Section: Pharmacology

Original Research Article

TO EVALUATE THE LEVEL OF KNOWLEDGE ATTITUDE AND PRACTISE OF PHARMACOVIGILANCE AND ADR REPORTING AMONG MEDICAL STUDENTS OF TERTIARY CARE HOSPITAL IN TAMIL NADU KANCHEEPURAM DISTRICT

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Abstract

Background: Spontaneous reporting plays a crucial role in pharmacovigilance. Nevertheless, the achievement of its goals relies on prescribers who are willing to work together and are driven to succeed. A prevalent issue is the under-reporting of adverse drug reactions (ADRs) by prescribers. The aim is to evaluate the level of KAP on pharmacovigilance among the prescribers in a medical college and hospital. **Materials and Methods:** The research was conducted using a cross-sectional design and relied on questionnaires for data collection. The research participants were physicians from several clinical departments of the medical and hospital. The KAP (knowledge, attitudes, and practices) questionnaire was developed to evaluate individuals' understanding of pharmacovigilance, their attitudes towards pharmacovigilance, and their adherence to ADR reporting. These questions were created using previous research to evaluate the knowledge, attitudes, and practices (KAP) related to adverse drug reaction (ADR) reporting. The questionnaire consisted of a total of 22 questions. Respondents were not obligated to disclose their identities on the surveys. **Result:** During the assessment of physicians' knowledge on pharmacovigilance, it was discovered that the largest percentage, 74%, of medical professionals provided accurate responses about the definition of pharmacovigilance. Based on the responses of 67% of participants, the primary objective of pharmacovigilance is to ascertain the safety of a medicine. A significant proportion of physicians, around 69%, consider the reporting of adverse drug reactions (ADRs) to be a professional duty. The majority of respondents, 90% to be exact, were aware that adverse drug reactions (ADRs) may also be reported by nurses and pharmacists, respectively. Likewise, 65% of physicians were knowledgeable with the presence of the National Pharmacovigilance Programme (NPP). Moreover, it was found that 44% of the respondents were aware of the location of the worldwide ADR monitoring center, while 80% of the prescribers knew that the regulatory organization responsible for monitoring ADRs in India is the Central Drugs Standard Control Organization (CDSCO). Just 22% of respondents were aware of the presence of a Pharmacovigilance center or ADR Monitoring Center (AMC) at their institution. Additionally, 51% of clinicians were knowledgeable with the specific period of clinical trials when unusual side events were frequently seen. **Conclusion:** The findings of our research demonstrate that a significant proportion of the medical practitioners had a commendable level of knowledge and exhibited a positive attitude towards pharmacovigilance. However, there was a significant disparity between the adverse drug reaction (ADR) that was really encountered and the ADR that was reported by the healthcare providers. Furthermore, a distinct and direct relationship was discovered between the training of pharmacovigilance and the reporting of adverse drug reactions (ADRs).

INTRODUCTION

Pharmacovigilance, as defined by the World Health Organization (WHO), encompasses the scientific and operational efforts involved in identifying, evaluating, comprehending, and averting any negative effects or potential issues associated with drugs.[1] Despite the requirement for new drugs to go through multiple clinical and non-clinical trials, pharmacovigilance is necessary because the information obtained from these trials is insufficient to fully assess the safety of drugs in terms of adverse drug reactions (ADR). This is due to the limited number of patients involved in the trials and the differences in conditions between clinical practice and regular use by patients.[2] The primary goal of pharmacovigilance is to ensure the safety of drug molecules that have been introduced onto the market for the treatment of various illnesses in the general population, including those with diverse medical conditions. Ensuring that health-care workers report suspected adverse drug reactions (ADRs) in a satisfactory manner is crucial in addressing this problem. The World Health Organization (WHO) defines an adverse drug reaction (ADR) as an unanticipated and harmful response to a medication that occurs at dosages typically used in humans for disease prevention, diagnosis, treatment, or physiological function change. Among the several techniques for identifying and examining adverse drug reactions (ADRs), the process of spontaneous reporting has played a crucial role in enhancing pharmacovigilance standards. It has a crucial function in identifying Adverse Drug Reactions (ADRs), and several medications with significant potential for damage have been removed from the market as a result of this. In order to enhance the occurrence of voluntary reporting by healthcare professionals, monitoring centers for adverse drug reactions (ADRs) are being built in India as part of the Pharmacovigilance Program of India (PvPI).[3-5] Pharmacovigilance is still in its early stages of development in India. Insufficient knowledge among health-care workers is a primary cause for this issue. While many studies have been conducted in various regions of India to assess the degree of knowledge and implementation of pharmacovigilance,[6-8] there is a limited number of research that have specifically examined this issue in Telangana. In addition, the majority of the studies have focused on health-care personnel, with minimal research conducted on the awareness levels among undergraduate students.[9-11] The Medical Council of India has proposed the inclusion of ADR monitoring in the curriculum for undergraduate students.[12] In order to encourage health-care professionals to engage in spontaneous reporting, it is crucial to develop strategies that address both intrinsic factors (such as knowledge, attitude, and practices) and extrinsic factors (such as the relationship between health professionals and their patients, the health system, and the regulators).[13] Medical students must get comprehensive training in identifying, preventing, and reporting adverse drug reactions (ADRs) in order to become proficient healthcare professionals. Teaching pharmacovigilance to medical students instills in them the understanding that all medications have the potential to induce adverse drug reactions (ADRs), which in turn encourages their involvement in the Pharmacovigilance Programme of India (PvPI).[14,15]

MATERIALS AND METHODS

The research was conducted using a cross-sectional design and relied on questionnaires for data collection. The research participants were physicians from several clinical departments of the medical and hospital. The KAP (knowledge, attitudes, and practices) questionnaire was developed to evaluate individuals' understanding of pharmacovigilance, their attitudes towards pharmacovigilance, and their adherence to ADR reporting. These questions were created using previous research to evaluate the knowledge, attitudes, and practices (KAP) related to adverse drug reaction (ADR) reporting. The questionnaire consisted of a total of 22 questions. Respondents were not obligated to disclose their identities on the surveys.

The details of the questionnaire are as follows:

Knowledge-related questions: The evaluation of participants' understanding of pharmacovigilance consisted of 10 questions (items) about the definition and objective of pharmacovigilance, the obligation to report adverse drug reactions (ADRs), familiarity with the National Pharmacovigilance Programme (NPP), and awareness of the regulatory authority responsible for monitoring ADRs.

Attitude-related questions: The evaluation of participants' attitudes towards pharmacovigilance included five inquiries (items) on the imperative of reporting adverse drug reactions (ADRs), instruction on pharmacovigilance, ADR avoidance, and views on ADR monitoring centers.

Practice-related questions: The evaluation of participants' proficiency in ADR reporting consisted of seven questions (items) regarding their experience with ADRs, reporting to the pharmacovigilance center, ADR reporting form, training in ADR reporting, reporting of serious adverse events, identification of rare ADRs, methods for monitoring ADRs of new drugs, and the existence of a Pharmacovigilance Committee in their institute.

Data collection: The lead investigator personally contacted all the available Doctors throughout the survey. The participants were instructed to answer each question in accordance with the response format specified in the questionnaire. The answer format consisted of multiple choice questions, where the participants were required to choose the most suitable response from a given list of possibilities. The investigator documented the physicians' comments in

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written form. The investigator thoroughly reviewed the finalized answer format.

One hundred questionnaires (100) were handed to the physicians in the morning. The questionnaires were gathered by the evening of the same day.

Statistical analysis: The collected data was inputted onto a personal computer using Microsoft Excel and examined. The variables were assessed based on their counts, percentages, and frequencies.

RESULTS

One hundred questionnaires were issued and all of them were returned and processed, resulting in a response rate of 100%. The majority of the respondents were men, comprising 65% of the total, while females accounted for 35%. In addition, the average age of the individuals included in the research was 36.73±3.65 years. During the assessment of physicians' knowledge on pharmacovigilance, it was discovered that the largest percentage, 74%, of medical professionals provided accurate responses about the definition of pharmacovigilance. Based on the responses of 67% of participants, the primary objective of pharmacovigilance is to ascertain the safety of a medicine. A significant proportion of physicians, around 69%, consider the reporting of adverse drug reactions (ADRs) to be a professional duty. The majority of respondents, 90% to be exact, were aware that adverse drug reactions (ADRs) may also be reported by nurses and pharmacists, respectively. Likewise, 65% of physicians were knowledgeable with the presence of the National Pharmacovigilance Programme (NPP). Moreover, it was found that 44% of the respondents were aware of the location of the worldwide ADR monitoring center, while 80% of the prescribers knew that the regulatory organization responsible for monitoring ADRs in India is the Central Drugs Standard Control Organization (CDSCO). Just 22% of respondents were aware of the presence of a Pharmacovigilance center or ADR Monitoring Center (AMC) at their institution. Additionally, 51% of clinicians were knowledgeable with the specific period of clinical trials when unusual side events were frequently seen.

During the evaluation of physicians' pharmacovigilance-related attitude, it was discovered that 98% of the respondents acknowledged the need of reporting adverse drug reactions (ADRs). In general, 94% of physicians expressed the opinion that a comprehensive education on pharmacovigilance should be provided to healthcare workers. Continuing from this, only a small percentage of respondents, namely 57%, had read publications on the avoidance of adverse drug reactions (ADRs). Additionally, 72% of physicians expressed the belief that it is necessary to build an ADR monitoring center in every hospital. Respectively, 40%, 32%, 19%, and 9% of respondents said that it is difficult to determine whether an adverse drug reaction (ADR) has happened or not. Insufficient time to report adverse drug reactions (ADRs), A solitary unreported instance may not have an impact on the ADR database and Possible reasons of underreporting of adverse drug reactions (ADRs) may include lack of compensation.

Upon evaluating the pharmacovigilance-related procedures, it was shown that 81% of physicians had encountered adverse drug reactions (ADRs) in patients throughout their medical practice. However, only a small minority of individuals, namely 25%, have ever submitted an adverse drug reaction (ADR) report to a pharmacovigilance center. In addition, it was shown that a mere 29% of medical practitioners had encountered the ADR reporting form.

Based on this, it was shown that just 16% of medical personnel had received training on reporting adverse drug reactions (ADRs). Furthermore, a mere 35% of clinicians acknowledged the existence of a Pharmacovigilance Committee inside their Institution.

Table 1: Assessment of pharmacovigilance related knowledge.

Concept question	Correct answer	Responders	Percentage
Pharmacovigilance Definition	Detection, Assessment, Understandi ng and prevention of adverse effects	74	74
Purpose of Pharmacovigilance	To identify safety of the drug	67	67
ADR reporting is professional obligation	Yes	69	69
Responsible for reporting ADR	All the above	90	90
Existence of NPP India	Yes	65	65
Monitoring ADRs	CDSCO	80	80
Your institution has an ADR monitoring Centre	Yes	22	22
International centre for adverse drug reaction	Sweden	44	44
Rare ADRs can be identified in the following phase of a clinical trial	During phase-4 clinical trials	51	51
Where is the nearest sub zonal centre for ADR monitoring located	Bangalore	78	78

Table 2: Assessment of pharmacovigilance- related attitude

Concept question	Correct answer	Responders	%
Reporting of adverse drug reaction is necessary	Yes	98	98
Pharmacovigilance to be taught in detail to healthcare professionals	Yes	94	94
Article on prevention of adverse drug reactions	Yes	56	56
Establishing ADR monitoring center	Should be in every hospital	72	72

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Factors discouraging reporting of ADRs	Difficult to decide whether ADR has occurred or not	40	40
	Lack of time to report ADR	32	32
	A single unreported case may not affect	19	19
	ADR database No remuneration	9	9

Table 3: Assessment of pharmacovigilance- related practices

Concept question	Correct answer	Responders	Percentage
Experienced adverse drug reactions	Yes	81	81
Reported ADR to centre	Yes	25	25
ADR reporting form	Yes	29	29
Trained to report ADR	Yes	16	16
Pharmacovigilance committee in your Institute	Yes	35	35
Methods commonly employed by the healthcare professional to monitor adverse drug reactions of new drugs	Spontaneous reporting system	32	32
How do you report ADR	Filled ADR form submitted to pharmacovig ilance centre	73	73

DISCUSSION

Adverse Drug Reaction (ADR) reporting is a crucial component of pharmacovigilance and plays a significant role in ensuring patient well-being. The significant risk to the effectiveness of the pharmacovigilance program is in the act of underreporting adverse drug reactions (ADR). The primary objective of pharmacovigilance is to guarantee the secure and logical utilization of medication. The primary objective of pharmacovigilance is to prevent patients from experiencing unnecessary damage caused by the adverse effects of pharmacotherapy.[16,17] The primary objective of this research was to evaluate the level of knowledge, attitude, and practice of pharmacovigilance among prescribers, as well as to identify any potential reasons for underreporting. The purpose of this research was to determine the factors contributing to the under reporting of adverse drug reactions (ADR) in order to develop an appropriate intervention strategy based on the study's findings. The majority of physicians (98%) acknowledged the need of reporting Adverse Drug Reactions (ADRs), and 94% expressed agreement that comprehensive education on pharmacovigilance should be provided to healthcare providers. These findings are consistent with the results of a research done by Gupta SK, et al.[18]

Most 65% of physicians were aware of the presence of NPP. Furthermore, a significant majority of physicians, namely 80%, were aware that the CDSCO in India serves as a regulatory authority with the responsibility of overseeing and monitoring Adverse Drug Reactions (ADRs). These results exhibit similarities when compared to previous research done among health-care providers.[18] Based on the results of our study, clinicians' adherence to ADR reporting fell well below our expectations. We noticed a significant disparity between the actual adverse drug reaction (ADR) occurrence rate of 81% and the rate of ADRs reported by healthcare professionals, which was only 25%. These findings align with the results of previous research done in other countries such as Malaysia, Portugal, and Nigeria.[19-21] This research also identified the causes accountable for the underreporting. The factors contributing to underreporting, as identified in our research, include absence of compensation, insufficient time for reporting adverse drug reactions (ADR), perception that a single unreported case may not impact the ADR database, and challenges in determining the occurrence of ADR. Additional factors included insufficient training, unfamiliarity with the ADR reporting form, lack of knowledge about the regulations, and unfamiliarity with the reporting process. The participants in our research were seen to be unable to effectively use their knowledge to carry out accurate ADR reporting due to a deficiency in training in this area. We discovered that a mere 16% of healthcare practitioners had received training on the proper procedures for reporting adverse drug reactions (ADRs). Similarly, a study done in the United Arab Emirates found that a mere 5.5% of physicians had received training on adverse drug reaction (ADR) reporting.[22] This demonstrates the pressing need for all parties involved to collaborate in order to guarantee the effective execution of the pharmacovigilance program. In his study, Nwokikein proposed that the focus should be shifted from health-care workers reporting ADRs spontaneously to patients reporting them themselves. Encouraging health-care professionals to self-report their personal experiences of ADRs may serve as a motivation for them to actively participate in pharmacovigilance activities after completing their education.[23]

Several studies conducted in India have shown that the understanding and attitude of health-care professionals towards pharmacovigilance are improving with time. However, the actual practice of reporting adverse drug reactions (ADRs) is still inadequate. It has been reiterated that there is a direct relationship between the training of Pharmacovigilance and the reporting of Adverse Drug Reactions (ADR) by healthcare personnel. Unfamiliarity with the process of determining the causal link between the adverse drug reaction (ADR) can only be eliminated via consistent training. Academic intervention may enhance the importance

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of monitoring and reporting unfavorable events. This would eventually enhance the efficacy of the pharmacovigilance program in India. Authors advocate for active involvement of hospital managements, pharmaceutical firms, and drug regulatory authorities in training clinicians about adverse drug reaction (ADR) monitoring and reporting. The research has some limitations, including the fact that it only focuses on a single teaching hospital. Additionally, it is vulnerable to the limitations inherent in questionnaire-based studies, such as subjective responses and recollection bias. To enhance the generalizability of our results, it would be prudent to expand this research to include additional teaching hospitals, private practitioners, professionals in allied professions, as well as students in medical and related disciplines.

CONCLUSION

The findings of our research demonstrate that a significant proportion of the medical practitioners had a commendable level of knowledge and exhibited a positive attitude towards pharmacovigilance. However, there was a significant disparity between the adverse drug reaction (ADR) that was really encountered and the ADR that was reported by the healthcare providers. Furthermore, a distinct and direct relationship was discovered between the training of pharmacovigilance and the reporting of adverse drug reactions (ADRs). Moreover, most of the participants agreed that it is essential to report adverse drug reactions (ADRs) and that healthcare workers should get comprehensive education on pharmacovigilance. It is recommended that healthcare personnel, particularly those in dentistry and nursing, get thorough training on adverse drug reaction (ADR) reporting in order to enhance the existing state of the country's pharmacovigilance program.

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