

Assessment of knowledge, attitude and practice of pharmacovigilance among postgraduate students in a tertiary care hospital

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Abstract

Introduction: The method of drug safety monitoring known as pharmacovigilance enhances patients' quality of life by gathering and analysing adverse drug reactions (ADRs). The majority of adverse drug reactions (ADRs) in our state are reported by a system of spontaneous reporting of individual instances from healthcare providers to the Adverse Drug Reaction Monitoring Centre (AMC) under the Pharmacovigilance Programme of India (PvPI). Monitoring and reporting of ADRs at the

earliest is main aim of PVPI, but underreporting of ADRs by doctors is common thus leading to various problems, as postgraduates are upcoming future doctors its necessary to educate them about pharmacovigilance and its importance since they have firsthand knowledge of all events that occur after drug administration. The primary goal of our study is to assess knowledge, attitudes, and practices of postgraduates regarding pharmacovigilance as ADR reporting was considered important primarily for patient safety.

Materials and Methods: A Pre-validated questionnaire was prepared and sent to postgraduates of all departments in King George Hospital, Andhra Medical College Visakhapatnam, Andhra Pradesh via google forms. Data was collected and analysed using Microsoft Excel and results were expressed as counts and percentages.

Result: Total 120 postgraduate students participated in the study voluntarily and most of postgraduates possess less knowledge and attitude towards it is appreciable 100% of them are aware that PV is important for health care professionals that increases patients safety, nearly 67.5% are encountered with ADRs but only 87% out of them are reported to ADR Monitoring centre, the reasons cited for this were lack of information on where and how to report.

Conclusions: This study showed that postgraduates are less aware of Pharmacovigilance and ADRs reporting. As underreporting of ADRs is more common because of lack of practice and knowledge can be improved by conducting more sensitisation programs at PG level itself thus to avoid ADRs as some are life-threatening thus following prevention is better than cure.

Keywords: Pharmacovigilance, Postgraduates, Knowledge, Attitude, Practice, Adrs

Introduction

Pharmacovigilance as defined by WHO is “the science and activities relating to the detection, assessment, understanding, and prevention of adverse effects or any other drug-related problem.[1] Animal studies and clinical trials have limited usefulness because they are carried out under highly technical laboratory conditions, with a small population, and for a brief period of time. Once a drug is commercially available, it leaves the safe scientific environment and can be used outside of the

regulated setting of clinical trials. Post-authorization Pharmacovigilance (Pv) is essential at this point since such medications must be checked for their efficacy and safety in actual patient situations.[2].

World Health Organization (WHO) defines Adverse Drug Reactions (ADR) as “a response to a drug that is noxious and unintended, and which occurs at doses normally used in man for prophylaxis, diagnosis or therapy of disease or for the modification of physiological function”. [3]

In a study from South India, it was observed that 3.7% of the total hospitalized patients were suffering from ADR, among which 1.3% were fatal. About 0.7% of hospital admissions were due to ADRs.[4] According to other studies, ADRs account for around 6.2% of hospital admissions, and 3.2% of them happen during the hospital stay.[5]. The possibility of ADRs causes a significant strain on the nation's economy as well as a decline in quality of life.[6]

In our nation, there is a significant genetic and cultural divergence among the population. Many of these concerns highlight the necessity for post-graduates to immediately and effectively report ADRs related to medications.

ADR reporting does not currently appear to be considered part of routine professional practice by health care professionals. This is essentially due to the absence of a vibrant and active ADR monitoring system and also lack of a reporting culture among health care professionals.[7,8] Underreporting of ADRs is a serious issue and some studies have estimated that only 6%-10% of ADRs are being reported.[9] Spontaneous reporting of ADRs is an important method for detecting new safety issues related to drugs.

The Pharmacovigilance Programme of India (PvPI) was launched on July 14, 2010, with its National Coordination Centre headquartered at the Indian Pharmacopoeia Commission in Ghaziabad, Uttar Pradesh, in response to the requirement for ADR monitoring in India.[10]. The main goal of NCC-PvPI is to encourage the safest use of medications by providing the necessary instruction during Pharmacovigilance training programmes around the nation. There are 444 Adverse Drug Reaction Monitoring Centres (AMCs) now operating under PvPI.[11] An international database of ADR reports from all around the world is maintained by the Sweden-based Uppsala Monitoring Centre (UMC).

Post-graduates can report ADRs to AMC or directly to NCC using Standardized ADR reporting forms, the Toll-Free number 18001803024, mail to pvpi@ipcindia.net.or, and mobile apps. The PvPI communication system is shown in Figure 1. The underreporting of adverse drug reactions is due to a lack of expertise in this area [12, 13] to reduce Adverse Events and ensure the smooth operation of the Pharmacovigilance system, it is important to adopt a favourable attitude towards the various workflows of the field.

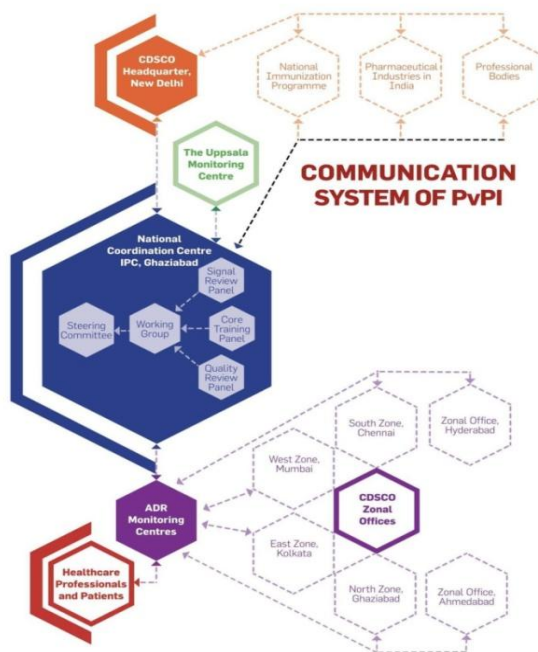


Figure 1: Communication system of PvPI

Therefore my study intends to assess the knowledge, attitude and practice of pharmacovigilance among postgraduates of Andhra Medical College, King George Hospital, Visakhapatnam.

Materials and Methods

Study design : It is a cross-sectional questionnaire based study. Before the study questionnaire was pre-tested, analysed and validated by expert staff of department of pharmacology.

Study Population: Postgraduates of all departments

Study setting: The study was conducted at Andhra Medical College and its hospital King George Hospital, a tertiary care teaching hospital, Visakhapatnam, Andhra Pradesh. The study was conducted during the month of December 2022

Study duration: This study was conducted for a duration of 1 month

Study subjects: 120 Postgraduates participated in the study.

Study data collection

A KAP study questionnaire was shared to postgraduates using Google forms through social media like WhatsApp and they were followed up for recording responses by sending a reminder. Participants had one day to read, comprehend, and respond to the questions.

Inclusion criteria

1. All postgraduate students from all departments of both sexes in King George Hospital, Andhra Medical College.
2. Whoever gave informed consent to participate in study.
3. Whoever responded to all questions.

Exclusion Criteria

1. Postgraduate students on leave
2. Whoever refused to participate in study

Statistical Analysis

Data was collected and analysed using Microsoft Excel and results were expressed as counts and percentages.

Results

Table 2: Knowledge of ADR reporting among Postgraduates

knowledge based questions	correct responses	wrong responses
Pharmacovigilance means	95%	5%
Who can report ADR	88.3%	11.7%
Where is the international centre for ADR located	55.8%	44.2%
In India which regulatory body is responsible for monitoring ADR	63.3%	32.5%
What is the mission and vision of pharmacovigilance	76.7%	23.3%
The toll free number of NCC- PvPI is	46.7%	53.3%
What is AMC	85%	15%

Basic demographic information

A total of 120 postgraduates (PGs) agreed to participate in this study and completed the questionnaire forms circulated among PGs. Table 1 provides a summary of the postgraduates' baseline demographic information.

Table 1: Basic demographic information of study participants.

Character	Male	Female
% of Participants	38.3%	61.7%

Assessment of Knowledge

Using the crucial questions shown in Table 2, knowledge of post-graduate training in reporting ADRs was assessed. When simple knowledge-related questions were asked, almost all PGs responded properly, but we may conclude that when questions were asked in-depth, knowledge levels decreased. According to the knowledge-based questionnaire, it is clear that post-graduates first answered all questions correctly when they were simple, but as we got more specific about the knowledge of Pv, the percentage fell to 46%.

Do you know about modes of ADR reporting to NCC-PvPI	80%	20%
A serious adverse event in India should be reported to the regulatory body within	55%	45%
Rare ADRs can be identified in the following phase of clinical trials	60.8%	39.2%

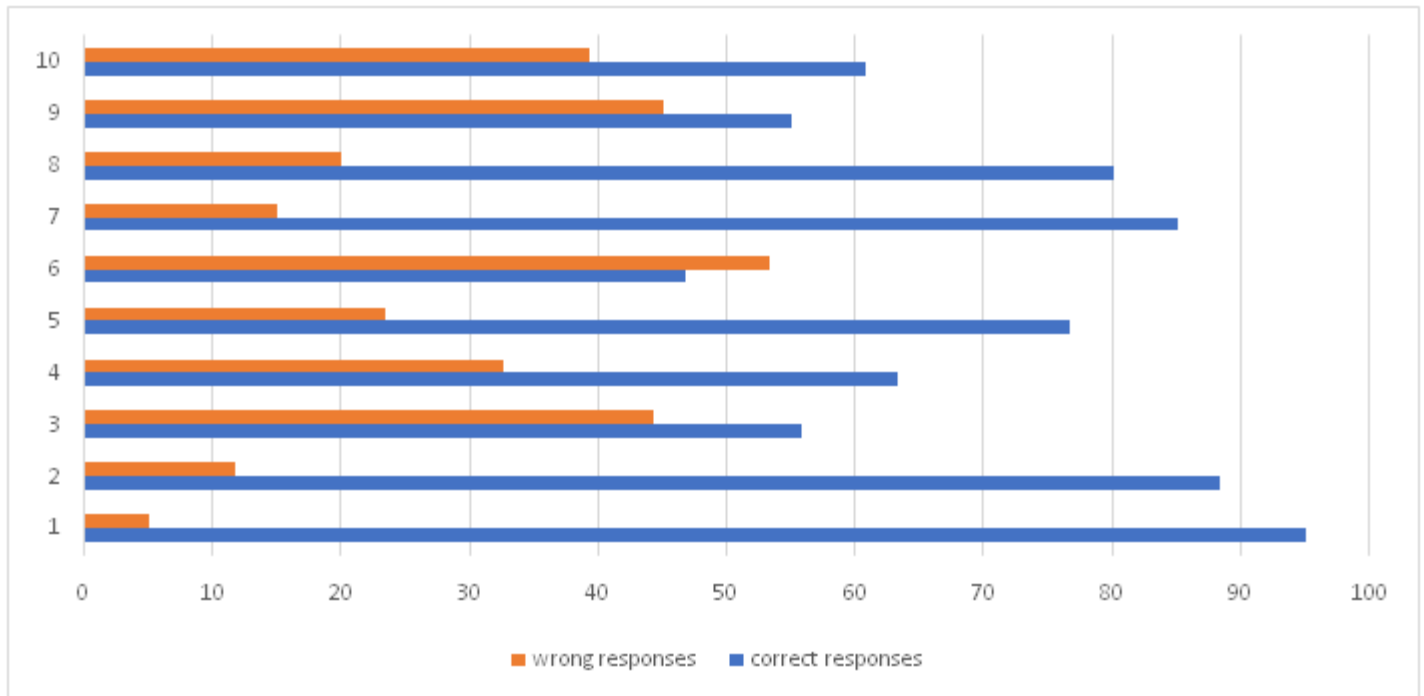


Figure 2: Graphical representation of responses of knowledge based questions

Assessment of attitude

According to the poll, post-graduates' attitudes are improving, which can be a key factor in addressing the

under-reporting of ADRs. Most of the study participants had a positive attitude towards reporting ADR.

Table 3: Attitude of Postgraduates with regard to ADR reporting.

Attitude based questions	Positive responses	Negative responses
Do you think ADRs will increase patient safety	100%	0
Do you think pharmacovigilance is important to health care professionals	100%	0
Can ADR monitoring help to promote rational use of medicines	98.3%	1.7%
Is it only necessary to report serious ADRs	70%	30%

Which of the following information about suspected drug is not submitted in suspected ADR reporting form 70.8% 29.2%

Assessment of practice

Majority of the postgraduates (67.5%) had an experience of ADR during their practice but 87.5% postgraduates have admitted to reporting an ADR. Majority of post-graduate students concur that reporting ADRs is a common duty of physicians, pharmacists, and nurses.

The study results show only 70.8% of respondents are aware of what information about the suspected drug should be and should not be submitted in the ADR reporting form. Majority of the participants believe that health care personnel should be given detailed training in pharmacovigilance.

Table 4: Practice of ADR among Postgraduates.

Practice based questions	Positive responses	Negative responses
Have you ever experienced ADRs in any patient during your professional practice	67.5%	32.5%
Have you ever reported an ADR to pharmacovigilance centre	87.5%	12.5%
Are you aware of ADR ALERT CARD system	83.3%	16.7%
Which of the following methods is commonly employed by a healthcare professional to monitor ADRs of new drugs once they are launched in the market	48.3%	51.7%
Which method is commonly used for cause assessment of ADR	58.3%	41.7%

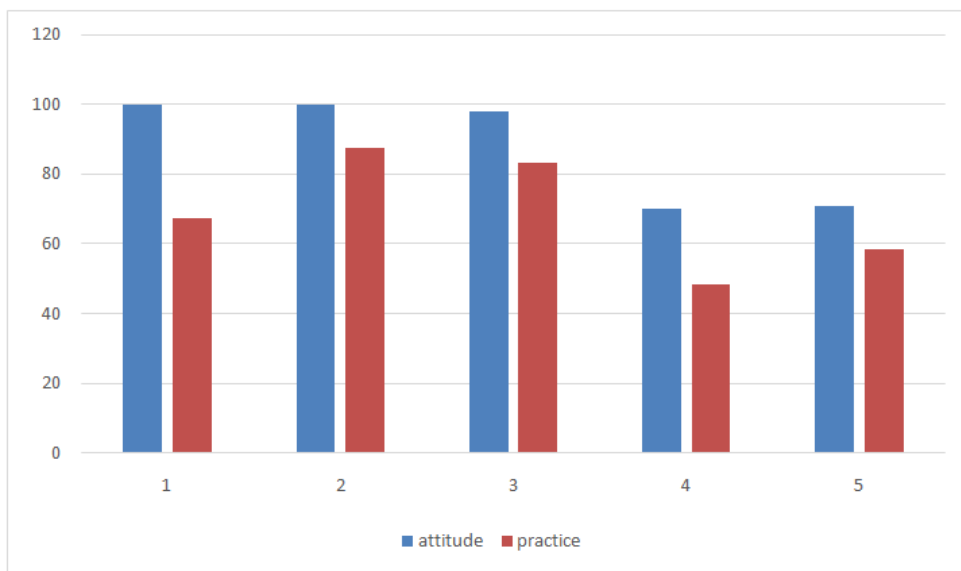


Figure 3: Comparative representation of correct responses for attitude and practice based questions.

Discussion

In this study, postgraduate students' knowledge, attitudes, and practices regarding pharmacovigilance are evaluated. In India, the primary method of drug safety surveillance is a spontaneous reporting system. Many studies are conducted to evaluate the KAP of pharmacovigilance among health care professionals, however postgraduates are the subject of far less studies.[14] Knowledge of pharmacovigilance among postgraduates is extremely important since they are in direct personal contact with all occurrences that occur after the administration of medications.

Nearly all postgraduates were aware of the Pv branch, ADR, and their significance. Of all the responders, 95% were able to define pharmacovigilance precisely. Post-graduates were cautious about what needed to be stated on the ADR reporting form in about 70.8% of cases. Only 48.3% of respondents were aware of the methods employed by health care professionals in monitoring ADRs. Among post-graduates, there is a greater proportional loss in pharmacovigilance expertise than anticipated.

As shown by the respondents' attitudes, 100% of PGs believe that reporting ADRs is crucial in increasing patient safety. 70% of the respondents believe only serious ADRs should be reported, Another study in resident doctors' has reported that 93% of the doctors' were more inclined to report an ADR if it is with a new drug.[15] ,this might be a cause for underreporting of ADRs. It is evident from the practice of postgraduates (see. Table 4) that 80.5% have reported an ADR but only 60.5% had experienced an ADR, this shows that some of the reporting was done by PGs who didn't have the firsthand experience of the ADR that they were reporting. Such practices may lead to errors in reporting.

Post-graduates' inability to perform pharmacovigilance tasks is primarily hampered by their incomplete understanding of ADR reporting.

Lack of information and disregard for reporting are the main causes of under-reporting.[16]. It is possible to reduce under-reporting by making registration forms easily accessible, streamlining paperwork, offering toll-free number support, establishing additional AMCs, enabling communication between registrars and pharmacovigilance centres, and offering financial incentives. [17,18]. The notice rates of medication-related issues would increase as a result of all these actions. Training and educational initiatives are required to raise public awareness of reporting ADRs. By periodically holding instructional, interventional, and sensitization programmes for the medical staff working in tertiary care hospitals, barriers to under-reporting can be addressed.[19-22].

Conclusions

This study's findings indicate that all postgraduates who answered have comparatively less knowledge than anticipated, but they have also demonstrated a positive attitude towards enhancing their knowledge and adopting procedures that will lessen the underreporting of ADRs. Post-graduates find it difficult to undertake pharmacovigilance activities because they lack a thorough understanding of reporting ADRs. Additionally, making reporting required and assuring doctors that it has no legal repercussions can discourage underreporting. Last but not least, while the majority of post-graduates have good attitudes about pharmacovigilance, in reality, there is a need to reduce the under-reporting of adverse drug reactions (ADRs) through imbibing knowledge. This study concludes that the major cause for under reporting is incomplete

knowledge of Pv and lack of practice of ADR reporting among Postgraduates.

List of abbreviations

ADR - Adverse Drug Reaction

AMC - Adverse drug reaction Monitoring Centre

PvPI - Pharmacovigilance Program of India

PGs - Postgraduates

KAP - Knowledge, attitude and practice

SPSS - Statistical package for social sciences

AE - Adverse Events

Pv - Pharmacovigilance

WHO - World Health Organisation

NCC - National coordination centre

UMC - Upsala Monitoring Centre

Ethics approval and consent to participate

Institutional ethics committee approval was taken prior to the study and participants consent was also obtained.

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