



Research Article

EFFICACY OF INHALED CORTICOSTEROID ‘MOMETASONE FUROATE (DPI) ALONE OR COMBINED WITH LONG ACTING BETA 2 AGONIST FORMETEROL (DPI) IN TREATMENT OF CHRONIC ASTHMA.

C. DEEPA LATHA, NARAYAN DESHPANDE

Assistant professor, Department of Pharmacology, Bhaskar Medical College, Yenkapally (V), Moinabad Mandal, R.R Dist, Professor & Head of Department, Department of Pharmacology, Bhaskar Medical College, Yenkapally (V), Moinabad Mandal, R.R Dist.

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ABSTRACT

An open label randomized comparative trial was carried out to assess the efficacy of corticosteroid Mometasone in dry powder inhaler form (dose of 400mcg) given once daily along with Formeterol a long acting beta-2 agonist (Dose -6mcg) in dry powder inhaler form given twice daily as compared to Mometasone 400mcg along with formeterol 6mcg given twice daily. This study shows that patients with 400mcg of mometasone given once daily have better control of asthma symptoms when compared to patients given twice daily. Patients are more benefited from low dose inhaled corticosteroid.

Keywords: DPI –Dry powder inhaler, MF- Mometasone furoate, PEF –Peak expiratory flow, FEV – Forced expiratory volume GINA- Global & international assessment score of asthma.

INTRODUCTION

Asthma is a chronic inflammatory disorder of the airways in which many cells and cellular elements play a role. The chronic inflammation is associated with airway hyper responsiveness that leads to recurrent episodes of wheezing, breathlessness, chest tightness and cough. These episodes are reversible with treatment. Inhaled corticosteroids are recommended as initial therapy in asthma patients. We investigated clinical efficacy of monotherapy with dry powder Inhaler corticosteroid (MF-DPI) and combined therapy with dry powder inhaler (DPI) long acting beta 2 agonist Formeterol in moderate persistent chronic asthma patients.

Formeterol is a long acting Beta -2 agonist having high lipid solubility. It has fast onset & long duration of action when compared to other beta -2 agonists.

Uses- Chronic asthma., COPD

Contra indicated - Acute bronchial asthma, Patients with liver impairment, Patients with renal impairment.

Drug interactions- Ritonavir & ketoconazole, MAO inhibitors, Tricyclic antidepressants, Drugs which prolong QT interval are not to be used.

METHODS

Ninety-five asthma patients of age group above 12 years according to GINA classification of clinical symptoms were enrolled in open label placebo Controlled study. Previously patients were on stable Inhaled corticosteroids BID for at least 30 days with FEV1 between 50%-85% of predicted value.

GINA Classification			
	Symptoms/Day	Symptoms/Night	PEF or FEV ₁ PEF variability
STEP 1 Intermittent	< 1 time a week Asymptomatic and normal PEF between attacks	≤ 2 times a month	≥ 80% ----- < 20%
STEP 2 Mild Persistent	> 1 time a week but < 1 time a day Attacks may affect activity	> 2 times a month	≥ 80% ----- 20-30%
STEP 3 Moderate Persistent	Daily Attacks affect activity	> 1 time a week	60%-80% ----- > 30%
STEP 4 Severe Persistent	Continuous Limited physical activity	Frequent	≤ 60% ----- > 30%

Patients were selected from out patient department of Rural Health centre of Bhaskar General Hospital, Moinabad.

Group- 1 Received only inhaled Mometasone furoate (MF-DPI) /day (400mcg) (n=25).

Group- 2 Received inhaled (MF-DPI) 400mcg/day & dry powder inhaler Formeterol 6 mcg BID (n=25).

Group- 3 Received inhaled (MF-DPI) (800mcg) 400mcg BID & dry powder inhaler Formeterol 6mcg BID (n=25).

Group- 4 received only placebo (n=20).

- Efficacy was assessed on the basis of total asthma symptom scores,
- Asthma control was assessed by changes in FEV1, PEFR.
- Validated 5-item Asthma Control test (ACT), patient/physician global assessments.

Patients were in the study for a period of 4 weeks.

Patients attended the OPD on first day (baseline readings were taken) then at the end of second week & at the end of fourth week.

On three study days, baseline forced expiratory volume in one second (FEV₁) was recorded immediately thereafter, the study drugs were inhaled and lung function was assessed for 60 min.

RESULTS

1) There were significant changes in FEV₁ from baseline to end of the treatment, with mean change of >0.15L increase in group 2 & 3

2) There was also a significant increase in mean PEFR by >10L/min from baseline to end of treatment in group 2 & 3. Group 1, 2 & 3 had better results compared to the placebo group. Significant improvement in total asthma symptom scores was first evident at the end of the 4th week in group-2 (p<0.05).

Wheezing was decreased by 64%,

cough decreased by 42%,

breathing difficulty decreased by 42%,

& nocturnal awakenings by 77%.

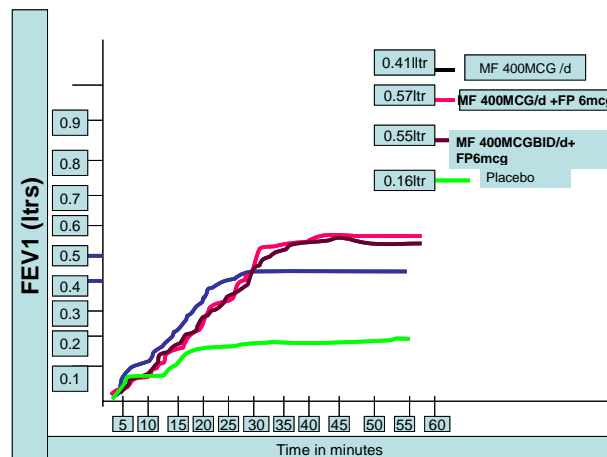
Quality of life scores were significantly better in group-2

When compared to those in group-1 (p<0.05).

Group 3 has not shown greater improvement than group -2.

This suggests that patients benefit more from low dose ICS.¹

Better PEFR, reduced use of rescue medication and an increased no of episode-free days



Graphical representation of FEV₁ against time in minutes at various doses of Mometasone and Formeterol,

1) 81% improvement of symptoms were seen in group 2 in physician assessment score.

2) 79% improvement is seen in group 2 in patient assessment score.

CONCLUSION

Our study has found that once daily administration of 400mcg Mometasone Rheocaps & twice daily formeterol 6mcg rheocaps, significantly improved asthma symptoms & lung function in patients with moderately severe asthma.³

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