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Original Research Article

KAP Study of Pharmacovigilance Among Medical Students: A Cross-sectional Questionnaire Study

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Abstract

Aim: Knowledge, attitude and practice of pharmacovigilance among medical students. **Methods:** A cross-sectional questionnaire study was conducted in the Department of Pharmacology Darbhanga Medical College , Darbhanga Bihar India for 1 year (1 September 2020 – 31 August 2021). The total number of students in the study was 100. The study participants were 2nd year MBBS students. Total 20 questions were given to the students and they were given one day to fill the answers in the questionnaire. **Results:** 94% students gave correct definition of pharmacovigilance. 45% students were aware that the most important purpose of pharmacovigilance is to identify safety of the drug. 95% students were having knowledge about existing National pharmacovigilance programme of India. Only 22% were aware about regulatory body responsible for monitoring ADRs in India, i.e. central drugs standard control organization (CDSCO). 96% gave correct answer of side effect occurring during pregnancy as teratogenicity. Total 46% students said that reporting ADR is professional obligation for them. 98% said that reporting ADR is necessary.95% said that Pharmacovigilance should be taught in detail to healthcare professionals. Only 37% students were agreeing about having Pharmacovigilance center in every hospital. Among students, 42% have read article on prevention of ADR. 25% have experienced ADR in patients during their clinical posting. 22% reported ADR to Pharmacovigilance center. 98% have seen ADR form. 95% have been trained on how to report ADR (Table 3). **Conclusion:** The students gave correct answer of knowledge-based questions. So, knowledge of pharmacovigilance is gradually improving. The study will bring awareness among students towards pharmacovigilance and help them in monitoring adverse drug effects.

Keywords: pharmacovigilance, knowledge, students

Introduction:

Drug therapy is an integral part of the medical management. It has many beneficial effects, but side-effects and adverse drug reactions (ADRs) are some of its major disadvantages. ADR is defined by World Health Organization (WHO) 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".[1] ADR is responsible for significant morbidity and mortality; it is fourth to sixth leading cause of death in USA.[2] Studies suggested that ADR is responsible for 0.2-24% of hospital admission.[3,4] ADR also has a significant impact on health care cost.[5] Pharmacovigilance is defined by WHO as "the science and activities relating to the detection, understanding, and prevention of adverse effects or any other drug-related problems".[6] To promote drug safety WHO started Program for International Drug Monitoring in 1961 and subsequent to that it promoted pharmacovigilance program at country level in collaboration with Center for International Drug Monitoring, Uppsala.[7]

To detect and spontaneously report ADR and to ensure drug safety, National Pharmacovigilance Program was initiated in India in the year 2004.[8] It is now renamed as Pharmacovigilance Program of India and operational since July 2010 under the aegis of Central Drug Standard Control Organization.[9]

The Uppsala Monitoring Centre (UMC), Sweden maintains the international database of ADR report received from different countries. India is an active participant in this program and its contribution to UMC database has rose from 0.5% in 2012 to 2% in 2013 making it seventh largest contributor of UMC drug safety database.[10] 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.[11] 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.[12-14] Medical students could play a major role and bring a paradigm shift in successful implementation of pharmacovigilance program if adequate knowledge and skill are imparted to them during undergraduate training career, but at present they don't have any significant role which is due to inadequate training to them regarding ADR reporting.[15-16] Very few studies are there to assess the knowledge, attitude, and practice (KAP) of pharmacovigilance among undergraduate medical students. Hence, this study has been done to assess of KAP among medical students about same and to compare the result among different groups according to year of study.

Materials and Methods

A cross-sectional questionnaire study was conducted in the Department of Pharmacology Darbhanga medical college, Darbhanga Bihar, India for 1 year (1 September 2020 – 31 August 2021) after taking the approval of the protocol review committee and institutional ethics committee.

Methodology

The total number of students included in the study was 100. The study participants were 2nd year MBBS students. Total 20 questions were given to the students and they were given one day to fill the answers in the questionnaire. Among 20 questions, 10 were based on knowledge, 4 were based on attitude and 5 were based on practice. One question was asked to determine the reasons for underreporting. These Questions were designed based on earlier studies for assessing KAP of ADR reporting.[17-20]

Results

Knowledge

94% students gave correct definition of pharmacovigilance. 45% students were aware that the most important purpose of pharmacovigilance is to identify safety of the drug. 95% students were having knowledge about existing National pharmacovigilance programme of India. Only 22% were aware about regulatory body responsible for monitoring ADRs in India, i.e. central drugs standard control organization (CDSCO). 96% gave correct answer of side effect occurring during pregnancy as teratogenicity. (Table 1).

Table 1: Knowledge based questions.

Questions	Correct (%)	Incorrect (%)
Define Pharmacovigilance.	94	6
The most important purpose of Pharmacovigilance is.	45	55
The health care professionals for reporting ADR in hospital are.	50	50
Do you know about existence of Pharmacovigilance program of India?	95	5
In India which regulatory body is responsible for monitoring ADRs?	22	78
Where is international center of Pharmacovigilance located?	94	6
Side effect occurring during pregnancy is called.	96	4
Rare ADR can be identified in which phase of Clinical Trial.	27	73
Where is National Pharmacovigilance center in India?	88	12
Is there any Pharmacovigilance Committee in your Institute?	98	2

Attitude

Total 46% students said that reporting ADR is professional obligation for them. 98% said that reporting ADR is necessary.95% said that Pharmacovigilance should be taught in detail to healthcare professionals. Only 37% students were agreeing about having Pharmacovigilance center in every hospital (Table 2).

Practice

Among students, 42% have read article on prevention of ADR. 25% have experienced ADR in patients during their clinical posting. 22% reported ADR to Pharmacovigilance center. 98% have seen ADR form. 95% have been trained on how to report ADR (Table 3)

Table 2: Attitude based questions.

Questions	Correct (%)	Incorrect (%)
Do you think ADR reporting is professional obligation for you?	46	54
Do you think reporting of ADR is necessary?	98	2
Do you think Pharmacovigilance should be taught in detail to healthcare professionals?	95	5
What is your opinion about establishing ADR monitoring center in every hospital?	37	63

Table 3: Practice based questions.

Questions	Yes (%)	No (%)
Have you read article on prevention of ADR?	42	58
Have you ever experienced ADR in patients during your clinical posting?	25	75
Have you ever reported ADR to Pharmacovigilance center?	22	78
Have you ever seen ADR form?	98	2
Have you ever been trained on how to report ADR?	95	5

Discussion

Table 4 shows comparison of knowledge and attitude- based questions with different studies. In our study, 94% students gave correct definition of pharmacovigilance. In a study conducted by Gupta et al this number was 62.5%.20 10 In our study, 98% students said that reporting of ADR is necessary. This was comparable by the study conducted by Gupta et al where correct answer was 96%. In our study, 95% students responded that Pharmacovigilance should be taught in detail to healthcare professionals. Similar response was obtained in the study conducted by Gupta et al, where the number was 92.1%. In our study, 88% gave correct location of pharmacovigilance center in India. In a study conducted by Meher et al only 34% gave correct answer about location of Pharmacovigilance center. Table 5 shows comparison of practice-based questions with different studies.[21,22]

Table 4: Comparison with results of other studies: knowledge and attitude-based questions.[20-22]

Questions	Our study (%)	Gupta et al[20](%)	Meher et al[22] (%)	Pimpalkhute et al[21] (%)
Define pharmacovigilance	94	62.4	41	67.85
Where is national pharmacovigilance center in India?	88	-	34	-
Do you know about existence of pharmacovigilance program of India?	94	75.2	-	38.4
The healthcare professionals for reporting ADR in hospital are.	50	-	40	-
Do you think ADR reporting is professional obligation for you?	46	69.3	23	35.2

Do you think reporting of ADR is necessary?	98	97	59	-
Do you think Pharmacovigilance should be taught in detail to healthcare professionals?	97	92.1	-	-

Table 5: Comparison with results of other studies: practice-based questions.[20,23,24]

Questions	Our study (%)	Gupta et al[20] (%)	Muraraiah et al[23] (%)	Desai et al[24] (%)
Have you ever experienced ADR in patients during your clinical posting?	27	64.4	85	60
Have you ever reported ADR to Pharmacovigilance center?	22	22.8	15	12.4
Have you ever been trained on how to report ADR?	95	53.5	-	-

Our study has several limitations including comprehensive and appropriate questionnaire adapted to Indian scenario, cross-sectional small sample size without randomization.

Conclusion

In our study most of the students gave correct answer of knowledge-based questions. So, knowledge of pharmacovigilance is gradually improving. The study will bring awareness among students towards Pharmacovigilance and help them in monitoring adverse drug effects.

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