
Effect of fibre, antispasmodics, and peppermint oil in the treatment of irritable bowel syndrome: systematic review and meta-analysis

Ford A C, Talley N J, Spiegel B M, Foxx-Orenstein A E, Schiller L, Quigley E M, Moayyedi P

CRD summary

This review concluded that fibre, antispasmodics and peppermint oil are more effective than placebo for treating irritable bowel syndrome. Overall, although the review was generally well conducted, the authors' analyses should be interpreted with caution given their reliance on an often limited number of small and sometimes potentially quite different studies.

Authors' objectives

To compare the effectiveness of fibre, antispasmodics and peppermint oil with placebo or control for treating irritable bowel syndrome.

Searching

MEDLINE (1950 to April 2008), EMBASE (1980 to April 2008) and the Cochrane Central Register of Controlled Trials (2007) were searched for publications in any language. In addition, references of retrieved articles and conference proceedings (2001 to 2007) were manually searched. Search terms were reported.

Study selection

Randomised controlled trials (RCTs) comparing fibre, antispasmodics and peppermint oil with placebo or no treatment control to treat patients, aged 16 years or over, with irritable bowel syndrome (IBS) not related to organic disease and diagnosed according to specific criteria (i.e. Manning, Krusik score, Rome I, II or III), were eligible for inclusion. Eligible studies were required to include treatment duration of at least one week and at least one week follow-up.

Studies were also required to report a global assessment of cure or improvement of symptoms, or cure or improvement of abdominal pain, as reported by the patient or health professional, as the primary outcome. Secondary outcomes reported adverse events and predominant stool patterns. Studies including patients with other functional gastrointestinal disorders had to report data separately.

Included studies assessed patients with and without constipation in secondary and tertiary settings in Denmark, Germany, UK, USA and India. The proportion of women included in the studies ranged from 20% to 90%. Interventions varied in type and dose. Treatment durations ranged between one and three months for fibre and peppermint oil, and between seven days and 12 months for antispasmodics.

Two reviewers independently screened papers for relevance and discrepancies were resolved by consensus.

Assessment of study quality

Two reviewers independently assessed study quality using the Jadad scale, including criteria on randomisation, blinding, allocation concealment and withdrawals. The Jadad scale awards scores between 0 and 5, with 5 representing the highest quality. It was unclear how discrepancies were resolved.

Data extraction

Dichotomous data on persistent or unimproved global symptoms of IBS or abdominal pain were extracted and relative risks (RRs) with 95% confidence intervals (CIs) were calculated. Secondary outcomes were extracted and percentage risk differences and RRs calculated. Data were extracted on an intention to treat basis. Where appropriate, the number needed to treat (NNT) was calculated for secondary outcomes. A two by two table was constructed and, where no patients reported adverse events in one or both treatment groups, 0.5 was added to each cell.

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Methods of synthesis

A random effects model was used to pool RRs for primary outcomes and percentage differences and RRs for secondary outcomes. Heterogeneity was assessed using the I^2 and X^2 tests, with a cut off point of 25% and a p-value of less than 0.10 respectively, indicating significant statistical heterogeneity. Subgroup analyses were undertaken by intervention type and pooled primary outcome data were graphically presented as forest plots. A priori sensitivity analyses were also conducted to assess the robustness of the results by removing studies according to type of subgroup intervention, study quality and predominant stool patterns of patients. Publication bias was investigated using funnel plots and the Egger and Begg tests.

Results of the review

Thirty-five RCTs (n=2,761; 1,402 receiving intervention, 1,359 receiving placebo) were included in the review. Sample sizes ranged between 20 and 80 patients (fibre), between 18 and 360 (antispasmodics), and between 47 and 178 (peppermint oil). The quality of studies was generally moderate to good.

Fibre (nine studies/12 treatment arms, n=591)

Significantly fewer patients in the intervention group reported persistent or unimproved symptoms in comparison with placebo or low-fibre diet (RR 0.87, 95% CI: 0.76, 1.00, p=0.05). The NNT with fibre to prevent one patient experiencing persistent symptoms was 11 (95% CI: 5, 100). There was no evidence of statistical heterogeneity or publication bias. Subgroup analyses showed similar results for Ispaghula husk, but the authors reported significant heterogeneity among studies ($I^2=34.4%$, p=0.18). However, subgroup analyses for bran and fibre (unspecified) showed that the differences between the treatment groups were no longer significant. Similarly, sensitivity analysis showed that the differences were no longer statistically significant.

Antispasmodics (19 RCTs/22 treatment arms, n=1778)

There were significantly fewer incidences of persistent symptoms reported in patients receiving antispasmodics in comparison with placebo (RR 0.68, 95% CI: 0.57, 0.81). However, there was evidence of statistical heterogeneity ($I^2=62.6%$, p<0.001). Subgroup analyses showed varying treatment effects for different types of antispasmodics.

Peppermint Oil (4RCTs, n=392)

Significantly fewer patients receiving intervention reported persistent symptoms compared with placebo; RR 0.43 (95% CI: 0.32, 0.59, p<0.001). However, the authors reported significant heterogeneity ($I^2=31.1%$, p=0.23). The NNT with peppermint oil to avoid persistent symptoms was 2.5 (95% CI: 2.0, 3.0).

Sensitivity analyses for antispasmodics and peppermint oil did not significantly alter the results. It was not possible to conduct sensitivity analysis by predominant stool pattern due to the small number of studies reporting this data.

Publication bias was detected by Egger's test for the antispasmodics studies, but this was not confirmed by the Begg test. Adverse events were also reported in the review.

Authors' conclusions

Ispaghula husks, antispasmodics, and peppermint oil are more effective than placebo for treating irritable bowel syndrome.

CRD commentary

This review answered a clear research question supported by appropriate inclusion criteria. Attempts were made to reduce the risk of both language and publication bias. Statistical tests were also performed to detect the presence of publication bias, although the reliability of these tests is questionable given the low number of included studies. Attempts were made to reduce the risk of reviewer error and bias, with relevant criteria used to assess the validity of the included studies. In general, the quality of the studies was rated as moderate to good, but a number failed to provide sufficient information regarding allocation concealment, which has been shown to be an important factor affecting the reliability of study data. Many of the studies also contained only limited numbers of participants. Statistical heterogeneity was assessed using stringent cut-off values. Further analyses were carried out to investigate a limited

number of potential factors which might affect the reliability of the results. However, the small numbers of studies and participants included in many of these additional analyses suggest that their findings might not always be reliable. In addition, there were few details about the baseline characteristics of participants and, in a number of cases, differences appear to exist between studies, particularly with regard to the duration of therapy and the dose regimens used. It should be noted that there were slight discrepancies between the figures cited in the text and those in the forest plots for the antispasmodics control group. The figures used in this review are taken from the text. Overall, although the review was generally well conducted, the authors' analyses should be interpreted with caution given their reliance on an often limited number of small and sometimes potentially quite different studies.

Implications of the review for practice and research

Practice: The authors stated that national guidelines for the management of IBS should be updated to incorporate their findings.

Research: The authors stated that large studies are warranted to further assess the use of fibre, antispasmodics and peppermint oil for the treatment of IBS, as defined by the Rome criteria, and should include validated tools to measure outcomes.

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Bibliographic details

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