HERBAL DRUG-INDUCED ADVERSE DRUG REACTION: A CASE REPORT

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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 of 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 herbal medicines 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 contain 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. 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.

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].
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 herbal 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]. At time

### 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/Emblica 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
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 measures 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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Fig. 4: Herbal drug 2