Use of nonhuman milks in the dietary management of young children with acute diarrhea: a meta-analysis of clinical trials.

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Authors' objectives
To assess the effects of continued feeding of nonhuman milks or formulas to young children during acute diarrhoea.

Searching
MEDLINE was searched using the following keywords: 'diarrhoea', 'gastroenteritis', 'milk', 'milk intolerance', 'lactose malabsorption ', 'lactose intolerance', 'nutrition' and 'dietary therapy'. Additional material was obtained by examining reference lists and contacting experts in the field.

Study selection
Study designs of evaluations included in the review
Randomised controlled trials were included, although the validity of randomisation could not be checked in most studies. The trials had to report at least one major outcome variable, and have study diets compatible with the group assignments.

Specific interventions included in the review
Soy formula plus lactose, milk formula, cows' milk and skimmed milk. Studies of yoghurt and of human milk were excluded, as were studies of milk added to mixed diets, unless milk was the predominant energy source.

Participants included in the review
Children with acute diarrhoea aged up to 59 months. Most studies included children younger than 36 months and only hospitalised patients. Projects that specifically included only children with persistent diarrhoea were excluded.

Outcomes assessed in the review
Stool frequency or amount; duration of diarrhoea; change in body weight; and treatment failures defined by differing criteria (stool frequency or amount either worsening or greater than cut-off; duration of symptoms of diarrhoea, vomiting, and/or dehydration greater than cut-off; recurrence of diarrhoea and/or dehydration; weight loss; evidence of lactose intolerance).

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

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

Data extraction
The outcome data were extracted into tabular form, and the data were summarised independently by two of the authors.

Methods of synthesis
How were the studies combined?
The data were pooled using a meta-analysis. The hypothesis of no treatment effect was assessed with Stouffer's combined test. For significant differences, the individual effect sizes were estimated using relative risk (RR) for treatment failure and weighted average for other continuous outcome measures.
How were differences between studies investigated?
Tests for homogeneity were undertaken. When significant heterogeneity was present, the individual studies were explored for differences in study design or participants. Where relevant, subgroup analysis was undertaken.

Results of the review
Twenty-nine studies involving a total of 2,215 patients were included.

Lactose-containing versus non-lactose-containing diets.

Thirteen studies (873 patients) compared treatment failures. The RR of treatment failure for children on lactose-containing diets was 2.1 (95% confidence interval, CI: 1.6, 2.7), compared to children who did not receive lactose (p<0.0001). The significant heterogeneity between studies was explained by analysing studies on the basis of initial severity of dehydration (moderate or severe and mild), year of the study (reflecting the management approach), or definition of treatment failure. Children with mild or no dehydration, and those who are managed according to appropriate treatment protocols, have similar treatment failure whether they receive lactose or not.

Four studies (387 patients) compared stool frequency and 4 studies (209 patients) compared stool amount. There was significant heterogeneity between studies, and any effects identified were not clinically significant.

Nine studies (826 patients) compared duration of diarrhoea. There was significant heterogeneity between studies, even when studies allowing the addition of solid foods were excluded.

The data on weight gain were insufficient to be reliably assessed.

Undiluted lactose-containing milk versus the same milk at reduced concentration or introduced later during therapy.

Fourteen studies (934 patients) compared treatment failures. The RR for undiluted milk was 1.3 (95% CI: 0.9, 1.8) and non significant; the results of the heterogeneity test were also non significant (p=0.45). Analysing by initial severity of dehydration, the RR was significantly higher for the more severe cases (2.0, 95% CI: 1.2, 3.3), but non significant for milder cases.

Six studies (480 patients) compared stool frequency and 3 studies (272 patients) compared stool amount. The analyses found a slight increase in stool output with undiluted diets, but the differences were of minor clinical importance.

Ten studies (876 patients) compared duration of diarrhoea. There were no significant differences by dietary group. Removal of those studies permitting consumption of other foods did not alter this conclusion.

Seven studies (509 patients) compared change in body weight. There was a significant advantage of undiluted milk, with an average effects size of 0.25 standard deviations (p=0.002). The effect was homogeneous across studies (p=0.16).

Authors' conclusions
Routine use of lactose-free milk or dilution of milk are unnecessary, especially when oral rehydration therapy and early feeding form the basic approach to the management of diarrhoea in infants and children.

CRD commentary
This is a thorough review, limited by the available data. The search years are not provided. The authors acknowledge the potential problem of publication bias: only 2 unpublished reports were included. The authors also acknowledge several problems: many measures were not supported with objective clinical measures, there was significant heterogeneity between the studies, and the studies did not consistently report relevant information. There is some inconsistency between the patient numbers presented in the tables and the text.
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