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A clinical study of Digestive Health Capsules in the management of *Grahani Roga* with special reference to Irritable Bowel Syndrome

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ABSTRACT

Background: Clinical manifestation of *Grahani Roga* is similar to irritable bowel syndrome (IBS). IBS is not a life-threatening condition but it can significantly impact the quality of life. The prevalence of IBS varies from 12% to 15% in India. It is 3 times more common in women and people of working age. Due to the wide spectrum of disease, much prevalence in society and lack of effective medicines, the disease has been chosen for the trial. Digestive Health Capsules manufactured by Bombay Hemp Company is used in patients suffering from *Grahani Roga* (IBS). **Aim:** The aim of this study was to study the safety and efficacy of Digestive Health Capsules in the management of *Grahani Roga* (IBS). **Materials and Methods:** Forty clinically diagnosed patients of *Grahani Roga* (IBS) were selected and administered Digestive Health Capsules - 1 capsule twice a day with water after meal for 8 weeks. **Study Design:** It was an open labeled, single center, single arm clinical study. **Results:** The result was highly significant for all the subjective and objective parameters. **Conclusion:** Digestive Health Capsules can be used as safe and effective drug of choice in patients suffering from *Grahani Roga* (Irritable Bowel Syndrome).

Key words: *Grahani Roga, Digestive Health Capsules, Irritable Bowel Syndrome, Quality of Life.*

INTRODUCTION

In today's era, the lifestyle of people has changed, which influences the physical and psychological health. This is the root cause of many non-communicable diseases, especially metabolic diseases. Due to sedentary lifestyle and busy schedule people are often dependent on the pre-cooked (ready to eat) food that results in lack of important nutrients required to maintains health. Irregular food habits and timing and sedentary life play an important role in manifestation of diseases. All these factors lead to the irregular functioning of gastrointestinal tract which are often ignored in their early phase. Once they convert into chronic stage, the disease becomes difficult to cure.

Irritable bowel syndrome (IBS) is a frequent cause of abdominal pain and altered bowel habits worldwide. As per the Rome IV criteria, the disorder is characterized by recurrent abdominal pain associated with defecation or changes in stool frequency or form.[1] The syndrome is not a significant cause of mortality, yet it is associated with substantial

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healthcare utilization and reduction of quality of life.[2] Health related quality of life (HRQoL) data suggest physical impairment similar to patients with diabetes and a greater degree of impairment than those with depression and gastro-esophageal reflux disease.[3] The exact pathophysiology of IBS remains unclear. Proposed mechanisms include gut motility dis-regulation, altered microbiomes, visceral hypersensitivity and altered brain-gut interaction.[4] Other factors are exposures, inflammatory triggering, genetic susceptibility and psychological states.[5]

According to *Acharya Charaka*, *Sharira* and *Manasika Doshas* are interdependent on each other.[6] Psychological factors like stress, anxiety etc., plays an important role in the manifestation of IBS.[7] IBS is relatively a recent concept and as such is a new entry into the realm of clinical medicine itself. As there is no single disorder in *Ayurveda* which can be exactly correlates with IBS because *Ayurveda* is based entirely on different basic principles. Some conditions in particular, quite practically similar with IBS in their clinical picture, are *Atisara*,[8] *Pravahika*, *Grahani*[9] and *Pakvashayagata Vata*.[10] In Ayurvedic system of medicine, the concept of psychosomatic disorders has been widely discussed.[11]

In the management of IBS, many formulations have been mentioned in modern medicine. Modern therapeutic molecules may provide instant relief in these cases, but are tend to develop a number of adverse drug reactions and provide no permanent cure. Historically, medical management has focused on symptomatic treatment of these individual complaints.[12] Knowing this, the current suffering population is looking toward other systems of medicines which can provide cure not only relief, without manifesting any inconveniency.

In *Grahani Roga* (IBS), mainly there is vitiation of *Agni*, usually *Mandagni* is seen. This ultimately results in *Ama* formation. In this condition, *Tikta Katu* dominant *Rasa* of the ingredients help in digestion of *Ama* and ultimately break the pathogenesis of the disease. Besides this, there is dominancy of *Laghu*, *Ruksha Gunas* in Digestive Health Capsules which also helps in *Kaphaghna* property. This formulation dominantly has two *Dravyas* with *Ushnavirya* and two *Dravya* with *Sheeta Virya* which helps to pacify the *Vata Dosha* while *Deepana* and *Pachana* properties of the ingredients help to digest the *Ama* and control the *Vata Dosha*. The result of this trial is being presented here.

Aims and Objectives

1. To evaluate the safety and efficacy of Digestive Health Capsules in the management of IBS.
2. To assess the change in the Quality of Life score in the study group.

Materials and Methods

In this study, with the above-mentioned aims and objectives, the clinical study progressed utilizing the clinical material is as under:

Selection of patients

A total of 40 patients of *Grahani Roga* between the age group of 18 and 65 having classical sign and symptoms of *Grahani Roga* (*Amavastha*), i.e., *Muhu Baddha* and *Drava Mala Pravritti*, *Aruchi*, *Udara Shoola*, *Vishtambha*,[13] etc., were randomly selected from survey study irrespective of their sex, religion, occupation, etc., attending the OPD of the *Roga Nidana Evum Vikriti Vigyana* department, National Institute of Ayurveda, Jaipur for the present study.

Subjects were enrolled for the study considering the criteria of inclusion and consent was obtained from each patient in the study. The registered patients were given Digestive Health Capsules for internal use with water after food for 8 weeks. Study evaluation visits were made at baseline and screened subjects were asked to visit after every 15th day i.e., visit 1 (day 0), visit 2 (day 15), visit 3 (day 30), visit 4 (day 45), visit 5 (day 60). The study was conducted in compliance with Good Clinical Practice guidelines (ICH) and the declaration of Helsinki and national regulations. This was an open label, single arm, investigator-initiated drug trial in phase-2, comparing the efficacy and safety of the drug before and after intervention, and also studying the same at every follow-up of the patient.

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Pattern of study: The study was an open labeled, single center, single arm clinical study.

Treatment period: 8 weeks

CTRI registration: This clinical trial has been registered under CTRI (Ref CTRI/2022/03/041004).

Ethical clearance: The study was approved by Institutional Ethics Committee (IEC/ACA/2021/02-83)

Diagnostic criteria

All the patients were diagnosed on the basis of classical signs and symptoms of *Grahani Roga* (*Amavastha*). For the purpose of perfect diagnosis and assessment, a special research proforma was designed for the study incorporating all the relevant points from both *Ayurvedic* and modern views. The routine hematological, biochemical, urine, and other examination were carried out to assess the general condition and exclusion of other pathogenesis of the patients.

Inclusion criteria

- Patients between 18 and 65 years of age.
- Ability to consent to the study and able to read and write in English or local language.
- Subjects who are non-regular users of cannabis in any form (three times per week or more) and are willing to abstain for 1 week prior and during the study.
- Normal liver function (defined as aspartate aminotransferase 10-40 U/L and alanine aminotransferase 7-56 U/L)
- Normal renal function (defined as serum creatinine level < 133 umo/L and Estimated Glomerular Filtration Rate (eGFR) equal or higher than 60)
- Accepting not to use products with the same end benefit during the entire study duration.
- Subjects willing to stop alcohol, caffeine and nicotine consumption during the study duration.
- Cooperating, ready to sign consent form and ready to comply with protocol procedures.

Exclusion criteria

- Previous serious adverse event or hypersensitivity to cannabis or cannabinoids. Subjects receiving opioids and other concomitant anxiety medications.
- Presence of significant cardiac disease (history of unstable ischemic heart disease, heart failure, severe and uncontrolled hypertension) that, in the opinion of the investigator, would put the patient at risk of a clinically significant arrhythmia or myocardial infarction.
- Current substance use disorder evaluated by history.
- Life-time history of dependence on cannabis or diagnosis of cannabis use disorder.
- Pregnant women tested positive in UPT and lactating women or women planning pregnancy during the trial period. willing to ensure that they or their partner use effective contraception during the study period.
- Current use of cannabis in any form more than 3 times per week or use of cannabinoid-based medications within 7 days of study entry and refusal to abstain for the duration of the study.
- Positive blood test for cannabinoids at screening or positive urine screening for other potential abuse substances (e.g., alcohol, cocaine, amphetamines and methamphetamines, un prescribed opioids).
- For whom the Investigator considers that he/ she will not be compliant with study procedures.
- Any clinically significant systemic or cutaneous disease, which may interfere with study procedures.
- Participation in another clinical trial within 90 days of screening visit.

Drug and method of its preparation

Digestive Health Capsule' was the drug selected for the trial. The formulation of drug was kept confidential as per the protocol of the company.

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Table 1: Each capsule contains extract of the following herbs

SN	Ingredients	Botanical Name	Part Used	Qty/Cap.
1.	*Vijaya*	*Cannabis sativa*	Leaf	200 mg
2.	*Shunthi*	*Zingiber officinale*	Rhizome	100 mg
3.	*Kutaja*	*Holarrhena antidysenterica*	Stem bark	300 mg
4.	*Bilva*	*Aegle marmelos*	Fruit	200 mg

The medicine was prepared in the Bombay Hemp Company Private Limited. All the subjects were advised to continue their regular diet and exercise regimen during the entire study.

Duration of clinical trial and follow up study

1. Oral drug administration for 8 weeks.
2. All patients were followed up on the interval of 15 days for 2 months.

Methods of assessment

The assessment of IBS was done at the interval of 15 days on the basis of relief in chief complaints of IBS, disease specific Ayurvedic parameters and IBS severity score[14] and IBS-36 Quality of life scale.

Withdrawal Criteria

- A patient is considered as a dropout if he/she does not report for a follow up visit for more than 15 days after the scheduled date of visit.
- If the participant withdraws the consent for any reason
- If the participant is lost to follow up.
- If the participant's clinical condition worsens in spite of currently prescribed medications.

Assessment criteria

The assessment was done by considering changes in the subjective parameters before and after the treatment. The primary and secondary efficacy variables were recorded, some at every visit and others, before and after treatment.

- Clinical sign and symptom of *Grahani Roga* were recorded before and at the end of the treatment. These included clinical signs and symptoms of *Grahani Roga* which were i.e., *Muhu Baddha* and *Drava Mala Pravritti*, *Aruchi*, *Udara Shoola*, *Vishtambha* etc.
- Assessment of change in IBSSS Scale[15] (Irritable Bowel Syndrome Severity Scoring Scale) on every follow up of patient. A questionnaire was made consisting of 6 questions. Each question was scored accordingly to the patient's symptoms. IBS-SSS is a composite score of abdominal pain, number of days with abdominal pain, bloating/distension, satisfaction with bowel habits and IBS-related quality of life (QoL). Each measure is rated from 0 to 100, with total scores ranging from 0 to 500.
- QoL was evaluated with a thorough 36-item IBS-related QoL questionnaire[16] (improvement in WHO IBS 36 - Quality of life score), analyzed as a total score before (day 0) and after (day 60) completion of trial and as subscales on dysphoria, interference with activity, body image, health-related worries, food avoidance, social reactions, sexual and relationships.
- Assessment of Safety of the product was assessed by the physician and subject on the global assessment scale (GAS).
- All patients were contacted via phone prior to each follow up to inquire about medicine dose and any adverse events (AEs).

Patients were questioned at every visit for common drug related symptoms as per a predetermined checklist and encouraged to add any other symptom they considered as a drug-related side effect. At the end of study, no adverse event was found.

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OBSERVATIONS

Out of 44 registered patients, 40 completed the study. Four patients dropped out as they didn't complete the follow-up. The maximum number of patients were in the age group of 18-32 years of age (60%), male (75%), and had weight in the range 61-70 kg (52.5%).

Maximum no. of subjects was married (57.5%) and Hindu (90%). In the study, 45% of subjects were graduate and 59.4% subjects were involved in sedentary work without physical labor as seen by desk work. Majority of the subjects were from *Sadharana Desha*.

Dashavidha Pariksha biostatistics revealed that maximum numbers of the patients were having *Vata-Pitta Deha Prakriti* (65%), 40 % were having *Rasa Sara* followed by 27.5 % *Mamsa Sara*, 60% of the subjects had *Madhyama Samhanana*, 77.6% had *Madhyama Pramana*, 80% had *Madhyama Satva*, 72.5% had *Madhyama Satmya*, 72.5% *Madhyama Vyayama Shakti*, 77.5% had *Madhyama Abhyavaharana Shakti*, and 81.5% had *Avara Jarana Shakti* and 72.5% subjects had *Mahyama Vyayama Shakti*.

Review of the personal dietary history showed that 52.5 % were vegetarian, 60.3% were facing *Aruchi*, 72.3 % were having regular diet pattern, 54.4% of patients were doing *Pramitasana*, 38.6 % & 22.8 % patients were consuming *Madhura* and *Katu Rasa* respectively and 74.3 % have taking *Ushna Tikshana Guna Pradhana Aahara* in their diet at any time. 47.5% of subjects were usually consuming heavy food, whereas 56.4 % subjects were sometimes taking street food.

Review of the personal history showed that maximum numbers of the patients (70.6%) were doing work for 6–8 hours and majority were involved in sedentary work or activities, 67.5% of the patients were having normal sleep and 67.5% were having unsatisfactory bowel habit, 67.5% were having anxiety/tension followed by 32.5% who were depressed. In 37.88% patients, the frequency of stool was observed 3 to 4 times in a day, and 37.5% patients were suffering from disease for more than three years.

Review of the etiological factors: *Ati Katu Ahara* in 82.5% patients, *Ati Snigdha* (61.4%), *Ati Amla Ahara* (32.6%), *Ati Guru Ahara* (54.5%), *Ati Sheeta Ahara* (43.6%), and *Vishamashana* (44.6%) were observed as *Aaharaja Nidana*. Whereas *Diva Swapana* in 46.6% patients, *Vega Vidharana* (54.5%), *Ratri Jagarana* (30.5%), and *Ati Vyayam* (30.6%) were observed as *Viharaja Nidana*, *Chinta* in 52.4% patients, *Shoka* (42.5%), *Krodha* (39.6%), and *Bhaya* (24.8%) were observed as *Manasa Nidana*. In 38.4% patients, *Atisara* was found as *Nidanarthakara Roga*.

Chief complaints observed in patients were *Muhu Baddha* and *Drava Mala Pravritti* (100%), *Apachana* and *Aruchi* each (72.3%), *Udara Shoola* (78.6%), *Udara Guarava* (67.8%), *Atop* (84.5%), *Vidaha* (45.8%), *Vistambha* (34.8%), *Aalasya* (36.6%), and *Praseka* in 16.5% patients.

Review of *Rasavaha Shrotas Dusti lakshanas* like *Angamarda* was found maximum i.e., in 85 % patients followed by 80 % *Aganimandhya*. *Aruchi* was also evident in 45 % patients.

In this present study, *Annavaha Srotas Dushti Lakshanas* like *Atopa* was found in 82.5 % of patients, *Anannabhilasa* in 67.5 %, *Arochaka* in 57.5 % and *Kanthadaha* in 47 %.

Amongst *Purishavaha Srotas Dushti Lakshanas*, *Anaha*, *Drava* and *Shleshmamalapravritti* were found in all the patients whereas *Alpa Pravritti* was found in 32.5 % of patients.

On assessing the patients on IBS severity score, maximum patients had a severity score of > 300 (57.5 %) followed by 42.4 % of patients having moderate severity score. None of the registered patient was having mild severity score.

Statistics used

- The data has analyzed using Instat graph pad-3, free trial version, Graph Pad by Dotmatics.
- For nonparametric data, Wilcoxon matched pairs signed ranks test is used, while for parametric data, paired t-test is used.

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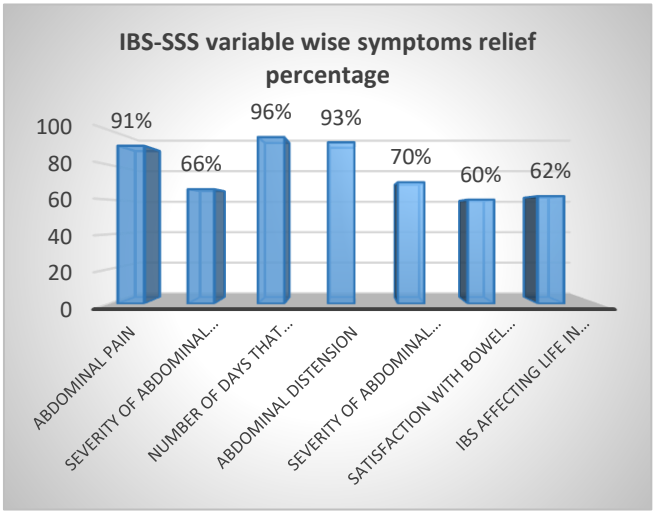
RESULT

Effect of therapy on Subjective Parameters

Table 2: Showing the effect of trial medicine (Digestive Health Capsule) on IBS Severity Scoring Scale in study group

Symptoms	Mean		Diff.	% Relief	± SD	SEM	W	P	Sig.
	B.T	A.T							
Abdominal pain	0.875	0.075	0.8	91	0.405	0.064	528.0	<0.0001	ES
Severity of abdominal pain	3.15	1.075	2.075	66	1.248	0.197	595.0	<0.0001	ES
Number of days that get the pain in every 10 days.	4.675	0.2	4.475	96	2.864	0.453	630.0	<0.0001	ES
Abdominal distension	1.00	0.075	0.925	93	0.267	0.042	703.0	<0.0001	ES
Severity of abdominal distension	3.5	1.05	2.45	70	1.108	0.175	741.0	<0.0001	ES
Satisfaction with bowel habit	3.075	1.225	1.850	60	0.864	0.137	703.0	<0.0001	ES
IBS affecting life in general	3.05	1.15	1.9	62	0.9	0.142	703.0	<0.0001	ES

The data above shows that the medicine provided extremely significant result (P<0.0001) in all the symptoms with maximum relief (96%) in number of days that get the pain in every 10 days followed by 93% improvement in abdominal distension, 91% in abdominal pain, 70% improvement in severity of abdominal distension, 66% in severity of abdominal pain, 62% in IBS affecting life in general, 60% in satisfaction with bowel habit.



Graph 1: IBS-SSS variable wise symptoms relief percentage

Table 3: Showing the effect of trial medicine on IBS Quality of life - 36 in study group

Symptoms	Mean		Diff.	% Relief	± SD	SEM	W	P	Sig.
Afraid to eat	4.675	1.050	3.625	78	1.254	0.198	820.0	<0.0001	ES
Felt angry	4.9	0.7	4.2	86	1.522	0.241	780.0	<0.0001	ES
Need to go suddenly when had a bowel movement	4.875	0.55	4.325	89	1.141	0.18	820.0	<0.0001	ES
Interfere with relationship with childre	1.825	0.25	1.575	82	1.852	0.293	190.0	<0.0001	ES

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n or partner									
Avoid food	4.35	1.225	3.125	72	1.488	0.235	703.0	<0.0001	ES
Bowel symptoms interfere with daily activities	4.275	0.475	3.8	89	1.418	0.224	780.0	<0.0001	ES
Other thought symptoms were not real	3.125	0.425	2.7	86	1.652	0.261	528.0	<0.0001	ES
Discouraged due to bowel problem	4.450	0.425	4.05	90	1.339	0.212	780.0	<0.0001	ES
Stop participating in sports activities	4.325	0.675	3.650	84	1.369	0.216	780.0	<0.0001	ES
Felt worried about never felling better	4.625	0.575	4.05	87	1.358	0.215	780.0	<0.0001	ES
Miss daily activities	4.25	0.3	3.950	93	1.154	0.182	780.0	<0.0001	ES
Bowel symptoms interfere to concentrate	4.3	0.425	3.875	90	1.114	0.176	820.0	<0.0001	ES
Felt isolated from family	3.4	0.4	3.0	88	1.32	0.209	703.0	<0.0001	ES
Embarrassed because of bowel symptoms	4.225	0.5	3.725	88	1.219	0.193	780.0	<0.0001	ES
Troubled by abdominal pain	4.125	0.15	3.975	96	1.847	0.292	630.0	<0.0001	ES
Afraid that bowel symptoms were getting worse	4.8	0.425	4.375	91	1.330	0.163	820.0	<0.0001	ES
Troubled by bowel movements that were hard/difficult to pass	4.525	0.4	4.125	91	1.067	0.169	820.0	<0.0001	ES

The data above shows that the medicine provided extremely significant in all the symptoms with maximum relief (96%) in troubled by abdominal pain followed by 93% improvement in missing daily activities, 91% in afraid that bowel symptoms were getting worse and troubled by bowel movements that were hard/difficult to pass, 90% improvement in discouraged due to bowel problem and interfere to concentrate, 89% in need to go suddenly when had a bowel movement and symptoms interfere with daily activities, 88% improvement in felt isolated from family and embarrassed because of bowel symptoms, 87% in

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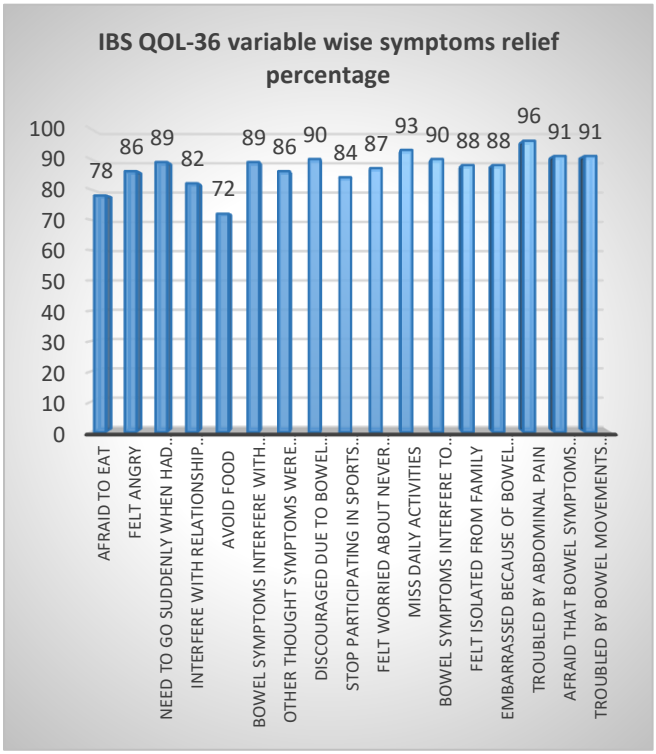
felt worried about never feeling better, 86% in other thought symptoms were not real and felt angry, 84% improvement in stop participating in sports activities, 82% in interfere with relationship with children or partner, 78% improvement in symptoms like afraid to eat, 72% improvement in avoid food.



Graph 2: IBS QOL-36 variable wise symptoms relief percentage

Table 4: Showing the effect of trial medicine on IBS Quality of life - 36 in study group

Symptoms	Mean		Diff.	% Relief	± SD	SEM	W	P	Sig.
Check diet from the previous day trying to find foods that might cause bowel symptoms	4.625	0.95	3.675	79	0.997	0.158	820.0	<0.0001	ES
Avoid travelling	4.275	0.625	3.65	85	1.122	0.177	780.0	<0.0001	ES
Shorten the length of work time of each day	4.00	0.275	3.725	93	0.847	0.134	820.0	<0.0001	ES
Bowel symptoms disturbed sound sleep	3.25	0.175	3.075	94	1.047	0.166	741.0	<0.0001	ES
Troubled by loose bowel movements	4.5	0.35	4.15	92	1.099	0.174	820.0	<0.0001	ES
Symptoms interfere with having sexual relations	1.825	0.425	1.4	82	1.566	0.248	190.0	<0.0001	ES
Bloating troubled	4.7	0.275	4.425	94	0.781	0.123	820.0	<0.0001	ES
Symptoms interfere with enjoyment	4.075	0.225	3.85	94	0.834	0.132	820.0	<0.0001	ES

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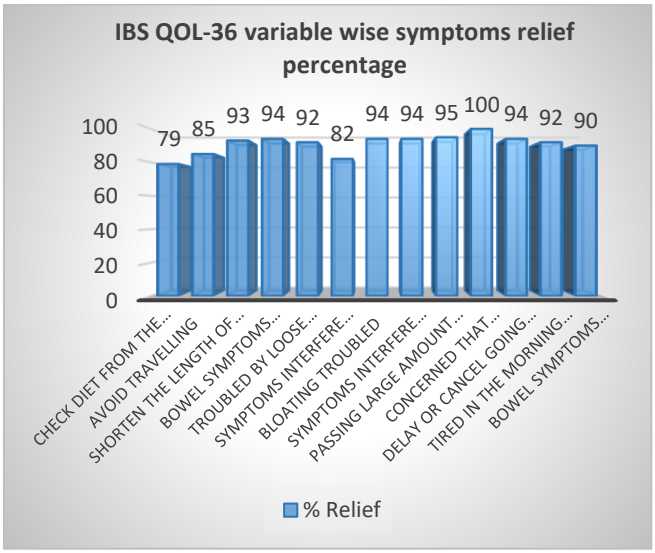
of sport or other activities									
Passing large amount of gas	5.425	0.25	5.155	95	0.662	0.105	820.0	<0.001	ES
Concerned that symptoms may be due to cancer	2.525	0.00	2.525	100	1.414	0.224	561.0	<0.001	ES
Delay or cancel going out socially	4.325	0.25	4.075	94	1.095	0.173	820.0	<0.001	ES
Tired in the morning because of bowel symptoms	4.625	0.375	4.25	92	1.149	0.182	820.0	<0.001	ES
Bowel symptoms interfere with desire to have sexual relations	1.875	0.175	1.7	90	1.8	0.285	210.0	<0.001	ES

The data above shows that the medicine provided extremely significant in all the symptoms with maximum relief (100%) in concerned that symptoms may be due to cancer followed by 95% improvement in passing large amount of gas, 94% in disturbed sound sleep, troubled by bloating, symptoms interfere with enjoyment of sport or other activities, delay or cancel going out socially, 93% improvement in shorten the length of work time, 92% in troubled by loose bowel movements and tired in the morning because of bowel symptoms, 90% improvement in symptoms interfere with desire to have sexual relations, 85% in avoid travelling, 82% improvement in symptoms interfere with having sexual relations and 79% improvement in check diet from the previous day trying to find foods that might cause bowel symptoms.



Graph 3: IBS QOL-36 variable wise symptoms relief percentage

Table 5: Showing the effect of trial medicine on IBS Quality of life - 36 in study group

Symptoms	Mean		Diff.	% Relief	± SD	SEM	W	P	Sig.
	B.T	A.T							
Need to go to the bathroom even	4.275	0.225	4.05	95	0.986	0.156	820.0	<0.001	ES

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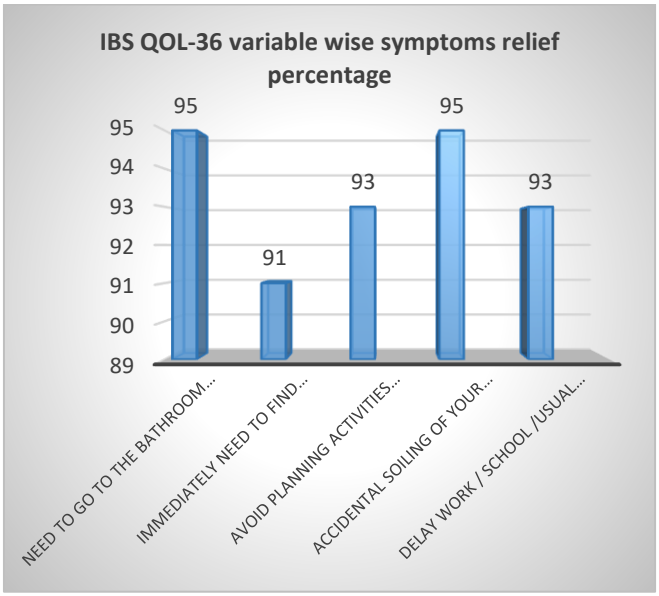
though bowels are empty troubled									
Immediately need to find where washrooms are at new place	4.075	0.35	3.75	91	0.877	0.139	820.0	<0.0001	ES
Avoid planning activities ahead of time because unsure of how bowel symptoms would be	4.425	0.3325	4.1	93	1.008	0.159	820.0	<0.0001	ES
Accidental soiling of your under wear troubled	2.75	0.15	2.6	95	1.336	0.211	703.0	<0.0001	ES
Delay work / school /usual daily activities because of bowel symptoms	4.25	0.275	3.975	93	1.05	0.166	820.0	<0.0001	ES

The data above shows that the medicine provided extremely significant in all the symptoms with maximum relief (95%) in need to go to the bathroom even though bowels are empty troubled and accidental soiling of your underwear troubled followed by 93 % improvement in avoid planning activities ahead of time because unsure of how bowel symptoms would be and in delay work / school /usual daily activities, 91 % improvement in immediately need to find where washrooms are at new place.



Graph 4: IBS QOL-36 variable wise symptoms relief percentage

Table 6: Showing the Effect of Digestive Health Capsules on Total Score of IBS Quality of life - 36 in Study Group

IBS-QOL 36 Scale	Mean Score	% Relief	± SD	SEM	W	P	Sig.
	130.15	92	19.486	3.081	820	<0.0001	ES

Table shows that trial medicine provided an extremely significant result (P<0.0001) with 92 % of relief on total score of IBS Quality of life -36 Scale.

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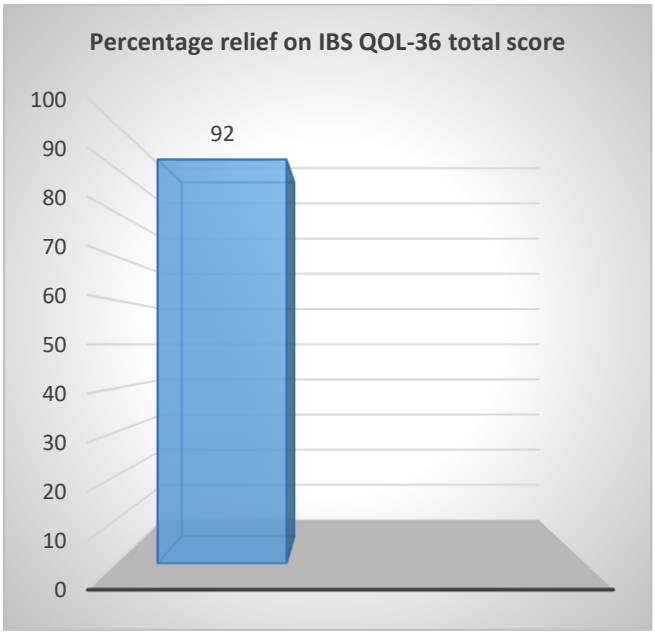

Graph 5: Percentage relief on IBS QOL-36 total score

A. Effect of therapy in objective parameters (lab investigations) (Paired T – Test)

- Hematological parameters like total RBC count were increased with the percentage of change by 4 % which is statistically extremely significant (P <0.0001) and Hb was increased with the percentage of change by 3 % which is statistically very significant (P = 0.0004). Other parameters like HCT, MCV, MCH, MCHC, RDW-CV, RDW-SD, total WBC count, Platelets with 1 %, 0 %, -2 %, 0 %, 0 %, -1 %, 4 %, 4 % respectively which did not showing significant result.
- WBC parameters like Neutrophil were increased with the percentage of change by 6 % which is statistically very significant (P =0.0008), remaining lymphocytes, monocytes, eosinophils, basophils were decreased with the percentage of change by -7 %, -10 %, -16 %, -10 % respectively which is statistically significant.
- LFT parameter SGOT showed significant result whereas SGPT and total serum bilirubin, direct bilirubin, indirect bilirubin, serum alkaline phosphatase, sr. albumin and sr. globulin showed statically non significant result.
- Lipid profile parameters like sr. cholesterol and sr. HDL were increased with the percentage of change by -6 % and 6 % respectively which is statistically extremely significant (P <0.0001).
- Other parameters like sr. triglyceride, serum VLDL both were found statistically non-significant with the percentage of change by -4 % and 4 % respectively. Sr. LDL was decreased with the percentage of change by -7 % which is statistically very significant.
- Random blood sugar level was decreased with the percentage of change by -3 % which is statistically non-significant.
- Sr. Urea was increased with the percentage of change by 6 % which is statistically non-significant and Sr. Creatinine was increased with the percentage of change by -1 % which is also statistically non-significant.
- Urine PH was increased with the percentage of change by 2 % which is statistically non-significant and there is no change in specific gravity which is also statistically non-significant.

DISCUSSION

Probable mode of action of the drug Digestive Health Capsules

Ingredients of Digestive Health Capsules are *Bhanga* (*Cannabis sativa*) 1/4 part, *Shunthi* (*Zingiber officinale)* 1/8 part, *Kutaja* (*Holorrhenaanti dysenterica* Linn.) 3/8 part, and *Bilva* (*A. marmelos* Corr.) 1/4 part.

In this combination, *Tikta Katu* dominant *Rasa* of the ingredients help in digestion of *Ama* and ultimately break the pathogenesis of the disease. Besides this, there is dominancy of *Laghu*, *Ruksha Gunas* in Digestive Health Capsules which also helps in *Kaphaghna* property. This formulation dominantly has two *Dravyas* with *Ushnavirya* and two *Dravya* with *Sheeta Virya* which helps to pacify the *Vata Dosha* while *Deepana* and *Pachana* properties of the ingredients help to digest the *Ama* and control the *Vata Dosha*.

Vijaya has been attributed with different pharmacological properties i.e., *Tikta Rasa*, *Laghu Guna*, *Usna Virya* and *Katu Vipaka*. It pacifies *Kapha*

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and *Vata Dosha*, increases *Pitta Dosha* and has *Dipana*, *Pachana*, *Rochana*, *Madakari* and *Vyavayi* action.

Kutaja (*Holorrhena antidysenterica* Linn.) possess *Tikta Kashaya Rasa*, *Katu vipaka*, *Sheeta Virya*, *Laghu*, *Ruksha guna*, and *Kapha-pittahara*. It has many qualities as *Deepana*, *Grahi*, *Jwarghna*, *Atisarghna*, *Arshoghna*, *Krimighna*, *Kushthaghna*, *Upashoshana*, *Raktastambhana*, *Dhatushoshana*, and *Vamaka*. It shows pharmacological actions such as antidiabetic, anti-urolithic, antibacterial activity, anti-hemorrhoidal, analgesic activity, anti-inflammatory, antimalarial, antidiarrheal, antimutagenic, antihypertensive, antioxidant/free radical scavenging, diuretic, anti-amoebic, anthelmintic, antitubercular, antispasmodic, antiprotozoal, antifungal, and anti-giardia properties.[17]

Bilwa (*A. marmelos* Corr.) possess *Kashaya Tikta Rasa*, *Laghu*, *Ruksha Guna*, *Ushana Virya*, and *Katu Vipaka*. It is *Deepana*, *Pachana*, *Graahi*, and *Vatakapha Shamana*. It works on *Grahani* due to *Grahi* property; on *Agni* due to *Laghu Guna Katu Vipaka* and *Deepana Guna*. It has property of *Amapachaka* due to *Tikta Rasa*, *Ushana Virya*, and *Laghu Guna*. It also possesses pharmacological actions such as antimicrobial, anti-inflammatory, antidiarrheal, antipyretic, analgesic, antidiabetic, hepatoprotective, and anticancer effects.[18]

Digestive heath capsule has *Deepana*, *Pachana*, *Graahi*, and *Vatakapha Shamana* properties along with anti-inflammatory, antidiarrheal, antispasmodic, antioxidant, analgesic activity, gut motility regulation, and immunomodulatory effect.

Conclusion

Based on *Rogaprakriti*, *Adhishthana*, and *Samutthana* as well as the clinical manifestations, *Grahani Roga* has a similarity with IBS. Vitiated *Vata Dosha* and the deranged status of *Agni* are the main components in the pathogenesis of *Grahani Roga*. No adverse or side effects were encountered during the study. Digestive health capsules are primarily found to be effective in the management of *Grahani Roga* as it has provided statistically significant relief in most of the symptoms. A further randomized controlled trial should be carried out to confirm the efficacy of Digestive health capsules in *Grahani Roga*.

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