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ORIGINAL RESEARCH ARTICLE

STUDY ON CLINICAL EFFICACY OF *SANJIVANI VATI* & *LASHUNADI VATI* IN MANAGEMENT OF DIARRHEA PREDOMINANT IBS: A PILOT STUDY

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ABSTRACT

Background: Irritable bowel syndrome (IBS) is a functional bowel disorder in which abdominal pain is associated with defecation or a change in bowel habit. IBS commonly causes cramping, abdominal pain, bloating associated with changes in bowel habits in the absence of any structural abnormality. Depending on the kind of discomfort and bowel habits, IBS can be sub classified into diarrhea-predominant (IBS-D), constipation-predominant (IBS-C) and IBS with alternate constipation and diarrhea (IBS-A). **Aims:** The present study was conducted to evaluate the efficacy of *Sanjivani vati* and *Lashunadi vati* in the management of diarrhea predominant irritable bowel syndrome (IBS-D). **Study Design:** The study was a single arm, open clinical trial. **Methods and Material**: 40 patients of IBS-D attending the OPD of All India Institute of Ayurveda, New Delhi were selected for the study. All patients were screened on the basis of Rome III criteria of IBS and were administered with a combination of *Sanjivani vati* (125 mg twice a day orally after principal meals) and *Lashunadi vati* (500 mg twice a day orally after principal meals) for 60 days. Scoring scale based on classical clinical features of IBS-D was adopted for the assessment of the disease. **Statistical analysis used**: Wilcoxon's signed rank test was applied using spss software to analyze the data. **Results:** After 60 days of treatment, improvement in clinical features like abnormal stool form, frequent bowel movements, abdominal pain, abdominal bloating, mucus in the stool, feeling of incomplete evacuation was found to be statistical significant ($p \leq 0.05$). No adverse event was observed during the administration of trial drugs. Post treatment follow-up was done after one month. No any recurrence of symptoms was reported. **Conclusions:** The combination of *Sanjivani vati* with *Lashunadi vati* is found to be effective in managing diarrhea predominant irritable bowel syndrome.

Key words: *Sanjivani vati*, *Lashunadi vati*, Diarrhea predominant IBS

INTRODUCTION

Irritable bowel syndrome (IBS) is a chronic, functional bowel disorder characterized by abdominal pain, bloating and changes in bowel habit. Depending on the kind of discomfort and bowel habits, IBS can be sub classified into diarrhea-predominant (IBS-D), constipation-predominant (IBS-C) and IBS with alternating stool pattern (IBS-A) i.e., alternate constipation and diarrhea [1].

Population-based studies estimate the prevalence of IBS at 10–20% in western countries and the incidence of IBS at 1–2% per year with a higher trend in young females than males. However in India the prevalence is estimated to be nearly 4.2-7.9% with males being more affected than females. Of people with IBS, only about 10–20% seek out for medical care. Studies also estimated that prevalence of IBS is inversely related to the socioeconomic status of the population [2]. IBS is troublesome, with a significant negative impact on quality of life and social functioning in many patients [3]. IBS generates significant health care costs, both direct, because of IBS symptoms & Patients with diarrhea have frequent defecation but produce low volume stools and rarely have nocturnal symptoms. Passage of mucus is common but rectal bleeding does not occur.

AIMS AND OBJECTIVES

To evaluate the efficacy of the *Sanjivani vati* and *Lashunadi vati* in management of diarrhea predominant IBS.

MATERIALS AND METHODS

Study design: Present study is an open, single arm clinical trial.

Trial Drug Review: Combination of *Sanjivani vati* [6] and *Lashunadi vati* [7] was given to the subjects enrolled for the study.

The required amount of medicines was supplied by the Indian Medicines Pharmaceutical Corporation Limited (A Government of India Enterprise) Mohan - Dist. Almora (via-Ramnagar-244715), Uttarakhand, with the following batch no. and date of manufacturing:

Formulation	Batch No.	Date of Manufacturing
Sanjivani vati	AVG 06	May 2013
Lashunadi Vati	AVG 07	July 2013

Study sample: Patients of age between 18 and 70, of either sex, satisfying the inclusion criteria were enrolled in the study after thorough baseline screening

Sample Size: A total of 40 patients of age above 18 years and below 70 years, of either sex, satisfying the inclusion criteria were finally enrolled in the study. During the study, 09 patients dropped out and only 31 were followed till the end.

Study Settings: Trial started in August 2013 and completed in April 2014. Patients attending O.P.D. of All India Institute of Ayurveda, New Delhi, with clinical symptoms of IBS-D were included in the study.

Informed consent was taken from the patients before including them in the trial.

Diagnostic Criteria: Recurrent abdominal pain or discomfort** per month for ≥ 3 days in the last 3 months, associated with 2 or more of the following

associated disorders, and indirect, because of absenteeism from work.

Although the pathophysiology of IBS is poorly understood, it is generally believed that most patients develop symptoms in response to psychological factors, altered gastrointestinal motility, altered visceral sensation or luminal factors [4].

Symptoms that are common in IBS, originally described by Manning [5], include altered stool form, increased frequency of stools**,** colicky abdominal pain**,** abdominal bloating**,** rectal mucus**,** and feeling of incomplete defecation.

- Improvement with defecation; and/or
- Onset associated with a change in frequency of stool; and/or
- Onset associated with a change in form (appearance) of stool

**Discomfort means an uncomfortable sensation not described as pain

Inclusion Criteria:

a. Willing to give written consent to participate in the study

b. Age above 18 years and below 70 years of either sex

c. Recurrent abdominal pain or discomfort for last 6 months

d. Recurrent abdominal pain or discomfort** per month for ≥ 3 days in the last 3 months, associated with 2 or more of the following

- Improvement with defecation; and/or
- Onset associated with a change in frequency of stool; and/or
- Onset associated with a change in form (appearance) of stool

**Discomfort means an uncomfortable sensation not described as pain

Exclusion Criteria:

a. Age below 18 years and above 70 years.
b. Any history of chronic liver disease, heart disease, pulmonary or renal disease
c. Pregnant women
d. Patients who drink over 2oz alcohol/day on a regular basis
e. Any other causes for diarrhea such as inflammatory bowel disease (IBD), microscopic colitis, celiac disease, history of abdominal obstruction, pancreatitis, ileus, or any gastrointestinal bleeding.
f. Patients with active malignancy in the past five years.
g. Patient with any history of hypersensitivity reactions.
h. Patients who have completed participation in any other clinical trial during the past six (06) months.

Withdrawal of Subjects:

Patients were withdrawn from the study on following grounds:

- Failure of subjects to adhere to protocol requirements.
- Subject consent withdrawal.
- Disease progression.
- Subject gets pregnant.

Lab Investigations:

1. Routine hematological investigations - Hb, TLC, DLC, E.S.R., P.C.V.
2. Stool examination - Routine and Microscopic.
3. C -reactive protein (CRP)

All above mentioned laboratory investigations were carried out before and after treatment.

Intervention:

Drug: Combination of *Sanjivani vati* [6] and *Lashunadi vati* [7]

Dose : ***Sanjivani Vati***- 125 mg twice a day ***Lashunadi vati-*** 500mg twice a day

Anupana : Water

Duration: 60 days (2 months)

Time of administration: BD i.e., two times in a day after principal meals

Diet: Patients were kept under normal diet with special restriction of *virudhh ahaar*[8] (incompatible foods) as described in *ayurvedic*

texts. A copy of diet chart was given to each patient.

Follow-up: After 60 days.

The patients were given medicine for 60 days and were assessed after every 15 days i.e., 4 times during the course of treatment to observe the extent of relief and side effects, if any. Post treatment follow up was also done one month after the treatment to check the recurrence of symptoms, if any.

Assessment Criteria

The patients registered for the trial were assessed before and after the study by observing graded clinical signs and symptoms. Following parameters were taken into consideration:

1. Abnormal stool form
2. Frequent bowel movements
3. Abdominal pain
4. Abdominal Bloating
5. Mucus in the stool
6. Feeling of incomplete evacuation after a bowel movement

For above symptoms, the scoring was given as follows-

Table 1: Abnormal stool form

Features	**Grade**
No abnormality, Soft blobs with clear-cut edges (passed easily)	**G0**
Soft blobs with clear-cut edges (passed easily)	**G1**
Fluffy pieces with ragged edges, a mushy stool	**G2**
Watery, no solid pieces, entirely liquid	**G3**

Table 2: showing grading of frequency of stools

Features	**Grade**
No abnormality	**G0**
Mild: 2-3 stools above normal per day	**G1**
Moderate: 4 to 6 stools above normal per day	**G2**
Severe: >7 stools above normal	**G3**

Table 3: grading of Abdominal pain

Features	**Grade**
No pain	**G0**
Mild Pain	**G1**
Moderate Pain	**G2**
Severe Pain	**G3**

Table 4: abdominal bloating

Features	**Grade**
No feeling of bloating	**G0**
Bloating after taking excess of heavy food	**G1**
Bloating even after taking light food	**G2**
Bloating throughout the day, even on empty stomach	**G3**

Table 5: grading of mucus in stool

Features	**Grade**
No mucus in the stool	**G0**
Mild mucus mixed in the stool	**G1**
Slimy stool mixed with mucus	**G2**
Mucus discharge after passing slimy stools	**G3**

Table 6: feeling of incomplete evacuation after a bowel movement

Features	**Grade**
No Feeling of incomplete evacuation	**G0**

feels very happy after a bowel movement	
Slight Feeling of incomplete evacuation feels satisfactory after a bowel movement	**G1**
Incomplete evacuation and feels unhappy after bowel movement	**G2**
Very unhappy and feels heavy after bowel movement	**G3**

Statistical analysis: The data generated during the study was subjected to Wilcoxon signed rank test through spss software to assess the statistical significance between before and after the administration of trial drugs.

RESULTS

In this study, all the patients selected were in the age group of 18-70 years. Out of total enrolled subjects, 31 completed the study of which 18 (58.1%) were male and 13 (41.9%) were female.

Table 7: showing changes in the severity of Abnormal stool form in IBS-D patients

Severity grade	BT		AT1		AT2		AT3		AT4	
	N	%	n	%	N	%	N	%	N	%
G_0	00	00.0	00	00	03	09.7	14	45.2	27	87.1
G_1	04	12.9	14	45.2	26	83.9	17	54.8	04	12.9
G_2	14	45.2	17	54.8	02	06.5	00	00.0	00	00.0
G_3	13	41.9	31	100.0	00	00.0	00	00.0	00	00.0

BT: Before treatment, AT1: After 15 days of treatment, AT2: After 30 days of treatment, AT3: After 45 days of treatment, AT4: After 60 days of treatment, n: Number of patients.

Table 8: showing changes in the severity of Frequent Bowel Movements in IBS-D patients

Severity grade	BT		AT1		AT2		AT3		AT4	
	N	%	n	%	N	%	N	S	N	%
G_0	00	00.0	00	00	03	09.7	13	41.9	30	96.8
G_1	01	03.2	10	32.3	22	71.0	16	51.6	01	03.2
G_2	13	41.9	17	54.8	06	19.4	02	06.5	00	00.0
G_3	17	54.8	04	12.9	00	00.0	00	00.0	00	00.0

Table 9: showing changes in the severity of Abdominal Pain in IBS-D patients

Severity grade	BT		AT1		AT2		AT3		AT4	
	N	%	n	%	N	%	N	%	N	%
G_0	01	03.2	04	12.9	13	41.9	23	74.2	30	96.8
G_1	11	35.5	18	58.1	18	58.1	08	25.8	01	3.2
G_2	17	54.8	09	29.0	00	00.0	00	00.0	00	00.0
G_3	02	06.5	00	00.0	00	00.0	00	00.0	00	00.0

Table 10: showing changes in the severity of Abdominal bloating in IBS-D patients

Severity grade	BT		AT1		AT2		AT3		AT4	
	N	%	n	%	N	%	N	%	N	%
G_0	07	22.6	07	22.6	09	29.0	13	41.9	30	96.8
G_1	01	03.2	01	03.2	16	51.6	18	58.1	01	03.2
G_2	13	41.9	23	74.2	06	19.4	00	00.0	00	00.0
G_3	10	32.3	00	00.0	00	00.0	00	00.0	00	00.0

Table 11: showing changes in the severity of Mucus in stools in IBS-D patients

Severity grade	BT		AT1		AT2		AT3		AT4	
	N	%	n	%	N	%	N	%	N	%
G_0	00	00.0	00	00.0	02	06.5	14	45.2	27	87.1
G_1	05	16.1	16	51.6	24	77.4	17	54.8	04	12.9
G_2	11	35.5	13	41.9	05	16.1	00	00.0	00	00.0
G_3	15	48.4	02	06.5	00	00.0	00	00.0	00	00.0

Table 12: showing changes in the severity of incomplete bowel evacuation in IBS-D patients

Severity grade	BT		AT1		AT2		AT3		AT4	
	N	%	n	%	N	%	N	%	N	%
G_0	06	19.4	08	25.8	13	41.9	22	71.0	28	90.3
G_1	06	19.4	14	45.2	17	54.8	08	25.8	03	09.7
G_2	15	48.4	09	29.0	01	03.2	01	03.2	00	00.0
G_3	04	12.9	00	00.0	00	00.0	00	00.0	00	00.0

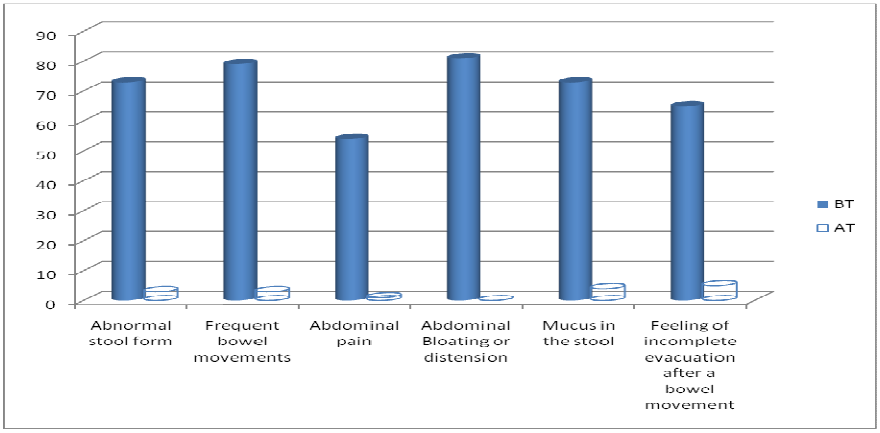
Table 13: showing improvement in clinical features of IBS-D after 60 days of treatment

S.	**Clinical features**	**Negative Ranks.**			**Positive ranks**			**Ties**	**Test Statistics**		**Remarks**
		Number	Sum	Mean	Number	Sum	Mean		Z	p (Asymp.Sig.)	
1	Abnormal stool form	0	0	0	31	496	16	0	-4.975	<0.05	S
2	Frequent bowel movements	0	0	0	31	496	16	00	-4.994	<0.05	S

3	Abdominal pain	0	0	0	29	435	15	02	-4.832	<0.05	S
4	Abdominal Bloating	0	0	0	24	300	12.5	07	-4.417	<0.05	S
5	Mucus in the stool	0	0	0	30	465	15.5	01	-4.885	<0.05	S
6	Feeling of incomplete bowel evacuation	0	0	0	25	325	13	06	-4.551	<0.05	S

Level of Significance α= 0.05 S= significant at p≤0.05

Fig. 1: Extent of symptomatic relief



After 60 days of treatment, statistically significant results were observed in all the features of IBS-D. No significant difference was observed in the mean change of hematological and bio chemical parameters after the drug administration.

Post treatment follow-up was also done, one month after the treatment. No recurrence of symptoms was observed.

DISCUSSION

The irritable bowel syndrome is a functional bowel disorder characterized by abdominal pain associated with defecation or change in bowel habit. It is one of the most common conditions that physicians are confronted with. In the civilized world, nearly 40 to 70% of the patients attending a gastroenterological clinic will have a functional disorder. Population studies have shown that 10 to 20 % of a western population and nearly 4.2 to 7.9% of Indian population [2] will have symptoms that are compatible with the irritable bowel syndrome. The vast majority of these will not consult a physician [9],[10],[11],[12] . Economic and cultural factors will influence the distribution of people with irritable bowel symptoms that will seek medical care.

The subjects included in the present study were screened on the basis of Rome III diagnostic criteria of IBS. The symptoms included for the assessment of diarrhea predominant IBS were based on those originally described by Manning [5]—namely bloating, abnormal stool form (loose stools in IBS-D), abnormal stool frequency (increased in IBS-D), pain abdomen straining at defecation, urgency, feeling of incomplete evacuation, and the passage of mucus per rectum.

Significant improvement was observed following 60 days of administration of drugs in all assessment parameters of IBS. One month post treatment follow up was also done and no any recurrence of the symptoms was reported.

From the *Ayurveda* perspective, this disease is caused as a result of *mandagni* (weak digestive fire) due to faulty diet and lifestyle in absence of any organic disease. *Mandagni*, causes improper digestion of ingested food, leading to accumulation of a number of unwanted by-products of digestion and metabolism called *ama*. This *ama dosha* is a root cause of most of the diseases. It has pivotal importance in the pathogenesis of IBS and manifestation of the aforesaid symptoms.

The trial drug *Sanjivani vati* has 11 ingredients and is indicated in *ajirna* (~indigestion), *gulma* (~fantum abdominal tumors), *visuchika* (~ cholera) [6].

Among the contents of *Sanjeevani Vati*, the drugs *Haritaki* (*Terminalia chebula* Retz.), *Vibhitak* (*Terminalia bellerica* Roxb.) *and Amalaki* (*Emblica officinalis* Gaertn.) known as *Triphala* are very well proved examples of *tridoshhara* (*sannipathara*) drugs. The *Shunthi* (*Zingiber officinalis* Roxb.) used in this compound is among one of the best *ama pachan* drugs mentioned in Ayurveda. Besides *Shunthi*, all other drugs in *Sanjeevani Vati* which also contribute with *Shunthi* to give this compound an excellent property to digest and remove *ama visha* from the body as well as to further extinguish the weakened *Agni*. *Gomutra* (cow's urine), *giloy* (*Tinosporia cordifolia* Willd Miers ex Hook f.& Thoms) are known for their antioxidant properties.

Lashunadi vati is polyherbal Ayurvedic medicine in tablet form which is used for treating dyspepsia, diarrhea and gastroenteritis. *Lashunadi vati* has carminative, laxative, stomachic and stimulant properties.

Garlic is a gastric stimulant and carminative [13]. It has been documented that garlic exerts a differential inhibition between beneficial intestinal micro flora and potentially harmful enterobacteria. The antibacterial activity is mainly attributed to allicin, since the antibacterial effectiveness of garlic extract is greatly reduced. Several fungi were shown to be susceptible, including Candida, Torulopsis, Trichophyton, Cryptococcus, Aspergillus, Trichosporon and Rhodotorula. Again, allicin showed antifungal activity but also diallyltrisulphide and ajoene[13].

Hingu (*Ferula narthex* Boiss) is antispasmodic, carminative and antiflatulent[14],[15]. *Jeerak* (*Cuminum cyminum* Linn.)is stimulant and carminative; stomachic and astringent and is also useful in dyspepsia and diarrhea [16].

A study indicated the crude extract of pepper. Pn.Cr (0.01–3.0 mg/mL) and piperine (30–1,000 μ*M*) relaxed spontaneous contractions, similar to loperamide and nifedipine in rabbit jejunum[17].

Psychological factors also affect gut motility and studies have indicated that patients with history of emotional distress, anxiety, stress, depression are associated with development of IBS. Studies from tertiary care suggest that up to half to two thirds of the IBS have a psychiatric disorder—most commonly anxiety or depressive[18],[19]. Recent large population based surveys suggest that even non-consulters have increased psychological distress compared with people who do not have IBS[20],[21].

Recently it has been reported that *Vacha* (*Acorus calamus* Linn.), one of the ingredients of *sanjivani vati* has antistressor activity and prevents stress induced changes in the rat brain by its antioxidant

activity[22]. It is also used as a sedative, tranquillizer, anxiolytic, nervine tonic and memory enhancer[23]. Asarone and beta-asarone are considered to be the active constituents. Its powdered rhizome is given in confused state of mind, depressed psychosis, dementia, and loss of consciousness, memory loss, anorexia and epilepsy [24].

Thus this combination of drugs apparently provides a comprehensive treatment for IBS that helps in breaking down pathogenesis as well as catering to the psychological aspect of etiology of the disease.

CONCLUSION

The combination of *Sanjivani vati* with *Lashunadi vati* is found to be effective in managing diarrhea predominant irritable bowel syndrome. Both the drugs are free from side effects. Moreover, by abiding the *pathya* (suitable/wholesome) and avoiding *apthya* (unsuitable/unwholesome) *aahaar-vihaar* (diet and lifestyle) patients have faster recovery and have reduced chance of recurrence.

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