WORLD JOURNAL OF PHARMACEUTICAL RESEARCH
SJIF Impact Factor 8.074
Volume 7, Issue 19, 345-350. Review Article ISSN 2277– 7105

PHARMACOVIGILANCE: A DIRE NEED IN UNANI SYSTEM OF MEDICINE

M. Nafees Khan*[1], Mumtaz Ahmad[2], Jamal Akhtar[3] and M. A. Khan[1]

[1]Central Research Institute of Unani Medicine Lucknow.

[2]Regional Research Institute of Unani Medicine Patna.

[3]Central Council for Research in Unani Medicine, New Delhi.

Article Received on
25 Sept. 2018,

Revised on 15 Oct. 2018,
Accepted on 04 Nov. 2018

DOI: 10.20959/wjpr201819-13703

***Corresponding Author**
Dr. M. Nafees Khan
Central Research Institute of Unani Medicine Lucknow.

ABSTRACT

Unani system of medicine, although originated in Greece, is one of the recognized systems of medicine in India. In the age of advance technology, scientific progress, consumer awareness and the advent of evidence based medicine, there is inadequate genuine clinical trial evidence supporting the efficacy and safety of Unani drugs, except that this system is practiced since thousands of years. Although, the technical term "Pharmacovigilance" does not feature in Unani texts, the spirit of pharmacovigilance is vibrant and is emphasized repeatedly in all major texts. The major goals of pharmacovigilance, namely to improve patient care and safety in relation to drug use and thus promote rational drug use on patients. The use of Unani medicine is popular in India and in recent time has become accepted in other countries. Now in this era of globalization certain concerns are raised in regards to their safety. Unani system of medicine has their own principles, has their own pharmacopoeia, but is practised in the country as OTC drugs and without an authentic prescription. Inclusion of Unani medicines in pharmacovigilence system is becoming increasingly important given the growing use of Unani products globally. Pharmacovigilence is an important tool to analyse the drug effect particularly its side effects, if any. This paper outline the need of pharmacovigilance, and the implementation of National pharmacovigilence program for Unani drugs.

KEYWORD: Pharmacovigilance, Adverse drug reaction, Unani Medicine.

OBJECTIVES

Though for centuries Unani drugs are considered as safe and innocuous drugs, this perception is likely to change in the light of some recent occurrence of incidence of adverse drug reaction during their use. This along with increased wide spread use of both national and international levels is likely to lead to increased interaction of these drugs with diverse genomic profiles. This is likely to more incidence of expression of unexpected effects, which may be useful or adverse in nature. Thus, it should be considered as the right time to explore a mechanism to record adverse drug reactions of Unani drugs. Since there is considerable social and economic consequences of adverse drug reactions and the positive benefit / cost ratio of implementing appropriate risk management, there is need to engage health care professionals and public at large in a well structured programme to build synergies for monitoring adverse drug reactions of Unani drugs. The purpose of pharmacovigilance is to collect and collate data, analyze it and use the inferences to recommend informed regulatory interventions, besides communicating risk to healthcare professional and public.

Need For Pharmacovigilance of Unani Medicines

In ancient times, the Unani physicians prepared formulations for their patients themselves. Now days, only few Unani practitioners follow this practice and production and sale of Unani medicines has become formalized into a thriving industry. This commercialization has brought with it many challenges about safe use of Unani drugs, bringing into focus the need for formal pharmacovigilance program in the field.

And yet, the number of adverse reactions to Unani medicines repeated or recorded in National pharmacovigilance programme in India is negligible. The strong belief that Unani medicines are safe contributes to a large extent to this situation. To compound this matter is the lack of knowledge about the concept and importance of pharmacovigilance in Unani system of medicine among Unani physicians.

Challenges In Introducing Pharmacovigilance In Unani System of Medicine

Although the national pharmacovigilance program has encouraged reporting of all suspected drug related adverse events including those caused by herbal / traditional / alternative medicines (protocol of NPP, version 1:2004, P 17), the number of reports related to be Unani/herbal drugs has been abysmally low. Several challenges that preclude identification and reporting of adverse reactions to Unani drugs can be identified related to detection, assessment and prevention of adverse reactions.

Detection of Adverse Reaction to Unani Medicines

Perhaps because of the firm belief among the doctors and prescribers alike, that Unani drugs are safe, the detection of adverse drug reaction to these medicines is a major challenge from obtaining a correct history, to diagnose and to pin- pointing the causal medicine the path is full of obstacles, including:

1. The concepts of terminologies related to adverse reaction monitoring are not covered in the Unani system of medicine curriculum precluding accurate identification of adverse reactions.
2. Methods to study drug safety problems have not evolved adequately in Unani system of medicine.
3. Although information related to medicines exists in the stanza in the ancient treaties of Unani, It is not easily accessible.
4. Signal detection is difficult because there is an inherent belief about safety of Unani medications leading to lack of reporting and collection of reports relating to any formulation.
5. Patients often use medicines from different system of medicine concomitantly leading to difficulties in assigning causality.
6. Lack of quality assurance and control in manufacturing of Unani medicine, which acts as confounding factor in diagnosing the adverse reaction.
7. The informal sector manufacturing and selling Unani drugs on a small scale are large and this often makes it impossible to identify the medicine that may be causing the adverse reaction.

Assessment of Adverse Reactions to Unani Medicines

Although several scales are available for causality assessment applying them for Unani medicines and ascribing causality is perhaps the greatest challenge for several reasons, including:

1. Interaction related to adverse effects is scattered in Unani literature and not in electronic form, hence making it is difficult to access. Many publications are not in peer reviewed journals and the quality of available publication is questionable.
2. Most Unani formulations are multi ingredient fixed dose formulations rarely prescribed alone (i.e. there are multiple herbal and herb- mineral FDCs being consumed at the same time.).

3. Additionally there is the confounding factor that the patient is often receiving allopathic medicines at the same time.
4. Pharmacokinetics and toxicokinetics are very difficult and this point of time, well nigh impossible making definite causality virtually impossible.
5. Dose-related responses are rarely measured and reported.
6. Rarely, if ever is de-challenge and re-challenge performed and there is no objective evidence of the adverse event.
7. One of the most challenging aspects is the lack of expertise in performing causality analysis with Unani medicines. A person trained in pharmaco vigilance rarely understands Unani system of medicine while an expert in Unani is not trained in the science of pharmacovigilance.

Prevention of Adverse Reactions to Unani Medicines

The success in any pharmacovigilance system is the ability to prevent further adverse reaction successfully by understanding and using the information collected. With Unani medicines, the challenges would be at multiple levels.

1. Communication between the practitioners and policy maker of orthodox western medicines and traditional Indian medicines not adequate. Unani practitioners are not aware of the need to report and where to report.
2. Unbiased drug information about Unani drugs including both classical and proprietary formulation is not available easily.
3. Patients are not adequately aware that Unani medicines can cause adverse reactions and can take medicines for years on end with no monitoring as they believe that these medicines can do harm. Hence they do not even give history of taking these medicines.
4. Education in Unani medicine at both under-graduate and post graduate levels does not cover pharmacovigilance of Unani medicines, thus never exposing the young physicians to this concept.
5. The Unani pharmaceutical industry is not motivated to focus on pharmacovigilance of Unani medicine. Hence there is no attempt at generating safety data either before or after marketing of the formulation.

Conclusion and Recommendations

There is no systematic data on the incidence of Unani medicine associated adverse effects. One of the difficulties has been that there are many complex issues relating to adverse event

detection with Unani products. These include the problems of products with multiple ingredients drug of multiple system of medicines, misclassification of names, poor standardization of products, lack of clinical trials, variation in manufacturing processes, contamination, adulteration and miss identification of herb. In particular rare adverse events and delayed effects may not be readily identified despite traditional use, countering the argument that many herbal remedies are safe because of previous traditional use.

Based on these observations, there are several ways we can move forward in attempting to embrace pharmacovigilance system into Unani system of medicine.

1. Introduce pharmacovigilance concepts into the curriculum of Unani system of medicine at the under-graduate and post-graduate level.
2. Encourage studies on drug safety.
3. Make reporting of adverse reactions to regulators mandatory for Unani formulations.
4. Make unbiased and easily accessible drug information available. The traditional knowledge digital library launched by the Government of India is an example of how ancient knowledge available in the ancient scriptures can be made digitally accessible.
5. Create awareness about the science of pharmacovigilance among Unani physicians, patients and paramedical staff.
6. Development and validation of scales to assess the causality of the reported reactions to Unani medicines.
7. It will be necessary to train Unani experts in the science of phamacovigilance and include them not only in reporting but also assessment of the adverse reactions. This direct involvement of Unani academic institutions in the NPv CC after appropriate training would be an appropriate first step in this direction. A strong cooperative effort from expert in pharmacovigilance and Unani medicine together can ensure that this system is up and functioning.

REFERENCES

1. Capacity building training program on pharmacovigilance. Regional pharmacovigilance cell for ASU drugs, National Institute of Ayurveda, Amer Road, Jaipur 7th & 8th Feb 2011.
2. Rehman HSZ. Historical perspective of traditional medicine with special reference to ADRs. National Symposium on relevance of pharmacovigilance for Indian system of

medicine. Department of AYUSH, Ministry of Health and Family welfare, Government of India and society of pharmacovigilence, India; 4th, November 2006; 53-61.

3. Singhal KC, Rehman SZ. Abdal al Advia (Substitution of drugs) – a challenge to pharmacovigilance (Chapter 3). In: Arunbha R, Kavita G, editors. Pharmacovigilance: an update New Delhi; Vallabh Bhai patel Chest Institute, 2004; 22-44.
4. Rehman SZ, Khan R A, Gupta V, Uddin M. Pharmacoenvironmentology : A component of pharmacovigilance. Environ Health 2007; 6:20 (online) http://www.ehjournal.net/content/6/1/20.
5. Rehman SZ, Singhal KC. Problem in pharmacovigilance of medicinal products of herbal origin & means to minimize them. Uppsala Report, 2002; 17: 1-4.
6. Latif A, Rehman SZ. A serious adverse drug interaction of two traditional medicines – a case report. J pharmacovigilance Drug Saf, 2005; 2: 26-29.
7. Dahanukar SA, Thatte UM. Ayurveda revisited. 1st ed. Mumbai: Popular Prakashan Private Ltd., 1989.
8. Available from: http://indianmedicine.nic.in/html/edu/aemain.htm (last Accessed on 2007 September 7).
9. Malik V, editor. Drugs and Cosmetic Act, 1940, "4th Chapter", Part I, 14th ed. Lucknow: Eastern Book Company, 2002; 37-44.
10. Available from: http//indianmedicine.nic.in/html/manufactures/manufacture htm#ad (Last Accessed on 2007 September 7).
11. Parab SM, Kalele SS, Verma S, Kulkarni RA, Shinde VJ, Bhalerao SS, etal. Safety issues with medicines from alternative system of medicine. In: Proceedings of Workshop on Pharmacovigilance: Promoting Drug Safety through Collaboration; 2003 December 5-6, Parel, Mumpai: Seth GS Medical College, 22.
12. Available from: http://203.200.90.6/tkdl/LangDefault/common/Abouttkdl.asp?GL = Eng (Last Accessed on 2007 September 7).
13. Urmila Thatte, Supriya Bhalerao, Pharmacovigilance of ayurvedic medicines in India. Indian J Pharmacol, February 2008; 40(1): S10-S12.
14. Ibn Sina, 2, Cairo; 1294/1877. 224-225.
15. Jabin Farkhanda, Singhal KC, Bhargava R, Latif A, Rahman SZ. Clinical trial of an herbal formulation and associated adverse drug reactions in patients of bronchial asthma. J Pharmacovigilance Drug Saf, 2005; 2: 16-19.