World Journal of Pharmaceutical ReseaRch

Volume 3, Issue 2, 2691-2697. Research Article ISSN 2277 – 7105

EVALUATION OF KNOWLEDGE, ATTITUDE AND PRACTICE OF PHARMACOVIGILANCE AMONG HEALTH CARE PROFESSIONALS IN TERTIARY CARE TEACHING MEDICAL COLLEGE IN NORTH INDIA

Dr. Pankaj Kumar Modi* [1] , Dr. Saurabh Kohli[2] , Dr. Uma Advani [3,] Dr. Harcharan Singh[4]

[1]Assistant Professor Department of Pharmacology RNT Medical College, Udaipur

[2]Assistant Professor Department of Pharmacology Himalayan Institute Of Medical Sciences, Dehradun

[3]Senior Demonstrator Department of Pharmacology SMS Medical College, Jaipur

[4]Senior Demonstrator Department of Pharmacology RNT Medical College, Udaipur

Article Received on
02 January 2014
Revised on 28 January2014,
Accepted on 21 February 2014

***Correspondence for Author**
Dr. Pankaj Kumar Modi
Assistant Professor
Department of
Pharmacology RNT
Medical College, Udaipur.

ABSTRACT

According to WHO, Pharmacovigilance is a science deals with detection, assessment, understanding and prevention of adverse effects or any other drug-related problems. The idea of pharmacovigilance came up as a consequence of the so-called thalidomide tragedy in 1960. Government of India started National Pharmacovigilance Programme (NPP) in 2004 with the goal to safeguards the health of the Indian population. Pharmacovigilance is still in initial stage in India. After observing the Pharmacovigilance programme of our institution we found that health professionals lack knowledge about pharmacovigilance and problems of underreporting of adverse drug reactions was prevalent in institute. This study shows poor knowledge, attitude and practice of pharmacovigilance among medical Professionals, So there is urgent need to improve the awareness of Pharmacovigilance among the healthcare professionals. Adverse drug reactions reporting should be intensively taught at undergraduates level, during internship and then periodically thereafter through continuous education programs.

Key Words – Adverse drug reactions, Healthcare professionals, Pharmacovigilance.

INTRODUCTION

Adverse Drug Reactions (ADR's) are an important cause of hospital admission and associated with a significant morbidity and mortality.[1-4] The first practical international co-operation in drug monitoring started in 1968. The ideas came up as a consequence of the so-called thalidomide tragedy in 1960. This tragedy became the modern starting point of a science focusing on ADR's caused by the use of medicines. This science, and activities associated with adverse drug monitoring, is now called pharmacovigilance. According to WHO, Pharmacovigilance is a science deals with detection, assessment, understanding and prevention of adverse effects. [5]

In recent time Importance of pharmacovigilance programme increasing constantly because when used effectively, pharmacovigilance allows for the intelligent, evidence-based use of medicines and has the potential for preventing many adverse reactions. It is important to monitor every undesirable effect of medicines in order to determine any new information available in relation to their safety profile. In order to identify the culprit drugs causing ADR's, several countries have initiated pharmacovigilance programs in the recent past.

In India national Pharmacovigilance Programme (NPP) was launched in 2004 by the Ministry of Health and Family Welfare, Government of India with the goal to ensure the benefits of use of medicine and outweighs the risks and thus safe guard the health of the Indian population. In a vast country like India with a population of over 1.3 billion with vast ethnic variability, different disease prevalence patterns, practice of different systems of medicines, different socioeconomic status, it is important to have a standardized and robust pharmacovigilance and drug safety monitoring programme for the nation. Although pharmacovigilance programs are successful in improving drug use patterns, under reporting of ADR's is felt as a major problem in India as well as in other countries. This can delay detection of important ADR's. Pharmacovigilance is still in initial stage in India and there exists very limited knowledge about this discipline. [6] Studies from different settings indicate inadequate knowledge about pharmacovigilance among healthcare professionals as well as their attitudes and practice is associated with a high degree of underreporting. [6-11]

Pharmacovigilance programme of our institution was also in incipient stage and in the previous years only few ADRs were reported from the health professionals. So the problems of underreporting and lack of awareness were prevalent in the institute. Therefore this study was conducted with the aim to assess Knowledge, Attitude and Practice (KAP) of

pharmacovigilance, to create awareness among the healthcare professionals and to uncover the causes of underreporting of ADR's in an Indian tertiary care teaching hospital. In this study we also aimed to know the suggestions to improve the ADRs reporting.

MATERIAL AND METHODS

This was a randomized, cross-sectional, observational, Questionnaire-based study, conducted at a 1000-bedded tertiary care teaching hospital in Jaipur, India. This questionnaire survey was conducted during January 2013.The questionnaire consists of 21 questions regarding knowledge, attitude and practices (KAP Study) of Pharmacovigilance along with suggestions to improve ADR reporting. Health professionals (doctors, nursing staff and pharmacists) working in the medical college and hospital were included in study. Pretesting of questionnaire was done with Pharmacovigilance committee and on 10 randomized selected health professionals of the institute to identify any potential bias and mistakes. In order to preclude any potential bias the disclosure of name of the responder was made optional. Initially KAP questionnaire was briefed to all participants (physician, pharmacist and nurses) about the aim of the study. For submission of questionnaire a suitable time of 5 days was given and for those who had not submitted back/lost the questionnaire, we resupplied the questionnaire and requested the responder to fill it before us. The information was recorded and analyzed.

RESULTS

The questionnaire was supplied to 140 health professionals and we get back 118 responses making an 84.28% of responses. The response rate was 68.57% among senior faculty members (Professor and Associate Professor), 88.57% among junior faculty members (assistant professor, senior resident and junior resident) and 91.42% among paramedics (pharmacist and nursing staff). Maximum responders (30%) are between 26-30 yr of age and sex ratio of male and female participants was 77: 23. (Table -1) Awareness about pharmacovigilance based on our assumption of response to question number 1 and 2 of the questionnaire were calculated and it was found that 72.88 % were aware and remaining 27.12% were unaware. Awareness of pharmacovigilance among senior faculty members was 79.16%, junior faculty members 80.64% while in paramedics were 46.87%. We did not include the responses of unaware respondents in further statistical analysis of questionnaire. We assess the knowledge of respondents on the basis of question number 3-10 and gave 1 mark to each question. The mean knowledge of senior faculty members was 4.15, junior

faculty members were 5.68 and paramedical staff was 3.47. In view of 78.94 % senior faculty members, 88 % junior faculty members and 70.58 % paramedical staff, ADR reporting is a professional obligation. Only 7% respondents receive training on how to report ADR to pharmacovigilance committee and 2% respondents had guided others on importance of ADR reporting but it is interesting that majority (97%) of respondent thinks that Pharmacovigilance should be taught in detail. Only 25% senior faculty come across with an unknown ADR but only 10% reported ADR to concerned authority. Junior faculty and paramedics had recorded 22% and 7% ADRs respectively. Among junior faculty 15% and only 2% paramedics reported ADRs to concern authority. Fifty five percent participants were in favour of establishing pharmacovigilance centre in every hospital. Among doctors 65% read any article or attend conference/workshop on pharmacovigilance but only 23% paramedics were involved in such activities. Majority (62%) of health professionals did not know how and where to report ADRs. Legal issues were also important factor for not reporting of ADRs (26%). Only few (9%) discourage from lack of remuneration for ADR reporting. (Table -2)

TABLE 1 DEMOGRAPHIC PROFILE OF STUDY POPULATION

Age (years)	Percentage (%)	Male : Female
21-25	24	77:23
26-30	30	
31-35	18	
36-40	13	
>40	15	

TABLE 2 DISCOURAGING FACTORS FOR NOT REPORTING ADR'S

Factor	Frequency of Senior Doctors (%)	Frequency of Junior Doctors (%)	Frequency of Paramedics (%)
Did not know how to report	26.32	36	58.83
Not known where to report	21.06	34	58.83
Did not think it to be important	0	8	17.64
Managing the patient is more important than reporting ADR	21.05	30	35.29
Lack of access to ADR reporting form	42.10	46	64.70
Due to legal issue	42.10	18	29.41
Lack of remuneration	5.26	8	17.64

TABLE 3: SUGGESTED METHODS OF IMPROVING ADR'S REPORTING

Suggestions	Frequency of Senior Doctors (%)	Frequency of Junior Doctors (%)	Frequency of Paramedics (%)
Make it easier process of submission	89.47	84	76.47
Remuneration for ADR submission	26.31	40	47
Providing electronic option for submission	73.68	90	64.70
Making reporting Mandatory	52.63	56	47.05
Ensure confidently of reports	84.21	94	88.23
Provide toll free number for reporting	68.42	86	52.94
Make health professional more aware for ADR	84.21	82	82.35
Health care professional should be trained in ADR reporting	89.47	94	94.11

DISCUSSION

In this study we involve the doctors and paramedical staff. In this study 23.72% of the respondents were not aware of the Pharmacovigilance. It means that training of pharmacovigilance among undergraduate and postgraduate was insufficient. Majority of respondents understands the importance of pharmacovigilance and their attitude towards it was positive but reporting of ADR's was poor. It means that there was a considerable gap between attitude and practice (KAP gap).

Although doctors are central figure for reporting ADR's but paramedical staff could also play an important role in ADRs reporting, because they are close to the patient and most of the time nursing staff are the first person whom patient complain for side effects . They can alert the responsible physician about possible ADRs without time gap. Thus it is crucial to encourage the paramedical staff towards ADR reporting. [12]

According to Inman [13], the reasons for under-reporting of ADRs can be complacency (belief that the serious ADRs are already documented when a drug is introduced in the market), diffidence (belief that reporting should be done when there is certainty that the reaction is caused by the use of a particular drug), financial incentives (rewards for reporting), ignorance (that only serious ADRs are to be reported), indifference (belief that a single report would

make no difference), legal aspects (fear of litigation) and lethargy (excuses about lack of time or disinterestedness). Some of these reasons were also documented in previous studies in India. [14, 15] In our study a major reason observed was respondents did not knew how and where to report an ADR. (Table - 2) It was also found that health care provider's ignorance towards this issue was also an important factor for under reporting of ADR's. Therefore, awareness programmes through conferences, workshops, literature and publicity, would necessary to create awareness and to improve ADR reporting. Majority of respondent also suggest that health care providers should train in different aspect of pharmacovigilance. (Table -3) Another important reason of underreporting was lack of access to ADR reporting form that's why about 81% of respondents are in favour of electronic option of ADR submission (Table - 3). Legal issues were also a concern for some health professionals so proper counselling, training and encouraged them to attend conferences and workshops on pharmacovigilance were necessary. The various methods suggested by the respondents to improve ADR reporting are presented in Table 3.

CONCLUSION

This study shows that medical persons were poor regarding knowledge, attitude and practices of pharmacovigilance. So there is urgent need for intensive pharmacovigilance training programme of healthcare professionals. A questionnaire based study due to certain limitations not appropriate to plan specific interventions to improve knowledge, attitude and practice of pharmacovigilance alone but this study unfolds the importance of ADR reporting. ADR reporting should be intensively taught at undergraduates level, during internship and then periodically thereafter through continuous education programs.

REFERENCES

1. Beard K. Adverse reactions as a cause of hospital admission in the aged. Drugs and Aging, 1992; 2 (4): 356-67.
2. Murphy BM, Frigo LC. Development implementation and results of a successful multidisciplinary adverse drug reaction reporting program in a university teaching hospital. Hosp Pharm, 1993; 28 (12): 1199-204, 1240.
3. Lazarou J, Pomeranz BH, Corey PN. Incidence of adverse drug reactions in hospitalized patients-a meta-analysis of prospective studies. JAMA, 1998; 279 (15): 1200-5.
4. Classen DC, Pestotnik SL, Evans RS. Adverse drug events in hospitalized patients. JAMA, 1997; 277(4):301-6.

5. World Health Organization. Safety of Medicines: A guide to detecting and reporting adverse drug reactions. Geneva, Switzerland ; 2002.
6. Figueiras A, Tato F, Fontainas J, Gestal-Otero JJ. Influence of physicians' attitudes on reporting adverse drug events: a case-control study. Med Care,1999; 37:809-814.
7. Williams D, Feely J. Underreporting of adverse drug reactions: attitudes of Irish doctors. Ir J Med Sci. 1999; 168:257-261.
8. Perlik F, Slanar O, Smid M, Petracek J. Attitude of Czech physicians to adverse drug reaction reporting. Eur J Clin Pharmacol. 2002; 58:367-369.
9. Belton KJ, Lewis SC, Payne S, Rawlins MD. Attitudinal survey of adverse drug reaction reporting by medical practitioners in the United Kingdom. Br J Clin Pharmacol, 1995; 39 (3):223-26.
10. Hasford J, Goettler M, Munter KH, Muller- Oerlinghausen B. Physicians' knowledge and attitudes regarding the spontaneous reporting system for adverse drug reactions. J Clin Epidemiol, 2002; 55 (9):945-50.
11. Herdeiro MT, Figueiras A, Polo´ nia J, Gestal- Otero JJ. Physicians' attitudes and adverse drug reaction reporting: a case-control study in Portugal. Drug Saf, 2005; 28 (9):825-33.
12. Bäckström M, Ekman E, Mjörndal T. Adverse drug reaction reporting by nurses in Sweden. Eur J Clin Pharmacol, 2007; 63 (6): 613-18.
13. Inman WH. Attitudes to adverse drug reaction reporting. Br J Clin Pharmacol, 1996; 41(5): 434-35.
14. Ramesh M, Parthasarathi G. Adverse drug reactions reporting: attitudes and perceptions of medical practitioners. Asian J Pharm Clin Res, 2009; 2 (2): 10-4.
15. Gupta P, Udupa A. Adverse drug reaction reporting and pharmacovigilance: Knowledge, attitudes and perceptions among resident doctors. J Pharm Sci Res, 2011; 3(2): 1064-69.