



Thought Leadership Article

Ayurvedic research, wellness and consumer rights



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ABSTRACT

The growing interest in using Ayurvedic medicine as a gentler, safer option to using modern medicine drugs with attendant side effects continues to be thwarted because claims about effectiveness and safety are not backed with evidence and clinical data. The focus of Ayurveda practice and research should be on building bridges to this knowledge for public benefit. The consumer is being denied basic knowledge, access to product information as well as the benefit of a common prescription written by a single treating physician because of three factors – Ayurvedic OTC medicine is generally sold with names and labels which cannot be understood by the consumer despite being easily available without prescription; the treating modern medicine doctor is being prevented from writing the name of a herbal product even when he is individually convinced about its usefulness (in given circumstances) and the absence of biomedical research using objective parameters proving the effectiveness of the drugs. Contemporary Ayurveda needs to be packaged to reach the modern consumer in a way that he gets the benefit of access to treatment options that assist healing within the ambit of the law. These obstacles have to be removed. Patient- based effectiveness studies using retrospective case material as well as research using interdisciplinary approaches are needed for public benefit. This has to be facilitated.

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1. Introduction

The year 2016 started on a new note for the world of AYUSH – the acronym for Indian systems of medicine including Ayurveda, Yoga, Unani, Siddha and Homoeopathy. This was the first time that at a public platform, while addressing an international conference on the frontiers of yoga, the Prime Minister spoke words yet unstated by his predecessors. The challenge he posed had seldom been confronted by the traditional medicine community—a large and influential group with wide public interface. He said,

“We must also apply the techniques and methods of modern science, to test and validate results, assure quality and explain benefits.” [1].

For a gathering of traditional medicine experts and practitioners it was to say the least unexpected, coming as it did from a strong proponent of Indian traditions. For years champions of the system have avoided undertaking rigorous clinical research with arguments ranging from the fact that Ayurveda is thousands of years

old, has been in active use for centuries, is recognised under the Drugs and Cosmetics Act, uses formulations that are well-documented in the Ayurvedic formularies and pharmacopoeias and the practitioners possess a medical degree and are registered under the Indian Medicine Council Act. Being a parallel setup to modern medicine, the approach by and large has been that there is no need for making comparisons – and least of all with modern medicine.

2. The dilemma facing Ayurveda

What the Prime Minister stated was extraordinary because he indirectly acknowledged that the benchmark for bio-medical research set by modern medicine (in the absence of any other standard) would need to be used to prove the claims about Ayurveda. India is in a piquant situation because every registered practitioner of the system can use the therapeutics and drugs to treat every kind of medical condition. The drugs are freely available across the counter in special shops and sometimes even stocked by regular chemists selling allopathic drugs [2,3]. Thousands of Ayurvedic formulations both classical as well as proprietary are sold in every state and their licencing and manufacture are backed by a legal process set out in a dedicated chapter of the Drugs and Cosmetics Act 1940. Ayurveda formulations run into thousands of items. Most formulations contain several plant-based, mineral and

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metallic ingredients but the processing into powders, pastes, wines, jellies, tablets, syrups or oils requires knowledge of the ingredients as well as of the processing. Only a few Ayurvedic drugs are sold as capsules or tablets. Although some items are easily identifiable, most of them have Sanskrit names which are unfamiliar to lay people. Although the drugs are marketed throughout India, there is distinctiveness about the drugs manufactured in the southern and western states of India where the use of Ayurveda is also more widespread and acceptable.

However diagnosis and treatment including drug prescription do not follow standard operating procedures or drug regimens both of which are integral features of allopathic treatment. In Ayurveda, each individual is believed to have a special and unique constitution and the choice of therapeutic treatment is individualistic and holistic [4]. Diagnosis is done in a patient specific manner and treatment is custom-made. While some physicians may be guided by the outcome of modern diagnostics and pathological findings, others may depend only on a clinical examination.

Patients seldom ask questions about ingredients or the basis of knowing the safety and efficacy of the drugs. If however such a question is asked, the standard reply is that the recipe is contained in the classical texts and that the formulations have been in use for hundreds of years. Either the clientele does not ask any further questions or remains dissatisfied, but silent. As a result the numbers of those who avail of Ayurvedic treatment are limited to those who have used it as a family tradition and have intrinsic faith in the system. Newcomers are curious but remain cautious despite a growing interest in finding natural ways of healing and an avoidance of strong, chemical medication.

In the absence of published clinical research which has investigated the safety and effectiveness of the Ayurvedic approaches in treating human beings, wider public remains unconvinced and unsure. Whether articulated or not, there is scepticism about the mode of action of Ayurvedic therapeutics and drugs. In Ayurveda more than medication the emphasis is on maintaining a healthy lifestyle as a precursor to treating a medical condition. This becomes daunting for patients who have been accustomed to fast diagnosis followed by a pill-popping regimen which generally provides quick relief.

3. Ayurvedic way of life-an essential component of patient management

The Ayurvedic approach is entirely different, is time-taking and often cumbersome. There is heavy dependence on ablutions, purgation, the use of medicated oils and the consumption of sometimes rather unpalatable decoctions and medication. Two precepts which are integral to Ayurveda are *Dinacharya* and *Ritucharya* which demand adherence to a strict daily regimen of eating, sleeping, taking a daily bath after evacuating the bowels first thing in the morning—extended even to the cultivation of a happy disposition [5]. There is a great emphasis on eating freshly cooked food, on the intake of green vegetables and on the observance of regular meal timings and intake of water. Taste is also very important and salty, sweet, spicy and bitter preparations are advised as a part of an Ayurvedic diet. Most Indian families even if they do not claim to be practising Ayurveda, understand the importance of eating what nature produces in abundance during a particular season. Vegetables like spinach and cabbage are discouraged during the rainy months because of the pathogens that exist in muddy water. The fact that cruciferous vegetables like cabbage and cauliflower produce gas (*vata*) is known to most Indian housewives and is routinely countered with the addition of anti-flatulence agents like ginger and cumin while cooking.

4. Traditional knowledge digital library

The properties of every single ingredient used in Indian cooking – turmeric, cumin, coriander, cayenne, fenugreek and spices like pepper, cinnamon, clove, cardamom and nutmeg have been described in hundreds of stanzas in the ancient Ayurvedic texts and classical literature written some 1500 years ago. And the fact that this is Ayurvedic knowledge has been acknowledged, certified and legitimised by the World Intellectual Property Organisation is indicative of its value. When patents on turmeric, jamun and karela (bitter gourd) were filed the Ministry in-charge of AYUSH established a Traditional Knowledge Digital Library (TKDL) to scan references to every single ingredient and formulation listed in selected classical texts. These were then translated into six UN languages and presented in a patent compatible format to the patent offices in different countries. The project required engagement of scores of Ayurvedic experts, Indian patent examiners and computer programmers but the outcome was that TKDL has been able to prevent the grant of some 300 patents simply because the domain knowledge could be shown as having existed in the ancient texts of Ayurveda for centuries. As a result knowledge about the healing properties of innumerable plants used in Ayurveda could no longer be claimed as an invention or a discovery [6].

5. The challenges of harnessing ayurvedic knowledge for research

Having thus established the primacy of Ayurveda's traditional knowledge before the world, a bigger challenge remains unmet: how can this knowledge be used for public benefit? Without research and publication in quality journals the process of validation will not be complete. Even if the properties of the medicinal plants can be established through research, it can only translate into larger public benefit if biomedical research proves that the treatment including the medication possesses the capacity to prevent ill-health, promote good health or cure disease. That requires research protocols that exclude bias, access to patients and tabulation of outcomes. That in fact has been the Achilles heel of Ayurveda.

Pharmacological research on the healing properties of plants has been undertaken for long. Things become complex when it comes to clinical research on human beings. And that takes us to the root of the problem. Clinical research conducted according to protocols set out for modern biomedical research requires that patients be treated using randomised controlled trials. These necessarily require three things at the minimum: sufficient number of patients, an inclusion and exclusion criteria for the selection of subjects, standardised medicine and sometimes even placebos. Ayurvedic medicine is by its very nature individualised. Ayurvedic herbs may have been collected from the wild, or from cultivated sources; they may have been collected during different seasons which impacts the properties of the plants including the effectiveness of the raw drugs. Although the term "standardisation" as applicable to modern pharmaceutical drugs does not apply to Ayurveda drugs, batch to batch quality testing and certification about compliance with permissible levels for contaminants, microbial and heavy metals cannot be ignored. But this needs investments in quality control which is not forthcoming. The Ayurveda industry has not given priority to such aspects, forever seeking subsidies for something as basic as batch to batch testing. The tests prescribed in the Ayurvedic pharmacopeias' are inadequate but even so, enforcement has been weak. In comparison the allopathic pharmaceutical industry has been investing in GMP and quality control and has

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