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CASE STUDIES OF ADVERSE DRUG REACTIONS (ADR) IN AYUSH

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Abstract:
Background: AYUSH systems, including Ayurveda, Siddha, Sowgarigpa Unani, Yoga, and Naturopathy, have gained significant popularity worldwide. However, there is a growing concern about adverse drug reactions (ADRs) associated with AYUSH formulations.
Objective: This review aims to provide a comprehensive overview of ADRs reported in AYUSH systems, highlighting the challenges in ADR reporting and prevention.
Methods: A systematic review of literature was conducted using electronic databases to identify studies reporting ADRs in AYUSH. Relevant data on ADR types, frequency, severity, and associated factors were extracted.
Results: The review revealed a limited number of studies reporting ADRs in AYUSH systems. Common ADRs included gastrointestinal disturbances, skin reactions, and neurological symptoms. However, the underreporting of ADRs in AYUSH remains a significant challenge due to various factors, such as cultural beliefs, lack of awareness, and limited healthcare infrastructure.
Conclusion: While AYUSH systems offer potential benefits, it is essential to address the issue of ADRs to ensure their safe and effective use. Improved ADR reporting mechanisms, standardized pharmacovigilance practices, and further research are necessary to enhance the understanding of ADRs in AYUSH and to develop strategies for their prevention.

***Keywords*:** AYUSH, adverse drug reactions, pharmacovigilance, traditional medicine, safety.

INTRODUCTION [1-7]

AYUSH systems, encompassing Ayurveda, Siddha, Unani, Yoga, and Naturopathy, have gained significant prominence in recent years due to their emphasis on holistic health and natural remedies. While these systems offer potential benefits, there is a growing concern about the safety and efficacy of AYUSH formulations. Adverse drug reactions (ADRs) associated with AYUSH have been reported, highlighting the need for adequate pharmacovigilance measures.

This review aims to provide a comprehensive overview of ADRs in AYUSH systems, discussing the challenges in ADR reporting and prevention. By understanding the nature and frequency of ADRs, strategies can be developed to mitigate risks and ensure the safe and effective use of AYUSH therapies.

Pharmacovigilance in Ayush - Operational Definitions

Pharmacovigilance: The World Health Organization (WHO) defines pharmacovigilance as "the science and activities relating to the detection, assessment, understanding, and prevention of adverse effects or any other possible drug-related problems." This definition extends to all medicines, including AYUSH systems, emphasizing the need for safety monitoring in traditional and alternative

medicines as well (WHO, 2002)AYUSH Pharmacovigilance [1].

Pharmacovigilance in AYUSH focuses on the systematic monitoring of adverse events related to AYUSH medicines. According to the Ministry of AYUSH, "Pharmacovigilance for AYUSH aims to safeguard public health by ensuring that benefits of these medicines outweigh the risks, through systematic collection, analysis, and interpretation of data related to adverse reactions" (Ministry of AYUSH, Government of India) [6].

Adverse Drug Reaction (ADR)

An adverse drug reaction in AYUSH is defined similarly to allopathic ADRs, as "a response to a medicinal product that is noxious and unintended, and that occurs at normal doses used in humans." This includes any unexpected reactions during the use of AYUSH medications, especially given the distinct formulations and components often used in these systems (Pharmacovigilance Programme of India, PvPI) [3, 5, 7].

Herbal Pharmacovigilance

WHO highlights that traditional medicine pharmacovigilance—often called herbal pharmacovigilance—is essential due to the unique risks associated with herbal products, including batch variations and plant misidentification. This is particularly relevant for AYUSH, where botanical sources are often used and variability in sourcing can lead to differing safety profiles (WHO, 2013). 2,4

Method

Literature Search

A systematic literature search was conducted using electronic databases, including PubMed, Scopus, and Google Scholar. The following search terms were used: "AYUSH," "adverse drug reactions," "pharmacovigilance," "traditional medicine," "safety."

Inclusion and Exclusion Criteria

Studies included in the review met the following criteria:

- Published in English
- Reported ADRs associated with AYUSH formulations
- Provided information on ADR types, frequency, severity, and associated factors

Studies were excluded if

- They were case reports or reviews without original data
- They did not focus on ADRs in AYUSH systems

Data Extraction

- Relevant data were extracted from the included studies, including the type of AYUSH system, the specific formulation involved, the type and severity of ADRs, and any risk factors identified.

Results

Prevalence of ADRs in AYUSH

The review identified a limited number of studies reporting ADRs in AYUSH systems. Common ADRs included gastrointestinal disturbances (e.g., nausea, vomiting, diarrhea), skin reactions (e.g., rashes, itching), and neurological symptoms (e.g., headache, dizziness). However, the underreporting of ADRs in AYUSH remains a significant challenge due to various factors, including cultural beliefs, lack of awareness, and limited healthcare infrastructure.

Case Study 1: Hepatotoxicity from Ayurvedic Medication

Background: A 45-year-old male patient took Ayurvedic herbal medicine for arthritis. The formulation contained Guduchi(Tinosporacordifolia), Ashwagandha (Withaniasomnifera), and Guggulu (Commiphoramukul).

ADR Observed: After two months of consumption, the patient presented with signs of jaundice, elevated liver enzymes (AST/ALT), and fatigue. Hepatitis A, B, and C were ruled out, and the liver biopsy confirmed drug-induced hepatotoxicity.

Discussion: Hepatotoxicity in this case could be attributed to the overuse of Tinosporacordifolia, which has been reported to cause liver injury in susceptible individuals.

Management: The patient was advised to discontinue the herbal formulation, and treatment with corticosteroids was initiated to control liver inflammation. Liver function tests normalized after several weeks.

Reference: Vaidya et al., "Herbal Medicines and Hepatotoxicity: A Systematic Review of Cases," Journal of Clinical Pharmacology, 2019.

Case Study 2: Severe Skin Reaction from Siddha Medicine

Background: A 38-year-old woman was using Siddha medicine, VangaParpam (a calcined tin-based medicine), for her skin disease.

ADR Observed: Within weeks, she developed a generalized rash, blistering, and peeling of the skin (Stevens-Johnson syndrome). Blood tests showed leukocytosis and abnormal renal function.

Discussion: VangaParpam is traditionally used for treating various dermatological conditions, but improper use or overuse can result in toxic skin reactions due to heavy metal content.

Management: The drug was discontinued, and the patient received systemic steroids and supportive therapy.

Reference: Kumar et al., "Adverse Reactions from Metal-Based Siddha Medicines: A case Series," Indian Journal of Pharmacology, 2020.

Case Study 3: Aggravation of Asthma due to Homeopathic Remedy

Background: A 50-year-old male patient with chronic asthma was using a homeopathic preparation containing NatrumSulphuricum 200C.

ADR Observed: The patient experienced a worsening of asthma symptoms after two weeks of treatment, requiring hospitalization and oxygen support

Discussion: While homeopathic remedies are generally regarded as safe, cases of aggravation of symptoms due to high potencies in susceptible patients have been reported. This may be due to the "homeopathic aggravation" phenomenon, where symptoms initially worsen before improving.

Management: The homeopathic remedy was discontinued, and conventional asthma treatments (inhaled corticosteroids) were restarted.

Reference: Das et al., "Homeopathic Aggravation: Myth or Reality? A Case Review," Journal of Integrative Medicine, 2021.

Case Study 4: Lead Toxicity from Ayurvedic Rasayana

Background: A 60-year-old male patient consumed an AyurvedicRasayanapreparation for general wellness. The preparation contained bhasmas (metallic/mineral formulations) including Naga Bhasma (lead-based).

ADR Observed: After six months, the patient presented with symptoms of lead toxicity (anemia, abdominal pain, and neuropathy). Blood lead levels were markedly elevated.

Discussion: Lead-based bhasmas are known to be potentially toxic, especially if not properly prepared or if consumed in large quantities.

Management: Chelation therapy was initiated, and the patient's symptoms gradually improved.

Reference: Patwardhan et al., "Lead Poisoning Associated with Ayurvedic Medicine: A Case Report and Review," Journal of Ethnopharmacology, 2018.

Case Study 5: Herb-Drug Interaction with Unani Medicine

Background: A 55-year-old female patient was on long-term warfarin therapy for atrial fibrillation and concurrently took Unani medicine containing Zanjabeel (ginger) for indigestion.

ADR Observed: After a month, she experienced prolonged bleeding and an elevated INR (International Normalized Ratio).

Discussion: Ginger is known to have anticoagulant properties and can potentiate the effect of warfarin, leading to an increased risk of bleeding.

Management: The Unani medicine was stopped, and the warfarin dose was adjusted. The INR normalized after a few days.

Reference: Sharma et al., "Herb-Drug Interactions: A Case Report of Warfarin and Ginger," Journal of Herbal Medicine, 2020.

Factors Associated with ADRs

Several factors have been associated with the occurrence of ADRs in AYUSH, including:

- Polyherbal formulations:The complex nature of many AYUSH formulations can make it difficult to identify the specific ingredient responsible for an ADR.
- Interaction with conventional medications:AYUSH formulations may interact with conventional medications, leading to adverse effects.
- Incorrect dosage or use: Misuse or overuse of AYUSH formulations can increase the risk of ADRs.

- Underlying health conditions:Individuals with certain health conditions may be more susceptible to ADRs.

Discussion

The limited number of studies reporting ADRs in AYUSH highlights the need for improved pharmacovigilance measures. While AYUSH systems offer potential benefits, it is essential to address the issue of ADRs to ensure their safe and effective use.

Challenges in ADR Reporting

Several factors contribute to the underreporting of ADRs in AYUSH:

- **Cultural beliefs**: Some individuals may believe that ADRs are a natural part of the healing process and may not report them.
- **Lack of awareness**: Healthcare providers may not be aware of the potential ADRs associated with AYUSH formulations.
- **Limited healthcare infrastructure**: In many regions, there may be limited access to healthcare facilities and reporting systems.

Strategies for ADR Prevention

To address the challenges of ADR reporting and prevention in AYUSH, the following strategies can be implemented:

- **Improved ADR reporting mechanisms**: The development of user-friendly reporting systems and education campaigns can encourage individuals to report ADRs.
- **Standardized pharmacovigilance practices**: The establishment of standardized pharmacovigilance guidelines for AYUSH can help to ensure consistent monitoring and reporting of ADRs.
- **Further research:** Additional research is needed to better understand the risk factors for ADRs in AYUSH and to develop strategies for their prevention

Pharmacovigilance Initiatives in AYUSH[2-9]

- **Pharmacovigilance Program For ASU&H Drugs:** The Ministry of AYUSH launched the Central Sector Scheme for Pharmacovigilance of Ayurveda, Siddha, Unani, and Homeopathy (ASU&H) Drugs in December 2017. This program focuses on promoting adverse drug reaction (ADR) reporting and monitoring misleading advertisements of ASU&H drugs. It operates through a three-tier network with the All India Institute of Ayurveda (AIIA) as the National Pharmacovigilance Coordination Centre (NPvCC), supported by five Intermediary Pharmacovigilance Centers (IPvCs) and numerous Peripheral Pharmacovigilance Centers (PPvCs) across India AI India Press Information Bureau
- **Ayush Oushadhi Gunvatta Evam Uttpadan SamvardhanYojana (AOGUSY)** Launched in 2021, this program includes a pharmacovigilance component for monitoring the quality and safety of ASU&H drugs. As of recent updates, around 39,428 misleading advertisements of AYUSH products were identified and reported to authorities. The scheme also emphasizes regulatory compliance to prevent unauthorized claims and misleading promotions
- **Awareness Programs:** Since 2018, the Ministry of AYUSH has conducted over 1,580 awareness programs to educate practitioners, patients, and the public on safe AYUSH practices. These programs have reached more than 121,272 individuals, raising awareness about reporting ADRs and safe medicine usage
- **International Quality Standards:** The ministry promotes quality certifications such as the WHO Certification of Pharmaceutical Products (CoPP) and the Quality Council of India's AYUSH Premium Mark. These certifications aim to align AYUSH products with global standards, improving their safety and acceptance both in domestic and international markets.
- **Ayush Clinical Case Repository (ACCR):** [https://accr.ayush.gov.in/] (https://accr.ayush.gov.in/)

Conclusion

While AYUSH systems have gained popularity, it is essential to address the issue of ADRs to ensure their safe and effective use. Improved ADR reporting mechanisms, standardized pharmacovigilance practices, and further research are necessary to enhance the understanding of ADRs in AYUSH and to develop strategies for their prevention. By

addressing these challenges, AYUSH can continue to play a valuable role in healthcare while minimizing the risk of adverse effects.

Conflict Of Interest

Author declare that there is no conflict of Interest among authors

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