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Survey Study

Pharmacovigilance study of Ayurvedic medicine in Ayurvedic Teaching Hospital: A prospective survey study

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Abstract

Introduction: Though Ayurveda is practiced in the Indian subcontinent since centuries, there is a paucity of systematic documentation related to the occurrence of adverse drug reactions (ADR) and other issues regarding the safety of Ayurveda medicines. **Aim:** To monitor and analyze the pattern and frequency of ADR to Ayurvedic medicines in an Ayurvedic hospital setup. **Materials and Methods:** In this prospective study, ADR monitoring was done in KLE Ayurveda Secondary Care Hospital, Belgaum, Karnataka, India by spontaneous and intensive monitoring technique for a span of 1-year (June 2010 to May 2011). Data pertaining to patient demography, drug and reaction characteristics, organ system involved and reaction outcomes were collected and evaluated. The reaction severity and predisposing factors were also assessed. **Results:** In a span of one year, 84 adverse drug events were reported out of which 52 confirmed as ADR. The overall incidence of ADR in the patient population was 1.14%, out of which 23 (44.23%) were related to *Panchakarma* (detoxification process), 13 (25.00%) related to the herbal formulations and 06 (11.53%) were of *Rasa Aushadhi* (mineral or herbo-mineral formulations). The commonly affected organ systems were gastrointestinal system 24 (46.15%) and skin 15 (28.84%). The majority of the reactions were moderate 30 (57.69%) to mild 20 (38.46%) in severity. Most patients recovered from the incidence. **Conclusion:** The present work has documented the incidence and characteristic of ADR to Ayurvedic medicine in a typical Ayurveda hospital setup. This will help in developing various strategies for boosting pharmacovigilance in Ayurveda, thereby ensuring safer use of Ayurveda medicines.

Key words: Adverse drug reactions, Ayurveda, herbal medicine, *Panchakarma* pharmacovigilance, *Rasaushadi*

Introduction

India is known to be rich in biodiversity and based on this it also has its own indigenous codified systems of healing. Ayurveda is one of such healthcare system and forms an important component of healthcare in India as it is practiced here for thousands of years.[1] It is the most commonly practiced form of nonallopathic medicine in India, comprising a wide range of therapeutic approaches such as use of herbs, minerals, various detoxifying regimes, dietary advices, and their combinations with various nondrug modalities. It is estimated that about 80% of Indian population use Ayurveda medicines for their healthcare needs.[2] Also, use of Ayurveda in the Western countries is increasing.[3] This increasing use of Ayurvedic medicines worldwide has led to increasing concern regarding their safety. Recently there are various publications which raise concern about the safety of Ayurveda medicines.[4-6] Today Ayurveda is gathering increasing global attention with regard to both; as a therapeutic option to treat various chronic and

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noninfectious diseases as well as due to the possibility of health hazards associated with it. Though Ayurveda is practiced for centuries, there is a paucity of systematic documentation related to the occurrence of adverse drug reactions (ADRs) and other issues regarding the safety of Ayurveda medicines. Moreover, as compared to the practice of Ayurveda in olden ages, today a major change is seen in various aspects related to its use. Hence, safety monitoring has became very essential in lights of change with respect to environmental factors, increasing use of insecticides, adulteration of herbs, concomitant use of herbs with drugs of other system of medicines, new manufacturing techniques, lack of proper regulations in pharmaceutical industry, and easy availability of combinations of herbs over the counter. With the increased concern related to safety of Ayurvedic medicines, a National Pharmacovigilance Program in Ayurveda, Siddha and Unani (ASU) drugs has been initiated by Department of Ayurveda, Yoga and Naturopathy, Unani, Siddha and Homeopathy (AYUSH); Ministry of Health and Family Welfare, Government of India.[7]

Pharmacovigilance program aims to collect data pertaining to the occurrence of ADR and to identify and quantify the risk associated with the use of drugs. Such data is used to reach at inferences to recommend informed regulatory interventions and communicating risks to health care professionals and the public. The aim of present study to undertake ADR monitoring in a Peripheral Pharmacovigilance Center of National Pharmacovigilance Program. The primary objective of the study was to analyze the pattern and frequency of ADR to Ayurvedic medicines in an Ayurvedic hospital setup. The secondary objective to evaluate and understand various aspects related to the safety of Ayurvedic medicines.

Materials and Methods

Research design

This prospective and observational study was conducted over a period of 1-year from June 2010 to May 2011 at KLE Ayurveda hospital, Belagavi, Karnataka, India after obtaining the approval of the Ethics Committee for Research on Human Subjects', KLE University's Shri BMK Ayurved Mahavidyalaya, Belagavi, with IEC number "IEC/09/PG/ADR/MA." The study was registered with the Clinical Trial Registry of India (CTRI) ref. no. CTRI/2010/091/001164.

Detection of adverse drug reactions

Spontaneous and intensive reporting techniques were followed to detect the ADRs according to the World Health Organization (WHO) definition of ADR as "A noxious and unintended response at doses normally used for prophylaxis, diagnosis, or therapy of diseases, or for the modification of physiological function."

All outpatient department (OPD) and inpatient department (IPD) patients presenting with the ADR were included in the study. The patients with intentional or accidental poisoning and under allopathic treatment were excluded from the study.

Under spontaneous reporting technique, the physicians of the hospital were provided with reporting cards on which they will record the suspected ADRs. The ward incharge, ward nurse, and internee were also provided with similar reporting forms. After the initial notification of the suspected ADR by the physician, additional details were collected by interviews and review of case record forms. Awareness of ADR monitoring was created through the clinical meeting with health and clinicians and nurses of the hospital.

In intensive monitoring technique, all the admitted patients (IPD) were screened for ADRs during the study period. Patients were interviewed, monitored daily throughout their hospital stay by doing rounds. The patients with suspected ADRs were followed up till resolution or till 45 days, whichever is earlier via telephone. Their medical records were also reviewed.

Data collection

In the suspected cases, past medical/medication history with their respective dosage form, route of administration, frequency, date of onset of reaction, and the patients allergy status (drug or food) along with constitution (*Prakriti*), area of residence (*Desha*), age (*Vayah*), time (*Kala*), strength (*Bala*), exercise capacity (*Vyayamashakti*), digestive capacity (*Agnibala*) and disease strength (*Rogabala*), etc., were collected. The suspected adverse events (AE) were carefully analyzed and documented in the standard ADR monitoring for ASU drugs forms provided from National Pharmacovigilance Program for ASU drugs Jamnagar, India.[8]

Causality analysis

The causality analysis was done as per approved group suggested in National Seminar cum Workshop on "Pharmacovigilance of Ayurvedic Medicine – 2006" and National Pharmacovigilance Programme for ASU medicine.[9] Accordingly each suspected case was thus defined under the WHO definition ADR and further case analyzed by presentation followed by intensive discussion with heads of *Dravyaguna*, *Rasashastra*, *Kayachikitsa*, *Panchakarma*, *Prasuti Tantra*, and modern pharmacology before coming to conclusion of suspected cause of occurrence of event. Subsequent analysis was done by following causality categories recommended by Uppsala Monitoring Center - WHO probability scale[10] and Naranjo's ADR probability scale[11] to assess the probability of ADRs.

The ADRs thus confirmed were classified according to demographic, system involved, medicine involved, organ system involved and symptom wise. Outcome and severity of suspected ADRs were determined by referring previous published study.[12]

Statistical analysis

Data analysis was performed using Predictive Analytics SoftWare statistics® version 18. Descriptive statistics including frequency distribution of key items and bivariate analysis was carried out to describe the relationship between reported ADRs and variables as age, gender, type of reaction and therapeutic modalities. Chi-square statistic was used to test the association between reported ADRs and patient's age, gender, and the seasonal occurrence of ADR. The association between reported ADRs and specific variables was assessed by an odd ratio (OR) at 95% confidence interval. The reported $P < 0.05$ were used to determine the statistical significance except where otherwise indicated.

Observations and Results

During the study period, a total of 60,000 patients visited OPD and 4196 patients to visits to IPD. Of these 2260 were female,

1936 were male. A total 84 AE reported from both IPD and OPDs. Out of which 52 were confirmed as ADRs. Of this, 04 ADR reported in OPD while 48 ADRs developed during the hospital stay (IPD). The overall incidence was 1.143%. Females experienced a slightly higher incidence of ADRs 28 (1.3%) than males 20 (1.03%) with OR being 1.2 and $P = 0.52$ which is insignificant ($P < 0.05$) [Table 1].

Age wise classification on the occurrence of incidents of ADR shows that old age (age of >41) group experienced more numbers of ADRs 25 (1.27%) compare to other groups [Table 2].

Season wise classification suggested that 25 (1.18%) patients suffered with ADRs in period between 16th January and 15th July (the Northern solstice, "*Adanakala*") which is high when compared period between 16th July and 15th January (the Southern solstice, "*Visargakala*") 23 (1.10%) with OR of 0.93. Statistical insignificant difference was seen in the incidence rate of ADR with respect to factors such as sex, age, and season.

Wills and Brown classification of ADR showed that most of the reactions 20 (38.46%) were of Type A followed by Type U 11 (21.15%) and there were no ADRs of Type B, E, and G. According to the Naranjo algorithm scale, 38 (73.07%) reactions were assessed to be probable, 12 (23.07%) as possible and, 01 (01.92%) as definite. As per WHO probability scale 19 (36.58%) were classified as possible and only 01 (01.92%) as certain. Severity assessment of the ADRs showed that the majority of the reactions reported were moderate 30 (57.69%) and severe were 02 (03.84%). There were no fatal reactions. In 46 (88.46%) ADRs complete recovery was achieved, 2 (03.84%) were still recovering till reporting period (followed 6-month) and 4 (07.69%) ADRs were classified as "unknown outcomes" in which the outcomes could not be assessed as the patients sought voluntary discharge from the hospital, and some were not followed by phone also [Table 3].

In relation to different routes of administration, maximum ADRs were from oral route 28 (53.84%) followed by topical application 14 (26.92%) and rectal 07 (13.46%) [Table 4].

In most common treatment modality causing the ADRs and their reaction, *Panchakarma* produced the highest number of reactions 23 (44.23%), and least numbers were associated restricted diet (*Pathya*) and material/environmental of 02 (03.84%) [Table 5].

Skin rashes 12 (23.07%) were the most common ADR reported followed by diarrhea 09 (17.30%), vomiting 07 (13.46%) [Table 6]. The organ systems affected due to ADRs are accordingly, gastrointestinal (GI) system was found to be the most commonly affected organ system 24 (46.15%) followed by the skin 15 (28.84%) [Table 7].

Table 1: Distribution of ADR with respect to sex and season

Characteristics	Number of patients with ADR (%)	OR	95% CI	*P*
Sex				
Male	20 (1.03)	1.2	0.67-2.14	0.52
Female	28 (1.3)			
Season				
Adana (16th January-15th July) (the Northern solstice)	25 (1.18)	0.93	0.52-1.6	0.54
Visarga (16th July-15th January) (the Southern solstice)	23 (1.10)			

CI: Confidence interval, OR: Odds ratio, ADR: Adverse drug reactions

Table 2: Demographic presentation of ADR

Age presentation according to Ayurveda	Number of patients	Number of ADR with (%) (*n*=48)
Balavasta (paediatric [1-20 years])	736	6 (0.81)
Yavvana (middle age [20-40 years])	1497	17 (1.13)
Vriddha (old age [>41])	1966	25 (1.27)

ADR: Adverse drug reactions

Table 3: Classification and assessment of ADRs

Parameter	Numbers (%) (*n*=52)
Wills and Brown classification	
Type A - Augmented reactions	20 (38.46)
Type B - Bugs reactions	00
Type C - Chemical reactions	03 (05.76)
Type D - Delivery reactions	07 (13.36)
Type E - Exit reaction	00
Type F - Familial reaction	04 (07.69)
Type G - Genotoxic reaction	00
Type H - Hypersensitive reaction	07 (13.36)
Type U - Unclassified	11 (21.15)
Naranjo's ADR probability scale	
Definite	01 (01.92)
Probable	38 (73.07)
Possible	12 (23.07)
Doubtful	01 (01.92)
WHO causality	
Certain	01 (01.92)
Possible	19 (36.58)
Probable	12 (23.07)
Unlikely	15 (28.84)
Unclassifiable	05 (09.61)
Severity	
Mild	20 (38.46)
Moderate	30 (57.69)
Severe	02 (03.84)
Outcomes	
Fatal	00
Fully recovered	46 (88.46)
Recovering	2 (03.84)
Unknown	4 (07.69)

ADRs: Adverse drug reactions, WHO: World Health Organization

Out of 52 ADRs reported *Vatapittaprakriti* (constitution) patients were the most vulnerable and experiencing the highest numbers of ADRs 15 (28.84%), followed by *Pitta kapha* 14 (26.92%), *Kaphapittaja* 08 (15.38%). There were no *Ekaprakriti* patients detected during the study period [Table 8].

Time period of ADR after their admission shows that number of ADRs were seen in <3 days 36 (75.00%), between >3 days and <6 days it was 07 (14.58%) and very few ADRs were seen in >7 days 05 (10.41%) [Table 9].

Table 4: Occurrence of ADR relation in relation to route of administration of drugs

Route of administration	ADR in numbers (%) (*n*=52)
Oral	28 (53.84)
Topical (local)	14 (26.92)
Rectal	07 (13.46)
Nasal	02 (03.84)
Ear	01 (01.92)
Environmental	01 (01.92)

ADR: Adverse drug reactions

Table 5: ADRs caused by treatment modalities

Treatment modality	Number (%) (*n*=52)
Panchakarma (detoxification process)	23 (44.23)
Rasaushadhi	06 (11.53)
Other classical	13 (25.00)
Proprietary	06 (11.53)
Pathya (restricted diet)	02 (03.84)
Material/environmental	02 (03.84)

ADRs: Adverse drug reactions

Table 6: Individual reactions reported for each therapeutic modality is presented

Drug/ medication type	Reaction detail	Total number (%) (*n*=52)
Panchakarma	Skin rashes 02, diarrhea 03, vomiting 03, headache/nausea 02, constipation 01, rectal prolapse 01, fewer 03, pain abdomen 03, duodenal ulcer 01, local pain and swelling 01, boils 01 and other 02	23 (44.23)
Rasaushadhis	Skin rashes 02, diarrhea 03, vomiting 01	06 (11.53)
Classical herbal preparations	Skin rashes 07, diarrhea 02, vomiting 01, fewer 01, pain abdomen 01, throat pain 01	13 (25.00)
Proprietary	Skin rashes 01, vomiting 01, fewer 03, irritability 01	06 (11.53)
Material/ environmental	Vomiting 01, boils 01	02 (03.84)
Pathya (restricted diet)	Diarrhea 01, headache/ nausea 01	02 (03.84)

Discussion

Observational studies help in understanding the tolerability profile of marketed medicines in a heterogeneous population and thus are an important source of evidence to know treatment outcomes.[13] Pharmacovigilance is one such observational study which deals with evaluating and monitoring the safety of medicines and thus helps in identifying risk factors. Large numbers of such studies are carried in modern hospitals. But very little information is available for the ADR profile of Ayurvedic drugs.

In the present study, out of all admissions, 1.143% of patients experienced ADRs. This is minimal in comparison to a study carried in an Allopathic Hospital that is, 3.17–3.4%.[14-16] Although this study used both spontaneous reporting and intensive reporting system for ADR monitoring, along with conducting regular seminars and guest lecturers among the Ayurvedic health workers and pharmacist to convey the importance in reporting ADRs in Ayurveda, there were more reports from intensive reporting method 48 (92.30%) with very few through spontaneous reporting 04 (07.69%) suggesting the lack of interest and subject ignorance among clinicians.[15]

The ADRs were found more in female patients 28 (1.3%) than males 20 (1.03%) which are similar as reported by studies from Allopathic system.[14-16] There were more number of ADRs from old age group (>40 years) patients 25 (1.27%) than other group (between 1–40 and <1 year) [Tables 1 and 2] this could

Table 7: Organ systems affected due to ADRs

Systems	Number of ADRs (%) (*n*=52)
Gastrointestinal	24 (46.15)
Skin	15 (28.84)
Other*	11 (21.15)
Respiratory	01 (1.92)
Ear	01 (1.92)
Cardiovascular	00
Musculoskeletal	00

*Fever, irritability etc., ADRs: Adverse drug reactions

Table 8: ADRs as per *Prakriti* of patients

Prakriti of reported ADR	Total number (%) (*n*=52)
Kapha-Pitta	08 (15.38)
Kapha-Vata	05 (09.61)
Pitta-Kapha	14 (26.92)
Pitta-Vata	03 (05.76)
Vata-Kapha	07 (13.46)
Vata-Pitta	15 (28.84)

ADRs: Adverse drug reactions

Table 9: Time period in the occurrence of ADR in IPDs

Duration	ADR in number (%) (*n*=48)
<3 days	36 (75.00)
>3 days-<6 days	07 (14.58)
>6 days	05 (10.41)

ADR: Adverse drug reactions, IPDs: In-patient departments

be as females, children and old age group are believed to have low immunity (*Alpabalayukta*) and more susceptible for drug sensitivity.[17,18]

Season (*Kala*) one of the very important factor to considered during Ayurvedic treatment. It was observed that more numbers of ADR were seen in the Northern solstice period (*Adanakala*) 25 (1.18%) than the Southern solstice (*Visargakala*) 23 (1.10%). As Ayurveda believed, the Southern solstice is best for preventing the occurrence of diseases.[19] In our study, it was observed that in Northern solstice occurrences of ADRs are more. Therefore, Ayurveda suggests the assessment of season before administering therapy plays a vital role in preventing drug events.

Wills and Brown ADR classification suggested that Type A reactions, 20 (38.46%) were more followed by Type U, which is unexplainable with Ayurvedic pharmacology (*Rasapancaka*). The study also observed Type D reactions, which might be due to a fault in drug delivery, which include the organoleptic character. One event was immaterialist wherein, suspected drug/therapy has no role in the occurrence of event hence, termed under pseudo allergic reaction.[20,21]

7 (13.36%) hypersensitive reactions observed in the present study and these are less than other reported studies. The cause would be selective drug allergy, idiosyncrasy, or pseudo allergic reactions to drugs.[22] Familial (Type F) reactions were observed in 4 (07.69%). These types of reactions were seen in susceptible individuals by administration of drugs that are opposite to genetic constitution (*Prakriti*).[23] There were no Type B, E, and G reactions, as the study was of short period the Type G (genetic toxicity) reactions, and Type B reactions (ADRs are related to microbial growth) could not be observed.

The causality assessment by WHO scale and Naranjo's ADR probability suggested possible and probable were more since, reactions were observed because of not only the drug, but also other factors like method of preparation of medicines, or improper diagnosis of disease.

Severity wise classification shows that moderate 20 (38.46%) to mild 30 (57.69%) reactions were more compare to severe 02 (03.84%). Wherein, other medical system results showed more severe (10.9%) reaction than other types.[14] In observed ADRs, complete recovery was achieved in most and no permanent disability was seen and can be manageable over a period.

Therapy wise classification of occurrence of ADR suggested that more number were related to Panchakarma (detoxification process) treatment and most of them predominantly by an iatrogenic factor, of these very few were severe. Hence, Ayurveda has laid special precautions while practicing Panchakarma.[24] Second main cause was found to be classical medications, and the reason could be irrational prescription, improper preparation or over dose of medication. There is misbelief that *Rasaushadi* are toxic and not safe in the community,[25] but the current study shows ADRs pertaining to *Rasaushadi* were less in comparison to others.

GI system was most affected organ system by ADRs which could be due to the fact that oral is major route of drug administration in Ayurveda and site of digestion (*Agni*) is stomach and Ayurveda believe that most of the diseases occurring in human body is because of impaired digestion (*Agnimandya*).[26] Skin related ADRs were second highest among the organ system affected; this could be because after the oral administration, skin is the second largest route of drug administration in Ayurveda and primary organ where, first sensitive reactions exhibits. Most of the hypersensitive reactions irrespective of drugs are seen on the skin.[27] There were no cardio vascular, central nervous system and kidney related symptoms suggesting that Ayurvedic ADRs are mostly mild, self-limiting and do not affect the major systems.

Vata-Pitta Prakriti patients were maximum sufferers of ADRs rather than other *Prakriti* signifies that, among the *Dwandvaja Prakriti* (two-fold of constitution), *Vata-Pitta Prakriti* is most vulnerable[28] and *Vata* predominant[29] persons are more prone for drug events probably as *Vata Prakriti* is said to be nastiest among other *Prakriti*.[28] No *Ekadoshaja Prakriti* (single constitution) patients were reported in our study as it is difficult to find *Ekadoshaja Prakriti* persons.

Skin rash was the most common symptom among reported ADRs which indicates that most of reaction of Ayurveda are mostly by the hypersensitive or skin allergy and it is thus easy to suspect the event. Diarrhea was the second commonest symptom of Ayurvedic ADRs, and this is similar as that of other studies.[14,16] The commonest used route of drug administration is oral or rectal route hence the primary symptom would be probably diarrhea. Also, many of the reported cases were self-limiting and doesn't pose a much financial burden on the patient hence they are safe when compared with the other systems of medicines.[14]

It is observed that most of the ADRs occurred within 3 days of admission to IPD most of them were from Panchakarma therapy. The drug intended events which occur in a short period are termed as *Badhana* (immediate effect) type of drug events.[30] In fact, there were few ADRs developed after 3-day of admission but these cannot be considered under the chronic effect of the drug, as the patients were followed only for 7-day.

Each reported case was discussed with the intention of identifying the underlying drug cause. It revealed that faulty technique, Bizarre, and drug interaction were common causes in ADRs of Ayurvedic drugs [Table 10].

Limitations

Conducted study was short termed hence, the chronic ADR related to Ayurvedic medicine could not be observed. Considering the patient discomfort, de-challenge and re-challenge were not followed. Low incidence of ADR could be due to loss of subjects during follow-up, owing to low awareness among patients, underreporting and unintentional ignorance of adverse effects by treating physician. There could be ambiguity in assessing ADR as it is difficult to trace the actual cause because a single formulation has many drugs, and mostly combinations of these are prescribed. So only a presumption can be made which is subjective.

All the detected ADRs were reported to National Pharmacovigilance program for ASU drugs Jamnagar, India.

Table 10: List of reported ADR

Ayurvedic drug/therapy	Mode of administration	Reported event	Prime ascertained cause after causality assessment
Aragwadadi Kashaya and syrup Talekt	Oral	Skin rashes	Bizarre cause
Mahavatavidvanshini Rasa	Oral	Diarrhea	Drug over dose
Vaishwanara Kalka, Goarka, Mutralakashaya	Rectal	Pain abdomen	Iatrogenic
Sashtikasali Pinda Sweda	Skin (external)	Skin rash	Bizarre cause
Erandamoola Niruha Basti	Rectal	Rectal prolapse	Iatrogenic
Haridrakhanda with milk	Oral	Exacerbation of tonsillitis	Bizarre cause
Jaloukavacharana (leech application)	Skin	Pain and swelling	Iatrogenic
Sahacharadi Taila	Rectal	Constipation and pain abdomen	Iatrogenic (*Sneha Asiddhi Lakshana*)
Karpasasthyadi Taila	Nasal	Headache	Iatrogenic
Erandamoola and *Gomutra Arka* (distillate of cow's urine)	Rectal	Pain abdomen and diarrhea	Improper *koshta* assessment
Brihat Saindavadi Taila	Skin (external)	Headache and wheezing	Pseudo allergic reaction
Madana Yoga (a preparation of *Randia dumetorum*)	Oral	Pain abdomen and dehydration	*Koshtha Viruddha Dravya Prayoga*
Trivrutta Leha along with milk	Oral	Vomiting and dehydration	Iatrogenic
Sahacharadi Taila	Skin (external)	Ear ache and partial deafness	Bizarre
Agnitundi Vati	Oral	Diarrhoea and vomiting	*Prakriti Viruddha Dravya Prayoga*
Saraswata Ghrita	Oral	Pain abdomen	Improper *Purvakarma* (preprocedural therapies)
Gandha Taila	Nasal	Vomiting and headache	Bizarre
Mahatiktaka Ghrita	Oral	Vomiting, diarrhea, and dehydration	Selective drug allergy
Agastya Haritaki Rasayana	Oral	Skin rashes	Bizarre
Asanadikashaya and Tab Histantin	Oral	Vomiting and dehydration	Bizarre
Suvarna Bindu Prashana	Oral	Fever, child irritability	Bizarre
Dashanga Lepa	Skin (external)	Skin rash	Bizarre
Shatadouta Ghrita	Skin (external)	Skin rash	Bizarre
Bala Ashwagandha Lakshadi Taila	Skin (external)	Skin rash	Bizarre
Combination of *Sutashekararasa* and *Mayurapiccha Bhasma*	Oral	Diarrhea	Over dose
Erandamoola Lekhana Basti	Rectal	Duodenal perforation	Iatrogenic
Gandhaka Rasayana	Oral	Skin rash	*Prakriti Viruddha Dravya Prayoga*
Sarsapa Lepa (mustard pack)	Skin (external)	Skin rashes	*Prakriti Viruddha Dravya Prayoga*
Combination of *Mahavatavidwanshini Rasa*, *Tinispora cordifolia* and *Samirapannagarasa*	Oral	Nausea and vomiting	Over dose
Kottamchukadi Taila	Skin (external)	Skin rash and periorbital swelling	*Prakriti Viruddha Dravya Prayoga*
IR light	Skin (external)	Boil and redness	Over dose
Shatapushpa (*Anethum sowa*)	Oral	Diarrhea	Bizarre
Decoction of *Ricinus communis*, *Eranda*, *Vitex negundo* and *T. cordifolia*	Oral	Nausea and oral tingling sensation and vomiting	Bizarre
Mutralakhada	Oral	Nausea and vomit	Drug organoleptic character

ADR: Adverse drug reactions

Conclusion

Pharmacovigilance study is the need of the hour as they help in understanding the safety profile of medicines. The present work is first of its kind with respect to Ayurvedic medicine.

As observed in the present study, ADRs in Ayurveda are very less 1.143% of total admissions compared to modern systems of medicine. Female to male ratio was 1.28; most are mild to moderate and are not fatal but recoverable and preventable. GI and skin are the most frequent system affected. Skin rash and

diarrhea were common symptoms. Panchakarma related drug events were found to be more frequent. Causality of ADRs of Ayurveda was probable to possible as per standard scales.

It has shows that maximum numbers of ADR in Ayurveda are iatrogenic in origin rather than medicine. The other causes include irrational prescription, drug interaction, good manufacturing practice concerns, etc.

Most of these ADRs can be prevented with a thorough knowledge of the texts. Pharmacovigilance is a certain challenge with Ayurvedic medicines as Ayurveda gives ample scope for the logical use of medicines based on various factors like *Prakruti*, *Desha*, *Kala*, etc., So the combination becomes multifold and varies from patient to patient and physician to physician. Also, proprietary medicines are also combined with the classical preparations making it further more complicated. Thereby causality analysis is difficult. The standard scales also need modification to suit ADRs of Ayurveda.

This epidemiological study was conducted not to test any hypothesis or to reach any conclusion; it was to generate the hypothesis. There is a need to test these issues associated with the Ayurvedic medicines which are responsible for causing adverse reactions and need attention, policies, training, and further experimental studies to prevent them.

The study which was a maiden in its nature to the Ayurvedic system, has provided base line information about the incidence of ADRs with their distribution and the data thus generated will help for more extensive studies.

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Conflicts of interest

There are no conflicts of interest.

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हिन्दी सारांश

आयुर्वेद शिक्षण अस्पताल में आयुर्वेदिक औषधियों का प्रतिकूल दवा प्रतिक्रिया पर एक सर्वेक्षण

मंजुनाथ एन. अजनाल, श्रद्धा यु. नायक, अविनाश पी. कदम, बी.एस. प्रसाद

यद्धपि आयुर्वेद सदियों से भारतीय उपमहाद्वीप में प्रचलित है, लेकिन प्रतिकूल दवा प्रतिक्रियाओं (ए.डी.आर.) और आयुर्वेद दवाओं की सुरक्षा के संबंध में अन्य मुद्दों की घटना से संबंधित व्यवस्थित दस्तावेज की कमी है। यह अध्ययन एक आयुर्वेदिक अस्पताल व्यवस्था में आयुर्वेदिक दवाओं के लिए ए.डी.आर. के प्रतिरुप और आवृति पर नजर रखने और विश्लेषण करने के उद्देश्य के साथ आयोजित किया गया। यह भावी अध्ययन, ए.डी.आर. निगरानी (जून २०१० से मई २०११ तक) एक साल की अवधि के लिए सहज और गहन निगरानी तकनीक द्वारा के.एल.ई. आयुर्वेद माध्यमिक देखभाल अस्पताल, बेलगांम, कर्नाटक, भारत में किया गया था। रोगी जनसांख्यिकी, दवा तथा विशेष प्रतिक्रिया संबंधित अंग प्रणाली और उनकी प्रतिक्रिया परिणामों के आंकडे एकत्र कर मूल्यांकन किया गया। इसके अलावा प्रतिक्रिया की गंभीरता और प्रवर्तन पूर्व कारणों का भी मूल्यांकन किया गया। १ साल की अवधि में, ८४ प्रतिकूल दवा प्रतिक्रिया की घटनाओं की सूचना मिलि जिसमे से ५२ की ए.डी.आर. के रुप मे पुष्टि की गयी। समग्र रोगियों में से केवल १.१४% रोगियों में, प्रतिकूल दवा प्रतिक्रिया पायी गयी जिसमें से ४४.२३% पञ्चकर्म से, २५% रोगियों में जड़ीबूटी युक्त योंगों से, ११.५३% रसऔषधियों से संबंधित थी। आमतौर पर प्रभावित अंग प्रणालियों मे से जठरांत्र प्रणाली २४ (४६.१५%) और त्वचा १५ (२८.८४%) प्रभावित थे। ५७.६९% रोगियों मे मध्यम तथा ३८.४६% रोगियों में अल्प प्रतिक्रिया पायी गयी। जिनमे सें अधिकांश रोगी चिकित्सा से पुनः ठीक हो गये थे। वर्तमान कार्य एक आयुर्वे द अस्पताल में आयुर्वेदिक चिकित्सा के लिए ए.डी.आर. की घटनाओं और विशेषता दस्तावेज है। इससे आयुर्वेद औषधियों के सुरक्षित उपयोग को सुनिश्चित करने, आयुर्वेद में आयुर्वेद औषधियों की प्रतिकूल दवा प्रतिक्रियाओं पर जागरूकता बढ़ाने के लिए विभिन्न रणनीतियों को विकसित करने में मदद मिलेगी।