RESEARCH ARTICLE

An evaluation of knowledge, attitude, and perception about adverse drug reactions and pharmacovigilance among postgraduate students in a Medical College Teaching Hospital of Sangli

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ABSTRACT

Background: National Pharmacovigilance (PV) program is an ongoing program to monitor the adverse drug reactions (ADRs) and reporting at the earliest. ADRs reporting by physicians, consultants are very less leading to various problems. As postgraduate students are future physicians and consultants, this study was undertaken with following objectives.

Aim and Objectives: The aim of the study was to study the knowledge about ADRs, PV, and to know the attitude about ADR reporting-in postgraduate students.

Materials and Methods: A cross-sectional questionnaire-based study was conducted after approval by our Institutional ethics committee pretested and validated questions consisting of 20 questions (knowledge, attitude, and perception) were administrated to postgraduate students. The filled questionnaires were collected and analyzed.

Results: In our study, postgraduates from all branches had fair enough idea about ADR and PV. In knowledge domain, postgraduate students were aware of term ADRs (100%), PV (89.6%). In attitude domain majority of students (87.9%) know the availability of ADR forms, compulsory of PV unit (96.5%). In perception domain very poor response (23.3%) had reported ADR filled form till duration of study. About 89.7% of them knew the meaning of re-challenge and de-challenge, and majority of students (98.3%) also know how to manage the ADRs in emergency conditions.

Conclusions: Under reporting problem can be improved by doing more sensitizing activities at UG and PG level including various workshops, CMEs, and problem based teaching. These exercises will improve their reporting frequency and sensitize them from the postgraduate days itself in their upcoming clinical practice in community to avoid drug related complications.

KEY WORDS: Pharmacovigilance; Adverse Drug Reactions; Postgraduates; Knowledge

INTRODUCTION

Adverse drug reactions (ADRs) are one of the fourth leading causes of morbidity and mortality of patients in the world.[1] ADRs are defined as a one which is noxious and unintended and which occurs in doses normally used in human for prophylaxis, diagnosis or therapy of disease, or for the modification of physiological functions.[2] Similarly, the World Health Organization (WHO) has defined serious ADR “untoward medical occurrence at any dose that results in death, life threatening, requires or prolongs hospitalization, or results in persistent or significant disability or incapacity.”[3]

Pharmacovigilance (PV) is defined as the science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other drug related problem. The World health organization started this program as international drug monitoring in 1961 after the thalidomide disaster in Germany. Along with various WHO collaborating centers for International Drug...
Monitoring, Uppsala, and the WHO promotes PV at the country level. The aims of PV are to enhance patient care and patient safety in relation to the use of medicines; and to provide public health programs by providing reliable, balanced information for the effective assessment of the risk benefit profile of drugs.\(^{[4]}\)

International database of reported ADRs is maintained at Uppsala Monitoring Centre, Sweden. In India, there is lot of underreporting of ADRs because of various reasons. PV program of India (PvPI) was launched in India to enhance the voluntary reporting. In 2011, the national coordinating center to monitor ADR shifted from AIIMS New Delhi to Indian Pharmacopoeia commission Ghaziabad.\(^{[5]}\)

A new drug in pipeline going through all tests such as preclinical studies and then clinical trials, after entering in to the community, it is exposed to large patient population with variety of genetic makeup of people as compared to study subjects in clinical trials. The various factors such as age, sex, genetic factors, food habit pattern, coexisting comorbidities, geographical variations, and concomitant medications play a much significant role in occurrence of ADRs. Thus, it is very important to monitor ADRs. Health workers such as doctors, nurses, and dentists, can voluntarily report the ADRs. Thus, active participation of health workers plays an important role in the successful implementation of PV program in India.

Hence, this study was taken to assess knowledge, attitude, and perception (KAP) among postgraduates students among all branches, working in Bharati Medical Hospital, a tertiary care teaching hospital of Bharati Vidyapeeth (Deemed to be University) Medical College, Sangli in Southwest Maharashtra.

MATERIAL AND METHODS

It was a cross-sectional, questionnaire-based study, consisting of 20 questions covering KAP components in a questionnaire. This study was conducted in Bharati hospital attached to Bharati Vidyapeeth (Deemed to be University) Medical College, a tertiary care medical teaching hospital situated in Sangli.

Prior approval of the Institutional Human Ethics Committee (IEC) was taken before initiating the study, (Approval. no. BV (DU) MC&H/Sangli/IEC/259/17).

Study was conducted within a total duration of 5 months from May to September-2018. As per the objectives, a questionnaire was designed. Based on Saurabh and Karnani,\(^{[6]}\) we prepared questions to assess KAP related with ADRs and PV. We compiled the questionnaire and pretested it before using it in the study. All questions were first analyzed and screened in detail and pre-tested, validated by expert staff. Based on the feedback from them certain questions were modified and reframed. After finalizing questions and obtaining approval from the IEC study was conducted.

Inclusion Criteria

All postgraduate students from various branches who gave voluntarily informed consent and responded to all questions.

Exclusion Criteria

Those postgraduates who were not willing to participate in study, who had incomplete responses and who did not return the questionnaire response sheet were excluded from the study.

Those postgraduates who gave consent were provided the filling response sheets and told to answer the questions mentioned, and return to us within 5 days. Only those who had answered all the questions were taken for our analysis. The questionnaire consists of 20 questions in which six questions were on knowledge based, seven questions were on attitude based and remaining seven questions were on perception based of ADR reporting and PV. Each correct response was given a score of “1” and wrong answer was given “0” total maximal score was 20. A convenient purposive sample of 120 was selected. After obtaining consent from the postgraduate students, response sheets were given to them with instructions to fill it and return within 1–2 day. A total of 120 postgraduates were given response sheets, whereas final numbers included for analysis were 116, as 4 were excluded from the final analysis in which 3 were incompletely filled, and 1 did not return the response sheet in spite of multiple reminders.

Statistical Analysis

The results were entered and analyzed question wise and their percentage, proportions and means are used for descriptive statistics with the help of Microsoft Excel 2010 spread sheet software.

RESULTS

In our study, 116 completed response sheets from postgraduate students were analyzed after removing incomplete respondents and those who did not return the response sheets even after multiple reminder. All the answers are mentioned in terms of numbers, percentages and mean ± SD, for KAP questionnaire. In our study, number of male participants 82 (70.7%) and females 34 (29.3%), average age of all students was 26.4 years.

In our questionnaire out of 20, we have given 6 knowledge based, 7 attitudes based and remaining 6 on perception based, randomly mixed in entire response sheet. Among knowledge
based questions, question 1 was regarding awareness of the term ADRs which was correctly answered by 100% of postgraduate students.

Question 2 was regarding awareness of the term PV which was correctly answered by 89.6% of students. Question 3 was regarding medical department taking care of ADR and PV, it was correctly answered by 84.4%. Question 11 was regarding reporting of ADRs to AMC by non-medicos, which showed that 91.3% were aware about it. Question 14 was about ADR reporting submission following route or process, for which 77.5% answered correctly. Question 17 was concerned with location of National Coordinating Centre in India, for which only 20.6% answered correctly [Table 1].

Seven questions were regarding attitude based questions in our response sheets. Question no 4 was regarding reporting of ADRs, for which 96.5% knew the correct answers. Question no 7 was regarding awareness of the ADR forms available in our college and hospital, for which 87.9% knew it about availability of forms. Question 9 was concerned with PV unit in our medical college, for which 96.5% students responded to have it compulsory in a medical college. Question 12 was concerned with reporting of ADRs by all doctors mandatory or compulsory, for which 84.5% students agreed to have it compulsory. Question 15 was concerned with phase IV clinical trial, for which 89.7% students answered it correctly. Question 19 was regarding inclusion of ADR reporting exercises in their 2nd year MBBS practical classes, for which 98.3% of students agreed to have it in undergraduate practical classes. Question 20 was regarding PVPi program will improve morbidity and mortality in clinical practice, for which 95.7% students answered it correctly [Table 2].

Seven questions were regarding perception based questions in our response sheets. Question 5 was regarding where you should report the ADRs, for which only 63.8% of students knew where to report. Question 6 was regarding types of ADRs to be reported, for which 94.5% of students answered correctly. Question 8 was regarding the awareness of Suspected ADR android app by National Coordination Centre (NCC)-PVPi for reporting of ADRs on play store of smartphones, for which 61.2% were aware about it. Question 10 was regarding the nearest AMC location, for which 86.2% students answered it correctly. Question 13 and 16 were two open ended questions asking about reporting of ADR till now and can they explain the de-challenge and re-challenge test in reference to ADRs, for which they replied as 23.3% have reported all kind of ADRs till now and 89.7% have idea of de-challenge and re-challenge test. Question 18 was regarding management of ADRs in emergency from progressing to mortality of patients, for which majority of

<table>
<thead>
<tr>
<th>Questionnaire No</th>
<th>Questions were asked for assessing knowledge (n=120, out of which 116 are taken in to consideration)</th>
<th>Correct response n (%)</th>
<th>Incorrect response n (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>Are you aware of the term ADRs?</td>
<td>116 (100)</td>
<td>0</td>
</tr>
<tr>
<td>2.</td>
<td>Are you aware of the term PV?</td>
<td>104 (89.6)</td>
<td>12 (10.4)</td>
</tr>
<tr>
<td>3.</td>
<td>Which medical department will take care of ADR reporting and PV?</td>
<td>98 (84.4)</td>
<td>18 (15.6)</td>
</tr>
<tr>
<td>11.</td>
<td>Can non-medicos report ADR to ADR Monitoring Centre (AMC)?</td>
<td>106 (91.3)</td>
<td>10 (8.7)</td>
</tr>
<tr>
<td>14.</td>
<td>ADR report submission follows which order?</td>
<td>90 (77.5)</td>
<td>26 (22.5)</td>
</tr>
<tr>
<td>17.</td>
<td>Where is National Coordinating Centre of PV located in India?</td>
<td>24 (20.6)</td>
<td>92 (79.4)</td>
</tr>
</tbody>
</table>

PV: Pharmacovigilance, ADRs: Adverse drug reactions

<table>
<thead>
<tr>
<th>Questionnaire No</th>
<th>Questions were asked for assessing attitude</th>
<th>Correct response n (%)</th>
<th>Incorrect response n (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>4.</td>
<td>Who can report ADRs (ADRs)?</td>
<td>112 (96.5)</td>
<td>04 (3.5)</td>
</tr>
<tr>
<td>7.</td>
<td>Are you aware of the ADR forms available in our college?</td>
<td>102 (87.9)</td>
<td>14 (12.1)</td>
</tr>
<tr>
<td>9.</td>
<td>Is it compulsory to have PV unit in medical college?</td>
<td>112 (96.5)</td>
<td>04 (3.5)</td>
</tr>
<tr>
<td>12.</td>
<td>Whether ADR reporting should be made compulsory for all doctors?</td>
<td>98 (84.5)</td>
<td>18 (15.5)</td>
</tr>
<tr>
<td>15.</td>
<td>What is known by the term phase IV clinical trial?</td>
<td>104 (89.7)</td>
<td>12 (10.3)</td>
</tr>
<tr>
<td>19.</td>
<td>Do you think ADR reporting exercises should be included in 2nd year MBBS pharmacology practical classes?</td>
<td>114 (98.3)</td>
<td>02 (1.7)</td>
</tr>
<tr>
<td>20.</td>
<td>Do you think PVPi program will improve the morbidity and mortality of patients in clinical practice?</td>
<td>111 (95.7)</td>
<td>05 (4.3)</td>
</tr>
</tbody>
</table>

PV: Pharmacovigilance, ADRs: Adverse drug reactions
students 98.3% answered it stating that they know to manage the ADRs in emergency from progressing it to severity leading to mortality [Table 3].

DISCUSSION

In the present days, spontaneous reporting of ADRs is an important responsibility of all health care workers such as doctors (undergraduate and postgraduate), nurses, pharmacist, and even patients.

As postgraduate students are one of the frontline healthcare workers in patient care, and are future consultants in community it’s their moral responsibility to watch for various adverse effects of drugs and note it down to PV or AMC. Our study was conducted in postgraduate students from all specialties of the departments in a tertiary care hospital of Sangli.

In our study, almost all postgraduate students were aware of the term ADRs. Around 89.6% of them were aware of the term PV which is quite satisfactory. Majority of them 84.4% were aware that pharmacology department will take care of ADR reporting and PV. These results were comparable and par with other studies conducted by Thakuria et al and Korde and Radhika.

Concerning the perception about ADR and PV, 63.8% of students were aware about where to report the filled ADR forms whereas, rest of them being postgraduate students had no idea where to report. Almost 94.5% of students answered correctly regarding the types of ADRs to be reported. Only 61.2% of students have the idea and usage of “Suspected ADR” android app by NCC-PvPI for reporting of ADRs on play store of your smart phone?

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In our study, postgraduates answered comparatively satisfactorily toward knowledge and attitude, where as in case of perception there is much improvement needed to improve the numbers. There are many studies conducted to assess knowledge of health care providers regarding PV, however very few studies involved the postgraduate students.
Similar studies were done by Agarwal et al., where participants had enough good knowledge and attitude but there was marked decrease in practice of reporting nature of forms.\cite{13} Postgraduate students in our study have reported only 23.3% cases of ADR forms, which is very less as a resident, reason being various accounting for under reporting of ADR forms. Underreporting is a matter of serious concern for PvPI as various new drugs for variety of indications are coming in to market along with older drugs, which would lead to masking of the reactions and conditions leading in increasing the morbidity and mortality of patients.\cite{14} Kalaiselvan et al. found that reporting by non-health care professionals was only 0.016% which is very very less as compared to the incidence of ADRs occurring.\cite{15}

The majority of the factors responsible for under reporting by postgraduate students may be: Their workload in their daily routine, lack of interest in picking up ADRs and reporting, lack of concern of non-reporting of ADRs, implications of non-reporting in time, laziness and casual approach, and lack of compulsion from institutes toward reporting. All these may have accounted in poor response of ADR filling forms. Similar responses were found in other published studies describing various hurdles in ADR detection and reporting.\cite{16-18}

Strengths and limitation of this study: (i) Being a tertiary care hospital we were able to recruit PG students from all clinical branches (ii) we were able to achieve sufficient sample size. However, (i) responses of close ended questions given by postgraduate students were totally dependent on honesty of participants included in study, (ii) participants were from one tertiary care center (postgraduate students) only, and these findings cannot be generalized. Many similar studies will have to be carried out in various postgraduate institutes to generalize the findings.

In our study, majority of the postgraduates have suggested that there is a need to teach the ADR and PV topic in detail in UG curriculum and also during their internship postings. To support this, it is seen recently that ADR filling exercises for MBBS students in practical classes has been introduced by new CBME curriculum as per NMC norms in competency based approach, which may improve the compliance of detecting and reporting of ADR forms in future budding consultants and physicians. Thus, we may expect much improvement in PV in coming days and in preventing drug related future complications.

**CONCLUSIONS**

The results of our present study show that postgraduate students had good amount of knowledge and lenient attitude toward PV; however, there is lack of reporting. Which has to be taken seriously and exercises must be implemented in postgraduate students to increase the reporting of ADRs. Hence, various educational interventions may be designed and implemented, beginning from UG curriculum and during internship to enhance their awareness and ADR reporting culture among the students. It will help them in their future clinical practice as consultants or specialist in community.

**ACKNOWLEDGMENTS**

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