Asian Journal of Pharmaceutical and Health Sciences
www.ajphs.com

Spirometric evaluation in asthmatics taking formoterol/budesonide v/s salmeterol/fluticasone

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ARTICLE HISTORY

Received: 25.05.2012

Accepted: 27.06.2012

Available online: 10.11.2012

Keywords:

Asthma, Salmeterol, Formoterol, Spirometry.

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ABSTRACT

Asthma is a major public health concern and one of the most common chronic disease worldwide. 50 asthmatic patients qualifying for third step in asthma treatment were enrolled for study. After assessing the lung function they were divided into two groups. One group was prescribed inhaled salmeterol (50mcg bid) and inhaled fluticasone (100mcg BID) and the other group was prescribed inhaled formoterol (6mcg BID) and inhaled budesonide (200mcgBID) for four weeks duration. Spirometric evaluation was done in both the groups to see the improvement in lung functions. Both the groups were compared.

INTRODUCTION

The word Asthma is a Greek word meaning 'breathless' or to breathe with open mouth. In 1698, Sir John Flayer, in his book 'Treatise of Asthma' used the word asthma particularly for episodic breathlessness. Asthma is a major public health concern and one of the most common chronic disease worldwide. Asthma is defined as chronic inflammatory disorder of airways characterized by 1) Airway obstruction that is reversible either spontaneously or with treatment 2) Airway inflammation, and 3) Airway hyper responsiveness to a variety of stimuli.

Whereas in mild intermittent asthma, no daily medication is given ; in mild persistent asthma short acting inhaled B2 agonists when required and an anti-inflammatory agent is added. In moderate asthma, short-acting inhaled B2 agonists when required and medium dose inhaled glucocorticoids is given. In severe persistent asthma, inhaled short acting B2 agonist bronchodilators and oral glucocorticoids are given. Therefore, inhaled glucocorticoids are most effective long term control medications for asthma. Among inhaled glucocrticoids, the relative vasoconstrictor potency of fluticasone propionate is substantially greater than that of fuocinolone acetnide or beclomethasone dipropionate. Patients with persistent inflammatory tissue injury, and airway wall remodeling with proliferation of airway smooth muscle and deposition of matrix proteins need long acting B2 agonists like salmeterol or formoterol. Salmeterol xinafoate is a saligenin derivative, and a selective B2 agonist. It produces bronchodilation for at least 12 hours following inhalaton of single 50 mcg dose. There is no evidence of tachyphylaxis to pulmonary effects of salmeterol.

Formoterol has a high intrinsic activity documented both in vitro in smooth muscle preparation and in vivo in asthmatic patients. Such a feature may be a crucial characterstic for bronchodilation drug that is to be used on an as needed basis [1].

MATERIAL AND METHODS

The study was conducted on 50 patients diagnosed as a case of bronchial asthma and reported in TB and chest department of Govt. Medical College, Amritsar. The patients who classify for the conditions laid down by second expert panel report 1997 for third step of bronchial asthma and can generate proper flow rate from rotahaler were included in the study.

FEV1 and PEFR of each patient was recorded , those having FEV1/PEFR exceeding 60% and PEFR variability exceeding 30% were included in the study. Detailed history of each patient was taken and complete general physical examination was done. Routine investigations of the patients were done.

Prior to each study day, inhaled short acting B2 agonists were withheld for atleast 8hrs, long acting B2 agonists for 72 hrs and leukotrienes and anticholinergics for 12 hrs prior to giving the study drug.

Patients were divided randomly into two groups of 25 each. One group of patients were given salmeterol (50mcg BID) and fluticasone (100mcg BID) and the other group were given formoterol (6mcgBID) and budesonide (200mcgBID). Serial

measurements of FEV1 were done every minute for 5 minutes and then at 7,10,15,30 and 60minutes and again at 2,3hrs of inhalation. Spirometry was done at 1 month to see the improvement in lung function in both the groups.

RESULTS

The present study was conducted on patients diagnosed as having moderate persistent asthma in department of Ttuberculosis and Respiratory diseases, at Govt. Medical College, Amritsar. 50 patients were included in the study and following observations were made.

DISCUSSION

The onset of action of bronchodilation of formoterol in group II was less than 3 minutes while it was about 15 minutes in salmeterol of group I. Spirometric evaluation at the end of 1 month revealed marginal difference in the two groups. So the above studies shows that formoterol has a much rapid onset of action as compared to salmeterol but there long tem effects are almost the same.

Brogden and Faulds [2] showed that prior inhalation of salmeterol 50 mcg significantly decreases the fall in FEV1 or PEFR induced by exercise in patients with exercise induced bronchoconstriction. The extent of protection elicited by salmeterol and salbutamol is similar but the effect of salmeterol is maintained upto 12 hours.

Pauwels et al [3] stated that adding regular treatment with long acting inhaled B2 agonist formoterol to therapy with the inhaled glucocorticoid budesonide would improve symptoms of asthma without a long term worsening of the disease. The addition of formoterol reduced the incidence of severe and mild exacerbations.

According to AE reading two drugs differ from each other with regard to onset of action . Wonder et al (2001) also showed that formoterol relieves severe acute bronchoconstriction significantly faster than salmeterol. The present study is also supported by earlier authors like Palkhiwala [4], Beier et al [5] and Lotvall et al [6].

Table 1 : Group, age and sex wise distribution of patients

AGE IN YEARS	GROUP I MALE	GROUP I FEMALE	GROUP II MALE	GROUP II FEMALE
19 – 30	2	3	3	2
31 – 45	5	5	5	5
46 and above	9	1	6	4

Group I had total of 16 males and 9 females and group II had 14 male and 11 females.

Table 2 : Improvement in FEV1 following inhalation of single dose of Salmeterol 50 mcg and Fluticasone 100 mcg in group I in age group of 19 -30 years.

Sr. No.	Pre-bronchodilator value of FEV1 in litres	Post-bronchodilator value of FEV1 in litres	Improvement in FEV1 in %age	Time of onset of action in minutes
1	1.29	1.63	26.4	15
2	1.28	1.58	23.4	15
3	1.40	1.69	20.7	15
4	1.32	1.58	19.7	15
5	1.44	1.69	17.4	15

Group I had total of 16 males and 9 females and group II had 14 male and 11 females.

Table 3 : Improvement in FEV1 following inhalation of single dose of Salmeterol 50 mcg and Fluticasone 100 mcg in group I in age group of 31 - 45 years.

Sr. No.	Pre-bronchodilator value of FEV1 in litres	Post-bronchodilator value of FEV1 in litres	Improvement in FEV1 in %age	Time of onset of action in minutes
1	1.32	1.64	23.2	15
2	1.34	1.64	22.7	15
3	1.41	1.71	21.3	15
4	1.26	1.56	23.1	15
5	1.24	1.61	24.2	15
6	1.31	1.64	23.4	15
7	1.44	1.71	19.2	15
8	1.31	1.64	23.4	15
9	1.29	1.63	26.4	15
10	1.29	1.89	23.7	15

Table 4 : Improvement in FEV1 following inhalation of single dose of Salmeterol 50 mcg and Fluticasone 100 mcg in group I in age group of 46 and above years.

Sr. No.	Pre-bronchodilator value of FEV1 in litres	Post-bronchodilator value of FEV1 in litres	Improvement in FEV1 in %age	Time of onset of action in minutes
1	1.31	1.64	23.4	15
2	1.34	1.64	21.4	15
3	1.37	1.67	21.7	15
4	1.26	1.64	27.1	15
5	1.24	1.64	24.2	15
6	1.28	1.66	21.0	15
7	1.40	1.69	20.7	15
8	1.20	1.63	19.1	15
9	1.37	1.67	21.7	15
10	1.29	1.62	19.7	15

Table 5 : Improvement in FEV1 following inhalation of single dose of Formoterol 6 mcg and Budesonide 200 mcg in group II in age group of 19 -30 years.

Sr. No.	Pre-bronchodilator value of FEV1 in litres	Post-bronchodilator value of FEV1 in litres	Improvement in FEV1 in %age	Time of onset of action in minutes
1	1.06	1.36	28.3	3
2	1.11	1.32	20.1	3
3	1.20	1.31	21.1	3
4	1.40	1.28	18.2	3
5	1.06	1.31	27.1	3

Table 6 : Improvement in FEV1 following inhalation of single dose of Formoterol 6 mcg and Budesonide 200 mcg in group II in age group of 31 - 45years

Sr. No.	Pre-bronchodilator value of FEV1 in litres	Post-bronchodilator value of FEV1 in litres	Improvement in FEV1 in %age	Time of onset of action in minutes
1	1.12	1.34	20.3	3
2	1.10	1.32	20.1	3
3	0.97	1.14	17.5	3
4	0.96	1.13	19.1	3
5	1.01	1.21	19.8	3
6	1.04	1.18	15.5	3
7	0.90	1.14	15.1	3
8	1.19	1.52	29.0	3
9	1.21	1.51	28.0	3
10	1.11	1.41	24.0	3

Table 7 : Improvement in FEV1 following inhalation of single dose of Formoterol 6 mcg and Budesonide 200 mcg in group II in age group of 46 and above years.

Sr. No.	Pre-bronchodilator value of FEV1 in litres	Post-bronchodilator value of FEV1 in litres	Improvement in FEV1 in %age	Time of onset of action in minutes
1	1.11	1.34	21.0	3
2	1.06	1.32	27.3	3
3	1.12	1.31	21.0	3
4	1.04	1.30	24.0	3
5	1.06	1.31	24.0	3
6	1.13	1.32	21.0	3
7	1.12	1.34	23.0	3
8	1.10	1.30	20.0	3
9	1.11	1.36	24.0	3
10	1.10	1.30	20.0	3

The mean time of onset of action in group I was 15 minutes and in group II was 3 minutes. So the time of onset of action of bronchodilation in group II i.e Formoterol group is significantly higher than the group I i.e Salmeterol group.

Comparison of improvement in FEV1 (group I and group II)

		Improvement Group I	Improvement Group II	't' value	'p' value
FEV1	Actual	0.54	0.61	0.95	>0.05
FEV1	% age of predicted	27.5	29.57	0.526	>0.05

Above table shows the FEV1 showed marginally more improvement in group II in comparison to group I. But the difference between the two is not statistically significant ($p>0.05$).

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