

Clinical Studies with Ayurvedic Formulations-A Practitioner's Preview

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Review Article

Volume 1 Issue 1

Received Date: August 02, 2017

Published Date: September 04, 2017

Abstract

Traditional Indian Medicine (TIM) is a storehouse for developing lead drugs for clinical trials. Although, clinical research in Ayurveda in TIM is a novel concept, it can be said that drugs like *Triphala*, (mild laxative) *Tikatu* (bioavailability enhancer) and *Dashmoola* (anti-inflammatory) are the outcome of trials conducted by ancient scientists. The review shows clinical studies done with formulations used in TIM. The formulations were grouped according to action on human system based on data generated from internet and literary search. Apparently, the studies may be uncontrolled but their importance in conducting or improving previously conducted clinical trials with TIM can't be ruled out. The knowledge may well-combine with 'reverse pharmacological' approach for cost-effective and potential cures from TIM.

Keywords: Traditional Indian Medicine; Clinical-Research; Anatomy; Formulations; Medicinal Phytochemistry

Abbreviations: TIM: Traditional Indian Medicine; TCM: Traditional Chinese Medicine; CCRAS: Central Council of Research In Ayurveda and Siddha; ABIM: Annotated Bibliography of Indian Medicine; CAM: Complementary and Alternative Medicine.

Introduction

Ayurveda or Traditional Indian Medicine (TIM) is considered to be the oldest- practicing system of medicine. Recently, the herbal drug industry has witnessed explosive growth. CAM systems are in great demand, particularly Traditional Chinese Medicine (TCM) and Traditional Indian Medicine (TIM). Growing popularity of CAM among people, has led to onset of research at molecular and clinical levels [1].

With development of new subjects like medicinal phytochemistry, phytopharmacology and phytopharmacotherapy, the importance of clinical research in TIM has become more significant. Analytical study of subjects like *Dravyaguna* (Medicinal plant Pharmacology) and *Kayachikitsa* (Internal medicine) is required for enhancing practical utility of TIM [2]. Lack/documentation of clinical trials in TIM has triggered controversies, regarding therapeutic application of formulations used in TIM [3].

Although, formulations of TIM have been used for centuries with success, testing at molecular levels is still a challenge [4]. Pharmacological intervening has opened new age in CAM and TIM research. The concept of reverse pharmacology is rapidly catching up for developing cost-

effective and potential drug candidates from medicinal plants [5].

In our view, clinical studies in TIM can be divided into two distinct groups:

1. Controlled studies
2. Uncontrolled studies

Recently, favorable clinical studies have appeared for single herb/polyherbal formulations used in TIM for varied ailments. The studies, seem to be appropriate with regard to several parameters like drug selection and standardization, design, patient participation and results.

The present review is dedicated to rare clinical studies done on formulations used in TIM. The list of plants or formulations discussed in the review may be incomplete. The leading factor is lack of indexed publication dealing with clinical aspects of TIM. Moreover, the clinical knowledge documented by authors in Ayurvedic journals were done mostly around 1960 when pharmacological and clinical research were not in limelight. Non-availability of full-length papers and English version also contributed to the incomplete list.

Materials and Methods

The key words for the present review were clinical trials, clinical studies, TIM, single herb, polyherbal formulations, and Ayurveda. ABIM (Annotated Bibliography of Indian Medicine), data bank on Indian Medicinal Plants provided by Central Council of Research in Ayurveda and Siddha (CCRAS) and journals related to clinical aspects of Complementary and Alternative Medicine (CAM) were used for searching data, updated until Feb 2007.

The references encountered in the search were later consulted. The data generated after systemic literature study was documented according to human anatomy.

Integument System

Sookshma triphala in lipoma, *Rudanti* (*Capparis moonii* Hook.f., Capparidaceae) in tubercular lymphadenitis, *Patoltriphala* and *Panchatiktaka kwatha* in scabies and *Arogyavardhini rasa* and *Gandhaka rasayana* in leucoderma [6-9].

Gastroenterology

Kutaja (*Holarrhena antidysenterica* Wall., Apocynaceae) in amoebiasis and giardiasis, *Mustaka* (*Cyperus rotundus*

Linn., Cyperaceae) and *Vibhituka* (*Terminalia bellerica* Roxb., Combretaceae) in chronic diarrhea, *Triphala* and *Haritaki* (*Terminalia chebula* Retz., Combretaceae) in constipation and worm infestation *Takrarishta* and *Sunthi* (*Zingiber officinale*) in malabsorption, *Tulasi* (*Ocimum sanctum* Linn. Lamiaceae) and *Patola* (*Trichosanthes dioica* Linn., Cucurbitaceae) in peptic ulcer [10-19].

Hepatology

Arogyavardhini Rasa in acute viral hepatitis, hepatic cirrhosis and jaundice, *Phalatrikadi kwatha* in hepatic cirrhosis and *Kalmegha* (*Andrographis paniculata* Nees., Acanthaceae) in jaundice [20-23].

Respiratory System

Haritaki leha, *Pippali kshira paka*, *Sirisa twak kvatha* *Hardira* (*Curcuma longa* Linn., Zingiberaceae), *Snuhi* (*Euphorbia prostrata* Linn. and *Euphorbia thymifolia* Linn., Euphorbiaceae) and *Pippali* (*Piper longum* Linn., Piperaceae) and *Pushkaramooladi choorna*, in bronchial asthma, *trikatu* in allergic rhinitis, and *Swarna basanta malti rasa*, *Pithecellobium dulce* Benth., Fabaceae, and *Rudanti* (*Capparis moonii* Linn.) and *Krishna tulasi* (*Ocimum sanctum* Linn.), in pulmonary tuberculosis [24-35].

Cardiovascular System

Lohasava and *Triphala mandoora* in anemia [36].

Nervous System

Asthawarga kwatha and *Dhanvantara yoga* in paralysis, *Smruti sagara rasa* in amnesia, *Ustookhudus churana* in migraine, and *Ashwagandha* (*Withania somnifera* Dunal., Solanaceae), in epilepsy [37-40].

Genitourinary System

Guduchi (*Tinospora cordifolia* (Willd.) Miers ex Hook.F., Menispermaceae) in uremia, and *Sveta parpati* with *Kulatha kwatha* in urolithiasis [41,42].

Musculoskeletal System

Sunthi guggulu, *Vatari guggulu* and *Maharasnadi kwatha* in rheumatoid arthritis, *Kanchanara guggulu kwatha* in rheumatic diseases, *Goraksa* (*Dalbergia lanceolaria* L.f., Fabaceae) in frozen shoulder and *Bhallataka* (*Semeecarpus anacardium* Linn., Anacardiaceae) in osteoarthritis, *Guggul* (*Commiphora mukul* Engl., Burseraceae) and *Eranda veej ksheer paka* in sciatica [43-48].

Endocrine System

Abnra (mica) and *Chandraprabha vati* in diabetes mellitus and *Arogyavardhini Rasa* in hypercholesterolemia/obesity [49-51].

ENT

Sharpunkha (*Tephrosia purpurea* Linn., Fabaceae) in adenoids and acute tonsillitis [52].

Eye

Sookshma triphala in chalazion [53].

Reproductive System

Ashokarishta and *Musalikhadiradi kwatha* in menorrhagia, and *Triphala kwath* in leucorrhoea [54,55].

Dental

Triphala in pyorrhea [56,57].

Results and Discussion

A systemic study afforded several single or poly-herbal, and herbo-mineral and purely mineral based formulations used in TIM. Much of the clinical research was related to respiratory and musculoskeletal system. Among polyherbal formulations, *guggul*-based formulations were cornerstone for treating arthritis and rheumatism. Use of *Triphala* was highlighted in various clinical conditions.

The major drawback of these clinical studies is lack of control. The studies do emphasize clinical utility of formulations used in TIM, which may be the basis of reinitiating clinical trials. We also believe that instead of expanding list of novel formulations, work should be initiated to evaluate potential of already reported formulations to overcome the shortcomings encountered in earlier clinical studies.

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