

How to Cite:

Ade, V., Parwe, S., & Nisargandha, M. (2022). Study of Mrudu Virechan effect of Trivruttha Ghanavati and Aragwadha Ghanavati in the management of Visthabdhajirna (constipation) according to body type: A study protocol. *International Journal of Health Sciences*, 6(S2), 464–474. <https://doi.org/10.53730/ijhs.v6nS2.5029>

Study of Mrudu Virechan effect of Trivruttha Ghanavati and Aragwadha Ghanavati in the management of Visthabdhajirna (constipation) according to body type – A study protocol

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Abstract---Constipation is a common clinical problem now a day also happens in so many diseases. In classical texts, it is not separately described as a disease. It is occurring due to change in lifestyle, mental stress, and irregular diet habit create constipation. The diagnosis and evaluation of *visthabdhajirna* depend on thorough clinical examination and investigation of the subject. This study aims to evaluate the effect of *Trivruttha Ghanavati* and *Aragwadha Ghanavati* in the management of *Visthabdhajirna*. A clinical trial will be conducted on two groups of patients. Diagnostic Criteria will be Rome III criteria and Bristol stool scale with constipation. Forty subjects will select by lottery method irrespective of their religions, race, occupations, sex etc. they will be administered internally by oral route with *Trivruttha Ghanavati* and *Aragwadha Ghanavati*, the dose of 500 mg two times a day after meal for 15th days. The symptoms of constipation like straining, lumpy, hard stool, satisfaction after defecation and nature of stool etc., will observe over the intervention. Analysis of work will be shown after improvement in *vishthasabdhajirna*. Will be drawn on the basis of analysis.

Keywords---*Visthabdhajirna*, *Trivrutta Ghanavati*, *Aragwadha Ghanavati*, constipation.

Introduction

Digestion of food with difficulty is known as *Ajirna*. It is a disease of *Annavahsrotas vyadhi* caused by the impairment of *Agni*. Also, *mandagni* is the root cause of all diseases, according to *Ayurveda*. Due to intake of an extreme diet without concern of *Kaal*, *matra*, *rashiguna*, and apposite food like sweet, salty item repeatedly consume routinely, and *chinta*, *shoka* and *bhaya* leads *dushti* of *annavaha srotas* which creates indigestion (*Ajirna*) [1].

Visthabdhajirna is a type of *Ajirna* is due to the vitiation of *Vata*. Due to *Nidan* *Seven* like *Atiambupana*, *Diwaswapa*, *Vegavidharana*, *Ratrijagarana*, *Ati guru*, *Snigdha*, *Vidahi Padartha seven*, *Agni* get diminished and *Ajirna* formed [2]. *Ajirna* characterized by pricking pain, long-standing tympanitis, an abnormal moment of *Vata*, other symptoms of *Vata Vridhi*, and obstruction to stool, flatus, delusion, general malaise [3-4]. Suppression of natural urges develop pain in the calf muscle, sneezing, headache, belching, fissure in ano, *hrudaya uparodha* also the upward movement of *Apan Vayu* [5] in *visthabdhajirna* there is *avasthambha* of *Vayu* and *Purusha* occur. Ashtang Hriday stated the importance of *mala*, i.e. '*Malochittwada dehasya*' excretion of a waste product should be a regular habit of the body; it creates clean the body, freshness of mind and lightness of body [6].

In *Ayurveda*, digestive power (*Agni*) is the crucial factor of all disease, and *vishamagni* is the main causative factor for *visthabdhajirna*, which is vitiated by *Vata dosha* [7]. "Constipation is a common disorder of Gastro Intestinal Tract (GIT). The prevalence of constipation in the general population is approximately 20%. It can range from 2% to 27%, it depends on the definition used, and the population studied. Choung R S reported in his population-based study that the cumulative incidence of chronic constipation (CC) is higher in the elderly (~20%) than in the younger population. In elderly women, severe constipation is more common, rates of constipation two to three times higher than that of their male counterparts"[8].

Virechana is the necessary therapy for evacuations of *pitta dosha* that are made a pass through *adhomarga* like an anus. In this process, *pitta dosha* and *malas* are cleared from the colon and rectum and cellular level of the whole-body [9]. *Ghana Vati* mean it is in a concentrated form of a specific drug. *Ghana Vati* is the form to take quick, focused, and cost-effective non-irritant to the gastrointestinal tract; that's why this study has chosen to compare the efficacy of two drugs in the form of *ghanavati*.

Trivruta is useful in *kruarakostha* (moderate) and *vata-pittajprakruti* patient while *Aragwadha* is useful in *mrudukostha* (mild) and *pitta kaphajprakruti*. *Trivrutta* considered the best drug for *Sukhavirechana* [10], and *Aragwadha* acts as *Mruduvirechaka* [11]. So the study will plan to compare the efficacy of *Trivruta* and *Aragwadha* as *Mruduvirechana* in *Visthabdhajirna*.

Rationale

Trivrutta Churn and *Araghwadha phalmajja* are well known and broadly utilized as *MruduVirechana* compounds for the management of *Malavastambha* (constipation). However, their effect in the *Ghanvati* form, which is of a more concentrated form, is not yet studied. Moreover, previous works have established efficacy in managing constipation but not in the management of *Vishtabdhajirna*, which is similar to *Malavashthamba*. In the current scenario, due to more spicy foods and irregular habit of diet, *Vishtabdhajirna* is more frequent than *Malavastambha*. Therefore the effect of *Trivruta* and *Araghwadha Ghanavati* is needed to be evaluated to fill a need of an hour.

Aim

To study the *Virechana* effect of *Trivrutta* and *Aragwadha Ghanavati* in the management of *Vishthabdhajirna* (Constipation)

Objectives:

- To study the effect of *Trivrutaghanvati* on Bristol Stool Scale and modified ROME-III questionnaire module
- To study the effect of *Aragwadha Ghana Vati* on Bristol Stool Scale and modified ROME-III questionnaire module
- To compare the effects of both the groups to ascertain which drug is better for relieving Bristol Stool Scale and the modified ROME-III questionnaire module.
- To study the efficacy of *Trivrutta Ghana Vati* and *Aragvadgha Vati* on *kostha* and *prakruti* of the subject.

Case Definition

A constipation person has three or more bowel movements per week with hard and dry stool; it is also painful to pass.

Due to *Nidan Seven* like *Atiambupana*, *Diwaswap*, *Vegavidharan*, *Ratrijagarana*, *Ati guru*, *Snigdha*, *Vidahi Padartha seven*, *Agni* get diminished and formation of *Ajirna*. In Ayurveda, digestive power (*Agni*) is the crucial factor of all disease; *vishamagni* is the main causative factor in *vishthabdhajirna*, which is vitiated by *Vata dosha*. Also, *Vishthabdhajirna* is a type of *Ajirna* due to the vitiation of *Vata*.

Research Question

Does *Trivrutta Ghana Vati* is more effective than *Aragvadha Ghana Vati* in the management of *Vishthabdhajirna*(constipation).

Hypothesis:

- Null Hypothesis:
Trivruta Ghana Vati is more effective than *Aragvadha Ghana Vati* in the management of *Vishthabdhajirna* (Constipation).
- Alternative Hypothesis:

Trivruta Ghana Vati is not more effective than *Aragvada Ghana Vati* in the management of *Visthabdhajirna*.

Trial design: Double arm open-labelled randomized clinical trial

Study Setting: Panchakarma Department, Mahatma Gandhi Ayurved Hospital, Wardha

Eligibility Criteria:

Inclusion criteria

- The subject of age group 20-50 years
- Subjects were fulfilling the criteria of Rome-III Questionnaires'.

Exclusion criteria

- Known case of an anorectal diseases like anal fissure, Fistula in ano, Cirrhosis of the liver, renal failure, congestive cardiac failure.
- Gastrointestinal diseases like Gastric or duodenal ulcer
- Psychiatric disorders like Anxiety, Depression
- Severe Anemia, hypothyroidism.

Interventions

Table 1
Methodology

Group	Sample size	Dose and Frequency	Anupana	Duration	Follow-up
Group –A <i>Trivruta Ghana Vati</i>	20	500 mg	<i>Koshnaja</i>	Twice a day	0,7,15 th days
Group-B <i>Aragvada Ghana Vati</i>	20	500 mg	<i>Koshnaja</i>	Twice a day	0,7,15 th days

Table 2
Drugs for *MruduVirechana*-

Sr no.	Drugs	Properties	Action	Uses
1	Trivruta	<i>madhur, tikta, katu, Kashayaras, laghu, ruksha, tikshnaguna, katuvipak and ushnavirya.</i>	<i>Sukhavirechak, bhedaniya</i> (purgative action)also balance <i>pitta</i> and <i>Kapha dosha</i>	<i>fever, worm infestation, ascites, inflammation, anaemia, hrudarog</i>
2	Aragvadh	<i>madhurras, guru, Snigdhguna,shitvirya and madhurvipak</i>	<i>Sramshan</i> (mild purgative) and <i>pitta kaphahar</i>	<i>fever, hrudarog, analdisorder, udarroga, kushtha,</i>

				<i>diabetes, rheumatic disorder, worm infestation and blood-related disorder</i>
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Criteria for discontinuing or modifying allocated interventions

If subjects will observe any side effects and subjects will stop the medicine. They will be withdrawn from the study. If any adverse effects are observed, they will get free medication from the principal investigator.

Follow up: 15th days

Primary Outcome: relief from symptoms of constipation

Secondary Outcome-

Statistical Analysis

Time duration till following up-15th days

Follow up period-15th days

Time schedule of enrolment, interventions: Subjects will be recruited for the study after clearance from the Institutional Ethical Committee. Interventions will be *MruduVirechana*.

Recruitment: 15 subjects in each group will be recruited by a single randomizing sampling method.

Methods

Drug collection/ authentication

The required drug will be collected from authentic Ayurveda raw drug supplier and authenticated by a pharmacognostic study at the Department of Dravyaguna, MGACH & RC.

Detail of drug preparation

Both drugs will be prepared in the Dattatraya Rasashala of MGACH & RC using standard operating procedures mentioned in Sharangdhara Samhita. Cut freshly obtained *Trivruta* roots into the small part and crush them. Immerse the crushed root in water and keep it aside for few hours to prepare a decoction. After few hours, the decoction is strained and heated on high flame to get pure *Trivruta* extract. When the extract gets thickened and converted into a gel-like consistency, put off the flame and allow it to cool. Dry the extract under direct sun for few days until there is no moisture left and it becomes crisp and powder in nature. Now mix the extract in the binding agent (Gum acacia) to hold the powder particle

together. Roll them into palm or machine into minute balls or tablet to make the *Ghanvati*. Same procedure applied for *Aragvadha Ghan Vati*.

Data collections: The Subjects will be selected from Kayachikitsa and Panchakarma OPD and IPD of Mahatma Gandhi Ayu College and Hospital, Wardha.

Data collections methods: Randomized sampling

Subjective Parameters

Results of the study will be assessed as per the modified ROME-III questionnaire module of constipation which included 17 questions [12].

S.No.	Questions	Grade	Score	
			Before treatment	After treatment
1	In the last three months, how often did you have discomfort or pain anywhere in your abdomen?	1.Never 2. Less than one day a month. 3. One day a month. 4. Two or three days a month. 5. One day a week. 6. more than one day a week 7. Every day		
2	For women: Did this discomfort or pain occur only during your menstrual bleeding and not at other time?	1.No 2.Yes 3. Does not apply because I have had the change in life (menopause) or a Male.		
3	Have you had this discomfort or pain for 6 months or longer?	1.No 2.Yes		
4	How often did this discomfort or pain get better or stop after you had a bowel movement?	1.Never or rarely 2.Sometimes 3.often 4. Most of the time. 5.Always		
5	When this discomfort or pain started, did you have more frequent bowel movement?	1.Never or rarely 2.Sometimes 3.often 4. Most of the time. 5.Always		
6	When this discomfort or pain started, did you have less frequent bowel movement?	1.Never or rarely 2.Sometimes 3.often 4. Most of the time. 5.Always		
7	When this discomfort or pain started, were your stool (bowel movement) looser.?	1.Never or rarely 2.Sometimes 3.often 4. Most of the time.		

		5.Always		
8	When this discomfort or pain started, how often did you have harder stools?	1.Never or rarely 2.Sometimes 3.often 4. Most of the time. 5.Always		
9	In these last 3months. How often did you have fewer than three bowel movement (0-2) a week.	1.Never or rarely 2.Sometimes 3.often 4. Most of the time. 5.Always		
10	In these last three months. How often did you have hard or lumpy stools?	1.Never or rarely 2.Sometimes 3.often 4. Most of the time. 5.Always		
11	In these last three months. How often did you strain during bowel movement?	1.Never or rarely 2.Sometimes 3.often 4. Most of the time. 5.Always		
12	In these last three months. How often did you have a feeling of incomplete emptying after bowel movement?	1.Never or rarely 2.Sometimes 3.often 4. Most of the time. 5.Always		
13	In these last three months. How often did you feel that the stool could not pass (i.e.blocked) when having a bowel movement.	1.Never or rarely 2.Sometimes 3.often 4. Most of the time. 5.Always		
14	In these last three months. How often did you press on or around your bottom or remove stool to complete a bowel movement?	1.Never or rarely 2.Sometimes 3.often 4. Most of the time. 5.Always		
15	In these last three months. How often did you difficulty relaxing or letting go to allow the stool to come out during a bowel movement?	1.Never or rarely 2.Sometimes 3.often 4. Most of the time. 5.Always		
16	Did any of the symptoms of constipation listed in question 9-15 above begin more than six months?	1.No 2.Yes		
17	In these last three months. How often did you lose mushy or watery stools?	1.Never or rarely 2.Sometimes 3.often 4. Most of the time. 5.Always		

Objective Parameters

Stool examination-with the help of Bristol Stool Scale [13] before and after the treatment.

	Type 1	Separate hard lumps	SEVERE CONSTIPATION
	Type 2	Lumpy and sausage like	MILD CONSTIPATION
	Type 3	A sausage shape with cracks in the surface	NORMAL
	Type 4	Like a smooth, soft sausage or snake	NORMAL
	Type 5	Soft blobs with clear-cut edges	LACKING FIBRE
	Type 6	Mushy consistency with ragged edges	MILD DIARRHEA
	Type 7	Liquid consistency with no solid pieces	SEVERE DIARRHEA

Investigations routine:

For screening-

- Hb %
- Blood Sugar-Random

Drug analysis: Routine physicochemical analysis of both formulations will do at the analytical lab of Dattatrey Rasashala

Data Management: Data coding will be done by the principal investigator.

Statistical Method

The data will be analyzed by using:

- Wilcoxon test-subjective criteria and grading
- Pairedt-test and Unpaired- t-test- objective criteria

Ethics and dissemination: Research ethical approval, after critical evaluation and presentation in front of SRC and then IEC, the ethical committee has approved the research topic.

Consent or assent: Before starting the interventions, subjects will be given detailed information regarding intervention, preparation of medicine and study in his /her language. Then written permission will be taken from patients.

Dissemination policy: Data will be disseminated in the form of paper publication and Monograph.

Informed Consent materials: Subjects will be given all consent material in the form of hard copy and other related documents.

Discussion

Digestion is the process that is essential for the formation of mala. *Koshta* is a site for the operation of digestion takes place. There are three types of *Koshta* mentioned in Ayurvedic text, i.e. *krurakoshtha* dominating *Vata Kapha*, in which the *virechana* should be given with *tikshnadraavyas* in large quantity. *Mrudukoshtha* is the dominance of pitta, in which *virechana* should be shared with *mrududraavyas* in less amount. *Madyamkoshtha* is of *samadoshaja*, in which *virechan* should be given in *madhyammatra*. In *mrudukoshtha*, the symptoms of *samyaksneha* are seen within three days, in *sadharankoshtha* after five days and in *krurakoshtha* after seven days [14].

Virechana pacifies the morbid *dosha* and helps carry out its function usually, hence helping the parts of *strotas*. *Virechana* is the purification therapy; it removes toxic materials from the body. It thoroughly cleansed cardiovascular level, gastrointestinal tract, at cellular level, the purification and cleansing of the body produced at cell membrane and molecules. Gut absorption improves, and metabolism also corrected. It corrects it by *Vatanulomana* and ultimately reducing *Rukshta* [15]. A number of related studies were reviewed [16-20].

Strength: *mruduvirechana* will be work for reducing symptoms of *vishtabdhajirna*.

Limitations

It is convincing the patients for *mruduvirechana* for the 15th days.

Scope and Implications of the proposed study

• Scope:

As the prevalence of *Vishtabdhajirna* is increasing due to the trend of spicy food and increased tendency of irregular diet, developing a potent, cost-effective formulation will help overcome *Vishtabdhajirna*. In the long term, *Vishtabdhajirna* may create complications. It is related to malnutrition, indigestion, deficiency of various micro-nutrients, and systemic diseases such as cardio-vascular manifestation, obesity, diabetes, etc. Its early management can be a preventive line of treatment to avoid the risk of those diseases in the early stage.

• Implications:

This study will create a preventive approach towards avoiding predisposing factors for many systemic diseases as well bowl habit results in good digestion of food and vital organs.

Translatory Component: If found effective, this study will establish a preventive guideline for systemic diseases such as cardio-vascular manifestation, obesity, diabetes, etc. This study will also serve in solving the increasing prevalence of *Vishtabdhajirna* with an affordable, cost-effective formulation.

Conclusion

Conclusion will be drawn after deliberate and analysis of data.

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