Study of Mrudu Virechan effect of Trivrutta 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 Trivrutta 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 Trivrutta 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 vishthsabdhaajirna. 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. Trivruta considered the best drug for Sukhavirechana [10], and Aragvadha acts as Mruduwirechaka [11]. So the study will plan to compare the efficacy of Trivruta and Aragvadha as Mruduwirechana 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 Malavastambha. 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 Ganavati is needed to evaluated to fill a need of an hour.

Aim

To study the Virechana effect of Trivrutta and Aragwadha Ghanavati in the management of Vishtabdhajirna (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 Aragvadhgha 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 visthabdhajirna, which is vitiates by Vata dosha. Also, Visthabdhajirna is a type of Ajirna due to the vitiation of Vata.

Research Question

Does Trivrutta Ghana Vati is more effective than Aragwadha Ghana Vati in the management of Vishtabdhajirna(constipation).

Hypothesis:

- Null Hypothesis:
  Trivrutta Ghana Vati is more effective than Aragwadha Ghana Vati in the management of Vishtabdhajirna (Constipation).
- Alternative Hypothesis:
Trivruta Ghana Vati is not more effective than Aragvada Ghana Vati in the management of Vishthabdhajirna.

Trail 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 Questionaries’.

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

<table>
<thead>
<tr>
<th>Group</th>
<th>Sample size</th>
<th>Dose and Frequency</th>
<th>Anupana</th>
<th>Duration</th>
<th>Follow-up</th>
</tr>
</thead>
<tbody>
<tr>
<td>Group –A Trivruta Ghana Vati</td>
<td>20</td>
<td>500 mg</td>
<td>Koshnajal</td>
<td>Twice a day</td>
<td>0,7,15th days</td>
</tr>
<tr>
<td>Group-B Aragvadha Ghana Vati</td>
<td>20</td>
<td>500 mg</td>
<td>Koshnajal</td>
<td>Twice a day</td>
<td>0,7,15th days</td>
</tr>
</tbody>
</table>

Table 2
Drugs for MruduVirechana-

<table>
<thead>
<tr>
<th>Sr no.</th>
<th>Drugs</th>
<th>Properties</th>
<th>Action</th>
<th>Uses</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Trivruta</td>
<td>madhur, tikta, katu, Kashayaras, laghu, ruksha, tikshnaguna, katuvipak and ushnnavirya.</td>
<td>Sukhavirechak, bhedaniya(purgative action)also balance pitta and Kapha dosha</td>
<td>fever, worm infestation, ascites, inflammation, anaemia, hrudarog</td>
</tr>
<tr>
<td>2</td>
<td>Aragwadh</td>
<td>madhurras, guru, Snigdhguna, shitvirya and madhurvipak</td>
<td>Sramshan(mild purgative) and pitta kaphahar</td>
<td>fever, hrudarog, analdisorder, udarroga, kushtha,</td>
</tr>
</tbody>
</table>
**Criteria for discontinuing or modifying allocated interventions**

If subjects will observe any side effects and subjects will stop the medicine. They will be windrows 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 mention in Sharangdhar 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 thicken and convert 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 acasia) 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].

<table>
<thead>
<tr>
<th>S.No.</th>
<th>Questions</th>
<th>Grade</th>
<th>Score Before treatment</th>
<th>Score After treatment</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>In the last three months, how often did you have discomfort or pain anywhere in your abdomen?</td>
<td>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</td>
<td></td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>For women: Did this discomfort or pain occur only during your menstrual bleeding and not at other time?</td>
<td>1. No 2. Yes 3. Does not apply because I have had the change in life (menopause) or a Male.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>3</td>
<td>Have you had this discomfort or pain for 6 months or longer?</td>
<td>1. No 2. Yes</td>
<td></td>
<td></td>
</tr>
<tr>
<td>4</td>
<td>How often did this discomfort or pain get better or stop after you had a bowel movement?</td>
<td>1. Never or rarely 2. Sometimes 3.often 4. Most of the time. 5.Always</td>
<td></td>
<td></td>
</tr>
<tr>
<td>5</td>
<td>When this discomfort or pain started, did you have more frequent bowel movement?</td>
<td>1. Never or rarely 2. Sometimes 3.often 4. Most of the time. 5.Always</td>
<td></td>
<td></td>
</tr>
<tr>
<td>6</td>
<td>When this discomfort or pain started, did you have less frequent bowel movement?</td>
<td>1. Never or rarely 2. Sometimes 3.often 4. Most of the time. 5.Always</td>
<td></td>
<td></td>
</tr>
<tr>
<td>7</td>
<td>When this discomfort or pain started, were your stool (bowel movement) looser.?</td>
<td>1. Never or rarely 2. Sometimes 3.often 4. Most of the time.</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Question</td>
<td>1. Never or rarely</td>
<td>2. Sometimes</td>
<td>3. Often</td>
</tr>
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<td>---</td>
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</tr>
<tr>
<td>8</td>
<td>When this discomfort or pain started, how often did you have harder stools?</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>9</td>
<td>In these last 3 months. How often did you have fewer than three bowel movements (0-2) a week.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>10</td>
<td>In these last three months. How often did you have hard or lumpy stools?</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>11</td>
<td>In these last three months. How often did you strain during bowel movement?</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>12</td>
<td>In these last three months. How often did you have a feeling of incomplete emptying after bowel movement?</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>13</td>
<td>In these last three months. How often did you feel that the stool could not pass (i.e. blocked) when having a bowel movement.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>14</td>
<td>In these last three months. How often did you press on or around your bottom or remove stool to complete a bowel movement?</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>15</td>
<td>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?</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>16</td>
<td>Did any of the symptoms of constipation listed in question 9-15 above begin more than six months?</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>17</td>
<td>In these last three months. How often did you lose mushy or watery stools?</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Objective Parameters**

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
- Paired t-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 tikshnadravyas in large quantity. Mrudukoshtha is the dominance of pitta, in which virechana should be shared with mrududravyas 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 formation 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.

References

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