Peppermint oil for irritable bowel syndrome: a critical review and metaanalysis

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Authors' objectives
To review the clinical trials of extracts of peppermint (Mentha X piperita L.) as a symptomatic treatment for irritable bowel syndrome (IBS).

Searching
MEDLINE, EMBASE, BIOSIS Previews, and CISCOM were searched from 1976 to February 1997; the Cochrane Library (Issue 2, 1997) was also searched. The search terms used were 'peppermint', 'mentha', 'menthol' and 'Pfefferminz'. Additional published and unpublished material were identified by contacting all manufacturers of peppermint oil preparations, and by searching the bibliographies of the studies and reviews retrieved. Publications in any language were considered.

Study selection
Study designs of evaluations included in the review
Only randomised controlled trials (RCTs) were included. Seven of the 8 studies were double-blind placebo-controlled. The one open trial compared peppermint oil with stress management. The treatment periods ranged from 2 to 6 weeks, with the exception of one study with a treatment period of 6 months (peppermint oil versus stress management).

Specific interventions included in the review
Peppermint oil monopreparations. The specific preparations were Colpermin, Elanco LOK capsules and enteric-coated capsules. Peppermint oil was given in three doses ranging from 0.2 to 0.4 mL.

Participants included in the review
The patients included in the trials had IBS. However, the authors stated that IBS was not diagnosed using accepted clinical features for IBS in 7 of the 8 included trials.

Outcomes assessed in the review
Global improvement of symptoms and adverse drug reactions was assessed.

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 standard scoring system of Jadad et al. (see Other Publications of Related Interest) was used to measure the likelihood of bias. This assessed randomisation, double-blindness, and the method of dealing with withdrawals and drop-outs. Two reviewers independently assessed validity, and any disagreements were resolved by discussion.

Data extraction
The data were extracted by two independent reviewers, and any disagreements were resolved by discussion. The number of participants who dropped out of treatment was reported.

Methods of synthesis
How were the studies combined?
The trials were combined using meta-analysis software issued by the Cochrane Collaboration (RevMan 3.0). The odds ratios and 95% confidence intervals were calculated using a random-effects model.
How were differences between studies investigated?
The chi-squared test was used to investigate differences between the treatment and placebo groups, and differences in the placebo response.

Results of the review
Eight trials involving a total of 295 participants (265 in the double-blind trials) were included in the review.

All included trials scored at least 2 on the 5-point quality assessment scale. The 2 highest scoring trials scored 4 points. Both of these studies suggested that peppermint oil was not superior to placebo in the symptomatic treatment of IBS.

Five double-blind, placebo-controlled RCTs with a quality score of at least 3 were included in a meta-analysis. Two trials did not demonstrate a significant difference between the peppermint oil and placebo. Three studies showed that treatment with peppermint oil was significantly superior to placebo. Overall, this meta-analysis suggested a significant (p<0.001) positive effect of peppermint oil, compared with placebo, in the symptomatic treatment of IBS.

The placebo response ranged from 13 to 52% (mean 31%). The highest placebo responses (38 and 52%) were found in the 2 studies showing no difference between the treatment and placebo. In 3 studies, the placebo response varied significantly (p<0.01).

Five of the 8 trials reported the frequency of adverse drug reactions (heartburn, perianal burning, blurred vision, nausea and vomiting) while taking the peppermint oil. The frequency ranged from 11 to 36% (mean 20%) of the patients studied.

Authors' conclusions
The role of peppermint oil in the symptomatic treatment of IBS is far from established. Well-designed and carefully executed studies are needed to clarify the role of peppermint oil in IBS.

CRD commentary
The review focused on a well-defined question. A substantial effort was made to search for all the relevant literature. The inclusion and exclusion criteria were appropriate. The validity of the included studies was adequately assessed. The primary studies were combined appropriately.

Some details of the individual studies were presented, but it would have also been useful to have included the age and gender of the participants. One of the included studies received a quality score of 4 out of 5, but it did not provide sufficient detail to be included in the meta-analysis. An attempt could have been made to contact the authors for this information, so that this study could have been included.

The authors addressed some limitations of the primary studies included in the review. First, only one of the eight included studies diagnosed IBS using the accepted clinical features for IBS. In addition, six of the eight included trials had treatment periods of less than or equal to one month. It has been suggested that because the natural course of the disease includes periods of exacerbation and remission, the minimum length of medication to generate valid clinical data should be 2 to 3 months. Only one trial included a washout period before each treatment to eliminate carryover effects.

The method by which global improvement of symptoms was measured was not stated. Thus it is possible that the measurement methods varied between studies.

This was a very thorough review. However, the results and conclusions should be interpreted with caution in view of the limitations of the primary studies.

Implications of the review for practice and research
The authors state that well-designed and carefully executed studies are needed to clarify the role of peppermint oil in
IBS.

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