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Original Research Article

Knowledge, attitude and practice of pharmacovigilance among medical students

Darshan Kharadi¹, Chintan M. Doshi^{2*}

¹Department of Pharmacology, Geetanjali Medical College, Udaipur, Rajasthan, India

²Department of Pharmacology, Pacific institute of Medical Sciences, Udaipur, Rajasthan, India

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***Correspondence:**

Dr. Chintan M. Doshi,

Email: doshichintan2@gmail.com

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ABSTRACT

Background: Spontaneous reporting of adverse drug reaction (ADR) is main part of pharmacovigilance. This study was done to assess knowledge, attitude and practice (KAP) of pharmacovigilance among 2nd year medical students.

Methods: This was a questionnaire based cross sectional study. The study participants were 2nd year MBBS students at pacific institute of medical sciences. Total number of questions given was 20. The data was analyzed by MS excel.

Results: Total 100 students were given 20 questions. 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. 95% students gave correct definition of pharmacovigilance. 96% students were having knowledge about existing National pharmacovigilance programme of India. 97% gave correct answer of side effect occurring during pregnancy as teratogenicity. 99 % said that reporting ADR is necessary.

Conclusions: In our study most of the students gave correct answers of knowledge-based questions. So, knowledge of pharmacovigilance is gradually improving among medical students.

Keywords: Pharmacovigilance, ADR, Knowledge, Attitude, Practice

INTRODUCTION

ADR is defined 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 Adverse effects are not rare; an incidence of 10–25% has been documented in different clinical settings.² Adverse drug effects are divided into: 1. predictable (type A or augmented) reactions, 2. unpredictable (type B or bizarre) reactions.² 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”.³ Their role in strengthening the Pharmacovigilance program by reporting ADRs that

would help increase patient safety cannot be overemphasized. Underreporting of ADRs is a common problem in the pharmacovigilance program.⁴ Findings from various studies have revealed that ADR reporting by healthcare providers is linked to their knowledge, attitude, and practice (KAP) about pharmacovigilance.⁵ Swedish study estimated that 3.1% of deaths in the general population were attributed to ADRs.⁶

METHODS

Total number of students

The total number of students in the study was 100.

Setting

This study was conducted at Pacific Institute of Medical sciences, Udaipur. The Duration of study was 2 months from November 2019 to December 2019.

Study design

This study was a cross-sectional questionnaire study. 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.⁷⁻¹⁰

RESULTS

Knowledge

95% students gave correct definition of pharmacovigilance. 46% students were aware that the most important purpose of pharmacovigilance is to identify safety of the drug. 96% students were having knowledge about existing National pharmacovigilance programme of India. Only 21% were aware about regulatory body responsible for monitoring ADRs in India, i.e. central drugs standard control organization (CDSCO). 97% gave correct answer of side effect occurring during pregnancy as teratogenicity (Table 1 and Figure 1).

Table 1: Knowledge based questions.

Questions	Correct (%)	Incorrect (%)
Define Pharmacovigilance.	95	5
The most important purpose of Pharmacovigilance is.	46	54
The health care professionals for reporting ADR in hospital are.	50	50
Do you know about existence of Pharmacovigilance program of India?	96	4
In India which regulatory body is responsible for monitoring ADRs?	21	79
Where is international center of Pharmacovigilance located?	95	5
Side effect occurring during pregnancy is called.	97	3
Rare ADR can be identified in which phase of Clinical Trial.	26	74
Where is National Pharmacovigilance center in India?	89	11
Is there any Pharmacovigilance Committee in your Institute?	99	1

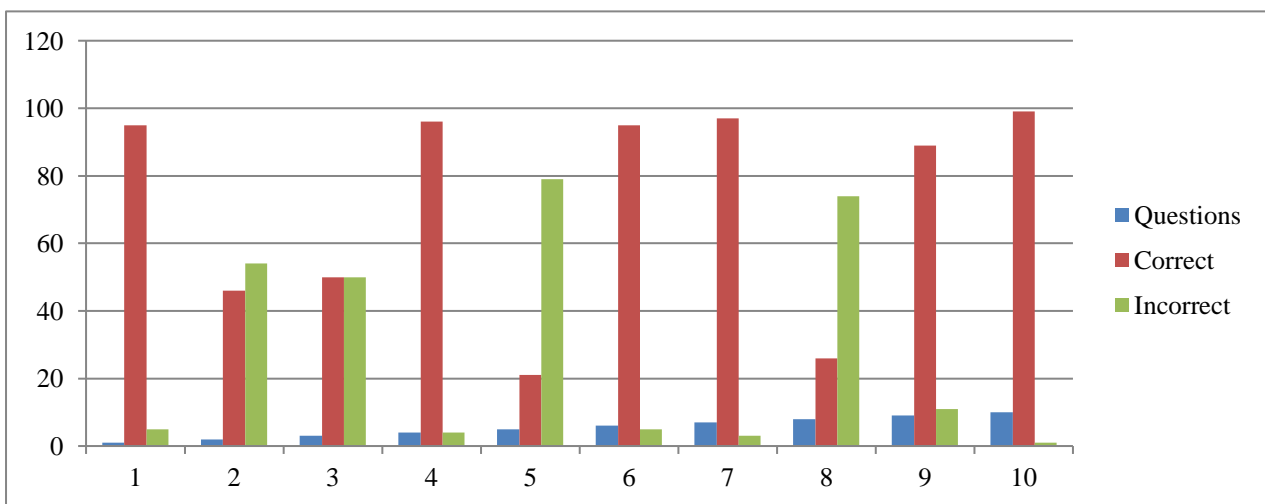


Figure 1: The percentage of responses of knowledge-based questions.

Attitude

Total 47% students said that reporting ADR is professional obligation for them. 99% said that reporting ADR is necessary. 96% said that Pharmacovigilance should be taught in detail to healthcare professionals. Only 36% students were agreeing about having Pharmacovigilance center in every hospital (Table 2 and Figure 2).

Practice

Among students, 41% have read article on prevention of ADR. 26% have experienced ADR in patients during their clinical posting. 21% reported ADR to Pharmacovigilance center. 99% have seen ADR form. 96% have been trained on how to report ADR (Table 3 and Figure 3).

Table 2: Attitude based questions.

Questions	Correct (%)	Incorrect (%)
Do you think ADR reporting is professional obligation for you?	45	55
Do you think reporting of ADR is necessary?	99	1
Do you think Pharmacovigilance should be taught in detail to healthcare professionals?	96	4
What is your opinion about establishing ADR monitoring center in every hospital?	36	64

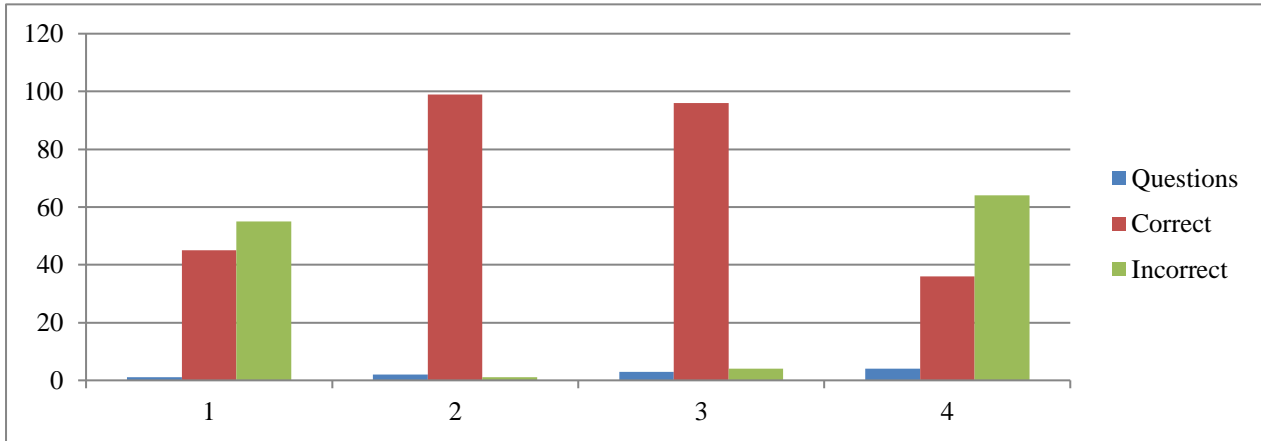


Figure 2: The percentage of responses of Attitude based questions.

Table 3: Practice based questions.

Questions	Yes (%)	No (%)
Have you read article on prevention of ADR?	41	59
Have you ever experienced ADR in patients during your clinical posting?	26	74
Have you ever reported ADR to Pharmacovigilance center?	21	79
Have you ever seen ADR form?	99	1
Have you ever been trained on how to report ADR?	96	4

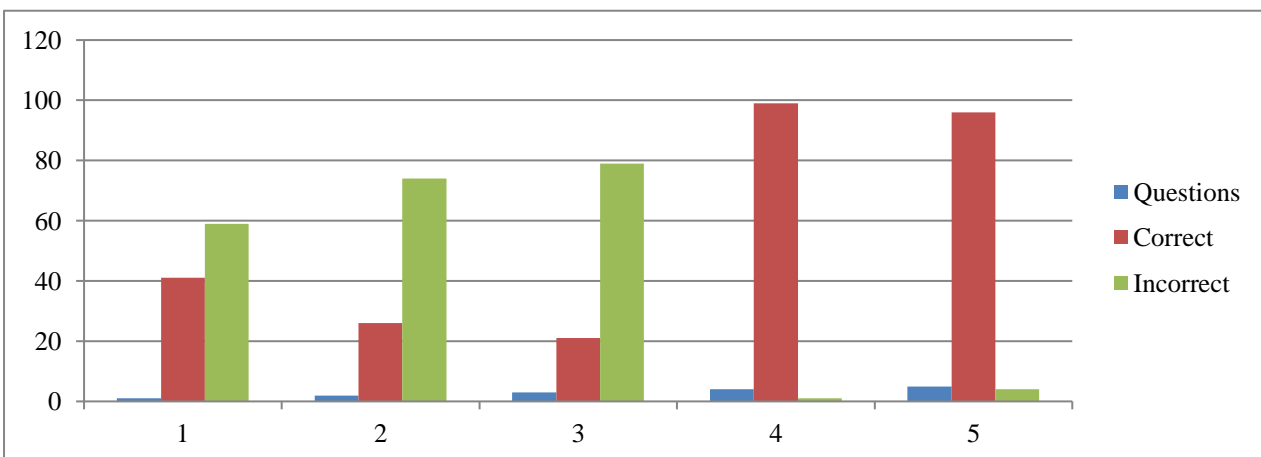


Figure 3: The percentage of responses practice based questions.

DISCUSSION

Table 4 shows comparison of knowledge and attitude-based questions with different studies. In our study, 95% students gave correct definition of pharmacovigilance. In a

study conducted by Gupta et al this number was 62.5%.¹⁰ In our study, 99% students said that reporting of ADR is necessary. This was comparable by the study conducted by Gupta et al where correct answer was 97%. In our study, 96% 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, 89% 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.^{11,12}

Table 4: Comparison with results of other studies: knowledge and attitude-based questions.¹⁰⁻¹²

Questions	Our study (%)	Gupta et al ¹⁰ (%)	Meher et al ¹² (%)	Pimpalkhute et al ¹¹ (%)
Define pharmacovigilance	95	62.4	41	67.85
Where is national pharmacovigilance center in India?	89	-	34	-
Do you know about existence of pharmacovigilance program of India?	96	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?	45	69.3	23	35.2
Do you think reporting of ADR is necessary?	99	97	59	-
Do you think Pharmacovigilance should be taught in detail to healthcare professionals?	96	92.1	-	-

Table 5: Comparison with results of other studies: practice-based questions.^{10,13,14}

Questions	Our study (%)	Gupta et al ¹⁰ (%)	Muraraiah et al ¹³ (%)	Desai et al ¹⁴ (%)
Have you ever experienced ADR in patients during your clinical posting?	26	64.4	85	60
Have you ever reported ADR to Pharmacovigilance center?	21	22.8	15	12.4
Have you ever been trained on how to report ADR?	96	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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Conflict of interest: None declared

Ethical approval: The study was approved by the Institutional Ethics Committee

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