Assessment of the Knowledge of Pharmacovigilance among Medical Students

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Abstract— *Safety of drug is very important. Pharmacovigilance Programme is there in India to reports any adverse reaction of drugs (ADRs). So this study was conducted to assess the knowledge of interns regarding pharmacovigilance. This cross sectional study was conducted at medical colleges of Rajasthan during the period of Oct. 2017 to April 2018. For this study, 150 medical students of internship were enrolled. Clearance from institutional ethical committee was taken prior to the study and written informed consent was taken from all the study participants. Knowledge of these intern students was assessed by a predesigned semi structured questionnaire. In the present study, 64% medical students gave correct response regarding the definition of pharmacovigilance. 65% students were aware that the most important purpose of pharmacovigilance is to identify safety of the drug. Only 42% of students were aware regarding the existence of a Pharmacovigilance Programme in India. 60% of interns were aware that the regulatory body responsible for monitoring ADRs in India is Central Drugs Standard Control Organization (CDSCO). 74% interns gave correct answer regarding professionals is responsible for reporting ADRs in a hospital. 95% agreed that ADR reporting is a professional responsibility for them. So it can be concluded that there is a great need to generate awareness regarding Pharmacovigilance among medical professionals and also to promote the reporting of ADRs. Reporting of ADRs is compulsory and it should be made an integral part of the patient care.*

Keywords: Adverse drug reactions, Knowledge, Pharmacovigilance.

I. INTRODUCTION

Pharmacovigilance word is originated from the Greek word “pharmakon” which refers to drug and from the Latin word “vigilance” which refers to careful or watchful. World Health Organization (WHO) has defined pharmacovigilance as the science and activities relating to understanding, detection, assessment, and prevention of the adverse drug effects[1].

Adverse drug reactions (ADRs) are one of the leading causes of mortality and morbidity all around the world. It has been reported from the previous researches that approximately 2.6-5.9% of all hospitalization are due to ADRs and almost 30% of hospitalized patients experience an ADR during the period of hospitalization[2]. According to WHO, ADRs are defined as any unintended, noxious and undesired effects of a drug, which occurs at doses that used for treatment, prophylaxis or diagnosis of a

disease. ADRs have a major impact on health by imposing a considerable morbidity and adverse events along with economic burden on the society with considerable mortality rates[3].

Pharmacovigilance is a structured and systematic process for the detection and monitoring of adverse drug reactions (ADRs) in the above context. The Pharmacovigilance Program in India was started in 1982 and still operated in its preliminary phase[4].

Pharmacovigilance Programing (PvPI) of India is currently suffering from underreporting of ADRs and events due to inadequate training about drug safety monitoring and lack of awareness among health care professionals. The ADRs reporting rate in India was reported to be less than 1% compared to the global rate of 5%[5]. Hence, the aim of pharmacovigilance is to ensure rational and safe use of drugs and prevention of negative consequences of medications. The Controller General of India (DCGI) and Indian Council of Medical Research (ICMR) have also established ADR monitoring centre's at all the major cities of India[6].

Assessment of knowledge of pharmacovigilance among the healthcare professionals is very critical for the reporting of adverse drug reactions. Therefore, this present study was conducted to assess knowledge of pharmacovigilance among the medical students

II. METHODOLOGY

This cross sectional study was carried out at Medical Colleges of Rajasthan (India) during the period of Oct. 2017 to April 2018.

For this study, 150 medical students of internship were enrolled. Clearance from institutional ethical committee was taken prior to the study and written informed consent was taken from all the study participants.

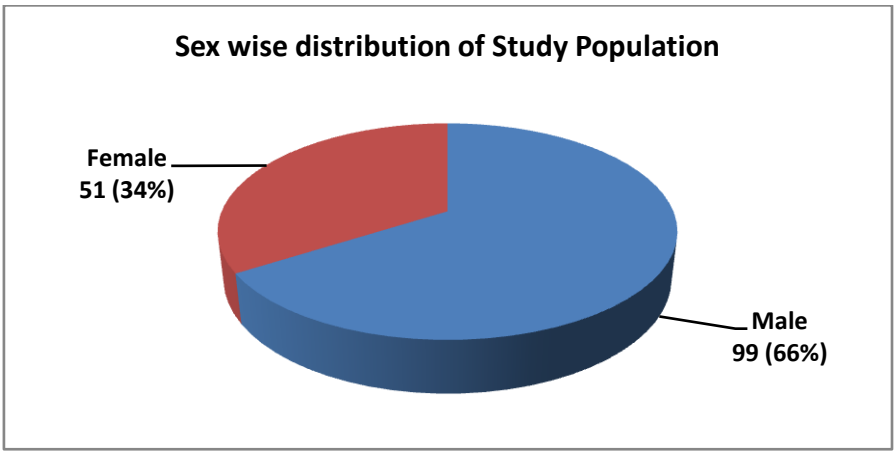
A brief description on the nature of the study and procedure to complete the questionnaire was explained. A pre designed semi structured questionnaire which was designed to assess the basic knowledge on pharmacovigilance was distributed among all the study participants. Students were asked to fill the questionnaires without asking anybody. These filled questionnaires were collected after 30 minutes.

Master chart was framed from filled questionnaires with the help of MS Excel 2010, Data base was prepared which was further analysed with statistical software Epi Info v7.

III. RESULTS

In the present study a total of 150 medical students who were doing internship were enrolled for the study and assessed regarding their knowledge about pharmacovigilance, of which 34% (n=51) were females and 66% (n=99) were males. The mean average age of the study participants was 22.3 ± 1.2 years. (Figure 1)

Figure 1



In the present study, 64% medical students gave correct response regarding the definition of pharmacovigilance and 65% students were aware that the most important purpose of pharmacovigilance is to identify safety of the drug. Only 42% of students were aware regarding the existence of a Pharmacovigilance Programme in India. And 60% of interns were aware that the regulatory body responsible for monitoring ADRs in India is Central Drugs Standard Control Organization (CDSCO) and 48% were aware that International Center for ADR monitoring is located in Sweden. In this study, 74% interns gave correct answers regarding professionals are responsible for reporting ADRs in a hospital. 95% agreed that ADR reporting is a professional responsibility for them. In the present study, 70% students said they haven't encountered any ADRs and 57% students think the likely cause of the ADRs was drug-drug interactions. 61% interns were saying that they will report ADRs to ADR monitoring committee of the hospital. (Table 1)

Table 1
Knowledge of pharmacovigilance among Intern students

S. No.	Questions	Correct Answers	
		Number	Percentage
1	Define Pharmacovigilance	96	**64**
2	The most important purpose of Pharmacovigilance	98	**65.33**
3	Are you aware of National Pharmacovigilance Programme in India?	63	**42**
4	In India which regulatory body is responsible for monitoring ADRs?	90	**60**
5	Where is the Regional Pharmacovigilance centre?	99	**66**
6	International centre for adverse drug reaction monitoring is located in?	72	**48**
7	Which of the healthcare professionals are responsible for reporting ADRs in a hospital?	111	**74**
8	Do you think ADR reporting is professional responsibility?	143	**95.33**

IV. DISCUSSION

In the present study a total of 150 medical students who were doing internship were enrolled for the study and assessed regarding their knowledge about pharmacovigilance, of which 34% (n=51) were females and 66% (n=99) were males. The mean average age of the study participants was 22.3 ± 1.2 years. In the present study, 64% medical students gave correct response regarding the definition of

pharmacovigilance while 36% were gave incorrect response. 65% students were aware that the most important purpose of pharmacovigilance is to identify safety of the drug while 35% were gave incorrect response.

In previous other researchers[7,8] conducted a study about knowledge and awareness of pharmacovigilance and ADR, reported that lack of knowledge and low awareness not only in medical students[7] but also among internship students and in postgraduate medical students.[8] A study conducted by Dr. Gupta et al[9] reported that only 43% of study participants are aware of ADRs reporting, where as in the present study higher than 60% of intern students know regarding pharmacovigilance and ADR reporting.

A study conducted by Rajesh R et al[10] on 255 study participants, reported that 83% of health professionals can define pharmacovigilance correctly and 43% can define the ADR correctly. In another study conducted by Kulmi M et al[11] among 229 medical students and reported that more than 40% MBBS students respond that ADRs reporting is compulsory. They also reported that in comparison to post graduate students regarding witnessed ADRs, MBBS students witnessed only 21%.[11] While, in the present study 74% interns gave correct answer regarding professionals are responsible for reporting ADRs in a hospital this may be because of study population here was of interns.

A study conducted by S Jeya et al[12] among 116 respondents of second year MBBS students found to have adequate knowledge and attitude regarding pharmacovigilance while compared to post graduate students and nursing students. Although the nursing students have good knowledge of pharmacovigilance but they did not reported to have adequate knowledge about reporting ADRs.[12] Another study conducted by Lakshmi Deepika Patchva[13] on 180 respondents of final year MBBS students and interns found that 76.7% students haven't seen any ADR. And 56.2% students said that the cause of the ADRs was due to drug interactions. 50.5% Students were agreed to report ADRs to ADR monitoring committee of the hospital.[13]

V. CONCLUSION

Present study concludes that although knowledge about pharmacovigilance has increased with time but still it is not at acceptable level. So there is a great need to generate awareness regarding Pharmacovigilance among medical professionals and also to promote the reporting of ADRs. Reporting of ADRs is compulsory and it should be made an integral part of the patient care. Educational intervention can raise the awareness of pharmacovigilance among the health care professionals and this knowledge of pharmacovigilance should be incorporated to the everyday clinical practice.

CONFLICT OF INTEREST

None declared till now.

REFERENCES

[1] Marimon RMP, Calvente AC, Prats CC, Juncà AP, Martí DF, Benavente JS, et al. Assessment of inappropriate drug prescription in older people through a screening tool.Eur J Hosp Pharm. 2012;19(2):131.2-131.

[2] Jeetu G, Anusha G. Pharmacovigilance: A Worldwide Master Key for Drug Safety Monitoring. J Young Pharm [Internet]. 2010;2(3):315. Available from: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2964775/

[3] Biswas P. Pharmacovigilance in Asia. J PharmacolPharmacother [Internet]. 2013;4(5):7. Available from:

http://www.jpharmacol.com/text.asp?2013/4/5/7/120941

[4] Lihite RJ, Lahkar M. An update on the PharmacovigilanceProgramme of India. Front Pharmacol [Internet]. 2015;6. Available from: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4585088/

[5] Kalaiselvan V, Thota P, Singh GN. PharmacovigilanceProgramme of India: Recent developments and future perspectives. Indian J Pharmacol [Internet]. 2016;48(6):624. Available from:

https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5155460/

[6] Naman M Singh K, Kanase HR. PharmacovigilanceProgramme of India: The Beginning, Current Status and Recent Progress. AdvPharmacoepidemiol Drug Saf [Internet]. 2017 Oct 26;06(04):1–3. Available from:

https://www.omicsonline.org/open-access/pharmacovigilance-programme-of-india-the-beginning-current-status-and-recent-progress-2167-1052-1000219-94493.html

[7] P. AA, Shajahan J, Purushothaman S. Awareness of pharmacovigilance and adverse drug reactions among second professional MBBS students of a medical college in Kerala, India. Int J Basic ClinPharmacol. 2017;6(12):2911.

[8] Tabassum R, Bhat M, Farhat S. A descriptive study of knowledge of Pharmacovigilance and adverse drug reactions among second professional undergraduate medical students in a teaching hospital.Int J Basic ClinPharmacol. 2015;4(5):1016–20.

[9] Gupta P, Aaditya Udupa D. Adverse Drug Reaction Reporting and Pharmacovigilance: Knowledge, Attitudes and Perceptions amongst Resident Doctors [Internet].. Available from:

https://search.proquest.com/openview/c1c838a93d1e8bd1f83d7e8f0e6b71e9/1?pq-origsite=gscholar&cbl=54977

[10] Rajesh R, Vidyasagar S, Varma DM. An Educational Intervention to assess Knowledge Attitude Practice of pharmacovigilance among Health care professionals in an Indian tertiary care teaching hospital. Int J PharmTech Res CODEN [Internet]. 2011;3(2):678–92. Available from:

http://www.sphinxsai.com/vol3.no2/pharm/pharmpdf/PT_11_678-692_AJ11.pdf

[11] Kulmi M, Reddy P, Dhakre S, Shinde M, Goyal C. Knowledge, attitude and practices of pharmacovigilance among the postgraduate and undergraduate medical students in a tertiary care hospital in Central India. Int J Basic ClinPharmacol [Internet]. 2017 Apr 24;6(5):1127. Available from: http://www.ijbcp.com/index.php/ijbcp/article/view/1459

[12] Ponmari SJ, Sivaraman M, Aruna T, Subashree V, Jawahar S. Knowledge and Awareness of Pharmacovigilance among Various Medical Fraternities. Asian J PharmacolToxicol. 2015;03(10):45–8.

[13] Patchva LD. Study on the knowledge of pharmacovigilance among medical students. Int J Basic ClinPharmacol. 2018;7(6):1105.