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Research Paper Medical Science

Comparison of Fluticasone propionate with Beclomethasone dipropionate in patients of Bronchial asthma"

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ABSTRACT

study was designed to compare the efficacy and safety of fluticasone propionate with an equal daily dose of Beciomethasone dipropionate in patients of Bronchial asthma. There were 64 patients of bronchial asthma . fluticasone propionate found to be more potent than Beciomethasone dipropionate

Keywords : Fluticasone,Beclomethasone,Asthama

AIMS AND OBJECTIVES
This study was designed to compare the efficacy and safety of fluticasone propionate with an equal daily dose of Beciomethasone dipropionate in patients of Bronchial asthma.

Introduction.
Bronchial asthma is a greek word & introduced by the greek physician which means "to pant or breathlessness " or to breath with open mouth .
HIPPOCRATES [460-357BC]THE FATHER OF MEDICINE has referred the term asthma .asthma is now recognized as a disease of airways which involves a special type of inflammation characterized by the presence of activated mast cells, eosinophils and lymphocytes with recognition that chronic than acute inflammatory events are more relevant to understanding the underlying mechanisms in asthma and role of cytokines Barnes PJ, Elwood W., Chung K 1991.
Inhaled corticosteroids are the most effective first line therapy currently available for treatment of asthma Paul Mo'Byrne ,Frederick E, Havgreave 1990.

Inspired by **Fabbri L, Burge P.S and Croonerburgh L.1993** study we decided to undertake a study of comparison inhaled fluticasone propionate 1500ug/ day administered either as dry powder via diskhaler or inhaler or pressurized inhaler and compared with beciomethasone dipropionate (1500ug/ day) administered by pressurized inhaler or dry powder inhaler.

It aims at studying efficacy and safety in asthmatic patients attending the department of Respiratory Medicine and Tuberculosis,

DISCUSSION

The present study was conducted in Govt Medical college , Nagpur from Jan 2003 to Jan 2004 . Total 64 cases of Bronchial asthma diagnosed on history and physical examination, lung function test, laboratory test and with reversibility. The selection being guided by the standard definition of disease given by American Thoracic Society, 1986.

The improvement in lung function was assessed by daily record card data were collected over the first 12 week of the study. Clinic lung function measurements were recorded over 12 months. The mean morning and evening PEF was calculated over each period for each patient and expressed as absolute values. Predicted lung function values were calculated from age, sex height and weight using standard formula Shankar PS 2003, Kamat SR.et al. 1977.

PEF rates and lung function values were analyzed by Student 't' test of significance. In the present study of 64 patient age of the cases ranged from 16 to 50 years. The maximum cases were between 31 to 50 years and mean age was 32.25 years. This finding was similar to that noted by Philips K. et al 2004 who studied 23 cases where mean age was 43 years.

Verona E, et al 2003 who studied 64 cases, whrer mean age was 53 years in Group A and 50 years in Group B. In the present study 48 males (75%), 16 females (25%). M : F = 3 : 1. Our finding correlate with the study of Fabbri L. et al 1993, who studied 142 cases of moderate to severe asthma, where 91 males (64%) and 51 females (36%). He compared Fluticasone propionate 1500 ug-1 treated for one year.

In the present study of 64 cases 100% were symptomatic, all the cases had breathlessness while 36 (56.25%) cases had cough, which was productive and 16 (25%) had rhinitis. The mean duration of disease was 10.34 +- 8.18 (Rang 11 months to 30 years) maximum i.e. 26 (40.62%) cases had duration of illness between 0 to 5 years.

Our finding correlate with the study of Pauwells RA. et al 1998, reported that duration of asthma between 0 to 5 years in the 31% of cases , 5 to 10 years in 13% of cases and more than 10 years in 56% of cases.

In the present study it was observed that change in season (78.12%) and inhalants (71.87%)were the chief precipitating factors. In the present study it was observed that only 28 (43.75%) patients had a family history of asthma and positive family history was more amongst males (31.25%). In the present study in Group A maximum cases 26 (81.27%) were having moderate asthma of which 19(59.30%) were males, 7 (21.90%) were females. ($x2 = 0.012$ & $P > 0.5$). In 6 cases (18.73%) were having severe asthma of which 5(15.70%) were males and 1 (3.01%) was female.

In group B 28 (87.60%) cases were having moderate asthma of which 21 (65.70%) were males ($p > 0.5$).

When group A and group B were compared for occurrence of moderate and severe asthmatics the number of moderate asthma was significantly higher. ($x2 = 0.47$, d.f. = 1, $P < 0.5$)

In the present study during the first 3 months diary card, PEF L/min and lung function measurements in clinic shows significantly greater improvement in patient receiving Fluticasone propionate as compared to Beclomethasone dipropionate.

The morning PEF values were increased in both groups from baseline values. However at week 1-4.5 -8.9-12 were all significantly in favour of fluticasone propionate. Increase in mean evening PEF in favour of Fluticasone propionate were also observed throughout the 12 weeks period. Mean evening PEF was greater in Fluticasone by 16 L/min. (95% CI 1 to 17; P<0.05). The mean change value in clinic PEF over 12 months period was (95% CI 1 to 38; P<0.05)This finding was similar to the study done by Fabbri L. et al 1993.

It was noted that Mean FEV1 increase by 0.9 L/min in fluticasone propionate over 12 months. The mean FEV1 increase by 1.80 L/min to 1.89 L/min over 12 months.

Significant treatment difference in favour of Fluticasone propionate were also found after 8 and 12 weeks of treatment. (P<0.05).Mean FVC values showed similar increase for Fluticasone propionate from 2.06 L/Min to 2.19 L/min over 12 months.

There was significant difference in the distribution of exacerbation reported as a single diagnosis adverse event between patient receiving Fluticasone propionate and Beclomethasone dipropionate (P<0.02). With statistically fewer patients experiencing exacerbation in Fluticasone Propionate group than in Beciomethasone dipropionate group (P<0.05).

In Fluticasone propionate group it was observed that 16% had mild to moderate exacerbation and in Beclomethasone dipropionate group had 28% of mild to moderate exacerbation (P< 0.02).It was observed that the most common adverse event was Hoaarseness of voice in Fluticasone propionate group was 9% and of Candidiasis was 7%.

OBSERVATION

TABLE NO -1 SHOWING AGE &SEX DISTRIBUTION

AGE	MALE	FEMALE	TOTAL
16-20	6[9%]	2[3.1%]	8
21-30	10[16%]	2[3.1%]	12
31-40	16[25%]	6[9.4%]	22
41-50	16[25%]	6[9.4%]	22
TOTAL	48[75%]	16[25%]	64

TABLE NO :2 SHOWING SYMPTOMS IN 64 CASES OF ASTHMA

SYMPYOMS	NO OF PTS	%
BREATHLESSNESS	64	100
COUGH	36	56.25
RHINITIS	16	25

TABLENO :3 SHOWINGCHIEF PRECIPITATING FACTORS IN 64 CASES OF ASTHMA

FACTORS	NO OF CASES	%
CHANGE IN SEASON	50	78.12
INHALANTS	46	71.87
HUMIDITY	36	56.25
INFECTION	16	25
INGESTANTS	0	0
OTHERS	18	28.13

TABLE NO 4 SHOWING DURATION OF DISEASES IN64 CASES OF ASTHMA

DURATION	NO OF CASES	%
0-5	26	40.62
5-10	16	25
10-15	8	12.5
15-20	8	12.5
20& ABOVE	6	9.38

TABLE NO 5 SHOWING FAMILY HISTORY PATTERN IN 64 CASES OF ASTHMA

FAMILY HISTORY	MALE	FEMALE	TOTAL
PRESENT	20[31.25%]	8[12.5%]	28[43.75%]
ABSENT	28[43.75%]	8[12.5%]	36[56/25%]
	48[75^]	16[25%]	

TABLE NO6 SHOWING SEVERITY PATTERN IOF ASTHMA IN TWO GROUPS OF BRONCHIAL ASTHMA

GROUP A

GRADE	MALE	FEMALE	TOTAL
MODERATE	19[59.40%]	7[21.90%]	26[81.27%
SEVERE	5[15.70%]	1[3.01%]	6[18.73%]
	24[75%]	8[25%]	

GROUP B

GRADE	MALE	FEMALE	TOTAL
MODERATE	21[65.70%]	7[21.90%]	28[87.60%]
SEVERE	3[9.03%]	1[3.01%]	4[12.40%]
MILD	24[75%]	8[25%]	

TABLE NO -7 SHOWING NUMBER OF PATIENTS REPORTING ADVERSE EFFECTS

	DURING FP TREATMENT		DURING BDP TREATMENT	
	NO	%	NO	%
WORSENING OF ASTHMA	5	16	9	28
HEADACHE	2	4	2	4
CANDIDIASIS	2	7	3	9
HOARSENESS OF VOICE	3	9	1	4
SORE THROAT	2	3	1	2

TABLE NO -8 SHOWING ASTHMA EXACERBATION

	FLUTICASONE PROPIONATE		PVALUE
N	32	32	-
TOTAL EXACERBATIONS	18	40	-
SEVERE EXACERBATION	2	12	<0.05
MILD-MOD EXACERBATI	16	28	<0.02

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MILD-MOD EXACERBATI	16	28	<0.02

SUMMARY AND CONCLUSION

The present study summarized as:

1. There were 64 patients of Bronchial Asthma (moderate to severe persistent)
2. The age of the cases ranged from 16 yrs. To 50 yrs. maximum i.e. 44 cases (68%) were between 31 to 50 years age group.(Table no 1)
3. Male : Female ratio being 3:1 . Mean age 35.25 yrs.
4. Commonest symptoms were breathiessness (100%), Cough (56.25%).(Table no 1)
5. The mean duration of illness in years was 10.34 -+ 8.18 (Range 30 yrs). Maximum i.e. 26 cases (40.62%) cases had duration of iliness between 0-5 yrs. .(Table no 2 & 4)
6. The chief precipitating factor was changes in season 78.12% of cases, inhalants >71.87%..(Table no 3)
7. In 43.75% patients had family history of asthma and positive family history was more amongst males 31.25%.(Table no 3)
8. In Group A there were 26 (81.27%) cases of moderate persistent asthma, 6 cases (18.73%) were severe persistent asthma.
9. In Group B there were 28 cases (87.60%) cases of moderate Persistent and 4 (12.40%) severe persistent. (Table no 5)
10. During the trial, 5 patients withdrawn from Fluticasone Propionate group and 7 from Bectomethasone dipropionate group.
11. The morming PEF values increased in both groups from the baseline value. The mean difference between the groups however at 1-4 weeks,5-8 weeks and 9-12 weeks, were significantly in favour of Fluticasone propionate. Over all mean difference was 16 L/min (95% C1.6 to25 P<0.05).(Table no 10)
12. Increase in mean evening PEF in favour of FP were also observed throughout 12 weeks period. The adjusted mean eveni ng PEF being significantly greater in PF by 20 L/min (95% C I 0 to 20, P<0.05).
13. The mean percentage of symptoms free days over 12 weeks at 1-4 weeks 28% in FP group, 24% in BDP group at 5-8 weeks 28% in EF and 24% in BDF group, at 12 weeks 40% in FP and 26% in BDF group.
14. The mean percentage of symptom free night 63% FP and 40% BDF.
15. The mean percentage of B2 agonist rescue free days 25% and 12% before and increased 33% and 18% over 12 weeks.
16. During the treatment period Group B (BDP) tended to use more rescue medication than Group A. This difference was significant for weeks 5-8 (P<0.05).
17. The mean change from baseline values in hospital PEF values over 12 FP by 16 L/min (95% C 1 to P<0.05 at 12 months).
18. The mean change from baseline values in hospital FEV1 values over 12 months period increased from 1.80 to 1.89 L/min significantly, Greater in FP by 0.09 L/min (95% C 1 to P < 0.05 at 12 months).
19. The mean change from baseline values in hospital FVC values over 12 months period increased from 2.04 to 2.19 L/min significantly, greater in FP by 0.15 l/min. (Table no 10)
20. The number of patients experiencing exacerbation of asthma during study 23%.(Table no 8)
21. Mid and Moderate exacerbation 16% in fluticasone proplonate group , mid and moderate exacerbation 28% in Beclomethasone dipropionate, group Significant fewer persistent had severe exacerbation on FP 2% (32) than BDF 12%(32) P<0.02.
22. The most common (>5%) adverse events were related to patients clinical symptoms (asthma, rhinitis). The incidence of expected harmacologically predictable (>5%) adverse events such as candidiasis and hoarseness of voice. .(Table no 7)
23. In trials of one year duration, inhaled fluticasone propionate was significantly more effective than Beciomethasone dipropionate with equal doses.
24. FP found to be more potent than BDP.
25. Inhaled FP administered for 1 year is well tolerated than BDF.
26. FP in a daily dose 1.5 mg inhaled results in significantly greater increase in PEF and asthma control than same dose BDP with no increase in systemic side effects.

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