Title The Challenges of Early Assessment: Leukotriene Receptor Antagonists

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Aim

– To evaluate the efficacy and safety of leukotriene receptor antagonists (LTRAs) as compared to inhaled corticosteroids (ICs) in the treatment of mild-to-moderate chronic or recurrent asthma.

Conclusions and results

Reviewers discovered that most of the evidence from 22 relevant randomized controlled trials was reported exclusively in the form of abstracts or conference posters. Drug manufacturers responsible for funding the trials were asked to clarify vague, missing, or problematic information and data, but did not respond. Given the sparsity of information, reviewers could not establish with any degree of confidence the methodological soundness of at least 65% of the included studies and the population(s) to which results of trials could be generalized. Meta-analysis was therefore considered inappropriate, and only a qualitative synthesis was possible. Reviewers also could not determine whether the low overall quality of the studies retrieved was due to major methodological shortcomings, publication status of trial reports, or both. Because the collective evidence for the efficacy and safety of the two LTRAs is not yet satisfactory, their value as monotherapy or as an adjunct to ICs cannot be determined at present.

Methods

This systematic review planned to compare LTRAs and ICs by identifying four basic definitions and concomitant research designs: three designs using LTRAs as an add-on to ICs, and the fourth comparing LTRAs and ICs head-to-head. Most of the studies identified (64.6%) fell into the latter design category, including 6 of 8 montelukast studies and 8 of 14 zafirlukast studies. Due to the sparsity of information, reviewers relaxed the inclusion criteria to include studies with vague or ad hoc definitions of "mild-to-moderate, chronic or recurrent asthma" to describe the trial populations, as well as studies with ambiguous information about participants' pre-trial symptom status while on ICs. However, the minimum, symptom-controlling IC dose had to be established before randomization.

Further research/reviews required

Most of the investigation comparing the utility of LTRAs in relation to ICs is currently in progress; full evaluation of the evidence concerning the value of these drugs awaits public availability of this information.

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