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Ayurveda

TO STUDY THE EFFICACY AND SAFETY OF AHAREY DRAVAYA (SAINDHAV&GHRIT) IN THE MANGEMENT OF FUNCTIONAL COSTIPATION

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ABSTRACT Constipation is a most wide spreading health problem in developing countries. Worldwide approximately 20% of individuals are suffering from this gastrointestinal tract complaint in which elder persons contribute more. In the majority of cases constipation is a functional disorder caused due to delay in the passage of fecal matter or due to an insufficient bulk of the feces. Constipation (Functional) is a possible condition may be correlated with Aanaaha. Present study was undertaken to find out the effect and safety of Ahareya dravya(saindhva&ghrita) in the management of functional constipation. Thirty two patients were studied and received Ahareyadravya(saindh&ghrit). After baseline visit (day 0), all subjects were called for follow-up visits on day 7, 14 and 21. Patients were advised to stop taking Ahareya dravya(saindh&ghrit). From day 14 to day 21 to observe recurrence Effect of drugs was observed at the end of 21 days. Data describing quantitative measures were expressed as mean + SD. Comparison of variables representing categorical data was performed using appropriate statistical methods. In study, Overall improvement in the signs and symptoms of functional constipation was graded as excellent improvement (>90% remission of the signs and symptoms of functional constipation), good improvement (75 to 90% remission of the signs and symptoms of functional constipation), satisfactory improvement (50 to 74% remission of the signs and symptoms of functional constipation), average improvement (25 to 49% remission of the signs and symptoms of functional constipation), and poor improvement (<25% remission of the signs and symptoms of functional constipation). None of the patients reported any adverse events during the entire study duration It was concluded that Ahareya dravaya(saindhav&ghrit) acts as an effective and safe laxative in treatment of functional constipation.

KEYWORDS : Ahareya dravya(saindhav&ghrit), Functional constipation, Bristol scale, VAS.

INTRODUCTION-

On a regular basis, constipation implies failure to evacuate waste matter from the body. There is no single definition of constipation. Most commonly, constipation is defined as complaints of one or more symptoms including hard stools, infrequent stools (typically fewer than three per week), a sense of incomplete bowel evacuation, defecation with excessive straining and excessive time spent on the toilet or in unsuccessful defecation. Worldwide approximately 20% of individuals are suffering from this gastrointestinal tract complaint in which elder persons contribute more. In Ayurveda, it is referred to as Aanaaha. Passage of faeces takes place in two phases. Propulsion from the colon and expulsion from the rectum. Interference with any aspect of this process may give rise to constipation. According to Ayurveda, it is usually a vaata disorder particularly, if it is a long-standing condition or in the elderly. It may also be due to high pitta (heat which dries out the stool) or high kapha (mucous congestion clogging the colon).Assimilation and elimination are the two basic needs for natural health. Inactivity of the eliminating organ i.e., the colon causes retention of waste and morbid matter, which results in systemic poisoning or autointoxication. When the colon does not function promptly, the result is an accumulation of offensive and highly poisonous wastes, which not only contaminate the body through absorption with the blood but also upset the whole digestive process. In general, the residue is passed into the colon or lower bowel and stored there until a convenient time comes to expel this refuse from the body. In this colonic garbage pile, there is no antiseptic digestive juice to prevent putrefaction and as a result, the microbes generate toxins with great rapidity. Ayurveda calls it “aama.”.The normal duration between the times the food is eaten until the faeces is expelled, is normally between 16 to 24 hours. If the residue remains for 24 hours or more, it gives rise to aama. There are several causes for constipation and constipation is also a symptom of several diseases. So while treating constipation, all the possible causes should be kept in mind. The causes of constipation are many—constitution of the individual (prakriti), habit of suppressing the urge over long periods (vegadhaarana), absence or non-availability of articles habitually used before defecation, such as smoking tobacco, drinking coffee or tea, frequent use of laxatives and purgatives etc., ingestion of vaata promoting food which is dry (rooksha), powdery (pishtha), cold (seeta), astringent (kashaaya), bitter (tikta), quickly digestive and residue-free diet (laghu), very little food or starvation (anasana), plenty of exercising (ativyaayaama); Intestinal obstruction (aantraavarodha) by foreign body or due to intussusceptions (sammoorchana), worms (krumi), impacted feces (pureesha), slow peristalsis due to debility during fevers, nervous diseases, tuberculosis, anemia etc. Psychological factors like grief (chinta), sorrow (shoka), hatred (dwesha); ingestion of certain drugs; inadequacy of water intake or excessive water elimination as in cases of vomiting (chhardi), diarrhea (ateesaara), diabetes (prameha).Constipation is caused due to both chronic and acute etiologies. The 'Rome III criteria' is a widely accepted format for diagnosis of Functional constipation. Though constipation is not considered as life threatening illness yet it needs proper medical attention. Though modern treatment modalities are well established and safe, they possess few side effects and do not provide satisfying improvement in many patients. The AAHAREY DRAVY help to soften the stool, thus relive constipation and related discomfort, increase peristaltic movements of the colon and stimulate gastrointestinal motility, reduce abdominal pain and flatulence. Help to improve indigestion and promote appetite.

The present clinical study was conducted with an aim to evaluate the efficacy of Aharey dravy(saindhav&ghrit) in the management of functional constipation.

AIMS- To study the efficacy and safety of Aharey dravy(saindav &ghrit)in the management of functional constipation.

Study Objective(s)-The purpose of the study is to evaluate the efficacy and safety of Ahareya dravya(saindahav&ghrita) in patients suffering from functional constipation.

A).Primary Objectives: To evaluate efficacy of Ahareya dravy(saindhav&lavana) in the Management of Functional Constipation by assessing changes in frequency of bowel movements

B).Secondary Objectives: To evaluate efficacy of Ahareya dravya(saindave&ghrita) in the Management of Functional Constipation by assessing

1. Changes in stool form (assessment using 'Bristol stool form scale).
2. Changes in symptoms of functional constipation [straining on defecation, sensation of incomplete evacuation, sensation of anorectal blockage, manual maneuvers required & average time spent for bowel evacuation]
3. Changes in associated clinical symptoms
4. Global assessment for overall improvement by the physician
5. Global assessment for overall improvement by the Patient
6. To evaluate safety of Ahareya dravya(saindave&ghrita) in the Management of Functional Constipation by assessing
7. Adverse events/adverse drug reaction
8. Biochemical / laboratory parameters

MATERIALS AND METHODS

Study type: open, prospective, interventional clinical study. Patients fulfilling criteria and attending OPD and IPD of shri dhanwanteri pg ayurvedic Medical research and hospital Mathura were selected for present study. An informed written consent of all 32 patients was taken in language best understood by them.

STUDY- DURATION: Total study period – 3 weeks (Study Treatment – 2 weeks)
Study follow up period – 1 week

Study Accountability and Administration- Investigator will be responsible for drug storage, dispensing and accountability. Investigational product accountability will be done at all the visits after screening. The study drugs will be dispensed on visit 2 & 3. The medication bottle for a particular visit with consumed or unconsumed medications will be taken back at visit 3 & 4 for the purpose of compliance check and drug accountability. A wash out period of 3 days was advised during which patients had to refrain from any medication (allopathic/Herbal /homeopathic etc.) that will have an effect on the constipation as well as digestive system. Patients were advised to come to hospital for baseline visit on third day after screening visit. All the subjects were advised to continue their routine diet and exercise regimen (which they had been following) during the entire study

MATRA:-Saindhav lavana -10 gm
Ghrita- 20gm (double of churna)
Anupana- hot water

TIME : Apana kaal at night (nisha kala)
Diet: According to the pathya apatya mentioned in ayurvedic text diet was prescribed in all selected patients of functional constipation

SAMPLE SIZE= considering 20% dropout rate, we propose to enroll 36 patients to get 32 evaluable cases (completers) at the end of the study.

INCLUSION CRITERIA-
Subjects meeting all of the following criteria will be included in the trial-

1 Subjects presenting with two or more of the following for the last 3 months with symptom onset at least 6months prior to diagnosis
a) Straining during at least 25% of defecations (2-3 times in a week)
b) Lumpy or hard stools at least 25% of defecations (2-3 times in a week)
c) Sensation of incomplete evacuation at least 25% of defecations. (2-3 times in a week)
d) Sensation of anorectal obstruction/blockage at least 25% of defecations (2-3 times in a week)
e) Manual maneuvers to facilitate at least 25% of defecations (e.g., digital evacuation, support of the Pelvic floor)
f) Fewer than three defecations per week

2. Subjects in whom loose stools are rarely present without the use of laxatives*
3. Subjects not meeting Rome diagnostic criteria for IBS*
4. Subjects in the age group of 18-70 years
5. Subjects having stool form between 1 to 3 on the 'Bristol Stool Form Scale
6. Willingness to sign informed consent document and to comply with the protocol.

(*The Rome III diagnostic criteria for Functional constipation)

EXCLUSION CRITERIA
Subjects meeting any of the following criteria will be excluded from the trial-

1. Subjects with diagnosed colonic inertia.
2. Subjects who have recently undergone abdominal surgery
3. Subjects with history of anorectal surgery.
4. Subjects having other functional gastrointestinal disorders other than Functional constipation (i.e. IBS, Belching disorders etc.)
5. Subjects diagnosed with structural abnormalities like Anorectal , rectal prolapse, rectocele, rectal Intussusceptions, anorectal stricture, solitary rectal ulcer syndrome Perineal descentColonic / rectal mass or tumor with obstruction e.g. adenocarcinoma Colonic stricture, radiation, ischemia, diveticulosis Intestinal obstruction
6. Subjects with serious uncontrolled & diagnosed systemic ailments like HIV, DM and Tuberculosis.
7. Subjects with renal or liver dysfunction

HYPOTHESIS
The present clinical study was conducted with a hypothesis that Ahareya dravya(saindhav&ghrit) will be helpful in the management of functional constipation. Hence, to test this hypothesis, a clinical study titled 'To study efficacy and safety of Ahareya dravaya (saindhav&ghrit) in the management of functional constipation' was carried out

Functional Constipation: Diagnostic criteria
1. Must include two or more of the following:
a) Straining during at least 25% of defecations ***At least often. (Question 11>1)***
b) Lumpy or hard stools at least 25% of defecations ***At least often. (Question 10>1)***
c) Sensation of incomplete evacuation at least 25% of defecations ***At least sometimes. (Question 12>0)***
d) Sensation of anorectal obstruction/blockage at least 25% of defecations ***At least sometimes. (Question 13>0)***
e) Manual maneuvers to facilitate at least 25% of defecations (e.g., digital evacuation, support of the pelvic floor) ***At least sometimes. (Question 14>0)***
f) Fewer than three defecations per week ***At least often. (Question 9>1)***

2. Loose stools are rarely present without the use of laxatives.
Loose stools occur never or rarely (Question 17=0)
3. Insufficient criteria for IBS Diagnostic criteria for IBS not met Criteria fulfilled for the last 3 months with symptom onset at least 6 months prior to diagnosis Yes.(Question 16=1)

Indications of Functional Constipation
- Subjects meeting **Rome III criteria** for Functional Constipation.
- Stool Form between 1 to 3 on the Bristol Stool Form Scale.

SAFETY EVALUATION-
- To measure the incidence of adverse events, serious adverse events, and lab parameters (hematology, biochemistry) and vitals during the study period.

Tools used for efficacy evaluation-
- Primary efficacy: clinical parameters
- Secondary efficacy: clinical parameters and Investigator's Global Efficacy Evaluation Scale

Procedures and Stages
Visit 1 (Screening visit/ Day -3)
- Assessment of Inclusion/ Exclusion Criteria
- Written Informed Consent
- 3 Days Washout Period
- Demographic Data and History
- History of medication and allergies if any
- General examinations (Physical and Systemic)
- Dosha Prakruti evaluation
- Patient's daily diary card
- Diagnosis of functional Constipation on Rome III criteria Vital signs
- Assessment of Stool Form on Bristol stool form scale
- Clinical symptoms assessment
- Assessment of associated symptoms of functional constipation
- UPT for female patients of child bearing potential only
- Lab Investigation (Hematology, Blood Sugar Fasting , Thyroid function test, HIV I and II, LFT, RFT, Lipid profile, Urine analysis, Stool analysis)
- Adverse Event (AE) assessments

Visit 2 (Baseline visit/ Day 0)
- This is done on third day after screening and a window period of $\pm$ 2 days exists for the visit.
- Assessment of Inclusion/ Exclusion Criteria
- General examinations (Physical and Systemic)
- Patient's daily diary card
- Assessment of Stool Form on Bristol stool form scale
- Clinical symptoms assessment
- Assessment of associated symptoms of functional constipation
- Drug Dispensing
- Assessment of Adverse Events/ adverse drug reactions

Visit 3 (Week 1/ Day 7)
- General examinations (Physical and Systemic)
- Patient's daily diary card
- Assessment of Stool Form on Bristol stool form scale
- Clinical symptoms assessment

- Assessment of associated symptoms of functional constipation
- Drug Dispensing
- Assessment of Drug Compliance
- Assessment of Adverse Events/ adverse drug reactions

Visit 4 (Week 2/ Day 14)

- This is done on day 14 after screening and a window period of ± 2 days exists for the visit.
- General examinations (Physical and Systemic)
- Patient's daily diary card
- Assessment of Stool Form on Bristol stool form scale
- Clinical symptoms assessment
- Assessment of associated symptoms of functional constipation
- Global assessment for overall improvement by the investigator and by patient
- Global assessment of tolerability of trial drug by the investigator and by patient
- Lab Investigation (Hematology, Blood Sugar Fasting, LFT, RFT, Lipid profile, Urine analysis, Stool analysis)
- Assessment of Drug Compliance
- Assessment of Adverse Events/ adverse drug reactions

Visit 5 (Week 3/ Day 21)

- This is done on day 21 after screening and a window period of ± 2 days exists for the visit.
- General examinations (Physical and Systemic)
- Assessment of Stool Form on Bristol stool form scale
- Clinical symptoms assessment
- Assessment of associated symptoms of functional constipation
- Global assessment for overall improvement by the investigator and by patient
- Assessment of Adverse Events/ adverse drug reactions
- Completion

STATISTICALANALYSIS-

Data describing quantitative measures were expressed as median or mean ± SD or SE or the mean with range. Comparison of variables representing categorical data was performed using "Chi-square test". Corresponding contrasts were tested using t-test for dependent samples and nonparametric test like "Wilcoxon Sign Rank" Test. All P values are reported based on two-sided significance test and all the statistical tests were interpreted at 5% level of significance.

RESULTS AND OBSERVATION-

A total of 38 subjects were screened in the present study of which 4 subjects did not meet the inclusion criteria and therefore were not recruited in the study. Out of 34 subjects who were recruited in the study, 32 subjects completed the study while 2 subjects dropped out from the study. The reason for drop out was lost to follow up because patient did not turn for follow up visit. Out of 32 patients who completed the trial, there were 40.% males and 60% females. Out of 32 patients, 6 (18.75%) patients were in the age group of 21 to 30 years; 10 (31.25%) patients were in the age group of 31 to 40 years; 14 (43.75%) patients were in the age group of 41 to 50 years; while remaining 5 (15.62%) patient were in the age group of 51 to 60 years. The most common symptoms presented at screening visit were lumpy hard stools, straining during defecation, sensation of incomplete bowel evacuation, and sensation of anorectal blockage. Few patients also reported acidity, flatulence, colic pain, headache, abdominal fullness, nausea, low backache, or a need of manual maneuvers for bowel evacuation.. No patient was dropped out or withdrawn due to the adverse event or an adverse reaction. Study treatment did not cause any significant change in vital signs like pulse rate, body temperature, respiratory rate, and the blood pressure.

Table 1: Showing the frequency of bowel movements

Sr. No	Baseline	Days 07	Day 14	Day 21
Mean + SD	6.30±2.20	14.20±5.30	13.34±4.34	9.68±3.10
P value		t=7.2 p<0.001	t=6.68 p<0.001	t=4.98p<0.001

Table 2: Showing the Change in Stool form on Bristol Scale

Sr. No	Baseline	Days 07	Day 14	Day 21
Mean + SD	3.51±0.98	6.45±0.95	6.34±0.98	5.47±0.89
P value		t=8.20 p<0.001	t=6.20p<0.001	t=4.99 p<0.001

Table 3 Showing the Mean Grade score of straining on defecation

Sr. No	Duration	Mean Grade Score ±SD	T Value (as compared to baseline visit)
1	Baseline Visit	42.88±15.88	
2	7 days	17.42±14.66	t- 6.14(p<0.001)
3	14 Days	8.10±9.98	t- 7.98(p<0.001)
4	21 days	9.28±12.57	t- 5.46(p<0.001)

Table 4: Showing the Mean score of Sensation of Ano-rectal Blockage

Sr. No	Duration	Mean Grade Score ±SD	T Value (as compared to baseline visit)
1	Baseline Visit	39±16.21	
2	7 days	14±11	t- 4.12(p<0.001)
3	14 Days	13.14±23.74	t- 5.27(p<0.001)
4	21 days	20.12±25.98	t- 2.40(p<0.001)

Table5: Showing the Average Time spent for bowel evacuation on weekly basis

Sr. No	Duration	Mean Grade Score ±SD	T Value (as compared to baseline visit)
1	Baseline Visit	13.22±8.12	
2	7 days	6.08±5.08	t- 6.13(p<0.001)
3	14 Days	6.98±4.20	t- 7.10(p<0.001)
4	21 days	8.72±7.45	t- 4.75(p<0.001)

Table 7: Showing other associated symptoms of constipation

Associated symptom	Value	Baseline	7Days	14Days	21Days
Headache	Mean ±SD	16.35 ±21.98	6.92 ±10.10	4.07±6.20	6±9.98
	t value pvalue		t=3.13 p<0.001	t-3.98 p<0.001	t-3.20 p<0.001
Acidity	Mean ±SD	21.35 ±24.46	15.88 ±23.07	13.46 ±21.68	17.83±22.78
	t value pvalue		t-1.90 p>0.05	t-1.95 p>0.05	t-0.99 p>0.05
Belching	Mean ±SD	14.71 ±15.19	7.14 ±8.62	9.68 ±21.60	13.46±22.44
	t value pvalue		t-2.94 p<0.05	t-1.98 p>0.05	t-1.84 p>0.05
Flatulence	Mean ±SD	24.92 ±16.23	12.11 ±11.12	11.76 ±9.34	15.23±14.31
	t value pvalue		t-4.83 p<0.001	t-5.11 p<0.001	t-3.85 p<0.05
Abdominal distension	Mean ±SD	22.57 ±9.95	10.48 ±6.18	11.30 ±7.62	13.23±11.05
	t value pvalue		t-3.45 p<0.001	t-3.09 p<0.001	t-2.07 p<0.005

Table 7: Showing laboratory investigation

Activity	Screening Visit (Day -3)	Baseline Visit (Day 0)	Visit 1 (Day 7)	Visit 2 (Day 14)	Visit 3 (Day 21)
CBC, ESR, Hb%	√	×	√	×	×
BSL Random	√	×	√	×	×
Liver Function Test	√	×	√	×	×
Renal Function Test	√	×	√	×	×
Lipid Profile	√	×	√	×	×
Thyroid function test	√	×	×	×	×
HIV- I & II	√	×	×	×	×
Urine Examination	√	×	√	×	×
Urine pregnancy test	√	×	×	×	×
Stool Examination	√	×	√	×	×

DISSCUSION-

Acharya Yogratnakar has described Saindhav&ghrita for treatment of Aanaaha(constipation). It shows the beneficial effect of Ahareya dravya(saindhav and ghrit) in functional constipation. In the present clinical study, the efficacy and safety of Ahareya dravya(saindhav and ghrit in subjects suffering from functional constipation was observed. Fourteen days of treatment with Ahareya dravya(saindhav and ghrit) showed significantly increase in frequency of bowel movements on day 14. Also, the increase in mean bowel frequency after 'no laxative (saindhav&ghrit) observatory period' of seven days (i.e. on day 21)

was statistically significant than baseline visit. Stool form was significantly improved on all the three follow up visits ($p < 0.001$). Improvement in straining during defecation, sensation of anorectal blockage and sensation of incomplete evacuation was statistically significant ($p < 0.001$) even after discontinuation of Ahareya dravya(saindhav and ghrit after day 14. Improvement in average time spent for bowel evacuation on weekly basis was statistically significant ($p < 0.001$) on every follow-up visit and even after stopping the saindhave&ghrit the subject required less time for bowel evacuation as compared to its initial readings. Also, significant improvement in the scores of associated symptoms like headache, flatulence, abdominal distension and bloating were observed at all the three follow up visits while symptoms like acidity and belching did not show significant improvement. No relapse/recurrence was observed in most of the symptoms of the functional constipation even after discontinuation of study medication for 7 days. The overall evaluation of efficacy and safety revealed excellent to good efficacy and safety by both the physician and subject. Laboratory parameters for safety evaluation showed no significant change in the values.

MODE OF ACTION OF AHERAYA DRAVY (SAINDHAV&GHRITA) IN COSTIPATION-

The Ahara undergoes two processes for complete digestion avasthapaka &Vipaka. Katu Avasthapaka , the materials phases down the pakvashaya from the Amashya and being dried by Agni and rendered into lumps. (paripindita pakva), During this process vaya and Mala are produced. Passage of faeces takes place in two phases. Propulsion from the colon and expulsion from the rectum. Interference with any aspect of this process may give rise to constipation. According to ayurveda, it is usually a vaata disorder particulary, if it is a long-standing condition or in the elderly. By nature Vaata is dry and irregular, and hence when someone has increased Vaata (or Air and Space) in the body, one will have a tendency towards irregularity and dryness (such as constipation and gas). Vata's "home base" is in the colon and therefore, when Vata is increased, one of the first areas that will be effected is the colon .By virtue of its Yogavahitwa property , ghee is infused with the Vata-reducing herbs that are soothing, healing and lubricating to the gut and colon.Decreased colonic motility is responsible for the constipation Hard stool are usually due to increased absorption of fluid as a result of prolonged contact of the luminal content with the colonic mucosa constituent to delayed transit.*Saindha* is one of the important formulations in ayurveda has *Sukshmasrotogami* properties . Charaka has mentioned the following actions imparted by lavana in the body. It is diffusive, liquifacient digestive, appetizing, inductive of defluxion, depletive and disruptive, acute, avoids accumulations and obstructions, stiffness and curative of Vata. It is also laxative, overpowers the rest of the tastes and increases the secretion of mouth. It liquefies the mucous secretion, clarifies the passage, softens all the limbs of the body, It is used for alimentary purpose. It is used for alleviating flatulence and pain in the stomach. saindhav not only cleans up the alimentary canal but also very favorably acts on several organs like liver, pancreas and kidneys by inducing a sort of internal massage to them. It also cleanses the circulatory system by bringing down the urea, creatinine and other toxic materials through its osmotic effect. The ingredients of ahareya dravya(saindhav&ghrit) having the property of srtotoshdhan,Vatanulomana,Rasayan and Brimhana which helps in maintain equilibrium of Dosha and Malas.] *Saindhava* also has *Sukshmasrotogami* properties

CONCLUSION-

1) The persistent use of purgatives and enemas are the commonest and routine causes, which convert an occasional Jron-evacution of the bowel in chronic constipation
2) All other purgatives produce roughness (rooksahta), also it produces certain adverse effects like, decreases colonic motility, gripping pain and wind formation in the stomach
3) The irnportant cause is the bad habits of neglecting the urge or nature's call for defection. Because of this the reflex is lost. Due to intake of low residue diet or starvation there may not be enough fecal matter to produce bowel evacuation.
4) Insufficient water intake, lack of exercise, inadequate allotment of time for full defecation and prolonged travel are one of the major causes for constipation in India.
5) When the patient also has symptoms such as fatigue, malaise, headache or anorexia, the possibility should be considered whether such symptoms reflect an 'underlying depression of which constipation is one component

The present study provides the evidence in support of the potential efficacy and safety of Ahareya dravy(saindhav&ghrit) in the treatment of functional constipation. Two weeks of treatment with the drug have prevented the relapse of most of the symptoms of functional constipation. Hence, the study concludes that of Ahareya dravy(saindhav&ghrit) is an effective, safe and non habit forming herbal laxative formulation for the management of constipation.

Suggestions:

In future study two compare group has to be taken one without giving any medicine and that group has to be compare with the treated group. I know this limited study has not covered all the aspects of the problem, but clinical trials show very encouraging result. More study is necessary on larger sample to draw the final inferences.

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