Print ISSN: 2319-2003 | Online ISSN: 2279-0780

IJBCP International Journal of Basic & Clinical Pharmacology

DOI: http://dx.doi.org/10.18203/2319-2003.ijbcp20180662

Original Research Article

Knowledge, attitude and practice of medical professionals towards adverse drug reaction reporting and pharmacovigilance in a tertiary care hospital: a cross sectional study

Mangala Srinivas*, Sangeeta Nath Sharma, Rajendra Holla

Department of Pharmacology, K.S. Hegde Medical Academy, Nitte University, Mangaluru, Karnataka, India

Received: 20 December 2017
Accepted: 29 January 2018

***Correspondence to:**
Dr. Mangala Srinivas,
Email: mangalmng@gmail.com

ABSTRACT

Background: The present study was planned to assess the knowledge, attitude and practice of healthcare providers regarding adverse drug reaction reporting and pharmacovigilance in a tertiary care hospital.
Methods: The study was conducted in a tertiary care teaching hospital, it's a observational, KAP cross-sectional questionnaire-based study. The KAP questionnaires was developed toward pharmacovigilance and ADRs and were used to assess the medical professionals.
Results: Only 64% of doctors, 52% PG's and 40% of nurses knew the correct knowledge regarding Pharmacovigilance (PhV). Regarding the attitude, all the respondents think reporting of ADR is a very necessary. 98% of doctors,80% of postgraduates and 96% of nurses have experienced ADR in the patient in their professional practice but reporting of same is very less. The factors discouraging them from reporting ADR's was also assessed. 34% said difficult to decide whether ADR has occurred or not, 34% said lack of time, 17%- no remuneration and 15% said a single unreported case may not affect ADR database.
Conclusions: This study demonstrated that knowledge and attitude towards pharmacovigilance is gradually improving among medical professionals, but unfortunately the actual practice of ADR reporting is still deficient among them.

Keywords: Attitude, Adverse drug reaction, Knowledge, Practice, Pharmacovigilance

INTRODUCTION

Newer medicines have changed the way in which diseases are treated and prevented. However, inspite of all their benefits, adverse effects due to medicines are common cause of morbidity and mortality.[1] Pharmacovigilance (PV) is the sum of activities related to the detection, assessment, understanding, and prevention of adverse drug reaction (ADRs) caused by drugs.[2]

The World Health Organization (WHO) defines ADR's as 'any noxious, unintended, and undesired effect of a drug, which occurs at doses used in humans for prophylaxis, diagnosis, or treatment of the disease'. The worldwide incidence of ADR occurrence leading to emergency hospitalization ranges from 0.2 to 41.3%, while 28.9% of these ADR's are preventable.[3]

The success of a pharmacovigilance program depends upon the active involvement of the healthcare professionals such as doctors, pharmacist, nurses. Spontaneous ADR reporting is important to monitor known and unknown adverse effects of medicines. A knowledge, attitude and practice (KAP) analysis may help us in understanding the reasons for under-reporting and in developing strategies for improving ADR monitoring as well as reporting.[4]

In India, the national Pharmacovigilance Programme of India (PvPI) was established by the Central Drugs Standard Control Organization (CDSCO) in 2004 to monitor ADRs and to provide drug safety reports to the WHO-ADR monitoring center in Uppsala, Sweden.[5]

To co-ordinate ADR monitoring throughout India, the Drug Controller General of India (DCGI) and Indian Council of Medical Research (ICMR) have established many peripheral Pv centers in various hospitals located in major Indian cities.[6]

Although many studies in India have evaluated the KAP of pharmacovigilance among the healthcare professionals, it is crucial to conduct similar studies and to assess the causation of underreporting of ADRs in teaching hospital in India.[7] Adverse Drug Reactions (ADRs) are associated with a significant morbidity and mortality. Spontaneous reporting of ADR is the cornerstone of pharmacovigilance. Underreporting of ADR is a huge problem due to lack of reporting knowledge amongst healthcare professionals.[8]

This study is aimed to investigate the knowledge, attitude, and practices (KAP) of doctors, postgraduates (PG's) and nurses about PhV and ADR reporting.

METHODS

The study was conducted in a tertiary care teaching hospital in Mangalore, India. It is a prospective, observational, KAP cross-sectional questionnaire-based study.

Convenient sampling method is used in which medical professionals (Doctors, PGs and Nurse) where, 100 each from all groups were enrolled in the study.

Before the study

The KAP questionnaires toward pharmacovigilance and ADRs were developed and peer viewed of all questions by expert faculties from pharmacology department in the institute. These questions were designed based on earlier studies for assessing KAP of ADR reporting. KAP questionnaire is designed to assess the knowledge of pharmacovigilance, attitudes towards pharmacovigilance, and their practice on ADR reporting in doctors, postgraduates and nurses. There are 20 questions in all (seven related to knowledge, four related to attitude, and eight related to practice). This study was approved by the institutional ethical committee.

Details and purpose of the study was explained to all the medical professionals and informed consent will be taken. And then the questionnaires were handed over and later collected after 30 min. Any clarification needed in understanding the questionnaires and additional time to fill form was provided. Those respondents who were busy at that moment were requested to return back the duly filled form within 1-week. The collected data was statistically analysed later.

RESULTS

All the doctors, postgraduates (PG) and nurses enrolled from different medical and surgical disciplines completed the questionnaire.

Most of the respondents knew the existence of National Pharmacovigilance (PhV) programme in India, but only 64% of doctors, 52% PG's and 40% of nurses knew the correct definition of PhV. Around 65% of doctors had obligation in reporting an ADR, while in PG's and nurses this was comparatively less (Table 1).

Table 1: Comparison of knowledge of doctors (N = 100), post graduates (N = 100) and nurses (N = 100) regarding pharmacovigilance and adverse drug reaction.

Questions	Correct responses (%)		
	Doctors	Postgraduates	Nurses
Define Pharmacovigilance: The detection, assessment, understanding and prevention of adverse effects.	64	52	40
The most important purpose of pharmacovigilance is to identify previously unrecognized ADR's	50	44	36
Do you think ADR reporting is professional obligation for you?			
Yes	65	45	47
No	35	55	53
The healthcare professionals responsible for reporting ADRs in a hospital is/are?	82	74	44
Existence of a National Pharmacovigilance Programme in India?	94	95	78
In India which regulatory body is responsible for monitoring ADRs?	73	66	47
Where the international center for adverse drug reaction monitoring is located?	58	62	36

Regarding the attitude, all the respondents think reporting of ADR is a very necessary and they wanted to be taught in detail about PhV and reporting of ADR's. 94% of doctors think that ADR monitoring centre is must for every

hospital and 78% of PG's and 47% of nurses also agree onto this (Table 2).

Table 2: Comparison of attitude of doctors (N = 100), post graduates (N = 100) and nurses (N = 100) toward monitoring and reporting ADRs.

Questions	Correct responses (%)		
	Doctors	Postgraduates	Nurses
Do you think reporting of adverse drug reaction is necessary?	100	100	98
Do you think Pharmacovigilance should be taught in detail to healthcare professionals? Yes	97	92	88
Have you anytime read any article on prevention of adverse drug reactions? Yes	74	52	27
What is your opinion about establishing ADR monitoring centre in every hospital?	94	78	47
Have you ever experienced adverse drug reactions in your patient during your professional practice?	98	80	96

Table 3: Comparison of practices of resident doctors (N=100), post graduates (N =100) and nurses (N=100) toward ADR monitoring and reporting.

Questions	Correct responses (%)		
	Doctors	Postgraduates	Nurses
Have you ever reported ADR to the Pharmacovigilance centre?			
Yes	38	24	15
No	58	66	64
Don't know where to submit the ADR reporting form	4	8	9
Don't know how to fill up the ADR reporting form	0	2	12
Have you ever seen the ADR reporting form? Yes	95	97	86
No	5	3	14
Have you ever been trained on how to report Adverse Drug Reaction (ADR)?			
Yes	14	5	8
No	86	95	92
A serious adverse event in India should be reported to the regulatory body within fifteen calendar days	43	28	17
Rare ADRs can be identified in the - Phase-4 of a clinical trial	76	58	38
Which of the following methods is commonly employed by the healthcare professional to monitor adverse drug reactions of new drugs once they are launched in the market?	57	33	15
Is there any Pharmacovigilance Committee in your Institute? Yes	86	65	74

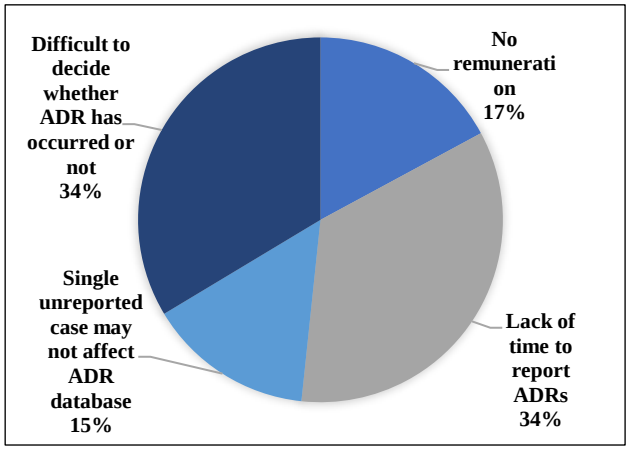

Figure 1: Factors for underreporting in medical professionals.

98% of doctors and 96% of nurses have experienced ADR but reporting of such ADR to the PhV centre was less. Very few of them didn't know where to submit the ADR reporting form and how to fill the form. Most of the respondents (avg- 94%) had seen an ADR form. A serious adverse event should be reported to the regulatory body within fourteen calendar days, and 43% of doctors and very few PG's and nurses knew the correct answer. Doctors (76%), PG's (58%) and nurses (38%) knew that a rare ADR's can be identified through phase 4 clinical trials. 57% of doctors knew that spontaneous reporting system is commonly employed to monitor ADR of new drugs once in market and very few PG's and nurses had knowledge regarding this (Table 3).

The factors discouraging them from reporting ADR's (in total the opinion was taken) 34% of them had difficult to

decide whether ADR has occurred or not, 34% said lack of time to report ADR, 17% no remuneration was given and 15% said a single unreported case may not affect ADR database (Figure 1).

DISCUSSION

The present study was a questionnaire-based study which assessed the KAP of doctors, postgraduates and nurses towards ADR and pharmacovigilance. A number of studies suggest that physicians attitude toward ADR reporting is a significant determinant of the reporting rate.[7,8] The existence of National Pharmacovigilance (PhV) programme in India was known to almost all the respondents. The doctors and PG's had better knowledge regarding PhV compared to nurses. This was in contrast to results seen in other studies showing where doctors had a better knowledge.[9-11]

98% of doctors and 96% of nurses have experienced ADR in their professional practice but reporting of such ADR to the PhV centre was 38% in doctors, 24% in PG's and 15% in nurses, which is significantly less compared to the occurrence of ADR's. Similar results were seen in the study conducted by Palaian et al, 70.8% of the health care providers (doctors, nurses and pharmacists) felt that ADR reporting should be made mandatory and a study showed only 15% of respondents had reported an ADR previously.[12,13]

Most of the medical professionals had seen an ADR form, but very few were trained on how to fill and report it to the PhV centre. This was similar in comparison with other study 71% of the physicians did not know where and how to report an ADR whereas, in a study shows 50% and 89% of respondents respectively knew about reporting center.[10,14,15]

When the healthcare providers were questioned about the factors discouraging them from reporting ADR's, most of postgraduates and nurses had difficult to decide whether ADR has occurred or not, most of doctors and PG's said lack of time as a reason to report ADR, few of nurses said no remuneration was given for reporting and some respondents said a single unreported case may not affect ADR database. The results were similar to a study showing that nearly one-fourth didn't report fearing legal liabilities, difficulty diagnosing ADR and negative impact on doctors.[11]

In this study, all of medical professionals are ignorant of various aspects of pharmacovigilance and adverse drug reactions. When the KAP scores were compared between the groups nurses scored lesser than doctors and PG's. whereas, nurses need to be trained adequately because ADR comes first to their notice and they are always in contact with the patients.

Therefore, the study suggests that there is need for continuous education and training to improve the knowledge. And give financial incentives or acknowledgement note on reporting ADRs might change the attitudes towards pharmacovigilance and ADR reporting system among the healthcare providers. And compulsorily keeping an ADR reporting form in all patient file at the hospital will be more helpful in reporting of the same. Which might help in improving the ongoing pharmacovigilance activities in at the hospital.

CONCLUSION

This study concluded that healthcare professionals had good knowledge and positive attitude towards pharmacovigilance and ADR reporting, but unfortunately the actual practice of ADR reporting is still deficient among them. The reporting of ADR's can be achieved with a combined effort by all the medical professionals, which can be improved by adequate training and motivation.

ACKNOWLEDGEMENTS

Authors would like to acknowledge the help of all the medical professionals and management of Justice K.S. Hegde charitable Hospital, Deralakatte, Mangaluru, India.

Funding: No funding sources
Conflict of interest: None declared
Ethical approval: The study was approved by the Institutional Ethics Committee

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Cite this article as: Srinivas M, Sharma SN, Holla R. Knowledge, attitude and practice of medical professionals towards adverse drug reaction reporting and pharmacovigilance in a tertiary care hospital: a cross sectional study. Int J Basic Clin Pharmacol 2018;7:486-93.

APPENDIX

Pharmacovigilance Questionnaire

Profession: ……....

(Please sign to consent)

Please tick on the most appropriate option.

1. Define Pharmacovigilance.

(a) The science detecting the type and incidence of ADR after drug is marketed

(b) The science of monitoring ADR's occurring in a Hospital

(c) The process of improving the safety of the drug

(d) The detection, assessment, understanding and prevention of adverse effects

2. The most important purpose of Pharmacovigilance is

(a) To identify safety of the drug

(b) To calculate incidence of ADRs

(c) To identify predisposing factors to ADR's

(d) To identify previously unrecognized ADR's

3. Do you think ADR reporting is professional obligation for you?

(a) Yes (b) No

4. The healthcare professionals responsible for reporting ADRs in a hospital is/are

(a) Doctor (c) Pharmacist

(b) Nurses (d) All of the above

5. Do you know regarding the existence of a National Pharmacovigilance Programme in India?

(a) Yes (b) No

6. In India which regulatory body is responsible for monitoring ADRs?

(a) Central Drugs Standard Control Organization (CDSCO)

(b) Indian Council of Medical Research (ICMR)

(c) Indian Clinical Research Institute (ICRI)

(d) Medical Council of India (MCI)

7. Where the international centre for adverse drug reaction monitoring is located?

(a) Unites States of America (b) United Kingdom

(c) France (d) Sweden

8. Do you think reporting of adverse drug reaction is necessary?

(a) Yes (b) No

9. Do you think Pharmacovigilance should be taught in detail to healthcare professionals?

(a) Yes (b) No

10. Have you anytime read any article on prevention of adverse drug reactions?

(a) Yes (b) No

11. What is your opinion about establishing ADR monitoring centre in every hospital?

(a) Should be in every hospital

(b) Not necessary in every hospital

(c) One in a city is sufficient

(d) Depends on number of bed size in the hospitals

12. Have you ever experienced adverse drug reactions in your patient during your professional practice?

(a) Yes (b) No

13. Have you ever reported ADR to the Pharmacovigilance centre?

(a) Yes

(b) No

(c) Don't know where to submit the ADR reporting form

(d) Don't know how to fill up the ADR reporting form

14. Have you ever seen the ADR reporting form?

(a) Yes (b) No

15. Have you ever been trained on how to report Adverse Drug Reaction (ADR)?

(a) Yes (b) No

16. A serious adverse event 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

17. Rare ADRs can be identified in the following phase of a clinical trial

(a) During phase-1 clinical trials (b) During phase-2 clinical trials

(c) During phase-3 clinical trials (d) During phase-4 clinical trials

18. Which of the following methods is commonly employed by the healthcare professional to monitor adverse drug reactions of new drugs once they are launched in the market?

(a) Meta-analysis (b) Spontaneous reporting system

(c) Population studies (d) Regression analysis

19. Is there any Pharmacovigilance Committee in your Institute?

(a) Yes (b) No

(c) Not yet formed (d) Don't know

20. Which of the following factor discourage you from reporting ADRs?

(a) No remuneration

(b) Lack of time to report ADR

(c) A single unreported case may not affect ADR database

(d) Difficult to decide whether ADR has occurred or no