



## Research Article

### THE EFFECT OF CONSTAC PLUS IN THE MANAGEMENT OF SEVERE CHRONIC CONSTIPATION: A PILOT STUDY

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#### ABSTRACT

The purpose of this study was to evaluate the efficacy of CONSTAC PLUS granulation in the management of severe chronic constipation. Total 450 patients were enrolled to receive a CONSTAC PLUS for maximum 60 days. Out of 450 patients, 33 were lost to follow up. The symptoms of constipation were evaluated by Longo's Obstructed Defecation Syndrome (ODS) score system. Patients' quality of life was assessed by the Patient Assessment of Constipation-Quality of Life Questionnaire and stool consistency were assessed by "Bristol stool form scale" before and after 15, 30 and 60 days. Analysis done for 417 patients. After treatment there was significant ( $p < 0.005$ ) improvement in defecation frequency per week. There was significant reduction in rectoperineal pain and discomfort, straining intensity, average time spent on toilet for bowel evacuation and digitations score. Stool consistency were significantly ( $p < 0.005$ ) improved in all follow-up visits. During study abdominal pain/cramping ( $n = 13 / 3.12\%$ ), bloating ( $n = 11 / 2.64\%$ ), diarrhea ( $n = 9 / 2.16\%$ ), and passing gas ( $n = 17 / 4.098\%$ ) adverse events were more commonly reported. All were treated by medical management. This result proves CONSTAC PLUS is an effective and safe herbal laxative formulation for severe chronic constipation.

**KEYWORDS:** Chronic constipation, Obstructed defecation syndrome score, laxative.

#### INTRODUCTION

Chronic constipation is infrequent bowel movements or difficult passage of stools that persists for several weeks or longer in elderly with considerable impact on quality of life and health expenses. It has a prevalence around 15–17% of adults and characterized by unsatisfying defecation associated with infrequent stools, difficult stool pass.<sup>[1,2]</sup> Most cases of chronic constipation are primary or idiopathic, but a some cases may be secondary to a number of medications or diseases.<sup>[3]</sup> For diagnosis of constipation "Rome III" is one of the most widely accepted criteria.<sup>[4]</sup> Treatment of constipation includes patient education, dietary fiber supplementation, adequate fluid intake, and regular physical activity.<sup>[5]</sup> Approximately 25% patients uses medical treatments, whereas a considerable proportion relies on alternative solutions, following advices given in pharmacies or herbalist's shops.<sup>[6]</sup> Depending on severity and chronicity of constipation various drugs such as osmotic agents, stimulants, stool softeners and bulk-forming agents are used, but they have side effects like abdominal cramping, hypokalemia, flatulence, abdominal distension, and alteration in electrolyte transportation which limit the long-term use of these drugs.<sup>[7-9]</sup> CONSTAC PLUS is an Ayurvedic polyherbal formulation in granulation form. All the ingredients of the formulation have been used for thousands of years and individual therapeutic efficacy of these herbs as laxative has also been reported in an ancient Ayurvedic literature.<sup>[10-12]</sup> Hence, a pilot study was

performed to evaluate the efficacy and safety of "CONSTAC PLUS" in patients with severe chronic constipation.

#### MATERIAL AND METHOD

**Study design:** This was an open-label, uncontrolled, Single arm, single-center study.

#### Study Drug

CONSTAC PLUS is an Ayurvedic polyherbal formulation in granulation form which comprises dried granulations of *Hirada* and *bal Hirada* (*Terminalia chebula*), *Behada* (*Terminalia Belerica*), *Amala* (*Embllica officinalis*), *Badishep* (*Foeniculum Vulgare*), *Elaichi* (*Elettaria cardamomum*) *Narikel lavan* (processed salt with coconut), *Sonamukhi* (*Cassia senna*), *Mulethi* (*Glycyrrhiza glabra*), *Nishottar* (*Ipomoea turpethum*), *Erand tail* (Caster oil).

#### Participant

We enrolled patients meeting the Rome III diagnostic criteria and patients with a stool form score ranging from 1 to 3 on the "Bristol Stool Form Scale from Healing Hand Clinic, Pune, one of the leading Proctology clinics in India. Patients with colorectal cancer, anal abscess, anal fissure, rectocele, inflammatory bowel disease, megacolon or mechanical bowel obstruction, unknown cause of gastrointestinal bleeding or acute infection, history of alcohol or drug abuser, women who are pregnant, received herb therapy within one month prior to enrollment were excluded.

**Study intervention:** All subjects gave written informed consent, then patient was recruited in the study if he/she fulfilled all the eligibility criteria. All patients completed a detailed questionnaire for assessing symptoms of constipation by Longo's ODS score system, stool consistency by Bristol stool form scale and quality of life by Patient Assessment of Constipation-Quality of Life Questionnaire (PAC-QOL). The patient received CONSTAC PLUS granulation 2 tablespoon at night with a glass of warm water for maximum 60 days. The patient was called for follow up on 15<sup>th</sup>, 30<sup>th</sup> and 60<sup>th</sup> days after the baseline visit.

**Statistical analysis**

All analyses were performed using SPSS version 21.0 software. Data describing quantitative measures were expressed as median or mean (SD). Comparison of variables representing categorical data was performed using "Chi-square test" or "Fisher's exact test." Group means of dependent sample were compared by means of ANOVA (repeated-measures design, generalized linear model procedure) or Wilcoxon sign rank test. Corresponding contrasts were tested using t-test for dependent samples and nonparametric test like "Wilcoxon Sign Rank" Test. p value <0.05 was considered to be statistically significant.

**RESULT**

Total 450 patients enrolled in the study out of that 33 patients were lost to follow up. An analysis done for 417 patients out of that, 287 (68.82%) were men while 31.18 (31.18%) were women and the mean age was 39.77 ± 13.08 years. Study treatment did not cause any significant change in vital signs like pulse rate, body temperature, respiratory rate, and the blood pressure.

After treatment there was significant (p<0.005) improvement in defecation frequency per week from baseline 2.76±0.89 to 7.55±0.43 on Day 60. Mean straining intensity score significantly decreased from baseline 2.09±0.54 to 0.25±0.16 on Day 60. Average time spent on toilet for bowel evacuation was significantly decreased significantly from a baseline 2.45±0.61 to 0.39±0.41 on Day 60. Sensation of incomplete of evacuation mean score improved from baseline 12.67±1.17 to 0.21±0.11 on Day 60. Mean rectoperineal pain and discomfort were significantly decreased from baseline 2.89±1.04 to 0.23±0.45. Mean activity reduction per week score improved from 3.01±1.84 to 1.65 (1.54) 0.47±0.77 on Day 60. Mean Digitation score decreased from baseline 2.87±2.77 to 0.24±0.47 on Day 60. (Table 1)

Stool consistency were significantly (p<0.005) improved on all the three follow-up visits, as shown in (assessed on a Bristol stool form scale), as shown in (Table 2). Total score of PAC-QOL and scores for each of the subscales (worries and concerns, physical discomfort, psychosocial discomfort, and satisfaction) significantly improved (p<0.005) from baseline to end of treatment, as shown in (Table 3).

During study adverse effects affecting the lower gastrointestinal tract (abdominal pain/cramping (n= 13/ 3.12%), bloating (n= 11/ 2.64%), diarrhea (n= 9/ 2.16%), and passing gas (n= 17/ 4.098%) were more common. Such side effects are common among laxatives and may be related to the one of the herbal compound of CONSTAC PLUS. All were treated by medical management. No major complications or serious adverse events were observed during the study.

**Table 1: Constipation symptoms on ODS scale**

Study Visits	Defecation Frequency per week mean±SD	Straining Intensity mean±SD	Extension of time in defecation mean±SD	Sensation of incomplete of evacuation mean±SD	Recto/ perineal pain/ discomfort mean±SD	Activity reduction per week mean±SD	Digitations mean±SD
Day 1 (n=417)	2.76±0.89	2.09±0.54	2.45±0.61	2.67±1.17	2.89±1.04	3.01±1.84	2.87±2.77
Day 15 (n=417)	5.60±1.07	0.93±0.29	1.82±0.42	1.17±0.79	1.19±0.92	1.98±1.34	1.87±1.53
Day 30 (n=213)	6.82±0.14	0.34±0.21	0.73±0.54	0.52±0.46	0.64±0.51	1.17±1.01	0.52±0.71
Day 60 (n=110)	7.55±0.43	0.25±0.16	0.39±0.41	0.21±0.11	0.23±0.45	0.47±0.77	0.24±0.47

\*p<0.005, significant by student 't' test as compared to baseline (Day1)

**Table 2: Stool consistency on Bristol stool form scale**

Study Visits	Mean (SD)
Day 1 (n=417)	2.22±0.52
Day 15 (n=417)	4.65±0.77
Day 30 (n=213)	4.13±0.79
Day 60 (n=110)	4.26±0.71

\*p<0.005, significant by student 't' test as compared to baseline (Day1)

**Table 3: Quality of life during study**

Study Visits	PAC- QOL Mean±SD	Worries and concern Mean±SD	Physical discomfort Mean±SD	Psychosocial discomfort Mean±SD	Satisfaction Mean±SD
Day 1 (n=417)	2.67±0.78	2.54±0.96	2.83±1.19	2.36±1.18	1.46±0.88
Day 15 (n=417)	1.78±0.74	1.45±1.25	1.25±1.19	1.91±1.05	0.71±0.41
Day 30 (n=213)	0.68±0.59	0.83±0.94	0.79±0.91	0.94±0.87	- 0.14±0.71
Day 60 (n=110)	0.49±0.52	0.49±0.77	0.71±1.13	0.71±0.75	- 0.64±0.69

\*p<0.005, significant by student 't' test as compared to baseline (Day1)

## DISCUSSION

This study confirms the beneficial effect of CONSTAC PLUS on severe chronic constipation. Now a day many therapeutic approaches for the treatment of severe chronic constipation. Like patient education, exercise, dietary fiber supplementation, adequate fluid intake, and regular physical activity, osmotic and stimulant laxatives. But new pharmacological therapies have different mechanisms of action and side effects. Plants have a wide range of bioactive principles and comprise a rich source of medicines.<sup>[13]</sup> CONSTAC PLUS is a polyherbal formulation in the form of granulation. It contains *Triphala*, *Badishep* (*Foeniculum Vulgare*), *Elaichi* (*Elettaria cardamomum*) *Narikel lavan* (processed salt with coconut), *Mulethi* (*Glycyrrhiza glabra*), *Nishottar* (*Ipomoea turpethum*), *Sonamukhi* (*Cassia senna*), *Erand tail* (Caster oil).

*Triphala* is an age old commonly used Ayurvedic powdered preparation in Indian systems of medicine. It contains *Terminalia chebula*, *Terminalia Belerica*, *Emblia officinalis*. *Triphala* formulation is prescribed in the first line treatment of many ailments and is used as laxative, detoxifying agent and rejuvenator.<sup>[14]</sup> *Badishep* (*Foeniculum Vulgare*) is an aromatic plant which has been used for several years as a flavouring herb. It is commonly known as Fennel. It is used as a laxative in the treatment of mild digestive disorders due to its gastrointestinal effects, namely stimulation of motility and, at higher concentrations, antispasmodic action.<sup>[15]</sup> *Elettaria cardamomum* commonly known as "*Elaichi*" is a perennial herb. It is widely used for culinary purpose, cardamom has a folkloric repute as carminative, stomachic, diuretic, abortifacient, antibacterial, antiviral, antifungal. It is useful in treatment of constipation, colic, diarrhea, dyspepsia, vomiting, headache, epilepsy and cardiovascular diseases.<sup>[16]</sup> *Mulethi* (*Glycyrrhiza glabra*) has an anti-allergic, anti-inflammatory, spasmolytic, mild laxative, antistress, antidepressive, antiulcer, liver protective, estrogenic, emmenagogue, and antidiabetic effect, and is widely used in the Indian system of medicine.<sup>[17]</sup> *Sonamukhi* (*Cassia senna*) is said to be cathartic, antiseptic, antispasmodic, and cleansing. It is one of the most commonly used laxative drugs in the Eastern and Western countries for the treatment of constipation.<sup>[18,19]</sup> *Nishottar* (*Ipomoea turpethum*) is an important herb, used in Ayurvedic system of medicine since ages. It is commonly used since centuries in Ayurvedic system of Medicine to treat fevers, edema, ascites, anorexia, constipation, hepatosplenomegaly, intoxication, haemorrhoids, fistula, anemia, obesity, abdominal tumors, ulcers/wounds, worm infestation, pruritus and other skin disorders.<sup>[20]</sup> *Narikel Lavan* is Ayurvedic medicine, in powder form and used in treatment of gastritis, acidity and abdominal pain.<sup>[21]</sup> *Erand tail* (Caster oil) belongs to the "stimulant laxatives".<sup>[22]</sup> It is used for controlling symptoms of constipation.<sup>[23]</sup> The individual therapeutic efficacy of these herbs as laxative has also been reported in an ancient Ayurvedic literature.<sup>[10-12]</sup> The exact mechanism of action of the CONSTAC PLUS is not clearly understood, but his synergistic effect of the different types of laxative ingredients has possibly made it a balanced formulation of effective management of severe chronic constipation.

## CONCLUSION

Our study result proves CONSTAC PLUS is safe and effective in the management of severe chronic constipation.

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