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What is the efficacy of peppermint oil in reducing the symptoms and improving the quality of life in patients with Irritable Bowel Syndrome (IBS)?

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A SELECTIVE EVIDENCE BASED MEDICINE REVIEW

In Partial Fulfillment of the Requirements For

The Degree of Master of Science

In

Health Sciences – Physician Assistant

Department of Physician Assistant Studies
Philadelphia College of Osteopathic Medicine
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Abstract

Objective: The objective of this selective EBM review is to determine whether or not peppermint oil reduces the symptoms and improves the quality of life in patients with irritable bowel syndrome (IBS).

Study Design: Review of three randomized, double-blind, placebo controlled clinical trials were used in this review. The articles were found on PubMed, and selected based on outcomes measured and relevance to the objective.

Outcomes Measured: The outcomes measured were based on Quality of life and Reduction in Symptoms. Quality of life was measured using the Persian translation of the SF-6 form for assessment of quality of life before and after treatment. Reduction of Symptoms was measured using a mean symptom scores before and after the treatment.

Results: The Merat, et al. study found a statistically significant improvement in reduction of symptoms including abdominal pain and discomfort, and show a statistically significant improvement in quality of life. Cappello, et al. also found a statistically significant reduction in symptoms including abdominal pain, discomfort, bloating, diarrhea and constipation. Alam, et al. also found a statistically significant reduction in symptoms especially abdominal pain, but did not see a statistically significant improvement in quality of life.

Conclusions: Based on these three randomized, double-blind, and placebo controlled clinical trials the efficacy of peppermint oil to treat irritable bowel syndrome is fairly conclusive as an effective treatment to reduce symptoms. The populations studied in these studies were not large and lost a lot of patients to follow-up, which are factors that should be addressed in future studies

Key Words: Irritable Bowel Syndrome, IBS, Peppermint Oil

Introduction

Irritable Bowel Syndrome (IBS) is a chronic disorder of the GI tract that affects a large population of people throughout the world. It is a gastrointestinal syndrome characterized by chronic abdominal pain and altered bowel habits in the absence of any organic cause¹. These symptoms are not explicable by the presence of structural or biochemical abnormalities². It is characterized by abdominal discomfort or pain that has two of the following three features: relieved with defecation, onset associated with a change in frequency of stool, or onset associated with a change in form (appearance) of stool². IBS is further categorized into four different types³. IBS with Constipation (IBS-C) is defined when the person's stool is hard or lumpy most of the time, and occasional bowel movements with loose stools³. IBS with diarrhea (IBS-D) is defined when the person's stool is loose or watery most of the time and occasional bowel movements with hard stool³. Mixed IBS (IBS-M) is defined as a mixture of IBS-D and IBS-C, specifically defined as a person with occasional hard bowel movements and occasional loose bowel movements³. Unspecified IBS is defined as insufficient abnormality of stool consistency to meet criteria for the other types of IBS³. There is no single pathophysiological marker of IBS⁴.

Despite being a common condition throughout the world, IBS is a chronic troublesome condition that puts both patients and the healthcare system into heavy expenses as a result of significant impairment in health-related quality of life and work productivity⁵. IBS is present in 10% to 20% of adults in the US³. Only about 15% of those affected actually seek medical attention³. The health care cost of IBS in the US is estimated at \$8 billion a year, and IBS is the most common cause for referral to gastroenterologists, up to 50% of referred patients³.

There is no definitive cure for IBS, only therapies to control symptoms. The first-line treatment for all types of IBS is typically lifestyle and dietary modifications³. The next line of treatment is pharmacologic treatment to control symptoms. Some examples of pharmacologic treatment include, laxatives used for constipation predominantly, loperamide for diarrhea not controlled by diet, and antidiarrheals and antispasmodics are used for diarrhea predominant³. Other adjunct treatments for IBS include cognitive behavioral therapy or tricyclic antidepressants³.

Since there is no definitive cure for IBS, various experimental treatments are undergoing research to become available to control symptoms of IBS. One of those experimental treatments is peppermint oil. The major component in Peppermint oil, is menthol⁵. Menthol has relaxing effects on gastrointestinal smooth muscle by blocking Ca²⁺ channels in the gut, which may be useful in improving IBS symptoms⁵. This systematic review evaluates three randomized control trials to determine the effectiveness of peppermint oil in reducing symptoms and improving quality of life for patients with IBS.

Objective

The objective of this selective EBM review is to determine whether or not peppermint oil reduces the symptoms and improves the quality of life in adult patients with irritable bowel syndrome (IBS).

Methods

Criteria used for selection of studies for this systematic review is based on population studied, interventions, and the outcomes measured. The populations studied in these articles were male and female adults that were diagnosed with IBS using the ROME II criteria. These patients did not present with any other conditions or had any abnormal lab studies. The

intervention was a dosage of peppermint oil compared to a visually matched placebo. The studies measured outcomes using patient-oriented evidence that matters including reduction in symptoms and improvement in quality of life.

Research for this systematic review was obtained using PubMed to find double-blind, randomized controlled trials published in peer-reviewed journals within the last 10 years in the English language. The key words used in searches for these articles were “irritable bowel syndrome” and “peppermint oil”. The articles selected during this search were based on their relevance to the objective in this systematic review. This included studies where the participant groups of adult patients were greater than 18 years old diagnosed with IBS, and whether or not they evaluated the outcome of the treatment based on patient-oriented evidence that matters. The exclusion criteria for this systematic review were scientific papers that included patients under the age of 18 years old, studies that were not randomized, double-blind, placebo controlled trials, and trials that measured treatment outcomes not based on patient-oriented evidence that matters. The statistics used by these articles analyzed the data using Chi-square, Mann-Whitney U and paired and unpaired t-tests. The data from the articles was analyzed in the systematic review using p-values, Relative Risk Ratio, numbers needed to treat, numbers needed to harm and Confidence Interval using dichotomous and continuous data from the articles to analyze the efficacy of peppermint oil in reducing symptoms and improving quality of life in patients with IBS compared to a visually matched placebo.

Outcomes Measured

The outcomes that were measured in these studies were reduction in symptoms and quality of life. Merat et. al assessed quality of life in the participants using the Persian translation of the SF- 36 form for assessment of quality of life⁵. The SF-36 form was a

questionnaire that was completed by the researchers when they visited the patients during treatment follow-up after 1 week and again after 4 weeks. They also used a separate questionnaire filled out by the researchers to rate the intensity and frequency of each symptom that was experienced by the patient on a scale of 0-3⁵. The symptoms that were assessed included abdominal pain, abdominal discomfort, heart burn, nausea, vomiting, abdominal distention and bloating, increased flatus, decreased or increased passage of stool, stool consistency, urgency and feeling of incomplete evacuation⁵. This same questionnaire also included any adverse events that occurred during the study while taking the treatment. The patients were also required to fill out a questionnaire that rated 6 different IBS symptoms and rated a general assessment of health and quality of life on a visual analogue scale (VAS)⁵. The patients were asked to complete this questionnaire every night before going to sleep for the first week, then weekly for the duration of the study⁵. The patient's scores on the VAS scale were converted to a number between 0 and 10⁵. The symptoms that were included on the patient's questionnaire were abdominal pain, intestinal gas or bloating, constipation, diarrhea, incomplete evacuation and urgency.

Cappello et. al assessed reduction of symptoms using symptom score that measured intensity and frequency of symptoms. Intensity of symptoms were measured on a scale from 0 to 4; with 0 being absent symptoms, 1 being mild, 2 being moderate, 3 being severe and 4 being unbearable symptoms⁶. Frequency of symptoms were also measured on a scale of 0 to 4; with 0 being absent, 1 being once per month, 2 being once per week, 3 being twice per week and 4 being more than 3 times per week⁶. The symptom scores were assessed at the beginning of the trial, the end of the trial and 4 weeks after the end of the trial⁶. The symptoms that were evaluated using the symptom score were abdominal bloating or distention, abdominal pain or

discomfort, diarrhea (> 3 stool/day), constipation (<3 stools/week), pain at evacuation, urgency of bowel movement, sense of incomplete evacuation and passage of gas or mucous⁶. A total IBS symptom score was then evaluation for each subject, by calculating the mean symptom score for each symptom, and then adding up the mean symptom scores for all the symptoms for each patient and getting the average for that⁶. Any subject with a $\geq 50\%$ reduction in overall IBS symptom score from baseline to either at the end of treatment or 4 weeks after treatment was defined as Remission of IBS symptoms⁶. Remission of symptoms was how the study defined a reduction in IBS symptoms for these patients.

Alam et. al assessed the changes in symptoms using a symptom score, which was assessed before treatment as a baseline, and at 3 week intervals during the treatment and then 2 weeks after the end of treatment⁴. Quality of life was assessed using a validated IBS quality of life instrument, which included 34 questionnaires for the patients to fill out⁴. Quality of life was assessed before and after treatment⁴. Three articles were chosen for this systematic review.

Table 1 represents the demographics and characteristics of each study that was selected.

Table 1 - Demographics & Characteristics of included studies

Study	Type	# Pts	Age (yrs.)	Inclusion Criteria	Exclusion Criteria	W/D	Interventions
Merat ⁵ (2010)	Randomized Control Trial	60	36	Adult patients with the diagnosis of Irritable bowel syndrome using Rome II criteria	Patients with any abnormal results, pt.'s with serum markers for Celiac Disease, or other diseases such as lactose intolerance and others.	30	Enteric-coated peppermint-oil (Colpermin)

Cappello ⁶ (2007)	Randomized double-blind Control Trial	57	41	Patients diagnosed with irritable bowel syndrome according to the Rome II criteria with no other abdominal diseases or abnormal diagnostic tests	Patients under 18 years old and over 80 years old; pt.'s with previous surgery on abdomen except appendectomy; pt.'s with other diseases of the abdomen	6	Peppermint oil (Mintoil®)
Alam ⁴ (2013)	Randomized double-blind controlled trial	74	28.74	Patients with diarrhea- predominant IBS who fulfilled ROME II criteria	Patient who had red flag signs such as weight loss, dysphagia, dehydration, bleeding, recurrent vomiting, fever, etc. Pregnant and breastfeeding women. Patient who had concomitant cardiac disease, liver disease, renal disease	9	Peppermint oil

Results

There were three randomized, double-blind, placebo controlled trials selected for this systematic review to determine the efficacy and safety of peppermint oil for the treatment of symptoms of IBS in adults. The Merat, et. al study used dichotomous data, but was unable to base this on an intention-to-treat analysis. The Cappello, et. al study used dichotomous data based on the intention-to-treat analysis of data. The data presented in Alam et. al, study was continuous, and couldn't be converted into dichotomous data⁴. The analysis of measured outcomes for each of the studies is based on overall improvement of symptoms, and improvement in quality of life.

In the Merat et. al study, 90 patients overall were included in this study based on the inclusion and exclusion criteria, and 60 were able to complete the study with 30 lost to follow-up (Table 1). This left 33 patients in the peppermint oil group and 27 patients to the placebo group.

The patients that participated in the study received 187 mg (or 0.2 ml) of peppermint oil (Colpermin) three times a day 30 minutes before each meal for 8 weeks⁵. The placebo group received an identical looking placebo with the same regimen⁵. The most common presenting complaints in the beginning of the study was abdominal pain, followed by distention and flatulence. Quality of life was evaluated during follow-up at 1 week and then again at 4 weeks. Reduction of symptoms was evaluated every day during the first week and then weekly throughout the rest of the study. The intensity of the abdominal pain and discomfort was significantly reduced in the colpermin group at week 8 compared to the placebo ($p < 0.001$) (Table 2). Quality of life did not differ significantly at the beginning of the trial. However, after 8 weeks, the patients on Colpermin showed statistically significant improvement in quality of life according to the SF-6 domains compared to the placebo group (Table 3). Thirty-three patients reported adverse events including heartburn during the study, 19 in the Colpermin group and 14 in the placebo group.

Table 2: Frequency and Intensity of Symptoms Abdominal pain and Discomfort at 0 and 8 Weeks of Treatment⁵

Frequency and intensity of Symptoms	Study group	Week 0	Week 4	Week 8
None	PG	0	11 (41%)	6 (22%)
	CG	0	14 (42%)	14 (42%)
Occasional	PG	17 (63%)	10 (37%)	7 (26%)
	CG	15 (46%)	11 (33%)	14 (42%)
Persistent	PG	9 (33%)	6 (22%)	14 (52%)
	CG	14 (42%)	7 (21%)	5 (15%)
Severe	PG	1 (4%)	0	0
	CG	4 (12%)	1 (3%)	0

PG= Placebo group, CG= Colpermin (peppermint oil) group

Table 3: Mean SF-6 Score in the Beginning and the End of Treatment⁵

Study group	Mean SF- 6 score beginning of trial (SD)	Mean SF- 6 score end of trial (SD)	p-value
Placebo Group	48.9 (29.8)	57.8 (29.3)	0.308
Colpermin Group	53.7 (26.4)	63.0 (28.2)	0.194

Based on the results of the study, the control event rate (CER), which included the placebo group was 77.7%, whereas the experimental event rate (EER), which included the peppermint oil group was 57.6%. The Relative Benefit Increase (RBI) was 0.26, and Absolute Benefit Increase (ABI) was 0.2. Based on these calculations, the numbers needed to treat for this study was determined to be 5. Meaning that for every 5 people with IBS that are treated with peppermint oil, 1 more patient will have relief from their symptoms compared to the placebo at 8 weeks.

The calculations for harm were based on the adverse events. The CER for harm was 11%, whereas the EER for harm was 9%. The Relative risk Increase (RRI) for harm was 0.18, and Absolute risk Increase (ARI) was 0.02. Based on these calculations, the numbers needed to harm for this study was determined to be 50. Meaning that for every 50 people with IBS who are treated with peppermint oil, 1 more patient will have an adverse event from treatment compared to the placebo at 8 weeks.

In the Cappello et. al study, 57 patients met the inclusion and exclusion criteria, 28 were placed in the peppermint oil group and 29 were placed in the placebo group. Six patients overall (three from each study group) were lost to follow-up, and were excluded from the study (Table 1). The peppermint oil group was advised to take 1 Mintoil capsule (containing 225mg of peppermint oil and 45 mg of Natrasorb, which is a starch that absorbs oil in solid powder) twice a day for 4 weeks⁶. The placebo group received a capsule that contained 225mg of maltodextrin with mint flavor and were also advised to take one capsule twice a day for 4 weeks⁶. At the end

of 4 weeks of treatment (T4) there was a significantly higher number of patients with a $\geq 50\%$ reduction in total IBS symptoms score in the peppermint oil group than in the placebo group ($p < 0.01$). There was also a persisting beneficial effect at another subsequent 4 weeks after that in the peppermint oil group ($p < 0.05$), whereas in the placebo group, a significant number of patients returned to baseline (Table 4).

Table 4: Number of patients with $\geq 50\%$ reduction in total IBS symptom score at end of treatment (T4) and 4 weeks after end of treatment (T8)⁶

Study Group	T4	T8
Peppermint oil	64%	46%
Placebo group	34%	10%

Based on the results in the Cappello et. al study, the CER for treatment was 10%, whereas the EER for treatment was 46%. The RBI for treatment was 3.6, and ABI for treatment was 0.36. Based on these calculations, the numbers needed to treat for this study was determined to be 3. Meaning that for every 3 people with IBS who are treated with peppermint oil, 1 more patient will have relief from their symptoms compared to the placebo at 4 weeks.

In the Alam et. al study, 74 patients were enrolled to participate in the study, and 9 patients dropped out of the study. Thirty-three patients were in the peppermint oil group and thirty two patients were in the placebo group (Table 1). Before treatment, there was no statistical difference of mean abdominal pain score between the peppermint oil group and the placebo group ($p < 0.05$). At six weeks of treatment, the mean pain score significantly improved in the peppermint oil group ($p > 0.001$), and was significant over the placebo group ($p > 0.05$). Two weeks after the end of treatment, pain score increased in both groups (Table 5). Quality of life did not improve significantly during this study.

Table 5: Mean symptom score throughout the study (baseline, 3 weeks, 6 weeks and 2 weeks after treatment), and mean overall symptom score of both study groups⁴

Study group	Mean Symptom Score				Mean overall score	p-value
	Baseline	3 weeks	6 weeks	2 weeks after treatment		
Peppermint oil	6.7	6.58	4.94	6.09	4.94	> 0.0001
Placebo	6.67	6.44	6.15	6.38	6.15	> 0.05

Based on the results in the Alam et. al study, the 95% Confidence Interval (CI) for the experimental group was 3.75-5.53. The 95% CI for the control group was 5.65-6.65. This means there is a 95% chance that the groups are different, not by chance. This is significant for this study showing the results that are significantly different, not by chance, and makes the results valid. The estimate of treatment affect was fairly precise with $p > 0.0001$.

Discussion

This systematic review compares three randomized, double blind, placebo controlled clinical trials, and all of them found that peppermint oil is effective at reducing the symptoms of IBS^{4, 5, 6}. Merat, et. al found significant improvement of abdominal pain and discomfort, and found some improvement in quality of life⁵. Cappello, et. al found significant improvement in symptoms of IBS in patients after 4 weeks of treatment, and found continued improvement in symptoms after the treatment⁶. Alam, et. al specifically found improvement in abdominal pain and diarrhea symptoms in diarrhea-predominant IBS⁴.

Peppermint is a plant that belongs to the mint family that is a cross between two types of mint, water mint and spearmint^{5, 7}. Today, peppermint oil is used as a folk or traditional remedy for various symptoms including nausea, indigestion, cold symptoms and headaches⁷. Peppermint oil appears to be safe for most adults when used in small doses, with possible side effects including allergic reactions and heartburn⁷.

Merat, et. al mentioned a significant limitation to their study was the number of participants who were lost to follow-up⁵. Almost 30% of their subjects did not refer for follow-up, which made them unable to do an intention-to-treat analysis⁵. Another significant limitation to their study was the researcher and patient questionnaires were not validated⁵. They were not concerned by this because they used the SF-6 questionnaire for analysis, and the results of the SF-6 questionnaire matched the results of the invalidated researcher and patient questionnaires⁵. Cappello, et. al found a significant limitation to their study was the short length of time of the study, and short follow-up on the patients. They suggested that in future studies therapeutic periods will be required before the establishment of definite impact of peppermint oil for IBS⁶. The limitation in the Alam, et. al study was the sample size and the duration of the treatment⁴. They suggested that in future studies, larger placebo controlled trials for a longer period of treatment are warranted for further evaluation of peppermint oil to reduce symptoms of IBS⁴.

Conclusion

Based on these three randomized, double-blind, and placebo controlled clinical trials the efficacy of peppermint oil treatment to reduce symptoms of IBS is fairly conclusive^{4, 5, 6}. The results for effectiveness in improving quality of life were inconclusive. All three randomized, double-blind, placebo controlled trials found a statistically significant improvement of symptoms of IBS, including abdominal pain, bloating and diarrhea, using peppermint oil for treatment^{4, 5, 6}.

In future studies, it would be useful to use larger sample sizes, and conduct the study for a longer period of time. The larger sample size and longer study observation would show a more accurate depiction of peppermint oil's effect on the patient population. This would further ensure the validity of peppermint oil's effectiveness at relieving symptoms and improving quality of life.

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