Commentary

Medicinal plants in India

Traditional medicines are used by about 60 per cent of the world's population. These are not only used for primary health care not just in rural areas in developing countries, but also in developed countries as well where modern medicines are predominantly used. While the traditional medicines are derived from medicinal plants, minerals, and organic matter, the herbal drugs are prepared from medicinal plants only.

Use of plants as a source of medicine has been inherited and is an important component of the health care system in India. In the Indian systems of medicine, most practitioners formulate and dispense their own recipes, hence this requires proper documentation and research. In western world also, the use of herbal medicines is steadily growing with approximately 40 per cent of population reporting use of herb to treat medical illnesses within the past year. Public, academic and government interest in traditional medicines is growing exponentially due to the increased incidence of the adverse drug reactions and economic burden of the modern system of medicine.

There are about 45,000 plant species in India, with concentrated hotspots in the region of Eastern Himalayas, Western Ghats and Andaman & Nicobar Island. The officially documented plants with medicinal potential are 3000 but traditional practitioners use more than 6000. India is the largest producer of medicinal herbs and is appropriately called the botanical garden of the world. There are currently about 250 000 registered medical practitioners of the Ayurvedic system (total for all traditional systems: approximately 291 000), as compared to about 700,000 of the modern medicine system. In rural India, 70 per cent of the population is dependent on the traditional system of medicine, the Ayurveda.

The major hindrance in the amalgamation of herbal medicines into modern medical practices is the lack of scientific and clinical data, and better understanding of efficacy and safety of the herbal products. To ensure the quality and safety of its products and practices standardization is of vital importance. Most of the herbal products do not have drug regulatory approval to demonstrate their safety and efficacy. The traditional use can provide valuable clues for the selection, preparation and indications for use of herbal formulation, as efficacy has been established by the common use. The historical use provides the source to study the specific plant species with potential to be used in a particular disease. A systematic approach through experimental and clinical validation of efficacy is required for a plant identified for traditional medicine, as is done in modern medicine; animal toxicity studies are also required to establish the potential adverse effects.

Efficacy testing of the traditional and new herbal products in experimental screening method is important to establish the active component and appropriate extract of the plant. However, there should be adequate data from in vivo and in vitro methods to validate the therapeutic potential claimed. There is a need to establish the pharmacological activities for identifying and comparing the various preparations for potency. Hewawasam et al. have evaluated the hepatoprotective effects of Epaltes divaricata, a herb traditionally used in Ayurveda, to treat jaundice, urethral discharge and acute dyspepsia, in chemically induced hepatotoxicity rat model. The plant extract decreased the hepatic injury, as evident by serum liver enzyme profile and histopathological evaluation. Further, the antioxidant enzymes in the liver could be assessed to delineate the mechanisms of action attributed to antioxidant activity of the extract. Vijayan et al. have done screening of medicinal plants of Nilgiris for antiviral activity, which have potential to treat herpes simplex virus (HSV)-1 infection by in vitro methods. Eighteen medicinal plants were selected with the history of traditional use as anti-infective agents. The study was done to identify the active plant and its part for further elucidation of active constituent. Three plants were found to have potent antiviral activity, which could be evaluated comprehensively for therapeutic potential.
Substandard source materials or finished products will yield therapeutically less effective drugs; hence the quality control of herbal drugs has to be dealt from cultivation of the plant to the finished product. The WHO guidelines on good agricultural and collection practices (GACP) for medicinal plants have been prepared to improve quality of herbal medicines with ecologically sound cultivation practices. These are to regulate the agriculture methods such as use of insecticides, cultivation, harvest, post-harvest transport and storage practices.

Identification of plants with botanical verifications is essential as contamination due to misidentification of plant species or parts is common. Characterizing compound or biomarker is identified from the plant part to assure the identity and quality of the preparation, this need not be responsible for the therapeutic activity. Details including various names (botanical, vernaculars etc) with collection conditions, and part(s) of plant to be used should be documented to ensure proper identification. In USA, accidental substitution of plantain with *Digitalis lanata* in 1997 used as a dietary supplement, led to serious cardiac arrhythmias as side effect. The analysis revealed that use of misidentified plantain over a two-year period had caused the complication. In India, in 1998, mustard oil contaminated with *Argemona mexicana* had caused an epidemic of dropsy. This could have occurred due to misidentification of the seeds and could have been identified if there had been quality control of source material by characterizing compound or biomarker.

Contaminants from the source materials such as microbes, microbial toxins, environmental pollutants, or heavy metals should be checked in herbal and traditional medicines. Estimation of the contaminants should be done with safety level identification and control. Stability of the finished product in various conditions to determine its shelf life is important for marketing of the product. The manufacture of the finished products should be in accordance with the good manufacturing practices (GMPs), with post-marketing quality assurance surveillance. Evaluation of the toxicity and adverse drug reaction of the herbal preparation has been a neglected area, as herbs are considered natural products and, therefore safe. This lack of information makes it difficult to compare the benefit-risk profile of herbal medicines. Further, the comparison of traditional medicines with modern drugs with comparative efficacy has not been conducted for most of the drugs.

The reported and documented side effects should be analyzed for single and also for polyherbal preparations. This will determine the toxicological studies to be done. Even if no adverse drug reaction is reported, the long-term toxicity, mutagenicity and genotoxicity studies need to be conducted, as they are not evident clinically easily. Toxicity studies for herbal products should be conducted as per the regulatory requirements of the country to be marketed.

There is a need to integrate traditional medicine into the modern medicine practices. This requires clinical validation by conducting controlled clinical trials. The methods used for clinical validation for modern medicines must be applied to prove the safety and efficacy of the finished herbal products. The design and the scope of the studies should be in accordance with traditional use and in consultation with the traditional medical practitioners. Herbs are supposed to be safe but many unsafe and fatal side effects have recently been reported. These could be direct toxic effects, allergic reactions, effects from contaminants and/or interactions with drugs and other herbs. Studies should be conducted to examine the side effects considering the interaction with other herbs and modern drugs. The risk-benefit ratio of the herbal drugs should be evaluated.

A small number of herbal medicines have been shown to have a more favourable safety profile than conventional drugs of similar effectiveness on the basis of comparative clinical trials. An example of comparative trials is the randomized controlled trials in patients with depression, the frequency of adverse effects with extracts of *St John's wort* was significantly lower than that for the conventional antidepressants. Further, in randomized controlled trials in men with benign prostatic hyperplasia (BPH) similar observations have been reported for extracts of saw palmetto, when compared with finasteride. The benefit-risk comparisons must be made for each case, as it cannot be assumed that this will apply to all comparisons of herbal medicines and conventional drugs. Nor should it be assumed that a benefit-risk analysis is applicable to all preparations of a particular herb. As with evidence of efficacy, evidence
of safety should be considered to be extract-specific or, at most, extended only to preparations of the same herb with a very similar profile of constituents.

Thus, the development of herbal medicines from the rich traditional source requires an integrated approach. This includes cultivation and procurement of raw material involving the producer to minimize the misidentification and contamination, manufacturing of the finished product with application of good manufacturing practice guidelines\textsuperscript{13}, and validating the therapeutic potential of the drugs by conducting controlled clinical trial with application of good clinical practices guidelines\textsuperscript{22}. The advantages of traditional systems of medicine with respect to their safety and efficacy could result in a better utilization of our herbal resources with application of the scientific methods.

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References