Effects of Antileukotriene Among Asthmatic Patients

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Abstract

Study objective : To determine the effect of antileukotriene (montelukast) 10 mg once daily for the treatment of mild to moderate asthma.

Design : Open label, prospective.

Patients : Thirty asthmatic patients ≥ 18 years of age with baseline FEV_1 > 60 per cent and ≤ 80 per cent of predicted values and evidence of reversible airway obstruction, as defined by an increase in FEV_1 of ≥ 20 per cent.

Interventions : Montelukast 10 mg once daily orally for 12 weeks, back up beta-2 agonist inhaler was available.

Measurement and results : Spirometry was performed during the screening period, and every month after starting antileukotriene. Subjects recorded asthma-related symptoms and use of supplement beta-2 agonists daily on diary cards. Over 12 weeks of treatment, the FEV_1 increased 10 per cent, 14 per cent and 19 per cent respectively, compared to the baseline ($p < 0.05$). The physician and patients evaluation scores were quite good in the study.

Conclusion : Oral montelukast once daily gave a favorable effect in management of mild to moderate asthmatic patients.

Key word : Asthma, Antileukotriene

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Current managements of asthma recognize asthma as a chronic inflammatory disease of the airways in which many cells and cellular elements play a role(1). In particular, mast cells, eosinophils, T lymphocytes, neutrophils, and epithelial cells have been identified as important contributors(2). Mediators which account for the collecting the above cells are cysteinyl leukotrienes(3). Montelukast (MK-

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Table 1. Demonstrated patients' profiles.

Gender : male/female	15/10
Age (years)	18-67 (mean 42.4)
% FEV_1/FVC	60–80 (mean 65.8)
Baseline exacerbation episodes (per month)	4.3
Exacerbation episode per month at the end of the study	0.8

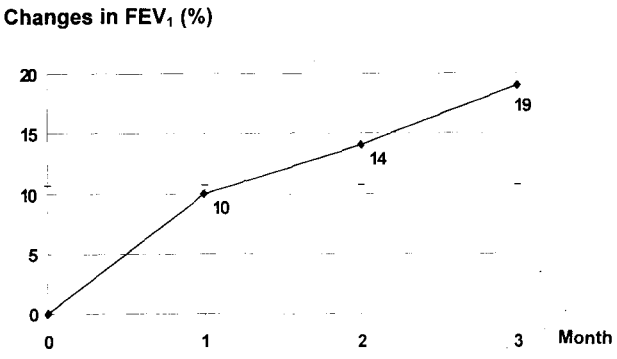

Fig. 1. Demonstrated the FEV_1 improvement (%) from baseline 10%, 14%, 19% at the first, second and third month ($p < 0.05$).

0476) is a specific and potent leukotriene D4 (LTD4) antagonist and should provide benefit in the treatment of asthma[4].

The objectives were to determine the clinical efficacy, side effects and safety of Montelukast compared to baseline for up to 12 weeks in patients with mild to moderate asthma.

MATERIAL AND METHOD

Study Design

All patients provided written, informed consent prior to study entry.

A run-in period lasting 14 days was conducted to determine patient eligibility and to collect baseline data. During the run-in, patients used the albuteral MDI as needed to relieve asthma symptoms. Following the run-in period, subjects who met all eligibity criteria were assigned to receive oral Montelukast 10 mg orally once daily for 12 weeks.

Patients

Thirty female and male patients ≥ 18 years of age with a diagnosis of asthma were enrolled in the study. Patients were excluded if they had any clinically significant disease other than asthma, had had an upper or lower respiratory infection within 3 weeks of the screening visit, or were hospitalized for asthma within 3 months of the screening visit. Patients were required to have a baseline FEV_1 > 60 per cent and ≤ 80 per cent of predicted values after asthma medications were withheld. Reversibility of disease was demonstrated by an increase in FEV_1 of at least 12 per cent above baseline within 30 minutes after the inhalation of albuterol (5). Patients who used oral, intravenous, intramuscular and inhaled corticosteriod within four weeks were also excluded.

Analysis

Student *t*-test was used to compare frequency of acute exacerbation attacks and the values of FEV_1 at first, second, third month compared to baseline. All p values ≤ 0.05 were considered statistically significant.

RESULTS

One hundred patients were screened and 30 patients were recruited in the study. Their ages were between 18-67 years of age, the mean age was 42 years. There were 19 female and 11 male. Of the 30 enrolled patients, 4 were lost to follow-up, one patient developed nausea and headache and was withdrawn from the study. Twenty five patients completed the study. Acute exacerbation had decreased from 4.3 episodes per month to 0.8 episodes per month at the end of the study ($P < 0.05$) (Table 1).

The result showed improvement of FEV_1 within 3 months. The mean and standard deviation of per cent change of FEV_1 at first, second and third month from baseline were 10.36 ± 17.62,

14.17 ± 21.78 and 19.89 ± 19.92 respectively. The P value was less than 0.05 for all of the three parameters (Fig. 1). The inhaled beta-2 agonist used also decreased 14 per cent from the baseline. The patient and physician's global evaluation was quite good in this study.

Adverse events

One patient had nausea, vomitting and headache and was withdrawn from the study.

Haematology and blood chemistry revealed no significant abnormalities within the 3 months of study.

Discussion

The study showed that antileukotriene (montelukast) 10 mg orally once daily up to 12 weeks gave a favorable effect in FEV_1 improvement. The patient and physician's evaluation scores were satisfactory

In 1988[6], Reiss et al reported such favorable effects compared with placebo. In their study, other than clinical improvement, the peripheral blood eosinophil also decreased significantly.

Other than the study, we had an opportunity to treat 8 cases of severe asthmatic patients. They do not have to use oral prednisolone, they are free from cushing appearance and have avoided hospitalization and emergency room visit.

Antileucotriene is nowadays considered as one of the long term treatments for chronic severe asthmatic patients[7]. However, cost of treatment must be weighed against benefit[8].

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ประสิทธิภาพของยาต้านลิวโคไทรอีนในผู้ป่วยโรคหอบหืด

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ได้วิจัยผลการตรวจสมรรถภาพปอด FEV_1 ในผู้ป่วยโรคหอบหืด 25 ราย หลังจากได้ยาต้านลิวโคไทรอีน (มอนติลิวคาส) 10 มก. 1 เม็ด รับประทานวันละครั้ง เป็นเวลา 12 สัปดาห์ พบว่าจำนวนครั้งของการเกิดอาการหอบหืดลดลงจาก 4.3 ครั้งต่อเดือน เหลือ 0.8 ครั้งต่อเดือน และ FEV_1 เพิ่ม 10%, 14% และ 19% ($P < 0.05$) ณ เวลา 1, 2, 3 เดือน เมื่อเทียบกับก่อนการได้รับยา

คำสำคัญ : โรคหอบหืด, ยาต้านลิวโคไทรอีน

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