Original Article

PERSPECTIVES OF PHARMACOVIGILANCE OF AYUSH DRUGS AMONG HEALTH CARE PROFESSIONALS - A CROSS-SECTIONAL SURVEY

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ABSTRACT

Objective: *To assess the knowledge of Pharmacovigilance of AYUSH drugs and recommendations for improving adverse drug reporting of AYUSH drugs among the healthcare professionals working in various disciplines.*

Methods: *This study was a cross- sectional questionnaire based survey conducted during a one day national seminar on "Pharmacovigilance of AYUSH drugs" conducted by Faculty of Pharmacy, Sri Ramachandra University. A structured questionnaire was designed and distributed among 500 delegates working in different districts of the state of Tamilnadu. The colleceted data were analysed using Epi Info software and expressed in percentage (%).*

Results: *Analysis of the data revealed that 36% were aware of the existence of the National Pharmacovigilance Program for AYUSH drugs in India, 24% knew that the National Pharmacovigilance Centre is located at Indian Pharmacopoeia Commission (IPC), Ghaziabad, 12% were aware that the International Centre of Pharmacovigilance is located at UPSALA, Sweden, 14% were familiar with a standardized form for Reporting ADRs of AYUSH drugs and 12% knew that most commonly used causality assessment scale is Naranjo's scale.*

Conclusion: *The present study revealed the lack of knowledge of pharmacovigilance of AYUSH drugs among the study population. There is a need for a regular training and the reinforcement for the ADR reporting among the health care personnel for the better clinical management of the patients in general.*

Keywords: *Pharmacovigilance. Adverse Drug Reaction, AYUSH.*

INTRODUCTION

Pharmacovigilance is defined as the science and activities relating to the detection, assessment and prevention of adverse events and all other problems related to medicines. Moreover, it has a vital role in therapeutic decision-making, either for an individual or national or in global perspective.[1]

More than 60 to 70% of modern medicines in the world market are directly or indirectly derived from plant products. The common myth regarding herbal medicines is that these medicines are completely safe and can therefore be safely consumed by the patient on his/her own, without a physician's prescription.[2] This belief has led to large-scale self-medication by people all over the world, often leading to disappointing end-results, side-effects, or unwanted aftereffects. The National Pharmacovigilance Program was launched in India keeping in view of the increasing global concern regarding safety of Ayurvedic drugs.[3,4]

Several recent high profile herbal safety concerns, such as renal failure and urothelial cancer associated with exposure to Aristolochia species, allergic reactions, skin inflammation with garlic, allergic dermatitis with aloe vera and hepatotoxicity associated with kava-kava have contributed to the increasing awareness of the need to monitor the safety of herbal medicines.[5,6,7]

With this background, the present study had an objective to assess the awareness about Pharmaco-vigilance of AYUSH drugs among the health care professionals and to discuss various ways to make it operationally better among the health care professionals and promote a culture for reporting regularly to the respective peripheral or higher centers.

MATERIALS AND METHODS

This cross-sectional survey was conducted during the National seminar on "Pharmacovigilance of AYUSH drugs" organized by Faculty of Pharmacy, Sri Ramachandra University on 19th January 2016. A list of 604 delegates from various disciplines including research scholars and students from AYUSH and pharmacy colleges, research scholars and officials from the Central Research Institute for Siddha and Central Research for Ayurveda, teachers from pharmacy and other life sciences institutions and health care practitioners of AYUSH drugs had participated in this seminar.

A structured questionnaire (Supplement-1) was distributed to the participants after the inaugural and before the session starts (pre-seminar). At the end of the session, the same questionnaire was circulated to all the participants (post-seminar). Data were expressed as N (%). Statistical difference between pre and post-seminar response was calculated using paired t-test in Graph Pad Prism.

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Name (Optional): Designation: Qualification:

Please answer the followings

1. Are you aware of existence of National Pharmacovigilance Program for AYUSH drugs in India?
   Yes ☐ No ☐
2. Where is the National Pharmacovigilance Center for AYUSH drugs situated?
   IPC, ☐ Ghaziabad ☐ Kolkata ☐ New Delhi ☐ Pune ☐
3. Where is the International Pharmacovigilance Center for AYUSH drugs situated?
   USA ☐ UK ☐ Sweden ☐ Australia ☐
4. Have you ever encountered any adverse event with AYUSH drugs?
   Yes ☐ No ☐
5. Have you ever reported any ADR? If Yes, How many? _____
   If not, what is the reason? _____
6. Are you familiar with standardized form for Reporting ADRs of AYUSH drugs?
   Yes ☐ No ☐
7. Do you know the commonly used scaleto establish the causality of an ADR?
   Yes ☐ No ☐ (If Yes, Can you name it? _____)
8. Can you give an example(s) of any AYUSH drug(s) banned due to ADRs?

AYUSH drug name	Adverse event

9. Have you attended any CME or training program about Pharmacovigilance of AYUSH drugs?
   Yes ☐ No ☐ (If Yes, Can you name it? _____)
10. What are your suggestions for improving ADR reporting of AYUSH drugs?

    _____

    _____

RESULTS AND DISCUSSION

A total of 500 questionnaires were distributed to the participants after the inaugural and before the session starts, out of which 358 were returned to us for evaluation. Out of 358, we could able to evaluate only 326 as 32 forms were rejected for various reasons such as incomplete information, overwriting, tearing, etc. Thus the response rate before the seminar (Pre-seminar) is 65.20%.

With respect to knowledge part of the questionnaire, 117 (36%) participants were aware of the existence of the National Pharmacovigilance Program for AYUSH drugs in India, 78 (24%) knew that the National Pharmacovigilance Centre is located at the Indian Pharmacopoeia Commission (IPC), Ghaziabad but an equal number of respondents said that the National Pharmacovigilance Centre is located at AIIMS, New Delhi. Only 39 (12%) respondents knew that the International Centre of Pharmacovigilance is located at UPSALA, Sweden, rest reported other countries.

Merely 46 (14%) participants were familiar with a standardized form for reporting ADRs of AYUSH drugs and thirty nine (12%) participants knew that most commonly used causality assessment scale is Naranjo's scale.

At the end of the session, the same questionnaire was circulated to all the participants and we received 142 forms for evaluation and the response rate at the end of the seminar (post-seminar) is 71.42%. When compared with pre-seminar, statistically significant improvement in response was observed for all the questionnaires in post-seminar evaluation (Table-1).

On accessing the familiarity and recommendations for improving ADR reporting by participants, only 12 (8.45%) respondents encountered adverse event with AYUSH drugs and merely 3 (2.12%) participants reported ADR. Maximum respondents i.e. 53 (37.32%) suggested that more advertisement is required about the pharmacovigilance of AYUSH drugs for improving ADR reporting of AYUSH drugs, 36 (25.35%) told more seminar or workshop on pharmacovigilance of AYUSH drugs need to be conducted, 24 (16.9%) said that pharmacovigilance should be a part of the curriculum and 18 (12.68%) participants did not respond (Table-2).

There is an ongoing problem with unexpected toxicity of herbal products due to quality issues, including

Table-1: Knowledge of Pharmacovigilance of AYUSH drugs by participants

Questions	Pre-seminar		Post-seminar		p-value
	n (326)	%	n (142)	%	
Are you aware of existence of National Pharmacovigilance Program for AYUSH drugs in India?					
Yes	117	36	142	100	<0.001
No	209	64	-	-	<0.001
Where is the National Pharmacovigilance Center for AYUSH drugs situated?					
IPC, Ghaziabad	78	24	80	56	<0.001
Kolkata	137	42	35	25	<0.001
New Delhi	78	24	27	19	<0.001
Pune	33	10	-	-	<0.001
Where is the International Pharmacovigilance Center for AYUSH drugs situated?					
USA	117	36	17	12	<0.001
UK	111	34	11	8	<0.001
Sweden	39	12	114	80	<0.001
Australia	59	18	-	-	<0.001
Are you familiar with standardized form for Reporting ADRs of AYUSH drugs?					
Yes	46	14	105	74	<0.001
No	280	86	37	26	<0.001
Do you know the commonly used scale to establish the causality of an ADR?					
Yes	39	12	37	26	<0.05
No	287	88	105	74	<0.01

Table-2: ADR familiarity and recommendations for improving ADR reporting

Question	Response (n)	%
Have you ever encountered any adverse event with AYUSH drugs?	Yes (12)	8.45
	No (130)	91.55
Have you ever reported any ADR?	Yes (3)	2.12
	No (139)	97.88
What are your suggestions for improving ADR reporting of AYUSH drugs?		
a. Pharmacovigilance should be a part of the curriculum	24	16.9
b. More seminar/workshop should be conducted	36	25.35
c. More advertisement is required	53	37.32
d. All the hospital should have Pharmacovigilance department	11	7.75
e. No response	18	12.68

use of poor quality herbal material, incorrect or misidentified herbs, incorrect processing methods, supply of adulterated or contaminated herbs or products.[8,9] These quality issues can be addressed to some degree by improved regulation requiring GMP standards for manufacturing. However, medicinal herbs/products come from many countries with differing manufacturing standards and enforcement of regulations. Hence, poor quality products are likely to remain a problem.

By recognizing the growing importance of the use of herbal medicines worldwide, World Health Organization (WHO) and AYUSH developed guidelines for the monitoring of herbal safety within the existing pharmacovigilance framework.[10] The First National Consultative meets of the National Pharmacovigilance Program for ASU Drugs was organized by the department of AYUSH, Ministry of Health and Family Welfare, New Delhi on August 2008, sponsored by WHO, where the draft protocol was technically reviewed and finalized. Based on the feedback received, final version of the protocol is prepared and the same is being released as a part of launching of the National Pharmacovigilance Program.[11,12]

The purpose of pharmacovigilance programme is to identify the ADRs in large populations, establish new and rare ADRs, record the frequency and to implement measures for further prevention of these ADRs.[20] Numerous studies on Knowledge, Attitude and Practice (KAP) of pharmacovigilance have been conducted in various parts of India, however, no such study was conducted in our region, thus we decided to undertake this observational survey. The response rate in our study was 65.2%. It was almost similar to other studies by Desai et al,[13] Hardeep et al,[14] and Agarwal R et al,[15] all of which showed a response rate of 61%.

Only 36% participants were aware of the existence of the National Pharmacovigilance Program for AYUSH drugs in India and 24% knew that the National Pharmacovigilance Centre is located at IPC, Ghaziabad. This knowledge was scarce in our health care professionals as compared to other studies of Ramesh M et al,[16] and Ghosh S et al,.[17]

In our study, a small number of respondents, 46 (14%) participants were familiar with a standardized form for reporting ADRs of AYUSH drugs and thirty nine (12%) participants knew that most commonly used causality assessment scale is Naranjo's scale. These figures show poor knowledge of our staff as compared to the study of Agarwal R et al. [15] All these parameters clearly show deficient knowledge about pharmacovigilance and ADR reporting among doctors, residents and nurses in our college for which we need to employ suitable measures to improve the knowledge and awareness at every level.

A total of only 8.45% respondents encountered adverse event with AYUSH drugs and merely 2.12% participants reported ADR in our study. This data were almost similar to the studies of Desai et al,[13] Pimpalkhute SA et al, [18] Sharma S et al [19] and Ghosh S et al. [17]

CONCLUSION

Our study revealed the overall lack of knowledge about pharmacovigilance and ADR reporting of AYUSH

drugs among the health care professionals. However, most of the healthcare professionals showed a favourable attitude towards ADR reporting and were also enthusiastic to learn and practice it. Thus, the study recommends for more sensitizing programs, advertisement about ADR reporting at grass root health care system. This step will not only promote ADR reporting, but also will be helpful in reducing overall economic burden of health care cost, morbidity & mortality.

CONFLICT OF INTEREST

The authors have none to disclose.

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