



MEETING ABSTRACT

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Real-life effectiveness of montelukast administered as monotherapy or in combination with inhaled corticosteroid (ICS) in pediatric patients with uncontrolled asthma

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Background

The efficacy of montelukast in the treatment of asthma has been demonstrated in numerous controlled clinical trials. The aim of this study was to assess the real-life effectiveness of montelukast administered as monotherapy or in combination with current ICS in children with uncontrolled asthma.

Methods

Twelve-week open-label, phase IV, multicenter, prospective cohort study. Eligible patients included children aged 2-14 years diagnosed with asthma for ≥ 6 months who were: (i) uncontrolled as per the Canadian Asthma Consensus Guidelines, and; (ii) either untreated, using a short-acting β_2 -agonist as-needed or using any dose ICS. In this analysis, patients with Asthma Control Questionnaire (ACQ) score >0.75 were included. Patients 6-14 and 2-5.9 years old were treated once-daily with montelukast 5mg and 4mg, respectively. Primary outcome measure was the proportion achieving asthma control (ACQ=0.75). Secondary outcomes were the absolute change in ACQ and in the Pediatric Asthma Caregiver's Quality of Life Questionnaire (PACQLQ) over time.

Results

Among the 328 patients included, 76 (23.2%) were treated with montelukast monotherapy and 252 (76.8%) with montelukast combined with ICS. By 4 weeks of treatment 61.3% and 52.9% of patients in the monotherapy and combination group, respectively, achieved asthma control.

These proportions increased to 75.0% and 70.9%, respectively, at week-12. Clinically and statistically ($P < 0.001$) significant improvements were observed in ACQ (monotherapy: mean (SD) of 1.67 (0.69) at baseline and 0.50 (0.52) at week-12; combination therapy: 2.02 (0.83) and 0.64 (0.86), respectively) and PACQLQ (monotherapy: mean (SD) of 5.34 (1.14) at baseline and 6.51 (0.85) at week-12; combination therapy: 4.42 (1.35) and 6.21 (1.03), respectively) in both patient subgroups. After a 12-week montelukast add-on therapy, 22.6% of patients reduced their ICS dosage.

Conclusions

Montelukast as monotherapy or in combination with ICS represents an effective treatment strategy for achieving asthma control in pediatric patients and improving caregivers' quality of life.

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Trial registration

Clinicaltrials.gov: 00832455.

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