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Ayurveda

IMPORTANCE OF PHARMACOGIVILANCE IN AYUSH SYSTEM OF MEDICINE

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ABSTRACT Except for the fact that Ayurveda has been practiced for hundreds of years, there is insufficient genuine clinical trial evidence supporting the efficacy and safety of Ayurveda drugs in this age of modern technology, scientific advancements, consumer awareness, and the advent of evidence-based medicine. Another point in its favor is the rarity of any negative side effects ever recorded. Even the IEC guidelines for human trials find refuge in the fact that Ayurvedic medicines have been around for a long time and do not require any clinical safety data to be approved for use in humans. However, this is a shortcoming that has hampered Ayurvedic medicine's adoption as a health-care system in the industrialized world. Furthermore, there is a widespread misunderstanding among the general public and a sizable number of practitioners that Ayurvedic medicines are safe and have no side effects. Pharmacovigilance is a crucial technique for analyzing a drug's effect, including any potential adverse effects. This article briefly discusses the idea of pharmacovigilance and the National Pharmacovigilance Program for Ayurvedic, Siddha, and Unani Drugs.

KEYWORDS : Pharmacovigilance, Adverse Drug Reactions, ASU Drugs, etc.

INTRODUCTION

Ayurveda has a long history of inquiry and growth as a discipline. Because of its core concepts of healthy life style management, nutritional intake, and the distinctiveness of keeping the individual's physiology and mental condition in mind throughout therapy, this ancient science's holistic approach anticipates disease prevention[1]. Too Much has been written and argued about the efficacy of one medication or another in a wide range of treatments, but worries about the drugs' safety and efficacy have always taken a second seat. Modern technology, scientific breakthroughs, consumer awareness, and the emergence of evidence-based medicine have all contributed to the rise of evidence-based medicine.

The AYUSH Department has made significant progress in developing infrastructure for pharmacovigilance reporting.[2] Though it is still in its early stages, we should strengthen the basic concept that has prompted us to think about and debate this topic. Ayurvedic doctors should be trained in the assessment of adverse responses, as well as the protocol for reporting them. To make reporting easier, the forms for assessing and reporting should be streamlined. All medication prescriptions should be closely monitored.

METHODOLOGY

The Pharmacovigilance related material collected from authentic websites like NCBI, J-AIM, etc. and articles, Literature etc.

CONCEPT OF PHARMACOVIGILANCE

Except for the fact that this method has been in use for hundreds of years and there is seldom any bad impact documented, there is very little data supporting the efficacy and safety of Ayurveda medications. Some time ago, major concerns were raised about Ayurveda medicines containing heavy metals and posing a harm to human life.[3] It was only after that research that the Indian government took actual efforts to better control the pharmaceuticals sector. Pharmacovigilance, often known as Drug Safety, is a branch of pharmacology concerned with the collection, identification, assessment, monitoring, and prevention of adverse reactions to pharmaceuticals. Adverse Medication Reactions (ADR) are described as any unpleasant and unexpected response to a drug, including lack of efficacy, that occurs at dosages typically used for disease prevention, diagnosis, or therapy, or for modifying physiological function in the body.

SIGNIFICANCE OF PHARMACOVIGILANCE IN AYURVEDA

There is a widespread belief among the general public and a sizable number of Ayurvedic practitioners that Ayurvedic medications are safe and have no side effects. In ancient scriptures, it is plainly stated that if a medication is used without understanding its correct effect, it would undoubtedly operate as a poison. [4] Though it may appear to be a hypothetical statement, the notion of Pharmacovigilance is alive and well at its heart. Furthermore, adverse responses can be greatly reduced if a medication is produced according to its SOP and used therapeutically in the dose indicated. The yukti of the physician and his minute evaluation of the Roga and Rogi bala, the time of drug administration (kala), the site of drug administration (Desha), satwa, Satmya, Ahara Shakti, and Vyayama Shakti are all factors that go into prescribing a medication. Aside from appropriate drug identification, characteristics, therapeutic dose,[5] and drug interactions, some subjective instruments and rudimentary concepts of Pharma covigilance have been utilized since ancient times to keep ADRs of Ayurvedic remedies under control. Under Ayurveda, ADR prevention includes taking into account the patient's age while administering doses and the contraindications of particular formulations in certain circumstances.

Ayurveda is proving its usefulness in today's environment. Pharmacovigilance will force us to work harder to create more safe and authentic medications, as well as to make Ayurveda more reasonable and trustworthy. However, this can only be taken seriously once reliable quality control is established for all commercially available formulations, whether traditional or proprietary.

PHARMACOVIGILANCE IS REQUIRED IN AYURVEDA.

- To guarantee the safety of medicines so that any negative effects are minimized.
- To ensure that the drug's effectiveness is maintained so that the patient receives the greatest benefit.

IMPLEMENTATION OF PHARMACOVIGILANCE IN AYURVEDA

I. ADRs are rarely reported.
II. Physicians' lack of knowledge about ADRs.
III. False trust in Ayurvedic medicines' universal safety.
IV. It's tough to keep track of too many goods with various component compositions.
V. Allopathic and herbal medications are frequently administered simultaneously.
VI. False notion that Ayurvedic medications have no expiration date, despite the fact that the Pharmaceuticals and Cosmetics Act of 1945 included a guideline governing the shelf life of all types of drugs.[6]
VII. Dispensing in bulk. One of the most common reasons of ADR is that certain medicines, such as Bhasma and Rasaushadhies, are administered in far larger dosages than they should be.
VIII. There is a concept linked to unfavorable responses that isn't mentioned,
IX. Inadequate study drug safety profile techniques and facilities.[7]
X. There is a lack of quality control in the production of conventional medication.

PRIMARY TARGET OF PHAMACOVIGILANCE[8]

Pharmacovigilance's main goal is to guarantee safe medical practice by reducing medication-related harms to patients and instilling a culture of feedback and drug hazard awareness. To ensure the success of Ayurveda, the idea and whole protocol of Pharmacovigilance should be envisioned in its own framework, taking into account the needs of this old indigenous system of treatment. In Ayurveda, pharmacovigilance deals with medicines that have been used for a long time and whose technique of production and quality of components are often unknown. Furthermore, unlike modern medications, no safety data for these items is accessible.

NATIONAL PHARMACOVIGILANCE PROGRAMME FOR ASU DRUGS

A workshop funded by WHO was held at IPGT and RA, Jamnagar, India in December 2007 to discuss the potential of creating a national pharmacovigilance programme for ASU medicines. At a meeting in August 2008, the Department of AYUSH of the Government of India drafted and discussed the protocol and ADR reporting forms. The Department of AYUSH finalized the draught on September 29, 2008, and issued it. IPGT and RA, Jamnagar, India, has served as the country's national pharmacovigilance resource center for ASU medicines from that time.[9]

WHAT IS THE REPORTING UNDER NPP-ASU

- All adverse events thought to have been caused by ASU medications alone or in combination with other medicines
- All potential drug interactions
- Reactions to any additional medications suspected of having a substantial impact on a patient's treatment, including reactions to the substances listed below.
- Death
- Life-threatening situation (real risk of dying)
- Inpatient care (initial or prolonged)[10]
- Incapacity (significant, persistent, or permanent)
- Anomaly congenital
- Intervention is required to avoid lasting impairment or harm.

WHO CAN BE REPORTING

A suspected adverse drug event can be reported by any health care practitioner. The programme does not accept instances submitted by members of the general public or non-health care professionals.

WHERE TO REPORTING

Reporting should be done through a local Pharmacovigilance center in a defined format.

IMPROVEMENT OF SUBMITTED INFORMATION

The confidential forms are sent from the peripheral Pharmacovigilance centres to their regional Pharmacovigilance centres, which do casualty analysis.[11] The data is subsequently aggregated, statistically analyzed, and submitted to the Department of AYUSH via the National Pharmacovigilance Resource Centre.

DISCUSSION

A frequent misunderstanding among the general public is that Ayurvedic medications are always safe. This mindset must be altered. Though these drugs are safer, this does not mean that they are free of adverse effects. It is a well-known truth that eating even a small quantity of additional food at supper time might induce discomfort. Similarly, if a medicine is not made according to established procedures or if incompatible (Viruddha) consumption is practiced, adverse effects are inevitable.

Pharmacovigilance may be properly included into Ayurveda's undergraduate curriculum. Prescription of Ayurvedic medications in conjunction with contemporary pharmaceuticals should be avoided in order to study the effects of drugs on the human body. Bulk medication dispensing is a serious problem that has to be addressed, and efforts should be done to keep track of it.[12] To offer a set dose, churna (powders) can be dispensed in sachets. Similarly, Bhasma can be taken as a capsule. Pharmaceutical companies must share the burden and responsibility for ensuring that the pharmacovigilance programme is properly implemented. Data from diverse research, such as clinical or pharmacological trials, should be updated in text books on a regular basis.

CONCLUSION

Physicians must be educated and encouraged to analyses and report any adverse effects that arise in a patient, no matter how little or insignificant they may appear. One of the most important cornerstones of effective therapy is high-quality medicines. Pharmaceutical companies are responsible for supplying high-quality medicines. The industry could take some real actions to boost product confidence and dependability. The morality of producing standard medications can go a long way toward reducing side effects and restoring faith in therapeutic efficacy. Additionally, this will lead to the classification of Ayurvedic pharmaceuticals as over the counter (OTC), prescription, or scheduled drugs in the long run, resulting in improved safety and acceptability of Ayurvedic medicines. At some point, self-preparation and administration of medicines by doctors will need to be regulated. This is simply the first step toward Ayurvedic medicines gaining worldwide recognition.

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