



International Journal of Research in Pharmacology & Pharmacotherapeutics



ISSN Print: 2278-2648

IJRPP |Vol.8 | Issue 3 | Jul - Sep - 2019

ISSN Online: 2278-2656

Journal Home page: www.ijrpp.com

Research article

Open Access

Evaluation of Knowledge, Attitude, and Practice of pharmacovigilance and adverse drug reactions among the healthcare professional in Bastar region of Chattisgarh

Dr Maya Ramteke¹, Dr Sanat Sharma², Dr Ratna Agrawal², Dr Mahendra Jaiswal²,
Dr Rupendra Bharti², Dr Raj Sharma²

^{1,2}Department of Pharmacology, Govt medical college Dimerapal, Jagdalpur. 494001

*Corresponding author: Dr Maya Ramteke (SR)

Email: rohanrahal2@gmail.com

ABSTRACT

Background

One of global problem encountered nowadays is adverse drug reaction, which affect the majority of population both the children and adults. Adverse drug reactions (ADRs) are the consequences of drug therapy, and it is fourth leading cause of morbidity and mortality in world. Pharmacovigilance plays an important role in the reduction of ADRs. Voluntary reporting of ADRs by health care professional is an important tool in the success of pharmacovigilance programme. So this study was conducted to assess the awareness of pharmacovigilance and to evaluate the knowledge, attitude and practices among doctors in tertiary care teaching hospital in Bastar region of Chhattisgarh in India.

Methods

A cross-sectional questionnaires based study was carried out among doctors of tertiary care teaching hospital with Govt. Medical College Jagdalpur. 85 doctors (physician) Were enrolled in our study. A Prevalidated 21 questionnaires of knowledge, attitude and practice towards Pharmacovigilance were developed and after taking inform consent, questionnaires were directly distributed to the physician, 7-8 days time was given to fill the form. The filled KAP questionnaires were analyzed question wise and their percentage value was calculated by Microsoft excel and graph pad prism version 6.01.

Result

In our study 120 questionnaires were distributed to healthcare professional of tertiary care teaching hospital of which 85(70.8%) responded, in which 45 consultant were from different clinical department and 40 intern were filled form and sent it back. ADRs reporting was considered very important by almost all of them, but actual practice was lacking as only 10.5% had reported any ADR.

Conclusion

The healthcare professional were aware of the importance of ADR reporting, but lack of knowledge about the procedure where to report, whom to report, unavailability of ADR reporting form, uncertain association are the

most common cause of underreporting. So there is need to conduct an awareness programme about the pharmacovigilance as it is tertiary care center for patients safety.

Keywords: Adverse drug reaction, Attitude, Awareness, Healthcare professional Pharmacovigilance, Knowledge.

INTRODUCTION

Drugs, biological substances, medical devices, transplant organ, tissue and cells play an important role in the management of disease of the patient. Apart from the beneficial effect there is possibility of adverse effect with every drug. [1] Adverse drug reactions (ADR) are the fourth leading cause of morbidity and mortality worldwide, it affects all the age groups irrespective of age. [2] According to WHO adverse drug reaction is “A response to a drug which is noxious and unintended and occurs at doses normally used in man for the prophylaxis, diagnosis or therapy of disease, or for medication of physiological function”. [1] The prevalence of adverse drug reaction (ADRs) is higher in developing countries may be due to self-medication, irrational and easy availability of medicine. [2, 3] According to S. Ganesan et al a study from South India revealed that 0.7% of hospital admissions were due to ADRs and a total of 3.7% hospitalized patients experienced ADRs, of which death accounts for 1.3%, of which 6.89% of admissions due to ADRs encountered in the emergency department. [3] So timely detection, assessment and prevention is required to decrease the economic burden due to ADRs as it increased hospital stay and cost of treatment.

Pharmacovigilance (PV) is important tool of monitoring and assessment of any drug related adverse event. According to World Health Organization (WHO), Pharmacovigilance is defined as “the science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other drug related problems” The idea of pharmacovigilance came in 1961, after the thalidomide tragedy was reported, In which a number of pregnancy causing the birth of thousands of congenitally deformed babies led to the initiation of first organized international efforts to address drug safety issues. WHO's Programme for International Drug Monitoring began in 1968, with Uppsala Monitoring Centre (UMC) in Sweden being the collaborating centre for this global initiative. The

aims of PV were to improve patient care and safety in relation to the use of medicines. [4]

The Pharmacovigilance Programme of India (PvPI) was launched under the Ministry of Health and Family Welfare in July 2010 with the All India Institute of Medical Sciences (AIIMS), New Delhi as the National Coordinating Centre (NCC) for monitoring Adverse Drug Reactions (ADR) in the country to safe-guard Public Health. In year 2010, 22 ADR monitoring centers (AMCs) including AIIMS, New Delhi had been set up under this Programme. The NCC was then shifted from the All India Institute of Medical Sciences (AIIMS), New Delhi to the Indian Pharmacopoeia Commission (IPC), Ghaziabad, (U.P.) in April, 2011. To safeguard the health of the Indian population by ensuring the safety of the marketed drugs. [5]

It is estimated that only 6-10% of adverse drug reactions (ADRs) are reported worldwide.⁶ and India contribute only 3% of ADRs reported globally, the spontaneous or voluntary reporting of ADR is the most common method of ADR reporting [7] The underreporting of ADR is due to lack of adequate knowledge, attitude and practice among healthcare professionals towards ADR reporting. Health care professional like physicians, pharmacist and nurses have immense responsibility in reporting ADR. [8]

Pharmacovigilance is still in its infancy in India and there exists very limited knowledge about this discipline. However, The Indian national pharmacovigilance programme lacks continuity due to lack of awareness and inadequate training about drug safety monitoring among healthcare professionals. Assessment of awareness of pharmacovigilance among the healthcare professionals in Bastar region is very important due to under reporting of adverse drug reactions, even no ADR reporting from this area. Therefore, this study was conducted to evaluate the knowledge, attitude and practices (KAP) of health care professional towards pharmacovigilance.

METHODS

The present study was an observational, questionnaire based study carried out among doctors of tertiary care teaching hospital with Govt. Medical College Jagdalpur in bastar region from 20 July to 30 July 2019 after taking informed Consent from physician before starting the study. In this study a prevalidated, pre-tested, questionnaire was designed to assess the knowledge of pharmacovigilence among medical doctors. Study population consists of 85 doctors. A brief description on the nature of the study and procedure to complete the questionnaire was explained. The questionnaire which was designed to assess the basic knowledge on pharmacovigilence was distributed among doctors.

Doctors who were ready to fill the answer for the given questionnaire were included in the study.

Doctors who were not interested/willing to answer the questionnaire were excluded from the study. Filled up forms were collected back from the doctors and were analyzed for the results. The statistics was done by using MS Excel and graph pad prism version 6 for obtaining the results. Final data was expressed as frequency and percentages.

RESULTS

In this study a total 120 set of questionnaires were circulated among doctors from different specialities of whom 60 were distributed to consultants and rest 60 were given to interns. Of them total 85 were responded and involved in study .Response rate of questions 1-10 among doctors and interns were shown in (Table 1)

Table 1: Percentage of average knowledge of consultant and interns

Sr No	Questions	Consultant/Faculties (n = 45) correct response	Interns (n – 40) correct response
1.	Have you heard the name of Pharmacovigilence ?	100 .00 % (45)	80.00% (30)
2.	Pharmacovigilence means. ?	77.77%(35)	67.50% (35)
3.	The most important purpose of pharmacovigilence.?	80.00% (36)	67.50 % (35)
4.	The healthcare professional responsible for reporting ADRs in a hospital is /are	88.88%(40)	67.50% (35)
5.	Do you know regarding the existence of national pharmacovigilence programme in india ?	77.77%(35)	65.00% (26)
6.	In India which regulatory body is responsible for monitoring ADRs?	84.44 % (38)	80.00% (30)
7.	Where the international center for adverse drug reaction monitoring is located ?	55.55%(25)	45.00 % (18)
8.	A serious adverse event in India should be reported to the regulatory body within	40.00% (18)	57.50%(23)
9.	Rare adverse effect can be identified in the following phase .	60.00 % (27)	70.00%(28)
10 .	Which of the following method is commonly employed by the healthcare professional to monitor adverse drug reaction of new drug once they are lauched in the market ?.	44.44%(20)	42.50% (17)
16.	Is there any pharmacovigilence committee in your institute ?	35.5%(16)	47.5%(19)
% of average knowledge of faculties and interns		67.66 %	62.72%

Figure: shown in percentage
In above table 1 shown, average knowledge of faculties was slightly more than interns but not up to

mark Both of them still need to be trained about ADR and pharmacovigilence.

Table -2 Comparison between the average knowledge mean score of faculties and interns

	Consultant /faculties	Interns
Mean score and standard error of mean	67.7 6.5	62.7 3.98

Above table shown by applied unpaired t-test, knowledge of ADR and Pharmacovigilance mean score of faculties are more than interns. The p-value

0.5240 so the mean difference was found not to be statistically significant.

Attitude

Table 3 Showing the attitude towards reporting of ADR

Sr no	Questions	Consultant Agree(N-45) %	Intern Agree(N-40) /%
11.	Do you think reporting of adverse drug reaction is necessary ?	100	84.44
12.	Do you think ADR reporting is professional obligation for you ?	77.77	67.5
13.	Do you think PV should be taught in detailed to health care professional ?	86.66	92.85
14.	Have you anytime read any article on prevention of adverse drug reaction ?	55.55	33.33
15.	What is your opinion about establishing ADR monitoring centre in every hospital ?	Should be in every hospital 26 (57.77%)	25 (62.50%)

*Figure shown in percentage

In table 3 shown, from 100 % ,77.77 % ,86.66% ,55.55% faculties and 84.44,67.5% ,92.85% ,33.33% interns were agreed that reporting ADRs is necessary, mandatory, should be taught in in detailed to healthcare professional, have read the article related

to ADR, to increased safety of patient, respectively. Of them 57.77 % of faculties and 62.50% interns thought that there should be establishing ADR monitoring centre in every hospital.

Practice

Table 4: practice of pharmacovigilance among healthcare professional

Sr no	Questions	Faculties (n- 45)		Interns (n- 40)	
		Yes	No	Yes	No
17.	Have you ever experience adverse drug reaction in your pt during your professional practice ?	Yes-28 (62.22%)	No- 15(37.78%)	Yes- 22(55%)	No – 12(45%)
18.	Have you ever reported ADR to the PV center ?	Yes – 6 (13.33%)	No – 35 (86.67%)	Yes - 3(7.5%)	No – 35(92.5%)
19.	Have you ever seen the ADR reporting form?	Yes -15 (33.33%)	No -27 (66.66%)	Yes - 4(10%)	No -36 (90%)
20.	Have you ever been trained on how to report Adverse drug reaction (ADR) ?	Yes -9 (20%)	No -36 (80%)	Yes- 3(7.5%)	No – 37(92.55%)
21.	Which of the following factor discourage you	Agree		Not agree	

from reporting of ADR .?

A) No remuneration	11(24.44%)	10(25%)
B) Lack of time to report ADR	14 (31.11%)	14(35%)
C) A single unreported case may not Affect ADR data base	3 (6.66%)	3(7.5%)
D) Difficult to decide whether ADR has occurred or not	10 (22.22%)	12(30%)

In table 4 shown, 62.22% of faculties and 55.5% interns were experience adverse drug reaction during his /her professional life respectively. Of them 13.33% and 7.5% in faculties and interns were reported ADR to PV centre respectively and found difficulties like patient co-operation and do not have time to report ADR. Only 33.33% and 10 % of faculties and interns have ever seen the ADR reporting form respectively and only 20% of faculties and 7.5% of interns has been trained for ADR reporting respectively. The following factors discourage to report ADR like no remuneration (24.4% faculties and 25% interns), lack of time to report (31.11% faculties ,35% interns), A single case does not affect the database (6.66%faculties 7.5% interns),and 22.22 % faculties and 30% interns found difficulty in decide whether it is ADR or not .

DISCUSSION

This was a questionnaire based study, which was conducted in healthcare professional among doctors and interns in a tertiary care teaching hospital of Bastar region in Chattisgarh India .To assess the knowledge ,attitude ,practice among the health care professional .The response rate of our study among healthcare professional was 70.8%.Of them the response rate of faculties (52.9%) faculties were higher than interns (47%). The reason behind not to fill the form were lack of time, no remuneration, not interested et al. The percentage of response was lower than the study conducted in western Odisha region of india (71.43%) [7], Netherlands (72.7%) [9] and Nigeria 82.5%, but higher than the study conducted in north india (53.25%) [11] and china (67.3%) ,Italy (59.1%) [12, 13]. The sex ratio was equal 50% respondents were male and 50% were female in our study.

Of them 66.8% faculties and 55% interns have the true knowledge about the pharmacovigilence .Which was slightly lower than the study conducted by Saha K et al in Odisha region of India (92%) faculties and

(100%) post graduates respectively⁷ and higher than the study conducted by Dr Mukeshkumar B vora et al in which 27.83% PGs and 40.78% faculties were found true knowledge about ADR and Pharmacovigilance. [11] The reason behind this may be due to lack of knowledge, less awareness about importance of pharmacovigilence .

In first question all the faculties 45 (100%) and 30 (80%) intern heard the name of pharmacovigilence but in second question only 35 (77.77%) faculties and 27(67.5%) can define correctly the pharmacovigilence and 36 (80 %) faculties and 27 (67.5%) resident doctors were aware about the purpose of pharmacovigilence is to identify safety of drugs. There was no significant difference between the knowledge of consultants and interns the reason behind this was in our institute there is no pharmacovigilence center, no ADR reporting is practiced where as the pharmacovigilence and ADR reporting is taught in lectures nowadays ,that may be the cause to not significantly difference in the knowledge of pharmacovigilence though they were aware about adverse reaction .

This study showed the right attitude for ADR reporting amongst faculties and interns, but the actual practice of ADR reporting was lacking. The majority of respondents thought to ADR reporting was necessary and mandatory (100%) and pharmacovigilence should be taught in detail to health care professional (86.66%) , but there was huge gape between experience of ADR during the professional life and actual practice of ADR reporting . In this study the ADR experienced (62.2%) and ADR reported (13.3%) by healthcare professional The reason behind underreporting, from our study include no remuneration, lack of time to report ADR, belief that a single unreported case may not affect ADR database, and difficulty to decide whether ADR has occurred or not.. According to study conducted by IA Eland Other reasons for not reporting were due to a lack of knowledge: not knowing how to report, not knowing which ADR to

report, and even unawareness of the existence of a reporting scheme.^{13,14,15} Similar findings also seen in study conducted by Hazell L et al 6% ADR were reported .[16]

So overall the most common cause of underreporting were lack of training, unawareness regarding the ADR reporting form, ignorance of the rules, and procedure for reporting. Which can be improved by three ways first through educational intervention, non-intervetional by facilitating the effective reporting ,and by other methods such as by making guidelines ,codes etc. [17, 18, 19]

A study from Northern Italy reported that the KAP regarding ADR monitoring was low and the knowledge scores needed an improvement and update knowledge, attitude and practices about ADR and Pharmacovigilance [12]. A survey among medical residents in France showed that the majority of them had a lower knowledge regarding Pharmacovigilance [13]. A recent study from India also identified that the awareness about Pharmacovigilance program and the knowledge of ADR reporting were very low among the doctors.

REFERENCES

- [1]. Medhi B, Prakash A .Tools for patient safety; pharmacovigilance, biovigillance. A textbook of Advanced pharmacology 1, 2018, 491-505.
- [2]. Lazarou J, Pomeranz BH, Corey PN. Incidence of Adverse Drug Reactions in Hospitalized Patients: A Meta-analysis of Prospective Studies. JAMA. 279(15), 1998, 1200-5.
- [3]. S.Ganesan, G. Vikneswaran, KC Reddy, DK Subrahmanyam, Ch. Adithan et al A Survey on Knowledge, Attitude and Practice of Pharmacovigilance towards Adverse drug reactions reporting among Doctors and Nurses in a Tertiary Care Hospital in South India . J Young Pharma, 8(4), 2016, 471-476
- [4]. Pharmacovigilance world health organization 2015 www.who.int accessed on 19
- [5]. Pharmacovigilance programme of india <https://ipc.gov.in/PvPI/about>.cited on 19
- [6]. Ratan JL, Mangala L. An update on the Pharmacovigilance Programme of India. Front Pharmacol.6, 2015, 194. 201
- [7]. Saha K,Rath B ,Agrawal R .A survey of knowledge attitude and practice of adverse drug reaction monitoring among doctors in western odisha region .Int J Basic Clin Pharmacology7(11), 2018, 2234-2239
- [8]. Dhananjay K ,Himasri . E .et al. A study of assessing the knowledge, attitude, practice of pharmacovigilance among the medical students of south Indian teaching hospital. Int J Basic Clin Pharmacol. 6(1), 2017, 43-47
- [9]. De Langen J,van Hunsel F,Passier A, de Jong –van den Berg L, van Grootheest K.Adverse drug reaction reporting by patients in the Netherlands three years of experience .Drug safety. 31(6), 2008, 515-24
- [10]. Oshikoya KA, Awobusuyi JO. Perceptions of doctors to adverse drug reaction reporting in a teaching hospital in Lagos, Nigeria. BMC Clin Pharmacol 14, 2009, 9
- [11]. B.vora.M, Barvalia M et al : A survey of the knowledge, attitude and practice towards the pharmacovigilance and adverse drug reaction in healthcare professional of tertiary care teaching hospital ,Bhavnager India IJPSR 11(5), 2014, 820-826
- [12]. Cosentino M ,Leoni O ,Banfi F ,Lecchini S ,Frigo G .Attitude to Adverse drug reaction reporting by medical practitioner in a Northern Italian district ,Pharmacological research . 35(2), 1997, 85-8.

CONCLUSION

The majority of the healthcare professionals felt ADR reporting and monitoring to be important, but only a few had ever reported an ADR. The major cause of underreporting may be the lack of knowledge and awareness among the health care professional towards the pharmacovigilance in our hospital .The main difficulty is they were willing to report but don't know where to report ,to whome they consult. The findings of the study suggest that there is need for continuous education and sensitization regarding Pharmacovigilance and ADR reporting system to resident's doctors and faculties that improving the ongoing Pharmacovigilance activities in our hospital to improve the patient safety.

Acknowledgements

Authors are thankful to all consultants and resident doctors who were enrolled in the study for their co-operation in conducting the study.

Funding: No funding sources

Conflict of interest: none: **Ethical approval:** Not required

- [13]. Eland IA, Belton KJ, van Grootheest AC, Meiners AP, Rawlins MD, Stricker BH. Attitudinal survey of voluntary reporting of adverse drug reactions. *Br J Clin Pharmacol* 48, 1999, 623-7.
- [14]. Radhakrishnan R, Danturulu SV, Varma M. An Educational Intervention to assess Knowledge Attitude Practice of pharmacovigilance among Health care professionals in an Indian tertiary care teaching hospital *Int J of Pharm Tech Research*. 3(2), 2011, 678-92.
- [15]. Meher BR, Joshua N ,Asha B,Mukherji D .A questionnaire based study to asses knowledge ,attitude and practice of pharmacovigilance among undergraduates medical students in a tertiary care teaching hospital of south India .*perspect clin Res* 6, 2015, 217-21.
- [16]. Hazell L, Shakir SA .underreporting of adverse drug reaction: a systemic review .*drug safty* 29(5), 2006, 385 - 96.
- [17]. Figueiras A, Herdeiro MT, Polonia J, et al. An educational intervention to improve physician reporting of adverse drug reactions: a cluster-randomized controlled trial. *JAMA* 296(9), 2006, 1086-93. 31.
- [18]. Tabali M, Jeschke E, Bockelbrink A, et al. Educational intervention to improve physician reporting of adverse drug reactions (ADRs) in a primary care setting in complementary and alternative medicine. *BMC Public Health* 9, 2009, 274.
- [19]. Bracchi RC, Houghton J, Woods FJ, et. al. A distance-learning programme in pharmacovigilance linked to educational credits is associated with improved reporting of suspected adverse drug reactions via the UK yellow card scheme. *Br J Clin Pharmacol* 60(2), 2005, 221-3.