Original Research Article

Comparison of effects of oral prednisolone with oral methylprednisolone in Acute Exacerbations of COPD

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Abstract

Background: Exacerbations are common in Chronic Obstructive Pulmonary Disease. Corticosteroids are the mainstay of therapy for treatment of acute exacerbation of COPD. The present study was carried out with an aim to compare the effects of 40mg oral prednisolone and an equivalent dose of 32mg oral methylprednisolone in patients with AECOPD. **Methodology:** This was a Hospital based analytical experimental study conducted on 44 admitted patients of Acute Exacerbation of COPD admitted at a tertiary care centre in central India over a period of one and a half years on 44. Patients were divided into two groups. Group A received 32mg methylprednisolone and Group B received 40 mg prednisolone respectively. **Results:** We observed that majority of the patients in both groups had symptom relief at the end of day 5 (Group A 72.2% vs. Group B 86.4%, p = 0.26). Mean length of hospital stay was similar in both the groups (Group A 9.09 days vs. Group B 8.77 days, p = 0.68). There was no difference in the number of patients who failed treatment in both the groups (p>0.26). Majority of the patients did not have any adverse effect (Group A 59.9% vs Group B 72.7%, p = 0.051). **Conclusion:** Five day course of either Oral systemic corticosteroid was sufficient in relieved symptoms in AECOPD patients. Side effects and LOHS were similar with both the steroids.

Keywords: Aecopd, Lohs, Gold, Copd.

Introduction

Exacerbations are common in Chronic Obstructive Pulmonary Disease. An exacerbation is described as worsening or flareup of symptoms of COPD. Acute exacerbations are frequent cause of hospitalization and significantly affect quality of life of an affected individual[1]. Exacerbations are associated with cumulative worsening of lung function over a period of time[4]. Corticosteroids are the mainstay of therapy for treatment of acute exacerbation of COPD. Corticosteroids improve the symptoms of COPD by reducing systemic inflammation and associated airway narrowing; thereby improving oxygenation and lung function (FEV1). Corticosteroids also helps in reducing length of hospital stay[2].Though, corticosteroids are beneficial in management of AECOPD, they are associated with various adverse effects such as hypertension, raised blood glucose levels, fluid retention, delirium etc[3]. Very few studies have directly compared the effects of two different oral corticosteroids on clinical outcomes in patients with Acute Exacerbation of COPD. The present study was therefore, conducted at a tertiary care centre to compare the effects of 40mg oral prednisolone with that of an equivalent dose of 32mg oral methylprednisolone in patients with AECOPD.

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Material and Methods

Study Design

This was an analytical, experimental study done at a tertiary care centre in central India, from December 2019 and May 2021. Study was done after approved from institutional ethical committee. Study was registered in clinical trial registry of India (approval No. CTRI/2020/05/025292).

Patients over 40 years of age diagnosed with Acute Exacerbation of COPD and admitted in Pulmonary Medicine ward were included in the study. Patients of COPD with Pneumonia, pneumothorax, cardiac disease, history of asthma, those not giving consent , those unable to take oral corticosteroid , those on corticosteroid within the past 1month and patients who had Hospital stay less than 5 days were excluded from the study. Forty four patients with AEOPD were included in the study.

Socio demographic characteristics such as age, gender, residence, socioeconomic status were noted. Detailed clinical history regarding COPD, duration of COPD, history and duration of smoking, frequency of exacerbation, family history of COPD were documented. Acute exacerbations of COPD was defined according to the GOLD 2019 guidelines. Severity of COPD was defined according to Burge et al scale (2003).

Classification of severity of COPD according to Burge S et al (2003)[12]

A scale for exacerbation severity incorporating exacerbations managed at home and in hospital

Mild	An exacerbation treated with antibiotics but no systemic corticosteroid. If no blood gases are available theabsence of respiratory failure is assumed
Moderate	An exacerbation treated with parenteral corticosteroids with or without an antibiotic. If no blood gases areavailable the absence of respiratory failure is assumed
Severe	Type 1 respiratory failure with hypoxaemia but no carbon dioxide retention or acidosis; Pa,O2v8 kPa (60 mmHg) and Pa,CO2v6 kPa (45 mmHg)
Very severe	Type 2 respiratory failure, compensated with hypoxia, carbon dioxide retention but no acidosis; Pa,O2v8 kPa(60 mmHg), Pa,CO2w6 kPa (45 mmHg) and hydrogen ion concentrationv44 nM (pHw7.35)
Life-threatening	Type 2 respiratory failure, decompensated with acidosis and carbon dioxide retention; Pa,CO2w6 kPa (45 mmHg)and hydrogen ion concentrationw44 nM (pHv7.35)

Written consent was obtained from all the study participants after explaining the nature and purpose of study. Assignment of the group was done by systematic randomization which matched patients in terms of age, sex and severity of COPD.

- **Group A** – received 32mg/d methylprednisolone for 5 days.
- **Group B -** received equivalent dose of prednisolone equal to 40mg/d for 5 days;

Both the groups received similar treatment for acute exacerbation of COPD.

All patients received nebulized bronchodilators and antibiotics. Glucometer blood sugar charting was done three times daily Before breakfast, 2hr after lunch and 2hr after dinner, patient were questioned about difficulty in micturition, any gastric symptoms and everyday check of oral cavity.

At the end of therapy, the two groups were compared with respect to relief in symptoms, LOHS, treatment failure and adverse events.

Statistical analysis

Data was compiled and analysed using IBM SPSS software version 20. Categorical variables were expressed as frequency and proportions whereas continuous variables were expressed as mean and SD. Chi square test was applied to assess the difference in proportions between two groups whereas difference in mean between two groups was assessed using independent t test. P value less than 0.05 was considered statistically significant.

Results

The mean age in both groups was similar (Group A 58.95 ± 9.21 years, Group B 61.45 ± 9.41years p>0.05). Majority of the patients in group A were 61 to 70 years of age whereas in group B, patients were equally distributed in all age groups. There was no difference in the age composition between the two groups. Group B had more patients in the age group ≥ 70 years than Group A.

Male preponderance was observed. More than 80% of the patients irrespective of treatment groups were males. The gender composition was similar (p>0.05). (Table – 1)

Table 1: Age and gender composition of the groups

		Group A (n =22)	Group B (n=22)	χ^2	P value
Age (years)	≤ 50	5 (22.7%)	5 (22.7%)	4.7	0.19
	51 – 60	6 (27.3%)	5 (22.7%)		
	61 – 70	10 (45.5%)	6 (27.3%)		
	≥ 70	1 (4.5%)	6 (27.3%)		
	Mean ± SD	58.95 ± 9.21	61.45 ± 9.41		
Gender	Male	18 (81.8%)	20 (90.9%)	0.8	0.38
	Female	4 (18.2%)	2 (9.1%)		
Mean SpO2 at Admission		84	85		0.57

Relief of symptoms was assessed at the end of day five of steroid treatment. We observed that majority of the patients had symptom relief at the end of day five (Group A 72.7% vs. Group B 86.4%, p = 0.26). Equal number of patients in both the groups had symptom relief at the end of steroid course. (Table – 2)

Table 2: Comparison of relief of symptoms between the two treatment groups at the end of Day 5

Relief of symptoms	Group A (n =22)	Group B (n=22)
No	6 (27.3%)	3 (13.6%)
Yes	16 (72.7%)	19 (86.4%)
χ^2	1.3	
P value	0.26	

There was no difference in the number of patients who failed treatment in both the groups (p>0.26). (Table - 3)

Table 3: Comparison of treatment failure between the two groups

Treatment failure	Group A (n =22)	Group B (n=22)
No	16 (72.7%)	19 (86.4%)
Yes	6 (27.3%)	3 (13.6%)
χ^2	1.3	
P value	0.26	

Majority of the patients did not have any adverse effect. The only side effect in patients on Prednisolone was hyperglycemia. Hyperglycemia was less frequent with methylprednisolone than with prednisolone. However, patients on methylprednisolone had other adverse effects, which were not seen with prednisolone, such as gastritis, oral candidiasis and UTI. (Table – 4)

Table 4: Comparison of adverse effects

Adverse effects	Group A (n =22)	Group B (n=22)
Gastritis	2 (9.1%)	0 (0)
Hyperglycemia	2 (9.1%)	6 (27.3%)
Oral Candidiasis	2 (9.1%)	0 (0)

UTI	3 (13.6%)	0 (0)
None	13 (59.1%)	16 (72.7%)
χ^2	9.3	
P value	0.051	

Mean length of hospital stay was similar in both the groups.(Table – 5)

Table 5: Comparison of length of hospital stay

LOHS	Group A (n =22)	Group B (n=22)	T value	P value
Mean	9.09	8.77	0.2	0.68
SD	3.84	5.53		

Discussion

This was an analytical, experimental study done at a tertiary care centre in central India, forty four patients of AECOPD were taken over a period of one and a half years from December 2019 to May 2021 with aim to evaluated the effects of 40mg oral prednisolone and an equivalent dose of 32mg oral methylprednisolone in patients of AECOPD admitted to Pulmonary Medicine ward.

In our study, mean age of patients with COPD in methylprednisolne group was 58.95 ± 9.21 years and that in prednisolne group was 61.45 ± 9.41 years. Majority of the cases with AECOPD were elderly and male preponderance was observed. More than 80% of the patients in both the groups were males.

Relief of symptoms was assessed at the end of day five of steroid treatment. We observed that five days course of oral steroid was adequate in achieving relief of symptoms in AECOPD patients, out of 44 (16 patients in methylprednisolone group and 19 in prednisolone group). Equal number of patients had significant symptom relief with a five day course of either steroid. In the REDUCE trial Leuppi et al observed that a short course of 5 days of glucocorticoids was comparable to 14 days of conventional treatment with syatemic steroid[5]. Ardestani et al (2017) compared methylprednisolone with dexamethasone and observed comparable efficacy of methyl prednisolone with dexamethasone in providing symptomatic relief[6].

There was no difference in the number of patients who failed treatment in both the groups (Methylprednisolone 6 patients vs prednisolone 3 patients, p>0.26).

In the year 2013 Cevikar et al studied 40 AECOPD patients who received 32mg oral methylprednisolone for 7 days in one group and intravenous methylprednisolone 1mg/kg for 4 days followed by 0.5mg/kg for next 3 days in another group. Only 4 out of 40 patients needed extended therapy beyond 7 days[7].

Though corticosteroids are beneficial in providing immediate symptomatic relief, they are associated with certain side effects[84]. In our study, majority (29/44 patients) did not have any adverse effect. The only side effect in patients on prednisolone was hyperglycemia. Six patients in the prednisolone group developed hyperglycemia. Hyperglycemia was less frequent with methylprednisolone (2 out of 22) patients. However, patients on methylprednisolone had other adverse effects, which were not seen with prednisolone, such as gastritis, oral candidiasis and UTI. These adverse effects were probably not seen with prednisolone because of small sample size.Leuppi et al (2013) observed that patients on **7** day short course corticosteroid therapy compared to longer conventional 14 day therapy had lower risk of hyperglycemia and hypertension. This was attributed to low cumulative dose of prednisolone[4].In our study all patients received five days of oral corticosteroid.

Niewoehner et al (1999) studied 271 patients of AECOPD**.** Hyperglycemia was the most common adverse event associated with systemic corticosteroid along with secondary infection and myopathy. In this study patients received longer course of steroid of either 8 weeks or 2 weeks[8].Both the treatment strategies were equally effective in improving oxygen saturation. The mean duration of oxygen therapy and oxygen free days was also identical between the two groups.These findings were similar to the findings of a study by Li et al (2003) in which mean SpO_2 improved within 7 days of methyl prednisolone and dexamethasone therapy, but the improvement was significantly better in methyl prednisolone group[9]. Renil et al (2020) studied 64 patients of AECOPD. One group (32 patients) was given methylprednisolone and the other group (32 patients) was given prednisolone**.** They found that methylprednisolone was better than prednisolone at improving oxygen saturation[10].

Previous studies have shown that corticosteroids reduced Length of Hospital stay in AECOPD.

In our study we found that mean Length of Hospital stay was similar in both the groups [methylprednisolone 9.09 days vs 8.77 days in prednisolone].

In a study by Aggarwal et al (2021)**,** 97 patients of AECOPD in emergency department, were randomly divided into two groups of 50 and 47. The emergency department length of stay was similar in both the groups (11.7 ± 6.96 hours in Group A and 13.5 ± 9.18 hours in Group B, P = 0.285)[11].

Conflict of Interest: Nil Source of support: Nil

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