

ORIGINAL ARTICLE

Efficacy and Safety of Short-Course Versus Long-Course Glucocorticoids in Acute Exacerbation of COPD

MUHAMMAD UMAR ABBAS¹, AIMAN ABBAS², ROSHAAN MIR³, SOHAIL AMJAD⁴, ADEEL AHMED⁵, RIMSHA ALI⁶, AKHTAR ALI⁷

¹MBBS, House Officer, Shalamar Institute of Health Sciences, Lahore

²MBBS Student, Akhtar Saeed Medical & Dental College, Lahore. **Email:** aimenabas123@gmail.com

³MIT, Shalamar Institute of Health Sciences, Lahore. **Email:** Roshaanmir76@gmail.com

⁴MBBS, House Officer, Shalamar Institute of Health Sciences, Lahore. **Email:** amjadsohail465@gmail.com

⁵Assistant Medical Director, Shalamar Institute of Health Sciences, Lahore. **Email:** aadeel93@hotmail.com

⁶Anesthesia, Shalamar Institute of Health Sciences, Lahore. **Email:** rimshale97@gmail.com

⁷Assistant Professor, Pulmonology, Shalamar Institute of Health Sciences, Lahore. **Email:** drakhtarshah@gmail.com

Correspondence to: Dr Muhammad Umar Abbas, **Email:** drumar70@icloud.com, **ORCID** <http://orcid.org/0009-0003-9279-9824>

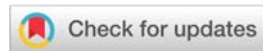
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**ABSTRACT**

Objective: To estimate the effectiveness and safety of short-course versus traditional long-course systemic glucocorticoid therapy in hospital patients with an acute exacerbation of chronic obstructive pulmonary disease (AECOPD).

Methods: It was a prospective comparative study that involved 170 patients admitted with AECOPD randomly divided into two treatment groups (n = 85 each). Group A was treated to short-course therapy comprising of oral prednisolone 40 mg, one dose per day taken over 5 days, Group B got conventional long-course therapy, comprising of oral prednisolone 40 mg, given once a day and over 14 days. The two groups were subjected to normal management based on guidelines (including inhaled bronchodilators, controlled oxygen, when necessary, antibiotics in case of possible bacterial infection and supportive care). The main eventual finding was successful treatment on Day 14, which is considered any clinical improvement without use of any further systemic corticosteroids, mechanical ventilator, intensive care unit (ICU) admission, or in-hospital death. Outcomes measured secondary were forced expiratory volume in one second (FEV₁), length of hospital stay, relapse, and corticosteroid adverse effects in 30 days.

Results: The study population mean age was 63.8 years old with a standard deviation of 9.7 years with 118 (69.4) of them being male. The short-course patients had 72 (84.7) patients treated successfully and the long-course patients had 70 (82.4) PR successfully, no significant difference being found between the two groups (p = 0.689). The mean improvement in post-treatment FEV₁ was comparable (0.18 ± 0.09 L vs. 0.19 ± 0.10 L; p = 0.522). There was also a significant difference in the mean hospital stay of patients undergoing short-course therapy compared to patients undergoing long-course therapy (4.8 ± 1.6 vs. 5.6 ± 1.9 days; p = 0.004). Relapse rates (30 days) were the same in the two groups (16.5% vs. 14.1%; p = 0.668). Nevertheless, hyperglycemia created by corticosteroids was much rarer in the short-course group as compared to the long-course group (15.3% vs. 29.4; p = 0.028).

Conclusion: Short-course systemic glucocorticoid therapy showed similar clinical efficacy to the conventional long-course therapy in hospitalized patients with AECOPD. Moreover, it was also found that shorter regimen was linked with fewer length of stay in hospitals and a much lower rate of corticosteroid hypoglycemia. The results can be utilized to justify administration of a 5-day oral prednisolone course as a safe and effective treatment measure in majority of COPD hospitalized patients with an acute attack.

Keywords: COPD exacerbation, glucocorticoids, prednisolone, short-course steroids, long-course steroids, treatment outcome.

INTRODUCTION

Chronic obstructive pulmonary disease (COPD) is a major cause of morbidity, mortality, and health-care utilization worldwide. Acute exacerbations of COPD are clinically important events because they accelerate lung-function decline, worsen quality of life, and frequently result in emergency visits or hospitalization^{1,2}. Exacerbations are typically characterized by worsening dyspnea, cough, and sputum production beyond normal day-to-day variation³.

Systemic glucocorticoids are a cornerstone of treatment in moderate-to-severe AECOPD because they improve airflow limitation, shorten recovery time, and reduce early treatment failure^{4,5}. Earlier trials demonstrated that corticosteroids improve lung function and symptoms in hospitalized patients with AECOPD, but the optimal duration of therapy remained uncertain for many years^{4,6}. Historically, treatment courses of 10 to 14 days were commonly used in clinical practice⁷.

More recent evidence has challenged the need for prolonged steroid exposure. The REDUCE trial showed that a 5-day course of systemic glucocorticoids was noninferior to a 14-day course in preventing re-exacerbation, while reducing cumulative steroid exposure⁸. Subsequent systematic reviews and guideline assessments have generally supported shorter courses of systemic corticosteroids for most exacerbations⁹⁻¹¹. Current GOLD guidance recommends systemic corticosteroids for up to 5 days in moderate or severe exacerbations, reflecting the shift toward shorter treatment strategies^{12,13}.

Despite this evidence, prolonged steroid courses are still prescribed in some settings, especially in hospitalized patients, due to concern about relapse, slow clinical response, or severe baseline disease^{10,14}. However, longer exposure to systemic steroids increases the risk of hyperglycemia, hypertension, delirium, secondary infection, myopathy, and other adverse effects^{5,10,15}. In low- and middle-income settings, minimizing avoidable drug-related complications is particularly important.

This study was conducted to compare short-term versus long-term glucocorticoid therapy in patients admitted with AECOPD, with emphasis on treatment success, relapse, lung function recovery, hospital stay, and steroid-related adverse events.

MATERIAL & METHODS

The study design and setting entail a randomized controlled trial (RCT).

The study is proposed as a prospective comparative study within the Department of Pulmonology, Shalamar Hospital, Lahore, Pakistan, during a 12-month time frame

of January 2025 to December 2025. The aim of the study was to compare the clinical effectiveness and safety of short course (5 days) versus the conventional long course (14 days) oral corticosteroid regimen in patients in the hospital who were acutely exacerbating chronic obstructive pulmonary disease (AECOPD). The facility is Shalamar Hospital, a tertiary-care, teaching hospital which deals with specialized respiratory care and a large number of COPD patients are attended to on an annual basis, which makes it a good environment to conduct this comparative study within the clinical setting.

Consecutively, eligible patients were screened to join the enrolment at the emergency department or pulmonology ward presenting with a known case of AECOPD. Informed written consent was obtained after which the participants meeting the eligibility criteria were included in the study and randomly assigned into two groups of treatment.

Sample Size

The WHO Sample Size Calculator was used with the following parameters: Confidence Level (95), Study Power (80) and anticipated difference in the success of both corticosteroid treatment options on clinical success based on published literature. To obtain the minimum possible sample, it was set at 170 patients. Thus, 170 patients who fulfilled the inclusion criteria of acute exacerbation of COPD were recruited. Study participants were divided into two treatment groups, including 85 patients each.

Inclusion Criteria

The inclusion criteria were as follows: patients had to meet the following criteria:

- Adult age 40 years and above.
- Prior known chronic obstructive pulmonary disease based on Global Initiative for Chronic Obstructive Lung Disease (GOLD) guidelines.
- A hospital hospitalization related to an acute attack of COPD as evidenced by an increase in dyspnea along with more coughing and/or sputum with the need to address them with the help of systemic corticosteroids.
- Capacity to make informed written consent or to have the presence of a representative who has the legal authority to give his/her consent.
- Stable in hemodynamic condition during the enrollment and deemed adequate to respond to oral corticosteroid therapy.

Exclusion Criteria

Patients were not eligible to the study in case they fit any of the following parameters:

P.M. bronchial asthma/asthma-COPD overlap syndrome.

- Pneumonia radiological indicators on the chest radiograph.
- Emergent invasive mechanical ventilation requirement.
- Active pulmonary tuberculosis.
- Uncontrolled diabetes mellitus with diabetic ketoacidosis or hyperosmolar hyperglycemic state.
- Severe forms of immunosuppression such as patients on chemotherapy treatment or immunosuppressive drugs.
- Other medical condition treated chronically with systemic corticosteroids.
- Pregnancy or lactation.
- Contraindicated or hypersensitive to corticosteroid therapy.
- Not giving informed consent.

Group Allocation and Treatment Protocol.

After enrolment, simple random allocation was used to assign patients to either as a treatment group or as a control group.

Group A (Short-course corticosteroid therapy)

Patients were treated with oral prednisolone 40 mg daily and was administered five days in a row.

Group B (Conventional corticosteroid therapy)

Oral prednisolone 40 mg daily was administered to the patients over a period of fourteen days.

Both treatment groups were given the same treatment based on the institutional COPD treatment guidelines other than length of corticosteroids treatment. Standard care included: Short-acting bronchodilators (salbutamol and/or ipratropium bromide) using either nebulizer or metered-dose inhaler with spacer.

Controlled oxygen therapy to ensure a oxygen saturation of 88 to 92%.

Improved empiric or culture-based antibiotic treatment in case of bacterial infection when it was clinically suspected.

- Nebulization treatment as needed.
- Sufficient hydration and production of medical care.
- Non-invasive ventilation (BiPAP) in patients with normal criteria to use ventilatory support.
- Treatment of comorbidities as per hospital guidelines.

The other systemic corticosteroids were not used unless there was a failure in treatment.

Data Collection

Trained investigators collected clinical information prospectively with the help of a pre-designed structured data collection proforma. All participants were registered

on baseline demographic, clinical, laboratory exploration, and clinical results.

The variables listed were as follows:

- Age (years)
- Gender
- History of smoking (current, former, never smoker)
- Duration of COPD
- Baseline spirometry findings

Stage III COPD: GOLD.

Comorbidities such as diabetes mellitus, hypertension, ischemic heart disease, chronic kidney disease, and heart failure.

Intake of oxygen (SpO₂) at the time of hospital admission.

- Severity of exacerbation
- Need of oxygen care.
- Non-invasive ventilation requirement.
- Length of hospital stay
- Forced expiratory volume in one second (FEV₁) at the time of admission and after treatment.
- Clinical treatment response
- Treatment failure
- Relapse in 30 days after discharge.
- Adverse drug reactions

Follow-up was done during the hospitalization, and 30 days after discharge to determine relapse and delayed complications.

Primary Outcome

The most important result was that treatment was successful, at least at Day 14 when corticosteroid therapy commenced. Success in treatment was based on a clinical improvement and no occurrence of any of the following:

- Need of further systemic corticosteroids other than the treatment protocol.
- Transfer to the intensive care unit (ICU).
- Invasive mechanical ventilation needed.
- In-hospital mortality.

Secondary Outcomes

Secondary outcome measures were:

- Pulmonary ease of breathing (monitored by a variation in FEV₁ since have been admitted up to the time of discharge (or by Day 14)).
- Number of days in hospital.
- Readmission or recurrence of COPD that necessitates hospital care or rehospital admission within 30 days of discharge.

Tolerance of adverse effects, such as:

- Hyperglycemia
- Hypertension
- Gastrointestinal symptoms
- Secondary infections
- Neuropsychiatric manifestations
- Sleep disturbances
- Fluid retention

Statistical Analysis

Statistical Package for Social Sciences was used to enter, code and clean data and analyze the data with version 26.0 of the software (IBM Corp., Armonk, NY, USA).

The continuous variables, including age, COPD duration, FEV₁, oxygen saturation, and length of stay, were reported in the terms of mean with standard deviation (SD), whereas the frequencies and percentages were reported in the form of categorical variables, including gender, smoker or not, comorbidity, treatment effectiveness, relapse, and adverse effects. The ShapiroWilks test was used to determine normality of continuous data. The Independent Samples t-test is used to compare continuous variables when the variables are normally distributed and the variables are in the treatment groups. Chi-square test or Fisher exact test was used to analyze categorical variables where suitable. The analyses were conducted as post stratifications based on age, gender, history of smoking, COPD severity, and comorbidities presence to determine whether any of these variables would have an impact on treatment outcomes.

The p-value was considered as significant when it was 0.05 or below on a two-tailed test.

Ethical Considerations

The study protocol was looked at and endorsed by the Institutional Review Board/Ethical Review Committee of the Shalamar Hospital, Lahore and the research study was

initiated. The study was carried out in the context of the ethical ideas provided in the Declaration of Helsinki. All participants had informed consent written before enrolling in the study after being informed about the aims, procedures, possible benefits, and potential risks of participating in the study. The study was voluntary and the patients were notified of their right to pull out or leave the study at any given time and this would not impact on their normal medical care. The privacy of patient information together with anonymity were observed strictly during the study. The research database was stripped of all personal identifiers and all the information collected was utilized with the sole purpose of research.

RESULTS

The two groups were comparable at baseline. There was no statistically significant difference in age, gender distribution, smoking history, COPD duration, baseline FEV₁, oxygen saturation, or major comorbidities.

Treatment success was slightly higher in the short-term group, although the difference was not statistically significant. Improvement in FEV₁ was similar in both groups. However, patients receiving short-term steroids had a significantly shorter hospital stay. Relapse within 30 days was comparable between groups, suggesting that shorter treatment did not increase early recurrence.

Steroid-related adverse effects were more frequent in the long-term treatment group. Hyperglycemia showed a statistically significant increase in patients receiving prolonged therapy. Overall adverse events were also significantly higher in the long-term group.

Hyperglycemia was more frequent in the long-term group in both diabetic and non-diabetic patients, indicating a consistent trend toward greater metabolic toxicity with prolonged steroid exposure.

Table 1. Baseline demographic and clinical characteristics of the study population

Variable	Group A (Short-term) n=85	Group B (Long-term) n=85	p-value
Age (years), mean ± SD	63.4 ± 9.4	64.2 ± 10.0	0.601
Male gender, n (%)	58 (68.2)	60 (70.6)	0.734
Smoking history, n (%)	67 (78.8)	69 (81.2)	0.697
Duration of COPD (years), mean ± SD	7.8 ± 3.1	8.1 ± 3.4	0.546
Baseline FEV ₁ (L), mean ± SD	0.91 ± 0.24	0.89 ± 0.22	0.573
SpO ₂ at admission (%), mean ± SD	86.8 ± 4.2	86.3 ± 4.6	0.458
Diabetes mellitus, n (%)	24 (28.2)	22 (25.9)	0.736
Hypertension, n (%)	31 (36.5)	34 (40.0)	0.639
Prior exacerbation in last year, n (%)	39 (45.9)	42 (49.4)	0.648

Table 2. Primary and secondary efficacy outcomes

Outcome	Group A (Short-term) n=85	Group B (Long-term) n=85	p-value
Treatment success at day 14, n (%)	72 (84.7)	70 (82.4)	0.689
Treatment failure, n (%)	13 (15.3)	15 (17.6)	0.689
Improvement in FEV1 (L), mean $\pm$ SD	0.18 $\pm$ 0.09	0.19 $\pm$ 0.10	0.522
Hospital stay (days), mean $\pm$ SD	4.8 $\pm$ 1.6	5.6 $\pm$ 1.9	0.004
Need for noninvasive ventilation after admission, n (%)	11 (12.9)	13 (15.3)	0.658
ICU transfer, n (%)	4 (4.7)	5 (5.9)	0.731
In-hospital mortality, n (%)	2 (2.4)	3 (3.5)	0.649
Relapse within 30 days, n (%)	14 (16.5)	12 (14.1)	0.668

Table 3. Adverse effects related to glucocorticoid therapy

Adverse effect	Group A (Short-term) n=85	Group B (Long-term) n=85	p-value
Hyperglycemia, n (%)	13 (15.3)	25 (29.4)	0.028
Elevated blood pressure, n (%)	9 (10.6)	17 (20.0)	0.090
Gastritis/dyspepsia, n (%)	8 (9.4)	14 (16.5)	0.172
Secondary infection, n (%)	5 (5.9)	10 (11.8)	0.180
Sleep disturbance/mood change, n (%)	6 (7.1)	13 (15.3)	0.089
Any steroid-related adverse effect, n (%)	27 (31.8)	43 (50.6)	0.013

Table 4. Subgroup analysis by diabetes status for hyperglycemia

Diabetes status	Group A (Short-term) n (%)	Group B (Long-term) n (%)	p-value
Diabetic patients with hyperglycemia	8/24 (33.3)	13/22 (59.1)	0.082
Non-diabetic patients with hyperglycemia	5/61 (8.2)	12/63 (19.0)	0.079

DISCUSSION

In this study, the short term glucocorticoid treatment was also similar to the long term treatment in terms of the success in the therapy, the improvement of the lung functions, the escalation of the ventilatory needs, the mortality, and the 30-day relapse in hospital patients with AECOPD. Meanwhile, shorter treatment period was also linked to a much shorter hospitalization and the number of adverse effects of steroids, especially hyperglycemia.

Systemic corticosteroids have well evidenced their role in management of AECOPD as they alleviate airflow, decrease failure of treatment and accelerate recovery of symptoms⁴⁻⁶. The question of whether steroids should be administered in the right patients or not has been supplanted by the question of how long they have to be used. The previous patterns of use were inclined toward 10-14 days regimens partly due to longer original trial periods, and partially due to the fears of relapse following discharge by clinicians^{6,7}. Subsequent experience was, however, badly inclined in favor of short regimens⁸⁻¹⁰.

The current research agrees with the REDUCE trial that showed non-inferiority of a 5-day course of steroids versus a 14-day course in the occurrence of re-exacerbation⁸. Similarly, the Cochrane review of Walters et al. indicated that 7 days or less of systemic

corticosteroid therapy was probable to be similarly effective to the use of the extended treatment courses of 7 days or longer with no convincing proof that any adversely affected the clinical results [9]. According to the NICE evidence reviews, recent guidance documents, shorter regimens can be quite adequate on most exacerbations, and can reduce unnecessary exposure to steroids^{11,13}. Recent GOLD guidelines still advocate systemic corticosteroids with as many as 5 days of treatment of moderate or severe exacerbations^{12,13}.

The success rate of treatment on the day 14 was no less than 84.7% and 82.4% as in short course and long course in our data respectively, which was not significantly different. The observation of the same level of post-treatment improvement in FEV1 between groups also favours the concept that the use of corticosteroids treatment over 5 days additional physiologic value is minimal in most patients. This is reminiscent of past randomized and comparative findings indicating that the large steroid effect is obtained at the early it is purchased in recovery^{5,8,9}.

An observable conclusion in this work was the vastly reduced hospitalization in the short-course. Even though length of stay depends on various clinical and organizational variables, a shorter recommended course of systemic steroid therapy can be associated with an earlier readiness to discharge, especially when the

clinicians are more likely to discharge these patients when the active treatment period is over. This observation is clinically significant as exacerbation of COPD contributes to a huge amount of inpatient burden and resources usage in the global context^{1,2}.

The safety results of our study are in a way pro-shorter therapy. The incidence of hyperglycemia was much greater in long-course group and the total cumulative burden of the steroid adverse effects was also more evident with long time. The findings are biologically feasible, and clinically significant. Metabolic, cardiovascular, neuropsychiatric and infectious complications are linked to systemic glucocorticoids and cumulative exposure is a known predictor of hurt^{10,14,15-20}.

The findings of our relapse are valuable as well. The relapse in 30 days did not significantly differ between groups which reflect that the long steroid use did not offer an extra protection against early recurrence. This is congruent with the main finding in the previous randomized trials and evidence syntheses^{8,9}. Practically, multifactoriality on relapse in AECOPD may have more to do with severity of the disease, inhaled maintenance therapy, infection, smoking, comorbidity burden, and discharge planning than merely the duration of systemic steroid use^{2,3,10}.

The current research favors a guideline-concordant and pragmatic approach to the AECOPD care. In the majority of hospitalized patients who are able to take oral medication, who do not experience significant comorbid complications, a 5-day treatment course consisting of prednisolone-equivalent seems adequate. This is most often given orally rather than intravenously where possible as a previous study has indicated similar results in oral prednisolone to intravenous prednisolone¹⁶⁻²⁰. The avoidance of prolonged treatment could be particularly beneficial in patients who are at a higher risk of steroid toxicity including patients with diabetes, high blood pressure, weakness, and frequent infection. This study has limitations. It was conducted at a single center, which may limit generalizability. The sample size, although adequate for group comparison, may not detect small differences in uncommon outcomes such as mortality. Follow-up was limited to 30 days for relapse assessment. In addition, as with many comparative clinical studies, some discharge and supportive care decisions may have been influenced by treating clinicians. Nevertheless, the study provides clinically relevant evidence in line with contemporary literature and guideline recommendations.

Overall, the findings suggest that short-term glucocorticoid therapy offers similar efficacy with better safety than long-term therapy in AECOPD. The results reinforce the trend toward shorter systemic steroid regimens in routine COPD exacerbation management.

CONCLUSION

Short-term systemic glucocorticoid therapy for AECOPD was as effective as long-term therapy in achieving treatment success and improving lung function, without increasing short-term relapse. In addition, short-course treatment reduced hospital stay and significantly lowered steroid-related adverse effects, especially hyperglycemia. A 5-day glucocorticoid regimen should be preferred in most hospitalized patients with COPD exacerbation unless specific clinical circumstances justify prolonged treatment.

DECLARATION

Conflict of Interest: The authors declare no conflict of interest.

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Author's Contribution: All authors contributed equally in the complication of current study.

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Data Availability Statement: The data that supports the findings of this research are available on request from Corresponding Author.

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