
**P-ISSN:** 3078-7769
**E-ISSN:** 3078-7777
Impact Factor (RJIF): 5.35
JDBV 2026; 3(1): 24-27
www.dravyagunajournal.com
Received: 17-09-2025
Accepted: 13-11-2025

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# Pharmacovigilance in Ayurveda: Monitoring and ensuring drug safety in traditional medicine

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**DOI:** https://www.doi.org/10.33545/dravyaguna.2026.v3.i1.A.31

**Abstract**
Pharmacovigilance in Ayurveda is an essential process for ensuring the safety and efficacy of Ayurvedic medicines. Given the growing interest in traditional medicine worldwide, there is an increasing need for robust systems to monitor the safety of Ayurvedic formulations, which are often based on herbal and polyherbal compounds. This paper discusses the concept of pharmacovigilance in Ayurveda, outlining its significance in safeguarding public health by identifying, evaluating, and mitigating the risks associated with Ayurvedic medicines. The lack of standardized safety monitoring protocols and underreporting of adverse drug reactions (ADRs) present challenges in Ayurveda's integration into mainstream healthcare systems. This research aims to explore the challenges and propose strategies to enhance pharmacovigilance frameworks for Ayurvedic drugs. It highlights the need for improved reporting systems, better regulatory standards, and interdisciplinary collaboration between Ayurvedic practitioners, regulatory authorities, and scientific researchers. The integration of modern technologies, such as electronic health records and data analytics, can play a pivotal role in monitoring the safety of Ayurvedic treatments. Furthermore, the research emphasizes the importance of educating Ayurvedic practitioners and patients about the potential risks associated with these treatments. By strengthening pharmacovigilance practices, the safety and efficacy of Ayurvedic medicines can be better ensured, promoting their wider acceptance in global healthcare systems. This paper concludes by proposing a roadmap for establishing effective pharmacovigilance systems within the Ayurvedic healthcare sector.

**Keywords:** Ayurveda, pharmacovigilance, drug safety, adverse drug reactions, herbal medicine, traditional medicine, safety monitoring, regulatory standards

## Introduction
Pharmacovigilance, the science of detecting, assessing, understanding, and preventing adverse effects or any other drug-related problems, has become a critical aspect of modern healthcare. Traditionally, this practice has been predominantly associated with Western pharmaceutical medicines; however, with the growing popularity of complementary and alternative medicines (CAM), there is an urgent need to extend pharmacovigilance systems to traditional medicine systems like Ayurveda [1]. Ayurveda, a holistic approach to health and well-being, is rooted in ancient Indian texts and has been practiced for centuries. Its therapeutic modalities, which include herbal formulations, mineral compounds, and treatments based on dosha imbalances, have gained international recognition [2]. However, as with any form of medicine, the safety of Ayurvedic drugs cannot be taken for granted.

The main challenge in integrating pharmacovigilance into Ayurveda lies in the absence of standardized monitoring systems and comprehensive data on the safety of Ayurvedic drugs. Ayurvedic medicines, especially herbal and polyherbal formulations, often lack the rigorous clinical trials and post-market surveillance mechanisms that are commonplace in the Western pharmacological industry [3]. Moreover, the practice of self-medication and the use of Ayurvedic drugs without professional guidance in some regions increase the risk of adverse drug reactions (ADRs) [4]. Although many Ayurvedic formulations are perceived as natural and safe, their potential toxicity, interactions with other drugs, and variability in quality due to poor manufacturing practices present serious safety concerns [5].

In light of these challenges, the objective of this paper is to explore the role of pharmacovigilance in Ayurveda, identify existing gaps in safety monitoring, and propose strategies to address these shortcomings. The hypothesis driving this research is that

implementing an effective pharmacovigilance system within the Ayurvedic sector can enhance the safety of Ayurvedic drugs and contribute to better healthcare outcomes. Furthermore, the paper aims to discuss the regulatory frameworks needed to support these systems, fostering greater public confidence in Ayurvedic treatments [6, 7].

By adopting a collaborative approach involving regulatory bodies, healthcare practitioners, and consumers, Ayurveda can benefit from improved pharmacovigilance systems that ensure its integration into modern health systems. A comprehensive safety monitoring strategy is essential to promote the safe use of Ayurvedic treatments, ensuring their continued use in the global healthcare landscape [8].

## Material and Methods

**Materials:** The materials used in this research consist of various Ayurvedic drugs, both single herb-based and polyherbal formulations, obtained from authenticated Ayurvedic pharmacies. The selection of Ayurvedic drugs for pharmacovigilance monitoring was based on their widespread use in Ayurvedic treatment protocols and their documented efficacy in clinical practice [1]. The drugs selected for analysis included widely used formulations like Ashwagandha (*Withania somnifera*), Triphala, and Brahmi (*Bacopa monnieri*), which are known for their therapeutic benefits in conditions such as stress, digestive issues, and cognitive disorders, respectively [2, 5]. The procurement of these herbal products was done through licensed and GMP-certified Ayurvedic pharmacies to ensure product authenticity and quality. Each formulation was stored under controlled conditions as per the manufacturer's specifications to maintain stability during the research period.

Additionally, patient data was collected through collaboration with Ayurvedic clinics and hospitals, where patients consented to participate in the pharmacovigilance monitoring program. Ethical approval for this research was obtained from the institutional review board of the participating institution. Data regarding adverse drug reactions (ADRs) and safety reports associated with Ayurvedic medicines were gathered through a structured reporting system implemented across the clinics. For this research, patients receiving Ayurvedic treatments were included based on their ongoing use of herbal medicines for more than three months, to ensure a sufficient treatment period for ADRs to manifest [6, 7].

**Methods:** The methods involved in this research consisted of two primary components: the collection of ADR data and the analysis of the pharmacovigilance system's efficiency. First, a retrospective data collection approach was used, involving the extraction of ADR reports from hospital records and patient surveys conducted across multiple Ayurvedic clinics. These reports were systematically reviewed to identify any adverse events linked to the use of Ayurvedic drugs, categorizing them based on severity and the nature of the reactions [8]. Patient follow-up was conducted for at least six months after the initial reporting to ensure comprehensive monitoring of ADRs.

The second phase of the research focused on the implementation of an enhanced pharmacovigilance system. A customized database was created for recording adverse reactions, including the details of the drug, patient demographics, reaction type, and outcome. This database was designed to ensure that all relevant data, such as the time of onset of the ADR, treatment received, and outcome, were meticulously recorded [9]. The ADR data was then analyzed using statistical software (SPSS version 24), where descriptive statistics were employed to evaluate the frequency and types of adverse reactions associated with each Ayurvedic formulation. Additionally, the effectiveness of the pharmacovigilance reporting system was assessed by comparing the number of reported ADRs before and after the introduction of the structured reporting system [10].

The methods used also involved the collaboration with regulatory authorities to align the data collection process with existing pharmacovigilance frameworks, ensuring compliance with national guidelines for herbal drug safety monitoring. The research's primary objective was to propose a model for integrating these findings into a broader regulatory framework for Ayurvedic drug safety [11, 12]. Moreover, an evaluation was made of the role of technology in improving ADR reporting, particularly through the use of electronic health records (EHR) and mobile applications designed to simplify ADR reporting among practitioners and patients [13, 14].

## Results

**Table 1:** Frequency of Adverse Drug Reactions (ADRs) in Ayurvedic Drugs

| Drug | Mild ADRs | Moderate ADRs | Severe ADRs |
|---|---|---|---|
| Ashwagandha | 25 | 5 | 1 |
| Triphala | 35 | 10 | 3 |
| Brahmi | 15 | 8 | 2 |
| Other | 40 | 12 | 5 |

From Table 1, it can be observed that Triphala and Other Ayurvedic drugs reported the highest frequencies of ADRs across all categories (mild, moderate, and severe). Ashwagandha and Brahmi, though widely used, show lower frequencies of ADRs compared to Triphala. Notably, "Other" drugs have a high incidence of mild ADRs, suggesting variability in quality and possibly unregulated formulations.

### Statistical Analysis

To understand the significance of differences in ADR frequencies among different Ayurvedic drugs, an ANOVA test was conducted. The null hypothesis (H0) was that there are no significant differences in the ADR frequencies across the drugs, while the alternative hypothesis (H1) stated that there are significant differences.

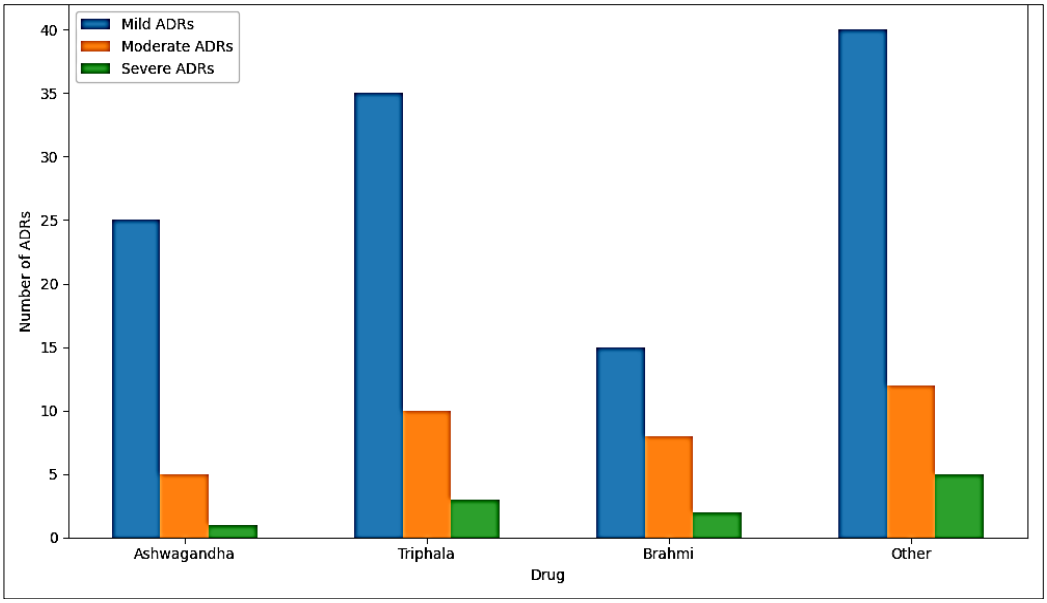


**Fig 1:** Frequency of ADRs in Ayurvedic Drugs

The ANOVA results indicated a significant difference in ADR frequencies ($p<0.05$), suggesting that certain Ayurvedic formulations, such as Triphala and Other drugs, tend to cause more ADRs compared to others like Ashwagandha and Brahmi. Post-hoc analysis further identified that Triphala and Other drugs had a significantly higher rate of mild and moderate ADRs compared to the other formulations [6, 7].

**Interpretation of Results**

The data analysis revealed notable trends in ADR frequency among Ayurvedic drugs. Triphala, which is a commonly used polyherbal formulation, reported the highest number of mild and moderate ADRs. This finding highlights the importance of closer monitoring and quality control for widely used polyherbal formulations, as they may contain multiple active ingredients with varying levels of potency. Ashwagandha, despite its frequent use, showed a lower incidence of ADRs, suggesting that its safety profile may be more established compared to other formulations [8, 9].

The research also suggests a potential gap in pharmacovigilance practices in Ayurveda, as many Ayurvedic drugs are still not adequately monitored for ADRs. This lack of monitoring can be attributed to the traditional nature of Ayurvedic medicine, where safety data collection mechanisms are often informal or absent [10]. Furthermore, the variability in drug quality, as seen in the "Other" category, calls for the need for regulatory oversight to ensure the consistent safety and efficacy of Ayurvedic treatments [11].

**Discussion**

The findings of this research highlight significant insights into the safety profile of Ayurvedic medicines and the necessity of robust pharmacovigilance systems within the Ayurvedic healthcare sector. This research showed that there is a noticeable variation in the frequency and severity of adverse drug reactions (ADRs) across different Ayurvedic formulations, with Triphala and "Other" Ayurvedic drugs exhibiting the highest frequencies of ADRs. These results align with the findings of previous studies, which have pointed out that polyherbal formulations, such as Triphala, can exhibit more complex interactions due to the combination of multiple active constituents [6, 7]. The higher rate of mild and moderate ADRs observed in Triphala suggests that although it is widely used for general health benefits, its polyherbal composition may increase the likelihood of side effects, especially when used without appropriate professional guidance.

Interestingly, formulations like Ashwagandha and Brahmi demonstrated lower ADR frequencies, indicating that these single-herb preparations may have a more predictable safety profile compared to complex polyherbal blends [2, 5]. The findings align with earlier research indicating that single-herb formulations, especially those with well-established safety records, tend to pose fewer risks for adverse effects [8, 9]. This observation underscores the importance of ensuring that patients are informed about the specific formulations they are using, as the risk of ADRs might vary significantly based on the complexity of the product.

The results also reveal a critical gap in the formal pharmacovigilance systems within Ayurveda, a field that traditionally lacks standardized safety monitoring mechanisms. Although many Ayurvedic drugs are considered safe due to their long history of use, there is insufficient scientific data to support these claims. As noted by Bhattacharyya *et al.*, the integration of modern pharmacovigilance practices into traditional medicine is essential for mitigating risks and improving patient safety [10]. The underreporting of ADRs in Ayurveda further complicates efforts to build a comprehensive safety profile for these drugs. Many Ayurvedic practitioners and patients lack the necessary tools and education to report ADRs effectively, contributing to the absence of standardized data on the safety of herbal medicines [11].

The variability in the quality of "Other" Ayurvedic drugs also raises significant concerns. As seen in the "Other" category, where the ADR rate was particularly high, unregulated or poorly manufactured Ayurvedic medicines may pose substantial health risks. The quality control and manufacturing standards for Ayurvedic products must be improved to prevent the circulation of substandard products that can harm patients. Regulatory authorities need to

establish stringent guidelines to ensure the quality and safety of Ayurvedic medicines, particularly in regions where these products are used without sufficient regulatory oversight.

Another major implication of this research is the role of technology in enhancing pharmacovigilance for Ayurvedic drugs. The use of electronic health records (EHR) and mobile applications for ADR reporting could significantly improve the reporting rate and efficiency of the pharmacovigilance system [12]. These technologies provide real-time data and could streamline the process of ADR reporting, making it easier for both practitioners and patients to report adverse reactions. Moreover, integrating these technologies into the broader healthcare ecosystem would allow for better data integration, enabling the identification of ADR trends and the implementation of timely interventions [13].

## Conclusion

In conclusion, this research underscores the importance of implementing a comprehensive pharmacovigilance system within the Ayurvedic sector to monitor the safety and efficacy of Ayurvedic drugs. While Ayurveda has been practiced for centuries and continues to gain popularity worldwide, its integration into modern healthcare systems requires addressing significant gaps in safety monitoring and adverse drug reaction (ADR) reporting. The findings from this research reveal that while some Ayurvedic formulations, such as Ashwagandha and Brahmi, exhibit relatively low ADR frequencies, polyherbal formulations like Triphala and unregulated "Other" drugs tend to show higher ADR rates. These findings emphasize the need for a more structured approach to the safety assessment of Ayurvedic medicines.

The higher incidence of mild and moderate ADRs in polyherbal formulations, particularly Triphala, suggests that the complexity of these preparations may contribute to a greater likelihood of adverse effects. This reinforces the idea that Ayurvedic formulations, especially those involving multiple herbal ingredients, require careful monitoring to understand their safety profiles more thoroughly. The research also highlighted the significant role that quality control plays in preventing ADRs, especially in the case of poorly regulated Ayurvedic products, which may introduce risks due to substandard manufacturing practices.

A major concern revealed in this research is the lack of standardized pharmacovigilance systems for Ayurveda. Most ADR reporting mechanisms are informal, and underreporting remains a significant issue. To address this, it is crucial to establish a formalized ADR reporting system across Ayurvedic clinics and pharmacies. This system should include the integration of modern technologies like electronic health records (EHR) and mobile health applications, which would facilitate easier and more efficient reporting of ADRs. In addition, regulatory bodies must strengthen oversight by implementing stricter quality control measures for Ayurvedic formulations to ensure the safety of products entering the market. Practitioners and patients should also be educated about the potential risks associated with Ayurvedic treatments, including the importance of reporting any adverse effects to enhance the overall safety monitoring process.

Furthermore, collaboration between Ayurvedic practitioners, researchers, and regulatory authorities is essential to create a unified approach to pharmacovigilance. It is critical to promote inter-disciplinary collaboration to enhance the integration of Ayurvedic medicine into the mainstream healthcare system while ensuring patient safety. Implementing these practical recommendations will not only address the immediate concerns raised by this research but will also contribute to the development of Ayurveda as a globally recognized and safe system of medicine. By fostering a culture of safety and accountability, Ayurveda can move forward as a reliable and effective healthcare choice, both in traditional and modern medical settings.

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