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ADVERSE DRUG REACTIONS AND PHARMACOVIGILANCE IN ASU MEDICINES: A CASE STUDY AND COMPREHENSIVE REVIEW

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ABSTRACT

Background: Adverse Drug Reactions (ADRs) are a concern in both modern and traditional medicine, including Ayurveda, Siddha, and Unani (ASU) systems. Pharmacovigilance is essential to ensure their safe use. **Case Report:** A 28-year-old female with sinusitis developed an extensive erythematous rash after taking *Vyoshadi Vati* and *Drakshasava*. With no prior allergies or chronic illness, the reaction was categorized as moderate and non-serious. Symptoms resolved within 24 hours of drug discontinuation and antihistamine administration. The case was reported to the Peripheral Pharmacovigilance Centre (PPvC) via the Ayush Suraksha portal. **Conclusion:** This case highlights the need for robust pharmacovigilance in ASU medicine. Standardization, quality control, and systematic ADR reporting can enhance safety, credibility, and global acceptance of traditional formulations.

INTRODUCTION

Adverse Drug Reactions (ADRs) are a critical concern in both modern and traditional medicine systems, including Ayurveda, Siddha, and Unani (ASU) drugs[1]. While ASU medicines are generally considered safe due to their natural origin and holistic approach, reports of ADRs highlight the necessity of vigilant monitoring and scientific validation[2]. The growing global acceptance and integration of ASU formulations into mainstream healthcare systems have further emphasized the need for a structured pharmacovigilance framework[3].

Pharmacovigilance is essential for ensuring the safety, efficacy, and quality of ASU medicines by identifying and mitigating potential risks associated with their use[4]. Factors such as herb-drug interactions, improper processing, contamination, incorrect dosage, and individual hypersensitivity may contribute to ADRs in herbal medicine[5]. Additionally, variations in raw material quality, lack of standardization, and inadequate regulatory oversight can further increase the risk of adverse effects. This article presents a documented ADR case associated with ASU drugs, specifically *Vyoshadi Vati* and *Drakshasava*, and evaluates its clinical implications. A detailed review of the pharmacovigilance measures necessary to enhance the safety of ASU formulations is also discussed. By implementing a robust pharmacovigilance system, the credibility, global acceptance, and scientific validation of ASU drugs can be significantly improved

Materials and Methods

A case of an adverse drug reaction (ADR) associated with Vyoshadi Vati and Drakshasava was documented and analyzed. The causality assessment was performed using standard pharmacovigilance tools, and the case was reported to the Peripheral Pharmacovigilance Centre (PPvC) via the Ayush Suraksha portal. A literature review was conducted to evaluate ADR patterns, risk factors, and pharmacovigilance strategies in ASU medicines

Observations and Results

Case Report:

A 28-year-old female patient (OPD-24019847) presented with symptoms of sinusitis and was prescribed *Vyoshadi Vati* and

Drakshasava by a physician at Parul Institute of Ayurved Vadodra, Guajarat. *Vyoshadi Vati,* commonly used for respiratory conditions, was administered at a dose of two tablets twice daily, while *Drakshasava*, an Ayurvedic fermented formulation, was prescribed at three teaspoons twice daily Onset and Progression of the ADR

On the 16th of August 2024, at approximately 2:00 PM, the patient experienced an adverse drug reaction following the consumption of *Vyoshadi Vati* and *Drakshasava. Vyoshadi vati* is recognized in Ayurvedic practice as a polyherbal formulation commonly used for respiratory conditions, including cough and sore throat. The formulation typically includes ingredients like *Piper longum* (Pippali), *Piper nigrum* (Maricha), and *Zingiber officinale* (Shunthi) and *Drakshasava* is described as a fermented liquid preparation made from grapes (*Vitis vinifera*) and other herbal ingredients. It is traditionally used as a general health tonic, carminative, and blood purifier, indicated for conditions such as anemia and digestive disorders. Within a few hours of administration, she developed an extensive erythematous rash that spread across her entire body. The patient had no history of allergic reactions to any drugs or substances and had not been diagnosed with any chronic illnesses. Additionally, she had no history of addictions that could have contributed to the reaction. A thorough review of her medical records confirmed that she was not on any other allopathic or Ayurvedic medications during this period, effectively ruling out polypharmacy as a contributing factor to the ADR. The immediate onset of symptoms following drug administration strongly suggested a hypersensitivity reaction induced by the suspected ASU drugs.

Clinical Examination and Management:

Upon noticing the adverse reaction, the patient discontinued both *Vyoshadi Vati* and *Drakshasava.* No systemic involvement, such as hepatic or renal dysfunction, was detected. Laboratory investigations revealed no significant abnormalities in hepatic or renal function tests. The patient was advised to discontinue the suspected drugs immediately, and symptomatic management was provided, including antihistamines to reduce the erythematous reactions. Dietary recommendations were given to avoid cold and fermented foods, which might have contributed to hypersensitivity. The symptoms gradually subsided within 24 hours after discontinuing the drugs, and the patient did not require hospitalization

Causality Assessment

Using the ADR Probability Scale, the reaction was assessed as moderate and categorized as non-serious. The absence of re-administration and improvement post-withdrawal confirmed the likelihood of *Vyoshadi Vati* and *Drakshasava* as causative agents.

ADR Reporting

The reported adverse drug reaction (ADR) case was documented and submitted to the Peripheral Pharmacovigilance Centre (PPvC), Vadodara (Code-004), in accordance with standard pharmacovigilance protocols. The case was officially reported through the Ayush Suraksha Portal, ensuring systematic monitoring and assessment within the framework of the Pharmacovigilance Programme for Ayurveda, Siddha, Unani, and Homoeopathy (ASU&H).

DISCUSSION

Pharmacovigilance and ADR Monitoring in ASU Drugs

Pharmacovigilance is the science and activity of detecting, assessing, understanding, and preventing adverse effects or any other drug-related problem. While ASU drugs are generally considered safe due to their natural origin, cases of ADRs emphasize the need for vigilant monitoring.

Importance of Pharmacovigilance in ASU Drugs:

Pharmacovigilance is the science and activity of detecting, assessing, understanding, and preventing adverse effects or any other drug-related problems. While Ayurveda, Siddha, and Unani (ASU) drugs are generally considered safe due to their natural origin, cases of Adverse Drug Reactions (ADRs) emphasize the need for vigilant monitoring. Ensuring the safety of ASU drugs is a critical aspect of traditional medicine practice. While these formulations have a longstanding history of therapeutic use, potential risks remain, especially in cases of improper processing, contamination, or inappropriate administration. Identifying and mitigating these risks requires a robust pharmacovigilance system, with comprehensive safety assessments at various stages, including raw material selection, processing, and clinical application. In particular, the presence of heavy metals, adulterants, or microbial contamination in certain formulations poses significant health risks. Therefore, rigorous safety evaluation, including preclinical toxicology studies and post-market surveillance, is imperative to ensure consumer safety[6].

Standardization and Quality Control in ASU Drugs

The standardization of ASU drugs is essential to ensure batch-to-batch consistency and therapeutic reliability. Unlike synthetic pharmaceuticals, which have well-defined active components, ASU drugs often consist of complex mixtures of bioactive compounds[7]. Therefore, developing standard operating procedures (SOPs) for raw material procurement, processing, and formulation is crucial[8]. Advanced analytical techniques such as chromatography (HPTLC, HPLC), spectroscopy (UV, FTIR), and DNA barcoding are increasingly employed to authenticate medicinal plants and assess their phytochemical profiles[9]. In addition, adherence to Good Manufacturing Practices (GMP) and pharmacopoeial standards, as outlined by regulatory authorities such as the AYUSH Ministry, can significantly enhance the quality and safety of ASU drugs[10.]

Monitoring Herb-Drug Interactions in ASU Medicine

Herb-drug interactions (HDIs) represent a growing area of concern, particularly as integrative medicine practices gain popularity[11]. ASU formulations contain a wide range of bioactive compounds that may interact with allopathic medications, leading to synergistic, antagonistic, or adverse effects[12]. For instance, herbal drugs with anticoagulant properties, such as turmeric (*Curcuma longa*) or guggulu (*Commiphora mukul*), may potentiate the effects of warfarin, increasing the risk of bleeding[13]. Similarly, certain herbal adaptogens like Ashwagandha (*Withania somnifera*) may interfere with thyroid medications[14]. Systematic studies on HDIs, coupled with real-world pharmacovigilance data, are essential to mitigate these risks and guide clinicians on safe co-administration of ASU and allopathic drugs[15].

Documentation of Rare Adverse Drug Reactions (ADRs)

A comprehensive pharmacovigilance framework for ASU medicine must include systematic documentation and reporting of rare ADRs[16]. While ASU drugs are generally regarded as safe due to their natural origin, adverse events may arise due to factors such as incorrect dosage, improper processing, or patient-specific hypersensitivity[17]. Establishing a dedicated ADR repository can facilitate early detection of safety concerns, thereby informing regulatory actions and clinical decision-making[18]. Integrating digital health tools and mobile applications for real-time ADR reporting can enhance the efficiency of this process, ensuring a more robust safety monitoring system[19].

Strengthening Pharmacovigilance in ASU Medicine

To enhance the safety and efficacy of ASU drugs, pharmacovigilance measures must be systematically reinforced. Key strategies include:

1. **Mandatory Reporting Systems:** Encouraging healthcare professionals, ASU practitioners, and patients to report ADRs to established pharmacovigilance centers can significantly improve ADR detection and response mechanisms[20]. The Pharmacovigilance Program for ASU & H (PPASU&H) should be further strengthened to increase participation and awareness[21].
2. **Regulatory Frameworks**: Strengthening regulatory guidelines for the manufacturing and quality control of ASU drugs is essential[22]. Measures such as enforcing Good Manufacturing Practices (GMP), mandatory heavy metal testing, and ensuring compliance with the Ayurvedic Pharmacopoeia of India (API) standards can improve drug safety[23].
3. **Public Awareness Initiatives:** Educating consumers about the safe use of ASU medicines, including proper dosages, potential interactions, and warning signs of ADRs, can help mitigate risks[24]. Public awareness campaigns, patient information leaflets, and pharmacist counseling play a crucial role in this regard.
4. **Research and Data Compilation:** Conducting systematic reviews, meta-analyses, and real-world observational

studies can help build a reliable database of ADR occurrences in ASU medicine. Collaborative research efforts between traditional medicine experts and modern pharmacologists can further elucidate the safety profiles of widely used herbal formulations.

The integration of pharmacovigilance in ASU medicine is vital to ensuring patient safety while preserving the therapeutic potential of these traditional formulations. A multi-pronged approach involving stringent quality control, proactive ADR monitoring, regulatory enforcement, and continuous research can significantly enhance the credibility and clinical acceptance of ASU drugs[25]. By adopting evidence-based safety assurance mechanisms, the traditional wisdom of ASU medicine can be effectively harmonized with modern healthcare systems for improved patient outcomes.

CONCLUSION

This case study underscores the importance of ADR monitoring in ASU drugs, highlighting the need for a robust pharmacovigilance system. While traditional medicine offers a wealth of therapeutic benefits, its integration into modern healthcare requires a balanced approach emphasizing safety, standardization, and evidence-based practice. Reporting and analyzing ADRs can significantly enhance the credibility and global acceptance of ASU formulations.

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Abbreviations: ADR – Adverse Drug Reaction
ASU – Ayurveda, Siddha, and Unani
API – Ayurvedic Pharmacopoeia of India
PPvC – Peripheral Pharmacovigilance Centre
PPASU&H – Pharmacovigilance Program for Ayurveda, Siddha, Unani, and Homoeopathy
GMP – Good Manufacturing Practices
HDI – Herb-Drug Interaction
HPTLC – High-Performance Thin-Layer Chromatography
HPLC – High-Performance Liquid Chromatography
UV – Ultraviolet Spectroscopy
FTIR – Fourier Transform Infrared Spectroscopy

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