



CLINICAL TRIAL TO EVALUATE THE EFFICACY OF HERBAL COMPOUND (BILVA, MUSTAK, JATAMANSI AND MANDUKAPARNI) IN THE MANAGEMENT OF IRRITABLE BOWEL SYNDROME (IBS)

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ABSTRACT

Irritable Bowel Syndrome (IBS) is a functional bowel disorder characterized by abdominal pain or discomfort and altered bowel habits. In ayurveda, there are several symptoms of vataja grahani roga that are related to IBS. Agnimandya is the root cause of grahani roga. **Objective:** To identify any adverse effect of the trial drug to decrease the morbidity of the disease and improve patients' quality of life. **Methods:** In an open randomized clinical study, 82 patients were diagnosed with IBS from the OPD and IPD of govt. Ayurvedic college and hospital, Guwahati. Patients were treated with the powder of herbal compound in a dose of 3gm twice a day with anupana of takra for 60 days. **Results:** Trial drug has shown an effective and statistically highly significant reduction in the symptoms score of various parameters, and no adverse effects have been found. **Conclusion:** concluded that the trial drug is safe and effective for the treatment of IBS.

Keywords: IBS, Agnimandya, Vataja-Grahani, Anupana

INTRODUCTION

Irritable bowel syndrome (IBS) is a common gastrointestinal disorder. IBS is characterized by abdominal pain or discomfort with altered bowel habits,^[1] in addition to other clinical features including nausea, loss of appetite, flatulence, mental distress, etc. IBS symptoms change over time and frequently overlap with other functional diseases. There is no permanent damage in the intestine, although IBS impacts the quality of life and hampers normal social activities. Modern medicine considers IBS a psychosomatic disorder. Subtypes of IBS: diarrhoea predominant (IBS-D), constipation-predominant (IBS-C), and mixed (IBS-M) (symptoms alternate between constipation and diarrhoea). Throughout the world, about 10-20% of adults and adolescents have symptoms of IBS. Pathogenesis of IBS might be caused by the abnormal gut motor and sensory activity, central neural dysfunction, psychological disturbance, mucosal inflammation, bile acid malabsorption, and altered gut flora. In ayurvedic literature, there are various signs and symptoms of vatika grahani roga^[2] that are also correlated with IBS. Vataja grahani is listed in the

grahani roga classification. According to ayurveda, "Rogah sarve api mandagnou"^[3] means the basic cause of the disease is Mandaagni and grahani is the adhistan(site)^[4] of Pachakagni. Grahani considers 'sixth pitta dhara kala'^[5] located in between amasaya and pakwasaya. Grahani roga is vividly described in ayurvedic literatures. Agni and vata dusti are important in the development of grahani roga. Dosa's involvement is mainly pachak pitta, Kledak kapha, prana vayu' saman vayu' and apana vayu^[6]. According to acharya charaka ayu (life) is defined as the combined state of sharira (body), indriya, (sense organs), satva (mind), and atma. (soul).^[7] Satva is a synonym of mana and thinking is related to the mind. Carak also described that body and mind (individually and in combination) are the asrayasthana (place) of diseases and happiness. Physical and mental disorders are caused by mithyayoga, ayoga, and atiyoga of kala, buddhi,^[8] and indriyas. As a result, psychological stress creates Manavaha srota dusti, which has an effect on sharirika dosas.

Table 01: Common symptoms of Vatik grahani roga and irritable bowel syndrome^{[2][9]}:

Vataja grahani	Irritable bowel syndrome
Punah- punaha srajat varcha	Increased frequency of stool
Annam pachyate dukham	Dyspepsia
Dravam sushkam tanu amam	Loose and hard and stool mucous stool
Suktapakam	Gastro esophageal reflux, due to hyperacidity
Parshava ruja	Pain in the abdomen flanks
Jeerne jeeryati cha adhmanam	Distention of abdomen and flatulence.
Uru vankshan ruja	Pain in the groin and lower limbs
Visuchika	Pricking pain in the abdomen
Hritpida	Noncardiac chest pain
Karsya dourvalya	Weight loss, fatigue, weakness
Parikartika	Pain in anus
Vairasyam	Distaste of mouth
Manasha sadanam	Psychological distress
Vata gulma, hrida roga pliha asanka	Doubt for any serious illness
Chirat dukham	Stool passes with pain
Sabdaphenvata	Excess gas formation and flatus

Aim and objectives:

1. To evaluate the efficacy of the herbal compound in the management of irritable bowel syndrome (IBS).
2. To identify the adverse effect of the herbal compound (if any).
3. To decrease the morbidity of the disease and improve quality of life.

Material and methods: CTRI reg no: ctri/2021/12/038944

Source of data

Literary source: the literature regarding this topic will be collected from ayurvedic classics and textbooks of modern medical sciences and research journals, and websites available over the internet.

Drug source: raw drugs were collected from the source of procurement after proper identification by an expert. Medicines were prepared at govt. Ayurvedic college Rasashala, Guwahati.

Sample source: patients fulfilling the diagnostic, inclusion, and exclusion criteria, which attending the OPD and IPD of the department of kayachikitsa at govt. Ayurvedic college & hospital, Guwahati.

Sample size and selection of the patients:

A total of 100 patients were enrolled in the study, but 18 patients dropped out at various stages of the study period and finally, 82 patients could complete the study. Randomized samples were selected for the clinical trial patients were selected in one single group irrespective of sex, religion, occupation, and socio-economic status and who fulfilled the diagnostic criteria, inclusion, and exclusion criteria for the study. In an open noncomparative clinical trial, there was no control group taken separately. The patient's information will be taken based on the demographic profile and clinical profile. **Demographic profile:** the patient's name, age, sex, religion, address, occupation, dietary habits,, socio-economic status,, etc. Are included in the demographic profile. **Clinical profile:** 1. Chief complaints with a duration of disease 2. Known history of other diseases, family history of any disease 3. Drug history, dietary history 4. Previ-

ous laboratory investigations (if any) etc. Are included in the clinical profile. After preliminary registration, thorough medical history and systemic examination and findings were recorded as per the proforma.

Diagnostic criteria:^[10]

- ‘Rome iv criteria’ for the diagnosis of irritable bowel syndrome.

Recurrent abdominal pain on average at least 1 day per week in the last 3 months, is associated with two or more of the following criteria:

1. Related to defecation
2. Associated with a change in the frequency of stool
3. Associated with a change in the form (appearance) of stool

(These criteria should be fulfilled for the last 3 months with symptom onset at least 6 months prior to diagnosis)

- Stool test routine examination was done for all the selected patients, to exclude the other illness.

Inclusion criteria:

- Patients fulfilling the diagnostic criteria.
- Patients of either sex between the age group of 18- 70 years, irrespective of sex, religion, occupation, and socio-economic status.
- Controlled non-communicable diseases (e.g- Diabetes, hypertension, etc.)

Exclusion criteria:

- Uncontrolled metabolic disorders and other systemic disorders (e.g- Diabetes, hypertension, renal dysfunction, liver disease, GI bleeding, hepatitis, recurrent fever, etc.)
- Patients suffering from major diseases like-
 - i. Coronary artery diseases
 - ii. Malignancy
 - iii. Tuberculosis
 - iv. STD, HIV
- Subjects who require surgical intervention for any such condition.
- Pregnancy and lactating period.

Table 02: Drug review: ^[11,12,13,14]

Ingredients of the trial drug	Botanical name	Family	Parts use	Proportion
Bilva	<i>Aegel marmelos</i>	Rutaceae	Unripe fruit	1 part
Mustak	<i>Cyperus rotundus</i>	Cyperaceae	Tubers	1 part
Jatamansi	<i>Nardostachys jatamansi</i>	Valerianaeeae	Rhizome	½ part
Mandukaparni	<i>Centella asiatica</i>	Umbelliferae	Whole plant	½ part

Preparation of trial drug: Churna (powder) of each herb bilva, mustak, jatamansi, and Mandukaparni coded as ‘BMJM chuma’ mixed in the ratio of 1: 1: 0.5: 0.5 and packed in a sterile airtight container.

Administration of drugs:

The trial drug was given to the selected patients through the oral route in a dose of 3 gm twice daily before meals with anupana of takra (buttermilk) for a period of 2 months and follow-up after 20 days intervals.

Dietary approach:^[15] Low-fodmaps diets, a diet low in fermentable oligosaccharides, disaccharides, mon-

osaccharides, and polyols appear to reduce the symptoms in patients with IBS.

Assessment criteria:

- Abdominal pain (udara shoola)
- Increased frequency of stool (puna- puna srijet bacha)
- Abnormal stool form (dravam suskam mala prabritti)
- Urgency in defecation
- Abdominal distension (adhmana)
- Mental stress (manasa sadana)

Table 03: Scoring pattern:

Sr. No	Assessment parameter	Grade	Symptoms
1	Abdominal pain (udara shoola) [a numerical rating scale (nrs) has been adopted to assess the intensity of abdominal pain]	0	No pain
		1	Mild pain 1-25%
		2	Moderate pain 26-50%
		3	Severe pain 51-75%
		4	Very severe pain 76-100%
2	Increased frequency of stool (puna- puna srijet vacha)	0	Once a day
		1	2-3 times a day
		2	4-5 times a day
		3	6-7 times a day or more frequently
3	Abnormal stool form (dravam suskham mala pravritti) [stool consistency evaluated by ‘the Bristol stool form scale’ chart] ^[16]	0	Normal consistency
		1	Soft blobs with clear-cut edges
		2	Fluffy pieces with ragged edges, mushy stool
		3	Watery, no solid pieces, entirely liquid
4	Urgency of defecation	0	Normal control
		1	Occasional feelings of the urgent need for defecation
		2	Frequent feelings of the urgent need for defecation
		3	Inability to control defecation
5	Abdominal distension (Adhman)	0	No abnormal flatulence
		1	Occasional discomfort for a short duration
		2	Frequent abdominal discomfort with increased flatulence and abdominal distension
		3	Gargling or rumbling sounds with flatulence and prolonged episodes interfering with social activities
6	Mental stress (manasa sadana) [perceived stress scale is used to assess the degree of nonspecific perceived stress, based on 10 questions]	0	Not feeling any stress
		1	Low stress
		2	Moderate stress

	3	High perceived stress
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(The scoring design was created according to the severity of symptoms)

Statistical analysis: The observations made before and after the completion of the study were considered for analysis. **Paired t-test** has been adopted for the assessment of the trial drug therapy.

Observations & results:

Table 04: Demographic characters:

Demographic characters	Highest recorded
Age	18-30 years (37.80%)
Gender	Males (60.97%)
Occupations	Jobs (24.39%)
Habitat	Urban area (59.75%)
Nature of sleep	Disturbed (70.73%)
Dietary habit	Non-vegetarian (91.46%)
Addiction	Alcohol (37.80%)
Lifestyle	Sedentary (57.31%)
Agni	Vishamagni (53.65%)
Jaranshakti	Avara (64.63%)
Deha prakriti	Vata-pittaja (48.78%)
Chronicity	1-5yrs (46.34%)
Kostha	Mridu (76.83%)

Table 05: Assessment parameter-wise distribution of 82 patients:

Si.no	Assessment parameter	Patients no.
1	Abdominal pain (udara shoola)	82
2	Increased frequency of stool (puna-puna srijit vacha)	82
3	Abnormal stool form (dravam susksham mala pravritti)	82
4	Urgency of defecation	68
5	Abdominal distension(adhman)	72
6	Mental stress (manasa sadana)	77

Table 06: Statistical analysis of the assessment parameters:

Assessment parameter n=82	(BT) Mean ± SD	(AT)mean ± SD	Df (n-1)	SE	t (81)	P-value
Abdominal pain	2.55± 0.93	0.33± 0.47	81	0.080	27.89	<0.001
Increased frequency of stool	1.85± 0.65	0.11± 0.31	81	0.073	23.81	<0.001
Abnormal stool form	2.29± 0.64	0.18± 0.39	81	0.067	31.38	<0.001
Urgency of defecation	1.96± 1.14	0.23± 0.42	81	0.114	15.21	<0.001
Abdominal distension	2.17± 1.00	0.20± 0.40	81	0.107	18.47	<0.001
Mental stress	1.63± 0.69	0.48± 0.50	81	0.088	13.22	<0.001

*p<0.001=highly significant, BT=before treatment, AT=after treatment, SD=standard deviation, SE=standard error

DISCUSSION

According to fundamental principles of ayurveda, agni has an important role to play in the physiological functioning of the body. Jathargni has been considered to be prime among all agnis and agni dusti is the primary cause of grahani vikara. The functioning of other agnis, like dhatvagni and bhutagni, is dependent upon the strength of jatharagni. According to Acharya caraka Aharaja and viharaja nidana are the causative factor for grahani roga. Grahani roga also manifested by saman avrita apan vayu dusti. Grahani roga mentioned in Mahagada. A wholesome diet is an important part not only of good health but also of curative aspects. In Carak Samhita 'Astavidha Aharavidhi Visesha ayatana' adhaya described different types of virudha ahara combination of foods which impact our good health. An unhealthy lifestyle including dietary habits and psychological disturbances like stress, anxiety, and depression is the triggering factor for IBS.

As trial drugs are concerned, the ingredients are bilva, mustaka, jatamansi, and Mandukaparni a proprietary herbal formulation, although various classical references are there were discussed about those herbal drugs.

Bilva (unripe fruit) having kashaya and tikta rasa, ushna virya, laghu, and ruksha guna, karma like-kaphavata samaka, grahi, dipana, pachana and indicated in atisara, Prabahika, grahani, agnimandya and

also has anti-microbial properties. **Mustak** (tubers) having tikta, katu, and kasaya rasa, sita virya, laghu and ruksha guna, karma like- kapha-pitta hara, dipana, pachana, grahi qualities and indicated in atisara, jvara, krimi, grahani, kandu, nidranasha. **Jatamansi** (rhizome) having tikta, kasaya and madhura ras, sita virya, laghu and snigdha guna, karma like- tridosahara, medhya, kusthaghna, balya. **Mandukaparni** (whole plant) having tikta rasa, laghu guna, madhura vipaka and sita virya, karma like- kapha pitta hara, medhya, Vayasthapana.

Anupana: takra ^[17,18,19] (buttermilk) increases strength, Agnideepak, grahi, easily digestible and nourishes the body. Takra has vata and kapha samak properties, mild amla and kasaya rasa, ushna virya, and having snigdha guna. It does not cause Pittaprakopa due to its madhura vipaka. The curd or yogurt are considered probiotics and takra is prepared by the churning of curd. So takra acts like a probiotic and helps in the growth of good bacteria, which plays an important role in maintaining gut flora and overall gut health. Probiotics are proven to be beneficial for IBS. In grahani roga, mainly agnidusti is there, usually mandagni. This results formation of ama and also may lead to shuktapaka. Trial drugs have properties like- tikta rasa, katu, kasaya rasa, katu vipaka, laghu and ruksha guna, acts as agni dipika and also amapachaka and increase Jathargni and act on grahani. Due to its laghu, ruksha, guna, and Katuvipaka it

acts as Srotoshodhaka, it's also penetrating minute srotasas. Psychological disturbance plays an important role in this disorder. So, a psychosomatic treatment approach has been undertaken in this study with the help of medhya rasayan, i.e., jatamansi and Mandukaparni. Hence, it is clear that bilva and mustaka act as Agnideepana, pachana, and grahi, which improve digestion, reduce frequency and correction in stool form. Where jatamansi and Mandukaparni are medhya rasayan, which act as a brain tonic, that aid to reduce mental stress levels, excitability and relaxing the mind, and also improve mental ability. So, help in samprapti vighatana.

CONCLUSION

It can be concluded from the study that trial drugs (Bilva, Mustak, Jatamansi, and Mandukaparni) were found effective in the remission of the symptoms of irritable bowel syndrome (IBS). The statistical analysis shows that result is highly significant in the assessment parameters. No adverse reactions to the trial drug were seen in the clinical study. The complete course of the treatment has improved in quality of life and health status of the patients. A total of 100 patients were registered for the clinical trial. However, 18 patients dropped out, and finally, 82 patients completed the trial. There is definite derangement of jatharagni, and some symptomatic correlations may be made with Vatik grahani, one of the types of Grahani roga. Doshas involvement are pachak pitta, Kledak kapha, prana vayu, saman vayu, and apana vayu. IBS is a functional gastrointestinal disorder having a cluster of symptoms and various etiological factors are there. Due to the chronic nature of this disease, there is a chance of recurrence which requires a long course of treatment. Medications having the properties like agnideepan, pachan, grahi, and medhya will be beneficial for IBS, along with lifestyle modification, dietary changes, and stress management are also very important.

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