ADVERSE EFFECT OF UNANI PHARMACOPOEIAL FORMULATION HABB-E-KARANJAWA

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ABSTRACT

Pharmacovigilance (PV), which is also known as drug safety. It is the pharmacological science relating to the detection, assessment, understanding and prevention of adverse effects, particularly long term, and short term side effects of medicines [1]. The key role of this field of medicine is to ensure the safe reception of drugs, examining the adverse side effects reported by patients. The compound causing side effects in the drug need to be identified and the remedy to counteract the side effect should be explored. This study was carried out at Regional Research Institute of Medicine (RRIUM), Srinagar, wherein a total of 10 patients suffering from general body ache, common cold and fever etc were analysed for the adverse side effects caused after prescribing the pharmacopoeial drug Habb-e-Karanjawa. It was observed that almost all patients suffered from gastritis after the consumption of the drug. After a thorough analysis of the ingredients of the drug it was concluded that the corrosive effect of compound copper sulphate or TutiaSabz present in Habb-e-Karanjawa can be the main reason of causing gastrointestinal problems in patients.

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Keywords: Habb-e-Karanjawa, Adverse drug reaction, TutiaSabz, Pharmacovigilance.

INTRODUCTION

Pharmacovigilance (PV) is defined by the world health organization (WHO) as "the science and activities relating to the detection, assessment, understanding, and prevention of adverse effects or any other drug related problems". It plays a key role in ensuring that patients receive safe drugs. An adverse drug reaction (ADR) can be defined as "an appreciably harmful or unpleasant reaction resulting from an intervention related to the use of a medicinal product; adverse effects usually predict hazard from future administration and warrant prevention, or specific treatment, or alteration of the dosage regimen [2]. In addition to the sufferings caused by these ADRs, increase in morbidity and mortality along with a financial burden on society are some more unfavorable factors associated with it [3]. PV is an important and integral part of clinical research [4]. It is the science which deals with the complex process of understanding and explaining the nature of ADRs occurring in a patient taking either oral or parenteral or intravenous (I.V) drugs for an ailment. Although the drugs being marketed undergo preclinical trials on animals and clinical trials on human subjects to assess the safety of the drug

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intended to treat a particular disease, there is still a major part of it that goes undetected and some of the ADRs are detected in post marketing surveillance. It is estimated that there is a significant amount of ADRs which decrease the quality of life, increase hospitalization stay and increases the mortality. In 1998, a landmark study by Lazarou described that in the USA, ADRs are the fourth to sixth leading cause of death including 3-7% of all hospital admissions [3]. According to the survey of World Health Organization (WHO), in developing countries nearly 80% of population depends on the traditional system for their primary healthcare. Unani System of Medicine (USM) which is well established in India is based on Hippocratic theory of humours. In USM drugs of plants, animals and mineral origin are used either in single or compound form. Compound preparations may be classical, pharmacopoeial and propriety/patent. The selection of drug for any ailment depends upon the choice of physicians. In USM drug can be divided into four groups according to their degree of temperament, i.e. first, second, third and fourth degree. First degree drugs produces pharmacological effect but their effect in terms of qualities, i.e., hot or cold, are not perceptible at recommended dose. Second. The effects produced by second degree drugs in terms of qualities, are perceptible, but they do not alter normal functioning of the body at recommended dose. The effects of third degree drugs are strong in terms of qualities and alter normal functioning of body remarkably, but not to the extent of causing harm. The effects of Fourth degree drugs because of their qualities are excessively strong and toxic to the extent of being fatal. However, after specific process of detoxification (tadbir) these drugs can be used safely [5]. So it would not be wrong to say that the myth that Unani drugs are safe and do not produce any adverse effect is baseless. Any substance which is a drug, has more or less side effects if not prepared as per their methods of preparation or if not detoxified properly before when needed.

Habb-e-Karanjawa is a pharmacopoeial preparation and is used for \textit{Humma} (fever), \textit{Diq al-Nafas} (bronchial asthma), \textit{WarameSo’baturreya} (bronchitis) and \textit{Waja’ al-Mafasil} (joint pain). It is a compound pharmacopoeial Unani formulation having two ingredients, Karanjawa (\textit{Caesalpinia bonducella}) and Tutiaisabazkham (copper sulphate) in a particular ratio [7]. It is seen that Habb-e-Karanjawa produce some adverse reactions in some patients suffering from the above mentioned disorders. This study is aimed to understand the cause of such ADRs produced due to the consumption of Habb-e-Karanjawa by patients suffering from fever, joint pain, general body ache.

**MATERIAL AND METHODS**

This study was carried out October 2021- February 2022 at Regional Research Institute of Unani Medicine OPD, Hazratbal, Srinagar-J&K, to understand the cause of adverse effect in Unani pharmacopoeial drug Habb-e-Karanjawa which is used to treat the ailments like fever, joint pain and common cold. 10 patients on various dates between the above mentioned months, including both males and females of age group 20-65 years, having common cold, general body ache and fever were thoroughly examined and were prescribed pharmacopoeial preparations Habb-e-Karanjawa, manufactured by Indian Medicines Pharmaceutical Corporation Limited (IMPCL) under Batch no. IME-0330. The ingredients, dosages and therapeutic actions/uses of Habb-e-Karanjawa are as follows.

**Habb-e-Karanjawa:**

The ingredients of Habb-e-Karanjawa are mentioned in Table 1 below:

<table>
<thead>
<tr>
<th>Ingredients</th>
<th>Scientific name</th>
<th>Weight</th>
</tr>
</thead>
<tbody>
<tr>
<td>Karanjawa</td>
<td>\textit{Caesalpinia bonducella} (L.) Roxb.</td>
<td>1 piece</td>
</tr>
<tr>
<td>Tutiaisabazkham</td>
<td>Copper sulphate</td>
<td>125 mg</td>
</tr>
</tbody>
</table>

Figure 1: Photograph of Habb-e-Karanjawa (I) and its packing (II), Ingredients, Batch no, Date of expiry written on packing (III).
Dosage: 1-2 tablets/orally

Therapeutic Uses:
- Ḍīq al-Nafas (bronchial asthma)
- Su’al/Surfa (cough)
- Ḥummā (seasonal ever)
- Dhat al-Janb (pleurisy)[7,8,9]

Observations
It was observed that after taking the first dose of Ḥabb-e-Karanjawa, all the patients subsequently reported that they are suffering from gastritis. Out of 10 patients, 3 suffered from moderate gastritis and profuse vomiting, while 7 patients suffered from mild gastritis. In order to identify whether the drug has caused the adverse effect or not, patients were advised to first discontinue Ḥabb-e-Karanjawa. Reportedly, the symptoms of gastritis disappeared. In second step, re-administration of Ḥabb-e-Karanjawa was done. Four patients out of 10 patients were advised for re-administration of Ḥabb-e-Karanjawa along with butter or ghee and in rest 6 patients, no such addition was advised. It was observed that after addition of butter or ghee the symptoms reduced significantly whereas after re-administration of Ḥabb-e-Karanjawa without butter or ghee, the symptoms of gastritis reappeared and these 6 patients were advised to stop taking Ḥabb-e-Karanjawa and to observe themselves for next 48 hours. After 12-48 hours there was improvement in the condition of patients and by 48-72 hours, they were normal.

DISCUSSION AND CONCLUSION
The compound formulation, Ḥabb-e-Karanjawa consists of two ingredients namely Karanjawa and TutiyaSabz. As per Unani literature the temperament of Karanjawa is hot in first degree and dry in second degree and it cause nausea and vomiting [9]. On the other hand TutiyaSabz or copper sulphate is a strong corrosive compound which is known to have corrosive effect on gastrointestinal tract. This is responsible for causing nausea, epigastric pain and vomiting [10]. In Unani Literature it is also described as Ḥakkal (corrosive) and Qatil (fatal) and it cannot be consumed orally without prior detoxification. Butter or RoghanZard has been mentioned as its corrective (muslah) [11]. This is the reason for advising some patients to take Ḥabb-e-Karanjawa along with butter or ghee which significantly reduced the symptoms. Therefore, it can be said that the gastrointestinal problem caused by Ḥabb-e-Karanjawa is mainly because of the presence of TutiyaSabz.

The study provides the key cause of the commonly reported ADRs by the consumption of Ḥabb-e-Karanjawa. Physicians needs to take extra care while prescribing such kind of medicines to their patients. Physicians should also keep this in mind that Such medicines should be prescribed along with the corrective in order to reduce the severity of Side effects. It is always encouraged to explore the content regarding any drug to avoid the reception of such ADRs. If reported, it is advised that they should inform about the suspected cases to regulatory authorities and associated pharmaceutical companies. Reporting of such cases are helpful for analysis of the ADRs produced from these drugs.

REFERENCES