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Review Article

THE CHALLENGES WITH THE STANDARDIZATION OF AYURVEDIC DRUGS

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ABSTRACT

The use of Traditional medicinal products continues to grow rapidly across all over the world while the safety of these products has been raised. As the last century saw a predominance of communicable disorders this century can be considered as a century of Non communicable Diseases. The main issue here is people consuming traditional medicine along with contemporary with a preoccupied thought that these medicines are free from adverse effects. But all traditional systems are not like that. Ayurveda which is a complete and ancient system with the present aim of accomplishment of physical, mental, social and spiritual well being at a global front. Even though substitution, adulteration, improper focus on quality is pulling down the popularity of Ayurveda, hence purity and safety of Ayurvedic medicines along with strict Standardization is need of an hour.

KEYWORDS: Ayurveda, Standardization.

INTRODUCTION

The standardization of drugs is the confirmation of its identity, quality and purity of the drug and later the reproducibility. Standardization also ensures the drug is safe throughout all its life including production, shelf-life and how long it can be used after opened. To standardize the creation and purity of Ayurvedic drugs is important to ensure the safety of a consumer and those who handle the drug. It also helps ensure that a consumer or patient is receiving the same product every time they use the drug. Standardizing drugs also ensures that they are receiving the highest quality of raw ingredients and herbs[1]. The challenge with standardization of Ayurvedic drugs and herbs is the lack of clear enforced guidelines on how herbs and oils need to be prepared, in what type of controlled environment and prepared by WHO. Another challenge with standardization is that if guidelines are in place, they differ depending on the country those drugs and herbs are used. Finally, the overall lack of research by the scientific community currently dedicated solely to Ayurvedic drugs, makes it difficult for drugs to be reproduced and standardized if doctors or consumers have no context to how they were created, prepared and kept.

Ayurvedic drug standardization is controlled under the Drugs and Cosmetics Act of 1940. Under this act, it is written how drugs must be packaged, and the product must follow certain guidelines, to ensure safety and quality. The guidelines exist but many times they are not followed or not enforced, which endangers consumers and handlers of these drugs. It can be poisonous to some patients and educe toxic reactions in the body. Any and all risks should be advertised in the packaging of drugs and herbal products. In a survey study conducted by the Department of Clinical Pharmacology, TNMC and BYL Nair Ch. Hospital in Mumbai, headed by Dr. Supriya Bhalerao, the prevalence of mislabeling or ignoring aspects of the Drug and Cosmetic Act was revealed. Found on all the Ayurvedic drug container labels was basic manufacturing details, references from authoritative books were mentioned in about 90%. Only about 55% of classical formulations mentioned an ingredient list, and only about 20% of classical formulations labeled any form of warning or cautions[2].When these guidelines are not followed by manufacturers, it endangers the consumer of these products. This will compromise any strides the government takes to change and increase the laws and guidelines surrounding the standardization of herbs and Ayurvedic drugs. The lack of warning and advised dosage for these drugs is very serious and can cause irrational use or abuse of these drugs by a consumer. The Ayurveda community cannot look forward to the standardization of their drugs and safety for their patients before clear guidelines are enforced or they are further outlined in the Drugs and Cosmetics Act of 1940.

Another challenge in the standardization of Ayurvedic drugs is how widespread and international Ayurvedic medicine is now, rather than just in India, holistic medicine has reached the western world. In a paper released by the PCTE Institute of Pharmacy, they claimed that, "There is no legal control model over medicinal plants. Different countries define medicinal plants or products derived from them in different ways and have adopted different approaches to licensing, dispensing, manufacturing and trading to ensure their safety, quality and efficacy"[3]. For example, in the United States, according to Mike Levy, Director of the Division of New Drugs and Labeling Compliance in the Office of Compliance, part of FDA's Center for Drug Evaluation and Research (CDER), Ayurvedic drugs, "are not generally reviewed or approved by the Food and Drug Administration (FDA)[4]. While in India Ayurvedic drugs need to have stronger, enforced guidelines, in the United States they need guidelines to be written and the FDA to be involved in these processes. Ayurvedic drugs and herbs are sold in the U.S either online illegally or they are advertised as dietary supplements, therefore do not need to follow and be held accountable for the same tests and standardization practices that regular FDA approved drugs must be. By no means are all Ayurvedic drugs dangerous or should be illegal in the United States, they are very useful and helpful to patients in the right hands of a trained professional. These drugs however, need to be standardized even when leaving India, it is the duty of the U.S FDA to be proactive in standardizing these medicines and be held responsible for the safety of international products being shipped and sold to United States residents.

It is important to note that research and the need for standardization go hand in hand. To have a successful standardization guidelines and process, there needs to be research on the herbs used and their reactions with and outside of the body. To properly research these reactions and benefits of these drugs and herbs, there needs to be an ability of replication of the drugs, therefore standardization practices must exist. The problem arises that in this modern era any research that is being conducted involving Ayurveda and its drugs are not benefiting the ancient medicine. Much of the research into Ayurveda is for the direct benefit and extend modern bioscience. According to Gokarn, S. Gokarn, R. the authors and researched of Problems faced in Ayurvedic Drug Research, "There are only few data bases such Researches in Ayurveda published by which provide information about Researches done all over India"[5]. Research should be centered around helping develop Ayurvedic practices rather than the extension of modern bioscience and medicine. With this focus on research consumers and prescribers will be able to more accurately and safely understand the drugs they are consuming or prescribing to a patient. Making the medical community aware of the proper documentation and publication could make research and develop for drug standardization more successful.

Standardization is very important to ensure the protection of consumers and the integrity of doctors and assistants. Many challenges arise out of this standardization of these drugs such as the lack of written and enforced guidelines from the government and medical boards for drugs. Also, the international guidelines need to be clear on the imports and exports into other countries such as the United States. Finally, the lack of research solely done on Ayurvedic drugs is a challenge to standardization practices and efforts as it makes it difficult to ensure replication of the drugs and analyze any consequences of taking those drugs. The Indian government must make strides for this standardization to ensure the safety for consumers both domestically and internationally. Making sure that consumers are receiving the same standardized drugs and herbs makes the benefits of these drugs greater and ensures that benefits are repeatable for many consumers, and holistic natural healing remains possible for future generations.

DISCUSSION

Ayurveda, traditional system of medicine of India is serving about 80% of Indian population. Most of the scholars are under impression that Ayurveda means it is Traditional Indian Herbal System. As like the other systems existing in the word like TCM (Traditional Chinese System of medicine) or Kempo (Japanese traditional system of medicine) Scholars must study the herbs and other sources as well as its various dosage modalities mentioned in Ayurvedic treatise. As above some scholars misinterpreted Ayurvedic drugs or its dosage modalities. De Smet[7] reviewed and comparing with system like TCM, He has listed 127 references, and reviewed on four Chinese herbs Ginkgo biloba, Hawthorn, Saw palmetto, and St. John's wort. While Many herbal compound are not properly described in the composition, they are sold on over the counter use [8]. But there is no clear indication of medical fraternities role as William Osler rightly mentioned "Learn to see, learn to hear, learn to feel, learn to smell, and know that by practice alone can you become expert" Though, adverse effects associated with herbal products. Japanese Ministry of Health, Labor and Welfare says that Chinese dietary supplements can damage liver[9]. Ayurveda focus on healthy natural products There are hundreds of natural products are

mentioned in Ayurvedic treatise. The intent are not providing an exclusive review on DSHEA (Food material other than drugs) Neutaraceuiticals. There are hundreds of databases available to gather more n formation about them. It is advocated that better to use natural products with better precautions. But in Ayurvedic medicine if you standardized as per Ayurveda siddanta (Principle). It will better to collect the information about Ayurvedic drugs in MEDLINE (Medical analysis and retrial system) Cochrane, Indian Ayurvedic Pharmacopeia Published by Government of India. *Bhasmas* (Incinerated or calcinated preparation) are unique Ayurvedic metallic preparations with herbal juices mentioned in Ayurvedic classics[10]. The authors of Traditional medicine. to approach for drug discovery maximum extent about reverse pharmacology[11] and as Ayurvedic classics mentions we are also think about Networking pharmacology. When C.P Thakur was the health minister of India, He was very keen to bring in CAM as a part of teaching and training programme in AIIMS, Delhi. Because of the severe objections of faculty of AIIMS he could't introduced CAM at that stage. Carry on message-What Rodalph Virchow said, He said "Medicine is a social science and politics is nothing but medicine on a large scale.

CONCLUSION

Every system has its own loopholes from infrastructure to lack of well experienced staffs. While it is our duty to not accepting blindly anything also as well as not promoting quackery. at a present around 200 universities running various kind of Ayurveda courses. It is clear there is no NEW method is required if we standardize drug by *Aptopadesh* i.e., method told in the different Ayurveda treatise. It is our duty to understand where exactly evidences required and where understanding is required. It is necessary for us to prepare Ayurveda standardized or prepare as per medicine Ayurveda pharmacopeia. But as we are in the era of Globalization we have to concentrate on standardization using advance technology need to study the herb-drug interactions etc. and make it evidence based medicine.

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