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Assessment of Knowledge and Attitude of Second Professional Medical Students for Pharmacovigilance in A Rural Tertiary Care Teaching Hospital of Uttar Pradesh, India.

Asha Pathak Associate Professor, Department of Pharmacology, Uttar Pradesh Rural Institute of Medical Sciences & Research, Saifai, Etawah, India.

*** Vinay Kumar Gupta** Lecturer, Department of Pharmacology, Uttar Pradesh Rural Institute of Medical Sciences & Research, Saifai, Etawah, India.
* Corresponding Author

ABSTRACT

Introduction: *The objective of this study was to analyze the baseline knowledge and awareness regarding the ADRs and pharmacovigilance (PV) activities among second professional undergraduate medical students.*

Method: *A cross-sectional survey was conducted to assess the knowledge of ADRs, PV program and attitude towards reporting of ADRs by using questionnaire. Data were expressed as percentage proportions.*

Results: *Out of the total of 96 enrolled students, 86 students filled and returned the questionnaire. Students having a mediocre knowledge about PV and majority of them (94%) were favoring the mandatory reporting, (96.51%) were in favor of regular sensitization programs and inclusion of PV in undergraduate curriculum.*

Conclusions: *For the better understanding of ADRs and management of patient and for the success of PV program, awareness and knowledge regarding ADRs and PV needs to be addressed on priority bases.*

KEYWORDS : – ADRs, PV, Knowledge, questionnaire.

INTRODUCTION

PV is defined as science and activities related to detection, assessment, understanding and prevention of adverse drug reaction or drug related problem. WHO has defined adverse drug reaction as any effect of a drug which is noxious , unintended and which occurs at doses which are normally used for prophylaxis , diagnosis , treatment and for modification of physiological functions.[1] Adverse drug reactions are one of the leading cause of morbidity and mortality [2]. ADRs are associated with large number of hazards leading to increased economic burden both for the individual and also for the community [3]. ADRs are responsible for 5% to 20% of hospital admissions [4,5]. Knowledge of PV is inadequate as well as underreporting attitude of health care professionals as evidenced by different studies[6].

Some studies were done in different countries for knowing the knowledge and attitude of medical students and faculty. Students knowledge based on yellow card system was assessed by 57% of the medical school in UK[7]. Majority of medical residents were lacking in the knowledge PV in a survey done in France[8].

To make PV program a success and improve reporting rate, it is important to improve the knowledge, attitude, and practice of the healthcare professionals and best time to do so is probably during undergraduate and postgraduate training of the doctors.

There are few studies of assessing the awareness of PV among medical student especially in rural area. In view of this, the present study was undertaken to assess the basic knowledge and attitude of PV among second professional medical students at UP Rural Institute of Medical Sciences & Research, Saifai.

MATERIALS AND METHODS

This was a cross-sectional questionnaire based an observational study conducted on second professional medical students in the Department of Pharmacology of UPRIMS & R, Saifai. Permission was obtained from the Institutional Ethical Committee. Purpose of the study was explained to the students.

Questionnaire was based on previous studies undertaken on PV and it was suitably modified for students. Out of 25 questions, 15 were of multiple choices involving choosing most appropriate answer while in the last 10 questions reply was given as yes or no. In the end of questions, suggestions were also asked for improvement of ADR reporting. The completed questionnaires were collected and data were analyzed by using descriptive statistics. Out of 100 students only 96 students participated in study. Four students were absent. 10 questionnaires were incomplete and eliminated while evaluating the results.

Table- 1: Assessment of knowledge

S.No	Multiple choice questions	Correct Answer	Wrong Answer
1.	Definition of PV	21(24.41%)	65(75.58%)
2.	Important purpose of PV is to assess	83(96.5%)	3(3.48%)
3.	A serious ADR in India should be reported to the regulatory body with in how many days	15(17.44%)	71(82.55%)
4.	In India highest regulatory body of PV is	20 (23.25%)	66(76.74%)
5.	The health care professional responsible for ADR reporting is/are	52 (60.46%)	34(39.53%)
6.	PV programme of India was started in	11(12.79%)	75(87.20%)
7.	WHO PV centre is situated in	19 (22.09%)	67(77.90%)
8.	Types of ADRs to be reported	32 (37.20%)	54(62.79%)
9.	Function of PV	57(66.27%)	29(33.72%)
10.	National coordination center of PV is	36(41.86%)	50(58.13%)
11.	The action taken by regulatory authorities on the basis of post marketing surveillance is	48(55.81%)	38(44.18%)
12.	ADR reporting forms are periodically reviewed by	38(44.18%)	48(55.81%)
13.	The online database for ADR reporting	23(26.74%)	63(73.25%)
14	Definition of ADR	63(73.25%)	23(26.74%)
15.	Definition of side effect	35(40.69%)	51(59.30%)

Table- 2: Assessment of Attitude

S.No	Answer in yes or no	Yes	No
1	Have you read any article or attended any workshop on PV	16(18.60%)	70(81.39%)
2	Have you ever come across with an ADR	56(65.11%)	30(34.88%)

3	Have you reported any ADR to concerned authority	11(12.79%)	75(87.20%)
4	PV should be included in the undergraduate curriculum	83(96.51%)	3(3.48%)
5	Do you think reporting should be mandatory	76(88.37%)	10(11.62%)
6	Do you think ADR monitoring centre should be in every hospital	84(97.67%)	2(2.32%)
7	Do you think PV should be taught in detail to health care professionals	86(100%)	nil
8	Do you aware of presence of AMC in the institute	72(83.72%)	14(16.27%)
9	Honorarium should be given to the health care professionals for reporting	69(80.23%)	17(19.76%)
10	PV sensitization program should be done regularly	83(96.51%)	3(3.48%)

RESULTS

Majority of the students had correct understanding regarding PV and its role in identifying the safety of drugs. 60.46% of the students were knowing that health care professionals (i.e. Doctors, pharmacists, nurses) are responsible for reporting ADR. Only 26.74% were aware of WHO online database for reporting ADRs. 23.25% had the correct understanding that CDSCO is the regulatory body for monitoring ADRs in India. 37.20% students thought that, all the ADRs (mild, moderate and severe) should be reported. 73.25% and 40.69 % of participants knew the correct definition of ADR and side effect respectively. 77.90% of respondents were not aware of WHO PV centre and 58.13% had incorrect answer regarding national coordination centre. 66.27% knew the function of PV. While correct answer regarding definition of PV was given by only 24.41% but 86.5% knew its important purpose.82.55% did not know the reporting time period of a serious reaction and 87.20% were not aware when the program of PV was started. The correct answer regarding the action taken by regulatory authorities and periodic review of ADR forms were given by 55.81%and 44.18% of respondents respectively.

Other findings include 18.60 % had read an article or attended a workshop on PV. While 65.11% came across an ADR but only 12.79% had reported. 97.67% thought that AMC should be in every hospital and 96.51% were agreed to be included in undergraduate curriculum.88.37% participants were thinking that reporting should be mandatory but 80.23% were in favor of honorarium for reporting. 96.51% were given positive response for regular sensitization program.

Discussion

The present study evaluated the baseline knowledge and attitude of second professional medical students regarding ADR reporting and PV which is depicted in tables 1 and 2 and needed further improvement as suggested by studies by Manjunath et al and Tabbasum et al.[9-10]

Although percentage of respondents knowing about the definition of PV, PvPI, regulatory bodies were less but a good number of students, i.e. 96.5% had an idea that aim of PV is to assess safety, 60.46% were aware of the fact that all the healthcare professionals, i.e. doctors, pharmacists and nurses are responsible for reporting ADR in a hospital, . In our study, 23.25% of participants were aware of the regulatory body responsible for monitoring ADRs which was low when compared to48.48% reported by Manjunath et al but it is near to study by Tabbasum et al .

Regarding reporting of ADRs based on severity, in our study 44.8% of students had opinion that all ADRs should be reported irrespective of the severity, whereas in a study done by Manjunath et al 66.66% had the similar opinion.

In our study 65.11% were experienced an ADR while 32.0% were came across with an ADR in study done by Tabbasum et al., 18.6% had attended a workshop on PV in our study while 16.4 % were trained in reporting in study by Tabbasum et al. In our study 88.37% were agreed that reporting should be mandatory while 94.0% were in favor of mandatory reporting in study done by Tabbasum et al and only 61% were in study by Manjunath SM et al., 99.2% were agreed that ADR reporting is beneficial for patients, In our study 96.51 % opined that this topic must be included in undergraduate curriculum while this figure was less (41.0%) I study by Tabbasum et al.

In our study around 50% of students were aware of ADRs and PV. They were aware of existence of AMC at their institute and most of the students had positive attitude regarding regular sensitization program, training for filling of ADR forms and inclusion of this topic in their curriculum.

Suggestion regarding improving PV included reporting of ADRs by patients and their relatives, conducting regular CMEs, sensitization cum training programs for filling and reporting, feedback for reporters, man power and effective bidirectional communication system.

As our study involved the students of one batch, further studies involving more number of students are required.

CONCLUSION

The present study identified the knowledge of the undergraduate medical students regarding ADR monitoring and PV and their attitude. It also provides ideas for possible interventions that could be planned to develop the culture of reporting among medical students.

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