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Original Research Article

A study on the knowledge, attitude and practice on adverse drug reactions and pharmacovigilance among post graduate residents in Gandhi Medical College, Bhopal

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ABSTRACT

Background: Resident doctors should consider adverse drug reaction (ADR) reporting as their professional obligation and should be aware of the existing pharmacovigilance mechanisms in their countries. In India, pharmacovigilance implementation is essential due to the absence of a vibrant ADR monitoring system. The present study primary objective was to evaluate the knowledge, attitude and practices (KAP) of the postgraduate students towards pharmacovigilance and ADR reporting in GMC, Bhopal as they observe and attend to the patients round the clock while the patient is admitted in the hospital.
Methods: A cross-sectional-observational study was carried out using a pretested questionnaire having 17 questions in all. Data was compiled, entered in Microsoft Excel sheet and analysed by descriptive statistics.
Results: A total of 127 duly filled responses were analysed. Study shows ADR is necessary and Pharmacovigilance should be taught in detail to postgraduate students is an important finding from our study. In this study there was also a wide gap between the ADR experienced in professional practice (71%) and ADR reported (23%).
Conclusions: In our present study, the average knowledge score was 64% in contrast to 32% residents who didn't answered correctly. Though majority (87%) of the residents had a positive attitude towards awareness about Pharmacovigilance and ADR reporting, however in clinical scenario even as ADR reporting was considered to be important by a large majority of the participants, the actual practices of ADR reporting was very low.

Keywords: Pharmacovigilance, Adverse drug reaction reporting, Postgraduate students, KAP study

INTRODUCTION

Adverse drug reactions (ADRs) are noxious, undesirable and unintended effects of drug administered at doses used for prophylaxis, diagnosis or therapy, and may be the major cause of morbidity, mortality and also increases the cost of the healthcare of the patient, health institutions as well as community.[1] ADRs are negative consequences of drug therapy, which are also responsible for significant number of hospital admissions and frequent physician or hospital visits. All drugs have inherent risk of producing adverse effects so whenever a drug is given a risk is taken. The incidence of ADRs varies 6-7% of all hospitalized patients and may be 10-20% of all patients taking drug therapy. Recent epidemiological studies estimated that ADRs are fourth to sixth leading cause of death.[2] It is one of the leading cause of morbidity and mortality with an estimated economic burden of about 30 billion to 130 billion US dollars annually. The study also showed that the average cost involved in treating these ADRs was INR 900/- (USD 15$) per patient.[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. WHO established its Programme for International Drug Monitoring in response to the thalidomide disaster detected in 1961. Together with the WHO Collaborating Centre for International Drug Monitoring, Uppsala, WHO promotes PV at the country level. At the end of 2010, 134 countries were part of the WHO PV Programme. The aims of PV are to enhance patient care and patient safety in relation to the use of medicines; and to support public health programmes by providing reliable, balanced information for the effective assessment of the risk-benefit profile of medicine.[4]

To detect and spontaneously report ADR and to ensure drug safety, National Pharmacovigilance Program was initiated in India in the year 2004, under aegis of Ministry of health and Family welfare, Government of India with All India Institute of Medical Sciences (AIIMS), New Delhi as a National Coordinating Center (NCC) to monitor ADR.[5,6] For more effective way to implementation of this program, recently NCC shifts from AIIMS, New Delhi to the Indian Pharmacopoeia Commission, Ghaziabad, (UP) in April, 2011 under aegis of Uppsala Monitoring Center-World Health Organization (UMC-WHO). The advantage of pharmacovigilance program includes the detection of medicines of substandard quality as well as prescribing pattern and administration errors. This program is essential due to the absence of a vibrant ADR monitoring system and also lack of a reporting culture among health care professional in India.[7]

The success of a pharmacovigilance program depends upon the active involvement of the healthcare professionals such as doctors, pharmacist, nurses.[8,9] With adequate knowledge and practices of pharmacovigilance and ADR reporting in India, there will be not only increasing reporting of ADR, but also reducing incidence rate as well as health care cost of patient and also banned harmful drug to the patient in actual clinical practices.

Although it has shown some improvement, but still lot is required to be done to increase the spontaneous reporting. Spontaneous reporting of ADR by health care professionals is backbone of pharmacovigilance program, but under reporting of ADR is still prevalent and is the cause of concern. Study showed that only 6-10% of all ADR cases are reported. Health care professional has a major role in pharmacovigilance program.[10] Therefore, the study was planned and primary objective was to evaluate the knowledge, attitude and practices (KAP) toward pharmacovigilance and ADRs reporting in postgraduate students of Gandhi Medical College, Bhopal because resident doctors observe and attend to the patients round the clock while the patient is admitted in the hospital.

METHODS

The study was planned to be conducted in the month of April 2019, with filling of questionnaire by resident doctors on a single working day (10th April 2019) followed by evaluation of data and compilation of result in next 20 days. After applying and obtaining approval from the Institutional Ethics Committee (IEC) of the college, a questionnaire-based cross-sectional-observational study was conducted among all the postgraduate students on duty in Gandhi Medical College and affiliated hospitals viz Hamidia Hospital, Kamla Nehru Hospital and Sultania Zanana hospital, Bhopal on 10th April 2019. The study participants consisted of all the postgraduate students who gave their informed consent and who were working at the hospital during the study period. KAP questionnaire was designed to assess the demographic details of the resident doctors, their knowledge of pharmacovigilance, attitudes towards pharmacovigilance, and their practice on ADR reporting. Pretesting of questionnaire was done on 12 randomly selected health professionals of the institute. The questionnaire was finalized after ambiguous and unsuitable questions were modified based on the result of pretest. There were 17 questions in all (six related to knowledge, four related to attitude, and seven related to practice). One question was even asked to determine the reasons for underreporting. The questionnaire was handed to the students after explaining the purpose of the study. These questions were designed based on earlier studies for assessing KAP of ADR reporting.[11-15] Any doubts regarding questionnaire were clarified by investigator. 25 min was given for filling the questionnaire. Of total of questionnaires that were submitted by the post graduate doctors, data was compiled, entered in Microsoft Excel sheet and analysed by descriptive statistics, and result was computed regarding the knowledge, attitude and practice of pharmacovigilance and ADR reporting by postgraduate students.

RESULTS

A total of 150 questionnaires were distributed among the postgraduate students of which 127 were returned, giving a response rate of 85%. Out of the total (n=127) postgraduate students responded, 52% were males (66) and 48% were females (61) residents (Figure 1).

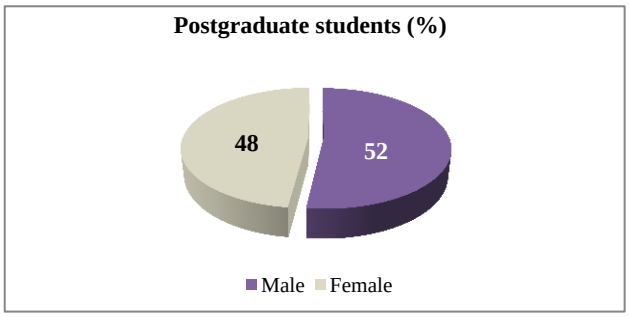

Figure 1: Postgraduate students respond.

The questionnaire consisted of six questions related to knowledge of postgraduate students about pharmacovigilance and ADRs. Of the total (n=127) filled

questionnaires received, at an average 64% residents correctly answered the questions in contrast to 32% residents who didn't answered correctly while those who weren't aware about the topic or didn't choose to answer constituted 4% of the questionnaires (Table 1).

Table 1: Knowledge of postgraduate students about pharmacovigilance and ADRs.

S. No.	Question	Yes	Yes (%)	No	No (%)	Don't know	Don't know (%)
1	Are you aware of National Pharmacovigilance Programme of India?	74	58	43	34	10	8
2	Are you aware of Pharmacovigilance Committee in your Institute?	64	50	60	48	3	2
	Question	**Correct**	**Correct**	**Incorrect**	**Incorrect**	**No response**	**No response**
3	What is Pharmacovigilance?	84	66	41	32	2	2
4	Main objective of Pharmacovigilance	56	44	65	51	6	5
5	Who can report ADRs in a hospital?	117	92	8	6	2	2
6	Which regulatory body is responsible for monitoring ADRs in India?	91	72	28	22	8	6
	Total		64		32		4

Table 2: Practices of postgraduate students toward ADRs.

S. No.	Question	Yes	Yes (%)	No	No (%)	Not attempted	Not attempted (%)
1	Have you ever experienced adverse drug reactions in your patient during your professional practice?	90	71	34	27	3	2
2	Have you ever given training on how to report Adverse Drug Reaction	29	23	95	75	3	2
3	Have you ever seen the ADR reporting form?	48	38	70	55	9	7
4	Have you ever reported ADR to the Pharmacovigilance centre?	29	23	90	71	8	6
5	If the above is yes, whom did you report to?						
	Total						
6	What do you expect from submitted ADR reporting form	Feedback – 91 (72%)		Publication – 31(24%)		NA – 5 (4%)	
7	Which of the following factor discourage you from reporting ADRs?	No remuneration–10(8%)	Lack of time to report ADR – 65 (51%)	Single unreported case wont affect ADR database – 23 (18%)	Difficult to decide wether ADR occurred or not – 9 (23%)		

The questionnaire consisted of seven questions related to practices of postgraduate students toward ADRs. Of the total (n=127) filled questionnaires received, at an average only 39% residents have experienced and practiced reporting ADR in contrast to 57% residents who didn't clinically experience or reported ADR while those who weren't aware about the topic or didn't choose to answer constituted 4% of the questionnaires. The factors discouraging participants from reporting ADRs were no remuneration (8%), lack of time to report ADR (51%), belief that a single unreported case may not affect ADR database (18%), and difficulty to decide whether ADR has occurred or not (23%) (Table 2).

The questionnaire consisted of four questions related to postgraduate students attitude toward Pharmacovigilance And ADRs reporting. Of the total (n=127) filled questionnaires received, at an average majority (87%) of the residents had a positive attitude towards awareness about Pharmacovigilance and ADR reporting with only

2% residents responding negatively while around 11% postgraduate students had a neutral attitude towards ADR reporting (Table 3).

In this study there was also a wide gap between the ADR experienced in professional practice (71%) and ADR reported (23%) by resident doctors showing the need of bringing Pharmacovigilance in practice (Figure 2).

Table 3: Postgraduate student's attitude toward pharmacovigilance and ADRs reporting.

S. No.	Question	Yes	Yes (%)	No	No (%)	May be	May be (%)	Cant say	Cant say (%)
1	Do you think to improve reporting, pharmacovigilance workshop / training should be provided to you	117	92	8	6	1	1	1	1
2	Do you think ADR reporting is beneficial for clinical practice	122	96	3	2	1	1	1	1
3	Do you think reporting of adverse drug reaction is necessary	113	89	1	1	5	4	8	6
4	What do you think, should ADR reporting be made mandatory?	89	70	0	0	21	17	17	13

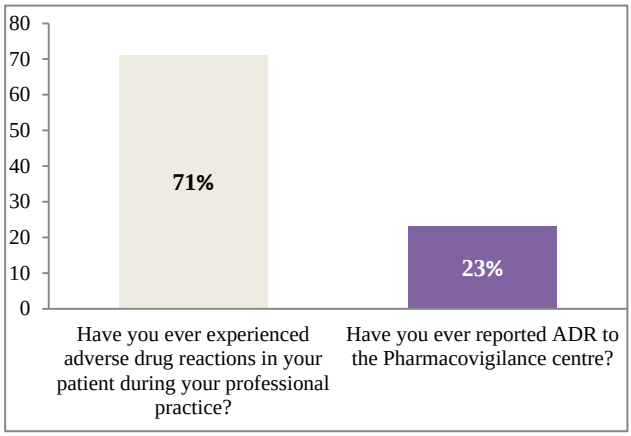

Figure 2: Gap between the ADR experienced in professional practice and ADR reported by resident.

DISCUSSION

Pharmacovigilance is an integral part of holistic health care as it helps in detection and prevention of ADR of medicinal products. Reporting ADRs is an essential component of pharmacovigilance programme. Spontaneous reporting system is important method for reporting ADR and also ADR because of newer drug.

In the present study, we observed that there was a lack of correct knowledge about ADRs reporting and Pharmacovigilance among the post graduate doctors. The average knowledge score was 64% in contrast to 32% residents who didn't answered correctly and it indicates that there is still a need to educate and sensitize postgraduate students about knowledge and importance of ADR reporting and Pharmacovigilance.

The fact that majority of respondents agreed that reporting of ADR is necessary and pharmacovigilance should be taught in detail to postgraduate students is an important finding from our study. In this study there was also a wide gap between the ADR experienced in professional practice (71%) and ADR reported (23%) by resident doctors showing the need of bringing Pharmacovigilance in practice.

In resemblance to our study, study conducted at Mysore, and Muzzafarnagar has also shown adequate knowledge but poor practice for ADR among prescribers. Another similar study at Mumbai, shows high knowledge but poor practices for ADRs reporting in doctors.[16-18]

In our study, the factors discouraging participants from reporting ADRs were no remuneration (8%), lack of time to report ADR (51%), belief that a single unreported case may not affect ADR database (18%), and difficulty to decide whether ADR has occurred or not (23%). In a similar study done at Spain, the major problem for under-reporting of ADRs were identified to be difficulty in diagnosis of ADRs, lack of knowledge regarding the ADR reporting system, clinical workload on the doctors, a concern for patient confidentiality and possible legal implications of reporting.[19]

In our present study, though majority (87%) of the residents had a positive attitude towards awareness about Pharmacovigilance and ADR reporting with only 2% residents responding negatively, however in clinical scenario even as ADR reporting was considered to be important by a large majority of the participants, the actual practices of ADR reporting was very low.

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