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Research article

COMPARATIVE STUDY OF FLUTICASONE PROPIONATE WITH BUDESONIDE AND BECLOMETHASONE DIPROPIONATE IN MILD PERSISTENT BRONCHIAL ASTHMA

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ABSTRACT

Objective: To compare the efficacy and adverse effects of fluticasone propionate with that of budesonide and beclomethasone dipropionate in mild persistent cases of bronchial asthma. **Methods:** This was an open label, randomized parallel group study done in Government General and Chest Hospital, Hyderabad for a period of 12 weeks. Each group had 20 patients. The group I was given fluticasone propionate inhalation therapy 100µg twice daily. Group II was given budesonide inhalation therapy 200µg twice daily. Group III was given beclomethasone dipropionate inhalation therapy 200µg twice daily. **Results:** Symptomatic improvement was observed in all three groups. At end point, mean FEV_1 in fluticasone propionate treatment group improved by 22.04% compared with 14.53% in budesonide and 12.02% in beclomethasone treatment groups. At end point, mean FVC value of the fluticasone propionate treatment group improved by 8.04% compared with 5.29% in budesonide and 4.27% in beclomethasone groups. Mean FEV_1 / FVC also improved by 12.76% in the fluticasone propionate group compared with 8.63 % in budesonide and 7.45 % in beclomethasone groups. No adverse effects were reported in any of the treatment groups. **Conclusion:** This study showed that fluticasone propionate is superior to budesonide and beclomethasone in improving lung function, decreasing symptoms and need for rescue medication in mild persistent asthma

Keywords: Fluticasone, Budesonide, Beclomethasone, Mild persistent asthma

INTRODUCTION

Bronchial asthma is a chronic inflammatory disorder of the airways. It is characterized by airflow obstruction that is typically reversible and by airway hyper responsiveness to various stimuli. According to National Asthma Education and Prevention Program (NAEPP) [1], mild persistent asthma is characterized by symptoms > 2 times a week but < 1 time a day, exacerbations may affect activity. Night time symptoms > 2 times a month, FEV1 or PEF > 80% predicted, PEF variability 20-30%.

This study was done to compare the clinical efficacy of three different inhaled glucocorticoids namely fluticasone propionate, budesonide and beclomethasone dipropionate in mild persistent cases of bronchial asthma.

MATERIALS AND METHODS

This was an open label, randomized parallel group study done in Government General and Chest Hospital, Hyderabad for a period of 12 weeks from May 2003 to December 2003. The study design was approved by Institutional ethics committee. A written informed consent was obtained from each patient.

Inclusion criteria:

1. Patients in the age group of 20-55 years of either sex
2. Patients with a history of episodic wheezing, difficulty in breathing, chest tightness and cough with or without expectoration
3. Patients having nocturnal symptoms and family history of asthma

Exclusion criteria:

1. Pregnant and lactating women
2. Smokers and patients with symptoms related to occupation
3. Patients who were already on steroid treatment for bronchial asthma
4. Patients with history of pulmonary tuberculosis, chronic obstructive pulmonary disease, recurrent pulmonary emboli, carcinoid tumor, tropical eosinophilia
5. Patients with history of diabetes mellitus, hypertension, chronic renal failure
6. Patients with history of bronchogenic carcinoma and suspected malignancy anywhere in the body

After history was taken, a detailed clinical examination was done, these are, complete blood picture, Sputum examination, Random blood sugar, Serum creatinine, Chest X ray PA view, Electrocardiography.

Pulmonary function tests with Microloop/Microlab spirometer (Figure 1): With this, forced vital capacity (FVC), forced expiratory volume in one second (FEV_1), forced expiratory ratio (FEV_1/FVC) are measured.

The total number of patients was randomized into 3 groups. Each group had 20 patients.

Group1: Fluticasone propionate inhalation therapy 100 µg twice daily

Group2: Budesonide inhalation therapy 200 µg twice daily.

Group3: Beclomethasone dipropionate inhalation therapy 200 µg twice daily

All the patients were advised to take Salbutamol inhalation (100 µg per puff) as needed. Metered dose inhaler with spacer (Figure 2) was used for taking medication. Patients were shown inhalation technique with spacers. They were advised to rinse their mouth after each inhalation. They were followed up once in every two weeks till a period of 12 weeks. At each visit, they were clinically assessed and pulmonary function tests were done. Scoring was done for cough, wheeze, breathlessness and severity of nocturnal symptoms. [2, 3]

0-Nosymptoms, 1- Mild,2- Moderate, 3- Severe.

Score for frequency of use of rescue medication[4]

0 - < 2 puffs/week, 1- < 2 puffs/day, 2- 2 to 4 puffs/day, 3- > 4 puffs/day

At each visit, patients were assessed for any adverse effects.

Statistical analysis

Data is presented in mean ± SEM and percentages as applicable. ANOVA was applied for comparison of the treatment groups. Unpaired Student's t-test was applied to test the level of significance. $P < 0.05$ was considered as the level of significance

Fig.1: Patient undergoing pulmonary function test

Fig.2: Spacer

RESULTS

Two patients each in Group II and Group III and one patient in Group I were excluded from study owing to noncompliance. Symptomatic improvement was observed in all three groups. The FEV_1, FVC, FEV_1/FVC improved with respect to baseline. A significant effect was observed in favour of fluticasone propionate compared with beclomethasone dipropionate and budesonide. At end point, mean FEV_1 in fluticasone propionate group improved by 0.57L (22.04%) compared with improvements of 0.38L (14.53%) in budesonide and 0.33L (12.02%) in beclomethasone dipropionate groups ($P < 0.001$). At end point, mean FVC value of the fluticasone propionate group improved by 8.04% compared with improvements of 5.29% in budesonide and 4.27% in beclomethasone dipropionate groups Mean FEV_1/FVC also improved by 12.76% in the fluticasone propionate group compared to 8.63% with budesonide ($P < 0.05$) and 7.45% in beclomethasone dipropionate groups ($P<0.01$). No adverse effects were reported in any of the treatment groups.

Table-1: Demographic data of patients with mild persistent asthma

Drug	Number of men	No of women	Mean age (in years) (± SEM)
Fluticasone propionate n=20	11	9	35.2 ± 1.4
Budesonide n=20	12	8	32.9 ± 1.1
Beclomethasone dipropionate n=20	10	10	33.4 ± 1.2

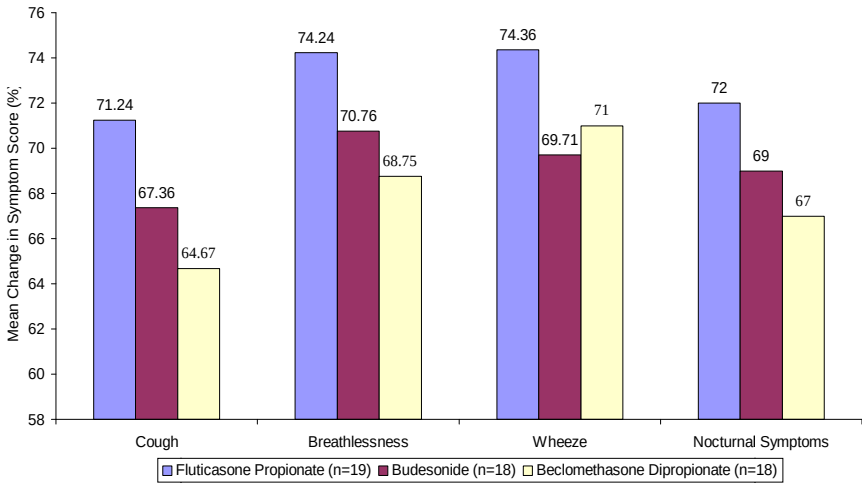

Fig.3: Improvement of symptoms in patient with mild persistent asthma

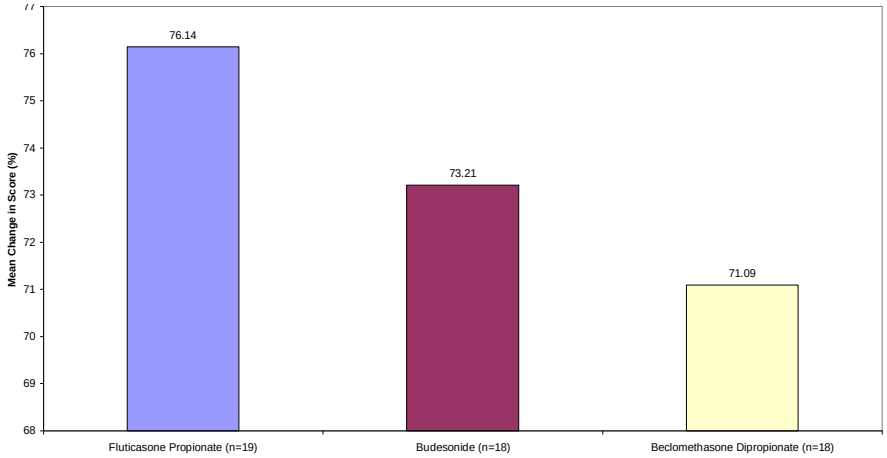

Fig.4: Reduction in frequency of use of rescue medication in patient with mild persistent asthma.

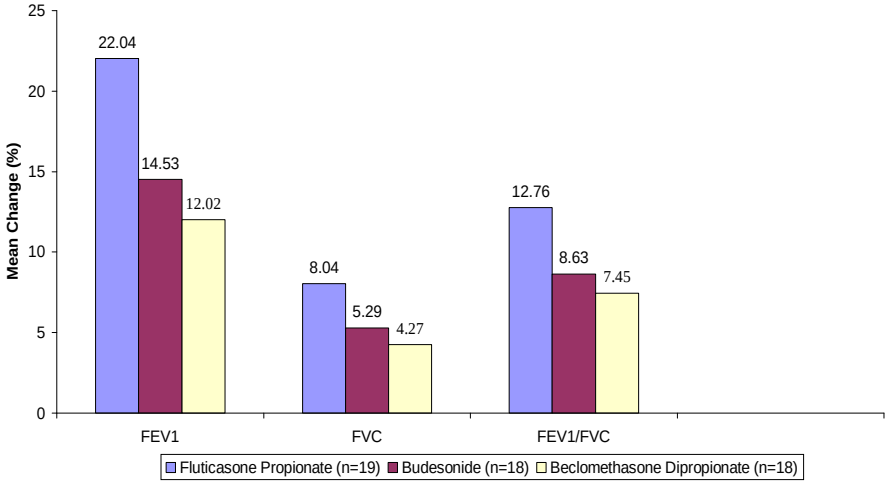

Fig.5: Assessment of FEV1, FVC, FEV1/FVC in patient with mild persistent asthma.

DISCUSSION

This study was done to compare commonly prescribed doses of inhalational steroids in mild persistent asthma. Fluticasone propionate 100µg twice daily, Budesonide 200 µg twice daily, Beclomethasone dipropionate 200 µg twice daily were given.

Fluticasone propionate treatment produced significantly greater improvements in lung function (FEV_1, FVC and FEV_1/FVC) than budesonide and beclomethasone dipropionate. Patient compliance was good which 90% in all the groups was.

Raphael et al., [2] in a study compared two doses of fluticasone propionate (88 µg twice daily, 220 µg twice daily) with two doses of beclomethasone dipropionate (168 µg twice daily, 336 µg twice daily) in subjects with persistent asthma. They reported that fluticasone propionate provides greater asthma control than beclomethasone dipropionate with a comparable adverse event profile.

Connolly et al., [5] compared fluticasone propionate 200 µg twice daily with budesonide 400 µg per day. He reported that fluticasone propionate produced significant improvement in asthma symptoms. Similar improvement in pulmonary function tests was observed in both the groups.

The present study supports the findings observed in the above studies. No adverse effects were reported in any of the treatment groups during the study period.

CONCLUSION

It can be concluded that fluticasone propionate is superior to budesonide and beclomethasone dipropionate in improving lung function, decreasing symptoms and need for rescue medication in mild persistent asthma. Patient compliance was good with all the three drugs.

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