ORIGINAL RESEARCH PAPER

Volume-9 | Issue-2 | February-2020 | PRINT ISSN No. 2277 - 8179 | DOI : 10.36106/ijsr

INTERNATIONAL JOURNAL OF SCIENTIFIC RESEARCH

COMPARATIVE STUDY OF FLUTICASONE PROPIONATE AND BECLOMETHASONE DIPROPIONATE IN PEDIATRIC PATIENTS OF BRONCHIAL ASTHMA

Pediatrics

Dr. Satyendra Paswan	Junior Resident, Department of Pediatrics, Darbhanga Medical College & Hospital, Laheriasarai, Bihar.
Dr. Nagendra Prasad Gupta*	Associate Professor, Department of Pediatrics, Darbhanga Medical College & Hospital, Laheriasarai, Bihar. *Corresponding Author
Dr. Shaantanu Kumar	Junior Resident, Department of Pediatrics, Darbhanga Medical College & Hospital, Laheriasarai, Bihar.
Dr. Krishna Kumar Jha	Assistant Professor, Department of Pediatrics, Darbhanga Medical College & Hospital, Laheriasarai, Bihar.
Dr. Nishant	Assistant Professor, Department of Pediatrics, Darbhanga Medical College & Hospital, Laheriasarai, Bihar.
Dr. Debarshi Jana	Young Scientist (DST), Department of Gynecology and Obstetrics, Institute of Post-Graduate Medical Education and Research, A.J.C. Bose Road, Kolkata-700020, West Bengal, India

ABSTRACT

The present study was done to compare the efficacy and adverse effects of two commonly prescribed inhaled corticosteroids beclomethasonedipropionate and fluticasone propionate in children with bronchial asthma.Present work were done in Department of Pediatrics, Darbhanga Medical College and Hospital, Laheriasaria.Total 120 patients were selected from outpatient and inpatient department of paediatrics and divided in 4 groups.Patients between 2-12 years of age were selected for study.Only diagnosed case of bronchial asthma after detailed history and clinical examination were included in the study.Conclusively this study showed that fluticasone propionate is as effective as, at half the dose of beclomethasonedipropionate in improving pulmonary function (FEV1 and PEFR). The adverse effect profile of FP is also similar to BDP at half of its dose.

KEYWORDS

INTRODUCTION

Bronchial asthma is a chronic disorder of the airway affecting all age groups. It is characterised by airflow obstruction that is typically reversible and by airway hyper responsiveness to various stimuli. It is associated with cough, wheezing and breathlessness.

According to recent data of WHO, 235 million people were affected worldwide with bronchial asthma and more than 1,80,000 deaths occur due this disease. In India 15-20 million people are suffering from asthma. It is the most common chronic disease of childhood and most common cause of school absenteeism due to chronic conditions. The prevalence of asthma has increased in recent times. According to International Study of Asthma and Allergies in Childhood, Phase 3 the prevalence of bronchial asthma in preschool children is 2.4-37.6%, with peak age incidence at 3 years and 0.8-32.6% in school going children. Worldwide childhood asthma appears to be increasing in prevalence despite considerable improvement in our knowledge of the disease and management.

Broncodilators and anti-inflammatory drugs are Cornerstone for the treating bronchial asthma. Inhaled corticosteroids therapy improved lung function as well as reduce asthma symtoms, AHR and use of rescue medication, most importantly it reduces exacerbation by approximately 50%. These drugs are beneficial in asthma of any duration and severity. Steroids are the only drugs which can modify the course of disease. Regular use of inhaled steroids improve asthma symptoms, decrease bronchial hyperreactivity and reduce exacerbations. With time many inhaled corticosteroids were used in asthma, those in widespread and frequent use are be clometha sonedipropionate, budesonide, fluticasone propionate, flunisolide and triamcinolone acetonide.

Inhaled steroids are associated with many local and systemic side effects. Local side effects being cough, hoarseness of voice and oropharyngeal candidiasis. Systemic side effects are dose dependent and most common in individuals receiving high dose of ICS and its systemic side effects are suppression of hypothalamic pituitary adrenal axis, osteoporosis, weight gain, hypertension, cataract, decrease in growth velocity in children etc.

AIMS AND OBJECTIVES

The aim of this study was to compare the efficacy and adverse effects of inhaled beclomethasonedipropionate with fluticasone propionate in patients of bronchial asthma.

MATERIALAND METHODS

Present work were done in Department of Pediatrics, Darbhanga Medical College and Hospital, Laheriasaria.

CRITERIA FOR SELECTION –

Total 120 patients were selected from outpatient and inpatient department of paediatrics.

a. Patients between 2-12 years of age were selected for study.
b. Only diagnosed case of bronchial asthma after detailed history and clinical examination were included in the study.

INHALED DRUG TREATMENT

Patients were divided into 4 groups each with 25 patients –
Group A patients have received treatment with 250µg fluticasone propionate, Group B patients with 500µg beclomethaso nedipr opionate, Group C with 500µg fluticasone propionate, and Group D with 1000µg beclomethasonedipropionate daily. Drugs were given by MDI with spacer in two equal morning and evening doses. Face mask was used in smaller children only when required.

POST TREATMENT PROCEDURE-

The study was done for 12 weeks duration.FEV1, PEFR and local adverse effects were noted at 0 week,4 weeks,8 weeks and 12 weeks of treatment.

Finally Group A was compared with Group B and Group C with Group

D at the completion of study.

RESULTS

Present work was done in the Department of Pediatrics, of Darbhanga Medical College and Hospital, Laheriasarai.

Total 120 patients were selected for the present work and divided into 4 groups.

AGE AND SEX DISTRIBUTION :

A. ACCORDING TO DURATION OF ILLNESS –

(a) EFFECT ON FEV_1 –

Mean FEV_1 according to duration of illness in patients of group C

(FP – 500 mg/day in 2 equal divided doses)

Table – 1 A

Duration of illness (in years)	FEV_1 (Mean ± SD)			
	0 week	4th week	8th week	12th week
<2	1.78±0.06	1.88±0.07*	1.93±0.05	1.96±0.08***
2-5	1.69±0.09	1.77±0.08**	1.83±0.06*	1.85±0.07***
>5	1.58±0.04	1.65±0.09***	1.70±0.07	1.72±0.06*

Mean FEV_1 according to duration of illness in patients of group D
(BDP – 1000 mg/day in 2 divided doses)

Table – 1 B

Duration of illness (in years)	FEV_1 (Mean ± SD)			
	0 week	4th week	8th week	12th week
<2	1.81±0.07	1.90±0.08*	1.96±0.09	1.99±0.07***
2-5	1.72±0.09	1.81±0.07**	1.85±11*	1.88±0.09***
>5	1.56±0.07	1.62±0.09***	1.65±0.08	1.67±0.06*

*P value = 0.07 **P value = 0.06 ***P value = 0.09

(b) EFFECT ON PEFR –

Mean PEFR according to duration of illness in patients of Group C
(FP – 500 mg/day in 2 divided doses)

Table – 1C

Duration of illness (in years)	PEFR (Mean ± SD)			
	0 week	4th week	8th week	12th week
<2 yrs	189±13.8	197.4±14.2*	202.8±15.7	206.9±11.6*
2-5 yrs	181±14.7	188.6±11.6**	193.8±12.8***	197.7±15.4
>5 yrs	172±10.2	178.1±12.1***	182.4±13.7***	185.5±12.9*

Mean PEFR according to duration of illness in patients of group – D -
(BPD – 1000 mg/day in 2 divided doses)

Table – 1 D

Duration of illness (in years)	PEFR (Mean ± SD)			
	0 week	4th week	8th week	12th week
<2 yrs	192±14.2	199.8±13.9*	204.9±11.9	208.7±14.9*
2-5 yrs	181.4±13.4	188.3±14.7**	193.1±15.7***	196.3±20.1
>5 yrs	173.2±11.7	178.8±17.2***	183.1±14.9***	186.9±19.7*

*P value = 0.09 **P value = 0.07 ***P value = 0.05

Table 5C vs 5D – Statistically Not Significant.

DISCUSSION

The present study was done to compare the efficacy and adverse effects of fluticasone propionate at half the dose of beclomethasone dipropionate in patients of bronchial asthma.

Inhaled corticosteroids are most effective anti-inflammatory drugs for treatment of bronchial asthma, but efficacy varies among different drugs. There is still some concern about safety of these drugs especially in children. Systemic side effects are rare and that too at very high doses but local side effects are more frequent at even moderate doses.

In the present study 120 patients were selected from in and outpatient department and were distributed into 4 groups with 30 patients each. Group A was put on FP-250 mg/day, Group B on BDP-500 mg/day, Group C on FP-500 mg/day and Group D on BPD-1000 mg/day.

The result were more than girls and ratio of boys and girls are 0.6:0.4. The patients between 6 to 12 years age group were more than 2 to 6 years age and percentage was 73.3% and 26.7% respectively. EilyadIssabeagloo, TaghiAharchi et al (2012) also studied male were more than female and its percentage were 60% and 40% respectively. The result were equal in ratio and its ratio is 1:1. The patients between 6 to 12 years age group were more than 2 to 6 years age and percentage was 76.7% and 23.3% respectively. Sailakshmi K, Vijayal K, Sirisha JV et al (2013) also study male and female were equal and maximum number of patients is between 6 to 12 years of age.

The result were less than girls and ratio of boys and girls are 0.4:0.6. The patients between 6 to 12 years age group were more than 2 to 6 years age group and percentage was 60% and 40% respectively. AkefehAhmadiafshar, Mohsen MogimiHadji and NimaRezaei (2010) also studied male were less than female and their percentage is 40% and 60% respectively and maximum number of patients in between 6 to 12 years of age.

The result and girls were equal in ratio and its ratio is 1:1. The patients between 6 to 12 years age group were more than 2 to 6 years age and percentage were 60% and 40% respectively. ElhamHossmy et al (2016) also studied male and female were equal in number and maximum number of patients in between 6 to 12 years of age.

The result shows increase in FEV1 with time in different age groups. Table 2A includes patients of group A (FP – 250 mg/day) and table 2B shows patients of group B (BDP-500 mg/day). In both these tables FEV_1 increases significantly on treatment at 4th, 8th& 12th week. Increase in FEV_1 was almost similar in both groups and results were non-significant statistically.

The result shows patients of group C (FP-500 mg/day) and The result shows patients of group D (BDP-1000 mg/day). Here also FEV_1 increases significantly on treatment at 4th, 8th and 12th week. The result shows increase in FEV_1 according to duration of illness in group A and B. The result shows increase in FEV_1 according to duration of illness in group C & D patients. Both these groups show increase in FEV_1 with time irrespective of duration of illness but increase was more in disease of lesser duration. The result show increase in PEFR in patients of group-A (FP-250 mg/day) and 2D show increase in PEFR in patients of group B (BDP-500 mg/day). Similarly Table 4C show increase in PEFR in patients of group C (FP-500 mg/day) and table 4D show increase in PEFR in patients of group D (BPD – 1000 mg/day). Increase in PEFR was significant in all groups with increase in group C and D better than A and B mostly due to increase in dose of inhaled steroid. Comparison between 2C and 2D and that between 4C and 4D failed to show any statistically significant difference.

Adverse effects observed during treatment were cough, hoarseness of voice, headache and oropharyngeal candidiasis. Since the study was only of 12 weeks duration so systemic adverse effects were not observed.Local side effects was not seen in patients of group – A (FP – 250mg/day) and group – B (BPD-500 mg/day). Among patients of group – C, cough was seen in 2 patients (8%) hoarseness of voice in 1 patient (4%) and oropharyngeal candidiasis in 2 patients (8%). In group – D patients 2(8%) showed cough, 1 (4%) had hoarseness of voice and 3 (12%) suffered from oropharyngeal candidiasis. On going through these we see that at low dose of steroid, local effects were not seen. Local side effects were seen among group C and D patients in almost equal frequency except oropharyngeal candidiasis which was slightly more in Group-D patients (12% vs 8%).

This finding was in accordance with Lasserson T.J. et al, Adams N.P. et al, A. Nayak et al and Alotaibi S. et al who found similar safety profile of FP at half the dose of BDP.

Pauwels et al found safety profile of FP to be better on bone density, but in this case since the study was of shorter duration effect of drugs on bone mineral density could not be studied.

Adams N.P. et al showed that there was no difference in incidence of

cough, pharyngitis, hoarseness of voice and oral candidiasis between the two drugs. Parekh et al also found that adverse effect profile of both the drugs are similar when FP is used at half the dose of BDP.

CONCLUSION:

1. FEV_1 and PEFR was significantly improved in all four groups. But patients taking higher dose of fluticasone propionate and Beclomethasonedipropionate, FEV_1 and PEFR was significantly increased. Better improvement was shown in patients presenting with acute disease as compare to chronic disease.
2. During treatment cough, hoarseness of voice and oral candidiasis were most commonly adverse effect. On low dose steroid these adverse effect were not seen but infrequently local side effect were seen in high dose of steroid.
3. Similar efficacy with almost similar safely profile was observed in bronchial asthma with fluticasone propionate at half the dose of Beclomethasonedipropionate.

REFERENCES

1. Aalderen WMCV, Price D, Bacts FMD, Price J : Bedomethasonedipropi onateextr afineacrosol versus fluticasone propionate in children with asthma : J. Resp. Med. – Vol. – 101, Issue – 7, July 2007, P – 1585-93.
2. Batemean ED, Hurd SS, Barnes PJ, Barnes PJ, Bosquet J, Drazen M, Fitzgerald M. et al. Global strategy for asthma management and prevention : GINA executive summary. Euro. Resp. J. Jan 1, 2008; 31(1) : 143-178.
3. Kelly H.W. : Comparison of inhaled steroid : An updatel The annals of Pharmacotherapy 2009, Vol. 43(3); 519-27.
4. Robroeks, Charlotte MH, Kant V, Kim DG, Vilet V et al. Comparison of anti-inflammatory effect of extrafine HFA bedomethasone versus fluticasone dry powder inhaler on exhaled inflammatory markers in childhood asthma : Annals of Allergy asthma and Immunology, Vol. – 100(6) : June – 2008; P-601-607.
5. Santigo AS, RatzanS : Acute adrenal crisis in asthmatic child treated with inhaled fluticasone propionate : Intern. J. of Ped. Endocrinology – Vol. – 2010, ID – 749239.
6. Sailakshmi K, Vijayal K, Sirisha JV et al : Comparative study of fluticasone propionate with budesonide and beclomethasonedipropionate in mild persistent bronchial asthma : Int J Med Res Health Sci, 2013;2(3): 518-522.
7. AkefehAhmadiafshar, Mohsen MoginiHadji and NimaPezaei : Comparison of effectiveness between beclomethasonedipropionate and fluticasone propionate in treatment of children with moderate asthma : Wao Journal 2010;3:250-252.
8. EilyadeIssabeagloo, TaghiAharchi, ParvizKermanizadeh and Mohammad Taghizadich : Comparison of inhalant fluticasone and beclomethasone in treating mild and moderate persistent asthma in children : Annals of Biological Research, 2012, 3 (3): 1536-1552.
9. Department of Pharmacology, Dr. V.R.K. Women's Medical College Teaching Hospital & Research Centre Aziz Nagar, R.R. District, A.P. India : Comparative study of fluticasone propionate with budesonide and beclomethasonedipropionate in wild persistent bronchial asthma : Int J Med Res Health Sci. 2013;2(3): 518-522.
10. Anju Singh, DevkiNandan and JhumaSankar : Comparison of clinical effect of beclomethasonedipropionate and budesonide in treatment of children with mild persistent asthma : A double-blind, randomized, controlled study : Indian J Med Res 144, August 2016, pp 250-257.
11. Dominic Fitzgerald, Peter Van Asperen, Craig Mellis, MareeaHonner, Lucia Smith, Geoffry Ambler : Fluticasone propionate 75 mg/day versus beclometha soned ipropionate 1500 mg/day : comparison of efficacy and adrenal function in paediatric asthma. : Published by group bmj.com. 2018.