A clinical review of montelukast in the treatment of seasonal allergic rhinitis
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CRD summary
This review aimed to compare the efficacy of montelukast with current therapies for seasonal allergic rhinitis. The authors concluded that there was no evidence to support the use of montelukast (alone or in combination with antihistamines) over intranasal corticosteroids. Limitations in the review methods and the reporting of included studies mean that these conclusions should be viewed with caution.

Authors’ objectives
To assess the efficacy of montelukast in comparison with current therapies for seasonal allergic rhinitis.

Searching
MEDLINE and EMBASE were searched (1990 to week 8, 2003); the search terms were reported. Only studies published in the English language were included.

Study selection
Study designs of evaluations included in the review
Randomised controlled trials (RCTs) of at least 7 days’ duration were eligible for inclusion. The included studies were double- or single-blinded and of parallel-group or crossover design.

Specific interventions included in the review
Studies of montelukast were eligible for inclusion. No inclusion criteria for the comparators were specified. The included studies compared montelukast (alone or in combination with antihistamine) with placebo, antihistamine or intranasal corticosteroids. Dosing regimens varied and were reported in detail. The duration of treatment in the included studies ranged from 2 to 7 weeks.

Participants included in the review
Studies of patients with seasonal allergic rhinitis were eligible for inclusion.

Outcomes assessed in the review
No inclusion criteria for the outcome measures were specified. The outcomes assessed in the included studies were daytime composite nasal symptom score, night-time nasal symptom score, composite nasal symptom score, hourly nasal symptom score, average peak inspiratory flow, nasal peak inspiratory flow and the Rhinoconjunctivitis Quality of Life Questionnaire (RQLQ).

How were decisions on the relevance of primary studies made?
The authors did not state how the papers were selected for the review, or how many reviewers performed the selection.

Assessment of study quality
The authors did not state that they assessed validity.

Data extraction
The authors did not state how the data were extracted for the review, or how many reviewers performed the data extraction. Data on treatment regimens, key end points and changes in symptom scoring were extracted.

Methods of synthesis
How were the studies combined?
The studies were combined in a narrative.

How were differences between studies investigated?
Between-study heterogeneity was not formally assessed. Some study details were presented in a table and in the text, but differences between the studies were not explicitly discussed.

Results of the review
Eleven RCTs (n=4,819), eight of which were double-blind and three single-blind, were included.

Montelukast monotherapy.

Five trials compared montelukast with placebo. Four of these trials found that montelukast was associated with a statistically significant improvement in daytime composite nasal symptom score; the fifth trial had non significant findings for this outcome measure. Three trials also found that loratadine was associated with a statistically significant improvement compared with placebo, and one showed a statistically significant improvement for fluticasone compared with placebo.

Three trials compared montelukast with fluticasone. Two found statistically significant improvements in their primary outcome measures (daytime composite nasal score and hourly nasal symptom score after allergen challenge) in favour of fluticasone; one trial found no significant difference.

Montelukast in combination with antihistamines.

Four trials compared montelukast in combination with loratadine with placebo. The primary outcomes assessed included daytime composite nasal symptom score and average a.m./p.m. peak inspiratory flow. All trials found a statistically significant improvement with montelukast in combination with loratadine compared with placebo. One trial also reported a statistically significant improvement in a.m./p.m. peak inspiratory flow with fexofenadine compared with placebo.

Two trials compared montelukast combined with loratadine with fluticasone. One found no significant difference between the two treatments on daytime composite nasal symptom score. The other found a statistically significant improvement in the RQLQ in favour of fluticasone.

The only trial comparing montelukast combined with loratadine with fexofenadine found no significant difference in average a.m./p.m. peak inspiratory flow.

Two trials comparing montelukast combined with cetirizine with placebo found a statistically significant improvement in favour of the combination in both nasal peak inspiratory flow and composite nasal symptom score. One of these trials also reported a statistically significant improvement with cetirizine alone and cetirizine combined with mometasone compared with placebo for both outcomes. The other trial reported a statistically significant improvement in favour of oral combined with nasal budesonide compared with placebo for both outcomes.

Cost information
The authors discussed the average wholesale price of montelukast in comparison with other therapies for seasonal allergic rhinitis.

Authors' conclusions
The evidence presented in this review does not support significant advantages of montelukast, compared with existing therapies (including non-sedating antihistamines and inhaled intranasal corticosteroids), in improving nasal congestion. The trials in the review showed that in the treatment of allergic rhinitis, leukotriene receptor antagonists are often more effective than placebo, comparable in efficacy to antihistamines, and potentially less effective than inhaled or intranasal corticosteroids.
CRD commentary
The review question was clearly stated. However, the authors did not specify any inclusion criteria for the outcome measures, beyond the statement that they aimed to assess efficacy, safety and tolerability. The search was limited to two electronic databases and only literature published in English was included. Hence, it is possible that relevant studies were missed and that language and/or publication bias might have been present. No details of the review process were reported, thus it was not possible to assess whether steps were taken to reduce errors and/or reviewer bias.

The results of the included studies were tabulated and discussed in a narrative in which studies were grouped by comparator (placebo or active control). The narrative lacked an overall summary and focused on reporting the individual study results. Some potentially important study details were not presented, e.g. the number of participants in each treatment arm and baseline characteristics. Given these limitations, the conclusions of the review should be interpreted with caution.

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

Bibliographic details

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This is a critical abstract of a systematic review that meets the criteria for inclusion on DARE. Each critical abstract contains a brief summary of the review methods, results and conclusions followed by a detailed critical assessment on the reliability of the review and the conclusions drawn.