IJCRT.ORG ISSN : 2320-2882

INTERNATIONAL JOURNAL OF CREATIVE RESEARCH THOUGHTS (IJCRT)

An International Open Access, Peer-reviewed, Refereed Journal

Pharmacovigilance: A Need In Ayurvedic Medicine System

AMEESHA ,* ANCHAL JAISWAL*, AMAN KUMAR YADAV*,

SIDDHARTHA SRIVASTAVA

Nirmala devi pharmacy college, Jaunpur

Abstract:

Clinical trials are used in the pharmaceutical industry to ensure the safety and efficacy of products, and the U.S. Food and Drug Administration oversees the approval process. To improve patient safety and lower safety-related withdrawals, pharmacovigilance is crucial. In order to guarantee the safety and effectiveness of Ayurveda, the Indian government launched a program similar to the International Drug Monitoring program, which was founded by the World Health Organization (WHO) in 1961. India is home to 55 postgraduate institutions and 196 undergraduate schools.

Key words: Adverse drug reaction, awareness, Ayurvedic medicine, pharmacovigilance, safety, U.S. Food and Drug Administration, World Health Organization

INTRODUCTION:

According to the World Health Organization, pharmacovigilance is the pharmaceutical science that deals with the identification, assessment, comprehension, and avoidance of medication side effects that necessitate clinical trials for safety and efficacy.

All areas are involved in complete medication safety, including measurement methods and comparison standards. A method for guaranteeing the safety of marketed medications for sizable populations is called pharmacokinetics, or PV. With 12 regional centers, India began PV in 1986. In 1987, it became a member of the WHO's adverse drug reaction (ADR) monitoring program.

The Drug Regulatory Authority of India received reports from three institutes that tracked adverse drug reactions in marketed medications. The National Pharmacovigilance Program was established in 2005.

The World Bank's Adverse Drug Reaction Monitoring (ADR) initiative, which was supported by the WHO, was halted in the middle of 2009. ADRs must be reported by physicians and scientists at 179 adverse drug reaction monitoring centers (AMCs) in medical colleges throughout India, according to the Health Ministry's 2010 amended PV Program of India. The WHO-UMC causality evaluation system is then used to analyze these reports.

By assuring that the advantages of medicine use balance the risks, this program gathers, evaluates, and suggests regulatory actions to safeguard the health of the Indian populace.

In AYURVEDA, PV:

PV is the process of identifying, evaluating, comprehending, and averting negative drug effects or other possible drug-related problems.

The word PV, which is absent from Ayurvedic scriptures, appears in traditional literature that discusses adverse drug responses, such as the Charaka Samhita.

PV's main duty is to improve patient health and safety during treatment by encouraging sensible drug usage, which is key to Ayurveda's philosophy and builds confidence in its security.

In Ayurvedic literature, the Charaka Samhita emphasizes drug-drug and drug-diet incompatibilities, stressing the use of "Shodhan" pharmacological principles and the "Anupan" therapeutic technique in averting negative reactions.

The market offers two types of Ayurvedic medications: traditional Ayurvedic formulations, as outlined in Ayurveda Samhitas.

Patented and proprietary compositions made from herb extracts fall under the second category.

ADR stands for adverse drug responses that impact organ function. These sources are used to make modern medications, which are mostly sourced from plants, microbes, and animals.

In both contemporary and herbal medicine, adverse reactions (ADRs) are categorized as Type A, B, C, and D. Type A is dose-dependent, Type B is idiosyncratic, Type C is cumulative, and Type D is carcinogenic.

According to Reginster and Heinrich, Aristolochia has been shown to display chronic toxicity (Type C), with the most frequent instance documented being.

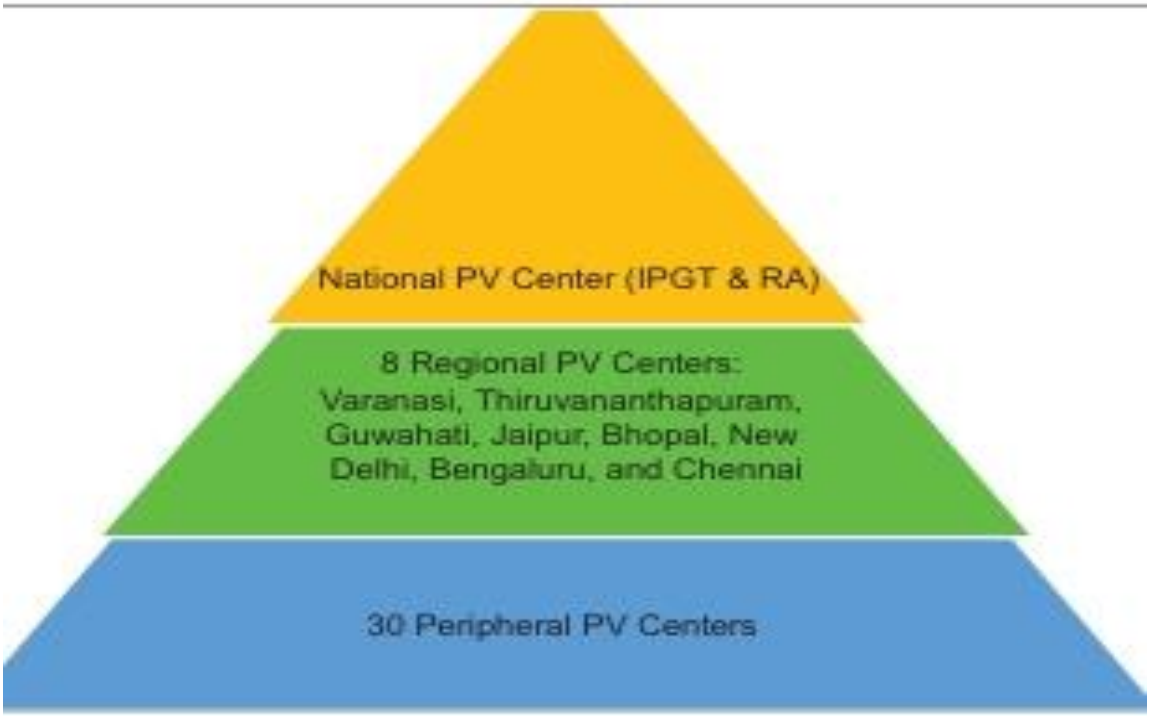

Figure 1: Pharmacovigilance centers in India

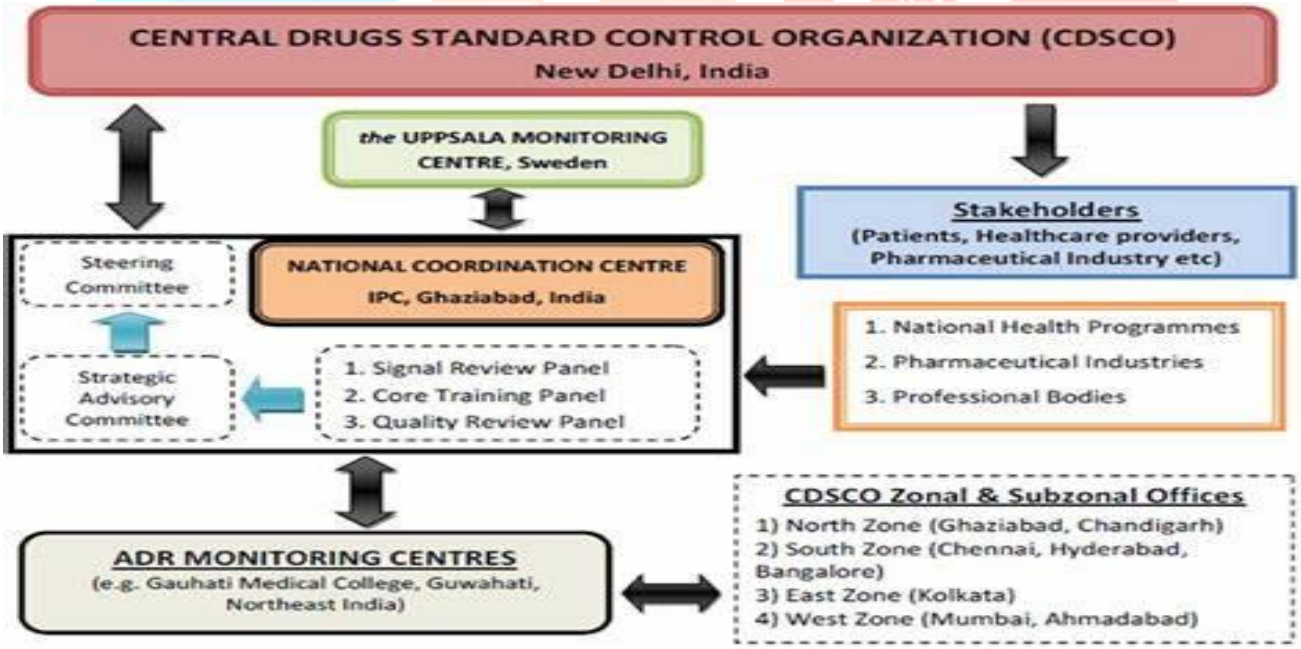

Figure.2 The program focuses on how reports of adverse medication reactions are communicated and handled.

The adverse effects of herbal and ayurvedic medications are mostly hepatic and renal in nature.

Because herbal and ayurvedic medications frequently contain several substances, it can be challenging to pinpoint the exact cause of adverse drug reactions. The recognized ADRs linked to herbal medications are included in Table 1.

Adverse drug reactions (ADRs) linked to herbal drugs are listed in Table 2.

❖ **Finding adverse reactions to ayurvedic drugs is the goal of the study;**

ADRs are harmful reactions to medical devices used for disease prevention, diagnosis, or treatment. A widespread misperception is that Ayurvedic medications are safe, however because of a number of obstacles, it might be difficult to identify adverse effects.

- The terminology used in adverse medication reaction monitoring is not thoroughly covered in the Ayurvedic literature.
- Drug safety techniques have not been progressively and satisfactorily established in Ayurveda.
- Although it is not readily available, the ancient Ayurvedic literature includes important information about drugs.
- Strong safety beliefs and a lack of reporting and data gathering regarding preparations or formulations make it difficult to detect microorganisms in drugs.
- To determine the underlying reason of their illness, patients use a variety of medical systems.
- The diagnosis of adverse reactions may be greatly aided by inadequate quality assurance and control in the preparation of Ayurvedic formulations.
- All suspected drug-related side effects, including those from herbal and alternative medicines, should be reported, according to the National Pharmaceutical Policy (NPP).

Figure 3 Herbs having known or suspected negative effects are on this list.

Despite the availability of numerous medications, the overall flow of PV is mainly undocumented.

People can report on several facets of their lives at the PV center:

- ✓ the practice of medicine.
- ✓ Professionals who work in the medical industry to create and enhance pharmaceutical products include scientists and pharmacists.
- ✓ A certified and experienced regulated manager from the pharmaceutical industry.
- ✓ Patients can report any side effects they encounter in clinical trials, which are ongoing product investigations.

There is no explicit guidance on what should be reported in the text:

This covers every kind of negative reaction that could arise from……

- ✓ The patient has passed away.
- ✓ The danger to life is a serious issue.
- ✓ At either the initial or protracted stage, the patient was admitted to the hospital.
- ✓ The statement might cause a serious, long-lasting, or irreversible handicap.
- ✓ Congenital anomalies are referred to by this word.
- ✓ There is not enough information in the text to create a summary.
- ✓ Drug interactions are the main subject of this essay.

Radiology contrast media, vaccines, diagnostics, traditional medicine medications, herbal remedies, cosmetics, medical equipment, and devices are among the many medical procedures and products that have been associated with adverse drug reactions (ADRs).

The information that has been provided may be reviewed and changed:

Causality analysis is carried out at Regional PV Centers after the confidential report has been sent there. After statistical analysis, the data is sent to the National Pharmacovigilance Resource Center and submitted to the Indian government's Department of AYUSH.

The text offers ideas for enhancement:

PV systems can be imposed on herbal and Ayurvedic therapies in a number of ways.

- The project investigates whether PV could be taught in undergraduate and graduate programs.
- The statement promotes the advancement of medication safety research.
- According to the statement, ADRs must be reported to authorities by law.
- In addition to creating and validating scales to measure responses to herbal and Ayurvedic medications, the objective is to increase knowledge of PV science among medical professionals, patients, and paramedical personnel.
- To properly record and assess adverse reactions, the pharmacovigilance area necessitates specialist training, underscoring the necessity of thorough and efficient training.

❖ CONCLUSION:

Because they should be used sparingly to reduce side effects, medicinal herbs are essential for both disease treatment and health maintenance.

The purpose of this study is to educate doctors and pharmaceutical businesses about the value of genuine medications for successful treatment.

- It is imperative that Ayurvedic medications be developed and standardized.
- One of the most important components of using Ayurvedic medications is their regulatory status.

REFERENCES

1. Wal P, Wal A, Gupta S, Sharma G. Pharmacovigilance of herbal products in India. J Young Pharm 2011;3:256-8.
2. . Gunasakaran S, Satheesh KR. A Practical Guide on Pharmacovigilance for Beginners. 1st ed.Taramani Magalir Co-operative Press, Chennai. 2010.
3. . Mann RD, Andrews EB, editors. Pharmacovigilance. Chichester: John Wiley & Sons Ltd.; 2002.

4. Gupta YK. Pharmacovigilance Programme for India; 2010. Available from: http://www.pharmabiz.com. [Last accessed on 2017 Mar 01].
5. Manjunath NA, Shradda UN, Avinash PK, Prasad BS. Pharmacovigilance study of Ayurvedic medicine in Ayurvedic Teaching Hospital: A prospective survey study. Int Q J Res Ayurveda 2015;36:130-7
6. Kalaiselvan V, Prasad T, Bisht A, Singh S, Singh GN. Adverse drug reactions reporting culture inPharmacovigilance Programme of India. Indian J Med Res 2014;140:563-4.
7. Rehan HS. Status of pharmacovigilance program of India. Tamil Nadu J Vet Anim Sci 2013;9:417-20.
8. Kalaiselvan V, Sharma S, Singh GN. Adverse reactions to contrast media: An analysis of spontaneous reports in the database of the pharmacovigilance programme of India. Drug Saf 2014;37:703-10.
9. Ratan JL, Mangala L. An update on the pharmacovigilance programme of India. Front Pharmacol 2015;6:194.
10. The Importance of Pharmacovigilance: Safety Monitoring of Medicinal Products, WHO, and Medicine WHO Guideline on Safety Monitoring of Herbal Medicines in Pharmacovigilance System. Available from: http://www. apps.who.int/medicinedocs/documents/s7148e/s7148e. pdf. [Last accessed on 2017 Mar 05]
11. Bhaleroa S, Thatte U. Proceedings of Pre-Conference Workshop. Pharmacovigilance of Ayurvedic Medicines; 2006
12. Wal P, Singh A, Mehra R, Rizvi S, Vajpayee R. Pharmacovigilance: Need and future prospective in herbal and ayurvedic medicines. Pharm Innov J 2014;3:18-22
13. Trikramji AJ, editor. Charak Samhita. 8th Adhyaya. 5th ed. Varanasi: Chaukhambha Sanskrit Sansthan; 2001. p. 275.
14. Edwards IR, Aronson JK. Adverse drug reactions: Definitions, diagnosis, and management. Lancet 2000;356:1255-
15. Kubde S. Adverse drug reactions and pharmacovigilance of herbal medicines in India. Int J Green Pharm 2016;10:S29-32.
16. Braun L, Cohen M. Herbs and Natural Supplements, An Evidence-Based Guide. 4th ed., Vol. 1. Australia: Elsevier Australia; 2015. p. 72.
17. Echinacea Drug Interactions. Available from: https:// www.drugs.com/drug-interactions/echinacea.html. [Last accessed on 2017 Mar 05].
18. Elvin-Lewis M. Should we be concerned about herbal remedies. J Ethnopharmacol 2001;75:141-64.
19. Health Canada. Release of the Guidance Documentfor Industry - Reporting Adverse Reactions to Marketed Health Products; 2009. Available from: https://www.canada.ca/en/health-canada/services/ drugs-health-products/reports-publications/medeffect canada/guidance-document-industry-reporting adverse-reactions-marketed-health-products-health canada-2011.html. [Last accessed on 2017 Mar 07.. [Last accessed on 2017 Mar 07].

20. Chaudhary A, Singh N, Kumar N. Pharmacovigilance: Boon for the safety and efficacy of ayuvedic formulations. J Ayurveda Integr Med 2010;1:251-6

21. Malik V. Laws Relating to Drugs and Cosmetics. Vol. 22. Lucknow: Eastern Book Company; 2012. p. 225.

22. Rastogi S, Ranjana R, Singh RH. Adverse effects of ayurvedic drugs: An overview of causes and possibilities in reference to a case of Vatsanabha (Aconite) overdosing. Int J Risk Saf Med 2007;19:117-25.

23. Malik V, editor. Drugs and Cosmetic Act, 1940. Ch. 4th. Part I. 14th ed. Lucknow: Eastern Book Company; 2002. p. 37-44.

24. . Pirmohamed M, Breckenridge AM, Kitteringham NR, Park BK. Adverse drug reactions. BMJ 1998;316:1295-8.

25. Hazell L, Shakir SA. Under-reporting of adverse drug reactions: A systematic review. Drug Saf 2006;29:385-96.

26. Verma S, Singh SP. Current and future status of herbal medicines. Vet World 2008;1:347-50.

27. Muhammad BY, Awaisu A. The need for enhancement of research, development, and commercialization of natural medicinal products in Nigeria: Lessons from the Malaysian experience. Afr J Tradit Complement Altern Med 2008;5:120-30.

28. Dahanukar SA, Thatte UM. Can we prescribe Ayurvedic drugs rationally? Indian Pract 1998;51:882-6.

29. Parab SM, Kalele SS, Verma S, Kulkarni RA, Shinde VJ, Bhalerao SS, et al. Safety issues with medicines from alternative system of medicine. In: Proceedings of Workshop on Pharmacovigilance: Promoting Drug Safety through Collaboration. Vol. 05. Parel, Mumbai: Seth GS Medical College; 2003. p. 22

30. Malik V. Laws Relating to Drugs and Cosmetics. Vol. 22. Lucknow: Eastern Book Company; 2012. p. 225.