

## HERBAL DRUG-INDUCED ADVERSE DRUG REACTION: A CASE REPORT

MANJU GARI, LAKHAN MAJHEE<sup>1</sup>, KAVITA KUMARI<sup>2\*</sup>

Department of Pharmacology, Rajendra Institute of Medical Sciences, Ranchi, Jharkhand, India. Email: kavitapandey681@gmail.com\*

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## ABSTRACT

The present study done to focus many adverse drug reactions unrecorded with either patients failing to present to health services due to herbal medicine or no pharmacovigilance analysis is being made. In this case, a 55-year-old female patient with 41 kg weight, she received herbal treatment for gastritis and menstrual disturbance since November 2015. After administration of drug, she suddenly developed 23 small vesicles over neck and upper chest. Few vesicles ruptured over 4–5 days and few gradually increased in size to form bulla. The use of herbal drug has increased tremendously across the world in recent times. Hence, it has become important for pharmacovigilance of herbal drugs and adverse effect issues for the consumers and health-care professionals as it is complex to analyze these products than the conventional pharmaceuticals. “Safe” and “natural” cannot be used anonymously. Sufficient adverse drug monitoring of herbal drugs is as important as any other formularies.

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

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## INTRODUCTION

Herbal drugs include plants and plant material which use for the promotion of healing and maintenance of health-related problems. The trend for use of herbal medicines originated in Egypt back in 1550 BC [1]. About 80% of the world population use some form herbal medicine and herb-related product. The use of herbal medicines is increasing day by day to avoid toxic effect of chemicals and they trust on natural products, its usage increases annually at a rate of 10–20% [2]. The safety of herbal medicines is necessary because the majority of these products is self-prescribed and is used to treat all types of conditions such as minor and chronic health-related problems. Most patient consuming herbal preparations are not aware of the potential. Adverse effects of these preparations may produce. They do not have the knowledge of herbal constituents and its risk. The number of adverse effects of herbal medicines is now increasing in the study of pharmacovigilance. Herbal drug-induced adverse effect cases also increased due to increased use of herbals and also probably due to increased awareness among the consumers and clinical practitioners [3]. The awareness of the environmental damage caused by industrialization, containing chemicals, a trend has developed to use products of natural ingredients [4]. Herbal supplements become more popular after several adverse effects have been reported by the users who take other medications and chemicals [5]. Directly or indirectly 60% of conventional medicines on the global market derived from natural products, including herbs [6]. This belief is augmented by many other unwarranted claims such as herbal products do not contain chemicals while conventional medicines do, thus contributing to the latter's side effects. From the awareness about pharmacovigilance analysis and clinicians, many cases of herbal drug reaction reported [7, 8].

## CASE REPORT

A 55-year-old female patient with 41 kg weight, she took herbal (ayurvedic) treatment by local doctor for gastritis and menstrual disturbance. She purchased drugs from Patanjali store which content details available in Table 1 and administered by oral route 1 time in a day since November 2015. After administration of drug, she suddenly developed 2–3 small vesicles over neck and upper chest. The patient presented in the outpatient department of Dermatology Department at Rajendra Institute of Medical Sciences (RIMS) hospital, Ranchi,

Jharkhand, with the complaints of multiple fluid lesions all over the body for the past 6 months, and she was admitted in hospital on October 19, 2016 in the Department of Dermatology of RIMS, Ranchi. The vesicles then appeared on face, oral mucosa, on exterior surface of upper limb, abdomen, lower limbs, scalp, and genital. Few vesicles ruptured over 4–5 days, few gradually increased to form bulla which shown in (Figs. 1, 2). The vesicles were associated with itching and burning sensation. There is no fever during eruption of vesicles. History revealed that patient was operated for dermoid cyst in gluteal region in September 2016. Clinician diagnosed that patient has symptoms of pemphigus vulgaris. The herbal drug details shown in (Figs 3, 4), which withdrawn after the reaction and admitted on the same day (October 18, 2016), patient also had been taken aloe vera juice as concomitant medication. She developed mouth ulcer, constipation during treatment of reaction. She has given proper treatment by skin department with Capsule Hikal Z, Ointment. Megaheal, Tablet Wysolone, Lotion Gention violet Solution, etc. Other skin investigation was done. She admitted in hospital from October 19, 2016, to December 6, 2016, for proper care and treatment, her reaction was in recovering condition. She has been 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 Pharmacovigilance Programme of India which is running at Department of Pharmacology, RIMS, Ranchi. Patient's cutaneous examination and lab investigation shown in Table 2-3.

## DISCUSSION

Use of herbal drug has increased tremendously across the world in recent times [9]. The main reason behind is the belief that it is good for healthy living, without any adverse reaction. People have belief for herbal drug due to lack of good quality control, inadequate labelling and proper information [10]. Hence, it has become important in pharmacovigilance of herbal drugs and adverse effect issues for the consumers and health-care professionals as it is complex to analyze these products than the conventional pharmaceuticals [11,12]. Pharmacovigilance of herbal drug become highlighted after reporting of some cases as ; multiple follicular development associated with herbal medicine [13]. Fessenden *et al.* A case report of herbal medicine and bleeding postoperatively from a laparoscopic cholecystectomy [14].

Table 1: Drug details

Drug	Contents	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 soles	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

A large number of Americans are using herbal products for preventive and therapeutic purposes [15]. The inclusion of herbal medicines in pharmacovigilance systems is becoming increasingly important given the growing use of herbal products and herbal medicines globally. For example, in the United States of America, some US\$ 17 billion was spent by more than 158 million Americans in 2000. Further, under the recent study indicated that more than 70% of the German population reported using "natural medicines" and that, for most of them, herbal medicinal products were the first choice in the treatment of minor diseases or disorders. The worldwide consumption of herbal medicines is enormous, so that, in terms of population exposure alone, it is essential to identify the risks associated with their use [9]. The manufacturers of herbals products are not required to submit proof of safety and efficacy to the U.S. regulatory agency (FDA) before marketing of herbals so the adverse effects of herbal remedies are largely unknown and unclear [15]. A time



Fig.1: Ruptured bulla



Fig. 2: Multiple Fluid Lesions



Fig. 3: Herbal drug 1

has come to make a strict policies to strengthen and standardization of herbal drugs. Physicians must be alert for the adverse effects associated with herbal remedies [15]. Physicians need to emphasize that many pharmaceuticals were originally derived from plant products and that herbal remedies can be as potent as pharmaceuticals. Physicians need to ask specific questions regarding the use of vitamins, minerals, herbs or other botanicals, amino acids, concentrates, metabolites, extracts, and any other dietary substances being used by their patients. They should also obtain information about directions for use, methods of preparation, and dosage formulations [16]. Safety of herbal medicines is therefore an important public health issue. Herbal medicines are frequently used in conjunction with other medicines, and it is essential



**Fig. 4: Herbal drug 2**

to understand the consequences of such combined use and monitor whether any adverse effects are arising. This can be achieved most readily within existing pharmacovigilance systems [9]. The problem of adverse reaction due to herbal drugs can be minimized by taking several complementary actions as clear identification of the nature of adverse events, management of the risks, institution of measure to prevent adverse events, good communication of the risks, and benefits of herbal medicines.

#### CONCLUSION

“Safe” and “natural” cannot be used anonymously. Sufficient adverse drug monitoring of herbal drugs is as important as any other formularies. It has become important for pharmacovigilance of herbal drugs and adverse effect issues for the consumers and health-care professionals.

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