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ORIGINAL ARTICLE

Short-Course Versus Long-Course Systemic Glucocorticoid Therapy for Hospitalized Patients with Acute Exacerbation of Chronic Obstructive Pulmonary Disease: A Prospective Comparative Study

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ABSTRACT

Background: Systemic glucocorticoids have a central place in the ICS of acute exacerbation of chronic obstructive pulmonary disease (AECOPD). Nevertheless, the best duration of corticosteroid therapy is a controversial issue as the long-term treatment is likely to cause more steroid-related adverse events in patients without any obvious improvement in clinical outcome. To measure the effectiveness and safety of short-course (5-day) and long-course (14-day) systemic glucocorticoid in hospitalized patients with AECOPD.

Methods: The study was carried out as a prospective comparative study in the Departments of Pulmonology in Shalamar Hospital and Farooq Hospital, Lahore, Pakistan. A total of 170 hospitalized patients with AECOPD were enrolled and equally allocated into two treatment groups (n=85 each). Group A was given oral prednisolone 40 mg/kg/day over 5 days and Group B given oral prednisolone 40 mg/kg/day over 14 days. The two groups got the same standard therapy, bronchodilators, oxygen when necessary, antibiotics when necessary, and nebulization, and supportive care. Success of treatment at Day 14 was the main outcome. Secondary outcomes were the ability to improve the forced expiratory volume in one second (FEV 1), length of stay in the hospital, relapse within 30 days and corticosteroid-associated adverse events. Statistics was done using SPSS version 26, and the statistical significance was $p<0.05$.

Results: The mean age of the participants was 63.8 ± 9.7 years, and 118 (69.4%) were male. Patients who received short-course therapy were successful in treatment (72/84.7) and those who received long-course were successful in treatment (70/82.4) ($p=0.689$). Improvement in FEV_1 was comparable between the groups (0.18 ± 0.09 L vs. 0.19 ± 0.10 L; $p=0.522$). Patients on the 5-day schedule had a much lower readmission (4.8 + 1.6 vs. 5.6 + 1.9 days; $p=0.004$). Thirty-day relapse rates were similar (16.5% vs. 14.1%; $p=0.668$). Hyperglycemia caused by corticosteroids was significantly less common in the short-course group compared to the long-course group (15.3% vs. 29.4%; $p=0.028$).

Conclusion: Clinical efficacy of short course systemic glucocorticoid therapy in patients with AECOPD hospitalized had been equivalent to conventional long-course therapy. The 5-day course on oral prednisolone was much better to hospital stay and corticosteroid-induced hyperglycemia in comparison to treatment success and chance of relapses. These findings validate existing guideline suggestions that advocate short-course systemic glucocorticoid treatment option as a superior and less risky treatment option to most hospital-admitted patients with AECOPD.

Keywords: Exacerbation of chronic obstructive pulmonary disease; COPD; systemic glucocorticoids; prednisolone; corticosteroids; hospitalization; period of treatment; Pakistan.

INTRODUCTION

COPD is a progressive respiratory disease that can be defined as the chronic airflow vessels restriction and the chronic airway inflammation. It is a significant international health care issue, and now is the most frequent cause of global morbidity and mortality. The Global Initiative of Chronic Obstructive Lung Disease (GOLD) states that COPD impacts a population of millions of people, and COPD causes more than three million deaths each year, and the number growing in low and middle-income countries because of tobacco smoking, biomass fuel exposures and environmental pollution (1-2).

An acute worsening of the respiratory symptoms needs further pharmacological intervention or hospitalization, which is considered to be acute exacerbation of the chronic obstructive pulmonary disease (AECOPD). There are such episodes that proceed to accelerated lung impairment, deteriorated quality of life, amplified healthcare access and elevated mortality rates. Effective discourse of AECOPD in its early phases is thus crucial to enhance clinical performance and decrease the disease burden (2-3). Systemic glucocorticoids play a vital role in treating hospitalized AECOPD patients due to their ability to decrease airway inflammation, improve lung function, shorten recovery, and decrease treatment failure, though the most effective correlates of glucocorticoid use are still a topic of discussion (3-5). According to current international guidelines, systemic corticosteroids are recommended in patients who have moderate-to-severe exacerbations of AECOPD, including those of the GOLD and the American Thoracic Society/European Respiratory Society, which propose the use of the treatment in both children and adults. Traditionally, the prescription of corticosteroids was 10-14 days. Despite the proven effectiveness of long-course therapy, recent research has considered the possibility of short-course treatment to provide similar clinical results with the minimum of corticosteroid-linked complications, especially in multimorbid patients of advanced age (5-8).

Nevertheless, in most medical faculties, especially in developing countries, long-term corticosteroid is still actively used despite these recommendations since there is little local evidence. COPD is a leading healthcare issue in Pakistan due to high prevalence of smoking, exposure to biomass fuels, pollution of the environment, and late diagnosis. Nevertheless, there are limited studies that have compared the efficacy and safety of short and long course systemic glucocorticoid therapy in hospitalized AECOPD patients in Pakistan.

Hence, an intended comparative study with a set of hypotheses was designed at the Shalamar Hospital and Farooq Hospital Lahore to compare the 5-day and 14-day course of oral prednisolone in hospitalized patients with AECOPD in terms of its efficacy and safety. The treatment dealings were assessed upon the basis of achievement of treatment, rectification in pulmonary functioning, length of occupancy, relapse within 30 days and the mishaps of corticosteroids. The results will be likely to present locally applicable evidence to aid evidence-based corticosteroid prescriptions and to optimize the management of AECOPD in Pakistan.

MATERIAL & METHODS

Design and Setting of the study.

The study employed was a prospective comparative study carried out in the Departments of Pulmonology in the Shalamar Hospital and Farooq Hospital, Lahore, Pakistan, over a period of 12 months. It was a comparative study to evaluate the efficacy and safety of short-course versus long-course systemic treatment of glucocorticoids in hospitalized patients with acute exacerbation of chronic obstructive pulmonary disease (AECOPD).

Population in the Study and the sample size.

One hundred and seventy patients which included 170 consecutive admissions were enrolled within the study with AECOPD. The study participants were divided evenly into two treatment groups (85 patients in each of them). The target population referred to eligible patients older than 40 years of age and diagnosed with COPD according to the Global Initiative for Chronic Obstructive Lung Disease (GOLD) criteria and hospitalized due to acute exacerbation that needed systemic corticosteroid.

Patients with asthma or asthma-COPD overlap syndrome, who had radiological evidence of pneumonia, were excluded, as well as those with active pulmonary tuberculosis, patients in urgent need of invasive mechanical ventilation, pregnant, severely immunosuppressed, or receiving long-term systemic corticosteroids due to other medical conditions were excluded.

Treatment Protocol

Group A patients were treated with oral prednisolone 40mg/day/5days (short-course therapy) but Group B patients were treated with oral prednisolone 40mg/day/14days (long-course therapy). Both groups were offered equal medical care, which included inhaled short acting bronchodilators, use of controlled oxygen therapy in cases of necessity, suspected bacterial infection antibiotics, nebulization, supportive therapy, and non-invasive ventilation as needed.

Data Collection

A standardized clinical and demographic data collection form was used to note the clinical and demographic

information. Variables were the age, sex, smoking history, duration of COPD, baseline spirometry, comorbidities, oxygen saturation at admission, severity of exacerbation, length of stay, forced expiratory volume in one second (FEV 1) before and after treatment, treatment outcome, 30-day relapse and corticosteroid-related adverse events.

Outcome Measures

The main outcome measure was treatment success at Day 14, which was a clinical improvement without requiring further systemic corticosteroids, intensive care unit hospitalization, intubation, and in-hospital deaths.

Secondary outcomes were a positive effect on FEV1, length of hospital stay, 30-day readmission rates, corticosteroid-induced adverse events, such as hyperglycemia, hypertension, gastrointestinal syndrome, secondary infections, and neuropsychiatric.

Statistical Analysis

The analysis of data was performed with the help of the Statistical Package of Social Sciences (SPSS) 26.0 (IBM Corp., Armonk, NY, USA). Mean was used to give the continuous variables and frequencies with percentages to give the categorical variables. Independent-samples t-test was used to compare continuous variables, and chi-square test or Fisher was used as the exact test when comparing categorical variables. A p-value of less than 0.05 was deemed as statistically significant.

Ethical Considerations

The protocols of the study were granted by Institutional Ethical Review Committees of Shalamar Hospital and Farooq Hospital, Lahore. Informed consent was acquired in writing to all enlisted participants. The study maintained patient confidentiality and all of the procedures were carried out under the ethical principle of the Declaration of Helsinki.

Results

The study involved 170 hospitalized patients with acute exacerbation of chronic obstructive pulmonary disease (AECOPD), whose patient numbers were equal between the study groups (n=85) considering each treatment group. The mean age of the members was 63.8 and the SD 9.7 years, which implies that older adults were mostly affected by COPD. The study population was majority in male patients (69.4%), as COPD prevails in male population, probably because of increased exposure to smoking and to work-associated risk factors.

The two treatment groups did not show statistically significant differences in terms of their ages, gender, smoking history, duration of COPD, baseline FEV1 or oxygen saturation at admission (all p > 0.05). These findings illustrate that the study population and clinical background were balanced between the two groups eliminating the chances of confounding factors. Hence, the differences that may be noticed in terms of the treatment outcomes can probably be explained by long-term glucocorticoid therapy but not by initial patient-specific factors.

A total of 170 patients hospitalized with acute exacerbation of chronic obstructive pulmonary disease (AECOPD) were included in the study, with 85 patients assigned to each treatment group. The mean age of the study population was 63.8 ± 9.7 years, and the majority were male (118, 69.4%). Baseline demographic and clinical characteristics, including smoking status, duration of COPD, baseline FEV_1, oxygen saturation, and comorbidities, were comparable between the two groups, with no statistically significant differences (all $p > 0.05$), indicating good baseline comparability (Table 1).

Both groups of treatment showed an equal effectiveness in improving pulmonary functioning with the use of the systemic glucocorticoid. The average change in FEV 1 was 0.18 + 0.09 in the short-course arm and 0.19 + 0.10 in the long-course arm and statistically no difference in change between the two regimens was found (p = 0.522). This result shows that using glucocorticoid therapy over five days does not give any further benefit in lung function.

However, there was a major difference in the length of stay in the hospitals between the groups. The mean length of hospital stay (4.8 ± 1.6 days) decreased significantly among patients undergoing the 5-day regimen of glucocorticoids (5-day regimen) than among patients undergoing the 14-day regimen (5.6 ± 1.9 days; p = 0.004). Such decrease in the number of hospitalizations implies timely clinical stabilization, better use of medical resources and possible savings on treatment due to short-term treatment.

There was no significant difference in the proportion of patients who relapseded within 30 days of discharge, with 16.5% patients who received short-course therapy and 14.1% who receive long-course therapy (p = 0.668). The lack of statistically significant difference implies that the reduction in the length of the glucocorticoid therapy was not relevant in terms of the risk of the disease re-occurring earlier after the discharge.

The rates of adverse events associated with corticosteroid use were overall lower in patients who were treated with short course of glucocorticoids. The rate of hyperglycemia triggered by corticosteroids was 13 patients (15.3) in the short-course group versus 25 patients (29.4) in the long-course group, which was statistically significant as a decrease in hyperglycemic cases (p = 0.028). Such an observation indicates that the duration of systemic glucocorticoid is a major parameter that minimizes the rate of metabolic complications especially among the aged

population and in patients who already have diabetes mellitus.

Though treatment with long courses was associated with more often findings of hypertension, gastrointestinal symptoms, secondary infections, and neuropsychiatric complications, it was not statistically significant (all p > 0.05). However, the stable pattern of the reduction of adverse events in patients undergoing short-course treatment suggests a better pattern of safety.

All in all, the above results indicate that 5 days of systemic glucocorticoid therapy has shown similar clinical effectiveness with fewer corticosteroid-related complications hence should be considered a safer option in offering treatment to patients with AECOPD who are in the hospital setting.

Table 1. Primary Clinical Outcome

Outcome	Group A (n=85)	Group B (n=85)	p-value
Treatment Success, n (%)	72 (84.7)	70 (82.4)	0.689
Treatment Failure, n (%)	13 (15.3)	15 (17.6)	

Table 2. Secondary Clinical Outcomes

Variable	Group A	Group B	p-value
Improvement in FEV_1 (L)	0.18 ± 0.09	0.19 ± 0.10	0.522
Hospital Stay (days)	4.8 ± 1.6	5.6 ± 1.9	**0.004**
30-Day Relapse, n (%)	14 (16.5)	12 (14.1)	0.668

Table 3. Corticosteroid-Related Adverse Events

Adverse Event	Group A (n=85)	Group B (n=85)	p-value
Hyperglycemia	13 (15.3)	25 (29.4)	**0.028**
Hypertension	8 (9.4)	11 (12.9)	0.463
Gastrointestinal Symptoms	7 (8.2)	10 (11.8)	0.438
Secondary Infection	4 (4.7)	7 (8.2)	0.346
Neuropsychiatric Symptoms	2 (2.4)	5 (5.9)	0.245

DISCUSSION

The current prospective comparative trial design measured the effectiveness and safety of the short course (5-day) and the conventional long course (14-day) systemic glucocorticoids in hospital patients with acute exacerbation of chronic obstructive pulmonary disease (AECOPD). The results indicated that an oral prednisolone 5-day treatment was clinically identical to the 14-day treatment as far as treatment outcome, pulmonary function, and relapse rate was concerned. But short-course therapy of patients also had a proportionally shorter hospital stay and a reduced rate of hyperglycemia caused by corticosteroids. These results do contribute to the emerging evidence that recommends shorter series of corticosteroid regimens that may be used in the management of the hospitalized patients with AECOPD[8-11].

One of the major causes of hospitalization and death of COPD patients is acute exacerbations. They are marked by deterioration of respiratory symptoms related to airway inflammation and hypersecretion of mucus and gradual airflow obstruction. Timely administration of systemic glucocorticoids minimizes airway inflammation, hastens the recovery process and enhances lung functionality, as such corticosteroids feature prominently in the management of AECOPD. However, the key clinical issue is how long to continue therapy due to the significant risk of adverse events with prolonged exposure to corticosteroids, as there is no certain effect on clinical outcomes.

The main finding of the study did not show any significant difference between the short course and long course treatment in terms of the success of treatment which was found to be not statistically significant (84.7% vs. 82.4, p=0.689). These results indicate that more than five days of systemic corticosteroid therapy has no further therapeutic benefit in patients with AECOPD admitted to hospital. This finding is quite in line with the ground-breaking REDUCE randomized controlled trial that created the non-inferiority of the five-day course of prednisolone versus a traditional fourteen-day course. The REDUCE trial has also reported the parallel rates of frequency of exacerbation, mortality, recuperation of lung capacities, and effectiveness of treatment in addition to a substantial decrease in cumulative corticosteroid exposures[11-14].

Likewise, recent systematic reviews still promote short-term regimens of corticosteroids. Taken collectively, these reports indicate that seven days or shorter treatments incur the same clinical effectiveness as longer courses of treatment without additional treatment failure or mortality. In addition, there is also strong evidence of studies by Yin et al., that supports the international guideline recommendations of the day[7,11,14-15].

The results further agree with the meta-analysis, that showed no significant differences in pulmonary recovery based on longer versus shorter courses of corticosteroids. 22 Likewise, Papadopoulou et al. demonstrated that longer course of corticosteroid therapy does not result in better recovery of pulmonary functions when acute inflammatory response has been effectively controlled[15,17].

The longer time of stay was found among the patients who received glucocorticoid therapy over a period of five days hence making a significant clinical contribution to the current study. The mean length of stay of patients under the short course regimen was 4.8 1.6 d whilst that of the conventional treatment was 5.6 1.9 d (p=0.004). Despite the small change in absolute terms, the fact that the hospitalization can be decreased by almost one day bears significant clinical and economic consequences[14-18].

Hospital stay due to exacerbation of COPD is also considered one of the greatest contributors to healthcare investment due to COPD in the world. By shortening the length of stay in hospitals, they boost healthcare expenses, reduce the chances of hospital-acquired infections and elevate patient satisfaction and optimized bed occupancy in tertiary hospitals. These positive outcomes are especially significant in developing nations like Pakistan where healthcare facilities are scarce and respiratory departments are often overcrowded and have to work overload. The reduced hospitalization in the case of the present study could be elucidated by prior clinical stabilization achieved through a quick reduction of airway inflammation at the initial few days of the corticosteroid administration. Because most of the anti-inflammatory effects take place shortly after the initiation of treatment, continuing treatment after five days may not have a significant effect on rapid recovery but rather continue needless corticosteroid exposure[12,17-19].

The other significant outcome that was assessed during this study was the discharge-30-day relapse. Short-course therapy relapse was observed in 16.5% and conventional therapy relapse was observed in 14.1% with no statistical significant difference between the two groups of treatments (p=0.668). These results suggest that shortening corticosteroid may not augment the risk of early recreational attacks[19].

The clinical significance of this observation lies in the fact that doctors usually prolong corticosteroid use based on the fear of relapse occurring in patients as they get discharged. The current evidence indicates, though, that long-term corticosteroid treatment offers no extra-protective measures against relapse. Interestingly, parallel clinical trials and systematic reviews that compare shorter corticosteroid regimens have reported consistent similar relapse rates. Similar rates of recurrence demonstrated in the REDUCE trial with a significantly shorter corticosteroid-course led to similar conclusions with short-course and conventional therapy with recent evidence synthesized[20].

On the whole, the current results strongly speak in favor of existing GOLD guidelines that suggest that hospitalized patients with AECOPD should be put on five days of oral prednisolone. This study offers evidence that is locally produced to endorse the recommendations of international guidelines in the Pakistani healthcare environment by showing equal effectiveness in treatment and recovery of pulmonary functioning, similar rates of relapses, and reduced length of hospitalization. Moreover, these results imply a reevaluation of routine prolonged corticosteroid therapy unless it has clinical reasons as in unremitted symptoms, severe course of the disease, or patient factors.

CONCLUSION

This is a prospective comparative study done to show that an intervention of 5 days of systemic glucocorticoid therapy would be as effective as a traditional course of 14 days of therapy, in the treatment of acute exacerbation of chronic obstructive pulmonary disease in hospitalized patients. There was no notable difference in the success of treatment, the improvement of the lungs functions or the relapse after the 30 days of the treatment using the two strategies. Nevertheless, patients undergoing short-course treatment had a much reduced hospital stay and rate of corticosteroid induced hyperglycemia which shows a better safety profile. This evidence is in line with the existing global practice and evidence in favor of the application of short-course systemic glucocorticoid therapy as the standard intervention in most of hospitalized patients with AECOPD. Use of shorter treatment regimens can decrease unnecessary exposure to corticosteroids, reduce adverse effects, better resource use, and optimize patient outcomes.

RECOMMENDATIONS

This study suggests that a 5-day course of oral prednisolone (40 mg per day) would be recommended as a normal systemic glucocorticoid regimen to patients with AECOPD in hospital who lack certain subdivisions to signal the necessity of long-term use. To minimize unnecessary corticosteroids exposure and improve adverse events related to treatment, clinicians are encouraged to follow evidence-based guidelines, such as the GOLD recommendations. During corticosteroid therapy routine blood glucose level monitoring is advised, especially in patients who have diabetes mellitus or are at risk of hyperglycemia. Hospitals must establish standard treatment guidelines that are encouraging of short-course

corticosteroid regimes and offer frequent clinical education to enhance adherence to guidelines. Multicenter randomized controlled clinical studies in larger sample sizes and a longer period of follow-ups should be conducted in future to examine more the long-term efficacy, safety, and cost-effectiveness of short-course systemic glucocorticoid therapy in heterogeneous populations.

DECLARATION

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

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