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**Is oral aloe vera effective in reducing symptoms in adults 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

Health Sciences – Physician Assistant

Department of Physician Assistant Studies  
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## ABSTRACT

Objective: The objective of this EBM review is to determine whether or not “Is oral aloe vera effective in reducing symptoms in adults with Irritable Bowel Syndrome (IBS) symptoms?”

Study Design: Systematic review of three English, randomized, controlled, double-blind studies, including one cross-over study, were selected based on their relevance to the clinical question. The studies were published in 2006, 2011, and 2015.

Data Sources: Three RCTs analyzing the effects on IBS symptoms of drinking aloe vera daily compared to a placebo drink were found using PubMed.

Outcomes Measured: Various patient-reported IBS symptom questionnaires were utilized to compare the effectiveness of drinking oral aloe vera versus the placebo on reducing symptoms in adults with irritable bowel syndrome (IBS). K. Davis used the Global Summated Symptom Score.<sup>2</sup> Storsrud S. used the IBS Symptom Severity Scoring System (IBS-SSS).<sup>4</sup> H.A. Hutchings used the Irritable Bowel Syndrome Quality of Life Questionnaire (IBSQOL).<sup>3</sup>

Results: In the Davis et al study, there was no significant improvement of IBS symptoms between the aloe vera and placebo group ( $p=0.12$ ). The NNT was -11.<sup>2</sup> In the Storsrud et al pilot study, there was no significant improvement in IBS symptoms in using the Aloe barbadensis Mill. extract in comparison to the placebo ( $p=0.09$ ). The NNT was 5.<sup>4</sup> In the Hutchings et al study, there was no significant improvement of IBS symptoms between the aloe vera and placebo group ( $p>0.05$ ). The mean change from baseline was 69-74 points on the ISBQOL score for period 1.<sup>3</sup>

Conclusions: Although two of the studies showed trends towards improvement, all three studies were not considered statistically significant in showing improvement in symptoms in IBS symptoms. Therefore, oral aloe vera is not considered effective in reducing symptoms in adults with irritable bowel syndrome. Additionally, after my further research via WebMD on the safety of drinking aloe vera, I found varying results for whom it was considered safe. I would suggest that future studies first assess its safety before evaluating its effectiveness in reducing IBS symptoms.

Key words: Aloe vera and IBS

## **Introduction**

Irritable bowel syndrome (IBS) largely affects the United States in population and cost. IBS is characterized by a collection of symptoms such as cramping, abdominal pain, bloating, diarrhea, and constipation for at least three months.<sup>5</sup> The condition does not permanently harm the large intestine, nor lead to serious disease like cancer. However, the frustrating symptoms may hinder the patient's quality of life, such as in traveling and working. Because no definitive cure exists, patients and providers are often searching for additional natural remedies for patients to try at home. This systemic review evaluates three double-blind, randomized, controlled trials, including a cross-over study, assessing the effectiveness of drinking aloe vera on symptomatic improvement in adults with IBS.

Up to 20 percent of U.S. adults suffer with IBS symptoms, making it one of the most common disorders diagnosed by doctors.<sup>5</sup> Women, individuals younger than 50 (usually beginning before age 35) and people with a family member who has IBS are most likely to develop IBS.<sup>5</sup> The total direct cost related to IBS was \$1.35 billion dollars and \$619 per patient.<sup>4</sup> IBS accounts for 3.5 million physician visits per year, accounting for 25% of all GI visits. Furthermore, only 10-25% of symptomatic patients seek medical care.<sup>4</sup>

The cause of IBS is not well understood and there is no cure. Although numerous treatments for IBS exist, each patient responds differently, and many still suffer with the frustrating IBS symptoms. Some physicians recommend diet alterations such as 4-5 smaller meals/day, high fiber meals, and 6-8 glasses of water/ day.<sup>5</sup> Physicians may also recommend medications such as fiber supplements, anti-diarrheal medications such as loperimide, antispasmodic agents such as dicyclomine or peppermint oil, antidepressants such as TCAs or SSRIs, or IBS medications such as Lubiprostone.<sup>5</sup> Cognitive and stress relief therapy are also often supplemental suggestions.



These include CBT, psychotherapy, and hypnotherapy.<sup>5</sup> Although several treatment options exist for patients with IBS, many patients are still searching for an effective option that is natural and easily maintainable.

## **Objective**

The objective of this selective EBM review is to determine whether or not “Is oral aloe vera effective in reducing symptoms in adults with irritable bowel syndrome (IBS)?”

## **Methods**

The criteria used for the selection of studies included the population, intervention, comparison, outcomes, and study type. The population consisted of individuals >18 y.o. with IBS according to Rome II or III criteria. The interventions included drinking aloe vera solutions of 50 ml QID, 60 ml BID, or 250 mg of AVH200 dissolved in water BID. The comparisons included drinking the placebo solution of 50 ml QID, 60 ml BID or 50 ml QID, or 60 mg tablets of ascorbic acid and excipients dissolved in water BID. The outcomes were evaluated via patient-reported questionnaires assessing the improvement of IBS symptoms with the use of daily aloe vera. The studies chosen were 3 randomized, double-blind, placebo controlled clinical trials, one of which being a cross-over study. The studies were published in 2006, 2011, and 2015.<sup>2,3,4</sup> See **Table 1** for demographics of each study.

The data were collected by searching the key words aloe vera and IBS on English, peer-reviewed journals via PubMed. Articles were selected based on their relevance to the clinical question and that the study outcomes were patient oriented (POEMS). Inclusion criteria included studies that were randomized, double-blind, and controlled including adults >18 y.o. who were

diagnosed with IBS. Exclusion criteria excluded studies performed before 2001 or previous Cochrane systemic reviews on my topic. The statistics reported were numbers needed to treat (NNT), relative benefit increase (RBI), absolute benefit increase (ABI), mean change from baseline, and p-values.

Table 1: Demographics and Characteristics of Included Studies

Study	Type	# Patients	Age (years)	Inclusion Criteria	Exclusion Criteria	W/D	Interventions
Davis <sup>2</sup>	Double-blind RTC	54	18-65	Adults 18-65y.o. who satisfy the Rome II criteria who had previously tried and failed conventional management	On medications other than related to IBS, other medical conditions, pregnant	1mo -9 3mo -8	Aloe vera (50 ml QID for 3 months)
Hutchings <sup>3</sup>	Double-blind RTC (Cross over)	110	>18	Adults >18y.o. diagnosed with IBS according to the Rome II criteria for > 1 year and had received previous treatment; c/o abdominal pain, seeking further treatment; willing and able to give consent to be randomized in the study; females with a negative pregnancy test	Significant GI tract disease, had undergone previous GI surgery, were known defaulters at clinic and might be difficult to follow up, were on drugs that might affect motility, or had a current or recent Hx of drug or alcohol abuse	63	Aloe vera (60 mg BID for 5 months, 2 week wash out period, 5 months alt. tx
Storsrud <sup>4</sup>	Double-blind RTC	68	18-65	Adults ages 18-65y.o. with IBS according to the Rome III criteria, and were	Other GI dz explaining the sx's, food allergy or intolerance	5	Aloe barbadenses Mill. Extract (250 mg in water BID,

				evaluated by a gastroenterologist	other than lactose intolerance, other severe disease, sxs indicating other severe dz		before breakfast and late in the evening for 4 weeks
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**Outcomes measured**

Various patient-reported IBS symptom questionnaires were utilized to compare the effectiveness of drinking oral aloe vera daily versus the placebo on reducing symptoms in adults with irritable bowel syndrome (IBS). K. Davis used the Global Summated Symptom Score for abdominal pain, distension, satisfaction with bowel habit, and global impact of symptoms on well-being. A reduction of  $\geq 50$  points qualified as improvement. S. Storsrud used the IBS Symptom Severity Scoring System (IBS-SSS), which assesses pain severity, pain frequency, bloating severity, bowel habit dissatisfaction, and life interference. An improvement was defined as a reduction of  $\geq 50$  points on the IBS-SSS questionnaire. H.A. Hutchings used continuous data from the Irritable Bowel Syndrome Quality of Life Questionnaire (IBSQOL) involving 8 subscales: emotional health, mental health, sleep, energy, physical functioning, diet, social role, and physical role.

**Results**

Three double-blind, placebo controlled RTCs were used to determine whether drinking aloe vera improves symptoms in adults with IBS. In the Davis et al study, there was no significant improvement of IBS symptoms between the aloe vera and placebo group ( $p= 0.12$ ).

For this study, 54 subjects were either randomized to receive 50 ml QID of an aloe vera solution or the 50 ml of placebo solution for 3 months. Patients were selected from gastroenterology clinics from two large hospitals in London and were allocated their medication through the central pharmacy of each hospital. Both the experimental and placebo solutions were pink syrup flavored with mango. Inclusion criteria included patients who had IBS according to the Rome II criteria, aged 18-65, and had previously tried but failed conventional management with antispasmodics, bulking agents, and dietary intervention. Exclusion criteria for this study excluded patients who were on medications other than those related to IBS, had other medical conditions, including those related to the bowel, or were pregnant or at risk of pregnancy.<sup>2</sup>

All of the patients, researchers, and doctors remained blind throughout the study. The data were presented at dichotomous data, and at the end of three months, the response by intention to treat was 5 of 18 (28%) and 5 of 26 (18%) in the placebo and active group respectively. At the conclusion of the study, 13 out of 54 subjects (24%) were lost to follow-up. Six patients withdrew due to nausea and vomiting. The outcome was measured by change in global summated symptom score and global impact of symptoms on well-being; a reduction of  $\geq 50$  points qualified as improvement. The experimental group was then compared to the placebo group results. The NNT was -11. Therefore, for every 11 patients treated with oral aloe vera, one less would show improvement in comparison to the placebo treatment.<sup>2</sup> The RBI was -0.32 and the ABI was -0.09. The results for calculations of efficacy may be found in Table 2.

In the Storsrud et al pilot study, there was no significant improvement in IBS symptoms in using the Aloe barbadensis Mill. extract in comparison to the placebo ( $p=0.09$ ). For this study, patients were selected from referrals to gastroenterology outpatient clinic as well as from advertisements in local newspapers. Inclusion criteria included adult patients (18-65y.o.) who

had signed a written informed consent, had IBS according to the Rome III criteria, were evaluated by a gastroenterologist, and have the ability to understand and willingness to comply to the study procedures. Exclusion criteria excluded those with other gastrointestinal disease(s) explaining the symptoms, food allergy or intolerance other than lactose intolerance, other severe disease(s) such as malignancy, severe heart disease, kidney disease neurological disease, symptoms indicating other severe disease(s) such as weight loss, gastrointestinal bleeding or fever, or severe psychiatric disease. Patients who were already using of aloe vera products or were pregnant or lactating were also excluded. Sixty-eight patients were eligible and 33 were randomized to receive Aloe barbadenses Mill. extract in water (250 mg AVH200®, 60 mg ascorbic acid and excipients) and 35 to the matching placebo BID, before breakfast and late in the evening, for 4 weeks. Patients completed weekly questionnaires to assess IBS symptom severity.<sup>4</sup>

Researchers, doctors, and patients were kept blind throughout the study, and the data were presented as dichotomous data. At the end of 4 weeks, the response by intention-to-treat was assessed with drop-outs counted as non-responders and missing data imputed from the previous assessment using the last observation carried forward technique, and was all included in the analysis. At the conclusion of the study, 55% of the aloe vera group and 31% of the placebo group qualified as an improvement in symptoms, and 5 subjects were lost to follow-up. Improvement was defined by a reduction of  $\geq 50$  points on the IBS-SSS questionnaire after 4 weeks. A follow-up symptom questionnaire via a telephone was additionally administered 2 weeks after the conclusion of the treatment period. The results of the experimental group were compared to the placebo group. NNT was calculated as 5, meaning for every 5 subjects treated with aloe vera, one patient would statistically improve as compared to the placebo treatment. The

RBI was 0.77 and the ABI was 0.24.<sup>4</sup> Results for calculations of efficacy may be found in Table 2.

Table 2

	RBI	ABI	NNT	p-value
Davis et al <sup>2</sup>	-0.32	-0.09	-11	0.12
Storsrud et al <sup>4</sup>	0.77	0.24	5	0.09

In the Hutchings et al study, there was no significant improvement of IBS symptoms between the aloe vera and placebo group ( $p > 0.05$ ). This study was a multi-centre prospective randomized, double-blind, cross-over study of 110 subjects. Inclusion criteria included those who were at least 18 years, diagnosed as suffering with IBS according to the ROME II Criteria for at least one year and had received previous treatment, complaining of abdominal pain and were seeking further treatment. The subjects must have been able and willing to give consent to be randomized into the study. Female patients were included if they were taking adequate contraceptive precautions and had a negative pregnancy test at baseline, patients on medication for stable medical conditions not considered to yield an effect on the study were eligible for recruitment, and specific medications for diarrhea or constipation were permitted. Exclusion criteria excluded those who had other significant GI tract disease, had undergone previous GI tract surgery, were known to be defaulters at clinic and might be difficult to follow up, were on drugs which might affect motility, or had a current or recent history of drug or alcohol abuse. Qualifying subjects in 3 hospitals in South West Wales, UK were randomized into groups of 55 patients to drink a 60 ml of aloe vera drink twice a day (Group AB) or a matching placebo drink twice a day (Group BA). Group AB drank the aloe vera for 5 months, had a 2-week “wash out” period, and continued with another 5 months with the placebo, while group BA began with the placebo and ended with the aloe vera for period 1.<sup>3</sup>

The researchers, doctors, and patients were kept blind throughout the study, and the data were continuous and not convertible to dichotomous data. The subjects were analyzed based on “intention to treat,” and improvement was assessed using The Irritable Bowel Syndrome Quality of Life Questionnaire (IBSQOL) at baseline, at the end of study period 1 (5 months), and at the end of study 2 (10 months).<sup>3</sup> The mean change from baseline was 69-74 points on the ISBQOL score for period 1. Independent sample T-tests or chi-square were also used to assess baseline differences in the groups before the study. By the end of the 10 months, only 47 out of the 110 (43%) finished the entire study, and 63 subjects (57%) were lost to follow-up.<sup>3</sup> Results for calculations of efficacy may be found in Table 3.

Table 3

	Mean change from baseline at the end of period 1 using the IBSQOL	p-value
Hutchings et al <sup>3</sup>	69-74	> 0.05

## Discussion

In the Davis et al study, there was no evidence that drinking aloe vera daily benefits patients with IBS ( $p= 0.12$ ). Nausea and vomiting with drinking the solution may have affected the outcome. However, the majority of the nausea and vomiting came from the placebo group and therefore, was not considered to be a significant side effect. According to the Davis et al study, the results were unable to rule out the possibility that improvement occurred in patients with diarrhea or alternating IBS while taking aloe vera (AV). Therefore, authors of the study suggested that further investigations be warranted in patients with diarrhea predominant IBS.<sup>2</sup>

In the Storsrud et al study, several limitations may have affected this study. First of all, this was a pilot study which was aimed to find tendencies towards group differences to detect potentially clinically meaningful differences, and to plan future studies based on the findings.<sup>4</sup> Now, a larger study is claimed to be proceeding with a sample size based on the observed effect size in this study.<sup>4</sup> Additionally, although the groups were randomized, the aloe vera group had a tendency towards higher severity of IBS symptoms at baseline, and some of the results could possibly be due to regression towards the mean. However, when using the adequate relief endpoint, a trend defined as improvement IBS-SSS reduction was noted. The ongoing larger study should help these limitations be overcome.<sup>4</sup>

In the Hutchings et al study, although both study groups were entirely compliant with the allocated treatments and all treatment containers were returned empty, poor recruitment numbers, a large number of patients withdrawing from the study, and the long treatment period all may have had an effect on the results. Moreover, only about 10% of over 1000 patients initially identified with symptoms suggestive of IBS were recruited, which could indicate that the sample was not truly representative of the wide spectrum of IBS patients. Additionally, the requirement to discontinue certain medications prior to entering the study may have further impacted those recruited.<sup>3</sup>

The combination of decreased recruitment rate and the number of drop-outs throughout the study reduced the power of the study. Patients discontinued the study for a variety of reasons including an increase in symptoms, which was noted more markedly in the *Aloe vera* group.<sup>3</sup>

Aloe is a cactus-like plant found in the United States growing in hot, dry environments and comes in two forms, gel and latex. Although not proven to be effective in many cases, aloe vera may be taken by mouth or applied topically to the skin for a vast variety of conditions.



According to WebMD, topical application of aloe vera may possibly be an effective treatment for acne, burns, genital herpes, pruritic rashes, oral submucous fibrosis, and psoriasis.<sup>1</sup> Ingestion of aloe vera may possibly be effective for weight loss and constipation.<sup>1</sup> It is important to note, however, that the U.S Food and Drug administration does not precisely regulate herbs and supplements, so there is no guarantee of the strength, purity, and safety of aloe vera. According to an overview in WebMD, applying aloe vera gel topically is “likely safe.”<sup>1</sup> However, ingesting aloe vera is “possibly safe” when taken short term.<sup>1</sup> Furthermore, ingesting aloe latex long-term is “possible unsafe” at any dose, but “likely unsafe” in high doses.<sup>1</sup> Side effects may cause stomach pain and cramps, and long-term use of large amounts of aloe latex could cause diarrhea, kidney problems, blood in the urine, low potassium, muscle weakness, weight loss, and heart disturbances.<sup>1</sup> Taking aloe latex 1 gram daily for several days can be fatal.<sup>1</sup> People who are pregnant, or have diabetes, intestinal conditions such as Crohn's disease, ulcerative colitis, or obstruction, hemorrhoids, kidney issues, or recent surgery should avoid use of aloe vera. Also, aloe vera has a major negative drug interaction with digoxin and should be avoided.<sup>1</sup>

## **Conclusion**

All three studies were not considered statistically significant in showing symptomatic improvement in adults with IBS. The Storsrud et al study was the only study to show a trend towards improvement of IBS symptoms. Therefore, oral aloe vera is not considered effective in reducing symptoms in adults with irritable bowel syndrome.

Additionally, after my further research via WebMD on the safety of drinking aloe vera, I found varying results for whom it was considered safe. I would suggest that future studies first

assess the safety of ingesting the aloe vera. Then, once statistically determined, supplemental studies could assess its effectiveness in reducing IBS symptoms.

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