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Research Article

A COMPARATIVE CLINICAL EVALUATION OF SHADDHARNA CHURNA AND PRE-PROBIOTIC CAPSULE IN CASES OF IRRITABLE BOWEL SYNDROME(IBS)

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ABSTRACT

Irritable bowel syndrome (IBS) is a functional disorder of Gastro-intestinal tract (GIT) with not well defined etiopathology in conventional system of medicine. As a disease entity it's comparable to Grahani roga & Pakvashayagata vata roga of Ayurveda, where motility of GIT is greatly hampered. The management of IBS seeks attention of research scholars because of inappropriateness of its management. In this emerging scenario the present clinical study was conducted in 90 patients to test the safety & efficacy of Ayurvedic formulation Shaddharan Churna in cases of IBS. In this series, a total 74 females and 16 male's cases were enrolled fulfilling the diagnostic criteria of Rome-III of IBS as well as exclusion and inclusion criteria. The patients were randomly allocated into three groups, viz- Group A- on preprobiotic, Group B on Shaddharan churna and Group C- on preprobiotic & Shaddharan churna as per prescribed dosing schedule. The cases were assessed on subjective and objective parameters for three successive follow ups on every third week. At the end of clinical trial patients of Group B showed significant improvement on different parameters such as Rome III, Birmingham questionnaire, IBS severity score (Frances et.al. quality of life), mucus present in stool and CRP. The overall assessment of degree of improvement in different trial groups reveals that patients of Group B showed significant results comparison to Group C & Group A. We finally conclude that Shaddharan churna is as effective as preprobiotic and imparts additive effect with ongoing preprobiotic therapy. No unwanted effects were noted during the trial period. So, the selected formulation is safe and effective in cases of IBS.

INTRODUCTION

Irritable Bowel Syndrome (IBS) is a major health problem of adult age group worldwide that influences their psychological behavior and quality of life. It is the most common functional gastrointestinal disorder with no organic cause imparts significant healthcare burden in developed as well as developing nations. It is characterized by chronic abdominal pain; discomfort, bloating, and alteration of bowel habits without any detectable structural pathology of lower GIT. Apart from the above symptoms, the patient may also experiences dyspepsia, increased flatulence, belching, heartburn, nausea and vomiting symptoms of upper GIT. Based on clinical features *"Atisrishtam vibadham va dravam tadupdishyate"*[1] of Ayurveda may be correlated with IBS of modern medicine up to some extent.The recent data indicates that a community prevalence of IBS ranging from 3%-22% with wide variations between countries. IBS affects 15-20% of Indian population. It occurs more often in women than in men and it begins before the age of 35 in about 50% of people[2]. The pathogenesis of IBS appears to be multifactorial and is still evolving in biomedical sciences. Traditionally IBS has been considered a disorder characterized by a dysfunction in the brain-gut axis, associated with: 1) psychosocial factors; 2) changes in intestinal motility; and 3) increased perception of stimuli arising from the intestine. More recently, several molecular and biochemical abnormalities have been identified such as genetic polymorphisms, transient gastrointestinal infections, neuro-immune interactions, increased mucosal permeability, altered serotonin metabolism, and the participation of luminal factors, including gut microbiota and dietary factors; that played a role in the diathesis of IBS. IBS is further classified according to the predominant bowel habit into diarrhoea predominant IBS (IBS-D), constipation predominant IBS (IBS-C) and mixed bowel pattern IBS (IBS-M). Currently, there is no biochemical, histo-pathological or radiological diagnostic test for IBS, with the diagnosis of IBS being based mainly on symptom assessment. The majority of gastroenterologists believe that a symptom-based diagnosis, such as that based on the Rome III criteria, without red flags is enough for the diagnosis of IBS and that no further investigations are needed. Treatment strategies for IBS

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management may include both nonpharmacologic and pharmacologic approaches. Lifestyle modifications that improve exercise, sleep, diet, and stress; are important tool for non-pharmacological approach and synthetic peripheral μ-opioid receptor agonist such as loperamide, antispasmodic agents, antidepressants, serotonin 5-HT_3 antagonists, laxative, dietary fiber, pre-probiotics, prosecretory agent's lubiprostone & linaclotide and the gut-specific antibiotic rifaximin are emerging as pharmacological approach. Interestingly, IBS patients had increased fecal levels of acetic and propionic acids which correlated with the severity of abdominal pain and bloating[3]. Researchers are continuing to optimize the use of available agents and evaluating new approaches to further improve the care of patients with IBS. . In Animals, it is studied reveals that germ-free environment exhibits abnormal GI tract development and functioning.[4] Ayurveda has a comprehensive description of drug and non-drug modalities of treatment for different kinds of GIT disorders dawn the ages with a wide range of herbal, mineral and herbo-mineral formulations. It seems profitable to explore the possibilities of developing an Ayurveda-inspired line of treatment of IBS for contemporary use today. In this emerging scenario, Ayurvedic formulation *'Shad-Dharana Churna'* (powder of six herbs) is selected as a trial by scanning large number publications and reports along with conventional oral pre-probiotic capsule. The selected Ayurvedic formulation is described by Sushruta in context of *Amashayagat vata*[5] and the same is also indicated for the management of *Pakvashayagata vata.* Such an exercise of 'Reverse Innovation' in the management of IBS is considered because of the fact that modern management of IBS is really not satisfactory.

MATERIAL AND METHOD

In the management of IBS many drugs and drug formulations have been mentioned in modern medicine, which provide instant relief up to some extent, but there are tend to develop a number of adverse drug reactions and no permanent cure is visible. Newer medications targeting the gut nervous system, such as different serotoninergic receptor modulators, are efficacious, but their availability is very limited due to restricted drug approval in selected countries, and some agents are suspected to have an unfavorable safety profile. Prebiotics &Probiotics are a preparation that contains viable commensal microorganisms, which have potential beneficial effects in the prevention or in the treatment of various gastrointestinal and other disorders (Sartor 2004) including IBS. These are considered as safe and usually well tolerated by the patients. Recent evidences support that prebiotic and probiotics have significant role in the management of IBS.

Shaddharan churna is a promising herbal drug formulation, mentioned in Sushruta samhita for the management of *Amashayagatavata* and *Pakvashayagatavata*[6].

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This formulation comprises of six herbal drugs as described below, which have pharmacological capacity to alter basic diathesis of IBS, relieves the clinical symptoms and maintain the integrity of GI mucosa without any unwanted and adverse effects. Therefore, this formulation will be tested in comparative manner with and without Cap containing prebiotic + probiotic to search out its role in the management of IBS.

Methods of Clinical Study

Selection of The Patients: Total 90 patients were selected irrespective of their sex, race, caste, religion for the above study from the OPD/IPD of Department of Kayachikitsa, SSL Hospital, BHU. The patients were registered and details of interrogation, examinations and investigations were carefully recorded in the proforma especially prepared for this purpose. Prior to enrolment, Institutional ethical approval and written inform consent were be undertaken**.**

Aims and Objectives

1. To evaluate the safety and efficacy of *Shaddharna churna* in cases of IBS
2. To evaluate the safety and efficacy of Pre-probiotic capsule in case of IBS
3. To develop *Shaddharana churna* as an adjuvant therapy with Pre-probiotic capsule in case of IBS

Ethical Approval: Ecr/526/Inst/Up/2014 Dt. 31.1.14

Nature of Study: Open randomized control clinical trial

Inclusion Criteria

a) Patients of either sex with age between 20 and 65 years
b) Known case of IBS as per Rome III criteria (2006):Symptoms of recurrent abdominal pain or discomfort and a marked change in bowel habit for at least 6 months, with symptoms experienced on at least 3 days/month in the last 3 months associated with two or more of the following:
c) Pain is relieved by defecation
(i) Onset associated with change of frequency of stools
(ii) Onset associated with a change in form (appearance) of stools.
d) Willing and able to participate in the study.

Exclusion Criteria

1. Patients of either sex below 20 year and above 65 years will be excluded from the study.
2. Patients with features of bleeding per rectum, mixed infection and evidence of malignancy.
3. Patients with diabetes mellitus, poorly controlled hypertension, major cardiac problems.
4. Patients on prolonged (>6 weeks) medication with corticosteroids, anti-depressants, anti-cholinergics, etc., or any other drugs that may have an influence on the outcome of the study.
5. Patients suffering from major systemic illness necessitating long term drug treatment Rheumatoid arthritis, tuberculosis, psycho-neuro-endocrinal disorders, etc.
6. Patients with concurrent serious hepatic disorder or renal disorders, severe pulmonary dysfunction or any other condition that may jeopardize the study.
7. Alcoholics and/or drug abusers.
8. History of hypersensitivity to the trial drug or any of its ingredients.
9. Pregnant/lactating woman.

10. Patients who have completed participation in any other clinical trial during the past 6 months.

Grouping of Patients

The selected patients were divided into three groups and following treatment was planned in respective group as below:

Grouping of clinical study data		
Group A (30) Control Group	Group B (30) Ayurvedic drug	Group C (30) Add on group
Trial drug- Capsule containing Pre + Probiotic (viable commensalmicroorganism)	Trial drug: *Shaddharana Churna*Anupana- Lukewarm water	Trial drug: (Ayurvedic drug *Shaddharana churna*+Drug of Group A)
Dose – 1 Cap OD	Dose-3 gms bid aftermeal	Dose – *Churna*-3 gms bid after meal + Treatment of group A.
Duration of Treatment- 9 weeks Follow ups - Every 3 weeks		

The selected patients were treated as above for full trial period and the findings were analyzed at the end of the trial. During the course of the treatment the patients were instructed to avoid oily & spicy food items, fried grains and raw vegetables and fruits.

Methods of Assessment Criteria To Assess The Trial Drug Response

The assessment of IBS was done at the interval of 3 weeks on following basis.

1. Rome III Criteria (2006) for diagnostic and assessment purpose.
2. Overall IBS severity score on VAS (develop by Francis CY, Morris J et.al, 1996). Here in this study the clinical assessment and investigation of irritable bowel syndrome have been facilitated by the introduction of a simple, easy to use severity scoring system.
3. Birmingham IBS symptom score: it is comprised a self-completed questionnaire, which is consists of 11 questions based on the frequency of IBS related symptoms. Each question had a standard response scale with symptoms all being measured on a 6-point Likert scale ranging from 0 = *none of the time* to 5 = *all of the time*.

Laboratory Profile

This disease being a functional disorder, rest of the biochemical and stool examinations were conducted to rule out the exclusion criteria and after treatment to assess the safety profile of the drug.

Hematological Investigations: Every patient was investigated for complete haemogram.

i. Blood urea and serum creatinine were estimated to assess the renal function status as well as to assess the safety profile of the drugs.
ii. Lipid profile was done to find out the lipid status of patients.
iii. Blood sugar fasting and PP were estimated to assess the metabolic state.
iv. Liver function test was done to assess the safety profile of the drugs.

Biochemical

C-Reactive Protein (CRP titre): This was done by the method of qualitative and semi quantitative latex fixation slide test. The test was based on the immunologic reactions between CRP as an antigen and Latex particle counted with nonspecific anti-human CRP and sensitized to detect levels greater than .6 microgram per milliliter (0.6 mg/dl).

Stool Examination (Microscopic): Mucous.Patients are advised for stool examination through concentration method at least 3 samples up to 3 consecutive days, to evaluate the mucus which is present in stool.

Therapeutic Study

Selection of The Trial Drug

In the present study *Shaddharana Churna* was taken as trial drug by scanning classical texts of Ayurveda and a large number of publications and reports in the management of gastro-intestinal disorders including, IBS and *Grahani roga*.

Preparation Of The Trial Drug

The useful part of *Shaddharan Churna* was taken from original sources and identified by the experts of the department of *Dravyaguna* and *Rasa Shastra*, Faculty of Ayurveda, IMS, BHU, Varanasi. The crude fine powder of six contents present in *Shaddharan churna* was prepared by Ayurvedic Pharmacy, BHU, Varanasi. Out of six, each drug was present in equal quantity in *churna*.

Dosage & Duration: The prepared *Shaddharan churna* was given 3 gms bid with luke warm water and Capsule Pre+ Probiotic- 1 OD, for 63 days.

STATISTICAL METHODS

Qualitative variables were assessed by Chi-square ($\chi 2$) test for significant difference among the groups. To assess the effect of drug from base line to different follow ups in Quantitative and Qualitative variables respectively unpaired 'T'-test, 'Z'-test and Mann Whitney Test was applied. To assess the Quantitative and Qualitative variables within the group respectively Paired 'T'-test, 'Z'-test and Wilcoxon signed ranks test was applied.

OBSERVATION AND RESULT

Demographic Profile

It was noted that maximum patients (33.3%) belonged to the age group 31-40 years followed by 41-50 years of age group i.e. 31.1%. The study also shows the incidence of IBS higher in females (74%) which lead to observations that IBS is more common in female. This area being predominantly Hindu dominated, so the study reflects more patients of Hindu religion. The present study covered a cross section of the society. It was found that majority of them were belonged to the lower middle socio-economic status (i.e. 97.0%) followed by 3.0% from upper middle socio-economic status and residing more or less equally in urban and rural areas.

Symptoms of Ibs

In patients, IBS symptoms can be categorized into three categories based on consistency of stool. It is observed that in 90 patients there were 55.55% had diarrhoea predominance,

36.66 % had constipation predominance, while 7.77% had mixed features of stool pattern.

Abhyvaharanshakti

Assessment of *Abhyvaharanshakti* was observed in all 90 cases of IBS, it is found that *Abhyvaharanshakti* was *Avara* in 68.89% and *madhyam* in 31.11% patients. This data show that disturbed appetite and improper intake of food may lead develops IBS.

Jaranashakti

Assessment of *Jaranashakti* was observed in all 90 cases of IBS (*Grahaniroga)*, it is observed that 72.22% patients had *Avara Jaranashakti* followed by 27.78% patients in *Madhyam Jaranashakti*. This data shows that improper digestion of food may lead to develop IBS.

Clinical Profile

Rome Iii Criteria

The mean score Rome III Criteria before treatment in Group A, B and C was 26.233, 25.333 and 26.172 respectively. In the first follow up i.e. after 21 days, there was no significant reduction in the mean score of any group. In the 2 and 3rd follow-up of patients Group-B and C, had significant improvement as compare to Gr-A (shown in TableI).

Ibs Severity Scores (Francis Et.Al.)

IBS severity score had 5 questions and each question had 100 marks. The mean was calculated after adding these 5 questions. The mean score of IBS severity score before treatment in Group A, B and C was 307.666±58.162, 267.133±63.829 and 311.1±63.177 respectively. After completion of trial treatment there was significant reduction in severity of symptoms in all three groups (shown in Fig. I).

Birmingham Questionnaire

The mean score of 'Birmingham Questionnaire' before treatment in Group A, B and C was 45.5, 43.266 and 42.13respectively. In the first follow up, there was some reduction in the mean score. In the 2 and 3rd follow-up patients of Group-A and C, little decrease in the mean score as compare to Group-B patients (Gr.B>Gr.C>Gr.A) (shown in Fig.II).

Therapeutic Profile

Crp Level

Before treatment CRP in terms of mean ± SD Group A, Group B and Group C was, 2.57 ± 1.47, 3.51 ± 1.50 and 2.54 ± 0.63 respectively, which were reduced at the end of trial treatment to 2.58 ± 1.31,3.30 ± 1.26 and 2.37 ± 0.67 in Group A, Group B and Group C, respectively (shown in Table II).

Mucous In Stool

The study reveals that in Group A there were 46.7% patients were having mucous in stool while in 53.30%mucous was absent likewise in Group B 53.30% patients were having mucous in stool while in 26.70% mucous was absent and in Group C 53.30% patients were having mucous in stool while in 53.30% mucous was absent (shown in Table III).

DISCUSSION

A total of 90 patients were registered. Out of which 9 patients were dropped out due to transferable job, familial restriction and drug compliance and 81 patients were completed the follow up. The observations of demographic profile suggests that IBS is a disease of upper middle class to lower middle class and confined to third to fourth decades of age group, occurring due to faulty lifestyle and stressful situations. The

Table I Effect of drug on ROME III Criteria in IBS patients (n=81)

Group	ROME III CRITERIA Mean ± SD				Within the group comparison
	BT	F1	F2	AT	Paired t test BT-AT
Group A (n=30)	26.233 ±4.407	19.533 ±3.54	15.733 ±2.288	11.4 ±3.682 (n=27)	14.83±6.15 t=13.191 p=0.000 (HS)
Group B (n=30)	25.333 ±2.106	19.966 ±2.399	12.633 ±1.79	7.566 ±2.329 (n=27)	17.76±2.87 t=33.871 p=0.000 (HS)
Group C (n=30)	26.172 ±2.673	20 ± 2.283	15.62 ±1.544	9.068 ±3.058 (n=27)	17.10±2.65 t=34.751 p=0.000 (HS)
Between the group comparison One way ANOVA	F = 0.728 p = 0.486	F = 0.257 p = 0.774	F = 25.461 p = 0.000 (HS)	F = 11.844 p = 0.000 (HS)	
Post Hoc test					
A vs B			p=0.000	p=0.000	
A vs C			p=0.000	p=0.014	
B vs C					

Table II Change in CRP level in patients of *IBS* (n=81)

Group	CRP Mean ± SD		Within the group comparison
	BT	AT	Paired t test BT-AT
Group A (n=30)	2.57±1.47	2.58±1.31 (n=27)	0.006±0.683 t=-0.053 p=0.958(NS)
Group B (n=30)	3.51±1.50	3.30±1.26 (n=27)	0.21±1.01 t=1.154 p=0.258(NS)
Group C (n=30)	2.54±0.63	2.37±0.67 (n=27)	0.16±0.69 t=1.281 p=0.211(NS)
Between the group comparison One way ANOVA	F=5.56 P=0.005	F=5.48 P=0.006	
Post Hoc test			
A vs B	p=0.016	p=0.044	
A vs C			
B vs C	p=0.014	p=0.007	

Table III Effect of drugs on mucous in stool in patients of *Grahani* (n=81)

Group		Mucous				Within the group comparison
		BT		AT		Cochrane's Q-test
Group A (n=30)	Present	14	46.70%	6	20.0%	Q = 8.000
	Absent	16	53.30%	24	80.0%	p = 0.005
Group B (n=30)	Present	22	73.30%	6	20.0%	Q= 16.000
	Absent	8	26.70%	24	80.0%	P = 0.000
Group C (n=30)	Present	16	53.30%	5	16.7%	Q = 11.000
	Absent	14	46.70%	25	83.3%	P = 0.001

present study reveals that women are more sufferer than men, which is quite similar to the recent study that in most of the populations, women reported more IBS symptoms than men. Rates in women are approximately 1.5- to 3-fold higher than those seen in men[7]. Recent evidence suggests that the prevalence of IBS increased significantly in third to fifth decades of life, which is quite comparable to our finding. This study recalls that present rural adaptation of urban dietary and lifestyle pattern has increased the incidence of this disease. It is well known fact that urbanization may leads to changes in lifestyle, which in turn increase the risk of IBS. It is also suggested that this is due to the higher level of stress perceived by people working in professional and managerial roles in urban areas.[8] This supports the argument that IBS is a disease of industrialization and urbanization, and that the higher rates now being reported in Asia, South America, and Africa are due to increased affluence in these regions.[9] This may be because those with higher income have greater access to health care and tendency to seek help and hence receive a diagnosis.[10] It could also reflect differing dietary choices[11] or greater internalization of stress in higher earning groups.[12]

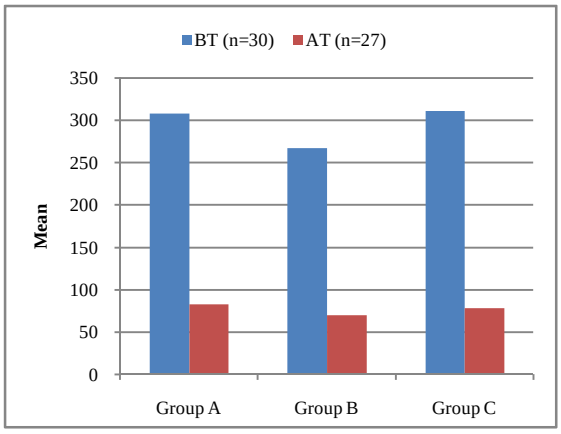

Figure I Effect of drug on IBS severity score (Francis etal.)in IBS patients (n=81)

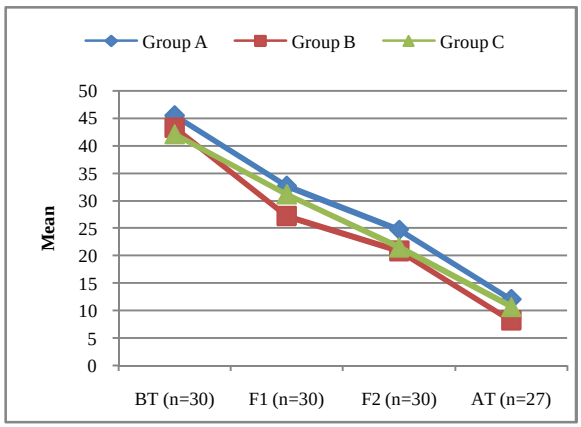

Figure II Effect of drug on Birmingham Questionnaire in IBS patients (n=81)

Clinical Presentation Profile

On the basis of aggregation of symptoms of Rome III criteria, it was observed that at the end of trial treatment the mean reduction in symptoms of Rome III was greater (17.76) in Ayurveda treated group B, followed by 17.10 in group C and 14.83 in group A. However, the overall better response was noted in group B followed by group C. This shows that *Shaddharna churna* is as effective as Pre-probiotic capsule and imparts additive effect when combine together (shown in table 1). This study also reveals that IBS severity score, which was based on quality of life showed better response in group C (74.85%) and group B (73.60%) while patients of group A shows lesser response (72.95%) in terms of % decrease. However, in overall better response was noted in group C followed by group B. This indicates that both *Shaddharna churna* & Pre-probiotic capsule jointly improve the quality of life and gut function in IBS patients (Shown in Fig 1). There was another questionnaire developed by Birmingham based on the Rome III criteria were observed in different trial groups of IBS patients before and after treatment. But greater response in terms of mean changes was noted in patients of group B (35.03) and group A (33.43), while patients of group C shows lesser response (31.40). However, overall better response was noted in group B followed by group A(shown in Fig 2).The drug treatment response was assessed in terms of CRP (quantitatively) and mucous in stool. In terms of decrease in mean the group B shows maximum decrease mean changes of CRP in the group B treated with Ayurvedic drugs and group C treated with Ayurvedic drugs + modern drug in comparison to modern drug treated group A (shown in table 2). In Group A there were 46.7% patients were having mucous in stool while in 53.30% mucous was absent likewise in Group B 53.30% patients were having mucous in stool, improvement present in all the three groups but maximum effect was seen in group B in term of mucus reduction in the cases of IBS (shown in table 3). The presence raised CRP level and mucus in stool signifies that there are chances of inflammation, which interfere in the functioning of Gut-brain axis. However, during the trial TLC, DLC, Hb%, Blood urea, Serum creatinine level, Liver function test are fluctuated within the normal range. Besides this, no unwanted effect were observed in case of LFT, RFT, haematological test and ECG before and after treatment. It reveals that selected Ayurvedic drugs and measures are safe and effective to ameliorate the clinical symptoms of IBS.

Probable Mode of Action of pre probiotics

Based On the Pharmacological Action

The term “probiotic” as originally defined by FAO/WHO refers to “live microorganisms that, when administered in adequate amounts, confer a health benefit on the host” in order to be beneficial. Probiotics can enhance gut barrier function, inhibit pathogen binding and modulate gut inflammatory response. Probiotics are useful also on D-IBS, as a probiotic mixture containg Lactobacillus acidophilus, Lactobacillus plantarum, Lactobacillus rhamnosus, Bifidobacteriumbreve, Bifidobacteriumlactis, Bifi dobacteriumlongum, and Streptococcus thermophilus has shown to be effective in controlling symptoms, but the effect on intestinal motility and transit time in this subtype of patients is less proven.

Probable Mode of Action of Shaddharan Churna in IBS

Shaddharan churna is a promising herbal drug formulation, mentioned in Sushruta samhita for the management of Amashayagatavata and Pakvashayagatavata. This formulation comprises of six herbal drugs as described below, which have pharmacological capacity to alter basic diathesis of IBS, relieves the clinical symptoms and maintain the integrity of

GI mucosa without any unwanted and adverse effects. The basic information of each drugs are given below.

1. Chitraka (*Plumbagozeylanica*): It has *Katu rasa* (pungent in taste) and *deepana-pachana* property. It is indicated in *Grahaniroga, Arsha, Krimi* etc. (B.P[13].).Its main ingredient is plumbagin and it is used in treatment of diarrhea and dysentery.[14]
2. Kutaja (*Holarrhenaantidysenterica*): It has *Tikta* (bitter) and *Kashaya* (astringent*) rasa.* Acts as *Samgrahi* and *Ama-pachana* due to *Tikta rasa*. It is used in diarrhea, haemorrhoids etc. (B.P.[15]) Kutaja is used in colic, dyspepsia, piles*; Kutaja* powder supports intestinal health and comfortable elimination of feces. It bolsters the G.I. Tracts and empower natural defenses. Promotes digestion and dispels natural toxins.[16]
3. Haritaki (*Terminaliachebula*)- It has *Kashaya* predominant rasa and it is directly mentioned in *Grahani roga* (C.Ci-1)[17].
4. Patha (*Cissampelospareira*)- It is used in abdominal pain, diarrhea, vomiting. It is *Grahi* in nature. (B.P[18]./C.Su.27[19])
5. Katuki (*Picrorhizakurroa*)- It is Katu (pungent) and Tikta(bitter) rasa predominant drug. It act as a *Deepana* drug and helpful in *Amapachana*. (B.P.)[20]. It has been found effective in in cases of colitis.[21]
6. Ativisha (*Aconitum heterophyllum*)-Ativisha is the best among *Deepana, Pachana* and *Samgrahik* drugs (C.Su.25[22], B.P.[23]).

SUMMARY & CONCLUSION

IBS is a complex condition that is not well linked to any readily measured physiological abnormality. Despite advances in understanding of basic neuroenteric mechanisms and the role of effectors and transmitters in the brain-gut axis, a reliable biologic marker of IBS has yet no to be defined in conventional gastroenterology. Pro measures of the signs and symptoms of the condition are the only currently available measures that can adequately define a treatment effect in a clinical trial. The selected formulation not only have encouraging results in terms of aggregation clinical symptoms of IBS (Rome III), Birmingham questionnaire but also improve the quality of life score (Francis *et al*). Besides, reduction of CRP and changes in stool pattern are also noted after completion of treatment. No adverse drug reaction seen during the trial period. The trial response of Ayurvedic formulation i.e. *Shaddharna churna* is comprable to Pre-Probiotic line of management of IBS in conventional Gastroenterology. Hence, the selected formulation is safe, effective and has capacity to improve overall health status of IBS subjects and emerging as an adjuvant with conventional pre-probiotic capsule. This indicates that this formulation act in similar as pre-probiotic capsule and potentiate its action at GIT level. Therefore, it will be new of its kind in cases of IBS.

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