

Clinical Evaluation of Triphala in Constipation: A Double Blind Placebo-Controlled Clinical Study

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ABSTRACT:

Triphala, an ancient herbal blend, is one of the most commonly used herbal remedies in Ayurveda, an Indian system of medicine. This well known formulation is made by combining Terminalia chebula, Terminalia bellerica, and Emblica officinalis in equal proportions based on the Ayurvedic Formulary of India (AFI). To establish its clinical validity, the present work was undertaken to evaluate its therapeutic potential and adverse effect in management of chronic constipation. One hundred patients suffering from chronic constipation were selected for the 30-day clinical study. They were divided into two groups of 50 patients each. Patients in Group 1 received placebo and patients in Group 2 received Triphala capsules, in a dose of 2 capsules at night time for 1 month. The effectiveness of trial drugs were judged on the basis of subjective and objective parameters. It was observed that the amount, frequency and consistency of stool improved in the Triphala-treated group. The reduction in mucus, flatulence, belching, and abdominal pain also improved. Two patients in placebo group and 3 patients Triphala group complained of gastritis, which did not require any change and the patients continued to take the medication till the end of the study. Triphala can be used effectively in the treatment of constipation. It is well-tolerated and safe.

INTRODUCTION

The use of herbal drugs is gaining popularity in the recent days. For thousands of years natural products have played an important role throughout the world in treating and preventing diseases¹. Although serious adverse drug reactions with herbal drugs are very rare events, these drugs need to be studied for their efficacy and safety. Triphala is a well-known phytomedicine used since several years in the Indian system of medicine². Triphala consists of equal parts of *Emblica officinalis* Gaertn, *Terminalia chebula* Retz., and *Terminalia bellerica* Linn. Triphala is traditionally used as a laxative in chronic constipation, colon cleansing, digestion problems, and poor food assimilation. It has also been used in cardiovascular diseases, poor liver functions, large intestine inflammation, and ulcerative colitis. The methanolic of Triphala has shown antioxidant activity³. The chloroform and acetone have been reported to have antimutagenic activity and act

as purgative⁴. The individual herbs of Triphala are reported to have a number of other pharmacological activities. *Emblica officinalis* is reported to possess anti-inflammatory⁵, antimutagenic⁶ anti-oxidant⁷, cytoprotective⁸, gastro-protective⁹, and hypolipidemic¹⁰ activities. Similarly, *Terminalia chebula* possesses antibacterial¹¹, anticancer¹², anticaries¹³, and antimutagenic¹⁴ potential and inhibits local anaphylaxis¹⁵. *Terminalia bellerica* is reported to prevent myocardial necrosis¹⁶, reduces cholesterol-induced atherosclerosis¹⁷, and acts as hepatoprotective¹⁸.

Recently, an oral formulation containing aqueous of Triphala has been introduced. The present study is planned to investigate the efficacy and safety of this formulation in the management of constipation in adults.

MATERIALS AND METHODS

Plant materials: An aqueous extract of Triphala was prepared from the powders of fruits of *Emblica officinalis* Gaertn. (Euphorbiaceae), *Terminalia chebula* Retz. (Combretaceae), *Terminalia bellerica* Linn. (Combretaceae), and by mixing them in equal proportion (1:1:1) based on the formula of Ayurvedic Formulary of India.

Patients and treatment: One hundred patients from Shubhdeep Ayurved Medical College Hospital, Indore were selected for the clinical trial, as this hospital gets several patients daily in its out patient department. The patients attending this hospital with complaints of constipation were detailed the nature of the study and their written consent was obtained in an official consent form. The study design and the protocol were approved by local ethics committee. These patients were clinically examined after a detailed history regarding their disease. They were divided into two groups of 50 patients each. Patients in Group 1 received placebo whereas patients in Group 2 received Triphala capsules (manufactured by The Himalaya Drug Company, Bangalore), in a dose of 2 capsules at night time for 1 month. The patients were examined on a weekly basis for a period of 1 month. Assessment was done on the basis of subjective and objective parameters, which were scored arbitrarily with 4 point scale for clinical parameters of the constipation (1=Stool frequency < once per week; 2=stool frequency <2 times per week; 3=stool frequency <3 times per week; 4=Regular). Score for stool consistency is 1= very hard, dry, pellet like, difficult to eliminate;

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Specially Contributed to "The Antiseptic"
Vol. 107 No. 1 & P : 33 - 34

2=hard, dry, small pieces, but can eliminate; 3=dry, semisolid, difficult to eliminate; 4=soft semisolid, easily evacuable). The parameters used to evaluate bowel movements were frequency, consistency and color of the feces, flatulence, abdominal pain, and belching. Adverse effects, as volunteered by the patients, were recorded in the case record forms.

Statistical analysis: The results were analyzed statistically by Repeated Measures of ANOVA using Friedman test or Fishers Exact test. The scores are expressed as Mean \pm SD or as the incidence of occurrence for clinical parameters of constipation. The analysis was performed using GraphPad Prism Version 4.01 for Windows, GraphPad Software, San Diego California USA, www.graphpad.com. The differences were considered significant at $p < 0.05$.

RESULTS

All the patients completed the study protocol except 6 patients who were on placebo therapy. On further analysis, these 6 patients revealed that they were withdrawing from the study, as no improvement was observed. Triphala produced a significant improvement in frequency, consistency, and mucus content of stools (Table 1). On the 30th day of study, number of patients complaining of flatulence was 16 from Group 1 and 5 from Group 2. Number of patients complaining of abdominal pain was 9 from Group 1 and 6 from Group 2 and number of patients complaining of belching was 13 from Group 1 and 5 from Group 2 (Table 2). This shows significant improvement in clinical parameters of constipation in patients of Group 2 as compared to patients in Group 1. Two of the patients from Group 2 and three patients from Group 1 complained of gastritis, which did not necessitate any change in medication and the patients continued to take the medication till the end of the study.

DISCUSSION

The present study indicates the clinical efficacy of Triphala in management of chronic constipation. Triphala clinically has been used for a very long time to enhance the bowel movements. Triphala has been

Table 1 Effect of Triphala on constipation

Parameter	Baseline		7 th day		15 th day		30 th day	
	Group 1	Group 2	Group 1	Group 2	Group 1	Group 2	Group 1	Group 2
Stool frequency score	0.80 ± 0.20	0.70 ± 0.60	0.90 ± 0.70	2.16* ± 0.40	1.00 ± 0.80	2.90* ± 0.40	1.00 ± 0.90	2.90* ± 0.50
Stool consistency score	1.00 ± 0.40	1.20 ± 0.60	1.20 ± 0.60	2.40* ± 0.40	1.30 ± 0.80	2.80* ± 0.30	1.80 ± 0.40	3.20 ± 1.40

* $p < 0.05$ as compared to respective baseline values
Statistical analysis: Repeated Measures of ANOVA using Friedman Test.

Table 2 Effect of Triphala on clinical parameters of constipation

Parameter	Number of patients					
	On entry		15 th day		30 th day	
	Group 1	Group 2	Group 1	Group 2	Group 1	Group 2
Flatulence	18	19	17	9*	16	5*
Abdominal pain	12	13	10	8*	9	6*
Belching	16	17	15	7*	13	5*
Mucus in stools	15	16	14	6*	12	6*

* $p < 0.05$ as compared to respective baseline values
Statistical analysis: Fishers Exact Test.

reported to be rich source of Vitamin C, ellagic acid, gallic acid, chebulinic acid, bellericanin, β -sitosterol and flavonoids¹⁹. Its components *Emblia officinalis*, *Terminalia belerica*, and *Terminalia chebula* are reported to possess anti-inflammatory, antimutagenic, antioxidant, cytoprotective, gastroprotective activity, hepatoprotective, antibacterial, and anticancer activities²⁰. Some studies have indicated the clinical efficacy of Triphala in the management of constipation²⁰ but the present study has evaluated the efficacy and safety of Triphala. This study also indicates that Triphala is well tolerated and safe in patients of constipation. Its components have cytoprotective, gastroprotective, and antibacterial activity, which could contribute to the beneficial clinical effects of Triphala. The frequency of stools improved within one week in patients of constipation and this significant result continued till the end of the study.

CONCLUSION

The present study indicates significant beneficial effects of Triphala in the management of

constipation. This formulation is well-tolerated and safe.

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