Montelukast versus inhaled corticosteroids as monotherapy for prevention of asthma: which one is best?

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CRD summary
The review’s conclusion appeared to be that inhaled corticosteroids were effective and should be the first choice treatment for paediatric persistent asthma, with montelukast as a possible alternative in children unable to use inhaled corticosteroids. The reliability of these conclusions is unclear given numerous limitations in the conduct and reporting of the review.

Authors' objectives
To compare the effectiveness of montelukast compared with inhaled corticosteroids as monotherapy in the prevention of asthma in children.

Searching
MEDLINE was searched (up to December 2008) for English-language papers. Search terms were reported. Reference lists of identified articles were handsearched.

Study selection
Randomised, double-blind, double-dummy trials that compared inhaled corticosteroids with montelukast or placebo in children with asthma were eligible for inclusion. Eligible trials had to have follow-up data on at least 80% of enrolled patients and have a Jadad score of 3 points or more.

The ages of included children varied and ranged from two to 18 years. Treatments considered included: triamcinolone (400μg/day); montelukast (4mg/day to 10mg/day); formoterol (24μg/day); budesonide (400μg/day or 800μg/day); fluticasone propionate (100 μg/day or 200 μg/day); and PACT combination (fluticasone propionate 100μg plus salmeterol 50μg in the morning and salmeterol 50μg in the evening). Baseline scores of inhaled corticosteroids and montelukast were varied. The durations of included trials ranged from eight weeks to 12 months.

Outcomes considered were varied and included: clinical scores (mean/day and night time clinical symptoms), use of rescue medications (beta-2 agonists, systemic steroids), asthma rescue-free days, asthma control days (without use of rescue medications, free of asthma symptoms, etc.), frequency and severity of daily symptoms scores.

The authors did not state how the studies were selected for the review or how many reviewers performed the study selection.

Assessment of study quality
Validity was assessed using the Jadad scale that typically assessed the adequacy of randomisation, blinding and level of drop-outs, awarding a score of between 0 to 5 points.

The authors did not state how many reviewers performed the validity assessment.

Data extraction
Data on baseline treatment scores and outcomes (clinical scores, use of rescue medications, rescue-free days, asthma control days, etc.) following inhaled corticosteroid and montelukast or placebo therapy were extracted and summarised narratively.

The authors did not state how the data were extracted for the review, or how many reviewers performed the data extraction.

Methods of synthesis
Data on study results were summarised in a narrative synthesis.
Results of the review
Eight randomised controlled trials (RCTs) were included in the review (2,032 children). Follow-up was high (mean rate of 90.4%). The Jadad quality scores of the trials were unclear.

There were no statistically significant differences in improvement in clinical scores (two RCTs, 142 children), use of rescue medication (beta-2 agonists, three RCTs, 204 children) and frequency and severity of symptoms (one RCT, 62 children) between inhaled corticosteroids (triamcinolone, formoterol, budesonide), montelukast or placebo groups.

Fluticasone propionate, compared with montelukast or placebo, was associated with significantly greater improvements in rescue-free days (two RCTs, 1,336 children), asthma control days (two RCTs, 429 children), and daily symptom scores (one RCT, 63 children).

Authors' conclusions
The authors’ conclusions appeared to be that: inhaled corticosteroids were effective and should be the first choice treatment for paediatric persistent asthma; montelukast appeared to be a valid alternative treatment for the prevention of mild persistent paediatric asthma in children unable to use inhaled corticosteroids.

CRD commentary
The review question was clear with regard to eligible participants, interventions (and comparisons), study designs but not explicit for outcome measures. Only one database was searched for English-language publications, and no attempts were made to search for unpublished papers. Therefore, the potential for language and publication bias (with consequent exaggeration of treatment estimates) cannot be excluded. Review methods (study selection, data extraction, quality assessment) were incompletely reported and their rigor was unclear, so the possibility of reviewer bias and error cannot be excluded.

Results of quality assessment were not reported, so it is not possible to judge the quality of included trials. The decision to combine trial results in a narrative synthesis was justified given differences in trial characteristics and endpoints.

The reliability of the authors’ conclusions is unclear (and estimates of treatment effects are probably overestimated) given numerous limitations in the conduct and reporting of review methods.

Implications of the review for practice and research
The authors did not state any implications for practice or further research.

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Record Status
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