

## RESEARCH ARTICLE

### Assessment of knowledge, attitude, and practice of pharmacovigilance among doctors practicing alternative systems of medicine in Southern India: A questionnaire-based study

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#### ABSTRACT

**Background:** Reporting adverse drug reactions (ADRs) are an essence of pharmacovigilance practice. Health-care professionals should know how and where to report an ADR. For Pharmacovigilance Programme of India (PVPI) to be successful, the health-care professionals such as allopathic doctors, nurses, and pharmacists must be actively involved along with the doctors who practice alternative systems of medicine. **Aims and Objective:** To assess the awareness and perception of pharmacovigilance among doctors practicing alternative systems of medicine in Tumkur, Southern India. **Materials and Methods:** A cross-sectional study was conducted among doctors practicing alternative systems of medicine in Tumkur, Southern India, using a validated questionnaire suitable for assessing the knowledge, attitude, and practice of pharmacovigilance was designed and distributed to the private practitioners. **Results:** Of 120 doctors who answered the questions, 28.3% reported to have heard the name pharmacovigilance, 14.2% doctors answered that drugs used in alternative systems of medicine cause ADRs, whereas 85.8% said they do not. Only 12.5% thought that reporting an ADR with Ayurveda, Siddha, and Unani (ASU) drugs is necessary, 9.2% had encountered an ADR with ASU drugs. Only 6.7% have been trained on how to report ADRs, whereas only 1 (0.8%) doctor had reported ADRs. **Conclusion:** Knowledge of doctors practicing alternative systems of medicine regarding pharmacovigilance is poor as well as their attitude and practice toward it. Sincere efforts should be made to include them under PVPI and to train through continued medical education programs as well as workshops on PVPI.


**KEY WORDS:** Pharmacovigilance; Adverse Drug Reactions; Pharmacovigilance Programme of India; Alternative Systems of Medicine

#### INTRODUCTION

Drug therapy of any disease is an integral part of the medical management. It has many beneficial effects, but side-effects

and adverse drug reactions (ADRs) are some of its major disadvantages.<sup>[1]</sup> Reporting ADRs are considered the essence of pharmacovigilance practice.<sup>[2]</sup>

The WHO started program for international drug monitoring in 1961 to promote drug safety, and subsequent to that it promoted pharmacovigilance program at country level in collaboration with Center for International Drug Monitoring, Uppsala.<sup>[3]</sup> To detect and spontaneously report ADR and to ensure drug safety, national pharmacovigilance program (NPP) was initiated in India in the year 2004.<sup>[4]</sup> It is now renamed as Pharmacovigilance Program of India and

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operational since July 2010 under the aegis of the Central Drug Standard Control Organization.<sup>[5]</sup>

Spontaneous reporting of ADR by health-care professionals is backbone of pharmacovigilance program, but under-reporting of ADR is still prevalent and is the cause of concern.<sup>[1]</sup> Health-care professionals should know how and where to report an ADR. ADR reporting can be improved by active participation of healthcare professionals.<sup>[6]</sup>

Studies conducted in India have shown poor attitude, knowledge, and practices involving ADR reporting among healthcare professionals. ADR reporting rate in India has gradually increased as compared to previous years. Pharmacovigilance Programme of India (PVPI) in-house assessment shows that 64.66% of individual case safety reports were reported by clinicians, 14.75% by pharmacists whereas other healthcare professionals including nurses, dentist, etc., was 18.83%.<sup>[7]</sup> But India's contribution to the database at Uppsala Monitoring Centre, Sweden is very little, even though India is one of the participants. This is essentially due to the absence of a vibrant ADR monitoring system and also a lack of a reporting culture among health-care professional in India. The major weaknesses of pharmacovigilance programme are the lack of awareness among health professionals regarding pharmacovigilance; under-reporting is another major limitation. Other reasons for under-reporting include uncertainty regarding the types of reaction to report, and a lack of awareness about the existence, function and purpose of the national ADR reporting scheme.<sup>[7]</sup>

In a study conducted by Kharkar and Bowalekar, it was reported that the practice of pharmacovigilance reporting is discouraging among medical practitioners in India; in spite of having knowledge about pharmacovigilance reporting in addition to the right perception toward pharmacovigilance reporting.<sup>[8]</sup>

In a country like India with a large drug consuming population, there is a general misconception that the drugs used in alternative systems of medicine such as Ayurveda, Unani, Siddha, and Homeopathy are safe and devoid of ADRs. It is important to establish an ADR reporting system and database with special emphasis on ADRs related to alternative systems of medicine. Department of Ayurveda, Yoga and Naturopathy, Unani, Siddha and Homeopathy, Ministry of Health and Family Welfare, Government of India, New Delhi, has initiated NPP in Ayurveda, Siddha and Unani (ASU) drugs due to the increased concern shown by WHO regarding the safety of traditional medicines.<sup>[9]</sup>

The number of ADRs to Ayurvedic medicines reported to the NPP in India is negligible which could be due to either the misconception that Ayurvedic drugs are safe or their lack of knowledge about the concept and importance of PV.<sup>[10]</sup>

Very few studies relating to the assessment of knowledge, attitude, and practice (KAP) of pharmacovigilance among doctors practicing alternative systems of medicine have been conducted in India. Hence, this study was conducted to assess the KAP of pharmacovigilance among doctors practicing alternative systems of medicine in Tumkur, Southern India.

## Objective

To assess the awareness and perception of pharmacovigilance among doctors practicing alternative systems of medicine in Tumkur, Southern India.

## MATERIALS AND METHODS

A questionnaire-based cross-sectional study was conducted between May and June 2016 among doctors practicing alternative systems of medicine working in private hospitals/clinics in Tumkur, Southern India. A validated questionnaire was distributed to the doctors practicing alternative systems of medicine for assessing their KAP of pharmacovigilance and reporting of ADRs. The questionnaire was based on few previous studies, and suitable modifications were made. The questionnaire contained a total of 16 questions, of which 6 were pertaining to the knowledge, 5 related to the attitude and 5 related to the practice of pharmacovigilance. The filled forms were collected from doctors practicing alternative systems of medicine after 1 day and the data were analyzed by Microsoft excel 2007. The study was conducted after obtaining approval from the Institutional ethical committee.

## Inclusion Criteria

All the doctors practicing alternative systems of medicine in Tumkur willing to participate voluntarily were included in the study.

## Exclusion Criteria

All those who do not wish to participate were excluded.

## RESULTS

A total of 136 doctors practicing alternative systems of medicine in Tumkur were included in the study and were distributed the questionnaire. Only 120 (88.2%) doctors responded by returning the filled questionnaire. Table 1 suggests that of the 120 doctors who answered the questions, 28.3% reported to have heard the name pharmacovigilance, while only 3.3% knew the meaning of pharmacovigilance. 14.2% doctors answered that drugs used in alternative systems of medicine cause ADRs, whereas 85.8% said they do not cause ADRs. 18.3% reported that they were aware of the existence of NPP in India for ASU drugs, 20% answered

**Table 1:** Knowledge of ADR reporting and pharmacovigilance among doctors practicing alternative systems of medicine

Questions	Correct answers	Wrong answers	No answers
Have you heard the name of pharmacovigilance?	34 (28.3%)	86 (71.7%)	-
Meaning of pharmacovigilance	4 (3.3%)	34 (28.3%)	82 (68.4%)
Does drugs used in alternative systems of medicine cause ADR?	17 (14.2%)	103 (85.8%)	-
The national center for Adverse drug reaction monitoring is located at?	3 (2.5%)	79 (85.8%)	38
Do you know regarding the existence of NPP in India for ASU drugs?	22 (18.3%)	98 (81.7%)	-
Which important factor is necessary to report an adverse drug reaction	24 (20.0%)	34 (28.3%)	62 (51.7%)

NPP: National pharmacovigilance program, ADR: Adverse drug reaction

correctly about the important factors that are necessary to report an ADR.

Table 2 indicates the response toward the questions related to the attitude, only 12.5% thought that reporting an ADR with ASU drugs is necessary, 9.2% had encountered an ADR with ASU drugs, 18.3% thought reporting ADR should be mandatory, while 22.5% thought to report ADRs will increase patient safety.

Table 3 suggests that 23.3% had seen the ADR reporting form, 22.5% knew whom to report, 9.2% answered correctly for the question regarding the time frame for reporting serious ADR to the regulatory body. Only 6.7% have been trained on how to report ADRs, whereas only 1 (0.8%) doctor had reported an ADR.

## DISCUSSION

There is a general misconception among the Indian population that drugs used in Ayurveda and other alternative systems of medicine such as Unani, Siddha, and Homeopathy are safe when compared to the allopathic medicine. Ayurveda is gaining greater relevance in the global level.<sup>[11,12]</sup> WHO emphasizes the need for consistent monitoring of ADRs related to drugs used in the alternative systems of medicine.<sup>[13]</sup>

This study revealed that 85.8% of the doctors practicing alternative systems of medicine believed that ASU drugs do not cause ADRs, and only 9.2% has encountered ADRs in their practice of which only 0.8% (1) had ever reported an ADR.

**Table 2:** Attitude towards ADR reporting and pharmacovigilance among doctors practicing alternative systems of medicine

Do you think reporting an ADR with ASU drugs is necessary?	15 (12.5%)	82 (68.3%)	13 (10.8%)
Have you ever encountered an ADR with ASU drugs?	11 (9.2%)	109 (90.8%)	-
Do you think reporting ADR should be mandatory?	22 (18.3%)	98 (81.7%)	-
Do you think that it is necessary to report only serious and unexpected reactions?	22 (18.3%)	75 (62.5%)	23 (19.2%)
Do you think reporting ADRs will increase patient safety?	27 (22.5%)	82 (68.3%)	11 (9.2%)

ASU: Ayurveda, Siddha and Unani, ADR: : Adverse drug reaction

**Table 3:** Practice towards ADR reporting and pharmacovigilance among doctors practicing alternative systems of medicine

Have you ever seen the ADR reporting form?	28 (23.3%)	18 (15%)	74 (61.7%)
To whom do you report ADRs?	27 (22.5%)	18 (15%)	75 (62.5%)
A serious ADR in India should be reported to the regulatory body within?	11 (9.2%)	24 (20.0%)	85 (70.8%)
Have you ever been trained on how to report ADRs?	8 (6.7%)	112 (93.3%)	-
Have you ever reported an adverse drug reaction?	1 (0.8%)	114 (95.0%)	-

ADR: Adverse drug reaction

Similarly according to Prakash *et al.*, 80% of the Ayurvedic doctors believed Ayurvedic medicines do not cause ADRs, and only 11% had encountered ADRs with Ayurvedic drugs in their practice, of which only 1 participant reported ADRs. The average knowledge score of the respondents was 38%.<sup>[14]</sup>

In contrast, another study conducted in Orissa has shown high knowledge but the poor practice of ADRs among Ayurvedic doctors.<sup>[15]</sup>

According to Rodríguez-Monguió *et al.*, apart from the implications for health, a substantial quantity of resources are used to treat adverse effects of drugs.<sup>[16]</sup>

Amancharla *et al.* conclude that the major discouraging factors for under-reporting were a lack of time and difficulty in detecting that the ADR was due to a particular drug. Better reporting can be encouraged by educating the

health-care professionals to utilize the assistance of Adverse Drug Reaction Monitoring centre A.M.C in identifying the ADRs.<sup>[17]</sup>

## CONCLUSION

Knowledge of the doctors practicing alternative systems of medicine regarding pharmacovigilance is poor as well as their attitude and practice toward it. Ayurveda and other traditional medicine systems are gaining popularity worldwide. WHO emphasizes the need for consistent monitoring of ADRs related to drugs used in the alternative systems of medicine. Sincere efforts should be made to include all doctors practicing alternative systems of medicine under PVPI, and they should be trained properly on when, how and where to report an ADR. A topic on PVPI should be included in the undergraduate curriculum to improve the knowledge of pharmacovigilance among the students admitted to alternative systems of medicine courses.

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