Systematic review: the effects of fibre in the management of chronic idiopathic constipation

Suares NC, Ford AC

CRD summary
This review concluded that soluble fibre could aid the management of chronic idiopathic constipation, but the data for insoluble fibre were conflicting, and better evidence was needed for both types of fibre. The limitations of the evidence mean that the authors’ conclusions seem appropriate, but the searches were not recent (2010), and further evidence may now be available.

Authors’ objectives
To evaluate the efficacy of soluble or insoluble fibre supplementation in the management of chronic idiopathic constipation.

Searching
MEDLINE, EMBASE, and Cochrane Central Register of Controlled Trials (CENTRAL) were searched in July (CENTRAL) or September (other databases), 2010, with no language restrictions. Search terms were reported. The bibliographies of identified studies were handsearched, as were relevant conference abstracts published between 2002 and 2010.

Study selection
Eligible were randomised controlled trials (RCTs) evaluating the efficacy of soluble or insoluble fibre for the management of chronic idiopathic (not linked to a disease) constipation, in adults. At least 90% of participants had to be over 16 years old. The first period of any eligible crossover RCT was included. Chronic idiopathic constipation had to be defined according to clinical symptoms; a physician’s diagnosis; or the Rome I, II, or III criteria. Therapy had to last for at least one week. The outcomes of interest were response to therapy, mean number of stools per week, mean symptom score, and adverse events. Trials of patients with organic or drug-induced constipation; highly selected groups of patients, such as elderly patients; or patients with irritable bowel syndrome or diverticular disease were excluded.

The included trials were conducted in the UK, the USA, Brazil, Spain, Italy or Finland; all were performed in tertiary care, except one. Most assessed soluble fibre supplements, including psyllium or a combination of inulin and maltodextrine. A few assessed insoluble fibre, in the form of wheat bran or rye bread. Treatments lasted from two to eight weeks. The dosage and timing of supplements varied. All control groups received placebo. The presence of chronic idiopathic constipation was confirmed by clinical diagnosis; reporting of three stools or less per week; Rome II criteria; or negative investigations. The percentage of female participants ranged from 64 to 100. One trial allowed a non-medicated cleansing enema for patients who did not have a bowel motion for eight consecutive days.

Two reviewers independently assessed studies for inclusion; any disagreements were resolved by discussion.

Assessment of study quality
Risk of bias was assessed by two independent reviewers, using Cochrane collaboration criteria, for randomisation; allocation concealment; blinding; completeness of follow-up; use of intention-to-treat analysis; and selective reporting. Any disagreements were resolved by discussion.

Data extraction
The outcome data were extracted, by two independent reviewers, according to the intention-to-treat principle (all drop-outs were assumed to be treatment failures). If information on drop-outs was unavailable, all sufficient data were analysed.

Methods of synthesis
The results from the individual trials were presented in a narrative synthesis.

Results of the review
Six RCTs were included (368 participants; range 22 to 201). The risks of bias in randomisation and allocation concealment were unclear in all trials; four trials were double-blind, one was single-blind, and one was unclear on blinding.

Compared with placebo, soluble fibre had greater improvements in outcomes (four RCTs). Each trial had a different definition of outcome, including global symptoms (86.5% versus 47.4% for placebo; 201 participants), mean stool frequency per week (0.9 versus 0.2 for placebo; 22 participants), normalisation of evacuation (86.7% versus 30% for placebo; 60 participants), and straining during defaecation (35.7% versus 78.6% for placebo; 32 participants).

Mixed results were shown for insoluble fibre (two RCTs). One trial (24 participants) demonstrated no significant difference between bran and placebo, in outcome (no further straining). The other trial (29 participants) demonstrated significant improvements with rye bread, compared with low-fibre bread; these included a greater mean number of stools per day, softer stools, and a reduction in difficulty with defaecation.

None of the trials reported total adverse events. Further results were reported in the paper.

**Authors' conclusions**
Soluble fibre could help to manage chronic idiopathic constipation, but the data for insoluble fibre were conflicting. More high-quality RCTs were needed for both types of fibre.

**CRD commentary**
The review question and inclusion criteria were clearly defined. Relevant databases were searched and no language and publication status restrictions were reported, reducing the likelihood of relevant studies being missed. The review processes were all carried out by two people independently, minimising the risk of reviewer error and bias.

Suitable quality assessment criteria were employed, revealing that all areas of risk were high or unclear. Given high diversity between the trials, the narrative synthesis was appropriate. The authors acknowledged the few participants included in the trials, and stated that adverse events were poorly reported.

Given the limitations of the evidence, the authors' conclusions seem appropriate, but the searches were not recent (2010), and further evidence may now be available.

**Implications of the review for practice and research**
**Practice:** The authors stated that there was a lack of high-quality evidence to support the national and international guidelines that recommend fibre in the early management of constipation, but fibre supplementation should not be avoided as there were likely to be few risks with this approach.

**Research:** The authors stated that large, rigorously designed RCTs were needed to investigate the efficacy of fibre in managing chronic idiopathic constipation. These trials should examine both soluble and insoluble fibre, recruit patients from primary care, use validated outcome measures, fully report any adverse events, and adhere to the recommendations of the Rome committee in their design.

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