



RESEARCH ARTICLE

Corticosteroids and Antibiotics Utilization in COPD Exacerbation: A Prospective Observational Study from a Tertiary Care Hospital

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ABSTRACT

Background: Chronic Obstructive Pulmonary Disease (COPD) is a leading cause of morbidity and mortality worldwide, with exacerbations significantly impacting disease progression, hospitalization rates, and mortality risk. The GOLD 2025 guidelines emphasize the critical role of corticosteroids and antibiotics in managing COPD exacerbations, yet prescribing practices in rural Indian healthcare settings remain inadequately documented.

Objective: This study aimed to assess the prescribing patterns of corticosteroids and antibiotics among patients with COPD exacerbations at a tertiary care hospital in rural Maharashtra, India, and evaluate adherence to GOLD 2025 treatment guidelines.

Methods: A prospective observational study was conducted over six months (June to November 2025) at Vilasrao Deshmukh Government Medical College and Hospital, Latur, Maharashtra. Patients aged ≥ 40 years with clinically confirmed COPD exacerbations were enrolled. Data on demographic characteristics, corticosteroid utilization (type, route, dose, duration), antibiotic prescribing patterns (class, specific agents), and therapy combinations were collected using a structured proforma. Descriptive statistics were employed for data analysis.

Results: Among 50 enrolled patients, the majority were aged ≥ 60 years (76%), with a nearly equal gender distribution (48% male, 52% female). Corticosteroid therapy was administered to 86% ($n=43$) of patients, with dual therapy (44%) and triple therapy (40%) being the predominant regimens. Antibiotics were prescribed rationally, with penicillins (35%) and macrolides (31%) being the most commonly utilized classes. Azithromycin (56%) and amoxicillin-clavulanate (44%) were the most frequently prescribed specific agents. The prescribing patterns demonstrated substantial alignment with GOLD 2025 recommendations, though opportunities for improvement were identified in eosinophil-guided inhaled corticosteroid prescribing and antimicrobial stewardship.

Conclusion: This study reveals that corticosteroid and antibiotic prescribing practices at the study hospital largely adhere to GOLD 2025 guidelines, reflecting appropriate clinical management of COPD exacerbations. However, gaps persist in consistent documentation of blood eosinophil counts and optimization of inhaled corticosteroid therapy. Enhanced disease awareness initiatives, regular prescription audits, and strengthened antimicrobial stewardship programs are essential to further improve COPD management outcomes in resource-limited rural Indian settings.

Keywords: Chronic Obstructive Pulmonary Disease, COPD exacerbation, corticosteroids, antibiotics, prescribing patterns, GOLD guidelines, rural India

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INTRODUCTION

Chronic Obstructive Pulmonary Disease (COPD) is a highly prevalent, preventable, and treatable respiratory condition characterized by persistent airflow limitation due to airway and/or alveolar abnormalities, typically caused by significant exposure to noxious particles or gases. It remains a leading cause of morbidity and mortality worldwide, with substantial economic and social burden. An exacerbation of COPD (ECOPD) is defined as an acute worsening of respiratory symptoms requiring a change in therapy, a critical event that negatively impacts health status, accelerates disease progression, worsens airflow obstruction, and

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increases hospitalization rates and mortality risk. GOLD 2025 emphasizes that even a single moderate or severe exacerbation before initiating maintenance therapy increases the risk of future exacerbations, and this risk escalates with increasing frequency and severity of events[1,2].

Classification of Exacerbations

The Rome Proposal criteria, now integrated into GOLD guidelines, provide a standardized classification system based on clinical parameters including respiratory rate, heart rate, mental status, and oxygen saturation. This classification guides the appropriate level of care from outpatient management for mild exacerbations to intensive care unit (ICU) admission for severe, life-threatening events characterized by severe dyspnoea, altered consciousness, worsening hypoxemia ($\text{PaO}_2 < 40 \text{ mmHg}$), severe respiratory acidosis ($\text{pH} < 7.25$), or hemodynamic instability. The GOLD 2025 ABE classification system has replaced the prior ABCD scheme: patients with ≥ 2 moderate exacerbations or ≥ 1 hospitalization per year are grouped as category E (highest exacerbation risk), while those with fewer events are grouped as A or B based on symptom severity measured by the COPD Assessment Test or mMRC dyspnoea scale[1].

Treatment Approaches: Corticosteroids

Systemic corticosteroids form a cornerstone of management for moderate-to-severe exacerbations. GOLD 2025 recommends oral prednisone 40 mg daily for 5 days, as this duration is non-inferior to 14-day regimens while significantly reducing cumulative steroid exposure and adverse effects. The oral route demonstrates equivalent efficacy to parenteral administration. Meta-analyses confirm that systemic corticosteroids reduce treatment failure by half (RR 0.48, 95% CI 0.35-0.67; NNT=9) and decrease relapse risk (HR 0.78, 95% CI 0.63-0.97), with improved FEV_1 at 72 hours (mean difference 140 mL). However, corticosteroids increase adverse events (RR 2.33), particularly hyperglycemia (RR 2.79). In selected patients, high-dose nebulized budesonide (1500-2000 μg , 3-4 times daily) demonstrates comparable efficacy to systemic steroids, though cost and administration frequency may limit its use.

For maintenance therapy, inhaled corticosteroids (ICS) are recommended based on blood eosinophil counts. GOLD 2025 strongly suggests ICS-containing regimens when blood eosinophils exceed 300 cells/ μL , particularly in patients with ≥ 2 moderate or ≥ 1 hospitalized exacerbation annually. ICS are suggested for eosinophils 100-300 cells/

μL and should be avoided when eosinophils $< 100 \text{ cells}/\mu\text{L}$ due to increased pneumonia risk. Triple therapy (LABA-LAMA-ICS) has demonstrated reduced all-cause mortality compared with dual bronchodilator therapy in the ETHOS trial[1,5,6-7].

Antibiotic Therapy

Antibiotics are indicated when patients exhibit clinical signs of bacterial infection, most classically increased sputum purulence and volume. GOLD 2025 recommends antibiotics when two or more cardinal symptoms are present: increased dyspnea, increased sputum volume, and purulent sputum. Empiric antibiotic choices include amoxicillin-clavulanate, macrolides (e.g., azithromycin 500 mg daily for 3 days), second- or third-generation cephalosporins, or fluoroquinolones, with a treatment duration of 5-7 days. Sputum culture should be considered in patients with frequent exacerbations, severe obstruction, or requiring mechanical ventilation. Cochrane meta-analyses demonstrate antibiotics reduce treatment failure in ambulatory patients (RR 0.72, 95% CI 0.56-0.94) and ICU patients (RR 0.19, 95% CI 0.08-0.45), though effects in hospitalized non-ICU patients are less consistent[1,8-9].

Burden of COPD in India

The prevalence of COPD among individuals aged ≥ 45 years in India is approximately 2.1%, with higher prevalence among men, rural populations, and those aged ≥ 60 years. Household factors such as cooking on open fires and exposure to passive smoking significantly heighten COPD risk. Regional variations persist, with elevated risks observed in Southern India and lower risks in the North-East. Alarming, disease awareness remains critically low: only 3% of patients in rural Indian settings are aware of their COPD diagnosis, with 43% not accepting the diagnosis and 54% lacking knowledge about the disease.

Treatment patterns in India reveal significant gaps in rational therapy. A large single-center study documented inhalation treatment use in only 58% of COPD cases, with 18% using levosalbutamol plus beclometasone and merely 9% receiving guideline-recommended combinations (formoterol plus budesonide or salmeterol plus fluticasone). Oral medications were prescribed in 42% of cases, including oral steroids in 19%. The high cost of long-acting inhalation therapies and improper drug selection by physicians were identified as major barriers to rational treatment. These findings underscore the urgent need for enhanced disease awareness and evidence-based prescribing practices in India[1-3,11-12].

The 2025 Maharashtra Floods

In July 2025, Maharashtra, particularly Mumbai, experienced severe flooding, a known trigger for COPD exacerbations through multiple mechanisms: increased exposure to mold, dampness, and air pollutants; disruption of healthcare access; and physical and emotional stress. During such events, prompt initiation of systemic corticosteroids for moderate-to-severe exacerbations is critical to prevent treatment failure and reduce the burden on overwhelmed healthcare systems. Rescue packs containing short courses of oral corticosteroids and antibiotics may be offered to patients with a history of exacerbations as part of self-management action plans[2,4].

Study Rationale

This study aims to assess the patterns of corticosteroid use, including inhaled corticosteroids (ICS), among COPD patients, with particular focus on treatment practices during exacerbations and the impact of the 2025 Maharashtra flood event on disease management.

MATERIALS AND METHODS

Study Design

A prospective observational study was conducted to evaluate the prescribing patterns of corticosteroids and antibiotics among patients with Chronic Obstructive Pulmonary Disease (COPD) exacerbations at a tertiary care hospital in Latur, Maharashtra, India. The study was carried out over a period of six months, from June 2025 to

November 2025, coinciding with the post-monsoon period following the severe flooding in Maharashtra. During this period, prescriptions of patients with clinically confirmed COPD exacerbations were reviewed at the time of hospital admission and throughout their course of treatment. Data were collected prospectively using a structured patient profile form that included demographic details, clinical diagnoses, and prescribed medications. Particular attention was given to the use of systemic and inhaled corticosteroids, classified by type (prednisolone, methylprednisolone, budesonide, beclomethasone, fluticasone), route of administration (oral, intravenous, inhaled), and duration of therapy. Antibiotic prescribing patterns, including class selection (penicillins, macrolides, cephalosporins, fluoroquinolones), spectrum of activity, and de-escalation practices, were also documented. All prescriptions meeting the inclusion criteria were documented and analysed to assess drug utilization patterns and adherence to GOLD 2025 treatment guidelines[10].

Study Setting

The study was conducted in the inpatient and outpatient departments of Vilasrao Deshmukh Government Medical College and Hospital, Latur, Maharashtra. The institution is a government-managed tertiary care hospital serving the surrounding rural and semi-urban population of the Marathwada region. It provides comprehensive primary, secondary, and tertiary healthcare services and admits patients with a wide range of respiratory conditions,

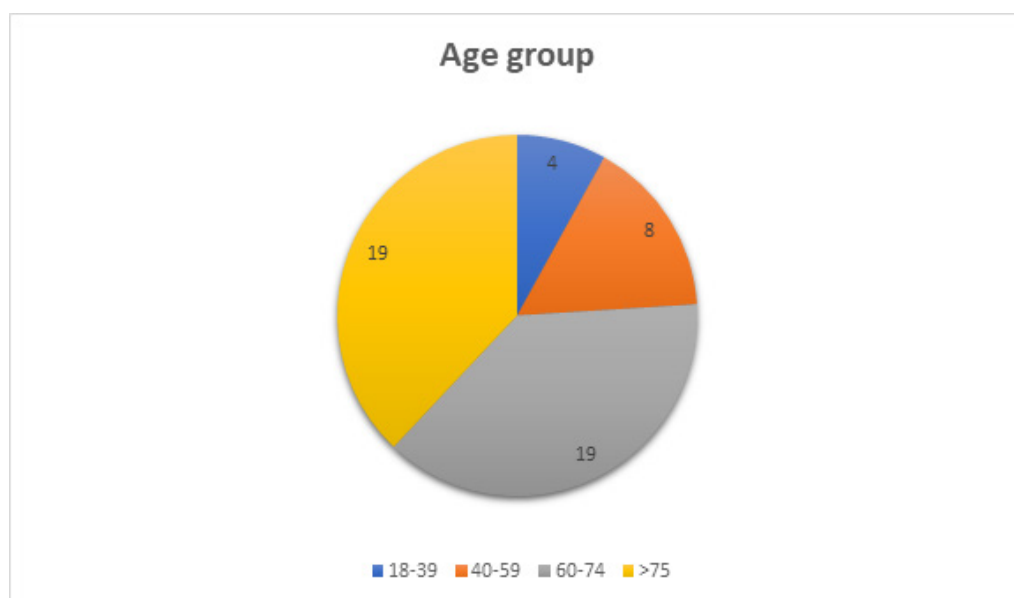


Figure 1: Age Distribution

including COPD exacerbations. Being a government healthcare facility, it plays a vital role in delivering affordable and accessible medical care to the community, particularly during natural disasters such as the July 2025 floods that affected the region.

Study Duration

The study was conducted over a period of six months, from June 2025 to November 2025. This timeframe was deliberately chosen to capture data during the monsoon and post-monsoon periods when exacerbation rates typically peak due to climatic triggers, including the severe flooding event that occurred in Maharashtra during July 2025. The duration allowed sufficient sample size accumulation while maintaining data quality and consistency in prescription documentation.

Inclusion Criteria

All patients diagnosed with COPD exacerbations and admitted to the hospital during the study period were prospectively evaluated. Patients who received corticosteroid therapy, either systemic or inhaled, as part of their treatment regimen were included in the study. Prescriptions containing complete demographic details, clinical diagnosis, and comprehensive drug therapy information were considered eligible for further analysis. Patients of either gender and all age groups (≥ 40 years) with a confirmed diagnosis of COPD based on GOLD criteria, including spirometric confirmation (post-bronchodilator $FEV_1/FVC < 0.70$), were included.

Exclusion Criteria

Patients who were unwilling to provide consent or unable to cooperate during data collection were excluded from the study. Prescriptions of patients with incomplete medical records, those admitted for less than 24 hours, and pregnant women were not considered. In addition, patients with a primary diagnosis of asthma, bronchiectasis, pulmonary tuberculosis, or other respiratory conditions mimicking COPD were excluded to maintain diagnostic specificity. Patients who had already received corticosteroid or antibiotic therapy before admission were excluded to minimize uncertainty and ensure accuracy in evaluating hospital-initiated prescribing patterns. Patients with a history of corticosteroid allergy or those participating in other interventional trials were also excluded.

Data Collection

At the time of admission, data were collected prospectively using a structured questionnaire adapted from previously published studies and validated by clinical experts. The questionnaire was divided into three sections. The first section captured socio-demographic details of the patients, including age, gender, weight, body mass index, occupation, smoking history (pack-years), and associated comorbidities (hypertension, diabetes mellitus, coronary artery disease, heart failure). The second section recorded clinical information, including type of admission (emergency or elective), clinical presentation (dyspnea severity using the mMRC scale, sputum characteristics, fever), oxygen saturation (SpO_2), arterial blood gas parameters, and

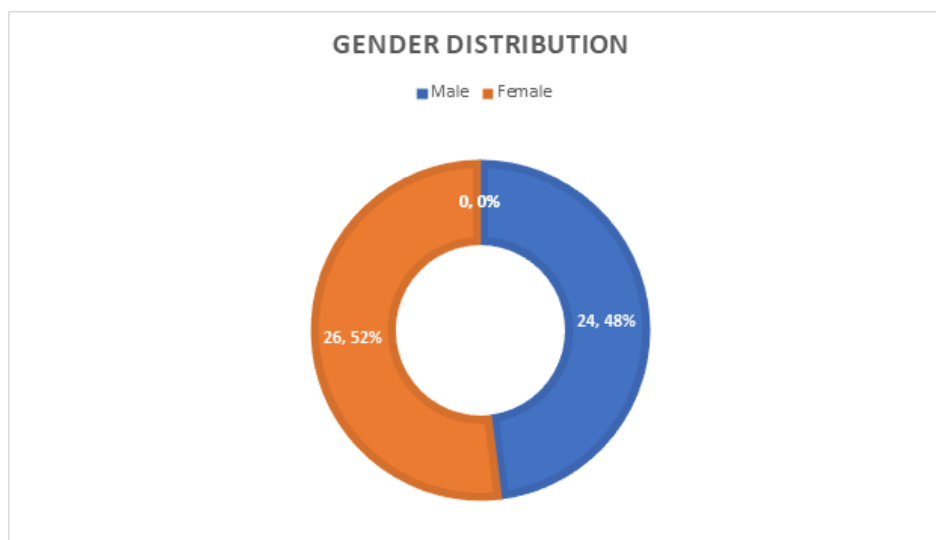


Figure 2: Gender Distribution

duration of hospital stay. The third section documented prescription-related data, including corticosteroids prescribed (type, dose, frequency, route, duration), antibiotics prescribed (name, class, dose, frequency, route, duration), bronchodilators (short-acting and long-acting), and supportive therapies (oxygen therapy, mucolytics, chest physiotherapy). The choice of antibiotics was classified into broad-spectrum and narrow-spectrum categories, and corticosteroids were categorized as systemic (oral/intravenous) or inhaled. Prescribing indicators recommended by the World Health Organization (WHO) were used to evaluate rational drug utilization.

Only patients who provided informed consent and were willing to participate were included. Pharm.D interns and postgraduate residents carried out data collection under the supervision of clinical preceptors and attending physicians. For each eligible patient, details of corticosteroid and antibiotic prescriptions were documented, including whether the therapy was empirical or based on a confirmed diagnosis. Patient interviews were conducted to gather information regarding presenting complaints, the clinical diagnosis made by the physician, and any history of medication use before hospital admission. All data were first entered into a patient profile form and subsequently transcribed into a Microsoft Excel spreadsheet for further analysis. A pre-designed form was used to record comprehensive prescription details, including the name of the corticosteroid/antibiotic, class, dosage form, strength, dose, frequency, duration, and number of units prescribed. For patients who were initiated on a new therapeutic regimen during hospitalization, these parameters were

Table 1: Age Distribution

Age Group	Number of Patients (n)	Percentage (%)
18–39	4	8%
40–59	8	16%
60–74	19	38%
≥75	19	38%
Total	50	100%

Table 2: Gender Distribution

Gender	Number of Patients (n)	Percentage (%)
Male	24	48%
Female	26	52%
Total	50	100%

Table 3: Corticosteroids used

Corticosteroids used	Number of Patients (n)	Percentage (%)
Yes	43	86%
No	7	14%
Total	50	100%

recorded throughout the treatment period until completion or discharge.

Data Management

For each participant, data were recorded on a structured patient profile sheet designed specifically for the study. The collected information was carefully entered into Microsoft Excel (Version 2019) to create a digital database. This dataset served as the basis for organizing, managing, and interpreting the findings. Data validation was performed regularly to identify and correct any errors. The processed data were then utilized to evaluate prescription patterns, assess adherence to GOLD 2025 guidelines, and generate meaningful conclusions for the study. Descriptive statistics were employed, with results expressed in terms of frequencies, percentages, and mean values with standard deviations.

Outcome Measures

The primary outcome measures included: (1) the proportion of COPD patients receiving corticosteroid therapy during exacerbations; (2) the distribution of corticosteroid types (systemic vs. inhaled) and specific agents prescribed; (3) the proportion of patients receiving antibiotic therapy and the distribution of antibiotic classes; (4) adherence to GOLD

Table 4: Type of Therapy used

Therapy Type	Patients (n)	Percentage %
Monotherapy	4	8%
Dual Therapy	22	44%
Triple Therapy	20	40%
Quadruple Therapy	4	8%

Table 5: Class of antibiotic used

Antibiotic Class	Number of Patients (n)	Percentage %
Penicillins	32	35%
Cephalosporins	14	15%
Macrolides	28	31%
Fluoroquinolones	12	13%
others	4	4%

Table 6: Types of Antibiotics used

Antibiotic Name	Patients (n)	Percentage (%)
Azithromycin (Azee)	28	56%
Amoxicillin + Clavulanate (Augmentin)	22	44%
Ceftriaxone (Monocef/Ofraamax)	12	24%
Levofloxacin (Levoflox)	12	24%
Piperacillin + Tazobactam (Piptaz/Tazomac)	10	20%
Metronidazole (Metro)	3	6%
Cefepime (Mono)	2	4%
Meropenem (Mero)	1	2%
Doxycycline (Doxy)	1	2%
Amikacin	1	2%

2025 recommendations regarding corticosteroid dose and duration; and (5) correlation of corticosteroid prescribing patterns with patient characteristics (eosinophil count, exacerbation frequency, severity). Secondary outcomes included the association between the July 2025 flood event and changes in prescribing patterns, the relationship between corticosteroid use and treatment outcomes (length of hospital stay, need for mechanical ventilation, mortality), and the frequency of adverse effects documented during treatment.

Statistical Analysis

Data were analyzed using descriptive statistical methods. Categorical variables were expressed as frequencies and percentages, while continuous variables were summarized as mean $\pm$ standard deviation (SD) for normally distributed data or median with interquartile range (IQR) for non-normally distributed data. Subgroup analyses were performed based on patient demographics, exacerbation severity, corticosteroid type, and timing of admission relative to the flood event. All analyses were conducted using Microsoft Excel and SPSS version 26.0 (IBM Corp., Armonk, NY, USA). Results were presented in the form of tables, graphs, and charts to illustrate prescribing trends.

Ethical Approval

Before the commencement of the study, ethical clearance was obtained from the Vilasrao Deshmukh Government Medical College and Hospital, Latur, Maharashtra. Only those patients who voluntarily agreed to participate and provided written informed consent were enrolled. The privacy and confidentiality of all participants were safeguarded throughout the study, and all procedures were performed in compliance with established ethical standards for clinical research as per the Declaration of Helsinki and Indian Council of Medical Research (ICMR) guidelines. Patients were informed of their right to withdraw from the study at any time without affecting their medical care. Data were anonymized before analysis to protect patient identities.

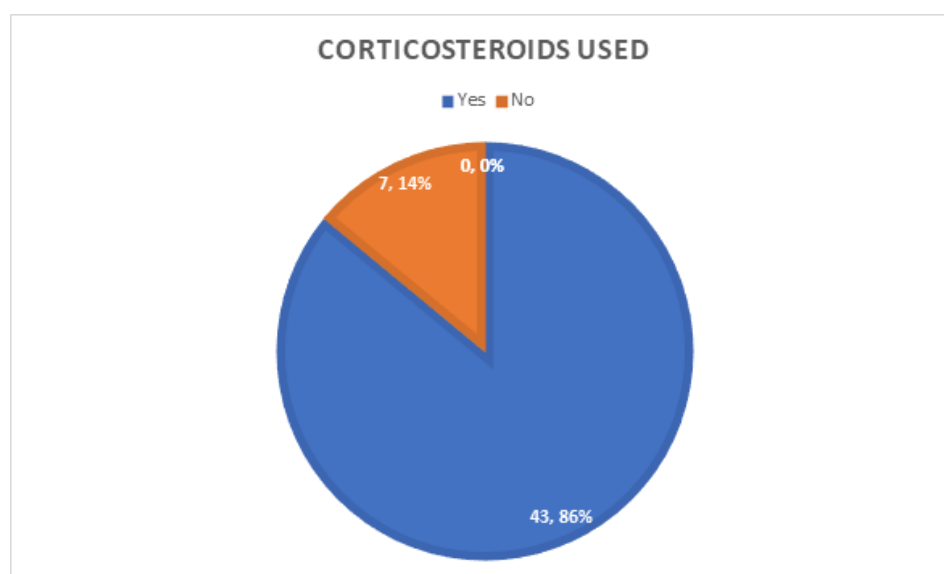


Figure 3: Corticosteroids used

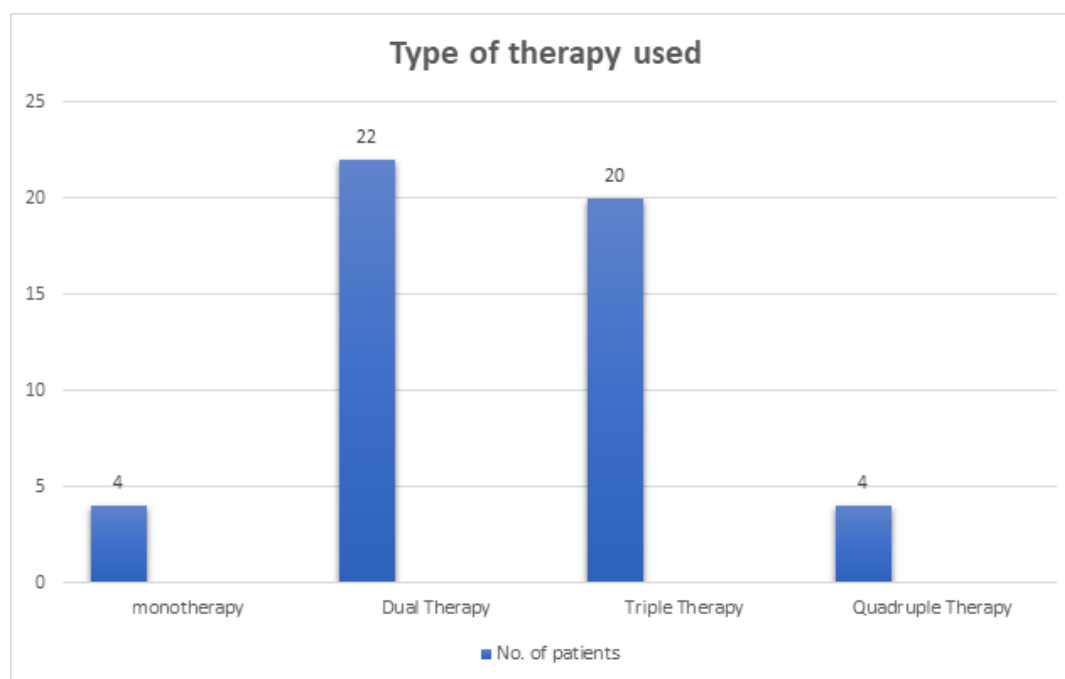


Figure 4: Type of Therapy used

RESULTS

Age Distribution

The majority of patients belonged to the 60-74 years age group (n=19; 38%) and the ≥ 75 years age group (n=19; 38%). Patients in the 40-59 years age group accounted for 8 cases (16%), while only 4 patients (8%) were in the 18-39 years age group. This distribution highlights that COPD exacerbations were more frequently observed among elderly populations aged 60 years and above, with none of the patients being below 18 years of age.

Gender Distribution

Among the 50 patients enrolled, 24 (48%) were male, and 26 (52%) were female. The study population showed a nearly equal gender distribution, with a slightly higher proportion of female patients.

Corticosteroid Utilization

Overall Corticosteroid Use

Corticosteroid therapy was administered to 43 patients (86%) during their COPD exacerbation management, while 7 patients (14%) did not receive corticosteroid therapy. This high utilization rate reflects the central role of corticosteroids in the management of moderate-to-severe COPD exacerbations.

Therapy Combinations

Among the 50 patients, monotherapy was observed in 4 patients (8%), dual therapy in 22 patients (44%), triple therapy in 20 patients (40%), and quadruple therapy in 4 patients (8%). The predominance of dual and triple therapy regimens indicates a comprehensive approach to COPD management, incorporating bronchodilators and corticosteroids as recommended by GOLD 2025 guidelines.

Antibiotic Prescribing Patterns

Antibiotic Class Distribution

Analysis of antibiotic prescriptions revealed that penicillins were the most commonly prescribed class, accounting for 35% (n=32) of all antibiotics. Macrolides followed closely at 31% (n=28), while cephalosporins comprised 15% (n=14), fluoroquinolones accounted for 13% (n=12), and other antibiotic classes constituted 4% (n=4) of prescriptions.

Specific Antibiotic Agents

Azithromycin was the most frequently prescribed antibiotic, administered to 28 patients (56%), followed by amoxicillin-clavulanate in 22 patients (44%). Ceftriaxone was prescribed to 12 patients (24%), levofloxacin to 12 patients (24%), and piperacillin-tazobactam to 10 patients (20%). Other antibiotics, including metronidazole (6%),

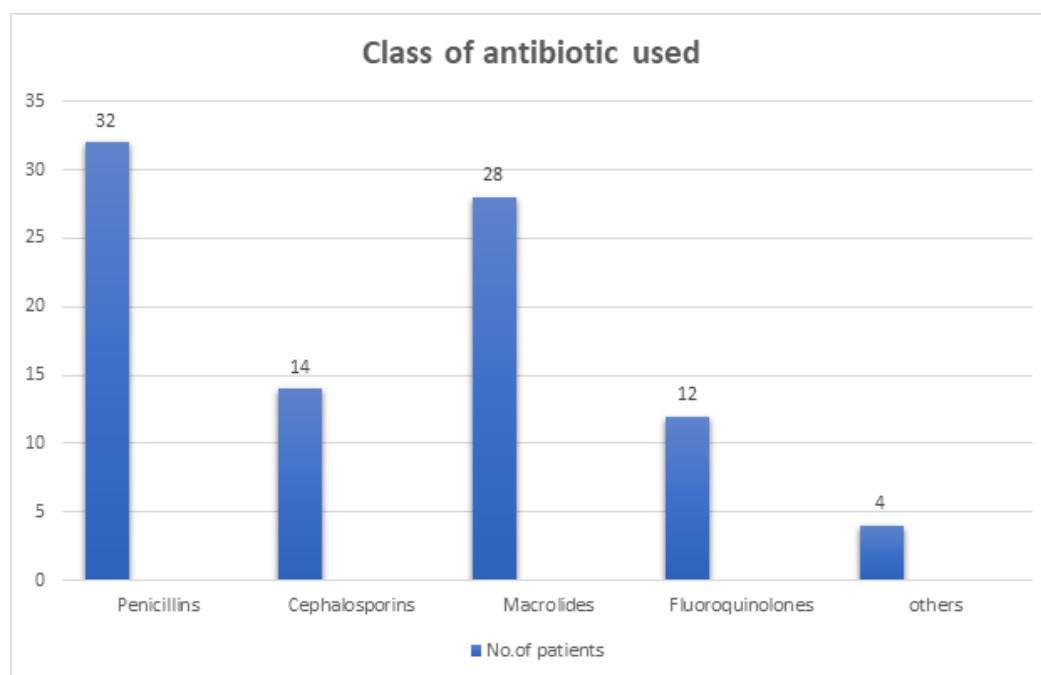


Figure 5: Class of antibiotic used

cefepime (4%), meropenem (2%), doxycycline (2%), and amikacin (2%), were less frequently utilized.

DISCUSSION

This study provides important insights into prescribing patterns of corticosteroids and antibiotics in patients with COPD exacerbations at a government-run tertiary care hospital in rural Maharashtra. The hospital serves as a critical healthcare provider for the surrounding rural population, often functioning as the primary referral center for respiratory emergencies.

Demographic Characteristics

The age distribution, with 76% of patients aged 60 years and above, is consistent with established COPD epidemiology. This aligns with findings from research^{3,11}, who reported a COPD prevalence of 2.1% among individuals aged ≥ 45 years in India. The nearly equal gender distribution, with slight female predominance (52%), may reflect changing smoking patterns, increased biomass fuel exposure among rural women, and improved healthcare-seeking behaviour.

Corticosteroid Prescribing Patterns

The high proportion of patients receiving corticosteroid therapy (86%) reflects appropriate clinical practice, as systemic corticosteroids are a cornerstone of management for moderate-to-severe exacerbations according to GOLD

2025. The predominance of dual and triple therapy regimens (84% combined) aligns with GOLD recommendations for patients with frequent exacerbations. However, the absence of consistent blood eosinophil documentation for guiding ICS use represents an opportunity for quality improvement, as GOLD 2025 strongly recommends ICS when eosinophils exceed 300 cells/ μ L and avoidance when < 100 cells/ μ L.

Antibiotic Prescribing Patterns

The antibiotic prescribing patterns demonstrate a rational approach to empiric therapy. The predominance of penicillins (35%) and macrolides (31%) is consistent with GOLD 2025 recommendations, which suggest amoxicillin-clavulanate and macrolides as preferred empiric choices. The frequent use of azithromycin (56%) and amoxicillin-clavulanate (44%) reflects adherence to these recommendations. However, the relatively high use of fluoroquinolones (13%) warrants attention given concerns about antimicrobial resistance.

Comparison with Indian Context

The treatment patterns observed reveal both strengths and gaps compared to previous Indian research, which documented inhalation therapy in only 58% of COPD cases, whereas our study reported higher utilization of combination therapy^[3,11,12]. However, research found sub-optimal COPD management in community settings,

with only 3% of rural patients aware of their diagnosis. These findings underscore the urgent need for enhanced disease awareness and evidence-based prescribing in India[3].

Impact of the 2025 Maharashtra Floods

The post-flood period provided a unique context for understanding COPD management during environmental crises. Flooding is a known trigger for exacerbations through increased exposure to pollutants, disrupted healthcare access, and stress. The high corticosteroid use (86%) may reflect exacerbation severity during this period, demonstrating the hospital's commitment to providing continued care during crises.

STRENGTHS AND LIMITATIONS

The study's strength lies in its focus on real-world prescribing in a rural hospital, a setting often overlooked in research. Limitations include single-center design, small sample size (n=50), lack of consistent spirometric confirmation, absence of routine blood eosinophil documentation, and incomplete clinical outcome assessment. Despite these limitations, the study provides meaningful insights into prescribing practices and highlights areas for improvement in COPD management.

CONCLUSION

This study reveals that corticosteroid therapy was administered to the majority of COPD exacerbation patients (86%), reflecting appropriate clinical practice aligned with GOLD 2025 guidelines. The predominance of dual and triple therapy regimens indicates a comprehensive management approach, though opportunities exist for improved eosinophil-guided prescribing for inhaled corticosteroids. Antibiotic prescribing patterns demonstrated rational empiric therapy, with penicillins and macrolides being most commonly prescribed, consistent with guideline recommendations.

The findings highlight several gaps requiring attention: inconsistent documentation of blood eosinophil counts, need for enhanced antimicrobial stewardship, and the critical importance of disease awareness initiatives in rural populations where only 3% of patients are aware of their COPD diagnosis. The study also underscores the resilience of healthcare delivery during the 2025 Maharashtra floods, emphasizing the need for disaster preparedness planning.

To improve COPD management in rural Indian settings, the study recommends regular prescription audits, enhanced access to diagnostic facilities including spirometry and eosinophil counts, strengthened antimicrobial

stewardship programs, expanded patient education initiatives, and development of disaster preparedness plans. While prescribing practices at the study hospital largely align with GOLD guidelines, continued efforts are needed to optimize personalized treatment selection, improve guideline adherence, and reduce the burden of COPD in resource-limited environments.

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AUTHORS CONTRIBUTIONS

All authors made substantial contributions to the study, including conceptualization, methodology, study design, data curation, patient enrolment, data collection, formal analysis, interpretation of results, manuscript drafting, revision, and final editing. All authors reviewed and approved the final manuscript and accept responsibility for the accuracy and integrity of the work.

CONFLICT OF INTERESTS

The authors declare that there is no conflict of interest regarding this publication.

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