ejpmr, 2022, 9(5), 306-310

SJIF Impact Factor 6.222

EUROPEAN JOURNAL OF PHARMACEUTICAL AND MEDICAL RESEARCH

www.ejpmr.com

Research Article

ISSN 2394-3211

EJPMR

ASSESSMENT OF KNOWLEDGE, ATTITUDE AND PRACTICE TOWARDS PHARMACOVIGILANCE AND ADVERSE DRUG REACTIONS AMONG HEALTH CARE PROFESSIONALS AT A TERTIARY CARE HOSPITAL, A CROSS- SECTIONAL STUDY

Soumya P. K.*[1] and A. N. Dattatri[2]

[1]Post Graduate, [2]Professor Guide and Head,
Department of Pharmacology, Karnataka Institute of Medical Sciences (KIMS) Hubballi, Karnataka.

***Corresponding Author: Dr. Soumya P. K.**

Post Graduate, Department of Pharmacology, Karnataka Institute of Medical Sciences (KIMS) Hubballi, Karnataka.

Article Received on 04/03/2022 **Article Revised on 25/03/2022** **Article Accepted on 15/04/2022**

ABSTRACT

Background: Adverse drug reactions (ADR) are a major health problem that causes increased mortality and morbidity. Health care professional's contribution is essential in early detection and reporting. Lack of awareness about Pharmacovigilance is one of the most important causes of under- reporting. **Aim:** To assess the knowledge, attitude and practice among health care professionals in a tertiary care hospital. **Methodology:** This was a cross-sectional study done among health care professionals at Karnataka Institute of Medical Sciences, Hubballi. Using a pre-validated questionnaire that included 22 questions to evaluate the participant's knowledge, attitude and practice towards pharmacovigilance and adverse drug reactions. The questionnaire was distributed to the participants (n=210) after taking their informed consent. **Statistical analysis:** The data collected was entered in Microsoft Excel. The data was analysed using SPSS software version 21. The analyzed data was expressed in frequencies and percentages. **Results:** In this study majority of the responders were males (60%), (40%) females. (20%) were students, (30%) were from clinical departments, (50%) from para-clinical departments. Even though majority were interested in reporting adverse drug reactions, did not know how to report the adverse drug reaction. **Conclusion:** In this study, even though participants from all division of health care system are having positive attitude towards Pharmacovigilance and ADR reporting, lack of proper knowledge about how to report an ADR leading to under-reporting. Therefore regular training programs are necessary to improve ADR reporting rate.

KEYWORDS: Pharmacovigilance; health care professionals, adverse drug reactions; ADR reporting; knowledge.

INTRODUCTION

Adverse drug reactions (ADR) are a major health problem that causes increased mortality and morbidity.[1] 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".[2] To detect and spontaneously report an ADR and to ensure drug safety, National Pharmacovigilance Program was initiated in India in the year 2004.[3] It is now renamed as Pharmacovigilance Program of India and operational since July 2010 under the aegis of Central Drug Standard Control Organization.[2]

The World Health Organization has defined Pharmacovigilance as the "science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other possible drug-related problems.[4]

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. India is the seventh largest contributor of UMC drug safety database.[5] Although it has shown some improvement, but still lot is required to be done to increase the spontaneous reporting.[2]

Spontaneous reporting of an ADR by health care professionals is backbone of pharmacovigilance program, but under-reporting of ADR is still prevalent and is the cause of concern. Studies have showed that only 6-10% of all ADR cases are reported. Health care professional has a major role in pharmacovigilance program.[2] Health care professionals are responsible for the identification, documentation and reporting of Adverse drug reactions and their contribution is essential in early detection and reporting of an Adverse drug reaction.[6]

ADR reporting is not been considered as a part of routine professional practice by many 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.[2]

Lack of awareness about Pharmacovigilance is one of the most important causes of under-reporting.[7] India contributes below 1% in terms of Adverse drug reactions reporting against the world rate of 5%.[8] According to the WHO, in many developing countries patients are not adequately safeguarded from accessing harmful and ineffective medicines due to poor Pharmacovigilance systems.[9] Therefore this study is conducted to assess the knowledge, attitude and practice towards pharmacovigilance and adverse drug reactions among health care professionals in a tertiary care hospital.

METHODOLOGY

This was a cross-sectional study done among health care professionals at Karnataka Institute of Medical Sciences, Hubballi. Using a pre-validated questionnaire that included 22 questions to evaluate the participant's knowledge, attitude and practice towards pharmacovigilance and adverse drug reactions. Health care professionals who were employed in the tertiary care hospital and who were willing to participate in the study and had given informed consent were included in the study. And health care professionals who were not willing to give informed consent were excluded from the study. The questionnaire was distributed to the participants (n=210) after taking their informed consent.

Statistical analysis: A total of 210 responders completed this questionnaire-based survey. The data collected was entered in Microsoft Excel. The data was analysed using SPSS software version 21. The analysed data was expressed in frequencies and percentages.

RESULTS

In this study of assessment of knowledge, attitude and practice towards pharmacovigilance and adverse drug reactions among health care professionals, a total of 210 participants provided the response. Among these (60%) were males, (40%) were females. Participants were belonging to age group between 19 - 40 years of age.

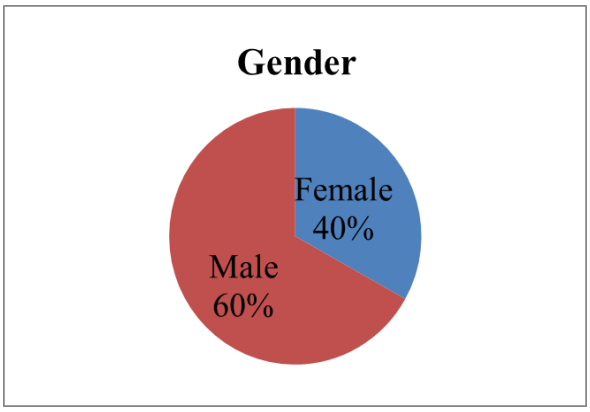

Figure 1: Showing gender distribution of participants in the study.

In figure 2 it is shown that, in this study, participants are from different divisions of health care system.

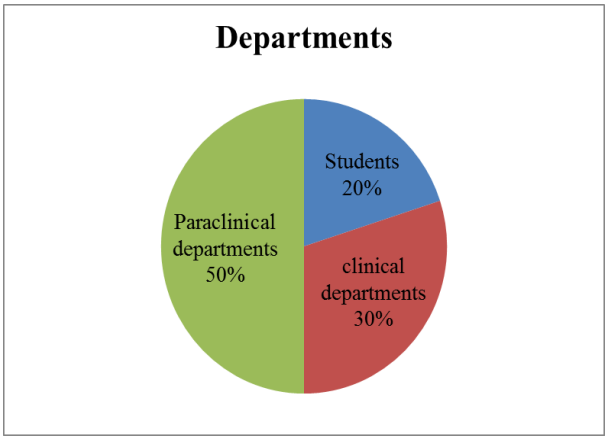

Figure 2: Showing departmental distribution of the participants in the study.

While assessing the Knowledge of health care professionals in this study, majority had a better knowledge about pharmacovigilance and adverse drug reactions. Table 1 depicts the knowledge status of the health care professionals.

Table 1: Showing the knowledge status of the participants in the study.

Knowledge about Pharmacovigilance (PV) and adverse drug reaction (ADR)	Correct answers	Incorrect answers
What is Pharmacovigilance and Adverse drug reaction	210 (100%)	-
Is it necessary to report an ADR	210(100 %)	-
Types of ADR should be reported	189 (90%)	21 (10 %)
Confirmation of ADR before reporting	197(93.8 %)	13 (6.2 %)
Who can report an ADR	137 (65.2%)	73(34.8%)
Within what duration a serious ADR should be reported to the regulatory body	80 (38%)	130(62 %)
Scales used for causality assessment of an ADR	95 (45.2 %)	115 (54.8%)
Can report an ADR in their instituition	189 (90 %)	21(10%)

On assessing the attitude and practice of health care professionals in this study, showed that all the participants had a positive attitude about pharmacovigilance and adverse drug reactions reporting. But only few were aware of reporting procedure, and only 79 (37.6%) had reported an ADR. This low rate of reporting is because of lack of knowledge about ADR reporting procedure. Table 2 depicts the attitude and practice status of the health care professionals.

Table 2: Showing the attitude and practice status of the participants in the study.

Attitude and Practice about PV and ADR	Yes(%)	No(%)
ADR reporting should be made compulsory	157 (75%)	53 (25%)
Are you interested in reporting an ADR	210 (100%)	-
PV should be made part of curriculum	168 (80.%)	42 (20%)
Reported an ADR	79 (37.6%)	131 (62.4%)
Attended teaching programme on reporting of an ADR	84 (40%)	126 (60%)

DISCUSSION

Pharmacovigilance has been the backbone for many drug safety interventions, such as drug withdrawals, labelling changes and prescription restrictions.[10]

It is important to have policy framing to incorporate PV measures in every country's drug regulatory mechanisms, so as to implement and sustain drug safety monitoring processes.[11]

Many medications have been withdrawn from the market due to their severe, harmful or life-threatening effects. Following marketing approval, once the first ADRs are reported, the reports will be analysed and the incident will be investigated; and if post marketing surveillance indicates harmful effects for the medication, it will be withdrawn from the market.[12]

A few examples of drugs which were withdrawn due to pharmacovigilance, Rofecoxib (Vioxx), manufactured by Merck & Co. in 1999, was used as an NSAID in the treatment of "osteoarthritis, rheumatoid arthritis, acute pain and menstrual pain".[11]

In 1938 Dr. Hofmann discovered Lysergic acid diethylamide (LSD), who was in Sandoz Laboratories in Switzerland.[13] After five years, it was found that the drug was causing hallucinations, euphoria, delusions, depression, as well as suicidal thoughts.[14]

In 1976 in France, Benfluorex (Mediator) was first marketed as an add-on therapy for hyperlipidemia and diabetes associated with obesity. In 1998, an official PV investigation was opened regarding the drug in France due to its "potential danger", and Italian regulators expressed apprehension to the European Medicines Agency (EMA). In 1999, two cardiovascular complications were reported in France- discovered that drug-induced valvular heart disease is associated with benfluorex.[11]

Sibutramine (Meridia, US; Reductil, UK)[11], a weight management and weigh loss agent, was approved in Europe[15], many cardiovascular events were reported, including hypertension, tachycardia, arrhythmia and myocardial infarction (MI). In Sibutramine Cardiovascular Outcomes Trial (SCOUT), results demonstrated that patients with preexisting cardiovascular disease who had taken sibutramine had an increased risk for MI or stroke.[16]

For the reporting procedure to be complete, communication of ADR reports to VigiBase, the WHO global database that receives contributions from national PV centres in different countries, is essential for the success of the WHO's International Drug Monitoring Programme.[17] The start-up of the WHO's Programme for International Drug Monitoring was in 1968 as a pilot project, with 10 countries already having established national systems for reporting of ADRs. The project then expanded to include more countries all over the world. New member countries developed PV centres to report the ADRs and coordinate with the WHO centre in Uppsala, where VigiBase is based. VigiBase contains more than 8 million ADR reports from more than 110 countries.[18] VigiFlow is an internet-based system that offers free access to all member countries to see all information and reports in VigiBase, and their analysis from all over the world.[19] In April 2015, the WHO launched VigiAccess, a web application that allows anyone to access information. This is a significant step, which encourages reporting ADRs.[20]

In this study overall response for knowledge and attitude-based questions was highly significant when compared to practice based questions, which is similar to a study conducted by Panneerselvam N et al[8], and also Haines H M et al.[1] In contrast to our study, in a study conducted by Korde R A et al,[7] participants had very less score regarding knowledge based questions.

In a study conducted by Panneerselvam N et al[8], found that, however in practice only knowledge does not help in increased ADR reporting and also in their study, after an educational intervention, which included powerpoint presentation and also hands on training in filling up the ADR forms and causality assessment which helped to overcome the practical issues, and increased the response in participants.[8]

In a study conducted by Husain R et al[6], Haines H M et al[1], and Korde RA et al[7], most of the participants

exhibited positive attitude regarding ADR reporting and majority stated ADR reporting is a Professional obligation, which is similar to our study.

In our study all the participants were interested in reporting an ADR. But majority were not aware of reporting procedure, only 37.6% had reported an ADR and only 40% had attended teaching programmes or sessions related to ADR reporting, which is similar to a study conducted by Panneerselvanm N et al[8], Husain R et al[6], and Haines H M et al.[1]

In this study majority of the participants were not aware of the National co-ordination centre for Pharmacovigilance and which regulatory body is responsible for monitoring an ADR in India. Majority of the participants were not aware that which is the online WHO database for ADR reporting and which country is the international centre for ADR monitoring.

In this study 80% of the participants stated that lack of knowledge about ADR reporting is the major reason for low rate of ADR reporting. And 15% of the participants stated that it is maybe due to increased workload and 5% stated maybe due to negligence.

CONCLUSION

In this study, participants from all division of health care system had positive attitude towards Pharmacovigilance and ADR reporting. But lack of proper knowledge about how to report an ADR is leading to under-reporting. Reporting should be encouraged in a manner that whether common or uncommon, serious or mild and known or unknown even with established medicines should not be missed. Even previous studies have proved that training healthcare professionals will improve ADR reporting rate. Therefore regular sessions and training programs are necessary to improve the ADR reporting rate. And which will reduce, even from mild to severe adverse drug reactions and help to provide safe and effective drugs to the mankind.

Funding: No funding sources.

Conflict of interest: None.

REFERENCES

1. Haines, H.M., Meyer, J.C., Summers, R.S. et al. Knowledge, attitudes and practices of health care professionals towards adverse drug reaction reporting in public sector primary health care facilities in a South African district. Eur J Clin Pharmacol, 2020; 76: 991–1001. https://doi.org/10.1007/s00228-020-02862-8.
2. Meher BR, Joshua N, Asha B, Mukherji D. A questionnaire based study to assess knowledge, attitude and practice of pharmacovigilance among undergraduate medical students in a Tertiary Care Teaching Hospital of South India. Perspect Clin Res., 2015; 6: 217-21.
3. Adithan C. National pharmacovigilance programme. Indian J Pharmacol, 2005; 37: 34.
4. Paul Beninger, Pharmacovigilance: An Overview, Clinical Therapeutics, 2018; 40(12): 1991-2004, ISSN 0149-2918, https://doi.org/10.1016/j.clinthera.2018.07.012.(https://www.sciencedirect.com/science/article/pii/S0149291818303175)
5. Smith CC, Bennett PM, Pearce HM, et al. Adverse drug reactions in a hospital general medical unit meriting notification to the Committee on Safety of Medicines. Br J Clin Pharmacol, 1996; 42(4): 423-429. doi:10.1046/j.1365-2125.1996.04376.x
6. Hussain, R., Hassali, M.A., Hashmi, F. *et al*. Exploring healthcare professionals' knowledge, attitude, and practices towards pharmacovigilance: a cross-sectional survey. *J of Pharm Policy and Pract.*, 2021; **14(**5). https://doi.org/10.1186/s40545-020-00287-3.
7. Korde RA, Radhika MS. A KAP study of pharmacovigilance among junior residents and interns of a tertiary care hospital. Int J Basic Clin Pharmacol, 2018; 7: 2178-83.
8. Panneerselvam N, Kathirvelu P, Manoharan R. Impact of educational intervention on the knowledge, attitude, and practice of pharmacovigilance among postgraduates of a tertiary care center, Kanchipuram, Tamil Nadu, India. Perspect Clin Res [Epub ahead of print] [cited 2022 Jan 31]. Available from: https://www.picronline.org/preprintarticle.asp?id=316108
9. Maigetter K, Pollock AM, Kadam A, Ward K, Weiss MG. Pharmacovigilance in India, Uganda and South Africa with reference to WHO's minimum requirements. Int J Health Policy Manag, 2015; 4: 295–305. doi: 10.15171/ijhpm.2015.55.
10. Paludetto MN, Olivier-Abbal P, Montastruc JL. Is spontaneous reporting always the most important information supporting drug withdrawals for pharmacovigilance reasons in France?. Pharmacoepidemiol Drug Saf., 2012; 21(12): 1289-1294. doi:10.1002/pds.3333
11. Alomar M, Palaian S and Al-tabakha MM. Pharmacovigilance in perspective: drug withdrawals, data mining and policy implications [version 1; peer review: 2 approved] F1000Research, 2019; 8: 2109. (https://doi.org/10.12688/f1000research.21402.1)
12. Sundaran S, Sankar S, Dhamodaran P, et al.: Drug recall: an overview. World J Pharm Res., 2013; 2: 297–307.
13. Nichols DE. Dark Classics in Chemical Neuroscience: Lysergic Acid Diethylamide (LSD). ACS Chem Neurosci, 2018; 9(10): 2331-2343. doi:10.1021/acschemneuro.8b00043
14. COHEN S, DITMAN KS. Complications associated with lysergic acid diethylamide (LSD-25). JAMA, 1962; 181: 161-162. doi:10.1001/jama.1962.03050280091013b

15. Pamukcu Gunaydin G, Dogan NO, Levent S, Kurtoglu Celik G. Herbal weight loss pill overdose: sibutramine hidden in pepper pill. Case Rep Emerg Med., 2015; 2015: 213874. doi:10.1155/2015/213874
16. Scheen AJ: Sibutramine on cardiovascular outcome. Diabetes Care, 2011; 34(2): S114–9.
17. World Health Organization. (2004). Pharmacovigilance: ensuring the safe use of medicines. World Health Organization. https://apps.who.int/iris/handle/10665/68782
18. Viola E, Opri S, Moretti U, et al.: α1-Adrenergic receptor antagonists and gynecomastia. A case series from the Italian spontaneous reporting system and VigiBase(™). Eur J Clin Pharmacol, 2014; 70(8): 1003–9.
19. Sten Olsson, Shanthi N Pal & Alex Dodoo Pharmacovigilance in resource-limited countries, Expert Review of Clinical Pharmacology, 2015; 8:4, 449-460. DOI: 10.1586/17512433.2015.1053391
20. World Health Organization: WHO essential medicines and health products: annual report 2015. World Health Organization, 2016.