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Clinical evaluation of Mustababbula churna and Takrarista In the management of Grahani

Research Article

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Abstract

Background: The disease in which *Grahani* or the small intestine gets vitiated and there is impairment of *agni* (digestive fire) is called *Grahani*. Anatomically *Grahani* is said to be situated above the umbilicus and between *amashaya* (stomach) and *pakwashaya* (intestines). Physiologically it holds the ingested food for the duration of its digestion before the undigested food residue is propelled into the *pakwashaya* (intestines). **Aim of study:** 1) To evaluate the efficacy of *Mustababbula churna* in the management of *Grahani*. 2) To evaluate the efficacy the *Mustababbula churna* and *Takrarista* in the management of *Grahani.* **Methods:** This is a prospective, randomized clinical trial. A total of 80 patients suggestive of features of *Grahani roga* were enrolled and were randomly divided into two groups- 40 patients each. Group A treated with *Mustababbula churna* and group B were given *Mustababbula churna* and *Takrarista.* The duration of study was 3 months. **Results**: Both the groups showed statistically significant results in clinical symptoms i.e. altered bowel movements, thirst, anorexia, nausea, blackouts, pain in bones and joints, sour eructations etc but the mean reduction in the symptoms of group B was more than group A. **Conclusion:** *Mustababbula churna* is very effective in the management of *Grahani* but when used with *Takrarista* it was more effective and also improved the state of *agni* (digestive fire).

Key words: *Grahani, Musta, Babbula, Takrarista, Agni, Arista*

Introduction:

When the digestive fire - *Agni,* which resides in the *Grahani,* is affected by incorrect lifestyle and eating habits affects the digestive process causing food to be either partially digested or over digested, it leads to the formation of *Grahani roga.* Ingested food is to be digested, absorbed and assimilated, which is unavoidable for the maintenance of life, and is performed by *Agni. (1)*

Diarrheal diseases are the most common infectious diseases now-a-days, and are predicted to remain a leading health problem. With contraindications of antimotility agents in infectious diarrhea and an increasing threat of drug resistance, various attempts for developing vaccines against diarrheal pathogens have been made. However, the response to vaccines in developing countries has not been encouraging. In the recent past, attempts have been made to treat infectious diarrhea with supportive therapy such as probiotics; but these are still under development. Therefore, medicinal plants may provide a cost-effective alternative for treatment of such ailments.

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The present study was conducted using the ancient ayurvedic literature. *Mustababbula churna and Takrarista were used as trial drugs.* The present trial drug *Mustababbula churna* is an *anubhoot* preparation taken because of its *deepan, pachana* and *sangrahi* properties. *Takrarista* is taken from the standard text *Charaka samhita*. It contains drugs like *panchlavanas, amalaki, haritaki, maricha, yawani*, which are herbo mineral in nature and are easily available and the preparation is simple as well as cost effective.(2)

Materials and Methods:

Study design: It is a prospective, randomized type of clinical trial.

Inclusion criteria:

- Patients between the ages of 16- 65 yrs were included.
- Patients with sign and symptoms of *Grahani* as explained in classics & which are devoid of any other complications, which does not disturb in treatment pattern. (3)

Exclusion criteria:

- Patients suffering from acute diarrhoea, intestinal tuberculosis, ulcerative colitis, crohn's disease, sprue, celiac disease, gastric and peptic ulcer, associated with significant complications like haemorrhage, perforation, strictures, colonic cancer, toxic mega colon etc.
- Patients suffering from ano-rectal diseases- hemorrhoids, fistula and rectal prolapse.
- Patients suffering from systemic disorders like diabetes mellitus, hypertension etc,

hyperthyroidism and hypothyroidism, pregnancy and lactation, and patients who have taken antibiotics in the last 15 days.

Selection of patients

A total of 80 patients were randomly selected irrespective of sex, caste, creed, religion, economic status, profession or marital status. The cases were recorded with the help of a special proforma prepared for this purpose. All patients had given informed consent for clinical examination, investigations and drug administration for the purpose of this study.

Grouping of patients:

Patients were randomly divided into two groups of 40 each.

- Group A: The patients were treated with *Mustababbula churna.* Out of 40 patients, 35 had completed the course of treatment and 5 patients were discontinued.
- Group B: The patients were treated with *Mustababbula churna* and *Takrarista*. In this group, all the patients had completed the course of treatment.

During the period of treatment patients were examined for every 15 days and changes were recorded. The study and observation were clinical in nature. During this period of treatment the patients were advised to follow the *pathya ahara viharas (do's and don'ts)* as per ayurvedic classics.

Criteria of assessment:

Assessment was done based on the improvement in signs and symptoms and investigations. The clinical symptomatology was divided into four grades (0-3) and change in these gradations of each symptom was to assess the effect of treatment provided.

Subjective criteria:

Altered bowel movements

Score	Grade	Criteria for grading
0	Absent	Regular bowel
1	Mild	2 times a week
2	Moderate	3- 4 times a week
3	Severe	5- 6 times a week

Increased thirst

0	Absent	Normal thirst
1	Mild	Satiated after drinking water
2	Moderate	Moderately satiated after taking water
3	Severe	Severely altered, not satiated by plain water

Anorexia

0	Absent	Normal appetite
1	Mild	Occasional
2	Moderate	Daily at least two times a day
3	Severe	Daily present most of the day

Bad taste in mouth

0	Absent	No bad taste
1	Mild	Occasional
2	Moderate	Frequent
3	Severe	Troublesome

Nausea

0	Absent	No nausea
1	Mild	Occasional
2	Moderate	1- 2 times per day
3	Severe	More than 2 times per day

Blackouts

0	Absent	No blackouts
1	Mild	Sometimes
2	Moderate	Often
3	Severe	Always

Swelling over extremities

0	Absent	No swelling
1	Mild	Noted only on keen observation
2	Moderate	Observable
3	Severe	Notable swelling

Pain in bones and joints

0	Absent	No pain
1	Mild	Occasional
2	Moderate	For some time everyday
3	Severe	Always/ most of the day

Vomiting

0	Absent	No vomiting
1	Mild	Occasional
2	Moderate	1- 2 times per day
3	Severe	More than 2 times per day

Fever

0	Absent	Afebrile
1	Mild	98°F - 99°F
2	Moderate	100°F - 101°F
3	Severe	102°F- 103°F

Sour eructation

0	Absent	No sour eructation
1	Mild	Occasional
2	Moderate	Frequent/ after meals
3	Severe	Very much frequent irrespective of meal

Associated symptoms

Frequency of bowel

0	Absent	1- 2 motions per day
1	Mild	3- 5 motions per day
2	Moderate	5- 7 motions per day
3	Severe	> 7 motions per day

Mucous in stool

0	Absent	No mucous
1	Mild	Often little amount of mucous
2	Moderate	Every time mucous with motion
3	Severe	Large amount of mucous with every stool

Tenesmus

0	Absent	No tenesmus
1	Mild	Occasionally mild tenesmus
2	Moderate	Tenesmus at every defecation
3	Severe	Severe tenesmus at every defecation, interrupting work

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Objective parameters

Abdominal Tenderness

0	Absent	No tenderness
1	Mild	Subjective experience of tenderness
2	Moderate	Wincing of face on pressure
3	Severe	Resist touching

Trial drugs:

Ingredients of *Mustababbula churna:*

Drug	Botanical name	Part used	Quantity
Mustak	*Cyperus rotundus* Linn.	Rhizome	1 part
Babbula	*Acacia Arabica* Linn.	Bark	1 part

Ingredients of *Takrarista:*

Drug	Botanical name	Part used	Quantity
Yamani	*Tachyspermum ammi* Sprague	Fruit	144 g
Amalaki	*Emblica officinalis* Gaertn.	Pericarp	144 g
Pathya	*Terminalia chebula* Retz.	Pericarp	144 g
Maricha	*Piper nigrum* Linn.	Fruit	144 g
Saindhava lavana	Rock salt		48 g
Sauvarcala lavana	Black salt		48 g
Vida lavana	Ammonium chloride		48 g
Samudra lavana	Sea salt		48 g
Romaka lavana	Sambhar salt		48 g
Takra (freshly prepared)	Buttermilk		3.2 lt

Method of preparation of Trial drugs:

Mustababbula churna: Both the drugs of pharmacopoeial quality were taken in equal amount. They were then washed (first with cold water and then with hot water respectively), dried, and then powdered individually and passed through sieve number 85. Both ingredients were then mixed together. The churna was then passed through sieve number 44 to obtain a homogenous blend and packed in an air tight container. (4)

Dose: 4- 6 grams orally with luke warm water twice a day after meals. The dose of patients between 16- 50 yrs was 4 grams and for those patients between 50-65 yrs was 6 grams respectively.

Takrarista:

Raw materials of pharmacopoeial quality were taken. Ingredient numbered 1 to 4 of the formulation composition were washed and crushed. Ingredients numbered 5 *(panchlavana*) of the formulation composition were cleaned, dried and powdered individually and passed through the sieve number 85 to obtain fine powder. All the above contents were mixed in freshly prepared *takra.* This solution was then strained and kept in the fermentation vessel. The mouth of the vessel was sealed. The container was kept in sunlight for 3 weeks. After 3 weeks, the lid was removed, and the contents examined to ascertain whether the process of fermentation had been completed according to Chakrapani's commentary that "*jatamiti amla rasataya jatam*". The fluid was first decanted and then strained after two or three days. When the fine suspended particles settled down, it was strained again and bottled. (5)

Dose: 20 ml of Takrarista with equal water orally after meals, two times a day.

Investigations:

Following investigations were carried out during the trial:

- Complete blood count
- Kidney function test and Liver function test
- Blood glucose- fasting and post prandial
- Urine- routine and microscopic
- Stool examination for consistency, presence of mucous, undigested fibres, harmful bacteria, viruses, occult blood, ova and cysts
- Ultrasonography if needed

Statistical analysis

The data generated in the clinical study was expressed in terms of mean, standard deviation. Appropriate "t" test was applied to test the significance of comparative mean values of before and after treatment by using statistical software – SPSS 17.0. The significance was assessed at 0.05, 0.01 and 0.001 levels.

Interpretation of results

Result:	Criteria for assessment
Marked relief	75 to 100% relief in signs and symptoms of Grahani
Moderate relief	More than 50% and less than 75%
Mild relief	More than 25% and less than 50%
No relief	Less than 25% was taken

Observations and Results:

The results were analysed on the basis of improvement in clinical features. Improvement in modern parameters of investigation was considered as supporting criteria. The observation of demographic profile revealed that males predominated the study

accounting for 73.75% of total number of cases. High incidence was noted among moderately working (68.75%), semi-urban (68.75%), lower middle class (55%), married (66.25%), illiterate (30%) and tea and coffee consuming group (43.75%).

People having *vata-pitta prakriti* were found more prone (61.25%) to *Grahani*. The *katu* (43.75%) and *amla* (22.50%) *rasa* consuming groups were affected more than rest of the patients. Common presenting symptoms were alternate bowel movements (100% in both the groups), anorexia (91.42% in group A and 100% in group B) and pain in bones and joints (82.85% in group A and 82.5% in group B).

In group A, patients have shown highly significant improvement in all symptoms except in *chardi* (vomiting) and *shoon pada kara* (swelling in limbs) *(p>0.05)*. Moderately significant in *vairasya* (bad taste in mouth)*(p<0.01)* and mildly significant in *jwara* (fever) *(p<0.05)*. In group B, patients have shown significant improvement in all symptoms except in *shoon pada kara* (swelling in limbs) and *chardi* (vomiting) *(p>0.05)*. Moderately significant result was seen in *jwara* (fever)*(p<0.01)*. Between group comparison, group B patients have shown better rate of improvement.

Observations	**Percentage**
Age group	
16- 25	28.75
26- 35	35
36- 45	18.75
46- 55	11.25
56- 65	6.25
Sex	
Male	73.75
Female	26.25
Habitat	
Urban	7.5
Semi- urban	68.75
Rural	23.75
Addiction	
Tobacco (smoking/chewing)	30
Alcohol	7.5
Tea/ coffee	43.75
Not present	18.75
Deha prakriti	
Vata kapha	16.25
Pitta kapha	22.5
Vata pitta	61.25
Dietary habits	
Vegetarians	25
Mixed diet	75
Agni	
Teekshnagni	0
Vishamagni	36.25
Mandagni	63.75
Dominant guna in diet	
Guru	10
Sheeta	33.75
Ruksha	23.75
Laghu	8.75
Snigdha	15
Ushna	8.75
Dominant rasa in diet	
Madhur	10
Amla	22.5
Lavana	18.75
Katu	43.75
Tikta	5
Kashaya	0

Table 1: Effect of *Mustababbula churna* (group A) on symptoms of *Grahani*

Sr. No	Parameter	BT	AT	%	S.D.	S.E.	t-value	"p"	Result (df-34)
1	*Vibadh va drava mala* (alternate bowel movements)	1.54	0.48	68.83	0.48	0.08	12.99	<0.001	HS
2	*Trishna* (thirst)	0.62	0.14	77.41	0.61	0.10	4.69	<0.001	HS
3	*Arochaka* (anorexia)	1.4	0.57	59.28	0.70	0.12	6.93	<0.001	HS
4	*Vairaisya* (bad taste in mouth)	0.45	0.11	75.55	0.54	0.09	3.76	<0.01	Moderately S
5	*Prasek* (nausea)	0.77	0.23	70.12	0.56	0.09	5.73	<0.001	HS
6	*Tamak* (blackouts)	1.2	0.69	42.5	0.51	0.08	6.00	<0.001	HS
7	*Shoon paad kara* (swelling in limbs)	0.08	0.06	25	0.17	0.03	1.00	> 0.05	IS
8	*Asthi sandhi ruk* (pain in bones and joints)	1.23	0.60	51.21	0.59	0.10	6.21	<0.001	HS
9	*Chardi* (vomitting)	0.14	0.08	42.85	0.23	0.03	1.43	> 0.05	IS
10	*Jwara* (fever)	0.14	0.03	78.57	0.32	0.05	2.09	<0.05	Mildly S
11	*Tikta amla udgar* (sour eructations)	1.1	0.45	59.09	0.59	0.09	6.57	<0.001	HS

It was observed that the effect of *Mustababbula churna* in this study showed highly significant results at p< 0.001 in all symptoms except in *shoon pada kara* and *chardi* where it showed insignificant result at p> 0.005. In *Vairasya* it showed moderately significant i.e p<0.01 and in *Jwara* it showed mildly significant result at p<0.05.

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Table 2: Effect of *Mustababbula churna* and *Takrarista* (group B) on symptoms of *Grahani*

Sr. No	Parameter	BT	AT	%	S.D.	S.E.	t-value	"p"	Result (df-39)
1	*Vibadh va drava mala* (alternate bowel movements)	1.37	0.25	81.75	0.61	0.95	11.72	<0.001	HS
2	*Trishna* (thirst)	0.90	0.15	83.33	0.74	0.11	6.38	<0.001	HS
3	*Arochaka* (anorexia)	0.7	0.15	78.57	0.67	0.10	5.13	<0.001	HS
4	*Vairaisya* (bad taste in mouth)	0.72	0.05	93.05	0.57	0.09	7.45	<0.001	HS
5	*Prasek* (nausea)	0.72	0.05	93.05	0.57	0.09	7.45	<0.001	HS
6	*Tamak* (blackouts)	1.02	0.45	55.88	0.63	0.10	5.71	<0.001	HS
7	*Shoon paad kara* (swelling in limbs)	0.12	0.07	41.66	0.22	0.03	1.43	> 0.05	IS
8	*Asthi sandhi ruk* (pain in bones and joints)	1.12	0.43	61.60	0.68	0.11	6.44	<0.001	HS
9	*Chardi* (vomiting)	0.12	0.05	58.33	0.26	0.04	1.77	> 0.05	IS
10	*Jwara* (fever)	0.2	0.05	75	0.36	0.05	2.62	<0.01	Moderately S
11	*Tikta amla udgar* (sour eructations)	1.07	0.35	67.28	0.64	0.10	7.16	<0.001	HS

In this study it was observed that the effect of *Mustababbula churna* and *Takrarista* showed highly significant results at $p< 0.001$ in all symptoms except in *shoon pada kara* and *chardi* where it showed insignificant results at $p>0.05$. In *Jwara* it showed moderately significant result at $p< 0.01$.

Table 3: Comparative effect of therapies on subjective parameters in Group A and Group B.

Sr. No	Chief complaints	No. of patients		Mean		S.D		S.E		t value	P value	
		A	B	A	B	A	B	A	B			
1	*Vibadh va drava mala* (alternate bowel movements)	35	40	0.48	0.25	0.56	0.43	0.09	0.06	2.03	0.04	Mildly S
2	*Trishna* (thirst)	18	26	0.14	0.15	0.35	0.36	0.06	0.05	-0.08	0.9	IS
3	Arochaka (anorexia)	32	40	0.57	0.50	0.65	0.59	0.11	0.09	0.49	0.62	IS
4	*Vairaisya* (bad taste in mouth)	14	19	0.11	0.15	0.32	0.42	0.05	0.06	-0.40	0.68	IS
5	*Prasek* (nausea)	22	25	0.02	0.05	0.16	0.22	0.02	0.03	-0.47	0.64	IS
6	*Tamak* (blackouts)	28	31	0.68	0.45	0.67	0.55	0.11	0.08	1.66	0.10	IS
7	*Shoon paad kara* (swelling in limbs)	02	04	0.05	0.07	0.23	0.26	0.03	0.04	-0.30	0.76	IS
8	*Asthi sandhi ruk* (pain in bones and joints)	29	33	0.60	0.42	0.65	0.50	0.11	0.07	1.31	0.19	IS
9	*Chardi* (vomitting)	04	04	0.08	0.05	0.28	0.22	0.04	0.03	0.60	0.54	IS
10	*Jwara* (fever)	05	07	0.02	0.05	0.16	0.22	0.02	0.03	-0.46	0.64	IS
11	*Tikta amla udgar* (Sour eructations)	27	31	0.45	0.35	0.65	0.53	0.11	0.08	0.77	0.43	IS
12	Frequency of stool	35	38	0.31	0.22	0.47	0.47	0.07	0.07	0.81	0.42	IS
13	Mucus in stool	09	11	0.14	0.10	0.42	0.30	0.07	0.04	0.50	0.61	IS
14	Tenesmus	14	15	0.22	0.10	0.42	0.30	0.07	0.04	1.51	0.13	IS
15	Abdominal tenderness	15	18	0.20	0.20	0.40	0.40	0.06	0.06	0.00	1.00	IS

On comparing the effect of therapies, it was observed that the difference in the results were insignificant at $p>0.05$ in all symptoms except in alternate bowel movement where it was observed to be mildly significant at $p< 0.05$.

Table No 4: Comparative effect of therapies on objective parameters in Group A and Group B.

Sr. No	Objective parameter	No. of patients		Mean		S.D		S.E		T	p	
		A	B	A	B	A	B	A	B			
1	Hb %	35	40	12.0	12.0	1.40	1.40	0.24	0.22	-0.03	0.97	IS
2	Weight	35	40	56.5	54.7	5.32	5.57	0.89	0.88	1.42	0.15	IS

On comparing the effect of therapies on objective parameters it was observed that there was insignificant difference between the therapies in hemoglobin and weight of the patients.

In Group A, 8.5 % patients got mild relief, 17.14 % got moderate relief and 68.57 % patients got marked relief. In Group B, 7.5 % patients got mild relief, 17.5 % patients got moderate relief and 80 % patients got marked relief. On comparison between the groups it was observed that in all the parameters the difference was statistically insignificant except in altered bowel movement where the difference was statistically mildly significant.

Discussion:

In today's era of lifestyle changes, improper food and dietary habits, the digestive system has suffered the most. *Grahani roga* is a disease where "*Grahani"* as a structure is unable to perform its normal function of holding on the uncooked food particles till they get digested. *Grahani* is a disease in which *agni* (digestive power) is at fault. So, to enhance the potency of *agni,* thereby reducing the formation of *Ama Dosha,* the trial drugs were selected.

In this study, 73.75% patients were males attributing to their unavoidable exposure to external environment along with food habits and drinking of contaminated water. Maximum incidence was observed in 3rd followed by 2nd decade of life. Young adults of these age groups are more exposed to unhygienic eating habits and mental stress. It was also observed that tea/ coffee intake group was affected more because tea/ coffee cause irritation in the gastrointestinal tract. Maximum patients had *vata pitta prakriti* which signifies that if such persons get indulged in *vata* and *pitta* aggravating factors, it may result in *agni dushti* as well as vitiation of *samana vayu* (more than patients with other prakriti) which are the main causes of Grahani roga. Both the groups showed statistically significant results in clinical symptoms i.e. altered bowel movements, thirst, anorexia, nausea, blackouts, pain in bones and joints, sour eructations, but the mean reduction in the symptoms of group B was more than group A. Better effect of group B were observed which may be due to better absorption of Takrarista and also because *arishta* is *Deepana* (appetizer) by nature.

Mode of action of drugs:

Musta (*Cyperus rotundus*) is pungent, bitter and astringent in taste, pungent in the post digestive effect and has cold potency. Acharya Charaka and Vagbhata has mentioned it as *Dipaniya* (appetizer), *Pachaniya* (digestant) and *Sangrahi* (anti-diarrhoeal). It is also well known for its *Amapacaka* property (digests ama). (6)

Musta has limited activity against different forms of infectious diarrhoea due to its selective activity against diarrheal pathogens, in the absence of a marked activity, this plant seems to have anti-diarrheal action because of its action on some features like bacterial colonization, production of cholera toxin and action on labile toxin. (7)

Babbula (*Acacia arabica*) is astringent in taste, pungent in post digestive effect and has cold potency. It possesses astringent property which makes it very useful in bleeding disorders like bloody diarrhoea. It offers marked liver protection and has anti- oxidant activity. Anti- bacterial activity has also been reported with highest activity against Escherichia coli, Staphylococcus aureus and Salmonella typhi. (8)

Takrarista is an ayurvedic formulation and is indicated against haemorrhoids, worm infestation, loss of appetite, *grahani* and diarrhoea. Most of the drugs used in this compound are *Laghu* and *Tikshna* in *guna* and has *Ushna* potency and therefore has *deepan* and *grahi* property. *Takra* in *Takrarista* is a fermented product and refermentation of the same with some more salts and herbal drugs yields more stable product containing little amount of alcohol and dominant characters of acidic fermentation. (9)

Lactic acid bacteria present in curd are reported for the anti- microbial activity due to the production of antibiotics like substances and peptides. *Amla, harda, ajowan* and *maricha* which are used in GI disorders, have also exhibited anti microbial activity. Piperin obtained from *maricha* is a bio- availability enhancer. So, the anti-bacterial activity of *Takrarista* may be ascribed to the presence of metabolites of lactic acid bacteria, anti-bacterial activity of herbal constituents and conversion products formed by microbial activity during fermentation. (10)

Scope of future research:

Larger number of sample size should be included to confirm our results and generalize the results to population outside this sample population.

Conclusion:

This is evident from both clinical and statistical improvement that the drugs Mustababbula churna and Takrarista are effective in the treatment of Grahani. The drug Mustababbool Churna is an anubhoot preparation and Takrarista described by Acharya Charaka in the management of Grahani Dosha, which was selected for study is an excellent combination of Deepana, Pachana drugs. Mustak exhibit the anti-diarrheal action because of its action on some features like bacterial virulence viz., bacterial colonization, production of Cholera Toxin and action of Labile Toxin. Acacia arabica offers marked liver protection, and has anti- oxidant activity. Takrarista has anti-diarrhoeal, anti-haemorrhoidal, anti-bacterial and anti-helmintic activity owing to the presence of metabolites of lactic acid bacteria, anti- bacterial activity of herbal constituents and conversion products formed by microbial activity during fermentation.

It can be concluded from the present study that Mustababbool churna is very effective in the management of Grahani but when used with Takrarista it was more effective and also improve the state of Agni.

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