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Resurgence of Traditional Medicine Systems with Special Reference to Indian Systems of Medicine and Modern Scientific Developments

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Abstract

With the revival of natural products there has been an increasing preference for herbal drugs, cosmetics, natural flavors, perfumes, dyes and pharmaceuticals as they are comparably less toxic and affordable. Thus there is an unprecedented demand for forest resources leading to over exploitation and even biopiracy. A significant aspect of the traditional medicine, which is mostly location specific-'Local Health Tradition' (LHT) is that it is self-reliant in nature and is almost entirely autonomous in character and rooted deep in the community, social traditions and cultural values. Traditional Knowledge (TK) is a community based system of knowledge that has been developed, preserved and maintained over generations by the local and indigenous communities through their continuous interactions, observations and experimentations with their surrounding environment. There are challenges ahead for the Traditional Medicine practitioners and the researchers working in this area and they endeavor to make this system of medicine a more acceptable and more standardized using modern science and technology. This can only be achieved if all the stakeholders of Traditional Medicine make a concerted effort with the proper backing of the governments to globalize and popularize this system of medicine by fusing ancient wisdom and modern science.

Keywords: Traditional medicine; Biogenetic resources; Equitable benefit sharing; Reverse pharmacology; Systems biology

Introduction

In order to standardize and globalize traditional medicines, Dr. R. A. Mashelkar, then Director General of CSIR, India while making recommendation after a national seminar on Ayurveda held at Chitrakoot in 2005 suggested a Golden Triangle consisting of traditional medicine, modern science and modern medicine. An earnest step in this regard is currently going on in selected twenty CSIR Laboratories in India along with a number of institutions in the private sector working on traditional medicine such as, Kottakkal Arya Vaidyasala. Currently, under CSIR's New Millennium India Technology Leadership Initiative (NMITLI) programme, several scientists have been working on establishing pharmaco epidemiological evidence-base to Ayurvedic medicines, practices and development of standardized herbal formulations. Randomized, controlled clinical trials for rheumatoid and osteoarthritis, liver diseases, diabetes, hypolipidemia, Parkinson's disease and many other ailments have been established.

Over 80% of the medicinal plants are collected from wild sources. But the increasing demand has led to over exploitation as well as unscientific extraction. Habitat degradation due to human interaction in the forest is also causing the rarity and even extinction of many important medicinal plants [1,2]. Therefore conservation, domestication and commercial cultivation of medicinal plants have become an urgent need of the day. Cultivation of medicinal plants is also essential to ensure quality of raw drugs, a pre- requisite for quality control and consistency in the manufacture of the finished herbal drugs. Cultivation and processing of medicinal plants can provide gainful mass rural employment. It is reported that in China about 100 million people are involved in medicinal plant industry. In India at present it is hardly 10 million [2]. Considering the rich and validated biodiversity and the great traditional medicinal heritage, India can involve rural masses in large scale cultivation and processing of medicinal plants enabling plant based pharmaceutical/drug industries to produce quality herbal drugs and successfully play a major role in the global market. Government of India has also established a National Medicinal Plant Board (NMPB) for promoting medicinal plant cultivation and its sustainable utilization. Still more concerted and coordinated efforts by all concerned are required to enable India to become a front runner in this fast developing sector of Industry.

Protection of traditional knowledge

Over the last 3 decades there emerged a great awakening on the link between sustainable livelihood and ecological health [3]. This understanding has led to various international, regional and local dialogues, development of laws and regulations in conservation and sustainable use of trade and commerce of bio resources. Side by side, breath taking research and development in science and technology led to the enhanced value addition in primary biological product and thereby creating wealth from the bio resources. The developmental strategy in the world in general is now focused for achieving a new world order marketed by equity and human welfare. The whole gamut or sustainable development of biodiversity is expressed in terms of conservation and sustainable utilization. The UN regulation like Convention on Biological Diversity (CBD) has provided a basic framework for countries to evolve appropriate regulatory mechanism for achieving above goals. Immediately after the adoption of CBD in December 1993, there emerged in June 1994 another international agenda-the World Trade Organization (WTO). WTO came out with another agenda to control economic order of the world. Throughout history, biodiversity has been the common asset of the local communities, with both resources and knowledge being freely exchanged and concept of sovereign rights

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or property rights in genetic resource was also alien particularly to the traditional communities of the third world countries. CBD has honoured this traditional practices and offered protection under Article 3, Article 8(j), Article 10(c) and Article 15.7 etc. The Trade Related Aspects of Intellectual Property Rights (TRIPS) Agreement of WTO brought in 1995, however, had a different agenda. CBD is founded on the principle that the local communities are dependent on biodiversity and should continue to benefit from it. The WTO administers a global trading system, much of which is founded on the private monopoly rights of traditional corporations over biodiversity [4].

CBD is centered on the principles of equity and ethics and, therefore, has more flexible provisions concerning protection of the rights of traditional communities over their intellectual property and traditional resources [4]. Article 8(j) and Article 15.7 of CBD explicitly expresses the need for recognition and rewards for indigenous peoples contributions to conservation and sustainable use of biodiversity. Article 8(j) of CBD states that "Respect, preserve and maintain knowledge, innovations, and practices of indigenous and local communities embodying traditional lifestyles relevant for the conservation and sustainable use of biological diversity and promote their wider application with the approval and involvement of the holders of such knowledge, innovations and practices and encourage the equitable sharing of benefits arising from the utilization of such knowledge, innovations and practices" [4]. The other important provisions of CBD that call for support and recognition of indigenous and traditional technologies are contained in Articles 10(c), 11, 12, 13 and 16. However, Article 16 is the one that is unequivocal about the protection of IPR of the traditional communities [4]. More detailed discussions and critical analysis on CBD and TRIPS, particularly on those provisions relating to informal innovations of IPR protection for traditional communities, are available in Gadgil et al. [5], Dutfield [6], Gupta [7] and Mashelkar [8].

Article 27 (3b) of the TRIPS excludes plants, animals (other than microorganisms), and essential biological processes for the production of plants or animals other than non- biological from patentability [4]. The same provision also requires the members to provide for the protection of plant varieties either by patents or by an effective *sui generis* system or by any combination thereof. These are the two rather contentious provisions in TRIPS, which the developing countries need to address carefully [4]. The main pitfalls in the TRIPS provisions are the failure to recognize the informal innovations emanating from traditional societies and imposing developing countries to develop *sui generis* system for plant variety protection based on the 1991 UPOV model [9]. The UPOV model is designed to provide protection for rights of plant breeders and other formal types on innovations. It excludes the rights of farmers who produce, select, improve and breed a plethora of diverse plant varieties [9]. However, the commitment to TRIPS make it obligatory for the members, especially the developing countries, to bring their national legislations pertaining to protection of patents and other intellectual property rights in harmony with the provisions of TRIPS, besides developing appropriate *sui generis* models for protection of plant varieties [4].

National Innovation Foundation (NIF)

National Innovation Foundation conceived by Prof. Anil Gupta of Indian Institute of Management, Ahmadabad, was established as autonomous society by Govt. of India in the year 2000 [10]. NIF works for recognizing, respecting and rewarding grass root level innovations and outstanding TK [10]. NIF has been scouting for documenting local innovations and linking their innovations for further valorization with science and technology experts. NIF has pooled a database of over 225,000 technological ideas, innovations and traditional knowledge practices (not all unique, not all distinct) from over 585 districts of India [10].

Botanic garden conservation international

In 2002, the Botanic Garden Conservation International (BGCI), U.K [2] with financial support from one of the world's largest financial services organization–the HSBC has launched an eco-partnership programme "Investing in Nature"-with the global mission of conserving threatened plants for ensuring the prosperity of future generation and local community through an effective world-wide network of botanic gardens. BGCI operates this botanic garden based global network programme in 11 countries-Argentina, Brazil, China, India, Indonesia, Japan, The Middle east, North America (including Canada and the USA) and South–East Asia. With Dr. P. Pushpangadan, then Director, National Botanical Research Institute (NBRI), Lucknow as the implementing agency for the 'Investing in Nature' Programme in India (IIN-India), NBRI organized a number of activities to support the partner botanic gardens in India to implement various conservation, education, data basing, networking, training, capacity building, and community empowerment programmes. The main focus of this five-year programme (2002-2006) was the implementation of the International Agenda for Botanic Gardens in Conservation [11] and the Global Strategy for Plant Conservation (GSPC) [2].

One of the significant activities under 'Investing in Nature-India' was to implement a Small Grant Project Scheme through awards of several grants per annum for 1 to 2 years in support of the best Indian botanic garden plant conservation projects that could contribute to biodiversity conservation, environmental education, and sustainable development initiatives for the benefit of the local communities. Under this new initiative, the Indian botanic gardens were poised to accept the challenge of conserving as many as 600 rare and threatened species of India's flora and making them in accessible *ex situ* collections for recovery and restoration programmes. Since 2003, 24 institutions representing botanic gardens, arboreta and community/conservation organizations under Central and State Government Departments, Universities and NGOs had been supported with small grant projects to undertake their activities, relevant to *ex situ* conservation and reintroduction research.

NBRI is now a national and international referral center for biodiversity conservation, sustainable utilization, bioprospecting, biotechnology and molecular biology with accreditations to several National and International agencies/organizations such as CBD, UNEP, WHO, IUCN, BGCI, MoEF, DBT, DST, etc. With its existing R and D expertise in plant conservation research and allied areas and with its recognition as a national coordinator of such an important global eco-partnership programmes as the Investing in Nature-India (BGCI-HSBC-NBRI collaboration), NBRI is well placed to function as a model of a Lead Botanic Garden. Such a garden should have facilities for conservation and germplasm augmentation cum training centre for the Rare, Endangered and Threatened (RET) plant–species and economically and ecologically important (flagship species, keystone plant species, indicator taxa etc.) plant resources of the Gangetic Plains. NBRI can certainly help in establishing such lead gardens. It is important to establish at least four to start with and later 10 such lead botanic gardens representing the ten biogeographic zones of India [2].

Nagoya protocol and India

India, being the leading country in ABS legislation with mechanisms in place, [12] developed in true sense the system of fair and equitable

sharing of benefits. On November 2014, the Ministry of Environment, Forests and Climate Change (MoEF and CC), GoI, in exercise of the powers conferred by section 64 read with subsection (1) of section 18 and subsection (4) of section 21 of the Biological Diversity Act 2002 (18 of 2003) and in pursuance of the Nagoya protocol on access to genetic resources and the fair and equitable sharing of benefits of their utilization to the CBD and in consultation with National Biodiversity Authority (NBA) issued guidelines of Access to Biological Resources and Associated Knowledge and Benefit Sharing Regulations, 2014, for research and operations of bio-survey and bio-utilization as well as procedure for access to biological resources [6]. The other aspect covered under the notifications includes the option of benefit sharing on sales price of the biological resources accessed for commercial utilization under regulation, collection of fees as well as procedure for transfer of results of research relating to biological resources. It also included the issues related to IPR and procedure for transfer of accessed biological resources and/or associated knowledge to the third party for research/ commercial utilization [12]. According to NBA, India's engagement with ABS issues has been progressive and noteworthy [13,14].

Knowledge based value added product

Knowledge based, value added product development and its commercialization has [1] become one of the fastest economic activities in the world. The liberalization of the global trade practice and other economic reforms evolving currently with the emergence of the United Nations Convention on Biological Diversity (UN-CBD) and the World Trade Organization (WTO) requires a deeper study and understanding, especially in the light of the latest path breaking achievements in science and technology particularly in areas like Information Technology (IT), Biotechnology (BT), Herbal technology (HT), and Nano-biotechnology (NBT). According to Mashelkar "Twenty first century will be the century of knowledge…" and "a nation's ability to convert knowledge into wealth and social good through the process of innovation will determine its future". A new thinking centered on the concept of 'knowledge engineering' for building future 'knowledge industries' is [1] now getting greater attention and acceptance in the world over.

India is also the first in the world to experiment a benefit sharing model wherein the traditional knowledge of a forest dwelling community was subjected to scientific study by scientists of Government owned national/regional laboratories and developed a value added, IPR covered and scientifically validated herbal drug which on commercialization shared the benefits(license fee and royalty) equally (1: 1) by the research institutes and the Kani tribe which is now known as Kani model/Pushpangadan model/JNTBGRI model of benefit sharing [1].

WHO's views

According to a survey conducted by WHO, the use of plant remedies is on the increase even in the developed countries especially among younger generation [15]. In the industrialized countries, the consumers are seeking visible alternatives to modern medicine with its associated dangers of side effects and over medication. The promotive and preventive aspects prevalent in oriental medicine, especially in the Indian (Ayurveda, Siddha, Unani and Amchi), and Chinese systems of medicine are finding increasing popularity and acceptance in the developed countries. During the past, WHO's Health Assembly has passed a number of resolutions in response to such a resurgence of interest in the study and use of traditional medicine [16].

The scientific evaluation and standardization of traditional remedies using exclusively the parameters of the modern medicine is both conceptually wrong and unethical. Evaluation of traditional remedies particularly those of the classical traditions has to be based on the theoretical and conceptual foundation of these classical systems of medicine, but may utilize the advancements made in modern scientific knowledge, tools and technology [16]. In fact it is important to combine the best of elements of concept and practice from traditional medicines and modern medicines with the objective to improve the health care system of humankind. Such an integrated approach to study and develop holistic health care system is termed as the Ethnopharmacological approach. The concept of ethnopharmacology research in India evolved in 1980s.

Ethnopharmacological and modern scientific methods

The concept and methods of ethnopharmacology research involve experts from diverse disciplines such as, Ayurveda, Siddha, scholars of Sanskrit and Tamil languages (who can correctly interpret the classical texts of Ayurveda and also its theoretical basis like 'Sankhya' and 'Vaiseshika' philosophy), ethnobotany/ethnomedicine, chemistry, pharmacognosy, pharmacology, biochemistry, molecular biology, pharmacy etc. [17]. The main objective of this approach was to develop appropriate techniques to evaluate the traditional remedies in line with the classical concepts of Ayurvedic pharmacy and pharmacology such as the 'Rasa', 'Guna', 'Veerya', 'Vipaka' and 'Prabhava', in other words 'Samagrah Guna' of the 'Dravya Guna' concept of Ayurveda.

Modern scientific methods and technology can contribute a great deal in conservation and sustainable utilization of biodiversity. Biotechnology could be profitably employed to undertake to study the structure, function and dynamics of every organism and also in conserving and optimal utilization of resources in a sustainable manner. *In vitro* conservation in the form of seed banks, tissue repositories, pollen/ovary bank or even DNA bank are some of the modern biotechnological methods of conservation of rare and endangered species besides other methods like the *in situ* conservation or other garden based *ex situ* conservation, etc. Biotechnological tools can also be employed in manipulating the living organisms to make and modify new value added products thereby converting biodiversity into economic wealth. Biotechnology is already playing a significant role in converting biodiversity into industrial and commercially valuable products, processes having increased productivity and application in many crucial areas such as agriculture (including aquaculture), health care (medicines, vaccines, diagnostics, gene therapy), environmental protection, bio-energy, etc. [1]. The emerging area of biotechnological application on biodiversity is known as bioprospecting. Mateo et al. [16] describes bioprospecting as the "systematic search for genes, natural compounds, designs and whole organisms in wild life with a potential for product development by biological observations and biophysical, biochemical and genetic methods without disruption to nature". Bioprospecting has thus three facets like "chemical prospecting, gene prospecting and bionic prospecting" [1].

Purity, batch to batch consistency in quality of medicinal plants are some of the critical requirements of botanicals. The most important things for assuring quality of botanical medicines require preparation of a comprehensive passport description of the species. This include correct identification of the plant species, selection of the correct genotype of the species, right edaphic and climatic conditions for its growing and right stage at which the harvesting of the medicinal parts to be made and proper post-harvest handling etc. A well-defined protocol and Standard Operation Procedure (SOP) from selection of the right genotype, cultivation methods, harvesting, post-harvest

handling, preprocessing, storage and upto manufacturing need to be worked out and meticulously followed for herbal drugs [2]. The various requirement of sourcing medicinal plants include correct taxonomic identification and authentication, study on the medicinal part: root, stem, bark, leaves, flowers, fruits, nuts, gum, resins etc., collection details such as, location, stage and developmental stage or growth of the plants for collection methods, pre-processing if any storage etc [2,18,19]. This is followed by the organoleptic examination of raw drug i.e. evaluation by means of sensory organs: touch, odour taste, microscopic and molecular examination, chemical composition (TLC, GLC, HPLC, HPTLC, GC, capillary electrophorosis, DNA fingerprinting), biological activity of the whole plant, and shelf life of raw drugs. This is followed by well-defined Good Manufacturing Practices (GMP) and scientific validation including toxicity evaluation, chemical profiling, pharmacodynamics of drug in the body, pharmacokinetics-absorption, distribution, metabolism, mechanism of action and execution, proper dosage form, proper presentation and packing and proper claim of therapeutic merits-compared with other drugs.

Reverse pharmacology

Reverse Pharmacology is the term used in the scientific elucidation of the pharmacological action of the clinically proven/time tested traditional remedies [2]. Ethnopharmacology is also considered to be a time saving cost effective method of new drug discovery. The classical drug discovery has become very complex, capital-intensive and time taking process in spite of the technological support such as High Throughput Screening (HTS) and combinatorial chemical synthesis etc. Traditional medicines like Ayurveda, Siddha and Unani are in vogue for over several millennia and therefore clinical evidence comes as a presumption. However, for bringing more objectivity and also to confirm traditional claims, systematic clinical trials are necessary. In Ayurvedic Medicine research, clinical experience, observations or available data becomes the starting point. In conventional drug research, it comes at the end. Thus the drug discovery based on Ayurveda follows a 'reverse pharmacology' path. Herbal drugs should also need to conform to the global standards such as dissolution time, microbial, pesticidal and heavy metal contaminations etc.

Application of DNA micro-arrays

The DNA array (micro array, gene array) is the latest molecular methodology applied to study herbal medicines [2]. The term DNA (gene) array refers to a solid surface to which is attached numerous small pieces of DNA representing short sequences of specific genes. The array may be macro-arrays which are usually fabricated membrane of nylon, or other relatively inert material, impregnated with scores or hundreds of pieces of DNA in the [2] form of discrete spots. In contrast the micro array is usually a siliconized glass slide to which thousands of pieces of DNA fragments or oligonucleotides are precisely spotted by a robot [20]. They demonstrated it in their pioneering study on DNA micro arrays that is relatively simple manipulation of cultured cells (mamalian or yeast) such as addition of fresh serum and medium could result in profound changes in the transcription profile, both qualitatively and quantitatively. This is obviously relevant to the use of herbal medicine, since the herbal drugs are mostly polyherbal mixtures comprising numerous potentially bio-active molecules, to all of which individual cells of superficial tissues might be exposed and hence modulated. Hudson et al. [19] have reviewed about 18 studies published during the period 2001-2003 in which some form of herbal medicine has been evaluated in cell cultures or in animals, by means of DNA arrays. There have been important studies on gene expression analysis, in response to herbal preparations, which involved examination of selected gene as well as gene arrays containing thousands of genes. Many of the array studies utilized Affymetrix or other commercial form of arrays or the custom prepared micro arrays on glass slides with wide variety of genes represented. The science of proteomics is rapidly approaching the same level of analytical capability as genomics and soon we will be able to correlate transcription changes with protein changes for a given herbal preparation [2].

System biology

Conventional medicines provide data on specific action of drugs. But with the better understanding on cell biology it is now clear that biological system is just not an assembly of tissues, cells, genes or its products, the proteins. But what is important is the traffic and cross talk between them, i.e., the biological function of the whole system i.e., system biology. System biology is defined as "studying biology as an integrated system of genetic, protein, metabolic, cellular and pathway events that are influx and interdependent". It was the advancement made in genomics that led to the development of system biology [15]. It involves massive profiling experiments at different biological levels such as DNA, mRNA (transcriptomics), protein (proteomics) and metabolites (metabolomics). This kind of approach, in fact, accounts for the holistic approach of most of the oriental systems of medicine more particularly Ayurveda and Siddha.

The latest advancements in molecular biology and genomics particularly after completion of Human Genome Project and development of novel diagnostic tools and technology etc. opened up a new world of possibilities providing a better insight into the mode of biological action of drugs by comparing the changes in the transcriptome, proteome and metabolome patterns when compared to those observed with known drugs [15]. Such an approach is now known as system biology and metabolomic approaches paving towards personalized medicines by measuring the activity in a living organism (which can be anything from cell culture, animals to patients) for extracts with different combinations of compounds that correlate with the activity. Good examples of this approach are the methods developed for urine analysis that allow the diagnosis of a variety of diseases as well as measuring possible liver or kidney toxicity [15]. Analysis of large numbers of urine samples of healthy persons and patients made by NMR has resulted in the identification of certain biomarkers for diseases. This is known as metabolomics approach. Using system biology approach for the organism and combining this with metabolomics data for different extracts of medicinal plant or fraction thereof, it should be feasible to make correlations between the occurrence of certain compounds in the extract and their activity. This means that activity due to synergism and pro-drugs might be proved, and even the responsible compounds can be identified [15].

Metabolomics

Metabolmics is a new born cousin of genomics and proteomics. Specifically, metabolomics involve rapid, high through put characterization of the small molecules [15] metabolomically found in organisms. Since the metabolism is closely tied to the genotypic of an organism its physiology and its environment, metabolism offers a unique opportunity to look at genotype-phenotype as well as genotype-envirotype relationships. Metabolites are the small chemical components in every cell. Major traits such as food quality, taste, nutritional value, toxicity, allergencity etc. are all directly correlated with the presence or absence of specific combination of metabolites.

Metabolomics is defined as the analysis of changes and regulation in the complete set of metabolite (small organic molecules, molecular

weight usually<1000). The term metabolomics introduced in the year 1990 is in analogy to genomic, transcriptomics and proteomics and the most recent of the "omic" sciences. The importance of identification and quantification of intra cellular metabolites has recently obtained a necessary role in system biology [21,22]. Thus metabolomics is the systematic study of small molecule biomarkers that represent the functional phenotype in a cell, tissue or organism [15].

Conclusion

Rapid and widespread environmental, economic and social changes have led to urgent global questions of standardizing traditional medicines with respect to quality and efficacy. Concerns of sustainability in developing countries like India can be very different from that of industrialized countries. In developing countries, equity and social justice are central to addressing sustainability, along with environmental concerns. An interdisciplinary approach making use of the advanced tools and methods of modern science has to be judiciously developed in evolving globally acceptable and universally applicable herbal drugs and formulations. Thus we have to develop an integrated perspective on sustainability of traditional medicine along ecological and social dimensions.

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