

RESEARCH ARTICLE

Knowledge, attitude, and practice of pharmacovigilance among doctors in a tertiary care teaching hospital of Tripura

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ABSTRACT

Background: Adverse drug reactions (ADRs) are important causes of morbidity and mortality worldwide. Spontaneous reporting of ADRs is the cornerstone of pharmacovigilance (PV) and is important in maintaining patient safety. **Aims and Objective:** The study was conducted to assess the knowledge, attitude, and practice (KAP) of PV among doctors of a medical college hospital. **Materials and Methods:** It was a questionnaire-based cross-sectional study. A questionnaire containing 10 questions on knowledge, 11 questions on attitude, and 3 questions on practice of PV was utilized to assess the KAP among the doctors. The questionnaire was analyzed by using Microsoft excel spreadsheet and SPSS version 16 for statistical significance. **Results:** A total of 120 doctors completed and returned the questionnaire. 98 (81.67%) doctors knew the specific aim of PV. A large number of doctors (88.33%) were aware that doctors including dentists, nurses, and pharmacists can report ADR in India. 66 (55%) doctors considered reporting of ADR as voluntary. A total of 52 (43.33%) doctors strongly agreed that ADR reporting was a professional obligation and 8 (6.66%) doctors strongly disagreed to this. The causes of underreporting were concern that reporting could cause legal challenge (38.33%), report might be wrong (50%), lack of time (53.33%), lack of confidence (33.33%), and absence of fee for reporting (16.67%). This study revealed that 66 (55%) doctors did not report any ADR. **Conclusion:** The study suggests that there is a great need of educational intervention to improve awareness among health-care professionals regarding PV.

KEY WORDS: Adverse Drug Reactions; Pharmacovigilance; Knowledge; Attitude; Practice; Spontaneous Reporting

INTRODUCTION

Pharmacovigilance (PV) is the science and activities related to detection, assessment, understanding, and prevention of adverse effects or any other drug-related problems.^[1]

Adverse drug reactions (ADRs) are important causes of morbidity and mortality worldwide.^[2,3] ADRs account for

0.2-24% of all hospital admissions out of which 3.7% of patients have fatal ADRs.^[4]

Spontaneous reporting of ADRs has played a major role in the detection of unexpected ADRs which were not identified in preclinical studies and clinical trials (Phase I-III). This improves safety of drug use and has led to the withdrawal of many unsafe drugs such as rofecoxib, cisapride, and terfenadine in the recent past.^[5]

PV programme was started in India in 1982, but the awareness among health-care professionals about its existence is still poor.^[6] It is found that only 6-10% of all ADRs are reported.^[7,8] Underreporting remains a major obstacle in the complete success of PV programme.^[9] To improve the spontaneous reporting rate, it is essential to improve the knowledge,

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attitude, and practice (KAP) of the health-care professionals with regard to the ADR reporting and the PV.^[10]

This study was conducted to assess the KAP of PV among doctors of a medical college hospital.

MATERIALS AND METHODS

Study Design

This was a questionnaire-based cross-sectional study to evaluate the KAP among doctors working at Tripura Medical College and Dr. BRAM Teaching Hospital (TMC) toward ADRs and PV.

Study Site

The study was conducted at TMC, a 500 bedded tertiary care hospital located in the North Eastern Region of India. An ADR monitoring center is functioning in this institute since 2011 under PV Programme of India.

Inclusion and Exclusion Criteria

Doctors (faculties, residents, and postgraduate students) from all specialties working in the hospital during the study period were included, after obtaining an informed consent. Those who were not willing to participate or would not return the questionnaire within the stipulated time were excluded in the study.

Ethical Clearance

The study was conducted after obtaining approval from the Institutional Ethical Committee of TMC, Agartala.

Study Tools

A KAP questionnaire containing 24 questions (knowledge 10, attitude 11, and practice 3) was designed using the precedence set by similar studies^[11-13] to obtain information regarding the KAP of ADR reporting. The demographics of the respondents were analyzed from the provided information in the KAP questionnaire form.

The prescribers were encouraged to complete the questionnaire and to return it within 1 day to their respective departmental offices. Any clarification needed in understanding the questionnaire was provided.

Data Analysis

The filled KAP questionnaires were analyzed by Microsoft excel spreadsheet and SPSS version 16 was used to analyze the descriptive statistics.

RESULTS

In this cross-sectional study, a total of 120 doctors from different departments of the hospital were included. Among the total 120 doctors, 64 (53.33%) were senior (Professor, $n = 16$; Associate professor, $n = 16$; Assistant professor, $n = 32$) and 56 (46.67%) were junior (residents, $n = 36$; medical officer, $n = 8$; post-graduate students, $n = 12$) (Table 1).

Among the junior doctors, most of them ($n = 38$) were in the age group of ≤ 40 years and among senior doctors mostly ($n = 28$) in the age group of ≥ 60 years. Most of the doctors were male in both the categories ($n = 58$, senior doctors; $n = 40$, junior doctors).

Assessment of Knowledge about PV

Knowledge about the PV among the participants was assessed by the knowledge questionnaires, and the responses are shown in Figure 1 and Table 2.

Most of the doctors (112; 93.33%) gave the correct answer regarding definition of PV. 98 (81.67%) doctors knew the specific aim of PV. There was a significant difference ($P = 0.012$) between senior and junior doctors regarding knowledge about the aim of PV. A large number of doctors (88.33%) were aware that doctors including dentists, nurses,

Table 1: Demographic details of the health care professionals who participated in the KAP study on pharmacovigilance

Prescribers' Profile	Senior prescribers ($n=64$)	Junior prescribers ($n=56$)
Designation of prescribers		
Professor	16	-
Associate professor	16	-
Assistant professor	32	-
Residents	-	36
Medical officer	-	8
Postgraduate student	-	12
Age of the prescribers		
≤ 40 years	20	38
41-60 years	16	2
≥ 60 years	28	16
Gender		
Male	58	40
Female	6	16
Personnel suffering from ADR		
Suffered	14	14
Did not suffer	50	42

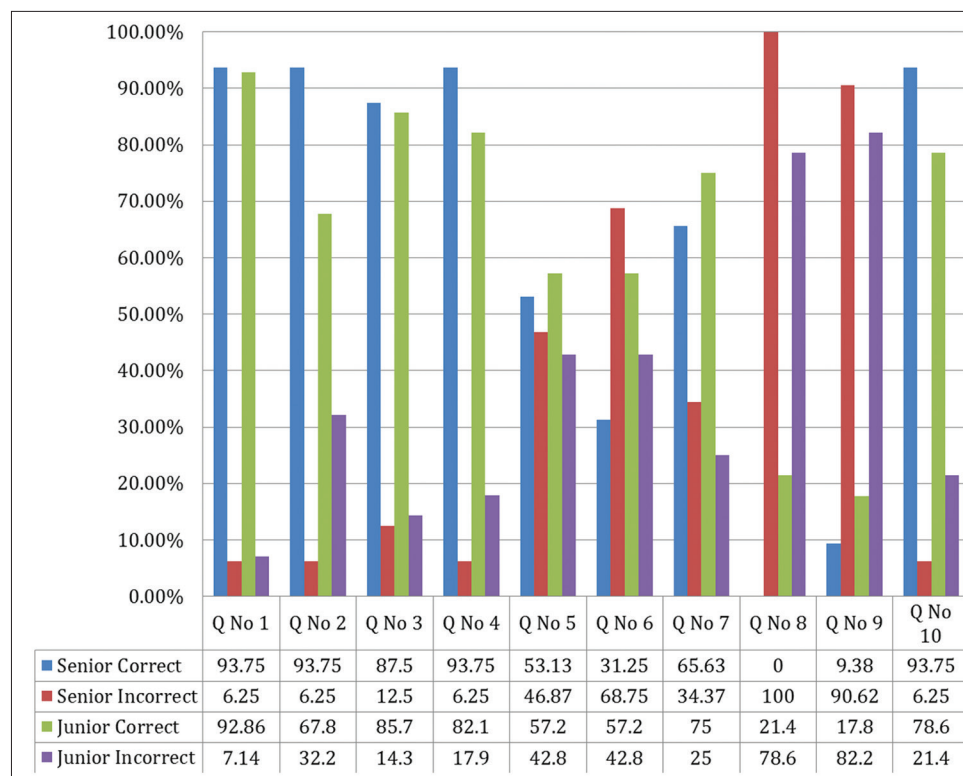


Figure 1: Assessment of knowledge of pharmacovigilance among prescribers

Table 2: Assessment of knowledge about pharmacovigilance among the prescribers

#Question (Q) Number (No)	Senior prescribers (n=64)		Junior prescribers (n=56)		Significance <i>P</i> value
	Correct (%)	Incorrect (%)	Correct (%)	Incorrect	
Q No. 1	60 (93.75)	4 (6.25)	52 (92.86)	4 (7.14)	0.445
Q No. 2	60 (93.75)	4 (6.25)	38 (67.8)	18 (32.2)	0.012
Q No. 3	56 (87.50)	8 (12.5)	48 (85.7)	8 (14.3)	0.419
Q No. 4	60 (93.75)	4 (6.25)	46 (82.1)	10 (17.9)	0.160
Q No. 5	34 (53.13)	30 (46.87)	32 (57.2)	24 (42.8)	0.479
Q No. 6	20 (31.25)	44 (68.75)	32 (57.2)	24 (42.8)	0.039
Q No. 7	42 (65.63)	22 (34.37)	42 (75)	14 (25)	0.305
Q No. 8	0 (0)	64 (100)	12 (21.4)	44 (78.6)	0.010
Q No. 9	6 (9.38)	58 (90.62)	10 (17.8)	46 (82.2)	0.280
Q No. 10	60 (93.75)	4 (6.25)	44 (78.6)	12 (21.4)	0.089

Q No. 1. Pharmacovigilance is the science that relates to the detection, assessment, understanding and prevention of

a. Genetic effects of drugs. b. Interaction of drugs. c. Adverse reaction of drugs. d. Pharmacokinetic properties of drugs.

Q No. 2. The specific aim of Pharmacovigilance is to improve

a. Patient care. b. Public health. c. Patient Safety. d. Patient compliance.

Q No. 3. The functions of National Pharmacovigilance Centre are all except

a. Collect reports of ADRs. b. Alert prescribers on ADRs. c. Analyse ADR reports. d. Penalise prescribers.

Q No. 4. Who can report an ADR in India?

a. Doctors including dentists. b. Nurses. c. Pharmacists. d. All of the above.

Q No. 5. Reporting of ADR in INDIA is

a. Mandatory. b. Voluntary. c. Compulsory. d. Regulatory.

Q No. 6. Which of the following scales is most commonly used to establish the causality of an ADR?

a. Hartwig scale. b. Naranjo algorithm. c. Schumock and Thornton scale. d. Karch & Lasagna scale

Q No. 7. Which of the following methods is commonly employed by the pharmaceutical companies to monitor ADRs of new drugs once they are launched in the market?

a. Meta-analysis. b. Post marketing Surveillance. c. Population studies. d. Regression analysis.

Q No. 8. A serious ADR in India should be reported to the regulatory body within

a. One day. b. Seven calendar days. c. Fourteen calendar days. d. Fifteen calendar days.

Q No. 9. Which of the following is a web based Individual Case Safety Report management system?

a. Medsafe. b. Vigibase. c. Medwatch. d. Vigiflow.

Q No. 10. In India which regulatory body is responsible for monitoring ADRs ?

a. Indian Institute of Sciences. b. Central Drugs Standard Control Organisation. c. Pharmacy council of India. d. Medical Council of India.

and pharmacists could report ADR in India. 66 (55%) doctors considered reporting of ADR as voluntary. Only 52 (43.33%) number of doctors knew about the scale to establish the causality of an ADR. There was a significant difference between senior and junior doctors regarding the knowledge of causality assessment scale ($P = 0.039$). All of the senior doctors were unaware of the time period when a serious ADR should be reported to the regulatory authority in India. Only 16 (13.33%) doctors gave the correct answer on web-based individual case safety report management system. Majority of the doctors (86.67%) had correct information about the regulatory body which is responsible for monitoring ADR in India.

Assessment of Attitude about PV

Assessment of attitude regarding ADR reporting among the doctors was assessed by Question No. 11-21. A total of 52 (43.33%) doctors strongly agreed that ADR reporting was a professional obligation and 8 (6.66%) doctors strongly disagreed to this (Table 3).

A total of 114 (95%) doctors were of the opinion that all ADRs should be reported and 6 (5%) of the doctors opined that only serious ADRs should be reported (Table 3).

92 (76.67%) doctors considered that ADR monitoring center should be in every hospital (Table 3).

Around 116 (96.67%) of the doctors agreed that PV should be taught in detail to health-care professionals. 74 (61.67%) doctors agreed that ADR reporting was the duty of pharmaceutical companies and legal medical authorities. 46 (38.33%) doctors considered that ADR reporting could cause legal challenges. 60 (50%) doctors were of the concern that report might be wrong. 64 (53.33%) doctors considered that physicians did not report ADRs due to a lack of time to fill in a report and a report would generate an extra work. 40 (33.33%) doctors agreed that physicians did not report ADRs because of lack of confidence and 20 (16.67%) doctors considered that physicians did not report ADRs due to the absence of fee for reporting (Table 3).

Assessment of Practice of PV

This study revealed that 66 (55%) doctors did not report any ADR in the past. Among the junior doctors only 16 (28.57%) reported ADRs. Among the senior doctors 38 (59.37%) reported ADRs and 26 (40.62%) did not report any ADR. Most of the doctors (80%) who reported ADRs did not maintain any log book on ADR (Table 4).

The main reasons for not reporting of ADRs were a lack of awareness about reporting procedures (37.83%), lack of knowledge about ADRs (16.21%), lack of time to report (13.51%), and lack of regulatory reporting system (2.70%).

Table 3: Assessment of attitude about pharmacovigilance among the prescribers

Attitude of prescribers	n (%)
Opinions on professional obligation of ADR reporting	
Strongly agree	52 (43.33)
Agree	42 (35)
Do not know	10 (8.33)
Disagree	8 (6.66)
Strongly disagree	8 (6.66)
Prescribers' opinion on types of ADR to be reported	
None	0
All ADRs	114 (95)
All serious ADRs	6 (5)
ADRs to new drugs	0
Unknown ADRs to old drugs	0
ADRs to herbal and non-allopathic drugs	0
ADRs to vaccines	0
Prescribers' opinion regarding establishing ADR monitoring center	
Should be in every hospital	92 (76.66)
Not necessary in every hospital	6 (5)
One in a city is sufficient	14 (11.66)
Depends on number of bed size in hospital	8 (6.66)
Reasons for under reporting of ADRs	
Concern that report may be wrong	60 (50)
Concern that it is the duty of pharmaceutical companies and legal medical authorities	74 (61.67)
Legal liability issues	46 (38.33)
Lack of time to fill in a report	64 (53.33)
Absence of fee for reporting	20 (16.67)
Report will generate an extra work	64 (53.33)
Lack of confidence	40 (33.33)

Reason for underreporting among junior doctors was mainly due to the fact that they did not encounter any ADR (29.72%). It was also found that 108 (90%) of the doctors did not undergo any training on ADR.

DISCUSSION

The pattern of drug use and ADRs in India is quite different due to socio-economic, ethnic, and nutritional, prevalence of diseases, and other factors. This type of study may suggest possible ways and educational intervention to improve the spontaneous reporting from the northeastern part of the country.^[14]

In our study, most of the doctors ($P = 0.012$) were aware regarding the specific aim of PV and this is similar to the result obtained by Hardeep et al.^[10] Majority of the doctors (88.33%) correctly answered that doctors including dentists,

Table 4: Assessment of practice about pharmacovigilance among the prescribers

Practice about pharmacovigilance	Yes (%)	No (%)
Do the prescribers report ADRs	45	55
Maintain log book on ADR	20	80
Counsel patients on ADR	88	12
Undergone any training on ADR	10	90

ADR: Adverse drug reaction

nurses, and pharmacists can report ADR in India. This finding is not comparable with the finding of Gupta and Udupa.^[15]

In this study, 86.67% of the participants could answer correctly the function of national PV center. This is contrast to the finding of Ray and Venugopal.^[16] 55% doctors answered that reporting of ADR in India is voluntary which is similar to the finding of Ray and Venugopal.^[16] It was observed that junior doctors were more aware regarding causality assessment scale as compared to senior doctors ($P = 0.039$).

Although the majority of doctors (78.33%) felt that ADR reporting is a professional obligation, but 13.32% doctors disagreed to this. It is comparable to the findings of Khan et al.^[17]

Desai et al.^[18] observed that the major reason of underreporting was ignorance about the reporting system. In this study, we have observed the most common reason (61.67%) for underreporting was due to the concern that ADR reporting was the duty of pharmaceutical companies and legal medical authorities. Various studies^[19,20] found that a main reason for underreporting of ADRs was the clinical negligibility of the adverse reaction, lack of time and little knowledge about the types of reactions to be preferentially reported. In our study, we have found that a large number of doctors 64 (53.33%) did not report ADRs due to lack of time to fill in a report, and a report would generate an extra work. We have seen that a large number of doctors (38.33%) considered ADR reporting could cause legal challenges.

About 60 (50%) doctors agreed that underreporting was mainly due to the concern that report may be wrong which is in agreement with the finding of the study done by Ray and Venugopal.^[16] Only 20 (16.67%) doctors considered that physicians did not report ADRs due to the absence of fee for reporting which is in contrary to the finding of Ray and Venugopal^[16] who found 54.7% doctors disagreed that absence of ADR reporting was due to lack of fee for reporting.

In this study, about one-third of junior doctors (29.72%) revealed that they had never encountered an ADR which is similar to the finding of Khan et al.^[17] We have found that 80% doctors did not maintain any log book on reported ADR which is in contrary to the finding of Kulkarni et al.^[14] It was found from this study that there was a lack of training

programme for doctors on ADR as only 12 (10%) doctors had received training on ADR.

Various studies have shown that enhancing knowledge, attitude, and practice of improving awareness can increase the number of ADR reports.^[21-23] Li et al. also showed that educational intervention improved awareness of knowledge, attitude, and practice of health-care professionals toward practice of PV.^[24,25]

CONCLUSION

In conclusion, underreporting of ADRs can be due to various reasons. The study suggests that there is a great need of educational intervention to improve awareness among doctors regarding PV. The ADR reporting can be made mandatory to improve the patient care as the majority of doctors felt that ADR reporting is important, but only a few had ever reported an ADR to the PV center.

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