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Thought Leadership Article

Ayurvedic research for direct public benefit

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ABSTRACT

Currently, interest in Ayurveda research from a public health perspective, is increasing globally due to its ability of improving quality of life and assist individuals to stay healthy. However, there is a dearth of evidence which can substantiate the credibility of this ancient traditional medicine system. Ayurveda today, has to face numerous challenges in collecting evidence and documenting it. The way forward may be understanding these challenges and developing policies which can make Ayurveda research beneficial for the public. © 2019 The Authors. Published by Elsevier B.V. on behalf of Institute of Transdisciplinary Health Sciences and Technology and World Ayurveda Foundation. This is an open access article under the CC BY-NC-ND license (<http://creativecommons.org/licenses/by-nc-nd/4.0/>).

1. Background

Research in Ayurveda covers an enormous canvas. While fundamental and literary research, drug research and the healing properties of medicinal plants are extremely important and cannot be dismissed as of secondary importance, however, from a public point of view, it is the capability of Ayurveda to improve the quality of life, assist individuals to stay healthy and mitigate the symptoms of disease that occupies centre stage today. With the spurt in Non-Communicable diseases – hypertension, diabetes and cancers – the interest in Ayurveda has grown. But the interest wanes as soon as concerns about the paucity of reliable published data on the efficacy and effectiveness of Ayurveda get raised [1,2].

Despite being acknowledged as a full-fledged system of medicine under various laws including the Drugs and Cosmetics Act and receiving full Government support first as an independent Department and now a Ministry for all traditional systems of medicine, which dominantly includes Ayurveda, the need to prove every claim which purports to prevent illness, promote good health and assist in healing, gets raised. In the absence of adequate high quality published research backed with evidence, the credibility of the entire system falters in public perception. Collecting evidence and documenting it becomes increasingly difficult when safety issues surface.

2. Why subscribing to allopathic standards of research is unattainable?

There is a need to identify the health indicators that would be taken into account condition-wise while starting any research and to prescribe the outcomes that would be examined to decide effectiveness of different strategies. Clinical research and therapeutic studies in Ayurveda are overwhelmingly needed much more than any other kind of research if the needs of millions of potential users of Ayurveda are placed above other kinds of research.

But, in their very nature, clinical research in Ayurveda is incapable of being standardised, except, under strict laboratory conditions and standardisation is the foundation on which the effectiveness of bio-medical research is based. In laboratory settings some standardisation can be attempted but clinical material is usually deficient. Even when there are thousands of patients in OPDs and IPDs of multi-speciality hospitals seeking treatment for say, osteoarthritis, gastrointestinal or respiratory conditions or for diabetes or BPH, conditions where it is claimed that Ayurveda has much to offer, such patients do not normally look towards traditional systems as an option. When availed of, it is generally on the basis of a word-of-mouth recommendation which becomes highly subjective. Even when treatment is availed of, it is more as a palliative or to delay surgery or reduce the dosage of allopathic medicine and less likely to be selected as a standalone therapy.

3. Questioning the basis of a purely drug based approach

Clinical material apart, following the research protocols designed for allopathic clinical research questions, the fundamental basis on which Ayurveda works which does not envisage a

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disease-medication-cure trajectory. It is a personalised, holistic system in which Ayurvedic formulations when used contain anything from six to sixty ingredients in an average compound formulation. Drugs are just one part of the Ayurvedic approaches and are used in conjunction within indeterminate inputs like lifestyle changes of diet, mental attitude, physical activity, and even spiritual or meditative healing-sometimes involving yoga, incantation and prayer. The role that these inputs play cannot be reduced into hard data and documented as it involves a highly personalised approach which, if the physician is honest to his calling would differ person to person. In such a milieu the question of RCTs and much less, placebos is unthinkable.

4. Regional variation within Ayurvedic practice

Within Ayurveda itself, there are vast differences in the approaches of different regions, Universities and PG colleges which necessarily influence healing practices. The academic training programs too, differ widely in content, duration and the importance attached to learning skills like *Nadi Pariksha*, *Panchakarma*, manipulation and other supportive therapies differs widely. The quality of medicine used, whether it is hand-prepared, a classical medicine from the South or a patent and proprietary medicine manufactured in the North, all affect outcomes-leaving the system open to doubts and cynicism which have been repeatedly expressed by potential users. In short, there is no uniformity within the country and instead of allowing each approach to flourish according to its own genius, the ongoing research efforts have often been manifested in a misplaced zeal to prove efficacy and effectiveness in isolation based on the use of formulations. This often results in research which is not taken seriously or accepted as reliable [3,4].

5. Need for rigorous therapeutic observational studies with 'whole system approach'

Against such a backdrop, what is needed is to mount therapeutic, observational studies on the effectiveness of Ayurvedic treatment extended by physicians identified to participate in research studies. Such *Vaidyas* have to be left free to examine the patient and undertake whatever is considered necessary whether it entails treating the mind, the digestive system through techniques, fasting, diet or drugs supported by personalised *Panchakarma* or any other treatment. The canvass of conditions to be treated is too large to start everything at once. Hence it is necessary to select 5–6 specific conditions which are common and have already generated wide interest among patient groups. These research studies should be organised leaving the selected physician to do whatever he considers necessary; however, the observations should be recorded uniformly for each study based on specific physical and pathological parameters which are relevant to the selected condition and further nuanced to include the patient's well-being (improvement in quality of life). The improvement must be documented relative to changes from the start of the study onwards, week by week and month by month and should be recorded by independent experts who are conversant with research methodology as well as interpreting the pathological and physical changes. In such observational studies there should be no inclusion and exclusion criteria for patients and no RCTs. Outcomes to be expected should be listed in advance and results measured against those benchmarks; for example, reduced frequency of urination in cases of BPH or ability to climb stairs when the patient could not even climb one stair at the start of the research study. If carried out with fullest rigor, such observational studies can be remodelled to meet the criteria for

prospective whole system trials without a control arm. This would place such studies a higher level in the evidence pyramid [5].

6. Limit choice of medical conditions

The choice of conditions and patients should be decided on the basis of the public demand as evinced by OPD, IPD figures in selected facilities over 3 years; more specifically, this refers to patients' own preference to avail of Ayurvedic treatment as a stand-alone therapy, something that is commonly seen in Ayurvedic hospitals. Including cases where Ayurveda is being sought only as adjuvant therapy will complicate the interpretation of results and could be left out. However, the possibility of the patient using allopathic drugs on his own (pain killers, suppressants and enhancers) cannot be ruled out and would have to be monitored through blood tests to justify discontinuance of further research on such subjects.

No control groups or standardised treatment protocols should restrict the physician in deciding the line of Ayurvedic treatment but the diagnostic/pathological parameters/indicators to be used as benchmarks should be decided in advance, both at the commencement of the study and related to pre-selected outcome benchmarks.

The suggested examples could include joint/orthopaedic/neurological conditions; BPH, liver related conditions, irritable bowel syndromes, chronic respiratory conditions and treatment of pregnancy/lactating issues through Ayurveda. The management of NCDs is even more important from a public health point of view but clarity on indicators would need to be drawn up carefully and only borderline cases may need to be included.

7. Inputs needed

Such research would require the following inputs:

1. Identification of Ayurvedic hospitals and physicians running relatively large OPDs and IPDs for specific conditions. Willingness of the practitioners/faculty members to join the research study must be obtained.
2. Willingness of patients needs to be obtained, including consent to be periodically examined on pathological and diagnostic parameters.
3. Identification of experts in therapeutic study research methodology, radiologists who can conduct ultra sounds where needed, technical experts competent to measure improvement in mobility, urination patterns, pathologists and biostatisticians would be needed and can be engaged in a need based way.
4. Funding can be supported by ICMR, CSIR and AYUSH who should assign at least 70% funding for clinical research through therapeutic and observational studies. The justification is on account of public need and resultant demand.
5. If the physical parameters and quality of life indicators improve over the baseline, the data would form the basis for informing the public through published research and for imparting knowledge about more effective approaches to Ayurveda faculty and students.

If Ayurveda is to be taken seriously as a powerful alternative to conventional biomedicine, it is strongly advocated that this approach be given overriding importance. Further, it is only when effectiveness is thus evident that investigation into the properties of the drugs should start.

8. End note

Unrelated to patients and hospitals but indirectly related to the development of the system and keeping contemporary trends in view, there is a need to establish an Institute for Survey & Documentation of different regional approaches and differences to encourage cross fertilisation of knowledge and experience. This should be done so as to identify the most acceptable and sought-after approaches for treatment including preventive aspects. While allopathic medical colleges may not come on board, practitioners from abroad would be interested in earning credits in such a cross-cutting research Institute where research methodology, bio-statistics and survey methods specific to traditional medicine can be additionally taught.

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