

Challenges and future prospects of herbal medicine

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ABSTRACT

Herbal medicine and treatment with herbs are not new to humanity, and it has been in practice since thousands of years back and still going on. Both the developed and developing countries are now focusing on the treatment based on herbal medicine because of its several benefits. India is the country of herbs, and the Indian traditional treatment system was also based on herbs and medicinal plant that is known as Ayurveda. India is the well-known mine of well-recorded herbal plants with their medicinal use. Herbal medicine is also called botanical medicines or phytomedicine. In a survey report of the World Health Organization, it was found that the 80% population of the world rely on traditional herbal medicine for primary health-care need. In fact in developed countries, alternative medicine is gaining popularity and it is increasing day by day because of their efficacy, safety, and lesser side effects. Herbal drugs possess a long history of its application and better patient tolerance on their application. This review article discusses the limitation and challenges faced for the production of herbal medicine.

Key words: Ayurveda, humanity, phytomedicine, traditional

INTRODUCTION

Herbal medicine or phytomedicines is related to use different parts of medicinal plants. Herbalism has a deep tradition of its application outside of conventional medicine. In the past decades, it is now becoming mainstream as advancement and developments in analysis and quality control along with advances in clinical research.^[1] As per the World Health Organization (WHO), phytomedicine or herbal medicine is the sum total of the knowledge, skill, and practices based on the theories and experiences indigenous to different cultures, whether explicable or not, used in the maintenance of health as well as in the prevention, diagnosis, improvement, or treatment of physical and mental illness.^[2] Traditional herbal medicines are naturally occurring, plant-derived substances with minimal or no requirement of industrial processing that has been used to treat illness within local or regional healing practices.^[3] Herbal medicines have been widely used for the beneficiary of mankind for the thousands of years much before the development of allopathic drug system.^[4] Phytomedicines initially from crude drugs include tinctures, tea, poultices, powder, and other herbal formations.^[5] The utilization and application of plants for healing purposes predate human history and lead to the origin of much modern medicine. Research and studies based on clinical, pharmacological, and chemical studies of these herbal medicines, which were derived predominantly from plants, were the only basis of most early medicines such as aspirin (willow bark), digitoxin (from foxglove), morphine (from the opium poppy), quinine (from cinchona bark), and pilocarpine (jaborandi).^[6] Herbal medicines still cover up about 70–80% primary health-care treatment of persons in the developing country of the world. The percentage for primary health-care treatment with herbal medicine is high because of the general belief that herbal drug

has no side effect instead of being cheap and easily available. As per the WHO, the use of phytomedicines exceeds to that of conventional medicines by about 3 times.^[7]

Classification of herbal medicines by the WHO on basis of their origin, evolution, and forms of the current use is as follows:

- Indigenous herbal medicines.
- Herbal medicines in systems.
- Modified herbal medicines.
- Imported products with a herbal medicine base.

Indigenous Herbal Medicines

Indigenous herbal medicines include those which were historically used in local community, tribal community or in region and are very well known due to its long usage by the local or specified population in terms of its composition, treatment and dosage. It must be easily available and can be used freely as well as easily by the local community or in that region.

Herbal Medicines in Systems

Herbal medicines in systems have been in use since many years and are documented with their special theories and concepts, and these are accepted by the countries.

Modified Herbal Medicines

Modified herbal medicines have been achieved by executing modification in shape, form including dose, dosage form, mode of administration or application, herbal medicinal ingredients, methods of preparation, and medical indications.

Imported Products with Herbal Medicine

Imported products with herbal medicine basically cover up all imported herbal medicines including raw materials and products.

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Imported herbal medicines must be registered and marketed in the countries of its origin.^[8] We have different systems of traditional medicine, and philosophy regarding the medicine and practices of each are influenced by the prevailing conditions, environment, and geographic area within which it was evolved.^[9,10]

Historical Background

Natural product coming from natural sources like plants was used by human beings over the years as food and medicines, especially plants parts or whole plant to cure and prevent disease.^[11] It is very much difficult to calculate the exact time when people started using plants as medicine, but some ancient literature and other sources are available which promises its start.

The oldest written evidence related to the use of medicinal plants for the preparation of drugs has been found on a Sumerian clay slab from Nagpur which is approximately 5000 years old. It comprised of 12 recipes for drug preparation and referring to over 250 various plants, some of them alkaloid such as poppy, henbane, and mandrake.^[12] The Indian holy books Vedas mention treatment with the help of plants, which are present in abundance in the country.

The Chinese book based on the use of roots and grasses "Pen T'Sao," written by Emperor Shen Nung circa 2500 BC, treats 365 drugs (dried parts of medicinal plants), many of which are being used nowadays.^[13,14]

Theophrastus (371–287 BC) led the foundation of botanical science through his books "De Causis Plantarum" - Plant Etiology and "De Historia Plantarum" - Plant History. In these books, he created a classification of about 500 medicinal plants known at the time.^[15,16] In the description of the plant toxicity action, Theophrastus underscored the important feature for humans to become familiar to them by a gradual increase in the doses.^[17,18]

Each country has their own document regarding the use of plants and herbs as medicine for treatment and cure of disease, and they differ from each other. In India, Ayurveda is the oldest system of medicine that is about 5000 years old.^[19] The Ayurveda text is actually the part of Atharvaveda which was in 1000 BC. In ancient time, it was transferred orally, and the first Ayurvedic text book was written and preserved in Sanskrit. Instead of fighting with disease ancient Ayurveda was meant essentially to promote health. Main text available regarding herbal medicine is Charak Samhita (1000 BC) and Sushrut Samhita (100 AD). Ayurveda text medica provides detailed descriptions of more than 1500 herbs and 10, 000 formulations. Diagnostics features along with signs and symptoms of over 5000 diseases or disorders are described in Madhav Nidan (800 AD). There are eight branches in the Ayurvedic study, and these are as follows:

- Kaya Chikitsa (general medicine),
- Kaumara Bhruthya (pediatrics),
- Bhutha Vidhya (psychiatry),
- Salakya (ENT and ophthalmology and dentistry),
- Shalya (surgery),
- Agada Tantra (toxicology),
- Rasayana (rejuvenation therapy), and
- Vajeekarana (sexual vitality).^[9]

Hippocrates, father of medicines, worked mainly on Anatomy and Physiology of human being and wrote more than 60 medicinal books.^[20] He also postulated a humoral theory that explains that

human body consists of four humor blood, phlegm, yellow bile, and black bile which are mainly responsible for the functioning of the body in healthy condition as well as in diseases.^[21] Hippocrates only used herb and is best known for saying; "Let your food be your medicine and let medicine be your food," "Sickness is caused by body's inability to digest its environment."^[22] The early 19th century is denoted as the turning point in the field of use and application related to medicinal plant. The discovery, substantiation, and isolation of alkaloids from poppy (1806) and other plants. In the meanwhile, the isolation of glycosides marked the beginning of scientific pharmacy. With the enhancement and upgradation of the chemical methods, other active substances from medicinal plants were also discovered.^[23]

Present Scenario

The herbal medicines or phytomedicines continue to expand rapidly throughout the world. Many people are now resorting to herbal products for the treatment of various health challenges in different national health-care settings. Last decades witnessed a surge in public interest towards natural therapies both in the developed and developing countries.^[24] The sections of the population that still rely on traditional practitioners and herbal medicines for their primary care in developing countries like, Africa up to 90% and India up to 70% of the population. In China, traditional medicine accounts around 40% of overall health care delivered, and more than 90% of general hospitals in China have units for traditional medicine.^[25-27] At present, herbs are applied for the treatment of chronic and acute disease and various ailments and problems such as cardiovascular disease, prostate problems, depression, and inflammation and to boost the immune system, to name but a few. In Africa, the Africa flower (traditional herbal medicine) has been used for decades to treat wasting symptoms associated with HIV.^[28,29] Now, it is believed that nature contributes about 90% to the new drug molecule. Nature has provided many effective drug agent such as dactinomycin, bleomycin, and doxorubicin, vinblastine, irinotecan, topotecan, etoposide, and paclitaxel (anticancer), mefloquine chloroquine, amodiaquine artemisinin, dihydroartemisinin, artemether, and arteether (antimalarial), metformin and eventually the other biguanide, harunganin, cryptolepine, and maprouneacin (antidiabetic), and calanolide A, curcumin, phenethyl isocyanate, and phenoxidiol (anti-HIV drugs).^[30,31] India has about 25,000 effective plant-based formulations used traditionally with over 1.5 million practitioners of the traditional medicinal system. There are 7800 medicinal drug manufacturing units in India that consumes about 2000 tonnes of herbs annually.^[32] The available data suggest that the traditional medicine has a significant market. Indian herbal market is of nearly 50 billion rupees with 14% annual growth. The worth of exported herbal product is about 1 billion rupees. The demand for medicinal plants is increasing everyday, and the WHO has projected that global herbal market will grow up to \$ 5 trillion in 2050 from the current level that is of \$ 62 billion. More than 70% of the global diversity are produced by India and China. The significant global herbal export market includes EU, USA, Canada, Australia, Singapore, and Japan, while Brazil, Argentina, Mexico, China, and Indonesia are new emerging herbal market.^[33]

Challenges Associated

Herbal medicines are introduced into the market without any mandatory safety or toxicological evaluation regarding the effect

of drug. Many of these countries also lack effective machinery to regulate manufacturing practices and quality standards of the herbal medicine. Challenges often encountered and common to many countries are those related to regulatory status, assessment of safety and efficacy, quality control, safety monitoring and inadequate or poor knowledge about traditional, complementary/alternatives^[34,35]

Challenges Associated to The Regulatory Status of Herbal Medicines

According to the definition, a dietary supplement is a product that is ingested and is intended to supplement the diet and contains a "dietary ingredient." The dietary ingredients in these products may include different vitamins, minerals, herbs, or other botanicals required by the body.^[36] Under the DSHEA, any additional toxicity studies are generally not required if the herb has been on the market before 1994.^[37] For this, FDA hauls the burden to prove that herbal medicinal product or "dietary ingredient" is toxic or not safe for use. The additional major challenge in many countries is related to the fact that regulatory information on herbal medicines is often not shared between regulatory authorities and safety monitoring or pharmacovigilance centers.

Challenges Associated to the Assessment of Safety and Efficacy

No one can contradict the fact that the requirements as well as the research protocols, standards, and methods needed for the evaluation of the safety and efficacy of herbal medicines are much more complex than those required for conventional or orthodox pharmaceuticals.^[38] A single herbal medicine or medicinal plant may contain more than hundreds of natural constituents, and a mixed herbal medicinal product may contain several times the number of one. In such an analysis of single active constituents may practically be impossible especially where an herbal product is a mixture of two or more herbs^[38]

Challenges Associated to Quality Control of Herbal Medicines

The quality of the raw materials used in the production of herbal medicines determines to a large extent the safety and efficacy. The quality of source or raw materials is dependent not only on intrinsic (genetic) factors but also on extrinsic factors such as environmental conditions, good agricultural, and good collection practices for medicinal plants, including plant selection and cultivation. It is the combination of many factors that make it difficult to perform quality controls on the raw materials of herbal medicines.^[39] According to good manufacturing practice (GMP), correct identification of species of medicinal plants, special storage, and special cleaning methods for various materials is important requirements for the quality control of starting materials. The major challenges are in the quality control of finished herbal medicinal products, especially mixture herbal products.^[38] Hence, the general requirements and methods for quality control of finished herbal products remain much more complex than for other pharmaceuticals. To ensure safety and efficacy of herbal medicines, the WHO continues to endorse the institution of quality assurance and control measures such as National Quality Specification and standards for herbal materials, GMP, labeling, and licensing schemes for manufacturing.

Challenges Associated to Safety Monitoring of Herbal Medicines

In the past few years, issues relating to increasing use of herbal or natural medicines or products in developed countries. Furthermore, the dependence of many people living in the developing countries on plants as a major source of medicines coupled with weak regulation of herbal medicines in most countries and the occurrence of high-profile safety concerns has increased awareness regarding the need to monitor safety and understanding of possible harmful as well as potential benefits linked with the use of herbal medicines.^[40] Adverse effects arising from consumption of herbal medicines are due to several factors among which include the use of the wrong species of plant, adulteration of herbal products, undeclared medicines, contamination, overdosage, misuse of herbal medicines by either health-care providers or consumers, and use of herbal medicines with other medicines. There is a lack of proper knowledge regarding the importance of taxonomic botany and documentation by most manufacturers of herbal medicines, and this poses peculiar challenges during identification and collection of medicinal plants used for herbal remedies.^[40] To overcome the confusion created because of the common names, it is necessary to adopt the most commonly used binomial names for medicinal plants. For example, *Artemisia absinthium* L., which has at least 11 common names, contains an active narcotic derivative. Hence, the effective monitoring of herbal medicine will require effective collaboration between botanists, phytochemists, pharmacologists, and other major stakeholders.

Future Prospects

Future is in the phase of increasing demand and fast-growing market of herbal medicines and other herbal healthcare products, in both developing and developed countries of the world.^[40]

CONCLUSION

In this scenario, the global acceptance and use of herbal medicines and related products continue to assume an exponential increase. Issues relating to adverse reactions in recent times are also becoming more vivid, increasing in prevalence, and no longer debatable because of the previous misconception of categorizing herbal medicinal products as "safe" as they are derived from "natural" source. Therefore, regulatory policies on herbal medicines need to be standardized and strengthened on a global scale. It is now laid in the shoulders of the regulatory bodies to monitor controlled and quality flow of herbal products and to facilitate their development to clinical trial stages.

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