

Pharmacovigilance: An ayurvedic viewpoint

Pharmacovigilance means monitoring the effect of medicine after it has been licensed for use and administered for a particular condition, especially in order to notice probable adverse reaction so that such incidences can be reduced by appropriate recording and reporting. Vigilance means to be more careful especially in order to notice possible danger or difficulties. Hence, in medical field, when a physician proceeds for the treatment of a case, an approach of diagnosis and planning a treatment protocol wherein chances of having insignificant error or adverse drug reactions (ADRs) may be considered as base for pharmacovigilance.

As per Ayurveda, any drug/management/procedure which, when administered, produces any untoward effect other than expected beneficial action is not considered a perfect treatment. Not only this, promotion of health and prevention of disease is the first approach in Ayurveda. Before starting any treatment, a multifaceted analysis of the status of the patient is mandatory so that the possibility of untoward symptoms due to error in diagnosis and planning of treatment is negligible. A possibility to consider environmental factors along with psychological status further adds an evidence that Ayurveda incorporates such concepts of being vigilant in the treatment.

Instructions and guidelines in the form of *Dashavidha Parikshya Bhava* and *Dashavidha Pariksha* (tenfold examination along with the consideration of ten factors to be examined before proceeding for treatment) indicate vigorous efforts to avoid errors in the diagnosis and management. Furthermore, individualistic approach of tenfold examination indicates that planning a treatment best suitable to an individual was conceptualized with these thoughts. A deep analysis of the effect of toxic substances and judicious use of herbo-minerals preparation also indicate an in-depth thought of pharmacovigilance. A list of adverse drug events or complications may occur due to misuse of these preparations is elaborately discussed along with probable antidotes and precautions. Standard operating procedures along with the implementation of pre- and post-patient care for *Panchakarma* procedures or para surgical interventions such as *Raktamokshana* (bloodletting) and *Agnikarma* (cauterization) and vigilant approach for the management of possible complications can be also considered as a part of implementation of pharmacovigilance. Not only this, for *Shadavidha Upakrama* (six basic treatments) such as *Langhana* (lightening therapy), *Brihana* (nourishing therapy) etc, a strategy in the form of *Samyaka Lakshana* (indication of achieving optimum effect of the therapy) has been mentioned with a warning that, if these procedures are not stopped after achieving the *Samyaka Lakshana*, adverse effects may be attained by the patient. Hence, management guidelines along with medicines to be used for future possibilities are framed for such conditions.

Hence, in spite of the claims of safety of Ayurvedic formulations, the same may not be extrapolated if it is not procured, produced, and used as per classical guidelines. Few factors may increase the chances of ADR related to Ayurvedic medicines and aggravate the need of reporting, such as the use of substitute drugs due to reduced availability of herbs, emergence of new diseases and treatment modalities, changed social structure and food habits, or chances of irrational combination of medicines. In addition, to tackle chronic, unresponsive, complicated cases with combination of several pathological involvement and indicating the need of holistic management (multiple drugs, consultation of multiple specialists, and therapies, often from different systems of medicine) may need strict new approaches of pharmacovigilance in Ayurveda. Few therapeutic factors which may also contribute to increase in chances of ADR of Ayurvedic medicines are noncompliance with classical guidelines such as the irrational use of medicines without logical appropriation of diagnosis, disease variant, stage of disease and individual prototype of the body. Hence, a hairline difference between errors due to diagnosis or improper procedure or purification and manufacturing of drugs and complications arising due to over or under dosage of medicines or patients not restricting to the precautions to be followed during treatment shall be kept in mind.

Thus, in the present scenario, restoration of recording of such events in the form of pharmacovigilance program in Ayurveda system of medicine becomes a necessity. Pharmaceutics and therapeutic variations, holistic approach, diverse and huge treasury of drugs and their formulations and numerous principles of diagnosis and management are potential sources of innovation for Ayurveda. Recording of such data may lead to establishment of safety of Ayurveda formulations and strengthen documentation of versatility of Ayurveda drugs. Implementation of pharmacovigilance program in Ayurveda may open arena of several fields and strengthen them. This may lead to the generation of data regarding Ayurvedic drugs as bioenhancer, having synergistic action or adjuvant effect, possibilities of interactions (drug–drug, drug–food, food–food interactions), cumulative effects of drugs and newer indications of same drug, which otherwise will require huge resources, if undertaken as research task. This may also be an appropriate step for global propagation of Ayurveda and to eradicate the common beliefs of community that Ayurvedic medicines are always free of side effects and thus can be used without proper prescriptions.

Initiatives taken by the Government of India for starting the National Resource Center for Pharmacovigilance is a

beginning step for it. From the day of its inception, various sensitizing programs and workshops have been conducted. Now, it is the duty of every health worker of Ayurveda to come forward and actively participate in this noble work and report such adverse drug events if any. Such activities will further strengthen the principles and approaches of Ayurveda and will open new path of developing recommendations for integrative approach of management.

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