

## **IMPACT OF AN EDUCATIONAL INTERVENTION ON AWARENESS OF PHARMACOVIGILANCE AND ADR REPORTING AMONGST AYURVEDIC POST-GRADUATE STUDENTS**

**MEENA ATRAY, ADITI BHANDARI\*, RAHUL DAMOR**

Department of Pharmacology, RNT Medical College, Udaipur, Rajasthan, India  
\*Corresponding author: Aditi Bhandari; \*Email: draditibhandari@gmail.com

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### **ABSTRACT**

**Objective:** Adverse drug reactions (ADR) are one of the major causes of morbidity and mortality. Ayurveda is one of the oldest healthcare systems, widely practiced in India and there is a misconception that AYU and H drugs are free from ADRs. Post-graduate (PG) students are fresh pass-out medical graduates and are major contributors in providing health care at tertiary care centres. The present study was planned with the aim of evaluation of knowledge, attitude and practice of pharmacovigilance amongst PG students and impact of an educational intervention on their knowledge and attitude.

**Methods:** A pre-test, post-test questionnaire based cross-sectional study was conducted. 41 postgraduate students from different branches were included. An educational intervention in the form of sensitization programme, including basic knowledge of pharmacovigilance, monitoring system for pharmacovigilance and case-based ADR reporting was conducted. A validated questionnaire consisting of questions regarding knowledge, attitude and practice of pharmacovigilance was provided as a pre-test and post-test and the results were statistically evaluated.

**Results:** Scores of pre-test reveals that the participants were aware of basic knowledge of pharmacovigilance but knowledge about reporting procedure and the monitoring system was lacking. The difference in mean scores of pre and post-test was statistically significant. Most of the participants agreed that reporting ADR improves drug safety and frequent sensitization programmes should be conducted but practically, they had not undergone any training/sensitization programme.

**Conclusion:** The study reveals that even with the favorable attitude towards drug safety and ADR reporting, the unawareness of PG students about the monitoring system and deficient ADR reporting indicates a strong need for the conduction of repeated training/sensitization programmes and other suitable methods for encouraging ADR reporting.

**Keywords:** Ayurveda, Pharmacovigilance, Adverse drug reactions, ASU and H drugs

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### **INTRODUCTION**

Ayurveda is an ancient yet very important and commonly practiced form of medicine in India. It is well known for providing a holistic approach to therapy for many multi-factorial illnesses. Approximately 80% of Indian population use one form or another of Ayurvedic preparations for healthcare needs. These forms of traditional medicines are even becoming popular worldwide, especially for chronic and non-communicable ailments. Though this form of therapy is amongst one of the oldest practices of medicine, but documentation regarding drug safety of these medicines and their adverse drug reactions is not sufficiently available [1, 2].

To begin with, ayurvedic treatment involved the uses of drugs derived from naturally existing sources but now this long-standing practice has been modified with the use of insecticides and adulterants in medicinal herbs. There are chances of drug interactions if these drugs are taken with allopathic drugs. Thus, easy availability of these drugs calls for need of regulatory interventions related to drug safety for Ayurvedic drugs.

The National Pharmacovigilance Programme for Ayurveda, Siddha and Unani drugs was started by Ministry of Health and Family Welfare, Government of India in 2008 and Homeopathy was included in it in 2018 (AUS and H) [3]. The aim of this Pharmacovigilance program is to improve the drug safety of indigenous Ayurvedic drugs. It includes collection of data pertaining to adverse drug reactions (ADRs) and evaluation of the risk associated with therapy. Inferences are drawn out of the collected data and regulatory interventions are done from time to time.

Despite the widespread practice of Ayurveda, very few studies are available regarding the awareness of pharmacovigilance amongst Ayurvedic healthcare professionals. Knowledge of Pharmacovigilance

and attitude towards its implementation among healthcare professionals directly affect the practice and reporting of adverse drug reactions (ADRs) [4]. Postgraduate students are essential part of a tertiary care centre and are the first contact person with the patient. Hence, this study was planned to assess the knowledge, attitude, and practice pharmacovigilance amongst Ayurveda postgraduate students and impact of an educational intervention on it, probably which will improve the practice of pharmacovigilance and drug safety [5, 6].

### **MATERIALS AND METHODS**

**Study design**—A pre-test, post-test questionnaire-based cross-sectional study

**Sample size**—41 Ayurveda postgraduate students, as per descriptive statistics, using convenient sampling

**Study population**—Postgraduate students in a college teaching Ayurveda in southern Rajasthan

**Inclusion criteria**—All willing Ayurveda PG students

**Exclusion criteria**—Those not willing to consent to be part of the study

### **Study tools**—

1. A questionnaire
2. ADR forms
3. A case history

### **Ethical consideration**

The study was under taken in accordance with the Declaration of Helsinki, after taking ethical clearance from the Institutional Ethics Committee.

### Educational intervention

A questionnaire consisting of questions related to knowledge, attitude and practice of pharmacovigilance and ADR reporting was developed using Google Forms. The contents of the questionnaire were reviewed and validated by senior faculty practicing pharmacovigilance. The questionnaire comprised of four sections. The first section for demographic data, second section with questions to evaluate knowledge, third section to evaluate attitude and fourth part to evaluate practice towards pharmacovigilance and ADR reporting.

ADR forms and a case history to demonstrate ADR reporting was provided to the participants before starting the intervention. After taking consent, a pre-test was conducted which was followed by a well-planned sensitization programme, which included basic knowledge regarding the topic, Pharmacovigilance Programme of India (PvPI), Ayush Suraksha, Pharmacovigilance of ASU and H drugs, implementation of Pharmacovigilance at International, National and Institutional Level. After this, practical training of ADR reporting and causality analysis for the given case history in

reporting form for suspected adverse drug reaction for ASU and H drugs was given. A brief description of online submission of the same ADR was also provided to the participants. The session was followed by a post-test.

### Data analysis

Mean score of the responses of the pre-test and the post-test to evaluate the knowledge were calculated and, statistical evaluation was done by paired 't' test and the response of the individual question were compared using Chi-Square test. The responses of attitude and practice were evaluated by calculating the percentage of participants that responded yes, no or maybe.

### RESULTS

The mean score of pre and post-tests were analyzed statistically using paired 't' test. There was a significant difference in mean score of knowledge in the pre-test (4.3, SD±1.4) and post-test (7.9, SD±1.4). The difference was found to be statistically significant and p value was <0.001.

**Table 1: Assessment of knowledge**

S. No.	Question (Knowledge)	Pre-test (n=41)	Post-test (n=41)	p value
1	What do you understand by the term Pharmacovigilance?	36 (92.3%)	40 (97.6%)	-
2	Case based detection of ADR?	29 (76.3%)	33 (80.5%)	-
3	Need of Pharmacovigilance?	7 (18.4%)	12 (30%)	-
4	Where to report ADR?	37 (92.5%)	39 (95.1%)	-
5	Who can report ADR?	12 (30%)	33 (80.5%)	Significant at p<0.001
6	The official website of pharmacovigilance program for ASU and H Drugs in India?	13 (32.5%)	39 (95.1%)	Significant at p<0.001
7	The international centre for ADR monitoring is located at ?	5 (13.9%)	39 (95.1%)	Significant at p<0.001
8	National coordination centre of Pharmacovigilance Programme of India for ASU and H drugs?	26 (65%)	41 (100%)	Significant at p<0.001
9	Probable consequences of ADR reporting?	10 (25%)	25 (61%)	Significant at p<0.001
10	What is SIGNAL?	3 (8.1%)	23 (56.1%)	Significant at p<0.001

**Table 2: Assessment of attitude**

S. No.	Questions (Attitude)	Yes	No	May be
1	Do you think that the ASU and H drugs have adverse drug reactions?	38(92.7%)	-	3 ((7.3%)
2	Do you think, you are responsible for Adverse drug reaction reporting?	39(95.1%)	-	2(4.9%)
3	Do you think that all ASU and H drugs are not safe?	28(68.3%)	7((17.1%)	6(14.6%)
4	Do you think that reporting adverse drug reaction will improve patient's safety?	41(100%)	-	-
5	Do you think that there is need of training/sensitization programme regarding Adverse drug reporting for every health professional?	39(95.1%)	1(2.4%)	1(2.4%)
6	Would you like to participate in future trainings/sensitization programme for Pharmacovigilance?	39(95.1%)	-	2(4.9%)
7	Do you think Adverse drug reactions are not adequately reported?	31(75.6%)	4(9.8%)	6(14.6%)

**Table 3: Assessment of practice**

S. No.	Questions (Practice)	Yes	No	May be
1	Have you ever noticed any adverse drug reaction of any medicine?	36(87.8%)	5(12.2%)	-
2	Have you ever reported any adverse drug reaction?	3 (7.3%)	38(92.7%)	-
3	Have you ever seen ADR reporting form?	12(29.3%)	29(70.7%)	-
4	Is there any Pharmacovigilance Committee in your Institute?	28(68.3%)	4(9.8%)	9(22%)
5	Have you ever undergone any training/sensitization programme on ADR reporting?	6(14.6%)	35(85.4%)	-

### DISCUSSION

The need of pharmacovigilance is to identify the adverse drug reaction, promote rational therapy and improve drug safety. Some studies have been conducted in different part of the country for health professionals pharmacists, but no such study has been conducted for the postgraduate students of Ayurveda. Regarding knowledge part, there was a significant difference in mean score (p value<0.001) of the pre-test and post-test, which indicates the need of such sensitization programmes at tertiary care centres. The students were aware of the terms 'Pharmacovigilance' and 'Adverse Drug Reaction', but the difference in pre-test and post-test about the

knowledge of who can report the ADR, what is Signal and what can be the consequence of ADR reporting was statistically significant (p<0.001). The knowledge about the official website, the national centre of pharmacovigilance program for ASU and H drugs in India and about the international centre for pharmacovigilance was also significantly improved by the sensitization programme (p<0.001). This result indicates that the students have good knowledge of the basic concept of pharmacovigilance but the knowledge regarding reporting and its consequences, and about the basic structure of the National and International Programme and its functioning need improvement. Many of the findings in results were similar to the study by Acharya *et al.* [9], Sharma *et al.* [10] and Sirsikar *et al.* [11],

though their study included Ayush health professionals and the intervention of sensitization was not done.

Regarding attitude, it was encouraging that majority of participants responded that the Ayurvedic drugs also have ADRs (92.7%), and they have responsibility to report them. 100% of the participants think that ADR reporting will definitely improve drug safety and for which such sensitization programmes should be planned and conducted and they are interested in attending the programmes also. A proportionate change in attitude was observed after sensitization programme was conducted for the students. The study by Acharya *et al.* also showed nearly similar results and the in study by Sharma *et al.* [10], the participants accepted that the regular trainings are required for health professionals. Though the study population in these studies were health professionals and the questionnaire was also partially similar.

Our study reveals that though the PG students have knowledge about basics of pharmacovigilance, favorable attitude towards reporting ADR and in practice they notice the ADRs but only 7.3% have reported ADR and only 14.6% have undergone training/sensitization programme. Similar results have been reported in studies by Acharya *et al.* [9] and Sirsikar *et al.* [11].

A study by Naik *et al.*<sup>5</sup> also stated that most participants had good awareness of pharmacovigilance, though proper practice seemed to be lacking.

This study being done at a single center and with small sample size, included only post graduate students, follow up was not done, so the effect of intervention on attitude and practice in future could not be analyzed. These were the limitations of the study, though, coverage of all aspects in pre-and post-test was the strength of the study.

The study can further be expanded, including larger sample size, comparing different groups of population, and planning advanced sensitization programme with follow up for improvement of rational prescribing and drug safety.

#### CONCLUSION

The present study reveals that the Ayurveda PG students are well aware of basic theoretical knowledge of pharmacovigilance but practical knowledge about ADR reporting and the monitoring system still needs improvement. Despite positive attitude towards ADR reporting, in practice the reporting is minimum. The analysis of impact of the sensitization programme indicate significant improvement in knowledge, reveals need of frequent conduction of such programmes to improve ADR reporting.

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Nil

#### AUTHORS CONTRIBUTIONS

All authors have contributed equally

#### CONFLICT OF INTERESTS

Declared none

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