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Complementary/Alternative Medicine Section

# Knowledge, Attitude and Practice of Pharmacovigilance among Ayurveda Doctors Practicing in Wardha, Maharashtra, India: A Cross-sectional Study

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# **ABSTRACT**

Introduction: Adverse Drug Reactions (ADRs) significantly, cause morbidity and mortality worldwide. As a result, proper ADR monitoring is required. Considering the consequence of this area, the Ministry of AYUSH has introduced a Pharmacovigilance programme for Ayurveda, Siddha, Unani and Homeopathy (ASU&H) drugs. Every Ayurveda Practitioner's (AP) immense responsibility is to detect and report ADR.

**Aim:** To evaluate the knowledge, attitude, and practice of pharmacovigilance among AP in Wardha, Maharashtra, India.

Materials and Methods: A cross-sectional survey was conducted in a Government Hospital, Wardha, Maharashtra, India, during March to May 2022. Total 38 Ayurveda Doctors of Wardha city having Bachelor of Ayurvadic Medicine and Surgery (BAMS), Doctor of Medicine (MD) degree, either working in private clinics and hospitals or as medical officers were enrolled in the study.

A validated questionnaire was prepared on Google form, circulated through WhatsApp to the doctors, and asked them to fill and submit it within seven days. The collected data were analysed using Microsoft excel 2007 and expressed in percentages (%).

**Results:** A 28 (73.67%) male, and 10 (26.31%) female doctors possessing BAMS degrees (68.42%) and postgraduate degrees (37.57%), with practice experience between 5-30 years participated in the study. Present study revealed that 32 (84.21%) of the BAMS doctors from Wardha city believed that Ayurveda drugs cause ADRs, and only 7 (18.4%) have encountered ADRs in their practice, of which only 02 (5.26%) reported an ADR.

**Conclusion:** The present study revealed that AP are well aware about ADR but lacking in the knowledge of its reporting. There is a strong need to organise sensitisation and awareness programmes to implement the pharmocovigilance effectively.

Keywords: Adverse drug reactions, Ayurveda medicines, Health, Herbal drugs

#### INTRODUCTION

Ayurveda, the science of life, is immortalised in the form of elegant Sanskrit stanzas in the Samhitas, which describe diagnosis and therapy and ways to sustain good health [1]. India is known for its biodiversity, and as a result, it has its indigenous codified healing systems. Ayurveda is one such healthcare system practiced in India for thousands of years and is a crucial component of the healthcare sector [2]. Approximately, 80% of the Indian population is estimated to utilise Ayurvedic medicines for their medical needs [3].

Ayurveda is also becoming more popular in Western countries [4]. The growing use of Ayurvedic medications worldwide has raised concerns about their safety. Several recent publications have expressed concern about the safety of Ayurvedic medicines [5,6]. Today, Ayurveda is gaining popularity worldwide, both as a therapeutic option for treating various chronic and noninfectious diseases and because of its potential health risks. Despite the fact that, Ayurveda has been practiced for centuries, there is a lack of systematic documentation concerning ADRs and other issues concerning the safety of Ayurvedic medicines [7,8].

Furthermore, compared to the practice of Ayurveda in the past, there is a significant difference in many aspects of its application today. As a result, the changes in environmental factors, adulteration of herbs, the ever increasing use of insecticides, modern drug manufacturing techniques, negligence of regulations, and an increase in over-the-counter sales, safety monitoring has become increasingly important [9,10].

With growing concerns about the safety of Ayurvedic medicines, the Department of Ayurveda, Yoga, and Naturopathy, Unani, Siddha Homeopathy (AYUSH); Ministry of Health and Family Welfare, Government of India has launched a National Pharmacovigilance Programme in Ayurveda, Siddha, and Unani (ASU) drugs [11]. "Pharmacovigilance is the science and activities relating to detecting, assessing and preventing adverse events and all other problems related to medicines moreover, it has a vital role in therapeutic decision making, either for an individual, national or global perspective" [12]. Nearly, 70% of modern medicines on the global market are derived directly or indirectly from plant products [13]. The common misconception about herbal medicines is that, they are entirely safe and can thus be consumed by the patient without a physician's prescription [13]. This belief has resulted in widespread self-medication by people all over the world, which frequently results in disheartening results, health consequences or undesired after-effects [14].

The National Pharmacovigilance Programme was established in India in response to the growing global safety of Ayurvedic drugs [15]. The goal of the pharmacovigilance programme is to collect data on the occurrence of ADR and to identify and quantify the risk associated with drug use. Such information is used to recommend informed regulatory interventions and communicate risks to healthcare professionals and the general public. As a result, proper ADR monitoring is required. All healthcare professionals in India, including doctors, nurses and pharmacists, can report an ADR by completing the Central Drugs Standard Control Organisation's

ADR form [16]. Healthcare professionals must understand how and where to report an ADR. Pharmacovigilance programme should be conducted to improve the knowledge of healthcare professionals regarding ADR [17].

Ayurveda practitioner's could be reliable scientific resources in pharmocovigilance reporting mechanism, but, no report is available so far, regarding the knowledge and behaviour on pharmocovigilance among AP of Wardha. Hence, the present study was conducted to identify the healthcare professionals practicing Ayurveda in Wardha, Maharashtra, India, and to evaluate their knowledge, attitude and practice of pharmacovigilance.

## **MATERIALS AND METHODS**

A cross-sectional study was conducted between March and May 2022 in Government Hospitals of Wardha, Maharashtra, India. An approval from the Institutional Ethical Committee was taken prior to the commencement of the study (Ref. No.MGACHRC/IEC/June-2021/256). Written informed consent was taken from the participants for inclusion in the study.

**Inclusion criteria:** All the doctors with BAMS degrees either working in private clinics and hospitals or as medical officers in Government hospitals in Wardha city willing to participate voluntarily were included in the study.

**Exclusion criteria:** Retired doctors, doctors who were not practicing alternative systems of medicine and unwilling to take part in the survey were excluded from the study.

**Sample size calculation:** The sample size was calculated as using the formula:

 $n=Z^2\times(p\times q)/e^2$ 

 $=1.64^2\times0.1657\times(1-0.1657)/0.1^2$ 

=0.3718/0.01

=38

where, n=required sample size, p=prevalence, 16.57 % [18], q=1-p, e=margin of error, 10%, Z=1.64 at 95% confidence interval.

#### **Study Procedure**

The demographic data concerning their age, gender, education qualification and practice experience was collected. The study comprised an online survey that assured the confidentiality and anonymity of the participants. A validated questionnaire was prepared by the researchers on Google form and circulated through WhatsApp group of the doctors for assessing their knowledge, attitude and practice of pharmacovigilance and reporting of ADRs. Each of them was asked to download the Google form and answer all the 16 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 and submit it within seven days. A total of 48 doctors with BAMS degrees from Wardha city were identified and included in the study and were distributed the questionnaire through WhatsApp. Only 38 doctors responded by submitting the filled Google form after repeated reminders and hence considered for the analysis.

Questionnaire: The questionnaire was prepared based on a few previous studies [19,20]. The questionnaire enclosed a total of 16 close ended questions, of which seven were pertaining to knowledge, five related to attitude and four related to the practice of pharmacovigilance with Y (yes) or N (no) or NA (not aware) options. The questionnaire was validated and approved by faculty from School of Health Professional Education and research (SHPER) of Jawaharlal Nehru Medical College, Datta Meghe Institute of Medical Sciences (Deemed to be University), Sawangi (Meghe) Wardha, India. At first, a pilot study was done by sending the Google form to 10 first year postgraduate students (pursuing BAMS, MD degree) of the college. On piloting, questionnaire was found to take

approximately three to four minutes to answer. In this pilot study, the Cronbach's alpha value was 0.79, so, the authors proceeded for the data collection from the study population.

#### STATISTICAL ANALYSIS

The collected data was entered in Microsoft excel sheet, version MS office 2013. The results were calculated in terms of frequency and percentage (%).

#### **RESULTS**

The majority, 19 (50%) respondents were in the age group of 25-34 years and 14 (36.84%) respondents were in 35-44 years age group. Among these 38 Ayurveda doctors, 28 (73.67%) were male, and 10 (26.31%) were female, possessing BAMS degrees 26 (68.42%) and postgraduate degrees 12 (37.57%), with most of the doctors, 18 (47.36) having practice experience between 5-15 years [Table/Fig-1].

S. No.	Demographic features	Subgroups	Total number	Percentage (%)
1.	Age	25-34 years	19	50
		35-44 years	14	36.84
		45 years and above	05	13.15
2.	Gender	Male	28	73.67
		Female	10	26.31
3.	Educational qualification	Graduates	26	68.42
		Postgraduates	12	31.57
4.	Practice experience	<5 years	10	26.31
		5-15 years	18	47.36
		>15 years	10	26.31

[Table/Fig-1]: Geographical distribution of data.

Total 35 (92.10%) reported to have heard the name pharmacovigilance, while only 14 (36.84%) knew the meaning of pharmacovigilance. A 30 (78.94%) of doctors answered the meaning of ADR, and 32 (84.21%) believe the Ayurveda drug can cause ADRs. Only 1 (2.63%) reported that they were aware of the location of the National Pharmacovigilance Centre and 18 (47.36%) answered correctly about the personnel eligible to report an ADR [Table/Fig-2].

Knowledge related questions	Yes	No	No answer
Do you know the term pharmacovigilance?	35 (92.10)	03 (7.89)	0
Do you know the meaning of pharmocovigilance?	14 (36.84)	22 (57.89)	02 (5.26)
Do you know the meaning of ADR?	30 (78.94)	08 (21.05)	0
Do you believe that Ayurveda drugs can cause ADR?	32 (84.21)	06 (15.78)	0
Do you know whether or not India has a pharmacovigilance programmes?	26 (68.42)	12 (31.57)	0
Do you know the location of the National Center for Adverse Drug Reaction (ADR) monitoring?	01 (2.63)	37 (97.36)	0
Do you know who can report the ADR?	18 (47.36)	20 (52.63)	00

**[Table/Fig-2]:** Knowledge related questions and percentage of correct and incorrect responses.

Only 37 (97.36%) thought reporting an ADR with Ayurveda, Siddha and Unani (ASU) drugs is necessary, while 37 (97.36%) believe that healthcare professionals should be trained in depth about pharmacovigilance. Only 19 (50%) were aware of ADRs through the article reading. A 37 (97.36%) thought it necessary to set-up an ADR monitoring centre at every hospital, while all the doctors were of the opinion that reporting ADRs will help enhance patient safety [Table/Fig-3].

A 7 (18.41%) had encountered an ADR with Ayurveda drugs, 18 (47.36%) were familiar with the ADR reporting form, and

2 (5.26%) knew how to report ADRs. In contrast, only 1 (2.63%) of doctors only keep a record of ADR [Table/Fig-4].

Attitude related questions	Yes	No	No answer
Do you believe it is necessary to report adverse medication reactions to ASU drugs?	37 (97.36)	01 (2.63)	0
Do you believe that healthcare professionals should be trained in depth about pharmacovigilance?	37 (97.36)	01 (2.63)	0
Have you ever read an article about how to avoid a negative drug reaction?	19 (50)	19 (50)	0
Do you think it is necessary to set-up an ADR monitoring centre at every hospital?	37 (97.36)	01 (2.63)	0
Do you think reporting ADRs will increase patient safety?	38 (100)	0	0

[Table/Fig-3]: Attitude-related questions and percentage of correct and incorrect responses.

Practice related questions	Yes	No	No answer
Have you ever noticed a patient have an unfavourable drug reaction during your clinical practice?	07 (18.41)	30 (78.94)	01 (2.63)
Are you familiar with ADR reporting form for ASU drugs?	18 (47.36)	20 (52.63)	00
Have you ever approached the pharmacovigilance centre to report ADR?	02 (5.26)	35 (92.11)	01 (2.63)
Do you keep the record of AD?	01 (2.63)	37 (97.36)	00

[Table/Fig-4]: Practice-related questions and percentage of response.

#### **DISCUSSION**

In the present study, it was observed that majority of the doctors practicing alternative systems of medicine in Wardha city were aware about the ADRs caused due to Ayurveda medicines but only 2 (5.26%) knew how to report ADRs which is very alarming.

Currently, a large amount of healthcare is given by treating illnesses using traditional, alternative and complementary medicine systems worldwide. AP in India utilise herbal medications, metals and minerals in the form of Kharaliya rasakalpa (herbo mineral formulations), parpati, or kupipakwa Kalpa, and Bhasmas (incinerated mineral formulations). During the initial days, Ayurveda physicians (Vaidyas) used to prepare medicines for their patients themselves, ensuring the safety and efficacy of the drugs. But in recent years, this practice has changed, and most Ayurveda physicians depend on the drug prepared by Ayurvedic drug manufacturing units. This widespread availability of Ayurvedic medicines has helped to bring many serious challenges, such as the quality and purity of drugs, highlighting the need for a pharmacovigilance programme in this field. ADRs can occur when strict procedures for preparing and prescribing specific drugs are not followed [21]. It is the common belief that the medications used in traditional treatment systems, such as Ayurveda, are safe and free of ADRs [21,22].

The present study revealed that 84.21% of the BAMS doctors from Wardha city believed that Ayurveda drugs cause ADRs. Only 21.05% have encountered ADRs in their practice, of which only 5.26% had ever approached the pharmacovigilance centre to report an ADR.

These findings are congruent with the results drawn by Prakash GB et al., in which 80% of the Ayurvedic doctors believed Ayurvedic medicines do not cause ADRs, and only 11% had come across ADRs with Ayurvedic drugs in their practice, of which only one physician reported ADRs [18]. In contrast, another study conducted in Orissa has shown high knowledge but poor practice of ADRs among Ayurvedic doctors [23]. Desai CK et al., also observed the right attitude toward ADR reporting subsisted among most participants but lacked the actual practice of ADR reporting [24]. Some such studies in India show similar results regarding attitude towards ADR reporting [25,26]. Amancharla MK et al., conclude that the major discouraging factors for under reporting were a lack of time and difficulty detecting that the ADR was due to a particular

drug [27]. Treating drug induced adverse effects is an additional cost of pharmaceutical treatment, so the under-reporting of ADRs should be taken more seriously [28]. This can only be avoided if healthcare professionals instill the habit of spontaneously reporting ADRs, which serves as the pharmocovigilance's primary data generation system [29]. Awareness and reporting of ADRs can be encouraged by educating the practitioners by organising Webinars and displaying banners and posters depicting ADRs through digital and print media [30,31].

Even though the name "pharmocovigilance" does not appear in Ayurvedic literature, the concept is found in all key Samhitas. pharmocovigilance's key goals are to develop patient care and safety regarding drug usage to encourage rational drug use. Wellknown text of Ayurveda medicine, Charaka Samhita, chronicles all adverse reactions to drugs that occur when they are improperly made or utilised. Even a potent toxin can be used as a good remedy if provided appropriately," Charaka believes. Contrary to this, even the most beneficial medicine might become poisonous if mistreated [32]. Ayurveda seers considered the prevalence of ADRs and categorised drug lists as toxic, semi-toxic, or to be taken with caution, among other things, as well as strategies to avoid or negate them [33]. In India, where a significant population consumes modern medicine and another system of medicine, it is even more critical to establish an ADR reporting system and maintain a proper ADR database so that any potentially dangerous drug can be removed from the market soon as possible [34].

#### Limitation(s)

The study had a small and convenience sample size that included AP from a single city only which may affect the generalisability of the study results.

# **CONCLUSION(S)**

Present study revealed the poor knowledge and practice of pharmocovigilance among the AP of Wardha. Also, despite the positive attitude of AP toward ADR reporting, there was a lack of knowledge on how to report and where to report, and it needs to be addressed through sensitisation and awareness programmes. There is strong need to sensitise the practitioners regarding the concept of pharmocovigilance and how to report and where to report, so that they actively participate in the process of drug monitoring. This study will encourage ADR reporting and help reduce the overall economic burden of healthcare expenditures, morbidity and mortality.

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