

A CLINICAL STUDY ON GRAHANI ROGA UNDER THE INFLUENCE OF SHADADHARAN CHURNA

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ABSTRACT

The management of Grahani seeks attention of research scholars because of inappropriateness of its management in conventional system of medicine. In this emerging scenario the present clinical study was conducted in 30 patients to test the safety & efficacy of Ayurvedic formulation *Shaddharan Churna* in cases of Grahani. In this series, a total 25 females and 5 males cases were enrolled fulfilling the exclusion and inclusion criteria, between the age group of 20-65 years. The patients were randomly selected. 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 showed

significant improvement on different parameters such as *Atibadha mala* (constipation) or *Atidrava mala* (diarrhea), *Udarashool* (pain in abdomen), *Aruchi* (decrease in desire to intake food), *Alasya* (feeling of lethargy), *Jwara* (feverish feeling), *Balabhransha* (feeling of reduced physical and mental strength). We finally conclude that *Shaddharan churna* was effective and no unwanted effects were noted during the trial period.

KEYWORDS: IBS, Grahani, Shaddharan Churna, Ama, Agni, Jwara, Gaurav.

INTRODUCTION

Ayurveda has strong and highly evolved theoretical backup of diathesis of disease such as "*Rogah sarveapi mandeagnau*".^[1] It means hypo-functioning of Agni play a direct role in the genesis of variety of disorders or play an indirect role through formation of *Ama* at the level GIT. The features, which are described in the context of IBS is specially related to the

functional impairment of *Grahani* region, which is the important seat of collection & digestion of diet, differentiation between absorbable and un-absorbable food items, and passed on feces via the anus. It is also important seat of bio-humors such as *Pachakagni*, *samanavayu* and *Kledakakapha*. If the physiological functions of these bio-humors specially *Pachakagni* function, are/is deranged may lead to derange the functions of *Grahani* region in vicious manner and finally lead to *Grahani roga*. Hence, based on symptoms, *Atisrishtamvibadhamvadravam*^[2] *grahani roga* of Ayurveda may be correlated with IBS of modern medicine up to some extent. But at the time of understanding of pathogenesis, diagnosis & management, the concept of *Ama* in relation to *Mandagni* is quite significant along with involvement of *Annavaha Purishava*, *Rasavaha* and *Manovaha Srotodushti*. The principal of treatment *Atisara*, *Ajirna*, *Grahani* are taken into account at the time of management. If it is not treated properly it may lead to develop serious medical conditions such as *Arsha*, *Udar roga* and other structural deformity related disorders of GIT.

One may find a comprehensive description of drug and non-drug modalities of treatment for different kinds of GIT disorders with a wide range of herbal, mineral and herbo-mineral formulations for the treatment of *Grahani roga*. 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.

It seems that issues depicted above can be tackled with the holistic approach of Ayurvedic medicine. The drugs of Ayurveda are claimed to produce bio-balancing effect, promoting GI biofire, digestant effect, promoting essential nutrition & immune enhancing effect along with maintain the integrity of GI mucosa and interfere in the process of diathesis of disease. Such a line of management is preferred in Ayurveda for the management of such type of disorders because of the role of *Agni* and *Ama* is considered as important initiating factors in the basic matrix of IBS. Because *Grahani* is considered as a seat of *Agni* & *Ama* formation, which can be effectively controlled by holistic approach of Ayurvedic drug therapy.

Shadadharana Churna consists of 6 drugs, which is described by *Sushruta* in context of *Amashayagatvata*^[3] and the same is also indicated for the management of *Pakvashayagatavata*. The basic information of each drug is 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./D.N.). Its main ingredient is plumbagin and it is used in treatment of diarrhea and dysentery.^[4]

2. *Kutaja (Holarrhena antidysenterica)*: 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.)^[5] *Kutaja* is used in colic, dyspepsia, piles; *Kutaja* powder supports intestinal health and comfortable elimination of feces. It bolsters the G.I. Tracts and empowers natural defenses. Promotes digestion and dispels natural toxins.^[6]

3. *Haritaki (Terminalia chebula)*- It has *Kashaya* predominant *rasa* and it is directly mentioned in *Grahaniroga* (C.Ci-1).^[7]

4. *Patha (Cissampelos pareira)*- It is used in abdominal pain^[8-9], diarrhea, vomiting. It is *Grahi* in nature. (B.P./C.Su.27)^[10-11]

5. *Katuki (Picrorhiza kurroa)*- It is *Katu* (pungent) and *Tikta* (bitter) *rasa* predominant drug. It acts as a *Deepana* drug and helpful in *Amapachana*. (B.P.).^[12] It has been found effective in cases of colitis.^[13]

6. *Ativisha (Aconitum heterophyllum)*- *Ativisha* is the best among *Deepana, Pachana* and *Samgrahik* drugs (C.Su.25, B.P.).^[14-15]

MATERIAL AND METHOD

Shadadharanchurna is a promising herbal drug formulation, mentioned in Sushruta samhita^[16] for the management of *Amashayagatavata* and *Pakvashayagatavata*.

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METHOD OF CLINICAL STUDY

Selection of the Patients: Total 30 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 after detail history, taking clinical and laboratory examination, subjective and objective assessment. After following the inclusion and exclusion criteria. Prior to enrollment Institutional ethical approval and written informed consent was undertaken.

Inclusion Criteria

- a) Patients of either sex with age between 20 and 65 years.
- b) Willing and able to participate in the study.
- c) Presence of cardinal features of *Grahani Roga* as described in Ayurvedic lexicons.

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.

Subjective grading scale for *Grahani* symptoms: To assess the subjective features of *Grahani* the clinical symptomatology was graded on VAS from (0-10) scale and the same is applied in each patient of *Grahani*. The Visual Analogue Scale (VAS) is a scale which is truly subjective in nature and measures the severity of pain of a patient.

The change in the gradations of each symptom was assessed the effect of given treatment. The seven important clinical symptoms of *Grahani* were used in this thesis as described in Ayurveda.

1. *Atidrava mala* (diarrhea predominant motion) or *Atibadha mala*(constipation predominant motion).
2. *Udarashool* (pain in abdomen).
3. *Aruchi* (decrease in desire to intake food).
4. *Alasya* (feeling of lethargy).
5. *Jwara* (feverish feeling).
6. *Balabhransha*(feeling of reduced physical and mental strength).

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.

(1) Hematological investigations: Every patient was investigated for complete haemogram.

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

2. Biochemical

(a) 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**).

3. 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. Some other investigations were also done to assess the general condition of the patient and rule out other diseases.

Most of the patients were diagnosed as presenting the signs and symptoms of irritable bowel syndrome.

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 *Grahani*.

Dosage and Duration

The prepared *shaddharan churna* was given 3 gms bid with luke warm water for 63 days.

Diet and regimen

During the course of the treatment the patient should avoid all oily, fried grains and spicy food items.

Follow up Studies

They were advised to come after 21 days interval for the assessment of therapeutic response.

Total duration of study was 63 days.

Calculation of Data: Statistical calculation was done by using Pearson chi-square test.

OBSERVATION AND RESULT

	Mean \pm SD				Within the group comparison BT-AT Paired t test
	BT	F1	F2	AT	
Atidrava/Atibadh amala (n=30)	5.37 \pm 2.06	4.22 \pm 1.01	1.89 \pm 0.69	0.81 \pm 0.12 (n=27)	4.55 \pm 2.20 t=10.725 p=0.000 (HS)
Udarashool (n=30)	5.15 \pm 1.19	3.74 \pm 1.02	2.11 \pm 0.64	0.48 \pm 0.58 (n=27)	4.66 \pm 1.10 t=21.857 p=0.000 (HS)
Aruchi (n=30)	5.93 \pm 1.56	4.78 \pm 1.01	3.04 \pm 0.89	0.56 \pm 0.64 (n=27)	5.37 \pm 1.73 t=16.081 p=0.000 (HS)
Alasya	5.56 \pm 1.08	3.15 \pm 1.23	2.96 \pm 0.80	0.56 \pm 0.64 (n=27)	4.66 \pm 1.17 t=20.607 p=0.000 (HS)
Jwara	5.56 \pm 1.08	3.15 \pm 1.23	2.96 \pm 0.80	0.56 \pm 0.64 (n=27)	5.00 \pm 1.10 t=19.533 p=0.000 (HS)
Balabhransha	5.96 \pm 1.60	5.15 \pm 0.94	3.15 \pm 0.94	0.81 \pm 0.68 (n=27)	5.14 \pm 1.56 t=17.130 p=0.000 (HS)

DISCUSSION

Probable Mode of Action of *Shaddharan Churna* in *Grahani*

Shadadharanchurna 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 *Grahani*, relieves the clinical symptoms and maintain the integrity of GI mucosa without any unwanted and adverse effects.

Based on the Pharmacological action

Properties of contents of <i>Shaddharanchurna</i>						
S. No.	Ingredients	Rasa	Guna	Virya	Vipaka	Doshakarma
1.	Chitraka	Katu	Ushna	Laghu, Ruksha, Tikshna	Katu	VK shamak
2.	Haritaki	Pancharasa (except lavana), kashayapradhan	Ushna	Laghu, Ruksha	madhura	VPK shamak
3.	Kutaja	Tikta, Kasaya	Laghu, Ruksha	Shita	Katu	Tridoshagna
4.	Patha	Tikta	Laghu, Tikshna	Ushna	Katu	Tridoshamaka
5.	Ativisha	Katu, Tikta	Laghu, Ruksha	Ushna	Katu	VPK shamak
6.	Kutaki	Tikta	Ruksha, Laghu	Sheeta	Katu	KP shamak

1. Study of *Rasa* in combination.

Rasa	No. of Drugs	%
Madhura	1/6	16.7
Amla	1/6	16.7
Lavana	0/6	0.0
Katu	3/6	50.0
Tikta	5/6	83.3
Kashaya	2/6	33.3

2. Study of *Guna* in combination.

Guna	No. of Drugs	%
Laghu	6/6	100
Ruksha	4/6	66.7
Tikshna	1/6	16.7

3. Study of *Virya* in combination.

Virya	No. of drugs	%
Ushna	4/6	66.7
Shita	2/6	33.3

4. Study of *Vipaka* in combination.

Vipaka	No. of Drugs	%
Madhura	2/6	33.3
Katu	4/6	66.7

5. Study of *Karma* in combination.

Karma	No. of Drugs	%
Dipana	4/6	66.7
Pachana	3/6	50.0
Shulaghna	1/6	16.7
Rasayana	1/6	16.7
Vatanulomana	1/6	16.7
Shoolhara	1/6	16.7
Krimighna	1/6	16.7
Shothaghna	3/6	50.0

6. Study of *Doshaghnta* in combination.

Dosha	No. of drugs	%
VK	2/6	33.3
KP	1/6	16.7
VPK	3/6	50.0

On the basis of Ayurvedic pharmacological properties of *Shaddharan churna* probable *samprativighatana* can be understood as follows.

(1) Probable Action on *Dosha*: In disease *Grahani*, *Vata* and *Pitta dosha* are the main culprits. The combination shows main action against *Vata* and *Pitta* doshas by virtue of its *virya* (about 81% of total drugs have an *Ushna virya*. It also exhibits *tridosha shamaka prabhava*, but to a lesser extent.

(2) Probable Action on *Dushya*: From the *samprapti* of *Grahani* it is clear that the main *dushya* involved is *rasa dhatu*. The combination shows, about 50% of total drugs have a *Katu rasa*. *Katu rasa* improves the digestion and made first *dhatu* in proper form, so the combination will act on the *rasa dhatu*.

(3) Probable Action on *Srotas*: The disease mainly exhibits *Sanga* type of *Srotodushti*. The combination by the virtue of *Dipana*, *Pachana* property and also by the virtue of *Ruksha guna* (about 66.7% of total drugs) does *Srotomukh vishodhana* and relieves *Sanga*. By *Ushnavirya* (about 66.7% of total drugs) the yoga will act on *Uplepa* and clean the *Srotasa*.

(4) Probable Action on *Agni*: In the combination, maximum percentage of the drugs like, *Chitraka*, *Haritaki*, *Kutaki*, *Ativisha* etc. show *Dipana*, *Pachana* property which improves the function of *Agni*. The *Churna* will stop the further *Ama* production and help to break the basic pathology.

(5) Probable Action on *AMA*: An *Ama* means unripe and undigested *Annarasa*. It needs proper *Paka*. By the virtue of *Ushna virya* (66.7% of total drugs) and *Dipana-pachana* property, *Amapachana* will take place. This *Amapachana* causes *Srotomukh vishodhana*.

(6) Probable Action on *Rupa*: All the drugs used in *Shaddharan churna* work on the disease *Grahani* collectively as well as separately. *Ativisha*, *Chitraka*, *Haritaki*, *Kutaki* are digestive and *Amapachaka*, so relieves the *Aruchi*, *Gaurav*, *Klam*, *Jwara*. *Haritaki*, *Chitraka*, *Patha* are *Udararogahara*, *Anulomaka* constipation, *Antrakunjana*. *Haritaki* is *Rasayana*, so it controls the further damage of cells and also free radicals.

CONCLUSION

The present study is a time bound research work and as such, it cannot be finally conclusive. However, the leads available from this work open newer vistas of enquiry into a new Ayurveda-inspired holistic approach to the management of IBS on larger samples of population for promising drug development based on scientific parameters in the field of Ayurveda Gastroenterology. The treatment used in this study seems to be effective and completely safe because no adverse side effects were noted during the sixty three days of trial in the present study.

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