Sindh Univ. Res. Jour. (Sci. Ser.) Vol. 47 (3) 605-608 (2015)

SINDH UNIVERSITY RESEARCH JOURNAL (SCIENCE SERIES)

The Awareness of Pharmacovigilance Among Medical Practitioners in Government Hospital of Hyderabad, Pakistan

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Received 26th February 2014 and Revised 4th May 2015

Abstract: Objective: To evaluate the awareness/knowledge of Pharmacovigilance/ADRs among medical practitioners in government hospital of Hyderabad, Pakistan.

Methodology: A survey based descriptive study was conducted randomly among 120 practitioners of all outpatient and inpatient departments of government hospital of Hyderabad for a period of 06 months, which was based on questionnaire for evaluating the basic awareness/knowledge related with adverse drug reactions with their written informed consent.

Results: Out of 120 prescribers, 75% were responded the questionnaire and majority were belonged to male gender i.e. 62.22%. Among responded samples only 22.22% (n=20) were know the word 'pharmacovigilance', 35.55% (n=32) know that how to report adverse drug reactions (ADRs), while 73.33% (n=66) were not asked any question about ADRs from patients and 64.44% (n=58) of the prescribers don't know about reporting of ADRs to the concerned authorities.

Conclusion: Pharmacovigilance or Adverse drug reaction is one of the important parameter of safety of medicine and also a prime objective of rational therapy. So it was concluded that a refresher and CME programs were conducted on urgent basis to give the knowledge related ADRs for proper detection and reporting to the concerned department, further there is also need for proper interaction between a patient and health care providers for the betterment of life of a patients and to reduce the chances of undesirable drug effects.

Keywords: Pharmacovigilance, Knowledge, Adverse drug reactions, Government Hospital

1. INTRODUCTION

Now a day's different diseases are treated in a changed way by inclusion of new drugs/medicines but with this there are various risks associated with these medicines. Pharmacovigilance may defined as, "The science and the activities which relate to the detection, assessment, understanding and the prevention of adverse effects or any other drug-related problems" (World Health Organization 2002). While according to the World Health Organization (WHO) definition, an Adverse Drug Reaction (ADR) is any noxious, unintended, and undesired effect of a drug, which occurs at the doses which are used in humans for prophylaxis, diagnosis, or therapy. The global record which is related with the maintenance of reported adverse drug reaction is the responsibility of Uppsala Monitoring Centre (UMC, WHO), Sweden. Only less than 10% of ADRs were reported according to feely *et al* (Feely *et al* 1990). Worldwide, the rate of death and disease factor is higher due to Adverse Drug Reactions (ADRs) which is an alarming situation and need to be focused (Lazarou *et al* 1998, Classen *et al* 1997). In last few years the expenditure on health has increased up to 4 billion dollars and it is increaseing day by day. In 1989, twelve thousand deaths were due to ADRs and this report is also published Food and Drug administration Authority (FDA), so for the management and prevention of ADRs, (Ahmad 2003). There is a required strict monitoring and this is the current need of our society as well. According to study conducted in south region of India by Ramesh *et al*, (2003) that, out of total patient admissions in hospitals, 0.7% were due to ADRs and 3.7% of the patients were experienced ADRS during their stay in hospital and 1.3% were serious (Ramesh *et al* 2003). While study conducted by Arulumani *et al*, 2007) were also related with previous study that 3.4% of admitted patients in hospitals were due to any type of adverse drug reactions and 3.7% were experienced during their stay in hospital (Arulmani *et al* 2007). The serious reaction were also evaluated that is 6.7% were due to adverse drug reaction (Importance of ADR cited 2013).So due to huge economic expenditure for treating the adverse drug reactions, the early reporting and their prevention is one of the necessary step that should be taken by healthcare professionals voluntarily as well as spontaneously because these two methods are used for monitoring the ADRs. There are some advantages of this system that leading to its use: this system is, inexpensive and easy to operate. It encompasses all medicines and patient populations, including special groups. However, two disadvantage of this method is also noted i.e. under-reporting and an inability to calculate the incidence of ADRs (Wasserfallen 2001, Goettler *et al* 1997).

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Although medical graduates have very significant role in detection of ADR still up to mark reporting is not practiced usually, as found in an estimation that up to 94 % under reporting occurs especially for non serious and un labeled reactions so this frequency is too high. This leads to delay of even important ADR reporting (Ahmad *et al* 2003, Wysowski *et a*l 2005, Moride *et al* 1997, Heeley *et al* 2001). Inadequate knowledge and attitudes of health care practitioners (HCP) are found to be the cause of under reporting in different studies [Figueiras 1999], as under reporting is serious issue therefore HCP should be assessed for their awareness about pharmacovigilance. With this objective of study was to evaluate the awareness about pharmacovigilance among HCPs.

2. MATERIALS AND METHODS

Study setting

This study was conducted in government hospital of Hyderabad, Pakistan which is also a teaching hospital providing all types of services to the patients.

Study design and Study population

A survey based, descriptive and questionnaire based study were carried out in inpatients and outpatients departments of hospital during the study period i.e. 06 months.

Sampling Procedure

A total of 120 medical practitioners were randomly selected from morning and evening shift at the time of study period in the hospital.

Research tool

A self-administered questionnaire was used to assess the awareness of pharmacovigilance among medical practitioners. The questionnaire was structured to obtain the demographics of the doctors, information about their knowledge, attitudes to reporting, and their training on adverse drug reaction reporting. The questionnaire after its preparation was reviewed by subject specialist in the field of Clinical Pharmacy. The questionnaire was first pretested randomly among 20 doctors. Suitable changing was done and the result of the above doctors was excluded from study.

Data collection

After getting the written informed consent from the practitioners, the questionnaires were distributed to them. The doctors were given sufficient time to answer the questions and then collected back promptly.

Analysis

Analysis was performed using Microsoft excel.

3. RESULTS

Out of 120 prescribers, 90 (75%) were filled the questionnaire, while 30 (25%) not fill due to lack of time and busy schedule. Of the 90 physicians, 56 (62.22%) was male gender while 34 (37.77%) was female. The age ranges of doctors were from 26 to 59 years. Out of respondents prescribers, 43 (47.77%) were from in-patients departments and 47 (52.22%) were from out-patients departments while the details of in-patients department was mentioned in **(Table 1)** and out patients department in **(Table 2)** respectively.

Out of total samples, 67.77% prescriber beloned to general practitioners category while remaining 21.11% were consultants. While for assessing the knowledge there were different questions in questionnaire Among them 77.77% (n=70) don't know the word ' pharmacovigilance' and only 20 (22.22%) knew the word, while only 14 (15.55%) respondents knew about the correct definition of ADRs while 76 (84.44%) did not know the correct definition. 35.55% (n=32) know that how to report adverse drug reactions (ADRs) and 58 (64.44%) did not know, 73.33% (n=66) were not asked any question about ADRs from patients and 64.44% (n=58) of the prescribers knew about the post marketing surveillances of different pharmaceutical companies. 18.88% (n=17) of responders opined that pharmacist's assistance in detection, reporting, monitoring and management of adverse drug reactions is useful while remaining i.e. 73 (81.11%) said about no any role of pharmacist in adverse drug reaction. As for as attitude is concerned regarding the ADR reporting, only 19 (21.11%) prescribers said that ADR reporting is mandatory part of their professional duty while 71(78.88%) said that it is the voluntary process.

(Table-3) showed that factors that were associated with ADRs reporting and under reporting, It was reported that 79 (87.77%) prescribers agreed that there is no any proper training of ADRs reporting, 61 (67.77%) said due to busy schedule no any ADRs was reported and 77 (85.55%) medical practitioners felt that there is no any facility of ADR reporting system in hospital. Furthermore the respondents view about which type of ADRs is reported, 76.66 % said that only severe ADRs reported, while 23.33% said all types of ADRs should be reported. In open questions, the respondents were agreed that adverse drug reaction should be reported to their senior doctors (68.88%), pharmacist (15.55%), head nurse (3.33%) and health authority (13.33%). Intervention of educational programmes for increase awareness about pharmacovigilance was agreed by 56.66%, while 21.11% said about the motivation during the final year teaching of medical classes, 14.44% of the HCPs said about the availability of ADRs forms in hospitals and only 7.77% give opinion about the toll free numbers available for guidance and reported ADRs.

4. DISCUSSION

Pharmacovigilance program is used by almost all countries for proper monitoring, safe and rational usage of therapy after their approval used to treat the various diseases in patients (World Health Organization, 2002).

The finding of the study uncovered many facts about the inadequate knowledge regarding the pharmacovovigilance and reporting the ADRs also showed the factors that may cause hindrance in reporting the ADRs just similar to many studies that was conducted around the world (Oshikoya 2009). In our study, 15.55% know about the definition of ADRs while same study conducted in China where only 2.7% of the doctors answered correctly (Qing, 2004), so the information regarding ADRs in government hospital was higher than the other studies. With this, from our study, 85.55% respondents said that there is no any facility for reporting ADRs while in other studies this ratio is too lower than our studies [Oshikoya 2009].About 76.66% of the respondents said that only severe ADRs be reported. Similar study was conducted by Williams and Feely (Williams 1999). Lack of knowledge (63.33%), heavy o.p.d (75.55%) followed by busy schedule/lack of timing (67.77%) were the main reasons for not reporting the ADRs, similar studies conducted by Li Quing *et al* (Qing, 2004) reported the same main reasons for not reporting the ADRs as our study highlighted. Another study conducted in India revealed the same reasons i.e. lack of knowledge for identification of ADRs (Pankaj *et al* 2011). 56.66% of the respondents agreed for the incorporation of training sessions about pharmacovigilance for better understand and increase knowledge regarding the pharma covigilance and same finding was assessed form other studies in Portugal and Nigeria (Kazeem *et al* 2009, Figueiras *et al* 2006).

Table- 1: In-patient department wise Doctors.

S/No	In-Patients departments	Number of doctors	Percentage %
1	Medicine	11	25.58%
2	Surgery	8	18.60%
3	Orthopaedic	4	9.30%
4	Gynaecology	5	11.62%
5	Dentistry	3	6.97%
6	Cardiology	7	16.27%
7	Nephrology	5	11.62%
	Total	43	100%

Table- 2: Out-patient department wise Doctors

S/No	Out-Patients departments	Number of doctors	Percentage %
1	Medicine	8	17.02
2	Surgery	10	21.27
3	Orthopaedic	3	6.38
4	Gynaecology	9	19.14
5	Dentistry	5	10.63
6	Cardiology	12	25.53
	Total	47	100%

Table-3: Factors associated with ADRs reporting

S/No	Factors	Agreed	Disagreed
1	No any proper training of ADRs	79 (87.77%)	11 (12.22%)
2	Lack of timing/Busy schedule	61(67.77%)	29 (32.22%)
3	Heavy o.p.d	68 (75.55%)	22 (24.44%)
4	Lack of facilities	77 (85.55%)	13 (14.44%)
5	Lack of knowledge	57 (63.33%)	33 (36.67%)

5. CONCLUSION

In present study, it was clearly showed that majority of practitioners had inadequate knowledge/awareness of any aspect of pharmacovigilance so there is an utmost need for framing the policies regarding the mechanism of reporting ADRs with the proper regular training to all the medical practitioner. The process of ADRs reporting in a practitioner view is difficult due to their heavy opds, shortage of time and lack of knowledge seemed to be the main reason for not reporting ADRs. However it was also concluded that the coordination between HCPs and patients is very important to improve the quality of therapy and to prevent the future happenings of the ADRs. Pharmacists have also a major role to play in the field of Pharmacovigilance.

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