A study about the awareness and importance of pharmacovigilance among health professionals in a South Indian Tertiary Care Hospital: A prospective study

Jeena Stephen¹, Sharath Kumar K.^{2,*}

¹Masters in Hospital Administration, ²Assistant Professor, Dept. of Pharmacology. A. J. Institute of Medical Sciences and Research Centre, Mangalore. Karnataka, India

*Corresponding Author:

Email: docsharath@gmail.com

Abstract

Drug safety is one of the least considered aspects of medicine in developing countries like India. Under-reporting of ADRs (Adverse Drug Reactions) is a major problem, affecting pharmacovigilance programme of India. Because of under reporting, Indian drug regulators are very much dependent on data and advice from other countries. The objective of the present study was to determine the level of awareness and attitude towards Pharmacovigilance among healthcare professionals and to monitor the extent of ADR reporting within the healthcare sector. The study was carried out in a tertiary care hospital in Mangalore considering 20 facts about awareness of Pharmacovigilance. A total number of 50 doctors, 50 nurses and 50 medical students (postgraduate doctors) were included in the study. Simple random sampling method was adopted to choose samples which include the collection of information through a structured close-ended questionnaire. Results were analyzed by using frequency and percentage. This study reveals that all the participants (100%) were aware of adverse drug reactions (ADRs) reporting. 38 (76%) of the doctors, 41(82%) of the nurses and 29 (58%) of the medical students encountered ADRs in their working hospital. Out of all respondents 43 (86%) doctors, 46 (92%) nurses and 38 (76%) medical students responded that reporting adverse drug reaction is a professional obligation according to the healthcare profession. Out of all respondents, 23 (46%) doctors, 29 (58%) nurses and 30(60%) medical students responded that they are aware of the pharmacovigilance programme of India. 27 (54%) doctors, 21 (42%) nurses and 20 (40%) medical students mentioned as they are not aware about the pharmacovigilance programme. Majority of the respondents; 47 (94%) doctors, 49 (98%) nurses and 38 (76%) medical students responded with the opinion as reporting adverse drug reaction is necessary among health care professionals.

Keywords: Awareness, Adverse Drug Reactions, Healthcare professionals, Pharmacovigilance.

Introduction

World Health Organization (WHO) defines, an adverse drug reaction (ADR) is any noxious, unintended and undesired effect of a drug, which occurs at doses used in humans for prophylaxis, diagnosis, or cure of a disease.¹ Long stay in hospital, increased cost burden and mortality in associated with adverse drug reactions.²⁻⁵

Pharmacovigilance Programme of India (PvPI) was initiated to monitor ADRs in 2010 by Government of India. The primary goal of the program is to protect and to safeguard health of the public by assuring the safety of medicine. Health professionals like Doctors, nurses, and pharmacists involved in prescribing, dispensing, administering, storage, and disposal of medicines play a key role in the success of the programme.⁶

Attitude, and practice (KAP) about pharmacovigilance from various studies have revealed that ADR reporting by healthcare providers is linked to their awareness and knowledge about ADRs.⁷

As an important factor, the healthcare professionals has to know how to report, when and where to report an ADR. The active participation of healthcare professionals in the pharmacovigilance program can improve the ADR reporting.⁸

For the success of the programme, awareness and importance of pharmacovigilance among health

professionals is important and keeping this in mind, the following prospective study was undertaken.

Material and Methods

Data collection: The methods used to collect the data are;

Primary data: Questionnaire method

Secondary data: Journals, magazines, references, articles, internet browsing.

Setting of the study: The study was undertaken in a tertiary care hospital located in the north of Mangalore with all basic health care services under one roof. The samples consist of doctors, nurses and medical students [postgraduate students (Doctors) pursing postgraduation course].

Sample selection: Simple random sampling method was adopted to choose 50 samples from each category of samples

Research approach: A descriptive cross-sectional approach was adopted for the study. It included collection of information and data directly from the subjects of the study through a structured close-ended questionnaire prepared using review of literature from books, journals and published research studies. A total number of 50 doctors, 50 nurses and 50 medical students (postgraduate doctors) were included in the study. Simple random sampling method was adopted to choose samples which include the collection of information through a structured close-ended

questionnaire. Based on the objectives the data was analysed using simple statistical tools such as frequency and percentage.

Results

This study reveals that all the participants (100%) were aware of adverse drug reactions (ADRs) reporting. 38 (76%) of the doctors, 41 (82%) of the nurses and 29 (58%) of the medical students encountered ADRs in their working hospital.

Out of all respondents 43 (86%) doctors, 46(92%) nurses and 38(76%) medical students responded that reporting adverse drug reaction is a professional obligation according to the healthcare profession.

Out of all respondents, 23(46%) doctors, 29(58%) nurses and 30(60%) medical students responded that they are aware of the pharmacovigilance programme of India.

In our study, we found about 27(54%) doctors, 21(42%) nurses and 20(40%) medical students mentioned as they are not aware about the pharmacovigilance programme.

Majority of the respondents; 47(94%) doctors, 49(98%) nurses and 38(76%) medical students responded with the opinion as reporting adverse drug reaction is necessary among health care professionals.

Discussion

ADRs incidence was found to be 6.7% in India.⁹ In one of the study conducted in south India, about 0.7% hospital admission were due to ADRs and about 3.7% hospitalised patients experienced ADRs among which 1/3% constituted fatal.¹⁰

Similarly, another study showed 3.4 % hospital admissions were due to ADRs and 3.7 % patients experienced ADRs during hospital admission.¹¹

Overall consequence of ADRs leads to burden of ongoing disease with drug related hospital admission, prolonged hospital stays and increased visit to emergency department.

As our A. J. Pharmacovigilance centre was the first to be established in Dakshina Kannada district, we conducted many awareness programme to our all health professionals by conducting many guest lectures and continued medical education inviting experienced guest speakers and hence all the health professional was aware of the pharmacovigilance programme as evident form the results of our study.

Conclusion

In order to make the pharmacovigilance programme success, a proper awareness is needed in all

health sectors ranging from a small clinic to super speciality hospital. However, the central and state government should implement this programme with adequate man power for constant reporting of the ADRs.

Funding: No funding sources. **Conflict of interest:** None declared.

References

- 1. Kamtane RA, Jayawardhani V. Knowledge, attitude and perception of physicians towards Adverse drug reaction reporting: A Pharmacoepidemiological study. *Asian J Pharmaceut Clin Res* 2012;5(3):210-14.
- J. Lazarou, B.H. Pomeranz, P.N. Corey. The incidence of adverse drug reactions in hospitalized patients-a metaanalysis of prospective studies. *JAMA* 1998;279:1200-05.
- H. Jick. Adverse drug reactions: the magnitude of the problem. J Allergy Clin Immunol 1984;74:555-57.
- M. Pirmohamed, S. James, S. Meakin, C. Green, A.K. Scott, T.J. Walley, K. Keith Farrar, B.K. Park, A.M. Breckenridge. Adverse drug reactions as cause of admission to hospital: prospective analysis of 18820 patients. *BMJ* 2014;329:15-19.
- M.el-B. Ahmed. Drug-associated admissions to a district hospital in Saudi Arabia. *J Clin Pharm Ther* 1997;22:61-6.
- Isfahani ME, Mousavi S, Rakhshan A, Assarian M, Kuti L, Eslami K. Adverse drug reactions: attitude and practice of pharmacy students. *J Pharm Care* 2013;1:145-8. Back to cited text no. 5
- Rishi RK, Patel RK, Bhandari A. Opinion of physicians towards adverse drug reactions reporting results of pilot study. *J Community Nutr Health* 2012;1:25-9.
- 8. Remesh A. Identifying the reasons for under reporting of ADR: A cross sectional survey. *Res J Pharm Biol Chem Sci* 2012;3:1379–86.
- Importance of ADR reporting in India. Available from: http://www.pharmacovigilance.co.in [Last accessed on 2014 Sep 15]
- Ramesh M, Pandit J, Parthasarathi G. Adverse drug reactions in a south Indian hospital – Their severity and cost involved. *Pharmacoepidemiol Drug Saf* 2003;12:687-92.
- Arulmani R, Rajendran SD, Suresh B. Adverse drug reaction monitoring in a secondary care hospital in South India. *Br J Clin Pharmacol* 2008;65:210-16.

How to cite the article: Stephen J., K. Sharath. A study about the awareness and importance of pharmacovigilance among health professionals in a South Indian Tertiary Care Hospital: A prospective study. *Int J Comprehensive Adv Pharmacol* 2018;3(3):96-97.