



RESEARCH IN AYURVEDA: CHALLENGES AND WAY FORWARD

Dua Pradeep^{1*}, Dua Pamila²

¹Research Officer-Central Council for Research in Ayurvedic Sciences (CCRAS), New Delhi, India

²Research Associate, Department of Pharmacology, All India Institute of Medical Sciences, New Delhi, India

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*Corresponding author

Dr. Pradeep Dua, Research Officer-Central Council for Research in Ayurvedic Sciences (CCRAS), Department of AYUSH, Ministry of Health & Family Welfare, Government of India, New Delhi, India Email: duadrpradeep@gmail.com

ABSTRACT

The science of Ayurveda is based on sound principles of its philosophy and not on mysticism, magic and anecdotes. Ayurveda is based on its unique principles of health and disease. The theories of Ayurveda (Siddhanta) were established by many ancient sages after rigorous testing in several ways and proving the same with reasoning.

Ayurveda, the world's most comprehensive, personalized; holistic and sustainable health system based on sound philosophical and scientific principles, is now poised to regain the global leadership it lost in the 19th century.

Keywords: Ayurveda, Research, Evidence Based Medicine, RCT, Pharmacopoeia, System Validation

INTRODUCTION

Ayurveda, according to Caraka, is knowledge which seeks to weigh life in the scales of wholesomeness and happiness against their opposites. Its main theme of health and disease, and recovery of health from disease take the stage against an inspiring background of intuitive philosophy, lofty idealism, and vivid compassion, which are the hallmarks of India's cultural inheritance¹.

Ayurveda literally means "the knowledge of life". In Sanskrit, the word Ayurveda consists of the words āyu, meaning "life" and veda, meaning "knowledge" or "science". The growth of science depends upon research and there is no denying the fact that the understanding of the health care personnel, scientists and researchers today, in any given stream of science is because of research. The fundamental purpose of research is to know the truth and to benefit the society. In terms of medical research, it aims at knowing or re establishing the new molecules / drugs which are good for our patients. Scientific journals spread the new knowledge, push forward the frontiers of current knowledge in every aspect, allow publication of creative ideas and form the basis of ongoing innovations. Reasons that drive research include-the desire to know the truth, and the quest for knowledge, the desire of recognition amongst peers and to enhance one's image and prestige. Over a period we have moved from expert based medical practice to evidence based medical practice.

The Wealth of Ayurveda

India has 45000 diverse plant species spread over 16 different agro-climatic zones, 10 vegetation zones, 25 biotic provinces and 426 habitats of specific species. Besides, India has up to 18,000 flowering plants, 2500 algae, 23,000 fungi, 1600 types of lichen and 1,800 varieties of bryophytes. Of this vast quantum around 15,000 to 20,000 are of medicinal value, but out of this only, 7,000 to 7,500 plants are used by traditional medicine systems in India². Herbs are eco-designed drugs consisting of several phyto-chemical ingredients in each, possessing divergent pharmacological activities³.

Ayurveda is the most ancient system of healthcare. India's share in the export of herbals is just 0.2% of the

total global herbal market. So there is obviously vast scope for Indian manufacturers for entering the growing worldwide opportunity of business in Herbal Pharmaceutical field. The worldwide market of Herbal Medicines is US \$ 60 billion (WHO 2002). The World Health Organization predicts the overall automotive medicine market to reach US \$ 5 trillion by 2050⁴.

The extraordinary importance attached to research has stigmatized the practicing clinicians as merely workers and has glorified the researchers as torch bearers of medical science. Ayurvedic researches undertaken during the last 50 years have not been very rewarding, except for the extremely useful exercise of literary research, which has at least made a few of the classical Ayurvedic texts accessible to contemporary readers and researchers^{5,6,7}.

Status of Research in Ayurveda

The so called scientific research of several decades has helped neither Ayurveda nor modern medicine to any significant extent except in creating awareness. The present challenges are globalization of Ayurveda and industrialization of the Ayurvedic drug sector that needs standardization and quality assurance of the in-use drugs, besides developing new drugs and formulations for more recent indications. Since there is a strong need to explain the fundamental principles of Ayurveda in modern context and addressing the growing demand for an 'evidence base', the research is the prime need of contemporary Ayurveda⁸.

The 'hits' on Ayurveda Clinical research in the reputed medical databases reflects an extremely pathetic status of evidence (Table 1).

To address the issue of standardization of Ayurvedic medicines, the Department of AYUSH, Government of India has set up the Ayurvedic Pharmacopoeia Committee. The committee with the help of eminent experts from across the country, has brought out Ayurvedic Formulary of India (AFI)- AFI Part I (444 formulations) and AFI Part II (191 formulations) and the Ayurvedic Pharmacopoeia of India (API)- Part-I {Volume I (80 monographs), Volume II (78 monographs), Volume III (100 monographs), Volume IV (68 monographs), Volume V (92 monographs), Volume VI

(101 monographs) and Volume VII (21 monographs) and (API)- Part-II-Formulations { Volume I (50 monographs), Volume II (51 monographs) and Volume III (51 monographs) }. This work has set up standards for single herbs and multi ingredient formulations described in the *Ayurvedic* texts.

Ayurveda lays emphasis on righteous conduct. 'All creatures seek happiness in whatever they do: but happiness cannot be had without righteous conduct. Therefore righteous conduct is obligatory for all'⁹. 'The whole world is a teacher for the wise in all he does; therefore, a man of action in the world's theatre should emulate its example'¹⁰. Ayurveda prized knowledge and skill highly, but rated compassion and virtuous conduct even higher in a physician's scale of priorities. Therein lies the key to its unbroken practice for 25 centuries and its resurgence in our times¹¹.

Challenges

A debate continues on whether the concept of Randomized Controlled Clinical Trials (RCT) is applicable to all treatment methods of Ayurveda. Therefore, non-RCT study designs have a crucial role in clinical studies. As only a small number of RCTs are available, Systematic Reviews should be conducted on other types of studies, to synthesize the evidence available. A recommendation out of such a Systematic Review would help to undertake new research, to upgrade the evidence level¹².

The use of controls and placebos, so central to clinical trials, would sit ill with Ayurveda which regards every individual as unique, and the package of therapeutic measures including virtuous conduct, life style, diet, procedure and drugs as inseparable. The time to experiment has arrived for Ayurveda. The fact is that use of modern science as a research tool in Ayurveda has never been more necessary, more promising, or more compelling than at the present time¹³.

Ethically conducted and systematically planned open label / observational studies can be as strong in evidence as the randomized controlled clinical trials. Randomized Controlled clinical trials, though considered as level-one evidence, are easily amenable to falsification^{14,15,16}.

On June 24, 2010, US District Judge handed down a six months sentence to an Anaesthesiologist, who pled guilty earlier this year to falsifying research on the use of analgesics celecoxib (celebrex-Pfizer) and rofecoxib (vioxx-Merck) for post-operative pain management, for fabrication of data in a paper published in reputed journal. Later, ten articles of same author were retracted from the same journal. Such fabricated papers leave a serious dent on the true value of evidence and raise a question mark on the veracity of the scientific literature.

The Department of AYUSH has a vision to reinvigorate the AYUSH systems and promote holistic health. It has a laudable mission to mainstream AYUSH at all levels in the health care system to improve access to and quality of public health delivery and to focus on promotion of health and prevention of diseases¹⁷.

4th World Ayurveda Congress (WAC) organized in Bengaluru during December 2010 by Vijanan Bharati, the Department of AYUSH, Government of India, and the Government of Karnataka witnessed an attendance of more than 4000 delegates from across the country, more

than 300 foreign delegates from 60 countries and over 3 lakh visitors to the Arogya Expo-Health Exhibition, offered a glimpse of the Ayurveda's growing popularity, and the increasing public curiosity towards all its aspects¹⁸.

Need of the Hour

The world is also in the need of a system of medicine that can treat chronic and degenerative diseases effectively. Ayurveda though having a strong potential, is not adequately appreciated. If practiced well, it is extremely effective. If well implemented, it could fulfill the needs of the nation. Ayurveda should not be reduced to being an 'Alternative', at least not in its own country¹⁹.

The most important single event that aroused the interest of modern medicine in the Ayurvedic pharmacopoeia was that one of the scientist reported in the British Heart Journal on the usefulness of Serpina, the whole extract of Sarpagandha (*Rauwolfia serpentina*) in the treatment of hypertension²⁰. The fear of depression with Reserpine has kept the most effective and in expensive single drug out of reach of millions of hypertensives in India and the developing World. Fear of depression with reserpine equates well with the fear of lactic acidosis with Metformin for type 2 Diabetes mellitus. Indian physicians have been using Metformin for over 40 years without encountering this problem, the fear of which kept American physicians deprived of this drug for three decades till 1995. The same holds true for vijaysaara (*Pterocarpus marsupium*) also which was researched for nearly twenty years by scientists of ICMR and found to be an excellent anti diabetic. But promising and cost-effective drugs like reserpine, vijaysaara, etc. are ignored as they have no commercial sponsors probably because of any IPR value and restrictions for use vide the provisions of the Biodiversity Act.

The way Forward

Scientists from Ayurveda and modern medicine must understand each other. Plucking ideas from imagination without adequate discussions between the two is a sure recipe for disaster²¹. It is the duty of the Indian people and the Indian Government to keep abreast with the modern science and enliven and popularize Ayurveda by removing the misunderstandings and misconceptions in its theory and practice, before the West attempts to export our knowledge back to us in a 'refined' form.

However, it cannot be overemphasized that ongoing research and development activities do not seem to be based on sound footings. Most of the current R&D programs in this field are still based on the conventional reductionist methodology, which is often applied by molesting the holistic theories of Ayurveda. There is a need to develop new appropriate research methodology for Ayurvedic research through intense interface between Ayurveda and conventional science. It is because of lack of such an appropriate research methodology that Ayurvedic research has not succeeded in yielding any breakthrough in the recent years. The research in science of Ayurveda, has remained largely unexplored, although now there is gradual paradigm shift, which can be visualized in Dr. Valiathan's project on Science Initiatives in Ayurveda²².

In the past decade there has been renewed attention and interest in the use of Traditional Medicine globally. In

India, 65% of the population in the rural areas uses Ayurveda and medicinal plants to help meet their primary health care needs. In China, Traditional medicine accounts for around 40% of all the health care delivered. In Chile, 71% of the population and in Columbia 40% of the population have used such medicine. In developed countries, traditional, complementary and alternative medicines are becoming more popular. At least 48% of the population in Australia, 31% in Belgium, 70% in Canada, 49% in France and 42% in the United States of America has used such medicines once²³.

In India, the health care services through the AYUSH systems of medicine are being successfully provided through a huge network of 754985 registered practitioners, 3371 hospitals, 22014 dispensaries, 9173 manufacturing units, 479 Undergraduate and 117 Post graduate colleges²⁴. The research activities in the field of Ayurveda are being carried out under the aegis of Central Council for Research in Ayurvedic Sciences (CCRAS), the apex body in India for the formulation, co-ordination, development and promotion of research on scientific lines in Ayurveda with the help of its thirty one institutes.

The need of the hour is to use the techniques of radio tracer and nuclear imaging to understand the mechanism of Ayurvedic drugs at the molecular level. Also the bioavailability studies of the Ayurvedic drugs are a totally neglected area due to which the translation of the in-vitro data into clinical applications is a 'blind spot' in Ayurveda herbal drug research. Poor bioavailability of curcumin and resveratrol are important illustrative examples²⁵. Cancer chemoprevention by dietary pharmaceuticals is already an important field of study²⁶. Similar chemoprevention of infection (tuberculosis, viral infections including HIV), malignancy and neurodegenerative disorders (Alzheimer's disease, Parkinson's disease, etc.) is going to be a major focus in the future Ayurvedic drug research. Also, Ayurveda's emphasis on Ahara as a preventive and curative entity needs to be explored further. Further study of Ahara's role in prevention may even obviate the need for curative drugs, and take us beyond both pharmacology and reverse pharmacology²⁷.

We need to encourage ambitious high impact research projects to bring contemporary relevance and deeper understanding to Ayurveda principles that are of great strategic importance to India. Certain significant developments in the form of projects like Golden Triangle Partnership project, New Millennium Indian Technology Leadership Initiative, and various schemes initiated by the Department of Science and Technology and the Department of Biotechnology, Government of India have boosted systematic research on various aspects of Ayurveda, and other traditional medicine in India. It is important to establish systems to ensure that such efforts synergize and multiply.

Data on consumption, safety and efficacy of Ayurvedic medicines is grossly inadequate, while that regarding their in-country consumption is not readily available. Nor is the data on safety and efficacy of Ayurvedic medicines and practices in India easily available. Systematic documentation of history of use over a defined period in a large population should be carried out as a team India effort using the principles of pharmacoepidemiology²⁸.

Ayurvedic pharmacoepidemiology can provide rich data on drug utilization safety and novel activities. Reverse pharmacology then make use of this data to embark on its three stages: experiential, exploratory and experimental. The reverse pharmacology path has led to several hits of drug like activities in medicinal plants. Leads have targeted mechanisms with well defined plant extracts. As a result plant principles have been identified as drug candidates with good safety and efficacy. Successful examples of this path include Kutaki on viral hepatitis, Atmaupta for Parkinsons disease, Haridra as a Cancer preventive, Amruta as an Immuno modulator and Ashwagandha in Anxiety Neurosis²⁹. Distinction between Ayurvedic Medicines, Herbal medicines, Dietary Supplements, Cosmeceuticals, health foods and nutraceuticals need to be clearly stated and distinct regulatory mechanisms evolved. There is also an urgent need for Translational research in Ayurveda³⁰.

CONCLUSION

Science evolves through a rigorous and continuous research, Ayurveda, the ancient Indian system of health care and longevity needs to be validated on modern scientific research methodology taking care not to compromise with its basic tenets and philosophy. A full system validation would be the right approach in this direction.

Scientific studies cannot make progress without the publication of research findings, which must welcome and withstand the scrutiny of peers. Research in Ayurveda is, however, seriously handicapped by the paucity of peer-reviewed journals which would appeal as much to scientists as to the Ayurvedic community.

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Table 1: Research in Ayurveda as reflected in certain reputed research databases

Keyword -->	Ayurveda	RCT and Ayurveda	Meta analysis and Ayurveda
CTRI	31	Nil	Nil
Cochrane	4	Nil	Nil
Pubmed	558	1 (curcuminoids in oral lichen planus)	1 (Rheumatoid arthritis)
IndMED	63	Nil	Nil

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