

Traditional Indian Systems of Medicine

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Abstract

Introduction: A number of traditional systems of medicine exist in India of which Ayurveda is the most popular. Despite being in use for more than 3000 years, few properly designed trials have scientifically examined the clinical potential of Ayurvedic and other medications. **Methods:** We reviewed the MEDLINE database to identify clinical trials conducted using traditional Indian medicines. Single case reports were excluded. **Results:** Ayurvedic preparations have been successfully used for the treatment of bronchial asthma, ischaemic heart disease and hyperlipidaemia. Formulations containing curcumin were reported to reduce inflammation and disability in double-blind clinical trials on patients with rheumatoid arthritis. A number of products are reported to be useful in patients with acute viral hepatitis. A multicentric study by the Indian Council of Medical Research showed that a preparation from *Pterocarpus marsupium* was effective in reducing levels of blood glucose and glycosylated haemoglobin in patients with non-insulin-dependent diabetes mellitus. In another multicentric trial, patients with fistula-in-ano were randomised to surgery or application of medicated seton (Ksharsootra). Surgical treatment led to a faster cure but recurrence rates were lower with medicated seton. Administration of extract from *Bacopa monnieri*, to children with mental retardation, was reported to significantly improve short-term and long-term memory. **Conclusions:** Evidence-based studies on the efficacy and safety of traditional Indian medicines are limited. The essential ingredient in most formulations is not precisely defined. High quality studies are necessary to evaluate and compare the value of traditional Indian drugs to modern medicine.

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Introduction

Traditional medicine includes the knowledge and practices that rely exclusively on practical experience and observations handed down from generations to generations, either verbally or in writing. Traditional systems of medicine in India are culturally acceptable and usually inexpensive. Failure of modern medicine in curing many diseases or the appearance of serious adverse effects of medications often prompt patients to try alternative systems of medicine. However, traditional medicine in India is poorly explored in terms of therapeutic potential and clinical evaluation.

In India, a number of traditional systems of medicine exist, of which the following are the most important: i) Ayurveda, ii) Siddha, iii) Unani-Tibb, and iv) Yoga.¹ Ayurveda, the most popular traditional system of medicine in India, has evolved by astute observations and experience gathered over thousands of years. Ayurvedic medicine has a long tradition behind it, having originated in India perhaps as long as 3000 years ago. It is still a favoured form of health care in India, where a large percentage of the

population uses this system exclusively or combined with modern medicine. The medications used are not isolated chemical principles but are mostly processed plant ingredients. Treatment is selected according to the disease and the constitution of the individual [determined by the three humoral concepts—wind (vata), bile (pitta) and phlegm (kapha)]. In addition, a lot of emphasis is placed on the modification of the diet and lifestyle.

The Siddha system, prevalent mostly in Tamil Nadu (south India), resembles the Ayurveda closely.² The Siddha system attaches tremendous importance to the examination of the pulse for determining the disposition of the three humors. However, a serious drawback of this system is its disregard towards systematic anatomy. The Unani-Tibb system, actually Greek medicine, also has much in common with Ayurveda, except that its concepts of disease and diagnosis are similar to those of early stages of modern medicine. Yoga is a distinct traditional system; the therapeutic aspect is merely a byproduct of its holistic doctrine of the evolution of the human personality.

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The rational approach to traditional system of medicine requires evidence that is direct and experimental as opposed to indirect, non-experimental studies. Such evidence is best provided by therapeutic trials.³ A number of Ayurvedic Indian drugs have been tested in animals. There is, however, a paucity of clinical trials that examine the efficacy and safety of these medicines in human subjects. We reviewed the MEDLINE database to identify trials, on human subjects, using traditional Indian medicines conducted between January 1966 to June 1999. The search was limited to one or more of the following publication types: clinical trial; clinical trial phase 1, 2, 3, or 4; controlled clinical trial; randomised controlled trial; meta-analysis; review; and limited to “human” trials only. Single case reports were excluded. In addition, a few review articles on medicinal plants were selected from *Indian Drugs*.

Bronchial Asthma

Several plants have been investigated for anti-asthmatic effects. Saponins isolated from *Solanum xanthocarpum*, *Solanum trilobatum*, *Albizia lebbek*, *Clerodendron serratum* and *Gardenia turgida* have been found effective in animal models.⁴⁻⁶ In a pilot study, 300 mg powdered plant of either *Solanum xanthocarpum* or *Solanum trilobatum* was administered orally to 60 patients with bronchial asthma.⁷ Treatment with either of the products significantly improved the forced vital capacity, forced expiratory volume and peak expiratory flow rates. The effect of treatment was, however, lower than that of deriphylline or salbutamol.⁷ This study confirmed the traditional claim for the usefulness of these herbs in bronchial asthma. In another study, a combination of 5 plants: *Adhatoda vasica*, *Solanum xanthocarpum*, *Albizia lebbek*, *Glycyrrhiza glabra*, and *Picrorrhiza kurroa*, was studied in 14 adult patients with chronic bronchial asthma.⁸ All patients showed clinical improvement with prevention of recurrences and reduction of the severity of symptoms. The medication was, however, not effective during acute exacerbation. The authors suggested that this product acts by modifying the immunological status and stabilising mast cell membranes.⁹ Both preparations were found to be safe and may have potential for development of new anti-asthmatic drugs.

Rheumatoid Arthritis

In a short-term, double-blind, crossover study conducted on 18 patients with rheumatoid arthritis, curcumin (turmeric) administered in a daily dose of 1200 mg was found comparable to phenylbutazone.¹⁰ Both groups showed similar improvement in morning stiffness, walking time and joint swelling. Similarly, in a double-blind clinical trial, a formulation containing *Curcuma longa*, *Withania somnifera* and *Boswellia serrata* significantly reduced the

severity of pain, morning stiffness and disability scores in patients with rheumatoid arthritis.¹¹

Curcumin is considered to have an anti-inflammatory effect by inhibiting the lipoxygenase and cyclooxygenase enzymes in the prostaglandin pathway.¹² In addition, other plants *Tinospora cordifolia*, *Balsamodendron mukul*, *Hibiscus vitifolius*, *Ricinus communis*, *Semicarpus anacardium*, *Lawsonia inermis*, *Embelia ribes* and *Ocimum sanctum* have been found to possess significant anti-inflammatory activity in animal and *in vitro* studies.¹³⁻¹⁷ Some of these plants may have a potential as substitutes for non-steroidal anti-inflammatory drugs without causing untoward side effects.

Hepatic Disorders

Lack of effective and safe medications for hepatic disorders has led to considerable interest in alternative forms of medicine. A large number of plants such as *Picrorrhiza kurroa*, *Tinospora cordifolia*, *Andrographis paniculata*, *Eclipta alba*, *Phyllanthus niruri* and *Phyllanthus amarus* have been investigated, chiefly in animal or *in vitro* models.^{18,19} Most literature on indigenous hepato-protective drugs are published in non-indexed journals.¹⁸

In a randomised, double-blind, placebo-controlled trial, *P. kurroa* was administered in a dose of 375 mg thrice daily for 2 weeks in patients with acute viral hepatitis.²⁰ This medication resulted in marked improvement in symptoms and signs along with significant reduction in blood levels of bilirubin and hepatic transaminases.²⁰ In another study, “Kamalahar” (an indigenous preparation containing *Tecoma undulata*, *Phyllanthus urinaria*, *Embelia ribes*, *Taraxacum officinale*, *Nyctanthes arbortistis*, *Terminalia arjuna* and “Sodhit” mineral salts) or placebo were administered to 52 patients with acute viral hepatitis.²¹ This therapy resulted in significant improvement in clinical signs and reduction in levels of hepatic enzymes.

In a placebo-controlled, double-blind trial, “Arogyawardhini” (containing mercury, sulfur, iron, mica and copper, powdered dried fruits of *Terminalia chebula*, *Terminalia belerica* and *Phyllanthus emblica*, *Shilajeet*, gum of *Commiphora mukul*, roots of *Plumbago zeylanica* and *Picrorrhiza kurroa*) was evaluated in 38 patients with acute viral hepatitis.²² As compared to placebo, blood levels of bilirubin and hepatic transaminases declined more rapidly in patients receiving the preparation. The medication was reported to be free from side effects.

In a controlled study, carriers of hepatitis B virus were treated with the powdered extract of *Phyllanthus amarus*, in a dose of 200 mg three times a day for 30 days.²³ Of 37 patients, 59% lost hepatitis B surface antigen when tested 15 to 20 days after the end of the treatment, compared with

only 4% in the placebo group ($n = 23$). Other workers have not, however, confirmed these results.²⁴⁻²⁶

Cardiovascular Disorders

Several plants have been claimed to be beneficial in cardiac diseases. In patients with stable angina pectoris, administration of bark stem powder of *Terminalia arjuna* resulted in significant reduction in episodes of angina.²⁷ Similarly, Bharani et al²⁸ reported beneficial effects of *T. arjuna* on left ventricular ejection fraction in patients with ischaemic cardiomyopathy. In another study, patients with post-myocardial infarction angina receiving a combination of bark stem powder of *T. arjuna* and standard therapy showed significant improvement in ejection fraction and reduction in the left ventricular mass.²⁹ The drug was found safe even after 3 months of administration. These studies suggest that *T. arjuna* may have a role in treatment of patients with ischaemic cardiac disease.

The search for a hypolipidaemic agent based on Ayurveda proved rewarding with the isolation of the oleoresin fraction from *Commiphora mukul* and development of “guggulipid”.³⁰ Administration of guggulipid has been shown to reduce levels of low-density lipoproteins, comparable to clofibrate.³¹ It also reduces platelet adhesiveness and increases fibrinolytic activity that may prevent myocardial infarction.

Maharishi Amrit Kalash-4 (MAK4) and Maharishi Amrit Kalash-5 (MAK5), two complex herbal ayurvedic mixtures have been shown to have significant antioxidant property and inhibit low density lipoprotein oxidation *in vitro*.³² In a study on 10 patients with hyperlipidaemia, MAK4 and MAK5 inhibited low-density lipoprotein oxidation.³³ These preparations may have the potential in prevention and treatment of atherosclerosis.

A large number of medicinal plants have been reported to have antiplatelet activity.³⁴ These include *Allium cepa*, *Allium sativum*, *Coleus forskohlii*, *Commiphora mukul*, *Cuminum cyminum*, *Curcuma longa*, *Eugenia caryophyllus*, *Ferula foetida*, *Inula racemosa*, *Myristica fragrans*, *Terminalia arjuna* and *Zingiber officinale*. Though experimental evidence is available, no trials have been conducted to confirm their efficacy or safety.

Diabetes Mellitus

Numerous claims have been made, based on data obtained from studies on animals, on the efficacy of a variety of traditional remedies in diabetes mellitus.^{35,36} The plants reported to have hypoglycaemic effects include *Gymnema sylvestre*, *Tinospora cordifolia*, *Coccinia indica*, *Casaria esculenta*, *Pterocarpus marsupium*, *Momordica charantia* and *Ficus bengalensis*. Recently, the Indian Council of Medical Research conducted a multicenteric, flexible-

dose, open trial of “Vijayasar” (*Pterocarpus marsupium*) on 97 patients with newly diagnosed non-insulin-dependent diabetes mellitus.³⁷ Patients with mild diabetes not controlled with dietary therapy, received oral treatment of Vijayasar for 12 weeks. At termination of the study, there was significant fall in blood levels of glucose and glycosylated haemoglobin. No adverse effects were observed. Vijayasar was considered useful in the treatment of mild, newly diagnosed patients with non-insulin-dependent diabetes mellitus. To further evaluate the efficacy of this preparation and compare with the available oral hypoglycemic agents, a randomised, controlled, multicentric trial has been initiated.

Skin Disorders

A large number of Ayurvedic products are used for dermatological disorders.³⁸ In a double-blind, randomised, placebo-controlled trial, four Ayurvedic formulations (Sookshma triphala, Thiostanin, Shankhabhasma vati and Sundervati) were examined for their efficacy in treatment of acne vulgaris.³⁹ A significant reduction in lesion count was observed in patients receiving “Sundervati” when compared with placebo and other formulations. In a 10-year study, 200 adult patients with *Pityriasis versicolor* infection received a single application of the extract of *Cassia alata* leaves.⁴⁰ The authors observed that a single application of the extract was effective in treating the condition. Further information on the efficacy of this product is, however, not available.

Fistula-in-ano

Ksharsootra (medicated seton) has been used widely to treat fistula-in-ano. The main ingredients of Ksharsootra are “kshara” (alkaline salt of *Achyranthus aspera*), “haridra churna” (fine powder of dried rhizomes of *Curcuma longa*, turmeric), and “snuhi kshara” (latex of *Euphorbia neriifolia*). Ksharsootra is passed through the fistulous tract and tied snugly outside the anal orifice. The seton is changed at weekly intervals until it falls out spontaneously. The use of this seton has been reported to be highly effective with low complication rates.^{41,42} The Indian Council of Medical Research, in a multicentric, randomised, controlled trial on 502 patients with fistula-in-ano, concluded that surgical treatment led to a faster response.⁴³ However, fistula-in-ano recurred in 11% of cases that were treated surgically compared to 4% in those treated with Ksharsootra ($P = 0.03$). The application of Ksharsootra was an effective and safe treatment for patients with fistula-in-ano.

Infectious Diseases

A large number of plants have been shown to possess anti-bacterial, anti-fungal and anti-parasitic properties.^{1,44}

There has been considerable interest in examining the efficacy of ayurvedic drugs in systemic infections. However, most studies are experimental and do not involve human subjects.¹ In a randomised, placebo-controlled, double-blind trial, treatment with Pipali rasayana (prepared from *Butea monosperma* and *Piper longum*) for 15 days led to cure of *Giardia lamblia* infection in 92% of patients compared to 20% in controls.⁴⁵

Psychoneurology

Plants proposed to have beneficial effects on the central nervous system include *Celastrus paniculatus*, *Withania somnifera*, *Centella asiatica*, *Acorus calamus* and *Bacopa monnieri*.⁴⁶⁻⁴⁸ However, clinical data on the use of these plant products are limited. Thirty-three patients with Parkinson's disease were administered 40 to 50 g powder of the seeds of *Mucuna pruriens* daily.⁴⁹ Twenty-three patients who completed the trial showed significant improvement in morbidity scores with no side effects.

In a placebo-controlled study, administration of Brahmi (*Bacopa monnieri*) for one year significantly improved the intelligence quotients, and short-term and long-term memory in 286 children with mild to moderate mental deficiency. No improvement was observed in those with severe mental retardation.⁵⁰ In another study, 32 normal and 38 adults with learning problems were administered extracts of Brahmi and Vacha (*Acorus calamus*) for a period of 3 months. The preparation resulted in significant improvement in short-term and long-term memory scores.⁵¹ These products may be a promising source for improving intelligence and memory in mentally retarded children.

Oncology

Plants have been proposed as a source for development of anti-cancer compounds. In an experimental study, 14 plants were examined for cytostatic activity.⁵² Of these, only extracts of flowers of *Calotropis procera* and nuts of *Semecarpus anacardium* showed strong cytotoxic effect on COLO 320 tumour cells. Other plant extracts did not show any effect even at 100 mg/ml, the highest concentration tested.

The above review suggests that evidence-based studies on the efficacy and safety of traditional Indian medicines are limited. So far, most research has been experimental or involving animal subjects. Even if a medication is found safe and effective in animals, a clinical study is still necessary before the same can be applied to human beings. The concept of reverse pharmacology (i.e. clinical experience precedes clinical trials that are then followed up by studies on pharmacology, safety and mechanism of action) is quite promising. Effort should be made to use years of experience by conducting original studies on traditional Indian drugs.

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