OM-85 BV, an immunostimulant in pediatric recurrent respiratory tract infections: a systematic review

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CRD summary

This review concluded OM-85 BV treatment reduced the risk of respiratory tract infection in children. These conclusions were supported by the results of the review, but should be interpreted with caution due to possible limitations of the search, unclear review process and lack of details regarding the analysis. The review was sponsored by the drug manufacturer.

Authors' objectives

To assess the efficacy of OM-85 BV (Broncho-Vaxom) in the prevention of paediatric recurrent respiratory tract infections.

Searching

PubMed, EMBASE, TOXLINE, HealthSTAR, AIDSLINE, CANCERLIT, AMED, The Cochrane Library, TOXMAP, TOXLINE Special, DART Special, HSDB, IRIS, ITER, GENE-TOX, ChemIDplus and Haz-Map were searched to April 2009. Search terms were reported. Reference lists of relevant review articles and books were screened. Relevant experts and manufacturers were contacted to identify additional studies. Both published and unpublished studies were eligible.

Study selection

Double-blinded randomised controlled trials (RCTs) that compared OM-85 BV to placebo in children (age one month to 12 years) with a history of recurrent respiratory tract infections were eligible for inclusion.

Studies were conducted in Western Europe and Mexico. All were partially or totally industry sponsored. One study required children to have an episode of respiratory tract infection at admission; other studies included children with a history of respiratory tract infection. The mean number of respiratory tract infection experienced in the previous year was six (where reported). Mean age at admission ranged from four to 10 years.

The author did not state how studies were assessed for inclusion.

Assessment of study quality

Studies were assessed for methodological quality using the Jadad criteria of randomisation, blinding and description of withdrawals. Studies were assigned a score from 1 to 5.

The authors did not state how many reviewers assessed study quality.

Data extraction

Data on continuous outcomes were extracted as means and standard deviations (SD) and used to estimate the mean difference together with 95% confidence intervals (CI). Dichotomous data were extracted as the number of patients with the outcome and total number of patients in each treatment group and used to calculate risk differences (RD) and odds ratios (OR) together with 95% CI. Where possible, data were extracted on an intention-to-treat basis.

The authors did not state how many reviewers performed the data extraction.

Methods of synthesis

The authors stated that dichotomous data were pooled using the Peto-Mantel-Haenszel fixed-effect model; no other details of pooling were reported. Summary measures reported in the review were odds ratios, number needed to treat

and weighted mean differences (WMD). Sensitivity analysis was made by sequential elimination of trials and by elimination of outlier trials. Heterogeneity was assessed, but no details of the methods used were reported. Publication bias was assessed with funnel plots.

Results of the review

Eight double-blind RCTs (851 children) were included. All studies provided an adequate description of withdrawals. Only one study provided an adequate description of randomisation. Two studies provided an adequate description of blinding.

Treatment with OM-85 BV led to a significant reduction in the proportion of children who experienced at least three respiratory tract infections over six months compared to placebo (OR 0.33, 95% CI 0.25 to 0.45, number needed to treat=4, 95% CI not reported). The proportion of children who experienced at least one respiratory tract infection was also significantly reduced (OR 0.33, 95% CI 0.23 to 0.49, number needed to treat=6, 95% CI not reported). The mean number of respiratory tract infections over six months was also significantly reduced in those treated with OM-85 BV compared to those treated with placebo (WMD -1.21, 95% CI -1.39 to -1.03). There was significant heterogeneity for all analyses. Sensitivity analysis did not alter the review findings.

The incidence of adverse events was similar in children who received placebo and OM-85 BV. There were no deaths or serious adverse events attributed or possibly attributable to the study medication.

There was no evidence of publication bias.

Authors' conclusions

The population treated with OM-85 BV had significantly and consistently fewer cases of recurrent respiratory tract infections.

CRD commentary

The review addressed a clear question. Inclusion criteria were defined, although they had to be deduced from a table rather than being clearly reported in the text. An extensive literature search for both published and unpublished literature was undertaken, but the search terms used appeared restrictive and so it was possible that relevant studies were missed. Study quality was assessed using appropriate criteria. The restriction of the review to randomised double-blinded studies meant that all included studies were of reasonable quality. Details of the review process were not reported, so it was not known whether any steps were taken to minimise bias and errors were taken. The statistical analysis lacked detail and the reporting of results was somewhat confusing, which made it difficult to determine the reliability of the analysis.

The authors' conclusions were supported by the results, but should be interpreted with caution due to possible limitations of the search, unclear review process and lack of details regarding the analysis. It should be noted that the review was sponsored by the drug manufacturer.

Implications of the review for practice and research

Practice: The authors did not state any implications for practice.

Research: The authors stated that future RCTs should provide details of respiratory tract infections from the follow-up period using a standardised clinical classification.

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