NEED OF INNOVATIVE APPROACH IN HERBAL DRUG DEVELOPMENT

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**ABSTRACT:**

Most modern drug discovery and development takes more fund but fewer new drugs were generated and thus every drug designer is wondering where the hope for drug discovery is? The historical experiences and empirical observation with ayurveda drugs provide valuable clues for finding new entity drugs. Age old ayurveda have relatively organized database with detail pharmacological principles coded in dravyaguna vigyan and provide exhaustive description of botanical material their properties which could be verified in vitro and in vivo using modern scientific methods. It has necessitated a novel method of ayurvedic practices and research, development of standard technique for quality raw drugs, clinical trials and focus on reverse pharmacology approach for better and safer new drugs. This will become an area of ever increasing importance in the health-care system in the future. In this paper effort has been made to discuss the way for quality drugs and reverse pharmacology approach in field of research and development in ayurvedic medicines for new diseases with interdisciplinary approach in a systematic manner.

**Key Words:** Ayurvedic drugs, Reverse pharmacology, Drug development

**INTRODUCTION**

India has a lot of opportunity to lead the global herbal market. For drug discovery historical experience is always significant. Black stated that the most fruitful basis for the discovery of new drug is to start with an old drug. [1] Now pharmaceutical industry turns to traditional and herbal experience again with an attempt to find novel drugs from traditional medicine [2]. The recent interest and resurgence of plant remedies result from several factors effective of plant medicines, side effects of most modern drugs, development of science and technology. In Current scenario allopathic medicines are helping to treat many pathological conditions but Besides relief they are associated with side effects, teratogenic effects, delayed reactions, drug resistance. Various medicines available in market are chemically derived directly or indirectly from plant species. New chemical entities based drug discovery are adding more expense, risk and years. A screening was done for selected bioassays of approximately 2000 plants for biological efficacy in Council of Scientific and Industrial Research of India. However screening failed to yield any new drug. [3] It would be cheaper and perhaps more productive to re-examine plant remedies described in ancient and mediaeval texts [4] since Ayurvedic drug research has a basis of ayurvedic database and philosophy, it needs to be undertaken within those principles. This allows more degree of success. Mechanical treatment normally followed in drug research may lead to misleading inferences. Failing compliance of complete Ayurvedic processes and adopting short-cuts can result into either compromised therapeutic gains or even dangerous poisonous side effects. Recent modern trend is selecting the path of prospective microanalysis of the drugs to develop isolated new chemical entities. But it is major drawback and will account for the extensive economic and time expense involved in whole task and probably the reason for the reduced success rate. In last few years have seen an alarming downturn in the industry as such and in particular, in the field of R & D. most of the big pharmaceutical manufacturers spend more on marketing than on research and development. Recent modern trend of Drug development is long, expensive and risk of post approval or marketing withdrawal cases. Consequently it shows drug development need some innovative approach. In this paper I want to highlight on some important point which is necessary for Successful Drug Development in Ayurveda.

1. Follow the procedure of reverse pharmacology.
2. Use of crude drug in place of isolated active ingredient.

**Follow the Procedure of Reverse Pharmacology**

This approach can provide new fundamental leads to reduce time, money, and toxicity Reverse
pharmacology procedure will help to know the probable mode of action of herbal drug by different technology involved in preclinical studies, therapeutic dose, dose fixation according to Prakriti and vikriti, and their frequencies. In this approach as the candidate travels a reverse path from clinics to laboratory rather than classical laboratory to clinics. Reverse pharmacology (RP) designed as an academic discipline to reduce 3 major bottlenecks of cost, time and toxicity. RP can be perceived to comprise of 3 phases.

I. Phase experimental studies - That includes robust documentation of clinical observation of the biodynamic effects of standardized drug by meticulous record keeping.

II. Phase exploratory studies- For tolerability, drug interactions, dose range finding in ambulant patients of defined subset of the diseases and preclinical studies in relevant in vitro and in vivo model to evaluate the target activity.

III. Phase-experimental studies- Basic and clinical at several levels of biological organization to identify, and validate the reverse pharmacological correlates of ayurvedic drug safety and efficacy.

To evaluate the efficacy of herbal and classical drugs as per Ayurvedic approach, the screening methods of modern Criteria are not sufficient in all cases. At this time we need to explore evaluation in its own theoretical framework.Efficacy issues are taken care by the traditional use data since these medicines are in practice from centuries. Pharmacological principle in Dravyaguna vijyan will help to explain dynamics and kinetics of various drugs with the rasapanchaka. It will assist to search new drugs for diseases. This innovative approaches based on ayurvedic medicine can reduce the major bottleneck and also reduce cost and development time.

Use of Crude Drug in Place of Isolated Active Ingredient

Second vital thing in herbal drug development is selection of Crude drugs. Crude drugs work more efficiently than the extract. Therapeutic activity of to 1 or few compound isolated from crude drug can be seen, but activity present in whole crude drug cannot be expected from isolated active ingredient compound. Isolated Compound needs toxicological studies to prove their safety. The typical strategies of drug research including activity directed fractionation do not necessarily work in case of Ayurvedic botanicals.

Following examples will illustrate this point further an experimental study was conducted in animal model of Sarcoma and adenoma with Bhallataka oil (Semicarpus anacardium) for antitumor activity at National chemical Laboratory, Institute of Science, Cancer Research Institute and Haffkine Institute under the program of Department of Science and Technology. Result was statistically significant; there was increase in life span of treatment group. Then scientist tried to isolate the active principle using preparative HPLC coupled with anticancer activity testing of pure fractions. But this study failed to identify any anticancer compound in pure form even after 4 years of intensive efforts. Thus just because we are not able to isolate pure anti compound from Semicarpus does not mean it has no anticancer activity. Crude extract and nut shell oil showed anti cancer activity probably by synergistic activity of all plant constituents. Standardization of crude drug is very vital and needs a broader consideration. New procedures, method of ensuring, safety and efficacy features, developing new presentation forms and designing suitable packing method are all part of this whole endeavour. In all these efforts the essential concern will be to stick an appropriate balance between the ayurvedic principle and the evolving needs of changing times. Necessary studies are needed to substantiate the equivalent effect of these forms with that of classical form.

Multidisciplinary Approach

Drug development is multistep procedure so it need close collaboration of experts, scientist from different allied fields. The scientific disciplines involved in drug discovery other than the ayurveda expert were: chemistry, pharmacology/physiology, Botany, Biotechnology, microbiology, biochemistry and molecular biology, medical statistician. they can contribute in following activity

- **Discipline:** Biochemistry,
  - **Activity:** Development of drug, biochemical changes and related physiological alteration in the body. Pathology of any disease.

- **Discipline:** Microbiology,
  - **Activity:** Microbial load, Pharmacological action-Antimicrobial study, fermentation process Science

- **Discipline:** Botany
  - **Activity:** Drug identification macro and microscopic examination, Adulteration, Market sample analysis.

- **Discipline:** Biotechnology
  - **Activity:** Alcohol production, Role in Asavarishta kalpana , Market sample analysis.

- **Discipline:** Chemistry,
  - **Activity:** Market sample analysis, phytochemistry

- **Discipline** molecular biology
  - **Activity:** Mode of actions of drugs
Discussion

Ayurveda is a science by the use of which, one can throw the light on such hidden facts. Ayurvedic treatment principles should be first explained by ayurvedic pharmacological principles i.e. dravyaguna, it will show the science concealed in Sanskrit literature. The need of the research in Dravyaguna speciality implies the exploration of new drugs, supported with the possible experiments with ancient science. In ayurveda customized prescription is mentioned that is based on human constitution disease constitution, Drug constitution. To develop the efficacious line of treatment with herbal drug we need to take care of above 3 points. Therefore herbal drug development which includes reverse pharmacology, safety remains the most important starting point and the efficacy becomes a matter of validation. In ayurvedic drugs mode of action is mainly dependent of their rasa, guna, veerya, vipaka, prabhava. In modern science pharmacology uses another term like receptor theory, i.e. chemical structure and activity, receptor binding, affinity, and intrinsic activity. A single drug with different anupana, sanskara can be used for the treatment of various types of diseases. Importance of pathya and anupana etc are to be viewed scientifically in the development of new drugs entities from herbal medicine. Crude drug selection is very important step, the whole plant philosophy can begin to be better understood by considering that a single plant is greater than the sum of its parts because any plant is literally made up of hundreds, if not thousands, of different chemicals that interact in a highly complex manner, an herbal medication cannot be reduced to the simple isolation of a certain plants active constituents or major ingredients. This phenomenon is known as synergism. Innovative approach in traditional medicine conducted with modern technique can help to enrich the sources of new drugs by absorbing new ideas and concepts from traditional plant medicine. While developing modern standards for herbal medicine an absolute match between the traditional standards and corresponding modern parameters cannot be expected. Ayurveda is a devine life science which is beginning less and is eternal. And finally it is the time tested life science based on philosophical and experiential principles and practices. No other Medical science could be, probably compared with Ayurveda in the world. This could be the precious point of pride, that we have a treasure of knowledge and wisdom regarding Health.

Conclusion

Dravyagunavijnanam is the backbone of Pharmacotherapeutics and Pharmaceutics but Rigorous quality research is needed to support the claim of herbal medicine for the benefit of mankind. Emerging diseases where no medicines are available have encouraged an interest in plants once again as a significant source of new medicines.

References


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