Meta-analysis: Saccharomyces boulardii for treating acute diarrhoea in children

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CRD summary
This review investigated the effectiveness of Saccharomyces boulardii in treating gastroenteritis in children. The authors concluded that Saccharomyces boulardii therapy appears to provide a moderate benefit in healthy infants and children, in terms of reduced duration of diarrhoea, but methodological limitations dictate that this result should be treated with caution. The conclusions are likely to be reliable.

Authors' objectives
To evaluate the effectiveness of Saccharomyces boulardii (S. boulardii) in treating gastroenteritis in children.

Searching
MEDLINE (1966 to August 2006), EMBASE (1980 to August 2006), CINAHL (1982 to August 2006), the Cochrane Database of Systematic Reviews (Issue 3, 2006) and the Cochrane Controlled Trials Register (Issue 3, 2006) were searched for papers in any language; the search terms were provided. In addition, references from original studies and review articles were screened and the manufacturer of S. boulardii was contacted to assist in identifying any other published or unpublished work.

Study selection
Study designs of evaluations included in the review
Randomised controlled trials (RCTs) were eligible.

Specific interventions included in the review
Studies comparing S. boulardii with placebo or no intervention were eligible for inclusion. The dosage of S. boulardii in the included studies ranged from 250 to 750 mg/day, taken over 5 to 6 days. Three of the included studies were placebo-controlled trials; the remaining studies gave no additional intervention to the control group

Participants included in the review
Studies with children with acute diarrhoea (as defined by the investigators) were eligible. The participants in the included studies were aged between 2 months and 12 years.

Outcomes assessed in the review
The primary outcomes were duration of diarrhoea, stool output, the percentage of children with diarrhoea at set investigator-defined cut-off points, and the percentage of children with diarrhoea lasting over 7 days. The secondary outcomes were stool frequency, vomiting, adherence to treatment, adverse effects and other reported outcomes. Only one included study gave a definition for the termination of diarrhoea.

How were decisions on the relevance of primary studies made?
Three reviewers independently screened the studies, and any discrepancies were resolved by discussion.

Assessment of study quality
Three reviewers independently assessed the quality of the studies using the following criteria: allocation concealment; blinding; intention-to-treat analysis; and comprehensive follow-up determined by percentage of participants excluded or lost to follow-up.

Data extraction
Three reviewers independently extracted the data using standard extraction forms, and any discrepancies were resolved.
Methods of synthesis
How were the studies combined?
Studies with similar outcomes were combined in a meta-analysis to estimate the pooled weighted mean difference (WMD) for continuous variables and risk ratios (RR) and the numbers-needed-to-treat for binary measures, alongside 95% confidence intervals (CIs). Fixed-effect models were used when the data were homogeneous. Publication bias was assessed using funnel plots.

How were differences between studies investigated?
Heterogeneity was assessed using the chi-squared test and the I-squared statistic. A sensitivity analysis was conducted, based on the methodological quality criteria.

Results of the review
Five studies (n=619) were included.

Only 2 studies were assessed as having a low risk of bias. An adequate method of concealment was identified in only one study. Three studies used double-blinding. All studies described withdrawals and drop-outs. Two trials reported an adequate description of the intention-to-treat analysis.

There was a statistically significant reduction in the duration of diarrhoea in the group receiving S. boulardii (WMD -1.1, 95% CI: -1.3, -0.83; 4 RCTs); the statistical test for heterogeneity was not significant. Participants receiving S. boulardii were statistically significantly more likely to be cured on days 2 and 4 than participants in the control group (1 RCT). Based on 2 RCTs presenting data for different time periods, participants receiving S. boulardii were statistically significantly less likely to experience diarrhoea on day 3, 6 and 7 than the control group. There was a statistically significant reduction in the risk of diarrhoea lasting for more than 7 days for the group receiving S. boulardii compared with the control group (1 RCT).

Based on 4 RCTs presenting data for different time periods, after day 1 there was a statistically significant reduction in the frequency of stools compared with the control group. There was no statistical difference in the duration of vomiting between groups (1 RCT). There was a statistically significant reduction in duration of hospitalisation in the group receiving S. boulardii compared with the control group (1 RCT).

Authors' conclusions
S. boulardii therapy for diarrhoea in healthy infants and children appears to provide a moderate benefit, in terms of reduced duration of diarrhoea, but methodological limitations dictate that this result should be treated with caution.

CRD commentary
The review question was well defined and inclusion criteria for the study designs, participants, interventions and outcomes of interest were clearly stated. A comprehensive search for relevant literature was conducted and no language restrictions were applied, thus reducing the risk of language bias. The authors also attempted to identify any unpublished data, thereby reducing the risk of publication bias. Three reviewers independently selected studies and extracted the data, which reduces the potential for bias and errors. All bar one of the included papers originated from non European countries, and the authors acknowledged that this may reduce the generalisability of the findings. Three reviewers assessed the validity of the included studies using adequate criteria. Statistical heterogeneity was assessed and the data synthesis appeared appropriate.

The authors presented a clear discussion of the potential limitations of the review. Their conclusions are likely to be reliable.
Implications of the review for practice and research
Practice: The authors did not state any implications for practice.

Research: The authors stated that further research into the cost-effectiveness of treatment, to further delineate the groups, and to determine the most effective dosage using validated outcomes, is warranted.

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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.