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Research Article

A STUDY OF KNOWLEDGE, ATTITUDE, AND PRACTICE OF PHARMACOVIGILANCE AMONG II-YEAR UNDERGRADUATE MEDICAL STUDENTS AND INTERNS AT A TERTIARY CARE TEACHING HOSPITAL

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ABSTRACT

Objectives: Understanding the importance of adverse drug reactions (ADRs) reporting in a timely and accurate manner is essential for the success of pharmacovigilance. The underreporting or delayed reporting of ADRs can hinder the effectiveness of pharmacovigilance efforts. Assessing the knowledge, attitude, and practice (KAP) of pharmacovigilance among medical students and interns is indeed crucial as they are future health-care practitioners.

Methods: The study was carried out at the tertiary care teaching hospital in Kallakurichi after receiving approval from the Institutional Ethics Committee of the Government Medical College, Kallakurichi. The participants of the study included interns and II-year MBBS students. They were enrolled in the study and given a questionnaire on the KAP of pharmacovigilance through Google Forms. The collected responses were analyzed using Microsoft Excel, and the findings were presented in the form of percentages.

Results: In the knowledge domain, 85.2% of participants demonstrated awareness regarding the individuals responsible for reporting ADRs. In the attitude domain, according to 92.8% of participants, pharmacovigilance and ADR should be integrated into the undergraduate curriculum. However, in the practice domain, the percentage of participants who actually practiced reporting ADRs was lower (33%). Despite the majority of participants exhibiting commendable knowledge and attitude, a noticeable disparity was observed in their practical implementation.

Conclusion: Our study has shown the importance of raising awareness on ADR reporting along with the recommendation for effective training in institutions and health-care centers, which is crucial for bridging the existing gap.

Keywords: Pharmacovigilance, Adverse drug reactions, Knowledge, attitude, and practice, Spontaneous reporting, Health-care center.

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INTRODUCTION

Adverse drug reactions (ADRs) refer to any harmful, unintended, and undesired effects caused by a drug [1]. Nowadays, ADRs are a significant cause of mortality and morbidity [2]. Pharmacovigilance encompasses the scientific processes of identifying, evaluating, comprehending, and averting ADRs and other issues associated with medications [3,4]. Many countries have established pharmacovigilance program to identify the drugs responsible for ADRs [5]. In India, the Indian Pharmacopoeia Commission (IPC) in Ghaziabad serves as the National Coordination Center (NCC) for the Pharmacovigilance Program of India (PvPI). Under the NCC-PvPI, 250 ADR monitoring centers (AMCs) have been set up in various medical institutions and hospitals across India to monitor and collect ADR reports [6]. The Uppsala Monitoring Centre in Sweden, which is a part of the World Health Organization, focuses on international ADR monitoring. However, it is noted that only a small percentage of ADRs are reported voluntarily in developed countries, emphasizing the need for improved reporting systems [7]. The effectiveness of pharmacovigilance programs greatly depends on the active participation of healthcare professionals and their voluntary reporting of ADRs [8,9]. The spontaneous reporting system of ADRs plays a significant role in the pharmacovigilance program [10,11]. Different research findings indicate that the reporting of ADRs is associated with the level of knowledge, attitude, and practice (KAP) regarding pharmacovigilance among health-care professionals [12,13]. Therefore, it is crucial for medical students and interns to have a solid understanding of the importance of pharmacovigilance right from the beginning of their clinical exposure. Hence, my study focuses on evaluating the KAP of pharmacovigilance among medical students and interns.

METHODS

The study was a cross-sectional questionnaire-based study, which was conducted after getting permission from the Institutional Ethics Committee of the Government Medical College, Kallakurichi. It aimed to survey 141 interns with over 10 months of internship experience and 149 II-year MBBS students undergoing clinical postings at the institution. Participants were asked to complete a questionnaire on pharmacovigilance KAP through Google Forms. The data collected from the participants were then analyzed using Microsoft Excel to present the findings in percentages form. The study employed the KAP questionnaire (Table 1), which consisted of a combination of multiple-choice and yes/no questions. It encompassed a total of 20 questions, with eight questions dedicated to assessing knowledge, six questions focused on attitude, and another six questions aimed at evaluating the practice of pharmacovigilance.

RESULTS AND DISCUSSION

Out of 290 participants, 250 submitted the questionnaire through Google Forms. Details of the participants as shown in Table 2.

Analysis of knowledge-related questionnaire

About 72% of participants correctly answered the definition of pharmacovigilance (Fig. 1). About 63.2% of participants were familiar

Table 1: The KAP questionnaire about pharmacovigilance

Pharmacovigilance knowledge-related questions
1. Pharmacovigilance has been defined by the WHO as a. The science of monitoring ADRs happening in hospitals b. The process by which safety of drugs is improved c. The detection, assessment, understanding, and prevention of adverse effects d. The science detecting the type and incidence of ADR after the drug is marketed.
2. The International Collaborating Center for adverse drug reaction monitoring is located in a. Australia b. Sweden c. France d. USA
3. The activities, which are not involved in pharmacovigilance are? a. Post-marketing surveillance b. Prescription event monitoring c. Computerized medical record linkage d. Population studies.
4. In India which regulatory body is responsible for monitoring of ADRs? a. Indian Institute of Science b. Medical Council of India c. Central Drugs Standard Control Organization d. Pharmacy Council of India
5. Do you know the history of the Thalidomide disaster? a. Yes b. No
6. Which are the standard algorithms for assessing causality of ADRs? a. Naranjo algorithm b. Cryptographic algorithm c. Sorting algorithm d. None of the above
7. How many percent of ADRs are reported voluntarily in developed countries? a. 40% b. ~10% c. 60–70% d. ~25%
8. Who can report ADRs? a. Doctors b. Nurses c. Pharmacists d. All of the above
Pharmacovigilance attitude-related questions
1. Do you think ADR reporting and monitoring would benefit the patient's care? a. Yes b. No
2. Which types of ADR should be reported? a. Only serious or life-threatening b. Only severe and new c. Mild-severe d. All type of ADRs
3. Have you read any article about ADR? a. Yes b. No
4. Are you willing to report ADR? a. Yes b. No
5. Is it required to establish ADR monitoring center in every hospital? a. Yes b. No

(*Contd*...)

Table 1: (*Continued*)

Pharmacovigilance attitude-related questions
6. Should pharmacovigilance and ADR be included in the Undergraduate curriculum? a. Yes b. No
Pharmacovigilance practice-related questions
1. Have you ever experienced ADRs in your clinical postings? a. Yes b. No
2. Do you know how to report ADR? a. Yes b. No
3. Are you willing to implement ADR reporting in practice? a. Yes b. No
4. Have you ever seen the ADR reporting form? a. Yes b. No
5. Have you faced any difficulty while reporting ADRs? a. Yes b. No
6. What is the most effective way to transmit ADR information to ADR reporting center? a. Direct contact b. Telephone c. By post d. To mail\on website

KAP: Knowledge, attitude, and practice, ADR: Adverse drug reactions

Table 2: Information regarding the participants engaged in the study

Study participants	Number of participants
II-Year MBBS students	140
Interns	110
Total	250

with the whereabouts of the International Collaborating Center for ADR monitoring, 43.2% of participants were knowledgeable about activities unrelated to pharmacovigilance, 78.4% of participants possessed information regarding the regulatory body overseeing the monitoring of ADRs in India, 75.2% participants knew about the history of thalidomide disaster, 48% participants were familiar with the standard algorithm for assessing the causality of ADRs, 40% of participants knew the percentage of ADRs reported voluntarily in developed countries, and 85.2% of participants were aware of who can report ADRs (Table 3).

Analysis of attitude-related questions

The vast majority of 99.2% of participants concurred that reporting and monitoring ADRs would enhance patient's care (Fig. 2). About 87.2% of participants knew that reporting all types of ADRs was necessary (Fig. 3), 39.2% of participants had read articles about ADRs, and 82.8% of participants expressed willingness to report ADRs. The concept of setting up AMCs in all hospitals received favorable response from 96.4% of the participants, 92.8% of participants thought that pharmacovigilance and ADRs should be part of the undergraduate curriculum (Table 4).

Analysis of practice-related questionnaire

About 41.6% of participants experienced ADRs during their clinical posting while 33.6% practiced reporting ADRs. The high willingness of 99.4% of participants to incorporate ADR reporting in practice applications is encouraging for pharmacovigilance efforts (Fig. 4).

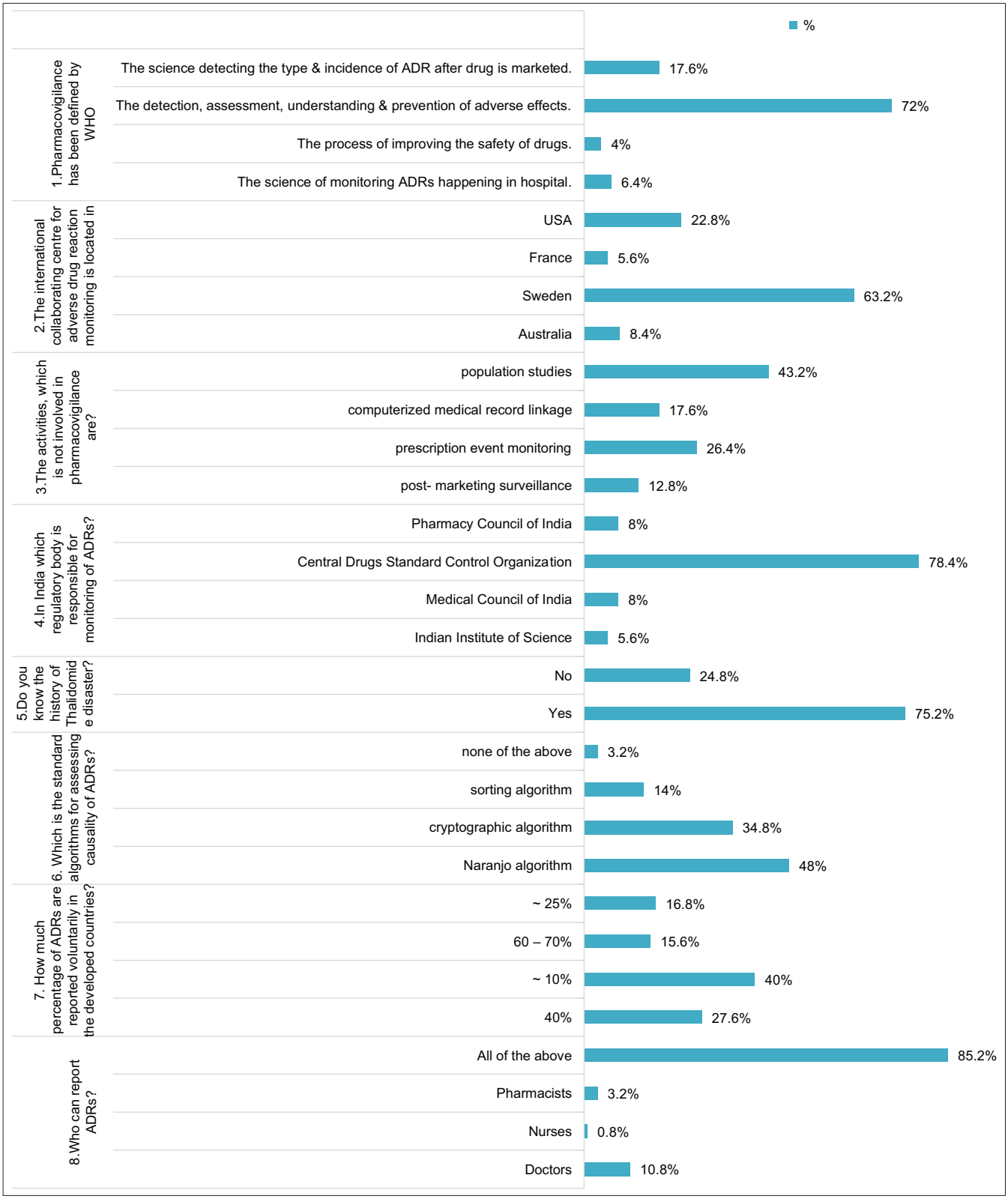

Fig. 1: Response of the participants for the knowledge-related questionnaire

Moreover, 72% of participants were familiar with the ADR reporting form, but 27.2% faced difficulties while reporting ADRs, indicating a need for further support or training in this area (Table 5). In terms of reporting preference, 68% of participants prefer to report ADRs through mail/website to center, while 20.4% prefer direct contact, 9.6% opt for telephone reporting, and 2% prefer reporting by post (Fig. 5).

The main objective of the study was to assess the understanding, perspective, and implementation of pharmacovigilance and ADR reporting among II-year MBBS students and interns. The problem of inadequate reporting of ADR poses a major challenge to the success of pharmacovigilance initiatives [14]. Reasons for this underreporting

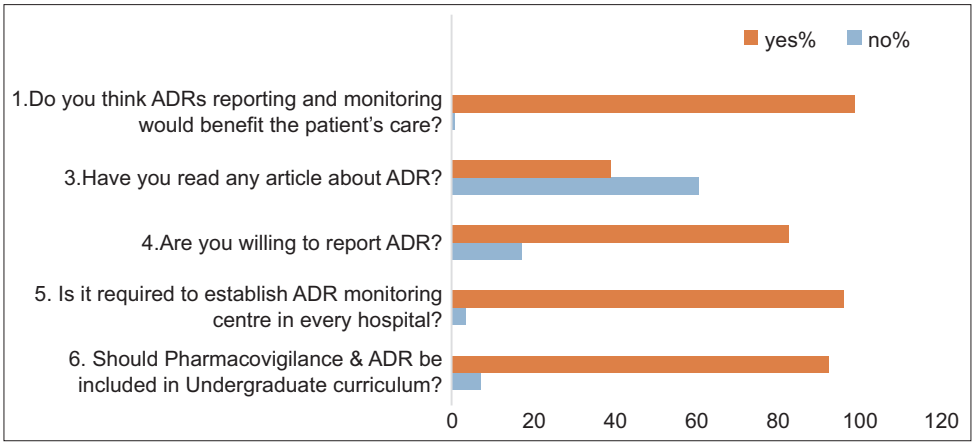

Fig. 2: Response of participants toward attitude-related questionnaire

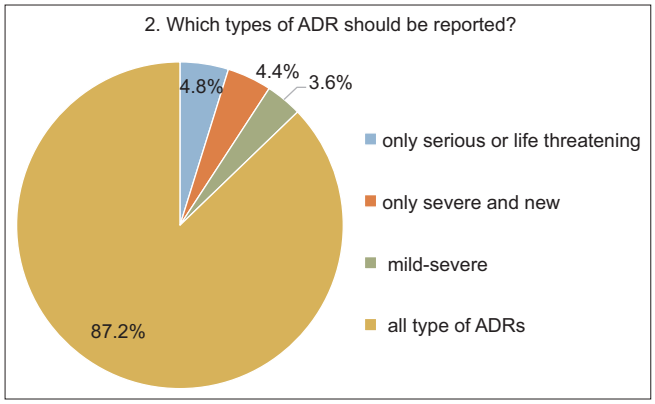

Fig. 3: Attitude of participants toward the type of adverse drug reactions should be reported

include factors such as the unavailability of ADR reporting forms, a lack of practice in reporting promptly, and misconceptions such as believing that only serious ADRs needed to be reported [1]. Addressing these barriers through education, training, and awareness can help improve ADR reporting practices among healthcare professionals.

Various websites and organizations have been established in India to address the challenges of ADR reporting. It is important to highlight that not only health-care professionals but also patients, their relatives, and the general public can report ADRs. All types of suspected ADRs, regardless of their severity or frequency, should be reported promptly. To facilitate ADR reporting, individuals can use "Suspected ADR reporting form" available on the official website of IPC and Central Drugs Standard Control Organization. In addition, ADR reporting forms translated into 10 Indian languages are accessible on the PvPI website, enabling patients to report ADRs. There is also a toll-free line (18001803024) for reporting ADRs. Furthermore, the NCC-PvPI collaborated with Netaji Subhash Chandra Bose Medical College, Jabalpur, to develop a mobile application in 2015. This app aids health-care professionals and consumers in reporting ADRs conveniently. The suspected ADR form can be sent to the nearest AMCs, directly to NCC, or even emailed as a scanned copy to PvPI for efficient reporting. These initiatives aim to streamline and enhance the ADR reporting process, ensuring that all potential adverse reactions are captured and reported for improved pharmacovigilance.

The study participants exhibit a commendable level of knowledge and attitude in comparison to the practice of pharmacovigilance. The knowledge and attitude have improved in our study participants due to conductance of Continuous Medical Education programs and various competitions about pharmacovigilance by the department of

Table 3: Response of knowledge-related questionnaire

Questions on knowledge of pharmacovigilance	Correct response %
1. Pharmacovigilance has been defined by WHO as	72
2. The international collaborating center for adverse drug reaction monitoring is located in	63.2
3. The activities, which are not involved in pharmacovigilance are?	43.2
4. In India which regulatory body is responsible for monitoring of ADRs?	78.4
5. Do you know the history of thalidomide disaster?	Yes–75.2 No–24.8
6. Which are the standard algorithms for assessing causality of ADRs?	48
7. How much percentage of ADRs are reported voluntarily in the developed countries?	40
8. Who can report ADRs?	85.2

WHO: World Health Organization, ADRs: Adverse drug reactions

Table 4: Responses of attitude-based questionnaire

Questions on attitude of pharmacovigilance	Response	%
1. Do you think ADRs reporting and monitoring would benefit the patient's care?	Yes	99.2
2. Which types of ADR should be reported?	Correct response	87.2
3. Have you read any article about ADR?	Yes	39.2
4. Are you willing to report ADR?	Yes	82.8
5. Is it required to establish ADR monitoring center in every hospital?	Yes	96.4
6. Should pharmacovigilance and ADR be included in undergraduate curriculum?	Yes	92.8

ADRs: Adverse drug reactions

pharmacology under the guidance of PvPI 92.8% of the participants supporting the inclusion of pharmacovigilance and ADR in the undergraduate curriculum, the similar response obtained in Korde and Radhika (92.9%) [15]. The interest was shown by 82.8% of participants in reporting ADRs, similar results were achieved in Dass *et al.* (78.6%) [16]. About 41.6% of the participants had experienced ADRs in their clinical posting, with 27.2% of the had faced difficulties while reporting ADRs. This difficulty in reporting may stem from a lack of familiarity with ADR reporting procedures. About 33.6% of the participants got trained to report ADR. It is encouraging to note that a significant number of participants express a positive response toward implementing ADR reporting in practice (Table 5). It is interesting that

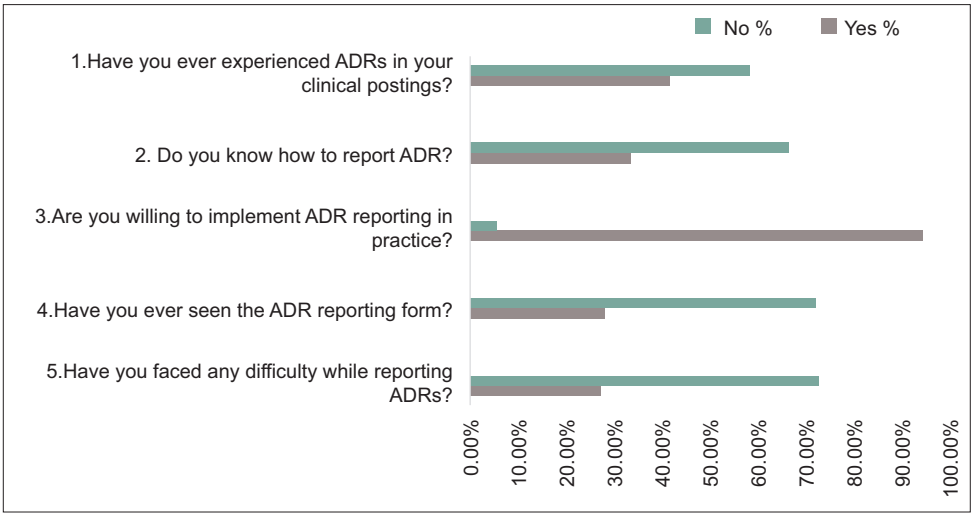

Fig. 4: Response of practice-related questionnaire

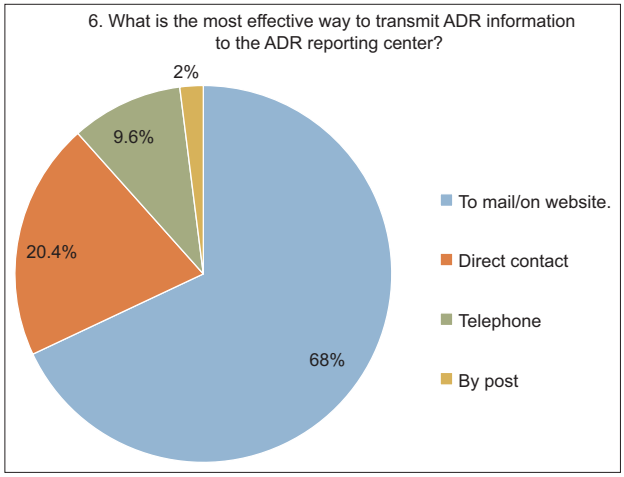

Fig. 5: Participants methods of preference for reporting an adverse drug reaction to the center

Table 5: Responses of practice-based questionnaire

Questions	Options	%
1. Have you ever experienced ADRs in your clinical posting?	Yes	41.6
	No	58.4
2. Do you know how to report ADR?	Yes	33.6
	No	66.4
3. Are you willing to implement ADR reporting in practice?	Yes	94.4
	No	5.6
4. Have you ever seen the ADR reporting form?	Yes	28
	No	72
5. Have you faced any difficulty while reporting ADRs?	Yes	27.2
	No	72.8
6. What is the most effective way to transmit ADR information to ADR reporting center?	To mail/on website	68
	Direct contact	20.4
	Telephone	9.6
	By post	2

ADRs: Adverse drug reactions

most participants in our study showed good knowledge and attitude toward pharmacovigilance compared to the previous studies [17], but they lacked practical experience in ADR reporting. Since many of them are II-year MBBS students beginning clinical exposure, this study could really highlight the significance of pharmacovigilance and ADR reporting for them.

According to a study carried out by Pawar *et al*. at Lokmanya Tilak municipal general hospital, it was found that most health-care professionals exhibited a positive understanding and attitude toward pharmacovigilance. However, there was a low rate of ADR reporting among them [18]. Another study conducted by Leena and Jose at PES Institute of Medical Sciences and Research, Kuppam emphasized the necessity of organizing educational programs for health-care professionals on a regular basis, with a special focus on training workshops, to enhance the quality and frequency of ADR reporting [19].

The results of our study support the importance of raising awareness about pharmacovigilance and ADR reporting. Conducting frequent and efficient training programs in health-care facilities and organizations can greatly contribute to bridging the gaps in practice and improving patient safety. It is essential to continue promoting the importance of pharmacovigilance and providing the necessary support for health-care professionals to report ADRs effectively.

CONCLUSION

Our study revealed that participants exhibited a strong understanding and favorable disposition toward reporting ADRs; however, a disparity was observed in their practical application of this knowledge, while most participants expressed interest in implementing ADR reporting in their practice. Conducting regular training sessions for ADR reporting in all institutions and healthcare centers is a valuable suggestion to improve pharmacovigilance practices. Implementing these recommendations could lead to significant improvement in ADR reporting and overall patient care.

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AUTHORS' CONTRIBUTIONS

The authors have individually acknowledged their accountability for the conceptualization, methodology, data collection, analysis, interpretation, drafting of the article, discussion of the results, and contribution to the final version of the manuscript. Dr. Anusha S. supervised the entire study until the manuscript was finalized.

CONFLICTS OF INTEREST

None.

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None.

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