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TOXICITY AND MISUSE OF HERBAL DRUGS: MYTHS AND SCIENTIFIC EVIDENCE

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ABSTRACT

For hundreds of years, herbs were utilized by humans; today, herbs are still widely recognized across the globe as alternatives to prescription medications because of their natural origin. Herbs are associated with cases of poisoning due to adverse effects like liver failure following use of kava or comfrey, heart disorders related to consumption of ephedra, and undesirable drug–herb interaction, such as St. John's wort. The main reason why herbs can be harmful is the lack of regulatory measures to regulate their quality, which leads to herb contamination and admixtures as well as uncontrolled dosages. Consequently, patients cannot distinguish herbs which can be helpful and harmful to them. It is crucial to disseminate information about herbs and promote awareness regarding herbs among the community in order to ensure the safety of their use. Using herbs safely while receiving their medicinal benefits is entirely possible by combining culture and science.

KEYWORDS: Herbal medicine, toxicity.

1. INTRODUCTION

Herbal medicines are perceived as “natural, hence safe.” However, scientific findings indicate a different reality. Herbal medicines have moderate toxicity, although improper use, quality concerns, and interactions with prescribed medication can be dangerous.

Herbal medications have long been utilized in Ayurvedic medicine, Traditional Chinese Medicine, and other traditions of Unani medicine.[1]

Myth vs. Reality:

The assumption that herbs are safe because "they have no side effects" is what drives people to self-medicate with herbs excessively, causing poisoning.[2]

The practice of withholding from healthcare professionals information about herbal therapy, together with the insufficient knowledge of clinical staff on the pharmacology of herbal medicines, increases risks even further.[3]

Types and Sources of Toxicity

Plant toxins: pyrrolizidine alkaloids, furan derivatives, anthraquinones, alkenyl benzenes, aristolochic acids, gink golic acids can cause hepatotoxicity, nephrotoxicity, genotoxicity, and carcinogenicity.[4]

Quality issues: identification errors, substitution with counterfeit drugs, heavy metal contamination, pesticide residues, mycotoxin contamination, and microbial contamination are common.[5]

Improper usage: Overdose, chronic intake, consumption during pregnancy or childhood, and improper administration are all factors that contribute to the increased likelihood of toxicity.[6]

2. Herb-drug interactions and misuse

Herbal supplements are frequently used in conjunction with prescription medications, but often not disclosed, making drug interactions possible due to changes in absorption, metabolism via CYP450 enzymes, transporters, and pharmacodynamics.[7]

Reported consequences have included therapy failure, potentiated toxicity, and clinically relevant drug-induced side effects, especially in patients undergoing cardiac.[8]

Safety Assessment and Regulation

According to systematic reviews, herbal medicines appear safe during clinical trials; however, there is poor monitoring, and most herbal preparations are not well tested.[9]

In modern toxicology studies, testing for toxicity employs in vitro, in vivo, omics, and DNA barcoding approaches; nevertheless, the regulatory authorities and labelling are still lagging behind.[10]

2. Strategies to Improve Safe Use of Herbal Medicines:

A large number of people who support the application of herbs hold that herbs that have been used for a long time and which have been known by the general population are safe to consume provided that the dose administered is right.[11]

The main problem is whether the absence of proof of hazard is proof of an absence of hazard.

Acute symptoms and immediate toxicological consequences, such as stomach disorders and skin reactions, are easily identified as being due to the herbs. The delayed toxic effects include cancer, diseases of the liver, kidneys, reproductive malfunction, birth defects.

In relation to drug products, a product's safety may be claimed only when the null hypothesis of toxicity has been rejected through proper experiments and adequate power.[12]

Important Measures for Safe Consumption of Herbal Medicines:

Solicit Professional Recommendations: Inform doctors or pharmacists that you are taking herbal medicines to avoid any bad interactions with your medication.[13]

Enhance Public Information Initiatives: Raise public information on the potential threat from interactions between herbs and other drugs.[14]

Adverse Drug Reaction Monitoring Systems: Adopt a program for monitoring adverse drug reactions to herbal products.[15]

3. Global Use of Herbal Medicines

Herbal Medicine, Phytotherapy, Botanical Medicine, and Plant Medicine refer to the use of seeds, berries, roots, leaves, bark, and flowers of plants for therapeutic purposes. One of the most ancient forms of medical practice is herbal medicine.

The reasons behind the renewed interest in herbal medicine in the recent years include the increase in medical costs, mistrust of artificial medications, prevention of diseases, the renaissance of medical traditions, and scientific researches proving the efficacy of medicinal plants.

Important Medicinal Plants Across the Globe:

It must be acknowledged that there are countless numbers of plants that possess some healing qualities. However, some plants are especially worth considering because of their widespread use and scientific support.

Turmeric (Curcuma longa) remains widely used throughout South and Southeast Asia. The herb is abundant with curcumin, which is beneficial for arthritic patients, individuals suffering from metabolic syndrome and inflammatory bowel disease.

Ginseng (Panax ginseng) is an essential herb in Traditional Chinese Medicine due to 2,000 years of its usage and revitalization and mental improvement effects. Ginsenosides have been extensively investigated in connection with their adaptogenic, immunomodulatory, and anti-cancer properties.

Aloe vera has been traditionally used throughout Africa, Asia, and North America in alternative medicine due to its ability to have anti-inflammatory effects, heal wounds, and serve as a laxative.

Artemisia annua (sweet wormwood) led to the creation of one of the most important antimalarial drugs known as artemisinin. Artemisinin was discovered by Chinese pharmacologist Tu Youyou in 2015, and she won the Nobel Prize because of her work on that drug.[16]

Factors to Consider Regarding Safety and Adverse Reactions:

It is often believed that natural products cannot pose any harm since they are considered natural. However, herbs can have serious adverse effects when used inappropriately, at high doses, or when taken in conjunction with medications prescribed by doctors.[17] One of the main factors in this regard is the issue of herb-drug interaction. One example of this is St. John’s wort (Hypericum perforatum), which is known to be a strong inducer of cytochrome P450 enzymes and an effective inhibitor of several medicines including antiretrovirals, oral contraceptives, warfarin, and cyclosporine.[18]

Education and Awareness

There is need to train healthcare professionals and pharmacists on contraindications, interactions, and safety through WHO and ISoP initiatives. Community education addresses the belief that herbal medications are "safe because they are natural," ensuring that people

consult before consumption, being aware of dangers such as those associated with Traditional Chinese Medicine and Western medication.[19]

Quality Control Strategies

The Good Manufacturing Practice (GMP), analysis of metal content and pesticide residue, and product standardization guarantee reliability and purity. The literature highlights the necessity of accurate labelling and scientific evidence in preventing contamination and differences in the botanical source, as recommended by WHO and EDQM.

Personalized drug therapy begins with the use of low-risk plants followed by the addition of one plant at a time, providing the opportunity to evaluate effectiveness and cater to vulnerable populations, such as pregnant women and older adults.[20]

Herb-drug interactions

Interaction between herbs and drugs could be considered an important issue in terms of the results of illness treatment.

Herbs could be divided into different classes of popularly used herbs. The widespread adoption of medicinal herbs has triggered numerous health-related issues concerning the safety and effectiveness of these herbs.[21]

Less than 40% of people have informed their physicians on their consumption of herbs, and physicians are not aware of the harmful consequences of drug-herb interactions.

Based on a survey conducted among 1,000 elderly people, 538 patients have stated 1,087 drug-herb interactions, 30 of which resulted in adverse reactions.[22]

4. Future Research Directions in Herbal Medicine

FUTURE PERSOECTIVES ON PLANT BASED AND HERBAL MEDICINES:
SCIENTIFIC RESEARCH: Higher number of studies to prove the effectiveness and safety of natural medicines
Innovation and technology: Innovation in the process of formulation and delivery mechanism of the compound derived from plants.
Sustainability and ethics: Importance of sustainability and ethics in the formulation of herbal medicine.

Research areas for the next five years (from 2021 to 2026)

Scientific validation, technology-based formulations, safety/efficacy standardization, integration with modern medicine, and harmonization of regulations across the globe are the major areas of future research in herbal medicine.[23]

Evidence-based clinical trials

Among many others, one of the most important research areas includes the performance of randomized control trials in regard to the use of herbs for treating chronic diseases such as diabetes, cancer, cardiovascular diseases, and neurodegeneration. The findings of studies conducted in 2021-2026 indicate the necessity to perform evidence-based trials to incorporate herbal medicines into integrative medicine in the developing world.[24]

Safety issues, interaction, and regulation of herbal medicine

The research carried out in the following period shows that among other issues, the key research topics include more investigations of the interactions, safety, and negative impacts of the herbal remedies used together with synthetic medications. The researchers suggest implementing strict regulations in order to comply with the WHO policy concerning the use of traditional medicine until 2034.[25]

Integration and Personalization of herbal medicine

Current research involves the application of Phyto-Pharmaco-Gene-Meta Bionomics and customized herbal medication, along with gene and metabolism analysis. Use of herbal medications with synthesized medications to treat ailments such as cancer and diabetes is proving to be a promising field for the future, because this would mean that customized medication treatment would be possible.[26]

5. Contamination and Quality Issues in Herbal Medicines

Herbal medicines, which are known for their natural healing properties, have been scrutinized in recent years due to the high level of contamination and poor quality, which may pose a risk to human health.

Types of Contaminants

There are three major types of contaminants: heavy metals, microorganisms, and pesticides. Heavy metals, such as lead (Pb), arsenic (As), cadmium (Cd), mercury (Hg), and copper (Cu), are impurities in herbs because of contamination from contaminated soil or water,

fertilizer, and environmental pollution. In an international study where 1,773 samples were analyzed, all contained heavy metals, 98.98% and 99.89% were lead and copper, respectively. Over the threshold of Pb and Cd contamination, rates of 5.75% and 4.96%, respectively, were reported compared to the standard set by the Chinese Pharmacopoeia. [27] Bacteria like E. coli, Salmonella, and fungi, which produce aflatoxins, multiply in herbal products as a result of inadequate drying and storage processes, representing 70% of the global market products according to estimates by the World Health Organization.

Causes and Sources

This is caused by the presence of the external and internal factors. High concentrations of Cadmium (Cd) and Lead (Pb) were recorded in the rhizome and root, while high concentrations of Copper (Cu) and Mercury (Hg) were found in the flower. Herba had the highest concentration that exceeded the limit level (58.16%). Lack of proper GACP at harvest stage, lack of good GMP during preparation, and contamination throughout the supply chain are the causes of the problem, particularly in China and India.[28]

Health Risks

The health problems arising from heavy metal include kidney toxicity, neurotoxicity, and cancer, whereby arsenic is the most dangerous in hazard assessment, because it has the highest HI index (HI = 11.47), and carcinogenic potential above 10^{-6}. Lead (Pb) and Cadmium (Cd) impair immune system functioning, and fetal development, while the fungus such as aflatoxins, is carcinogenic. [29]

Studies that Have Disclosed Heavy Metal Contamination

There was one study published in 2021 which showed 30.51% of 1,773 Chinese herbs contained over-limit heavy metals which include Plantago Asiatica and Curcuma Longa. In India, 70% of ayurvedic herb samples were found to contain heavy metals while microbe presence in raw herbs and pesticides in 40% of samples is reported. Issues about microbial contamination are seen in studies done in Africa from 2000-2024.[30]

QUANTITATIVE ANALYSIS OF HEAVY METALS PRESENCE IN SAMPLES

Average, the rate of detection, and the rate of heavy metals detection in herbs have been analyzed. Figures were drawn using R software [no IDE-R, the Linux terminal; R version 3.5.1. (2018-007-02) "Feather Spray" Copyright © 2018, The R Foundation for Statistical Computing on: x86_64-pc.[31]

ISSUES IN EVALUATING THE SAFETY AND EFFECTIVENESS: There is no doubt that the criteria and methods of evaluation of the safety and effectiveness of herbal medicines differ greatly and even sometimes do not coincide with those criteria applied to ordinary medications.[32]

6. Scientific Evidence: Safety and Efficacy

Herbal medicines lie at a critical point between traditional medicine and pharmaceutical drug therapy. Their international usage has surged dramatically due to natural perceptions, cultural beliefs, and availability, although scientific validation regarding their safety and efficacy is inconsistent. [33]

Efficacy Evidence

Herbal efficacy evidence is evaluated using the same evidence hierarchy used for conventional medicine; RCTs and meta-analysis are high-quality forms of evidence.[34]

Methodology and Regulatory Issues:

There are several common issues that compromise the credibility of evidence available to date. Most studies carried out on herbs are usually small, short in duration, and badly designed[35] (for example, heterogeneity within groups, insufficient dosages, no control group or blinding, and weak outcome measures).[36] Standardizing the active constituents is another issue affecting the interpretation of dose-response relationships.[37] While regulations in some areas require evidence from clinical or pre-clinical testing before allowing marketing, others permit marketing without evidence, particularly when the herb has a rich tradition of use.[38]

7. Documented Toxicities and Adverse Effects

The side effects that have been identified from the use of pharmaceuticals are numerous and diverse, from relatively harmless conditions to onces severe enough to inflict harm at the organ level and even lead to death.

These side effects arise from the direct effects of drugs, both target-specific and otherwise, such as idiosyncratic effects of the drug through immune response, drug metabolites, and drug dose-related toxicity.

Adverse reactions on hematology and immunology:

Pharmacological reactions affecting the blood are those where cytopenias are involved, meaning drug-induced anemia, leukopenia, and thrombocytopenia; drug-induced disorders in

blood clotting; and immune reactions damaging the body's hematopoiesis.[39] Some examples of adverse reactions in this case are thrombocytopenia induced by heparin, agranulocytosis by quinidine and quinolones, and thrombosis due to certain immunological reactions from vaccines and biologics. Another immunological effect is hypersensitivity.[40]

Broader implications

Based on the systematic study of other drugs, such as herbal drugs and cannabidiol, it has been found that there is a predominance of mild to moderate toxicity effects; nevertheless, they must be closely monitored for any serious toxic outcomes and potential drug interactions[41] Overall, from this set of literature, one thing becomes evident about the significance of toxicity and adverse effects, which are not just limited to safety analysis, but require consistent updates as well.[42]

8. Pharmacovigilance of Herbal Medicines

Herbal medicines are widely used across the world, but are regarded as "natural and safe."[43] But many herbs remain untested without regulatory authority; besides, the harmful effects of many herbs remain unnoticed. Phyto-Vigilance is one of the types of pharmacovigilance involving the monitoring, evaluation, and prevention of adverse reactions due to herbs.[44]

Need for PV on Herbal Drugs:

Herbal products are likely to cause liver or kidney damage, allergic reaction, toxic reactions and interaction with drug substances, which are likely to pose a threat to users' safety.[45]

The data on safety is incomplete because some of these herbs have neither been tested nor evaluated.

Measures for improving Safety:

Approaches and future possibilities Incorporate herbs into PV: Use the same reporting forms and databases for both conventional drugs and herbal products.[46]

Improve regulation and quality management: Set standards in manufacturing, labelling, botany for avoiding contamination and inconsistencies.

Education for participants: Educating healthcare professionals, herbalists, manufacturers and consumers about hazards of the herbs and need for adverse events reporting.

Adverse events reporting made easier: User friendly and multichannel methods with feedback.[47]

Current System of Pharmacovigilance and Its Limitations:

Most countries have their regulations and PV agencies at national level, however, safety evaluation of herbal medicines is generally insufficient.[48]

The WHO has developed guidelines for integrating herbs in existing pharmacovigilance systems.[49]

This is exemplified by examples from various countries where, although systems exist, the reporting system, lack of proper training, and inferior systems dominate.[50]

9. CONCLUSION

However, the recent increase in the use of herbal medicines around the globe over the past three decades has seen scientific scrutiny into the safety, efficiency, and toxicity of phyto therapeutic drugs.

Herbal medicines should be used cautiously by pregnant women since most plants possess uterotonic, teratogenic, or abortifacient characteristics. The usage of aloe vera, pennyroyal, and blue cohosh is forbidden while pregnant.

Myth-Reality Duality: Scientific Perspective: Numerous myths have been debunked in the course of clinical and empirical research. First, the statement "centuries of usage suggest safety" is scientifically inaccurate. Centuries of usage do not equal clinical.

Educational and Public Health Duties: The findings from this investigation highlight the urgent need for public health education on the safety of herbal items. There is a severe lack of public awareness regarding this issue. Survey findings show that the majority of herbal product users believe that there is no risk involved with using these items. Users are being misled by manufacturers who emphasize the natural and traditional nature of these products but fail to inform them of any potential dangers.

Future Directions and New Developments: A few factors are shaping the future of herbal medicine.

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