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## Research Article

### A RANDOMIZED, SINGLE BLIND, ACTIVE MEDICINE STUDY TO INVESTIGATE THE EFFICACY AND SAFETY IN PATIENTS OF CHRONIC CONSTIPATION

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#### ABSTRACT

Constipation is very common problem in present era due to change in lifestyle, food habits, stress, excessive travelling, watch night, late night sleeping, sedentary lifestyle..... This may lead to different digestion problems, ano-rectal diseases- Fissure, hemorrhoids, abscess, prolapsed rectum structural and functional deformity in rectum (sometimes leads to vital diseases like rectal cancer). Modern science has very little to offer in terms of medicinal treatment for Constipation. But in *Ayurved* science there is variety of treatment modalities. In fact the proper and complete evacuation of rectum is basic treatment in all diseases. It is the principle therapy of every plan of treatment. *Gudavarti* (i.e. rectal suppository) application is easiest, minimum invasive treatment with less complications.. The preparation of *Gudavarti* contains *Pippali*, *Marich*, *Sarshap*, *Ardrak*, *Saindhav* and *Gud(Jaggery)* which are cost effective and easily available. It is administered by rectal route for 3 days regularly and follows up after every 24 hrs was taken for following symptoms. On administration of *Gudavarti* to 100 subjects of constipation shows 96% relief from lumpy and hard stool of defecation, 95% relief from fewer than 3 defecation per week, 95% relief to straining during defecation, 94% relief from sensation from incomplete evacuation, 93% relief for sensation of ano-rectal obstruction or blockage defecation, 98% relief for symptom manual maneuvers to facilitate for defecation (e.g. Digital evacuation, support of pelvic floor.)

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#### INTRODUCTION

Constipation is not a well defined disease entity, but a general term used to describe the difficulties that a subject experiences with moving their bowels.<sup>1</sup> Healthcare providers typically define constipation as stool frequency of less than 3 bowel movements per week.<sup>2</sup> In contrast, patients define constipation defecation” as any such form as of feeling of incomplete evacuation, and nonproductive urge.<sup>3, 4</sup> Compared to younger patients, the elderly report more frequent straining, self-digitations, and feelings of anal blockage.<sup>4,5</sup>

*Varti* basically come under *Vati Kalpana*, they only differ in shape & size. *Varti* is elongated with tapering end and are used externally. They help in expelling the collected mala, mutra, puya, rakta, kapha etc dosha and thus help in therapeutic field. Explanation of *varti* its size and preparation has been mentioned in *sharangadhara samhitha uttarakhanda* 7th chapter. *Guda varti* is one amongst the number of *varti prayogas* mentioned in the classics.

Modern science has very little to offer in terms of medicinal treatment for Constipation. Prevalent modern suppositories are having their own limitations and complications. Hence treatment modality which is easy to administer with lesser complications and better rate of success with cost effectiveness should be the criteria in choosing the management of Constipation.

Here comes the importance of *varti prayoga* as prescribed in Ayurvedic texts. Therefore study is planned to study the efficacy of *Gudavarti* in the treatment of patients having Constipation.

##### Aim

To study the efficacy of *Gudavarti* in minimizing symptoms and Cost-effectiveness in treatment of constipation.

##### Objectives

1. To prepare and standardize *Gudavarti*.
2. To conduct clinical trial on diagnosed patients of constipation.

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- To study the efficacy of *Gudavarti* by qualitative data collection and statistical analysis.
- To check the commercialization potentials of the product with respect to its cost effectiveness.

### Hypothesis

H<sub>0</sub>: *Gudavarti* is not having efficacy in the treatment of patients having Constipation.

H<sub>1</sub>: *Gudavarti* is having efficacy in the treatment of patients having Constipation.

## MATERIALS AND METHODS

### Materials

Following ingredients were used as raw material for a preparation of *Gudavarti*

Table No.1

Sr. No.	Sanskrit Name	Botanical Name	Parts used
1	<i>Pippali</i>	<i>Piper longum</i>	Fruit
2	<i>Maricha</i>	<i>Piper Nigram</i>	Fruit
3	<i>Sarshapa</i>	<i>Brassica alba</i>	Fruit
4	<i>Ardrak</i>	<i>Zingiber officinale</i>	Stem (Root)
5	<i>Saindhava</i>	Rock Salt	Natural form
6	<i>Guda</i>	Jaggery	Natural form

Authentication of above materials was done.

- Gruta/Taila*: Used as local application.
- Rular /scale of camlin company.
- Weighing machine.

The above instrument was calibrated before use.

### Method of Study

#### Preparation of Drug

*Gudavarti* (rectal suppository) was prepared by using ingredients mentioned in table no.1 as per method given in *Bhaishajya Kalpana Vidnyan of Ayurved*.

- Dried plants parts 50 grams of ingredients 1, 2, and 3 were taken and made into fine powder.
- Fine powder was taken in bowl and 50 gms of Saindhav and paste of ardrak was added to it.
- 50 Gms of *Gud* (jaggery) was mixed with the powder.
- The above mixture was mixed homogenously in a mixing pan.
- Gudvarti* was prepared customized for each patient, based on the size of his/her right/left thumb.
- On drying *Gudavarti* were kept in UV light and stored in dry clean glass bottle.
- Random sample of *Gudavatri* sent for standardization and quality control analysis.

### Questionnaire

Standard format of questionnaire get prepared for data collection and used for diagnosis for constipation.

#### Designing a clinical trial

- Age Group- patients having age group 18-65 years of either sex.
- Time of treatment therapy: 3 days
- Dose: 2gm/day for 3 days
- Administration : By rectal route

- Observation for relief of symptom.
- Open label, single group, single centre study was conducted by using *Gudavarti*.

- Data Collection:-A case record sheet was prepared for collection of data of clinical; trail which was also peer reviewed and standardized.
- Cost Comparison, formulation and packing feasibility was checked with modern suppositories.

### Study population

The study population will be patients diagnosed of having constipation who will be mainly recruited from the SSAM hospital. The investigator should complete a subject screening log to document subjects considered for enrolment, but never enrolled to establish that the subject population is selected without bias. Recruitment will continue until 100 subjects.

### Inclusion Criteria

- Adult male or female having age more than 18-65 years.
- No significant diseases or clinically significant abnormal laboratory values during screening
- 12-lead ECG without significant abnormalities
- On no regular medical treatment.
- Able to communicate effectively with study personnel.
- Able to be informed of the nature of the study and willing to give written informed consent (Consent must be obtained before any study-related procedures are conducted).

### Exclusion Criteria

- Hypersensitivity or idiosyncratic reaction to any drugs or herbal products.
- Any disease or condition which might compromise the haematopoietic, renal, endocrine, pulmonary, central nervous, cardiovascular, immunological, dermatological, gastrointestinal or any other body system.
- History of allergic conditions –asthma, urticaria, eczema.
- History or presence of dyspepsia, gastric ulcer or duodenal ulcer.
- History of autoimmune disorders e.g. systemic lupus erythematosus, haemolytic anemia.
- History of psychiatric disorders.
- Intake of any medication within 14 days before start of the study
- Subjects who are scheduled to undergo hospitalization for surgery during the study period.
- Presence of clinically significant abnormal laboratory results during screening.
- Pregnancy or breastfeeding.
- Females of childbearing age potential not using medically accepted contraceptive Measures, as judged by the investigator.
- Use of any recreational drugs or a history of drug addiction.
- Participation in a clinical study of any investigational product 1 month prior to visit 1 or during the study.

**Safety Endpoints**

1. Adverse events (type and frequency)
2. Physical examination parameters (body mass, height, etc)
3. Vital signs: blood pressure, heart rate, respiratory rate, body temperature
4. ECG
5. Laboratory tests

**Rome II criteria for diagnosis for constipation:**

Question	Criteria	Observation
1. Hard and lumpy stools.	0 Never or rarely	
	1 Sometimes	
	2 Often	
	3 Most of the time	
	4 Always	
2. Fewer than three bowel movements (0-2) in a week	0 Never or rarely	
	1 Sometimes	
	2 Often	
	3 Most of the time	
	4 Always	
3. Strain during bowel movements	0 Never or rarely	
	1 Sometimes	
	2 Often	
	3 Most of the time	
	4 Always	
4. Feeling of incomplete bowel emptying after bowel movement	0 Never or rarely	
	1 Sometimes	
	2 Often	
	3 Most of the time	
	4 Always	
5. Sensation that stool could not be passed (i.e. blocked) when having bowel movement.	0 Never or rarely	
	1 Sometimes	
	2 Often	
	3 Most of the time	
	4 Always	
6. Pressing on or around your bottom or remove the stools on order to complete the bowel movement.	0 Never or rarely	
	1 Sometimes	
	2 Often	
	3 Most of the time	
	4 Always	

**Specific detail on measurements**

**Relief from symptoms of constipation**

Patient will be assessed for the relief of symptoms of constipation. Patient were assessed from relief of symptoms by using CRF.

**Observations**

Observations were studied with day wise percentage of patients showing symptoms after giving treatment.

**Symptom 1-Hard and lumpy stools**

	% of patients showing symptom	Percentage of Patient showing symptom day-wise after treatment		
		Day-1	Day-2	Day-3
Sometimes	45	40	40	01
Often	10	10	10	02
Most of times	30	25	10	0
Always	25	20	05	01
Total	100	95	65	04
% of patients showing relief from symptom		5	35	96

**Symptom 2 Fewer than three bowel movements (0-2) in a week**

Frequency of symptom	% of patients showing symptom	Percentage of Patient showing symptom day-wise after treatment		
		Day-1	Day-2	Day-3
Sometimes	10	08	06	0
Often	50	48	25	0
Most of times	20	19	08	02
Always	20	15	15	03
Total	100	90	54	05
% of patients showing relief from symptom		10	46	95

**Symptom 3 Strain during bowel movements**

Frequency of symptom	% of patients showing symptom	Percentage of Patient showing symptom day-wise after treatment		
		Day-1	Day-2	Day-3
Sometimes	15	13	10	02
Often	20	18	12	01
Most of times	60	57	45	01
Always	05	04	03	01
Total	100	92	70	05
% of patients showing relief from symptom		08	30	95

**Symptom 4 Feeling of incomplete bowel emptying after bowel movement**

Frequency of symptom	% of patients showing symptom	Percentage of Patient showing symptom day-wise after treatment		
		Day-1	Day-2	Day-3
Sometimes	32	30	10	0
Often	23	17	08	0
Most of times	15	12	07	03
Always	30	22	10	03
Total	100	81	35	06
% of patients showing relief from symptom		19	65	94

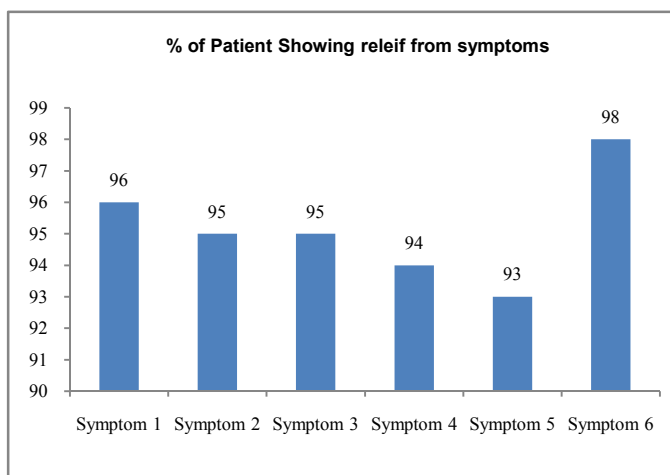
**Symptom 5 Sensation that stool could not be passed (i.e. blocked) when having bowel movement**

Frequency of symptom	% of patients showing symptom	Percentage of Patient showing symptom day-wise after treatment		
		Day-1	Day-2	Day-3
Sometimes	03	02	01	01
Often	34	20	10	0
Most of times	38	28	10	02
Always	25	15	08	04
Total	100	65	29	07
% of patients showing relief from symptom		35	81	93

**Symptom 6 Pressing on or around your bottom or remove the stools on order to complete the bowel movement**

Frequency of symptom	% of patients showing symptom	Percentage of Patient showing symptom day-wise after treatment		
		Day-1	Day-2	Day-3
Sometimes	01	01	01	01
Often	65	50	22	01
Most of times	18	14	05	0
Always	16	08	03	0
Total	100	73	31	02
% of patients showing relief from symptom		27	69	98

## RESULTS



Diagnosis of the patients complaining with constipation was done considering six symptoms. The diagnosis was done based on the four stages of symptom viz. Often(O), Sometimes (S), Most of the times (M), Always(A). On the diagnosis for symptom-1, 45% of the patients showed sometimes(S) hard lumpy stools, 10% shown often of the symptom 25% showed Most of times(M) and 20% showed always of hard and lumpy stools. On completion of the treatment after 3 days, 1% showed Sometimes(S) of symptoms, 2% showed Often of symptom (O), 1% of patients showed Always (A) of symptom.

This shows that overall 96% of patients showed total relief from symptom at end of treatment. Accordingly for Symptom-2, Symptom-3, Symptom-4, Symptom-5, Symptom-6-95%, 95%, 94%, 93%, 98% of patients showed total relief from symptom respectively.

## CONCLUSION

1. The *Gudavarti* prepared, is found to be very effective showing 95% of efficacy with an average of 24 out of 25 patients showing relief in all the six symptoms after completion of treatment for three days.
2. The *Gudavarti* is quite safe and stable at room temperature and does not require special conditions of packing and preservations.
3. It is very easy to prepare and handle.
4. It is very cheap in common man's reaction as compared to modern suppositories available in market.
5. It is having high potential for commercialization.

## Commercial benefits

- Cost effectiveness
- Availability of ingredients
- Easy for preparation
- No use of refrigerator for preservation
- Does not melt in normal environment
- No side-effects

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