

Pharmacovigilance for the Unani Medicine: Present Scenario and Future Prospects

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ABSTRACT

Treatment is the noblest, as well as the most challenging art. The safe and effective use of medicinal products and procedures is always the core concern of healthcare treatment. In the present scenario, there is an organized adverse event reporting system called pharmacovigilance, has developed to improve patient care and safety regarding the use of medicinal products. The Unani is an ancient system of medicine and is deeply rooted in Asian civilization. It is a popular belief that the Unani medicinal products and procedures are safe, but it is not always true. The acute and chronic adverse drug effects, adverse interactions of drugs with other substances, abuse, and misuse of drugs are discussed in the text of the Unani medicine. Hence, pharmacovigilance is a pressing priority to establish the safety and efficacy of Unani medicinal products to make them more precise.

Keywords: Pharmacovigilance, Unani medicine, Traditional Medicine, AYUSH

INTRODUCTION

Hippocrates said, "You need to abide by two things: the first is to help the patient, the other not to harm him".^[1] The Unani system of medicine is based on the humoral doctrine of Hippocrates (460-370 BC).^[2] Humoral theory is the first theory of

scientific medicine, according to this theory there are four categories of body fluid - blood, phlegm, yellow bile, and black bile; collectively called humours. Optimum quality, quantity, and proper proportion of humours in the body constitute good health; any deviation in quality or quantity of any of the humours reflects in disease.^[3,4] Since ancient times Greek and Roman physicians have used three modalities of treatment: (1) the first cured by diet called Diaetetic, (2) the second by medicines called pharmaceutice, and the third by manual operations called Chirurgice.^[5] To minimize the harmful effects of pharmaceutical substances, the drugs are classified into four grades. The noxious effects of drugs gradually increase from Grade I to IV. The effects of drugs of the first grade are mild, the second-grade drugs are stronger than first and do not harm the normal function of organs but repeated use of these drugs may cause impairment in the function of organs. The noxious effect of grade III drugs is more than the grade I and II, in a healthy person the single use of these drugs, may produce a strong enough effect to cause impairment in normal physiology, but these drugs are not lethal. Fourth-grade drugs are termed toxic drugs; hence these drugs should be used with caution.^[6] The safety of the patient has been of utmost importance in medicine since the early days. Ancient physicians like Hippocrates, Galen, Celsus,

all placed great emphasis on the safety of the patient. However, the modern pharmacovigilance emerged with the anesthesia accidental death of Hannah Greener during her tonsillectomy on Jan 29, 1848, which was more organized later.^[7,8]

Concept of Pharmacovigilance in Ayurveda, Siddha and Unani: The word "pharmacovigilance" comes from *pharmakon* (drug in Greek) and *vigilare* (keep a watch on/monitor in Latin).^[9] As such, it chiefly focuses on adverse drug reactions (ADR), that are outlined as any response to a drug that is vesicatory and unmotivated, as well as lack of efficaciousness. Pharmacovigilance is outlined by the United Nations agency as a science, with activities that relate to the detection, assessment, understanding, and interference of adverse effects or the other drug-related issues.^[10] The common story relating to herbal medicines is that these medicines are utterly safe and may thus be safely consumed by the patient on his/her own, without a physician's prescription. This belief has diode to large-scale self-medication by folks everywhere the globe, typically resulting in unsatisfying end-results, facet effects, or unwanted aftereffects. Traditionally herbal (Unani) medicines are considered to be safe for

therapeutic usage without any major harmful effects. However, besides beneficial therapeutic effects several suspected adverse effects have been reported in the literature as well as clinical practice that include hepatotoxicity, renal failure and allergic reactions.^[11] Hence, AYUSH practitioners and customers currently have to be compelled to be argus-eyed regarding the protection observance of medicine within the interest of Public Health. Pharmacovigilance has taken a centre stage in this whole process, as many herbal products are laden with quality issues, incorrect or misidentified herbs, incorrect processing methods, supply of adulterated or contaminated herbs or products.^[12]

Need and scope of Pharmacovigilance for Unani drugs: Pharmacovigilance initiative can facilitate detection of doubtless unsafe Unani medicines and dishonorable advertisements for taking restrictive action against them. Ibn-e-Sina has done a pioneering work in this regard. An elaborated general and systemic pharmacology of the then existing drugs includes cardio-active drugs, code of recipes and a valuable knowledge on the methods of preparation of more than 2000 simple & compound drugs (figure.1).^[13]



Figure.1: Need of Pharmacovigilance for Unani drugs

As per the report printed by UN agency, ancient medication has widespread acceptance throughout the globe and seventieth of the globe population depends on traditional health care system for management of varied diseases. The use of herbal medication has multiplied, the reports of suspected toxicity and adverse reactions have additionally multiplied proportionately. Majority of the adverse events associated with the uses of those herbal medicine are attributed either to poor product quality or to improper use.^[6,8] Lack of correct restrictive mechanism, weak internal control system and for the most part uncontrolled distribution channels (e.g., web sale), is taken into account to be the most issue for the incidence of such adverse events. Such adverse reactions can be observed and categorized as:^[14]

- a) Facet Effects (usually foreseeable and detectable by pharmacodynamics).
- b) Reactions occurring as a result of over-duration, tolerance, dependence.
- c) Allergic, sensitized and individual reactions (detected by pharmacovigilance).
- d) Mid-term and semipermanent unhealthful effects as well as urinary organ, hepatic, internal organ and neurotoxicity and teratogenicity (detected by in-vitro and in-vivo materia medica studies or by pharmacovigilance).

Impediments in implementation for Pharmacovigilance programme in Unani medicine

Unani drug formulations contain substances of varied origins like plant, animal and mineral source in varied proportions.^[15] They include both relatively crude preparations, such as herbal tinctures, *Joshanda* (decoction), *Khaisanda* (infusion) and manufactured or finished herbal medicinal products such as tablets, capsules, syrups, oils etc. and are also available for purchase without prescriptions.^[16] People under this pathy are not actually very serious about Unani Pharmacovigilance

programmes. Many of the people are still not aware of the Pharmacovigilance. There is a huge gap of knowledge and communication. One of the common problems with Unani drugs is that a specific medicine is having multiple uses and may be taken by healthy individuals for “general well-being” as well as by patients with chronic diseases. Processing techniques of the crude Unani drugs can also affect the quality and quantity of various chemical constituents.^[17] Back then Ibn-e-Sina emphasized upon the need to watch constantly the action of drugs in most of the cases and the drug being just in proportion to the nature and severity of the disease both in quality and quantity.^[13] He indicated that the experiment on humans should be done at last and not on animals as both have a different temperament.

Suggestion for Future prospect

Pharmacovigilance is the need of the hour for all systems of medicine because it ensures patients safety. Following are sure aspects wherever a lot of stress is required for higher pharmacovigilance to apply in Unani system of medicines.

1. A separate subject of Pharmacovigilance should be enclosed within the syllabus of graduate & post-graduate level studies in Unani drugs.^[10]
2. Clinical analysis units of various pharmacies as well as establishments conducting postgraduate/doctoral level analysis ought to embrace Pharmacovigilance mutually of the standards in their analysis.
3. Drug licensing authorities of Unani medicines ought to embrace Pharmacovigilance mutually of the pre-requisites for giving selling permission for brand spanking new medicine.
4. Regularity framework governing the producing and licensing of the Unani medicine ought to be revisited.
5. Unani pharmacy group should ought to demonstrate the standard, safety and effectivity of their merchandise before selling.

6. Drug manufacturer ought to have applicable internal control and quality assurance procedures for his or her merchandise.
7. Diagnosing and clinical trials of the Unani merchandise ought to be created necessary.
8. Post selling police work of studies ought to be a routine for every product.
9. A delegated qualified and knowledgeable person ought to have a continuing access to the producing method for quality assurance.
10. Drug Extract magnitude relation indicating the strength and therefore the formulation of the merchandise e.g., tablets, syrups, tincture etc. ought to be standardized.^[18]

DISCUSSION

There is a three-tier system of pharmacovigilance in the National pharmacovigilance program for ASU drugs in India. At the national level, the National Pharmacovigilance Centre (NPvCC) is located in All India Institute of Ayurveda, New Delhi; Intermediary Pharmacovigilance Centres (IPvCCs) are located at all National Institutes of AYUSH system and several Peripheral Pharmacovigilance Centres (PPvCC) are working all across the country. In Unani medicine, a large number of herbs, shrubs, minerals, and animal-origin drugs are used in crude and processed form. Several types of compound formulation of drugs are also needed for medication; hence the chance of error, adulteration, Contamination, and drug interaction cannot be denied. To improve the efficacy and minimize the risk of medication proper pharmacovigilance must be established.^[6,18]

CONCLUSION

If we wish to market Unani medicine among general public, pharmacovigilance is an absolute demand to confirm public safety and to market the healthy development of ASU systems of medication. All the stakeholders of Unani system of medicine have

to be compelled to be educated through intensive coaching and content relating to pharmacovigilance aspects of those drugs and Government and pharmaceutical sectors ought to take initiation during this regard by providing a lot of monetary help through monetary fund provisions. The protection of Unani medicine could be a concern throughout the entire life amount of the drug. Internal control remains one among the most problems in Unani medicine safety considerations. Standardization and social control of GMP and producing tips can support any safety initiative. In order to achieve operational competence in the development of pharmacovigilance for Unani drugs and for the best practice model for Unani medicine, a systematic analysis of the areas to be focussed upon and the challenges ahead, starting from proper nomenclature of Unani drugs, cultivation, procurement, drying, transportation, processing, labelling and dispensing should be undertaken.

Declaration by Authors

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