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RESEARCH ARTICLE

A Comparative Study of Fluticasone Propionate with Budesonide and Beclomethasone Dipropionate in Moderate 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 moderate 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. Group A was given fluticasone propionate inhalational therapy 250 mcg twice daily. Group B was given budesonide inhalational therapy 400 mcg twice daily. Group C was given beclomethasone dipropionate inhalational therapy 400 mcg twice daily.

Results: Symptomatic improvement was observed in all three groups. At end point, mean FEV_1 in fluticasone propionate treatment group improved by 23.84% compared with 15.24% in budesonide and 12.93% in beclomethasone treatment groups. At end point, mean FVC value in fluticasone propionate treatment group improved by 6.44% compared with 1.5 % in budesonide and 1.06% in beclomethasone groups. Mean FEV_1 / FVC also improved by 16.56% in fluticasone propionate group compared with 13.68 % in budesonide and 11.93 % 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 moderate persistent asthma

Keywords: Fluticasone, budesonide, beclomethasone, moderate persistent asthma.

1. INTRODUCTION:

Bronchial asthma is a chronic inflammatory disorder of airways. It is characterized by air flow obstruction that is typically reversible and by airway hyper responsiveness to various stimuli. Inhalational glucocorticoids are commonly used in the treatment of asthma. According to National Asthma Education and Prevention Program (NAEPP) [1], moderate persistent asthma is characterized by daily symptoms. Exacerbations affect activity. Night time symptoms > 1 time a week, FEV1 or PEF > 60% to <80% predicted, PEF variability >30%.

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

2. 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.

2.1. 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

2.2. Exclusion criteria:

1. Pregnant and lactating women

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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, 2): With this, forced vital capacity (FVC), forced expiratory volume in one second (FEV_1), forced expiratory ratio (FEV_1/FVC) are measured. A written informed consent was obtained from each patient.

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

Group A: Fluticasone propionate inhalational therapy 250 mcg twice daily

Group B: Budesonide inhalational therapy 400 mcg twice daily.

Group C: Beclomethasone dipropionate inhalational therapy 400 mcg twice daily

All the patients were advised to take Salbutamol inhalation (100 mcg per puff) as needed. Metered dose inhaler with spacer (Figure 3) 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 - No symptoms
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.

2. 3. 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: Microloop/Microlab Spirometer

Fig 2: Patient undergoing pulmonary function Test

Fig 3: Spacer

3. RESULTS

Six patients were excluded from study, two each in Group A and Group B as they did not turn up for regular follow up. Two patients in Group C were excluded owing to non compliance. 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 0.52L (23.84%) compared with improvements of 0.31L (15.24%) in budesonide ($P < 0.001$) and 0.25L (12.93%) in beclomethasone dipropionate groups ($P < 0.001$). At end point, mean FVC value in fluticasone propionate group improved by 6.44% compared with improvements of 1.5% in budesonide ($P < 0.001$) and 1.06% in beclomethasone dipropionate groups ($P < 0.001$). Mean FEV_1/FVC also improved by 16.56% compared with 13.68% in budesonide ($P < 0.05$) and 11.93% in beclomethasone groups ($P<0.01$). No adverse effects were reported in any of the treatment groups

Drug	Number of men	No of women	Mean age (in years)(± SEM)
Fluticasone propionate n=20	13	7	34.5 ± 1.4
Budesonide n=20	09	11	36.3 ± 1.5
Beclomethasone dipropionate n=20	12	08	33.7 ± 1.2

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

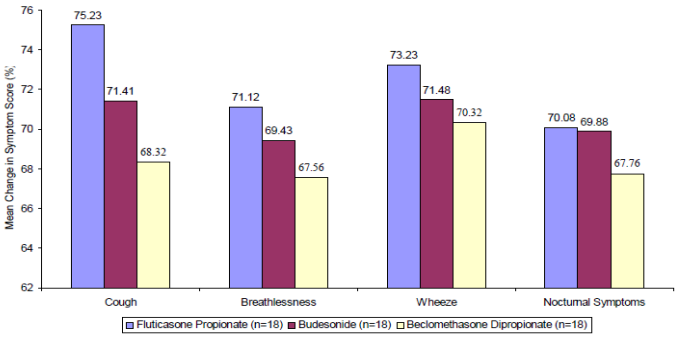

Fig 4: Improvement of symptoms in patients with moderate persistent asthma

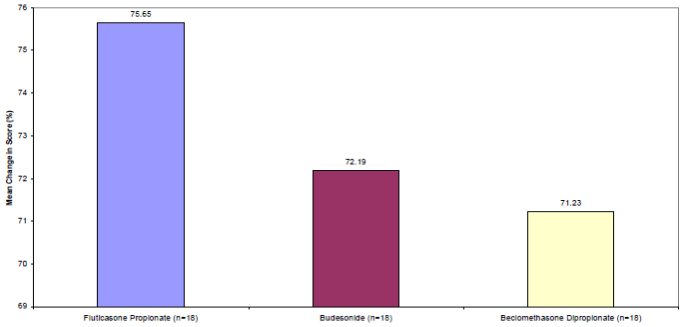

Fig 5: Reduction in frequency of use of rescue medication in patients with moderate persistent asthma.

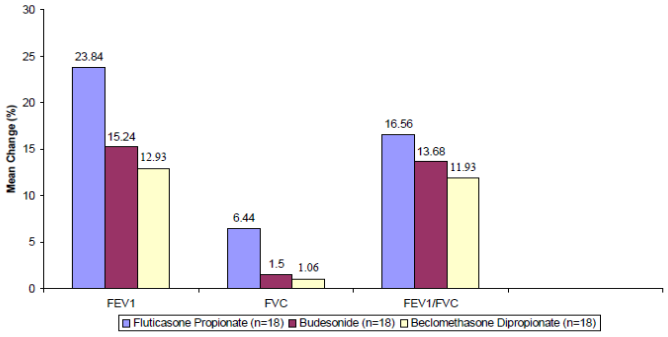

Fig 6: Assessment of FEV1, FVC, FEV1/FVC in patients with moderate persistent asthma.

4. DISCUSSION:

This study was done to compare commonly prescribed doses of inhalational steroids in moderate persistent asthma. Fluticasone propionate 250 mcg twice daily, Budesonide 400 mcg twice daily, Beclomethasone dipropionate 400 mcg 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 was 90% in all the groups.

Ige et al [5] compared fluticasone propionate at a daily dose of 220 mcg with beclomethasone dipropionate at a daily dose of 400 mcg.They found that fluticasone propionate is more efficacious than beclomethasone dipropionate in the treatment of mild to moderate bronchial asthma.

Connolly [6] in a study compared fluticasone propionate 200 mcg twice daily with budesonide 400 mcg 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. Beclomethasone dipropionate was compared with budesonide over a wide range of doses in previous studies. These studies showed that the two drugs have similar effects on asthma control. Present study supports the findings observed in the above studies. No adverse effects were reported in any of the treatment groups during study period. Local adverse effects like oral candidiasis was not observed in any of the treatment groups. This might be due to the use of spacer and thorough rinsing of mouth after each inhalation.

In conclusion, present study showed that fluticasone propionate is superior to budesonide and beclomethasone dipropionate in improving lung function, decreasing symptoms and need for rescue medication in moderate persistent asthma. Patient compliance was good with all the three drugs. All the three drugs were well tolerated at the doses used in this study.

5. REFERENCES

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Conflict of Interest: None Declared

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