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Original Article

Role of Budesonide in Management of COPD Patients

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ABSTRACT

Background: Chronic obstructive pulmonary disease is the fourth leading reason of death in the nation, and its prevalence and mortality are increasing in the coming decades. Exacerbations of COPD are common in some subjects and they need a larger dose of corticosteroids for its management during that period of time.The dosage of the drug varies between 1-8 mg and it varies according to patient's condition, method of use and history. The efficacy of systemic and nebulised corticosteroids are similar. The aim of the present study is to determine the role of budesonide in management of COPD patients. **Materials and methods**: The present study was conducted using 150 subjects of COPD reporting to the institute. The study was approved by the institutional ethical board. The criteria given by the American Thoracic Society was used to classify subjects of COPD. They were given 8 nebulised doses of corticosteroid and were given infusion of 50 ml of saline every visit. Same type of nebuliser was also used for giving the nebulised dose. All the subjects were randomly divided into two groups. Group I patients were given bronchodilator with salbutamol (2.5 mg qid)and 0.5mg/ 2ml of ipratropium bromide. Group 2 patients were given a combined nebulised solution of salbutamol and ipratropium bromide q.i.d. and they were also given nebulised budesonide (1500 mg qid). Student t test and annova test were used for the comparative analysis. Probability value of less than 0.05 was considered significant. **Results**: The present study enrolled 150 subjects; out of this majority were males. The subjects were divided into two groups randomly. There were 75 subjects in each group. The mean FVC% in group 1 at 24 hours was 64.4+/-21.3 and at 7th day was 64.7+/-19.8. The mean FVC% in group II at 24 hours was 63.3+/-20.5 and at 7th day was 68.7+/-22.6. There was no significant difference between the two as the p value was more than 0.05. **Conclusion:** From the above study we can conclude that high doses of budesonide were found to be equally effective as systemic corticosteroids in management of acute exacerbations of COPD.

Key words: budesonide , corticosteroids, exacerbations

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INTRODUCTION

Chronic obstructive pulmonary disease is the fourth leading reason of death in thenation[1], and its prevalence and mortality are increasing in the coming decades.[2]It poses a seriousand disabling burden on the patients, healthcare authority and the society. There is progressive deterioration of the lung function in this condition with increase in symptoms over the years. In later stages of the disease, acute exacerbations are very common and have a significant effect on patient's well being and daily chores.[3]Systemic corticosteroids are strongly used during the management of acute and chronic exacerbations of chronic obstructive pulmonary disease according to international guidelines.[4,5] Even if they are widely used, there are still some disadvantages associated with their use. COPD is generally seen amongst the elderly and they are already in compromised conditions due to other systemic conditions therefore side effects of steroids are of major concern. The cumulative dose of corticosteroids is an important factor in development of adverse events like osteoporosis, fractures, development of cataract, glucose intolerance and myopathy.[6-9] Exacerbations of COPD are common in some subjects and they need a larger dose of corticosteroids for its management during that period of time.[10,11] Therefore the chances of development of adverse events is increased to several fold in this subgroup and many physicians are in search for alternatives for this. The use of nebulised corticosteroids that have topical anti inflammatory are now being used for management of COPD and can be used as a substitute for systemic corticosteroids. There are only few studies in literature that have studies their use during management of exacerbations of respiratory conditions.[12-17] The dosage of the drug varies between 1-8

mg and it varies according to patient's condition, method of use and history. The efficacy of systemic and nebulised corticosteroids are similar. The aim of the present study is to determine the role of budesonide in management of COPD patients.

MATERIALS AND METHODS

The present study was conducted using 150 subjects of COPD reporting to the institute. The study was approved by the institutional ethical board. All the subjects were informed about the study and a written consent was obtained from all subjects in their vernacular language. The criteria given by the American Thoracic Society was used to classify subjects of COPD. Patients already on systemic corticosteroids and having frequent exacerbation of COPD were not included in the study. All the patients received similar treatment. They were given 8 nebulised doses of corticosteroid and were given infusion of 50 ml of saline every visit. Same type of nebuliser was also used for giving the nebulised dose. All the subjects were randomly divided into two groups. Group I patients were given bronchodilator with salbutamol (2.5 mg qid)and 0.5mg/ 2ml of ipratropium bromide. Group 2 patients were given a combined nebulised solution of salbutamol and ipratropium bromide q.i.d. and they were also given nebulised budesonide (1500 mg qid). All the patients were given nebulised salbutamol as a rescue medication. Hospitalization of the subjects was done for 10 days and after discharge they were given inhalers of salbutamol and ipratropium bromide. All the subjects underwent complete blood count, biochemical analysis and spirometric examination. Arterial blood gas examination was evaluated amongst all subjects. Spirometric examination was done amongst all subjects to obtain baseline values for comparison. Patients who missed more than one spirometric examination were excluded from the study. Standard techniques were used to obtain the FEV1 and FVC values. All the data was arranged in tabulated form and analysed using SPSS software. Student t test and annova test were used for the comparative analysis. Probability value of less than 0.05 was considered significant.

RESULTS

The present study enrolled 150 subjects; out of this majority were males. The subjects were divided into two groups randomly. There were 75 subjects in each group. The mean FVC% in group 1 at 24 hours was 64.4+/-21.3 and at 7^{th} day was 64.7+/-19.8. The mean FVC% in group II at 24 hours was 63.3+/-20.5 and at 7^{th} day was 68.7+/-22.6. There was no significant difference between the two as the p value was more than 0.05. The mean FEV1% in group 1 at 24 hours was 36.6+/-12.1 and at 7^{th}day was 68.5+/-20.6. The mean FEV1% in group II at 24 hours was 38.6+/-13.2 and at 7^{th} day was 44.9+/-12.8. There was no significant difference between the two as the p value was more than 0.05. The mean FEV1/FVC in group 1 at 24 hours was 45.8+/-16.9 and at 7^{th} day was 46.3+/-14.6. The mean FEV1/FVC in group II at 24 hours was 47.4+/-14.2 and at 7^{th} day was 49.2+/-14.7. There was no significant difference between the two as the p value was more than 0.05. The mean partial pressure of oxygen in group 1 at 24 hours was 52.4+/-12.1 and at 7^{th} day was 54.4+/-11.9. The mean pressure of oxygen in group II at 24 hours was 50.6+/-13.8 and at 7^{th} day was 55.4+/-13.1. There was no significant difference between the two as the p value was more than 0.05. The mean partial pressure of carbon dioxide in group 1 at 24 hours was 47.3+/-15.7 and at 7^{th} day was 48.1+/-15.6. The mean pressure of carbon dioxide in group II at 24 hours was 46.9+/-13.7 and at 7^{th} day was 49.8+/-9.5. There was no significant difference between the two as the p value was more than 0.05.

Table 1: Comparison of respiratory characteristics between the two groups

VARIABLE	GROUP	AT 24 H	AT 7 DAY
FVC%	1	64.4+/-21.3	64.7+/-19.8
	2	63.3+/-20.5	68.7+/-22.6
P value		>0.05	>0.05
FEV1%	1	36.6+/-12.1	68.5+/-20.6
	2	38.6+/-13.2	44.9+/-12.8
P value		>0.05	>0.05
FEV1/FVC	1	45.8+/-16.9	46.3+/-14.6
	2	47.4+/-14.2	49.2+/-14.7
P value		>0.05	>0.05
PP oxygen (mmHg)	1	52.4+/-12.1	54.4+/-11.9
	2	50.6+/-13.8	55.4+/-13.1
P value		>0.05	>0.05
PP carbon dioxide (mmHg)	1	47.3+/-15.7	48.1+/-15.6
	2	46.9+/-13.7	49.8+/-9.5
P value		>0.05	>0.05
Glucose (mg/dl)	1	114.0+/-32.7	110.0+/-32.5
	2	115.3+/-25.9	114.7+/-26.9

DISCUSSION

Cigarette smoking is the chief etiological reason behind COPD and smoking cessation can drastically improve the rate of decline in forced expiratory volume in one second (FEV1).[18,19] However, the inflammatory process of the airways that is initiated by smoking persists after termination ofsmoking[20], and efficient treatment is required in previous smokers with chronic obstructive pulmonary disease.[21]The pharmacotherapy for management of COPD majorly consists ofmucolytics, bronchodilators, like b2-agonists, anticholinergics, and anti-inflammatory agents like inhaled corticosteroids and are often used in combination.[2] There is a need for better management options to relieve symptoms, decrease exacerbations and to provide a good quality of life for individual subjects. Systemic corticosteroids efficiently improve the clinical results when compared with placebo treatment. However, the results are only significant for short term effect and lesser during long term follow ups. A study conducted by MALTAIS et al.[16]showed that a significant difference existed in FEV1 between the groups with systemic prednisolone and nebulised budesonide of 60 ml over a period of 3 days. According to MORICE et al.[15]there was no significant difference between the two groups over a period of 5 days. The subjects were given 30 mg oral prednisolone or 4 mg nebulised budesonide per day. As per our study, the mean FVC% in group 1 at 24 hours was 64.4+/-21.3 and at 7th day was 64.7+/-19.8. The mean FVC% in group II at 24 hours was 63.3+/-20.5 and at 7th day was 68.7+/-22.6. There was no significant difference between the two as the p value was more than 0.05. The mean FEV1% in group 1 at 24 hours was 36.6+/-12.1 and at 7th day was 68.5+/-20.6. The mean FEV1% in group II at 24 hours was 38.6+/-13.2 and at 7th day was 44.9+/-12.8. There was no significant difference between the two as the p value was more than 0.05. The mean FEV1/FVC in group 1 at 24 hours was 45.8+/-16.9 and at 7th day was 46.3+/-14.6. The mean FEV1/FVC in group II at 24 hours was 47.4+/-14.2 and at 7th day was 49.2+/-14.7. There was no significant difference between the two as the p value was more than 0.05. The mean partial pressure of oxygen in group 1 at 24 hours was 52.4+/-12.1 and at 7th day was 54.4+/-11.9. The mean pressure of oxygen in group II at 24 hours was 50.6+/-13.8 and at 7th day was 55.4+/-13.1. There was no significant difference between the two as the p value was more than 0.05. The mean partial pressure of carbon dioxide in group 1 at 24 hours was 47.3+/-15.7 and at 7th day was 48.1+/-15.6. The mean pressure of carbon dioxide in group II at 24 hours was 46.9+/-13.7 and at 7th day was 49.8+/-9.5. There was no significant difference between the two as the p value was more than 0.05According to a recent study byMIRICI et al.[17] that included arterial blood gas markers along with spirograms. According to his findings there was no significant improvement at 6 hours, 24 hours and 10 days after hospitalization. The adverse events associated with the use of corticosteroids cannot be neglected. There has been a significant risk of fracture amongst the elderly subjects with single dose of corticosteroids.[22] The total dose of corticosteroids received during the lifetime is of major concern in the appearance of side effects.6,13,23 Subjects with COPD frequently undergo exacerbations and therefore are more likely to receive higher doses of steroids.

CONCLUSION

From the above study we can conclude that high doses of budesonide were found to be equally effective as systemic corticosteroids in management of acute exacerbations of COPD. The systemic effects of nebulised budesonide were found to be less compared to systemic corticosteroids. Therefore it can be safely administered in subjects with exacerbations of chronic obstructive pulmonary disease.

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