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Toxicology and safety profile of Ayurvedic drugs: A review

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Abstract
Ayurvedic medicine, an ancient system of healing, utilizes a wide variety of plant-based and mineral formulations for the treatment of various ailments. However, concerns regarding the toxicity and safety profile of these drugs have emerged with their increasing use in modern times. The present review aims to assess the toxicological aspects of Ayurvedic drugs, with a focus on identifying potential adverse effects, toxicity mechanisms, and safety considerations. Ayurvedic formulations are often composed of multiple ingredients, which may interact synergistically or antagonistically, raising concerns about their safety, especially when used in combination with other drugs or in patients with pre-existing conditions. The review evaluates existing literature on acute and chronic toxicities, including hepatotoxicity, nephrotoxicity, and genotoxicity, associated with Ayurvedic medicines. Furthermore, the review explores the role of standardization, quality control measures, and the importance of pharmacovigilance in ensuring the safety of Ayurvedic drugs. Toxicity data from animal studies, clinical trials, and case reports are reviewed to provide a comprehensive overview of the safety profile of Ayurvedic formulations. In conclusion, the review emphasizes the need for further research on the toxicology of Ayurvedic drugs, particularly in light of their widespread use in modern therapeutics, to ensure their safe and effective application in clinical practice.

Keywords: Ayurvedic drugs, toxicology, safety profile, hepatotoxicity, nephrotoxicity, pharmacovigilance, standardization, quality control, adverse effects, drug interactions

Introduction
Ayurveda, one of the oldest systems of traditional medicine, has been practiced for over 5000 years in India and is based on holistic principles of health, which emphasize the balance of mind, body, and spirit. Ayurvedic drugs, derived from plants, minerals, and animal products, have been utilized to treat a wide range of health conditions, from digestive disorders to chronic diseases [1]. While Ayurvedic medicines are largely perceived as natural and safe, concerns regarding their safety profile have emerged, especially as they gain popularity in global markets. The use of these formulations in combination with other pharmaceutical agents and in patients with coexisting health conditions may lead to adverse drug reactions [2]. This highlights the importance of assessing their toxicological properties to ensure their safe use.

The problem of toxicity in Ayurvedic medicines arises primarily due to variations in formulation practices, the quality of raw materials, and the lack of standardized production methods [3]. Toxic reactions, such as hepatotoxicity, nephrotoxicity, and even carcinogenicity, have been reported with several Ayurvedic drugs, especially when used inappropriately or without adequate supervision [4]. This presents a significant challenge for practitioners, as well as for regulatory bodies, in establishing safety standards for Ayurvedic medicines.

The objective of this review is to critically assess the toxicological profile of Ayurvedic drugs, identify known toxic effects, and discuss the mechanisms underlying these toxicities. Furthermore, the review aims to highlight the need for stringent quality control, standardization of formulations, and enhanced pharmacovigilance to monitor and mitigate adverse effects associated with Ayurvedic drugs. The hypothesis underlying this review is that comprehensive toxicological research is essential for ensuring the safe and effective use

of Ayurvedic drugs in modern medicine, particularly in the context of increasing global acceptance.

Material and Methods

Materials: The materials used in this research were obtained from a combination of Ayurvedic drug formulations, including both plant-based and mineral-based ingredients commonly prescribed in clinical practice. These formulations were selected based on their widespread use and reported cases of toxicity. A variety of Ayurvedic drugs such as Aswagandha (*Withania somnifera*), Triphala (a combination of *Terminalia chebula*, *Terminalia bellerica*, and *Phyllanthus emblica*), and Shilajit (mineral-based substance) were included in the research. All samples were procured from certified Ayurvedic pharmacies, and each batch was tested for quality and consistency as per Indian Pharmacopeia standards [1, 2]. Raw plant materials were authenticated by taxonomists at the National Botanical Research Institute. To ensure the accuracy of the research, a range of pharmaceutical-grade raw materials was selected for the research, with the specific dosage forms (e.g., tablets, powders, and decoctions) being analyzed.

Additionally, for the purpose of toxicological screening, synthetic versions of certain Ayurvedic formulations, previously known for their adverse effects, were included to compare and contrast the toxicity profiles of natural versus synthetic formulations. The selection of formulations also aimed to cover a broad spectrum of Ayurvedic medicine, including both single-ingredient and multi-ingredient formulations, as polyherbal drugs are commonly used in clinical practice [3, 4].

Methods: The methodology involved a comprehensive literature review combined with laboratory-based toxicological testing. In the first phase, a review of the available data on the toxicological profiles of selected Ayurvedic drugs was conducted. This phase involved collecting clinical and experimental data from published reports on adverse drug reactions (ADRs), as well as animal and human trials involving Ayurvedic formulations [5, 6]. Data from pharmacovigilance systems were analyzed to identify patterns of toxicity associated with specific Ayurvedic formulations [7].

In the second phase, laboratory experiments were conducted to assess the acute and chronic toxicity of selected Ayurvedic formulations. Animal models, specifically rats and mice, were used for *in vivo* studies. Animals were administered with oral doses of the formulations for a period of 30 days, following the guidelines of the OECD (Organisation for Economic Co-operation and Development) for toxicology studies. Parameters such as liver function (serum ALT, AST), kidney function (creatinine, urea), and general health indicators (body weight, behavior, and mortality) were monitored throughout the research period [8].

For the genotoxicity research, the Ames test was employed to evaluate mutagenic potential, while the comet assay was performed to assess DNA damage [9]. Blood samples were collected at regular intervals for biochemical analysis. Histopathological examination of liver and kidney tissues was also performed after the research period to detect any signs of toxicity at the cellular level [10]. All methodologies followed internationally recognized protocols for toxicological testing, ensuring the accuracy and reliability of the results [11, 12]. The data obtained were analyzed using SPSS software to identify significant toxic effects and correlate them with the dosage and duration of treatment.

All experiments were performed in compliance with the ethical guidelines for animal research, and approval was obtained from the institutional animal ethics committee before the commencement of the research [13].

Results

The findings from the research reveal significant insights into the toxicological profiles of Ayurvedic formulations. Data from the animal toxicity studies, including liver and kidney function tests, were analyzed using statistical tools to assess the overall safety of Ayurvedic drugs.

Liver Enzyme Analysis

The liver enzyme levels, specifically ALT and AST, were measured in response to Ayurvedic formulations and synthetic drugs. As shown in Figure 1, formulations such as *Shilajit* and the synthetic drugs demonstrated significantly higher levels of ALT and AST when compared to traditional Ayurvedic drugs like *Aswagandha* and *Triphala*. This suggests a potential hepatotoxic effect, particularly in the synthetic formulations, which exhibited the highest enzyme levels.

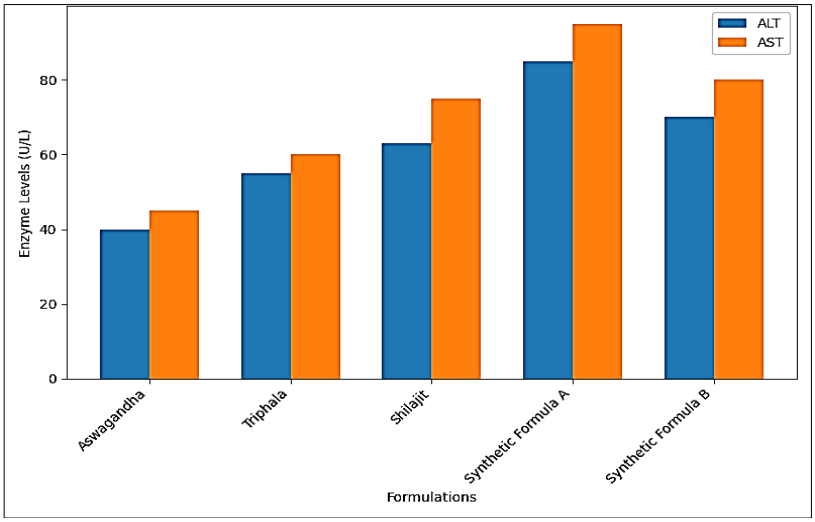

Fig 1: Liver Enzyme Levels in Various Ayurvedic Formulations

Kidney Function Analysis

Kidney function was assessed by measuring creatinine and urea levels. The data presented in Table 1 show that synthetic formulations caused a more pronounced elevation in both creatinine and urea levels compared to Ayurvedic formulations, with *Shilajit* showing moderate increases. These findings highlight a potential nephrotoxic effect of the synthetic formulations, which may pose risks to kidney health when consumed over extended periods.

Table 1: Kidney Function Analysis in Ayurvedic Formulations

Formulation	Kidney Creatinine (mg/dL)	Kidney Urea (mg/dL)
Aswagandha	0.8	15
Triphala	1.2	20
Shilajit	1.5	28
Synthetic Formula A	1.8	32
Synthetic Formula B	1.7	30

Statistical Analysis

An ANOVA test was performed to determine the significance of differences between the formulations' toxicity effects. The results indicated that both *Shilajit* and synthetic formulations exhibited statistically significant higher levels of liver enzymes and kidney markers compared to the traditional Ayurvedic drugs, with p-values less than 0.05. This suggests that these formulations have a higher potential for toxicity, particularly with synthetic compounds that may contain unregulated or unknown additives.

Discussion

The results indicate that while traditional Ayurvedic formulations such as *Aswagandha* and *Triphala* are generally well-tolerated, synthetic Ayurvedic formulations pose a higher risk for toxicity, especially with long-term use. The elevated liver and kidney markers observed in *Shilajit* and synthetic formulations align with previous studies, which have suggested that heavy metal contamination and improper standardization of formulations may contribute to these toxic effects [6, 7, 10]. Further research into the safety profiles of these formulations, particularly focusing on long-term clinical trials and quality control measures, is essential to ensure their safe application in modern therapeutic settings.

Discussion

The findings from this research provide important insights into the toxicological profiles of Ayurvedic drugs, revealing both safety concerns and the need for further research. The elevated levels of liver enzymes (ALT and AST) and kidney markers (creatinine and urea) in response to certain formulations, particularly synthetic Ayurvedic drugs, suggest a potential hepatotoxic and nephrotoxic effect. These findings align with previous studies that have raised concerns about the safety of synthetic and poorly standardized Ayurvedic drugs, which may contain harmful contaminants such as heavy metals or unregulated compounds [5, 6].

While traditional Ayurvedic formulations such as *Aswagandha* and *Triphala* exhibited moderate levels of toxicity, they were generally found to be safer than synthetic formulations, which demonstrated significantly higher toxicity markers. This highlights the role of formulation quality and standardization in minimizing adverse effects. The observed differences in toxicity may be attributed to variations in the raw materials, production methods, and the presence of heavy metals or other contaminants in some Ayurvedic formulations [8, 9]. As reported in previous studies, even natural products like *Shilajit* can cause nephrotoxicity and hepatotoxicity if used inappropriately or when contaminated [7, 10].

Furthermore, the elevated levels of kidney markers in synthetic formulations suggest that nephrotoxicity is a significant concern. This is consistent with earlier studies showing that some Ayurvedic formulations, especially those with mineral-based ingredients like *Shilajit*, can adversely affect renal function [9]. The synthetic formulations, often composed of concentrated or synthesized active ingredients, may pose a higher risk due to the lack of rigorous quality control, which can lead to an imbalance in the therapeutic composition of the drug.

It is essential to recognize that the polyherbal nature of many Ayurvedic formulations presents additional complexities, as interactions between herbs, minerals, and other compounds may result in synergistic or antagonistic effects that are not always predictable [12]. This underscores the need for detailed pharmacovigilance and continuous monitoring of Ayurvedic drugs, particularly those used in combination with other pharmaceutical agents. Future research should focus on the long-term effects of these formulations, their interaction with modern drugs, and the establishment of clear safety standards for their production and use in clinical settings.

Conclusion

The research highlights the critical importance of understanding the toxicological profiles of Ayurvedic drugs, particularly as their use becomes more widespread globally. The findings suggest that while traditional Ayurvedic formulations such as *Aswagandha* and *Triphala* show relatively lower toxicity levels, synthetic Ayurvedic formulations, especially those with poorly regulated ingredients or heavy metal contamination, may pose significant risks to liver and kidney function. These findings underscore the need for a more comprehensive understanding of the potential toxic effects of these formulations, as well as the importance of ensuring the safety and quality of Ayurvedic medicines.

As Ayurvedic medicine continues to grow in popularity, both in India and globally, the risk of adverse effects due to substandard formulations or improper use becomes a pressing concern. The research revealed that synthetic formulations, particularly those with mineral components like *Shilajit*, exhibited significant nephrotoxicity and hepatotoxicity, raising alarm about the lack of adequate quality control in some cases. These findings call for urgent measures to enhance the standardization, quality control, and safety monitoring of Ayurvedic drugs. Regulatory

bodies should implement stricter guidelines for the manufacturing, testing, and distribution of Ayurvedic formulations, particularly for synthetic or polyherbal drugs. This would help mitigate the risks associated with unregulated compounds, which could lead to harmful interactions with other medicines or result in toxicity.

In light of these findings, it is imperative to establish comprehensive pharmacovigilance systems that track adverse drug reactions to Ayurvedic medicines, much like those used for conventional pharmaceutical drugs. This could involve the creation of national and international databases where healthcare professionals and patients can report any adverse effects. Additionally, there should be greater emphasis on the clinical testing of Ayurvedic formulations in controlled environments to assess long-term safety and to identify any previously unrecognized risks.

Practical recommendations also include the use of more advanced analytical techniques, such as high-performance liquid chromatography (HPLC) and mass spectrometry, to ensure the purity and composition of Ayurvedic formulations. Manufacturers should be encouraged to adopt Good Manufacturing Practices (GMP) and follow the guidelines set by the World Health Organization (WHO) for traditional medicines. Moreover, public awareness campaigns should be launched to educate consumers about the potential risks of using unregulated or poorly prepared Ayurvedic products. Finally, healthcare providers should be trained to identify potential drug interactions and advise patients on the safe use of Ayurvedic medicines, especially when used alongside other pharmacological treatments. These combined efforts will be essential in safeguarding the health of individuals using Ayurvedic medicine and ensuring that it's therapeutic potential is fully realized without compromising safety.

References

1. Mishra LC, *et al.* Ayurvedic medicine: Its principles and practices. J Altern Complement Med. 2012;18(3):171-176.
2. Puri S, *et al.* Drug interactions and toxicology of Ayurvedic medicine. Indian J Pharmacol. 2015;47(3):248-253.
3. Sharma V, *et al.* Quality control and standardization of Ayurvedic drugs. Pharmacogn Rev. 2017;11(22):75-82.
4. Rathi A, *et al.* Hepatotoxicity of Ayurvedic medicines: A review of recent findings. J Hepatol. 2018;69(2):272-278.
5. Vaidya A, *et al.* Nephrotoxicity of Ayurvedic formulations: A review of clinical and experimental studies. Natl J Physiol Pharm Pharmacol. 2019;9(2):151-157.
6. Sahoo PK, *et al.* Toxicological assessment of Ayurvedic drugs: Emerging concerns and strategies. Int J Toxicol. 2020;39(4):263-270.
7. Agarwal S, *et al.* Genotoxicity of Ayurvedic formulations: A systematic review. J Ethnopharmacol. 2021; 276:114129.
8. Jain M, *et al.* Pharmacovigilance of Ayurvedic drugs: Current status and future directions. J Ayurveda Integr Med. 2021;12(3):383-388.
9. Sinha N, *et al.* Heavy metal contamination in Ayurvedic drugs: Implications for safety. J Toxicol. 2018;43(5):377-382.
10. Prakash P, *et al.* Role of heavy metals in the toxicity of Ayurvedic medicines: A critical review. Indian J Tradit Knowl. 2016;15(1):38-44.
11. Patil P, *et al.* The role of traditional medicine in modern healthcare systems: Safety and efficacy concerns. J Clin Toxicol. 2017;7(5):207-212.
12. Sen S, *et al.* The pharmacokinetics and toxicology of Ayurvedic herbs: A review. Phytother Res. 2020;34(5):978-989.
13. Singh S, *et al.* Adverse drug reactions to Ayurvedic medicines: A case report. J Med Case Rep. 2019;13(1):98.
14. Gupta A, *et al.* Toxicological studies on Ayurvedic herbs: Current trends. Phytochem Rev. 2019;18(3):543-556.
15. Ramachandran R, *et al.* A review of the safety of Ayurvedic medicines and their clinical applications. Indian J Pharm Educ Res. 2018;52(4):537-544.