellitus, HTN- Hypertension.

Most patients receiving losartan therapy had comorbid conditions such as diabetes, dyslipidaemia, or hypothyroidism. Blood pressure readings during the study period indicated adequate control in the majority of patients receiving both branded and generic formulations.

Losartan Generic Tablets

Despite minor variability in individual plasma drug concentrations, the mean plasma concentrations of both atorvastatin and losartan were comparable between branded and generic groups. These findings suggest similar systemic exposure and support the pharmaceutical equivalence observed in the *in vitro* quality control tests.

Patient monitoring and clinical records also indicated comparable tolerability and therapeutic response between the two groups. The findings therefore support the use of generic formulations as cost-effective alternatives without compromising drug exposure or patient outcomes.

Statistical analysis

All quantitative data are expressed as mean±Standard Deviation (SD). Student's *t*-test was employed to evaluate statistically significant differences between quality control parameters and plasma drug concentrations of branded-generics and generics. $p < 0.05$ was considered statistically significant.

Table 6: A comparison table of peak concentration of Branded Losartan.

Sl. No.	Age/ Sex	Social Habits/ Risk-Factors	Comorbidity/ Intervening Factors	BP Levels (mmHg)	Plasma con (µg/mL)	Mean Conc (µg/mL)
1.	75Y/F	N/A	DM, DLP	120/70	30.59	32.726 µg/mL
2.	80Y/F	N/A	DM, HTN, Hypothyroidism, CKD	150/80	12.39	
3.	67Y/M	N/A	DM, HTN, Hypothyroidism	155/77	22.003	
4.	75Y/M	N/A	DM, HTN, CAD	170/80	37.30	
5.	72Y/M	N/A	HTN, DLP	140/70	41.01	

Table 7: A comparison table of peak concentration of generic Losartan.

Sl. No.	Age /Sex	Social Habits/ Risk-Factor	Comorbidity/Intervening factors	BP Levels (mmHg)	Plasma Conc (µg/mL)	Mean Conc (µg/mL)
1.	51Y/M	ALCOHOL	DM	110/70	31.19	36.84 µg/mL
2.	49Y/F	N/A	-	150/100	28.20	
3.	60Y/F	N/A	Hypothyroidism	150/100	112.517	
4.	62Y/F	N/A	DM, DLP	170/80	51.13	
5.	49Y/M	N/A	-	140/70	5.67	

DISCUSSION

The findings demonstrate that both branded and Jan Aushadhi drug formulations complied with pharmacopeial specifications for key quality parameters. These results indicate that Jan Aushadhi drugs can achieve pharmaceutical equivalence comparable to branded counterparts while offering significantly lower cost.

Despite strong regulatory frameworks ensuring pharmaceutical equivalence, the acceptance of Jan Aushadhi drugs remains limited in healthcare settings owing to patient-related perceptions. A key contributing factor is the “placebo effect of price,” wherein higher-priced treatments are perceived as more effective regardless of their actual pharmacological quality. The belief that higher-priced treatments are inherently superior generates a self-fulfilling expectation, whereby patients perceive enhanced clinical benefits, including improved symptom relief (Humphreys *et al.*, 2025). Conversely, more affordable options such as Jan Aushadhi drugs are frequently perceived as less effective despite equivalent therapeutic performance. In many communities, branded medicines are perceived as more reliable and prestigious, whereas Jan Aushadhi medicines are often viewed as options intended for economically weaker populations. Several studies have reported that patients prefer branded medicines because they tend to associate higher prices with superior quality. These misconceptions significantly hamper patient decision-making and result in the underutilization of Jan Aushadhi medicines even when they offer substantial cost savings (Alrasheedy *et al.*, 2014).

Beyond economic concerns, the social and psychological value associated with branded medicines also influences patient choice. In many communities, branded medicines are perceived as symbols of better healthcare and are considered more prestigious than generic drugs. Some patients express embarrassment when requesting generic medicines because they fear being perceived as unable to afford branded drugs. This social stigma surrounding generics contributes to hesitation among patients, even when they are aware of the financial benefits (Patel *et al.*, 2020). Furthermore, factors such as a drug’s appearance, packaging, brand reputation, and familiarity influence patient trust. Branded medicines often have distinctive packaging, consistent tablet appearance, and a strong marketing presence, which reinforce perceptions of superior quality and reliability among patients and their families. Such visual and psychological impressions may generate a placebo-like effect in favor of branded medicines simply because patients believe that branded drugs work better (Faasse *et al.*, 2016).

Patient attitudes are also strongly influenced by the behaviour and perceptions of healthcare professionals. In some settings, physicians hesitate to prescribe Jan Aushadhi drugs because of concerns regarding patient acceptance and perceived variability in quality. As prescribers predominantly recommend branded drugs, patients may interpret this as confirmation that branded products are superior, thereby reinforcing existing misconceptions. Several studies have shown that inadequate knowledge among healthcare professionals regarding generic medicines has contributed to reduced prescribing of Jan Aushadhi drugs (Colgan *et al.*, 2015).

The pharmaceutical industry also plays a significant role in shaping perceptions regarding branded medicines. Pharmaceutical companies invest heavily in marketing strategies designed to promote brand recognition and maintain market share. These strategies involve promotional campaigns, advertising, and interactions with healthcare professionals. Such marketing activities can create the perception among patients that branded drugs are more reliable than generic medicines (Alves *et al.*, 2019).

Overall, patient acceptance of generic medicines is influenced by misconceptions about cost, quality, reputation, social stigma, brand image, and pharmaceutical marketing practices. Addressing these barriers requires improved patient education, stronger regulatory guidelines that encourage generic prescribing that ensure affordability and access to medicines.

LIMITATIONS

This study has several limitations. As a pilot study, the small and unequal sample sizes, specially the plasma drug concentration groups, limit the statistical power and generalizability of the findings. Although plasma drug concentrations were assessed after patients had received the respective formulations for a sufficient duration to achieve steady state concentration, inter-individual variability in age, comorbidities, concomitant medications, and other patient-related factors may have influenced the observed plasma concentrations. Also, the observational and cross-sectional nature of the study, along with the evaluation of only one brand and one Janaushadhi formulation of each drug, limits the broader applicability of the findings. Therefore, plasma concentration findings should be interpreted as exploratory. Larger studies with adequately powered and more balanced patient groups and evaluation of multiple manufacturing batches are required to confirm these findings.

CONCLUSION

The present study demonstrates that branded and Jan Aushadhi formulations of atorvastatin and losartan comply with standard established pharmacopeial quality control parameters and show comparable plasma drug concentrations, indicating similar pharmaceutical performance and systemic drug exposure. These findings confirm that both formulations exhibit comparable pharmaceutical quality. The results support the potential use of Janaushadhi medicines as cost-effective alternatives, while emphasizing the need for further rigorous clinical investigations.

Patient perceptions, societal stigma associating lower-cost medicines with reduced socioeconomic status, and the influence of brand image and pharmaceutical promotion, continue to drive preference for higher-priced branded medications.

Addressing these barriers through targeted patient education, improved awareness regarding the safety and efficacy of Jan Aushadhi formulations, along with policies promoting their use, can help improve the availability, affordability, and accessibility of essential medicines, particularly in LMIC countries.

ABBREVIATIONS

LMIC: Low- and Middle-Income Countries; **PMBJP:** Pradhan Mantri Janaushadhi Pariyojana; **HPLC:** High-Performance Liquid Chromatography; **APIs:** Active Pharmaceutical Ingredients; **CDSCO:** Central Drugs Standard Control Organization; **WHO-GMP:** World Health Organization Good Manufacturing Practices; **NABL:** National Accreditation Board for Testing and Calibration Laboratories; **IEC:** Institutional Ethics Committee; **USP:** United States Pharmacopeia; **IP:** Indian Pharmacopoeia; **SD:** Standard Deviation; **EDTA:** Ethylenediaminetetraacetic Acid; **DM:** Diabetes Mellitus; **HTN:** Hypertension; **CAD:** Coronary Artery Disease; **CVA:** Cerebrovascular Accident; **BPH:** Benign Prostatic Hyperplasia; **MVR:** Mitral Valve Replacement; **CKD:** Chronic Kidney Disease; **DCLD:** Decompensated Chronic Liver Disease; **HRS:** Hepatorenal Syndrome; **AKI:** Acute Kidney Injury; **CLD:** Chronic Liver Disease; **COPD:** Chronic Obstructive Pulmonary Disease; **DLP:** Dyslipidemia.

CONFLICT OF INTEREST

The authors declare that there is no conflict of interest.

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