Systematic review and meta-analysis: the clinical and physiological effects of fibre-containing enteral formulae
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CRD summary
The authors concluded that fibre in enteral feeding is well tolerated and has clinical benefits for patients with diarrhoea and possibly those with constipation. It may moderate extremes of bowel function. These conclusions should be regarded with caution due to the small amount of data on clinical outcomes and the questionable quality of the included studies.

Authors' objectives
To evaluate the effect of fibre-supplemented enteral feeds on gastrointestinal function among patients and healthy volunteers.

Searching
PubMed, EMBASE and BIOSIS Previews were searched in July 2006. Search terms were reported. The reference lists of articles retrieved were hand searched and experts in the field were consulted for additional studies. The search was not restricted by year of publication, format or language, provided studies had an abstract in English.

Study selection
Randomised controlled trials (RCTs), non-randomised controlled trials and observational cohort studies in any setting that compared fibre-supplemented versus fibre-free enteral feeding were eligible for inclusion, provided that participants were healthy volunteers or patients (of any nutritional status) and at least one year old. Oral or tube feeding, for at least three days, was required to be the main source of nutrition. Studies with a self-selected (SS) diet arm were eligible, provided they included a fibre-free or fibre-containing enteral feeding arm. The review outcome was gastrointestinal function, including clinical and physiological effects and tolerance. Studies of infant formula or without a fibre-free intervention were excluded.

In the included studies, volunteer populations were fed orally and patient populations were tube fed by various routes (e.g. nasogastric, naso-jejunal or via jejunostomy). Interventions included over 15 different fibre sources. The number of fibre sources used and the dosage varied widely. In about half of the studies the fibre was an integrated part of the feeding formula used. Over one third of studies reported use of antibiotics as a co-intervention. Diarrhoea and constipation were the most frequently reported clinical outcomes. Commonly reported physiological outcomes were: frequency, transit time, weight, and consistency of stools; faecal short chain fatty acids; and faecal microflora. Measures of tolerance included nausea, vomiting, flatulence, cramps and bloating. The definitions used for outcomes such as diarrhoea and constipation varied widely. The mean duration of treatment was 10 days for volunteers, nine to 24 days for adult patients and 18 to 93 days for paediatric patients.

Potentially relevant articles were selected by one reviewer and checked for eligibility by a second reviewer. Disagreements were referred to a panel of authors.

Assessment of study quality
Study validity was assessed with the JADAD tool (which measures adequacy of randomisation, blinding, and management of withdrawals and dropouts). Each study was awarded a score out of a maximum of five points. The higher the JADAD score, the better the study quality. A published tool for grading study design was also used.

The validity assessment was conducted by one reviewer and checked by a second.

Data extraction
Odds ratios (OR) were calculated for dichotomous outcomes and mean differences (MD) for continuous outcomes, with 95% confidence intervals (CI) or standard errors (SE). Data were extracted using a standardised format.

The authors did not state how the data were extracted for the review or how many reviewers performed the data extraction.
Methods of synthesis
Data were pooled using a fixed effect model. Heterogeneity was assessed using the I^2 statistic and was explored with meta-regression, to determine whether specific variables (e.g. acute/chronic setting, adult/paediatric population) accounted for variability in results. Publication bias was assessed using funnel plots, Begg's and Egger's tests. An a priori decision was taken not to combine results from healthy volunteers with those of patient populations.

Results of the review
Fifty-one studies were included in the review (n=1,762: 171 volunteers and 1,591 patients); 43 were RCTs and eight were non-RCTs (or of unclear design). Thirteen studies were available in abstract form only. The methodology of RCTs was poorly reported in many cases: one scored five on the Jadad scale; the rest scored nought to four points.

Fibre versus fibre-free nutrition outcomes

Diarrhoea
Two RCTs reported this outcome in volunteer populations. Both trials reported increased watery stools in the fibre-free groups. When 13 RCTs (n=683) of patients were pooled there was a significantly reduced incidence of diarrhoea in the groups receiving fibre (OR 0.68, 95% CI: 0.48, 0.96, p=0.03). Meta-regression (13 RCTs) indicated that beneficial effects of fibre were significantly more likely when the incidence of diarrhoea was high (p=0.0002).

Constipation
There was no statistically significant difference between groups of patients in the incidence of constipation in acute settings (7 RCTs, n=144) and few data on this outcome in chronic care settings.

Bowel frequency (times daily)
A statistically significant increase was associated with fibre supplementation among volunteers (MD 0.14, SE 0.05, p=0.005, 9 RCTs, n=307) and chronic-care patients (MD 0.27, SE 0.08, p=0.001, 5 RCTs, one non-RCT, n=80). However, among studies of patients in an acute setting there was a statistically significant decrease in the group receiving fibre (MD -0.22, SE 0.08, p=0.006; 3 RCTs, n=200): there was statistically significant heterogeneity for this result (p=0.03, I^2=72%). Meta-regression of studies from both volunteer (9 RCTs) and patient (9 RCTs, 1 non-RCT) settings indicated that fibre supplementation significantly increased bowel frequency in those with low bowel frequency and decreased it in those with high frequency (p=0.00002, p<0.00001 respectively).

Tolerance
The incidence of intolerance symptoms were mentioned in twenty six studies. Four studies in volunteers and 17 in patients reported no differences between the groups. Four patient studies reported increased flatulence, abdominal distension or vomiting. One volunteer study reported an increase of all three symptoms in the group receiving fibre supplementation.

Other results were reported in the paper.

Authors' conclusions
Fibre in enteral feeding is well tolerated and has clinical benefits for patients with diarrhoea and possibly those with constipation. It may moderate extremes of bowel function.

CRD commentary
The review objectives were broad and the outcomes were not explicitly prioritised or limited to the most clinically relevant, with the consequence that a very large number of findings were reported. Relevant sources were searched for studies, but it does not appear that specific efforts were made to retrieve unpublished studies. This created potential publication bias, though statistical testing found no significant evidence of such bias. Moreover the requirement for an abstract in English may have created language bias. Initial selection of studies was undertaken by a single reviewer, which increased the risk of error and bias in the review. Validity assessment was conducted independently by two reviewers, but it is unclear whether this also applied to data extraction. Some relevant factors were considered in validity assessment, but no details were provided on methodological, clinical or demographic characteristics of individual studies (e.g. sample number, allocation concealment, nature of blinding, follow-up rate, duration of intervention, participant age, indication for tube feeding). This lack of information makes it difficult to interpret the
reliability or applicability of the findings. Appropriate statistical techniques were used to combine the studies and to assess for heterogeneity and publication bias, though it was not always clear whether reported results were based on between-group comparisons or changes from baseline. Potential sources of heterogeneity were appropriately explored by meta-regression and were well addressed in the text, along with other possible sources of bias, such as regression to the mean. The results of RCTs were given priority over non-randomised studies, but the poor quality of many RCTs did not appear to be taken into account in the interpretation of findings. A relatively small proportion of the included studies reported relevant data on clinical outcomes and CIs were wide. The authors’ conclusions should be regarded with caution due to the small amount of data on clinical outcomes and the questionable quality of the included studies.

Implications of the review for practice and research
Practice: the authors stated that fibre supplementation should be considered as a first line treatment in clinical care. Research: the authors stated that the use of fibre supplementation in long-term care should be evaluated in a community setting, as should the use of laxatives in long-term tube-fed patients. They recommended clinical studies on the effect of fibre supplementation on constipation, along with investigation of the mechanisms of constipation and diarrhoea. They noted that such studies need to be clearly defined and consistent end points and markers of gastrointestinal function.

Funding
Partial industry-funding from Numico.

Bibliographic details

PubMedID
17922802

DOI
10.1111/j.1365-2036.2007.03544.x

Original Paper URL

Indexing Status
Subject indexing assigned by NLM

MeSH
Adult; Anti-Bacterial Agents /therapeutic use; Child; Constipation /chemically induced /epidemiology; Defecation /drug effects; Diarrhea /chemically induced /epidemiology; Dietary Fiber /administration & dosage /adverse effects /classification; Dose-Response Relationship, Drug; Enteral Nutrition /adverse effects /methods; Fatty Acids, Volatile /metabolism; Feces /chemistry /microbiology; Gastrointestinal Transit /drug effects; Humans; Incidence; Randomized Controlled Trials as Topic

AccessionNumber
12008103675

Date bibliographic record published
23/12/2008

Date abstract record published
31/03/2009

Record Status
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.