

# Cumin Extract for Symptom Control in Patients with Irritable Bowel Syndrome: A Case Series

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## ABSTRACT

### BACKGROUND

Irritable bowel syndrome is one of the most common gastrointestinal disorders. Characterized by chronic abdominal pain, altered bowel habits or changes in stool consistency. Unfortunately, no specific treatments for relieving IBS symptoms have been suggested yet. This pilot study was conducted to evaluate the efficacy of the Cumin extract, a kind of herbal used in the treatment of gastrointestinal disorders like bloating, and other symptoms of IBS.

### METHODS

Fifty seven patients with IBS (according to the ROME II diagnostic criteria) with no nay other accompanying illness enrolled in study. Patients were advised to discontinue their other treatments during the study course, then 20 drops per day of Cumin essential oil was administered for included patients. IBS-associated symptoms including abdominal pain, nausea, painful defecation, presence of mucosa in stool, changes in stool consistency and defecation frequency were evaluated using a questionnaire before treatment, 2 and 4 weeks after beginning treatment and 2 and 4 weeks after stopping treatment.

### RESULTS

Abdominal pain, bloating, incomplete defecation, fecal urgency and presence of mucus discharge in stool were statistically significant decreased during and after treatment with Cumin extract. Stool consistency and defecation frequency were also both statistically significant improved in patients with constipation dominant pattern of IBS.

### CONCLUSION

Cumin extract can be effective in improving all IBS symptoms. Considering its low cost and easy availability Cumin administration in patients with IBS may have economic benefits.

### KEYWORDS

Irritable Bowel Syndrome; Cumin Cyminum; Cumin; Herbal medicins

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## INTRODUCTION

Irritable Bowel Syndrome (IBS) is one of the most common functional disorders of the gastrointestinal (GI) tract and its clinical presentation is not progressive recurrent lower abdominal pain accompanied by bowel habit changes (in consistency and frequency).<sup>1</sup> Usually a

physical or emotional stress or a specific nutritional habit triggers the Symptoms and typically there is no systemic presentation like weight loss or fever in patients with IBS.<sup>2</sup>

Prevalence of IBS has a wide range in different reports (from 3.5% in Iran to 30% in Nigeria). most studies show that patients with IBS are increasing in developing Asian countries.<sup>3,4</sup>

Twenty eight percent out of 44% of patients with functional GI disorders are suffering from IBS and they compose 20-50% of patients who are referred to gastroenterologists.<sup>5</sup> The recurrent visits alongside the multiple diagnostic and therapeutic interventions have a high economic burden on patient and the public health system. As a study in France showed, IBS has a total annual cost of 726 Euros per patient.<sup>6</sup>

IBS is a common but unrecognized clinical disorder.<sup>7</sup> The ultimate goal of treatment in patients with IBS is providing a complete symptom relief and improved quality of life which can lead to decreased disease burden on patient, health care system and the community at all. Patients with mild to moderate symptoms are usually treated with antispasmodic, antidiarrheal, fiber supplements and serotonin modulators but the patients with more severe symptoms accompanied with psychosocial problems are best treated with antidepressants and cognitive behavioral therapy.<sup>7</sup>

Unfortunately none of the available treatments has beneficial effects on all IBS symptoms concurrently and most of medications which are usually prescribed for patients with IBS have a negative effect on some symptoms of patient beside their positive effects.<sup>8</sup> Some of available drugs are expensive and some of them have significant side effects in chronic use.<sup>9</sup> These problems encourage patients to use the complementary and alternative medicine (CAM). In a study on 1012 patients with IBS in United States, was showed that 35% of patients with IBS use CAM treatments (most commonly the ginger, massage therapy and yoga) to relieve their symptoms.<sup>9</sup>

Herbals which are among the most common therapeutic modalities of CAM are cheaper, safer

and more available than synthetic drugs all over the world especially in chronic use.<sup>9</sup>

“CuminumCuminum” from “A Piaceae” family known as Cumin is one of the oldest herbal. It is extensively cultivated in Iran. The fruit of Cumin has an essential oil composed of terpenoids (like  $\beta$ -pinene,  $\alpha$ -pinene, Cumin alcohol,  $\beta$ -phellandrene)<sup>10</sup> and has been used as energy and immunity enhancing, digestive, diuretic, anti-parasitic, anti-convulsant and anti-flatulence in traditional Iranian medicine and is used for weight loss in community.<sup>11</sup> Although it makes diarrhea or constipation in some patients but it can regulate and balance the GI motility if used in proper doses. A study in Germany in 1996 showed that herbal essential oil containing Cumin can be beneficial in abdominal pain control in patients with non-ulcerative GI disorders.<sup>12</sup>

In another study on 120 patients in 1999, Cumin decreased the abdominal pain of patients with IBS significantly<sup>13</sup> and a study in 2000 showed that Cumin can alleviate the pain in patients with functional GI disease.<sup>14</sup> Fazel et al. showed also that Cumin can be useful in preventing GI complications after emergency cesarean section by decreasing the bowel distention, colicky pains, heart burn and delayed gas passage and defecation.<sup>15</sup> Cumin has been also effective in neurogenic and inflammatory pain control in mice.<sup>11</sup>

This prospective clinical trial was conducted to evaluate the therapeutic effects of Cumin on different clinical symptoms of IBS as a pilot study.

## MATERIALS AND METHODS

This prospective trial was conducted as a pre-post study in an academic GI clinic from May-October 2009. Cumin extract containing 2% essential oil was used as oral drop (Cumin oral drop, Barij Essence Pharmaceutical Co. Kashan, Iran). Study was approved by institutional ethics committee. Informed consent was obtained from patients and all patients were allowed to refuse to participate in study when they desired.

Patients who had IBS depending on the ROME II criteria were included in our study. According to ROME II criteria, IBS is considered in a patient

based on the presence abdominal discomfort or pain for at least 12 weeks (not necessarily consecutive) that has two of these three features: Relieved with defecation, associated with a change in frequency of stool, associated with a change in consistency of stool. In all included patients organic causes of pain were ruled out and laboratory tests (including complete blood count, sedimentation rate, C-reactive protein and thyroid stimulating hormone) were assessed.

We excluded patients with abnormal findings in their colonoscopy (if they had undergone colonoscopy previously) or laboratory results; patients allergic to milk and its extracts by their past medical history; patients who had received treatments other than the Cumin during the study course; patients with chronic respiratory or endocrine diseases like asthma, diabetes mellitus, thyroid diseases; patients with known psychiatric disorders; pregnant or breastfeeding women; patients who showed allergic reactions to Cumin extract and the patients.

Study subjects were advised not to change their nutritional habits and regimen during the study course and not to use any other medications for IBS control 2 weeks before and during the study course. After 2 weeks stopping any other drugs symptom control, patients were visited and IBS-associated symptoms including abdominal pain, nausea, painful defecation, presence of mucus in stool, changes in stool consistency and defecation frequency were recorded in a questionnaire which was gathered by the clinicians based on different studies and references.

Cumin oral drop was administered in a similar way for all patients (two times a day, 10 drops at morning and 10 drops at night in a glass of warm water, 15 minutes after meal with a minimum of 12 hours' time interval, this time interval is to eliminate the effects of confounding factors like the time of drug use, time intervals between drug intake and time between last meal and drug intake.)

A telephone follow up was considered for patients 2 and 4 weeks after beginning Cumin drop administration and 2 and 4 weeks after stopping it and any changes in symptoms were recorded again

by the same questionnaire used before Cumin administration.

Descriptive statistics were presented as minimum, maximum, mean and standard deviation. (the proportions of two-by-two contingency tables were compared by the chi-square test, and t-test was used for continuous variables. We considered  $p < 0.05$  as significant. All analyses were performed with SPSS, version 18 (SPSS, Inc., Chicago, IL).

## RESULTS

Twenty eight patients included in study. Five patients refused to continue their participation because they experienced severe symptoms (2 cases with severe nausea, 1 case with severe abdominal pain) or inadequate symptom relief during the study course (2 cases). Two patients were not available and lost to follow up 4 weeks after stopping Cumin extract. At last, 50 patients were analyzed.

### Demographic Data

Mean age of patients was 34.5 years, 23 (46%) of patients were male and 27 (54%) of them were female. Twenty six (52%) of patients had diarrhea dominant IBS and 24 (48%) had constipation dominant IBS. Mean duration of disease in studied patients was 36 months and mean duration of their recent symptomatic period was 2.5 months. No patient had fecal incontinency.

### Overall Symptom Relief

All IBS-related symptoms decreased after 2 and 4 weeks of beginning Cumin extract, symptom relief was more pronounced in fourth week of treatment (compared with second week). Two and four weeks after stopping the Cumin symptoms recurred, but with a less severity (except for painful defecation which returned to its baseline). Symptoms are discussed by details in the continuing. P-values, SD and means is coming in tables 1 and 2.

### Abdominal Pain Relief

Twenty eight percent of patients had severe abdominal pain and 44 % of them had moderate abdominal pain before Cumin extract administra-

**Table 1: Frequency of Defecation in Patients with Constipation Dominant IBS during the study course**

	Frequency	Mean ( $\pm$ SD)	Minimum	Maximum	p value*
Before treatment	Per day	0.08 ( $\pm$ 0.28)	0	1	-
	Per week	3.50 ( $\pm$ 1.10)	2	6	
2 weeks after beginning Cumin	Per day	0.87 ( $\pm$ 0.53)	1	2	>0.05
	Per week	6.21 ( $\pm$ 2.48)	3	14	
4 weeks after beginning Cumin	Per day	1.17 ( $\pm$ 0.38)	0	2	>0.05
	Per week	7.83 ( $\pm$ 1.78)	6	12	
2 weeks after stopping Cumin	Per day	1.08 ( $\pm$ 0.58)	0	2	<0.05
	Per week	8.38 ( $\pm$ 3.28)	4	5	
4 weeks after stopping Cumin	Per day	0.33 ( $\pm$ 0.48)	0	1	<0.05
	Per week	5.08 ( $\pm$ 1.17)	3	7	

\* paired t-test

**Table 2: Frequency of defecation in patients with diarrhea dominant IBS during the study course**

	Frequency	Mean ( $\pm$ SD)	Minimum	Maximum	p value*
Before treatment	Per day	3.62 ( $\pm$ 1.35)	2	7	<0.05
	Per week	26.23 ( $\pm$ 9.17)	14	50	
2 weeks after beginning Cumin	Per day	2.58 ( $\pm$ 0.80)	1	4	<0.05
	Per week	18.27 ( $\pm$ 6.04)	7	30	
4 weeks after beginning Cumin	Per day	2.00 ( $\pm$ 0.80)	1	3	>0.05
	Per week	13.92 ( $\pm$ 6.05)	6	23	
2 weeks after stopping Cumin	Per day	2.12 ( $\pm$ 0.90)	1	4	>0.05
	Per week	15.27 ( $\pm$ 6.85)	7	30	
4 weeks after stopping Cumin	Per day	3.15 ( $\pm$ 1.25)	2	6	>0.05
	Per week	21.77 ( $\pm$ 8.99)	10	40	

\* paired t-test

tion but after 4 weeks of treatment, no patient had severe abdominal pain and just 22% of them still experienced moderate abdominal pain ( $p < 0.001$ ). 4 weeks after stopping the drug 5% of patients had severe abdominal pain and 52% of them had moderate abdominal pain again ( $p < 0.001$  and SD in Tables 1 and 2).

### Bloating Relief

Bloating was severe in 54% and moderate in 46% of patients before treatment with Cumin, but 0% and 8% of patients experienced severe and moderate bloating after 4 weeks of treatment ( $p < 0.001$ ). 4 weeks after stopping the Cumin, severe bloating recurred in 12% of patients which was statistically significant lower than the beginning of treatment

( $p < 0.001$ ) but patients with moderate bloating did not change significantly.

### Incomplete Defecation and Urgency

Before treatment incomplete defecation, fecal urgency and presence of mucous stool were seen in 86%, 92% and 76% of patients accordingly. After 4 weeks treatment with Cumin drop they decreased to 14%, 8% and 0% ( $p < 0.05$ ). But 4 weeks after stopping the treatment these symptoms increased and were seen accordingly in 74%, 70% and 52% of patients.

### Changes in Bowel Habit Frequency

In diarrhea dominant patients 17 (65%) had watery diarrhea and 9 (35%) had loose stool before

medication administration. after 4 weeks of treatment with Cumin, 3 (11.%) of patients had loose stool and 23 (88.5%) had normal stool consistency. After 2 weeks of stopping drug use 6 (23%) of patients had loose stool and 20 (77%) had normal stool ( $p=0.08$ ) and after 4 weeks of stopping drug 12 (46%) of patients had loose stool and 6 (23%) had watery stool and 8(30%) of patients had normal stool ( $p<0.001$ ). In constipation dominant patients constipation was experienced by 11.5% and 58.3% of patients 4 weeks after beginning treatment and 4 weeks after stopping it ( $p<0.001$ ).

Frequency of defecation was increased in patients with constipation dominant pattern of disease 4 weeks after beginning the drug, although 4 weeks after stopping it the defecation frequency decreased again but it was more than before treating with Cumin drop ( $p<0.001$ ).

In patients with diarrhea dominant IBS the frequency of defecation decreased after 4 weeks of treatment with Cumin but it was increased again 4 weeks after stopping the drug ( $p=0.001$  and SD in Tables 1 and 2).

### Nausea Relief

Fifty eight percent of patients had no nausea before treatment with Cumin, 8% had mild nausea and 34% had moderate nausea. After 4 weeks of treatment 90% had no nausea and 10% had mild nausea, no patients had severe nausea.

### Painful Defecation Relief

Before treatment with Cumin, 21 (87%) patients who had constipation dominant IBS experienced painful defecation. After 2 and 4 weeks of treatment, 6 (25%) had painful defecation but this increased to 19 (72%) 4 weeks after of stopping the treatment.

In patients with diarrhea dominant pattern of IBS 1 patient had painful defecation which showed symptom improvement during treatment but his symptoms recurred after treatment cessation.

## DISCUSSION

This study showed that all IBS-related symptoms

decrease during the treatment with Cumin extract and the longer period of treatment provides more relief. Although most symptoms recur after stopping the treatment but the symptoms' severity is still decreased significantly after 4 weeks of treatment cessation.

IBS is a common disease all over the world with a high economic burden (for example in United States with a 8-20% prevalence of IBS, 1.35 Billion dollars are consumed directly and 205 Million dollars are consumed indirectly to treat the patients with IBS). None of available drugs has satisfactory effects on symptoms control and patients quality of life.

To the best of our knowledge this is the first study on Cumin extract use in patients with IBS in Iran and shows that Cumin relieves IBS-related symptoms significantly. Other herbal medicines like melatoni and peppermint oils have also studied in patients with IBS and have been more effective than placebo.<sup>8</sup> A study on *Fumaria Officinalis* (fumitory) and *Curcuma Xanthorrhiza* (turmeric) showed that they can't decrease the symptoms in patients with IBS.<sup>4</sup>

A review on fibers, peppermint oil and anti-spasmodic drugs on 2008 showed that *Plantago Psyllium* (fleawort) which has been studied in 6 researches and peppermint oil which has been studied in 4 researches and anti-spasmodic drugs can be effective in patients with IBS.<sup>17</sup>

## LIMITATIONS

We did not use placebo and other placebo controlled studies may help to verify the results of our study. This is a pilot study with a small sample size and studies with larger sample size are needed. We used fixed dose of drug which was suggested by the drug company but the other doses with other intervals may show different results in IBS patients. Our follow up period was 4 weeks, longer follow up periods may show different results. Some of our studied patients showed nausea, abdominal pain and dizziness after Cumin extract consumption and other specific studies on adverse effects of this medicinal herb can be helpful.

Cumin extract may be a cheap, available, safe and effective as a complementary therapeutic modality in patients with different patterns of IBS-related symptoms.

#### CONFLICT OF INTEREST

The authors declare no conflict of interest related to this work.

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