Current Theme

Problems faced in Ayurvedic Drug Research

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Abstract: Constant research in Ayurveda is essential to update and upgrade the existing knowledge with current research trends. Several problems have been encountered in Ayurvedic research, hence it is essential for researches to know these problems and find ways to resolve it. The major issues in Ayurvedic research include quality control, standardisation, lack of standard protocol, and lack of publication awareness. Raw drug standardisation can be achieved by taxonomy and pharmacognostic tools like fingerprinting techniques, GMP and GAP could be few measures for standardisation of manufacturing process and the end product. The experimental and clinical models chosen should be designed in accordance with the principles of Ayurveda. Interdisciplinary research can bring much needed development in the field of Ayurveda.

Key words: Ayurveda, Research, Standardisation.

Introduction:

Research should aim to enrich the existing knowledge with the help of advancements in science and technology. *Acharya* Charaka after describing the 500 *Mahakashayas*, says that the drugs mentioned under these are enough for a person of lower intellect but people of higher intellect can add further to the existing.[1] Thus a continuous upgrading of knowledge is essential while keeping the principles of Ayurveda intact. In this era of globalization, to make Ayurveda a globally accepted science there is a need to update and upgrade the existing knowledge with current research trends. Further with the recent ban of Ayurvedic medicines in Europe and claims of Ayurvedic medicines being toxic it is the need of the hour to address questions put on the quality of Ayurvedic medicines. There is a growing need for an "evidence based medicine" hence research is the prime need of contemporary Ayurveda.[2]

Ayurveda being a holistic science, Research in Ayurveda with the modern research designs is facing lot of problems thus it is essential for researchers to know the problems faced so as to find a proper solution and make the research work fruitful.

Materials and Methods:

A review of Ayurvedic classics and Research works was done to know about the limitations and backdrops of Ayurvedic drug Research and the aim of this paper is to highlight the problems faced in drug research.

Observation & Results:

The major problems faced in the field of research in Ayurveda over the years are absence of a standard protocol, Controversies in the identity of raw herb, Quality control and standardization of raw drug, the process and the finished product, ability to assess the efficacy of Ayurvedic drugs with experimental and clinical models based on modern research and methodology, toxicity studies, lack of publication awareness.

Controversies in identification of classical drugs is one major hurdle faced due to various reasons like regional differences eg. *Shankahapushpi* is identified as *Convolvulus pluricaulis* chois(Convolvulaceae), *Evolvulous alsinoides* Linn.(Convolvulaceae) and *Canscora*

diffusa R.Br.(Gentianaceae) all over India except south india and *Clitorea ternatea* Linn.(Papilionaceae) is used in south India,[3] lack of understanding of the herb and inability to identify with the information present in classics is another reason eg: *Murva*, and unavailability in certain regions: eg : *Berberis aristata* being unavailable *Coscinium fenestratum* is used as *Daruharidra* in south india.[4] Quality control and standardization is another important area of concern. The method of harvesting, processing and storage effect the quality of the drug to a great extent where excessive and improper harvesting may destroy the natural habitat of the drug, improper processing and storage will hamper the quality of the drug. Herbal adulteration is one of the common malpractices in herbal raw material trade which affects the quality of raw drug. Adulteration is a practice of substituting original crude drug partially or wholly with other similar looking substances but the later is either free from or inferior in chemical and therapeutic properties.[5]

Ayurvedic medicines were prepared by the physician based on the need of patients in earlier days but in the present day when people want to buy ready medicaments from the market it becomes essential to maintain uniformity in the manufacturing process. Variation in the end product is seen due to variation in the techniques right from the source of the drug used to the operating procedure. The problems faced in the finished product is mainly with the palatability of the dosage form where the modern day patients demand better palatability and user friendly form of drug. Further Ayurvedic medicines do not have a single indication, they have wide application because every disease arises because of the imbalance of *Doshas* and our treatment is targeted at the correction of the *Doshas*. Ayurveda believes in the use of the drug as a whole where every single ingredient of the drug has a specific role to play in the drug action.[6] A drug can act through any of its properties viz *Rasa*, *Guna*, *Veerya*, *Vipaka*, and *Prabhava*.[7] Interaction of properties is also important and any of these properties can dominate. The use of active principle of a drug may serve a limited purpose because Ayurveda believes in a broad spectrum approach where the minor and unidentified principles present in the whole drug are expected to play their respective role.

Preclinical and clinical researches help to validate the safety and efficacy of a drug. Toxicity in Ayurvedic formulation maybe a result of reasons like improper identification of raw drug, adulteration or substitution, improper *Shodhana*, improper processing method and so on. Animal studies are carried out to understand the mode of action of drugs but the animal models designed based on modern pharmacology may not match with the pharmacodynamics and pharmacokinetics of Ayurveda.

Ayurveda and other traditional medical systems often prescribe complex treatments consisting of a combination of drugs, diet, detoxification procedures, lifestyle changes, and yoga practices, customized to the needs of individual patients.[8] Thus making it difficult to match with modern concepts of research. In Ayurvedic medicine research, clinical experiences, observations or available data becomes a starting point. In conventional drug research, it comes at the end. Thus, the drug discovery based on Ayurveda follows a 'reverse pharmacology' path.[9]

Lastly lack of publication awareness and documentation in Ayurveda is one more concern thus making it difficult to prove the efficacy of Ayurvedic medicines. Many good researches go unnoticed eventually leading to repetitions thus causing loss of valuable time and energy.

Discussion

The aim of standardisation is to combat the problems faced in the research. Research topic itself is a problem where researchers will look up on justification. The concepts of standardisation and its techniques were prevalent even during ancient times and they were extremely scientific. As circumstances have changed, it has become necessary for the incorporation of modern

methods in streamlining the standardisation techniques, alongside with the existing ones. Standardization is a system that ensures a predefined amount of quantity, quality & therapeutic effect of ingredients in each dose.[10]

The question now is how far a standardisation can be achieved with the identity of the various controversial drugs. The drug only when properly identified and used in the right dosage form is effective in disease management.[11] Thus taxonomic and Pharmacognostic studies should help in providing proper identity and to clear the controversy. Tools like fingerprinting techniques, molecular DNA etc may provide better understanding of issues of raw drug standardization.

Variation in the raw drug may occur due to various factors like regional, seasonal, storage pattern etc. Establishing standards for identity is only the first stage or level of standardization of a raw material. Higher level standards can be established when a raw material is also standardized in terms of its traditionally prescribed collection time, region of collection, and way of processing and storage conditions. (*Venkatasubramanian,* 2001) and scientific studies have shown that using a traditionally recommended medium for processing a raw drug can increase the bioactivity several fold (*Sudha et al*., 2004).[12]

` Process standardization is one thing which plays an important role in determining quality of the medicament and hence the process can be controlled with implementation of standard operating procedures. Concerns related to palatability may be tackled by opting different dosage forms of the same medicament as told by *Acharya* Charaka in context of *Panchavidha Kashaya kalpana* which is further explained by Chakrapani that the palatability of the dosage form varies for each individual.[13] Modification in dosage forms is also an area where researchers have been constantly working on. *Vatis* are manufactured with sugar coating to enhance the palatability and outer appearance, bitter tasting *Kashayas* are made into *Kashayam* tablets but it may lead to change in the properties of the medicine and the same action may not be achieved. So if only palatability is the concern, should we not resort to other *Kalpanas* such as *Avalehas*. This itself is an area of research where we can evaluate the difference in efficacy of a classical dosage form to that of an altered form like *Kashayam* tablet or sugar coated tablet.

In any research, the goal of research should not be compromised to suit the convenience of research methods. But unfortunately in Ayurvedic research, there has always been a reverse compromise. Modern research on Ayurveda has not been very rewarding for Ayurveda itself. Much of it uses Ayurveda to extend modern bioscience.[14] Drug development includes various steps, starting from a passport data on raw materials, correct identification, pharmacognostic and chemical quality standardization, safety and preclinical pharmacology, clinical pharmacology and randomized controlled clinical trials.[15] There are only few databases such as Researches in Ayurveda published by *Dr.M.S.Baghel* which provide information about Researches done all over India. DHARAonline is also one such step towards bringing all Ayurvedic publications under one roof.

Conclusion

Early implementation of the GMP and GAP regulations will ensure the quality assurance and standardisation. Drug evaluation could be done by following the reverse pharmacology approach. The experimental and clinical trials should be designed so as to help the development of Ayurveda and interdisciplinary research can bring much needed development in Ayurveda. Awareness of proper documentation and publication could make researches in Ayurveda useful.

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