COMPARISON OF EFFICACY OF METHYL PREDNISOLONE AND PREDNISOLONE ORAL THERAPY IN EXACERBATION OF CHRONIC OBSTRUCTIVE PULMONARY DISEASE

Catherine Sara Renil*,1, Nimmy Tom1, Rahul R1, Bincy K. Chacko1, Dr. Doye George2 and Dr. Santosh M. Mathews1

1Associate Professor, Department of Pharmaceutics Pushpagiri College of Pharmacy, Thiruvalla.

2Associate Professor, Department of Pulmonary Medicine Pushpagiri Medical College Hospital, Thiruvalla.

ABSTRACT

Introduction: Chronic obstructive pulmonary disease is a major cause of morbidity and mortality worldwide and results in an economic and social burden that is both substantial and increasing. Corticosteroids are routinely used in the management of exacerbation of COPD. In this study we compared the efficacy of Methylprednisolone and Prednisolone oral therapy in the treatment of COPD exacerbation.

Methods: 64 AECOPD patients were randomly divided into 2 groups. One group received oral MP and the other group received oral prednisolone. The subjects entered into the study based on inclusion and exclusion criteria. Patient’s data collection form will be used for recording the demographic details of the patients. It is a 6 month study. During the study period, the patients are assessed for the impact of COPD on health status using CAT and the improvement in the pulmonary function is evaluated by observing the changes in the PEF values and SpO2 values. Any adverse drug events reported are measured using Naranjo’s causality assessment scale. Result: Symptoms, pulmonary function and pulse oximetry were improved after treatment in the two groups and significant differences were observed between the two (p<0.05). Incidence of adverse events (bloating, pedeleedema and hyperglycemia) in methyl prednisolone group was lower than prednisolone group.

Conclusion: Administration of oral methyl prednisolone to exacerbated COPD patients
improved pulmonary function, caused lesser number of adverse reactions and decreased the length of hospital stay than prednisolone.

**KEYWORDS:** Chronic obstructive pulmonary disease, exacerbation, methyl prednisolone, prednisolone.

**INTRODUCTION**
Chronic Obstructive Pulmonary Disease (COPD) is a lung disease characterised by chronic obstruction of lung airflow that interferes with normal breathing and is not fully reversible. COPD is a term that is used to include chronic bronchitis, emphysema or combination of both conditions. The global initiative for chronic obstructive lung disease (GOLD) defines COPD exacerbation as an event in the natural course of the disease that is characterised by a change in patients baseline dyspnea, cough and sputum that is beyond normal day-to-day variations, is acute in onset and warrents a change in regular medication. Recurrent exacerbations are associated with accelerated decline in lung function that is hallmark of COPD. Frequent exacerbations are associated with reduced physical activity, poorer quality of life and even an increased risk of death.

The main symptom of COPD is daily cough and mucus atleast 3 months a year for two consecutive years. Symptoms of exacerbation: Chronic cough, frequent respiratory infections, fatigue wheezing produce higher amount of mucus. Exacerbations can be caused by infection, air pollution, and changes in ambient temperature. Severe exacerbations are associated with worsening of pulmonary gas exchange due to increased inequality between ventilation and perfusion and subsequent respiratory muscle fatigue.

Corticosteroids due to its anti inflammatory actions are used in asthma, acute exacerbation of COPD. Mechanism of action of corticosteroids are inhibition of phospholipase A₂, reduction of production of interluken (IL)-1, complex effect on lymphoid system-reduction of circulating lymphocytes, inhibition of chemotactic responses, endocrine effect-glucose tolerance is reduced. Methyl prednisolone is a glucocorticoid used in the treatment of COPD with doses in range 16-96mg daily. Prednisolone was among the earliest of synthetic steroid drugs. Prednisolone 5-10mg orally single dose or divided dose can be effective in COPD. Larger doses may be required temporarily during exacerbations. Hyperglycemia, GI distress, weight gain, increased risk forinfection, sodium and fluid retention, insomnia mood swings are the common adverse effects of corticosteroids.
The COPD assessment test (CAT) is a validated test for evaluation of COPD impact on health status and is not a diagnostic tool but it can identify the health impairment of COPD patients and is better correlated with disease progression. Pulse oximetry provides estimates of arterial oxyhemoglobin saturation (SaO2) by utilizing selected wavelengths of light to noninvasively determine the saturation of oxyhemoglobin (SpO2). Peak expiratory flow rate (PEFR) is the maximum flow rate generated during a forceful exhalation, starting from full lung inflation.

MATERIALS AND METHODS
A prospective observational study was conducted in Department of Pulmonary Medicine at Pushpagiri Medical College Hospital on the topic “Comparison of efficacy of methyl prednisolone and prednisolone oral therapy in the treatment of patients with exacerbation of Chronic obstructive pulmonary disease”. The entire study was carried out after the approval of Institutional Ethics Committee. The selection of patients was based upon the inclusion and exclusion criteria. All patients were provided with a brief introduction regarding the study and the confidentiality of the data. A written Informed Consent was obtained from the patient or the care-giver.

Patient’s data collection form was used for recording the demographic details of the patients. It was a 6 month study. During the study period, the patients were assessed for the impact of COPD on health status using CAT and the improvement in the pulmonary function was evaluated by observing the changes in the PEF values and SpO2 values. Adverse drug events reported were measured using Naranjo’s causality assessment scale.

RESULTS AND DISCUSSION
In 6 month study, a total of 64 patients with COPD exacerbation were enrolled as per inclusion and exclusion criteria from in patient department of Pulmonary Medicine, Pushpagiri Medical College, Thiruvalla. 32 patients with COPD exacerbation prescribed with oral Methyl prednisolone and 32 patients with COPD exacerbation prescribed with oral Prednisolone were selected.

Group 1: Methyl prednisolone

Group 2: Prednisolone
The following are the results

Table 1: Distribution of pef among the patients in each group.

<table>
<thead>
<tr>
<th>Group 1</th>
<th>Pef initial</th>
<th>Pef final</th>
<th>Group 2</th>
<th>Pef initial</th>
<th>Pef final</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean ±SD</td>
<td>85.00 ±22.576</td>
<td>317.19±56.066</td>
<td>Mean ±Sd</td>
<td>83.59 ±20.448</td>
<td>276.88 ±69.720</td>
</tr>
</tbody>
</table>

![DISTRIBUTION OF PEF AMONG PATIENTS](image1)

**Figure: 1.**

In group 1, PEF improved from 85L/min to 317.19L/min and in group 2, PEF improved from 83.59L/min to 276.88L/min. There is significant difference (p<0.004) in the effect of oral corticosteroids in improving pulmonary function in COPD exacerbation. From this study, it was found that oral therapy of methyl prednisolone improves the pulmonary function in COPD exacerbation.

Table 2: Distribution of spo2 among patients in each group.

<table>
<thead>
<tr>
<th>Group 1</th>
<th>SpO2 Initial</th>
<th>SpO2 Final</th>
<th>Group 2</th>
<th>SpO2 Initial</th>
<th>SpO2 final</th>
</tr>
</thead>
<tbody>
<tr>
<td>MEAN ±SD</td>
<td>87.78 ±1.680</td>
<td>97.13±3.608</td>
<td>MEAN ±SD</td>
<td>87.97 ±1.513</td>
<td>92.19 ±4.284</td>
</tr>
</tbody>
</table>

![DISTRIBUTION OF SpO2 AMONG PATIENTS IN EACH GROUP](image2)

**Figure: 2.**
It was found that in group 1 the mean SpO$_2$ changed from 87.78% to 97.13% and in group 2 the mean SpO$_2$ 87.97% to 92.19%. Oral therapy with methyl prednisolone and prednisolone have shown improvement in COPD exacerbations based on SpO$_2$ values, but the SpO$_2$ values of patients treated with methyl prednisolone improved greater than in patients treated with prednisolone.

**Table: 3 Distribution of cat score among the patients.**

<table>
<thead>
<tr>
<th>Group 1</th>
<th>Cat Initial</th>
<th>Cat Final</th>
<th>Group 2</th>
<th>Cat Initial</th>
<th>Cat Final</th>
</tr>
</thead>
<tbody>
<tr>
<td>MEAN ±SD</td>
<td>34.06±3.110</td>
<td>13.25±2.514</td>
<td>MEAN ±SD</td>
<td>34.56±2.793</td>
<td>19.75±3.852</td>
</tr>
</tbody>
</table>

![DISTRIBUTION OF CAT SCORE AMONG THE PATIENTS](image)

**Figure: 3.**

The mean CAT score reduced from 34.06 to 13.25 in group 1 and from 34.96 to 19.74 in group 2. Methyl prednisolone and prednisolone have shown to reduce the CAT scores in COPD exacerbations. There is a significant difference ($p<0.000$) in the effect of methyl prednisolone and prednisolone oral therapy in COPD exacerbation.

**Table 4: Distribution of adr among patients in each group.**

<table>
<thead>
<tr>
<th>Drug 1</th>
<th>FREQUENCY</th>
<th>PERCENTAGE</th>
</tr>
</thead>
<tbody>
<tr>
<td>Adr</td>
<td>2</td>
<td>6.3</td>
</tr>
<tr>
<td>No adr</td>
<td>30</td>
<td>93.8</td>
</tr>
<tr>
<td>Total</td>
<td>32</td>
<td>100</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Drug 2</th>
<th>FREQUENCY</th>
<th>PERCENTAGE</th>
</tr>
</thead>
<tbody>
<tr>
<td>Adr</td>
<td>4</td>
<td>12.5</td>
</tr>
<tr>
<td>No adr</td>
<td>28</td>
<td>87.5</td>
</tr>
<tr>
<td>Total</td>
<td>32</td>
<td>100</td>
</tr>
</tbody>
</table>
6.3% and 12.5% of patient population have experienced adverse drug reaction from group 1 and group 2 respectively. Patients administered with oral methyl prednisolone is shown to have lesser percentage of adverse drug reaction than patients administered with oral prednisolone.
The duration of hospital stay is found to be longer in patients receiving oral prednisolone compared to methyl prednisolone.

**DISCUSSION**
Administration of oral methyl prednisolone showed significant improvement in the pulmonary function (PEF, SpO₂) and in the COPD exacerbation when comparing those taking oral prednisolone. CAT scores showed significant reduction in the impact of COPD on health status of patients. The development of ADR was more in patients treated with prednisolone. The duration of hospital is comparatively shorter for methyl prednisolone and overall treatment outcome is more in patients treated with methyl prednisolone.

**CONCLUSION**
Our study helps in choosing the better oral corticosteroid for COPD patients presenting with exacerbation. Administration of oral methyl prednisolone to exacerbated COPD patients improved pulmonary function, caused lesser number of adverse reactions and decreased the length of hospital stay than prednisolone. Hence methyl prednisolone provides better patient care.

**ACKNOWLEDGEMENT**
The authors would like to thank the staff of Pushpagiri College of Pharmacy and Hospital, Kerala, India.

**REFERENCE**
12. WH et al); Controlled trial of oral prednisone in outpatients with acute COPD exacerbation, 1996.