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# MODERATE PERSISTENT ASTHMA IN CHILDREN;
## COMPARISON OF INHALED BECLOMETHASONE WITH ORAL MONTELUKAST IN THE MANAGEMENT

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**ABSTRACT…. Objective:** The objective of this study is to compare the effects of inhaled beclomethasone with oral montelukast in long term management of moderate persistent asthma in children. **Design:** Quasi experimental study. **Period:** 6 months, from July 20,2007 to January 20, 2008. **Settings:** Out patient paediatric department at Fauji Foundation hospital, Rawalpindi. **Material and Methods:** 8o children between 5-12yrs of age presenting with moderate persistent asthma, divided in two groups of 40 each. Group A treated with beclomethasone inhaler while Group B was started on oral montelukast. Drugs effect was recorded on a 2 wkly proforma for 8 weeks. **Results:** There were 54(67.5%) male and 26(33%) female. Most common triggering factor seen in 54(67.5%) patients was recent history of respiratory tract infection, exposure to carpet dust in 43(53.75%), cigarette smoke in 42(52.5%),recent psychological stress in 28(35%) , pollen allergy in 26 (32.5%) , pets exposure in 8 (10%) and to mite was noticed in 5(6.25%) children. Marked improvement was observed in day time cough in group A with 10(25%) patients being free of cough with inhaler, while 20(50%) showed mild intermittent symptoms. 1(2.5%) showed mild persistent symptoms. In Group B 3(7.5%) patients were symptom free, 23(57.5%)with mild intermittent and 4(10%) with mild persistant symptoms while 6(15%) continued to have moderate persistent symptoms. P value was 0.01. Regarding day time breathlessness, P value was significant of 0.258. Similarly marked improvement was observed in night symptoms of breathlessness, cough and sleeplessness in both groups. P value was less than 0.05 in majority of the variables showing statistically significant improvement with inhaled beclomethasone than with oral montelukast. **Conclusions:** Inhaled beclomethasone is superior to oral montelukast in controlling chronic symptoms of childhood asthma.

**Key words:** Moderate persistent asthma, inhaled beclomethasone, montelukast

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## INTRODUCTION

Asthma is a chronic inflammatory condition of the lung airways resulting in episodic airflow obstruction[1]. It is a major public health problem, affecting over a hundred million people worldwide. Incidence of asthma is rising all over the world, especially in children[2]. Major contributors to increased prevalence are genetic predisposition, urbanization, air pollution, pollen and tobacco smoke[3]. In Pakistan almost 10 million people are affected[4]. About 4% children attending the outpatient department suffer from bronchial asthma[2]. Asthma prevalence has reached 19% during the last decade and studies showed an annual 9% increase in the number of such cases in Pakistan[4]. Clinical manifestations of asthma are intermittent. Dry coughing, expiratory wheezing, chest tightness and dyspnea are provoked by physical exertion and air way irritants. (cold and dry air, smoke)[1].

Asthma is classified as mild, moderate and severe by intensity. Moderate persistent asthma is labeled when the patient has daily day symptoms requiring short acting beta agonist and has more than 1 episode per week of night symptoms[1]. Clinical practice guidelines from National Asthma Education and Prevention Program (NAEPP) and

Global Initiative for Asthma (GINA) recommend inhaled steroids as first line therapy because of their broad anti- inflammatory properties. Alternatively other non-steroidal agents have been introduced including leukotriene modifiers and long acting beta-2 agonists[1,5].

The comparison of ICS and anti leukotrienes has not been done in Pakistani asthmatic children. The aim of this study is to compare the effect of inhaled beclomethasone with oral montelukast in children between 5-12 years of age suffering from moderate persistent asthma. It will help to improve the long term management and quality of life of asthmatic children.

## MATERIAL AND METHODS

This Quasi experimental study was conducted on 80 patients in outpatient paediatric department at Fauji Foundation hospital, Rawalpindi over the period of six months from July 2007 to January 2008. Children included in this study between 5-12 years of age with moderate persistent asthma after taking verbal consent from the parents. Children with chronic lung disease like cystic fibrosis, emphysema, tuberculosis, pulmonary hypertension and with congenital heart disease were excluded.

After taking permission from ethical committee and informed consent from the parents or guardians, history regarding daily day and more than one episode of night symptoms every week was taken. Recent episode of upper respiratory tract infection, stress, exposure to smoke, pets, carpet dust, mites, pollen and dyspnea on exertion. Each patient assigned with serial number. Patients with odd serial numbers (group A) were treated with inhaled beclomethasone 2-4puffs/day while even numbers(group B) were treated with oral montelukast 5mg at night for 8 weeks. Both groups were followed at 2 weekly intervals on day 14,28,42 and 56. Reduction in severity and frequency of acute attack at day and night and PEFR was recorded on study proforma.

SPSS version 12 was used for data analysis. Frequencies and percentages were calculated of demographic characteristics of the patients and also of the triggering factor. Student t-test was applied to show the significance of difference in the effect of two drugs. Level of significance was 0.05.

## RESULTS

Total 80 patients with moderate persistent asthma were included. 40 in each group i-e inhaled beclomethasone(Group A) and oral montelukast (Group B). 11(13.75%) patients were lost to follow up.

There were 54(67%) male and 26(33%) female (M:f=2.07:1) (Figure1).

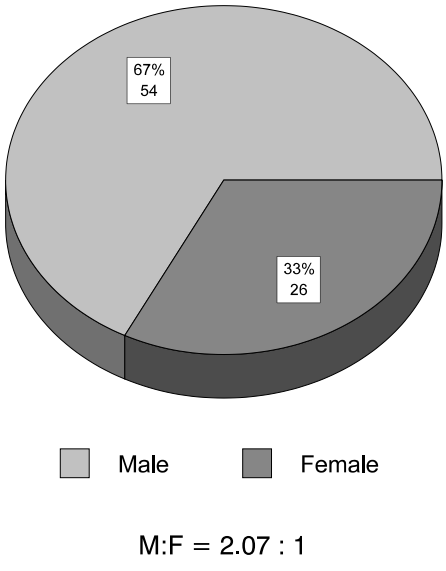


**Fig-1. Sex distribution of children (n=80)**

Average age of children in group A was 8.5±2.2 years. In group B it was 7.43±2.3 years (Figure2) Over all mean age was 7.98±2.3 years (Range=5-12years).

The most common triggering factor seen in 54(67.5%) patients was recent history of respiratory tract infection. Exposure to carpet dust in 43(53.75%) and was the second most common cause, smoke in 42(52.5%), physiological stress recently in 28(35%), pollen allergy in 26(32.5%), exposure to pets in 8(10%) and mite in 5 (6.25%) children were noticed. (Table-I)

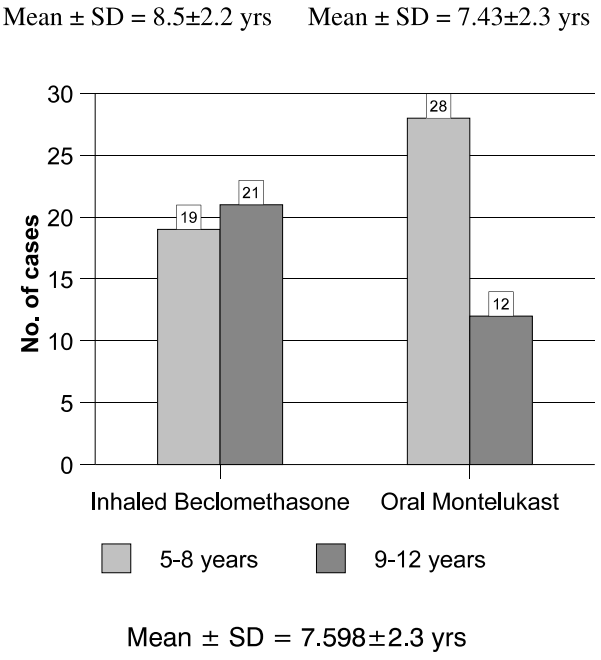


**Fig-2. Age distribution of children (n=80)**

| History | No. of patients | Percents * |
|---|---|---|
| Recent Respiratory Tract Infection | 54 | 67.5 |
| Exposure to Carpet Dust | 43 | 53.75 |
| Exposure to Cigarette Smoke | 42 | 52.5 |
| Recent Psychological Stress | 28 | 35 |
| Pollens | 26 | 32.5 |
| Exposure to Pets | 8 | 10 |
| Exposure to Mites | 5 | 6.25 |

**Table-I. History of Patients (n=80)**

**Multiple Response Exist (Each of eighty)*

Comparative study of improvement in day symptoms of cough, breathlessness and night symptoms of cough, breathlessness and sleeplessness, PEFR and frequency of acute attack after starting both drugs was recorded for total eight weeks at two weekly intervals.

Marked improvement was observed in day time cough in Group A with 10(25%) patients free of cough with beclomethasone, while 20(50%) had mild intermittent symptoms and 1 (2.5%) showed mild persistent symptoms. 7(17.5%) were lost to follow up. Similarly in oral montelukast group, 3 (7.5%) patients were symptom free, 23 (57.5%) with mild intermittent, 4(10%) with mild persistent symptoms while 6(15%) still reported with moderate persistent symptoms. There was significant difference; Mean±SD was 1.85±0.76 in Group A and 2.36± 0.87 in Group B, p value being 0.01(Table-II).

Regarding day time breathlessness, at the end of eight weeks, 26(65%) in Group A were symptom free, 5(12.5%) had mild intermittent and 1 (2.5%) had mild persistent symptoms. In Group B, 15 (37.5%) were symptom free, 13(32.5%) had mild intermittent, 4 (10%) had mild persistent and 4(10%) had moderate persistent symptoms. Mean symptom score was 1.97±0.79 in group A and 2.5±0.9 in group B respectively with significant p value of 0.258(Table-III).

Improvement in night symptoms (cough, breathlessness, sleeplessness) was observed in both groups. 17(42.5%) were cough free at night , 13 (32.5%) had mild intermittent and 1(2.5%) had mild persistent symptoms in Group A. In Group B, 7(17.5%) had no symptoms, 16 (40%) continued with mild intermittent and 6(15%) with mild persistent symptoms. 7 (17.5%) showed no improvement. Mean ±SD was 1.6±0.82 and 2.4±1.01 in group A and B respectively with significant p value of 0.002 (Table-IV).

30 (75%) in group A had no breathlessness at night while 2(5%) retained moderate persistent symptoms. Mean symptom score was 1.9±1.13,p value=0.003 (Table-V).

| Drugs | | | | |
|---|---|---|---|---|
| **Days** | **Frequency** | **Inhaled Beclomethasone N = 40** | **Oral Montelukast n = 40** | **P-Values** |
| 1 | Mean ± SD = | 3.98 ± 0.16* | 3.98 ± 0.16* | 1 |
| | <3 times/week | 0 | 0 | |
| | >3 times/week | 1 (2.5) | 1 (2.5) | |
| | Daily | 39 (97.5) | 39 (97.5) | |
| | lost | 0 | 0 | |
| 14 | Meant ± SD = | 3.08 ± 0.67 | 3.19 ± 0.62 | 0.449 |
| | <3 times/week | 8 (20) | 4 (10) | |
| | >3 times/week | 21 (52.5) | 22 (55) | |
| | Daily | 11 (27.5) | 11 (27.5) | |
| | lost | 0 | 3 (7.5) | |
| 28 | Mean ± SD = | 2.5 + 0.69 | 2.7+ 0.78 | 0.235 |
| | <3 times/week | 23 (57.5) | 18 (45) | |
| | >3 times/week | 11 (27.5) | 12 (30) | |
| | Daily | 4 (10) | 7 (17.5) | |
| | lost | 2 (5) | 3 (7.5) | |
| 42 | Mean ± SD = | 2.21 ± 0.65 | 2.44 ± 0.73 | 0.17 |
| | <3 times/week | 28 (70) | 23 (57.5) | |
| | >3 times/week | 2 (5) | 9 (22.5) | |
| | Daily | 3 (7.5) | 4 (10) | |
| | lost | 7 (17.5) | 4 (10) | |
| 56 | Mean ± SD = | 1.85 ± 0.76 | 2.36 ± 0.87 | 0.01 |
| | nil | 10 (25) | 3 (7.5) | |
| | <3 times/week | 20 (50) | 23 (57.5) | |
| | >3 times/week | 1 (2.5) | 4 (10) | |
| | Daily | 2 (5) | 6 (15) | |
| | lost | 7 (17.5) | 4 (10) | |

**Table-II. Comparison Of Day Time Cough Between Inhaled Beclomethasone And Oral Montelukast (n=80)**

**Day time cough score, average of the responses of scale 1-4***
***1= Nil (no cough), 2= (<3time/week), 3= (>3time/week), 4=Daily, (Nil = No Cough)*

| Drugs | | | | |
|---|---|---|---|---|
| **Days** | **Frequency** | **Inhaled Beclomethasone** | **Oral Montelukast** | **P-Values** |
| 1 | Mean ± SD = | 3.4 ± 1.13* | 3.73 ± 0.78* | 0.139 |
| | nil | 6 (15) | 2 (5) | |
| | <3 times/week | 2 (5) | 2 (5) | |
| | >3 times/week | 2 (5) | 1 (2.5) | |
| | Daily | 30 (75) | 35 (87.5) | |
| | lost | 0 | 0 | |
| 14 | Mean ± SD = | 2.65 ± 0.89 | 3.86 ± 0.75 | 0.000 |
| | nil | 6 (15) | 2 (5) | |
| | <3 times/week | 7 (17.5) | 7 (17.5) | |
| | >3 times/week | 22 (55) | 22 (55) | |
| | Daily | 5 (12.5) | 6 (15) | |
| | lost | 0 | 3 (7.5) | |
| 28 | Mean ± SD = | 2.5 ± 0.79 | 2.7 ± 0.78 | 0.258 |
| | nil | 10 (25) | 3 (7.5) | |
| | <3 times/week | 21 (52.5) | 19 (47.5) | |
| | >3 times/week | 5 (12.5) | 8 (20) | |
| | Daily | 2 (5) | 7 (17.5) | |
| | lost | 2 (5) | 3 (7.5) | |
| 42 | Mean ± SD = | 1.7 ± 0.9 | 2.2 ± 0.9 | 0.015 |
| | nil | 18 (45) | 8 (20) | |
| | <3 times/week | 11 (27.5) | 18 (45) | |
| | >3 times/week | 2 (5) | 6 (15) | |
| | Daily | 3 (7.5) | 4 (10) | |
| | lost | 6 (15) | 4 (10) | |
| 56 | Mean ± SD = | 1.4 ± 0.8 | 1.9 ± 1 | 0.017 |
| | nil | 26 (65) | 15 (37.5) | |
| | <3 times/week | 5 (12.5) | 13 (32.5) | |
| | >3 times/week | 1 (2.5) | 4 (10) | |
| | Daily | 2 (5) | 4 (10) | |
| | lost | 6 (15) | 4 (10) | |

**Table-III. Comparison Of Day Time Breathlessness Between Inhaled Beclomethasone And Oral Montelukast (n = 80)**

**Day time Breathlessness score, average of the responses of scale 1-4**.*
***1= Nil (no Breathlessness), 2(<3time/week), 3=(> 3time/week), 4= Daily*

| Drugs | | | | |
|---|---|---|---|---|
| **Days** | **Frequency** | **Inhaled Beclomethasone** | **Oral Montelukast** | **P-Values** |
| 1 | Mean ± SD = | 4 ± 0* | 3.95± 0.316* | 0.32 |
| | nil | 0 | 0 | |
| | <3 times/Month | 0 | 1 (2.5) | |
| | >3 times/Month | 0 | 0 | |
| | >1 times/week | 40 | 39 (97.5) | |
| | lost | 0 | 0 | |
| 14 | Mean ± SD = | 3.3 ± 0.607 | 3.2 ± 0.58 | 0.54 |
| | nil | 0 | 0 | |
| | <3 times/Month | 3 (7.5) | 3 (7.5) | |
| | >3 times/Month | 22 (55) | 23 (57.5) | |
| | >1 times/week | 15 (37.5) | 11 (27.5) | |
| | lost | 0 | 3 (7.5) | |
| 28 | Mean ± SD = | 2.5 ± 0.76 | 2.73 ± 0.84 | 0.22 |
| | nil | 2 (5) | 0 | |
| | <3 times/Month | 19 (47.5) | 19 (47.5) | |
| | >3 times/Month | 13 (32.5) | 9 (22.5) | |
| | >1 times/week | 4 (10) | 9 (22.5) | |
| | Lost | 2 (5) | 3 (7.5) | |
| 42 | Mean ± SD = | 2.00 ± 0.707 | 2.4 ± 0.88 | 0.016 |
| | nil | 6 (15) | 3 (7.5) | |
| | <3 times/Month | 23 (57.5) | 19 (47.5) | |
| | >3 times/Month | 2 (5) | 8 (20) | |
| | >1 times/week | 2 (5) | 6 (15) | |
| | lost | 7 (17.5) | 4 (10) | |
| 56 | Mean ± SD = | 1.6 ± 0.82 | 2.4 ± 1.01 | 0.002 |
| | nil | 17 (42.5) | 7 (17.5) | |
| | <3 times/Month | 13 (32.5) | 16 (40) | |
| | >3 times/Month | 1 (2.5) | 6 (15) | |
| | >1 times/week | 2 (5) | 7 (17.5) | |
| | lost | 7 (17.5) | 4 (10) | |

**Table-IV. Comparison Of Night Time Cough Between Inhaled Beclomethasone And Oral Montelukast (n=80)**

**Night time cough score, Average of the Responses of Scale 1-4**.*
***1= Nil (no cough), 2=(<2time/Month), 3=(> 2time/Month), 4= (> time/Week)*

| Drugs | | | | |
|---|---|---|---|---|
| **Days** | **Frequency** | **Inhaled Beclomethasone** | **Oral Montelukast** | **P-Values** |
| 1 | Mean ± SD = | 2.9 ± 1.4* | 3.7 ± .85* | 0.003 |
| | nil | 12 (30) | 3 (7.5) | |
| | <3 times/Month | 3 (7.5) | 1 (2.5) | |
| | >3 times/Month | 1 (2.5) | 0 | |
| | >1 times/week | 12 (60) | 36 (90) | |
| | lost | 0 | 0 | |
| 14 | Mean ± SD = | 2.3 ± 1.03 | 2.8 ± .87 | 0.012 |
| | nil | 13 (32.5) | 4 (10) | |
| | <3 times/Month | 7 (17.5) | 5 (12.5) | |
| | >3 times/Month | 16 (40) | 21 (52.5) | |
| | >1 times/week | 4 (40) | 7 (17.5) | |
| | lost | 0 | 3 (7.5) | |
| 28 | Mean ± SD = | 1.7 ± 0.80 | 2.4 ± 1.01 | 0.002 |
| | nil | 18 (45) | 7 (17.5) | |
| | <3 times/Month | 14 (35) | 15 (37.5) | |
| | >3 times/Month | 5 (12.5) | 8 (20) | |
| | >1 times/week | 1 (2.5) | 7 (17.5) | |
| | Lost | 2 (5) | 3 (7.5) | |
| 42 | Mean ± SD = | 1.3 ± 0.68 | 1.97 ± 1.08 | 0.003 |
| | nil | 26 (65) | 16 (40) | |
| | <3 times/Month | 5 (12.5) | 10 (25) | |
| | >3 times/Month | 1 (2.5) | 5 (12.5) | |
| | >1 times/week | 1 (2.5) | 5 (12.5) | |
| | lost | 7 (17.5) | 4 (10) | |
| 56 | Mean ± SD = | 1.2 ± 0.74 | 1.9 ± 1.13 | 0.003 |
| | nil | 30 (75) | 19 (47.5) | |
| | <3 times/Month | 1 (2.5) | 6 (15) | |
| | >3 times/Month | 0 | 6 (15) | |
| | >1 times/week | 2 (5) | 5 (12.5) | |
| | lost | 7 (17.5) | 4 (10) | |

**Table-V. Comparison Of Night Time Breathlessness Between Inhald Beclomethasone And Oral Montelukast (n=80)**

**Night time Breathlessness score, average of the responses of scale 1-4**.*
***1= Nil (no cough), 2=(<2time/Month), 3=(> 2time/Month), 4= (> time/Week)*

| Drugs | | | | |
|---|---|---|---|---|
| **Days** | **Frequency** | **Inhaled Beclomethasone (n=40)** | **Oral Montelukast (n=40)** | **P-Values** |
| 1 | Mean ± SD = | 3.35 ± 1.14 | 3.8 ± 0.72* | 0.039 |
| | nil | 6 (15) | 2 (5) | |
| | <3 times/Month | 3 (7.5) | 1 (2.5) | |
| | >3 times/Moth | 2 (5) | 0 | |
| | >1 times/week | 29 (72.5) | 37 (92.5) | |
| | lost | 0 | 0 | |
| 14 | Mean ± SD = | 2.6 ± 1.03 | 2.97± .83 | 0.081 |
| | nil | 8 (20) | 3 (7.5) | |
| | <3 times/Month | 8(20) | 4 (10) | |
| | >3 times/Month | 16 (40) | 21 (52.5) | |
| | >1 times/week | 8 (20) | 9 (22.5) | |
| | lost | 0 | 3 (7.5) | |
| 28 | Mean ± SD = | 1.82 ± 0.80 | 2.51± 0.99 | 0.001 |
| | nil | 15 (37.5) | 5 (12.5) | |
| | <3 times/Month | 16 (40) | 16 (40) | |
| | >3 times/Month | 6 (15) | 8 (20) | |
| | >1 times/week | 1 (2.5) | 8 (20) | |
| | Lost | 2 (5) | 3 (7.5) | |
| 42 | Mean ± SD = | 1.45 ± 0.83 | 2.06±1.09 | 0.013 |
| | nil | 23 (57.5) | 15 (37.5) | |
| | <3 times/Month | 7 (17.5) | 9 (22.5) | |
| | >3 times/Month | 1 (2.5) | 8 (20) | |
| | >1 times/week | 2 (2.5) | 8 (20) | |
| | lost | 7 (17.5) | 4 (10) | |
| 56 | Mean ± SD = | 1.3 ± 0.81 | 1.97± 1.13 | 0.006 |
| | nil | 28 (70) | 18 (45) | |
| | <3 times/Month | 2 (5) | 6 (15) | |
| | >3 times/Month | 1 (2.5) | 7 (17.5) | |
| | >1 times/week | 2 (5) | 5 (12.5) | |
| | lost | 7 (17.5) | 4 (10) | |

**Table-VI. Comparison Of Night Time Sleeplessness Between Inhaled Beclomethasone And Oral Montelukast (n=80)**

**Night time Sleeplessness score, average of the responses of scale 1-4**.*
***1= Nil (no cough), 2=(<2time/Month), 3=(> 2time/Month), 4= (> time/Week)*

Regarding night sleeplessness in group A 28(70%) were cured, 2(5%) had mild intermittent, 1 presented with mild persistent and 2(5%) with moderate persistent symptoms. Mean symptom score was 1.3±0.81. 18 (45%) had no symptoms in group B, 6(15%) had intermittent, 7 (17.5%) had mild persistent and 5(12.5%) continued to have moderate persistent symptoms. Mean score was 1.97±1.13. p value was 0.006 (Table-VI). In group A, acute attack was observed in 1(2.5%) case with mean score of 1.96±0.17. 3 (7.5%) cases in group B had acute attack and mean symptom score was 1.9±0.28.p value was 0.354(Table-VII).

29 (72.5%) children in group A showed improvement in PEFR, while 2 (5%) were unable to perform and 2(5%) showed a deterioration. Mean score was 1.3±0.84. In group B , 28(70%) had an improvement ,5(12.5%)were unable to perform and 3(7.5%) had deterioration. Mean score was 1.5±1.03 and p value =0.299( Table-VIII).

| Drugs | | | | |
|---|---|---|---|---|
| **Days** | **Frequency** | **Inhaled Beclomethasone (n=40)** | **Oral Montelukast (n=40)** | **P-Values** |
| 1 | Mean ± SD = | 2 ± 0.0 | 1.93 ± 0.267* | 0.083 |
| | Yes | 0 | 3 (7.5) | |
| | No | 40 | 37 (92.5) | |
| | lost | 0 | 0 | |
| 14 | Mean ± SD = | 2 ± 0.0 | 1.97 ± 1.16 | 0.871 |
| | Yes | 0 | 1 (2.5) | |
| | No | 40 | 36 (90) | |
| | lost | 0 | 3 (7.5) | |
| 28 | Mean ± SD = | 2 ± 0.0 | 1.89 ± 0.315 | 0.05 |
| | Yes | 0 | 4 (10) | |
| | No | 38 (95) | 33 (82.5) | |
| | lost | 2 (5) | 3 (7.5) | |
| 42 | Mean ± SD = | 1.96 ± 0.17 | 1.94 ± 0.23 | 0.609 |
| | Yes | 1 (2.5) | 2 (5) | |
| | No | 32 (80) | 34 (85) | |
| | lost | 7 (17.5) | 4 (10) | |
| 56 | Mean ± SD = | 1.96 ± 0.17 | 1.9 ± 0.28 | 0.354 |
| | Yes | 1 (2.5) | 3 (7.5) | |
| | No | 32 (80) | 33 (82.5) | |
| | lost | 7 (17.5) | 4 (10) | |

**Table-VII. Comparison Of Acute Attacks ! Between Inhaled Beclomethasone And Oral Montelukast (n=80)**

*! Acute Attack includes Shortness of Breath, Cough, Wheezing, and Chest Tightness.*
**Acute Attack symptoms Score was the average of the responses on a scale, 1 = yes and 2= No*

| Drugs | | | | |
|---|---|---|---|---|
| **Days** | **Frequency** | **Inhaled Beclomethasone (n=40)** | **Oral Montelukast (n=40)** | **P-Values** |
| 1 | Mean ± SD = | 2.18 ± 0.38* | 2.3 ± 0.51* | 0.0323 |
| | Improved | 0 | 0 | |
| | Able to perform | 33 (82.5) | 30 (75) | |
| | Unable to perform | 7 (17.5) | 9 (22.5) | |
| | Deteriorated | 0 | 1 (2.5) | |
| | lost | 0 | 0 | |
| 14 | Mean ± SD = | 1.4 ± 0.84 | 1.41 ± 0.86 | 0.978 |
| | Improved | 31 (77.5) | 29 (72.5) | |
| | Able to perform | 4 (10) | 3 (7.5) | |
| | Unable to perform | 3 (7.5) | 3 (7.5) | |
| | Deteriorated | 2 (5) | 2 (5) | |
| | lost | 0 | 3 (7.5) | |
| 28 | Mean ± SD = | 1.4 ± 1.03 | 1.5 ± 1.12 | 0.707 |
| | Improved | 31 (77.5) | 29 (72.5) | |
| | Able to perform | 0 | 0 | |
| | Unable to perform | 3 (7.5) | 3 (7.5) | |
| | Deteriorated | 4 (10) | 5 (12.5) | |
| | lost | 2 (5) | 3 (7.5) | |
| 42 | Mean ± SD = | 1.3 ± 0.84 | 1.53 ± 1.03 | 0.302 |
| | Improved | 29 (72.5) | 30 (75) | |
| | Able to perform | 0 | 0 | |
| | Unable to perform | 2 (5) | 3 (7.5) | |
| | Deteriorated | 3 (7.5) | 3 (7.5) | |
| | lost | 6 (15) | 4 (10) | |
| 56 | Mean ± SD = | 1.3 ± 0.84 | 1.5 ± 1.03 | 0.299 |
| | Improved | 29 (72.5) | 28 (70) | |
| | Able to perform | 0 | 0 | |
| | Unable to perform | 2 (5) | 5 (12.5) | |
| | Deteriorated | 2 (5) | 3 (7.5) | |
| | lost | 7 (17.5) | 4 (10) | |

**Table-VIII. Comparison Of Peak Expiratory Flow Rate Between Inhaled Beclomethasone And Oral Montelukast (n=80)**

**Average of the responses on scale 1 to 4**.*
***1= Improved, 2= Able to performe, 3= Unable to Perform, 4= Deteriorated*

## DISCUSSION

Asthma is a serious global health issue involving the people of all ages. Prevalence is increasing everywhere especially in children. Asthma is a significant burden, not only in terms of health care cost but also of lost productivity and reduced participation in family life.

Numerous clinical studies have shown that any asthma which is more than mild intermittent, is more effectively controlled by intervening to suppress and reverse the inflammation rather than by only treating bronchioconstriction and related symptoms[6,7,8].

Medications are used to reverse and prevent symptoms and air flow limitation and include controllers and relievers. Controllers are taken daily on long term basis that are useful in getting and keeping persistent asthma under control. These include anti inflammatory agents[9]. The latest modalities include inhaled glucocorticoids and leukotriene modifying agents.

Although the effectiveness of ICS is well established and different studies have also supported it[10,11]. But the effectiveness of Leukotriene modifiers is still under experimentation. In one study using montelukast (leukotriene modifiers) in children less than 14 has proven useful possibly because of significantly better compliance with oral route[10].

My study was carried out to record the improvement in chronic symptoms of asthma in response to inhaled beclomethasone and oral montelukast. There were few limitations in this study. It was done over 6 months from summer to winter, with difficulty to treat symptoms in winter. Drug delivery could not be directly observed so patient compliance and method of drug intake, which influence the symptom improvement, could not be ascertained. Some children were unable to perform PEFR properly despite repeated demonstrations of technique. A major limitation of the study was the subjective nature of the symptom observation which is influenced by the parental educational status, memory and IQ.

Although day time cough and breathlessness markedly improved in both groups. However, more patients were symptom free after taking inhaled beclomethasone ( p=0.01 and 0.017) showing a statistically significant superiority of beclomethasone over montelukast.

More improvement ( 42.5% and 75% respectively) than oral drug group ( 17.5% and 47.5% respectively) with a significant P value of 0.002 and 0.003 for night time cough and breathlessness respectively.

Ducharme has shown similar outcome with better improvement in night symptoms with beclomethasone[12].

The overall results refute the null hypothesis and thus support the alternate hypothesis i.e inhaled beclomethasone is more effective than montelukast.

Zsigmond G concluded that use of montelukast has reduced the usage of short acting B-2 agonist from 5 inhalations to 1 in 4 weeks[13]. In another study, Becker A, Swern A, Tozzi CA et al concluded that montelukast significantly improved FEV1 and peak expiratory flow(PEF) , reduced nocturnal awakenings and improved quality of life in children with mild persistent asthma[14]. Hakim F, Vilozni D, Adler A et al evidenced that four week therapy with montelukast resulted in a decreased bronchial hyperactivity in pre school children[15].

Similarly Zeidler MR, Kleerup EC,Goldin JG et al have shown improvement in distal airway disease detected with high resolution computed tomography in asthmatics treated with montelukast[16]. A study carried out in Karachi has also shown reduction in day night symptoms with mild persistent asthma[17].

Among the ICS, studies comparing fluticasone and montelukast show equal effectivity in mild to moderate asthma[18].

However studies comparing inhaled beclomethasone with oral montelukast have

shown variable results, where some studies have concluded that montelukast was as effective as Beclomethasone in controlling mild to moderate chronic asthma[19,20]. While other studies render antileukotrienes less effective than inhaled corticosteroids in chronic asthma and do not recommend their use as first line monotherapy in asthmatic patients[21,12].

## CONCLUSIONS

Inhaled beclomethasone is more effective than oral montelukast in controlling chronic symptoms of moderate persistent asthma and also significantly improve life quality in these patients.



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Unknown