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THE IMPACT OF PHARMACOVIGILANCE SENSITIZATION PROGRAMME IN MEDICAL STUDENTS IN A TERTIARY CARE HOSPITAL IN INDIA

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ABSTRACT

Adverse Drug Reactions (ADRs) are most commonly encounteredin the daily practice. In addition to the obvious morbidity and the mortality which are caused by them, they also contribute to an enormous economic burden on the health care system. Adverse drug reactions can be prevented if adequate reporting of such reactions following the administration of a particularmedication is done. This laid to the foundation of the Pharmacovigilance program of India (PvPI)to incorporate successful ADR reporting and monitoring. The present study was undertaken to assess the awareness, knowledge and the methods of application of pharmacovigilance among the first year post graduate medical students, (preclinical, paraclinical and clinical specialities) in a tertiary care hospital.A questionnaire for 80 post graduate students comprising of 10 questions were designed and distributed as pretest and posttest. An ADR reporting form was also distributed both before the workshop and at the end of it. The knowledge of the students was analyzed on the basis of the number of correct entries in both the questionnaire form as well as the ADR reporting form. A total of 80 questionnaires and ADR reporting forms were analyzed in pretest and in posttest respectively. The comparison between the pretest and posttest values showed that the knowledge and awareness regarding the adverse effects and its reporting was greatly improved at the end of the workshop.The study suggested that it was imperative to includepharmacovigilance (PV)in the post graduate training programmeand they should be sensitized to the ADR reporting during their training period. Importance also need to be given to encourage the dissemination of the information which was required, to improve the application of the rational use of drugs and to reduce the unnecessary suffering of the patients.

KEYWORDS: Adverse drug reaction, Pharmacovigilance, Pharmacovigilance program of India, Adverse drug reaction monitoring center, causality assessment.

INTRODUCTION

The World Health Organisation (WHO)defined theAdverse Drug Reactions (ADR) or adverse reaction as a response to a medicine used in humans or animals, which is noxious and unintended, including lack of efficacy, and which occurs at any dosage and can also result fro overdose, misuse or abuse of a medicine (1).

Studies have revealed that ADRs are a leading cause of hospitalization among the population and constitutes a significant economic burden on patients in our country (2).

Hospital admissions due to ADR accounts for approximately 8.7% of total admissions and deaths due to ADRs are nearly 1.8% of total admissions in tertiary referral centers in India (3).

In order to prevent, detect and assess all these ADRs, Pharmacovigilance came into being which 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 foundation of pharmacovigilance was laid on the following aims as specified by the WHO such as,the detection of increase in frequency of reported reactions, identification and quantification of risk factors and preventing the patients from being affected unnecessarily.

In June 2010, Central Drugs Standard Control Organization (CDSCO), Directorate General of Health Services under the aegis of Ministry of Health & Family Welfare, Government of India initiated a nation-wide Pharmacovigilance programme known as the Pharmacovigilance Program of India(PvPI) for protecting the health of the patients by assuring drug safety with well-defined goals to ensure its future growth and progress.

Initially its National Coordinating Centre was at AIIMS, New Delhi but now it has been shifted to IPC Ghaziabad, UP. The prime activity of the Pharmacovigilance Program of India (PvPI) is to collect, collate and analyse data on adverse drug

reactions to arrive at an inference to recommend regulatory interventions, besides communicating associated risks to healthcare professionals.

The primary objectives of the program are to monitor Adverse Drug Reactions in Indian population, to create awareness amongst healthcare professionals about the importance of ADR reporting in India, to monitor benefit-risk profile of medicines, generate independent, evidence based recommendations on the safety of medicines and to support the CDSCO for formulating safety related regulatory decisions for medicines (4). Our institute was first assigned the status of an ADR Monitoring Centre (AMC) in January, 2014 decided to join this mission to promote patient safety.

After being granted the status of AMC, the major challenge in front of us was to ensure its smooth functioning and regular reporting; by motivating the clinicians to participate and report any drug-related adverse effects. The concept of pharmacovigilance is relatively new in India, and medical fraternity is also not very much informed about it. Before initiating ADR reporting activity in the institution, we thought that it would be prudent to know the extent of understanding and awareness of the faculty and resident doctors about the concept of pharmacovigilance (PV) and ADR reporting. Pharmacovigilance centers have an important role in the dissemination of current pharmacovigilance knowledge. Their data are mainly based on post-marketing reporting, which is essential for identifying previously undetected, uncommon, or serious ADRs. In most countries, the causality assessment of ADRs rely on a mixture of spontaneous reporting by healthcare professionals (physicians, pharmacists, nurses, and dentists) and patients. Since healthcare professionals have a different focus in ADR reporting, it is important to involve all parties (5-6). With population aging, the increased use of prescription drugs and polypharmacy will probably lead to a drastic rise in the number of ADRs. This together with ADR underreporting (7) and the lack of awareness and understanding of ADRs could lead to an even greater burden on patients and healthcare systems in the near future.

Hence, the present study aimed to create awareness amongst postgraduate medical students regarding the identification and reporting of the adverse drug reactions and to assess the knowledge gained at the end of the workshop.

MATERIALAND METHODS

This was a cross sectional, questionnaire-based studyconducted at atertiarycare hospital in Lucknow, Uttar Pradesh, India.The study was conducted in 80 postgraduate medical students enrolled in various paraclinical and clinical subjects after taking approval from the institutional ethics committee. Those who were not willing to participate and those who did not return the questionnaires in the stipulated time were excluded from the study. The questionnaire was distributed among 80 first year postgraduateswho were working at our institute. The participants were personally briefed about the questionnaire and they were requested to return the duly filled in forms. The participants were given 30 minutes to answer the questionnaire prior to the lecture by the faculty and they were not allowed to consult anyone during that time. They could maintain anonymity with regards to their names. To assess their understanding of the subject a post test questionnaire comprising of the same set of questions was distributed after the lecture.

The questionnaire consisted of subjective type of 10 questions. The questionnaires were evaluated on the basis of correct entries.The second evaluation part of the evaluation was based on their knowledge about ADR form filling. The SUSPECTED ADR REPORTING FORM issued by the Indian pharmacopeia commission was used for the study (annexure 1). The ADR reporting form comprises of 4 subparts: Part A, B, C and D. the part A was about the patient details, the part B described the type and occurrence of Adverse event. Part C contained the details of the suspected medications and Part D contained the details of the reporter.The ADR reporting forms were distributed among the same 80 first year postgraduate students and they were required to fill in the forms as a pretest. The forms were collected and a suspectedadverse drug reaction reporting form filling sensitization lecture by a specialized faculty memberwas taken. After the sensitization lecture, a post test regarding the same was done. The new unfilled forms were then distributed and the students were asked to fill the forms on the basis of the knowledge acquired by the previous lectures. This was considered as posttest. The values obtained after pretest and posttestwere tabulated, analyzed and compared.

RESULTS

A total of 80 filled questionnaires were distributed and all the duly filled forms were collected after 30 minutes. The number of correct entries in ADR knowledge based questionnaires were recorded and evaluated and are depicted in the fig 1.

This figure shows a comparison between the pretest and posttest values obtained from the questionnaire distributed consisting of 10 ADR related questions. The pretest values ranging between 0-2 & 2.5-5 were higher than the posttest suggesting that a majority obtained a score upto 5. This clearly depicted a limited

knowledge of the students at the time of the initiation of the workshop. The scores reached the range of 8.5-10 in majority of the students following sensitization by the faculty members fig 1 .

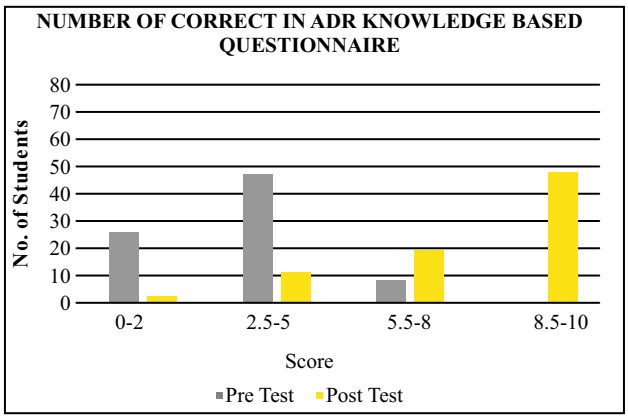

Fig1: Number of Correct Entries in ADR Knowledge Based Questionnaire

Further, the evaluation of knowledge regarding filling of ADR form was done. The ADR forms which were filled as pretest suggested that the students lacked knowledge regarding filling the form correctly fig 2.

The number of students who incorrectly filled the ADR related query in the form was greater as compared to the correct entries in pretest fig 2.

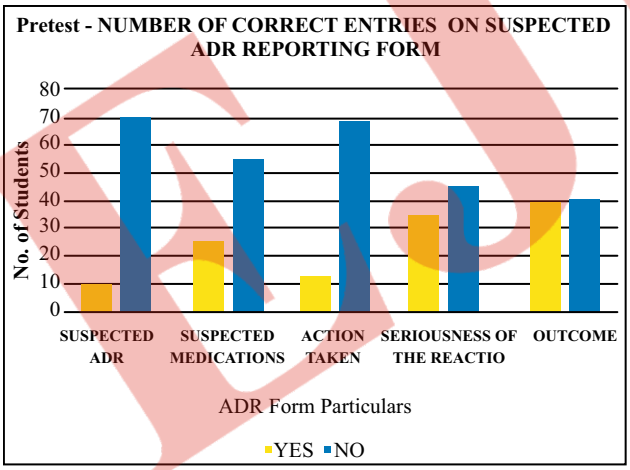

Fig 2: Pretest- Number of Correct Entries on Suspected ADR Reporting Form

The freshly distributed unfilled ADR reporting forms weregiven atthe completion of the workshop and posttest was conducted. The duly filled forms were collected after 30 mins and were evaluated fig 3.

The number of correct entries on suspected ADR reporting form in posttest suggested that the students understood the fundamentals of form filling well and the majority of them filled in the details correctly as compared to the incorrect entries fig 3.

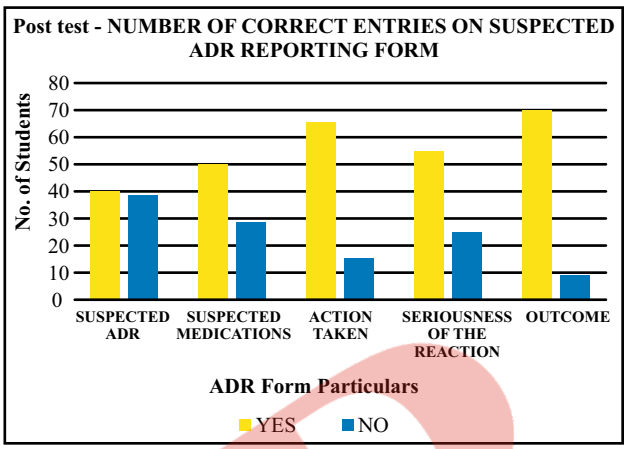

Fig 3: Posttest- Number of Correct Entries on Suspected ADR Reporting Form

DISCUSSION

The reporting of the ADRs is the building block of any pharmacovigilance program. The present study shows that the first year post graduate medical students in a tertiary care hospital are not very adept in ADR reporting and the awareness about PV program and the knowledge of ADR reporting was quite low amongst them. This finding corroborates withother studies showing similar results (8-9).

The main prerequisite of pharmacovigilance is the reporting of suspected adverse drug reactions. A proper coordination amidst the health care professionals and the medical institutions is required for a successful pharmacovigilance programme. Many factors are associated with the adverse drug reaction under-reporting among the healthcare professionals, hence, in order to improve the reporting rate, it is important to properly educate the healthcare professionals regarding ADR reporting and the pharmacovigilance programme. The most appropriate time to do so, is during the undergraduate and the postgraduate training of the doctors. This study endeavoured to evaluate the extent of the awareness, knowledge and the methods of application of pharmacovigilance of the first year postgraduates of a tertiary care hospital.

A cross sectional, questionnaire based, multi-centric study which was done in six different medical colleges in Gujarat indicated that the overall knowledge of pharmacovigilance was poor in undergraduate medical students (10). A study which was conducted at a paediatric tertiary care center in Bangalore suggested that educational interventions and the improvement of the facilities would help in enhancing the reporting rate (11). A study which was conducted in Malaysian Public Universities in pharmacy students, suggested that a customized comprehensive curriculum which was related to pharmacovigilance should be designed and implemented in the pharmacy schools (12)In this

knowledge based questionnaire study, the postgraduate medical students successfully understood the principles of ADR monitoring and reporting at the end of the session as compared to the pretest data fig 1.

The suspected ADR reporting form filling exercise was conducted and it showed an improvement in the understanding of the former as determined by posttest when compared to pretest Fig 2,3.

Major challenge ahead is to develop awareness among healthcare providers of the potential risks of medicines while also understanding the extent of their benefits. Often neglected, is the ongoing and routine monitoring of patients for adverse effects. The patients should be encouraged to actively report any intolerance or adverse effect to a drug throughout the course of therapy. Ultimately, these interventions are intended to make medicines safer to use. To recognize and properly manage ADRs, careful observation and high index of clinical suspicion are of crucial importance. Moreover, it is also possible to detect an unusual adverse reaction associated with an old drug that is widely used and with known side effects profile. All such efforts will lead to a better ADR management which in turn contributes to the safety of the patients.

CONCLUSION

The study was conducted to evaluate the knowledge and understanding of Adverse drug reaction and its reporting amongst first year post graduate medical students. The study also showed that there was a positive impact on the understanding of ADR and Pharmacovigilance after the sensitization programme.

Hence, the pharmacovigilance aims to increase the alertness towards any untoward reaction due to any medication. In order to achieve this, the contribution of all medical health care professionals including the doctors, nurses, paramedics, etc. is of utmost importance. The above mentioned steps would ensure the alleviation of the unnecessary suffering of the patient.

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