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A study to find the bacteriological profile and biomarkers in COPD patients and correlation with different comorbidities

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ABSTRACT

Background: Chronic obstructive pulmonary disease (COPD) is a progressive inflammatory disorder and a leading global cause of morbidity and mortality. Acute exacerbations (AECOPD) are frequently triggered by bacterial infections, yet pathogen profiles and antimicrobial resistance (AMR) patterns vary regionally. Conventional spirometry is insufficient for early detection, while biomarkers such as C-reactive protein (CRP), interleukin-6 (IL-6), and procalcitonin (PCT) offer additional diagnostic and prognostic insights. Comorbidities, including diabetes, cardiovascular disease, and prior tuberculosis, further influence infection risk and biomarker expression.

Objective: To determine the bacteriological profile and AMR patterns in COPD patients, evaluate systemic biomarkers (CRP, IL-6, PCT), and analyze their correlations with disease severity (GOLD grade, CAT score, mMRC, FEV_1%) and comorbidities.

Materials and Methods: This prospective cross-sectional study will be conducted at Jawaharlal Nehru Medical College and AVBRH, Wardha (2022–2025). Sputum and BAL specimens from 457 spirometry-confirmed COPD patients will undergo microscopy, culture, and antimicrobial susceptibility testing as per CLSI M100 standards. Fasting venous blood will be collected for biomarker analysis. Clinical data, GOLD classification, and comorbidities will be documented. Statistical analyses will assess pathogen prevalence, biomarker distributions, and correlations with disease severity and comorbidity patterns.

Expected Results: We anticipate defining the local spectrum of COPD-related pathogens and resistance profiles, identifying biomarker thresholds predictive of bacterial exacerbations, and establishing associations between infection, biomarkers, and comorbidities.

Conclusion: This study will provide integrated bacteriological and biomarker data, enabling tailored antibiotic use, improved prognostication, and personalized COPD management in resource-limited Indian settings.

KEYWORDS: COPD, AECOPD, bacteriological profile, antimicrobial resistance, CRP, IL-6, procalcitonin, comorbidities.

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INTRODUCTION

Chronic obstructive pulmonary disease (COPD) is a preventable, inflammatory airway disorder and a leading cause of morbidity and mortality worldwide. Global prevalence rose substantially between 1990 and 2015, and COPD deaths are projected to keep increasing, especially in low- and middle-income countries (1). In India, cases nearly doubled from 1990 to 2016, underscoring the need for robust local data (2).

Acute exacerbations of COPD (AECOPD) are commonly triggered by respiratory infections and air pollution. Bacterial infections contribute to a large proportion of AECOPD, but the causative species and their antimicrobial resistance (AMR) patterns vary by region and over time (3). Frequently isolated organisms include Klebsiella pneumoniae, Pseudomonas aeruginosa, and Staphylococcus aureus, with Indian series highlighting similar spectra and resistance concerns.

While spirometry (e.g., FEV_1) remains essential for diagnosis and staging, it has limited sensitivity in early disease and does not fully capture inflammatory activity (4). Biomarkers such as C-reactive protein (CRP), interleukin-6 (IL-6), and procalcitonin (PCT) add pathophysiologic insight and may help differentiate bacterial from non-bacterial exacerbations, guide antibiotic stewardship, and inform prognosis (5). Oxidative stress markers (e.g., glutathione, SOD) also reflect disease biology (6).

Comorbidities—including diabetes, cardiovascular disease, prior tuberculosis, and hypertension—shape susceptibility to infection, influence biomarker levels, and worsen outcomes. However, comprehensive studies that jointly evaluate bacteriology,

biomarkers, COPD severity (e.g., GOLD grade, CAT, mMRC, FEV_1% predicted), and comorbidities remain limited. This study addresses these gaps with prospective, locally relevant evidence.

Need for Research

Therapeutic precision: Empiric antibiotics for AECOPD are often chosen without current local AMR data, risking undertreatment or overuse (7).

Biomarker utility: CRP, PCT, and IL-6 are promising but underutilized in routine care to distinguish bacterial vs non-bacterial exacerbations and to prognosticate (8,9).

Comorbidity interplay: The combined effect of comorbidities on infection profiles and biomarker signatures is insufficiently characterized in Indian settings (6).

Generating contemporary local data linking pathogens, AMR, and biomarkers to clinical severity and comorbidities can refine antibiotic stewardship and enable more personalized COPD management.

AIM AND OBJECTIVES

Aim: To characterize the bacteriological profile and biomarkers in COPD patients and correlate these with different comorbidities.

Primary objectives

Profile respiratory pathogens from stable COPD and AECOPD (sputum/BAL), and report AMR patterns.

Quantify systemic/airway biomarkers (CRP, PCT, IL-6) and compare levels between stable COPD and AECOPD.

Assess correlations between specific pathogens/biomarker levels and COPD severity (GOLD grade, CAT, mMRC, FEV_1% predicted) and prior-year exacerbation frequency.

Research Question and Hypothesis

Question: Is there a correlation between COPD-associated bacteria and biomarkers (CRP, PCT, IL-6) in relation to comorbid conditions?

Null hypothesis: No correlation exists between these biomarkers and COPD severity or comorbidities.

REVIEW OF LITERATURE

Evidence from LMIC settings highlights COPD's growing burden and the centrality of infection in AECOPD. Regional studies report Gram-negative predominance and concerning resistance trends (9). Spirometry alone incompletely reflects disease biology, while biomarkers add diagnostic and prognostic value: CRP/PCT can reduce inappropriate antibiotics, and IL-6 tracks inflammatory activity in exacerbations (6). Systematic reviews support roles for oxidative stress and airway cytokines in COPD pathophysiology (4). Despite this, integrated analyses that connect local bacteriology, AMR, biomarkers, severity metrics, and comorbidities are scarce—motivating the present work.

MATERIALS AND METHODS

Design & Setting: Prospective, cross-sectional analytical study in the Department of Microbiology, Jawaharlal Nehru Medical College (JNMC) & AVBRH, Sawangi, Wardha (June 2022–May 2025).

Population & Samples: Adults (>18 years) with spirometry-confirmed COPD (FEV_1/FVC <0.7). Samples include early-morning sputum (preferred) and/or BAL where indicated.

Inclusion: Adults with COPD (both sexes), smokers with/without comorbidities (e.g., diabetes, hypertension, PAH), who provide informed consent.

Exclusion: Minors; pregnancy; asthma, bronchiectasis, active/treated TB, lung cancer or other chronic respiratory diseases; ≥4 weeks of systemic steroids/antibiotics/immunosuppressants; radiographic pneumonia; severe systemic illnesses (e.g., renal failure, cirrhosis, malignancy); concurrent trial participation; genetic disorders affecting lung function.

Sample size: Using $n = 4pq/L^2$ with p=28% (Indian prevalence estimates) and absolute error = 15% of p, the calculated sample size is 457 (10).

Clinical Data: Demographics, smoking history, comorbidities, prior treatments; symptom assessment; severity grading (GOLD), CAT, mMRC; exacerbation frequency (prior 12 months).

Specimen Collection & Microscopy: Standardized sputum collection after oral rinse; Gram stain for quality (>25 PMN and <10 epithelial cells/LPF proceed to culture). AFB/modified AFB staining as indicated.

Culture & Identification: Inoculation on blood and MacConkey agar; incubation at 37 °C for 24–48 h; Gram reaction and

standard biochemical tests (oxidase, catalase, IMViC, TSI) as appropriate.

Antimicrobial Susceptibility Testing (AST): Modified Kirby–Bauer disc diffusion on Mueller–Hinton agar; interpretation per CLSI M100 contemporaneous standards (11).

Biomarkers: Fasting venous blood for CRP, PCT, and IL-6 (processed promptly as per laboratory SOPs).

Outcomes & Analyses:

Primary: Prevalence of bacterial isolates and their AMR patterns; biomarker distributions (CRP/PCT/IL-6) across stable vs AECOPD.

Secondary: Correlations between (a) specific pathogens and biomarker levels; (b) biomarkers and severity (GOLD, CAT, mMRC, FEV_1%); (c) pathogen/biomarker profiles and comorbidities.

Statistics: SPSS v25; descriptive statistics; group comparisons (t-test/Mann–Whitney; χ^2/Fisher's exact); correlation/regression as appropriate. Two-sided $p<0.05$ considered significant.

ETHICAL CONSIDERATIONS

Written informed consent will be obtained; confidentiality preserved. Clinical care will not be affected by participation decisions.

Expected Outcomes and Translational Relevance

Local epidemiology & AMR map: A current profile of COPD-related pathogens and resistance patterns to optimize empiric antibiotics and stewardship (6).

Biomarker guidance: CRP/PCT/IL-6 thresholds associated with bacterial AECOPD and worse clinical status, supporting rational antibiotic initiation/de-escalation (9).

Risk stratification with comorbidities: Integrated pathogen-biomarker-comorbidity signatures that predict severity and exacerbation risk, informing personalized care pathways.

System strengthening: Data applicable to local antibiograms, SOP updates, and clinical decision support for COPD services.

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