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RANDOMIZED, OPEN LABEL, ACTIVE CONTROLLED COMPARATIVE STUDY TO ASSESS SAFETY, EFFICACY OF MOMETASONE & FORMOTEROL VERSUS FLUTICASONE & FORMOTEROL DRY POWDER INHALER IN TREATMENT OF MILD TO MODERATE PERSISTENT ASTHMA

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ABSTRACT

Background: This study conducted to assess and compare the safety and efficacy of Mometasone & Formoterol versus Fluticasone & Formoterol. in patients with mild to moderate persistent asthma on symptom control and rescue medication usage.

Method: The present study was conducted during March 2011 to February 2012. 120 patients were randomized in to two groups and were given Mometasone & Formoterol to group 1 and Fluticasone & Formoterol to group 2 for 12 weeks.

Result: Out of 60 patients recruited in each group 7 were lost to follow up in Fluticasone group and 4 in Mometasone group. Out of 53 patients in Fluticasone group, 11 developed adverse reactions. Whereas in Mometasone group out of 56 patients- 7 developed adverse reactions. The overall improvement in Spirometry parameters was better in Mometasone group compared to Fluticasone which was not statistically significant suggesting both were equally efficacious. There was reduction in dosage of rescue medication used from baseline to the end of 12 weeks in Mometasone group compared to Fluticasone group.

Conclusion: Both combinations were safe and equally efficacious in treating mild to moderate persistent asthma patients.

Keywords: Mild to moderate persistent Asthma; dry powder inhaler; safety; efficacy

INTRODUCTION

Asthma is a disease characterized by airway inflammation and recurrent episodes of symptoms of wheezing and chest tightness that are associated with variable airway obstruction and bronchial hyper responsiveness. [1] The main strategy in the management of asthma includes patient's education, environment control, pharmacotherapy and immunotherapy.

The efficacy of inhaled corticosteroids is primarily due to the suppression of airways inflammation and associated airways hyperresponsive-

ness. The addition of an inhaled long-acting β2-agonist (LABA) to an inhaled corticosteroid (ICS) gives optimal control of asthma in most patients and two fixed combination inhalers are increasingly used as a convenient controller in patients with persistent asthma. There is a strong scientific rationale for the combination of these two drug classes.[2] ICS suppress the chronic inflammation of asthma and reduce airway hyper responsiveness and this is achieved at low doses in most patients. LABA in addition to their bronchodilator action, also inhibit mast cell mediator release, plasma exudation and may reduce sensory nerve activation. Thus these two classes of drug address complementary aspects of the pathophysiology of asthma that neither drug class is able to achieve alone.[2]

Mometasone has low systemic bioavailability and high glucocoticoid receptor affinity compared with most other inhaled corticosteroids and modifies inflammatory mediators involved in the pathogenesis of asthma. Studies have shown that Mometasone significantly improves lung function and symptom control in patients with mild, moderate or severe asthma.[3]

Formoterol and Salmeterol have similar duration of bronchodilation of at least 12hrs, but Formoterol is less lipophilic than Salmeterol. Hence has a fast onset of action of <3min, whereas Salmeterol can take up approximately 20 min to produce clinically relevant bronchodilation.[4] Mometasone significantly improves lung function and control symptom in asthma patients when used in combination with Formoterol.[3] In India very few studies have been conducted to compare the safety, efficacy using Formoterol & Mometasone. Hence, the present study was conducted to compare safety, efficacy between Formoterol & Mometasone versus Formoterol & Fluticasone using dry powder inhaler in patients with mild to moderate persistent asthma.

Objectives of the study were to assess the safety and efficacy of Mometasone & Formoterol versus Fluticasone & Formoterol using dry powder inhaler in patients with mild to moderate persistent asthma and to assess the effect of Mometasone & Formoterol versus Fluticasone & Formoterol using dry powder inhaler on symptom control and rescue medication usage.

METHOD

It was a Randomized, open label, active - controlled, comparative study in patients with mild to moderate persistent asthma attending Allergy clinic, Preventive Medicine Unit and TB & Chest diseases OPD, Kempegowda Institute of Medical Sciences (KIMS) Hospital, Bangalore.

A total of 120 patients (60 in each group) with mild to moderate persistent bronchial asthma (GINA guidelines) were recruited based on inclusion and exclusion criteria and willing to sign the written informed consent following Institutional Ethics Committee approval.

Inclusion Criteria: Patients between 18-65 years of age; Patients with an established diagnosis of mild to moderate persistent bronchial asthma (GINA guidelines) requiring a combination of long acting β2-agonists & inhalation corticosteroids under supervision of pulmonologist; and patients willing to give consent and available for follow up were included in the study.

Exclusion Criteria: Patients with severe persistent asthma and severe COPD; Patients with h/o severe respiratory tract infection in past 4 weeks; Smoking history of 15 or more pack years; Asthmatic patients on oral or parenteral corticosteroids; History of known hypersensitivity to any ingredients of study formulations; Recent history of myocardial infarction, heart failure, or cardiac arrhythmia requiring treatment and uncontrolled hypertension, severe renal or hepatic disease, active peptic ulcer disease; Pregnant or lactating woman; or Patients being a part of any clinical study in previous 1 month were excluded from the study.

Baseline investigations like blood routine (Hemoglobin, Total Count, Differential Count, Absolute Eosinophil Count), Chest X-ray and Spirometry were done. Spirometry (ERS'93/Polgar) was done with pre and post bronchodilator (Salbutamol nebulization). Spirometry was incorporated with a correction factor 0.88 of European respiratory society (ERS) for South Indians.[5]

Symptoms were assessed at baseline, 6 and 12 weeks. Patients were given medications for first 6 weeks and were assessed for improvement in symptoms like cough, shortness of breath, tightness in chest and also number days and nights free from symptom in a week for 6 weeks. Subsequently medications were given for next 6 weeks and again improvement in symptoms was assessed and were advised to report in case of any adverse reaction following medications. At the end of 12-weeks patients were assessed and compared for safety, efficacy after medications. Spirometry was done again at the end of 12

weeks and results were compared with the baseline parameters.

Patients were permitted to use the inhaled Salbutamol as a rescue medication during exacerbations. The use of inhaled Salbutamol during treatment was recorded at baseline and 12 weeks. Concomitant medications if taken were also recorded. Data analysis was done using SPSS 17 version.

RESULTS

Socio demographic profile of Asthma patients: Out of 60 patients, who were included in Fluticasone & Formoterol group, majority i.e. 20 (33.33%) were in the age group of 31-40 years, next highest i.e., 16 (26.67%) in the age group of 21-30 years and least i.e., 4 (6.67%) were in the age group of 18-20years. 40 (66.67%) patients were males and the remaining 20 (33.33%) were females. The age of the youngest and the oldest patient was 18 years and 65 years respectively. The mean age of patients was 37.1 ± 13.10 years. The mean age of male and female patients were 36.4 ± 13.73 years and 38.7 ± 11.94 years respectively. In Mometasone & Formoterol group out of 60 patients, who were included majority i.e. 22(36.67%) were in the age group of 31-40 years, next highest i.e., 17(28.33%) in the age group of 21-30 years and least i.e. 2(3.33%) in the age group of 51-60 years. 20 (33.33%) were males and the remaining 40 (66.67%) patients were females. The age of the youngest and the oldest patient was 18 years and 63 years respectively. The mean age of patients was 35.3±11.00 years. The mean age of male and female patients were 37.4 ± 14.62 years and 34.3± 8.63 years respectively. (Table-1)

Out of 60 patients in Fluticasone & Formoterol group, 22(36.67%) were degree holders or graduates next highest i.e., 17(28.33%) had studied up to PUC and least i.e., 4(6.67%) each had studied up to primary school and postgraduates respectively. In Mometasone & Formoterol group 22(36.67%) had studied up to PUC next highest i.e., 16 (26.67%) had studied up to high school and least i.e., 3(5.00%) were postgraduates. (Table-1)

Majority in Fluticasone & Formoterol group i.e., 21 (35.00%) patients were self-employed, next highest i.e., 16 (26.67%) were housewives and least i.e., 4 (10.00%) were labourers. In Mometasone & Formoterol group majority i.e., 23 (38.33%) patients were housewives, next highest i.e., 13 (21.67%) were self-employed and least i.e., 4 (6.67%) were doing business. (Table-1)

Modified Kuppuswamy classification was adopted for socio-economic classification of patients.[6] Out of 60 patients in Fluticasone & Formoterol group, majority i.e., 18 (30.00%) were belonging to upper class, next highest i.e., 16 (26.67%) were belonging to lower middle class and least i.e., 6(10.00%) were belonging to upper lower class. In Mometasone & Formoterol group, majority i.e. 17(28.33%) were belonging to lower middle class, next highest i.e., 14(23.33%) each were belonging to upper middle & upper lower class respectively and least i.e.,2(3.33%) were belonging to lower class. (Table-1)

Table 1: Socio demographic profile of patients

Character	Grpup 1(n=60)	Group 2(n=60)
Age (in years)		
18-20	04(6.67)	06(10.00)
21-30	16(26.67)	17(28.33)
31-40	20(33.33)	22(36.67)
41-50	10(16.67)	10(16.67)
51-60	05(8.33)	02(03.33)
>61	05(8.33)	03(05.00)
Sex		
Male	40(66.67)	20(33.33)
Female	20(33.33)	40(66.67)
Education		
Primary	04(6.67)	06 (10.00)
High school	13(21.67)	16 (26.67)
PUC	17(28.33)	22 (36.67)
Graduate	22(36.67)	13 (21.67)
Post graduate	04(06.67)	03 (05.00)
Occupation		
Housewife	16(26.67)	23(38.33)
Professional	05(08.33)	07(11.67)
Business	06(10.00)	04(06.67)
Self-employed	21(35.00)	13(21.67)
Labourer	04(06.67)	07(11.67)
Unemployed/ retired/student	08(13.33)	06(10.00)
Socio-economic status (Class)		
Upper	18(30.00)	13(21.67)
Upper middle	12(20.00)	14(23.33)
Lower middle	16(26.67)	17(28.33)
Upper lower	06(10.00)	14(23.33)
Lower	08(13.33)	02(03.33)

Group 1: Fluticasone & Formoterol group; Group 2: Mometasone & Formoterol group; Figures in parenthesis indicate percentages)

Smoking history: Out of 60 patients in each Fluticasone & Formoterol and Mometasone & Formoterol group, 5(8.66%) were smokers in Fluticasone & Formoterol group and 6(10.00%)

were smokers in Mometasone & Formoterol group.

Table 2: Distribution of asthma patients according to their adverse drug reactions

Adverse drug reaction	Group 1 (n= 53)	Group 2(n=56)
Hoarseness of voice	3(27.27)	2(28.57)
Recurrent URTI	4(36.36)	2(28.57)
Cough	2(18.18)	1(14.29)
Headache	1(9.09)	-
Tremors	1(9.09)	-
Altered taste	-	1(14.29)
Vomiting	-	1(14.29)
Total	**11(100.00)**	**7(100.00)**

Group 1: Fluticasone & Formoterol group; Group 2: Mometasone & Formoterol group; Figures in parenthesis indicate percentages)

Table 3: Distribution of asthma patients according to their Spirometry parameters before and after medications

Parameters	Group 1	Group 2	t value	P Value
FVC (% predicted)				
Baseline	73.34 ± 15.62	71.66 ± 17.66	0.53	0.60
12-wks	83.74 ± 13.50	83.98 ± 12.33	0.10	0.92
% change	**14.2**	**17.2**	-	-
FEV_1 (% predicted)				
Baseline	62.77 ± 17.72	55.52 ± 17.08	2.18	0.03
12-wks	73.21 ± 16.74	73.61 ± 13.83	0.14	0.89
% change	**16.6**	**32.6**	-	-
FEV_1/FVC (% predicted)				
Baseline	88.26 ± 13.15	80.52 ± 16.83	2.67	0.01
12-wks	91.66 ± 13.31	90.89 ± 14.76	0.29	0.78
% change	**3.9**	**13.3**	-	-
FEF 25-75% (%predicted)				
Baseline	35.43 ± 17.45	28.98 ± 16.96	2.19	0.03
12-wks	45.43 ± 21.03	45.43 ± 21.03	0.44	0.67
% change	**29.7**	**56.8**	-	-
PEF (% predicted)				
Baseline	56.47 ± 20.33	50.25 ± 17.83	1.70	0.09
12-wks	71.93 ± 20.33	69.25 ± 19.40	0.70	0.48
% change	**27.4**	**37.8**	-	-

Group 1: Fluticasone & Formoterol group; Group 2: Mometasone & Formoterol group; Values expressed in Mean ± SD; * t value obtained using unpaired t-test

Assessment of safety: In the present study 11 were lost to follow-up, of which 7(11.67%) were in Fluticasone & Formoterol group and 4 (6.67%) in Mometasone & Formoterol group. Out of 53 patients in Fluticasone & Formoterol group, 11 developed adverse reactions. Out of them 4 developed recurrent URTI, 3 developed hoarseness of voice, 2 developed cough and one each developed headache and tremors respectively. Out of 56 in Mometasone & Formoterol group, 7 developed adverse reactions, out of them 2 each developed recurrent URTI & hoarseness of voice respectively, followed by one each had cough, altered taste and vomiting respectively. All the adverse reactions resolved itself without any medications. There were no any serious adverse reactions during the study period (Table 2). Adverse reactions were more among Fluticasone & Formoterol group 11(18.33%) compared to Mometasone & Formoterol group 7(11.67%). However the difference in adverse drug reaction was not statistically significant (Z= 1.05; P=0.29).

Assessment of efficacy based on Spirometry parameters: Spirometry was done with pre and post bronchodilator (Salbutamol nebulization). Improvement was assessed from baseline to end of 12 weeks following medications. There was significant improvement in Spirometry parameters within and between the group from baseline to end of 12 weeks in terms of FVC, FEV1, FEV1/FVC, FEF25-75%, PEF. Percentage change in Spirometry parameters in Fluticasone & Formoterol group after medications were FVC-14.2%, FEV1-16.6%, FEV1/FVC-3.9%, FEF25-75%-29.7%, PEF-27.4% where as percentage change in Mometasone & Formoterol group were FVC-17.2%, FEV1-32.6%, FEV1/FVC-13.3%, FEF25-75%-56.8% and PEF-37.8%.

The overall improvement in Spirometry parameters was better in Mometasone & Formoterol group compared to Fluticasone & Formoterol group. This difference in improvement of Spirometry parameters was not statistically significant suggesting both were equally efficacious. (Table 3)

Assessment of efficacy based on symptom control: In Fluticasone & Formoterol group with Greenhouse- Geisser correction there was significant difference in reduction of symptoms from baseline to end of 12 weeks i.e., Cough F1.54, 17.64 =33.66; Shortness of breath F1.68, 10.81=78.70; Tightness of chest F1.52,19.35=55.10; P=0.001. Similarly in Mometasone & Formoterol group with Greenhouse- Geisser correction, there was a significant difference in reduction of symptoms from baseline to end of 12 weeks i.e., Cough F1.46, 24.58=63.29, Shortness of breath F1.51, 20.97=62.56, Tightness of chest F1.54,18.88=18.42; P=0.001 . But the reduction in symptoms was not statistically significant from baseline to end of 12 weeks between Fluticasone & Formoterol and Mometasone & Formoterol

groups suggesting both are equally efficacious. (Table 4)

Table 4: Distribution of asthma patients according to their symptom before and after medications

Symptom score	Baseline	6-wks	12-wks	Greenhouse Geisser value	P-value
Fluticasone & Formoterol group (n=53)					
Cough	2.32 ± 0.91	1.81 ± 0.79	1.30 ± 1.01	33.66	0.001
Shortness of breath	2.47 ± 0.54	1.51 ± 0.69	1.13 ± 0.96	78.70	0.001
Tightness in chest	2.15 ± 0.93	1.21 ± 0.72	1.09 ± 0.77	55.10	0.001
Total Score	7.02 ± 1.38	4.60 ± 1.73	3.58 ± 2.38	86.46	0.001
Mometasone & Formoterol group (n=56)					
Cough	2.61 ± 0.62	1.80 ± 0.52	1.36 ± 0.84	63.29	0.001
Shortness of breath	2.18 ± 0.88	1.16 ± 0.78	0.79 ± 0.99	62.56	0.001
Tightness in chest	2.16 ± 0.97	1.29 ± 0.56	1.23 ± 1.26	18.42	0.001
Total Score	6.93 ± 1.77	4.25 ± 1.38	2.84 ± 1.81	123.75	0.001

(Values expressed in Mean ± SD); #0 = no symptoms; 1 = symptoms, but not affecting any activities during day/sleep at night.; 2 = symptoms affecting at least one activity or disturbing sleep; 3 = symptoms affecting >2 daily activities or disturbing sleep all night or most on the night.

Table 5: Distribution of asthma patients on symptom free in a week after medications

Symptom control	Baseline	6-wks	12-wks	Greenhouse-Geisser value	P-value
Fluticasone & Formoterol group(n=53)					
Symptom free days in a week	1.60±1.63	3.81±2.19	4.49±2.39	69.30	0.001
Symptom free nights in a week	2.04±2.14	3.75±2.35	4.55±2.35	47.18	0.001
Mometasone & Formoterol group(n=56)					
Symptom free days in a week	1.68±1.91	4.54±1.57	5.50±1.58	136.9	0.001
Symptom free nights in a week	1.54±1.79	4.60±1.74	5.59±1.89	149.2	0.001

Table 6: Comparison on symptom free in a week between the groups at the end of 12 weeks

Symptom control	Group 1 (n=53)	Group 2 (n=56)	t- value	P- value
Symptom free days in a week	4.49 ± 2.39	5.50 ± 1.58	2.62	0.002
Symptom free nights in a week	4.55 ± 2.35	5.59 ± 1.89	2.55	0.11

Group 1: Fluticasone & Formoterol group; Group 2: Mometasone & Formoterol group; Values expressed in Mean ± SD; * t value obtained using unpaired t-test

With Greenhouse-Geisser correction there was a significant improvement in symptom free days (F1.61, 14.1=69.29; P=0.001) and symptom free nights in a week (F1.51, 19.73=47.18; P=0.001) from baseline to end of 12 weeks in Fluticasone & Formoterol group. Similarly in Mometasone & Formoterol group with Greenhouse-Geisser correction there was a significant improvement from baseline to end of 12 weeks in symptom free days (F1.39,30.44=136.9; P=0.001) and symptom free night in a week (F1.44, 25.25=149.2; P=0.001) (Table 5).

When the improvement of symptom free days and symptom free nights in a week was compared at the end of 12 weeks between the group, there was significant difference in improvement in symptom free days in a week (P=0.002) whereas there was no significant difference in improvement of symptom free nights in a week (P=0.11).(Table 6)

Usage of rescue medications: In Fluticasone & Formoterol group out of 60 patients, 12 were on rescue medications (inhaled Salbutamol) of which 7 were on 100 micrograms and 5 were on 200 micrograms of inhaled Salbutamol. At the end of 12 weeks following medications only 8 required the rescue medications of which 5 used 100 micrograms and 3 used 200 micrograms of inhaled Salbutamol. In Mometasone & Formoterol group out of 60 patients, 10 were on rescue medications (inhaled Salbutamol) of which 6 were on 200 micrograms and 4 were on 100 micrograms of inhaled Salbutamol. At the end of 12 weeks following medications only 2 required the 100 micrograms of inhaled Salbutamol.

DISCUSSION

Only few studies are available to compare the safety, efficacy of Mometasone & Formoterol in the treatment of mild to moderate persistent asthma compared to other combinations.

In the present Randomized, open label comparative study 120 mild and moderate persistent bronchial asthma patients aged between 18 and 65 years were recruited which differs from the study conducted by David I Bernstein et al[7] in a multicentre, 12 week, open label, evaluator-blinded, active-controlled trial to find the efficacy and onset of action of Mometasone & Formoterol versus Fluticasone & Salmeterol combination treatment in 722 subjects between 12-80 years with persistent asthma were included.

In the present study among 60 patients, who were included in Mometasone & Formoterol group. Majority i.e., 22 (36.67%) were in the age group of 31-40 years, next highest i.e., 17(28.33%) in the age group of 21-30 years and least i.e. 2(3.33%) in the age group of 51-60 years. 20 (33.33%) were males and the remaining 40 (66.67%) patients were females. The age of the youngest and the oldest patient was 18 years and 63 years respectively. The mean age of patients was 35.3±11years. The mean age of male and female patients were 37.4 ± 14.6 years and 34.3± 8.6 years respectively which is differs from study conducted by David I Bernstein et al[7] where the mean age of the patients was 44.8 years (range 12–82 years) in Mometasone & Formoterol group (n=371). Of these, 239(64.4%) were females.

In the present study out of 53 patients in Fluticasone & Formoterol group, 11 developed adverse reactions. Out of them 4 developed recurrent URTI, 3 developed hoarseness of voice, 2 developed cough and one each developed headache and tremors respectively. Out of 56 patients, in Mometasone & Formoterol group, 7 developed adverse reactions, out of them 2 each developed recurrent URTI & hoarseness of voice respectively, followed by one each had cough, altered taste and vomiting respectively, which differs from study conducted by David I Bernstein et al[7] where the adverse events were similar in both the groups. Out of 371 patients in Mometasone & Formoterol group, 29 (7.8%) developed adverse reactions. Out of them 6 (1.6%) developed dysphonia, 4(1.1%) had oropharyngeal pain, 3(0.8%) had headache, 2(0.5%) developed oropharyngeal candidiasis. Only 1 serious adverse event ventricular extrasystoles which was considered probably due to the medications. In Fluticasone & Salmeterol group out of 351patients, 29(8.3%) developed adverse reactions. Out of them 10(2.8%) developed dysphonia, 3(0.9%) had headache, 2 (0.6%) each developed oropharyngeal pain and oropharyngeal candidiasis.

In the present study there was significant improvement in Spirometry parameters from baseline to end of 12 weeks in both the groups in terms of (FVC, FEV1, FEV1/FVC, FEF25-75%, PEF) this improvement was statistically significant. Percentage change in Spirometry parameters in Fluticasone & Formoterol group after medications were FVC-14.2%, FEV1-16.6%, FEV1/FVC-3.9%, FEF25-75%-29.7%, PEF-27.4% and percentage change in Mometasone & Formoterol group were FVC-17.2%, FEV1-32.6%, FEV1/FVC-13.3%, FEF25-75%- 56.8% and PEF-37.8%. The overall improvement in Spirometry parameters was better in Mometasone & Formoterol group compared to Fluticasone & Formoterol which was not statistically significant these findings are similar to the findings of the study conducted David I Bernstein et al[7] where the percentage change in FEV1 from baseline (73.8%) to the end of 12 weeks was 12.7% for Mometasone & Formoterol group and the percentage change in from baseline (74.4%) to the end of 12 weeks was 12.1% in Fluticasone & Salmeterol group. The percentage change in PEF from baseline to the end of 12 weeks for Mometasone & Formoterol group was 6.9 % and the percentage change from baseline to the end of 12 weeks in Fluticasone & Salmeterol group was 7.9%. There was no significant difference between the groups at the end of 12-weeks.

In the present study the improvement in symptom free days and nights in a week was statistically significant from baseline to the end of 12 weeks in both the group suggesting both were equally efficacious, which is similar to the study conducted by David I Bernstein et al[7] where Mometasone & Formoterol was found to be non inferior to Fluticasone & Salmeterol DPI in the proportion of symptom-free days and nights; both treatment groups demonstrated improvements from baseline.

CONCLUSION

Both Formoterol & Mometasone and Formoterol & Fluticasone combinations were safe and equally efficacious in control of symptoms and were effective in reducing the dose of rescue medica-

tions among patients with mild to moderate persistent asthma.

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