Pharmacovigilance in Ayurveda – Concept and Regulations

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Abstract: Background: The Indian system of medicine has its origin in India and has been practiced since centuries in India and its neighbouring South East Asian countries. Mostly the practice of this system of medicine is believed to be the safest form of therapy, however, incidences of adverse drug reactions owing to the consumption of traditional drugs led to the origin of pharmacovigilance of Ayurvedic drugs.

The Concept of Pharmacovigilance: Pharmacovigilance is the science of detection, understanding, assessment and prevention of adverse drug reactions and related untoward effects.

Concepts and Regulations of Pharmacovigilance in Ayurveda: Given the current scenario of the usage of the traditional and alternative medicine at a global scale, it becomes imperative to ensure the safety of the patients consuming these medications. This makes the science of pharmacovigilance, a significant domain in the field of medicine and public health as well. Nevertheless, the adverse drug reaction of traditional Ayurvedic medicine may range from trivial effects to serious fatal outcomes leading to the death of a patient. Furthermore, the application of the principles of pharmacovigilance in the realm of Ayurveda is a challenging job owing to several of the inherent characteristic features associated with such a science. Albeit recent researches are based on in-vivo and/or in-vitro trials of many herbal preparations, however, the science of Ayurveda is the science of ages and is transmitted from generation to generation. During the recent past considering the significance of pharmacovigilance in Ayurveda and other indigenous systems of medicine, a national pharmacovigilance unit of ASU (Ayurveda, Unani and Siddha) systems of medicine has been initiated at Gujrat Ayurveda University in the year 2008.

Keywords: Adverse drug reactions, ASU drugs, drug therapy, indian system of medicine, patient safety, traditional medicine.

1. INTRODUCTION

Pharmacovigilance refers to the ways and means to reduce the drug-related adverse effects. Thus, the origin of Pharmacovigilance traces back to the felt need among the physicians in order to protect their patients from preventable adverse drug reactions. Pharmacovigilance deals with the prevention of untoward and unwanted effects of drugs and other medical interventions intended for treatment and diagnosis of morbidities [1]. Pharmacovigilance motivates healthcare professionals to participate in the continuous process of surveillance of safety and efficacy of pharmaceutical products used in clinical practice. Continuous evaluation of benefits and harms of pharmaceutical products would lead to the ultimate goal of making safer and effective treatment available to the patients [2]. Pharmacovigilance refers to the process of identifying side effects of drugs, their treatment, documentation, reporting, and regulatory decisions based on these findings [3]. It is the natural or the implied willingness in the part of a healthcare provider to ensure safety to the patients. The philosophy behind Pharmacovigilance is first do no harm towards a wider and systematic application in clinical practice [4]. Moreover, most of the national programs make efforts to expand the horizons of pharmacovigilance by incorporating blood transfusion, vaccination, and traditional health care within its domain [5]. In this way, ASU (Ayurveda, Unani and Siddha) drugs also come under the ambit of Pharma-

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covigilance. This article delineates the scope of Pharmacovigilance and its application in the field of Indian systems of Medicine, especially Ayurveda.

2. INTRODUCTION TO TRADITIONAL AYURVEDA MEDICAL SYSTEM

Most of the existing traditional systems of medicine in India, including Ayurveda, have their roots in folk medicine. However, Ayurveda has got a well-defined and distinct conceptual framework that is consistent throughout the ages compared to other systems of medicine in India. On conceptual basis, it is one of the highly evolved systems of medicine and is always far ahead of time. It is amongst the first systems of medicine to advocate an integrated approach towards matters of health and disease. Contrast to other traditional systems of medicine Ayurveda first provided a philosophical framework that determined the therapeutic practice with good effects where other systems determined the effects based on the results obtained with the use of drugs and therapy. The philosophical base of Ayurveda is partly derived from ‘Samkhya’ and ‘Nyaya vaisheshika’ streams of Indian philosophy. This probably enabled Ayurveda to evolve into a rational system of medicine quite early in its evolution and to get detached from religious influence. This helped bringing in the value of evidence of senses and human reasoning [6].

Ayurveda in India is not just considered as an ethnomedicine rather accepted as a complete system of medicine which has the capacity to take care of the physical, psychological, philosophical, ethical and spiritual well-being of mankind [7]. It is the ethnic bequest deeply buried in the traditional believes of the people of India [8]. It primarily focuses on living in harmony with the universe and harmony of nature and science. This approach emphasizes the significance of maintenance of proper lifestyle for keeping positive health. This was in vogue since long, however, the practitioners of modern medicine have accepted this idea very recently [7]. Interestingly the definition of health pronounced by WHO is in close approximation with the idea of health described by Ayurveda [9].

3. THE CONCEPT OF DRUG THERAPY IN AYURVEDA

Before comprehending the concept and need of Pharmacovigilance in Ayurveda it becomes imperative to briefly understand the concept of drug therapy in Ayurveda. Ayurveda lays greater emphasis on the identification and properties, however, it also lays equal emphasis on the use of proper drugs in proper clinical conditions. Ayurveda emphasizes on three important concepts of drug therapy; Yoga, Yukti and Mana. Yoga refers to the appropriate usage of one drug or the combination of one or more drugs for patients. Mana refers to the dosage and its individualization as per the patient needs. Yukti refers to the tactful usage of medicines as per the individual needs. These are the three important principles based on which a safe and efficacious treatment is ensured to the patients. Furthermore, Ayurveda renders flexibility in terms of choice, dosage, combination and duration of the therapy as per the sensitivity of the patient and the seriousness of the ailment. Thus it proves that practice of Ayurveda in accordance with the delineation of the classical Ayurveda texts would minimize the adverse drug reactions to a great extent [10, 11].

4. THE CONCEPT OF PHARMACOVIGILANCE IN AYURVEDA

Ayurveda, the science of life, is the most ancient medical doctrine of human civilization [12]. This has evolved gradually from its classical treatise based knowledge to the present day text books and from Gurukul education to college based education system. The classical Ayurveda texts do not make a clearer distinction across the disciplines except a few [13]. This is equally applicable to the realm of pharmacovigilance as well. There are descriptions regarding drug formulation and the adverse reactions as well in different classical treatises of Ayurveda. These classical Materia Medicas are known as Nighantus in Ayurveda. The term Nighantu refers to a Sanskrit term for a traditional collection of words, grouped into thematic categories, often with brief annotations. These are glossary like texts that are comprised of information pertaining to substances used as therapeutics with a primary objective of determining the correct substances as delineated in classical treatises of Ayurveda [14]. With the passage of time, these Nighantus started describing the pharmacological profile and therapeutic applications of the substances in addition to the synonyms. As on date, there are about 57 Nighantus available in Ayurveda [14]. In addition to this, one of the forefathers of Ayurveda, Acharya Charak, has cautioned about the right usage of drugs; “a strong poison can act as an excellent medicine if administered properly and the most useful drug can act as a poison if handled carelessly”[15]. Acharya Charak has described situations where drugs are utilized properly with respect to their order, proportion, combinations, or indications required as per the individual needs [15]. Furthermore, Acharya Charak emphasizes three important aspects for the safer usage of drugs; knowledge about the name of the drug, its physical identification and its properties [15]. Thus, it proves that albeit the concept has not been delineated in its current parlance, however, descriptions are found in the form of proper usage of drugs and the repercussions as a result of improper usage.
5. THE CONCEPT OF ADVERSE DRUG REACTION IN AYURVEDA

As a classical text, Ayurveda does not really use the term “Adverse Drug Reaction (ADR)” in its delineation; however, similar concepts are found which have got contemporary relevance. Ayurveda lays utmost importance toward safety and benefit of patients in each aspects of treatment which includes selection and collection of drugs, processing techniques and proper administration to proper patients. The major concepts of ADR delineated in Ayurveda and relevant examples are tabulated below in Table 1 [16].

<table>
<thead>
<tr>
<th>Concept of ADR in Ayurveda</th>
<th>Modern Parlance/ Equivalence</th>
<th>Examples</th>
</tr>
</thead>
<tbody>
<tr>
<td>Viruddadravyaprayoga</td>
<td>Drug Interactions</td>
<td>Bleeding tendency after intake of Phenprocoumon along with ginger and Warfarin with Fenugreek, claw, garlic, mango or papaya [17, 18].</td>
</tr>
<tr>
<td>Vaidhyakruti</td>
<td>Iatrogenic effect</td>
<td>Could be due to wrong selection of drugs with respect to disease condition, complications due to a therapist and improper examination of patients [19].</td>
</tr>
<tr>
<td>Atimatradravyaprayoga</td>
<td>Drug Over dose</td>
<td>Excessive administration of Vatsanabha (Aconitum ferox Wall.) causes hypotension and bradycardia [20].</td>
</tr>
<tr>
<td>Ahitatamadravyas</td>
<td>Administration of unwholesome drugs</td>
<td>Usage of Semicarpus anacardium can lead to the formation of blisters [21].</td>
</tr>
<tr>
<td>Avastanusaradravyaprayoga</td>
<td>Administration of medicine in diverse pathological stages</td>
<td>‘Astringent drugs are contraindicated in patients with fever of recent origin (Tarunajwara) [22].</td>
</tr>
<tr>
<td>Panchakarmavyapad</td>
<td>Therapeutic procedural complications</td>
<td>Could be due to faulty preparation of drugs, improper assessment of patient and faulty administration of drugs [23].</td>
</tr>
</tbody>
</table>

6. THE NEED OF PHARMACOVIGILANCE IN AYURVEDA

It has been mentioned earlier that the practice of Ayurveda in accordance with the delineation of the classical Ayurveda texts would minimize the adverse drug reactions to a great extent. Thus, ADR in Ayurveda is primarily due to improper use or poor quality of drugs [24]. This makes it clear that the assurance of safe and efficacious treatment outcome is dependent upon a thorough decision-making process based on multiple factors. This is difficult as there is no objective tool in Ayurveda which can help making choices of drugs thus the chances of subjective variation are inevitable [25]. These sorts of subjective variation resulting in ADR are mentioned in Table 1. Thus, Pharmacovigilance can be of great help in arriving at a clinical decision with regard to ADR in Ayurveda [4]. The flip side of the coin is that most of the Ayurvedic physicians are not aware of ADR as reported by one of the studies conducted among institutionally qualified Ayurvedic physicians in the states of Uttar Pradesh and Bihar [26]. Another study in the state of Maharashtra also reported similar findings [27]. This further necessitates the incorporation of Pharmacovigilance to the field of Ayurveda. Moreover, the emblematic idea that Ayurvedic drugs are safe is no more valid these days owing to a rampant report of ADR as a result of Ayurvedic drugs consumption during these days [28, 29]. Furthermore, Ayurvedic drugs are tested inadequately for their safety in vulnerable populations like the elderly, children, pregnant and lactating women, and seriously ill patients [30]. Thus, the practice of Pharmacovigilance in Ayurveda would help in making the patients safe through various interventions and establishing the practice of Ayurveda in a rational and accountable manner [4]. In addition, the practice of Pharmacovigilance would help in differentiating the ADRs occurring as result of genuine drugs and other forms such as adulteration, contamination or poor quality of drugs [4].

7. THE EFFECTIVE UTILIZATION OF PHARMACOVIGILANCE IN AYURVEDA

In the realm of modern medicine, the practice of Pharmacovigilance ensures patient safety by means of continuous monitoring. This is particularly applicable to new drugs to understand the drug behaviour where no data is available [31]. The situation in Ayurveda drug therapy is aptly opposite to this concept as the classical drug therapy has been in practice since centuries about which delineations are available in classical treatises of Ayurveda. However, the irrational approach, sell of drugs by street vendors and subjective variations necessitate the practice of Pharmacovigilance in Ayurveda. The ADR needs to be reported to a
competent authority for the effective utilization of the Pharmacovigilance in the field of Ayurveda. For this purpose, the reporting format designed by the National Pharmacovigilance Resource Centre for Ayurveda, Siddha and Unani Drugs (NPRC-ASU) could be used. This format is very comprehensive and designed based on the conventional ADR reporting and the need of Ayurveda [32].

8. PHYSICIANS’ BENEFITS AND CHALLENGES AS A RESULT OF PHARMACOVIGILANCE IN AYURVEDA

This is an obvious issue in relation to the practice of Pharmacovigilance by a physician. The benefits of practicing Pharmacovigilance could be multifaceted and could include immediate and remote benefits to the physician and his/her community. The immediate benefit of practicing Pharmacovigilance is the gain of knowledge regarding the cause-effect relationship between a drug and ADR. This knowledge would lead to better and precise decision making with regard to patient safety and treatment. In the long run, the collected information of ADR can take the form of a repository and help the peers, paramedics and consumers [4].

9. NATIONAL PHARMACOVIGILANCE RESOURCE CENTRE OF ASU DRUGS

Based on the WHO guidelines, regarding the safety of herbal drugs the Department of AYUSH, Ministry of Health and Family Welfare, Govt. of India, New Delhi, took initiatives and established a National Pharmacovigilance Resource Centre for Ayurveda, Siddha and Unani Drugs (NPRC-ASU) in India under the central sector scheme, for upgradation to the centre of excellence, in the financial year 2008-09 and sanctioned an amount of INR 5.766 million. The NPRC-ASU Drugs is coordinating the National Pharmacovigilance Program (NPP-ASU) under the aegis of the Department of AYUSH, Ministry of Health and Family Welfare, Govt. of India, under the guidance of the National Pharmacovigilance Consultative Committee for ASU Drugs (NPCC-ASU). National Pharmacovigilance Consultative Committee for ASU Drugs (NPCC-ASU) consists of administrative heads of national institutes, regulatory and technical authorities having the responsibility of monitoring and regulating administrative and financial aspects related to this program. Furthermore, this program is guided by National Pharmacovigilance Technical Advisory Committee (NPTAC-ASU), a technical committee primarily concerned with the reviewing and analysing the ADRs reported at different levels and suggesting appropriate remedial measures [33].

The NPRC-ASU drugs, further consist of eight Regional Pharmacovigilance Centres (RPC) and 30 Peripheral Pharmacovigilance Centre (PPC) for ASU drugs. Adverse drug reactions of ASU drugs are being reported to these PPCs, in a specially designed ADR reporting form, which are further promoted after being evaluated at each level [33].

In the process of developing a culture of notification and involving healthcare professionals and associations in the drug monitoring and information dissemination processes, teachers, physicians and pharmacists of ASU systems are being sensitized on the concept of pharmacovigilance and reporting tools of ADR through CME programs, across the country. Several professionals have been trained and oriented by this process. A specific web-portal “http://ayushsuraksha.com/” has been launched for online reporting of ADR of ASU drugs [34].

In order to achieve operational efficiencies to meet the global standards of pharmacovigilance, concepts of pharmacovigilance have been included in the curricula of graduate and post-graduate studies of Ayurveda. Steps are also being taken to open pharmacovigilance centres at each affiliated ASU college. Clinical research units of different pharmacies and educational institutions catering to postgraduate and doctoral level research were requested to include pharmacovigilance aspect as one of the criteria for their research projects. The department of AYUSH, Govt. of India, has also been requested to instruct the drug licensing authorities to include pharmacovigilance aspect as one of the criteria for approving a new drug [32].

10. FUTURE PROSPECTS

Despite Ayurveda being an established doctrine of medicine in India, the scientific values and origin of this traditional system of medicine have always been questioned by the western world. During the recent years, this indigenous form of medicine has imbibed many scientific advances into its body; however, the same is minuscule compared to the modern medicine. Moreover, the practice of Ayurveda as per the classical delineation would never land up in situations of ADR. ADR is mainly due to subjective variation and irrational approach of practice. As the subjective variations are inevitable owing to the lack of an objective tool in Ayurveda for making choices of drugs, the practice of Pharmacovigilance would bring rationality and patient safety. Albeit the tangible benefits of practicing Pharmacovigilance is negligible; however, the same would serve to win the trust of the patients, treat patient safely and bring in accountability.

CONCLUSION

As per the different reports of ADR as a result of the consumption of Ayurvedic drugs, the practice of drug therapy in Ayurveda is no safer these days owing to several factors. Subjective variation, irrational use,
adulteration, contamination, poor quality of drugs and inadequate clinical research necessitate the practice of Pharmacovigilance in Ayurveda. Moreover, the practice of Pharmacovigilance would bring benefits to the practicing physician, the patient, the society and the science at large as ADR is no more confined to the realm of medical science rather the same is an emerging public health issue as well.

CONSENT FOR PUBLICATION
Not applicable.

CONFLICT OF INTEREST
The authors declare no conflict of interest, financial or otherwise.

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REFERENCES
[34] National Pharmacovigilance program for ASU drugs. Institute of Post Graduate Teaching and Research in Ayurveda, Gujarat Ayurveda University, Jamnagar, Gujarat. Available from: (http://ayushsuraksha.com/) [Last accessed on October 03, 2018]