Bronchodilatation Effects of Dry Powder Formoterol Fumarate in Asthmatic Patients

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Abstract

Ten asthmatic patients were enrolled in our study of the effects of dry powder formoterol fumarate. The onest was 2-5 minutes and a long duration of action (over 12 hours) appeared. The mean baseline FEV_1 was 1.67 liters (49-74%). Mean reversibility was 17 per cent (range 15-19%). There was no adverse effect in this study.

Formoterol fumarate is a selective long acting beta-two adrenergic receptor agonist. The previous studies[1,2] had shown effects on airway smooth muscle *in vitro* and bronchodilatation *in vivo*. One study also demonstrated the effects on mediator release, microvascular leakage and inflammatory cells accumulation[3].

We conducted a prospective study of dry powder formoterol fumarate on 10 asthmatic patients in order to investigate the effects of the drug.

MATERIAL AND METHOD

From February 1997 to March 1997, ten adult chronic stable asthmatic patients at the out patient department were enrolled in the study. Exclusion criterias were pregnancy, hypersensitivity to beta agonist drugs, smokers or ex-smokers, restrictive pulmonary diseases such as pulmonary tuberculosis, poor communicable, unable to perform the pulmonary function tests and using oral or inhaled corticosteroid.

Informed consents were obtained.

All of the patients were not allowed to take any medication after mid-night. In the morning, they had to perform the base line spirometry. Then they would inhale dry powder of formoterol fumarate and perform the pulmonary function tests at 3 minutes, 30 minutes, 1 hour, 2,3,4,5,6,7,8,10 and 12 hours. During this period of study, patients' signs, symptoms, vital signs and adverse drug effects were recorded.

Pulmonary tests were performed three times using vitalograph and the best value (BTPS corrected) was entered in the Case Record Form. The following parameters were recorded.

- Forced Expiratory Flow in 1 second (FEV_1)
- Forced Vital Capacity (FVC)
- Mean Forced Expiratory Flow (FEF 25-75%)

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RESULTS

Ten chronic asthmatic patients completed our study. There were 6 females and 4 males. The average age was 42.3 years (range 19-58). The mean body weight was 54.0 kilograms (range 45.0 - 81.0). All were non-smokers. The mean duration of disease was 12 years (range 5-30). The mean baseline of FEV_1 was 1.67 liters (range 1.42 - 1.9) which was 58.7 per cent of predicted value (range 49.6% - 74.2%) (Table 1).

Table 1. Baseline FEV_1 per cent of predicted value and per cent change after 3 minutes.

Patient No.	Baseline FEV_1 (liters)	% of predicted value	% change after 3 minutes
1	1.78	63.5	16.1
2	1.60	61.2	15.3
3	1.42	49.6	19.1
4	1.71	62.2	16.2
5	1.53	69.8	17.9
6	1.54	58.2	18.4
7	1.90	67.3	16.0
8	1.81	74.2	15.0
9	1.56	60.2	18.7
10	1.82	70.3	15.5

The mean per cent change of FEV_1 at 3 minutes was 16.8 (range 15 - 19.1%).

The onset of action was rapid (within 2-5 minutes), and the duration sustained for 12 hours (Table 2).

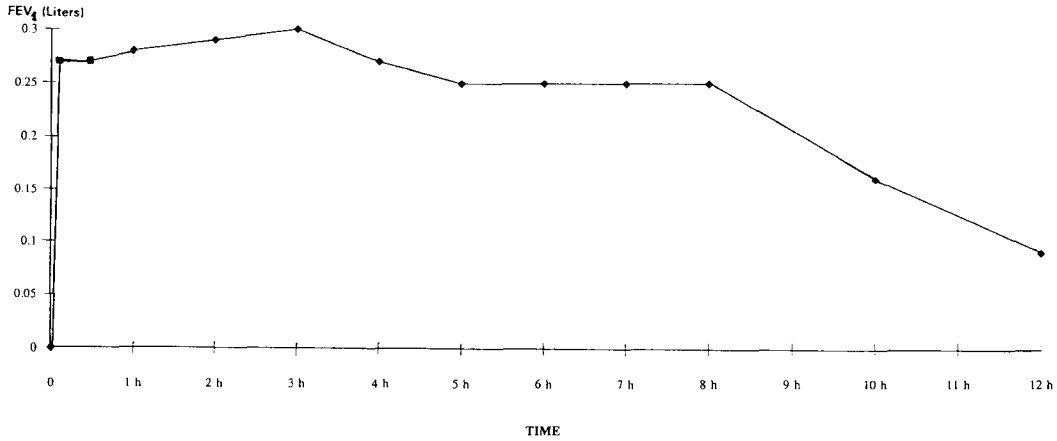
The results of FVC and FEF 25-75 per cent were similar to FEV_1 (Table 3 and 4). The mean FVC was 1.9 liters and increased to be 2.2 liters (15.7% change) in 3 minutes, while the mean FEF 25-75 per cent was 1.39 liters/sec and increased to be 2.1 liters/sec. No adverse effect occurred in this study.

DISCUSSION

We demonstrated that dry powder formoterol fumarate causes a significant increase in FEV_1, FVC and FEF 25-75 per cent among ten chronic asthmatic patients. All of the parameters increased more than 15 per cent of the baseline within 3 minutes. The medication has a rapid onset and also a long duration that lasted for twelve hours. Then, this advantage could lead to the practical use of twice daily and also apply to the cases of nocturnal asthma. The another important property of this powder is that this dry powder does not contain CFC (chloro-fluoro-carbon) substance,

Table 2. FEV_1 after baseline correction in 12 hours after administration of formoterol.

Time	0	3 min	30 min	1 h	2 h	3 h	4 h	5 h	6 h	7 h	8 h	10 h	12 h
FEV_1 (Liters)	0.00	0.27	0.27	0.28	0.29	0.30	0.27	0.25	0.25	0.25	0.25	0.16	0.09



which destroys the ozone layer. Dry powder inhaler is also suitable for elderly patients who are unable to coordinate actuation of the metered-dose inhaler.

Table 3. Mean FVC after administration of formoterol.

Time	0 min	3 min	30 min	1 h	2 h	3 h	4 h	5 h	6 h	7 h	8 h	10 h	12 h
FVC (Liters)	1.90	2.20	2.50	2.20	2.10	2.05	2.20	1.98	1.96	1.95	1.96	1.95	1.94

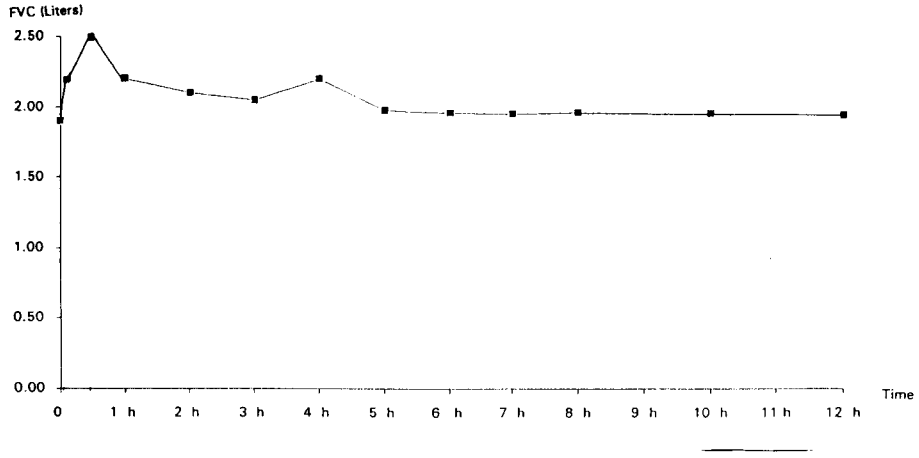
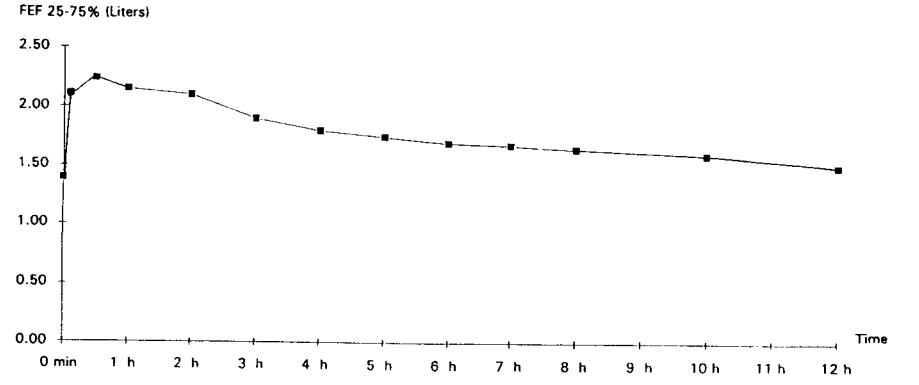


Table 4. Mean FEF 25-75 per cent after administration of formoterol.

Time	0 min	3 min	30 min	1 h	2 h	3 h	4 h	5 h	6 h	7 h	8 h	10 h	12 h
FEF 25-75% (Liters)	1.39	2.10	2.20	2.15	2.10	1.90	1.80	1.75	1.70	1.68	1.65	1.60	1.50



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ประสิทธิภาพยาขยายหลอดลม ฟอร์โมเตรอล ฟูมาเรท ชนิดผงในการดูแลผู้ป่วยโรคหอบหืดเรื้อรัง

*สว่าง แสงหิรัญวัฒนา, พ.บ.**

ได้ให้ยาพ่นชนิดผงของ formoterol fumarate แก่คนไข้โรคหอบหืดเรื้อรัง 10 ราย พบว่า FEV_1, FVC และ FEF 25–75% เพิ่มขึ้น 15% ในเวลา 3 นาที และมีฤทธิ์อยู่นานถึง 12 ชั่วโมง ไม่พบอาการข้างเคียงของยานี้

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