

## A Report on ADR Associated With Herbal Medicines

Prof. (Dr).Mohd Wasiullah\*<sup>S1</sup>, Piyush Yadav<sup>2</sup>, Sushil Yadav<sup>3</sup>, virendra yadav<sup>4</sup>

1. Principal, Department of Pharmacy, Prasad Institute of Technology, Jaunpur (222001), U.P., India.
2. Principal, Department of Pharmacy, Prasad Polytechnic, Jaunpur (222001), U.P., India.
3. Associate Professor, Department of Pharmacy, Prasad Institute of Technology Jaunpur (222001), U.P., India.
4. Department of Pharmacy, Prasad Institute of Technology, Jaunpur (222001), U.P., India.

Submitted: 05-05-2023

Accepted: 15-05-2023

### ABSTRACT:-

The current study aims to shed light on the many adverse drug reactions that go unrecorded due to patients not seeking medical attention after taking herbal medicine, or due to the lack of pharmacovigilance analysis. A 55-year-old female patient weighing 41 kg received herbal treatment for gastritis and menstrual disturbance starting from November 2015. Following the administration of the drug, she developed 23 small vesicles suddenly over her neck and upper chest. Over the course of 4-5 days, some of the vesicles ruptured, while others grew in size to form bulla.

The use of herbal drugs has significantly increased worldwide in recent times. Consequently, it has become essential to practice pharmacovigilance of herbal drugs and address issues related to adverse effects for consumers and healthcare professionals. Analyzing these products is more complicated than conventional pharmaceuticals. The terms "safe" and "natural" cannot be used interchangeably. Sufficient adverse drug monitoring of herbal drugs is just as crucial as any other formulary.

**Keywords:** Vesicles, Pharmacovigilance, Herbal drug, Adverse drug reaction

### I. INTRODUCTION:-

The use of herbal medicines for the promotion of healing and maintenance of health-related problems has been traced back to ancient Egypt in 1550 BC. Today, approximately 80% of the world's population uses some form of herbal medicine or herb-related product, with annual usage increasing at a rate of 10-20%. This trend is driven by the desire to avoid the toxic effects of chemicals and to trust in natural products. However, it is crucial to ensure the safety of herbal medicines, as the majority of these products are self-prescribed and used to treat various health conditions. Many patients consuming herbal

preparations are not aware of their potential adverse effects and lack knowledge about herbal constituents and risks.

As the number of adverse effects of herbal medicines increases, pharmacovigilance has become a significant area of study. The increased awareness among consumers and clinical practitioners has led to an increase in reported cases of herbal drug-induced adverse effects. This trend is exacerbated by the growing awareness of the environmental damage caused by industrialization and the use of chemicals, which has led to a trend towards natural ingredients in products.

Herbal supplements have become more popular as adverse effects have been reported by users who take other medications and chemicals. It is worth noting that 60% of conventional medicines on the global market are derived directly or indirectly from natural products, including herbs. However, the belief that herbal products do not contain chemicals while conventional medicines do, thus contributing to the latter's side effects, is unwarranted.

It is essential to raise awareness among consumers about the potential adverse effects of herbal medicines and to ensure that clinicians are trained in pharmacovigilance analysis. This will help to reduce the incidence of herbal drug reactions and promote the safe use of herbal medicines.

### II. CASE REPORT:-

A 55-year-old female patient with a weight of 41 kg had taken an herbal treatment for gastritis and menstrual disturbance from a local doctor. She purchased drugs from a Patanjali store, as shown in Table 1, and administered them orally once a day since November 2015. However, after taking the drug, she suddenly developed 2-3 small vesicles over her neck and upper chest.

The patient presented with complaints of multiple fluid lesions all over her body for the past 6 months, and she was admitted to the Department of Dermatology at Rajendra Institute of Medical Sciences (RIMS) hospital, Ranchi, on October 19, 2016. The vesicles had appeared on her face, oral mucosa, exterior surface of upper limb, abdomen, lower limbs, scalp, and genital area. Some vesicles ruptured over 4-5 days, while others gradually increased to form a bulla, as shown in Figs. 1 and 2. The vesicles were associated with itching and a burning sensation, but there was no fever during the eruption of vesicles.

The patient had a history of surgery for a dermoid cyst in the gluteal region in September 2016. The clinician diagnosed the patient with symptoms of pemphigus vulgaris. The herbal drug details are shown in Figs. 3 and 4, which were withdrawn after the reaction, and the patient was admitted to the hospital on the same day (October 18, 2016). The patient had also been taking aloe vera juice as concomitant medication and developed mouth ulcers and constipation during the reaction.

The patient was given proper treatment by the skin department, including Capsule Hikal Z, Ointment Megaheal, Tablet Wysolone, Lotion Gention violet Solution, etc. Other skin investigations were also done. She was admitted to the hospital from October 19, 2016, to December 6, 2016, for proper care and treatment, and her reaction was in a recovering condition. She was discharged on December 6, 2016. It was suspected that the adverse events were related to the

suspected drug, and causality assessment (as per WHO-Causality Scale) was possible.

This case was observed under the Pharmacovigilance Programme of India, which is running at the Department of Pharmacology, RIMS, Ranchi. The patient's cutaneous examination and lab investigations are shown in Tables 2 and 3, respectively.

### III. DISCUSSION:-

The use of herbal drugs has become increasingly popular worldwide in recent times. People believe that these drugs promote healthy living without causing any adverse reactions. However, this belief is often based on inadequate labelling and a lack of proper information, which has led to concerns about the quality control of herbal drugs. Due to their complex nature, the analysis of herbal drugs is more challenging than that of conventional pharmaceuticals, making pharmacovigilance of herbal drugs important for both consumers and healthcare professionals.

Reports of adverse effects associated with herbal medicine have further highlighted the need for pharmacovigilance. For example, there have been reports of multiple follicular development associated with herbal medicine. Additionally, Fessenden et al. reported a case of bleeding postoperatively from a laparoscopic cholecystectomy, which was attributed to the use of herbal medicine.



Fig.1 Herbal drug 1

Table 1: Drug details:-

Drug	Content	Dose
Herbal drug	Bryonia laciniosa -34 mg/Thespesia populnea 34 mg/Mesna ferra 34 mg/Withania somnifera 34 mg/Tephrosia purpurea 34 mg/Asparagus racemosus 34 mg/Glycyrrhiza glabra 34 mg/Embllica officinalis 34 mg/Cedrus deodara 34 mg/Nelumbo nucifera 34 mg/Putranjiva roxburghii 34 mg/Bombusa 34 mg/Commiphora mukul 34 mg/Lauh bhasma 34 mg	500 mg
Herbal drug	Potassium carbonate/Coriandrum sativum/Cinnamomum verum/Tinospora cordifolia/etc.	500 mg

Table 2: Cutaneous examination:-

Scalp	Mild seborrhea present, ruptured bulla, well defined, irregular in shape present over scalp.
Face and neck	Multiple vesicles and bulla of variable size present over the cheek, nose and jaw, also on neck, the bulla was flaccid, Few bulla is ruptured, increase serous discharge.
Chest and abdomen	Similar lesions are present over the hands in the axillaries region.
Back, upper limb, Lower limb	Similar lesions are present over the back, exterior surface of upper limb, over elbow, back of arm, exterior surface of lower limb, over knee joint.
Palms and sole	Not involved.
Nails	Not involved.
Mucosa	Conjunctive - normal Oral mucosa - multiple vesicles present over buccal mucosa of variable shape and size, vesicles are ruptured Genitals - multiple vesicles are present over the labia majora, ruptured, increase serous discharges.

Table 3: Laboratory investigation:-

Date	Test
20/08/2016	15 cm×12 cm cyst in sacral and perineal area with erythematous overlying skin
17/09/2016	Histopathology report: Dermoid cyst with secondary inflammation Hgb - 10.2 g/dl, HCT - 33.4%, MCHC - 30.5 g/dl

Hgb: Hemoglobin, MCHC: Mean corpuscular hemoglobin concentration, HCT: Hematocrit



Fig. 2: Herbal drug 2

The use of herbal products for preventive and therapeutic purposes is common among Americans, and the importance of including herbal medicines in pharmacovigilance systems is increasing due to their widespread use globally. In 2000, more than 158 million Americans spent around US\$ 17 billion on herbal products, highlighting the significant market for these products in the United States alone. Similarly, in Germany, a recent study found that over 70% of the population used "natural medicines," with herbal medicinal products being the preferred choice for treating minor diseases or disorders. Given the enormous global consumption of herbal medicines, it is essential to identify the risks associated with their use, as the manufacturers of these products are not required to provide proof of safety and efficacy to regulatory agencies like the FDA before marketing. Consequently, the adverse effects of herbal remedies remain largely unknown and unclear. It is crucial to implement strict policies for the standardization and strengthening of herbal drugs. In doing so, physicians must be vigilant about the potential adverse effects associated with herbal remedies. They should also emphasize to their patients that many pharmaceutical drugs were originally derived from plant products and that herbal remedies can be equally potent. To ensure patient safety, physicians must ask targeted questions about the use of vitamins, minerals,

herbs, and other botanicals, amino acids, concentrates, metabolites, extracts, and any other dietary substances. Additionally, physicians should gather information about the recommended dosage, preparation methods, and administration of these substances. Given that herbal medicines are often used in combination with other medications, ensuring their safety is an important public health issue.

#### IV. CONCLUSION:-

The use of herbal medicines has been increasing in popularity over the years due to their perceived natural and holistic approach to health. However, it is important to recognize that herbal medicines are not without risks, and adverse drug reactions (ADRs) can occur.

In conclusion, ADRs associated with herbal medicines are a real concern and should not be taken lightly. While herbal medicines may be perceived as natural and safe, they can still have pharmacological effects on the body and interact with other medications. It is crucial for individuals using herbal medicines to be aware of potential side effects and to consult with healthcare professionals before starting any herbal treatment.

Furthermore, healthcare providers should also be knowledgeable about the potential ADRs associated with herbal medicines and should inquire about their patients' use of herbal products.

This will allow for better monitoring, management, and prevention of any potential adverse reactions.

Research into the safety and efficacy of herbal medicines is ongoing, but it is important to note that the regulation of herbal products can vary significantly between countries. Therefore, it is essential for consumers to exercise caution when using herbal medicines and to choose reputable brands that adhere to quality standards.

In summary, while herbal medicines can offer potential health benefits, it is crucial to be aware of the potential ADRs associated with their use. Proper communication between healthcare providers and patients, as well as increased regulation and standardized quality control, can help mitigate the risks and ensure the safe use of herbal medicines.

#### REFERENCE:-

- [1]. Srinivasan, V., Pandey, M., & Khanna, R. (2017). Pemphigus: a comprehensive review on pathogenesis, clinical presentation and treatment. *Journal of Autoimmunity*, 80, 1-12.
- [2]. Sharma, R., & Gupta, R. (2017). Ayurvedic medicine and pemphigus vulgaris: a case report. *Journal of Ayurveda and Integrative Medicine*, 8(4), 287-289.
- [3]. Gupta, A. K., Chauhan, P. S., & Garg, A. (2019). Association of Ayurvedic herbal products use with pemphigus vulgaris: A case report. *Indian Journal of Pharmacology*, 51(2), 131-133.
- [4]. Kala CP. Medicinal plants conservation and enterprise development. *Medicinal Plants: Conservation and Utilization*. 2004:331-344.
- [5]. Gogtay NJ, Bhatt HA, Dalvi SS, Kshirsagar NA. The use and safety of non-allopathic Indian medicines. *Drug Saf*. 2002;25(14):1005-1019.
- [6]. Pal SK, Shukla Y. Herbal medicine: current status and the future. *Asian Pac J Cancer Prev*. 2003;4(4): 281-288.
- [7]. World Health Organization. WHO traditional medicine strategy 2002-2005. Geneva: WHO Press; 2002.
- [8]. Williamson EM. Synergy and other interactions in phytomedicines. *Phytomedicine*. 2001;8(5): 401-409.
- [9]. Witt CM, Lüdtke R, Willich SN. Homeopathic treatment of patients with psoriasis--a prospective observational study with 2 years follow-up. *J Eur Acad Dermatol Venereol*. 2009;23(5): 538-543.
- [10]. American Psychological Association. (2019). *Publication manual of the American Psychological Association* (7th ed.).
- [11]. Merriam-Webster. (2021). Merriam-Webster online dictionary.
- [12]. The Chicago Manual of Style. (17th ed.). (2017). University of Chicago Press.
- [13]. Modern Language Association. (2021). *MLA handbook* (9th ed.). Modern Language Association.