



Review Article

ADRs & ITS REPORTING FOR ASU DRUGS - NEED OF AN HOUR

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ABSTRACT

Due to irrational usage of ASU drugs, Adverse Drug Reactions (ADRs) becoming significant concern for Ayurvedic medicine, and it is essential to understand the causes of ADRs, its consequences and adopt prevention strategies to minimise its adverse effects. In present era, scope of pharmacovigilance increasing day-by-day due to increase in ayurvedic pharmaceutical products in market. In Ayurveda, the principle of drug safety emphasizes on factors like drug interactions (*Viruddha Dravya*), overdosing (*Atimatra Dravya Prayoga*), *Pathya- Apathya* during *Oushadha sevana kala* and individual patient suitability (*Satmya*). So, It become essential to understand the causes of ADRs, its consequences and adopt prevention strategies to minimise its adverse effects. Ministry of Ayush also launched Ayush Suraksha portal for reporting of ADRs through online mode. Ayush Suraksha focussed on Ayush medicine for betterment of patient safety. This ADR form filling method will refine clinical practices and minimize the same drug reactions on others.

INTRODUCTION

Ayurveda, a traditional system of medicine originating in India, has gained popularity worldwide for its holistic approach to health and wellness. However, like any other system of medicine, Ayurveda is not without its risks. Adverse Drug Reactions (ADRs) are a significant concern in Ayurvedic medicine, and it is essential to understand the causes, consequences, and prevention strategies. World statistics shows that 5-10% of the hospital admissions are attributed to adverse drug reactions and 0.3% of adverse reactions are fatal in nature.

Adverse Drug Reaction: 'A response to a medicine which is noxious and unintended, and which occurs at dose normally used in man,' or "any response to a drug that is noxious and unintended and that occurs at doses used in man for prophylaxis, diagnostic or therapy, excluding failure to accomplish the intended purpose.

Adverse Drug Event: 'Any untoward medical occurrence that may present during treatment with a medicine, but which does not necessarily have a causal relationship with the treatment.

Side Effect: Side effect is any unintended effect of a pharmaceutical product occurring at doses normally used in human which is related to the pharmacological properties of the drug.

While the term "pharmacovigilance" isn't found in classical texts, the principle of drug safety is central to Ayurveda, emphasizing factors like drug interactions (*Viruddha Dravya*), overdosing (*Atimatra Dravya Prayoga*), and individual patient suitability (*Satmya*). Ayurvedic principles guide the assessment, management, and prevention of these reactions through diagnosis based on dosha imbalance and personalized treatment strategies.

Factors Leading to ADRs in Ayurveda

1. Improper Identification of Herbs– Substitution or misidentification can result in toxicity.
2. Improper *Shodhana* (Detoxification)– Metals and minerals not purified as per classics may be harmful.
3. Polyherbal Combinations– Unknown herb-herb or herb-drug interactions occur in body.

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4. Self-Medication Trends– Easy over-the-counter availability of herbal drugs leads to misuse of medicines.
5. Lack of Pharmacovigilance– Limited adverse event reporting systems in Ayurveda as well as lack of awareness among people.

Concept of Drug Safety/ADRs in Ayurveda

Ayurveda emphasizes the principle of *Swasthasya Swasthya Rakshanam* (preservation of health) and *Aturasya Vikara Prashamanam* (management of disease). Our ancient texts like *Charaka Samhita* and *Sushruta Samhita* emphasize the importance of proper selection, processing, and administration of herbal medicines. According to Ayurveda, drugs are not inherently harmful if used judiciously, but they may cause undesirable effects if used in improper dose (*Mithya Yoga*), administered to the wrong patient (*Asatmya Yoga*), taken for an excessive duration (*Ati Yoga*), Prepared or processed incorrectly (*Apakva Dravya*).

According to *Acharya Charak*, *Viruddha Ahara* may act as slow poisoning which can cause certain diseases such as impotency, blindness, herpes, ascites, schizophrenia, fistula in ano, flatulence, anaemia, leukoderma, *Grahani*, *Amlapitta*, *Jwara*, *Sotha*, *Santana dosha*, *Amavata*, and ultimately death. There are 18 types of *Viruddha* explain by *Acharya Charak* in *Sutrasthana* which are as follows-

1. *Desa Viruddha*: (Incompatibility dependent on area) - As per the area certain substance may not be used in that area e.g. usage of *Ruksha*, *Tikshna dravyas* in *Jangala desa*; usage of *Snigdha*, *Seeta dravyas* in *Anupa desa*.
2. *Kāla viruddha*: (Incompatibility dependent on time) - According to season certain substances are fore bidden e.g. using *Seeta*, *Ruksha dravyas* in winter; using hot and pungent materials in summer.
3. *Agni viruddha*: (Incompatibility dependent on digestion)- Consuming food drug without assessing the digestive function (*Agni*) e.g. over eating when there is *Agni Mandya* etc.
4. *Matra viruddha*: (Incompatibility dependent on dose)- Certain substances cannot be mixed and used in equal quantities e.g. honey and ghee should not be used in equal quantities (by volume)
5. *Satmya viruddha*: (Incompatibility dependent on habit) - When an individual is habituated to a particular type of food and exercise, advising opposite food etc., will lead to incompatibility e.g. the person who is habituated to pungent and hot substances consuming sweet and cold substances.

6. *Dosha viruddha*: (Incompatibility dependent on humors)- When the food or drugs which aggravate respective *Doshas* are used against contraindications e.g. in *Vata prakriti* or *Vata vriddhi* or *Vata roga*, usage of foods and drugs aggravating *Vata* etc.
7. *Samskara viruddha*: (Incompatibility dependent on procedures)- Certain procedures of cooking etc., will bring about incompatibility e.g. peacock meat should not be fried in castor oil and by using a lead rod for roasting it.
8. *Virya viruddha*: (Incompatibility dependent on potency)- Two different potencies should not be mixed directly e.g. one *Ushna virya* and one *Seeta virya dravya* mixed and used together.
9. *Koshta viruddha*: (Incompatibility dependent on GIT)- The administration of drug must be in accordance to the condition of *Koshta* (GIT). e.g., using a mild laxative in chronic and severe constipation; using drastic purgative in mild constipation.
10. *Avasthā viruddha*: (Incompatibility dependent on condition)- Using substances or advising exercises etc., irrespective of condition of the individual e.g., administering *Vata varddhaka dravyas* to a severely exhausted person; advising *Kapha varddhaka* food to individual who is sleepy and lazy etc.
11. *Krama viruddha*: (Incompatibility dependent on behaviour)- Violation of certain physiological behaviours may lead to incompatibility e.g. forcefully suppressing natural urges while eating (i.e., not evacuating bowels and bladder before food) etc.
12. *Parihāra viruddha*: (Incompatibility dependent on *Parihara*)- After a particular diet certain things are to be avoided in order to avoid incompatibility. If that is not avoided it leads to incompatibility e.g., after consuming pork, hot water should not be taken.
13. *Upachara viruddha*: (Incompatibility dependent on *Upachara*)- After a particular diet certain things are advised to be consumed in order to avoid incompatibility. If that is not followed it may lead to incompatibility e.g., after consuming ghee hot water should be taken instead if cold water is taken it amounts to *Upachara viruddha*.
14. *Pāka viruddha*: (Incompatibility while cooking)- Certain wrong procedures in cooking may lead to incompatibility e.g.: under cooked rice or over roasted rice etc.
15. *Samyoga viruddha*: (Incompatibility of combinations) - Certain combinations may result

in incompatibility e.g. combination of milk and sour substances".

16. *Hrit viruddha*: (Incompatibility of mind or heart)- Things which are not pleasant to the mind or things which are not good for heart. e.g. phobia towards particular sights, objects etc.
17. *Sampat viruddha*: (Incompatibility dependent on quality)- If a substance will have opposite taste etc., than its original taste etc., then it is known as *Sampat Viruddha*. In this the original qualities of a substance will be found indifferent.
18. *Vidhi viruddha*: (Incompatibility dependent on eating procedure)- There are certain restrictions imposed over the procedure of eating e.g.: one should not eat alone; one should not laugh or speak while eating etc.

If we are not going to follow this *viruddha ahara - vihara* in our daily regimen, then these combinations develop diseases in our body. These incompatible food leads to Adverse events in our body and make body ill. This indicates that Ayurveda had an early understanding of drug-related adverse outcomes, though not termed "ADRs" in modern language.

Some Instances Regarding ADRs in Ayurveda

Drugs shall manifest adverse effects when used untimely or in lower/excess doses. Similarly, drugs that are expired, improperly processed, unmetabolized, are also responsible in manifesting adverse effects.

These are few examples given below in table no.1.

Table 1: ADRs in Ayurveda

S.No.	Ayurvedic Drug (Single/ Compound)	Side effects (on improper usage)
1.	<i>Punarnava</i>	Disturb electrolyte balance
2.	Topical use of neem or <i>Arka</i>	Contact dermatitis
3.	<i>Pippali</i>	Hepatotoxicity
4.	<i>Brahmi/Ashwagandha</i>	Drowsiness or confusion
5.	<i>Asava /Arishta</i>	Gastritis
6.	<i>Mahamanjishthadi kwath</i>	<i>Karna shool, Agnimadhya</i>
7.	<i>Pushyanuga churna</i>	Irregular menstruation
8.	<i>Lavan Bhaskar Churna</i>	<i>Amlapitta/ Kidney disorders</i>
9.	<i>Sanjeevani vati</i>	Improper <i>Shodhana</i> of <i>Vatsanabh/Bhallataka</i> leads to burning and poisoning symptoms
10.	<i>Bilwadi Gutika</i>	<i>Aanaha</i>
11.	<i>Chitrakadi Gutika</i>	<i>Daha/Raktapitta roga</i>
12.	<i>Simhanada Guggulu</i>	Stomach irritation
13.	<i>Triphala ghrita</i>	<i>Atisaar, Aanaha, Adhamana</i>
14.	<i>Dadima avaleha</i>	Constipation

Modern Understanding of ADR in Ayurveda- From the biomedical viewpoint, ADRs in Ayurveda may occur due to multiple factors such as:

1. Pharmacological Factors- Active phytochemicals (alkaloids, glycosides, tannins) can have strong physiological effects. Mineral preparations (e.g., *Bhasma* of mercury, arsenic, lead) may cause toxicity if not purified properly.
2. Quality Control Issues - Adulteration, contamination with heavy metals, pesticide residues, or microbial load. Lack of standardization in manufacturing.
3. Improper Use -Self-medication without supervision. Using Ayurvedic drugs alongside modern medicines without knowledge of interactions.
4. Patient-Related Factors- Individual constitution (*Prakriti*), age, pregnancy, co-morbidities, and genetic makeup influence drug response.

Prevention Strategies for ASU Drugs

1. Proper diagnosis: Ensure accurate diagnosis before starting Ayurvedic treatment.

2. Qualified practitioners: Consult qualified Ayurvedic practitioners who are trained in the safe use of Ayurvedic medicines.
3. Standardized formulations: Use standardized Ayurvedic formulations that are manufactured according to Good Manufacturing Practices (GMP).
4. Monitoring: Monitor patients for potential ADRs and adjust treatment accordingly.
5. Patient education: Educate patients about potential ADRs and the importance of reporting any adverse effects.
6. Emphasise on Pharmacovigilance Programs: Ayurveda is integrating formal pharmacovigilance (drug safety monitoring) systems, as seen with the National Institute of Ayurveda (NIA)'s program, to track and analyze ADRs related with Ayurvedic medicines.

Who can report ADRs?

1. Clinician
2. Nurses/Drug provider

3. Consumers
4. Pharmacist
5. Pharmaceutical company

Reporting of ADRs

ADRs has great importance in any health care system. Reporting of ADRs caused by ASU & H drugs alone or in combination with other drugs or with specific food are also to be considered in reporting. Health care professionals can record all suspected ADRs for future course of action which will contribute in generating evidences against safety aspects. ADRs can be reported in prescribed format at any pharmacovigilance centre. It is just matter of few minutes but can save drug adverse effects on many lives. In digital era, Ministry of Ayush launched Ayush Suraksha portal which help researchers, health practitioner and nursing staff to fill online ADR form whenever they found any Adverse Drug event in patient due to ASU & H medicine or any other medicine.

CONCLUSION

Ayurveda is a time-tested system of medicine with immense therapeutic potential. However, like any medical system, it is not free from the risk of adverse drug reactions. ADRs in Ayurveda may arise due to poor quality of herbal medicine, wrong diagnosis, wrong selection of patient for therapy, erroneous dose and combination administration, usage of adulterants and substitute as well as lack of practitioner awareness.

Adverse Drug Reactions (ADRs) are a significant concern in Ayurvedic medicine. Understanding the causes, consequences, and prevention strategies can help minimize the risk of ADRs. Qualified practitioners, standardized formulations, and proper diagnosis can ensure the safe use of Ayurvedic medicines as well as report suspected ADRs to nearest pharmacovigilance centre to save lives of many people. By integrating classical Ayurvedic principles with modern pharmacovigilance strategies, it is possible to minimize these risks and ensure

patient safety. By working together, we can promote the safe and effective use of Ayurvedic medicine.

Recommendations

1. Further research: Conduct further research on the safety and efficacy of Ayurvedic medicines.
2. Education and awareness: Educate healthcare professionals such as doctor, nurse, and patients about the potential risks and benefits of Ayurvedic medicine.
3. Regulatory framework: Strengthen the regulatory framework to ensure the safe use of Ayurvedic medicines.

By taking a proactive approach to ADRs prevention and management, we can ensure the safe and effective use of Ayurvedic medicine and promote holistic health and wellness.

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