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Research Article

A CLINICAL STUDY TO EVALUATE THE BOWEL REGULATORY POTENTIAL OF SHRIPHALADI KHANDA-AN AYURVEDIC FORMULATION

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ABSTRACT

Lifestyle of humans has changed substantially in this modernized world. Technology has given easy access to almost everything under our fingers, but has led to reduced physical activity leading to increased incidence of lifestyle related disorders. Recent trends have shown people taking high amount of calories from animal products, sugars, fats & refined food items. Consumption of fibers in the diet has reduced. Young generation is more into the habit of junk food. Further level of stress has increased both at personal and professional life. All these factors are having ill effects on every organ system of body. Due to these lifestyle changes gastrointestinal symptoms like constipation, heartburn, abdominal discomfort & diarrhea are frequently encountered in clinical practice. Constipation is a common prevalent problem in general population with prevalence 2-28%. Constipation is associated with significantly impaired quality of life and psychological distress, as well as increased health care costs and impaired work productivity. Constipation has been defined as a frequency of defecation less than three times per week with subjective complaints of excessive straining, hard stools, lower abdominal fullness and a sense of incomplete evacuation. Different classes of laxatives have various limitations in one or another form. Hence present study was planned to evaluate the bowel regulatory potential of a herbal formulation Shripthaladi khanda. The trial drug was found to be an effective, clinically safe and non habit forming herbal formulation with good palatability.

Keywords: Constipation, Laxative, Herbal, Bilva, *Cassia fistula*, Gastrointestinal symptom.

INTRODUCTION

In today's fast moving world, life style of mankind has changed substantially and it is now hard to keep up with the pace of life. Major factors which have changed our lifestyle are technological advancements, faulty dietary habits, reduced physical activity and stress. Workplaces are now equipped with computers and automated machines. Sporting activities have been reduced, young generation is more interested in videogames as compared to outdoor games. People's dietary habits have changed substantially with increase in consumption of animal products, milk and milk products, sugars, fats, oils and alcoholic beverages. People are more into the habit of junk and spicy food. Fiber in the diet has reduced a lot.¹ Stress has become an inescapable part of modern life. These life style changes have impact on every organ system of human body in some or other way. That's why the incidence of life style disorders such as hypertension, diabetes, obesity,

heart diseases and constipation etc. is on rise. Like any other system the digestive system is also sensitive to changing life style and it can be easily disrupted by a poor diet, lack of fluid, too little exercise, absence of routine and high level of stress.² The digestive system releases the fuel we need to lead our lives and dispose off the waste that is left. Ensuring it remains free flowing plays an essential part in achieving inner health. Almost one third of the general population have some form of bowel problems varying from heartburn and abdominal discomfort, to constipation and diarrhea.³ Constipation is one of the most common gastrointestinal disorders encountered in patients visiting to the medical OPD. Most studies estimate the prevalence of constipation in general population to be 2-28%. The prevalence increases with age and is more frequent in females.⁴ It is believed that India is having lesser prevalence of constipation in comparison to more developed Asian and Western nations, but still patient number is large. A study involving 4,767 participants from rural areas in the northern

part of India has found the prevalence of constipation 11%, which if translated into real numbers, it is estimated that around 130 million Indians are suffering from constipation³. Constipation is both a symptom and when chronic, a multi symptom disorder which can overlap with other GIT disorders such as dyspepsia and GERD⁵. Discrepancies in the population prevalence of constipation have been attributed to the lack of uniform diagnostic criteria and the number of patients who seek medical care. Constipation is associated with significantly impaired quality of life and psychological distress, as well as increased health care costs and impaired work productivity³. Although it is not a life threatening problem, even then it causes great distress to those afflicted and can be difficult to cure. Constipation is change in bowel habits, when one goes to toilet less often than usual for him. There is wide range of normal bowel habits in different populations and it can range from three times a day to three times a week. Constipation has been defined as a frequency of defecation less than three times per week with subjective complaints of excessive straining, hard stools, lower abdominal fullness and a sense of incomplete evacuation.⁶ Although this disease has not been described in classical texts of ayurveda as a separate disease entity, but its description is available in almost every text as a prodromal symptom, sign or complication of various diseases. It has been described at different places using various nomenclatures signifying the same meaning. Different classes of laxatives used for the treatment of constipation has various limitations in one or other form due to the latency period of action, habit forming nature or due to adverse effects of the drugs⁷. Various herbal formulations are also available for the treatment of constipation which are non-habit forming but palatability is the limiting factor for their use. Present study was planned to formulate an effective, safe, non habit forming, cost effective, and palatable herbal remedy for constipation. Keeping all these facts in mind trial drug Shriphaladi khanda was selected for the trial which is an anubhuta yoga having Bilwa (*Aegle marmelos*), Amaltas (*Cassia fistula*), Saunf (*Foeniculum vulgare*) and Guda (Jaggery) prepared in the form of granules.

MATERIALS AND METHODS

Selection of the patients

The current study was open clinical trial carried out on a single group. 23 patients fulfilling the inclusion criteria were selected randomly after their voluntary informed consent irrespective of their sex, caste, religion, education etc.

Criteria for selection of patients

Inclusion Criteria

1. Patients willing for the trial
2. Patients in age group between 18-60 years
3. Patients of habitual constipation
4. No associated chronic ailment

Exclusion Criteria

1. Haemorrhoids (3rd and 4th degree), Anal strictures & Rectal prolapse
2. Intestinal obstruction & Perforation
3. Diabetes & Diabetic enteropathy.
4. Diarrhoea

5. Pregnant women
6. Different types of hernia
7. Carcinoma (Malignancies)
8. Patients showing any allergy to trial drug
9. Any other thought fit for exclusion

Protocol of Research

Institutional Ethics committee approval was taken before conducting the clinical trial.

Consent of Patient

Written informed consent of every selected patient for the trial was taken after explaining the nature of the study including merits and demerits.

Clinical Research Form

Detailed information of every patient including complete demographic profile of patient, chief complaints with duration, family history, personal history, socio-economic history, general physical examination, systemic examination along with ashtavidha pariksha, dashvidha pariksha and srotas examination was recorded in the clinical research form.

Trial drug and its Ingredients

The selected patients were given the trial drug "Shriphaladi khanda". The drug was named so using synonym of Bilva i.e. Shriphal. The drug was prepared using following ingredients.

1. Pakva Bilva Majja Churna (Pulp of ripe fruit of *Aegle marmelos*) - 3 parts
2. Amaltas Phala Majja (Pulp of pod of *Cassia fistu*)- 2 parts
3. Shatpushpa (Saunf) (Fruits of *Foeniculum vulgare*)-1 part
4. Guda (Jaggery) - Q.S.

Preparation of Drug

The different ingredients of the trial drug were got identified by dravya guna department of the college. Trial drug was prepared in the form of granules by using *guda* as binding agent. The drug was prepared in the college pharmacy under the supervision of in-charge of the pharmacy.

Administration and Dose of Drug

Administration	-	Orally after meals
Dose	-	10gm BD
Anupana	-	Luke warm water.

Duration of the trial & Follow-up

The total duration of the trial was of 15 days. The patients were advised to come for follow up after 7 days of initiation of trial and at the end of trial to observe the effects and adverse effects of trial drug.

Criteria of Assessment

Assessment was done on the basis of relief in signs and symptoms. Total eleven criterias were selected for assessment. Scoring system was adopted for statistical analysis of results obtained. Each criteria was assigned four grades ranging from 0-3 depending upon the severity of the symptom. Criterias selected for the trial were consistency of stool, discomfort in abdomen, pain in abdomen, bloating in abdomen, painful bowel movement, rectal bleeding or tearing during bowel movement, satisfaction after bowel movement, straining, squeezing or manual maneuvers to pass bowel, number of visits to toilet, average time spent in toilet per visit and visual analogue scale.

Statistical Analysis

The information gathered regarding demographic data is shown in terms of percentage. The scores of criteria of

assessment were analyzed statistically in terms of mean score B.T. (Before treatment), A.T. (After treatment), (B.T. – A.T.) difference of mean, S.D. (Standard deviation), S.E. (Standard error). Student's paired 't' test was carried out at $p < 0.05$ and $p < 0.001$.

The results were considered significant or insignificant depending upon the value of p.

- Highly significant - $p < 0.001$
- Significant - $p < 0.05$
- Insignificant - $p > 0.05$

Overall results were established in terms of percentage relief obtained in criterias of assessment.

- Cured - 100%
- Excellent improvement - 75-99%
- Moderate Improvement - 50-74%
- Mild Improvement - 25-49%
- No improvement - 0-24%

OBSERVATIONS

In the present study, total 23 patients were registered out of which one patient did not turn up for follow up and was considered dropout hence statistical analysis of results were carried out on 22 patients. It was observed during the trial that maximum number of patients i.e. 43.48% (10) were between 51-60 years of the age, 52.17% (12) patients were males, 91.30% (21) were of Hindu religion, 30.44% (7) of the patients were farmers, 39.13% (9) of the patients were illiterate, 82.61% (19) were married, 60.87% (14) were of middle class, 56.52% (13) patients had no addiction, 52.17% (12) of the patients were of vata-pittaj prakriti, 78.26% (18) were having krura koshta, 91.30% (21) were from rural area, 60.87% (14) of the patients were having mixed dietary habits, 60.87% (14) of the patients were having normal appetite, 73.91% (17) were having irregular bowel habits, 56.52% (13) of the patients had moderately active lifestyle, 86.96% (20) of the patients were of madhyama satva, 39.13% (9) of the patients had chronicity of the disease for 3-6 months.

RESULTS

Effect of therapy was observed on the basis of relief in criterias of assessment (Table 1). Statistically significant results were obtained in consistency of stool with $p < 0.001$. There was marked improvement in discomfort in abdomen with statistically significant value of $p < 0.001$. Pain in abdomen was relieved by 80.18% in terms of percentage but statistically it was insignificant with $p > 0.05$ due to small sample size. Statistically significant improvement was seen in bloating in abdomen with $p < 0.001$. Painful bowel movement also showed 100% improvement in terms of percentage but it was statistically insignificant with $p > 0.05$ again due to presence of this symptom in lesser number of patients. Relief in symptom of rectal bleeding or tearing during bowel movement was statistically insignificant with $p > 0.05$ due to small sample size. Satisfaction after bowel movement was improved with statistically significant value of $p < 0.001$. Symptom of straining, squeezing or manual maneuvers to pass bowel showed significant improvement statistically with $p < 0.001$. Average number of visits to toilet after treatment were once a day which was statistically significant with $p < 0.05$. With treatment average time spent in toilet per visit was reduced which was significant statistically with $p < 0.001$. Overall feeling of well being was also assessed in the patients with the help of visual analogue scale which showed statistically significant results with $p < 0.001$.

OVERALL EFFECT OF THERAPY

Overall effect of therapy was calculated on the basis of percentage relief in signs and symptoms. Out of 22 patients 22.73% patients were completely cured i.e. they had no symptom present at the end of study, 54.54% patients showed excellent improvement and 22.73% patients showed moderate improvement. There were no such patients who showed mild improvement or were unimproved. Patients after completion of trial were further observed for next 15 days for recurrence of symptoms. None of the patient reported back with complaint of constipation (Table 2).

Table 1: Effect of Therapy on Criterias of Assessment

Sl. No	Assessment Criteria	N	Mean		X (X ₁ -X ₂)	Percentage Relief (%)	S.D. ±	S.E. ±	t	p
			BT (X ₁)	AT (X ₂)						
I	Consistency of Stool	22	1.59	0	1.59	100	0.74	0.16	9.94	<0.001
II	Discomfort in abdomen	22	1.32	0.32	1.00	75.76	0.62	0.13	7.69	<0.001
III	Pain in Abdomen	9	1.11	0.22	0.89	80.18	1.28	0.43	2.07	>0.05
IV	Bloating in abdomen	19	1.53	0.74	0.79	51.63	0.53	0.12	6.58	<0.001
V	Painful bowel movement	6	1.17	0	1.17	100	2.13	0.87	1.35	>0.05
VI	Rectal bleeding or tearing during bowel movement	3	1.00	0.33	0.67	67	2.15	1.24	0.54	>0.05
VII	Satisfaction after bowel movement	22	2.27	0.59	1.68	74.01	0.71	0.15	11.2	<0.001
VIII	Straining squeezing or Manual maneuvers to pass bowel	21	1.62	0.29	1.33	82.10	0.65	0.14	9.5	<0.001
IX	Number of visits to toilet per day	10	2	0	2	100	2.49	0.79	2.53	<0.05
X	Average time spent in toilet per visit	16	1.13	0.25	0.88	77.88	0.74	0.19	4.63	<0.001
XI	Visual Analogue Scale	22	1.45	0.05	1.40	96.55	0.67	0.14	10	<0.001

N: Number of patients; BT: Before treatment; AT: After treatment; X: Difference of mean;

S.D: Standard deviation; S.E: Standard Error

Table 2: Overall Effect of Therapy

Overall Effect of Therapy	No. of patients	% Relief
Cured	5	22.73
Excellent Improvement	12	54.54
Moderate Improvement	5	22.73
Mild Improvement	0	0
No Improvement	0	0

DISCUSSION

In the present clinical trial the most common presentation with which the patients reported were hard consistency of stool (100%), discomfort in abdomen (100%), reduced satisfaction after bowel movement (100%), increased straining-squeezing and using manual maneuvers to pass bowel (95.45%), bloating in abdomen (86.36%), increased average time spent in toilet per visit (72.73%) and reduced number of visits to toilet (45.45%). Other important but less common presentations were pain in abdomen (40.91%), painful bowel movements (27.27%) and rectal bleeding or tearing during bowel movements (13.64%). These symptoms are in accordance with the symptoms often encountered in constipated subjects. It was observed that relief in symptom of hard consistency of stool was gradual and at the end of trial this symptom was found to be completely relieved. Two patients also reported with loose consistency of stool with frequency 2-3 times/day after taking recommended trial drug dosage for few days. Discomfort in abdomen occurs due to incomplete evacuation of bowel and presence of gases in the intestinal lumen. The effect of drug in improving the discomfort in abdomen was due to its carminative and stomachic properties which are described while describing the probable mode of action of drug. Moreover as the bowel clearance gets better, discomfort in abdomen also improves. Pain in abdomen occurs due to pressure effects of impacted stool and intra luminal gases on the intestinal wall. Severity of pain in abdomen is proportional to the chronicity of constipation. With improvement in consistency of stool, pain in abdomen also improves. Improvement in pain in abdomen was also related to bowel clearance and the stomachic and carminative properties of fennel which is having proven antispasmodic effect. Fennel seeds produce a reduction in acetylcholine and histamine induced contractions and thus improve pain in abdomen. Painful bowel movements occur due to hard consistency of stool. Hard consistency of stool results into excessive straining during defecation, which results into painful defecation. Painful bowel movements can be due to associated anorectal disorders viz. fissure-in-ano, haemorrhoids, and fistula-in-ano etc., caused as a result of constipation. It was observed that number of visits to toilet after taking treatment was once or twice a day on an average. Average time spent in the toilet per visit also got reduced as there was improvement in consistency of stool.

PROBABLE MODE OF ACTION OF SHRIPHALADI KHANDA

On the basis of Ayurvedic pharmacological properties

This formulation is made up of Pakva Bilva majja churna, Amaltas phal majja, Saunf and Guda. These drugs are widely

described in classical texts. Amaltas and Pakva Bilva are described as mriduvirechaka^{8,9}, whereas Satpushpa as vibandhnashak and vatanulomaka¹⁰. From the pathogenesis of constipation it is evident that apana vata is mainly vitiated and is the main causative factor of this disease as excretion of stool is function of apana vayu¹¹. Due to various nidanas, ruksha(dry), chala and sheet guna of vayu get vitiated causing hardening of faeces. Therefore for the treatment of vibandha(~constipation), criteria of drug selection should be based on the gunas of the drugs which are able to pacify vitiated sheeta, chala and ruksha gunas. Hence the drugs which are snigdha, ushna, sthir and anulomaka should be selected for the treatment of constipation. Mentioning the properties of rechaka dravyas Charaka has described that rechaka dravyas should be sarvarasa, ushna, tikshna, sukshma, vyavayi and vikasi¹². According to Sushruta rechak dravyas should be guru in nature owing to their prithvi and jal bahul constitution¹³. Due to this they have the potential to move intestinal contents towards adhomarga. Pakva Bilva phal due to its madhura rasa and guru guna,¹⁴ have potential of pacifying vata and moving the intestinal contents towards rectum.

Amaltas is mentioned under virechana gana by Charak and adbhogahara dravya by Sushruta. It is madhura(~sweet) in taste, with guru, mridu and snigdha properties, madhura vipaki and sheeta virya. Due to madhura and snigdha guna it has potential of pacifying vata dosha and has anulomaka(~carminative) effect. Due to snigdha guna it also softens the stool.¹⁵ It has rechana effect due to prabhava and is described as best mridurechana dravya by Charaka.¹⁶

Saunf is vata shamaka due to its madhur and snigdha properties. It has anulomana property which helps in propagation of intestinal contents downwards. Being deepana and pachana it has potential to remove amadosha associated mala(~waste) and hence help in nirama-malapravriti.¹⁷

Jaggery is used mainly to improve palatability of drug but it also has emollient and laxative effect due to its guru & snigdha properties.¹⁸ Hence this formulation complies with all the required properties of a rechana drug.

Probable mode of action on the basis of chemical constituents

This blend is formulated as a medium strength laxative. All the three drugs used in the formulation are having laxative effect. Along with laxative effect formulation is also having antispasmodic and carminative effect. This formulation as a whole exhibits its laxative effect through mixed type of mode of action. The ripe fruits of Bilva (*Aegle marmelos*) are valuable for its rich nutritive, sweet, aromatic, cooling, astringent, febrifuge, laxative and tonic properties. It is very good for all kind of stomach disorders and helps in improving appetite and digestion. It is a unique fruit which is famous as laxative and at the same time as an intestinal astringent also.¹⁹ The use of ripe fruits is highly efficacious in the case of chronic constipation⁹, and where patients complain of incomplete evacuation. The fruit pulp contains high amount of moisture (60.7%), mucilage, pectin (2.52%), along with other constituents. It is febrifuge and laxative due to its high moisture, mucilage and pectin contents¹⁹. It probably works as

laxative through its stool softening as well as bulk forming nature.

Amaltas (*Cassia fistula*) has been used as a highly effective, mild laxative that is safe even for children, older persons and in pregnancy.²⁰ Cassia is supposed to act as a stimulant and bulk forming laxative. The purgative action of cassia is due to the presence of Cathartic acid, Aloe emodine (Anthraquinone) and Chrysophanic acid²¹. It is having a sufficient amount of fiber content in the form of mucilage and pectin. Thus it acts like a bulk forming laxative. Its action being chiefly on the large bowel, it is especially suitable in habitual constiveness. The fruit pulp of *Cassia fistula* is rich in Anthraquinone derivatives e.g. rhein, sennidin and related dianthrones and sennoside and related dianthrone glycosides which are responsible for laxative properties. The sugar moiety in glycosides increases water solubility of the molecules and thus facilitates transport to the site of action i.e. colon. They are hydrolyzed in the colon by the β -glucosidase enzyme of the intestinal flora to give free anthraquinones which are further reduced to anthrones. The anthrones formed in-situ are the active laxative form of anthraquinone compounds which affect the intestinal motility and increase peristaltic movements of the colon and sigmoid, by its local action upon the intestinal wall²².

Fennel is a common herb used as a flavouring agent in many herbal formulations for making their palatability better. It helps to promote good digestion and ease gas and bloating.²³ The major constituents of fennel include the terpenoid, anethole, fenchone and other terpenoids, inhibit spasm in smooth muscles of gastrointestinal tract and is thought to contribute to fennel's use as a carminative and stomachic. Fennel traditionally has been used as an antifatulent.²⁴ Fennel seeds also contain fiber and complex carbohydrates. Fennel seeds used in the form of powder, act as bulk forming laxative.²⁵ Fiber content present in fennel seeds helps to clear off the bowels. The stimulating effect of fennel seeds helps in creating proper peristaltic movement of the intestine. This in turn helps to improve a person's digestive and excretory systems. Fennel seeds increase gastro-intestinal motility and act as antispasmodic at high doses. Fennel seeds produce reduction in acetylcholine and histamine induced contraction and decrease maximum possible contractility. Fennel seeds have also shown prostaglandin and oxytocin inhibiting activity in mice^{26, 27}.

CONCLUSION

From the above observations and discussion, it can be concluded that, this formulation as a whole is a good medium strength laxative along with carminative and stomachic properties. It exhibits its laxative action through mixed type of effects on the intestinal wall and stool i.e. due to chemical irritation (cathartic acid and anthraquinone derivatives), through mechanical irritation (fiber content) and as stool softener (due to moisture content and soothing effect of all the three drugs). The drugs used in this formulation also help in improving digestion and metabolism by their well known effect at the level of agni (~digestive fire) thus targeting the root cause of various gastrointestinal disorders.

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