Oral Montelukast Versus Inhaled Budesonide in Children with Mild Persistent Asthma: A Pilot Study

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Abstract

**Background:** Inhaled corticosteroids and montelukast are both recognised as first-line treatment for children with mild persistent asthma. **Objective:** The aim of this study was to compare budesonide dry powder, 200 mcg twice a day, with montelukast 5 mg nocte in children with mild persistent asthma. **Methods:** Children with mild persistent asthma were recruited from the out-patient department in a non teaching hospital. Double-blinded, double-placebo, randomised, crossover design was used. After a run-in period of two weeks, patients received either montelukast (6 to <=14 years, 5 mg; >14 years, 10 mg) and a placebo dry powder inhaler, 1 puff twice a day or budesonide dry powder, 200 mcg twice a day and a placebo tablet once a day for 8 weeks. After a washout period of two weeks, they were then switched over to receive the alternative treatment for 8 weeks. Outcome measures included change in force expiratory volume in 1 second (FEV-1), symptoms of asthma documented in asthma diary and the time to first exacerbation of asthma. **Results:** 19 Children were enrolled (13 boys and 6 girls, mean age 8.58 ± 2.4 years). For the 13 children who received oral montelukast, five dropped out during the washout period. For 15 children who received budesonide Turbuhaler, seven dropped out during washout period. The dropout rates were similar in both treatment groups. (Oral montelukast: 50.0%, budesonide Turbuhaler: 53.8%, p=1.00). Budesonide provided significant greater improvement in FEV-1 compared to montelukast after 4 weeks and 6 weeks of treatment (p=0.031 and p=0.027 respectively). Montelukast group had more asthma exacerbation than the budesonide group (p=0.0419). **Conclusions:** The current pilot study suggested that montelukast was less effective than budesonide DPI, 200 mcg twice a day, in preventing asthma exacerbation although the symptom-free days and FEV-1 changes at the end of treatment periods were found to be similar. Budesonide achieves faster improvement of FEV-1 and less asthma exacerbation than montelukast. Multicentre trial enrolling more patients to test this observation is needed.

**Keyword:** Asthma; Budesonide; Children; Montelukast; Randomised controlled trial