



Opinion

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Evidence Based Pharmacology of Herbal Formulations: Need of The Hour

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Abstract

Herbal medicine from ages has an edge over the synthetic medicines because of its use in preventive therapy. The revival of herbal drug industry can be understood due to irrational use of the chemical drugs leading to microbial resistance and people's growing concern over fitness because of the changing life styles with no time left to exercise. Herbal medicine has a great role in promoting general health and well-being whether it is used alone or with combinations for specific health problems. Many potent and novel compounds isolated from the plants are still the drug of choice for various life threatening diseases like cancer, HIV etc. The reason for the delay of inclusion of herbal drugs in the health care system can be understood by the facts like geographical variation in most of the species, methods of processing pharmaceutical formulation which invariably contain varying content and proportions of active chemical components, which results into their lack of validation and characterization. Evidence based pharmacology is also important because of the fact that using herbal supplements together with prescribed medications could lead to harmful, even life threatening results. So, keeping in view their interactions with other drug molecules and significant pharmacological actions it is need of an hour for the countries to develop and include traditional and modern evidence based medicine (EBM) into their respective health care system.

Keywords: Traditional and complementary medicine; Evidence-based medicine; Randomized clinical trials; WHO; Quality assurance

Abbreviations: EBM: Evidence Based Medicine; RCT: Randomized Clinical Trials; TM: Traditional Medicine; CM: Complementary Medicine; ICH: International Conference on Harmonization; QA/QC: Quality Assurance and Quality Control; EBM: Evidence-Based Medicine

Introduction

In recent years, there is increased number of Randomized clinical trials RCTs on traditional herbal medicine. From 1990-2012, WHO has indicated that there is uniform increase in the development of national policy in regulating traditional medicine/ complementary medicine (TM/CM). It is estimated that 25% of the crude drugs used in recent years are derived from plants, of which 5-15% have been explored for bioactive compounds. According to the reports of WHO, China, Africa, Indonesia, India, Japan, Singapore, Republic of Korea etc. are some countries where more than 50% of the population rely upon their traditional and complementary system of medicine. Developed countries too do not lag behind in using TM/CM. In USA, a survey conducted in 2007, indicated that 11% of children and about 40% of adults used CM therapy out of which 17.7% population rely on natural products. Despite of this fact very few of these products have been subjected to randomized clinical trials (RCTs) under the International Conference on Harmonization (ICH) - Good Clinical Practice Guidelines to determine their efficacy and/or safety [1].

Challenges towards Evidence Based Pharmacology

The most crucial factor affecting the quality of herbal medicines is the lack of effective policies on quality assurance and quality control (QA/QC) in the processing and manufacturing of herbal products under Good Manufacturing Practices. There are many factors like natural contaminants, presence of ample number of chemical constituent with different mechanism of actions as whole, are some of the common hurdles in establishing the quality control parameters of the herbal formulation. For example, the mechanism of action of a Chinese herbal medicine formula (consisting of seven herbs) was hypothesized from a study of its in vitro effect on rat peritoneal mast cells and macrophage cells. It was found that the formula significantly inhibited the release of much kind of inflammatory mediators, which led the researchers to conclude that it has multiple mechanisms of actions and potential synergistic effects of the individual herbal constituents that contributed to the significant activity of the formula. But unfortunately, the potential clinical anti-allergic effects of the formula are still not tested through

adequately powered RCTs, which doubt the validity of such postulations [2].

Further, the translation of an *in vitro* and/or *in vivo* biological/ pharmacological effect of a herbal medicine to human therapeutic use may not be successful due to geographical variation in most of the species, simple attribute of a biological or clinical outcome by the name of the mother herb, while neglecting the type of plant extract, methods of processing pharmaceutical formulation which invariably contain varying content and proportions of active chemical components. For example, many herbs, such as *Panax ginseng*, possess a wide range of pharmacological activities but there is still lack of evidence in understanding the mechanism through which it possess various pharmacological actions and which are the compounds responsible for the activity. Thus, it has been recommended in achieving evidence based pharmacology, quality-certified standardization must be the prerequisite for future laboratory and clinical investigations [3].

Future Perspectives

Herbal medications that are considered for integrative therapy must first undergo preclinical pharmacological assessment for safety and efficacy studies. Suitable methods for testing toxicity need to be established so that herbal constituents and their derived products can be assessed easily. Testing of herbal products for the presence of heavy metals such as lead, mercury, and arsenic should be mandatory, as these toxic substances are environmental contaminants often present in many herbs. Therefore, assessment of preclinical, pharmacological, and safety represents a critical step in the scientific integration of herbal medicines into the evidence-based health care paradigm [4]. Increasing clinical evidence on its efficacy, safety, substantial reports of the chemical composition of constituent herbs and pharmacological activities of the identified compounds are clearly warranted. Identification of the active compounds and describing their mechanisms of action will inevitably lead to new and improved therapeutic agents for the treatment of human diseases. WHO also suggests that it is high time for the countries to include traditional and modern evidence-based medicine (EBM) as a part of their constituent health care system [5]. Author and his co-workers are also contributing significantly towards quality management and regulatory perspectives of herbal and traditional products [6-10] and extensively reviewed and established preliminary clinical evidences for herbal drugs/formulations in treatment of erectile dysfunction, sexual disorders [11-15], diabetes [16-18], hepato-toxicity [19,20], cancer [21] and for antioxidant potential [20,22,23] and in cosmetics [24]. Further in depth pharmacological evaluation and mechanistic studies are in progress.

Conclusion

In recent years, reviews of the key chemical compounds present in the individual herbs used in the herbal formulae

are most useful, which will definitely help in generating evidence based pharmacology reports. Keeping in mind the various problems being encountered in the whole process of evidence based pharmacology, we sternly need the backing by pharmacokinetics studies and reporting of adverse events and herb-drug interactions as central to the safety assessment of herbal medicine. On the other hand, systematic review and analysis of the existing clinical evidence should be conducted in line with the intrinsic factors of herbal medicines so there should be good and substantial use of the herbal medicines in the daily health care system keeping in view their remarkable pharmacological properties with lesser side effects.

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