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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 un-stated 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

been able to maintain high international standards. So even if the same level of standardisation is not required, basic uniformity and adherence to pharmacopeia standards would have to be certified [7].

6. Ethical requirements relating to non-toxicity of Ayurvedic ingredients

When it comes to administering Ayurvedic medicine as a part of a research study, ethical requirements would necessitate that the patient is told about the ingredients. While it may be possible to use instruments like the Inductively Coupled Plasma Analyser or the more commonly used Atomic Absorption Spectrophotometer to detect impurities and rule out the presence of substances that exceed permissible levels, this cannot be done across the board without heavy investment in laboratories and equipment. Such investment may exceed even the budget available for research. Meanwhile the use of mercury, lead, gold, pearls and coral which are integral to some Ayurvedic formulations (albeit used in some 5% of the formulations only) may deter many a patient from opting for Ayurvedic treatment as part of a research project. The mere statement that the ingredients have been purified according to a complex Ayurvedic process and converted into “nanoparticles” will not satisfy the tenets of science or the anxiety of the patient.

The fair name of Ayurveda has regularly come in for international criticism on account of the issue of toxicity. This fear is deterring many countries from according official recognition to Ayurveda. An increasing number of negative reports have been published over the years (at least 45 are found on PubMed as of now). The usual reaction is either to say that western lobbies are deliberately portraying Ayurvedic medication in poor light or to blame the manufacturer for non-adherence to the rigorous methods of purification. Clinical research using the approaches of modern medicine cannot be conducted against a backdrop of distrust.

The issue must be confronted by pre-empting criticism instead of deflecting adverse reports. Needed is a mandatory requirement for toxicity screening (liver and renal function tests, blood parameters etc.) in patients who are on Ayurveda drugs which contain metallic ingredients. Public cooperation must be sought in completing the prescribed forms which alone can facilitate regular pharmaco-vigilance to report adverse drug reactions. In the long run this alone can provide safety data on Ayurvedic formulations.

7. Where is the evidence? where is the data?

Apart from toxicity, there is the question of efficacy and effectiveness. With all the constraints, a section among thinking, knowing and educated people has been voluntarily opting for Ayurvedic treatment for certain conditions, particularly in the states of Kerala and Maharashtra. When cases of infertility are successfully tackled by Ayurvedic physicians, where is the evidence that such cases earlier relegated to the status of failures by allopathic hospitals were the result of Ayurvedic treatment? Where is the evidence that people with chronic back or joint pain who have recovered substantially have done so because of Ayurvedic panchakarma treatment? Where is the evidence that the quality of life of terminally ill patients or those on chemotherapy actually improved with the intake of Ayurvedic medicine? What is the way of converting some extraordinary outcomes which are today in the realm of subjective evidence only, into dependable research findings backed by credible data? While whatever treatment is undertaken is completely covered by Indian laws, where is the

evidence that it has had any positive effect and no negative effects on the patient?

8. Clinical research and public benefit

Having posed all these problems is there a solution? First, in no case is this article an argument to support clinical research to the exclusion of other kinds of research. The fundamentals of Ayurveda, the basic precepts like *tridosha*, *panchamahabootas*, *ojas*, *chakras* and *dhatu*s must be undertaken because that is the foundation on which Ayurveda rests. When the mode of action and the basis for diagnosis is questioned it is only through such research that answers can be given. It is equally important that literary research on the ancient manuscripts, on drug standardisation, on the effectiveness of reverse pharmacology as an alternative way of explaining the Ayurvedic phenomena are undertaken and supported. But while these outcomes may benefit Ayurveda as a medical system, it will not give direct quantifiable medical options for patient benefit in the foreseeable future. In the eyes of a curious public looking for new, better and safer options and preferably natural options, the need of the hour is to conduct clinical research in the most acceptable way, recognising that RCTs are virtually unattainable. It may be noted that there have been suggestions from experts regarding the need for ‘whole system trials’ which should adhere to the principles of Ayurveda [8,9].

Alternatives are feasible but they must be given a chance. Against the backdrop of so many obstacles standing in the way of clinical research as prescribed by modern medicine, perhaps clinical research on Ayurvedic treatment should be channelised differently.

9. Clinical research without RCTs

First, there is a need to seek volunteers from among patients that through the OPD's of large hospitals dealing with speciality medical conditions – arthritis, early diabetes, hypertension, irritable bowel syndrome and skin diseases, physical disability related to computer overuse and suchlike would find many takers. Only the Ministry of Health can authorise notices to be displayed in allopathic clinics seeking volunteers who seek Ayurvedic treatment at government cost. Ideally such volunteers should be informed about the treatment regimen but the physician should be allowed to prescribe the treatment according to his judgement, on a case to case basis. The progress can be assessed by a multi-disciplinary group which has not been associated with the treatment and their findings could be limited to examining the pathological parameters before, during and after treatment and observing improvements or the lack thereof using such diagnostic tools and pathological investigations. The patient's own account of improvement or the absence thereof should also be recorded along with observation on the patient's outward capacity to perform functions which were impeded earlier. In this way at least some broad idea about the benefits of Ayurvedic treatment would be available.

10. Retrospective studies to establish efficacy and effectiveness

Second, there is huge scope for undertaking retrospective studies. There are perhaps thousands if not tens of thousands of patient case records lying in several Ayurveda centres, especially in Ayurveda colleges of South India, Maharashtra (Kottaikal, Udupi, Pune and Thiruvananthapuram) to name just a few. Uncomplicated user friendly software could be developed which would enable the data to be analysed in a simple, efficient way. A

dozen post-graduate scholars should be trained to study the case sheets of patients who had been under treatment for around 15 health conditions which are commonly treated at leading Ayurvedic centres. The results could be analysed and published covering the beneficial effects of Ayurvedic interventions in say 1000 cases of stroke, paralysis after spinal injury, of improvement in the quality of life (appetite, reduction of nausea, constipation, diarrhoea, sleep disorders) in the case of patients undergoing tuberculosis treatment or chemotherapy to name just two. Not only will this encourage other hospitals which wish to get involved in research in maintaining proper records but it will give acceptable, publishable data on what Ayurveda can achieve without starting clinical research *de novo*. Even the experts have suggested that gathering evidence from Ayurveda practise needs to be encouraged [10].

Although retrospective have inherent limitations but discharge summaries are considered verifiable and authentic documents from the point of view of research [11]. Perhaps retrospective studies might reveal more information than what clinical efficacy studies might bring out as many of them would provide data over several years. This approach would enable valuable data which is available being used and would save precious time on creating new protocols and finding suitable clinical material.

11. Bridging the Ayurveda – Allopathy divide

Third, since the biggest proponents of the efficacy of Ayurvedic drugs are often the modern medicine practitioners themselves, they need to be approached in an upfront manner. This is an area which today is fraught with confusion and there is hesitation in addressing it at a policy level. Some Ayurvedic drug manufacturers have held extensive clinical trials using Ayurvedic single herbs and formulations which are on the whole is simpler than the classical formulations. As a part of what is called “ethical marketing” modern medicine physicians are regularly being made aware about the constitution of the Ayurvedic drugs, their therapeutic action, indications for use, limitations and their role in clinical practice.

Ayurvedic products are accepted by modern medicine physicians if they are approached on similar lines as is done for introducing modern pharmaceutical drugs. If the data shows that the research studies were undertaken with a proper design and the outcomes have been published in good journals, modern medicine physicians are prepared to listen because every professional doctor has a desire to heal his patient. It is for that reason that wherever the ethical marketing route has been adopted there have been questions on the dosage schedule and advise on combining the adjuvant use of Ayurvedic medication with allopathic treatment. Many physicians add Ayurvedic drugs to their prescription only to help the healing process. However they are arraigned by allopathic medical associations – even for prescribing something as simple and harmless as garlic or ginger capsules, a liver tonic or a pain massage balm. Coming down heavily on cross practice even the simplest applications are railed against even as the inter-disciplinary medical warfare continues. This intrinsically harms the interests of patients more than the doctors and must be seen that way.

“Cross practice” was a term used by the Supreme Court when a homoeopathic doctor administered allopathic drugs which led to the death of the patient. In that context the apex court had restricted the practice of medicine to the branch in which the practitioner had been trained. But the circumstances and the context were entirely different and the way cross practice is being interpreted now begs the question as to who is being helped and

who is being harmed by preventing the use of what would fall in the realm of herbal supplements. Ayurvedic drugs do not require a prescription for sale but even so in allopathic doctor is precluded from suggesting adjuvant use alongside allopathic treatment.

12. Ayurveda as Adjuvant therapy

A survey conducted under the aegis of the Central Council for Research in Ayurveda [3], an organisation set up by the union government, one thousand patients attending the OPDs of five selected hospitals were asked about their preference for Ayurvedic treatment as adjuvant therapy. Their reasons included a need to avoid allopathic drugs which had side effects, prevent or postpone surgery, to improve the quality of life, to mitigate symptoms, to reduce the dosage of strong allopathic medicine and to avoid injections as a mode of drug administration. Ayurvedic doctors from the Municipal Corporation of Delhi and the ESI dispensaries indicated how they were using Ayurvedic drugs as adjuvant therapy while the treatment for diabetes, tuberculosis and other diseases was in progress [3].

Manufacturers of proprietary have reported that the use of their Ayurvedic formulations is particularly high in therapeutic categories like liver diseases; as immunomodulatory drugs to prevent recurrent infections; for the nonsurgical management of urinary disorders including renal calculus; to regulate irregular menstruation; for chronic skin ailments and the nonsurgical management of haemorrhoids.

Given this background, to prevent an allopathic physician from writing the name of an Ayurvedic medication on a prescription when any citizen can access the medicine on his own (assuming he can even recall the name) without prescription and labelling it as cross practice is tantamount to distorting the intention behind the judgement to deny the consumer the benefit of accessing simple remedies available over-the-counter. Since the consumer market has already determined the utility of Ayurveda and the law of the land allows medical pluralism, there is a need for a legal clarification on the prescription of routine over-the-counter drugs by modern medicine physicians. Debarring them from writing the name of a single herb is preventing consumers from accessing what is easily available but cannot be bought for want of knowledge about the nomenclatures of Ayurvedic and botanical products.

There is a need to spread awareness about the efficacy of standard, non-scheduled Ayurvedic medication which is in any case available over-the-counter just like vitamins, tonics, cough syrups et cetera. Even if there is no overt encouragement, at least the present scope for discouraging modern medicine doctors from suggesting the use of Ayurvedic drugs as adjuvants and palliative agents needs clarification. The government could even seek a review before the Supreme Court in the interest of consumers. Otherwise medical lobbies and the modern Pharma sector will continue to chide medical practitioners who use simple Ayurvedic medicine as palliatives, immune system boosters and health enhancers. This is a travesty of justice and the consumer is the one who gets short-changed.

13. Conclusion

When all is said and done, the antiquity, the experience and the goodness of Ayurveda must be harnessed for the public good far beyond what has been achieved until now. There is every need to take up clinical research projects which would satisfy the tenets of biomedical research but can be packaged differently. Perhaps the best way of doing this is by throwing open not just the windows of the mind but also genuine openness to multidisciplinary collaboration with disciplines which have a stake in disease prevention,

natural healing and consumer rights. Finding partners among sociologists, anthropologists modern medicine physicians and teaming up with pharmacologists, biochemists, pharmacists and qualified Ayurvedic experts in India as well as foreign countries would bring fresh ideas and new ways of steering collaborative research.

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