

A questionnaire based study on the knowledge, attitude and the practices of pharmacovigilance among the postgraduate students at a tertiary care hospital in south India

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ABSTRACT

Background: Adverse drug reactions (ADRs) are common cause of morbidity in the practice of medicine. Pharmacovigilance is the science of detection, assessment and understanding and prevention of adverse effects or any drug related problems. Post graduates are perhaps the first to notice ADRs in outpatient/inpatient setup as they spend most of the time bedside. Thus, this study was conducted to assess the knowledge, attitude and practices (KAP) of postgraduates about Pharmacovigilance.

Methods: A prevalidated and pretested questionnaire with 20 questions related to KAP of pharmacovigilance is administered to postgraduate students after obtaining their consent. All the completed and returned questionnaires were analysed for results using appropriate statistics.

Results: 180 pretested questionnaires were distributed among postgraduates out of which, 122 were returned from postgraduates of all major medical and surgical allied departments. 90.2 % defined pharmacovigilance correctly, 83.6% thought reporting ADRs is a professional obligation, while only 65.6% knew regarding the existence of national pharmacovigilance program. 58.4% have experienced ADRs, of which only 24.6% reported ADR to pharmacovigilance centre. Major reasons for under reporting are lack of time to report and difficulty to decide whether ADR has occurred or not.

Conclusions: In this study, the knowledge and attitude related to Pharmacovigilance is good amongst postgraduates, but practical implementation in reporting of ADRs is poor. Sensitization programs on pharmacovigilance practice in tertiary care hospitals and regular review meetings to ensure ADR reporting to pharmacovigilance centre will strengthen the health care setup.

Keywords: Adverse drug reaction, Attitude, Knowledge, Pharmacovigilance, Postgraduates, Practice

INTRODUCTION

Adverse drug reactions (ADRs) are one of the leading causes of morbidity and represent a substantial economic burden on healthcare resources.¹ It has been reported that 2.4-6.5% of the total admissions in the hospitals are due to the adverse reactions, many of which are preventable.² The incidence of serious ADRs is 6.7% in India.³ It is estimated that only 6-10% of all ADRs are reported.⁴ In India, all healthcare professionals including doctors, nurses, and pharmacists can report an ADR by filling an ADR form of the Central Drugs Standard Control Organization.⁵ It is

important for healthcare professionals to know how to report and where to report an ADR. The active participation of healthcare professionals in the Pharmacovigilance program can improve the ADR reporting.⁶

This study was undertaken to assess the knowledge, attitude and practice of Pharmacovigilance of post graduate students at Alluri Sitarama Raju academy of Medical Sciences, Eluru a tertiary care hospital in South India. The major reason for choosing post graduates is that they form the vital link between all stakeholders of patient

care allied services in hospital like undergraduate students, nursing department and faculty of teaching hospital.

METHODS

The present study was done at Alluri Sitarama Raju Academy of Medical Sciences. The study was approved by institutional ethics committee. The study was a cross sectional questionnaire based study. The study participants are post graduate students from all clinical departments in the hospital. Prior written informed consent was obtained from all the participants after explaining them about the study and questionnaire. KAP (Knowledge, attitude and practice) Questionnaire was designed to assess the knowledge about pharmacovigilance, attitude towards Pharmacovigilance and their practice on ADR reporting.

There were a total of 20 questions (seven related to knowledge, four related to attitude and eight related to practice). One question was to know the cause for under reporting. The questionnaire was designed based upon earlier studies for assessing KAP of ADR reporting.⁵⁻¹² The KAP questionnaire was validated and pretested to confirm appropriateness and identify whether questionnaire can be self-administered by the doctors. One day time was given to complete and return the questionnaire.

Study criteria

Inclusion criteria

Participants who are willing to answer all the questions in questionnaire.

Exclusion criteria

Incomplete questionnaires were excluded from study.

Statistical analysis

Statistical analysis was performed using the tabulated data from completed and returned questionnaires. Data were presented either as mean±standard deviation (SD) or as percentage and percentages or proportions. All statistical analysis was performed using the Graph Pad PRISM software (version 4, USA).

RESULTS

In this study a total of 122 post graduates from all 3 years of postgraduation courses from clinical departments were assessed with KAP questionnaire about pharmacovigilance, of which 55.7% (n=68) were males and 54 (n=54) were females. The mean average age of the respondents was 30.46±7.53 years. Postgraduates from first year were 32.8% (n=40), second year were 31.1% (n=38) and third year were 36.1% (n=44). The demographic details of postgraduates are presented in Table 1.

Table 1: Demographic details of the post graduate students (N=122).

	N=122	Frequency (%)
Gender		
Male	68	55.7
Female	54	44.3
Mean age (in years)	30.46±7.53	
Post graduates		
1 st year	40	32.8
2 nd year	38	31.1
3 rd year	44	36.1

A total of 122 postgraduate students from 8 clinical departments of which 17% from general medicine, 16% from general surgery, 20% from obstetrics and gynaecology, 8% from dermatology, 8% from pulmonology, 15% from paediatrics, 8% from orthopaedics and 8% from psychiatry were assessed in the study for KAP about pharmacovigilance as shown Figure 1.

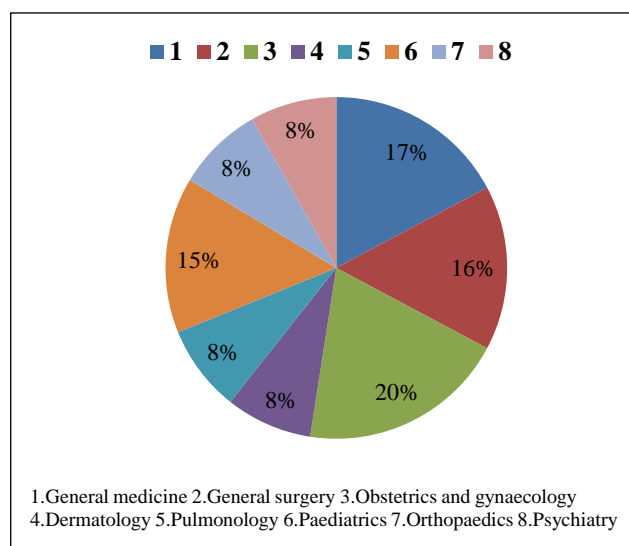


Figure 1: Department wise distribution (%).

Response rate

One hundred and eighty questionnaires were distributed among the post graduates and 122 responded by returning completed questionnaires (response rate 67.78%).

Knowledge domain

In the questions based on knowledge, 90.2% post graduates knew definition of Pharmacovigilance. About 88.5% considered most important purpose of Pharmacovigilance is to assess safety of drug. 83.6% felt ADR reporting as a professional obligation, 75.4% answered correctly health care professional responsible for ADR reporting and 65.6% were aware regarding the existence of a National Pharmacovigilance Programme in India.

While only 57.4% know CDSCO as regulatory body responsible for monitoring ADRs and 44.3% gave correct response for international monitoring centre for ADR

reporting as Uppsala Monitoring Center, Sweden (Table 2).

Table 2: Knowledge based questions and responses.

Knowledge based questions	Correct	Incorrect
Define Pharmacovigilance	90.2	9.8
The most important purpose of Pharmacovigilance is	88.5	11.5
Do you think ADR reporting is professional obligation for you?	83.6	16.4
The healthcare professionals responsible for reporting ADRs in a hospital is/are	75.4	24.6
Do you know regarding the existence of a National Pharmacovigilance Programme in India?	65.6	34.4
In India which regulatory body is responsible for monitoring ADRs?	57.4	42.6
Where the international centre for adverse drug reaction monitoring is located?	44.3	55.7

Attitude domain

Around 94.3% postgraduates think it's necessary to report an ADR and 90.2% feel Pharmacovigilance should be

taught in detail to health care professionals. About 50.8% have read an article on prevention of ADRs and around 73.8% opined positively about establishing adverse drug reaction monitoring centre in every hospital (Table 3).

Table 3: Attitude based questions and responses.

Attitude based questions	Correct	Incorrect
Do you think reporting of adverse drug reaction is necessary?	94.3	5.7
Do you think Pharmacovigilance should be taught in detail to healthcare professionals?	90.2	9.8
Have you anytime read any article on prevention of adverse drug reactions?	50.8	49.2
What is your opinion about establishing adverse drug reaction monitoring centre in every hospital?	73.8	26.2

Practice domain

58.4% post graduates have experienced ADRs in their patients, from which only 24.6 % have ever reported ADR to Pharmacovigilance centre. Only 49.2% have ever seen the ADR reporting form. 60.7% postgraduates knew regarding Pharmacovigilance committee in their institute. About 55.7 % had ever been trained on reporting ADRs. Around 23% postgraduates answered correctly that serious adverse event should be reported to the regulatory authority within 14 calendar days. 36.1% were aware that rare ADRs can be identified during phase 4 clinical trial and 55.3% acknowledged spontaneous reporting system as a method to monitor ADRs of new drugs in market.

Factors influencing under-reporting

The most common factor discouraging postgraduates from reporting ADRs is lack of time to report ADR (54.1%), followed by 21.3% postgraduates who opined that it's difficult to decide whether ADR has occurred or not. 15.6% felt that a single unreported case may not affect

ADR database, whereas only 9% expected remuneration for reporting ADRs.

DISCUSSION

This study was undertaken to assess the KAP of Pharmacovigilance of postgraduate students at our hospital. It is a collective responsibility of all health care professionals in ADR reporting, however we have conducted this study only in postgraduates from all clinical departments. Postgraduate's students coordinate across nursing staff, senior staff and other allied hospital services like pharmacists in the delivery of health care. They are more actively and responsibly involved in patient care services and often the first ones to either witness or get reported about the ADRs from nursing staff. Further, considering their awareness about Pharmacovigilance in their graduation, we conducted this study amongst postgraduate students of all years from all departments.

A modest response rate of around 67.78 is seen in our study, which is comparable to other similar studies.¹²⁻¹⁴ Post graduates from all medical allied (56.6%) and

surgical allied departments (43.4%) participated in the study.

In our study, participants awareness regarding knowledge related questions is better compared to other studies which were done in health care professionals.¹¹⁻¹³ For the questions relating to attitude about Pharmacovigilance, results were comparable to other studies done in centres in south India.¹³⁻¹⁵ The reasons for good knowledge and attitude towards Pharmacovigilance can be attributed to the sensitization about ADRs and pharmacology training in undergraduate course. Further seminars and conferences attended by postgraduates and emphasis of importance of ADR reporting under Pharmacovigilance Program of India help strengthen their understanding and knowledge about pharmacovigilance.

In this study, the practice related duties of Pharmacovigilance amongst postgraduates as assessed by questions like the reporting of the ADRs, training on reporting, use of suspected adverse drug reaction reporting form by CDSCO (Central drug standard control organization and timelines for reporting were low and similar to other Indian studies.^{6,10,15} Translation of knowledge and attitude of pharmacovigilance to practice is a major concern as it adversely influences the health care system. The reasons for underreporting in our study could be attributed to busy academic schedules and lack of time for postgraduates followed by difficulty to decide the occurrence and causality of ADR. This study emphasizes the need to fill the gaps existing in knowledge and attitude to practice by various measures like CMEs, PVPI awareness programs, regular meetings at tertiary care level to assess ADR reporting and monitoring by health care professionals.

CONCLUSION

In this study, knowledge and attitude aspects of Pharmacovigilance of postgraduates are reasonably good, attributed to the improving awareness about ADRs. A huge gap was observed between the translation of knowledge and attitude to the implementation and practice of reporting ADRs as a routine practice in hospitals. Guidelines and strict protocols are the need of the hour to improve underreporting of ADRs by conducting awareness and hands on training programs regularly for all health care professionals to encourage ADR reporting practices. Monthly review meetings by heads of the departments and hospital superintendents about the quantity and quality of ADR reporting conforming to standard reporting norms would help build a robust Pharmacovigilance centre in tertiary care hospitals.

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