

# CURRENT SCIENCE

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GUEST EDITORIAL

## Ayurveda: Putting the house in order

A paper by Saper and others on the heavy metal content of 70 samples of Ayurvedic herbal medicines manufactured in South Asia and sold in the Boston area of US<sup>1</sup> was greeted with dismay and concern in India. It produced a chain reaction against Ayurvedic herbal products in Canada and other countries and prompted the Government of India to notify that labels of products must henceforth disclose their metallic content. A similar flurry of activity was seen earlier when a House of Lords Committee in the UK classified Ayurveda under herbal therapy. It has become a habit for us to cheer or protest loudly on the sound of praise or censure from the West. For all the claims of Ayurveda as alternative and complementary medicine in the West, its name failed to appear in three articles on traditional medicine in the *New Engl. J. Med.*<sup>2-4</sup> which added insult to injury by refusing to publish a letter from India on the glaring omission<sup>5</sup>. What should really concern us is not the analysis of herbal products done by western workers, their bias against Ayurveda or the opinion of a committee in the UK, but what we have done to safeguard the health of our people and promote the science and healthy practice of Ayurveda in India. After all Ayurveda has been practised in India for over two thousand years and continues to provide health care to a large percentage – 70% according to some estimates – of rural India's millions. If Ayurveda is proven to be safe and effective for people living in India, what others say scarcely matters.

From the hype in the media, it would seem that Ayurveda never had it so good as now in its long history. It enjoys unprecedented patronage with Government Departments at the Central and State levels. Nearly two hundred colleges and two universities offer undergraduate and postgraduate courses in Ayurveda all over India. There are half a million 'registered practitioners' who are not necessarily the products of Ayurvedic Colleges. The WHO, NIH, Russia and several European countries recognize Ayurveda as alternative and complementary medicine. Diet, cosmetics, tourism, and whatever else are marketable are paraded in Ayurvedic hues. The publication of books on Ayurveda in English and regional languages is mounting year after year. The search for drugs from medicinal plants which used to be a pastime of organic chemists is now a global operation involving MNCs. The herbal products

industry in India is on a cusp, eyeing the global market with eager anticipation. These are signs of the vitality of Ayurveda but growth in an unequal and competitive world calls for more than vitality.

Consider clinical research. The WHO guidelines insist no longer on randomized, double-blind, controlled trials for traditional medicine which is free to employ study designs based on single cases where the patient serves as his/her control; or on a black box approach where no component of the treatment package is isolated; or on observation which collects findings on a treatment with or without controls. Nevertheless clinical studies which would satisfy the liberalized criteria have been alarmingly few from India in spite of patients crowding in Ayurvedic hospitals. The WHO guidelines do not insist that traditional medicine should be evaluated within the theoretical framework of modern medicine. They clarify that evaluation could be done within its own theoretical framework provided the framework, treatment protocol, findings and outcome are fully documented for peer review. The guidelines were prepared by an International Committee of experts with resource persons from many developing countries including India. Nothing stops the Indian professional authorities from improving or extending, but not diluting, the guidelines to suit local conditions. As long as clinical studies based on the WHO guidelines are ignored and scientific papers remain few, Ayurveda would be handicapped in claiming greater acceptance in India and abroad.

Turning to drugs from medicinal plants, the characterization of plants had been done in India for a century but the outcome in terms of drugs was poor thanks to the disorganized and thinly spread effort. None of the important plant drugs of the classical era – codeine, atropine, ephedrine, quinine, emetine, digoxin, for example – were derived from Indian medicinal plants. The success stories were limited to *rouwolfia* and *guggul* which had been used in India for many centuries. The initial observation on *rouwolfia* was made by Vakil<sup>6</sup> in Mumbai, and the drug was developed by CIBA in Switzerland. An inspired guess from a verse in *Sushruta Samhita* by Satyavati<sup>7</sup> led to the discovery of the hypolipidemic effect of *guggul*, and the drug was developed jointly by CDRI and NCL. The downstream phase of the development of a drug is a long and costly process

beset with setbacks and failures. Nevertheless the interest in screening plant extracts grows because higher plants constitute a largely untapped source of novel compounds that might serve as leads for the development of new drugs. The march from plant extracts and molecules to the market would however be faster if the random testing of thousands of compounds against varied diseases were replaced by a selective approach based on clues from traditional knowledge. This is shown by not only the examples of *rouwolfia* and *guggul* but also by *artemisinin*. The plant *kwing hasavu* had been used in China for 2000 years as a febrifuge and its extract was tested for antimalarial activity because malaria was the most important among fevers. In all three instances, a plant extract was investigated for a specific pharmacological activity on the basis of traditional clues. The focus and intensity of this approach would be missing if thousands of compounds from numerous plants are tested for a variety of pharmacological activities. In the former mode a hunter follows a hot trail whereas the latter represents an angler on a leisurely fishing expedition. Yet much of the current work for developing drugs from plants follows the angler's trail.

For plant-derived drugs, there must be an assurance of the continuous supply of plants, which is difficult and prone to create ecological problems. Higher plants, especially trees, would take many years to regenerate. The experience with the commercialization of *guggul* would however suggest that the supply of plant material on a commercial basis without ecological damage is far from easy in India.

Quality assurance is something else again. Assuring the quality of Ayurvedic medicines was traditionally the responsibility of the physician who prepared the medicine himself and maintained a fiduciary relationship with the patient. Even though the Drugs and Cosmetics Act brought Ayurveda under its purview in 1964, individual physicians require no license to prepare medicines and administer them to patients even today. The Act included 56 classical texts and gave approval to medicines prepared according to their directions besides specifying the provisions of GMP for Ayurveda. Subsequently three volumes of *Ayurvedic Formulary* were brought out by an official committee of the Ministry of Health, which listed 635 formulations of which 431 had pharmacopoeial standards specified. Between 1999–2001, the *Ayurvedic Pharmacopoeia* of India was published in three volumes, which gave the botanical identity of plants, composition, analytical procedures, etc. In spite of the efforts made for the standardization of Ayurvedic medicines, major problems remain because the Formulary lists only 635 whereas the herbal medicines in actual use are believed to be at least 1000 with many regional variations. The absence of post-market surveillance and the paucity of test laboratory facilities also make the quality control of Ayurvedic medicines exceedingly difficult at this time.

Ayurveda means science of life of which medicine is no more than a part. No wonder P. C. Ray called the interval

from 600 BC to 800 AD 'Ayurvedic period' because Ayurveda was the cradle of not only medicine but also of chemistry and sciences of plants and animals in India. Unfortunately, research in Ayurveda has become identified with herbal products to the detriment of much else that is valuable in this ancient system of knowledge. There are many questions calling out for investigation, which are very different from drug development and clinical research. For example, *dosha prakritis* are specific and determine the manifestation of a disease and the response to treatment in individuals. Do these *prakritis* or phenotypes have genomic counterparts? Does the highly popular *panchakarma* which apparently detoxifies the body alter the biochemical and immunologic profile of a subject? Do *rasayanas* speed up the healing of DNA chain breaks? Would they inhibit the accumulation of beta-amyloid in the brain of a mouse-model of Alzheimer's? The answers to these and a host of similar questions could become the building blocks of Ayurvedic biology.

Ayurveda is applauded but there is little coordination among the stakeholders in regard to clinical research, quality control of herbal medicines or the scientific study of Ayurvedic concepts and practices. There is no platform where the Ayurvedic and scientific communities could interact on a regular basis. The New Millennium Technology Leadership Initiative (NMITLI) of the CSIR has made a promising start for the development of herbal medicines but a long road lies ahead. The need of the hour is to put our house in order by coordinating the overlapping efforts of AYUSH, DST, ICMR, DBT and CSIR and working for specific targets in Ayurveda within a five or six year time frame. My favourite targets would include fifty papers based on clinical research from Ayurvedic institutions; a molecular drug from *medhya* plants for cognitive disorders; five single plant, herbal drugs employed alone or as synergists, adjuvants, bioenhancers, etc., in the management of diabetes and hepatic, cardiovascular and musculo-skeletal diseases; publication of a complete Ayurvedic pharmacopoeia of 1000 products; introduction of an effective post-market surveillance system for herbal medicines; and the initiation of coordinated, multicentric studies in Ayurvedic biology. The question is whether the Government, Ayurvedic and scientific communities and industry would have enough will to accomplish the Ayurvedic mission.

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