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RESEARCH ARTICLE

Clinical Study of 'Triphala' – A Well Known Phytomedicine from India

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ABSTRACT

Triphala' is an age old commonly used Ayurvedic powdered preparation in Indian systems of medicine. This well known formulation is made by combining *Terminalia chebula, Terminalia belarica* and *Emblica officinalis*, in equal proportions based on the observation of Ayurvedic Formulary of India (AFI). The formulation is prescribed in the first line treatment of many aliments and is used as laxative, detoxifying agent and rejuvenator. To establish its clinical validity the present work was undertaken to evaluate its therapeutic potentials and adverse effects. The Triphala formulation was standardized by HPTLC (High Performance Thin Layer Chromatography), using Gallic acid as a marker and was subjected to clinical studies. After proper screening 160 patients of age between 16–52 years were selected for 45 days clinical study. The effectiveness of trial drugs were judged on the basis of the subjective and objective parameters. It was observed that the amount, frequency and consistency of stool were improved in Triphala treated group. The changes of odor, mucous, flatulence, belching and abdominal pain where also taken into account. The well being was assessed on the basis of the parameters like concentration, appetite, thirst, sleep, hyperacidity in arbitrary scoring system. Triphala was found to have good laxative property, help in management of hyperacidity and also improve appetite. No adverse effect was observed in the treated group when compared to normal patients. Triphala can be used effectively in the treatment of constipation and other gastric problems.

Keywords: *Triphala, Clinical Study, Ayurveda*

Although serious adverse drug reactions (ADRs) with herbals drugs are very rare events, the occurrence of side-effects is not a rare phenomenon. A commonly heard argument in favor of herbal medicines is that these products have a longstanding history of traditional use, resulting in considerable experience with and knowledge about their wanted and unwanted effects. Of course the traditional experience is a powerful tool for the identification of adverse effects which occur in the majority of users and develop rapidly after the start of therapy [1]. Many studies during the last 2 decades have shown that 20-30% of patients experience unwanted effects of herbal drugs and it seems that in ambulant patients this incidence is even higher. Though herbal medicines have been used since ancient times there is need of safety evaluation. Proper clinical and phamacovigilance study of traditional medicines can ensure their safer use in the patient care [2]. In-light of these observations we planned to evaluate clinically one formulation from Ayurvedic medicine 'Triphala' (In-house and marketed). 'Triphala' is one of the well known powdered preparation (churna) in Indian system of medicine (ISM), being used in Ayurveda since ancient time. Triphala consists of equal parts of the *Emblica officinalis* Gaerth, *Terminalia chebula* Retzr. and *Terminalia belerica* Linn. Triphala is traditionally been used as laxative in chronic constipation, colon cleansing, digestion problems and poor food assimilation. It has also been used in cardiovascular disease, high blood pressure disease, serum cholesterol reduction, poor liver function, large intestine inflammation, and ulcerative colitis [3]. Methanolic extract (70%) of Triphala has shown significant antioxidant activity *in vitro.* Oral administration of the extract reduced the blood sugar level in diabetic rats [4]. Triphala has been found to have radio-protective effect in mice exposed to gamma radiation [5]. The water, chloroform and acetone extracts of Triphala have shown significant antimutagenic activity, in *Sallmonella typhi-*

Table 1. Effect of Triphala on bowel movement.

Groups	Amount of Stool (gm.)	Frequency of Stool (per day)	Undigested Food in Stool	Color of Stool	Consistency of Stool
Group 1 (Normal)	178.33 ± 17.4226	2.10 ± 0.33	0.433 ± 0.164	0.066 ± 0.066	2.10 ± 0.1745
Group 2 (Triphala A)	235.0 ± 21.1476***	1.30 ± 0.1528*	0.10 ± 0.10	0.0 ± 0.0	2.90 ± 0.10**
Group 3 (Triphala B)	240.0 ± 19.4365**	1.10 ± 0.10*	0.10 ± 0.10	0.0 ± 0.0	2.7 ± 0.1528*
Group 4 (Triphala standard)	240.0 ± 19.4365***	1.30 ± 0.1528*	0.10 ± 0.10	0.0 ± 0.0	2.90 ± 0.10**

Results are mean ± SE (n=40)
*$p < 0.05$, **$p < 0.01$, ***$p < 0.001$, when compared when compared with normal group

murium [6] and act as purgative [7]. The individual herbs, used in the formulation are reported to have several other health benefits. *Emblica officinalis* is reported to possess anti-inflammatory [8], antimutagenic [6], antioxidant [9], cytoprotective [10], gastroprotective [11], hypolipidaemic [12] activity. Similarly, *Terminalia chebula* possesses antibacterial [13], anticancer [14], Anticaries [15], antimutagenic [16] potential and inhibits local anaphylaxis [17]. *Terminalia belerica* is reported to protect myocardial necrosis [18], reduces cholesterol-induced atherosclerosis [19] and acts as hepatoprotective [20].

For the present study we have prepared in-house Triphala (IH) and selected two marketed Triphala (M1 and M2), we have standardized the individual constituents of Triphala with respect to their gallic acid and mixed them to obtain in-house Triphala. After this all three Triphala formulations (IH, M1 and M2) were also standardized using gallic acid as marker. Gallic acid, is a common phytoconstituent present in all the three herbs used in the Triphala [2] and is reported to possess hepatoprotective [20] and antioxidant activity [21]. To establish its clinical validity the present work was undertaken to evaluate its therapeutic potentials and adverse effects. Triphala formulations (IH, M1 and M2) were standardized and were subjected to clinical studies.

MATERIALS AND METHODS

Plant Materials

Fruits of *Terminalia chebula* Retz. (Combretaceae), *Terminalia belerica* Linn. (Combretaceae) and *Emblica officinalis* Gaertn. (Euphorbiaceae), were purchased from local market and were authenticated at Botanical Survey of India, Shibpur, India. A voucher specimen is preserved in our laboratory for future reference. Seeds from individual fruits were removed and the dried fruit pulp was crushed to powder using a grinder. Triphala was prepared from these powders by mixing them in equal proportions (1:1:1) based on formula of Ayurvedic Formulary of India [22], to give in-house (IH) sample. These powders were stored in a closed vessel for future use. Marketed Triphala supplied from two different companies were also procured and named as M1 and M2.

Instruments and Chemicals Used

For HPTLC standardization, CAMAG (Muttenz, Switzerland) HPTLC system made up of a Linomat IV sample applicator, a twin trough plate development chamber, TLC Scanner 3 and winCATS integration software was used. Aluminum backed HPTLC plates 20 x 20 cm with 0.2 mm layers of silica gel 60 F_{254} (E. Merck, Mumbai, India), previously pre-washed with methanol was used.

HPTLC Standardization

Triphala and its individual constituents were standardized using gallic acid (GA) as the analytical marker compound. Extracts of *Emblica officinalis*, *Terminalia chebula* and *Terminalia belerica* and the formulation Triphala made using them were used for HPTLC on silica gel plates and the same was developed in toluene: ethyl acetate: glacial acetic acid: formic acid (20: 45: 20: 05) solvent system. The GA content in Triphala viz IH, M1 and M2 with its individual constituents like *Emblica officinalis*, *Terminalia chebula* and *Terminalia belerica*, was found to be 14.38, 11.07, 12.71, 17.50, 16.60 and 11.92 mg g^{-1}, respectively compared with standard GA (R_f 0.80) at 254 nm while scanned through HPTLC densitometer (CAMAG, Switzerland).

Selection of Patients and Treatment

J. B. Roy State Ayurvedic Medical College and Hospital, Kolkata - 700 004, India, was selected for the clinical trial, since the hospital is situated at the heart of Kolkata, it gets several patients daily at its Outdoor Patients Department (OPD). The patient attending the OPD of the hospital were considered for study after their proper consent was obtained in signed official consent format. Proper history taking and clinical examination confirmed the diagnosis. After proper screening 160 patients were selected for study, age of the patients ranging from 15 to 75 years of either sex. The patients were divides into 4 groups having 40 patients in each group.

Patients of group I were considered as control (pla-

Table 2. Effect of Triphala on bowl habits and associated symptoms.

Groups	Odor of Stool	Mucous of Stool	Flatulence in stomach	Belching in Stomach	Abdominal Pain in Stomach
Group 1 (Normal)	0.50 ± 0.16667	1.033 ± 0.2823	0.966 ± 0.2813	0.266 ± 0.1463	0.30 ± 0.1528
Group 2 (Triphala A)	0.20 ± 0.13333	0.40 ± 0.1633*	0.50 ± 0.1667*	0.10 ± 0.10	0.00 ± 0.00
Group 3 (Triphala B)	0.20 ± 0.13333	0.30 ± 0.1528*	0.30 ± 0.1528*	0.10 ± 0.10	0.10 ± 0.10
Group 4 (Triphala standard)	0.10 ± 0.10	0.30 ± 0.1528*	0.20 ± 0.1333*	0.10 ± 0.10	0.10 ± 0.10

Results are mean ± SE (n=40)
*$p < 0.05$, **$p < 0.01$, ***$p < 0.001$, when compared when compared with normal group.

Table 3. Effect of different preparations of Triphala on well-being.

Groups	Mental Concentration of Individual Patient	Sleep of Individual Patient	Appetite of Individual Patient	Thirst of Individual Patient	Digestion of Individual Patient	Hyper acidity of Individual Patient	Physical strength of Individual Patient
Group 1 (Normal)	1.70 ± 0.2603	1.80 ± 0.2735	1.56 ± 0.2167	1.87 ± 0.2603	1.63 ± 0.1978	0.67 ± 0.2603	1.57 ± 0.2012
Group 2 (Triphala A)	1.70 ± 0.2603	2.00 ± 0.2981	2.0 ± 0.2108	2.10 ± 0.2333	1.90 ± 0.1795	0.40 ± 0.1633	1.50 ± 0.2236
Group 3 (Triphala B)	1.8 ± 0.20	1.80 ± 0.2494	1.60 ± 0.1633	2.10 ± 0.2333	1.80 ± 0.20	0.30 ± 0.2134	1.70 ± 0.2134
Group 4 (Triphala standard)	1.70 ± 0.2134	1.80 ± 0.2494	1.80 ± 0.20	2.10 ± 0.2333	1.80 ± 0.1333	0.40 ± 0.1633	1.60 ± 0.1633

Results are mean ± SE (n=40)
*p < 0.05, **p < 0.01, ***p < 0.001, when compared when compared with normal group.

cebo), group II and III were treated with Marketed Triphala M1 and M2. Group IV was treated with Triphala (IH), at the dose of 2.5 g twice daily for 1 month. Weekly observations were recorded as per proforma to assess the effect of treatment.

The effectiveness of treatment was judged on the basis of the subjective and objective parameters with the respective drugs on bowel movement and well being and compared with normal group. The parameters selected to observe bowel movement were amount, frequency, undigested food, consistency, color, odor and mucous present the faeces, flatulence, belching and abdominal pain. Similarly, for well being were concentration, appetite, thirst, sleep, hyperacidity, digestion and physical strength. Observations were made and recorded in arbitrary scoring system.

Statistical Analysis

The statistical analyses were performed by paired t-test with the statistical software SPSS/Windows (SPSS 9.0. LNK). The results were expressed as the mean ± SEM to show variations in a group. Differences are considered significant at a p <0.05.

RESULTS

Mixed types of response were observed with different preparations of Triphala both on bowel movement and well being as shown in the Table 1-3. It has been observed that the amount, frequency and consistency of stool in triphala treated groups have improved significantly, when compared with the normal group. From Table 3 it is clear that the mucous of stool and flatulence in group II, III and IV has also improved significantly, compared to the normal group, in case of other parameters no significant changes were observed. No toxicity or adverse drug reactions (ADRs) were observed in the patients and hence triphala was found to be safe and effective during the clinical trial.

DISCUSSION

Ayurveda is one of the major health care system developed since human civilization in the Indian subcontinent which is based upon the experiences with nature and natural resources. Scientific evidences to prove the rationale of using this formulation in health care are essential to develop and prevent cultural heritage [23].

Ayurveda is based on empirical knowledge of Indian medical professionals for a long time. However, there is a long gap regarding all information due to lack of documentation. Therefore, scientists felt it urgent to make the information evidence based. Pharmaco-vigilance study is the best way to establish the evidence-based medicine. Pharmaco-vigilance study indicates the clinical trial of any known drug for its known activity, which is yet to be establish under modern scientific techniques [2]. Present study, therefore, aimed to investigate Triphala clinically, which are being used for a long time for its effect on bowel movement and well being. The study disclosed the avenue properly for evaluating the therapeutic efficacy of a common preparation like 'Triphala' on constipated bowel habit and well being. However, it was observed that three preparations M1, M2 and IH showed almost similar activity.

CONCLUSION

The study disclosed the avenue properly for evaluating the therapeutic efficacy of a common preparation like 'Triphala' on constipated bowel habit and well-being. However, it was observed that three preparations showed almost similar activity. In house (IH) Triphala prepared at our laboratory was used as standard and two different marketed brands were procured from two different marketed Triphala M1 and M2 as described.

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