

Pharmacovigilance: a study to evaluate knowledge, attitude, and practices of and impact of educational intervention among doctors in teaching hospital, in rural area of Jalna, India

Ajay R. Chandrakapure*, Sapna P. Giri, Imran N. Khan, Mohammed Mateenuddin, Mohammed Faheem

Department of Pharmacology,
IIMSR, Warudi, Jalna,
Maharashtra, India

Received: 04 March 2015

Accepted: 24 April 2015

***Correspondence to:**

Dr. Ajay R. Chandrakapure,
Email: drajayrc3412@gmail.com

Copyright: © the author(s), publisher and licensee Medip Academy. This is an open-access article distributed under the terms of the Creative Commons Attribution Non-Commercial License, which permits unrestricted non-commercial use, distribution, and reproduction in any medium, provided the original work is properly cited.

ABSTRACT

Background: According to WHO Pharmacovigilance is “The science and activities which are related to the detection, assessment, understanding, and the prevention of adverse effects or any other drug-related problems.” A majority of India’s population prefers government hospitals when they are in need of health care facilities. The patients also prefer other available free health care facilities. Hence, these hospitals can be a good source for generating an adverse drug reactions database. However, the Herculean task is to foster a culture of reporting among the doctors, especially among the junior doctors, as they are more closely associated with the patient care, hence the present study to assess awareness of pharmacovigilance among the doctors and to evaluate the impact of an educational intervention for improving awareness of pharmacovigilance among doctors in an Indian tertiary care teaching hospital.

Methods: A suitable self-administered knowledge, attitude, practice (KAP) survey questionnaire was designed, based on previous studies. An interventional educational activity was organized and the impact of the educational Intervention was evaluated by again administering the similar questionnaire. The statistical analysis was carried for comparing the pre- and post-intervention.

Results: It was seen that the KAP of pharmacovigilance among doctors is low. The results also showed that there was an improvement after the educational intervention.

Conclusions: The KAP of pharmacovigilance is low among doctors and educational intervention can improve it.

Keywords: Pharmacovigilance, Knowledge, Attitude, Practices, Educational intervention

INTRODUCTION

Pharmacovigilance is a science and activities relating to detection, assessment, understanding, and prevention of adverse effects or any other drug-related problems WHO.¹ Although India are participating in the program. Its Contribution to Uppsala Monitoring Centre (UMC), Sweden is very little.²

Adverse drug reactions (ADR) accounts for 0.2-24% of hospital admissions, 3.7% of patients have fatal ADRs. ADR leads to number of medical and economic consequences like prolong hospital stay; increase the cost of treatment and risk of death also increases.³

In a country like India, with a large population and vast diversity, it is necessary to introduce a standard pharmacovigilance program.⁴ Though pharmacovigilance program was started in India in 1982, the awareness about it is much lower.³ It was revived in 2010 and a 5 years road map has been planned.

Few studies had been carried out in different countries to assess the knowledge of Pharmacovigilance among the medical students and practitioners. For e.g., the studies conducted in U.K., France, and Nigeria showed that a majority lacked knowledge on pharmacovigilance.⁴ Studies from different settings indicate inadequate knowledge about Pharmacovigilance among healthcare professionals as well as attitudes that are associated with a high degree of underreporting.⁵⁻⁷

Pharmacovigilance is still in its infancy in India and there exists very limited knowledge about this discipline.⁸ Several studies carried out in India have concluded that there is a lack of knowledge and awareness about pharmacovigilance among doctors, practitioners, and students.

Hence, the present study was carried out to assess knowledge, attitude, and practices (KAP) of pharmacovigilance and to create awareness about pharmacovigilance among the doctors.

METHODS

Study design

This was a cross-sectional, questionnaire-based study which was conducted in a tertiary care hospital Indian Institute of Medical Sciences and Research, Warudi, Jalna, Maharashtra.

The study instrument was a pre-designed questionnaire and it was prepared by the faculty of the Department of Pharmacology based on previous studies.^{3,4,8}

Study population

For the study purpose, 50 doctors were included and given KAP questionnaire. The doctors were instructed not write their names so that their identity was not revealed so as to avoid any kind of bias.

Study procedure

The KAP questionnaire included twenty questions (Table 1). A pre-test was conducted they were given 20 min to answers the questions. A CME on pharmacovigilance was conducted by Department of Pharmacology and (an Educational intervention), i.e., a seminar was given by senior Professor of Pharmacology.

The impact of effectiveness of educational intervention among health care professionals was evaluated by means of post-KAP questionnaire survey, with reference to previous study.⁸

Statistical analysis

The results were calculated by using MS Excel spreadsheet and expressed in terms of percentage of observations.

RESULTS

It was seen that the knowledge, awareness, and practice of pharmacovigilance among doctors are low. The results also showed that there was an improvement after the educational intervention.

DISCUSSION

Pharmacovigilance is an integral and essential part of patient care. However, underreporting of ADRs is one of the major problems associated with pharmacovigilance programs. Even in countries like UK where Pharmacovigilance programs are well established, a high level of underreporting is documented.³

Some Indian studies e.g., by Rehan et al.⁹ which was conducted at the Lady Harding Medical College, New Delhi, showed that the knowledge, attitude, and the practices of both the undergraduates and the prescribers were comparable, but they needed further improvement.⁹ A similar study by Desai et al.¹⁰ which was conducted at the Civil Hospital, Ahmedabad, concluded that under-reporting and a lack of knowledge about the reporting system were clearly evident among the prescribers. In other studies like Kulkarni et al.,³ it was seen that the major reasons for underreporting of ADRs are lack of knowledge about the reporting procedure, unavailability of reporting center, mailing addresses, unavailability of ADR report form, lack of knowledge of the existence of a national ADR reporting system, the belief that ADR in question was already well known, ADR is not serious, uncertainty concerning the causal relationship between the ADR and drug, forgetting to report the ADR and lack of time, ignorance of reporting procedure.³

In the present study, it was seen that (Table 1) the knowledge about pharmacovigilance (e.g., its definition scope, reporting systems) was low. Regarding awareness (e.g., article reading, prevention of ADRs, how to report ADR, giving ADR information to the patients) results show that the percentage of awareness is also less. About practices (e.g., trained, keeping ADR reports) it was found to be low. Therefore, our study supports the claims of previous studies.^{3,9,10}

Conducting CME on pharmacovigilance and giving training to prescribers about pharmacovigilance seems to be an immediate necessity. The training program should cover the location of pharmacovigilance centers, reporting procedure and method of filling ADR reporting form, according to Kulkarni et al., the participants of the study by Sushma et al.,¹¹ stated that reporting of ADRs can be improved by increasing the awareness by educational programs, which was also seen in other studies from Portugal¹² and Nigeria.¹³ A study by Sushma et al.,¹¹ also suggested that providing more ADR forms would improve reporting rate which is inconsistent with another study by Castel et al.,¹⁴ Li et al.,¹⁵ showed that educational intervention improved awareness of knowledge, attitudes, practice of healthcare professionals toward practice of pharmacovigilance.

In our study (an Educational intervention), i.e., CME was conducted by Department of Pharmacology and the ADR forms were distributed. The result showed that there was an improvement in knowledge and attitude of pharmacovigilance after the educational intervention and would also improve

Table 1: Results.

S. No	KAP questionnaire	CME Response, N=50, n(%)	
		Pre	Post
1.	Define pharmacovigilance? (most appropriate any one only)		
	a) The science of monitoring ADR's happening in a Hospital	4 (8)	4 (8)
	b) The process of improving the safety of drugs	5 (10)	4 (8)
	c) *The detection, assessment, understanding, and prevention of adverse effects	33 (66)	40 (80)
	d) The science detecting the type and incidence of ADR after drug is marketed	8 (16)	2 (4)
2.	Aim of the pharmacovigilance is to assess?		
	a) *Safety	44 (88)	48 (96)
	b) Efficacy	6 (12)	1 (2)
	c) Cost	0 (0)	0 (0)
	d) None	0 (0)	1 (2)
3.	Pharmacovigilance includes		
	a) Drug-related problems	29 (58)	7 (14)
	b) Blood related products	2 (4)	1 (2)
	c) Herbal products	19 (38)	0 (0)
	d) *All of the above	0 (0)	42 (84)
4.	Is ADR and ADE same?		
	Yes	6 (12)	9 (18)
	*No	44 (88)	41 (82)
5.	The commonly seen ADRs such as headache, fever, vomiting has to be reported?		
	*Yes	23 (46)	41 (82)
	No	27 (54)	9 (18)
6.	Does ADR reporting have any specific format?		
	*Yes	41 (82)	46 (92)
	No	9 (18)	4 (8)
7.	In India which regulatory body is responsible for monitoring of ADR's?		
	a) *Central Drugs Standard Control Organization	38 (76)	46 (92)
	b) Indian Institute of Sciences	1 (2)	2 (4)
	c) Pharmacy Council of India	6 (12)	2 (4)
	d) Medical Council of India	5 (10)	0 (0)
8.	The international center for ADR monitoring is located in?		
	a) United States of America	28 (56)	5 (10)
	b) Australia	3 (6)	1 (2)
	c) France	4 (8)	1 (2)
	d) *Sweden	15 (30)	43 (86)
9.	The healthcare professionals responsible for reporting ADR in a hospital is/are?		
	a) Doctor	11 (22)	3 (6)
	b) Pharmacist	1 (2)	1 (2)
	c) Nurses	1 (2)	1 (2)
	d) *All of the above	37 (74)	45 (90)
10	Which among the following factors discourage you from reporting ADR? (Anyone only)		
	a) Non-remuneration for reporting	8 (16)	6 (12)
	b) Lack of time to report ADR	16 (32)	18 (36)
	c) A single unreported case may not affect ADR database	6 (12)	7 (14)
	d) Difficult to decide whether ADR has occurred or not.	19 (38)	19 (38)

Contd...

Table 1: (Continue)

S. No	KAP questionnaire	CME Response, N=50, n(%)	
		Pre	Post
11.	Do you think reporting of ADR is necessary?		
	Yes	43 (96)	49 (98)
	No	2 (4)	1 (2)
12	Is there a need to include pharmacovigilance in undergraduate curriculum to create awareness among the budding Doctors?		
	Yes	46 (92)	50 (100)
	No	4 (8)	0 (0)
13.	Do you think pharmacovigilance should be taught in detail to healthcare professionals?		
	Yes	45 (90)	50 (100)
	No	5 (10)	0 (0)
14.	Have you anytime read any article on prevention of ADR?		
	Yes	27 (54)	50 (100)
	No	23 (46)	0 (0)
15.	Have you ever been trained on how to report ADR?		
	Yes	13 (26)	50 (100)
	No	37 (74)	0 (0)
16.	Do you give ADR information of prescribed drug?		
	Yes	21 (42)	39 (78)
	No	29 (58)	11 (22)
17.	Have you ever come across with an ADR?		
	Yes	35 (70)	37 (74)
	No	15 (30)	13 (26)
18.	Have you reported ADR at any time?		
	Yes	16 (32)	12 (24)
	No	34 (68)	38 (76)
19.	Do you keep the records of ADR?		
	Yes	11 (22)	19 (38)
	No	39 (78)	31 (62)
20.	Are you willing to make ADR reporting?		
	Yes	44 (88)	48 (96)
	No	6 (12)	2 (4)

ADR: Adverse drug reactions, ADE: Adverse drug event, KAP: Knowledge, attitude, practice, Note-(*): Indicates correct answer (regarding knowledge)

practices of pharmacovigilance. The findings of the present study are similar to previous study.^{3,11,12,15}

According to Sushma et al.¹¹ The reasons for not reporting an ADR were mainly lack of facilities (50%), followed by the belief that ADR in question is well known (33%), lack of knowledge (12%), and lack of time (6%). Though the teaching faculty felt that the facilities for reporting ADRs needs to be improved, the students were in doubt that the ADR to be reported was well known. This indicates that the students may need more training about what needs to be reported to the ADR center.¹¹ A study by Li et al.,¹⁵ reported lack of facilities and knowledge to be the main reasons for

not reporting ADR. Another Indian study by Gupta¹⁶ from Mumbai stated lack of clinical knowledge to identify ADR and its reporting were the main reasons for under-reporting.

A study conducted by Salehifa et al.¹⁷ in which there is a lack of satisfactory knowledge of pharmacovigilance among nurses and pharmacists should educate nursing staff in reporting and managing ADRs. A study by Clarkson et al.¹⁸ showed that establishment of a proactive scheme like regional pediatric ADR monitoring center in Trent, UK successfully increased the reporting of suspected ADRs in that region and also improved awareness toward drug surveillance in children. A similar type of focused approach for drug surveillance

for children was also shown to be very successful in North America by Carleton et al.¹⁹

Therefore from findings of the present study and previous studies it can be summarized that the knowledge, awareness, and practice of pharmacovigilance among doctors are low and several steps like educational intervention (conducting CME) on pharmacovigilance for doctors, adding pharmacovigilance to the undergraduate curriculum, teaching pharmacovigilance to nurses and pharmacist, setting up of a regional pharmacovigilance center can bring about improvement in the field of pharmacovigilance. This can help to improve ADR reporting and which in turn will lead to decrease in medical and economic consequence due to ADRs, i.e., it will lead to decrease in hospital stay, decrease in cost of treatments and risk of deaths attributed to ADRs. The above-mentioned interventions can minimize the risks and maximize the safety of patient's health and strengthen the working of pharmacovigilance of the country and world over under main Pharmacovigilance Center (UMC, Sweden).

CONCLUSIONS

- 1) The knowledge awareness and practices of Pharmacovigilance is low among doctors.
- 2) Educational intervention (CME) on Pharmacovigilance can improve knowledge, awareness, and practices.
- 3) It will minimize the risk to patient's health and improves the safety of patient's health.

Hence, this type of study and educational intervention can strengthen the working of pharmacovigilance of the Nation and at International level.

ACKNOWLEDGMENTS

Authors would like to acknowledge support from Dr. A.B. Solepure, Dean, IIMSR, Warudi, Jalna and Dr. Quadri R.M., Medical Superintendent, IIMSR, Warudi, Jalna.

Funding: No funding sources

Conflict of interest: None declared

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

REFERENCES

1. WHO. The Importance of Pharmacovigilance. Geneva: World Health Organization; 2002.
2. Hardeep, Bajaj JK, Rakesh K. A survey on the knowledge, attitude and the practice of pharmacovigilance among the health care professionals in a teaching hospital in northern India. J Clin Diagn Res. 2013;7(1):97-9.
3. Kulkarni MD, Baig MS, Chandaliya KC, Doifode SM, Razvi SU, Sidhu NS. Knowledge, attitude and practice of pharmacovigilance among prescribers of government medical college and hospital, Aurangabad (Maharashtra). Int J Pharm Ther. 2013;3(3):10-8.
4. Hema NG, Bhuvana KB, Sangeetha. The extent of awareness

- among the final year students, interns and postgraduates in a government teaching hospital. J Clin Diagn Res. 2012;6(7):1248-53.
5. Williams D, Feely J. Underreporting of adverse drug reactions: attitudes of Irish doctors. Ir J Med Sci. 1999;168(4):257-61.
6. Perlik F, Slanar O, Smid M, Petráček J. Attitude of Czech physicians to adverse drug reaction reporting. Eur J Clin Pharmacol. 2002;58(5):367-9.
7. Belton KJ, Lewis SC, Payne S, Rawlins MD, Wood SM. Attitudinal survey of adverse drug reaction reporting by medical practitioners in the United Kingdom. Br J Clin Pharmacol. 1995;39(3):223-6.
8. Radhakrishnan R, Sudha V, Varma DM. An educational intervention to assess knowledge, attitude, practice of pharmacovigilance among health care professionals in an Indian tertiary care teaching hospital. Int J Pharm Tech Res. 2011;3(2):678-92.
9. Rehan HS, Vasudev K, Tripathi CD. Adverse drug reaction monitoring: knowledge, attitude and practices of medical students and prescribers. Natl Med J India. 2002;15(1):24-6.
10. Desai CK, Iyer G, Panchal J, Shah S, Dikshit RK. An evaluation of knowledge, attitude, and practice of adverse drug reaction reporting among prescribers at a tertiary care hospital. Perspect Clin Res. 2011;2(4):129-36.
11. Sushma M, Kavitha R, Divyasree S, Deepashri B, Jayanthi CR. A questionnaire study to assess the knowledge, attitude and practice of pharmacovigilance in a paediatric tertiary care centre. J Chem Pharm Res. 2011;3(6):416-22.
12. Figueiras A, Herdeiro MT, Polónia J, Gestal-Otero JJ. An educational intervention to improve physician reporting of adverse drug reactions: a cluster-randomized controlled trial. JAMA. 2006;296(9):1086-93.
13. Oshikoya KA, Awobusuyi JO. Perceptions of doctors to adverse drug reaction reporting in a teaching hospital in Lagos, Nigeria. BMC Clin Pharmacol. 2009;9:14.
14. Castel JM, Figueras A, Pedrós C, Laporte JR, Capellà D. Stimulating adverse drug reaction reporting: effect of a drug safety bulletin and of including yellow cards in prescription pads. Drug Saf. 2003;26(14):1049-55.
15. Li Q, Zhang SM, Chen HT, Fang SP, Yu X, Liu D, et al. Awareness and attitudes of healthcare professionals in Wuhan, China to the reporting of adverse drug reactions. Chin Med J (Engl). 2004;117(6):856-61.
16. Gupta P, Udupa A. Adverse drug reaction reporting and pharmacovigilance: knowledge, attitudes and perceptions amongst resident doctors. J Pharm Sci Res. 2011;3(2):1064-9.
17. Salehifar E, Gholam KH. Knowledge, attitude and performance of pharmacists and nurses in Mazandaran province, Iran regarding adverse drug reaction and its reporting. J Mazandaran Univ Med Sci. 2007;16:115-25.
18. Clarkson A, Conroy S, Burroughs K, Choonara I. Surveillance for adverse drug reactions in children: a paediatric regional monitoring centre. Paediatr Perinat Drug Ther. 2004;6:20-3.
19. Carleton B, Lesko A, Milton J, Poole RL. Active surveillance systems for pediatric adverse drug reactions: an idea whose time has come. Curr Ther Res. 2001;62(10):738-42.

doi: 10.18203/2319-2003.ijbcp20150008

Cite this article as: Chandrakapure AR, Giri SP, Khan IN, Mateenuddin M, Faheem M. Pharmacovigilance: a study to evaluate knowledge, attitude, and practices of and impact of educational intervention among doctors in teaching hospital, in rural area of Jalna, India. Int J Basic Clin Pharmacol 2015;4:427-31.