National Journal of Physiology, Pharmacy and Pharmacology

RESEARCH ARTICLE

Knowledge, attitude, and practice of pharmacovigilance among Ayurvedic practitioners: A questionnaire survey in Andhra Pradesh, India

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Received: June 28, 2016; **Accepted:** July 15, 2016

ABSTRACT

Background: Adverse drug reactions (ADRs) commonly encountered in daily practice are one of the well-known causes of morbidity and mortality in both hospital and community settings. Ayurveda, the holistic science of herbal medicine that is regarded as the safest medical system, is presently being looked as an important module towards alternative medicine by the world and because of this WHO emphasizes the need for consistent monitoring of its ADRs. Most of the ADRs are preventable with an accomplishment of pharmacovigilance (PV) by the involvement of healthcare providers. **Aims and Objectives:** To assess the knowledge, attitude, and practices (KAPs) about ADR reporting of Ayurvedic drugs among 60 Ayurvedic practitioners (vaidyas) in Andhra Pradesh. **Materials and Methods:** A cross-sectional survey was done by a questionnaire that comprised 15 questions regarding KAP of PV in 60 vaidyas of Andhra Pradesh by WhatsApping them the questionnaire and asking to resend it after answering. The collected data were analyzed using MS Excel 2007 and expressed in percentage (%). **Results:** Among 60 vaidyas, 55 responded to our survey questionnaire. Only 38% of them were aware of the term, "PV," 31% knew about its concept, 25% about National PV programme (NPP), 7% knew about the ADR reporting form and only 2% reported an ADR. **Conclusion:** Our study indicates that the majority of the Ayurvedic health-care professionals had a poor knowledge and attitude about PV and very few practiced it. Hence, they should be trained properly on ADR reporting to improve the current scenario in the NPP.

KEY WORDS: Adverse Drug Reactions; Pharmacovigilance; Ayurvedic Medicine; Knowledge; Attitude; Practice

INTRODUCTION

The use of Ayurvedic medicines as remedy for various diseases has been in practice since time immemorial. However, a popular misconception that Ayurvedic medicines are safe and are devoid of adverse reactions is rampant among masses and also the majority of Ayurvedic practitioners. However, "Charaka Samhita," one of the foundational texts of the medical tradition in India, describes all the adverse reactions to medicines when they are prepared or used inappropriately. In Charaka's opinion "Even a strong poison can serve as an excellent medicine if administered properly. On the other hand, even the most useful drug can act like a poison if handled carelessly."[1] As per WHO definition, adverse drug reaction (ADR) is defined 'as a response to a drug which is noxious and unintended and which occurs

Access this article online	
Website: www.njppp.com	Quick Response code
DOI: 10.5455/njppp.2016.6.0720115072016	

at doses normally used in man for prophylaxis, diagnosis or therapy of disease or for modification of physiological function'.[2] Pharmacovigilance (PV) is "the science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other drug-related problems."[3] Recent inclusions to this definition are herbals, traditional and complementary medicines, blood products, biologicals, medical devices, and vaccines. Although the term "PV" is not figured in Ayurvedic texts, its concept is vibrant across all major texts (Samhitas). The major goals of PV like improving patient care and safety in relation to drug usage with the aim of promoting rational drug use, are recurrent themes of Ayurvedic pharmacology (Dravyaguna Vignana) and therapeutics (Chikitsa).[4]

In a country like India, with a large drug consuming population, not only of modern medicine but also of alternative systems of medicine such as Ayurveda, Unani, Siddha, and Homeopathy; it is more important that a system of ADR reporting is established and a proper ADR database of our own is maintained such that any harmful drug can be easily withdrawn from the market.[5] Being responsible for about 5-20% of hospital admissions ADRs they have a devastating impact on nation's health and economy. India rates below 1% in terms of ADR reporting against the world rate of 5%.[6] To overcome this, in 2003 the Ministry of Health and Family Welfare has initiated the National PV Programme (NPP) which is coordinated by the Central Drugs Standard Control Organization in New Delhi. In July 2010, with the All India Institute of Medical Sciences (AIIMS), New Delhi as the National Coordinating Centre (NCC) for monitoring ADRs, 22 ADR monitoring centers (AMCs) were set up in the country to safeguard public health. To ensure implementation of this programme in a more effective way, the NCC was then shifted from the AIIMS, New Delhi to the Indian Pharmacopoeia Commission, Ghaziabad, Uttar Pradesh in April 2011. The vision of PV Programme of India (PvPI) is to improve patient safety and welfare in Indian population by monitoring drug safety and thereby reducing the risk associated with the use of medicines.[7]

Due to the increased concern by WHO regarding the safety of traditional medicines, a NPP 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, New Delhi on June 29, 2008, with Institute for Post-graduate Teaching and Research in Ayurveda, Gujarat Ayurved University, Jamnagar, as National PV Resource Center for ASU Drugs (NPRC-ASU) Drugs in India.[8]

The main aim of NPP for ASU drugs is to collect data pertaining to the occurrence of ADRs, and to identify and quantify the risk associated with the use of ASU drugs that will be used to reach at inferences to recommend informed regulatory interventions and to communicate risks to health-care professionals and the public.[9]

Under NPRC-ASU drugs, there are 8 Regional PV Centers (RPCs) and 30 Peripheral PV Centers (PPCs) for ASU drugs across the country.[10] ADRs related to any ASU drugs should be reported to PPC, in a specially designed ADR reporting form, which after proper evaluation by the concerned RPC are transmitted to NPRC and from there to Department of AYUSH.[11]

Till date, the number of ADRs to Ayurvedic medicines reported or recorded in the NPP in India is negligible which can be due to either the firm belief among practitioners that Ayurvedic drugs are safe or their lack of knowledge about the concept and importance of PV.[12] Hence, this study was done to assess the awareness about PV in Ayurvedic drugs among vaidyas.

MATERIALS AND METHODS

This cross-sectional survey was conducted in June 2016 in 60 Ayurvedic practitioners all over Andhra Pradesh after obtaining their consent to participate who were informed that the participation is voluntary and confidentiality will be maintained. A preformed and semistructured questionnaire was designed for assessing the basic knowledge, attitude, and practice (KAP) of PV in vaidyas. The PV questionnaire (document form) was WhatsApped to the mobile phones of 60 vaidyas practicing in different parts of Andhra Pradesh and each of them was asked to download, open and answer all the 15 questions by opting for Y (yes) or N (no) or NA (not aware) that were already present opposite to each question through the edit option of the document. The answered and saved questionnaire was asked to send back to us through WhatsApp. Data obtained from the filled questionnaires were analyzed using Excel 2007 and expressed as a percentage.

RESULTS

In our survey, out of the 60 vaidyas to whom the questionnaire was sent, only 55 responded among whom, only 20% believed that Ayurvedic medicines can cause ADRs while almost 62% were unaware of the term, "PV" and the KAPs of PV in the remaining 38% who were aware of it was as shown in Table 1.

Nearly, 31% knew about the PV concept, 26% were aware of NPP for ASU drugs, 22% about NPC, and 15% felt that PV unit was mandatory in AMCs, 13% felt PV center (PVC's) audit was a must, 11% had encountered an ADR, 7% knew about ADR reporting form, 2% reported an ADR, 18% felt to be paid for reporting ADRs, 15% felt patient himself cannot report an ADR, 13% felt an M.D. candidate in Dravyaguna/ Rasashastra & Bhaishajya Kalpana could be a coordinator for

Table 1: Assessment of knowledge, attitude and practice of PV in vaidyas

Question	Yes (%)	No (%)	NA (%)
Does Ayurvedic medicine cause an ADR?	11 (20)	44 (80)	-
Have you ever heard the term PV?	21 (38.2)	34 (61.8)	-
Is assessing drug safety the main concept of PV?	17 (31)	2 (3.6)	36 (65.4)
Did Ministry of AYUSH, GOI start a National PV programme for ASU drugs?	14 (25.5)	3 (5.5)	38 (69.9)
Is the NPC for ASU drugs in India situated at Gujarat Ayurveda University, Jamnagar?	12 (21.8)	3 (5.5)	40 (72.7)
Is it mandatory to have a PVU in AMCs in India?	8 (14.6)	2 (3.6)	45 (81.8)
Is audit of PVC mandatory?	7 (12.7)	11 (20)	37 67.3)
Have you ever encountered any ADR with an Ayurvedic drug?	6 (11)	49 (89)	-
Is there any standardized form available in India for reporting ADRs of ASU drugs?	4 (7.2)	17 (31)	34 (61.8)
Have you ever reported any ADR?	1 (1.8)	54 (98.2)	-
Do you think you should be paid for reporting an ADR?	10 (18)	45 (82)	
Can a patient on Ayurvedic medicine himself report an ADR form?	8 (14.6)	7 (12.7)	40 (72.7)
Can a M.D. candidate in Dravyaguna/Rasashastra & Bhaishajya Kalpana be a coordinator for PVC?	7 (12.7)	6 (11)	42 (76.3)
Have you ever attended any CME or training programme on PV of ASU drugs?	4 (7.3)	51 (92.7)	-
Should the patient's information be maintained confidential while reporting an ADR?	10 (18.2)	7 (12.7)	38 (69.1)

ADR: Adverse drug reaction, ASU: Ayurveda, Siddha and Unani, NPC: National Pharmacovigilance Center, PVU: Pharmacovigilance unit, AMCs: Adverse drug reactions monitoring centers, PVC: Pharmacovigilance Center, CME: Continuing medical education, AYUSH: Ayurveda, Yoga and Naturopathy, Unani, Siddha and Homeopathy, PV: Pharmacovigilance

PVC, 7% had attended continuing medical education (CME) or training programme on PV of ASU drugs and 18% felt that the patient's identity should be kept confidential while reporting ADRs.

DISCUSSION

At present, a major portion of health care is being provided by traditional, alternative, and complementary systems of medicines worldwide, even more in the industrialized nations because of the concerns over side effects of synthetic drugs. Among these, Ayurveda has been gaining global relevance by virtue of its systematic approach to cure the ailments using natural resources. Several issues and challenges have been faced because of this new upsurge of interest in Ayurveda and its rapidly increasing public utilization.[13,14] With this increased demand for herbal products worldwide, WHO forecasts that the global herbal market would be around $5 trillion by 2050.[15]

During ancient period, most of the vaidyas used to prepare medicines for their patients themselves. With time, this practice has faded and at present this is followed only by few which lead to large-scale production and sale of Ayurvedic drugs by pharmaceutics covered under the Drugs and Cosmetics Act, 1940.[16] In market, as on now, 2 categories of Ayurvedic medicines are available: One is classical Ayurvedic formulation based on the descriptions in the Samhitas like Kutajarishta, Chandraprabhavati, etc. and the other is the patented proprietary formulation made of herbal extracts.[17] The Ayurvedic pharma companies with an annual turnover of around 4-5 thousand crores, nearly account for one-third of the Indian pharmaceutical industry. This commercialization of Ayurvedic medicines has brought with it many serious challenges like quality assurance control, spurious and counterfeit drugs bringing into focus the need for formal PV programmes in this field.

Other than herbal drugs, metals and minerals given as Bhasmas (incinerated mineral formulations) or in combination with plants as herbo mineral formulations (e.g. Arogyavardhini Vati) are prescribed as medicines by classical Ayurveda. When stringent precautions are not followed during either manufacturing or administering these medicines, ADRs can occur.[18] In spite of wide usage in India, their long-term safety is still doubted because of the toxic metal contents in them[19] and even some ADRs have been reported.[20]

Post-marketing surveillance, a non-interventional, observational study helps in understanding the tolerability profile of marketed modern medicines in a heterogeneous population and thus is an important source of evidence in knowing treatment outcomes.[21] Another such observational study that deals with monitoring and evaluation of the safety of medicines is PV. Such studies carried by many modern physicians helped in detecting uncommon/idiosyncratic ADRs, unsuspected interactions (drug-drug or drug-food) or even those that occur only after long-term drug usage. Drug interactions, like *Ginkgo biloba* (used for Alzeimer's disease) caused increased bleeding with aspirin, St. John's Wort (used as antidepressant) reduced the blood levels of warfarin, oral contraceptive pills, etc., have been observed when they were used in conjunction with herbal drugs.[22] Hence, patients taking drugs with low therapeutic index such as warfarin, digoxin, cyclosporine, and phenytoin should be strictly discouraged from using herbal drugs.[23] Patterns of drug utilization and even newer indications for older drugs can emerge from these observation studies. Contrary to this, very little information is available regarding the Ayurvedic

drugs ADR profile; although, Ayurveda was the first medical system which considered the occurrence of ADRs and classified the lists of drugs as toxic, semi-toxic or to be used with precaution, etc., and also incorporated methods to avoid or nullify them.[11] Therefore, PV serves as an important postmarketing safety tool in ensuring the safety of Ayurvedic medicines which lack clinical trials unlike the conventional drugs except that they are in use since hundreds of years and safety, and efficacy of individual drugs are reported in Samhitas.[24]

In our survey, it was revealed that 80% of the 55 vaidyas believed Ayurvedic medicines do not cause ADRs (Table 1) and only 11% had encountered ADRs with Ayurvedic drugs in their practice, of whom excluding 1 participant others have never reported ADRs which was due to non-availability of ADR reporting forms and also unawareness of what, how and where to report them. In contrast to another study in Orissa which has shown high knowledge, but the poor practice of ADRs among vaidyas,[25] our study has found not only poor practice but also inadequate knowledge regarding ADR reporting. The average knowledge score of the respondents was 38%, indicating that there is still much to be done to educate them regarding ADR reporting. This under-reporting of ADRs should be taken more seriously as the cost of treatment of drug-induced adverse effects is an additional cost of pharmaceutical treatment.[26] This can only be prevented if the health-care professionals inculcate the habit of spontaneous reporting of ADRs, which serves as the core data generating system of PV.[27]

A thorough knowledge of the Samhitas can prevent most of these ADRs. An ample scope for the logical use of medicines based on various factors such as Prakruti, Desha, Kala etc. is given by Ayurveda, PV of Ayurvedic medicines is a definite challenge. Hence, the combination becomes multifold and varies from patient to patient and physician to physician. Furthur complications arise due to combined use of proprietary medicines with the classical preparations. As a result, causality analysis becomes difficult. Furthermore, standard scales need to be modified to suit ADRs of Ayurveda.[10]

CONCLUSION

In present day scenario, both the rational use of drugs and voluntary spontaneous ADR reporting are the two most essential needs of the hour for the successful cure of diseases in any system of medicine. Currently, the PV activities including reporting of ADRs in Andhra Pradesh are more of an accidental nature and vaidyas are less or not at all informed about this activity. Although the majority of the studied doctors had a favorable attitude toward reporting ADRs, a small number expected to be paid for this activity. Mere inclusion of PV as a topic in the curriculum of graduate and post-graduate level studies of Ayurveda is not enough but they should be emphasized that practicing PV helps not only in understanding the safety profile of Ayurvedic medicines but also plays a key role in therapeutic decision-making, either for an individual or national or in global perspective. Teachers, physicians, and pharmacists of Ayurveda should be sensitized on the concept of PV and how to report an ADR through CME programmes across the country so that they actively participate in processes of drug monitoring, ADR reporting and information dissemination to make PV programme for ASU drugs a successful one.

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How to cite this article: Prakash GB, Subash KR, Reddy KVC, Kumar DSS, Prasad KJ, Rao KU. Knowledge, attitude and practice of pharmacovigilance among Ayurvedic practitioners: A questionnaire survey in Andhra Pradesh, India. Natl J Physiol Pharm Pharmacol 2016;6(5):475-479.

Source of Support: Nil, **Conflict of Interest:** None declared.