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Knowledge, Attitude and Perception of Pharmacovigilance Science in Ayurveda among Ayurved pharmacy undergraduates - A Cross Sectional Study

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ABSTRACT

Background: India is known for its traditional medicinal systems. Ayurveda, Siddha and Unani systems are being practised since ages and their use have accepted in other countries in era of globalisation. There is a wide spread misconception that all drugs of "natural" origin are "safe". Many drugs not only of allopathy but homeopathy as well Ayurved, having undesirable unwanted effects beyond therapeutic action called Adverse Drug Reaction (ADR). Ministry of AYUSH, Government of India, New Delhi has initiated the Pharmacovigilance Program for Ayurved, Siddha, Unani & Homeopathy drugs (ASU & H drugs). **Aim and Objectives:** To evaluate knowledge, attitude and perception of Pharmacovigilance among Ayurved pharmacy undergraduates. **Materials and Methods:** It was a prospective, cross-sectional study conducted among Ayurved pharmacy undergraduates perusing their study at government Ayurved College during 2022. The questionnaire was designed to test knowledge, attitude and perception of Pharmacovigilance. Basic and study data was entered in Microsoft Office Excel 2016 and descriptive statistics was used. **Result:** Majority students had knowledge about "ADR" and "Pharmacovigilance" and "ADR" reporting Centre" but where and to whom and how to report was lacking as there have not been exposed to any practical training and awareness session. Majority participants were agreed that all the drugs including ASU & H has adverse drug reaction and need to report and should be mandatory. **Conclusion:** There is a need of more awareness and practical/ hand to hand training programme related to Pharmacovigilance and ADR reporting to Undergraduate Ayurved Pharmacy Students to sensitise them and to strengthen the reporting culture for ASU & H drugs from early stage.

Key words: ADRs, Adverse Drug Reaction, ASU & H drugs, Ayurved, Siddha, Unani & Homeopathy drugs, NPP, National Pharmacovigilance Programme, PvPI, Pharmacovigilance

INTRODUCTION

India is known for its traditional medicinal systems - Ayurveda, Siddha and Unani. Medical systems are

found mentioned even in the ancient Vedas and other scriptures. The Ayurvedic concept appeared and developed between 2500 and 500 BC in India.^[1] Since ages Ayurveda, Siddha and Unani systems are being practised in India. The use of Ayurvedic medicines is popular and has become accepted in other countries in recent times.^[2] Drugs are used for prevention and treatment of diseases. Many drugs not only of allopathy but homeopathy as well Ayurved, having undesirable unwanted effects beyond therapeutic action so called adverse effect. Monitoring of such adverse events is essential.^[3] Pharmacovigilance is the science dedicated to reduce the risk of drug-related harms to patients. World Health Organisation (WHO) define the Pharmacovigilance (PvPI) is the pharmacological science relating to the detection,

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evaluation, understanding and prevention of adverse effects, particularly long term and short-term side effects of medicines.^[4] The major goals of pharmacovigilance, namely to improve patient care and safety in relation to drug use, and thus promote rational drug use are recurrent themes of ayurvedic pharmacology (*Dravyaguna Vigyan*) and therapeutics (*Chikitsa*).^[5]

Ayurveda, Siddha, Unani and Homeopathy (ASU & H) systems of medicines have their own principles and have their own pharmacopoeia, but at times even are practised in the country as Over The Counter (OTC) drugs without any authentic prescription.^[6] There is a wide spread misconception that all drugs of “natural” origin are “safe”. There is also a common belief that long term use of a medicine based on tradition, assures both safety and efficacy. In this era of globalization, concerns are being raised with regards to their clinical safety. Considering the significance of this WHO emphasizes the provision of traditional medicine in pharmacovigilance system and has published guidelines on safety monitoring of herbal medicines in pharmacovigilance system in 2004.^[7] Ministry of AYUSH, Government of India, New Delhi has initiated the Pharmacovigilance Program for Ayurved, Siddha, Unani & Homeopathy drugs (ASU & H drugs) hence all health care team member should have thorough knowledge about it. ADR reporting of ASU are in still in infancy age and need to boost up the awareness about reporting culture among health care professional. Looking into the conditions prevailing in the present scenario, it is high time to deliberate regarding the concerns over sensitizing about pharmacovigilance practice in ASU from vary beginning.^[6]

Pharmacist are also an important member of the health care team and contribute in the detection and reporting of suspected ADRs. If pharmacist have a good knowledge of pharmacovigilance he play vital role in adverse drug reporting and can prevent drug related morbidity and mortality. Considering these aspects current study was aimed to evaluate knowledge, attitude and perception of pharmacovigilance in Ayurveda among Ayurved pharmacy undergraduates' students studying at institute.

MATERIALS AND METHODS

Type of study: It was a prospective, cross-sectional study

Inclusion criteria: All undergraduate students of Ayurved pharmacy speciality perusing in Institute of Teaching and Research in Ayurveda - Pharmacy, Jamnagar during 2022 willing to participate voluntarily were included in the study.

Exclusion criteria: Those who were not willing to participate in the study.

Sampling method: Convenience sampling

Sample size: Purposive

Data collection tool: The questionnaire was designed and prepared from previously published scientific literature with similar interest.^[8] A questionnaire included the questions related to participants' knowledge about ADR and pharmacovigilance, attitude and perception towards adverse drug reactions (ADRs) reporting and Pharmacovigilance. The questionnaire was reviewed by Pharmacovigilance experts, and checked for consistencies, clarity and relevant modification before the conduct of the study.

Data collection procedure: Data were collected at Institute of Teaching and Research in Ayurveda - Pharmacy during their academic classes. Physical form of questionnaire was circulated and filled up form were collected after 20 minutes. The data was entered in Microsoft office excel 2016 and analysed with descriptive (frequencies with percentages) Statistical test.

RESULT

Mean age of 20 years and with male: female ratio of 0.83. (Table 1).

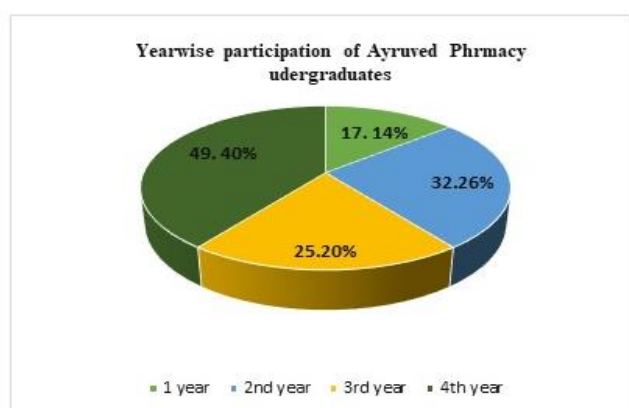
Table 1: Sociodemographic characteristic of students, N=118

Sociodemographic parameters		No. (%)
Age (yrs.) (Mean± SD)		20 (1.8)
Gender	Male	51 (43)

	Female	61 (51)
Year	1 st year	21 (17)
	2 nd year	32 (27)
	3 rd year	25 (21)
	4 th year	40 (33)

Majority students were 4th year students followed by 2nd year and 3rd year. (Figure 1)

Figure 1: Year-wise student’s participation in study



89% of study participants know about term “ADR” and 88% were aware about the term “Pharmacovigilance”. 60.16% respondents had knowledge of existing of separate ADR reporting centre for ASU&H drugs and 49.15% students knew that Ministry of AYUSH, New Delhi monitoring Pharmacovigilance for ASU & H drugs. Very few students (1.18%) had knowledge of website for pharmacovigilance of ASU & H drugs in India. Half of the students were aware about ITRA; Jamnagar is one of national pharmacovigilance resource centre for ASU & H drugs. (Table 2)

Table 2: Knowledge of pharmacovigilance among Ayurved pharmacy undergraduates, N=118

Questions	Response	Frequency (%)
Do you know the term “Adverse drug reaction (ADR)”?	Yes	106 (89.83)
	No	12 (10.16)
	Yes	105 (88.98)

Do you know term “Pharmacovigilance (PV)”?	No	13 (11.01)
Do you know is there any separate ADR reporting program for ASU& H drugs in India?	Yes	71 (60.16)
	No	40 (33.89)
	Not attempted	07 (5.93)
Do you know who is monitoring pharmacovigilance of ASU& H drugs in India?	CCRAS	09 (7.62)
	Ministry of Ayush, New Delhi	58 (49.15)
	CCIM, New Delhi	05 (4.23)
	Not aware	41 (34.74)
	Not attempted	05 (4.23)
Which of the following is the web site for pharmacovigilance for ASU&H drugs in India?	Ayusuraksha.com	10 (1.18)
	Pharmacovigilance.com	43 (36.44)
	Ayupharma.com	02 (1.69)
	Not aware	60 (50.84)
	Not attempted	03 (2.54)
Is there National Pharmacovigilance Resource Centre for ASU& H drugs situated at ITRA, Jamnagar, India?	Yes	62 (52.54)
	No	43 (36.44)
	Not sure	13 (11.01)

More than half of study participants agreed to reporting of ADR of ASU&H drugs should be mandatory while 23.72% were not sure about it. 52.54% of study participants were agreed that ADR related to use of cosmetic should be also included in purview of pharmacovigilance while 34.74% were not sure to answer of this question. 86.44% of the study participants were agreed that all the types of ADRs should be reported and 66.94% agreed that all medical and paramedical staff should report ADRs. More than half of students had not received any education training session regarding reporting of ADR and pharmacovigilance and agreed to have this topic in their core syllabus. (Table 3)

Table 3: Attitude and perception of pharmacovigilance among Ayurved pharmacy, N=118

Questions	Response	Frequency (%)
Should reporting of adverse drug reaction by ayurvedic drugs be mandatory for Ayurved Pharmacist?	Yes	75 (63.55)
	No	07 (5.93)
	Not sure	28 (23.72)
	Not attempt	08 (6.77)
Does cosmetics containing ayurvedic drugs come under the preview of pharmacovigilance?	Yes	62 (52.54)
	No	13 (11.01)
	Not sure	41 (34.76)
	Not attempt	02 (1.69)
Which type of ADR should be reported?	Only serious ADR	06 (5.08)
	Mild- severe	08 (6.77)
	Only new	02 (1.69)
	All ADRs	102 (86.44)
Which methods should be preferred by you for reporting adverse drug reaction?	Online	52 (44.06)
	Phone	22 (18.64)
	Email	35 (29.66)
	Post	04 (3.38)
	Not attempt	05 (4.23)
Do you know who should be responsible for reporting adverse drug reaction?	Med/paramedical personal	03 (2.54)
	Pharmacist(A/Ayu/Ho)	21 (17.79)
	Patients/consumers	08 (6.77)
	All of the above	79 (66.94)
	Not attempt	06 (5.08)
	Yes	46 (38.98)

Have you ever come across educational session specific about pharmacovigilance?	No	67 (56.77)
	Not sure	68 (57.62)
	Not attempt	24 (20.33)
Do you agree that "Pharmacovigilance" should be included in core syllabus of ayurveda?	Yes	93 (78.81)
	No	06 (5.08)
	Not sure	15 (12.71)
	Not attempt	04 (3.38)
Do you think reporting is a professional obligation to you	Yes	35 (29.66)
	No	28 (23.72)
	Not sure	52 (44.06)
	Not attempt	23 (19.49)

DISCUSSION

Response to various questions was vary with different questions. Overall, non-attempt of questions by study participants was in range of 1.69 to 19.49 in various questions in this study. 'Not sure' answer certainly reflects about lack of knowledge or understating about the concept of pharmacovigilance.

Majority study participants were aware about the "ADR" and "Pharmacovigilance" terminology. Study participants believed that ASU&H drugs including cosmetics may have ADR and there should be reporting system there. There is also a common belief that use of a medicine based on tradition from the ancient time are safe and efficacious. *Charaka Samhita*, a classic text book of Ayurveda, describes all the adverse reactions to medicines when they are prepared or used inappropriately.^[9] During ancient era, most of the *Vaidyas* used to prepare medicines for their patients themselves and now this practice is replaced by large-scale production and sale of Ayurvedic drugs (classical Ayurvedic formulation and patented proprietary formulation made of herbal extracts) by pharmaceuticals covered under the Drugs and Cosmetics Act, 1940.^[10] Ayurvedic medicine is affected by so many factors like source and properties of drugs (how raw material was

obtained, storage, which part of plant used, chemical and physical properties, actions, habits, pharmaceutical processing) and host factors (constituent of patients, age, disease, tolerance, psychological state, digestive capacity etc).^[9] Further when ASU & H medicines are used in conjunction with other medicines, there is a possibility of drug interactions.^[6]

Ayurvedic literature, *the Charaka Samhita*, has mentioned about drug-drug and drug-diet incompatibilities when synergistic medicines are prepared or used without considering incompatibilities. Hence, these factors along with "Anupan" therapeutic method and "Shodhan" pharmaceuticals principles prevent the onset of many unfortunate reactions. Prevention of this kind is a major goal of PV programs.^[11] There are also examples of ASU & H medicines being adulterated or contaminated with allopathic medicines, chemicals such as corticosteroids, non-steroidal anti-inflammatory agents etc. Currently, majority of adverse events related to the use of herbal/traditional products that are reported are attributed either due to poor product quality or to improper use.^[6]

Study participants were also aware about ADR reporting system but only half of them had knowledge about the separate monitoring system for Ayurveda, Siddha and Unani. Study participants opined that all the type of ADR related to ASU & H drugs (mild, moderate and severe) should be reported. Majority of study participant agreed that online media would be preferred way of communication for reporting ADR. There was no clarity to the study participants about the reporting ADR will be professional obligation or not. There is need of training session about spreading awareness and boosting the reporting culture among students as well faculties of this speciality.

The National Pharmacovigilance Programme (NPP) has given support to report all suspected drug-related adverse effects including all type of herbal and alternative medicines Though the programme has started more than 12 years back in Gujarat, however, the total reporting related to herbal drugs under

pharmacovigilance programme have been appallingly low. The purpose of pharmacovigilance of ASU & H is to establish and developing system wise database of Adverse Drug Reactions (ADR) and evolving evidence-based recommendations towards clinical safety of ASU & H Drugs. This less reporting of ADRs may be due to either the firm belief among teachers, practitioners and pharmacist that ASU&H drugs are safe or their lack of knowledge about the concept and importance of Pharmacovigilance and how they play important role in adverse drug detection and reporting for ASU & H drugs.

In a huge populated country like India, access to drugs is very easy. Most of the people buy the medicines from local community pharmacies without consulting a physician for many illnesses as it is easy, less time consuming and economic.

The pharmacists' contribution will remain an important element in effective pharmacovigilance. Pharmacists have a central role in drug safety by contributing to the prevention, identification, documentation and reporting of ADRs. All healthcare providers have key roles to play in maintaining a balance between medicines' benefits and risks.^[12]

CONCLUSION

The purpose of this study to spread awareness about pharmacovigilance and explain their role in adverse drug reporting among undergraduates of Ayurved pharmacy. There is a need of regular training session for undergraduate pharmacy students and faculties to sensitize and to encourage for developing the culture for ADR reporting for ASU & H drug. There is a need of development of regulatory aspects of Ayurveda, Siddha and Unani medicine as well action plan for reporting of ASU & H drugs with timeline.

Ethical consideration: The study was started after getting approval from Institutional Ethic Committee and consent from the students.

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