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Review Article

PHARMACOVIGILANCE AND AYURVEDA

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ABSTRACT

In the age of modern technology, scientific advancements, consumer awareness and the advent of evidence based medicine, there is inadequate genuine clinical trial evidence supporting the efficacy and safety of Ayurveda drugs, except that this system is practised since hundreds of years. Another fact that supports it is the rarity of any adverse effect ever reported. Even the IEC guidelines for human trials take shelter under the fact that Ayurvedic drugs are time tested and require no evidence base of clinical safety data for approval of their use in humans. But this is a limitation which all along has interfered in acceptance of Ayurvedic medicines in developed world as a health care system. Further, a common misconception prevails among the masses and also a large population of practitioners is that Ayurveda drugs are safe and do not have any adverse reaction. Pharmacovigilance is an important tool to analyse the drug effect particularly its side effects, if any. This paper outlines briefly the concept of Pharmacovigilance, and the implementation of National Pharmacovigilance Programme for Ayurveda, Sidhha, Unani Drugs.

Keywords: Pharmacovigilance, Adverse Drug Reactions, Evidence Based Medicine

INTRODUCTION

Ayurveda as a science has a vast history of research and development. The holistic approach of this ancient science envisions prevention of disease[1] by virtue of its basic principles of healthy life style management, dietary intake and the uniqueness of keeping in view the individual's physiology and mental state during treatment.[2] A lot has been said and discussed about the effectiveness of one drug or the other in a wide spectrum of therapeutics but concerns regarding the safety and efficacy of these drugs have always been on the back seat. In the age of modern technology, scientific advancements, consumer awareness and the advent of evidence based medicine, there is very sparse evidence supporting the efficacy and safety of Ayurveda drugs, except that this system is in practice since hundreds of years and there is rarely any adverse effect reported. Some time back serious concerns were raised in relation to Ayurveda drugs that they contained heavy metals and were a threat to life.[3] It was only after that study, the authorities in India initiated some concrete steps to regulate the drug industry more effectively.

Concept of Pharmacovigilance and ADR

Pharmacovigilance, also known as Drug Safety, is the pharmacological science relating to the collection, detection, assessment, monitoring and prevention of adverse effects with pharmaceutical products. Adverse Drug Reactions (ADR) are defined as any response to a drug which is noxious and unintended, including lack of efficacy, which occurs at doses normally used for prophylaxis, diagnosis or therapy of disease or for modification of physiological function in the body. However, the term Pharmacovigilance does not figure in the Ayurvedic texts, but its concept is vibrant across all texts of Ayurveda.

Relevance of Pharmacovigilance in Ayurveda

There is a major misconception among masses and also a large population of practitioners that Ayurveda drugs are safe and do not have any adverse reaction. Ancient texts clearly mention that if a drug is used without the knowledge of its proper action, it would certainly act as a poison.[4] Though it may seem to be a hypothesised statement, but its soul is vibrant with the concept of Pharmacovigilance. Moreover, if a drug is prepared according to its SOP and used clinically in the dose prescribed, then the adverse reactions can be minimized to a great extent. The decision making regarding prescription of a drug also relies upon the yukti of the physician and his minute assessment of the roga and rogi bala, the time of administration of drug (kala), its place (desha), satwa, satmya, ahara Shakti, vyayam Shakti.[5] Besides the knowledge of proper identification of drug, its properties, therapeutic dosage and its combination with other drugs some of the subjective tools and crude principles of Pharmacovigilance used since ancient times to keep ADR's of Ayurveda medicines at bay. Consideration regarding age of the patient for dose administration and contraindications of some formulations in certain conditions also speaks of ADR prevention in Ayurveda. However, scientific assessment of the ADR's and AE's (adverse events) on objective parameters is the need of the hour that would definitely help

Ayurveda proves its worth to the modern world. Practice of pharmacovigilance will compel us to strive harder to make more safer and authentic medicines and make Ayurveda more rational and reliable. However, this can only be seriously followed after the quality control is ensured reliably for all the marketed formulations, either traditional or proprietary.

Need of Pharmacovigilance in Ayurveda

- To ensure safety of drugs, so as to minimize adverse effects, if any.
- To maintain efficacy of drug, so as to provide maximum benefit to the patient.

Difficulty in Successful Implementation of Pharmacovigilance in Ayurveda

- Very low reporting of ADR's.
- Ignorance among physicians regarding ADR's.
- False belief about the universal safety of Ayurveda drugs.
- Too many products and multiple ingredient formulations are difficult to monitor.
- Herbal and allopathic drugs are generally prescribed together
- False belief that Ayurveda drugs have no expiry date, though this factor has been taken care of by introducing a rule regarding shelf life of all forms of drugs in Drugs and Cosmetics Act, 1945.[6]
- Bulk dispensing. This is one of the most important causes of ADR as some drugs like Bhasma and Rasaushadhies are prescribed in much higher doses than actual dose.
- Concept related to adverse reactions not covered in curriculum.
- Inadequate methods and facilities of study drug safety profile.
- Lack of quality control to produce standard medicine.
- Informal pharmacy sector- selling spurious, misbranded and sub-standard drugs.[7]
- A lot of Ayurvedic drugs which are available in the market do not have the actual ingredients as are described in Ayurvedic literature. This may be due to non-identification/false identification or non-availability of that drug.[7] As such formulation with similar names may have different ingredients thereby and Pharmacovigilance observation of one may not be applicable to other till their content and quality of components are same.
- Also assessment of adverse reactions is difficult because of multi ingredient composition of most drugs.[8]
- Practice of Pseudo-allopathy which refers to co-administration of Allopathy drugs along with Ayurveda drugs.
- Poor patient compliance and ignorance, apart from self-medication and home remedies that are practised by many people.
- Non-availability of compendium of ADR's for Ayurvedic medicines
- Innovative formulations being prepared and used by some Ayurvedic physicians.

The Way Out

The primary objective of Pharmacovigilance is to ensure safe medical practice by minimizing the drug related harms to the patient, by inculcating the habit of feedback and awareness about drug hazards. The concept and whole protocol of Pharmacovigilance in Ayurveda should be envisaged in its own framework keeping in view the requirements of this ancient indigenous system of medicine so as to ensure its success. Pharmacovigilance in Ayurveda has to deal with drugs used since a long time, whose method of preparation and quality of ingredients used is sometimes not known. Also, no safety data of these products is available in contrary to the contemporary medicines. The only short cut to the successful implementation of Pharmacovigilance programme is to pool in the collected information and analysing it to prevent further adverse reactions.

National Pharmacovigilance Programme for ASU Drugs (NPP-ASU)

The National Pharmacovigilance Programme for ASU drugs was envisaged in December 2007, when a workshop, sponsored by WHO was organised at IPGT and RA, Jamnagar, India on possibility of implementing Pharmacovigilance programme for ASU drugs.[9] The protocol and ADR reporting forms were prepared and discussed by the Department of AYUSH, Govt. of India at a meeting held in August 2008. It was on 29 September 2008 that the draft was finalised and released by Department of AYUSH. Since then, IPGT and RA, Jamnagar, India has been working as National Pharmacovigilance Resource Centre for ASU drugs in India.

What to report under NPP-ASU

The programme particularly solicits reporting of

- All adverse reactions suspected to have been caused by ASU drugs either alone or in conjunction with other drugs
- All suspected drug interactions
- Reactions to any other drugs suspected of significantly affecting a patient's management, including reactions suspected for events in the following categories
- Death
- Life threatening (real risk of dying)
- Hospitalization (initial or prolonged)
- Disability (significant, persistent, or permanent)
- Congenital anomaly
- Required intervention to prevent permanent impairment or damage.

Who can Report

Any health care professional may report suspected adverse drug events. The cases reported by lay members of the public, or non-health care professionals are not accepted under the programme. However, they can report through the physician under whom they have undergone treatment.

Where to Report

Reporting should be done in a prescribed format[9] (Table 3) through a local Pharmacovigilance centre.

Progress of submitted information

The peripheral Pharmacovigilance centres forward the confidential forms to their regional Pharmacovigilance centres where casualty analysis is carried out. The information is then forwarded to the National Pharmacovigilance Resource Centre, where it is consolidated, statistically analysed, and forwarded to the Department of AYUSH.

DISCUSSION

A general misconception that prevails among the common people is that Ayurveda medicines are always safe. This mind

set needs to be changed. Though these medicines are safer, but there intake being immune from any side effects is not the case. A common fact experienced by everybody, that taking even a little extra amount of food at dinner time can cause discomfort. Similarly, if a drug is not manufactured as per set protocols or if any incompatible (viruddh) intake is done and then side effects are bound to occur. The Department of AYUSH has gone a long way in creating infrastructure for pharmacovigilance reporting. Though this is still in its infancy, but we should strengthen the basic idea which has led us to think and discuss upon this issue. The clinicians of Ayurveda should be given training regarding assessment of adverse reactions and must be taught the procedure for reporting of such reactions. The forms for assessing and reporting should be simplified to facilitate easy reporting. Close monitoring of all drug prescriptions should be done. Adequate inclusion of pharmacovigilance may be done in the undergraduate curriculum of Ayurveda. Prescription of Ayurveda drugs along with modern drugs should be avoided so that the effect of drugs on human body can be analysed. Bulk dispensing of drugs is a major issue and it steps should be taken to monitor it. Dispensing of churna (powders) in sachets can be done to provide fixed dose. Similarly Bhasma can be dispensed in capsule forms. Pharmaceutical houses need to share the burden and as well as responsibility for proper implementation of pharmacovigilance program. Data generated from various studies like clinical or pharmacological trials should be regularly updated in the text books. Experts of Ayurveda may also be reoriented and trained as experts in pharmaco-vigilance. The drug information should be easily available and should be completely digitalised so that the knowledge is available instantly. Though, the Traditional Knowledge Digital Library is a positive step in this direction.[10] More institutes should be involved in the process so as to create a deeper penetration of the concept. Students should be educated and the institutes may serve as satellite areas for data collection for any ADR and AE.

Table 1: Some common terms used in Pharmacovigilance for ASU Drugs

Side effect: Any unintended effect of a Pharmaceutical product occurring at doses normally used in man which is related to the pharmacological properties of the drug.
Adverse event/Adverse experience: Any untoward medical occurrence that may present during treatment with a pharmaceutical product, but which does not necessarily have a causal relationship with the treatment.
Adverse reaction: A response to a drug which is noxious and unintended, and which occurs at doses normally used in man for the prophylaxis, diagnosis, or therapy of disease or modification of physiological function

Table 2: Basic information to be known for reporting an ADR

Who Can Report? : Any Health care professionals like ASU Doctors / Dentists / Nurse / Pharmacists etc.
What to Report? : All suspected adverse reactions, Lack of effects, Resistance, Drug interactions, Dependence and Abuse
Confidentiality:

1) The patient's identity will be held in strict confidence and protected to the fullest extent. Programme staff will not disclose the reporter's identity in response to a request from the public.
2) Submission of report doesn't constitute an admission that, medical personnel or manufacturers or the product caused or contributed to the reaction.

Table 3: Reporting form for suspected ADR to ASU drugs

NATIONAL PHARMACOVIGILANCE PROGRAMME FOR AYURVEDA, SIDDHA and UNANI (ASU) DRUGS.

Reporting Form For Suspected Adverse Reactions To ASU Drugs

Please note:

1. All consumers / patients and reporters information will remain confidential.
2. It is requested to report all suspected reactions to the concerned, even if it does not have complete data, as soon as possible.

1. Patient / consumer identification (please complete or tick boxes below as appropriate)

Name		Patient record Number(PRN)
Ethnicity	IPD/OPD	
Address Vill/Town Post/Via Dist/State		Age Sex: M/F Prakriti/Mizaj

2. Description of the suspected Adverse Reactions (please complete boxes below)

Date and time of initial observation	
Description of reaction	

3. List of all ASU drugs including drugs of other systems used by the patient during the reporting period:

Medicine Name	**Manufacturer Batch no.**	**Daily dose**	**Form Route of administration**	**Date**		**Reason for use**
				Starting	**Stopped**	

4. Brief details of the suspected ASU Medicine:

a) Composition of the formulation / Part and form of the raw material used
b) Expiry date if any:
c) Remaining part of drug / Product label
d) Please tick (any one): Ayurveda, Siddha, Unani, any other
e) Adjuvant
f) Dietary Restrictions if any

g) Whether the drug is consumed under medical supervision or used as self-medication
h) Any other relevant information.

5. Treatment provided for suspected adverse reaction:

6. Outcome of the suspected adverse reaction (please complete the boxes below)

7. Any laboratory investigations done which provides suspicion of drug involvement:

Recovered	Not recovered	Unknown	Fatal:	If Fatal Date of death:
Severe: Yes/ No		Reaction abated after drug stopped or dose reduced		
		Reaction reappeared after re introduction		
Was the patient admitted to hospital? If yes, give name and address of hospital				

8. Whether the patient is suffering with any chronic disorders?

Hepatic Renal Cardiac
Diabetes Malnutrition Any Others

9. H/O previous allergies / Drug reactions:

10. **Identification of the Reporter**

Type (please tick): Nurse / Doctor / Pharmacist / Health worker / Patient / Attendant / Manufacturer / Distributor / Supplier / Any others (please specify)
Name:
Address:
Telephone / E mail if any

Signature of the reporter: **Date:**

Please send the completed form to: The centre from where the form is received or
To
The Coordinator, National Pharmacovigilance
Resource Centre For ASU Drugs
I.P.G.T. and R.A., G.A.U., Jamnagar,
Gujarat - 361 008
(O) 0288 2552699 Fax : 0288 2676856
Email: nprcasu@gmail.com

CONCLUSION

The need of the hour is to educate the physicians and encourage them to analyse and report any adverse effects that occur in a patient, no matter how petty or irrelevant they may seem. Quality drugs are one of the main pillars of effective therapy. The onus of providing quality drugs lies with the pharmaceutical houses. The industry should take some concrete steps to generate confidence and reliability for its products. The morality of manufacturing standard drugs can go a long way in minimizing the adverse effects and generating confidence in therapeutic efficacy. Further, this shall in long term lead to characterization of Ayurvedic drugs as OTC (over the counter), prescription or scheduled drugs for better safety and acceptance of Ayurvedic medicines. At some stage, there also needs to be regulation of self-preparation and administration of drugs by clinicians. This shall only be a step towards global acceptance of Ayurvedic drugs.

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