

## RESEARCH ARTICLE

### Assessment of knowledge, attitude, and practice of pharmacovigilance among private practitioners in Southern India: A questionnaire-based study

Rajesh B<sup>1</sup>, Dharani Devangi R<sup>2</sup>, Waseem Anjum<sup>3</sup>

<sup>1</sup>Department of Pharmacology, Shridevi Institute of Medical Sciences & Research Hospital, Tumkur, Karnataka, India, <sup>2</sup>Department of Pharmacology, Shimoga Institute of Medical Sciences, Shimoga, Karnataka, India, <sup>3</sup>Department of Community Medicine, Shridevi Institute of Medical Sciences & Research Hospital, Tumkur, Karnataka, India

Correspondence to: Rajesh B, E-mail: drrajeshb83@gmail.com

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#### ABSTRACT

**Background:** Pharmacovigilance has constantly gained importance in last 15 years, relating to absolute amount of adverse drug reactions (ADRs) and to the fact that several hospital admissions are due to ADRs. The success of Pharmacovigilance Programme of India (PVPI) depends on the active involvement of health-care professionals such as doctors, dentists, nurses, and pharmacists, particularly in the private sector. **Aims and Objective:** To assess the awareness and perception of pharmacovigilance among private practitioners in Tumkur, Southern India. **Materials and Methods:** A cross-sectional study was carried out among doctors working in private hospitals/clinics in Tumkur, Southern India, using a validated questionnaire suitable for assessing the knowledge, attitude, and practice of pharmacovigilance and reporting of ADRs was designed and distributed to the private practitioners. **Results:** Out of 82 private practitioners who were handed the questionnaire, 68 returned the filled questionnaire. 88.2% believed that reporting an ADR is a professional obligation and 85.3% thought reporting ADR should be made mandatory, whereas 91.2% believed that reporting ADRs will increase the patient's safety. 79.4% of the private practitioners had seen an ADR reporting form, 64.7% knew who to report; 67.6% had difficulty in reporting an ADR, and only 13.2% had ever reported an ADR. **Conclusion:** The private practitioners had better knowledge and also attitude about pharmacovigilance. However, they faced difficulty while reporting an ADR and only very few of the private practitioners had ever reported an ADR.


**KEYWORDS:** Pharmacovigilance; Adverse Drug Reactions; Pharmacovigilance Programme of India; Private Practitioners

#### INTRODUCTION

Adverse drug reactions (ADRs) are a serious public health problem.<sup>[1]</sup> Despite all their benefits, evidence continues to mount that ADR is common, yet often preventable cause of

illness, disability, and even death. ADR is responsible for a significant number of hospital admissions ranging from 0.3% to 11%.<sup>[2]</sup> ADRs have a major impact on public health because of considerable economic burden on the society.<sup>[3]</sup> It is estimated that only 6-10% of all ADRs are reported and underreporting of ADR is a major problem.<sup>[4]</sup> Over 7,70,000 people are injured or die each year from adverse drug events.<sup>[5]</sup>

In addition to the human cost, ADRs having major impact on public health by imposing considerable economic burden on the society and already stretch health-care system.<sup>[6]</sup> Therefore, timely and accurate detection of ADRs is critical in improving patient's safety and thereby reducing health-care cost.

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Pharmacovigilance has constantly gained importance in last 15 years, relating to absolute amount of ADRs and to the fact that several hospital admissions are due to ADRs.<sup>[7,8]</sup>

The success of a pharmacovigilance program depends on active involvement of the health-care professionals such as doctors, pharmacist, and nurses. Reporting ADRs have immense responsibility toward patient care and strengthen the pharmacovigilance programs.<sup>[9,10]</sup> Being the key health-care professionals, providing information on suspected ADRs is as much a moral duty for the DOCTOR as other aspects of patient care.<sup>[11]</sup> An ongoing ADR monitoring and reporting program can provide benefits to the organization, doctors, nurses, pharmacists, and also patients. The benefit includes increasing level of awareness regarding ADRs and to reduce morbidity and mortality of patient due to ADRs.<sup>[12]</sup> ADR reporting does not currently appear to be considered a part of routine professional practice by health-care professional.<sup>[13]</sup>

It is imperative to monitor ADRs to minimize or prevent harm to patients arising from the drugs, to detect ADRs before they are clinically manifested, and to obtain much more knowledge to ensure safe usage of drugs. To improve the reporting rate and successful running of pharmacovigilance program and also prevent underreporting of ADRs, it is important to improve the knowledge, attitude, and practices (KAP) of the health-care professionals regarding ADR reporting and pharmacovigilance. 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 private practitioners in Tumkur, Southern India.

## MATERIALS AND METHODS

A cross-sectional study was carried out among doctors working in private hospitals/clinics in Tumkur, Southern

India, from April to June 2016. After obtaining approval from the Institutional ethical committee, a validated questionnaire suitable for assessing the awareness and perception of pharmacovigilance, and reporting of ADRs was designed and distributed to the private practitioners. The questionnaire was based on few previous studies and suitable modifications were made. The questionnaire contained a total of 23 questions, of which 9 were pertaining to the knowledge, 8 related to the attitude, and 6 related to the practice of pharmacovigilance. The filled forms were collected and analyzed by Microsoft Excel 2007.

## Inclusion Criteria

All the private practitioners willing to participate voluntarily were included in the study.

## Exclusion Criteria

All those who do not wish to participate were excluded.

## RESULTS

Out of 82 private practitioners who were handed the questionnaire, 68 returned the filled questionnaire.

About 72.1% of the private practitioners knew the meaning to pharmacovigilance, whereas 67.4% knew the actual purpose. 79.4% were aware of the existence of the National Pharmacovigilance Programme in India, and 82.4% knew about the nearest regional pharmacovigilance reporting center (Table 1).

Regarding the question about the health-care professional(s) who are responsible for reporting ADR in a hospital and who is qualified to report an ADR, 83.8% and 86.8% answered correctly, respectively. 79.4% believed it is necessary to confirm that an ADR is related to a particular drug before reporting it. 88.2% believed that reporting an ADR is a professional obligation and 85.3% thought reporting ADR

**Table 1:** Knowledge of ADR reporting and pharmacovigilance among private practitioners

Questions	Correct answers/ Yes (%)	Wrong answers/ No (%)	No answer (%)
Have you heard the name of pharmacovigilance?	60 (88.2)	8 (11.8)	-
Meaning of pharmacovigilance	49 (72.1)	18 (26.5)	1 (1.4)
The purpose of pharmacovigilance is?	46 (67.4)	20 (29.4)	2 (2.9)
The international center for adverse drug reaction monitoring is located in?	22 (32.4)	41 (60.3)	5 (7.3)
Do you know regarding the existence of national pharmacovigilance program in India?	54 (79.4)	5 (7.3)	9 (13.3)
The national center for ADR monitoring is located at?	35 (51.5)	27 (39.7)	6 (8.8)
As per new PVPI, the zonal pharmacovigilance Center in South Zone, India is located at?	38 (55.9)	27 (39.7)	3 (4.4)
Where is the nearest regional pharmacovigilance reporting center?	56 (82.4)	10 (14.7)	2 (2.9)
Which important factor is necessary to report an adverse drug reaction	62 (91.2)	6 (8.8)	-

ADR: Adverse drug reaction, PVPI: Pharmacovigilance Programme of India

should be made mandatory, whereas 91.2% believed that reporting ADRs will increase the patient's safety (Table 2).

About 79.4% of the private practitioners had seen an ADR reporting form, 64.7% knew who to report; 70.6% were aware of the time frame for reporting a serious ADR. 67.6% had difficulty in reporting an ADR, and only 13.2% had ever reported an ADR. (Table 3).

## DISCUSSION

Many previous studies conducted in India, particularly among doctors in tertiary care teaching hospitals, indicate a lack of awareness about PVPI and ADR reporting.

In the present study, 72.1% and 67.4% of the private practitioners were found to know the meaning and purpose of pharmacovigilance, respectively. 82.4% knew where the nearest regional pharmacovigilance center was 88.2% believed that reporting an ADR is a professional obligation and 85.3% thought reporting ADR should be made mandatory, whereas 91.2% believed that reporting ADRs will increase the patient's safety. 79.4% of the private practitioners had seen an ADR reporting form, 64.7% knew who to report; 67.6% had difficulty in reporting an ADR and only 13.2% had ever reported an ADR.

Similarly, Swain *et al.* found that 96.3% of the private practitioners in urban Odisha strongly agreed that it is necessary to report ADRs. Only 24.1% of the private practitioners were found to have actually reported ADR to pharmacovigilance center. 77.8% stated to have faced difficulty in reporting ADR.<sup>[14]</sup>

According to a study in a tertiary care teaching hospital in Nagpur, only 52.38% resident doctors were aware of an ADR reporting system in India.<sup>[15]</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>[16]</sup>

Lopez-Gonzalez *et al.* suggest that under reporting is a general phenomenon.<sup>[17]</sup> It is found that only 6-10% of all ADRs are reported.<sup>[4,18]</sup> The high rate of underreporting is a matter of great concern which can have a major negative impact on the public health.

Inman has described the factors responsible for underreporting ADRs as "seven deadly sins" namely: Financial incentives,

**Table 2: Attitude toward ADR reporting and pharmacovigilance among private practitioners**

Questions	Correct answers/ Yes (%)	Wrong answers/ No (%)	No answer (%)
The health-care professional(s) responsible for reporting ADR in a hospital is/are?	57 (83.8)	11 (16.2)	-
In your opinion, who are qualified to report ADRs?	59 (86.8)	9 (13.2)	-
Adverse drug reaction is serious, when?	65 (95.6)	3 (4.4)	-
Do you think reporting adverse drug reaction is a professional obligation?	60 (88.2)	8 (11.8)	-
Do you think reporting adverse drug reaction should be mandatory?	58 (85.3)	8 (11.8)	2 (2.9)
Do you think it is necessary to confirm that an ADR is related to a particular drug before reporting it?	54 (79.4)	11 (16.2)	3 (4.4)
Do you think that it is necessary to report serious and unexpected reactions?	49 (72.1)	14 (20.6)	5 (7.3)
Do you think reporting adverse drug reaction will increase patient safety?	62 (91.2)	6 (8.8)	-

ADR: Adverse drug reaction

**Table 3: Practice toward ADR reporting and pharmacovigilance among private practitioners**

Questions	Correct answers/ Yes (%)	Wrong answers/ No (%)	No answer (%)
Have you ever seen the ADR reporting form?	54 (79.4)	14 (20.6)	-
To whom do you report ADRs?	44 (64.7)	20 (29.4)	4 (5.9)
What is the time frame for reporting serious ADR in India?	48 (70.6)	16 (23.5)	4 (5.9)
Do you find any difficulty in reporting adverse drug reactions?	46 (67.6)	22 (32.4)	-
Upon occurrence of serious ADR, what needs to be done with the suspected drug?	61 (89.7)	7 (10.3)	-
Have you ever reported an adverse drug reaction?	9 (13.2)	59 (86.8)	-

ADR: Adverse drug reaction

legal aspects, complacency, diffidence, indifference, ignorance, and lethargy.<sup>[19]</sup>

## CONCLUSION

The present study shows that the private practitioners had better knowledge and also attitude about pharmacovigilance. However, they faced difficulty while reporting an ADR and only very few of the private practitioners had ever reported an ADR. They believed that reporting ADRs will increase the patient's safety. Private practitioners are in a large number in India compared to doctors in medical colleges. Reporting an ADR by the private practitioners is the need of the hour to prevent ADRs and the complications associated with it, both financial and health wise. In collaboration with local Indian Medical Associations, steps should be taken to conduct continued medical education programs and workshops periodically to train the private practitioners regarding how to report an ADR and other aspect of PVPI.

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