Navigating Adverse Drug Reactions in Ayurvedic Pharmacology: A Comprehensive Analysis

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Abstract
Ayurveda, the esteemed and venerable Indian system of medicine, encodes the very essence of existence within its sacred textual canon, the Samhitas. These revered scriptures elucidate the diagnostic nuances of disease, proffer treatment strategies, and enunciate principles for the preservation of optimal health. Although the term "Adverse Drug Reaction" (ADR) may not be explicitly enshrined in Ayurvedic literature, its philosophical substrata are nonetheless suffused with the imperatives of safety and rational drug utilization. This ancient and venerable discipline acknowledges that the improper preparation or deployment of medicinal agents can precipitate deleterious consequences, as meticulously delineated in the Charaka Samhita and other seminal texts. Ayurvedic medicines, inclusive of those incorporating metallic and mineral elements, are not immune to the potential for adverse reactions, notwithstanding their perceived natural provenance. The factors influencing these reactions encompass the quality and properties of plant material, environmental contingencies, and patient-specific characteristics, including constitution (prakriti), digestive strength (agni), and mental state. The Ayurvedic concept of ADRs encompasses misuse, incompatibility, and individual variations in response. This paper undertakes an exhaustive exploration of Ayurveda's perspective on ADRs, emphasizing the imperative need for pharmacovigilance and proposing methodologies to integrate these practices into traditional medicine with optimum efficacy. By prioritizing patient safety, promoting responsible medicine utilization, and enhancing awareness among practitioners and patients, Ayurveda can optimize therapeutic outcomes while minimizing potential harm from medication use.
Concept of Adverse Drug Reaction in Paradigm of Ayurveda Pharmacology

Introduction
Ayurveda the ancient Indian System of medicine encapsulates the wisdom of life in its sacred texts and the samhitas. These revered scriptures outline the diagnosis of diseases, & treatment of diseases as well as strategies for maintaining optimal health. While the term “adverse drug reaction” may not be explicitly mentioned in Ayurvedic literature the principles of ADR are deeply ingrained in it’s philosophy. The primary objectives of concept of ADR is ensuring patient, safety & promoting rational drug use.

Global popularity of ayurvedic medicine has raised concerns about safety of ayurvedic medicine. Contrary to popular belief, Ayurvedic medicines can have adverse reactions. The ancient ayurvedic text, Charaka Samhita extensively describes the potential side effects of medicine when prepared or used improperly. To minimise the risks, Ayurvedic practitioner must consider various factors:

- Physical characteristics & properties of plant material used.
- The environment & season in which the plants grow.
- Patient's prakriti, bala, Vaya, Roga bala
- Psychological state, digestive capacity, physical strengths & tissue quality of patient.

Interestingly Ayurveda also uses metals and minerals as minerals which are prepared through a rigorous process to ensure safety. However concerns about long term safety & reports of adverse reaction hence raised questions about their use.

As charak samhita aptly states" A potent poison can become a valuable medicine when used properly, while even the most beneficial drug can become harmful if mishandled. This highlight the importance of careful preparation, administration and monitoring in ayurvedic medicine.

Concept of ADR in ayurveda [1]

1. Vyapad(Misuse/ Improper use) - ADR can occur due to incorrect doses, inappropriate combination of herbs or wrong timing of administration .
2. Virudhha(Incompatibility) - Certain combinations of foods or medicines can be incompatible & cause adverse effects.for eg-equal quantity of ghee & honey.
3. Prakriti - Each individual's prakriti affects how they respond to a particular treatment.
4. Agni – Strength of one’s digestive fire influences the metabolism of medicines. Weak Agni can lead to incomplete digestion and assimilation of medicine cause adverse effects

This paper aims to explore the ayurvedic perspective on adverse reaction to medicines the need for concept of ADR in ayurveda, the challenges in implementing pharmacovigilance and offers recommendations for successfully integrating these practices into the traditional system of medicine.

AIMS
- To safeguard the health and well being of individuals receiving ayurvedic care
- To encourage responsible and rational use of ayurvedic medicine.
- To mitigate potential harm and risk related to ayurvedic medication use.

OBJECTIVES
• Investigate and record adverse events associated with ayurvedic medications to ensure safety profiles
• Uncover the underlying causes and physiological mechanisms driving ADRs in ayurvedic pharmacology.
• Establish a robust surveillance system to monitor and track ADRs.
• Enhance the quality and safety of ayurvedic medicines through evidence based development.
• Optimize patient outcomes and care in ayurvedic practice through informed decision making.
• Educate and raise awareness among ayurvedic practitioners and patients about ADRs and their management.

**METHODOLOGIES**

1. **Classical text review** - Analysis of ancient ayurvedic texts like Charak Samhita, Sushruta Samhita & Ashtanga Hridayam
2. **Case study review** - Examination of individual case reports and series published in ayurvedic journals.
3. **Survey & questionnaire** – Analysis of data collected through surveys & questionnaires from ayurvedic practitioners & patients.
5. **Ayurvedic database search** - Search of databases like Ayurvedic pharmacopoeia, ayurvedic formulary & ayurvedic literature diseases.

**OBSERVATION AND RESULT**

<table>
<thead>
<tr>
<th>DRUG</th>
<th>ADR</th>
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<tbody>
<tr>
<td>Kajjali</td>
<td>Gastrointestinal symptoms, renal damage and neurological disorder.</td>
</tr>
<tr>
<td>Ras sindur</td>
<td>Nephrotoxicity, neurotoxicity and gastrointestinal symptoms.</td>
</tr>
<tr>
<td>Swarna bhasma</td>
<td>Gastrointestinal symptoms, renal damage and allergic reactions</td>
</tr>
<tr>
<td>Lauha bhasma</td>
<td>Gastrointestinal symptoms, renal damage and neurological disorder</td>
</tr>
<tr>
<td>Tribhuvan kirti ras</td>
<td>Sudden black out and bradycardia</td>
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<table>
<thead>
<tr>
<th>DRUG</th>
<th>PRAKRITI and GENDER</th>
<th>REASONS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Kajjali</td>
<td>Pitta and Males</td>
<td>Mercury toxicity, improper preparation, overdosage, individual sensibility</td>
</tr>
<tr>
<td>Ras sindur</td>
<td>Pitta-Vata and males</td>
<td>Mercury toxicity, Improper Manufacture, agni imbalance, liver and kidney dysfunction.</td>
</tr>
<tr>
<td>Swarna Bhasma</td>
<td>Pitta and females</td>
<td>Smaller particle size, poor manufacture, dosha imbalance, drug interactions</td>
</tr>
<tr>
<td>Lauha Bhasma</td>
<td>Pitta and females</td>
<td>Contamination, Rakta dhatu imbalance, poor manufacture, particle size</td>
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DISCUSSION
The burgeoning concern surrounding Adverse Drug Reactions (ADRs) in Ayurveda necessitates a thorough examination of the underlying factors contributing to their occurrence. Despite the perceived natural and harmless essence of Ayurvedic remedies, they are not entirely exempt from eliciting deleterious reactions. The etiology of ADRs in Ayurveda can be attributed to various factors, including:
- Subpar preparation and quality control measures
- Insufficient knowledge of herb-drug interactions and contraindications
- Patient-specific variables, such as prakriti, agni, and dosha imbalances
- Overdosage or protracted use
- Contamination or adulteration of herbal formulations

Common ADRs encountered in Ayurveda encompass:
- Gastrointestinal disturbances, including nausea and diarrhea
- Allergic reactions, manifesting as rashes and itching
- Renal damage
- Hepatotoxicity
- Respiratory complications

To mitigate the incidence of ADRs in Ayurveda, it is imperative to:
- Ensure stringent preparation and quality control protocols
- Conduct comprehensive patient assessments
- Monitor patients for potential herb-drug interactions and contraindications
- Initiate treatment with low doses and gradually escalate as necessary
- Foster open communication between patients and practitioners

Further research is imperative to elucidate the complexities of ADRs in Ayurveda, thereby ensuring the safe and efficacious deployment of these traditional medicines.

CONCLUSION
The paramount importance of drug safety in patient care and disease management is a ubiquitous concern that transcends medicinal disciplines. However, when it comes to the safety of herbal and Ayurvedic remedies, the matter assumes a profound significance, as it perturbs the deeply ingrained beliefs of patients regarding the harmlessness of Ayurveda. It is crucial to acknowledge that the use of all medicinal agents entails some degree of risk, and it is the sole responsibility of the treating physician to strike a balance between the therapeutic benefits and potential risks. This risk can be substantially mitigated by the judicious use of high-quality medications and adherence to the guidelines and instructions delineated in Ayurvedic classics pertaining to drug administration.
In conclusion, the phenomenon of Adverse Drug Reactions (ADRs) in Ayurveda is a vital consideration in ensuring the safe and efficacious use of traditional Ayurvedic remedies. Although Ayurvedic medicines are regarded as natural and harmless, they can still precipitate harmful reactions due to various factors, including inadequate preparation, insufficient knowledge of herbal interactions, and individual patient characteristics.

To achieve this, a comprehensive understanding and study of the principles of drug safety as espoused in Ayurveda is essential. Ayurvedic texts provide an elaborate exposition on Adverse Drug Reactions (ADRs) and their prevention. A profound knowledge of these texts is indispensable for practitioners to minimize the occurrence of ADRs. Furthermore, extensive research is necessary to elucidate the rationale and conceptual framework underlying the classical principles of drug administration and safety. Such investigations can potentially uncover novel paradigms related to pharmacokinetics, pharmacodynamics, and pharmacogenomics. Moreover, spontaneous reporting of ADRs associated with Ayurvedic treatments will play a vital role in generating signals and formulating innovative research queries.

Key takeaways:
- ADRs can occur in Ayurveda, despite the natural origin of medicines.
- Meticulous preparation, patient assessment, and monitoring are crucial to minimize ADRs.
- Further research is necessary to fully comprehend and address ADRs in Ayurveda.
- Ayurvedic practitioners must prioritize patient safety and well-being.

REFERENCES
8. "Rasaratna Samuchchaya" by Nagarjuna Chapter 12, Verse 13-15: Describes the adverse effects of Mercury on Pitta-Vata individuals. Chapter 18, Verse 21-23: Mentions the increased susceptibility of males to Mercury toxicity.