

LETTER TO THE EDITOR

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The Efficacy of Montelukast Monotherapy in Moderate Persistent Asthmatic Children

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ABSTRACT

Although current guidelines place single leukotriene receptor antagonists use as a therapeutic option in mild persistent asthma, there is still uncertainty about its place. In this study efficiency of montelukast monotherapy in children with moderate persistent asthma was evaluated. Children (age 6 to 16) with persistent moderate asthma were treated prospectively with budesonide combined with montelukast (n=20), or only montelukast (n=15) during six months. Asthma symptoms and exacerbations were obtained from diary data. This study suggests that both treatments were effective and well tolerated. It could be concluded that sole montelukast treatment in children with moderate persistent asthma is effective.

Key words: Asthma; Efficacy; Leukotriene antagonists; Montelukast; Pediatrics;

LETTER

In our study, we intended to investigate whether montelukast monotherapy alone would be useful in the treatment of Moderate Persistent Asthma (MPA).

220 children with asthma attended the pediatric allergy clinic during March to June 2003. In a random manner

35 children 6 to 16 years of age with MPA which had shown low adherence up to 3 months were selected to participate in this study. The study was approved by the ethical committee of the hospital and written consent forms were taken from children or their parents.

Children were treated either with combination of the budesonide (BUD) 400µg daily and montelukast (MON) (5 mg daily) combined treatment group (CTG) (n=20) or MON monotherapy group (MMG) (5 mg daily) (n=15) for 6 months. Asthma symptom diaries were recorded daily, regarding complaints (daytime, nighttime, morning time and cough complaints) between 0-4 ranges correlating with the intensity every day. The sum of those variables was calculated and was defined as mean asthma complaints score (MACS). Information regarding asthma attack rate for six months before the study and during the study were obtained by using a standardized questionnaire. Statistical analysis was done by SPSS 9.5. MACS of 1st month were found to be 3.96 ± 3.33 for CTG, and 4.76 ± 3.1 for MMG. MACS of 6th month were found to be 0.47 ± 0.31 for CTG, and 0.49 ± 0.43 for MMG. The amount of changes in MACS; -3.49 for CTG and -4.27 for MMG, were similar in both groups ($P=0.0866$) (Figure 1).

For CTG mean asthma exacerbation the rate decreased significantly from $1.4 \pm 1.3/6$ months before treatment to $0.6 \pm 0.5/6$ months during treatment ($P=0.007$).

For MMG, mean asthma exacerbation the rate decreased significantly from $1.4 \pm 1.1/6$ months before treatment to $0.5 \pm 0.5/6$ months during treatment ($P=0.004$). The degree of reduction in mean asthma exacerbation rate was found to be similar in both groups ($P>0.05$).

Monthly, mean total asthma scores showed similar changes in both groups during the study period ($P>0.05$) (Figure 1).

In this study we compared MON monotherapy alone or with added inhaled budesonide in the treatment of moderate persistent childhood asthma. We observed no significant therapeutical difference between MON monotherapy and combined therapy in MPA. Symptoms score and attack rate improvement were found similar in both groups.

Viral infections account for up to 85% of childhood asthma exacerbations, daily symptoms in children with asthma.¹ Bisgaard et al² showed that montelukast significantly decreased the rate of asthma exacerbations and increased time to exacerbation in 2- to 5-year-old patients with asthma whose symptoms were intermittent.

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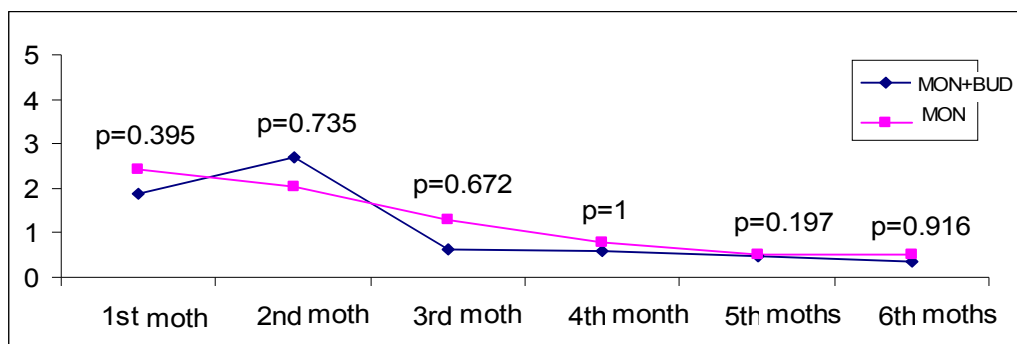


Figure 1. Comparison of progressive monthly changes in MACS during treatment period between CTG and MMG

Protective effect of MON against viral infections may be enough to control such MPA diagnosed children against exacerbations of asthma as in our study Viral infections may also increase asthma morbidity and as a result that may lead to misclassification of the asthma severity, so it is possible that some patients had mild persistent asthma rather than MPA. That also explains the improvements of the daily symptoms.

In our study children with moderate persistent asthma could be treated with higher doses of inhalant corticosteroids other than medium dose BUD+MON combined therapy. Even it might be used as control in one group of patients. According to current guidelines both of them seem to be equal treatment alternatives in treatment of MPA. But we believed that medium dose BUD+MON combined therapy was superior. Because, we know that if ICS doses higher than those used in the current study were administered, possibly a relatively flat dose-response relationship would have been obtained at such doses. Most of the benefit from inhaled glucocorticosteroids is achieved in adults at relatively low doses, equivalent to 400 ug of budesonide per day.³ Increasing doses provides little further benefit in terms of asthma control but increases the risk of side effects.^{3,4} So instead of giving higher doses of inhalational corticosteroids to children with moderate persistent asthma, using medium dose BUD+MON combination for treatment seems to be sufficiently effective, and also more ethical.

With data of spirometry, our results would have been more objective. But spirometry is not always feasible especially in young children.⁵ Owing to a possible spirometric variability occurring in our set of patients 6-17 years of age, spirometry as screening test was not taken into consideration. Koopman and et al.⁶ showed in their study that clinically masked increases in bronchial inflammation occur in treated patients. In our study we

only analyzed clinical improvement of asthmatic patients. Evaluating inflammatory mediators of different times during both treatments along with clinical assessment should be done in future studies.

The use of multiple drugs complicates treatment regimens in asthma and lowers patient compliance. MON monotherapy may offer clinical advantages of easier use and avoidance of ICS and combined treatments which have possible side effects.^{3,4}

Our results justify that montelukast monotherapy may be the effective initial alternative for the treatment of MPA.

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